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ORIGINAL ARTICLE

Incidence and risk factors for incisional hernia and recurrence: Retrospective analysis of the French national database

Benoit Gignoux[1] | **Yves Bayon**[2] | **Damien Martin**[3] | **Raksmey Phan**[4] | **Vincent Augusto**[4] | **Benjamin Darnis**[1] | **Marianne Sarazin**[4]

[1]Clinique de la Sauvegarde, Lyon, France

[2]Sofradim Production, a Medtronic company, Trevoux, France

[3]Ecole des Mines d'Albi, Albi, France

[4]Ecole des Mines de Saint-Etienne, Saint-Etienne, France

Correspondence
B. Gignoux, Digestive Surgeon, Clinique de la Sauvegarde, Lyon, France.
Email: gignoux@chirurgien-digestif.com

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Abstract

Aim: The aim of this work was to determine the rate of incisional hernia (IH) repair and risk factors for IH repair after laparotomy.

Method: This population-based study used data extracted from the French Programme de Médicalisation des Systèmes d'Informations (PMSI) database. All patients who had undergone a laparotomy in 2010, their hospital visits from 2010 to 2015 and patients who underwent a first IH repair in 2013 were included. Previously identified risk factors included age, gender, high blood pressure (HBP), obesity, diabetes and chronic obstructive pulmonary disease (COPD).

Results: Among the 431 619 patients who underwent a laparotomy in 2010, 5% underwent IH repair between 2010 and 2015. A high-risk list of the most frequent surgical procedures (>100) with a significant risk of IH repair (>10% at 5 years) was established and included 71 863 patients (17%; 65 procedures). The overall IH repair rate from this list was 17%. Gastrointestinal (GI) surgery represented 89% of procedures, with the majority of patients (72%) undergoing lower GI tract surgery. The IH repair rate was 56% at 1 year and 79% at 2 years. Risk factors for IH repair included obesity (31% vs 15% without obesity, $p < 0.001$), COPD (20% vs 16% without COPD), HBP (19% vs 15% without HBP) and diabetes (19% vs 16% without diabetes). Obesity was the main risk factor for recurrence after IH repair (19% vs 13%, $p < 0.001$).

Conclusion: From the PMSI database, the real rate of IH repair after laparotomy was 5%, increasing to 17% after digestive surgery. Obesity was the main risk factor, with an IH repair rate of 31% after digestive surgery. Because of the important medico-economic consequences, prevention of IH after laparotomy in high-risk patients should be considered.

KEYWORDS
healthcare costs, hernia recurrence, hernia repair, incisional hernia, laparotomy, quality of life

WHAT DOES THIS PAPER ADD TO THE LITERATURE

Based on the French PMSI database, this nationwide study allows to give the real rates of incisional hernia (IH) repair after laparotomy. The risk factors of IH repair can be accurately assessed, especially the type of surgery or comorbidities.

INTRODUCTION

Incisional hernia (IH) is a common complication of laparotomy involving the abdominal wall, with a risk of developing IH ranging from 5% to 20% in published studies [1,2] and a 5-year prevalence of up to 69.1% in some high-risk patient groups [3]. According to the systematic review and meta-regression of 56 selected publications (14 618 patients) conducted by Bosanquet et al. [4], the prevalence of IH after midline incision was 12.8% (range 0%–35.6%) at a weighted mean of 23.7 months. In a 10-year prospective study, Mudge and Hughes [5] showed that <50% of IHs occur in the first year after surgery, and in another study Fink et al. [6] showed that the rate of IH increased significantly from 12.6% at 1 year to 22.4% at 3 years after surgery. The latter authors suggested that follow-up for at least 3 years should be mandatory to adequately assess the true incidence of IH after midline laparotomy.

Several risk factors have been associated with an increased IH rate after midline laparotomy, including greater patient age, type of surgery (surgery for abdominal aortic aneurysm or surgery using an upper midline incision), previous laparotomy or previous IH [4], local wound infection [7–9], obesity [4,9–12], the surgical technique used to close a midline abdominal incision [9,13–15] and the presence of comorbidities, including diabetes, exposure to tobacco smoke (smokers and ex-smokers), high blood pressure (HBP) and chronic obstructive pulmonary disease (COPD) [2].

