Int J Clin Exp Med 2015;8(11):21611-21616
www.ijcem.com /ISSN:1940-5901/IJCEM0013624

Original Article

Prospective randomized trial of mesh fixation with absorbable versus nonabsorbable tacker in laparoscopic ventral incisional hernia repair

Elif Colak, Nuraydin Ozlem, Gultekin Ozan Kucuk, Recep Aktimur, Sadik Kesmer, Kadir Yildirim

Department of General Surgery, Samsun Training and Research Hospital, Samsun, Turkey

Received July 29, 2015; Accepted October 31, 2015; Epub November 15, 2015; Published November 30, 2015

Abstract: The aim of this prospective randomized trial was to compare 2 main fixation devices in regard to pain and recurrence in laparoscopic ventral incisional hernia repair (LVIHR). A total of 51 patients were evaluated in this study (n = 25, nonabsorbable tack (NAT) and n = 26, absorbable tack (AT) groups). A visual analogue scale (VAS) was performed on both groups preoperatively and on the postoperative (PO) first day, second week, and sixth month. All patients were followed for recurrence by clinical examination, ultrasonography, and/or abdominal computed tomography. The median follow-up time was 31 months (15-45). The mean age and the mean body mass index (BMI) of the patients were 53.1 ± 11 years and 34 ± 5 kg/m^2, respectively. The median defect size was 60 cm^2 (35-150) and median operation time was 110 minutes (40-360). In 2 patients from AT group and 2 from NAT group (7.8%), recurrence occurred. The 2 groups had similar features regarding demographics, operation time, postoperative hospital stay, morbidity, and VAS scores. The 2 fixation methods were found similar for PO pain and recurrence. In our opinion, the choice of either of these fixation methods during surgery should not be based on the concerns of pain or recurrence. AT may be the preferable option in LVIHR due to the lower cost.

Keywords: Laparoscopic ventral hernia repair, mesh fixation, pain

Introduction

The laparoscopic technique offers a variety of advantages over conventional open surgery in repairing ventral hernias, such as shorter recovery time and lower recurrence and wound complication rates [1-3]. Despite these advantages, patients who undergo laparoscopic ventral incisional hernia repair (LVIHR) tend to have more pain in the early postoperative period than after any other minimally invasive operations [4, 5]. The occurrence of postoperative pain in these patients has been ascribed to commonly used mesh fixation methods, transfascial sutures (TS), and metal fixation devices [6, 7]. For this reason alternative fixation methods, such as fibrin sealant and nonmetallic absorbable fixation devices, were developed, and they were compared in a variety of studies [8-10]. However, the comparison of nonabsorbable tack (NAT) and absorbable tack (AT) mesh fixation techniques regarding pain and recurrence has not been established by randomized clinical trials. In this prospective randomized clinical trial, we aimed to investigate whether pain and recurrence after LVIHR varied according to use of these 2 fixation devices.

Patients and methods

Patients

The protocol for this study was approved by the local ethics committee of Samsun Training and Research Hospital. Patients who were treated for midline incisional ventral hernia between December 2010 and June 2014 were considered for enrollment in the study. Patients who required urgent surgery were excluded. The other exclusion criteria were conversion to open surgery and contraindication for general anesthesia induction. All patients who enrolled in the trial provided an informed consent form. The American Society of Anesthesiologists (ASA) scores and visual analogue scale (VAS; range 0-10) scores were evaluated 1 day prior

to the surgery (VASP). Also, the scores on the PO first day (VAS1), second week (VAS2), and sixth month (VAS3) were recorded.

Procedures

Two staff surgeons of our clinic performed the operations. A pneumoperitoneum was produced by using a Veress needle in the left subcostal area. Three trocars were used. One 10-mm trocar was placed as laterally as possible on the abdominal wall to obtain adequate distance from the hernia orifice. A 30° endoscope was inserted through this 10-mm trocar. Other trocars (5 mm) were inserted under direct visualization. The abdominal wall defects were freed from peritoneal and visceral adhesions by using electrosurgical dissection or a harmonic scalpel (Ultracision, Ethicon Endosurgery, Johnson & Johnson, Cincinnati, OH, USA). When necessary, adhesiolysis was performed. The hernia was exposed, and the surrounding anterior abdominal wall was prepared for mesh placement. A large-pore composite mesh (PhysioMesh; Ethicon, Johnson & Johnson Company, Germany) was used in all patients. The mesh was tailored to overlap all hernia margins, extending by at least 5 cm. The method of mesh fixation for each patient was determined by means of computerized random generation of a number just before the operation. The number was given to the surgeon, and the mesh fixation technique previously assigned to that number was used. Patients were randomly assigned to the NAT and AT mesh-fixation groups.

