ORIGINAL ARTICLE

Outcomes of mesh fixation versus non fixation in laparoscopic transabdominal preperitoneal inguinal hernia repair: a randomized clinical study

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Abstract

Objective: The present study aimed to compare the results of laparoscopic transabdominal preperitoneal (TAPP) inguinal hernia repair with and without mesh fixation regarding postoperative pain, recurrence, operative time, and complications.

Methods: This randomized controlled clinical trial included 100 patients who underwent TAPP inguinal hernia with mesh fixation (group A) or a fixation-free procedure (group B) for early onset inguinal hernia at the General Surgery Department, Kafrelsheikh University Hospital, from January 2021 to June 2022.

Results: The parameters for pain assessment (NRS) in the first week (mean 7 (5 – 8)), the first month (mean 3 (1 – 5)), and after three months (mean 0 - (70% of patients), (mean 1- (30% of patients) were significantly higher in the fixation group (p<0.001). The fixation group had significantly more operative time than non fixation, with a mean (69.34±13.55, 60.92±10.18) respectively. Recurrence rate and postoperative complications did not show any significant difference between the studied groups.

Conclusion: Mesh non-fixation for laparoscopic TAPP hernia repair is safe, practical, and effective with minimal postoperative pain and no increased risk of recurrence.

Keywords: Hernia, Inguinal, Herniorrhaphy, Seroma, Laparoscopy, Hematoma, Edema

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Introduction

Abnormal protrusion of a viscous or fatty tissue through the abdominal wall is called a hernia. In all countries, the hernia is considered a big healthcare concern. Surgical repair is the management of all hernias, with many procedures done worldwide every year.[1] The publications have no unanimity about the ideal repair technique or prosthetic mesh used to ensure a good, long-lasting result .[2]

Hernias of the abdominal wall are prevalent; seventy-five percent of these abdominal wall hernias are inguinal hernias.[3] Hernia risk is higher in men than women; however, it decreases after age 45.[4] Males are seven times more liable to develop an inguinal hernia than females.[5]

An inguinal hernia is diagnosed by a thorough history and physical assessment that confirms the presence of a swelling in the groin region. This inguinal hernia could be treated by careful waiting, open hernioplasty, or laparoscopic repairs using mesh.[6] The common type of inguinal hernia repair is open surgery. Recognizing the anatomy and type of repair lead to a successful procedure; this is vital to any general surgery trainee. It starts with a junior resident and continues throughout the surgical career; this is similar to how inguinal hernia repair has evolved, one of the oldest surgical treatments, over time.[7]

The hernia repair represents the history of surgery; the groin hernia had different modifications of management throughout its history.[8] About 20 years ago, laparoscopic inguinal hernia repair started in practice with an increased performance rate as a definite treatment.[9] Laparoscopic inguinal hernia repair has different approaches, such as the laparoscopic transabdominal preperitoneal (TAPP) approach and the laparoscopic extraperitoneal (TEP) approach and the intraperitoneal Onlay mesh approach.[10] Laparoscopic hernia repair shares the same advantages as the other laparoscopic procedures; decreasing the musculofascial incision causes decreased postoperative pain and early return to normal activities.[11] TAPP hernia repair is one of those laparoscopic operations with the advantages of minimally invasive approaches.[12]

Laparoscopic mesh fixation was accused of causing some complications such as neuralgia and chronic groin pain caused by entrapment of nerves after fixation of the mesh.[13] The present research was designed to compare mesh fixation and non-fixation of laparoscopic TAPP hernia repair, considering postoperative pain, recurrence, operative time, and other postoperative complications.

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Patients and methods

The research was conducted as a randomized clinical study in the General Surgery Department, Kafrelsheikh University Hospital, from January 2021 to June 2022. Included were 100 patients who had laparoscopic TAPP hernia repair for early inguinal hernia (unilateral or bilateral) with or without mesh fixation. The procedures were performed for patients of either gender, from 18 to 65 years age.

Each patient provided informed written consent. The study was done after approval from the Ethical Committee of Kafrelsheikh University Hospitals. Subjects with either recurrent, inguinoscrotal, or complicated hernia (incarcerated or strangulated) and patients having ascites or connective tissue disease, heart, kidney failure, and hypoalbuminaemia were excluded from the study. Depending on whether the mesh was fixed or not, the subjects were randomized into two equal populations. Group 1 is the fixation group, while group 2 is the non-fixation group. The study RCT registeration no was NCT05430984.

