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FULL PAPER

Mesh fixation using conventional non-absorbable sutures versus skin staples in patients undergoing primary inguinal hernioplasty

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One hundred patients were included in this randomized prospective trial; 50 patients were enrolled in the suturing group, and the other 50 enrolled in the staples group. The statistical analysis did not reveal any discernible differences between the two groups regarding patient or hernia characteristics. However, the use of sutures for mesh fixation was associated with a significant prolongation in the operative time (56.2 vs. 44 minutes in the staple group). The mean duration of hospitalization was 12.56 hours in the suture group and 12.3 hours in the staple group. The incidence of early postoperative adverse events, including hematoma, seroma, wound infection, and urine retention, was comparable between the two groups. Regarding late complications, the incidence of hernia recurrence was 4% in the suturing group and 2% in the stapler group (p = 0.558). In addition, postsurgical inguinodynia was reported by 14% and 12% of patients in the same groups, respectively. We conclude that use of skin staples in the fixation of mesh during inguinal hernioplasty is not associated with extra benefits compared to the conventional suturing method, apart from the shorter operative time. It should be used when available or when shorter operative time is required (risky anesthetic patients).

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KEYWORDS

Inguinal hernioplasty; mesh fixation; sutures; staples.

Introduction

Inguinal hernia is a common surgical entity that is frequently encountered and operated in the daily surgical practice not only in Egypt but around the world [1,2] and it represents about 75% of all abdominal wall hernias [3].

The lifetime risk of getting that pathology is about 27% for men, which is much higher than for women (3%) [1]. Surgical repair is the definitive management option for inguinal hernia, and it is one of the fundamental procedures in the field of general surgery [4]

The traditional method of covering the defect with mesh involves using polypropylene sutures, important and difficult surgical procedure that prevents the mesh from migrating and from curling and wrinkling. Lichtenstein and his associates described their tension-free approach to the surgical repair of adult inguinal hernia in

1989 [5]. That approach entails reinforcement of the posterior wall of the inguinal canal using a synthetic mesh. This technique has become the standard approach in open inguinal hernia repair because of its associated lower recurrence rates compared to traditional herniorrhaphy [4,6].

Despite the evolvement of laparoscopic-based hernial repair, open Lichtenstein repair is still common because of its excellent perioperative outcomes and cost-effectiveness [7] which makes it more suitable in poor countries with a high prevalence of poverty, like Egypt [8].

Traditionally, non-absorbable sutures (like polypropylene) have been used to fix the mesh to the underlying posterior inguinal canal wall during Lichtenstein repair [9]. However, another method of mesh fixation has been described, which entails the use of staples. That method offers a great advantage over the classic suturing approach, which is the shorter operative time without an increased risk for postoperative complications [10-12].

Although hernial repair is commonly performed in Egyptian surgical settings, and some surgeons prefer to use staples for fixation, numerous strategies to lower the risk of infection, seroma development, and post-hernia retention have been investigated. It is evident that using skin staples to secure the mesh is mentioned to have numerous benefits, such as a decrease in operating time, the incidence of surgical site infections, the creation of post-operative seromas, and urine retention [12].

The aim of this study to compared the use of non-absorbable suture vs. skin stapler in fixation of inguinal hernia mesh.

Patients and methods

This randomized prospective trial was conducted at Al-Azhar University General Surgery Department over a two-year period, from August 2021 to August 2023. Our study was designed for adult male patients diagnosed with the unilateral inguinal hernia and aged less than 70 years. Patient assessment and enrolment started after gaining ethical approval from the local ethical committee of our faculty of medicine.

Before the surgical procedure, all patients were properly assessed, and that included detailed history taking clinical examination and routine preoperative laboratory investigations. Pelviabdominal ultrasonography was ordered for all patients to exclude the presence of intraabdominal space-occupying lesions. In addition, patients with chronic respiratory or prostatic symptoms were referred to the chest or urology departments, respectively, located in the same university hospitals. The patients were further assessed by our aesthetic team, and the patient's overall health status was classified according to the "American Society of Anaesthesiologists" (ASA) [13].

