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**FMUP** FACULDADE DE MEDICINA  
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José Chen Xu

Incisional hernia in hepatobiliary and pancreatic surgery

– incidence and risk factors

Hérnia incisional em cirurgia hepatobiliar e pancreática

– incidência e fatores de risco

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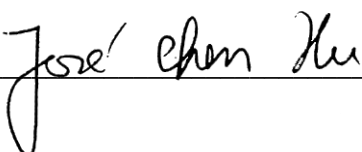
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Incisional hernia in hepatobiliary and pancreatic surgery – incidence and risk factors

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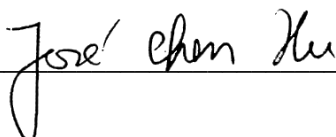
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To my **tutor**, who guided me through this roller coaster of a journey.

To my **family**, who supported me unconditionally throughout the years.

To my **friends**, who were always there to cheer me up whenever I needed.

“Seek not the favour of the multitude; it is seldom got by honest and lawful means.  
But seek the testimony of few; and number not voices, but weigh them.”

Immanuel Kant

# **Incisional hernia in hepatobiliary and pancreatic surgery – incidence and risk factors**

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## **ABSTRACT**

**Purpose.** The occurrence of incisional hernia (IH) is one of the main complications after open abdominal surgery. However, its incidence in hepatobiliary and pancreatic surgery are not known. Studies on partial hepatectomy and necrotizing pancreatitis show that the incidence can reach up to 42%. This study aims at evaluating the incidence of IH and its risk factors.

**Methods.** Patients submitted to open hepato-pancreato-biliary surgery at our Center between 2010 and 2016 were selected. IH was defined as discontinuity in the abdominal fascia reported during physical examination or on computed tomography. Variables analysed range from individual characteristics and medical history to surgical and postoperative aspects.

**Results.** The cumulative incidence of IH was 14.6% at 36 months. In pancreatic patients, this incidence was 11.6%, while hepatobiliary patients presented an incidence of 16.0%, reaching 27,0% at 72 months. Cox regression showed that height ( $p=0.028$ ), subcutaneous fat ( $p=0.037$ ), wound dehiscence ( $p=0.001$ ) and superficial surgical site infection ( $p=0.001$ ) correlate positively with IH in pancreatic surgery patients. BMI ( $p=0.037$ ) and perirenal fat ( $p=0.043$ ) associated independently with IH in patients submitted to hepatobiliary surgery.

**Conclusions.** Height, obesity and wound complications are risk factors for IH in patients submitted to pancreatic surgery, whereas obesity presents as risk factor in hepatobiliary surgery patients. The incidence of IH goes up to 12% in patients submitted to pancreatic surgery, while this risk is higher in the hepatobiliary group (27%). It is suggested the adoption of strategies in the clinical practice which prevent this high incidence, namely in high-risk patients.

**Keywords.** Incisional hernia; incidence; risk factors; hepatobiliary surgery; pancreatic surgery

## INTRODUCTION

The occurrence of incisional hernia is one of the most common complications of the open abdominal surgical procedure. However, its incidence in hepatobiliary and pancreatic surgery is not known. Most of the available literature mentions its occurrence after hepatic metastasis resection [1], laparotomy [2,3], colorectal carcinoma [4] and liver transplantation [5-7]. Few articles refer to the incidence of IH in partial hepatectomy [8,9] and necrotizing pancreatitis [10]. The data show that it can reach up to 42% [10], even though the incidence can vary according to the characteristics of the population of the study. However, many risk factors have been associated with an increased incidence of IH, such as gender, age, preoperative chemotherapy, midline incision, open laparotomy, surgical site infection, obesity, blood transfusion and aortic aneurysm [11,4,8,12]. Besides affecting a patient's quality of life and body image [13,11], IH has a complicated treatment, with rates of recurrence above 30%, even when prosthetic mesh repair is performed [11]. Preventive measures should be taken to decrease postoperative complications and costs in healthcare. The aim of this retrospective study is to determine the incidence and risk factors for incisional hernia after laparotomy in hepatobiliary and pancreatic surgery.

## METHODS

*Study Design and Patients.* Between January 2010 and December 2016, 1071 patients were submitted to hepatobiliary and pancreatic surgery in our Hospital Center. Among these patients, 696 patients underwent elective laparotomy. Patients under 18 were also excluded, as well as patients with no follow up data. After applying the exclusion criteria, 654 patients were selected. This retrospective study was approved by the Ethics Commission of our Center.

*Outcome of interest.* The aim of this study was to assess the incidence of IH after laparotomy in hepatobiliary and pancreatic surgery. Incisional hernia was defined as a discontinuity in the abdominal fascia, shown as a protrusion of intraperitoneal structures through a defect in the incision site of the abdominal wall [4,12,1]. This complication of laparotomy can be diagnosed through physical examination, shown through medical records, or observation on the computed tomography (CT). In this study, the diagnosis of incisional hernia was considered when it was reported during the physical examination or when the CT showed fascial discontinuity of the abdominal wall with protrusion.

*Data Extraction.* Data was extracted from medical records, including age, gender, height, weight, body mass index (BMI), perirenal fat thickness, subcutaneous fat thickness, smoking, diabetes mellitus, previous incisional hernia, history of chemotherapy, previous surgery, American Society of Anaesthesiologists (ASA) score [14], preoperative albumin, preoperative creatinine, operative procedure, duration of surgery, type of incision, type of closing suture (and their characteristics: reabsorption, monofilament), prosthetic prophylaxis, diagnosis, malignancy and staging, operative bleeding, operative blood transfusion and postoperative hospital stay. We also assessed complications, such as: seroma, superficial wound dehiscence, superficial surgical site infection (superficial SSI), and pulmonary complications – pleural



effusion, pneumonia and atelectasis; finally, we determined the postoperative use of antibiotics, chemotherapy and complications at 30-day according to the Clavien-Dindo classification [15].

The preoperative CT scan was analysed to determine the perirenal fat thickness and subcutaneous fat thickness [16]. The subcutaneous fat thickness was defined as the longest distance between the skin tissue and the outer limit of the muscular layer of the abdominal wall, assessed at the level of the umbilicus, further defining a perirenal fat thickness as the maximum distance between the posterior wall of the kidney and the inner limit of the abdominal wall in a slice that contains the renal vein [16]. The most recent CT scans available were assessed to determine the occurrence of IH when no IH was reported in the clinical records.

