

Efficacy and Safety of Barbed Sutures versus Standard Fixation Techniques using Tackers in Laparoscopic Ventral and Incisional Hernia Repair: A Prospective, Single Blinded, Randomized Controlled Trial

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Abstract:

Background: The success of laparoscopic hernia repair relies on effective mesh fixation methods.

Objectives: To determine the efficacy and safety of barbed sutures versus standard fixation techniques using tackers in laparoscopic ventral and incisional hernia repair.

Methods: This was a single centre, hospital based, prospective, single blinded, randomized controlled trial conducted in the Department of General Surgery of a tertiary teaching healthcare facility in South India between January 2023 and June 2024.

Results: This study involved 80 patients undergoing elective laparoscopic hernia repair, with 40 patients in Group A (tackers group) and 40 in Group B (suture group). Both groups were comparable in terms of age, gender distribution, BMI, comorbidities, hernia type, defect location, and defect size, with no significant differences observed. The mean mesh fixation time was significantly ($p < 0.05$) shorter in Group A (23.4 minutes) compared to Group B (44.2 minutes), and the total operative time was also shorter in Group A (62.1 minutes) than in Group B (83.5 minutes). Surgical site infections occurred more frequently in Group A (12.5%) than in Group B (2.5%), though this difference was not statistically significant. Group A also had a significantly higher need for rescue analgesia (72.5% vs. 40.0%). While recurrence was noted in 7.5% of Group A, no recurrences were observed in Group B. Postoperative pain, measured using the Visual Analogue Scale (VAS), was consistently lower in Group B from postoperative day 1 onwards, with significant differences observed at all time points, including at 1-month, 3-month, and 6-month follow-ups ($p < 0.05$).

Conclusion: These results suggest that barbed sutures may offer a significant advantage in reducing postoperative pain compared to tackers.

Keywords: Barbed sutures, Tackers, Laparoscopic Ventral and Incisional Hernia Repair, Postoperative pain, randomized controlled trial.

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Introduction

Laparoscopic hernia repair has become a widely accepted approach for managing both ventral and incisional hernias due to its minimally invasive nature and associated benefits, including reduced postoperative pain, shorter recovery times, and improved cosmetic outcomes.[1,2] The success of this technique heavily relies on effective mesh fixation methods, which aim to secure the mesh and facilitate proper healing of the hernia defect.[3] Traditional fixation techniques have utilized absorbable tackers and sutures, each with its advantages and limitations.[4] Absorbable tackers

are commonly used for mesh fixation in laparoscopic hernia repair. They offer the advantage of quick and straightforward application, with minimal need for additional surgical incisions.[5] However, issues such as pain at the tacker sites and potential for tack migration or extrusion have been reported, raising concerns about their long-term efficacy and patient comfort.[6] Barbed sutures represent an alternative fixation method that has gained attention for their ease of use and potential benefits over traditional suturing techniques. These sutures are designed

with barbs that eliminate the need for knotting, potentially reducing operative time and simplifying the fixation process.[7] Initial studies suggest that barbed sutures may result in less postoperative pain and quicker recovery compared to standard suturing techniques.[8] However, the comparative efficacy of barbed sutures versus traditional fixation methods like tackers in the context of laparoscopic hernia repair remains a topic of ongoing investigation. Several studies have explored the outcomes associated with different fixation techniques, but results have been inconsistent. For instance, a study by Li & Zhang (2018) found that barbed sutures were associated with reduced postoperative pain and shorter operative times compared to standard sutures, but did not directly compare these outcomes with tackers.[9] Conversely, a study by Ahmed et al. (2018) reported similar pain levels between tackers and sutures, highlighting the need for further research to clarify these findings.[10]

Against this background, the aim of the present study was to determine the efficacy and safety of barbed sutures versus standard fixation techniques using tackers in laparoscopic ventral and incisional hernia repair in terms of postoperative pain, operative time, complications, and recurrence.

Materials and Methods

This was a single centre, hospital based, prospective, single blinded, randomized controlled trial conducted in the Department of General Surgery of a tertiary teaching healthcare facility in South India between January 2023 and June 2024. The study was approved by the Institutional Human Ethics Committee (IHEC). The participants were given the Participant Information Sheet (PIS) in their native language, and its contents were verbally explained to ensure their understanding and satisfaction. Enrolment into the study proceeded upon receipt of written informed consent. Shankaran et al. (2023) noted the mean visual analogue scale scores at 6 weeks among patients in the tackers group to be 3.0 and that among patients in the suture group to be 1.0. Using this information, considering the level of significance to be 5% (type I error), power to be 80% (or 20% type II error), and attrition rate (non-response rate) to be 10%, the minimum required sample size was computed to be 80 – 40 in each group with 95% confidence. The patients were enrolled using nonprobability sampling – convenience sampling technique. However, to allot patients randomly into Groups A (tackers group) and B (suture group), simple randomization was done – computer generated random numbers were used.

