pISSN 2349-3305 | eISSN 2349-2902

# **Original Research Article**

DOI: https://dx.doi.org/10.18203/2349-2902.isj20211287

# Evaluation of intra-abdominal adhesion formation after laparoscopic ventral hernia repair with composite mesh using abdominal ultrasound: a prospective observational study

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Received: 27 January 2021 Revised: 06 March 2021 Accepted: 08 March 2021

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#### **ABSTRACT**

**Background:** Laparoscopic ventral hernia repair has revolutionized treatment of ventral hernia by offering shorter recovery time, decreased pain, reduced wound complications and lower recurrence rates as compared to conventional open hernia repair. But intra-abdominal mesh placement is associated with a high risk of complications including adhesions, bowel obstruction and fistula formation. Many different types of meshes with adhesion barriers have been developed to overcome these problems. This prospective observational study evaluated the outcomes of laparoscopic repair of ventral hernias in terms of Intra-abdominal adhesion formation with composite mesh using ultrasound.

**Methods:** The study was conducted from August 2017 to February 2019. All patients underwent standard laparoscopic ventral hernias repair using composite mesh secured with tackers. Omentum was interposed between the mesh and underlying bowel. At a mean follow-up of one year, all patients were subjected to ultrasound examination using visceral slide technique to detect Intra-abdominal adhesions.

**Results:** Our study included 50 patients with a mean age of 43 years (range 26-59 years) and mean body mass index of 29.07±2.35 kg/m<sup>2</sup> (range, 24-33 kg/m<sup>2</sup>). Mean fascial defect size of hernia was 13.4±3.77 cm<sup>2</sup> (range12-16 cm<sup>2</sup>). There were no mesh-related complications and recurrence during the follow-up period of 1 year.

**Conclusions:** Laparoscopic ventral hernia repair using composite mesh seems to be a promising technique for treating ventral hernias. However, longer follow-up periods are needed to confirm effectiveness and safety of the composite mesh.

Keywords: Intra-abdominal adhesions, Laparoscopic ventral hernia repair, Composite mesh

### INTRODUCTION

During the past 50 years, hernia repair techniques have evolved from primary suture repair to the use of synthetic mesh products to accomplish a tension-free repair to minimally invasive laparoscopic techniques.

Laparoscopic ventral hernia repair was first described by LeBlanc and Booth in 1993.<sup>1</sup> The adaptation of laparoscopy to ventral hernia repairs has led to shortened hospital stays, faster recovery time, reduced pain,

decreased wound morbidity, and reduced recurrence rates. These benefits are achieved by eliminating abdominal incisions and improving detection of unsuspected secondary defects that might not otherwise be detected during open repair.

One drawback of laparoscopic ventral hernia repair (LVHR), however is the placement of prosthetic mesh materials inside the abdomen. These mesh materials are in direct contact with the abdominal viscera and can form adhesions leading to pain, fistula formation, bowel

obstruction, or adhesiolysis related complications, such as enterotomy and unplanned bowel resection during subsequent surgical procedures.

The evolution of modern ventral hernia repair started in 1958 by Francis Usher, who published the first of his many papers describing the use of polypropylene mesh for hernia repairs.<sup>2</sup> This mesh was rightly recognized as a major leap forward in the reduction of recurrence rates after hernia repairs. However, the same properties that led to incorporation of mesh into the abdominal wall also resulted in adherence of bowel to mesh if the mesh is exposed to underlying bowel. However, development of adhesions can be prevented by interposing omentum between mesh and bowel. Using this technique, Franklin et al documented no adhesion-related complications in over 170 patients who underwent laparoscopic ventral hernia repair.3 However, meshes with adhesion barrier coatings such as fish oil, oxidized cellulose, or hyaluronic acid have been utilised as solutions for this concern.

To promote better tissue integration and to prevent adhesions, composite mesh was developed. Basic constructs of these mesh materials include lightweight polypropylene or polyester. Absorbable barriers are typically composed of Seprafilm, oxidized regenerated cellulose, and omega-3 fatty acids.

Composite mesh used in this study is composed of an inner non-absorbable Polypropylene layer surrounded by PDS on each side. One side of the mesh is covered with a bioresorbable oxidized regenerated cellulose layer that helps to decrease bowel adhesions, thus preventing many of the complications associated with traditional synthetic mesh. Experimental data have shown both efficacy as well as safety of this composite mesh for intraperitoneal placement in ventral hernia repair. The objective of our study was to evaluate intra-abdominal adhesions after laparoscopic ventral hernia repair using composite mesh with the help of abdominal ultrasound.

# **METHODS**

This prospective observational study was conducted in the Department of General Surgery, VMMC and Safdarjung Hospital, New Delhi over a period of 1.6 years from August 2017 to February 2019. The study was undertaken after approval from institutional ethic committee and informed consent was taken from all participants.

