



and Other Interventional Techniques

Comparison of laparoscopic and open repair of incisional and primary ventral hernia: results of a prospective randomized study

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Received: 22 February 2006/Accepted: 11 April 2006/Online publication: 23 October 2006

Abstract

Background: Incisional hernia is an important complication of abdominal surgery. Its repair has progressed from a primary suture repair to various mesh repairs and laparoscopic repair. Laparoscopic mesh repair is a promising alternative, and in the absence of consensus, needs prospective randomized controlled trials.

Methods: Between April 2003 and April 2005, 66 patients with incisional, primary ventral and recurrent hernias were randomized to receive either open retrorectus mesh repair or laparoscopic mesh repair. These patients were followed up at 1-, 3-, and 6-month intervals thereafter for a mean of 12.17 months (open repair group) and 13.73 months (laparoscopic repair group).

Results: Lower abdominal hernias after gynecologic operations constituted the majority of the hernias (~50%) in both groups. There was no significant injury to viscera or vessel in either group and no conversions. The defect size was 42.12 cm² in the open (group 1) and 65.66 cm² in the laparoscopic group (group 2), and the prosthesis sizes were, respectively, 152.67 cm² and 203.83 cm². The hospital stay was 3.43 days in open group and 1.47 days in laparoscopic group ($p = 0.007$). There was no significant difference in the pain scores between the two groups. More wound-related infectious complications occurred in the open group (33%) than in the laparoscopic group (6%) ($p = 0.013$). There was one recurrence in the open repair group (3%) and two recurrences in laparoscopic group (6%) ($p = 0.55$).

Conclusions: Laparoscopic repair of incisional and ventral hernias is superior to open mesh repair in terms of significantly less blood loss, fewer complications, shorter hospital stay, and excellent cosmetic outcome.

Key words: Incisional hernia — Laparoscopic mesh repair — Open mesh repair — Primary ventral hernia — Recurrent incisional hernia — Polypropylene mesh — Seroma — Wound complications

The repair of incisional and primary ventral hernias remains a challenge to general surgeons because of unacceptably high recurrence rates after anatomic suture techniques. Recurrence rates after such repair range from 31% to 54% [1, 23]. The use of prosthetic material has significantly reduced recurrence rates to less than 10% [22]. However, the extensive tissue dissection required for mesh placement leads to increased wound infections and other wound-related complications (to an incidence of 12% or more) [2, 4, 7, 14, 19, 20, 24, 25, 35–37, 39, 40].

Patients and surgeons have rapidly accepted laparoscopic repair for incisional and primary ventral hernia over the past decade. As expected, a significant reduction in wound-related problems has led to this acceptance. The feasibility of laparoscopic incisional and ventral hernia repair has been clearly established (even in the absence of level 1 evidence) with large number of published case series [12, 16, 17]. In the current study, a prospective randomized comparison between open and laparoscopic techniques was performed.

Patients and methods

The current prospective randomized study was conducted at a single surgical unit of the Department of Surgical Disciplines at the All India Institute of Medical Sciences, New Delhi, India, between April 2003 and April 2005. The diagnosis of incisional and ventral hernia was based on clinical examination.

Inclusion and exclusion criteria

All uncomplicated primary ventral, incisional, and recurrent incisional hernias, including irreducible hernia in the adult population, were

included in the current study. Patients with obstruction or strangulation, local or systemic infection, or a psychiatric problem precluding informed consent for surgery were excluded from the randomization process, as well as patients unfit for general anesthesia and pneumoperitoneum.

Method of randomization

Each patient was informed about the nature of both laparoscopic and open repair, after which informed consent was obtained for randomization and the operative procedure. A total of 66 patients were recruited for the current study after evaluation based on the inclusion and exclusion criteria.

Random numbers derived from the Web site www.randomization.com were used to prepare 33 slips for the open repair group (group 1) and 33 slips for the laparoscopic repair group (group 2). Each slip was kept in a separate sealed envelope. On the evening before surgery, the patient was informed about the study. If the patient expressed preference for either of the two techniques, he or she was not included in the study. Once a patient signed informed consent, an envelope was picked at random and opened to reveal the type of repair to be undertaken.