The patients more than 18 years of age with ventral or incisional hernia who underwent elective

laparoscopic hernia repair were enrolled in the present study. However, patients with chronic cough, active abdominal infection, loss of abdominal domain, and ascites were excluded from the present study.

Surgical procedure:

All surgeries were conducted under general anaesthesia with the administration of prophylactic antibiotics at the time of induction. Port size and placement were determined and upon entering the abdomen and maintaining a CO₂ pressure of 10-12 mmHg, adhesiolysis was performed using diathermy and scissors to assess the defect size. The mesh size was selected to ensure a 5 cm overlap around the defect. The Intraperitoneal Onlay Mesh (IPOM) used ranged in size from 15x15 cm to 20x20 cm, rectangular in shape, with a 5 cm overlap. To confirm mesh size and positioning, the abdomen was desufflated, and markings were made over the abdomen. The mesh was introduced into the peritoneal cavity through a 10 mm port and carefully unrolled with the soft, biocompatible, collagen side facing the viscera. Four points on the anterior abdominal wall were marked to guide the placement of transfascial sutures using a suture passer. The sutures were then drawn through the skin and held in place under traction. Depending on the fixation method used, transfascial sutures were either tied (in the Tacker method) or cut and removed without knotting (in the barbed suture method). In the tacker method, absorbable 5 mm helical titanium tackers were used at intervals of 1.5-2 cm, employing either the single crown (SC) method for defects smaller than 4 cm or the double crown (DC) method for defects 4 cm or larger. No additional ports were necessary for securing the mesh perimeter. In the barbed suture method, V-Loc 180 absorbable barbed sutures were used for continuous suturing at 1.5-2 cm intervals. Depending on mesh size, two or three foils of sutures were employed. The barbed suture's loop eliminates the need for an initial knot, and a simple knot suffices to secure the suture end. Random sutures were taken in cases of defects larger than 4 cm to prevent sagging. Additional 5 mm ports were used to secure the mesh to the blind corners and sides as needed. The duration for mesh fixation using sutures was recorded.

Postoperative analgesia followed the WHO pain management ladder. Intravenous paracetamol was administered every 6-8 hours for the first 24 hours, with diclofenac suppositories used for rescue analgesia based on patient weight. After 24 hours, oral analgesics, including paracetamol and tramadol, were provided. The patients were followed by for six months postoperatively at serial intervals (POD 0, 1, 2, 3, 4, 5, 6, 7, at 1 month, 3 months and at 6 months).

Statistical analysis: The data obtained was manually entered into Microsoft Excel and analysed using Statistical Package for Social Sciences (SPSS) v23. All the categorical variables were summarised using frequencies and percentages. Continuous variables were summarized using mean (standard deviation) and/or median (interquartile range) (based on the results of data normality, tested using Kolmogorov–Smirnov test and the Shapiro–Wilk test). To test for statistical significance, Chi square test or Fisher exact test (for categorical variables) and independent “t” test or Mann Whitney U test (for continuous variables) was used. Statistical significance was considered at p value less than 0.05.

Results

The present study included 80 patients with ventral or incisional hernia who underwent elective laparoscopic hernia repair – 40 patients in Group A (tackers group) and 40 patients in Group B (suture group). The mean age of patients in Group A was 41.8 years (SD 6.5), while in Group B, it was 42.4 years (SD 7.2), with no significant difference between the groups ($p > 0.05$). In terms of gender distribution, 60.0% of Group A and 52.5% of Group B were male ($p > 0.05$).

The majority of patients in both groups had a normal BMI, with 82.5% in Group A and 90.0% in Group B ($p > 0.05$). Comorbidities were present in 55.0% of Group A and 47.5% of Group B, which was not statistically significant ($p > 0.05$). The defect location was central in 40.0% of both groups, with other locations being less common and not significantly different between the groups ($p > 0.05$). Both groups had an equal distribution of hernia types, with 50.0% having primary ventral hernias and 50.0% incisional hernias in Group A, compared to 47.5% and 52.5% respectively in Group B ($p > 0.05$). The defect size ranged from 1.0 to 6.0 cm in most patients, with no significant differences between the groups ($p > 0.05$). Only one patient in Group B had a defect size greater than 6.1 cm.

