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Closure Vs Non-Closure of Fascial Defect in Laparoscopic Ventral Hernia Repair: A Randomized Observational Study

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Abstract

Background: surgery for ventral hernia has always been challenge for surgeons. The management approach has shifted from open to minimally invasive methods, and nowadays emphasis is not only on the improvement of symptomatology but also the cosmesis. Aim of present study was to evaluate beneficial effect of closure of fascial defect over non closure in patients with ventral hernia undergoing laparoscopic repair.

Material and methods: sixty patients of ventral hernia (both primary & incisional) were randomized into two groups. Thirty patients underwent standard laparoscopic hernia repair without closure of fascial defect. In other 30 patients closure of fascial defect was also performed in addition to standard procedure. Both the patient groups were prospectively followed up.

Results: Mean operative duration and need for non opioid analgesics for first 48 hours was higher in study group in whom closure of fascial defect was performed. Mesh bulging was noticed in control group but not in study group. Seroma formation, recurrence, and surgical site infections were comparable in both the groups.

Conclusion: Accepting higher pain on VAS manageable by nonopioid analgesics and slight increase in operative duration on account of closure of fascial defect during laparoscopic mesh repair of primary ventral or incisional hernia is an acceptable alternative to non fascial closure with less postoperative pain, but with added risk of seroma formation, mesh bulging, recurrence and/or other wound related complications.

Key words: ventral hernia; fascial defect; seroma; recurrence; laparoscopic repair

Introduction

Primary ventral and incisional hernia is a common surgical problem and continues to challenge surgeons despite advances in surgical technology. Approximately 3-50% of the abdominal incisions are complicated by incisional hernia [1-5]. Optimal management of incisional and ventral hernia is debatable [6]. Main concern following repair of hernia is recurrence and functional

outcome. Reported recurrence rates following anatomical/sutured repair is 8% to 63% [1, 5, 7-10]. The reinforcement of the defect with prosthetic material is considered gold standard, but results are still suboptimal with recurrence rates ranging from 10 % to 24 % by open methods [8, 9]. In the era of laparoscopy, patient's & surgeons' perseverance for minimal invasive approach to hernia problem and its distinct advantage over traditional open approaches in terms of minimal wound related complications, has led to paradigm shift in management of primary ventral & incisional hernia. Laparoscopic approach although having distinct advantages over traditional open repairs in terms of smaller incision, shorter hospital stay also has its limitations like seroma formation, mesh bulging and recurrence rate of 2-5% [1]. Several attempts are being made to minimize these complications and improve cosmesis. The current study has been undertaken to compare the effectiveness and outcome of closure versus non closure of fascial defect in laparoscopic ventral and incisional hernia repair in terms of postoperative pain, seroma formation, mesh bulging or recurrence within 6 months.

Material and methods

The present prospective study was conducted in the Department of Surgery, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi from July 2015 through March 2017. A total of 60 patients meeting the inclusion criteria were recruited in study and randomized in two groups of 30 each, by sealed envelope method.

In Study Group, primary repair of fascial defect was carried out in addition to intraperitoneal on lay mesh placement. In Control Group hernia was repaired using mesh without closing the fascial defect.

Inclusion criteria

1. All adults with central reducible ventral hernia, either primary or Incisional.
2. Ventral hernia with defect ≥2cm and ≤6 cm.
3. ASA grade I & II
4. Body Mass Index <40 kg/m²

All the patients meeting the inclusion criteria and fit for laparoscopic surgery were admitted one day prior to surgery. Age, sex, BMI, associated comorbidities, primary /Incisional hernia, past abdominal surgery, previous hernia repair, history of recurrence was noted down. European hernia society classification (2009) was used to classify the hernia. The entire patients were assessed clinically and sonographically for size and number of hernia defects.

Operative technique

Surgery was performed by same surgical team under general anesthesia with patients lying supine in 10-15° trendelenberg tilt and hands tucked on sides. Injection Cefazolin was administered intravenously as prophylactic antibiotic just before induction of anesthesia. Foley's catheterization and Ryle's tube insertion was done as per requirement. After thorough preparation of the surgical field, Ioban drape was used to avoid mesh contact to skin.

