Is Laparoscopic Inguinal Hernia Repair More Effective than Open Repair?

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ABSTRACT

Objective: To systematically review randomized controlled trials, (RCT) evidence comparing Lichtenstein to total extraperitoneal (TEP) hernia repair in terms of clinical and cost effectiveness.

Study Design: Case series.

Place and Duration of Study: The study was conducted at University of Abderdeen, U.K.

Methodology: A comprehensive online literature search was undertaken using databases such as MEDLINE, PubMed, EMBASE and Springerlink. Studies were then shortlisted according to the selection criteria (RCT with over 100 subject and English language publications from 1995 onwards) and appraised using the SIGN Methodology Checklist. A meta-analysis of the data was also performed using RevMan software.

Results: Analysis of reported data shows that TEP has less postoperative pain and return to work than Lichtenstein method. Operation time is shown to be longer in the TEP but this difference is shortened with increasing surgeon experience. The meta-analysis of the data on complications shows that there are no significant differences between the two types of procedures. TEP causes more short-term recurrences which are attributed to the learning curve effect. Long-term recurrence rates on the other hand show no significant differences. At present TEP is slightly more expensive than Lichtenstein repair.

Conclusion: Both TEP and Lichtenstein repair are clinically effective procedures. The choice between them should be made on a case-by-case basis; which depends on the patients' preference and characteristics such as age, work and health status.

Key words: *Inguinal hernia. Laparoscopic repair. Lichtenstein repair. TEP. Randomised controlled trial.*

INTRODUCTION

The majority of open hernia repairs utilise the 'tension-free' mesh methods which include Lichtenstein, Stoppa, Nyhus and Rutkow. Currently Lichtenstein method is the method of choice.

Laparoscopic repair is a minimally invasive approach and the two main methods are trans-abdominal preperitoneal (TAPP) repair and totally extraperitoneal (TEP) repair. The TEP method accesses the hernia site through the pre-peritoneal plane without entering the peritoneal cavity and is now the preferred method.[1]

Comprehensive background research showed that Lichtenstein and TEP repairs are currently the methods of choice in their respective open and laparoscopic categories for inguinal hernia repair. Therefore, this review focuses on comparing these two methods in terms of clinical and cost effectiveness.

METHODOLOGY

For the purposes of this review, a comprehensive online literature search was undertaken during May 2010 using the EBM reviews (All, Ovid), EMBASE from 1980 to present (Ovid), MEDLINE from 1950 to present (Ovid), PubMed and SpringerLink data bases.

All published randomised controlled trials (RCTs) after 1995 with study size of over 100 and in English comparing the effectiveness of laparoscopic inguinal hernia repair with open mesh inguinal hernia repair were eligible for inclusion. The short-listed papers were then each critically appraised twice using the Scottish Intercollegiate Guidelines Network (SIGN) RCT methodology checklist by all of the report authors. Meta-analysis of the collected data was performed using Mantel-Haenszel method using RevMan software version 5 from Cochrane IMS to generate a pooled mean difference and odd ratio for the continuous and dichotomous outcomes respectively. Corresponding 95% confidence intervals were calculated. A test of overall effect was also performed.[2] Heterogeneity was assessed using the test for (statistical) heterogeneity and I^2 statistic.[3] Where a meta-analysis was not possible, a narrative review of the evidence is provided.

RESULTS

Following database searches 37 possible studies were identified. Studies which reported data on intra-operative or post-complications and hernia recurrence as primary outcomes were prioritised. In addition to RCTs, systematic reviews and meta-analysis studies

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which met the inclusion criteria were also identified. The date of publication of the studies was restricted from, 1995 to present in order to avoid studies which evaluated TEP in its infancy. The sample size had to be over 100, with a minimum follow-up period of 12 months. This left 9 papers still eligible for inclusion, each was then critically appraised by 2 of the report authors using the SIGN guidelines which identified one paper (Liem *et al.*) to be excluded due to poor methodology - only 3% of patients in the open surgery group Lichtenstein repairs but most were done using the older Bassini method which made the study unreliable for meta-analysis. There were 8 studies remaining. Their results are given in Table I.

