

Uzun Dönem Takipte TEP ve Lichtenstein Tekniğinin Karşılaştırılması: Randomize Kontrollü Çalışma

Comparison of TEP and Lichtenstein Technique in Long-Term Follow-up: A Randomized Controlled Trial

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ÖZ

Giriş: Açık gerilimsiz mesh onarımı (Lichtenstein) ve laparoskopik total ekstraparitoneal (TEP) onarım, inguinal herni cerrahisinde en çok tercih edilen tekniklerdir. Bu çalışma, bu iki tekniğin erken dönem ve uzun dönem sonuçlarını karşılaştırmayı amaçlamıştır.

Yöntem: Yüz iki hasta (102) randomize olarak iki gruba ayrıldı (TEP, n=51; Lichtenstein, n=51). Gruplar, komplikasyon (erken, geç), postoperatif ağrı durumu, işe dönüş süresi ve nüks açısından karşılaştırıldı.

Bulgular: TEP grubunda, erken postoperatif ağrı skorunun (VAS) (2 vs. 5.27; p<0.001) daha düşük, postoperatif analjezi kullanımı gereksiniminin daha az (%31.4 vs %70.6; p<0.001) ve işe dönüş süresinin daha kısa (4.2 vs 20.4; p<0.001) olduğu bulundu. Ameliyat sonrası erken ve geç dönem komplikasyon oranı, her iki grupta benzerdi. Ortalama takip süresi 72,8±17,9 aydı ve nüks açısından gruplar arasında fark yoktu (TEP'e karşı Lichtenstein; %2'ye karşı %2, p: 0.999).

Sonuç: Her iki teknik, düşük uzun dönem nüks ve komplikasyon oranları ile inguinal herni onarımında etkilidir. İki yaklaşım arasında TEP prosedürünü öne çıkaran en önemli avantajlar, ameliyat sonrası daha az ağrı olması ve işe dönüş süresinin kısa olmasıdır.

Anahtar Kelimeler: TEP, inguinal herni, Lichtenstein

ABSTRACT

Objective: Open tension-free mesh repair (Lichtenstein) and laparoscopic totally extraperitoneal (TEP) repair are the most preferred techniques for inguinal hernia surgery. This study aimed to compare these two techniques' early and long-term results.

Method: One hundred two patients were randomly divided into two groups (TEP, n=51; Lichtenstein, n=51). The groups were compared regarding complications (early, late), postoperative pain status, time to return to work and recurrence.

Results: The TEP group had a lower early postoperative visual analogue scale score (2 vs 5.27; p<0.001), less requirement for postoperative analgesia use (31.4% vs 70.6%; p<0.001), and earlier time to return to work (4.2 vs 20.4; p<0.001). Both groups had similar results regarding early and late postoperative complications. The mean follow-up period was 72,8±17.9 months. There was no difference between the groups regarding recurrence (TEP vs Lichtenstein; 2% vs 2%, p: 0.999).

Conclusion: Both techniques are effective in inguinal hernia repair with low long-term recurrence and complication rates. Among the two approaches, the most significant advantages highlighting the TEP procedure are less postoperative pain and a shorter time to return to work

Keywords: TEP, inguinal hernia, Lichtenstein

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INTRODUCTION

Inguinal hernia repair is one of the most common surgical procedures performed worldwide. (1). Many different techniques have been defined depending on the primary or mesh repair of the hernia, the location for mesh placement (anterior, posterior), and the order technique (open, laparoscopic). Open tension-free mesh repair technique (Lichtenstein) is the most preferred technique since it can be performed under local anaesthesia and has a lower risk of recurrence than traditional hernia repairs (Shouldice, Bassini), with an easy learning curve (2,3).

In recent years, the minimally invasive approach has become increasingly common in hernia repair, as in other surgical procedures. Laparoscopic inguinal hernia repair, in which the mesh is placed in the preperitoneal space without tension, can be performed either by a transabdominal or extraperitoneal approach. The total extraperitoneal (TEP) approach, which has a relatively low risk of significant complications (visceral injury, vascular injury), is a more preferred technique in this field (4).

Various studies comparing the TEP and Lichtenstein techniques have been reported (5–7). These studies have shown that TEP repair is associated with less postoperative pain and faster recovery (6,7). However, there are different views on the long-term (recurrence, chronic pain, etc.) results of the two techniques (5–8). This study was designed to compare the open tension-free mesh and laparoscopic repair techniques (TEP) in terms of postoperative pain, time to return to activities of daily living, complications (early and late), and long-term recurrence.

