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Mid-urethral sling operations for stress urinary incontinence in women (Review)

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[Intervention Review]

Mid-urethral sling operations for stress urinary incontinence in women

Abigail A Ford[1], Lynne Rogerson[2], June D Cody[3], Patricia Aluko[4], Joseph A Ogah[5]

[1]Department of Urogynaecology, Imperial Healthcare Trust, St Mary's Hospital, London, UK. [2]Department of Urogynaecology, The Leeds Teaching Hospitals NHS Trust, Leeds, UK. [3]c/o Cochrane Incontinence Group, Newcastle University, Newcastle upon Tyne, UK. [4]Institute of Health and Society, Newcastle University, Newcastle Upon Tyne, UK. [5]Obstetrics and Gynaecology, University Hospitals of Morecambe Bay NHS Foundation Trust, Barrow in Furness, UK

Contact: Joseph A Ogah, Obstetrics and Gynaecology, University Hospitals of Morecambe Bay NHS Foundation Trust, Dalton Road, Barrow in Furness, Cumbria, LA14 4LF, UK. joe.ogah@mbht.nhs.uk, joeogah007@hotmail.com.

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ABSTRACT

Background

Urinary incontinence is a very common and debilitating problem affecting about 50% of women at some point in their lives. Stress urinary incontinence (SUI) is a predominant cause in 30% to 80% of these women imposing significant health and economic burden on society and the women affected. Mid-urethral sling (MUS) operations are a recognised minimally invasive surgical treatment for SUI. MUS involves the passage of a small strip of tape through either the retropubic or obturator space, with entry or exit points at the lower abdomen or groin, respectively. This review does not include single-incision slings.

Objectives

To assess the clinical effects of mid-urethral sling (MUS) operations for the treatment of SUI, urodynamic stress incontinence (USI) or mixed urinary incontinence (MUI) in women.

Search methods

We searched: Cochrane Incontinence Specialised Register (including: CENTRAL, MEDLINE, MEDLINE In-Process, ClinicalTrials.gov) (searched 26 June 2014); Embase Classic (January 1947 to Week 25 2014); WHO ICTRP (searched 30 June 2014); reference lists.

Selection criteria

Randomised or quasi-randomised controlled trials amongst women with SUI, USI or MUI, in which both trial arms involve a MUS operation.

Data collection and analysis

Two review authors independently assessed the methodological quality of potentially eligible studies and extracted data from included trials.

Main results

We included 81 trials that evaluated 12,113 women. We assessed the quality of evidence for outcomes using the GRADE assessment tool; the quality of most outcomes was moderate, mainly due to risk of bias or imprecision.

Fifty-five trials with data contributed by 8652 women compared the use of the transobturator route (TOR) and retropubic route (RPR). There is moderate quality evidence that in the short term (up to one year) the rate of subjective cure of TOR and RPR are similar (RR 0.98, 95% CI 0.96 to 1.00; 36 trials, 5514 women; moderate quality evidence) ranging from 62% to 98% in the TOR group, and from 71% to 97% in the RPR group. Short-term objective cure was similar in the TOR and RPR groups (RR 0.98, 95% CI 0.96 to 1.00; 40 trials, 6145 women). Fewer

trials reported medium-term (one to five years) and longer-term (over five years) data, but subjective cure was similar between the groups (RR 0.97, 95% CI 0.87 to 1.09; 5 trials, 683 women; low quality evidence; and RR 0.95, 95% CI 0.80 to 1.12; 4 trials, 714 women; moderate quality evidence, respectively). In the long term, subjective cure rates ranged from 43% to 92% in the TOR group, and from 51% to 88% in the RPR group.

MUS procedures performed using the RPR had higher morbidity when compared to TOR, though the overall rate of adverse events remained low. The rate of bladder perforation was lower after TOR (0.6% versus 4.5%; RR 0.13, 95% CI 0.08 to 0.20; 40 trials, 6372 women; moderate quality evidence). Major vascular/visceral injury, mean operating time, operative blood loss and length of hospital stay were lower with TOR.

Postoperative voiding dysfunction was less frequent following TOR (RR 0.53, 95% CI 0.43 to 0.65; 37 trials, 6200 women; moderate quality evidence). Overall rates of groin pain were higher in the TOR group (6.4% versus 1.3%; RR 4.12, 95% CI 2.71 to 6.27; 18 trials, 3221 women; moderate quality evidence) whereas suprapubic pain was lower in the TOR group (0.8% versus 2.9%; RR 0.29, 95% CI 0.11 to 0.78); both being of short duration. The overall rate of vaginal tape erosion/exposure/extrusion was low in both groups: 24/1000 instances with TOR compared with 21/1000 for RPR (RR 1.13, 95% CI 0.78 to 1.65; 31 trials, 4743 women; moderate quality evidence). There were only limited data to inform the need for repeat incontinence surgery in the long term, but it was more likely in the TOR group than in the RPR group (RR 8.79, 95% CI 3.36 to 23.00; 4 trials, 695 women; low quality evidence).

A retropubic bottom-to-top route was more effective than top-to-bottom route for subjective cure (RR 1.10, 95% CI 1.01 to 1.19; 3 trials, 477 women; moderate quality evidence). It incurred significantly less voiding dysfunction, and led to fewer bladder perforations and vaginal tape erosions.

Short-and medium-term subjective cure rates between transobturator tapes passed using a medial-to-lateral as opposed to a lateral-to-medial approach were similar (RR 1.00, 95% CI 0.96 to 1.06; 6 trials, 759 women; moderate quality evidence, and RR 1.06, 95% CI 0.91 to 1.23; 2 trials, 235 women; moderate quality evidence). There was moderate quality evidence that voiding dysfunction was more frequent in the medial-to-lateral group (RR 1.74, 95% CI 1.06 to 2.88; 8 trials, 1121 women; moderate quality evidence), but vaginal perforation was less frequent in the medial-to-lateral route (RR 0.25, 95% CI 0.12 to 0.53; 3 trials, 541 women). Due to the very low quality of the evidence, it is unclear whether *t*he lower rates of vaginal epithelial perforation affected vaginal tape erosion (RR 0.42, 95% CI 0.16 to 1.09; 7 trials, 1087 women; very low quality evidence).

Authors' conclusions

Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence (SUI) in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term. This review illustrates their positive impact on improving the quality of life of women with SUI. However, a brief economic commentary (BEC) identified three studies suggesting that transobturator may be more cost-effective compared with retropubic. Fewer adverse events occur with employment of a transobturator approach with the exception of groin pain. When comparing transobturator techniques of a medial-to-lateral versus a lateral-to-medial insertion, there is no evidence to support the use of one approach over the other. However, a bottom-to-top route was more effective than top-to-bottom route for retropubic tapes.

A salient point illustrated throughout this review is the need for reporting of longer-term outcome data from the numerous existing trials. This would substantially increase the evidence base and provide clarification regarding uncertainties about long-term effectiveness and adverse event profile.

PLAIN LANGUAGE SUMMARY

Mid-urethral sling operations for stress urinary incontinence in women

Background information

Stress urinary incontinence (involuntary leakage of urine on effort or exertion; or on sneezing, coughing or laughing) is the commonest form of incontinence in women and leads to a reduction in their quality of life. Women with stress urinary incontinence can also have problems with sexual intercourse, as leakage of urine can occur. A significant amount of the woman's and her family's income can be spent on managing the symptoms. One in three women over the age of 18 years will be affected by stress urinary incontinence at some point in her lifetime.

Over the years, surgery to stop this problem has become less invasive. Mid-urethral sling operations are one of the various types of surgeries available. These operations are suitable for women who are having their first operation and those who had previous unsuccessful surgery. In a mid-urethral sling operation a tape is placed underneath the urethra, which is the tube that carries urine out of the bladder. When the woman coughs, the tape compresses the tube, thus providing the support necessary to prevent urine leakage.

There are two main ways of carrying out these operations, either by inserting a tape behind the pubic bone through the abdomen ('retropubic'), or through the groin ('transobturator').

What this review tried to find out

We looked at the effects and costs of mid-urethral sling operations using the two different methods. We also compared different ways of inserting the tape, and using tapes made from different materials. The purpose of this review was to find out how effective these operations are in the treatment of stress urinary incontinence and help determine potential complications rate.

Main findings of this review

We performed a thorough literature search up to June 2014. We identified 81 trials that had a total of 12,113 women. These trials showed that over 80% of women with stress urinary incontinence are cured, or have significant improvement in their symptoms, with either operation, for up to five years after surgery, irrespective of the tapes used and the route of tape insertion. The studies used different questionnaires to assess quality of life, which meant that we could not combine their results . However, the information available for quality of life shows that it improves as a result of these operations, though there is no clear difference between the two procedures. In terms of costs, a non-systematic review of economic studies suggested that transobturator had lower costs than retropubic methods. Only a few trials provided information about the effectiveness of these tapes more than five years after surgery. The evidence that we have been able to assess indicates that the positive effects persist.

Adverse effects

Tapes passing behind the pubic bone (retropubic) seem to carry a greater risk of injuring the bladder during the operation and of women experiencing problems emptying their bladder completely after surgery. However, this operation leads to less groin pain in the short term. There is some limited evidence that this way of inserting the tape has a lower risk of requiring a repeat operation in the long term compared to tapes passing through the groin (transobturator). There is moderate quality evidence that overall reported rates of tape-related complications are low, such as erosion of the tape into the vagina at about 2% for both routes of tape insertion. The reported occurrence of problems with sexual intercourse including pain was low, and leakage of urine during intercourse are improved following insertion of these tapes.

Limitations of the review

Most of our results are based on moderate quality evidence. Most trials did not describe their methods clearly, thus leading to some degree of uncertainty in the findings. At present there are only a limited number of randomised controlled trials (these produce the most reliable results) that have published data beyond five years after surgery. This means that evidence about how effective and safe these procedures are in the longer term lags behind the evidence for them in the short and medium term (up to five years). Longer-term data are required to help increase the reliability of longer-term results.

Summary of findings for the main comparison. Transobturator (TOR) compared to retropubic (RPR) route for stress urinary incontinence in women

Transobturator (TOR) compared to retropubic (RPR) route for stress urinary incontinence in women

Patient or population: women with stress urinary incontinence
Settings: Secondary care
Intervention: transobturator (TOR)
Comparison: retropubic (RPR) route

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Retropubic (RPR) route	Transobturator (TOR)				
Subjective cure (Short term < 1 year)	Study population		RR 0.98 (0.96 to 1.00)	5514 (36 RCTs)	⊕⊕⊕⊖ MODERATE [1]	
	844 per 1000	827 per 1000 (810 to 844)				
	Mean control group risk across studies					
	833 per 1000	816 per 1000 (800 to 833)				
Subjective cure (medium term, 1 to 5 years)	Study population		RR 0.97 (0.92 to 1.03)	683 (5 RCTs)	⊕⊕⊖⊖ LOW [2,3]	
	881 per 1000	854 per 1000 (810 to 907)				
	Mean control group risk across studies					
	869 per 1000	843 per 1000 (799 to 895)				
Subjective cure (long term, > 5 years)	Study population		RR 0.95 (0.87 to 1.04)	714 (4 RCTs)	⊕⊕⊕⊖ MODERATE [4]	
	707 per 1000	671 per 1000 (615 to 735)				
	Mean control group risk across studies					

	843 per 1000	801 per 1000 (733 to 877)			
Bladder or urethral perforation	Study population		RR 0.13 (0.08 to 0.20)	6372 (40 RCTs)	⊕⊕⊕⊖ MODERATE [5]
	49 per 1000	6 per 1000 (4 to 10)			
	Mean control group risk across studies				
	25 per 1000	3 per 1000 (2 to 5)			
Voiding dysfunction (short and medium term, up to 5 years)	Study population		RR 0.53 (0.43 to 0.65)	6217 (37 RCTs)	⊕⊕⊕⊖ MODERATE [6]
	72 per 1000	38 per 1000 (31 to 47)			
	Mean control group risk across studies				
	55 per 1000	29 per 1000 (24 to 36)			
De novo urgency or urgency incontinence (short term, up to 12 months)	Study population		RR 0.98 (0.82 to 1.17)	4923 (31 RCTs)	⊕⊕⊕⊖ MODERATE [7]
	82 per 1000	80 per 1000 (67 to 96)			
	Mean control group risk across studies				
	83 per 1000	81 per 1000 (68 to 97)			
Groin pain	Study population		RR 4.62 (3.09 to 6.92)	3226 (18 RCTs)	⊕⊕⊕⊖ MODERATE [8]
	14 per 1000	66 per 1000 (44 to 99)			
	Mean control group risk across studies				
	45 per 1000	208 per 1000 (139 to 311)			

Suprapubic pain	Study population		RR 0.29 (0.11 to 0.78)	1105 (4 RCTs)	⊕⊕⊕⊖ MODERATE [9]
	29 per 1000	8 per 1000 (3 to 23)			
	Mean control group risk across studies				
	18 per 1000	5 per 1000 (2 to 14)			
Vaginal tape erosion (short and medium term, up to 5 years)	Study population		RR 1.13 (0.78 to 1.65)	4743 (31 RCTs)	⊕⊕⊕⊖ MODERATE [10]
	20 per 1000	22 per 1000 (15 to 32)			
	Mean control group risk across studies				
	21 per 1000	24 per 1000 (16 to 34)			
Repeat incontinence surgery (short term, within 12 months)	Study population		RR 1.64 (0.85 to 3.16)	1402 (9 RCTs)	⊕⊕⊕⊖ MODERATE [11]
	19 per 1000	31 per 1000 (16 to 60)			
	mean control group across studies				
	24 per 1000	39 per 1000 (20 to 76)			
Repeat incontinence surgery (long term, > 5 years)	Study population		RR 8.79 (3.36 to 23.00)	695 (4 RCTs)	⊕⊕⊖⊖ LOW [12,13]
	11 per 1000	100 per 1000 (38 to 262)			
	Mean control group across studies				
	67 per 1000	589 per 1000 (225 to 1000)			
Quality of life	16 different validated questionnaires were used by different studies to assess QoL. This outcome was reported in 11 RCTs, but reported in different ways which precluded meta-analysis. In all but one of the RCTs where QoL was assessed there was improvement in the QoL in women after the inter-		-	(11 RCTs)	

	vention, irrespective of which route was used, with no significant difference in scores between groups. Where assessment of sexual function was performed, there was an equal amount of improvement in sexual function following surgical treatment, irrespective of the route employed

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CAD: Canadian dollars

CI: confidence interval

RCT: randomised controlled trial

RPR: retropubic route

RR: risk ratio
QoL: quality of life

TOR: transobturator route

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low quality: We are very uncertain about the estimate

[1]Random sequence generation was unclear in 13 studies and at high risk of bias in 2 studies, and allocation concealment was unclear in 20 studies and at high risk in 2/37 studies
[2]Allocation concealment was unclear in 2/5 trials and sequence generation was unclear in 1/5 trials, so we decided to downgrade by 1 level
[3]There was potential substantial heterogeneity with an I^2 value of 67%, so we downgraded the quality rating by 1 level
[4]There was potential substantial heterogeneity among studies with an I^2 value of 65%, which lead us to downgrade by 1 level
[5]As allocation concealment was unclear in 18/40 trials and at high risk in 3/40, and sequence generation was unclear in 14/40 trials and at high risk in 3/40, we decided to downgrade by 1 level
[6]As allocation concealment was unclear in 16/37 trials and at high risk in 2/37, and sequence generation was unclear in 11/37 trials and at high risk in 2/37, we decided to downgrade by 1 level
[7]Random sequence generation was unclear in 10/31 studies and at high risk of bias in 2/31, and allocation concealment was unclear in 15/31 studies and at high risk in 2/31, so we downgraded by 1 level
[8]Random sequence generation was unclear in 4/18 studies and at high risk in 2/18, and allocation concealment was unclear in 9/18 studies and at high risk in 2/18, so we downgraded the quality of the evidence by 1 level
[9]Random sequence generation was at high risk in 1/4 studies, while allocation concealment was unclear in 2/4 and at high risk in 1/4, so we downgraded by 1 level
[10]Allocation concealment was unclear in 12/31 trials and at high risk in 1/31, while sequence generation was unclear in 6/31 trials and at high risk in 1/31, so we decided to downgrade by 1 level
[11]The wide confidence interval was judged to include a threshold for appreciable harm considered to be > 25% increase in RR, in this case there was much more than a 25% increase in RR for harm, so we downgraded the level by 1
[12]There was potential substantial heterogeneity with an I^2 value of 46%, so we downgraded the quality rating by 1 level

[13]Due to the low number of studies reporting data for this outcome, and the low number of events and wide CI around the estimate of the effect, we downgraded the quality of evidence by 1 level due to imprecision

Summary of findings 2. Retropubic bottom-to-top approach compared to retropubic top-to-bottom approach for stress urinary incontinence in women

Retropubic bottom-to-top approach compared to retropubic top-to-bottom approach for stress urinary incontinence in women

Patient or population: women with stress urinary incontinence
Settings: Secondary care
Intervention: retropubic bottom-to-top approach
Comparison: retropubic top-to-bottom approach

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	retropubic top-to-bottom approach	Retropubic bottom-to-top approach				
Subjective cure (short term, ≤ 1 year)	Study population		RR 1.10 (1.01 to 1.20)	492 (3 RCTs)	⊕⊕⊕⊖ MODERATE [1]	
	770 per 1000	847 per 1000 (778 to 924)				
	Mean control group across studies					
	890 per 1000	979 per 1000 (899 to 1000)				
Subjective cure (medium term, 1 to 5 years)	No studies reported this outcome		-	(0 studies)		
Subjective cure long term: > 5 years	No studies reported this outcome		-	(0 studies)		
Bladder or urethral perforation	Study population		RR 0.55 (0.31 to 0.98)	631 (5 RCTs)	⊕⊕⊕⊖ MODERATE [2]	
	85 per 1000	47 per 1000 (26 to 83)				
	Mean control group across studies					
	115 per 1000	63 per 1000				

		(36 to 113)			
Voiding dysfunction	Study population		RR 0.40 (0.18 to 0.90)	631 (5 RCTs)	⊕⊕⊕⊖ MODERATE [2]
	60 per 1000	24 per 1000 (11 to 54)			
	Mean control group across studies				
	49 per 1000	20 per 1000 (9 to 44)			
De novo urgency or urgency incontinence	Study population		RR 0.84 (0.52 to 1.34)	547 (4 RCTs)	⊕⊕⊖⊖ LOW [3,4]
	123 per 1000	103 per 1000 (64 to 165)			
	Mean control group across studies				
	187 per 1000	157 per 1000 (97 to 250)			
Vaginal tape erosion	Study population		RR 0.27 (0.08 to 0.95)	569 (4 RCTs)	⊕⊕⊕⊖ MODERATE [5]
	35 per 1000	9 per 1000 (3 to 33)			
	Mean control group across studies				
	69 per 1000	19 per 1000 (6 to 65)			
Repeat incontinence surgery short term	No studies reported this outcome		-	(0 studies)	
Repeat incontinence surgery long term	No studies reported this outcome		-	(0 studies)	
Quality of life (IIQ scores)	The mean quality of life (IIQ scores) in the control group was 49.9	The mean quality of life (IIQ scores) in the intervention group was 4.6 lower (14.17 lower to 4.97 higher)	-	84 (1 RCT)	

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval

IIQ: Incontinence Impact questionnaire

RCT: randomised controlled trial

RR risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low quality: We are very uncertain about the estimate.

[1]Sequence generation and allocation concealment was unclear in 2/3 trials, so we downgraded by 1 level
[2]Sequence generation and allocation concealment was unclear in 3/5 trials, so we downgraded by 1 level
[3]Sequence generation was unclear in 2/4 studies and allocation concealment unclear in 3/4 studies, so we downgraded by 1 level
[4]The wide confidence interval was judged to include a threshold for appreciable harm considered to be > 25% increase in RR, in this case there was much more than a 25% increase in RR for harm, so we downgraded the level by 1
[5]Sequence generation unclear in 3/4 studies and allocation concealment unclear in 2/4 studies, so we downgraded by 1 level

Summary of findings 3. Obturator medial-to-lateral approach compared to obturator lateral-to-medial approach for stress urinary incontinence in women

Obturator medial-to-lateral approach compared to obturator lateral-to-medial approach for stress urinary incontinence in women

Patient or population: women with stress urinary incontinence
Settings: Secondary care
Intervention: obturator medial-to-lateral approach
Comparison: obturator lateral-to-medial approach

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Obturator lateral-to-medial approach	Obturator medial-to-lateral approach				
Subjective cure (short term ≤ 1 year)	Study population		RR 1.00 (0.96 to 1.06)	759 (6 RCTs)	⊕⊕⊝⊝ LOW [1]	
	877 per 1000	877 per 1000 (842 to 930)				
	Mean control group risk across studies					

	880 per 1000	880 per 1000 (845 to 933)			
Subjective cure (medium term, 1 to 5 years)	Study population		RR 1.06 (0.91 to 1.23)	235 (2 RCTs)	⊕⊕⊝⊝ LOW [2]
	711 per 1000	753 per 1000 (647 to 874)			
	Mean control group risk across studies				
	736 per 1000	780 per 1000 (670 to 905)			
Subjective cure	No studies reported this outcome		-	(0 studies)	
Bladder or urethral perforation	Study population		RR 0.38 (0.07 to 1.92)	794 (6 RCTs)	⊕⊕⊕⊝ MODERATE [3]
	11 per 1000	4 per 1000 (1 to 20)			
	Mean control group risk across studies				
	6 per 1000	2 per 1000 (0 to 12)			
Voiding dysfunction (short and medium term, up to 5 years)	Study population		RR 1.74 (1.06 to 2.88)	1121 (8 RCTs)	⊕⊕⊕⊝ MODERATE [4]
	40 per 1000	70 per 1000 (43 to 116)			
	Mean control group risk across studies				
	55 per 1000	96 per 1000 (58 to 158)			
De novo urgency or urgency incontinence (short term, up to 12 months)	Study population		RR 1.01 (0.46 to 2.20)	357 (3 RCTs)	⊕⊕⊝⊝ LOW [5]
	63 per 1000	63 per 1000 (29 to 138)			
	Mean control group risk across studies				
	64 per 1000	65 per 1000			

		(29 to 141)			
Groin pain	Study population		RR 1.15 (0.75 to 1.76)	837 (6 RCTs)	⊕⊖⊖⊖ VERY LOW [6,7]
	80 per 1000	92 per 1000 (60 to 140)			
	Mean control group risk across studies				
	74 per 1000	85 per 1000 (56 to 130)			
Vaginal tape erosion (short and medium term, up to 5 years)	Study population		RR 0.42 (0.16 to 1.09)	1087 (7 RCTs)	⊕⊖⊖⊖ VERY LOW [7,8]
	24 per 1000	10 per 1000 (4 to 26)			
	Mean control group risk across studies				
	17 per 1000	7 per 1000 (3 to 19)			
Repeat incontinence surgery (short term, up to 12 months)	Study population		RR 0.64 (0.32 to 1.30)	532 (2 RCTs)	⊕⊕⊖⊖ LOW [7,9]
	71 per 1000	45 per 1000 (23 to 92)			
	Mean control group risk across studies				
	58 per 1000	37 per 1000 (19 to 75)			
Repeat incontinence surgery	No studies reported this outcome		-	(0 studies)	
Quality of life	The mean quality of life in the control group was 0	The mean quality of life in the intervention group was 16.54 higher (4.84 higher to 28.24 higher)	-	46 (1 RCT)	⊕⊖⊖⊖ VERY LOW [10,11]

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval

RCT: randomised controlled trial

RR: risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low quality: We are very uncertain about the estimate

[1]Random sequence generation was unclear in 4/6 studies, allocation concealment was unclear in5/6 and at high risk in 1/6 studies, so we downgraded the quality of evidence due to risk of bias by 2 levels
[2]Random sequence generation was unclear in all both studies, allocation concealment was unclear in 1 and high risk of bias in the other study, so we downgraded by 2 levels
[3]Sequence generation was unclear in 2 studies and allocation concealment was unclear in 3 studies, so we downgraded the quality rating by 1 level
[4]Sequence generation was unclear in 3 studies and at high risk in 1 study, while allocation concealment was unclear in 4 studies and at high risk in 1 study, so we downgraded by 1 level
[5]Sequence generation was unclear in 2/3 studies and at high risk in 1/3, allocation concealment was unclear in 2/3 studies and high in 1/3, so we downgraded by 2 levels
[6]Random sequence generation was unclear in 2/5 and high in 1/5 studies, while allocation concealment was unclear in 2/5 and high in 2/5 studies, so we downgraded the quality of evidence due to high risk of bias by 2 levels
[7]The wide confidence interval was judged to include a threshold for appreciable harm considered to be > 25% increase in RR, in this case there was > 65% increase in RR for harm, so we downgraded by 1 level
[8]Sequence generation was unclear in 3/7 studies and at high risk in 1/7. Allocation concealment was unclear in 5/7 studies and at high risk in 1/7. We downgraded the quality rating by 2 levels
[9]Sequence generation and allocation concealment were unclear in 1/2 studies, so we downgraded by 1 level
[10]Sequence generation and allocation concealment were unclear, so we downgraded by 1 level
[11]As there was only 1 study with very few events and CIs around estimates of effect included appreciable benefit and appreciable harm, we downgraded by 2 levels

Summary of findings 4. Monofilament compared to multifilament tapes for stress urinary incontinence in women

Monofilament compared to multifilament tapes for stress urinary incontinence in women

Patient or population: women with stress urinary incontinence
Settings: Secondary care
Intervention: monofilament
Comparison: multifilament tapes

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	multifilament tapes	Monofilament				
Subjective cure (short term ≤ 1 year)	Study population		RR 1.07 (0.98 to 1.16)	505 (4 RCTs)	⊕⊕⊕⊖ MODERATE [1]	
	784 per 1000	839 per 1000				

	(768 to 909)				
	Mean control group risk across studies				
	810 per 1000	867 per 1000 (794 to 939)			
Subjective cure (medium term: 1 to 5 years)	No studies reported this outcome		-	(0 studies)	
Subjective cure (long term: > 5 years)	No studies reported this outcome		-	(0 studies)	
Bladder or urethral perforation	Study population		RR 0.76 (0.29 to 1.99)	496 (4 RCTs)	⊕⊕⊕⊖ MODERATE [1]
	37 per 1000	28 per 1000 (11 to 73)			
	Mean control group risk across studies				
	32 per 1000	25 per 1000 (9 to 64)			
Voiding dysfunction	Study population		RR 2.20 (0.98 to 4.92)	400 (3 RCTs)	⊕⊕⊖⊖ LOW [2,3]
	41 per 1000	89 per 1000 (40 to 200)			
	Mean control group risk across studies				
	65 per 1000	143 per 1000 (64 to 320)			
De novo urgency or urgency incontinence	Study population		RR 1.09 (0.66 to 1.82)	496 (4 RCTs)	⊕⊕⊖⊖ LOW [4,5]
	102 per 1000	111 per 1000 (67 to 186)			
	Mean control group risk across studies				
	107 per 1000	117 per 1000 (71 to 195)			
Vaginal tape erosion	Study population		RR 0.43 (0.16 to 1.14)	396 (3 RCTs)	⊕⊕⊕⊕ HIGH

	62 per 1000	26 per 1000 (10 to 70)			
	Mean control group risk across studies				
	43 per 1000	18 per 1000 (7 to 49)			
Repeat incontinence surgery (short term ≤ 1 year)	No studies reported this outcome		-	(0 studies)	
Repeat incontinence surgery (long term > 5 years)	No studies reported this outcome		-	(0 studies)	
Quality of life scores ICIQ	The mean quality of life scores ICIQ in the control group was 2.1	The mean quality of life scores ICIQ in the intervention group was 0.6 lower (0.76 lower to 0.44 lower)	-	96 (1 RCT)	⊕⊕⊕⊕ HIGH

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval

ICIQ: International Consultation on Incontinence questionnaire

RCT: randomised controlled trial

RR: risk ratio

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low quality: We are very uncertain about the estimate

[1]Random sequence generation and allocation concealment unclear in 2/4 studies, so we downgraded by 1 level
[2]Random sequence generation and allocation concealment unclear in 2/3 studies, so downgraded by 1 level
[3]The wide confidence interval was judged to include a threshold for appreciable harm considered to be > 25% increase in RR, in this case there was much more than a 25% increase in RR for harm, so we downgraded by 1 level
[4]Sequence generation and allocation concealment were unclear in 2/4 studies, so we downgraded the quality rating by 1 level
[5]The wide confidence interval was judged to include a threshold for appreciable harm considered to be > 25% increase in RR, in this case there was > 65% increase in RR for harm, so we downgraded by 1 level

BACKGROUND

Urinary incontinence is a very common condition in women. It is associated with significant physical morbidity, sexual dysfunction, loss of independence and a reduction in psychological well being, with consequent decreased participation in social and domestic activities (Wetle 1995; Thom 1998; Van Oyen 2002; Salonia 2004; Botlero 2010). Overall the prevalence of urinary incontinence in adult women has been estimated to be between 10% and 40%, and is considered severe in about 3% to 17%, with annual incidence ranging from 2% to 11% (Hunskaar 2002; Milsom 2009). The prevalence of stress urinary incontinence (SUI) in women is between 12% to 46% (Botlero 2008; Coyne 2009; Irwin 2006). This is a potentially debilitating social problem, with significant cost implications to the individuals and the healthcare service. The estimated annual cost to the healthcare system in the UK exceeds GBP 700 million (1999/2000 GBP) (Turner 2004) while in the USA, the annual total direct costs in both men and women is over USD 16 billion (1995 USD) (Chong 2011) with societal costs of USD 26.2 billion (1995 USD) (Wagner 1998). Approximately, USD 13.12 billion (1995 USD) of the total direct costs of urinary incontinence is spent on SUI (Chong 2011; Kunkle 2015). In the USA,about 70% of this USD 13.12 billion is borne by the patients mainly through routine care (purchasing pads and disposable underwear (diapers), laundry and dry cleaning). Of the remaining 30%, 14% is spent on nursing home admission, 9% on treatment, 6% on addressing complications and 1% on diagnosis (Chong 2011). In the UK an estimated more than GBP 178 million (1999/2000 GBP) is borne by women on an individual basis annually (Turner 2004; Papanicolaou 2005).This constitutes a significant individual financial burden.

A study reported that about 1% of the median annual household income (USD 50,000 to USD 59,999) was spent by women on incontinence management. This study estimated that women spent an annual mean cost of USD 751 to USD 1277 (2006 USD) on incontinence. This cost increases based on the severity of the symptoms (Subak 2008).The indirect cost associated exerts social and psychological burdens which are unquantifiable. (Chong 2011; Kilonzo 2004). Nevertheless, Birnbaum 2004 estimated that the annual average direct medical costs of SUI for one year (1998 USD) was USD 5642 and USD 4208 for indirect workplace costs.The cost of management and treatment of SUI appears to have increased over time due to increasing prevalence and an increased desire for improved quality of life (QOL). This in turn has resulted from improved recognition of the condition, as well as increased use of surgical and non-surgical managements.

Continence is achieved through interplay of the normal anatomical and physiological properties of the bladder, urethra, urethral sphincter and pelvic floor, with the nervous system co-ordinating these organs. The urethra and its sphincter act as a closure mechanism during bladder filling to contain urine within the bladder, thereby allowing storage of urine until a convenient time and place to void is reached. The pelvic floor provides support to the bladder and urethra, and allows normal abdominal pressure transmission to the proximal urethra, which is essential in the maintenance of continence. Crucial to the healthy functioning of the bladder, urethra, sphincter and pelvic floor is co-ordination between them, which is facilitated by an intact nervous system.

There are many theories hypothesizing the pathophysiology of stress urinary incontinence. Historically Goran Enhorning was first to measure simultaneous bladder and urethral pressures. He suggested that during the cough impulse, pressure is transmission from the abdomen to the urethra with a concurrent reduction in urethral closure pressure that results in SUI (Enhorning 1961). McGuire's modified classification of SUI emphasizes the principle of intrinsic sphincter deficiency (ISD) as a cause of SUI. This is said to occur due to poor urethral closure function resulting from defective urethral mucosal coaptation. These two theories informed procedures such as the Burch Colposuspension and Marshall Marchetti Krantz operations. De Lancey's 'hammock' theory suggested that abdominal pressure transmission to the bladder neck and urethra leads to the proximal urethra being compressed against the pubo-vesical fascia and anterior vaginal wall, thus maintaining continence (DeLancey 1994).

Recent findings on the pathophysiology of urinary incontinence have demonstrated that mid-urethral support, provided by the pubo-urethral ligaments, also plays an important role in maintaining continence when the intra-abdominal pressure rises. This has led to the 'integrated theory' for the maintenance of continence in female SUI (Petros 1990; Petros 1993). This theory, in turn, is the basis for the current use of minimally invasive mid-urethral tapes in the treatment of SUI.

When performing mid-urethral tape surgery there are different types of synthetic materials used. Synthetic meshes are divided into four groups:

- type 1 are macroporous, monofilament;
- type 2 are microporous;
- type 3 are macroporous, multifilament;
- type 4 are submicronic, coated biomaterials with pore sizes of less than 1 µm.

Type 1 mesh has the highest biocompatibility with the least propensity for infection. Differences in their efficacy and complications are likely to be due to several factors including the different knits and weaves of the various tape materials, their biomechanical properties and histological biocompatibility. Pore size affects the inflammatory response and resultant connective tissue formation within and into the mesh, and the rearrangement of materials such as collagen within the mesh structure. Macroporous meshes (pore size in excess of 75 µm) easily allow macrophages, leukocytes, fibroblasts, blood vessels and collagen to transverse the pores: thus macroporous meshes promote tissue host ingrowth with resultant biocompatibility and low risk of infection (Amid 1997). Monofilament tapes are widely available and now predominate in current clinical practice.

In contrast, microporous meshes (pore size greater than 10 µm) allow bacteria to pass through and replicate, but exclude macrophages. Multifilament tapes have smaller pore sizes, and are thus microporous. This perhaps explains why tape erosion was more common in the multifilament tapes, though statistical significance was not reached.

Description of the condition

Incontinence occurs when this normal relationship between the lower urinary tract components is disrupted, as a result of nerve damage or direct mechanical disruption to the pelvic organs. Advancing age, higher parity, vaginal delivery, obesity and post

menopausal status are all associated with an increased risk of urinary incontinence (Wilson 1996).

There are different forms of urinary incontinence of which SUI is the most common type, accounting for at least 50% of cases of urinary incontinence in women (Hannestad 2000). SUI is the involuntary loss of urine that occurs with physical exertion (e.g. sporting activities), or on sneezing or coughing (Haylen 2010). Urodynamic stress incontinence (USI) is the involuntary leakage of urine observed during filling cystometry, it is associated with increased intra-abdominal pressure, in the absence of a detrusor contraction (Haylen 2010). Two mechanisms for stress incontinence are recognized: hyper-mobility or significant displacement of the urethra and bladder neck during exertion, and intrinsic urethral sphincter deficiency (Blaivas 1988). These mechanisms may co-exist in women (O'Donnell 1994). Few clinical trials have distinguished between the two conditions, probably because there is currently no standardised and validated test available for this (Blaivas 1988; McGuire 1993). We considered women whose incontinence could be due to either mechanism together in this review.

The diagnosis of urodynamic stress incontinence implies that urodynamic investigation has been done to confirm stress incontinence; it may also identify the presence of detrusor overactivity, in mixed urinary incontinence. Standard clinical assessment includes history taking, physical examination, frequency/volume charts and urine analysis. Some authors described women with the symptom of stress urinary incontinence only (diagnosis made on clinical evaluation without urodynamics). Women with stress urinary incontinence and those with urodynamic stress incontinence have been included in this review.

Urgency urinary incontinence (UUI) is a sudden, compelling desire to pass urine, which is difficult to defer (urgency), accompanied by the involuntary loss of urine. Detrusor overactivity (DO) is a diagnosis that denotes involuntary detrusor contractions observed during the filling phase of a urodynamic assessment. It may be spontaneous or provoked and can be qualified according to cause - neurogenic or idiopathic (Haylen 2010). We included women with UUI and the formal urodynamic diagnosis of DO in the review only if they had co-existing stress incontinence (so called mixed urinary incontinence (MUI)).

Women with MUI who were included in this review had symptoms of SUI plus either urgency or UUI, or urodynamic stress incontinence (USI) plus DO (urodynamic diagnosis).

Description of the intervention

Management of SUI includes conservative, mechanical, pharmacological and surgical interventions.

- Conservative management centres on lifestyle modifications, physical methods including pelvic floor muscle training, electrical stimulation, biofeedback and the use of weighted cones.
- Mechanical devices that prevent or reduce urinary leakage are available, and include metal plugs or patches and urethral or vaginal inserts.
- Drug therapies, such as oestrogens and alpha adrenergic agents, have been used in the past. Recently, inhibitors of serotonin and norepinephrine reuptake have been proposed as new drug therapy for SUI, used alone or in combination with other conservative management (Ghoniem 2005).

A trial of such conservative treatments should be undertaken before resorting to surgery. The following interventions are the subject of separate Cochrane reviews.

- Lifestyle interventions for the treatment of urinary incontinence in adults (Imamura 2010).
- Bladder training for urinary incontinence in adults (Wallace 2004).
- Comparisons of approaches to pelvic floor muscle training for urinary incontinence in women (Hay-Smith 2011).
- Feedback or biofeedback to augment pelvic floor muscle training for urinary incontinence in women (Herderschee 2011).
- Pelvic floor muscle training added to another active treatment versus the same active treatment alone for urinary incontinence in women (Ayeleke 2013).
- Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women (Dumoulin 2014).
- Combined conservative interventions for urge, stress or mixed incontinence in adults (French 2010).
- Weighted vaginal cones for urinary incontinence (Herbison 2013).
- Mechanical devices for urinary incontinence in women (Lipp 2011).
- Oestrogen therapy for urinary incontinence in post-menopausal women (Cody 2012).
- Adrenergic drugs for urinary incontinence in adults (Alhasso 2005).
- Serotonin and noradrenaline reuptake inhibitors (SNRI) for stress urinary incontinence in adults (Mariappan 2005).
- Acupuncture for stress urinary incontinence in adults (Wang 2013).

Surgical procedures to remedy SUI generally aim to lift and support the urethro-vesical junction, but in the last decade the emphasis has been on suburethral support at the mid-urethral level. Owing to disagreement on the precise mechanism by which continence is achieved, the choice of surgical procedure is influenced by co-existent problems, surgeon's preference and the physical features of the person affected.

Numerous surgical methods for SUI have been described and evaluated in Cochrane reviews. Traditionally, they fall into seven categories:

- suburethral slings (including traditional suburethral slings and minimally invasive sling operations; Rehman 2011);
- open abdominal retropubic suspension (e.g. colposuspension (Burch/modified Burch), Marshall-Marchetti-Krantz (MMK); Lapitan 2012);
- laparoscopic retropubic suspension (Dean 2006);
- anterior vaginal repair (anterior colporrhaphy; Glazener 2001);
- needle suspensions (Glazener 2004);
- urethral injections (Kirchin 2012); and
- artificial sphincters.

Suburethral slings have become the favourite primary continence surgery in current clinical practice. Several developments in type and technique have resulted in the separation of the original sling review, Bezerra 2005, into three different reviews focusing on:

- traditional suburethral slings (Rehman 2011)
- minimally invasive slings such as TVT and TOT (Ogah 2009), and
- single incision slings, also known as mini-slings (Nambiar 2014).

The materials that have been used for slings may be biological or synthetic. The first of these reviews concentrates on traditional (biological) suburethral sling operations (Rehman 2011). A traditional suburethral sling operation requires a combined abdominal and vaginal approach. Strips of material are tunnelled under the proximal urethra. They are attached either to the rectus muscle or the iliopectineal ligaments, resulting in a tightening of the sling and increased bladder support every time the woman strains to prevent leaking. They are applied under open surgery and are fixed with sutures.

This current review is an update of the second of these reviews, focusing on minimally invasive suburethral sling operations using artifical (synthetic) non-absorbable sling materials (Ogah 2009). The techniques of these procedures are described below. This review does not include single incision slings.

The third of these reviews is a new, recently published review that compares a new type of sling, the single incision sling, which is also known as the mini-sling (Nambiar 2014). The technique differs from that of the original synthetic slings in that a single incision is made within the vagina using a significantly shorter tape and there are no tape exit incisions.

How the intervention might work

The current review focuses on mid-urethral sling operations. These involve the insertion of a tape covered by a plastic sheath around the mid-urethra without suture fixation, performed in some centres under local anaesthesia (Ulmsten 1995a; Ulmsten 1996; Smith 2002). The aim is to restore or enhance the patient's urethral support during a sudden movement, such as a cough or sneeze, which would prevent the involuntary loss of urine. Ultrasound studies suggest that the mechanism of action is the intermittent or dynamic obstruction of the urethra by the tape when increased abdominal pressure occurs (such as when coughing or sneezing; Dietz 2004).

There are two main types of surgical approaches.

- **Retropubic:** This procedure involves the insertion of two needles passed through the retropubic space blindly from the vagina to abdomen or from the abdomen to the vagina. Cystoscopy is recommended to detect any perforation of the bladder or urethra (Ulmsten 1995a; Ulmsten 1995b).
- **Transobturator;** This is another type of minimally invasive synthetic suburethral sling operation in which the tape is inserted in a horizontal plane underneath the middle of the urethra between the two obturator foramina. The ends of the tape are tunnelled percutaneously with a tunneller (curved needle), again without suture fixation. As the retropubic space is not breached, it is argued that cystoscopy is not required (Delorme 2001; Delorme 2003; Delorme 2004). Shortly after the development of this technique a similar operation was described in which a tape is passed percutaneously through the obturator foramina, using an inside-to-outside technique, i.e. medio-lateral (de Leval 2003; de Leval 2005).

We included only mid-urethral sling operations, with synthetic tape materials applied through minimally invasive surgeries, either through the retropubic space or the transobturator route in this review. However, a number of modifications of transobturator surgery using the same route have been described and we have included these too.

In this update, in contrast to the original review in which trials of minimally invasive slings were compared to traditional slings, open colposuspension, or laparoscopic colposuspension, these comparator techniques have not been included, as these are now covered by other Cochrane reviews (Dean 2006; Rehman 2011; Lapitan 2012).

A concern of using synthetic material is the potential risk of complications caused by infection and tissue reaction to the tapes. Some aspects of the material that may vary include pore size, mono- or multifilament design, and biocompatibility. We included all types of mesh used in different minimally invasive slings in this review, and assessed possible differences between the risk of complications.

Why it is important to do this review

There is a plethora of minimally invasive synthetic tapes available and used worldwide for treatment of SUI. The reported effectiveness and safety of these procedures have made them very popular, but in the past there has been controversy about which of these procedures is best, as the introduction of many of these procedures and tapes was market driven and was not accompanied by rigorous prospective randomised controlled trials of effectiveness. Now more randomised controlled trials that assess their effectiveness have been published, but many trials are too small to draw definitive conclusions, hence the need for the first review.

Our initial review, Ogah 2009, showed evidence of efficacy in the short-term, as many trials only reported a 12-month follow-up. A significant advantage of a Cochrane review is not only the rigorous database search and methodology, but most importantly the ability to update the review and meta-analysis as new evidence becomes available. This meta-analysis of the trials available is necessary to help make judgements on medium- and longer-term efficacy, since we now have 18 years-worth of data since the initial report of the retropubic mid-urethral tape, and it is over 11 years since the first randomised trials of the tension-free vaginal tape and transobturator tapes were published. It is also necessary to provide evidence on medium- and longer-term safety of the devices both suspected and expected, and the unexpected adverse events in the long-term. This review update aims to clarify the uncertainty surrounding the use mid-urethral slings in terms of surgical approach, route of insertion and the type of tape used.

This current update analyses only the effects of mid-urethral slings, and excludes both single incision slings and other surgical procedures e.g. traditional slings and colposuspension. The options of no treatment, conservative treatment and pharmacological treatment are also excluded, as this will be addressed in a future Cochrane review.

OBJECTIVES

To assess the clinical effects of mid-urethral sling (MUS) operations for the treatment of stress urinary incontinence (SUI), urodynamic stress incontinence (USI) or mixed urinary incontinence (MUI) in women.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised controlled trials amongst women with USI (urodynamic diagnosis), or symptoms of SUI or MUI (clinical diagnosis), in which both trial arms involve a mid-urethral sling operation.

Types of participants

Adult women with SUI due to hyper-mobility and intrinsic sphincter deficiency, or both, diagnosed clinically or with urodynamics, and women with MUI in which stress incontinence was the predominant symptom. Classification of diagnoses were accepted as defined by the trialists.

Types of interventions

Both trial arms of a study must involve mid-urethral sling operations to treat SUI or MUI.

We made the following comparisons.

- Transobturator route (TOR) versus retropubic route (RPR).
- Retropubic bottom-to-top approach versus retropubic top-to-bottom approach.
- Obturator medial-to-lateral approach versus obturator lateral-to-medial approach.
- One method of mid-urethral tape insertion versus another method, same route.
- One type of tape material versus another

Comparisons with other types of surgery (i.e. traditional slings, single incision slings and colposuspension) for urinary incontinence are covered in other recent Cochrane reviews. The options of no treatment, conservative treatment and pharmacological treatment have also been removed as these will be addressed in a future Cochrane review.

Types of outcome measures

Primary outcomes

We selected the outcome measures used in this review on the basis of their relevance to the clinical cure or improvement of incontinence. We regarded the principal measures of effectiveness as being:

1. Women's observations

- the proportion of women cured (continent or dry) following surgery;
- the proportion of women whose incontinence is improved;
- cure and improvement measured in the short term (less than one year); medium term (one to five years); and long term (more than five years).

Secondary outcomes

2. Women's observations

- Urgency symptoms or urgency incontinence.

3. Quantification of symptoms

- Pad changes (from self-reported number of pads used).
- Incontinence episodes (from self-completed bladder chart).
- Pad tests of quantified leakage (mean volume or weight of urine loss).

4. Clinician's observations

- Objective cure rates in the short term (less than one year); medium term (one to five years); and long term (more than five years).
- De novo detrusor overactivity (urodynamic diagnosis).

5. Surgical outcome measures

- Duration of operation.
- Length of inpatient stay.
- Time to return to normal activity level.
- Operative blood loss.

6. Adverse events

- Major vascular or visceral injury.
- Bladder, urethral or bowel perforation.
- Nerve damage.
- Perioperative surgical complications (e.g. infection, bacteriuria, haemorrhage with or without major vessel lesion).
- Voiding dysfunction or difficulty after three months (with or without urodynamic confirmation) or need for long-term catheterisation.
- Infection related to use of synthetic mesh.
- Tape erosion or extrusion or exposure into the vagina.
- Tape erosion or extrusion or exposure into the bladder or urethra.

7. Need for further treatment

- Physiotherapy treatment.
- Drug treatment for urinary incontinence or symptoms.
- Pelvic organ prolapse (e.g. cystocoele, rectocoele, enterocoele).
- Repeat incontinence surgery.
- Later prolapse surgery.

8. Quality of life

Quality of life assessed by means of:

- general health status measures (e.g. Short Form 36 (Ware 1993));
- condition-specific instruments designed to assess incontinence, e.g. the Bristol Female Lower Urinary Tract Symptoms questionnaire (BFLUTS; Jackson 1996);
- condition-specific sexual function assessment e.g. via Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12;Rogers 2003);
- psychological measures.

9. Other outcomes

- Non-prespecified outcomes judged to be important when performing the review.

Search methods for identification of studies

Unless otherwise stated we did not impose language or other restrictions on any of the searches which are described below.

Electronic searches

This review drew on the search strategy developed for the Cochrane Incontinence Group. We identified relevant trials from the Cochrane Incontinence Group Specialised Trials Register. For more details of the search methods used to build the Specialised Register please see the Group's module in *The Cochrane Library*. The Register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, and MEDLINE in process, ClinicalTrials.gov and handsearching of journals and conference proceedings. Most of the trials in the Cochrane Incontinence Group Specialised Register are also contained in CENTRAL. The date of the last search was 26 June 2014.

The terms used to search the Incontinence Group Specialised Register are given in Appendix 1.

Additionally the following electronic databases were searched, details of the searches and the terms used are given in Appendix 1.

- Embase and Embase Classic (January 1947 to Week 25 2014; searched on 26 June 2014; limited to those years not searched via the CENTRAL search of Embase, i.e. 1 January 2010 to Week 25 2014 inclusive).
- WHO ICTRP (searched on 30 June 2014)

Details of the searches performed for the previous version of this review can be found in Appendix 2.

We performed additional searches for the Brief Economic Commentaries (BECs). We conducted them in MEDLINE(1 January 1946 to March 2017), Embase (1 January 1980 to 2017 Week 12) and NHS EED (1st Quarter 2016). We ran all searches on 6 April 2017. Details of the searches run and the search terms used can be found in Appendix 3.

Searching other resources

We searched the reference lists of relevant articles.

Data collection and analysis

Selection of studies

Randomised and quasi-randomised trials were identified using the above search strategy. We excluded studies from the review if they were not randomised or quasi-randomised controlled trials for incontinent women, or if they made comparisons other than those pre-specified. Excluded studies are listed in the Characteristics of excluded studies table along with reasons for their exclusion. We evaluated all potentially eligible studies for appropriateness for inclusion without prior consideration of the results. We retrieved reports of potentially eligible trials in full.

Data extraction and management

We extracted data independently using a standard form containing pre-specified outcomes. Where data may have been collected but not reported, we sought clarification from the trialists. We processed included trial data as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved differences of opinion relating to study inclusion, methodological quality or data extraction by discussion among the reviewers, and when necessary, referred them to a third party for arbitration.

Assessment of risk of bias in included studies

Miss Abigail Ford and Mr Joseph Ogah (review authors) extracted data and independently assessed the included trials for methodological quality and validity using the 'Risk of bias' assessment tool (Higgins 2011). We assessed the risk of bias in the results of the included trials by examining the following features: selection bias, which results from insecure random allocation of treatments; performance bias that occurs when knowledge of the procedure actually performed might have affected the participant or care provider; attrition bias caused by incomplete reporting of outcome data, or from dropouts or losses to follow-up, particularly if there is a differential dropout rate between groups; and biased ascertainment (detection bias) of outcome where knowledge of the allocation might have influenced the measurement of outcome. These were assessed under the headings below:

- sequence generation;
- allocation sequence concealment;
- blinding of participants and personnel;
- blinding of outcome assessment;
- incomplete outcome data.

These were presented in the 'Risk of bias' tables, graphs and summary figures.

The GRADE (Grades of Recommendation, Assessment, Development and Evaluation) system was used to assess and grade the quality of evidence for each individual outcome (Guyatt 2011a; Guyatt 2011b; Guyatt 2013a; Guyatt 2013b).

Measures of treatment effect

The review was conducted using the standard Cochrane software Review Manager 'Revman' version 5.2 (Reference Manager 2012). For categorical outcomes we related the numbers reporting an outcome to the numbers at risk in each group to derive a summary risk ratio (RR). For continuous variables we used means and standard deviations to derive a mean difference (MD) if the outcomes were measured in the same way between trials. Any continuous data that were the product of a number of different scales (for example, scales used to assess symptoms such as pain or quality of life) we summarised as the standardised mean difference (SMD) using a fixed-effect model. A fixed-effect model was used for calculation of all summary estimates and 95% confidence intervals (CIs) except when there was significant heterogeneity. When appropriate, we undertook meta-analysis.

We undertook a narrative review of eligible trials where statistical synthesis of data from more than one study was not possible, or considered inappropriate.

Unit of analysis issues

We did not perform analysis of trials with non-standard designs, such as cross-over trials and cluster-randomised trials, as there were no such trials. We analysed trials with multiple treatment groups by treating each pair of arms as a separate comparison, as appropriate.

Dealing with missing data

We defined 'intention-to-treat analysis' as meaning that all participants were analysed in their randomised groups whether or not they received the allocated intervention. We included data as they were reported for each outcome and did not impute missing values, but used the data as presented by the trialists. Where intraoperative outcomes were reported, we used the number of patients undergoing the described procedure as the denominator. Follow-up outcomes were reported with the exclusion of patients lost to follow-up. We would have performed sensitivity analyses had there been differential dropout from the randomised groups, or another reason to suspect systematic bias from missing data.

Assessment of heterogeneity

We used a fixed-effect approach for the analysis unless there was evidence of heterogeneity across trials. Differences between trials were investigated when apparent either through visual inspection of the results, or when statistically significant heterogeneity was demonstrated by using the Chi^2 test at the 10% probability level or assessment of the I^2 statistic (Higgins 2003).

Assessment of reporting biases

We examined publication bias by means of a funnel plot where there were 10 or more trials contributing to a meta-analysis.

Data synthesis

We used fixed-effect model analysis for the meta-analyses, except when significant heterogeneity was suspected, when we used a random-effects model.

Subgroup analysis and investigation of heterogeneity

Heterogeneity

Where there was no obvious reason for heterogeneity to exist (after consideration of populations, interventions, outcomes and settings of the individual trials), or it persisted despite the removal of trials that were clearly different from the others, we used a random-effects model.

Subgroup analysis

Clinical factors such as symptoms of SUI, USI, MUI, diagnosis of intrinsic urethral sphincter deficiency or urethral hypermobility, obesity, previous incontinence surgery, presence or absence of prolapse, anaesthesia used, or experience of the surgeon and other concomitant surgical intervention, might all influence the outcomes of surgery and consideration of subgroup analysis was taken into account.

Sensitivity analysis

We performed sensitivity analysis to explore the robustness of the results in some outcomes. We planned to carry out sensitivity analysis for the primary outcomes by restricting our analysis to trials assessed as having a low risk of bias for the of domain attrition bias; if more than 30% of participants had been lost to follow-up, these trials would have been excluded from sensitivity analyses. This was not necessary.

Summary of findings

We employed the GRADE approach to interpret findings (Guyatt 2011a; Guyatt 2011b; Guyatt 2013a; Guyatt 2013b; Langendam 2013), and the GRADE profiler (GRADEpro) was used to import data from RevMan 5.2 to create 'Summary of findings' tables. These tables provide outcome-specific information concerning the overall quality of evidence from trials included in a comparison, the magnitude of effect of the interventions examined, and the sum of the available data on the outcomes we considered.

We included the following outcomes in the 'Summary of findings' tables.

- Subjective cure: medium term (one to five years).
- Subjective cure: long term (more than 5 years).
- Bladder or urethral perforation.
- Voiding dysfunction: short term and medium term (up to five years).
- De novo urgency or urgency incontinence: short term (less than one year).
- Vaginal tape erosion: short term and medium term (up to five years).
- Repeat continence surgery: short term (less than one year).
- Repeat continence surgery: long term (more than five years).
- Groin pain: short term (less than one year).
- Quality of life.

We assessed the overall quality of evidence for these outcomes and downgraded the evidence level from high quality by one level for serious, or by two levels for very serious study limitations (risk of bias), indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias.

RESULTS

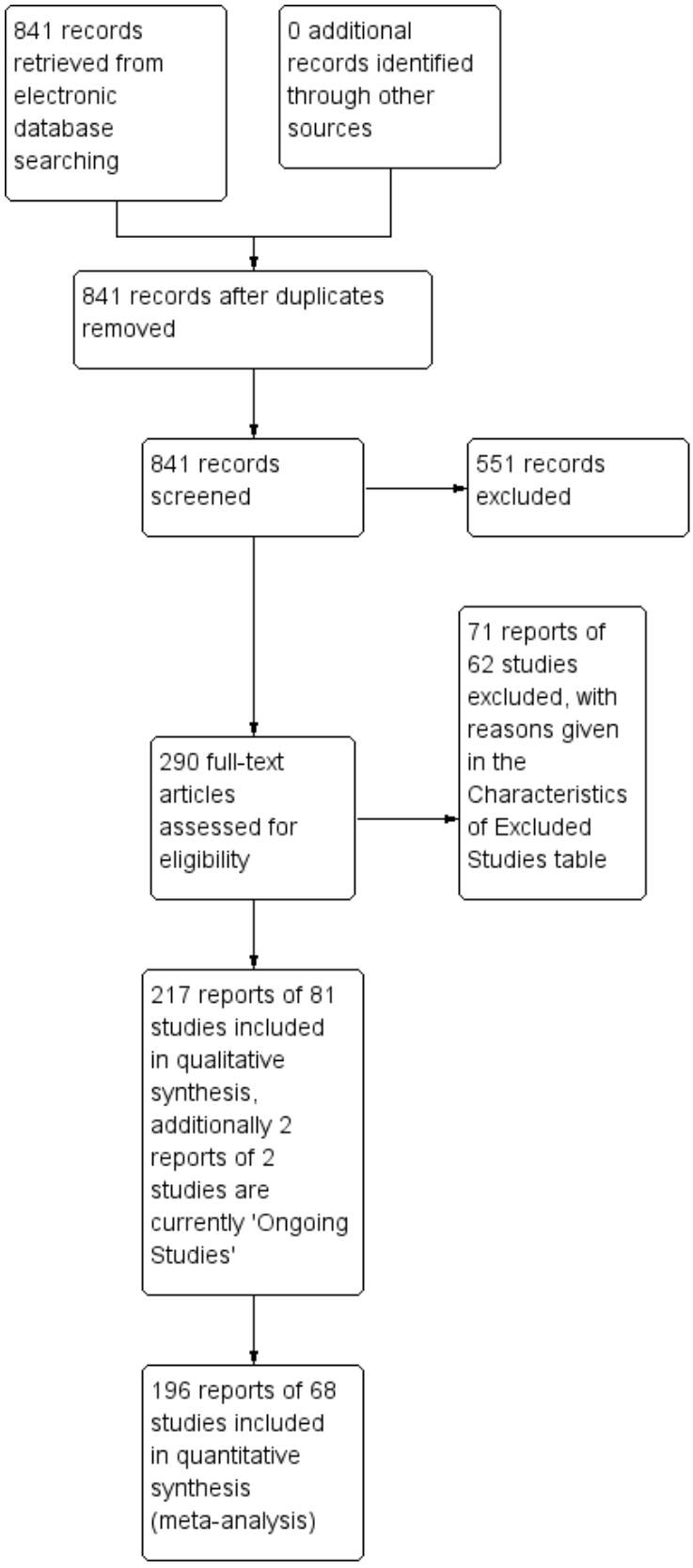
Description of studies

Results of the search

We screened the 841 records identified by the literature searches and obtained a total of 290 full-text articles for further assessment. Altogether 217 reports concerning 81 randomised trials met the inclusion criteria. A further two trials were ongoing.

We excluded 551 records on the basis of either the title or abstract alone, and 71 reports relating to 62 studies after retrieval of the full text publication. Exclusion was either because they were not randomised trials, they did not include a mid-urethral sling operation, or because the women included in the trial were not urinary incontinent. A full description of these trials can be found in the Characteristics of excluded studies section of this review. The flow of literature through the assessment process is shown in Figure 1.

Figure 1. PRISMA study flow diagram



We analysed trials with multiple treatment groups by treating each pair of arms as a separate comparison, as appropriate. There were six trials in this review that supplied data and for which this method was employed, thus leading to 87 comparisons. There were no trials with non-standard designs, such as cross-over trials and cluster-randomised trials.

Included studies

Further characteristics of the trials are reported in the Characteristics of included studies table.

Comparisons and interventions

1. Transobturator (TOR) versus retropubic route (RPR)

This comparison of mid-urethral sling operations was based on the routes that the tapes traverse, i.e. transobturator route (TOR) versus retropubic route (RPR). There were 55 trials that investigated this (Aigmuller 2014; Alkady 2009; Andonian 2007; Aniuliene 2009; Araco 2008; Barber 2008; Barry 2008; Cervigni 2006; Chen 2010; Chen 2012; Choe 2013; Darabi Mahboub 2012; David-Montefiore 2006; Deffieux 2010; de Tayrac 2004; Diab 2012; El-Hefnawy 2010; Enzelsberger 2005; Freeman 2011; Hammoud 2011; Jakimiuk 2012; Kamel 2009; Karateke 2009; Kilic 2007; Kim 2005; Krofta 2010; Laurikainen 2007; Leanza 2009; Lee 2007; Liapis 2006; Mansoor 2003; Mehdiyev 2010; Meschia 2007; Nerli 2009; Nyyssonen 2014; Oliveira 2006; Palomba 2008; Porena 2007; Rechberger 2009; Richter 2010; Riva 2006; Ross 2009; Salem 2014; Scheiner 2012; Schierlitz 2008; Tanuri 2010; Tarcan 2011; Teo 2011; van Leijsen 2013; Wang 2006; Wang 2008; Wang 2009; Wang 2010; Wang 2011; Zullo 2007).

2. Retropubic bottom-to-top approach versus retropubic top-to-bottom approach

Trials in this group compared the retropubic bottom-to-top approach (e.g. tension-free vaginal tape (TVT™); tape inserted from the vagina through the retropubic space and exiting onto the abdominal skin in the suprapubic region) with a retropubic top-to-bottom approach (e.g. suprapubic urethral support sling (SPARC™); tape inserted from the abdomen in the suprapubic region through the retropubic space and exiting in the vagina). There were five such trials (Andonian 2005; Kim 2004; Lim 2005; Lord 2006; Tseng 2005).

3. Obturator medial-to-lateral approach versus obturator lateral-to-medial approach

Ten trials reported on this comparison which compared tapes traversing the obturator route: obturator lateral-to-medial approach, (e.g. TOT™ tape inserted in the thigh crease and through the obturator route exiting in the vagina) with obturator medial-to-lateral approach (e.g. TVT-O™ tape inserted in the vagina and through the obturator route exiting in the thigh crease; Abdel-Fattah 2010; But 2008; Chen 2010; Hassan 2013; Houwert 2009; Lee 2008; Liapis 2008; Park 2012; Peattie 2006; Scheiner 2012).

4. One method of mid-urethral tape insertion versus another method, same route

Ten trials compared different methods of carrying out operations using the same route (Cho 2010; de Leval 2011; Elbadry 2014; Juang 2007; Naumann 2006; Paparella 2010; Rechberger 2011; Tommaselli 2012; Ugurlucan 2013; Zhang 2011).

The trials compared the following operations.

Transobturator lateral to medial

- Monarc® TOT versus TOT® (Cho 2010).
- TOT versus adjustable TOT (Elbadry 2014).
- TOT versus TOT with two-point fixation sutures (Rechberger 2011).
- Synthetic TOT versus biological TOT (Paparella 2010; Ugurlucan 2013).

Transobturator medial to lateral

- TVT-O versus modified TVT-O (shorter tape and less lateral dissection; de Leval 2011).
- TVT-O versus TVT-O plus Ingleman-Sundberg bladder denervation procedure (Juang 2007).
- TVT-O versus modified TVT-O (reduced dissection; Tommaselli 2012).
- TVT-O versus modified TVT-O (self-tailored mesh; Zhang 2011).

Retropubic

- TVT versus modified TVT, bottom-to-top (suburethral pad; Naumann 2006).

5. One type of tape material versus another

A final group compared different mid-urethral sling operations based on the properties of the tape material. All used synthetic non-absorbable mesh for the tape material, but differed in the structure of the material, i.e. monofilament tapes versus multifilament tapes. There were four such trials (Lim 2005; Meschia 2006; Okulu 2013; Rechberger 2003), which made the following comparisons.

- Monofilament (TVT SPARC) verus multifilament (IVS; Lim 2005).
- Monofilament (TVT) versus multifilament (IVS; Meschia 2006).
- Synthetic monofilament (prolene light mesh) versus a combined synthetic mesh coated with a biological film (Ultrapro mesh) versus a multifilament mesh (Vypro; Okulu 2013).
- Monofilament (TVT) versus multifilament (IVS; Rechberger 2003).

Publication type and sample characteristics

1. Retropubic route versus transobturator route

The sample sizes ranged from 20 to 597; with a median of 131.

Twelve of the 55 trials were reported only as abstracts (Cervigni 2006; Choe 2013; Darabi Mahboub 2012; Diab 2012; Hammoud 2011; Kamel 2009; Leanza 2009; Mansoor 2003; Oliveira 2006; Riva 2006; Salem 2014; Tarcan 2011).

Inclusion and exclusion criteria were not clearly stated in eight trials (Cervigni 2006; Chen 2010; Darabi Mahboub 2012; Kamel 2009; Mansoor 2003; Mehdiyev 2010; Oliveira 2006; Tarcan 2011).

All trials had women either presenting with SUI or had USI confirmed. In addition other characteristics included:

- 23 trials included women with MUI (Alkady 2009; Aigmuller 2014; Andonian 2007; Barber 2008; Barry 2008; Cervigni 2006; David-Montefiore 2006; Deffieux 2010; El-Hefnawy 2010; Freeman 2011; Kim 2005; Krofta 2010; Laurikainen 2007; Lee 2007; Nerli

2009; Nyyssonen 2014; Porena 2007; Richter 2010; Riva 2006; Scheiner 2012; Tarcan 2011; van Leijsen 2013; Wang 2011).

- ten trials included women with previous incontinence surgery (Andonian 2007; Aniuliene 2009; Barber 2008; Barry 2008; David-Montefiore 2006; de Tayrac 2004; Kim 2005; Lee 2007; Richter 2010; Wang 2010).
- 28 trials included women with pelvic organ prolapse (POP; Alkady 2009; Andonian 2007; Aniuliene 2009; Barber 2008; Barry 2008; Cervigni 2006; Chen 2012; David-Montefiore 2006; El-Hefnawy 2010; Freeman 2011; Krofta 2010; Laurikainen 2007; Mansoor 2003; Meschia 2007; Nerli 2009; Porena 2007; Rechberger 2009; Richter 2010; Riva 2006; Scheiner 2012; Schierlitz 2008; Tanuri 2010; Tarcan 2011; van Leijsen 2013; Wang 2006; Wang 2008; Wang 2009; Wang 2010).
- in 13 trials women had concomitant pelvic or prolapse surgery (Andonian 2007; Barber 2008; Barry 2008; Cervigni 2006; David-Montefiore 2006; Richter 2010; Riva 2006; Scheiner 2012; Schierlitz 2008; Tarcan 2011; Wang 2008; Wang 2009; Wang 2010).

Follow-up for women ranged from one month to five years with a median follow-up of 12 months.

2. Retropubic bottom-to-top approach versus retropubic top-to-bottom approach

Five trials investigated a retropubic bottom-to-top approach versus a retropubic top-to-bottom approach (Andonian 2005; Kim 2004; Lim 2005; Lord 2006; Tseng 2005). One of the five trials was reported only as an abstract (Kim 2004), and this was the only study without clear inclusion and exclusion criteria.

The sample sizes ranged from 62 to 304; the average sample size, *'n'* (standard deviation), for retropubic in-out was 62 (49) and for retropubic out-in was 64 (53).

All trials had women either presenting with SUI or had USI confirmed. All trials except Tseng 2005 included women with MUI. Andonian 2005 and Lord 2006 included women with previous incontinence surgery.

All the trials included women with POP and had concomitant pelvic or POP surgery performed.

Follow-up for women ranged from 1.5 months to 2 years with a median of 12 months.

3. Obturator medial-to-lateral approach versus obturator lateral-to-medial approach

Nine trials compared the obturator medial-to-lateral approach with the obturator lateral-to-medial approach (Abdel-Fattah 2010; But 2008; Chen 2010; Hassan 2013; Houwert 2009; Lee 2008; Liapis 2008; Park 2012; Scheiner 2012). With the exception of Hassan 2013, which was reported only as an abstract, the other eight trials were reported as full articles. Peattie 2006 appears in a trials registry but its status is unclear; we have contacted the authors and are awaiting a response.

The sample sizes ranged from 74 to 341 with a median size of 110.

Inclusion and exclusion criteria were not clearly stated in two trials (But 2008; Hassan 2013).

All trials had women either presenting with SUI or had USI confirmed.

Five trials included women with MUI (Abdel-Fattah 2010; But 2008; Lee 2008; Park 2012; Scheiner 2012), and two trials included women who had undergone previous incontinence surgery (Abdel-Fattah 2010; Scheiner 2012). Scheiner 2012 included women with POP and women with concomitant pelvic or POP surgery.

Follow-up ranged from three months to three years with a median follow up of 12 months.

4. One method of mid-urethral tape insertion versus another method, same route

Ten trials investigated one method of mid-urethral tape versus another method, using the same route (Cho 2010; de Leval 2011; Elbadry 2014; Juang 2007; Naumann 2006; Paparella 2010; Rechberger 2011; Tommaselli 2012; Ugurlucan 2013; Zhang 2011). Three of these trials were reported only as abstract publications (Cho 2010; Elbadry 2014; Naumann 2006). The sample sizes ranged from 72 to 463 with a median of 156.

All the trials included women with SUI or USI. Rechberger 2011 reported women with ISD. Inclusion and exclusion criteria were not clearly defined in four of the ten trials (Cho 2010; Elbadry 2014; Juang 2007; Naumann 2006). Juang 2007, Tommaselli 2012 and Ugurlucan 2013 included women with MUI, whilst de Leval 2011 and Ugurlucan 2013 included women who had undergone previous incontinence surgery. Women with prolapse were included in de Leval 2011 and Ugurlucan 2013, but concomitant POP surgery was performed only in Ugurlucan 2013.

Follow-up ranged from three months to three years.

5. One type of tape material versus another

Four trials investigated the use of monofilament tape versus multifilament tape (Lim 2005; Meschia 2006; Okulu 2013; Rechberger 2003). All four trials were reported as full article publications.

The sample sizes ranged from 70 to 182 with a median value of 144.

The trials had women either presenting with SUI or had USI confirmed: all had clear inclusion and exclusion criteria. Three trials included women with POP (Lim 2005; Meschia 2006; Rechberger 2003). Two trials included women with MUI (Lim 2005; Meschia 2006). Three trials included women with previous incontinence surgery (Lim 2005; Okulu 2013; Rechberger 2003), whereas only Lim 2005 included women who had concomitant pelvic or POP surgery.

Follow-up for women ranged from three months to three years.

