ORIGINAL RESEARCH PAPER
Volume - 12 | Issue - 05 | May - 2023 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

COMPARISON OF OUTCOME FOLLOWING TOTALLY EXTRAPERITONEAL REPAIR AND LICHTENSTEIN TENSION FREE HERNIOPLASTY FOR PRIMARY UNILATERAL INGUINAL HERNIA IN MALES

General Surgery

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ABSTRACT

In spite of a steep learning curve, laparoscopic Totally Extraperitoneal repair (TEP) promises less wound complications and shorter hospital stays over Lichtenstein's repair for primary unilateral inguinal hernia. We randomly allocated 50 male patients with primary unilateral inguinal hernia into two groups (21 in TEP group and 29 in open group) during a one year period and followed them up for a minimum of 3 months. Mean duration of surgery was 88.00 ± 28.12 minutes in laparoscopic repair versus 77.97 ± 22.22 minutes for open repair (p = 0.30). TEP group had significantly lesser wound complications overall **(p = 0.004)**, significantly shorter mean post-operative stay **(p< 0.001)** and earlier return to occupational work **(p< 0.00001)**. The incidence of groin pain at 3 months was again less in the TEP group (p = 0.70) with similar recurrences in both groups. So, TEP did not lead to increased recurrence but surprisingly offered better post-operative outcomes than Lichtenstein's repair.

KEYWORDS

Primary unilateral inguinal hernia, Laparoscopic repair, Totally Extraperitoneal repair, Lichtenstein repair

INTRODUCTION

The repair of inguinal hernia dates back to the ancient times. The breakthrough in understanding of the groin anatomy in the 18th century coupled with the pioneering herniorrhaphy technique of Edoardo Bassini (1844-1924) in the 19th century catapulted inguinal hernia repair into a successful venture with minimal morbidity [1]. Lichtenstein et al. ushered in a new era in 1989 by introducing the concept of open tension free hernia repair using prosthetic mesh reinforcement [2]. Inguinal hernia repair further underwent a paradigm shift with the description of Transabdominal Preperitoneal (TAPP) repair by Arregui [3] and Totally Extraperitoneal (TEP) repair by Ferzli and associates in 1992 [4].

Both Lichtenstein repair and endoscopic methods are now recommended for treatment of symptomatic primary unilateral inguinal hernia in adult men [5] but tension-free anterior mesh repair remains the clear favorite because of its lack of need for specialized equipment. Touted by critics to be burdened with steep learning curve, technical challenges, increased cost and longer operative times; the endoscopic techniques can lessen early postoperative pain resulting in less narcotic use and swifter return to normal activity and occupational work.

With the consistent reporting of ever decreasing recurrence rates, focus of hernia research has been drawn to issues like chronic groin pain and quality of life [6]. Small improvements in the post-operative outcomes of inguinal hernia surgery, which is being performed in more than 20 million people annually [7], can go a long way in alleviating the burden of this disease on society and this is where the laparoscopic repair of inguinal hernia can chip in.

Going with this analogy, we started TEP for primary unilateral inguinal hernia in males and report our experience and outcomes in this study.

METHODS

The present prospective randomized study was conducted in the Department of General Surgery, Pt. B. D. Sharma Institute of Medical Sciences, Rohtak from February, 2020 to March, 2021 after obtaining approval from institution ethics committee.

The study aimed at comparing the outcomes of TEP repair versus Lichtenstein's repair for primary unilateral inguinal hernia in males in terms of duration of surgery, post-operative pain, local complications and length of stay.

Inclusion Criteria

Male patients aged 18 years and above with primary unilateral inguinal hernia

Exclusion Criteria

Female patients, bilateral hernia, femoral hernia, recurrent and complicated hernias

Operative Procedure

Patients in both groups were given injection amoxicillin 1000 mg and clavulanic acid 200 mg intravenously half an hour before induction of anesthesia. Lichtenstein's repair was done under spinal anesthesia and TEP repair under general anesthesia.

