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Factors of selection and failure of ambulatory incisional hernia repair : a cohort study of 1429 patients

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Introduction

Incisional hernia is a common complication following abdominal surgery with an incidence of 12.8% after midline incision [1]. It is estimated that about 35000 incisional hernia repairs (IHR) are performed every year in France [2].

In the mid-2000s, the first publications of day-case IHR have emerged [3–8]. Nevertheless, these studies were mainly based on a small number of patients and reported the results of IHR carried out by a laparoscopic approach only. Ambulatory IHR seems to be safe and feasible but no recommendations support this practice so far.

The aim of this study was to assess the ambulatory practice for IHR in France and to identify preoperative factors of selection and situations of non-fulfillment of an ambulatory procedure.

Method

Data collection

A large scale database concerning IHR practice in France was established at the initiative of the “Club Hernie”. “Club Hernie” is a group of experienced surgeons, spread across France and particularly familiar with abdominal wall surgery. Within this group, surgeons prospectively collect their data regarding every performed abdominal wall procedure in a dedicated registry [9].

Surgeons of the “Club Hernie” prospectively gathered the data of successive IHR between 08/09/2011 and 22/04/2016. Data concerning patient characteristics were completed preoperatively. ASA grade was determined by the anesthesiologist. Surgical technique employed was left to the discretion of the surgeon. Perioperative items were filled out online in real time after each procedure. Post-operative items were completed along the way of the follow-up.

Data collected in the database were:

- Patient characteristics : age, sex, body mass index (BMI), ASA grade
- Incisional hernia characteristics : preoperative symptoms, site of the incisional hernia, hernia recurrence, hernia width according to the EHS classification (small <4cm, medium 4-10cm, large >10cm) [10]
- Procedure : surgical technique employed, operating time, ambulatory or inpatient setting, length of stay, complication, grade of the complication according to Clavien-Dindo [11]
- Causes if ambulatory was not proposed or failed

The patients were admitted to the hospital in the morning, operated on, monitored and then discharged if they satisfied the conditions of an ambulatory procedure : satisfying vital signs, absence of bleeding or pain, oral intake, deambulation and urination. If not, they were admitted in the surgical department for further surveillance and counted as a failure of the ambulatory setting. Then, each patient was seen by the surgeon one month after the surgery or before if necessary.

One-day surgery was defined as a hospital stay < 12 hours, with admission and discharge on the same day, according to the current definition of the International Association for Ambulatory Surgery [12]. The ambulatory setting was decided by both the surgeon and the anesthesiologist. The reasons why the patient had not been selected for an ambulatory procedure were reported in the database as well as the causes of failure of a previously selected ambulatory setting.

Complications were divided into medical complications, surgical site collections (SSC) and surgical complications. Early post-operative complications were medical (acute urinary retention, cardiovascular or neurological disorders) or surgical complications likely to delay the discharge of the patient. Infected and uninfected collections (seroma, hematoma) were considered as surgical site collections.

Statistical analysis

Comparisons of qualitative and quantitative data were respectively performed using the chi-squared test and Student's T-test. Multivariate regression logistic models were used to identify predictive factors of (i) whether or not an ambulatory procedure was proposed (yes/no) and (ii) whether a proposed ambulatory procedure was successful or not (yes/no).

To facilitate an easy interpretation of the model coefficients, all numeric variables were centered at their mean value.

Statistical analyses were performed using the statistical software R version 3.3.1 (R: A language and environment for statistical computing. R foundation for Statistical Computing, Vienna, Austria). A statistical significance level of 0.05 was used.

Results

A total of 1429 patients were operated on for IHR between 08/09/2011 and 22/04/2016. The mean age was 63.3 (22-97) years. 697 (48.8%) patients were males. The mean BMI was 29.4 kg/m² and 481 (33.7%) patients had an ASA grade $\geq$ III. Most of the patients suffered from incisional hernias less than 10 cm wide. Patients' characteristics are presented in Table 1.

