



AN EVALUATION OF LAPAROSCOPIC GROIN HERNIA REPAIR- RETROSPECTIVE AND PROSPECTIVE EVALUATION STUDY

General Surgery

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ABSTRACT

Introduction: A hernia is a common surgical problem of modern world. Laparoscopy offers hernia repair by minimal incisions with more favourable postoperative outcome. Recently there has been a debate about the relative roles of laparoscopic inguinal hernia repair, and their effect on quality of life postoperatively. This study has been designed with following aims To investigate the efficacy and safety in terms of recurrence and chronic groin pain retrospectively from a prospectively maintained database as well prospectively following laparo-endoscopic repair (TEP & TAPP) of Groin hernia repair and To assess the quality-of-life following laparo-endoscopic repair of groin hernia using SF-36 Health survey for 24 months. **Methods:** Retrospective (Prospectively maintained database) as well as Prospective Cohort Study. All consecutive patients with the clinical diagnosis of groin hernia were admitted in the Single Surgical unit, Department of Surgery, Mahatma Gandhi Hospital between 1st June 2018 to 30th June 2021 were included in the study with the following inclusion and exclusion criteria. **Results:** In the present study, there was significant improvement in the quality of life at 24 months in all the 8 domains of Short Form 36 questionnaire with significant p value (<0.0005) for each domain. **Conclusion:** The Laparo-endoscopic hernia techniques have been standardized. From our study, we can conclude that laparo-endoscopic hernia repair are safe and effective as there are reduced intra-operative, acute post-operative and delayed post-operative complications with excellent long-term outcomes.

KEYWORDS

RAND-Research and Development Corporation, -Short Form-36 Survey, TAPP-Trans-Abdominal Pre-Peritoneal, TEP-Totally Extra-Peritoneal

INTRODUCTION

A hernia is a common surgical problem of modern world. Hernia is an abnormal protrusion of an organ or tissue through a defect in its surrounding wall. Various sites of the body are vulnerable for hernia, but the abdominal wall and particularly the inguinal region is most commonly involved region. Approximately seventy five percent (75%) of hernias are groin hernias, out of which 95% are inguinal hernias and the remainder being femoral defects.

The aims of successful hernia repair include, achieving an effective repair with lowest possible recurrence rate, minimal postoperative complications, rapid return to normal work, and performing a cost-effective procedure. To achieve these goals, different methods of hernia repair have been applied which have progressed from open repair to various laparoscopic approaches.

Laparoscopy offers hernia repair by minimal incisions with more favourable postoperative outcome including reduced pain and quicker return to work especially more pronounced in bilateral inguinal hernia. In years attempts to evaluate the outcome of different health care interventions have increased. Inguinal hernia repair is one of the most common procedures done throughout the world. Recently there has been a debate about the relative roles of laparoscopic inguinal hernia repair, and their effect on quality of life postoperatively. The short form 36 (SF-36) is a popular health status measure which was originally developed in North America as part of the RAND -Research and Development Corporation- medical outcomes study. It is a 36-item questionnaire which measures eight categories of Health on multi-item scales, plus a further dimension on a single item scale which measures change in health over the last year.

The present study has been designed to evaluate the short-term and long-term outcome of laparoscopic repair of groin hernia particularly Quality of Life aspects using Short Form 36 survey pre and 24 months post-operatively. This study has been designed with following aims and objectives: To investigate the efficacy and safety in terms of recurrence and chronic groin pain retrospectively from a prospectively maintained database as well prospectively following laparo-endoscopic repair (TEP & TAPP) of Groin hernia repair and To assess

the quality-of-life following laparo-endoscopic repair of groin hernia using SF-36 Health survey for 24 months.

MATERIALS AND METHODS

PATIENTS AND METHODS

Type of Study: Retrospective (Prospectively maintained database) as well as Prospective Cohort Study.

Period of Study:

Retrospective Cohort Group- 1st June 2018 to 31st December 2019
Prospective Cohort Group - 1st January 2020 to 30th June 2021
Prospectively maintained database

Sample Size

All consecutive patients with the clinical diagnosis of groin hernia were admitted in the Single Surgical unit, Department of Surgery, Mahatma Gandhi Hospital between 1st June 2018 to 30th June 2021 were included in the study with the following inclusion and exclusion criteria.

