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Baessler K, Christmann-Schmid C, Maher C, Haya N, Crawford TJ, Brown J

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Surgery for women with pelvic organ prolapse with or without stress urinary incontinence.
Cochrane Database of Systematic Reviews 2018, Issue 8. Art. No.: CD013108.
DOI: [10.1002/14651858.CD013108](https://doi.org/10.1002/14651858.CD013108).

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[Intervention Review]

Surgery for women with pelvic organ prolapse with or without stress urinary incontinence

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Editorial group: Cochrane Gynaecology and Fertility Group.

Publication status and date: New, published in Issue 8, 2018.

Citation: Baessler K, Christmann-Schmid C, Maher C, Haya N, Crawford TJ, Brown J. Surgery for women with pelvic organ prolapse with or without stress urinary incontinence. *Cochrane Database of Systematic Reviews* 2018, Issue 8. Art. No.: CD013108. DOI: [10.1002/14651858.CD013108](https://doi.org/10.1002/14651858.CD013108).

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ABSTRACT

Background

Pelvic organ prolapse (POP) is common in women and is frequently associated with stress urinary incontinence (SUI). In many cases however, SUI is present only with the prolapse reduced (occult SUI) or may develop after surgical treatment for prolapse (de novo SUI).

Objectives

To determine the impact on postoperative bladder function of surgery for symptomatic pelvic organ prolapse with or without concomitant or delayed two-stage continence procedures to treat or prevent stress urinary incontinence.

Search methods

We searched the Cochrane Incontinence Group Specialised Register, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE-In-Process, ClinicalTrials.gov, WHO ICTRP, handsearching journals and conference proceedings (searched 11 November 2017) and reference lists of relevant articles. We also contacted researchers in the field.

Selection criteria

Randomised controlled trials (RCTs) including surgical operations for POP with or without continence procedures in continent or incontinent women. Our primary outcome was subjective postoperative SUI. Secondary outcomes included recurrent POP on examination, overactive bladder (OAB) symptoms, and voiding dysfunction.

Data collection and analysis

We used standard methodological procedures as expected by Cochrane.

Main results

We included 19 RCTs (2717 women). The quality of the evidence ranged from low to moderate. The main limitations were risk of bias (especially blinding of outcome assessors), indirectness and imprecision associated with low event rates and small samples.

POP surgery in women with SUI

Surgery for women with pelvic organ prolapse with or without stress urinary incontinence (Review)

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Vaginal repair with vs without concomitant mid-urethral sling (MUS)

A concomitant MUS probably improves postoperative rates of subjective SUI, as the evaluated clinical effect appears large (risk ratio (RR) 0.30, 95% confidence interval (CI) 0.19 to 0.48; 319 participants, two studies; $I^2 = 28%$; moderate-quality evidence), and probably decreases the need for further continence surgery (RR 0.04, 95% CI 0.00 to 0.74; 134 participants, one study; moderate-quality evidence). This suggests that if the risk of SUI with POP surgery alone is 39%, the risk with an MUS is between 8% and 19%.

Rates of recurrent POP on examination, OAB, and voiding dysfunction were not reported.

Vaginal repair with concomitant vs delayed MUS

Evidence suggested little or no difference between groups in reporting postoperative SUI (RR 0.41, 95% CI 0.12 to 1.37; 140 participants, one study; moderate-quality evidence).

Rates of recurrent POP on examination, OAB, and voiding dysfunction and the need for further surgery were not reported.

Abdominal sacrocolpopexy with vs without Burch colposuspension

An additional Burch colposuspension probably has little or no effect on postoperative SUI at one year (RR 1.38, 95% CI 0.74 to 2.60; 47 participants, one study; moderate-quality evidence), OAB symptoms (RR 0.85, 95% CI 0.61 to 1.18; 33 participants, one study; moderate-quality evidence), or voiding dysfunction (RR 0.96, 95% CI 0.06 to 14.43; 47 participants, one study; moderate-quality evidence). Rates of recurrent POP and the need for further surgery were not reported.

POP surgery in women with occult SUI

Vaginal repair with vs without concomitant MUS

MUS probably improves rates of subjective postoperative SUI (RR 0.38, 95% CI 0.26 to 0.55; 369 participants, five studies; $I^2 = 44%$; moderate-quality evidence). This suggests that if the risk with surgery alone is 34%, the risk with a concomitant MUS is between 10% and 22%. Evidence suggests little or no difference between groups in rates of recurrent POP (RR 0.86, 95% CI 0.34 to 2.19; 50 participants, one study; moderate-quality evidence), OAB symptoms (RR 0.75, 95% CI 0.52 to 1.07; 43 participants, one study; low-quality evidence), or voiding dysfunction (RR 1.00, 95% CI 0.15 to 6.55; 50 participants, one study; low-quality evidence). The need for further surgery was not reported.

POP surgery in continent women

Vaginal repair with vs without concomitant MUS

Researchers provided no conclusive evidence of a difference between groups in rates of subjective postoperative SUI (RR 0.69, 95% CI 0.47 to 1.00; 220 participants, one study; moderate-quality evidence). This suggests that if the risk with surgery alone is 40%, the risk with a concomitant MUS is between 19% and 40%. Rates of recurrent POP, OAB, and voiding dysfunction and the need for further surgery were not reported.

Abdominal sacrocolpopexy with vs without Burch colposuspension

We are uncertain whether there is a difference between groups in rates of subjective postoperative SUI (RR 1.31, 95% CI 0.19 to 9.01; 379 participants, two studies; $I^2 = 90%$; low-quality evidence), as RCTs produced results in different directions with a very wide confidence interval. We are also uncertain whether there is a difference between groups in rates of voiding dysfunction (RR 8.49, 95% CI 0.48 to 151.59; 66 participants, one study; low-quality evidence) or recurrent POP (RR 0.98, 95% CI 0.74 to 1.30; 250 participants, one study; moderate-quality evidence). No study reported OAB symptoms and need for further surgery.

Vaginal repair with armed anterior vaginal mesh repair vs anterior native tissue

Anterior armed mesh repair may slightly increase postoperative de novo SUI (RR 1.58, 95% CI 1.05 to 2.37; 905 participants, seven studies; $I^2 = 0%$; low-quality evidence) but may decrease recurrent POP (RR 0.29, 95% CI 0.22 to 0.38; 848 participants, five studies; $I^2 = 0%$; low-quality evidence). There may be little or no difference in rates of voiding dysfunction (RR 1.65, 95% CI 0.22 to 12.10; 125 participants, two studies; $I^2 = 0%$; low-quality evidence). Rates of OAB and the need for further surgery were not reported.

Adverse events were infrequently reported in all studies; cost was not studied in any trial.

Authors' conclusions

In women with POP and SUI (symptomatic or occult), a concurrent MUS probably reduces postoperative SUI and should be discussed in counselling. It might be feasible to postpone the MUS and perform a delayed (two-stage) continence procedure, if required.

Although an abdominal continence procedure (Burch colposuspension) during abdominal POP surgery in continent women reduced de novo SUI rates in one underpowered trial, another RCT reported conflicting results. Adding an MUS during vaginal POP repair might reduce postoperative development of SUI.

An anterior native tissue repair might be better than use of transobturator mesh for preventing postoperative SUI; however, prolapse recurrence is more common with native tissue repair.

PLAIN LANGUAGE SUMMARY

Surgery for women with pelvic organ prolapse with or without continence procedures

Review question

To assess the outcomes of operations for pelvic organ prolapse (POP) with or without operations to treat or prevent stress urinary incontinence (SUI).

Background

Pelvic organ prolapse is a common condition, especially among women who have given birth and who are postmenopausal. It involves the descent of pelvic organs such as the womb (uterus), bladder, bowel, and vagina within and outside of the vaginal opening. It is often associated with urinary leakage on coughing or physical exertion as in sports (termed 'stress urinary incontinence'). However, in some women, the prolapse prevents leakage from the urethra and stress urinary incontinence might be present only with re-placement of the prolapsed organs in the vagina during vaginal examination (termed 'occult SUI'). Stress urinary incontinence may also develop only after surgical treatment of prolapse (termed 'de novo SUI'). To date, the best treatment for women undergoing surgery for symptomatic pelvic organ prolapse with and without incontinence conditions is not known.

Study characteristics

Cochrane review authors searched different registers for relevant studies and collected, summarised, and analysed appropriate data to help identify the optimal treatment. Data are current to December 2017.

Key results

Reviewers included 19 randomised controlled trials in this review (2717 women), including surgical operations for POP with or without continence procedures in continent or incontinent women. Our primary outcome was subjective postoperative SUI. Secondary outcomes included recurrent POP on examination, overactive bladder (OAB) symptoms, voiding dysfunction, and need for further surgery.

Surgery to treat women with POP and stress urinary incontinence

In two studies of moderate quality, women with stress incontinence benefited from an additional continence procedure (mid-urethral sling) at the time of vaginal prolapse repair for the outcome of postoperative SUI. The continence procedure might also be postponed for three months after prolapse surgery with similar success rates. In this situation, some women might avoid an additional continence operation.

It remains unclear whether abdominal prolapse repair (sacrocolpopexy or sacrohysteropexy) with an additional abdominal continence procedure (Burch colposuspension) improves urinary leakage after surgery.

Surgery to treat women with POP and occult stress urinary incontinence

Five moderate-quality studies of women with prolapse and observed urinary leakage during vaginal examination with a reduced prolapse reported benefit from an additional continence procedure (mid-urethral sling) when undergoing vaginal prolapse surgery.

Surgery to treat continent women with POP

Evidence from one moderate-quality study was inconclusive as to any benefit of an additional continence procedure (mid-urethral sling) when women underwent vaginal prolapse surgery.

Whether abdominal prolapse repair (sacrocolpopexy) with an additional abdominal continence procedure (Burch colposuspension) improves urinary leakage after surgery remains unclear, as two low-quality studies reported conflicting results.

Seven low-quality studies reported that fewer women had urinary leakage after vaginal native tissue repair compared to women who received a vaginal mesh implant for prolapse. However, vaginal mesh placement reduced the chance of recurrent prolapse.

Quality of the evidence

The quality of the evidence ranged from low to moderate. The main limitations in the quality of the evidence were risk of bias when those assessing the outcome of the surgery were not blinded to the type of surgery, indirectness when a study had a different focus to our review, and imprecision associated with small numbers of women who participated in the trials.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. POP surgery with concomitant continence procedure compared to no concomitant continence procedure in women with POP and SUI

POP surgery with concomitant continence procedure compared to without concomitant continence procedure in women with POP and SUI

Patient or population: women with POP and SUI
Setting: hospital
Intervention: POP surgery with continence procedure
Comparison: POP surgery without continence procedure

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with POP surgery without continence procedure	Risk with POP surgery with continence procedure				
Vaginal POP surgery with vs without MUS Follow-up: 12 months	Subjective postoperative SUI	394 per 1000	118 per 1000 (75 to 189)	RR 0.30 (0.19 to 0.48)	319 (2 RCTs)	⊕⊕⊕⊖ Moderate ^a
	Recurrent POP on examination	No data available				
	Overactive bladder symptoms (cured/improved)	No data available				
	Voiding dysfunction	No data available				
Vaginal POP surgery with vs without MUS Follow-up: mean 12 months	Further continence surgery	169 per 1000	7 per 1000 (0 to 125)	RR 0.04 (0.00 to 0.74)	134 (1 RCT)	⊕⊕⊕⊖ Moderate ^a
Vaginal POP surgery with concomitant vs delayed continence surgery: additional concomitant MUS vs delayed MUS Follow-up: mean 12 months	Subjective postoperative SUI	113 per 1000	46 per 1000 (14 to 155)	RR 0.41 (0.12 to 1.37)	140 (1 RCT)	⊕⊕⊕⊖ Moderate ^a
	Recurrent POP on examination	No data available				
	Overactive bladder symptoms (cured/improved)	No data available				

	Voiding dysfunction	No data available					
	Further continence surgery	No data available					
Abdominal POP surgery with vs without concomitant continence surgery: additional Burch colposuspension vs sacrocolpopexy alone: 1-year FU	Subjective postoperative SUI	391 per 1000	540 per 1000 (290 to 1000)	RR 1.38 (0.74 to 2.60)	47 (1 RCT)	⊕⊕⊕⊖ Moderate ^a	
	Recurrent POP on examination	No data available					
	Overactive bladder symptoms (cured/improved)	882 per 1000	750 per 1000 (538 to 1000)	RR 0.85 (0.61 to 1.18)	33 (1 RCT)	⊕⊕⊕⊖ Moderate ^a	
	Voiding dysfunction difficulties	43 per 1000	42 per 1000 (3 to 627)	RR 0.96 (0.06 to 14.43)	47 (1 RCT)	⊕⊕⊖⊖ Low ^{a,b}	
	Further continence surgery	No data available					

*The basis for the **assumed risk** is the *mean control group risk* across studies. 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; FU: follow-up; MUS: mid-urethral sling; POP: pelvic organ prolapse; RCT: randomised controlled trial; RR: risk ratio; SUI: stress urinary incontinence;

GRADE Working Group grades of evidence.

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded one level for serious risk of bias - no blinding of patients or assessors.

^bDowngraded one level for serious imprecision with very low event rate and very wide confidence intervals, which cross line of no effect.

Summary of findings 2. Vaginal POP surgery with concomitant continence procedure compared to no concomitant continence procedure in women with POP and occult SUI

Vaginal POP surgery with concomitant continence procedure compared to no concomitant continence procedure in women with POP and occult SUI

Patient or population: women with POP and occult SUI

Setting: hospital

Intervention: vaginal POP surgery with continence procedure

Comparison: vaginal POP surgery without continence procedure

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with vaginal POP surgery without concomitant continence procedure	Risk with vaginal POP surgery with concomitant continence procedure				
Vaginal POP surgery with or without concomitant continence surgery: additional MUS vs vaginal repair alone	Subjective postoperative SUI	397 per 1000	151 per 1000 (103 to 218)	RR 0.38 (0.26 to 0.55)	369 (5 RCTs)	⊕⊕⊕⊖ Moderate ^a
	Recurrent POP on examination	280 per 1000	241 per 1000 (95 to 613)	RR 0.86 (0.34 to 2.19)	50 (1 RCT)	⊕⊕⊖⊖ Low ^{a,b}
	Overactive bladder symptoms (cured/improved)	870 per 1000	652 per 1000 (452 to 930)	RR 0.75 (0.52 to 1.07)	43 (1 RCT)	⊕⊕⊖⊖ Low ^{a,b}
	Voiding dysfunction	80 per 1000	18 per 1000 (5 to 64)	RR 1.00 (0.15 to 6.55)	50 (1 RCT)	⊕⊕⊖⊖ Low ^{a,b}
	Further continence surgery	No data available				

*The basis for the **assumed risk** is the *mean control group risk* across studies. 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; FU: follow-up; MUS: mid-urethral sling; POP: pelvic organ prolapse; RR: risk ratio; SUI: stress urinary incontinence.

GRADE Working Group grades of evidence.

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded one level for serious risk of bias - no blinding of patients or assessors, or insufficient information on blinding.

^bDowngraded one level for serious imprecision with low event rate and wide CI crossing the line of no effect.

Summary of findings 3. Vaginal or abdominal POP surgery with concomitant continence procedure compared to no concomitant continence procedure in continent women with POP

Vaginal or abdominal POP surgery with concomitant continence procedure compared to no concomitant continence procedure in continent women with POP

Patient or population: continent women with POP

Setting: hospital

Intervention: vaginal or abdominal POP surgery with concomitant continence procedure

Comparison: vaginal or abdominal POP surgery without concomitant continence procedure

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with vaginal or abdominal POP surgery without concomitant continence procedure	Risk with vaginal or abdominal POP surgery with concomitant continence procedure				
Vaginal POP surgery with or without concomitant continence surgery: additional MUS vs vaginal repair alone	Subjective postoperative SUI	407 per 1000	281 per 1000 (191 to 407)	RR 0.69 (0.47 to 1.00)	220 (1 RCT)	⊕⊕⊕⊖ Moderate ^a
	Recurrent POP on examination	No data available				
	Overactive bladder symptoms (cured/improved)	No data available				
	Voiding dysfunction difficulties	No data available				
	Further continence surgery	No data available				
Abdominal POP surgery with or without concomitant continence surgery: additional Burch colposuspension vs sacrocolpopexy alone	Subjective postoperative SUI/ de novo SUI 1-year FU	347 per 1000	455 per 1000 (66 to 1000)	RR 1.31 (0.19 to 9.01)	379 (2 RCTs)	⊕⊕⊖⊖ Low ^{b, c}
	Recurrent POP on examination	436 per 1000	427 per 1000 (323 to 567)	RR 0.98 (0.74 to 1.30)	250 (1 RCT)	⊕⊕⊕⊖ Moderate ^c
	Overactive bladder symptoms (cured/improved)	No data available				
	Voiding dysfunction difficulties	0 per 1000	0 per 1000 (0 to 0)	RR 8.49 (0.48 to 151.59)	66 (1 RCT)	⊕⊕⊖⊖ Low ^d

Further continence surgery

No data available

*The basis for the **assumed risk** is the *mean control group risk* across studies. 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; FU: follow-up; MUS: mid-urethral sling; POP: pelvic organ prolapse; RCT: randomised controlled trial; RR: risk ratio; SUI: stress urinary incontinence.

GRADE Working Group grades of evidence.

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded one level for serious indirectness - women without SUI symptoms were included; some of them had occult SUI but results were presented separately.

^bDowngraded one level - studies showed diverging results with a high grade of heterogeneity.

^cDowngraded one level due to imprecision - wide confidence interval.

^dDowngraded two levels for very serious imprecision - very wide confidence interval.

Summary of findings 4. Vaginal POP surgery with armed mesh compared to anterior native tissue repair for continent women with POP

Vaginal POP surgery with armed mesh compared to anterior native tissue repair for continent women with POP

Patient or population: continent women with POP

Setting: hospital

Intervention: vaginal POP surgery with armed mesh

Comparison: anterior native tissue repair

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with anterior native tissue repair	Risk with vaginal POP surgery with armed mesh				
One type of POP surgery vs another: armed anterior mesh vs anterior native tissue repair	Subjective postoperative SUI	73 per 1000	115 per 1000 (76 to 172)	RR 1.58 (1.05 to 2.37)	905 (7 RCTs)	⊕⊕○○ Low ^{a,b}
	Recurrent POP on examination	475 per 1000	138 per 1000 (104 to 180)	RR 0.29 (0.22 to 0.38)	848 (5 RCTs)	⊕⊕○○ Low ^{a,b}
	Overactive bladder symptoms (cured/improved)	No data available				-

Voiding dysfunction difficulties	16 per 1000	27 per 1000 (4 to 195)	RR 1.65 (0.22 to 12.10)	125 (2 RCTs)	⊕⊕○○ Low ^{a,b}
Further continence surgery	No data available				

*The basis for the **assumed risk** is the *mean control group risk* across studies. 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; POP: pelvic organ prolapse; RCT: randomised controlled trial; RR: risk ratio; SUI: stress urinary incontinence.

GRADE Working Group grades of evidence.

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aDowngraded one level for serious risk of bias - no blinding of outcome assessors.

^bDowngraded one level for indirectness - primary outcome was POP.

BACKGROUND

Pelvic organ prolapse (POP) is common and is seen on examination in 40% to 60% of parous women (Handa 2004; Hendrix 2002). POP is often associated with stress urinary incontinence (SUI); approximately 55% of women with stage 2 POP (prolapse to the hymen ± 1 cm) have concurrent SUI, and only 33% of women with stage 4 POP have SUI (Slieker-ten Hove 2009), probably due to kinking of the urethra when the prolapse advances.

When the prolapse is reduced digitally, with the help of a pessary or speculum during clinical examination, SUI might be demonstrated in up to 68% (Haessler 2005; Reena 2007; Visco 2008). If SUI is present only when the prolapse is reduced in otherwise continent women, this type of SUI is defined as 'occult SUI'. Women with occult SUI are at risk of developing symptomatic SUI after POP surgery (Haessler 2005).

Also, preoperatively continent women with POP and no symptomatic or occult SUI on examination may develop SUI symptoms postoperatively (Haessler 2005). This situation is defined as 'de novo stress urinary incontinence'. De novo SUI might occur after repair of POP because the surgery has unkinked the preoperatively obstructed urethra.

Therefore, this systematic review aims to determine the outcome of surgery with or without concomitant or delayed continence procedures in women with symptomatic pelvic organ prolapse with or without symptomatic or occult SUI on postoperative bladder function.

Description of the condition

Pelvic organ prolapse is the descent of one or more of the pelvic organs (uterus, vagina, bladder, or bowel). Types of prolapse include:

- upper vaginal prolapse (i.e. uterus, vaginal vault (after hysterectomy when the top of the vagina drops down));
- anterior vaginal wall prolapse (i.e. cystocele (bladder descends), urethrocele (urethra descends), paravaginal defect (pelvic fascia defect)); and
- posterior vaginal wall prolapse (i.e. enterocele (small bowel descends), rectocele (rectum descends), perineal deficiency).

Women with prolapse commonly have a variety of pelvic floor symptoms. Symptoms of prolapse include pelvic heaviness; a bulge, lump, or protrusion coming down from the vagina; a dragging sensation in the vagina; and backache. Symptoms of bladder, bowel, or sexual dysfunction are frequently present. For example, women may need to reduce the prolapse by using their fingers to push the prolapse up to facilitate urinary voiding or defecation. These symptoms may be directly related to the prolapsed organ, for example, poor urinary stream when a cystocele is present, or obstructed defecation when a rectocele is present. They may also be independent of the prolapse, for example, symptoms of overactive bladder (OAB) when a cystocele is present.

Stress urinary incontinence is the "complaint of involuntary loss of urine on effort or physical exertion (e.g. sporting activities), or on sneezing or coughing" (Haylen 2010). It occurs in approximately 50% of postmenopausal women and is often associated with POP. If the prolapse is more advanced, SUI might disappear as the result of kinking of the urethra (Slieker-ten Hove 2009). However, on examination with the prolapse reduced, SUI can be often be demonstrated (Haessler 2005; Reena 2007; Visco 2008). This is defined as "occult or latent stress incontinence: (new) stress incontinence only observed after the reduction of co-existent prolapse" (Haylen 2010). In this review, we will consistently use the term 'occult SUI'. To date it is not clear which method is best for reducing POP: neither reduction with speculum nor pessary provided acceptable positive predictive values to identify women who would benefit from a concomitant continence procedure during POP surgery. However, negative predictive values were 92.5% (95% confidence interval (CI) 90.3 to 1.00) and 91.1% (95% CI 88.5 to 99.7), respectively, which shows that women who test negative for occult SUI are at low risk of developing SUI postoperatively (Ellström 2011). If SUI develops after POP surgery in preoperatively continent women without occult SUI, this is termed 'de novo SUI' consistently in our review.

Causes of pelvic organ prolapse and SUI are complex and multi-factorial. Possible risk factors include pregnancy, childbirth, congenital or acquired connective tissue abnormalities, denervation or weakness of the pelvic floor, ageing, hysterectomy, menopause, and factors associated with chronically raised intra-abdominal pressure (ICI 2017).

Description of the intervention

Treatment for POP with or without SUI depends on the severity of the prolapse, associated symptoms, the woman's wish and general health, and surgeon preference and capabilities. Options available for treatment include conservative, mechanical, and surgical interventions. Surgical methods to treat anterior, posterior, and apical compartment POP and use of transvaginal mesh are described in conjoint reviews: Maher 2016a; Maher 2016b; Maher 2016c; and Mowat 2018.

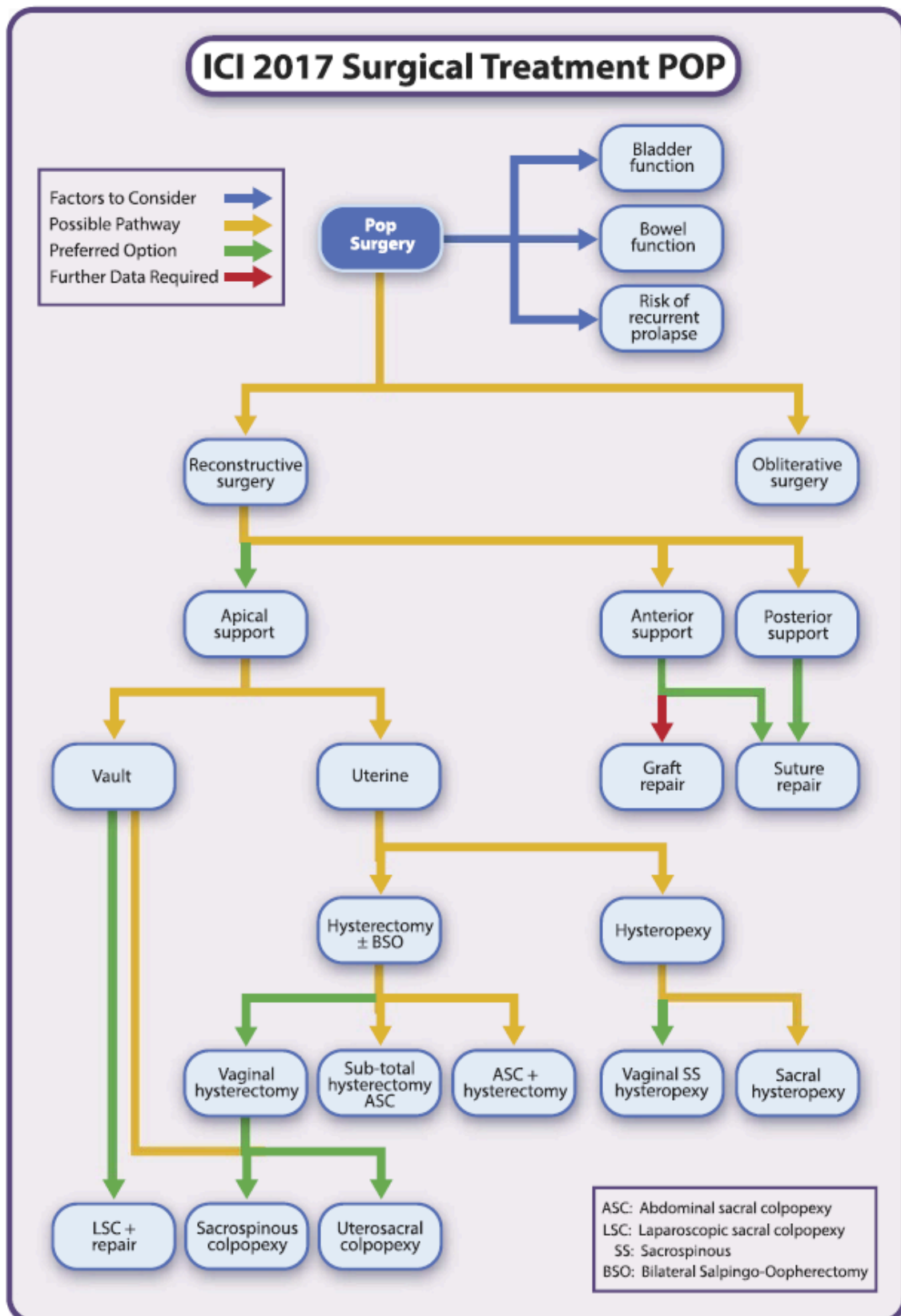
Conservative and mechanical interventions have been considered in separate Cochrane reviews: Bugge 2013 and Hagen 2011.

This review considers surgical procedures for women with symptomatic pelvic organ prolapse with or without concomitant SUI or occult SUI. Aims of surgery include restoration of normal vaginal anatomy and restoration or maintenance of normal bladder, bowel, and sexual function.

A wide variety of abdominal, laparoscopic, and vaginal surgical techniques are available for the treatment of individuals with POP and SUI. The Committee for "Pelvic Organ Prolapse Surgery" of the International Consultation on Incontinence published an algorithm for the surgical management of pelvic organ prolapse, taking into account evidence from randomised and non-randomised trials (Figure 1; ICI 2017).

Figure 1. Decision pathway pelvic organ prolapse surgery - published with permission of Wolters Kluwer. Maher CF, Baessler KK, Barber MD, Cheon C, Consten ECJ, Cooper KG, et al. Summary: 2017 International Consultation on

Incontinence Evidence-Based Surgical Pathway for Pelvic Organ Prolapse. Female Pelvic Medicine & Reconstructive Surgery 2018 April 28 [Epub ahead of print]. <https://insights.ovid.com/pubmed?pmid=29727373>. (Maher 2018)



ASC: Abdominal sacral colpopexy
LSC: Laparoscopic sacral colpopexy
SS: Sacrospinous
BSO: Bilateral Salpingo-Oophorectomy

Two main approaches can be differentiated but can also be combined during surgery (for further description of the procedures, see [Appendix 1](#)).

- Vaginal approaches to treat POP include hysterectomy, anterior or posterior vaginal wall repair (colporrhaphy), McCall culdoplasty, Manchester repair (amputation of the cervix with uterine suspension to the cardinal ligaments), prespinous and sacrospinous colpexy, enterocele ligation, paravaginal repair, the Le Fortes procedure (colpocleisis), and perineal reconstruction.
- Abdominal approaches to treat POP include total or subtotal hysterectomy, sacrocolpopexy, sacrohysteropexy or cervicopexy, paravaginal repair, vault suspension and uterosacral ligament plication, enterocele ligation, and posterior vaginal wall repair. Abdominal surgery can be performed through an open incision or through keyhole incisions via the laparoscope or robot.

A combination of some of these procedures may be employed in the surgical correction of prolapse, as frequently more than one type of prolapse may occur.

Although any restoration of the anterior vaginal wall anatomy by anterior colporrhaphy or suspension of the uterus or the vaginal vault may already reduce SUI symptoms, these procedures are not considered formal continence surgery in this review. We will include in this review the following current standard continence procedures.

- Vaginal mid-urethral sling (MUS) procedures (e.g. tension-free vaginal tape (TVT), transobturator tape (TOT), single-incision slings).
- Abdominal (open or laparoscopic) colposuspension procedures: Burch colposuspension and its modifications.
- Urethral bulking agents.

Although a Burch colposuspension is considered formal continence surgery, it may also restore normal anatomy of the anterior vaginal wall. This is particularly true if a cystocele is caused by paravaginal defects. Historically, Burch colposuspension and its modifications were also considered POP surgery, whereas anterior colporrhaphy was deemed a continence procedure.