#### Inclusion criteria

All patients undergoing elective laparoscopic ventral hernia repair were included in the study.

#### Exclusion criteria

Patients of age less than 12 years, pregnant female, obstructed or strangulated ventral hernia were not included in the study.

#### Sample size

The study of Juliane Bingener, et al4 observed that 35% had adhesions. Taking this value as reference, the minimum required sample size with 13.5% margin of error and 5% level of significance is 48 patients. To reduce margin of error, total sample size taken is 50.

Formula used is:

$$N \ge (p(1-p)) \div (ME \div Z \propto)2$$

Where Z  $\alpha$  is value of Z at two sided alpha error of 5%, ME is margin of error and p

is proportion of patients with adhesions.

**Calculations** 

$$n \ge ((0.35 \times (1 - 0.35)) \div (0.135 \div 1.96)2 = 47.95$$
  
= 48 (approximately)

#### Repair technique

One surgeon performed all cases using a standard technique, all patients received prophylactic antibiotics before the first incision based on individual drug allergy information. The patient was positioned supine on the operating table. Gastric decompression was accomplished with an oral gastric tube in all patients. A Veres needle was used to access the peritoneal cavity, pneumoperitoneum was established to 12 mm Hg. Total two 5-mm blunt-tip trocars and one 10-mm blunt-tip trocar were inserted under direct visualization. A 5-mm and 10mm 30° laparoscope was used to fully explore the abdomen and to perform adhesiolysis. For an incisional hernia, a complete lysis of adhesions was performed to evaluate the entire length of the incision. The hernia sac contents were reduced, sac was pulled inside and tacked to the margin of the defect. The composite mesh was then introduced through the 10 mm trocar. After proper positioning of the mesh, a suture passer was used to pull the delayed absorbable transcutaneous sutures through separate incisions and tied down, taking care to ensure that the mesh overlapped the fascial defect by at least 5 cm in each direction. The circumference of the mesh was secured with absorbable spiral tacker at 1-2-cm intervals with a double crown technique. Omentum was interposed between the mesh and the underlying bowel.

After the operation, patients were shifted to the surgical ward. Postoperative analgesia consisted of paracetamol and non steroidal anti-inflammatory drugs or intravenous analgesics if necessary. Patients were discharged from the hospital when they mobilized autonomously.

#### Follow-up

All operated patients were offered an abdominal ultrasound examination at 1st week, 8th week, 12th week

and 1 year following surgery. Ultrasound done using 3-7 MHz linear transducer, supplemented by a curvilinear transducer. A visceral slide technique was used specifically to detect adhesions. All patients were also observed for pain at the operative site (assessed by using Visual analogue scale), hernia recurrence, wound infection and seroma formation during follow up.

#### Visceral slide

Validated by previous study, this method is based on the demonstration of bowel movement at the abdominal wall interface during real-time ultrasound imaging.<sup>5</sup> Such movement can occur spontaneously as a result of respiratory excursions or may be induced by manual compression. During longitudinal surface scanning, a normal spontaneous visceral slide may range from 2 cm to more than 5 cm in distance. Visceral slide detected if is less than 1 cm, it is considered abnormal due to adhesions.

#### Statistical analysis

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean  $\pm$  SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was used.

Statistical tests were applied as follows:

Quantitative variables were compared using Wilcoxon signed rank test (as the data sets were not normally distributed) for comparing pre and post pain score. Qualitative variables were compared using Fisher's exact test. A p value of <0.05 was considered 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**

During the study period, we identified 50 patients who met the inclusion criteria. The mean patient age was 43 years (range 26-59 years) at the time of the operation, 22 patients are female, and 28 patients are male with a mean body mass index (BMI) of 29.07±2.35 kg/m<sup>2</sup> (range, 24-33 kg/m<sup>2</sup>), with 19 patients (38%) having a previous history of laparotomy. Hernia types include 10-epigastric hernia (20%), 19-incisional hernia (38%) and 21-umbilical hernia (42%). Mean fascial defect size of hernia was 13.4±3.77 cm2 (range12-16 cm<sup>2</sup>) and median fascial defect size was 13.5 cm<sup>2</sup> requiring a mean mesh size of 225 cm<sup>2</sup>. There were no major intra-operative morbidities or deaths. All 50 patients had their repairs completed laparoscopically, without the need of conversion to open repair. The mean operative time and hospital length of stay was 1.76±0.15 hrs and 2 days respectively. There were no major complications. One of the patients developed subacute

intestinal obstruction on 2nd postoperative week was managed conservatively and got resolved.

Among 50 patients majority experienced moderate pain (VAS 4-5) at the surgery site during 1st post-operative week, while 15 patients stated they experienced mild to moderate pain with activity usually near the edges of the repair during 8th week follow up. Most patients were pain free by the end of 12 weeks.