In the study, 90.0% of patients in Group A and 92.5% in Group B underwent elective surgery, with

no significant difference between the groups ($p > 0.05$). The entry technique used was Hasson in 30.0% of Group A and 32.5% of Group B, and Veress in 70.0% of Group A and 67.5% of Group B, which was also not statistically significant ($p > 0.05$). The mean mesh fixation time was significantly shorter in Group A (23.4 minutes, SD 4.3) compared to Group B (44.2 minutes, SD 9.5), with a p-value of < 0.001 .

Similarly, the total operative time was significantly shorter in Group A (62.1 minutes, SD 10.7) compared to Group B (83.5 minutes, SD 20.6), with a p-value of < 0.001 . Surgical site infections occurred in 12.5% of Group A and 2.5% of Group B, though this difference was not statistically significant ($p > 0.05$). However, the need for rescue analgesia was significantly higher in Group A (72.5%) compared to Group B (40.0%), with a p-value of 0.003. Recurrence was noted in 7.5% of Group A patients, while no recurrences were observed in Group B, though this difference was not statistically significant ($p > 0.05$).

The Visual Analogue Scale (VAS) scores, measured at various postoperative days (POD) and follow-up intervals, showed a significant difference between Group A and Group B. On POD 0, the mean VAS score was slightly higher in Group A (8.2, SD 1.6) compared to Group B (7.5, SD 1.1), but this difference was not statistically significant ($p > 0.05$). From POD 1 onwards, Group B consistently had significantly lower VAS scores compared to Group A.

On POD 1, the mean VAS score in Group A was 7.7 (SD 1.2) versus 6.3 (SD 1.0) in Group B ($p < 0.001$). This trend continued through POD 7, with Group A scoring 3.4 (SD 0.7) and Group B scoring 1.3 (SD 0.5) ($p < 0.001$). At the 1-month follow-up, the mean VAS score in Group A was 2.4 (SD 0.4), while in Group B, it was 1.1 (SD 0.2) ($p < 0.001$). The difference in VAS scores remained significant at both the 3-month (Group A: 2.1, SD 0.3; Group B: 0.6, SD 0.1) and 6-month follow-ups (Group A: 1.6, SD 0.3; Group B: 0.5, SD 0.2), with p-values of < 0.001 for both. These results indicate a significantly lower pain perception in Group B across all time points.

Table 1: Baseline characteristics of the study groups

		Group A N = 40	Group B N = 40	P value
		n (%)	n (%)	
Age (in years) Mean (SD)		41.8 (6.5)	42.4 (7.2)	0.697
Gender	Male	24 (60.0)	21 (52.5)	0.498
	Female	16 (40.0)	19 (47.5)	
BMI (in kg/m ²)	Underweight	2 (5.0)	1 (2.5)	0.618
	Normal	33 (82.5)	36 (90.0)	
	Overweight or obese	5 (12.5)	3 (7.5)	
Comorbidity	Present	22 (55.0)	19 (47.5)	0.502
	Absent	18 (45.0)	21 (52.5)	

Location of defect	Central	16 (40.0)	16 (40.0)	0.545
	Lower midline	13 (32.5)	8 (20.0)	
	Upper midline	3 (7.5)	4 (10.0)	
	Others	8 (20.0)	12 (30.0)	
Hernia type	Primary ventral	20 (50.0)	19 (47.5)	0.823
	Incisional	20 (50.0)	21 (52.5)	
Defect size (in cm)	1.0 to 3.0	21 (52.5)	20 (50.0)	0.994
	3.1 to 6.0	19 (47.5)	19 (47.5)	
	≥6.1	0 (0.0)	1 (2.5)	

*Statistically significant at p<0.05, SD, Standard deviation; BMI, Body mass index

Table 2: Comparison of study groups, by operative characteristics and rate of recurrence

		Group A N = 40 n (%)	Group B N = 40 n (%)	P value
Priority of surgery	Elective	36 (90.0)	37 (92.5)	0.692
	Emergency	4 (10.0)	3 (7.5)	
Entry technique	Hasson	12 (30.0)	13 (32.5)	0.809
	Veress	28 (70.0)	27 (67.5)	
Mesh fixation time (in minutes) Mean (SD)		23.4 (4.3)	44.2 (9.5)	<0.001*
Total operative time (in minutes) Mean (SD)		62.1 (10.7)	83.5 (20.6)	<0.001*
Surgical site infection	Present	5 (12.5)	1 (2.5)	0.089
	Absent	35 (87.5)	39 (97.5)	
Need for rescue analgesia	Present	29 (72.5)	16 (40.0)	0.003*
	Absent	11 (27.5)	24 (60.0)	
Recurrence	Yes	3 (7.5)	0 (0.0)	0.166
	No	37 (92.5)	40 (100)	

