

Perioperative Outcome and Cost-utility of Mesh Fixation vs Non-fixation in Laparoscopic Transabdominal Preperitoneal Inguinal Hernioplasty: A Prospective Randomized Controlled Trial

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ABSTRACT

Aim: To analyze laparoscopic transabdominal preperitoneal (TAPP) mesh fixation and non-fixation in the perioperative outcome and cost-utility for inguinal hernia repair. Patients with groin hernias were introduced to laparoscopic TAPP repair to reduce the possibility of recurrence and other complications. Postoperative pain and nerve injury may be exacerbated by mesh fixation. Following preperitoneal inguinal hernia repair, there is controversy as to whether mesh should be fixed to prevent recurrences.

Materials and methods: From the month of February 2017 to January 2018, 60 patients with inguinal hernias were studied prospectively. Using the TAPP approach under general anesthesia (GA) by the same team, thirty hernias were selected randomly and repaired with the fixation of mesh, and the other thirty ones were repaired without mesh fixation with no attention to the type of hernia (direct or indirect) or the size of the defect. Routine clinical examinations were performed for 6 months on all patients as a regular follow-up.

Results: The operative time ranged from 37 to 92 minutes, (with a mean time of 60.44 minutes) in the mesh fixation group and from 40 to 83 minutes (with a mean time of 54.9 minutes). In the mesh fixation group, 15 cases were Rt indirect inguinal hernias. In the mesh non-fixation group, 18 cases were Rt indirect inguinal hernia. The length of the hospital stays ranges from 1 to 3 days with no significance. No statistical significance was noted as regards operative time, intraoperative injury, hospital stay, mesh migration, nerve entrapment, and postoperative analgesia. The significance was observed in cost-utility which represented the cost of trackers mainly.

Conclusion: No recorded significance as regards operative time, intraoperative injury, hospital stay, mesh migration, nerve entrapment, and postoperative analgesia within the analysis of laparoscopic TAPP mesh fixation and non-fixation.

Clinical significance: Mesh without fixation is a viable method and less costly that has the same benefits and excludes risks of fixation.

Keywords: Cost, Inguinal, Laparoscopic, Outcome, Transabdominal preperitoneal.

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INTRODUCTION

Laparoscopic inguinal hernia repair has been demonstrated to be a secure and efficient procedure, resulting in reduced postoperative discomfort, decreased reliance on pain medication, and a more expedient recovery to normal function levels. The use of the transabdominal preperitoneal (TAPP) technique is a popular approach with debatable fixation of the prosthetic patch. It was proposed to form a preperitoneal pocket, insert the patch into it, and then close the peritoneum over it. The results suggest this is a satisfactory method, although follow-up is limited. There are rare reports of tacker-related complications of adhesions, pain, intestinal obstruction, and perforation of the bowel or urinary bladder.^{1,2}

Non-fixing the prosthesis can prevent complications such as nerve entrapment and osteitis, causing neuralgia or meralgia-paresthetica. The prosthesis is fixed by the growth of fibrotic tissue upon completion, so it will not recur unless it is anatomically incorrect, the abdominal wall defect is vastly larger than the prosthesis, or a new abdominal wall defect is present next to the

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prosthesis. Among the first widely used methods was TAPP. With successful peritoneal access, the anatomical identification of the myopectineal orifice (MPO) of Fruchaud is an easy task to achieve.^{3,4}

During laparoscopic TAPP, there is a controversy about prosthetic fixation. There is no clear correlation between prosthetic fixation and recurrence experience and pain incidence.⁵ A comparison will be held between prosthesis fixation and non-fixation during TAPP repair in terms of the perioperative outcome and cost-utility.