The choice of operation depends on a number of factors, which include the nature, site, and severity of the prolapse; whether additional symptoms are affecting urinary, bowel, or sexual function; the general health of the woman; and surgeon preference and capability.

Procedures to treat or prevent SUI can be performed at the same time or later, depending on preoperative symptoms or demonstration of occult incontinence. Concurrent as well as delayed continence surgery will therefore also be considered in this review.

These issues require extensive counselling of the patient and may include discussions on the need for concomitant hysterectomy, continence surgery, and the use of mesh.

How the intervention might work

The aim of POP surgery is to restore pelvic floor anatomy and function by correcting the support defect or incorporating surrogate structures. This may include:

- repair of defects of the endopelvic fascia: anterior and posterior repair (colporrhaphy);
- (re)attachment of the uterus or vaginal vault to the uterosacral ligaments: uterosacral ligament fixation;
- attachment of the uterus or vaginal vault to the sacrospinous ligament: sacrospinous colpexy, sacrospinous hysteropexy;
- attachment of the uterus, cervix (after subtotal hysterectomy), or vaginal vault to the sacrum with mesh interposition: sacrocolpopexy, sacrocervicopexy, sacrohysteropexy; and
- if fascia or ligaments are not available or are deemed insufficient, vaginal mesh might be employed: anterior mesh overlay or inlay and anterior armed mesh (transobturator/obturator fixation with or without apical fixation).

The aim of formal continence surgery at the time of POP repair is to prevent or treat SUI by increasing support to the urethra and the bladder neck (bladder neck elevation during Burch colposuspension) or to support the mid-urethra (mid-urethral slings).

As POP surgery might already restore anatomy and function in the anterior compartment, this review will compare different POP operations alone as well as in contemporaneous or delayed combination with formal continence surgery.

These surgical approaches are available to prevent or treat women with symptomatic POP with and without SUI.

- POP surgery alone.
- POP surgery with concomitant continence surgery.
- POP surgery and subsequent delayed continence surgery (two-stage operation).

Why it is important to do this review

Although a wide variety of surgical treatments are available for POP with or without SUI, the optimal treatment for the individual situation with or without symptomatic SUI or findings on examination like occult SUI has not been established. It is unclear when continence procedures should be performed concomitantly or delayed as a two-stage POP that includes a continence procedure, and which POP operations might sufficiently support the urethra or bladder neck, thereby treating or preventing postoperative symptomatic SUI in women with preoperative symptomatic or occult SUI and symptomatic POP.

Provided that sufficient numbers of trials of adequate quality have been conducted, the most reliable evidence is likely to come from consideration of randomised controlled trials, and this is the basis for this review. The aim is to help identify optimal practice while highlighting topics that need further research.

OBJECTIVES

To determine the impact on postoperative bladder function of surgery for symptomatic pelvic organ prolapse with or without

concomitant or delayed two-stage continence procedures to treat or prevent stress urinary incontinence.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs). Studies were required to have a sample size of at least 20 in each group and a follow-up time of at least six months.

Types of participants

Adult women seeking treatment for symptomatic pelvic organ prolapse with or without symptomatic or occult SUI.

Pelvic organ prolapse (POP) includes:

- upper vaginal prolapse (uterine or vaginal vault);
- anterior vaginal wall prolapse (cystocele, urethrocele, paravaginal defect); and
- posterior vaginal wall prolapse (enterocele, rectocele, perineal deficiency).

We will include studies of the following groups of women with POP.

- Women with stress urinary incontinence.
- Women with occult stress urinary incontinence on examination with the prolapse reduced.
- Continent women.

Stress urinary incontinence may have been diagnosed or described or excluded by employing standardised or preferably validated questionnaires, a clinical stress test with and without the prolapse reduced, or urodynamic studies.

We will include women with or without previous pelvic floor surgery including operations for POP or incontinence.

Types of interventions

We assessed trials comparing any type of abdominal or vaginal surgery for pelvic organ prolapse with or without concomitant or delayed continence surgery. We did not include comparisons of conservative interventions like pessaries or pelvic floor muscle training.

We included the following surgical operations to correct pelvic organ prolapse.

- Abdominal or laparoscopic sacrocolpopexy or sacrohysteropexy.
- Vaginal sacrospinous colpopexy or hysteropexy.
- Anterior native tissue repair (colporrhaphy).
- Anterior repair with mesh placement: armed or as overlay or inlay.

Although any restoration of the anterior vaginal wall anatomy by anterior colporrhaphy or suspension of the uterus or the vaginal vault may already reduce SUI symptoms, we do not consider these procedures formal continence surgery for the purposes of this review. We will include the following current standard continence procedures in the review.

- Vaginal mid-urethral sling (MUS) procedures (e.g. tension-free vaginal tape, transobturator tape, single-incision sling).
- Abdominal (open or laparoscopic) colposuspension procedures: Burch colposuspension and its modifications.
- Urethral bulking agent.

Types of outcome measures

Primary outcomes

- Women's observations related to stress urinary incontinence (subjective outcome)
 - * Subjective postoperative stress urinary incontinence (de novo, persistent, cured, or improved SUI)

Secondary outcomes

- Clinicians' observations related to stress urinary incontinence and pelvic organ prolapse (objective outcome)
 - * Objective stress urinary incontinence on examination (positive stress test) or urodynamic studies
 - * Recurrent POP on examination
- Associated pelvic floor symptoms
 - * Overactive bladder symptoms (de novo, persistent, cured, or improved OAB)
 - * Voiding dysfunction (de novo, persistent, cured, or improved VD)
 - * Pelvic pain
 - * Sexual problems including dyspareunia
 - * Perceived cure of or improvement in prolapse symptoms
 - * Condition-specific quality of life questionnaires (related to pelvic floor function)
- Surgical outcome measures
 - * Further continence surgery
- Complications
 - * Adverse effects (e.g. return to theatre, damage to surrounding viscera, mesh or graft exposure, graft rejection)
- Economic measures
 - * Costs of interventions or resources
 - * Formal economic evaluations

Search methods for identification of studies

We did not impose any language restrictions or other limits on any of the searches, which we have detailed below.

Electronic searches

This review drew on the search strategy developed for the Cochrane Incontinence Review Group. Relevant trials were identified from the Group's Specialised Register of controlled trials, which is described, along with the Review Group search strategy, under the Group's [module](#) in the Cochrane Library. The Register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), in the Cochrane Library, MEDLINE, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and by handsearching of journals and conference proceedings. The Incontinence Group Specialised Register was searched using the Group's own keyword system (all searches were of the keyword field of Reference Manager 12, Thomson Reuters; last search date 30 November 2017). These are the search terms that were used.

{{design.cct*} OR {design.rct*}}

AND
 ({topic.prolapse*})
 AND
 ({intvent.surg*})

Trials included in the Incontinence Group Specialised Register are also contained in CENTRAL.

Searching other resources

We handsearched conference proceedings of the annual meetings of relevant societies (i.e. International Urogynecologic Association (IUGA), International Continence Society (ICS), and American Urogynecologic Society (AUGS)), searched the reference lists of relevant articles, and contacted researchers in the field.

Data collection and analysis

Selection of studies

We assessed titles and abstracts of all possibly eligible studies. Two review authors (KB and CS) independently assessed the full report of each study likely to be eligible, using our inclusion criteria. Review authors agreed on whether or not to include the study based on the inclusion criteria for the review.

We have listed excluded studies with reasons for their exclusion in the [Characteristics of excluded studies](#) table.

Data extraction and management

At least two review authors (from KB, CS, and CFM) independently extracted and compared data to ensure accuracy. We resolved discrepancies by discussion or by referral to a third party. When trial data were not reported adequately, we attempted to acquire the necessary information from authors in the trial list.

We corresponded with study investigators to ask for further data on methods and/or results, as required.

Assessment of risk of bias in included studies

Two review authors (KB and CS) independently evaluated the included studies for risk of bias using the Cochrane risk of bias assessment tool to assess selection (random sequence generation and allocation concealment), performance (blinding of participants and personnel), detection (blinding of outcome assessors), attrition (incomplete outcome data), reporting (selective reporting), and other bias ([Higgins 2011](#)). We assigned judgements as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Chapter 8.5) ([Higgins 2011a](#)). We resolved disagreements by discussion. We fully described all judgements and presented them in the conclusions in the 'Risk of bias' tables, which we incorporated into our interpretation of review findings by performing sensitivity analyses.

Measures of treatment effect

For categorical and dichotomous data, we used the numbers of events in control and intervention groups of each study to calculate a risk ratio (RR). For continuous variables, we calculated mean differences (MDs) between treatment groups. If similar outcomes were reported on different scales, we calculated standardised mean differences (SMDs). We reversed the direction of effect of individual studies, if required, to ensure consistency across trials.

We assessed whether estimates calculated in the review for individual studies were compatible in each case with estimates reported in the study publications.

Unit of analysis issues

Analysis was performed per woman randomised.

Dealing with missing data

We analysed the data on an intention-to-treat basis as far as possible (i.e. including all randomised participants in analysis, in the groups to which they were randomised), using Review Manager software ([RevMan 2014](#)). We attempted to obtain missing data from the original trialists. When we could not obtain these, we analysed only available data.

If studies reported sufficient detail to calculate mean differences but no information on associated standard deviation (SD), we assumed the outcome to have a standard deviation equal to the highest SD from other studies within the same analysis.

Assessment of heterogeneity

We considered whether clinical and methodological characteristics of included studies were sufficiently similar for meta-analysis to provide a clinically meaningful summary. We assessed statistical heterogeneity by measuring I^2 . We regarded an I^2 measurement greater than 50% as indicating substantial heterogeneity ([Higgins 2011](#)).

Assessment of reporting biases

In view of the difficulty of detecting and correcting for publication bias and other reporting biases, we aimed to minimise their potential impact by ensuring a comprehensive search for eligible studies and by staying alert for duplication of data. If we included ten or more studies in an analysis, we planned to use a funnel plot to explore the possibility of small-study effects (i.e. a tendency for estimates of the intervention effect to be more beneficial in smaller studies).

Data synthesis

We combined trials only if the interventions were similar enough based on clinical criteria.

We processed included trial data as described in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)). We undertook meta-analyses to synthesise trial data, when appropriate. We used a fixed-effect model for calculations of summary estimates and their 95% confidence intervals (CIs), except where heterogeneity indicated a change to a random-effects model.

We made the following comparisons.

- Vaginal POP surgery with versus without concomitant continence surgery.
- Vaginal POP surgery with concomitant versus delayed continence surgery.
- Abdominal POP surgery with versus without concomitant continence surgery.
- Abdominal POP surgery with one type of concomitant continence procedure versus another type.

- One type of POP surgery versus another type of POP surgery.

We conducted separate analyses for different population groups, as follows.

- Women with stress urinary incontinence.
- Women with occult stress urinary incontinence.
- Urinary continent women.

Subgroup analysis and investigation of heterogeneity

When we suspected important heterogeneity from visual inspection of the results, and when the Chi² test for heterogeneity (at 10%) or the I² statistic (I² > 50%) indicated substantial heterogeneity (I² > 50%) (Higgins 2003), we explored possible explanations through subgroup analyses such as clinical or methodological differences between trials. We took any statistical heterogeneity into account when interpreting the results, especially if we noted any variation in the direction of effect.

Sensitivity analysis

We planned to conduct sensitivity analyses for the primary outcomes to determine whether the conclusions were robust to arbitrary decisions made regarding eligibility and analysis. These analyses would have included consideration of whether review conclusions would have differed if:

- eligibility had been restricted to studies without high risk of bias (defined as studies that we rated as at low risk of bias with respect to sequence generation and allocation concealment, and that we did not rate as at high risk of bias in any of the domains assessed); or

- a random-effects model had been adopted.

Overall quality of the body of evidence: 'Summary of findings' table

We prepared 'Summary of findings' tables using GRADEpro and Cochrane methods (GRADEproGDT 2015; Higgins 2011). These tables evaluated the overall quality of the body of evidence for main review outcomes (subjective postoperative stress urinary incontinence, recurrent POP on examination, overactive bladder, voiding dysfunction, and need for further surgery) for the main review comparison (POP surgery with vs without a concomitant continence procedure). We prepared a separate 'Summary of findings' table for each population group of interest. We assessed the quality of the evidence using the following GRADE criteria: risk of bias, consistency of effect, imprecision, indirectness, and publication bias. Two review authors (KB and CS) independently made judgements about evidence quality (high, moderate, low, or very low) and resolved disagreements by discussion. We justified, documented, and incorporated judgements into reporting of results for each outcome.

RESULTS

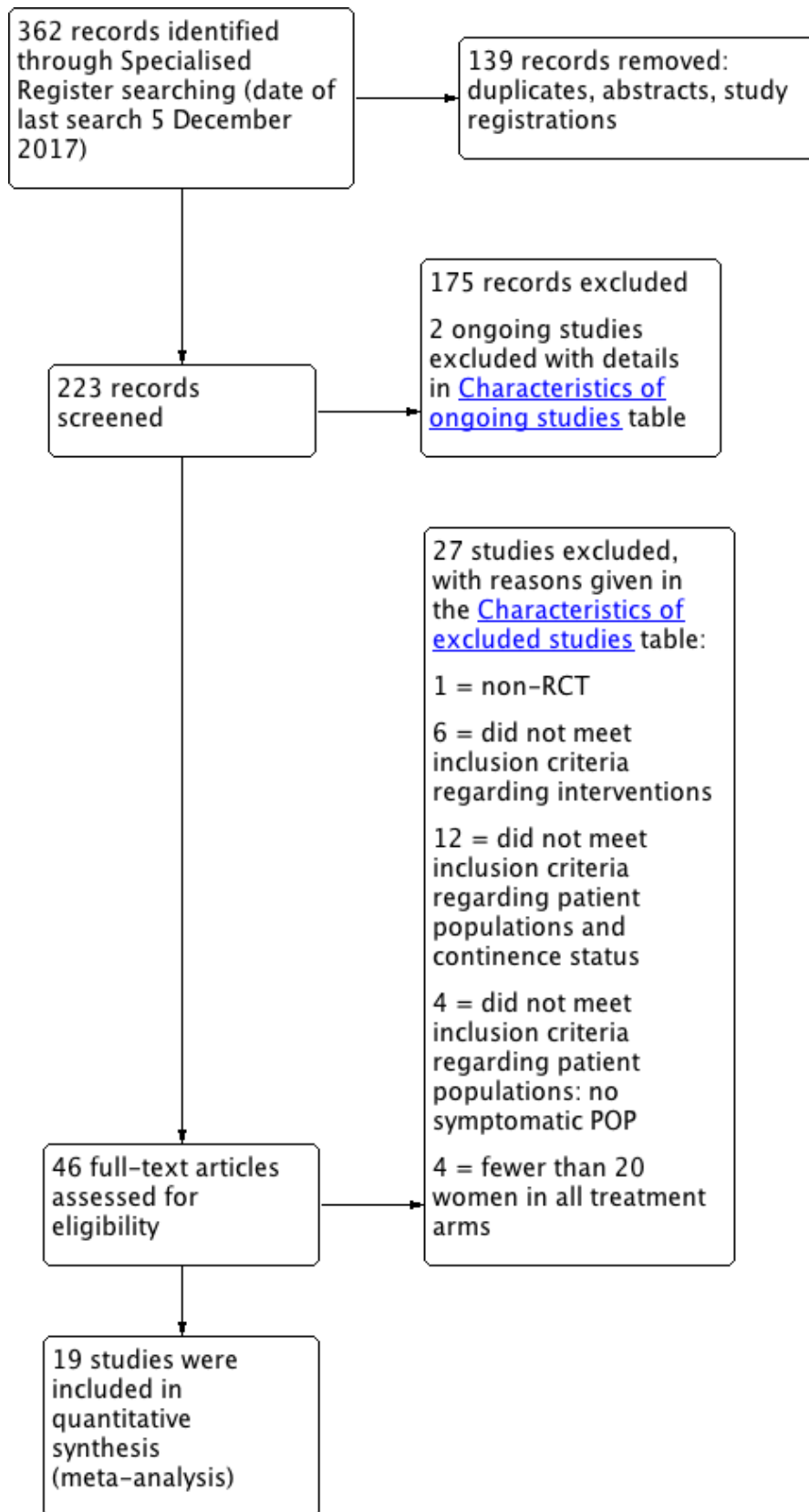
Description of studies

Results of the search

We assessed full reports of 95 potentially eligible studies.

We have shown the flow of studies through the assessment process in the PRISMA flowchart (Figure 2).

Figure 2. PRISMA study flow diagram.



Included studies

We included 19 studies reporting on 2717 randomised women.

We included the following.

- Five studies that assessed continence issues in continent women (Altman 2011; Brubaker 2006; Costantini 2007; Sivaslioglu 2008; Turgal 2013). Two studies are ancillary reports to Altman 2011, and they provide additional information (Ek 2010; Ek 2011). Brubaker 2006 and Costantini 2007 published extended follow-up at two years and several additional reports, which are clearly marked and assess the same patients.
- Four further studies provided separate data on de novo stress urinary incontinence at 3, 12, 24, or 36 months, although trials included women with and without SUI (Hiltunen 2007; Iglesia 2010; Rudnicki 2014; Withagen 2011). Hiltunen 2007 and Rudnicki 2014 also published longer-term (three years) follow-up data.
- Five studies analysed postoperative SUI in women with POP and occult SUI who did or did not receive an additional mid-urethral sling (Fuentes 2011; Meschia 2004; Schierlitz 2014; van der Ploeg 2016 (CUPIDO II); Wei 2011). Three trials used a retropubic mid-urethral sling; Fuentes 2011 used a transobturator tape. van der Ploeg 2016 (CUPIDO II) used both retropubic and transobturator slings. Fuentes 2011 published only an abstract. Schierlitz 2014 published four-year follow-up data (Walsh et al).
- Five studies assessed continence issues in preoperatively stress urinary incontinent women with POP (Borstad 2010; Colombo 2000; Costantini 2008; Trabuco 2014; van der Ploeg 2015 (CUPIDO I)). Trabuco 2014 also reported two-year outcomes (Trabuco et al 2016), and Costantini 2008 provided five-year data.

Design and setting

All studies used computer-generated randomisation lists and none were quasi-randomised trials, although Fuentes 2011 did not comment on this. Most studies concealed allocation in opaque envelopes that were opened at the time of surgery. Only one study did not conceal the allocation and used an open list (Colombo 2000), and some studies did not mention concealment strategies (Fuentes 2011; Sivaslioglu 2008; Turgal 2013; Wei 2011; Withagen 2011).

Trials were performed in nine countries (USA, Italy, Netherlands, Finland, Sweden, Denmark, Norway, Turkey, Australia).

Some studies specifically mentioned the setting as a secondary referral centre (Colombo 2000), others as a tertiary referral centre (Brubaker 2006; Costantini 2007; Costantini 2008). Iglesia 2010 emphasised that fellowship-trained urogynaecologists performed the surgeries. All studies were performed in a dedicated urogynaecological or urological setting.

Twelve trials were multi-centre studies (Altman 2011; Borstad 2010; Brubaker 2006; Hiltunen 2007; Iglesia 2010; Rudnicki 2014; Schierlitz 2014; Sivaslioglu 2008; van der Ploeg 2015 (CUPIDO I); van der Ploeg 2016 (CUPIDO II); Wei 2011; Withagen 2011).

Only four trials used a double-blind design (blinding of participants and assessors) (Brubaker 2006; Iglesia 2010; Wei 2011; Withagen 2011), and three trials reported a single-blind approach (Altman

2011; Costantini 2007; Costantini 2008). Wei 2011 also used sham dressings.

Participants

All studies included continent or incontinent women with symptomatic pelvic organ prolapse quantification (POPQ) stage 2 or higher and Baden-Walker grade 2 or higher, respectively. Researchers randomised 2717 women and followed up on 2429 of them. Most participants were postmenopausal; no studies focused on premenopausal, elderly, or obese women.

Interventions

Although a great variety of surgeries can be performed for POP, these studies evaluated only the Burch colposuspension or mid-urethral slings for SUI.

- Three studies compared sacrocolpopexy with or without Burch colposuspension (Brubaker 2006; Costantini 2007; Costantini 2008), and one study compared MUS and Burch colposuspension at the time of sacrocolpopexy (Trabuco 2014).
- Seven studies compared anterior native tissue repair versus vaginal mesh augmented surgery: two self-tailored mesh (Hiltunen 2007; Sivaslioglu 2008), three Prolift (Altman 2011; Iglesia 2010; Withagen 2011), one Sofradim (Turgal 2013), and one Avaulta (Rudnicki 2014).
- Six studies compared vaginal POP surgery with and without mid-urethral slings: Meschia 2004, Schierlitz 2014, and Wei 2011 retropubic TVT, Fuentes 2011 one transobturator sling, and both van der Ploeg 2015 (CUPIDO I) and van der Ploeg 2016 (CUPIDO II) retropubic or transobturator slings.
- One study compared vaginal POP surgery with concomitant versus delayed retropubic TVT (Borstad 2010).
- One study compared Burch colposuspension versus anterior repair (Colombo 2000).

Outcomes

All studies assessed subjective bladder function outcomes. Not all studies reported on POP outcomes. Most trialists employed the POPQ, and only one trial used the Baden-Walker halfway system (Colombo 2000).

All included trials described stress urinary incontinence symptoms. Some studies also reported results of cough stress tests and urodynamic studies. Researchers infrequently described symptoms of overactive bladder or voiding dysfunction.

All but four trials - Colombo 2000, Meschia 2004, Borstad 2010, and Hiltunen 2007 - used various validated questionnaires to assess bladder, bowel, prolapse, and sexual symptoms. Lack of validated quality of life questionnaires in their native language was one reason (Hiltunen 2007).

Length of follow-up was 12 months or exceeded 12 months in most trials (Altman 2011; Brubaker 2006; Colombo 2000; Costantini 2007; Costantini 2008; Hiltunen 2007; Iglesia 2010; Meschia 2004; Rudnicki 2014; Schierlitz 2014; Sivaslioglu 2008; van der Ploeg 2015 (CUPIDO I); van der Ploeg 2016 (CUPIDO II); Wei 2011; Withagen 2011). Two trials reported on continence outcomes after six months (Fuentes 2011; Trabuco 2014). Subsequently, Trabuco 2014 published a two-year follow-up. Owing to the study design comparing vaginal POP surgery with concomitant versus delayed

mid-urethral sling placement, [Borstad 2010](#) presented results at three months.

Excluded studies

We excluded 27 studies, mainly because the patient populations did not meet our inclusion criteria of women with symptomatic POP with OR without SUI. Many of these studies explored different surgeries for POP but did not include continence outcomes in their study aims and did not assess continent or incontinent women, resulting in different patient populations. Some studies performed POP surgery as an adjunct in asymptomatic women; patient-centred outcomes cannot be assessed in asymptomatic patients, and interpretation of subjective outcomes is impossible. Furthermore, some studies did not include the minimum of 20 participants in each group.

We have provided full details in the [Characteristics of excluded studies](#) tables.

Risk of bias in included studies

Allocation

Sequence generation

We found that all but three studies adequately described the sequence generation process ([Fuentes 2011](#); [Trabuco 2014](#); [Turgal 2013](#)). [Fuentes 2011](#) provided an abstract with limited information.

Allocation concealment

Seven trials ensured secure concealment of the randomisation process ([Altman 2011](#); [Borstad 2010](#); [Brubaker 2006](#); [Hiltunen 2007](#); [Iglesia 2010](#); [Rudnicki 2014](#); [van der Ploeg 2015 \(CUPIDO I\)](#)); 11 trials indicated that this was unclear ([Costantini 2007](#); [Costantini](#)

[2008](#); [Fuentes 2011](#); [Meschia 2004](#); [Schierlitz 2014](#); [Sivaslioglu 2008](#); [Trabuco 2014](#); [Turgal 2013](#); [van der Ploeg 2016 \(CUPIDO II\)](#); [Wei 2011](#); [Withagen 2011](#)). [Colombo 2000](#) used an open list, which is considered inadequate, so we assessed this study as having high risk.

Blinding

Women and surgeons could not be blinded to the procedure when different surgical routes or incisions were compared ([Colombo 2000](#)), although [Wei 2011](#) and [Altman 2011](#) used sham incisions. [Iglesia 2010](#) and [Trabuco 2014](#) applied sham dressings for trocar incisions. Eight trials blinded patients and postoperative reviewers ([Altman 2011](#); [Brubaker 2006](#); [Costantini 2007](#); [Costantini 2008](#); [Iglesia 2010](#); [Trabuco 2014](#); [Wei 2011](#); [Withagen 2011](#)).

We rated four studies as having low risk of performance bias ([Altman 2011](#); [Brubaker 2006](#); [Iglesia 2010](#); [Wei 2011](#)), seven as having unclear risk ([Colombo 2000](#); [Costantini 2007](#); [Fuentes 2011](#); [Meschia 2004](#); [Sivaslioglu 2008](#); [Trabuco 2014](#); [Turgal 2013](#)), and eight as high risk ([Borstad 2010](#); [Costantini 2007](#); [Hiltunen 2007](#); [Rudnicki 2014](#); [Schierlitz 2014](#); [van der Ploeg 2015 \(CUPIDO I\)](#); [van der Ploeg 2016 \(CUPIDO II\)](#); [Withagen 2011](#)).

We rated seven studies as having low risk of detection bias ([Altman 2011](#); [Brubaker 2006](#); [Costantini 2007](#); [Costantini 2008](#); [Iglesia 2010](#); [Trabuco 2014](#); [Wei 2011](#)), four unclear risk ([Colombo 2000](#); [Fuentes 2011](#); [Meschia 2004](#); [van der Ploeg 2015 \(CUPIDO I\)](#)) and eight high risk ([Borstad 2010](#); [Hiltunen 2007](#); [Rudnicki 2014](#); [Schierlitz 2014](#); [Sivaslioglu 2008](#); [Turgal 2013](#); [van der Ploeg 2016 \(CUPIDO II\)](#); [Withagen 2011](#)).

We have summarised these findings in [Figure 3](#) and [Figure 4](#).

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

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Altman 2011	+	+	+	+	+	?	?
Borstad 2010	+	+	-	-	+	?	?
Brubaker 2006	+	+	+	+	+	?	+
Colombo 2000	+	-	?	?	+	?	?
Costantini 2007	+	?	?	+	+	?	?
Costantini 2008	+	?	-	+	+	?	?
Fuentes 2011	?	?	?	?	?	-	-
Hiltunen 2007	+	+	-	-	+	+	+
Iglesia 2010	+	+	+	+	+	+	?
Meschia 2004	+	?	?	?	+	+	?
Rudnicki 2014	+	+	-	-	+	+	?
Schierlitz 2014	+	?	-	-	?	+	?
Sivaslioglu 2008	+	?	?	-	+	?	+
Trabuco 2014	?	?	?	+	+	+	?
Turgal 2013	?	?	?	-	+	?	?
van der Ploeg 2015 (CUPIDO I)	+	+	-	?	+	+	?
van der Ploeg 2016 (CUPIDO II)	+	?	-	-	+	+	?
Wei 2011	+	?	+	+	+	+	+
Withagen 2011	+	?	-	-	?	+	-

Figure 3. (Continued)

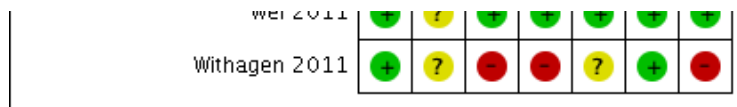
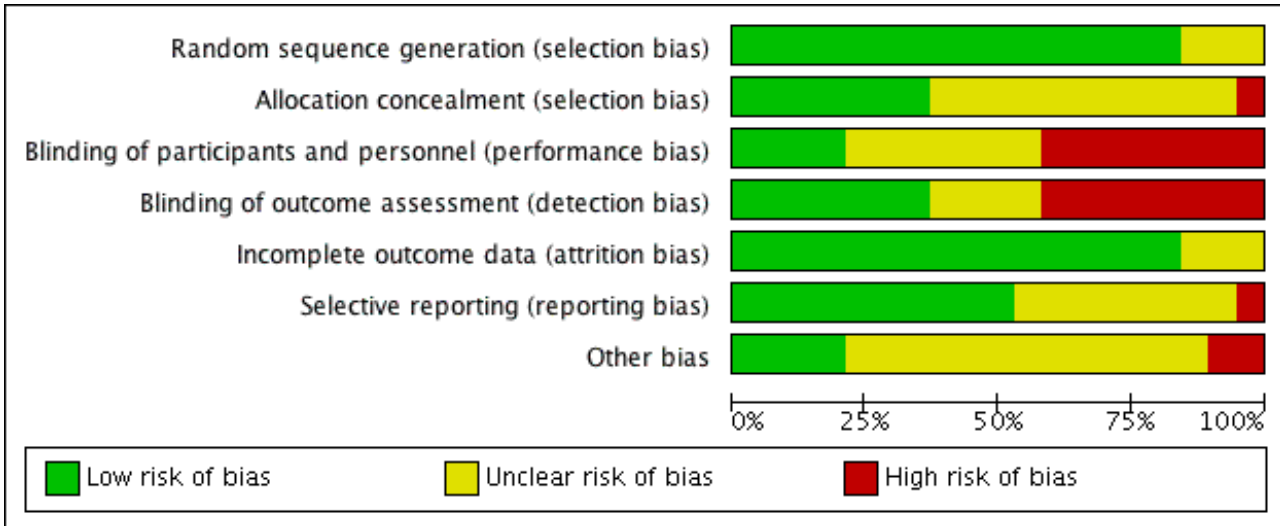


Figure 4. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Incomplete outcome data

Loss to follow-up was a variable problem, ranging from zero in Meschia 2004 to 25% in Schierlitz 2014.

We rated 16 studies as having low risk of attrition bias (Altman 2011; Borstad 2010; Brubaker 2006; Colombo 2000; Costantini 2007; Costantini 2008; Hiltunen 2007; Iglesia 2010; Meschia 2004; Rudnicki 2014; Sivaslioglu 2008; Trabuco 2014; Turgal 2013; van der Ploeg 2015 (CUPIDO I); van der Ploeg 2016 (CUPIDO II); Wei 2011), and three as having unclear risk (Fuentes 2011; Schierlitz 2014; Withagen 2011).