Inclusion Criteria:

All adult patients aged 18-70 years, who presented with groin hernia and fit for general anaesthesia were operated by laparo-endoscopic techniques. A detailed informed consent was obtained from all the patients.

Exclusion Criteria:

- Patients unfit for general anaesthesia.
- Incarcerated, irreducible or strangulated hernia or any evidence of vascular compromise on imaging.
- Ventral/incisional hernia.
- Uncontrolled bleeding diathesis.
- Suspected intra-abdominal or pelvic malignancy.

Methodology

All patients attending General Surgery OPD of Mahatma Gandhi Medical College and Hospital with groin hernia were considered after detailed medical history, a thorough physical examination with

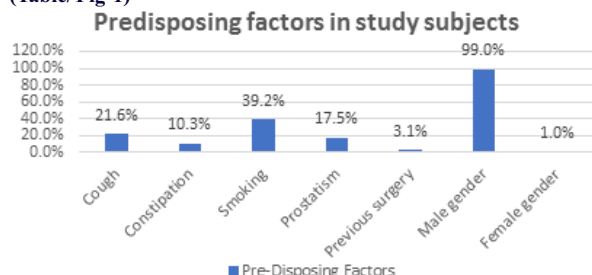
estimation of the hernia defect. All routine blood parameters including, complete blood counts, renal and hepatic function tests, coagulation profile were evaluated. Patients with medical co-morbidities like diabetes, hypertension, COPD, h/o allergies were appropriately evaluated and optimized. Once declared fit for surgery under General Anaesthesia were then included in the study. USG abdomen was done to confirm the groin hernia and its contents and other associated hernia(s). USG abdomen was performed whenever indicated for evaluation of prostate and post-void residue. This study is an analysis of retrospective data (obtained from prospectively maintained database) in Mahatma Gandhi Medical College and Hospital, Jaipur between 1st June 2018 to 30th June 2021.

All patients were evaluated for pain and other symptoms were recorded. A clinical examination was conducted to look for any of the complications – Acute or Chronic. Appropriate investigations were done to establish diagnosis of any clinically appreciable finding. SF 36 survey was also given to each patient at 1 week, 1 month, 3 months and 6 months, 12 months, 18 months, 24 months. follow up. Depending on the date of the surgery, the patients were divided into 3 groups. All included patients were given SF-36 survey in Hindi or English pre-operatively. The same proforma was given at 1 week, 1 month, 3 months and 6 months, 12 months, 18 months, 24 months. follow-up. All the acquired data was entered into a pre-structured proforma. In case the patients were unable to attend the follow-up at clinic, the proformas were completed by telephonic conversation.

RESULTS

A total of 97 patients of inguinal hernias were operated on laparoscopically during the defined period. The Mean age was 50.66 ± 16.28 (Range, 11-85 years). Only 1 (1.1%) out of 93 patients was female (1.1%), rest 92 (98.9%) were male. It showed that groin hernia predominantly occurs in males. Smoking had the strongest predisposition for groin hernia, 38 (39.2%) out of 97. Chronic cough was found in 21 (21.6%). (Table/ Fig-1)

(Table/ Fig-1)



Total 114 hernia surgeries were performed on 97 patients. Out of those, 19 (16.6%) were complete and 95 (83.3%) were incomplete. Right sided unilateral hernia was the most common site i.e. 47 (48.5%) followed unilateral by left sided i.e. 33 (34%) and bilateral hernia were 17 (17.5%). Out of the 97 included patients, 94 (96.9%) had primary defect while 3 (3.1%) had recurrence after previous open technique. Out of the total 114 surgeries, 29 (25.4%) were TAPP, 84 (71.0%) were TEP and only 1 (0.93%) was converted to open due injury to Deep Inferior Epigastric Artery. (Table/ Fig-2)

(Table/ Fig-2)

Total No Of Surgery Performed	No.	%
Conversion to open	1	0.9
TAPP	29	25.4
TEP	84	71.8

