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Evaluation of new technique of mesh fixation in laparoscopic inguinal hernia repair

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ABSTRACT

Background: Hernia is a common problem of the modern world with an incidence ranging from 5 to 7%. Of all groin hernias, around 75% are inguinal hernias. Recently with the advancement in laparoscopy, endoscopic repairs seem to offer better quality of life, decreasing hospital stay and early return to work. Aim of the work was to evaluate a new technique for mesh fixation by Zein method of suturing and compare it with stapled mesh fixation in laparoscopic inguinal hernia repair transabdominal preperitoneal approach.

Methods: The study is a randomized, prospective single group study. The study was conducted after the approval of the ethical committee of the surgical department, Menoufia University. It was conducted in Menoufia University Hospital on 50 patients with inguinal hernia who were operated upon between September 2018 and September 2019 with a minimal follow-up of 6 months.

Results: Age of studied patients ranged from 27 to 55 years with mean 42.82±7.90 age/years. Regarding sex of studied patients, more than half (74%) of studied patients were males and (26%) were females. Regarding comparsion between high and low overall cost burden on the patient, it was interestingly found that high cost is associated with presence of complication like hematoma, prolonged stay in the hospital and prolonged use of antibiotics.

Conclusions: Both the use of sutures and fixation of mesh by absorbable tacks approaches are similarly effective in terms of operative time, the incidence of recurrence, complications, and chronic pain coinciding with all the available literature.

Keywords: Laparoscopic inguinal hernia repair, Mesh fixation, Transabdominal preperitoneal, Zein technique

INTRODUCTION

Hernia is a common problem of the modern world with an incidence ranging from 5 to 7%. Of all groin hernias, around 75% are inguinal hernias.1 In the early 1990s Arregui and Doin described the techniques of the inguinal laparoscopic hernioplasty including: transabdominal preperitoneal (TAPP) repair. Around the same time Phillips and McKernan described the totally extraperitoneal (TEP) technique of hernioplasty. In both these repairs, the mesh in direct contact with the fascia of the transversalis muscle in the preperitoneal space allows tissue ingrowths leading to the fixation of the mesh.2

The general indications for laparoscopic inguinal hernia repair as opposed to watchful waiting are the same as those for open inguinal hernia repair. Classically, the existence of an inguinal hernia has been considered sufficient reason for operative intervention.³ Some reports have listed specific indications for laparoscopy over open repair, including recurrent hernias, bilateral hernias, and the need for earlier return to full activities.⁴ Several studies have demonstrated salutary outcomes for laparoscopic repair of recurrent hernias.⁵ In TAPP repair, titanium tacks also have traditionally been used to fix the mesh and can also be used to close the peritoneal flap. However, a 2011 report showed that acute pain was increased when more than 10 tacks were placed. A

number of surgeons have now switched to using absorbable tacks to fix the mesh and close the peritoneum. Sutures or hernia stapling devices can also be used.⁶ Some authors have advocated the use of fibrin glue to fixate the mesh.⁷ Still other authors use no fixation at all but instead rely on peritoneal pressure to maintain the mesh in proper position.⁸ Other surgeons use a self-fixating mesh (ProGrip mesh): self-adhesive meshes are a relatively new advancement in inguinal hernia repair. They have been on the market since 2006 and have been used in both open and laparoscopic operations.

Recently, another method of mesh fixation was added; transfascial, nonabsorbable sutures. This technique offers initially greater tensile strength than spiral tackers. Postoperative pain following suture fixation is significantly higher at 6 weeks postoperatively, and some patients suffered from nerve irritation at sites of sutures. However, after 6 months, no difference is found between the two techniques. Pain after mesh fixation with sutures is likely due to nerve irritation or entrapment and the relatively small distance between individual sutures used. The significant reduction of pain between 6 weeks and 6 months post operation in these patients could be due to desensitization of entrapped nerve fibers or due to resolution of local inflammation.

Moreover, sutures provide more rigid fixation to the fascia of the abdominal wall. These findings are of importance for the treatment of hernias especially those typically exposed to more intra-abdominal pressure requiring increased tensile strength for mesh fixation.

In the study, a new method of suture fixation of mesh in laparoscopic inguinal hernia is discussed as regards the intraoperative time, complications, postoperative pain, return to normal activity, and incidence of recurrences.

METHODS

This study is a randomized, prospective single group study conducted after the approval of the ethical committee of the surgical department, Menoufia University.

All the patients who participated in the study were informed about all the steps and signed the informed consent of the whole work. It was conducted in Menoufia University Hospital on 50 patients with inguinal hernia who were operated upon between September 2018 and September 2019 with a minimal follow-up of 6 months. An informed consent was taken from all patients who accepted to participate in the study.

