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ORIGINAL ARTICLE

Laparoscopic versus hybrid approach for treatment of incisional ventral hernia: a prospective randomized multicenter study of 1-month follow-up results

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Abstract

Purpose The seroma rate following laparoscopic incisional ventral hernia repair (LIVHR) is up to 78%. LIVHR is connected to a relatively rare but dangerous complication, enterotomy, especially in cases with complex adhesiolysis. Closure of the fascial defect and extirpation of the hernia sack may reduce the risk of seromas and other hernia-site events. Our aim was to evaluate whether hybrid operation has a lower rate of the early complications compared to the standard LIVHR.

Methods This is a multicenter randomized-controlled clinical trial. From November 2012 to May 2015, 193 patients undergoing LIVHR for primary incisional hernia with fascial defect size from 2 to 7 cm were recruited in 11 Finnish hospitals. Patients were randomized to either a laparoscopic (LG) or to a hybrid (HG) repair group. The outcome measures were the incidence of clinically and radiologically detected seromas and their extent 1 month after surgery, peri/postoperative complications, and pain.

Results Bulging was observed by clinical evaluation in 46 (49%) LG patients and in 27 (31%) HG patients ($p=0.022$). Ultrasound examination detected more seromas (67 vs. 45%, $p=0.004$) and larger seromas (471 vs. 112 cm^3, $p=0.025$) after LG than after HG. In LG, there were 5 (5.3%) enterotomies compared to 1 (1.1%) in HG ($p=0.108$). Adhesiolysis was more complex in LG than in HG (26.6 vs. 13.3%, $p=0.028$). Patients in HG had higher pain scores on the first postoperative day (VAS 5.2 vs. 4.3, $p=0.019$).

Conclusion Closure of the fascial defect and extirpation of the hernia sack reduce seroma formation. In hybrid operations, the risk of enterotomy seems to be lower than in laparoscopic repair, which should be considered in cases with complex adhesions.

Clinical trial number NCT02542085.

Keywords Incisional ventral hernia · Hybrid · Seroma formation · Enterotomy

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Introduction

Laparoscopic treatment is widely used in incisional hernia repair because of its favorable postoperative outcome compared to open surgery [1, 2].

A standard laparoscopic intraperitoneal onlay mesh (IPOM) procedure consists of reducing the hernia content and patching the abdominal wall defect with an overlapping, non-absorbable synthetic mesh, which is tacked to the abdominal wall [3]. Though in wide routine use, the method is associated with postoperative problems such as bulging and seroma formation [3, 4], especially in cases with complex adhesiolysis [5, 6]. Laparoscopy is also associated with the risk of bowel injury, which is a relatively rare but potentially dangerous perioperative complication [7].

The incidence of seromas varies from 0.5 to 78% [8, 9] according to the literature. The real importance of seroma formation, however, is unclear, since it is mostly an asymptomatic clinical or radiological finding. According to the seroma definition published by Morales-Conde, seromas lasting more than 3 months or causing pain, discomfort, cellulitis, or infection are considered postoperative complications [9]. The infection of the seroma is considered one of the most unfortunate complications, since it might lead to mesh removal [10] and hernia recurrence [11, 12].

In a relatively new laparoscopic technique called hybrid or "IPOM plus", the fascial defect is closed before the augmentation of the mesh. The closure of the defect attempts to recreate a functional, dynamic abdominal wall while also reducing the dead space. Hernia sack removal seems to have an influence on diminishing seroma formation [13]. A hybrid method including a minilaparotomy incision enables openly performed adhesiolysis, hernia sack resection, and fascial closure. This method has been reported to be associated with lower seroma [14] and recurrence rates [15–17]. However, there are no studies comparing the results of the laparoscopic and hybrid methods. With this randomized multicenter trial, we aim to explore the potential benefits of the hybrid technique over the laparoscopic operation in terms of seroma formation and the risk of enterotomy.