Post-operative pain

Eklund *et al.* used a visual analogue scale (VAS) (0-440 mm) showing the TEP group experienced less pain one week postoperative (105 mm) compared to the Lichtenstein group (175 mm).[4] Cumulative pain scores recorded during the first postoperative week were 105 mm in the TEP group and 175 mm in the Lichtenstein group. Neumayer *et al.* used a VAS (0-150 mm) showing the open group had significantly higher levels of pain shortly after surgery than those in the laparoscopic group by 10.2 mm (95%, CI 4.8-15.6).[5] Colak *et al.* showed the mean VAS was significantly lower with TEP compared to open mesh repair (p=0.001).[6] Bringman *et al.* reported mean VAS was lower in the TEP group than Lichtenstein group after 2 hours (p=0.009).[7] Langeveld *et al*. showed significantly lower VAS scores for TEP at day 1, 2, 3, week 1, and week 4 (overall $p < 0.001$).[8] Gokalp *et al.* measured using pain analogue scores and it showed no significant difference.[9]

Operating time

Operating time was reported by six of the papers showing times for each TEP operation to be 47 $\pm$ 12, 50, 54, 62 $\pm$ 14, 81 $\pm$ 27 and 55 minutes respectively.[6-11] The Lichtenstein method operating times were 58 $\pm$ 12, 45, 49, 46 $\pm$ 11, 59 $\pm$ 20 and 55 minutes repectively.[6-11]

Time to discharge

Andersson *et al.*, Eklund *et al.*, Gokalp *et al.* and Langeveld *et al.* all reported data on time to discharge however, none showed any significant difference between the TEP group and the open repair group, with neither group needing to stay in hospital for more than 48 hours on average.

Return to work

There were six papers which discussed the duration of sick leave, showing that the duration of sick leave was shorter in the TEP group when compared with the open repair group.

The meta-analysis of the three papers[9-11] which reported sufficient data, gave mean difference of 3.4 (95% CI -4.2,-2.7; p-value < 0.001) days in favour of the laparoscopic procedure. Bringman *et al*. reported it to be 5 days in the TEP group and 7 days in the Lichtenstein group (p=0.02).[7] Similarly Langeveld *et al*. reported this to be 1.0 week in the TEP group and was 1.4 week in

Table I: Study characteristics.

	Comparision	Number of subjects	Subject ages in years (median)	Follow-up (months)	Follow-up rate	Randomisation	Years of study	Number of sugeons
Anderson *et al.*	Lichtenstein vs. TEP	168	30-65 (49)	7.3 years (median)	92%	Sealed enveloped in blocks of 10	1996 - 1997	3
Eklund *et al.*	Lichtenstein vs. TEP	1370	30-70 (52)	5 years	94%	Computer generated blocks of 20, in envelopes	1996 - 2000	48
Neumayer *et al.*	Lichtenstein vs. TEP (90%) and TAPP (10%)	2164	18+ (58)	2 years	78%	Computer generated permuted-block sequence and stratified by hernia type and study site	1999 - 2001	78
Pokorny *et al.*	3 open (Bassini, Shouldice and Lichtenstein) vs. 2 laparoscopic (TEP and TAPP)	365	19 - 85 (47)	3 years	100%	External biometric department	1998 - 2002	Not reported
Gokalp *et al.*	Lichtenstein vs. TEP	140	18 - 60 (45)	18 months (median)	85%	Sealed envelopes opened day before surgery	2000 - 2001	4
Colak *et al.*	Lichtenstein vs. TEP	134	16 - 77 (49)	12 months (mean)	77%	Computer generated by an independent consultant	2000 - 2001	3
Bringman *et al.*	Lichtenstein vs. TEP	299	30 - 75 (54)	19.8 months (median)	98%	Consecutive opening of sealed envelopes	1997 - 2000	10
Langeveld *et al.*	Lichtenstein vs. TEP	660	Not reported (55)	5 years	75%	By telephone or fax by central study coordinator according to a stratified computerised list	2000 - 2004	Not reported

Table II: Meta-analysis of the data on complications .

Complication	Occurrence rate in TEP	Percentage	Occurrence rate in Lichtenstein	Percentage	p-value
Heamatoma	237/2313	10%	209/2403	9%	0.08
Seroma	121/1648	7%	64/1694	4%	0.0001
Wound infection	25/2313	1%	41/2400	2%	0.08
Sensory loss	10/325	3%	47/345	14%	0.00001
Testicular complications	47/2227	2%	37/2328	2%	0.12
Chronic pain	185/2254	8%	260/2330	11%	0.0001

