

Open randomized clinical trial of laparoscopic versus open incisional hernia repair

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Abstract

Background Incisional hernia is a common complication following abdominal surgery. Although the use of prosthetics has decreased recurrence rates, the standard open approach is still unsatisfactory. Laparoscopic techniques are an attempt to provide similar outcomes with the advantages of minimally invasive surgery.

Methods Open randomized controlled clinical trial with follow-up at 1, 2, 3, 7, and 15 days, and 1, 3, and 12 months from hernia repair. The study was carried out in the surgery departments of three general hospitals of the Valencia Health Agency.

Objectives To compare laparoscopic with anterior open repair using health-related quality of life outcomes as main endpoints.

Results Eighty-four patients with incisional hernia were randomly allocated to an open group (OG) ($n = 39$) or to a laparoscopic group (LG) ($n = 45$). Seventy-four patients completed 1-year follow up. Mean length of stay and time to oral intake were similar between groups. Operative time was 32 min longer in the LG ($p < 0.001$). Conversion rate

was 11%. The local complication rate was superior in the LG (33.3% versus 5.2%) ($p < 0.001$). Recurrence rate at 1 year (7.9% versus 9.7%) was similar in the two groups. There were no significant differences in the pain scores or the EQ5D tariffs between the two groups during follow-up. **Conclusions** Laparoscopic incisional hernia repair does not seem to be a better procedure than the open anterior technique in terms of operative time, hospitalization, complications, pain or quality of life.

Keywords Incisional hernia · Laparoscopic repair · Open repair · Mesh repair · Quality of life · Complications

Incisional hernia (IH) is a common complication following abdominal surgery and is estimated to occur in approximately 11% of cases, and in up to 23% of those who develop wound infection [1]. In 2002, the ventral hernia repair rate in the Spanish National Health System was about 6.7 per 10,000 inhabitants, generating about 28,500 surgical procedures that year [2].

Although the use of prosthetics has decreased recurrence rates, the standard open approach to IH is still unsatisfactory and the use of biomaterials carries the risk of severe wound complications. The only randomized clinical trial (RCT) with reliable data on the outcomes of open IH repair reported a recurrence rate of 43% for sutured repair and 24% for mesh repair [3], and the incidence of wound complications may be greater than 40% [4].

Laparoscopic techniques for the treatment of IH are an attempt to provide similar outcomes as open repair with the advantages of minimally invasive surgery. The use of laparoscopy for the treatment of IH was first reported in 1993 by LeBlanc and Booth [5]. Although there are data suggesting that laparoscopic repair leads to a lower rate of

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complications and relapses and to a shorter hospitalization compared with open surgery [6–8] a paucity of level 1 evidence makes it imperative that RTCs be conducted to assess the real benefits of laparoscopy. A meta-analysis published in 2007 [9] identified only one randomized clinical trial (RCT) comparing the laparoscopic approach with conventional open surgery in ventral hernia repair [6]. No conclusive differences could be identified between the two operative techniques. To date, only four small RCTs [10–13] and the design of a larger one with longer follow-up [14], have been published.

Surgical treatment outcome has usually been measured by mortality and morbidity rates accompanying the operation. If the purpose of the intervention is to improve patient well-being, it is necessary to confirm that quality of life has actually been improved. Combining medical with patient-centered outcome measurements provides a rigorous evaluation of clinical practice [15]. Korolija et al., in their study about the use of quality-of-life (QoL) instruments in laparoscopic surgery, remark on the importance of evaluating this outcome, since it detects advantages not evaluated by other endpoints [16]. Nevertheless, with the exception of a recent small observational study (24 patients with laparoscopic surgery matched with 24 controls) [17], we were not able to find data evaluating this important outcome when comparing open and laparoscopic IH repairs.

The aim of this study was to compare laparoscopic with anterior-open IH repair, done in three public institutions using health-related quality-of-life outcomes as main endpoints.