Patients and methods

Study design

From November 2012 to May 2015, following informed consent, 193 patients undergoing incisional ventral hernia repair (IVHR) using a Parietex® composite mesh (Covidien) were randomly assigned to receive either a conventional laparoscopic mesh repair or a hybrid repair. In the latter group, laparoscopic operation was combined with a fascial closure and hernia sack resection through a minilaparotomy incision. Eleven Finnish hospitals participated in the study. In each participating hospital, one or two surgeons were responsible for the patients' enrollment and performed the operations. According to patient flow in the participating hospitals, we estimated the recruitment period to last 1 year.

A separate randomization list was created by computer for each participating center. The list was made by a biostatistician who was not involved in the clinical care of the patients in the trial. The randomization was performed in blocks, where block size varied randomly between 4, 6, and 8. A research assistant, who was not involved in patient care, sealed the randomization lists into numbered, opaque envelopes, ensuring concealment.

The study was approved by the local ethical committee of each hospital, and it was registered in Clinical Trials (NCT02542085).

Patients

We included adult patients with incisional ventral hernias after informed consent was obtained. Exclusion criteria were age ≤ 18 or ≥ 80 years, American Society of Anesthesiologists score (ASA) ≥ 4, body mass index (BMI) ≥ 40, a previous mesh repair, width of hernia defect under 2 cm or over 7 cm, emergency operation, and the impossibility for adequate follow-up.

Surgical technique

Perioperative care included the assessment and optimization of medical risk factors. Thromboprophylaxis and prophylactic antibiotics were used according to each hospital's normal protocol.

Laparoscopic hernia repair was performed as a standard procedure using a Parietex® composite mesh, which was fixed to the peritoneum by the double crown technique using the Securestrapp® tacking device (Ethicon). Four pretied transabdominal sutures (two absorbable on the lateral sides and two non-absorbable in the midline) were used to anchor the mesh. The size of the mesh was chosen to cover the whole length of the scar and to be three times wider than the width of the hernia defect (or the overlap of the mesh to be at least 5 cm). In the hybrid group, the hernia sack was resected, and the fascial defect was closed with a slowly absorbing monofilament suture (0–0 Maxon® or PDS®) through a minilaparotomy incision before the standard mesh repair. If a patient had multiple hernia defects, the

one causing the symptoms was sutured, and the other defects were covered with the mesh.

Data recording and follow-up

The patient-related baseline characteristics were recorded at the preoperative visit. The sizes of the hernia defect and hernia sack were measured using an ultrasound scan.

During the operation, surgeons estimated the type of intra-abdominal adhesions (none, omental, or bowel) and the complexity of adhesiolysis (none, simple, or complex). The blood loss (milliliters) and operative time (min) were recorded.

During the hospital stay, possible complications and a pain score [Visual Analog Scale (VAS)] were registered. Postoperative complications were graded according to the Clavien–Dindo scale [18].

Follow-up, including physical and radiological examination and VAS questionnaires, was scheduled at 1 month postoperatively. The follow-up ultrasound examination was performed in the supine position during rest to show possible seromas. Seroma was defined as an anechoic fluid collection. The sizes of seromas were measured and recorded into a database.

Study outcome

The primary endpoint of this study was the number of patients with seroma formation in a 1-month control. The secondary endpoints were peri/postoperative complications and evaluations of pain (VAS).

Statistical analysis

The current study is a part of a study comparing the results of hybrid and laparoscopic techniques on hernia recurrences after mid- and long-term follow-up. The primary end point of the main study is the hernia recurrence at 1 year postoperatively. According to sample size calculation, assuming 6% difference (2% in HG versus 8% in LG, $\alpha = 0.05$, power 0.80, and a drop-out rate of ~20%) in the hernia recurrence rate at 1-year follow up, 200 patients per group needed to be randomized.

Summary measurements are presented as mean with standard deviation unless otherwise stated. Between-group comparisons were performed by Chi-square test or Fisher's exact test (categorical variables) and by Student's *t* test or Mann–Whitney *U* test (continuous variables). All analyses were done according to the intention to treat (ITT) principle unless otherwise stated. Two-tailed *p* values < 0.05 were considered statistically significant. Analyses were performed by SPSS for windows (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.).

