

Laparoscopic extraperitoneal repair versus open inguinal hernia repair: 20-year follow-up of a randomized controlled trial

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Abstract

Purpose This study compared the long-term recurrence rates of laparoscopic totally extraperitoneal (TEP) and open inguinal hernia repair in patients from a randomised trial completed in 1994. Laparoscopic inguinal hernia surgery, especially TEP repair, has gained widespread acceptance in recent years. There is still paucity of data on long-term follow-up comparing recurrence rates for open and laparoscopic techniques. This is the first study providing direct long-term comparative data about these techniques.

Methods A randomised controlled trial was conducted between 1992 and 1994 on patients undergoing a laparoscopic TEP or an open inguinal hernia (Shouldice) repair at our institution. Of the original 104 participants, contemporary follow-up data could be obtained for 98 patients with regards to long-term recurrence. These data were collected with the help of questionnaires, telephone calls and retrieval of case records. Medical records were reviewed for all patients. Data were analysed using a Cox proportional hazards model.

Results There were 7/72 (9.7%) recurrences in the open group and 9/35 (25.7%) recurrences in the laparoscopic group. This difference in recurrence rates was statistically significant (HR = 2.94; 95% CI 1.05–8.25; $p = 0.041$.)

Conclusion Laparoscopic TEP inguinal hernia repair performed in 1992–1994 had a higher recurrence rate than open

Shouldice inguinal hernia repair during the same period. The original study was undertaken in the inceptive days of laparoscopic surgery and results need to be interpreted considering the technology and expertise available at that time.

Keywords Extraperitoneal · Laparoscopy · Inguinal hernia · Long term outcomes

Introduction

The most frequent operation performed by general surgeons is inguinal hernia repair [1]. Inguinal hernias account for 75% of all abdominal wall hernias, with men and women having a lifetime risk of 27% and 5%, respectively [2].

The two surgical options for inguinal hernia repair are the minimally invasive laparoscopic approach or an open approach. Analysis of outcomes for both interventions do not provide a definitive answer as to which is more successful. Some studies have shown that the laparoscopic approach can lead to lower rates of postoperative pain [3–7] and numbness [5] with shorter periods of sick leave along with a shorter timeframe for resumption to normal physical activity when compared with open techniques [3, 6, 7]. However, other studies contradict this and have shown higher rates of complications in laparoscopic groups when compared to open repair [8]. Furthermore, some studies have revealed that there is no benefit for laparoscopic repairs in regard to complication rates [6], length of hospital stay [7] and return to work and patient satisfaction [9].

Reports on long-term outcomes remain sparse. According to the NICE guidelines, a totally extraperitoneal (TEP) laparoscopic hernia repair is suitable primarily for recurrent and bilateral inguinal hernias [10]. Furthermore, NICE stated in 2004 that the laparoscopic approach can be considered

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in unilateral repair as well [11]. In 2004 Neumayer demonstrated that over a 2-year period, there were higher recurrence rates following a laparoscopic technique (10.1%) compared with open repair (4.0%) [8]. Some trials have found no difference in the recurrence rates between the two techniques over a medium term [12], while others showed lower recurrence rates after 4 years in the laparoscopic group (4.9%) as compared with the open group (10%) [13].

Ambiguity thus remains regarding the best approach to inguinal hernia repair in terms of long-term recurrence rates. An extensive literature search failed to reveal any randomised controlled trial that compares recurrence rates of inguinal hernias with follow-up longer than 5 years. The aim of this study is to compare long-term recurrence rates following open and laparoscopic TEP repair of inguinal hernias in a cohort of patients recruited in a randomised trial more than 20 years ago.

Research design

A randomised controlled trial was performed between 1992 and 1994 comparing open (Shouldice) versus laparoscopic hernia repair with a totally extraperitoneal approach (TEP) [14]. The short-term results of this trial were published in 1996 [14]. This study presents the results of long-term follow-up of this trial and was approved by the Human Research Ethics Committee of The Queen Elizabeth Hospital/Lyell McEwin Hospital/Modbury Hospital. Records of 98 of the original 104 participants were retrieved and reviewed. The original study planned for 54 open repairs and 50 TEP repairs. Of the laparoscopic group, 18 were converted to open repairs for various reasons outlined in Table 1. The final analysis in the initial trial included 72 open and 32 laparoscopic participants.

