Hernia (2002) 6: 182–187
DOI 10.1007/s10029-002-0083-z

ORIGINAL ARTICLE

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Laparoscopic ventral hernia repair during the learning curve

Received: 24 May 2002 / Accepted: 12 August 2002 / Published online: 1 October 2002
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Abstract Large series of laparoscopic ventral hernia repair have shown excellent results. However, published comparative studies have had conflicting outcomes. We retrospectively reviewed the first 29 laparoscopic ventral hernia repairs performed at a VA Medical Center from January 2000 to June 2001. The outcome was compared to that of open repairs performed during the same time period. Outcomes between the groups were similar in all respects, except for the length of stay. The conversion rate for the laparoscopic approach was 13.8%. There was one death in the laparoscopic group due to an unrecognized enterotomy. There were three recurrences in the open group and one in the laparoscopic group with a mean follow up of 13 months. In our series, laparoscopic hernia repair resulted in a shorter hospital stay but no other significant benefits, along with a risk of missed enterotomy. The risk-benefit ratio for this procedure may be high during the learning curve.

Keywords Ventral Hernia · Incisional Hernia · Laparoscopic Surgery · Clinical Trial

Introduction

The first laparoscopic ventral hernia repair was reported in 1992 [15]. Although the feasibility of laparoscopic incisional herniorrhaphy has since been clearly demonstrated, its advantages over the open technique are still unproven. Open prosthetic repairs require large incisions, wide fascial dissection and subcutaneous flap creation, thus still involving a high morbidity in the form of prolonged postoperative pain, wound infection, seroma formation, and frequently a long hospital stay related to postoperative ileus [24]. Stoppa, for example, reported an infection rate of 12% in a series of 466 open incisional hernia repairs [20]. Many large case series of laparoscopic ventral and incisional hernia repairs, each including 100 or more patients, have been published and are summarized in Table 1. They all show a 0–7% conversion rate, a low morbidity, and no mortality. However, there have been very few comparative studies (Table 2) between these two repairs, and the results are conflicting. Although a few of these studies were unable to demonstrate a significant advantage to laparoscopic ventral hernia repair in terms of patient-centered outcomes, such as morbidity and hospital stay [4, 24], none of them showed a worse outcome. Laparoscopy seems to be at least equivalent to the open repair. In fact, in many other studies [3, 6, 12, 17, 18], including the only prospective randomized study published to date by Carbajo et al., laparoscopic ventral hernia repair resulted in a significantly shorter postoperative stay and fewer complications. Our present study demonstrated a statistically significant decrease in length of hospitalization with the laparoscopic approach. However, equivalent results were obtained with both repairs in terms of operating time, blood loss, ileus, wound infection, seroma, and overall morbidity in the hands of surgeons early in their laparoscopic repair experience. This may be related to the learning curve, although it is consistent with the findings of some of the studies referred to earlier.

Effective surgical therapy for ventral and incisional hernias remains problematic. Laparoscopic ventral hernia repair is currently gaining wider acceptance as an alternative to the different open repairs with low perioperative complication rates, short hospital stays, and few recurrences ranging from 1.1 to 9.3% as shown by

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Table 1. Published case series of 100 or more patients

	Patients	Conversion	Complications	Mortality	Recurrence	Follow-up (months)
Franklin (1998) [7]	176	0%	5.1%	0%	1.1%	1–84
Toy (1998) [22]	144	–	22.2%	0%	4.1%	7.4
Carbajo (2000) [2]	100	1%	Minor 15% Major 1%	0%	2%	30
Heniford (2000) [9]	100	0%	Minor 12% Major 2%	0%	3%	22.5
Heniford (2002) [8]	415	1.9%	13%	0%	3.4%	23
Chowbey (2000) [5]	202	–	18–32%	0%	1%	34.8
LeBlanc (2001) [14]	100	4%	Major 4.1%	0%	9.3%	51
Ben-Haim (2002) [1]	100	7%	Minor 18% Major 6%	0%	2%	19