Recurrence of IH is also a problem after IH repair, with a prevalence of 27.7% at 2 years [16] and a cumulative 5-year frequency of reoperation of 12.3%, with over 23% of patients undergoing reoperation by 13 years [8]. In the latter study, the 5-year reoperation rate was 23.8% after the first IH repair, 35.3% after the second IH repair and 38.7% after the third IH repair [16]. A large number of risk factors for recurrence of IH have been identified, including age >45 years, male gender, obesity, previous hernia repair, lateral hernia, concomitant digestive operations and surgical site complications, with patients having three or more risk factors being most likely to suffer recurrence during follow-up [17]. Mesh repair was an independent protective factor for IH recurrence [1,16,17]. Repeated IH repairs are generally more complicated and can lead to poor quality of life (QoL) [18,19] and a vicious cycle of complications and costs [20,21] as IH occurrence and recurrence after laparotomy involve significant direct and indirect medical costs. The median direct cost of IH repair was estimated by Alli et al. in 2018 [21] to be USD 20 000, and Gillion et al. reported a mean total cost of IH repair in France in 2011 of EUR 6451, ranging from EUR 4731 for unemployed individuals to EUR 10 107 for employed patients [22].

The French nationwide hospital discharge database, Programme de Médicalisation des Systèmes d'Informations (PMSI), has collected data from all public and private hospital stays in France since 2006, including patient trajectories after laparotomy [23]. It currently holds inpatient care data such as type of surgery, dates, diagnoses and hospital reimbursements for over 25 million hospital stays and 11 million patients, who can each be followed by a unique anonymous ID number. The database has increasingly been used to study trends in surgery in terms of practice and clinical outcomes.

Based on data extracted from the PMSI database, the present retrospective study aimed to assess the rate of IH repair after laparotomy in a large cohort of patients. In addition to defining the rate of IH repair, we hope to generate new information on the profiles of patients at risk, the impact of surgery type and comorbidities, the time to IH repair and recurrence rates.

METHOD

Data source

Hospital and patient data were extracted from the French database Système National des Données de Santé (SNDS; National System of Health Data), more specifically from its PMSI component.

Study population

For the first stage of the analysis, data were extracted for patients who were hospitalized for laparotomy in mainland France in 2010. For the second stage of the analysis, data were extracted for patients who were hospitalized for management of abdominal IH repair following surgery in mainland France in 2013.

Selection criteria

During their hospital stay in 2010, patients were selected who underwent surgical intervention including laparotomy according to Classification Commune des Actes Médicaux (CCAM) codes, representing a total of 549 codes, and surgical intervention for ventral hernia according to corresponding CCAM codes (i.e. LMMA004, LMMA010 and LMMC015) [24]. Discriminatory elements that were considered included patient age at the time of surgery, gender and the presence of comorbidities identified during the hospital stay coded according to ICD-10 (International Classification of Diseases version 10) [25]. Among the IH risk factors that were identified in the PMSI database, the following comorbidities were recorded: obesity [body mass index (BMI) ≥30 kg/m^2] (E66_); diabetes (E10_, E11_, E12_, E13_, E14_); HBP (I1_) and COPD (J44_) [2] (other surgical conditions cannot be accessed through the PMSI database).

Study organization

The study was conducted between 2010 and 2015 inclusive, to allow enough time to track any possible ventral hernia complications after laparotomy. Linking of hospital stays for each patient was done via the anonymized NIR (social security number) and the connection key between tables in the SNDS database.

The study consisted of two stages. Stage 1 comprised the identification of patients who had undergone a laparotomy in 2010 and determination of their hospital visits over a 5-year period from 2010 to 2015. Patients were classified into two groups: (i) those with new PMSI records/events after ventral laparotomy; and (ii) patients without any new events. Patients were further filtered to isolate the initial laparotomy leading to most IH cases (i.e. the high-risk laparotomy list), according to two criteria: (i) >100 patients in 2010 per surgery; (ii) >10% of IH repairs within the next 5 years after surgery. Stage 2 consisted of the identification of patients from the high-risk laparotomy list who had a first IH repair performed in 2013. Any patient having another IH repair or primary ventral hernia repair between 2010 and 2013 was removed from the list. Comorbidities were identified from the PMSI data recorded in 2011, 2012 and 2013. For the corresponding patients, all recorded events were isolated to make up their hospital journey from 2010 to 2015. The second stage of the study was intended to understand the rate of IH recurrence and the time from first IH repair to recurrence, and to evaluate these events based on initial laparotomy type and patient risk factors.

