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LAPAROSCOPIC MANAGEMENT OF NON-MIDLINE INCISIONAL HERNIA: A MULTICENTRIC STUDY

Running title: management of non-midline incisional hernia

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Abstract

Background

Laparoscopic repair of Non Midline Ventral Hernia is actually debated. The aim of this study is to analyze the 6 years' experience of laparoscopic approach in NMVH in northwest of Italy.

Methods

We analyzed 78 patients who underwent to Laparoscopic repair of Non-Midline ventral hernia (LNM) between March 2008 and March 2014 in the selected institutions. We retrospectively analyzed perioperative and postoperative data and recurrence rate of 4 subgroups of NMVH: subcostal, sovrapubic, lumbar and epigastric. We also performed a literature review.

Results

There is no difference in 4 subgroups in terms of demographic data, defect characteristics, admission data and complications. Subcostal defects have a lower operating time. Obesity was a risk factor for recurrence.

Conclusions

In our experience Subcostal defects seems easier to perform, with a lower recurrence rate, lower chronic pain and faster surgical performance. Attending more specific prospective randomized trial with larger sample, we conclude that laparoscopic approach is a safe treatment for NMVH hernias in specialized centers.

Keywords: Non-Midline Ventral Hernia, ventral hernia, laparoscopic repair

Abbreviations:

NMVH: Non-Midline ventral hernia LNM: Laparoscopic repair of Non-Midline ventral hernia SCd: Subcostal defects (SCd), SPd: Sovrapubic defects (SPd), Ld: Lumbar defects (Ld), Ed: Epigastric defects (Ed). BMI: Body Max Index-BMI, COPD: Chronic Obstructive Pulmonary Disease COPD, NRS: numerical rating scale ASA: American Society of Anesthesiologist score

1. Introduction

Incisional hernias are defined as 'Any abdominal wall gap with or without a bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging' [1]. The incidence of incisional hernia following open surgery is about from 2 to 11% [2-4]. In 2000 Chevrel made a classification of ventral hernia and he proposed three parameters for a correct classification: localization of defects (median or lateral), size of hernia and recurrence at diagnosis [5]. The use of laparoscopy in last years reduced incisional hernia incidence [6, 7], but overall impact remains high. Non-Midline Ventral Hernia (NMVH) is a subgroup of ventral hernias and its incidence ranges between 6 and 17% of all ventral hernias. Moreno-Egea et al. [8] defined that the role of laparoscopy is not so clear in NMVH, because of involvement of different muscle groups; actually there are few articles about mini-invasive repair of these specific defects. Certainly, laparoscopic approach in abdominal surgery plays a key role in terms of length of incision, total hospital stay and patient preference. The main rules in laparoscopic abdominal wall surgery seem to be the adequate patient selection, correct defect dimension misurement and surgical ability. It is impossible to establish a gold standardized technique for all NMVH repair because of different topographic variations of these defects [9].

The aim of this study is to analyze the 6 years' experience of laparoscopic approach NMVH in northwest of Italy and to analyze the stratifications of results for age.

2. Methods

A multicentric prospective study involving 7 North-Italian institutions led to the recruitment of 78 patients who underwent to Laparoscopic repair of Non-Midline ventral hernia (LNM) between March 2008 and March 2014 in the selected hospitals. Patients were divided into four subgroups according to defect position: Subcostal defects (SCd), Sovrapubic defects (SPd), Lumbar defects (Ld), Epigastric defects (Ed).

We retrospectively analyzed: demographic data (age, gender, Body Max Index-BMI, Chronic Obstructive Pulmonary Disease COPD, previous surgery), defects data (localization, numbers, kind of previous surgery), type of pre-operative study, intraoperative data (operating time, conversion rate, drain), devices characteristic (mesh, method of fixation) and surgical complications (seroma, hematoma, recurrence, chronic pain) (Table 1).