Inclusion criteria

Inguinal hernia whether primary or recurrent, which is reducible hernia, indirect hernia or direct hernia,

unilateral or bilateral hernia, and male or female patient age 14-60 years.

Exclusion criteria

Strangulated or obstructed hernia, irreducible hernia, concurrent femoral hernia, patients who had a predisposing factor which was untreated as prostatic enlargement, chronic obstructive airway disease, chronic constipation or patients who could not withstand general anesthesia were also excluded from this study, patients of age less than 14 or more than 60 years, Prior pelvic surgery or prostatectomy, and patients with bleeding tendency.

All patients in the study were under supervision of the same surgical team. The 50 patients were divided into two groups according to the overall cost of the procedure. Patient selection was randomized using the closed envelope method. Laparoscopic TAPP approach was offered to all patients.

- Group A: 28 patients with inguinal hernia which an overall cost exceeds 2000 Egyptian pound.
- Group B: 22 patients with inguinal hernia which an overall cost exceeds 2000 Egyptian pound.

Methods

The patients were subjected to the following preoperative assessment.

Clinical history

- Personal history including age, occupation, and special habits of medical importance particularly smoking, complaint, and its duration.
- History of present illness including complaint analysis; onset, duration, increasing and decreasing factors, and a review of other body systems especially chest complaints, bowel and urinary problems like constipation and prostatism.
- Past history of medical issues, allergy to drugs, prior blood transfusion, and previous operations done before, with special concern to complications of the hernia or prior attempts of treatment.
- Family history of inguinal hernia and other common diseases in the family.

Clinical examination

- General examination including vital data; examination of chest for signs of chronic obstructive lung disease; examination of the abdomen for abdominal masses, and digital rectal examination for enlargement of the prostate.
- Local examination of the inguinal region and scrotum to confirm the diagnosis of inguinal hernia and its type, and for the presence of complications.

Routine investigations

All patients were requested to undergo the routine investigations, including complete blood picture, coagulation profile, liver and kidney function tests, fasting blood sugar, chest radiograph and pelviabdominal ultrasound. Special investigations were requested for patients with specific problems such as pulmonary function tests for patients with manifestations of chronic obstructive airway disease; ECG for patients above the age of 40 years.

Intraoperative assessment

An infraumbilical incision was done, with placement of a 10-12 mm trocar, and the abdomen is insufflated. A10-mm 30° scope is then placed through the trocar, allowing viewing the peritoneal cavity. Two lateral trocars (5 and 12 mm) are placed at the level of the umbilicus and just lateral to the rectus at approximately the midclavicular line. After ports were placed, diagnostic laparoscopy of the whole abdomen was necessary to exclude other pathology or contraindications for surgery and for identifying hernia defects and to confirm whether they were direct or indirect defects.

The following key structures should be identified:

- Median and medial umbilical ligaments.
- Lateral umbilical ligament and epigastric vessels.
- Vas deferens and spermatic vessels.
- Iliac vessels.
- Hernia defect (direct or indirect).

After identification of the anatomy, we used laparoscopic scissors to raise the peritoneal flap extending between the anterior superior iliac spine and the medial umbilical ligament. Special attention was needed to keep the incision superior to the potential spaces for both direct and indirect hernia defects. We extended the peritoneal flap far enough the cephalad to ensure that it can cover the mesh completely and exclude it from the peritoneal cavity. Before dissection of the hernia sac, the following structures should be identified:

- Pubic symphysis.
- Cooper's ligament.
- Iliopubic tract.

During dissection, care was taken to identify the triangle of doom, which contains the external iliac vessels and is bound medially by the vas deferens and laterally by the gonadal vessels. If the hernia sac was not reduced during the dissection of the peritoneal flap, it was usually reduced by applying gentle traction on the peritoneal attachments within the defect. In cases of long indirect sac, transection of the sac using electrocautery was applied. We will apply direct absorbable sutures over mesh. After peritoneal closure, the ports were removed under direct vision. All skin incisions were then closed.

Assessment parameters

Intraoperative parameters such as operative time (min) was calculated from the induction of pneumoperitoneum till wound closure and intraoperative complications.

Postoperative parameters (within the hospital stay) such as postoperative pain, postoperative complications (scrotal edema, hematoma, and infection) and early ambulation.

All the patients were discharged on the next postoperative day and instructions were given to them including medication, wound dressing, and recommended activity profile.

Follow-up parameters

All patients were followed up at surgery outpatient clinic after 1 week, 1 month, 3 months and 6 months. However, all patients were instructed to seek our advice whenever they notice something abnormal.