Technique Of Lichtenstein's Tension Free Meshpasty

Through a groin incision, cord structures were dissected from cremaster muscle and transversalis fascia fibers and retracted off the inguinal canal floor to explore for hernia sac. Indirect sacs were ligated at the neck, cut and then inverted. The direct sacs were simply inverted. Posterior wall strengthening was done if found to be weak. A trimmed 7.5 cm × 15 cm polypropylene mesh was sutured to the aponeurotic tissue over the pubic tubercle, shelving edge of the inguinal ligament, rectus abdominis muscle and conjoint tendon with prolene sutures. A slit made at the lateral end of the mesh for the cord was sutured beyond it to create a new internal ring. External oblique aponeurosis was then re-approximated and skin closed with staples. Patient was made ambulatory after twenty-four hours and planned for discharge on second post-operative day unless there were complications.

Technique Of TEP Procedure

Through a sub-umbilical 1.2 cm skin incision, subcutaneous tissues were dissected till the visualization of anterior rectus sheath. The sheath was incised, rectus muscle fibers were retracted and the posterior rectus sheath was left intact. Space was created over the posterior rectus sheath by advancing a hemostat with a wet gauze piece at its tip. A 10 mm reusable port was then inserted, through which a zero-degree telescope was advanced till the pubic symphysis resulting in the separation of peritoneum from the rectus muscle. The pre-peritoneal space thus created was insufflated with carbon dioxide gas at a pressure of 12 to 14 mm Hg. Remaining two 5 mm ports were inserted in the midline under direct vision of the zero degree scope, the first at two finger breadths above the symphysis pubis and the second at midway between the two previously placed ports. Further lateral dissection was done till the anterior superior iliac spine with the assistance of 30-degree telescope. Medial dissection was done till the opposite iliopubic tract was exposed. Direct sacs were simply reduced and indirect sacs dissected free from the cord, ligated at neck and divided. Pneumoperitoneum created inadvertently was managed with insertion of a 5 mm port at Palmer's point. A 10 cm × 15 cm piece of polypropylene mesh was inserted via umbilical port after proper preparation, positioned and unfolded so that the entire myopectineal orifice was covered with good inferior, medial (crossing the midline) and lateral overlap. Mesh was then fixed at two points with tacks on the iliopubic tract. Gas was desufflated and skin closed with staples after re-approximation of anterior rectus sheath at the umbilicus. The patient was discharged the next day once he was ambulatory, started accepting orally and had passed urine comfortably.

Post-operative Management

In the post-operative period, two shots of amoxicillin 1000 mg and clavulanic acid 200 mg were given on the day of surgery and continued as oral amoxicillin 500 mg and clavulanic acid 125 mg tablet three times a day for next 2 days. Patients in both groups were given intra-muscular injections of diclofenac 75 milligrams eight hourly on the day of surgery, oral diclofenac 50 milligrams tablet thrice a day for next 2 days and then as per demand. Intra-muscular injection of diclofenac 75 milligrams was given as rescue analgesic. Oral fluids were allowed 6 hours after surgery and normal diet the next day. Visual analog scale was used to assess pain six hourly from day one till time of discharge.

Patients were followed up in the out-patient department at 1 week, 1 month and 3 months after surgery. The follow-up data for those patients who did not turn up for further follow-up was obtained by the means of telephonic interview.

Statistical Analysis

Statistical analysis was done using the IBM Statistics for Windows, version 25.0 (IBM Corp., Armonk, New York, USA). Continuous data were presented as Mean ± Standard Deviation and categorical data as numbers and percentages. Variables were compared using various statistical tests which-ever applicable and a p value of < 0.05 was considered as statistically significant.

RESULTS

A total of 75 patients who presented to the outpatient clinic over this period with groin hernia were assessed for inclusion into this study. Out of them, 50 patients were included and randomized into the two arms of the study. 29 patients underwent Lichtenstein tension free repair and 21 underwent TEP repair.