Follow up period was considered until up to the diagnosis of incisional hernia, the occurrence of death, last follow up appointment or discharge of hospital appointments.

*Statistical Analysis.* All results are shown as a median, presenting the range of the variable. Continuous variables were evaluated using the Mann-Whitney test, whereas categorical data were compared using the  $\chi^2$  test or Fisher Exact test. ROC curves were designed for the development of IH to find the optimal threshold for continuous variables (charts not shown). The incidence of IH during the period was assessed by the Kaplan-Meier method, through the estimation of the cumulative risk. In order to identify independent risk factors of incisional hernia, a univariable analysis was carried out using the Cox Regression method, with proportional hazard ratios (HRs). Factors with a significance value of  $p < 0.10$  from the univariable analysis were subjected to a multivariable analysis using the same method of Cox Regression model. All statistical analysis was performed using IBM SPSS Statistics version 25 (IBM Corporation).

## RESULTS

Between January 2010 and December 2016, 654 patients underwent hepato-pancreato-biliary laparotomy, which were included in this study (295 women, 359 men). In total, 83 patients developed incisional hernia after the surgery. Of those, 21 underwent pancreatic surgery and 62 were submitted to hepatobiliary surgery. A Kaplan-Meier plot estimated a 7.6% cumulative incidence rate of incisional hernia at 12 months (error of 1.1%), 12.2% at 24 months (error of 1.4%) and 14.6% at 36 months (error of 1.7%), reaching up to 21.6% at 72 months (error of 2.8%) (Figure 1).

The median follow-up period was 28 months. The range of the follow up period was between 0.3 – 94 months. Patients that were considered between the period of 0.3 – 1.9 months had a short follow up period but were still included due to presence of IH.

Patients' characteristics, as well as pre-, peri- and post-operative data are shown in Table 1. The median age of the patients was 60.31 years, and the median body mass index (BMI) 26.1 kg/m<sup>2</sup>. Diabetes mellitus was present in 130 patients (19.9%), while 77 (11.8%) were smokers. Previous chemotherapy was noted in 218 patients (33.3%) and 480 subjects (73.4%) had a previous surgery. Regarding the American Society of

Anaesthesiologists (ASA) score, 60 patients (9.2%) were classified with ASA 1, 428 (65.4%) with ASA 2, 161 (24.6%) with ASA 3 and 5 patients (0.8%) with ASA 4.

In this study, we accounted for 444 patients (67.9%) who underwent hepatobiliary surgery, while 205 (31.3%) were submitted to pancreatic surgery, and 5 (0.8%) to hepato-biliary-pancreatic surgery (HBP). Several types of incisions were performed in the surgeries: J incision (n=419 – 64.7%), L incision (n=17 – 2.6%), midline (n=103 – 15.9%), subcostal (n=102 – 15.7%) and transverse (n=7 – 1.1%). No reference to the type of incision performed was noted in 12 patients, which were considered missing values. Concerning the fascial closing suture, there were main four types: Monomax® (poly-4-hydroxybutyrate), utilised in 7 patients (1.3%), PDS® (poly (p-dioxanone).1), used in 206 patients (39.5%), Prolene® (polypropylene), in 268 (51.4%) and Vicryl® (polyglactin 910), used in 40 patients (7.7%). In 133 patients the operative records did not refer the type of closing suture used, having been considered missing values. Malignancy was verified in 76% of the surgeries.

Regarding postoperative complications, the performed surgeries showed the occurrence of seroma (n=26 – 4.0%), superficial wound dehiscence (n=33 – 5.0%), superficial SSI (n=68– 10.4%) and pulmonary complications, such as pleural effusion (n=169 – 25.8%), pneumonia (n=16 – 2.4%) and atelectasis (n=83 – 12.7%).

Another important data collected was the diagnosis, which can be seen in Tables 2a and 2b. Patients submitted to pancreatic surgery have most frequently pancreatic duct adenocarcinoma (n=34 – 16.2%) and ampulla of Vater Disease (n=31 – 14.8%). In hepatobiliary surgery, most patients presented colorectal liver metastases (n=219 – 49.3%) and benign hepatic disease (n=52 – 11.7%). Due to the great range of diagnosis attributed to the patients, this variable was not considered in any further statistical analysis.

Univariate and Multivariate Cox Regression analysis were carried out for the development of incisional hernia in all patients. The analysis showed that p values of superficial dehiscence (p=0.001) and superficial SSI (p<0.001) were statistically significant in hepato-pancreato-biliary patients, with hazard ratios of 3.556 [1.738-7.275] and 3.140 [1.806-5.459], respectively.

A separate data analysis of hepatobiliary surgery and pancreatic surgery was then carried out, due to the difference of procedures and length associated with each type of surgery.

### *Pancreatic Surgery*

Of the 210 patients submitted to pancreatic surgery, 21 patients developed incisional hernia. The Kaplan-Meier method shows an estimated cumulative incidence of incisional hernia of 9.2% at 12 months (error of 2.1%) and 10.5% at 24 months (error of 2.3%), reaching 11.6% at 36 months, with an error value of 2.5% (Figure 2).

Within this population sample, 93 patients were female and 117 were male. The median follow-up time was 29.41 months, within a range of 0.33 to 90.10 months. Detailed characteristics of the group are shown in Table 3.

The Cox Proportional Hazard Ratio was applied to the population, in a univariate and a multivariate analysis (Table 4). The multivariate Cox Regression included 11 variables, which had a  $p < 0.10$  in the univariate analysis. Of those, 4 presented statistical significance: superficial SSI, superficial wound dehiscence, height and subcutaneous fat thickness.

### *Hepatobiliary Surgery*

There were 444 patients submitted to open hepatobiliary surgery, 62 of which developed incisional hernia during the follow up period. The characteristics of the group are described in Table 5.

