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[Intervention Review]

Shouldice technique versus other open techniques for inguinal hernia repair

Bruno Amato¹, Lorenzo Moja², Salvatore Panico³, Giovanni Persico⁴, Corrado Rispoli⁵, Nicola Rocco⁶, Ivan Moschetti⁷

¹Dipartimento di Chirurgia Generale (Edif. 6), Università degli Studi di Napoli, Napoli, Italy. ²Department of Biomedical Sciences for Health, University of Milan, Milan, Italy. ³Clinica Medica, AUP FEDERICO II NAPOLI, Napoli, Italy. ⁴Department of General Surgery, Geriatrics and Endoscopy, University of Naples Federico II, Naples, Italy. ⁵Department of General Surgery, PO Ascalesi, Naples, Italy. ⁶Department of General, Geriatric surgery, diagnostic and operative endoscopy, Faculty of Medicine and Surgery, University Federico II of Naples, Naples, Italy. ⁷Italian Cochrane Centre, Mario Negri Institute for Pharmacological Research, Milan, Italy

Contact address: Bruno Amato, Dipartimento di Chirurgia Generale (Edif. 6), Università degli Studi di Napoli, Via S. Pansini, 5, Napoli, 80131, Italy. bramato@unina.it.

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ABSTRACT

Background

Inguinal hernia repair is the most frequent operation in general surgery. There are several techniques: the Shouldice technique is sometimes considered the best method but different techniques are used as the "gold standard" for open hernia repair. Outcome measures, such as recurrence rates, complications and length of post operative stay, vary considerably among the various techniques.

Objectives

To evaluate the efficacy and safety of the Shouldice technique compared to other non-laparoscopic techniques for hernia repair.

Search methods

We searched MEDLINE, EMBASE, and The Cochrane Central Register of Controlled Trials (CENTRAL), April 2008 and updated the searches September 2011, for relevant randomised controlled trials.

Selection criteria

Any randomised or quasi-randomised controlled trials (RCT) on the treatment of primary inguinal hernia in adults were considered for inclusion.

Data collection and analysis

All abstracts identified by the search strategies were assessed by two independent researchers to exclude studies that did not meet the inclusion criteria. The full publications of all possibly relevant abstracts were obtained and formally assessed. Missing or updated information was sought by contacting the authors.

Main results

Sixteen trials contributed to this review. A total of 2566 hernias were analysed in the Shouldice group with 1121 mesh and 1608 non-mesh techniques. The recurrence rate with Shouldice techniques was higher than mesh techniques (OR 3.80, 95% CI 1.99 to 7.26) but lower than non-mesh techniques (OR 0.62, 95% CI 0.45 to 0.85). There were no significant differences in chronic pain, complications and post-operative stay. Female were nearly 3% of included patients.

Shouldice technique versus other open techniques for inguinal hernia repair (Review)

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Authors' conclusions

Shouldice herniorrhaphy is the best non-mesh technique in terms of recurrence, though it is more time consuming and needs a slightly longer post-operative hospital stay. The use of mesh is associated with a lower rate of recurrence. The quality of included studies, assessed with Jaded scale, were low. Patients have similar characteristics in the treatment and control group but seem more healthy than in general population, these features may affect the dimension of effect in particular recurrence rate could be higher in general population. Lost to follow-up were similar in the treatment and control group but the reasons were often not reported. The length of follow-up varies broadly among the studies from 1 year to 13.7 years.

PLAIN LANGUAGE SUMMARY

Shouldice technique is better than other open techniques, not using mesh

Inguinal hernia is a very common disease that mainly affects men in young and middle age and its repair is the most frequent operation in general surgery. Hernias present as bulges in the groin area that can become more prominent when coughing, straining, standing up and in all situations where the abdominal pressure grows. If uncomplicated they are rarely painful, and the bulge commonly disappears on lying down. There are various surgical strategies which may be considered in the planning of inguinal hernia repair. These include the consideration of mesh use (mesh is a prosthesis made up of a net of synthetic material that helps to counteract abdominal wall tension). A tension-free repair method has been proposed to achieve better results in terms of pain and infections and to avoid the problem of presenting again (recurrence).

We found that the Shouldice technique is the best way to cure an inguinal hernia without using a prosthesis in terms of recurrence. The use of a prosthesis reduces the recurrence even more. The persisting pain, post-operative stay and complications after the intervention do not show significant differences between the techniques. Nevertheless, the methodological quality of the most included studies is low, length of follow-up is different among studies and findings lack in patients-oriented outcomes so the unwelcome results, particularly in patients with chronic disease, for example diabetic or patients under steroidal therapy, should be considered with caution.

BACKGROUND

Inguinal hernia repair is the most frequent operation in general surgery (Schumpelick 1994; Rutkow 2003; Mc Vay 1978). Since Bassini introduced his method for radical treatment of inguinal hernia (Bassini 1887), opening the modern era of herniorrhaphy, many other techniques have been developed using tension sutures between musculo-aponeurotic tissues. These so-called "non-mesh" techniques have since been followed by many procedures that use synthetic fabrics made of various polymers to reinforce weak tissues ("mesh" techniques). Recurrence rates (reappearance of the hernia) vary considerably for the various techniques: reports vary from less than 5% to 25% (Grant 2002) and many of these recurrent hernias need repeated surgery (SHR 2002; Nilsson 1993). Improving the results would therefore have a useful medical and economic impact. The best results are achieved by surgeons reporting personal series using standard surgical procedures (Glassow 1986; Lichtenstein 1987; Wantz 1989). Some authors consider the Shouldice technique the best conventional method for open hernia repair (Bendavid 1997; Arvidsson 2005; Schippers 1996) while others prefer the Lichtenstein technique, achieving lower recurrence rates and shorter operating times (Nordin 2002). The main differences between the Shouldice technique and the other herniorrhaphies are the excision of the weakened fascia transversalis and the reconstruction of posterior wall of the inguinal canal with a running suture in three or four layers (Benard 1986; Devlin 1986). Recurrence rates for the Shouldice technique in specialist centres are as low as 0.6 - 1.4% (Schumpelick 1994; Glassow 1986; Wantz 1989). However, under trial conditions in non-specialised centres they range between 0 and 10% (Arlt 2002; Tons 1991; Kux 1994; Hoffmann 1991; Oosterhuis 1986; Tran 1992; Paul 1994; Panos 1992; Kingsnorth 1992; Fingerhut 1993; Kux 1994b). The superiority of this technique is therefore uncertain (Simons 1996). Moreover, chronic pain is common after repair, and it is not clear to what extent the different techniques influence its incidence (Koninger 2004). Some authors report a lower incidence of chronic pain after the Shouldice technique, while others found no difference after different operative techniques (Bay-Nielsen 2004).

Even though the last search (2011) for additional included studies identified no new evidence, we decided to present this updated review, because Shouldice repair can be still the objective of new research (Higgins 2008).

OBJECTIVES

The primary objective of this review is to evaluate the efficacy of the Shouldice technique compared to other non-laparoscopic techniques in reducing inguinal hernia recurrence rates in adults.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised (allocating participants to a treatment on a not strictly random basis e.g. date of birth, hospital record number or alternation) controlled trials on the treatment of inguinal hernia were considered for inclusion. If the randomisation method was not specified the trial was included anyway. Trials in any language were included. We also considered studies including

either primary and recurrent inguinal hernia when the report allowed the separate extraction of data on the primary repair.

Types of participants

Adults (age >18 years) of either sex presenting for treatment of primary inguinal hernia were included. The only specific definition of inguinal hernia was a groin protrusion. We excluded patients referred for femoral hernias.

Types of interventions

Treatment group:

All forms of Shouldice technique, performed in the standard manner or slightly modified (e.g. differences in suture materials, number of layers).

Control group:

The surgical strategies were classified as:

- "mesh" techniques (synthetic fabrics to reinforce weakened tissues):
 - Lichtenstein;
 - Plug and mesh;
 - Stoppa;
 - Trabucco.
- "non-mesh" techniques (tension sutures between musculo-aponeurotic tissues):
 - Plication darn;
 - Bassini;
 - McVay.

There were three possible comparisons:

- Shouldice versus "mesh" techniques;
- Shouldice versus "non-mesh" techniques;
- Shouldice versus all techniques.

Types of outcome measures

Primary outcome

Recurrence of hernia defined as a clinically manifest bulge or protrusion exacerbated by a Valsalva manoeuvre in the operated groin. The assessor could be a surgeon, a physician or the patient himself. For the primary outcome we considered studies with at least one year follow-up .

Secondary outcome:

- Postoperative hospital stay (days).
- Chronic pain, i.e. pain persisting for more than three months (only presence or absence)
- Post-operative satisfaction (including general satisfaction and satisfaction with appearance. Numbers of participants dissatisfied, or the level of dissatisfaction on a visual analogue scale (0-100) at the end of the trial were used).
- Other complications, such as wound infection (SSI), hematoma and seroma

- Conversion to the "opposite" technique after the procedure had started.
- Duration of operation (minutes).

Search methods for identification of studies

The following databases were searched for relevant articles:

The Cochrane Library, EMBASE, MEDLINE.

Data collection and analysis

Eligibility

All abstracts identified by the above search strategies were assessed by two independent researchers to exclude studies that did not meet the inclusion criteria. The full publications of all possibly relevant abstracts were obtained and formally assessed for inclusion. Review authors were not blinded to the names of the authors, their institutions, the journal of publication, or the results.

Data extraction

A data extraction form was developed to record details of study design, participants, setting and timing, interventions, patients characteristics, follow-up and outcomes. Data was extracted independently by two authors (CR and NR), seeking information on the patients: age, activities (i.e. job, sport, hobbies), health status (i.e. COPD, constipation, prostatism), hernia bilaterality, type of study, surgical techniques (standard or modified manner, kind of mesh, duration of intervention), outcomes, follow-up, enter all data from the original articles onto specially designed, pre-tested paper forms. Where a difference of opinion arose between reviewers, they were resolved through discussion with a third author (LM). Missing or updated informations were sought by contacting study authors.

Assessment of methodological quality

All studies that met meet the selection criteria were assessed for methodological quality, as recommended by the Cochrane Collaboration's Reviewers' Handbook ([CC Handbook 2008](#); [Deeks 2006](#)).

The internal validity of individual trials was assessed using the scale devised by Jadad et al. ([Jadad 1996](#)) and a single-component approach exploring some important potential sources of bias:

1. The comparability of patients in the treatment and control groups (type of hernia, sex, age, abdominal pressure factors and bilaterality);
2. The randomizations method and concealed treatment allocation;
3. Exclusions after randomisation or losses to follow-up without appropriate intention-to-treat analysis (particularly if related to one or other surgical approaches);
4. Ascertainment of outcome where knowledge of the allocation might have influenced the outcome measurement (we stress the importance of an independent assessor for diagnosis of recurrence ([Schulz 1996](#); [Smythe 1977](#)), e.g. a surgeon unaware of the procedure performed).

Analysis of data from individual trials

Dichotomous outcomes

Dichotomous outcomes (e.g., presence/absence of chronic pain) were reported as proportions (or response rates for each treatment) and compared directly (difference in proportions). We used these proportions to calculate odds ratios (OR), absolute risk reductions (risk differences), and numbers-needed-to-treat (NNT), with 95% confidence intervals (CI). NNT were calculated as the reciprocal of the absolute risk reduction ([Altman 1998](#)). For unwanted effects (e.g., adverse events), the NNT becomes the number-needed-to-harm (NNH), and was calculated in the same way.