Outcomes of interest

The primary outcome for this study was the rate of IH repair after ventral laparotomy. The secondary outcomes were the time to IH repair after laparotomy, risk factors for IH repair, including type of surgery and comorbidities, and IH recurrence rates.

Data treatment and statistical analysis

Due to the high volume of data, use of the programming language Python was necessary to clean and convert the data. After treatment, Excel was used for data preparation and formatting. Statistical analysis was performed using Minitab™ v.15.0 software and http://biostatgv.sentiweb.fr/?module=tests/chideux (chi-square test). Qualitative variables are described by their relative number and frequency (%) and quantitative variables are described as median values.

Bivariate statistical analyses were performed using two-sample *t*-tests, Mann–Whitney or chi-square tests to compare results using Minitab™ software and http://biostatgv.sentiweb.fr/?module=-tests/chideux.

The rate of IH repair based on the first recorded occurrence after ventral laparotomy was calculated from Stage 1 study results and compared with the number obtained from Stage 2 study results. The total rate and cumulative rates over time are reported. Patients were categorized into four groups according to the type of comorbidity: (i) obesity, (ii) HBP, (iii) COPD and (iv) diabetes. A comparison of the IH repair rate between groups was carried out using the Mann–Whitney test with a 5% risk level.

A process mining approach was used to model the journey of patients after ventral laparotomy in and out of hospital, including the journey preceding IH repair when recorded. This then supports simulation of a journey (e.g. Monte Carlo in the case of Markov models or discrete-event simulation in the case of flow models) [26].

RESULTS

Analysis of laparotomies in mainland France in 2010

A total of 431 719 patients who underwent ventral laparotomy in 2010 were retrieved from interrogation of the PMSI database and the 549 CCAM codes (ranging from caesarean section to colectomy) corresponding to laparotomies (Figure 1). The majority of the patients were female (71%) and median age at the time of surgery was 42 years. Among these 431 719 patients, 22 088 (5%) developed an IH and underwent their first IH repair surgery within 5 years (2010–2015) after laparotomy [55% female; median age at IH repair 62 years vs 40 years ($p < 0.001$) for patients with no IH].

In order to determine the types of surgery most likely to lead to development of IH we excluded rare cases (case numbers of <100) and selected 65 CCAM codes that resulted in a relevant level of IH repair (>10%) over 6 years. Using this selection criterion, 71 863 patients were identified for the high-risk laparotomy list. The flow diagram for the study population is presented in Figure 1.

The main comorbidities of the 71 863 patients are shown in Figure 2. The mean rate of IH was 17% overall and 13% in patients without comorbidities. When assessing comorbidities individually, IH occurrence rates were 19% in patients with diabetes, 19% in patients with HBP and 20% in those with COPD (Figure 2A). Strikingly, while nonobese patients had an IH occurrence rate of 15%, obese patients had a significantly higher rate of 31% ($p < 0.001$, chi-square test) (Figure 2B), regardless of other comorbidities. The relative risk of IH repair for these comorbidities is shown in Table 1.

When the high-risk laparotomy list was examined, 89% of patients had undergone digestive surgery with the remaining 11% undergoing mainly gynaecological or cardiovascular procedures (Figure 3A). The majority (72%) of patients had surgical procedures involving the lower gastrointestinal tract (colon 29%, rectum 22%, small intestine 21%) (Figure 3B). Time to first IH repair for the 71 863 patients is shown in Figure 4. Over half (56%) of IH repairs occurred during the first year after laparotomy and 79% during the first 2 years. The median time to IH repair occurrence was 9.6 months.

Clinical pathway of patients with IH repair after laparotomy

A total of 21 993 patients underwent IH repair in 2013. Of these patients, 18 688 patients had an IH repair after previous laparotomy. A total of 7730 of this latter group were selected who had not