Outcomes

The trials reported their outcomes in a variety of different ways. The primary outcome, subjective cure of urinary incontinence (UI), was defined as follows:

- no subjective report of UI (Aniuliene 2009; Barber 2008; But 2008; Cho 2010; Darabi Mahboub 2012; de Leval 2011; de Tayrac 2004; Deffieux 2010; El-Hefnawy 2010; Freeman 2011; Hassan 2013; Houwert 2009; Jakimiuk 2012; Kim 2004; Laurikainen 2007; Leanza 2009; Liapis 2006; Lim 2005; Lord 2006; Mansoor 2003; Naumann 2006; Nerli 2009; Okulu 2013; Paparella 2010; Porena

2007; Richter 2010; Riva 2006; Scheiner 2012; Schierlitz 2008; Tanuri 2010; Tarcan 2011; Ugurlucan 2013; van Leijsen 2013; Wang 2010; Wang 2011; Zhang 2011);

- no subjective report of UI and negative stress test (Lee 2007; Meschia 2006; Meschia 2007; Park 2012; Rechberger 2003; Rechberger 2009; Wang 2008);
- no or improved subjective report of UI (Abdel-Fattah 2010; Aigmuller 2014; Barry 2008; Karateke 2009; Ross 2009; Teo 2011; Zullo 2007).

Secondary outcome objective cure was defined by the trialists as follows:

- absence of USI on urodynamics (UDS) (Abdel-Fattah 2010; Araco 2008; Barry 2008; Cervigni 2006; Enzelsberger 2005; Kamel 2009; Karateke 2009; Kilic 2007; Kim 2005; Krofta 2010; Lim 2005; Riva 2006; Schierlitz 2008; Zullo 2007);
- absence of SUI and negative stress test (Alkady 2009; Paparella 2010; Porena 2007);
- one-hour pad test less than 2 g (Andonian 2005; Andonian 2007; But 2008; Ross 2009; Tseng 2005);
- 24-hour pad test less than 5 g (Darabi Mahboub 2012; Okulu 2013; Teo 2011);
- negative stress test (Aigmuller 2014; Aniuliene 2009; Barber 2008; Chen 2010; David-Montefiore 2006; de Leval 2011; de Tayrac 2004; Deffieux 2010; El-Hefnawy 2010; Juang 2007; Kim 2004; Kim 2005; Laurikainen 2007; Lord 2006; Meschia 2007; Nerli 2009; Tarcan 2011; van Leijsen 2013; Wang 2009; Wang 2011);
- multiple objective measures used (El-Hefnawy 2010; Juang 2007; Kamel 2009; Kim 2005; Krofta 2010; Liapis 2006; Liapis 2008; Mansoor 2003; Meschia 2006; Naumann 2006; Nyyssonen 2014; Oliveira 2006; Rechberger 2011; Richter 2010; Scheiner 2012; Tanuri 2010; Tommaselli 2012; Wang 2006; Wang 2008; Wang 2010).

Excluded studies

We excluded 62 studies after retrieval of the full text publication because they were not randomised trials, did not include a mid-urethral sling operation, the participants did not have urinary incontinence, or the participants were randomised to an intervention other than a mid-urethral sling (such as no treatment, pelvic floor muscle training, drugs, or a different class of surgery). The details of the reasons for exclusion are given in the Characteristics of excluded studies table.

Ongoing trials

There are two ongoing trials: Cavkaytar 2013 and Sung 2013.

Cavkaytar 2013 is a randomised controlled trial (RCT) comparing RPR and TOR for the treatment of SUI in women with no intrinsic sphincter deficiency. This study is currently recruiting and includes women with SUI and excludes women with MUI or detrusor overactivity (DO), previous incontinence surgery, and women with a body mass index greater than 35. Fifty women have been randomly assigned into each arm for evaluation.

Sung 2013 is an RCT comparing mid-urethral sling operations and behavioural or pelvic floor therapy in combination versus suburethral sling operations alone for women with MUI. The ESTEEM trial includes women over 18 years of age who have had urodynamic investigation within the last 18 months, and excludes women with prolapse, previous incontinence surgery, and women currently on antimuscarinic medication. This trial is currently recruiting participants.

Studies awaiting classification

There are no studies awaiting classification.

New trials included in this update

We have included 48 new trials in this update (Abdel-Fattah 2010; Aigmuller 2014; Alkady 2009; Andonian 2007; Aniuliene 2009; Chen 2010; Chen 2012; Cho 2010; Choe 2013; Darabi Mahboub 2012; de Leval 2011; Diab 2012; Elbadry 2014; El-Hefnawy 2010; Freeman 2011; Hassan 2013; Hammoud 2011; Jakimiuk 2012; Juang 2007; Kamel 2009; Karateke 2009; Kilic 2007; Krofta 2010; Leanza 2009; Mehdiyev 2010; Naumann 2006; Nerli 2009; Nyyssonen 2014; Okulu 2013; Palomba 2008; Paparella 2010; Park 2012; Peattie 2006; Rechberger 2011; Richter 2010; Ross 2009; Salem 2014; Scheiner 2012; Tanuri 2010; Tarcan 2011; Teo 2011; Tommaselli 2012; Ugurlucan 2013; van Leijsen 2013; Wang 2008; Wang 2010; Wang 2011; Zhang 2011).

Previously included trials with new outcome data

We have included new data from 11 trials previously included in this review, including the report of medium- or long-term outcomes (Barber 2008; But 2008; David-Montefiore 2006; Deffieux 2010; Houwert 2009; Laurikainen 2007; Porena 2007; Rechberger 2009; Schierlitz 2008; Wang 2009; Zullo 2007).

Previously included trials with no new outcome data

Twenty-two trials included in the earlier version of this review have not published new outcome data (Andonian 2005; Araco 2008; Barry 2008; Cervigni 2006; de Tayrac 2004; Enzelsberger 2005; Kim 2004; Kim 2005; Lee 2007; Lee 2008; Liapis 2006; Liapis 2008; Lim 2005; Lord 2006; Mansoor 2003; Meschia 2006; Meschia 2007; Oliveira 2006; Rechberger 2003; Riva 2006; Tseng 2005; Wang 2006).

Risk of bias in included studies

Details of the criteria used to assess the risk of bias and the ratings for each study are reported in the 'Risk of bias' tables that accompany the Characteristics of included studies. Further information on the risk of bias in included trials is shown in Figure 2 the 'Risk of bias' graph and Figure 3 the ‘Risk of bias' summary.

Figure 2. Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.

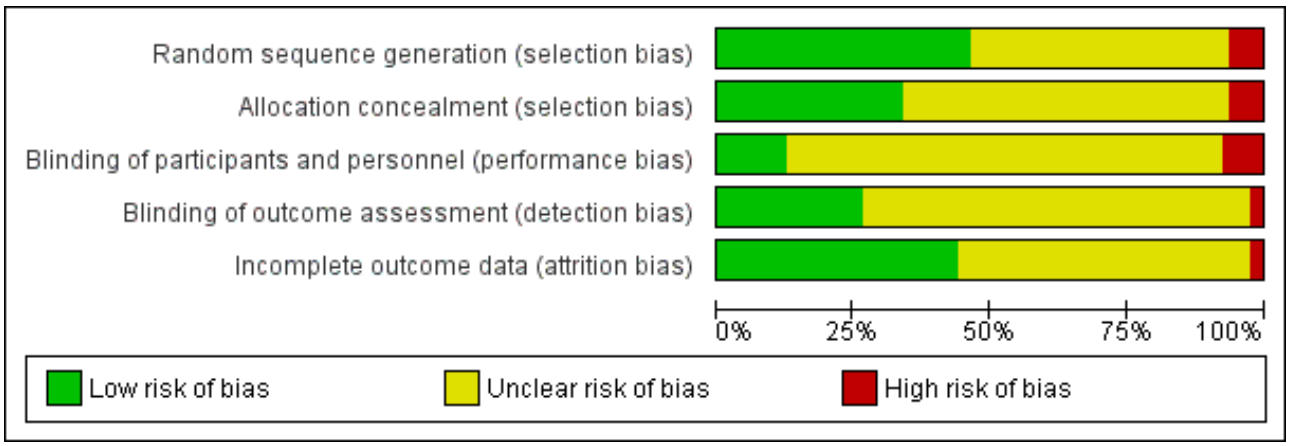


Figure 3. Risk of bias summary: review authors' judgments about each risk of bias item for each included study.

Figure 3. (Continued)

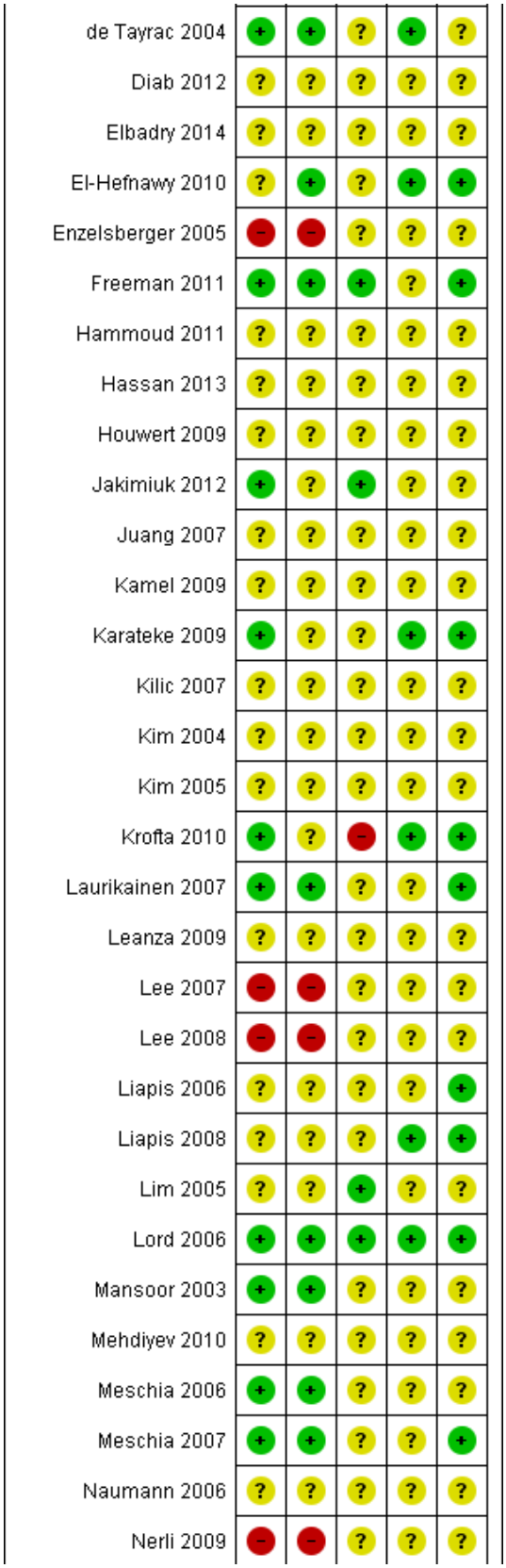
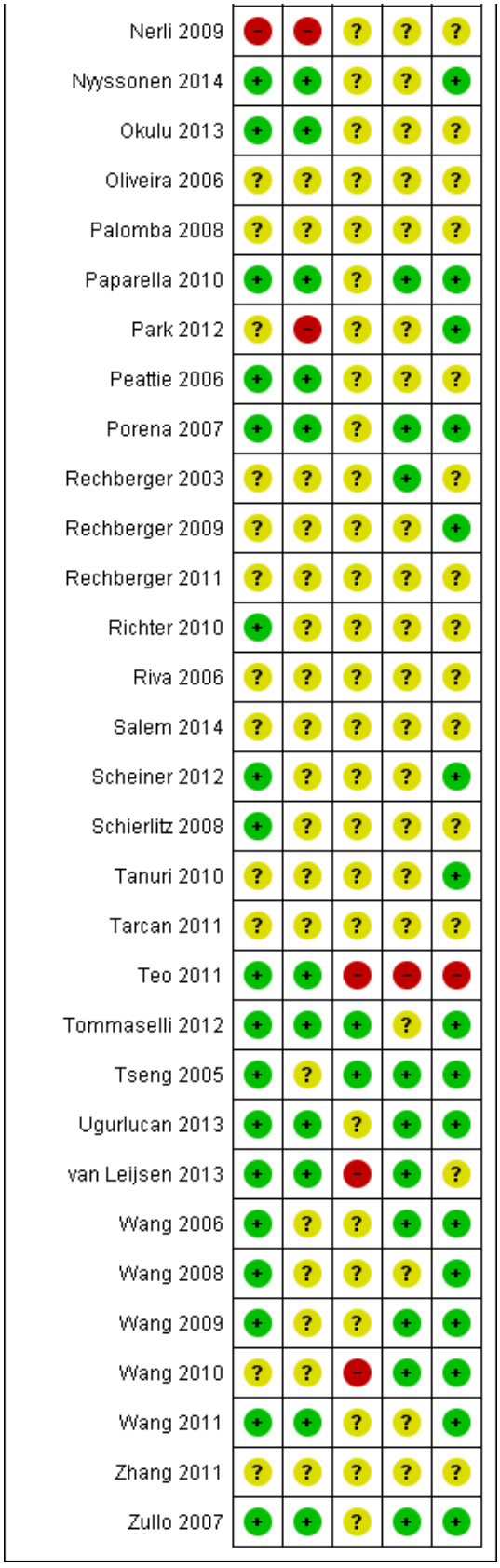


Figure 3. (Continued)



The risk of bias in the trials included was variable, though overall only few trials were judged to be at high risk of bias. In over 50% of trials the random sequence generation was judged to be adequate, for example with the use of a computer-generated list or a table of random numbers. Approximately 30% of trials confirmed that secure concealment of the randomisation process was used, for example allocation by a remote person or the use of sealed envelopes.

Blinding of participants was unclear in the majority of trials. This is an obvious limitation with trials comparing surgical interventions, though one trial described the use of a 'sham' procedure (Jakimiuk 2012). Blinding of patients and the post-operative reviewer was not reported in most trials. Loss to follow-up in most trials was minimal, and in approximately 50% of included trials the risk of attrition bias was judged to be low.

We judged that 39 trials had adequate random sequence generation (Abdel-Fattah 2010; Aigmuller 2014; Alkady 2009; Andonian 2005; Araco 2008; Barber 2008; But 2008; Cervigni 2006; Chen 2012; David-Montefiore 2006; Deffieux 2010; de Tayrac 2004; Freeman 2011; Jakimiuk 2012; Karateke 2009; Krofta 2010; Laurikainen 2007; Lord 2006; Mansoor 2003; Meschia 2006; Meschia 2007; Nyyssonen 2014; Okulu 2013; Paparella 2010; Porena 2007; Richter 2010; Ross 2009; Scheiner 2012; Schierlitz 2008; Teo 2011; Tommaselli 2012; Tseng 2005; Ugurlucan 2013; van Leijsen 2013; Wang 2006; Wang 2008; Wang 2009; Wang 2011; Zullo 2007).

We judged that adequate allocation concealment occurred in 26 trials (Abdel-Fattah 2010; Aigmuller 2014; Alkady 2009; Andonian 2005; Araco 2008; Barber 2008; David-Montefiore 2006; Deffieux 2010; de Tayrac 2004; El-Hefnawy 2010; Freeman 2011; Laurikainen 2007; Lord 2006; Mansoor 2003; Meschia 2006; Meschia 2007; Nyyssonen 2014; Okulu 2013; Paparella 2010; Porena 2007; Ross 2009; Teo 2011; Tommaselli 2012; van Leijsen 2013; Wang 2011; Zullo 2007).

We judged that 24 trials had an adequate randomisation process and secure concealment of the randomisation process (Aigmuller 2014; Alkady 2009; Andonian 2005; Araco 2008; Barber 2008; David-Montefiore 2006; Deffieux 2010; de Tayrac 2004; Freeman 2011; Laurikainen 2007; Lord 2006; Mansoor 2003; Meschia 2006; Meschia 2007; Nyyssonen 2014; Okulu 2013; Paparella 2010; Porena 2007; Ross 2009; Teo 2011; Tommaselli 2012; van Leijsen 2013; Wang 2011; Zullo 2007).

We judged that 22 trials adequately blinded outcome assessors (Abdel-Fattah 2010; Andonian 2005; Andonian 2007; Araco 2008; Barber 2008; de Tayrac 2004; El-Hefnawy 2010; Karateke 2009; Krofta 2010; Liapis 2006; Liapis 2008; Lord 2006; Paparella 2010; Porena 2007; Rechberger 2003; Tseng 2005; Ugurlucan 2013; van Leijsen 2013; Wang 2006; Wang 2009; Wang 2010; Zullo 2007).

We judged 36 trials to be at a low risk of attrition bias (Abdel-Fattah 2010; Aigmuller 2014; Alkady 2009; Andonian 2005; Aniuliene 2009; Barber 2008; Barry 2008; But 2008; Deffieux 2010; de Leval 2011; El-Hefnawy 2010; Freeman 2011; Karateke 2009; Krofta 2010; Laurikainen 2007; Liapis 2006; Liapis 2008; Lord 2006; Meschia 2007; Nyyssonen 2014; Paparella 2010; Park 2012; Porena 2007; Rechberger 2009; Ross 2009; Scheiner 2012; Tanuri 2010; Tommaselli 2012; Tseng 2005; Ugurlucan 2013; Wang 2006; Wang 2008; Wang 2009; Wang 2010; Wang 2011; Zullo 2007).

Effects of interventions

See: **Summary of findings for the main comparison** Transobturator (TOR) compared to retropubic (RPR) route for stress urinary incontinence in women; **Summary of findings 2** Retropubic bottom-to-top approach compared to retropubic top-to-bottom approach for stress urinary incontinence in women; **Summary of findings 3** Obturator medial-to-lateral approach compared to obturator lateral-to-medial approach for stress urinary incontinence in women; **Summary of findings 4** Monofilament compared to multifilament tapes for stress urinary incontinence in women

The results of all the included studies can be found in Table 1.

Comparison 1. Transobturator versus retropubic route

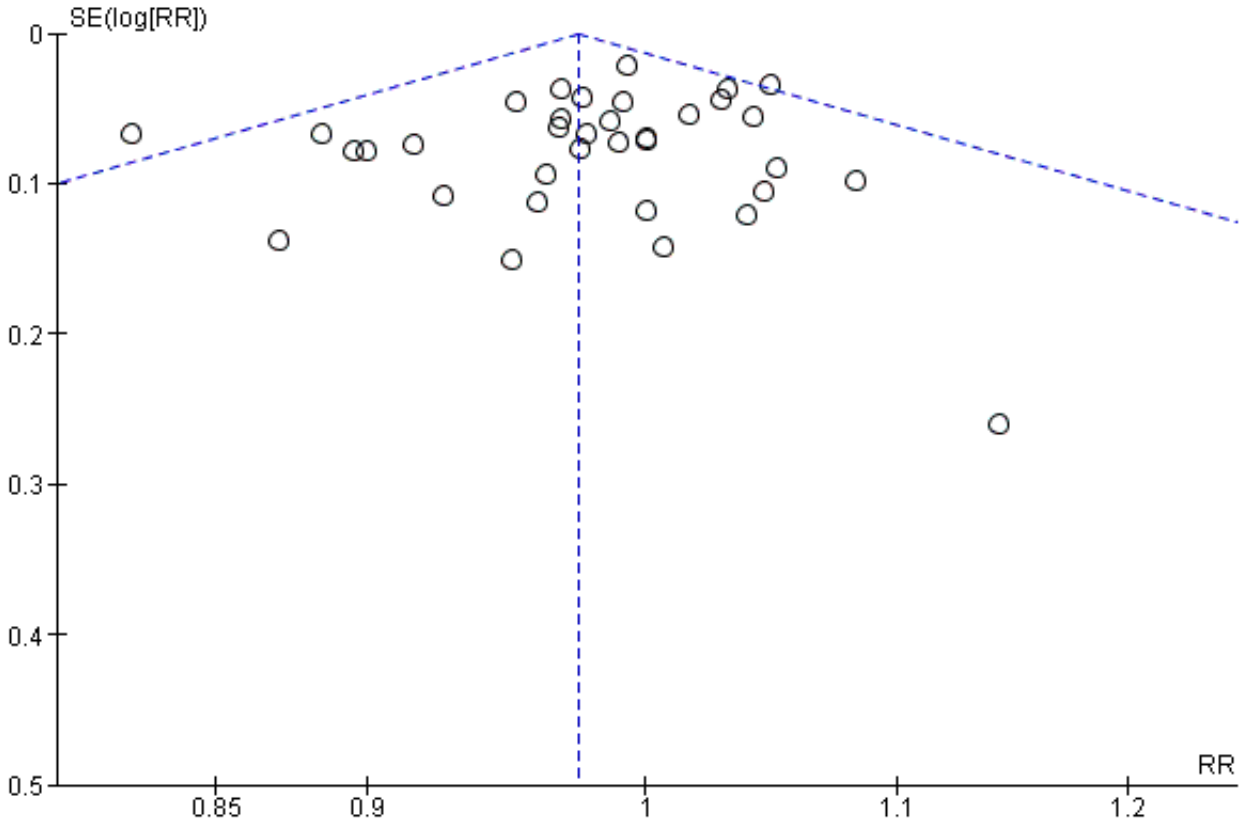
Fifty-five trials addressed this comparison (Aigmuller 2014; Alkady 2009; Andonian 2007; Aniuliene 2009; Araco 2008; Barber 2008; Barry 2008; Cervigni 2006; Chen 2010; Chen 2012; Choe 2013; Darabi Mahboub 2012; David-Montefiore 2006; de Tayrac 2004; Deffieux 2010; Diab 2012; El-Hefnawy 2010; Enzelsberger 2005; Freeman 2011; Hammoud 2011; Jakimiuk 2012; Kamel 2009; Karateke 2009; Kilic 2007; Kim 2005; Krofta 2010; Laurikainen 2007; Leanza 2009; Lee 2007; Liapis 2006; Mansoor 2003; Mehdiyev 2010; Meschia 2007; Nerli 2009; Nyyssonen 2014; Oliveira 2006; Palomba 2008; Porena 2007; Rechberger 2009; Richter 2010; Riva 2006; Ross 2009; Salem 2014; Scheiner 2012; Schierlitz 2008; Tanuri 2010; Tarcan 2011; Teo 2011; van Leijsen 2013; Wang 2006; Wang 2008; Wang 2009; Wang 2010; Wang 2011; Zullo 2007).

1.1 Women's observations

Subjective cure within 12 months was reported in 36 trials with a total of 5514 participants. Assessment of cure was self-reported by participants and by responses to symptom-based questionnaires. The combined results from the 36 trials showed no statistically significant difference in the subjective cure rates between the two routes (RR 0.98, 95% CI 0.96 to 1.00; Analysis 1.1). The short-term subjective cure ranged from 62% to 98% for TOR and from 71% to 97% for RPR.

The mean subjective cure rate across both groups was 83.3% and, using this as the assumed control subjective cure rate in the RPR group, for every 1000 women there were 17 fewer cured in the TOR group (95% CI from 0 fewer to 33 fewer per 1000). This was not statistically significant and is also unlikely to be considered to be a clinically significant difference. The funnel plot inspection shows no strong evidence of publication bias Figure 4.

Figure 4. Funnel plot of comparison: 1 Transobturator (TOR) versus retropubic (RPR) route, outcome: 1.1 Subjective cure (short term, ≤ 1 year)



There was also no statistically significant difference between the two groups in terms of symptomatic improvement and cure rate (RR 0.98, 95% CI 0.96 to 1.00; Analysis 1.2).

Medium-term outcomes

Only seven trials provided information after the first year (Deffieux 2010; Laurikainen 2007; Nyyssonen 2014; Porena 2007; Schierlitz 2008; Tarcan 2011; Zullo 2007). Five trials (683 participants) contributed medium-term data between one and five years after surgery, which showed no significant difference in subjective cure between the two groups (RR 0.97, 95% CI 0.87 to 1.09; Analysis 1.3). Subjective cure rates ranged from 82% to 91% in the TOR group and from 77% to 98% in the RPR group.

The average medium-term subjective cure rate across both groups was 86.9% and, using this as the assumed control cure rate in the RPR group, for every 1000 women there were 26 fewer women cured in the TOR group (95% CI from 26 per 1000 more to 70 per 1000 fewer).

Long-term outcomes

Four trials (714 women) reported long-term results for subjective cure after five years (Laurikainen 2007; Porena 2007; Richter 2010; Zullo 2007); the difference between the groups was not statistically significant (RR 0.95, 95% CI 0.80 to 1.12; Analysis 1.4). Subjective cure rates range from 43% to 92% in the TOR group and from 51% to 88% in the RPR group.

The average long-term subjective cure rate across both groups was 84.3% and, using this as the assumed control cure rate in the RPR group, for every 1000 women there were 42 fewer women cured in the TOR group (95% CI from 110 per 1000 less to 34 per 1000 more).

Two trials with 340 women reported long-term data for subjective cure and improvement and the difference between the groups was not statistically significant (RR 0.92, 95% CI 0.67 to 1.28; Analysis 1.5); due to significant heterogeneity we also performed a random-effects analysis that produced similar results and, as there were only two trials, the fixed-effect analysis was maintained.

1.2 Quantification of symptoms

Only two trials provided data about pad test weights (Tanuri 2010 used a non standardised modified/simplified pad test and Wang 2006 used the standard one-hour pad test). The information provided was not suitable for meta-analysis, but each reported a significant reduction in pad weight postoperatively in each group without a significant difference between the groups.

1.3 Clinician's observations

Objective cure was assessed by 40 trials with 6145 participants in the short term using a variety of measures such as urodynamic assessment, negative cough-stress test, one-hour pad test of 2 g or less, one-hour pad test of 1 g or less, and 24-hour pad test of 5g or less. The cure rate with the obturator route was 85.7% versus 87.2% for the RPR (RR 0.98, 95% CI 0.96 to 1.00, Analysis 1.6). The confidence interval was narrow and this statistically

non significant difference between the groups (2%) is unlikely to represent a clinically significant difference in outcome between the two methods in the short term.

The small difference in the objective cure and improvement rate in the short term was not statistically - nor was it likely to be clinically - significant (RR 0.98, 95% CI 0.96 to 1.01; 10 studies, 1478 women; Analysis 1.7). The same holds true for the medium-term objective cure rates (RR 1.00, 95% CI 0.95 to 1.06; 5 studies, 596 women; Analysis 1.8), and long-term cure rates (RR 0.97, 95% CI 0.90 to 1.06; 3 studies, 400 women; Analysis 1.9).

1.4 Surgical outcome measures

Duration of operation was significantly shorter, by an average of approximately seven minutes, with the TOR compared with the RPR (MD -7.54 minutes, 95% CI -9.31 to -5.77). There was statistically significant heterogeneity, but all the trials reported a shorter operating time with the TOR. This may be attributable to most surgeons routinely performing a cystoscopy following a RPR procedure, but not necessarily doing this after a TOR procedure.

To investigate this theory, we performed a sensitivity analysis to assess the difference in operative time between the RPR and TOR approach in trials where cystoscopy was performed in both comparison groups as defined by the trialists. In eight trials where cystoscopy was performed in both TOR and RPR groups we still found a shorter operating time with the TOR in comparison to the RPR (MD -6.50 95% CI -7.57 to -5.44) although high heterogeneity persisted. Using a random-effects method on the full analysis of 31 trials still showed the duration of operation to be statistically significantly shorter with TOR approach (MD -7.54 minutes, 95% CI -9.31 to -5.77; Analysis 1.10).

Intraoperative blood loss was small (mean loss ranged from 15 ml to 125 ml), but was significantly less with the TOR approach (MD -6.49 ml, 95% CI -12.33 to -0.65; Analysis 1.11). There was significant heterogeneity that was accounted for by three small trials (Nerli 2009; Wang 2008; Zullo 2007). In view of the small blood volumes involved, this is unlikely to be a clinically significant finding.

Length of stay was also significantly shorter by an average of 0.17 days with the TOR compared with the retropubic route (MD -0.17, 95% CI -0.25 to -0.10; Analysis 1.12). A high level of between-study heterogeneity (I^2 94%) was present with the length of stay, thus a random-effects model was used, which then showed no significant difference (MD -0.25, 95% CI -0.59 to 0.09; Analysis 1.12).

The mean time the women took to return to normal activity ranged from under two weeks to just over five weeks, with no statistically significant difference between the two surgical approaches (MD -0.05, 95% CI -0.15 to 0.06; Analysis 1.13). This confirms the minimally invasive nature of both operations, compared with a more normal recovery period of three months after major abdominal surgery.

1.5 Adverse events

In trials where overall perioperative complication rates were reported there were no statistically significant differences in the rate of perioperative complications between the TOR and RPR groups (RR 0.91, 95% CI 0.73 to 1.14; Analysis 1.14).

In trials where specific complications were recorded there were significant differences in the rate of each individual complication sustained.

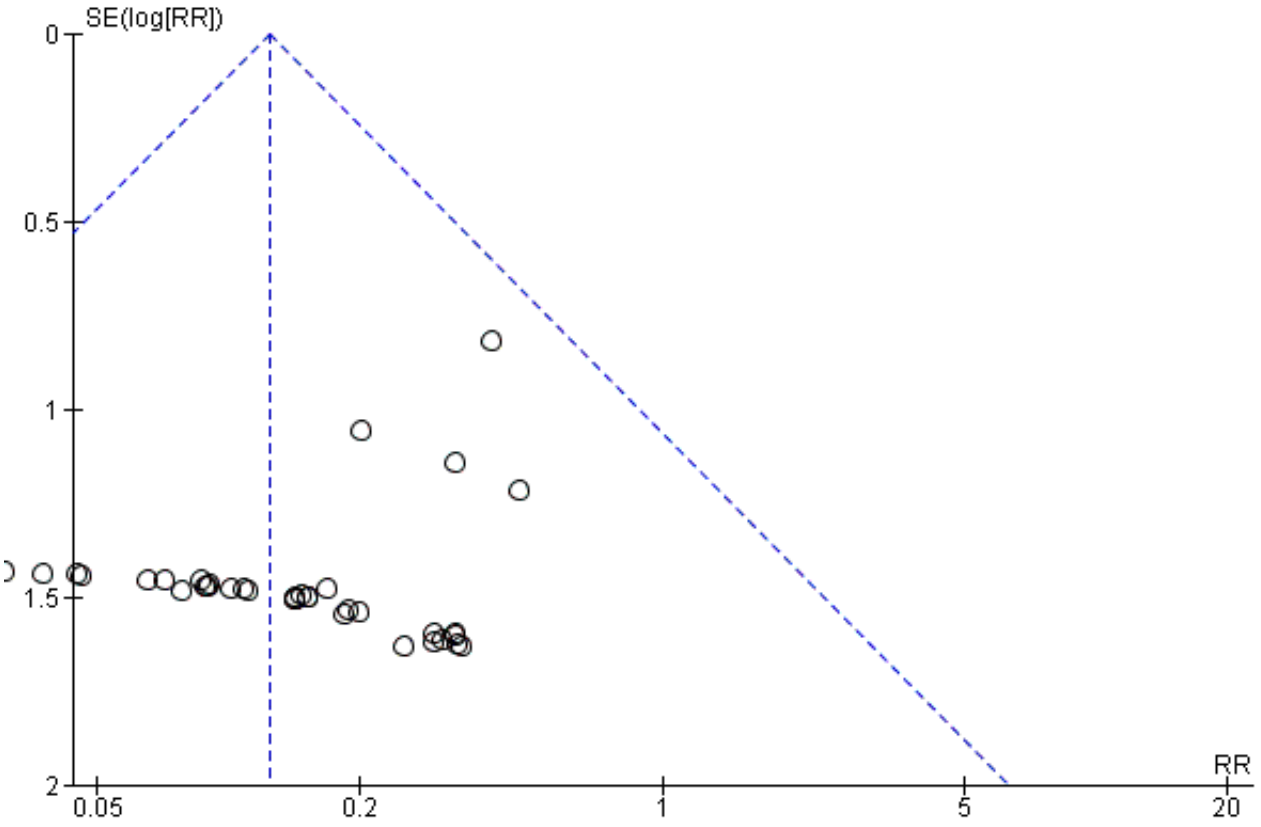
Major vascular/visceral injury

Major vascular injury such as retropubic haematoma or major visceral injury, for example bowel perforation, was reported by 28 trials with 4676 women. This occurred significantly less often with TOR than with RPR (RR 0.33, 95% CI 0.19 to 0.55; Analysis 1.15).

Bladder/urethral perforation

Forty trials assessed rate of bladder perforation. The rate was significantly lower in the TOR group than the RPR group (RR 0.13, 95% CI 0.08 to 0.20; Analysis 1.16). The average bladder perforation rate across both groups was 2.54% and, using this as the assumed control bladder perforation rate in the RPR group, there were 22 fewer perforations per 1000 in the TOR group (95% CI from 20 to 23 per 1000 fewer). There was some degree of asymmetry in the funnel plot, which raised the possibility of some publication bias Figure 5.

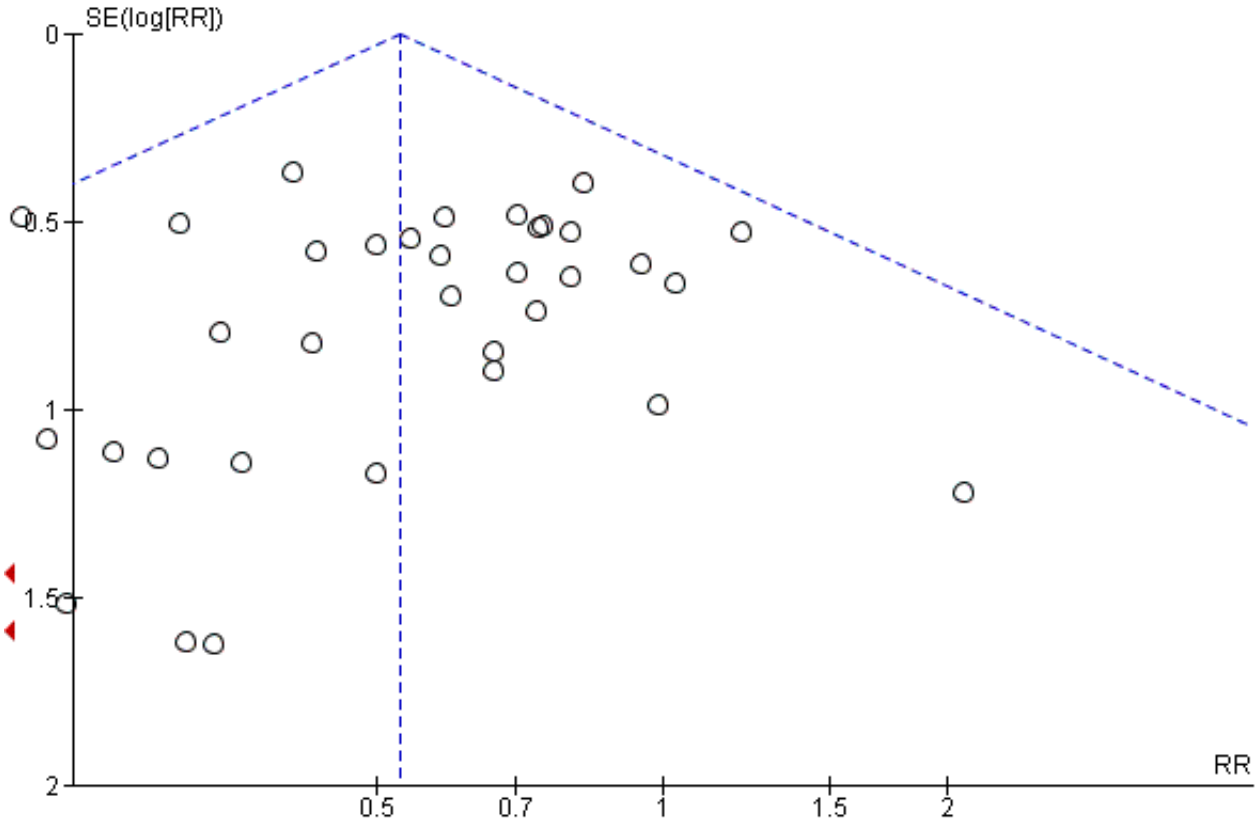
Figure 5. Funnel plot of comparison: 1 Transobturator (TOR) versus retropubic (RPR) route, outcome: 1.16 Bladder or urethral perforation



Postoperative voiding dysfunction (POVD)

Rates of postoperative voiding dysfunction (POVD) was assessed in 37 trials with 6200 participants. This showed significantly lower rates in the TOR group than in the RPR group (RR 0.53 95% CI 0.43 to 0.65; Analysis 1.17). The average POVD rate across both groups was 5.53% and, using this as the assumed control rate in the RPR group, there were 26 fewer POVD per 1000 in the TOR group (95% CI from 19 to 32 per 1000 fewer). The funnel plot showed symmetry on visual inspection, which suggests a low likelihood of publication bias Figure 6.

Figure 6. Funnel plot of comparison: 1 Transobturator (TOR) versus retropubic (RPR) route, outcome: 1.17 Voiding dysfunction



Urgency and urgency urinary incontinence (UUI)

The 31 trials (4923 women) that reported de novo urgency and urgency urinary incontinence (UUI) showed no statistically significant difference between the two groups (RR 0.98, 95% CI 0.82 to 1.17; Analysis 1.18). In the short term the average rate of de novo urgency/UUI across both groups was 8.35% and, using this as the assumed control rate in the RPR group, there were two fewer cases per 1000 in the TOR group (95% CI from 15 per 1000 fewer to 14 per 1000 more).

Equally, in the medium term the rate of de novo urgency and UUI was not significantly different (RR 0.98, 95% CI 0.55 to 1.73, Analysis 1.19). Laurikainen 2007 reported long-term data for de novo urgency and UUI for 253 women; this showed no difference between the groups (RR 0.81, 95% CI 0.18 to 3.53; 253 women; Analysis 1.20).

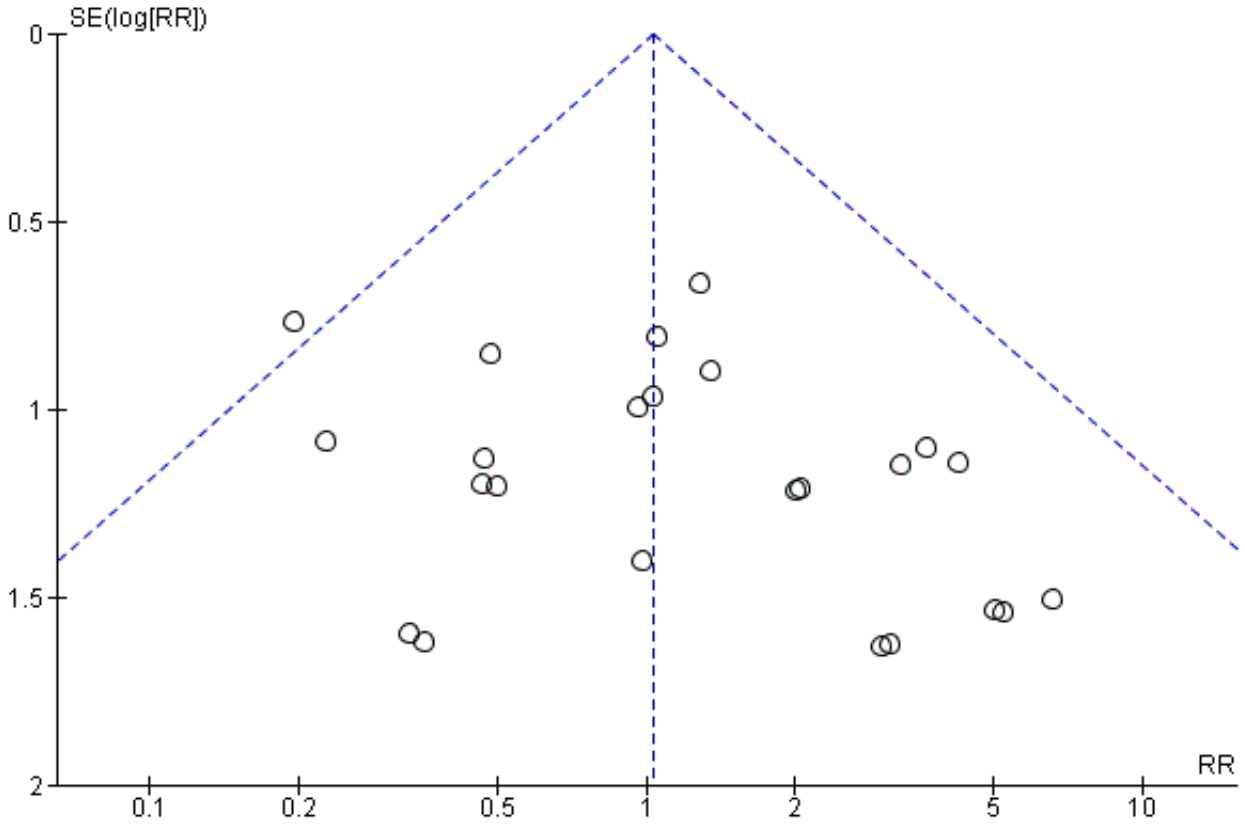
Four trials with 853 women with DO showed a rate of 8% in both groups (RR 1.00, 95% CI 0.58 to 1.73; Analysis 1.21).

In one trial of women with MUI (Laurikainen 2007), 84% who had pre-existing moderate or severe urinary frequency and urgency symptoms were cured of these symptoms post operatively at the five-year follow-up.

Vaginal tape erosion

Vaginal tape erosion was assessed in 31 trials with 4743 participants. No significant difference was demonstrated between the groups (RR 1.13, 95% CI 0.78 to 1.65; Analysis 1.22). The average rate of vaginal tape erosion across both groups was 2.09%, and, using this as the assumed control rate in the RPR group, there were three more cases per 1000 in the TOR group (95% CI from 5 per 1000 fewer to 14 per 1000 more). The funnel plot showed symmetry on visual inspection suggesting low likelihood of publication bias Figure 7. In the one trial that reported long-term tape erosion (Laurikainen 2007), no tape erosion was reported in either group. Bladder or urethral tape erosion was assessed in four trials with 374 participants. No significant difference was demonstrated between the groups (RR 0.34, 95% CI 0.01 to 8.13; Analysis 1.23).

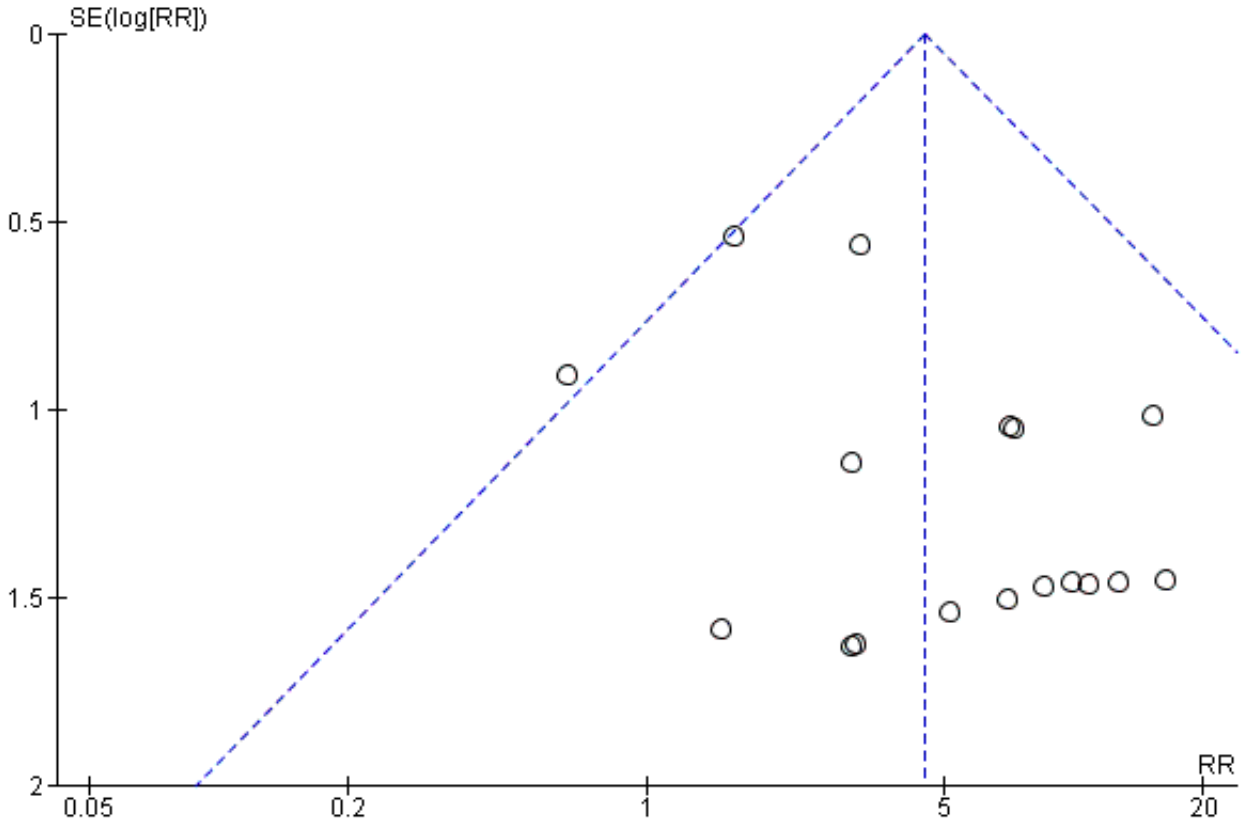
Figure 7. Funnel plot of comparison: 1 Transobturator (TOR) versus retropubic (RPR) route, outcome: 1.22 Vaginal tape erosion



Pain

There was a significantly higher occurrence of groin pain in women who underwent a TOR procedure than in women who underwent a RPR procedure (RR 4.12, 95% CI 2.71 to 6.27; Analysis 1.24). The average rate of groin pain across both groups was 4.51% and, using this as the assumed control rate in the RPR group, there were 163 more cases per 1000 in the TOR group (95% CI from 94 to 266 per 1000 more). Conversely, suprapubic pain was found to be significantly lower in women who underwent a TOR procedure than a RPR procedure (RR 0.29, 95% CI 0.11 to 0.78; Analysis 1.25). Both groin and suprapubic pain occurrence were short-lasting, with most resolving within the first six months. The duration of pain ranged from two to 52 weeks, with a median duration of eight weeks. The funnel plot for groin pain showed symmetry on visual inspection, suggesting low likelihood of publication bias Figure 8.

Figure 8. Funnel plot of comparison: 1 Transobturator (TOR) versus retropubic (RPR) route, outcome: 1.24 Groin pain



1.6 Need for further treatment

Nine trials (1402 women) reported the number of women who required repeat incontinence surgery in the short term (up to one year). The difference between the TOR and RPR groups was not statistically significant (RR 1.64, 95% CI 0.85 to 3.16; Analysis 1.26). The average rate of repeat incontinence surgery in the short term across both groups was 2.43% and, using this as the assumed control rate in the RPR group, there were 12 more cases per 1000 in the TOR group (95% CI from 3 per 1000 fewer to 41 per 1000 more).

More women required repeat incontinence surgeries in the TOR group in the medium term (RR 21.89, 95% CI 4.36 to 109.77; two studies, 355 women; Analysis 1.27).

In the long term, three trials with data from 487 women, found that more women required repeat incontinence surgery in the TOR group (RR 8.79, 95% CI 3.36 to 23.00; Analysis 1.28). The average rate of repeat incontinence surgery in the long term across both groups was 5.34% and, using this as the assumed control rate in the RPR group, there were 231 more cases per 1000 in the TOR group (95% CI from 45 to 767/1000 more).

1.7 Quality of life

Thirty-three of the 55 trials in this comparison assessed quality of life (QoL; Aigmuller 2014; Andonian 2007; Barber 2008; Barry 2008; Chen 2012; Darabi Mahboub 2012; David-Montefiore 2006; Deffieux 2010; de Tayrac 2004; El-Hefnawy 2010; Freeman 2011; Jakimiuk 2012; Karateke 2009; Kim 2005; Krofta 2010; Laurikainen 2007; Leanza 2009; Mansoor 2003; Meschia 2007; Nerli 2009; Porena 2007; Richter 2010; Riva 2006; Ross 2009; Scheiner 2012; Schierlitz 2008; Tanuri 2010; Tarcan 2011; Teo 2011; Wang 2008; Wang 2010; Wang 2011; Zullo 2007); however only 11 of these trials reported QoL scores (Andonian 2007; Barber 2008; Barry 2008; David-Montefiore 2006; de Tayrac 2004; Laurikainen 2007; Meschia 2007; Porena 2007; Riva 2006; Schierlitz 2008; Wang 2008).

A wide variety of measures were used by different trials to assess this outcome, including:

Condition-specific measures

- Incontinence Impact Questionnaire (IIQ-7).
- Urogenital Distress Inventory (UDI-6).
- International Consultation on Incontinence Questionnaire (ICIQ).
- Urinary Incontinence Quality of Life Scale (I-QOL).
- Kings Health Questionnaire (KHQ).
- Bristol Female Lower Urinary Tract Symptoms questionnaire (BFLUTS).
- Women Irritative Prostate Symptoms Score (W-IPSS).
- Urinary Incontinence Severity Score (UISS).
- Detrusor Instability Score (DIS).
- A Visual Analogue Scale (VAS).
- CONTILIFE.

Generic measures

- EuroQoL 5-Dimensional Classification Component Scores (EuroQoL-5D).
- Short-Form Health-Related QoL (SF-36).
- Patient Global Impression of Severity (PGI-S).
- Patient Global Impression of Improvement (PGI-I).

The data on quality of life outcomes were reported in different ways, which precluded meta-analysis. In general, with the exception of Araco 2008, all trials found that women's QoL improved significantly post-operatively within each group, but no statistically significant differences were found between the randomised groups. Only the Araco 2008 trial found the I-QOL scores to be statistically significantly higher postoperatively after the retropubic approach.

Sexual function quality of life measures

Sexual function was addressed in 10 trials (Barber 2008; Barry 2008; Deffieux 2010; de Tayrac 2004; Freeman 2011; Krofta 2010; Richter 2010; Ross 2009; Scheiner 2012; Schierlitz 2008), which used a variety of measures including validated questionnaires and direct questioning. Questionnaires employed were:

- Prolapse/Incontinence Symptoms Questionairre (PISQ-12);
- Bristol Female Lower Urinary Tract Symptoms questionnaire (BFLUTS);
- International Consultation on Incontinence Questionnaire Lower Urinary Tract Symptoms quality of life questionnaire (ICIQ-LUTSqol); and
- Visual Analogue Scale (VAS).

In all the trials there was significant improvement in sexual function from baseline scores during the follow-up period that spanned six to 24 months. There were no significant differences between the two groups. At 24-month follow-up, rates of superficial and deep dyspareunia were low, with no difference between the groups.

Comparison 2. Retropubic bottom-to-top approach versus retropubic top-to-bottom approach

Five small trials, with 636 women in total, addressed this comparison (Andonian 2005; Kim 2004; Lim 2005; Lord 2006; Tseng 2005).

2.1 Women's observations

Three trials (477 women) investigated subjective cure defined as self-reported absence of urinary leakage on stress (Kim 2004; Lim 2005; Lord 2006). In the 12 months following surgery, women were significantly more often dry with the bottom-to-top approach (TVT^{TM}) compared to the top-to-bottom approach (SPARC^{TM}; 87.34% versus 79.58%; RR 1.10, 95% CI 1.01 to 1.19; Analysis 2.1).

2.2 Quantification of symptoms

No data were reported for this outcome.

2.3 Clinician's observation

Five trials assessed objective cure using a variety of measures (Andonian 2005; Kim 2004; Lim 2005; Lord 2006; Tseng 2005): one-hour pad test of 2g or less, negative stress test on urodynamics (UDS), the observed absence of urinary leakage when the patient coughed while supine and with a comfortably full bladder, and one-hour pad test of 1g or less, respectively. In a total of 622 participants, the objective cure rate was similar between the two groups (94.19% versus 89.10%; RR 1.06, 95% CI 0.97 to 1.17; Analysis 2.2).

2.4 Surgical outcome measures

Two small trials, Kim 2004 and Tseng 2005, reported that there were no statistically significant differences in duration of operation (Analysis 2.3) or length of hospital stay (Analysis 2.4).

2.5 Adverse events

No statistically significant difference was seen in overall perioperative complications, but the confidence interval was wide (RR 0.98, 95% CI 0.53 to 1.84; Analysis 2.5).

Significantly fewer women experienced certain complications with the bottom-to-top approach (TVT^{TM}), which included:

- bladder perforation (RR 0.55, 95% CI 0.31 to 0.98; 5 trials; Analysis 2.6);
- voiding dysfunction after the bottom-to-top approach (TVT^{TM}; RR 0.40, 95% CI 0.18 to 0.90; 5 trials; Analysis 2.7);
- vaginal tape erosions (RR 0.27, 95% CI 0.08 to 0.95; 4 trials; Analysis 2.10).

There were no statistically significant differences between the two groups with respect to:

- postoperative de novo urgency symptoms and UUI (RR 0.84, 95% CI 0.52 to 1.34; 4 trials; Analysis 2.8); or
- DO (1 trial; Analysis 2.9).

However, the confidence intervals were wide for each of these five outcomes, which reflects the small number of trials.

2.6 Need for further treatment

No data were reported on the need for further treatment.

2.7 Quality of life

Only one of the five trials, Andonian 2005, assessed the QoL of women using the Incontinence Impact Questionnaire (IIQ; Shumaker 1994), where a score of less than 50 represents a good QoL, 50 to 70 represents moderate QoL, and over 70 indicates a poor QoL. In this study the mean IIQ scores were similar in the groups preoperatively and improved postoperatively, but there was no significant difference between the groups after operation. At one year follow-up, there was no statistically significant difference in the mean IIQ scores (mean difference of -4.6; 95% CI: -7.5 to 16.7).

Comparison 3. Obturator medial-to-lateral approach versus obturator lateral-to-medial approach

Ten trials reported this comparison (Abdel-Fattah 2010; But 2008; Chen 2010; Hassan 2013; Houwert 2009; Lee 2008; Liapis 2008; Park 2012; Peattie 2006; Scheiner 2012).

3.1 Women's observations

Six trials investigated short-term subjective cure rate and five of these assessed subjective cure and improvement in the short term (within 12 months of surgery). There were no statistically significant differences in either subjective cure rates (RR 1.0, 95% CI 0.96

to 1.06; Analysis 3.1) or subjective cure and improvement rates (RR 1.02, 95% CI 0.97 to 1.08 Analysis 3.2), and the confidence intervals for each were quite narrow. Two trials reported no statistically significant difference in subjective cure in the medium term (RR 1.06, 95% CI 0.91 to 1.23; Analysis 3.3) and a further two trials reported no significant difference in subjective cure and improvement in the medium term (RR 1.00, 95% CI 0.90 to 1.11; Analysis 3.4). There are no published trials with long-term data.

3.2 Quantification of symptoms

No data were reported for this comparison.

3.3 Clinician's observation

Six trials assessed objective cure (short term, ≤ 1 year); there was no statistically significant difference between the two groups (RR 0.99, 95% CI 0.95 to 1.04; Analysis 3.5), and the confidence interval was narrow. There was also no statistically significant difference in the objective cure or improvement rate between the two groups (RR 1.00, 95% CI 0.95 to 1.07; Analysis 3.6).

3.4 Surgical outcome measures

There were no statistically significant differences between the two groups in terms of:

- duration of operation, (in minutes, MD 0.52, 95% CI -1.09 to 2.13; 4 studies, 481 women; Analysis 3.7);
- operative blood loss (in ml, MD 1.11, 95% CI -6.01 to 8.22; 3 studies, 255 women; Analysis 3.8);
- length of hospital stay (in days, MD -0.77, 95% CI -2.54 to 0.99; 2 studies, 190 women; Analysis 3.9);
- time to return to normal activity (in weeks, MD -0.60, 95% CI -1.80 to 0.60; 1 study, 100 women; Analysis 3.10).

3.5 Adverse events

Vaginal perforation was significantly less likely to occur with the medial-to-lateral approach (RR 0.25, 95% CI 0.12 to 0.53; I^2 of 43%; Analysis 3.13). The average rate of vaginal wall perforation across both groups was 7.39% and, using this as the assumed control rate in the lateral-to-medial group, there were 55 fewer cases per 1000 in the medial-to-lateral group (95% CI from 35 per 1000 fewer to 65 per 1000 more).

Voiding dysfunction occurred significantly more in the medial-to-lateral compared to the lateral-to-medial group (RR 1.74, 95% CI 1.06 to 2.88; I^2 of 0%; 8 studies, 1121 women; Analysis 3.15). The average rate of POVD across both groups was 5.53% and, using this as the assumed control rate in the lateral-to-medial group, there were 41 more cases per 1000 in the medial-to-lateral group (95% CI from 3 to 104 per 1000 more).

There were no statistically significant differences between the two groups in terms of:

- overall perioperative complication rate (RR 1.30, 95% CI 0.23 to 7.51; 2 studies, 214 women; Analysis 3.11);
- major vascular/visceral injury (RR 0.71, 95% CI 0.23 to 2.19; 4 studies, 622 women; Analysis 3.12);
- bladder perforation (RR 0.38, 95% CI 0.07 to 1.92; 6 studies, 794 women; Analysis 3.14);
- de novo urgency symptoms and UUI rates (RR 1.01, 95% CI 0.46 to 2.20; 3 studies, 357 women; Analysis 3.16);
- detrusor overactivity (RR 0.87, 95% CI 0.27 to 2.84; 1 study, 114 women; Analysis 3.17);
- vaginal tape erosions (RR 0.42, 95% CI 0.16 to 1.09; 7 studies, 1087 women; Analysis 3.18);
- groin/thigh pain (9.2% versus 8%; RR 1.15, 95% CI 0.75 to 1.76; 6 studies, 837 women; Analysis 3.19).

3.6 Need for further treatment

Two large trials showed no significant difference in the rates of repeat incontinence surgery in the medium term (4.6% versus 7.1%; RR 0.64, 95% CI 0.32 to 1.30; Analysis 3.20).

3.7 Quality of life

Quality of life was assessed in five of the ten trials using validated QoL questionnaires. All of these trials reported QoL scores.

Condition-specific QoL scores

- Houwert 2009 used the short forms of the IIQ-7 and UDI-6. Within each group there was significant improvement postoperatively compared to scores obtained preoperatively, but no significant postoperative differences between the two groups (MD 16.54, 95% CI 4.84 to 28.24; 1 study, 42 women).
- But 2008 assessed QoL with IIQ and UDI questionnaires and VAS scores, but reported no results.
- Lee 2008 used a validated Korean version of the Incontinence QoL questionnaire (I-QoL) and showed improvements within the groups, but with no significant differences between the groups after surgery.
- Scheiner 2012 used the KHQ and found no significantly difference between the groups at baseline and postoperatively, but with improvement following surgery compared to baseline scores in all domains.
- Abdel-Fattah 2010 used the KHQ, Birmingham Bowel and Urinary Symptoms Questionnaire (BBUSQ-22), PISQ-12, PGI-I and the short form of the ICIQ (ICIQ-SF) to assess QoL. Overall there was statistically significant improvement in total scores, as well as in each of the nine domains of the KHQ. This remained the case when comparing baseline score in each group postoperatively; there was no significant difference in the QoL scores between the two routes.

Sexual function

Sexual function was addressed in three trials that used a variety of measures including validated questionnaires and direct questioning (Abdel-Fattah 2010; Houwert 2009; Park 2012). Questionnaires included: the PISQ-12, and BFLUTS (Abdel-Fattah 2010). There was significant improvement in PISQ-12 scores following surgery (improved sexual function compared to baseline), but no significant difference between the two groups at follow-up. Rates of dyspareunia following surgery were extremely low, with evidence of resolution by 24 months.

Comparison 4. One method of mid-urethral tape insertion versus another method, same route

Ten trials compared different methods of carrying out TOR and RPR operations using the same route (Cho 2010; de Leval 2011; Elbadry 2014; Juang 2007; Naumann 2006; Paparella 2010;

Rechberger 2011; Tommaselli 2012; Ugurlucan 2013; Zhang 2011). The following operations were compared.

Transobturator lateral-to-medial

- Monarc® TOT versus TOT® (Cho 2010).
- TOT versus adjustable TOT (Elbadry 2014).
- TOT versus TOT with two-point fixation sutures (Rechberger 2011).
- Synthetic TOT versus biological TOT (Paparella 2010; Ugurlucan 2013).

Transobturator medial-to-lateral

- TVT-O versus modified TVT-O (shorter tape and less lateral dissection; de Leval 2011).
- TVT-O versus TVT-O plus Ingleman-Sundberg bladder denervation procedure (Juang 2007).
- TVT-O versus modified TVT-O (reduced dissection; Tommaselli 2012).
- TVT-O versus modified TVT-O (self-tailored mesh; Zhang 2011).

Retropubic

- TVT versus modified TVT, bottom-to-top (suburethral pad; Naumann 2006).

Each comparison group included only a small single trial, which precluded any meaningful statistical analysis of the outcomes measured, except for the synthetic versus biological TOT comparison, for which there were two small trials (Analysis 4.1; Analysis 4.2; Analysis 4.3; Analysis 4.5; Analysis 4.4; Analysis 4.6; Analysis 4.7; Analysis 4.8; Analysis 4.10; Analysis 4.11; Analysis 4.12; Analysis 4.13; Analysis 4.14; Analysis 4.15; Analysis 4.16). Naumann 2006 reported no usable data.

For all outcomes measured in each trial, there were no statistically significant differences reported, with the exception of Juang 2007, where significant differences were found in favour of TVT-O plus Ingleman-Sundberg bladder denervation procedure for objective cure, operative time and intraoperative blood loss. Objecture cure in the short term for synthetic versus biological TOT showed no significant difference (RR 1.03, 95% CI 0.94 to 1.14; 2 trials; Analysis 4.5.2)

Sexual function was assessed by Paparella 2010 and Tommaselli 2012 using the PISQ-12. The PISQ-12 scores decreased after the procedure in both groups, indicating improved sexual function after surgery. No significant differences were observed between groups after the procedures.

Comparison 5. One type of tape material versus another

Four trials compared different mid-urethral sling operations based on their tape properties, e.g. monofilament tapes versus multifilament tapes (Lim 2005; Meschia 2006; Okulu 2013; Rechberger 2003). The interventions compared were:

- monofilament (TVT SPARC) verus multifilament (IVS; Lim 2005);
- monofilament (TVT) versus multifilament (IVS; Meschia 2006);
- synthetic monofilament (prolene light mesh) versus combined synthetic and biological (Ultrapro mesh) versus multifilament mesh (Vypro; Okulu 2013);
- monofilament (TVT) versus multifilament (IVS; Rechberger 2003).

5.1 Women's observations

In the short and medium term there was no statistically significant difference between monofilament and multifilament tapes in terms of their subjective cure rates; neither was there a significant difference found where the combined synthetic and biological tapes were compared to monofilament tapes (RR 1.03, 95% CI 0.95 to 1.10; RR 0.91, 95% CI 0.79 to 1.05; RR 1.10, 95% CI 0.96 to 1.26; Analysis 5.1: RR 1.03, 95% CI 0.85 to 1.23; RR 0.91, 95% CI 0.78 to 1.06; RR 1.13, 95% CI 0.96 to 1.32; Analysis 5.2).

5.2 Quantification of symptoms

No data were reported for this comparison.

5.3 Clinician's observation

The objective cure rate for monofilament tape and multifilament tapes show no significant difference between the groups (RR 1.07, 95% CI 0.96 to 1.19; Analysis 5.3).

5.4 Surgical outcome measures

There were no statistically significant differences in the duration of operation or length of hospital stay reported (RR 0.00, 95% CI -1.49 to 1.49; Analysis 5.4: RR 0.20, 95% CI -0.09 to 0.49; Analysis 5.5).

5.5 Adverse events

There were few perioperative complications with no statistically significant difference between the groups (RR 1.16, 95% CI 0.36 to 3.69; Analysis 5.6). No major vascular/visceral injury was reported in any of the trials (Analysis 5.7). Bladder perforation occurred in 4.49% of monofilament and 3.67% of multifilament tape procedures (RR 1.15, 95% CI 0.49 to 2.70; Analysis 5.8).

There were no statistically significant differences between the groups for:

- POVD (RR 2.10, 95% CI 0.96 to 4.59; Analysis 5.9);
- de novo urgency symptoms and UUI (RR 1.11, 95% CI 0.68 to 1.82; Analysis 5.10);
- DO (RR 0.70, 95% CI 0.12 to 4.06; Analysis 5.11).

In three trials, vaginal tape erosions were more common in the multifilament group, but this did not reach statistical significance (RR 0.79, 95% CI 0.09 to 6.84; Analysis 5.12).

5.6 Need for further treatment

No data were reported regarding the need for further treatment in this comparison.

5.7 Quality of life

Only the Okulu 2013 study assessed QoL and showed improvement from baseline scores, with no significant difference between the comparison groups. At 48 months mean postoperative ICI-Q QoL scores were significantly better in the monofilament group than in the multifilament group (MD -0.06, 95% CI -0.76 to -0.44; 1 study, 96 women; Analysis 5.13).

DISCUSSION

Summary of main results

1. Transobturator (TOR) versus retropubic route (RPR)

Comparison of the transobturator (TOR) versus retropubic route (RPR) was addressed by 55 trials that included 8652 women. Thirty-six of these trials (5514 women) contributed data to the primary outcome of subjective cure, which showed that in the short term there was no difference between TOR and RPR. Only six of these 53 trials reported medium- or long-term data, again with relatively small numbers of women showing no significant difference in symptomatic cure. These small numbers limit the judgements that can be made about cure rates in the longer term for both the efficacy of individual tapes, or for comparison of the route of tape insertion. There was potential for at least 22 of these trials to have published either medium- or longer-term outcomes, given their dates of publication. Similarly, objective cure rates showed no significant difference between the two routes.

Evidence from 40 trials (6372 women) showed a 30 fold percentage increase in the rate of bladder perforation with the RPR approach compared to the TOR approach. In practice, for this reason, some clinicians favour the TOR for patients at higher risk of bladder/urethral perforation, for example, those who have had previous pelvic or incontinence surgery. Similarly, 37 trials (6217 women) that assessed postoperative voiding dysfunction (POVD) showed this adverse outcome to be significantly less frequent when the TOR was employed. However, the reported sequale for both of these outcomes is usually of short duration.

Thirty-one trials (4743 women) that assessed vaginal tape erosion showed no significant difference when either route was used. More women experienced groin pain in the TOR group than in the RPR group. This groin pain was usually of short duration and resolved within eight weeks in most cases. The occurrence of suprapubic pain following an RPR procedure was poorly reported. This was more common in the RPR group; however, when data was provided, only a minority of women suffered this symptom and for a short period of time.

Overall mid-urethral slings are a highly effective treatment for stress urinary incontinence (SUI). In the short term there is equivalence in the efficacy between the two routes, and this persists into the medium and longer term, though the data for this is somewhat limited by small numbers. There is some evidence that suggests women are more likely to require repeat incontinence surgery in the longer term with the TOR, but this requires cautious interpretation, as there are extremely small numbers. There is an equal improvement in the overall quality of life of women for both routes. Sexual function improved in both groups as a result of the surgery, most probably from reduction in coital incontinence, with no significant difference in sexual function between the two groups.

To supplement the main systematic review of effects, we sought to identify economic evaluations which have compared TOR with RPR in the treatment of SUI in women. A supplementary search in Ovid MEDLINE, Embase and NHS EED, identified three economic evaluations (Lier 2011; Lier 2016; Seklehner 2014). The search strategies used are given in Appendix 3. Lier 2016 reported both a cost-utility and cost-effectiveness analysis while Lier 2011 was a cost-effectiveness analysis. Both studies analysed costs and resources used from public payer perspective (Alberta, Canada) and used clinical data from the same RCT (Ross 2009) with results presented at one year (Lier 2011) and five years (Lier 2016) post-surgery. Seklehner 2014 reported a decision model based cost-effectiveness analysis with clinical evidence collected from MEDLINE search of RCTs on TOR and RPR. This study adopted a US healthcare system perspective with a 10-year time horizon. Lier 2016, which was a further follow-up of Lier 2011, reported that TOR was slightly more effective than RPR with a mean QALY gain of 0.04 over five years (95% CI -0.06 to 0.14). Seklehner 2014 reported that on average TOR was slightly more effective, with a QALY gain of 0.03 over 10 years. Both Lier 2016 and Lier 2011 reported no statistically significant difference in the cure rate (81% for TOR versus 77% for RPR, P value not stated) but there was a significant difference in the number of patients in the TOR arm with groin pain and palpation of the surgical tape on vaginal examination (26% difference, P = 0.001) even after five years (Lier 2016). In all three studies TOR was less costly in when compared with RPR (Lier 2011; Lier 2016; Seklehner 2014). In Lier 2016, TOR was on average less costly, with an average total cost difference which rose from CAD -414 (95% CI -1415 to 587) (Lier 2011) to CAD -2368 (95% CI -7166 to 2548) at five years (2011 Canadian dollars). In Seklehner 2014 the average cost difference was CAD -562 (CI not stated).The three studies each suggested that TOR may be cost-effective.

2. Retropubic bottom-to-top approach versus retropubic top-to-bottom approach

Five trials with 636 women compared the retropubic bottom-to-top with the retropubic top-to-bottom approach. These showed that passage of the tape through the retropubic route in a bottom-to-top path (e.g. TVT^{TM}) was more effective than passage in a top-to-bottom path (e.g. SPARC^{TM}), and resulted in fewer intra and postoperative adverse events.We took the same approach for TOR versus RPR to identify economic evaluations, but found no results.

3. Obturator medial-to-lateral approach versus obturator lateral-to-medial approach

Ten trials with 1199 women compared the obturator medial-to-lateral approach with the obturator lateral-to-medial approach. Evidence from the ten trials, two of which reported medium-term data, showed no difference between the two approaches with respect to most outcomes measured. The only exceptions were voiding dysfunction, where higher rates were reported in the medial-to-lateral group, and vaginal perforation, which had higher rates in the lateral-to-medial group. Despite this, there was no resultant increase in the rate of tape erosion. It is, therefore, not unreasonable to exercise operator preference when deciding which of these two approaches to adopt. Notably, each route improved quality of life and sexual function postoperatively. We took the same approach for TOR versus RPR to identify economic evaluations, but found no results.

4. One method of mid-urethral tape insertion versus another method, same route

Ten trials with 1569 women compared one method of mid-urethral tape insertion with another using the same route. Despite several design or procedural modifications to tapes traversing the same route, there was no difference in the efficacy, surgical outcomes or occurrence of adverse events.The same approach done for TOR versus RPR was carried out to identify economic evaluations but yielded no result.

5. One type of tape material versus another

Four trials with 505 women compared monofilament tapes with multifilament tapes. There was no statistical difference in physician-observed cure rates or patient-reported cure between the groups. There was no significant difference in the rate of vaginal tape erosion. We took the same approach for TOR versus RPR to identify economic evaluations, but found no results.

