İstanbul Med J 2018; 19 (4): 289-94
DOI: 10.5152/imj.2018.67674

Early-Term Pain Management After Laparoscopic Total Extraperitoneal Inguinal Hernia Repair

Laparoskopik Total Ekstraperitoneal İnguinal Fıtık Onarımı Sonrası Erken Dönem Ağrı Kontrolü

Mete Şişman[1], Mehmet Tolga Kafadar[2], Önder Sürgit[3], Muhammet Gözdemir[4], Aydın İnan[5]

Abstract / Öz

Introduction: The aim of the present study was to determine if the use of local anesthesia by different ways would reduce postoperative pain after laparoscopic total extraperitoneal inguinal hernia repair.

Methods: Thirty patients were randomly divided into three groups. Upon completion of the prolene mesh repair, Group 1 (mean age: 45.8±8.6 years) received 5 cc levobupivacaine installed into the preperitoneal space every 6 h for 24 h via a catheter placed to the preperitoneal space. In Group 2 (mean age: 44.9±11.5 years), levobupivacaine-soaked spongostan was placed into the preperitoneal space after the placement of the prolene mesh. Group 3 (mean age: 45.4±10.7 years) was determined as the control group and received 75 mg diclofenac sodium after inguinal hernia repair. Pain was assessed by using a Visual Analog Scale of 1 (minimal pain) to 10 (worst pain) at fixed time intervals of 0, 6, 12, 18, and 24 h after surgery.

Results: The trend of postoperative pain in 0, 6, and 18 h of Group 1 was significantly lower than that of Group 3 ($p<0.001$). There was no significant difference between Group 1 and Group 3 in terms of postoperative 12 ($p=0.012$) and 24 ($p=0.037$) hour pain levels. The trend of postoperative pain in 0, 6, 12, 18, and 24 h of Group 2 was lower than that of the other two groups ($p<0.001$).

Conclusion: Placement of bupivacaine-soaked spongostan into the preperitoneal space resulted in least postoperative pain between the three groups. The application of placement of bupivacaine-soaked spongostan is a safe and effective method.

Keywords: Inguinal hernia, laparoscopic repair, postoperative pain, local anesthesia

Amaç: Bu çalışmanın amacı, laparoskopik total ekstraperitoneal fıtık onarımı sonrası gelişen erken dönem ağrıya yönelik farklı yöntemler ile uygulanan lokal anestezik ilacın etkinliğini ortaya koymaktır.

Yöntemler: Çalışmaya tek taraflı laparoskopik total ekstraperitoneal inguinal herni onarımı uygulanan 30 hasta dahil edildi. Hastalar randomize olarak 10' ar kişilik üç ayrı gruba ayrıldı. Yaş ortalaması 45,8±8,6 olan 1. gruba, fıtık onarımı sonrasında, operasyon sahasına, trokar giriş yerinden laparoskopik olarak yerleştirilen epidural (perifix) kateter yardımı ile ameliyat sonrası 0. saatten başlamak üzere 6 saat ara ile 24 saat süresince, 5cc levobupivakain hidroklorür uygulandı. Yaş ortalaması 44,9±11,5 olan 2. gruba, yapılan fıtık onarımı sonrasında, ameliyat sahasına vücut içerisinde eriyebilen bir materyal olan spongostan, dilimlenip hazırlanarak, levobupivakaine hidroklorür emdirilmiş olarak yerleştirildi. Yaş ortalaması 45,4±10,7 olan 3. grup ise kontrol hasta grubu olup, hastalara nonsteroid antiinflamatuvar (Diklofenak Sodyum 75mg intramuskuler) tedavisi verildi. Yapılan işlemler sonrasında hastalar 24 saat süresince (0, 6, 12, 18 ve 24. saatlerde) ağrı yönünden vizüel analog skala ile (en düşük 1, en yüksek 10 puan) değerlendirildi.