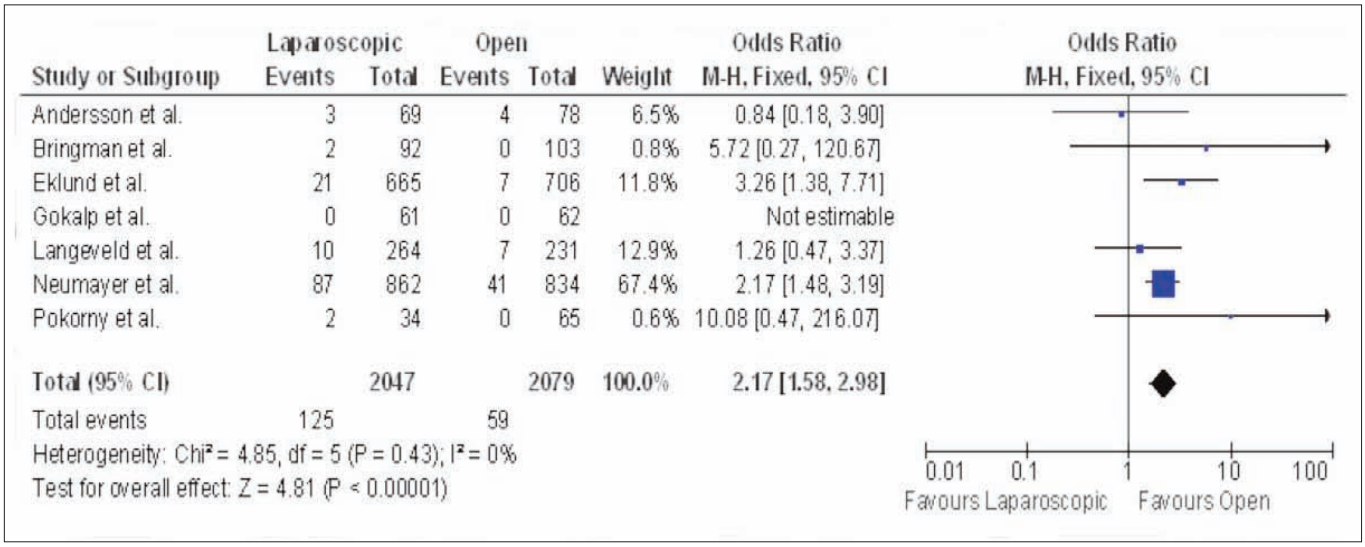

Figure 1: Meta-analysis of recurrence.

the Lichtenstein group (p=0.01).[8]

Overall complication rates showed no significant difference between the two modalities each having overall rate of 6% (n=625/11080 TEP and 658/11500 Lichtenstein, p=0.40, Table II).

Recurrence rates in the TEP group ranged from 10.1% to 0% and between 4% and 0% in the Lichtenstein groups.[5,9,12] The meta-analysis of the data from 6 studies had odds ratio of 2.17 (95%, CI 1.58, 2.98; p < 0.001) showing greater recurrence in the Lichtenstein group (Figure 1). There was no evidence of any heterogeneity between studies.

Economic cost

Four out of the 8 studies provided economic data regarding the cost of the procedure. In this review both direct and indirect costs were considered. Direct cost is the burden of the procedure on the hospital, which includes instruments, operating theatre time, ward cost and complications. Indirect cost includes sick leave, cost of home care and loss of productivity.

According to Andersson *et al*. the operation time was much longer for TEP which accounted for half of the $1091 cost difference with the other half being from the instrumentation.[10] The indirect cost difference (+ $349 for TEP) was also calculated however, not found to be statistically significant (p=0.21).

Eklund *et al*. included details of how they calculated cost per minute as well as adjusting for the capital costs in purchase of laparoscopic kit which was either not mentioned or just omitted by others in their calculations.[11] The cost difference after 5 years was 292 more for TEP which was an indirect cost inclusive of any complications and social costs. Had re-usable equipment been used, the direct hospital cost difference would have been 290 lower giving a difference at 5 years of only 2.

The paper by Langveld *et al.* was the most recently published paper included in this review and the only one to find a total cost saving for laparoscopic surgery after adjustment for social and patient costs which was reported as 102 (3,096 for TEP, 3,198 for Lichtenstein).[8]