Results

During the 30-month recruitment period, 193 patients with incisional ventral hernia were randomly assigned to either the laparoscopic group (LG) or the hybrid group (HG). From these, 94 patients in LG and 90 in HG were operated on and analyzed. A flowchart is shown in Fig. 1.

Baseline characteristics are presented in Table 1. The operative outcome did not differ between the groups (Table 2). In the LG group, eight operations were converted to hybrid of which four cases due to intense bowel adhesions and four cases with an enterotomy during the laparoscopic phase. One patient had a wide scar that needed to be removed. Three laparoscopic operations were converted to open after a complex adhesiolysis, including one with enterotomy. All these bowel injuries were managed immediately with no further complications. In the HG, one operation was performed laparoscopically, and two were converted to open due to extensive adhesions. The conversion rates were 3.2% in LG and 2.2% in HG.

There were 15 (16%) patients in LG and 11 (12.2%) patients in HG who had postoperative complications. The pain score was significantly higher on the first postoperative day in HG compared to LG (4.3 versus 5.2, $p = 0.019$). Otherwise, the short-term postoperative outcome showed no difference between study groups (Table 3). There were five reoperations reported during the 30-day postoperative period. In LG, one patient had a reoperation due to pain and a high C-reactive protein (CRP) level. A part of the omentum was necrotic and, therefore, resected. This patient recovered well and was discharged on the sixth postoperative day. The other four were in the HG group. In HG, one patient suffered from an intra-abdominal infection and underwent a laparotomy with mesh removal. Another patient had a wound infection, which was treated with vacuum-assisted therapy, and finally, the wound was covered with a skin graft. One patient suffered from intensive pain in the area of the lateral transabdominal suture. In a reoperation, this suture was found to be entangled with a subcutaneous nerve and was removed. The pain was relieved afterwards. In this study, there were six bowel injuries, from which one in HG remained undetected. Regardless of the reoperation on the third postoperative day and the open abdomen treatment in the intensive care unit, this event led to multi-organ failure and finally to the death of this patient, giving a mortality rate of 0.5%.