Preoperative care

All the patients received perioperative antibiotic prophylaxis at the time of general anesthesia induction. High-risk patients, who had a higher body mass index (BMI) or chronic obstructive pulmonary disease (COPD), were informed about chest physiotherapy with incentive inspiratory spirometry.

Operative techniques

Group 1 (open repair)

A Foley catheter was used to decompress the urinary bladder if the duration of the procedure was expected to be long (large defect) or the defect was in the lower abdomen. The skin incision was made according to the site and the size of the defect. Subcutaneous flaps were raised for 3 to 5 cm around the defect depending on the available healthy fascial tissue around the margins of the defect. The hernia sac was opened and the contents reduced. Dissection was carried forward between the posterior rectus sheath and the rectus muscle or in the lower abdomen between the rectus muscle and the peritoneum. Whenever possible, the posterior sheath/peritoneum was closed primarily with 2-0 absorbable suture. Polypropylene mesh of a suitable size (with minimum of 3 cm overlap beyond the margins of the defect) was placed between the posterior rectus sheath/peritoneum and the rectus muscle. The mesh was fixed at the four corners with 2-0 polypropylene suture taken out through abdominal muscles on the anterior rectus sheath. The anterior rectus sheath was closed over the mesh with a loop of polypropylene or nylon continuous suture if possible without excessive tissue tension. The skin was closed over the suction drain or drains (on a few occasions, two drains were placed).

Group 2 (laparoscopic repair)

A Foley catheter was used to decompress the urinary bladder if the duration of the procedure was expected to be long (large defect), or if the defect was in the lower abdomen.

Laparoscopic instruments. All the instruments were reusable except the tacker (Protack 5 mm (Ref. 174006), Titanium, Made in USA by Autosuture; Manufactured by; United States Surgical, A division of Tyco healthcare Group LP, Norwalk, Connecticut, 06856, USA) used for fixation of the mesh.

Creation of safe pneumoperitoneum. The Veress needle was used to create pneumoperitoneum for all the patients. The Veress

needle was inserted at the umbilicus or in the left hypochondrium depending on the previous laparotomy incision. Carbon dioxide (CO₂) gas was used to achieve pneumoperitoneum, and an intraabdominal pressure of 14 mmHg was considered safe. In the case of large hernial defects, preferential distension of the hernia sac prevented adequate distension of the remainder of the abdomen. In such patients, one of the assistants had to keep the hernial sac compressed with the hand to allow CO₂ to distend the remainder of the abdomen for safe performance of the operative procedure.

Port placement. A 10-mm port was used for the 30° 10-mm telescope. Two additional 5-mm ports were placed as deemed appropriate depending on the location of the hernial defect. The placement of the ports was lateral or away from the margins of the defect so that all the margins of the defect were in view throughout the procedure. The most frequent location of the three ports was in the left flank. A 10-mm port was placed at the level of the umbilicus, with one 5-mm port above and one 5-mm port below.

Omental and bowel adhesions were taken down using monopolar diathermy or a harmonic scalpel. No effort was made to dissect the hernia sac. The defect was identified, and a careful survey of the whole parietal wall from within was performed to search for additional defects.

Defect and mesh size

The operating surgeon gauged the size of the defect with the help of two, three, or four fingers (laparoscopic procedure) or with a scale (open procedure) intraoperatively if this was not possible preoperatively because of irreducible hernia. A polypropylene mesh of adequate size was used in all the patients. It was ascertained that the mesh should overlap by at least 3 to 5 cm from the margins of the defect. Therefore, 15 × 15-cm mesh was considered adequate for defects measuring up to 8 × 8 cm. Any deficient coverage at any margin was supplemented with extra patches. If the multiple defects could not possibly be covered with a single mesh, additional mesh was used. Mesh fixation was accomplished with a 5-mm tacker (Protack, Titanium, AutoSuture; Tyco Healthcare, USA) in all cases. The tacks were placed at each corner, then at a 2- to 2.5-cm distance along the peripheral margin, and again in a second row close to the defect margin. The 10-mm port was closed with a 2-0 polyglactin 910 suture. The skin of all the ports was closed with 3-0 monofilament nylon or a skin stapler. A ball of gauze was placed over the region of the hernia defect, with a pressure dressing applied and maintained for 2 weeks. The Foley catheter was removed at the end of the procedure.