Selective reporting

Ancillary reports were available for two trials (Altman 2011; Brubaker 2006), and longer-term follow-up for seven trials (Brubaker 2006; Costantini 2007; Hiltunen 2007; Iglesia 2010; Rudnicki 2014; Schierlitz 2014; Trabuco 2014). Researchers reported most of the prespecified outcome measures with an emphasis on subjective patient-related outcomes. Many studies were first published as conference abstracts (e.g. International Urogynecological Association, International Continence Society); later, full manuscripts became available.

We rated 10 studies as having low risk of selective reporting (Hiltunen 2007; Iglesia 2010; Meschia 2004; Rudnicki 2014; Schierlitz 2014; Trabuco 2014; van der Ploeg 2015 (CUPIDO I); van der Ploeg 2016 (CUPIDO II); Wei 2011; Withagen 2011), eight as having unclear risk (Altman 2011; Borstad 2010; Brubaker 2006; Colombo 2000; Costantini 2007; Costantini 2008; Sivaslioglu 2008; Turgal 2013), and one as having high risk (Fuentes 2011).

Other potential sources of bias

All trials reported baseline descriptive characteristics. Withagen 2011 noted important differences between groups.

We rated four studies as having low risk of other bias (Brubaker 2006; Hiltunen 2007; Sivaslioglu 2008; Wei 2011), 13 unclear risk (Altman 2011; Borstad 2010; Colombo 2000; Costantini 2007; Costantini 2008; Iglesia 2010; Meschia 2004; Rudnicki 2014; Schierlitz 2014; Trabuco 2014; Turgal 2013; van der Ploeg 2015 (CUPIDO I); van der Ploeg 2016 (CUPIDO II)), and two high risk (Fuentes 2011; Withagen 2011).

Effects of interventions

See: **Summary of findings for the main comparison** POP surgery with concomitant continence procedure compared to no concomitant continence procedure in women with POP and SUI; **Summary of findings 2** Vaginal POP surgery with concomitant continence procedure compared to no concomitant continence procedure in women with POP and occult SUI; **Summary of findings 3** Vaginal or abdominal POP surgery with concomitant continence procedure compared to no concomitant continence procedure in continent women with POP; **Summary of findings 4** Vaginal POP surgery with armed mesh compared to anterior native tissue repair for continent women with POP

1 COMPARISONS OF SURGERY TO TREAT WOMEN WITH PELVIC ORGAN PROLAPSE AND SYMPTOMATIC STRESS URINARY INCONTINENCE

1.1 Vaginal POP surgery with vs without concomitant continence surgery

1.1.1 Additional mid-urethral sling vs vaginal repair alone

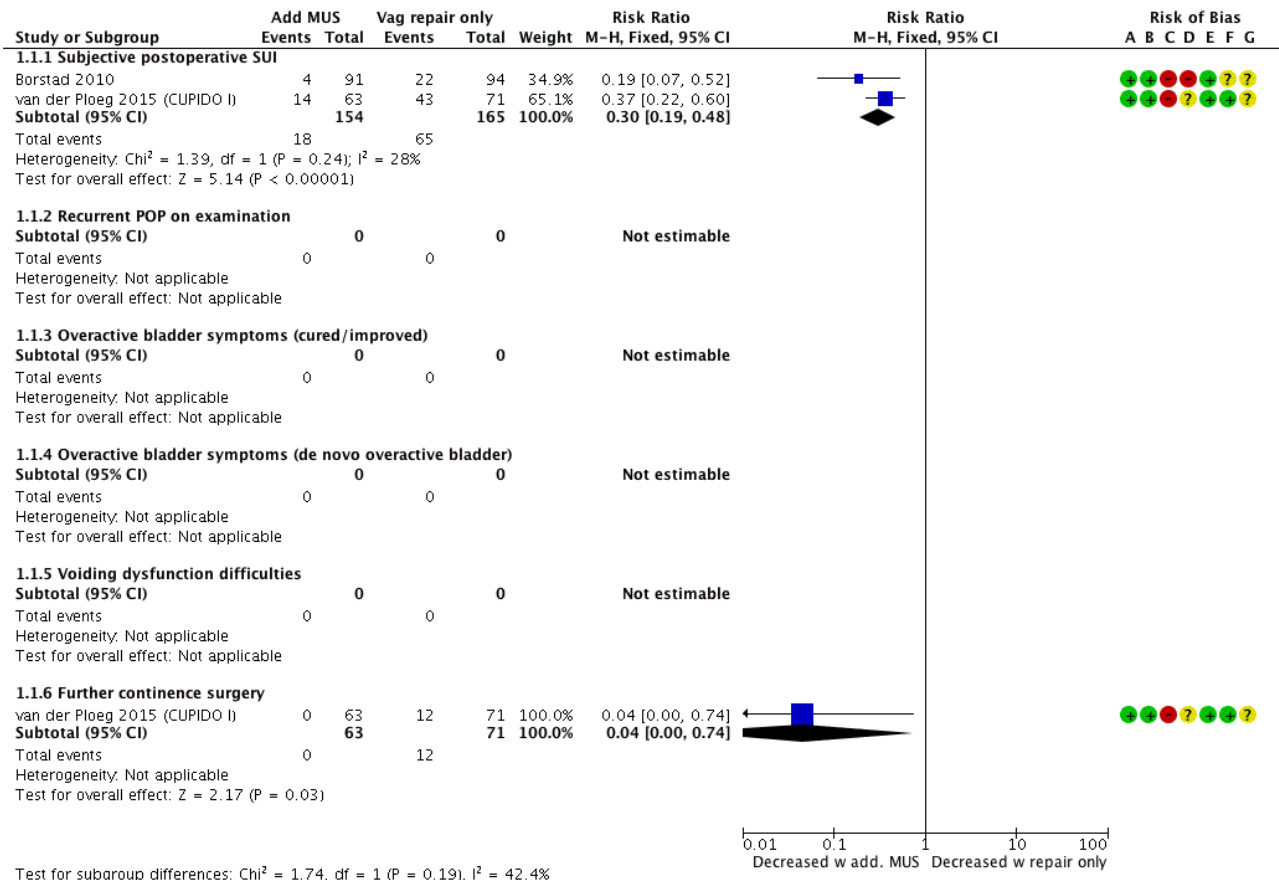
Primary outcome

1.1.1.1 Women's observations: subjective postoperative stress urinary incontinence

Fewer women reported postoperative stress urinary incontinence following concomitant mid-urethral sling compared with vaginal

repair alone; therefore a concomitant MUS probably improves postoperative rates of subjective SUI, as the evaluated clinical effect appears large (risk ratio (RR) 0.30, 95% confidence interval (CI) 0.19 to 0.48; 319 participants, two studies; $I^2 = 28%$; moderate-quality evidence; Analysis 1.1; Figure 5 Borstad 2010; van der Ploeg 2015 (CUPIDO I)). This suggests that if the risk of SUI with POP surgery alone is 39%, the risk with an MUS is between 8% and 19%.

Figure 5. Forest plot of comparison: 1 Comparisons of surgery in women with POP and SUI, outcome: 1.1 Vaginal POP surgery with vs without concomitant continence surgery: additional MUS vs vaginal repair alone.



Risk of bias legend
 (A) Random sequence generation (selection bias)
 (B) Allocation concealment (selection bias)
 (C) Blinding of participants and personnel (performance bias)
 (D) Blinding of outcome assessment (detection bias)
 (E) Incomplete outcome data (attrition bias)
 (F) Selective reporting (reporting bias)
 (G) Other bias

As Borstad 2010 was assessed as high risk in blinding patients (which was not possible given the trial design) while also blinding assessors, we performed the analysis without this study (RR 0.37, 95% CI 0.22 to 0.60; 134 participants, one study; van der Ploeg 2015 (CUPIDO I)), which did not markedly change the result. Also, employing a random-effects model resulted in minimal changes.

Secondary outcomes

1.1.1.2 Clinician's observations: POP on examination or objective stress urinary incontinence

No data were available.

1.1.1.3 Associated pelvic floor symptoms

No data were available.

1.1.1.4 Surgical outcome measures

Further continence surgery

Further continence surgery was less likely in the group that had additional MUS; therefore a concomitant MUS may decrease the need for further continence surgery (RR 0.04, 95% CI 0.00 to 0.74; 134 participants, one study; [Analysis 1.1](#); [van der Ploeg 2015 \(CUPIDO I\)](#)).

1.1.1.5 Complications

No data were available.

1.1.1.6 Economic measures

No data were available.

1.2 Vaginal POP surgery with concomitant vs delayed continence surgery

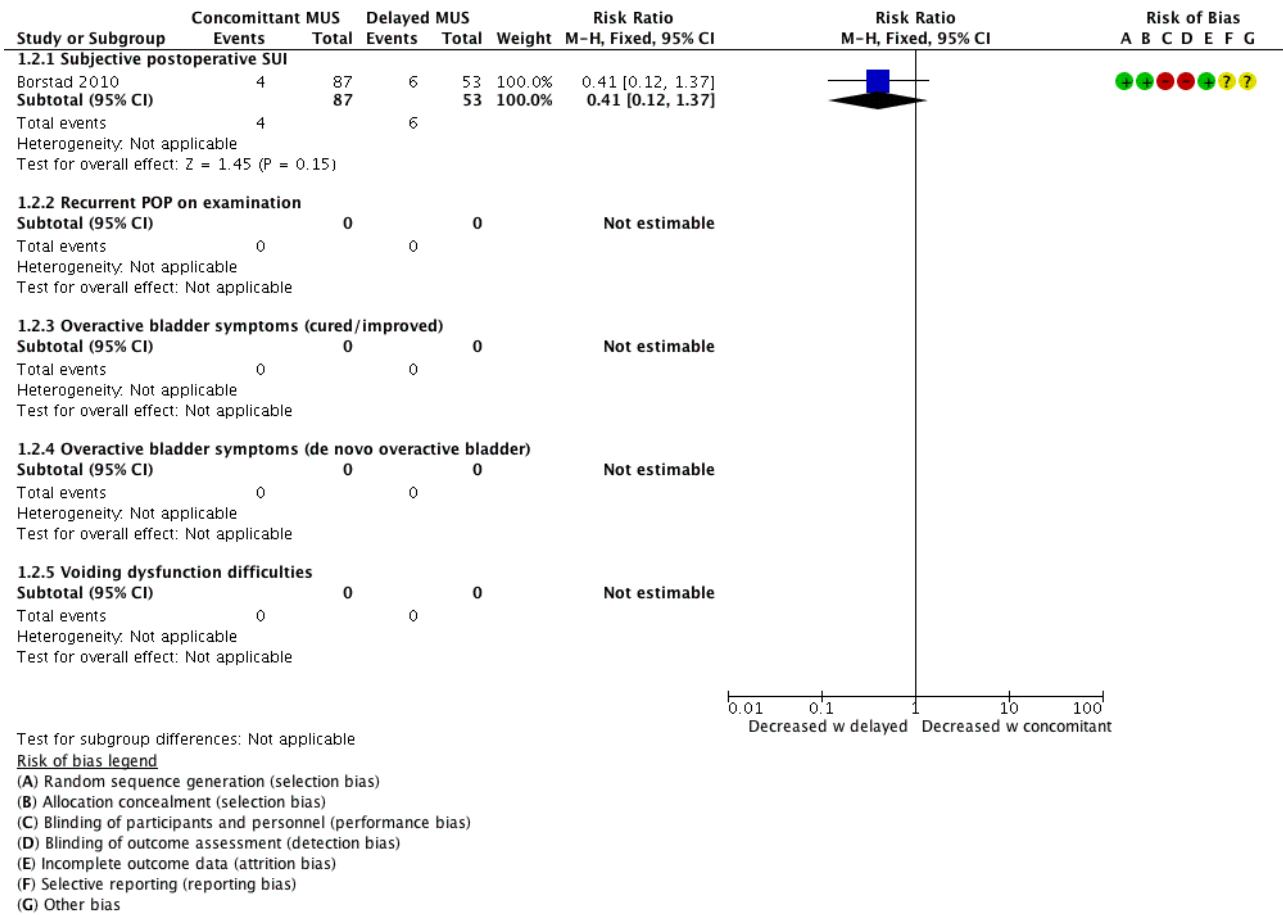
1.2.1 Vaginal POP surgery with concomitant vs delayed MUS

Primary outcome

1.2.1.1 Women's observations: subjective postoperative stress urinary incontinence

There appeared to be little or no difference between groups in reporting postoperative SUI (RR 0.41, 95% CI 0.12 to 1.37; 140 women, one study; [Analysis 1.2](#); [Figure 6](#); [Borstad 2010](#)). This suggests that if the risk of postoperative SUI with delayed MUS is 11%, then the risk with concomitant MUS would be between 1% and 16%, which is considered a clinically negligible effect.

Figure 6. Forest plot of comparison: 1 Comparisons of surgery in women with POP and SUI, outcome: 1.2 Vaginal POP surgery with concomitant vs delayed continence surgery: additional concomitant MUS vs delayed MUS.



Secondary outcomes

1.2.1.2 Clinician's observations: POP on examination or objective stress urinary incontinence

No data were available.

1.2.1.3 Associated pelvic floor symptoms

No data were available.

1.2.1.4 Surgical outcome measures

No data were available.

1.2.1.5 Complications

No data were available.

1.2.1.6 Economic measures

No data were available.

1.3 Abdominal POP surgery with vs without concomitant continence surgery

1.3.1 Abdominal sacrocolpopexy with additional Burch colposuspension vs sacrocolpopexy alone

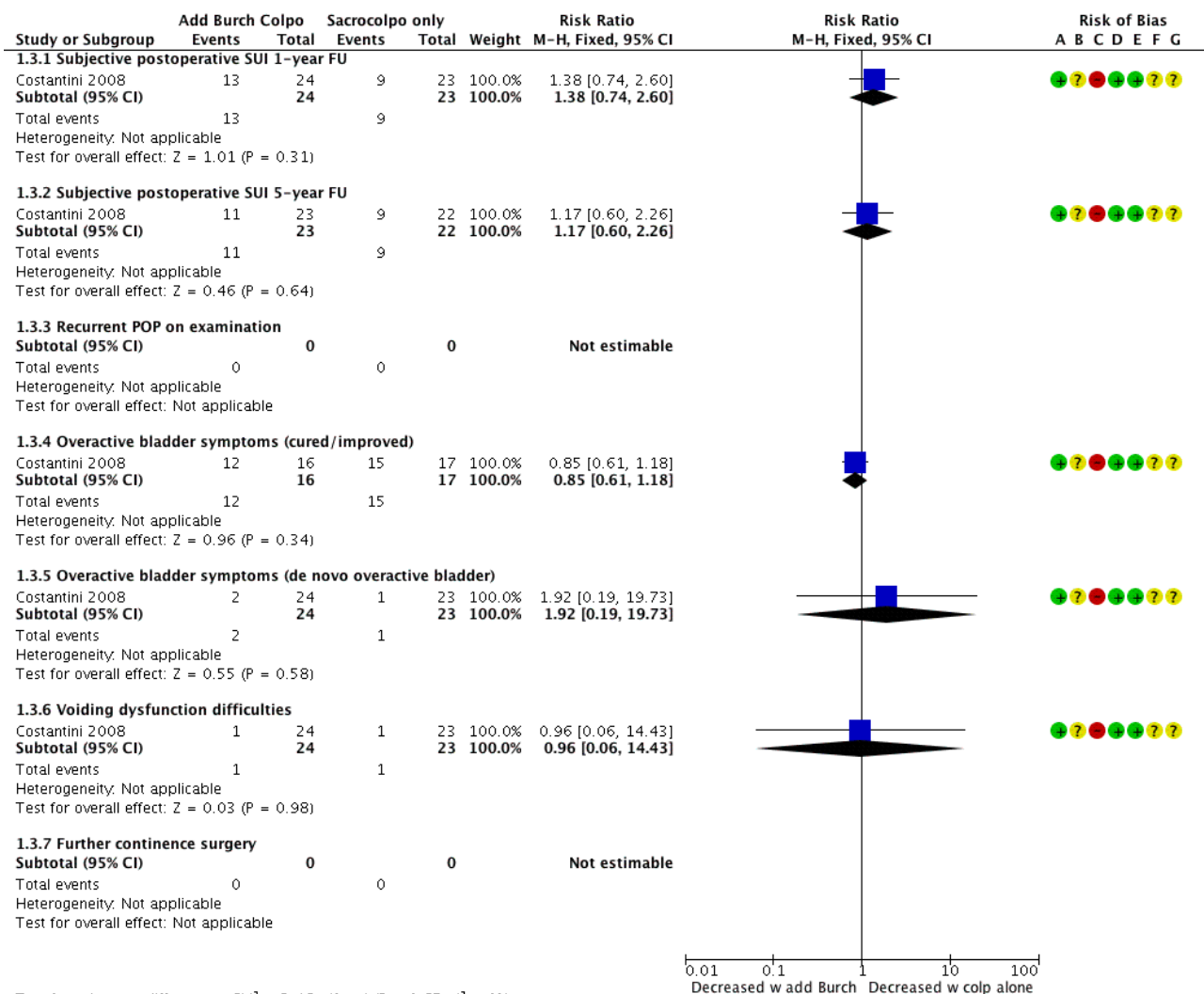
Primary outcome

1.3.1.1 Women's observations: subjective postoperative stress urinary incontinence

An additional Burch colposuspension may have little or no effect on postoperative SUI at one-year follow-up (RR 1.38, 95% CI 0.74

to 2.60; 47 women; Costantini 2008), or at five-year follow-up (RR 1.17, 95% CI 0.60 to 2.26; 45 women, one study; Analysis 1.3; Figure 7; Costantini 2008). This suggests that if the risk of postoperative SUI without additional Burch colposuspension is 39%, the risk with Burch colposuspension would be between 29% and 100%.

Figure 7. Forest plot of comparison: 1 Comparisons of surgery in women with POP and SUI, outcome: 1.3 Abdominal POP surgery with vs without concomitant continence surgery: additional Burch colpo vs sacrocolpopexy alone.



Secondary outcomes**1.3.1.2 Clinician's observations: POP on examination or objective stress urinary incontinence**

No data were available.

1.3.1.3 Associated pelvic floor symptoms**Overactive bladder symptoms**

An additional Burch colposuspension may have little or no effect on the number of women with cured or improved symptoms (RR 0.85, 95% CI 0.61 to 1.18; 33 participants, one study) nor on the number of women with de novo overactive bladder (RR 1.92, 95% CI 0.19 to 19.73; 47 participants, one study; [Analysis 1.3](#)).

1.3.1.4 Surgical outcome measures

No data were available.

1.3.1.5 Complications

No data were available.

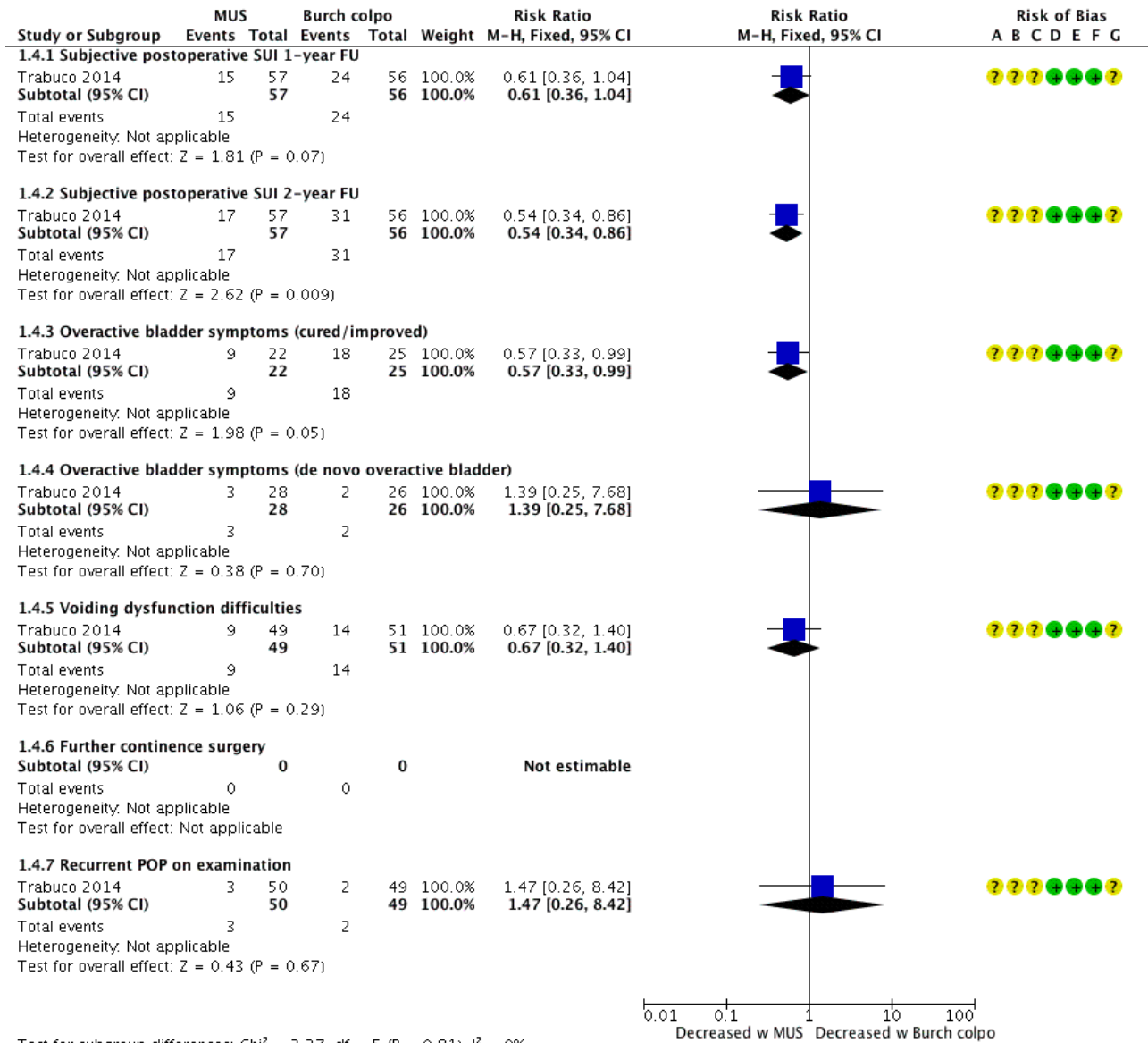
1.3.1.6 Economic measures

No data were available.

1.4 Abdominal POP surgery with different concomitant continence procedures**1.4.1 Abdominal sacrocolpopexy with MUS vs Burch colposuspension****Primary outcome****1.4.1.1 Women's observations: subjective postoperative stress urinary incontinence**

There was probably little or no difference in postoperative subjective SUI between groups at one-year follow-up (RR 0.61, 95% CI 0.36 to 1.04; 113 women, 1 study; [Analysis 1.4](#); [Figure 8](#); [Trabuco 2014](#)).

Figure 8. Forest plot of comparison: 1 Comparisons of surgery in women with POP and SUI, outcome: 1.4 Abdominal POP surgery with different concomitant continence procedures: additional MUS vs Burch colpo at sacral colpopexy.



Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

However, at two years postoperatively, an additional MUS probably reduced postoperative SUI compared with a concomitant Burch colposuspension (RR 0.57, 95% CI 0.33 to 0.99; 113 women, one study; [Analysis 1.4](#)).

Secondary outcomes

1.4.1.2 Clinician's observations: POP on examination

Additional MUS or Burch colposuspension may have little or no effect on postoperative POP on examination (RR 1.47, 95% CI 0.26 to 8.42; 99 women; [Analysis 1.4](#); [Trabuco 2014](#)).

1.4.1.3 Associated pelvic floor symptoms

Overactive bladder symptoms

Fewer women in the MUS group reported cured or improved symptoms; therefore the MUS in addition to a sacrocolpopexy may slightly reduce postoperative OAB symptoms (RR 0.57, 95% CI 0.33 to 0.99; 47 participants, one study; [Analysis 1.4](#)).

There was probably little or no difference in the number of women with de novo overactive bladder (RR 1.39, 95% CI 0.25 to 7.68; 54 participants, one study; [Analysis 1.4](#)).

Voiding dysfunction

There was probably little or no effect of MUS or Burch colposuspension on postoperative voiding dysfunction (RR 0.67, 95% CI 0.32 to 1.40; 100 participants, one study; [Analysis 1.4](#)).

1.4.1.4 Surgical outcome measures

No data were available.

1.4.1.5 Complications

No data were available.

1.4.1.6 Economic measures

No data were available.

1.5 One type of POP/continence surgery vs another type of POP surgery

1.5.1 Abdominal continence surgery (Burch colposuspension) vs vaginal POP surgery (anterior repair)

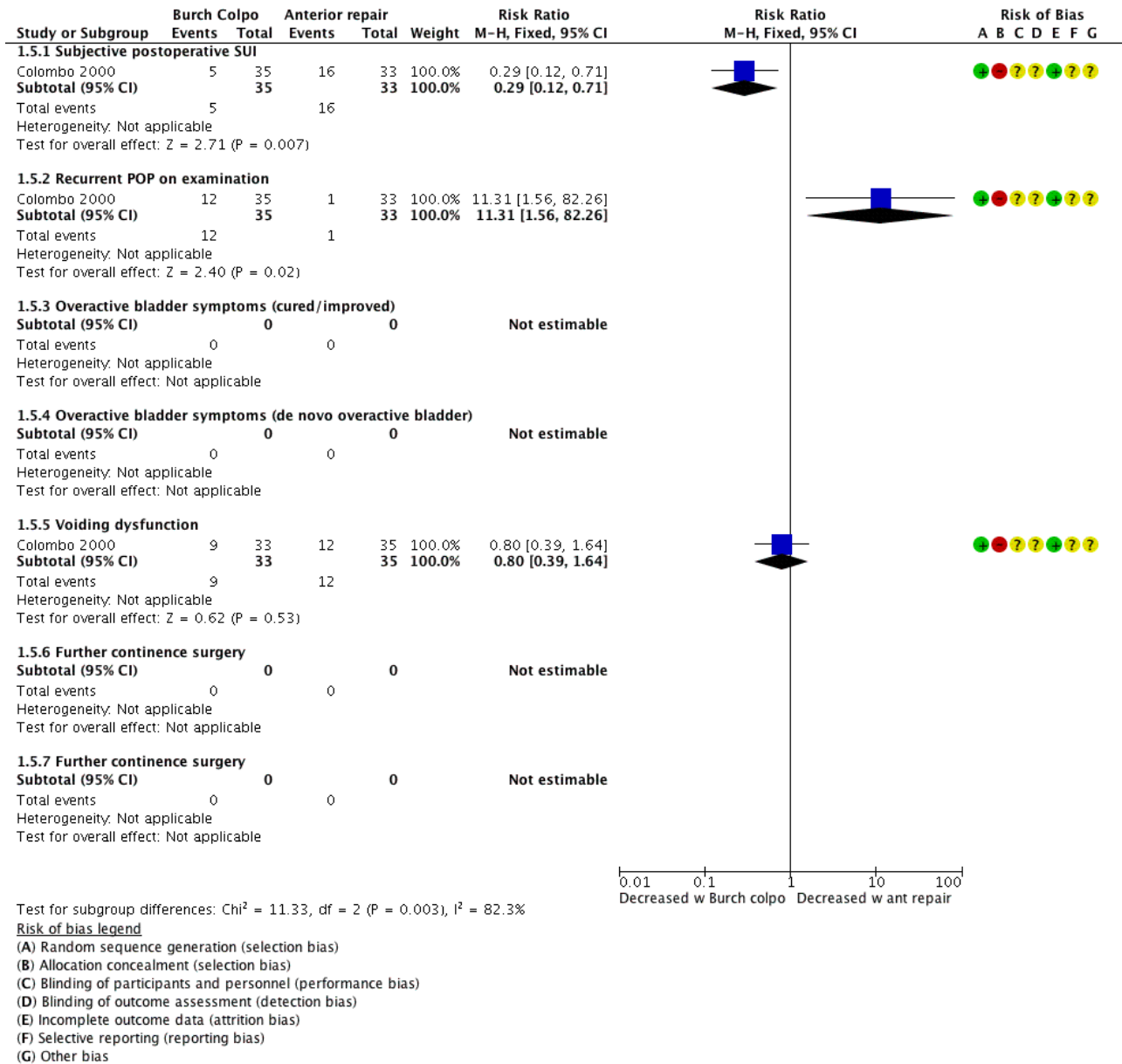
One small trial compared Burch colposuspension versus anterior colporrhaphy to treat women with SUI and cystocele ([Colombo 2000](#)). Although a Burch colposuspension is primarily considered as continence surgery, we include it here as it also addresses anterior vaginal wall prolapse, especially if a cystocele is caused by paravaginal support defects.

Primary outcome

1.5.1.1 Women's observations: subjective postoperative stress urinary incontinence

Fewer women reported postoperative stress urinary incontinence following Burch colposuspension compared with anterior colporrhaphy; therefore a Burch colposuspension may improve postoperative SUI rates (RR 0.29, 95% CI 0.12 to 0.71; 68 women, one study; [Analysis 1.5](#), [Figure 9](#); [Colombo 2000](#)).

Figure 9. Forest plot of comparison: 1 Comparisons of surgery in women with POP and SUI, outcome: 1.5 Abdominal continence surgery vs vaginal POP surgery: Burch colpo vs anterior repair.



Secondary outcomes

1.5.1.2 Clinician's observations: POP on examination

Women who underwent Burch colpo suspension were more likely to have recurrent POP on examination than women who had anterior colpoorrhaphy; therefore an anterior native tissue repair may improve postoperative POP (RR 11.31, 95% CI 1.56 to 82.26; 68 women, one study; [Analysis 1.5](#); [Colombo 2000](#)).

1.5.1.3 Associated pelvic floor symptoms

Voiding dysfunction

Burch colpo suspension or anterior colpoorrhaphy may have little or no effect on postoperative voiding function (RR 0.80, 95% CI 0.39 to 1.64; 68 participants, one study; [Analysis 1.5](#); [Colombo 2000](#)).

1.5.1.4 Surgical outcome measures

No data were available.

1.5.1.5 Complications

No data were available.

1.5.1.6 Economic measures

No data were available.

