

Meta-analysis of patient-reported outcomes after laparoscopic *versus* open inguinal hernia repair

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Background: Inguinal hernia repair is a common low-risk intervention. Patient-reported outcomes (PROs) are being used increasingly as primary outcomes in clinical trials. The aim of this study was to review and meta-analyse the PROs in RCTs comparing laparoscopic *versus* open inguinal hernia repair techniques in adult patients.

Methods: A systematic review and meta-analysis was carried out in accordance with PRISMA guidelines. Only RCTs in peer-reviewed journals were considered. PubMed, Ovid Embase, Scopus and the Cochrane Library were searched. In addition, four trial registries were searched. The search interval was between 1 January 1998 and 1 May 2018. Identified publications were reviewed independently by two authors. The review was registered in the PROSPERO database (CRD42018099552). Bias was assessed using the Cochrane Collaboration risk-of-bias tool.

Results: Some 7192 records were identified, from which 58 unique RCTs were selected. Laparoscopic hernia repair was associated with significantly less postoperative pain in three intervals: from 2 weeks to within 6 months after surgery (risk ratio (RR) 0.74, 95 per cent c.i. 0.62 to 0.88), 6 months to 1 year (RR 0.74, 0.59 to 0.93) and 1 year onwards (RR 0.62, 0.47 to 0.82). Paraesthesia (RR 0.27, 0.18 to 0.40) and patient-reported satisfaction (RR 0.91, 0.85 to 0.98) were also significantly better in the laparoscopic repair group.

Conclusion: The data and analysis reported in this study reflect the most up-to-date evidence available for the surgeon to counsel patients. It was constrained by heterogeneity of reporting for several outcomes.

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Introduction

Inguinal hernia is a common surgical condition, with a lifetime risk in the UK of 27 per cent for men and 3 per cent for women. Hernia repair is one of the most common low-risk general surgical interventions in Europe and North America¹.

When assessing the efficacy of common low-risk procedures, traditional outcome measures may be less appropriate. Traditional quality measurements include: duration of surgery, length of hospital stay and mortality. Although important and easy to capture using routinely recorded data, they do not depict patients' postoperative recovery after low-risk procedures. Understanding patient experience, viewpoint and functional outcome after hernia surgery is crucial in evaluating different procedures, to provide informed patient-centred care and encourage standards to improve².

Patient-reported outcomes (PROs) may include any aspect of health or function which is patient-reported rather than observer-reported. The outcomes themselves may be either individual outcomes (such as symptoms, satisfaction ratings, time until return to specific activities) or summative outcomes produced from multiple information points (such as Short Form (SF) 12 and EuroQol Five Dimensions questionnaires). Patient-reported outcome measures (PROMs) are a common way for health-related quality of life to be reported².

However, their quality of reporting varies in the literature. In 2013 the PRO CONSORT guideline extension³ was published. This extension of the pre-existing CONSORT guidelines provides a framework for the improved reporting of PROs in RCTs and their subsequent interpretation by clinicians.

To date, there has been no systematic review or meta-analysis of outcomes after inguinal hernia surgery

from the patient's perspective. The aim of this study was to summarize PROs from RCTs of laparoscopic *versus* open inguinal hernia repair.

Methods

This systematic review was conducted in accordance with the PRISMA statement⁴. A review protocol was registered with the PROSPERO systematic review database (CRD42018099552).

Study eligibility criteria

Adults diagnosed with an inguinal hernia (primary or recurrent) who were aged 18 years or more at time of intervention were included. Operative interventions were either laparoscopic or open repair, irrespective of type of repair, presentation (elective or emergency) or hospital setting (inpatient or outpatient).

The primary outcome was PROs, presented as both crude rates and, after meta-analysis, risk ratio (RR) or weighted mean difference (MD). Only RCTs were included. Only papers published in an indexed medical journal were included, with English as the language of publication; conference abstracts were excluded. Age of publication was restricted to the past two decades (1 January 1998 to 1 May 2018) and there were no geographical limitations. Only studies investigating surgical technique (rather than anaesthetic or analgesic) were analysed. Both unilateral and bilateral, primary and recurrent hernias were included.

Information sources and search

Four databases were searched: PubMed, Ovid Embase, Scopus and the Cochrane Library. The search strategy was 'Inguinal hernia' AND 'RCT'. Additionally, the ISRCTN register, ClinicalTrials.gov, ICTR Platform and EU Clinical Trials Register were searched with the phrase 'Hernia'.

For PubMed, the search was conducted using both Medical Subject Heading (MeSH) terms and the advanced search option. The MeSH terms ('Hernia, Inguinal') AND ('Randomised Controlled Trial') were used. An advanced search was conducted using the terms 'Hernia' AND 'Randomised controlled trial'. Ovid Embase and Scopus were searched with the same terms. The Cochrane Library and trial registries were searched using the term 'Hernia'.

Study selection and data collection process

Two independent reviewers reviewed all titles, placing any screened citations into an Excel® database (Microsoft, Redmond, Washington, USA). Duplicates were eliminated

and, if possible, a decision was made on inclusion of each article based on the abstract. The full text was then assessed; disagreements between reviewers were resolved by consensus, or arbitration by a senior author, if necessary. If an RCT had been reported in more than one publication, the most recent publication that reported the trial was used as the reference article in this review. Once each author had completed data extraction, the data files were compared electronically, and discrepancies in data entry were investigated and resolved.

Data items

The following variables were recorded in an Excel® spreadsheet: basic information – first author, publication year and country of origin; demographic information – total number of patients, number of men and women in each group, number of hernias repaired in each group, minimum age, maximum age and median age; treatment information – type of open or laparoscopic repair used; and follow-up information – mean and median follow-up, planned follow-up interval and number of study participants who completed follow-up.

