

A Comparative Study of Tackers Versus Sutures in Transabdominal Preperitoneal Hernia Repair: Tackers Versus Sutures in Mesh Fixation and Peritoneal Closure in Tapp

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KEYWORDS

TAPP, inguinal hernia repair, mesh fixation, sutures, tackers, postoperative outcomes, quality of life

ABSTRACT

Background: This study evaluates the surgical outcomes of using tackers versus sutures for mesh fixation and peritoneal closure in transabdominal preperitoneal (TAPP) mesh repair of inguinal hernia, focusing on postoperative pain, quality of life, and other key metrics. Although there are many studies in studying various outcomes of Transabdominal preperitoneal mesh repair (TAPP), there exists only few trials that compare peritoneal closure techniques in TAPP

Methods: A prospective comparative study was conducted at Mahatma Gandhi Medical College and Research Institute. Sixty patients undergoing TAPP were divided into two groups: one using non-absorbable sutures and the other using non-absorbable titanium tackers for mesh fixation and peritoneal closure. Intraoperative and postoperative outcomes were assessed, including time taken for procedures, postoperative pain (measured using the Visual Analog Scale), incidence of seroma formation, and short-term quality of life assessed using the Carolinas Comfort Scale.

Results: The suture group demonstrated significantly less postoperative pain on postoperative day (POD) 1 and at 3 months compared to the tacker group ($p=0.001$ and $p=0.004$, respectively). The time taken for mesh fixation and peritoneal closure was shorter in the tacker group, but the overall operative time was significantly longer in the suture group ($p=0.001$). The cost of using sutures was substantially lower than tackers. Quality of life scores at 3 months indicated better outcomes in the suture group ($p=0.001$).

Conclusions: Sutures for mesh fixation and peritoneal closure in TAPP repair provide better postoperative outcomes in terms of pain, quality of life, and cost compared to tackers, despite a longer operative time. These findings suggest that sutures may be a preferable option for TAPP inguinal hernia repair.

1. Introduction

Background and Rationale

Hernia means “to protrude” – the protruding of an organ through an area of weakness of the fibromuscular tissues of the body wall. Among all hernia, the inguinal hernia is the most common type (73%).^[1] The repair of inguinal hernia is a procedure which is most often performed in General surgery.

The inguinal hernia repair by laparoscopic means has been described using Trans abdominal preperitoneal (TAPP) or totally extra peritoneal approach (TEP) gives a better view of the inguinal anatomy.^[2] These two different approaches emulating the open posterior approaches soon became the basis for today’s minimally invasive inguinal hernia repair.

In the evolution of laparoscopic surgery, postoperative pain evaluation has become more significant due to the importance given to pain relief after surgery.^[3] Despite the benefits of TAPP, the optimal method for mesh fixation and peritoneal closure remains debated, with common techniques. Staples, both absorbable and nonabsorbable tackers, tissue glue, and sutures have been employed by different authors. Many studies have shown that the usage of tackers for mesh fixation is associated with a high rate of postoperative pain, increased postoperative movement limitation, high incidence of urine retention, hematoma and periostitis.^[4-8] There are very few studies in the literature that have compared sutures versus tackers for peritoneal closure.

Postoperative pain and quality of life are critical considerations in hernia repair, influencing patient satisfaction and recovery. This study was conducted to evaluate and compare the surgical outcomes of using tackers versus sutures for mesh fixation and peritoneal closure in TAPP inguinal hernia repair. Understanding these differences could guide surgeons in selecting the most appropriate fixation method, thereby enhancing patient care in

inguinal hernia repair.

2. Objectives and Hypotheses

Primary Objective

To compare the postoperative outcomes of using sutures versus tackers for mesh fixation and peritoneal closure in TAPP, focusing on postoperative pain on Postoperative day (POD) 1,7,14 days, pain at 3 months after surgery and short-term quality of life(QOL) at 3 months of surgery.