Pneumoperitoneum was created using veress needle at palmer's point (left or right subcoastal margin at tip of 11th rib, corresponding to anterior axillary line). A telescope was inserted through 10 mm port and the pressure was kept at 12mm Hg. After abdominal exploration, two more (10 mm & 5 mm) ports were inserted in lateral abdominal wall under telescopic vision far away from hernia defects. Using endograsper and endoshears with electrocautery or harmonic, adhesiolysis was done and visceral contents of hernia were reduced.

The location of defect/s, size of defect, numbers of defects, content of hernia sac were noted down. After lowering the intra abdominal pressure to about 8-10 mm

Hg, fascial defect was measured in vertical and horizontal dimension using silk thread and a scale.

In study group fascial defects were closed with endosuturing device (10 mm covedien device) with intracorporeal knotting using zero ethibond sutures. This step was omitted in control group.

A 15x15 cm marking was done on the abdominal wall with defect in the centre. After closure of the defect in study group a composite mesh of 15x15 cm with 5 transfascial sutures (Prolene 00) one at the centre and test at midpoint of four edges of the mesh on the parietal surface, was introduced into the abdominal cavity through 10 mm port, The mesh was unrolled and all transfascial sutures were brought out through the abdominal wall at predetermined positions using suture passer and tied with knots buried in subcutaneous plane. The mesh was fixed to anterior abdominal wall using combination of transfascial sutures and double crowning of absorbable tacks with minimum overlap of 4 cm all around. Abdominal cavity was thoroughly inspected and hemostasis ensured. After lowering intra-abdominal pressure, fascial closure of 10 mm port was performed using vicryl 00. Skin was closed with non absorbable 3-0 nylon sutures. Total operative duration was noted down.

Compressive pressure bandage was applied at the defect site for at least 10 days along with abdominal binder for 6 weeks. In immediate post operative period, transdermal nonopioid analgesic patch containing 100 mg of diclofenac sodium was applied and two dosage of cefazolin 1gm was administered intravenously 12 hrs apart. Patients were allowed to take normal diet postoperatively after appearance of bowel sounds and carry out routine activities as per their level of comfort.

Pain was assessed using visual analogue scale at 24 hrs and 48 hrs at the time of discharge and additional requirement of nonopioid analgesic was noted. Discharge was planned when patients were accepting orally and pain on VAS was ≤ 40. Patients were followed up at 1 week, 1 month, 3 month and 6 months. Pain on VAS was measured at every visit. Surgical site was examined for incidence of surgical site infection before discharge, subsequently at 1 week and after suture removal at 10^{th} to 12^{th} post operative day. Seroma formation at subsequent follow up, if detected clinically was confirmed by ultrasound examination and other details regarding the size, location were noted. Patients with seroma were managed conservatively with oral antibiotics to prevent secondary infection. Follow up examination was scheduled up to 6 months to detect mesh bulging or recurrence. Ultrasound scan or computed tomography was used to differentiate mesh bulging from recurrence.

Statistical analysis

Statistical package for social sciences (SPSS) version 21.0 was used for analysis. Categorical variables were presented in number and percentages and continuous variables were presented as mean ±SD and median. Quantitative variables were compared using unpaired t test/Man-Whitney test between the two groups. Qualitative variables were analyzed using Chi-square/Fischer's exact test. A p value of <0.05 was considered statistically significant.

Observation and results

A total of 60 patients were recruited in study (30 in each group). The mean age of patients were 41.83 (27 to 70 yrs) and 42.97 (25 to 65) years respectively in Study and Control Group. Females outnumbered males in both the groups (70% in study group and 83.33% in Control group). Mean body mass index (BMI) in study group was 28.5 as compared to 29.49 in control group and the difference was not statistically significant (p=0.147). Table 1shows distribution of hernia as per European hernia society classification (2009).

Table 1: Distribution of hernia according to European hernia society classification

Diagnosis		Study group (n=30)	Control group (n=30)	Total
Primary	Epigastric hernia	2	5	7
	Umbilical hernia	13	10	23
Incisional	Umbilical hernia	7	9	16
	Infraumbilical hernia	8	6	14

The defect was located at umbilical region in 66.67% of study group and 60% in control group. Mean size of defect in study group was 3.7 cm (2.5 to 6 cm) as compared to 3.77 cm (2 to 6 cm) in control group and the difference was not statistically significant (p=0.577).