Figure 1: Ultrasonogram of the patient after laparoscopic ventral incisional hernia repair showing sliding of the bowel. No seroma or recurrence is detected.



Figure 2: Ultrasound image showing mesh (arrow), no seroma or recurrence is detected.

The mean follow-up period was one year. There were no recurrences documented in any patients at their follow-up visits during this period. No mesh-related complications, including infection, have been documented, and no patients required re-operation. 13 patients developed seromas (detected by ultrasound) which got resolved spontaneously by the end of 12 week without requiring any intervention. Among 50 patients adhesions were detected in 3 patients during 1st week scan (p value 0.237). No adhesions detected during 8th and 12th week scan. Only one patient had ultrasonographically detected adhesions by the end of 1 year (p value 0.127), however patient had no complaints and these patients are still in follow-up.

#### **DISCUSSION**

The optimal approach and technique for performing ventral hernia repair is still subject of debate. Laparoscopic ventral hernia repair is documented as an excellent choice for both primary and incisional ventral hernias in numerous studies.<sup>6,7</sup> Ventral hernia repair has changed considerably with advancements in laparoscopy and the use of synthetic mesh. Laparoscopic approach resulted in reduction of the number of infections, recurrences, and the length of hospital stay. For laparoscopic repair, a different type of mesh is needed, as the mesh will be in contact with the abdominal contents. The composite mesh consists of a non-absorbable polypropylene mesh layer and an absorbable tissue-separating layer of ORC (Oxidise Regenerated Cellulose). The polypropylene part is separated by a layer of PDS polymer film. The function of the polypropylene side of the mesh is to allow adequate tissue in growth, whereas the ORC should provide a bioabsorbable layer that physically separates the polypropylene from the underlying tissue and organ surfaces in order to minimize adhesions. The PDS film provides a thin flexible bond between the mesh and the ORC. As the ORC and PDS layers are bioabsorbable, i.e., after ingrowth of the polypropylene the mesh contains much less polypropylene and can be considered as a light weight mesh.

The data in our study were prospectively collected. Majority of the patient in our study had moderate pain during 1st post-operative week, however most patients were pain free by the end of 12 weeks. The result from our study in terms of pain were comparable to study done by Berrevoet et al.<sup>11</sup>

Fifteen patients did have seromas in the early postoperative period. None of these seromas were symptomatic (pain and/or infection), and they did not require aspiration; thus, they were not included as complications. The development of a seroma is multifactorial and is likely related to the introduction of a foreign body eliciting an inflammatory response, as well as leaving the hernia sac intact.<sup>8</sup>

Ultrasonographically detected adhesions found in three patients during 1st week scan and all 3 patients were asymptomatic, 12th week scan in these patients showed no adhesions. During last scan (1 Year) adhesions detected in one patient who is asymptomatic. The results are consistent with study done by Fraklin et al.<sup>3</sup> Nonetheless, no recurrence and infection were observed, only one patient encountered minor complication in the form of subacute intestinal obstruction which was managed conservatively, subsequent ultrasound scan in this patient revealed no adhesions.

The recurrence rate using composite mesh in previous studies was 0%, 0%, and 3.5% with mean follow-up periods of 8, 17, and 27 months, respectively. 9-11 Comparable with previous studies, during 12-month follow-up period there were no recurrences in our study. These patients are still in follow up.

The results of our study are comparable with the study done by Moreno-Egea et al using composite mesh in treating incisional hernia. Only one patient in our study

had minor complication in the form of subacute obstruction which got resolved by conservative management. Both the studies have equal number of study group. During their follow-up there were no intraabdominal complications associated with the use of the composite mesh.

The results of this study are important but limited as the negative predictive value of the visceral slide method is approximately 80%; therefore, it is possible that some patients who were deemed free of adhesions might have had mild or filmy adhesions not detectable by ultrasound. In any case, these adhesions, even if present are unlikely to have any clinical impact, because no visceral complications have been observed.

#### **CONCLUSION**

Data from 50 consecutive patients show that laparoscopic ventral hernia repair with composite mesh and omental coverage has no additional risk of intra-abdominal adhesions as no mesh-related complications such as bowel obstruction or enterocutaneous fistula, no recurrences or other complications requiring re-interventions were seen in this study. Thus, laparoscopic ventral hernia repair using the composite mesh seems to be a promising technique for treating ventral hernias as it does not lead to intra-abdominal adhesions. However, longer follow-up periods are needed to confirm effectiveness and safety of the composite mesh.

Funding: No funding sources
Conflict of interest: None declared

Ethical approval: The study was approved by the

Institutional Ethics Committee

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Cite this article as: Arora JK, Sankal M, Ghasi RG, Thakur R. Evaluation of intra-abdominal adhesion formation after laparoscopic ventral hernia repair with composite mesh using abdominal ultrasound: a prospective observational study. Int Surg J 2021;8:1143-7.