Patient Demographics

Patient characteristics have been shown in Table 1. Both the groups were comparable in terms of demographic profile.

Table 1: Patient demographics

Parameters	Procedure		p value
	Lichtenstein's repair (n = 29)	TEP repair (n = 21)	
Age (years) Mean ± SD	44.31 ± 17.64	41.81 ± 16.87	0.61[a]
BMI (kg/m2) Mean ± SD	21.90 ± 2.54	22.37 ± 2.99	0.85[b]
Occupation (%)			1.00[b]
Heavy	12 (41.4%)	8 (38.1%)	
Light	14 (48.3%)	11 (52.4%)	
Retired	3 (10.3%)	2 (9.5%)	
Duration of symptoms (months) Mean ± SD	11.72 ± 22.90	19.82 ± 35.45	0.76[c]

a: t-test, b: Fisher's Exact Test, c: Wilcoxon-Mann-Whitney U Test

Details Of Surgery

The operative details have been enlisted in Table 2.

Table 2: Details of surgery

Parameters	Procedure		p value
	Lichtenstein's repair (n = 29)	TEP repair (n = 21)	
Operative findings (%) Adhesions	2 (6.9%)	2 (9.5%)	1.00[b]
Direct sac	10 (34.5%)	4 (19.0%)	0.23[d]
Indirect sac	19 (65.5%)	17 (81.0%)	0.23[d]
Omentum as content	26 (89.7%)	21 (100.0%)	0.25[b]
Gut as content	3 (10.3%)	0 (0.0%)	0.25[b]
Duration of surgery (minutes) Mean ± SD Overall	77.97 ± 22.22	88.00 ± 28.12	0.30[c]
Hernia sac adhesions	65.50 ± 21.92	129.00 ± 72.12	0.67[c]
Direct hernia	73.00 ± 28.22	76.50 ± 3.87	0.32[c]
Indirect hernia	80.58 ± 18.67	90.71 ± 30.73	0.68[c]
Intra-operative bleeding (%)	0 (0.0%)	1 (4.8%)	0.42[b]
Cost (cost of mesh in rupees)	1450	4200	-

b: Fisher's Exact Test, c: Wilcoxon-Mann-Whitney U Test, d: Chi-Squared Test

Post-operative Outcomes

The Mean VAS scores for pain, incidences of complications, length of stay and return to work are shown in Table 3.

Table 3: Post-operative outcomes

Parameters	Procedure		p value
	Open Meshplasty (n = 29)	TEP (n = 21)	
VAS pain scores Mean ± SD At 24 hours	1.45 ± 1.68	0.95 ± 1.50	0.26[c]
At 30 hours	2.53 ± 1.60	1.75 ± 1.98	0.21[c]
At 36 hours	2.00 ± 1.57	1.20 ± 1.79	0.35[c]
At 48 hours	2.00 ± 2.19	2.00 ± 0.00	0.92[c]
Complications Any	12 (41.4%)	1 (4.8%)	**0.004**[d]
Scrotal edema	5 (17.2%)	0 (0.0%)	0.07[b]
Hematoma	3 (10.3%)	1 (4.8%)	0.63[b]
Seroma	5 (17.2%)	0 (0.0%)	0.07[b]
Surgical site infection	1 (3.4%)	0 (0.0%)	1.00[b]
Surgical emphysema	0 (0.0%)	1 (4.8%)	0.42[b]
Post-operative stay (days) Mean ± SD	2.41 ± 1.64	1.24 ± 0.54	**< 0.001**[c]
Range	1 - 8	1 - 3	
Return to occupation (days)			
Mean ± SD	5.5 (1.3)	3.4 (1.1)	**< 0.00001**[c]

