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Laparoscopic Treatment of Incisional and Ventral Hernia

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ABSTRACT

Background and Objectives: Although several large studies regarding patients undergoing minimally invasive repair of incisional hernia are currently available, the results are not particularly reliable as they are based on heterogeneous groups, different surgical techniques, different mesh types, or with a too short follow period.

Methods: We conducted a retrospective observational trial, collecting data from patients who underwent laparoscopic repair of a primary abdominal wall or an incisional hernia using the laparoscopic Intraperitoneal Onlay Mesh technique and a single mesh type, i.e., a composite polyester mesh with a hydrophilic film (Parietex Composite™ mesh – Medtronic, Minneapolis, MN - USA). All patients signed an informed consent.

Results: One thousand seven hundred seventy-seven patients were enrolled. The median surgery time was 50 minutes and the median length of hospital stay was 2 days. Intraoperative complications occurred in 12 patients (0.7%), while early postoperative surgical complications occurred in 115 (6.5%); during follow-up, bulging mesh was diagnosed in 4.5% of cases and hernia recurred in 4.3% of patients. An overlap equal or greater than 4 cm resulted as a significant protective factor, while the use of absorbable fixing devices was a risk factor for recurrence (odds ration: 9.06, $p < 0.001$, 95% confidence interval: 4.19 – 19.57).

Conclusions: Minimally invasive treatment of primary and postincisional abdominal wall hernias is a safe, effective, and reproducible procedure. An overlap equal or greater than 4 cm, the use of nonabsorbable fixing devices and a postoperative care and follow-up regime are crucial in order to obtain good results and low recurrence rates.

Key Words: Ventral hernia, Incisional Hernia, Laparoscopy, Mesh, Fixing devices.

INTRODUCTION

Abdominal wall defects are a common issue,[1,2] with a reported incidence of incisional hernia of up to 30% after open surgery.[3–5] The minimally invasive approach was described for the first time by Leblanc and Booth in 1993[6] and is considered a safe and effective method.[5] Key factors for optimal outcomes and low recurrence rate include the careful patient selection and correct choice of the mesh and fixing devices.[7,8] Several studies are currently available, but the data are not particularly reliable as they are based on heterogeneous groups or different surgical techniques or materials, or with too short follow up periods resulting inadequate to analyze the long-term outcomes.[9]

The present study enrolled patients who underwent laparoscopic repair of abdominal wall or incisional hernia using the laparoscopic Intraperitoneal Onlay Mesh (IPOM) technique and a single mesh type, i.e., a composite polyester mesh with a hydrophilic film (Parietex Composite™ mesh – Medtronic, Minneapolis, MN – USA). The main aim of the study was to assess risk factors for long-term recurrence.

MATERIALS AND METHODS

Study Design

We conducted a multi-center, retrospective, observational study collecting data from patients treated between

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Informed consent: Dr. Alberto Oldani declares that written informed consent was obtained from the patient/s for publication of this study/report and any accompanying images.

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January 1, 2001 and December 31, 2017 in four surgical units that primarily focus on open and minimally invasive surgical repair of abdominal wall defects. For all subjects, the following data were collected: age, gender, body mass index (BMI), comorbidities, American Society of Anesthesiologists score, size and site of the defect, previous abdominal surgery, surgical timing (elective or emergency), operative time, intraoperative complications, fixation devices, laparotomy conversion rate, comorbidities, re-operation, and length of hospital stay.

The primary objective was the risk factors assessment for recurrence.

Study Population

Inclusion criteria were patients with a symptomatic hernia of the abdominal wall and/or an incisional abdominal hernia, laparoscopic repair with intraperitoneal mesh (IPOM technique), nonclosure of the wall defect, and use of the composite polyester mesh (Parietex Composite™ mesh – Medtronic, Minneapolis, MN - USA).