Regarding the outcome of the study, the Kaplan-Meier plot applied to this population estimated a cumulative incidence of incisional hernia of 6.8% at 12 months (error of 1.3%), 12.9% at 24 months (error of 1.8%), and 16.0% at 36 months (error of 2.2%), reaching 27.0% at 72 months, with an error of 4.1% (Figure 3).

The univariate and multivariate analysis were carried out by applying the Cox Proportional Hazard Ratio (Table 5). In the second analysis, 14 variables were accounted for. Of these, two showed statistical significance: perirenal fat thickness and BMI.

## **DISCUSSION**

This retrospective study has showed a cumulative incidence of incisional hernia in hepatobiliary and pancreatic laparotomy respectively of 6.8% and 9.2% at 12 months, 10.5% and 12.9% at 24 months, and 11.6% and 16.0% at 36 months. Overall, that reflects on an incidence of 21.6% at 72 months in patients submitted to open HBP surgery. Higher incidence is shown in the group of patients submitted to hepatobiliary surgery, which goes up to 27.0% at 72 months. It can also be noticed that IH may have a late onset after hepatobiliary surgery (up to 80 months), which does not happen in pancreatic surgery (up to 29 months). This difference might be related to intraoperative risks and worse prognosis in this type of surgery, especially in patients with pancreatic cancer [17]. Data on previous studies include incidences ranging from 5% [8,9] to 31.3% [18,1] after liver resection, and up to 42% in necrotising pancreatitis patients [10].

The variables analysed as risk factors differ between the two groups. For the pancreatic laparotomy group, preoperative factors such as having a height  $> 167.5$  cm (HR = 4.835 [1.181-19.798];  $p = 0.028$ ) and presenting a subcutaneous fat  $> 23.25$  mm (HR = 3.692 [1.080-12.621];  $p = 0.037$ ) influences positively the occurrence of incisional hernia, as well as postoperative factors such as superficial wound dehiscence (HR = 26.402 [4.114-160.43];  $p = 0.001$ ) and superficial SSI (HR = 6.698 [2.116-21.199];  $p = 0.001$ ), as

previously shown in other studies [19-21]. The preoperative subcutaneous fat has also been described before as a risk factor for IH by other studies [4], which suggest that increased subcutaneous fat might play a role in not only slowing but also endangering the closure of the abdomen after pancreatic suture. A height > 167.5 cm seems to be a risk factor for incisional hernia, even though it has also been shown to be a risk factor for pancreatic cancer [22]. Wound complications are major determinants of outcome of pancreatic surgery, being reliable negative predictors of outcome of pancreaticoduodenectomy [23]. In this study, these complications augmented the incidence of IH in our patients submitted to pancreatic surgery.

Regarding the patients submitted to open hepatobiliary surgery, preoperative factors such as body mass index > 25.95 kg/m<sup>2</sup> (HR = 2.694 [1.063-6.824]; p = 0.037) revealed to have a positive influence on the incidence of IH. This correlation was shown to be positive in previous studies [24,25]. Another preoperative factor that presented statistical significance was having a perirenal fat thickness > 14.65 mm (HR = 2.251 [1.028-4.931]; p = 0.043). As perirenal fat correlates negatively with subcutaneous fat in women and positively with waist circumference in the male population [16], this strengthens the stance that the higher the BMI, and the prevalence of obesity, the higher the risk of incisional hernia, as several other studies have shown before [1,9,12].

Other preoperative factors, as well as perioperative factors, have not shown significance in the incidence of IH. or have no statistical correlation, namely in the case of seroma and pulmonary complications (pleural effusion, pneumonia and atelectasis).

The weaknesses of the study are mainly due to its retrospective nature and selection bias. Even though the decision of doing a laparotomy is discussed in multidisciplinary meetings, this type of surgery is more likely to be chosen for patients with high-risk factors, such as obesity and cancer. It should be stressed out the absence of some data in variables collected, which rely solely in records. Furthermore, the size and location of hernias was not assessed.

New strategies to decrease the incidence of IH should be adopted in the clinical practice. These measures might entail weight control in the preoperative period, which has been shown to have positive outcomes in rehabilitation programs and preoperative admission criteria and thus could impact favourably in postoperative complications [26], such as wound healing and incisional hernia. It was also studied the use of prophylactic prosthetic mesh in colorectal surgery, which has been shown to prevent the occurrence of IH [27]. Other studies also mention the possible role of peritoneal drainage after pancreatic surgery in affecting complications and lowering mortality [28], but further research is needed to prove the efficacy of this technique in preventing postoperative complications. Another study reports the prophylactic single-use negative pressure wound therapy system to prevent surgical site complications, as SSI, dehiscence and length of stay [29]. This technique might have a relevant role in the occurrence of incisional hernia, as it prevents wound complications described as risk factors for IH in the present study.

## **CONCLUSION**

In conclusion, height, obesity and wound complications are risk factors for IH in pancreatic surgery patients, while obesity has independently associated with an increase of incidence of IH, being risk factor in the group of open hepatobiliary surgery. The incidence goes up to 12% in patients submitted to pancreatic surgery, while the risk of IH is higher in patients submitted to hepatobiliary surgery (27%). Postoperative complications are cause for extended hospitalisation, but these also carry increased costs and deterioration of long-term quality of life. These complications impact work, health, and recovery, and should be carefully monitored and prevented for the sake of healthcare. It is suggested the adoption of strategies in the clinical practice which prevent this high incidence, namely in high-risk patients.

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## Captions

**Figure 1** – Kaplan-Meier plot showing cumulative incidence of IH in patients submitted to hepato-pancreato-biliary laparotomy.

**Figure 2** – Kaplan-Meier plot of patients with incisional hernia who were submitted to pancreatic laparotomy

**Figure 3** – Kaplan-Meier plot showing the cumulative incidence of IH among the patients submitted to open hepatobiliary surgery between 2010 and 2016

**Table 1** – Information about the population of the study, including pre-, peri- and post-operative characteristics, as well as the method applied to study the variable

BMI: Body Mass Index; ASA score: American Society of Anaesthesiologists score

**Table 2a** – Diagnosis of the patients submitted to pancreatic surgery. The values shown are the frequency and percentage of patients with a determined diagnosis within each group. Due to the great range of diagnosis attributed to the patients, only the most frequent diagnosis in each group are shown.