b: Fisher's Exact Test, c: Wilcoxon-Mann-Whitney U Test, d: Chi-Squared Test

Table 4: Complications versus Duration of surgery

Parameters			Duration of surgery (minutes) Mean ±SD	p value
Hematoma	Lichtenstein's repair	Present (n = 3)	92.00 ± 24.25	0.26[c]
		Absent (n = 26)	76.35 ± 21.90	
	TEP repair	Present (n = 1)	180.00 ± NA	0.11[c]
		Absent (n = 20)	83.40 ± 19.09	
Seroma	Lichtenstein's repair	Present (n = 5)	103.80 ± 26.63	0.04[c]
		Absent (n = 24)	72.58 ± 17.39	
	TEP repair	Present (n = 0)	-	-
		Absent (n = 21)	88.00 ± 28.12	
Surgical site infection	Lichtenstein's repair	Present (n = 1)	120.00 ± NA	0.17[c]
		Absent (n = 28)	76.46 ± 21.07	
	TEP repair	Present (n = 0)	-	-
		Absent (n = 21)	88.00 ± 28.12	

c: Wilcoxon-Mann-Whitney U Test

Follow up

On follow up, four patients (13.8 %) in the open meshplasty group complained of groin pain at three months compared to one patient (4.8 %) in the TEP group. Recurrence occurred in one case in each group. The difference was not statistically significant (p = 0.70).

DISCUSSION

The number of randomized trials comparing TEP and Lichtenstein repair for primary unilateral inguinal hernia in males remains limited and results are at odds with one another.

Some studies have reported significantly shorter times for TEP [8-10] whereas some significantly longer [11]. Here, it took more time to perform a TEP compared to an open meshplasty (p = 0.30). One can supposedly complete a TEP within an hour after 80 – 100 procedures [12]. The variations in duration of surgery reported in literature could in part be attributed to the varied experience levels of the surgeons and residents performing the repair [8-10, 13]. The longer mean duration of surgery for TEP in this study can be attributed to the hospital being a low volume center in terms of TEP. Further, repair of indirect sacs took longer in both groups, especially in TEP. Unlike Lichtenstein repair, TEP was also affected by adhesions. These findings are in corroboration with the findings of Gutlic et al. where surgeons

considered TEP more difficult than Lichtenstein repair ($p< 0.001$), and an indirect (14.4 %) more difficult than a direct (1.2 %) hernia, irrespective of the operative technique ($p< 0.001$) [9].

Again, difference in anesthesia, analgesic medications and scales for assessing severity of pain in previous studies make comparison difficult. In the present study, severity of pain was assessed from post-operative day one to negate the effect of anesthesia. In compliance with the findings of previous studies [8, 14, 15], TEP led to less acute pain. Also, after TEP, patients on an average reached zero VAS score earlier than after open surgery.

When talking about complications, vascular injuries occur more commonly with TEP repair [16] as the inferior epigastric artery, external iliac vessels, corona mortis as well as spermatic cord vessels are exposed during surgery and although rare, any such injury may require conversion to an open procedure [15]. Here, only one patient had intra-operative bleeding during TEP from the inferior epigastric artery which was managed with harmonic cautery. Inadvertent peritoneal tears during TEP may need conversion [15]. In the present study, iatrogenic pneumoperitoneum was decompressed by inserting a 5 mm port at the Palmer's point. Larger tears needed suturing but there were no conversions.

Reporting of hematomas and seromas after TEP have been variable in literature [8, 11, 15, 17]. In the present study the incidence of hematoma was less for TEP than open group ($p = 0.63$). One patient in the open group required negative suction drainage of hematoma which was removed in the outpatient clinic after 7 days on follow-up. In the current study, there were no seromas in the TEP group whereas five patients in the open group developed seromas in the post-operative period ($p = 0.07$). Complying with previous studies [8, 9, 11], there were no cases of wound infection after TEP. Gutlic et al. [9] had reported more short-term complications after Lichtenstein repair versus TEP ($p = 0.02$). Similarly, when calculating the number of cases having any of the above complications, the incidence was significantly more in the open meshplasty group compared to the TEP group **($p = 0.004$)**.