Patients with class III or higher were excluded from our study. In addition, we excluded patients with the following criteria: bilateral inguinal hernia, recurrent hernia, intraabdominal malignancy, bleeding disorders, or hernia complications (incarceration, strangulation, or obstruction). One hundred patients were found eligible for our trial, and we simply explained the aim of the research, the benefits, and the possible complications of each approach, and then they signed a written consent before the operation to document their approval. Using the computer-generated randomization, the included patients were assigned into two groups: the suturing group (n = 50) and the staples group (n = 50). The procedures were performed under spinal anesthesia, and the operating surgeon was located at the side of hernia. A broad-spectrum was administered at the time of skin incision (ceftriaxone 2 g IV). After creating the inguinal skin incision, dissection was continued downwards through the subcutaneous tissue and abdominal wall fascia till reaching the external oblique aponeurosis. It was carefully opened using a surgical scissor with great

caution so as not to injure the spermatic cord or its contents. Both ilioinguinal and iliohypogastric nerves were identified and preserved. If not possible, a neurectomy was performed. In patients with the indirect hernia, the spermatic cord was opened, and the hernial sac was dissected from its contents, followed by its ligation at the neck and excision. In patients with the direct hernia, the sac was plicated without opening. All of the previous steps were performed in patients containing both hernia types.

A polypropylene mesh (EgyMesh), measuring 6 x 11 cm, was used to achieve tension-free repair in all cases. The mesh was fixated to the underlying posterior inguinal canal wall using interrupted prolene 2/0 sutures in the suture group. The first suture was taken 1 cm median to the pubic tubercle, and it was fixated to the covering fascia, not to the underlying periosteum. The mesh was fixated as much as possible to reach the conjoint tendon superiorly and to cover at least 2 cm lateral to the internal inguinal ring. The lateral edge of the mesh was split to contain the spermatic cord, and the two leaves were sutured by two prolene sutures.

In the staples group, we used the skin stapler; Skin Stapler (Ethicon) containing 35 preloaded stainless steel staples was used to secure it (Figure 1). The mesh fixation was done in the same way as the suture group (Figure 2). We took care not to apply much pressure when applying the staples to avoid injury to the underlying vasculature (femoral vessels).

A surgical drain was inserted over the mesh according to the surgeon's preference. Then, the external oblique aponeurosis was closed by interrupted vicryl 2/0 sutures. Finally, the subcutaneous tissue was approximated using the same sutures, and the skin was closed using subcuticular prolene 2/0 sutures.The operative time was recorded (from the start of the skin incision to its complete closure). All patients were discharged within 24 hours after the operation. Before discharge, we taught the patients how to express their postoperative pain according to the "visual analog scale" (VAS) [14].

It was recorded on the first postoperative day before discharge, and they were asked to record it manually every other day till the two-week follow-up visit. During that visit, the presence of early complications, including wound infection, seroma, and hematoma, was noticed and recorded. The skin stitches were removed if the wound was free from complications. The patients were followed up for at least one year after the operation (at three-month intervals), and delayed complications, including recurrence and chronic inguinal pain (inguinodynia), were recorded. The latter was diagnosed if the patient reported pain in the same operative side beyond three months following the repair procedure [15].

Following surgery, patients were evaluated after receiving the first analgesic dose at the bedside at 45 minutes, 2 hours, 6 hours, 12 hours, and 24 hours from their allocated regimen. Patients' numeric rating scale (NRS) pain ratings were recorded on postoperative monitoring charts. The scale ranges from 0 to 10, where 0 means no pain and 10 corresponds to the maximum possible pain [16].

The main outcome of our trial was the one-year recurrence rate, while secondary objectives included the operative time, hospitalization period, the incidence of early postoperative complications, and the incidence of postsurgical chronic inguinal pain.