2. COMPARISONS OF SURGERY TO TREAT WOMEN WITH POP AND OCCULT SUI

All studies in this population compared POP surgery with a concomitant continence procedure versus POP surgery alone.

2.1 Vaginal POP surgery with vs without concomitant continence surgery

2.1.1 Vaginal POP surgery with an additional MUS vs vaginal repair alone

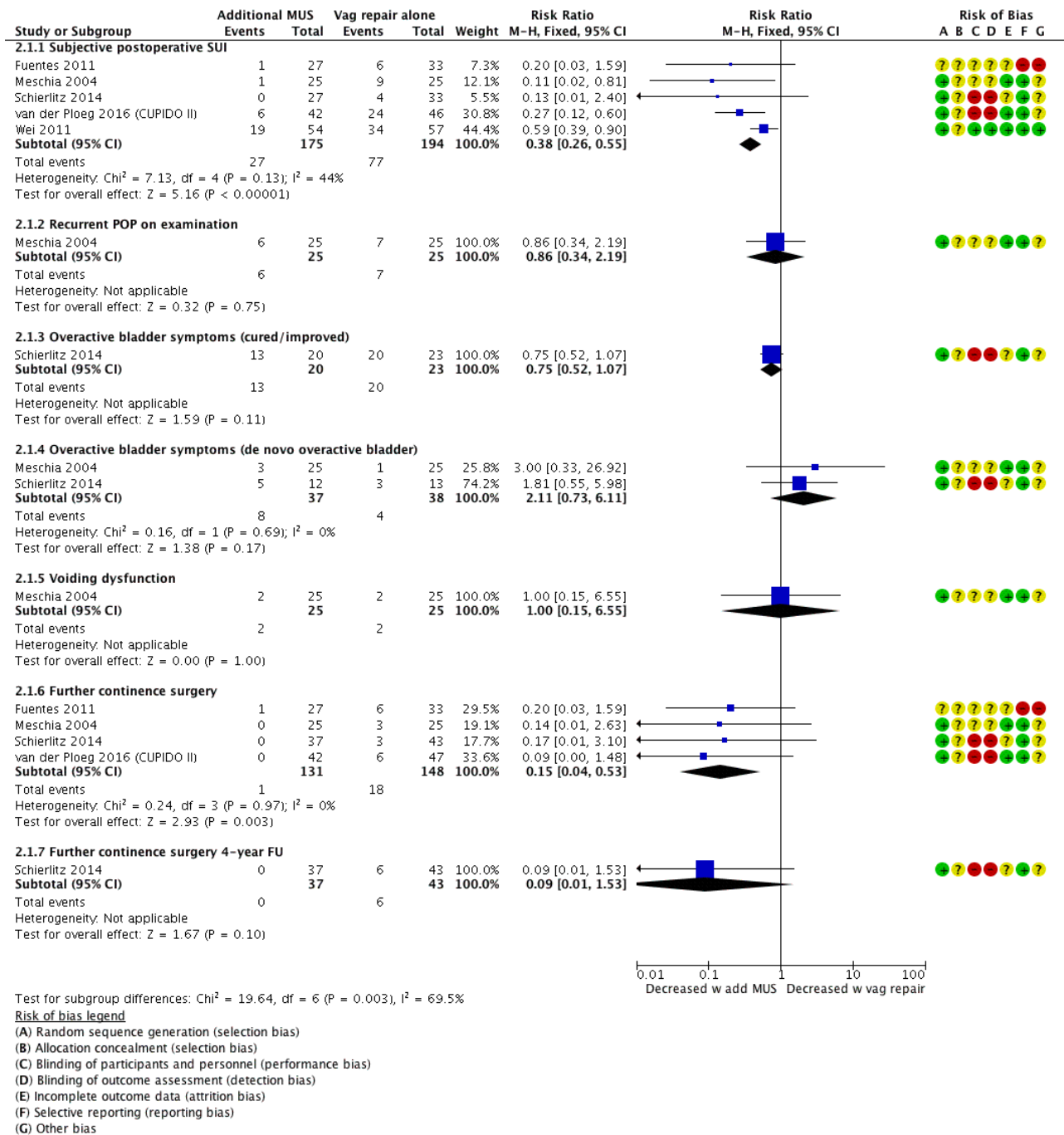
Primary outcome

2.1.1.1 Women's observations: subjective postoperative stress urinary incontinence

Rates of subjective postoperative SUI were lower in the group receiving a concurrent sub-urethral sling; therefore a concomitant

MUS probably improves postoperative subjective SUI rates (RR 0.38, 95% CI 0.26 to 0.55; 369 participants, five studies; $I^2 = 44%$, moderate-quality evidence; [Analysis 2.1](#); [Figure 10](#)). This suggests that if the risk with surgery alone is 34%, the risk with a concomitant MUS is between 10% and 22%.

Figure 10. Forest plot of comparison: 2 Comparisons of surgery in women with POP and occult SUI, outcome: 2.1 Vaginal POP surgery with or without concomitant continence surgery: additional MUS vs vaginal repair alone.



As all studies were assessed as having unclear risk of allocation concealment, we could not perform the prespecified sensitivity analysis as all studies would have to be excluded. The random-effects model showed a marginal difference from the fixed-effect model (RR 0.33, 95% CI 0.17 to 0.66). We conclude that despite only moderate-quality evidence, an additional concomitant MUS leads to a large clinical effect and benefit.

Secondary outcomes

2.1.1.2 Clinician's observations: POP on examination

Recurrent POP on examination was not different between groups in one study, implying that there may be little or no difference in postoperative POP (RR 0.86, 95% CI 0.34 to 2.19; 50 participants, one study; low-quality evidence; Analysis 2.1).

2.1.1.3 Associated pelvic floor symptoms

Overactive bladder symptoms

There is probably little or no difference between groups in rates of cured or improved overactive bladder (RR 0.75, 95% CI 0.52 to 1.07; 43 participants, one study; low-quality evidence; [Analysis 2.1](#)) or in the number of women with de novo overactive bladder (RR 2.11, 95% CI 0.73 to 6.11; 75 participants, two studies; $I^2 = 0\%$, moderate-quality evidence; [Analysis 2.1](#)).

Voiding dysfunction

Additional MUS may have little or no effect on postoperative voiding function (RR 1.00, 95% CI 0.15 to 6.55; 50 participants, one study; low-quality evidence; [Analysis 2.1](#)).

2.1.1.4 Surgical outcome measures

Rates of further continence surgery were lower in the group receiving additional MUS; therefore the additional MUS probably reduces the need for further continence surgery (RR 0.15, 95% CI 0.04 to 0.53; 279 participants, four studies; $I^2 = 0\%$; moderate-quality evidence; [Analysis 2.1](#)). At four-year follow-up in one single study, the additional MUS may have had little or no effect on further continence surgery, although the clinical effect was of moderate

size, at 15% difference (RR 0.09, 95% CI 0.01 to 1.53; 80 participants, one study; [Analysis 2.1](#)).

2.1.1.5 Complications

No data were available.

2.1.1.6 Economic measures

No data were available.

3. COMPARISONS OF SURGERY IN CONTINENT WOMEN WITH POP

3.1 Vaginal POP surgery with vs without concomitant continence surgery

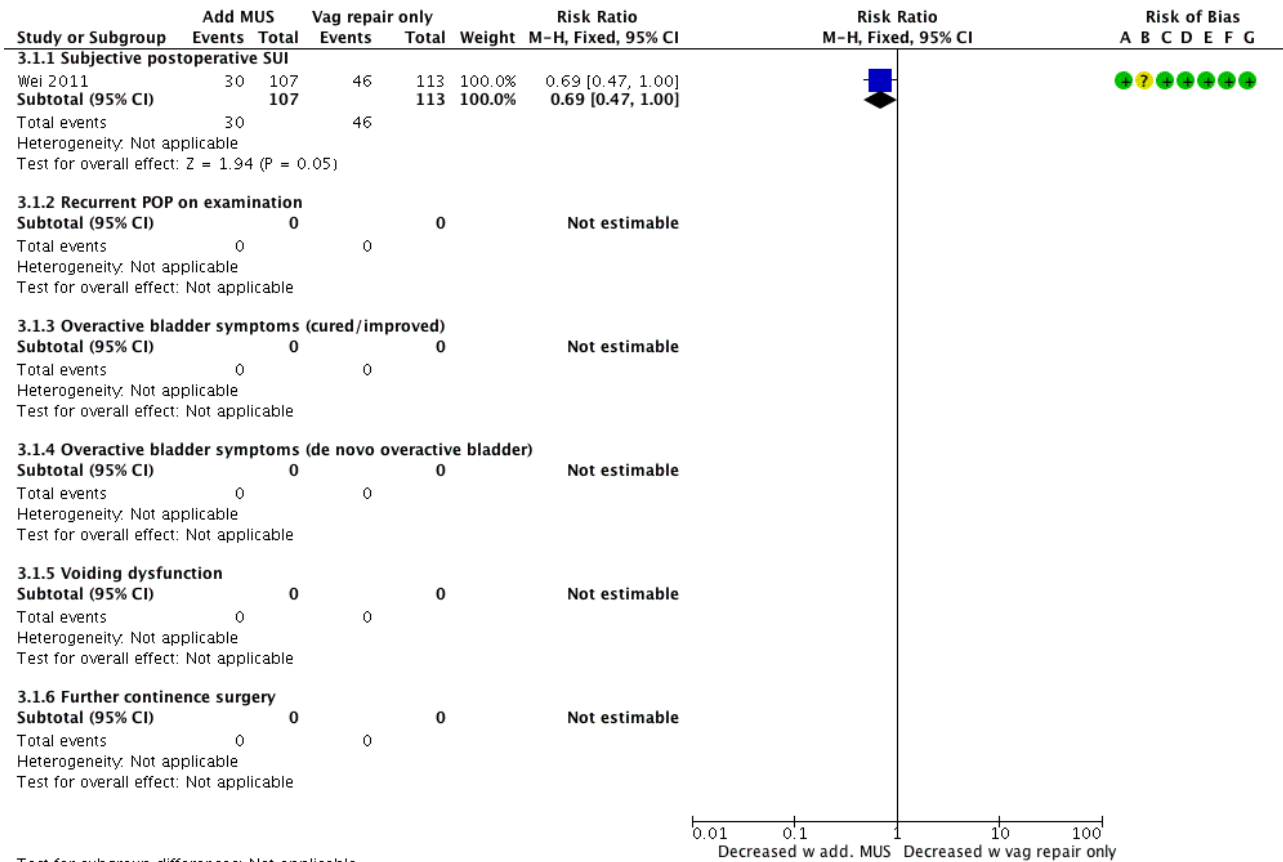
3.1.1 Additional MUS vs vaginal repair only

Primary outcome

3.1.1.1 Women's observations: subjective postoperative stress urinary incontinence

Prophylactic MUS may have little or no effect on reducing postoperative de novo SUI based on low clinical treatment effect of 11% (RR 0.69, 95% CI 0.47 to 1.00; 220 participants, one study; moderate-quality evidence; [Analysis 3.1](#); [Figure 11](#)). This suggests that if the risk with surgery alone is 40%, the risk with a concomitant MUS is between 19% and 40%.

Figure 11. Forest plot of comparison: 3 Comparisons of surgery in continent women with POP, outcome: 3.1 Vaginal POP surgery with or without concomitant continence surgery: additional MUS vs vaginal repair alone.



Secondary outcomes

No data were available on any of our secondary outcomes.

3.2 Abdominal POP surgery with vs without a concomitant continence procedure

3.2.1 Abdominal sacrocolpopexy with additional Burch colposuspension vs sacrocolpopexy alone

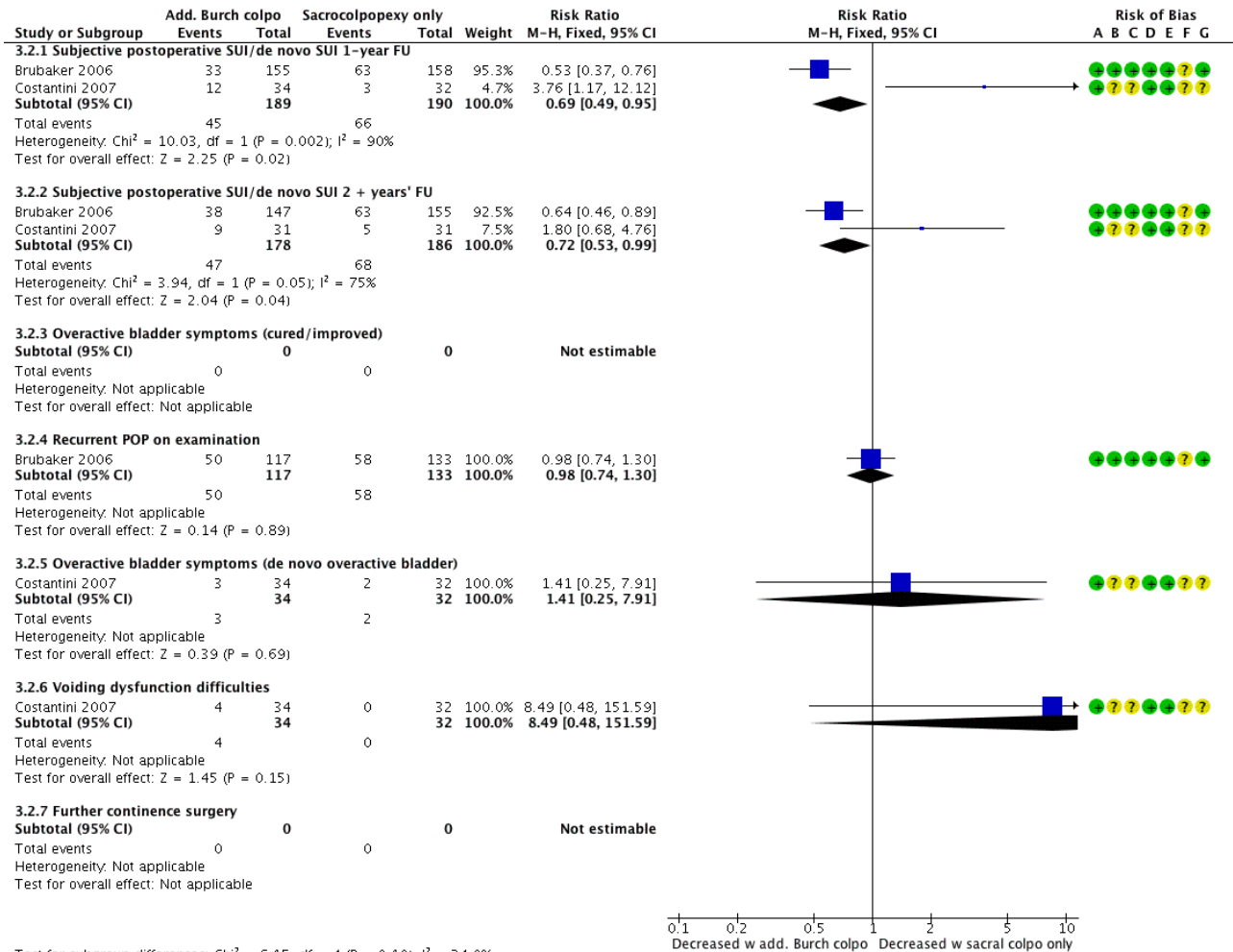
Primary outcome

3.2.1.1 Women's observations: subjective postoperative stress urinary incontinence

Additional Burch colposuspension at the time of sacrocolpopexy probably has little or no effect on subjective postoperative SUI at

one-year follow-up (RR 1.31, 95% CI 0.19 to 9.01; 379 participants, two studies; I² = 90%; low-quality evidence; Analysis 3.2; Figure 12) and at least two-year follow-up (RR 0.96, 95% CI 0.35 to 2.62; 364 participants, two studies; I² = 75%; moderate-quality evidence; Analysis 3.2). Because of the high I² value, we used a random-effects model for analysis. Study results were divergent, and one study was at moderate risk of bias. As prespecified, the sensitivity analysis without Costantini 2007 showed that the additional Burch colposuspension reduces postoperative rates of de novo SUI (RR 0.53, 95% CI 0.37 to 0.76; 313 participants, one study; moderate-quality evidence).

Figure 12. Forest plot of comparison: 3 Comparisons of surgery in continent women with POP, outcome: 3.2 Abdominal POP surgery with or without concomitant continence surgery: additional Burch colpo vs sacral colpopexy alone.



Secondary outcomes

3.2.1.2 Clinician's observations: POP on examination

There was little or no difference in recurrent POP on examination in one trial (RR 0.98, 95% CI 0.74 to 1.30; 250 participants, one study; moderate-quality evidence; [Analysis 3.2](#)).

3.2.1.3 Associated pelvic floor symptoms

Overactive bladder symptoms

There was little or no effect on postoperative rates of de novo overactive bladder (RR 1.41, 95% CI 0.25 to 7.91; 66 participants, one study; moderate-quality evidence; [Analysis 3.2](#)).

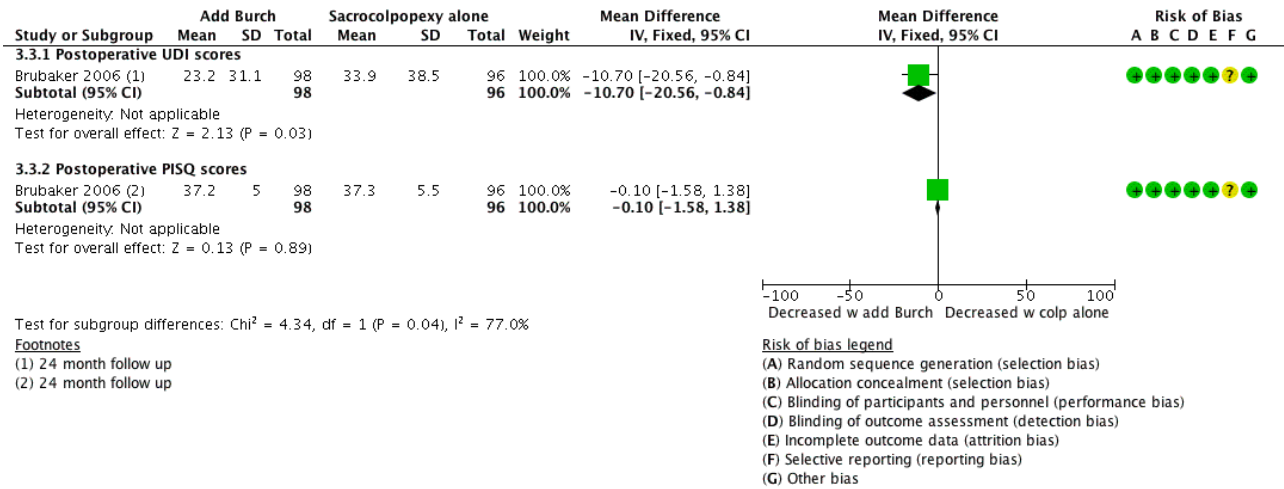
Voiding dysfunction

There was little or no effect on postoperative voiding dysfunction (RR 8.49, 95% CI 0.48 to 151.59; 66 participants, one study; low-quality evidence; [Analysis 3.2](#)).

Pelvic-floor related quality of life measures

There was little or no difference between groups in symptoms measured using the UDI (mean difference (MD) -10.70, 95% CI -20.56 to -0.84; 194 participants, one study; I² = 0%; moderate-quality evidence; [Analysis 3.3](#)) or the PISQ questionnaire (MD -0.10, 95% CI -1.58 to 1.38; 194 participants, one study; moderate-quality evidence; [Analysis 3.3](#); [Figure 13](#)).

Figure 13. Forest plot of comparison: 3 Comparisons of surgery in continent women with POP, outcome: 3.3 Additional Burch colpo vs sacrocolpopexy alone: QoL data.



3.2.1.4 Surgical outcome measures

No data were available.

3.2.1.5 Complications

No data were available.

3.2.1.6 Economic measures

No data were available.

3.3 One type of POP surgery vs another type of POP surgery

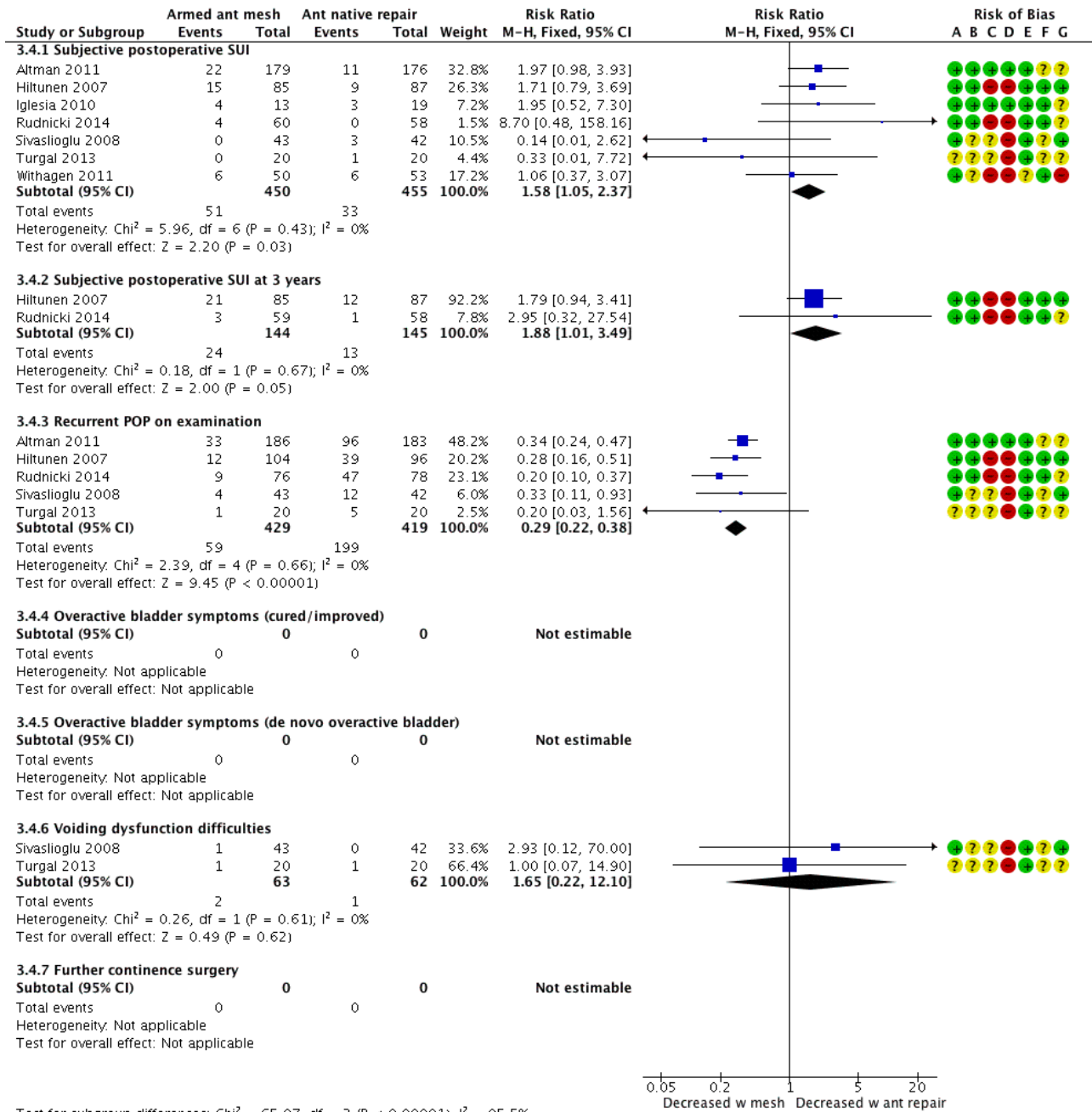
3.3.1 Armed anterior vaginal mesh repair vs anterior native tissue repair

Primary outcome

3.3.1.1 Women's observations: subjective postoperative stress urinary incontinence

Evidence suggests that SUI develops more frequently after anterior vaginal mesh than after anterior repair, implying that anterior mesh repair probably increases postoperative de novo SUI (RR 1.58, 95% CI 1.05 to 2.37; 905 participants, seven studies; $I^2 = 0\%$; low-quality evidence; Analysis 3.4; Figure 14). At two- to three-year follow-up of two studies, this result was maintained (RR 1.88, 95% CI 1.01 to 3.49; 289 participants, two studies; low-quality evidence; Analysis 3.4).

Figure 14. Forest plot of comparison: 3 Comparisons of surgery in continent women with POP, outcome: 3.4 One type of POP surgery vs another: armed anterior mesh vs anterior native repair.



Test for subgroup differences: Chi² = 65.97, df = 3 (P < 0.00001), I² = 95.5%

Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

We conducted a prespecified sensitivity analysis to test this result by removing studies that were not at low risk with respect to sequence generation and allocation concealment, and were at high risk in any domain. In this analysis, two studies remained (RR 1.96, 95% CI 1.06 to 3.64; 387 participants, two studies; I² = 0%), but the direction of effect remained the same.

We also tested the effect estimate using a random-effects model and found that changes were minimal. From this, we conclude that an anterior native tissue repair probably reduces postoperative SUI rates; however, the clinical size of the effect was small at only 4% at one-year follow-up and 8% at three-year follow-up.

Secondary outcomes

3.3.1.2 Clinician's observations: recurrent POP on examination

Armed mesh implants probably reduce recurrent POP on examination (RR 0.29, 95% CI 0.22 to 0.38; 848 participants, five studies; $I^2 = 0\%$; low-quality evidence; [Analysis 3.4](#)). We conducted the sensitivity analysis as described in 3.3.1.1, with only one remaining study (RR 0.34, 95% CI 0.24 to 0.47; 369 participants, one study), and the direction of effect remained the same.

3.3.1.3 Associated pelvic floor symptoms

Voiding dysfunction difficulties

There may be little or no difference between groups regarding postoperative voiding dysfunction (RR 1.65, 95% CI 0.22 to 12.10; 125 participants, two studies; $I^2 = 0\%$; low-quality evidence; [Analysis 3.4](#)).

3.3.1.4 Surgical outcome measures

No data were available.

3.3.1.5 Complications

No data were available.

3.3.1.6 Economic measures

No data were available.

DISCUSSION

Summary of main results

Surgery to treat women with pelvic organ prolapse (POP) and symptomatic stress urinary incontinence

Few trials assessed the outcome of pelvic organ prolapse (POP) surgery with or without concomitant continence surgery in women with POP and stress urinary incontinence (SUI), and conclusions are based on rather small studies.

An additional concomitant mid-urethral sling procedure at the time of vaginal POP repair significantly reduced postoperative SUI in two studies. Mid-urethral sling insertion might also be delayed three months after surgery (two-stage POP-continence surgery), resulting in similar SUI rates, but some women declined the subsequent delayed continence operation.

One trial did not demonstrate any benefit of an additional Burch colposuspension at the time of abdominal sacrocolpopexy or hysteropexy. When a concomitant continence procedure was planned, in one trial a mid-urethral sling achieved better results than a Burch colposuspension in women undergoing sacrocolpopexy.

A Burch colposuspension was superior to an anterior repair with regard to SUI and is now considered a continence procedure with limited effect on anterior vaginal wall prolapse, whereas an anterior colporrhaphy is predominantly an operation to treat anterior vaginal wall prolapse.

Surgery to treat women with POP and occult stress urinary incontinence

Women with POP and occult SUI might benefit from a concurrent mid-urethral sling during vaginal POP surgery.

Surgery to treat continent women with POP

In continent women with symptomatic POP, an anterior vaginal repair proved better than anterior armed mesh regarding de novo SUI postoperatively. However, anterior vaginal mesh placement reduced recurrent POP significantly.

An additional suburethral tape during vaginal POP surgery does not necessarily prevent postoperative SUI. Similarly, during abdominal sacrocolpopexy, an additional Burch colposuspension might not reduce de novo SUI.

Overall completeness and applicability of evidence

We included randomised controlled trials that included continent or stress urinary incontinent women with symptomatic POP and addressed continence issues among their aims. Our defined comparisons followed clinical needs discussed when counselling women: which POP operation should be performed, and should a prophylactic or therapeutic continence procedure be performed in women with POP and SUI or occult SUI or no SUI. Unfortunately, many studies did not include continent or incontinent patient populations and had to be excluded. In contrast, many included studies focused on continence issues and did not present prolapse outcomes.

Quality of the evidence

The quality of the evidence ranged from low to moderate according to GRADE assessment. The main limitations in the quality of the evidence were risk of bias, indirectness when a study had a different focus on outcome measures than our review, and imprecision associated with low event rates and small samples. Whereas blinding of participants and staff was not feasible in many trials, we considered non-blinding of outcome assessors as high risk and specifically downgraded those studies.

Generally, the validity of these studies seems to have improved, with more trials conforming to CONSORT statements and using validated patient-centred outcome measures and questionnaires. However, owing to different definitions and inclusion criteria, few meta-analyses could be performed.

Potential biases in the review process

We are not aware of any biases in the review process. All review authors have been co-authors on associated reviews within the group in the past. Regarding publication bias, we took specific care to ensure that all ancillary reports on the same patient populations, as well as publication of long-term results, were estimated as supplementary material. As the literature search included all studies on any POP surgery, we excluded numerous studies based on patient populations, interventions, or comparisons not meeting our inclusion criteria. This might be considered a potential risk for reporting bias. As the aim of this review was to determine effects of POP surgery in clearly distinguishable preoperatively continent or stress urinary incontinent women with POP, we had to exclude studies that failed to include these populations.

Agreements and disagreements with other studies or reviews

Our main results are in concordance with those of a systematic review of randomised controlled trials conducted by Matsuoka ([Matsuoka 2015](#)). However, this review analysed all continence

procedures together (Burch colposuspension and MUS), which appears difficult from a clinical point of view. Typically, during a vaginal POP repair, a concomitant mid-urethral sling would be performed (or not), rather than an abdominal Burch colposuspension.

AUTHORS' CONCLUSIONS

Implications for practice

In women with POP and SUI (symptomatic or occult), a concurrent MUS probably reduces postoperative SUI and should be discussed during counselling. It might be feasible to postpone the MUS and perform a two-stage continence procedure.

Although an abdominal continence procedure (Burch colposuspension) during abdominal POP surgery in continent women reduced de novo SUI rates in one underpowered trial, another RCT reported conflicting results. Adding an MUS during vaginal POP repair might slightly reduce the postoperative development of SUI.