MATERIALS AND METHODS

Study Design and Recruitment

It was a prospective randomized controlled study that included sixty male patients with inguinal hernia of direct and indirect types, whether primary or recurrent, who underwent laparoscopic hernioplasty after securing the patients' consent and the ethical approval from the institutional research board of Mansoura faculty of medicine. The trial was ethically following the Declaration of Helsinki. These patients were admitted from the outpatient clinics at Mansoura University Hospital during the period between February 2017 and January 2020. Based on the clinical examination, the diagnosis was proved. Using the TAPP approach under general anesthesia (GA), thirty hernias were selected randomly and repaired with fixation of mesh, and the other thirty ones were repaired without mesh fixation with no attention to the type of hernia (direct or indirect) or the size of the defect. All patients more than 18-years-old and fit for pneumoperitoneum were recruited. unfit patients for pneumoperitoneum were excluded. Routine investigations were requested for all patients with preoperative optimization of the co-morbidities.

Steps of Laparoscopic TAPP Repair

Preoperative Preparation

A Foley catheter was inserted if intraoperatively mandated and preoperative voiding was sufficient. The hair from the costal margin to midhigh was shaved off the abdomen and groin. At the time of induction of anesthesia, one gram of 3rd generation cephalosporin was given.

Operative Theater Setup

To facilitate access, the upper limbs were tucked into the operating table. After anesthesia is administered, a routine scrub is performed to the area from the nipples down to the midhigh.

Peritoneal Access

A maximum of 15 mm Hg of carbon dioxide was injected into the peritoneal cavity after open peritoneal access. To visualize the MPO, the candidate is positioned in a Trendelenburg position at 15–30°. The intraabdominal contents are inspected with a 30°, 10 mm laparoscope through the cannula. Next, secondary trocars of 5 mm are introduced.

Exposure of the Defect

Reduction of the sac with proper dissection of the MPO. The prosthesis was placed on the spermatic cord after it was detached from the peritoneum.

Mesh Placement

By housing a large patch of polypropylene mesh measuring about 15 cm × 12 cm (depending on the size of the defect) in the dissected

MPO. Thirty cases of hernioplasty were fixed by the tackers. The other thirty cases of hernioplasty were repaired.

Perioperative Follow-up

All patients received one dose of antibiotics postoperatively. Upon completion of the operation, patients were allowed home between 24 and 48 hours later. There are no reports of inguinal discomfort. There is no requirement for inactivity. A follow-up appointment follows the surgery about a week after the procedure.

Parameters Intraoperatively

Operation duration (in min), Intraoperative complications, Type of hernia (Rt or Lt, direct or indirect), and size of the defect.

The Postoperative Parameters Evaluated Included

Mesh curling, recurrence incidence, analgesic need, neurologic affection, infection, LOS, and cost-utility. The follow-up schedule was set at a week, a month, 3 months, and a half of a year, and could be conducted in person or over the phone.

Statistical Assessment

The IBM SPSS software package version 20.0 (Armonk, NY) was utilized to analyze data that were fed into the computer. Quantitative data were described using range (minimum and maximum), mean, standard deviation, and median, while qualitative data were described using numbers and percentages. The normality of distribution was verified using the Kolmogorov-Smirnov test, and the significance of the obtained results was determined at the 5% level. The p -value > 0.05 was deemed insignificant (NS).

RESULTS

Transabdominal preperitoneal repair has been used to treat 60 hernial defects laparoscopically in this study by the same team with or without mesh fixation. For 6 months, patients were examined routinely or contacted by phone. The age within this trial ranged from 24 to 65 years. This table shows the difference as regards age (years), there were mean (41.11 ± 11.67 and 38.70 ± 13.35) respectively, and no statistical significance was noted, with p -value $0.682 = NS$. The duration of the procedure ranged from 37 to 92 minutes (with a mean time of 60.44 min) in the prosthetic fixation cases and from 40 to 83 minutes (with a mean time of 54.9 min) in other cases. Table 1 shows the difference as regards intraoperative time, there was a mean (of 60.44 ± 18.60 and 54.90 ± 12.38) respectively, and there was no statistically significant difference recorded, however, it was longer in the 1st group, with a p -value of $0.450 = NS$.

