Fixation versus non fixation of mesh in laparoscopic totally extraperitoneal inguinal hernia repair (TEP)

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Abstract

Background: Persistent groin pain is reported by a significant number of patients following laparoscopic totally extraperitoneal hernia repair (TEP). Mesh fixation has been implicated as a possible cause, but is widely considered essential for mesh stabilization and early recurrence prevention. This study questioned whether elimination of fixation of the mesh during TEP inguinal hernia repair leads to decreased postoperative pain or complications, or both, without an increased rate of recurrence.

Methods: A randomized prospective study was carried out on 60 adult male patients who underwent laparoscopic TEP inguinal hernia repair with group A (30) or without group B (30) fixation of the mesh.

Results: Patients in whom the mesh was not fixed had less postoperative pain (P value <0.001), shorter hospital length of stay (24.2 versus 28.8 and P value <0.034)and used less postoperative narcotic analgesia. No significant differences occurred in the rate of postoperative complications, time to return to normal activity or the difficulty of the operation between the two groups. No hernia recurrences were observed in either group (follow-up range, 1 to 12 months).

Conclusion: Non fixation of mesh during laparoscopic TEP inguinal hernia repair significantly reduces the level of postoperative pain, hospital length of stay and the economic cost. On other hand, non fixation of mesh does not lead to an increased rate of recurrence.

Key words: Hernia, TEP, laparoscopic.

Introduction:

Approximately 20% of all inguinal hernias are repaired laproscopically, primarily in a preperitoneal fashion totally extraperitoneal (TEP) in which the hernia defect is covered with a prosthetic mesh that is fixed to the abdominal wall with spiral tacks, clips, or sutures. The need for fixation of the mesh is controversial. Some have suggested that fixation of mesh during endoscopic TEP inguinal hernia repair is necessary to prevent hernia recurrence.[1] However whilst usually less problematic than following open repairs, new postoperative groin pain is still reported by approximately one fifth of patients following TEP; the common practice of using metal staples to fixate mesh to the groin has been implicated as a possible cause.[2]

The purpose of this study was to compare between fixation of mesh versus non fixation during laparoscopic total extraperitoneal inguinal hernia repair.

Patients and methods:

This study is a randomized prospective study. It was conducted on sixty adult male patients presenting with inguinal hernias. These patients were admitted from those attending the surgical outpatient clinics of Ain-Shams University Hospitals, during the period from October 2007 till April 2010 with inclusion criteria included inguinal hernia of any type direct or indirect, primary or recurrent, unilateral or bilateral (Nyhus type I, II and IIIA). The exclusion criteria included patients with indirect large hernia "scrotal type" (Nyhus classification type IIIB), femoral hernia (Nyhus classification type IIIC), incarcerated hernia, patients with pervious lower abdominal surgery as Pfannenstiel, lower midline and other

abdominal incisions below the umbilicus on the same side of the hernia were excluded from this study. Patients who wouldn't be able to participate in the post-operative follow up owing to drug misuse and psychiatric disorders were also excluded. Patients with an untreated predisposing factor as prostatic enlargement, chronic obstructive air way disease, chronic constipation or patients unfit for general anesthesia were also excluded from this study. All patients in this study were under the care of one surgical team under supervision of consultant surgeon. After obtaining a clear informed consent, the patients were randomized into two groups by computer - generated random allocation software. The first group (A) includes thirty patients and was operated upon by a laparoscopic totally extra-peritoneal inguinal hernioplasty technique with fixation of the mesh by spiral tacks, clips, or sutures. While the second group (B) includes thirty patients and were operated upon by a laparoscopic totally extra-peritoneal inguinal hernioplasty technique without fixation of the mesh.