Ordinal outcomes

When outcome data were provided on an ordinal scale (e.g., for chronic pain: none, mild, moderate, severe, extremely severe), we selected a threshold based on the definition of clinically significant improvement and converted these data into dichotomous form. When it was not possible to split ordinal data into dichotomous outcomes meeting our *a priori* definition and no continuous data were reported, we assigned a numeric score to each category and analyse the results as continuous data.

Continuous outcomes

For continuous data (e.g., duration of intervention), results are presented as weighted mean differences (WMD). However, when different scales were used to measure the same outcome, standardized mean differences (SMD) are used instead. We expected some studies to report treatment and control group means, without any data on the variance associated with these means. In such cases, we calculated or estimated variances based on primary data or test statistics, if these were reported.

Combining results across studies

For each broad comparison of surgical techniques (mesh/non-mesh), we conducted a summary analysis of data on primary outcomes to provide an overall quantitative estimate of the relative Shouldice effect. The final summary analysis was conducted irrespective of the mesh comparator status (Shouldice vs. all techniques).

We did not combine data from trials judged by consensus to be too clinically heterogeneous. When outcomes were reported at different time points greater than one year, data were pooled for each point and combined with data from other trials at similar time points. This allowed an estimate of the onset and persistence of treatment effect, at least over the time points available for combination of the data. A decision about which time points to be included in the final analysis was made by consensus after the data were collected with preference to outcomes measured at the end of the treatment period but also with the goal of comparing them if possible. outcomes at different points. We used the Cochrane Collaboration software Review Manager 5 (RevMan 5) for the figures and statistical analyses.

Heterogeneity

Heterogeneity of effect sizes was assessed using the Z score and the Q (Chi-square) and I-squared statistic. The Q (Chi-square) statistic was set at $P < 0.10$ because of the low statistical power of the test. I^2 indicates the percent variability due to between or inter-study variability as opposed to within or intra-study variability. An I-squared value greater than 50% was considered large ([Higgins 2002](#)). If statistical evidence was obtained for homogeneity of effect sizes, the analysis was to use a fixed-effect model ([Deeks 2001](#)). Where there was significant statistically heterogeneity, a careful clinical review of the data was done to find the source ([Thompson](#)

2001). The reviewers then decided either: (1) to redo the analysis using the homogenous subgroup (only if there was a clear and compelling reason to exclude the heterogeneous data can be made); (2) to abandon statistical combining of the trials in favour of a narrative review of the literature; or (3) to redo the analysis using the random-effects model. (DerSimonian 1986).

Sensitivity and subgroup analyses

We planned a sensitivity analyses to explore how the following factors influenced the effect size:

1. Repeating the analysis taking account of study quality, as specified above;
2. Repeating the analysis excluding any very long or large studies to establish how much they dominate the results.

Subgroup analyses were done to explore effect size differences, as follows:

1. Setting (specialised/non specialised surgery centre);
2. Trial country (Canada/other countries).

Evidence and clinical implications will be graded based on the quality single-component approach in the following order of preference: detection bias, selection bias and attrition bias. Discordance between data sources was resolved using this grading system, with higher-graded studies taking precedence over lower-graded one.

RESULTS

Description of studies

From the searches performed in April 2008, we identified 225 eligible studies; 111 were duplicates and were removed. According to the title or the abstract, 74 studies were excluded because they did not meet the inclusion criteria: 24 were not RCTs, 31 were about laparoscopic techniques and 19 papers were outside of the topic. Forty study reports were considered potentially relevant and the full text was sought.

The updated search (September 2011) revealed one study (Prieto-Diaz-Chavez 2009), potentially eligible for inclusion, but excluded because data about primary inguinal hernia were not extractable.

We could not find the full text of four papers (Pyka 2003; Stanislawek 2003; Strand 1998; Panos 1992) in either digital or in hard version and it was not possible to contact the authors; these articles were excluded. Sixteen articles were excluded because they did not meet the inclusion criteria (see 'Characteristics of excluded studies' table). The most common reason for exclusion was not being a RCT. Five studies are still awaiting classification because of translation (Koning 1998; Kux 1994; Mittelstaedt 1999; Schmitz 1997; Porrero 2005).

The characteristics of the 16 studies included are summarised in the "Characteristics of included studies" table, and assessment of the methodological quality of these 16 studies are presented in Table 1. All the authors of the included studies were contacted by mail to obtain further information. All additional data was considered unpublished data.

Sixteen trials were included in this review: the earliest were published in 1992 (Kingsnorth 1992; Tran 1992) and the most recent in 2004 (Miedema 2004; Koning 2004).

A total of 2566 hernias were analysed in the Shouldice group and compared with 1121 mesh techniques and 1608 non

mesh techniques. Of the 16 studies included: seven compared the Shouldice technique versus mesh techniques (Barth 1998; Danielsson 1999; Hetzer 1999; Koning 2004; McGillicuddy 1998; Nordin 2002; Zieren 1998), eight studies compared Shouldice and non mesh techniques (Beets 1997; Hay 1995; Kingsnorth 1992; Kovacs 1997; Kux 1994b; Paul 1994; Thapar 2000; Tran 1992), one study compared Shouldice with both mesh and non-mesh techniques (Miedema 2004). All the sixteen studies considered a Shouldice hernioplasty using layers of unabsorbable continuous suture (Shouldice 1945; Glassow 1986); one study also considered a two-layer Shouldice arm (Kux 1994b) and was excluded from the analysis. All the mesh hernioplasties were done according to the Lichtenstein technique (Lichtenstein 1989), except for one (Zieren 1998) that was a plug and mesh reconstruction (Rutkow 2003). Non-mesh procedures were performed either according to the Bassini technique (Bassini 1887; Wantz 1989) in five studies (Beets 1997; Hay 1995; Kovacs 1997; Kux 1994b; Paul 1994); or according to the Mc Vay technique (Mc Vay 1978) in two studies (Hay 1995; Miedema 2004); and finally one study (Thapar 2000) used the Moloney's herniorrhaphy technique (Moloney 1972). The mean number of patients randomised in the included studies was 331 and ranged from 50 (Hetzer 1999) to 1647 (Hay 1995).

Even though the Shouldice technique was developed in Canada most of the included trials were performed and conducted in Europe and USA. None of the included studies were from Canada. Only one trial (McGillicuddy 1998) was performed in a centre specialized in hernia repair; the others were in general surgery units.

CHARACTERISTICS OF OUTCOME MEASURES

Recurrence rate

Thirteen of the included studies (Danielsson 1999; Hay 1995; Kingsnorth 1992; Kovacs 1997; Kux 1994b; McGillicuddy 1998; Miedema 2004; Nordin 2002; Paul 1994; Thapar 2000; Tran 1992; Zieren 1998) reported the recurrence rate, which was one of the most commonly recorded outcomes. Given that the timing of follow-up to recurrence varied widely, recurrence rates were analysed at the longest follow-up. Follow-up varied between one year (Danielsson 1999; Kovacs 1997) and 13.7 years (Beets 1997) with a mean of 3.6 years. Seven studies considered recurrence as a lump in the groin not necessarily repaired; one considered a bulge at the operated groin and operated again, and four did not specify what they considered as a recurrence.

Length of post-operative stay

Eight studies reported the post-operative stay, as the mean, in days +/- SD. Data expressed in hours were converted to days. When variability was reported as range or SEM, those data were converted to SD.

Chronic pain

Seven studies reported data for pain persisting for more than eight weeks. If different times of follow-up were available, only the longest was considered.

Other complications

13 studies reported data about surgical site infection. Only four reported the incidence of seroma; testicular atrophy was reported in five studies and haematoma was reported as an outcome in ten papers.

Duration of the operation

Seven studies reported the duration of the operation, expressed as minutes in the operating room.

Risk of bias in included studies

- Randomization methods (allocation concealment and generation sequence)

Most trials did not describe the generation of the random sequence or an adequate method to conceal allocation. Only one (Miedema 2004) reported a good method of allocation concealment (randomizations list held by a person not associated with the study) and proper sequence generation (random digit table). Of the remaining trials three (Nordin 2002; Paul 1994; Zieren 1998) reported the use of random number tables or computer randomisation but did not give any information about the allocation concealment; five trials (Beets 1997; Butters 2007; Hay 1995; Kingsnorth 1992; Thapar 2000) reported only allocation concealment and four (Barth 1998; Danielsson 1999; Kux 1994b; Tran 1992) did not give any information about randomizations or allocation concealment. Three trials (Hetzer 1999; Kovacs 1997; McGillicuddy 1998) used an inadequate method of randomizations (tossing a coin) or did not use any method and the method of allocation concealment was also considered inadequate for these trials.

- Dropouts and withdrawals

Reporting of drop-outs and withdrawals was unsatisfactory in most trials and intention-to-treat analysis was very rare. Twelve trials reported data about exclusions after randomizations (four also specified the reasons). Dropout rate and length of follow-up differed significantly between trials from 0% (Thapar 2000; Zieren 1998) to 51.8% (Kovacs 1997); 614 patients were lost to follow-up (15.5%). Four studies had 20% or more losses to the longest follow-up (Koninger 2004; Kovacs 1997; McGillicuddy 1998; Miedema 2004). Losses to follow-up did not vary between treatment and control groups in any study. Mean follow-up was 3.6 years (from 7 days (Barth 1998) to 13.7 years (Beets 1997)).

- Blinding

Outcome assessors were unaware of the techniques used in six cases. The outcome assessor differed significantly in the trials: an independent surgeon was the assessor in three, the operating surgeon himself in three and a physician in three other studies.

Many data about methodological quality and results were reported in unclear terms and incompletely.

These shortcomings on quality aspects and reporting are not surprising considering that the majority of trials were published before the arrival of initiatives and tools to improve the standards of trial reporting, such as the CONSORT Statement.

Table 1 reports the quality score according to Jadad 1996.

Effects of interventions

In our protocol we planned to present the final summary analysis irrespective of mesh comparator status. However, in view on the wide heterogeneity among the majority of analyses for broad comparisons of surgical techniques (mesh / non-mesh) we decided to report the subgroup separately in a single Forest plot, without showing the final pooled estimate, but only the subgroup pooled estimates.

Shouldice vs. other techniques for recurrence rates (primary outcome)

A Peto odds ratio was used to calculate the effect estimate because of the low event rate, with a high frequency of zero events in series.

Sub-category: Shouldice vs. mesh

Five studies reported this outcome, comparing Shouldice with mesh (all) techniques. Five studies with 1415 patients reported lower recurrence rates in the control group (Peto OR 3.65, 95% CI 1.79 to 7.47, NNH 36). One of these five reported no events so it was excluded from the meta-analysis. Three reported an OR in favour of control techniques; only one (Miedema 2004) showed an OR for recurrence in favour of Shouldice, but it was not significant. There were 31 recurrences in this sub-group (25 in the Shouldice group and six in the control group). Heterogeneity was wide ($I^2=43.6\%$).

Sub-category: Shouldice vs. non-mesh

Eight trials comprising 2865 patients compared rates of recurrence after Shouldice and non-mesh techniques. There was a significant difference in favour of the Shouldice technique (Peto OR 0.62, 95% CI 0.45 to 0.85, NNH 40). Heterogeneity was low ($I^2=29.2\%$). A total of 163 recurrences developed in this subgroup (63 Shouldice and 100 controls). One study reported no events so it was excluded from the meta-analysis. Only one reported an OR (2.0, 95% CI 0.60 to 6.67) in favour of the control technique (modified Bassini technique); six studies reported an OR in favour of the Shouldice technique with OR ranging from 0.23 to 0.88 (Paul 1994; Kovacs 1997). Hay 1995 reported the most of data and its weight in the analysis was 59.56%.