Problems of mesh introduction and orientation and the central orienting stitch technique

Mesh 15 × 15 cm in size was introduced via the 10-mm port without difficulty. However, because larger mesh was difficult to introduce through the 10-mm sleeve, a skin incision was made in the center of the defect, and the mesh was pushed into the peritoneal cavity. The skin incision was closed with 3-0 monofilament nylon. For larger defects and mesh size, it was cumbersome to orient the mesh all around and to accomplish fixation, particularly toward the side of the ports. To keep the mesh in the correct orientation, a central stitch through the mesh was useful for keeping the mesh lifted. A 2-0 absorbable suture was taken on the needle inside the abdomen through skin at the center of the defect. The needle then was brought out through the 10-mm sleeve. The suture was tied in the center of the mesh before the mesh could be introduced into the abdomen.

Postoperative pain assessment and analgesic need

Intramuscular diclofenac sodium 75 mg was used until the patient resumed oral intake, after which a combination of oral paracetamol and ibuprofen was administered according to the patient's requirement. If the patient reported excessive pain, additional analgesia with

injections of diclofenac sodium, tramadol, or both were given after assessment of the visual analog scale pain score on a 10-cm horizontal scale, with choices ranging from 0 (no pain) to 10 (worst pain).

Follow-up evaluation

After discharge from the hospital, the patients were followed up at 1-week, 4-week, 12-week, and 6-month intervals. Subsequent visits were replaced by telephone contact. All the data were prospectively entered onto a prestructured performa designed for the purpose for each patient.

Statistical analysis

The Student's *t*-test was applied to determine the significance of differences between continuous variables. The Mann-Whitney test and Fisher's exact test were used as appropriate. All tests of significance were at the 5% level, and all *p* values were two-tailed.

Results

For this study, 66 patients with primary ventral and incisional hernias were prospectively randomized to open (group 1) or laparoscopic (group 2) repair, with 33 patients in each group. There were 7 men and 26 women in group 1, as compared with 11 men and 22 women in group 2. The average ages were comparable in the two groups: 45.20 years (range, 25–65 years) in group 1 and 45.96 years (range, 24–70 years) in group 2. The average BMI was 25.43 (range, 18–49.3) in group 1 and 26.28 (range, 17.48–41.1) in group 2.

There were 9 primary ventral hernias and 24 incisional hernias in group 1, as compared with 9 primary ventral hernias, 3 recurrent primary ventral hernias, and 21 incisional hernias in group 2. Obstetrical (lower segment cesarean section) and other gynecologic indications for laparotomy represented the most common index surgery leading to the development of incisional hernia: 17 of 24 indications (70.83%) in group 1 and 16 of 24 indications (66.67%) in group 2 (Table 3).

Recurrent hernia (Table 4)

There were nine recurrent hernia repairs in each of the two groups. Seven (group 1) and five (group 2) recurrent hernias were subjected to surgery for a second repair after one failed previous open repair. For three (group 2) and two (group 1) patients, it was the third repair (after two previously failed open repairs). One patient in group 2 had a fourth attempt at repair after three failed open repairs.

Location of hernia defect (Table 5)

The majority of incisional hernias occurred through a lower midline incision, and primary ventral hernias were located at or around the umbilicus.

Hernia and operation characteristics

The defect size, hernia contents, operative time, and the like are listed in Table 1. Omentum was the most fre-

quent content in the hernial sac. There were no intra-operative complications such as bowel or vascular injury requiring conversion to open technique. There was no significant difference in the average defect size, mesh size, or operative time between the two groups. Blood loss was significantly greater (0.001) in group 1. However, no patient required blood transfusion. A closed suction drain was placed under the subcutaneous flaps of 19 patients in group 1. Only one patient in group 2 had a drain placed within the abdominal cavity to drain the blood and fluid used for irrigation.

Postoperative pain (Table 6)

There was no significant difference in the pain scores or analgesic requirements between the two groups during first 24 h postoperatively. Nine patients (3 in the group 1 and 6 in the group 2) continued to be distressed by their pain and required referral to the pain clinic during the first 3 months of the follow-up period. They were treated by one local injection or a repeat injection of bupivacaine 0.25% along with triamcinolone and oral tricyclic antidepressants amitriptyline and Gabapentin, which provided much relief. Persistent pain at 6 and 12 months was similar in the two groups.

