

Factors associated with hernia recurrence after laparoscopic total extraperitoneal repair for inguinal hernia: a 2-year prospective cohort study

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Abstract

Background Laparoscopic total extraperitoneal repair (TEP) of inguinal hernia has been associated with higher rates of recurrence compared to open methods. The aim of the present study was to determine independent risk factors for recurrence within 2 years after TEP.

Methods This was a single-centre prospective cohort study with consecutive inclusion of patients undergoing inguinal hernia repair from 2010 to 2014. Systematic follow-up was conducted 6 months and 2 years postoperatively. Risk factors for recurrence after 2 years were analysed in univariate and multivariate analyses.

Results A total of 1194 patients underwent TEP for inguinal or femoral hernia in the study period, of which 1047 were eligible for analyses. After 2 years, 56 (5.3%) patients had presented with recurrence. The following factors were associated with recurrence in univariate analyses: body mass index (BMI) >30 (HR 3.64; $p = 0.011$), medial vs. lateral hernia (HR 2.37; $p = 0.004$), repair of recurrent hernia vs. primary repair (HR 2.12; $p = 0.049$), and length of stay >1 day (HR 1.77; $p = 0.043$). In multivariate analyses, factors independently associated with recurrence after 2 years were BMI >30 (HR 3.74; $p = 0.026$) and medial vs. lateral hernia (HR 2.39; $p = 0.004$).

Conclusion The recurrence rate after TEP is higher than reported after open hernia repair. Attempts to decrease the rate should be persuaded. Good surgical technique with precise dissection and correct placement of the mesh,

especially in medial hernias and obese patients, may be key points to improve outcomes after TEP.

Keywords Total extraperitoneal repair · Inguinal hernia · Risk factors · Recurrence · TEP

Introduction

Inguinal hernia repair is one of the most frequently performed procedures in general surgery. A tension-free technique with mesh placement is now considered gold standard and has reduced the risk of recurrence rate with 50–75% compared to direct suture [1]. Since the utilization of mesh placement in inguinal hernia repair, the recurrence rates have been reported from 1 to 10% [2–4]. The mesh can be placed by open or laparoscopic surgery. There are two methods of laparoscopic inguinal hernia repair: total extraperitoneal repair (TEP) or transabdominal preperitoneal repair (TAPP) [5]. With TEP, the dissection is performed and the mesh is placed preperitoneal. With TAPP, the peritoneal cavity is entered and the mesh is placed through a peritoneal incision.

Compared to open methods of inguinal hernia repair, the laparoscopic methods have been associated with less chronic pain and faster recovery after surgery [6]. In contrast, the laparoscopic methods have been associated with higher recurrence rates compared to open inguinal hernia repair [7, 8]. Lamb et al. have suggested that inadequate dissection and poor mesh placement may be possible explanations to the higher rates of recurrence after laparoscopic compared to open inguinal hernia repair [9]. Improved surgical technique and identification of perioperative factors associated with recurrence may reduce the recurrence rate after TEP.

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The aim of the current study was to determine independent risk factors for inguinal hernia recurrence after TEP. All consecutive patients who underwent TEP and consented to the study were included prospectively and followed up 6 months and 2 years postoperatively to capture an event of recurrence.

Methods

Study population

The local research ethics committee approved this single-centre prospective study before patients were included. Patients undergoing TEP from January 2010 through August 2014 were included preoperatively after written informed consent. All included patients were subject to questionnaire-based follow-up 6 months and 2 years after surgery to capture all recurrences. Patients that were lost-to-follow-up were excluded from the analyses. Patients who had TEP performed for sports hernia (e.g. functional chronic groin pain without hernia) were excluded, as they were not at risk of recurrence.

Patient management and surgical technique

This is a population-based cohort study according to the STROBE statement [10]. Patients were referred to our outpatient clinic and diagnosed by clinical examination and patient history. Outpatient surgery (patients discharged the same day as surgery) was performed unless the patients were classified as American Society of Anesthesiologist physical status classification (ASA score) 3 or 4, lived alone, lived geographically far from the hospital, or required admission due to surgical complications. Each TEP was defined and analysed as unilateral in one patient to best preserve characteristics regarding the hernia repair (e.g. laterality, location, size of mesh and operative events). As such, the same patient would be included more than once in cases of repair of primary hernia and recurrence within the study period or repair of bilateral hernia.