Ninety percent of patients had single defect in both the groups. Study group consisted of 10% of cases with two defects. Control group consisted of 6.67% cases with two defects and 3.33% of case with three defects. Both the groups were comparable in terms of previous abdominal surgery (50% vs. 53.3%). One patient in each group was diagnosed as a case of recurrent incisional hernia.

Mean operative duration was 142.83 min, with range from 130 to 175 min in study group and 114 min with range from 85 to 140 min in control group as shown in Table 2. The difference in operative duration was statistically significant ($p < 0.001$). Operative duration was higher in patients who have undergone previous surgeries and those in which fascial defect was closed as shown in Table 2.

Table 2: Past abdominal surgeries and operative duration

No of previous surgery	Operative duration in minutes		P value
	Study group	Control group	
Any	142.83 (n=30)	114 (n=30)	<0.001
0	130.4 (n=15)	110.2 (n=14)	0.001
1	137.86 (n=7)	111.36 (n=11)	0.001
≥2	150 (n=8)	127 (n=5)	0.01

Postoperative pain on visual analogue scale (VAS) was compared in both the groups and is summarized in Table 3. Patients in study group in whom fascial closure was done experienced more pain on VAS at 24 hours and 48 hours. Pain scores were relatively higher at 1wk, 1 month & 3 months follow up in study group but it was not statistically significant.

Table 3: Postoperative pain score on VAS

Postoperative period	Mean pain score		P value
	Study group	Control group	
24hrs	40.5 (30-50)	27.33(20-40)	<0.0001
	≥40 (76.66%)	≥40 (3.33%)	
48 hrs	26 (10-40)	18.8 (10-30)	0.0004
	≥30 (56.67%)	≥30 (13.33%)	
1wk	13.67 (0-30)	12.17 (0-30)	0.339
	≥10 (93.33%)	≥ (93.33%)	
1 month	6.33 (0-20)	8.33 (0-30)	0.302
	<10 (90%)	<10 (86.67%)	
3 months	4.67 (0-10)	3.33 (0-20)	0.153
	<10 (100%)	<10 (93.33%)	

Non opioid analgesic for pain relief was needed for significantly longer duration in study group (6.97 days with range from 6 to 9 days) as compared to control group (5.37 days with range from 4 to 8 days) ($p<0.001$).

Seroma was documented clinically in 7 (23.3%) of patients in study group as compared to 13 (43.3%) in control group. The difference was not statistically significant (p=0.1). Two patients in study group and 6 patients in control group developed surgical site infection, however the difference was not statistically significant (p=0.25). All the patients with seroma and surgical site infections were managed conservatively.

Mesh Bulging/ Eventration was noted in 3 (10%) of patients in control group whereas none of the patient in study group presented with these symptoms. The difference was also not statistically significant (p=0.23)

Two patients in study group and 5 patients in control group developed recurrence, however it was not statistically significant (p=0.42). There was no visceral injury or mortality in either of the groups.

Discussion

Ventral hernia is a common surgical problem and always requires surgical management. Prevalence of incisional

hernia has also increased due to large number of open abdominal surgeries in 20th century. Management of ventral and incisional hernia has undergone tremendous change over years ranging from primary sutured repair to open mesh repair to minimally invasive approach with an aim to improve outcome and expedite patient's recovery. Le Blanc et al in 1993 were first to use laparoscopic approach for the management of ventral and incisional hernia. Since then the laparoscopic approach has gained more popularity owing to its distinct advantages like reduced level of postoperative pain, fewer wound complications, and shorter hospital stay [11-14]. However exact technique of repair is debatable [6] and there is no improvement in rate of recurrence [3, 15, 16].

According to La Place's law, a central nonfunctional portion of the abdominal wall in primary or incisional ventral hernia acts like a ''sail in the wind'' and is prone to bulge [17]. Primary fascial closure not only restores the anatomy by reapproximating the abdominal wall under physiologic tension, but also restores its function and prevents bulging.

Ventral Hernia Working Group has recommended primary closure of fascial defect before mesh reinforcement for quality hernia repair [18]. When compared to the standard laparoscopic ventral hernia repair with mesh, fascial closure appears to yield lower rates of seroma, hernia recurrence and clinical bulging [19].