For each PRO, the data recording method, score and crude rate, and time after surgery when data were collected was recorded. If values were recorded at multiple time points during follow-up for each variable, the value recorded at the last time point was reported. Pain, which was expected to be the most common PRO, was subdivided into: postoperative (0–2 weeks), acute (from 2 weeks to within 6 months), early chronic (6 months up to 1 year) and later chronic (after 1 year). For studies that reported pain as visual analogue scale (VAS) data, the only patients included in the present analysis were those who experienced moderate or severe pain, represented by a VAS score of over 4 on a scale from 1 to 10. Outcome values for all other PROs were grouped. Mean duration of follow-up was presented for each outcome.

Risk of bias in individual studies and across studies

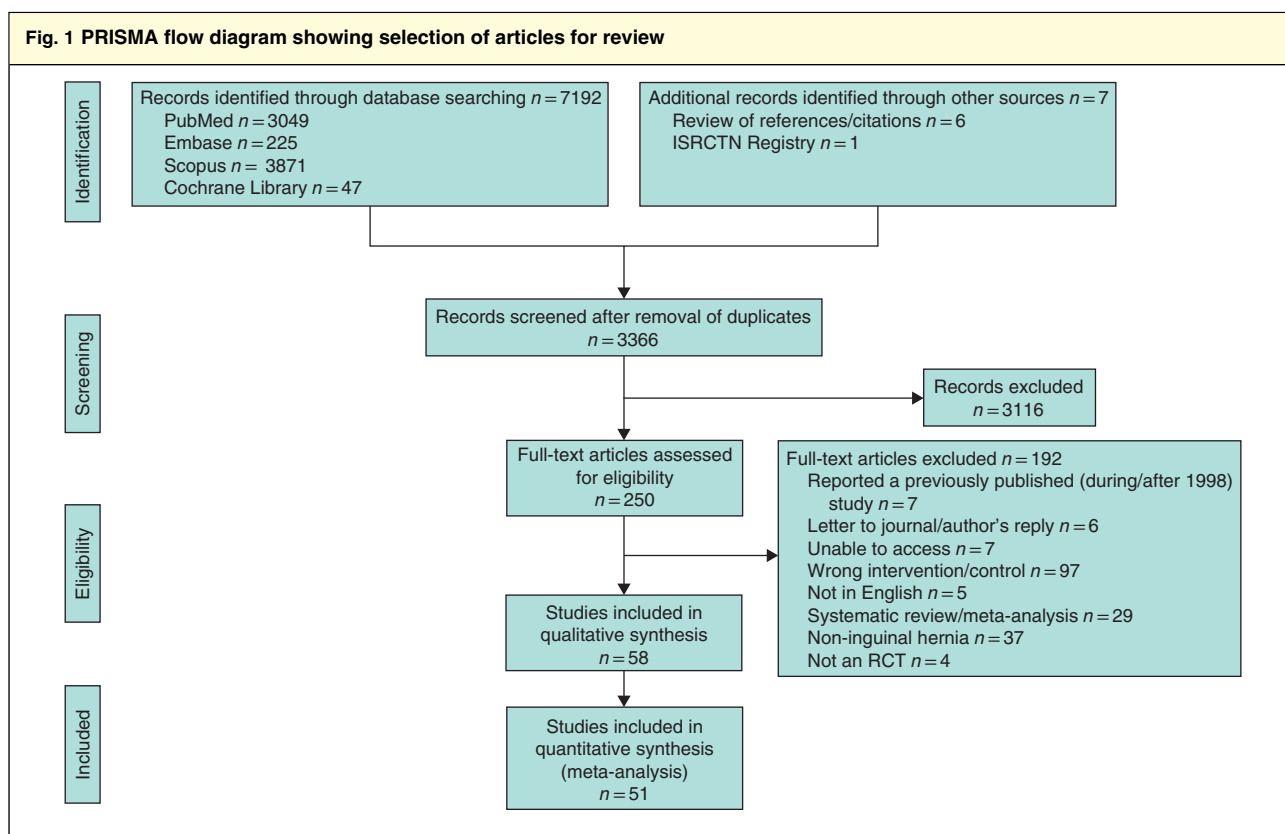
Two authors assessed the potential bias independently using the Cochrane Collaboration risk-of-bias tool⁵.

Summary measures and synthesis of results

PROs are shown as crude rates and, if appropriate, mean scores.

Meta-analysis

Meta-analysis was undertaken for each distinct outcome if there were two or more RCTs that examined the same



outcome. The outcome groups were divided into open and laparoscopic, with subdivision into specific techniques if there were sufficient data (2 or more homologous studies).

Review Manager 5 software (The Nordic Cochrane Centre, Copenhagen, Denmark) was used for results synthesis⁶. If the outcome data were presented in the form of dichotomous categorical variables, RRs were reported with corresponding 95 per cent confidence intervals. Statistical heterogeneity between studies was checked and reported using the I^2 measure of study heterogeneity. If low heterogeneity between studies was reported (I^2 below 50 per cent), a fixed-effect model was used⁷. If higher heterogeneity was evident, a random-effects model was used. If a meta-analysis had a heterogeneity of more than 75 per cent, it was excluded from the results. The MD was calculated for outcome data presented in the form of continuous data⁸.

The primary summary measure of the meta-analysis was RR, with 95 per cent confidence intervals. If the total number of a specific event was zero for any given study, the study was still entered into the overall data pool. A sensitivity analysis was also undertaken. Only studies in

which the majority of areas of potential bias (4 or more) were low risk were analysed.

Results

Study characteristics

Sixty-seven studies met the inclusion criteria. Nine studies had the same participants with different durations of follow-up, resulting in 58 RCTs^{9–66} with unique populations (Fig. 1).

