Nonfixation of Mesh In Laparoscopic Totally Extraperitoneal Inguinal Hernia Repair: A Single-Center Experience

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Research Article

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Abstract

Background: In terms of the need for mesh fixation in total extraperitoneal inguinal hernia repair (TEP), overseas data revealed no significant difference in the recurrence rate between patients with and without fixation. Moreover, there is no information available on this treatment outcome from Japan. We aimed to analyze the outcomes of nonfixation TEP with those of fixation at our institute.

Methods: In May 2016, the nonfixation TEP technique was launched. The fixation group (165 patients) was compared to the nonfixation group (195 patients). Bilateral, large, and impaction cases were eliminated from the corrective comparison, and the outcomes for the fixation group (80 patients) and the non-fixation group (111 patients) were compared.

Results: One patient in the nonfixation group experienced recurrence. It was a hernia case with a large orifice. In the fixation group, seroma was more prevalent. There was no recurrence and no significance in surgical complications in the correction comparison. The nonfixation group had a shorter operation time and stayed in the hospital for a shorter period after surgery.

Conclusions: The nonfixation TEP was deemed adequate, at least for typical hernia cases.

Introduction

Every year, about 350000 inguinal hernia operations are performed in Japan. In Japan, half of them are done endoscopically [1]. Total extraperitoneal inguinal hernia repair is one of the laparoscopic techniques (TEP). TEP, which includes entering the hernia site through the preperitoneal plane rather than peritoneal cavity, may reduce the occurrence of postoperative complications [2]. As a result, in our facility, TEP is the treatment of choice for inguinal hernia. In Japan, the recurrence rate after TEP was estimated to be approximately 2%, attributable entirely to mesh migration [1]. According to the original description of the TEP method, most surgeons in Japan attach the mesh to the abdominal wall with a tack. Mesh fixation is necessary for inguinal hernia surgery to avoid mesh migration, which can lead to recurrence. In contrast, fixing the mesh is suggested to enhance postoperative pain and the risk of nerve injury. Estimates suggest that nerve injury occurs in 2–4% of laparoscopic inguinal hernia surgeries [3]. Mesh fixation should be eliminated if there is no increase in recurrence without it. Several randomized controlled trials (RCTs), meta-analyses, and systematic reviews have recently demonstrated that the nonfixation of mesh in TEP does not increase recurrences [4–14]. However, no treatment outcomes have been reported from Japan. This is because many Japanese surgeons do not consider not repairing the mesh, or if they do, they are unwilling to incur risks. Nonfixation of mesh in TEP (nonfixation TEP) was adopted at our institution in June 2016. In this study, we evaluated our clinical practice experience to compare the surgical results of TEP with and without mesh fixation.

Methods

Patients and methods

A total of 360 patients who underwent TEP for inguinal hernia between April 2014 and December 2019 at the Nakatsu Municipal Hospital were eligible for this study. Patients with femoral hernia or obturator hernia were excluded. In the initial part of the abovementioned period, until May 2016, BARD 3D Max (BD) or Parietex™ Folding Mesh (Medtronic) was mainly used and was fixed routinely with the laparoscopic titanium fixation device (ProTack™, Medtronic). Nonfixation of the mesh in TEP (nonfixation TEP) was introduced in June 2016, and the meshes were unified into SURGIMESH®XD (Aspide Medical, France; Fig. 1). However, the final decision to fix the mesh or not was at the surgeon's discretion. Patients were divided into two groups: the fixation group consisted of patients in whom mesh was fixed (n = 195) and the nonfixation group consisted of patients in whom the mesh was not fixed (n = 165). The classification of inguinal hernias followed the European Hernia Society (EHS) Groin Hernia Classification [15]. In the analysis of normal hernia cases, bilateral hernias, large hernias visually, cases with large hernia orifice (L3 and M3 in EHS), and the impaction cases were excluded. All patients were followed in an outpatient clinic. The patients were examined in the first postoperative month to examine for the presence of any postoperative complication. Our study was approved by the institutional Ethics Committees of the Nakatsu Municipal Hospital (Approved number: NMH2020034) and conducted in accordance with the ethical guidelines of the Declaration of Helsinki. In a non-invasive observational study, Japanese law requires no written informed consent from individual participants (https://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/0000080278.pdf). Therefore, all study protocols are displayed on our institutional website, and the participants were allowed to opt-out.