Mean operative time for unilateral TAPP repair was 56.18 ± 6.75 minutes and for unilateral TEP repair was 53.40 ± 7.40 minutes. The mean operative time for bilateral TEP repair was 51.0 ± 4.04 minutes and bilateral TAPP repair was 59.40 ± 5.64 minutes (Table/ Fig-3)

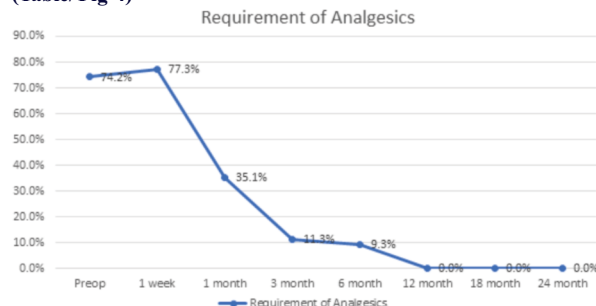
(Table/ Fig-3)

	Site	No.	Mean Operative Time
TEP	Unilateral	57	53.40 ± 7.40
	Bilateral	12	51.0 ± 4.04
TAPP	Unilateral	22	56.18 ± 6.75
	Bilateral	5	59.40 ± 5.64
Total			54.11 ± 7.03

72 (74.2%) out of 97 patients had used analgesics pre-operatively for

groin pain. Post-operatively, pain was managed by intravenous diclofenac (75mg) in 8 hourly doses for the first 24 hours and then oral analgesics were prescribed for next 72 hours. The number of patients using oral analgesics at 1 week increased to 75 (77.3%). Then it started to decrease, it was 34 (35.1) at 1 month, 9 (9.3) at 6 months. None of the patients required analgesia after 6 months of surgery. (Table/ Fig-4)

(Table/ Fig-4)



Intra Operative Complications: There were no major intraoperative complications, no hollow viscus, urinary bladder or major vessel injury. 84 (71.8%) out of the 97 patients were operated by TEP technique and total 81 procedures were done. 15 (15.5%) of the TEP 84 patients had peritoneal injury. Only 1 patient (1.1%) out of 97 had a vascular injury (Inferior Epigastric Artery) while inserting the laparoscopic port which led to conversion to open surgery.

Post-Operative Care: Oral liquids were started 6 hours post-operatively and full diet on post-operative day 1. Patients were mobilized within 24 hours post-operatively. Discharge was done on post-operative day 2. They were advised for tight scrotal support, to avoid strenuous exercise/work, to avoid lifting weights. Treatment was prescribed for chronic cough or constipation, if present. They were advised to stop smoking. They were asked to follow up after 1 week.

Post-Operative Complications-

In the immediate post-operative period, 9 out of 97 (8.6%) patients had Acute Urinary Retention. All 9 were treated by TEP technique (9.1%). Out of the 9, 2 (22.2%) had bilateral hernia. Late Post-operative complications were observed at 1 week, 1 month, 3 months, 6 months, 12 months, 18 months, 24 months.

Seroma Formation – Seroma was defined as localized fluid collection that appeared on the operated site and was diagnosed clinically.

On follow up at 1 week, 5 (5.1 %) out of the 97 had seroma, all were in the TEP group. It persisted in 2 (40 %) till 1 month, 1 (20 %) at 3 month and none at 6 months or beyond. They all were managed conservatively by tight scrotal support.

Hematoma Formation – Only 1 (1.0%) had hematoma. He was in the TAPP group. It disappeared within 1 month. No intervention was required to treat.

Cord edema – It was present in 3 (3.1%) patients at 1 week, in 1 (1%) at 1 month and in none at 3 months. All 3 were operated by TAPP technique. All were managed conservatively.

Hydrocele – It was seen in 1 patient (1.1%) at 1 week and persisted till 6 months. It was diagnosed clinically and confirmed by Ultrasonography. It was treated by tight scrotal support.

Port site infection - Only 1 patient (1.1%) had port site infection, in 10mm umbilical port site at 1 month follow up. It was treated by daily dressing and oral antibiotics. It was superficial and didn't require any surgical intervention.