Post-operative pain was evaluated using a VAS one-dimensional numerical rating scale (NRS), graded from 0 to 10 [10]. Evaluation was performed at day one after surgery, at the discharge and one month after surgery; the patients were also invited to contact us if pain occurred in 4 months after. We used definition proposed in prevention of chronic postoperative pain guidelines, in which chronic pain was defined as pain that persists for more than six months after the operation and that is due to synthetic material (mesh and fixing devices) used to repair the defect [11]. Exclusion criteria were: patients with American Society of Anesthesiologist (ASA) score > 3, urgent approach and neoplastic patients.

2.1 Surgical technique

All repairs were performed in laparoscopic approach; in 74 % of cases, the pneumoperitoneum was established at 12 mmHg by open Veress-assisted approach. Numbers of trocars depends on size and defects localization; in all cases we used triangular trocars position philosophy. Additional trocars placement depends on new defects discovery during laparoscopic abdominal wall exploration and on a difficult large mesh fixation. Lysis of adhesion was performed "à la demande" and a bladder catheter was inserted in all procedures for lower defects (SPd and Ld). Hernia fibrotic ring was always closely cleared and type of mesh was choosen during operation according to intraoperative defect measurement. Five centimeters overlap was respected; some surgeons used a suture-passer needle to place the mesh using guidewire previously placed on mesh cardinal points. Different fixation techniques at the same time. Pneumoperitoneum is always reduced (at 10 mmHg) before fixing. Trocars were removed under visual control and umbilical trocar access fascia was sutured. All procedures were performed by expert surgeons in abdominal wall reconstruction.

2.2 Follow-up evaluation

Follow-up analysis was performed in ambulatory setting at 1 week and a 1 months after surgery. We performed physical examinations and, only in selected cases, CT scan for detecting delayed complications. Chronic pain, recurrence rate and patient satisfaction were evaluated.

2.3 Bibliographic study

We performed a literature review to identify all case-series, review and case reports of NMVH. Pubmed, OVID platform, Cochrane library, Scopus, ISI web of Knowledge and Google Scholar were used to detect scientific publications using the following headings: non-midline ventral hernia, laparoscopy/ventral hernia, ventral hernia, laparoscopic hernioplasty, incisional hernia.

2.4 Statistical analysis

Statistical proportions of dichotomous variables (classification and type of hernia, number of complications) were compared using the Chi-square test and Fisher's exact test.

Continuous variables (age distribution, BMI distribution, mean operative time, postoperative length of hospital stay, operating time, ASA evaluation) were expressed as the average (range) and analyzed using Mann-Whitney U test. All statistical analyses were performed using R software (vers. 2.6.2); a P value of <0.05 was considered statistically significant.

3. Results

Patient clinical characteristics are shown in Table 1. All patients were > 55 years (89 % > 60 yeasr). The mean age was 61 years (+/- 7.1) Fourty patients of 78 were female (%) and mean BMI was 28 kg/m² (+/- 6). The most common defect was Ld, followed by SCd, Ed and SPd. Ld were more often single defects; Ed had the highest multiple defects incidence. Preoperative study was performed with TC scan in 54/78 patients; US evaluation was performed in 46/78 patients. "Skin to skin time" (in min) was significantly different and surgery for SCd (87.9 min) seems to be faster than other procedures; SPd repair was the longest (131.3 min). An additional trocars was added in 8 case of SCd, 6 cases of Ld, 4 cases of Ed and 1 case of SPd. Ed and SPd were similar at midline defects and fixation was performed by tacks in all defect perimeter (also on bone). In 50% of SCd, surgeon used tacks and suture passed association; in only 1 case glue was used to fix the mesh. In Ld usually meshes were fixed with resorbable tacks; in only 5 cases, additional suture pass was used. Five conversions to open surgery were required: 1 in SPd, 2 in Ld and 2Ed. No conversion was made in SCd. Intra- and post-operative complications, early and delayed, were similar to different groups (Table 1); seroma was the most common post-operative complications in all groups. We describe 4 cases of chronic pain, 2 in SCd 1 in SPd and 1 in Ed: pain persisted up to 6 months after surgery.

Fixing system was different depending on defect type and localization; the use of passed suture was significative different between subcostal defects and others.