Overall completeness and applicability of evidence

Many of the trials contributing to this review did provide evidence regarding the primary outcome, which was to determine the effectiveness of mid-urethral sling operations in the treatment of urinary incontinence. They confirm that mid-urethral sling operations for SUI are an effective surgical treatment available in current practice. A major limitation was the variable quality of many of the trials.

We did not attempt to analyse the data by subgroups according to the clinical characteristics of the women, such as symptoms of SUI, urodynamic stress incontinence, diagnosis of intrinsic urethral sphincter deficiency or urethral hypermobility, obesity, previous incontinence surgery, presence or absence of prolapse, anaesthesia used, or experience of the surgeon. In fact the majority of trials did not describe these characteristics of the women.

We did not subject the three identified economic evaluations to critical appraisal and we do not attempt to draw any firm or general conclusions about the relative costs or efficiency of TOR for treatment of SUI. However, the economic evidence available suggests that TOR is cost-effective when compared with RPR in the treatment of SUI in women.

Complications

Major complications such as nerve, bowel or major vascular injuries, pelvic haematoma, necrotizing fasciitis, ischiorectal abscess and death are uncommon and unlikely to be picked up by small randomised controlled trials (RCTs). There is potential to determine a more accurate incidence from large national registries and voluntary reporting registries or databases for reporting complications, such as the United States Food and Drug Administration's (FDA) manufacturer and user facility device experience (MAUDE). One must bear in mind, though, the limitations of this method. Several of these registries have reported their findings (Collinet 2008; Dyrkorn 2010; Kuuva 2002; Koops 2005; Tamussino 2001; Tamussino 2007; Tincello 2011).

Retropubic tapes

From the above list of registries, for tension-free vaginal tape the number of procedures reported ranged from 809 to 4281, and there were found to be low rates of major complications.

- Bladder perforation occurred in 2.7% to 3.9% of cases.
- Reoperation rates relating to tape insertion or postoperative voiding dysfunction (POVD) ranged from 1.6% to 2.4%.
- Urinary retention rate was 1.6%.
- Pelvic haematoma occurred in 0.7% to 1.9% of women.
- Infection rate was 0.7%.
- Vaginal tape erosion/extrusion rate was 1.5%.
- Groin pain occurred in 0.4% of women.

These rates are largely of the same order as those reported in the trials included in this review. There were also a few cases of major visceral injuries such as bowel and urethral injuries.

Transobturator tapes

Registries of transobturator tapes reported much lower rates of complications.

- Bladder perforation occurred in 0.4% of cases.
- Reoperation rates relating to tape insertion ranged from 0.8% to 2.2%.
- Urinary retention rate was 0.5%.
- Pelvic haematoma occurred in 0.5% of women.
- Infection rate was 0.6%.
- Vaginal tape erosion/extrusion rate was 0.4%.
- Groin pain occurred in 1.6% of women.

The FDA received 1876 reports of complications associated with the use of slings for SUI in the period between 1 January 2008 to 30 September 2011. The most common complications reported were pain, vaginal tape erosion (exposure, extrusion or protrusion), infection, urinary problems, recurrent incontinence, pain during sexual intercourse (dyspareunia), bleeding, organ perforation, neuro-muscular problems and vaginal scarring. Many of these complications required further medical intervention, and sometimes required surgical treatment or hospitalisation, or both. With the exception of tape erosion, the above complications were also found to occur following non-mesh surgical repairs for SUI. It should be borne in mind that this sort of reporting system is a passive surveillance system limited by the inclusion of the potential submission of incomplete or inaccurate data, under-reporting of events, lack of denominator data (number of tapes), and the lack of report timeliness.

It should be noted that the latest FDA white paper and safety communications on meshes released in 2011 - unlike the previous 2008 release (FDA 2008) - relates to ongoing concern with mesh used to treat pelvic organ prolapse (POP) and not the small strip of mesh/tape/sling used to treat SUI (FDA 2011a; FDA 2011b). In fact the FDA states that the safety and effectiveness of mid-urethral slings is well established in clinical trials with 1-year follow-up (FDA 2013).

Equally, because of the increasing numbers of adverse events and patient concerns reported, in 2012 the Medicines and Healthcare Products and Regulatory Agency (MHRA) in Europe published a commissioned report on the most frequently reported adverse events associated with different meshes/tapes/slings (MHRA 2012). The report showed that for the treatment of SUI the rate of vaginal tape erosion was low, at between 1.1% to 2.5%. Even in a selected cohort of women presenting primarily with adverse events of mesh, those with mid-urethral sling were significantly less likely to present with mesh erosions than those who had mesh for POP repair. Presentation of mesh erosion following SUI treatment is less severe, and less likely to require surgical treatment under general anaesthesia than erosion following mesh insertion for POP repair. This relates to complication classification severity grade 4 (Abbott 2014; Strasberg 2009).

In their 2014 report, the MHRA concluded that from the review of the information available, there appeared to be no evidence that

vaginal mesh implants for SUI are unsafe, nor was there evidence to justify MHRA taking enforcement action to take them off the market, or remove them from use. The report concluded that the overall benefit outweighed the relatively low rate of complications (MHRA 2014).

Although the number of adverse events was generally low and they were rarely serious, it is recognised that the ability of RCTs to identify rarer adverse effects is poor. With the increasing popularity of MUS procedures the occurrence of complications in the short term is well established, but in general these are easily treated or resolve spontaneously. However, because few trialists have carried out long-term follow-up, there is very little information about whether there is a hidden cache of serious adverse effects that might be set against the benefits of curing incontinence.

Longer-term outcomes after MUS

Observational studies of MUS show data confirming effectiveness in the long term with some data that cover 15 to 17 years (Aigmueller 2011; Athanasiou 2014; Heinonen 2013; Nilsson 2013; Serati 2012; Serati 2013; Svenningsen 2013a; Svenningsen 2013b). These trials of MUS, like similar observational studies for open colposuspension, show a decline in effectiveness that is time-dependent, and also reveal high rates of de novo urgency symptoms (15%) and voiding difficulties (23%). It is difficult to elucidate the reasons for these long-term symptoms, but they could be age related, or due to new pathology, or a true consequence of the surgery. Nevertheless, they emphasise the need for longer-term data from RCTs to help counsel women appropriately.

With regard to long-term data from RCTs, there is a paucity of trials that reported longer-term outcomes and most long-term data reported for both open colposuspension and MUS are for five to six years. If evidence from RCTs mirrors that from observational studies, we will not only require the many RCTs that have been published for MUS to report their longer-term data, but will in fact need to follow these women up for at least 10 to 15 years. This would allow us to discover whether there is a time-dependent decline in effectiveness, and enable us to elucidate the development in the long term of new adverse effects.

Comparisons with other methods of continence surgery

'Gold standard' surgical treatment for stress urinary incontinence (SUI)

Open abdominal retropubic colposuspension used to be considered the gold standard treatment for SUI. It is noteworthy that there are no randomised controlled trials of open colposuspension versus no treatment. Two small trials that compared open colposuspension with conservative treatment were unreliable because of very small numbers of participant and a high risk of bias (Lapitan 2012). Equaliy the evidence for MUS versus no treatment or conservative treatment is limited and we will be addressing this in a future Cochrane review.

Our initial review showed the effectiveness of MUS in the short term and, as time has moved on, it was hoped that with reports of long-term data it would become clear whether long-term efficacy of MUS could be compared with that of open retropubic colposuspension. A Cochrane review of open retropubic colposuspension identified 15 RCTs that compared the mid-urethral sling operations (12 RPR and three TOR) with colposuspension (Lapitan 2012). This review concluded that there was no significant difference in incontinence rates between the two procedures for all time periods assessed. Both procedures led to improvement in the quality of life of women. While some complications, such as bladder perforation, were reported more with MUS, the numbers were small. Other complications such as POVD, which were reported to be higher with MUS, were influenced by a large trial that reported no risk of voiding difficulties at all after colposuspension, but consistent data from TVT trials showed no significant difference in the risk of voiding dysfunction between MUS and colposuspension. MUS had a shorter operating time, length of hospital stay and cost. Only one RCT that compared MUS with open colposuspension has reported results for a five-year follow-up, and it failed to detect significant difference between the success rates of MUS and colposuspension. It also showed that the effect on cure of incontinence and improvement in quality of life was maintained for both procedures at five years (Ward 2008).

Observational data for open colposuspension with follow-up of 10 to 20 years show high rates of effectiveness in the long term (Alcalay 1995; Kjolhede 2005; Brubaker 2012). This long-term cure is shown to be time-dependent with cure rates plateauing at about 69% at 10 to 12 years. In addition some reports show continence rates of only 44% at 14 years, with high rates of voiding difficulties (of 36%) at 14-year follow-up.

Mid-urethral sling operations versus traditional slings

Historically, traditional suburethral sling procedures were used for women who had recurrent stress incontinence (after a previous failed continence operation). However, the review did not report the results separately for women with new or recurrent incontinence (Rehman 2011). These procedures were designed to restore normal urethrovesical junction support by mechanical compression or kinking of the proximal urethra.

Minimally invasive synthetic suburethral slings appeared to be as effective as traditional suburethral slings in short-term incontinence rates (RR 0.97; 95% CI 0.78 to 1.20), although the confidence interval is compatible with minimally invasive slings being 20% better or 12% worse. The operating time and length of stay were also significantly shorter with minimally invasive synthetic suburethral sling operations, and women had fewer perioperative complications and less detrusor overactivity.

Mid-urethral sling operations versus open retropubic colposuspension

Although 14 RCTs were found that compared TVT operations with colposuspension (Lapitan 2012), data from five of them showed no clear differences in the short- or medium-term chance of incontinence compared with open colposuspension. While there were more complications after the sling operations, the numbers were small.

Mid-urethral sling operations versus laparoscopic colposuspension

Another Cochrane review identified eight trials that compared mid-urethral sling operations to laparoscopic colposuspension (Dean 2006). Overall, the review showed that the subjective cure rates were similar for both of these minimal access techniques in the short term, while operation times were shorter for the slings. Long-term data are lacking, however.

Mid-urethral sling operations versus single incision slings

Single-incision slings compared with retropubic mid-urethral slings

Women were twice as likely to be incontinent after a single-incision sling as after a retropubic TVT (RR 2.08, 95% CI 1.04 to 4.14; Nambiar 2014), although the surgery took less time to perform. However, this finding mostly related to one type of single-incision sling (TVT-Secur), which has now been withdrawn from the market due to this lack of efficacy.

Single-incision slings compared with transobturator mid-urethral slings

Women were twice as likely to be incontinent after a single-incision sling procedure as after a transobturator sling procedure (RR 1.91, 95% CI 1.53 to 2.39; Nambiar 2014). In addition, they were more likely to need a further operation for complications or repeat surgery for their incontinence. However, the risks of postoperative pain and long-term pain were slightly higher with transobturator slings.

For the economic evidence, two cost-effectiveness analyses also compared single-incision mini-slings with transobturator mid-urethral slings. These adopted the perspective of the Spanish (Castañeda 2014) and UK healthcare systems (Boyers 2013) respectively. Boyers 2013 used clinical evidence from a prospective RCT (Mostafa 2012), while Castañeda 2014 used evidence from a retrospective observational study, using a one-year follow-up in both cases. Both studies reported no statistically significant differences in the clinical outcomes: 6.7% difference, 95% CI -6.6 to 20.0, P = 0.527 (Castañeda 2014); 5% difference, 95% CI 0.38 to 2.26, P = 1.000 (Boyers 2013), and also no statistically significant differences in intraoperative complications: P = 0.023 (Boyers 2013); P = 0.553 (Castañeda 2014). Boyers 2013 also reported the impact on health-related quality of life reported as quality adjusted life years (QALYs). There was no significant difference in QALYs (mean difference -0.003, 95% CI -0.008 to 0.002) (Boyers 2013).However, in the single-incision sling arm, there were statistically significant improved postoperative pain scores up to four weeks with a pain score of zero compared with mid-urethral slings with a total pain score of two (P < 0.001, 95% CI 1.245 to 1.853). There was also a statistically significant one day earlier return to normal activities with single-incision slings (P = 0.025, 95% CI 6.1 to 9.4 days) (Boyers 2013) and less repeated urinary tract infections (Castañeda 2014). Single-incision mini-slings were less costly in both studies. The mean total direct cost of single-incision mini-sling in Boyers 2013 was GBP 1277 (2011 GBP) while that of transobturator sling procedure was GBP 1462 (2011 GBP), with a 94% probability (95% CI GBP -316.99 to GBP 32.17) of being cost-saving compared to the transobturator sling procedure, irrespective of whether single-incision mini-slings were performed under local or general anaesthesia. In Castañeda 2014, the average cost of single-incision mini-slings (2013 euro) was EUR 2059 (95% CI 1914 to 2285), while the cost of the transobturator sling procedure was EUR 2821 (95% CI 2661 to 2997). There was a 100% probability of single-incision mini-slings being cost-saving. Both studies (Boyers 2013; Castañeda 2014) suggested that the transobturator sling procedure is less cost-effective when compared with mini-sling based on comparative effectiveness of both interventions and lower costs associated with single-incision mini-slings.

Mid-urethral sling operations versus anterior repair

To date, no trials have been identified that compared the original operation for SUI, anterior repair (with urethral buttressing sutures, or Kelly sutures) directly to mid-urethral slings (Glazener 2001). However, in the current climate of concern about adverse effects from the use of synthetic mesh or tape materials, perhaps it is time to reassess the value of this operation, not least because of its additional role in the management of prolapse.

Quality of the evidence

We judged the quality of evidence using the GRADE classification as moderate for the majority of outcomes. The remaining outcomes assessed were low level evidence. The main reason for the decrease in the quality of evidence for many outcomes was a high risk of bias where allocation concealment or random sequence generation were deemed uncertain. Imprecision of effects estimates also contributed to the variable quality of evidence in some outcomes.

In the main comparison between TOR and RPR, the quality of evidence for most outcomes was moderate. The downgrade from high quality to moderate quality evidence was mainly because of a small proportion of trials in which there was a high risk of bias from either study design or implementation, which then reduced our confidence in the estimates of effects.

Potential biases in the review process

GRADE-specific outcomes were selected at the time of the original review. These have been modified for this update. There is potential for introduction of bias, as ideally these GRADE-specific outcomes should have been selected at the time of the protocol, and there would have been consistency between the outcomes selected in the original review and in the update.

AUTHORS' CONCLUSIONS

Implications for practice

Mid-urethral sling operations are now widely accepted as a routine surgical treatment for stress urinary incontinence (SUI). This review has identified evidence that addresses the comparative effects of different ways of inserting tapes, including different insertion routes, surgical approaches and tapes.

Irrespective of the routes traversed, these procedures are highly effective in the short and medium term and mounting evidence demonstrates their effectiveness in the long term.

There is low to moderate quality evidence that retropubic tapes and transobturator tapes have comparable effects on cure of incontinence between one and five years, and limited evidence for the same in the long term. With the exception of a two-fold increase in the incidence of groin pain, transobturator tapes have fewer adverse events. Retropubic tapes have an eight-fold increase in the incidence of bladder perforation and a two-fold increase in the incidence of post operative voiding difficulties. Although women's outcomes for quality of life and sexual function improved significantly after all surgical approaches, our analyses could not establish whether there was any difference between retropubic and transobturator tapes. Evidence for longer-term effects is required to evaluate the need for further surgery following either approach.

There was moderate quality evidence that when a retropubic route (RTR) is employed a bottom-to-top approach is more effective in terms of subjective cure than a top-to-bottom approach. When traversing the transobturator route (TOR), there was moderate quality evidence showing that medial-to-lateral ('inside-out') and lateral-to-medial ('outside-in') approaches have similar effects.

Implications for research

Many trials have evaluated the use of mid-urethral tapes in the short term. However, the long-term effects of surgery, and how the different insertion routes affect long-term outcome, have not been established. It is unfortunate that although 35 of the 81 trials included should be in a position to report their long-term data (i.e. over five years), only three have done so. More of the trials included in this review should publish the results of their longer-term follow-up to increase the robustness of evidence supporting the use of mid-urethral sling (MUS) in the long term, to provide answers about the long-term adverse events of these operations, including whether there is a significant decline in the effectiveness of these procedures over time, and to identify the point at which decline becomes significant enough to require women to need repeat procedures.

More research is required into trials assessing the clinical effectiveness of different routes (RPR or TOR) in women with urodynamic stress incontinence where hypermobility is differentiated from intrinsic urethral sphincter deficiency, as data for most of the outcomes are sparse. Equally, trials assessing the effectiveness of RPR or TOR in a cohort of women presenting with recurrent SUI after a failed MUS procedure are needed. More adequately powered trials are needed to address the issue of MUS in women who also have symptomatic or asymptomatic pelvic organ prolapse, as presently it is unclear whether concomitant pelvic organ prolapse surgery is necessary, and, if performed, whether it enhances or detracts from the effectiveness of the MUS. Conversely, there is only indirect evidence to suggest that MUS are more effective than anterior repair, as no RCTs have compared them directly.

Future randomised controlled trials should be robustly designed to be of good quality and adequately powered with standardised woman-reported (subjective) outcome measures and objective outcomes. When reporting, these trials should follow the CONSORT guidelines (Moher 2001; Schulz 2010). There needs to be long-term follow-up and adequate reporting of adverse effects. It is essential that outcomes relevant to both women and policy makers who commission treatments are incorporated into these trials. In particular, quality of life, sexual function and economic implications should be assessed.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Abdel-Fattah 2010

Methods	RCT of TVT-O vs TOT–ARIS
Participants	341 women from the west of Scotland, UK, Urogynaecology tertiary referral centre Inclusion criteria: women with USI or MUI (but with SUI as the predominant troublesome symptom). Women with previous incontinence surgery were included. All women had failed or declined pelvic floor muscle training Exclusion criteria: predominant OAB symptoms; or had specific co-morbidities such as known neurological conditions (e.g. multiple sclerosis); diabetes; ≥ stage 2 POP-Q or concomitant surgery, or both There were no significant differences in participant characteristics between the 2 groups Mean age (years): Group A: 51.5; Group B: 52.1 Mean BMI kg/m^2: Group A: 28.1; Group B: 28.9 MUI: Group A: 40/170; Group B: 43/171 Previous incontinence surgery: Group A: 28/170; Group B: 18/171
Interventions	Group A: TVT-O (n = 170) Group B: TOT (n = 171)
Outcomes	Primary outcome: absence of USI on UDS Secondary outcome measures: • patient-reported success rates on the PGI-I • objective cure (ICS 1-hr pad test) • subjective success on PGI-I • bladder/urethral perforation • voiding dysfunction • tape erosion • groin pain • repeat continence surgery • QoL assessed via: KHQ, Birmingham Bowel Urinary Symptom (BBUSQ-22)and PISQ-12. In addition PGI-I and ICIQ-SF questionnaires. • sexual dysfunction: PISQ-12 employed • intermediate (3 year) subjective success on PGI-I
Notes	Loss to follow up at 1 year: Group A: 18/170, Group B: 24/171 Loss to follow up at 3 years: Group A: 44/170, Group B: 59/171

Risk of bias

Bias	Authors' judgement	Support for judgement

Abdel-Fattah 2010 *(Continued)*

Random sequence generation (selection bias)	Low risk	Quote: "A single-blinded, prospective, randomized study … Women were assigned to either procedure by random allocation (computer generated)"
Allocation concealment (selection bias)	Low risk	Quote: "Allocation was concealed using opaque sealed envelopes, which were opened by the nursing staff on the morning of the operation"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: “a single-blinded, prospective, randomized study… Women were informed about the type of operation if they wished, for ethical considerations, but they were instructed not to disclose this information to the clinician at follow-up”
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: “Post-operative assessment at 6 months was performed by an independent clinician who was blinded to the type of surgery … “
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: “No woman assigned to an arm asked to change her operation or to withdraw from the study prior to the operation. Withdrawals, unattendants and untraceables were accounted for without significant inter group differences”

Aigmuller 2014

Methods	RCT of Gynecare TVT vs Gynecare TVT-O; Gynecare, Ethicon
Participants	Trial conducted by Austrian Urogynecology Working Group in 25 gynaecology units in Austria and Germany 554 women Inclusion criteria: women with USI (positive cough stress test at bladder filling of 300 ml); no concomitant prolapse surgery or hysterectomy Exclusion criteria: DO or a predominant complaint of OAB; concomitant prolapse surgery; other major concomitant surgery (e.g. hysterectomy); previous incontinence surgery other than colporrhaphy; residual urine ≥100 ml; neurologic disease; allergy to local anaesthetic agents; and coagulation disorders or other contraindications for surgery Age (years): Group A: 59.7 ± 11.3; Group B: 58.6 ± 10.7 BMI kg/m^2: Group A: 27.7 ± 5.3; Group B: 28.5 ± 4.9 Parity: Group A: 2.2 ± 1.2; Group B: 2.2 ± 1.3
Interventions	Group A: TVT: (n = 285; 38 of whom were lost to follow-up) Group B: TVT-O: (n = 269; 36 of whom were lost to follow-up)
Outcomes	Participants were evaluated at 3 months, with a further evaluation scheduled at 5 years • Objective cure of SUI: defined as a negative cough stress test and stable cystometry to 300 ml • Subjective cure defined on PGI as 'very much better' and 'better' • Objective cure • Subjective cure • Subjective cure and improvement • Operating time • Bladder perforation • Vascular injury

Aigmuller 2014 *(Continued)*

- Voiding dysfunction
- Major visceral injury
- Infection
- De novo OAB

Notes	QoL: Short-Form Health Survey (SF-12), EuroQol-5D (EQ-5D) condition-specific QoL was assessed with the German language version of the KHQ, the Incontinence Outcome Questionnaire (IOQ), and PGI-S and PGI-I Cystoscopy was performed with all retropubic placements but not routinely with transobturator insertions The number of women in each group seen at 5-year follow-up was not available, so the data reported could not be used for meta-analysis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "randomized according to a computer generated random list allocating trial identification number and treatment group. Randomization was by fax through the central office"
Allocation concealment (selection bias)	Low risk	Quote: "computer generated random list allocating trial identification number and treatment group"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Patients, surgeons, and physicians performing follow-up exams were not blinded to the type of surgery
Blinding of outcome assessment (detection bias) All outcomes	High risk	Patients, surgeons, and physicians performing follow-up exams were not blinded to the type of surgery
Incomplete outcome data (attrition bias) All outcomes	Low risk	Accounted for and no differentials in the groups in terms of loss to follow-up

Alkady 2009

Methods	RCT of TVT vs TVT-O
Participants	30 women with SUI in Kuwait Maternity Hospital Inclusion criteria: SUI with or without a prolapse; USI with or without urethral hypermobility; MUI without urodynamic DO; absence of a contractile urinary bladder or obstruction Exclusion criteria: acute cystitis; predominant urge incontinence; urodynamic DO; maximum flow (Qmax) less than 15 ml/s and/or PVR urine of more than 20% of the volume voided; genital prolapse of stage 4 or 5 Menopausal: Group A: 3/15; Group B: 4/15
Interventions	Group A: TVT (n = 15)

Alkady 2009 *(Continued)*

	Group B: TVT-O (n = 15)
Outcomes	• Objectively cure: absence of SUI and a negative stress test • Objective improvement: lower volume and frequency of SUI, but positive stress test • Objectively cure • Objective cure & improvement • Mean blood loss • Mean hospital stay • Bladder perforation • Major vascular injury • Voiding dysfunction • Tape erosion
Notes	No participants lost to follow-up at 6 and 12 months

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Women were randomised using numbered, opaque, sealed envelopes containing computer-generated random allocations in a ratio of 1:1 in balanced blocks of 10.
Allocation concealment (selection bias)	Low risk	Women were randomised using numbered, opaque, sealed envelopes containing computer-generated random allocations in a ratio of 1:1 in balanced blocks of 10.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: “All accounted for”

Andonian 2005

Methods	RCT comparing TVT with SPARC
Participants	84 women presenting with SUI, or SUI with MUI if cystometrogram showed normal capacity, compliance and no uninhibited contractions. Women with previous failed anti-incontinence surgeries or bulking agents treatments were also eligible for the study. Both groups were similar in terms of age, severity of symptoms, 1-h pad test and preoperative IIQ (of Shumaker)
Interventions	Group A: SPARC (n = 41) Group B: TVT (n = 43)
Outcomes	Primary endpoint: objective cure defined as 1-h pad test of 2g

Andonian 2005 *(Continued)*

	Secondary endpoint: QoL assessed through Shumaker's IIQ, a score of <50 represented good QoL, 50-70 moderate QoL, and >70 poor QoL
Notes	Follow-up assessment of cure at 1 year was unavailable in 1 woman (Group B) who died from a myocardial infarct

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were blinded to the procedure and had envelope randomization immediately prior to the start of the surgery"
Allocation concealment (selection bias)	Low risk	Adequate
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Both groups and outcome assessors were said to have been blinded but how this was achieved was not clear. Quote: "Patients were blinded to the procedure and had envelope randomization immediately prior to the start of the surgery"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded, quote: "dedicated UDS nurse (BS), who was blinded to the procedure"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Addressed

Andonian 2007

Methods	RCT of TOT (Obtape) versus **d**istal **u**rethral **p**olypropylene **s**ling (DUPS) versus TVT
Participants	190 women Inclusion criteria: women with SUI with or without POP or pelvic surgery; previous failed anti-incontinence surgeries or bulking agent treatments permitted; women with MUI were not excluded as long as their cystometrogram showed normal capacity; compliance and no uninhibited contractions Exclusion criteria: obstruction; unstable bladder function, or neurogenic bladder; UTI
Interventions	Group A: Obtape (n = 78) Group B: DUPS (n = 32) Group C: TVT (n = 80) 1 participant in the Obtape group had a urethral diverticulum, which was repaired, but the Obtape procedure was cancelled, leaving 77 patients in the Obtape group for the final analysis
Outcomes	Primary outcome: objective cure defined by 1-h pad test of ≤ 2 g Secondary outcome: subjective cure rates determined by the ICIQ-SF Postoperatively, all women were re-evaluated by history and physical examination at 1, 6, and 12 months. At the 12-month visit, participants completed the ICIQ-SF, and underwent the 1-h pad test conducted by the dedicated UDS nurse who was blinded to the procedure

Andonian 2007 *(Continued)*

Notes	Mentor's Obtape is a non woven monofilament thermally bonded micropore (50 µm) polypropylene mesh which was withdrawn by its manufacturers in 2006. There have been many reports of tape erosions and some cases of ischiorectal abscess and necrotizing fasciitis DUPS is not a minimally invasive sling, but a woven polypropylene mesh (by Ethicon, New Jersey). Absorbable sutures are used to fix the sling into position until adhesions form and adhere it naturally to the retropubic space. As it was not a minimally invasive sling there was no need to compare DUPS in the review The DUPS procedure was discontinued because of a higher postoperative retention rate combined with several complaints of suprapubic abdominal discomfort on straining

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomization was performed by an envelope method immediately before the start of surgery."
Allocation concealment (selection bias)	Unclear risk	Not mentioned
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The patients were blinded to the procedure
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded, but how this was achieved was not explained
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear

Aniuliene 2009

Methods	A prospective RCT of TVT-O vs TVT
Participants	264 women with SUI in Lithuania hospital setting. The degree of incontinence was 2–3 according to the Ingelman-Sundberg scale Inclusion criteria: women with SUI Exclusion criteria: urogenitale prolapse greater than stage 2; urinary retention; OAB and psychiatric problems Post menopausal: Group A: 47/150; Group B: 48/114 Mean BMI kg/m^2 (SD): Group A: 28.2 (3.8); Group B: 27.9 (4.0) Previous incontinence surgery: Group A: 18/150; Group B: 16/114 POP-Q stage 2: Group A: 29/150; Group B: 22/114
Interventions	Group A: TVT-O (n = 150) Group B: TVT (n = 114)

Aniuliene 2009 *(Continued)*

Outcomes	• Objective cure: negative stress provocation test with 300 ml of urine in the bladder • Subjective cure: self-reported absence of SUI with or without mild urgency incontinence. • Mean duration of procedure • Mean hospital stay days • Bladder perforation • Post operative urinary retention • Haematoma
Notes	Urodynamics assessment was not performed in all participants Cystoscopy and cough test were routinely performed only in the TVT group No patients were lost to follow-up

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	No participants lost to follow-up

Araco 2008

Methods	RCT of TVT-O versus TVT
Participants	240 women with different degrees of SUI Inclusion criteria: symptomatic SUI grades 1 and 2a (McGuire classification) Exclusion criteria: women with ISD; OAB; associated prolapses; neurovegetative disorders and recurrent SUI or under rehabilitative/medical therapies Diagnosis based on ambulatory UDS Average age of 54 years
Interventions	Group A: TVT-O (n = 120) Group B: TVT (n = 120)

Araco 2008 *(Continued)*

Outcomes	Primary outcome: cure rate of SUI evaluated with the postoperative ambulatory urodynamic tests 1 year after surgery Secondary outcomes: • operating times • length of hospitalisation • number of catheterization days • postoperative pain • other complications (haematomas, bladder obstructions/perforations, vaginal perforations) • number of additional operations required A positive pad weight result was defined as > 2g of leakage
Notes	The participants were classified according to the SUI system on the basis of urodynamics studies (McGuire classification), performed at 250 ml bladder volume. SUI was classified into 3 grades considering the severity of symptoms referred (SUI1 = loss of urine during excessive strains, SUI2 = during minor strains, SUI3 = at rest) and the urodynamic evaluation (McGuire classification: SUI1 = abdominal leak-point pressure (ALPP) > 90 cm water, SUI2 = ALPP of 60-90 cm water, SUI 3 = intrinsic sphincter deficiency and ALPP < 60 cm water) Cystoscopy was performed in all cases Loss to follow-up: 32 women were lost to follow-up due to work commitments, Group A:12/120 TVT, Group B: 20/120

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A stratified randomisation was carried out. Presented two identical closed envelopes to patients, one containing the paper “TVT” and the other “TVT-O”. After choosing and opening of the envelope, further stratification was performed with a sampling chart. Four groups were formed on the basis of which operation they were going to receive."
Allocation concealment (selection bias)	Low risk	Quote: "Presented two identical closed envelopes to patients, one containing the paper “TVT” and the other “TVT-O”
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Data was analysed by a surgeon who was not involved in the surgical intervention"
Incomplete outcome data (attrition bias) All outcomes	High risk	Disproportionately higher numbers lost to follow-up in TVT-O group

Barber 2008

Methods	RCT of TVT vs Monarc TOT
Participants	Setting: 3 USA tertiary academic medical centres

Barber 2008 *(Continued)*

	Inclusion criteria: 170 women aged over 21 years with USI with or without concurrent POP Exlusion criteria: DO; previous incontinence surgery; PVR > 100 ml; desiring future childbearing; history of hidradenitis suppurativa, inguinal lymphadenopathy, or an inguinal or vulvar mass; history of a bleeding diathesis or ongoing anticoagulation therapy; current genitourinary fistula or urethral diverticulum Mean age in years (SD): Group A: 52 (11); Group B: 53 (12) Mean BMI kg/m^2 (SD): Group A: 30 (7); Group B: 29 (6) Postmenopausal: Group A: 53/88; Group B: 58/82 Previous continence surgery: Group A: 5/88; Group B: 10/82 MUI: Group A: 76/88; Group B: 66/82 VLPP: < 60 cm/H_2O: Group A: 14/88; Group B: 16/82
Interventions	Group A: TVT (n = 88) Group B: TOT (n = 82)
Outcomes	Primary outcome: presence or absence of 'abnormal bladder function', a composite outcome defined as the presence of any the following: incontinence symptoms - any type (ISI > 0), a positive cough-stress test, re-treatment for SUI or postoperative urinary retention assessed 1-year after surgery Secondary outcomes: assessed by use of SF12, PISQ-12, bladder diary at 12 and 24 months: • subjective cure (self-reported) • objective cure (negative cough stress test) • mean operating time • bladder perforation • major vascular injury • tape erosion • de novo urgency/UUI • voiding dysfunction • re-operation • QoL: overall improvement in QoL and sexual function scores at follow-up assessments compared with preoperative baseline scores. No difference between the groups. Used PFDI-20, PFIQ-7, PISQ-12 • sexual dysfunction assessed using PISQ-12. Scores improved post operatively and at 12 months follow up in both groups, though the relative change in scores post-operatively was small (1.9%) showing moderate responsiveness to incontinence specific outcome measures. There was no significant difference reported between the two groups.
Notes	Intraoperative cystoscopy performed in both groups Concomitant surgery performed in Group A: 48/88; Group B: 45/82 Loss to follow-up: Group A: 3/88; Group B: 7/82

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "were randomised using computer generated random allocation"
Allocation concealment (selection bias)	Low risk	Quote: "group assignment were concealed in consecutively numbered sealed opaque envelopes"

Barber 2008 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "blinding of surgeon and participants was not possible ..."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "all post op assessments were performed by research nurses who were blinded to treatment given"
Incomplete outcome data (attrition bias) All outcomes	Low risk	All accounted for

Barry 2008

Methods	RCT of TOT (Monarc) versus TVT Random allocation of participants but method of sequence generation and allocation concealment not described
Participants	140 women diagnosed with USI Participants in both groups had similar background characteristics including age, BMI, parity, HRT use, menopausal status, previous incontinence surgery, prolapse etc Inclusion criteria: participants had either failed conservative management for symptomatic stress incontinence or required prophylactic incontinence surgery during prolapse repair for occult stress incontinence (no preoperative subjective complaint of urinary stress leakage but found to have USI) Exclusion criteria: significant voiding dysfunction (maximum urine flow rate < 10th percentile according to Liverpool nomogram and PVR volume > 50 ml); known allergy to polypropylene; immunosuppressant therapy and a past history of neurological disease; urogenital malignancy; fistula or pelvic radiotherapy
Interventions	Group A: TOT (n = 58) Group B: TVT (n = 82)
Outcomes	Outcomes included Immediate- and short-term complications, cure rates and patient satisfaction Primary outcome: reduction in incidence of bladder injury Secondary outcomes: • other intra-operative complications • improvement of symptomatology • incontinence impact • improvement in incontinence episodes and pad usage • objective improvement on UDS: defined as no visible leakage on coughing at the external urethral meatus • postoperative complications, such as sling erosion; • blood loss: surgeon's subjective estimate of blood volume lost • sexual dysfunction via the BFLUTS questionnaire Improvement of a particular symptom denoted at least 50% reduction in frequency of occurrence in 3-day bladder diary when compared to preoperative state Measures used for assessment included:

Barry 2008 *(Continued)*

	• symptomatology (using standardised, validated BFLUTS) • incontinence impact (using standardised, validated short IIQ-7) • 3-day bladder diary findings and pad usage • clinical examination findings (POP-Q ICS) • UDS findings
Notes	23 women from the TVT group and 21 from TOT group were lost to follow-up. Thus, at follow-up complete data set available for 82 women in TVT group and 58 in the TOT group. There were no differences between the group unavailable for analysis when compared to those finally analysed No mention of intraoperative cystoscopy in either group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were blinded and randomly allocated in a balanced way (blocks of 20) Randomisation was stratified according to a history of previous incontinence surgery
Allocation concealment (selection bias)	Unclear risk	Unclear
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were blinded. How this was achieved was not explained
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential loss to follow-up or differential attrition

But 2008

Methods	RCT of TVT-O versus TOT (Monarc)
Participants	120 women with SUI (31) and MUI (89) Inclusion criteria: women with SUI, or MUI, with SUI as the predominant symptom Exclusion criteria: MUI with predominant UUI Performed under local anaesthesia Mean age years (SD): 52.6 (6.8)
Interventions	Group A: TVT-O (n = 60) Group B: TOT (n = 60)
Outcomes	• Objective cure rates: negative pad test • Subjective cure rates: absence of reported SUI • Post operative voiding difficulties

But 2008 *(Continued)*

	• Tape erosion • Duration of operation • Duration and intensity of postoperative pain according to a modified VAS • QoL (UDI) significantly improved post operatively in each group with no significant intergroup difference.
Notes	Follow-up 3 months All women attended for follow-up

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Before the beginning of the study, the computer-generated list of 120 random numbers (from one to 120) was made for two groups (60 random numbers for each group, optimum allocation ratio 1)"
Allocation concealment (selection bias)	Unclear risk	Quote: "the consecutive study numbers were given after admission, and based on this admission number, either inside-out or outside-in procedure was selected later in the OR according to a computer- generated list of random number"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	All data/information accounted for at follow-up

Cervigni 2006

Methods	RCT of TVT versus Monarc TOT
Participants	118 women Inclusion criteria: women with SUI and POP-Q ≥ stage 2 Mean age 57.43 years All women had cystocoele repair and levator myorraphy 73 women were post menopausal
Interventions	Group A: TVT Group B: TOT (exact numbers in each group not reported)
Outcomes	Cure rates: TVT (98.3%), TOT (97.1%) as exact number of women in each group was not given there were no data that could be extracted

Cervigni 2006 *(Continued)*

	Intraoperative and postoperative complications
Notes	Numbers in each group unreported. It was, thus, impossible to abstract results

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Women randomised into 2 groups (computer generated randomisation list)
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Chen 2010

Methods	RCT comparing TVT, TOT and TVT-O
Participants	187 women Inclusion criteria: women with urodynamically proven SUI in the urology department of a Chinese hospital
Interventions	Group A: TVT (n = 77) Group B: TOT (n = 45) Group C: TVT-O (n = 65)
Outcomes	• Objective cure: negative stress test • Mean operative time in minutes • Mean postoperative hospital stay days (SD) • Bladder perforation • Vascular injury • Voiding dysfunction
Notes	No quality of life measures undertaken Cystoscopy performed in TVT group

Risk of bias

Bias	Authors' judgement	Support for judgement

Chen 2010 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	No information
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Chen 2012

Methods	RCT of TVT vs TVT-O Recruitment Feb 2009-Feb 2010
Participants	205 women with SUI Inclusion criteria: women with urodynamically proven SUI with or without prolapse Exclusion criteria: DO; MUI All women had similar background characteristics
Interventions	A: TVT (n = 102) B: TVT-O (n = 103)

Outcomes	Follow-up 12-24 months
	• Objective cure: negative pad test and stress test
	• Objective cure
	• Cure and improvement
	• Operative time
	• Blood loss (ml)
	• Length of stay (days)
	• QoL via questionnaires
	• Adverse effects:
	  ○ Bladder injury
	  ○ Voiding dysfunction
	  ○ Groin pain

Notes	Needs translation for further information Article written in Chinese and translated to English for interpretation and extraction

Risk of bias

Chen 2012 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Stated: 'randomly allocated '
Allocation concealment (selection bias)	Unclear risk	Stated: 'randomized'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Cho 2010

Methods	RCT of Monarc system and TOT system
Participants	93 women having urodynamic evaluation
Interventions	Group A: Monarc TOT (n = 48) Group B: TOT (n = 45)
Outcomes	Outcomes assessed 12 months postoperatively • Subjective cure • Voiding dysfunction • Tape erosion
Notes	Monarc is outside-to-in TOT with open edge polypropylene mesh that contains an absorbable tensioning suture threaded into the length of the mesh. The tension free obturator tape (TOT) system used here is the same outside-in type, but has a closed edge polypropylene mesh without absorbable tensioning suture

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "93 female patients were prospectively, randomly assigned to the study"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias)	Unclear risk	No information

Cho 2010 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Choe 2013

Methods	RCT OF TVT vs TOT
Participants	41 women Inclusion criteria: women with SUI; able to complete a questionnaire Exclusion criteria: prior spine surgery; back pain; scoliosis; traumatic spine injury; neurological disease; or hip or knee surgery
Interventions	41 women, number in each group was not given
Outcomes	Postoperative pain was assessed using a 10-point visual analogue scale (VAS) at fixed time-points: 30 minutes, 3hr and 24hr after surgery Length of procedure (minutes)
Notes	We were not able to use the data provided, as the number in each group was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "were randomized to receive"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Darabi Mahboub 2012

Methods	RCT of TOT versus TVT
Participants	Women with SUI Age in years (SD): Group A: 52.02 (0.88); Group B: 52.27 (7.34)
Interventions	Group A: TOT (n = 40) Group B: TVT (n = 40)
Outcomes	A validated stress and urge incontinence questionnaire 24-h pad test 6-month follow-up of ICIQ Operative time Mean hospital stay
Notes	Intraoperative cystoscopy not mentioned in either group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "In this randomised clinical trial, eighty female patients with SUI were randomly allocated to "
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

David-Montefiore 2006

Methods	RCT comparing TOR and RTR of sling procedures for SUI using the I-STOP device
Participants	Multicentre (3 gynaecology and 2 urology departments in France) 88 women Inclusion criteria: women > 18 years with SUI, proven by clinical and urodynamic examinations, or MUI Exclusion criteria: women with previous history of radio- or chemotherapy; on anticoagulant or antipsychotic treatment; or pregnant

David-Montefiore 2006 *(Continued)*

	Mean age: Group A: 58.8 years; Group B: 53.4 years
Interventions	Group A: RPR (n = 42) Group B: TOR (n = 46) The I-STOP device (CL Medical, Lyon, France) was used for both the RPR and the TOR procedures

Outcomes	• Objective cure (success or improved):
	  ○ participants considered cured (success) if they had no stress incontinence by clinical and urodynamic examinations, no incontinence during the stress provocation test, and no urinary retention or a residual urine volume of < 150 ml
	  ○ participants were considered cured (improved) if no incontinence occurred during stress provocation test. All other cases were considered failures
	• QoL via validated questionnaires: UDI, IIQ at first postoperative visit (4-6 weeks after surgery), and 3, 6, 12, and 24 months postoperatively. Quality of life as measured by UDI and IIQ questionnaires showed significant improvement following both RPR and TOR tape insertion at 1 year. At 4 yr review, there was a reduction in the initial improvement in quality of life.
	• Reported results for within 1 year, though follow-up was at 1, 3, 6 and 12 months and 4 years
	• De novo urgency and urge incontinence

Notes	Loss to follow-up at 4 years: Group A: 8/42; Group B: 9/46 Length of follow-up ranged from 48 months to 61 months (RPR) and 48 months to 63 months (TOR) The mean follow-up was 10 months, with 37 women having 6 months of follow-up and 51 women having at least 12 months of follow-up Cystoscopy was performed for both procedures

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	" ... Prospective randomised Multicentre study .... using a predetermined computer generated randomisation code ..."
Allocation concealment (selection bias)	Low risk	Surgeon informed of allocated procedures by an uninvolved third-party immediately before the operation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear

de Leval 2011

Methods	QRCT of TVT-O vs modified TVT-O

de Leval 2011 *(Continued)*

Participants	175 women Inclusion criteria: women aged 25-85 years with USI; positive stress test with at least a maximum cystometric capacity of 300 ml Exclusion criteria: DO or detrusor acontractility; neurogenic bladder; or POP stage 3 or above Mean age years (SD): Group A: 60.0 (11.7); Group B: 57.2 (2.7) BMI kg/m^2 (SD): Group A: 26.4 (4.8) Group B: 26.8 (5.3) Previous surgery for SUI: Group A: 4/87; B Group: 4/88 Previous surgery for POP: Group A: 4/87; Group B: 2/88
Interventions	Group A: TVT-O (n = 87) Group B: modified TVT-O (n = 88)
Outcomes	At 1 -year follow-up: • objective cure: negative cough test • subjective cure: disappearance of SUI using symptom scoring system • subjective cure and improvement: • Intraoperative complications • de novo urgency • mesh erosion • groin pain At 3-year follow-up: • objective cure: negative cough test • subjective cure
Notes	The modified TVT-O was shortened to a total tape length of 12 cm and had a reduction in the depth of lateral dissection, the obturator membrane was not perforated with the scissors or the guide Follow-up assessments carried out at 1, 6, 12 months, and 3 years Lost to follow-up: • at 1 year: Group A: 3/87; Group B: 2/88 • at 3-year follow-up: Group A: 13/87; Group B: 9/88

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "The randomisation process was performed with five sequential patients undergoing one approach before alternating surgical modality"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Patients were blinded to the type of surgery they underwent

de Leval 2011 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "no patients withdrew from the study prior to their operation". 2 participants were completely lost to follow-up after the 1-month visit and 2 more after the 6-month visit. One patient died before the 6-month visit; the cause of death was unrelated to the surgery

de Tayrac 2004

Methods	RCT comparing TVT with TOT
Participants	61 women Inclusion criteria: USI Exclusion criteria: predominant urge incontinence; urodynamic detrusor instability; or prolapse Mean age (years; SD): Group A: 54.7 (11.9); Group B: 53.6 (12.5) Mean BMI kg/m^2 (SD): Group A: 24 (3.2); Group B: 25.2 (4.3) Postmenopausal status: Group A: 18/30; Group B: 16/31 Previous continence surgery: Group A: 4/30; Group B: 1/31 Previous prolapse surgery: Group A: 4/30; Group B: 1/31 ISD: Group A: 4/30; Group B: 3/31
Interventions	Group: A: TOT (n = 30) Group: B: TVT (n = 31)
Outcomes	• Subjective cure • Objective cure (negative cough stress test) • Objective cure and improvement • Mean operating time • Mean length of hospital stay • Bladder perforation • Vaginal tape erosion • Urethral tape erosion • De novo urgency/UUI • Voiding dysfunction • Sexual dysfunction measured using mean VAS score. No significant difference between the 2 groups in terms of improvement of sexual function
Notes	The full article was retracted at the request of authors because appropriate ethics committee approval was not received prior to starting study. Nevertheless, participants did give written consent to be included in the trial and consented for the procedures. No methodological flaws were identified: the review authors therefore decided to include the data TOT: Uratape mentor-porges Cystoscopy performed following TVT procedure

de Tayrac 2004 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Women were randomised using numbered, opaque sealed envelopes containing computer-generated random allocations in a ratio of 1:1 in balanced blocks of 10. Envelopes were opened in the operating room by a nurse just before starting the procedure
Allocation concealment (selection bias)	Low risk	Adequate
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors were blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Deffieux 2010

Methods	RCT of TVT and TVT-O
Participants	Multicentred RCT, 14 centres in France (university hospitals and 3 general hospitals) 149 women with SUI Inclusion criteria: age >18 years; isolated or mixed USI; indication for surgical treatment of USI; positive cough stress test Exclusion criteria: concomitant POP surgery; concomitant hysterectomy; previous incontinence surgery; pregnancy; anticoagulant therapy; higher than stage 1 urogenital prolapse (POP-Q ICS) All women had similar background characteristics Mean age (years; SD): Group A: 54.6 (10.9); Group B: 52.8 (9.8) Mean BMI kg/m^2 (SD): Group A: 26.3 (4.5); Group B: 26.3 (5.7) Postmenopausal: Group A: 43/75; Group B: 40/74 POP-Q stage 1: Group A: 245/75; Group B: 24/74
Interventions	Group A: TVT (n = 75) Group B: TVT-O (n = 74)
Outcomes	Outcomes assessed at 2, 6, 12 and 24 months • Subjective cure: self-reported via questionnaires • Objective cure: negative cough stress test • Bladder injury

Deffieux 2010 *(Continued)*

	• Major vascular injury • Tape erosion • Voiding dysfunction • Groin/suprapubic pain • Re-operation rates • QoL and sexual function: CONTILIFE questionnaire and use of VAS to determine sexual activity satisfaction and reported dyspareunia
Notes	Cystoscopy performed in both groups Loss to follow-up: at 12 months: Group A: 6/75; Group B: 5/74 Loss to follow-up at 24 months: Group A: 8/75; Group B: 9/74

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The patients were randomized using sealed opaque envelopes, following computer-generated random allocations"
Allocation concealment (selection bias)	Low risk	Quote: "The patients were randomized using sealed opaque envelopes, following computer-generated random allocations, with a ratio of 1:1 in balanced blocks of four. The envelopes were opened just before each participant's surgical procedure"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "blinding of surgeons and participants not possible"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data complete

Diab 2012

Methods	RCT of TOT vs TVT
Participants	70 women with SUI
Interventions	Group A: TOT (n = 31) Group B: TVT (n = 32)
Outcomes	• Cure rates • Voiding dysfunction • De novo urgency • Reoperation rate • Postoperative groin/thigh pain • Impact of incontinence on QoL assessed by I-QoL questionnaire

Diab 2012 *(Continued)*

- Operative time
- Estimated blood loss
- Operative complications
- Retropubic haematoma
- Vaginal tape extrusion

Notes	Mean follow up in months (SD): A: 28 (12.3) and B: 26 (13.6)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "were randomly distributed to two groups"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

El-Hefnawy 2010

Methods	RCT comparing Gynecare TVT ^{R} and Aris TOT^{R} outside-in
Participants	40 women Inclusion criteria: women with urodynamically proven SUI Exclusion criteria: women who reported urgency incontinence as predominant complaint; had pelvic or vaginal surgery within the preceding 6 months; had associated urethral and/or bladder pathology or active UTI; neuropathic bladder; POP > stage 2 (Baden Walker classification) Mean age (years; SD): Group A:47 (5); Group B: 45 (7) Concomitant POP stage 1-2: Group A: 10; Group B: 13 Mean BMI kg/m^2 (SD): Group A: 34 (5); Group B: 32(5)
Interventions	Preliminary results: Group A: TVT: (n = 19) Group B: TOT: (n = 21) At 24 months: Group A: TVT: (n = 45)

El-Hefnawy 2010 *(Continued)*

	Group B: TOT: (n = 42)
Outcomes	Follow-up at 3, 6, 12 and 24 months • Objective cure: negative stress test, 1-h pad test <2g, and no re-treatment for stress incontinence • 12 months negative stress test • 24 months negative stress test • 24 months negative 1hr pad test • Subjective cure: no reported SUI • Mean operative time • Mean blood loss • Vascular injury • Bladder injury • Groin pain (no report of suprapubic pain) • Tape erosion • De novo urgency • QOL measured using UDI-6 and IIQ-7 at baseline, 12 and 24 months
Notes	Intraoperative cystoscopy carried out only in the TVT group to exclude bladder or urethral injury Concomittant surgery was performed in 9 participants; 5 participants underwent abdominal hysterectomy, 4 participants underwent anterior colporrhaphy Lost to follow-up at 12 months: Group A: 0/19; Group B: 0/21 Lost to follow-up at 24 months: Group A: 9/45; Group B: 7/42

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patient's randomisation is accomplished through closed envelopes. A randomly selected envelope is dispatched to a running nurse with the patient's name and ID hand typed on the envelope"
Allocation concealment (selection bias)	Low risk	Quote: "randomisation is accomplished through closed envelopes. A randomly selected envelope is dispatched to a running nurse with the patient's name and ID hand typed on the envelope"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Follow up was carried out by a nurse blinded to the procedure"
Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcomes included

Elbadry 2014

Methods	RCT of adjustable TOT vs TOT

Elbadry 2014 *(Continued)*

Participants	96 women with SUI, with a mean age of 53 + 9.9 years
Interventions	Group A: adjustable TOT (n = 48) Group B: TOT: (n = 48)
Outcomes	• Cure • Mean operative time • Operative blood loss • bladder injury • number of tape ajdustments • Length of hospital stay
Notes	The advantage of the adjustable tape is that it can be adjusted postoperatively to address over- or under-correction

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were randomized into 2 equal groups"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Enzelsberger 2005

Methods	QRCT comparing TVT and TOT
Participants	110 women Inclusion criteria: women with SUI, all had preoperative stress test Exclusion criteria: previous surgery for SUI; mixed incontinence; renal disease; metabolic disorders; or POP Mean age was 51 years
Interventions	Group A: TOT (n = 56) Group B: TVT (n = 54)

Enzelsberger 2005 *(Continued)*

Outcomes	• Operative time • Objective cure rate • Operative complications • Bladder perforation • Voiding dysfunction • Detrusor overactivity • Tape erosion • Groin pain
Notes	No mention of intraoperative cystoscopy Followed-up at 15 months

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quasi-RCT
Allocation concealment (selection bias)	High risk	Inadequate
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Freeman 2011

Methods	RCT comparing TOT and TVT
Participants	Multicentre RCT – 21 centres across the UK 192 women Inclusion criteria: women >21 years of age; USI or MUI for which SUI was the predominant symptom; must have failed with conservative measures Exclusion criteria: women with neurological disease; previous surgery for USI (those with previous prolapse surgery were not excluded); urodynamic DO or low compliance; POP extending beyond the hymen
Interventions	Group A: Monarc TOT (n = 100) Group B: Gynaecare TVT (n = 92)
Outcomes	Follow-up at 4 weeks, 6 months and 12 months

Freeman 2011 *(Continued)*

- Subjective cure: self-reported via response to ICIQ-FLUTS questionnaire:
- Mean operation time
- Operative blood loss
- Bladder perforation
- Vaginal perforation
- Tape erosion
- Voiding dysfunction
- De novo OAB
- Groin pain
- Sexual function: assessed via ICIQ-LUTSqol scores.

Notes	The trial was a non-inferiority design. Outcome measures calculated by intention-to-treat Assessed via ICIQ-FLUTS long form, ICIQ LUTSqol; KHQ questionnaires and 4-day urinary diary Sexual function assessed by ICIQ-LUTSqol question, 'does your urinary problem affect your sex life?' Cystoscopy: not mentioned whether routinely performed in either group Lost to follow-up: Group A: 5/100; Group B: 7/92 (and 1 excluded as she did not have the operation)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "randomisation list was stratified by study sites, using randomly permuted blocks of varying sizes of 4, 6 and 8"
Allocation concealment (selection bias)	Low risk	Quote: "The study co-ordinator placed a treatment into consecutively numbered opaque envelopes which were opened immediately before surgery by someone other than the surgeon. Allocation concealment was therefore ensured"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Patients and ward staff were blinded to the intervention group by ensuring that dressings were applied both suprapubically and to the obturator areas"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	Patients and their data accounted for

Hammoud 2011

Methods	RCT of TVT vs TVT-O
Participants	110 women with SUI
Interventions	Group A: TVT (n = 60)

Hammoud 2011 *(Continued)*

	Group B: TVT-O (n = 50)
Outcomes	Subjective cure:
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "in a prospective randomized trial ... women were randomized between TVT and TVT-O for treatment"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Hassan 2013

Methods	RCT of inside-out TOT vs outside-in TOT
Participants	250 women Inclusion criteria: women with SUI in a university teaching hospital in Cairo, Egypt
Interventions	Group A: inside-out TOT (n = 125) Group B: outside-in TOT (n = 125)
Outcomes	Primary outcomes: • improvement of stress incontinence symptom and signs • intraoperative time • intra- and postoperative complications Secondary outcomes: • recurrence of stress incontinence at 12 months • subjective cure at 12 months • vascular injury/haematoma • groin/thigh pain • tape erosion
Notes	Lost to follow-up: Group A: 23/125; Group B: 28/125

Hassan 2013 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "A prospective single-blinded randomised trial"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Houwert 2009

Methods	RCT of TVT-O and TOT (Monarc)
Participants	191 women Inclusion criteria: women with SUI, USI and MUI. Those with MUI failed anti-cholinergic medical treatment before surgical treatment Exclusion criteria: women with recurrent UTIs; those with predominantly symptoms of UUI; post voiding residuals of > 150 ml and bladder capacity < 100ml There was no concomitant POP surgery Preoperative multichannel urodynamic investigation was carried in all women Mean age (years; SD): Group A: 49.2 (8.9); Group B: 49.5 (10.3) SUI: Group A: 74/93 (80%); Group B: 74 /98 (76%) MUI: Group A: 19/93 (20%); Group B: 23/98 (24%) Postmenopausal: Group A: 33/93; Group B: 34/98 Previous incontinence surgery: Group A: 8/93; Group B: 9/98 Previous POP surgery: Group A: 19/93; Group B: 15/98 Urethral hypermobility: Group A: 80/93; Group B: 90/98 POP ≥ grade 1: Group A: 25/93; Group B: 24/98 ISD: Group A: 5/93; Group B: 1/98 DO: Group A: 5/93; Group B: 7/98
Interventions	Group A: TVT-O (n = 93) Group B: Monarc TOT (n = 98)

Houwert 2009 *(Continued)*

Outcomes	• Cure of SUI: defined as woman stating she did not experience any loss of urine upon physical exercise • QoL measured with validated Dutch short forms of the IIIQ-7 and the UDI-6 • Subjective cure at 12 months (short term): A: 66/86, B: 73/95 • Subjective cure and improvement at 12 months (short term) • Subjective cure at 2-4years (medium term) • Subjective cure and improvement at 2-4years (medium term) • Operating time • Voiding dysfunction at 2 months • Vaginal tape erosion at 12 months • Thigh pain • De novo urgency/UI • Repeat incontinence surgery • QOL: Assessed using IIQ-7 and UDI-6 • Sexual dysfunction
Notes	No concomitant urogynaecological surgery performed Follow-up occurred at 12 months and at 2 -4 years Loss to follow-up at 12 months: Group A: 15/39; Group B: 14/36. Loss to follow-up at 4 years: Group A: 18/93; Group B: 12/98 Cystoscopy was performed only when bloody urine was encountered Analysis of cure used the numbers that completed follow-up as denominator

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Women with an indication for surgical treatment of SUI were at random assigned to either TVT-O or Monarc..."(from abstract Vervest HAM 2005)
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Jakimiuk 2012

Methods	RCT comparing TVT and TVT-O: POLTOS study
Participants	Multicentre RCT in Poland

Jakimiuk 2012 *(Continued)*

	35 women Inclusion criteria: women with urodynamically proven (bladder filled to a minimum of 300 ml) SUI; no prior incontinence surgery Exclusion criteria: women with UTI; BMI > 33 kg/m^2; previous hysterectomy; neurological incontinence; POP; PVR > 150 ml; OAB and MUI Age: 40-80 years
Interventions	Group A: TVT (n = 19) Group B: TVT-O (n = 16)
Outcomes	• Subjective cure: self-reported • Objective cure: negative cough test and pad test • Bladder perforation • Voiding dysfunction • Vascular injury • Mean procedure time • Mean hospital stay • QoL: used non-validated KHQ and validated SF-36 questionnaires.
Notes	Follow-up at 6 months Cystoscopy was performed in both groups Lost to follow-up: Group A: 4/19; Group B: 0/16 (3 participants with bladder perforation had the tape removed and were excluded)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The randomisation was done through a web page secured with a 128-bit code"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "every patient had extra skin incisions for masking the type of procedure ("sham operation"). Each patient had 4 skin incisions in localization typical for needle introduced in TVT and TVT-O procedure"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Information not clear

Juang 2007

Methods	RCT of trans-obturator tension-free vaginal tape (TVT-O) versus TVT-O with modified Ingelman-Sundberg (IS) procedure
Participants	96 women Inclusion criteria: women with MUI after poor response to medical treatment DO at baseline: Group A: 19/43; Group B: 15/49 Post menopausal: Group A: 32/43; Group B: 27/49
Interventions	Group A: TVT-O (n = 47) Group B: TVT-O plus IS: (n = 49)
Outcomes	• Objective cure: defined as 1-h pad test < 2g and complete discontinuation of antimuscarinic medication • Objective improvement: defined as improvement of urine leakage on pad test or decreased dosage of antimuscarinic medication • Blood loss • Operating time • Mean hospital stay • Bladder perforation • Major vascular injury • Tape erosion • Post operative complications • QOL: assessed with IIQ-7 and UDI-6 Follow-up QOL scores: Both IIQ-7 and UDI-6 demonstrated a significant decrease at the 3-months follow-up in the TVT-O plus IS group. Scores remained relatively stable after 3 months of follow-up and until the end of the study.
Notes	The IS bladder denervation procedure is designed to disrupt most of the innervations from the inferior hypogastric plexus to the bladder to treat refractory urgency or urge incontinence (the vaginal epithelium and perivesical fascia were dissected off the trigone. The plane of dissection was just within the serosal layer of the bladder. Lateral and posterior sharp dissection was performed to obtain more extensive division in the area of the terminal branches of the pelvic nerve). Follow-up was at 12-months, but urodynamic profile was repeated at the 3-month follow-up Loss to follow-up: Group A: 2/47; Group B: 1/49

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: “After an objective evaluation, 96 eligible patients were randomised”
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information

Juang 2007 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Kamel 2009

Methods	RCT of TVT vs TVT-O
Participants	120 women Inclusion criteria: women with urodynamically proven SUI and urethral hypermobility Exclusion criteria: not defined
Interventions	A: TVT (n = 60) B: TVT-O (n = 60)
Outcomes	• Objective cure • Bladder perforation • Vascular injury • Mean operative time
Notes	TVT group underwent cystoscopy

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Stated: "randomised"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Karateke 2009

Methods	RCT comparing TVT and TVT-O
Participants	167 women Inclusion criteria: women with urodynamically proven SUI Exclusion criteria: urogenital prolapse > stage 1 (POP-Q); DO; symptoms of OAB; urinary retention; previous anti-incontinence surgery including anterior colporrhaphy and neurological bladder Mean age (years; SD): Group A: 49.31 (5.00); Group B: 49.08 (4.93) Postmenopausal: Group A: 16/83; Group B: 14/84 Mean BMI kg/m^2 (SD): Group A: 25.99 (1.27); Group B: 26.18 (1.88)
Interventions	Group A: TVT (n = 83) Group B: TVT-O (n = 84)
Outcomes	• Subjective cure (very satisfied and satisfied) • Obective cure (negative cough test at cystometry) • Mean operative time • Vascular injury/haematoma • Bladder perforation • Tape erosion • Voiding dysfunction • De novo UI • De novo DO • Mean hospital stay • Time to return to normal activity • QOL: IIQ-7 and UDI 6 questionnaires
Notes	Cystoscopy only performed in TVT group Lost to follow-up: Group A: 2/83; Group B: 1/84

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "predetermined computer-generated randomisation code"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "two independent physicians blinded to the different procedures"
Incomplete outcome data (attrition bias) All outcomes	Low risk	All data included

Kilic 2007

Methods	RCT of TVT vs TOT
Participants	20 women Inclusion criteria: women with SUI confirmed on urodynamics Mean age (years; SD): Group A: 55.8 (13.7); Group B: 60.2 (12.2)
Interventions	Group A: TVT (n = 10) Group B: TOT (n = 10)
Outcomes	• Primary outcome: Subjective cure: improvement of urinary incontinence (after coughing, laughing and during stairs climbing) • Mean operative time
Notes	None lost to follow-up Follow-up assessment at 12 months

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Kim 2004

Methods	RCT comparing the IRIS (Innovative Replacement of Incontinence Surgery) tape with TVT and SPARC procedure
Participants	96 women with SUI were randomised
Interventions	Group A: TVT (n = 32) Group B: SPARC (n = 30) Group C: IRIS (n = 34).