Secondary Objectives

To evaluate

1. The time taken for mesh fixation and peritoneal closure
2. The incidence of seroma formation.
3. The cost implications

Hypotheses

Mesh fixation and peritoneal closure using sutures will give better outcomes than tackers

3. Materials and Methods

Study Design

This study is a prospective comparative trial designed to evaluate the outcomes of two different methods for mesh fixation and peritoneal closure in TAPP inguinal hernia repair. Non-absorbable sutures were used in one group and titanium tackers were used in the other group. The study aimed to assess differences in postoperative pain, quality of life, operative time, seroma formation, and cost between the two methods.

Sample Size

The mean Visual Analog Pain Scale (VAS) score of patient undergoing TAPP by using tackers and suture method were taken as 0.3 +/- 0.1 and 0.2 +/- 0.1 respectively.

By assuming $\alpha = 0.01$ and power as 80 % . The sample size will be 24 per group and rounded of to 30 per group.

$$2\sigma^2(Z_{1-\beta} + Z_{1-\alpha/2})^2$$

$$n = \frac{(\mu_1 - \mu_2)^2}{\sigma^2}$$

Setting and Participants

The study was conducted at Mahatma Gandhi Medical College and Research Institute, a tertiary care center in Pondicherry, India, from February 2022 to January 2024. A total of 60 patients diagnosed with unilateral or bilateral inguinal hernia were enrolled in the study. The study was approved by the Institutional Medical Ethics Committee, and informed consent was obtained from all participants prior to inclusion in the study.

Inclusion and Exclusion Criteria

Inclusion Criteria:

- Adults aged 18 years and older.
- Patients presenting with unilateral or bilateral inguinal hernia.
- Patients providing informed consent for participation in the study and undergoing TAPP repair.

Exclusion Criteria:

- Patients with complicated hernias, such as irreducible, obstructed, or strangulated hernias.
- Patients with a history of recurrent hernia repair.
- Patients with previous lower abdominal surgeries.
- Patients with major comorbidities that contraindicate laparoscopic surgery.

4. Methodology

Both methods of mesh fixation and peritoneal closure are in accordance with standardized protocols and are being practiced by different surgeons. Patients were matched based on age (average of 40 to 50 years) and sex (all patients were male) and divided into Group A and Group B. (**Group A- Suture group**) underwent mesh fixation and peritoneal closure with non-absorbable sutures, ETHIBOND -II sutures and the other group (**Group B – Tackers group**) with non-absorbable titanium tackers

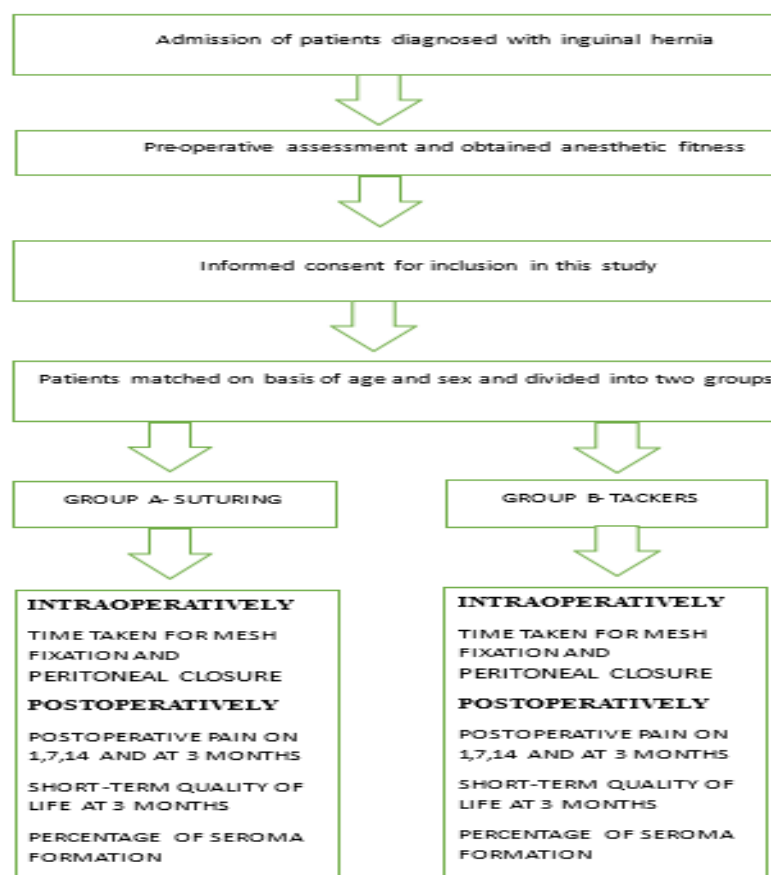
The surgical procedures were performed by experienced surgeons following standardized protocols to ensure consistency across the study. The time taken for mesh fixation, peritoneal closure, and the total operative time were recorded for each procedure.