Table 2. Comparative studies published to date between laparoscopic ventral hernia repair (LHR) and open ventral hernia repair (OHR)

	Study Design	Patients	Follow-up (months)	Conclusion
Holzman (1997) [12]	Retrospective	21 LHR 16 OHR	18.8–20	LHR had longer operative time but statistically shorter postoperative stays and costs. Similar postoperative morbidity and recurrence
Park A (1998) [17]	Retrospective	56 LHR 49 OHR	–	LHR had longer operative time but had fewer perioperative complications and a shorter hospital stay [a]
Carbajo (1999) [3]	Prospective randomized	30 LHR 30 OHR	27	LHR presented significantly lower surgery time, hospitalization time, postoperative and longer-term complications and recurrence
Ramshaw (1999) [18]	Retrospective	79 LHR 174 OHR	21	LHR had shorter operative time, shorter hospital stay, fewer complications, and lower recurrence rate
Chari (2000) [4]	Retrospective (Case-controlled study)	14 LHR 14 OHR	6–24	No statistical difference in blood loss, hospital days, days to oral intake, or complications. LHR took 40% longer. No mortality or early recurrences in either group
DeMaria (2000) [6]	Prospective	21 LHR 18 OHR	–	LHR had decreased hospitalization, postoperative pain, overall cost, and disability [a]
Robbins (2001) [18]	Retrospective	36 LHR 18 OHR	–	LHR had decreased rate of major wound complications [a]
Wright (2002) [24]	Retrospective	86 LHR 209 OHR [b]	24–32	No significant advantage to LHR. Similar recurrence rate between LHR and OHR with mesh

[a] A meaningful comparison of recurrence rates in the two groups was not made
[b] Two separate groups: 90 OHR with mesh and 119 OHR without mesh

reports of large case series [2, 7, 9, 10, 14]. There have not been any multicenter prospective studies to validate these findings, and it is unclear whether these results are only achieved by surgeons highly experienced in advanced laparoscopic surgery or if they are in the reach of every general surgeon. In fact, the few published comparative studies have had conflicting results with some unable to demonstrate a significant advantage to laparoscopic ventral hernia repair [4, 24], while others showed some clear advantages over the open techniques [3, 6, 12, 17, 18]. With this in mind, we retrospectively reviewed the results of laparoscopic ventral hernia repair performed by general surgeons during their learning curve and compared them to those of open ventral hernia repairs performed by the same surgeons during the same period of time.

Material and methods

We retrospectively reviewed the charts of all patients having undergone laparoscopic as well as open ventral hernia repair proce-

dures at the Houston Veterans Affairs Medical Center starting from the date the first laparoscopic repair was performed. The procedures were identified by their ICD-9 codes. The study period extended from January 2000 to June 2001. Umbilical hernias were excluded from the study as well as incarcerated and strangulated ventral hernias. Four attending general surgeons, supervising the different senior general surgery residents rotating at the VA Hospital at the time, performed all procedures. Open procedures included primary repairs as well as various mesh repairs, according to the surgeon's judgment and preference. Laparoscopic repairs were performed using expanded polytetrafluoroethylene (ePTFE) mesh (Dualmesh; W.L. Gore, Flagstaff, Ariz., USA) with a minimum of 3-cm overlap circumferentially with normal fascia and secured with spiral tacks and transfascial sutures every 5 cm. Patient demographic characteristics and clinical data were recorded including age, gender, Body Mass Index (BMI), American Society of Anesthesiologists (ASA) class, comorbidities, preoperative serum albumin level as well as the hernia type (primary or recurrent), its size, and the history and technique of previous repairs. The operative details studied included the operative technique, the use of mesh and its type and size, the use of drains, the operative time, the estimated blood loss (EBL), and any intraoperative complications and their management. Postoperative complications, length of hospital stay, and recurrence at follow-up were also noted. An appropriate Internal Review Board approved the study.