Materials and methods

Study design

This was an open randomized controlled clinical trial with follow-up at 1, 2, 3, 7, and 15 days, and 1, 3, and 12 months from hernia repair.

Setting

The study was carried out in the surgery departments of three general hospitals of the Valencia Health Agency, a public healthcare network of the Valencia Government. The participating surgeons of the three teams had wide experience with both surgical approaches. A minimum of 20 laparoscopic hernia procedures was required.

Participants

A total of 87 patients scheduled for an elective IH repair were included in the study. Eligibility criteria were the

patients with age equal or greater than 18 years with IH between 5 and 15 cm in largest diameter without contraindication for laparoscopic surgery. Patients were randomly assigned to open (OG) or laparoscopic (LG) mesh repair. The exclusion criteria were: patients with any type of stoma, and nonresidents, due to expected difficulty in follow-up.

Surgical technique

All patients received the same preoperative regimen (antibiotic and heparin prophylaxis). Nasogastric tube was inserted in LG patients and removed at the end of the procedure.

Laparoscopic technique (LG)

All hernias were approached laterally, and the side of the abdomen farther from the hernia defect was used for placement of the ports. Pneumoperitoneum was established with Veress needle in the subcostal position. In some patients an open technique was performed. Three trocars were considered to be sufficient for most procedures. A 10-mm 30° laparoscope was inserted with Optiview 10-mm trocar (Ethicon). The camera port was inserted as laterally as possible. Under direct vision, two additional 5-mm trocars were placed laterally and used as working ports. All abdominal wall adhesions were divided. The abdominal wall defect was identified and measured extra-abdominally with spinal needles. Abdomen was desufflated to prevent overestimation of the hernia defect. Multiple orifices were measured as one, so that a single piece of mesh could be used to cover all the defects. A double-layer polypropylene–expanded polytetrafluoroethylene (ePTFE) mesh was chosen (Composix, Bard), allowing at least 3 cm overlap on all sides. Four stay sutures were attached at the four cardinal points of the mesh. The mesh was then placed into the peritoneal cavity via the 10-mm port or directly through the port site. The ePTFE side of the mesh was placed against the viscera, thus decreasing mesh visceral adhesion formation. The four previously placed sutures were brought up to the abdominal wall with the aid of a suture passer. The mesh was centered on the defect by stretching the anchoring sutures. The edge of the mesh was secured with spiral tacks in a double ring shape at 1- to 2-cm intervals. A minimum of four transabdominal absorbable sutures were inserted to help prevent mesh migration and tied in the subcutaneous tissue. No drains were used in LG patients.

Open technique (OG)

Standard polypropylene mesh was positioned as an inlay (i.e., under the rectal muscles, preperitoneally), as

described by Rives/Stopppa [18] or as an onlay over the external oblique fascia (i.e., subcutaneously), as preferred by the operating team. The mesh was fixed with absorbable stitches. Drains were usually placed. Twelve cases were done by the Rives/Stopppa technique and 27 with an onlay mesh.

At the end of each surgery, surgeons were to complete a questionnaire indicating technical aspects of the repair including size of the defect and size of the mesh as well as any incidences during surgery.

Postoperative instructions were the same for both groups, including standard fluids and analgesia (metamizol IV/8 h or equivalent dosage p.o. for 3 days). Patients were advised to wear an orthopedic binder for 4 weeks and to resume normal activities as tolerated.

During follow-up, patients were assessed for recurrence. If there was any question or doubt about the recurrence status, computed tomography was used. Patients were invited to fill in the EuroQol-5D questionnaires on every visit.

