



Factors Associated with Postoperative Chronic Pain and Recurrence After Laparoscopic Total Extraperitoneal Inguinal Hernia Repair

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Abstract

Objective: To assess the risk factors for chronic pain and recurrence after laparoscopic total extraperitoneal (TEP) inguinal hernia repair.

Methods: Data of the patients who underwent laparoscopic TEP repair were analyzed. Clinical and surgical characteristics, including learning curve, mesh weight, the pore size of the mesh, use of mesh fixation, and fixation methods, were assessed. Fixation by absorbable or non-absorbable tacks was performed in all procedures except for self-fixating meshes. Mesh brands were tiered into groups regarding pore size and weight. Operative time was defined as the duration between skin incision and dressing. The minimum follow-up was 24 months. Postoperative chronic pain was defined as moderate to severe groin pain, which was accepted as a Visual Analog score ≥ 3 longer than three months. Pain and recurrence were evaluated at 1 and 6 weeks in clinic visits and at 3, 12, and 24 months by telephone questionnaires. The occurrence of a fascial defect in physical examination or ultrasound was defined as recurrence.

Results: Three-hundred and eighty-two procedures were included. Postoperative chronic pain was seen in 31 (8.1%) patients and was higher with micropore mesh ($p=0.004$), mesh fixation ($p=0.002$), fixation with titanium tacks ($p<0.001$) and at first 50 cases ($p=0.043$). Fifteen (3.9%) patients had a recurrence. Older age ($p=0.046$), prolonged operative time ($p=0.040$), body mass index (BMI) ($p=0.008$) and learning curve ($p=0.034$) were significantly associated with higher recurrence rate. In multivariate analysis pore size [Odds ratio (OR): 2.911, 95% confidence interval (CI): 1.153-7.351, $p=0.024$] and fixation with titanium tacks (OR: 8.776, 95% CI: 4.040-14.893, $p=0.004$) were independent risk factors for chronic pain; BMI (OR: 1.307-95% CI: 1.138-1.501, $p<0.001$) was the only independent risk factor for recurrence.

Conclusion: The outcome of laparoscopic TEP repair is related to the technic as well as patient-based factors. Titanium tacks and micropore meshes increase postoperative pain risk without any benefit on recurrence. Patients with higher BMI have an increased recurrence risk.

Keywords: Laparoscopy, hernia repair, inguinal hernia, total extraperitoneal repair, groin hernia

INTRODUCTION

The main goal of the on inguinal hernia repair has been the better surgical outcome, particularly regarding chronic pain and recurrence during recent years. Approximately 10% of the patients suffer from chronic pain (longer than three months), and 10-15% require reoperation for recurrence after open or laparoscopic inguinal hernia repair (1). Minimally invasive approaches that provide reduced nerve damage and postoperative pain with satisfactory recurrence rates have been emerged to improve

quality of life after inguinal hernia repair (2). In a meta-analysis comparing laparoscopic transabdominal preperitoneal and total extraperitoneal (TEP) technics with Lichtenstein procedure revealed no difference in recurrence rates but fewer wound infection and chronic pain and earlier return to work with laparoscopic technics (3). Laparoscopic TEP is the most preferred minimally invasive repair with fewer complications, including visceral injury, ileus, and port-site hernia, shorter hospital stay, and reduced postoperative pain (4,5). In a prospective study, 10.555 Lichtenstein and 6.833 TEP procedures were compared,



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Cite this article as: Özdenkaya Y, Arslan NÇ, Basım P, Olmuşçelik O. Factors Associated with Postoperative Chronic Pain and Recurrence After Laparoscopic Total Extraperitoneal Inguinal Hernia Repair. Eur Arch Med Res 2020; 36 (1):57-62

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European Archives of Medical Research published by Galenos Publishing House.

Received: 21.01.2019

Accepted: 23.06.2019

and no difference in recurrence and chronic pain was found, however postoperative complications ($p < 0.001$) and early pain at rest ($p = 0.011$) and exertion ($p < 0.001$) were lower in TEP group (6).

Despite several randomized trials and meta-analyses, guidelines still do not mention any of those procedures as the standard of care (7). Either Lichtenstein or laparoscopic techniques can be chosen based on resources and expertise. Moreover, there is no consensus on mesh selection and fixation (7). There is still a need for large-scale, controlled studies comparing different types of surgical materials. This study presents the mid-term results of TEP repair in a single center with an analysis of risk factors for chronic pain and recurrence.

