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To Compare Absorbable Versus Non-absorbable Tacker for Laparoscopy Ventral Hernia Repair: A Prospective, Randomized Study

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Abstract

Context: Laparoscopic incisional ventral hernia repair (LIVHR) has been associated with a high incidence acute and chronic pain due to use of non-absorbable tackers. Several absorbable tackers have been introduced to overcome these complications.

Aims: To compare postoperative effectiveness, comfort, complications of mesh fixation using absorbable and non-absorbable tacks in laparoscopic ventral hernia repair.

Settings and design: A Prospective randomized clinical trial. Randomization was done by computer generated randomization number method for a period of 2-year study duration.

Material and methods: A total of 60 patients were randomized in two groups. Patients of Group A were subjected to mesh fixation with absorbable tacks and group B were subjected to mesh fixation with no-absorbable tacks. All were evaluated for visual analogue scale (VAS) postoperative, length of hospital stay, time to resume normal activity.

Statistical analysis used: Results were compared by student *t* test or Mann Whitney *U* test for continuous variables, and chi-square or Fisher's exact tests were used for categorical variables.

Results: Patients in both the groups were comparable in terms of demographic profile and hernia characteristics. No significant difference found in VAS score at day 0, 1 week, 3 months and 6 months. No significant difference found in hospital stay, time to return to normal activity, postoperative complications.

Conclusions: As per our opinion, the choice of either of these fixation methods during surgery should not be based on the concerns of pain or recurrence. AT may be the preferable option in LIVHR due to the lower cost.

Keywords: Laparoscopic incisional ventral hernia repair; Non-absorbable tackers; Mesh fixation; Pain; Visual analogue scale.

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Introduction

The ventral hernia repair surgery has evolved from direct suture repair to the use of synthetic mesh to obtain a tension-free repair during last 50 years. Open ventral hernia surgeries were commonly practiced in past but laparoscopic repair of ventral hernia has gained popularity since many studies have reported encouraging results in term of outcome and recurrence rate.[1,2] Laparoscopic technique offers a variety of advantages over conventional open surgery in the repairing of ventral hernia, such as shorter recovery time and lower recurrence rates and lower wound complication rates.[3]

The ventral hernia repair surgery has evolved from direct suture repair to use of synthetic mesh,

mesh fixation with suture to fixation by non-absorbable tacks, absorbable tacks and fibrin glue to obtain tension-free repair.[4] In laparoscopic ventral hernia repairs both non-absorbable and absorbable tacks are used for fixation of mesh. Non-absorbable tacks (NAT) have several complications such as adhesion formation and bowel perforations, post-operative pain.[5,6] Recently absorbable tacks (AT) have been introduced for use in combination with light weight meshes, under the assumption that permanent fixation is no longer needed after mesh has integrated with the host tissue, nevertheless, there is no evidence that absorbable tacks may guarantee the same results as non-absorbable tacks in terms of strength of fixation and recurrence rates.[7,8]

The direct comparison of non-absorbable with absorbable tacks seems to be the best way to assess their efficacy and safety for short and long term. The aim of our study is to compare absorbable tacks with non-absorbable tacks for fixation of mesh in laparoscopic ventral hernia repair in term of postoperative pain, length of hospital stay, complications and recurrence rates.

Materials and Methods

This prospective study was conducted from August 2017 to August 2019 after getting clearance from Institutional Review Board. All the patients diagnosed with ventral hernia attending surgery OPD was taken as study population. Informed and written consent for Anesthesia and Surgery was taken from each patient in their local language. Patient of both sexes with age group 18–65 years with uncomplicated ventral hernia including incisional hernia. Patients with recurrent hernias, significant comorbidities such as diabetes mellitus, coronary artery disease and requiring any additional intra abdominal procedure, defect size >5 cm, unfit for general anesthesia, converted to open hernia repair due to any reason and requiring component separation were excluded from the trial.

Total 60 patients were randomized into 2 groups using computer generated random numbers in sealed envelopes numbered serially to ensure concealed allocation with block randomization. Informed consent was obtained from each patient before randomization. Patients of group A were subjected to mesh fixation with absorbable tacks (Absorba Tack, COVIDEN, U.S.A.) and patients of Group B were subjected to mesh fixation with non-absorbable tacks (ProTack, COVIDEN, U.S.A.).