Main endpoint

Health status as self-evaluated on the visual analogue scale (VAS) of EuroQol-5D (EQ-5D) 1 week after operation was the main endpoint. The EQ-5D is a general health-related quality-of-life scale [19] with a validated Spanish version [20], that has been widely used, including for several surgical conditions. The EQ-5D identifies 132 possible health states based on five questions concerning mobility, self-care, usual activity, pain or discomfort, and anxiety or depression. Each item has three possible levels (0, 1 or 2) and *utilities* or societal valuations have been placed on each state through a sample of 2,124 persons, using time trade-off techniques to determine valuations (perfect health and death have utilities of 1 and 0, respectively). The EuroQol also contains a visual analogical scale (EQ-5D VAS) on which persons can rate their overall health state by placing a mark on a vertical scale which ranges from 0 (worst imaginable health state) to 100 (best imaginable health state). Because of its simplicity, the EuroQol is particularly useful and easy to administrate.

Secondary and tertiary endpoints

As secondary endpoints we used the self-evaluated health status items using the questionnaire of the EQ-5D at days 1, 2, 3, and 15, and at 1, 3, and 12 months after surgery. A VAS for pain measuring (from 0, no pain, to 100, worse imaginable pain); the EQ5D tariffs, a measure of health-related quality of life (HRQoL) from 0 to 1 (perfect HRQoL); and the pain question from the EQ5D (from 0 to 2) were also used as secondary endpoints. All were

measured at days 1, 2, 3, 7, and 15, and at 1, 3, and 12 months. As tertiary endpoints we used postoperative length of stay (in days), time from surgery to food intake (in days), operative time (in minutes), rate of local and general complications, and recurrence rate evaluated at 15 days, and at 1, 3, and 12 months after surgery. Conversion rate was also measured.

Other variables and definitions

Age, sex, body mass index (BMI), American Society of Anaesthesiology (ASA) score, some comorbidities (such as diabetes, chronic obstructive pulmonary disease or cancer), presence of anticoagulant treatment, time from previous surgery, and size of wall defect were also recorded.

Sample size and randomization

With an α error of 0.05, a power of 0.80, and a ratio between groups of 1:1, we estimated that 90 patients (45 in each group) were needed to detect a change in the main endpoint (self-evaluated health at day 7 in the EQ5D VAS) from 60 to 80 points, assuming a maximum standard deviation of 40 points. We had no references for EQ5D VAS scores or standard deviation in patients with IH repair surgery, so we fixed a control point at half of the study to re-evaluate the sample size if this parameter changed greatly from our assumptions. This sample was initially distributed as 30 patients for each participant hospital. Randomization was centrally generated in the Valencia School for Health Studies for 50 cases (25 per group) for each hospital. A closed envelope containing group allocation was opened just before surgery for each participating patient.

Ethics and Informed Consent.

The final protocol was approved by the Ethics Committees of the three participant hospitals. Informed written consent was obtained from all the patients before inclusion in the trial.

Analysis

We used Student's *t*-test or one-way analysis of variance (ANOVA) to compare continuous variables, and the test for difference of proportions to compare categorical variables as appropriate. In all cases 95% confidence intervals (CI95) were estimated. Analyses were carried out to compare differences between OG and LG in patient characteristics at baseline, operative findings, complications, recurrence rate, and health and quality-of-life measures. We analyzed data on an intention-to-treat basis, so

conversions remained in the laparoscopic original group. *p* values less than 0.05 (two-sided) were considered statistically significant, and no correction for multiple tests was made. All analyses were carried out using Stata[®] version 9 (StataCorp, College Station, TX, USA).

Results

Eighty-seven patients were recruited. Of these, three were finally excluded: two patients voluntarily left the study before intervention and one was excluded after intraoperative measurement of the defect (< 5 cm). The remaining 84 patients were randomly allocated to an open group (OG) (*n* = 39) or to a laparoscopic group (LG) (*n* = 45). Seventy-four patients completed 1-year follow-up (35 in OG and 39 in LG). Some missing data were encountered during evaluation. These cases include missing data at day 1 (*n* = 1; OG), day 2 (*n* = 1; LG), day 3 (*n* = 3; one in the OG and two in the LG), day 7 (*n* = 2; one in the OG, and one in the LG), day 15 (*n* = 1; LG), and month 3 (*n* = 1; LG).