An anterior native tissue repair might be better than transobturator mesh for preventing postoperative SUI; however, prolapse recurrence is more common with native tissue repair.

Implications for research

Apart from emphasising the need for improved methods and reporting of results, further studies should address the concurrent treatment of SUI in women with POP in clearly distinguishable populations of continent or stress urinary incontinent women or women with occult SUI on examination. Future research should also assess the impact of different POP surgeries on bladder function among patient populations with or without SUI.

ACKNOWLEDGEMENTS

We acknowledge the work of Elisabeth J Adams and Suzanne Hagen as co authors on the original review, and Charis Glazener as co-author on the original POP reviews and update.

The authors of the 2018 update would like to thank Sheila Wallace, Information Specialist for the Cochrane Incontinence Review Group, for designing the search strategy and running the searches for this review.

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CHARACTERISTICS OF STUDIES
Characteristics of included studies [ordered by study ID]

Altman 2011

Methods	Trial design: multi-centre, parallel-group, randomised controlled trial involving 58 surgeons at 53 centres
Participants	<p>Number of participants randomised: 410 (transvaginal mesh = 206, colporrhaphy = 204)</p> <p>Number of participants analysed: 389 (transvaginal mesh = 200, colporrhaphy = 189)</p> <p>Mean age (mean ± SD): transvaginal mesh = 64.3 ± 9.8, colporrhaphy = 65.1 ± 9.8</p> <p>Inclusion criteria: > 18 years, ≥ stage 2 symptomatic cystocele POPQ</p> <p>Exclusion criteria: previous cancer of any pelvic organ, systemic glucocorticoid treatment, insulin-treated diabetes, an inability to participate or to provide consent, need for concomitant surgery</p> <p>Setting: hospitals throughout Sweden, Norway, Finland, and Denmark</p> <p>Timing: December 2007 to December 2008</p>
Interventions	<p>Intervention: Gynecare transvaginal anterior mesh (Prolift), absorbable sutures, excessive vaginal trimming discouraged, catheter care discretion surgeon (191 underwent surgery as assigned)</p> <p>Comparison: anterior colporrhaphy slow absorption monofilament thread, sham skin markings, excessive trimming vagina discouraged (182 underwent surgery as assigned)</p> <p>Follow-up at 2 and 12 months</p>
Outcomes	<p>Primary outcome: a composite measure defined as POPQ stage 0 or 1 of the anterior vaginal wall (i.e. point Ba of the anterior vaginal wall positioned more than 1 cm above the hymen) + the answer "no" to the question on vaginal bulging (item 16 of the Urogenital Distress Inventory (UDI))</p> <p>Secondary outcomes: individual components of the primary outcome (Ba < -1 on POPQ, Q16 on UDI-ve, surgical complications, adverse events, patient-reported UDI (compared to baseline at 2 months and 1 year post surgery), sexual function as measured on the PISQ-12 questionnaire (compared to baseline at 1 year post surgery))</p>
Notes	<p>Intention-to-treat analysis: stated in the protocol that ITT will be used as well as per-protocol analysis</p> <p>Sample size calculation: yes</p> <p>Trial registration: ClinicalTrials.gov NCT00566917</p> <p>Funding: funded by grants from the Swedish Society of Medicine, the Karolinska Institutet Research Foundations; regional agreement on clinical research between the Stockholm County Council, the Karolinska Institutet, and Ethicon</p> <p>Conflicts of interest: statement in text of manuscript asserting that although Ethicon co-sponsored the trial, the manufacturer did not provide the products used and had no involvement in data collection and analysis or in the decision to submit the results for publication. Author financial disclosures are</p>

Altman 2011 (Continued)

available from the *New England Journal of Medicine* website as supplementary material; however this does not include other members of the Nordic Transvaginal Mesh Group who were reviewers of surgery

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisations
Allocation concealment (selection bias)	Low risk	Secure concealment with remote computer
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were blinded to surgical intervention through the use of sham skin markings and were not aware of their group assignment until 1-year follow-up had been completed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	When possible, postoperative examination was performed by a gynaecologist other than the operating surgeon Reviewers: surgeon 1/3, non-surgeon 2/3 Participant-completed questionnaires Statistical analysis was conducted by an independent statistician blinded to group assignment until data analysis for primary outcome has been completed
Incomplete outcome data (attrition bias) All outcomes	Low risk	Patient flow accounted for completely in both groups Women who underwent surgery as per group assignment: transvaginal mesh: 191, colporrhaphy: 182 Loss to follow-up: 21 participants (6% overall), transvaginal mesh: 14 (7%), colporrhaphy: 7 (4%) Analysed at one year: transvaginal mesh: 186, colporrhaphy: 182
Selective reporting (reporting bias)	Unclear risk	All prespecified outcomes are reported on
Other bias	Unclear risk	Groups appear balanced at baseline

Borstad 2010

Methods	Trial design: multi-centre, parallel-group randomised controlled trial (7 centres)
Participants	Number of participants randomised: 194 (TVT concomitantly with prolapse repair 95, TVT 3 months after prolapse repair 99) Number of participants analysed: 140 (TVT concomitantly with prolapse repair 87, TVT 3 months after prolapse repair 53) Mean age (mean (range)): TVT concomitantly with prolapse repair 57.2 (31 to 89), TVT 3 months after prolapse repair 59.9 (38 to 85) Inclusion criteria: non-consecutive women awaiting prolapse surgery with symptomatic and objective (provocation 300 mL) SUI or occult SUI (SUI with pessary in position)

Surgery for women with pelvic organ prolapse with or without stress urinary incontinence (Review)

Borstad 2010 (Continued)

Exclusion criteria: not specified

Setting: regional hospitals and University clinics, Norway

Timing: 2002 to 2006

Interventions	<p>Intervention: TVT performed at the same time as prolapse repair surgery</p> <p>Comparison: TVT performed 3 months after prolapse repair surgery if still clinically indicated (of 99 participants randomised to this group, 53 underwent TVT 3 months post prolapse repair)</p> <p>Follow-up at 12 months</p>
Outcomes	<p>Primary outcome/s: cure of SUI at 12-month follow-up, defined as no symptoms of SUI and no visible leakage during coughing in the lithotomy position</p> <p>Secondary outcome/s: reduction in POPQ score</p>
Notes	<p>Intention-to-treat analysis: yes; also "on-treatment" analysis</p> <p>Sample size calculation: yes - calculated to require 71 participants in each group for 80% power to detect a 20% difference in primary outcome</p> <p>Trial registration: ClinicalTrials.gov NCT00308009</p> <p>Funding: no details provided of trial funding</p> <p>Conflicts of interest: study authors state no conflicts of interest</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was performed centrally by the Department of Epidemiology and Biostatistics, Centre for Clinical Research, Oslo University Hospital; no further information was provided on the method used to generate random sequence.
Allocation concealment (selection bias)	Low risk	Sealed, opaque envelopes, opened consecutively
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and trial personnel were aware of group allocation
Blinding of outcome assessment (detection bias) All outcomes	High risk	Preoperative and postoperative assessors were not blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up at 1 year: 4 participants at 1 year (3%), TVT concomitantly 4 (4%), TVT after 3 months 0 (0%)
Selective reporting (reporting bias)	Unclear risk	Outcomes stated are reported on. Complications are reported but not pre-specified.
Other bias	Unclear risk	75% of TVT concomitant group had co-morbidities, compared to 89% of delayed TVT group, whereas 9% of this group had previous prolapse or incontinence surgery compared to 3% of the TVT concomitant group.

Brubaker 2006

Methods	Trial design: multi-centre, parallel-group randomised controlled trial (7 sites)
Participants	<p>Number of participants randomised: 322 (Burch colposuspension 157, control group 165)</p> <p>Number of participants analysed: 322 (Burch colposuspension 157, control group 165) underwent 3-month follow-up and were included in the primary analysis, 305 (Burch group 152, control group 153) underwent 1-year follow-up, 302 completed some or all of the 2-year follow-up (Burch group = 147, control group = 155) and are included in the secondary analyses</p> <p>Mean age (mean \pm SD): Burch group = 62.4 \pm 9.7, control group = 60.3 \pm 10.6</p> <p>Inclusion criteria: POPQ stage 2 to 4 prolapse (Aa must be -1 or worse) and stress continent based on responses of 'never' or 'rarely' to 6 of the 9 SUI questions of MESA. Despite these criteria, preoperatively 19.2% of participants had SUI defined by PFDI, 10% had bothersome stress urinary incontinence (PFDI Questionnaire), and 39% had a positive stress test with or without prolapse reduction before intervention. From Table 2 of the 3-month data it appears that these participants were equally distributed between groups.</p> <p>Exclusion criteria: immobile urethrovesical junction, pregnancy, anticipated move away after surgery</p> <p>Setting: hospitals and University medical centres throughout USA</p> <p>Timing: March 2002 to February 2005</p>
Interventions	<p>Intervention: abdominal sacrocolpopexy with Burch colposuspension</p> <p>Comparison: abdominal sacrocolpopexy without Burch colposuspension</p> <p>Follow-up: 3 months, 1 year, and 2 years postoperatively</p>
Outcomes	<p>Primary outcome/s: stress incontinence and urge symptoms 3 months after surgery (defined as symptoms (a "yes" response on any of 3 questions on the PFDI stress incontinence questionnaire regarding leakage with coughing, sneezing, laughing, or other physical exertion), stress incontinence during standardised stress testing (coughing at maximal bladder capacity or 300 mL (whichever is less) in supine or standing position), or any treatment for stress incontinence after the study surgery</p> <p>Secondary outcome/s: quality of life measures, serious adverse events</p>
Notes	<p>Standardised surgery for colposuspension: not standardised paravaginal repair or sacrocolpopexy (17% biological grafts, 43% Mersilene, and 39% polypropylene and minimal use of PFTE (Gore-tex) (6%)</p> <p>Although surgery was standardised for colposuspension, neither paravaginal repair nor sacrocolpopexy was standardised, with variation in suture type and graft materials used: 17% biological grafts, 43% Mersilene, 39% polypropylene, 6% Gore-tex. No data on further performed surgeries are provided in the publication.</p> <p>Study terminated after 322 women had been randomised because of significant differences in UI outcomes</p> <p>Results not reported separately according to whether concomitant hysterectomy performed</p> <p>Women remained in allocated groups for analysis (ITT), but analysis was based on endpoint data actually available.</p> <p>Further data were made available in a new report depending upon status of occult stress incontinence (Visco 2008). The prolapse reduction during preoperative stress testing was performed via 5 different methods (swab, manual, speculum, pessary, or forceps), with each woman undergoing 2 types of prolapse reduction. Data from all prolapse reductions (2 for each participant) were reported as a total at 3 months only. Visco concluded that none of the techniques to demonstrate occult urinary incontinence could predict which women would become incontinent or not with or without concomitant continence surgery, although women who did have occult incontinence were more likely to be incontinent afterwards regardless of randomised allocation. Data from all prolapse reductions (2 for each patient) were reported as a total, and in analysing the postintervention continence status of women who did and did</p>

Brubaker 2006 (Continued)

not have occult stress incontinence preoperatively, the decision was made to halve the reported total numbers for the analysis.

Stress continence at baseline was defined based on responses of 'never' or 'rarely' to 6 of the 9 SUI questions on the MESA Questionnaire (medical, epidemiological, and social aspects of aging questionnaire). Preoperatively, 19% of participants had SUI defined by the PFDI (Pelvic Floor Distress Inventory), 10% had bothersome stress urinary incontinence according to the PFDI, and 39% had a positive stress test with or without prolapse reduction before surgery.

Different and complicated definitions were used to categorise stress continence before and after the interventions, making it more difficult to be classified as stress continent after interventions than before interventions (see included studies tables). 39% classified as stress continent before surgery would have been classified as stress incontinent based on the post-intervention definition.

Use of imputation in the 2-year results by the study authors is to be applauded. The process utilised ensures that in women undergoing further continence surgery, their continence status before the second intervention or after the surgical intervention outcomes, whichever is worse, is included in the final outcome data.

Intention-to-treat analysis: yes

Sample size calculation: yes, 480 women were required to detect a 10% difference in stress incontinence between the 2 groups

Trial registration: no details of trial registration, but protocol is available (Brubaker 2003)

Funding: funded by grants from the National Institutes of Health - National Institute of Child Health and Human Development

Conflicts of interest: Dr Brubaker has received research support and a research consulting fee from Pfizer (New York, NY) and research support from Allergan Inc (Irvine, CA). Dr Richter has received research support and consultant fees from Pfizer. Dr Visco is a paid surgical proctor and consultant for product/procedure development for Intuitive Surgical (Sunnyvale, CA). The other study authors had no potential conflicts to disclose.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated block randomisations
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes opened at the time of surgery after anaesthetic was administered
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were blinded to group allocation for a minimum of 3 months, and the intention was to maintain this blinding for 2 years. At 2-year follow-up, 38% had been unblinded and were aware of their treatment.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers and examiners were blinded. Surgeons were unaware of urodynamic findings including urodynamic stress incontinence or occult stress incontinence with or without the prolapse reduced.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No substantial losses to follow-up
Selective reporting (reporting bias)	Unclear risk	Most prespecified outcomes are reported. The protocol states that direct medical cost data will be obtained, but these do not appear to have been reported as yet..

Brubaker 2006 (Continued)

Other bias	Low risk	Groups were comparable at baseline on age, race, ethnic group, marital status, education, parity, method of delivery, distribution of women with positive stress test, OAB, prior hysterectomy, continence, and prolapse surgery.
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Colombo 2000

Methods	Trial design: single-centre, parallel-group randomised controlled trial	
Participants	Number of participants randomised: 71 (Burch group 37, anterior colporrhaphy 34) Number of participants analysed: 68 (Burch group 35, anterior colporrhaphy 33) Mean age (mean \pm SD): Burch group = 54.9 \pm 8.6, anterior colporrhaphy group = 55.7 \pm 10.3 Inclusion criteria: USI, cystocoele > 2 or 3, swab test > 30% Exclusion criteria: detrusor overactivity, previous pelvic floor surgery, high risk for abdominal operation Setting: Department of Obstetrics and Gynecology, University of Milan, Italy Timing: October 1981 to November 1986	
Interventions	Intervention: Burch group: total abdominal hysterectomy and vault to uterosacral ligament, Moschcowitz, Burch with 3-4 Ethibond (n = 35) Comparison: anterior colporrhaphy: vaginal hysterectomy, pouch of Douglas obliteration and anchoring of vaginal cuff to uterosacral ligament, catgut plication (n = 33) Follow-up: 3 months and 6 months postoperatively; thereafter annually for 15 years	
Outcomes	Primary outcomes: long-term subjective (no incontinence episodes by history) and objective (negative stress test result) cure rates Secondary outcomes: incidence of prolapse recurrence, vaginal length, dyspareunia	
Notes	Intention-to-treat analysis: no Sample size calculation: not stated Trial registration: not stated Funding: not stated. Conflicts of interest: not stated	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random number table
Allocation concealment (selection bias)	High risk	Inadequate: open list
Blinding of participants and personnel (performance bias)	Unclear risk	No details provided of blinding of trial participants or personnel

Colombo 2000 (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details provided of blinding of outcome assessors
Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal loss to follow-up Postoperative: Burch group = 1, anterior colporrhaphy group = 2 10-year follow-up: Burch group = 2, anterior colporrhaphy group = 1 15-year follow-up: Burch group = 9, anterior colporrhaphy group = 8
Selective reporting (reporting bias)	Unclear risk	Prespecified outcomes are reported.
Other bias	Unclear risk	Groups appear balanced at baseline.

Costantini 2007

Methods	Trial design: single-centre randomised controlled trial	
Participants	Number of participants randomised: 66 (group A 34, group B 32) Number of participants analysed: 66 Mean age (mean \pm SD): group A = 63 \pm 9, group B = 61 \pm 8 Inclusion criteria: continent women (women with negative stress test before and after prolapse reduction, no preoperative symptoms of urinary incontinence, negative symptom questionnaire, and no leakage during urodynamics) with 'severe' uterovaginal and vault prolapse (not clearly defined) Exclusion criteria: not stated Setting: University of Perugia, Itali Timing: January 2000 to December 2004	
Interventions	Intervention: group A sacrocolpopexy + Burch colposuspension (n = 34) Comparison: group B sacrocolpopexy alone (n = 32)	
Outcomes	Primary outcome/s: changes in continence status, anatomical outcome of prolapse repair Secondary outcome/s: changes in subjective symptoms, quality of life measured by IIQ-7 and UDI-6	
Notes	Urinary incontinence was clinically classified "on the basis of the ICS definition and graded on the Ingelman Sunderberg scale". Intention-to-treat analysis: All randomised participants were analysed. Sample size calculation: yes, 66 participants calculated to provide 80% to 85% power to detect a 25% to 30% difference in proportion of postoperative incontinence between groups Trial registration: no Funding: not stated Conflicts of interest: not stated	

Costantini 2007 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated
Allocation concealment (selection bias)	Unclear risk	No details provided of method used to conceal group allocation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Trial personnel who performed the surgery were not blinded. No details of blinding of participants were provided.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors were blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	3/34 group A and 2/32 group B participants lost to follow-up
Selective reporting (reporting bias)	Unclear risk	Preoperative UDI scores were given, but no postoperative UDI scores were available.
Other bias	Unclear risk	Primary continence assessments were based on a non-defined stress test and symptoms from the UDI Questionnaire.

Costantini 2008

Methods	Trial design: single-site RCT
Participants	<p>Number of participants randomised: 47 (group A n = 24, group B n = 23)</p> <p>Number of participants analysed: 47</p> <p>Mean age (mean \pm SD): group A = 60 \pm 10, group B = 61 \pm 13</p> <p>Inclusion criteria: women age 18 to 75, POP > stage 2 (BW and POPQ), urinary incontinence defined by ICS</p> <p>Exclusion criteria: uterine fibroids, uterine/cervical malignancy, active PID, allergy to synthetic graft/suture materials, pregnancy/lactation, significant illness, inability to provide informed consent or comply with study protocol</p> <p>Setting: Urology Department, University of Perugia, Italy</p> <p>Timing: January 2002 to June 2006</p>
Interventions	<p>Intervention: group A - sacrocolpopexy + Burch 14, sacrohysteropexy + Burch 10 (n = 24)</p> <p>Comparison: group B - sacrocolpopexy 17, sacrohysteropexy 6, no colposuspension (n = 23)</p> <p>Preoperatively incontinence defined by urodynamics: 13 USI, 30 mixed, 4 occult (incontinence with coughing or Valsalva manoeuvre with the prolapse reduced). Distribution of patients with prolapse and incontinence preoperatively between groups is unclear.</p>

Costantini 2008 (Continued)

Outcomes **Primary outcome/s:** change in incontinence rate measured by combination of bladder diary, number of pads and stress test without clear definition, anatomical outcome of prolapse as measured by B7W and POPQ

Secondary outcome/s: changes in subjective symptoms and quality of life measured by questionnaires, postoperative satisfaction as measured by VAS

Notes CONSORT statement: yes

Intention-to-treat analysis: All participants randomised were analysed.

Sample size calculation: yes, 47 participants calculated to provided 80% power to detect up to 30% difference in postoperative conditions between the 2 groups

Trial registration: yes (post hoc)

Clinicaltrials.gov NCT00576004

Funding: not stated.

Conflicts of interest: not stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated list
Allocation concealment (selection bias)	Unclear risk	No details were provided of the method used to conceal group allocation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Trial personnel who performed the operations were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors were blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up
Selective reporting (reporting bias)	Unclear risk	All prespecified outcomes appear to have been reported.
Other bias	Unclear risk	Distribution of POP between groups not clear: 24 uterovaginal, 13 vault, 8 cystocele, 2 cystocele and rectocele
		Methodological problems with this paper include lack of clear and equal distribution of prolapse grading and incontinence between groups preoperatively, inconsistency of preoperative and postoperative incontinence classifications (urodynamics preoperatively and symptoms postoperatively), and lack of definition of success of prolapse grading and data related to perioperative parameters and complications.

Fuentes 2011

Methods	Trial design: parallel-group randomised controlled trial
Participants	<p>Number of participants randomised: 60 (group A POP surgery + TVTo = 27, POP surgery alone = 33)</p> <p>Number of participants analysed: 60</p> <p>Mean age: not stated</p> <p>Inclusion criteria: women with occult urinary stress incontinence defined as symptomatically continent women with urodynamic stress incontinence</p> <p>Exclusion criteria: not stated</p> <p>Setting: Perez Carreno Hospital, Caracas, Venezuela</p> <p>Timing: February 2008 to December 2010</p>
Interventions	<p>Intervention: any POP surgery including Prolift/vag repairs/colpocleisis with TVTo (n = 27)</p> <p>Comparison: any POP surgery including Prolift/vag repairs/colpocleisis without TVTo (n = 33)</p> <p>Median FU: 20 months</p>
Outcomes	<p>Primary outcome/s: need for subsequent anti-incontinence surgery</p> <p>Secondary outcome/s: urodynamics testing, 1-hour pad test, 3-day bladder diary, UDI 6 SF, IIQ 7 SF, PISQ, and visual analogue scale (VAS) score</p>
Notes	<p>Intention-to-treat analysis: All women randomised are analysed.</p> <p>Sample size calculation: no details</p> <p>Trial registration: no details</p> <p>Funding: no details</p> <p>Conflicts of interest: no details</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear loss to follow-up. Abstract states that further women were recruited to the study to allow for participants who were deceased, lost to follow-up, or withdrawn.

Fuentes 2011 (Continued)

Selective reporting (reporting bias)	High risk	Conference abstract only; unable to determine if outcomes reported were all those specified for the trial
Other bias	High risk	Conference abstract only

Hiltunen 2007

Methods	Trial design: multi-centre randomised controlled trial (5 centres)
Participants	<p>Number of participants randomised: 202 (POP repair with mesh 105, POP repair without mesh 97) Number of participants analysed: 200 (1 withdrawal from mesh group, 1 loss to follow-up in no mesh group)</p> <p>Mean age (mean \pm SD): mesh group = 66 \pm 9, no mesh group = 65 \pm 9</p> <p>Inclusion criteria: postmenopausal women with symptomatic anterior vaginal wall prolapse to the hymen or beyond</p> <p>Exclusion criteria: apical defect indicating vaginal fixation or stress urinary incontinence necessitating surgery or main symptomatic prolapse component in the posterior vaginal wall. Also patients with gynaecological tumour or malignancy calling for laparotomy or laparoscopy and those with untreated vaginal infection</p> <p>Setting: 5 hospitals throughout Finland</p> <p>Timing: April 2003 to May 2005</p>
Interventions	<p>Intervention: anterior colporrhaphy (AC) + self-tailored (from a 6 \times 11-cm mesh patch), 4 armed low-weight polypropylene mesh (n = 104)</p> <p>Comparison: AC using a 0 or 2/0 multi-filament suture (n = 96)</p> <p>Type of mesh: non-absorbable monofilament polypropylene (Parietene light, Sofradim, France)</p> <p>Sutures for AC: absorbable 0 or 2/0 multi-filament suture</p> <p>Concomitant surgery: vaginal hysterectomy, posterior repair, culdoplasty as required, no concomitant continence surgeries performed</p> <p>Follow-up for 24 months</p>
Outcomes	<p>Primary outcome/s: recurrence of anterior vaginal wall prolapse reaching stage 2 by the POPQ system</p> <p>Secondary outcome/s: perioperative and postoperative complications, symptom resolution, post voidal urine residual volume</p> <p>Objective failure</p> <p>Symptomatic prolapse</p> <p>Awareness of bulge at 1 year</p> <p>Awareness of bulge at 2 years</p> <p>Further prolapse surgery</p> <p>Further continence surgery</p> <p>Operating time (minutes)</p> <p>Blood loss (mL)</p>

Hiltunen 2007 (Continued)

Stress incontinence de novo

Mesh erosion

Mesh exposure

Further surgery for mesh exposure

Sexual function

Notes

Two inconsistencies between 1-year and 2-year data. Reduction in mesh exposures from 17% at 1 year to 8% at 2 years is difficult to explain. Furthermore, the percentage of patients having undergone previous prolapse surgery at 1 year was 27% in the AC group and 18% in the mesh group, and the 2-year report quotes 20% and 14%, respectively.

There is also a further discrepancy. At 1 year, de novo SUI was 9/96 as compared to 15/104, and at 3 years the reported rate was lower at 5/96 vs 7/104 rate. Even if some of these underwent continence surgery, they should still be recorded as having de novo stress urinary incontinence.

CONSORT statement: yes

Intention-to-treat analysis: No. 1 withdrawal from mesh group, 1 loss to follow-up in no mesh group

Sample size calculation: yes, 202 participants calculated to allow for 15% dropout and to provide 80% power to detect a 20% difference in primary outcomes between groups

Trial registration: Clinicaltrials.gov NCT00420225

Funding: supported by a grant from the Medical Research Funds of the Central Hospital of South Ostrobothnia, Seinäjoki, and Tampere University Hospital, Tampere, Finland.

Conflicts of interest: study authors had no potential conflicts of interest to disclose.

3-year follow up published (Nieminen et al)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisations
Allocation concealment (selection bias)	Low risk	Opaque sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding as to the operative technique was not used.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessors were not blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	202 randomised, 1 withdrawal, and 1 loss to follow-up. 200 analysed
Selective reporting (reporting bias)	Low risk	All prespecified outcomes appear reported.

Hiltunen 2007 (Continued)

Other bias	Low risk	No significant differences in baseline demographics, prior hysterectomy, or prolapse surgeries between the 2 groups
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Iglesia 2010

Methods	Trial design: multi-centre randomised controlled trial involving 6 surgeons at 3 sites	
Participants	Number of participants randomised: 65 (mesh group 32, no mesh group 33) Number of participants analysed: 65 Mean age: (mean \pm SD): mesh group = 64.4 \pm 10.8, no mesh group = 63.5 \pm 8.9 Inclusion criteria: \geq 21 years, grade 2 to 4 (POPQ) uterovaginal or vaginal prolapse and agreed to undergo vaginal surgery, available for 12 months' review, can complete questionnaires Exclusion criteria: multiple medical contraindications, short vagina, uterus > 12 weeks in size, desire future fertility, postpartum Setting: 3 University hospitals in USA Timing: January 2007 to August 2009	
Interventions	Intervention: anterior Prolift or total vaginal mesh (Prolift) if point C or D on POPQ \geq 3. No T incisions were performed and hysterectomy was performed if uterus was present (n = 32). Comparison: anterior colporrhaphy with uterosacral colpopexy with polytetrafluoroethylene sutures or sacrospinous colpopexy with Goretex sutures and hysterectomy performed if uterus was present (n = 33)	
Outcomes	Primary outcome/s: objective failure rate at 1 year (any stage 2 or greater prolapse) Secondary outcome/s: subjective failure, reoperation for prolapse, surgery for mesh exposure, de novo dyspareunia, de novo SUI, responses to a range of quality of life questionnaires, postoperative complications, long-term complications, serious adverse events	
Notes	Intention-to-treat analysis: Manuscript states that 1 participant assigned to the mesh group did not receive mesh and was analysed as a member of the no-mesh arm. This participant was analysed in the mesh group for 3-year follow-up. Sample size calculation: yes, calculated to require 90 participants (45 per arm) to provide 80% power to detect a 20% difference in primary outcome Trial registration: yes. Clinicaltrials.gov NCT00475540 Funding: supported by a grant from the AUGS Foundation and the MedStar Health Research Institute Intramural Grant Program. Prolift mesh kits used in this trial were donated by the mesh manufacturer (Ethicon Women Health and Urology, Somerville, New Jersey, USA). Conflicts of interest: study authors did not report any potential conflicts of interest. The ethics committee stopped the study before completion owing to predetermined stopping criteria of mesh erosion rate >15% being reached, with 65 of the desired sample size of 90 having undergone interventions.	

Risk of bias

Bias	Authors' judgement	Support for judgement
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Iglesia 2010 (Continued)

Random sequence generation (selection bias)	Low risk	Computer-generated randomisations
Allocation concealment (selection bias)	Low risk	Opaque sealed envelopes were opened in the operating theatre after participant had received anaesthesia.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Trial co-ordinator at each site and participants were blinded to treatment by use of sham dressings. Trial personnel not blinded (e.g. operating theatre staff, inpatient and office personnel) were instructed to not disclose treatment assignment to participants.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Three- and 12-month follow-up examinations were conducted by evaluator blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up 3 months postoperatively 27/32 in mesh group and 33/33 in no mesh group underwent 1-year follow-up. 25/33 in mesh group and 26/32 in no mesh group underwent 3-year follow-up.
Selective reporting (reporting bias)	Low risk	Prespecified outcomes appear reported on.
Other bias	Unclear risk	Before surgery, all demographic details were similar between the 2 groups, except group B had lower POPDI-6 score than group A. The ethics committee stopped the study before completion owing to predetermined stopping criteria of mesh erosion rate > 15% being reached, with 65 of the desired sample size of 90 having undergone interventions.