METHODS

Prospectively collected database of patients who underwent laparoscopic TEP inguinal hernia repair between January 2012 and January 2017 was reviewed. Patients older than 18 years old with primary inguinal hernia were included in the study. All the procedures were performed under general anesthesia by the same team. The preoperative condition of the patients was recorded according to the American Society of Anesthesiologists classification. Age, gender, body mass index (BMI), type of hernia (unilateral and bilateral), type of defect (direct, indirect and combined), mesh weight, pore size of the mesh, use of mesh fixation and fixation methods (absorbable tackers and titanium tackers) were retrospectively gathered from the registry.

Mesh brands were tiered into groups regarding pore size and weight. BARD 3Dmax™ (Bard Davol Inc., RI, USA) and Prolene™ (Ethicon, LLC, USA) mesh comprised micropore group, where ProGrip™ (Medtronic, MN, USA) and Parietex™ (Medtronic, MN, USA) meshes were included in macropore group. BARD 3Dmax™, Prolene™, Parietex Hydrophilic Anatomical Mesh™ and ProGrip™ mesh were included in heavy-weight (> 50 g/m²) group. The light-weighted group was comprised of Parietex Lightweight Mesh™. Tacker fixation by Protack™ or Absorbatack™ was used in all procedures except for those performed using ProGrip™. The selection of mesh and tacker brands was due to the subjective choice of the surgeon and the availability of the materials at present.

Operative time was defined as the duration between skin incision and dressing. The procedures were divided into two groups (first 50 cases and after 50 cases) to assess the effect of the learning curve. Postoperative analgesia was provided with paracetamol and diclofenac sodium. All patients were assessed for Visual Analog scale score (VAS) and examined for seroma and

recurrence at 1 and 6 weeks. At 3, 12 and 24 months, telephone questionnaire was performed, and VAS scores were recorded. Patients with any complaints were invited to the outpatient clinic for an in-person examination. Postoperative chronic pain was defined as moderate to severe groin pain, which was accepted as a VAS score lasting greater than 3 for 3 months. Recurrence was evaluated by physical examination, and ultrasound was performed for confirmation in case. Any fascial defect in the previous hernia site determined by the surgeon was recorded as recurrence. If the physical examination did not reveal a finding associated with a recurrent hernia, ultrasound was performed in patients with symptoms.

Statistical Analysis

Statistical analysis was done using IBM SPSS Statistics for Windows, Version 24.0. Categorical data were compared by chi-square or Fisher's exact tests. Continuous data were compared using the Student's t-test. A multivariate logistic regression model was conducted to determine risk factors for chronic pain and recurrence. $P < 0.05$ was considered statistically significant.

Approval of the local Ethics committee was received for the study (Istanbul Medipol University Ethics committee number: 10840098-604.01.01-E.53651). All the patients gave written consent for the surgery and permission for the use of data in studies.

RESULTS

Two hundred and fourteen patients were meeting the inclusion criteria. Bilateral repairs were assessed individually, and 382 procedures were analyzed. The demographic and surgical characteristics of the patients are given in Table 1. The brand of the mesh was BARD 3Dmax mesh in 64 (16.8%) patients, Parietex Lightweight mesh in 44 (11.5%), Parietex Hydrophilic Anatomical mesh in 77 (20.2%), ProGrip Laparoscopic self-fixating mesh in 69 (18.1%) and Prolene mesh in 128 (33.5%) patients. There were 192 (50.3%) and 190 (49.7%) patients in micropore and macropore groups. High-weighted meshes were used in 338 (88.5%) patients; 44 (11.5%) patients had light-weighted mesh. No fixation was performed in 69 (18%) patients who underwent hernia repair using self-fixating mesh.

The mean VAS score at one week was 3.6 ± 1.9 ; at six weeks was 1.4 ± 0.8 ; at three months was 0.57 ± 0.4 ; at six months was 0.32 ± 0.3 , at 12 months 0.22 ± 0.5 and 0.1 ± 0.2 at 24 months. Postoperative chronic pain was seen in 31 (8.1%) patients. Conservative treatments were given to those patients. At 12 months, only 5 (1.3%) patients had remaining chronic pain.