Postoperative pain was assessed on POD1, POD7, and POD14 using the VAS which is a 10-point scale where 0 means feeling no pain while 10 means the worst possible pain. Incidence of seroma and return to normal daily activities in both groups were compared. The short-term QOL is measured as a hernia-specific quality of life by using the Carolinus Comfort Scale (CCS) developed by the Carolinus hernia center (Annexure 1).^[9] QOL is evaluated by answering 8 questions about activities of daily living on a 6-point Likert scale that measures symptoms over three primary domains: pain, mesh sensation, and activity limitation. In this study, patients completed the CCS questionnaire at 3 months of the postoperative period which measured the short-term QOL postoperatively using the questionnaires and scores given as follows. The Carolinas Equation for Quality of Life (CeQOL) mobile application was used to predict the risk of impaired QOL.

Scores of 0-1 (mild but no bothersome) were classified as asymptomatic whereas 2 (mild and bothersome) to 5 were classified as symptomatic.^[10,11] The patients were followed up for 3 months and looked for pain, mesh sensation, and movement limitation at 3 months through telecall.

This study adheres to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for reporting cohort studies, ensuring comprehensive and transparent reporting. A completed STROBE checklist is submitted as a supplementary file.

Flowchart:



Outcomes

Primary Outcomes:

- Postoperative pain was assessed using the VAS on POD 1, 7, 14, and at 3 months.
- Short-term QOL was evaluated at 3 months postoperatively

Secondary Outcomes

- Time taken for mesh fixation and peritoneal closure during the procedure.
- Total operative time.
- Incidence of seroma formation in the postoperative period.
- Cost of materials used for mesh fixation and peritoneal closure.

Data Collection

Data were collected prospectively during the hospital stay and follow-up visits. Postoperative pain was measured using the VAS, a 10-point scale where 0 indicates no pain and 10 represents the worst possible pain. QOL was assessed using the CCS questionnaire, which evaluates symptoms across three domains: pain, mesh sensation, and activity limitation. Intraoperative data, including time taken for various procedures and total operative time, were recorded by the surgical team. The incidence of seroma formation was assessed clinically during follow-up. Cost analysis was based on the prices of sutures and tackers used in the procedures.

Statistical Analysis

Statistical analysis was conducted using SPSS software (Version 19). Continuous variables were expressed as means and standard deviations, while categorical variables were presented as percentages(*Table 1*). A p-value of <0.05 was considered statistically significant.

Table 1

S. No	Name of the dependent/ independent variables	Scale of measurement (Quantitative/ qualitative)	Descriptive/ Inferential Statistics to be used
1	Time taken for mesh fixation and peritoneal closure	Quantitative	Mean +/- SD Unpaired t-Test
2	Postoperative pain on POD 1,7,14 and at 3 months	Quantitative	Repeated measures of ANOVA
3	Percentage of seroma formation	Quantitative	Mean +/- SD Unpaired t-Test
4	Short term Quality of life	Quantitative	Mean +/- SD Unpaired t-Test

5. Results

This section presents a comparison of the outcomes between the two techniques used for mesh fixation and peritoneal closure in TAPP inguinal hernia repair: non-absorbable sutures and titanium tackers

Clearly Defined Outcome Measures

- Postoperative pain (measured at POD 1, 7, 14 and 3 months)
- Short term QOL (assessed at 3 months using the CCS)
- Total Operative time
- Incidence of seroma formation
- Cost implications

Participant Characteristics

A total of 60 patients were enrolled in the study, with 30 patients in each group. The mean age in the suture group was 50 years, while the tacker group had a mean age of 43 years (*Table 2*). All participants were male, and both groups were comparable in terms of demographic characteristics and type of hernia, with the most

common being Nyhus type 3a (direct inguinal hernia)(Table 3).