Operative techniques: Surgery was conducted under general anaesthesia and endotracheal intubation. The subjects were placed in the Trendelenburg position and the abdomen was accessed via the umbilical port, and the pneumoperitoneum at 15 mmHg was subsequently obtained. After achieving optimal pneumoperitoneum, we inserted a 30° telescope through the umbilical port, explored the abdomen, and identified the hernia defect. Two 5mm trocars were placed along the mid-clavicular line on either side at the umbilicus level.

When entering the abdominal cavity, 3 cm above the defect level, the peritoneum was cut curvingly. To prevent causing harm to the urinary bladder during dissection, one must be careful not to cross the level of the medial umbilical fold. Additionally, inferior epigastric vessels can be found while slicing the peritoneum in the central region.

Then the sac of the oblique hernia was dissected from vas and vessels in males or round ligament in females. Lipoma was removed if it was big and outside the sac. Dissection should extend medially to symphysis pubis identifying retropubic space, pubic ramus, and coopers ligament, laterally to anterior superior iliac spine and psoas major, and superiorly up to 3cm above defect. For optimum perietalization of the spermatic cord, the dissection should be extended 3 cm beneath the pectineal ligament (medial, inferior, and lateral); the sac is detached from the spermatic cord by 6–8 cm. This optimum dissection helps proper placement of 15x10 cm proline mesh.

The spiral tuckers fixed the mesh to the abdominal wall in the fixation group, while the mesh was flattened and left without fixation in the other group. We closed the peritoneum using vicryl 3/0 to reduce the possibility of fistula formation, erosion, and small intestinal obstruction caused by the mesh adhering to the intestines.

Postoperative care: Period of hospital stay, return to full activity, work, and complications (early, late) were recorded. Patients were followed in the out-patient clinic for one week, one month, three months, six months, and one year after surgery.

Randomization: We used an online software (Research Randomizer); all participants who were included and consented to have surgery were randomly assigned. Each patient received a sealed blue or red envelope without a label. The medical staff was aware of each colour's code. The blue colour was the group (A) mesh fixation using tuckers, and the red colour was the group (B) with non-fixation.

Sample Size Calculation: Determination of the sample size was done by Power Analysis and Sample Size Software.[13] As mentioned in a previous study[7], the mean (SD) of postoperative pain scores in the fixation group was nearly 4.5 o,9, while in the non-fixation group, it was about 3.6 (0.5). Thus, a minimal total hypothesized sample size of 100 patients undergoing laparoscopic TAPP inguinal hernia repair in the General Surgery Department, Kafrelsheikh University Hospital (50 per group) can reject the null hypothesis taking into consideration a 5% level of significance and 80% power using independent t-test.[14]

Statistical analysis: Statistical software IBM SPSS v27 was used for statistical analysis. Quantitative data were presented by the mean and standard deviation (SD); frequency and percentage (%) were used to present qualitative variables. The unpaired student t-test and the Chi-square test or Fisher's exact test, when appropriate, were used to analyze quantitative and qualitative data. Statistical significance was set at $P < 0.05$.

Results

We included 100 participants with early onset inguinal hernia (unilateral or bilateral). Most of the patients were men; the fixation group included 50 patients with right side hernia (n=31), left side hernia (n=17), and bilateral (n=2). The non-fixation group included 50 patients with right side hernia (n=32), left side (n=18), and no bilateral hernias. The fixation group had a significantly longer operative time (69.34 ± 13.55 minutes) than the non-fixation one (60.92 ± 10.18 minutes), as shown in Table 1. The two populations showed no significant difference considering the occurrence of recurrence (Table 2). In both groups, no

patients had recurrent hernias in the first week, one month, and three months after surgery. After the postoperative six

Table-1: Comparison between the studied groups regarding operative data

	Suture type (Tucker)	50 (100%)	-	--
	Mesh size: 15*10 cm	50 (100%)	50 (100%)	--
	Mesh type (Proline)	50 (100%)	50 (100%)	>0.999
Operative data	Type Direct	9 (18%)	14 (28%)	0.235
	Indirect	41 (82%)	36 (72%)	
	Complications:			
	Scrotal edema	1 (2%)	0 (0%)	>0.999
	Operative time (minutes)	69.34 ± 13.55	60.92 ± 10.18	<0.001**

** indicates a highly significant difference

Table-2: Comparison between the studied groups regarding postoperative recurrence, hematoma, port site infection, seroma and NRS over time.