Kim 2004 *(Continued)*

	All 3 groups had comparable background characteristics
Outcomes	• Subjective cure • Objective cure • Operating time • Length of hospital stay • Perioperative complications • Bladder perforation • Voiding dysfunction • De no urgency/urgency urinary incontinence • Vaginal tape erosions
Notes	Follow-up was for 1 year

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "In this controlled, prospective, randomised study ...."
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Kim 2005

Methods	RCT comparing Monarc TOT with SPARC retropubic tape
Participants	130 women Inclusion criteria: women with SUI with similar background characteristics Preoperative assessment included the use of voiding diaries, stress and pad tests, and urodynamics Mean age (years; SD): Group A: 45.7 (9.8); Group B: 45.4 (12.4)
Interventions	Group A: Monarc (TOR; n = 65) Group B: SPARC (RPR; n = 65)
Outcomes	• Subjective and objective cure assessed via questionnaires and UDS respectively • Stress and pad test and uroflowmetry with PVR • Operative time in mins

Kim 2005 *(Continued)*

- Perioperative complications
- Bladder perforation
- Voiding dysfunction
- De no urgency/urgency urinary incontinence
- Vaginal tape erosion
- Bladder erosion

Notes	Follow-up at 3 months. Cystoscopy only in the TVT group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "43 women withUI were randomly assigned..."
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Krofta 2010

Methods	RCT of TVT vs TVT-O
Participants	300 women Inclusion criteria: women with SUI after failed conservative treatment. All confirmed on a positive stress test (cough provocation). Women with symptoms of MUI were included if SUI was the predominant symptom Exclusion criteria: DO; previous incontinence, POP surgery, or pelvic radiotherapy; POP-Q ≥ stage 2; PVR > 100 ml; preoperative use of anticholinergics; need for concomitant surgery Cough provocation test, multichannel UDS, urethral pressure profilometry and uroflometry were done preoperatively and at 12-month follow-up
Interventions	Group A: TVT^{TM} (n = 149) Group B: TVT –O^{TM} (n = 151)
Outcomes	• Objective cure (negative stress cough provocation test with 300 ml of saline in the bladder during UDS and 1-hour pad test weight < 5g) • Subjective cure (self-reported absence of SUI) • Subjective improvement (women's perception of urine loss less than the presurgical loss)

Krofta 2010 *(Continued)*

- De novo urge/urgency urinary incontinence
- Duration of operation
- Mean blood loss
- Haematoma
- Groin/suprapubic pain
- Tape erosion/extrusion
- Quality of life: ICIQ UI- SF and CONTILIFE questionnaires used
- Sexual dysfunction: assessed using PISQ-12

Notes	All women with TVT had intraoperative cystoscopy but this was not performed in those with TVT-O Loss to follow-up: Group A: 8/141; Group B: 4/147

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "women were prospectively, randomly assigned to the study. We used the method of block randomisation with a random-number generator"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "The current randomised, non-blinded study"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All participants were evaluated at follow-up by 3 urogynaecologists, blinded to the different procedures
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "In the TVT group, 141/149 patients returned for a 1-year follow-up (dropout rate of 5.3%), and in the TVT-O group, 147/151 patients were present for the 1-year follow-up (dropout rate of 2.6%)"

Laurikainen 2007

Methods	RCT comparing TVT and TVT-O
Participants	Multicenter study from 7 Finnish hospitals (4 university hospitals and 3 central hospitals) 267 of the 273 patients originally randomized underwent the allocated operation. After randomisation 6 patients dropped out Inclusion criteria: history of SUI; indication for surgical treatment of stress incontinence; positive cough-stress test; detrusor instability score (DIS) ≤ 7 Exclusion criteria: previous incontinence surgery; PVR volume > 100 ml; lower urinary tract anomaly; current (UTI or > 3 UTI episodes within the past year; urogenital prolapse of more than second degree (Baden-Walker); BMI > 35 kg/m^2; previous radiation therapy of the pelvis; active malignancy; anticoagulant therapy; haemophilia; neurogenic disease that can be associated with bladder disorders; anticholinergic medication; duloxetine medication; patient unable to understand the purpose of the trial; patient immobile
Interventions	Group A: TVT-O (n = 131) Group B: TVT (n = 136)

Laurikainen 2007 *(Continued)*

Outcomes	• Objective cure: defined as a negative stress test. • 24 hour pad test • Subjective cure: evaluated by questionnaires through short, medium and long term • Perioperative complications • Mean operating time (minutes) • Length of hospital stay (days) • Time to return to normal activity (weeks) • Operative blood loss (ml) • Major vascular injury • Bladder perforation • De novo urgency/urgency urinary incontinence • Voiding dysfunction • Repeat incontinence surgery • Tape erosion • Groin pain • Tape erosion • QoL questionnaires include: urinary incontinence severity score (UISS), detrusor instability score (DIS), incontinence impact questionnaire - short form (IIQ-7), urogenital distress inventory - short form (UDI-6), EuroQOL-5D questionnaire, Visual analogue scale (VAS-0 to 100)
Notes	Cystoscopy with 70° optic was performed twice during the TVT and once during the TVT-O to detect possible bladder injury Follow-up was for 5 years: • loss to follow-up: at 12 months: Group A: 2/136; Group B: 0/131 • loss to follow-up: at 36 months: Group A: 5/136; Group B: 5/131 • loss to follow-up: at 60 months: Group A: 5/136; Group B: 9/131

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The investigator called an independent randomisation centre to enter the patient participant in the allocated group. Participant were randomized using computer-generated random allocations in a ratio of 1:1 in balanced blocks of 4.
Allocation concealment (selection bias)	Low risk	The investigator called an independent randomisation centre to enter the patient participant in the allocated group. Participant were randomized using computer-generated random allocations in a ratio of 1:1 in balanced blocks of 4.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The 3-year postoperative evaluation was performed by an independent physician or by the operating surgeon together with a study nurse
Incomplete outcome data (attrition bias) All outcomes	Low risk	All data accounted for

Leanza 2009

Methods	RCT of retropubic versus transobturator tension-free incontinence cystocoele treatment (TICT) procedures
Participants	449 women with USI
Interventions	Group A: r-TICT (n = 229; retropubic) Group B: t-TICT (n = 220; transobturator)
Outcomes	• Subjective cure • QoL: using KHQ
Notes	TICT, a retropubic technique developed using a polypropylene T-shaped mesh made up by a central body (positioned under both urethra and bladder) and 2 wings that cross the Retzius (retropubic TICT or r-TICT) and the transobturator foramen (transobturator TICT or t-TICT). The advantage of T-shaped mesh is to give a good support both on the mid-urethral complex (with tapes) and on the whole anterior compartment (with body of mesh). The target consists of treating the functional (incontinence) and the anatomical defect (cystocoele) Average follow-up was 45 months. Loss to follow-up: Group A: 14/229; Group B: 12/220

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: “women with urodynamic stress incontinence were randomly allocated to 2 treatment groups”
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Lee 2007

Methods	RCT of TVT versus TVT-O
Participants	120 women Inclusion criteria: women with USI Exclusion criteria: predominant urge incontinence or POP

Lee 2007 *(Continued)*

	Women had similar characteristics with regard to age, parity, incontinence symptoms and menopausal status
Interventions	Group A: TVT (n = 60) Group B: TVT-O (n = 60)
Outcomes	• Duration of operation • Intraoperative blood loss • Postoperative pain • Patient satisfaction • Operative complications • Cure: defined as no SUI symptoms and a negative cough-stress test. Participants were considered to have improved if they had no leakage on the cough-stress test but may have had occasional urine leakage during stress. However, this occasional leakage did not influence daily activities or require any further treatment. Participants who did not meet these criteria treatment were considered to have failed Follow-up was for 12 months
Notes	Cystoscopy was performed only in the TVT group Mean follow-up 13 months

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Patients were alternately assigned to the TVT or TVT-O group" (Randomisation was by alternation method)
Allocation concealment (selection bias)	High risk	Not concealed
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Lee 2008

Methods	QRCT comparing the efficacy and safety of TVT-O and TOT (TOT, Dow Medics, Korea)
Participants	100 women Inclusion criteria: women with USI Exclusion criteria: predominant urge incontinence or POP

Lee 2008 *(Continued)*

	Preoperative work-up included a medical history, physical examination, urinalysis, urodynamic evaluation, and I-QOL questionnaire
Interventions	Group A: TVT-O (n = 50) Group B: TOT (n = 50)
Outcomes	Surgical outcomes were evaluated by the cough-stress test and symptom questionnaire and scored as cured, improved, or failed. Participants were considered 'cured' of SUI if they had a negative cough-stress test result and there were no reports of urine leakage during stress. Participants were considered 'improved' if they did not leak on the cough-stress test but may have had occasional urine leakage during stress; this occasional leakage did not influence their daily activities or require further treatment. Participants who did not meet these criteria were considered to have 'failed' treatment
Notes	Surgical outcomes in the 2 groups were compared about 1 year after surgery. TOT, Dow Medics, Korea = woven monofilament polypropylene mesh

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	100 women with SUI were alternately assigned
Allocation concealment (selection bias)	High risk	Quasi-randomised study with no mention of allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Liapis 2006

Methods	RCT comparing TVT and TVT-O
Participants	89 women Inclusion criteria: women with confirmed SUI without DO Exclusion criteria: DO; other gynaecological disease requiring hysterectomy; other gynaecologic operation; failed surgical treatment for incontinence Mean age (years): Group A: 53; Group B 52 Post menopausal: Group A: 22/46; Group B: 26/43
Interventions	Group A: TVT (n = 46)

Liapis 2006 *(Continued)*

	Group B: TVT-O (n = 43)
Outcomes	Participants assessed by means of voiding diaries, pad test, negative cough-stress test at UDS, unvalidated symptom questionnaire • Objective cure: negative cough-stress test during multichannel UDS study, and 1-h pad test with a weight of <1g • Objective improvement: negative cough-stress test during multichannel UDS study, and 1-h pad test with a weight of <5g • Failure: defined as positive cough-stress test during multichannel UDS study, and 1-hr pad test with a weight of >5g Subjective cure and failure determined by direct questions using an unvalidated questionnaire Follow-up 12 months
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "... All patients were randomly assigned to an operation from the outpatient department ..."
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential loss to follow-up or differential attrition

Liapis 2008

Methods	RCT comparing Monarc TOT and TVT-O
Participants	120 women were randomised Inclusion criteria: women with USI without DO Exclusion criteria: preoperative maximum urethral closure pressure < 20 cm water; urodynamic findings of DO; previous operation of the anterior vaginal wall or prolapse > stage 1 according to the ICS classification
Interventions	Group A: TVT-O (n = 61) Group B: Monarc TOT (n = 53)

Liapis 2008 *(Continued)*

Outcomes	• Objective cure: defined as a negative cough-stress test during multichannel urodynamic examination and a 1-hr pad test giving a weight of <1g • Objective improvement: defined as a negative cough-stress test and a 1-hr pad test weight of <5g • Failure: defined as a positive cough-stress test and urine leakage >5g in the 1-hr pad test • Subjective cure, improvement, and failure were assessed with the use of a simple questionnaire administered by a blinded outcome assessor
Notes	Both groups had perioperative cystoscopy. Groin or thigh pain was resolved with simple analgesics within 1 week to 4 months Follow-up was 12 months. 6 lost to follow-up leaving a total of 114 women

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomly allocated on an alternative fashion to one or another operation."
Allocation concealment (selection bias)	Unclear risk	Unclear
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential loss to follow-up or differential attrition

Lim 2005

Methods	RCT comparing TVT with IVS and SPARC
Participants	195 women Inclusion criteria: women with USI were randomly allocated to suburethral slingoplasty with either TVT, IVS or SPARC. Exclusion criteria: women with a past history of urogenital malignancy, fistula or pelvic radiotherapy At 6-12 weeks follow-up, 4, 5 and 4 women from the TVT, IVS and SPARC groups, respectively, were excluded from statistical analysis because of incomplete or missing hospital charts
Interventions	Group A: TVT (n = 61) Group B: IVS (n = 60) Group C: SPARC (n = 61)
Outcomes	• Objective cure based on UDS • Subjective cure

Lim 2005 *(Continued)*

	• Postoperative morbidity
Notes	Group A: 4 patients; Group B: 5 patients; and Group C: 4 patients were excluded from the analysis due to incomplete or missing data. Those with missing records, those lost to follow-up and those who failed to have postoperative UDS were assumed to be failures in the assessment of objective cure. Occult cases were excluded from subjective cure rates Follow-up initially for 12 weeks and results reported, a follow-on study reviewed the incidence of erosion and tape infections

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "...195 consenting patients with urodynamic stress incontinence (USI) were randomly allocated in a balanced way (three groups of 65 patients each)..."
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: " ... and the patients were blinded to the type of slings being implanted ..." No description of how this was achieved.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear

Lord 2006

Methods	RCT comparing TVT with SPARC sling
Participants	301 women Inclusion criteria: women presenting with SUI whether or not they had had previous incontinence or other pelvic surgery, or both Exclusion criteria: < 18 years old; pregnant; had a major voiding dysfunction specified as an abnormal flow (i.e. maximum urinary flow rate < 10 ml/s) or residual urinary volume of > 150 ml 254 women had UDS and USI diagnosed MUI: 47 women
Interventions	Group A: TVT (n = 147) Group B: SPARC (n = 154)
Outcomes	Primary outcome:

Lord 2006 *(Continued)*

	bladder perforation Secondary outcomes: • blood loss • voiding difficulty • urgency • cure of SUI symptoms at 6 weeks after surgery The subjective assessments of cure were the participants' reported use of protection, their perceptions of the severity of their SUI symptoms and a scale of improvement (1 to 100). The objective definition of cure was the observed absence of urinary leakage when the participant coughed while supine and with a comfortably full bladder Follow-up was 6 weeks
Notes	The women and the outcome assessors were blinded, but no clear description was provided for how this was achieved

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were stratified based on previous UI surgery (yes, no) and the experience of the surgeon (consultant, registrar) and allocated to either TVT or SPARC using computer-generated random numbers. The biostatistician generated the random allocations, which were sealed in opaque, sequentially numbered envelopes. The surgeons recruited participants and accessed the allocations by a telephone call to a third party. Varying block sizes of 4, 6 and 8 were used within each stratum to preclude prediction of allocation by the surgeons
Allocation concealment (selection bias)	Low risk	Concealed
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "The analyst was unaware of the treatment allocation, but it was obviously not possible to ensure that the surgeons were unaware of treatment, although the patients were unable to detect, from their incisions, which sling they had received"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The analyst was unaware of the treatment allocation, but it was obviously not possible to ensure that the surgeons were unaware of treatment, although the patients were unable to detect, from their incisions, which sling they had received"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential loss to follow-up or differential attrition

Mansoor 2003

Methods	RCT comparing TVT-O and TVT
Participants	102 women with SUI with or without POP Preoperative urodynamics carried out
Interventions	Group A: TVT-O (n = 48)

Mansoor 2003 *(Continued)*

	Group B: TVT (n = 54)
Outcomes	• Subjective cure rate • Objective cure rate • Complications
Notes	Follow-up 6 months

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A prospectively randomised and comparative study....."
Allocation concealment (selection bias)	Low risk	Quote:"...technique was randomly drawn using blinded envelopes containing the same no of ..."
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Mehdiyev 2010

Methods	RCT of TVT vs TOT
Participants	32 women with SUI
Interventions	A: TOT (n = 17) B: TVT (n = 15)
Outcomes	Subjective cure Bladder Injury Major vascular injury: De novo UUI Mean operative time
Notes	I-QoL questionnaire was used

Risk of bias

Bias	Authors' judgement	Support for judgement

Mehdiyev 2010 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomised for TOT and TVT operations"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Meschia 2006

Methods	RCT of TVT compared with IVS
Participants	190 women randomised with 11 lost to follow-up, thus 179 available for analysis at 2-year follow-up. The 2 groups were no different in terms of age, parity, BMI, previous hysterectomy, or presence of OAB symptoms Inclusion criteria: women with urodynamically proven SUI and urethral hypermobility Exclusion criteria: previous anti-incontinence surgery; vaginal prolapse requiring treatment; coexisting pelvic pathology; known bleeding diathesis or current anticoagulant therapy; DO; and urethral hypomobility (Q-tip <20° from the horizontal with straining)
Interventions	Group A: TVT (n = 92) Group B: IVS (n = 87)
Outcomes	Primary outcome: success rate Secondary outcome measure: complication rate The outcome of surgical treatment was estimated both subjectively and objectively. Objective cure was defined as no leakage of urine while performing the cough provocation test, with at least 300 ml of saline in the bladder and as a pad weight gain < 1g during the 1-h test. Test-retest reliability of the cough test and 1-hr pad test have been previously demonstrated. Subjective cure was defined as no urine loss during 'stress' and failure as any reported leakage of urine during exertion
Notes	IVS = multifilament threads with smaller pores with insertion similar to TVT

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "...a prospective randomised multicenter trial ... were randomly assigned to treatments according to a centralized computer-generated random list.... Researchers randomly assigned participants by a telephone system to 1 of the treatment groups"

Meschia 2006 *(Continued)*

Allocation concealment (selection bias)	Low risk	Concealed
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Meschia 2007

Methods	RCT of TVT versus TVT-O
Participants	Inclusion criteria: women with urodynamic SUI and urethral hypermobility Exclusion criteria: previous anti-incontinence surgery; vaginal prolapse requiring treatment; coexisting pelvic pathology; known bleeding diathesis or current anticoagulant therapy; DO and urethral hypomobility (Q-tip <20° from the horizontal with straining)
Interventions	206 women randomised, but 25 lost to follow-up Group A: TVT (n = 114) Group B: TVT-O (n = 117)
Outcomes	Primary outcome: success rate Secondary outcome: complication rate Outcome of surgical treatment was estimated both subjectively and objectively. Objective cure was defined as no leakage of urine whilst performing the cough provocation test. Subjective cure was defined as no urine loss during 'stress', and failure as any reported leakage of urine during exertion ICIQ-SF, Women Irritative Prostate Symptoms Score (W-IPSS), PGI-S and PGI-I questionnaires were used to evaluate the impact of incontinence and voiding dysfunction on QoL, and to measure the participant's perception of incontinence severity and improvement
Notes	Median follow-up time was 6 months 6 women from Group A and 7 from Group B were lost to follow-up without outcome data; reasons for loss to follow-up not explored Cystoscopy was performed in all cases of TVT and 50% of cases of TVT-O

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Women with SUI and urethral hypermobility were randomised to treatments according to a centralised computer-generated random list. Researchers randomised participants by a telephone system to one of the treatment groups

Meschia 2007 *(Continued)*

Allocation concealment (selection bias)	Low risk	Concealed
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential loss to follow-up or differential attrition

Naumann 2006

Methods	RCT of classic TVT tape by Gynecare compared with LIFT by Cousin Biotech, with the distinctive feature of a suburethral pad (assumed to be inserted as classic TVT)
Participants	254 women with SUI
Interventions	Group A: TVT (n = 123) Group B: LIFT (n = 125)
Outcomes	• Subjective cure or improvement: assessed with VAS • Subjective evaluation of QoL • Objective cure: evaluation of preoperative and postoperative urodynamic measurements, or results of a pad or clinical stress test • Subjective cure, 6 months and 12 months • Subjective cure or improvement, 6 months and 12 months • Bladder perforation • Excess bleeding • Need for division of tape • Tape erosion into bladder or urethra • Vaginal mesh erosion
Notes	Follow-up 12 months LIFT is a woven monofilament polypropylene tape that can be passed through the transobturator and also the retropubic routes The study seemed to compare the 2 tapes (TVT and LIFT), which have similar characteristics and were both passed through the retropubic routes

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "..an open, prospective, randomised, multicentric study". How sequence generation was achieved not mentioned

Naumann 2006 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Nerli 2009

Methods	QRCT of TVT vs TOT
Participants	Inclusion criteria: women > 18 years; with SUI or MUI if SUI is the predominant symptom; women with ISD Exclusion criteria: predominant urge incontinence; UTI; malignancy; pregnancy; POP stage 3 or 4 Mean age (years; SD): Group A: 39.5 (1.95); Group B: 50.2 (1.89) Post menopausal status: Group A 8/18; Group B: 6/18
Interventions	Group A: TVT (n = 18) Group B: TOT (n = 18)
Outcomes	• Objective cure: negative cough stress test • Subjective cure: self-reported absence of SUI • Improved: persistence of SUI not affecting daily activity or requiring further treatment plus negative cough test • Mean operative time • Mean operative blood loss • Voiding dysfunction • Bladder perforation • De novo urge incontinence • Tape erosion • Days to return to normal activity
Notes	Cystoscopy performed only in the TVT group I-QOL questionnaire assessed at 12 month F/U: significant improvement in I-QOL total scores in both groups from the pre-operative baseline scores.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Nerli 2009 *(Continued)*

Random sequence generation (selection bias)	High risk	Allocation of participants by alternation (quasi randomised)
Allocation concealment (selection bias)	High risk	Allocation not concealed
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Nyyssonen 2014

Methods	RCT of TVT (Gynecare) vs TOT ('outside-in' Monarc)
Participants	100 women Inclusion criteria: women with SUI or MUI with a predominant stress component, after failed conservative treatment Exclusion criteria: urge incontinence; previous mini invasive operation for SUI and the need for another concomitant surgical procedure SUI diagnosed with a positive cough test Urodynamic testing was only done in 5 patients (10%) Pure SUI: Group A: 38/50; Group B: 30/50 Preoperative characteristics similar between groups
Interventions	Group A: TOT (n = 50) Group B: TVT (n = 50)

Outcomes	• Subjective cure at 14 and 46 months: success defined as a postoperative UISS < 8 and failure as ≥ 8
	  ○ At 14 months
	  ○ At 46 months
	• Vaginal tape erosion
	• Voiding dysfunction
	• De novo UUI
	Follow-up at 3, 14 and 46 months
	Cough stress test was performed.
	Subjective cure and patient satisfaction recorded with aid of UISS and Detrusor Instability Score questionnaires with a specific question about satisfaction

Notes	Cystoscopy only performed in the TVT group

Nyyssonen 2014 *(Continued)*

	Number available for follow-up assessments: 14 months: Group A: 43/50; Group B: 43/50 At 46 months: Group A: 46/50; Group B: 47/50

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "This prospective randomized study included ... 100 patients were randomized either to the TVT or to the TOT"
Allocation concealment (selection bias)	Low risk	Quote: "randomization was performed with sealed and numbered envelopes"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	No evidence suggestive of attrition bias

Okulu 2013

Methods	RCT of Vypro mesh (Ethicon, USA) vs Ultrapro mesh (Ethicon) vs Prolene light mesh (condensed monofilament non-absorbable polypropylene)
Participants	144 women with SUI in Turkey Inclusion criteria: previous incontinence surgery or hysterectomy; SUI or USI; positive stress test Exclusion criteria: urodynamically MUI and DO; ≥ 100 ml PVR; contraindication to anaesthesia; POP; pregnancy; neurogenic bladder; bladder outlet obstructions; urinary fistula; or active urinary or vaginal infection Mean age (years; SD): Group A: 50.06 (9.2); Group B: 50.9 (8.8); Group C: 48.1 (7.9) Mean BMI kg/m^2 (SD): Group A: 27.8 (3.4); Group B: 27.9 (4.1); Group C: 27.7 (2.9) Post menopausal: Group A: 10/48; Group B: 11/48; Group C: 8/48 Previous incontinence surgery: Group A: 4/48; Group B: 5/48; Group C:4/48
Interventions	Group A: Vypro mesh: (n = 48; multifilament) Group B: Ultrapro mesh: (n = 48; monofilament + biological combined mesh) Group C: Prolene light mesh: (n = 48; monofilament)
Outcomes	Primary outcome: urinary continence rates at 4-year follow-up Secondary outcomes assessed at 4-year follow-up:

Okulu 2013 *(Continued)*

- urinary retention
- suture granuloma rates at 4 years.
- cure defined as no need for pad use or pad weight of < 2g on 24-hr pad test
  - Subjective cure at 12 months
  - Subjective cure at 48 months
- bladder perforation
- major vascular visceral injury
- de novo urgency
- tape erosion
- mean 24hr pad weight at 12 months and 48 months
- QOL: ICIQ-SF questionnaire at pre-op, 12 months follow up and 48 months follow up.

Notes	Follow-up at 6, 12, 24 and 48 months Loss to follow-up Group A: 2/48; Group B: 0/48; Group C: 1/48 QoL and incontinence was evaluated with the ICIQ-SF

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: “The patients and the mesh materials were randomised 1:1:1 to each group in blocks of three via a centralized computerized system to ensure a good balance of participant characteristics in each group."
Allocation concealment (selection bias)	Low risk	Quote: “via a centralized computerized system to ensure a good balance of participant characteristics in each group”
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Oliveira 2006

Methods	RCT of TVT-O and TVT
Participants	45 women Inclusion criteria: women with SUI with and without ISD Exclusion criteria: women with stage 2 or more POP, women with ISD Mean age of 53.9 years Participants had preoperative UDS diagnosis

Oliveira 2006 *(Continued)*

Interventions	Group A: TVT (n = 17) Group B: TVT-O (n = 28)
Outcomes	• Objective cure by UDS: negative stress test at UDS and pad testing • Complications
Notes	Follow-up 12 months

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "...women with SUI were randomly assigned ..."
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Palomba 2008

Methods	RCT of TOT + mesh repair of POP vs TVT + mesh repair of POP
Participants	Inclusion criteria: 15 women with cystocoele and SUI with urethral hypermobility Exclusion criteria: BMI > 30 kg/m^2; previous incontinence surgery and detrusor instability and/or intrinsic sphincter dysfunction
Interventions	Group A: TOT + mesh repair of POP Group B: TVT + mesh repair of POP
Outcomes	Trial terminated due to poor recruitment, no results published
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Stated: "randomised"

Palomba 2008 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Paparella 2010

Methods	RCT of synthetic UretexTO® vs biological PelviLaceTO® outside-inside TOT
Participants	Inclusion criteria: women with SUI and USI; SUI with urethro-vesical junction hypermobility without ISD Exclusion criteria: POP > stage 1; previous urogynaecological or anti-incontinence surgery; concurrent diseases such as psychiatric disease, diabetes, peripheral vascular disease; history of pelvic radiation; urge and mixed incontinence; DO; urgency or neurologic bladder; maximum urethral closure pressure < 20 cm H_2O and VLPP < 60 cm H_2O (indicators of intrinsic sphincter deficiency); maximum flow ≤ 12 ml/s; and PVR volume ≥ 100 ml Mean age (years; SD): Group A: 60.7 (7.1); Group B: 59.4 (8.4) Mean BMI kg/m² (SD): Group A: 25.4 (1.8); Group B: 24.9 (1.8) Menopausal: Group A: 26/34; Group B: 30/36 (participants in menopause were subjected to at least 1 month of local hormone replacement therapy both before and after the surgery) QoL and sexual impact measured via: KHQ and PISQ-12
Interventions	Group A: synthetic UretexTO® (n = 34) Group B: biological PelviLaceTO® (n-36)
Outcomes	• Objective cure of incontinence was defined as the absence of SUI, with a negative cough stress test; objective improvement as the improvement of SUI, with a positive cough stress test at a higher bladder filling than in the preoperative test; in all other cases it was considered a failure. • Subjective cure rates were self-evaluated by the participants as 'very satisfied', 'satisfied', or 'not satisfied'. • Mean operating time • Mean length of hospital stay days • Perioperative complications • Major vascular injury • Voiding dysfunction • Tape erosion • QoL: assessed with KHQ • PISQ-12 scores pre-operatively and at 2 years follow up.

Paparella 2010 *(Continued)*

Notes	Group A: synthetic (UretexTO®; Bard, Covington, GA) is self-anchoring transobturator suburethral sling (1.2 cm wide and 45 cm long) made of the same monofilament polypropylene fibres used in many modern tension-free sling devices (for example TVT, TVT-O, TOT Monarc, TOT ARIS etc). Polypropylene is a very biocompatible material that has been used for many years in the construction of medical-grade synthetic meshes. The important difference is how the polypropylene fibres are knitted to form a cohesive macroporous mesh Group B: biological material (PelviLaceTO®; Bard, Covington, GA) is a tension-free and self-anchoring transobturator suburethral sling (1.5 cm wide and 40 cm long). It consists of a porcine dermal collagen implant that is intended to provide a matrix for the incorporation of new tissue, cells and blood vessels, thanks to a natural porosity and artificial V-shaped holes along the arms. Its collagen matrix consists of 3 amino acid chains arranged in a triple helix that has been cross-linked with hexamethylenediisocyanate to improve durability making the collagen non-resorbable by the collagenase (enzymes produced by inflammatory cells and fibroblasts that increase during surgery). It is also described as an acellular and deproteinised material so it should not cause an immune response Follow-up evaluation was carried out after 6 weeks, 6 months, 1, and 2 years 2-year follow-up: Group A: 16.6 (3.0); Group B: 17.2 (3.0) Loss to follow-up: Group A: 1/34; Group B: 0/36

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: “Randomization was done using sealed opaque envelopes containing computer-generated random allocations in a ratio of 2:2 in balanced blocks of 4”
Allocation concealment (selection bias)	Low risk	Quote: “Randomization was done using sealed opaque envelopes containing computer-generated random allocations in a ratio of 2:2 in balanced blocks of 4”
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: “Follow-up evaluation was carried out after 6 weeks, 6 months, 1, and 2 years (and/or earlier if problems were experienced) for all patients by two independent physicians”
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: “All patients in both arms completed the follow-up (2 years)”

Park 2012

Methods	Pseudo RCT of TVT-O vs TOT (Monarc)
Participants	74 women Inclusion criteria: women with SUI including those with MUI Exclusion criteria: neurogenic bladder; POP; suspected ISD; or a past history of radical pelvic surgery Mean age (years): Group A: 54.4 (10.13); Group B: 55.1 (10.63)

Park 2012 *(Continued)*

	Mean BMI kg/m^2: Group A: 28.9 (0.53); Group B: 25.9 (0.48) Urgency/UUI: Group A: 25/39; Group B: 22/35
Interventions	Group A: TVT-O (n = 39) Group B: TOT Monarc (n = 35)
Outcomes	Cure was defined as the absence of any episodes of involuntary urine leakage during stressful activities and a stress test. Improvement was defined as a significant reduction in urine leakage, such that it did not require further treatment • Objective cure at 12 months and 3 years • Subjective cure at 12 months and 3 years • Subjective cure & improvement at 1yr and 3 years • Voiding dysfunction • Bladder and urethral perforation • Groin pain • Post operative dyspareunia
Notes	Cystoscopy was performed in all women

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: “were included in this randomised, prospective, observational study”
Allocation concealment (selection bias)	High risk	Quote: "The procedure was performed by a single surgeon, and patients underwent one of the two techniques in accordance with the scheduling order (MONARC and TVT-O), in alternation"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	All accounted for

Peattie 2006

Methods	RCT TVT-O vs Monarc TOT
Participants	Inclusion criteria: women having a primary continence procedure without other surgery; diagnosis of USI; completed course of physiotherapy; completed family Exclusion criteria: previous continence or prolapse surgery; neurological disease; pregnancy; UTI or vaginal infection; DO; voiding problem; anticoagulant use

Peattie 2006 *(Continued)*

Interventions	Group A: TVT-O Group B: TOT
Outcomes	Primary outcomes: objective and subjective cure of USI Secondary outcomes: • operating time • blood loss • complications • pain • catheter use postoperatively • voiding
Notes	Note: trial started recruitment 2006 but no evidence of current status i.e. completed or recruitment stopped or abandoned. No data published

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "patient allocation by random numbers with blocking"
Allocation concealment (selection bias)	Low risk	Quote: "patient allocation by random numbers with blocking"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information.

Porena 2007

Methods	RCT of TVT versus TOT
Participants	145 women Inclusion criteria: women with stress or MUI (stress component clinically predominant) associated with urethral hypermobility (ICS definitions) Exclusion criteria: previous anti-incontinence surgery and POP > stage 1, according to the Half-Way system and POP-Q system classification, in any vaginal compartment With the exception of DO, which was significantly more common in the TOT group, no significant intergroup differences emerged with regard to surgical histories, SUI grade, frequency of mixed incontinence, preoperative voiding or storage symptoms and preoperative urodynamic parameters

Porena 2007 *(Continued)*

	VLPP determined at a bladder volume of 200 mL and participants performed several Valsalva manoeuvers with a gradual increase in abdominal pressure. Participants stratified by VLPP > 60 cm H_2O or VLPP ≤ 60 cm H_2O VLPP ≤ 60 cm H_2O (ISD): Group A: 25/70; Group B: 25/75 Mean age (years; SD): Group A: 61.8 (10.7); Group B: 60.6 (10) Postmenopausal: Group A: 61/70; Group B: 64/75 SUI: Group A: 42/70; Group B: 41/75 MUI: Group A: 28/70; Group B: 34/75 DO: Group A: 4/70; Group B: 14/75
Interventions	Group A: TVT (n = 70) Group B: TOT (n = 75)
Outcomes	Primary outcomes: • objective cure: participants were classified in 2 categories: 'dry' (no leakage during clinical examination and/or stress test and/or reported by participants) vs 'wet'. Wet participants were then sub-divided into 'improved' (> 50% reduction in incontinence episodes) or 'failure' • operating time • intra- and postoperative complications including bladder injury, vaginal penetration and major vascular injury Secondary outcomes: • postoperative lower urinary tract dysfunctions including voiding dysfunction • subjective and objective changes in SUI • tape erosion All participants completed 2 validated questionnaires on QoL, the UDI-6 and the IIQ-7 before surgery, at 3, 6, 12 months postoperatively and then annually Patient satisfaction outcome was measured via a VAS scale Objective cure (dry) Objective cure and improved (dry + wet but improved) Subjective cure (dry) Subjective cure and improved(dry + wet but improved) Bladder injury Vaginal perforation Major vascular injury Voiding Dysfunction Tape erosion Long-term follow-up (> 6 years, mean 99 ± 19 months): 83 participants (45 TOT; 38 TVT) underwent a telephone interview in October 2012.
Notes	TVT™ (Gynecare; Ethicon, Somerville, NJ, USA)

Porena 2007 *(Continued)*

	TOT™ was a fusion-welded, non woven, non knitted polypropylene tape (Obtapej; Mentor-Porges, Le Plessis-Robinson, France) All participants underwent a preoperative urodynamic assessment and intraoperative cystoscopy Follow-up was at 3, 6, and 12 months postoperatively, and then annually Lower urinary tract dysfunctions and continence status were measured at each follow-up visit by a blinded assessor The overall median follow-up was 35 months

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "prospectively randomized by a predetermined computer-generated randomization code, to the retropubic approach (TVT) or the transobturator route (TOT)"
Allocation concealment (selection bias)	Low risk	Quote: " Randomization was done using sealed, opaque, numbered envelopes, which contained the randomized allocation"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "No patient was lost during follow-up"

Rechberger 2003

Methods	RCT comparing TVT and IVS
Participants	100 women Inclusion criteria: women with USI without concomitant pelvic pathology requiring surgery, some had had anti-incontinence surgery previously Exclusion criteria: ISD
Interventions	Group A: TVT (n = 50) Group B: IVS (n = 50)
Outcomes	• Cure rates • Operative and postoperative complications Participants were considered totally cured when free of all SUI symptoms, and cough tests in supine and standing positions were negative. The operation was noted as a failure if the participant still reported urine leakage during increases in intra-abdominal pressure, the cough test with a comfortably full bladder was positive, and the woman had to change her pads because of being wet during the day

Rechberger 2003 *(Continued)*

	In the improvement group the cough test was negative but participants still experienced stress urinary leakage (much less frequent than previously) and the pads were occasionally wet Postoperative UDS was not performed
Notes	Median follow-up of 13.5 months (range 4 to 18 months)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear
Allocation concealment (selection bias)	Unclear risk	Simple randomisation was used from pseudo-random numbers (pseudo-random number means that the participants were operated on by the TVT or the IVS method in a ratio of 1:1). Generated by computer in order to allocate participant to the monofilament or the multifilament group. Investigator KR was not involved in surgical procedure but was responsible for proper randomisation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear

Rechberger 2009

Methods	RCT of retropubic IVS-02 vs transobturator IVS-04, multifilament type 3 tape
Participants	Inclusion criteria: women with SUI with a positive cough provocation test Exclusion criteria: presence of uterine myoma; ovarian cyst; or advanced uterine or vaginal prolapse (POP-Q scale > grade 1) Mean age (years; SD): Group A: 55.56 (10.19); Group B: 55.75 (11.29) Postmenopausal: Group A: 119/269; Group B: 125/268 VLPP: leak pressure during Valsalva manoeuvre was measured. VLPP was determined at 180 ml of bladder filling. ISD was defined as VLPP of ≤ 60 cm H_2O ISD: Group A: 45/269; Group B: 40/268
Interventions	Group A: retropubic (IVS-02; n = 269) Group B: transobturator (IVS-04; n = 268)

Rechberger 2009 *(Continued)*

Outcomes	• Subjective cure • Subjective improvement • Mean operating time • Bladder perforation • Major vascular injury • De novo urgency/UI • Voiding dysfunction • Vaginal tape erosion
Notes	The follow-up visits were at 1, 4, 6, 12, and 18 months Cystoscopy only performed in the retropubic group Loss to follow-up: Group A: 68/269; Group B: 71/268

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: “Simple randomisation was used from pseudorandom numbers generated by a computer to allocate patients into the IVS-02 group or the IVS-04 group”
Allocation concealment (selection bias)	Unclear risk	Investigators Jankiewicz and Futyma were not involved in the surgical procedures, but they were responsible for the randomisation process
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "the surgeon was aware of the procedure being used”
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote:"Only investigators Jankiewicz and Futyma were involved in the follow-up process, and they were blinded with regard to the treatment procedure used"
Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcome data accounted for and the equivalent no of women were lost to follow-up in the 2 groups

Rechberger 2011

Methods	RCT of standard TOT vs TOT with 2-point tape fixation sutures to prevent tape displacement
Participants	463 women Inclusion criteria: women with urodynamically proven SUI, Including women with ISD Exclusion criteria: OAB, MUI Mean age (years; SD): Group A: 55.8 (11.3); Group B: 54.8 (9.8) Mean BMI kg/m^2 (SD): Group A: 28.9 (6.7); Group B: 28.2 (3.8) ISD: Group A: 41/232; Group B: 42/231
Interventions	Group A: TOT (n = 232)

Rechberger 2011 *(Continued)*

	Group B: TOT with fixation (n = 231)
Outcomes	• Cured: self-reported subjective cure plus negative pad test plus negative cough stress test • Improved: negative cough stress test, negative pad test, but occasional symptoms persisting • Subjective cure and improvement • Objective cure • Bladder perforation • ISD cohort: Objective cure
Notes	Both tapes were monofilament Lost to follow-up: Group A: 19/232; Group B: 26/231

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were randomly allocated to 2 groups"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Richter 2010

Methods	RCT: multi-centre randomised equivalence trial conducted in the USA
Participants	597 women Inclusion criteria: age >21 years; predominant SUI for >3 months (urgency UI allowed); positive urinary stress test; bladder volume >300 ml Exclusion criteria: not defined Baseline characteristics similar between groups Mean age (years; SD): Group A: 52.7 (10.5); Group B: 53.1 (11.5) Previous incontinence surgery: Group A: 38/297; Group B: 41/298 Previous prolapse surgery: Group A: 13/297; Group B: 10/298 Postmenopausal: Group A: 209/297; Group B: 206/298 BMI kg/m^2: Group A: 30.6; Group B: 30

Richter 2010 *(Continued)*

	HRT: Group A: 81/297; Group B: 90/298 Concomitant pelvic surgery: Group A: 73/298; Group B: 78/299
Interventions	Group A: retropubic sling (TVT; n = 298) Group B: transobturator tapes (TVT-O, and TOT Monarc; n = 299) (Group C (?): TVT-O (inside-out) - separate data not provided) (Group D (?): TOT (Monarch, outside-in) - separate data not provided)
Outcomes	Composite primary outcomes: • objective cure: negative stress test, dry pad test, no repeat treatment; • subjective cure: no SUI symptoms on questionnaire, no leakage in urinary diary Secondary outcomes: • median blood loss • median operative time • bladder or urethral perforation • vaginal perforation • voiding dysfunction • mesh erosion/exposure • vascular injury • suprapubic/groin pain • de novo urgency incontinence • QOL: UDI questionnaire, IIQ questionnaire, • Sexual function: assessed via PISQ-12
Notes	TOMUS trial NCT00325039 Per protocol Lost to follow-up: Group A: 18/298; Group B: 14/299 PISQ measures dyspareunia, coital incontinence and fear of coital incontinence

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Permuted block randomisation schedule with stratification by centre
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information

Richter 2010 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Quote: "patients who were lost to follow-up were considered to have had treatment failure and when patients who were lost to follow-up were excluded"

Riva 2006

Methods	RCT TVT versus TOT
Participants	Inclusion criteria: SUI with urethral hypermobility; age 40-85 years; urethro-cystocoele of grade 0-2 Exclusion criteria: previous prolapse or IU surgery; anterior or posterior vaginal wall repair with mesh No difference recorded between the 2 groups for age, parity, or incontinence severity
Interventions	Group A: TOT (n = 65) Group B: TVT (n = 66)
Outcomes	Gynaecological examination, full urodynamic evaluation, voiding diary and KHQ were performed pre- and postoperatively
Notes	12-month follow-up

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "A randomised study". No description of how randomisation was achieved or if allocation was concealed
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Salem 2014

Methods	RCT of TOT vs TVT
Participants	76 women with SUI, all had urodynamics
Interventions	Group A: TOT (n = 37)

Salem 2014 *(Continued)*

	Group B: TVT (n = 39)
Outcomes	• Cure of SUI: defined as no leak during Bonny test, and high leak point pressure and urethral pressure profile • Mean operative time • Perioperative complications • Intraoperative blood loss • Hospital stay • Postoperative urodynamic • Time to return to normal activities
Notes	No usable data provided

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "were included in this randomized controlled study .... Patients were randomly grouped"
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Scheiner 2012

Methods	RCT of TVT vs TOT (Monarc) vs TVT-O
Participants	2 public teaching hospitals in Switzerland Inclusion criteria: women with urodynamically confirmed SUI, or MUI with predominant SUI Exclusion criteria: missing urodynamic assessment; previous sling procedure; predominant OAB; a PVR > 100 ml Mean age (years; SD): Group A: 57.8 (13.0); Group B: 56.6 (10.3); Group C: 59.3 (12.1) Mean BMI kg/m² (SD): Group A: 26.4 (3.7) Group B: 27.8 (4.6); Group C: 27.6 (4.8)
Interventions	Group A: TVT (n = 80) Group B: TOT outside-in approach (Monarc; n = 40) Group C: TVT-O inside-out approach (Gynecare; n = 40)

Scheiner 2012 *(Continued)*

Outcomes	• Objective cure: negative cough test (performed with a bladder filling of 300 ml) and a negative short-pad test (pad weight gain <3g was defined as negative) • Subjective cure: participant's global impression (cured, improved, failed) • Subjective cured and improved • Mean operation time • Mean blood loss • Mean hospital stay • Bladder perforation • Vaginal perforation • Thigh/groin pain • Vascular damage • Voiding dysfunction • Tape erosion • QoL: assessed by means of the validated German version of the KHQ • Sexual function: assessed by direct questioning.
Notes	Preoperatively, conservative measures for SUI were recommended, such as use of local estrogens, pelvic floor re-education, or incontinence pessaries. A symptomatic cystocele stage 2 or higher according to the POP-Q system was corrected first. Participants with concomitant sling insertion to repair prolapse were included Cystoscopy was mandatory for every procedure Lost to follow-up: Group A: 15; Group B: 6; Group C: 3

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Predetermined computer generated block randomisation in blocks of 8 to promote group balance
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for

Schierlitz 2008

Methods	RCT of retropubic (TVT™) versus transobturator (Monarc™)) sling in the treatment of women with USI and ISD
Participants	163 women

Schierlitz 2008 *(Continued)*

	Inclusion criteria: women with SUI who had unsuccessful conservative therapy and, on UDS, had a diagnosis of USI and ISD ISD was defined as either a maximum urethral closure pressure (measured both with the bladder empty and at capacity) of <20 cm H_2O and/or a pressure rise from baseline required to cause incontinence (Valsalva or cough leak point pressure) of ≤60 cm H_2O Exclusion criteria: presence of pelvic infection; a persistent PVR volume > 100 ml; malignancy; fistula; or congenital or neurogenic bladder disorder Mean age (years; SD): Group A: 60 (11.5); Group B: 60 (10.9) Post menopausal: Group A: 66/82; Group B: 68/82 Previous incontinence surgery: Group A: 6/82; Group B: 11/82 Concomitant surgery: Group A: 29/82; Group B: 26/82
Interventions	Group A: TVT (n = 81) Group B: Monarc sling (n = 82)
Outcomes	• Objective cure: absence of USI • Subjective cure: absence of self-reported SUI • Bladder perforation • Major vascular injury • Groin pain • Voiding dysfunction • De novo urgency • De novo urgency incontinence • De novo urgency and UUI • Re-operation • Vaginal perforation • QoL: via UDI-6 AND IIQ-7 ○ The short forms of the UDI-6 and the IIQ-7 were used for subjective assessment of QoL. • Sexual function: via PISQ-12
Notes	Follow-up was at 6 weeks and 6 months, then yearly for 3 years Loss to follow-up: Group A: 5/82; Group B: 4/82 At 3-year follow-up: Group A: 72 followed-up with 70 completing questionnaires, and 48 completing examination Group B: 75 followed-up with 60 completing questionnaires, and 40 completing examination The number available for follow up or number lost to follow up at 5yrs was not made clear (authors have been contacted and response is awaited)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "... A prospective, randomised controlled trial was conducted using computer generated random allocation."
Allocation concealment (selection bias)	Unclear risk	No description of how allocation was concealed

Schierlitz 2008 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The number of participants who withdrew or were lost to follow-up (dropouts) was higher in the TVT group

Tanuri 2010

Methods	RCT of retropubic Safyre VS adjustable sling system and Safyre T adjustable transobturator sling system
Participants	30 women Inclusion criteria: women with SUI Exclusion criteria: use of drugs (adrenergic, anticholinergic or serotonergic); hormone therapy within the previous 6 months; prior pelvic radiotherapy or current chemotherapy or hormone therapy; POP > stage 2; MUI
Interventions	Group A: Safyre VS retropubic tape (n = 10) Group B: Safyre T transobturator tape (n = 20)
Outcomes	• Subjective cure: no reported SUI • Objective cure: negative stress test or <1g urine weight at modified pad test • Pad test • De novo urgency incontinence • Voiding dysfunction • Groin pain • Bladder perforation • Tape erosion • Mean QoL Scores: via KHQ
Notes	Follow-up was at 1, 6 and 12 months

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Participants were randomised into 2 groups
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias)	Unclear risk	No information

Tanuri 2010 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data for all participants accounted for

Tarcan 2011

Methods	RCT: TVT (Advantage^{R}) vs TOT (Obtryx^{R})
Participants	54 women with urodynamic SUI SUI: n = 10; MUI: n = 35 Median age in years (range): 54 (31-76) BMI kg/m^2: Group A: 27.8 (4.6); Group B: 27.4 (4.04) Concomittant POP surgery: Group A: 5/27; Group B: 2/27
Interventions	Group A: TVT (n = 27) Group B: TOT (n = 27)
Outcomes	12-month follow-up assessed: • cure: negative stress provocation test • mean operative time in minutes 2 year follow-up assessed: • subjective cure • mean operating time • QoL: via SEAPI
Notes	Concomitant POP surgery was performed in 7 women (6 cystocele, 1 rectocoele) No mention of intraoperative cystoscopy

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No information
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information

Tarcan 2011 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Teo 2011

Methods	RCT of TVT vs TVT-O
Participants	127 women recruited from 2 hospitals in the UK Inclusion criteria: women with USI Exclusion criteria: previous continence surgery; OAB symptoms; DO; POP-Q > stage 1; presence of voiding dysfunction (defined as maximum flow rate < 15 ml/s or PVR volume ≥ 100 ml) Women in both groups had similar background characteristics, degree of severity of symptoms and QoL scores Mean age (years; SD): Group A: 52.4 (11.8); Group B: 50.9 (11.4) Median BMI kg/m^2 (range): Group A: 27 (21-37); Group B: 29 (21-50) Postmenopausal: Group A: 24/66; Group B: 19/61
Interventions	Group A: TVT (n = 66) Group B: TVT-O (n = 61)

Outcomes	• Objective cure: via 24-hour pad test (cure defined as a test result of < 5 g)
	• Subjective cure: self-reported on PGII scale - considered cured if they were "very much better"
	• Major vascular injury
	• Voiding dysfunction
	• Bladder perforation
	• De novo urgency/UI
	• Tape erosion
	• Groin pain
	• QoL: via KHQ14 and ICIQ-SF15 questionnaires
	  • Baseline scores:
	  ○ Median KHQ score (range) A: 384 (122–814), B: 399 (106–814)
	  ○ Median ICIQ-SF score (range): A: 15 (7–21), B: 14 (3–21)
	  • 12 months follow up scores:
	  ○ Median KHQ score (range): A: 50 (0–510), B: 61 (0–748)
	  ○ Median ICIQ-SF score (range): A: 4 (0–16), B: 0 (0–11)

Notes	Intraoperative cystoscopy with a 70° cystoscope performed in all cases Loss to follow-up at 12 months: Group A: 25/66; Group B: 32/61

Risk of bias

Bias	Authors' judgement	Support for judgement

Teo 2011 *(Continued)*

Random sequence generation (selection bias)	Low risk	Randomisation was done by a computer generated list randomised in blocks to ensure balanced allocation
Allocation concealment (selection bias)	Low risk	Randomization was done by a computer generated list randomised in blocks to ensure balanced allocation. Block size was randomised between 4 and 10. Numbered opaque envelopes were opened immediately before surgery
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and assessors were not blinded to the treatment received
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants and assessors were not blinded to the treatment received
Incomplete outcome data (attrition bias) All outcomes	High risk	High numbers lost to follow-up; disproportionately higher in TVT-O group

Tommaselli 2012

Methods	RCT comparing TVT-O and a modified version of TVT-O
Participants	72 women Inclusion criteria: urodynamically proved SUI; age > 30 years; and previously failed pelvic floor muscle training Exclusion criteria: previous surgery for SUI; isolated OAB; POP ≥ stage 2; neurological disease Mean age (years; SD): Group A: 51 (9.5); Group B: 55 (6.8) Mean BMI kg/m² (SD): Group A: 27.5 (4.9); Group B: 28.9 (3.7)
Interventions	Group A: TVT-O (n = 48) Group B: modified TVT-O (n = 24)
Outcomes	• Objective cure (negative stress test) • No intraoperative complications reported in either group. • Voiding dysfunction • Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (QoL: via PISQ-12 and PGI-S)
Notes	For the modified TVT-O: "Briefly, in contrast with the traditional technique, the paraurethral dissection was minimal and carried only up to the pubic ramus, without perforating the obturator membrane with the scissors The aim of this reduced dissection was to create a passage of very limited size to introduce the guide only up to the bone, without perforating the membrane. Thus, as opposed to the original procedure, the obturator membrane was perforated only by the helical passer" Lost to follow-up: Group A: 2/48; Group B: 1/24

Risk of bias

Bias	Authors' judgement	Support for judgement

Tommaselli 2012 *(Continued)*

Random sequence generation (selection bias)	Low risk	Quote: “Patients were randomised using a randomisation list generated by computer”
Allocation concealment (selection bias)	Low risk	Quote: "The allocation sequence was concealed from the researchers (CF and AF) who enrolled, assessed, and assigned the participants to the interventions in sequentially numbered, opaque, sealed, and stapled envelopes. The envelopes were opened on the morning of the procedure for the surgeon to perform the allocated procedure"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: “Patients were blinded to the procedure until the end of the study”
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	All data accounted for

Tseng 2005

Methods	RCT comparing TVT with SPARC
Participants	62 women Inclusion criteria: women with USI with or without POP Exclusion criteria: those with POP > ICS stage 2 and those with previous anti-incontinence surgery Mean age was 51 years and median parity of 3. The 2 groups were similar in terms of age, parity and menopausal status
Interventions	Group A: SPARC (n = 31) Group B: TVT (n = 31)
Outcomes	Objective cure: defined as pad weight ≤1g Improved: participants whose loss decreased to < half of the preoperative value were considered to have improved
Notes	All women had routine suprapubic ultrasonography for detecting unrecognised subcutaneous or retropubic haematoma on the day immediately after the operation, and 7/8 of those with retropubic haematoma of >5 cm diameter were discharged uneventfully from the hospital within 7 days of the operation. Ultrasonography performed at the 1 month follow-up visit revealed complete resolution of the haematoma for every participant Follow-up at 2 years Women and their outcome assessors were blinded, but the exact method used to achieve this was unclear

Risk of bias

Bias	Authors' judgement	Support for judgement

Tseng 2005 *(Continued)*

Random sequence generation (selection bias)	Low risk	By using a predetermined computer-generated randomisation code, those subjects who acquiesced and satisfied the inclusion criteria were assigned randomly by the authors (except LHT) to the SPARC or TVT procedure at the outpatient clinic
Allocation concealment (selection bias)	Unclear risk	Unclear
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "The patients were blinded to the procedure, but the principle based on the integral theory was briefly explained to them"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential loss to follow-up or differential attrition

Ugurlucan 2013

Methods	RCT of PELVILACE TO (biological TOT material) vs synthetic TOT material (ALIGN TO urethral support system)
Participants	100 women Inclusion criteria: women >18 years with SUI, MUI or USI in whom conservative treatment had failed. Women with or without POP were included Exclusion criteria: women with ISD Pre- and postoperative assessments included evaluation of urinalysis and urine culture POP evaluation using POP-Q system, 1-hr pad test, 4-day bladder diary, stress test, Q-tip test, and QoL assessment using the KHQ, UDI-6, and the IIQ-7. This was repeated at the 12-month follow-up. Postoperative urodynamics was performed in all patients accepting the procedure Mean age (years; SD): Group A: 55.0 (12.3); Group B: 52.9 (10.6) Mean BMI kg/m² (SD): Group A: 31.8 (6.6); Group B: 31.3 (4.8) Postmenopausal: Group A: 29 (56.9%); Group B: 30 (58.8%) Previous incontinence surgery: Group A: 2 (4%); Group B: 2 (4%) Concomitant POP surgery: Group A: 28/50; Group B: 28/50
Interventions	Group A: biological PELVILACE TO (n = 50) Group B: synthetic TOT ALIGN ®TO (n = 50)
Outcomes	Primary outcome: patient-reported improvement in urinary incontinence (either completely dry or improvement in symptoms of SUI; reported as 'cure,' 'better than before,' 'no change at all,' and 'worse than before.') Secondary outcomes: • objective cure: defined as the absence of SUI and a negative stress test at 200 ml in the standing position

Ugurlucan 2013 *(Continued)*

- objective improvement: defined as improvement in the bladder diary and questionnaires
- Subjective evaluation by the patients was reported as “cure,” “better than before,” “no change at all,” and “worse than before.”
- intra- and postoperative complications
- reoperation rate
- Groin pain
- Vaginal tape erosion
- QoL: assessed via KHQ, P-QoL, UDI-6, and IIQ-7

Notes	Biological tape was PELVILACE® TO system; Bard, Covington, GA, USA and the synthetic tape was ALIGN ®TO urethral support system; Bard TOT operation. The PELVILACE® TO system consists of a PELVICOL® self-anchoring, natural tissue sling implant and an introducer system. This system contains a self-anchoring, 1.5 cm wide, and 40 cm long suburethral sling of porcine dermal collagen. The ALIGN® TO urethral support system is a suburethral sling device made of type 1 monofilament polypropylene mesh designed for the treatment of SUI through the TOR Postmenopausal patients received local estrogen treatment for 1 month before and after the operation Concomitant POP was performed in a cohort of women

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: " In this prospective randomized study ... Randomization was carried out using computer-generated random allocations prepared by an investigator with no clinical involvement in the trial"
Allocation concealment (selection bias)	Low risk	Quote: "computer-generated random allocations prepared by an investigator with no clinical involvement in the trial"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "The patients were blinded to the sling material used."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Follow-up was performed ... by the same physician who was blinded to the type of sling used"
Incomplete outcome data (attrition bias) All outcomes	Low risk	All accounted for

van Leijsen 2013

Methods	RCT comparing RPR and TOT
Participants	Dutch multicentre diagnostic cohort study with an embedded RCT 587 women with SUI; 123 randomised to surgery Inclusion criteria: women with urodynamically-proven SUI, or MUI with SUI as predominant symptom following failed conservative treatment Exclusion criteria: prior incontinence surgery; POP > stage 2 POP-Q; post PVR of >150 ml (by USS or characterisation)

van Leijsen 2013 *(Continued)*

	MUI: Group A: 18/33; Group B: 61/90
Interventions	Group A: RPR (n = 33) Group B: TOT (n = 90)
Outcomes	Outcome results for TOT and RPR not reported as separate figures; we contacted the authors who supplied separate figures • Subjective cure: defined as self-reported absence of SUI • Objective cure: defined as negative stress test (any leakage of urine was a defined as a failure) • Subjective cure3 • Objective cure • De novo urgency incontinence • Voiding dysfunction • Tape release for POVD • Repeat incontinence surgery
Notes	QoL questionnaires: UDI

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A web-based application was used for block randomisation and computer-generated random number list prepared by a database designer"
Allocation concealment (selection bias)	Low risk	Quote: "Patient data were entered into a password-protected web- based database"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Participants and health professionals were not blinded to the allocated arm and the urodynamic results"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Data input of subjective outcome measurements was per-formed by researchers who were blinded to the treat-ment allocation"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Wang 2006

Methods	RCT of TOT (Monarc) and SPARC suburethral sling procedures
Participants	60 women with an average age of 50 years (SD 10.71) Inclusion criteria: women with USI Exclusion criteria: women suffering from preoperative voiding dysfunction, which was defined as either: free Q max of ≤ 12ml/s in repeated free uroflow studies combined with Pdet Q max of ≥20cm H_2O, PVR urine ≥ 100 ml, and participants with a pad increase of at least 10cm H_2O, compared to the baseline abdominal pressure in a pressure-flow study. Women who had previous anti-incontinence surgery and/or with pelvic prolapse > stage 2 of the ICS grading system were also excluded.

Wang 2006 *(Continued)*

Interventions	Group A: Monarc (n = 31) Group B: SPARC (n = 29)
Outcomes	Assessed via 1-hr pad test, multichannel urodynamic assessment, complications and postoperative voiding function. Transabdominal USS to detect subcutaneous, retropubic or obturator haematoma
Notes	The women were blinded to the procedure performed Intraoperative cystoscopy was performed in both groups

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "By using a predetermined computer-generated randomisation code ... were assigned randomly by the senior author ..."
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: " ... The patients were blinded to the procedure ..." How this was achieved was not explained
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "an independent continence advisor and one of the authors both of whom were blinded to the procedures performed carried out the follow-up examinations and post operative outcome assessments"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential loss to follow-up or differential attrition

Wang 2008

Methods	RCT of TVT vs TVT-O Single-blinded
Participants	69 women Inclusion criteria: severe female SUI with or without prolapse (< POP-Q stage 3) Exclusion criteria: pregnancy; previous surgery for urinary incontinence Mean BMI kg/m^2 (SD): Group A: 25 (3); Group B: 25 (3) Mean age (years; SD): Group A: 52 (11); Group B: 52 (11)
Interventions	Group A: TVT (n = 35) Group B: TVT-O (n = 34)
Outcomes	• Subjective cure: no self-reported leaking and negative stress test: • Subjective cure and improvement • Failure: 1-h pad test not reduced by 50%

Wang 2008 *(Continued)*

- Operative time
- Blood loss
- Length of hospital stay
- Bladder/visceral perforation
- Voiding dysfunction
- Haematoma
- QoL: UDI-6 and IIQ-7 before and after surgery

Notes	Concomittant surgery: some women also had transvaginal hysterectomy and prolapse repair Follow-up: mean 14.5 months Cystoscopy performed in TVT group only Article written in Chinese and translated to English for interpretation and data extraction

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation schedule
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Single-blinded (no information about who was blinded)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Single-blinded (no information about who was blinded)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "All patients were evaluable"

Wang 2009

Methods	RCT of TVT vs inside-out TVT-O 55 were participants in a previous study (ref 8, Zhu 2007: 23870; 27325) – already included
Participants	300 women Inclusion criteria: demonstrable severe SUI, or mild to moderate SUI that failed to respond to conservative treatment. All women had urodynamically confirmed USI (no detrusor contraction on leakage) Exclusion criteria: ;ISD MUI; pregnancy; UTI; UUI; PVR volume > 100 ml; neurological disease; urogenital malignancy, fistula, or pelvic radiotherapy Menopausal: Group A: 87/154; Group B: 88/146 Previous prolapse surgery:

Wang 2009 *(Continued)*

	Previous incontinence surgery: Group A: 5; Group B: 5
Interventions	Group A: TVT (n = 154) Group B: TVT-O (n = 146)
Outcomes	• Cure: negative cough test at follow-up (possibly objective): • Improvement: frequency of UI episodes and urine weight on pad test reduced by > 50% • Failure: frequency of UI episodes ad urine weight on pad test reduced by < 50% or worse than before surgery) • Mean operative time in minutes • Mean blood loss • Operative time • Mean length of hospital stay • Adverse effects • Urinary retention • De novo UUI • Vaginal tape erosion: • Groin/thigh pain
Notes	Signed informed consent, approved by Ethics committee Mean follow-up: (months; SD): Group A: 19.6 (11.9); Group B: 20.5 (10.7; twice in first year, then yearly) Loss to follow-up: Group A: 6; Group B: 8, + 1 withdrawn (operation postponed) Cystoscopy only performed in the TVT group Concomitant prolapse and other surgery

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The 315 women were allocated to the TVT or the TVT-O group by an SAS randomisation schedule (SAS Institute Inc, Cary, NC, USA)
Allocation concealment (selection bias)	Unclear risk	Stated: 'randomly allocated', no further information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blind: 'independent gynaecologist'
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential dropout (Group A: 6; Group B: 9)

Wang 2010

Methods	RCT comparing TVT and TOT-outside/in
Participants	140 women Inclusion criteria: women with urodynamically proven SUI Exclusion criteria: OAB syndrome dry or wet Age (years; SD): Group A: 60 (10.8); Group B: 58 (11.6) Previous incontinence surgery: Group A: 5; Group B: 3 BMI kg/m^2 (SD): Group A: 24 (2.4); Group B: 24.6 (2.6) Concomitant POP: Group A: 30/70; Group B: 22/70
Interventions	Group A: TVT (n = 70) Group B: TOT (n = 70)
Outcomes	• Subjective cure • Objective cure: negative cough test, 1-h pad test of <2g. • Improved: persistence of SUI (though occasional) not affecting daily activities or requiring further treatment • Vascular injury/haematoma • Tape erosion • Bladder perforation • Voiding dysfunction • De novo urgency/UII • QoL assessed by UDI-6) and IIQ-7-SF
Notes	Cystoscopy only performed when bladder perforation suspected in TOT group. All TVT participants cystoscoped post procedure Concomitant surgery: All participants with POP had this repaired at the time of tape insertion Lost to follow-up: Group A: 0 women; Group B: 0 women

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Our study was a single blind randomised trial and the patients were randomly allocated to ..."
Allocation concealment (selection bias)	Unclear risk	Quote: "Our study was a single blind randomised trial and the patients were randomly allocated to ..."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "The patients were not blinded to the operative procedure"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "post op assessment was performed by FMW who did not take part in the operation , YFS who performed the surgery was not involved in follow up"
Incomplete outcome data (attrition bias)	Low risk	No participants withdrew. None were lost to follow-up

Wang 2010 *(Continued)*
All outcomes

Wang 2011

Methods	RCT comparing TVT, TVT-O and TVT-Secur
Participants	Total of 102 women included in this Chinese trial Inclusion criteria: women with urodynamically proven SUI. If MUI, then SUI was the predominant symptom Exclusion criteria: women with previous surgical procedures for SUI Mean age (years; SD): Group A: 56.6 (9.6); Group B: 56.0 (9.1) Mean BMI kg/m² (SD): Group A: 25.3 (2.0); Group B: 27.3 (1.9)
Interventions	Group A: TVT (n = 32) Group B: TVT-O (n = 36) Group C: TVT- Secur (data not included in this review)
Outcomes	• Objective cure: negative cough stress test • Subjective cure: absence of SUI symptoms • Improvement: negative or a positive cough stress test and reduced SUI symptoms: • Mean length of surgery • Bladder perforation • Voiding dysfunction • Groin pain • De novo urgency or urgency incontinence • Vascular injury
Notes	Power test calculation performed Women with SUI were put on anticholinergic treatment prior to surgery QoL assessment was performed using the ICI-Q-SF pre-operatively; no data for post-operative scores Cystoscopy routinely performed in TVT. Cystoscopy only performed if bladder injury was suspected in the TVT-O group Follow-up 1, 3, 6 and 12 months All women completed the trial (no loss to follow-up)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "computer generated randomisation"
Allocation concealment (selection bias)	Low risk	Quote: “allocation was concealed using opaque sealed envelopes”

Wang 2011 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants completed follow-up. All outcomes reported

Zhang 2011

Methods	RCT comparing TVT-O with a modified version of TVT-O using a self-tailored mesh
Participants	156 women in a Chinese hospital Inclusion criteria: women with SUI aged > 18 years Exclusion criteria: women with urgency; persistent urinary retention (PVR > 50 ml); dysuria; other urologic diseases and psychiatric disorders Mean age (years; SD): Group A: 61.4 (5.4); Group B: 62.6 (3.2)
Interventions	Group A: TVT-O (n = 76) Group B: modified TVT-O (n = 80)
Outcomes	• Subjective cure: disappearance of SUI symptoms • Subjective improvement • Mean operative time • Mean blood loss • Mean hospital stay in days • Voiding dysfunction • QOL: self-administered I-QOL
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: “stratified randomisation”
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information

Zhang 2011 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information

Zullo 2007

Methods	RCT comparing TVT and TVT-O
Participants	72 women Inclusion criteria: women affected by SUI with no contraindications to vaginal surgery Excluded criteria: women with urogenital prolapse > stage 1; DO; symptoms of OAB; intrinsic urethral sphincter deficiency; urinary retention; previous anti-incontinence surgery; neurologic bladder; and psychiatric disease Age (years; SD): Group A: 52.8 (11.8); Group B: 53.4 (10.7) BMI kg/m^2: Group A: 25.7 (2.9); Group B: 26.5 (2.7) Menopausal: Group A: 6/35; Group B: 8/37 POP stage 1 and 2: Group A: 34/35; Group B: 35/37
Interventions	Group A: TVT (n = 35) Group B: TVT-O (n = 37)
Outcomes	• Objective cure (no leakage of urine with urodynamic stress testing) • Subjective cure: VAS used to quantify participant perception of SUI symptom severity • Incidence of overall perioperative complications • De novo urgency and urge incontinence • Tape erosion • Voiding dysfunction
Notes	Intraoperative cystoscopy only performed in the TVT group 12 participants did not return for 5-year follow-up: 3 participants were lost (2 in the TVT group and 1 in the TVT-O group), and 9 withdrew (4 in the TVT group and 5 in the TVT-O group)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: " .. were randomly allocated to undergo a TVT or TVTO procedure by using a predetermined computer-generated randomisation code"
Allocation concealment (selection bias)	Low risk	Allocation concealed
Blinding of participants and personnel (performance bias)	Unclear risk	No information

Zullo 2007 *(Continued)*
All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Low risk	" ... outcome assessors at 5 years follow up blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No differential loss to follow-up or differential attrition

Abbreviations
BFLUTS: Bristol lower urinary tract symptoms questionnaires
BMI: body-mass index
DO: detrusor overactivity
DUP: distal urethral polypropylene sling
EQOL-5D: Euro Quality of life -5 Dimension
g: gram
hr: hour
HRT: hormone replacement therapy
ICIQ: International Consultation on Incontinence questionnaire
ICIQ-FLUTS: International Consultation on Incontinence questionnaire - female lower urinary tract symptoms
ICIQ- LUTSquol: International Consultation on Incontinence questionnaire - lower urinary tract quality of life questionnaire
ICIQ-SF: International Consultation on Incontinence questionnaire short form
ICIQ-SF15: International Consultation on Incontinence questionnaire short form 15
IIQ: Incontinence Impact questionnaire
ICS: International Continence Society
I-QoL: Incontinence Quality of Life questionnaire
ISD: intrinsic sphincter deficiency
IVS: intravaginal slingoplasty
KHQ: King's Health questionnaireMUI: mixed urinary incontinence
MUCP: Maximum urethral closure pressure
MUI: mixed urinary incontinence
OAB: overactive bladder
PGI-I: Patient Global Impression of Improvment
PGI-S: Patient Global Impression of Severity
PISQ-12: pelvic organ prolapse/urinary incontinence sexual questionnaire
POP: pelvic organ prolapse
POP-Q: pelvic organ prolapse quantification
POP-Q ICS: pelvic organ prolapse quantification International Continence Society
PVR: post void residual
RCT: randomized controlled trial
RPR: retropubic route
QoL: quality of life
QRCT: quasi-randomised trial
SEAPI-QMM: Stress related leak, Empyting ability, Anatomy, Protection, Inhibition-Quality of life, Mobility and Mental status incontinence classification system
SD: standard deviation
SIS: Single incision sling
SPARC: suprapubic arc (procedure)
SUI: stress urinary incontinence
TOR: transobturator
TOT: transobturator tape
TOT-ARIS: transobturator tape-ARIS
TVT: tension-free vaginal tape
TVT-O: transobturator tension-free vaginal tape
UDI: Urinary Distress Impact questionnaire
UDI-6: Urinary Distress Impact questionnaire short form
UDS: urodynamics study
UI: urinary incontinence
UISS: urinary incontinence severity score

USI: urodynamic stress incontinence
USS: ultrasound
UTI: urinary tract infection
UUI: urgency urinary incontinence
VAS: visual analogue scale
VLPP: Valsalval leak point pressure

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Al-Tayyem 2007	Not an RCT
Amat 2007	Sling apparently equivalent to TVT, but too little information provided to determine equivalence
Ballert 2010	Not an RCT
Bekker 2009	Sexual function analysis of 2 retrospective studies (not RCTs)
Borrell 2005	Retrospective study, not an RCT
Bracken 2012	RCT of bupivacaine and saline versus saline only for hydrodissection during TVT
Bruschini 2005	Not an RCT
Chen 2008	Not randomized
Chen 2011	Prospective comparative study with participants assigned not randomized.
Chene 2009	Was prospective, but not stated that randomized
Chong 2003	All women had TVT. Intervention groups were division vs no division of tape
Corcos 2001	Traditional slings. No minimally invasive sling
Corcos 2005	No minimally invasive sling
Cotte 2006	An ultrasound study comparing tape position between RPR and TOR
Courtney-Watson 2002	Trial stopped due to difficulty recruiting. Planned to recruit 30 participants to each arm but actually randomized less than 15 participants in total
Debodinance 2006	Non randomized prospective study
Dietz 2005	Imaging study: aim of the study was to determine the mobility of the slings from ultrasound imaging of slings inserted in the parent trial (SUSPEND trial, Lim 2005)
Du 2008	Not an RCT
Falconer 2001	All had TVT
Fischer 2005	Not an RCT
Foote 2012	Monarc vs mini single incision sling
Goldberg 2001	No minimally invasive sling

Study	Reason for exclusion
Gopinath 2013	Qualitative analysis on nonresponders of single incision sling RCT
Harmanli 2011	RCT of antibiotic use preoperatively for TVT and TOT (surgeons discretion for what tape was used)
Jackson 2013	RCT of antibiotic vs. placebo for MUS surgery
Jeon 2008	Not an RCT
Jones 2010	Not an RCT
Karagkounis 2007	A prospective cohort study not an RCT
Kim 2005a	Retrospective review of medical records
Kim 2006	Not an RCT
Kulseng-Hanssen 2004	RCT - does not meet the inclusion criteria. Not MUS vs MUS. Tradition Sling vs TVT. This trial compares three techniques for performing sling surgery: TVT, porcine xenograft (Pelvicol) sling and the short autologous fascial sling technique 'Sling on a string'.
Kulseng-Hanssen 2007	A prospective cohort study not an RCT
Kwon 2002	Prolapse trial not urinary incontinence
Liapis 2007	RCT with randomisation based on the type of anaesthesia used for one minimally invasive sling procedure (TVT)
Liapis 2010	RCT of TVT-O vs TVT-O plus 6 months postoperative estrodiol therapy. Both groups had TVT-O performed
Markland 2007	RCT of Burch colposuspension versus traditional sling - SISTEr Trial. Not MUS vs MUS
McClure 2006	Statistical modelling and not a trial in itself. No minimally invasive sling
Meschia 2002	1 tape used (TVT) and only occult urinary incontinence investigated
Osman 2003	No minimally invasive sling arm in the trial
Pace 2008	Prospective study of SPARC vs Monarc TOT but no evidence of randomisation
Padilla-Fernández 2013	Randomisation based on immediate or deferred cutting and readjustment of tape
Park 2008	Same tape TOT randomized to either high-tension or tension-free
Sabadell 2008	Cohort study, not an RCT
Schierlitz 2007	Investigated occult incontinence
Schostak 2001	Not an RCT and no minimally invasive sling
Seo 2007	Not an RCT, retrospective study
Shin 2010	Non randomized longitudinal study
Sivaslioglu 2007	No minimally invasive sling

Study	Reason for exclusion
Surkont 2007	Not an RCT and only 1 arm, IVS
Takeyama 2006	Improvised instrument used
Tantanasis 2013	A review article, not an RCT
Tincello 2009	RCT of colposuspension or TVT with concomitant anterior repair (1 tape)
Tinelli 2007	Same tape TVT: randomized to either immediate TVT or TVT after 21 days of preoperative estrogen treatment
Trezza 2001	Investigated occult urinary incontinence
Wang 2001	All women received TVT. Compared types of anaesthesia
Wei 2012	RCT of women with occult stress urinary incontinence undergoing POP surgery with and without concomitant MUS insertion
Williams 2003	Statistical modelling and not a trial in itself
Yang 2012	Non randomised inferiority study
Yoo 2007	A comparative study but not an RCT
Yoon 2011	RCT of single incision sling and TOT
Zaccardi 2010	RCT of pelvic floor muscle training on comfort.
Zullo 2005	All had TVT. Women were randomly allocated to receive TVT plus postoperative vaginal oestrogen therapy (ET group) or TVT without adjunctive medical treatment (no ET group)

Abbreviations
IVS: intravaginal slingoplasty
MUS: mid-urethral sling
POP: pelvic organ prolapse
RCT: randomized controlled trial
RPR: retropubic route
SIS: Single incision sling
TOR: transobturator route
TOT: transobturator tape
TVT: tension-free vaginal tape
TVT-O: tension-free vaginal tape - Obturator

Characteristics of ongoing studies *[ordered by study ID]*

Cavkaytar 2013

Trial name or title	Prospective randomised study comparing TVT and TOT in female SUI with no ISD
Methods	RCT
Participants	Inclusion criteria: women aged 18-70 years; with USI; with or without POP Exclusion criteria: previous incontinence surgery; UI or OAB; mixed incontinence; ISD; BMI > 35

Cavkaytar 2013 *(Continued)*

Interventions	Participants underwent either TVT or TOT procedures
Outcomes	Primary outcome: postoperative UDI-6 and IIQ-7 score <10 and negative cough test will be defined as 'cured' Secondary outcomes: • objective effectiveness by cough test at 6 and 12 months postoperatively • short-term and long-term surgical complications • bleeding • bladder and bowel perforation • mesh erosion • prevalence of voiding dysfunction at 1 and 12 months postoperatively
Starting date	June 2013
Contact information	
Notes	NCT01903590, expected completion date June 2014

Sung 2013

Trial name or title	**E**ffects of **s**urgical **t**reatment **e**nhanced with **e**xercise for **m**ixed urinary incontinence (ESTEEM)
Methods	
Participants	Women > 21 years Inclusion criteria: • presence of both SUI and UUI • reporting at least 'moderate bother' from UUI item on the UDI question "Do you usually experience urine leakage associated with a feeling of urgency, that is a strong sensation of needing to go to the bathroom?" • reporting at least 'moderate bother' from SUI item on the UDI question "Do you usually experience urine leakage related to coughing, sneezing, or laughing?" • diagnosis of SUI defined by a positive cough stress test or urodynamic evaluation within the past 18 months • desire surgical treatment for SUI symptoms • urinary symptoms for >3 months • subjects understand that BPTx is a treatment option for MUI outside the ESTEEM study protocol • urodynamics within past 18 months Exclusion criteria: • anterior or apical compartment prolapse at or beyond the hymen (>0 on POP-Q), regardless of whether patient is symptomatic (women with anterior or apical prolapse above the hymen (<0) who do not report vaginal bulge symptoms will be eligible) • planned concomitant surgery for anterior vaginal wall or apical prolapse > 0a (women undergoing only rectocoele repair are eligible) • women undergoing hysterectomy for any indication • active pelvic organ malignancy • aged <21 years • pregnant or plans for future pregnancy in next 12 months, or within 12 months post-partum • PVR >150 ml on 2 occasions, or current catheter use

Sung 2013 *(Continued)*

	• participation in other trial that may influence results of this study • unevaluated haematuria • prior sling, synthetic mesh for prolapse, implanted nerve stimulator for incontinence • spinal cord injury or advanced/severe neurologic conditions including multiple sclerosis and Parkinson's disease (women on anti-muscarinic therapy will be eligible after 3 week wash-out period) • non-ambulatory • history of serious adverse reaction to synthetic mesh • not able to complete study assessments according to clinician's judgment, or not available for 12 month follow-up • women who only report "other IE" on bladder diary, and do not report at minimum 1 stress and 1 urge IE/3 days • diagnosis of and/or history of bladder pain or chronic pelvic pain • women who had intravesical Botox injection within the past 12 months
Interventions	Group A: mid-urethral sling combined with peri- and postoperative behavioral/pelvic floor therapy Group B: mid-urethral sling
Outcomes	
Starting date	October 2013, expected completion date October 2016
Contact information	
Notes	NCT01959347

Abbreviations
BMI: body-mass index
BPTx: behavioural/pelvic floor therapy
ESTEEM: **E**ffects of **s**urgical **t**reatment **e**nhanced with **e**xercise for **m**ixed urinary incontinence trial
IE; incontinence event
IIQ-7: Incontinence Impact questionnaire
ISD: intrinsic sphincter deficiency
MUI: mixed urinary incontinence
OAB: overactive bladder
POP: pelvic organ prolapse
POP-Q: pelvic organ prolapse quantification
PVF: post void residual
SUI: stress urinary incontinence
TOT: transobturator tape
TVT: tension-free vaginal tape
UDI: Urinary Distress Impact questionnaire
UDI-6: Urinary Distress Impact questionnaire short form
UI: urinary incontinence
USI: urodynamic stress incontinence
UUI: urgency urinary incontinence

DATA AND ANALYSES

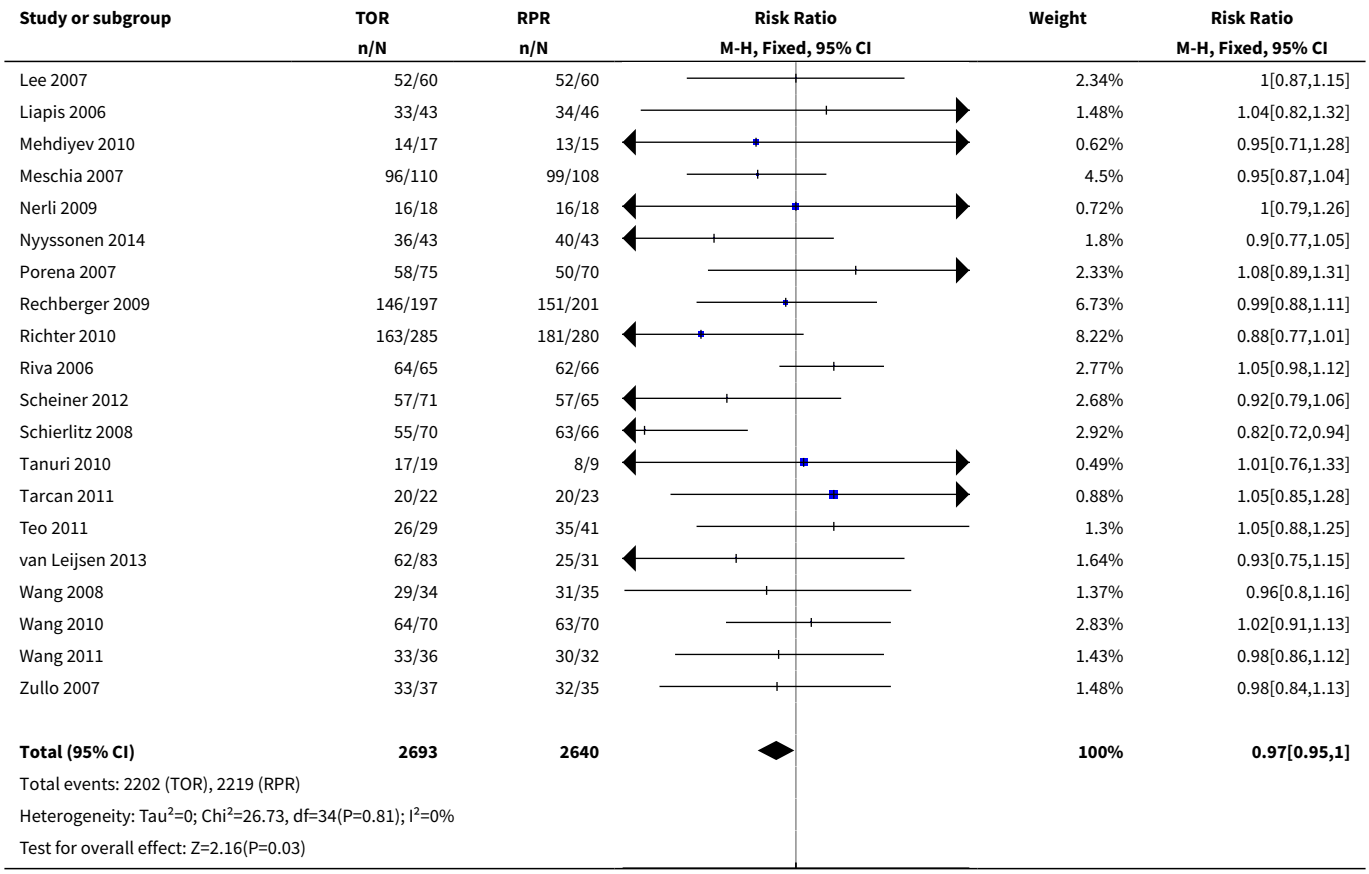
Comparison 1. Transobturator (TOR) versus retropubic route (RPR)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Subjective cure (short term, ≤ 1 year)	35	5333	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.95, 1.00]
2 Subjective cure and improvement (short term, ≤ 1 year)	10	1651	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.96, 1.00]
3 Subjective cure (medium term, 1 to 5 years)	5	683	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.87, 1.09]
4 Subjective cure (long term, > 5 years)	4	714	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.80, 1.12]
5 Subjective cure and improvement (long term, > 5 years)	2	340	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.67, 1.28]
6 Objective cure (short term, ≤ 1 year)	39	5974	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.96, 1.00]
7 Objective cure and improvement (short term, ≤ 1 year)	10	1478	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.96, 1.01]
8 Objective cure (medium term, 1 to 5 years)	5	596	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.95, 1.06]
9 Objective cure (long term, > 5 years)	3	400	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.90, 1.06]
10 Operative time (minutes)	31	4713	Mean Difference (IV, Random, 95% CI)	-7.54 [-9.31, -5.77]
11 Operative blood loss (ml)	14	1869	Mean Difference (IV, Random, 95% CI)	-6.49 [-12.33, -0.65]
12 Length of hospital stay (days)	17	2170	Mean Difference (IV, Random, 95% CI)	-0.25 [-0.59, 0.09]
13 Time to return to normal activity level (weeks)	4	626	Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.15, 0.06]
14 Perioperative complications	15	2205	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.73, 1.14]
15 Major vascular or visceral injury	28	4676	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.19, 0.55]
16 Bladder or urethral perforation	39	6173	Risk Ratio (M-H, Fixed, 95% CI)	0.12 [0.08, 0.20]
17 Voiding dysfunction	37	6200	Risk Ratio (M-H, Fixed, 95% CI)	0.53 [0.43, 0.65]
18 De novo urgency or urgency incontinence (short term, ≤ 1 year)	31	4923	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.82, 1.17]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
19 De novo urgency or urgency incontinence (medium term, 1 to 5 years)	4	481	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.55, 1.73]
20 De novo urgency or urgency incontinence (long term, > 5 years)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
21 Detrusor overactivity	4	566	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.58, 1.73]
22 Vaginal tape erosion	30	4568	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.70, 1.51]
23 Bladder/urethral erosion	4	374	Risk Ratio (M-H, Fixed, 95% CI)	0.34 [0.01, 8.13]
24 Groin pain	17	3050	Risk Ratio (M-H, Fixed, 95% CI)	4.45 [2.80, 7.08]
25 Suprapubic pain	4	1105	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.11, 0.78]
26 Repeat incontinence surgery (short term, ≤ 1 year)	8	1221	Risk Ratio (M-H, Fixed, 95% CI)	1.69 [0.75, 3.80]
27 Repeat incontinence surgery (medium term , 1 to 5 years)	2	355	Risk Ratio (M-H, Fixed, 95% CI)	21.89 [4.36, 109.77]
28 Repeat incontinence surgery (long term > 5 years)	4	695	Risk Ratio (M-H, Fixed, 95% CI)	8.79 [3.36, 23.00]

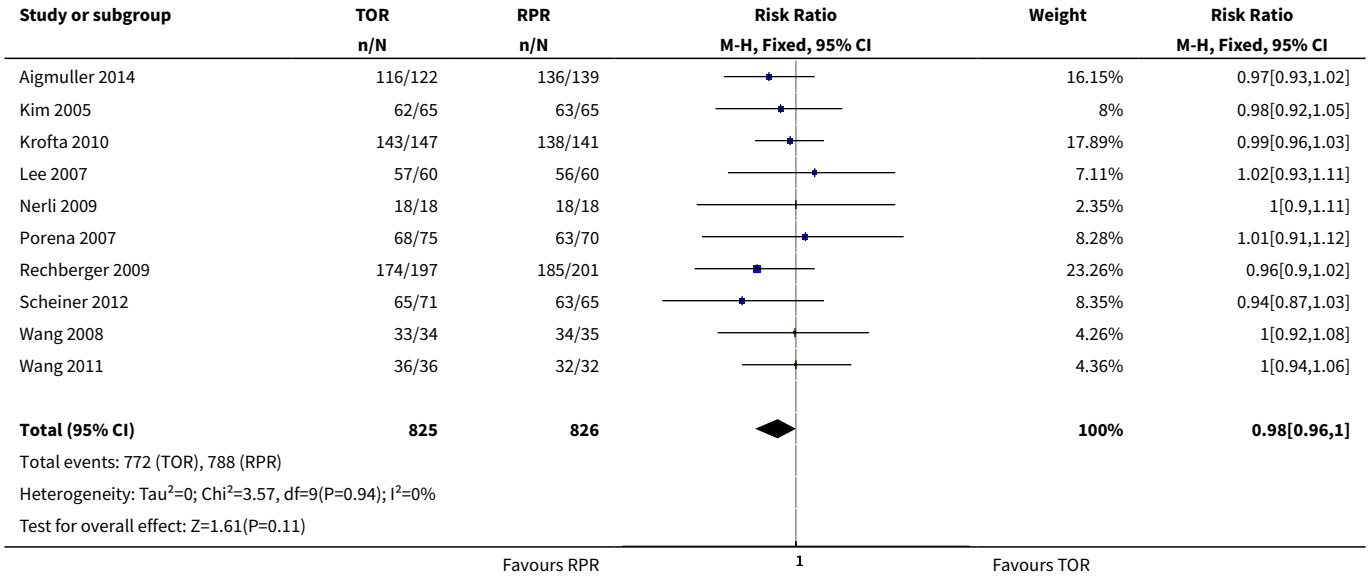
Analysis 1.1. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 1 Subjective cure (short term, ≤ 1 year).

Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aigmuller 2014	107/122	123/139		5.17%	0.99[0.91,1.08]
Aniuliene 2009	145/150	111/114		5.68%	0.99[0.95,1.04]
Barber 2008	68/75	74/85		3.12%	1.04[0.93,1.16]
Barry 2008	49/58	70/82		2.61%	0.99[0.86,1.14]
de Tayrac 2004	26/30	30/31		1.33%	0.9[0.77,1.05]
Deffieux 2010	61/69	63/69		2.83%	0.97[0.87,1.08]
Freeman 2011	59/95	55/85		2.61%	0.96[0.77,1.2]
Hammoud 2011	48/50	56/60		2.29%	1.03[0.94,1.12]
Jakimiuk 2012	13/16	14/15		0.65%	0.87[0.66,1.14]
Karateke 2009	76/83	76/81		3.46%	0.98[0.9,1.06]
Kilic 2007	8/10	7/10		0.31%	1.14[0.69,1.9]
Kim 2005	56/65	56/65		2.52%	1[0.87,1.15]
Krofta 2010	112/147	111/141		5.1%	0.97[0.85,1.1]
Laurikainen 2007	122/131	121/134		5.38%	1.03[0.96,1.11]
Leanza 2009	178/208	190/215		8.41%	0.97[0.9,1.04]
		Favours RPR	1	Favours TOR	



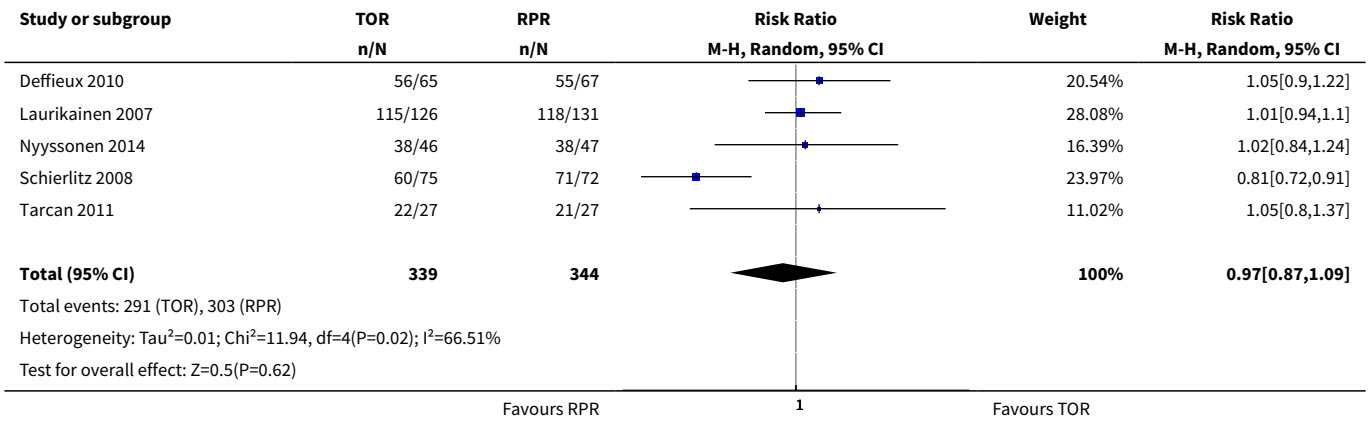
Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Lee 2007	52/60	52/60		2.34%	1[0.87,1.15]
Liapis 2006	33/43	34/46		1.48%	1.04[0.82,1.32]
Mehdiyev 2010	14/17	13/15		0.62%	0.95[0.71,1.28]
Meschia 2007	96/110	99/108		4.5%	0.95[0.87,1.04]
Nerli 2009	16/18	16/18		0.72%	1[0.79,1.26]
Nyyssonen 2014	36/43	40/43		1.8%	0.9[0.77,1.05]
Porena 2007	58/75	50/70		2.33%	1.08[0.89,1.31]
Rechberger 2009	146/197	151/201		6.73%	0.99[0.88,1.11]
Richter 2010	163/285	181/280		8.22%	0.88[0.77,1.01]
Riva 2006	64/65	62/66		2.77%	1.05[0.98,1.12]
Scheiner 2012	57/71	57/65		2.68%	0.92[0.79,1.06]
Schierlitz 2008	55/70	63/66		2.92%	0.82[0.72,0.94]
Tanuri 2010	17/19	8/9		0.49%	1.01[0.76,1.33]
Tarcan 2011	20/22	20/23		0.88%	1.05[0.85,1.28]
Teo 2011	26/29	35/41		1.3%	1.05[0.88,1.25]
van Leijsen 2013	62/83	25/31		1.64%	0.93[0.75,1.15]
Wang 2008	29/34	31/35		1.37%	0.96[0.8,1.16]
Wang 2010	64/70	63/70		2.83%	1.02[0.91,1.13]
Wang 2011	33/36	30/32		1.43%	0.98[0.86,1.12]
Zullo 2007	33/37	32/35		1.48%	0.98[0.84,1.13]
Total (95% CI)	**2693**	**2640**		**100%**	**0.97[0.95,1]**
Total events: 2202 (TOR), 2219 (RPR)					
Heterogeneity: Tau^2=0; Chi^2=26.73, df=34(P=0.81); I^2=0%					
Test for overall effect: Z=2.16(P=0.03)					

Analysis 1.2. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 2 Subjective cure and improvement (short term, ≤ 1 year).

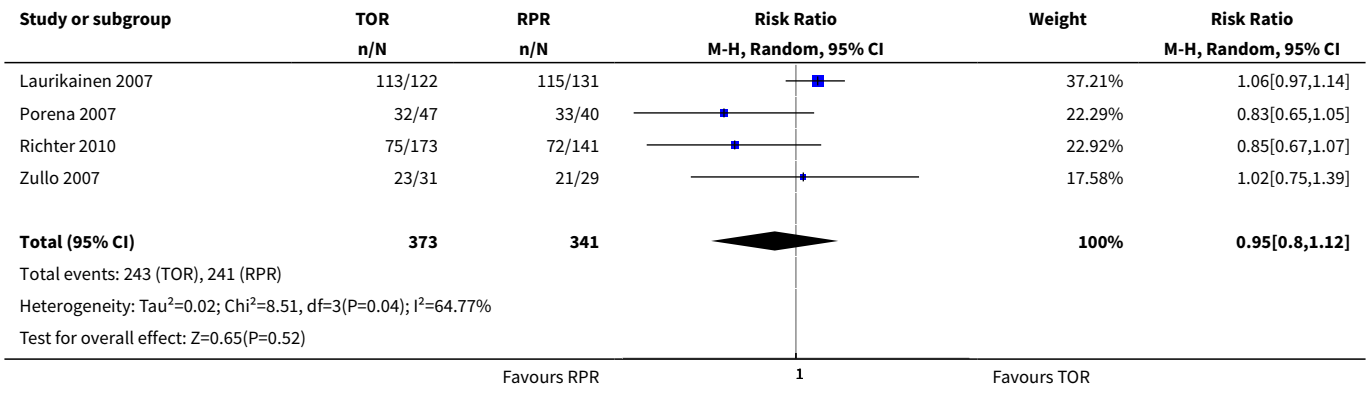


Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aigmuller 2014	116/122	136/139		16.15%	0.97[0.93,1.02]
Kim 2005	62/65	63/65		8%	0.98[0.92,1.05]
Krofta 2010	143/147	138/141		17.89%	0.99[0.96,1.03]
Lee 2007	57/60	56/60		7.11%	1.02[0.93,1.11]
Nerli 2009	18/18	18/18		2.35%	1[0.9,1.11]
Porena 2007	68/75	63/70		8.28%	1.01[0.91,1.12]
Rechberger 2009	174/197	185/201		23.26%	0.96[0.9,1.02]
Scheiner 2012	65/71	63/65		8.35%	0.94[0.87,1.03]
Wang 2008	33/34	34/35		4.26%	1[0.92,1.08]
Wang 2011	36/36	32/32		4.36%	1[0.94,1.06]
Total (95% CI)	**825**	**826**		**100%**	**0.98[0.96,1]**
Total events: 772 (TOR), 788 (RPR)					
Heterogeneity: Tau^2=0; Chi^2=3.57, df=9(P=0.94); I^2=0%					
Test for overall effect: Z=1.61(P=0.11)					

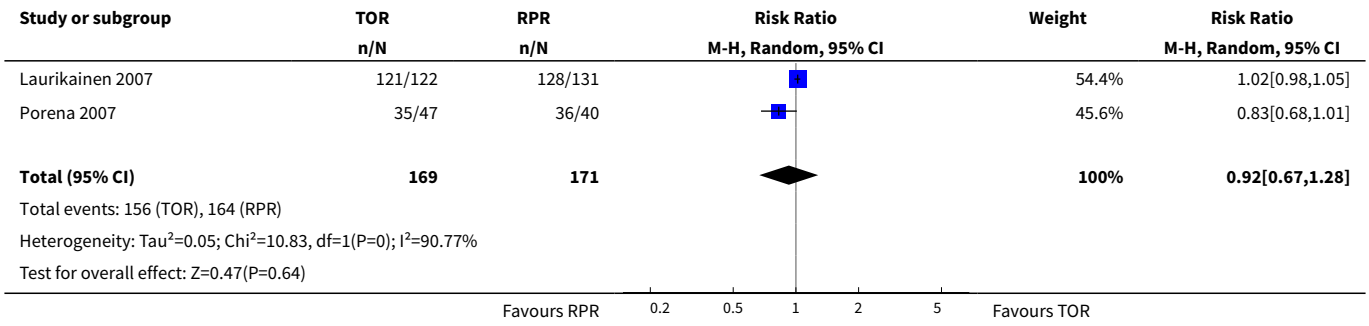
Analysis 1.3. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 3 Subjective cure (medium term, 1 to 5 years).



Analysis 1.4. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 4 Subjective cure (long term, > 5 years).

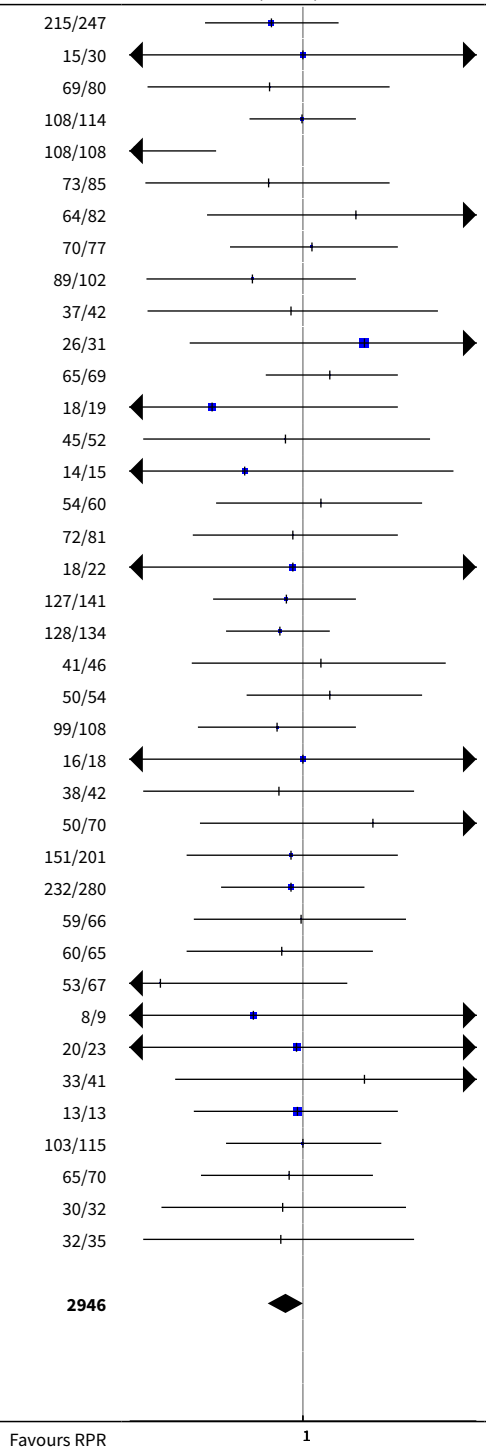


Analysis 1.5. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 5 Subjective cure and improvement (long term, > 5 years).



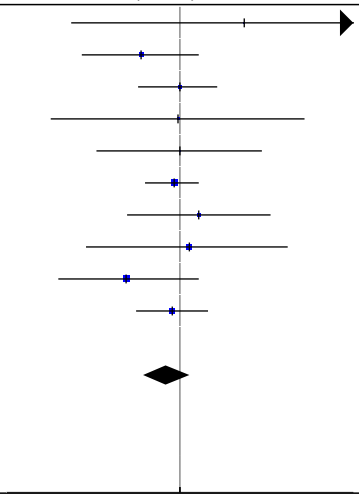
Analysis 1.6. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 6 Objective cure (short term, ≤ 1 year).

Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aigmuller 2014	196/233	215/247		8.07%	0.97[0.9,1.04]
Alkady 2009	15/30	15/30		0.58%	1[0.6,1.66]
Andonian 2007	64/77	69/80		2.62%	0.96[0.84,1.1]
Aniuliene 2009	142/150	108/114		4.75%	1[0.94,1.06]
Araco 2008	83/100	108/108		4.04%	0.83[0.76,0.91]
Barber 2008	62/75	73/85		2.65%	0.96[0.84,1.1]
Barry 2008	48/58	64/82		2.05%	1.06[0.9,1.25]
Chen 2010	101/110	70/77		3.18%	1.01[0.92,1.11]
Chen 2012	85/103	89/102		3.46%	0.95[0.84,1.06]
David-Montefiore 2006	40/46	37/42		1.5%	0.99[0.84,1.16]
de Tayrac 2004	27/30	26/31		0.99%	1.07[0.88,1.3]
Deffieux 2010	67/69	65/69		2.51%	1.03[0.96,1.11]
El-Hefnawy 2010	18/21	18/19		0.73%	0.9[0.74,1.11]
Enzelsberger 2005	45/53	45/52		1.76%	0.98[0.84,1.15]
Jakimiuk 2012	14/16	14/15		0.56%	0.94[0.75,1.18]
Kamel 2009	55/60	54/60		2.09%	1.02[0.91,1.14]
Karateke 2009	73/83	72/81		2.82%	0.99[0.89,1.11]
Kim 2005	17/21	18/22		0.68%	0.99[0.74,1.32]
Krofta 2010	130/147	127/141		5.01%	0.98[0.91,1.06]
Laurikainen 2007	122/131	128/134		4.89%	0.97[0.92,1.03]
Liapis 2006	39/43	41/46		1.53%	1.02[0.89,1.17]
Mansoor 2003	46/48	50/54		1.82%	1.03[0.94,1.14]
Meschia 2007	98/110	99/108		3.86%	0.97[0.89,1.06]
Nerli 2009	16/18	16/18		0.62%	1[0.79,1.26]
Oliveira 2006	37/42	38/42		1.47%	0.97[0.84,1.13]
Porena 2007	58/75	50/70		2%	1.08[0.89,1.31]
Rechberger 2009	146/197	151/201		5.78%	0.99[0.88,1.11]
Richter 2010	233/285	232/280		9.05%	0.99[0.91,1.07]
Riva 2006	58/65	59/66		2.26%	1[0.89,1.12]
Scheiner 2012	64/71	60/65		2.42%	0.98[0.88,1.08]
Schierlitz 2008	48/71	53/67		2.11%	0.85[0.7,1.05]
Tanuri 2010	16/19	8/9		0.42%	0.95[0.7,1.28]
Tarcan 2011	19/22	20/23		0.76%	0.99[0.79,1.25]
Teo 2011	25/29	33/41		1.06%	1.07[0.87,1.32]
van Leijsen 2013	57/59	13/13		0.85%	0.99[0.89,1.11]
Wang 2009	106/118	103/115		4.03%	1[0.92,1.09]
Wang 2010	64/70	65/70		2.51%	0.98[0.89,1.08]
Wang 2011	33/36	30/32		1.23%	0.98[0.86,1.12]
Zullo 2007	33/37	32/35		1.27%	0.98[0.84,1.13]
Total (95% CI)	**3028**	**2946**		**100%**	**0.98[0.96,1]**
Total events: 2600 (TOR), 2568 (RPR)					
Heterogeneity: Tau^2=0; Chi^2=24.86, df=38(P=0.95); I^2=0%					
Test for overall effect: Z=1.9(P=0.06)					



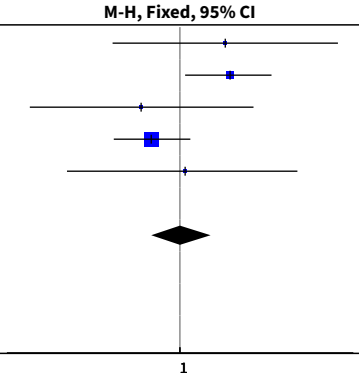
Analysis 1.7. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 7 Objective cure and improvement (short term, ≤ 1 year).

Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Alkady 2009	15/15	14/15		2.04%	1.07[0.89,1.28]
Chen 2012	96/103	99/102		13.99%	0.96[0.9,1.02]
David-Montefiore 2006	46/46	42/42		6.24%	1[0.96,1.04]
de Tayrac 2004	28/30	29/31		4.01%	1[0.87,1.14]
Kim 2005	21/21	22/22		3.09%	1[0.92,1.09]
Krofta 2010	144/147	139/141		19.96%	0.99[0.96,1.02]
Liapis 2006	42/43	44/46		5.98%	1.02[0.95,1.1]
Porena 2007	68/75	63/70		9.17%	1.01[0.91,1.12]
Rechberger 2009	138/156	131/140		19.42%	0.95[0.88,1.02]
Wang 2009	115/118	113/115		16.1%	0.99[0.95,1.03]
Total (95% CI)	**754**	**724**		**100%**	**0.98[0.96,1.01]**
Total events: 713 (TOR), 696 (RPR)					
Heterogeneity: Tau^2=0; Chi^2=4.84, df=9(P=0.85); I^2=0%					
Test for overall effect: Z=1.35(P=0.18)					



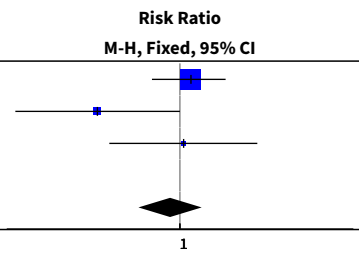
Analysis 1.8. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 8 Objective cure (medium term, 1 to 5 years).

Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
David-Montefiore 2006	32/37	27/34		10.51%	1.09[0.88,1.35]
Deffieux 2010	65/65	61/67		22.64%	1.1[1.01,1.19]
El-Hefnawy 2010	28/35	31/36		11.42%	0.93[0.75,1.15]
Laurikainen 2007	113/126	124/131		45.43%	0.95[0.88,1.02]
Wang 2009	25/30	29/35		10%	1.01[0.81,1.25]
Total (95% CI)	**293**	**303**		**100%**	**1[0.95,1.06]**
Total events: 263 (TOR), 272 (RPR)					
Heterogeneity: Tau^2=0; Chi^2=8.42, df=4(P=0.08); I^2=52.47%					
Test for overall effect: Z=0(P=1)					



Analysis 1.9. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 9 Objective cure (long term, > 5 years).

Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Laurikainen 2007	106/122	111/131		62.71%	1.03[0.93,1.13]
Porena 2007	33/47	35/40		22.15%	0.8[0.64,1]
Zullo 2007	27/31	25/29		15.13%	1.01[0.83,1.23]
Total (95% CI)	**200**	**200**		**100%**	**0.97[0.9,1.06]**



Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Total events: 166 (TOR), 171 (RPR)					
Heterogeneity: Tau²=0; Chi²=4.13, df=2(P=0.13); I²=51.54%					
Test for overall effect: Z=0.62(P=0.53)					

Favours RPR 1 Favours TOR

Analysis 1.10. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 10 Operative time (minutes).

Study or subgroup	TOR N	TOR Mean(SD)	RPR N	RPR Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Aigmuller 2014	269	16.8 (8.8)	285	21 (12.2)		3.62%	-4.2[-5.97,-2.43]
Aniuliene 2009	150	19 (5.6)	114	27 (7.1)		3.65%	-8[-9.58,-6.42]
Araco 2008	120	34 (11)	120	48 (7)		3.53%	-14[-16.33,-11.67]
Barber 2008	88	28 (7)	82	29 (10)		3.47%	-1[-3.61,1.61]
Barry 2008	58	14.6 (6)	82	18.5 (6.5)		3.57%	-3.9[-5.99,-1.81]
Chen 2010	45	20 (13.5)	77	48.2 (21.9)		2.55%	-28.2[-34.48,-21.92]
Chen 2012	103	18.5 (7.4)	102	27.3 (13.3)		3.4%	-8.8[-11.75,-5.85]
Darabi Mahboub 2012	40	64 (9.5)	40	64.5 (9)		3.13%	-0.5[-4.56,3.56]
David-Montefiore 2006	46	17 (6.6)	42	21 (9.5)		3.29%	-4[-7.45,-0.55]
de Tayrac 2004	30	14.8 (4.3)	31	26.5 (7.7)		3.36%	-11.7[-14.82,-8.58]
Deffieux 2010	74	18.7 (8)	75	20.3 (9)		3.45%	-1.6[-4.33,1.13]
El-Hefnawy 2010	21	19.6 (5)	19	23.8 (5)		3.37%	-4.2[-7.3,-1.1]
Enzelsberger 2005	53	15 (7)	52	26 (10)		3.32%	-11[-14.31,-7.69]
Freeman 2011	99	28 (15)	88	30 (14.2)		3.1%	-2[-6.19,2.19]
Jakimiuk 2012	16	12.4 (3.5)	19	47.8 (42.9)		0.68%	-35.35[-54.71,-15.99]
Karateke 2009	84	18.6 (2.5)	83	31.3 (4.7)		3.7%	-12.67[-13.82,-11.52]
Kilic 2007	10	26 (9.5)	10	32 (5.3)		2.43%	-6[-12.74,0.74]
Kim 2005	65	26.8 (11.8)	65	31.6 (9.6)		3.23%	-4.8[-8.5,-1.1]
Krofta 2010	151	23.8 (12)	149	32.6 (9.3)		3.51%	-8.86[-11.29,-6.43]
Laurikainen 2007	131	29 (8)	136	29 (16)		3.39%	0[-3.02,3.02]
Lee 2007	60	11.5 (1.4)	60	15.2 (1.8)		3.74%	-3.7[-4.28,-3.12]
Liapis 2006	43	17.4 (6.9)	46	26.7 (8.6)		3.34%	-9.3[-12.53,-6.07]
Meschia 2007	117	17 (7)	114	26 (9)		3.57%	-9[-11.08,-6.92]
Nerli 2009	18	18.4 (1.9)	18	21.4 (2.8)		3.65%	-3[-4.53,-1.47]
Rechberger 2009	268	12 (4)	201	23 (5)		3.72%	-11[-11.84,-10.16]
Scheiner 2012	40	25.8 (9.7)	80	26.7 (11.5)		3.17%	-0.9[-4.82,3.02]
Tarcan 2011	27	33.4 (13.9)	27	39.1 (17.7)		2.01%	-5.7[-14.19,2.79]
Wang 2006	31	33.8 (8.4)	29	39.7 (12.2)		2.8%	-5.88[-11.21,-0.55]
Wang 2008	35	18 (5)	35	27 (5)		3.52%	-9[-11.34,-6.66]
Wang 2011	36	16.2 (1.5)	32	34.5 (6.3)		3.54%	-18.3[-20.54,-16.06]
Zullo 2007	37	16.9 (6.2)	35	28.3 (9.8)		3.2%	-11.4[-15.21,-7.59]
Total * **	**2365**		**2348**			**100%**	**-7.54[-9.31,-5.77]**
Heterogeneity: Tau²=21.65; Chi²=656.66, df=30(P<0.0001); I²=95.43%							
Test for overall effect: Z=8.36(P<0.0001)							

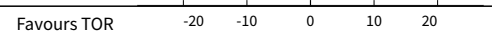
Favours TOR -20 -10 0 10 20 Favours RPR

Analysis 1.11. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 11 Operative blood loss (ml).

Study or subgroup	TOR N	TOR Mean(SD)	RPR N	RPR Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Alkady 2009	15	22 (7.2)	15	26 (10.2)		8.25%	-4[-10.32,2.32]
Barry 2008	58	49 (31.2)	82	64 (41.4)		6.58%	-15[-27.03,-2.97]
Chen 2012	103	15 (17.6)	102	18 (15.4)		8.66%	-3[-7.53,1.53]
El-Hefnawy 2010	21	40 (13)	19	52 (14)		7.68%	-12[-20.4,-3.6]
Freeman 2011	96	48.7 (45.9)	83	61.7 (65)		5.22%	-13[-29.73,3.73]
Krofta 2010	151	32.3 (34.8)	149	31.6 (31.9)		7.92%	0.69[-6.86,8.24]
Laurikainen 2007	131	46 (57)	136	55 (86)		5.03%	-9[-26.44,8.44]
Lee 2007	60	31.1 (28.6)	60	40 (23.8)		7.38%	-8.9[-18.31,0.51]
Meschia 2007	117	27 (33)	114	31 (25)		7.93%	-4[-11.54,3.54]
Nerli 2009	18	18.4 (1.9)	18	38.7 (5.1)		8.98%	-20.3[-22.8,-17.8]
Scheiner 2012	40	31.5 (22.2)	80	34.4 (36.5)		7.04%	-2.9[-13.45,7.65]
Wang 2006	31	117.2 (79.4)	29	125.1 (81.2)		1.68%	-7.93[-48.61,32.75]
Wang 2008	34	20 (7)	35	21 (6)		8.91%	-1[-4.08,2.08]
Zullo 2007	37	42.5 (8.6)	35	38.9 (9.4)		8.73%	3.6[-0.57,7.77]
Total ***	**912**		**957**			**100%**	**-6.49[-12.33,-0.65]**

Heterogeneity: Tau²=97.23; Chi²=158.23, df=13(P<0.0001); I²=91.78%

Test for overall effect: Z=2.18(P=0.03)

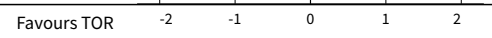


Analysis 1.12. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 12 Length of hospital stay (days).

Study or subgroup	TOR N	TOR Mean(SD)	RPR N	RPR Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Alkady 2009	15	1.2 (0.9)	15	1.1 (1)		5.5%	0.1[-0.58,0.78]
Aniuliene 2009	150	1.5 (0.5)	114	4 (1.6)		6.67%	-2.5[-2.8,-2.2]
Chen 2010	77	5 (2.4)	45	4 (2.2)		4.94%	1[0.16,1.84]
Chen 2012	13	3.1 (1.8)	102	3.4 (2.1)		4.19%	-0.3[-1.36,0.76]
Darabi Mahboub 2012	40	2.5 (0.5)	40	2.6 (0.5)		6.85%	-0.04[-0.25,0.17]
David-Montefiore 2006	46	1.4 (0.5)	42	1.8 (1.7)		6.01%	-0.4[-0.93,0.13]
de Tayrac 2004	30	1.2 (1.3)	31	1.1 (0.4)		6.16%	0.1[-0.39,0.59]
Jakimiuk 2012	16	2 (0)	19	2.4 (1.4)		5.73%	-0.41[-1.03,0.21]
Karateke 2009	84	1.3 (0.7)	83	1.4 (0.8)		6.85%	-0.11[-0.33,0.11]
Laurikainen 2007	131	0.7 (0.6)	136	0.6 (0.4)		6.98%	0.13[0.01,0.25]
Liapis 2006	43	1 (0.2)	46	1.3 (1.3)		6.44%	-0.22[-0.61,0.17]
Meschia 2007	117	1.6 (0.8)	114	1.8 (1)		6.82%	-0.2[-0.43,0.03]
Scheiner 2012	40	3.2 (0.5)	80	3.5 (1.1)		6.71%	-0.3[-0.59,-0.01]
Wang 2006	31	3.4 (1.5)	29	3.9 (1.4)		5.33%	-0.48[-1.21,0.25]
Wang 2008	34	3.2 (2.2)	35	3.9 (4.4)		2.69%	-0.7[-2.33,0.93]
Wang 2009	146	3.9 (2.8)	154	3.6 (2.9)		5.63%	0.3[-0.35,0.95]
Zullo 2007	37	1.1 (0.3)	35	1.2 (1.1)		6.49%	-0.1[-0.48,0.28]
Total ***	**1050**		**1120**			**100%**	**-0.25[-0.59,0.09]**

Heterogeneity: Tau²=0.43; Chi²=264.87, df=16(P<0.0001); I²=93.96%

Test for overall effect: Z=1.43(P=0.15)

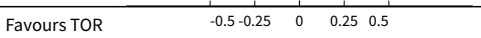


Analysis 1.13. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 13 Time to return to normal activity level (weeks).

Study or subgroup	TOR N	TOR Mean(SD)	RPR N	RPR Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Karateke 2009	84	2.4 (2)	83	2.7 (2.4)		2.51%	-0.27[-0.94,0.4]
Laurikainen 2007	131	1.7 (0.6)	136	1.7 (0.6)		60.73%	0[-0.14,0.14]
Lee 2007	60	4.9 (3.3)	60	5.2 (3.3)		0.81%	-0.3[-1.48,0.88]
Zullo 2007	37	2 (0.2)	35	2.1 (0.5)		35.95%	-0.1[-0.28,0.08]
Total ***	**312**		**314**			**100%**	**-0.05[-0.15,0.06]**

Heterogeneity: $Tau^2=0$; $Chi^2=1.39$, df=3(P=0.71); $I^2=0\%$

Test for overall effect: Z=0.83(P=0.41)



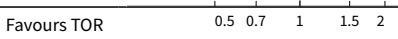
Analysis 1.14. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 14 Perioperative complications.

Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Andonian 2007	11/77	6/80		4.19%	1.9[0.74,4.9]
Araco 2008	6/120	21/120		14.96%	0.29[0.12,0.68]
Barry 2008	0/58	2/82		1.48%	0.28[0.01,5.75]
David-Montefiore 2006	5/46	9/42		6.7%	0.51[0.18,1.39]
Enzelsberger 2005	6/53	10/52		7.19%	0.59[0.23,1.5]
Kim 2005	1/21	2/22		1.39%	0.52[0.05,5.36]
Laurikainen 2007	32/131	22/136		15.38%	1.51[0.93,2.46]
Liapis 2006	2/43	11/46		7.57%	0.19[0.05,0.83]
Meschia 2007	6/99	7/107		4.79%	0.93[0.32,2.66]
Porena 2007	14/75	13/70		9.58%	1.01[0.51,1.99]
Riva 2006	4/65	4/66		2.83%	1.02[0.27,3.89]
Schierlitz 2008	7/82	3/80		2.16%	2.28[0.61,8.5]
Wang 2006	4/31	2/29		1.47%	1.87[0.37,9.46]
Wang 2009	27/146	24/154		16.64%	1.19[0.72,1.96]
Zullo 2007	2/37	5/35		3.66%	0.38[0.08,1.82]
Total (95% CI)	**1084**	**1121**		**100%**	**0.91[0.73,1.14]**

Total events: 127 (TOR), 141 (RPR)

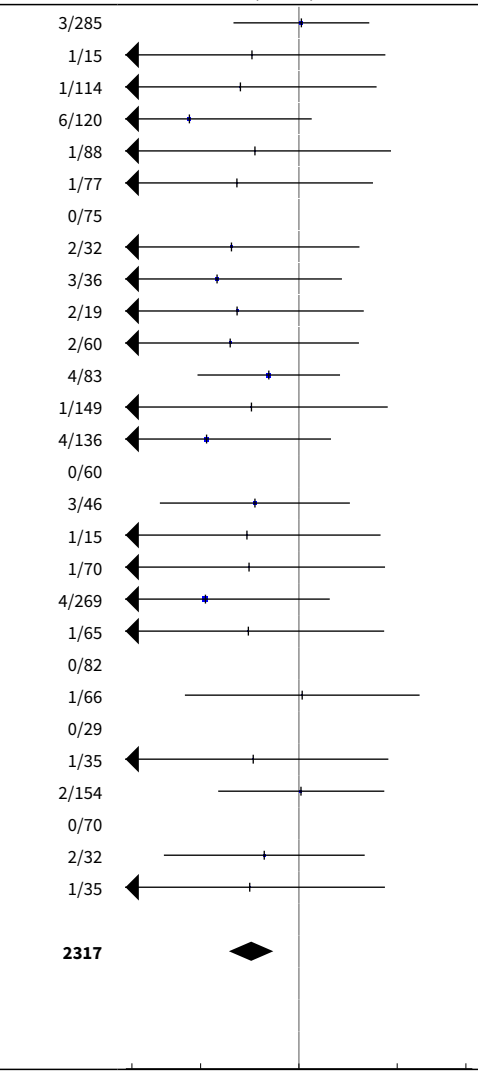
Heterogeneity: $Tau^2=0$; $Chi^2=25.53$, df=14(P=0.03); $I^2=45.16\%$

Test for overall effect: Z=0.78(P=0.43)



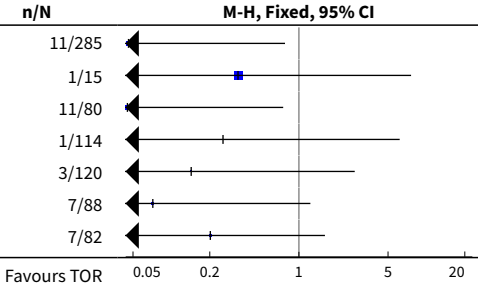
Analysis 1.15. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 15 Major vascular or visceral injury.

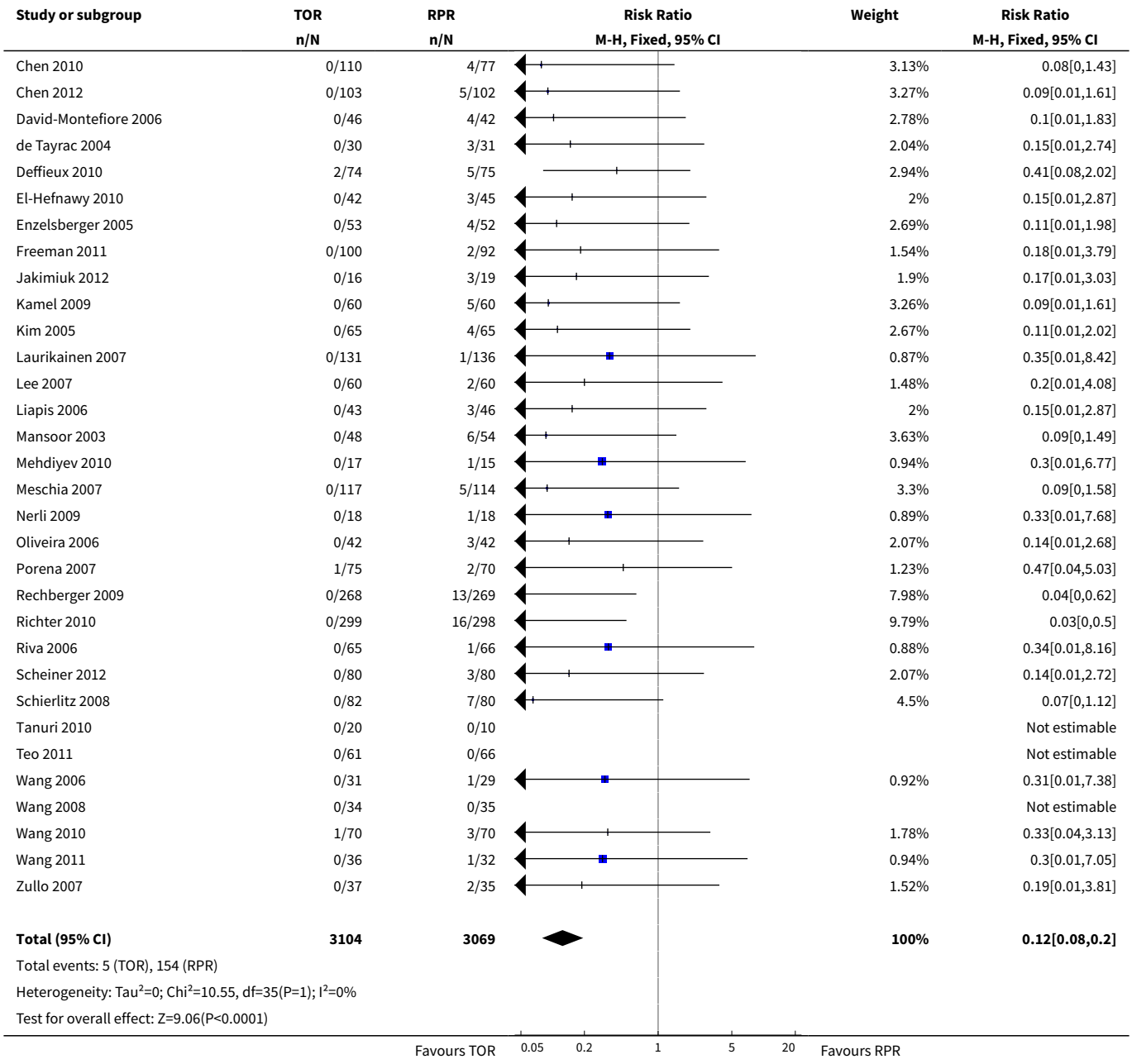
Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aigmuller 2014	3/269	3/285		5.14%	1.06[0.22,5.2]
Alkady 2009	0/15	1/15		2.65%	0.33[0.01,7.58]
Aniuliene 2009	0/150	1/114		3.01%	0.25[0.01,6.17]
Araco 2008	0/120	6/120		11.48%	0.08[0,1.35]
Barber 2008	0/82	1/88		2.56%	0.36[0.01,8.65]
Chen 2010	0/110	1/77		3.11%	0.23[0.01,5.67]
Deffieux 2010	0/74	0/75			Not estimable
Diab 2012	0/31	2/32		4.35%	0.21[0.01,4.13]
El-Hefnawy 2010	0/35	3/36		6.1%	0.15[0.01,2.74]
Jakimiuk 2012	0/16	2/19		4.06%	0.24[0.01,4.57]
Kamel 2009	0/60	2/60		4.41%	0.2[0.01,4.08]
Karateke 2009	2/84	4/83		7.11%	0.49[0.09,2.62]
Krofta 2010	0/151	1/149		2.67%	0.33[0.01,8.01]
Laurikainen 2007	0/131	4/136		7.8%	0.12[0.01,2.12]
Lee 2007	0/60	0/60			Not estimable
Liapis 2006	1/43	3/46		5.12%	0.36[0.04,3.3]
Mehdiyev 2010	0/17	1/15		2.8%	0.3[0.01,6.77]
Porena 2007	0/75	1/70		2.74%	0.31[0.01,7.52]
Rechberger 2009	0/268	4/269		7.93%	0.11[0.01,2.06]
Scheiner 2012	0/71	1/65		2.76%	0.31[0.01,7.37]
Schierlitz 2008	0/82	0/82			Not estimable
Teo 2011	1/61	1/66		1.7%	1.08[0.07,16.92]
Wang 2006	0/31	0/29			Not estimable
Wang 2008	0/34	1/35		2.61%	0.34[0.01,8.13]
Wang 2009	2/146	2/154		3.44%	1.05[0.15,7.39]
Wang 2010	0/70	0/70			Not estimable
Wang 2011	1/36	2/32		3.74%	0.44[0.04,4.67]
Zullo 2007	0/37	1/35		2.72%	0.32[0.01,7.5]
Total (95% CI)	**2359**	**2317**		**100%**	**0.33[0.19,0.55]**
Total events: 10 (TOR), 48 (RPR)					
Heterogeneity: Tau^2=0; Chi^2=7.12, df=22(P=1); I^2=0%					
Test for overall effect: Z=4.23(P<0.0001)					



Analysis 1.16. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 16 Bladder or urethral perforation.

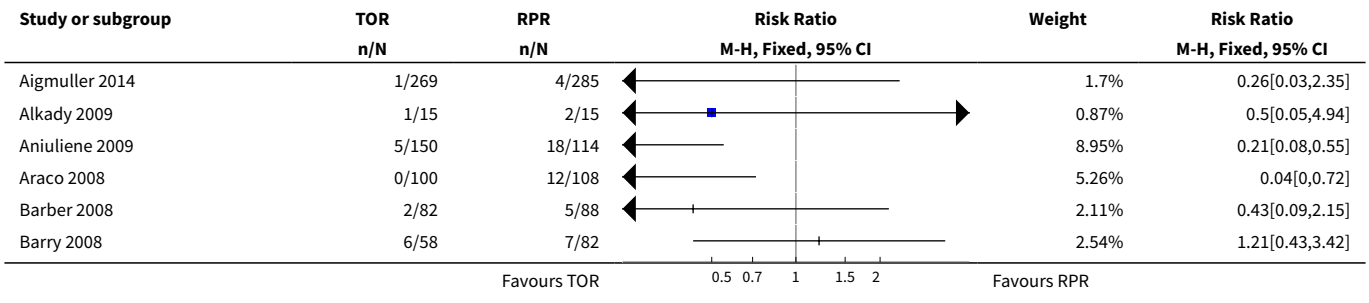
Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aigmuller 2014	0/269	11/285		6.61%	0.05[0,0.78]
Alkady 2009	0/15	1/15		0.89%	0.33[0.01,7.58]
Andonian 2007	0/77	11/80		6.68%	0.05[0,0.75]
Aniuliene 2009	0/150	1/114		1.01%	0.25[0.01,6.17]
Araco 2008	0/120	3/120		2.07%	0.14[0.01,2.74]
Barber 2008	0/82	7/88		4.29%	0.07[0,1.23]
Barry 2008	1/58	7/82		3.43%	0.2[0.03,1.6]





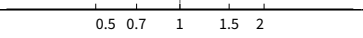
Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Chen 2010	0/110	4/77		3.13%	0.08[0,1.43]
Chen 2012	0/103	5/102		3.27%	0.09[0.01,1.61]
David-Montefiore 2006	0/46	4/42		2.78%	0.1[0.01,1.83]
de Tayrac 2004	0/30	3/31		2.04%	0.15[0.01,2.74]
Deffieux 2010	2/74	5/75		2.94%	0.41[0.08,2.02]
El-Hefnawy 2010	0/42	3/45		2%	0.15[0.01,2.87]
Enzelsberger 2005	0/53	4/52		2.69%	0.11[0.01,1.98]
Freeman 2011	0/100	2/92		1.54%	0.18[0.01,3.79]
Jakimiuk 2012	0/16	3/19		1.9%	0.17[0.01,3.03]
Kamel 2009	0/60	5/60		3.26%	0.09[0.01,1.61]
Kim 2005	0/65	4/65		2.67%	0.11[0.01,2.02]
Laurikainen 2007	0/131	1/136		0.87%	0.35[0.01,8.42]
Lee 2007	0/60	2/60		1.48%	0.2[0.01,4.08]
Liapis 2006	0/43	3/46		2%	0.15[0.01,2.87]
Mansoor 2003	0/48	6/54		3.63%	0.09[0,1.49]
Mehdiyev 2010	0/17	1/15		0.94%	0.3[0.01,6.77]
Meschia 2007	0/117	5/114		3.3%	0.09[0,1.58]
Nerli 2009	0/18	1/18		0.89%	0.33[0.01,7.68]
Oliveira 2006	0/42	3/42		2.07%	0.14[0.01,2.68]
Porena 2007	1/75	2/70		1.23%	0.47[0.04,5.03]
Rechberger 2009	0/268	13/269		7.98%	0.04[0,0.62]
Richter 2010	0/299	16/298		9.79%	0.03[0,0.5]
Riva 2006	0/65	1/66		0.88%	0.34[0.01,8.16]
Scheiner 2012	0/80	3/80		2.07%	0.14[0.01,2.72]
Schierlitz 2008	0/82	7/80		4.5%	0.07[0,1.12]
Tanuri 2010	0/20	0/10			Not estimable
Teo 2011	0/61	0/66			Not estimable
Wang 2006	0/31	1/29		0.92%	0.31[0.01,7.38]
Wang 2008	0/34	0/35			Not estimable
Wang 2010	1/70	3/70		1.78%	0.33[0.04,3.13]
Wang 2011	0/36	1/32		0.94%	0.3[0.01,7.05]
Zullo 2007	0/37	2/35		1.52%	0.19[0.01,3.81]
Total (95% CI)	**3104**	**3069**		**100%**	**0.12[0.08,0.2]**
Total events: 5 (TOR), 154 (RPR)					
Heterogeneity: Tau²=0; Chi²=10.55, df=35(P=1); I²=0%					
Test for overall effect: Z=9.06(P<0.0001)					

Analysis 1.17. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 17 Voiding dysfunction.



Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aigmuller 2014	1/269	4/285		1.7%	0.26[0.03,2.35]
Alkady 2009	1/15	2/15		0.87%	0.5[0.05,4.94]
Aniuliene 2009	5/150	18/114		8.95%	0.21[0.08,0.55]
Araco 2008	0/100	12/108		5.26%	0.04[0,0.72]
Barber 2008	2/82	5/88		2.11%	0.43[0.09,2.15]
Barry 2008	6/58	7/82		2.54%	1.21[0.43,3.42]

Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Chen 2010	5/110	7/77		3.6%	0.5[0.16,1.52]
Chen 2012	2/103	2/102		0.88%	0.99[0.14,6.9]
de Tayrac 2004	8/30	10/31		4.3%	0.83[0.38,1.81]
Deffieux 2010	2/65	6/67		2.58%	0.34[0.07,1.64]
Enzelsberger 2005	3/53	4/52		1.77%	0.74[0.17,3.13]
Freeman 2011	5/100	5/95		2.24%	0.95[0.28,3.18]
Jakimiuk 2012	0/16	2/19		1%	0.24[0.01,4.57]
Karateke 2009	6/84	8/83		3.52%	0.74[0.27,2.04]
Kim 2005	4/65	5/65		2.19%	0.8[0.22,2.85]
Laurikainen 2007	2/131	1/136		0.43%	2.08[0.19,22.62]
Lee 2007	0/60	0/60			Not estimable
Mansoor 2003	1/48	5/54		2.06%	0.23[0.03,1.86]
Meschia 2007	6/99	11/107		4.62%	0.59[0.23,1.53]
Nerli 2009	2/18	3/18		1.31%	0.67[0.13,3.53]
Nyyssonen 2014	4/46	7/47		3.03%	0.58[0.18,1.86]
Oliveira 2006	3/42	5/42		2.19%	0.6[0.15,2.35]
Porena 2007	6/75	7/70		3.17%	0.8[0.28,2.26]
Rechberger 2009	7/268	10/269		4.37%	0.7[0.27,1.82]
Richter 2010	5/299	16/298		7.01%	0.31[0.12,0.84]
Riva 2006	0/65	1/66		0.65%	0.34[0.01,8.16]
Scheiner 2012	2/80	3/80		1.31%	0.67[0.11,3.88]
Schierlitz 2008	4/82	9/80		3.99%	0.43[0.14,1.35]
Tanuri 2010	0/20	1/10		0.86%	0.17[0.01,3.94]
Teo 2011	1/61	3/66		1.26%	0.36[0.04,3.38]
van Leijsen 2013	7/80	5/31		3.15%	0.54[0.19,1.58]
Wang 2006	7/31	16/29		7.23%	0.41[0.2,0.85]
Wang 2008	4/34	4/35		1.72%	1.03[0.28,3.79]
Wang 2009	4/146	6/154		2.55%	0.7[0.2,2.44]
Wang 2010	6/70	8/70		3.5%	0.75[0.27,2.05]
Wang 2011	1/36	3/32		1.39%	0.3[0.03,2.71]
Zullo 2007	0/37	1/35		0.67%	0.32[0.01,7.5]
Total (95% CI)	**3128**	**3072**		**100%**	**0.53[0.43,0.65]**
Total events: 122 (TOR), 222 (RPR)					
Heterogeneity: Tau²=0; Chi²=21.14, df=35(P=0.97); I²=0%					
Test for overall effect: Z=5.98(P<0.0001)					

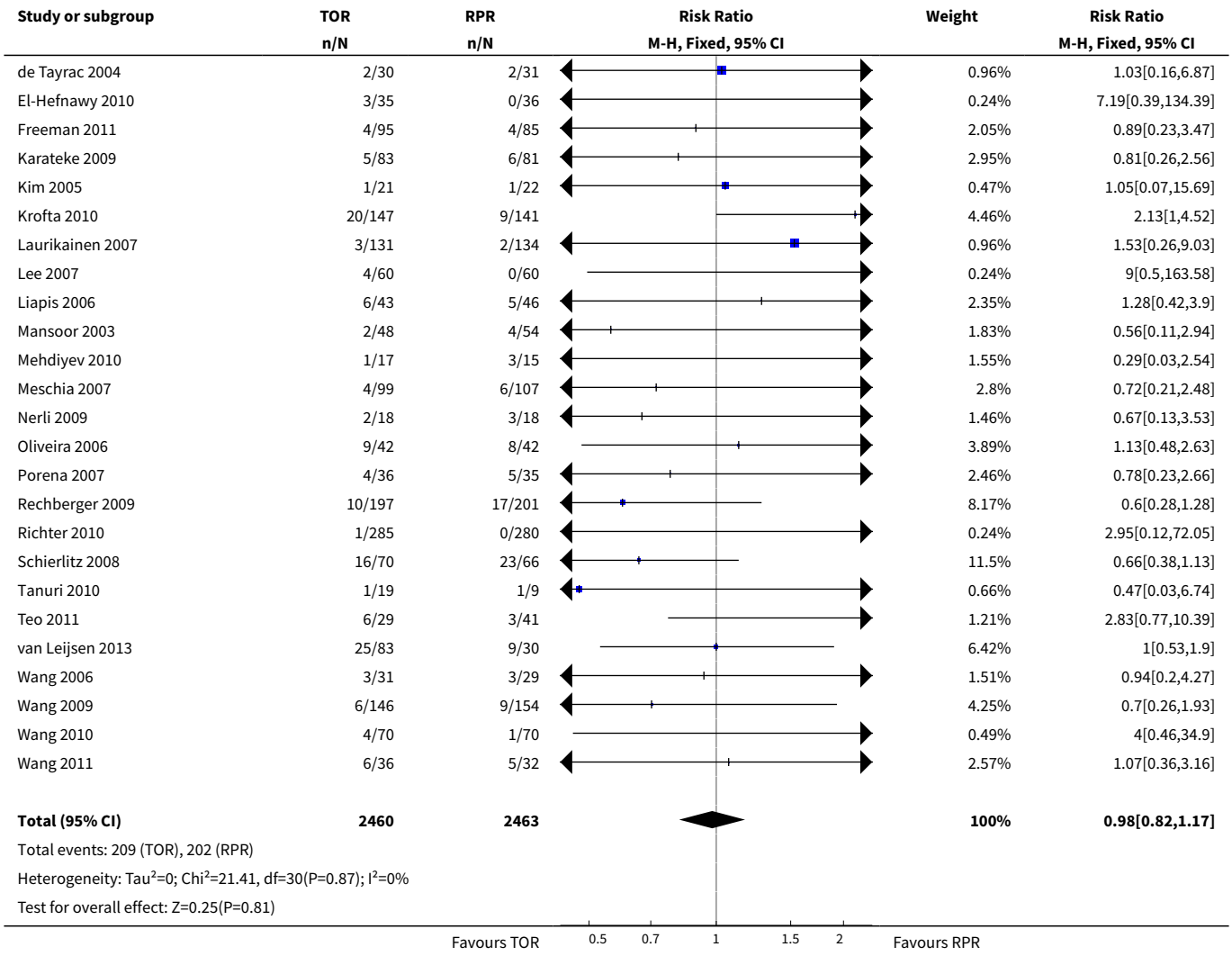


Favours TOR — Favours RPR

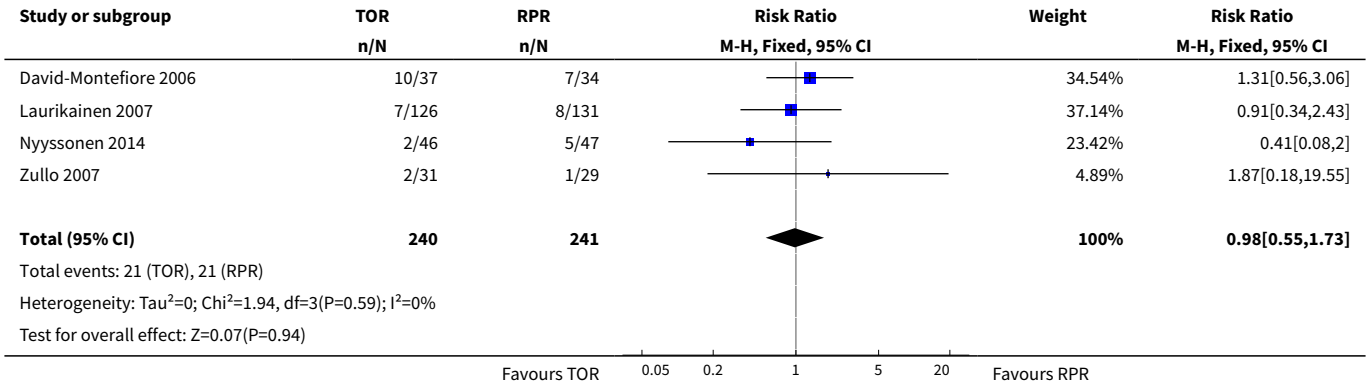
Analysis 1.18. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 18 De novo urgency or urgency incontinence (short term, ≤ 1 year).

Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aigmuller 2014	24/233	26/247		12.26%	0.98[0.58,1.65]
Andonian 2007	6/77	5/80		2.38%	1.25[0.4,3.92]
Araco 2008	6/100	8/108		3.74%	0.81[0.29,2.25]
Barber 2008	21/75	27/85		12.29%	0.88[0.55,1.42]
Barry 2008	0/58	1/82		0.61%	0.47[0.02,11.31]
David-Montefiore 2006	4/46	6/42		3.05%	0.61[0.18,2.01]

Favours TOR — Favours RPR

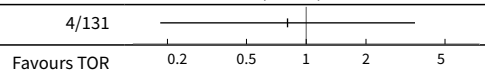


Analysis 1.19. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 19 De novo urgency or urgency incontinence (medium term, 1 to 5 years).



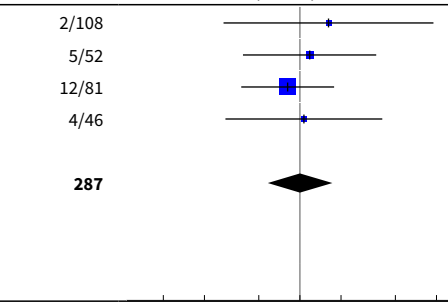
Analysis 1.20. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 20 De novo urgency or urgency incontinence (long term, > 5 years).

Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Laurikainen 2007	3/122	4/131		0.81[0.18,3.53]



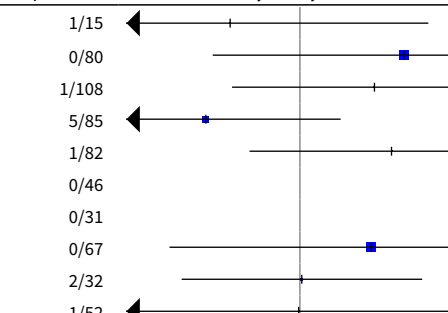
Analysis 1.21. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 21 Detrusor overactivity.

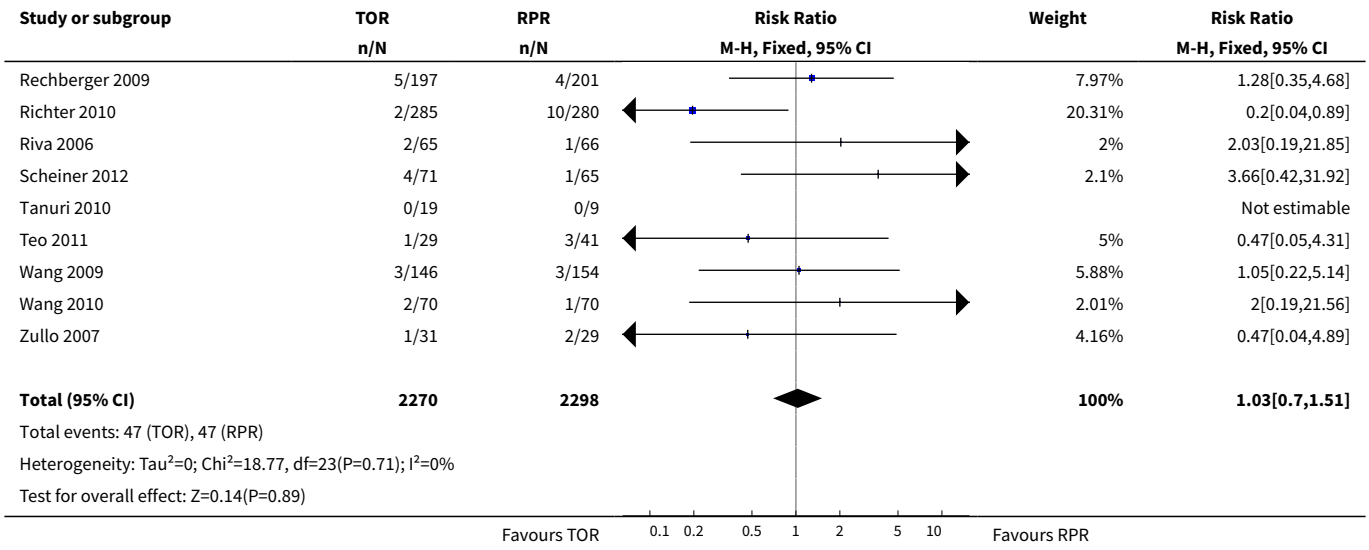
Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Araco 2008	3/100	2/108		8.37%	1.62[0.28,9.5]
Enzelsberger 2005	6/53	5/52		21.96%	1.18[0.38,3.62]
Karateke 2009	10/83	12/81		52.85%	0.81[0.37,1.78]
Liapis 2006	4/43	4/46		16.82%	1.07[0.29,4.01]
Total (95% CI)	**279**	**287**		**100%**	**1[0.58,1.73]**
Total events: 23 (TOR), 23 (RPR)					
Heterogeneity: Tau^2=0; Chi^2=0.65, df=3(P=0.89); I^2=0%					
Test for overall effect: Z=0.01(P=0.99)					



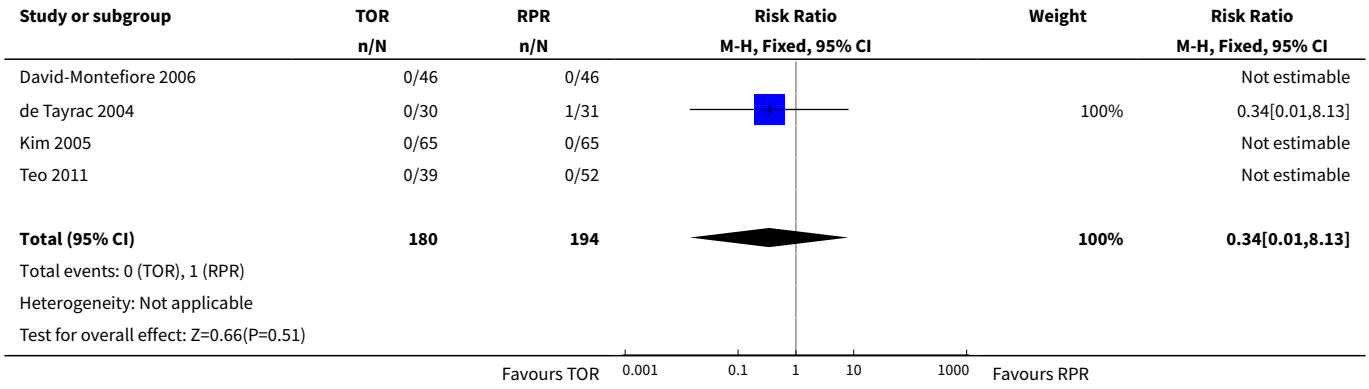
Analysis 1.22. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 22 Vaginal tape erosion.

