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A COMPARATIVE STUDY OF MESH FIXATION BY ABSORBABLE VERSUS NON-ABSORBABLE TACKS IN LAPAROSCOPIC VENTRAL HERNIA REPAIR.

Surgery

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ABSTRACT

Background: Laparoscopic repair is gold standard for Ventral Hernia. Non absorbable tacks were used for mesh fixation. Absorbable tacks are also used commonly in recent time. Comparision of both fixation technique is done in regard to pain, recurrence and complications.

Methods: A prospective, randomised, comparative study was conducted on sixty patients with ventral hernia in the Surgery department of Sanjay Gandhi Memorial Hospital, Delhi over two years starting from October 2015. These patients were randomly assigned to two groups- A and B using online random number generator. Patients of group A underwent mesh fixation by Absorbable tacks and those of group B underwent mesh fixation by Absorbable tacks . Overall patient satisfaction, pain, complications and recurrence rate were compared.

Results: Mean pain score-Day 0(6.47 in AT group and 6.6 in NAT group), Day 1(3.47 in AT group and 3.33 in NAT group), Day 2(1.8 in AT group and 1.7 in NAT group), The mean days of hospitalization (1.5 in AT group and 1.43 in NAT group), The time to return normal activity in days(11.2 in AT group and 11.57 in NAT group), At 1 week of follow up(43.3% had mild pain,36.7% had moderate pain and 10% had severe pain in AT group and 50% had mild pain,36.7% had moderate pain and 6.7% had severe pain in NAT group),), At 1 month of follow up(36.7% had mild pain,20% had moderate pain and 6.7% had severe pain in AT group and 33.3% had mild pain,16.7% had moderate pain and 6.7% had severe pain in NAT group),), At 3 months of follow up(20% had mild pain,6.7% had moderate pain in AT group and 26.7% had mild pain,6.7% had moderate pain in NAT group), recurrence rate was seen in 3.3% of the AT group and no complications were recorded in both group.

Conclusions: Mesh fixation by absorbable tacks and Non-Absorbable Tacks shown no difference with respect to pain scores, the requirement of analgesics, No. of days of hospital stay, complications and recurrence rate.

KEYWORDS

Absorbable Tacks(AT), Non-Absorbable Tacks(NAT), Laparoscopic Ventral Hernia Repair(LVHR),Recurrence, and Post operative pain.

INTRODUCTION:

Ventral Hernias is one of the commonest surgical procedures worldwide. Ventral Hernia constitutes a major health care problem. The ventral hernia repair surgery has evolved from direct suture repair to mesh repair and from suture to fixation by absorbable and non absorbable tacks.

Patient selection and patient compliance, The choice of mesh and fixation methods are crucial issue to achieve optimal results and reduce recurrence rates.[1,2,3]

The main cause of hernia recurrence is mesh rupture, mesh slippage and mesh shrinkage. these factors could be partly prevented by an appropriate mesh overlap and fixation technique.[4,5] but the applied fixation system is an important cause of the chronic post operative pain.[6]

In laparoscopic ventral hernia repair both absorbable and non absorbable tacks used. Non absorbable tacks have several complications such as chronic post operative pain, adhesions and bowel perforations.[7,8] Absorbable tacks therefore used under assumption that permanent fixation is no longer needed after mesh integration.[9,10]

The direct comparision of non absorbable with absorbable tacks appear to be the best way to assess their efficacy and safety. The objective of our study is to compare absorbable tacks with non absorbable tacks for fixation of mesh in laparoscopic ventral hernia repair in term of post-operative pain, length of hospital stay, complications and recurrence rates.

METHODS:

A prospective, randomised, comparative study was conducted on patients diagnosed with ventral hernia in the Surgery department of Sanjay Gandhi Memorial Hospital, Govt. of NCT of Delhi. Sixty patients of ventral hernia who were candidates for operative treatment were included in the study from October 2015 till october 2017. These patients were randomly assigned to two groups - A and B using online random number generator (http://stattrek.com/statistics/random-number-generator.aspx). Patients of group A underwent mesh fixation by absorbable tacks and those of group B underwent mesh fixation by non absorbable tacks. Clearance from institutional ethical committee was obtained before the study was started. An informed bilingual and written consent was obtained from each patient before they were included into the study.

Sample size was calculated by setting significance level at 5% and power at 80%. All the outcomes were in terms of mean plus minus standard deviation so for sample size calculation we used the formula[11]:

$$N = (Z_{1-\alpha/2} + Z_{1-\beta})^2 (\sigma_1^2 + \sigma_2^2)/d^2$$

Where, N= minimum number of cases to be included in each group

$Z_{1-\alpha}$ =1.96: normal deviate corresponding to level of significance i.e. 0.05

$Z_{1-\beta}$ =0.84: normal deviate corresponding to power of 80%
σ_1= Standard deviation of group 1
σ_2= Standard deviation of group 2
d= μ_1-μ_2Difference of means of group 1 and group 2
μ_1= (mean of group 1) and μ_2(mean of group 2) .