A total of 17 510 randomly assigned patients were included in this analysis; 8475 patients underwent laparoscopic hernia repair and 9035 had open hernia repair. There were 18 431 inguinal hernia repairs included in the analysis. The studies used different open techniques, Lichtenstein repair being the most common (38 studies), followed by Shouldice (14), Stoppa (5), Bassini (4), narrowing on the internal inguinal ring (2), plication with darn (2), properitoneal repair (1), Jean Rives repair (1), Nyhus repair (1), mesh plug (1) and Kugel repair (1). Two laparoscopic techniques, totally extraperitoneal (TEP) and transabdominal preperitoneal (TAPP) repair, were encountered, in

27 and 31 studies respectively. Details of the studies are described in *Table S1* (supporting information).

Patient characteristics

Patient characteristics were heterogeneous regarding both sex and age. Of 48 studies that reported the sex of the population, 23 included men only. Across the 48 studies, 97.6 per cent of the population were men in the laparoscopic group, and 97.8 per cent in the open group. The mean or median age of study participants was reported in 51 studies, and ranged from 23.6 to 65.4 years. Study-specific patient characteristics are summarized in *Table S2* (supporting information).

Risk of bias within studies

An individual risk-of-bias analysis for each study is presented in *Table S3* (supporting information).

Crude rates and results of meta-analysis

Results of comparisons of laparoscopic *versus* open procedures are described in the text. Technique subgroup analyses are shown in *Table 1*. Pain was the most commonly reported PRO, with 57 of 58 studies reporting this as an outcome.

Postoperative pain

Thirty studies^{10,11,13,15–17,19,23–25,27,35–37,39,44–48,52,53,55–58,61,63,65,66} (52 per cent) reported pain within the first 2 weeks after surgery, with 4616 patients randomized in the open repair group and 4585 in the laparoscopic repair group.

Nine studies reported this as a dichotomous variable (pain *versus* no pain). The crude rate of pain at last follow-up during this interval was 4.3 (range 0–8.9) per cent in the open group and 4.4 (1.4–18.2) per cent in the laparoscopic group, after a mean(s.d.) of 7.4(4.3) (range 2–14) days. Meta-analysis demonstrated no significant difference between the open and laparoscopic groups (RR 0.86, 95 per cent c.i. 0.63 to 1.16) (*Fig. 2*). All trials included in this group were rated as having a low risk of bias, so a sensitivity analysis was not carried out.

Twenty-one studies reported pain as a mean VAS score. The crude mean VAS score, on a scale from 1 to 10, at last follow-up during this interval was 2.98 (range 0.6–5.2) in the open repair group and 2.27 (0–4.2) in the laparoscopic group, after a mean of 7.1(5.1) (range 0.5–14) days. Eleven studies also reported s.d. values along with mean scores, which allowed meta-analysis. This demonstrated that the laparoscopic group had significantly lower pain scores (MD –0.69, 95 per cent c.i. –0.78 to –0.61). After

exclusion of trials at high risk of bias, the laparoscopic group still showed better clinical results (MD –0.31, –0.40 to –0.21).

Acute pain

Thirteen studies^{15,16,23,26,27,31,42,47,50,57,62,63,65} (22 per cent) reported pain as an outcome more than 2 weeks and less than 6 months after surgery; 2115 patients were randomized to open hernia repair and 1988 to laparoscopic repair.

Ten studies reported this as a dichotomous variable. The crude rate of pain at last follow-up during this interval was 11.5 (range 0–16.4) per cent in the open repair group and 8.4 (0–22.7) per cent in the laparoscopic group, after a mean(s.d.) of 2.2(0.9) (range 1–3) months. Meta-analysis showed that there was significantly less pain reported in the laparoscopic group (RR 0.74, 95 per cent c.i. 0.62 to 0.88) (*Fig. 3*). After exclusion of trials at high risk of bias, the laparoscopic group still had better clinical results (RR 0.68, 0.54 to 0.86).

Three studies reported pain as a mean VAS score. The crude mean VAS score (scale from 1 to 10) at last follow-up during this interval was 2.3 (range 0.5–3.3) in the open repair group and 1.5 (0–2.5) in the laparoscopic group, after a mean(s.d.) of 2.0(0.9) (range 1.5–3) months. Two studies also reported s.d. values along with mean scores, which allowed meta-analysis; this showed that the laparoscopic group had significantly lower pain scores (MD –0.88, 95 per cent c.i. –1.39 to –0.36).

Early chronic pain

Twenty studies^{9,12,13,16,18,20,26,29–31,33,38,40,43,48–50,55,57,66} (34 per cent) reported pain between 6 months and up to 1 year, with 3133 patients randomized to open hernia repair and 2999 to laparoscopic hernia repair.

All studies reported this as a dichotomous variable. The crude rate of pain at last follow-up during this interval was 13.4 (range 0–34.9) per cent in the open repair group and 10.3 (0–27.7) per cent in the laparoscopic group, after a mean(s.d.) of 9.7(3.0) (range 6–12) months. Meta-analysis showed that significantly less pain was reported in the laparoscopic group (RR 0.74, 95 per cent c.i. 0.59 to 0.93) (*Fig. 4*). After exclusion of trials at high risk of bias, the laparoscopic group still had less chronic pain at this stage (RR 0.75, 0.60 to 0.95).

Later chronic pain

Twenty-one studies^{12,14,16,18,22,23,28,29,34,37,41,42,45,48,51,57,59,60,62–64} (36 per cent) reported pain as an outcome after 1 year, with 4481 patients randomized in the open repair group and 4290 in the laparoscopic repair group.

