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Original Research

Laparoscopic ventral hernia repair: Results of a two thousand patients prospective multicentric database

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ABSTRACT

Laparoscopic incisional and ventral hernia repair (LIVHR) has been largely employed by the surgical community worldwide, despite the use of different types of mesh and fixation devices.

A large nationwide prospective multicentric database collected 2005 operations from 8 high-volume centers, to investigate the perioeperative and long-term outcomes.

The laparoscopic operations were completed in 1979 patients (98.7%), with a mean age of 60.7 years and a Body Mass Index of 28.8 kg/m^2. Two hundred and one patient (18.8%) had a previous failed open repair. The average surface areas of the major defects were 47.4 and 18.2 cm 2 for postincisional and primary hernias. The mean operation time and postoperative stay were 94.4 min and s 3.7 days, respectively. We collected a total of 50 (2.5%) intraoperative and 414 (20.6%) postoperative complications, with reoperation needed in 38 cases (1.8%). After a mean follow-up period of 24 months, we recorded 62 (3.8%) confirmed recurrences. Length of surgery, hospital stay, and a previous recurrence were all risk factors for recurrence. Primary hernias had better perioperative outcomes compared to incisional hernias, except for the pain.

The laparoscopic approach of both post-incisional and primary hernias seemed to be safe and feasible in short-to medium-term periods.

1. Introduction

Surgical repair of ventral hernias, including both postincisional and primary defects, represents a major challenge in many hospitals worldwide. The reported incidence of postincisional herniation can reach more than 22% at 3 years after a midline laparotomy [1], leading to considerable social costs and impairment, with up to 10% of these cases requiring further emergent surgery [2,3]. The exact incidence of primary abdominal wall herniation (excluding the groin) varies widely, but it has been reported to be more than 10% in surgical reviews [4,5].

No standard operative technique has been accepted by the surgical community due to the high incidence of morbidity and recurrences [6]. Although the use of prosthetic mesh [7]to reinforce the abdominal wall strength and to minimize recurrence has become the cornerstone of any approach, many differences remain regarding the site of mesh positioning, including the subcutaneous, retrofascial, retromuscular, preperitoneal or intra-abdominal layer [8,9]. Interestingly, the use of prosthetic mesh has been reported in association with larger incisions and dissections, which could lead to increased seroma formation and wound infections, with recurrence still occurring in up to 30% of cases [5,7].

Since the advent of laparoscopy, many surgical teams have begun to place an intraperitoneal mesh utilizing trocar ports to correct any wall defects. From a theoretical perspective, laparoscopic incisional and ventral hernia repair (LIVHR) could guarantee an excellent cure for the disease while avoiding extensive surgical dissection and wide reincisions. Furthermore, LIVHR was also expected to reduce the incidence of recurrence, postoperative pain, and the length of hospital stay and to

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improve patient satisfaction.

Despite a large number of encouraging retrospective, prospective, randomized trials (very few), reviews, evidence-based international guidelines [10,11] and meta-analytic studies that have been published [12], including a Cochrane review [13] suggesting that LIVHR could be superior to the open approach with regard to the aforementioned outcomes, others reported equivalent or suboptimal results [14–16], and its widespread acceptance is not yet realized. For this reason, most ventral hernia defects are still repaired by traditional open surgery in Italy.

Therefore, a prospective, multicentric, Web-designed database for LIVHRs was maintained from November 1999 to December 2014 to collect a large number of cases from the principal group performing this technique. The purpose was to provide an image of the field experience and results from different centers involving many surgeons.

2. Materials and methods

From November 1999 to December 2014 a prospective, multicentric, Web-designed database (called "*Caligola*") was maintained to investigate the results of a large Italian experience. The participating hospitals were 8 high-volume centers in the north, center and south of Italy. Exclusion criteria were the presence of skin infections, fistulas or loss of domain, although adult patients with challenging characteristics were included (i.e., urgency, morbid obesity, severe comorbidities and those who receive concomitant surgeries). The collection of cases was subjected to an intention-to-treat policy, considering the converted patients in the definitive analysis. Each surgical team involved more than one surgeon, but all of them had substantial (> 20 cases) prior experience in LIVHR.

The management of the dataset and the further studies were conducted according to the Declaration of Helsinki, but no specific Local Ethics Committee approval was required. Informed written consent was obtained from all patients before surgery, together with standardized approval of anonymous personal data management for scientific purposes only. The work was reported in line with the STROCSS criteria [17].