In the NAT group, titanium helical tacks (ProTack; TycoUSS, Norwalk, CT, USA) were placed approximately 5 mm inside the edge of the mesh along its entire perimeter, about 1.5-2.0 cm apart. In the AT group, the mesh fixation was provided by absorbable tack (AbsorbaTack; Covidien, Mansfield, MA, USA). After fixation of the mesh, the trocars were removed, and the 10-mm fascial defects were closed. Patients' operative characteristics were recorded after the operations.

All patients received standard PO care, including mobilization and return to normal diet as quickly as possible. A patient-controlled analgesia (contramal 100 mg) was provided for the first 24 hours after surgery. A nonsteroidal anti-inflammatory agent (diclofenac 25 mg, intramuscular, 2 times daily) was provided until discharge from the hospital.

Follow-up

All patients were scheduled to return for an outpatient visit in the second week and every sixth month after the surgery. The primary outcome measure in the study was the presence and severity of PO pain, as determined by VAS score, which was obtained during the outpatient visits (VAS2 and VAS3). Also, recurrence of the hernia was evaluated by clinical examination, ultrasonography, or abdominal computed tomography every 6 months. Any wound seromas or hematomas were considered PO complications when they limited daily activities or required drainage.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics version 20.0 (SPSS Inc., Chicago, IL, USA, 2011) for Windows. Results were compared by Student *t* test or Mann-Whitney *U* test for continuous variables, and chi-square or Fisher exact tests were used for categorical variables. A P value <0.05 was considered to represent statistical significance.

Results

Fifty-one patients (NAT group, n = 25 and AT group, n = 26) were enrolled in the study, 32 female (62.7%) and 19 male (37.3%). The mean age was 53.1 ± 11 years. The mean BMI was 34 ± 5 kg/m^2. The median defect size was 60 cm^2 (range 35-150).

The 2 groups had similar features regarding the patients' demographics, BMIs, ASA scores, comorbidities, hernia size, number of previous surgeries, operation times, PO hospital stay, morbidity, and VASP, VAS1, VAS2, and VAS3 scores (**Tables 1**, **2**). The median operation time was 110 minutes (40-360). Serious perioperative complication was not seen in either group. PO complications are presented in **Table 3**. The median PO hospital stay was 2 days (1-8).

The median follow-up time was 31 months (15-45). In 2 patients from AT group and 2 from NAT group (7.8%), recurrence occurred. The mean VAS3 score was found to be higher in these patients (3 ± 0.8 vs 0.6 ± 0.8, P = 0.001). Other

Table 1. Patient demographic and hernia charecteristics, according to mesh fixation group

Characteristics	Mesh fixation group		Overall (n = 51)	*P* values
	NAT (n = 25)	AT (n = 26)		
Mean (± SD) age in years	56.1 (11.8)	50.7 (9.9)	53.1 (11)	0.110Χ
Sex: F/M	15/10	17/9	32/19	0.537 Γ
Mean (± SD) BMI (kg/m^2)	35.4 (5.1)	32.9 (4.6)	34 (5)	0.102Χ
ASA class (no. of patients)				0.685 Γ
1	5	3	8	
2	15	16	31	
3	5	7	12	
Hernia size (cm^2)	62.9 (22.4)	67 (23.1)	65 (22)	0.624Χ
Number of prior abdominal surgery (no. of patient)				0.559 Γ
1	11	10	21	
2	12	13	25	
3	2	1	3	
4	1	1	2	
Co-morbidity (no of patients)				0. 881 Γ
Absent	7	9	16	
Diabetes	6	7	13	
Hypertension	3	6	9	
Asthma	4	6	10	
CAD	2	1	3	
Recurrent hernia (% of patients)	8	7.6	7.8	0.685 Γ

