

A prospective randomized control trial comparing intracorporeal sutures and tackers for mesh fixation in laparoscopic ventral hernias repair: intraoperative considerations**Anil Kumar^{a*}, Adla Rao^a, Animesh Gupta^b**^aDepartment of Surgery, ESIC Medical College, Faridabad (Delhi NCR), Haryana, India.^bDepartment of Plastic Surgery, Patna Medical College & Hospital, Bihar, India.**Abstract****Background:** Laparoscopic ventral hernia repair (LVHR) has covered a long distance since its first reported case in 1993. It is an established procedure, but the mesh fixation technique is a contested area. There is a paucity of literature comparing intracorporeal suturing with tackers for mesh fixation.**Objectives:** This study was done to check the feasibility of intracorporeal suture mesh fixation by comparing its intraoperative dynamics with tacker fixation.**Patients and methods:** 43 patients with defect size less than 8 cm were considered. They were randomized into two groups: group I, intracorporeal suture fixation, and group II, tacker fixation. Randomization was ascertained by assigning computer-generated random numbers using the technique of block randomization. Further, sealed envelopes were used for concealed allocation. Intraoperative variables were recorded and analyzed for 40 patients (20 in each group) as 3 were excluded from the study due to non-progression of dissection due to dense adhesions.**Results:** Operative mesh fixation time (49.4 ± 7.83 min versus 17.2 ± 2.86 min, $p < 0.0001$) was found much lesser in group II. Total operative time was found to be significantly higher in group I (113.6 ± 0.91 min versus 88.35 ± 8.27 min, $p < 0.0001$). Average blood loss was less in group I compared to group II (30.25 ± 8.95 ml versus 37.75 ± 11.41 ml, $p = 0.026$).**Conclusion:** Intracorporeal suturing is a viable alternative for mesh fixation in LVHRs. Though intracorporeal suturing is associated with longer operative times, patients have less intraoperative blood losses statistically significantly.**Keywords:** Laparoscopy; Fixation of mesh; Intracorporeal suturing; Ventral hernia.**DOI:** 10.21608/svuijm.2022.151888.1348***Correspondence:** doctor.070anil@gmail.com.

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Introduction

The treatment of ventral hernia has evolved over many decades. As open mesh repair was introduced instead of open suture repair, the overall recurrence rate significantly decreased from 63% to 32%. It was documented that mesh repair reduced recurrence rate, and tension-free repair with mesh was accepted as the new gold standard (**Singhal et al., 2012**). Subsequently, laparoscopic ventral hernia repair (LVRH) gained wide acceptance among surgeons and patients alike compared to open repair ever since the first reported case by **LeBlanc and Booth (1993)**. Randomized trials have established advantages of laparoscopic over open incisional hernia repair (**Carbajo, 1999; Olmi et al., 2005; Misra et al., 2006; Barbaros et al., 2007**). Currently so many different techniques are being used to fix a mesh during laparoscopic repair (**Harslof et al., 2014; Muysoms et al., 2012**). Among all these techniques, metallic tacks or staple and transfacial suture, either alone or in combination are most commonly used (**Baccari et al., 2009**). Yet no standard technique of mesh fixation has been accepted so far. Recently absorbable tacks, fibrin glue, and intracorporeal suturing of the mesh also have been described (**Olmi et al., 2007; Tayar et al., 2007; Melman et al., 2010**).

Tackers reduce the operative time but also result in excessive postoperative pain and increase cost of surgery (**Kitamura et al., 2013; Eriksen et al., 2013**). Unidirectional or bidirectional barbed sutures prevent slippage and are being used currently in various gynecological surgeries (**Cong et al.,**

2016). This prospective randomized study was done to explore mesh fixation with intracorporeal sutures and compare it with prevalent tackler fixation technique.

Patients and methods

This study was conducted from 1st October 2016 to 31st March 2018 in a tertiary care teaching hospital in a surgical unit doing routine laparoscopic surgeries. Prior consent from Institutional Ethics Committee was taken before starting the study. Procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional) and with the Helsinki Declaration of 1975 that was revised in 2013.