Sample size calculation

We used IBMª SPSS Sample Power software (version 3.0.1) to estimate the proper sample size. The previous study conducted by Van der Zwaal and his colleagues reported a 10% incidence of recurrence in the suture group and 1% in the staples group (difference = 10%) [17]. Assuming a 15% difference in the same parameter between our two groups, we

needed to enrol 46 patients in each one to achieve 0.05 significance and 80% study power. With an expected drop-out rate during the follow-up period, the number was increased to 50 patients in each group.

Statistical analysis

We used SPSS software for Windows (Version 26) to statistically analyse the collected data, considering any obtained p-value less than 0.05 as a significant difference. We applied the Chi-Square test to compare categorical parameters, which were presented as numbers and frequencies. Moreover, the Mann-Whitney test was used to compare skewed quantitative parameters, which were expressed as medians and ranges. Furthermore, the student-t test was used to compare non-skewed quantitative parameters presented as means and standard deviations.

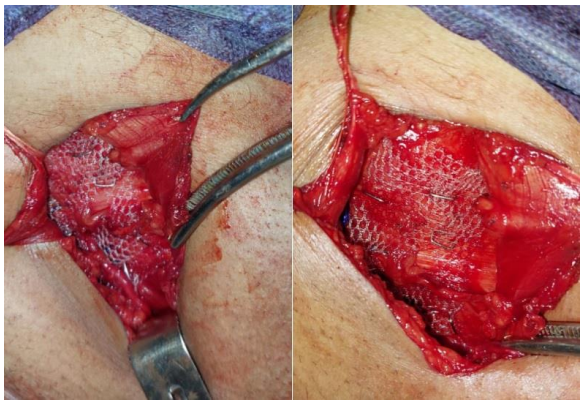

FIGURE 1 Fixation of the mesh by the stapler during inguinal hernioplasty.

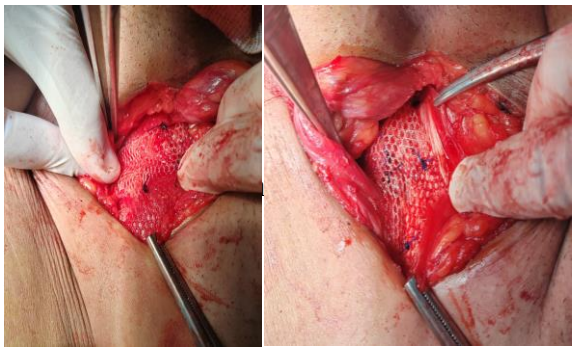

FIGURE 2 Fixation of the mesh by Non-Absorbable Sutures during inguinal hernioplasty

Results

The included patients had a mean age of 47.72 years in the suturing group compared to 46.56 years in the staple group. Their mean BMI values were 29.36 and 28.42 kg/m^2 in the same groups, respectively. Most patients had ASA class I, as they formed 66% and 70% of the included cases in the same groups, respectively. The remaining patients were ASA class II. As regards hernia characteristics, the right side was affected in 54% of cases in the suture group and 48% of cases in the staple group. The remaining cases had their left side affected. In the suture group, the type of hernias was as follows: direct (42%), indirect (44%), and combined (14%). In the staple group, the same three types were detected in 40%, 50%, and 10% of cases, respectively. Table 1 presents the absence of any statistical difference between the two groups regarding either of the previously mentioned parameters.