*Statistically significant at p<0.05, SD, Standard deviation

Table 3: Comparison of study groups, by visual analogue scale (VAS) scores

Visual analogue scale (VAS) scores	Group A N = 40 Mean (SD)	Group B N = 40 Mean (SD)	P value
	POD 0	8.2 (1.6)	7.5 (1.1)
POD 1	7.7 (1.2)	6.3 (1.0)	<0.001*
POD 2	6.6 (0.9)	5.1 (0.6)	<0.001*
POD 3	5.9 (1.0)	3.9 (0.6)	<0.001*
POD 4	5.4 (1.1)	3.2 (0.5)	<0.001*
POD 5	5.4 (0.9)	3.1 (0.5)	<0.001*
POD 6	4.3 (0.8)	2.0 (0.3)	<0.001*
POD 7	3.4 (0.7)	1.3 (0.5)	<0.001*
1 month follow up	2.4 (0.4)	1.1 (0.2)	<0.001*
3 months	2.1 (0.3)	0.6 (0.1)	<0.001*
6 months	1.6 (0.3)	0.5 (0.2)	<0.001*

*Statistically significant at p<0.05, SD, Standard deviation

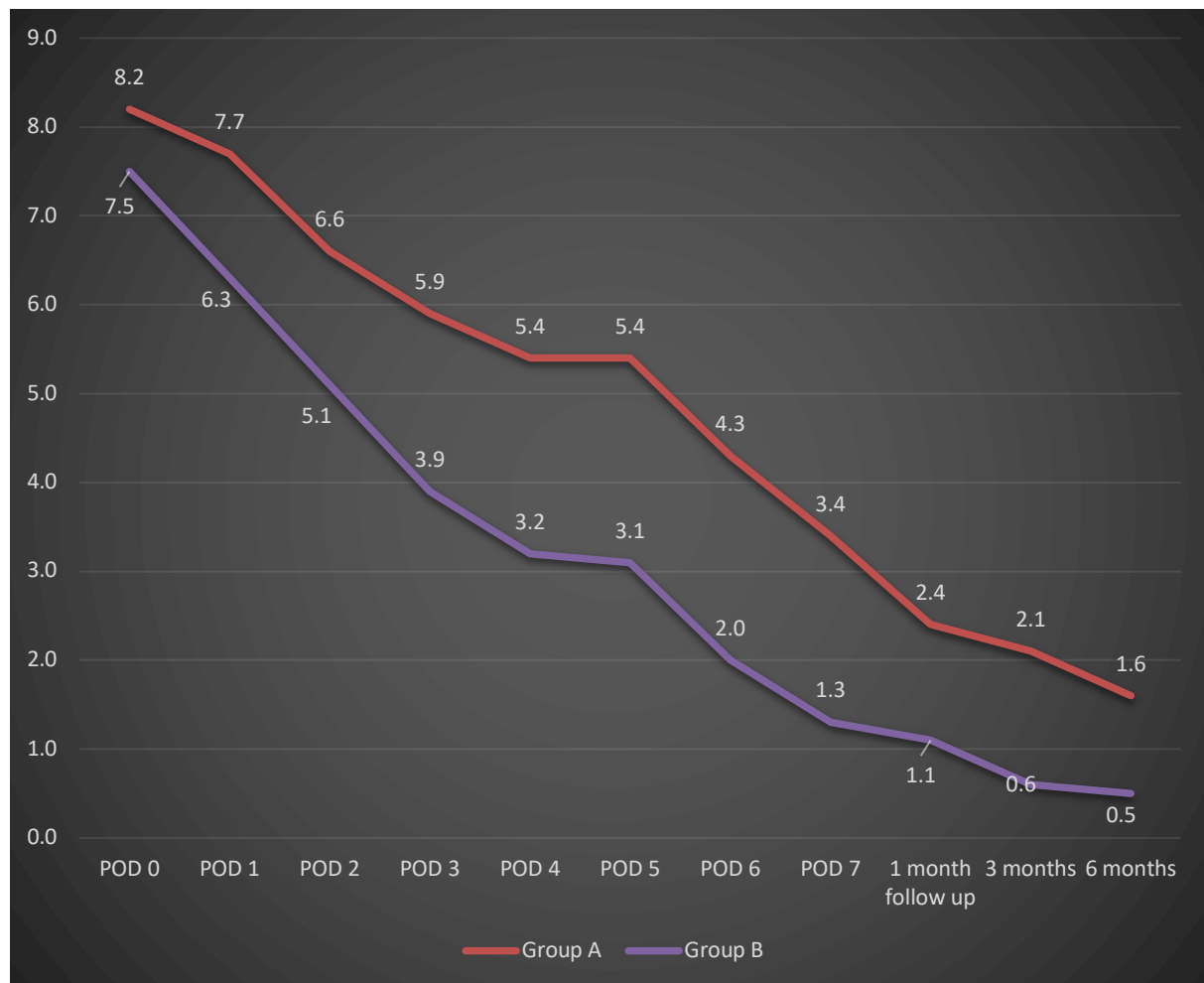


Figure 1: Comparison of study groups, by visual analogue scale (VAS) scores

Discussion

The present study aimed to compare the efficacy and safety of barbed sutures versus standard fixation techniques using tackers in laparoscopic ventral and incisional hernia repair. The study included 80 patients, divided into two groups: Group A (tackers) and Group B (sutures), with 40 patients each. The demographic characteristics, including age, gender distribution, and BMI, were comparable between the two groups, with no statistically significant differences ($p > 0.05$). This similarity in baseline characteristics is crucial as it minimizes confounding variables, ensuring that any differences observed in outcomes can be attributed more directly to the fixation techniques used rather than patient demographics. The distribution of comorbidities was also similar between the groups, with no significant differences. This is in line with studies by Köckerling et al. (2018), who emphasized the importance of controlling for comorbidities in hernia surgery to avoid bias in outcomes.[11] The equal distribution of hernia types (primary ventral and incisional) further supports the comparability of the groups, a critical factor highlighted by Köckerling et al. (2021) in

their work on hernia repair outcomes.[12] One of the key findings in this study was the significant difference in mesh fixation time and total operative time between the groups. Group A (tackers) had a significantly shorter mesh fixation time (23.4 minutes) compared to Group B (sutures) (44.2 minutes), with a p -value of < 0.001 . This difference was mirrored in the total operative time, where Group A also had a shorter duration (62.1 minutes vs. 83.5 minutes, $p < 0.001$). The shorter operative time associated with tacker use aligns with previous studies, such as those by Kingsnorth et al. (2009), who noted that tackers provide a quicker method for mesh fixation, particularly in laparoscopic procedures.[13]