Intestinal Obstruction – Only 1 patient post-operative intestinal obstruction (post-operative ileus). It was after a TAPP procedure. It was managed conservatively and resolved without any intervention. His discharge was delayed due to ileus. There were no symptoms of obstruction in follow up period.

Trocar site hernia – It was observed in 2 (6.9 %) out of 29 patients of the TAPP group at 12 months follow up and were confirmed by ultrasonography. All defects occurred in the 12mm supra-umbilical

port. None of the patients have any symptoms arising due to the defect and were not advised surgical intervention (table-5). In our study, The SF 36 questionnaire administered to each patient for self-completion pre-operatively and post-operatively at 1 week, 1 month, 3 months and 6 months, 12 months, 18 months, 24 months.

(Table/ Fig-5)

	1 week	1 month	3 months	6 months	12 months	18 months	24 months
Seroma/Haematoma	5	2	1	0	0	0	0
Cord oedema	3	1	0	0	0	0	0
Hydrocoele	0	1	1	1	0	0	0
Port site infection	0	1	0	0	0	0	0
Mesh Infection	0	0	0	0	0	0	0
Intestinal obstruction	1	0	0	0	0	0	0
Trochar hernia	0	0	0	2	2	0	0

The data collected pre-operatively was compared to data at 24 months. Scoring the RAND 36-Item Health Survey is a two-step process. First, pre-coded numeric values are recoded per the scoring key. Note that all items are scored so that a high score defines a more favourable health state. In addition, each item is scored on a 0 to 100 range so that the lowest and highest possible scores are 0 and 100, respectively. The data were analysed with IBM.SPSS statistics software 23.0 Version. To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. To find the significant difference between the bivariate samples in Paired groups the Paired sample t test was used. In the above statistical tools the probability value .05 is considered as significant level. (Table/ Fig-6)

(Table/ Fig-6)

Variables	Group	N	Mean	SD	t value	p value
General health	Preop	97	65.59	9.49	9.33	<0.001
	24 months	97	79.33	11.69		
Limitation of activities	Preop	97	70.41	21.88	8.39	<0.001
	24 months	97	84.84	17.01		
Physical health problems	Preop	97	63.91	38.01	21.41	<0.001
	24 months	97	96.39	10.81		
Emotional health problems	Preop	97	69.41	39.86	16.58	<0.001
	24 months	97	95.53	17.10		
Social functioning	Preop	97	58.37	11.79	12.63	<0.001
	24 months	97	77.96	17.47		
Pain	Preop	97	64.38	11.49	9.66	<0.001
	24 months	97	90.18	10.19		
Emotional well being	Preop	97	64.90	12.01	7.26	<0.001
	24 months	97	74.41	14.93		
Energy/ fatigue	Preop	97	63.45	12.99	14.98	<0.001
	24 months	97	74.69	17.46		

DISCUSSION

Groin hernia repair is one of the most common general surgical procedure performed by general surgeons(1). Open mesh repair has been the standard of care until laparoscopic repair introduced in the 1990's. Laparo-endoscopic inguinal hernia repairs have the certain distinct advantages over open repair (2)viz. reduced postoperative discomfort and recovery time, allowing an earlier return to full activity, easier repair of a recurrent hernia, the ability to treat bilateral hernias simultaneously, the performance of a simultaneous diagnostic laparoscopy (TAPP), the highest possible ligation of the hernia sac and an improved cosmesis(2,3,4,5,6,7). In this study, we have evaluated the short-termed and long-term surgical outcomes of Laparo-endoscopic Groin Hernia Repair techniques (TEP or TAPP technique) such as the incidence of chronic groin pain, recurrence and change in quality of life post-operatively using the Short Form 36. The mean age of the patients was 50±17 years (Range 11 to 85 years). Majority of the patients were male i.e.98.9% (96 out of 97), this was similar to the studies by **Lawrence et al. (8)** which had 97% male patients and **Muschalla et al(9)**, it had 91% male population in their study. The most common predisposing factor in this study was Smoking, it was presenting 38(39.2%) out of 97 patients. This was in coherence with the study of **Burcharth et al(10)** which states that smoking substantially increased the risk of occurrence of inguinal hernia. Chronic Cough was second, it was present in 21(21.6%) patients.

