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The effect of tack number and balloon trocar use on acute post-operative pain scores of patients who underwent TEP repair of inguinal hernia

TEP inguinal herni onarımı yapılan hastalarda tack sayısının akut post-operatif ağrı skoruna etkisi

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Abstract

Aim: As the novel technology on surgical procedures evolve, the management and amelioration strategies for postoperative pain gains importance for surgeons to improve patients' life quality and postoperative outcomes. In this study, we aimed to compare the number of tacks placed during surgery and the use of intra-operative balloon trocars during TEP repair of inguinal hernias with respect to post-operative early pain scores.

Methods: A total of 83 patients were included in this prospective cohort study, 59 being in the 0-1 tack group and 24 in the 2 tacks group. Balloon trocar was used in 32 patients. All patients underwent laparoscopic TEP inguinal hernia repair. Groups were compared with respect to pain scores on 3rd, 12th and 24th postoperative hours.

Results: Pain score was better in no balloon trocar+2 tacks group when compared to balloon trocar+2 tacks and no balloon trocar+0-1 tack group at the 24th postoperative hour (P=0.02 and P=0.007, respectively), and in the balloon trocar+0-1 tack group than that of the no balloon trocar+0-1 tack group (P=0.004). There was no statistically significant difference between these four groups in terms of pain score on the 3rd and 12th hours of surgery (P=0.46 and P=0.24, respectively). Patients in the 0-1 tack group reported less pain on the 24th postoperative hour (3.1 (6.3) vs 14.1 (21.8); P=0.32).

Conclusion: Using less number of tacks and avoiding using balloon trocar result in lower pain scores following laparoscopic TEP repair of inguinal hernias.

Keywords: Tack number; Mesh fixation, Inguinal hernia, Laparoscopy, Post-operative pain

Öz

Amaç: Cerrahi prosedürler yeni teknoloji kullanılarak geliştikçe, postoperatif dönemde hastaların yaşam kalitesinin ve ameliyat sonrası dönemin iyileştirilmesi açısından bu dönemde ağrı yönetimi ve ağrıyı azaltma stratejileri cerrahlar için önem kazanmaktadır. Bu nedenle, çalışmamızda, tack sayısı ve intraoperatif balon trokar kullanımının TEP inguinal herni operasyonu sonrası erken dönem ağrı skorlarına etkisinin retrospektif olarak karşılaştırılması amaçlanmıştır.

Yöntemler: Bu prospektif kohort çalışmasına toplam 83 hasta dahil edildi; 59'u 0-1 tack kullanılan grupta ve 24'ü 2 tack kullanılan grupta idi. 32 hastada balon trokar kullanıldı. Tüm hastalara laparoskopik TEP inguinal herni onarımı yapıldı. Gruplar ameliyat sonrası 3., 12. ve 24. saatlerde ağrı skorlarına göre karşılaştırıldı.

Bulgular: Ameliyattan sonraki 24. saatte balon trokar kullanılmayan ve 2 tack kullanılan grupta balon trokar + 2 tack ve balon trokar + 0-1 tack grubuna göre ağrı skoru daha iyi idi (Sırasıyla P=0,02 ve P=0,007). Ağrı skoru balon trokar + 0-1 tack grubunda, balon trokar kullanılmayan ve 0-1 tack kullanılan gruba kıyasla daha iyiydi (P=0,004). Ameliyatın 3. ve 12. saatlerinde ağrı skoru açısından bu dört grup arasında istatistiksel olarak anlamlı bir fark saptanmadı (Sırasıyla P=0,46 ve P=0.24). 0-1 tack grubundaki hastalar postoperatif 24. saatte daha az ağrı hissettiklerini bildirdi (3,1 (6,3)'e karşı 14,1(21,8); P=0,32).

Sonuç: İnguinal hernilerin laparoskopik TEP onarımını takiben daha az sayıda tack kullanımı ve balon trokar kullanımının sınırlanması, daha iyi postoperatif ağrı skoru ile ilişkilidir.

Anahtar kelimeler: Tack sayısı, Mesh fiksasyonu, İnguinal herni, Laparoskopi, Postoperatif ağrı

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Introduction

Inguinal hernia repair is one of the most frequent surgical operations worldwide. Following the first report of laparoscopic hernia repair in 1993, and introduction of mesh placement, post-operative complication and recurrence rates decreased dramatically [1,2]. Similar to physicians in other disciplines of medicine, surgeons are continuously seeking novel methodologies to reduce post-operative pain and increase the life quality of patients who underwent surgical procedures.