The use of sutures for mesh fixation was associated with a significant prolongation in the operative time (56.2 vs. 44 minutes in the staple group). Posterior wall plication was required in 64% of cases in the suturing group and 58% of cases in the staple group (p = 0.539). The mean duration of hospitalization was 12.56 hours in the suture group and 12.3 hours in the staple group (p = 0.542) (Table 2). Table 3 provides that the incidence of early postoperative complications did not show any discernible differences between the two groups. Superficial surgical site infection occurred in only one patient in each group (2%), and both cases were successfully managed by frequent dressing, topical, and IV antibiotics. Urine retention occurred in only one patient (2%) in the suturing group, and that patient was managed by a Nelaton catheter for bladder evacuation. No clinically significant seromas were encountered in the enrolled 100 patients. Postoperative hematoma occurred in one patient in each group (2%), and both patients did not need surgical evacuation. The hematomas were small in size, and they responded well to local antithrombotic gels and systemic anti oedematous medications (Alpha

Chymotrypsin). The recorded postoperative pain scores during the initial two weeks following the operation had comparable median values and ranges between the two groups, as indicated in Table 4. Regarding late complications, the incidence of hernia recurrence was 4% in the suturing group and 2% in the stapler group (p = 0.558). In addition, postsurgical inguinodynia was reported by 14% and 12% of patients in the same groups, respectively (Table 5).

TABLE 1 Baseline criteria

	Suture group (n = 50)	Staple group (n = 50)	P-value
Age (years)	47.72 ± 12.89	46.56 ± 12.84	0.653
BMI (kg/m2)	29.36 ± 3.63	28.42 ± 3.50	0.190
ASA status			
-I	33 (66%)	35 (70%)	0.184
-II	17 (34%)	15 (30%)	
Hernia side			
-Right	27 (54%)	24 (48%)	0.360
-Left	23 (46%)	26 (52%)	
Hernia type			
-Direct	21 (42%)	20 (40%)	
-Indirect	22 (44%)	25 (50%)	0.549
-Combined	7 (14%)	5 (10%)	

TABLE 2 Intraoperative characteristics and the duration of hospitalization

	Suture group	Staple group	P-value
Operative time (min)	56.20 ± 13.46	44 ± 6.78	< 0.001*
Posterior wall plication	32 (64%)	29 (58%)	0.539
Hospitalization period (hours)	12.56 ± 2.11	12.30 ± 2.14	0.542

TABLE 3 Early postoperative complications

	Suture group	Staple group	P-value
Surgical site infection	1 (2%)	1 (2%)	1
Urine retention	1 (2%)	0 (0%)	0.315
Clinically significant seroma	0 (0%)	0 0%)	_____
Hematoma	1 (2%)	1 (2%)	1

TABLE 4 Postoperative pain

	Suture group	Staple group	P-value
1st	5 (4 – 7)	6 (4 – 7)	0.393
3rd	3 (2 – 6)	3 (2 – 5)	0.732
5th	3 (2 – 5)	3 (2 – 5)	0.855
7th	2 (1 – 4)	2 (1 – 4)	0.977
9th	1 (1 – 3)	1 (1 – 3)	0.580
11th	0 (0 – 3)	0 (0 – 3)	0.565
13th	0 (0 – 2)	0 (0 – 2)	0.833
15th	0 (0 – 2)	0 (0 – 2)	0.823

TABLE 5 Late postoperative complications

	Suture group	Staple group	P-value
Recurrence	2 (4%)	1 (2%)	0.558
Chronic postoperative pain	7 (14%)	6 (12%)	0.766

Discussion

Despite the wide spread of inguinal hernioplasty procedures in general surgical practice, there is no standardized consensus regarding the best method that should be used to fixate the mesh to the underlying posterior inguinal canal wall [18]. Multiple fixation methods have been described, including conventional sutures, chemical materials (fibrin glue and cyanoacrylate), and staples [19].

Herein, we compare the outcomes of sutures versus staples in patients undergoing unilateral inguinal hernioplasty. No previous studies have addressed such a perspective in

the Egyptian setting, which poses a major advantage in favour of this study. Another advantage that should be considered is the absence of any statistical difference between our two groups regarding patients and hernia characteristics. That should decrease the possibility of any bias skewing our findings in favour of one group rather than the other. In addition, that reflects our proper randomization method. Our findings revealed that the operative time was significantly prolonged in association with the suturing method. We find our result reasonable, as it would take much more time to take sutures than to apply staples. The time needed for holding the needle, passing through the mesh and tissues, knot tying, and cutting the suture after tying should be markedly diminished by staple application. Likewise, Shaikh *et al.* reported that the same parameter ranged between 55 and 80 minutes when the staples were used (median = 60), while it ranged between 60 and 105 minutes in the suturing group (median = 90) [20].