Postoperative complications (Table 2)

Wound-related complications were seen largely in group 1 patients. There were nine superficial wound infections in group 1, characterized by erythema and edema requiring a course of empirical antibiotics. One patient in group 1 had severe infection requiring stitch removal, daily dressing, and antibiotics, which resolved over 3 weeks. One patient had a frank purulent abscess and mesh infection requiring debridement and daily dressing in the hospital for 1 month. However, the wound healed without removal of the mesh. One patient had superficial necrosis of the flap margins, which was treated by daily dressing. There was one symptomatic seroma in group 1, requiring one-time aspiration, and four symptomatic seromas in the group 2, requiring needle aspiration once for three of the patients and twice for one patient.

Hospital stay (Table 2)

The mean hospital stay was 3.43 days (range, 1–34 days) in group 1 and 1.47 days (range, 1–3 days) in group 2. The lone patient who experienced severe wound infection and necrosis requiring hospitalization for 34 days was in group 1 and 1.47 days (range, 1–3 days) in group 2. The difference between the two groups was highly significant statistically ($p < 0.007$).

Follow-up evaluation

The mean follow-up period was 12.97 months (range, 8–30 months) for group 1 and 13.73 months (range, 8–29 months) for group 2. Five patients in group 1 and

Table 1. Operative characteristics

Variable	Group 1	Group 2	<i>p</i> Value
Size of defect (cm ²)	42.12	65.66	0.446
Range (cm ²)	1–670	1–875	
No. of defects	1.3	1.4	0.774
Range	1–6	1–6	
Contents			
Omentum	23	20	
Bowel	1	0	
Omentum & bowel	1	4	
None	8	9	
Size of mesh (cm ²)	152.67	203.83	0.176
Range	9–625	21–935	
Requirement for suction drainage	19	1 (2 days)	
Mean duration of suction drainage: days (range)	3.52 (1–16)		
Intraoperative complications	0	0	
Operative time (min)	86.0	75.0	0.371
Range	30–150	25–245	
Blood loss (ml)	127.0	28.5	0.001
Range	5–500	5–100	
Conversion	—	0	

four patients in group 2 were lost to follow-up evaluation after 1 month.

Recurrence (Table 2)

Patients were examined for evidence of recurrence both lying down and standing. The seromas and the bulge of the mesh were confusing and mistaken for recurrence in group 2 patients. However, ultrasonography or computed tomography (CT) scan was performed in doubtful cases. There was one recurrence in the group 1 and two recurrences in group 2. The one recurrence in the open group (group 1) was detected by the patient herself at 6 months. One of the two recurrences in the laparoscopic group was detected at 14 months when the patient came for the follow-up visit. The other recurrence in group 2 was detected on a CT scan performed for evaluation of a renal cyst. The operative details for both of these recurrence cases in group 2 were reviewed. It was noted that the defects in both of these patients were in the lower abdomen, and that the mesh fixation was not adequate because the defects were very close to the inguinal ligament.

Discussion

Laparoscopic incisional and primary ventral hernia repair is steadily being accepted as a better alternative both by surgeons and patients. It is believed that laparoscopic repair is less painful and cosmetically superior, with a better outcome in terms of reduced hospital stay and total avoidance of recurrence and wound complications [13, 16, 18, 21]. However, a paucity of level 1 evidence makes it imperative that randomized controlled trials be conducted to assess the real benefits offered by minimal access repair of incisional and primary ventral hernia.

The prime etiology of incisional hernias in our study followed lower abdominal gynecologic operations in

Table 2. Postoperative complications and hospital stay

Complication	Group 1	Group 2	<i>p</i> Value
Superficial wound infection	9	2 (10-mm port)	
Deep wound infection	1	0	
Mesh infection	1	0	
Flap necrosis	1	0	
Postoperative ileus	0	0	
Urinary retention	1	1	
Seroma	1	4	
Total	14	7	0.058
Hospital stay in days			
Mean	3.43	1.47	0.007
Range	1–34	1–3	
Recurrence	1/30	2/32	0.954
%	3.33	6.25	

both the groups, as compared with upper and central abdominal incisions after aortic, gastric, and colonic surgery in the West [5, 21]. The overall female-to-male ratio in the current study was 2.3 to 1.