Chronic constipation 10(10.3%) out of 97 patients. Recurrence after previous open surgical method 3 (3.1%) out of 97 were found to be weakly associated with the occurrence of groin hernia. The most

common site for occurrence of groin hernia was 47 (48.5%) unilateral right hernia, unilateral left hernias were 33 (34%) and 17 (17.5%) were bilateral inguinal hernia. **Florin et al(11)** published similar results, 50% were unilateral right sided hernia, 35% were unilateral left sided and 15% were bilateral inguinal hernia. These results were contradicted by the study published by **Misra et al (12)**, which reported 54% bilateral hernias, 29% unilateral right hernia and 17% unilateral left hernias. A total of 114 repairs were performed on 97 patients. 84 (71.0%) were TEP repair, 29(25.4%) were TAPP repair and one (0.93%) was converted to open procedure due to injury to Inferior Epigastric Artery during TAPP repair. The mean operative time in TAPP was higher than TEP for both unilateral and bilateral repairs. In unilateral repair, it was 56.18±6.75 minutes for TAPP vs 53.40±7.40 minutes for TEP. For bilateral repair, it was 59.40±5.64 minutes vs 51.0±4.04 minutes. It was in accordance with the study published by **Bansal and Misra et al(12)**, which also showed that TAPP repair took more operative time in both unilateral and bilateral repairs.

Intra-operative Complications

In this study, 15 (15.5%) out of the 84 patients in TEP group had inadvertent peritoneal laceration. In **Hasbahceci et al (13)** 33.3% was the prevalence of peritoneal laceration in TEP procedure and 7 cases out of 42 cases i.e.16.67% were converted from laparo-endoscopic to open surgery. The study conducted by **Muschalla et al. (14)** had 1010 patients and it showed 0.4 % bowel injury, 0.1% of urinary bladder injury, 0.1% deep inferior epigastric vessel injury and only 0.3% conversion rate. This study had lesser incidence of intra operative complications compared to our study because of small number of patients in our study.

A study published by **Srsen et al(15)** compared the open hernia repair (using Lichtenstein's technique) with laparo- endoscopic hernia repair (using TAPP).

The study had 216 patients and it showed only 6 complications overall in the intra and early post-operative period and out of those 3 were after TAPP. One of those was bleeding from trocar placement site which was resolved by laparotomy and sewing of the bleeding vessel.

Requirement of Analgesics

In our study, 72 (74.2%) out of 97 patients had pre-operatively consumed oral analgesic for groin pain

At 1 week post-operatively, the percentage increased to 77.3% because of stitches, tacker places placed for mesh fixation and mesh itself.

At 1 month post-operatively, the percentage declined to 35.1%. It reached 6.5% at 3 months and 9.3% at 6 months. The patients who required analgesia at 3 months and 6 months post-operatively had dull aching pain over the port sites, mainly over the umbilical port.

At the most recent follow up, <1% are using analgesic for groin pain.

This result is in accordance with the study done by **Wennergren et al (15)**, which measured pain post operatively using the Visual Analogue Scale (VAS) in which 0 being no pain and 100 being severe pain, it stated that mean score of pain in the pre-operative period was 17 which increased to 20 after 7 days post-operatively. It declined to 6 at 6 months post-operatively. The study conducted by **Bansal and Misra et al (12)**, compared TAPP vs TEP techniques to assess post-operative difference in the quality of life and pain. They concluded that the TAPP technique had higher incidence of early post-operative pain, at 6 hours, 24 hours and 1 week. But there was no significant difference at 6 months follow up. Both the laparoscopic procedures led to significant decrease in groin pain.

Post-Operative Complications

In the present study, post-operative complications were defined as immediate, acute post-operative and late post-operative complications.