Preoperative assessment:

Detailed history was obtained from patients including personal history, history of present illness, past history and family history and full clinical examination including, general examination and 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 were requested for all patients, including complete blood picture, coagulation profile, liver and kidney function tests, fasting blood sugar, chest x-ray and pelvi-abdominal U/S. Special investigations were requested for patients with specific complaints as pulmonary function tests for patients with manifestations of chronic obstructive airway disease; ECG for patients above the age of 40, sigmoidoscopy for patients with chronic constipation; hepatitis markers and serological tests in patients with elevated liver enzymes; scrotal U/S for cases associated with varicocele or hydrocele. Preoperative management of co-morbidities like smoking, chest disease, diabetes mellitus, cardiac disease, hepatic disease and chronic constipation was properly carried out so that all patients were properly prepared for surgery. All patients were fit for general anesthesia.

Surgical techniques:

TEP endoscopic inguinal hernia repairs were performed with the patients under general anesthesia by using a midline, 3-trocar technique. After creation of preperitoneal space and pneumo preperitoneum occurred, identification of the anatomical land marks was necessary which are; inferior epigastric vessels in the roof of the dissected space, pubic bone and the arcuate line. The retropubic space was opened by blunt dissection so that the whole of the pubic arch could be seen well across the midline. Dissection of hernial sac occurred from medial to lateral until it was completely separated and delivered back into the abdominal cavity. For all cases we have used a standard polypropylene 10cm x 15cm mesh placed down through the 10mm port. The mesh was trimmed to the appropriate size to cover the entire myopectineal orifice including the hernia defect(s) without fixation in the non fixation group (Group B) **Figure(1)**. In the fixation group (Group A) the mesh was tacked to Cooper's ligament and the anterior abdominal wall using 4 titanium spiral tacks) **Figure(2)**. Certain parameters were assessed during the operation including operative time in minutes which was calculated from the time of induction of pneumo-peritoneum till closure of the wounds and the occurrence of intra-operative complications.

Figure (1): Placement of the mesh. (Non fixation).

Figure (2): Placement of the mesh. (Fixation with spiral tacks).

Postoperative assessment:

Postoperative pain was assessed using the visual analogue scale (VAS), which is a straight line (10 cm) with the left end of the line representing no pain and the right end of the line representing the worst pain (Briefly, patients were asked to indicate an image of a face that most closely expressed their level of post-operative pain). Each image was associated with a score between 0 (no pain) and 10 (severe pain). Patients were asked to rate their pain in this way at 24 hours, 7 days, and after 4 weeks. Early postoperative complications (scrotal edema or hematoma, wound seroma or infection and urinary retention), postoperative hospital stay in hours, early ambulation and lastly the economic cost all were also assessed **Figure(3)**.

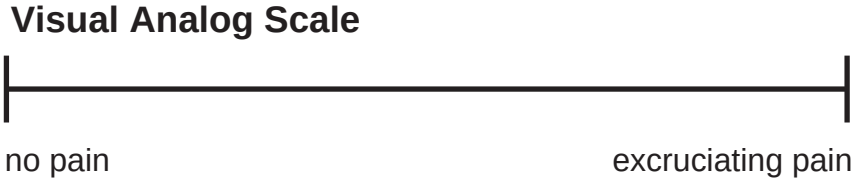

Figure (3): Visual Analogue Scale.

Follow-up parameters:

All patients were followed-up at surgery outpatient clinic after 1 week, then 1, 4 and 12 months later using a standardized telephone script. However, all patients were instructed to seek our advice whenever they notice something abnormal. During follow-up visits, time at which the patient returned to his work, late post-operative complications like chronic pain (chronic pain which was defined as the presence of inguinal or scrotal pain or pain in the mid thigh area postoperatively, lasting for more than 3 months, in accordance with international association for the study of pain recommendations with or without an alteration in sensitivity, as mentioned by the patient and located on physical examination) and detection of recurrence and its type were recorded. Recurrence was defined as a palpable hernia or a clear defect of the abdominal wall, which in the event of doubt was confirmed by ultrasound.

