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Meta-analyses of randomized controlled trials of laparoscopic vs conventional inguinal hernia repairs

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Abstract
Background: Despite randomized controlled trials, the merits of laparoscopic hernia repair remain poorly defined. A meta-analysis may provide a timely overview.
Methods: An electronic MEDLINE search, supplemented by a manual search, yielded 14 randomized controlled trials with usable statistical data, involving 2,471 patients. The trials were grouped for separate meta-analyses according to the control operation, either a tension-free or sutured repair, used for comparison. The effect sizes for operating time, postoperative pain, return to normal activity, and early recurrence were calculated, using a random-effects model when the effect sizes were heterogeneous and without subcategories.
Results: In all meta-analyses, the laparoscopic operation was significantly longer. When compared with tension-free repairs, the laparoscopic operation showed no advantage in terms of postoperative pain, but resulted in a shorter recovery (marginal significance). As compared with sutured repair, both postoperative pain and recovery were in favor of the laparoscopic operation. When all 14 trials were analyzed together, laparoscopic repairs still had moderately reduced postoperative pain and recovery time.
Conclusions: Laparoscopic hernia repair has a modest advantage over conventional repairs. This advantage is more apparent when laparoscopic repairs are compared with sutured repairs rather than tension-free repairs.

Key words: Inguinal hernia repair — Laparoscopic hernia repair — Laparoscopy — Meta-analysis

Inguinal hernia repair, one of the most frequently performed elective operations, has been refined continuously over the past century. Today, the conventional operation is an ambulatory or day surgical procedure performed with patient under local anesthesia, resulting in low morbidity and mortality. Laparoscopic hernia repair, introduced as a minimally invasive procedure since the late 1980s [6], has been increasingly performed.

Although a survey of the literature and expert panel in 1996 [9] indicated that the new operation is safe and effective, the claimed advantages over the conventional repair are deemed only potential and unproven. Negative randomized controlled trials [2, 12, 15, 17], suggesting that the laparoscopic technique offers little gain, have been offset by many positive randomized controlled trials [8, 10, 11, 13, 14, 18–23]. However, faster return to work, touted as the salient advantage of the laparoscopic repair by its proponents, was not supported by data in six trials [2, 8, 12, 15, 17, 19]. Further compounding the confusion are the different operations being compared in different trials (e.g., transabdominal preperitoneal [TAPP] or total preperitoneal [TPP] vs Lichtenstein, Shouldice, or a mix of other open operations). At this writing, no quantitative review of the published data exists.

Because conventional hernia repair already is an operation of low morbidity, any potential improvement, unless dramatic, may not be demonstrable by a trial of inadequate size. A large study of 994 subjects [14] comparing TPP with sutured repairs concluded that TPP is superior to sutured open repairs in terms of postoperative pain, time off work, and recurrence rate. However, there are no studies of comparable size comparing TPP or TAPP with tension-free repairs. In fact, many small trials in this category show substantially different findings [12, 15, 17]. A meta-analysis of the randomized controlled trials published so far is needed for a timely quantitative summary to improve the statistical power for resolution of conflicts and to determine if indeed a new large trial is indicated.

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Table 1. Compilation of published data from all trials (the database for the meta-analyses). Numbers are medians if followed by range in brackets, and means when given alone or followed by 95% confidence intervals