ASA American Society of Anesthesiologists, *BMI* body mass index, *NAT* nonabsorbable tack, *AT* absorbable tack, *CAD* coronary artery disease. ΧDifferences between groups were determined by two tailed Student's t-tests. Γ Differences between groups were determined by Chi-square test.

factors were not found to be related to the recurrence of the hernias. One patient in the NAT group was readmitted to the hospital with an enterocutaneous fistula due to mesh migration into the small bowel. The patient was treated with mesh extraction and segmental small bowel resection in the PO third month. There was no mortality in the study groups during follow-up.

Regarding the cost effectiveness, the additional charges of the tacks to the total operation costs were US $190 and US $325 for ATs and NATs, respectively.

Discussion

Pain remains a relevant complaint during the early PO period, leading to the increased consumption of pain medications, delayed bowel function, and extended hospital stays. The incidence of chronic pain after laparoscopic incisional hernia repair has been reported to be approximately 1% to 3% [11]. PO pain after laparoscopic ventral hernia repair was investigated in a variety of studies [4, 5, 7]. Most of these studies focused on the association between mesh fixation devices and PO pain. The mesh fixation technique has been one of the most controversially discussed topics in LVIHR since the introduction of laparoscopic surgery was described by LeBlanc and Booth in 1993 [12]. LeBlanc used transfacial suture (TS) and titanium tack together in the operations. However, over time, chronic pain of the patients after LVIHR caused new searches for fixation methods. The majority of reports describe the use of TS or tack fixation [13, 14]. These studies reported no difference between using only TS or tack for pain and recurrence. Subsequently, fibrin sealants and absorbable tacks were used by some researchers [10, 15, 16]. Although absorbable fixation devices have been developed to achieve a sufficient tensile fixation strength with acceptable PO pain compared to conventional nonabsorbable devices, their effectivity has not been confirmed by randomized controlled clinical trials. In this first prospective randomized trial, we have found no

Table 2. Operative and postoperative characteristics and VAS scores, according to mesh fixation group*

	Mesh fixation group		*p*-Value
	NAT	AT	
VASP	0.5 (0.6)	0.5 (0.7)	0.872X
VAS1	3 (1.1)	3 (1)	0.778 Γ
VAS2	1.1 (0.8)	1.5 (0.7)	0.204X
VAS3	0.6 (1)	1.1 (1.1)	0.079X
Postoperative stay (days)	2.5 (1.7)	2.1 (1.1)	0.312X
Operating time (min)	122 (50)	124 (58)	0.740 Γ

VAS visual analogue scale (0-10), *VASP* preoperative prior day, *VAS1* postoperative first day, *VAS 2* postoperative second week, *VAS3* postoperative sixth month, *NAT* nonabsorbable tack, *AS* absorbable tack. *Values are mean (± SD). XDifferences between groups were determined by Mann Whitney *U* test. Γ Differences between groups were determined by two tailed Student's t-tests.

Table 3. Complications of surgery, according to mesh fixation groups

Complications	Mesh fixation group		No% of all patients
	NAT	AT	
Seroma	5	4	9 (17.6)
Hematoma	1	1	2 (3.9)
Prolonged ileus	-	1	1 (1.9)
Trocar hernia	1	1	2 (3.9)
Cellulitis	2	3	5 (9.8)
Hernia recurrence	2	2	4 (7.8)
Mesh migration	1	-	1 (1.9)

NAT nonabsorbable tack, *AS* absorbable tack.

significant difference between absorbable and nonabsorbable fixation devices in LVIHR regarding PO pain and recurrence.