The recruitment and surgical procedures of the initial trial are detailed in the original publication by Bessell et al. [14]. Six patients from the original trial were excluded, two from the open group and four from the laparoscopic group (leaving 70 patients from the open group and 28 from

laparoscopic group for comparison). In the laparoscopic group, three patients had an inadvertent peritoneal breach (converted to a laparoscopic transperitoneal repair-TAPP) during the procedure and were excluded, and one individual had developed dementia and was unable to complete the questionnaire. The two exclusions from the open group were patients who had deceased and their data could not be retrieved by any alternative means.

The final cohort included 70 patients (including 2 bilateral = 72 hernia repairs) in the open group and 28 (with 7 bilateral = 35 hernia repairs) in the TEP group. A total of 107 hernia repairs were reviewed from 98 participants. Table 2 shows the patient demographics of the participants followed-up.

Data from the original study completed by Bessell et al. [14] was recorded in a de-identified work sheet. Given the long-term nature of the study, the Department of Births, Deaths and Marriages were approached to provide accurate mortality data. Of the study group, 28 were deceased. Case notes for these patients were examined and if a recurrence was identified, the date of either the repeat surgical repair or, if managed conservatively, the time of diagnosis was recorded. Clinical records of the patients who did not have a documented recurrence were reviewed and their date of death was noted.

After approval from ethics, all surviving patients were sent a letter and questionnaire with an opt-out consent option. If the questionnaire was not returned within 2 weeks the participants were contacted by telephone. The date of return of the questionnaire or the phone call was recorded as the last date of follow-up. Finally, if the participant was no longer living at the last recorded address and telephone contact failed, their clinical records were reviewed. If there was no recurrence, the date of the last abdominal exam was recorded.

Statistical analysis

The data were summarised as the number of events and censored observations with stratification by group, sex and side of hernia. Age and length of follow-up were reported as

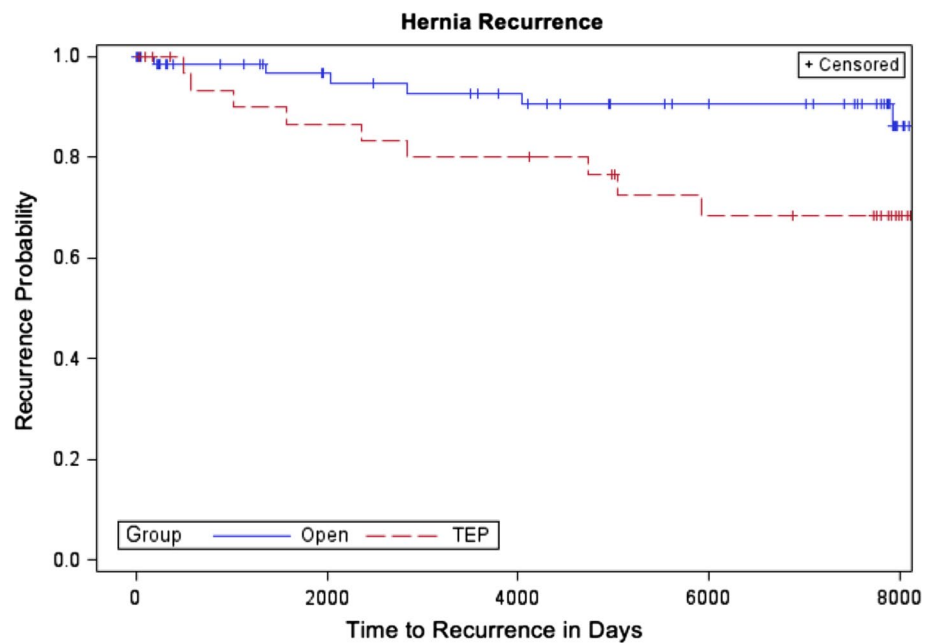
Table 1 Reasons for conversion from laparoscopic to open repair in the original study [7]

Reason for conversion	Number of participants
Failed	6
Scars	4
Unsuitable	3
Bilateral	2
Refused	2
Anaesthetic risk	1
Total number	18

Table 2 Demographics of participants in this follow-up study

Demographic	Open group <i>n</i> = 70	TEP <i>n</i> = 35	Total
Unilateral	70	28	98
Bilateral	2	7	9
Male	67	24	91
Female	3	4	7
Mean age (years)	51.7 (±17.2)	53.0 (±17.5)	
Median age (years)	53.2 (20.9–86.6)	56.7 (19.8–79.1)	

Fig. 1 Recurrence rates of Open and TEP groups over a 20-year period (colour figure online)



means and medians with standard deviations and range. An intention to treat ITT analysis based on the original randomisation was not performed as the participants remained in the study for different lengths of time and this was a follow-up study in patients assessing outcomes of the actual surgery performed. Recurrence-free survival was summarised using a Kaplan–Meier curve and assessed using a Cox proportional hazards model. The proportional hazards assumption held for both models.