In our study the mean operative duration was higher in study group as compared to control group and those with previous abdominal surgeries that can be attributed to: [1] mainly, the time required for the closure of fascial defect [2] time taken for adhesiolysis in patients with previous abdominal surgeries. Similar findings were noted in study conducted by Zeichen et al however; overall operative duration was less in both the groups as compared to our study [20]. The difference in mean operative duration can be attributed to technique of mesh fixation, as mesh was fixed only with suture or tacks in some patients and with combination of both in some patients by Zeichen et al. We have utilized uniform methodology for mesh fixation using four transfascial sutures and double crowning of tacks using a fixation device.

The mean pain score on VAS was higher in study group both at 24hrs and 48 hrs, as compared to control group requiring non opioid analgesics for longer duration up to 1 week. Higher incidence of pain in the study group has been attributable to closure of fascial defect, as rest of the technique in both the groups including the technique of mesh fixation was similar and approximation of the edges of fascial defect led to deviation from the concept of tension- free surgery. There are no prospective studies in the literature comparing the incidence of immediate post-operative pain in laparoscopic ventral hernia repair with closure and non-closure of fascial defect. There was no statistically significant difference in pain in both the groups at 1wk, 1 month and 3 month. A nonrandomized study conducted by Chelala et al has also reported higher pain score in early postoperative period that becomes negligible beyond 3 months [21]. Contrary to expectations, as analyzed in our study and also reported in different ones, the defect closure without extensive tension or under physiological tension does not cause excessive pain and resolves over time [22].

Incidence of seroma was lower in study group; however difference between two groups didn't reach statistical significance. Variable reports are available in literature regarding incidence of seroma formation. The prospective study conducted by Lambrecht et al concluded that closure of fascial defect did not reduce seroma formation compared to non closure of fascial defect [23]. Zeichen et al in their retrospective analysis reported higher incidence of seroma in closure group [20]. Clapp et al and Orenstein

SB reported lower incidence of seroma in closure group mainly attributed to near total decrease of the dead space between the margins of the defect, between prosthetic mesh and skin or any residual hernia sac after closure of fascial defect [24, 25]. Lower incidence of seroma following closure of fascial defect during laparoscopic ventral hernia repair has been reported in a meta analysis involving 16 studies comprising 3638 patients [26].

Incidence of surgical site infection in our study group was very low and corresponds to available literature [20, 24].

Mesh bulging although not statistically significant, was reported in control group but not in study group. Clapp et al have reported significantly lower incidence of mesh bulging in fascial closure group as compared to non fascial closure group [24].

In our study recurrence was lower in fascial closure group although statistically insignificant. Study by Clapp et al on 72 cases has reported no recurrence in primary defect closure group [24]. Lower recurrence rates in fascial closure groups have been reported in several studies [20, 27].

There are many proposed advantages of performing primary defect closure before applying the mesh [20, 28]. Re-approximating the abdominal fascia is thought to be a more physiologic repair, and thus stronger. Additionally, it provides a greater surface area of abdominal wall for the mesh to be in contact with. Furthermore, it prevents postoperative bulging of the mesh into the defect. Bulging is not ideal for cosmesis, and may allow mesh to come closer to the skin surface, which can increase the risk of mesh infection and erosion. Conversely, closing the defect increases tension, which may be counterproductive. Also, placement of extra suture in the abdominal wall increases the risk of postoperative pain. Many surgeons have yet to adopt this technique, most likely due to the technical difficulty, and the current lack of evidence suggesting its superiority when compared to mesh placement alone. Retrospective study by Nguyen et al has also reported superiority of fascial closure over non fascial closure in terms of recurrence and seroma rate [28].

The current study has been undertaken as there is paucity of literature regarding the effectiveness of concomitant primary defect closure during laparoscopic ventral and incisional hernia repair. Majority of the currently available literature is based on retrospective analysis of data and metaanalysis.

Conclusion

Laparoscopic ventral or incisional hernia repair needs meticulous surgical technique. As ventral abdominal wall exists under constant physiologic tension with mobile margins, failure to return the abdominal wall to its normal anatomic position risks a non-functional abdomen. Fascial defect closure before mesh reinforcement by eliminating the dead space reduces not only the incidence of seroma, bulging and recurrence but also has very less wound related complications. Accepting higher pain on VAS manageable by nonopioid analgesics and slight increase in operative duration on account of closure of fascial defect during laparoscopic mesh repair of primary ventral or incisional hernia is an acceptable alternative to non fascial closure with less postoperative pain, but with added risk of seroma formation, mesh bulging, recurrence and/or other wound related complications. However larger randomized study is needed to validate the outcome.

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