Statistical analysis

Data are reported as mean ± the standard deviation or as percentages. Analysis was conducted using the Statistical Analysis System program (SAS v6.12, Cary, N.C., USA). Categorical variables were analyzed by Chi square analysis or 2-sided Fisher exact test when appropriate. Continuous variables were analyzed by student's *t*-test methodology. The analysis was considered significant at a *P*-value of ≤ 0.05.

Results

The study included 31 open repairs and 29 laparoscopic repairs. The two groups (Table 3) were identical as far as age (average 55.1 vs 56.9), gender (male 97% vs 93%), comorbidities, ASA class, and BMI (29.7 ± 4.9 vs 29.7 ± 5.3). The preoperative albumin (3.49 ± 0.71 v/s 3.64 ± 0.41) was statistically lower in the open group ($P = 0.01$). The fascial defects varied in size from a single 9 cm^2 defect to a very large 432 cm^2 defect and "Swiss-cheese" type defects. Of all the hernias, 16.6% were recurrent hernias following one or two previous repairs with 20% of them having required a mesh; there was no difference in the types of hernias between the two groups. The open repairs were done by primary closure in 46% or by using polypropylene mesh (11%) or ePTFE mesh (43%). The mean operative time was 110 ± 76 minutes in the open group and 173 ± 95 minutes in the laparoscopic group (including converted cases), but the difference was not statistically significant. The difference between the blood loss in the open group (63.3 ± 93.4 cc) and in the laparoscopic group including converted cases (39.4 ± 67.8 cc) was not statistically significant.

The conversion rate from laparoscopic to open approach one was 13.8% or four cases, three of them due to dense adhesions and one of them secondary to recognized enterotomies. The outcome data analysis for the converted cases was included with the open group data (Table 4). The morbidity was 37.1% for the open/converted cases and 32% for the laparoscopic cases, which was not statistically significant ($P = 0.68$). The complications included seroma, wound infection, urinary retention, urinary tract infection, pancreatitis, and others. One patient in the open arm had multiple readmissions for small bowel obstruction that eventually required re-exploration for lysis of adhesions. The incidence of seromas appeared higher in the laparoscopic group (12% vs 5.7%), but the difference was not statistically significant. The presence of a drain did not change the incidence of postoperative seromas in the open group. All seromas spontaneously resolved at follow-up. Two patients in the laparoscopic repair arm developed wound and mesh infections requiring removal of the ePTFE mesh. Seven patients developed wound infections in the open repair arm; however, only one of them required mesh removal. The mean hospital stay was 2.8 days in the open cases and 2.3 days in the laparoscopic cases, which was highly significant ($P < 0.01$).

There was one death in the laparoscopic group due to a missed enterotomy. The patient developed overwhelming sepsis despite open re-exploration within 10 h of the procedure. There were no deaths in the open group.

The mean follow-up was 13 months with a range of 9 to 28 months; two patients were lost to follow-up. There

Table 3. Demographic and preoperative clinical data in open and laparoscopic ventral hernia repair arms. BMI = body mass index; ASA = American Society of Anesthesiologists class

		Open ($n = 31$)	Laparoscopic ($n = 29$)	*P* value
Age		55.1 ± 9.1	56.9 ± 8.8	0.87
Sex: Male		97%	93%	0.51
BMI		29.7 ± 4.9 (21–39)	29.7 ± 5.3 (18–40)	0.67
ASA	I	6.5% (2)	3.5% (1)	1.00[a]
	II	41.9% (13)	38.0% (11)	0.80
	III	41.9% (13)	55.2% (16)	0.44
	IV	9.7% (3)	3.5% (1)	0.61[a]
Albumin		3.49 ± 0.71 (1.6–4.3)	3.64 ± 0.41(3.0–4.7)	**0.01**
Comorbidities		64.5%	72.4%	0.51
Smoking		35.5%	48.3%	0.32
Alcoholism		9.7%	6.9%	1.00[a]
Recurrent		9.7%	3.5%	1.00[a]