This prospective randomized study was done to compare two methods of intraperitoneal onlay mesh fixation (IPOM) - intracorporeal suturing (group I) and tackers (group II). Our objective was to check feasibility and effectiveness of intracorporeal suture mesh fixation. Both groups (sample size – 20 each) were compared for outcomes in terms of mesh fixation time, intraoperative blood loss and total operating time.

All patients who presented in surgical outpatient department with a ventral hernia having defect size of less than 8 cm were considered for the study. Recurrent hernias, complicated hernias like incarcerated hernia, strangulated hernia or patients with significant comorbidity were excluded. Study was explained in depth to patients including two treatment groups, and written consent was obtained from those willing to be a part of study. They were randomized into two groups: group I, intracorporeal suture fixation, and group

II, tacker fixation. Randomization was ascertained by assigning computer-generated random numbers using technique of block randomization. Further, sealed envelopes were used for concealed allocation.

Preoperative relevant investigations were performed for all patients. The size of the defect was estimated by clinical examination and ultrasound for all patients. Both were recorded on a patient proforma. Preoperative anesthesia evaluation was done and patients were taken to surgery after optimization.

Materials included standard laparoscopic cart with instruments including suture passer needle, hemostatic clamp, monofilament polypropylene 2-0 suture, needle holder, composite mesh (15*15, 20*20 cm

Proceed), barbed suture 1-0 (V-Loc™ Wound Closure Device medtronic), and tacker device (Covidien Protack), among others.

All surgeries were performed under general anesthesia. Patients were positioned supine with the arms adducted and tucked at the sides. Stomach and bladder decompression done in most cases. Prophylactic first generation cephalosporin was administered. After prepping and draping, standard Veress needle technique was used for pneumoperitoneum creation. Three trocars were placed in standard fashion laterally along anterior to mid-axillary line (**Fig.1**). Often, a fourth 5-mm port was placed contralaterally to facilitate intra-abdominal mesh introduction and fixation.



Fig.1. Patients position with port placement in laparoscopic ventral hernia repair

Adhesiolysis was performed using limited use of electro-surgery. Reduction of the hernial contents was performed using blunt graspers and sharp

dissection which was facilitated, at times, by manual compression from outside. The borders of the abdominal wall defect were delineated with a combination of

laparoscopic vision and external palpation after reduction of hernial contents, and marked externally.

Spinal needles were placed through the abdominal wall at the internally visualized defect edges to accurately determine the size of the hernia. An umbilical tape was used for internal measurement of defect at reduced intraperitoneal pressure. The mesh was tailored to overlap all margins of the hernia by at least 5 cm wearing fresh gloves. 2-0 permanent monofilament sutures were placed at the mid-point and at one corner of the mesh. Corresponding points of reference on the abdominal wall were marked to aid in orienting the mesh after its introduction into the abdomen.

The mesh was rolled up at both edges with parietal side inwards and pushed into the abdomen through a 10/12 mm trocar site maintain proper orientation at all times. Contralateral trocar was used for pulling mesh in cases with large prosthesis. Limbs of suture applied earlier on mesh were pulled through the abdominal wall with a suture passer. Once sufficient overlap is confirmed, sutures were tied with knots buried in subcutaneous tissues.

In group I, after transfascial fixation of mesh at 2 points, mesh was fixed to the abdominal wall with intracorporeal sutures using V-loc barbed sutures 1/0 at 1-1.5cm interval bites around the defect in a continuous fashion (**Fig.2**).



Fig.2. Intracorporeal suturing of mesh

Whereas, in group II, the perimeter of the mesh was stapled to the abdominal wall with 5-mm spiral absorbable tacks at approximately 1 cm intervals to prevent intestinal herniation. Tack placement was facilitated by the external manual

palpation of the tack's tip. Double crown technique was used for placement of tacks, i.e., two circular rows of tacks, with the first row at the extreme periphery of the mesh all around (single crown), and an inner row of tacks to

reinforce the middle portion of the mesh closer to the margin of the defect (double crown) (DeMaria et al., 2000).

Blood loss estimated in the present study was intraoperative visible blood loss (VBL). It was measured based on the sum of total amount of blood in the aspirator/suction chamber (excluding lavage fluid) and weight gained by used gauze. The weight gained by gauze (due to blood) was calculated by subtracting the dry weight of the gauze from weight of gauze soaked with blood at the completion of mesh fixation.