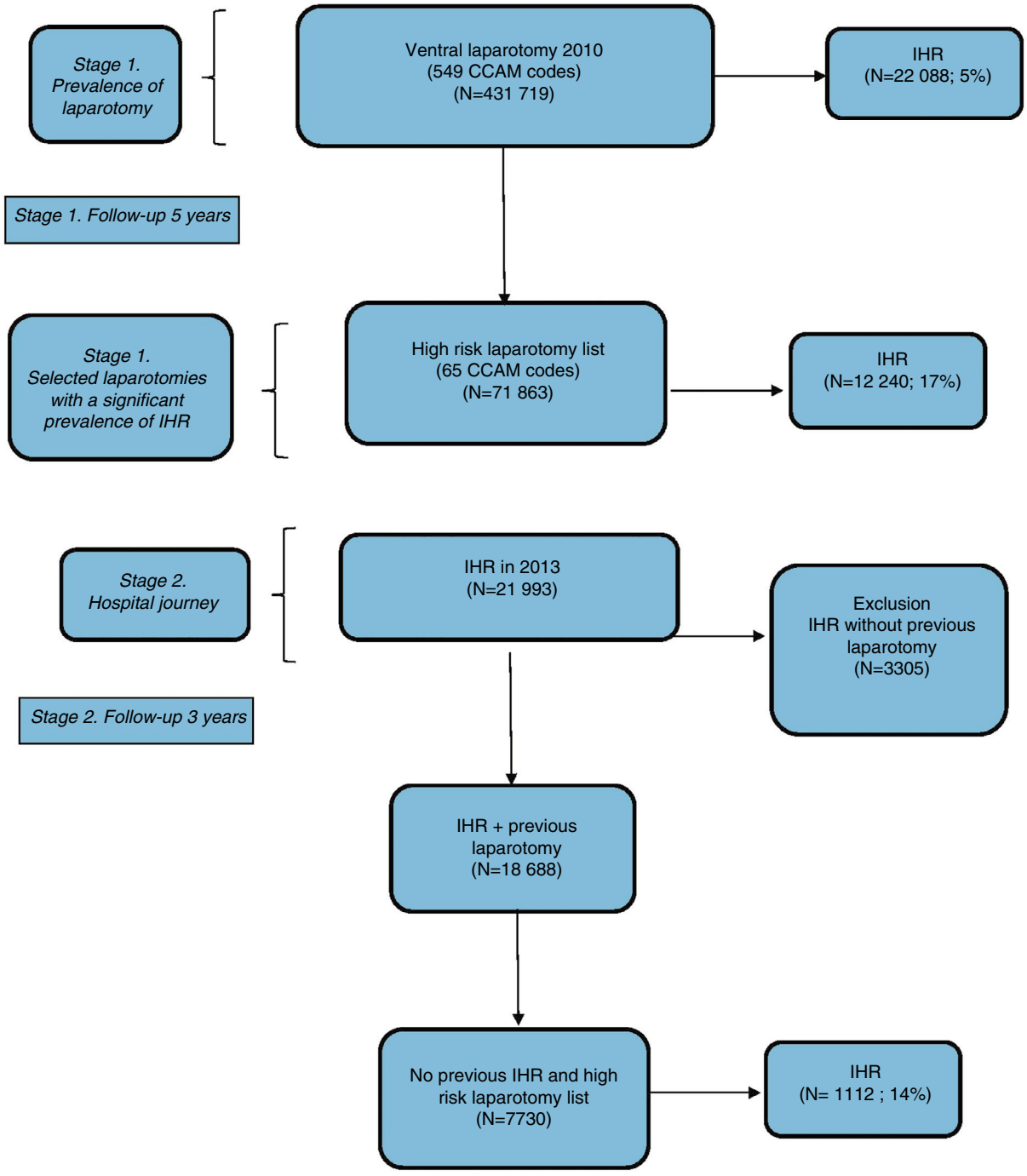


FIGURE 1 Flow diagram of study populations analysed

undergone a previous IH repair and were on the high-risk laparotomy list (Figure 1).

In this group the median time to IH repair was 7.7 months with an observed gender difference (6.2 months for women vs 8.6 months for men; $p < 0.001$). The median time to IH recurrence after repair was 14 months for women vs 13 months for men. The overall recurrence rate was 14% (15% for women vs 13% for men).

When the impact of obesity was investigated there was no difference in time to first IH repair between nonobese and obese patients (8 months vs 7 months, respectively), nor in the time to IH recurrence (13 months vs 15 months, respectively). Among risk factors investigated in this study, obesity was the most significant. (19% obese vs 13% nonobese; $p < 0.001$). Notably, the rate of occurrence of IH after digestive surgery increased from 17% in nonobese patients to 31% in obese subjects.