	n	Operation time	Less pain?	Recovery/days off work	No. of early recurrence
Group 1: Laparoscopic (TAPP) versus tension-free repairs					
Maddern [5]	L = 42	35 (23–55)	ns	17.5 (5–73)	2
	O = 44	30.5 (15–70); ns		30 (7–78); ns	0
Payne [18]	L = 48	68	—	8.9	0
	O = 52	56; ns	—	17; $p < 0.001$	0
Stoker [20]	L = 75	50	Yes; $p < 0.001$	14	0
	O = 75	35; $p < 0.001$		28; $p < 0.002$	0
Lawrence [12]	L = 58	72; 95% CI, 67, 75	Yes; $p = 0.001$	22 (2–99)	1
	O = 66	32; 95% CI, 30, 34		28 (1–103); $p = 0.13$	0
		$p < 0.0001$			
Heikkinen [8]	L = 20	71.5 (43–140)	Yes; $p < 0.01$	14 (8–26)	0
	O = 18	45 (16–83); $p < 0.001$		39 (5–40); ns	0
Paganini [17]	L = 54	L longer; $p = 0.02$	ns	ns	2
	O = 55				
Subtotal	L = 297				
	O = 310				
Group 2: Laparoscopic (TAPP/TPP) versus sutured repairs (Shouldice)					
Champault [4]	L = 92 (TAPP)	60 (45–35)	Yes; $p < 0.001$	12.5 (4–36)	0
	O = 83	58 (41–90); ns		24.3 (10–46); $p = 0.001$	0
Leibl [13]	L = 54 (TAPP)	65 (30–135)	Yes; $p < 0.001$	21	0
	O = 48	48 (30–110); $p = 0.00001$		38; $p < 0.001$	0
Tschudi [21]	L = 44 (TAPP)	87 (45–150)	Yes; VAS; $p = 0.001$; Analgesic, $p = 0.05$	25	1
	O = 43	59 (30–85); $p < 0.0001$		48	2
Schrenk [19]	L = 52 (TAPP, TPP)	40 ± 14; 38.4 ± 9.7	TAPP vs. Shouldice, ns	ns	11
	O = 34	ns			1
Liem [24]	L = 487 (TPP)	45	$p < 0.001$	14 (7–21)	17
	O = 507	40; $p < 0.001$		21 (12–33)	31
				$p < 0.001$	$p = 0.05$
Kald [10]	L = 110 (TAPP)	72 ± 30	—	12	0
	O = 89	62 ± 25; $p = 0.009$	—	23	3
				$p < 0.0001$	
Subtotal	L = 869				
	O = 842				
Group 3: Laparoscopic versus mixed open repairs					
Barkum [1]	TAPP = 33; IPOM = 10	87 ± 30	VAS: ns; Morphine; $p = 0.02$	9.6 ± 7.6	0
	Shouldice = 29	80 ± 59		11 ± 7.4	1
	Lichtenstein = 17				
	McVay = 2	ns		ns	
Kozol [11]	TAPP = 30	126 ± 37	Yes; $p = 0.02$	—	—
	McVay = 12	128 ± 38		—	—
	Bassini = 11	ns			
	Lichtenstein = 9				
Subtotal	L = 73				
	O = 80				

L, laparoscopic; O, open; N, subjects in the trial; ns, nonsignificant; VAS, visual analogue scale; IPOM, intraperitoneal on-lay mesh repair

Methods

An electronic search of the MEDLINE database was conducted using the following key words: inguinal hernia, herniorrhaphy, laparoscopic hernia repair, and randomized controlled trial of laparoscopic hernia repair. This search was supplemented by manual scanning of Current Contents and society abstracts. Four complete searches were conducted at 6-month intervals over a 2-year period. In all, 18 trials were found, the earliest published in May 1994 and the latest in March 1997. Papers written in foreign languages were translated into English. Fourteen trials (Table 1) met the minimal inclusion criteria of true randomized design comparing laparoscopic hernia repair with conventional open operation and having usable statistical data. Four studies were excluded from this project due to major deviation from the intention to treat principle and thus not of true random design (one trial [2]); missing key statistical data; and the authors did not respond to written enquiries (three trials [16, 22, 23]).

As shown in Table 1, several different operations were compared in different trials. Of 18 trials, 15 used the transabdominal preperitoneal repair (TAPP) as the laparoscopic technique, three used the TPP, and one used the intraperitoneal on-lay mesh method (IPOM). For the control operation, seven studies used the Lichtenstein repair (or a similar operation); six used some form of sutured repair (notably Shouldice, but also others including Bassini and McVay); and three used a mixture of open repairs in the same trial (Shouldice, McVay, Bassini, and Lichtenstein).

The 14 trials were first examined to see if the data could be combined. The nature of the hernia, the rate of conversion from laparoscopic to open surgery (failure to treat), age, gender ratio, proportion of bilaterality or recurrent hernias, and anesthetics used were found comparable among the studies. Surgeon experience in the laparoscopic technique was rated as proficient in all but three trials.