The following TEP technique was used: three trocars were placed in the midline; the preperitoneal space was dissected blunt with a 10 mm camera in the cranial trocar and completed with blunt dissection with graspers through the caudal trocars; the entire posterior wall and the cord were dissected and a polypropylene heavyweight mesh placed (3DMax™, Bard Davol Inc., New Jersey, USA). The mesh was routinely fixed with one or two resorbable tacks medially to Coopers ligament in the majority of medial and bilateral hernias. According to the institutional guidelines during the study period, mesh fixations should be used routinely in medial and bilateral hernias, irrespective of hernia

defect size, and not in lateral hernias. The final decision to use mesh fixation was at the discretion of the surgeon based on the peroperative assessment. Peritoneal tears were not sutured unless the defect was big. Eight attending surgeons with laparoscopic experience (all had performed TEP and/or TAPP repairs before the current study) and 8 resident/fellow surgeons with 0–3 years of surgical training conducted the procedures. Inexperienced residents and fellows were supervised by attending surgeons until assessed as sufficiently trained. Hernia recurrence rates were not determined for each surgeon individually as this would require adjustment for different patient characteristics, to which most surgeon-subgroups would be underpowered. Most of the patients received bupivacaine in the wound edges at the end of the procedure. Postoperative pain was controlled with standard oral medication: paracetamol 1 g and morphine on demand. The patients were fully mobilized early and could leave the hospital after emptying the bladder. Mortality and morbidity were assessed 30 days postoperatively.

Prospective follow-up

A systematic follow-up was conducted 6 months and 2 years postoperatively using a questionnaire to capture an event of recurrence and level of pain. To capture an event of recurrence, all patients were asked for symptoms such as bulging or pain in the operated groin. Pain was assessed with a visual analogue scale (VAS; the value 0 represented no pain; the value 10 represented worst pain possible). All patients with positive or indeterminate answers for recurrence or pain were summoned to our outpatient clinic for clinical examination. Variables of the questionnaire and other registered variables are listed in Table 1.

Statistical analyses

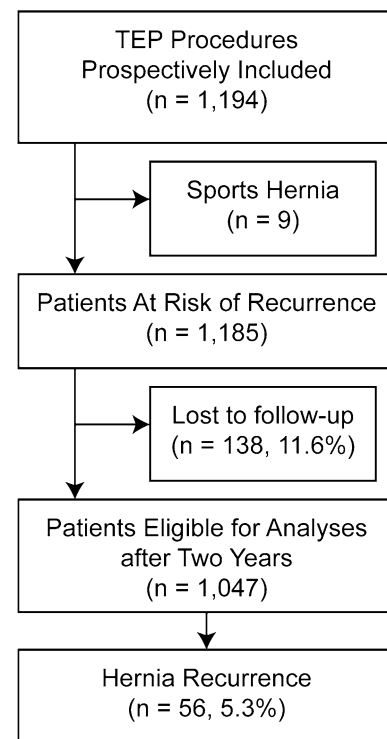
Shapiro–Wilk test was used to assess normal distribution of continuous data allowing expression as the mean with standard deviation and comparison with independent *t* tests. Otherwise, continuous data were expressed as median with range and compared with Mann–Whitney *U* test. Categorical data were compared with Pearson Chi squared tests or Fisher's exact test if the expected cell count was less than 5 for one or more cells. A *p* value of less than 0.05 was considered statistically significant. Factors with *p* value of less than 0.1 from univariate analyses were entered into multivariate analyses. Binary logistic regression with enter method for the covariates was used to perform multivariate analysis to assess predictors of hernia recurrence. SPSS v.19.0 (SPSS Inc., IBM, Chicago, IL, USA) was used to perform the statistical analyses.