		Groups		P-value
		Fixation group N=50(%)	**Non-fixation group N=50(%)**	
Recurrence	1 week	0 (0%)	0 (0%)	>0.999
	1 month	0 (0%)	0 (0%)	>0.999
	3 months	0 (0%)	0 (0%)	>0.999
	6 months	1 (2%)	2 (4%)	>0.999
	12 months	**N=49 (%)**	**N=48 (%)**	
		1 (2%)	1 (2.1%)	>0.999
Haematoma	1 week	3 (6%)	5 (10%)	0.461
	1 month	0 (0%)	0 (0%)	>0.999
	3 months	0 (0%)	0 (0%)	>0.999
Port-site infection	1 week	2 (4%)	1 (2%)	>0.999
	1 month	0 (0%)	0 (0%)	>0.999
Seroma	1 week	4 (8%)	5 (10%)	0.726
	1 month	0 (0%)	0 (0%)	>0.999
	3 months	0 (0%)	0 (0%)	>0.999
	Median (Range)	**Median (Range)**		
	1 week	7 (5 – 8)	4 (3 – 6)	<0.001**
	1 month	3 (1 – 5)	1 (1 – 3)	<0.001**
NRS over time	3 months	0 (0 – 1)	0 (0 – 1)	
	0	35 (70%)	49(98%)	
	1	15(30%)	1(2%)	<0.001**
	6 months	1 (0 – 2)	1 (0 – 1)	0.302
	12 months	0 (0 – 0)	0 (0 – 0)	>0.999

Data are presented as median or frequency (%) **: Statistically different as P value ≤ 0.05. NRS: Numerical Rating Scale

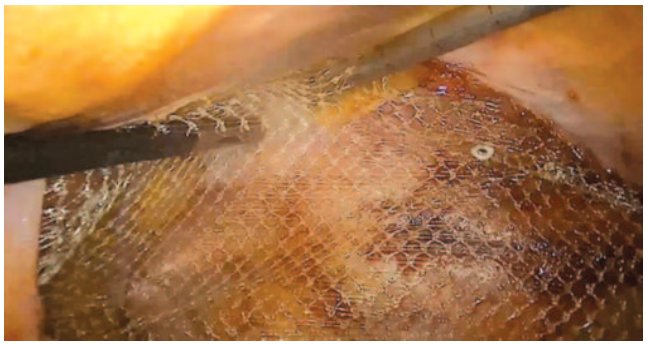

Figure 1: During mesh fixation with tucker

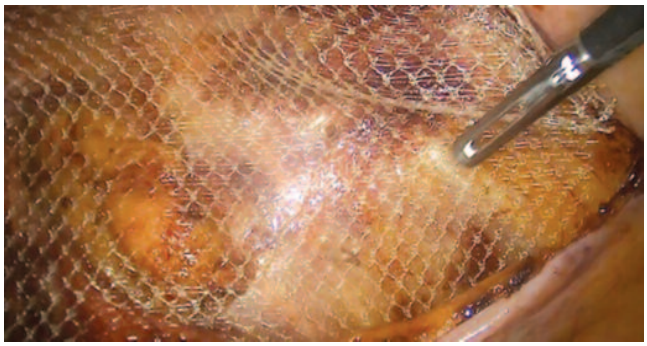

Figure 2: Mesh flattening during non-fixation

months, one case in the fixation group versus two in the non-fixation developed a recurrence. One patient in each group had recurrence 12 months after surgery.

The studied groups had no significant difference regarding haematoma, port site infection, and seroma, as in Table 2. Three cases in the fixation group versus five in the nonfixation population developed a haematoma in the first postoperative week that was treated conservatively. Two patients in the fixation group versus one in the nonfixation had port site infection in the first postoperative week that was treated conservatively. Four cases in the fixation group versus five cases in the other group developed seroma in the first postoperative week.