Two hundred and seventy-two (19%) procedures were performed as an ambulatory surgery (Table 2). Mean length of stay of hospitalized patients was 4.6 days (1-84).

Open IHR were mainly performed (962 patients, 67.3%). The mean operating time was 54.7 minutes.

A total of 190 (13.3%) patients experienced at least one complication (Table 3). The most frequent complications were uninfected surgical site collections, broncho-pulmonary complications and small bowel obstructions. There were less complications in the ambulatory group as compared to the inpatients.

Complications were mainly minor according to the Clavien-Dindo classification [11]. Twenty-six (1.8%) patients experienced serious complications ($\geq$ IIIb) and 2 (0.1%) of them died. No severe complications or unplanned readmissions were reported in the ambulatory group.

A total of 1124 (78.7%) patients were not selected preoperatively for an ambulatory procedure. It has been reported that ambulatory was not proposed in about 25% of the patients because of organizational issues (supporting problems, combined act during the same admission, comprehension or social problem, long distance from hospital, or unavailability of the ambulatory care unit). Medical conditions such as ASA grade $\geq$ III, sleep-disordered breathing or medication relay were other main reasons for not proposing an ambulatory setting for IHR (Table 4).

Age (OR 0.97; $p < 0.001$), BMI (OR 0.95, $p < 0.001$), ASA grade $\geq$ III (OR 0.23, $p < 0.001$), hernia width ≥ 4 cm (OR 0.44, $p < 0.001$), recurrent hernia (OR 0.55, $p = 0.01$) and laparoscopic IHR (0.56, $p < 0.01$) were identified as factors influencing practitioners for not selecting patients for an ambulatory care (Table 5).

Conversely, 305 patients were selected pre-operatively for an ambulatory procedure. Among these patients initially selected for a one-day procedure, 272 (89.2%) patients were successfully managed in an ambulatory setting.

In the database, half of the ambulatory failures were caused by medical problems such as pain (10 patients, 33%), vomiting (6 patients, 18%) or fainting/headache (2 patients, 6%). Social or organizational issues (supporting problem, late check-out from the operating room

or stress) explained about 15% of the failures although one-day surgery was initially planned (Table 6).

Although hernia width ≥ 4 cm, laparoscopic incisional hernia repair or occurrence of an early post-operative complication tended to be associated with a failure of ambulatory care, none of these factors reached statistical significance (Table 7).

Discussion

Little is reported concerning one-day surgery for IHR and the majority of the studies concerned laparoscopic IHR. In this multicenter study, we aimed to assess the practice of ambulatory surgery for IHR in France using a prospective large-scale database. Data concerning 1429 successive IHR have been gathered by senior surgeons, working all around the country, during a period of nearly 5 years. Two hundred and seventy-two (19%) patients underwent an ambulatory IHR. Only 33 (11%) of the 305 preoperatively selected patients for ambulatory failed and were finally kept in the hospital for further surveillance. Ambulatory surgery for IHR is safe and feasible but relies on a good preoperative selection of the patients.

Increasing age, BMI, ASA grade $\geq$ III, incisional hernia width ≥ 4 cm, recurrent hernia and laparoscopic procedure were identified as pre-operative factors influencing practitioners for not selecting patients for an ambulatory procedure. Ambulatory surgery was sometimes not proposed because of organizational issues which do not endanger the patients. However, none of these factors were identified to be predictive of ambulatory failure. Particularly, IHR of hernias wider than 4cm in obese patients appeared to be feasible.

As a comparison, a previous study of our group highlighted that an ASA grade $\geq$ III, a bilateral hernia repair, an emergency care for incarcerated hernia, a spinal anesthesia or the occurrence of an early postoperative complication were risk factors for ambulatory failure in patients initially selected for one-day surgery [13].

The mean age of the patients was 63.3 (22-97) years old in the whole cohort. Age alone is not considered as a contra-indication for ambulatory surgery as such. Older patients probably benefit less from outpatient surgery because of higher comorbidities and wider incisional hernias. Qin et al. assessed the incidence of 30-day complications and unplanned readmissions, following outpatient ventral hernia repair, based on the national surgical quality improvement project data files [14]. They highlighted that age and body mass index were predictors of overall complications and surgical complications.