Table 1 Characteristics of patients with and without recurrence after 2 years

	All	Recurrence after 2 years	No recurrence after 2 years	<i>p</i>
Total, <i>n</i> (%)	1047	56 (5.3)	991 (94.7)	
Patient				
Sex, <i>n</i> (%)				
Female	75	3 (4.0)	90 (96.0)	0.589
Male	971	53 (5.5)	918 (94.5)	
Age, mean (SD)	59.4	59.4 (14.9)	59.6 (14.9)	0.938
BMI, mean (SD)	24.4	24.4 (3.2)	25.1 (4.2)	0.118
Hernia, <i>n</i> (%)				
Location (side)				
Left	491	29 (5.9)	462 (94.1)	0.493
Right	556	27 (4.9)	529 (95.1)	
Location (laterality)				
Medial	356	29 (8.1)	327 (91.9)	0.001
Lateral	556	20 (3.6)	536 (96.4)	
Medial and lateral	98	2 (2.0)	96 (98.)	
Femoral	13	1 (7.7)	12 (92.3)	
Uncertain	4	4 (17.4)	19 (82.6)	
Type of care, <i>n</i> (%)				
Outpatient surgery	740	33 (4.5)	707 (95.5)	0.047
Hospital admission	307	23 (7.5)	284 (92.5)	
Surgery, <i>n</i> (%)				
Previous repair				
Primary repair	956	47 (4.9)	909 (95.1)	0.044
Repair of recurrence	91	9 (9.9)	79 (90.1)	
Size of mesh				
<11 × 16 cm	989	53 (5.4)	936 (94.6)	0.330
>11 × 16 cm	47	1 (2.1)	46 (97.9)	
Fixation				
No	533	27 (5.1)	506 (94.9)	0.900
Yes	477	25 (5.2)	452 (94.8)	
Bilateral repair				
No	741	36 (4.9)	705 (95.1)	0.273
Yes	306	20 (6.5)	286 (93.5)	
Converted				
No	1011	52 (5.1)	959 (94.9)	0.121
Yes	36	4 (11.1)	32 (88.9)	
Experience of surgeon				
Resident/fellow	345	18 (5.2)	327 (94.8)	0.895
Attending	702	38 (5.4)	664 (94.6)	
Postoperative factors				
Complication, <i>n</i> (%)				
No	949	49 (5.2)	900 (94.8)	0.407
Yes	98	7 (7.1)	91 (92.9)	
Reoperation, <i>n</i> (%)				
No	1040	56 (5.4)	984 (94.6)	0.528
Yes	7	0 (0)	7 (100)	
LOS, days, mean (SD)	1.3	1.6 (1.0)	1.3 (0.7)	0.007

P-values < 0.05 highlighted in bold text

BMI body mass index, VAS visual analogue scale, LOS length of stay

**Fig. 1** Flow chart of excluded and included patients

Results

Patient characteristics

A total of 1194 patients underwent TEP and were included in the study in the study period of which 138 were lost to follow-up and 9 were treated for sports hernia and subsequently not at risk for recurrence (Fig. 1). After exclusion of the above-mentioned patients, the number of patients eligible for analyses was 1047. A total of 56 (5.3%) presented with recurrence within 2 years after surgery: 44 patients presented with recurrence within 6 months and 12 patients presented with recurrence from 6 months to 2 years post-operatively. The mean age was 59.4 years and 971 patients were males. Additional patient, hernia, and surgery characteristics stratified on recurrence after 2 years are presented in Table 1.

Risk factors for recurrence

In univariate analyses, body mass index (BMI) >30 (hazard ratio [HR], 3.64; 95% confidence interval [CI], 1.34–9.87; *p* = 0.011), medial vs. lateral hernia (HR 2.37; 95% CI 1.32–4.27; *p* = 0.004), repair of recurrent hernia vs. primary repair (HR 2.12; 95% CI 1.01–4.49; *p* = 0.049), and length of stay (LOS) >1 day (HR 1.77; 95% CI 1.02–3.08; *p* = 0.043) were factors associated with hernia recurrence

Table 2 Perioperative factors associated with recurrence 2 years after TEP

	Univariate			Multivariate		
	HR	95% CI	<i>p</i>	HR	95% CI	<i>p</i>
Male (female)	1.39	0.43–4.54	0.590			
Age >60 years (≤60 years)	1.01	0.59–1.74	0.972			
BMI >30 (≤30)	3.64	1.34–9.87	0.011	3.74	1.18–11.9	0.026
Location left (right)	1.23	0.72–2.11	0.452			
Medial (lateral)	2.37	1.32–4.27	0.004	2.39	1.32–4.39	0.004
Admission (outpatient)	1.74	1.00–3.01	0.050	1.24	0.27–5.63	0.779
Repair recurrence (primary)	2.12	1.01–4.49	0.049	1.57	0.64–3.90	0.328
Mesh small (large)	2.61	0.35–19.3	0.348			
Mesh fixed (unfixed)	1.04	0.59–1.81	0.900			
Bilateral (unilateral)	1.37	0.80–2.41	0.274			
Converted (laparoscopic)	2.31	0.79–6.76	0.128			
Resident/fellow (attending)	0.96	0.54–1.71	0.895			
Complication (no)	1.41	0.62–3.21	0.409			
Reoperation (no)	–	–	–			
LOS >1 day (0–1 day)	1.77	1.02–3.08	0.043	1.09	0.24–5.05	0.909