The mean BMI was 26.4 ± 3.2 in patients with chronic pain and significantly higher than the mean BMI of patients having no pain (24.8 ± 2.7 , $p=0.010$). Type of the hernia or defect and mesh weight was no effect on postoperative pain. Postoperative chronic pain was seen in 23 (12%) patients in the microporous mesh group and 8 (4.2%) patients in the macroporous group ($p=0.004$). Mesh fixation significantly increased postoperative pain rate. None of the patients with self-fixating meshes suffered chronic pain. The chronic pain rate was significantly higher with mesh fixation (0% vs 9.9%, $p=0.002$). Among 31 patients with chronic pain, 30 had titanium tacks, and 1 had absorbable tacks.

Number of patients	382
Age (mean \pm SD)	50.8 \pm 14.9
Sex	
Male	359 (94%)
Female	23 (6%)
BMI (kg/m ² , mean \pm SD)	24.9 \pm 2.8
ASA class	
1-2	303 (79.3%)
2-4	79 (20.7%)
Type of hernia	
Unilateral	45 (11.8%)
Bilateral	337 (88.2%)
Type of defect	
Direct	146 (38.2%)
Indirect	220 (56.7%)
Combined	16 (4.2%)
Type of mesh	
Highweight	338 (88.5%)
Lightweight	44 (11.5%)
Pore size	
Micropore	192 (50.3%)
Macropore	190 (49.7%)
Mesh fixation	
No	69 (18%)
Yes	313
Titanium	187 (49%)
Absorbable	126 (33%)
Operative time (min \pm SD)	39.6 \pm 14.1
Learning curve	
First 50 cases	50
After 50 cases	332 (86.9%)
ASA: American Society of Anesthesiologists classification, BMI: Body mass index, SD: Standard deviation, Min: Minute	

Titanium tacks were associated with higher pain rate ($p<0.001$) (Table 2).

The median follow-up was 26 (24-62) months. The recurrent hernia was seen in 15 (3.9%) patients who had significantly higher mean BMI (27.9 ± 3.8 vs 24.8 ± 2.7 , $p=0.008$). Female patients had no recurrence ($p=0.387$). The mean age was significantly higher in patients with recurrence (51 ± 18.4 vs 43.2 ± 16.1 , $p=0.046$). None of the patients with unilateral hernia suffered a recurrence, where 15 recurrences out of 337 procedures (4.5%) were seen, but the difference between patients with unilateral and bilateral

n=382	Pain		p
	No (n=351)	Yes (n=31)	
Age (mean \pm SD)	50.6 \pm 14.3	52.7 \pm 19.7	0.457
Sex			0.575
Male	330	29 (8.1%)	
Female	21	2 (8.7%)	
BMI (kg/m ² , mean \pm SD)	24.8 \pm 2.7	26.4 \pm 3.2	0.010
ASA class			0.349
1-2	277	26 (8.6%)	
2-4	74	5 (6.3%)	
Type of hernia			0.264
Unilateral	43	2 (4.4%)	
Bilateral	308	29 (8.6%)	
Type of defect			0.895
Direct	135	11 (7.5%)	
Indirect	201	19 (8.6%)	
Combined	15	1 (6.3%)	
Type of mesh			0.490
High weight	311	27 (8%)	
Lightweight	40	4 (9.1%)	
Pore size			0.004
Micropore	169	23 (12%)	
Macropore	182	8 (4.2%)	
Mesh fixation			0.002
No	69	0	
Yes	282	31 (9.9%)	
Titanium	157	30 (16%)	<0.001
Absorbable	125	1 (0.8%)	
Operative time (min \pm SD)	39.9 \pm 14.1	36.4 \pm 14.2	0.277
Learning curve			0.043
First 50 cases	43	7 (14%)	
After 50 cases	308	24 (7.2%)	
SD: Standard deviation, BMI: Body mass index, ASA: American Society of Anesthesiologists classification, Min: Minute			

hernias was not statistically significant ($p=0.147$). Alike as hernia type, the difference in recurrence rates in light-weighted (0%) and high-weighted (4.4%) mesh groups ($p=0.154$) and also microporous (5.7%) and macroporous (2.1%) groups ($p=0.058$) did not reach a statistical significance. The recurrence rate was similar in patients with and without mesh fixation. There were 3 (4.3%) recurrences in the self-fixating mesh group and 12 (3.8%) recurrences in patients who underwent titanium or absorbable tack fixation ($p=0.074$). In the first 50 cases, 5 (10%) recurrences were seen, which was significantly higher when compared with the following cases ($n=10$, 3.1%) ($p=0.034$) (Table 3).

