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Comparison of laparoscopic repair of incisional and ventral hernia with tacker or suture mesh fixation- A prospective randomized controlled study

KEYWORDS

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ABSTRACT Ventral and incisional hernias are commonly encountered condition hernias which can be asymptomatic or cause a considerable degree of discomfort, bulge and pain and may enlarge over time. The laparoscopic repair of incisional and ventral hernia with mesh placement is becoming the standard of care these days. Commonly used methods of mesh fixation are metallic tacks with or without trans-fascial sutures and transfascial sutures alone. Aim of the study is to compare the recurrence rate, complications and cost of tackers versus transfacial polypropylene sutures for laparoscopic mesh repair of ventral hernias. Sixty patients of ventral hernia or incisional hernia were included and divided into two study groups on the basis of draw of lots. Patients were called on 7th-9th post operative day for removal of stitches and later followed up after 1 month, 3 months and then after 6 months. It was concluded that the suture fixation method is a cost-effective alternative to tacker fixation with equally effective regarding the recurrence rates, complications, hospital stay, chronic pain, quality of life determinants, return of activities and patient satisfaction.

Introduction

Hernia is derived from the Greek word 'Henios' which means a branch or off shoot. A hernia is a protrusion of viscus through an abnormal opening in wall of its containing cavity1. Ventral hernia can be acquired or congenital. Acquired hernias may develop via slow architectural deterioration of muscular aponeurosis or they may develop from failed healing of the anterior abdominal wall incision (incisional hernia). Incisional hernias make about 80 % of the ventral hernias that surgeons encounter.[2]

Risk factors for incisional ventral hernia include wound infection, abdominal distension, pulmonary complications, male gender, age, obesity, emergency procedures, early re-operations, jaundice, underlying disease process, type of closure, suture material used in closure, and choice of original incision[3]. They can also be the result of too much tension with the initial closure of the abdominal incision, which creates poor healing swelling and wound separation.[4]

Ventral hernias may be asymptomatic or cause a considerable degree of discomfort and generally enlarge over time5. The most common finding is a mass or bulge in the anterior abdominal wall which may increase on valsalva. The bulge may cause varying degree of discomfort or may present as a cosmetic concern. Treatment of ventral hernias, wherever its site, is repair either open or laparoscopic.

The traditional primary open repair of incisional hernia has shown to be associated with a recurrence rate of up to more than 60% and even with the use of prosthetic meshes the recurrence have been reported to be as high as 32% in some series with long term follow up.6 There is also a lot of morbidity associated with open repair in the form of post-operative pain, hospital stay, wound infections and other complications (12% or higher).7,8 The laparoscopic repair of incisional and ventral hernia is fast becoming the standard of care. It has decreased the recurrence rates to less than 10% and in some series a recurrence of less than 2% with long term follow-up has been reported. [9,10,11] Randomized trials, comparing open versus laparoscopic repair of incisional and ventral hernias, have shown better results in favour of laparoscopic repair in terms of wound infection rates, overall complications, postoperative hospital stay, recurrence rates and shorter operating times.12-16 The technique of laparoscopic repair of incisional and ventral hernia has almost been standardized and issues like access to the abdominal cavity, mesh size and extent of overlap have been resolved. But issues like ideal prosthetic material to be used, management of hernia defect and technique of fixation of the mesh to the abdominal wall are still areas of debate. There is no description of a standard technique of mesh fixation. Common methods of mesh fixation are metallic tacks with or without trans-fascial sutures and transfascial sutures alone.[17,18,19] Recently absorbable tacks, fibrin glue and intra-corporeal suturing of the mesh has also been described.[20,21,22] Although mesh fixation with tacks is convenient and time saving,23 the tensile strength of a mesh fixed by transfascial sutures has shown to be up to 2.5 times greater than when fixed by tacks.[24] Transfascial sutures penetrate all layers of the abdominal wall, thereby enabling fixation of the mesh to the entire fascio-muscular layer of the abdominal wall.

There is paucity of published evidence comparing the various methods of mesh fixation in laparoscopic incisional and ventral hernia repair and that too are small studies with variable results. The present study was to compare the two techniques of mesh fixation i.e. four corner trans-fascial polypropylene sutures with tacks versus trans-fascial sutures alone instead of tacks.