**Table 2b** – Most frequent diagnosis of the patients submitted to hepatobiliary surgery. The values shown are the frequency and percentage of patients with a determined diagnosis within each group. Due to the great range of diagnosis attributed to the patients, only the most frequent diagnosis in each group are shown.

**Table 3** - Characteristics of the patients submitted to pancreatic surgery

DPC: Duodenopancreatectomy; BMI: Body Mass Index; ASA score: American Society of Anaesthesiologists score

**Table 4** – Cox Proportional Hazard Ratio test (Cox Regression) applied to the population which underwent pancreatic surgery

BMI: Body Mass Index; ASA score: American Society of Anaesthesiologists score

**Table 5** - Characteristics of the patients submitted to hepatobiliary surgery

BMI: Body Mass Index; ASA score: American Society of Anaesthesiologists score

**Table 6** – Cox Proportional Hazard Ratio applied to the patients submitted to hepatobiliary surgery.

BMI: Body Mass Index; ASA score: American Society of Anaesthesiologists score

Figure 1

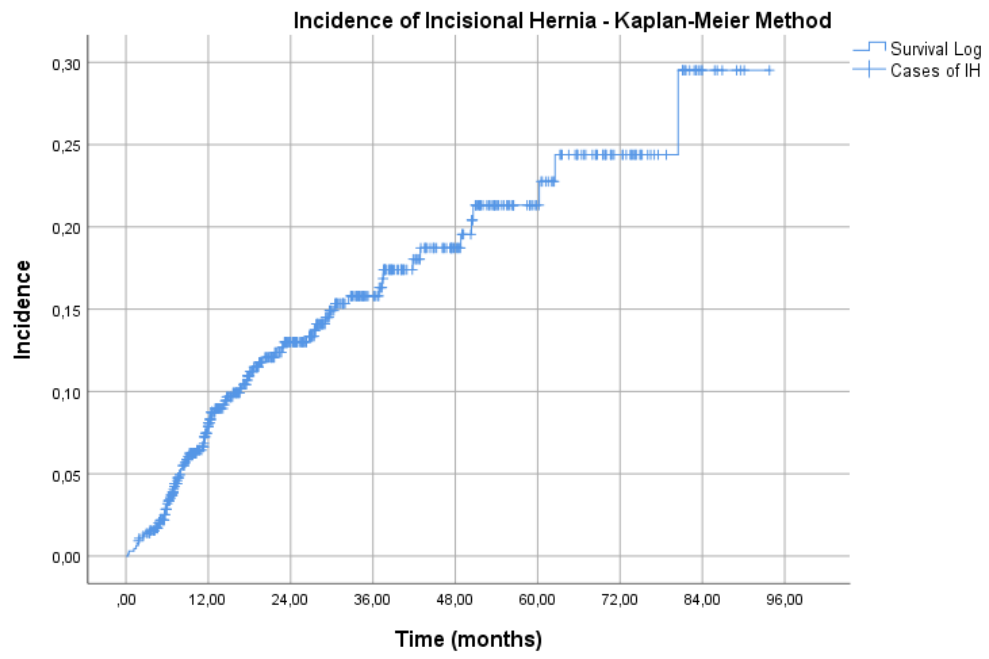


Figure 2

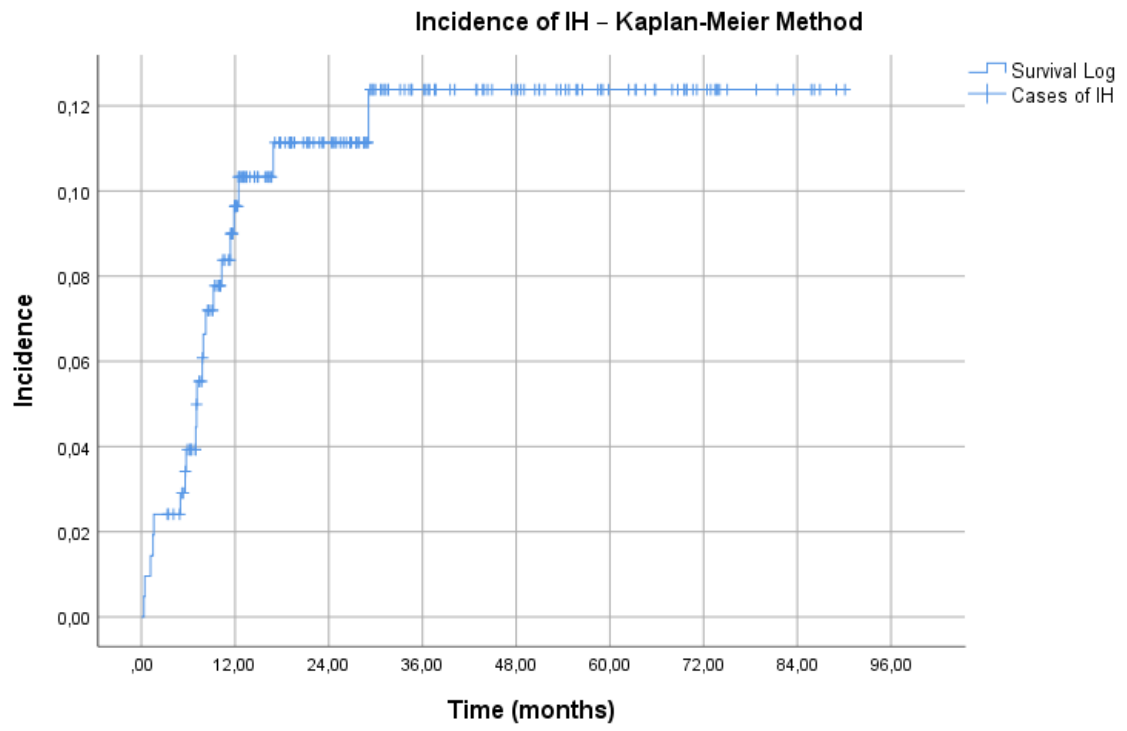
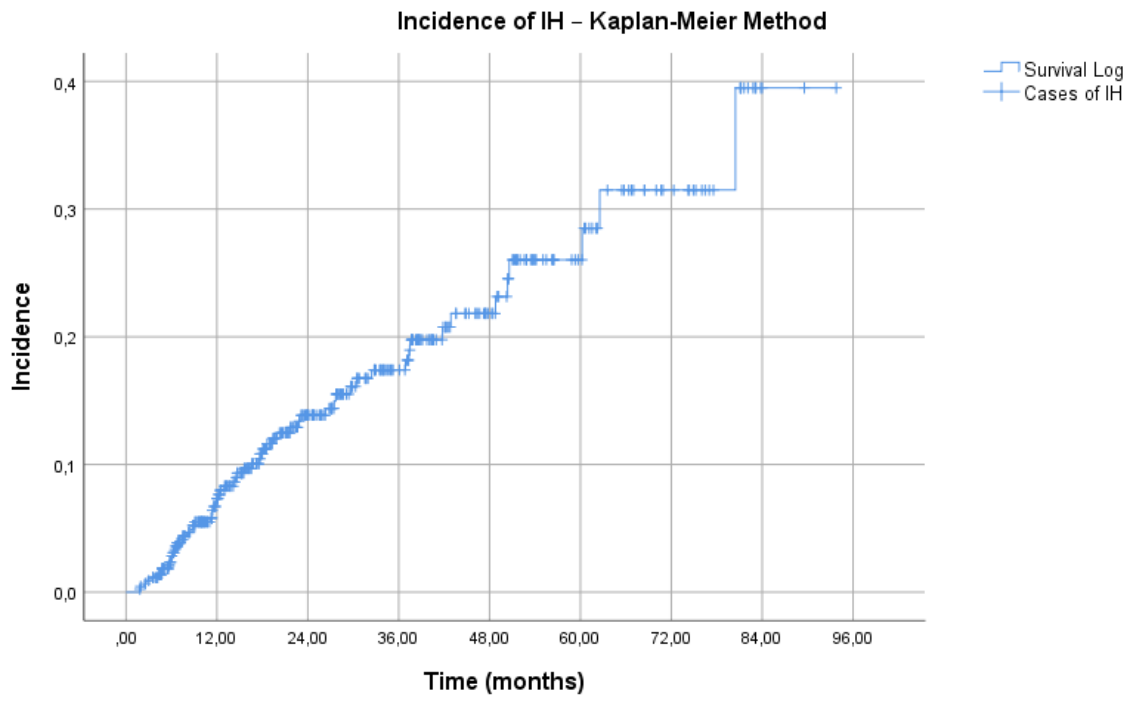