Multivariate analysis was performed for factors predicting postoperative chronic pain (mesh fixation, fixation material, pore size, and BMI) and recurrence (BMI and learning curve). Using microporous meshes [Odds Ratio (OR): 2.911, 95% confidence interval (CI): 1.153-7.351, $p=0.024$] and fixation with titanium tacks (OR: 8.776, 95% CI: 4.040-14.893, $p=0.004$) were independently associated with postoperative pain. BMI was the only independent predictor of recurrence (OR: 1.307, 95% CI: 1.138-1.501, $p<0.001$) in multivariate analysis (Table 4).

DISCUSSION

Postoperative chronic pain and recurrence are the major problems of inguinal hernia repair. Our results indicated the inessentiality of mesh fixation, which has already been shown before. Apart from confirming previous literature, this study revealed the predictive factors for postoperative pain and recurrence. We found an increased risk of pain with microporous mesh and fixation with titanium tacks. The only independent predictor of recurrence was BMI.

The incidence of chronic pain after inguinal hernia repair has been reported up to 30% (8,9) and decreased less than 3% since laparoscopic technics emerged (10). This benefit may be associated with direct vision and protection of inguinal sensory nerves. In a study of 626 TEP repair published by Patel et al. (11) in 2016, significant and severe pain incidences were reported as 25% and 0.09% at the end of 2 years. They used Surgical Outcomes Measurement system and Carolinas Comfort scale and defined significant pain as mild but bothersome or worse on either specific tool. Mesh brand (Parietex anatomic, parietexprogrrip, and physiomesh), size of the mesh, and fixation method had no effect on pain. Poor quality of life and general health status were predictors of pain longer than six months. In another study, Westin et al. (9) reported that 20% of the patients suffered from some degree of pain after TEP at one year, but severe pain was reported by 2.1%. The Inguinal Pain

Questionnaire was used in this study. In our study, the VAS score >3 lasting longer than three months was accepted as chronic

Table 3. Univariate analysis of the factors associated with recurrence

n=382	Recurrence		p
	No (n=367)	Yes (n=15)	
Age (mean \pm SD)	51 \pm 18.4	43.2 \pm 16.1	0.046
Sex			0.387
Male	344	15 (4.2%)	
Female	23	0	
BMI (kg/m ² , mean \pm SD)	24.8 \pm 2.7	27.9 \pm 3.8	0.008
ASA class			0.623
1-2	291	12 (4%)	
2-4	76	3 (3.8%)	
Type of hernia			0.147
Unilateral	45	0	
Bilateral	322	15 (4.5%)	
Type of defect			0.368
Direct	138	8 (5.5%)	
Indirect	214	6 (2.7%)	
Combined	15	1 (6.3%)	
Type of mesh			0.154
High weight	323	15 (4.4%)	
Lightweight	44	0	
Pore size			0.058
Micropore	181	11 (5.7%)	
Macropore	186	4 (2.1%)	
Mesh fixation			0.074
No	66	3 (4.3%)	
Yes	301	12 (3.8%)	
Titanium	176	11 (5.9%)	
Absorbable	125	1 (0.8%)	
Operative time (min \pm SD)	39.8 \pm 14.2	32.3 \pm 7.9	
Learning curve			0.034
First 50 cases	45	5 (10%)	
After 50 cases	322	10 (3.1%)	

SD: Standard deviation, BMI: Body mass index, ASA: American Society of Anesthesiologists classification, Min: Minute

Table 4. Multivariate analyses of the factors predicting pain and recurrence

	Variable	OR (95% CI)	p
Pain	Pore size	2.911 (1.153-7.351)	0.024
	Mesh Fixation with titanium tacks	8.776 (4.040-14.893)	0.004
Recurrence	BMI	1.307 (1.138-1.501)	<0.001

OR: Odds ratio, CI: Confidence interval, BMI: Body mass index

pain, as defined before by The International Association for the Study of Pain. Our chronic pain rate was 8.1% and seemed to be higher than previous studies; however, the measurement tools and the definition of severe or chronic pain were quite different between our study and those others. Our mean VAS score at two years was compatible with the literature. The main drawback of our study may be the lack of quality of life questionnaires. Indeed, this is also a drawback of the literature that there are no standard definitions and measurement tools of postoperative pain and quality of life after inguinal hernia repair. There are few studies assessing the predictors of pain after TEP repair. On-lay mesh placement, fixation of the mesh, strenuous physical activity, young age, and poor general health have been suggested to increase postoperative chronic pain incidence (11-14). In our study, we found higher pain incidence with higher BMI, using microporous mesh, mesh fixation, fixation with titanium tacks, and at the beginning of the learning curve.