Endoscopic totally extraperitoneal (TEP) repair is one of the minimally-invasive (laparoscopic) methods for inguinal hernia repair and despite its negative sides such as longer learning period and difficulties in performing, TEP is highly preferred by surgeons since it offers lower rate of complications including acute postoperative pain, chronic postoperative inguinal pain, recurrence, and its requirement of less number of closing material [3,4]. In the laparoscopic inguinal hernia repair (LIHR) using TEP approach, a prosthetic mesh is placed to cover all current and future possible hernia sites in order to fix the herniated bowel and prevent recurrence through an extraperitoneal incision [5,6].

Sometimes mesh material requires fixing with different techniques, such as tack, stapler, fibrin glue, or suture. The correct replacement and fixation of mesh to the fasciomuscular layer of the abdominal wall is crucial to reinforce the posterior wall and prevent future recurrences [2].

Although tack closure is shown to be associated with less post-operative pain, nerve injury and hematoma and also is time-saving, the effects of tacks on the bowel are reportedly etiological factors in the development of an intestinal fistula following LIHR [7-9].

Even though laparoscopy is associated with less incidence and ratio of postoperative pain, patients who underwent inguinal hernia repair still report post-operative pain and often require analgesia medication including even opioids. The number of tacks and the replacement sites of tacks on the mesh have significant impact on prevention of post-operative acute pain [10]. And inadequate control of the acute pain following the surgery has been shown to be associated with postoperative chronic pain [11].

In the present study, we analyzed and compared the clinical outcomes of laparoscopic TEP using different number of tacks for mesh fixation and accessing the peritoneal cavity with or without use of balloon trocar. We investigated whether the use of a smaller number of tacks may be beneficial in reducing acute postoperative pain in patients underwent TEP repair for the treatment of inguinal hernia.

Materials and methods

Patients and surgical procedure

This is a prospective cohort study on patients who underwent laparoscopic repair of inguinal herniation. It was approved by the Ethical committee of Istanbul Education and Research Hospital (Date: 12/06/2020. Approval Number: 2447). Our laparoscopic inclusion criteria consisted of patients aged 18 years or more, those with unilateral hernia (direct or indirect), ASA score of I, II or III, and patients with hernias between 2-5 cm in size. Those with hernias less than 2 cm and greater than 5 cm, ASA score IV, bilateral and/or recurrent hernia were excluded. Patients with significant comorbidity and not those suitable for pneumoperitoneum were also excluded. Informed consent was obtained from all patients prior to surgery. All cases were elective, and none were transferred emergently.

The hernias were classified according the criteria defined by Schumpelick-Arit. All laparoscopic repairs were performed by following the same surgical protocol by two specialist surgeons highly experienced in laparoscopic inguinal hernia repair. All patients were given prophylaxis against infectious conditions and antithrombotic agents were used when necessary.

A standardized TEP approach under general anesthesia was performed using three different ports, one inserted just below the umbilicus through a 1 cm incision, one placed above the pubic symphysis, and one placed between the other two ports. Hasson trocar was fixed by present sutures on both sides of the trocar wings to prevent air discharge through the port incision. If the operating surgeon preferred using the balloon trocar, it was introduced to provide a passageway through the peritoneum into the abdomen after insufflation with 30 cc air.

Following the definition of anatomical structures in the inguinal region, the hernia defect was closed with a polypropylene or polyvinylidene fluoride mesh of appropriate size. The mesh was then secured with 0-1 5 mm titanium tacks, one being on the pubic tubercle, and then on the anterior superior iliac spine if second tacks were needed. Decision for replacement of a second tack was made by the operating surgeon depending on the characteristics of the hernia. Whenever possible, our decision was to use the least number of tacks for mesh fixation. Following mesh fixation, the trocars were removed, and the fascial scars were closed.

While we evaluated our LIHR patients retrospectively, we created four different groups:

Balloon trocar + 0-1 tack; Balloon trocar + 2 tacks; No balloon trocar + 0-1 tack, and No balloon trocar + 2 tacks. The purpose of this subgrouping was to define whether the tacks used for mesh fixation results in a tissue injury led to an increased pain score during the postoperative period. Since the number of the patients with 0 tacks were low for creation of an individual subgroup, we defined a single group for the patients with 0-1 tacks.