Fig. 1 Flowchart

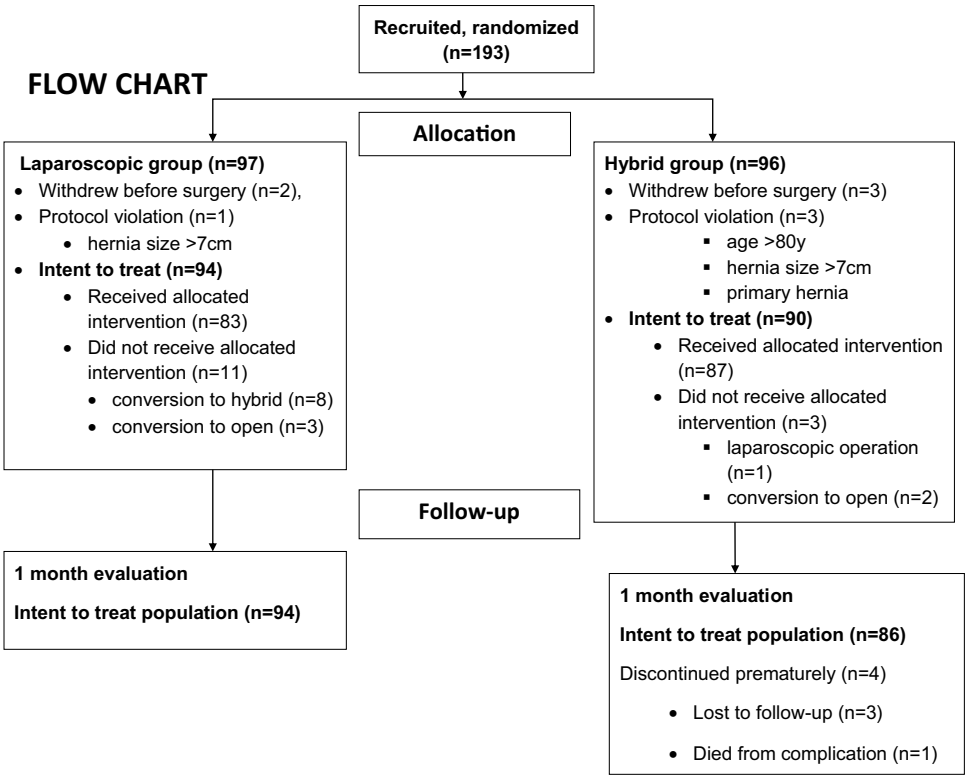

Table 1 Baseline characteristics

	Laparoscopic group, $n=94$	Hybrid group, $n=90$
Age, years, mean (SD)	57 (SD 11.4)	60 (SD 12.8)
Females, *n* (%)	54 (59.3)	54 (61.4)
BMI, kg/m^2 (SD)	30.2 (SD4.4)	29.2 (SD 4.2)
ASA class, *n* (%)		
1	10 (10.9)	12 (13.6)
2	48 (52.2)	44 (50)
3	34 (37.0)	32 (36.4)
Smoking, *n* (%)	17 (18.1)	11 (12.2)
Hernia defect size, cm^2, mean (SD)	13.2 (SD 11.1)	10.5 (SD 8.9)
Hernia sack size, cm^3, median (25th–75th) [min–max][a]	245 (108–656) [21–4189]	261 (111–612) [4–5014]
Number of hernias, *n* (%)		
1	66 (70.2)	65 (73)
2	17 (18.1)	16 (18.0)
≥3	11 (11.7)	8 (9)

Nominal variables are reported as counts and percentages (in parentheses); continuous variables are reported as mean and standard deviation

ASA American Society of Anesthesiologists

[a]Data from 74 patients in LG and 69 patients in HG

One-month outcome

Data on the 1-month control were not available for four patients in HG. Three patients did not attend the control, and one patient had died due to a complication. At the time of the 1-month control 47 (50%) out of 94 patients in the LG and 34 (39.5%) out of 86 patients in HG had some symptoms ($p=0.179$) (Table 4). Seromas were clinically detected in 73 (39.7%) and radiologically in 102 (55.4%) of the 180 patients. There was more seroma formation in LG than in

Table 2 Perioperative outcome

	Laparoscopic group, no. 94	Hybrid group, no. 90	*p* value
Mesh size, cm^2 (SD)	393.2 (SD 140.7)	362.5 (SD 152.7)	0.16
Perioperative complication			
Enterotomy	5 (5.3)	1 (1.1)	0.11
Bleeding	1 (1.1)	4 (4.4)	0.16
Urinary bladder injury	0	1 (1.1.)	0.41
Blood loss, ml (SD)	22 (SD 43.9)	22 (SD 29.17)	> 0.90
Adhesions			0.69
None	36 (38,3)	38 (42,2)	
Omental	32 (34)	32 (35.6)	
Bowel	26 (27.7)	20 (22.2)	
Adhesiolysis			0.081
None	36 (38.3)	39 (43.3)	
Simple	33 (35.1)	39 (43.3)	
Complex	25 (26.6)	12 (13.3)	
Operation time, min (SD)	81 (SD 46.7)	84 (SD 29)	0.66

HG [63 (67%) vs. 39 (45.3%), $p = 0.004$]. The seromas in LG were significantly larger, and six of these patients needed seroma puncture. According to the Morales–Conde classification, only half of these postoperative seromas—31 (49.2%) in LG and 19 (48.7%) in HG—are graded as complications.

Discussion

This study is the first randomized trial comparing laparoscopic and hybrid incisional hernia operations. The research was carried out by Finnish surgeons from 11 hospitals, giving it real multicenter nationwide relevance.

Primary closure of the defect before placement of the mesh is currently recommended in laparoscopic hernia repair [8, 15, 19]. At the design phase of this trial, laparoscopic suturation was not a commonly used technique among Finnish surgeons, and there was concern about the potential impact of a learning curve if this technique was to be used. To guard against this, based on the best available evidence at the time, the hybrid technique was chosen to assure proper defect closure.