To date, several studies have confirmed the efficacy of tack-only fixation. Carbajo et al [17] reported a very low recurrence rate (4.4%) with this technique. Kitamura et al [13] reported the data of 83 patients: 33 in the suture group and 53 in the tack group. Hernia recurrence occurred in 3 patients in the suture group, while in 2 patients in the tack group ($P > .05$). In the International Endohernia Society (IEHS) Guidelines, which evaluated the outcomes of 5884 patients in 23 studies, a cumulative recurrence rate of 3.95% for all 3 (sutures + tacks, sutures only, and tacks only) groups was reported during a median follow-up period of 35.5 months. The recurrence rates for the groups were as follows: 3.65% (range 2.45%-5.75%) for the suture and tacks fixation group comprising 2211 patients, 1.05% (0.82%-1.27%) for the sutures-only fixation comprising 1121 patients, and 4.5% (2.4%-6.17%) for the tacks-only fixation group comprising 2473 patients. The 3 groups did not differ significantly in terms of recurrence rates or follow-up periods [18].

To provide reliable mesh fixation with acceptable PO pain, alternative mesh fixation techniques were studied. Fibrin sealant fixation has been investigated in numerous studies, with a special intention toward pain reduction. Some of these studies suggested that this technique is safe and feasible, while others reported higher recurrence rates than the other methods, especially in larger hernia defects [8, 9, 19, 20]. In a systematic review, Fortelny et al [8] reported that fibrin glue or fibrin sealant was associated with less acute and chronic PO pain than tissue-penetrating mesh fixation methods. Despite the proven effectivity and lower recurrence rates of mesh fixation with tacks, the quality of life outcomes of the studies are conflicting. Nguyen et al [14] showed no significant difference at PO 1 week, 1 month, and 2 months regarding pain assessment in suture (n = 29) and tack (n = 21) groups. Bansal et al [21] randomized 68 patients into nonabsorbable suture (n = 32) and tack (n = 36) groups. Tack fixation resulted in significantly higher pain scores than suture fixation at 1, 6, and 24 hours and also at 1 week and 3 months postoperatively. They reported no significant difference in the incidence of chronic pain and seroma development in the follow-up of 32.2 months. In a randomized controlled trial that compared methods for securing the mesh during LVIHR, the absorbable sutures with tacks (n = 56), double crown (n = 60), and nonabsorbable sutures with tacks (n = 56) techniques were associated with similar PO pain and quality-of-life findings [22].

Eriksen et al. reported the results of 40 patients who were assigned randomly into 2 groups: fibrin sealant fixation (n = 20) and titanium tacks fixation (n = 20). The assessment of acute pain (PO 0-2 days) by VAS showed significantly less pain in the fibrin sealant group than in the tack group at rest (19 vs 47 mm, $P = .025$) and during activity (38 vs 60 mm, $P = 0.014$) [9].

Reabsorbable tacks, which are a newer alternative method for mesh fixation in LVIHR, have been available for some years. Leper et al [10] have published one prospective multicenter trial investigating these devices. They performed all mesh fixation with I Clip, and pain level was assessed with VAS. At PO 1 month, 90% of patients (90/100) were totally pain free, and only 10 patients reported a mild pain. No mesh sepsis or recurrence was observed. Hollinsky et al [23] presented an experimental study and compared I Clip (Covidien Corp., Mansfield, MA, USA), Pro Tack (TycoUSS, Norwalk, CT, USA), AbsorbaTack (Covidien, Mansfield, MA, USA), and transfascial sutures. After 2 months, the retention strength of transfascial sutures was significantly higher (13.2 N/cm^2) than that of ProTack (9.7 N/cm^2) or AbsorbaTack (8.7 N/cm^2). But these studies are not clinical trials. Guidelines of EAES (European Association for Endoscopic Surgery and other interventional techniques) and the EHS (European Hernia Society) reported that, at present, there are no adequate clinical studies about the use of absorbable devices, and they could not make any recommendation [24]. Therefore, we believe that this study will contribute to the literature. In the study, we have found a 7.8% recurrence rate in 51 patients during our median follow-up period of 31 months (15-45). In 2 patients from both the AT and NAT groups, hernias recurred. One patient in the NAT group was readmitted to the hospital with an enterocutaneous fistula due to mesh migration into the small bowel. This patient was treated with mesh extraction and segmental small bowel resection in the PO third month. In this case, whether it was due to mesh erosion or bowel adhesion to tacks could not be determined. The patients who experienced recurrence had a larger defect size (76 vs 60 cm^2) than the others. Two of these patients had chronic obstructive pulmonary disease. The PO first day, second week, and sixth month VAS scores were found to be similar in both groups, with an exception in recurred patients. In these patients, the PO sixth month VAS scores were found to be significantly higher than the others. Permanent pain after the operation may be a presenting symptom of recurrence after LVIHR.