[a]Fisher Exact (2-sided)

Table 4. Outcome of open and converted vs laparoscopic ventral hernia repairs

	Open/Conversion ($n=35$)	Laparoscopic ($n=25$)	P value
Ileus over 24 h	17.1% (6/35)	20% (5/25)	0.78
Complications	37.1% (13/35)	32% (8/25)	0.68
Seroma	5.7% (2/35)	12% (3/25)	0.64 [a]
Wound infection	20% (7/35)	8% (2/25)	0.28 [a]
Mesh removal	2.8% (1/35)	8% (2/25)	0.57 [a]
Urinary retention	2.8% (1/35)	8% (2/25)	0.57 [a]
Other	8.5% (3/35)	8% (2/25)	1.00 [a]
Mortality	0% (0/35)	4% (1/25)	0.42 [a]
Length of stay	2.8 ± 3.3 (0–15)	2.3 ± 1.5 (1–5)	< 0.01
Recurrence	8.5% (3/35)	4% (1/25)	0.63 [a]

[a] Fisher Exact Test (2-sided)

were three recurrences in the open group (8.5%), two following primary repair and one following mesh repair; there was one recurrence in the laparoscopic group (4%).

Discussion

Some specific complications of the laparoscopic approach need to be addressed. The first complication is the seroma formation. In our series, the incidence of seroma was 12%; this was not significantly higher than the incidence in the open group. We did, however, use abdominal binders after the laparoscopic repairs in many of the patients, and this may have contributed to these findings. In fact, in a prospective study [21] examining the true incidence of seroma formation after laparoscopic repair of incisional hernia with PTFE patch in 20 patients, seroma was diagnosed clinically in 35% of cases, while ultrasound examination revealed the presence of seroma in 100% of patients. Cauterization of the hernia sac may prevent seromas [23], but this is time-consuming and rarely performed, since seromas usually resolve spontaneously without complications. We did encounter two seromas (5.7%) in the open repair group; they seemed to be independent of the type of mesh used (one polypropylene and one PTFE) and of the use of drains (one with drain and one without drain).

Wound-related complications, mainly wound infections, seem to be reduced with the laparoscopic approach. In our series, we encountered an incidence of 20% wound infection in our open hernia repairs ranging from cellulitis to more severe infections requiring mesh removal. This was, however, not statistically different than the wound infection rate in the laparoscopic group (8%). Wright et al. [24], in their retrospective comparative study of open and laparoscopic repairs, had an overall greater postoperative complication rate in the open group with mesh, yet when specific wound complications were analyzed, there was no difference between the groups. Not all comparative studies had these findings. In a study by Robbins et al. [19] looking specifically at this complication, 28 and 16 percent of patients undergoing open and successful laparoscopic repairs respectively had wound complications. However, only 3 percent of patients undergoing laparoscopic repair had a major wound complication as compared with 22 percent of patients undergoing open herniorrhaphy.

Mesh infection requiring mesh excision is uncommon, yet remains a risk with any mesh hernioplasty, whether open or laparoscopic. It is felt, however, that the risk of mesh infection from cutaneous pathogens is lower in the laparoscopic group due to the distance between the actual incisions and the prosthesis. Although this may be true, it seems that wound infection after laparoscopic repairs, especially when PTFE material is used, more frequently results in seeding of the mesh. In fact, both our patients with wound infection after laparoscopic repairs developed mesh infection and had to have the mesh removed. In addition, although we did not encounter it in our series, inadequate sterile technique during aspiration of persistent seromas complicating laparoscopic repairs introduces a high risk of mesh infection.