Statistical Analysis:

The collected data was revised, coded, tabulated and introduced to a PC using statistical package for social science (SPSS 15.0.1 for windows). Data was presented and suitable analysis was done according to the type of data obtained for each parameter. Continuous data were presented as mean ± standard deviation, and discrete data were presented as counts and percentages. For independent-samples T-test was used to assess the statistical significance of the difference between two study group means and the Chi-square test was used to examine the relationship between two qualitative variables. P-value (level of significance) was non significant (NS) if > 0.05, significant if P < 0.05 and highly significant (HS) if P<0.01.

Results:

Randomization (Group A: with fixation, Group B: without fixation) and follow-up were complete in all 60 male patients **Table(1)**. Group A patients had higher levels of pain throughout the postoperative course in the early 24hours, after one week and after 4 weeks **Table(2)**. Level of pain experienced by patients postoperatively correlated with the use of postoperative narcotic analgesia and was measured using visual analog scale with a mean VAS 2.9±0.7 for Group B versus 3.5±0.7 for group A in the early 24 hours with a highly significant p value (P=0.0016). Additionally, patients in whom mesh was not fixed (Group B) used significantly less postoperative narcotic analgesia in the immediate postoperative period compared with patients in whom mesh was fixed (mean VAS 1.1±0.3 versus 1.6±0.4 with P=0.06). Group B patients experienced reduced hospital length of stay and were less likely to be admitted to the hospital for 23-hour observation compared with Group A patients. Group B patients had a mean hospital length of stay of 23.2±3.45 hours versus 28.8±4.70 hours for group A patients (P=0.034). Use of preformed mesh without fixation did not result in increased operative difficulty or operative time with a mean time of 32.8±5.7 minutes for group B versus 39.7±6.4 minutes for group A (P=0.480). We had no early or late post-operative complications. No difference was noted in the time to return to normal activity with lifting restrictions between the 2 groups. None of the patients in either group returned to normal activity at one week. Long-term follow-up (range, 1, 4 and 12 months) showed no recurrences or nerve injuries.

Table (1): Patient demographics.

	Fixed mesh (n=30)*	Nonfixed mesh (n=30)*	P value
Age	43.9±5	44±5	0.938
Total hernias			
- Indirect	19(63.3%)	21(70%)	0.71
- Direct	8(26.7%)	7(23.3%)	
- Pantaloon	3(10%)	2(6.7%)	
Site of hernia			
- Unilateral	23(76.7%)	25(83.3%)	0.671
- Bilateral	7(23.3%)	5(16.7%)	
Type of hernia			
- Primary	28(93.3%)	27(90%)	0.77
- Recurrent	2(6.7%)	3(10%)	

**Data expressed as mean ± SD or proportion (percentage of population).*

Table (2): Operative and post operative data.

	Fixed mesh (n=30)*	Nonfixed mesh (n=30)*	P value
Operative time	39.7±6.4 min.	32.8±5.7 min.	0.480
Post operative pain			
- Early 24 hr	3.5±0.7	2.9±0.7	0.0016
- After 1 week	1.6±0.4	1.1±0.3	0.06
- After 4 weeks	0.9±0.3	0.6±0.24	0.08
Post-operative hospital stay			
- < 24 hr	15 (50%)	24 (80%)	
- 25 - 48 hr	9 (30%)	5 (16.7%)	
- 49 - 72 hr	6 (20%)	1 (3.3%)	0.034

**Data expressed as mean ± SD or proportion (percentage of population).*

Discussion:

The necessity of fixing the mesh to prevent recurrence of hernias following endoscopic preperitoneal inguinal hernia repair is still an unresolved issue. Many surgeons who perform TEP appear to hold the unproven belief that mesh fixation is necessary for the prevention of hernia recurrence. At the same time it is widely acknowledged that this need for surgical fixation is only temporary, as tissue incorporation into the mesh, characterized by significant cellular ingrowth by two weeks and collagen deposition within two months, achieves effective permanent fixation.[3] Various fixation techniques have been described. Laparoscopic placement of sutures is time consuming and cumbersome. A recent report describes the use of biodegradable adhesives to secure the mesh in place. The adhesive theoretically fixes the mesh until fibrosis takes place. The glue then degrades and is absorbed. Although this technique avoids the risks of mechanical stapling, experience is limited and it requires further evaluation. Mechanical fixation using staples involves added expense and operating time is associated with specific complications. For example, staples placed medially into the pubis can result in troublesome osteitis. Pain or paresthesia can result from impinging on the ilioinguinal, iliohypogastric , or lateral cutaneous nerve of the thigh.[4] There has been no consensus on the indications for stapling the mesh during TEP. Our study included 60 adult patients with inguinal hernias (Nyhus type I, II, IIIA). The patients were randomly divided; via the closed envelop method into two equal groups 30 patients each, to be treated by totally extra-peritoneal laparoscopic hernioplasty with fixation of mesh using single use titanium tackers versus non fixation of the mesh. The patients were followed up for a period of 1, 4 and 12 months. We compared both procedures in different aspects as regard the operative time, the occurrence of intra-operative complications (blood loss, vascular injuries, bladder injury), postoperative pain that was assessed using the patient dependant Visual Analog Scale, hospital stay in hours from the time of operation till the time of discharge, postoperative complications (including postoperative urinary retention, hematoma or seroma formation, pain and infection), recurrence rates and return to normal activity and finally the financial costs in Egyptian pounds. As regard operative time there was no significant difference between both techniques with a mean operative time 39.7±6.4 minutes for the fixation group and 32.8±5.7 minutes for the non fixation group, thus it is shown that there is around 7 minutes in favor of the non-fixation, that was proved to be statistically insignificant when proved by the P-value which was 0.48, thus the operative time is nearly the

same in both techniques. Our comparative study had a single case with intra-operative complications in both groups in which bleeding and oozing from abnormal obturator artery occurred and it was controlled by bipolar diathermy. This low complication rate was due to the very meticulous nature of our surgeons in their learning curves. We had two cases converted from laparoscopic to open repair in our study due to extensive adhesions which couldn't be dissected with the laparoscopic technique, and those cases were eliminated from the results of our study. Postoperative pain level in our study was assessed in both groups using the visual analogue scale that was decreased in the non-fixation group of patients compared with patients in whom the mesh was fixed; it was shown to be around 2.9 in the 1st 24 hours in the non fixation group and 3.5 in the fixation group with a P-value of 0.0016 (highly significant) and the same was in the late post-operative time of 4 weeks which was shown to be 0.6 in the non-fixation group versus 0.9 in the fixation group with a highly significant P value (0.08), thus the non-fixation has shown to have a significant effect in one of the most annoying postoperative conditions for the patients that is the postoperative pain. The post operative hospital stay in the non fixation group was statistically significantly less in the non fixation group, that parameter is evident in the 1st 24 hours discharged patients (24 patients for the non-fixation versus 15 patients of the fixation group), thus the non-fixation is shown to have an extra economic value in minimizing the overall costs.