Results

Follow-up was attempted with questionnaires of which 23 were returned, phone calls of which 18 were answered and by examining medical records for remainder of the participants ($n = 50$). In seven cases, there was no response and records were not contributory, hence the last date of follow-up noted in the original study by Bessell et al. [14] was recorded. Sixteen hernias recurred. Of the sixteen recurrences, four were identified by questionnaire, one by phone call and 11 were found by case note review. The date of diagnosis of the recurrence was recorded.

There was a significant male predominance in the study which reflects the ratio of male to female distribution of groin hernias in the community [15]. There were seven (9.7%) recurrences out of 72 hernias in the open group and nine (25.7%) recurrences in 35 hernias in the TEP group. In the unadjusted analysis, the hazard of recurrence was significantly higher in the TEP group when compared to the open group (HR = 2.94; 95% CI 1.05–8.25; $p = 0.041$) as

Table 3 Mean and median length to follow-up for the open and TEP groups

	Mean (standard deviation) (months)	Median (range)
Open	162.1 (106.2)	190.9 (0.30–276.6) months
TEP	167.3 (103.4)	194.8 (1.05–272.7) months
		$p = 0.669$

depicted in Fig. 1. Adjustment for age had little effect on the magnitude or significance of the hazard ratio (HR = 2.92; 95% CI 1.04–8.22; $p = 0.042$). Late recurrences (after 10 years), however, occurred proportionately more in the open group (42% of open vs. 33% of TEP). The median and mean length to follow-up is outlined in Table 3.

Discussion

These results indicate that after long-term follow-up, open repair with a Shouldice method led to a lower recurrence rate compared to a laparoscopic TEP repair. Recent studies, however, report a much lower recurrence rate for contemporaneous laparoscopic TEP repairs. This may reflect improved training and advancements in equipment and technique over the last 20 years. A trial from 2016 found a recurrence rate of 1.1% in a TEP trial with most of the recurrences being identified early in the trial and one 6-years post-operatively [16]. Another recent study reported a recurrence rate of 0.94% in the TEP group and 0.83% in the Lichtenstein open group after very brief 1-year follow-up [17].

The results of our study correlate with a meta-analysis in 2012 that revealed a relative risk for recurrence of 3.72 (95% CI 1.66–8.35; $p = 0.001$) when comparing TEP to open repairs [5]. The meta-analysis reviewed 27 randomised control trials from a similar time period to which Bessell et al. [14] performed the original trial.

A study published in 2005 analysed 466 patients two years after Shouldice repair and reported a recurrence rate of 6.7%. As with the trial completed by Bessell et al., these participants were recruited between February 1993 and March 1996 [18]. A prospective randomized single-centre trial published in 2007 found that the Shouldice technique had a recurrence of 8.1% after a median follow-up of 52 months [19]. Given the length of follow-up in the current study, the authors believe that the recurrence rate for the Shouldice repair (9.7%) is comparable to these studies.

The main strength of this study is the 21-year follow-up. No other published study has followed patients up to this extent. Long-term studies often stop at 5 years follow-up. Given the results of the current study, however, this may be grossly inadequate and provide erroneous recurrence rate data. Some authors even estimate that recurrence will not occur until 20 years post-operatively [14].

The higher recurrence rates in the TEP arm could be due to multiple reasons. Early recurrences are often attributable to technical failures. At the time, this trial was originally undertaken, laparoscopic surgery was in its inceptive stages and laparoscopic hernia repairs even more so. This coupled with the fact that the learning curve for laparoscopic hernia repairs, especially, the TEP approach is long and requires significant expertise, may account for the higher recurrence rates at that time. It has also been suggested that 75% of hernias that recur will do so in the first 10 years, with 20% recurring 15–20 years post-operatively [14]. Our study showed a recurrence rate of 33% in laparoscopic and 42% in the open group in between 10 and 20 years of follow-up. A follow-up of only 10 years would have thus shown a significantly fewer recurrences in both groups.