DISCUSSION

This study, which used real-life data extracted from the PMSI database, analysed the occurrence and recurrence of IH repair after

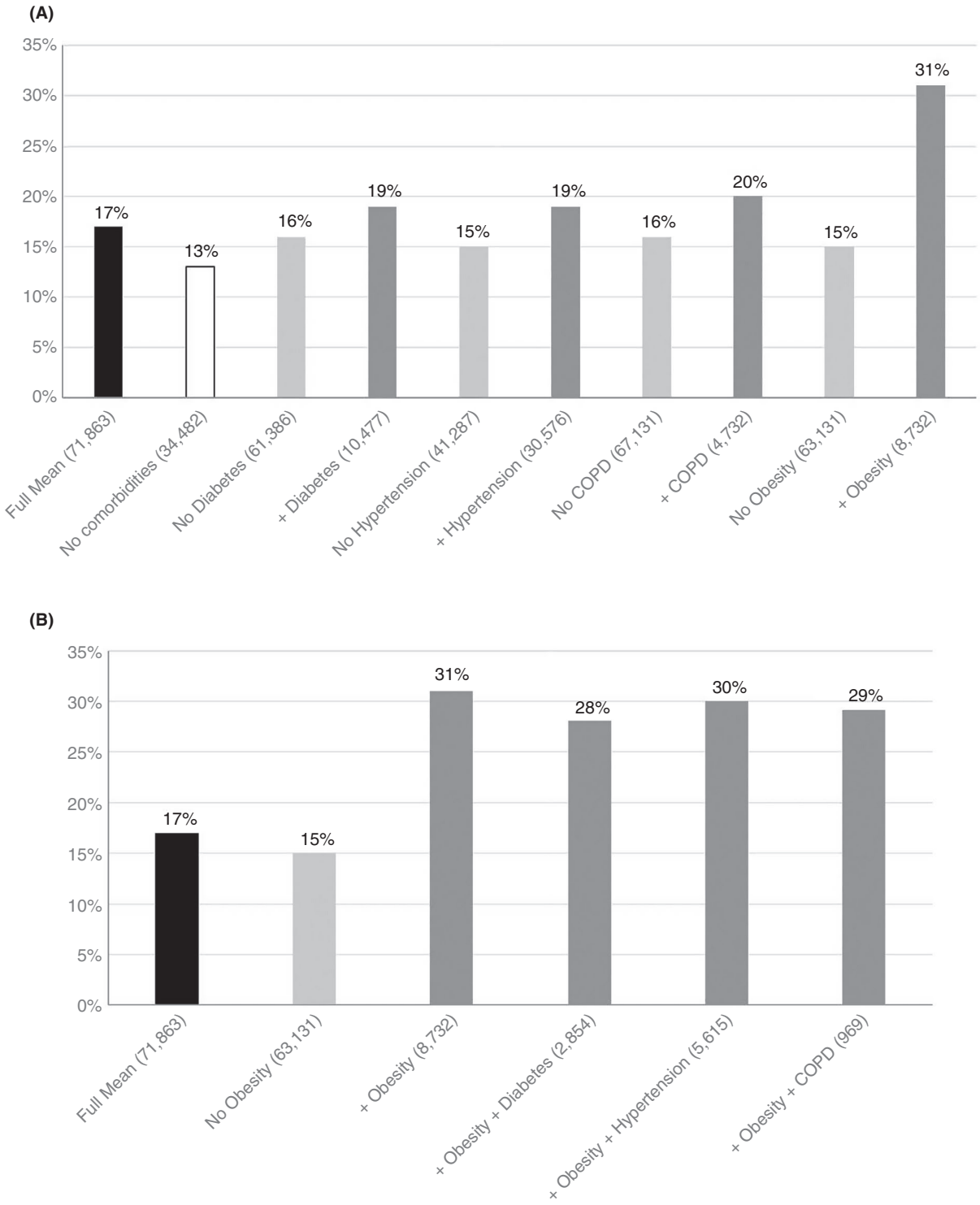


FIGURE 2 Rates of incisional hernia (IH) repair in the patient population, extracted from the high-risk laparotomy list (n = 71 863). (A) Rate of IH repair according to comorbidities (COPD, chronic obstructive pulmonary disease). (B) Rate of IH repair in obese patients without or with additional comorbidities

laparotomy surgery and according to the type of surgery. To our knowledge, this is the first study to investigate the incidence of IH repair after a laparotomy in France using the national database. Our study sheds light on the types of surgery most commonly associated with IH repairs. The PMSI database records repairs of IH but not their incidence, which is obviously higher. In 2007, from UK National Health Service figures, more than 120 000 laparotomies were performed and about 7000 IH surgeries were subsequently reported. This corresponds to a rate of 6% for IH surgery, which appears to be about half the average evaluated incidence of IH of about 13% [27]. Bosanquet et al. [4] shared similar figures from a large metanalysis of 56 selected papers, corresponding to 14 618 patients. The observed

incidence of IH was close to 13% at a weighted mean of 2 years. Half of the reported hernias were symptomatic and 36% were surgically repaired, representing a risk of IH repair of 5.2% after ventral laparotomy. Our study recorded IH repair within 3 years following surgery, which corresponds to the timeframe when most cases appear (about two-thirds of cases) even if followed through 10 years [28].