Pneumoperitoneum was deflated under direct vision, and fascial defects of 10/12 mm trocar were closed with vicryl no. 1 sutures. WHO pain ladder was used as guide for treatment of postoperative pain. Injection paracetamol was given intravenously at 6-8 hourly for the first 24 hours. Oral analgesics such as tablet paracetamol and tablet diclofenac were used after the first 24 hours.

Statistical analysis

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean \pm SD and median. Continuous variables in two groups were assessed for statistically significant difference using unpaired Student t-test. Qualitative variables were correlated using Chi-Square test. A p - value of less than 0.05 was considered as statistically significant.

The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

Results

A total of 43 patients with ventral hernia were enrolled for the study. In all patients, pneumoperitoneum could be created satisfactorily. Procedure could not be completed in 3 patients by the intended modality. 3 cases underwent conversion to open hernia repair. The causes of conversion were non progression of dissection due to dense adhesion in all the 3 cases. So, these 3 cases were excluded from the study as suture or tackers could not be applied in these cases.

In our study, majority of patients (52%) belonged to age group (35-45) years (Table 1). Mean age of cases who underwent LVHR with sutures and tackers were 42.1 ± 7.7 years and 41.25 ± 7.2 years respectively. Age distribution in two groups was not statistically significant (p-value = 0.7). Our study has equal participation from both sexes (50% - females and 50% - males). Out of 20, 11 females and 9 males have undergone LVHR with suture, whereas 9 females and 11 males underwent LVHR with tackers application. So, sex distribution in two groups was comparable (p-value = 0.5).

Table 1. Age distribution in two groups

Age group (years)	Group I	Group II
26-30	2	1
31-35	1	3
36-40	5	5
41-45	6	5
46-50	2	4
51-55	4	2

Cases composition in our study can be broadly categorized in 3 types of hernias - epigastric, paraumbilical and incisional hernias. Out of these, paraumbilical hernias constituted 52.5% of total cases; 27.5% were epigastric and 20% were incisional hernias. Both groups were comparable in terms of hernia location (p-value = 0.9). The size of the hernial defect was detected clinically and by sonography in all cases. Out of 40 cases, 6 (15%) patients had defect less than 2cm, 30 (75%) patients had defect between 2-5 cm, and 4 (10%) patients had defect more than 5 cm. Both groups were comparable in terms of size of hernial defect (p-value = 0.76).

The mean mesh fixation time in group I was 49.4 ± 7.83 min, whereas it was 17.2 ± 2.86 min in group II. The

minimum and maximum time taken for mesh fixation in group I were 36 min and 62 min respectively. Similarly minimum and maximum time taken for mesh fixation in group II were 12 min and 24 min respectively.

The mean total operative time in group I was 113.6 ± 10.92 min, whereas in group II, it was 88.35 ± 8.27 min. The minimum time taken for surgery in group I was 95 min and maximum taken was 132 min. Whereas, minimum and maximum time taken for surgery in group II were 75 min and 104 min respectively. Significant difference was found in mesh fixation time and mean operative time in both the groups as p-value is less than 0.05 in both cases (Table 2 & 3).

Table 2. Comparison of mean mesh total operative time (TOT) in two groups

Group	Number of Patients	Mean Total Operative Time	Standard Deviation
Group I	20	113.6 min	10.92 min
Group II	20	88.35 min	8.27 min
P - value	Not applicable	< 0.0001	Not applicable

Table 3. Comparison of mean mesh fixation time in two groups.

Groups	Number of Patients	Mean Mesh Fixation Time	Standard Deviation
Group I	20	49.4 min	7.83 min
Group II	20	17.2 min	2.86 min
P - value	Not applicable	< 0.0001	Not applicable