Table 2 Age Difference in Both Groups

AGE IN YEARS	GROUP A	GROUP B	
<30	2	5	
31-40	5	8	
41-50	7	9	
51-60	10	4	
61-70	5	3	
71-80	1	1	
MEAN AGE	50 Years	43 years	p= 0.91

Table 3 Type of hernia

TYPE OF HERNIA	GROUP A	GROUP B
TYPE 1 Indirect with Normal internal ring	10	10
TYPE 2 Indirect with dilated internal ring	-	-
TYPE 3a Direct inguinal hernia	16	17
TYPE 3b Direct plus indirect inguinal hernia	4	3
TYPE 3c Femoral hernia	0	0

Intraoperative Findings

The time taken for mesh fixation and peritoneal closure was significantly longer in the suture group compared to the tackler group (23.80 ± 4.33 minutes vs. 11.13 ± 2.09 minutes for mesh fixation, and 29.27 ± 4.60 minutes vs. 10.33 ± 2.92 minutes for peritoneal closure; $p=0.001$ for both)(Table 4). The total operative time was also longer in the suture group (77.76 ± 1.42 minutes vs. 45.7 ± 4.24 minutes; $p=0.001$)(Table 5).

Table 4: Time taken for mesh fixation and peritoneal closure

Time taken	Group A n = 30	Group B n = 30	p value
Mesh fixation	23.80 ± 4.33	11.13 ± 2.09	0.001
Peritoneal closure	29.27 ± 4.60	10.33 ± 2.916	0.001

Table 5: Total operative time

TIME	Group A n = 30	Group B n = 30	p value
Total operative time	77.76 ± 1.422	45.7 ± 4.243	0.001

Postoperative Outcomes

Postoperative pain, as measured by the VAS, was significantly lower in the suture group on POD 1 (5.23 ± 0.77 vs. 6.00 ± 0.74 ; $p=0.001$) and at 3 months (0.00 ± 0.00 vs. 0.23 ± 0.43 ; $p=0.004$)(Table 6). There was no significant difference in pain on POD 7 and 14.

Table 6 Postoperative pain

Postoperative pain	Group A n = 30	Group B n= 30	p value
POD 1	5.23 ± 0.77	6.00 ± 0.74	0.001
POD 7	$1.90 \pm .125$	2.17 ± 0.74	0.284
POD 14	0.23 ± 0.430	0.43 ± 0.504	0.104
POD 3 Months	0.0 ± 0.00	0.23 ± 0.430	0.004

QOL Assessment

At 3 months, the QOL assessment using the CCS showed that the suture group had significantly better outcomes in terms of pain (3.3% vs. 26.7% symptomatic; $p=0.005$), mesh sensation (13.3% vs. 46.6% symptomatic; $p=0.001$), and activity limitation (13.3% vs. 46.6% symptomatic; $p=0.004$) (Table 7). The risk of impaired quality of life, as predicted by the CeQOL application, was also significantly lower in the suture group (10.73 ± 1.48 vs. 12.50 ± 1.97 ; $p=0.001$) (Table 8).

Table 7 Quality of life at 3 months

QOL Symptomatic % at 3 months	Group A n = 30	Group B n = 30	p value
Pain	3.3 %	26.7 %	0.005
Mesh sensation	13.3 %	46.6 %	0.001
Activity limitation	13.34 %	46.6 %	0.004

Table 8: Risk of impaired QOL

Risk for impaired QOL	Group A n = 30	Group B n = 30	p-value
At 3 months	10.73 ± 1.48	12.50 ± 1.97	0.001

Postoperative Complications

Seroma formation was noted in one patient in the tacker group, while no cases were observed in the suture group, indicating a significant difference (p=0.001)(Table 9).