Meshes most frequently used were 10x15 cm and 15x20 cm, usually Flexible Composite Polypropylene Mesh. We report only one early recurrence in epigastric hernia; instead, we had 3 delayed recurrence, one in Ed and 2 in SPd (1 at 10 months from the repair, 1 at 18 month e 1 at 24 months). Despite no statistical significance (p>0.05), comparation between defects site and recurrence rate showed that epigastric defects recurred earlier and frequently, while sovrapubic defects recurred later (Table 1). No recurrence has been reported in subcostal and lumbar group.

Univariate analysis concerning recurrence shows no significant correlation between recurrence incidence and defects localization, gender or age. We focused on SPd that in our experience was not a significative risk factor in recurrence, but only on limit range (p=0.0552). Instead, there is a statistical significance between recurrence rate and obesity (Table 2); all patients who have relapsed had BMI > 31.

Mean hospital stay was higher (6.4 days) for Ed and lower (4.55 days) for Ld.

Results for NMVH repair literature review are shown in Table 2. After primary research, we found 23 articles dealing with NMVH; we excluded 9 articles because they concerned peristomal defects, inguinal hernias recurrence and Grynfelt&Petits hernias. Finally included articles are 14: 4 case reports, 3 case series, 4 prospective studies, 3 retrospective studies. These studies were analyzed according to variables of interst for our study.

4. Discussion

In 1971 Ryan was one of the first authors describing NMVH repair with open approach; he presented a series of two patients (one male and one female, with a mean age of 36.5 years) affected by two single sovrapubic defects; the mean follow-up of 12 years. In 1994, Bendavid described a series of 7 patients that underwent to open NMVH repair, followed by only one recurrence. In the same year, Norris described a surgical repair of a sovrapubic defect in a 54 years-old man [13]. In 1999, the first two articles about NMVH laparoscopic repair were published: Matuszewski reported a case report of a 56 years-old man affected by sovrapubic defect after prostatectomy [14]. Surgical result was excellent, but follow-up was only of 6 months. Hirasa described a 7 defects serie, 6 male and 1 female, with one recurrence at 5.8 months follow-up [15]. Afterwards, other authors studied laparoscopic approach feasibility in NMVH (Table2); Moreno-Egeas and his group performed many appropriate studies: a randomized prospective trial in 2002 [16], a clinical study in 2007 [17] and 3 prospective studies in 2008 [18, 19] and 2012 [8].

According to laparoscopic instruments development, laparoscopic approach becomes safe and effective in most patients (young and elderly, elective and emergency surgery) [20, 21, 22] and mini-invasive approach for hernia repair become seductive for surgeon in terms of lower hospital stay and patient satisfaction, as shown in a meta-analysis published in 2011 [23].

In our series all procedures were performed in laparoscopy because of our belief that mini-invasive approach, in specialized centers, may be an excellent strategy also in elderly.

Mean hospital stay in our series is 5.2 days; Moreno-Egea et al. show a hospital stay of only 2.7 days [24] and Lal et al. published a mean hospital stay of 7 days [19].

We believe that hospital stay is a really important element, expecially for patients with clinical relevant co-morbidity and risk factors for early and delayed complications.

In our series, "Skin to skin time" was significantly different between different types of wall defects: SCd repair was the fastest procedure compared to other defects surgery; SPd repair was the longest.

This result does not have a clear explanation: we believe that a possible explanation could be that in SCd, defect is more "localized", so trocars setting and adhesion-lysis could be easier than in midline-defects, in which trocars positioning is often obstructed by adhesions all-over abdominal wall.

Some articles published before 2005 show that laparoscopic approach for incisional hernias is associated with pain related to transmural sutures and tackers used to fix the mesh on posterior abdominal wall, causing long hospital stay [25-29]. In 2000 DeMaria et al. conducted a comparative study between open and laparoscopic approach: laparoscopic approach could be performed in outpatient for 90% of cases, with less postoperative pain and lower hospital cost [30]. In 2014 Lal et al. described a zero rate of chronic pain in their NMVH laparoscopic experience [31]. Moreno-Egea prospective study published in 2012 reports a chronic pain rate of 9.5 %[25]. According with literature, we report 4 cases of postoperative chronic pain (5.1 %): 2 in SCd , 1 in SPd and Ed repair. A meta-analysis of randomized controller trial of open versus LS approach in ventral and incisional hernia published in 2009, demonstrated that there was no difference in perioperative complications [8]. Olmi shown that laparoscopic incisional hernia repair is associated with shorter operative time and hospital stay and lower

wound infections incidence compared to the anterior-open procedure [32].