In all studies, follow-up examination was used as a method of determining recurrence, which could be considered as early only if there was a follow-up of 12 to 18 months (the Liem study, with a mean follow-up of 2 years also was treated as early). We selected early postoperative pain (first 2 days) for analysis, relying on the published *p* values to compute an effect size (see statistical analysis). Where more than one measure of pain existed (e.g., narcotics administered, rating on visual analog scale), the least significant *p* value was used. The definition of return to work or

Table 2. Effect sizes of four outcome measures: meta-analysis of group 1 trials

	Operation time	Pain	Recovery	Recurrence: Rate difference	Recurrence: Odds ratios
	Group 1: TAPP versus tension-free repairs				
Effect size *d*	0.61	−0.18	−0.29	0.02	0.00
95% CI					
Upper limit	0.16	−0.79	−0.58	−0.14	−0.16
Lower limit	1.07	0.43	−0.01	−0.18	0.16
Based on no. of trials	6	5	6	6	6
No. of subjects	607	507	607	607	607
Model: fixed or random effects	Random	Random	Random	Fixed	Fixed
Significance	Yes	No	Yes	No	No

Negative indicates laparoscopic < open

normal activity was not uniform across the studies, a major reason for using the effect-size statistic for meta-analysis (see Discussion section).

To make meta-analysis meaningful, the studies were grouped according to the operations compared, as shown in Table 1. The grouping was based on the consideration that the differences between TAPP and TPP were relatively small compared with the differences between Shouldice and Lichtenstein repairs, so the two laparoscopic operations were considered together to make the analysis manageable.

In group 1, the laparoscopic operation (mostly TAPP, but also TPP) was compared with a tension-free repair (Lichtenstein or a similar operation). In group 2, the laparoscopic repair was compared with sutured repair (Shouldice or a similar operation). This group included a large trial [14] with 994 patients comparing TPP with Shouldice and other sutured repairs. Group 2 was analyzed with and without this trial to evaluate whether a large trial may affect the conclusion.

In group 3, the laparoscopic repair was compared to a control group made up of different operations (e.g., Lichtenstein, Shouldice, McVay, Bassini), stemming from the decision of the investigators to leave the control operation to " the discretion of the surgeon." Separate meta-analyses are performed for groups 1 and 2 to deal with the problem of comparing different operations. The group 3 trials were not analyzed separately.

The published data of four outcome measures found in almost all the trials (operating time, early postoperative pain, recovery to full activity including work, and early recurrence) are compiled in Table 1, which forms the sole database for our mathematical calculations.

Statistical analysis

The meta-analytic technique best suited for the task was to calculate the effect-size statistic *d*, as prescribed by Hedges and Olkin [7]:

$$d = c\,(X_1 - X_2)/SD,$$

where X_1 (laparoscopic hernia repair) and X_2 (conventional hernia repair) were the group means of the outcomes compared, *SD* was the pooled sample standard deviation, and *c* was a normalizing constant, a correction for small sample bias, to yield an unbiased estimate of effect size. Negative effect size indicated that the mean values for conventional hernia repair were larger than those for the laparoscopic operation.

In studies for which variances were missing, the effect size was imputed using *p* values. The effect size was 0 when there was no significant difference. Otherwise, the sign of effect size was first determined, a positive or negative effect, and then the absolute value calculated as:

$$t\sqrt{}\,(1/n_1 + 1/n_2),$$

where *t* was the value of Student's *t* test statistic for a two-sided test for the associated comparison, obtained from the *p* values (either the exact *p* values or the significance level), and n_1 and n_2 were the sample sizes in the groups compared.

Because recurrence was reported in all trials as instances, it was amenable to analysis as an odds ratio and the effect size of rate difference. We calculated both as a confirmatory check.

The effect sizes were then tested for homogeneity using the Q statistics, an adaptation of the chi-square goodness-of-fit test [5, 7]. When found heterogeneous, the effect sizes were examined for subcategories, which may account for the heterogeneity. Because obvious subcategories that contribute to heterogeneity could be detected, a random-effect model analysis was used to make adjustment for heterogeneity [5]. 95% confidence intervals constructed around the effect sizes established their statistical significance. If the intervals did not cross zero, they were significant.

Results

Group 1 (Table 2): TAPP vs Lichtenstein or Maloney Darn repairs

In group 1, consisting of 607 subjects, the largest effect size was seen in operating time (effect size = 0.61; 95% confidence interval [CI], 0.16, 1.07), indicating that the laparoscopic repair was a longer operation. Postoperative pain, measured as analgesic administered or its rating on a visual analog scale, was not significantly different between the two operations (effect size = −0.18; 95% CI, −0.79, 0.43). Recovery was shorter for the laparoscopic repair, but barely reached statistical significance (effect size = −0.29; 95% CI, −0.58, −0.01). Early recurrence also was not different between the two operations, as calculated by both the effect size of rate difference and the odds ratio.