PATIENT-ORIENTED OUTCOMES

Shouldice vs. other techniques for length of post-operative stay

Trials were pooled using a weighted mean difference with a random effect model due to the expected wide heterogeneity.

Sub-category: Shouldice vs. mesh

Four trials assessed length of post-operative stay, using data from 1045 patients. Three reported a WMD slightly in favour of Shouldice (Danielsson 1999; Hetzer 1999; Nordin 2002); one trial reported a significantly shorter post-operative stay after a mesh technique (Zieren 1998). Pooling the data showed a WMD of 0.38 days (95% CI -0.41 to 1.18) in favour of mesh techniques, indicating that the post-operative stay did not differ in the two groups.

Sub-category: Shouldice vs. non-mesh

Patients undergoing Shouldice herniorrhaphy had a longer post-operative stay (WMD 0.25, 95% CI 0.01 to 0.49). None of the four studies (565 patients) reported a shorter post-operative stay for the Shouldice group; WMD varied from 0 (Kovacs 1997; Tran 1992) to 0.70 (Paul 1994).

Shouldice vs. other techniques for chronic pain

A Peto OR was used to calculate the effect estimate because of the low event rate, with a high frequency of zero events in series.

Sub-category: Shouldice vs. mesh

Five trials reporting data about chronic pain in 1371 patients were pooled; 94 patients experienced chronic pain (44 in the Shouldice group, 50 in the mesh group). Peto OR was in favour of Shouldice (Peto OR 0.87, 95% CI 0.55 to 1.39), but not significantly. Heterogeneity was wide ($I^2 = 59.6\%$). Two studies reported a Peto OR in favour of the Shouldice technique (McGillicuddy 1998; Miedema 2004) but only the second one was significant. The other

three reported a higher rate of chronic pain in the Shouldice group (Koninger 2004; Nordin 2002; Zieren 1998) none of these was significant.

Sub-category: Shouldice vs. non-mesh

Only three trials involving 1968 patients compared the Shouldice and non-mesh techniques. Peto OR was 0.30 (95% CI 0.40 to 1.22) in favour of Shouldice. One trial (Hay 1995), with 1647 patients had a substantial weight in the pooled data (81.83%).

Shouldice vs. other techniques for patient satisfaction level

We were unable to develop a Forest plot because we found only one study (Miedema 2004) that considered this.

OTHER COMPLICATIONS

Shouldice vs. other techniques for complications

A Peto OR was used to calculate the effect estimate because of the low event rate with a high frequency of zero events in series.

Sub-category: Shouldice vs. mesh

Seven trials assessed wound infection rates. One (Barth 1998) reported no events so it was excluded from the meta-analysis. Patients who underwent Shouldice herniorrhaphy had fewer wound infections (Peto OR 0.74, 95% CI 0.37 to 1.49).

Seroma and testicular did not differ in the two groups (Peto OR 0.96 and 1.05).

The haematoma rate was slightly in favour of the Shouldice group (Peto OR 0.63, 95% CI 0.24 to 1.66).

Sub-category: Shouldice vs. non-mesh

Seven trials pooling 1635 patients showed a slightly higher infection rate in the Shouldice group (Peto OR 1.34, 95% CI 0.70 to 2.54). Thapar 2000 reported no events in both groups. Only one trial (Tran 1992) reported seroma rates (Peto OR 2.86, 95% CI 0.39 to 20.74). Three studies considered testicular atrophy; one (Kovacs 1997) reported no events. Pooling the other two (Hay 1995; Beets 1997) resulted in a Peto OR 1.09 (95% CI 0.21 to 5.50). Seven reported a lower haematoma rate in the Shouldice group (Peto OR 0.84, 95% CI 0.63 to 1.13).

TECHNICAL OUTCOMES

Shouldice vs. other techniques for conversion to another technique

No trials reported on this outcome.

Shouldice vs. other techniques for duration of operation

Trials were pooled using a WMD with a random effect model on account of expected wide heterogeneity.

Sub-category: Shouldice vs. mesh

Five trials involving 1251 patients reported the duration of the operation. The mesh techniques took less time (WMD 9.64 minutes, 95% CI 6.96 to 12.32). Four studies (Barth 1998; Danielsson 1999; Hetzer 1999; Zieren 1998) reported a shorter operating time for the mesh group (WMD between 2 and 15 minutes). Only Miedema 2004 reported a longer time in the mesh group (WMD - 2 minutes, 95% CI -15.86 to 11.86). Heterogeneity was wide ($I^2 = 63.9\%$).

Sub-category: Shouldice vs. non-mesh

Three trials involving 372 patients assessed operating time as an outcome. Shouldice was a longer procedure than non-mesh techniques (WMD 10.10, 95% CI 6.78 to 13.42). Miedema 2004

reported no differences in the duration of the operation (WMD 0 minutes, 95% CI -13.86 to 13.86). Test for heterogeneity was significant ($I^2 = 83.4\%$).

We planned a series of sensitivity and sub-group analyses but were not able to do the planned subgroup analysis because of the small number of studies found or the lack of variability among them.

DISCUSSION

Our results showed that Shouldice herniorrhaphy is a good technique for inguinal hernia repair compared to other non-mesh techniques, giving better results in terms of recurrence (4.4% vs. 6.9%; Peto OR 0.62, 95% CI 0.45 to 0.85, NNH 40). Comparing Shouldice to mesh techniques, the recurrence rate was lower in the control group (3.6% vs. 0.8%; Peto OR 3.65, 95% CI 1.79 to 7.47, NNH 36). The review by Scott (Scott 2001) also found Shouldice to be the best non-mesh technique in terms of recurrence. These results mainly reflect differences in the control procedures and different degrees of familiarity of the surgeons with the techniques, making it impossible to eliminate the "handcraft" variable from surgical trials. Data about recurrences were recorded at different times of follow-up; however, this source of heterogeneity does not affect the overall direction or strength of our results.

None of the trials reported a shorter duration of operation for the Shouldice group and in fact all the control techniques took less time to perform regardless of whether they used mesh or not (WMD 9.64 and 10.10 minutes vs. mesh and non-mesh respectively). However, this outcome showed wide heterogeneity (time to perform a Shouldice techniques from 47 to 121 minutes) for various reasons (e.g. different ways of collecting data about the duration of the operation (skin-to-skin, time in the operating room) and different levels of skill).

There were no significant differences about chronic pain, complications and post-operative stay for the various techniques.

The lack of differences between Shouldice and other techniques for chronic pain might reflect the small number of trials.

Complications rates did not differ either, between Shouldice and other techniques indicating that these are mainly due to the dissection time of the procedure rather than to the reconstruction technique.

The Shouldice technique seemed to require a longer post-operative stay but these data were not significant and highly heterogeneous. Only one trial (Miedema 2004) considered satisfaction as an outcome and found no difference between Shouldice and other techniques.

These conclusion from this systematic review of RCT is flawed by some problems:

- 1) The quality of included studies, assessed by using the Jadad scale (Jadad 1996), were low.
- 2) the outcome assessor wasn't blind in a relevant number of trials often the outcome evaluator was the same surgeon that performed the intervention.
- 3) Patients have similar characteristic in the treatment and control group but seems more healthy than in general population, this features may affect the dimension of effect in particularly recurrence rate in general population could be higher, for example patients with chronic disease, that could affect tissue reparation, were often excluded. We do not find data on patients employment

that we considered relevant in terms of recurrence rate causal condition (heavy workers vs office workers). Female were nearly 3% of included patients.

4) Lost to follow-up were similar in the treatment and control group but the reasons were often not reported and the length of follow-up vary broadly among the studies (from 1 year to 13.7 year)

5) The data on perioperative treatment are missing or not comparable, especially the duration of intervention.

6) None of the included trials report if the authors have some conflict of interest or the source of funding to develop the study

7) Patient-oriented outcomes (satisfaction and post-operative discomfort) were rare and should be investigated as primary outcomes

The absence of some relevant information on blinding, generation of allocation sequence, type of randomizations, allocation concealment, reasons of withdrawals and lost to follow-up or declaration of conflict of interest are mainly ascribable to poor reporting, this is imputable to the date of publication of the studies (most of them have been published before CONSORT Statement

development). Nevertheless the large amount of patients included in the review makes our results consistent and reliable.

AUTHORS' CONCLUSIONS

Implications for practice

Shouldice herniorrhaphy is the best non-mesh techniques in terms of recurrence even though longer to perform and needs a slightly longer post-operative hospital stay. However the use of mesh markedly reduces recurrences (3.6% vs. 0.8%).

When mesh is not available, is too costly or is refused by the patient, the Shouldice technique is the best alternative.

Implications for research

Further investigations in hernia surgery are still needed. Patient-oriented outcomes (satisfaction and post-operative discomfort) should be investigated as primary outcomes, like recurrence rates. The low methodological quality and poor data reporting of most of the trials call for improvement in surgical RCTs, in accordance with CONSORT requirements.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Barth 1998

Methods	Multicenter, two arms RCT of Shouldice vs Lichtenstein. Randomization: methods not stated. Maximum follow up: 7 days. Exclusions after randomizations: not reported. Protocol violations: 2 patients randomised to Shouldice received Lichtenstein(analysed in Shouldice group). Analyses by protocol. Jadad quality score: 1.
Participants	Country: USA. Setting: 2 centres not specialized in hernia repair. Total enrolled patients: 105 (105 hernias) 51 Shouldice vs 54 Lichtenstein. Mean age (SEM): Shouldice 51 (2,4); Lichtenstein 53 (2,2). Gender: 104 M; 1 F. Inclusion criteria: age> 18, inguinal primary hernia, only elective repair. Exclusion criteria: not reported.

Shouldice technique versus other open techniques for inguinal hernia repair (Review)

Barth 1998 (Continued)

Demographic and baseline data reported: comparable for hernia duration (months), age, hernia type and diameter, employment.