Bulgular: Gruplar arasında ağrı açısından visual analog scale (VAS) ile yapılan değerlendirme sonucunda, kateter yolu ile levopubivakaine uygulanan grup ile diklofenak sodyum tedavisi verilen grup arasında 0, 6, 18. saatlerde anlamlı fark ($p<0,001$) saptanırken, 12 ($p=0,012$) ve 24. ($p=0,037$) saatlerde fark saptanmadı. Levobupivakain emdirilmiş spongostan uygulanan 2. grup ile diğer iki grup karşılaştırıldığında ise ağrı değerlerinin diğer iki gruba kıyasla, değerlendirmenin yapıldığı tüm saatlerde anlamlı olarak düşük olduğu görüldü ($p<0,001$).

Sonuç: Ameliyat sonrası kateter yolu ile verilen aralıklı levobupivakain hidroklorür infüzyon tedavisinin, ameliyat sonrası gelişen erken dönem ağrıyı azaltmasına rağmen ağrı kontrolü açısından yeterli olmadığı düşüncesindeyiz. Levobupivakain hidroklorür emdirilmiş spongostanın preperitoneal alana uygulanması yönteminin, diğer iki tedavi yöntemine göre ameliyat sonrası gelişen erken dönem ağrı üzerine anlamlı derecede etkili ve güvenli olduğu görüldü.

Anahtar Kelimeler: İnguinal fıtık, laparoskopik onarım, postoperatif ağrı, lokal anestezik

ORCID IDs of the authors: M.T.K. 0000-0002-9178-7843; Ö.S. 0000-0003-2531-7138.

[1]Clinic of General Surgery, Bursa State Hospital, Bursa, Turkey
[2]Department of General Surgery, Health Sciences University Mehmet Akif İnan Training and Research Hospital, Şanlıurfa, Turkey
[3]Clinic of General Surgery, Medicana International Ankara Hospital, Ankara, Turkey
[4]Clinic of Anesthesiology and Reanimation, Air Clinic Occupational Health and Safety Center, Ankara, Turkey
[5]Clinic of General Surgery, Ankara Umut Hospital, Ankara, Turkey

Address for Correspondence/Yazışma Adresi:
Mehmet Tolga Kafadar, Department of General Surgery, Health Sciences University Mehmet Akif İnan Training and Research Hospital, Şanlıurfa, Turkey
E-mail: drtolgakafadar@hotmail.com

Received/Geliş Tarihi: 25.09.2017
Accepted/Kabul Tarihi: 16.05.2018

Introduction

Defined as an abnormal prolapse of a tissue or organ through a defect in the overlying wall, hernia can involve any body site although it most commonly involves the abdominal wall, especially the inguinal region. Advances in hernia repair coinciding with the history of surgery have gained momentum with the description of the first true hernia repair by Eduardo Bassini (1). This was followed by the introduction of tension-free hernia repair and, after 1990s, laparoscopic hernia repair techniques. Today, total extraperitoneal (TEP) hernia repair, a laparoscopic technique, is used in many centers worldwide. Pain is one of the major complications of hernia surgery. Multiple recently performed studies have used various methods to control early postoperative pain (2-4). The aim of the present study was to investigate the efficacy of a local anesthetic and some other methods considered to prolong the duration of action of local anesthesia in early postoperative pain control after laparoscopic TEP hernia repair.

Methods

Among patients who presented to our clinic, 30 male patients diagnosed with unilateral inguinal hernia who met the below specified study inclusion criteria were enrolled in the study. Patients were randomized into three groups, and all were operated by laparoscopic unilateral TEP inguinal hernia repair under general anesthesia in the operation theater. The present study was performed according to the framework of the Declaration of Helsinki. Postoperative pain was rated by the Visual Analog Scale (VAS) for 24 h postoperatively. Informed consent was obtained from the patients who participated in the study. Study data were analyzed using the Statistical Package for Social Sciences for Windows ver. 11.5® software package (SPSS Inc.; Chicago, IL, USA).