Risk factors for a recurrent inguinal hernia include female gender, direct versus indirect inguinal hernia, limited surgical experience, and low volume centers (7). Compatible with the literature, the recurrence rate was 10% at the beginning of our learning curve and decreased to 3.1% after the first 50 cases ($p=0.034$). Similarly, postoperative chronic pain was 14% and 7.2% before and after the 50th case ($p=0.043$). In a recent study, Berndsen et al. (14) reported a 2.5% recurrence after 485 laparoscopic inguinal hernia repairs at a 5-year follow-up. Strenuous work (OR: 13.7), technically challenging repairs (OR: 7.2), and chronic discomfort (OR: 6.7) were the risk factors for recurrence in their study. We did not assess the technical difficulty of the operation; however, operative time, which may be a predictor of difficulty, was associated with recurrence in our study ($p=0.040$). Another drawback was the lack of records regarding postoperative activity and strenuous work of the patients; instead, we found higher BMI ($p=0.008$) and older age (0.034) were risk factors for recurrence.

There is an important heterogeneity among surgical technics and used materials, particularly in fixation fashion and mesh brands in TEP inguinal hernia repair. Recent guidelines strongly state that in almost all cases, any type of mesh fixation is unnecessary (7). Mesh fixation is recommended in only large direct hernias and with atraumatic fixation technics such as fibrin glue and cyanoacrylate (7,15). Consistent with these recommendations, none of the patients with no-fixation in our study had chronic pain (0% vs 9.9%, $p=0.002$). The recurrence rates were similar between no-fixation (4.3%) and tack-fixation (3.8%) groups ($p=0.074$). Fixation with titanium tack was the only independent

risk factor for chronic pain in our study. The main conflicting issue in laparoscopic TEP repair is selecting the best mesh material. Despite several published randomized trials and meta-analysis, there are no standardized recommendations. The porosity, elasticity, strength, and the material of the mesh all influence tissue reaction; however, a general classification, which is based on a specific property of the mesh and which can reflect all risks, is not currently available, and even hardly conceivable. The limited literature on those properties mostly focused on the weight classification (lightweight versus heavyweight), and no further details of the meshes were given in the published data. The Herniasurge group 2018 Guideline stated that there is no single perfect mesh, and a mesh classification reflecting all possible risks or benefits does not exist and is not possible to develop (7). Small pore and heavyweight meshes are considered to carry a high-risk for fibrotic bridging and long-term mesh-related problems. Only a few studies in the literature have compared lightweight and heavyweight meshes and shown the superiority of lightweight mesh regarding better pain scores, comfort, and sexual dysfunction over conventional heavyweight polypropylene (13). However, long-term results have raised concerns about an increased risk of mesh displacement and recurrence with the use of lightweight mesh (16,17). A recent Swedish nationwide population study, including 13.839 laparoscopic TEP hernia repairs, revealed that lightweight meshes were associated with an increased risk of reoperation for recurrence (HR 1.56, $p<0.001$) compared to heavyweight meshes. This difference was more distinct in direct hernias and larger defects. In our study, there was no difference in chronic pain ($p=0.895$) and recurrence ($p=0.368$) rates between direct and indirect hernias. The chronic pain rates were also similar to lightweight (8%) and heavyweight (9.1%) meshes ($p=0.490$). There was no recurrence at two years with lightweight meshes, where in the heavyweight mesh group, our recurrence rate was 4.4%, but this difference did not show a statistical significance ($p=0.154$).

CONCLUSION

Laparoscopic TEP repair is a safe and effective method for inguinal hernia treatment. Mesh fixation is associated with a high risk of postoperative chronic pain with no benefit on long-term recurrence rates. Macroporous meshes provided favorable early postoperative outcome regarding pain. Mesh weight, pore size, and the brand did not affect recurrence. There is a need for large randomized trials in order to find the best classification of mesh materials and identify the perfect mesh.

Ethics

Ethics Committee Approval: Approval of the local Ethics committee was received for the study (Istanbul Medipol University Ethics committee number: 10840098-604.01.01-E.53651).

Informed Consent: All the patients gave written consent for the surgery and permission for the use of data in studies.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: Y.Ö., P.B., Concept: Y.Ö., O.O, Design: Y.Ö., N.Ç.A., Data Collection or Processing: P.B., O.O., Y.Ö., Analysis or Interpretation: N.Ç.A., Literature Search: N.Ç.A., Y.Ö., Writing: N.Ç.A., Y.Ö.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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