During follow-up visits, the following were to be detected:

- Time of return of the patient to his work.
- Wound infection.
- Late postoperative complications (chronic pain was
 defined as the presence of inguinal or scrotal pain or
 pain in the midthigh area postoperatively, which
 lasts for more than 3 months, in accordance with the
 International Association for the Study of Pain
 recommendations with or without an alteration in
 sensitivity, as mentioned by the patient and by
 physical examination).
- Detection of recurrence and its type (recurrence was defined as a palpable hernia or a clear defect in the abdominal wall, which can be confirmed by an ultrasound).

Statistical analysis

Data were collected, revised, coded, and entered to the Statistical Package for the Social Sciences (IBM SPSS, Cairo, Egypt), version 23. The quantitative data were presented as mean, SDs, and ranges when their distribution was found parametric. Also qualitative variables were presented as number and percentages. The comparison between groups with qualitative data were done by using the $\chi 2$ test and Fisher's exact test instead of the $\chi 2$ only when the expected count in any cell was found to be less than 5.

The comparison between two independent groups with quantitative data and parametric distribution was done by using the Independent t test while the comparison between the two paired groups with quantitative data and parametric distribution was done by using the paired t test. The confidence interval was set to 95% and the

margin of error accepted was set to 5%. So, the p value was considered significant as the following:

- P value more than 0.05: nonsignificant.
- P value less than 0.05: significant.
- P value less than 0.01: highly significant.

RESULTS

This is a prospective study that was done in Menoufia university hospital (Shebeen Elkom, Egypt) conducted in Menoufia University Hospital on 50 patients with inguinal hernia who were operated upon between September 2018 and September 2019 with a minimal follow-up of 6 months.

The included consecutive patients included in this study are divided into two groups:

- Group A: 28 patients with high overall cost.
- Group B: 22 patients with low overall cost

Age of studied patients ranged from 27 to 55 years with mean 42.82 ± 7.90 age/years. Regarding sex of studied patients, more than half (74%) of studied patients were males and (26%) were females. Time of operation ranged from 32-45 minutes with mean 40.06 ± 3.260 minutes. While, Post-operative pain ranged from 1 to 3 with mean 1.90 ± 0.36 (VAS score).

All of the studied patients hadn't seroma and infection. On the other hand, 2% of the studied patient had Hematoma and 98% had not Hematoma. Most of the studied patients hadn't recurrence of disease after 3 and 6 months except 1 patient (2%) had recurrence after 6 months. Hospital stay of studied patients ranged from 1 day to 6 days with mean 1.52±0.81 day. Regarding Antibiotic use ranged from 4 to 7 with mean 6.48±0.76.

Regarding comparison between high and low overall cost burden on the patient, it was interestingly found that high cost is associated with presence of complication like hematoma, prolonged stay in the hospital and prolonged use of antibiotics with significant p value (0.04, 0.02, 0.01 respectively).

Table 1: Distribution of the studied patients regarding age and sex.

Variable	Studied patients (n=50)		
Age in year			
Mean±SD	42.82±7.90		
Range	27-55		
Sex	N	%	
Male	37	74	
Female	13	26	
Total	50	100.00	

Table 2: Distribution of the studied patients regarding time of operation and post-operative pain.

Variable	Studied patients (n=50)		
Time of operation			
Mean±SD	40.06±3.260		
Range (min)	32-45		
Post-operative pain			
Mean±SD	1.90±0.36		
Range (no)	1-3		

Table 3: Distribution of the studied patients regarding seroma, hematoma and infection.

Studied patients (n=50)	N	%
Seroma	•	
No	50	100.0
Yes	0	0.00
Hematoma		
No	49	98.00
Yes	1	2.00
Infection		
No	50	100.00
Yes	0	0.00

SD: standard deviation

Table 4: Comparison between high cost and low cost groups regarding complication.

Complication	All participants	(n=50)	High cost	(n=28)	Low cost	(n=22)	X² test/ Anova	P value
	Number	(%)	Number	(%)	Number	(%)		
Seroma	0	0	0	0	0	0	1.2	0.87
Hematoma	1	2	1	3.50	0	0	42	0.04
Infection	0	0	0	0	0	0	1.2	0.87
Recurrence (3 months)	0	0	0	0	0	0	1.2	0.87
Recurrence (6 months)	1	2	1	3.50	0	0	42	0.04

Table 5: Comparison between high cost and low cost groups regarding intraoperative parameters.