Although the skin stapler costs more money than the prolene sutures in Egypt, the shortened operative time could compensate for that increase. Douglas *et al.* reported that the operative time increased when the sutures were used for mesh fixation (105.5 ± 31.7 vs. 86.0 ± 35.2 minutes in the stapler group), with no significant statistical difference [12].

Contrarily, other authors reported longer operative time with the stapling method (56 ± 16 vs. 50 ± 17 minutes in the suturing group). Nonetheless, that difference turned out to be insignificant in the statistical analysis ($p > 0.05$) [17].

One could expect some differences between studies according to the experience of the operating surgeon, the difficulty of dissection, and the incidence of intraoperative complications. We did not notice any significant impact of the fixation method on the severity of postoperative pain, as measured by VAS. Van der Zwaal *et al.* reported no significant findings in follow-up pain scores between the same two fixation methods [17]. Mills *et al.* reported similar outcomes regarding postoperative pain [11].

Superficial wound infection occurred in only one patient in each of our two groups (2%), meaning that the fixation method did not significantly influence that adverse event. The incidence of that adverse event lies between 0.9% and 8%, which is the reported incidence range in the current literature [20]. Another study reported a similar finding, as the same complication occurred in 1% of the suturing cases vs. no cases in the stapling group ($p > 0.05$) [17].

Wound hematoma was encountered in only one patient in each of our two groups (2%), with no discernible difference in the statistical analysis. Other authors reported a 1% incidence of the same complication in both groups [17] which is near our findings.We did not encounter any cases of seroma in our study. The incidence of seroma following inguinal hernioplasty is common, especially when ultrasound is used for the diagnosis (may be reach up to 64%) [22].

In our study, we only considered clinically significant seroma (swelling related to the operation site) rather than the radiological diagnosis. That could explain our extremely low incidence. Recurrence occurred in 4% of patients in the suturing group and 2% in the staples group, according to our results indicating that the fixation method did not significantly impact recurrence outcomes. Other studies reported 0% recurrence rates with either fixation protocol with a maximum mean follow-up of 21 months. Nonetheless, Van der Zwaal *et al.* reported the superiority of the stapling method over the suture one regarding postoperative recurrence rates (11% vs. 1%, respectively, $p < 0.01$) [17].

The incidence of postsurgical inguinodynia was 14% in the suturing group and 12% in the staples group, according to our findings. The pathogenesis of that problem is complex and could be divided into neuropathic or non-neuropathic pain. The former is caused by nerve injury or compression secondary to the

procedure, whereas the latter is caused by extensive tissue scarring, spermatic cord compression, or hematoma formation [23,24].

Our ranges in both groups lie within the reported incidence of the same complication reported in the literature, which ranges between 0% and 75% [23,25].

In line with our findings, Shaikh *et al.* reported an incidence of 7% and 11.4% for the same adverse event in the suturing and staples groups, respectively (p = 0.7) [20]. Moreover, Mills *et al.* denied the incidence of the same complication in the stapler group (0%), compared to 3% in the suturing group (p = 0.1) [11].

Conclusion

The use of skin staples to secure mesh in

the Lichtenstein inguinal hernia repair significantly reduced the operation duration and was as effective as conventional mesh fixation with polypropylene.

Limitation of the study

The limitation of this study is the small number of the included patients and single centre study.

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Conflicts of interest

The authors declare that there is no conflict of interest in this study.

Ethical approval

An informed written consent from all participants involved in the study is approved by the Al-Azhar University Local Ethics Committee, Faculty of Medicine (for Girls), accepted the study methodology..

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