The operative time has been one of the important determinants in assessing the effectiveness of an operative procedure. It is generally accepted that it takes longer to perform laparoscopic incisional and ventral hernia repair [13, 26, 28]. In the current study, laparoscopic repair could be accomplished in less time than open repair, although the difference was not statistically significant. This was possible because of the surgical team's experience, a standardized technique, and the predominant use of tacks for fixation of the mesh.

Laparoscopic incisional and primary ventral hernia repair was associated with significantly less blood loss ($p = 0.001$) than open repair, although none of the patients in either group 2 or group 1 required blood transfusion.

There is scant information on pain after hernia repair. DeMaria et al. [15] and Raftopoulos et al. [29] in their series reported reduced postoperative pain after laparoscopic repair. It is generally believed that laparoscopic surgery results in less postoperative pain. However, in the current study, there was no statistically

Table 3. Incisional hernia and index operation

Index operation	Group 1	Group 2
Gastrointestinal operation	5	1
Obstetric (LSCS) & other gynecologic operations (lower midline incision)	15	15
Cholecystectomy through Right subcostal incision	1	1
Upper midline incision	0	1
Appendectomy incision	1	1
Others ^a	0	2

LSCS, lower segment cesarean section

^a 1 = suprapubic cystostomy; 1 = left pyelolithotomy**Table 4.** Recurrent hernia

No. of previous repairs	Group 1	Group 2
Hernia for first repair	24	24
Hernia for second time repair	7	5
Hernia for third time repair	2	3
Hernia for fourth time repair	—	1

Table 5. Location of hernia defect

Location	Group 1	Group 2
Upper midline	6	5
Umbilicus	8	9
Lower midline	17	16
Right subcostal	1	1
Right iliac fossa	1	1
Left lumbar	0	1

Table 6. Postoperative pain

Variable	Group 1	Group 2	<i>p</i> Value
VAS score on day 1	6.05	5.95	0.857
VAS score on day 2	4.43	4.75	
VAS score on day 3	2.16	2.33	
Chronic pain at 3 months	3	6	
Chronic pain at 6 months	2	2	
Chronic pain at 12 months	1	1	
Oral analgesic doses in first 3 days	5.47	5.00	0.104
Injection analgesic doses in first 3 days	3.77	3.50	0.333

VAS, visual analog scale

significant difference in the pain scores or analgesic requirements during the immediate postoperative phase between the two groups, although analgesic requirements decreased rapidly, with improved pain scores in group 2 (laparoscopic) beyond 24 h postoperatively. The lack of a difference in the first 24 h may be attributable to the use of multiple tackers. Even then, the majority of the patients in group 2 could be discharged from the hospital on postoperative day 1 or 2. Subjectively, most of the patients in group 2 were more comfortable and tolerated oral intake earlier than the patients in group 1. They also were ambulatory and willing to go home early. In contrast, the group 1 pa-

Table 7. Patient satisfaction

	Open repair	Lap repair	<i>p</i> Value
Patient satisfaction	7.60	8.27	0.259

Lap, laparoscopic

Table 8. Cost (Indian rupees)

	Open repair	Lap repair	<i>p</i> Value
Cost	1,536.66	13,786.90	0.01
SD	1,062.53	6,792	

Lap, laparoscopic; SD, standard deviation

tients stayed in the hospital significantly longer ($p = 0.007$) because of pain and the presence of drains.

The incidence of long-term chronic pain after laparoscopic repair is reportedly 3% to 4.5% [16, 17, 21, 32]. Up to 3 months postoperatively, 10% of the group 1 patients and 20% of the group 2 patients in the current study reported significant pain, but all except one were pain free at 1 year. One patient kept reporting pain at the subcostal scar from the previous open cholecystectomy. The higher incidence of postoperative pain was noted even in the absence of transabdominal fixation sutures. The pain was poorly characterized and not suggestive of nerve entrapment. The exact cause of this pain could not be ascertained. It could have been attributable to an inflammatory and fibrous tissue response to the polypropylene mesh.