Table 9: Postoperative complication (Seroma formation)

	Group A n = 30	Group B n = 30	p value
Seroma formation	0	1	0.001

Cost Analysis

The cost of using sutures for mesh fixation and peritoneal closure was significantly lower than that of tackers (Rs. 1500 vs. Rs. 25000; p=0.001)(Table 10).

Table 10: Cost

Cost	Group A	Group B	p value
Cost	1500	25000	0.001

Conclusion of Results Section

In summary, the use of non-absorbable sutures for mesh fixation in TAPP inguinal hernia repair is associated with lower postoperative pain and improved short-term quality of life compared to titanium tackers, though at a longer operative time.

6. Discussion

This study demonstrates that using sutures for mesh fixation and peritoneal closure in TAPP inguinal hernia repair results in better postoperative outcomes compared to tackers. Notably, patients in the suture group experienced significantly less postoperative pain, particularly on POD 1 and at 3 months, which aligns with our hypothesis that sutures could minimize nerve irritation and chronic discomfort.

Comparison with Existing Literature

Demographic details in our study showed that the middle age group (40-60 years) patients were more common in both groups. The mean age of the patients included in both groups was similar (p=0.91, Table 2). Similar to the study conducted by Oguz et al¹², our study showed that patients in both groups were predominantly male from the middle age group(Table 2).

Both the groups in our study were comparable in terms of type of hernia. The most common hernia was Nyhus type 3a (direct hernia) which is similar to the study carried out by Oguz et al¹²(Table 3).

In our study, the duration of mesh fixation using sutures was 23.80± 4.33 minutes, and the duration in the tacker group was 11.13± 2.09 minutes (Table 4, p-value= 0.001). The time taken for peritoneal closure using sutures was 29.27 ± 4.60 minutes and the duration in the tacker group was 10.33 ± 2.92 minutes (Table 4, p =0.001). The duration of peritoneal closure using sutures was 14.5 ±6.5 minutes and 4.2 ± 2.4 minutes in the tacker group as reported by Oguz et al from their study conducted in 2015(p<0.001)¹².

The total operative time was 77.76 ± 1.422 minutes in the suture group and 45.7 ± 4.243 minutes in the tacker group (Table 5, p=0.001). Similar operative times were noted by Oguz et al and have documented that the total operative time was 58.5 ±14.1 minutes in the suture group and 50.1 ± 10.3 minutes in the tacker group (p = 0.008)¹².

Zahid Mehmood et al in 2017 from his study concluded that total operative time was high in suture group.^[13] Elhadidi et al, from their study comparing suture versus tackers for peritoneal closure had reported total duration of surgery was more in suture group (p-value = 0.001).^[14]

There are no studies reported in the literature that have observed the individual time taken for mesh fixation and peritoneal closure using sutures or tackers. Our study is the first to include separate time duration for mesh fixation, peritoneal closure and for entire operative procedure. By comparing these studies with our results, we found that the duration for peritoneal closure and total operative time was significantly high in the suture group.

In the majority of the studies that report peritoneal closure using a suture, mesh fixation was done using tackers. In our study, we have used suturing as the technique for both mesh fixation and peritoneal closure in patients allotted under the suture group. Very few studies are available in the literature where authors have used suturing both for fixing the mesh and closing the peritoneal flap.^[13,15]

The postoperative pain assessment by VAS scores on POD 1, 7, 14 days, and at 3 months and were compared in both the groups in our study. Our analysis of the results showed that the mean VAS scores were 5.23, 1.90, 0.23, and 0 in the suture group on POD 1,7,14 days and at 3 months respectively (*Table 6*). The mean VAS scores for the tackler group were 6.0, 2.17, 0.43, and 0.23 on POD 1,7,14, and at 3 months respectively (*Table 6*). This showed that the postoperative pain in the suture group was significantly less on POD1 and at 3 months than in the tackler group.