The most serious complication, somewhat unique to laparoscopic ventral hernia repairs, remains the potentially devastating risk of a missed enterotomy. In one of our patients, this occurred and led to overwhelming sepsis and death despite reoperation. Wright el al. [24] report two bowel injuries not discovered until the respective patients developed abdominal sepsis; this resulted in removal of the mesh, multiple returns to the operating room, prolonged hospital stay, and death in one patient. Many other comparative studies and case series have reported this complication, which unavoidably resulted in a protracted postoperative course [1, 3, 9, 13, 18]. This complication seems to be more common early in the learning curve in patients requiring extensive adhesiolysis. In one study of a surgeon's first 100 cases [1], four out of six inadvertent enterotomies occurred in the first 25 cases. These bowel injuries, when unrecognized, can lead to a potentially disastrous outcome, and it only takes one such major complication to wipe out the potential benefits for the entire series. In a recent study, 67% of surgeons attending a 1-day course on laparoscopic ventral herniorrhaphy returned home and performed the procedure [8]. Less than half of these surgeons were precepted in their local hospitals. Since enterotomy appears to be more likely to occur in a surgeon's early experience, caution must be exercised in

rapidly adopting this new technique without proper training and supervision.

The primary outcome of interest in ventral hernia repair remains the recurrence rate, and this seems to be the area where the laparoscopic repair may have the most impact. Primary repairs are associated with a high recurrence rate ranging from 25% to 52% [9]. Open prosthetic repairs have reduced the recurrence to a still unacceptable rate of 24% [16]. Most published large series of laparoscopic ventral hernia repairs show a recurrence rate varying between 1 and 9.3% with a mean follow-up ranging from 20 to 51 months. These results are intuitively superior to the historic open herniorrhaphy data. Although three of the retrospective comparative studies that included a meaningful comparison of recurrences as well as our present study failed to show a statistically significant difference in recurrence rates, other studies, such as the study by Ramshaw et al. [18] did show fewer recurrences in the laparoscopic repair arm. Our follow-up averaged 13 months, which is not long enough to adequately detect all recurrences. Carbajo et al. [3] in a prospective randomized study showed a lower recurrence rate in the laparoscopic repairs with a follow-up of 27 months, which is an adequate follow-up. In fact, Hesselink et al. [11] showed that 45 percent of recurrences occur in the first year, 64 percent in the second year, and 78 percent of all recurrences occur within 3 years. A larger multicenter prospective randomized study with long-term follow-up of a minimum of 3 years is needed to show a clear advantage for the laparoscopic repair in reducing recurrence rates, while achieving equivalent or better outcomes for patient-centered measures than open repair. Such a study is currently underway at our institution.

As in any clinical study, our present report has flaws. Because it is a retrospective review there is an obvious selection bias. There was probably a tendency to perform traditional open repair for the larger more complex hernias and for small hernias. In addition, the lack of uniformity with respect to the open technique chosen decreases the strength of the data. Although some open hernia repairs were done without mesh based on the surgeon's judgment, these patients typically had small hernia defects. However, by including the surgeon's technique of choice, we feel that the open group adequately represents the current surgical practices for open incisional hernia repairs.

Conclusion

Laparoscopic hernia repair in the hands of surgeons in their learning curve results in a shorter hospital stay but no statistically significant difference in operating time, blood loss, morbidity, or recurrence. Although the laparoscopic technique of ventral hernia repair is conceptually straightforward, the lysis of adhesions requires special attention. The threat of a missed enterotomy is real in the early learning curve. It is potentially devastating and should be carefully watched for intraoperatively and immediately ruled out postoperatively in the event of any clinical deterioration. Proper training and advanced laparoscopic skills should be obtained before attempting this procedure. During the learning curve, mentoring by a surgeon experienced in this technique would be ideal. However, the average length of the learning curve is currently undefined.

Acknowledgements This work was supported by a grant from the Society of American Gastrointestinal Endoscopic Surgeons (SAGES).

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