However, this advantage must be weighed against other outcomes, particularly postoperative pain and complications. Interestingly, the need for rescue analgesia was significantly higher in Group A (72.5%) compared to Group B (40.0%). This finding suggests that despite the quicker operative times associated with tackers, the method may be associated with increased postoperative pain. The increased pain in the tacker group may be related to the mechanical fixation method, which can cause

more localized trauma to the abdominal wall compared to the barbed suture method (Suárez-Grau et al., 2024).[14] This observation is consistent with the findings of Xu et al. (2023),[15] who reported that patients undergoing hernia repair with tackers experienced higher levels of postoperative pain compared to those treated with sutures. The use of barbed sutures, which distribute tension more evenly across the mesh, may contribute to lower pain levels, as supported by research from Nambi Gowri & King, 2023; and Wiessner et al., 2017.[16,17]

While the incidence of surgical site infections (SSIs) was higher in the tacker group (12.5%) compared to the suture group (2.5%), this difference was not statistically significant ($p > 0.05$). The literature on SSIs following hernia repair presents mixed results, with some studies suggesting a higher risk associated with tackers due to potential tissue necrosis caused by the mechanical fixation (Kar et al., 2015).[18] However, others, such as the study by Bansal et al. (2012),[19] found no significant difference in SSI rates between the two methods. The recurrence rate was higher in the tacker group (7.5%) compared to the suture group, where no recurrences were observed. Although this difference was not statistically significant, the trend aligns with findings from Chelala et al. (2016),[20] who suggested that barbed sutures might offer superior long-term fixation strength compared to tackers, potentially reducing the risk of recurrence. This may be due to the continuous nature of barbed sutures, which provide a more uniform distribution of tension across the repair site, as opposed to the point fixation provided by tackers.