Aims and Objectives

- To compare the recurrence rate following two techniques of mesh fixation- tackers versus transfacial polypropylene sutures for laparoscopic mesh repair of incisional and ventral hernias.
- To compare the incidence of early post-operative pain and chronic pain following the two techniques of mesh fixation.
- To compare quality of life, return to physical activity and patient satisfaction following the two techniques of mesh fixation
- To compare the cost of procedure for the two techniques of mesh fixation

Inclusion Criteria

Only good risk patients who met the following criteria were selected
Patients having divarication of recti
Patient having epigastric hernia (fatty hernia of linea alba)
Paraumblical hernia
Incisional hernia

Exclusion criteria

Patients excluded from our study had one of the following criterias

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Densely scarred abdomen
Acute abdomen with strangulated or infracted bowel
Incarcerated hernias
Multiple operated scars
Children < 18 yrs of age

Material and Methods

A total of 60 patients of ventral hernia or incisional hernia were included in the study to evaluate laparoscopic repair of ventral hernia with four corner trans fascial sutures with tackers versus application of transfascial sutures only. The patients were divided into two study groups on the basis of draw of lots. Patients in study group 1, the repair of ventral hernia was done using a mesh fixation technique of four corner transfascial sutures + tackers. In study group 2 the repair was done using transfascial sutures only.

In patients in group 1 Mesh fixation was done with a 5 mm tacker (Protack, Autosuture, Tyco Healthcare, USA) along with four trans-fascial sutures. Double crown technique was used for tack placement. The tacks were placed at all four corners and then at 2-3cm distance along the peripheral margin. Another row of tacks was placed near the defect margins and additional tacks were fired at places deemed necessary for proper fixation of mesh.

In Group II, similarly for fixation of mesh at four corners, a small stab incision was made 1.5 -2 cm away from the anticipated margins of the mesh at the midway between two corners of mesh on each side. An epidural needle or spinal needle 16-18G were passed through the abdominal wall and .5 to 1 cm inner to the lateral margin of mesh. Prolene 0 suture were passed through lumen of epidural/spinal needle and grasped with Maryland dissector inside peritoneal cavity and was pulled for adequate length of 7-8cm.Needle was taken out while keeping hold the free end of suture with grasper inside abdominal cavity so that it did not come out accidently Through the same incision, epidural needle loop was reintroduced into the abdomen at a different angle so that it penetrated the fascia only not the mesh The graspers feed the long suture end in the epidural needle prolene loop and the assistant pulls the needle thereby getting the suture length out. Sutures were tied outside subcutaneously. The sutures were placed at the midway between two coners on each side. Thus four trans fascial sutures are applied instead of tackers in addition to four corner transfascial sutures in study group II.

Careful note was made of operating time, operating technique regarding mesh placement and fixation, size of mesh, intra-operative handling of the mesh and any difficulties encountered during the surgery

Intraoperative complications were analysed as follow:

Veress needle injury
Insufflation problems (extraperitoneal insufflations)
Trocar injury
Haemorrhage (both trocar site and elsewhere) and its cause
Injury to bowel during enterolysis or otherwise
Complications related to handling of mesh

Post operatively note was made of:

Time taken for oral feeding to be started.
Assessment of pain status, nausea and vomiting
Duration of hospital stay

Any occurrence of complications like haemorrhage, prolonged ileus and wound infection, intra abdominal collection were noted Patients were discharged on resumption of oral feeding, when post operative pain was tolerable.

Patients were called for first visit to surgical OPD on 7^{th}-9^{th} post operative day for removal of stitches, assessment of port site for any sign of infection, hematomas, sarcomas or any evidence of continuing pain and discomfort etc. Patients were called for follow up after 1 month, 3 months and then after 6 months.

A note was made of any recurrence of hernia, chronic pain, port site infection, port site herniation, seromas, hematomas etc. occurring during this period. Postoperative pain was assessed using a visual analogue scale (VAS). Patients were explained that pain may presented by a straight line of 10 cm length, the extremes of which corresponds to No Pain (0) at one cm and worst imaginable pain at the other end (10)

Patients were asked to rate their pain depending on 1^{st} post operative day, 1 week after the operation, one month after the operation, three month after the operation and six months after the operation.

All patients were given the quality of life assessment proforma Short Form-36 version 2 (SF-36v2) in Punjabi/English after admission to hospital. The same proforma was given to them at 3 months after the procedure along with a different questionnaire for assessment of return to physical activity and patient satisfaction. Permission was obtained from Quality Metric Health Survey for application of SF36v2 in the current study. Overall satisfaction score was labeled on a verbal rating scale (VRS) with scores of 0 = not satisfied, 1 = partially satisfied, 2 = satisfied, 3 = very satisfied.