Using the values of mean & standard deviation in the above formula, a sample size of 27 patients in each group was thus obtained. A 16% attrition rate was assumed. Thus, sample size was increased to 30 in each group taking attrition into consideration.

A detailed history of Ventral hernia followed by complete examination was done. All ventral hernia patients falling under exclusion criteria were excluded. History of associated diseases like chronic cough, constipation, urinary obstruction was also taken.

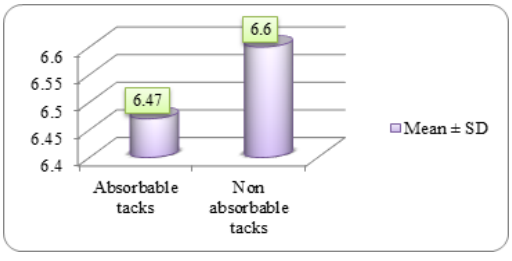
Past history of any operative procedure and history of recurrence was taken. History of any co-morbid illness (viz. diabetes mellitus, hypertension, ischemic heart disease, chronic obstructive airway disease, tuberculosis) was taken. Complete general physical examination with vitals, systemic examination. Local examination of the swelling was performed in detail.

All data thus obtained was entered in Microsoft Excel spreadsheet. Numerical data was reported as mean ± SD and range. Categorical variables were reported as number and percentages. Student's t-test was used to compare numerical variables and the chi-square test or Fischer's exact test were used for categorical variables. Data was processed using Statistical Package for Social Sciences (SPSS version 20.0 for Windows, SPSS inc., IBM, Armonk, NY) statistical software. For all statistical tests, a p value of less than 0.05 was taken to indicate significant difference.

RESULTS:

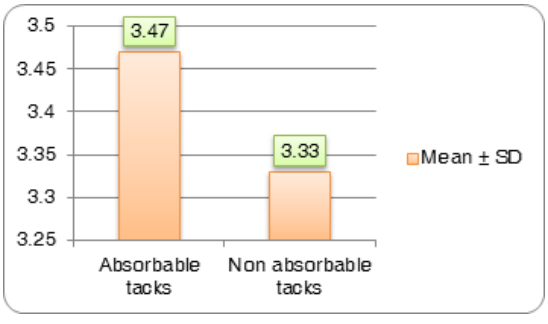
The mean age of AT group was 48.23 (± 7.82) years and NAT group was 48.4 (± 7.578) years. About 73.3% in the AT group and 76.7% of the study subjects in NAT group were females.

Chart 1. Distribution of the study group according to Pain score post operative day 0 (visual analogue scale)



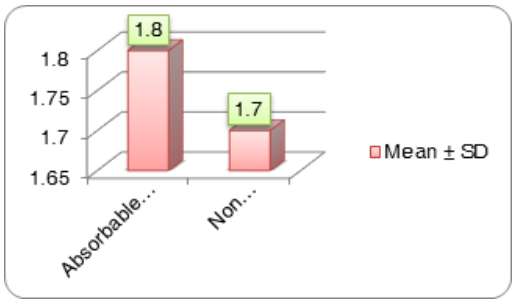
The mean (± SD) pain score in AT group was 6.47 (± 1.57) and NAT group was 6.6 (± 1.19). This difference in pain scores was statistically not significant at day 0.

Chart 2. Distribution of the study group according to Pain score post operative day 1 (visual analogue scale)



The mean post operative day 1 pain scores in AT group was 3.47 (± 0.94) and NAT group was 3.33 (± 0.76). This difference in post operative pain scores at day 1 was not statistically significant.

Chart 3. Distribution of the study group according to Pain score post operative day 2 (visual analogue scale)

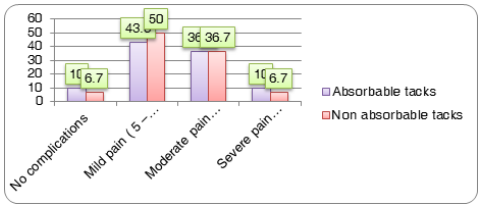


The mean post operative day 2 pain scores was 1.8 (± 0.664) in AT group and 1.7 (± 0.794) in NAT group. This difference in post operative pain scores at day 2 was not statistically significant.

The mean days of hospitalization in AT group was 1.5 days (± 0.572) and 1.43 (± 0.679) days in NAT group. The mean time to return to normal activity in days was 11.2 in AT group 11.57 in NAT group.

There was no analgesics requirement above normal dose in 53.3% of the AT group was 50% of the NAT group.