Interventions	Shouldice standard (n=51) performing 4 layers. Polypropylene 2/0. Lichtenstein standard (n=54). Polypropylene Mesh. Polypropylene 2/0.
Outcomes	Length of postoperative stay. Wound infection. Haematoma. Duration of operation.
Notes	Conflict of interest: not reported. Sources of funding: not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Beets 1997

Methods	<p>Single centre, four arms RCT - comparisons: Shouldice vs Bassini (considered in this review); Bassini vs Ring Narrowing (the two arms are not considered in this review). Randomization: generation of sequence not stated; allocation concealment using sealed envelopes. Maximum follow up: 13.7 years. Exclusions after randomizations: 6 hernias (reasons not specified). Protocol violations: 49 Shouldice repairs converted to Bassini (reasons: surgeon not familiar with Shouldice technique or not aware about patient's enrolled in the trial). Analyses by protocol. Losses to follow up (data collapsed for all arms): 30 patients (11,4%). Jadad quality score: 4.</p>
Participants	<p>Country: Netherlands. Setting: centre not specialized in hernia repair. Total enrolled patients (four arms): 375 (hernias 425). Two interest arms: 263 hernias, 103 Shouldice and 160 Bassini. Mean age (SD): Shouldice 57 (13); Bassini 57 (14). Gender: 375 M. Inclusion criteria: age>18, primary inguinal hernia, elective repair. Exclusion criteria: life expectancy <2 year, major concomitant operation. Demographic and baseline data reported: comparability for activities, COPD, prostatism, constipation, bilaterality, experience of operating surgeon; unbalance between arms for previous repair of inguinal hernia (Shouldice 11% vs Bassini 22%).</p>
Interventions	<p>Bassini modified by Stetten (n=160). Non Mesh. Nylon 2/0. Shouldice modified (n=103) performing 3 layers. Nylon 2/0.</p>
Outcomes	<p>Recurrence (lump in groin not necessarily re-operated). Chronic pain. Wound infection Testicular atrophy. Haematoma.</p>
Notes	<p>Recurrence at 13.7 follow up years assessed by an independent surgeon in 179/194 hernias (four arms); 15/194 by telephone interview. 89 patients (100 hernias) died during the study.</p>

Shouldice technique versus other open techniques for inguinal hernia repair (Review)

Beets 1997 (Continued)

Conflict of interest: not reported.
 Sources of funding: not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	A - Adequate

Butters 2007

Methods	Single centre, three arms RCT - Comparisons: Shouldice vs Lichtenstein vs TAPP (not considered). Randomization: generation of sequence not stated, Allocation concealment using sealed envelopes. Maximum follow up: 52 months. Exclusion after randomizations: no. Losses to follow up: Shouldice 19, Lichtenstein 17 (9 deaths, 5 moved to other places and 22 refused to continue). Analyses by protocol
Participants	Country: Germany. Setting: centre specialized in hernia repair. Total enrolled patients: 186 (93 Shouldice vs 93 Lichtenstein). Mean age: Shouldice: 53; Lichtenstein 56. Gender: 186 M. Inclusion criteria: age >18, primary inguinal hernia, elective repair. Exclusion criteria: no known. Demographic and baseline data reported: comparability for age, type of hernia.
Interventions	Shouldice (n=93). Technical notes not specified. Lichtenstein standard (n=93).
Outcomes	Recurrence (definition of recurrence not reported). Chronic pain (data from Koninger 2004). Postoperative satisfaction level Testicular atrophy
Notes	52 months follow up assessed by a resident surgeon by physical examination in 150 patients (80.6%) Conflict of interest: not reported. Sources of funding: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	A - Adequate

Danielsson 1999

Methods	Single centre, two arms RCT of Shouldice vs Lichtenstein. Randomization: methods not reported. Maximum follow up: 1 year. Exclusions after randomizations: 22 (reasons not specified). Analyses by protocol Losses to follow up: 8 patients. Jadad quality score: 2.
Participants	Country: Sweden. Setting: centre not specialized in hernia repair.

Shouldice technique versus other open techniques for inguinal hernia repair (Review)

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Danielsson 1999 (Continued)

Total enrolled patients: 200; 178 hernias (89 Shouldice vs 89 Lichtenstein).
 Mean age (SD): Shouldice 56 (16); Lichtenstein 58 (14).
 Gender: 200 M.
 Inclusion criteria: age > 18, inguinal primary hernia, only elective repair.
 Exclusion criteria: incarcerated hernias and emergency operations.
 Demographic and baseline data reported: comparable for activities (data not provided) and age.

Interventions	Shouldice standard (n=89) performing 4 layers. Non-absorbable monofilament. Lichtenstein standard (n=89). Polypropylene Mesh.
Outcomes	Recurrence (symptomatic lump in groin and re operated). Length of postoperative stay. Wound infection. Duration of operation.
Notes	Recurrence at 1 year follow up assessed by surgeon or patient himself in 170 patients (84 Shouldice; 86 Lichtenstein). Conflict of interest: not reported. Sources of funding: not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Hay 1995

Methods	Multicenter, four arms RCT - comparisons: Shouldice steel and Shouldice polypropylene (pooled together) vs Bassini vs Mc Vay. Randomization: generation of sequence not reported; allocation concealment by un stapling corner of the questionnaire. Maximum follow up: 8,5 years. Exclusions after randomizations: 57 patients (most were foreigners who returned their countries). Intention to treat analyses. Losses to follow up: 86 patients (5,6%). Jadad quality score: 3.
Participants	Country: France. Setting: centres not specialized in hernia repair. Total enrolled patients: 1578(1706 hernias); 1521patients (1647 hernias) (829 Shouldice, 420 Bassini, 407 Mc Vay). Mean age (SD): Shouldice 52,5 (15,6); Bassini 55 (15,2); Mc Vay 54,2 (14,8). Gender: 1578 M. Inclusion criteria: age > 15, inguinal primary hernia, elective or emergency repair. Exclusion criteria: Females, foreigners, femoral ipsilateral hernia associated. Demographic and baseline data reported: comparable for sex, age, activities, COPD, constipation and dysuria, healing influencing factors (all data reported).
Interventions	Shouldice steel (n=401). 4 layers. Steel wire and polypropylene. Shouldice polypropylene (n=419). 4 layers. Polypropylene. Bassini modified (n=420). Polypropylene. Mc Vay modified (n=407). Polypropylene.
Outcomes	Recurrences (lump in groin not necessarily re operated) - data not extractable Length of postoperative stay

Shouldice technique versus other open techniques for inguinal hernia repair (Review)

Hay 1995 (Continued)

Chronic pain
 Wound infection
 Testicular atrophy
 Haematoma

Notes
 Recurrence at 8,5 years follow up assessed by an independent surgeon or patient himself or physician.
 Conflict of interest: not reported.
 Sources of funding: not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
------	--------------------	-----------------------

Allocation concealment (selection bias)	Low risk	A - Adequate
---	----------	--------------

Hetzer 1999

Methods
 Multicenter, two arms RCT of Shouldice vs Lichtenstein.
 Randomization: Day of intervention. Allocation concealment inadequate.
 Maximum follow up: 3 months.
 Exclusions after randomizations: 562 hernias (randomizations performed before evaluation of inclusion criteria).
 Analyses by protocol.
 Losses to follow up: none.
 Jadad quality score: 1.

Participants
 Country: Switzerland.
 Setting: centres not specialized in hernia repair.
 Total enrolled patients (two arms): 385 patients; number of hernias: 410 (171 Shouldice vs 239 Lichtenstein).
 Mean age (SD): Shouldice 53 (16,77); Lichtenstein 58 (17,36).
 Gender: 385 M.
 Inclusion criteria: age>18, primary inguinal hernia, elective repair.
 Exclusion criteria: incarcerated hernia, previous operation in the inguinal region, coagulopathy, diabetes, prostatic hyperplasia, wish for general anaesthesia.
 Demographic and baseline data reported: comparability for age, type of hernia(all data reported).

Interventions
 Shouldice Standard (n=171). 4 layers. PDS 2/0.
 Lichtenstein (n=239). Polypropylene meshes. Polypropylene 2/0.

Outcomes
 Length of postoperative stay.
 Wound Infection.
 Duration of operation.

Notes
 Conflict of interest: not reported.
 Sources of funding: not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
------	--------------------	-----------------------

Allocation concealment (selection bias)	High risk	C - Inadequate
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Kingsnorth 1992

Methods	Single centre, two arms RCT of Shouldice vs Plication Darn (Bassini modified). Randomization: generation of sequence not stated, allocation concealment: randomizations just before skin incision. Maximum follow up: 2 years. Exclusions after randomizations: no. Intention to treat analyses. Losses to follow up: 98 (reasons not specified). Jadad quality score: 3.
Participants	Country: UK. Setting: centre not specialized in hernia repair. Total enrolled patients: 322; 322 hernias (151 Shouldice vs 171 Plication Darn). Mean age: Shouldice 58,3; Plication Darn 57. Gender: 304 M; 18 F Inclusion criteria: age>18, primary inguinal hernia, elective repair. Exclusion criteria: no known. Demographic and baseline data reported: comparability for age, type of hernia, sex (all data reported).
Interventions	Shouldice (n=151). Technical notes not specified. Plication Darn (Bassini modified) (n=171).
Outcomes	Recurrence (definition of recurrence not reported). Length of postoperative stay. Wound infection. Haematoma.
Notes	Recurrence at 2 years follow up assessed by a consultant or a surgical registrar or pro forma in 224 patients. Recurrence at 4 years follow up only in 61 (18,9%) patients so data from this follow up will not be considered. Conflict of interest: not reported. Sources of funding: not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	A - Adequate

Kovacs 1997

Methods	Single centre, two arms RCT of Shouldice vs Bassini-Kirschner. Randomization: date of birth, allocation concealment not specified. Maximum follow up: 1 year. Exclusions after randomizations: no. Losses to follow up: Shouldice 18, Bassini-Kirschner 26 (reasons not specified). Jadad quality score: 2.
Participants	Country: Hungary. Setting: centre not specialized in hernia repair. Total enrolled patients: 129 (63 Shouldice vs 66 Bassini-Kirschner). Mean age: Shouldice 52; Bassini-Kirschner 54. Gender: 129 M. Inclusion criteria: age>18, primary inguinal hernia. Exclusion criteria: no known.

Shouldice technique versus other open techniques for inguinal hernia repair (Review)

Kovacs 1997 (Continued)

Demographic and baseline data reported: comparability for age, bilaterality and sex.

Interventions	Shouldice standard (n=63) performing 4 layers. Non-absorbable monofilament. Bassini-Kirschner (n=66). Suture in Mersilene 0.
Outcomes	Recurrence (lump in groin and re operated). Length of postoperative stay. Wound infection. Testicular atrophy Haematoma. Duration of the operation.
Notes	Recurrence at 1 year follow up assessed by a hospital staff surgeon in 85 patients (66%). Conflict of interest: not reported. Sources of funding: not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	C - Inadequate

Kux 1994b

Methods	Single centre, four arms RCT - comparison: Shouldice vs Bassini (Bassini with absorbable sutures and two-layers Shouldice not considered). Randomization: methods not stated. Maximum follow up: 2 years. Exclusions after randomizations: not reported. Analyses by protocol. losses to follow up: 50 (reasons not specified) Jadad quality score: 2.
Participants	Country: Austria. Setting: centre not specialized in hernia repair. Total enrolled patients: 400. 307 primary hernia repair. (Shouldice 4 rows 160; Bassini unabsorbable 147). Mean age (SD): not reported. Gender: data not clear. Inclusion criteria: Inguinal hernia (also recurrent hernias). Exclusion criteria: not reported. Demographic and baseline data reported: comparability for sex, type of hernia, recurrence, obesity, bronchitis, hernia sac >8 cm (all data reported).
Interventions	Shouldice standard (n=160). 4 layers. Polypropylene. Bassini modified (n=147). Polyester.
Outcomes	Recurrence (lump in groin not necessarily re operated).
Notes	Recurrence at 2 years follow up assessed by a hospital staff surgeon in 683 patients(93,6%). Conflict of interest: not reported. Sources of funding: not reported.