Some authors reported a risk of 26 % for early minor complication in LS approach: hematoma and seroma rates are 6.5-17% [33].

In our analysis seroma appears in 20.5 % and no hematoma was observed: the higher seroma rate may be due to lightweight mesh use.

Although some authors aim that large pore-sized lightweight meshes are not better compared to "classic" heavyweight meshes [19], we agree with other authors that have demonstrated that seroma formation is related to small pore-sized heavyweight meshes [34].

Heniford, in a retrospective review of 407 patients undergoing laparoscopic repair, reported a recurrence rate of 3-4 % [35]. Moreno-Egea et al. published 11 recurrences in 199 ventral hernia laparoscopic repair (146 midline defects and 53 NMVH) [19].

We described 4 cases of recurrence (5%): 2 in Ed and 2 in Ld. Two recurrence occours in the first year of surgical experience, so they could depend on a technical error. The last recurrence has a multifactorial genesis. We believe that most of recurrences developed in first 12-14 months of surgical experience depends on technical error like inadequate fixation, excessive mesh shaping, inadequate tension of the prothesis when fixed on a non-physiologic wall (damaged wall) [36].

Some authors describe defect site like a non-dependent recurrence factor [37]. In our series there wasn't a statistical significance about this, but we believe that the absence of recurrence observed after SCd could be due to bone wall as a stronger substrate for fixing the mesh, although it could give a higher rate of chronic pain.

Defect size is a variable universally defined as independently associated with long-term recurrences. In our series the accurate patient selection has allowed to include all patients with defects in range with literature guideline.

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Our study results are notable for prosthetic infection absence: its incidence is reported in literature as low (2 cases in Moreno-Egea [19] serie and 1 in Carbonell [38]), but its consequences can be dire as severe sepsis, re-operation and septic shock to exitus.

Patients with ventral hernia are generally complex patients with many risk factors associated and strong co-morbidities [39, 40]. In literature, the risk factors that are principally related at the increasing of recurrence are: previous hernia repair, obesity and obstructive pulmonary disease [3]. Also in our experience obesity has proved to be a related factor in recurrence. In according to Moreno-Egea et al., we believe that obesity could be an adeguate indication for laparoscopic surgery, but it can also be considered as a limiting factor [8].

In literature, there is not consensus concerning drainage positioning after incisional hernia repair [41]. Some authors demostrated that drain can decrease seroma rate but may increase mesh infections risk [42]. In our experience we apposed an abdominal drain in only 8 cases: 4 in ld, and 2 in SPd and 2 in Ed. No drain was apposed in subcostal defects repair.

5. Conclusion

The retrospective, nonrandomized nature of this study, the multicentric data and the requirements of different patients in terms of environment are the major limitations of this study.

Laparoscpic approach in NMVH should be a safety procedure also in patients > 60 years old.

In our experience Subcostal defects seems to be the easier to performed, with a lower recurrence rate, lower chronic pain and faster surgical performance.

We are in agreement with Moreno-Egea that declared that technical difficulty of laparoscopic repair, in expert hands, is not a prognostic factor in non-midline incisional hernias [8].

We believe that excellent knowledge of abdominal wall anatomy and consciousness that a wall defects requires a normal abdominal wall anatomy restore are crucial points.

In clinical practice all patients with NMVH have their own defect characteristics, unique medical e surgical history, regardless age, so trying to defend a single technique seems to be complicated and wrong.

Attending more specific prospective randomized trial with larger sample, we conclude that, in our experience, the laparoscopic approach is a safe treatment for NMVH in specialized centers.