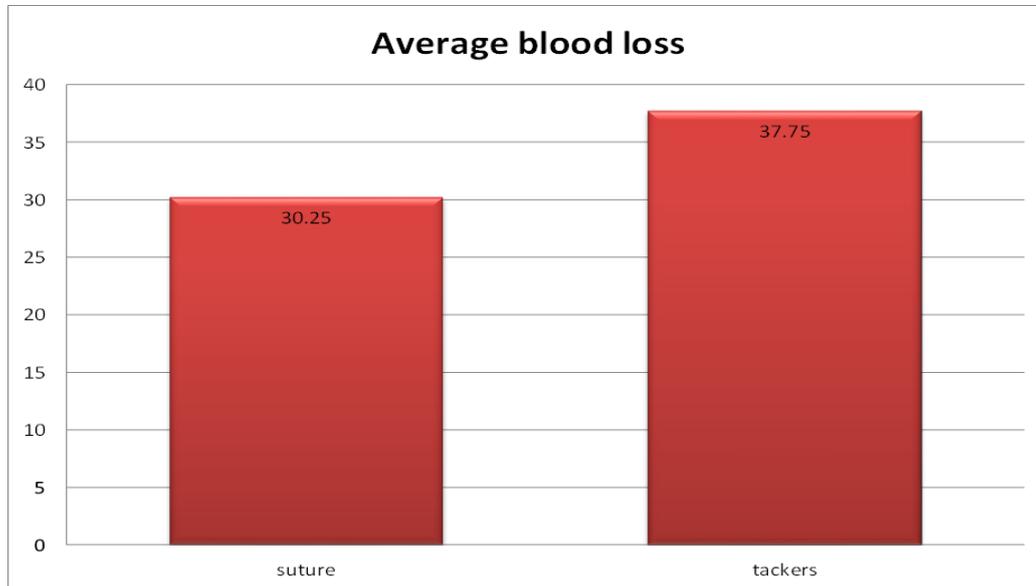
Average blood loss was found to be 30.25 ml in group I whereas it was 37.75 ml in group II (Fig.3). Blood loss

in laparoscopic ventral hernia repair is mainly due to injury to some abdominal wall vessels. In group I, 21-30 ml blood loss occurred in 15 cases out of 20.

Whereas in group II, 8 had 21-30 ml, 6 had 31-40 ml, 4 had 41-50 ml and 2 had 51-60 ml of blood loss. Amount of blood

loss in two groups is statistically significant (p-value = 0.026).

Fig.3.Average blood loss: Left - group I; Right - group II



Significant bowel injury which may lead to contamination (iatrogenic perforation) was not reported in any of the groups. Only 2 in group I had serosal tears, whereas, no patient in group II had similar complication. Though intraoperative serosal tears occurred in a few cases, none of them were repaired intraoperatively. There is no significant difference in two groups in terms of serosal tear (p-value = 0.15).

Discussion

Till the end of year 1992, all ventral hernia repairs used to be done as an open surgical procedure only, which was associated with a lot of morbidities like pain, wound infection, seroma formation, etc. Repair of ventral abdominal wall hernia by laparoscopic route evolved rapidly and now this is well accepted and preferred approach since first case by Karl Le Blanc (Christoffersen et al., 2015; LeBlanc et al., 2003; LeBlanc et

al., 2001; Sasse et al., 2012).

Commonly practiced technique of mesh fixation in LVHR involves circumferential application of tacks after fixation of mesh with transfascial stay sutures at the four corners. Majority of reports come up in favor of this traditional technique (Sasse et al., 2012; Muysoms et al., 2012). LeBlanc (2007) recommended minimum mesh overlap of 4–5 cm without transfascial sutures and at least 3 cm with transfascial sutures. Further maximum spacing between transfascial sutures was recommended up to 5 cm. In our study, 4-5 mesh overlap on all sides was done in all cases. But at the same time, several studies have come up with the equally good result with tackers only fixation. Though very few randomized trials have been done to compare open versus laparoscopic repair, all have supported laparoscopic repair (Carbajo et al., 1999; Olmi et al., 2005; Misra et al., 2006; Barbaros et

al., 2007).

Tackers, which are commonly used fixation device for laparoscopic mesh fixation are associated with inappropriate tacker length, either too long or too short, depending on patient's abdominal wall characteristics (LeBlanc, 2003). Similarly, transfascial sutures are associated with high postoperative pain scores in various studies (Kitamura et al., 2013; Heniford et al., 2000). Clinical sense makes us think that intracorporeal suturing can resolve these issues. But intracorporeal suturing is not used generally due to handling and problems in suturing on roof in ventral hernias. Hence, this pilot study was planned to explore and gain insights. The aim was to evaluate intraoperative considerations in intracorporeal suture fixation and compare it with tacker fixation of mesh in LVHR.