Likewise, ASA grade $\geq$ III has been identified as a predictor of unplanned readmissions after outpatient ventral hernia repair (OR 1.46, $p=0.008$) [14]. In our experience, only 11% of patients with an ASA grade $\geq$ III underwent an ambulatory IHR and 20% of the patients were not selected preoperatively for one-day surgery because of such a condition. In France, the health care system does not recommend to consider patients from ASA grade $\geq$ III with unstable disease for ambulatory surgery [15]. Sanjay et al. compared postoperative complications after inguinal hernia repair and did not find significant differences between ASA grades I-II and ASA grades III-IV patients [16]. Inguinal hernia surgery was mainly performed under local anesthesia in this report. As a result, ASA grade III and IV patients should not be strictly contraindicated for one-day surgery.

We also identified the size of the hernia to be paramount in the ambulatory selection. The EHS classification was used in our registry [10]. Hernia width $\geq$ 4 cm was identified to be

predictive of non-selection for an ambulatory care. Indeed, almost 65% of the patients selected for an ambulatory care suffered from small incisional hernias (<4 cm) whereas the majority of medium or large incisional hernias were excluded. All the above confirms the external validity of this classification [17]. The hernia size should be definitely considered when selecting the patients for an ambulatory procedure.

One hundred and ninety (13.3%) patients experienced at least one complication. There were less complications among the patients benefiting from ambulatory surgery as compared to the inpatients. The main complications reported were uninfected superficial subcutaneous collections, broncho-pulmonary complications and small bowel obstructions. Among uninfected superficial subcutaneous collections, the occurrence of a seroma is a common situation, but it usually arises later and thus does not delay the patient outlet. However, the rate of seroma was not higher in the ambulatory group. Two patients suffered from an abdominal compartment syndrome and 2 patients experienced an early recurrence of incisional hernia. These latter rare but serious complications occurred in hospitalized patients. Two patients died of a complication. In their experience concerning 259 consecutive laparoscopic IHR, performed in a short stay surgery department, Lorente-Herce et al. reported a 9.8% rate of complications [6]. Main complications were intraoperative (intestinal wound, bleeding, need for conversion) or early postoperative ones such as prolonged ileus or hematoma. Forty (15.74%) seroma requiring percutaneous evacuation occurred in this study but were considered as late post-operative complications and were not included in the total complication rate. Three patients experienced serious complications (bile peritonitis, acute peritonitis following an intestinal perforation and intestinal obstruction caused by an inadequate fixation of the mesh) and were reoperated on. They

only readmitted two patients (<1%) due to intra-abdominal hematoma or colo-cutaneous fistula. This data was not gathered at the time of the study in our registry.

One thousand one hundred and fifty-seven (81%) patients were hospitalized for the management of their incisional hernia. One in four patients were not selected preoperatively for ambulatory IHR because of organizational issues (supporting problems, combined act during the same admission, comprehension or social problem, long distance from hospital or unavailability of the ambulatory care unit). These reasons for not proposing one-day surgery could be reconsidered particularly concerning healthy patients. Selection criteria for one-day surgery should take into account age, body mass index, ASA grade, hernia recurrence and hernia width according to our findings. In their experience, Donati et al. proposed hernia size <10 cm, reducible hernia sac and negative history for obstructive symptoms as selection criteria for ambulatory IHR performed under local anesthesia [4].

Apart from organizational or social issues, pain and vomiting were the main reasons of ambulatory failure in respectively 30 and 18% of the patients who failed for initially planned ambulatory setting. Strict anesthetic protocols should be proposed to prevent post-operative pain and vomiting such as early administration of analgesia, loco-regional anesthesia (infiltration of the incisions, TAP-block) and anti-emetic drugs [18].

Unfortunately, some data were missing to better specify the causes of non-selection or failure of ambulatory such as age, hernia width or the need for post-operative drainage. These criteria were reported in the “other causes” or were not available.