The hybrid operation should also facilitate safe adhesiolysis. In addition, we thought that hernia sack removal might have an effect on reducing the seroma formation. The primary outcome measure, thus, was postoperative seroma formation based on the hypothesis that the defect closure leads to lower incidence of seromas.

As expected, the main finding of our study is that patients treated with the hybrid method for incisional ventral hernias do, indeed, have significantly less seroma formation, and the size of the seromas is clearly smaller compared to patients operated on using the laparoscopic technique. In the 1-month control, seromas were found in only 45% of the cases in HG compared to 67% after laparoscopy by US examination. This figure is much lower compared to two other studies performing a systematic postoperative radiological evaluation after LIVHR, the incidence of seromas being 95.2% [9] and 100% [20].

Seroma-related cellulitis is a rather common problem, which can lead to mesh infection [10] and, therefore, hernia recurrence [21]. In our study, there was only one mesh removal performed due to infection.

There was no difference in the nature of adhesions between operative groups. Nevertheless, adhesiolysis was reported as complex clearly more often in LG than in HG. Dividing adhesions openly is presumably easier [22] and thus can affect the number of perioperative enterotomies, as also seen in another study [23].

There was one death in HG. This was a case where the first trocar inserted into the abdominal cavity caused a small bowel injury. The lesion was found postoperatively by a CT scan and was sutured in a laparotomy within 24 h. However, the patient developed a multi-organ failure, and after multiple relaparotomies and open abdomen treatment, he succumbed after 22 days.

The pain score was higher on the first postoperative day after the hybrid technique than after laparoscopy alone, but the scores assimilated the next day. These findings are in line with other studies [8, 24]. Interestingly, 13 patients in LG were readmitted to the hospital due to pain within 30 days of follow-up—nine of them had seroma and two with pain in the area of transabdominal suture, and the reason for pain in other two remained unexplained.

One drawback of the study is that we failed to reach the estimated sample size of 400 patients, even though we prolonged the recruitment period from 1 year up to 30 months. Thus, for the current study, the number of recruited and

Table 3 Short-term postoperative outcome

	Laparoscopic group, $n=94$	Hybrid group, $n=90$	p value
In-hospital mortality	0	1 (1.1)	0.31
In-hospital stay (days), mean (SD)	2.4 (SD 1.9)	3.1 (SD 3.2)	0.090
Pain severity (VAS), mean (SD)			
First postop day[a]	4.3 (SD 2.37)	5.2 (SD 2.57)	0.019
Second postop day[b]	4.5 (SD 2.46)	5.2 (SD 2.27)	0.16
Third postop day[c]	4.3 (SD 2.73)	5 (SD 2.36)	0.29
Readmission due to pain	13 (13.8)	3 (3.3)	0.017
Postoperative complications, *n* (%)[d]			
Wound infection	2 (2.1)	3 (3.3)	0.62
Wound dehiscence	0	1 (1.1)	0.31
Intra-abdominal infection	1 (1.1)	1 (1.1)	0.090
Seroma	3 (3.2)	3 (3.3)	0.96
Hematoma	4 (4.3)	4 (4.4)	0.95
Myocardial ischemia	1 (1.1)	0	0.33
Pneumonia	2 (2.1)	1 (1.1)	0.59
Pulmonal embolus	0	1 (1.1)	0.31
Intestinal obstruction	4 (4.3)	2 (2.2)	0.44
Urinary tract infection	3 (3.2)	1 (1.1)	0.62
Urinary retention	1 (1.1)	0	0.49
Clavien–Dindo grading, *n* (%)			0.45
No complication	79 (84)	79 (87.8)	
gr 1	4 (4.3)	4 (4.4)	
gr 2	10 (10.6)	4 (4.4)	
gr 3	1 (1.1)	3 (3.3)	
gr 4	0	0	
gr 5	0	1 (1.1)	
Reoperation, *n* (%)	1 (1.1)	4 (4.4)	0.16

Nominal variables are reported as counts and percentages (in parentheses); continuous variables are reported as mean and standard deviation; pain severity was estimated by the Visual Analog Scale (VAS) score from 1 to 10

[a]Data from 178 out of 184 patients (LG 94, HG 88)

[b]Data from 114 out of 124 patients (LG 55, HG 59)

[c]Data from 62 out of 87 patients (LG 29, HG 33)

[d]Some patients had more than one complication

analyzed patients has shown to be sufficient. As the study proceeded, the hybrid method started to become more convenient to use. Thus, enthusiasm to recruit patients into study abated, which eventually led to a marked variance in the number of recruited patients between centers. Furthermore, we did not have a complete screening log from all the centers, which may show as selection bias.