Table 1 Subgroup analysis of included studies

Patient-reported outcome	Outcome categories	Subgroups	Result	Effect size
Postoperative pain	Pain <i>versus</i> no pain	TAPP <i>versus</i> Lichtenstein ^{15,39,47}	Favoured neither	RR 0.55 (0.28, 1.07)
		TEP <i>versus</i> Lichtenstein ^{16,23,46}	Favoured neither	RR 0.76 (0.43, 1.34)
	Mean VAS scores (0–10)	TAPP <i>versus</i> Lichtenstein ^{19,27,45,52,66}	Favoured laparoscopic	MD –1.59 (–1.74, –1.44)
		TEP <i>versus</i> Lichtenstein ^{23,61}	Favoured laparoscopic	MD –0.54 (–0.75, –0.33)
Acute pain	Pain <i>versus</i> no pain	TEP <i>versus</i> Stoppa ^{10,58}	Favoured laparoscopic	MD –1.8 (–2.41, –1.19)
		TAPP <i>versus</i> Lichtenstein ^{15,38,47,62}	Favoured neither	RR 0.65 (0.29, 1.45)
		TAPP <i>versus</i> Shouldice ^{26,57}	Favoured neither	RR 0.82 (0.55, 1.21)
		TEP <i>versus</i> Lichtenstein ^{16,23,31,50,63}	Favoured laparoscopic	RR 0.62 (0.48, 0.82)
Early chronic pain	Pain <i>versus</i> no pain	TAPP <i>versus</i> Lichtenstein ^{9,12,38,66}	Favoured neither	RR 0.48 (0.17, 1.34)
		TAPP <i>versus</i> Shouldice ^{26,57}	Favoured neither	RR 1.02 (0.53, 1.96)
		TEP <i>versus</i> Lichtenstein ^{16,18,20,29,31,33,49,50,55,66}	Favoured laparoscopic	RR 0.71 (0.56, 0.89)
		TAPP <i>versus</i> Lichtenstein ^{12,45,62,64}	Favoured neither	RR 0.36 (0.06, 2.06)
Later chronic pain	Pain <i>versus</i> no pain	TAPP <i>versus</i> Shouldice ^{34,42,51,57}	Favoured neither	RR 0.60 (0.21, 1.73)
		TEP <i>versus</i> Lichtenstein ^{14,16,18,23,29,63}	Favoured laparoscopic	RR 0.58 (0.39, 0.86)
		TAPP <i>versus</i> Lichtenstein ^{11,38,39,47,64}	Favoured neither	RR 0.31 (0.10, 1.02)
		TEP <i>versus</i> Lichtenstein ^{14,16,18,20,23,31,50,55,63}	Favoured laparoscopic	RR 0.22 (0.12, 0.41)
Paraesthesia	Paraesthesia <i>versus</i> no paraesthesia	TEP <i>versus</i> Shouldice ^{17,48}	Excluded owing to extreme heterogeneity ($I^2 = 83\%$)	–
		TAPP <i>versus</i> Lichtenstein ^{47,62,64}	Excluded owing to extreme heterogeneity ($I^2 = 80\%$)	–
	Satisfied <i>versus</i> not satisfied	TAPP <i>versus</i> Shouldice ^{34,64}	Favoured neither	RR 0.92 (0.80, 1.05)
		TEP <i>versus</i> Lichtenstein ^{23,61,65}	Favoured neither	RR 0.91 (0.68, 1.22)
Period of disability	Length of time (days)	TAPP <i>versus</i> Shouldice ^{42,51}	Excluded owing to extreme heterogeneity ($I^2 = 97\%$)	–
		TEP <i>versus</i> Lichtenstein ^{55,66}	Favoured laparoscopic	MD –4.51 (–6.21, –2.81)
Time until return to work	Length of time (days)	TAPP <i>versus</i> Lichtenstein ^{11,12,66}	Favoured laparoscopic	MD –3.55 (–6.46, –0.63)
		TEP <i>versus</i> Lichtenstein ^{11,20,29,33,50,61,66}	Favoured laparoscopic	MD –3.66 (–5.23, –2.09)
Recurrence	No. of recurrences in laparoscopic <i>versus</i> open	TAPP <i>versus</i> Lichtenstein ^{9,11,15,25,27,38,45,47,52,62,64,66}	Favoured neither	RR 0.79 (0.52, 1.21)
		TAPP <i>versus</i> Shouldice ^{21,25,26,34,35,42,51,57}	Favoured neither	RR 0.96 (0.69, 1.33)
		TEP <i>versus</i> Lichtenstein ^{11,14,16,20,23,29,33,45,49,50,55,61,63,66}	Favoured neither	RR 1.05 (0.58, 1.91)
		TEP <i>versus</i> Shouldice ^{17,48}	Favoured neither	RR 1.73 (0.07, 40.38)

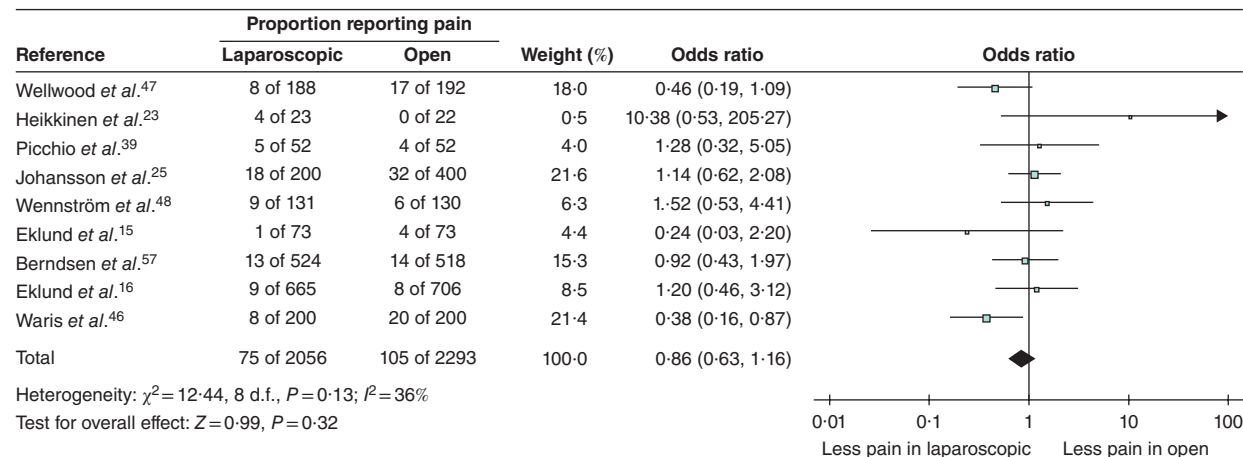
TAPP, transabdominal preperitoneal; RR, risk ratio; TEP, totally extraperitoneal; MD, mean difference.