The indications for surgery included symptomatic or large (more than 5 cm^2) postincisional abdominal hernias and primary ventral hernias of any region, including umbilical, epigastric or Spigelian defects. A recurred operated primary hernia was considered as a post-incisional hernia. In most of the hospitals involved in the study, defects smaller than 5 cm^2 were not considered suitable for laparoscopic repair. In these circumstances, the preferred approach was direct or mesh repair under local anesthesia. Despite this fact, the dataset included some very small defects concomitant with other laparoscopically operated diseases. Urgent operations were considered those performed for strangulation if performed within 6 h after admission to the Emergency Department.

The perioperative management of patients was not standardized among the participating centers, but prophylactic ultrashort-term (single-dose) antibiotic therapy (2nd generation cephalosporin) and antithrombotic therapy (heparin or low-weight molecular heparin in more recent years) were also administered routinely. Naso-gastric suction and bladder catheterization were utilized for the duration of the surgery only. All operations were conducted under general anesthesia, according to local preferences.

The laparoscopic technique was standardized in the main steps during previous meetings (hernia reduction and mesh fixation), but each surgeon was free to choose his or her preference regarding the pneumoperitoneum, number and size of trocars, instruments for dissection and adhesiolysis and management of the hernia sac. The type of mesh was an expanded polytetrafluoroethylene (ePTFE) mesh (DualMesh®, WL Gore, Flagstaff, AZ, USA) placed intraperitoneally and overlapping the wall defect for at least 4 cm in all directions. Mesh fixation was achieved with a double circular line of helicoidal clips (ProTack® 5 mm, AutoSuture USSC, Norwalk, CT, USA), the first at the edge of the mesh and the second as an inner circle, avoiding to clip the sac. Definitive sutures at the cardinal points were not employed routinely. The use of any compressive dressing (5–7 days until the first outpatient visit) and drainage suction was also employed in selected cases. The treatment of perioperative pain was also performed according the preference of each center, including "on-demand," oral and intravenous analgesic therapy. Oral feeding and deambulation were permitted rapidly. After discharge, patients were scheduled for outpatient clinic visits at one and four weeks, and encouraged to return periodically and contacted by phone to complete the medium/long-term follow-up.

Demographics, BMI, ASA status, comorbidities, and all perioperative records, including hernia characteristics, surgical details, outpatient files and long-term follow-up, were collected prospectively from the database for each center. In details, the incidence of recurrences was measured by phone interviews as well as by clinical examination. Patients who complained a recurrence during phone interviews were also invited to the outpatient clinic for confirmation. In doubtful cases, further radiologic (CT-scan) examination was also scheduled. The outpatient visits were scheduled according to each Center preferences. Moreover, a further additional telephone call was achieved at the time of the closure of the present study. If a patient was lost during follow-up, we registered the case with/without recurrence at the time of the last visit/interview.

The data were transposed on an electronic spreadsheet and were analyzed using commercially available software, i.e., the SPSS® software package, version 18.0 (SPSS Inc., Chicago, IL, USA). Quantitative variables were examined by Student's t-test, while proportions were compared using the chi-square test or Fisher's exact test when appropriate. The Mann-Whitney *U* test was also used for comparisons of nonparametric data. Univariate and multivariate analyses were performed using Kaplan-Meier and Cox regression analyses for long-term follow-up (different time, censored data), introducing in the model variables with the highest or the lowest ($p < 0.5$) univariate risks only. Statistical significance was defined as $p < 0.05$, while the results are described with hazard ratios and 95% confidence intervals. All the p-values reported were two-tailed. $P < 0.05$ was considered statistically significant in each test.

3. Results

The "*Caligola*" database included a total of 2005 patients from 8 participating centers distributed throughout Italy. The mean number of recruited patients was equally distributed for each hospital (ranging from 10 to 18%), except for one that included only 1% of the whole cohort.

The baseline and demographic preoperative characteristics of the patients, including concomitant illnesses, are summarized in Table 1. The mean BMI was 28.8, reflecting a tendency toward morbid obesity that is consistent with a Western population. Only 127 (6.7%) patients were operated on under urgent regimens, while almost a quarter (23.6%) fell into the American Society of Anesthesiology status (ASA) of 3–4. Notably, a large percentage of patients suffered from hypertension (40.6%), morbid obesity (24.7%) and heart disease (12.6%). Almost one quarter of the entire cohort consisted of smokers (22.2%).

The characterization of the defects were more than half post-incisional hernias (53.3%) and 24.7% of primary hernias, with the remainder being combined or multiple defects. In more than 10%, the surgeons failed to provide a clear description of the hernia. The average surface areas of the major defects were 47.4 and 18.2 cm^2 for post-incisional and primary hernias, respectively.

A previous attempt at repair was undertaken in more than 18.8% of the patients before the laparoscopic repair, most of which were achieved by laparotomy with anterior mesh positioning (60.8%). A detailed classification of post-incisional and primary hernias is provided