We note that crossover of participants to the open group could have skewed the results of this study. There were a high proportion of open conversions in the TEP group, which may indicate a low threshold for conversion from TEP to open technique due to the early learning curve with the technique at that time.

The authors acknowledge that there have been significant technological and procedural advances in the field of laparoscopic inguinal hernia repair over the last 20 years, which have led to a more sophisticated and refined procedure. This has likely improved the early recurrence rates significantly in this time. The open repair was performed using a Shouldice technique as described in the original paper in 1996 [14]. At the time, this was the conventional treatment. A mesh (Lichtenstein) repair is now commonly used in Australia. A

polypropylene mesh, which was individually sized to each patient and was stapled to the posterior wall of the inguinal canal using an endoscopic multi feed stapler, was used in the TEP group. Current materials and techniques are vastly different. Dissecting and the use of structural balloons help to open up the pre-peritoneal space in a very elegant and safe manner. Lighter, more anatomically designed mesh with better handling properties, along with superior fixation devices and materials are now used making the procedure considerably refined and technically easier compared to its earlier versions.

Despite these refinements, some important lessons from this study remain pertinent even today. TEP repair is a complex operation and should be performed by surgeons who have completed their learning curve. This can be achieved by performing surgeries under supervision of an expert to start with. Recent advances in surgical simulation make it attractive to utilise this modality to train surgeons and help to overcome the learning curve quicker and in a safe manner. Reports suggest that the laparoscopic technique has a relatively long learning curve and studies show that one needs to perform between 80 and 250 operations to be proficient in this procedure [20]. This is borne out by the fact that recurrence rates of open and laparoscopic techniques are similar for surgeons who have performed over 250 laparoscopic procedures [8]. A systematic review published in 2014 found that of the 11 studies comparing overall performance of laparoscopic procedures, 10 reported that simulator-trained participants scored significantly better than control groups [21]. Such modalities can be potentially of immense value while training less experienced surgeons.

Conclusion

In conclusion, there was a statistically significant higher recurrence rate for TEP laparoscopic hernia repair performed from 1992 to 1994 compared with an open Shouldice technique on a per-protocol-based analysis. This may be a result of the steep learning curve incipient in the evolution of laparoscopic surgery at the time and less elegant surgical techniques, devices and materials; however, it emphasises that an experienced surgeon must be engaged in laparoscopic hernia repair to deliver low recurrence rates over the long term.

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Compliance with ethical standards

Conflict of interest Author AB declares no conflict of interest. Author HK declares no conflict of interest. Author JB declares no conflict of interest. Author GM declares no conflict of interest.

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Ethical approval All procedures performed in studies involving human participants were in accordance with ethical standards of the institution and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Human and animal rights This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