Risk of bias

Kux 1994b (Continued)

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

McGillicuddy 1998

Methods	<p>Single centre, two arms RCT of Shouldice vs Lichtenstein. Randomization: coin toss, allocation concealment inadequate. Maximum follow up: 5 years. Exclusion after randomizations: 31 (patients decided to undergo a laparoscopic repair). Intention to treat analyses. Losses to follow up: 251(35,5%) Jadad quality score: 1.</p>
Participants	<p>Country: USA Setting: private centre specialized in hernia repair. Total enrolled patients: 672. 717 hernias. Mean age (SD): data not reported Gender: 672 M. Inclusion criteria: inguinal hernia. Demographic and baseline data reported: comparability for sex, age, activity (data not reported).</p>
Interventions	<p>Shouldice standard (n=337) performing 4 layers. Non-absorbable monofilament. Lichtenstein standard (n=371). Polypropylene Mesh.</p>
Outcomes	<p>Recurrence Chronic pain Wound infection Testicular atrophy</p>
Notes	<p>Recurrence at 5 years follow up assessed by the operating surgeon in 99% of patients. Conflict of interest: not reported. Sources of funding: not reported.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	C - Inadequate

Miedema 2004

Methods	<p>Single centre, three arms RCT of Shouldice vs Lichtenstein vs Mc Vay. Randomization: generation of sequence by random digit table; allocation list maintained by a person unassociated with the study. Follow up: 7 years. Exclusions after randomizations: not reported. Losses to follow up: 29 (could not be contacted). Analyses by protocol. Jadad quality score: 4.</p>
Participants	<p>Country: USA.</p>

Shouldice technique versus other open techniques for inguinal hernia repair (Review)

Miedema 2004 (Continued)

Setting: centre not specialized in hernia repair.
Total enrolled patients: 146. Three arms: 150 hernias (52 Shouldice, 49 Lichtenstein and 49 Mc Vay).
Mean age: 62 Shouldice, 63 Lichtenstein, 65 Mc Vay.
Gender: 146 M.
Inclusion criteria: Primary inguinal hernia.
Exclusion criteria: age <18 years, use of systemic steroids, incarcerated hernia, recurrent hernia, collagen or vascular disease, ASA 4 or 5, allergy to acetaminophen or codeine.
Demographic and baseline data reported: comparability for sex, COPD, prostatism and constipation.

Interventions	Shouldice modified (n=41). 4 layers. Polypropylene. Lichtenstein standard (n=39). McVay standard (n=41).
Outcomes	Recurrence (lump in groin not necessarily re-operated). Length of postoperative stay. Postoperative satisfaction level. Wound infection. Haematoma. Duration of the operation.
Notes	Recurrence at 6-9 years follow up assessed by clinical examination in 121 patients(29 lost at follow up). Conflict of interest: not reported. Sources of funding: not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	A - Adequate

Nordin 2002

Methods	Single centre, two arms RCT of Shouldice vs Lichtenstein. Randomization: generation sequence by computer generated in blocks of ten patients, allocation concealment not specified. Maximum follow up: 6 years. Exclusions after randomizations: 2 patients refused to continue, 1 hernia not found. Losses to follow up: 9 (reasons not specified). Intention to treat analyses Jadad quality score: 3.
Participants	Country: Sweden. Setting: centre not specialized in hernia repair. Total enrolled patients: 300. 297 hernias (148 Shouldice 149 Lichtenstein). Age range: 25-75. Gender: 300 M. Inclusion criteria: age >18, primary inguinal hernia. Exclusion criteria: irreducibility of hernia, coagulation abnormalities or anticoagulant treatment. Demographic and baseline data: comparability for age, type of hernia, activities, testicular preoperative size (data not reported).
Interventions	Shouldice Standard (n=148). 4 layers. Polypropylene 2/0. Lichtenstein (n=149). Marlex meshes. Polypropylene 2/0.
Outcomes	Recurrence (lump in groin not necessarily re operated). Length of postoperative stay.

Shouldice technique versus other open techniques for inguinal hernia repair (Review)

Nordin 2002 (Continued)

Chronic pain.
Wound infection.
Seroma.
Testicular atrophy.
Haematoma.
Duration of operation.

Notes
Recurrence at 3-6 years follow up assessed by an independent surgeon in 284 patients.
Conflict of interest: not reported.
Sources of funding: not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Paul 1994

Methods
Single centre, two arms RCT of Shouldice vs Bassini.
Randomization: balanced blocks, allocation concealment not specified.
Maximum follow up: 5 years.
Exclusions after randomizations: no.
Losses to maximum follow up: 21 (reasons not specified).
Analyses by protocol
Jadad quality score: 2.

Participants
Country: Germany.
Setting: centre not specialized in hernia repair.
Total enrolled patients: 265. (119 Shouldice vs 125 Bassini)
Mean age (SD): data not reported
Gender: 265 M.
Inclusion criteria: Primary inguinal hernia.
Exclusion criteria: Bilaterality, femoral hernias, incarcerated hernias, renal and liver failure.
Demographic and baseline data reported: comparability for constipation, obesity, bronchitis(data not reported).

Interventions
Shouldice modified (n=119). 4 layers. unabsorbable suture.
Bassini modified (n=125). 2 layers. interrupted stitches of unabsorbable suture.

Outcomes
Recurrence (symptomatic lump in groin and re operated).
Length of postoperative stay.
Duration of operation.

Notes
Recurrence at 3 years follow up assessed by clinical examination in 91,5%of Shouldice group and 92,6% of Bassini group.
Conflict of interest: not reported.
Sources of funding: not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Shouldice technique versus other open techniques for inguinal hernia repair (Review)

Thapar 2000

Methods	Single centre, two arms RCT of Shouldice vs Moloney's Darn. Randomization: generation sequence: Unclear; allocation concealment: randomizations just before skin incision. Maximum follow up: 2 years. Exclusions after randomizations: no. Losses to follow up: none. Jadad quality score: 2.	
Participants	Country: India. Setting: centre not specialized in hernia repair. Total enrolled patients: 50 (25 Shouldice vs 25 Moloney's darn). Age range: 18-40. Gender: 50 M. Inclusion criteria: age >18. Exclusion criteria: bilaterality, recurrent hernias and inguinoscrotal pathologies Demographic and baseline data: comparability for side and type of hernia (data reported).	
Interventions	Shouldice standard (n=25). 4 layers. unabsorbable suture. Moloney's darn (n=25). 2 layers. unabsorbable suture.	
Outcomes	Recurrence (lump in groin not necessarily re operated). Length of postoperative stay. Wound infection. Haematoma.	
Notes	Conflict of interest: not reported. Sources of funding: not reported.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	A - Adequate

Tran 1992

Methods	Single centre, two arms RCT of Shouldice vs Bassini-Kirschner. Randomization: method not specified, allocation concealment not specified. Maximum follow up: 2 years. Exclusions after randomizations: 5 (2 recurrent hernias, 1 femoral hernia, 1 refused the randomizations and in 1 for technical matters). Analyses by protocol. Losses to follow up: 8 patients (reasons not specified). Jadad quality score: 1.	
Participants	Country: Germany. Setting: centre not specialized in hernia repair. Total enrolled patients: 138. 142 hernias (70 Shouldice vs 72 Bassini-Kirschner). Mean age: Shouldice: males 55, females 62; Bassini-Kirschner: males 54, females 47. Gender: 114 M, 24 F. Inclusion criteria: age >14, primary inguinal hernia. Exclusion criteria: not specified.	

Tran 1992 (Continued)

Demographic and baseline data reported: comparability for age, sex, weight, height, type of hernia, qualification of operating surgeon (data reported).

Interventions	Shouldice unclear (n=70). Bassini-Kirschner unclear (n=72). Vicryl metric 1.
Outcomes	Recurrence (lump in groin not necessarily re operated). Length of postoperative stay. Wound infection. Seroma. Haematoma. Duration of operation.
Notes	Recurrence at 24 months follow up assessed by a general physician or one of the author in 128 patients. Conflict of interest: not reported. Sources of funding: not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Zieren 1998

Methods	Single centre, three arms RCT - comparisons: Shouldice vs Plug and patch vs TAPP (not considered for the analyses). Randomization: computer generated. Allocation concealment not specified. Maximum follow up: 25 months. Exclusions after randomizations: not reported. Analyses by protocol Losses to follow up: none. Jadad quality score: 3.
Participants	Country: Germany. Setting: centre not specialized in hernia repair. Total enrolled patients: 160 (80 for each group) Mean age (SD): Shouldice 46 (15); Plug and Patch 47 (14). Gender:147 M, 13 F. Inclusion criteria: Primary inguinal hernia repair, age >18. Exclusion criteria: incarcerated hernias, coagulation disorders, contraindication for general anaesthesia, cardiac insufficiency (NYHA 3-4). Demographic and baseline data: comparability for age, sex, type of hernia (Nyhus), occupation, BMI (all data reported).
Interventions	Shouldice modified (n=80). 4 layers. Unabsorbable monofilament. Plug and Patch (n=80). Polypropylene meshes and plugs.
Outcomes	Recurrence (method not stated). Length of postoperative stay. Chronic pain. Wound Infection. Seroma. Haematoma.

Zieren 1998 (Continued)

Duration of operation.

Notes
 Recurrence at 25 months assessed for 96% of Shouldice group and 94% of Plug and Patch.
 Conflict of interest: not reported.
 Sources of funding: not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Aust 1993	Comment to Kingsnorth 1992
Bay-Nielsen 2004	Review
Bergin 1998	Comparison about different suture materials
Carter 1993	Comment to Kingsnorth 1992
Cunningham 1996	No comparisons between surgical techniques
Deysine 2006	CCT
Kawji 1999	CCT
Kingsnorth 1995	Comment on Kingsnorth 1992
Koninger 2004	Data considered in Butters 2007
Manson 1993	Comment to Kingsnorth 1992
Negro 1997	Comment to Schrenk 1996
Panos 1992	Full text not available
Paul 1993	Data reprised in Paul 1994
Prieto-Diaz-Chavez 2009	Data on primary inguinal hernia not extractable
Pyka 2003	Full text not available
Stanislawek 2003	Full text not available
Strand 1998	Full text not available
Wayman 1996	Out of topic
Woodward 1995	Letter to Paul 1994

Shouldice technique versus other open techniques for inguinal hernia repair (Review)

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Study	Reason for exclusion
Wyatt 1995	Comment to Kingsnorth 1992

Characteristics of studies awaiting assessment *[ordered by study ID]*

Koninger 1998

Methods	RCT
Participants	280 patients
Interventions	Shouldice, Lichtenstein, TAPP
Outcomes	Recurrence, Duration of Operation, Wound infection, Complications
Notes	

Kux 1994

Methods	RCT
Participants	209 patients
Interventions	Shouldice, Lichtenstein
Outcomes	Recurrence, Postoperative pain
Notes	

Mittelstaedt 1999

Methods	RCT
Participants	119 patients
Interventions	Shouldice, Bassini, Mc Vay
Outcomes	Recurrence
Notes	

Porrero 2005

Methods	RCT
Participants	54 patients
Interventions	Shouldice, Lichtenstein

Shouldice technique versus other open techniques for inguinal hernia repair (Review)

Porrero 2005 (Continued)