Statistical Analysis

Data was collected and managed using Microsoft Excel. Unpaired student's t- test was used to determine the significance of difference between two independent groups among continuous variables like age, defect size and operative time. For skewed data a corresponding non-parametric test, Mann - Whitney test was applied to see the difference between the two independent groups. For qualitative data Chi-square test was used to see the significant difference in proportion between the two groups. A p value of < 0.05 is considered as significant. All the statistical analysis was carried out using statistical package SPSS 14.

RESULTS

The patients age ranged from 19 years to 75 years with a mean of 49.94 ± 13.04 years. The age distribution was comparable between the two groups, 48.9 ± 10.94 years (22 – 72 years) in Group I versus 52.13 ± 14.55 years (19 – 75 years) in Group II (p= .431). The study population showed an uneven gender distribution with more females (37 patients, 61.7%) as compared to males (23 patients, 38.3%). The distribution among the two groups was uneven with female to male ratio of 2:1in group I and 30:1 in group II. Primary ventral hernias were almost equally distributed among females and males (F24:M21) while incisional hernias were present in much higher frequency in females (12;3 80% females). The two groups are comparable in terms of sex distribution (P Value .426)

The defect size was calculated by multiplying the largest dimension with the dimension perpendicular to it as measured with a ruler after marking the defect on overlying skin. The defect size ranged from 2.25 cm to 30 cm^2. Mean size of defect for study group I was 13.9± 7.6 cm2 the mean defect for study group II 15.96 ±2.86 cm^2.

The mean duration of operation was 49.85±7.2 minutes. The operating time in study group I was 46.03±6.8 while mean operating time in study group 2 is 53.67±6.789minutes. The difference was attributed to different techniques of mesh fixation, and more time was required for fixation of mesh with transfascial sutures as compared to fixation with tacks. On comparing the operating time in two study group p value is.001 which was statistically significant.

Post operative pain was comparable in two groups on follow up on 1st post operative day, 1 week after the operation, one month after the operation, three month after the operation and six months after the operation. It was not statically significant. There was also no statistically significant difference in the hospital stay among two groups.

The mean cost per patient for group I was Rs. 26545, i.e., 2.5 times the mean cost per patient calculated for group II (Rs10446). The difference was statistically highly significant with p<0.001.

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Quality of life- Short form 36 version 2 (SF 36v2) was administered for self completion by patients preoperatively and at 3 months postoperatively.

Comparison of Pre-operative SF-36 Health Dimensions

Health Dimensions	Total (n = 60)	Group I (n = 30)	Group II (n = 30)	p value
Physical Functions (n (%))	73.8 ± 21.7	71.8 ± 22.1	75.6 ± 21.8	0.56
Role Physical (n (%))	61.1 ± 24.8	59.1 ± 28.5	63.0 ± 24.9	0.58
Bodily Pain (n (%))	56.1 ± 27.1	51.8 ± 29.3	60.1 ± 24.9	0.30
General Health (n (%))	55.2 ± 21.6	60.0 ± 21.5	50.7 ± 21.2	0.15
Vitality (n (%))	49.3 ± 23.1	50.8 ± 26.5	47.9 ± 19.9	0.67
Social Functions (n (%))	70.6 ± 25.0	67.6 ± 31.2	73.4 ± 17.8	0.44
Role Emotional (n (%))	64.7 ± 28.1	64.0 ± 27.3	65.3 ± 29.4	0.88
Mental Health (n (%))	67.9 ± 19.6	70.0 ± 21.2	66.0 ± 18.2	050
Physical Component Summary (n (%))	44.3 ± 7.4	43.5 ± 8.3	45.0 ± 6.6	0.49
Mental Component Summary (n (%))	43.5 ± 11.7	44.2 ± 13.2	42.9 ± 10.5	0.71