Surgical procedure

All patients were operated on under general anesthesia. The patients were Injected with 1000 mg Cefazolin intravenously as prophylaxis at the time of starting the surgery. Postoperative antibiotics were not used in this experiment. A 12-mm paraumbilical port was created on the side of the hernia. In bilateral hernias, the port was created on the side of the larger hernia. The rectus muscle was retracted laterally after incising the anterior rectus sheath, and a preperitoneal access was obtained with an extraperitoneal space expansion balloon or without (this was based on the surgeon's preference). Two working 5-mm ports were created in the midline between the umbilicus and pubis. The preperitoneal space was dissected caudally Cooper's ligament and medially beyond the pubic symphysis. The lateral side of the inferior epigastric vessels was dissected to identify the peritoneal edge and secure the mesh placement. Dissection along the peritoneal edge medially was performed to identify the hernia sac. Complete removal of the sac was attempted in all cases, although in the case of adhesions, the sac was divided at the inguinal ring. After treatment of the hernia sac, a rolled mesh was inserted via the 12-mm port. The mesh was then spread in the preperitoneal space to not fold it. The port sites were closed with 4-0PDS. Oral intake was allowed the next day.

Statistical analyses

Chi-square tests and Mann–Whitney U-tests were performed to compare the two groups. Univariate analyses were performed using a logistic regression model. All statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), a graphical user interfaces for R (The R Foundation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of R commander designed to add statistical functions frequently used in biostatistics (http://www.nature.com/bmt/journal/v48/n3/pdf/bmt2012244a.pd). $P < 0.05$ represents a statistically significant difference.

Data availability

Available if requested.

Results

Following the implementation of nonfixation TEP in June 2016, 240 patients underwent TEP at our facility. Nonfixation TEP was done on 165 of them. The mesh was fixed due to bilateral hernias, large hernias, and impaction cases. During the research period, a total of 195 patients underwent TEP with mesh fixation, including cases up to May 2016. Table 1 describes the patient characteristics of the fixation and nonfixation groups. In terms of patient characteristics, there was no difference between the two groups. The great majority of the patients, as expected, were males. In terms of hernia variables (Table 2), the proportion of patients with bilateral hernias in the fixation group was considerably greater than in the nonfixation group (30.3% vs 3.6%, $P < 0.001$). On visual inspection, the fixation group had more patients with big hernias (>7 cm) than the nonfixation group (26.2% vs 12.1%, $P < 0.001$). Shown in Table 3, the mean operating times for unilateral hernia in the nonfixation group were considerably lower than in the fixation group (98.0 ± 36.7 min vs 81.7 ± 30.2 min, $P < 0.001$). Furthermore, the proportion of patients with larger hernia orifices (>3 cm) in the fixation group was considerably larger in the nonfixation group. The fixation group had a lengthier postoperative hospital stay (4.9 ± 2.0 days vs 4.0 ± 2.1 days, $P < 0.001$). In terms of postoperative complications (Table 4), the fixation group had higher complications than the nonfixation group. The incidence of seroma was greater in the fixation group than in the nonfixation group (13.8% vs 6.7%, $P = 0.027$). There were 3 (1.5%) patients in the fixation group and none in the nonfixation group who had persistent groin discomfort. Only one patient in the nonfixation group with a large hernia opening had a recurrence (L3 in EHS classification). Due to the significant bias in the hernia factors between the two groups, only the so-called typical hernia cases were studied, eliminating bilateral hernias, visually bigger cases, impaction cases, and those with large hernia orifices (L3 and M3 in EHS classification). Eighty patients in the fixation group were compared to 111 patients in the nonfixation group (Table 5). Patients in the nonfixation group were older than those in the fixation group (63.5 ± 16.1 years vs 69.0 ± 10.7 years, $P = 0.005$)). The fixation group had a greater proportion of direct hernia (16.3% vs 7.2%, $P = 0.049$). The nonfixation group's mean operational time was significantly shorter than the fixation group's (91.0 ± 37.0 min vs 80.4 ± 30.4 min, $P = 0.03$). In addition, the fixation group had a longer postoperative hospital stay (4.8 ± 1.5 days vs 3.7 ± 1.6 days, $P < 0.001$). In terms of postoperative problems, there was no difference between the two groups in terms of the number of

patients who had any complaints or the incidence of difficulties. In the fixation group, there were 2 (2.5%) patients who had chronic groin discomfort. In both groups, there was no recurrence.