The NRS was higher in the fixation group than in the non-fixation one at the first week, first month, and after three months. However, at six and twelve months, non-significant differences were found between the two groups in terms of NRS, as shown in Table 2.

Discussion

In the present study the operative time was significantly higher in the fixation group than in the non-fixation group with a mean time (69.34 ± 13.55 vs. 60.92 ± 10.18, minutes respectively). In agreement with our results, Abd El Wahhab et al.[15] performed a retrospective study on 50 participants who had laparoscopic TAPP repair of inguinal hernia (two groups; fixation and non-fixation) for one year. The operative time was significantly shorter in the non-fixation group; the mean period in the fixation group was 163.333 minutes, and non-fixation was 109.222 minutes.

In contrast to what we found, Kalidarei et al.[16] found that the operative time did not significantly change in the study groups; Group A (mesh fixation with sutures n=41) and B (non-fixation n=39). The operative time was 73.8 ± 0.54 min and 70.2 ± 0.44 min in groups A and B, respectively (P = 0.585). A relatively small sample size was included in their study, and ethnic consideration between the Egyptian and Iranian populations could confer a reasonable justification for this contradiction.

Consequently, our results could explain why suture fixation is hardly practiced, as it takes a lot of time and offers no advantages over non-fixation or tacker fixation.

Mesh migration and fear of recurrence are the main reasons for avoiding non-fixation, although in the present study the two studied groups showed no significant difference regarding recurrence frequency. Also, Mohammad et al.[17] findings were compatible with our results as they recorded one case of recurrence in the non-fixation group but without statistical significance compared with the fixation group (P=0.31).

Similar to our results, Abd El Wahhab et al.,[15] in their study, reported no cases of hernia recurrence in non-fixation and fixation groups. Hence, they concluded that recurrence risk did not increase with non-fixation of mesh in TAPP.

The results of earlier research are supported by our investigation, which demonstrated no evidence of a rise in recurrence rate when the mesh was not fixed during TAPP. In our investigation, postoperative sequelae such as seroma, haematoma scrotal oedema, and port site infection did not have a significant difference between the analyzed groups.

Our findings concur with those published by Zayed et al.[18] Following surgery, seroma formed in six (12%), five (10%), and no patients in group B (without fixation) after one week, respectively. Only two patients in group A (4%) showed seroma formation one month after surgery, whereas group B showed no seroma formation at that time. After three months, neither patient in either group has a surgical seroma. The differences were statistically significant (P>0.05). Additionally, neither group of patients showed signs of wound infection throughout the follow-up duration. The postoperative scrotal haematoma did not significantly change between the studied groups (P>0.05). Because of this, our investigations and earlier research findings confirm that mesh fixation in TAPP does not appear to have any immediate advantages, such as fewer postoperative complications.

It was stated that fixing staple mesh increases the tendency to develop acute and long-term pain rather than leaving it unfixed.[19] When mesh fixation is not employed, chronic pain levels are equal to or lower, according to a meta-analysis[20, 21] In our study, NRS was notably higher in the fixation group compared to the non-fixation group in the first week, first month, and after three months. Between the two groups, there was no statistically significant difference in NRS at the sixth and 12-months marks. In agreement with our observations, Zayed et al.[18] reported that Postoperative VAS scores on day 1, three months, and six months were all substantially lower in group B (without fixation of mesh) than in group A (mesh fixation) (P0.05).

Our findings contrasted those reported by Mohammad et al.[17]. Early postoperative pain using VAS had no significant difference, (5.65±0.98) in group A (mesh fixation) and (5.9±1.12) in group B (mesh nonfixation). In addition, chronic pain described as foreign body sensation or discomfort was slightly higher in group A without statistically significant differences. A possible justification for this contradiction between both might be related to using different pain scales and as they utilized VAS scores while we used NRS. Publications about the harmony between NRS and VAS have yielded inconsistent results.[22-24] The present study had some limitation. It was a single centre study with a small sample use. The impact of various meshing techniques or mesh types on the frequency of recurrence has not been studied, and a single-center study with tiny sample size.

Conclusion

Non-fixation of the mesh in laparoscopic TAPP repair of the inguinal hernia is a safe, feasible, and effective method without increased risk of hernia recurrence. It is also associated with reduced postoperative pain and shorter operative time.

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Conflict of interest: None to declare

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