

STUDY OF LAPAROSCOPIC INGUINAL HERNIA REPAIR WITH PSEUDOSAC FIXATION: DOES IT REALLY PREVENT SEROMA FORMATION AND MESH MIGRATION?

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Abstract: *The study was conducted to determine the effectiveness and safety profile of hernial pseudosac fixation in TAPP and TEP meshplasty and whether it is associated with a reduced incidence of post-operative complications. A total of 60 patients were divided into two groups. Group A of 31 underwent pseudosac fixation while the other group B of 29 patients were treated without pseudosac fixation. Patients were followed up for 6 months and a significant difference in post-operative complications between the two groups was noted.*

Conclusion: *Our early findings suggested that Pseudosac fixation is a practical and successful way to stop mesh migration, recurrence and seroma development during laparoscopic inguinal hernia repair.*

Keywords: Direct Hernia, Inguinal Hernia, Pseudosac fixation, Seroma, Mesh migration

1. INTRODUCTION

One of the most frequent general surgical procedures worldwide is the correction of inguinal hernias, which are normally diagnosed utilizing a complete medical history and physical exam. Both a congenital and an acquired component are thought to exist in inguinal hernias, with conditions with established association including chronic obstructive pulmonary disease (COPD), Ehlers-Danlos syndrome, and Marfan syndrome. Increased intra-abdominal pressure has also been known to have a strong association with the occurrence of inguinal hernias. [1]

75% of abdominal wall hernias are inguinal hernias, with indirect hernias being more common (two-thirds of all inguinal hernias). Only 3% of inguinal hernias are femoral hernias, of which 70% are found in women. 90% of all inguinal hernias are in men, compared to 10% in women. On the right, an indirect hernia occurs more frequently. [2]

Patients with inguinal hernias have a variety of treatment choices, such as watchful waiting, open primary repair, open tension-free repairs utilizing mesh prosthetics, and laparoscopic repairs frequently utilizing mesh prosthetics.

[3] Currently, laparoscopic repair utilizing mesh prosthetics is a commonly performed surgery, with methods including the Trans-abdominal Preperitoneal (TAPP) method, the Totally Extraperitoneal (TEP), and the Intraperitoneal Onlay Mesh (IPOM) which has lost popularity due to high recurrence rates.

[4]

This study intends to discover more about the effectiveness and safety profile of hernial pseudosac fixation in TEP and TAPP meshplasty, and whether this procedure truly reduces the occurrence of issues such as seroma formation and mesh migration, odynohernia, SSI, etc. from occurring in the future.

2. MATERIALS AND METHODS

The study was conducted from June 2021 to June 2022 on patients reporting to Department of General Surgery, SVBP Hospital affiliated to LLRM Medical College with a Direct Inguinal Hernia in a prospective format with a sample size of 60 patients.

Sample design: Sixty (60) empty envelopes numbered 01 to 60 were used for random allocation of surgical intervention measures. Odd numbers were assigned to the fixation group and even numbers to the non-fixation group.

Using a pen and the random number table, the initial number was chosen with the intention of moving in that direction of therapy.

The first envelope was given to the first patient with an inguinal hernia who visited the department following the start of data collection and met all inclusion and exclusion criteria. Intervention steps were then conducted in accordance with that patient's needs. The remaining envelopes were given out to other patients who arrived later and met the inclusion and exclusion criteria.

Thus, 30 patients were finally planned for pseudosac fixation while the other 30 were not

Inclusion Criteria: 1) A patient with direct inguinal hernia admitted to the surgical department; 2) Patient is fit for General Anaesthesia; 3) Patient grants consent for laparoscopic repair.

Exclusion criteria: 1) Patient unwilling to take part in study; 2) Patient unfit for General Anaesthesia; 3) Had a prior suprapubic, paramedian, or midline incision; 4) Experienced blocked or severe inguinoscrotal hernia; 5) TAPP repairs that were converted to open repairs;

6) Any persistent hernias

Method: Each patient got an exhaustive history collection and complete physical examination, and informed consent was taken. Details on the patient particulars, hernia's onset, duration, associated risk factors such as COPD, blockage of the bladder outlet, and persistent constipation, as well as any past experiences with discomfort or irreducibility and previous midline or paramedian incisions, are included in the clinical history. Thus, compliance with inclusion criteria was established.

Age-wise, the two treatment groups were evenly matched.

Relevant investigations were performed, including Haemogram-TLC, DLC, ESR, Routine urine Examination, Blood Sugar, Urea, Creatinine, CT- Scan. USG Lower Abdomen and Scrotal Area, and documentation was maintained by clinical and photographic records.

Variables to be studied: Demographic profile like age, sex, Duration of operation, Intra and Postoperative complications, Recurrence, Groin pain, etc.

Operative procedures: The operation methods were thoroughly discussed to the patients (Trans abdominal pre peritoneal/ Totally Extraperitoneal inguinal hernia repair with fixation and without fixation of Pseudosac). Patients are put through a trans abdominal pre-peritoneal/Totally Extraperitoneal inguinal hernia repair procedure, one group of 31 patients with Pseudosac fixation and the other group of 29 without fixation of pseudosac.