Study or subgroup	TOR n/N	RPR n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Alkady 2009	0/15	1/15		3.02%	0.33[0.01,7.58]
Andonian 2007	2/77	0/80		0.99%	5.19[0.25,106.44]
Araco 2008	3/100	1/108		1.94%	3.24[0.34,30.64]
Barber 2008	1/75	5/85		9.44%	0.23[0.03,1.9]
Barry 2008	3/58	1/82		1.67%	4.24[0.45,39.76]
David-Montefiore 2006	0/46	0/46			Not estimable
de Tayrac 2004	0/30	0/31			Not estimable
Deffieux 2010	1/65	0/67		0.99%	3.09[0.13,74.52]
Diab 2012	2/31	2/32		3.96%	1.03[0.15,6.88]
Enzelsberger 2005	1/53	1/52		2.03%	0.98[0.06,15.28]
Freeman 2011	3/95	2/85		4.25%	1.34[0.23,7.84]
Karateke 2009	2/83	4/81		8.15%	0.49[0.09,2.59]
Kim 2005	0/65	0/65			Not estimable
Krofta 2010	2/147	2/141		4.11%	0.96[0.14,6.72]
Laurikainen 2007	1/136	0/134		1.01%	2.96[0.12,71.93]
Lee 2007	0/60	0/60			Not estimable
Liapis 2006	0/43	1/46		2.92%	0.36[0.01,8.51]
Nerli 2009	0/18	0/18			Not estimable
Nyyssonen 2014	2/43	0/43		1.01%	5[0.25,101.18]
Oliveira 2006	1/42	2/42		4.03%	0.5[0.05,5.31]
Porena 2007	3/75	0/70		1.04%	6.54[0.34,124.38]

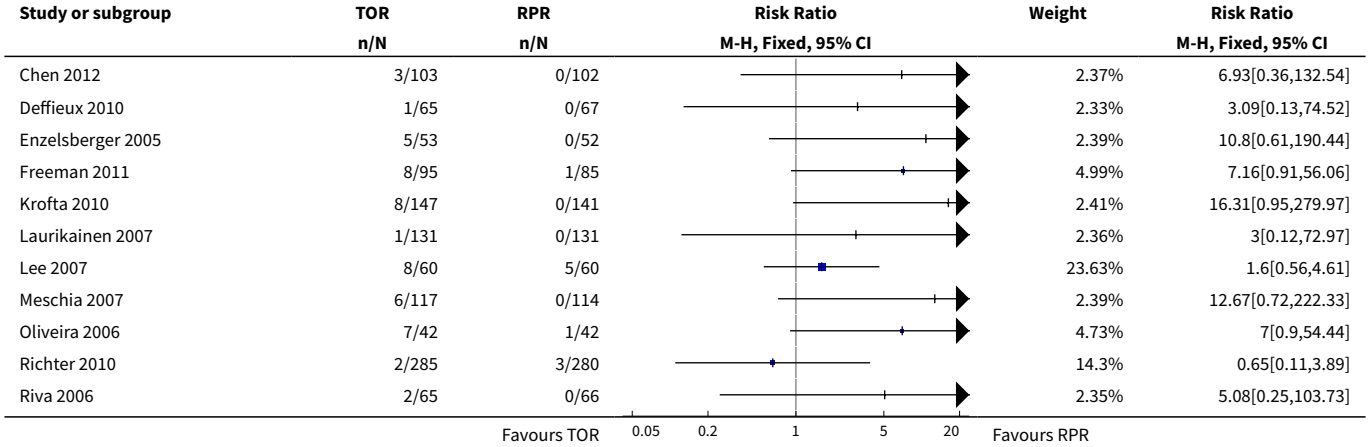


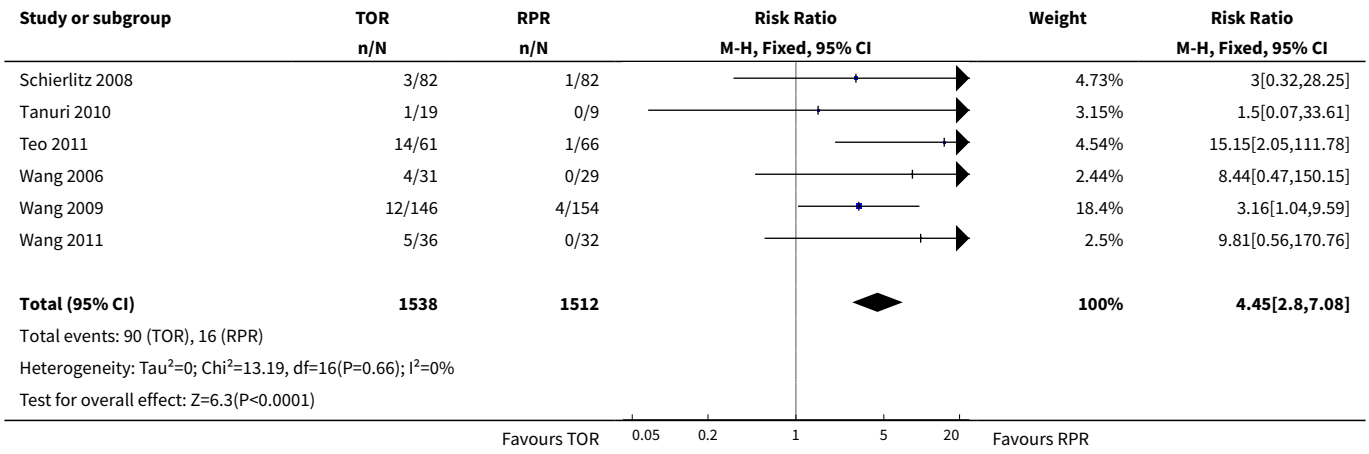


Analysis 1.23. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 23 Bladder/urethral erosion.

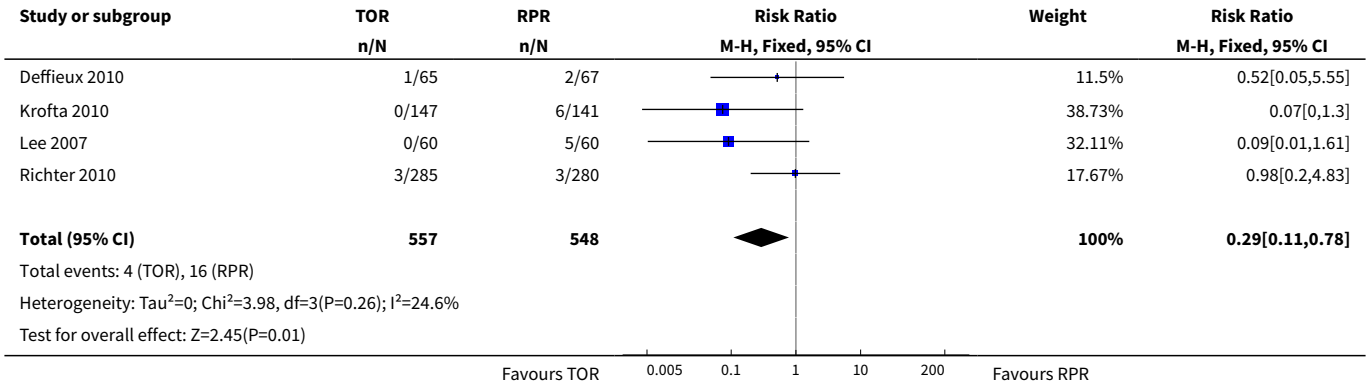


Analysis 1.24. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 24 Groin pain.

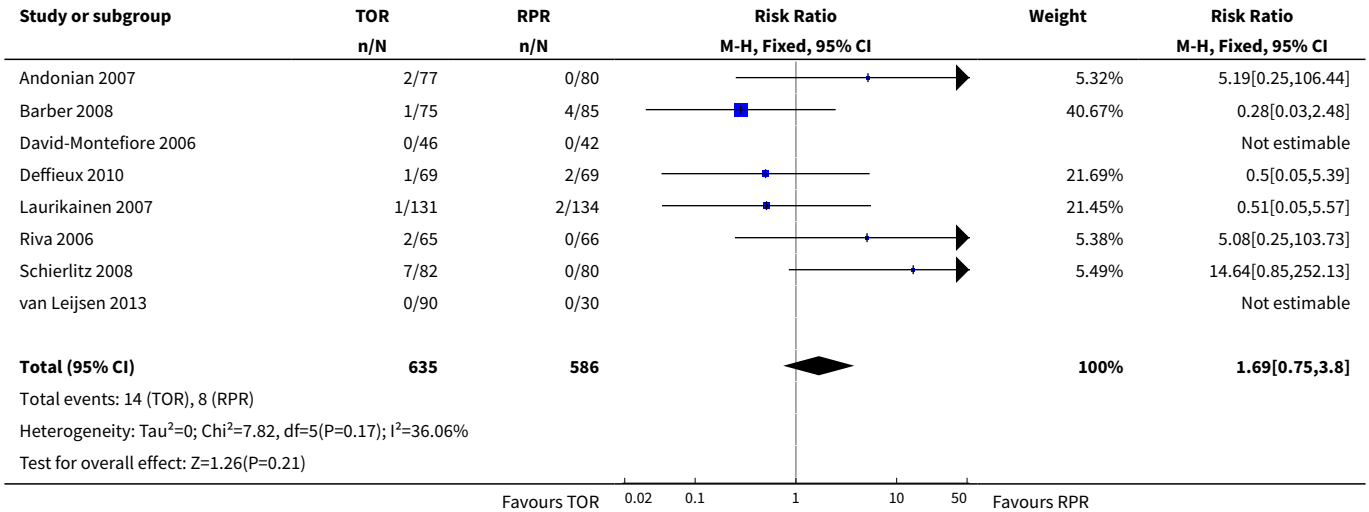




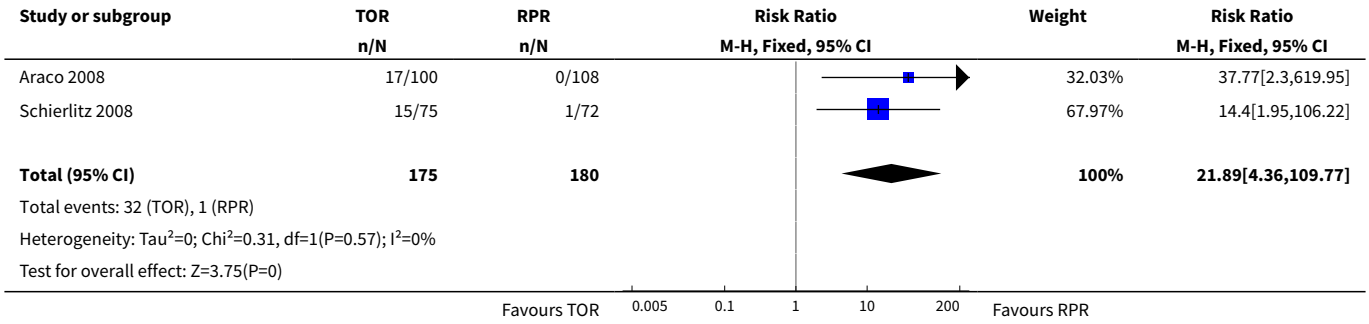
Analysis 1.25. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 25 Suprapubic pain.



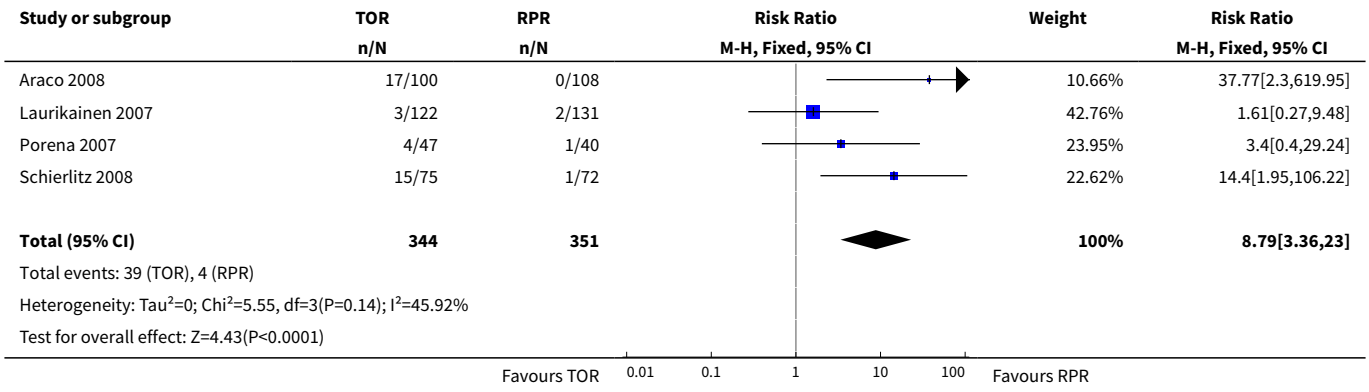
Analysis 1.26. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 26 Repeat incontinence surgery (short term, ≤ 1 year).



Analysis 1.27. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 27 Repeat incontinence surgery (medium term , 1 to 5 years).



Analysis 1.28. Comparison 1 Transobturator (TOR) versus retropubic route (RPR), Outcome 28 Repeat incontinence surgery (long term > 5 years).



Comparison 2. Retropubic bottom-to-top approach versus retropubic top-to-bottom approach

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Subjective cure (short term, ≤ 1 year)	3	477	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [1.01, 1.19]
2 Objective cure (short term, ≤ 1 year)	5	622	Risk Ratio (M-H, Random, 95% CI)	1.06 [0.97, 1.17]
3 Operative time (minutes)	2	124	Mean Difference (IV, Fixed, 95% CI)	-2.15 [-4.68, 0.38]
4 Length of hospital stay (days)	2	124	Mean Difference (IV, Fixed, 95% CI)	-0.03 [-0.37, 0.30]
5 Perioperative complications	4	507	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.53, 1.84]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6 Bladder or urethral perforation	5	631	Risk Ratio (M-H, Fixed, 95% CI)	0.55 [0.31, 0.98]
7 Voiding dysfunction	5	631	Risk Ratio (M-H, Fixed, 95% CI)	0.40 [0.18, 0.90]
8 De novo urgency or urgency incontinence	4	541	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.52, 1.34]
9 Detrusor overactivity	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
10 Vaginal tape erosion	4	563	Risk Ratio (M-H, Fixed, 95% CI)	0.27 [0.08, 0.95]
11 QoL specific	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

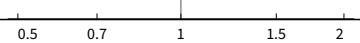
Analysis 2.1. Comparison 2 Retropubic bottom-to-top approach versus retropubic top-to-bottom approach, Outcome 1 Subjective cure (short term, ≤ 1 year).

Study or subgroup	Bottom-to-top n/N	Top-to-bottom n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Kim 2004	31/32	29/30		15.76%	1[0.91,1.1]
Lim 2005	48/58	45/57		23.89%	1.05[0.88,1.25]
Lord 2006	128/147	117/153		60.35%	1.14[1.02,1.27]
Total (95% CI)	**237**	**240**		**100%**	**1.1[1.01,1.19]**
Total events: 207 (Bottom-to-top), 191 (Top-to-bottom)					
Heterogeneity: Tau^2=0; Chi^2=4.41, df=2(P=0.11); I^2=54.64%					
Test for overall effect: Z=2.25(P=0.02)					

Favours top-to-bottom — Favours bottom-to-top

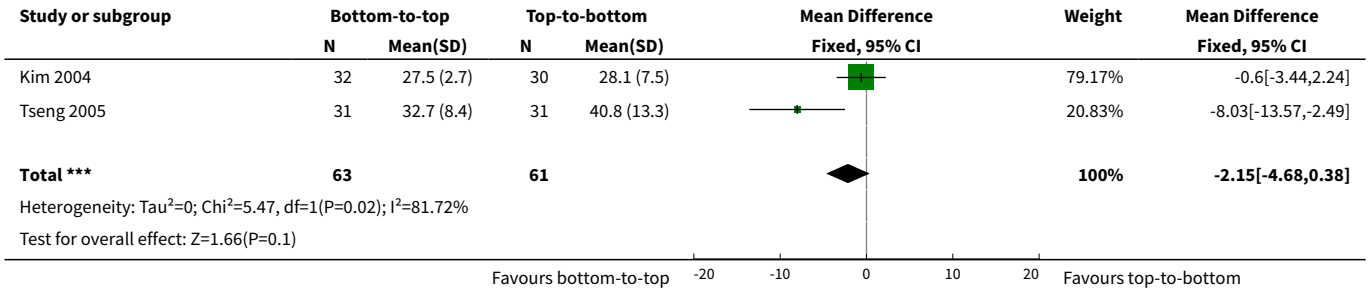
Analysis 2.2. Comparison 2 Retropubic bottom-to-top approach versus retropubic top-to-bottom approach, Outcome 2 Objective cure (short term, ≤ 1 year).

Study or subgroup	Bottom-to-top n/N	Top-to-bottom n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Andonian 2005	40/42	34/41		17.39%	1.15[0.98,1.34]
Kim 2004	31/32	29/30		25.15%	1[0.91,1.1]
Lim 2005	51/58	42/58		14.41%	1.21[1.01,1.46]
Lord 2006	143/147	148/152		31.31%	1[0.96,1.04]
Tseng 2005	27/31	25/31		11.75%	1.08[0.87,1.34]
Total (95% CI)	**310**	**312**		**100%**	**1.06[0.97,1.17]**
Total events: 292 (Bottom-to-top), 278 (Top-to-bottom)					
Heterogeneity: Tau^2=0.01; Chi^2=13.5, df=4(P=0.01); I^2=70.38%					
Test for overall effect: Z=1.28(P=0.2)					

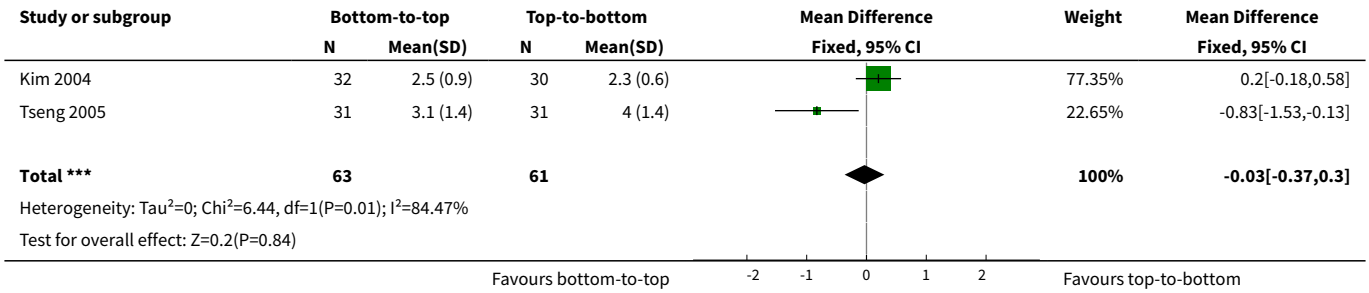


Favours top-to-bottom — Favours bottom-to-top

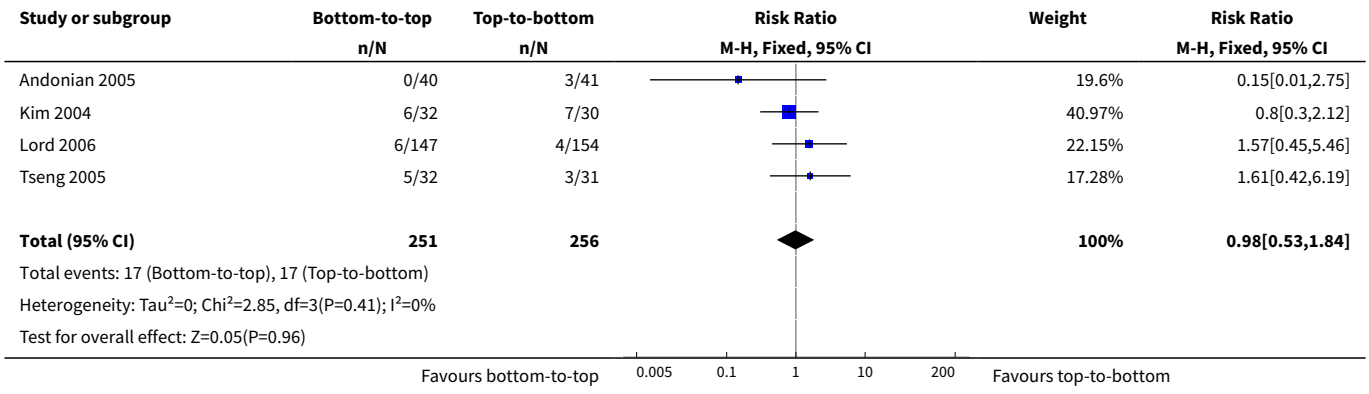
Analysis 2.3. Comparison 2 Retropubic bottom-to-top approach versus retropubic top-to-bottom approach, Outcome 3 Operative time (minutes).



Analysis 2.4. Comparison 2 Retropubic bottom-to-top approach versus retropubic top-to-bottom approach, Outcome 4 Length of hospital stay (days).

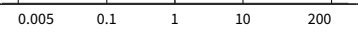


Analysis 2.5. Comparison 2 Retropubic bottom-to-top approach versus retropubic top-to-bottom approach, Outcome 5 Perioperative complications.



Analysis 2.6. Comparison 2 Retropubic bottom-to-top approach versus retropubic top-to-bottom approach, Outcome 6 Bladder or urethral perforation.

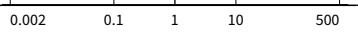
Study or subgroup	Bottom-to-top n/N	Top-to-bottom n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Andonian 2005	10/43	10/41		36.87%	0.95[0.44,2.05]
Kim 2004	3/32	3/30		11.15%	0.94[0.2,4.29]
Lim 2005	1/61	7/61		25.21%	0.14[0.02,1.13]
Lord 2006	1/147	3/154		10.55%	0.35[0.04,3.32]
Tseng 2005	0/31	4/31		16.21%	0.11[0.01,1.98]
Total (95% CI)	**314**	**317**		**100%**	**0.55[0.31,0.98]**
Total events: 15 (Bottom-to-top), 27 (Top-to-bottom)					
Heterogeneity: Tau^2=0; Chi^2=5.46, df=4(P=0.24); I^2=26.76%					
Test for overall effect: Z=2.03(P=0.04)					



Favours bottom-to-top — Favours top-to-bottom

Analysis 2.7. Comparison 2 Retropubic bottom-to-top approach versus retropubic top-to-bottom approach, Outcome 7 Voiding dysfunction.

Study or subgroup	Bottom-to-top n/N	Top-to-bottom n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Andonian 2005	4/43	2/41		10.28%	1.91[0.37,9.86]
Kim 2004	0/32	3/30		18.12%	0.13[0.01,2.49]
Lim 2005	2/61	2/61		10.04%	1[0.15,6.87]
Lord 2006	0/147	10/154		51.51%	0.05[0,0.84]
Tseng 2005	1/31	2/31		10.04%	0.5[0.05,5.23]
Total (95% CI)	**314**	**317**		**100%**	**0.4[0.18,0.9]**
Total events: 7 (Bottom-to-top), 19 (Top-to-bottom)					
Heterogeneity: Tau^2=0; Chi^2=7.02, df=4(P=0.13); I^2=43.06%					
Test for overall effect: Z=2.22(P=0.03)					



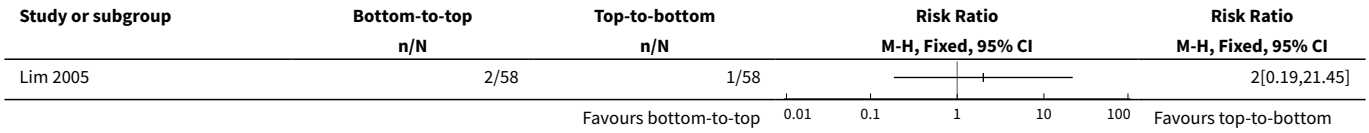
Favours bottom-to-top — Favours top-to-bottom

Analysis 2.8. Comparison 2 Retropubic bottom-to-top approach versus retropubic top-to-bottom approach, Outcome 8 De novo urgency or urgency incontinence.

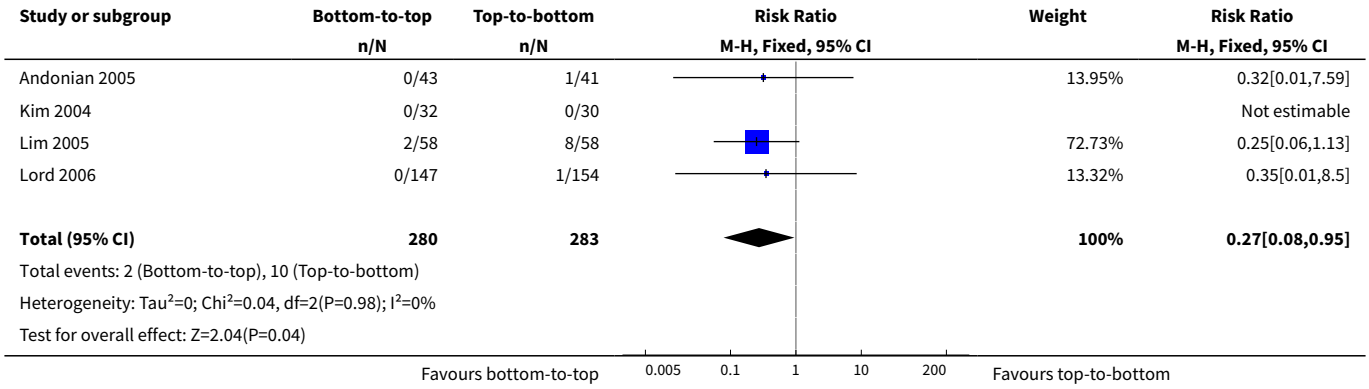
Study or subgroup	Bottom-to-top n/N	Top-to-bottom n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Kim 2004	3/32	1/30		3.07%	2.81[0.31,25.58]
Lim 2005	8/58	9/58		26.76%	0.89[0.37,2.14]
Lord 2006	12/147	17/154		49.36%	0.74[0.37,1.49]
Tseng 2005	5/31	7/31		20.81%	0.71[0.25,2.01]
Total (95% CI)	**268**	**273**		**100%**	**0.84[0.52,1.34]**
Total events: 28 (Bottom-to-top), 34 (Top-to-bottom)					
Heterogeneity: Tau^2=0; Chi^2=1.39, df=3(P=0.71); I^2=0%					
Test for overall effect: Z=0.74(P=0.46)					

Favours bottom-to-top — Favours top-to-bottom

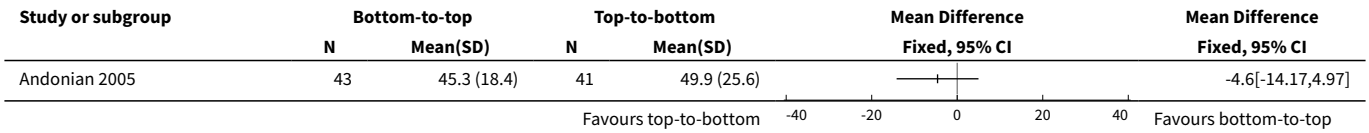
Analysis 2.9. Comparison 2 Retropubic bottom-to-top approach versus retropubic top-to-bottom approach, Outcome 9 Detrusor overactivity.



Analysis 2.10. Comparison 2 Retropubic bottom-to-top approach versus retropubic top-to-bottom approach, Outcome 10 Vaginal tape erosion.



Analysis 2.11. Comparison 2 Retropubic bottom-to-top approach versus retropubic top-to-bottom approach, Outcome 11 QoL specific.



Comparison 3. Obturator medial-to-lateral approach versus obturator lateral-to-medial approach

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Subjective cure (short term, ≤ 1 year)	6	759	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.96, 1.06]
2 Subjective cure and improvement (short term, ≤ 1 year)	5	732	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.97, 1.08]
3 Subjective cure (medium term, 1 to 5 years)	2	235	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.91, 1.23]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4 Subjective cure and improvement (medium term, 1 to 5 years)	2	399	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.90, 1.11]
5 Objective cure (short term, ≤ 1 year)	6	745	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.95, 1.04]
6 Objective cure and improvement (short term, ≤ 1 year)	2	214	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.95, 1.07]
7 Operative time (minutes)	4	481	Mean Difference (IV, Random, 95% CI)	0.52 [-1.09, 2.13]
8 Operative blood loss (ml)	3	255	Mean Difference (IV, Fixed, 95% CI)	1.11 [-6.01, 8.22]
9 Length of hospital stay (days)	2	190	Mean Difference (IV, Random, 95% CI)	-0.77 [-2.54, 0.99]
10 Time to return to normal activity level	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
11 Perioperative complications	2	214	Risk Ratio (M-H, Fixed, 95% CI)	1.30 [0.23, 7.51]
12 Major vascular or visceral injury	4	622	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.23, 2.19]
13 Vaginal perforation/injury	3	541	Risk Ratio (M-H, Fixed, 95% CI)	0.25 [0.12, 0.53]
14 Bladder or urethral perforation	6	794	Risk Ratio (M-H, Fixed, 95% CI)	0.38 [0.07, 1.92]
15 Voiding dysfunction	8	1121	Risk Ratio (M-H, Fixed, 95% CI)	1.74 [1.06, 2.88]
16 De novo urgency or urgency incontinence	3	357	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.46, 2.20]
17 Detrusor overactivity	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
18 Vaginal tape erosion	7	1087	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.16, 1.09]
19 Groin/thigh pain	6	837	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.75, 1.76]
20 Repeat incontinence surgery	2	532	Risk Ratio (M-H, Fixed, 95% CI)	0.64 [0.32, 1.30]
21 QoL specific	1	46	Mean Difference (IV, Fixed, 95% CI)	16.54 [4.84, 28.24]

Analysis 3.1. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 1 Subjective cure (short term, ≤ 1 year).

Study or subgroup	Medial-to-lateral n/N	Lateral-to-medial n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
But 2008	59/60	59/60		17.72%	1[0.95,1.05]
Hassan 2013	102/102	95/97		29.39%	1.02[0.99,1.06]
Houwert 2009	66/86	73/95		20.83%	1[0.85,1.17]
Liapis 2008	49/61	41/53		13.17%	1.04[0.86,1.26]
Park 2012	35/39	32/35		10.13%	0.98[0.85,1.14]
Scheiner 2012	29/37	28/34		8.76%	0.95[0.76,1.2]
Total (95% CI)	**385**	**374**		**100%**	**1[0.96,1.06]**
Total events: 340 (Medial-to-lateral), 328 (Lateral-to-medial)					
Heterogeneity: Tau^2=0; Chi^2=1.29, df=5(P=0.94); I^2=0%					
Test for overall effect: Z=0.19(P=0.85)					

Favours lateral-to-medial — Favours medial-to-lateral

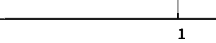
Analysis 3.2. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 2 Subjective cure and improvement (short term, ≤ 1 year).

Study or subgroup	Medial-to-lateral n/N	Lateral-to-medial n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Abdel-Fattah 2010	121/149	111/143		35.93%	1.05[0.93,1.18]
Houwert 2009	79/86	89/95		26.83%	0.98[0.9,1.06]
Liapis 2008	57/61	47/53		15.96%	1.05[0.94,1.18]
Park 2012	37/39	33/35		11.03%	1.01[0.9,1.12]
Scheiner 2012	34/37	31/34		10.25%	1.01[0.87,1.16]
Total (95% CI)	**372**	**360**		**100%**	**1.02[0.97,1.08]**
Total events: 328 (Medial-to-lateral), 311 (Lateral-to-medial)					
Heterogeneity: Tau^2=0; Chi^2=1.5, df=4(P=0.83); I^2=0%					
Test for overall effect: Z=0.76(P=0.45)					

Favours lateral-to-medial — Favours medial-to-lateral

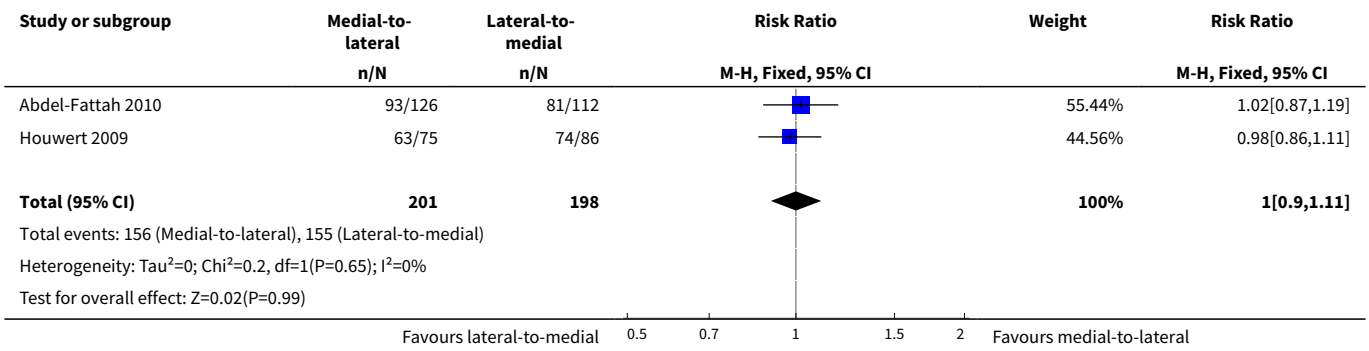
Analysis 3.3. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 3 Subjective cure (medium term, 1 to 5 years).

Study or subgroup	Medial-to-lateral n/N	Lateral-to-medial n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Houwert 2009	54/75	56/86		62.26%	1.11[0.9,1.36]
Park 2012	33/39	30/35		37.74%	0.99[0.82,1.19]
Total (95% CI)	**114**	**121**		**100%**	**1.06[0.91,1.23]**
Total events: 87 (Medial-to-lateral), 86 (Lateral-to-medial)					
Heterogeneity: Tau^2=0; Chi^2=0.7, df=1(P=0.4); I^2=0%					
Test for overall effect: Z=0.77(P=0.44)					

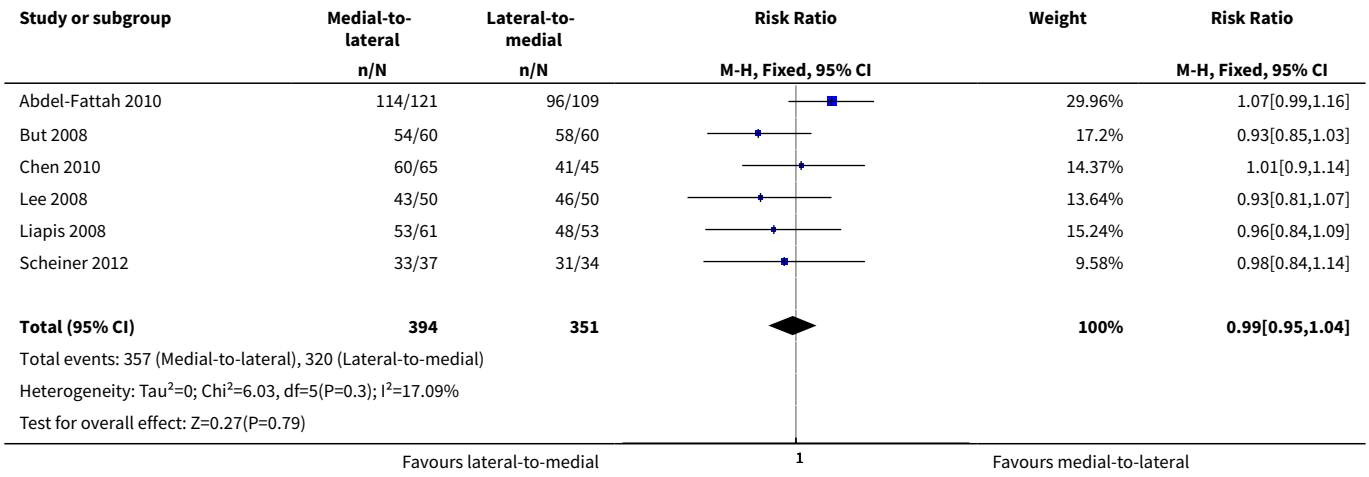


Favours lateral-to-medial — Favours medial-to-lateral

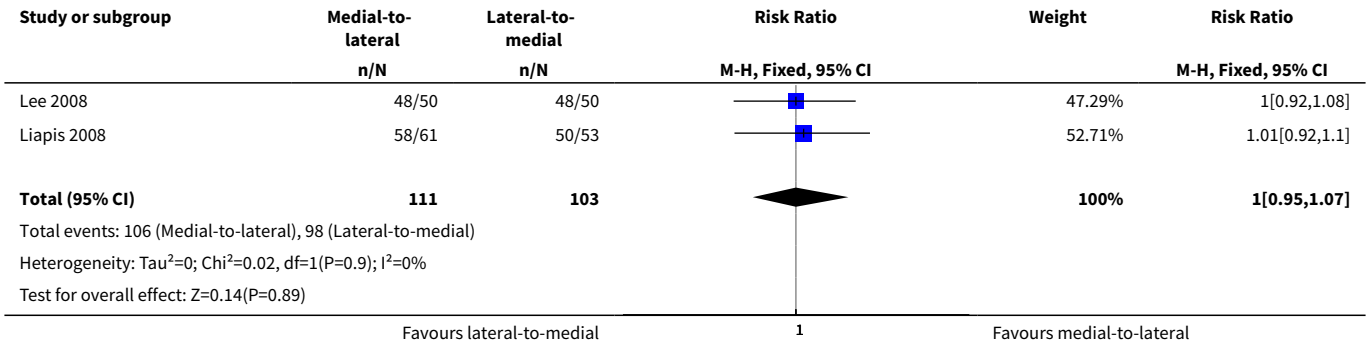
Analysis 3.4. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 4 Subjective cure and improvement (medium term, 1 to 5 years).



Analysis 3.5. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 5 Objective cure (short term, ≤ 1 year).



Analysis 3.6. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 6 Objective cure and improvement (short term, ≤ 1 year).

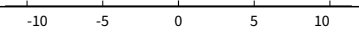


Analysis 3.7. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 7 Operative time (minutes).

Study or subgroup	Medial-to-lateral N	Mean(SD)	Lateral-to-medial N	Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Chen 2010	65	26.9 (16.8)	45	20 (13.5)		7.01%	6.9[1.22,12.58]
Houwert 2009	93	16 (5)	98	16 (6)		35.73%	0[-1.56,1.56]
Lee 2008	50	11.2 (2.6)	50	11.5 (1.9)		46.19%	-0.3[-1.19,0.59]
Scheiner 2012	40	27.4 (10)	40	25.8 (9.7)		11.07%	1.6[-2.72,5.92]
Total ***	**248**		**233**			**100%**	**0.52[-1.09,2.13]**

Heterogeneity: Tau^2=1.26; Chi^2=6.62, df=3(P=0.08); I^2=54.69%

Test for overall effect: Z=0.63(P=0.53)



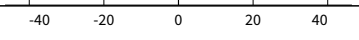
Favours medial-to-lateral — Favours lateral-to-medial

Analysis 3.8. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 8 Operative blood loss (ml).

Study or subgroup	Medial-to-lateral N	Mean(SD)	Lateral-to-medial N	Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Houwert 2009	39	54.9 (34.2)	36	55.6 (34.5)		20.88%	-0.7[-16.26,14.86]
Lee 2008	50	33.1 (19.2)	50	32.9 (23.1)		72.95%	0.2[-8.13,8.53]
Scheiner 2012	40	49.4 (89.6)	40	31.5 (22.2)		6.18%	17.9[-10.71,46.51]
Total ***	**129**		**126**			**100%**	**1.11[-6.01,8.22]**

Heterogeneity: Tau^2=0; Chi^2=1.42, df=2(P=0.49); I^2=0%

Test for overall effect: Z=0.3(P=0.76)



Favours medial-to-lateral — Favours lateral-to-medial

Analysis 3.9. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 9 Length of hospital stay (days).

Study or subgroup	Medial-to-lateral N	Mean(SD)	Lateral-to-medial N	Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Chen 2010	65	2.3 (0.8)	45	4 (2.2)		48.53%	-1.7[-2.37,-1.03]
Scheiner 2012	40	3.3 (0.8)	40	3.2 (0.5)		51.47%	0.1[-0.19,0.39]
Total ***	**105**		**85**			**100%**	**-0.77[-2.54,0.99]**

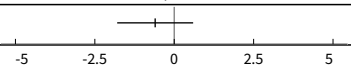
Heterogeneity: Tau^2=1.55; Chi^2=23.2, df=1(P<0.0001); I^2=95.69%

Test for overall effect: Z=0.86(P=0.39)

Favours medial-to-lateral — Favours lateral-to-medial

Analysis 3.10. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 10 Time to return to normal activity level.

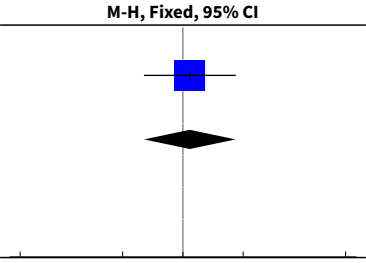
Study or subgroup	Medial-to-lateral N	Medial-to-lateral Mean(SD)	Lateral-to-medial N	Lateral-to-medial Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
Lee 2008	50	5.1 (3)	50	5.7 (3.1)		-0.6[-1.8,0.6]



Favours medial-to-lateral | Favours lateral-to-medial

Analysis 3.11. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 11 Perioperative complications.

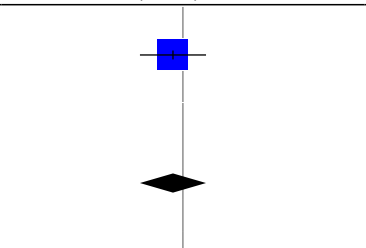
Study or subgroup	Medial-to-lateral n/N	Lateral-to-medial n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Lee 2008	0/50	0/50			Not estimable
Liapis 2008	3/61	2/53		100%	1.3[0.23,7.51]
Total (95% CI)	**111**	**103**		**100%**	**1.3[0.23,7.51]**
Total events: 3 (Medial-to-lateral), 2 (Lateral-to-medial)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.3(P=0.77)					



Favours medial-to-lateral | Favours lateral-to-medial

Analysis 3.12. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 12 Major vascular or visceral injury.

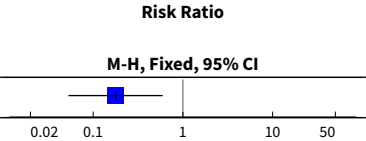
Study or subgroup	Medial-to-lateral n/N	Lateral-to-medial n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Chen 2010	0/65	0/45			Not estimable
Hassan 2013	5/125	7/125		100%	0.71[0.23,2.19]
Houwert 2009	0/93	0/98			Not estimable
Scheiner 2012	0/37	0/34			Not estimable
Total (95% CI)	**320**	**302**		**100%**	**0.71[0.23,2.19]**
Total events: 5 (Medial-to-lateral), 7 (Lateral-to-medial)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.59(P=0.56)					



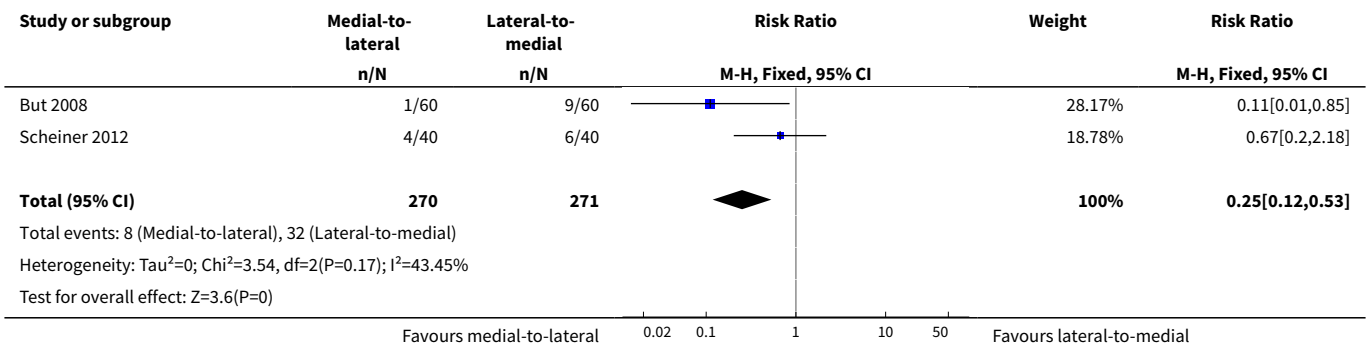
Favours medial-to-lateral | Favours lateral-to-medial

Analysis 3.13. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 13 Vaginal perforation/injury.

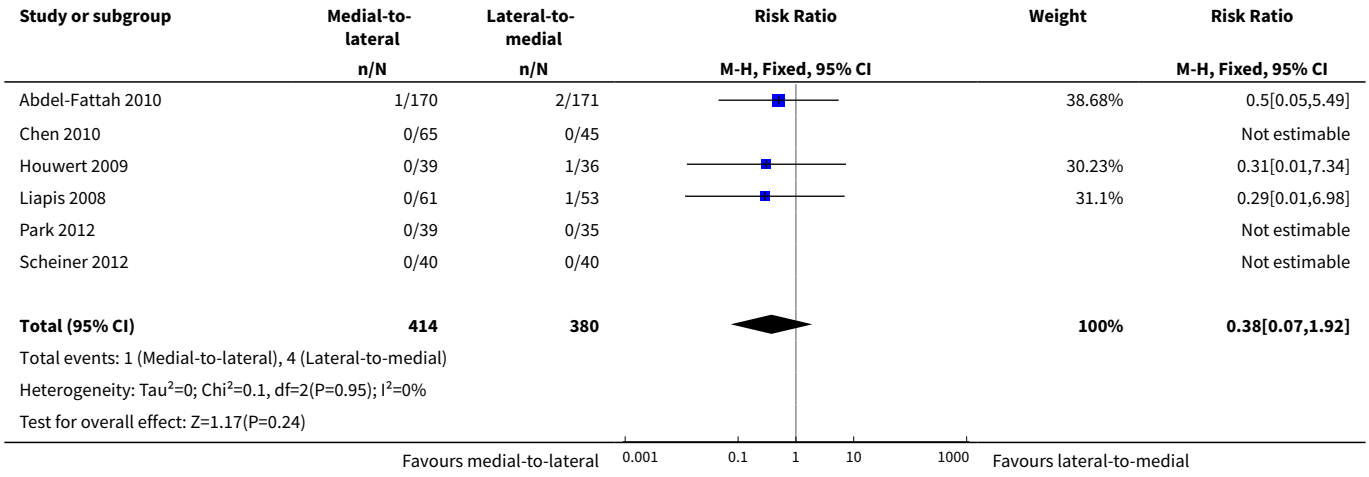
Study or subgroup	Medial-to-lateral n/N	Lateral-to-medial n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Abdel-Fattah 2010	3/170	17/171		53.05%	0.18[0.05,0.59]



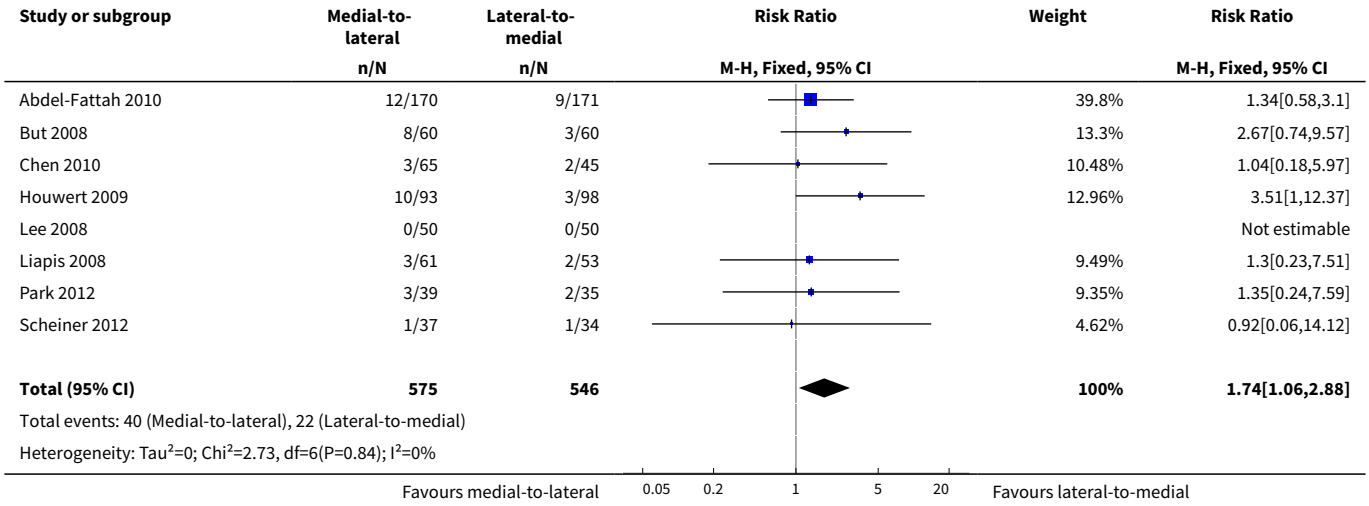
Favours medial-to-lateral | Favours lateral-to-medial

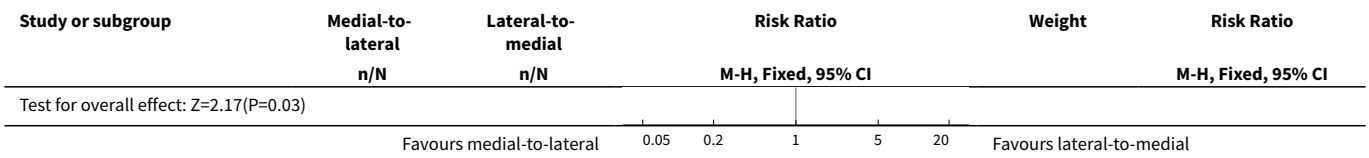


Analysis 3.14. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 14 Bladder or urethral perforation.

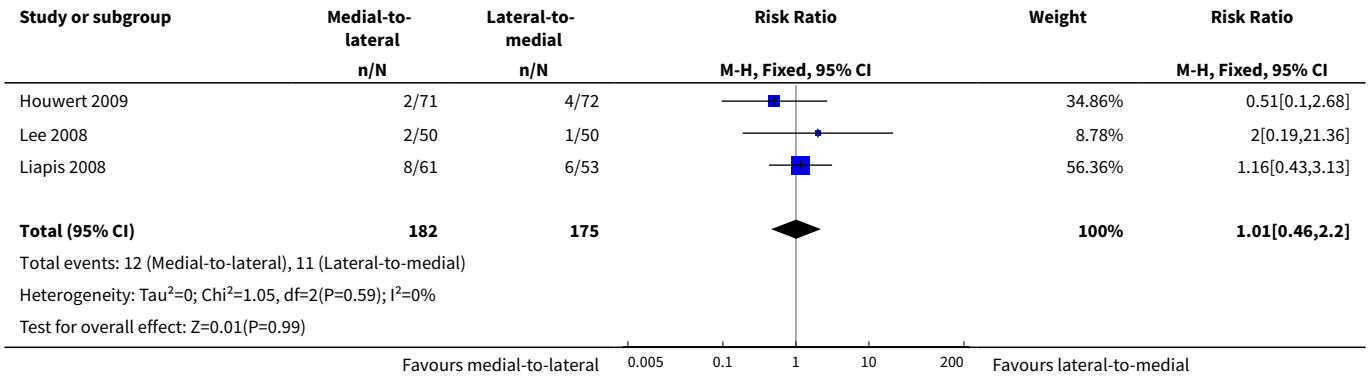


Analysis 3.15. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 15 Voiding dysfunction.

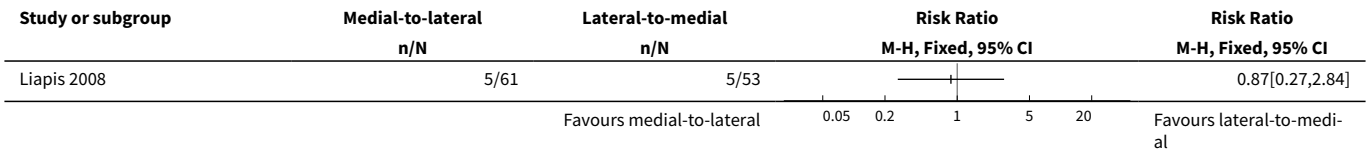




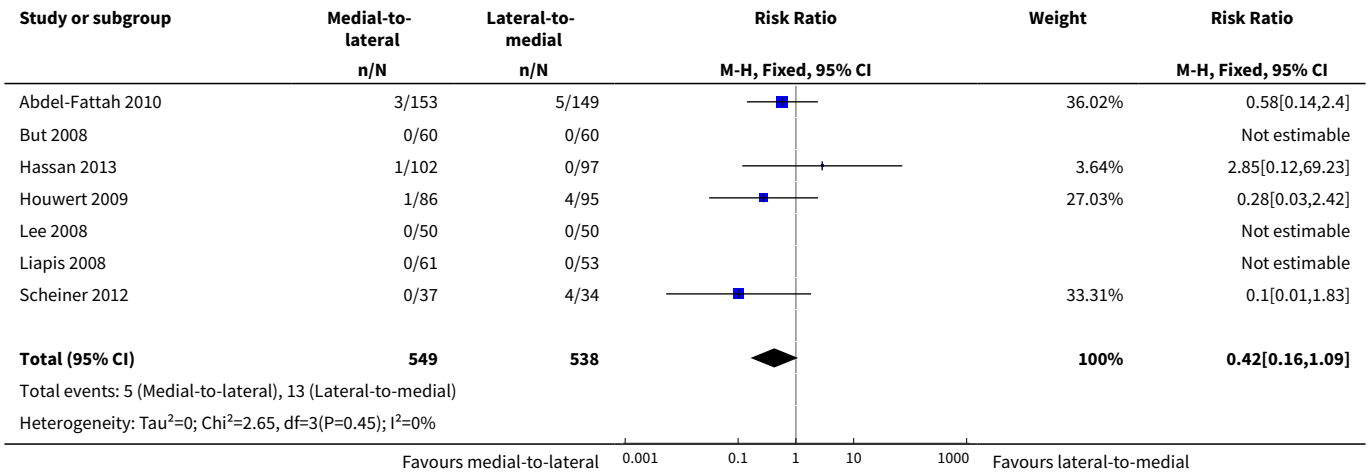
Analysis 3.16. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 16 De novo urgency or urgency incontinence.

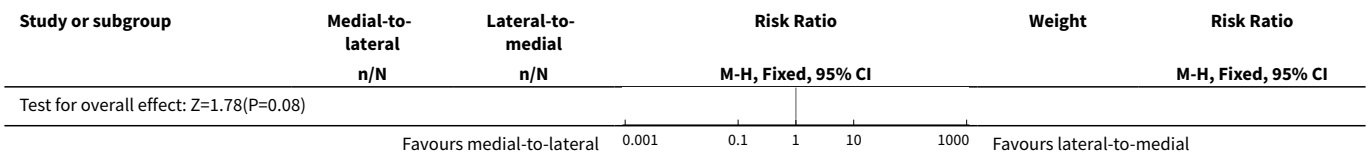


Analysis 3.17. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 17 Detrusor overactivity.

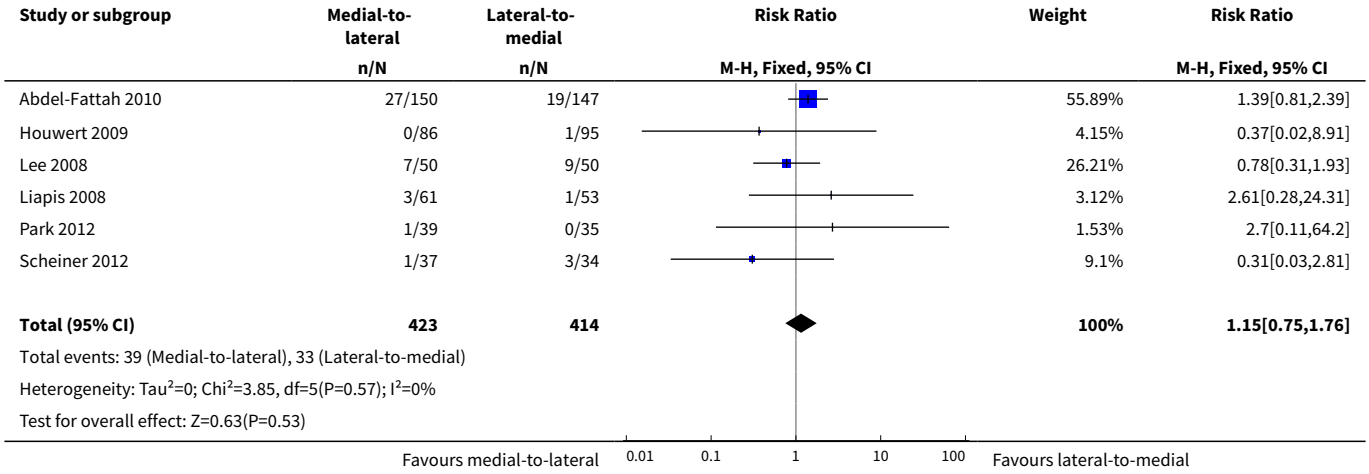


Analysis 3.18. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 18 Vaginal tape erosion.

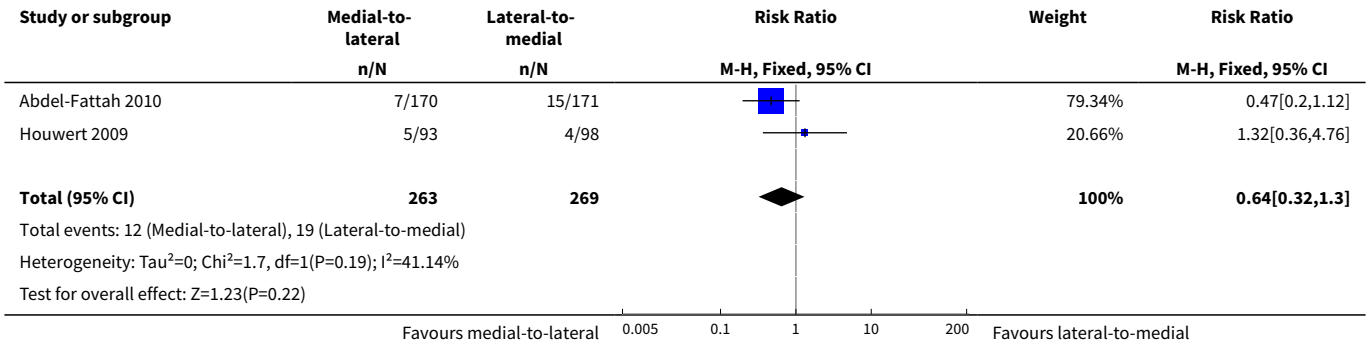




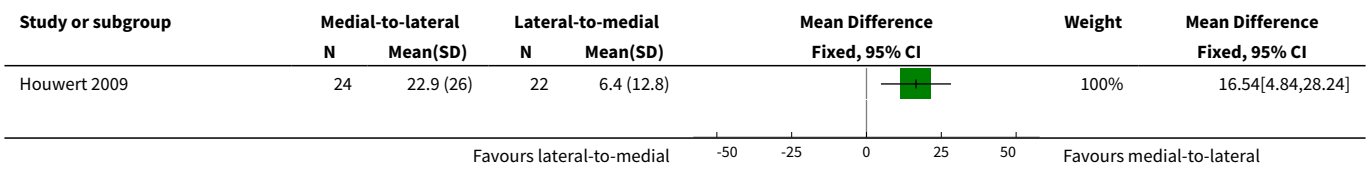
Analysis 3.19. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 19 Groin/thigh pain.

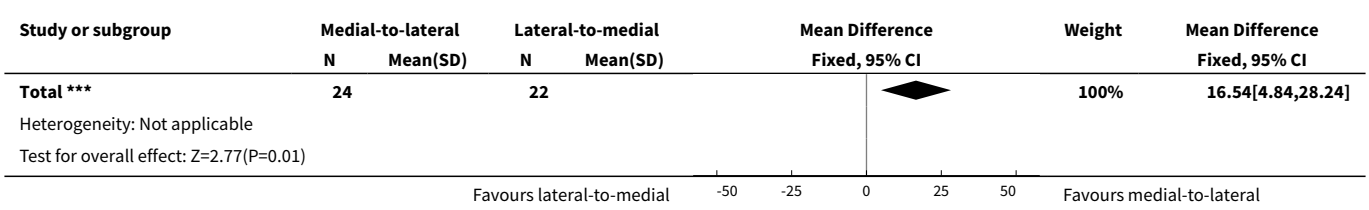


Analysis 3.20. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 20 Repeat incontinence surgery.



Analysis 3.21. Comparison 3 Obturator medial-to-lateral approach versus obturator lateral-to-medial approach, Outcome 21 QoL specific.





Comparison 4. One method of mid-urethral tape insertion versus another method, same route

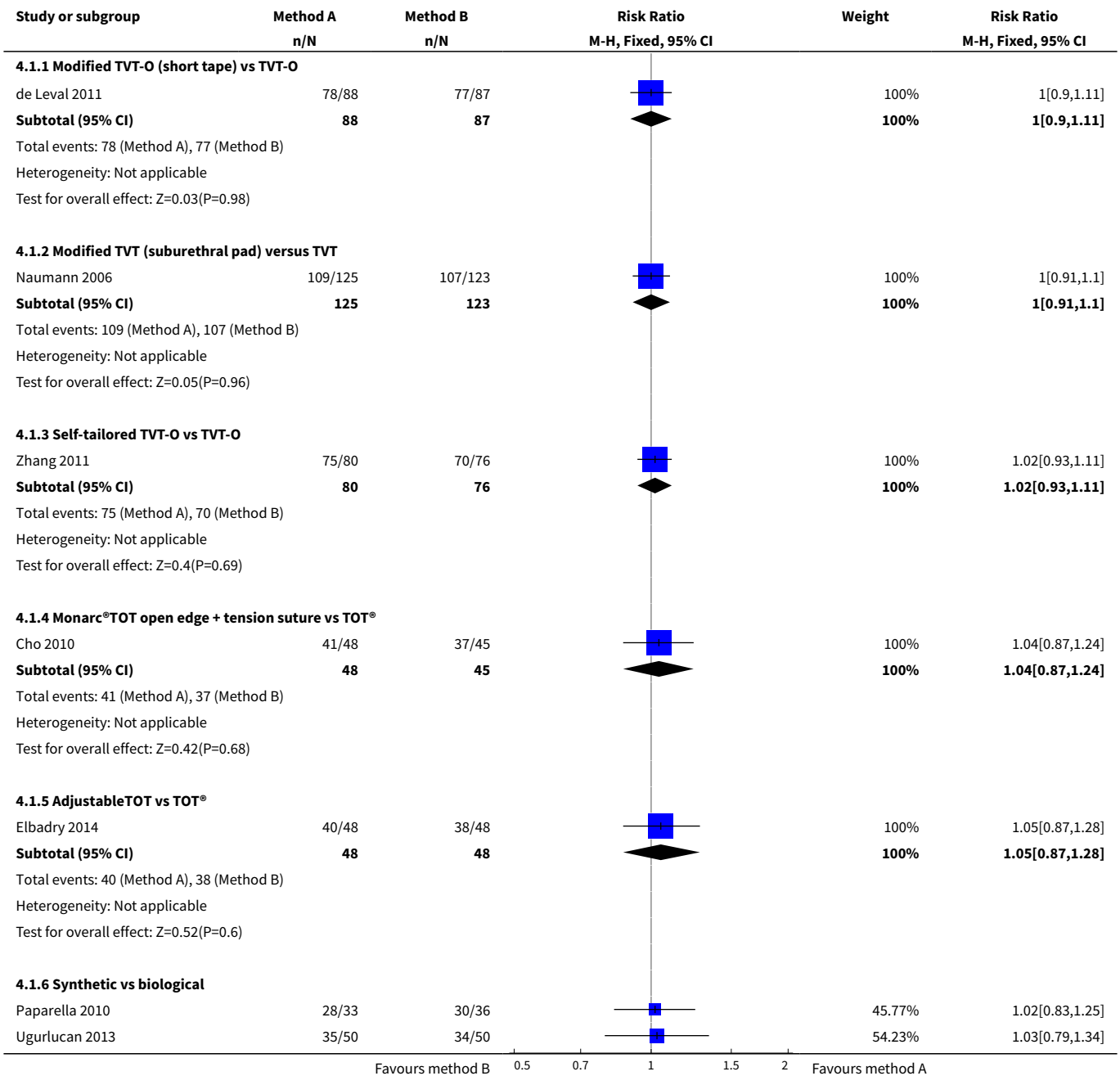
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Subjective cure (short term, up to 1 year)	7		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Modified TVT-O (short tape) vs TVT-O	1	175	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.90, 1.11]
1.2 Modified TVT (suburethral pad) versus TVT	1	248	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.91, 1.10]
1.3 Self-tailored TVT-O vs TVT-O	1	156	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.93, 1.11]
1.4 Monarc®TOT open edge + tension suture vs TOT®	1	93	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.87, 1.24]
1.5 AdjustableTOT vs TOT®	1	96	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.87, 1.28]
1.6 Synthetic vs biological	2	169	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.86, 1.22]
2 Subjective cure and improvement (short term, up to 1 year)	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Modified TVT-O (short tape) vs TVT-O	1	170	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.97, 1.09]
2.2 TOT + 2-point tape fixation vs TOT	1	418	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [1.00, 1.14]
2.3 TVT versus modified TVT (suburethral pad)	1	248	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.98, 1.08]
3 Subjective cure (medium term, 1 to 5 years)	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 Modified TVT-O (short tape) vs TVT-O	1	153	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.86, 1.12]
4 Objective cure (medium term, 1 to 5 years)	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
4.1 Modified TVT-O (short tape) vs TVT-O	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

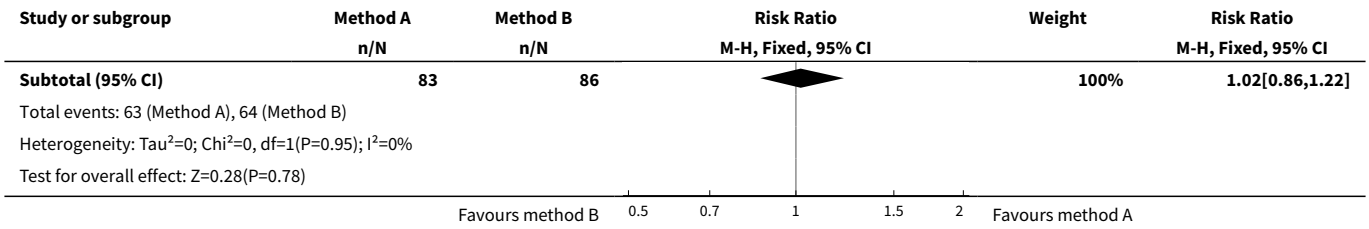
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5 Objective cure (short term, ≤ 1 year)	5		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.1 Modified TVT-O (less dissection) vs TVT-O	1	69	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.91, 1.15]
5.2 Synthetic vs biological	2	136	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.94, 1.14]
5.3 TVT-O + IS vs TVT-O	1	93	Risk Ratio (M-H, Fixed, 95% CI)	1.45 [1.02, 2.06]
5.4 TOT + 2-point tape fixation vs TOT	1	418	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [1.01, 1.13]
6 Operative time (minutes)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
6.1 TVT-O + IS vs TVT-O	1	96	Mean Difference (IV, Fixed, 95% CI)	12.0 [8.91, 15.09]
6.2 Self-tailored TVT-O vs TVT-O	1	156	Mean Difference (IV, Fixed, 95% CI)	-25.0 [-26.73, -23.27]
7 Operative blood loss (ml)	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
7.1 TVT-O + IS versus TVT-O	1	92	Mean Difference (IV, Fixed, 95% CI)	52.10 [43.73, 60.47]
7.2 Self-tailored TVT-O vs TVT-O	1	156	Mean Difference (IV, Fixed, 95% CI)	-13.00 [-16.57, -13.43]
7.3 Synthetic vs biological	1	70	Mean Difference (IV, Fixed, 95% CI)	-0.40 [-0.92, 0.12]
8 Length of hospital stay (days)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
8.1 TVT-O + IS vs TVT-O	1	96	Mean Difference (IV, Fixed, 95% CI)	12.0 [8.91, 15.09]
8.2 Self-tailored TVT-O vs TVT-O	1	156	Mean Difference (IV, Fixed, 95% CI)	-3.0 [-3.16, -2.84]
9 Perioperative complications	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
9.1 Synthetic vs biological	2	170	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Major vascular or visceral injury	4		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
10.1 TVT-O + IS vs TVT-O	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.17, 3.04]
10.2 Synthetic vs biological	2	170	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.3 AdjustableTOT vs TOT®	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11 Bladder/urethral perforation	4		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
11.1 TVT-O + IS vs TVT-O	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11.2 TOT + 2-point tape fixation vs TOT	1	463	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.17, 3.33]
11.3 TVT versus modified TVT (suburethral pad)	1	248	Risk Ratio (M-H, Fixed, 95% CI)	0.49 [0.05, 5.36]
11.4 AdjustableTOT vs TOT®	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
12 Voiding dysfunction	6		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
12.1 Modified TVT-O (less dissection) vs TVT-O	1	72	Risk Ratio (M-H, Fixed, 95% CI)	2.0 [0.13, 30.61]
12.2 TVT versus modified TVT (suburethral pad)	1	248	Risk Ratio (M-H, Fixed, 95% CI)	2.21 [0.70, 7.00]
12.3 Self-tailored TVT-O vs TVT-O	1	156	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.06, 14.92]
12.4 Monarc®TOT open edge + tension suture vs TOT®	1	93	Risk Ratio (M-H, Fixed, 95% CI)	0.47 [0.04, 4.99]
12.5 Synthetic vs biological	2	170	Risk Ratio (M-H, Fixed, 95% CI)	5.0 [0.25, 101.58]
13 De novo urgency or urgency incontinence	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
13.1 Modified TVT-O (short tape) vs TVT-O	1	170	Risk Ratio (M-H, Fixed, 95% CI)	1.22 [0.51, 2.94]
14 Vaginal tape erosion	6		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
14.1 Modified TVT-O (short tape) vs TVT-O	1	170	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 7.88]
14.2 TVT versus modified TVT (suburethral pad)	1	248	Risk Ratio (M-H, Fixed, 95% CI)	2.30 [0.61, 8.68]
14.3 TVT-O + IS vs TVT-O	1	93	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.06, 14.55]
14.4 Monarc®TOT open edge + tension suture vs TOT®	1	93	Risk Ratio (M-H, Fixed, 95% CI)	0.13 [0.01, 2.53]
14.5 Synthetic vs biological	2	169	Risk Ratio (M-H, Fixed, 95% CI)	3.0 [0.13, 71.92]
15 Bladder/urethral erosion	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
15.1 TVT versus modified TVT (suburethral pad)	1	248	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.06, 15.56]
16 Groin pain	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

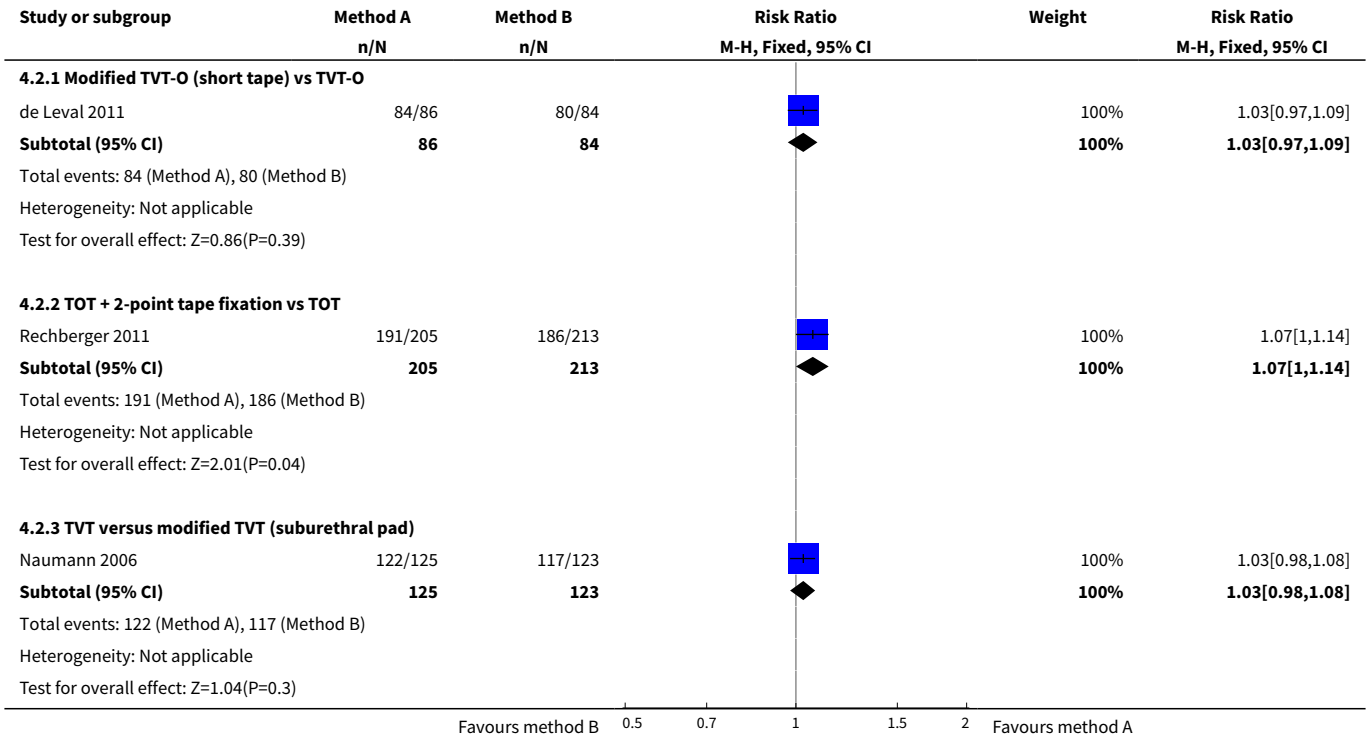
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
16.1 Modified TVT-O (short tape) vs TVT-O	1	170	Risk Ratio (M-H, Fixed, 95% CI)	1.30 [0.30, 5.64]
16.2 Synthetic vs biological	1	69	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 4.1. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 1 Subjective cure (short term, up to 1 year).