Pre-operative Assessment

Patients underwent a clinical examination; ultrasonography (US), computed tomography (CT), or magnetic resonance (MR) imaging were performed depending on the surgeon's choice. A short-term antibiotic prophylaxis (2 g of intravenous (IV) cefotaxime or 20.2 g of IV amoxicillin-clavulanic acid) was administered 1 hour before surgery; deep vein thrombosis prophylaxis with compression stockings and 0.3 ml of SC nadroparin calcium (0.4 ml in cases of BMI $\geq 30\,kg/m^2$) were employed 12 hours before surgery. Written informed consent was obtained by all the patients.

Surgical Technique

All the procedures were approached laparoscopically under general anesthesia and, in some cases, combined with an abdominal wall analgesia technique (transversus abdominis plane block). In most cases 3 ports were placed on the left side of the abdomen; for defects larger than 10 cm, one or two additional ports were positioned on the right side. Pneumoperitoneum was created using a Veress needle or open introduction of a blunt-tip trocar to achieve an intra-abdominal pressure of 14 mmHg. In all cases, a 30° laparoscope was used. The wall defects were measured, both in the longitudinal and transverse direction, under 14 mmHg pneumoperitoneum, in all cases the Parietex Composite™ mesh was used. The defect and the overlap were marked on the abdominal wall surface. The mesh was then moistened and rolled with the film on the inside; introduced through a 12-mm port, unfolded, orientated, and centered on the defect; with the hydrophilic film placed towards the bowel and the polyester side towards the abdominal wall. The mesh was suspended using four transcutaneous sutures and fixed in place with the circumferential application of either absorbable or nonabsorbable tacks (Medtronic Absorba Tack™, Covidien Pro Tack™, respectively), forming a double crown or fibrin glue. In all cases the mesh was secured in place after the pneumoperitoneum had been reduced from 14 to 10 mmHg, to allow a tension-free placement. No abdominal or subcutaneous drains were placed.

Follow-up Evaluation

The follow-up included a clinical and US evaluation at 1 month; clinical examination at 3, 6, 12 months, and annually.

Statistical Analysis

Categorical variables are reported as frequencies and percentages, whereas continuous variables are reported as a median and interquartile range (IQR) due to nonnormal distributions (normality distribution was tested with the Shapiro-Wilk normality test). Univariate analysis of the differences between groups was performed using the χ^2 test for categorical data (with Fisher correction when needed) and using the nonparametric Mann-Whitney test for continuous variables. In order to assess potential predictors of recurrence and early postoperative surgical complications, a multivariate analysis using logistic regression models was then performed. The covariates included in the final model were those with a univariate p-value < 0.05. Results are expressed as Odds Ratios (OR) with 95% Confidence Intervals (CI). The recurrence rate was analyzed using a Kaplan-Meier survival analysis. A Spearman's correlation was run to assess the relationship between surgery time and the overlap measurement. For all the tests used, the statistical significance level was set at the conventional $P < .05$. The results were analyzed using StataSE 15 statistical software (Stata Corp., College Station, TX).

RESULTS

One thousand seven hundred seventy-seven patients were enrolled, 943 males (53.1%) and 834 females

(46.9%). The median age was 61 years (range 19 – 91) and the median BMI was 27 kg/m^2 (range 16.6 – 74). Comorbidities are presented in **Table 1**, along with demographic data.

The majority of cases were diagnosed clinically (60.1%); for the remaining cases a radiological examination was necessary.

Dividing the pre-operative assessment in three groups, i.e., clinical diagnosis, US diagnosis, and radiological diagnosis (CT and/or MRI), the median BMI was significantly higher in the radiological group (26.8 vs. 27.5 vs. 28 kg/m^2, P = .019), which was the same for the percentage of patients who had undergone previous abdominal surgery (67.5% vs. 55.2% vs. 73.1%, $P < .001$), thus confirming that abdominal wall excessive thickness and abdominal wall scars are common indications for the need of pre-operative instrumental diagnosis for the confirmation of the clinical data and for assessing the defect width. The vast majority (93.6%) of patients underwent an elective operation, while 6.4% had emergency surgery. For 4.9% cases the overlap was 1 – 3 cm, in 15.3% 4 cm, in 58.9% 5 cm, in 20% 6 – 9 cm, and in 0.9% more than 10 cm. No significant correlation between the overlap size and the hernia width has been detected.