P-values < 0.05 highlighted in bold text

Reference category shown in parentheses (HR 1)

HR hazard ratio, CI confidence interval

after 2 years (Table 2). In multivariate analyses, the only two factors independently associated with recurrence were BMI >30 (HR 3.74; 95% CI 1.18–11.9; *p* = 0.026) and medial vs. lateral hernia (HR 2.39; 95% CI 1.32–4.39; *p* = 0.004).

Mesh fixation and recurrence in medial and lateral hernias

The recurrence rate was similar in patients with fixed mesh (*n* = 477) and in patients with unfixed mesh (*n* = 533); 5.2 and 5.1% (*p* = 0.900), respectively. In contrast, the rate of recurrence was higher after repair of medial hernias (*n* = 356) than repair of lateral hernias (*n* = 556); 8.1 and 3.6% (*p* = 0.001), respectively. Mesh fixation was used significantly more often in medial hernias than in lateral hernias; 77.2 and 21.2% (*p* < 0.001), respectively. For medial hernias, the recurrence rate among unfixed meshes and fixed meshes was the same; 12.3% (*n* = 9) and 7.0% (*n* = 19; *p* = 0.138). For lateral hernias, the recurrence rate among unfixed meshes and fixed meshes was the same; 3.6% (*n* = 15) and 3.3% (*n* = 4; *p* = 0.856).

Experience of surgeon

Resident or fellow surgeons with 0–3 years of surgical training performed 345 (33.0%) of the procedures and the 2-year recurrence rate was 5.2%. Attending surgeons performed 702 procedures and the recurrence rate was

Table 3 Rate of recurrences according to the experience of surgeon

	Total, <i>n</i>	Recurrence, <i>n</i> (%)
Resident/fellow assisted by attending	199	8 (4.0)
Resident/fellow without assistance	146	10 (6.8)
Attending	702	38 (5.4)

similar, 5.4%. Out of the 345 procedures performed by residents and fellows, 146 were performed without supervision of an attending surgeon and 199 were performed supervised by an attending and the recurrence rates were not statistically different, 6.8 and 4.0% (*p* = 0.353), respectively (Table 3).

Discussion

In the current study, the 2-year recurrence rate after TEP was 5.3% and factors significantly associated with recurrence were BMI >30 and medial hernia. This is the first single-centre prospective study including more than 1000 patients who underwent TEP investigating factors associated with recurrence. In addition, the recurrence rate was unaffected by the experience of the surgeon, which is in contrast to the majority of the existing literature.

Previous studies investigating hernia recurrence after TEP have been limited by any of the following factors: few

included patients, a retrospective study design, endpoints other than recurrence, or inclusion of patients who underwent open surgery [11, 12]. Subsequently, the current literature lacks data regarding hernia recurrence and also risk factors for recurrence after TEP.

In a large randomized trial comparing open hernia repair with TEP, Eklund et al. reported that bruising 1 week postoperatively was the only factor associated with recurrence [7]. However, the primary endpoints of the study were recurrence rates in the treatment groups and not risk factors for recurrence. The cumulative recurrence rate after TEP in the Eklund et al. study was 3.5% after 5 years, which was lower than the 5.3% recurrence rate after 2 years in the current study [7].

The current study showed a hazard ratio of 2.39 ($p = 0.004$) for recurrence after TEP for a medial hernia compared to TEP for a lateral hernia. This finding is in agreement with data from the Swedish Hernia Register (<http://www.svensktbrackregister.se/en>) showing a doubled risk of recurrence after repair for medial hernias compared to repair for lateral hernias. In the Swedish Hernia Register, only 20% of inguinal hernias were repaired laparoscopically. Interestingly, another study reported greater risk of reoperation for recurrence for medial hernias than for lateral hernias, but found no difference for medial hernias comparing laparoscopic and open methods [13]. For lateral hernias, the reoperation rate was higher in the laparoscopic group that may reflect a different pathophysiology.