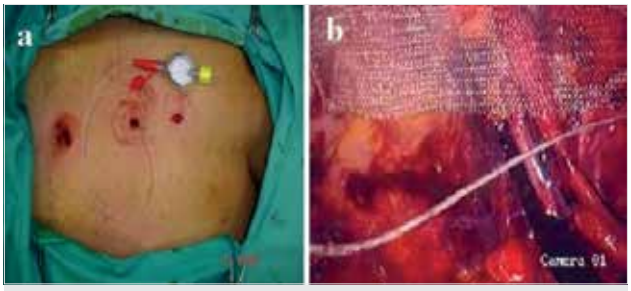

Figure 1. a, b. Catheter placement to the preperitoneal area after hernia repair

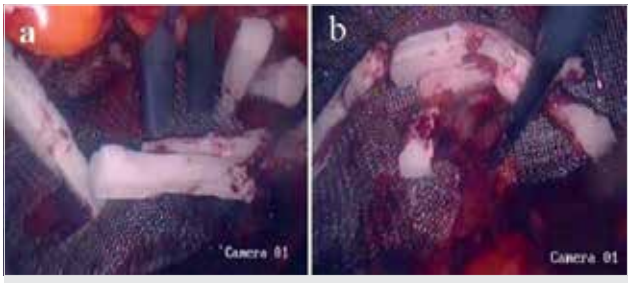

Figure 2. a, b. Spongostan placement after hernia repair

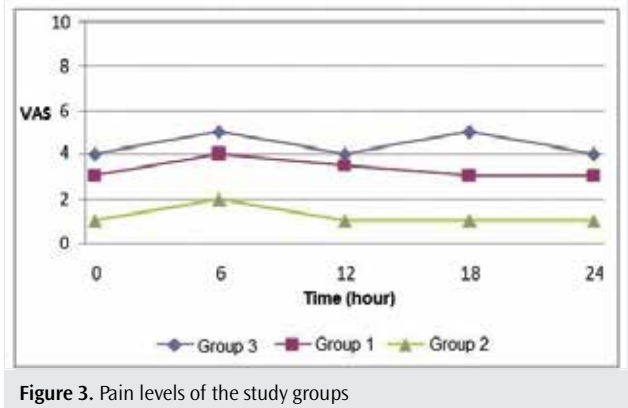

Figure 3. Pain levels of the study groups

Inclusion criteria were as follows:
1. Aged 20-60 years old,
2. Being in the American Society of Anesthesiologists (ASA) I-II risk group,
3. Having unilateral inguinal hernia,
4. Providing consent to participate in the study.

Exclusion criteria were as follows:
1. Having known allergy to one of the study medications,
2. Having morbid obesity (body mass index >35 kg/m^2),
3. Having current renal, hepatic, cardiovascular, and neuromuscular disorders; atrioventricular conduction disorder; or bleeding diathesis,
4. Having a history of opioid and analgesic abuse and using opioid, non-steroidal anti-inflammatory medications,
5. Having a history of inguinal hernia or abdominal surgery,
6. Being in the ASA III risk group,
7. Having a history of surgery to the Retzius space.

Levobupivacaine

Levobupivacaine (Chirocaine; Abbott Inc., Norway) is a novel member of an amino acid class of local anesthesia. Local anesthesia block the production and conduction of nerve impulses by raising the electrical excitation threshold of the nerves, slowing nerve impulses and reducing the rate of the increase of the action potential. In general, anesthesia propagation is correlated with diameter, myelinization, and conduction rate of the involved nerves. Epidural anesthesia, local infiltration can be applied with the purpose of peribulbar block in oral and ophthalmological surgery. The dose of administration for local infiltration is 1.25-2.5 mg/kg, with a maximum dose of 150 mg.

Spongostan

Spongostan (absorbable hemostatic gelatin sponge; Ethicon Inc., USA) is a sterile, water insoluble, shapeable, white, porous gelatin sponge designed for applying hemostasis on the bleeding surface. It can be administered dry or impregnated with isotonic saline.

Rating of postoperative pain

Rating of pain provides important clues for baseline severity, perception quality, and temporal course of pain. Rating these variables allows differential diagnosis for pain etiology. It is also necessary to determine the most efficacious pain treatment and compare different treatment methods. It involves the use of VAS, which is a numerical scale. The most commonly used form of VAS contains a vertical or horizontal line anchored by the two verbal descriptors, one for each symptom extreme, that is, "no pain" and "unbearable pain." Patients mark the severity of their pain on this 10 cm line. The distance in centimeters between the marked point and the point for the lowest pain on the VAS is recorded in digits from 1 to 10 as the numerical measure of pain severity.