DISCUSSION

Surgeon experience and operator influence

From the meta-analysis of three studies reporting operation time it was found that open repairs were on average 7 minutes shorter than TEP (p=0.0006).[6,9,10] However, surgeon's experience clearly has an impact on TEP repair time, increasing experience leads to decreasing operating times. Other outcomes included in this review such as the various complications, recurrence and operating time have also been shown to

be affected by surgeon's experience.[13] Not all the operations in the studies reviewed were conducted by equally experienced surgeons. If an accurate assessment of the safety and effectiveness of laparoscopic mesh repair surgery compared to open surgery is to be made, the experience of different surgeons should be standardised in each study. However, defining experience is subjective and trying to quantify the experience required to eliminate learning curve effects is difficult. Neumayer *et al.*[5] suggested that surgeons performing TEP should have experience of between 30 and 250 laparoscopic repairs, until this point they should be supervised. In this review the following studies implemented a minimum number of previous cases across all TEP surgeons: Pokorny *et al*. mentioned 30,[12] Eklund *et al.* 25,[4] Neumayer *et al.*[5] (n=25) and Langeveld *et al.*[8] (n=30) in an attempt to minimize its effects. These results are better indicative of how well TEP performs in clinical practice as it minimizes the learning curve effects whereas the other studies did not specify surgeon experience. This is evident from Neumayer *et al*.[5] who reported that surgeons who had previously performed more than 250 laparoscopic repairs had significantly less recurrence rates (< 5%) than those who had performed with 250 or less repairs (> 10%).

Similarly, learning curve effects could have affected the open groups as none of the studies, except Pokorny *et al*.[12] reported surgeon experience with the Lichtenstein technique as part of their study.

Eklund *et al*.[11] highlighted in their complication analysis that 4 out of 5 short term recurrences in the TEP group were attributed to just one surgeon and significantly, 3 of these occurred in his first dozen cases. Furthermore 83% of all postoperative complications were caused by just 6 surgeons. This further proves that competency rather than just numbers determine the quality of a surgeon's work.

The total surgeon numbers participating in a study has an impact on the reliability and generalisability of the results of each technique. In a study like Andersson *et al.*[10] with only 3 participating surgeons, the results are more likely to be a reflection on their individual surgical ability than results from papers which included more surgeons such as Eklund *et al*.[11] where the combined results from 48 surgeons make up the overall results.

Postoperative pain

Several papers evaluated postoperative pain showing that in general, pain was lower in patients who underwent TEP compared to Lichtenstein repair.[4-8] However, it should be noted that there was no standardised scale for assessing pain across the studies as mentioned in the results section. Since pain perception and analgesic requirement are variable and can be influenced by cultural and environmental factors, a bias could surface when patients are asked to grade their own pain levels. Thus a more objective method of pain measurement is preferable.

Gokalp *et al.*[9] showed that there was no significant difference in the pain scores between the two groups. This inconsistency could possibly be due to the low power of the study as well as possible differences in anaesthetic pain management between hospitals. Eklund *et al*.[4] also reported that patients did not always use the prescribed analgesic drug after surgery. However, it is unlikely to have affected the results since this was observed in both groups.

At 12 weeks follow-up all studies demonstrated that the pain difference between patients in the two surgical procedures is eliminated. Of all the outcomes considered, short-term pain is one of the most conclusive in that TEP causes significantly less pain in the recovery phase. This has a direct correlation with return to normal daily activity/work but not evident in the long-term.

Time to discharge and return to work

All studies show that the method of inguinal hernia repair (TEP and Lichtenstein) has no impact on discharge time. Since both methods are day case procedures, finding any time difference is not clinically significant as the outcome is confounded by hospital routines and the time of day the procedure is done.

The duration of sick leave is shorter in the TEP group when compared with the Lichtenstein group. TEP is more advantageous than open repair in the working age group as it offer a significantly faster return to work. This is due to reduced postoperative pain, decreased infection rates and fewer chronic complications. Furthermore open surgery allows for the option of local or regional anaesthesia which is crucial for patients unfit for general anaesthesia. An example of this is the large proportion of elderly patients who require inguinal hernia repair, in whom Lichtenstein is a more clinically sound choice as return to work is irrelevant.

Complications

This review concentrated on the commonly encountered clinically significant complications that were caused by inguinal hernia repair. It is vital that any newly proposed intervention has similar if not fewer complications than the current standard, Lichtenstein, for it to be widely adopted. Complications not specific to inguinal hernia repair were excluded from the analysis; urinary retention which is confounded by spinal anaesthesia was not used as an indicator of surgical technique safety because it maybe biased towards TEP since general anaesthesia is always used during laparoscopic operations. However, it is important to note that several of the studies attribute surgeon error to be the cause for the development of certain complications post-operatively in patients in the TEP group. This was mainly due to the learning curve issue and increased

experience will help reduce number of complications. The meta-analysis of the data on complications shows that there is no significant statistical difference between the two types of surgery used to repair inguinal hernias. This does not however, imply that the two techniques are clinically equal in terms of safety as some complications are more severe than others.