The study performed by Kleidari et al reported that VAS scores measured on POD1,7, and 14 were higher in the tackler group when compared to the suture group.^[8] In 2020, Aziz et al presented a study that compared the postoperative pain at 6 hours and 24 hours in patients undergoing suture fixation versus tack fixation of mesh.^[15] His study showed that pain was significantly high at 6 and 24 hours (p= < 0.001) in the tackler group. Similar to these studies, we found that the postoperative pain was less in the suture group when compared to the tackers group.

There are many methods of mesh fixation and peritoneal closure which include tackers, staples, sutures, and fibrin glue. A study performed by Elhadidi et al in 2023 compared chronic groin pain (CGP) in TAPP using stapler versus sutures for mesh fixation.^[14] They found that chronic pain was most likely due to nerve entrapment and from deep penetration of the abdominal wall from the staples. This study also concluded that even though the CGP in both groups was insignificant (p=0.632), early postoperative pain was more common in the staples group. Kapisir et al study had reported reduced complaints of persistent inguinal pain when they adopted a suture technique for both mesh fixation and peritoneal closure.^[16] Few studies have clearly shown that the use of more than 10 tacks for mesh fixation and peritoneal closure doubled the incidence of postoperative pain when compared to fewer tacks.^[17] Many studies have quoted fibrin glue as a better alternative to tackers in terms of pain and postoperative complications and the advantages of less tissue damage and reduced postoperative pain.^[7,18,19]

Recently, the major decisive outcome following inguinal hernia repair that has been extensively studied is the postoperative QOL. This aspect has been clearly demonstrated by large database studies from the NHS, UK. Very few studies from India have reported on QOL following TAPP using different methods of fixation. Our study is the first of its kind to be carried out in a rural University Teaching Hospital setting, with the main focus on QOL following TAPP using tackers or sutures. The available validated scales to assess disease-specific QOL in hernia patients are the Eura HS Quality of Life Scale (EuraHS QoL), the Hernia-Related Quality of Life Survey (HerQles) and the Carolinas Equation for Quality of Life (CeQOL).^[20-24]

The authors proposed that patients who had undergone peritoneal closure using sutures may have better short-term QOL than those undergone peritoneal closure using tacks or staples which have the risk of penetrating the abdominal wall muscles more deeply. The main objective to observe is QOL at 2 and 4 weeks in terms of three terms – pain, activity limitation and mesh sensation.^[25] With the above postoperative complications, QOL also has become a major outcome measured by the surgeons. It aimed to reduce the postoperative complications and to improve the QOL. For this, multiple studies have been published with special interest in QOL. The QOL is calculated by using the Carolinas Comfort Scale (CCS). This was initially developed by the team from the Carolinas Hernia Center in 2008. This CCS was used in multiple studies.^[10,11] It is used for hernia-specific QOL. The CCS uses a questionnaire to calculate the QOL(*Annexure 1*).

The major advantage of CeQOL is that it is available as a mobile application. This application was developed

in 2008 and validated in the same year and has been used in multiple studies.^[10,11,20] This is a good interactive tool for surgeons and patients to predict risk for impaired post-operative QOL outcomes. It has been used in more than 50 countries and downloaded more than ten thousand times.

Ross et al compared the peritoneal closure methods using tackers, staples and sutures and calculated the QOL in terms of activity limitation using the CeQOL application.^[10,11] The QOL is calculated based on a questionnaire that evaluated the pain, mesh sensation and movement limitation. This group conducted the study at Carolinas Hernia Center at Charlotte in USA in 2014 with a short follow-up of 2 weeks and 4 weeks and again analyzed the long-term follow-up data of 24 months follow up in 2016.^[10,11]

They concluded that the majority of patients in the tacker group had pain at 2 weeks when compared to the suture group, thus significantly improving the 2-week postoperative activity limitation in the suture group.^[11] The follow-up study published in 2016 revealed that patients undergoing TAPP inguinal hernia using tackers, sutures or staples had no significant difference in QOL at 12 and 24 months.^[10]

In our study, we analyzed the QOL in terms of the pain, mesh sensation and activity limitation at 3 months of the postoperative period. All three domains had high scores and were significantly worse in the tackers group compared to the suture group (*Table 7*).