Post-operative follow-up: For the first three days following surgery, the postoperative patient was observed daily, with pain, ambulatory status, and complications such as bleeding at the port site, seroma development, and emphysema formation being noted.

With the use of a pretested and predesigned proforma, the history-taking and clinical examination were both completed.

Then follow-up was done every two weeks, then every month, then every three months, and finally every six months.

Pain, cough impulse, apparent swelling, surgical scar, and difficulties with daily tasks and mesh migration were all considered post-operative complications.

An evaluation of post-operative pain on a 100mm VAS (Richard Sadovsky) scale was performed postoperatively at 12, 24, 36, 48

hours, 1 month, and 6 months.

VAS pain ratings of 30mm or below were classified as having light discomfort, 31-69 mm were classified as having moderate discomfort, and significant pain was defined as 70mm or greater. Calculated in both groups was the minimum clinically meaningful difference in the visual analogue pain score

Data Analysis: Analysis of collected data was done using SPSS software. All traits were enumerated in descriptive detail. The summary statistics of N, mean, and standard deviation (SD) were employed for continuous variables. Number and percentage were utilized in the data summaries for categorical data, and data was analyzed using the Chi-square test for association, the T- test to compare means and the ANOVA test for the differences among the means of the population. In this study, routine, systematic investigations or interventions were necessary.

This research did not involve any animal testing.

3. RESULTS AND DISCUSSION

The present study which was carried out between June 2021 and June 2022 comprised of a total of 60 cases of a direct inguinal hernia.

The patients were divided into two groups: one which underwent pseudosac fixation during operative inter and the other which did not, to determine whether this procedure actually prevents future complications such as seroma formation and mesh migration etc.

In comparison to open repair, the laparoscopic method has been found to reduce postoperative discomfort and allow patients to return to their regular activities sooner. [5]

The two types of laparoscopic approaches used in this study were TAPP and TEP.

While bilateral hernias, significant sized defects and recurrent cases benefit vastly from TAPP, and it is possible to fill the direct, indirect and femoral spaces with a sizeable mesh, a complication to other intraperitoneal structures is a drawback to this approach.

The TEP approach reduces the chance of harm to intraperitoneal structures, prevents intraperitoneal adhesions from previous surgery and results in a speedier and simpler dissection. The drawback to the TEP approach is that the surgeon must perform dissection in a small area and conversion to TAPP may be necessary.

The results of this study and relevant discussion is as follows:

Age: The majority of patients (20/60), or 33.33%, in the current research, were between the ages of 36 and 45. Only 7 of 60 patients

(11.6%) were between the ages of 18 and 25. The average age (in years) of the research participants was 44.766/13.732, with a median range of 18th-70th percentile.

Past studies have established bimodal peaks in prevalence in children aged 1-5 years (17.3%) and senior patients aged 50-59 (12.8%), 60-69

(17.3%), and 70-79 (15.6%). [6]

Socioeconomic status: In the current study, socioeconomic status was assessed and listed using the kuppasamy classification. The majority of the patients (22/60 and 21/60, respectively) are from the lower middle and upper middle classes. As a result, 72% are classified as middle-class.

Only 1/60 and 5/60 are from the higher and lower classes, respectively.

As per past studies, 80% of hernia patients come from middle class backgrounds [7] while patients of low status are more likely to require emergency surgery. [8]

Symptomatology: Nearly 47% of individuals had symptoms for less than 3 months. More than 3 months of symptoms were present in about 53% of instances.

In the majority of cases, the right side exhibits the most symptoms. (43/60).

Around 38% of patients presented with pain and discomfort symptoms.

In the past, 40% of patients in research by Cody A. et al., 2006, [9] reported experiencing pain.

Comorbidity: Approximately 62% of cases had no comorbidities. Nine of the 60 cases had hypertension, four had thyroid disorders, nine had diabetes, and one had asthma.

In a similar vein, Trevison M et al. (2015) discovered that 789 out of 49,657 patients had hypertension, diabetes and COPD. [10]

Precipitating factor: In 11 occurrences of hernias, a precipitating factor existed.

There were seven instances of constipation, two cases of lower urinary tract syndrome, and two more COPD cases.

In the past, Diabetes, constipation, cardiovascular disease, and the occurrence of chronic obstructive pulmonary disease were established as independent risk factors for readmission in multivariate analysis adjusted for the presence of COPD. [11]

Duration of surgery: Of the 60 cases, 39 cases required one hour for surgery. 10 cases took 45 minutes for surgery. 11 instances, on average, required surgery for up to one hour and thirty minutes.

In a 2016 study, it was found that non-fixation of pseudosac reduced valuable operating time by 14.11 minutes. This study found a statistically significant correlation between the absence of Psuedosac fixation and a lower mean operating time. ($P=0.001$). [12]

Catheterisation: In this study, In 65% of instances, catheterization was performed prior to surgery. This is in contrast to prior studies where 49% patients underwent catheter placement. [13]

Choice of laparoscopic approach: TAPP type was more commonly used (32/60 or 53.33%) while TEP was utilised in 28 cases.