At baseline (Table 1), there were no significant differences between the OG and LG in age, percentage of men, body mass index (BMI), ASA score, percentage of patients with diabetes, chronic obstructive pulmonary disease, cancer or anticoagulant treatment. Recurrences from previous hernia repair procedures accounted for 33.3% of the OG and 15.6% of the LG (*p* = 0.056). Time from previous surgery and hernia size were also similar in the two groups.

Mean length of stay and time to oral intake were similar between groups (Table 2). No patients required reoperation during hospitalization. There was no operative mortality or

deaths during follow-up. Operative time was 32 min longer in the LG (*p* < 0.001). There were no intraoperative complications in the OG, whereas three (6.66%) occurred in the LG: a colonic perforation (detected and repaired after conversion), technical difficulties with the laparoscopic equipment in another case, and parietal haemorrhage due to trocar placement in a third patient. Conversion to open repair was required in five patients (conversion rate 11.11%).

Local complication rate was superior in the LG (33.3% versus 5.2%) (*p* < 0.001). Except for a colonic fistula in the patient with bowel perforation, and a port-site hematoma, the other local complications were seromas of the unresected hernia sac, the majority of which did not require aspiration. No long-term complications caused by seromas were observed whether they were aspirated or not. No cases of wound infection were detected in either group.

Hernia recurrence rate at 15 days (0.0%), 1 month (2.6% OG versus 0.0% LG), 3 months (2.6% versus 2.2%), and 1 year (7.9% versus 9.7%) were similar in the two groups.

There were no significant differences in pain scores or EQ5D tariffs between the two groups during follow-up (Table 3). In the EQ5D VAS, the LG had worse scores during the first 2 days (*p* < 0.05), but they were not different in the rest of the follow-up period (Fig. 1).

Discussion

Incisional hernia can be repaired by an anterior approach, through direct sutures or mesh placement, or by a laparoscopic transperitoneal approach. Mesh can be used in

Table 1 Patient characteristics

	Open group (<i>n</i> = 39)		Laparosc. group (<i>n</i> = 45)		<i>p</i> value
	Mean or %	95CI	Mean or %	95CI	
Age (years)	60.55	56.48–64.63	58.02	54.02–62.02	0.375
Sex (men, %)	28.21	15.00–44.87	40.00	25.69–55.66	0.256
Body mass index (kg/(height in meters) ²)	30.61	29.03–32.19	31.35	29.71–32.99	0.517
ASA score	2.05	1.86–2.23	2.08	1.93–2.24	0.749
Diabetes (%)	10.25	0.73–19.78	6.67	0.62–13.95	0.552
COPD (%)	5.12	1.79–12.05	2.22	2.08–6.52	0.474
Cancer (%)	12.82	2.32–23.31	2.22	2.08–6.52	0.060
Anticoagulant treatment (%)	7.69	0.67–16.05	8.88	5.74–17.20	0.843
Relapsed hernia (%)	33.33	18.53–48.12	15.55	4.96–26.14	0.056
Time from previous surgery (years) ^a	8.31	5.83–10.80	9.75	6.28–13.21	0.509
Hernia diameter (cm) ^b	10.19	9.02–11.36	9.51	8.45–10.56	0.380

ASA American Society of Anesthesiologists score; 95CI, 95% confidence interval; COPD chronic obstructive pulmonary disease