Procedures applied to the study participants

Our study included 30 patients with unilateral inguinal hernia meeting the criteria specified above. Patients were randomized into three groups, each with 10 patients. All patients were operated by laparoscopic TEP hernia repair operation using a unilateral graft (15×10 cm) and three trocars (one is 10 mm and two are 5 mm). All operations were performed under general anesthesia at the operating theater.

Group 1: After hernia repair, when the operative field was still sterile, 5 cc levobupivacaine hydrochloride mixed with 5 cc isotonic saline was applied to the operative field with the aid of an epidural (Perifix) catheter laparoscopically placed via the trocar entry site (Fig. 1a, b). Then, it was re-applied every 6 h beginning from hour 0 for 24 h. The catheter was removed after the procedure at postoperative day 1.

Group 2: A 7×5×1 cm spongostan, a material that is soluble in the human body and used as a hemostat during the operation, was sliced, impregnated with levobupivacaine, and placed on the operative field (Fig. 2a, b). Spongostan was adjusted to cover the entire width of the operative field and impregnated with levobupivacaine hydrochloride in a way that the maximum dose of the latter would not exceed 20 ml.

Group 3: The control group was administered a non-steroidal anti-inflammatory drug (diclofenac sodium 1 mg/kg via intramuscular (IM) route).

Patients were monitored for early postoperative pain for 24 h after the operation. Pain severity was rated by the VAS (0-10 points).

Table 1. Distribution of the study groups by age and history of comorbidity

Variables	Group 1	Group 2	Group 3	p
Age (years)	45.8±8.6	44.9±11.5	45.4±10.7	0.981
Comorbidity	2 (20%)	3 (30%)	4 (40%)	0.617

Table 2. Distribution of the study groups by frequency of hernia types

Hernia type	Group 1	Group 2	Group 3
Direct	1 (10%)	1 (10%)	1 (10%)
Indirect	8 (80%)	8 (80%)	9 (90%)
Direct+indirect	1 (10%)	1 (10%)	-

Table 3. VAS levels of the study groups by follow-up time points (Group 1-3)

Variables	Group 1	Group 3	p
0 h	3 (2-4)	4 (4-5)	<0.001
6 h	4 (3-5)	5 (3-6)	<0.001
12 h	3.5 (3-5)	4 (4-6)	0.012
18 h	3 (3-5)	5 (4-7)	<0.001
24 h	3 (2-5)	4 (3-5)	0.037

Group 1: Patient group in which levobupivacaine was administered via a catheter.
Group 3: Patient group in which diclofenac sodium was administered.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences for Windows ver. 11.5® (SPSS Inc.; Chicago, IL, USA) software package. Descriptive variables were expressed as mean±standard deviation for age, median (minimum-maximum) for VAS, and number (percentage, %) for nominal variables.

Differences between the mean ages of the groups were tested using the one-way analysis of variance test. Nominal variables were compared using the Pearson's chi-square test. A p-value <0.05 was accepted as statistically significant.

Differences between the VAS levels at each follow-up time point was analyzed using the Kruskal-Wallis test with Bonferroni correction. A non-parametric multiple comparison test was used to determine which groups were contributing a significant difference. A p<0.01 was accepted as statistically significant for Bonferroni correction.

Differences between the VAS levels of each group at different time points were tested using the Wilcoxon signed-rank test with Bonferroni correction. A p-value <0.0017 was accepted as statistically significant for Bonferroni correction.

Results

A total of 30 patients were enrolled in the present study, including 10 control group patients with a mean age of 45.4±10.7 years who were administered diclofenac sodium IM, 10 patients with a mean age of 45.8±8.6 years who were administered levobupivacaine via a catheter placed intraoperatively, and 10 patients with a mean age of 44.9±11.5 years in whom a spongostan impregnated with levobupivacaine was placed on the preperitoneal area intraoperatively. None of the enrolled subjects had any complications during or after the procedure. All procedures were performed using the laparoscopic approach. In Group 1, one patient had hypertension, and one patient had hypertension and asthma. In Group 2, two patients had hypertension, and one patient had diabetes mellitus. In Group 3, one patient had cataract, two patients had diabetes mellitus, and one patient had hypertension (Table 1). There were no significant differences between the groups with respect to age and comorbidities. There were no significant differences between the groups with respect to hernia types (Table 2).