Past studies have found that Even surgeons who are experts in TEP chose to conduct a TAPP for difficult hernias, such those in obese patients and huge scrotal hernias.

Patients under the age of 18 and those beyond the age of 70 are preferred to use the open method. [15]

Pseudosac fixation: 31/60 (52%) of cases underwent pseudosac fixation while 29 cases did not.

Additional findings: About 6.66% of individuals had hernias on the other side, according to further findings acquired during surgery. 8.33% of cases had another hernia on the same side.

Cord lipoma is detected in 5% of cases.

A past study with a larger sample size detected a 22.5% incidence of lipomas of the cord and 18% of hernias found on the opposite side of the patients. [16]

Outcome measures: VAS scoring was used to measure the pain among study population. Mean/SD of VAS score was 4.66/0.72 with range of 3 to 6.

Past studies have found an incidence of 6% for persistent discomfort after laparoscopic hernioplasty. [17]

VAS ratings after 24 hours following surgery were substantially higher in the Psuedosac fixation compared to non fixation (3.8 / 2.1 vs. 5.3 / 2.7; $P<0.0001$). [18]

Duration of hospital stay: Distributions in average duration of hospital stay among 60 cases was 13 and 47 (>5 days and < 5 days).

Hospital stay was found to be prolonged (1 week) in the pseudosac fixation group in a past study. [19]

Post op complications:

Pain/Soreness: After a six-month follow-up, issues like soreness were entirely resolved in the pseudosac group, whereas three cases of persistence were noted in the non-Psuedosac group. Similar outcomes were stated by a previous study held on 772 cases (90) while previous studies showed lesser instances of pain while coughing in the non-fixation group. ($P<0.05$) [20]

Cough impulse: One occurrence of a slight cough impulse was observed in the non-fixation group 6 months post surgery, but complications like this entirely vanish in the pseudosac fixation group.

Visible swelling: After six months of follow-up, visible swelling entirely ceased in both groups. In every case, a healthy operation scar was seen following a six-month follow-up.

Difficulty in daily activity: Chores are readily completed by 28 cases in the non-fixation group, while they are challenging for 31 patients in the Psuedosac fixation group, even after 6 months post surgery.

Seroma formation:

1. In present study Seroma formation appeared to be settled and persisting. 1 incidence of settled seroma was seen in the first month, 3 cases in the third month, and 3 cases in the sixth month of follow-up.
2. Only four instances had persistent seroma throughout the first month of follow-up.
57 patients had no seroma development during the 6-month follow-up period.
3. A prospective investigation of 76 patients using the Endoloop approach demonstrated a low incidence of seroma development (3.9% after 2 weeks). [21]
4. In a prospective clinical research including 40 patients with indirect inguinal hernias, the fibrin sealant group experienced reduced volumes ($P < 0.001$) and incidences of seroma development (5% vs. 15%). [22]
5. In the first, third, and sixth months of the follow-up, Seroma formation were observed in both the Psuedosac fixation and non-Psuedosac fixation groups.
6. To investigate the relationship between Psuedosac and non-Psuedosac fixation groups, a chi-square test of independence was used in post OP and 1 month of follow-up. Both $p > 0.05$, then these variables seem to be statistically non significant. M Lodha et al., 2022 discovered a substantial link in Seroma development between the Psuedosac and non-Psuedosac groups. [23]

Wound Infection: In post operative follow up, wound infection was found in both groups (2 in fixation versus 4 in nonfixation).

To investigate this apparent relationship, a chi-square test was applied where $X^2=0.7017$, odds ratio - 0.4827 then $p > 0.05$, then these variables seem to be statistically non significant.

Mesh migration: No instances of mesh migration were discovered during the follow up period in both groups. Recurrence: Recurrences were observed in both the Psuedosac fixation (2/31) and non-fixation (8/29) groups. To investigate the relationship between Psuedosac and non-Psuedosac groups, a odds ratio : risk assessment of outcome with exposure was used in post-op. (X2- 4.81, odds ratio - 0.1810 then $p < 0.05$, then these variables seem to be statistically significant.

4. CONCLUSION

Our early findings suggested that psuedosac fixation is a practical and successful way to stop mesh migration, recurrence and seroma development during laparoscopic inguinal hernia repair. Six of the 60 patients developed infections in their surgical wounds. 54 instances or so were seen without wound infection.

In this investigation, there were seven seroma cases. This suggests that the hernia has returned.

To quantify the level of pain among the study population, VAS scoring was employed. The VAS score ranged from 3 to 6, with a mean/SD of 4.66/0.72.

The typical hospital stay for psuedosac fixation was greater than or equal to five days.

Post-operative problems included pain, cough impulse, visible swelling, surgical scar, challenges performing everyday duties, and mesh migration.

The Psuedosac fixation group and the non- fixation group both had issues in the trial's first, third, and sixth months.

None of them exhibit mesh migration in either group.

57 individuals were followed for 6 months with no seroma development.

Recurrence was seen both in the pseudosac group and the non- fixation group over the post-operative period, and an odds ratio: risk assessment of outcome with exposure was performed. (X2-4.81, odds ratio - 0.1810 then $p < 0.05$, then these variables appear to be statistically significant.

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