^a One case with missing data in the laparoscopic group

^b One case with missing data in the open group

Table 2 Operative findings, complications and recurrence rate

	Open group (<i>n</i> = 39)		Laparosc. group (<i>n</i> = 45)		<i>p</i> value
	Mean or %	95CI	Mean or %	95CI	
Operative time (min)	70.00	62.94–77.05	101.88	91.68–112.08	<0.001
Midline hernia versus lateral (%)	89.74	80.22–99.26	84.44	73.85–95.03	0.472
Conversions (%)	–	–	11.11	1.56–20.65	–
Operative complications (%)	0.00	–	6.66	0.00–13.95	0.101
Local complications (%)	5.12	0.00–12.05	33.33	19.56–47.10	0.001
Time to oral intake (days) ^a	0.89	0.68–1.10	1.06	0.73–1.39	0.393
Mortality rate at 30 days	0.00	–	0.00	–	–
Total LOS (days)	3.33	2.76–3.90	3.46	2.68–4.25	0.787
Recurrence 15 days (%)	0.00	–	0.00	–	–
Recurrence at 1 month (%)	2.56	0.00–7.52	0.00	–	0.285
Recurrence at 3 months (%)	2.56	0.00–7.52	2.22	0.00–6.52	0.918
Recurrence at 1 year (%) ^b	7.89	0.00–16.46	9.75	0.67–18.83	0.771

LOS length of stay; 95CI 95% confidence interval

^a One case with missing data in the laparoscopic group

^b One case with missing data in the open group and four in the laparoscopic group

Table 3 Health, pain, and health-related quality of life

		Open group (<i>n</i> = 39)		Laparosc. group (<i>n</i> = 45)		<i>p</i> value
		Mean	95CI	Mean	95CI	
Health (visual analogue scale EuroQol) 0–100	Day 1	60.78	55.99–65.58	49.67	44.11–55.21	0.003
	Day 2	69.69	64.56–74.81	62.25	56.83–67.66	0.048
	Day 3	74.18	69.17–79.19	69.18	63.25–75.12	0.203
	Day 7	76.76	71.91–81.61	74.70	69.56–79.84	0.561
	Day 15	80.33	74.96–85.70	82.90	78.41–87.40	0.456
	1 month	84.53	79.44–89.63	83.88	78.80–88.97	0.856
	3 months	86.78	81.05–92.52	86.84	81.98–91.70	0.988
	1 year	89.82	84.85–94.79	89.10	83.44–94.76	0.847
Pain (analogue visual scale) 100–0	Day 1	42.86	36.02–49.70	47.66	41.72–53.61	0.285
	Day 2	30.56	24.25–36.87	36.68	30.57–42.79	0.163
	Day 3	26.02	19.27–32.77	31.30	24.66–37.93	0.264
	Day 7	22.55	15.30–29.79	28.93	21.92–35.93	0.205
	Day 15	19.53	13.55–25.51	20.52	14.75–26.29	0.811
	1 month	10.43	5.70–15.17	17.48	11.52–23.45	0.071
	3 months	7.10	3.25–10.95	13.51	8.30–18.72	0.056
	1 year	6.00	1.98–10.01	10.38	4.93–15.83	0.201
Quality of life (EuroQol ET) 0–1	Day 1	0.1682	0.0397–0.2966	0.1136	–0.0054 to 0.2326	0.530
	Day 2	0.4977	0.3713–0.6241	0.4652	–0.3439 to 0.5864	0.708
	Day 3	0.5661	0.4661–0.6661	0.5874	0.4635–0.7113	0.791
	Day 7	0.7496	0.6657–0.8334	0.7002	0.5995–0.8009	0.457
	Day 15	0.8089	0.7264–0.8914	0.8139	0.7531–0.8746	0.921
	1 month	0.9536	0.9328–0.9744	0.9004	0.8445–0.9564	0.093
	3 months	0.9805	0.9648–0.9962	0.9218	0.8598–0.9838	0.090
	1 year	0.9767	0.9594–0.9939	0.9318	0.8808–0.9827	0.110

95CI 95% confidence interval. Cases with missing data: day 1 (one in open group), day 2 (one in laparoscopic group), day 3 (one in open group, two in laparoscopic group), day 7 (one in open group, one in laparoscopic group), day 15 (one laparoscopic group), 3 months (one laparoscopic group), 1 year (four in open group, six in laparoscopic group)