Comparison of Improvement in SF-36 Health Dimensions

Health Dimensions	Total (n = 60)	Group I (n = 30)	Group II (n = 30)	p value
Physical Functions (n (%))	6.81 ± 17.7	8.16 ± 15.7	5.29 ± 20.1	0.63
Role Physical (n (%))	10.24 ± 15.1	8.88 ± 15.2	11.7 ± 15.2	0.57
Bodily Pain (n (%))	15.19 ± 20.9	14.95 ± 21.3	15.47 ± 21.1	0.94
General Health (n (%))	10.28 ± 21.1	4.79 ± 21.5	16.41 ± 19.7	0.10
Vitality (n (%))	12.67 ± 20.1	12.50 ± 21.8	12.86 ± 18.6	0.95
Social Functions (n (%))	5.21 ± 23.7	7.24 ± 27.7	2.94 ± 19.0	0.59
Role Emotional (n (%))	10.18 ± 17.3	9.21 ± 14.9	11.27 ± 20.1	0.72
Mental Health (n (%))	12.36 ± 15.6	11.05 ± 17.3	13.82 ± 13.8	0.60
Physical Component Summary (n (%))	3.24 ± 5.8	2.68 ± 5.4	3.86 ± 6.4	0.55
Mental Component Summary (n (%))	5.71 ± 7.9	5.37 ± 9.9	6.08 ± 5.2	0.79

Group I showed significant improvement in dimensions of physical function, bodily pain, vitality, role emotional and mental health Group II showed significant improvement in role physical and general health also but failed to show improvement in physical functions. Overall physical and mental component summaries showed significant improvement in both the groups. There was no statistically significant difference in improvement in health scores between both the groups in any of the dimensions.

Patient satisfaction score was measured on a verbal rating scale from 0 to 3 at three months post surgery. Patients in Group II had higher satisfaction scores as opposed to those in Group I(2.15±.9 versus 1.98± .8) but the difference was statistically insignificant (p = 0.18).

Return to activity

	Total (n = 60)	GroupI N==30	Group 2 n=30	p value
Started Walking (hrs)	20.8 ± 11.3 (12 – 48)	22.8 ± 12.5 (12 – 48)	18.8 ± 8.9 (12 – 48)	0.29
Moving freely (days)	3.4 ± 1.5 (1 - 7)	3.7 ± 1.6 (1 – 7)	3.1 ± 1.2 (1 – 7)	0.43
Resumed usual activity (days)	18.9 ± 10.1 (5 – 60)	20.2 ± 11.1 (5 – 60)	17.6 ± 7.7 (5 – 42)	<0.25
Required help for dressing up (days)	4.1 ± 1.6 (1 – 8)	3.9 ± 1.5 (2 – 7)	4.2 ± 1.7 (1 – 8)	0.53
Cimbing stairs (days)	14.5 ± 8.3 (4 – 56)	15.4 ± 10.3 (4 – 56)	13.6 ± 4.5 (7 – 21)	0.32
Driving vehicle/ kitchen work (days)	25.9 ± 8.5 (14 – 60)	27.3 ± 7.8 (14 – 42)	24.4 ± 8.9 (14 – 60)	0.11
Lifting objects (days)	53.0 ± 16.7 (28 – 90)	52.6 ± 17.4 (28 – 90)	53.3 ± 16.3 (28 – 90)	0.86
Patients having a job	Total (n = 30)	Group I (n = 16)	Group II (n = 14)	
Work (taking easy, days)	14.0 ± 13.3 (5 – 84)	15.8 ± 16.1 (5 – 84)	11.8 ± 8.8 (5 – 42)	0.32
Work unrestricted	25.4 ± 10.8 (14 – 56)	26.5 ± 9.4 (14 – 42)	24.1 ± 12.3 (14 –56)	0.44
Time off work (days)	15.4 ± 15.8 (0 – 90)	16.5 ± 13.2 (7 – 70)	14.1 ± 18.9 (7 – 90)	0.61

The patients resumed their usual activities at an average interval of 17.1 days, with climbing stairs at 13.1 days and lifting objects at 53.0 days. Most of our patients were reluctant to give answers regarding return of sexual activites so we voluntarily omitted this activity from our study. There was no stastical significance difference between two groups.

Discussion

The laparoscopic approach for incisional and primary ventral hernia has gained popularity because of its low recurrence rate, short hospital stay, good cosmetic outcome and low complication rate as compared to open repairs12-16. The laparoscopic approach also provides the surgeon the ability to clearly define the margins of the hernia defect and to identify additional smaller "swiss-cheese" defects which may not be clinically apparent preoperatively and can be missed in an open approach.