In this randomized control trial study, two well matched and randomized groups - intracorporeal suture mesh fixation and tackers mesh fixation, were compared for mesh fixation time, mean operative time and intraoperative complication such blood loss, serosal tear or bowel injury. In our study, we had 43 patients of ventral hernia undergoing laparoscopic ventral hernia repair. Out of these, 3 underwent conversion to open repair due to non-progression of dissection due to dense adhesions. 20 cases had LVHR using suture technique and rest 20 had LVHR using tackers.

Most of the study participants who underwent laparoscopic ventral hernia repair belonged to age group of 35-45 years (52%). The mean age of patients who underwent suture fixation was 42.1 ± 7.7 years. It was 41.25 ± 7.2 years for

patients who underwent tacker fixation. So, both groups were well matched in terms of age distribution. Bangash and Khan (2013) found it to be 38.3 years and 41.9 years for suture and tacker groups respectively. It was 52 years and 57 years in LVHR with suture and tackers respectively in a study by Nguyen et al. (2008); 44.6 years in suture fixation and 45.9 years in tacker fixation in a study by Bansal et al. (2012); 45.9 years in suture group and 49.4 years in tacker group in a study by Kitamura et al. (2013).

In our study, 55% were females and 45% were males in suture fixation group whereas 45% were females and 55% were males in tacker fixation group. Difference in sex composition of two groups was not statistically significant (p-value = 0.5) in our study and were comparable. In a study by Bansal et al. (2012), 40% were males and 60% were females in suture group, whereas, 21.8% were males and 78.2% were females in tacker group. Study by Bangash and Khan (2013) had composition of 60% males and 40% females in tacker group whereas 71.1% males and 28.9% females in suture group.

In our series, mean operative time was 113.6 ± 10.92 min and 88.35 ± 8.27 min in suture and tacker groups respectively. Whereas in a study by Bangash and Khan (2013), it was 179 ± 26.8 min and 156 ± 37.8 min in suture and tacker groups respectively. In a study by Nguyen et al. (2008), it was 132 min and 122 min in suture and tacker groups respectively. In a study by Kitamura et al. (2013), the mean operative time in suture technique was 98 ± 6.48 min, and in tacker technique it

was 93.59 ± 5.97 min. Hence, statistically significant difference in mean operative times in both groups in our study is corroborated by other similar studies.

Further, mean mesh fixation time in suture technique was 49.4 ± 7.83 min and 17.2 ± 2.86 min in suture and tacker groups in our study. Difference in mesh fixation times was found to be statistically significant. Our findings are in sync with other studies. In a study conducted by **Bangash and Khan (2013)**, the mean mesh fixation time in suture technique was 81.3 ± 17.1 min and in tacker technique it was 51.6 ± 11.2 min.

In our study, average blood loss during surgery in suture group was 30.50 ml, whereas, it was 37.75 ml in tacker group. Thereby, average blood loss in suture group was found to be less which is also statistically significant. Further, in suture group, one patient had 60 ml of bleeding, thereby, increasing the operative time significantly to 125 min. In tacker group, two patients had blood losses of 65 ml and 65 ml respectively and their operative times were 101 min and 88 min respectively. Serosal tears occurred in two patients which were repaired promptly during surgery. No patient had any mucosal or submucosal breach in bowel in either of the groups.

Conclusion

Use of intracorporeal sutures for mesh fixation is a viable option in laparoscopic ventral hernia repairs. Though Mesh fixation with tackers is easier and faster, intracorporeal sutures are more likely to avoid unpredictable bleeding associated with tackers. Both are equally effective regarding the intraoperative

complications like, bowel injury or serosal tear.

In a nutshell, laparoscopic ventral hernia repair using intracorporeal sutures is a technically challenging operation requiring relatively more time and expertise compared to LVHR using tackers, but it holds promise in overcoming problems associated with tackers and transfacial sutures. We recommend a multicentric study with larger sample size and longer follow up comparing intra and post operative outcomes to overcome problems related with learning curve and accurate assessment of benefits.

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