All studies reported this as a dichotomous variable. The crude rate of pain at last follow-up during this interval was 9.4 (range 0–27.9) per cent in the open repair group and 6.6 (0–18.1) per cent in the laparoscopic group, after a mean(s.d.) of 53.9(28.6) (range 16–120) months. In meta-analysis, there was significantly less pain reported in the laparoscopic group (RR 0.62, 95 per cent c.i. 0.47 to 0.82) (*Fig. 5*). After exclusion of trials at high risk of bias,

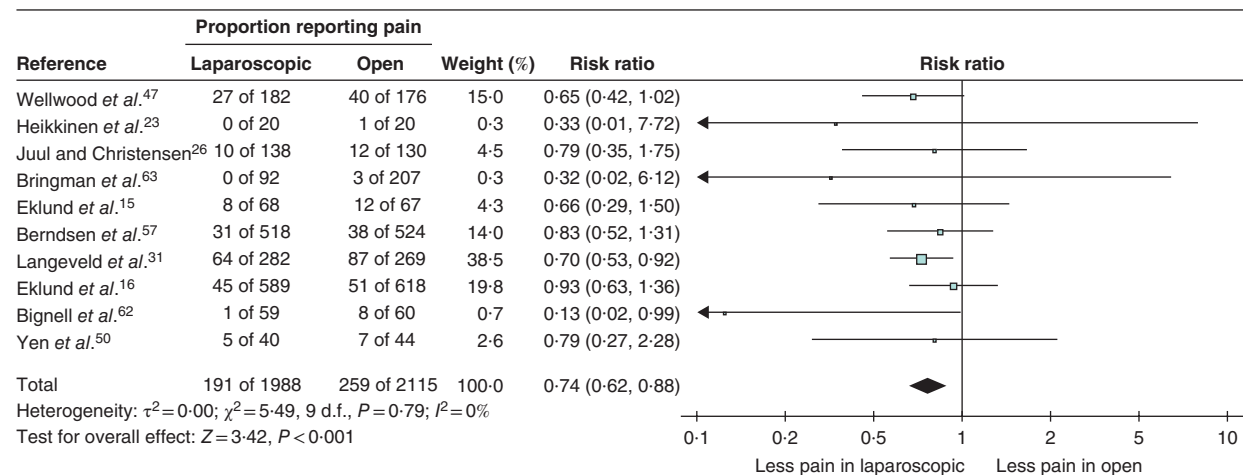
the laparoscopic group still had less chronic pain (RR 0.62, 0.48 to 0.82).

Paraesthesia

Twenty-two studies^{11,13–15,17,18,20,22–24,31,38–40,43,47,48,50,55,57,63,64} (38 per cent) reported paraesthesia, with 3446 patients randomized to open hernia repair and 3237 to laparoscopic repair.

Fig. 2 Meta-analysis of postoperative pain up to 2 weeks after laparoscopic versus open hernia repair

Risk ratios are shown with 95 per cent confidence intervals. A Mantel–Haenszel fixed-effect model was used for meta-analysis.