Increased risk of mesh displacements in medial hernias has been proposed as an explanation to the higher rates of recurrences and mesh fixation has been used to overcome this problem. However, in the current study we found no recurrence difference between fixations and non-fixation of the mesh. Furthermore, the finding is in agreement with recent guidelines from The European Hernia Society as well as two recent studies: a meta-analysis by Sajid et al. [14] and a randomized controlled trial by Garg et al. [15].

Garg et al. concluded in their study that adequate dissection and large-sized meshes were important factors to avoid recurrences [15]. Given the fact that surgical technique may be the most important factor to prevent recurrence after TEP; previous reports have concluded that the experience of the surgeon was a major risk factor of hernia recurrence after TEP. It has been explained by the complexity of the procedure and a long learning curve [16, 17]. Dulucq et al. and Feliu-Pala et al. reported reduced recurrences after 200 and 100 procedures, respectively [18, 19]. Some studies have suggested that between 40 and 250 cases are required for adequate training [20, 21]. Subsequently, others have concluded that TEP should be recommended only in experienced hands and restricted to enthusiasts [16, 22].

The overall experience of the surgeon and surgeon TEP experience were not associated with recurrence in the

current study. This finding may be a result of focus on team driven surgery with sufficient training and a low threshold to ask for assistance or an intraoperative second opinion, even among the most experienced surgeons. Surgical technique is important to prevent recurrence after TEP [9, 23]. Therefore we believe experienced assistance is crucial levelling out the outcome differences from the inexperienced surgeons. In agreement with our findings, Wilkiemeyer et al. did not find any difference in recurrence rate between resident level 1 and 3 in laparoscopic repair, while there was a recurrence difference after open hernia repair when comparing surgeon experience [24]. As such, in our opinion a more complex procedure with longer learning curve should not preclude surgeons from adapting the procedure if otherwise beneficial for the patient. Furthermore, our data may indicate that the debate regarding the long learning curve is oblate and in fact may be an indicator of insufficient surgical training and supervision.

The current study had the following limitations. First, the follow-up was performed after 6 months and 2 years and will not capture recurrence after 2 years. Interestingly, there are data indicating that the large majority of hernia recurrences after TEP occur within months, and not years, after surgery. In a study by Liem et al., 71% of the recurrences occurred within the first year after surgery [2]. In a study by Feliu-Pala et al., all recurrences presented within 10 months after surgery [19]. In a study by Eklund et al., the cumulative incidence of recurrence was the same after 1 year as after 3 years from surgery [7]. Also in the current study, 79% ($n = 44$) of the recurrences had occurred after 6 months and only 12 more presented between 6 months and 2 years postoperatively. The mechanisms behind recurrence after open hernia repair and TEP may be different, and subsequently appear at different time intervals after surgery. Another limitation is the fact that the recurrence status of the 138 (11.6%) patients lost to follow-up remains unknown. However, our hospital serves the vast majority of the patients operated and it is, therefore, unlikely that a significant number of recurrences would have been missed. A third limitation of this study was the inability to identify the driving causes of recurrence among the subgroup of patients that underwent in-patient surgery, as hospital admission itself was significantly and independently associated with increased recurrence. Also, the size of the hernia defect was not part of the variables that were prospectively registered and, therefore, precluded mesh-to-hernia size ratio analysis. Finally, the use of patient-based questionnaires to capture an event of recurrence remains uncertain and debated. In a study by Vos et al., questionnaires failed compared to physical examination, but this was not confirmed in two Swedish studies [25–27]. Furthermore, physical examination was performed in all patients in the current study if

recurrence was suspected or uncertain upon receipt of the completed questionnaires.

Hernia recurrences after TEP occur in about 1 in 20 patients, but should not preclude further means to lower the recurrence rate. Identification of risk factors may provide insights into this. In the current study, BMI <30 and medial hernias were significant risk factors for recurrence. Furthermore, the recurrence rates were the same regardless of the TEP experience of the surgeon, indicating that good surgical training and supervision overcome the obstacles of learning curve. Good surgical technique with precise dissection and correct placement of the mesh remains key points to prevent recurrences.

Compliance with ethical standards

Conflict of interest LSI declares no conflict of interest. AR declares no conflict of interest. KWB declares no conflict of interest.

Ethical approval The study was approved by the local research ethics committee (REC).

Human and animal rights Compliance with ethical standards was adhered to through Institutional Review Board approval and the study including human participants have been performed in accordance with the ethical standards of the Declaration of Helsinki and its later amendments.

Informed consent All patients were included after written informed consent.

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