Pain score

Postoperative pain scores were evaluated on the 3rd, 12th, and 24th postoperative hours using a personal pain scoring method. Patients were given a grading scale where a score of 0 points meant no pain and 100 points meant intense and the worst pain experienced so far by the patient. The questionnaire was applied by the same supervising nurse of the general surgery ward. The education levels of all patients were similar between the groups, and all were literate. The baseline educational level of all subjects were high school, corresponding to at least 12-years of schooling in the country's educational system.

They were allowed to resume normal diet and mobilized as soon as possible.

A self-controlled analgesia device and oral paracetamol or a non-steroidal anti-inflammatory drug were provided for the patients to use when needed.

Statistical analysis

The demographic data of the patients were given as number and percentages, and numerical variables were presented as mean (SD). Normality of the data distribution was tested using Kolmogorov-Smirnov test. Statistical analysis was performed using Analysis of Variance (ANOVA) test between the study groups. The lowest *P*-values were reported in the tables. Comparison of two data were performed using a Chi-square test for percentages. A *P*-value of <0.05 was considered statistically significant. All statistical analysis was carried out using the GraphPad Prism 8.0 statistical package. The comparisons of the significant results in the Kruskal Wallis test were re-evaluated with post-hoc correction. Sample sizes for each group were calculated using the equations determined by MacCallum et al [12]. A power analysis determined the minimum sample size. Briefly the formula as follows was used for sample size calculation: Effect size f=0.40; α err prob=0.05; Power (1-β err prob)=0.80; number of groups=4 ; Output: Total sample size=76.

Results

Patient and operation characteristics and are summarized in Table 1. Eighty-three patients were enrolled in the study, including 71 males (85.5%) and 12 females (14.5%). The mean age was 44.7 (15.4) years. The mean BMI was 26.5 (2.85) kg/m^2. The mean hernia size was 2.08 (0.53) cm in diameter. The hernia was localized on the right side in 51 (61.6%) patients and left side in 32 (38.4%). The most common hernia type was Mc II (Combined hernia with hernia orifice 3 cm) in 39 patients followed by L II (Lateral (indirect) hernia with hernia orifice 3 cm) in 15. The mean operation time was 71(26) minutes (24-200; median: 50).

Polypropylene was the most commonly used mesh [66 (79.5%) patients] whereas polyvinylidene was used in 17 (20.5%) patients. Intraoperative balloon trocar was not used in 51 (61.5%) of the patients. The number of tacks used was 0-1 in 59 (71.0%) patients and 2 in 24 (29.0%) patients (Table 2). A tack number of more than 2 was not administered to any of the patients.

When patients were divided into subgroups and compared in terms of intraoperative balloon trocar use and number of tacks, pain score was better in no balloon trocar+2 tacks group when compared to balloon trocar+2 tacks and no balloon trocar+0-1 tack group at the 24th hour following the surgery (*P*=0.02 and *P*=0.007, respectively), and in balloon trocar+0-1 tack group than that of the no balloon trocar+0-1 tack group (*P*=0.004). The mean pain scores on the 3rd, 12th and 24th post-operative hours were depicted in Table 2. There was no statistically significant difference between these four groups in terms of pain score at the 3rd and 12th hours of surgery (*P*=0.46 and *P*=0.24, respectively).

While we evaluated tack number alone, patients in the 0-1 tack group reported less total mean pain at the 24th postoperative hour (3.1(6.3) vs. 14.1(21.8); *P*=0.32) (Table 3).

The patients with polyvinylidene mesh fixation reported significantly higher pain compared to the patients with polypropylene mesh at the 24th postoperative hour (42.9(32.5) vs. 6.1(10.1); *P*<0.001). The ratio of self-administered pain medication use was shown in Table 3. There was no statistically significant difference between the ratios of pain medication use among the tack number specified groups on the 3rd, 12th, and 24th hours postoperatively (*P*=0.60, *P*=0.39 and *P*=0.67, respectively).

The median post-operative hospital stay was 2 days (1-5). There were no reports of any post-operative early complications in patients.