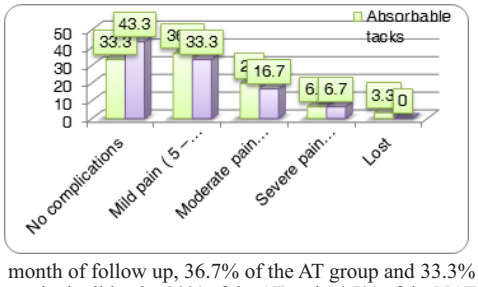
Chart 4. Distribution of the study group according to follow up at 1 week



χ^2 Value= 0.543 df=3 p value= 0.909, NS

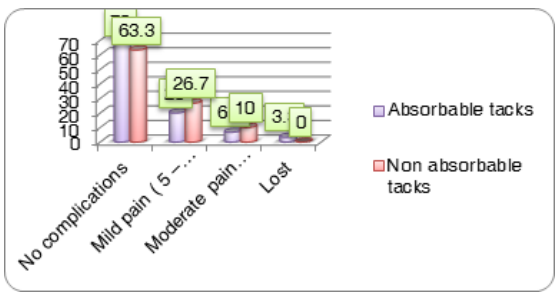
At 1 week of follow up, 43.3% of the AT group and 50% of the NAT group had mild pain, 36.7% of the study subjects belonging to both the groups had moderate pain and 10% of the AT and 6.7% of the NAT group had severe pain. There was no statistically significant difference between the two groups.

Chart 5. Distribution of the study group according to follow up at 1 month



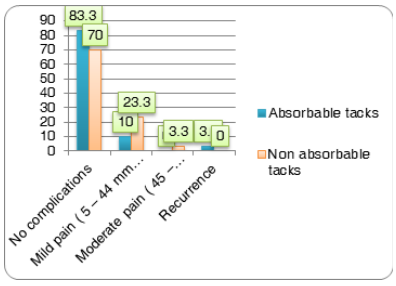
After 1 month of follow up, 36.7% of the AT group and 33.3% of the NAT group had mild pain, 20% of the AT and 16.7% of the NAT group had moderate pain, 6.7% of the both the groups had severe pain and 3.3% of the AT group lost to follow up. This difference was not statistically significant between the AT and NAT groups.

Chart 6. Distribution of the study group according to follow up at 3 months



After 3 months of follow up, about 20% of the AT and 26.7% of the NAT group had mild pain and 6.7% of the AT and 10% of the NAT group had moderate pain. This difference was not statistically significant between the AT and NAT groups.

Chart 7. Distribution of the study group according to follow up at 6 months



The 6 months follow up had shown that, 10% of AT group and 23.3% of the NAT group had mild pain, 3.3% of the NAT group had moderate pain. Recurrence was seen in 3.3% of the AT group. This difference was not statistically significant between the AT and NAT groups.

No complications were recorded in both AT and NAT group. Recurrence was seen in 3.3% of AT group.

DISCUSSION:

Hernia constitutes a major health care problem and repair of ventral hernias is one of the commonest surgical procedures worldwide, irrespective of country, race or socioeconomic status. 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. 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.[12,13,14]

The mean age of AT group was 48.23 (± 7.82) years and NAT group was 48.4 (± 7.578) years. The difference in the age between the AT and NAT group was not statistically significant. Thus the two group were comparable with respect to age. Most of the subjects in AT and NAT group belonged to 41 – 60 years of age. In a study by Colak et al, the mean age of AT group was 50.7 years and Nat group was 56.1 years.[15] In a study by Bangash et al, the mean age of the tacks group was 41.9 years and suture group 38.3 years.

Majority of the study subjects in this study were females in both AT and NAT group. In a study by Colak et al, about 52.9% of the AT group and 66.7% of the NAT group were females.[15] In a study by Bangash et al, males outnumbered females in Suture and tacks groups unlike this study.

The mean (± SD) pain score in AT group was 6.47 (± 1.57) and NAT group was 6.6 (± 1.19). On day 1 the mean pain scores were almost half than the day of operation. On the day 2, the AT group and NAT group had minimal pain. Pain scores had no statistical significance. A study by Colak et al also observed no significant difference between the AT and NAT groups with respect pain scores at 0, 1 and 2 days.[15] In a study by Bangash et al, the pain scores were higher in suture groups compared to the tacks group. 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. Bansal et al randomized 68 patients into nonabsorbable 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. In a randomized controlled trial that compared methods for securing the mesh during LVIHR, the absorbable sutures with tacks (n = 56), double crown (n = 60), and nonabsorbable sutures with tacks (n = 56) techniques were associated with similar PO pain and quality-of-life findings.

This study had shown that, the mean days of hospitalization in AT group was 1.5 days (± 0.572) and 1.43 (± 0.679) days in NAT group which was not statistically significant. In a study by Colak et al, the mean post operative stay in AT group was 2.1 days and 2.5 days in NAT groups.[15] In a study by Bangash et al, the mean days of hospitalization was 4.3 days and 4.7 days in suture group.