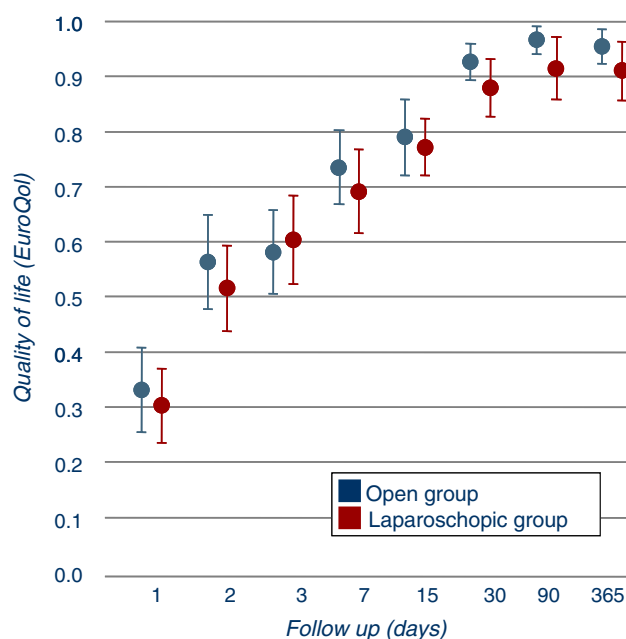


Fig. 1 Quality-of-life scores (EuroQoL visual analogue scale) during follow-up (mean and 95% confidence intervals)

several ways. It can be used as an onlay graft, or it may be placed in the subfascial extraperitoneal space or as an intraperitoneal onlay (IPOM). In addition, multiple types of synthetic mesh are available, being polypropylene and expanded polytetrafluoroethylene (ePTFE) the most widely used. Reports of enterocutaneous fistulae with polypropylene meshes have limited their use to the extraperitoneal space, while PTFE, due to its versatility, minimal foreign-body response, and lack of association with enterocutaneous fistulae, is the mesh of choice for intraperitoneal positioning [21, 22].

The lowest reported rates of recurrence after ventral and IH repairs (4–18%) have been with the retrorectus position (Stoppa technique), intra- or extraperitoneally or with the mesh sutured to the patient's tissues as an onlay [22–24]. Thus, these are the open techniques against which laparoscopic repair should be compared.

Laparoscopy is accepted as a more rational technique for repair of a ventral or IH than for repair of an inguinal hernia because an abdominal procedure and general anesthetic are requirements, whether open or laparoscopic [14]. Laparoscopic use of prosthetic materials for repair of incisional hernias has been practised for over a decade with good results. However, randomized controlled trials with long-term follow-up are lacking, and it is still debated which of the two approaches is the better treatment. In addition, many technical aspects of the procedure remain controversial and have not been standardized. The optimal type, size, and method of mesh fixation have not been established. A composite mesh provides the relative

adhesion barrier of ePTFE, and the rigidity and incorporation of polypropylene. The size of mesh chosen for laparoscopic repair is important to achieve substantial overlap of the defect in the event of mesh shrinkage or migration. Many authors believe that a prosthetic overlap of more than 3 cm from the edge of the hernia orifice is needed [5, 25, 26]. A combined fixation technique that includes both tacks and transfascial sutures is commonly used. Sutures provide reliable full-thickness abdominal wall fixation. Poor fixation of the mesh will ultimately lead to recurrence as the mesh migrates into the defect. Conversely, sutures can cause prolonged postoperative pain, limiting mobility [27]. Carbajo et al. [28] obtained a recurrence rate of 12% with the double-crown technique, but other series have attributed early failures to insufficient tack fixation alone [14]. In our series the fixation method was the combined one.

Operative time has been shown to be longer with the laparoscopic approach [1, 29] even if a recent meta-analysis found no statistically significant difference in operative times between the laparoscopic and open groups [9]. Our experience also shows longer operative time in the laparoscopic group. Reduction in hospitalization as has been reported by other authors [28, 30, 31]. Mean hospitalization was similar for LG patients (2.7 days) and for OG patients (9.9 days) in our study. No drains were placed in LG patients. This is one of the main advantages of laparoscopy. In fact drains are often a source of infection and the open procedure requires subcutaneous drainage placement [10].