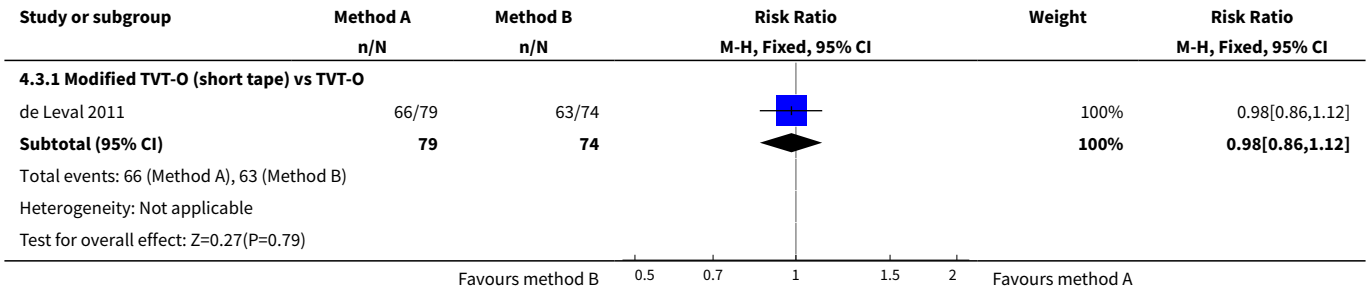




Analysis 4.2. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 2 Subjective cure and improvement (short term, up to 1 year).



Analysis 4.3. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 3 Subjective cure (medium term, 1 to 5 years).

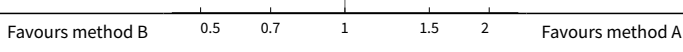


Analysis 4.4. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 4 Objective cure (medium term, 1 to 5 years).

Study or subgroup	Method A n/N	Method B n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
4.4.1 Modified TVT-O (short tape) vs TVT-O				
de Leval 2011	50/57	48/56		1.02[0.89,1.18]

Analysis 4.5. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 5 Objective cure (short term, ≤ 1 year).

Study or subgroup	Method A n/N	Method B n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
4.5.1 Modified TVT-O (less dissection) vs TVT-O					
Tommaselli 2012	22/23	43/46		100%	1.02[0.91,1.15]
Subtotal (95% CI)	**23**	**46**		**100%**	**1.02[0.91,1.15]**
Total events: 22 (Method A), 43 (Method B)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.39(P=0.7)					
4.5.2 Synthetic vs biological					
Paparella 2010	30/33	33/36		51.2%	0.99[0.86,1.15]
Ugurlucan 2013	35/36	28/31		48.8%	1.08[0.95,1.22]
Subtotal (95% CI)	**69**	**67**		**100%**	**1.03[0.94,1.14]**
Total events: 65 (Method A), 61 (Method B)					
Heterogeneity: Tau^2=0; Chi^2=0.7, df=1(P=0.4); I^2=0%					
Test for overall effect: Z=0.66(P=0.51)					
4.5.3 TVT-O + IS vs TVT-O					
Juang 2007	34/48	22/45		100%	1.45[1.02,2.06]
Subtotal (95% CI)	**48**	**45**		**100%**	**1.45[1.02,2.06]**
Total events: 34 (Method A), 22 (Method B)					
Heterogeneity: Not applicable					
Test for overall effect: Z=2.08(P=0.04)					
4.5.4 TOT + 2-point tape fixation vs TOT					
Rechberger 2011	195/205	189/213		100%	1.07[1.01,1.13]
Subtotal (95% CI)	**205**	**213**		**100%**	**1.07[1.01,1.13]**
Total events: 195 (Method A), 189 (Method B)					
Heterogeneity: Not applicable					
Test for overall effect: Z=2.39(P=0.02)					



Analysis 4.6. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 6 Operative time (minutes).

Study or subgroup	Method A N	Method A Mean(SD)	Method B N	Method B Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
4.6.1 TVT-O + IS vs TVT-O							
Juang 2007	49	28.3 (10.2)	47	16.3 (4.1)		100%	12[8.91,15.09]
Subtotal ***	**49**		**47**			**100%**	**12[8.91,15.09]**
Heterogeneity: Not applicable							
Test for overall effect: Z=7.62(P<0.0001)							
4.6.2 Self-tailored TVT-O vs TVT-O							
Zhang 2011	80	24 (6)	76	49 (5)		100%	-25[-26.73,-23.27]
Subtotal ***	**80**		**76**			**100%**	**-25[-26.73,-23.27]**
Heterogeneity: Not applicable							
Test for overall effect: Z=28.33(P<0.0001)							

Favours method A — Favours method B

Analysis 4.7. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 7 Operative blood loss (ml).

Study or subgroup	Method A N	Method A Mean(SD)	Method B N	Method B Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
4.7.1 TVT-O + IS versus TVT-O							
Juang 2007	49	82.4 (25.1)	43	30.3 (15.2)		100%	52.1[43.73,60.47]
Subtotal ***	**49**		**43**			**100%**	**52.1[43.73,60.47]**
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%							
Test for overall effect: Z=12.2(P<0.0001)							
4.7.2 Self-tailored TVT-O vs TVT-O							
Zhang 2011	80	55 (5)	76	70 (5)		100%	-15[-16.57,-13.43]
Subtotal ***	**80**		**76**			**100%**	**-15[-16.57,-13.43]**
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%							
Test for overall effect: Z=18.73(P<0.0001)							
4.7.3 Synthetic vs biological							
Paparella 2010	34	10.4 (1)	36	10.8 (1.2)		100%	-0.4[-0.92,0.12]
Subtotal ***	**34**		**36**			**100%**	**-0.4[-0.92,0.12]**
Heterogeneity: Not applicable							
Test for overall effect: Z=1.52(P=0.13)							

Favours method A — Favours method B

Analysis 4.8. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 8 Length of hospital stay (days).

Study or subgroup	Method A N	Method A Mean(SD)	Method B N	Method B Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
4.8.1 TVT-O + IS vs TVT-O							
Juang 2007	49	28.3 (10.2)	47	16.3 (4.1)		100%	12[8.91,15.09]

Favours method A — Favours method B

Study or subgroup	Method A N	Method A Mean(SD)	Method B N	Method B Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Subtotal ***	**49**		**47**			**100%**	**12[8.91,15.09]**
Heterogeneity: Not applicable							
Test for overall effect: Z=7.62(P<0.0001)							
4.8.2 Self-tailored TVT-O vs TVT-O							
Zhang 2011	80	5 (0.5)	76	8 (0.5)		100%	-3[-3.16,-2.84]
Subtotal ***	**80**		**76**			**100%**	**-3[-3.16,-2.84]**
Heterogeneity: Not applicable							
Test for overall effect: Z=37.46(P<0.0001)							

Favours method A -10 -5 0 5 10 Favours method B

Analysis 4.9. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 9 Perioperative complications.

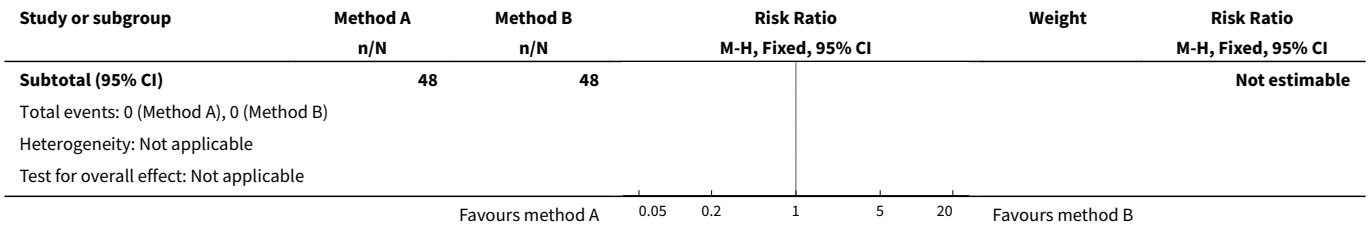
Study or subgroup	Method A n/N	Method B n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
4.9.1 Synthetic vs biological					
Paparella 2010	0/34	0/36			Not estimable
Ugurlucan 2013	0/50	0/50			Not estimable
Subtotal (95% CI)	**84**	**86**			**Not estimable**
Total events: 0 (Method A), 0 (Method B)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					

Favours method A 0.02 0.1 1 10 50 Favours method B

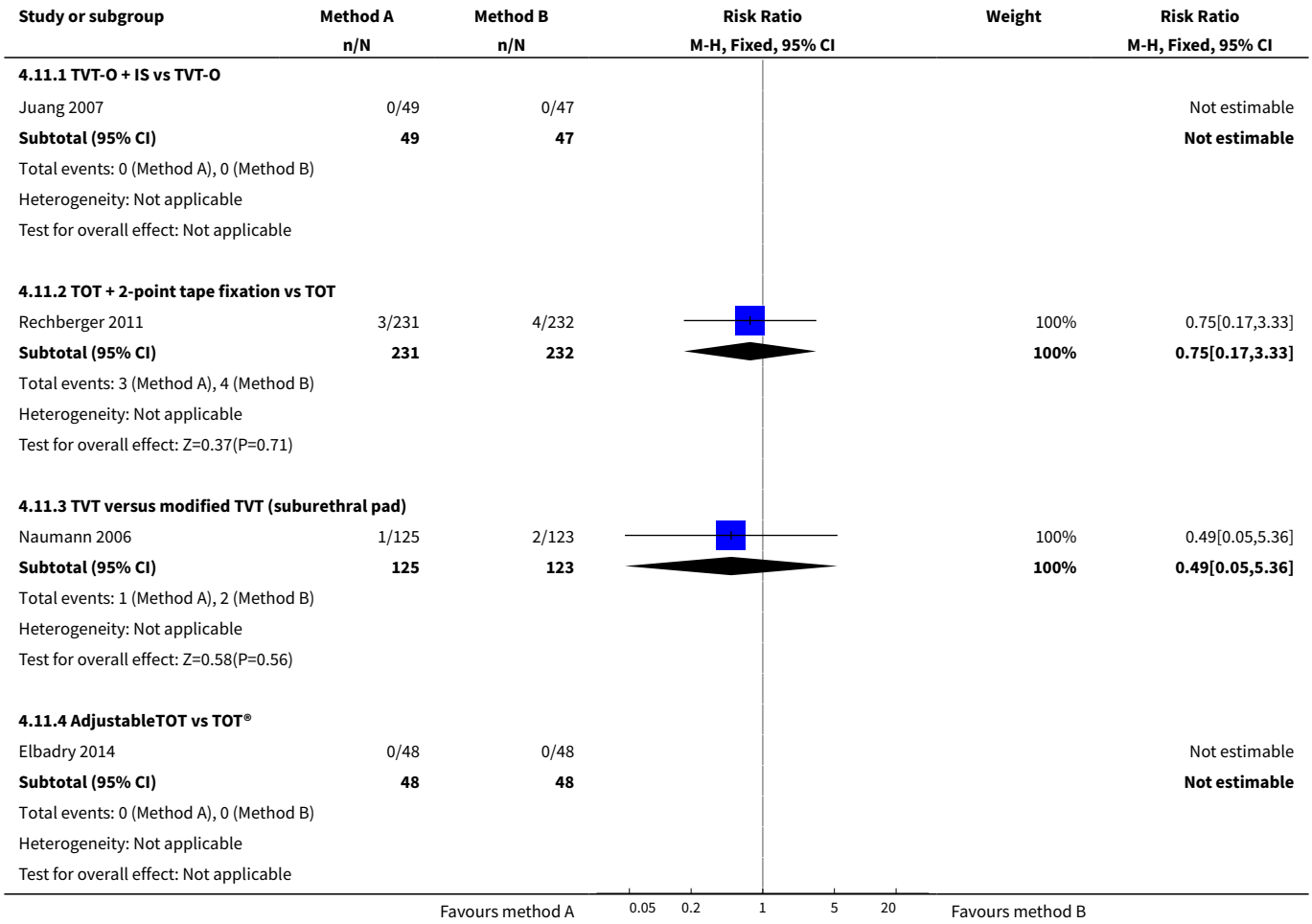
Analysis 4.10. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 10 Major vascular or visceral injury.

Study or subgroup	Method A n/N	Method B n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
4.10.1 TVT-O + IS vs TVT-O					
Juang 2007	3/49	4/47		100%	0.72[0.17,3.04]
Subtotal (95% CI)	**49**	**47**		**100%**	**0.72[0.17,3.04]**
Total events: 3 (Method A), 4 (Method B)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.45(P=0.65)					
4.10.2 Synthetic vs biological					
Paparella 2010	0/34	0/36			Not estimable
Ugurlucan 2013	0/50	0/50			Not estimable
Subtotal (95% CI)	**84**	**86**			**Not estimable**
Total events: 0 (Method A), 0 (Method B)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
4.10.3 AdjustableTOT vs TOT®					
Elbadry 2014	0/48	0/48			Not estimable

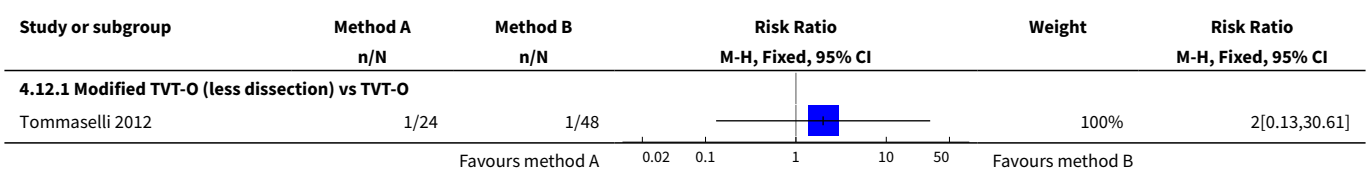
Favours method A 0.05 0.2 1 5 20 Favours method B

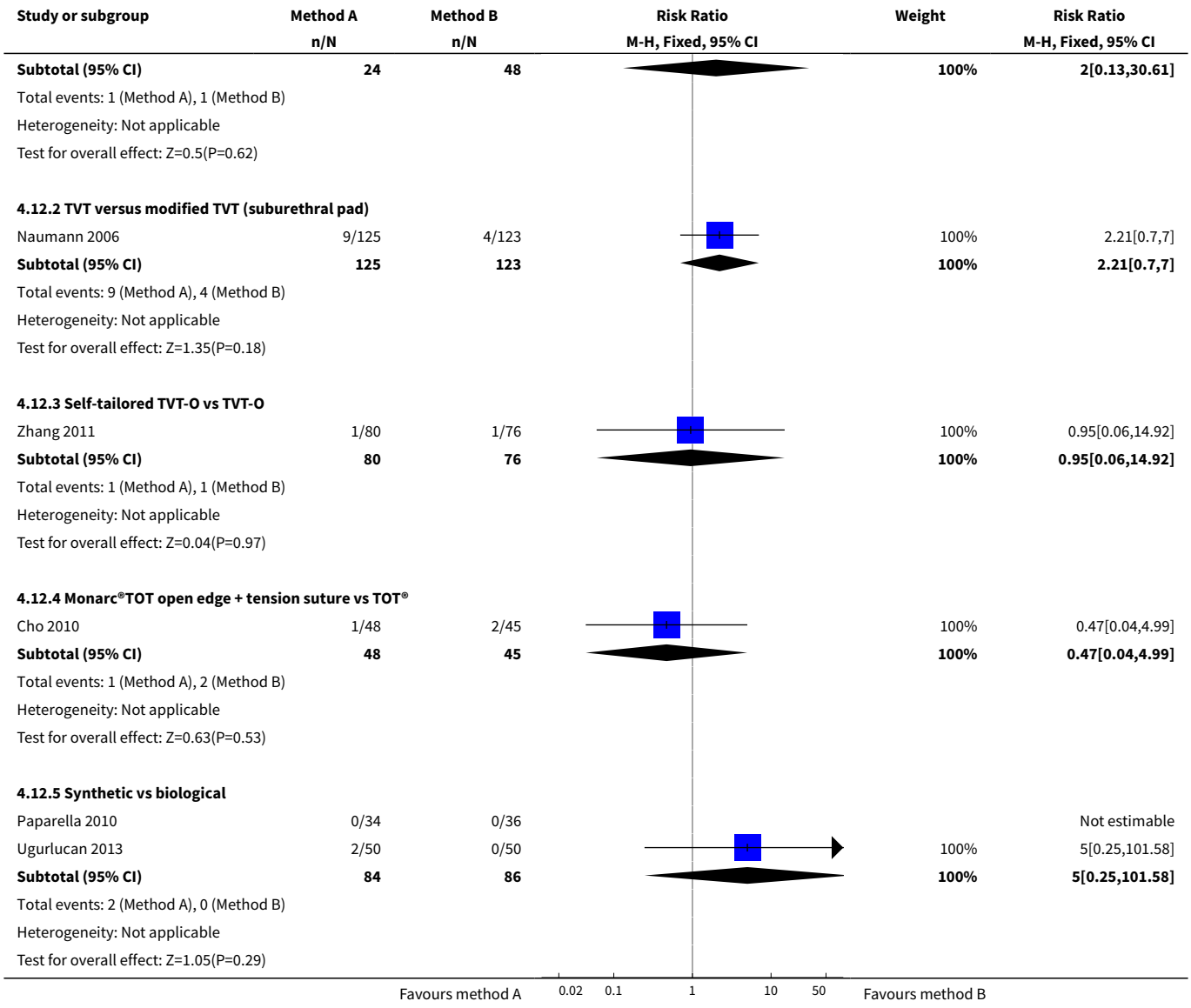


Analysis 4.11. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 11 Bladder/urethral perforation.

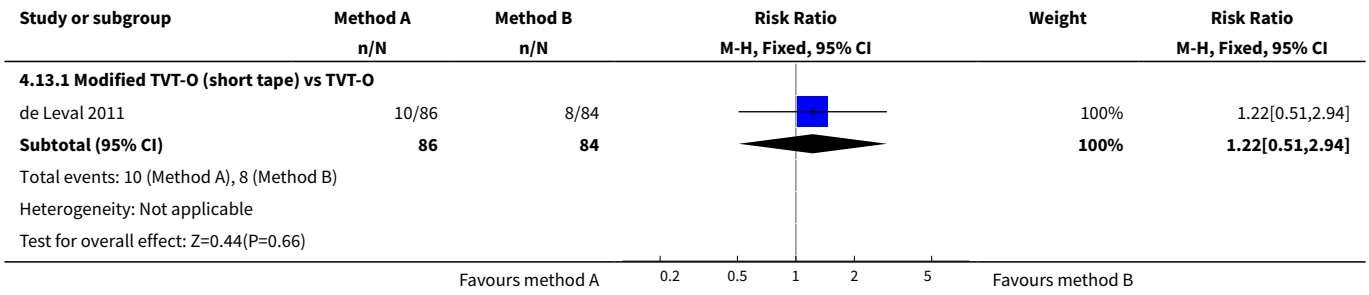


Analysis 4.12. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 12 Voiding dysfunction.

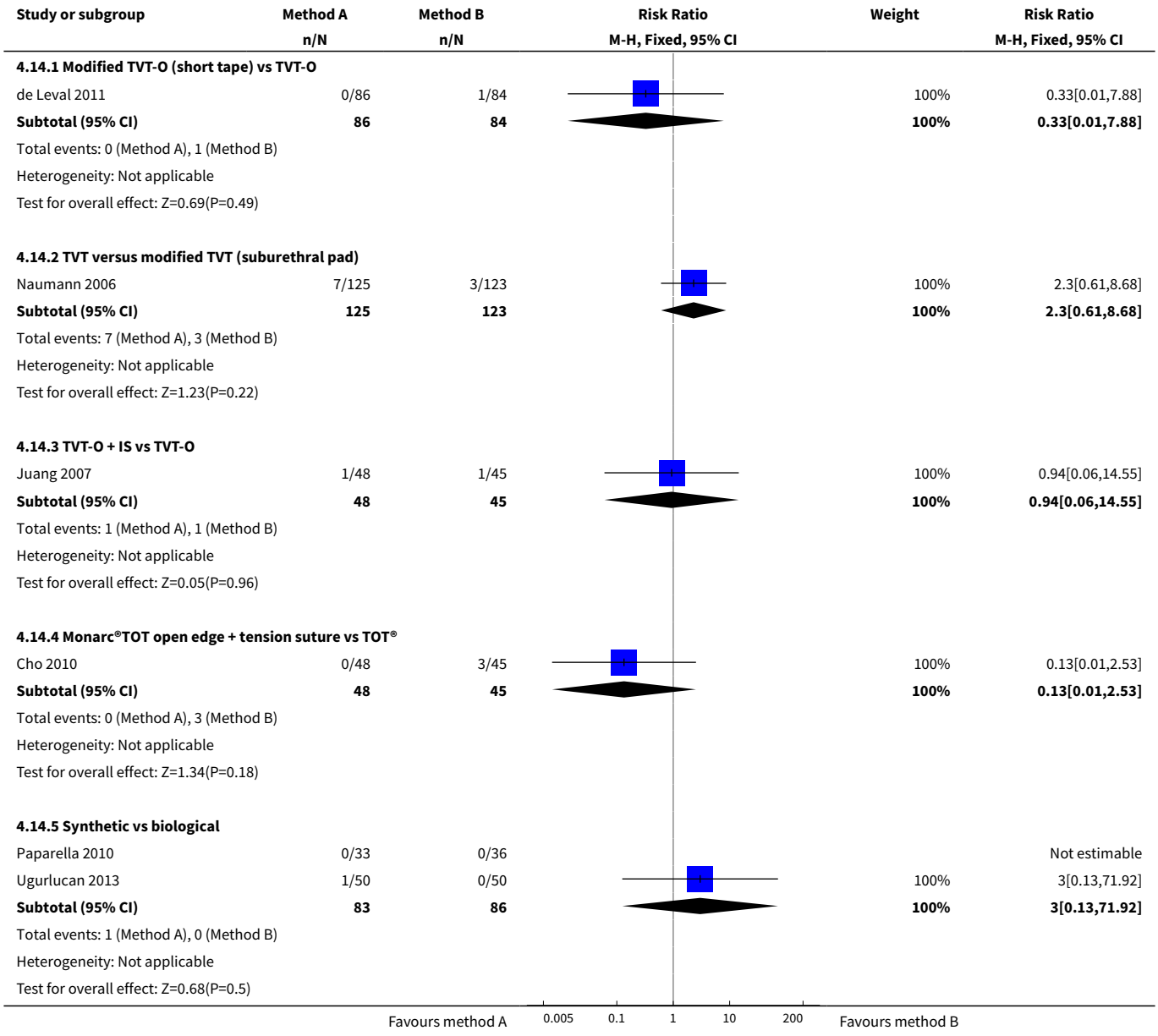




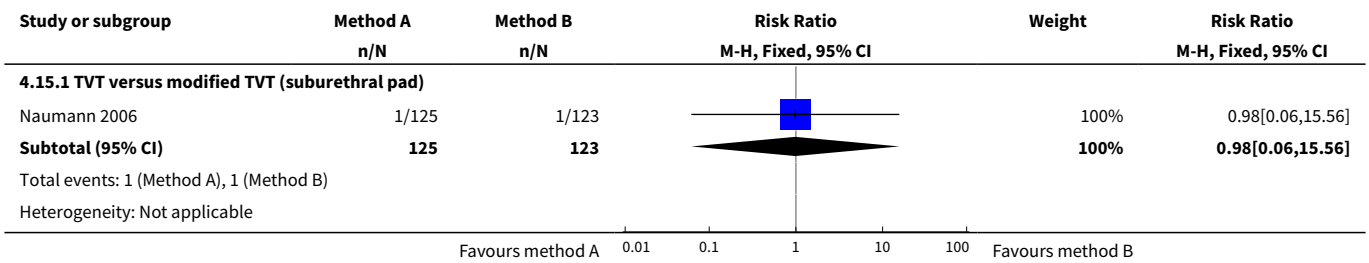
Analysis 4.13. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 13 De novo urgency or urgency incontinence.

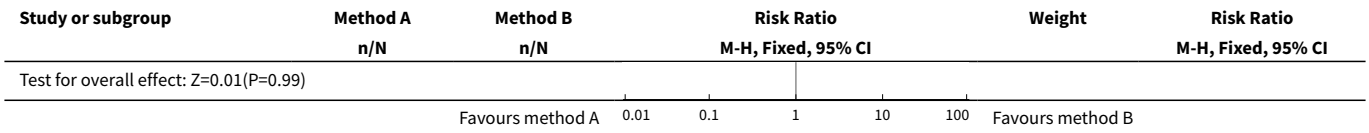


Analysis 4.14. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 14 Vaginal tape erosion.

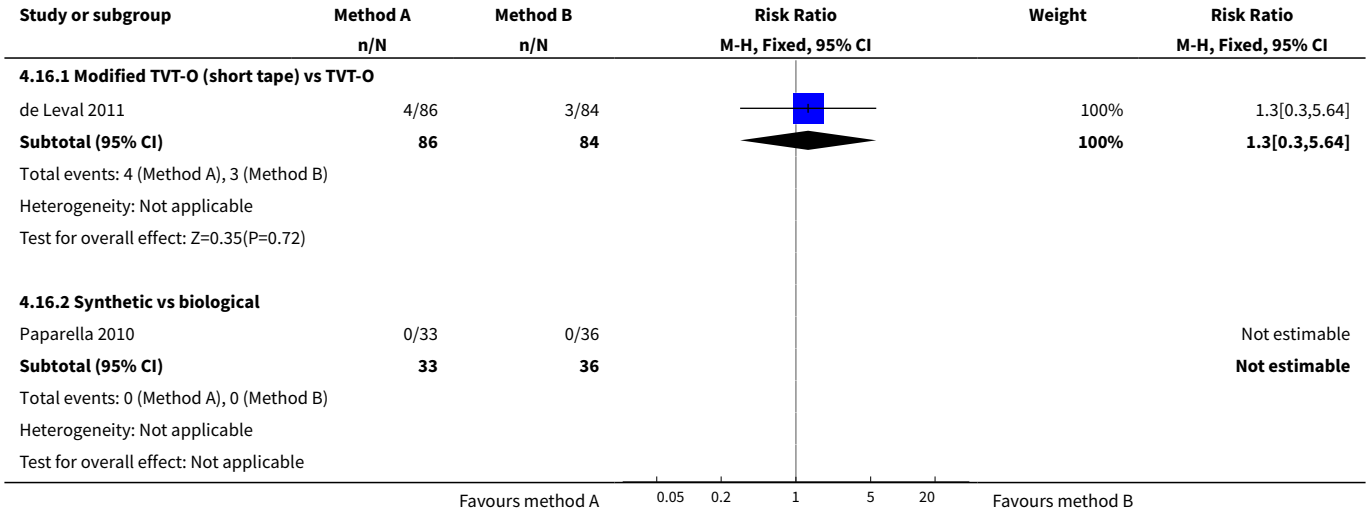


Analysis 4.15. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 15 Bladder/urethral erosion.





Analysis 4.16. Comparison 4 One method of mid-urethral tape insertion versus another method, same route, Outcome 16 Groin pain.



Comparison 5. One type of tape material versus another

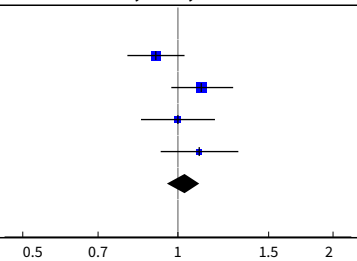
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Subjective cure (short term, ≤ 1 year)	4		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Monofilament versus multifilament	4	546	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.95, 1.10]
1.2 Monofilament versus combined monofilament and biological	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.79, 1.05]
1.3 Combined monofilament and biological vs multifilament	1	96	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.96, 1.26]
2 Subjective cure (medium term, 1 to 5 years)	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Monofilament vs multifilament	1	96	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.85, 1.23]
2.2 Monofilament vs combined monofilament and biological	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.78, 1.06]

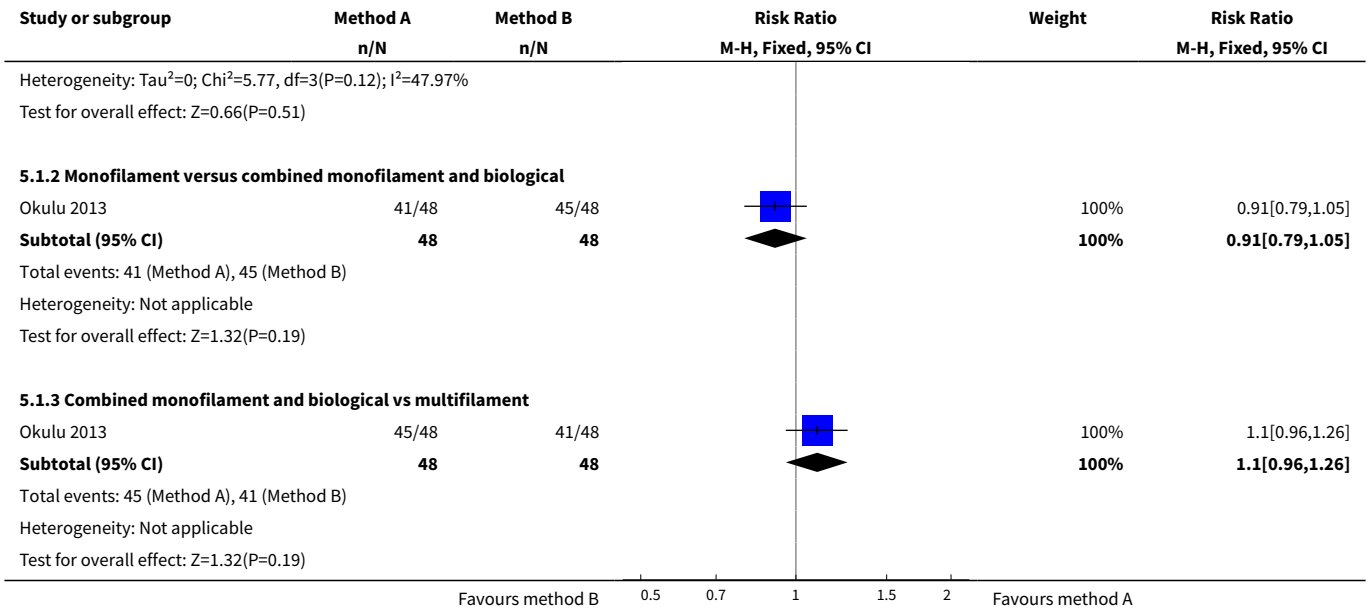
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.3 Combined monofilament and biological vs multifilament	1	96	Risk Ratio (M-H, Fixed, 95% CI)	1.13 [0.96, 1.32]
3 Objective cure (short term, ≤ 1 year)	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 Monofilament vs multifilament	2	349	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.96, 1.19]
4 Operative time (minutes)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 Monofilament vs multifilament	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Length of hospital stay (days)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
5.1 Monofilament vs multifilament	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Perioperative complications	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
6.1 Monofilament vs multifilament	2	279	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.36, 3.69]
7 Major vascular or visceral injury	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
7.1 Monofilament vs multifilament	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.2 Monofilament vs combined monofilament and biological	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.3 Combined monofilament and biological vs multifilament	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Bladder or urethral perforation	4	749	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.49, 2.70]
8.1 Monofilament vs multifilament	4	557	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.49, 2.70]
8.2 Monofilament vs combined monofilament and biological	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8.3 Combined monofilament and biological vs multifilament	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Voiding dysfunction	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9.1 Monofilament vs multifilament	3	461	Risk Ratio (M-H, Fixed, 95% CI)	2.10 [0.96, 4.59]
10 De novo urgency or urgency incontinence	4		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
10.1 Monofilament vs multifilament	4	545	Risk Ratio (M-H, Fixed, 95% CI)	1.11 [0.68, 1.82]
10.2 Monofilament vs combined monofilament and biological	1	96	Risk Ratio (M-H, Fixed, 95% CI)	2.0 [0.38, 10.41]
10.3 Combined monofilament and biological vs multifilament	1	96	Risk Ratio (M-H, Fixed, 95% CI)	0.4 [0.08, 1.96]
11 Detrusor overactivity	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
11.1 Monofilament vs multifilament	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
12 Vaginal tape erosion	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
12.1 Monofilament vs multifilament	3	445	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.09, 6.84]
12.2 Monofilament vs combined monofilament and biological	1	96	Risk Ratio (M-H, Random, 95% CI)	3.0 [0.32, 27.83]
12.3 Combined monofilament and biological vs multifilament	1	96	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.04, 3.09]
13 QoL specific (ICIQ)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
13.1 Monofilament vs multifilament	1	96	Mean Difference (IV, Fixed, 95% CI)	-0.60 [-0.76, -0.44]

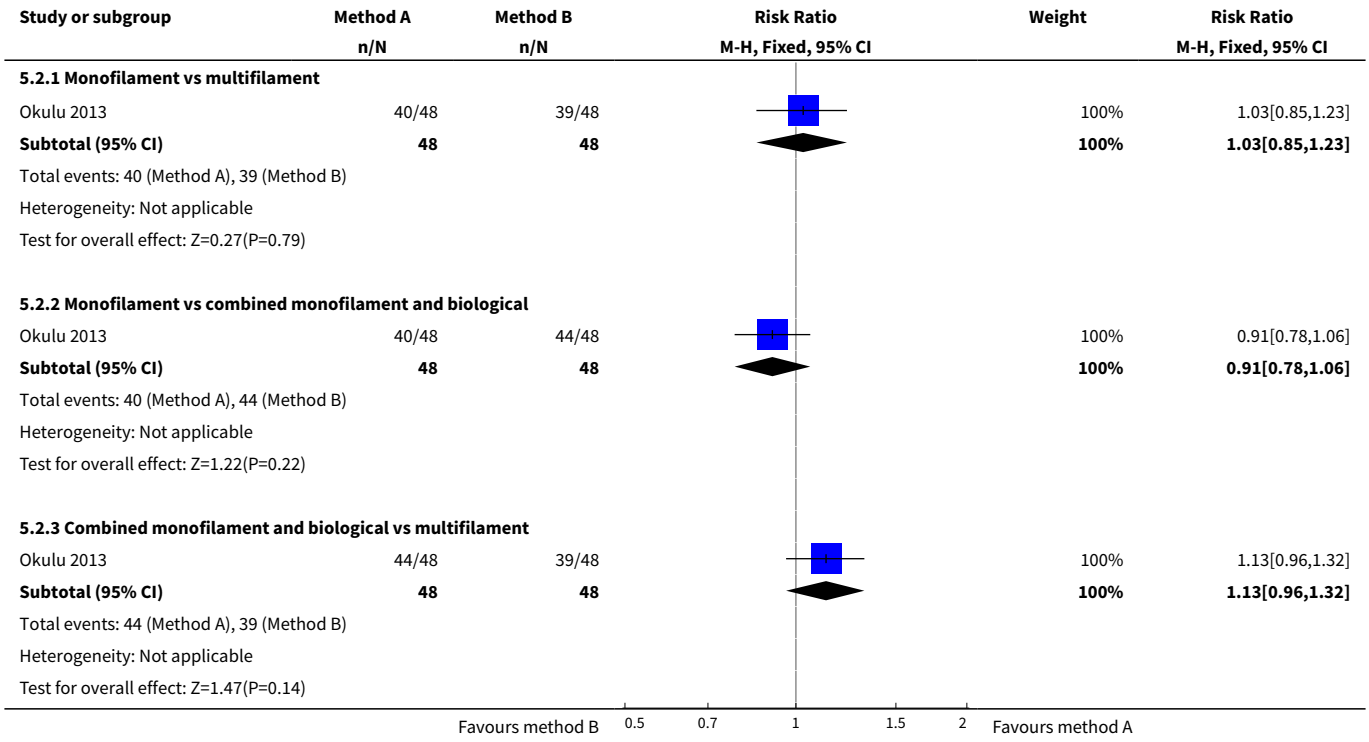
Analysis 5.1. Comparison 5 One type of tape material versus another, Outcome 1 Subjective cure (short term, ≤ 1 year).

Study or subgroup	Method A n/N	Method B n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
5.1.1 Monofilament versus multifilament					
Lim 2005	93/115	50/56		30.83%	0.91[0.8,1.03]
Meschia 2006	80/92	68/87		32.04%	1.11[0.97,1.28]
Okulu 2013	41/48	41/48		18.79%	1[0.85,1.18]
Rechberger 2003	44/50	40/50		18.34%	1.1[0.93,1.31]
Subtotal (95% CI)	**305**	**241**		**100%**	**1.03[0.95,1.1]**
Total events: 258 (Method A), 199 (Method B)					

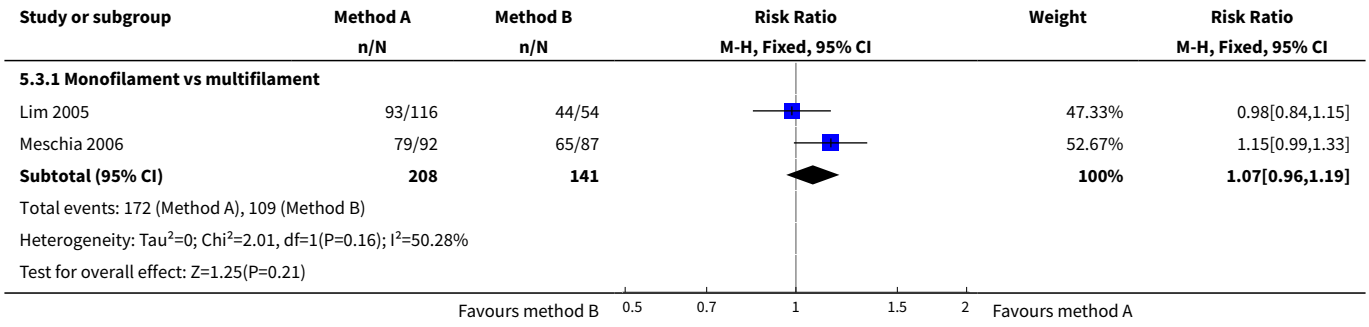




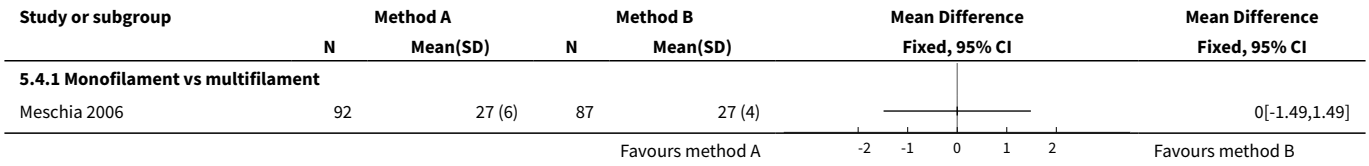
Analysis 5.2. Comparison 5 One type of tape material versus another, Outcome 2 Subjective cure (medium term, 1 to 5 years).



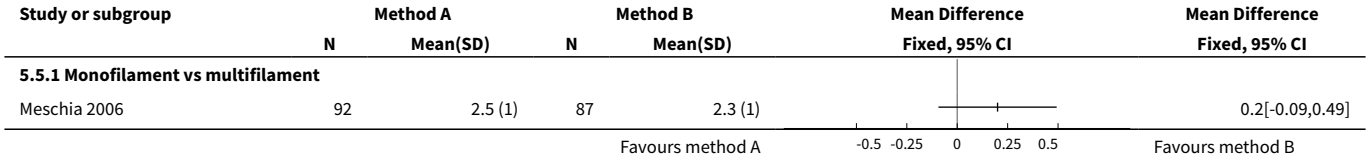
Analysis 5.3. Comparison 5 One type of tape material versus another, Outcome 3 Objective cure (short term, ≤ 1 year).



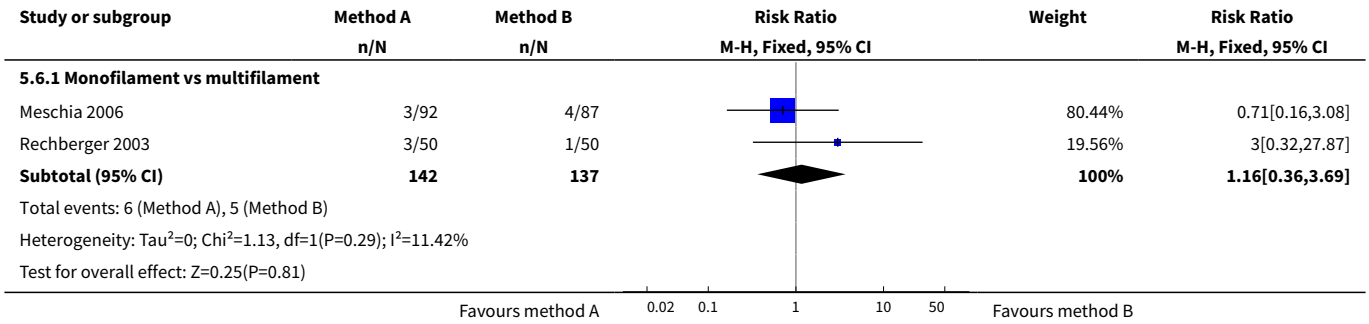
Analysis 5.4. Comparison 5 One type of tape material versus another, Outcome 4 Operative time (minutes).



Analysis 5.5. Comparison 5 One type of tape material versus another, Outcome 5 Length of hospital stay (days).

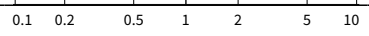


Analysis 5.6. Comparison 5 One type of tape material versus another, Outcome 6 Perioperative complications.



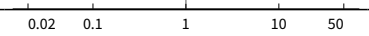
Analysis 5.7. Comparison 5 One type of tape material versus another, Outcome 7 Major vascular or visceral injury.

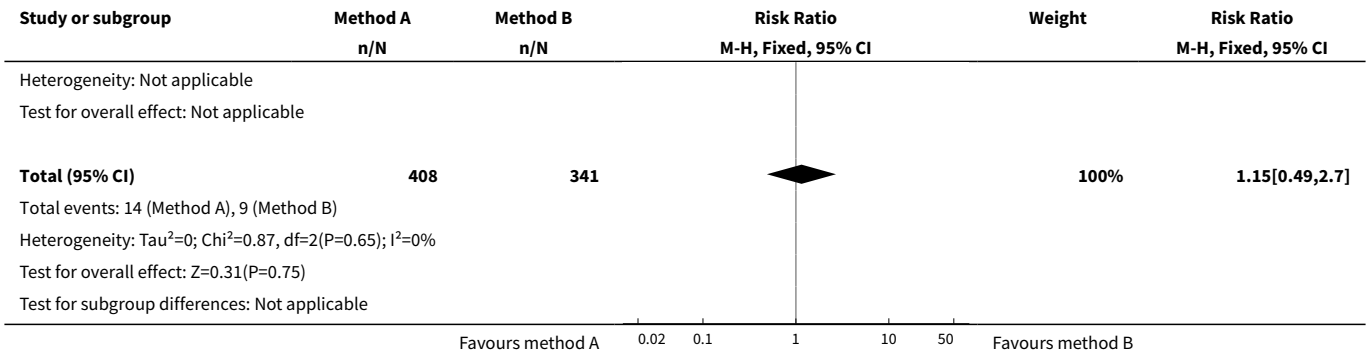
Study or subgroup	Method A n/N	Method B n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
5.7.1 Monofilament vs multifilament					
Okulu 2013	0/48	0/48			Not estimable
Subtotal (95% CI)	**48**	**48**			**Not estimable**
Total events: 0 (Method A), 0 (Method B)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
5.7.2 Monofilament vs combined monofilament and biological					
Okulu 2013	0/48	0/48			Not estimable
Subtotal (95% CI)	**48**	**48**			**Not estimable**
Total events: 0 (Method A), 0 (Method B)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
5.7.3 Combined monofilament and biological vs multifilament					
Okulu 2013	0/48	0/48			Not estimable
Subtotal (95% CI)	**48**	**48**			**Not estimable**
Total events: 0 (Method A), 0 (Method B)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
Test for subgroup differences: Not applicable					



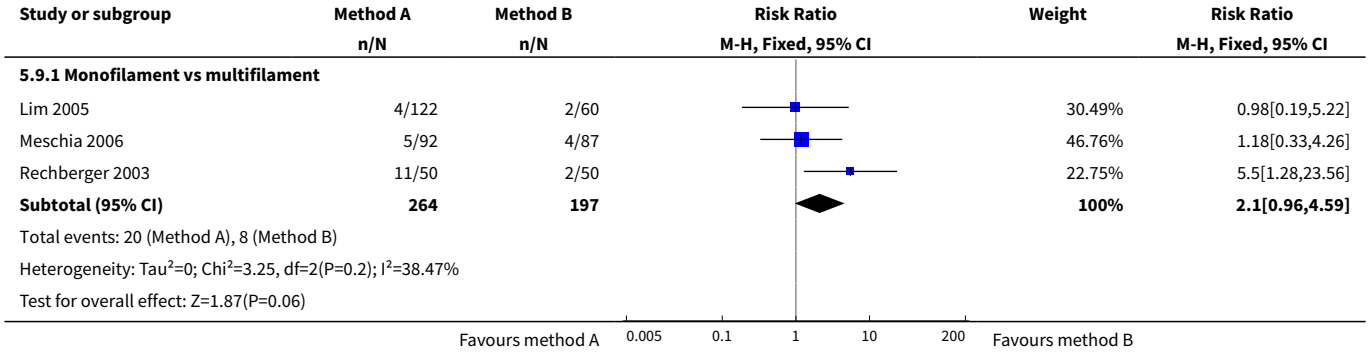
Analysis 5.8. Comparison 5 One type of tape material versus another, Outcome 8 Bladder or urethral perforation.

Study or subgroup	Method A n/N	Method B n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
5.8.1 Monofilament vs multifilament					
Lim 2005	8/122	2/60		27.46%	1.97[0.43,8.98]
Meschia 2006	3/92	3/87		31.58%	0.95[0.2,4.56]
Okulu 2013	0/48	0/48			Not estimable
Rechberger 2003	3/50	4/50		40.96%	0.75[0.18,3.18]
Subtotal (95% CI)	**312**	**245**		**100%**	**1.15[0.49,2.7]**
Total events: 14 (Method A), 9 (Method B)					
Heterogeneity: $Tau^2=0$; $Chi^2=0.87$, df=2(P=0.65); $I^2=0\%$					
Test for overall effect: Z=0.31(P=0.75)					
5.8.2 Monofilament vs combined monofilament and biological					
Okulu 2013	0/48	0/48			Not estimable
Subtotal (95% CI)	**48**	**48**			**Not estimable**
Total events: 0 (Method A), 0 (Method B)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
5.8.3 Combined monofilament and biological vs multifilament					
Okulu 2013	0/48	0/48			Not estimable
Subtotal (95% CI)	**48**	**48**			**Not estimable**
Total events: 0 (Method A), 0 (Method B)					

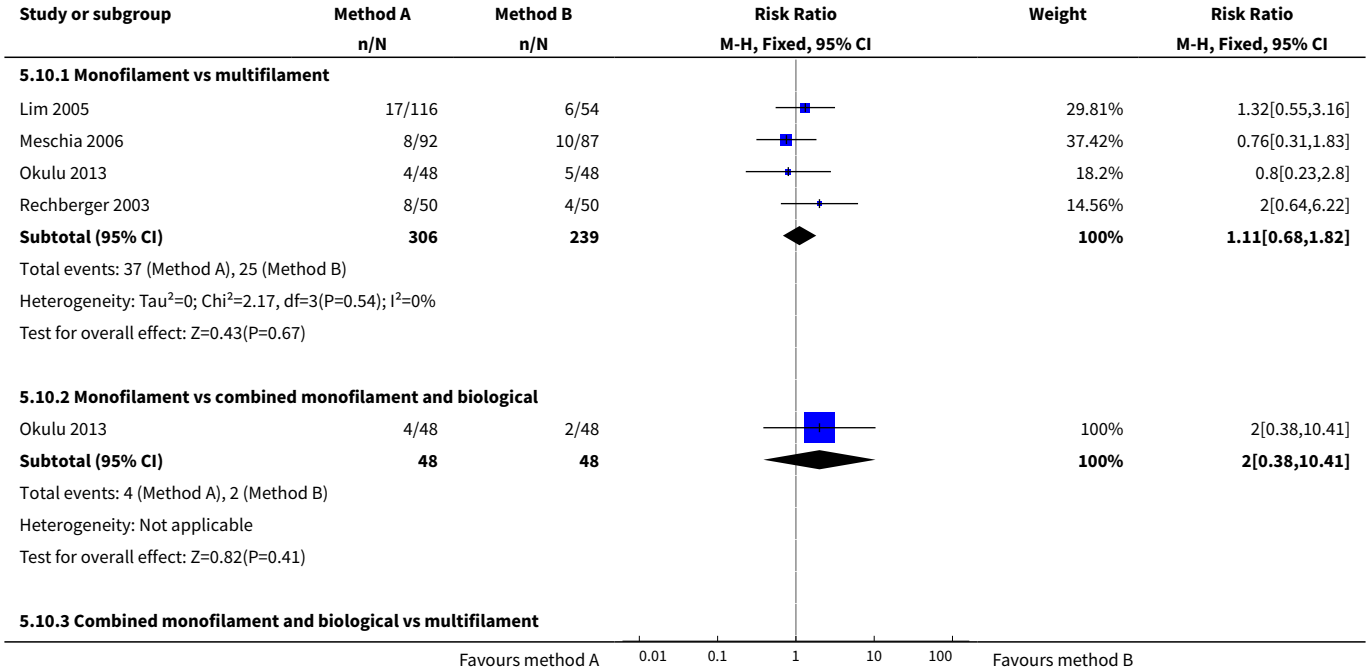


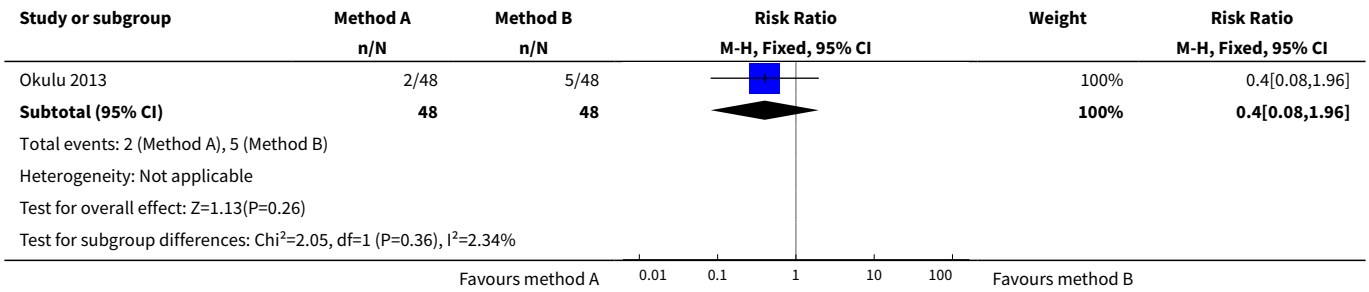


Analysis 5.9. Comparison 5 One type of tape material versus another, Outcome 9 Voiding dysfunction.

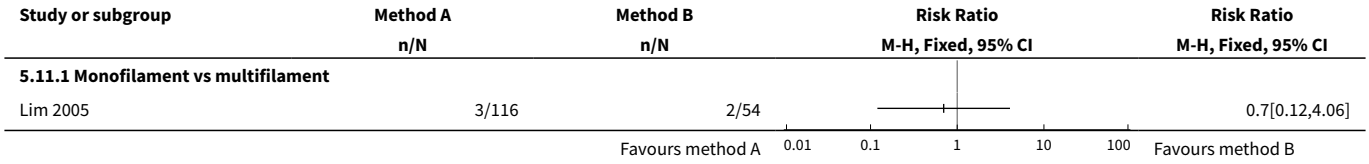


Analysis 5.10. Comparison 5 One type of tape material versus another, Outcome 10 De novo urgency or urgency incontinence.

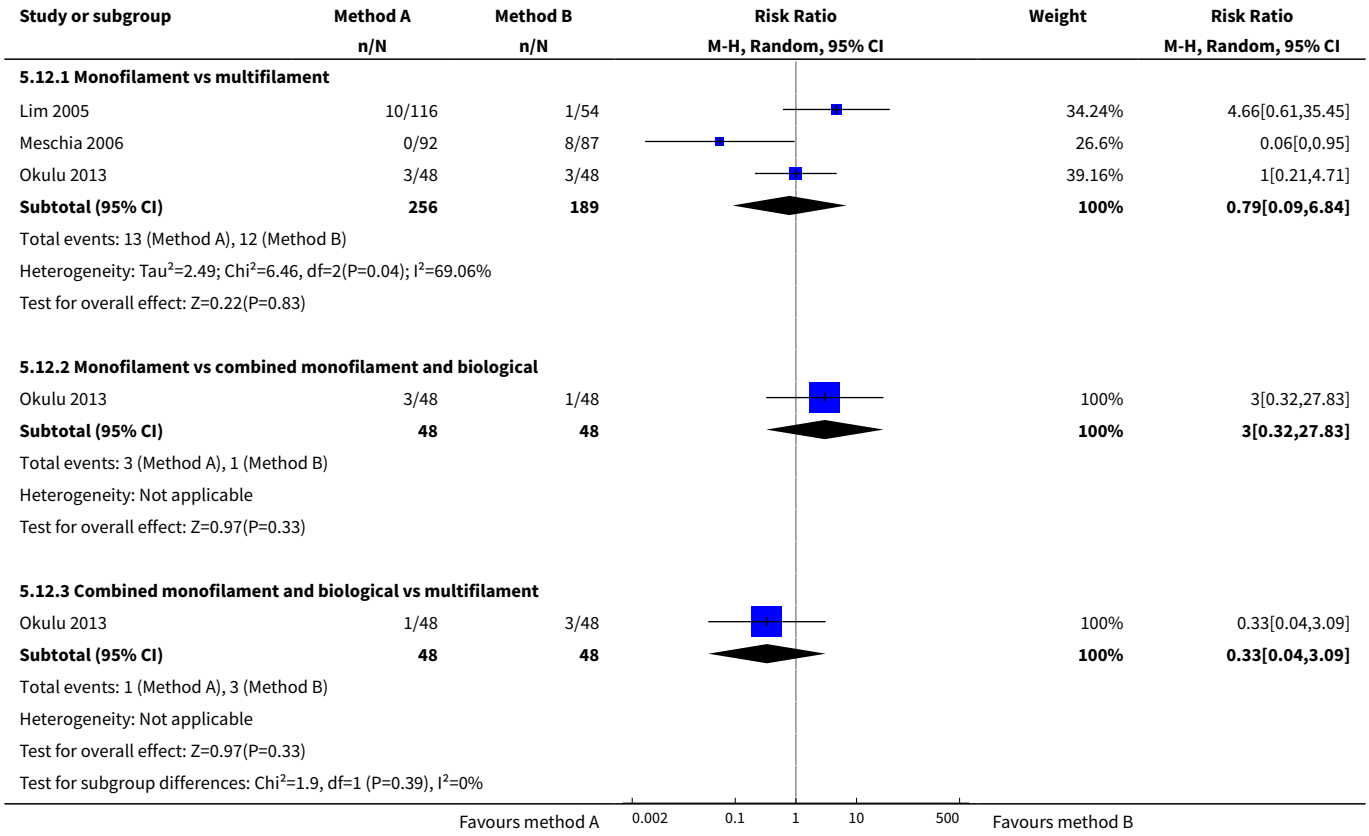




Analysis 5.11. Comparison 5 One type of tape material versus another, Outcome 11 Detrusor overactivity.

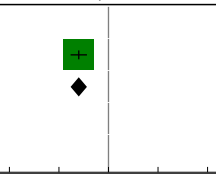


Analysis 5.12. Comparison 5 One type of tape material versus another, Outcome 12 Vaginal tape erosion.



Analysis 5.13. Comparison 5 One type of tape material versus another, Outcome 13 QoL specific (ICIQ).

Study or subgroup	Method A N	Method A Mean(SD)	Method B N	Method B Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
5.13.1 Monofilament vs multifilament							
Okulu 2013	48	1.5 (0.3)	48	2.1 (0.5)		100%	-0.6[-0.76,-0.44]
Subtotal ***	**48**		**48**			**100%**	**-0.6[-0.76,-0.44]**
Heterogeneity: Not applicable							
Test for overall effect: Z=7.13(P<0.0001)							



ADDITIONAL TABLES

Table 1. Tabulated Results of Included Studies

Study	Outcome data
Abdel-Fattah 2010	Group A: TVT-O (n = 170) Group B: TOT (n = 171) Loss to follow up at 1yr: A: 18/170, B: 24/171 Loss to follow up at 3yrs: A: 44/170, B: 59/171 Objective cure: A: 114/121, B: 96/109 Subjective success: A: 121/149, B: 111/143 Bladder/urethral perforation: A: 1/170, B: 2/171 Voiding dysfunction: A: 12/170, B: 9/171 Tape erosion: A: 3/153, B: 5/149 Groin pain: A: 27/150, B: 19/147 Repeat continence surgery: A: 7/170, B: 15/171 QoL assessed via: King's Health Questionnaire (KHQ) [10], Birmingham Bowel Urinary Symptom (BBUSQ-22) [11] and Pelvic Organ Prolapse/Incontinence Sexual Function Questionnaire (PISQ-12). In addition Patient Global Impression of Improvement (PGI-I) [13] and International Consultation on Incontinence Questionnaire- Short form (ICIQ-SF) [14] questionnaires. QOL scores were much improve following surgery with no significant inter group (A vs B) differences. Sexual dysfunction: PISQ-12 employed. 199 patients completed this assessment and in most domains a significant improvement in postoperative PISQ-12 scores was found with no significant difference demonstrated between the two groups. Intermediate (3 yr) Subjective success (very much & much improved) on PGI-I: A: 93/126, B: 81/112
Aigmuller 2014	Group A: TVT: (n = 285; 38 of whom were lost to follow-up) Group B: TVT-O: (n = 269; 36 of whom were lost to follow-up) Participants were evaluated at 3 months, with a further evaluation scheduled at 5 years • Objective cure of SUI: defined as a negative cough stress test and stable cystometry to 300 ml • Subjective cure defined on PGI as 'very much better' and 'better' • Objective cure: A: 215/247, B: 196/233

Table 1. Tabulated Results of Included Studies *(Continued)*

	• Subjective cure A: 123/139, B: 107/122 • Subjective cure and improvement: A: 136/139, B: 116/122 • Operating time (minutes; SD): A: 21±12.22, B: 16.8±8.8 • Bladder perforation: A: 11/285, B:0/269 • Vascular injury: A: 2/285, B: 3/269 • Voiding dysfunction: A: 4/285, B: 1/269 • Major visceral injury: A: 1/285, B: 0/269 • Infection: A: 1/285, B: 0/269 • De novo OAB: A: 26/247, B: 24/233 At 5-year review: • A negative cough stress test was seen in 83% of patients after TVT and 76% of patients after TVT-O. • No pad use was reported by 56% of patients after TVT and 58% of patients after TVT-O. None of these differences reached statistical significance. • One tape exposure was noted after TVT and 3 after TVT-O. • There were 9 (6%) re-operation after TVT and 5 (3%) after TVT-
Alkady 2009	Group A: TVT (n = 15) Group B: TVT-O (n = 15) • Objective cure: absence of SUI and a negative stress test • Objective improvement: lower volume and frequency of SUI, but positive stress test • Objective cure: A 13/15, B: 13/15 • Objective cure & improvement: A 14/15, B: 15/15 • Mean blood loss (ml)s (SD): A: 26(10.23), B: 22(7.15) • Mean hospital stay (days)s (SD): A: 1.1(1.0), B: 1.2(0.9) • Bladder perforation: A: 1/15, B: 0/15 • Major vascular injury: A: 1/15, B: 0/15 • Voiding dysfunction: A: 2/15, B: 1/15 • Tape erosion: A: 1/15, B: 0/15
Andonian 2005	Group A: SPARC Group B: TVT • Objective Cure: A: 34/41, B: 40/42 • Perioperative complications: A: 3/41, B: 0/40 • Bladder perforation: A: 10/41, B: 10/43 • Voiding dysfunction: A: 2/41, B: 4/43 • Tape erosion: A: 1/41, B: 0/41
Andonian 2007	Group A: Obtape (n = 78) Group B: DUPS (n = 32) - suspended Group C: TVT (n = 80) • Objective cure short term: A: 64/77, B: 69/80 • Perioperative complications: A: 11/77, B: 6/80 • Bladder perforation: A: 0/77, B: 11/80 • De novo urgency or urgency incontinence: A: 6/77, B: 5/80 • Tape erosion: A: 2/77, B: 0/80 • Repeat incontinence surgery: A: 2.77, B:0/80
Aniuliene 2009	Group A: TVT-O (n = 150)

Table 1. Tabulated Results of Included Studies *(Continued)*

	Group B: TVT (n = 114) • Objective cure: negative stress provocation test with 300 ml of urine in the bladder: A: 142/150, B: 108/114 • Subjective cure: self-reported absence of SUI with or without mild urgency incontinence. A: 145/150, B: 111/114 • Mean duration of procedure (SD): A: 19 (5.6), B: 27 (7.1) • Mean hospital stay days (SD) A: 1.5 (0.5), B: 4.0 (1.6) • Bladder perforation: A: 0/150, B: 1/114 • Post operative urinary retention: A: 5/150, B: 18/114 • Haematoma: A: 0/150, B: 1/114
Araco 2008	Group A: TVT-O (n = 120) Group B: TVT (n = 120) • Objective cure short term: A: 83/100, B: 108/108 • Operative time in minutes (standard deviation): A: 34 (11), B: 48 (7) • Perioperative complications: A: 6/120, B: 21/120 • Major vascular injury: A: 0/120, B: 6/120 • Bladder perforation: A: 0/120, B: 3/120 • Voiding dysfunction: A: 0/100, B: 12/108 • de novo urgency/UUI: A: 6/100, B: 8/108 • Detrusor overactivity: A: 3/100, B: 2/108 • Vaginal tape erosion: A: 3/100, B: 1/108 • Repeat incontinence surgery medium term (1-5 years): A: 17/100 B: 1/108
Barber 2008	Group A: TVT (n = 88) Group B: TOT (n = 82) • subjective cure (self-reported): A: 74/85, B: 68/75 • objective cure (negative cough stress test): A: 73/85, B: 62/75 • mean operating time (minutes; no concomitant surgery): A: 29(10), B: 28(7) • bladder perforation: A: 7/88, B: 0/82 • major vascular injury: A: 1/88, B: 0/82 • vaginal tape erosion: A: 5/85, B: 1/75 • de novo urgency/UUI: A: 27/85, B: 21/75 • voiding dysfunction: A: 5/88, B: 2/82 • re-operation: A: 4/85, B: 1/75 • QoL: overall improvement in QoL and sexual function scores at follow-up assessments compared with preoperative baseline scores. No difference between the groups.Used PFDI-20, PFIQ-7, PISQ-12 • sexual dysfunction assessed using PISQ-12. Scores improved post operatively and at 12 months follow up in both groups, though the relative change in scores post-operatively was small (1.9%) showing moderate responsiveness to incontinence specific outcome measures. There was no significant difference reported between the two groups.
Barry 2008	Group A: TOT (n = 58) Group B: TVT (n = 82) • Subjective cure: A: 49/58, B: 70/82 • Objective cure: A: 48/58, B: 64/82 • Operating time: A: 14.6 (6), B: 58 (18.5) • Operative blood loss in mls A: 49 (31.2), B: 64 (41.4) • Peri-operative complications: A: 0/58, B: 2/82 • Bladder perforation: A: 1/58, B: 7/82

Table 1. Tabulated Results of Included Studies *(Continued)*

	• Voiding dysfunction: A: 6/58, B: 7/82 • de novo urgency/UUI: A: 0/58, B: 1/82 • Vaginal tape erosionL A: 3/58, B: 1/82
But 2008	Group A: TVT-O (n = 60) Group B: TOT (n = 60) • Objective cure rates: negative pad test. A: 54/60, B 58/60 • Subjective cure rates: absence of reported SUI: A: 59/60, B 59/60 • Post operative voiding difficulties: A: 8/60, B: 3/60 • Tape erosion: A: 0/60, B: 0/60 • Duration of operation: • Duration and intensity of postoperative pain according to a modified VAS • QoL (UDI) significantly improved post operatively in each group with no significant intergroup difference.
Cervigni 2006	Numbers in each group unreported. It was, thus, impossible to abstract results
Chen 2010	Group A: TVT (n = 77) Group B: TOT (n = 45) Group C: TVT-O (n = 65) • Objective cure: negative stress test: A: 70/77, B: 41/45, C: 60/65 • Mean operative time in minutes (SD): A: 48.2 (21.9), B: 20 (13.5), C: 26.9 (16.8) • Mean postoperative hospital stay days (SD): A: 5.0 (2.4), B: 4.0 (2.2), C: 2.3 (0.8) • Bladder perforation: A: 4/77, B: 0/45, C: 0/65 • Vascular injury: A: 1/77, B: 0/45, C: 0/65 • Voiding dysfunction: A: 7/77, B: 2/45, C: 3/65
Chen 2012	A: TVT (n = 102) B: TVT-O (n = 103) • Objective cure: negative pad test and stress test • Objective cure: A: 89/102, B: 85/103 • Cure and improvement: A: 99/102, B: 96/103 • Operative time (mean minutes (SD)): A: 27.3 (13.3) 102, B: 18.5 (7.4) • Blood loss (ml): A: 18 (15.4), B: 18.5 (7.4) • Length of stay (days): A: 3.4 (2.1), B: 3.1 (1.8) • Bladder injury: A: 5/102, B: 0/103 • Voiding dysfunction: A: 2/102, B: 2/103 • Groin pain: A: 0/102, B: 3/103
Cho 2010	Group A: Monarc TOT (n = 48) Group B: TOT (n = 45) • Subjective cure: A: 41/48, B: 37/45 • Voiding dysfunction: A: 1/48, B: 2/45 • Tape erosion: A: 0/48, B: 3/45
Choe 2013	We were not able to use the data provided, as the number in each group was not specified
Darabi Mahboub 2012	Group A: TOT (n = 40)