Meschia 2004

Methods	Trial design: randomised controlled trial
Participants	<p>Number of participants randomised: 50 (25 per arm)</p> <p>Number of participants analysed: 50</p> <p>Mean age (mean \pm SD): 65 \pm 8</p> <p>Inclusion criteria: severe symptomatic genital prolapse and occult stress urinary incontinence Exclusion criteria: age > 70 years, BMI > 30 kg/m², diabetes, previous pelvic or continence surgery, symptoms of SUI, detrusor overactivity, cotton-swab test > 30 degrees</p> <p>Setting: Department of Obstetrics & Gynecology, Urogynecology Unit, University of Milan, Italy.</p> <p>Timing: February 2000 to June 2001</p>
Interventions	<p>Intervention: vaginal prolapse repair and TVT (with Prolene tape) (n = 25)</p> <p>Comparison: vaginal prolapse repair and urethrovesical plication (with 2-0 permanent-braided polyester sutures) (n = 25)</p> <p>All women also had vaginal hysterectomy, McCall culdoplasty, and cystocele repair. Cystocele (anterior repair) with 2-0 delayed absorbable sutures (polydioxanone) No sacrospinous ligament fixation performed Rectocele repair: A: 20/25, B: 23/25</p>

Meschia 2004 (Continued)

Outcomes	<p>Primary outcome/s: occurrence of de novo stress urinary incontinence after operation</p> <p>Secondary outcome/s: rate of prolapse recurrence for each vaginal site, anatomical outcomes, urodynamic assessment</p> <p>Subjective prolapse symptoms, failure rate</p> <p>Objective failure (overall)</p> <p>Objective failure (anterior)</p> <p>Objective failure (posterior)</p> <p>Objective failure (apex)</p> <p>Further prolapse surgery</p> <p>Further continence surgery</p> <p>SUI subjective</p> <p>SUI objective</p> <p>OAB de novo (new)</p> <p>Voiding dysfunction</p> <p>Recurrent UTIs</p> <p>Adverse effects (bladder perforation, retropubic haematoma)</p> <p>Perioperative outcomes</p> <p>Operation time (minutes)</p> <p>Blood loss (mL)</p> <p>Hb change</p> <p>Days in hospital</p> <p>Time to spontaneous voiding (days)</p>
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Notes	<p>Intention-to-treat analysis: all women randomised were analysed as per group allocation.</p> <p>Sample size calculation: yes, 50 participants (25 per arm) was calculated to provide 80% power to detect a 30% to 40% difference in primary outcomes between groups.</p> <p>Trial registration: no details</p> <p>Funding: no details</p> <p>Conflict of interest: no details</p>
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation
Allocation concealment (selection bias)	Unclear risk	Sequentially labelled, sealed envelopes with numbers assigned from a computer-generated random number list. Unclear if opaque
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	All women randomised appear to be analysed.

Meschia 2004 (Continued)

Selective reporting (reporting bias)	Low risk	All prespecified outcomes appear to be reported.
Other bias	Unclear risk	Groups comparable at baseline

Rudnicki 2014

Methods	Trial design: multi-centre, parallel-group randomised controlled trial involving 6 centres in Denmark, Norway, Sweden, and Finland	
Participants	<p>Number of participants randomised: 161 (transvaginal mesh 79, anterior colporrhaphy 82)</p> <p>Number of participants analysed: 154 (transvaginal mesh 76, colporrhaphy 78)</p> <p>Mean age (mean \pm SD): transvaginal mesh = 64.9 \pm 6.4, colporrhaphy = 64.7 \pm 6.6</p> <p>Inclusion criteria: \geq 55 years, \geq stage 2 anterior vaginal wall prolapse POPQ</p> <p>Exclusion criteria: previous major pelvic surgery, with the exception of a hysterectomy for reasons other than genital prolapse, previous vaginal surgery, or hysterectomy for POP; concomitant prolapse of the uterus, or an enterocele of stage 1 or higher; previous incontinence sling surgery performed through the obturator membrane; current treatment with corticosteroids; history of genital or abdominal cancer</p> <p>Setting: hospitals in Sweden, Norway, Finland, and Denmark</p> <p>Timing: April 2008 to December 2010</p>	
Interventions	<p>Intervention: four-arm transobturator vaginal anterior mesh (Avaulta); the central section is coated with an absorbable hydrophilic film of porcine collagen. Vaginal pack for \geq 6 hours (79 underwent surgery as assigned)</p> <p>Comparison: anterior colporrhaphy, fascia plicated using intermittent 2–0 absorbable sutures, excessive trimming of vagina (all 82 underwent surgery as assigned)</p> <p>Follow-up at 3, 12, and 13 months</p>	
Outcomes	<p>Primary outcome: recurrent anterior prolapse (POPQ stage $>$ 1)</p> <p>Secondary outcomes: quality of life, symptoms, and complications (frequency of erosions, postoperative infections, and dyspareunia). Questionnaires: PFIQ-7, PFDI-20, PISQ-12, UIQ-7, CRAIQ-7, POPIQ-7, POPDI-6, CRADI-8, UDI-6</p>	
Notes	<p>Intention-to-treat analysis: yes</p> <p>Sample size calculation: yes, to detect a difference of 20% in recurrence rate (defined as \geq stage 2 cystocele at 12-month follow-up) between the 2 groups. Accordingly, 112 participants had to be randomised. In anticipation of a dropout rate of 15%, the number of participants was increased to 130.</p> <p>Trial registration: ClinicalTrials.gov (NCT00627549): http://clinicaltrials.gov/ct2/show/NCT00774215</p> <p>Funding: no funding by industry. Funded by Region Sealand Health research fund</p> <p>Conflicts of interest: none declared</p>	

Risk of bias

Bias	Authors' judgement	Support for judgement
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Rudnicki 2014 (Continued)

Random sequence generation (selection bias)	Low risk	Computer-generated block design stratified by centre
Allocation concealment (selection bias)	Low risk	Opaque sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss of FU for 3/79 in mesh group and 4/82 in anterior repair group. All accounted for
Selective reporting (reporting bias)	Low risk	Outcomes stated are reported on.
Other bias	Unclear risk	No significant differences in baseline demographics

Schierlitz 2014

Methods	Trial design: multi-centre randomised controlled trial (2 sites)
Participants	<p>Number of participants randomised: 80 (no TVT group 43, TVT group 37)</p> <p>Number of participants analysed: at 6 months: no TVT group 39, TVT group 35</p> <p>Mean age (mean \pm SD): no TVT group = 66 \pm 9.1, TVT group = 67 \pm 10.9</p> <p>Inclusion criteria: symptomatically continent women with urodynamically demonstrable stress incontinence with or without reduction of prolapse (POPQ \geq stage 3)</p> <p>Exclusion criteria: contraindications to pelvic surgery such as pelvic infection, fistula, congenital or neurogenic bladder disorder, malignancy, or being medically unfit</p> <p>Setting: 2 tertiary hospitals, Australia</p> <p>Timing: May/June 2003 to August/September 2009</p>
Interventions	<p>Intervention: non-standardised vaginal prolapse surgery with TVT (n = 37)</p> <p>Comparison: non-standardised vaginal prolapse surgery without TVT (n = 43)</p> <p>No women had bladder neck plications</p> <p>6 months minimum review, n = 60 at 24 months</p>
Outcomes	<p>Primary outcome/s: need for subsequent anti-incontinence surgery due to symptomatic SUI after 6 months</p> <p>Secondary outcome/s: subjective cure rates, intraoperative and postoperative complications, voiding function, urgency, urge urinary incontinence (UUI) symptoms, change in quality of life as assessed by UDI-6 and IIq-7, overall satisfaction with prolapse repair</p>

Schierlitz 2014 (Continued)

Notes	<p>Intention-to-treat analysis: not stated</p> <p>Sample size calculation: sample size required calculated at 62 participants (31 per group) based on 90% power to detect a reduction from 50% to 10% in SUI after prolapse repair</p> <p>Trial registration: Australian New Zealand Clinical Trials Registry ACTRN: 12611000844943</p> <p>Funding: no details</p> <p>Conflicts of interest: study authors report no conflicts of interest</p> <p>Occult SUI was defined as symptomatically continent women with urodynamically demonstrable stress incontinence with or without reduction of the prolapse (POPQ \geq stage 3)</p> <p>Study authors calculated that a clinician would have to insert 1 TVT sling unnecessarily to prevent 1 woman from needing a sling postoperatively.</p> <p>2-year follow-up; published as an abstract (Walsh et al 2017)</p>
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated
Allocation concealment (selection bias)	Unclear risk	No details provided of method used to conceal allocation to treatment groups
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding of patients
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding of assessors
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Some women declined postoperative urodynamic studies as they were asymptomatic, but subjective SUI is main outcome measure.
Selective reporting (reporting bias)	Low risk	Prespecified outcomes are reported.
Other bias	Unclear risk	Non-standardised surgery was performed.

Sivaslioglu 2008

Methods	Trial design: multi-centre RCT (2 sites)
Participants	<p>Number of participants randomised: 90</p> <p>Number of participants analysed: 85</p> <p>Mean age: (mean \pm SD): mesh group = 57.7 \pm 9.4, site-specific group = 50.1 \pm 9.9</p> <p>Inclusion criteria: primary cystocele</p>

Sivaslioglu 2008 (Continued)

Exclusion criteria: stress urinary incontinence, concomitant rectocele or enterocele or recurrent cystocele

Setting: urogynaecology clinics of Ankara Etlik Maternity and Women's Health Teaching Hospital

Timing: January 2006 to January 2007

Interventions	<p>Intervention: self-styled 4-armed polypropylene (Parietene, Sofradim, France) mesh, no anterior repair (n = 43)</p> <p>Comparison: site-specific Polyglactin 910 anterior repair (n = 42)</p> <p>Concomitant surgery not standardised, management of concomitant apical prolapse not specified in either group</p> <p>Follow-up: mean 12 months (range 8 to 16)</p>
Outcomes	<p>Primary outcome/s: objective failure (\geq stage 2 POPQ)</p> <p>Secondary outcome/s: PQoL score postop (mean \pm SD), further prolapse surgery, SUI, dyspareunia de novo, mesh erosion</p>
Notes	<p>Intention-to-treat analysis: not stated</p> <p>Sample size calculation: 45 in each arm required</p> <p>Trial registration: not stated</p> <p>Funding: not stated</p> <p>Conflicts of interest: not stated</p> <p>CONSORT statement: yes</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	High risk	Non-blinded reviewers performed objective assessment of patient-completed questionnaires.
Incomplete outcome data (attrition bias) All outcomes	Low risk	90 women randomised and 5 lost to follow-up balanced between groups
Selective reporting (reporting bias)	Unclear risk	No further validated or structured reporting of secondary outcome findings apart from PQoL score
Other bias	Low risk	No funding and no COI

Trabuco 2014

Methods	Trial design: parallel randomised controlled multi-centre superiority trial
Participants	<p>Number of participants randomised: 113</p> <p>Number of participants analysed: 104</p> <p>Mean age: 56 years</p> <p>Inclusion criteria: symptomatic \geq stage 2 apical or anterior vaginal wall prolapse, opted for an abdominal prolapse repair. Women with a uterus were eligible to participate.</p> <p>Exclusion criteria: known or suspected disease that affects bladder function (e.g. multiple sclerosis, Parkinson disease); pregnancy; desired fertility; urethral diverticulum; history of radical pelvic surgery or pelvic radiation therapy; current chemotherapy or radiation therapy for malignancy</p> <p>Setting: urogynaecology clinics at Mayo Clinic in Rochester, Minnesota, and University of Missouri, Kansas City, Missouri</p> <p>Timing: June 2009 to August 2013</p>
Interventions	<p>A: SCP with MUS (n = 53)</p> <p>B: SCP with Burch colposuspension (n = 57)</p>
Outcomes	<p>Primary outcome/s: overall continence and stress-specific continence</p> <p>Secondary outcome/s: patient satisfaction, voiding dysfunction, elevated post void residual, apical or anterior prolapse failure, de novo or resolution of urgency Incontinence, and incontinence severity</p> <p>No differences in age, BMI, history of POP surgeries, POP stage, continence severity.</p> <p>Six-month review: 104 patients</p> <p>Objective continence: A, 35/53; B, 28/51</p> <p>Stress-specific continence: A, 43/53; B, 32/51</p> <p>De novo UUI: A, 3/28; B, 2/26</p> <p>Satisfaction rate (answered somewhat or completely): A, 50/53; B, 37/51</p> <p>Patient perception of improvement (10/10 VAS): A, 38/53; B, 26/51</p> <p>Report successful operation for SUI (10/10 VAS): A, 38/53; B, 24/51</p> <p>No difference in mesh exposure</p> <p>No difference in rate of complications</p>
Notes	<p>Intention-to-treat analysis: yes</p> <p>Sample size calculation: 46 women per group required based on a 2-sided \times 2 test with a type I error level of .05. Assuming a 20% dropout rate, the plan was to recruit 115 trial participants.</p> <p>Trial registration: NCT00934999</p> <p>Funding: Mayo Clinic Center for Clinical and Transitional Science grant number UL1 TR000135 from the National Center for Advancing Translational Sciences, a component of the National Institutes of Health</p> <p>Conflicts of interest: none</p> <p>2-year follow-up: published as an abstract</p>

Trabuco 2014 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not clear
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	113 randomised. 104 followed up at 6 months; MUS (53), Burch (51)
Selective reporting (reporting bias)	Low risk	Full report of primary and secondary outcome findings
Other bias	Unclear risk	2-year follow-up: reported only as an abstract

Turgal 2013

Methods	Trial design: computer-randomised prospective trial
Participants	Number of participants randomised: 40 Number of participants analysed: 40 Inclusion criteria: stage 2 or 3 cystocele according to POPQ Exclusion criteria: urinary incontinence, previous gynaecological operation, concomitant rectocele or enterocele, recurrent cystocele Setting: Urogynecology Clinic of Etlik Zubeyde Hanim Maternity and Women's Health Teaching and Research Hospital Timing: June 2006 to February 2007
Interventions	Intervention: anterior vaginal mesh: polypropylene mesh (Sofradim) through the obturator foramen (n = 20) Comparison: anterior colporrhaphy (n = 20)
Outcomes	Primary outcome/s: anatomical (POPQ) and functional effectiveness Secondary outcome/s: urinary and faecal incontinence, pelvic pain Success rate De novo SUI

Turgal 2013 (Continued)

Preop frequency
 Postop frequency
 Preop urgency
 Postop urgency
 Assessed at 6 weeks, 6 months, 1 year

Notes
 Intention-to-treat analysis: not stated
 Sample size calculation: not stated
 Trial registration: not stated
 Funding: not stated
 Conflicts of interest: not stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Allocated by a computer programme
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding; surgeon performed assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Prespecified variables reported on
Selective reporting (reporting bias)	Unclear risk	Not detected
Other bias	Unclear risk	Unclear

van der Ploeg 2015 (CUPIDO I)

Methods
 Trial design: multi-centre RCT (14 centres)

Participants
 Number of participants randomised: 138
 Number of participants analysed: 134
 Inclusion criteria: POP ≥ stage 2, scheduled for transvaginal prolapse surgery with co-existing SUI

van der Ploeg 2015 (CUPIDO I) (Continued)

Exclusion criteria: occult SUI, post voiding residual \geq 300 mL, isolated prolapse of posterior compartment, previous urinary incontinence surgery, recent prolapse surgery

Setting: multi-centre

Timing: 2007 to 2009 according to trial registration

Interventions	Intervention: vaginal prolapse repair with MUS (n = 63) Comparison: vaginal prolapse repair without MUS (n = 71)
Outcomes	Primary outcome/s: absence of urinary incontinence and SUI 12 months after index surgery and additional treatment for SUI and overactive bladder (OAB) in the first postoperative year Secondary outcome/s: bothersome SUI, objective SUI, a composite endpoint
Notes	Intention-to-treat analysis: yes Sample size calculation: sample size calculation was based on a 1-sided test. Accounting for 10% loss to follow-up, 63 participants per group were needed to detect a 20% decrease in subjective SUI (30% vs 10%) with 80% power and a 1-sided significance level of 5%. Trial registration: NTR1197 Funding: Academic Medical Center (AMC) Department of Gynaecology Conflicts of interest: Jan-Paul W.R. Roovers: medical consultant for American Medical Systems (AMS). C. Huub van der Vaart: medical consultant for BARD Medical

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation sequence was created by a central computer random number generator using blocks of 4 and stratified for centre and the leading edge of the POP in a 1:1 ratio for the 2 comparison groups.
Allocation concealment (selection bias)	Low risk	Sequence list was concealed from investigators and those groups including participants.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details
Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal loss to follow-up
Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported
Other bias	Unclear risk	No clarification

van der Ploeg 2016 (CUPIDO II)

Methods	Trial design: multi-centre RCT - 13 teaching hospitals
Participants	<p>Number of participants randomised: 225</p> <p>Number of participants analysed: MUS group 42, no MUS group 47, control group 136</p> <p>Inclusion criteria: women undergoing vaginal prolapse surgery for \geq stage 2 POP with preoperative occult stress urinary incontinence</p> <p>Exclusion criteria: women with post voiding residuals $>$ 300 mL, previous incontinence surgery, recent prolapse surgery, unable to give informed consent, recently pregnant or wished to become pregnant, systemic disease that could influence bladder function (e.g. multiple sclerosis; Parkinson's disease), underwent or were scheduled for chemotherapy or radiotherapy, continent women</p> <p>Setting: 13 centres across The Netherlands</p> <p>Timing: 2007 to 2009 according to trial register</p>
Interventions	<p>Intervention: vaginal prolapse surgery with MUS (n = 42)</p> <p>Comparison: vaginal prolapse surgery without MUS (n = 47)</p> <p>Control group: POP alone without objective SUI (n = 136)</p>
Outcomes	<p>Primary outcome/s: absence of urinary incontinence and SUI 12 months after index surgery and additional treatment for SUI and overactive bladder (OAB) in the first postoperative year</p> <p>Secondary outcome/s: bothersome SUI, objective SUI, a composite endpoint</p>
Notes	<p>Intention-to-treat analysis: yes</p> <p>Sample size calculation: based on 1-sided test. For 80% power to detect a 15% difference in subjective SUI (5% SUI in the MUS group vs 20% SUI in the control group) and accounting for 10% loss to follow-up, 80 women per group were needed.</p> <p>Trial registration: NTR1070</p> <p>Funding: Academic Medical Center (AMC) Department of Gynaecology</p> <p>Conflicts of interest: Jan-Paul W.R. Roovers: medical consultant for American Medical Systems (AMS). C. Huub van der Vaart: medical consultant for BARD Medical</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Central computer random-number generator using blocks of 4 and stratified for centre and the leading edge of the POP. After obtaining written informed consent from participants, we used a central password-protected web-based application for randomisations and patient data entry.
Allocation concealment (selection bias)	Unclear risk	Researchers state that the sequence list was concealed from investigators and participants but also state that participants and outcome assessors were not blinded.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were not blinded.

van der Ploeg 2016 (CUPIDO II) *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessors were not blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	225 were randomised and 222 were analysed.
Selective reporting (reporting bias)	Low risk	Prespecified outcomes were reported.
Other bias	Unclear risk	Unclear

Wei 2011

Methods	Trial design: multi-centre (7 clinical sites), randomised, single-blind, sham-controlled, surgical intervention trial
Participants	<p>Number of women randomised: 337</p> <p>Number of women analysed: 327</p> <p>Inclusion criteria: vaginal prolapse surgery for symptomatic stage 2 anterior compartment prolapse, negative response to 3 questions from PFDI related to stress incontinence</p> <p>Exclusion criteria: prior sling placement, prior urethral surgery or radiation, planing pregnancy, 2 or more hospitalisations in the prior year</p> <p>Setting: multi-centre trial</p> <p>Timing: Enrollment began in May 2007, and follow-up was completed in January 2011.</p>
Interventions	<p>Intervention: vaginal prolapse surgery with TVT (n = 165)</p> <p>Comparison: vaginal prolapse surgery without TVT (n = 172)</p> <p>Follow-up at 12 months</p>
Outcomes	<p>Primary outcome/s: urinary incontinence (stress, urge, or mixed) at 3 months, defined as a positive cough stress test, bothersome incontinence symptoms, treatment for urinary incontinence; and urinary incontinence (stress, urge, or mixed) at 12 months, regardless of whether interim treatment for incontinence had been provided</p> <p>Secondary outcome/s: Medical Outcomes Study 36-Item Short-Form Health Survey, Pelvic Floor Distress Inventory, Pelvic Floor Impact Questionnaire, Incontinence Severity Index, Pelvic Organ Prolapse/Urinary Incontinence Sexual Functioning Questionnaire Short Form, visual analogue pain scale adapted for suprapubic pain; severe adverse events</p>
Notes	<p>Intention-to-treat analysis: yes</p> <p>Sample size calculation: 150 participants per group would provide the study with 80% power to detect a 15% between-group difference in the primary 3-month endpoint on the basis of a 2-sample test of proportions, with a 2-sided significance level of 5%</p> <p>Trial registration: NCT00460434</p> <p>Funding: grants from Eunice Kennedy Shriver National Institute of Child Health and Human Development and National Institute of Health Office of Research on Women's Health</p>

Wei 2011 (Continued)

Conflicts of interest:

OPUS trial: A significant weakness of the evaluation is that definitions for inclusion as stress continent (-ve answer to 3 PFDI questions related to sui) were less stringent than the definition of UI positive, as outcome includes +ve stress test, questions related to stress or urge incontinence, or treatment for any incontinence. Actually as 108 (group A, 57; group B, 54) women had +ve prolapse reduction stress test before intervention, they would have been deemed positive stress incontinent post intervention and were -ve stress incontinent preoperatively on the criteria defined.

Women who declined to undergo randomisations were offered the opportunity to participate in a patient-preference cohort in which the decision for a sling was left up to the patient and her surgeon.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated block design stratified by surgeon and type of prolapse surgery
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Sham dressings. Participants in the randomised cohort, interviewers, and coordinators were unaware of study group assignments, and operative notes and surgical consent forms did not reveal the study group.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Primary outcomes were questionnaires assessed by blinded reviewers.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intention to treat and failure of review counted as failure, minimal loss to follow-up
Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported
Other bias	Low risk	Grants from Eunice Kennedy Shriver National Institute of Child Health and Human Development and National Institute of Health Office of Research on Women's Health

Withagen 2011

Methods	Trial design: multi-centre randomised controlled trial (13 centres, 22 surgeons)
Participants	Number of participants randomised: 194 Number of participants analysed: 190 Inclusion criteria: recurrent \geq stage 2 anterior and or posterior wall prolapse Exclusion criteria: pregnancy, future pregnancy, prior vaginal mesh repair, a compromised immune system or any other condition that would compromise healing, previous pelvic irradiation or cancer, blood coagulation disorders, renal failure, upper urinary tract obstruction, renal failure and upper urinary tract obstruction, presence of large ovarian cysts or myomas Setting: 13 centres in The Netherlands

Withagen 2011 (Continued)

Timing: June 2006 to July 2008

Interventions	Intervention: anterior transobturator mesh (Prolift, n = 95) comparison: vaginal anterior colporrhaphy (n = 99)
Outcomes	<p>Primary outcome/s: anatomic failure in any of the treated vaginal compartments, defined as POPQ \geq stage 2</p> <p>Secondary outcome/s: blood loss, length of hospitalisations, complications and subjective improvement (Patient Global Impression of Improvement), change in bother and quality of life measured by Urogenital Distress Inventory, Defecatory Distress Inventory, and Incontinence Impact Questionnaire scores</p>
Notes	<p>Intention-to-treat analysis: not stated</p> <p>Sample size calculation: based on the assumption of an estimated overall failure rate of 30% in the conventional surgery group (cure rate of 70%) and 13% in the tension-free vaginal mesh group (cure rate of 87%). Based on a 2-tailed hypothesis test with type I error of 5% and 80% power, 88 patients in each group would be required to detect a significant difference \geq 17%. Anticipating a 10% dropout rate, we planned to enrol 194 patients.</p> <p>Trial registration: NCT00372190</p> <p>Funding: University-administered research funds</p> <p>Conflicts of interest: Drs. Milani and den Boon have a consultancy agreement with Ethicon Women's Health & Urology. Drs. Withagen and Milani are on the Speaker's Bureau of Ethicon Women's Health and Urology. Drs. Withagen and Vierhout received an unrestricted educational grant from Ethicon Women's Health & Urology. Dr. Vervest has received payment from Ethicon Women's Health & Urology for lectures.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Non-blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Non-blinded reviewers: patient-completed questionnaires
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Minimal loss for follow-up but incomplete assessment (e.g. questionnaire vs exam)
Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported

Withagen 2011 (Continued)

Other bias	High risk	<p>University research fund: all study authors reported financial support from Ethicon Company manufacturing product being evaluated by non-blinded reviewers.</p> <p>Preoperatively, group A is significantly different from mesh group B as demonstrated by greater degree of prolapse at Ap, Bp, and GH, having significantly higher number with \geq stage 2 apical compartment prolapse among those in Table I undergoing prior apical surgery, 36% (16/45) in the non-mesh group versus 18% (10/56) in the mesh group ($P = 0.04$, odds ratio (OR) 2.54); finally prior sacrocolpopexy was 3 times as frequent in the mesh group.</p>
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BMI: body mass index.
 Hb: haemoglobin.
 ICS: International Continence Society.
 IVS: intravaginal slingplasty.
 MUCP: maximum urethral catheter pressure.
 OAB: overactive bladder.
 PDS: polydioxanone surgical suture (PDS).
 PFDI: Pelvic Floor Distress Inventory.
 PFIQ: Pelvic Floor Impact Questionnaire.
 PGI-I: Patient Global Impression of Improvement.
 PISQ: Pelvic organ prolapse/urinary Incontinence Sexual Questionnaire.
 POP: pelvic organ prolapse.
 POPQ: pelvic organ prolapse quantification (according to ICS).
 P-QoL: Prolapse Quality of Life Questionnaire.
 QoL: quality of life.
 RCT: randomised controlled trial.
 SUI: stress urinary incontinence (symptom diagnosis).
 TVT: tension-free vaginal tape.
 UDI: Urogenital Distress Inventory.
 UI: urinary incontinence.
 UTI: urinary tract infection.
 VAS: visual analogue scale.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Allahdin 2008	No incontinence issues; different patient population
Barber 2006	Barber compared 2 independent population cohorts. Arm 1 was the pessary group, in which women were randomly allocated between 2 pessary types, and arm two underwent a surgical intervention. As patients were not randomly allocated between pessary and surgery groups, this paper failed to meet the criterion of a randomised controlled trial and was excluded.
Bergman 1989	RCT on anterior colporrhaphy, Pereyra or Burch colposuspension, no data on pelvic organ prolapse given, different patient populations
Biller 2008	Biller and colleagues evaluated inclusion and exclusion of anal purse string suture to minimise contamination during prolapse surgery. This study was excluded from the review as it failed to evaluate pelvic organ prolapse surgical procedures.
Boccasanta 2004	RCT on 2 transanal stapled techniques for outlet obstruction. Outlet obstruction caused not only by rectoceles but also by descending perineum and intussusception, different patient populations. Prolapse data not presented

Study	Reason for exclusion
Carramao 2008a	Camarro and colleagues presented results for 15 women in the hysterectomy group and 16 in the hysteropexy group. This paper was excluded owing to the poor sample size and lack of data regarding continence outcomes, quality of life, and complications.
Choe 2000	RCT on mesh vs vaginal wall sling for stress incontinence. Not all women had pelvic organ prolapse before the operation.
Colombo 1996b	RCT on Burch colposuspension and paravaginal defect repair for stress incontinence. No report on treatment of associated anterior vaginal wall prolapse
Cruikshank 1999	RCT on 3 operations for prevention of enterocoele. Study does not include treatment of prolapse.
Debodinance 1993	Comparison of 2 different procedures for stress incontinence and prolapse on examination but no symptomatic pelvic organ prolapse included
Del Roy 2010	Del Roy compared in a single-centre RCT anterior colporrhaphy vs NAZCA TC™, macroporous polypropylene mesh, in surgical treatment to greater (grade III and IV) anterior vaginal prolapse. 78 women were included in this study. This study was excluded from this review owing to different patient populations and paucity of data regarding distribution of patients within the 2 procedures.
Di Palumbo 2003	RCT with unclear operations and comparisons. No clear definition of success or failure
Duggan 2010	Duggan and Barry assessed short-term results in an RCT comparing traditional colporrhaphy (n = 16) and mesh repair (n = 19) for anterior compartment prolapse. Because of a predefined decision that papers with fewer than 20 in each treatment group would not be included in the review, the manuscript was excluded.
Glazener 2009	Study did not include continence outcomes in its aims. No separate analysis of incontinence outcomes
Hviid 2010	Study authors did not include continence outcomes in their aims.
Lamblin 2014	Study included women with mixed continence status at baseline and did not provide data separately; therefore different patient populations are included.
Lundarelli 2009	Lundarelli compared polypropylene mesh vs site-specific repair in the treatment of stage 3 or 4 or recurrent prolapse of the anterior vaginal wall prolapse. This study was excluded from the review, as the sample size of 16 in each group was less than our predetermined group minimum of 20. Furthermore, a mixed continence status was noted at baseline.
Menefee 2011	Study authors did not include continence outcomes in their aims; therefore they reported on different patient populations.
Minassian 2014	Study authors included women with mixed continence status at baseline and did not provide data separately. Some patients in both groups received suburethral tapes; therefore different study populations were reported.
Natale 2009	Study authors did not include continent OR incontinent women in their study.
Pantazis 2011	Study authors included women with mixed continence status at baseline, thus assessing different patient populations. They did not report continence outcomes.
Quadri 1985	Conference abstracts with unclear patient populations, numbers, and definitions, and with limited prolapse data.

Study	Reason for exclusion
Rane 2004	RCT of 3 different operations (vaginal sacrospinous fixation (SSF), posterior intravaginal slingplasty (IVS), sacrocolpopexy (SCP) (abdominal or laparoscopic)) with MRI findings presented. Study authors did not study required patient population.
Roovers 2004	Study authors did not include continent OR incontinent women and did not report on incontinence outcomes based on baseline continence status.
Svabik 2014	Svabik compared sacrospinous fixation and Prolift mesh but did not include incontinent OR continent women in study aims.
Tincello 2009	Tincello reported a pilot randomised patient preference study comparing colposuspension or TVT for urinary incontinence at the time of anterior repair for prolapse. Thirty-one women were recruited; however only 4 or 2 in each arm randomised. Owing to a predefined decision that papers with fewer than 20 in each treatment group would not be included in the review, the manuscript was excluded.
Zargham 2013	Zargham included women with SUI as the primary complaint, with no symptomatic POP.

IVS: intravaginal slingplasty.
 MRI: magnetic resonance imaging.
 POP: pelvic organ prolapse.
 RCT: randomised controlled trial.
 SCP: sacrocolpopexy.
 SSF: sacrospinous fixation.
 SUI: stress urinary incontinence.
 TVT: tension-free vaginal tape.