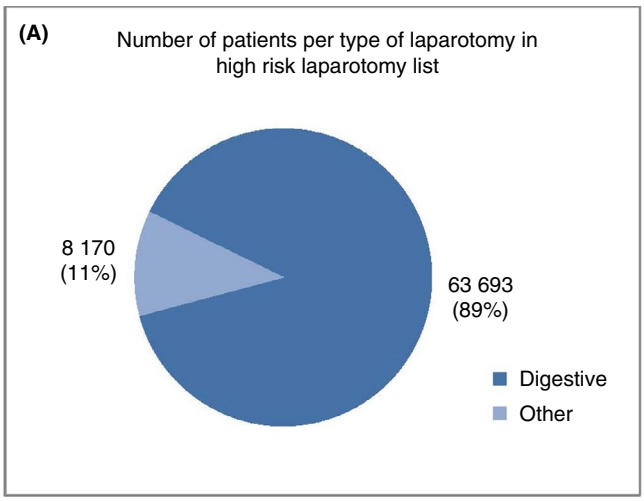
In our total study population, the incidence of IH repair in the 5 years after laparotomy was 5%, which concurs with the reported incidence of 5%–20% [1,2,4,27]. As reported by Bosanquet et al. [4], we found that older age was associated with a greater risk of IH repair (median age at IH repair surgery 63 years vs 40 years for patients with no IH repair, $p < 0.001$). We then analysed the types of surgery most likely to lead to IH repair by excluding rare cases (<100 cases) and selecting 65 CCAM codes (the high-risk laparotomy list) that resulted in a relevant level of IH repair (>10%) over 6 years. In this analysis, 89% of patients in this group had undergone digestive surgery with the remaining 11% undergoing mainly gynaecological or cardiovascular procedures. The majority of patients (72%) had surgery involving the lower gastrointestinal tract (colon 29%, small intestine 21%, rectum 22%) (Figure 3B). In our study, the rate of IH occurrence varied from one disease condition to another.

In a study published in 2013, Helgstrand et al. [29] described the results of a prospective nationwide study on 3268 elective IH repairs registered in the Danish Ventral Hernia Database from 2007 to 2010, with a median follow-up of 21 months. Readmission and reoperation rates 30 days post-IH repair surgery were 13.3% and 2.2%, respectively. Independent risk factors for poor early outcomes included older age, open repair, large hernia and vertical incision at the primary laparotomy site. The cumulative risk of recurrence after IH repair ranged from 15.5% to 21.1%. Risk factors for poor late

TABLE 1 Comorbidities and relative risk of incision hernia after laparotomy

	Relative risk	95% CI	*p*
Diabetes	1.17	1.12–1.22	<0.0001
HBP	1.27	1.23–1.31	<0.0001
COPD	1.21	1.14–1.28	<0.0001
Obesity	2.06	1.99–2.14	<0.0001
Obesity + diabetes	1.73	1.63–1.84	<0.0001
Obesity + HBP	1.91	1.85–2.01	<0.0001
Obesity + COPD	1.76	1.59–1.94	<0.0001

Abbreviations: COPD, chronic obstructive pulmonary disease; HBP, high blood pressure.