Pain, as measured by the Visual Analogue Scale (VAS), was consistently lower in the suture group across all time points, from postoperative day 1 through the 6-month follow-up. On the day of surgery (POD 0), the mean VAS score was slightly higher in Group A (8.2) compared to Group B (7.5), but this difference was not statistically significant ($p > 0.05$). This initial similarity in pain perception can likely be attributed to the immediate postoperative effects, where factors such as anaesthesia wear-off and the initial trauma from the surgery itself play a more prominent role than the fixation technique used.

This finding is consistent with other studies that report similar pain levels on the day of surgery, regardless of the fixation method (Fränneby et al., 2006).[21] However, starting from POD 1, a significant divergence in pain scores was observed between the groups. Group B consistently reported lower VAS scores, indicating less pain compared to Group A. For instance, on POD 1, Group A had a mean VAS score of 7.7, whereas Group B had a significantly lower score of 6.3. This trend

continued throughout the early postoperative period, with Group B maintaining significantly lower pain scores at all subsequent time points, including the 1-month, 3-month, and 6-month follow-ups. The differences in pain perception between the two groups can be attributed to the inherent characteristics of the fixation techniques. Tackers, which involve mechanical fixation of the mesh to the abdominal wall, can cause more localized trauma, leading to higher levels of postoperative pain. The pressure and potential tissue damage from the tacker points may lead to increased inflammation and nerve irritation, which could explain the higher pain scores observed in Group A (Silfvenius et al., 2024).[22] This localized trauma might be particularly pronounced in the immediate days following surgery, as seen in the significant differences in VAS scores from POD 1 onwards. In contrast, barbed sutures provide a more distributed tension across the repair site, potentially reducing localized trauma and subsequent pain. The continuous nature of barbed sutures, which do not require knots and distribute tension more evenly, may contribute to lower inflammation and irritation of surrounding tissues, leading to reduced postoperative pain (Kumar et al., 2005).[23] The significant reduction in pain scores in the suture group supports this theory, indicating that the barbed sutures may offer a gentler fixation method with fewer adverse effects on postoperative comfort. The significant difference in VAS scores persisted beyond the immediate postoperative period, with Group B continuing to report lower pain levels at the 1-month, 3-month, and 6-month follow-ups. For example, at the 6-month mark, Group A had a mean VAS score of 1.6, while Group B had a significantly lower score of 0.5. This sustained reduction in pain is particularly noteworthy, as chronic pain following hernia repair can significantly impact a patient's quality of life (van Veenendaal et al., 2021).[24] Chronic postoperative pain, often defined as pain persisting for more than 3 months after surgery, is a well-documented complication of hernia repair, particularly with fixation techniques that cause more tissue trauma (Olsson et al., 2023).[25] The results of this study suggest that barbed sutures may reduce the risk of chronic pain development, providing a more favourable long-term outcome for patients. This aligns with findings from other studies, such as those by Bittner et al. (2019),[26] who reported lower chronic pain rates in patients undergoing hernia repair with barbed sutures compared to those with traditional suture or tacker fixation.

The present study, while providing valuable insights into the comparative efficacy and safety of barbed sutures versus tackers in laparoscopic hernia repair, has several limitations that should be acknowledged. Firstly, the study was conducted at

a single centre, which may limit the generalizability of the findings to other settings with different patient populations or surgical practices. Additionally, the relatively small sample size of 80 patients, although adequate for detecting significant differences in pain scores, may not be sufficient to capture the less common complications or outcomes, such as hernia recurrence over a longer follow-up period. The study's design also relied on subjective measures of pain, which, despite the use of the VAS, could be influenced by individual patient factors such as pain tolerance, expectations, or psychological state. Furthermore, the study did not account for potential confounding variables, such as variations in surgical technique, the experience level of the surgeons, or the use of adjunctive pain management strategies, which could have affected the outcomes. Lastly, the follow-up period, while extending to six months, may not be long enough to fully assess long-term outcomes, including chronic pain or hernia recurrence, thus warranting further studies with extended follow-up durations to confirm these findings.

Conclusion

The findings demonstrate that the use of barbed sutures is associated with significantly lower postoperative pain and a reduced need for rescue analgesia compared to tackers, particularly from the first postoperative day through to six months of follow-up. Additionally, while the mesh fixation and total operative times were longer in the suture group, this technique did not lead to increased complication rates, and there were no recurrences observed in the barbed suture group during the follow-up period. These results suggest that barbed sutures may offer a preferable alternative to tackers, particularly for patients where pain management and long-term outcomes are of concern.

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