To our knowledge, this is the first study reporting one-day surgery for incisional hernia in so many patients operated on regardless of the technique. The data are based on a nationwide registry, rigorously filled-out by experienced surgeons. Three hundred and five patients were

selected for one-day IHR and 272 achieved ambulatory care. Nevertheless, the global rate of ambulatory surgery for IHR remained modest.

Conclusion

Based on a nationwide database of 1429 patients operated on for IHR, we assessed the current practice of ambulatory surgery for IHR in France. Only 33 on 305 patients (11%) failed for a previously planned ambulatory care. Increasing age, body mass index, ASA grade $\geq$ III, hernia width $\geq$ 4 cm and laparoscopic IHR were identified as factors influencing practitioners for not proposing an ambulatory care. One-day surgery was sometimes not proposed because of organizational issues which do not endanger the patient. A good preoperative selection, based on objective criteria, is required to achieve ambulatory surgery for IHR. Such a care setting should be systematically proposed for IHR of small incisional hernias (<4cm) in young patients with few comorbidities.

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<i>Age (years)</i>	<i>63.3 ± 14 (22-97)</i>
<i>Sex (n, %)</i>	
- Male	697 (48.8)
- Female	732 (51.2)
<i>BMI (kg/m²)</i>	<i>29.4 ± 6.4 (16-75)</i>
<i>ASA grade ≥ III (n, %)</i>	<i>481 (33.7)</i>
<i>Hernia width ≥ 4cm (n, %)</i>	<i>746 (52.2)</i>
<i>Recurrent incisional hernia (n, %)</i>	<i>257 (18)</i>

Table 1. Patients characteristics. Age and BMI are summarized by their mean, standard deviation and range. Categorical variables are summarized by the number of patients in each category and the corresponding percentages.

<i>Ambulatory procedure (n, %)</i>	<i>272 (19)</i>
<i>Surgical technique (n, %)</i>	
- Open IHR	962 (67.3)
- Laparoscopic IHR	467 (32.7)
<i>Operating time (minutes)</i>	<i>54.7 ± 48.8 (5-480)</i>
<i>Complication (n, %)</i>	<i>241 (16.9)</i>
- Medical	71 (5)
- Surgical site collection	110 (7.7)
- Surgical	60 (4.2)

Table 2. Procedures characteristics. Operating time is summarized by mean, standard deviation and range. Categorical variables are summarized by the number of patients in each category and the corresponding percentages.

<i>Complications</i>	<i>Ambulatory IHR</i>	<i>Inpatient IHR</i>	<i>Total</i>
<u><i>Medical (n, %)</i></u>			
<i>Broncho-pulmonary</i>	0	23 (2)	23 (1.6)
<i>Acute urinary retention</i>	0	13 (1.1)	13 (0.9)
<i>Cardio-vascular</i>	0	6 (0.5)	6 (0.4)
<u><i>Surgical site collections (n, %)</i></u>			
<i>Uninfected sc col.</i>	7 (2.6)	65 (5.6)	72 (5)
<i>Uninfected pp col.</i>	0	18 (1.5)	18 (1.3)
<i>Infected subcutaneous col.</i>	1 (0.4)	16 (1.4)	17 (1.2)
<i>Infected pp col.</i>	0	6 (0.5)	6 (0.4)
<u><i>Surgical (n, %)</i></u>			
<i>Small bowel obstruction</i>	1 (0.4)	12 (1)	13 (0.9)
<i>Intraperitoneal abscess/peritonitis</i>	0	6 (0.5)	6 (0.4)

Table 3. Complications. Only the most common complications are reported. Complications were distinguished by medical complications, surgical site collections or surgical complications. SC, Sub Cutaneous. Col, Collection. PP, Pre-peritoneal.