Table 1
Patient characteristics between the fixation and nonfixation groups

Variables	Fixation group (n = 195)	Non-fixation group (n = 165)	*P* value
Age (years)*	66.4 ± 15.0	68.9 ± 11.2	0.072
Sex (male/female)	169/26	148/17	0.377
Body mass index (kg/m^2)*	23.2 ± 3.1	23.1 ± 2.6	0.741
ASA-PS class III	7 (3.6%)	8 (4.8%)	0.552
Diabetes mellitus	31 (15.9%)	18 (10.9%)	0.217
Anticoagulation therapy	36 (18.5%)	26 (15.8%)	0.498
Previous lower abdominal surgery	36 (18.5%)	38 (23.0%)	0.217
Previous inguinal hernia repair (same/opposite side)	2/25	4/20	0.842
ASA-PS: American Society of Anesthesiologists physical status			
* Mean ± SD.			

Table 2
Hernia factors between the fixation and nonfixation groups

Variables	Fixation group (n = 195)	Nonfixation group (n = 165)	*P* value
Unilateral hernia	136 (69.7%)	159 (96.4%)	<0.001
Indirect	115 (59.0%)	140 (84.8%)	<0.001
Direct	18 (9.2%)	14 (8.5%)	0.804
Combined	3 (1.5%)	5 (3.0%)	0.339
Bilateral hernia	59 (30.3%)	6 (3.6%)	<0.001
Large hernia visually (>7cm)	51 (26.2%)	20 (12.1%)	<0.001
Duration of bulge (months) *	33.9 ± 92.3	28.5 ± 105.1	0.612
Impaction of hernia	15 (7.7%)	8 (4.8%)	0.272
* Mean ± SD.			

Table 3
Operative factors between the fixation and nonfixation groups

Variables	Fixation group (n = 195)	Non-fixation group (n = 165)	*P* value
Emergency surgery	3 (1.5%)	1 (0.6%)	0.400
Operative time (min) *			
Unilateral	98.0 ± 36.7	81.7 ± 30.2	<0.001
Bilateral	117.2 ± 44.1	118.8 ± 30.5	0.928
Large hernia orifice (L3 or M3)	39 (20.0%)	9 (5.5%)	<0.001
Complication of direct and indirect hernia	2 (1.0%)	7 (4.2%)	0.107
Postoperative hospital stay (days) *	4.9 ± 2.0	4.0 ± 2.1	<0.001
*Mean ± SD.			

Table 4
Postoperative complications

Variables	Fixation group (n = 195)	Non-fixation group (n = 165)	*P* value
Postoperative inguinal pain	21 (10.8%)	15 (9.1%)	0.597
Scrotal edema	8 (4.1%)	1 (0.6%)	0.075
Seroma	27 (13.8%)	11 (6.7%)	0.027
Perceptual abnormality	2 (1.0%)	0	0.553
Chronic pain	3 (1.5%)	0	0.309
Recurrence	0	1 (0.6%)	0.933
Any complaint	61 (31.2%)	29 (17.6%)	0.003

Table 5
Comparison of normal hernia cases between the fixation and nonfixation groups

Variables	Fixation group (n = 80)	Non-fixation group (n = 111)	*P* value
Age (years)*	63.5 ± 16.1	69.0 ± 10.7	0.005
Sex (male/female)	65/15	99/12	0.120
Body mass index (kg/m^2)*	23.0 ± 2.9	23.2 ± 2.7	0.531
ASA-PS class III	3 (3.8%)	5 (4.5%)	0.800
Diabetes mellitus	8 (10.0%)	10 (9.0%)	0.817
Anticoagulation therapy	13 (16.3%)	12 (10.8%)	0.339
Previous lower abdominal surgery	12 (15.0%)	26 (23.4%)	0.150
Previous inguinal hernia repair (same/opposite side)	1/7	2/8	0.817
Indirect hernia	67 (83.8%)	100 (90.0%)	0.192
Direct hernia	13 (16.3%)	8 (7.2%)	0.049
Combined hernia	0	3 (2.7%)	0.138
Duration of bulge (months) *	26.8 ± 90.6	30.6 ± 120.0	0.814
Operative time (min) *	91.0 ± 37.0	80.4 ± 30.4	0.030
Complication of direct and indirect hernia	1 (1.3%)	3 (2.7%)	0.857
Postoperative hospital stay (days) *	4.8 ± 1.5	3.7 ± 1.6	<0.001
Postoperative inguinal pain	7 (8.8%)	8 (7.2%)	0.906
Scrotal edema	0	0	
Seroma	7 (8.8%)	5 (4.5%)	0.233
Perceptual abnormality	1 (1.3%)	0	0.870
Chronic pain	2 (2.5%)	0	0.340
Recurrence	0	0	
Any complaint	21 (26.3%)	17 (15.3%)	0.062
ASA-PS: American Society of Anesthesiologists physical status			
* Mean ± SD.			