According to Bonferroni correction, the VAS levels at different time points were not significantly different within each group (p>0.0017) (Tables 3-5).

Group 1 had significantly lower pain severity than Group 3 at 0, 6, and 18 h (p<0.001). Although Group 1 had lower pain severity than Group 3 at 12 and 24 h, the difference lost statistical significance in Bonferroni correction (p=0.012 and p=0.037, respectively).

Group 2 had significantly lower pain severity than Group 3 at 0, 6, 12, 18, and 24 h (p<0.001).

Group 2 had significantly lower pain severity than Group 1 at 0, 6, 12, 18, and 24 h (p<0.001).

Table 4. VAS levels of the study groups by follow-up time points (Group 2-3)

Variables	Group 2	Group 3	p
0 h	1 (1-3)	4 (4-5)	<0.001
6 h	2 (1-2)	5 (3-6)	<0.001
12 h	1 (1-3)	4 (4-6)	<0.001
18 h	1 (1-2)	5 (4-7)	<0.001
24 h	1 (1-2)	4 (3-5)	<0.001

Group 2: Patient group in which spongostan impregnated with levobupivacaine was placed
Group 3: Patient group in which diclofenac sodium was administered

Table 5. VAS levels of the study groups by follow-up time points (Group 1-2)

Variables	Group 1	Group 2	p
0 h	3 (2-4)	1 (1-3)	<0.001
6 h	4 (3-5)	2 (1-2)	<0.001
12 h	3.5 (3-5)	1 (1-3)	<0.001
18 h	3 (3-5)	1 (1-2)	<0.001
24 h	3 (2-5)	1 (1-2)	<0.001

Group 1: Patient group in which levobupivacaine was administered via a catheter
Group 2: Patient group in which spongostan impregnated with levobupivacaine was placed

Discussion

Today, inguinal hernia repair continues to be one of the most commonly performed procedures by general surgeons. Complications, such as bleeding, recurrence, pseudorecurrence, orchitis, organ injuries, wound infection, seroma, osteitis pubis, and pain, may occur after both open and laparoscopic hernia repair. Pain, one of the chief problems after hernia surgery, may occur early after surgery or persists chronically (5, 6). As it is a subjective symptom, previous studies have provided a wide range of figures and descriptions for its prevalence, quality, and severity. Recent studies have shown that the incidence of postoperative pain ranges between 0% and 53% (7). In addition to analgesic medications administered via IM, intravenous, oral, or rectal route, many different treatment methods to relieve early postoperative pain after inguinal hernia repair have been described (8-15).

LeBlanc et al. (16) investigated the effect of postoperative local anesthetic infusion on pain severity in patients undergoing unilateral tension-free open hernia repair. Their study involved 52 patients in whom a catheter was placed between the patch and the fascia, and bupivacaine was infused for 48 h after hernia repair with a standard prolene patch; pain severity was rated with the aid of the VAS at the postoperative period. The other group was administered isotonic solution infusion. Local anesthetic infusion significantly lowered pain severity and reduced the need for analgesic drugs.

Similar to our study, Suvikapakornkul et al. (17) explored the efficacy of preperitoneal bupivacaine for pain control after laparoscopic inguinal hernia repair. Similarly, they excluded patients with bleeding diathesis, an ASA III risk group, cardiac or respiratory disorders precluding general anesthesia, drug or alcohol addiction, history of surgery to the Retzius space, or morbid obesity. They randomized 40 patients into two groups to receive either bupivacaine or isotonic solution after a TEP procedure performed by a single surgeon. After placing one 12 mm and two 5 mm trocars and performing dissections, they placed a 15×12 or 15×15 cm patch on the operative field and fixated it with an endotucker. Then, they administered a single dose of 40 ml bupivacaine or isotonic saline to the preperitoneal area and monitored patients using the VAS for 24 h postoperatively. Similar to our results, they found lower postoperative pain scores in the intervention group than in the control group, with borderline significant difference. However, they found no significant difference between the groups with respect to analgesic requirement at the postoperative period. Our study also revealed a lower postoperative pain severity in patients who were administered local anesthesia via a catheter than in the control group. In contrast to the study by Suvikapakornkul et al. (17), our study used a local anesthetic administered via a catheter as intermittent infusions during postoperative monitoring. Group 1 and Group 3 had significantly different results at 1, 6, and 18 h but not at 12 and 24 h.