Parameter	All participants	High cost	Low cost	X² test/Anova	P value
Time of operation	40±3.2	43.7±4.2	38.1±3.3	3.9	0.04
Postoperative pain	1.9±0.3	1.96±0.33	1.8±0.39	2	0.16
Hospital stay	1.5±0.8	2.8±1.2	0.9 ± 0.3	4.5	0.02
Antibiotic use	5.4±0.76	7.2 ± 0.86	4.3±0.32	6.8	0.01
Overall cost	2096± 221	2290±264	1840± 28	12.4	0.001

Table 6: Comparison between high cost and low cost groups regarding sociodemographics.

Parameter	All participants	High cost	Low cost	X² test/Anova	P value
Age	42.8±7.9	43.4±8.1	42±7.6	0.37	0.54
Sex				52.1	0.001
Male	23	11	12		
Female	27	17	10		

DISCUSSION

The choice of an appropriate surgical approach is difficult in the treatment of inguinal hernia. ¹⁰ Laparoscopic repairs provide very good results as it has lower postoperative pain, fewer wound infection, and quick return to daily activity. ¹¹ A recent meta-analysis comparing between the laparoscopic repair versus open Liechtenstein procedure showed that significantly fewer patients with chronic pain were found in the laparoscopic group. Patients treated by laparoscopy had a significantly earlier return to normal daily activities than patients of the Lichtenstein group but the main disadvantage of laparoscopic repair has been the duration of the operation as the mean operative time was significantly longer in the laparoscopic operations. ¹⁰

The longstanding standard practice for TAPP was to use mesh fixation with tackers to prevent recurrence but atraumatic mesh fixation methods are being increasingly used to prevent chronic pain in the wake of traumatic fixation methods. The current surgical options for mesh fixation include sutures, tacks or staples, self-fixing meshes and fibrin or other glues. However, there is no consensus on the best surgical technique and the choice of options often depends on surgeons' personal preference. 13

This study was conducted to evaluate mesh fixation by absorbable sutures from different points of view including operation duration, postoperative pain that was assessed using the patient-dependent visual analog score, postoperative complications, postoperative hospital stay, time needed to return to normal activity, and most importantly the recurrence. We wanted also to present our experience in using this novel method of fixation and evaluate early outcomes of patients who had undergone TAPP inguinal hernia repair. The study enrolled 50 patients with inguinal hernia who underwent laparoscopic TAPP inguinal hernia repair for 12 months (from September 2018 till September 2019), and the patients were divided into two groups:

Group A: 28 patients with inguinal hernia which an overall cost exceeds 2000 Egyptian pound.

Group B: 22 patients with inguinal hernia which an overall cost exceeds 2000 Egyptian pound.

The patients were seen at the outpatient clinic for following up the recurrence rate in both groups after 1 week, 3 month, and 6 months by adequate history and physical examination. None of the patients recruited into the study was excluded, withdrew from or died during the course of the trial, and thus all patients were included in the analysis.

Patients in both groups were similar with respect to age; the patients ages ranged from 14 to 60 years, with mean age 42 years. Regarding sex of studied patients, more than half (74%) of studied patients were males and (26%) were females. This age of presentation is noticed to be earlier than various studies assessing the Mesh fixation as in a recent study conducted by Birk et al.9 More than 220 hernias with a mean follow-up at 23 months in Germany, the mean age of the studied population was 54 years, the younger age of presentation in our study is surely explained by the heavy occupational nature of most of the studied cases adding to the value of our study in evaluating the procedure in different age groups. The same age group was observed in an Indian study recently which studied the inguinal hernia risk factors. It stated that the age range of the most common patients who suffered from inguinal hernia ranged from 46 to 60 years.16 Most of the studied patients were men to match the male predominance as regards the patient's flow for recruitments and this predominance of hernia in men was attributed to the fact that there was involvement of more strenuous exercises and lifting of weights by them and the anatomical differences between the two sexes. 17

The mean operative time in the SGM group was 40 minutes ± 3.2 min for and this is low than the operation time taken during a prospective randomized trial conducted by the University of Turin in Italy which

assessed stapled mesh fixation in laparoscopic inguinal hernia repair in young and elderly patients as their operation time ranged from 74.4±12.8 min. ¹⁸ The same operation time was taken in a study which included 96 patients comparing in a prospective manner between SGM versus staple fixation in laparoscopic inguinal hernia where the mean duration of the procedures was 43 min in the staple group. ¹⁵ No significant difference was found between the operation time length needed to apply mesh versus mesh fixation with tacks approach. However, the sutures needed some experience to place it correctly and this handling improved with time.