Interestingly, upon analyzing the relation of occurrence of complications with duration of surgery it was found out that for Lichtenstein repair, prolonged duration of surgery was significantly associated with wound seroma formation in the post-operative period **($p = 0.04$)**. This was not seen in the TEP group despite lengthy procedures.

The length of hospital stay can be affected by a number of factors namely hospital or study policy, pre-operative comorbidities, type of anesthesia, occurrence of any intra-operative event, post-operative complications and requirement of re-operations [8, 10, 11, 13]. In the present study, the mean post-operative stay was shorter in the TEP group **($p< 0.001$)**. The patients undergoing TEP were discharged the next day once they had passed urine comfortably, accepted orally and were ambulatory. This along with very few wound complications resulted in a mean hospital stay of about one and half days for the TEP group. Whereas, patients undergoing Lichtenstein repair were given spinal anesthesia which necessitated supine posturing for twenty-four hours. Duration of stay also increased in open group due to wound complications that needed dressings or placement of drains. Co-morbidities unrelated to hernia or hernia surgery may also prolong duration of hospital stay for the patient. One patient in the open group complained of straining at micturition in the post-operative period, he was diagnosed as having urethral stricture and required cystoscopy guided Foley's catheterization. Bridging therapy for another patient on anticoagulants in the open group also led to a longer hospital stay. Though duration of surgery was longer in the TEP group, patients could be discharged much early in comparison to the open group.

Several randomized studies [8, 9, 11] and meta-analyses [16, 17] have established earlier return to work after TEP repair. Here, less post-operative pain, lower wound complications and shorter hospital stays culminated in earlier return to work for the TEP group **($p< 0.00001$)**.

The center for the current study being a government hospital, there were no inpatient, theatre, anesthesia or medication charges. Evaluation of social costs due to absence from work and patient costs from visits to the hospital or homecare were beyond the scope of this study. Thus, apparent costs for the patient arose mainly from the cost of mesh, ports and fixation device when required [18]. Larger mesh used in the TEP group was costlier than the mesh used in open group. As ways of cutting costs, reusable ports were used whenever possible and telescope was used for creation of space in place of balloon expander. One can be hopeful that the increased initial costs faced with TEP can be offset by the shorter hospital stays and earlier joining of work by the patient.

Previous meta-analyses [16, 17] have reported significantly lower incidence of groin pain at 3 months after TEP compared to Lichtenstein repair. In this study, pain persisting at 3 months was reported in a smaller number of patients after TEP compared to open group ($p = 1.00$).

Finally, discussing hernia surgery outcomes can never be complete without comparing recurrence rates. It is said that, the use of mesh rather than the method of placement reduces the risk of recurrence [17]. Performance in TEP improves with experience [15] but still about 100 supervised laparo-endoscopic repairs are needed to match the recurrence rates of Lichtenstein repair [5]. Varied recurrence rates have been reported for TEP in literature [8, 9, 11]. In the current study, recurrence was found in one patient in each group ($p = 0.70$).

The study had its own limitations. It was a single center study. Modes of anesthesia and surgeons were different which could have affected outcomes like post-operative pain, duration of surgery and complications. Comparatively short duration of follow-up precluded accurate assessment of long-term outcomes like chronic groin pain and recurrence.

CONCLUSION

The present study suggests that TEP for primary unilateral inguinal hernia in males is associated with less post-operative pain, lower wound complications, shorter duration of hospital stay, earlier return to work, less chronic groin pain and similar recurrences when compared to Lichtenstein repair. But, TEP is difficult to perform with longer duration of surgery and is associated with increased upfront costs of surgery. Further prospective studies need to be conducted with larger number of cases to evaluate the outcomes of TEP for primary unilateral inguinal hernia in males and address the limitations inherent to the present study design. Despite the debate, laparoscopic inguinal hernia repair is here to stay. It becomes our responsibility then, to obtain efficiency in a technique that has shown improvement in patients' post-operative outcomes and potentially find ways to improve the expenditure gap.

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