Group 2 (Tables 3 and 4): TAPP/TPP vs Shouldice or other sutured repairs

Group 2 was analyzed in two ways, with or without the Liem study [14], which was 5 to 9 times as large as the smaller trials, to determine whether the conclusions were altered by the large trial.

When all the trials in group 2 were included ($n = 1711$; Table 3), the laparoscopic operation was longer (effect size = 0.48; 95% CI, 0.07, 0.89), the postoperative pain significantly less (effect size = −0.49; 95% CI, −0.80, −0.18), and recovery also shorter (effect size = −0.55; 95% CI, −0.89, −0.21). Early recurrence was no different from that of the open operation by difference in either rates or odds ratio.

As shown in Table 4, when the Liem study was excluded from the calculations, the results were essentially unaltered for all outcome measures. When the results of both meta-analyses (including or excluding the Liem trial) were compared with the Liem trial [14], the operating time,

Table 3. Effect sizes of four outcome measures: meta-analysis of group 3 trials

	Operation time	Pain	Recovery	Recurrence	
				Rate difference	Odds ratios
	Group 2: TAPP/TPP versus sutured repairs				
Effect size *d*	0.48	−0.49	−0.55	−0.01	−1.48
95% CI					
Upper limit	0.07	−0.8	−0.89	−0.11	−4.31
Lower limit	0.89	−0.18	−0.21	−0.08	1.34
Based on no. of trials	6	5	5	6	6
No. of subjects	1,711	1,512	1,624	1,711	1,711
Model: fixed or random effects	Random	Random	Random	Fixed	Random
Significance	Yes	No	Yes	No	No

Table 4. Effect sizes of four outcome measures: meta-analysis of group 2 trials (excluding the Liem study [14])

	Operation time	Pain	Recovery	Early recurrence	
				Rate difference	Odds ratios
	Group 2: TAPP/TPP versus sutured repairs (excluding the Liem (study [14])				
Effect size *d*	0.52	−0.56	−0.29	0.02	0.00
95% CI					
Upper limit	0.03	−0.94	−0.58	−0.14	−0.16
Lower limit	1.02	−0.18	−0.01	−0.18	0.16
Based on no. of trials	5	4	4	5	5
No. of subjects	717	518	630	717	717
Model: fixed or random effects	Random	Random	Random	Fixed	Random
Significance?	Yes	Yes	Yes	No	No

postoperative pain, and time off work also were in agreement. For early recurrence, however, the Liem trial showed that laparoscopic herniorrhaphy was superior, reaching a *p* value of 0.05 at 2 years of follow-up, indicating borderline significance. It should be noted that in Liem's Kaplan-Meier analysis of recurrences, significance was not seen at 18 months of follow-up [14], which is identical to our analysis.

All trials (Table 5)

It is not possible to do a meta-analysis on a mix of open operations (group 3) without making the fundamental assumption that all open hernia repairs are the same. Under such an assumption, then, it is logical to analyze *all* laparoscopic operations against *all* open operations. Table 5 lists the results of such a meta-analysis covering 14 trials ($n = 2{,}471$). The results indicate that the laparoscopic operation is significantly longer (effect size = 0.48; 95% CI, 0.20, 0.75), the postoperative pain less (effect size = −0.37; 95% CI, −0.68, −0.06; note the marginal significance), and the recovery shorter (effect size = −0.31; 95% CI, −0.51, −0.12). Early recurrence is unchanged, calculated either as rate difference or odds ratio.

Discussion

One common difficulty in conducting randomized controlled trials of surgical operations is recruitment of sufficient subjects for the desired statistical power. All conclusions from small trials are at best tentative, and when the differences are only modest, conflicting conclusions among trials may be expected. Sample size appears to explain some of the divergent conclusions within groups. However, as shown by separate meta-analyses, the two groups have different effect sizes (e.g., postoperative pain), strongly suggesting that the postoperative courses of tension-free and sutured repairs are not the same. Tension-free, rather than sutured repair, more resembles laparoscopic repair because both used mesh implantation. Nevertheless, the effect sizes of all analyses are modest as a whole and quite heterogeneous, making firm conclusion difficult in individual trials.