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

[NCT01095692](#)

Trial name or title	ATHENA
Methods	RCT
Participants	Women with occult UI
Interventions	POP + SUI surgery vs POP surgery alone
Outcomes	<p>Primary:</p> <p>To compare the postoperative prevalence of stress incontinence in patients with or without TOT implant during a pelvic organ prolapse surgery [Time Frame: 6 months]</p> <p>Secondary:</p> <ul style="list-style-type: none"> To compare the severity of postoperative stress urinary incontinence between the 2 groups [Time Frame: 6 months] To compare the prevalence of new-onset overactive bladder postoperatively between the 2 groups [Time Frame: 6 months] To compare the severity of new-onset overactive bladder between the 2 groups [Time Frame: 6 months] To compare the prevalence of postoperative dyspareunia at 6 months between the 2 groups [Time Frame: 6 months] To compare the prevalence of postoperative urinary retention between the 2 groups [Time Frame: 6 months]

NCT01095692 (Continued)

- To compare the severity of postoperative dyspareunia at 6 months between the 2 groups [Time Frame: 6 months]
- To compare the prevalence of dyschezia and constipation at 6 months between the 2 groups [Time Frame: 6 months]
- To compare preoperative and postoperative urodynamic tests of patients when they are incontinent at 6 months [Time Frame: 6 months]
- To compare the postoperative Patient Global Impression of Improvement and degree of satisfaction at 6 months between the 2 groups [Time Frame: 6 months]

Starting date	July 2010
Contact information	A Cortesse: ariane.cortesse@sls.aphp.fr, Assistance Publique, Hôpitaux de Paris.
Notes	clinical trials.gov; NCT01095692

NCT01802281

Trial name or title	SUPeR
Methods	RCT
Participants	Symptomatic POP
Interventions	Native tissue repair with vaginal hysterectomy and suture apical suspension vs uterine conservation with mesh hysteropexy
Outcomes	Composite primary outcome of success defined as no prolapse symptoms, no objective prolapse beyond the hymen, and no retreatment of prolapse, with a minimum of 36 months' post surgery follow-up using survival analyses
Starting date	April 2013
Contact information	Charles W Nager, MD. University of California at San Diego, UCSD Women's Pelvic Medicine Center
Notes	NCT01802281

POP: pelvic organ prolapse.
RCT: randomised controlled trial.
SUI: stress urinary incontinence.
TOT: transobturator tape.
UI: urinary incontinence.

DATA AND ANALYSES

Comparison 1. Comparisons of surgery in women with POP and SUI

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal POP surgery with vs without concomitant continence surgery: additional MUS vs vaginal repair alone	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Subjective postoperative SUI	2	319	Risk Ratio (M-H, Fixed, 95% CI)	0.30 [0.19, 0.48]
1.2 Recurrent POP on examination	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.3 Overactive bladder symptoms (cured/improved)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.4 Overactive bladder symptoms (de novo overactive bladder)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.5 Voiding dysfunction difficulties	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.6 Further continence surgery	1	134	Risk Ratio (M-H, Fixed, 95% CI)	0.05 [0.00, 0.74]
2 Vaginal POP surgery with concomitant vs delayed continence surgery: additional concomitant MUS vs delayed MUS	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Subjective postoperative SUI	1	140	Risk Ratio (M-H, Fixed, 95% CI)	0.41 [0.12, 1.37]
2.2 Recurrent POP on examination	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.3 Overactive bladder symptoms (cured/improved)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.4 Overactive bladder symptoms (de novo overactive bladder)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.5 Voiding dysfunction difficulties	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Abdominal POP surgery with vs without concomitant continence surgery: additional Burch colpo vs sacrocolpopexy alone	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 Subjective postoperative SUI 1-year FU	1	47	Risk Ratio (M-H, Fixed, 95% CI)	1.38 [0.74, 2.60]
3.2 Subjective postoperative SUI 5-year FU	1	45	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.60, 2.26]
3.3 Recurrent POP on examination	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.4 Overactive bladder symptoms (cured/improved)	1	33	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.61, 1.18]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.5 Overactive bladder symptoms (de novo overactive bladder)	1	47	Risk Ratio (M-H, Fixed, 95% CI)	1.92 [0.19, 19.73]
3.6 Voiding dysfunction difficulties	1	47	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.06, 14.43]
3.7 Further continence surgery	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Abdominal POP surgery with different concomitant continence procedures: additional MUS vs Burch colpo at sacral colpopexy	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1 Subjective postoperative SUI 1-year FU	1	113	Risk Ratio (M-H, Fixed, 95% CI)	0.61 [0.36, 1.04]
4.2 Subjective postoperative SUI 2-year FU	1	113	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.34, 0.86]
4.3 Overactive bladder symptoms (cured/improved)	1	47	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.33, 0.99]
4.4 Overactive bladder symptoms (de novo overactive bladder)	1	54	Risk Ratio (M-H, Fixed, 95% CI)	1.39 [0.25, 7.68]
4.5 Voiding dysfunction difficulties	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.32, 1.40]
4.6 Further continence surgery	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.7 Recurrent POP on examination	1	99	Risk Ratio (M-H, Fixed, 95% CI)	1.47 [0.26, 8.42]
5 Abdominal continence surgery vs vaginal POP surgery: Burch colpo vs anterior repair	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.1 Subjective postoperative SUI	1	68	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.12, 0.71]
5.2 Recurrent POP on examination	1	68	Risk Ratio (M-H, Fixed, 95% CI)	11.31 [1.56, 82.26]
5.3 Overactive bladder symptoms (cured/improved)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.4 Overactive bladder symptoms (de novo overactive bladder)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.5 Voiding dysfunction	1	68	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.39, 1.64]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.6 Further continence surgery	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.7 Further continence surgery	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 Comparisons of surgery in women with POP and SUI, Outcome 1 Vaginal POP surgery with vs without concomitant continence surgery: additional MUS vs vaginal repair alone.

Study or subgroup	Add MUS n/N	Vag repair only n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
1.1.1 Subjective postoperative SUI					
Borstad 2010	4/91	22/94		34.87%	0.19[0.07,0.52]
van der Ploeg 2015 (CUPIDO I)	14/63	43/71		65.13%	0.37[0.22,0.6]
Subtotal (95% CI)	154	165		100%	0.3[0.19,0.48]
Total events: 18 (Add MUS), 65 (Vag repair only)					
Heterogeneity: Tau ² =0; Chi ² =1.39, df=1(P=0.24); I ² =28.07%					
Test for overall effect: Z=5.14(P<0.0001)					
1.1.2 Recurrent POP on examination					
Subtotal (95% CI)	0	0			Not estimable
Total events: 0 (Add MUS), 0 (Vag repair only)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
1.1.3 Overactive bladder symptoms (cured/improved)					
Subtotal (95% CI)	0	0			Not estimable
Total events: 0 (Add MUS), 0 (Vag repair only)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
1.1.4 Overactive bladder symptoms (de novo overactive bladder)					
Subtotal (95% CI)	0	0			Not estimable
Total events: 0 (Add MUS), 0 (Vag repair only)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
1.1.5 Voiding dysfunction difficulties					
Subtotal (95% CI)	0	0			Not estimable
Total events: 0 (Add MUS), 0 (Vag repair only)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
1.1.6 Further continence surgery					
van der Ploeg 2015 (CUPIDO I)	0/63	12/71		100%	0.05[0,0.74]
Subtotal (95% CI)	63	71		100%	0.05[0,0.74]
Total events: 0 (Add MUS), 12 (Vag repair only)					
Heterogeneity: Not applicable					

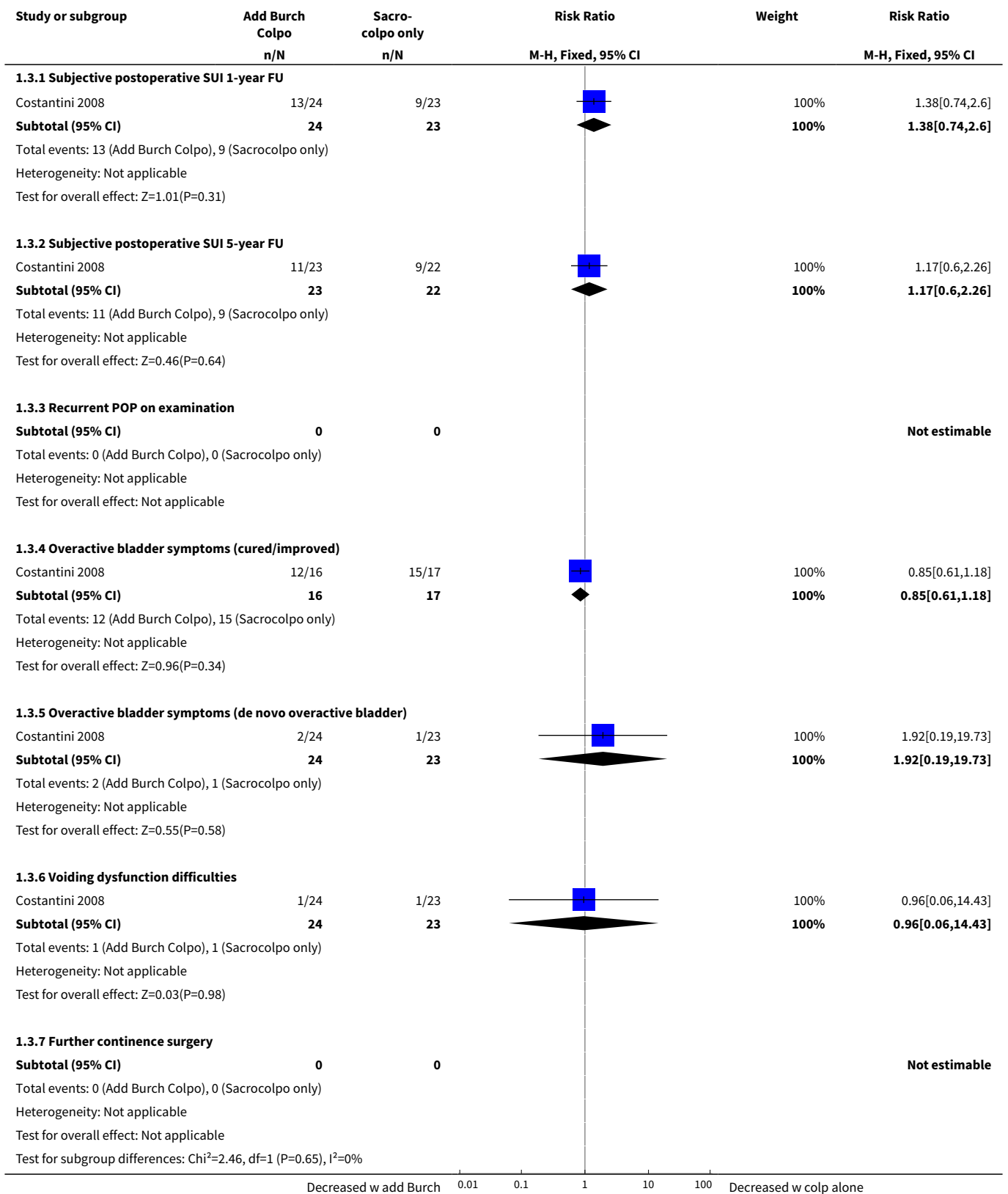
Decreased w add. MUS 0.01 0.1 1 10 100 Decreased w repair only

Study or subgroup	Add MUS n/N	Vag repair only n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Test for overall effect: Z=2.17(P=0.03)					
Test for subgroup differences: Chi ² =1.74, df=1 (P=0.19), I ² =42.44%					
Decreased w add. MUS 0.01 0.1 1 10 100 Decreased w repair only					

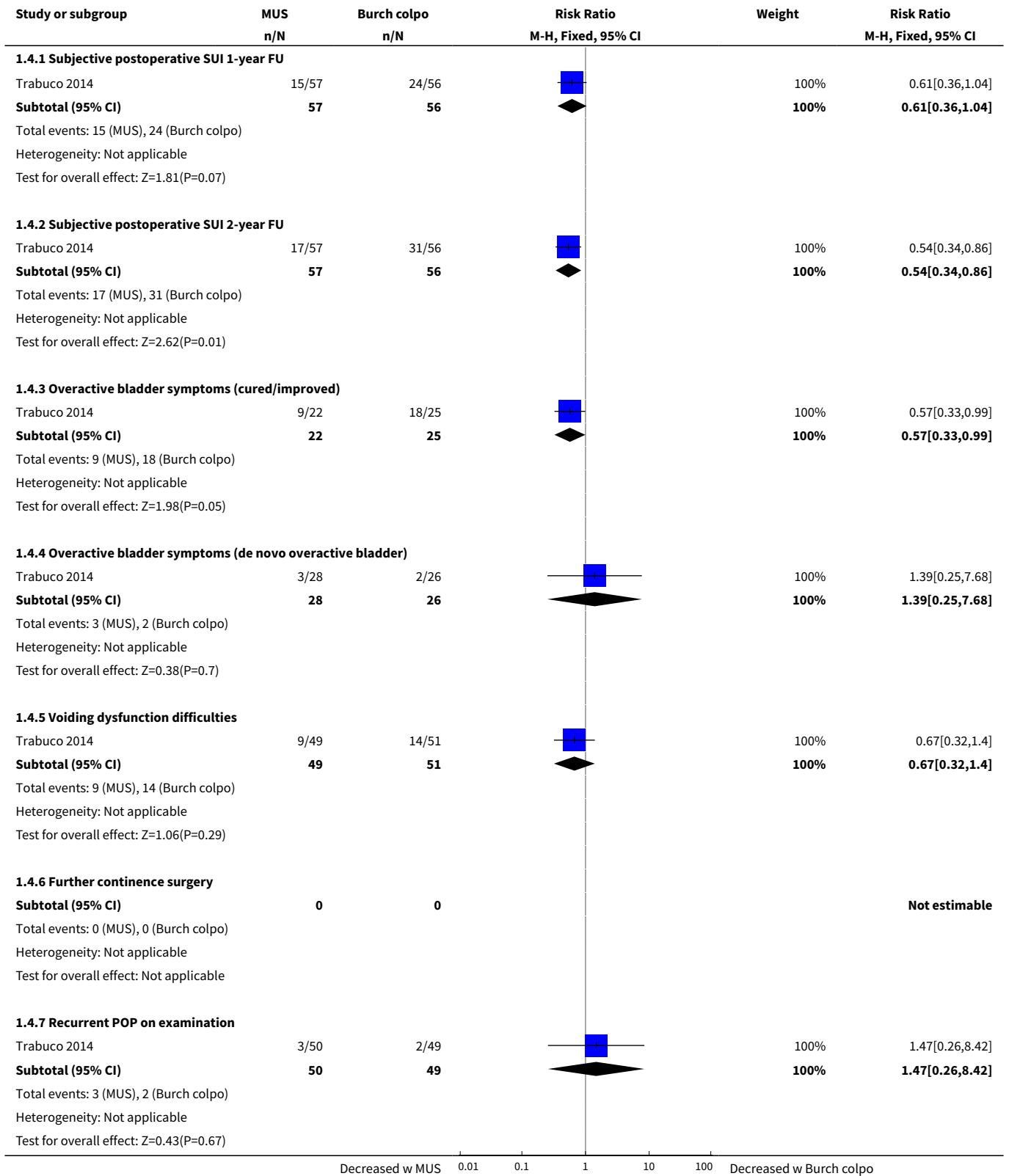
Analysis 1.2. Comparison 1 Comparisons of surgery in women with POP and SUI, Outcome 2 Vaginal POP surgery with concomitant vs delayed continence surgery: additional concomitant MUS vs delayed MUS.

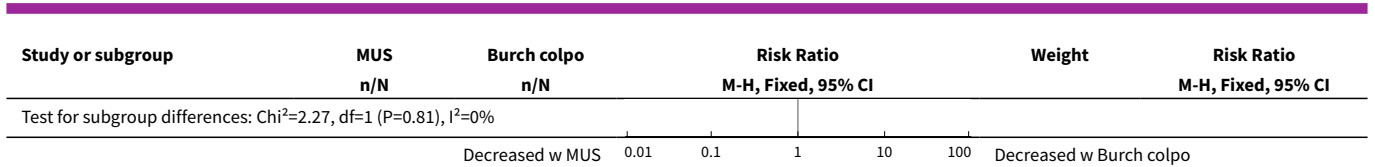
Study or subgroup	Concomitant MUS n/N	Delayed MUS n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
1.2.1 Subjective postoperative SUI					
Borstad 2010	4/87	6/53		100%	0.41[0.12,1.37]
Subtotal (95% CI)	87	53		100%	0.41[0.12,1.37]
Total events: 4 (Concomittant MUS), 6 (Delayed MUS)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.45(P=0.15)					
1.2.2 Recurrent POP on examination					
Subtotal (95% CI)	0	0			Not estimable
Total events: 0 (Concomittant MUS), 0 (Delayed MUS)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
1.2.3 Overactive bladder symptoms (cured/improved)					
Subtotal (95% CI)	0	0			Not estimable
Total events: 0 (Concomittant MUS), 0 (Delayed MUS)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
1.2.4 Overactive bladder symptoms (de novo overactive bladder)					
Subtotal (95% CI)	0	0			Not estimable
Total events: 0 (Concomittant MUS), 0 (Delayed MUS)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
1.2.5 Voiding dysfunction difficulties					
Subtotal (95% CI)	0	0			Not estimable
Total events: 0 (Concomittant MUS), 0 (Delayed MUS)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					
Test for subgroup differences: Chi ² =0, df=1 (P<0.0001), I ² =100%					
Decreased w delayed 0.01 0.1 1 10 100 Decreased w concomitant					

Analysis 1.3. Comparison 1 Comparisons of surgery in women with POP and SUI, Outcome 3 Abdominal POP surgery with vs without concomitant continence surgery: additional Burch colpo vs sacrocolpopexy alone.

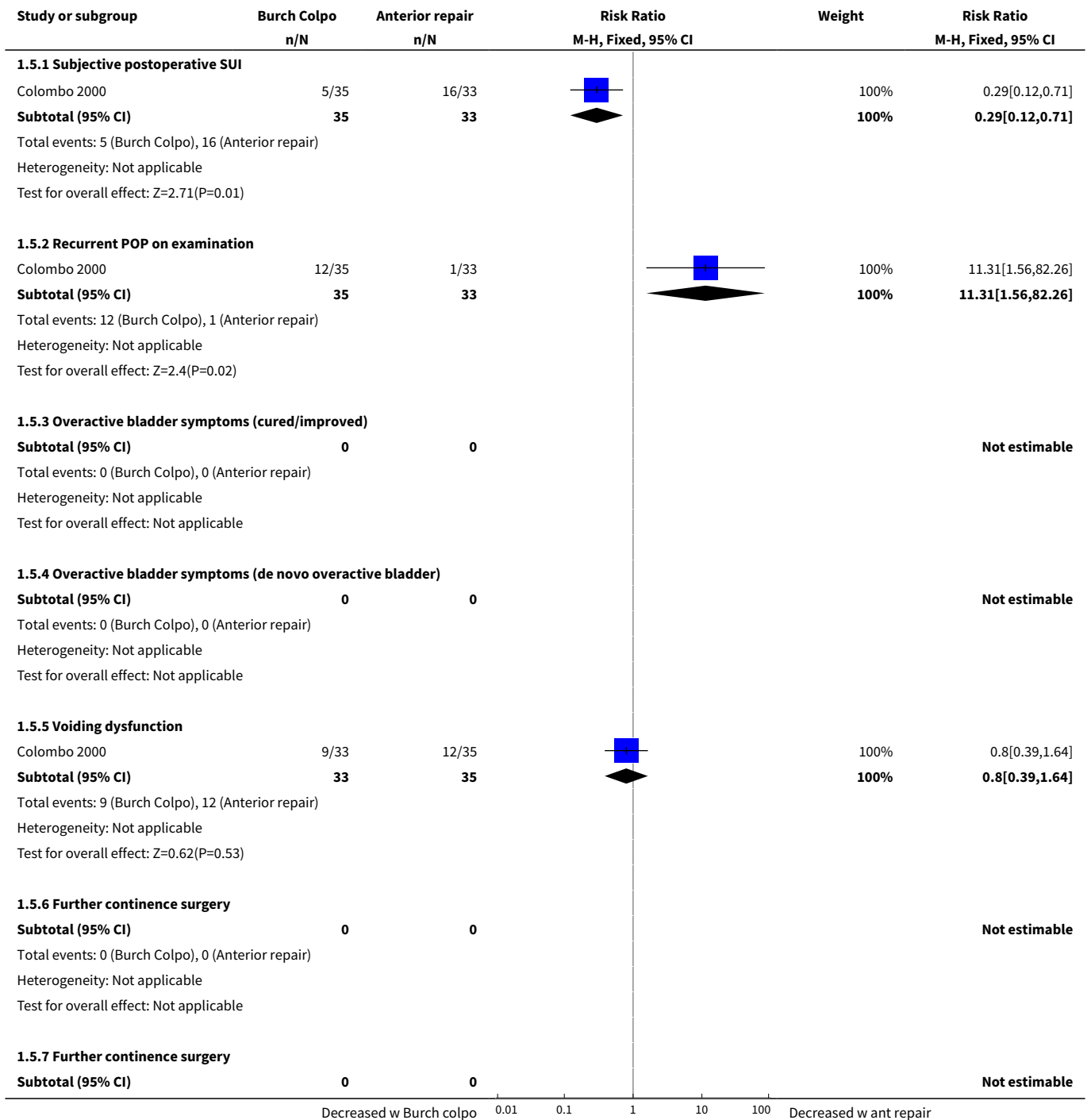


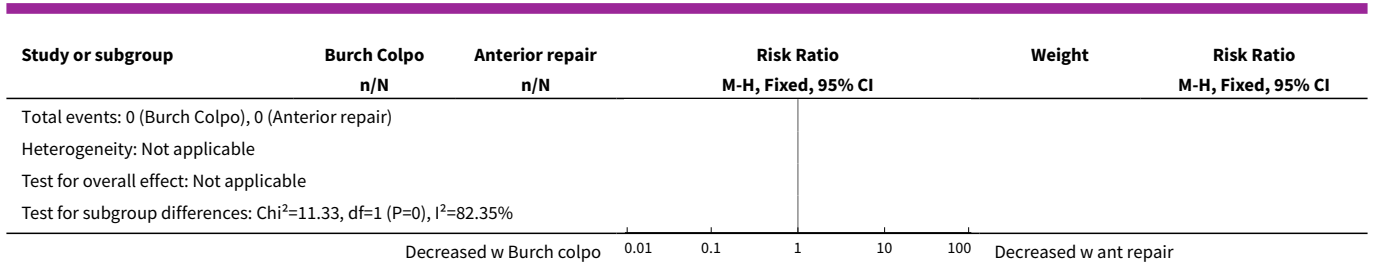
Analysis 1.4. Comparison 1 Comparisons of surgery in women with POP and SUI, Outcome 4 Abdominal POP surgery with different concomitant continence procedures: additional MUS vs Burch colpo at sacral colpopexy.





Analysis 1.5. Comparison 1 Comparisons of surgery in women with POP and SUI, Outcome 5 Abdominal continence surgery vs vaginal POP surgery: Burch colpo vs anterior repair.

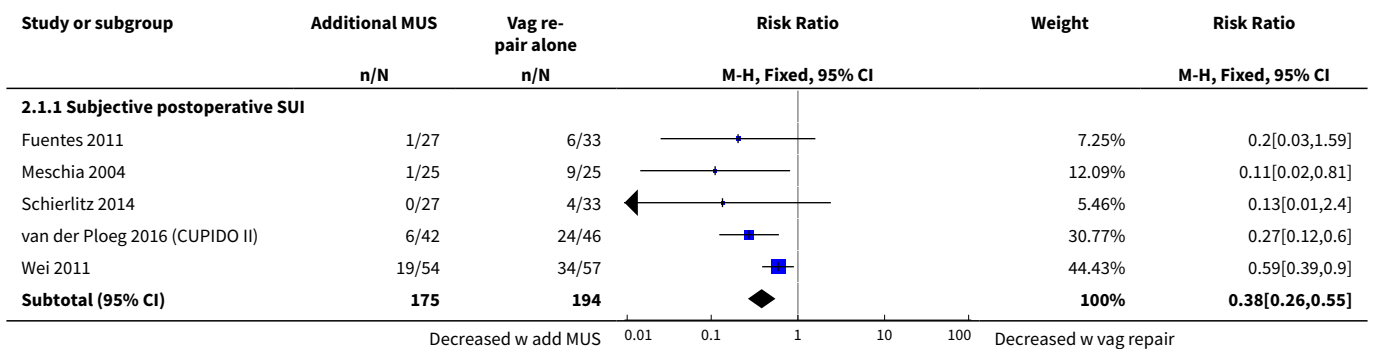


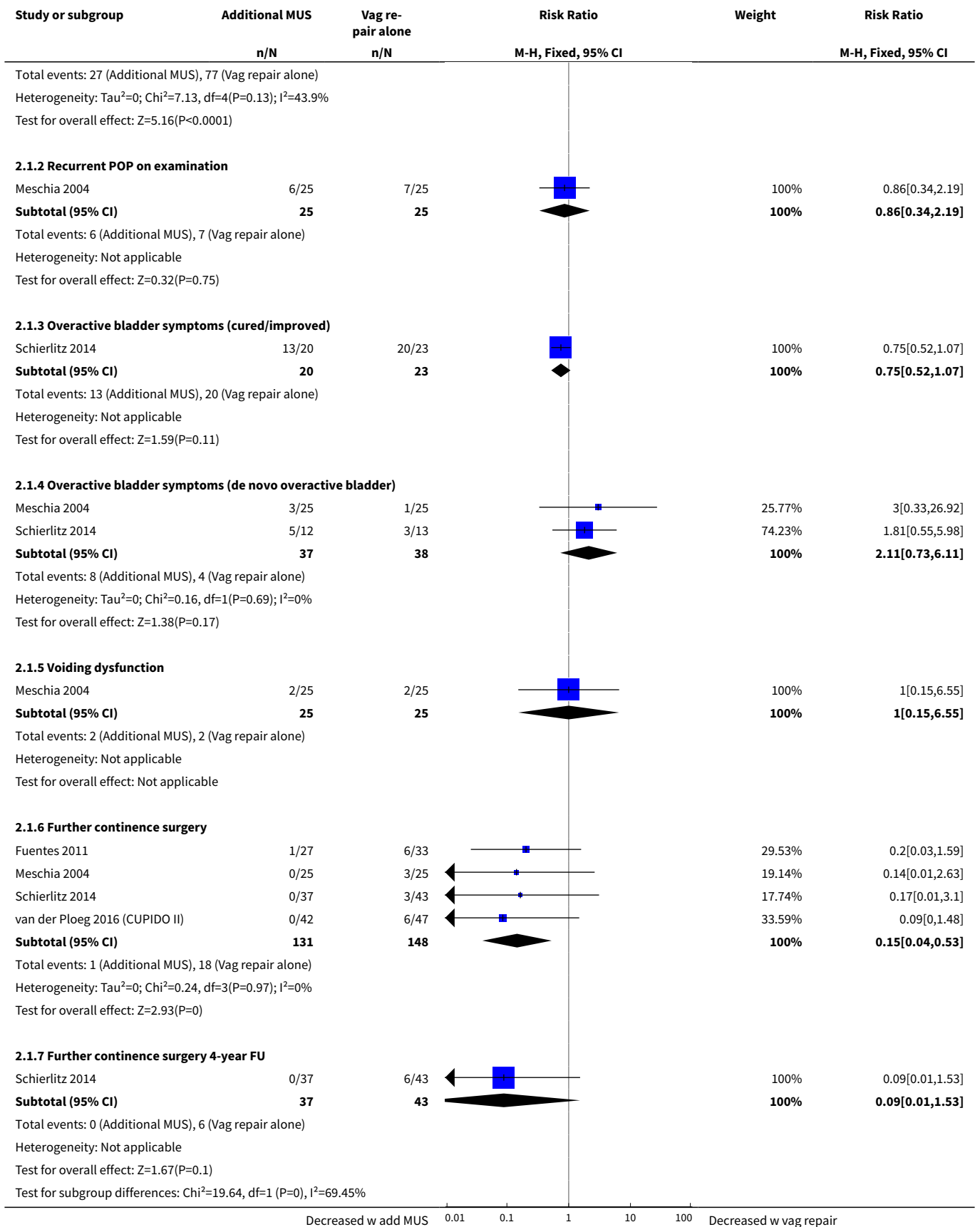


Comparison 2. Comparisons of surgery in women with POP and occult SUI

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal POP surgery with or without concomitant continence surgery: additional MUS vs vaginal repair alone	5		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Subjective postoperative SUI	5	369	Risk Ratio (M-H, Fixed, 95% CI)	0.38 [0.26, 0.55]
1.2 Recurrent POP on examination	1	50	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.34, 2.19]
1.3 Overactive bladder symptoms (cured/improved)	1	43	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.52, 1.07]
1.4 Overactive bladder symptoms (de novo overactive bladder)	2	75	Risk Ratio (M-H, Fixed, 95% CI)	2.11 [0.73, 6.11]
1.5 Voiding dysfunction	1	50	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.15, 6.55]
1.6 Further continence surgery	4	279	Risk Ratio (M-H, Fixed, 95% CI)	0.15 [0.04, 0.53]
1.7 Further continence surgery 4-year FU	1	80	Risk Ratio (M-H, Fixed, 95% CI)	0.09 [0.01, 1.53]

Analysis 2.1. Comparison 2 Comparisons of surgery in women with POP and occult SUI, Outcome 1 Vaginal POP surgery with or without concomitant continence surgery: additional MUS vs vaginal repair alone.