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 ranges from 3.5% to 18%, whereas for laparoscopic repair the reported overall incidence is 2% [32–37]. The high complication rate associated with open anterior repair seems to be due to extensive lateral dissection and subcutaneous drainage placement, which increase infection rate. Infection is one of the major risks in the development of recurrent incisional hernias. Laparoscopic IH repair is thought to be a better approach because it does not require extensive dissection of subcutaneous tissue and postoperative drainage. The risk of wound infection should be lower, as much as the overall complication rate. On the other hand, infection occurring at the laparoscopy trocar site is self-limited [14]. The local complication rate in our cases was higher in LG patients than in OG patients. No major complications occurred in OG patients, whereas there was one serious complication among the patients in LG. No cases of wound infection were reported in either group. This is a surprisingly good result that can only be attributed to chance. Other authors have also reported a

zero infection rate after the laparoscopic procedure [34, 38]. Retained hernia sacs cause unavoidable seromas after laparoscopic repair. In the study of ultrasonographic examinations of ventral hernias by Berger et al. most of the patients developed seromas postoperatively (139 of 150 cases) [38]. Birch et al. [27] identified an incidence of postoperative seromas of 78% 3 weeks after surgery. In our series, postoperative seromas were identified in one-third of LG patients. None of these patients required reoperation because of the presence of pain or infection. Most surgeons, including us, report postoperative seromas but because they are often asymptomatic they should not be considered complications unless symptomatic or not self-resolving after 4–6 weeks postoperatively [13, 29]. The implications of a conservative versus an aggressive approach to seroma remains to be established. We evacuate only persistent seromas or symptomatic ones. To prevent seroma/hematoma formation we use a pressure dressing with a binder after the repair as others have advocated [13].

An editorial comment [39] called attention to the fact that none of the published studies adequately addresses the differences in postoperative pain. Because less postoperative pain has been used as a strong argument for laparoscopic technology in other procedures, pain should be carefully assessed in any analysis comparing the open and laparoscopic techniques for ventral hernia. Incidence of long-term chronic pain after laparoscopic repair is reportedly 3–4.5% [31, 37, 40]. Up to 3 months postoperatively, 22% of the LG and 7% of the OG patients in the current study reported significant pain (scores of 30 or higher), but all were pain free at 1 year. The exact cause of this pain could not be ascertained but could be related to presence of transabdominal anchoring stitches as observed by others [7, 36].

Most authors report low recurrence rates, although few studies have sufficient follow-up to give reliable data. The possibility of the laparoscopic approach to detect Swiss-cheese-type defect and wide fixation of the mesh well beyond the margins of the fascial defect without the need for wide subcutaneous flaps can be considered factors that can result in lower recurrence rate. On average, 74% of recurrences usually appear within the first 3 years of initial repair [41]. In follow-up after laparoscopic repair the mesh tends to display considerable laxity and can bulge in patients with large abdominal wall defects. This should be carefully assessed in order to rule out recurrence. In doubtful cases, computed tomography (CT) is recommended.

The impact of IH repair and its complications on health-related quality of life has not been documented with patient self-reported data, as we do in this study. If the purpose of the intervention is to improve patient well-being, it is necessary to document that quality of life has actually been

improved. Health-related quality of life is best evaluated using information reported by patients themselves, rather than through clinical ratings or interpretation of data by health professionals. Reliable instruments have been developed in recent years, sensitive enough to detect subtle changes of patient health status [14, 42, 43].

Laparoscopic incisional and ventral hernia repair should be considered an advanced laparoscopic procedure that should be performed only after adequate training and experience.

Conclusions

In case of wall defects up to 15 cm wide, laparoscopic IH repair is a safe, feasible, and effective alternative to open techniques. Nevertheless laparoscopic IH repair does not seem to be a better procedure than the open anterior technique in terms of operative time, hospitalization, complications, pain or quality of life. Our data did not extend more than 12 months beyond surgery and consequently does not adequately address recurrence rate.

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