MATERIALS AND METHODS

Patients: This prospective randomised study protocol was approved by Kocaeli University Faculty of Medicine's Clinical Research Ethics Committee (KOU KAEK 2012/161-17/14). After approval, adult patients (aged 18-70 years) admitted to Kocaeli Training and Research Hospital for inguinal hernia repair (primary, unilateral, bilateral, recurrence) between January 2012 and December 2014 were evaluated for inclusion in the study. The study included patients diagnosed with inguinal hernia (primary, recurrent, unilateral, bilateral), had an American Society of Anesthesiologists (ASA) score of I and II and gave informed consent to participate. Patients with scrotal, strangulated, or obstructed hernia, periumbilical or sub umbilical incision scar (median, right or left paramedian), undergoing prostatectomy or abdominal bladder surgery, Phanneilsteil incision scar, and ASA score >3 were excluded from the study. A total of 236 patients were evaluated for inclusion in the study. One hundred-two patients who met the criteria were included in the study. The patients were consecutively divided into two groups (TEP, n=51; Lichtenstein, n=51). Demographic characteristics (age, gender, body mass index), location and type of hernia were recorded preoperatively. This study was registered in the Clinical Trials Registry under identification number NCT05504122.

Follow-up and Data Collection: All patients were postoperatively followed up in the general surgery ward. After the operation, a single dose of 75 mg analgesic diclofenac sodium was intramuscularly administered. Following that, all patients were advised to take analgesics

(50 mg diclofenac sodium tablets) in case of need. After discharge, patients were asked to record the amount of analgesic they used. Postoperative 12-hour and 24-hour pain status was assessed with the visual analogue scale (VAS), with scores ranging from 0 to 10 points. This scoring was explained to all patients before the surgical procedure. Patients were allowed to continue their diet and normal activities in the postoperative period. All patients were given the exact postoperative instructions and recommendations. They were encouraged to return to work and normal activities immediately. All patients were examined in the outpatient clinic ten days after discharge. Early complications (hematoma, seroma, pneumoscrotum, wound infection, early recurrence, etc.), time to return to work (days), and requirement for analgesics were recorded in this evaluation. In case of no problem, the patients were followed up after six months and then at one-year intervals in the outpatient clinic or by telephone. Recurrence status, pain, loss of sensation, and inguinal sensitivity were recorded during these follow-ups by asking standard questions. Pain lasting over three months at the surgical site was defined as chronic pain.

Endpoints: The primary outcome measures of the study were long-term recurrence and complication status. The secondary outcomes included postoperative pain (VAS score, total analgesic requirement), postoperative complications, and time to return to work after surgery.

Statistical Analysis: The normality distribution of quantitatively measured parameters such as age, VAS score, and time to return to work in the laparoscopic and open hernia repair groups was evaluated using the Kolmogorov-Smirnov test. Normally distributed parameters were analysed with the student's t-test, while non-normally distributed parameters were analysed using the Mann-Whitney U test. Analysis of qualitative group variables was conducted with Fisher's Exact and Pearson's chi-square tests. Demographic information was summarised using descriptive statistics (n, mean, SD, minimum, maximum, median, difference between percentiles) or frequency distribution (n and %), depending on the data type. All statistical analyses were performed with SPSS version 23.0 (IBM, Armonk, NY).

RESULTS

Two hundred thirty-six patients were evaluated for inclusion in the study between January 2012 and December 2014. Ninety-six patients still needed to meet the inclusion criteria. Thirty-eight patients who refused randomisation were excluded from the study. As a result, the study was completed with 102 patients (TEP group, n=51 patients; Lichtenstein group, n=51 patients). Patients were discharged 24 hours after the operation without any problems. All patients' 10-day, 6-month, 1-year, and 2-year follow-ups were performed with outpatient clinic examination or by telephone. The first 2-year follow-up was completed in all patients, the 3-year follow-up was completed in 95,1%, the 4-year follow-up was achieved in 90,2%, the 5-year follow-up was completed in 83,3%, the 6-year follow-up was completed in 75,5%, and the 7-year follow-up was completed in 62,7 % of the patients (Figure 1).