In the mesh fixation group, 15 cases were Rt indirect inguinal hernias 50%, 12 cases were Lt indirect inguinal hernias 40% and 3 cases were bilateral hernias 10%. In the non-fixation group, 18 cases were Rt indirect inguinal hernia 60%, and 12 cases were Lt indirect inguinal hernia. No statistical significance was noted.

Table 1 shows the discrepancy between group I and group II in site incidence, which was maximum in group II (60%) in Rt indirect inguinal hernias. While it was the minimum group I (40%) in Lt inguinal ones. Using Chi-square with p -value $0.580 NS$. The size of the defect will be calculated by the multiply of defect length to the defect width which was with no significant variation.

Table 1 shows the difference as regards the size of the defect, there was a mean (12.70 ± 6.18 and 14.60 ± 5.44) respectively, and there was no statistically significant difference between groups, with a p -value of $0.475 NS$. In this clinical trial, no single migration was observed during follow-up time.

Table 1: Comparative assessment of the two groups as regards the perioperative outcome and cost

	Group (I) (n = 30) (mesh fixation group)	Group (II) (n = 30) (mesh non-fixation group)	t-test	
			t	p-value
Age (years), mean ± SD	41.11 ± 11.67	38.70 ± 13.35	0.417	0.682
Operative time	60.44 ± 18.60	54.90 ± 12.38	0.772	0.450
LOS	1.80 ± 0.72	1.40 ± 0.91	-0.928	0.366
The cost (in USD)				
The cost of anesthesia	290 ± 48.76	230 ± 44.31		0.041
The mean cost of the LOS	2140 ± 33.98	2110 ± 35.52		
The total cost of the management	4380 ± 235.55	3830 ± 421.56		
Size of defect mean ± SD	12.70 ± 6.18	14.60 ± 5.44	-0.730	0.475
Types of hernia			χ^2	
Rt indirect inguinal hernia	15	18	1.091	0.580
Lt indirect inguinal hernia	12	12		
Bilateral	3	0		
Perioperative complications				
Recurrence rate	2	3	3.529	0.068
Intraoperative injury	0.00	0.00	-	-
Seroma formation	3	2	2.889	0.071

LOS, length of stay

Five cases of seroma were controlled conservatively during the postoperative period within 2–3 weeks and the patients were just reassured during follow-up. Table 1 shows the difference also as regards intraoperative injury, seroma formation, nerve entrapment, and recurrence. No statistical significance was reported, with a p-value of 0.071 NS. There were no reported cases of recurrence in this study.

All patients received non-steroidal anti-inflammatory drugs post-operation for 3–5 days with no significant variation or signs of severe pain. There were no reported cases of nerve entrapment nor mesh or surgical site infection.

The length of hospital stays ranges from 1 to 2 days with no significant difference with a p-value 0.366 NS. Table 1 shows the difference in cost (USD) between the two groups which represents the cost of tackers and the difference in operative time used for mesh fixation.

DISCUSSION

General surgery patients most commonly undergo inguinal hernia repair. As a result of the need to prevent recurrences, numerous modifications have been made to the laparoscopic and open hernia repair techniques since 1982, when Ger described the first endoscopic technique.^{6,7}

Laparoscopic inguinal hernia repair has been achieved with various methods of fixation for the prosthetic mesh, such as tackers, sutures, or glues. In primary hernias, these neuropathic complications occur at a rate of 0–3%; in recurrent hernias, the rate rises to 5.7%.⁸ The cost reduction upon eliminating prosthetic patch fixation is a major concern in low-income countries.⁹

The current trial compared perioperative outcomes and cost efficiency of patch fixation versus prosthetic non-fixation in TAPP repair of groin hernia in sixty patients with inguinal hernia. Data were collected regarding age, gender, duration of surgery, LOS, type of inguinal defect, defect size, prosthetic curling, incidence of recurrence, NSAIDs consumption, neurologic complications,

prosthetic patch infection, and cost within the period of 6-months follow-up. The study included patients whose ages ranged from 24 to 66. Approximately 65.7 minutes were spent performing TAPP.¹⁰