Figure 3



**Table 1**

Patients' Characteristics	Incisional Hernia	No Incisional Hernia	p (significance)
Number of patients	83	571	-
Type of Surgery			
Hepatobiliary surgery	62	382	0.289
Pancreatic surgery	21	184	
Mixed (hepatobiliary and pancreatic surgery)	0	5	
Gender			
Female	29	266	0.058
Male	54	305	
Age (years)	63.77 (34-81)	59.80 (21-86)	0.007
Weight (kg)	76.54 (50-122)	69.53 (40-130)	< 0.0001
Height (cm)	165.57 (144-185)	164.15 (110-194)	0.129
BMI (kg/m <sup>2</sup> )	27.96 (20.20-42.74)	25.82 (16.41-66.94)	< 0.0001
Smoker	11	62	0.575
Diabetes mellitus	20	110	0.305
Perirenal fat (mm)	21.96 (3.5-50.5)	16.94 (1.2-53.1)	< 0.0001
Subcutaneous fat (mm)	27.08 (6.8-56.0)	22.91 (4.2-54.9)	0.022
History of Chemotherapy	26	192	0.710
Previous Incisional Hernia	7	18	0.019
History of Surgery	64	416	0.506
ASA Score			
1	3	57	0.074
2	55	373	
3	23	138	
4	2	3	
Preoperative albumin (g/l)	37.91 (17.7-52.6)	38.40 (7.1-51.4)	0.609
Preoperative creatinine	0.85 (0.37-2.22)	0.81 (0.29-8.29)	0.045
Malignancy	65	430	0.405
Stage			
I	11	32	0.107
II	13	92	
III	26	196	
IV	15	97	
Duration of surgery (min)	267.9 (60-506)	263.47 (25-615)	0.762
Type of incision			
J Incision	53	366	0.296
L Incision	3	14	
Midline	17	86	
Subcostal	7	95	
Transverse	1	6	
Type of closing suture			
Monomax®	0	7	0.377
PDS®	29	177	
Prolene®	27	241	
Vicryl®	6	34	
Absorbable	35	219	0.224
Monofilament	56	425	0.456
Prosthetic prophylaxis	1	1	0.238
Operative blood loss (ml)	31.81 (0-1200)	13.35 (0-1000)	0.900
Blood Transfusion	7	38	0.492
Postoperative hospital stay (days)	21.37 (4-221)	12.47 (2-204)	0.002
Antibiotic therapy	38	190	0.036
Postoperative chemotherapy	44	345	0.231
Morbidity (Clavien-Dindo ≥ 3)	15	43	0.002
Seroma	5	21	0.360
Superficial wound dehiscence	10	23	0.002
Superficial surgical site infection	22	46	<0.0001
Pleural effusion	32	137	0.007
Pneumonia	3	13	0.442
Atelectasis	12	71	0.597
Follow up time (months)	16.59 (0.33-80.47)	29.83 (1.83-93.77)	< 0.0001

**Table 2a**

Most Frequent Diagnosis in Pancreatic Surgery	Frequency	Percentage
Pancreatic Duct Adenocarcinoma	34	16,2
Ampulla of Vater Disease	31	14,8
Intraductal Papillary Mucinous Neoplasm	23	11,0
Pancreatic Neuroendocrin Tumor	20	9,5
Pancreatic Cystadenoma	15	7,1
Cholangiocarcinoma	13	6,2

**Table 2b**

Most Frequent Diagnosis in Hepatobiliary Surgery	Frequency	Percentage
Colorectal Liver Metastases	219	49,3
Benign Hepatic Disease	52	11,7
Non-Colorectal Liver Metastases	49	11,0
Hepatocarcinoma	39	8,8
Cholangiocarcinoma	28	6,3
Gallbladder cancer	19	4,3