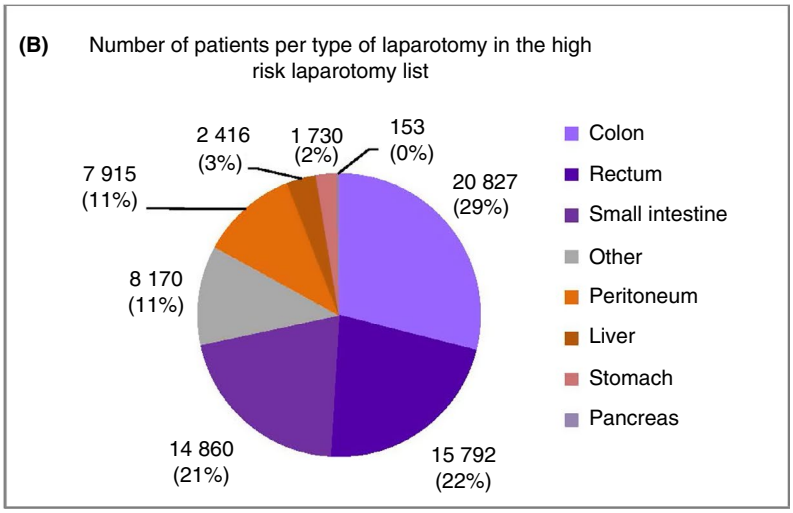


FIGURE 3 (A) Proportion (*n*, %) of patients by type of laparotomy surgery in the high-risk laparotomy list ($n = 71\,863$). (B) Proportion (*n*, %) of patients undergoing digestive surgery in the high-risk laparotomy list

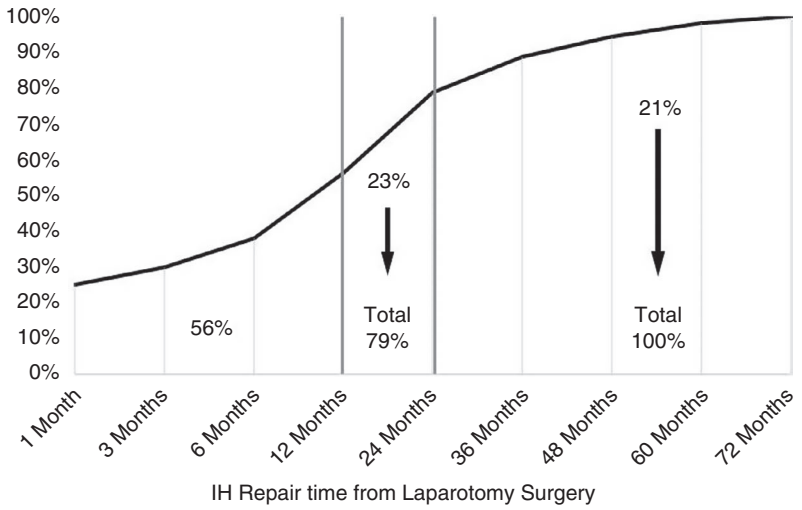


FIGURE 4 Time to occurrence of incisional hernia (IH) repair for the high-risk laparotomy list (n = 71 863)

outcomes included younger age, open repair, large hernia (>7 cm) and mesh positioning in open repair [29]. Söderbäck et al. published the results of a population-based study on the incidence of IH and risk factors for developing IH following surgery for colorectal cancer using data registered in the Swedish Colorectal Cancer Register [30] and reported a cumulative incidence of IH of 5.3% 5 years after surgery. Risk factors for IH in this study included male gender, long operation time (>180 min), obesity, age and postoperative wound complications [30].

Obesity (BMI ≥30 kg/m^2) is consistently reported as one of the main risk factors for IH and IH repair [8–10,29]. Our study confirms these findings as the relative risk (RR) of IH repair was highest for obese subjects (RR = 2.06, 95% CI 1.14–1.28) and for obese subjects with other comorbidities (Table 1). While there was no difference in time after laparotomy surgery to first IH repair between obese and nonobese subjects (7 months vs 8 months, respectively), the recurrence rate of IH repair after first repair was significantly higher in obese subjects (19% vs 15% for nonobese patients; $p < 0.001$, chi-square test). Similar high odds ratios (ORs) for IH recurrence in obese subjects have been described elsewhere (OR = 4.4, 95% CI 1.2–15.5; $p = 0.01$) [31].

The PMSI database records patient comorbidities and types of laparotomy surgery but does not provide information on the surgery conditions (e.g. emergency versus elective surgery, wound closure technique, etc) which can affect the clinical outcome. Emergency surgeries, for example, are well-known as surgical conditions with more early complications that could compromise the quality of IH repair [32].