Table 1: Demographics of the patients and intraoperative specifications

Parameters	n=83
Male/Female	71/12
Age (years)	44.7(15.4)
BMI	26.50(2.85)
Location of the hernia	
Left	32 (38.3%)
Right	51 (61.7%)
Hernia size (cm)	2.08(0.53)
Duration of operation (minutes)	71.0(26.0)
Type of hernia (According to Aachen classification)	
L I (Lateral (indirect) hernia with hernia orifice <1.5 cm)	9 (10.9%)
L II (Lateral (indirect) hernia with hernia orifice 3 cm)	15 (17.8%)
M II (Medial (direct) hernia with hernia orifice 3 cm)	5 (5.5%)
M III (Medial (direct) hernia with hernia orifice >3 cm)	7 (8.2%)
Mc I (Combined hernia with hernia orifice <1.5 cm)	2 (2.7%)
Mc II (Combined hernia with hernia orifice 3 cm)	39 (46.6%)
Mc IIII (Combined hernia with hernia orifice >3 cm)	6 (8.2%)
Number of tacks used for mesh fixation	1.16±0.5
Type of mesh used	
Polypropylene	66 (79.5%)
Polyvinylidene	17 (20.5%)
Intraoperative balloon trocar use	
Yes	32 (38.5%)
No	51 (61.5%)

Table 2: Pain scores of the patients sub-grouped according to intra-operative tack number and balloon trocar use

Intraoperative variables	Pain score			Age	M/F	BMI
	3rd hour	12th hour	24th hour			
Balloon trocar + 0-1 tack (n=18)	20(20.8)	11(9.9)	7(12.2)	41.7(11.2)	5.8	25.4(2.56)
Balloon trocar + 2 tacks (n=14)	30(17.3)	10(10.0)	10(10.0)	43.4(11.7)	4.2	27.2(3.02)
No balloon trocar + 0-1 tack (n=41)	26(12.8)	16.2(11.4)	15.8(6.0)	47.6(8.9)	4.8	24.8(3.16)
No balloon trocar + 2 tacks (n=10)	17(11.6)	11(7.3)	1(3.1)	42.2(14.1)	5.4	26.7(1.86)
P-value	0.46	0.24	0.004	0.89	0.32	0.67

Table 3: Pain scores of the patients sub-grouped according to intra-operative tack number, type of mesh used, and self-administration of postoperative analgesia

	Pain score		
Number of tacks used for mesh fixation	3rd hour	12th hour	24th hour
0-1 tack (n=59)	25.1 (17.3)	13.4 (10.9)	3.1 (6.3)
2 tacks (n=24)	27.7 (12.3)	10.8 (7.6)	14.1 (21.8)
P-value	0.38	0.44	<0.05
Type of mesh used			
Polypropylene (n=66)	23.3 (13.3)	12.7 (9.9)	6.1 (10.1)
Polyvinylidene (n=17)	40 (43.5)	13.4 (15.2)	42.9 (32.5)
P-value	0.08	0.90	<0.001
Number of patients used postoperative pain medication			
0-1 tack (n=59)	12 (20.3%)	14 (23.7%)	4 (6.7%)
2 tacks (n=24)	8 (33.3%)	10 (41.6%)	2 (8.3%)
P-value	0.60	0.39	0.67

Discussion

Despite its long duration of learning and cost, laparoscopic repair of inguinal hernias is preferred for its favorable effects on quality of life, short duration for return to daily activities and work, and less pain among other positive sides such as lower rate of complications and recurrence as well as better cosmetic results [10,13].

The use of mesh in LIHR is related with a low rate of complications and recurrence, along with better effects on resuming normal daily activities [14]. Fixation of the mesh in appropriate measures might be the most crucial step of LIHR, since rolling of the mesh, inflammatory reaction and fibrous tissue production around the mesh were shown to be related with chronic post-operative pain and recurrence [6]. Different mesh fixation techniques have various advantages or disadvantages when compared with each other. Cost, intra-operative

complication and recurrence rates, post-operative pain, and operative time are among the indicators on the decision-making process by the surgeon when choosing one over another [2].

Post-operative acute pain within 48 hours after the surgery is still an issue to be solved by different intra- and post-operative approaches to mitigate the general well-being of the patients [15]. Different intra-operative interventions were recruited to reduce suture-site pain including injection of local anesthetic agents to the suture region [16]. Post-operative acute pain is a restricting factor for the patients for return to daily activities, and pain medications including morphine equivalents are prescribed for the patients.