We also used the CeQOL application to predict the risk for impaired QOL. The risk for activity limitation was 12.50 ± 1.97 in the tackers group and 10.73 ± 1.48 in the sutures group ($p = 0.001$, *Table 8*). This prediction of the risk for poor QOL provides an opportunity for both the surgeon and the patient to anticipate the symptoms, evaluate them and resolve them.

The majority of studies on TAPP in the last decade have focused on methods of fixation and their effect on seroma, hematoma, orchitis, signs of mesh infection, neuralgia and subsequent hernia recurrence.^[8] The study by Kleidari et al, compared the outcomes in mesh fixation using tackers versus sutures.^[8] They observed the postoperative complications of seroma, hematoma, orchitis, and signs of mesh infection/ neuralgia on follow-up and found there was no evidence of seroma, hematoma, neuralgia, orchitis, or signs of mesh infection in either group. Considering the other postoperative complications, seroma formation was also looked for in both groups in our study. There was no seroma formation in the suture group and in the tacker group, one patient developed seroma on the 7th postoperative day ($p = 0.001$, *Table 9*).

The tacker used in this study was a non-absorbable titanium 30 tacker (Covidien) at a price of Rs. 25000 (\$300) per procedure. The suture used was ETHIBOND 2-0 that was less expensive (Rs.1500, \$20 per procedure) (*Table 10*). The cost of sutures was less compared to the tackers. This makes it possible for the majority of the population who are from lower socioeconomic groups to undergo minimal access surgery, which can be practiced efficiently in the institution or hospital setup in the rural area likewise in our study

7. Limitations

While this study offers valuable insights, it is not without limitations. The sample size was relatively small, and the follow-up period was limited to 3 months, which may not capture long-term outcomes such as hernia recurrence. Additionally, the study was conducted in a single center, which may limit the generalizability of the findings.

Implications for Clinical Practice

The results suggest that sutures are a viable option for mesh fixation in TAPP, offering benefits in terms of pain reduction, quality of life, and cost-effectiveness. The results of this study indicate that surgeons might consider implementing suture techniques for mesh fixation in TAPP procedures, especially for patients at higher risk for postoperative pain or those requiring a more financially considerate approach. By choosing sutures, clinicians can potentially enhance patient satisfaction and outcomes while minimizing healthcare costs associated with hernia repairs.

Future Research Directions

Future research is warranted to further explore the long-term outcomes associated with the use of sutures versus tackers in the context of hernia repair. Specifically, studies should focus on the followings for enhanced patient care strategies:

1. Long-term follow-up to assess rates of hernia recurrence and chronic pain.

2. Investigating alternative fixation methods, such as fibrin glue or self-gripping meshes, to optimize TAPP procedures and mitigate any potential complications associated with current techniques.
3. Multi-center trials to evaluate the generalizability of these findings across diverse populations and practice settings.

8. Conclusion

The mesh fixation and peritoneal closure in Transabdominal preperitoneal mesh repair are being performed by many methods. We compared the usage of tackers and sutures for the mesh fixation and peritoneal closure.

Based on the results and the methodology employed, we have concluded that using sutures for mesh fixation and peritoneal closure in TAPP has better outcomes in terms of postoperative pain, seroma formation, short-term quality of life, and cost. Although sutures require a longer operative time, their benefits in terms of patient comfort and cost-effectiveness make them a preferable choice for mesh fixation in TAPP procedures. The findings suggest that adopting sutures as the preferred fixation method could be particularly beneficial in clinical settings where patient comfort and cost-effectiveness are prioritized, such as in resource-limited environments

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Disclosures

The authors declare no conflicts of interest related to this study. The study was conducted in accordance with ethical guidelines and approved by the Institutional Medical Ethics Committee. All participants provided informed consent prior to inclusion. Additionally, the research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Declaration by Author

The authors declare that this research is original and has not been published elsewhere in any form or language, except in abstract form. Additionally, this manuscript is not under consideration for publication by any other journal.

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