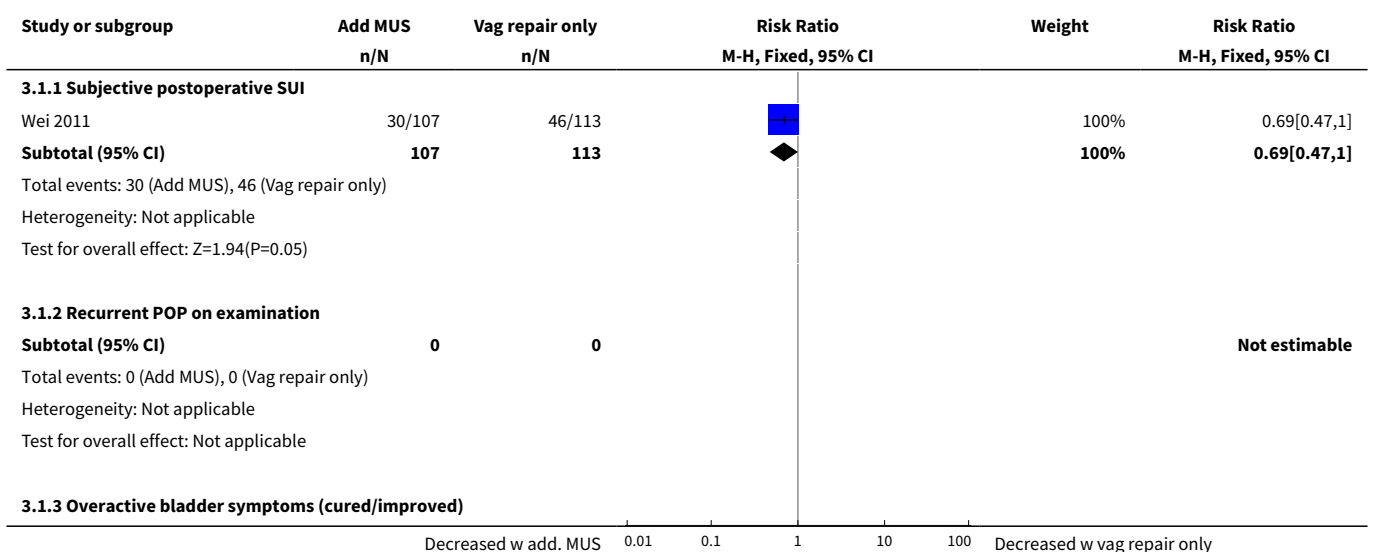


Comparison 3. Comparisons of surgery in continent women with POP

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal POP surgery with or without concomitant continence surgery: additional MUS vs vaginal repair alone	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Subjective postoperative SUI	1	220	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.47, 1.00]
1.2 Recurrent POP on examination	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.3 Overactive bladder symptoms (cured/improved)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.4 Overactive bladder symptoms (de novo overactive bladder)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.5 Voiding dysfunction	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.6 Further continence surgery	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Abdominal POP surgery with or without concomitant continence surgery: additional Burch colpo vs sacral colpopexy alone	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Subjective postoperative SUI/de novo SUI 1-year FU	2	379	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.49, 0.95]
2.2 Subjective postoperative SUI/de novo SUI 2 + years' FU	2	364	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.53, 0.99]
2.3 Overactive bladder symptoms (cured/improved)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.4 Recurrent POP on examination	1	250	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.74, 1.30]
2.5 Overactive bladder symptoms (de novo overactive bladder)	1	66	Risk Ratio (M-H, Fixed, 95% CI)	1.41 [0.25, 7.91]
2.6 Voiding dysfunction difficulties	1	66	Risk Ratio (M-H, Fixed, 95% CI)	8.49 [0.48, 151.59]
2.7 Further continence surgery	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Additional Burch colpo vs sacrocolpopexy alone: QoL data	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Postoperative UDI scores	1	194	Mean Difference (IV, Fixed, 95% CI)	-10.7 [-20.56, -0.84]
3.2 Postoperative PISQ scores	1	194	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-1.58, 1.38]
4 One type of POP surgery vs another: armed anterior mesh vs anterior native repair	7		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1 Subjective postoperative SUI	7	905	Risk Ratio (M-H, Fixed, 95% CI)	1.58 [1.05, 2.37]
4.2 Subjective postoperative SUI at 3 years	2	289	Risk Ratio (M-H, Fixed, 95% CI)	1.88 [1.01, 3.49]
4.3 Recurrent POP on examination	5	848	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.22, 0.38]
4.4 Overactive bladder symptoms (cured/improved)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.5 Overactive bladder symptoms (de novo overactive bladder)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.6 Voiding dysfunction difficulties	2	125	Risk Ratio (M-H, Fixed, 95% CI)	1.65 [0.22, 12.10]
4.7 Further continence surgery	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 3.1. Comparison 3 Comparisons of surgery in continent women with POP, Outcome 1 Vaginal POP surgery with or without concomitant continence surgery: additional MUS vs vaginal repair alone.



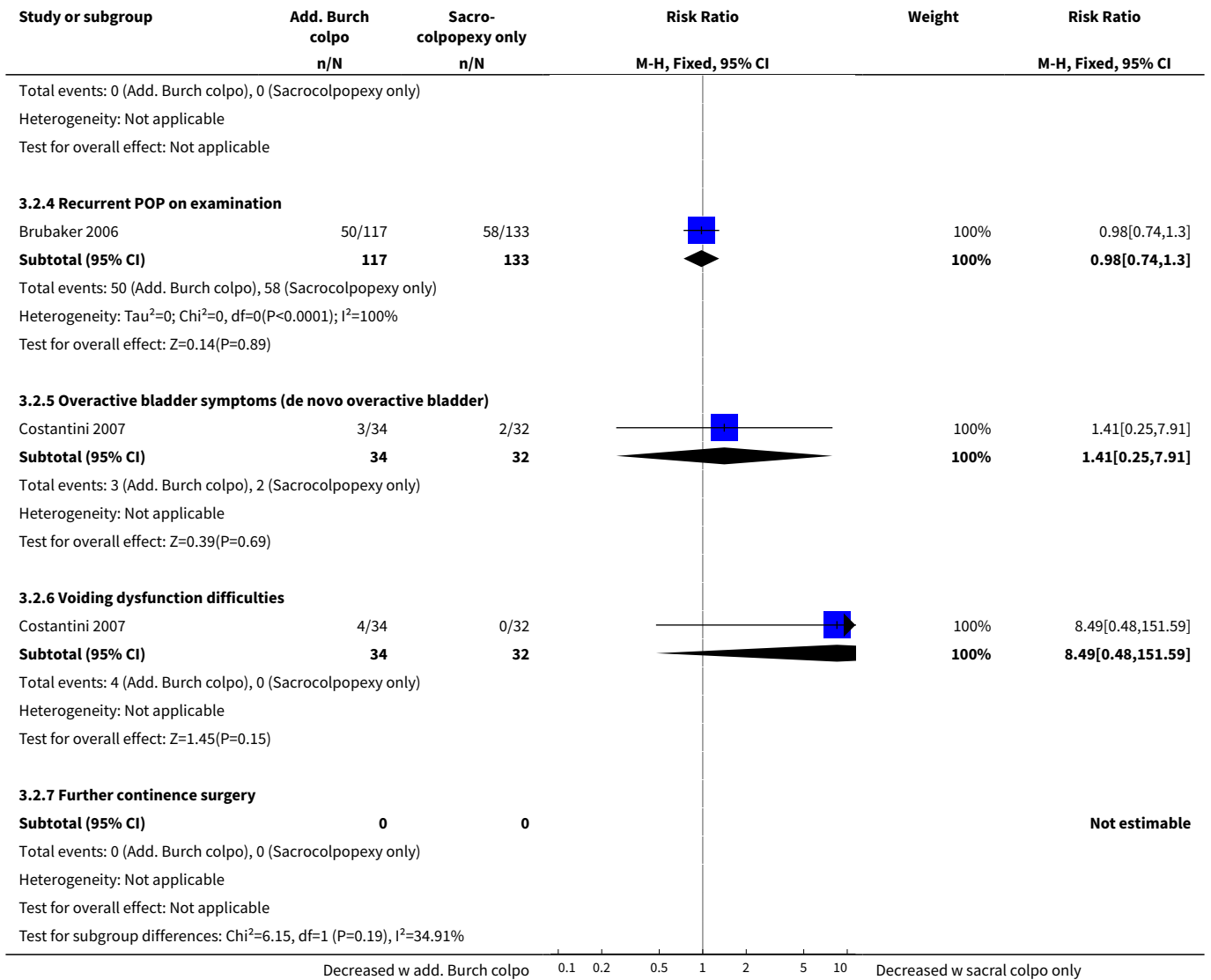
Study or subgroup	Add MUS n/N	Vag repair only n/N	Risk Ratio		Weight	Risk Ratio M-H, Fixed, 95% CI
			M-H, Fixed, 95% CI			
Subtotal (95% CI)	0	0				Not estimable
Total events: 0 (Add MUS), 0 (Vag repair only)						
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
3.1.4 Overactive bladder symptoms (de novo overactive bladder)						
Subtotal (95% CI)	0	0				Not estimable
Total events: 0 (Add MUS), 0 (Vag repair only)						
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
3.1.5 Voiding dysfunction						
Subtotal (95% CI)	0	0				Not estimable
Total events: 0 (Add MUS), 0 (Vag repair only)						
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
3.1.6 Further continence surgery						
Subtotal (95% CI)	0	0				Not estimable
Total events: 0 (Add MUS), 0 (Vag repair only)						
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
Test for subgroup differences: Not applicable						

Decreased w add. MUS 0.01 0.1 1 10 100 Decreased w vag repair only

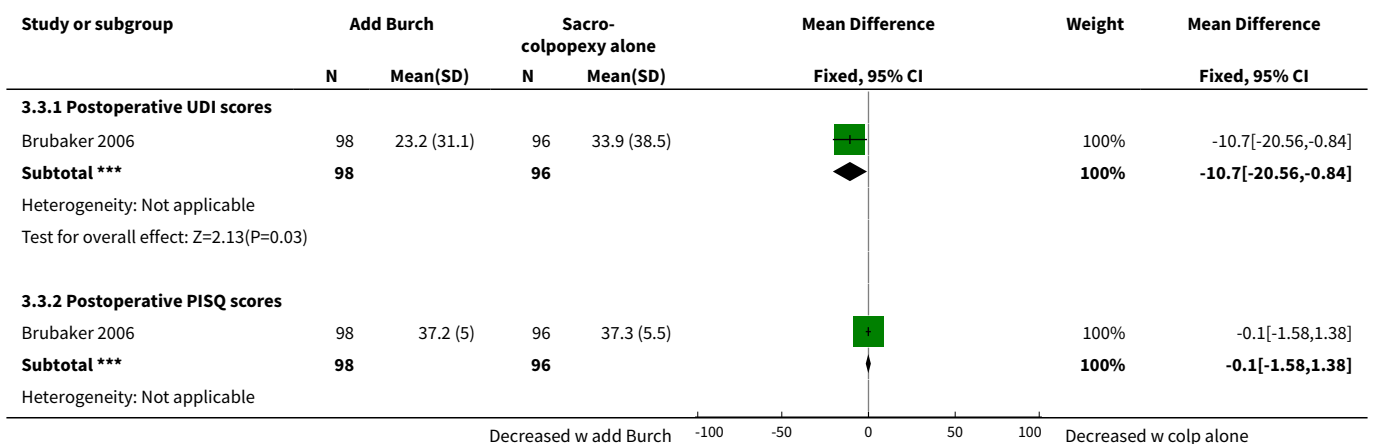
Analysis 3.2. Comparison 3 Comparisons of surgery in continent women with POP, Outcome 2 Abdominal POP surgery with or without concomitant continence surgery: additional Burch colpo vs sacral colpopexy alone.

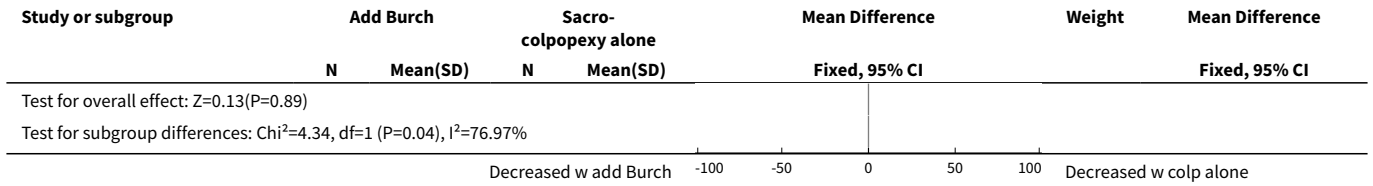
Study or subgroup	Add. Burch colpo n/N	Sacro-colpopexy only n/N	Risk Ratio		Weight	Risk Ratio M-H, Fixed, 95% CI
			M-H, Fixed, 95% CI			
3.2.1 Subjective postoperative SUI/de novo SUI 1-year FU						
Brubaker 2006	33/155	63/158			95.28%	0.53[0.37,0.76]
Costantini 2007	12/34	3/32			4.72%	3.76[1.17,12.12]
Subtotal (95% CI)	189	190			100%	0.69[0.49,0.95]
Total events: 45 (Add. Burch colpo), 66 (Sacrocolpopexy only)						
Heterogeneity: Tau ² =0; Chi ² =10.03, df=1(P=0); I ² =90.03%						
Test for overall effect: Z=2.25(P=0.02)						
3.2.2 Subjective postoperative SUI/de novo SUI 2+ years' FU						
Brubaker 2006	38/147	63/155			92.46%	0.64[0.46,0.89]
Costantini 2007	9/31	5/31			7.54%	1.8[0.68,4.76]
Subtotal (95% CI)	178	186			100%	0.72[0.53,0.99]
Total events: 47 (Add. Burch colpo), 68 (Sacrocolpopexy only)						
Heterogeneity: Tau ² =0; Chi ² =3.94, df=1(P=0.05); I ² =74.64%						
Test for overall effect: Z=2.04(P=0.04)						
3.2.3 Overactive bladder symptoms (cured/improved)						
Subtotal (95% CI)	0	0				Not estimable

Decreased w add. Burch colpo 0.1 0.2 0.5 1 2 5 10 Decreased w sacral colpo only

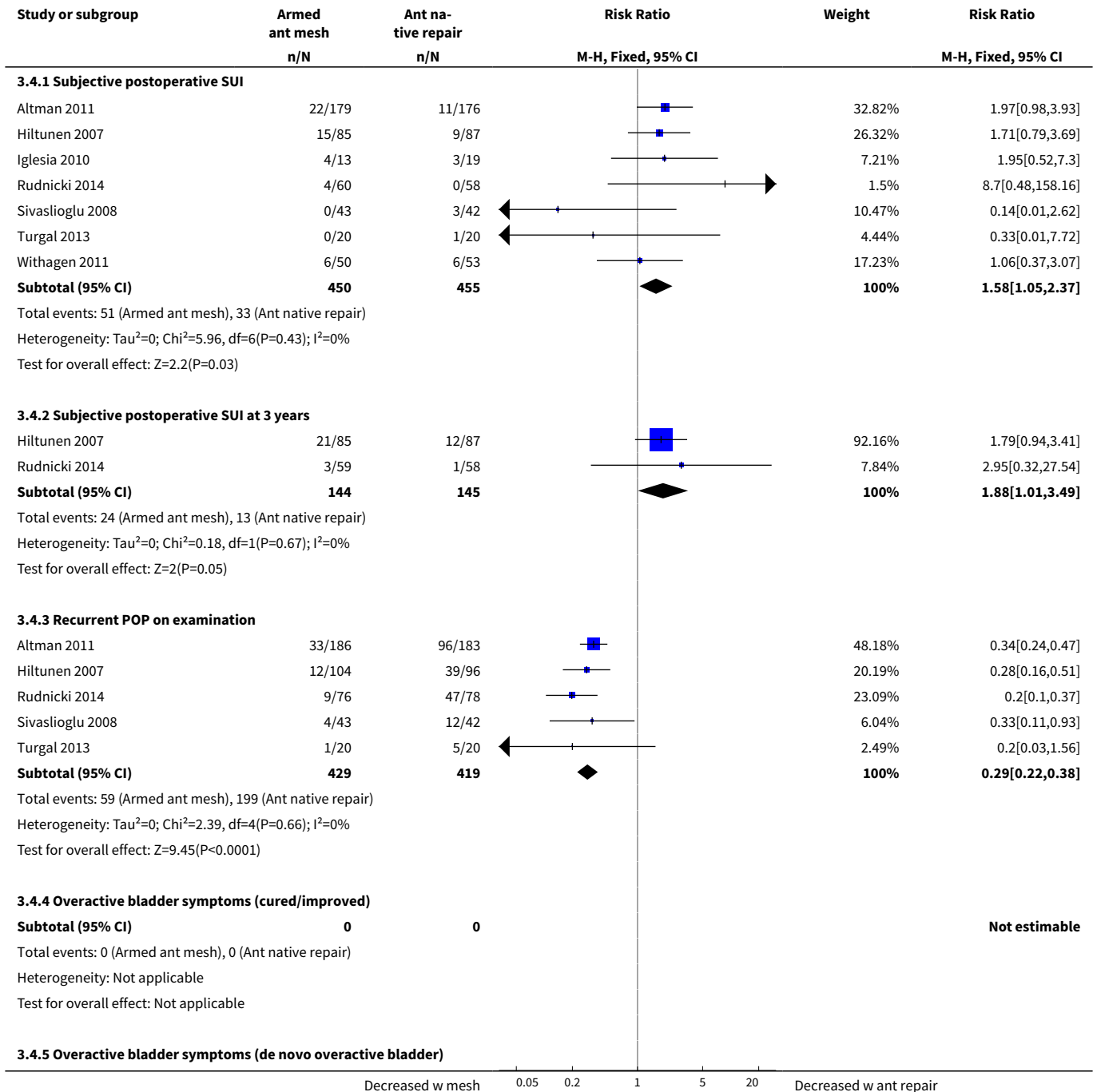


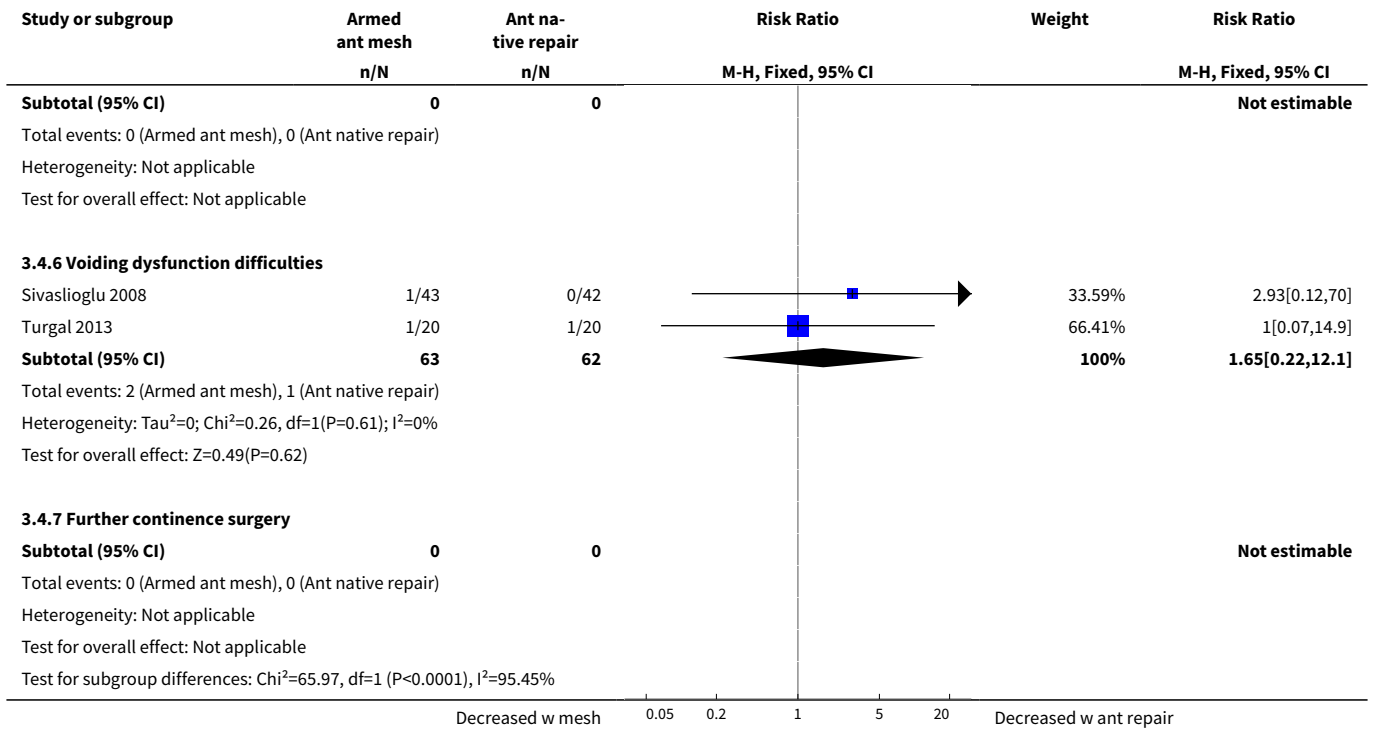
Analysis 3.3. Comparison 3 Comparisons of surgery in continent women with POP, Outcome 3 Additional Burch colpo vs sacrocolpopexy alone: QoL data.





Analysis 3.4. Comparison 3 Comparisons of surgery in continent women with POP, Outcome 4 One type of POP surgery vs another: armed anterior mesh vs anterior native repair.





APPENDICES

Appendix 1. Types of operations

Sacral colpopexy

Aim

To correct upper genital tract prolapse

Indication

Usually reserved for recurrent prolapse of the upper vagina (recurrent cystocele, vault, or enterocele) or massive vaginal eversion

Surgical technique

- Usually performed under general anaesthesia
- Performed through an incision on the lower abdomen or keyhole
- The bladder and rectum are freed from the vagina and permanent mesh supports the front and back wall of the vagina
- This mesh is secured to the sacrum (upper tailbone)
- Peritoneum (lining of the abdominal cavity) is closed over the mesh
- Other repairs are performed as required at the same time including paravaginal repair, perineoplasty, colposuspension, or rectopexy
- Bowel preparation is required before surgery

McCall culdoplasty

Indications

- Vault prolapse or an enterocele
- Often performed at the time of vaginal hysterectomy to prevent future prolapse

Surgical technique

- After the uterus is removed at the time of hysterectomy, the uterosacral ligaments are identified and incorporated into the closure of the peritoneum and upper vagina using 1 to 2 sutures
- An anterior or posterior vaginal repair is often performed at the same time

Sacrospinous fixation

Aim

This surgery offers support to the upper vagina, minimising risk of recurrent prolapse at this site. The advantage of this surgery is that vaginal length is maintained.

Indication

Upper vaginal prolapse (uterine or vault prolapse, enterocoel)

This procedure can be used in reconstructive vaginal surgery in which increased vaginal length is required.

Procedure

- The procedure can be performed under regional or general anaesthesia
- A routine posterior vaginal incision is made and is extended to the top of the vagina
- Through sharp dissection, the vagina is freed from the underlying rectovaginal fascia and rectum until the pelvic floor (puborectalis) muscle is seen
- Through sharp and blunt dissection, the sacrospinous ligament running from the ischial spine to the sacral bone is palpated and identified
- Two sutures are placed through the strong ligament and are secured to the top of the vagina. This results in increased support to the upper vagina. There is no shortening of the vagina
- Other fascial defects in the vagina are repaired and the vaginal skin is closed

Anterior vaginal repair (colporrhaphy)

Indication

- Prolapse of the bladder or urethra
- Sometimes used to treat urinary stress incontinence

Surgical technique

- The procedure can be performed under regional or general anaesthesia
- The vagina overlying the bladder and urethra is incised in the midline
- Dissection in a plane directly below the vagina allows the damaged fascia supporting the bladder and urethra to be exposed
- The fascia is plicated in the midline using delayed absorbable or permanent sutures
- Sometimes excessive vaginal skin is removed
- The vaginal skin is then closed
- Other sites of prolapse are then repaired as required

Posterior vaginal repair and perineoplasty

Indications

Treatment of rectocele (rectum bulges or herniates forward into the vagina) and defects of the perineum (area separating entrance of the vagina and anus)

Aim

Correct defects in the rectovaginal fascia separating rectum and vagina while allowing bowel function to be maintained or corrected without interfering with sexual function

Surgical technique

- An incision is made on the posterior wall of the vagina starting at the entrance and finishing at the top of the vagina
- Dissecting the vagina and rectovaginal fascia from the vagina until the pelvic floor muscles (puborectalis) are located
- Defects in the fascia are corrected by centrally plicating the fascia using delayed absorption sutures
- The perineal defects are repaired by placing deep sutures into the perineal muscles to build up the perineal body
- The overlying vaginal and vulval skin is then closed
- A pack is usually placed into the vagina and a catheter into the bladder at the end of surgery

Anterior or posterior vaginal repair, or both (colporrhaphy)

Indications

Anterior repair: treatment for prolapse of bladder (bladder bulges forward into the vagina; cystocele) or urethra.

Posterior repair: correction of bowel prolapse (rectum bulges forward into the vagina; rectocele).

Vault repair: treat prolapse of upper vagina.

Depending on the side of the defect, the repair can be anterior, posterior, vault, or total. The repair is achieved by the placement of permanent mesh that may result in a stronger repair.

Surgical technique

The procedure can be performed under regional or general anaesthesia.

Anterior vaginal repair

- Midline incision to the vagina overlying the bladder and urethra
- Dissection in a plane directly below the vagina and lateral of the bladder allows the damaged fascia supporting the bladder to be exposed
- The fascia is plicated in the midline using sutures
- Mesh can be used to reinforce the repair and can be used as an inlay, or anchored through the obturator foramen and exiting through small incisions at both sides of the upper inner thigh
- The vaginal skin is closed

Posterior and vault repair

- An incision is made to the posterior wall of the vagina
- Dissection below the vagina identifies the rectovaginal fascia and opens the space between the rectum and the pelvic floor muscle to the sacrospinous ligaments
- Defects in the fascia are corrected by centrally plicating the fascia using sutures
- Mesh can be used to reinforce the repair and can be used as an inlay or anchored bilaterally to the pelvic side wall and exiting through a small incision approximately 3 cm lateral and down from the anus
- The vaginal skin is then closed

Vaginal paravaginal repair

Aim: the objective of this surgery is to reattach detached lateral vaginal fascia to its normal point of insertion on the lateral side wall. This firm area of attachment is termed the white line or arcus tendineus fascia pelvis.

Indication

The repair of anterior wall prolapse due to defects of the lateral supporting tissues.

Procedure

The procedure can be performed under regional or general anaesthesia

Routine anterior repair

The sharp dissection of the vagina from the bladder fascia continues laterally until the pelvic side wall can be identified.

Permanent or delayed absorbable sutures are placed from the lateral vagina to the firm pelvic side wall tissue (white line or arcus tendineus fascia pelvis). Three to four sutures are placed on each side.

A routine anterior repair with midline plication of the fascia, trimming of excess vaginal skin as required, and closure of the vaginal skin.

WHAT'S NEW

Date	Event	Description
26 April 2018	New citation required and conclusions have changed	The addition of 5 new trials has led to a change to the conclusions of this review.

Date	Event	Description
26 April 2018	New search has been performed	Comparison of interventions for management of stress urinary incontinence was formerly part of the 2013 Cochrane review titled "Surgical management of pelvic organ prolapse in women". We now present this as a separate review. Five new trials are included that were not included in the previous review: Rudnicki 2014 ; Trabuco 2014 ; Turgal 2013 ; van der Ploeg 2015 (CUPIDO I) ; van der Ploeg 2016 (CUPIDO II) .

HISTORY

Review first published: Issue 8, 2018

Date	Event	Description
29 January 2013	New citation required but conclusions have not changed	Review updated incorporating 16 new trials
29 January 2013	New search has been performed	Review updated incorporating 16 new trials
14 April 2010	Amended	Changed citation; added conflicts
17 November 2009	New citation required but conclusions have not changed	<p>Full reports of 59 potentially eligible studies were assessed; for this update, 23 new eligible studies were assessed (Al-Nazer 2007a; Ali 2006a; Allahdin 2008; Barber 2006; Biller 2008; Borstad 2008; Braun 2007a; Carramao 2008a; Constantini 2008; de Tayrac 2008; Dietz 2008a; Glavind 2007; Guerette 2006a; Lim 2007a; Meschia 2007a; Natale 2007; Natale 2009; Nguyen 2008; Nieminen 2008; Pantazis 2008a; Schierlitz 2007a; Segal 2007; Sivaslioglu 2008). Overall, 17 studies were excluded from the review, six during this update (Barber 2006; Biller 2008; Carramao 2008a; Glavind 2007; Meschia 2007a; Segal 2007): full details are given in the "Characteristics of excluded studies" table.</p> <p>In this, the second update, 18 new trials were added (Al-Nazer 2007; Ali 2006; Allahdin 2008; Borstad 2008; Braun 2007a; Constantini 2007; Constantini 2008; de Tayrac 2008; Dietz 2008a; Guerette 2006; Lim 2007; Natale 2007; Natale 2009; Nguyen 2008; Nieminen 2008; Pantazis 2008; Schierlitz 2007; Sivaslioglu 2008) and 3 previously included studies were updated (Brubaker 2008; Meschia 2007; Roovers 2004).</p>
9 February 2009	New search has been performed	New search February 2009
10 October 2008	Amended	Converted to new review format
17 April 2007	New citation required and conclusions have changed	Substantive Update, Issue 3, 2007. 22 RCTs (8 new included trials). Findings are still insufficient to provide robust evidence to support current and new practice (such as whether to perform a concurrent continence operation, or to use mesh or grafts).

CONTRIBUTIONS OF AUTHORS

All review authors contributed to writing the protocol. Three review authors (K Baessler, C Christmann-Schmid, C Maher) assessed the relevance and eligibility of studies for inclusion in the 2018 review. They then assessed the quality of included studies; independently extracted data from trial reports, interpreted the results, and contributed to the writing of the draft version of the review. All review authors read and approved the review.

DECLARATIONS OF INTEREST

KB, JB, CC, TC, NH, and CM have no conflicts of interest to declare.

SOURCES OF SUPPORT

Internal sources

- Cochrane, UK.
Cochrane Review Support Programme: pelvic organ prolapse reviews

External sources

- National Institute for Health Research (NIHR), Other.

This project was supported by the NIHR, via Cochrane Infrastructure funding to the Cochrane Incontinence Group. The views and opinions expressed therein are those of the review authors and do not necessarily reflect those of the Systematic Reviews Programme, the NIHR, the NHS, or the Department of Health.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

2013: there were no changes from the protocol. The protocol was written with available studies and clinical needs in mind.

2018: a comparison of surgical interventions for management of continence outcomes was formerly part of the 2013 Cochrane review "Surgical management of pelvic organ prolapse in women". We now present this as a separate review.

INDEX TERMS

Medical Subject Headings (MeSH)

*Suburethral Slings; Pelvic Organ Prolapse [*complications] [*surgery]; Randomized Controlled Trials as Topic; Surgical Mesh; Urinary Incontinence, Stress [*complications]

MeSH check words

Female; Humans