This study is not without limitations. Mainly, the number of patients is low. Another limitation of the study is the absence of quality-of-life assessment. Despite these limitations, we believe that this first randomized clinical trial provides beneficial information about the choice of absorbable and nonabsorbable tacks in LVIHR.

Finally, the most obvious advantage of ATs is to have lower cost than NATs. In Turkey the additional charges of ATs and NATs are US $190 and US $325 for each LVIHR procedure, respectively. ATs have a cost nearly 2 times smaller than NATs.

In conclusion, we have found no significant differences between the 2 fixation techniques regarding recurrence, complications, and PO pain. ATs may be a preferable option due to lower cost in LVIHR. In our opinion, the choice of either of these fixation methods during surgery should not be based on the concerns of pain or recurrence.

Disclosure of conflict of interest

None.

Address correspondence to: Dr. Elif Colak, Department of General Surgery, Samsun Training and Research Hospital, Fevzicakmak mh., Altinyunus sk., No. 18, Mira sitesi, A/21, Ilkadim, Samsun, Turkey. Tel: +905323754163; Fax: +90362277-8865; E-mail: elifmangancolak@hotmail.com

References

[1] Aher CV, Kubasiak JC, Daly SC, Janssen I, Deziel DJ, Millikan KW, Myers JA and Luu MB. The utilization of laparoscopy in ventral hernia repair: an update of outcomes analysis using ACS-NSQIP data. Surg Endosc 2015; 29: 1099-1104.

[2] Zhang Y, Zhou H, Chai Y, Cao C, Jin K and Hu Z. Laparoscopic versus open incisional and ventral hernia repair: a systematic review and meta-analysis. World J Surg 2014; 38: 2233-2240.

[3] Pham CT, Perera CL, Watkin DS and Maddern GJ. Laparoscopic ventral hernia repair: a systematic review. Surg Endosc 2009; 23: 4-15.

[4] Eriksen JR, Poornoroozy P, Jørgensen LN, Jacobsen B, Friis-Andersen HU and Rosenberg J. Pain, quality of life and recovery after laparoscopic ventral hernia repair. Hernia 2009; 13: 13-21.

[5] Colavita PD, Tsirline VB, Belyansky I, Walters AL, Lincourt AE, Sing RF and Heniford BT. Prospective, long-term comparison of quality of life in laparoscopic versus open ventral hernia repair. Ann Surg 2012; 256: 714-722.