O'Riordain et al. (18) enrolled 56 male patients with a mean age of 48 years into two groups: one was randomized to receive bupivacaine (0.25%, 40 ml) and adrenaline mixture (n=29) and the other isotonic solution (n=27). Indirect hernia was diagnosed in 40 patients, direct hernia in 13, and trousers hernia in 1. All patients were applied the TEP procedure, and no stapler was used for patch fixation. A 40 ml bupivacaine or isotonic solution was applied to the preperitoneal area. Patients were discharged at 6 h after surgery at the latest, and they were re-evaluated for pain at 1, 7, and 30 days. The bupivacaine group had a significantly lower mean pain severity at 24 h than the isotonic solution group. Additionally, analgesic need was eliminated earlier, and time to return to activities was shortened with bupivacaine. In conclusion, their study stressed the superior efficacy of local anesthesia for adequate pain control.

With the advances of hernia repair techniques and reduced rates of recurrences and other complications, pain has currently become one of the main problems after hernia repair (14,16-18). Previous studies with local anesthesia have suggested that the two most important factors related to adequate pain control are a better local anesthetic diffusion into the operative field and a longer duration of action at a greater dose (16, 19). The first studies using local anesthetic applications to control pain after hernia repair used direct applications of these agents to the operative field, whereas later studies aimed to diffuse the anesthetic agent into the whole operative field with the aid of a catheter (20). This was followed by studies where the anesthetic agent was administered intermittently or as a continuous infusion via a catheter placed intraoperatively, in an attempt to preserve its efficacy for longer periods (16). In an arm of our study, we administered the local anesthetic agent as intermittent infusions via a catheter placed intraoperatively.

Several studies have emphasized the importance of local anesthetic agents acting longer at a more effective dose in the operative field. Several studies used adrenaline, which is reported to prolong diffusion time and, thereby, to reduce toxic effects, to achieve that goal in addition to intermittent or continuous local anesthetic in-

fusion via a catheter (19, 21). We believe that the duration of action of the local anesthetic agent was longer with spongostan used in our study. Placed in a sliced form in a way to cover the entire retroperitoneal area, as well as some anatomic structures that may be well associated with pain, such as spermatic cord and nervous structures, spongostan increased the duration of action and the efficacy of the local anesthetic agent.

The pain score of Group 1 was lower than that of the control group for 24 h. However, local anesthetic treatment administered via a catheter was not associated with a significant benefit at all time points; the difference between pain levels was significant at 0, 6, and 18 h ($p<0.001$) but not at 12 ($p=0.012$) and 24 h ($p=0.037$). Our clinical observations also indicated that levobupivacaine administered via catheter did not provide adequate control of early postoperative pain. Suvikapakornkul et al. (17) also reported that this treatment method reduces pain scores, although at a borderline significance. In their study, the intervention and control groups did not differ significantly with regard to analgesic requirement. Whereas some studies in the medical literature have reported that local anesthetics infused via a catheter are effective for pain control (22), other studies have suggested otherwise (19, 20). We think that local anesthetics administered postoperatively via a catheter were ineffective for pain control at the early postoperative period.

Spongostan, a protein-based, absorbable, hemostatic gelatin sponge, is primarily used to control bleeding in the clinical practice, although it can also be utilized for other purposes. Having the ability to absorb up to 45 times its own weight, spongostan, impregnated with chemotherapeutic, analgesic, and antibiotic medications, has been used in a number of studies (23-26). Ferroli et al. (24) placed spongostan impregnated with mitoxantrone on the operative field following resection of glioblastoma multiforme. Ragusa et al. (25) obtained a higher drug concentration and longer duration of action on the wound surface with spongostan impregnated with an antibiotic than systemic therapy. Kafalı et al. (26) investigated the efficacy of spongostan impregnated with bupivacaine for pain control after episiotomy. They applied lignocaine to episiotomy line in the first group and spongostan impregnated with bupivacaine in conjunction with lignocaine in the second. A total of 110 patients were enrolled in their study, where pain control was rated by the VAS at 0, 1, 1.5, 2, 6, and 24 h postoperatively. They demonstrated that bupivacaine significantly reduces postpartum pain and analgesic requirement. They attributed these results to a significantly prolonged duration of action and increased concentration of the anesthetic agent in the operative field. Similarly, our study demonstrated that spongostan impregnated with a local anesthetic agent was efficacious for pain management. In agreement with Kafalı et al. (26), we suggest that this method increased the duration of action and efficacy of the analgesic treatment.