Table 1. Tabulated Results of Included Studies *(Continued)*

	Group B: TVT (n = 40) Operative time (minutes (SD): A: 64.50 (9.04), B: 64.00 (9.48) Mean hospital stay (days): A: 2.56 (0.51), B: 2.52 (0.47)
David-Montefiore 2006	Group A: RPR (n = 42) Group B: TOR (n = 46) • 4 year objective cure A: 27/34, B: 32/37. There is a significant reduction in cure at 4 years in comparison to 1 year. • De novo urgency and urge incontinence: A: 7/34, B: 10/37
de Leval 2011	Group A: TVT-O (n = 87) Group B: modified TVT-O (n = 88) • subjective cure: disappearance of SUI using symptom scoring system: A: 77/84, B: 78/86. • subjective cure and improvement: A: 80/84, B: 84/86 • Intraoperative complications: A: 0/87, B: 0/88 • de novo urgency: A: 8/84 B: 10/86 • mesh erosion: A: 1/84, B: 0/86 • groin pain: A: 3/84, B: 4/86 At 3-year follow-up: • objective cure: negative cough test A: 48/56, B: 50/57 • subjective cure: A: 63/74, B: 66/79
de Tayrac 2004	Group: A: TOT (n = 30) Group: B: TVT (n = 31) • Subjective cure: A: 26/30, B: 30/31 • Objective cure (negative cough stress test): A: 27/30, B: 26/31 • Objective cure and improvement: A: 28/30, B: 29/31 • Mean operating time (minutes): A: 14.8(4.3), B: 26.5(7.7) • Mean length of hospital stay (days): A: 1.2(1.3), B: 1.1(0.4) • Bladder perforation: A: 0/30, B: 3/31 • Vaginal tape erosion: A: 0/30, B: 0/31 • Urethral tape erosion: A: 0/30, B: 1/31 • De novo urgency/UUI: A: 2/30, B: 2/31 • Voiding dysfunction: A: 8/30, B: 10/31 • Sexual dysfunction measured using mean VAS score. No significant difference between the 2 groups in terms of improvement of sexual function: A: Pre-operatively 8.73 (2.18), post operatively: 9.86 (0.54), B: Pre-operatively 8.12 (2.93), post operatively: 8.25 (4.12)
Deffieux 2010	Group A: TVT (n = 75) Group B: TVT-O (n = 74) • Subjective cure (self-reported via questionnaires) short term: A: 63/69 , B: 61/69 • Subjective cure at 24 months: A: 55/67, B: 56/65 • Objective cure (negative cough stress test) short term: A: 65/69 , B: 67/69 • Objective cure at 24 months: A: 61/67, B: 65/65 • Bladder injury: A: 5/75, B: 2/74 • Major vascular injury: A: 0/75, B: 0/74

Table 1. Tabulated Results of Included Studies *(Continued)*

	• Tape erosion: A: 0/67, B: 1/65 • Voiding dysfunction: A: 6/67, B: 2/65 • Groin/suprapubic pain: A: 2/67, B: 1/65 • Re-operation rates: A: 2/67, B: 1/65
Diab 2012	Group A: TOT (n = 31) Group B: TVT (n = 32) • Retropubic haematoma: A: 0/31, B: 2/32. • Vaginal tape extrusion: A: 2/31, B: 2/32 All the preoperative parameters were comparable in both groups. The mean operative time was significantly longer and bladder injury was significantly higher in the TVT group. There were no significant difference in cure rates, voiding dysfunction, de novo urgency and reoperation rate. The postoperative groin/thigh pain was higher in the TOT group.
El-Hefnway 2010	Preliminary results: Group A: TVT: (n = 19) Group B: TOT: (n = 21) At 24 months: Group A: TVT: (n = 45) Group B: TOT: (n = 42) • Objective cure: negative stress test, 1-h pad test < 2g, and no re-treatment for stress incontinence • 12 months negative stress test: A: 18/19, B: 18/21 • 24 months negative stress test: A: 31/36, B: 28/35 • 24 months negative 1hr pad test: A:29/36, B: 26/35 • Subjective cure: no reported SUI • Mean operative time in minutes (SD): A: 23.8(5), B: 19.6(5) • Mean blood loss (ml): A: 52(14), B: 40(13) • Vascular injury: A 3/36, B: 0/35 • Bladder injury: A: 3/45, B: 0/42 • Groin pain: A: 0/36, B: 2/35 (no report of suprapubic pain) • Tape erosion: A: 0/19, B: 1/21 • De novo urgency: A: 0/36 , B 3/35 • QOL: Pre-operative UDI-6 mean scores (SD): A: 13 (3), B: 15(3) • Pre-operative IIQ-7 mean scores (SD): A: 17 (3), B: 17 (4) • UDI-6 at 12- and 24-month follow-up (SD): A: 2.8 (3), B: 4.7 (6) • IQ-7 at 12- and 24-month follow-up (SD): A: 3.2 (5), B: 4.3 (7) • 24 month follow up UDI-6 (SD): A: 3.5 (4), B: 4.6 (4) • 24 month follow up IIQ-7: A: 3.6 (6), B: 3.0 (4)
Elbadry 2014	Group A: adjustable TOT (n = 48) Group B: TOT: (n = 48) • cure rates: A: 40/48, B: 38/48. • Mean operative time in group 2 was significantly shorter than that in group A (11 minutes versus 20 minutes, respectively). • Major vascular injury: A: 0/48, B: 0/48 • bladder injury: A: 0/48, B: 0/48

Table 1. Tabulated Results of Included Studies *(Continued)*

	• Postoperative adjustment of the tape was only required in 3 cases in group • Length of hospital stay: No statistically significant difference was found between the 2 group
Enzelsberger 2005	Group A: TOT (n = 56) Group B: TVT (n = 54) • Objective cure rate: A: 45/53, B: 45/52 • Operative complications: A: 6/53, B: 10/52 • Operative time in minutes (standard deviation): A: 15 (7), B: 26 (10) • Bladder perforation: A: 0/53, B: 4/52 • Voiding dysfunction: A: 3/53, B: 4/52 • Detrusor overactivity: A: 6/53, B: 5/52 • Tape erosion: A: 1/53, B: 1/52 • Groin pain: A: 5/53, B: 0/52
Freeman 2011	Group A: Monarc TOT (n = 100) Group B: Gynaecare TVT (n = 92) • Subjective cure: A: 59/95, B: 55/85 • Mean operation time (minutes), SD): A: 28 (15), B: 30 (14.2) • Operative blood loss (ml) SD: A: 49 (46), B: 62 (65) • Bladder perforation: A: 0/100, B:2/92 • Vaginal perforation: A: 4/100, B: 0/92 • Tape erosion: A: 3/95, B: 2/85 • Voiding dysfunction: A: 5/100, B: 5/95 • De novo OAB: A: 4/95, B: 4/85 • Groin pain: A: 8/95 , B: 1/85 • Sexual function: assessed via ICIQ-LUTSqol scores. QoL were improved by both operations from baseline scores without a significant difference between the groups at 12 months follow up. Percentage of women reporting moderate or severe impact of incontinence on sexual function reduced post-operatively by 27.9% in the TVT group and by 30.7% in the TOT group.
Hammoud 2011	Group A: TVT (n = 60) Group B: TVT-O (n = 50) Subjective cure: A: 56/60, B: 48/50
Hassan 2013	Group A: inside-out TOT (n = 125) Group B: outside-in TOT (n = 125) • subjective cure at 12 months: A: 102/102, B: 95/97 • vascular injury/haematoma: A: 5/125, B: 7/125 • groin/thigh pain: A: 91/125, B: 84/125 • tape erosion: A: 1/102, B: 0/97
Houwert 2009	Group A: TVT-O (n = 93) Group B: Monarc TOT (n = 98) • Subjective cure at 12 months (short term): A: 66/86, B: 73/95 • Subjective cure and improvement at 12 months (short term): A: 79/86, B: 89/95 • Subjective cure at 2-4years (medium term): A: 54/75, B: 56/86 • Subjective cure and improvement at 2-4years (medium term): A: 63/75, B: 74/86 • Operating time (minutes) (SD): A: 16 (5), B: 16 (6)

Table 1. Tabulated Results of Included Studies *(Continued)*

	• Voiding dysfunction at 2 months: A: 10/93, B: 3/98 • Vaginal tape erosion at 12 months: A: 1/86, B: 4/95 • Thigh pain: A: 0/86, B: 1/95 • De novo urgency/UI: A: 2/71, B: 4/72 • Repeat incontinence surgery: A: 5/93, B: 4/98 • QOL: both the IIQ-7 and UDI-6 demonstrated a statistically significant increase in QoL decrease in impairment caused by symptoms of SUI after 2 months, 1 year, and 2–4 years in both TOT groups. • Sexual dysfunction: Rates of post operative dyspareunia were low with only 1 patient in each group reporting the complication at 12 months, and by 24 months this had resolved in the TOT group.
Jakimiuk 2012	Group A: TVT (n = 19) Group B: TVT-O (n = 16) • Subjective cure: self-reported: A: 14/15, B: 13/16 • Objective cure: negative cough test and pad test: A: 14/15, B: 14/16 • Bladder perforation: A: 3/19, B: 0/16 • Voiding dysfunction: A: 2/19, B: 0/16 • Vascular injury: A: 2/19, B: 0/16 • Mean procedure time (minutes) (SD): A: 47.75 (42.89), B: 12.4 (3.52) • Mean hospital stay (days) (SD): A: 2.41 (1.37), B: 2.0 (0) • QoL: used non-validated KHQ and validated SF-36 questionnaires the result showed post operative improvement from baseline scores in all domains with no significant differences demonstrated between groups.
Juang 2007	Group A: TVT-O (n = 47) Group B: TVT-O plus IS: (n = 49) • Objective cure: A:22/45, B:34/48 • Objective improvement: A:5/45, B:5/48 • Blood loss (mls) (SD): A: 30.3 (15.2), B: 82.4 (25.1) • Operating time (minutes) (SD): A: 16.3 (4.1), B: 28.3 (10.2) • Mean hospital stay (days) (SD): A: 1.7 (0.8), B: 3.2 (2.8) • Bladder perforation: A: 0/47, B: 0/49 • Major vascular injury: A: 1/47, B: 3/49 • Tape erosion: A: 1/45, B: 1/48 • Complications: One subject in the TVT-O plus IS group, who presented with temporary adductor muscle weakness and a numbness sensation in the medial aspect of right thigh, was noted to have obturator nerve injury, which resolved at 3-months follow-up after conservative treatment, with resolution of symptoms. At the 1-yr follow-up, about 25% of subjects in the TVT-O plus IS group still needed antimuscarinics,whereas about 45% of subjects in the TVT-O alone group still needed some antimuscarinic medication
Kamel 2009	A: TVT (n = 60) B: TVT-O (n = 60) • Objective cure: A: 54/60, B: 55/60 • Bladder perforation: A: 5/60, B: 0/60 • Vascular injury: A: 2/60, B: 0/60 • Mean operative time (minutes): A: 30 mins, B: 15 mins
Karateke 2009	Group A: TVT (n = 83) Group B: TVT-O (n = 84)

Table 1. Tabulated Results of Included Studies *(Continued)*

	• Subjective cure (very satisfied and satisfied): A: 76/81, B: 76/83 • Obective cure: A: 72/81, B: 73/83 • Mean operative time (minutes) (SD): A: 31.27 (4.73), B: 18.64 (2.47) • Vascular injury/haematoma: A: 4/83, B: 2/84 • Bladder perforation: A: 3/83, B: 0/84 • Tape erosion: A: 4/81, B: 2/83 • Voiding dysfunction: A: 8/83, B: 6/84 • De novo UI: A: 6/81, B: 5/83 • De novo DO: A: 12/81, B: 10/83 • Mean hospital stay (days) (SD): A: 1.36 (0.76) B: 1.25 (0.66) • Time to return to normal activity (weeks): A: 2.7 (2.4), B: 2.43 (2.02) • QOL: Mean IIQ-7 scores; mean (SD): TVT A: Preop 13.83 (3.88), Postop 6.94 (3.40), TVT-O B: Preop 13.83 (3.88), Postop 6.88 (3.38)
Kilic 2007	Group A: TVT (n = 10) Group B: TOT (n = 10) • Subjective cure: A: 7/10, B: 8/10 • Mean operative time in mins (standard deviation): A: 32 (5.3), B: 26 (9.5)
Kim 2004	Group A: TVT (n = 32) Group B: SPARC (n = 30) Group C: IRIS (n = 34). • Subjective cure: A: 31/32, B: 29/30 • Objective cure: A: 31/32, B: 29/30 • Operating time in mins (standard deviation): A: 27.5 (2.7), B: 28.1 (7.5) • Length of hospital stay (days): A: 2.5 (0.9), B: 2.3 (0.6) • Perioperative complications: A: 6/32, B: 7/30 • Bladder perforation: A: 3/32, B: 3/30 • Voiding dysfunction: A: 0/32, B: 3/30 • De no urgency/urgency urinary incontinence: A: 3/32, B: 1/30 • Vaginal tape erosions: A: 0/32, B: 0/30
Kim 2005	Group A: Monarc (n = 65) Group B: SPARC (n = 65) • Subjective cure: A: 56/65, B: 56/65 • Subjective cure and improvement: A: 62/65, B: 63/65 • Objective cure: A: 17/21, B: 18/22 • Objective cure and improvement: A: 21/21, B: 22/22 • Operative time in mins (standard deviation): A: 26.8 (11.8), B: 31.6 (9.6) • Perioperative complications: A: 1/21, B: 2/22 • Bladder perforation: A: 0/65, B: 4/65 • Voiding dysfunction: A: 4/65, B: 5/65 • De no urgency/urgency urinary incontinence: A: 1/21, B: 1/22 • Vaginal tape erosion: A: 0/65, B: 0/65 • Bladder erosion: A: 0/65, B: 0/65
Krofta 2010	Group A: TVT^{TM} (n = 149) Group B: TVT –O^{TM} (n = 151)

Table 1. Tabulated Results of Included Studies *(Continued)*

	• Objective cure: A: 127/141, B: 130/147 • Subjective cure: A: 111/141, B: 12/147 • Subjective improvement: A: 27/141, B: 31/147 • De novo urge: A: 9/141, B: 20/147 • Duration of operation (minutes) (SD): A: 32.62 (9.3) B: 23.76 (12.01) • Mean blood loss (SD): A: 31.57 (31.92), TVT-O: 32.26 (34.80) • Haematoma: A: 1/149, B: 0/151 • Groin/suprapubic pain: A: 6/141, B: 8/147 • Tape erosion/extrusion: A: 2/141, B: 2/147 • QOL: ICIQ UI- SF and CONTILIFE questionnaires were used pre- postoperatively both showing significant improvement in mean QoL scores following surgery with no significant difference between the two comparators. • Sexual dysfunction: assessed using PISQ-12 which showed a significant improvement post operatively from baseline scores but not significant difference between the groups.
Laurikainen 2007	Group A: TVT-O (n = 131) Group B: TVT (n = 136) • Objective cure short term: A: 122/131, B: 128/134 • Objective cure medium term: A: 113/126, B: 124/131 • Objective cure long term: A: 106/122, B: 111/131 • Subjective cure short term: A: 122/131, B: 121/134 • Subjective cure medium term: A: 115/126, B: 118/131 • Subjective cure long term: A: 113/122, B: 115/131 • Subjective cure and improvement long term: A: 121/122, B: 128/131 • Perioperative complications: A: 32/131, B: 22/136 • Mean operating time (minutes) (standard deviation): A: 29 (8), B: 29 (16) • Length of hospital stay (days) (standard deviation): A: 0.71 (0.58), B: 0.58 (0.42) • Time to return to normal activity (weeks) (standard deviation): A: 1.71 (0.57), B: 1.71 (0.57) • Operative blood loss (mls) (standard deviation): A: 46 (57), B: 55 (86) • Major vascular injury: A: 0/131, B: 4/136 • Bladder perforation: A: 0/131, B: 1/136 • De novo urgency/urgency urinary incontinence: A: 4/131, B: 6/134 • De novo urgency/urgency urinary incontinence long term: A: 3/122, B: 4/131 • Voiding dysfunction: A: 2/131, B: 1/136 • Repeat incontinence surgery: A: 1/131, B: 2/134 • Repeat incontinence surgery long term: A: 3/122, B: 2/131 • Vaginal tape erosion: A: 1/131, B: 2/134 • Groin pain at 2 months: A: 21/131, B: 2/136 • Groin pain at 12 months: A: 0/131, B: 0/131 • Tape erosion: A: 1/131, B: 0/136 • Tape erosion long term: A: 0/122, B: 0/131 QoL: The scores of the condition specific quality of life questionnaires were significantly lower at the 3 and 5 year follow up compared with pre-operative scores. This improvements were statistically significant, but with no difference between the groups. 84% of women with pre-operative moderate and severe frequency and urgency symptoms were cured of these symptoms at the 5 year follow up.
Leanza 2009	Group A: r-TICT (n = 229; retropubic) Group B: t-TICT (n = 220; transobturator) Subjective cure: A: 190/215, B: 178/208

Table 1. Tabulated Results of Included Studies *(Continued)*

Lee 2007	Group A: TVT (n = 60) Group B: TVT-O (n = 60) • Subjective cure: A: 52/60, B: 52/60 • Subjective cure and improvement: A: 56/60, B: 57/60 • Duration of operation mins (standard deviation): A: 15.2 (1.8), B: 11.5 (1.4) • Intraoperative blood loss mls (standard deviation): A: 40 (23.8), B: 31.1 (28.6) • Postoperative pain: A: • Major vascular injury: A: 0/60, B: 0/60 • Time to return to normal activities in weeks (SD): A: 5.2 (3.3), B: 4.9 (3.3) • Bladder perforation: A: 2/60, B: 0/60 • Voiding dysfunction: A: 0/60, B: 0/60 • De novo urgency/urgency urinary incontinence: A: 0/60, B: 4/60 • Vaginal tape erosion: A: 0/60, B: 0/60 • Groin pain: A: 5/60, B: 8/60 • Suprapubic pain: A: 5/60, B: 0/60
Lee 2008	Group A: TVT-O (n = 50) Group B: TOT (n = 50) • Subjective cure short term: A: 43/50, B: 46/50 • Objective cure and improvement: A: 48/50, B: 48/50 • Operative time minutes (SD): A: 11.2 (2.6), B: 11.5 (1.9) • Operative blood loss mls (SD): A: 33.1 (19.2), B: 32.9 (23.1) • Time to return to normal activity in weeks (SD): A: 5.1 (3), B: 5.7 (3.1) • Perioperative complications: A: 0/50, B: 0/50 • Voiding dysfunction: A: 0/50, B: 0/50 • De novo urgency/urgency urinary incontinence: A: 2/50, B: 1/50 • Vaginal tape erosion: A: 0/50, B: 0/50 • Groin pain: A: 7/50, B: 9/50
Liapis 2006	Group A: TVT (n = 46) Group B: TVT-O (n = 43) • Subjective cure short term: A: 34/46, B: 33/42 • Objective cure: A: 41/46, B: 39/43 • Objective cure and improvement: A: 44/46, B: 42/43 • Operative time in mins (SD): A: 26.7 (8.6), B: 17.4 (6.9) • Length of hospital stay days (SD): A: 1.26 (1.34), B: 1.04 (0.21) • Perioperative complications: A: 11/46, B: 2/43 • Major vascular injury: A: 3/46, B: 1/43 • Bladder perforation: A: 3/46, B: 0/43 • De novo urgency/urgency urinary incontinence: A: 5/46, B: 6/43 • Detrusor activity: A: 4/46, B: 4/43 • Vaginal tape erosion: A: 1/46, B: 0/43
Liapis 2008	Group A: TVT-O (n = 61) Group B: Monarc TOT (n = 53) • Short term subjective cure: A: 49/61, B: 41/53 • Subjective cure and improvement: A: 57/61, B: 47/53

Table 1. Tabulated Results of Included Studies *(Continued)*

	• Objective cure short term: A: 53/61, B: 48/53 • Objective cure and improvement: A: 58/61, B: 50/53 • Peri-operative complications: A: 3/61, B: 2/53 • Bladder perforation: A: 0/61, B: 1/53 • Voiding dysfunction: A: 3/61, B: 2/53 • De novo urgency/urgency urinary incontinence: A: 8/61, B: 6/53 • Detrusor activity: A: 5/61, B: 5/53 • Vaginal tape erosion: A: 0/61, B: 0/51 • Groin pain: A: 3/61, B: 1/53
Lim 2005	Group A: TVT (n = 61) Group B: IVS (n = 60) Group C: SPARC (n = 61) • Subjective cure: A: 48/58, B: 50/56, C: 45/57 • Objective cure: A: 51/58, B: 44/54, C: 42/58 • Bladder perforation: A: 1/61, B: 2/60, C: 7/61 • Voiding dysfunction: A: 2/61, B: 2/60, C: 2/61 • De novo urgency/urgency urinary incontinence: A: 8/58, B: 6/54, C: 9/58 • Detrusor activity: A: 2/58, B: 2/54, C: 1/58 • Vaginal tape erosion: A: 2/58, B: 1/54, C: 8/58
Lord 2006	Group A: TVT (n = 147) Group B: SPARC (n = 154) • Subjective cure: A: 128/147, B: 117/153 • Objective cure: A: 143/147, B: 148/152 • Perioperative complications: A: 6/147, B: 4/154 • Bladder perforation: A: 1/147, B: 3/154 • Voiding dysfunction: A: 0/147, B: 10/154 • De novo urgency/urgency urinary incontinence: A: 12/147, B: 17/154 • Vaginal tape erosion: A: 0/147, B: 1/154
Mansoor 2003	Group A: TVT-O (n = 48) Group B: TVT (n = 54) • Objective cure: A: 46/48, B: 50/54 • Bladder perforation: A: 0/48, B: 6/54 • Voiding dysfunction: A: 1/48, B: 5/54 • De novo urgency/urgency urinary incontinence: A: 2/48, B: 4/54
Mehdiyev 2010	A: TOT (n = 17) B: TVT (n = 15) • Subjective cure: A: 14/17, B: 13/15 • Bladder Injury: A: 0/17, B: 1/15 • Major vascular injury: A: 0/17, B: 1/15 • De novo urgency/urgency urinary incontinence: A: 1/17, B: 3/15 • The mean operation time of TOT group (13.5 min) was significantly shorter than TVT groups (18.3 min).
Meschia 2006	Group A: TVT (n = 92) Group B: IVS (n = 87)

Table 1. Tabulated Results of Included Studies *(Continued)*

	• Subjective cure: A: 80/92, B: 68/87 • Objective cure: A: 79/92, B: 65/87 • Mean operating time mins (SD): A: 27 (6), B: 27 (4) • Length of hospital stay days (SD): A: 2.5 (1), B: 2.3 (1) • Perioperative complications: A: 3/92, B: 4/87 • Bladder perforation: A: 3/92, B: 3/87 • Voiding dysfunction: A: 5/92, B: 4/87 • De novo urgency/urgency urinary incontinence: A: 8/92, B: 10/87 • Vaginal tape erosion: A: 0/92, B: 8/87
Meschia 2007	Group A: TVT-O (n = 117) Group B: TVT (n = 114) • Subjective cure: A: 96/110, B: 99/108 • Objective cure: A: 98/110, B: 99/108 • Operative time mins (SD): A: 17 (7), B: 26 (9) • Operative blood loss mls (SD): A: 27 (33), B: 31 (25) • Length of hospital stay days (SD): A: 1.6 (0.8), B: 1.8 (1) • Perioperative complications: A: 6/99, B: 7/107 • Bladder perforation: A: 0/117, B: 5/114 • Voiding dysfunction: A: 6/99, B: 11/107 • De novo urgency/urgency urinary incontinence: A: 4/99, B: 6/107 • Groin pain: A: 6/117, B: 0/114
Naumann 2006	Group A: TVT (n = 123) Group B: LIFT (n = 125) • Subjective cure, 6 months: A: 90/123, B: 92/125 • Subjective cure, 12 months: A: 107/123, B: 109/125 • Subjective cure or improvement, 6 months: A: 118/123, B: 119/125 • Subjective cure or improvement, 12 months: A: 117/123, B: 122/125 • Bladder perforation: A: 2/123, B: 1/125 • Excess bleeding: A: 2/123, B: 0/125 • Need for division of tape: A: 4/123, B: 9/125 • Tape erosion into bladder or urethra: A: 1/123, B: 1/125 • Vaginal mesh erosion: A: 3/123, B: 7/125
Nerli 2009	Group A: TVT (n = 18) Group B: TOT (n = 18) • Objective cure: A: 16/18, B: 16/18 • Subjective cure: A: 16/18, B: 16/18 • Improved: A: 2/18, B: 2/18 • Mean operative time in minutes (SD): A 21.4 (2.75), B: 18.4 (1.85) • Mean operative blood loss in ml (SD): A: 38.7 (5.09), B: 37.2 (4.53) • Voiding dysfunction: A: 3/18, B: 2/18 • Bladder perforation: A:1/18, B: 0/18 • De novo urge incontinence: A: 2/18, B: 3/18 • Tape erosion: A: 0/18, B: 0/18 • Days to return to normal activity (SD): A: 4.8 (3.2), B: 5.1 (3.1)
Nyyssonen 2014	Group A: TOT (n = 50)

Table 1. Tabulated Results of Included Studies *(Continued)*

	Group B: TVT (n = 50)
	• Subjective cure at 14 and 46 months:
	  ○ At 14 months: A: 36/43, B: 40/43
	  ○ At 46 months: A: 38/46, B: 38/47
	• Vaginal tape erosion: A: 2/43, B: 0/43
	• Voiding dysfunction: A: 4/46, B: 7/47
	• De novo UUI: A: 2/46, B: 5/47

Okulu 2013	Group A: Vypro mesh: (n = 48; multifilament)
	Group B: Ultrapro mesh: (n = 48; monofilament + biological combined mesh)
	Group C: Prolene light mesh: (n = 48; monofilament)
	• cure:
	  ○ Subjective cure at 12 months: A: 41/46, B: 45/48, C: 41/47
	  ○ Subjective cure at 48 months: A: 39/46, B: 44/48, C: 40/47
	• bladder perforation: A: 0/48, B: 0/48, C: 0/48
	• major vascular visceral injury: A: 0/48, B: 0/48, C: 0/48
	• de novo urgency/urgency incontinence: A: 5/46, B: 2/48, C: 4/47
	• vaginal tape erosion: A: 3/46, B: 1/48, C: 3/47
	• mean 24hr pad weight (g) (SD):
	  ○ Preop: A: 27.2 (9.1), B: 28.7 (9.3), C: 32.4 (0.2)
	  ○ Post op 12 months: A: 2.1 (1.4), B: 2.0 (1.1), C: 2.4 (3.8)
	  ○ Post op 48 months: A: 2.3 (1.1), B: 1.3 (0.8), C: 2.4 (1.1)
	• Mean Total ICIQ-SF score (SD):
	  ○ Preop: A: 19.3 (1.2), B: 20.1 (0.4), C: 18.8 (1.4)
	  ○ Post op 12 months: A: 2.0 (0.7), B: 1.2 (0.6), C: 1.7 (0.4)
	  ○ Post op 48 months: A: 2.1 (0.5), B: 0.8 (0.5), C: 1.5 (0.3)

Oliveira 2006	Group A: TVT (n = 17) Group B: TVT-O (n = 28) • Objective cure: A: 38/42, B: 37/42 • Bladder perforation: A: 3/42, B: 0/42 • Voiding dysfunction: A: 5/42, B: 3/42 • de novo urgency/urgency incontinence: A: 8/42, B: 9/42 • vaginal tape erosion: A: 2/42, B: 1/42 • Groin pain: A: 1/42, B: 7/42
Palomba 2008	Trial terminated.
Paparella 2010	Group A: synthetic UretexTO® (n = 34) Group B: biological PelviLaceTO® (n-36) • Objective cure: A: 30/33, B: 33/36 • Subjective cure: A: 28/33, B: 30/36 • Mean operating time (minutes) (SD): A: 10.4 (1.0), B: 10.8 (1.2) • Mean length of hospital stay days (SD): A: 2.1 (0.3), B: 2.1 (0.4) • Perioperative complications: A: 0/34, B: 0/36 • Major vascular injury: A: 0/34, B: 0/36 • Voiding dysfunction: A: 0/34, B: 0/36 • Tape erosion: A: 0/33, B: 0/36

Table 1. Tabulated Results of Included Studies *(Continued)*

	• QoL: assessed with KHQ improved in most domains from preoperative values but no significant difference between the groups
	• Mean PISQ-12 scores
	  ○ Preoperative: A: 24 (2), B: 24.4 (2.4)
	  ○ 2yrs Follow up: A: 16.6 (3.0), B: 17.2 (3.0)

Park 2012	Group A: TVT-O (n = 39) Group B: TOT Monarc (n = 35) • Objective cure at 1yr: A: 35/39, B: 32/35 • Subjective cure at 1yr: A: 35/39, B: 32/35 • Objective cure at 3yrs: A: 33/39, B: 30/35 • Subjective cure at 3yrs: A: 33/39, B: 30/35 • Subjective cure & improvement at 1yr: A: 37/39, B: 33/35 • Subjective cure & improved at 3yr: A: 36/39, B: 33/35 • Voiding dysfunction: A: 3/39, B: 2/35 • Bladder and urethral perforation: A: 0/39, B: 0/35 • Groin pain: A: 1/39, B: 0/35 • Post operative dyspareunia: A: 1/39, B: 1/35
Peattie 2006	No published data.
Porena 2007	Group A: TVT (n = 70) Group B: TOT (n = 75) • Objective cure (dry): A: 50/70, B: 58/75 • Objective cure and improved (dry + wet but improved): A: 63/70, B: 68/75 • Subjective cure (dry): A: 50/70, B: 58/75 • Subjective cure and improved (dry + wet but improved): A: 63/70, B: 68/75 • Bladder injury: A: 2/70, B:1/75 • Vaginal perforation: A: 0/70, B: 4/75 • Major vascular injury: A: 1/70, B: 0/75 • Voiding Dysfunction: A: 7/70, B: 6/75 • Tape erosion: A: 0/70, B: 3/75 • Subjective cure long term: A: 30/38, B: 27/45
Rechberger 2003	Group A: TVT (n = 50) Group B: IVS (n = 50) • Subjective cure: A: 80/92, B: 68/87 • Perioperative complications: A: 3/92, B: 4/87 • Bladder perforation: A: 3/50, B: 4/50 • Voiding dysfunction: A: 11/50, B: 2/50 • de novo urgency/urgency incontinence: A: 8/50, B: 4/50
Rechberger 2009	Group A: retropubic (IVS-02; n = 269) Group B: transobturator (IVS-04; n = 268) • Subjective cure: A: 151/201, B: 146/197 • Subjective improvement: A: 34/201, B: 28/197 • Mean operating time in minutes (SD): A: 23(5), B: 12(4) • Bladder perforation: A: 13/269, B: 0/268

Table 1. Tabulated Results of Included Studies *(Continued)*

	• Major vascular injury: A: 4/269, B: 0/268 • De novo urgency/UI: A: 17/201 ,B: 10/197 • Voiding dysfunction: A: 10/269, B: 7/268 • Vaginal tape erosion: A: 4/201, B: 5/197
Rechberger 2011	Group A: TOT (n = 232) Group B: TOT with fixation (n = 231) • Subjective cure and improvement: A: 186/213, B: 191/205 • Objective cure: A: 189/213, B: 195/205 • Bladder perforation: A: 4/232, B: 3/231 • ISD cohort: Objective cure: A: 31/41, B: 39/42
Richter 2010	Group A: retropubic sling (TVT; n = 298) Group B: transobturator tapes (TVT-O, and TOT Monarc; n = 299) (Group C (?): TVT-O (inside-out) - separate data not provided) (Group D (?): TOT (Monarch, outside-in) - separate data not provided) Objective cure at 1 year: A: 232/280 (80.8%), B: 233/285 (77.7%) Subjective cure at 1 year: A: 181/280 (62.2%), B: 163/285 (55.8%) Secondary outcomes: • median blood loss (ml): A: 50mls; B: 25mls p=0.001 • median operative time (minutes): A: 30mins; B: 25mins p=0.001 • bladder or urethral perforation: A: 16/298, B: 0/299 • vaginal perforation: A: 6/298, B: 13/299 • voiding dysfunction: A: 16/298, B: 5/229 • mesh erosion/exposure A: 10/280, B: 2/285 • vascular injury: A: 20/298, B: 7/299 • suprapubic/groin pain: A: 3/280, B: 2/285 • de novo urgency incontinence: A: 0/280, B: 1/285 • mean (SD) of change in UDI score Total: A: 106.7 (48), B: 110.3 (51.2) P=0.47 • mean of change in IIQ score Total: A: 126.8 (94.5), B: 132.9 (97.8) P=0.41 PISQ-12 (Prolapse / urinary incontinence sexual questionnaire): Analysis of results for group A and group B combined showed significant improvement in sexual function in both groups with a mean PISQ-12 score increase from 32.8+/-7.1 at baseline to 37.3+/- 6 at 24 months. These changes are >0.6 SD units, which reflects “medium” improvement in the PISQ-12 score after surgery. Compared with women with successful surgery, women who experienced surgical failure, regardless of assigned type of surgery, reported worse adjusted sexual function scores at all postoperative time points. Improvement in PISQ-12 scores was consistent with change in the 3 specific items from the sexual function measure of interest: (1) the experience of pain during sexual activity, (2) UI during sexual activity, and (3) fear of incontinence during sexual activities. Pain with intercourse was reported by 153 of 406 of sexually active women (38%) at baseline and decreased to 27% at 12 months after surgery (P.003). Self-reported UI and the fear of incontinence occurring during sexual activity also significantly improved by 12 months after surgery, regardless of sling route. To specifically investigate the association of synthetic mesh slings on dyspareunia, we repeated the analysis on the 247 women who underwent MUS only (no concurrent procedures) and who completed baseline and 12-month assessments. In this subset of women, dyspareunia decreased from 57% at baseline to 43% at 12 months after surgery (P .03).

Table 1. Tabulated Results of Included Studies *(Continued)*

	5-year data provided, but without numbers in each group, so could not be used for meta-analysis
Riva 2006	Group A: TOT (n = 65) Group B: TVT (n = 66)
Salem 2014	Group A: TOT (n = 37) Group B: TVT (n = 39) No significant difference was noticed between the two groups as regard the mean operative time, perioperative complications, intraoperative blood loss, hospital stay, and time to return to normal activities. The mean of abdominal leak point pressure and urethral closure pressure showed marked and maintained improvement for 5 years later in group I whereas in group II, they showed marked and maintained improvement for only one year then shows significant decline in comparison with group I. As regard the mean of objective SEAPI score shows marked decrease (improvement) in both groups and this was maintained for the five years in group I but in group II, it increased after one year later. No usable data provided.
Scheiner 2012	Group A: TVT (n = 80) Group B: TOT outside-in approach (Monarc; n = 40) Group C: TVT-O inside-out approach (Gynecare; n = 40) • Objective cure: A: 60/65, B: 31/34, C: 33/37 • Subjective cure: A: 57/65, B: 28/34, C: 29/37 • Subjective cure and improvement: A: 63/65, B: 31/34, C: 34/37 • Mean operation time (minutes) (SD) A: 26.7 (11.5), B: 25.8 (9.7) C: 27.4 (10.0) • Mean blood loss (ml) A: 34.4 (36.5), B: 31.5 (22.2), C: 49.4 (89.6) • Mean hospital stay in days (SD): A: 3.5 (1.1), B: 3.2 (0.5), C: 3.3 (0.8) • Bladder perforation A: 3/80, B: 0/40, C: 0/40 • Vaginal perforation A: 1/80, B: 6/40, C: 4/40 • Thigh/groin pain: B: 3/34, C: 1/37 • Vascular damage: A: 1/65, B: 0/34, C: 0/37 • Voiding dysfunction: A: 3/80, B: 1/40, C: 1/40 • Tape erosion: A: 1/65, B: 4/34, C: 0/37 • Sexual function: Two percent (1/52) of sexually active patients after TVT, 17% (5/29) after TOT, but 0% (0/25) after TVTO reported de novo female sexual dysfunction (P=0.011). Complaints included de novo dyspareunia in one TVT and two TOT, a feeling of vaginal narrowing in two TOT, and neuralgiform pain at the ischiocrural tape exit point in one TOT. In two patients with TOT, de novo FSD subsided after 12 months. The other four patients preferred an expectant procedure. No association between tape exposure or FSD and surgeon was found.
Schierlitz 2008	Group A: TVT (n = 81) Group B: Monarc sling (n = 82) • Objective cure: absence of USI: A: 53/67, B: 48/71 • Subjective cure: absence of self-reported SUI: A: 63/66, B: 55/70 • Bladder perforation: A: 7/82, B: 0/82 • Major vascular injury: A: 0/82, B: 0/82 • Groin pain: A: 1/82, B: 3/82 • Voiding dysfunction: A: 9/82, B: 4/82 • De novo urgency: A: 14/66, B: 7/70 • De novo urgency incontinence: A: 9/66, B: 9/70

Table 1. Tabulated Results of Included Studies *(Continued)*

	• De novo urgency and UUI: A: 23/66, B: 16/70 • Re-operation: A: 0/82, B: 9/82 • Vaginal perforation: A: 0/82, B: 4/82 • QOL: The baseline QoL assessment (UDI-6, IIQ-7) did not differ between the two groups. In both the TVT and transobturator tape groups, there was an overall marked improvement postoperatively in UDI-6 and IIQ-7 scores with no difference in improvement between groups. • Sexual function: Comparison of pre-operative and post-operative mean total PISQ-12 scores revealed a significant improvement in both groups at 6 months, which was maintained at 12 months. There was a significant difference between the TVT and the Monarc mean score at 6 months, with the TVT score being greater. At 12 months, there was no difference between slings, coital incontinence and fear of incontinence were significantly reduced in both treatment groups at 6 and 12 months with no difference between slings. No change to dyspareunia or orgasm intensity was detected in either sling group, and no difference existed between the two slings at 6 or 12 month. At least 8 of 57 (14%) women who were not sexually active prior to their surgery had resumed intercourse at 6 months post-operatively, and this was unchanged at 12 months 7 of 57 (12%). No change to dyspareunia or orgasm intensity was detected in either sling group, and no difference existed between the two slings at 6 or 12 months. • The 3-year primary end point was symptomatic stress incontinence considered as failure requiring a repeat procedure on request of the patient. • Repeat incontinence surgery: A: 1/72, B: 15/75 • Subjective cure @ 3 yrs (intermediate term): A: 71/72, B: 60/75 • The baseline quality-of- life assessment (Urogenital Distress Inventory short form, Incontinence Impact Questionnaire short form) did not differ between groups. At 36 months on average, the overall mean UDI short form and IIQ short form scores improved by 5.8 (SD 4.34) and 6.0 (SD 5.48), respectively (P<.001); no between-group difference was found. • 5yrs Follow up: • Mean follow up in months was A: 63, B: 64 • Primary outcome was subjective SUI requiring repeat surgery • Subj cure at 5yrs A: 69/72, B: 56/75 • Repeat surgery: A: 3/82, B: 19/82 • Median time to repeat surgery months (25th to 75th percentile): A: 82 (43 to 82), B: 24 (12 to 52)Both groups showed improvement in QoL scores post surgery at 5 yrs follow up but no difference between the groups.
Tanuri 2010	Group A: Safyre VS retropubic tape (n = 10) Group B: Safyre T transobturator tape (n = 20) • Objective cure: A: 8/9, B: 16/19 • Subjective cure: A: 8/9, B: 17/19 • Pad test: mean weight of urine grams (SD) A: 0.0(0.0), B: 1.2(5.4) • De novo urgency incontinence: A: 1/9, B: 1/19 • Voiding dysfunction: A: 1/10, B: 0/20 • Groin pain: A: 0/9, B: 1/19 • Bladder perforation: A: 0/10, B: 0/20 • Tape erosion: A: 0/9 B: 0/19 • Mean QoL Scores: via KHQ ○ Improvement in the domains between baseline pre-op scores and 12 months scores without a significant difference between the two groups.
Tarcan 2011	Group A: TVT (n = 27) Group B: TOT (n = 27) 12-month follow-up assessed: • cure: negative stress provocation test

Table 1. Tabulated Results of Included Studies *(Continued)*

	○ objective cure rates: A: 20/23, B: 19/22 ○ subjective cure rate: A: 20/23, B: 20/22 • mean operative time in minutes (SD) A: 32.6 (16.6), B: 31.6 (7.7) 2 year follow-up assessed: • subjective cure: A: 21/27, B: 22/27 • mean operating time in mins (SD): A: 39.1 (17.7), B: 33.4 (13.9) • QoL: via SEAPI ○ scores were significantly improved in both groups post-operatively with no significant difference between groups • No significant post operative complications in either group.
Teo 2011	Group A: TVT (n = 66) Group B: TVT-O (n = 61) • Objective cure: A: 33/41, B: 25/29 • Subjective cure: A: 35/41, B: 26/29 • Major vascular injury: A: 1/66, B: 1/61 • Voiding dysfunction: A: 3/66, B: 1/61 • Bladder perforation: A: 0/66, B: 0/61 • De novo urgency incontinence: A: 3/41, B: 6/29 • Tape erosion A: 3/41, B: 1/29 • Groin pain: A: 1/66, B: 14/61 • There was a significant improvement in quality of life, symptom severity and pad use from baseline in both groups • QoL: • Baseline scores: ○ Median KHQ score (range): A: 384 (122–814), B: 399 (106–814) ○ Median ICIQ-SF score (range): A: 15 (7–21), B: 14 (3–21) • 12 months follow up scores: ○ Median KHQ score (range): A: 50 (0–510) B: 61 (0–748) ○ Median ICIQ-SF score (range): A: 4 (0–16) B**:** 0 (0–11)
Tommaselli 2012	Group A: TVT-O (n = 48) Group B: modified TVT-O (n = 24) • Objective cure: A: 43/46, B:22/23 • No leakage with urodynamic studies: A: 43/46, B: 21/23 (91.3) • No intraoperative complications reported in either group. • Voiding dysfunction: A: 1/48, B: 1/24 • QOL/sexual function: • The PISQ-12 score showed a slight decrease after the procedure in both groups, but did not reach statistical significance (A: 18.8±6.7 vs 12±5.3, P00.3; B: 16.9±5.3 vs 12.6±4.9, P00.6). No differences were observed between groups before or after the procedure. The PGI-S score was significantly lower 6 months after surgery in both groups (P<0.001).
Tseng 2005	Group A: SPARC (n = 31) Group B: TVT (n = 31) • Objective cure: A: 25/31, B: 27/31 • Operative time in mins(SD): A: 40.77 (13.29) B: 32.74 (8.43) • Length of hospital stay (days) (SD): A: 3.97 (1.43), B: 3.14 (1.38) • Perioperative complications: A: 3/31, B: 5/32 • Bladder perforation: A: 4/31, B: 0/31

Table 1. Tabulated Results of Included Studies *(Continued)*

	• Denovo U/UUI: A: 7/31, B: 5/31 • voiding dysfunction: A: 2/31, B: 1/31
Ugurlucan 2013	Group A: biological PELVILACE TO (n = 50) Group B: synthetic TOT ALIGN ®TO (n = 50) • Subjective cure: A: 34/50, B: 35/50 • Objective cure: A: 28/31, B: 35/36 • groin pain: A: 2/50, B: 1/50 • voiding dysfunction: A: 0/50, B: 2/50 • vaginal tape erosion: A: 0/50, B; 1/50 • QOL: There was an improvement in quality of life in both groups in all domains when the preoperative and postoperative KHQ, P-QoL, UDI-6, and IIQ-7 were compared. There was no difference between the two groups regarding the improvement in quality of life.
van Leijsen 2013	Group A: RPR (n = 33) Group B: TOT (n = 90) • Subjective cure: A: 25/31, B: 62/83 • Objective cure: A: 13/13, B: 57/59 • De novo urgency incontinence: A: 9/30, B: 25/83 • Voiding dysfunction: A: 5/31, B: 7/80 • Tape release for POVD: A: 1/31, B: 1/80 • Repeat incontinence surgery: A: 0/33, B: 0/90
Wang 2006	Group A: Monarc (n = 31) Group B: SPARC (n = 29) • Operative time in mins (SD): A: 33.83 (8.4) B: 39.21 (12.18) • Blood loss ml (SD): A: 117.2 (79.43), B: 125.13 (81.2) • Length of hospital stay (days) (SD): A: 3.44 (1.48), B: 3.92 (1.40) • Perioperative complications: A: 4/31, B: 2/29 • Major vascular injury: A: 0/31, B: 0/29 • Bladder perforation: A: 0/31, B: 1/29 • Denovo U/UUI: A: 3/31, B: 3/29 • voiding dysfunction: A: 7/31, B: 16/29 • Vaginal tape erosion: A: 4/31, B: 0/29
Wang 2008	Group A: TVT (n = 35) Group B: TVT-O (n = 34) • Subjective cure: A: 31/35, B: 29/34 • Subjective cure and improvement: A: 34/35, B: 33/34 • Failure: A: 1/35, B: 1/34 • Operative time in minutes; mean (SD): A: 27 (5) 35, B: 18 (5) • Blood loss ml (SD): A: 21 (6) B: 20 (7) • Length of hospital stay (days) (SD): A: 3.9 (4.4), B: 3.2 (2.2) • Bladder/visceral perforation: A: 0/35, B: 0/34 • Voiding dysfunction: A: 4/35, B: 4/34 • Haematoma: A: 1/35, B; 0/34 • No significant differences in postoperative complications: including tape erosion, pain in thigh or behind pubis

Table 1. Tabulated Results of Included Studies *(Continued)*

Wang 2009	Group A: TVT (n = 154)
	
	Group B: TVT-O (n = 146)
	
	• 6 months
	  ○ cured: A: 144/154, B: 133/146
	  ○ Improved: A 8, B 10
	  ○ Failed: A 2, B 3
	• 12 months
	  ○ cured: A: 103/115, B: 106/118
	  ○ Improved: A 10, B 9
	  ○ Failed: A 2, B 3
	• 24 months
	  ○ cured: A: 68/78, B: 75/87
	  ○ Improved: A 8, B 10
	  ○ Failed: A 2, B 2
	• 36 months
	  ○ cured: A: 29/35, B: 25/30
	  ○ Improved: A 5, B 4
	  ○ Failed: A 1, B 1
	• Mean operative time in minutes (SD) N: A: 25.1 (4.8) 68, B: 18.4 (4) 68, P<0.001
	• Mean blood loss in ml (SD) N): A: 22.5 (12.5) 68, B: 20.7 (11.8) 68 P=0.18
	• With concomitant prolapse surgery:
	  ○ Operative time (mean mins (SD) N): A: 46.6 (16.3) 86, B: 54.9 (24.4) 78 P=0.06
	  ○ Blood loss (mean ml (SD) N): A: 47.9 (35.3) 86, B: 60.8 (41.8) 78 P=0.12
	• Mean length of hospital stay (days) (SD) N: A: 3.6 (2.9) 154, B: 3.9 (2.8) 146
	• Adverse effects:
	  ○ Any: A: 24/154, B: 27/146
	  ○ haematoma: A: 2, B: 2
	  ○ wound infection: A: 0, B: 0
	• Urinary retention: A: 6, B: 4
	• De novo UUI: A: 9/154, B: 6/146
	• Vaginal tape erosion: A: 3/154, B: 3/146 (no urethral or bladder erosion)
	• Groin/thigh pain: A: 4/154, B: 12/146 (no incapacitating pain)

Wang 2010	Group A: TVT (n = 70) Group B: TOT (n = 70) • Subjective cure: A: 63/70, B: 64/70 • Objective cure: A: 65/70, B: 64/70 • Vascular injury/haematoma: A: 0/70, B: 0/70 • Tape erosion: A: 1/70, B: 2/70 • Bladder perforation: A: 3/70, B: 1/70 • Voiding dysfunction: A: 8/70, B: 6/70 • De novo urgency/UII: A: 1/70 B: 4/70 • QoL assessed by UDI-6 and IIQ-7-SF • QoL Scores: • Pre-op UDI-6: A: 49 (21), 1 yr f/u: 15 (15), Pre-op UDI-6: B: 46 (20), 1 yr f/u: 14 (17) • Pre-op IIQ-7: A: 40 (21), 1 yr f/u: 13 (12), Pre-op IIQ-7: B: 42 (20), 1 yr f/u: 10 (12) • Lost to follow up: A: 0 women, B: 0 women
Wang 2011	Group A: TVT (n = 32) Group B: TVT-O (n = 36)

Table 1. Tabulated Results of Included Studies *(Continued)*

	• Objective cure: A: 30/32, B: 33/36 • Subjective cure: A: 30/32, B: 33/36 • Improvement: A: 2/32, B: 3/36 • Mean length of surgery (minutes) (SD): A: 34.5 (6.3), B: 16.2 (1.5) • Bladder perforation: A: 1/32, B: 0/36 • Voiding dysfunction: A: 3/32 , B: 1/36 • Groin pain: A: 0/32, B: 0/36 • De novo urgency or UI: A: 5/32, B: 6/36 • Vascular injury: A: 2/32, B: 1/36
Zhang 2011	Group A: TVT-O (n = 76) Group B: modified TVT-O (n = 80) • Subjective cure: A: 70/76, B: 75/80 • Subjective improvement: A: 6/76, B: 5/80 • Mean operative time (minutes) (SD): A: 49 (5), B: 24 (6) • Mean blood loss in (mls); SD: A 70 (5), B: 55 (5) • Mean hospital stay in days (SD): A: 8 (0.5),B: 5 (0.5) • Voiding dysfunction: A: 1/76, B: 1/80 • QOL: self-administered I-QOL: A: 23.9 (2.7), B: 24.6 (3.5)
Zullo 2007	Group A: TVT (n = 35) Group B: TVT-O (n = 37) • Objective cure: A: 25/29, B: 27/31 • Subjective cure: A: 21/29, B: 23/31 • Incidence of overall perioperative complications • De novo urgency and urge incontinence: A: 1/29, B: 2/31 • Tape erosion: A: 2/29, B: 1/31 • Voiding dysfunction: A: 0/35, B: 0/37

Abbreviations

BFLUTS: Bristol lower urinary tract symptoms questionnaires
BMI: body-mass index
DO: detrusor overactivity
DUP: distal urethral polypropylene sling
EQOL-5D: Euro Quality of life -5 Dimension
hr: hour/s
HRT: hormone replacement therapy
ICIQ: International Consultation on Incontinence questionnaire
ICIQ-FLUTS: International Consultation on Incontinence questionnaire - female lower urinary tract symptoms
ICIQ- LUTSquol: International Consultation on Incontinence questionnaire - lower urinary tract quality of life questionnaire
ICIQ-SF: International Consultation on Incontinence questionnaire short form
ICIQ-SF15: International Consultation on Incontinence questionnaire short form 15
IIQ: Incontinence Impact questionnaire
ICS: International Continence Society
I-QoL: Incontinence Quality of Life questionnaire
ISD: intrinsic sphincter deficiency
IVS: intravaginal slingoplasty
KHQ: King's Health questionnaireMUI: mixed urinary incontinence
MUCP: Maximum urethral closure pressure
MUI: mixed urinary incontinence
OAB: overactive bladder
PGI-I: Patient Global Impression of Improvment
PGI-S: Patient Global Impression of Severity

PISQ-12: pelvic organ prolapse/urinary incontinence sexual questionnaire
POP: pelvic organ prolapse
POP-Q: pelvic organ prolapse quantification
POP-Q ICS: pelvic organ prolapse quantification International Continence Society
PVR: post void residual
RCT: randomized controlled trial
RPR: retropubic route
QoL: quality of life
QRCT: quasi-randomised trial
SEAPI-QMM: Stress related leak, Empyting ability, Anatomy, Protection, Inhibition-Quality of life, Mobility and Mental status incontinence classification system
SD: standard deviation
SIS: Single incision sling
SPARC: suprapubic arc (procedure)
SUI: stress urinary incontinence
TOR: transobturator
TOT: transobturator tape
TOT-ARIS: transobturator tape-ARIS
TVT: tension-free vaginal tape
TVT-O: transobturator tension-free vaginal tape
UDI: Urinary Distress Impact questionnaire
UDI-6: Urinary Distress Impact questionnaire short form
UDS: urodynamics study
UI: urinary incontinence
UISS: urinary incontinence severity score
USI: urodynamic stress incontinence
USS: ultrasound
UTI: urinary tract infection
UUI: urgency urinary incontinence
VAS: visual analogue scale
VLPP: Valsalval leak point pressure

APPENDICES

Appendix 1. Searches performed for the 2014 version of this review

Cochrane Incontinence Group Specialised Register

The terms used to search the Incontinence Group Specialised Register 26 June 2014 are given below:

(TOPIC.URINE.INCON*)
AND
({DESIGN.CCT*} OR {DESIGN.RCT*})
AND
{INTVENT.SURG.SLIN*} OR {INTVENT.SURG.SUBURETHRAL SLING.} OR {INTVENT.SURG.ABDO.SLING.}
(All searches were of the keyword field of Reference Manager 2012.)

Embase and Embase Classic (on OVID SP) was searched from 1947 to Week 25 20014 on 26 June 2014 and was limited to those years not fully covered by the Embase search for CENTRAL carried out by the Cochrane Collaboration. Limited to: (2010* to 2014*).em. The following search strategy was used:

1. Randomized Controlled Trial/

2. crossover procedure/ or double blind procedure/ or parallel design/ or single blind procedure/

3. Placebo/

4. placebo$.tw,ot.

5. random$.tw,ot.

6. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw,ot.

7. crossover.tw,ot.

8. cross over$.tw,ot.

9. allocat$.tw,ot.

10. trial.ti.

11. parallel design/

12. triple blind procedure/

13. or/1-12

14. exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/

15. exp human/ or exp "human tissue, cells or cell components"/

16. 14 and 15

17. 14 not 16

18. 13 not 17

19. incontinence/ or mixed incontinence/ or stress incontinence/ or urge incontinence/ or urine incontinence/

20. continence/

21. overactive bladder/

22. micturition disorder/ or lower urinary tract symptom/ or pollakisuria/

23. urinary dysfunction/ or bladder instability/ or detrusor dyssynergia/ or neurogenic bladder/ or urinary urgency/ or urine extravasation/

24. (incontinen$ or continen$).tw.

25. ((bladder or detrusor or vesic$) adj5 (instab$ or stab$ or unstab* or irritab$ or hyperreflexi$ or dys?ynerg$ or dyskinesi$ or irritat$)).tw.

26. (urin$ adj2 leak$).tw.

27. ((bladder or detrusor or vesic$) adj2 (hyper$ or overactiv$)).tw.

28. (bladder$ adj2 (neuropath$ or neurogen* or neurolog$)).tw.

29. (nervous adj pollakisur$).tw.

30. or/19-29

31. (tape* or sling*).tw.

32. 18 and 30 and 31

33. (2010* or 2011* or 2012* or 2013* or 2014*).em.

34. 32 and 33

WHO ICTRP (on http://www.who.int/ictrp/en/) was searched on 30 June 2014 using the following search string: Continent OR continence OR incontinent OR incontinence AND tape* OR sling* AND random*

Appendix 2. Search terms for the first version of this review published in 2009

The terms that we used to search the Incontinence Group Specialised Register are given below:
(TOPIC.URINE.INCON*)
AND
({DESIGN.CCT*} OR {DESIGN.RCT*})
AND
{INTVENT.SURG.SLIN*} OR {INTVENT.SURG.SUBURETHRAL SLING.} OR {INTVENT.SURG.ABDO.SLING.}
(All searches were of the keyword field of Reference Manager 9.5 N, ISI ResearchSoft). Date of last search: 20 March 2008.

The review authors also searched MEDLINE (January 1950 to April 2008), EMBASE (January 1988 to April 2008), CINAHL (January 1982 to April 2008), and AMED (January 1985 to April 2008) on 28 April 2008.

The following terms were used to search these electronic databases:

(Urinary incontinence OR urodynamic stress incontinence OR urgency urinary incontinence OR urge incontinence urinary)

AND

(suburethral slings OR tension free vaginal tape OR tvt OR transvaginal tape OR transobturator tape OR tot OR tvt-o OR ivs OR uretrex OR safyre OR I-stop OR sparc OR lynx OR monarc OR obtryx OR obtape OR aris)

The review authors also searched the UK National Research Register and ClinicalTrials.gov on 28 April 2008 using the term: urinary incontinence.

Appendix 3. Search strategies for brief economic commentary

We performed additional searches for the Brief Economic Commentary (BECs). These were conducted in MEDLINE(1 January 1946 to March 2017), Embase (1 January 1980 to 2017 Week 12) and NHS EED (1st Quarter 2016). All searches were conducted on 6 April 2017. We used two different search strategies on MEDLINE and EMBASE (OvidSP) and one on NHS EED (OVID). Details of the searches run and the search terms used can be found below. There were no year, publication type or language restrictions applied.

NHS EED (Ovid) (1st Quarter 2016)

NHS EED was searched using the following search strategy:

1. Urinary incontinence/

2. Urinary incontinence, stress/

3. ((stress$ or mix$ or urg$ or urin$) adj3 incontinen$).tw.

4. Colporrhaphy.tw.

5. Colpoperineoplast$.tw.

6. Sling procedure$.tw.

7. Sling$ procedure$.tw.

8. Bladder neck needle suspension$.tw.

9. Anterior vaginal repair$ .tw.

10. Or/1-9

MEDLINE (1 January 1946 to March 2017) and Embase (1 January 1980 to 2017 Week 12)

We used two different search strategies on MEDLINE and Embase (OvidSP) - these are given below.

Search strategy 1:

1. Economics, Pharmaceutical/ or Economics, Medical/ or Economics/ or Economics, Hospital/ or economics.mp. or Economics, Nursing/

2. exp "costs and cost analysis"/

3. "Value of Life"/

4. exp "fees and charges"/

5. exp budgets/

6. budget*.ti,ab.

7. cost*.ti.

8. (economic* or pharmaco?economic*).ti.

9. (price* or pricing*).ti,ab.

10. (cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.

11. (financ* or fee or fees).ti,ab.

12. (value adj2 (money or monetary)).ti,ab.

13. ((energy or oxygen) adj cost).ti,ab.

14. (metabolic adj cost).ti,ab.

15. ((energy or oxygen) adj expenditure).ti,ab.

16. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15

17. exp Urinary Incontinence/

18. ((stress* or mix* or urg* or urin*) adj3 incontinen*).tw.

19. Urodynamics/ or Urinary Incontinence, Stress/ or Urinary Incontinence/ or Suburethral Slings/ or mixed incontinence.mp. or Urinary Bladder/ or Urinary Incontinence, Urge/

20. 17 or 18 or 19

21. anterior vaginal repair*.tw.

22. 16 and 20 and 21

23. anterior colporrhaphy*.tw.

24. 21 or 23

25. 16 and 20 and 23

26. bladder neck needle suspension$.tw.

27. 16 and 20

28. 26 and 27

29. open abdominal retropubic colposuspension*.tw.

30. retropubic colposuspension*.tw.

31. burch colposuspension*.tw.

32. 29 or 30 or 31

33. 27 and 32

34. laparoscopic retropubic colposuspension*.tw.

35. laparoscopic colposuspension*.tw.

36. 34 or 35

37. 27 and 36

38. traditional suburethral retropubic sling procedure$*.tw.

39. traditional sling procedure$*.tw.

40. suburethral retropubic sling procedure$*.tw.

41. retropubic sling procedure$*.tw.

42. traditional suburethral sling*.tw.

43. Suburethral Slings/ or Urinary Incontinence, Stress/ or Urologic Surgical Procedures/

44. 27 and 43

45. remove duplicates from 44

Search strategy 2:

1. economics.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, sy, tn, dm, mf, dv, kw, fs]

2. value of life.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, sy, tn, dm, mf, dv, kw, fs]

3. exp "costs and cost analysis"/

4. exp economics, hospital/

5. exp economics, medical/

6. economics, nursing.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, sy, tn, dm, mf, dv, kw, fs]

7. economics, pharmaceutical.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, sy, tn, dm, mf, dv, kw, fs]

8. exp "fees and charges"/

9. exp budgets/

10. budget*.ti,ab.

11. cost*.ti.

12. (economic* or pharmaco?economic*).ti.

13. (price* or pricing*).ti,ab.

14. (cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.

15. (financ* or fee or fees).ti,ab.

16. (value adj2 (money or monetary)).ti,ab.

17. or/1-16

18. economics.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, sy, tn, dm, mf, dv, kw, fs]

19. value of life.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, sy, tn, dm, mf, dv, kw, fs]

20. exp "costs and cost analysis"/

21. exp economics, hospital/

22. exp economics, medical/

23. economics, nursing.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, sy, tn, dm, mf, dv, kw, fs]

24. economics, pharmaceutical.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, sy, tn, dm, mf, dv, kw, fs

25. exp "fees and charges"/

26. exp budgets/

27. budget*.ti,ab.

28. cost*.ti.

29. (economic* or pharmaco?economic*).ti.

30. (price* or pricing*).ti,ab.

31. (cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.

32. (financ* or fee or fees).ti,ab.

33. (value adj2 (money or monetary)).ti,ab.

34. 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33

35. ((energy or oxygen) adj cost).ti,ab.

36. (metabolic adj cost).ti,ab.

37. ((energy or oxygen) adj expenditure).ti,ab.

38. 34 or 35 or 36 or 37

39. urinary incontinence.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

40. ((stress$ or mix$ or urg$ or urin$) adj3 incontinen$).tw.

41. URINARY INCONTINENCE, STRESS.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

42. stress urinary incontinence*.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

43. 39 or 40 or 41 or 42

44. intervention surgery*.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

45. colporrhaphy.tw.

46. Bologna procedure*.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

47. Kelly-Kennedy.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

48. Marion Kelly.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

49. Diaphragmplasty.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

50. Vaginal urethrocystopexy.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

51. Cystocele repair.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

52. Kelly plication.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

53. anterior vaginal repair$.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

54. anterior colporrhaphy.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

55. 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54

56. 38 and 43 and 55

57. remove duplicates from 56

58. Bladder neck needle suspension$.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

59. 38 and 43 and 58

60. burch colposuspension.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

61. open abdominal retropubic colposuspension.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

62. Paravaginal defect repair.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

63. Marshall-Marchetti-Krantz.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

64. abdominal burch.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

65. abdominal colposuspension.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

66. endopelvic Fascia Plication.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

67. 60 or 61 or 62 or 63 or 64 or 65 or 66

68. 38 and 43

69. 67 and 68

70. laparoscopic retropubic colposuspension.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

71. laparoscopic colposuspension.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

72. retropubic colposuspension.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

73. 70 or 71 or 72

74. 68 and 73

75. remove duplicates from 74

76. suburethral sling.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

77. abdominal sling.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

78. traditional sling procedure$*.tw.

79. suburethral sling procedure.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

80. 76 or 77 or 78 or 79

81. 68 and 80

82. remove duplicates from 81

83. mid$urethral sling.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

84. retropubic sling procedure$*.tw.

85. transobturator sling procedure$.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

86. 83 or 84 or 85

87. remove duplicates from 86

88. 68 and 87

89. TVT-Secur.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

90. mini-arc.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

91. ajust.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

92. needleless.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

93. solyx.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

94. single$incision sling$.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

95. miniarc.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

96. mini$sling.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

97. Ophira.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

98. Tissue Fixation System.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

99. 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98

100. 68 and 99

101. remove duplicates from 100

102. ((urethra$ or periurethra$ or transurethra$) adj3 (agent$ or bulk$ or injection$ or injectable$)).tw.

103. injection therapy.tw.

104. injectable$.tw.

105. (injectable$ adj2 agent$).tw.

106. (bulk$ adj3 agent$).tw.

107. Peri$urethral injection$.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

108. Autologous fat.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

109. Macroplastique.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

110. Calcium hydroxylapatite.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

111. Hyaluronic acid with dextranomer.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

112. Porcine dermal implant.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

113. Ethylene vinyl alcohol copolymer.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

114. Silicon particles.mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, an, eu, pm, sy, tn, dm, mf, dv, kw, fs]

115. 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113 or 114

116. 68 and 115

117. remove duplicates from 116

WHAT'S NEW

Date	Event	Description
10 July 2017	Amended	Brief economic commentary (BEC) added. Economics related sections revised: the Abstract, Plain language summary, Background, Methods (outcomes, search methods), and Discussion were amended. Appendix added with details of search strategies for BECs.
10 July 2017	New citation required but conclusions have not changed	Brief economic commentary (BEC) added. Economics-related sections revised.

HISTORY

Protocol first published: Issue 1, 2007
Review first published: Issue 4, 2009

Date	Event	Description
21 May 2015	New citation required but conclusions have not changed	Following new trials were added in this update: Abdel-Fattah 2010; Aigmuller 2014; Alkady 2009; Aniuliene 2009; Barber 2008; But 2008; Chen 2010; Chen 2012; Cho 2010; Choe 2013; Darabi Mahboub 2012; David-Montefiore 2006; Deffieux 2010; de Leval 2011; Diab 2012; Elbadry 2014; El-Hefnawy 2010; Freeman 2011; Hammoud 2011; Hassan 2013; Houwert 2009; Jakimiuk 2012; Juang 2007; Kamel 2009; Karateke 2009; Kilic 2007; Krofta 2010; Laurikainen 2007; Leanza 2009; Mehdiyev 2010; Nerli 2009; Nyyssonen 2014; Okulu 2013; Palomba 2008; Paparella 2010; Park 2012; Peattie 2006; Rechberger 2009; Rechberger 2011; Richter

Date	Event	Description
		2010; Ross 2009; Salem 2014; Scheiner 2012; Schierlitz 2008; Tanuri 2010; Tarcan 2011; Teo 2011; Tommaselli 2012; Ugurlucan 2013; van Leijsen 2013; Wang 2008; Wang 2009; Wang 2010; Wang 2011; Zhang 2011
21 May 2015	New search has been performed	Following new trials were added in this update: Abdel-Fattah 2010; Aigmuller 2014; Alkady 2009; Aniuliene 2009; Barber 2008; But 2008; Chen 2010; Chen 2012; Cho 2010; Choe 2013; Darabi Mahboub 2012; David-Montefiore 2006; Deffieux 2010; de Leval 2011; Diab 2012; Elbadry 2014; El-Hefnawy 2010; Freeman 2011; Hammoud 2011; Hassan 2013; Houwert 2009; Jakimiuk 2012; Juang 2007; Kamel 2009; Karateke 2009; Kilic 2007; Krofta 2010; Laurikainen 2007; Leanza 2009; Mehdiyev 2010; Nerli 2009; Nyyssonen 2014; Okulu 2013; Palomba 2008; Paparella 2010; Park 2012; Peattie 2006; Rechberger 2009; Rechberger 2011; Richter 2010; Ross 2009; Salem 2014; Scheiner 2012; Schierlitz 2008; Tanuri 2010; Tarcan 2011; Teo 2011; Tommaselli 2012; Ugurlucan 2013; van Leijsen 2013; Wang 2008; Wang 2009; Wang 2010; Wang 2011; Zhang 2011
16 September 2009	Amended	changed conclusion in abstract, typographical error
4 March 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Abigail Ford and Joseph Ogah wrote the text of the main review.

Abigail Ford performed the initial screening of studies for inclusion into the review, assessment of methodological quality, data extraction, and analysis of results.

Joseph Ogah performed the second and confirmatory screening of studies for inclusion, assessment of methodological quality, and data extraction.

Abigail Ford, Joseph Ogah, June Cody and Lynne Rogerson assisted in the analysis and interpretation of the results.

Abigail Ford, Joseph Ogah and Lynne Rogerson were also responsible for the clinical input for the review and made a significant input to the writing of the final review.

For the July 2017 addition of the BECs to this review: Patricia Aluko was responsible for the entire BECs-related work on this review, i.e. she ran the search for studies, screened the search results, extracted data from relevant studies, revised any existing economics-related text, added the BECs-related text, and responded to any peer referee comments. All authors had the opportunity to comment on the revised review.

DECLARATIONS OF INTEREST

Abigail A Ford: For the 2015 review: Johnson and Johnson for part sponsorship to attend International Urogynaecology Association conference (IUGA), Washington, 2014. For the 2017 BECs review update: Astellas: money given towards travel costs to IUGA meeting 2016, no other financial benefit. This had no impact on this current work.

Lynne Rogerson: For the 2015 review: Astellas: Paid in full for attendance at European Urogynaecological Association meeting in Berlin. For the 2017 BECs review update: registration fee for ICS Rio 2014 paid by Boston Scientific for October 2014 - paid directly to the conference but nothing to do with Cochrane.

June D Cody: For the 2015 review: nothing to declare. For the 2017 BECs review update: None known.

Joseph Ogah: For the 2015 review: part sponsorship for conference registration fees and speaker honoraria by Astellas UK; sponsored to attend workshops by Johnson and Johnson and Speciality European Pharma. All these sponsorships are unrelated to this review. For the 2017 BECs review update: None known.

Patricia Aluko: For the 2017 BECs review: This project, to add Brief Economic Commentaries to our 'Surgery for UI in women' reviews, was supported by the National Institute for Health Research (NIHR), via the Cochrane Review Incentive Scheme 2016, to the Cochrane Incontinence Group. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

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Internal sources

- No sources of support supplied

External sources

- The National Institute for Health Research (NIHR), UK.

  This project was supported by the National Institute for Health Research, via Cochrane Infrastructure funding to the Cochrane Incontinence Group. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health. The NIHR is the largest single funder of the Cochrane Incontinence Group.
- National Institute for Health Research, UK.

  This project, to add Brief Economic Commentaries to our surgery for UI in women reviews, was supported by the National Institute for Health Research (NIHR), via the Cochrane Review Incentive Scheme 2016, to the Cochrane Incontinence Group. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The review authors decided to focus this update on the use of minimally invasive mid-urethral slings in women with urinary incontinence, as this has become the gold standard for surgery for stress urinary incontinence (SUI). The alternative surgical treatments, including single incision slings, have been addressed in linked Cochrane reviews and are therefore not included, but are summarised and referenced in the Discussion. Conservative and pharmacological treatments will be addressed in a future Cochrane review. This review therefore now addresses the effectiveness of mid-urethral slings in the treatment of SUI in women compared to another mid-urethral sling.

The primary outcome remains the same, but has been measured in time scales that differ from those previously set out; short term (less than 12 months), medium term (one to five years) and long term (over five years). This was done after the first review showed evidence of tape efficacy to establish whether this procedure continued to be effective in the longer term. The primary outcome was repeated as a secondary outcome and this repetition has been amended.

A Dealing with missing data section has been added into the review. Very few trials reported outcome data for clinically relevant subgroups, therefore no subgroup analyses were performed.

July 2017 update: we have added Brief Economic Commentaries (BECs) to all of our 'Surgery for UI in women' Cochrane Reviews. We have revised the economic elements throughout the review; if incorrect, we have stripped them out. We have added new economics-related text. This involved revisions to the Background section, Methods section, e.g. search section referring to added Appendix, Discussion section, Abstract and Plain Language Summary. We have added an appendix with details of the economics searches. The Conclusions section of the review has not changed. The rest of the review has not changed.

INDEX TERMS

Medical Subject Headings (MeSH)

*Suburethral Slings [adverse effects]; Pain, Postoperative [etiology]; Postoperative Complications [etiology]; Quality of Life; Randomized Controlled Trials as Topic; Reoperation [statistics & numerical data]; Urethra [injuries]; Urinary Bladder [injuries]; Urinary Incontinence, Stress [*surgery]; Urologic Surgical Procedures [adverse effects] [*methods]

MeSH check words

Adult; Female; Humans