Wound closure technique after laparotomy has also been shown to affect the rate of IH occurrence, and mesh repair has been reported as an independent protective factor for IH recurrence [1,16,17]. In a systematic review of the literature on wound closure techniques including 23 randomized controlled trials (RCTs) (including nine using prophylactic mesh), Fortelny [1] reported that the use of slowly absorbable suture material for continuous closure using the small bites technique resulted in significantly fewer IHs compared with the large bites technique (OR = 0.41, 95% CI 0.19–0.86). These authors also showed that the use of prophylactic mesh versus suture midline closure resulted in a significant reduction in the IH rate (OR = 0.14, 95% CI 0.07–0.27). In a meta-analysis of 12 RCTs involving 1661 patients conducted in 2017, Wang et al. also reported that mesh reinforcement could decrease the rate of IH compared with nonmesh (RR = 0.19, 95% CI 0.09–0.42) and is associated with an improved QoL [33]. These authors recommended the use of surgical mesh in some high-risk patients and suggested that individual risk factors should be taken into account when selecting patients who would most benefit from mesh insertion. Another recent meta-analysis and sequential analysis of 12 RCTs involving 1815 patients by Jairam et al. [34] reported that prophylactic mesh reinforcement using an onlay or retromuscular technique after midline abdominal surgery significantly decreased the rate of occurrence of IH in high-risk patients and that onlay mesh reinforcement could become the standard treatment for high-risk patients undergoing midline laparotomy.

Patient QoL has been reported to be severely affected by IH and IH repair [18,19]. When assessed using the Hernia-related Quality-of-life Assessment Tool (HerQLes), patients reported effects on QoL including chronic pain, interference with daily activities and an impact on social and sexual activities [18]. Using the 36-item Short Form Health Survey (SF-36), Saijo et al. [19] compared pre- and 1-year postoperative QoL in 33 patients who underwent laparoscopic ventral and IH repair. Compared with presurgery SF-36 scores, scores for five of the eight domains and one of the three SF-36 components improved 1-year postsurgery. QoL was correlated with obesity, hernia size, operating time and mesh size.

IH repair is a costly complication of surgery, but the actual healthcare costs associated with IH repair were largely unknown until recently. In 2016, Fisher et al. carried out a cost analysis of IH after elective abdominal surgery in 12 373 patients, with an incidence of surgically treated IH of 3.5%. They showed that the cost of surgical repair and associated management of complications was more than USD 175 million [35]. In another analysis of 14 290 patients, Alli et al. [21] reported a median direct cost of IH occurrence of USD 20 000. In 2016, Gillion

et al. [22] carried out a literature review and analysed direct costs (healthcare costs) associated with IH repair, obtained from a cost analysis performed among 51 French public hospitals and involving 3239 IH repairs, and indirect costs (costs of postoperative sick leave and loss of profits) estimated from the Hernia Club registry, involving 790 patients. The mean total cost for IH repair in France was estimated to be EUR 6451 in 2011, ranging from EUR 4731 for unemployed individuals to EUR 10 107 for employed patients [22]. Based on the occurrences of IH repair in our study (22 088 IH repairs after laparotomies done in 2010), the overall cost of primary IH repair in France should be about EUR 140 million, for 2011 cost figures. Gillion et al. estimated that reducing the incidence of IH after abdominal surgery by 5%, by implementing the European Hernia Society Guidelines on closure of abdominal wall incisions or by using prophylactic mesh in high-risk patients, could result in national cost savings of EUR 4 million [22] and even more based on the IH repair rate observed in our study.

This study has several strengths and limitations relating to the French PMSI database. The data used in the study were real-life data extracted from the PMSI database; thus, the results are a true reflection of everyday events and their impact on healthcare on a nationwide scale. The study design has the benefit over clinical trials in that the database provides a massive quantity of data for a very large patient cohort with long-term follow-up. Using the unique identification numbers, it is also possible to follow the same patient throughout his or her hospital journey without limitations of time from the recording of the first surgery event. A major limitation of the study is the high rate of IH repair at T0 (25%), due to IH repair taking place during the same surgery or during another surgery in the same hospital stay.

Although we did not carry out a cost analysis of the IH repairs described in this study, the PMSI database contains sufficient data on the healthcare pathway of laparotomy patients at risk of IH to support a health economics study of IH repair in the future. In addition, the SNIIRAM database provides information on healthcare reimbursement and may give additional information on the costs incurred in France.

CONCLUSION

From the national database, the real rate of IH repair after laparotomy was 5%, increasing to 17% after digestive surgery. Obesity was the main risk factor, with the rate of IH repair increasing to 31% after digestive surgery. Because of the important medico-economic consequences, surgeons should be aware of this problem and prevention of IH after laparotomy in high-risk patients should be considered.

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CONFLICT OF INTERESTS

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DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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