Several fixing devices were employed, which were characterized as absorbable in 256 patients (14.4%), nonabsorbable in 1, 383 (77.8%), sutures or fibrin glue in 29 (1.6%) and multiple devices in 109 patients (6.1%). The median surgery time was 50 minutes (IQR 35 – 75, range 10 – 270 min). Intraoperative complications occurred in 12 patients (0.7%), namely 5 cases of bleeding and 7 bowel perforations. Laparotomy conversion occurred in 21 cases (1.2%). Postoperative pain was measured through both a VRS (verbal rating scale) and an NRS (numeric rating scale). With the VRS score, postoperative pain was absent in 21.2% of patients, mild in 59.5%, moderate in 18.9% and severe in 0.5%. Using NRS categories, patients reported no pain in 20.4% of cases, mild in 61.2%, moderate in 18.0% and severe in 0.5%. Postoperative pain was compared between patients in whom the mesh was fixed with absorbable and nonabsorbable devices, resulting in no differences being seen using the VRS score, while with the NRS score there was a statistically significant difference in the category percentages (no, mild, moderate, severe pain) for absorbable staples were 25.0%, 60.6%, 14.5%, 0% respectively; for nonabsorbable staples, the rates were 18.2%, 62.8%, 18.4%, 0.6%, P = .042), suggesting higher postoperative pain for nonabsorbable mesh fixation staples. The median length of hospital stay was 2 days (IQR 2 – 3; range 0 – 54 days). Specifically, 17.3% of patients stayed 1 day, 58.2%, 2 or 3 days, 15.6% 4 or

Table 1.
Demographic and Pre-operative Data

	N (%) or median (IQR)
Gender	
Male	943/1777 (53.1%)
Female	834/1777 (46.9%)
Age, years	61 (49; 70)
BMI, Kg/m^2	27 (24; 31.2)
ASA score	
I	382/1755 (21.8%)
II	1000/1755 (57.0%)
III	367/1755 (20.9%)
IV	6/1755 (0.3%)
Comorbidities	
COPD	258/1749 (14.8%)
Type II diabetes	237/1749 (13.6%)
Heart disease	176/1752 (10.1%)
Arterial hypertension	824/1754 (47.0%)
Oral anticoagulant therapy	63/1748 (3.6%)
Steroid therapy	16/1749 (0.9%)
Previous radiation therapy	47/1749 (2.7%)
Tobacco smoking	391/1753 (22.3%)
Normoweight	462/1528 (30.2%)
Overweight (BMI ≥ 25)	577/1528 (37.8%)
Obesity (BMI ≥ 30)	489/1528 (32.0%)
Others:	51/1777 (2.9%)
Cancer	9/1777 (0.5%)
Chronic renal insufficiency	1/1777 (0.1%)
Depression	14/1777 (0.8%)
Liver disease and/or HCV	
Hernia site, EHS classification	
M1 midline, subxiphoidal	81/1704 (4.8%)
M2 midline, epigastric	687/1704 (40.3%)
M3 midline, umbilical	1006/1704 (59.0%)
M4 midline, infraumbilical	238/1704 (14.0%)
M5 midline, suprapubic	105/1704 (6.2%)
L1 lateral, subcostal	56/1704 (3.3%)
L2 lateral, flank	96/1704 (5.6%)
L3 lateral, iliac	67/1704 (3.9%)
L4 lateral, lumbar	1/1704 (0.1%)
Type of hernia	
Incisional hernia	1189/1777 (66.9%)
Primary hernia	576/1777 (32.4%)
Both	12/1777 (0.7%)
Swiss-cheese type hernia	201/1704 (11.8%)
EHS width classification	
W1 (< 4 cm)	606/1698 (35.7%)
W2 (≥ 4/<10 cm)	569/1698 (33.5%)
W3 (≥ 10 cm)	515/1698 (30.3%)
Multiple	8/1698 (0.5%)

IQR, interquartile range; BMI, Body Mass Index; ASA, America Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease; HCV, hepatitis C virus; EHS, European Hernia Society.