Discussion

The most essential aspect of inguinal hernia surgery is the postoperative recurrence rate. Mesh fixation is used frequently during laparoscopic hernia surgery to avoid mesh migration. There was no significant difference in the recurrence rate of TEP with or without mesh fixation, according to certain RCTs, meta-analyses, and systematic reviews [4–14]. According to the meta-analysis, the recurrence rate after mesh fixation repairs was 0.19% (1/540) compared to 0.55% after nonfixation repairs (3/546); no significant difference was detected between the two groups [11]. We were concerned about recurrence via mesh migration when we implemented the nonfixation TEP at our institution. As a result, we chose SURGIMESH®XD, nonwoven material with high tissue adhesion and a form suitable to the architecture of the inguinal area. This is, to the best of our knowledge, the first report that makes use of this mesh. However, the potential of avoiding mesh fixation in situations of extensive hernias, bilateral hernias, or impaction remains debatable. It is up to the surgeon in actual practice, not clinical trials, to decide whether or not the mesh has to be repaired. All of the surgeons in this research were aware of the worldwide standards for inguinal hernia repair [16] and decided whether or not to repair the mesh. As a result, big hernias and bilateral hernias were deemed to be at high risk of recurrence, and mesh fixation was done in the majority of patients. Even after the nonfixation TEP was introduced; mesh fixation was done in 75 of 240 patients (31.3%) for the reasons stated above. The lone patient in this research who had a recurrence was very elderly (95-years-old) and had a low-performance status (ECOG-PS3). His hernia was classified as L3 by the EHS. We hypothesized that the patient did not have adequate intraabdominal pressure to fix the mesh as a result of the lengthy period spent in bed, which may have resulted in mesh migration [17, 18]. We must use caution while treating patients with low PS. Because of the significant bias between the fixation and nonfixation groups, only the normal hernia was studied. As a consequence, no patient experienced recurrence following nonfixation TEP. As a result, based on our experience, it was assumed that if SURGIMESH®XD was utilized for typical hernia cases, the mesh might be unfixed. Claus et al. investigated mesh movement in bilateral hernia repair and found that TEP with no mesh fixation is safe in bilateral inguinal surgery [19]. Despite the small number of patients in the current investigation, no recurrence of bilateral hernias was found.

The most serious problem with hernia surgery, aside from recurrence rates, is postoperative groin discomfort caused by mesh fixation [20]. Groin discomfort is difficult to measure since definitions and evaluation techniques are inconsistent. Previous research found a difference between fixation and nonfixation groups in persistent groin pain [8, 21]. The majority of patients in the fixation group who complained of groin discomfort said it was minor and had little impact on their everyday lives. Mesh fixation in TEP is generally unneeded in most situations, although it may cause severe discomfort in a few. In our study, three patients had persistent groin discomfort, all of whom were in the fixation group. One of the three was in so much agony that it was interfering with his everyday life that he underwent surgery more than six months following TEP. He experienced significant relief from groin discomfort when the tack was removed under local anesthesia. There is no need to be concerned about groin pain produced by tacking in the nonfixation group.

The final significant benefit is increased economic efficiency by lowering the cost of the tack applicator. The tacking device used at our institute cost around $385. It has also been claimed that the reduced use of analgesics due to less postoperative discomfort caused by no tacking may have led to cost savings [4, 5, 8].

Previous research has indicated that the nonfixation group has lower urine retention rates, shorter operating times, shorter hospital stays, and quicker return to work [10–14]. In our investigation, the nonfixation group had a considerably shorter surgery time. This was most likely owing to the time saved repairing the mesh; however, the explanation for the lack of change in bilateral hernia cases was unknown. Similarly, the explanation for the shorter hospital stay in the nonfixation group was unknown, but we speculated that it was probably owing to the fixation group's more severe postoperative pain, albeit no such data were provided. Our research has some limitations. First, because this was retrospective research, the patient population was limited. As stated in the review articles [14], further high-quality prospective trials are required to show that tacking is unnecessary in TEP. Second, the number of main surgeons in this research was not limited. The procedures were carried out by young residents under the supervision of medical experts in many cases. Third, there were a lot of elderly people in our region, and the average patient age in our research was rather old. Some of them had died or were unable to be reached.