 Outcomes Duration of operation, Length of postoperative stay, Costs

Notes

Schmitz 1997

 Methods RCT

 Participants 64 patients

 Interventions Shouldice, Tension-free

 Outcomes Postoperative pain, Complications

Notes

DATA AND ANALYSES
Comparison 1. Shouldice vs other techniques

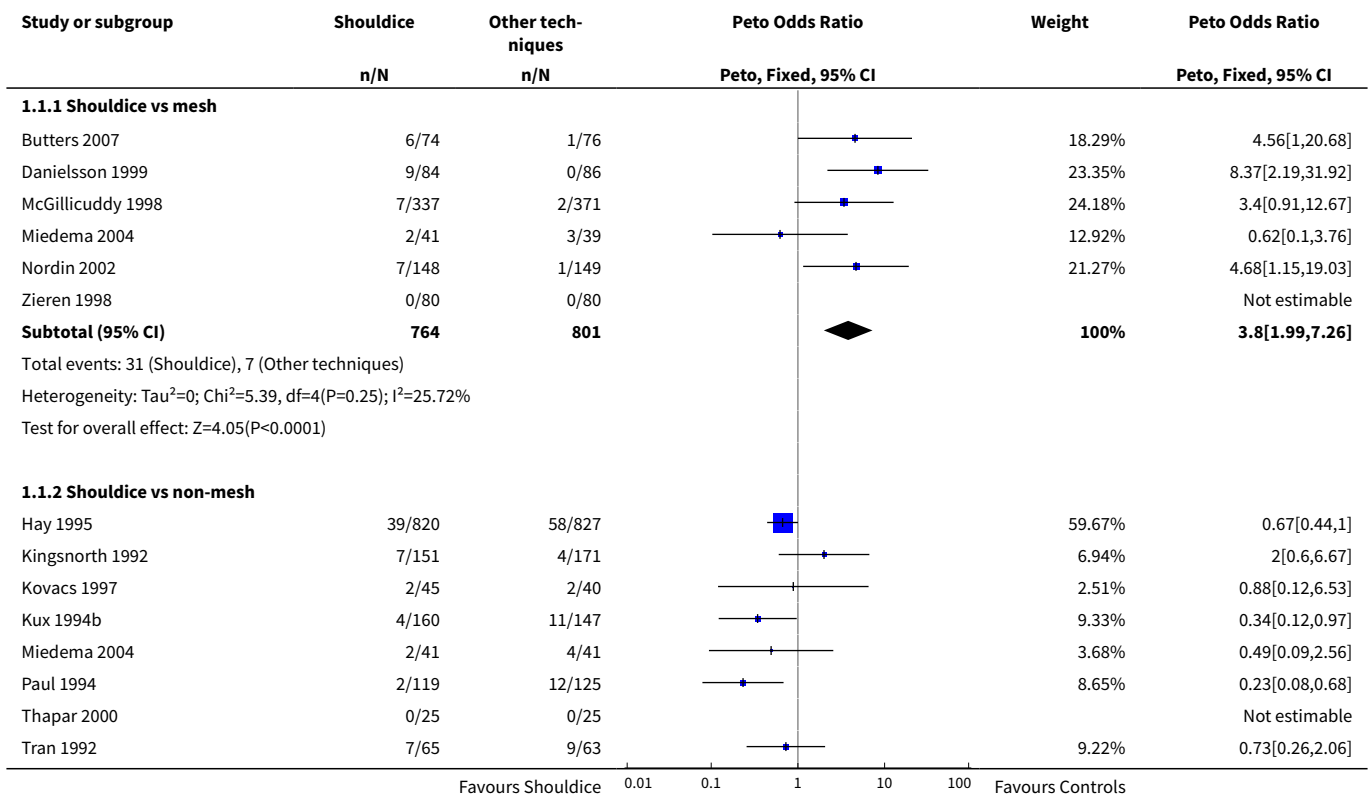
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Recurrence	13		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
1.1 Shouldice vs mesh	6	1565	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.80 [1.99, 7.26]
1.2 Shouldice vs non-mesh	8	2865	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.62 [0.45, 0.85]
2 Length of postoperative stay (days)	8		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Shouldice vs mesh	4	1045	Mean Difference (IV, Random, 95% CI)	0.38 [-0.41, 1.18]
2.2 Shouldice vs non mesh	4	565	Mean Difference (IV, Random, 95% CI)	0.25 [0.01, 0.49]
3 Chronic pain	7		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
3.1 Shouldice vs mesh	5	1371	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.87 [0.55, 1.39]
3.2 Shouldice vs non mesh	3	1968	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.70 [0.40, 1.22]
4 Wound Infection	13		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
4.1 Shouldice vs mesh	7	1938	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.74 [0.37, 1.49]
4.2 Shouldice vs non mesh	7	2635	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.34 [0.70, 2.54]
5 Seroma	4		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only

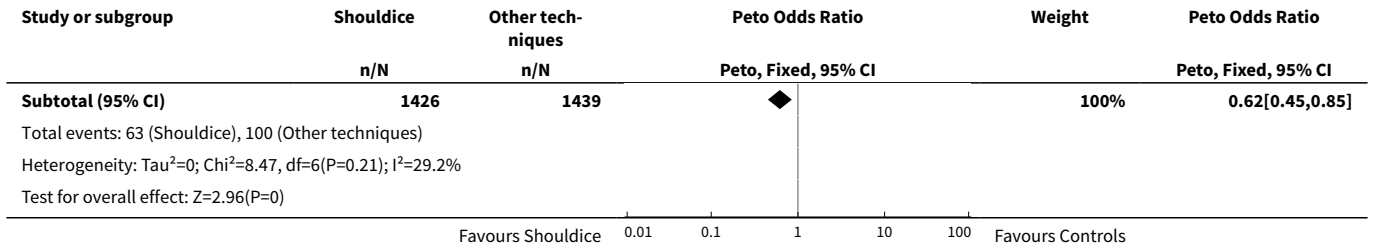
Shouldice technique versus other open techniques for inguinal hernia repair (Review)

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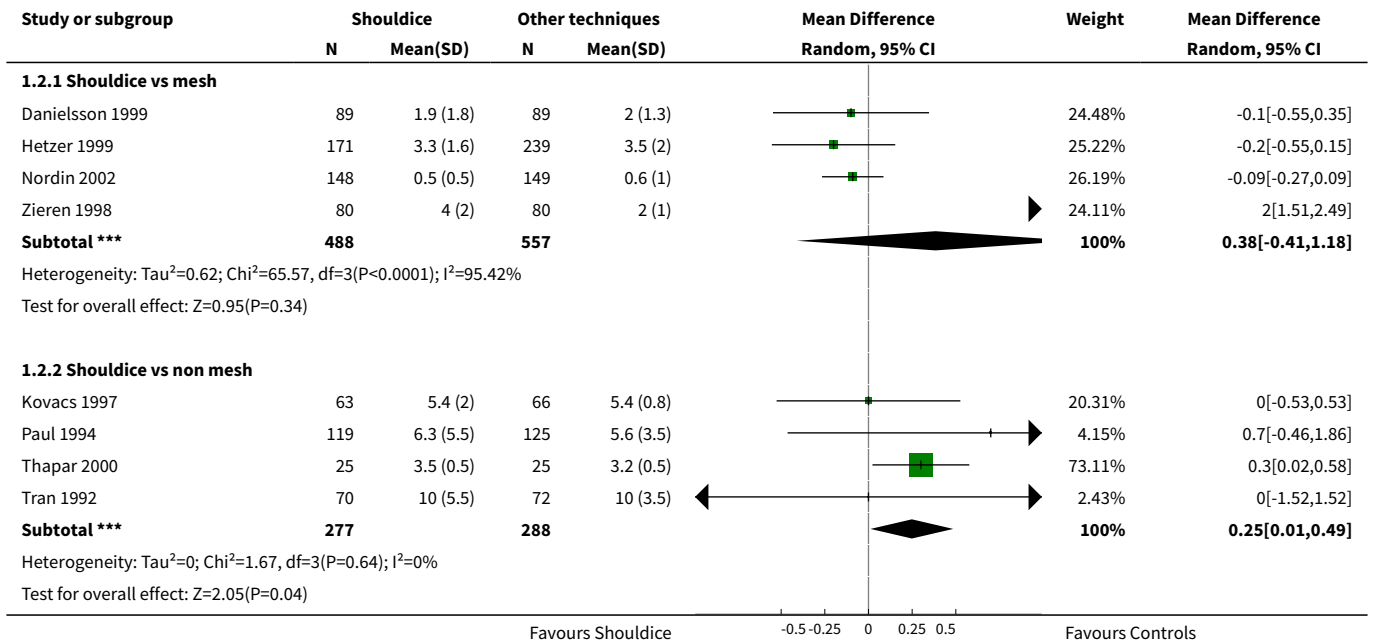
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Shouldice vs mesh	3	1165	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.96 [0.37, 2.50]
5.2 Shouldice vs non mesh	1	142	Peto Odds Ratio (Peto, Fixed, 95% CI)	2.86 [0.39, 20.74]
6 Testicular atrophy	6		Odds Ratio (M-H, Random, 95% CI)	Subtotals only
6.1 Shouldice vs mesh	3	1155	Odds Ratio (M-H, Random, 95% CI)	1.05 [0.04, 27.38]
6.2 Shouldice vs non mesh	3	1995	Odds Ratio (M-H, Random, 95% CI)	1.09 [0.21, 5.50]
7 Haematoma	10		Peto Odds Ratio (Peto, Fixed, 95% CI)	Subtotals only
7.1 Shouldice vs mesh	3	562	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.64 [0.25, 1.64]
7.2 Shouldice vs non mesh	7	2797	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.84 [0.63, 1.13]
8 Duration of the operation (Minutes)	7		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
8.1 Shouldice vs Mesh	5	954	Mean Difference (IV, Fixed, 95% CI)	9.64 [6.96, 12.32]
8.2 Shouldice vs non mesh	3	372	Mean Difference (IV, Fixed, 95% CI)	10.10 [6.78, 13.42]

Analysis 1.1. Comparison 1 Shouldice vs other techniques, Outcome 1 Recurrence.

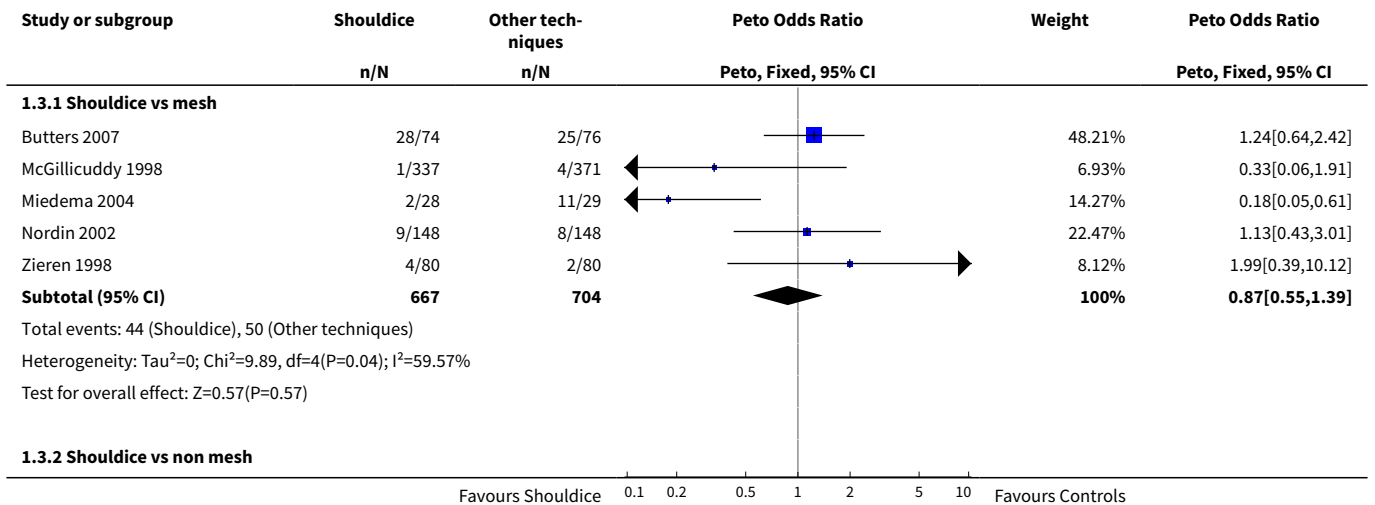


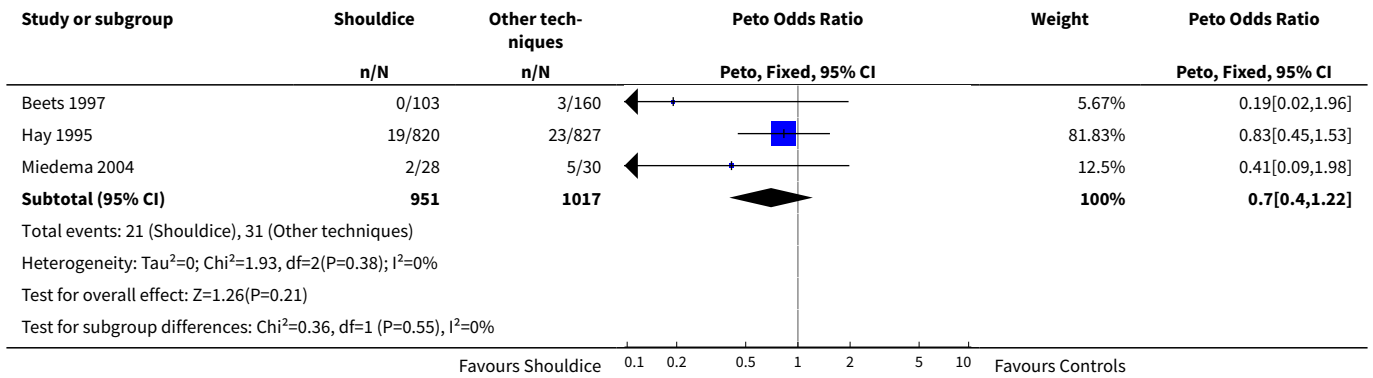


Analysis 1.2. Comparison 1 Shouldice vs other techniques, Outcome 2 Length of postoperative stay (days).