5 days, and only 8.8% of patients stayed for 6 days or more. Early postoperative complications were detected in 115 cases (6.5%): wound seroma occurred in 77 patients (4.3%), wound hematoma in 31 (1.7%), mesh infection in 6 (0.3%), postoperative bowel occlusion in 7 (0.4%), postoperative peritonitis in 4 (0.2%) and hemoperitoneum in 1 (0.1%). Early surgical reintervention occurred in 15 cases, 12 of which were laparoscopic and 3 with open approach. The median follow-up duration was 58.9 months (IQR 24.4 – 91.9, range 21.0 – 110.2). The mesh bulging was diagnosed in 80 patients (4.5%), while hernia recurrence was diagnosed in 75 cases (4.2%). Among the 75 patients with hernia recurrence, 72 underwent a repeat surgical procedure, that was performed laparoscopically in 54 and by open surgery in 18. The **Figure 1** presents the Kaplan-Meier analysis for hernia recurrence.

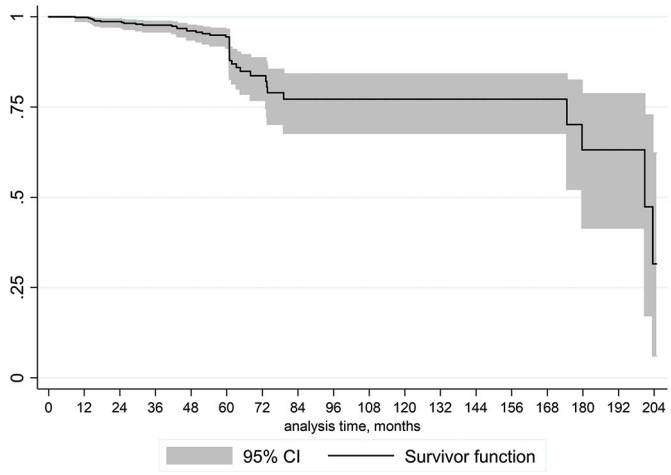

Figure 1. Kaplan-meier analysis for hernia recurrence.

All patients presenting with bulging or who were suspected of recurrence underwent radiological evaluation with basal abdominal CT scan; recurrence was defined as the presence of omental tissue and/or viscera throughout the wall defect.

All but 5 patients diagnosed with recurrence underwent laparoscopic re-operation. Laparoscopic exploration confirmed in all treated cases the mesh dislocation and/or detachment.

A recurrence risk factor analysis showed that the recurrence rate was higher for smaller overlap sizes, for M1 (i.e., midline, subxiphoid) and L3 (i.e., lateral, iliac) European Hernia Society (EHS) hernia types, in patients with absorbable fixation devices and in patients with bulging. In the logistic regression analysis, recurrence was closely related to the patient's age (OR 1.03, $P = .037$, 95% CI 1.00 – 1.05) and the M3 EHS classification type (i.e., lateral iliac) (OR 6.82, $P < .001$, 95% CI 2.44 – 19.07). Mesh overlap greater than 3 cm appeared to be a significant protective factor, while the use of absorbable mesh staples appeared to be a significant risk factor for recurrence (OR 9.06, $P < .001$, 95% CI 4.19 – 19.57). The defect size was not related to recurrence risk. Finally, mesh bulging and mesh infection were significant risk factors for hernia recurrence (OR 9.30 and 41.64, respectively), as shown in **Table 2**. The Spearman correlation showed a statistically significant negative correlation (rs = −0.11, $P < .001$) among overlap size in cm and surgery time in minutes.