Patients were operated under general anesthesia with endotracheal intubation. Three ports were used, first 12 mm camera port for a 30° 10 mm telescope and 2 additional 5 mm working ports. Additional ports were used if required. Adhesions were taken down and the size of the defect was measured. A mesh of appropriate size to have a 5 cm overlap on all sides was taken in through 12 mm port and mesh was fixed with tackers in a double-crown fashion and placing the tackers at a distance of 1.5 to 2 cm and at least 4 corner transfacial suture placement was used. The method of mesh fixation for each patient was determined by means of computerized random generation of a number just before the operation. The number was given to the surgeon, and the mesh fixation technique previously assigned to that number was used. Patients were randomly assigned to the NAT and AT mesh-fixation groups. In the AT group, the mesh fixation was provided by absorbable tack and in the NAT group, titanium helical tacks were placed approximately 5 mm inside the edge of the mesh along its entire perimeter, about 1.0 – 2.0 cm apart. After fixation of the mesh, the trocars were removed, and the 10 mm fascial defects were closed. All patients provided standard postoperative care, including mobilization. A patient-controlled analgesia was provided for the first 24 hours after surgery.

Patients were followed up to 9 months after the surgery. Follow-up was done in the surgery outpatient department at day 1, day 7, 1 month, 3 months and 6 months from the date of surgery. Those who not reported back in OPD were be contacted on phone. Following parameters were evaluated: early postoperative pain and chronic pain, pain score was evaluated on VAS ranging from no pain (0) to worst possible pain (10). Postoperative hospital stay, time to resume normal activity, any wound seromas or hematomas, recurrence of the hernia.

Statistical Analysis

Numerical data were presented as mean ± SD and range. Categorical variables were presented as number and percentages. Student's *t*-test will be used to compare numerical variables and the chi-square test or Fischer's exact test will be used for categorical variables. Data were processed using statistical package for social sciences (SPSS version 20.0 for Windows, SPSS Inc., IBM, and Armonk, NY) statistical software. For all statistical tests, a p value of less than 0.05 was taken to indicate significant difference.

Results

Total 60 patients were enrolled in the study. The mean ages were 48.23 ± 7.82 and 48.4 ± 7.57 years for AT and NAT groups respectively. Both groups were comparable in terms of demographic profile like age and gender (Tables 1 and 2).

Table 1: Distribution of the study group according to the age group

Age group	Group A *N* (%)	Group B *N* (%)
21–30 years	0	1 (3.3)
31–40 years	6 (20.0)	4 (13.3)
41–50 years	11 (36.7)	13 (43.3)
51–60 years	12 (40.0)	11 (36.7)
More than 60 years	1 (3.3)	1 (3.3)
Total	30 (100)	30 (100)
Mean ± SD	48.23 ± 7.82	48.4± 7.578
t-value	0.084	
p-value, Sig	0.933, NS	

Data were expressed as Number (Percentage). NS = Not Statistical significant

Table 2: Distribution of the study group according to gender

Sex	Group A *N* (%)	Group B *N* (%)
Male	8 (26.7)	7 (23.3)
Female	22 (73.3)	23 (76.7)
Total	30 (100)	30 (100)

χ^2 value = 0.089, df = 1, *p*-value = 0.766, NS

Data were expressed as number (Percentage). Data were compared using chi-square test and *p*-value is not significant. NS = Not statistical significant. df = degree of freedom.

There was no statistically significant difference in the mean VAS pain scores between the 2 groups at day 0, day 1 and day 2, 1 week, 1 month, 3 months, 6 months postoperatively (Table 3). Two patients in AT group and 3 patients in NAT group have moderate pain at 6 months. One patient was lost to follow-up 6 months in both the groups.

The time to return to normal activity in Group A was 11.2 ± 2.53 days and Group B was 11.57 ± 2.14 days which were also not statistically significant (Table 4). On 6 months follow-up, no recurrence was noted in the patient in any of the group.

Table 3: VAS score of the study group on postoperative days

Pain score post -operative day 0 (visual analogue scale)	Group A	Group B	*t*-value	*p*-value, Sig
Day 0	6.47 ± 1.57	6.6 ± 1.19	0.71	0.13, NS
Day 1	3.47 ± 0.94	3.33 ± 0.76	0.60	0.54, NS
Day 2	1.8 ± 0.66	1.7 ± 0.79	0.52	0.59, NS
1 week	1.46 ± 0.81	1.43 ± 0.72	0.16	0.86, NS
1 months	1.13 ± 1.16	0.86 ± 0.93	0.97	0.33, NS
3 months	0.5 ± 0.83	0.46 ± 0.68	0.14	0.88, NS
6 months	0.4 ± 0.21	0.6 ± 0.27	0.65	0.51, NS