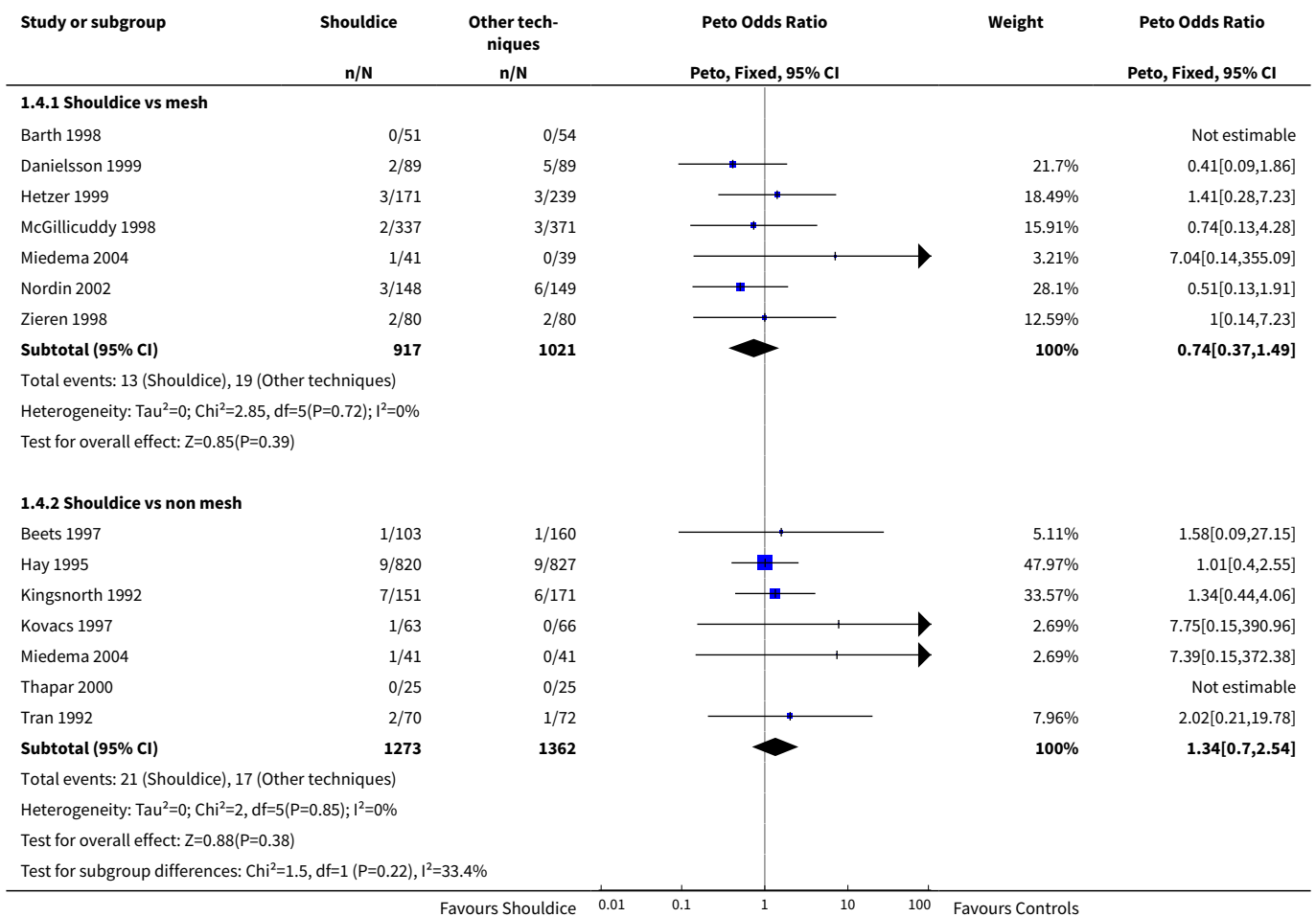


Analysis 1.3. Comparison 1 Shouldice vs other techniques, Outcome 3 Chronic pain.

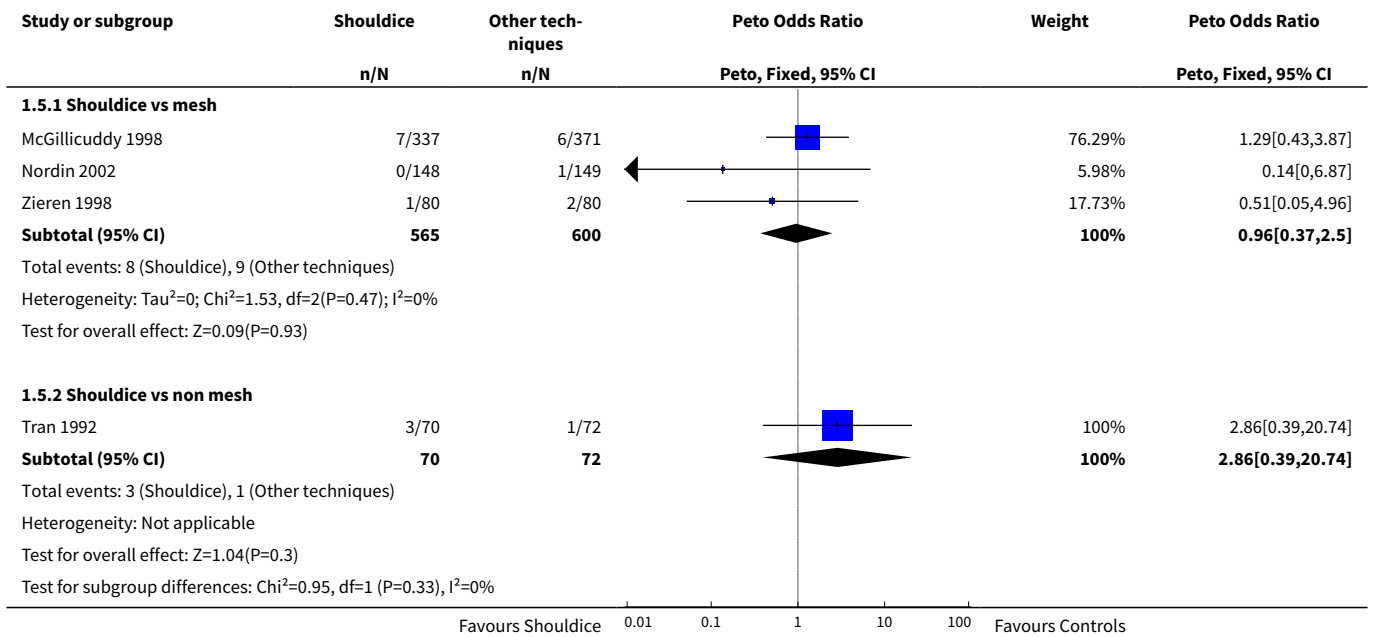




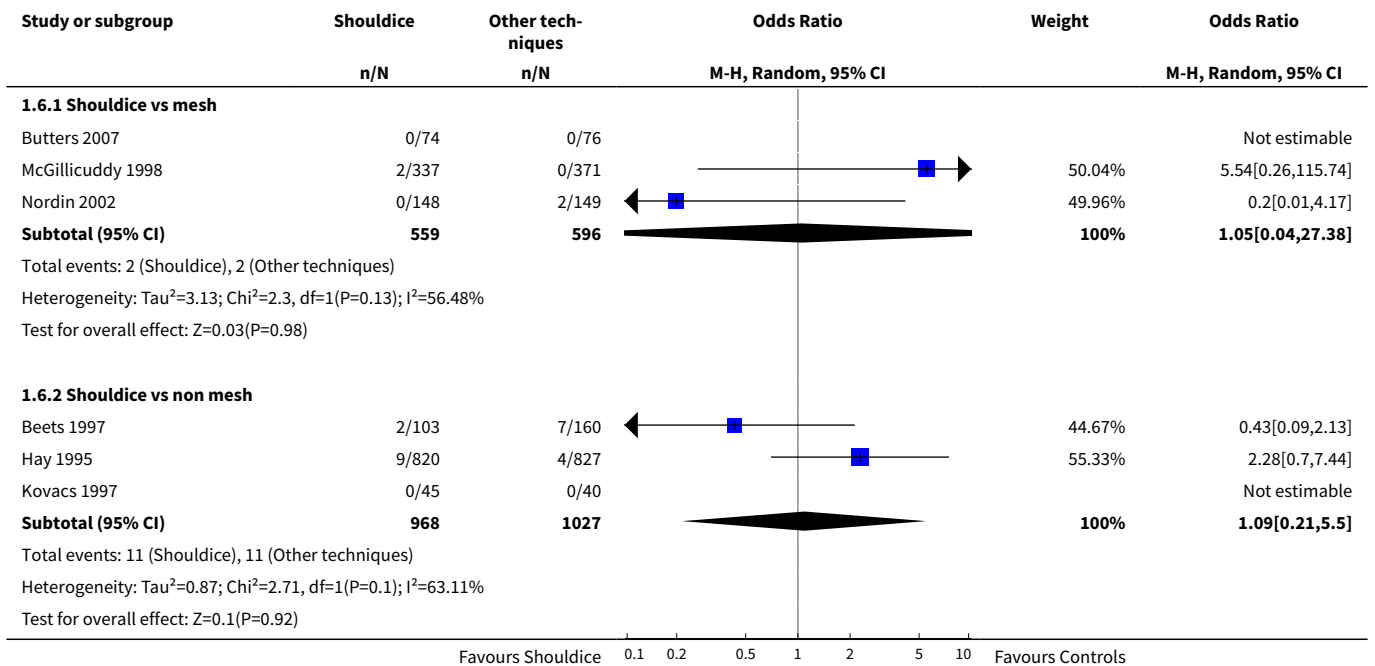
Analysis 1.4. Comparison 1 Shouldice vs other techniques, Outcome 4 Wound Infection.