The average operative time in the MRC trial group was 58.4 minutes. In this study, a mean of 60.44 minutes was recorded for those with mesh fixation and 40–83 minutes for those without.¹¹ The technical issues and learning curve were the reasons for the wide range of diversity in the procedure duration. Compared to other studies, ours had a similar operating time. No significant difference in operative time between the groups of the study, so prosthetic patch fixation is not a major factor affecting operative time.

A rate of 6–31% of complications occur perioperatively with TAPP. Among intraoperative complications, laparoscopic access injuries are the most common, followed by vascular injuries and spermatic cord injuries.¹² An intraoperative complication or technical failure and conversion to an open technique or visceral injury was not observed in this study.

The average hospital stay for the TAPP group was 1.52 ± 0.51.¹³ In this study, the average hospital stay in the mesh fixation group was 1.8 ± 0.72 days, and in the mesh non-fixation group it was 1.4 ± 0.91 days in comparison with other studies, there was no difference in LOS between the two groups. The endoscopic repair had the major advantage of allowing a rapid resume of work duties within a few weeks, even strenuous activities.

Prosthetic patch curling and migration are rarely recorded as a postoperative event. This problem may have been caused by the patch fixation patterns and mesh composition as well. Migration rates can be altered by changes in mesh tensile strength and movement. Biomaterials also have a role to play, since they determine the extent and degree to which they interact with the neighboring structures.¹⁴ In this clinical trial, no prosthetic patch curling or migration was recorded.

Patch infection and septic complications are rare events.¹⁵ In our study, mesh infection was not reported. Recurrence was not reported. As the mesh rolls away from the space of Retzius and medial inguinal triangle, various mechanisms of hernia recurrence

have been investigated. Incomplete dissection of MPO and improper patch size are the most common causes of recurrence.¹⁶

A randomized trial comparing stapled and non-stapled hernia repairs was conducted by Smith et al. in 502 consecutive patients undergoing elective TAPP. About 263 non-stapled repairs and two hundred seventy-three stapled repairs were performed, and the median follow-up was 16 months. The incidence of recurrence was not statistically different.¹⁷

During the preparation and placement of mesh, the number of clips was reduced, and the autonomic nerve course was carefully observed, thus reducing nerve irritations significantly.¹⁸ Due to meticulously avoiding nerve sites, there was no nerve entrapment in our study.

Non-steroidal anti-inflammatory drugs were given twice daily for 3–5 days with sufficient control of pain. In three studies, the financial burden of prosthesis fixation versus non-fixation was compared, and the biggest difference was in the cost of the tacks. Non-fixation is less expensive than permanent fixation since it provides the same effectiveness.¹⁹ It was the costs of tacks used in prosthetic patch fixation that determined the difference in financial burden between the two groups and it ranges from 425 to 480 USD according to the cost of tacker used. So, mesh fixation is costly in our country.

There is doubt about repair without mesh fixation and the risk of recurrence. Transabdominal preperitoneal repair with fixation increases cost which is important in developing countries. It was a significant parameter, especially in low-income countries which may determine the approach. This study had some limitations like a small sample size, selection bias, and the cost of tackers. It needs to be extended to include different strata of people in multiple centers on a wide scale.

CONCLUSION

Non-fixation of mesh is a valid method and less costly that has the same benefits and excludes risks of fixation. Hernia recurrence seems not to be increased by non-fixation with no difference as regards procedure duration, intraoperative injury, patch migration, nerve entrapment, stay, and postoperative analgesia.

Clinical Significance

Transabdominal preperitoneal hernia repair with fixation increases the cost which is important in developing countries with no significant difference with non-fixation about the postoperative outcome.

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