References

- McCormack K, Scott NW, Go PM, Ross S, Grant AM, Collaboration EUHT (2003) Laparoscopic techniques versus open techniques for inguinal hernia repair. *Cochrane Database Syst Rev*. doi:10.1002/14651858.CD001785
- Jenkins JT, O'Dwyer PJ (2008) Inguinal hernias. *BMJ* 336(7638):269–272. doi:10.1136/bmj.39450.428275.AD
- Eklund A, Rudberg C, Smedberg S, Enander LK, Leijonmarck CE, Osterberg J, Montgomery A (2006) Short-term results of a randomized clinical trial comparing Lichtenstein open repair with totally extraperitoneal laparoscopic inguinal hernia repair. *Br J Surg* 93(9):1060–1068. doi:10.1002/bjs.5405
- Grant AM, Scott NW, O'Dwyer PJ, Group MRCLGHT (2004) Five-year follow-up of a randomized trial to assess pain and numbness after laparoscopic or open repair of groin hernia. *Br J Surg* 91(12):1570–1574. doi:10.1002/bjs.4799
- O'Reilly EA, Burke JP, O'Connell PR (2012) A meta-analysis of surgical morbidity and recurrence after laparoscopic and open repair of primary unilateral inguinal hernia. *Ann Surg* 255(5):846–853. doi:10.1097/SLA.0b013e31824e96cf
- Berndsen F, Arvidsson D, Enander LK, Leijonmarck CE, Wingren U, Rudberg C, Smedberg S, Wickbom G, Montgomery A (2002) Postoperative convalescence after inguinal hernia surgery: prospective randomized multicenter study of laparoscopic versus shouldice inguinal hernia repair in 1042 patients. *Hernia* 6(2):56–61
- Collaboration EUHT (2000) Laparoscopic compared with open methods of groin hernia repair: systematic review of randomized controlled trials. *Br J Surg* 87(7):860–867. doi:10.1046/j.1365-2168.2000.01540.x
- Neumayer L, Giobbie-Hurder A, Jonasson O, Fitzgibbons R Jr, Dunlop D, Gibbs J, Reda D, Henderson W, Veterans Affairs Cooperative Studies Program I (2004) Open mesh versus laparoscopic mesh repair of inguinal hernia. *N Engl J Med* 350(18):1819–1827. doi:10.1056/NEJMoa040093
- Schrenk P, Woisetschlager R, Rieger R, Wayand W (1996) Prospective randomized trial comparing postoperative pain and return to physical activity after transabdominal preperitoneal, total preperitoneal or Shouldice technique for inguinal hernia repair. *Br J Surg* 83(11):1563–1566
- National Institute for Clinical Excellence (2001) Guidance on the use of laparoscopic surgery for inguinal hernia. NICE, London
- National Institute for Clinical Excellence. Technology appraisal guidance no 83: guidance on the use of laparoscopic surgery for inguinal hernia. London: NICE, 2004 uptake report
- Douek M, Smith G, Oshowo A, Stoker DL, Wellwood JM (2003) Prospective randomised controlled trial of laparoscopic versus open inguinal hernia mesh repair: five year follow up. *BMJ* 326(7397):1012–1013. doi:10.1136/bmj.326.7397.1012
- Liem MS, van Duyn EB, van der Graaf Y, van Vroonhoven TJ, Coala Trial G (2003) Recurrences after conventional anterior and laparoscopic inguinal hernia repair: a randomized comparison. *Ann Surg* 237(1):136–141. doi:10.1097/01.SLA.0000041049.69383.0E
- Bessell JR, Baxter P, Riddell P, Watkin S, Maddern GJ (1996) A randomized controlled trial of laparoscopic extraperitoneal hernia repair as a day surgical procedure. *Surg Endosc* 10(5):495–500
- Burcharth J, Pedersen M, Bisgaard T, Pedersen C, Rosenberg J (2013) Nationwide prevalence of groin hernia repair. *PLoS ONE* 8(1):e54367. doi:10.1371/journal.pone.0054367
- Berney CR, Descallar J (2016) Review of 1000 fibrin glue mesh fixation during endoscopic totally extraperitoneal (TEP) inguinal hernia repair. *Surg Endosc* 30(10):4544–4552. doi:10.1007/s00464-016-4791-3
- Kockerling F, Stechemesser B, Hukauf M, Kuthe A, Schug-Pass C (2016) TEP versus Lichtenstein: Which technique is better for the repair of primary unilateral inguinal hernias in men? *Surg Endosc* 30(8):3304–3313. doi:10.1007/s00464-015-4603-1
- Arvidsson D, Berndsen FH, Larsson LG, Leijonmarck CE, Rimback G, Rudberg C, Smedberg S, Spangen L, Montgomery A (2005) Randomized clinical trial comparing 5-year recurrence rate after laparoscopic versus Shouldice repair of primary inguinal hernia. *Br J Surg* 92(9):1085–1091. doi:10.1002/bjs.5137
- Butters M, Redecke J, Koninger J (2007) Long-term results of a randomized clinical trial of Shouldice, Lichtenstein and transabdominal preperitoneal hernia repairs. *Br J Surg* 94(5):562–565. doi:10.1002/bjs.5733
- Eklund AS, Montgomery AK, Rasmussen IC, Sandbue RP, Bergkvist LA, Rudberg CR (2009) Low recurrence rate after laparoscopic (TEP) and open (Lichtenstein) inguinal hernia repair: a randomized, multicenter trial with 5-year follow-up. *Ann Surg* 249(1):33–38. doi:10.1097/SLA.0b013e31819255d0
- Dawe SR, Pena GN, Windsor JA, Broeders JA, Cregan PC, Hewett PJ, Maddern GJ (2014) Systematic review of skills transfer after surgical simulation-based training. *Br J Surg* 101(9):1063–1076. doi:10.1002/bjs.9482