Regarding post operative complications either early like urinary retention, hematoma or seroma collection, and wound infection or late like chronic groin pain in both groups, we had no complications reported. Also we had no recurrent cases in both groups in the relatively short follow-up period that was around 1 year postoperative. Regarding the financial costs, the tacker device that was used for fixation of the mesh via titanium tacks price was 1800 LE, for a single use disposable tacker per patient, thus the supposed savings in our study only was about 54,000 LE. Thus it is extremely evident that the non-fixation is a valuable technique in saving money not only in the shorter postoperative hospital stay but also in the actual costs that is highly significant in a country like ours with limited financial resources. Our results corroborate the results of others showing that inguinal hernia repair without mesh fixation is a safe alternative. A few multicenter studies have been performed to identify the mechanisms of hernia recurrence after laparoscopic hernioplasty. Inadequate fixation of the mesh, particularly at the lower medial corner, was found to be a common cause for the recurrence of inguinal hernia.[5] Phillips et al recommended using the largest possible piece of mesh and stapling it securely.[6] Lowham et al suggested that all small prostheses (12x12 cm^2) required fixation to the Cooper's ligament, the transversus abdominis aponeurosis, and the antero-lateral abdominal wall.[7] Tucker et al considered adequate fixation of the mesh critical in preventing early recurrence.[8] However, the results of others show that inguinal hernia repair without mesh fixation is a safe alternative. Ferzli et al conducted a randomized, prospective study comparing endoscopic TEP inguinal hernia repair with or without fixation of mesh and found that no increased incidence of recurrence occurred and that elimination of mesh fixation resulted in savings of $120 per operation.[9] Khajanchee et al conducted a retrospective review of 172 endoscopic inguinal hernia repairs of which 105 were performed with fixation of the mesh, and 67 were performed without mesh fixation and found no increased risk of recurrence in the group in which the mesh was not fixed and that fixing the mesh was associated with an increased risk of neuropathic complications.[10] Choy et al found that unfixed mesh could not be induced to move confirmed on inspection of the mesh by re-laparoscopy of the preperitoneal space.[11] This inherent stability was further confirmed by Irving through postoperative X-ray studies.[12] As TEP without fixation may not be appropriate in everyone, we support the recommendation of Lau and Patil that mesh fixation should be used in patients with larger hernial defects. Avoiding tacks when repairing small to medium indirect inguinal hernias and smaller direct defects seems to be logical.[13] The main arguments for

widespread use of TEP techniques without mesh fixation include less postoperative complications and early recovery. Lau and Patil conducted a case-control study comparing endoscopic TEP inguinal hernia repair with and without mesh fixation and found that early postoperative pain levels upon coughing were decreased in patients in whom the mesh was not fixed (P 0.05).[13] The issue of chronic inguinal pain following open and laparoscopic techniques is frequently discussed. Chronic groin pain was defined as the presence of inguinal or scrotal pain or pain in the mid thigh area postoperatively, lasting for more than 3 months, in accordance with International Association for the Study of Pain recommendations with or without an alteration in sensitivity, as mentioned by the patient and located on physical examination.[14] Reports of intractable pain syndromes vary considerably with regard to the prevalence of pain. Whereas a large-scale study by Tamme et al disclosed a prevalence of only 0.3% after TEP repair, the literature contains numerous studies documenting chronic pain prevalence rates of 9.2-22.5% after laparoscopic hernia repair.[15] Comparison of published papers shows that studies focusing on pain syndromes invariably report pain prevalence rates from 5% to more than 25%.[15] Callesen et al are therefore right in describing chronic inguinal pain as "the most serious problem that may affect the results of hernia surgery".[16] The use of the popular single-use titanium spiral tack applicator is costly high, adding much to the cost of laparoscopic hernia repair. The higher cost of laparoscopic hernia repair compared with open techniques has been a source of criticism by some surgeons, and has impeded its introduction into many public teaching hospitals.[17] As evidenced from the above discussion, the non-fixation technique is a successful choice in the TEP inguinal hernial repair that has no significant disadvantage over the conventional fixation of the mesh as regard the intra-operative and postoperative complications or the operative time, with an advantage of decreased postoperative pain and analgesia requirements, along with the highly significant financial advantages of the non-fixation method.

Conclusion:

Based on this study, there was no difference in recurrence rates between patients undergoing TEP repair with and without fixation of the mesh. No differences were found in the rates of return to work. Positioning of the mesh without stapling in TEP procedure eliminates the potential nerve damage that has been reported in the literature. Mesh fixation appears to be unnecessary in TEP repair of small hernial defects. It is associated with higher operative costs and an increased likelihood of developing chronic groin pain. The omission of mesh fixation did not increase the risk of early hernia recurrence.

However, additional studies with larger numbers of patients and longer follow-up will be required to answer the question unequivocally.

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