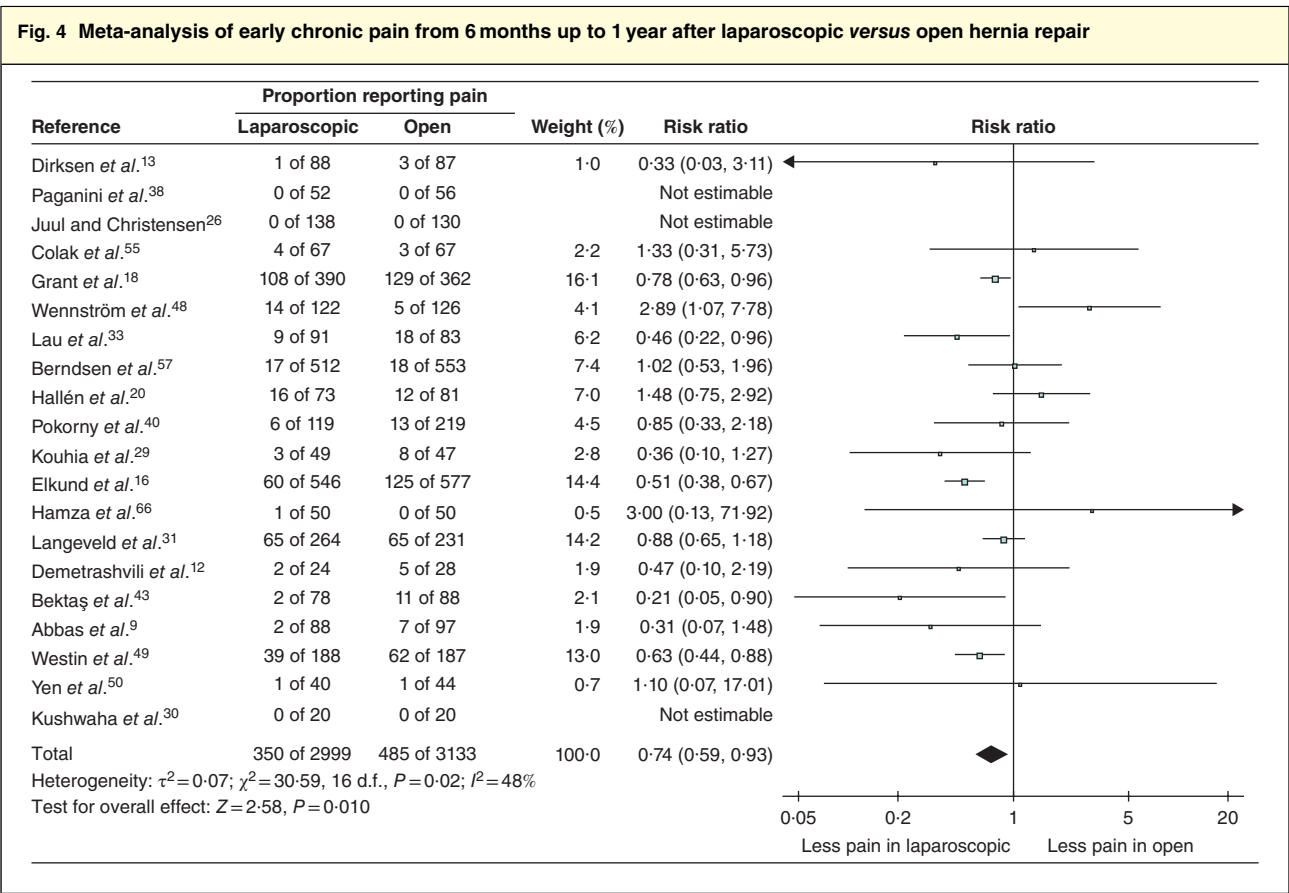
Fig. 3 Meta-analysis of acute pain from 2 weeks to within 6 months after laparoscopic versus open hernia repair

Risk ratios are shown with 95 per cent confidence intervals. A Mantel–Haenszel random-effects model was used for meta-analysis.

All studies reported this as a dichotomous variable. The crude rate of paraesthesia was 15.5 (range 0–80.9) per cent after open repair and 4.8 (0–18.1) per cent after laparoscopic repair, a mean(s.d.) of 18.4(21.6) (range 1–60) months following surgery. Meta-analysis showed that there was significantly less numbness reported in the laparoscopic group (RR 0.27, 95 per cent c.i. 0.18 to 0.40). After exclusion of trials at high risk of bias, the laparoscopic group still had less paraesthesia (RR 0.27, 0.15 to 0.49).

Other patient-reported symptoms

One study⁵⁷ reported that 1.5 per cent of patients in the laparoscopic (TAPP) group had postoperative nausea and/or abdominal discomfort at 7 days. The same study⁵⁷ also documented stiffness associated with the procedure, with one patient in each subgroup (open 1.7 per cent; laparoscopic 1.6 per cent) reporting this as an adverse effect. Another study²² reported groin tension after 5 years, affecting 1.7 per cent in the laparoscopic (mixed



Risk ratios are shown with 95 per cent confidence intervals. A Mantel–Haenszel random-effects model was used for meta-analysis.

TAPP/TEP) group and 5.1 per cent in the open (Lichtenstein) repair group.

One study⁵⁷ asked the patients at 3-month follow-up if they were experiencing any problems with sexual intercourse related to the procedure. Overall, 0.6 per cent of patients in the open (Shouldice) group and 0.4 per cent of patients in the laparoscopic (TAPP) group experienced this as an adverse effect⁵⁷.

One study⁶⁴ reported a VAS score for overall discomfort and/or pain. After 52 months, this was ongoing in 6.6 per cent of those in the TAPP group, 1.2 per cent in the Lichtenstein group and 6.8 per cent in the Shouldice group.