In the early post-operative period, the incidence of urinary retention was 9 out of 97 (8.6%). All the patients were of TEP group. The retention was treated by catheterization. All the patients were discharged only after making sure that they had no difficulty in micturition. No patient had complaint of micturating difficulty, burning micturition or urinary tract infection in the entire follow up. In

various studies like **Kim et al(17)** , **Kwon et al(18)** , it was found to be ranging from 3.2% to 22%. At 1 week post-operatively, 5 (5.1%) out of the 97 patients had seroma formation. They all belonged to TEP group. **Muschalla et al (14)** reported 0.6% patients with persistent seroma and nerve deficiency in 0.3%. In studies of **Kim et al (17)** , **Kwon et al(18)** , it was reported from 2.1% to 17%.

All patients of seroma formation resolved with reassurance on expectant management.

At 3 months post-operatively, persistent seroma was found in only 1 (20%) patient. He was an elderly male, chronic smoker with poor nutritional status and poor compliance in wearing tight scrotal support. His seroma resolved at 6 months follow up.

At 1 week post-operatively, only 1.1% (1 out of 93) patients had hematoma formation, which resolved by conservative management at 1 month follow up. The study conducted by **Srsen et al (15)** had only 1 patient out of 216 with scrotal hematoma, and 1 with wound hematoma after TAPP procedure which were managed conservatively as well.

In the present study, 3 (3.1%) patients at 1 week, in 1 (1.0%) at 1 month and none at 3 months. All 3 were operated by TAPP technique. All were managed conservatively. While in the study done by **Bansal et al(12)**, 15.9% and 14.3% cases had cord edema which was done by senior and junior surgeon respectively.

One patient developed intestinal obstruction post-operatively, he was an elderly male of 85 years age who complained of obstipation post-operatively. . He was found to have hypokalaemia with dilated bowel loops on X-ray FPA and diagnosed to have adynamic intestinal obstruction, it was treated by Ryle's tube insertion and correction of dyselectrolytemia (hypokalaemia). On post-operative Day 2 of surgery, patient passed flatus. He was then allowed oral liquids and gradually escalated to full diet. The study by **Muschalla et al(14)** , also had only 1 case of Ileus which was possibly caused by a gap left open or reopened after suture closure of peritoneum, he was reoperated six days after the previous surgery using laparoscopy and the gap was closed with suture.

Superficial Port site infection was noticed in 1 patient (1.1%) (1 out of 97) at 1 month follow up, umbilical 12mm port was infected. It was successfully treated by regular dressings and oral antibiotics .In the study by **bansal and misra et al(12)** , the rate of superficial port site infection was higher. It was 1.8% in TEP group and 3.2% in TAPP group.

On routine clinical assessment, 1(1.1%) patient was found to have hydrocele at 1 month follow up, it was confirmed by ultrasonography. He was advised conservative management i.e.to wear tight scrotal support, a course of antibiotic was also given. Hydrocele persisted till 6 months and then resolved. He did not require any surgical intervention. These results were compared to the study conducted by **Muschalla et al(14)** had 0.3% incidence of hydrocele.

At 12 months follow up, in 2 (6.9%) out of 29 patients of the TAPP group at 12 months had Trocar site hernia, both of them at 12 mm supra-umbilical port. It was confirmed by ultrasonography and its content was omentum. Study published by **Muschalla et al (14)** had 3.17% incidence of Trocar Hernia. Both the patients in our study are being followed up for possible surgical intervention. There was no incidence of mesh infection in our study. None of the patients developed recurrence in the entire follow up of our study, while in study done by **Kim et al** it was minimum of 0.5% and in **Mathur et al** study, it was 3%. In the study conducted by Bansal et Misra et al, recurrence was 0.3%. Only a handful studies have been done to assess the quality of life post inguinal hernia repair surgeries. A recent study done by **Myers et al(20)** showed significant improvement in all the categories of SF 36 survey except social functioning and mental health. Another study done by **McCormack et al (21)** in 2005 concluded that both TAPP and TEP provided better outcomes in terms of quality adjusted life years as compared to open repair techniques.

CONCLUSION

The Laparo-endoscopic hernia techniques have been standardized. From our study, we can conclude that laparo endoscopic hernia repair are safe and effective as there are reduced intra-operative, acute post-operative and delayed post-operative complications with excellent

long-term outcomes. Second, these methods significantly improve the quality of life post-operatively and are associated with the faster return to normal activities/work. Laparo-endoscopic groin hernia must become integral part of the surgical training.

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