DISCUSSION

Minimally invasive surgical treatment of primary and incisional hernia is considered an effective approach, particularly for small and medium size defects.[2] The 2015 Consensus Conference[10] assessed that laparoscopy is safe, effective, and superior to the open technique in terms of hospital stay, postoperative pain, and short-term overall morbidity. In 2016, Ecker[11] reported lower complication rates, postoperative readmissions, and revisional surgeries; moreover, Al Chalabi[12] described a five times lower wound infection rate. Although several experiences[10–18] have demonstrated good postoperative outcomes for laparoscopy, long-term results are less well recorded.[13,19,20] Our study is based on one of the largest patient cohorts treated with a standardized procedure and a single mesh type (Parietex Composite™). Composite meshes seem to offer the advantage of combining both the resistance of a permanent intraperitoneal structure and an anti-adhesion barrier to protect the visceral layer. The correct fixation is crucial, influencing both postoperative pain and both short and long-term hernia recurrence.[11,21] Previous studies present conflicting data about recurrence related to the use of absorbable or nonabsorbable staples,[7,10,12,22,23] with some authors suggesting that the use of fibrin glue significantly reduces postoperative pain with very low recurrence rates.[24] In our experience, different tacks were employed, depending on the surgeon's choice, which enabled us to compare results for different device categories. In addition, the distribution of the subjects between the three fixation groups was uneven, and all the variances were similar in order to not invalidate the statistical analysis. We recorded a small increase in early postoperative pain related to nonabsorbable fixing devices, whereas a significant difference in recurrences rates was reported comparing absorbable and nonabsorbable tacks (11% vs. 3%, $P < .001$); we encourage the use of nonabsorbable tacks.

Table 2.
Multivariate Analysis for Hernia Recurrence

	Univariate Analysis p value	Multivariate Analyses		
		OR	p value	95% CI
Age	0.015	1.03	0.037	1.00 – 1.05
COPD	0.008	1.58	0.228	0.75 – 3.32
Previous radiation therapy	0.031	1.31	0.682	0.36 – 4.81
Other comorbidities:	0.005			
Cancer		2.41	0.258	0.52 – 11.13
Chronic renal insufficiency		1	–	–
Depression		1	–	–
Liver disease and/or HCV		21.87	0.001	3.74 – 127.70
Previous abdominal surgery	0.032	0.24	0.116	0.04 – 1.43
M1 midline, subxiphoidal	<0.001	2.00	0.188	0.71 – 5.62
M3 midline, umbilical	0.001	0.54	0.080	0.27 – 1.08
L3 lateral, iliac	<0.001	6.82	<0.001	2.44 – 19.07
Type of hernia	0.007			
Incisional hernia		reference	–	–
Primary hernia		0.20	0.098	0.03 – 1.35
Both		2.60	0.437	0.23 – 29.12
EHS width classification	0.008			
W1 (<4 cm)		reference	–	–
W2 (≥ 4/<10 cm)		0.61	0.257	0.26 – 1.43
W3 (≥ 10 cm)		0.99	0.993	0.43 – 2.33
Multiple		1	–	–
Overlap	<0.001			
1 cm		reference	–	–
2 cm		0.47	0.604	0.03 – 7.92
3 cm		0.53	0.615	0.05 – 6.22
4 cm		0.03	0.006	0.003 – 0.38
5 cm		0.05	0.009	0.004 – 0.47
6 cm		0.12	0.090	0.01 – 1.39
7 cm		0.05	0.031	0.003 – 0.76
8 cm		111	–	–
9 cm			–	–
10 /15 cm			–	–
Fixation devices	<0.001			
Nonabsorbables		reference	–	–
Absorbables		9.06	<0.001	4.19 – 19.57
Sutures or fibrin glue		3.21	0.300	0.35 – 29.12
Multiple devices		0.98	0.981	0.23 – 4.25
Mesh bulging	<0.001	9.30	<0.001	3.74 – 23.09
Mesh infection	0.001	41.64	<0.001	5.51 – 314.76

OR, odds ration; CI, confidence interval; COPD, chronic obstructive pulmonary disease; HCV, hepatitis C virus; EHS, European Hernia Society.