Satisfaction and patient-reported cosmesis

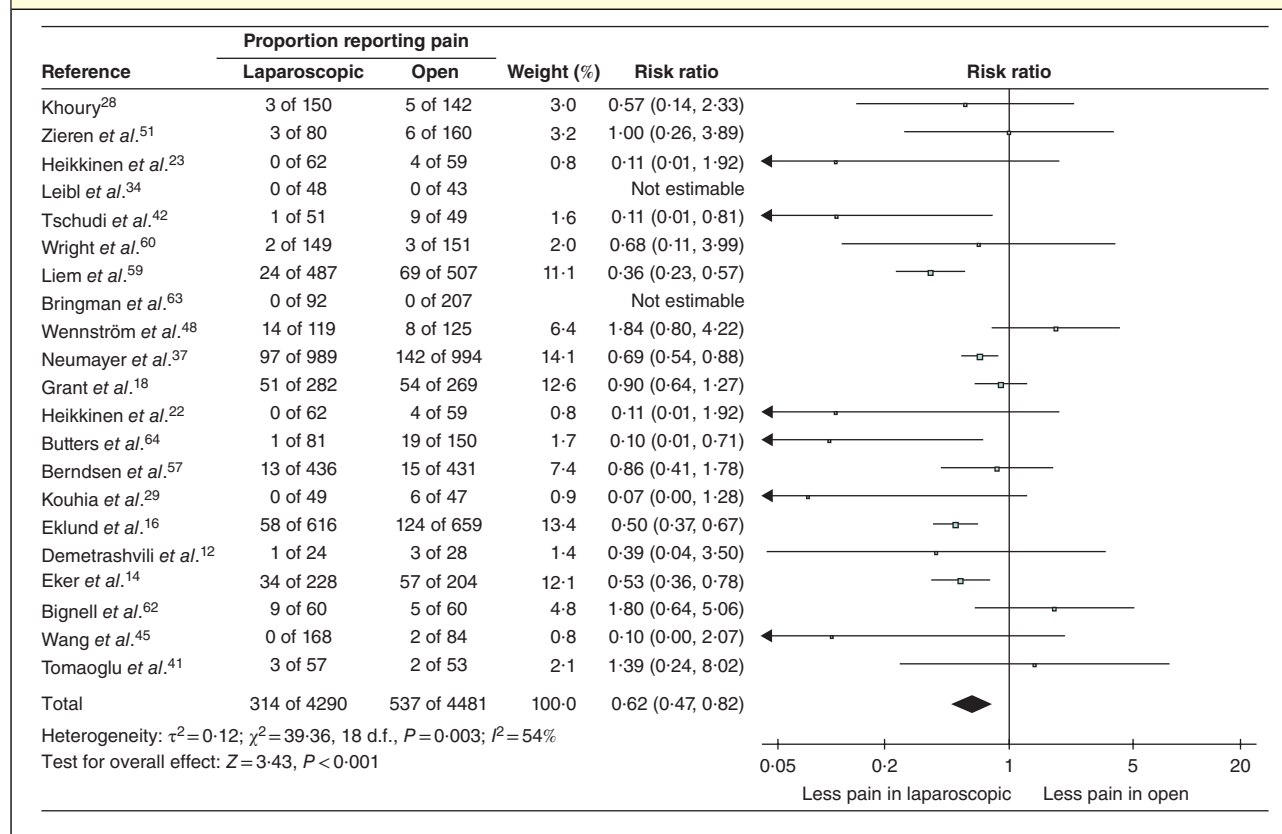
Fourteen studies^{14,20,22–24,32,34,36,42,43,47,62,64,65} reported patient satisfaction as a PRO. In total, 1654 patients were randomized in the laparoscopic repair group and 1750 in the open repair group. The crude rate of satisfaction at last follow-up was 79.3 (range 56–100) per cent in the open repair group and 88.7 (77–98.8) per cent in

the laparoscopic group, after a mean(s.d.) follow-up of 21.9(24.6) (range 3–72) months. Meta-analysis demonstrated significantly more patient-reported satisfaction after laparoscopic repair (RR 0.91, 95 per cent c.i. 0.85 to 0.98). After exclusion of trials at high risk of bias, the laparoscopic group still had a higher level of patient satisfaction (RR 0.89, 0.80 to 0.99).

The two studies^{14,20} (both TEP *versus* Lichtenstein) that did not report satisfaction as dichotomous data instead reported satisfaction ratings at 12 months (median 98 of 100 points after Lichtenstein *versus* 100 of 100 after TEP repair) and 60 months (mean 8 of 10 points after Lichtenstein *versus* 8.5 of 10 after TEP repair).

In total, three studies^{14,36,61} reported data on scar cosmesis. In the two studies^{36,61} that presented dichotomous data, the laparoscopic groups reported 100 per cent patient satisfaction with the cosmetic outcome at a mean of 13 months, and 28 per cent in both open groups. The remaining study¹⁴ presented a mean satisfaction rating at 60 months: 8.4 of 10 in the TEP repair group and 8.8 of 10 in the Lichtenstein group.

Fig. 5 Meta-analysis of later chronic pain from 1 year onwards after laparoscopic versus open hernia repair



Risk ratios are shown with 95 per cent confidence intervals. A Mantel–Haenszel random-effects model was used for meta-analysis.

Patient-reported outcome measures

In total, seven studies^{9,30,37,44,47,62,65} (12 per cent) reported PROMs; 1423 patients were randomized in the laparoscopic repair group and 1437 in the open group. Six studies^{9,30,37,44,47,65} presented scores on SF-36 version 1 or 2; of these, five reported no significant difference between scores at 3, 6 and 24 months. One study⁹ reported statistically significant results, with better physical health component and overall SF-36 (version 1) scores in the laparoscopic group at the end of follow-up. Only one study⁶² presented data for the SF-12 PROM, and reported no significant difference between the groups.

One study⁶² obtained scores on the Pain Impact Questionnaire 6, and reported no significant difference between groups. The Carolinas Comfort Scale was the only hernia-specific scale used. In the one study⁴⁴ that used it, although discomfort levels increased after surgery, they never differed significantly, and after 15 days had returned to baseline.

Time until return to work

Twenty-nine studies^{11–16,20,23,25,28,29,31–33,35–39,41,47,50,51,56,57,61–63,66} (50 per cent) reported time taken to return to work; 5543 patients were randomized in the open repair group and 5118 in the laparoscopic repair group. The crude mean time to return to work was 10.9 (range 2–27) days after laparoscopic repair and 16.8 (5–27) days after open repair.

Thirteen of these studies reported a measure of dispersion (s.d.) along with mean values, allowing meta-analysis. This meta-analysis produced an I^2 value of 81 per cent, showing extreme heterogeneity in study results, so was excluded from the analysis. This heterogeneity was also demonstrated after exclusion of trials judged to be at high risk of bias ($I^2 = 87$ per cent).

Period of disability and time until full recovery

Thirteen studies^{13,23,26,31,34,42,43,47,49,51,54,55,66} (22 per cent) documented patient-reported disability after surgery, defined as time to return to normal activities of daily

living. There were 1449 patients randomized in the open repair group and 1365 in the laparoscopic repair group. The crude mean period of self-reported disability was 14.8 (range 2–39) days after laparoscopic repair and 17.1 (3–40) days after open hernia repair. Seven of these studies presented mean(s.d.) values, allowing meta-analysis. This had an I^2 value of 98 per cent demonstrating extreme heterogeneity in study results, so was excluded from the analysis. Considerable heterogeneity was still evident after the exclusion of trials judged to be at high risk of bias ($I^2 = 79$ per cent). Subgroup analysis of TAPP *versus* Shouldice (2 studies) also demonstrated extreme heterogeneity ($I^2 = 97$ per cent).