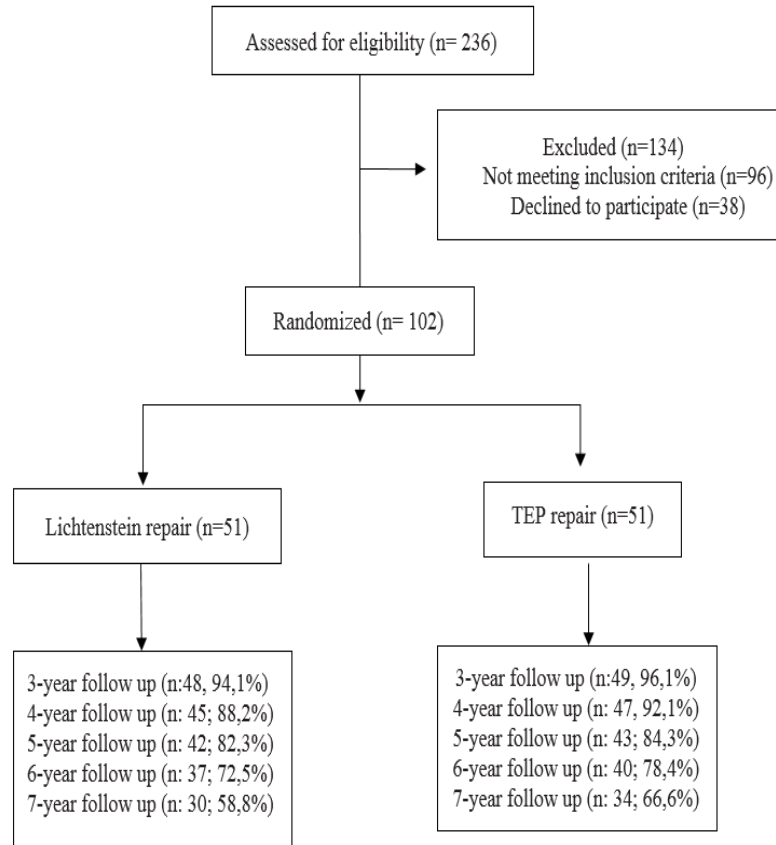


Figure 1. CONSORT diagram of trial profile.

Patient and hernia characteristics: The patients included in the study were predominantly male (82.4%). The groups were similar in terms of age, gender distribution, body mass index (BMI), type and location of hernia ($p>0.05$) (Table 1).

Intraoperative and early postoperative results: There was no difference between the two techniques regarding operative time (TEP vs Lichtenstein; 69.4 ± 14.5 vs 63.8 ± 14.5 ; $p: 0.0540$). No conversion occurred in any of the patients in the TEP group. In the early postoperative period, two patients in the open surgery group developed a hematoma at the incision line, which was treated conservatively. One patient in the TEP group developed subcutaneous emphysema. It spontaneously regressed without the requirement of additional intervention. There was no significant difference between the two groups regarding early complication rates (TEP vs Lichtenstein; 2% vs 3.9%, respectively; $p: 0.558$). The analysis of postoperative early pain status revealed a lower mean 24-hour VAS score in the TEP group (TEP vs Lichtenstein; 2 ± 2.59 vs 5.27 ± 1.44 ; $p<0.001$). During outpatient follow-ups, the requirement for analgesia use was higher in patients in the Lichtenstein group (TEP vs Lichtenstein; 31.4% vs 70.6%; $p<0.001$). The time to return to work was statistically significantly lower in the TEP group than in the Lichtenstein group (TEP vs Lichtenstein; 4.22 ± 1.74 vs 20.43 ± 4.99 ; $p<0.001$) (Table 2).

Long-term results: The mean follow-up period was 72.8 ± 17.9 (min-max; 24-84) months. In the late postoperative period, chronic pain was observed in three patients, loss of sensation in one patient, and hyperesthesia in one patient. Although the late complication rate was higher in the Lichtenstein group, there was no statistically significant difference between the groups (TEP vs Lichtenstein; 2% vs 9.8%; $p: 0.329$). Recurrence was observed in one patient in the TEP group at the postoperative 7th month and one in the Lichtenstein group at the postoperative 9th month. There was no statistically significant difference between the groups regarding recurrence (TEP vs Lichtenstein; 2% vs 2%; $p: 0.999$) (Table 3).