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Type of defects Statist	tical Analysis

	TOTAL	Subcostal	Sovrapubic	Lumbar	Epigastric	chi-square	p-value
Number	78	22	13	27	16	em-square	<i>p</i> -value
Follow-up	70	15.8	11	22.7	11.7		ns
(months)		15.0	11	22.7	11.7		115
(montins)							
Age (years)		55.6	61.5	61.3	58.25		ns
Male		12	4	14	8	2.09	ns
Female		12	9	13	8	2.07	ns
BMI (Obesity)		24.9	26.9	26.2	30		ns
Diabets		9	20.9	8	14	18.7	ns
COPD		15	4	18	16	6.4	ns
COLD		15	4	10	10	0.4	115
Drovious surgory	Digestive	22	0	26	11	36.3	ns
Previous surgery	Gynechologic	0	9	0	0	50.9	ns
	Urologic	0	4	1	0	30.9	
		0	0	0	5		ns
	Other	0	0	0	5		ns
Defe etc	C:	13	11	20	6	8.7	
Defects	Single			20		8./	ns
	Multiple	9	2	7	10		ns
	Size (diam cm)	6.7	7.5	7.37	11.7		ns
D	110	10	5	1.4	10	4.12	
Preoperative	US	12	5	14	12	4.13	ns
Staging		1.4			10	1.00	
TT 1 / T	TC	14	8	20	12	1.23	ns
Hospital	Mean H stay (days)	5.2	4.77	4.55	6.4		ns
admission		1.2	0.55		1.0		
	Discharge (days)	4.3	3.77	3.22	4.9		ns
Intraoeprative	Operating time (min)	87.9	131.3	97.44	111.87		< 0.05
variables							
	N° of port	3	3	3	3		ns
	Additional trocar	8	1	6	4	4.47	ns
	Drain	0	2	4	2	3.58	ns
	Conversion in open	0	1	2	2	2.58	ns
	procedure						
	Other defects	0	3	3	1	5.63	ns
	Other procedure	0	3	3	1	5.63	ns
	associated						
Early	Hematoma	0	0	0	0		ns
complications							
	Seroma	4	1	7	4		ns
	Recurrence	0	0	0	1		ns
	Port-site infection	0	0	1	0		ns
	Mesh infection	0	0	0	0		ns
Delayed	Chronic pain	2	1	0	1	1	ns
complications							
•	Recurrence	0	2	0	1	1	ns
	1		1	1	1	1	
Fixing devices	Resorbable tacks	6	6	12	4	2.99	ns
0	Titanium tacks	2	4	5	2	2.29	ns
	Glue	0	1	0	0	1	ns
	Stitches	1	0	1	6	1	ns
	Resorbable tacks +	11	1	5	1	1	< 0.05
	stitch	**	[•]		1		\$ 0.05
	Resorbable tacks +	1	1	2	1	1	ns
	Glue	-	-		1		
Type of mesh	Polyester	4	7	11	11	5.36	ns
- jpc of mean	Composite	16	2	7	2	20.6	< 0.05
	polypropylene	10	2	'	2	20.0	< 0.0 <i>J</i>
	Carboxymethylcellulo	1	3	3	2	2.77	ns
	se	1	5	5	-	2.11	115
	Polietrafluoroethylene	0	0	4	1	+	ns
	Prolene and	1	1	2	0	1	ns
	Prolene and						

Measures of mesh	10 x 15 cm	7	4	11	4	1.23	ns
	15 x 20 cm	12	5	7	5	4.55	ns
	12 cm	1	0	0	1		ns
	15 cm	2	2	2	0		ns
	20 cm	0	1	2	2		ns
	20 x 30 cm	0	1	5	4		ns

 Table 1: Perioperative data

 (BMI: boody max index, COPD: Chronic Obstructive pulmonary disease)

		Recurrence	Non Recurrence	p-value
Age		61.4 ± 7.2	61.2 ± 7.0	ns
Gender	М	1	37	ns
	F	3	37	ns
BMI (Obesity)		4	55	< 0,05
COPD		3	50	ns
Site defects	SC	0	22	ns
	SP	2	11	0,0552
	L	0	27	ns
	Е	2	14	ns

Table 2: Analysis of risk factors in recurrence.

(SC: subcostal defect SP: sovrapubic defect L: lumbar defect E: epigastric defect , BMI: boody max index, COPD: Chronic Obstructive pulmonary disease)