The important methodologic question of whether meta-analysis of small trials is comparable with a single large randomized controlled trial was studied recently [3]. This study showed that the two usually are compatible unless there is a clearly explainable difference, a conclusion supported by the results from analyses of the group 2 trials with or without a single large study.

The group 2 meta-analyses agree not only with each other, but also with those of the single large trial (see Results section). We therefore believe that a new randomized trial comparing laparoscopic and conventional hernia repair of at least 2,400 subjects is unlikely to produce substantially different conclusions. Rather, effort should be directed to long-term follow-up of the patients included in the trials because hernia recurrence is known to be a function of time. Such recurrence data then are amenable to a meta-analysis of high significance, and could form a solid basis for final judgment on the relative merit of the operations.

Table 5. Effect sizes of four outcome measures: meta-analysis of all 14 trials

	Operation time	Pain	Recovery	Recurrence Rate difference	Recurrence Odds ratio
	All laparoscopic vs all open repairs				
Effect size *d*	0.48	−0.37	−0.31	−0.005	0.61
95% CI					
Upper limit	0.20	−0.68	−0.51	−0.09	−1.93
Lower limit	0.75	−0.06	−0.12	−0.08	0.72
Based on no. of trials	14	12	13	13	13
No. of subjects	2,471	2,172	2,409	2,409	2,409
Model: fixed or random effects	Random	Random	Random	Fixed	Fixed
Significance	Yes	Yes	Yes	No	No

The meta-analytic technique we selected is advantageous for another common difficulty in surgical trials, the intertrial variability of study endpoints. For example, resumption of normal activity was not defined well across studies in the reported meta-analyses. Several trials provided data on the recovery time required to reach different levels of activity, and one trial used standardized exercises to quantify work performance [18], but such details are missing in most studies. Postoperative pain, being intrinsically heterogeneous, has been estimated by various methods in different studies. The effect-size technique used in the reported meta-analyses was used originally in psychology research to combine the results of different psychosomatic tests that measured the same phenomenon. This technique is advantageous in dealing with interstudy end-point variability. Undoubtedly end-point variability contributes to effect-size heterogeneity, for which a random-effects model can be used to compensate [5] (see also Appendix).

Conceptually, for any given anatomic defect, the best hernia repair is as much a function of the surgeon's skill as the technology employed. According to the results of this quantitative review, laparoscopic hernia repair offers only a modest advantage in return for a substantially longer operation. It is the operation of choice for a patient who demands the fastest recovery money can buy, and whose surgeon is as facile with the laparoscopic as the open repair, especially when using sutured repair (e.g., Shouldice) as the open operation of choice. This advantage would be less, however, if the surgeon does tension-free open repair routinely. Although other conditions may make the laparoscopic operation attractive, such as bilateral and recurrent hernias, these were not addressed specifically in most of the trials, so no new information can be added by meta-analysis.

Appendix: notes on meta-analytic methods used in this study

Effect size

Effect-size statistics were used to answer "How much?" instead of "Is it different from 0?" Many effect-sized indicators were used commonly in this article for continuous measures (e.g., minutes). We computed effect size, *d*, as the difference between the two means expressed as a ratio to the pooled standard deviation. A 95% confidence interval constructed around this value established its significance: If the confidence interval touched or crossed the null point (0), the difference due to chance could not be excluded. For events recorded as counts that occurred infrequently (e.g., wound infection), odds ratios were used. An odds ratio is the ratio across groups for the odds that the event will occur, calculated as the fraction of afflicted persons divided by the fraction of those not afflicted.

Homogeneity of effect sizes and the technique used to combine them

After calculation of effect sizes for each trial, the next decision was the choice of models to estimate overall effect size and its variability. One model assumed that all effect sizes found in the trials arose from a single distribution (homogeneous effect sizes). This is known as a fixed-effect model. Another model assumed that the values potentially arose from distributions having different mean values, with significant variation among these mean values (heterogeneous). This is known as a random-effects model. Many nonquantitative factors, such as skill, affect the outcome of an operation, so trials of operations tend to produce heterogeneous effect sizes, necessitating the use of a random-effects model.

To select the appropriate model, we used the Q test [7] derived from chi-square statistics to determine if the effect sizes were heterogeneous or homogeneous. If heterogeneous, then subcategories of effect sizes attributable to differences in method or population should be sought that may adequately explain the heterogeneity. If no subcategories are found, then the random-effects model should be used.

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