	Lichtenstein Group (n: 51)	TEP Group (n: 51)	Total (n: 102)	p value
Age (year)	44 (43,24±14,26)	50 (48,51±17,55)	46,5 (45,87±16,13)	0,099
Gender n (%)				0,299
Male	40 (78,4%)	44 (86,3%)	84 (82,3%)	
Female	11 (21,6%)	7 (13,7%)	18 (17,7%)	
BMI (kg/m ²)	26 (26,27±2,54)	25 (25±4,11)	26 (25,64±3,46)	0,105
Hernia Side n (%)				0,399
Right	28 (54,9%)	24 (47,1%)	52 (51%)	
Left	20 (39,2%)	20 (39,2%)	40 (39,2%)	
Bilateral	3 (5,9%)	7 (13,7%)	10 (9,8%)	
Type of Hernia n (%)				0,517
Direct	11 (21,6%)	5 (9,8%)	16 (15,7%)	
Indirect	31 (60,8%)	33 (64,7%)	64 (62,7%)	
Femoral	3 (5,9%)	3 (5,9%)	6 (5,9%)	
Pantaloon	3 (5,9%)	5 (9,8%)	8 (7,8%)	
Recurrent	3 (5,9%)	5 (9,8%)	8 (7,8%)	

	Lichtenstein Group (n: 51)	TEP Group (n: 51)	Total (n: 102)	p value
Time of Operation (minute)	63.8±14.5	69.4±14.5		0.0540
Early complication n (%)				0,558
Yes	2 (3,9%)	1 (2%)	3 (2,9%)	
No	49 (96,1%)	50 (98%)	99 (97,1%)	
Analgesic Requirement n (%)				<0,001
Yes	36 (70,6%)	16 (31,4%)	52 (51%)	
No	15 (29,4%)	35 (68,6%)	50 (49%)	
VAS Score (M (mean±sd))	5 (5,27±2,54)	2 (2±2,59)	2 (3,93±1,86)	<0,001
Return to work (day)	20 (20,43±4,99)	4 (4,22±1,74)	11,5 (12,32±8,96)	<0,001

	Lichtenstein Group (n: 51)	TEP Group (n: 51)	Total (n: 102)	p value
Late Complication				0,329
Chronic Pain	2 (3,9%)	1 (2%)	3 (2,9%)	
Hyperesthesia	1 (2%)	0 (0%)	1 (1%)	
Loss of Sensation	2 (3,9%)	0 (0%)	2 (2%)	
No	46 (96,2%)	50 (98%)	96 (94,1%)	
Recurrence				0,999
Yes	1 (2%)	1 (2%)	2 (2%)	
No	50 (98%)	50 (98%)	100 (98%)	
Follow up (month) (mean ±sd)	71,5 ± 18,7	74,1 ± 17,1	72,8 ± 17,9	0,467

DISCUSSION

The best evidence-based options for inguinal hernia repair are laparoscopic (TAPP, TEP) and the Lichtenstein technique (Level of Evidence: Grade A) (2). TEP, one of the laparoscopic repair techniques, is a complex procedure with a long learning curve (2). Some studies have found the operative time to be longer and the complication rate higher than the Lichtenstein technique (6,9). Contrary to this result, the results of our study demonstrated similar operative time and complication rates for both techniques (TEP vs Lichtenstein). This result may be explained by the surgical instruments used, the technique's development, and the procedure's performance by an experienced surgeon in the present study. As a matter of fact, Köckerling et al. (10) reported a decreased complication rate and improved postoperative results after TEP repairs performed by professional teams (>25 TEP repairs per year).

Postoperative pain is a factor that negatively affects patients' quality of life and healthcare costs. Our study demonstrated that patients who underwent laparoscopic hernia repair (TEP) had lower pain scores (VAS) and less postoperative analgesic consumption in the acute period. The first reported studies on this subject have concluded that the pain is similar to open repair in the postoperative 30-day period, except for the first day of (11)—However, the meta-analysis of Aiolfi et al. (12) showed a significantly lower pain score (VAS) at different postoperative hours (12, 24, 48 hours) in patients who underwent minimally invasive surgery compared to the open technique. Chen (13) and Bansal et al. (14), on the other hand, reported that the TEP procedure reduced the requirement for postoperative analgesia use, similar to our results. The technical differences between the TEP and the Lichtenstein techniques are the wound size, the mesh placement location, and the mesh fixation type to the abdominal wall. Less pain in laparoscopic repair can be explained by less surgical trauma than open surgery (15) and the lower risk of nerve-related complications (injury, compression) in the preperitoneal area.