In our study, there were no cases of severe chronic pain in the sutures, similarly Ferrarese et al. also had the same finding on the assessment of chronic pain, after TAPP surgical repair with sutures over 142 patients. 18 Only 20% of cases suffered from mild thigh and scrotal pain in the stapled group which improved after 2 months. We believe that pain was attributed to mild neuritis because of the application of tacks nearby the neurovascular structures. No serious adverse event was reported. Sutures by Zein method has the advantage of atraumatic fixation which is associated with reduced risk of neurovascular injury or chronic postoperative pain and consequent earlier resumption of physical and social activities. That finding coincides with most of the prospective studies which assessed the sutures in terms of postoperative and chronic pain, as in a German study; 169 male and female patients with 220 primary inguinal hernias had surgical repair by the laparoscopic TAPP approach with 23 months' follow-up, where the majority of patients had no pain and only mild pain was experienced by 3.6% of patients, and 1.2% of patients experienced severe pain confirming that our method is rapid, efficient, and safe resulting in a very low incidence of chronic groin pain.9

Even though fixation of the mesh might have an impact on recurrence rates, surgical site infections, postoperative chronic pain or quality of life, no accepted gold standard exists on whether, when, and how to fixate the mesh.²¹ In the 'guidelines for laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia' of the International Endohernia Society, it is stated that only one study compared fixation versus nonfixation in TAPP repair and found no significant differences in the incidence of recurrence between fixated and nonfixated repairs.²² Then the International Endohernia Society updated its guidelines for TEP and TAPP hernia repair in 2015 and concluded 'in case of TAPP repair nonfixation should be considered in types LI, II, and MI, II hernias (EHS classification)' (grade B recommendation).²³ Another recent analysis compared the recurrence rates on 1-year follow-up in respect of mesh fixation versus nonfixation in TAPP. Univariable analysis did not find any significant difference between these two parameters, confirming that mesh fixation did not have any relevant impact on the recurrence rate regardless of the defect size.¹² In a meta-analysis examining the use of tacker fixation versus no fixation of mesh in laparoscopic inguinal hernia repair conducted by Sajid et al. concluded that 'nonmesh fixation in laparoscopic inguinal hernia repair does not increase the risk of hernia recurrence' and stated 'based upon the results of this review nonmesh fixation approach may be adopted routinely and safely in laparoscopic inguinal hernia repair.'24 Also according to Amirzargar et al. who conducted a study in 2013 comparing mesh fixation with nonfixation in TAPP repair stating that 'laparoscopic TAPP inguinal hernia repair without mesh fixation is safe and feasible with no increase in recurrence rate.²⁵ In addition, it offers a significantly shorter operation time than TAPP mesh fixation.' Our data agreed with all that previously mentioned literature, no difference in terms of recurrence was detected between sutures fixation versus mesh fixation by absorbable tacks. Studies have shown that nonfixation hernia repair is generally more cost-effective than repair with mesh fixation.²⁶ However, the use of sutures avoids the cost of a fixation device (instrument or fibrin glue), therefore, decreasing the overall cost of the TAPP procedure. As confirmed by Romario F et al., the cost of the material used for suturing was lower than the cost of the material for staples, making it also costeffective and weighs in favor of suturing.¹⁵ However, Elden A et al reported that there is less postoperative pain in mesh fixation with fibrin glue and less analgesia is needed after the operation compared with mesh fixation with staples.²⁷

This study demonstrates that laparoscopic inguinal hernia repair using the TAPP technique with implantation of a new Suture mesh fixation technique is a fast, effective, and reliable Laparoscopic inguinal hernia repair TAPP technique Khalil et al. method in experienced hands, which combines the advantages of laparoscopic approach with simple and practical implantation of self-fixation mesh, which, according to our results, reduces the occurrence of chronic pain and the recurrence rate. The current study has some limitations related to the relatively small number of pooled patients and to overcome this limitation, we recommend a further study on a larger scale with larger numbers of study population. Also, most of the patients are men, but since it is reasonable to assume that hernia types in women are similar, and possibly also easier to repair, women might also benefit from this type of procedure, provided there are no copathologies that are contraindications for laparoscopic surgery. The average follow-up of the patients was just 6 months which is reasonable for detecting early recurrences as an evaluation of both laparoscopic methods. However, more time is required for longer follow-up of the patients to detect late recurrences (which is more relevant) and to conclude the outcome of both approaches.

CONCLUSION

Both the use of sutures and fixation of mesh by absorbable tacks approaches are similarly effective in

terms of operative time, the incidence of recurrence, complications, and chronic pain coinciding with all the available literature. High cost is associated with presence of complication like hematoma, prolonged stay in the hospital and prolonged use of antibiotics

However, further research is recommended for a longer period of time and a bigger sample size in order to generalize the results.

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Institutional Ethics Committee

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