Although laparoscopic incisional and ventral hernia repair has gained popularity, there are many technical issues which need to be resolved. The issues of access to the abdominal cavity, mesh overlap and mesh size have more or less been resolved. Further, issues like the ideal mesh to be used, the fixation technique and the necessity for closure of the defect before mesh fixation are areas of ongoing debate. In our study it was observed that the mean duration of operation was 49.06 ± 7.2 mm. The operating time in study group 1 was 46.023 ± 6.84 min while the mean operating time in study group II is 53.62 ± 6.7 min. On comparing the operating time between the two study groups the p value is 0.001, which is significant. The difference in operative time can be attributed to the reason that long time required for applying transfascial sutures as compared to applying tacks. It has been found that average time required for tying one suture was 1 min 45 seconds.

The incidence of chronic pain following laparoscopic incisional hernia repair has been reported to be about 1-3% in literature[25]. However, the overall pain scores may not be higher and it may not affect the early ambulation and discharge from the hospital although the requirement of postoperative analgesia may be higher. A case-controlled study by Nguyen et al[26]. suggested that TAS fixation and tack fixation are equally likely to be associated with postoperative pain. However, Carbajo et al[18]. reported a high rate of persistent pain (7.4%) after LVIHR procedures in which two circles of tacks alone (no TAS) were used to secure the mesh. Bageacu et al27. observed severe pain in patients in whom tacks were used in laparoscopic repair of incisional hernias. In our study found the two methods of mesh fare similar in relation to the post operative pain and analgesia requirement on short term and long term follow up.

It has been noted that recurrences commonly occur at the mesh margins along the mesh-tissue interface. This finding has been

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validated by an experimental study which found that increasing the mesh overlap to 4 cm from the defect edges eliminated mesh disruption[28] . In our study none of the patients have reported any recurrence in either study group. This could be attributed to the fact that while performing mesh repair utmost care was taken to ensure that the mesh covered the hernia defect with at least 3-5 cm of overlap on all sides. Care was also taken to ensure that mesh was properly anchored to the abdominal wall with the help of transfascial sutures on all four corners and tacks or transfsacial suture in between.

Bansal et al[29] found that although the operative time is significantly higher in suture group the overall cost of the procedure was significantly lower in this group. This difference in the cost of the procedure is statistically highly significant and the tacker fixation group patients spent on an average 2.1 times more than the suture fixation group patients. The cost of the tacker contributed to the higher cost associated with the procedure in tacker group. Misra et al30 reported significantly higher cost involved in laparoscopic repair compared to open repair due to the high cost of the disposable tacker used for mesh fixation. Average cost required for study group I is approximately 2.5 times higher than study group II. The mean cost per patient for group I was Rs 25545±1766, i.e., 2.5 times the mean cost per patient calculated for group II Rs10446±925 The difference was statistically significant with p<0.001.

Wassenaar et. Al[31] compared methods for securing the mesh during LVIHR, the AS (absorbable sutures), DC (double crown) and NS(nonabsorbable techniques were associated with similar postoperative pain and QoL findings. Bansal et al[29].post operative quality of life and satisfaction score similar in two groups. Group I showed significant improvement in dimensions of physical function, bodily pain, vitality, role emotional and mental health Group II showed significant improvement in role physical and general health also but failed to show improvement in physical functions . Overall physical and mental component summaries showed significant improvement in both the groups. There was no statistically significant difference in improvement in health scores between both the groups in any of the dimensions

Misra et al[19] showed higher satisfaction scores (8.3 versus 7.6) in laparoscopic repair as compared to open repair though it was not significant. Bansal et al[29].reported post operative QOL and satisfaction score were comparable between LVIHR repaired with four corner transfascial sutures with tackers versus transfascial sutures only. In our study on a verbal rating scale patients in group II had high satisfaction score (2.15±.9) versus groupI (1.89±.8). But the difference was statstically insignificant (pvalue=.18).

Nguyen et al[26] compared suture and tack fixation and found that time to return to work was comparable between the two groups with 50 patients in suture group and 42 patients in tacks group returning to work in 1 week. Itani et al[32] reported time to resume work activities was shorter for the laparoscopic group than for the open repair group (median, 23.0 days vs 28.5 days). Toy et al[33] reported return to normal activity after a mean of 15 days postoperatively following laparoscopic ventral hernioplasty. The statstical difference between groups regarding return of activities was insignificant.

So it was concluded that the suture fixation method is a cost-effective alternative to tacker fixation in patients with small- to medium-sized defects in laparoscopic incisional and ventral hernia repair. Mesh fixation with tackers is easier and faster than transfascial suture fixation. The two procedures are equally effective regarding the recurrence rates, complications, hospital stay, chronic pain, quality of life determinants, return of activities and patient satisfaction.

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