Time to return to activities of daily living and work is an essential factor affecting the technique for inguinal hernia repair. Prolonging this period after surgery may lead to negative socio-cultural and economic consequences. Hence, it should be considered when evaluating the success of the surgery. Our study showed a shorter time to return to activities of daily living and work in the TEP group (TEP vs Lichtenstein; 4 vs 13 days). Complex variables such as anaesthesia type, postoperative pain control, early complications, preoperative patient expectations, patient motivation, sociocultural level, and insurance system may affect the objective evaluation of this period (16,17). In our study, the factors affecting this period were not directly assessed. However, the shorter time in the TEP group with less postoperative pain suggests that this period may be correlated with pain. As a matter of fact, Bay-Nielsen et al. (18) reported that the main reason for a prolonged time to return to work in most patients (>60%) was postoperative pain and wound complications. In their study, Königer et al. (19) reported a lower rate of postoperative pain that causes movement restriction in laparoscopic repair compared to open repair techniques (Shouldice, Lichtenstein) (2.4% vs 13 to 15%), with a possibility to return to activities of daily living earlier in laparoscopic repair. Compared to other studies with TEP repair (5,12), the time to return to activities of daily living was shorter in our study. Because each patient in the present research was encouraged

to return to work and activities of daily living as soon as possible, as a standard independent of work type, no restrictions were applied in the postoperative period. There is no formal recommendation for time to return to activities of daily living and work postoperatively (20). At this point, the most critical concern is that an early return to work may increase the risk of recurrence. However, it has been shown that this is not associated with the risk of recurrence (18). Therefore, in our study, a standard recovery period was not recommended for patients, and they were instructed to return to activities of daily living and work as soon as possible.

One of the most significant clinical problems after inguinal hernia repair is recurrence. The preferred surgical approach (open vs laparoscopic, mesh vs non-mesh) may affect the risk of recurrence. Neumayer et al. (9) reported a higher rate of recurrence (TEP vs Lichtenstein; 10.1% vs 4.9%) in TEP repair compared to open tension-free repair during a two-year follow-up. A meta-analysis conducted in 2012 found that mainly TEP repair caused a higher recurrence rate than available repair (8).

However, the results of these two studies should be interpreted with caution. In the meta-analysis, a significant portion of the data (41.6%) was taken from the survey of Eklund et al. (21), where a single surgeon was responsible for one-third of all recurrences. Moreover, Neumayer et al. (9) also emphasised in their study that the recurrence rate was similar for both techniques (TEP vs Lichtenstein) as the surgical experience increased. Our study demonstrated a similar recurrence rate for both methods (TEP vs Lichtenstein; 2% vs 2%) at a mean follow-up period of 72 months. The performance of TEP repair by an experienced surgeon can explain this result.

Studies reported from experienced centres support our result (22). Long-term effects regarding recurrence are limited—the meta-analysis of Bobo et al. (5) wrote about a similar risk of recurrence for both techniques (Lichtenstein vs TEP) in the first three years, with an increased risk of recurrence for TEP repair after three years. The authors thought this might be due to the dehiscence of the lateral edge of the mesh or the use of the wrong mesh size. Contrary to this study, all recurrences in our study were observed within the first year. The absence of long-term recurrence may be due to the standard fixation of the lateral edge and the use of an appropriate mesh size (10×15 cm).

Along with the solution of the recurrence problem in inguinal hernia repair to a great extent, discomforts such as pain, numbness, or sensitivity of the repair area, which affect long-term patient comfort and quality of life, have become more remarkable. It has been reported that patients are affected by these discomforts at rates ranging from 15% to 53% after repair (23). Our study showed that 5.9% of the patients had long-term discomforts such as pain and numbness. The need for more standardisation for the assessment and definition of this subject may be the reason for the differences in the reported results. Furthermore, the fact that telephone calls in our study mainly obtained these data may also have affected the results. The evaluation of both techniques (Lichtenstein vs TEP) by ignoring this fact showed no statistical difference between the groups regarding this complication in our study. Studies with many patients have reported that chronic pain and discomfort complaints are

more common in open repair (24,25). In our research, these complications were seen in more patients operated on with the Lichtenstein technique. However, the relatively small sample size may be why more statistical differences are needed.

The major limitation of our study is that long-term results were mainly evaluated by telephone calls rather than clinical examination. The difficulty of following up on this group of patients with long-term clinical assessment has been reported in various studies (26,27). This difficulty also affected our study. Although Bakker et al. (26) said that recurrence could be detected safely after inguinal hernia repair with the right questions via telephone interview; the difficulty in diagnosing asymptomatic recurrence may have affected our recurrence rates. This should be considered when evaluating our results.

This study showed that TEP repair had less postoperative pain, a shorter time to return to activities of daily living, and similar long-term recurrence rates for both techniques (TEP vs Lichtenstein).

Ethics Committee Approval: Ethics committee approval was received for this study from the Clinical Research Ethics Committee of Kocaeli University Faculty of Medicine (KOU KAEK 2012/161-17/14).

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