We found significantly lower pain scores in Group 2 than in Group 3 (control group) ($p<0.001$). In addition, Group 2 demonstrated significantly lower pain levels than Group 1 ($p<0.001$). Although spongostan has been reported to have various clinical uses, it has not been used yet for analgesia in hernia surgery. In this sense, to the best of our knowledge, this is the first study in the medical literature demonstrating the efficacy of this method. We suggest that pain severity was lower in the spongostan group as a result of a longer local anesthetic diffusion time and a longer, high-concentration contact between the local anesthetic agent and peritoneum, spermatic cord, and nervous structures, which are traditionally considered as a source of postoperative pain. We think that the technique of the application of spongostan impregnated with levobupivacaine on the preperitoneal area may effectively reduce early postoperative pain (Figure 3). A reduced early postoperative pain would in turn lead to a lower risk of chronic pain after laparoscopic hernia repair.

Conclusion

We believe that postoperative intermittent levobupivacaine hydrochloride treatment administered via a catheter was not adequate enough for pain control despite reducing early postoperative pain to some extent. The application of spongostan impregnated with levobupivacaine hydrochloride to the preperitoneal area was significantly more effective on early postoperative pain than the application of diclofenac sodium and intermittent levobupivacaine administration via a catheter. We think that this yet untested method is an effective means for reducing early postoperative pain.

Ethics Committee Approval: Authors declared that the research was conducted according to the principles of the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", (amended in October 2013).

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - M.Ş., M.T.K.; Design - M.Ş., M.T.K.; Supervision - M.Ş., Ö.S., A.İ.; Resources - M.T.K., M.G.; Materials - M.Ş., M.T.K., Ö.S., M.G.; Data Collection and/or Processing - M.Ş., Ö.S., M.G. .; Analysis and/or Interpretation - M.Ş., M.T.K.,A.İ.; Literature Search - M.Ş., M.T.X.; Writing Manuscript - M.Ş., M.T.K.; Critical Review - M.T.K., A.İ.

Conflict of Interest: The authors have no conflict of interest to declare.

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

Etik Komite Onayı: Yazarlar çalışmanın World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", (amended in October 2013) prensiplerine uygun olarak yapıldığını beyan etmişlerdir.

Hasta Onamı: Yazılı hasta onamı çalışmaya katılan hastalardan alınmıştır.

Hakem Değerlendirmesi: Dış bağımsız.

Yazar Katkıları: Fikir - M.Ş., M.T.K.; Tasarım - M.Ş., M.T.K.; Denetleme - M.Ş., Ö.S., A.İ.; Kaynaklar - M.T.K., M.G.; Malzemeler - M.Ş., M.T.K., Ö.S., M.G.; Veri Toplanması ve/veya İşlemesi - M.Ş., Ö.S., M.G. .; Analiz ve/veya Yorum - M.Ş., M.T.K.,A.İ.; Literatür Taraması - M.Ş., M.T.X.; Yazıyı Yazan - M.Ş., M.T.K.; Eleştirel İnceleme - M.T.K., A.İ.

Çıkar Çatışması: Yazarlarların beyan edecek çıkar çatışması yoktur.

Finansal Destek: Yazarlar bu çalışma için finansal destek almadıklarını beyan etmişlerdir.

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Cite this article as: Şişman M, Kafadar MT, Sürgit Ö, Gözdemir M, İnan A. Early -Term Pain Management After Laparoscopic Total Extraperitoneal Inguinal Hernia Repair. İstanbul Med J 2018; 19 (4): 289-94.