**Table 3**

Patients' Characteristics	Incisional Hernia	No Incisional Hernia	p (significance)
Number of patients	21	189	-
Procedure			
DPC+Partial hepatectomy	0	5	0.706
Distal pancreatectomy	2	16	
Partial pancreatectomy	2	10	
Proximal pancreatectomy	0	2	
Subtotal pancreatectomy	0	5	
Radical duodenopancreatectomy	16	150	
Non-specified intervention	1	2	
Gender			
Female	6	87	0.166
Male	15	102	
Age (years)	62.48 (38-81)	60.93 (29-85)	0.636
Weight (kg)	75.16 (53-107)	66.86 (40-120)	0.006
Height (cm)	169.29 (154-181)	164.71 (140-187)	0.012
BMI (kg/m <sup>2</sup> )	26.21 (20.20-33.39)	24.60 (16.41-45.79)	0.072
Smoker	2	26	0.747
Diabetes mellitus	4	46	0.788
Perirenal fat (mm)	22.61 (3.5-50.5)	17.58 (1.2-43.6)	0.075
Subcutaneous fat (mm)	23.85 (10.6-39.9)	20.14 (4.3-42.6)	0.139
History of Chemotherapy	1	8	1.000
Previous Incisional Hernia	0	3	1.000
History of Surgery	12	112	1.000
ASA Score			
1	2	23	0.158
2	12	131	
3	6	34	
4	1	1	
Preoperative albumin (g/l)	35.71 (18.1-52.6)	36.54 (7.1-48.8)	0.731
Preoperative creatinine	0.89 (0.37-2.22)	0.84 (0.29-8.29)	0.373
Malignancy	15	127	0.809
Stage			
I	4	9	0.123
II	2	34	
III	7	72	
IV	2	11	
Duration of surgery (min)	332.90 (60-475)	325.11 (25-615)	0.343
Type of incision			
J Incision	11	103	0.933
Midline	3	20	
Subcostal	6	59	
Transverse	1	6	
Type of closing suture			
PDS®	3	34	0.336
Prolene®	6	94	
Vicryl®	1	3	
Absorbable	4	42	0.725
Monofilament	9	133	0.249
Blood Transfusion	1	10	1.000
Postoperative hospital stay (days)	45.48 (9-221)	19.07 (3-204)	<0.0001
Antibiotic therapy	13	107	0.817
Postoperative chemotherapy	6	83	0.245
Morbidity (Clavien-Dindo ≥ 3)	9	26	0.001
Seroma	1	5	0.473
Superficial wound dehiscence	8	8	<0.0001
Superficial surgical site infection	13	20	<0.0001
Pleural effusion	15	65	0.001
Pneumonia	1	7	0.576
Atelectasis	7	35	0.146
Follow up time (months)	8.18 (0.33-29.10)	31.79 (3.33-90.10)	<0.0001

**Table 4**

Patients' Characteristics	Cox Regression Univariate		Cox Regression Multivariate	
	HR (95% CI)	p	HR (95% CI)	p
Procedure	0.792 (0.458-1.369)	0.403		
Gender (Female/Male)	0.472 (0.183-1.216)	0.120		
Age > 66.7 (years)	1.156 (0.486-2.746)	0.743		
Weight > 69.5 (kg)	3.703 (1.356-10.109)	0.011	2.919 (0.458-18.584)	0.257
Height > 167.5 (cm)	4.704 (1.823-12.135)	0.001	4.835 (1.181-19.798)	0.028
BMI > 24.5 (kg/m <sup>2</sup> )	2.319 (0.936-5.748)	0.069	1.992 (0.472-8.401)	0.348
Smoker	0.601 (0.140-2.582)	0.493		
Diabetes mellitus	0.767 (0.258-2.281)	0.634		
Perirenal fat > 16.55 (mm)	2.912 (1.037-8.178)	0.042	0.996 (0.227-4.369)	0.995
Subcutaneous fat > 23.25 (mm)	2.533 (1.000 -6.419)	0.050	3.692 (1.080-12.621)	0.037
History of Chemotherapy	1.530 (0.204-11.462)	0.679		
Previous Incisional Hernia	0.049 (0.000 - >100.00)	0.719		
History of Surgery	0.892 (0.376-2.116)	0.795		
ASA Score (1/2:3/4)	1.090 (0.763-1.556)	0.637		
Preoperative albumin > 37.55 (g/l)	0.983 (0.417-2.316)	0.969		
Preoperative creatinine > 0.755	1.410 (0.594-3.346)	0.436		
Malignancy	1.407 (0.544-3.639)	0.481		
Duration of surgery > 327.5 (min)	2.107 (0.871-5.093)	0.098	1.402 (0.371-5.300)	0.618
Type of incision	1.103 (0.771-1.580)	0.591		
Type of closing suture	1.241 (0.334-4.612)	0.747		
Blood Transfusion	0.928 (0.125-6.919)	0.942		
Postoperative hospital stay > 17,5 (days)	3.100 (1.251-7.682)	0.015	0.750 (0.172-3.271)	0.701
Antibiotic therapy	1.170 (0.485-2.825)	0.727		
Postoperative chemotherapy	0.564 (0.218-1.454)	0.236		
Morbidity (Clavien-Dindo $\geq$ 3)	4.088 (1.722-9.705)	0.001	0.232 (0.037-1.468)	0.121
Seroma	1.630 (0.219-12.148)	0.634		
Superficial wound dehiscence	15.075 (6.128-37.082)	<0.0001	26.402 (4.114-160.43)	0.001
Superficial surgical site infection	11.667 (4.823-28.224)	<0.0001	6.698 (2.116-21.199)	0.001
Pleural Effusion	4.334 (1.681-11.172)	0.002	2.243 (0.615-8.176)	0.221
Pneumonia	1.110 (0.149-8.274)	0.919		
Atelectasis	2.032 (0.820-5.036)	0.126		