The use of a balloon trocar to approach the hernia region might be related with intra-operative bleeding, and post-operative pain on the trocar site and peritoneum. In a large group of hernia patients, Belyansky et al. [10] showed increased ratio of post-operative pain after LIHR in patients with more than >10 tacks and when adjustments were made for tack number, they could not find a relationship between the operation type (modified Lichtenstein, TAPP or TEP) and pain score. It has been shown that various techniques used for LIHR and mesh fixation are related with different recurrence rates. Thus, since TEP repair and tack fixation were shown to be related with less recurrence rate, we use the combination of these two when available and appropriate for the patient. Furthermore, combination of these has also been shown to be related with less post-operative acute pain [17,18].

Our study aimed to evaluate the pain scores of patients who underwent TEP repair of inguinal hernias in terms of number of tacks used for mesh fixation and introduction of a balloon trocar to go forward through the peritoneal cavity.

In our study, patients reported significantly better pain scores in no balloon trocar+2 tacks group when compared to balloon trocar+2 tacks and no balloon trocar+0-1 tack group on the next day of the operation. Although we expected to find that use of more number of tacks and balloon trocar have an exacerbating effect on post-operative pain score, we could not find this correlation in all comparisons. In the patients without balloon trocar introduction, the reason for a more comfortable post-operative process with less pain might be resulting from the better placement of the mesh with two tacks, hence providing a better intra-abdominal fixation and relief.

Additionally, despite the exclusion of patients who chose to receive self-controlled pain medication with opioids, other medications such as Paracetamol and NSAIDs might be reducing the pain and complicating the evaluation process between these groups. However, the ratios of self-administered pain medication on the pain score evaluation visits was similar between the study groups.

Furthermore, pain score was worse in balloon trocar+0-1 tack group than that of the no balloon trocar+0-1 tack group, showing that balloon trocar use might be a cause of acute post-operative pain after LIHR. While we evaluated tack number alone and excluding balloon trocar use as a variable, patients in the 0-1 tack group reported significantly less pain at the 24th postoperative hour. Although the pain score on the 3rd, 12th and 24th post-operative hours were worse for the balloon trocar+2 tacks group, this finding did not reach significance for all inter-group comparisons.

Among our patients, some patients did not require mesh fixation, thus no tack was used for these group of patients since non-fixation of mesh was shown to be adopted routinely and safely in LIHR by different studies worldwide [19].

Despite providing valuable data to evaluate TEP repair patients with different intra-operative approaches, our study has some limitations. Personal specifications such as gender, age, educational and social status, economic wealth are among the most common indicators of pain perception by an individual [20]. However, these factors except age were not been recorded and evaluated in the context of our study. Replacing 0-1 or 2 tacks did not have a significant influence on operating time, so we did not use operation time between the groups as a variable. Patients' duration until return to daily activities, comfort, and life quality a few months after the operation and presence of any chronic post-operative pain also have not been recorded. Most post-operative complications are preventable depending on the operating surgeon's anatomy knowledge and laparoscopic experience. The operations presented here were performed by two different surgeons with similar experience, using the same procedure for LIHR. Although inter-individual variations might apply to our study too, both surgeons were raised from the same teaching clinic and share similar experience and operation number performed.

Limitations

Our study has several limitations to declare. First, the number of the individuals in comparison groups are not equal. Furthermore, we did not subgroup the patients depending on the type of hernia, thus, a more severe form of hernia and complicated repair process might be a cause of the increased pain score irrespective of the balloon trocar or the number of the tacks used. Further studies with homogenous patient groups are required for better understanding of the effect of these variables on postoperative pain scores in inguinal hernia patients,

Conclusion

While surgeons worldwide are seeking novel methodologies and techniques in hernia surgery to keep complications at minimum, LIHR using TEP procedure is a convenient procedure in terms of pain control together with small number of tack use for mesh fixation. Introduction of balloon trocar also provides disadvantages due to tissue injury during the creation of a passage to the hernia site. Our suggestion is the use of possible lowest number of tacks for mesh fixation and limited use of balloon trocar for the laparoscopic TEP repair of inguinal hernias.

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