The major disadvantage of conventional incisional and primary ventral hernia repair has been wound-related complications. This is the most compelling argument in favor of laparoscopic repair. The wound-related complications include wound hematoma, infection, dehiscence, necrosis, chronic sinus, seroma, and long-term chronic pain. The incidence of wound-related complications from open mesh repair reportedly ranges from 3.5% to 18% (average, 8.1%) [2, 4, 7, 8, 14, 19, 24, 25, 28, 35–37, 40], whereas for laparoscopic repair, its reported overall incidence is 2% [12, 16, 17, 30–32].

In the current study, there were 36% wound-related complications in group 1 (open), as compared with 6.6% in the group 2 (laparoscopic). The difference is statistically significant ($p = 0.058$). Most of the wound infections in group 1 were superficial, but nevertheless required a course of antibiotics for skin pathogen. In group 1, there was one patient with major wound infection, dehiscence, and necrosis requiring readmission. We were able to treat the patient using debridement and dressings without the need for mesh removal. None of the patients in group 2 experienced serious complication requiring rehospitalization.

Seroma formation has been one of the most commonly reported postoperative complications after laparoscopic incisional and primary ventral hernia repair. The incidence of seroma varies from 1% to 14% in different reported series [3, 8, 9, 10, 11, 12, 16, 17, 30–33]. In our study, seroma developed in 13.3% of the patients.

However, seroma did not contribute much to the morbidity and resolved without intervention for most patients. For some patients, percutaneous needle aspiration was required once or twice. Seromas are known to develop after open repair as well, and its incidence is unaffected by the use of suction drainage [6]. We believe it was possible in the current study to prevent seroma formation by keeping a pack of gauze over the defect and applying pressure dressing with adhesive tape, leaving it for 2 weeks.

A 4% recurrence rate after open retrorectus repair (group 1) was quite acceptable, as compared with the rates in published series [27, 34, 38]. There were two recurrences (7.4%) in group 2. The difference was not statistically significant. One of the recurrences involved a patient with incisional hernia after an abdominal hysterectomy through a Pfannenstiel incision. The defect was located quite low, and there was inadequate space for fixation of mesh at the lower margins of the mesh, which contributed to the recurrence. The patient was admitted for relaparoscopic surgery. The mesh was found to be detached along the lower margin, leading to recurrent hernia. The same patient had another defect on the left side of midline, which probably was missed at the first laparoscopic operation.

Additional defects are not as likely to be missed during laparoscopic repair, but it is possible if the defect is hidden behind the telescope. It may have happened in our case because the telescope was coming from the left side, and the defect did not come into telescopic view. We have made it a routine practice to put the telescope through another port to view the abdomen comprehensively so that such clinically nonapparent lateral defects are not missed. It also is important to realize that new weak areas keep manifesting as new defects along the incision line, so it is advisable to cover the entire incision that contains the hernia rather than only the actual defect [21]. It is possible that after the obvious defect has been plugged, the raised intraabdominal pressure will try to push abdominal contents through other weak areas along the incision not covered with mesh.

To avoid recurrence, we have modified the technique for lower abdominal incisional hernias. It is important to expose Cooper's ligament as well as the ileopubic tract anatomy, and then to fix the mesh with Cooper's ligament whenever it is technically feasible.

One major problem during laparoscopic incisional and ventral hernia repair is mesh insertion into the abdominal cavity through the 10-mm trocar sleeve, particularly if the size of the mesh exceeds 15 × 15 cm for larger defects. We make a skin incision at the center of the defect, push the mesh (kept in a plastic bag to avoid contact with the skin) inside, close the skin with 3–0 monofilament suture, and continue the remainder of the procedure laparoscopically.

The group 2 patients scored better (despite higher cost per procedure - Table 8) than the group 1 patients on overall satisfaction, although the difference was not statistically significant (Table 7). This was because of overall fewer postoperative complications and better cosmetic outcome after laparoscopic repair. Therefore,

reduced postoperative morbidity, operative time, blood loss, and hospital stay as well as advantages in terms of superior cosmesis, avoidance of drains, and ability to perform the procedure in obese patients and in multiply scarred abdomens have led to wide acceptance for laparoscopic repair, which is fast becoming the standard approach for the surgical repair of incisional, primary ventral, and recurrent ventral hernias. However, laparoscopic incisional and ventral hernia repair is considered an advanced laparoscopic procedure that should be performed only after adequate training and experience.

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