**Table 5**

Patients' Characteristics	Incisional Hernia	No Incisional Hernia	p (significance)
Number of patients	62	382	-
Procedure			
Liver Biopsy	1	5	0.317
Partial Hepatectomy	58	367	
Liver Lobectomy	3	6	
Non-specified intervention	0	4	
Gender			
Female	23	179	0.170
Male	39	203	
Age (years)	64.21 (34-81)	59.25 (21-86)	0.004
Weight (kg)	77.01 (50-122)	70.82 (40-130)	0.004
Height (cm)	164.31 (144-185)	163.88 (110-194)	0.673
BMI (kg/m <sup>2</sup> )	28.55 (20.90-42.74)	26.42 (17.16-66.94)	0.002
Smoker	9	36	0.218
Diabetes mellitus	16	64	0.107
Perirenal fat (mm)	21.70 (4.0-48.0)	16.67 (2.0-53.1)	0.001
Subcutaneous fat (mm)	28.31 (6.8-56.0)	24.10 (4.2-54.9)	0.067
History of Chemotherapy	25	184	0.274
Previous Incisional Hernia	7	15	0.013
History of Surgery	52	304	0.496
ASA Score			
1	1	34	0.185
2	43	242	
3	17	104	
4	1	2	
Preoperative albumin (g/l)	38.82 (17.7-48.0)	39.51 (10.4-51.4)	0.423
Preoperative creatinine	0.83 (0.40-1.78)	0.79 (0.36-5.60)	0.070
Malignancy	50	303	0.603
Stage			
I	7	23	0.514
II	11	58	
III	19	124	
IV	13	86	
Duration of surgery (min)	245.85 (120-506)	233.48 (50-540)	0.281
Type of incision			
J Incision	42	263	0.172
Midline	3	14	
Subcostal	14	66	
Transverse	1	36	
Type of closing suture			
Monomax®	0	7	0.587
PDS®	26	138	
Prolene®	21	147	
Vicryl®	5	31	
Absorbable	31	177	0.551
Monofilament	47	292	1.000
Prosthetic prophylaxis	1	1	0.141
Blood Transfusion	6	28	0.451
Postoperative hospital stay (days)	13.21 (4-42)	9.21 (2-109)	0.001
Antibiotic therapy	25	83	0.002
Postoperative chemotherapy	39	260	0.422
Morbidity (Clavien-Dindo ≥ 3)	6	17	0.114
Seroma	4	16	0.503
Superficial wound dehiscence	2	15	1.000
Superficial surgical site infection	9	26	0.070
Pleural effusion	17	72	0.125
Pneumonia	2	6	0.310
Atelectasis	5	36	1.000
Follow up time (months)	19.51 (1.83-80.47)	28.86 (1.83-93.77)	< 0.0001

**Table 6**

Patients' Characteristics	Cox Regression Univariate		Cox Regression Multivariate	
	HR (95% CI)	p	HR (95% CI)	p
Procedure	1.336 (0.895-1.994)	0.156		
Gender (Female/Male)	0.610 (0.364-1.024)	0.061	1.019 (0.439-2.365)	0.964
Age > 61.5 (years)	1.492 (0.898-2.480)	0.122		
Weight > 71.95 (kg)	2.011 (1.200-3.370)	0.008	0.735 (0.290-1.861)	0.516
Height > 163.75 (cm)	1.537 (0.928-2.546)	0.095	1.066 (0.499-2.273)	0.869
BMI > 25.95 (kg/m <sup>2</sup> )	1.785 (1.047-3.042)	0.033	2.694 (1.063-6.824)	0.037
Smoker	2.051 (1.005-4.185)	0.048	2.243 (0.930-5.409)	0.072
Diabetes mellitus	1.535 (0.869-2.712)	0.140		
Perirenal fat > 14.65 (mm)	2.829 (1.490-5.370)	0.001	2.251 (1.028-4.931)	0.043
Subcutaneous fat > 23.7 (mm)	1.472 (0.821-2.638)	0.194		
History of Chemotherapy	0.685 (0.412-1.139)	0.144		
Previous Incisional Hernia	2.187 (0.990-4.830)	0.053	1.451 (0.574-3.669)	0.432
History of Surgery	1.091 (0.568-2.094)	0.794		
ASA Score (1/2:3/4)	1.077 (0.622-1.866)	0.791		
Preoperative albumin > 40.45 (g/l)	0.816 (0.470-1.417)	0.471		
Preoperative creatinine > 0.715	1.976 (1.155-3.380)	0.013	1.586 (0.761-3.303)	0.218
Malignancy	0.907 (0.492-1.675)	0.756		
Duration of surgery > 224.5 (min)	1.141 (0.693-1.880)	0.604		
Type of incision	1.077 (0.878-1.321)	0.476		
Type of closing suture	0.716 (0.460-1.114)	0.138		
Prosthetic prophylaxis	2.997 (0.414-21.673)	0.277		
Blood Transfusion	1.287 (0.554-2.989)	0.558		
Postoperative hospital stay > 6.5 (days)	2.116 (1.231-3.638)	0.007	1.509 (0.761-3.079)	0.258
Antibiotic therapy	2.206 (1.327-3.666)	0.002	1.563 (0.767-3.188)	0.219
Postoperative chemotherapy	0.633 (0.377-1.062)	0.083	0.526 (0.264-1.047)	0.068
Morbidity (Clavien-Dindo $\geq$ 3)	1.957 (0.843-4.545)	0.118		
Seroma	1.833 (0.663-5.063)	0.243		
Superficial wound dehiscence	1.173 (0.285-4.825)	0.825		
Superficial surgical site infection	2.387 (1.171-4.865)	0.017	1.425 (0.553-3.674)	0.463
Pleural effusion	1.806 (1.031-3.162)	0.039	1.091 (0.485-2.454)	0.833
Pneumonia	3.691 (0.896-15.211)	0.071	1.425 (0.302-20.188)	0.400
Atelectasis	0.902 (0.361-2.253)	0.825		

## **ANNEXES**

Approval by São João Hospital Center Ethics Commission

Hernia | Springer – Instructions for Authors

**Unidade de Investigação**

Tomei conhecimento. Nada a opor.

22 de Maio de 2017

A Coordenadora da Unidade de Investigação

(Prof.ª Doutora Ana Azevedo)

## PEDIDO DE AUTORIZAÇÃO

**Realização de Investigação**

Aprovado. Ao CA.