<i>Ambulatory not proposed</i>	
<i>Total no. of patients (n, %)</i>	1124
<i>Supporting problem</i>	118 (10.5)
<i>Comprehension/Social problem</i>	45 (4)
<i>Distance from hospital</i>	36 (3.2)
<i>Combined act</i>	68 (6)
<i>Ambulatory unavailable</i>	6 (0.5)
<i>ASA ≥ III</i>	230 (20.5)
<i>Sleep-disordered breathing</i>	12 (1)
<i>Medication relay</i>	17 (1.5)
<i>Other causes</i>	330 (29.4)
<i>Multiple causes</i>	262 (23.3)

Table 4. Ambulatory not proposed. Specified reasons for not proposing an ambulatory setting are reported.

	<i>Selected for ambulatory</i>	<i>Not selected for ambulatory</i>	<i>OR</i>	<i>p</i>
<i>Total no. of patients (n, %)</i>	305 (21.3)	1124 (78.7)	-	-
<i>Age (years)</i>	57.4	65	0.97	<0.001
<i>Male gender (n, %)</i>	143 (46.9)	554 (49.3)	1.01	0.85
<i>Body Mass Index (kg/m²)</i>	27.2	30	0.95	<0.001
<i>ASA grade ≥III (n, %)</i>	34 (11.1)	447 (39.8)	0.23	<0.001
<i>Physical occupation (n, %)</i>	36 (11.8)	88 (7.8)	0.97	0.75
<i>Intensive sport practice (n, %)</i>	23 (7.5)	24 (2.1)	2.06	0.01
<i>Hernia width ≥4 cm (n, %)</i>	108 (35.4)	638 (56.8)	0.44	<0.001
<i>Recurrent hernia (n, %)</i>	32 (10.5)	225 (20)	0.55	0.01
<i>Laparoscopic IHR (n, %)</i>	82 (26.9)	385 (34.2)	0.56	<0.001

Table 5. Comparison of patients selected and not selected for ambulatory upon multivariate analysis. Age, BMI and operating time are summarized by their mean, standard deviation and range. Categorical variables are summarized by the number of patients in each category and the corresponding percentages.

<i>Ambulatory failure</i>	
<i>Total no. of patients (n, %)</i>	33
<i>Pain</i>	10 (30)
<i>Acute urinary retention</i>	1 (1.7)
<i>Fainting, headache</i>	2 (6)
<i>Vomiting</i>	6 (18)
<i>Supporting problem</i>	2 (6)
<i>Late check-out from operating room</i>	1 (3)
<i>Stress</i>	2 (6)
<i>Other causes</i>	6 (18)
<i>Multiple causes</i>	4 (12)

Table 6. Causes of ambulatory failures. Specified reasons of ambulatory failure are reported.

	<i>Outpatient IHR</i>	<i>Ambulatory failure</i>	<i>OR</i>	<i>P</i>
<i>Total no. of patients</i>	272	33	-	-
<i>Age (years)</i>	57.5	58.3	1	0.88
<i>Male Sex (n, %)</i>	132 (48.5)	11 (33.3)	2.29	0.08
<i>Body Mass Index (kg/m²)</i>	27.1	27.5	0.99	0.81
<i>ASA grade ≥ III (n, %)</i>	30 (11)	4 (12.1)	1.09	0.9
<i>Physical occupation (n, %)</i>	34 (12.5)	2 (6)	1.28	0.76
<i>Intensive sport practice (n, %)</i>	21 (7.7)	2 (6)	0.81	0.78
<i>Hernia width ≥ 4cm (n, %)</i>	92 (33.8)	16 (48.5)	0.50	0.10
<i>Recurrent hernia (n, %)</i>	27 (9.9)	5 (15.2)	0.68	0.53
<i>Laparoscopic IHR</i>	70 (25.7)	12 (36.4)	0.46	0.07
<i>Early post-operative complication (n, %)</i>	3 (1.1)	2 (6)	0.13	0.058

Table 7. Comparison of outpatient procedures achieved and ambulatory failures upon multivariate analysis. Age and BMI are summarized by their mean. Categorical variables are summarized by the number of patients in each category and the corresponding percentages.