Data were expressed as Mean ± SD. Both groups were compared using unpaired *t*-test and showed no statistical significance. NS = Not Statistical significant

Table 4: Time to return normal activity for study groups

Time to return to normal activity	Group A	Group B	*t*-value	*p*-value, Sig
Mean ± SD	11.2 ± 2.53	11.57 ± 2.41	0.573	0.569, NS

Data were expressed as Mean ± SD. Both groups were compared using unpaired *t*-test and showed no statistical significance. NS = Not Statistical significant

Discussion

Laparoscopic repair has been described as the "Standard of Care" according to the recent guidelines of International Endohernia Society for patients undergoing incisional and ventral hernia repair.[9] Over the open repair, laparoscopic repair have advantages of low recurrence rate, shorter hospital stay, good cosmetic outcome, and low complication rate.[10]

Few case series and retrospective studies have shown that absorbable tackers cause less pain as compare to other approaches. A study by Colak et al. observed no significant difference between the absorbable and non-absorbable groups with respect pain scores at 0, 1 and 2 days.[11] In a study by

Bangash et al., the pain scores were higher in suture groups compared to the tacks group.[12] Nguyen et al. showed no significant difference at PO 1 week, 1 month, and 2 months regarding pain assessment in suture (n = 29) and tack (n = 21) groups.[13] Bansal et al. randomized 68 patients into non-absorbable suture (n = 32) and tack (n = 36) groups. Tack fixation resulted in significantly higher pain scores than suture fixation at 1, 6, and 24 hours and also at 1 week and 3 months postoperatively. They reported no significant difference in the incidence of chronic pain and seroma, development in the follow-up of 32.2 months.[14] In a randomized controlled trial that compared methods for securing the mesh during LIVHR, the absorbable sutures with tacks (n = 56), double crown (n = 60), and non-absorbable sutures with tacks (n = 56) techniques were associated with similar PO pain and quality-of-life findings.[15] In our study, there was no significant difference found in PO VAS score in both the groups. The higher VAS pain scores with tackers are hypothesized to be due to the screwing action of the sharp tips by which the tacks penetrate tissues that causing compression and twisting of nerve fibers.[16]

Present study had shown that, the mean days of hospitalization in A group was 1.5 days ± 0.572 and 1.43 ± 0.679 days in B group which was not statistically significant. In a study by Colak et al., the mean postoperative stay in Absorbable group was 2.1 days and 2.5 days in non-absorbable groups.[11] In a study by Bangash et al., the mean days of hospitalization was 4.3 days and 4.7 days in suture group.[12]

There was no statistical significant difference found in time to return to normal activity on comparing between the 2 groups. Our findings were consistent with the previous study by Bansal et al., that also showed no statistical difference in time to return to normal activity in both AT and NAT groups.[14]

The incidence of chronic pain was however similar in both AT and NAT groups. Only 5 (16.7%) patients, 3 with NAT and 2 with AT had chronic pain by 3 months follow-up, among them only 1 required local analgesic infiltration at 6-month follow-up. Lepere et al. reported no recurrence during a follow-up period of 1 year using absorbable tacker.[17] Cavallaro et al. showed similar results on comparing non-absorbable and absorbable tackers in a non-randomized study.[18] In our study, we notice only 1 recurrence in AT group which was not statistically significant. Although the follow-up duration was for 6 months. It has been reported in literature that true incidence of recurrence in incisional and ventral hernia repair can be found, only if the patients are followed up for >5 to 10 years.[14]

Although this is a randomized trial, the study has some limitations. Few patients were given injectable analgesics during the induction of anesthesia which may have impacted the early pain VAS scores. Our follow-up period is around 6 months. A longer follow-up of minimum 3 to 5 years would have been better to comment upon the recurrence rates. Finally, the most obvious advantage of ATs is to have lower cost than NATs[11,14] but we didn't compare the price in this study as secondary objective.

Conclusion

In conclusion, we have found no significant differences between the AT and NAT fixation techniques regarding recurrence, complications, and PO pain for 6 months duration. ATs may be a preferable option due to lower cost in LIVHR. Based on this study results, the choice of either of these fixation methods during surgery should not be based on the concerns of pain or recurrence.

Key Message

Both fixation method, absorbable and non-absorbable tackers have same outcome for long duration in laparoscopic incisional ventral hernia repair. So, choice of mesh fixation will not be depend on outcome and complication of these methods.

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