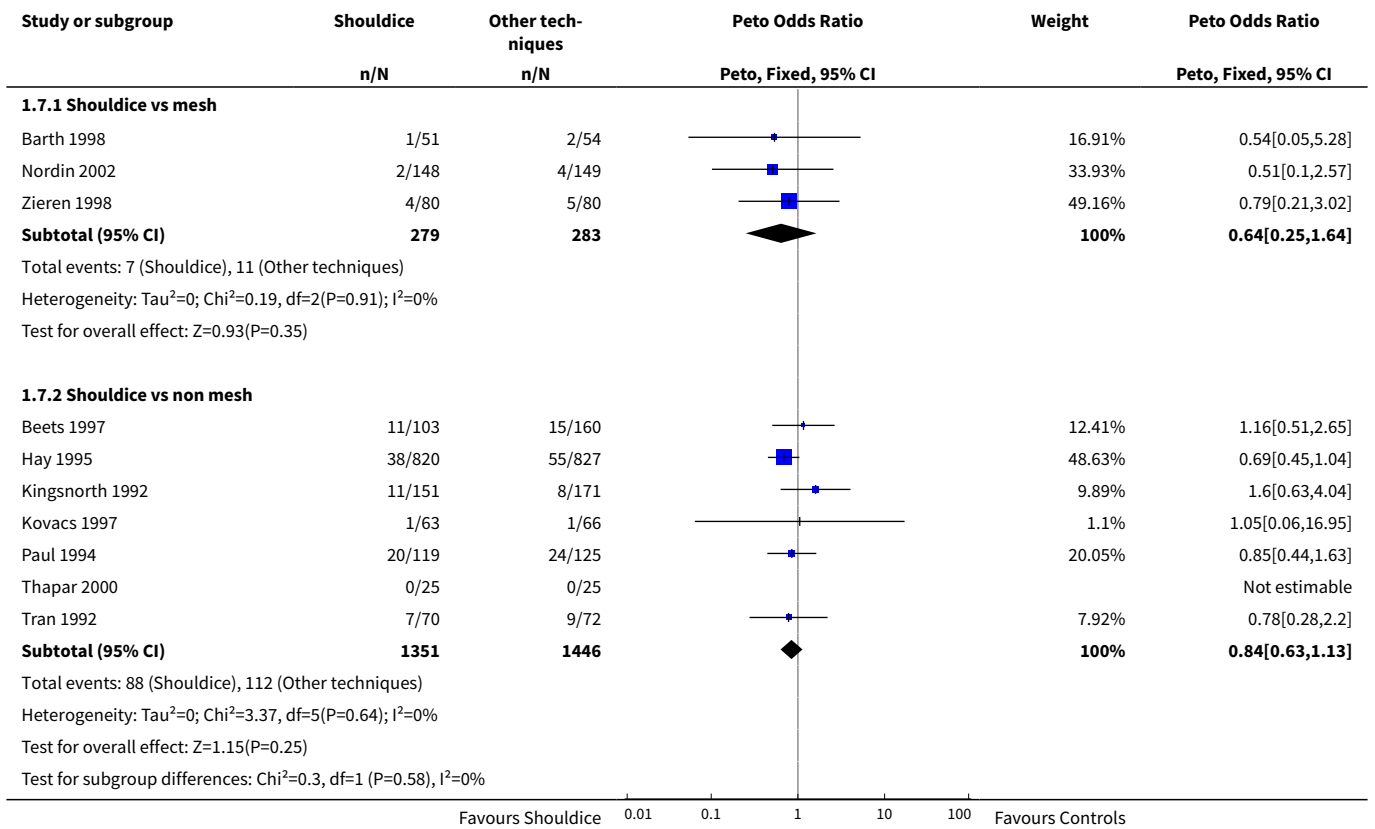
Analysis 1.5. Comparison 1 Shouldice vs other techniques, Outcome 5 Seroma.



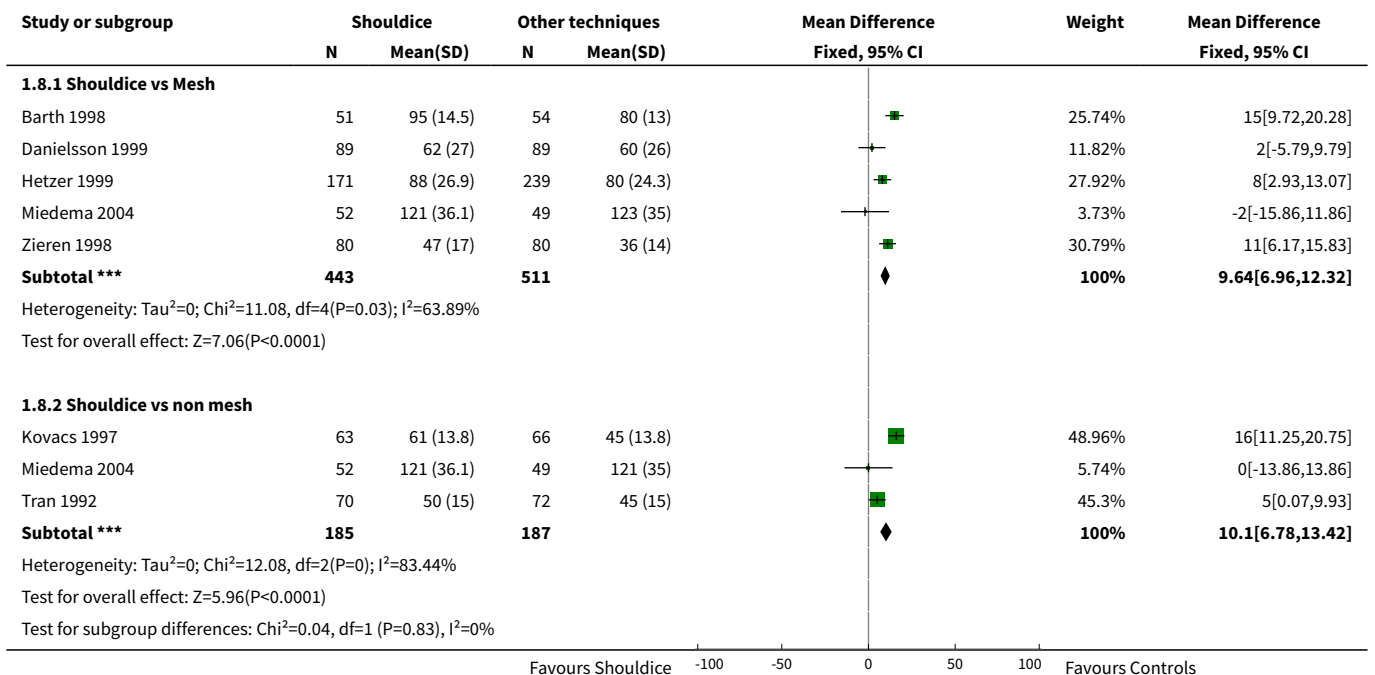
Analysis 1.6. Comparison 1 Shouldice vs other techniques, Outcome 6 Testicular atrophy.



Analysis 1.7. Comparison 1 Shouldice vs other techniques, Outcome 7 Haematoma.



Analysis 1.8. Comparison 1 Shouldice vs other techniques, Outcome 8 Duration of the operation (Minutes).



ADDITIONAL TABLES

Table 1. Assessment of methodological quality: Jadad Scale

Study	Randomiza- tion	Double-blind- ing	Dropout/With- drawls	TotalScore
Barth	1	0	0	1
Beets	2	2	0	4
Butters	2	1	1	3
Danielsson	1	0	1	2
Hay	2	1	0	3
Hetzer	0	0	1	1
Kingsnorth	2	1	0	3
Kovacs	0	1	1	2
Kux	0	1	1	2
McGillicuddy	0	0	1	1
Miedema	2	1	1	4
Nordin	1	2	0	3
Paul	1	1	0	2
Thapar	1	0	1	2
Tran	1	0	0	1
Zieren	1	1	1	3

APPENDICES

Appendix 1. EMBASE search strategy

1. exp inguinal hernia
2. inguinal hernia.mp.
3. 1 or 2
4. shouldice technique.mp.
5. shouldice.mp.
6. 4 or 5
7. 3 and 6
8. randomized controlled trial
9. randomization
10. controlled study
11. multicenter study

12. phase 3 clinical trial
13. phase 4 clinical trial
14. double blind procedure
15. single blind procedure
16. ((singl* or doubl* or trebl* or tripl*) adj (blind* or mask*)).ti,ab.
17. (random* or cross* over* or factorial* or placebo* or volunteer*).ti,ab.
18. 13 or 10 or 14 or 16 or 9 or 15 or 11 or 8 or 17 or 12
19. "human*".ti,ab.
20. (animal* or nonhuman*).ti,ab.
21. 20 and 19
22. 20 not 21
23. 18 not 22
24. 7 and 23

Appendix 2. MEDLINE search strategy

1. exp Hernia, Inguinal
2. inguinal hernia.mp.
3. 1 or 2
4. shouldice technique.mp
5. shouldice.mp.
6. 4 or 5
7. 3 and 6
8. randomized controlled trial.pt.
9. controlled clinical trial.pt.
10. randomized.ab.
11. placebo.ab.
12. clinical trial.sh.
13. randomly.ab.
14. trial.ti.
15. 8 or 9 or 10 or 11 or 12 or 13 or 14
16. humans.sh.
17. 15 and 16
18. 7 and 17

Appendix 3. COCHRANE LIBRARY search strategy

1. MeSH descriptor Hernia, Inguinal, this term only in MeSH products
2. inguinal-hernia in All Fields in all products
3. (#1 OR #2)
4. (shouldice technique) in All Fields in all products
5. shouldice in All Fields in all products
6. (#4 OR #5)
7. (#3 AND #6)

WHAT'S NEW

Date	Event	Description
7 August 2012	Review declared as stable	It is unlikely that there will be new studies to add to this systematic review

HISTORY

Protocol first published: Issue 2, 2006
 Review first published: Issue 4, 2009

Date	Event	Description
14 March 2012	New citation required but conclusions have not changed	Review updated - no new trials included
14 March 2012	New search has been performed	xxx
27 February 2012	New search has been performed	Searches updated
7 March 2009	New search has been performed	major update
22 July 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Bruno Amato worked on the whole project and coordinated the reviewers.

Corrado Rispoli and Nicola Rocco were involved in the review design and in writing the protocol, results, discussion, collection and interpreting the data.

Giovanni Persico and Salvatore Panico were involved with interpreting the data and commenting on the studies included.

Lorenzo Moja designed and wrote the review draft and was the supervisor for data collection and interpretation; he was also involved in data analyses.

Ivan Moschetti provided general advice on the review and contributed to the interpretation of data, commented on successive drafts of the manuscript and coordinated the review process.

DECLARATIONS OF INTEREST

Corrado Rispoli, Nicola Rocco, Bruno Amato and Giovanni Persico are general surgeons; in their hospital they usually employ Trabucco or Lichtenstein techniques. Ivan Moschetti, Lorenzo Moja and Salvatore Panico are clinicians/researchers. None of them received grants from any pharmaceutical industry involved in mesh or other device production.

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External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Fasciotomy; *Suture Techniques; Hernia, Inguinal [prevention & control] [*surgery]; Inguinal Canal [surgery]; Length of Stay; Postoperative Complications [etiology]; Randomized Controlled Trials as Topic; Secondary Prevention; Surgical Mesh

MeSH check words

Adult; Female; Humans; Male