According to recent non-randomized studies, the fascial closure (IPOM plus) results in fewer adverse events, including a lower rate of seroma formation compared to LIVHR [8, 19]. However, no randomized studies supporting the use of this technique have been carried out until now. In our randomized study the combination of fascial closure and hernia sack resection, using the hybrid technique, led to a significant decrease in seroma formation without increased incidence of wound infections. The latter finding is important, since surgical site infections are much more common after open hernioplasties compared to laparoscopic operations [6, 25, 26]. In the hybrid operation, the resection of the sack is simple to perform, but creates larger wounds and dissection areas and potentially increases the risk of surgical site infections. In our study, prophylactic antibiotics were used in 93% of the cases, which may be one reason for the low infection rate. Although not yet scientifically proven, it may be that hernia sack resection included as a part of the method to diminish the dead space could reduce the seroma formation and possible further adverse events. The sack removal technique has been more commonly used in robotic hernia operations [27, 28], where the instrumentation enables

Table 4 One-month clinical outcome in the study groups

	Laparoscopic group, $n=94$	Hybrid group, $n=86$	p value
Symptoms, n (%)			
None	47 (50)	52 (60.5)	0.18
Movement restrictions	39 (42.4)	29 (34.1)	0.28
Pain	32 (34.4)	25 (29.8)	0.52
VAS, mean (SD)	2.19 (SD 1.84)	2.22 (SD 1.51)	> 0.9
Clinical findings, n (%)			
Wound infection	1 (1.1)	1 (1.2)	> 0.9
Seroma	46 (48.9)	27 (31.4)	0.022
Radiological findings			
Seroma	63 (67)	39 (45.3)	0.004
Seroma puncture	6 (6.4)	0	0.017
Seroma size, cm^3, median (25th⁻75th) [min–max]	162 (30–388) [2–8495]	50 (13–145) [0.1–670]	0.025

Nominal variables are reported as counts and percentages (in parentheses); continuous variables are reported as the mean and standard deviation

VAS visual analog scale; pain severity was estimated by the VAS scale from 1 to 10

easier hernia sack dissection and suturation of the abdominal wall compared to the conventional laparoscopy.

Conclusion

The LIVHR hybrid method, including hernia sack resection combined with fascial closure, carries a low risk of enterotomy and is associated with clearly diminished seroma formation compared to laparoscopic repair alone.

Author contributions Ahonen-Siirtola: conception and design of the study, acquisition, analysis, and interpretation of data, and writing the article. Nevala: design of the study, acquisition of data, writing the article, and critical revision. Vironen: design of the study, acquisition, analysis and interpretation of data, and critical revision. Kössi: design of the study, acquisition, analysis and interpretation of data, and critical revision. Pinta: design of the study, acquisition of data, and critical revision. Niemeläinen: design of the study, acquisition of data, and critical revision. Keränen: design of the study, acquisition of data, and critical revision. Ward: design of the study, acquisition of data, and critical revision. Vento: design of the study, acquisition of data, and critical revision. Karvonen: design of the study, acquisition of data, and critical revision. Ohtonen: design of the study, analysis and interpretation of data, writing the article, and critical revision. Mäkelä: conception and design of the study, and critical revision. Rautio: conception and design of the study, acquisition, analysis and interpretation of data, and writing the article.

Compliance with ethical standards

Conflict of interest Authors MAS, TN, JV, TP, SN, UK, JW, PV, JK, PO, JM, and TR declare no conflict of interest. Author JK declares conflict of interest not directly related to the submitted work (one lecturing fee from Medtronic, not related to the submitted work).

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Human and animal rights This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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