The time to return to normal activity was almost same in AT group and NAT group. No studies compared these findings.

More than half patients did not need any analgesic in both AT and NAT groups. Once oral analgesic was given in 30% of the AT group and 30% of the NAT group. The injectable analgesic was used in few patients of AT and NAT groups. In a study by Bangash et al, the injectable analgesics were used in Tacks and suture groups.

Mild, moderate pain were encountered in both AT and NAT groups. About 6.7% of the NAT group had severe pain. This difference was not statistically significant between the two groups. After 1 months of follow up, 36.7% of the AT group and 33.3% of the NAT group had mild pain, 20% of the AT and 16.7% of the NAT group had moderate pain, 6.7% of the both the groups had severe pain and 3.3% of the AT group lost to follow up. After 3 months of follow up, about 20% of the AT and 26.7% of the NAT group had mild pain and 6.7% of the AT and 10% of the NAT group had moderate pain. This difference was not statistically significant between the AT and NAT groups.

The 6 months follow up had shown that, 10% of AT group and 23.3% of the NAT group had mild pain, 3.3% of the NAT group had moderate pain. Recurrence was seen in 3.3% of the AT group. This difference was not statistically significant between the AT and NAT groups. In a study by Colak et al, recurrence of hernia was observed in 7.6% of the AT and 8.0% of the NAT group.[15] In a study by Bangash et al, the recurrence was present in 6.6% of the tacks group and 6.6% of the suture group. Carbajo et al reported a very low recurrence rate (4.4%) with this technique. Kitamura et al reported the data of 83 patients: 33 in the suture group and 53 in the tack group. Hernia recurrence occurred in 3 patients in the suture group, while in 2 patients in the tack group ($P > .05$).

No complications were recorded in both AT and NAT group. Colak et al had observed that, seroma, hematoma, prolonged ileus, trocar hernia, cellulitis and hernia recurrence were the common complications in AT group and seroma, hematoma, trocar hernia, cellulitis, hernia recurrence and mesh migration were the complications in AT group unlike this study.[15] In a study by Bangash et al, the wound infection and adherence obstruction were the complications in Tacks group and suture group.

CONCLUSIONS:

This study was mainly undertaken to compare the efficacy of Absorbable and Non Absorbable Tacks in ventral hernia repair. The study had shown that, there was no statistically significant difference between the absorbable and non absorbable tacks with respect to pain scores, the requirement of analgesic no of days of hospitalization, time to return to normal activity and complications. Absorbable tacks may be a preferable option due to lower cost in repairing ventral hernia. The choice of either of these fixation methods during surgery should not be based on the concerns of pain or recurrence. But this study is not without limitations. The number of patients was low. The quality of life of the patients was not assessed. But this study was able to bring some important facts about the use of absorbable and non absorbable tacks.

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DECLARATIONS

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Conflict of interest: None

Ethical approval: Approved

Abbreviations:

AT- Absorbable Tacks, NAT- Non Absorbable Tacks, LVHR- Laparoscopic Ventral Hernia Repair, LVIHR- Laparoscopic Ventral Incisional Hernia Repair

Figure 1: Mesh fixation by Absorbable tacks

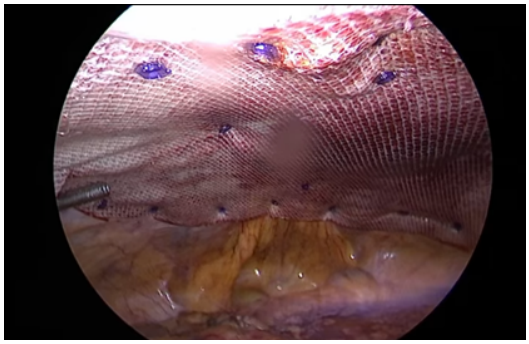
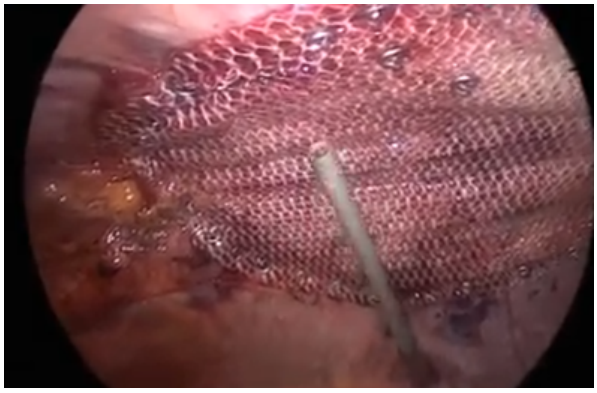


Figure 2: Mesh Fixation by Non Absorbable tacks



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