[6] LeBlanc KA. Laparoscopic incisional and ventral hernia repair: complications-how to avoid and handle. Hernia 2004; 8: 323-331.
[7] Eriksen JR. Pain and convalescence following laparoscopic ventral hernia repair. Dan Med Bull 2011; 58: B4369.
[8] Fortelny RH, Petter-Puchner AH, Glaser KS and Redl H. Use of fibrin sealant (Tisseel/Tissucol) in hernia repair: a systematic review. Surg Endosc 2012; 26: 1803-1812.
[9] Eriksen JR, Bisgaard T, Assaadzadeh S, Jorgensen LN and Rosenberg J. Fibrin sealant for mesh fixation in laparoscopic umbilical hernia repair: 1-year results of a randomized controlled double-blinded study. Hernia 2013; 17: 511-514.
[10] Lepere M, Benchetrit S, Bertrand JC, Chalbet JY, Combier JP, Detruit B, Herbault G, Jarsaillon P, Lagoutte J, Levard H and Rignier P. Laparoscopic resorbable mesh fixation. Assessment of an innovative disposable instrument delivering resorbable fixation devices: I-Clip(TM). Final results of a prospective multicentre clinical trial. Hernia 2008; 12: 177-183.
[11] Jenkins ED, Yom V, Melman L, Brunt LM, Eagon JC, Frisella MM and Matthews BD. Prospective evaluation of adhesion characteristics to intraperitoneal mesh and adhesiolysis-related complications during laparoscopic re-exploration after prior ventral hernia repair. Surg Endosc 2010; 24: 3002-3007.
[12] LeBlanc KA and Booth WV. Laparoscopic repair of incisional abdominal hernias using expanded polytetrafluoroethylene: preliminary findings. Surg Laparosc Endosc 1993; 3: 39-41.
[13] Kitamura RK, Choi J, Lynn E and Divino CM. Suture versus tack fixation of mesh in laparoscopic umbilical hernia repair. JSLS 2013; 17: 560-564.
[14] Nguyen SQ, Divino CM, Buch KE, Schnur J, Weber KJ, Katz LB, Reiner MA, Aldoroty RA and Herron DM. Postoperative pain after laparoscopic ventral hernia repair: a prospective comparison of sutures versus tacks. JSLS 2008; 12: 113-116.
[15] Olmi S, Scaini A, Erba L and Croce E. Use of fibrin glue (Tissucol) in laparoscopic repair of abdominal wall defects: preliminary experience. Surg Endosc 2007; 21: 409-413.
[16] Eriksen JR, Bech JI, Linnemann D and Rosenberg J. Laparoscopic intraperitoneal mesh fixation with fibrin sealant (Tisseel) vs. titanium tacks: a randomised controlled experimental study in pigs. Hernia 2008; 12: 483-491.
[17] Carbajo MA, Martp del Olmo JC, Blanco JI, Toledano M, de la Cuesta C, Ferreras C and Vaquero C. Laparoscopic approach to incisional hernia. Surg Endosc 2003; 17: 118-122.
[18] Bittner R, Bingener-Casey J, Dietz U, Fabian M, Ferzli GS, Fortelny RH, Köckerling F, Kukleta J, Leblanc K, Lomanto D, Misra MC, Bansal VK, Morales-Conde S, Ramshaw B, Reinpold W, Rim S, Rohr M, Schrittwieser R, Simon T, Smietanski M, Stechemesser B, Timoney M and Chowbey P; International EndoherniaSociety (IEHS). Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society (IEHS)-part 1. Surg Endosc 2014; 28: 2-29.
[19] Morales-Conde S, Suárez-Artacho G, Socas M and Barranco A. Influence of fibrin sealant in preventing postoperative seroma and normalizing the abdominal wall after laparoscopic repair of ventral hernia. Surg Endosc 2013; 27: 3214-3219.
[20] Melman L, Jenkins ED, Deeken CR, Brodt MD, Brown SR, Brunt LM, Eagon JC, Frisella M and Matthews BD. Evaluation of acute fixation strength for mechanical tacking devices and fibrin sealant versus polypropylene suture for laparoscopic ventral hernia repair. Surg Innov 2010; 17: 285-290.
[21] Bansal VK, Misra MC, Babu D, Singhal P, Rao K, Sagar R, Kumar S, Rajeshwari S and Rewari V. Comparison of long-term outcome and quality of life after laparoscopic repair of incisional and ventral hernias with suture fixation with and without tacks: a prospective, randomized, controlled study. Surg Endosc 2012; 26: 3476-3485.
[22] Wassenaar E, Schoenmaeckers E, Raymakers J, van der Palen J and Rakic S. Mesh-fixation method and pain and quality of life after laparoscopic ventral or incisional hernia repair: a randomized trial of three fixation techniques. Surg Endosc 2010; 24: 1296-1302.
[23] Hollinsky C, Kolbe T, Walter I, Joachim A, Sandberg S, Koch T, Rülicke T and Tuchmann A. Tensile strength and adhesion formation of mesh fixation systems used in laparoscopic incisional hernia repair. Surg Endosc 2010; 24: 1318-1324.
[24] Silecchia G, Campanile FC, Sanchez L, Ceccarelli G, Antinori A, Ansaloni L, Olmi S, Ferrari GC, Cuccurullo D, Baccari P, Agresta F, Vettoretto N and Piccoli M. Laparoscopic ventral/incisional hernia repair: updated guidelines from the EAES and EHS endorsed Consensus Development Conference. Surg Endosc 2015; 29: 2463-2484.