Finally, the absence of mesh fixation in TEP was deemed clinically appropriate for normal hernias (hernia orifice < 3 cm). In terms of form and substance, the mesh utilized in this study, SURGIMESH®□XD, was appropriate for the nonfixation TEP.

Declarations

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Author contributions

All authors were involved in this study design. SN was involved in data analysis and SN and HO involved in interpretation of the results. All authors read and approved submission.

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Competing interests

The authors declare no competing interests.

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Figures

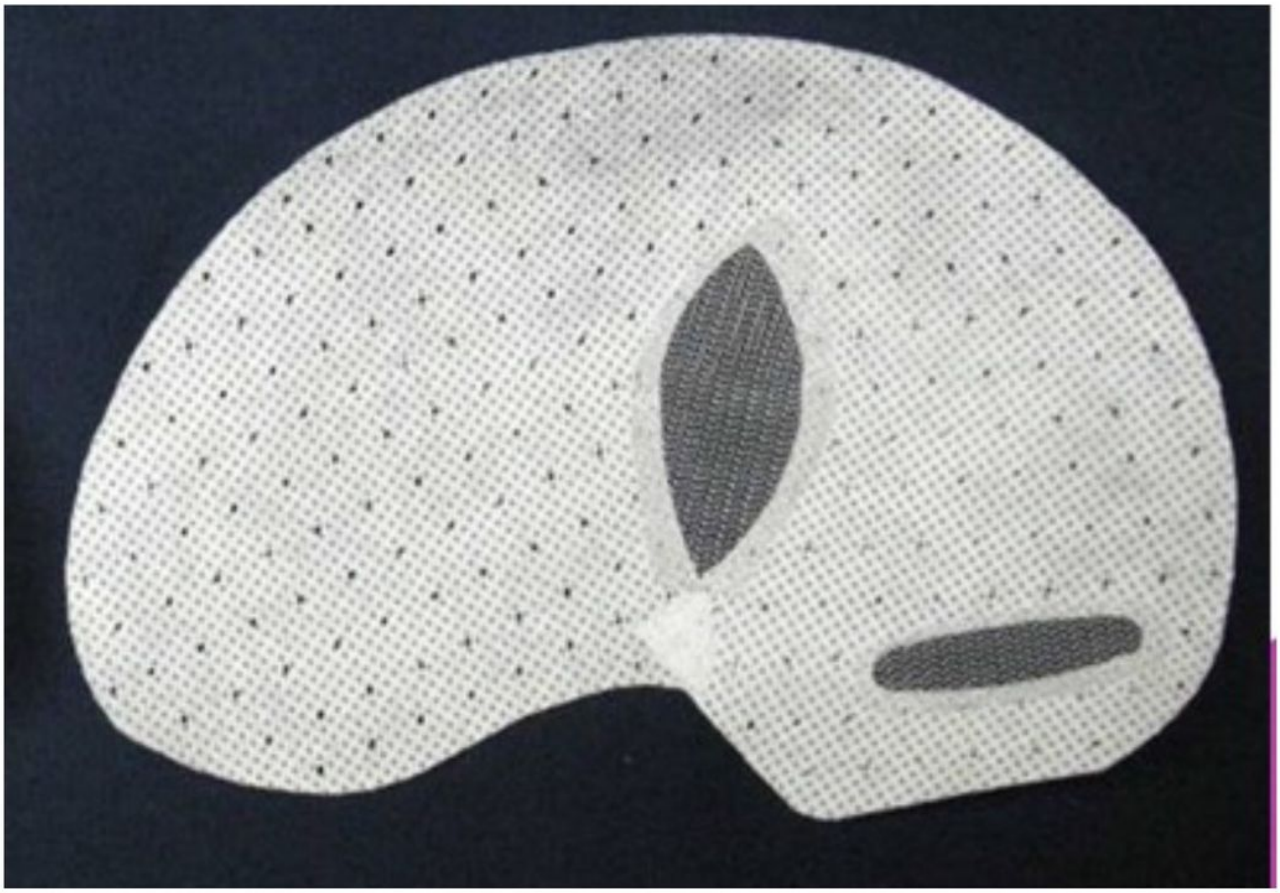

Figure 1

SURGIMESH®XD The nonwoven polypropylene mesh is a 3D-shaped, reversible, trimmable mesh with two windows for better visibility. The vertical window fits with the epigastric vessels, and the horizontal window fits with Cooper's ligament. The lower slit of the mesh fits on the external iliac vessels, including the spermatic cord