In total, six studies^{17,25,47,49,51,63} reported patient-assessed time until full recovery, including 865 patients randomized to open repair and 874 to laparoscopic hernia repair. The crude mean time was 22.5 (range 14–18.4) days after laparoscopic repair and 24.9 (21–28.5) days after open hernia repair.

Hernia recurrence

Forty-six studies^{9–11,13–17,20,21,23,25–30,32–38,40–43,45,47–55,57,59–64,66} (79 per cent) reported hernia recurrence as an outcome. There were 7991 hernias randomized to open repair and 7614 to laparoscopic hernia repair. The crude mean rate of recurrence was 3.9 (range 0–21.4) per cent in the open group and 4.4 (0–16.7) per cent in the laparoscopic group, after a mean(s.d.) follow-up of 35.4(29.3) (range 1–120) months. Meta-analysis showed no significant difference in recurrence rates across all time points (RR 0.94, 95 per cent c.i. 0.72 to 1.24). The result was similar when trials at high risk of bias were excluded (RR 1.13, 0.84 to 1.52).

Discussion

This systematic review and meta-analysis of PROs included 58 unique RCTs. Comparisons were made between laparoscopic and open groups, along with smaller subgroups comprising specific techniques. Several outcome comparisons were conducted between TAPP *versus* Lichtenstein, TEP *versus* Lichtenstein, TAPP *versus* Shouldice, TEP *versus* Shouldice and TEP *versus* Stoppa.

Laparoscopic hernia repair caused significantly less pain than open repair in the postoperative (0–2 weeks), acute (over 2 weeks and within 6 months), early chronic (6 months to 1 year) and later chronic (over 1 year) time intervals. Although the definition of chronic pain varies in the literature, this result correlates with findings of other meta-analyses comparing laparoscopic and open techniques^{67,68}.

Notably, most studies lacked assessment of preoperative pain, and only one⁴⁴ employed a hernia-specific pain measure to capture preoperative pain. In addition, anaesthetic and analgesic regimens were often poorly documented. These regimens have a large impact on a patient's initial experience of pain. Their low rate of documentation makes it difficult to draw conclusions in favour of either laparoscopic or open techniques in the postoperative phase.

Regarding postoperative pain, when VAS pain scores were compared, a significant advantage was found for the laparoscopic group. However, analysis of studies comparing dichotomous variables showed no significant difference. The subjectivity of a dichotomous response may be less effective in capturing a patient's experience than a continuous variable such as a VAS score. The presence of early postoperative pain is important clinically as, along with age and hernia recurrence, it is a risk factor for chronic inguinal pain after hernia repair^{69,70}.

Paraesthesia was also reported less frequently after laparoscopic repair, presumably owing to the proximity of an open approach to the ilioinguinal or genitofemoral nerves⁷¹.

The rate of testicular swelling and sexual dysfunction was higher after open hernia repair. This may be due to the dissection around the spermatic cord which occurs during most procedures. However, when counselling a patient, it should be noted that inguinal hernia repair generally has a positive effect on sexual function⁷².

Patient satisfaction, along with perceived cosmesis, was also better after laparoscopic hernia repair. This is in keeping with the trend demonstrated for other laparoscopic, minimally invasive procedures^{73,74}.

PROMS were generally well reported and in keeping with the PRO CONSORT statement³. However, only seven studies (12 per cent) reported these measures and meta-analysis was not possible owing to the variety of PROMs used and outcomes reported by the authors. Five of the six studies that used the SF-36 instrument reported no significant difference between the laparoscopic and open repair groups.

Return to work was quicker after laparoscopic hernia repair, concurring with the finding of a previous meta-analysis⁶⁷. The authors grouped those in moderate and strenuous occupations together for this analysis; a smaller effect is likely for those in sedentary occupations. Extreme heterogeneity when analysing the duration of disability reported by patients prevented meta-analysis. Standardization of measurement of this variable should be introduced to allow accurate meta-analysis^{67,75}.

Meta-analysis showed no significant difference in hernia recurrence between laparoscopic and open repairs. These results are in keeping with the non-significant differences reported in a previous meta-analysis and large cohort studies^{76–78}. Thirty-eight of the 46 studies that examined this outcome used clinical examination for diagnosing recurrence; the rest reported the use of a questionnaire or telephone interview. The signs of recurrence at clinical examination may lead to an increased number of asymptomatic hernias being reported. Only one study¹³ documented whether the hernias were symptomatic at the time of diagnosis of recurrence. Only eight studies^{13,15,16,21,34,38,41,43} reported on reoperation for recurrence. If reoperation alone was used as a marker of recurrence, the actual recurrence rate would be under-reported.

The present data may be used by the clinician who wishes to provide their patient with the most up-to-date outcome data following inguinal hernia repair. This study described PROs only, which in fact were little different from those of previous meta-analyses^{67,75}.

The authors adopted a broad definition of the disease in this study, with both primary and recurrent inguinal hernias being included. Likewise, all different procedures were included. The authors acknowledge that the subgrouping of open or laparoscopic repairs for comparison (for example into tension-free *versus* TAPP/TEP) may produce different results. Laparoscopic hernia repair may not have such a significant advantage over open hernia repair in certain situations. In addition, because the results are patient-subjective in nature, to complete a picture of how a patient's clinical state has improved, a knowledge of their baseline and any change from this is required. Nevertheless, this study suggests that laparoscopic inguinal hernia repair has patient-centred advantages over open inguinal hernia repair.

Disclosure

The authors declare no conflict of interest.

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