Follow-up and recurrence

The follow-up period of the studies reviewed is critical to assessing the recurrence rate of the inguinal hernias. Inguinal hernias commonly recur within 2 years of the operation.[14] Recurrence is the most common complication after inguinal hernia repair that may require the need for additional operations. Therefore, this outcome is of significance when comparing different methods of repair.

All of the papers reviewed for the recurrence outcome had a minimum follow-up time of 18 months, increasing the reliability on the likelihood of recurrence following both open and laparoscopic procedures. Recurrence in the study conducted by Bringman *et al.*[7] was self-reported by the patients, possibly leading to under-estimation of true recurrence of the hernias. Patients probably lack the ability to identify recurrence on self examination or may not report recurrence to avoid the hassle of repeat treatment.

All the studies reviewed reported their dropout rates however, only Pokorny *et al*.[12] Eklund *et al.*[11] Neumayer *et al*.[5] Andersson *et al*.[10] and Langveld *et al*.[8] carried out intention to treat analysis accounting for the missing patients in their conclusions. Furthermore Langveld *et al.*[8] and Neumayer *et al*.[5] had end point follow-up rates of less than 80% which even considering their intention to treat analysis may mean their results are unreliable. In laparoscopic repair misplacement of the mesh due to surgeon error could result in early recurrence whereas open recurrences generally occur later as true recurrences. Length of follow-up could contribute to bias; papers which only followed-up for one year might only pick-up on the short-term recurrences and underestimate the true recurrences within the open group which occur later.

Economic evaluation

Economic evaluation and cost effectiveness are critical in determining whether or not a new technique is widely adopted within the health care system. Normally any new technique will cost more and this is reflected in all the studies reviewed apart from Langeveld *et al.*[8] which was just published in May 2010. These conflicting results may arise from lack of consensus concerning study methodology, differences between medical service systems and variations in the experience levels of surgeons.[15]

One major factor in the increased cost of TEP is the longer operation time compared to open repair; mean of 9 minutes from the meta-analysis. However, this outcome has been proven to be affected by the learning curve which may make it economically less attractive compared to older, simpler techniques. Eklund *et al*.[11] suggests that increasing experience with the technique decreases the operation times. Langeveld *et al.*[8] which is the most recent study reviewed shows that laparoscopic surgery is now cheaper than open surgery. This indicates that a global increase in laparoscopic surgery experience may be improving its cost effectiveness.

The other major factor leading to increased cost of TEP is the use of disposable laparoscopic equipment. But McCormack *et al*.[16] reported that replacing the disposable equipment with re-usable ones would drastically decrease the cost difference by as much as £100 - £150 per case. This is further supported by another UK multi-centre study[17] which also reported significant savings.

In the near future as efficiency increases and surgeons start moving to reusable instruments the costs may decrease further. An area of bias which occurred in most of the papers considered was the skill of the surgeon which would also reflect on their operating time and recurrence rate which have a direct effect on the overall cost. Fully trained surgeons can now complete a laparoscopic repair in the same time or faster than an open one which has only become clear over the past few years due to the learning curve surgeons had been on when some of the earlier papers were published.

It should be noted that all papers reviewed did not include any blinding - one short-listed paper by Butler *et al.*[18] did manage to achieve double-blinding using large bandages however, it was not reviewed as it did not meet the inclusion criteria. Future studies should try to use double-blinding to minimise bias of the reporting and recording of outcomes. In addition the reviewed papers all excluded patients who were unfit for surgery or had undergone previous abdominal surgery; this is not representative of the population as a whole. Therefore, efforts to try and include such populations as part of the inclusion criteria should be sought.

As mentioned previously in the 'Postoperative Pain' section, reviewed papers used different VAS to assess pain. It would be beneficial if future studies could utilise a standardised VAS for pain assessment in order to obtain clearer comparisons between studies.

From existing evidence it is clear that higher rates of surgical error are attributable to the learning curve.[5] Therefore, TEP simulators could be developed in the future to help train surgeons overcome the learning curve before performing actual surgeries. As discussed in the cost-effectiveness section re-usable equipment reduces the overall cost of TEP. Use of re-usable equipment in all hospitals should be recommended in order to reduce the overall cost of the procedure.

CONCLUSION

The results from the reviewed papers suggest there is no definitive answer to whether TEP repair is more advantageous than Lichtenstein for primary inguinal hernias when taking all factors into account. For patients who are of working age and recovery time is important as well as recurrent hernias, TEP is advantageous. However, for older patients and those less suitable for general anaesthesia the open Lichtenstein method is favoured.

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