The Italian Laparoscopic Ventral Incisional Hernia Guidelines[8] recommends a minimum 3 cm overlap size, while other authors[16,23,25] suggest an overlap of 5 cm, especially for larger defects. In our experience only 5% of patients had an overlap smaller than 4 cm; in these cases, the recurrence rate was 25%, whereas it dropped to 3% for an overlap $\geq$ 4 cm. Moreover, a negative correlation was demonstrated between overlap size and surgery time, with a larger overlap not only being safer, but also technically easier. Minimally invasive approach resulted in shorter hospital stays, and in 75% of cases less than 3 days. Larger wall defects and age over 65 years were risk factors, thus enabling the pre-operative selection of patients at risk of a prolonged hospital stay. An overall morbidity rate of 6.5% was recorded, considerably lower than the 20% rate recently reported by Sanchez et al.,[14] and less than the 13% by Heniford.[19] We also recorded a bulging and recurrence rate of $< 5\%$. Literature reports heterogeneous recurrence rates, ranging from 23% (Lund et al.[21]) and 5% or less in other studies.[2,26,27] Logistic regression analyses enabled us to identify as independent risk factors for recurrence: overlap smaller than 4 cm, use of absorbable fixation devices, bulging, and mesh infection; while patient-related risk factors were advanced age and L3 lateral iliac hernia type. The L3 lateral iliac location is an anatomically challenging site, due to the difficulties in obtaining a sufficient overlap and adequate fixation. Although laparoscopy is safe and effective even in these cases,[28] it is important to ensure optimal treatment for the patient, by evaluating the benefits and risks of minimally invasive and open surgery. While defect and mesh size and inadequate overlap and fixation have been demonstrated to affect negatively the recurrence rate, as assessed by several authors,[24,29,30] we did not find correlations with obesity.[7]

In the literature, the transversus abdominis muscle release technique is recommended for large and very large midline, lateral, or combined abdominal wall defects.[31] In recent years, some innovative approaches were proposed for the treatment of incisional and/or ventral hernias; Reinpold et al. developed a trans-hernia minimally invasive approach (mini–or less–open sublay operation) combining the advantages of open sublay and laparoscopic IPOM repair, with lower morbidity and recurrence rates when compared to IPOM;[32] the extended totally extraperitoneal repair (eTEP) and the Totally Endoscopic Sublay Anterior Repair (TESAR) would be valuable alternative to IPOM in centers with advanced laparoscopic skills and in carefully selected cases.[33–35] Further data with a larger patient cohort and a longer observation period would be needed in order to validate these techniques.

The choice to combine primary and incisional ventral hernia may raise objections; but in our practice, primary and incisional ventral hernias show several common aspects, especially in terms of clinical assessment, diagnosis, indications and principles of surgical treatment. Also, the statistical preliminary evaluation demonstrated homogeneity between the two patients' subgroups.

CONCLUSIONS

Our experience demonstrates that laparoscopic treatment of primary and postincisional abdominal wall hernias is a safe, effective, and reproducible procedure. Strict adherence to surgical recommendations is a crucial factor in obtaining good results, especially the mesh overlap $\geq$ 4 cm and the use of nonabsorbable fixation staples, in addition to an adequate postoperative care and follow-up regime. L3 hernia type presents a higher risk of recurrence, while patients with larger defects should be informed about the risk of a prolonged stay.

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