DIRECÇÃO CLÍNICA

245 / 17

(Prof.ª Doutora Ana Azevedo)

Exmo. Senhor Presidente do Conselho de Administração  
do Centro Hospitalar de São João

**Nome do Investigador Principal:**

José Chen Xu

**Título da Investigação:**

Hérnia Incisional em cirurgia hepatobiliar e pancreática - incidência e fatores de risco

**AUTORIZADO**

CONSELHO DE ADMINISTRAÇÃO - REUNIÃO DE 25 MAI 2017			
Presidente do Conselho de Administração			
(Dr. António Oliveira e Silva)			
Director Clínico	Enfermeira-Directora	Vogal Executivo	Vogal Executivo
(Prof. Dr. José Artur Pinhal)	(En.ª Flávia Cardoso)	(Dr. Luís Pinto Guimarães)	(Dr. Renata C. Moutão)

Pretendo realizar no(s) Serviço(s) de:

Cirurgia Geral

a investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador/Promotor, autorização para a sua efetivação.

Para o efeito, anexo toda a documentação referida no dossier da Comissão de Ética do Centro Hospitalar de São João/Faculdade de Medicina da Universidade do Porto respeitante à investigação, à qual enderecei pedido de apreciação e parecer.

Com os melhores cumprimentos.

O Investigador/Promotor

Porto, 9 de fevereiro de 2017.

  
assinatura

Parecer da Comissão de Ética para a Saúde do  
Centro Hospitalar de São João / Faculdade de Medicina da Universidade do Porto

**Título do Projecto:** Hérnia Incisional em cirurgia hepatobiliar e pancreática - Incidência e fatores de risco

**Nome do Investigador Principal:** José Chen Xu, aluno do Mestrado Integrado em Medicina da FMUP

**Onde decorre o Estudo:** No Serviço de Cirurgia Geral do CHSJ. Dispõe de autorização do Dr. José Costa Maia.

**Objectivos do Estudo:**

Determinar a incidência de hérnia incisional após cirurgia aberta hepatobiliar e pancreática.

Determinar fatores de risco de hérnia incisional em cirurgia hepatobiliar e pancreática.

Inserir-se no âmbito do Mestrado Integrado em Medicina da FMUP, sob orientação do Dr. Renato José Bessa de Melo.

**Benefício/risco:** N/A

**Confidencialidade dos dados:**

Os dados serão utilizados recorrendo a uma referência numérica, garantindo o seu anonimato.

**Respeito pela liberdade e autonomia do sujeito de ensaio:** N/A

**Curriculum do investigador:** Adequado à investigação.

**Data previsível da conclusão do estudo:** Março de 2018

**Conclusão:** Proponho um parecer favorável à realização deste projecto de investigação.

Porto, 21 de Abril de 2017

O Relator da CES, Dr. John Preto





## Questionário para submissão de Investigação

Exmo. Sr. Presidente da Comissão de Ética do Centro Hospitalar de São João/  
Faculdade de Medicina da Universidade do Porto,

Pretendo realizar a investigação infracitada, solicito a V. Exa., na qualidade de Investigador, a sua apreciação e a elaboração do respetivo parecer. Para o efeito, anexo toda a documentação requerida.

**IDENTIFICAÇÃO DO ESTUDO**

Título da investigação: Hérnia Incisional em cirurgia hepatobiliar e pancreática - incidência e fatores de risco

Nome do investigador: José Chen Xu

Endereço eletrónico: josechenx@gmail.com

Contacto telefónico: 917862758

Caracterização da investigação:

Estudo retrospectivo

Estudo observacional

Estudo prospetivo

Inquérito

Outro. Qual? \_\_\_\_\_

Tipo de investigação:

Com intervenção

Sem intervenção

Formação do investigador em boas práticas clínicas (GCP):  Sim  Não

Promotor (se aplicável): \_\_\_\_\_

Nome do orientador de dissertação/tese (se aplicável): Renato José Bessa de Melo

Endereço eletrónico: rbmelo@gmail.com

Local/locais onde se realiza a investigação: Centro Hospitalar de São João

Data prevista para início: 09 / 02 / 2017

Data prevista para o término: 01 / 03 / 2018

**PROTOCOLO DO ESTUDO**

Síntese dos objetivos:

- Determinar a incidência de hérnia incisional após cirurgia aberta hepatobiliar e pancreática.
- Determinar fatores de risco de hérnia incisional em cirurgia hepatobiliar e pancreática.

Fundamentação ética (ganhos em conhecimento/ inovação; ponderação benefícios/riscos):

O presente estudo permitirá averiguar fatores de risco que refletir-se-ão potencialmente em ganho de conhecimento e beneficiar futuros doentes a serem submetidos a cirurgia aberta em hepatobiliar ou pancreática. Permitirá portanto a concetualização de estratégias para minimizar o risco de desenvolvimento de hérnias ventrais após cirurgia aberta.



## CONFIDENCIALIDADE

De que forma é garantida a anonimização dos dados recolhidos de toda a informação?

Os dados serão utilizados recorrendo a uma referência numérica, garantindo o seu anonimato.

O investigador necessita ter acesso a dados do processo clínico?  Sim  Não

Está previsto o registo de imagem ou som dos participantes?  Sim  Não

Se sim, está prevista a destruição deste registo após o sua utilização?  Sim  Não

## CONSENTIMENTO

O estudo implica recrutamento de:

Doentes:  Sim  Não Voluntários saudáveis:  Sim  Não

Menores de 18 anos:  Sim  Não

Outras pessoas sem capacidade do exercício de autonomia:  Sim  Não

A investigação prevê a obtenção de Consentimento Informado:  Sim  Não

Se não, referir qual o fundamento para a isenção:

Não serão causados riscos ou incómodos a outrem, uma vez que não será necessário contacto direto com os doentes. Irão ser utilizados os dados do processo, que serão submetidos a tratamento de dados eletrónico.

Existe informação escrita aos participantes:  Sim  Não

## PROPRIEDADE DOS DADOS

A investigação e os seus resultados são propriedade intelectual de:

Investigador  Promotor  Ambos  Serviço onde é realizado

Não aplicável

Outro: \_\_\_\_\_

## BENEFÍCIOS, RISCOS E CONTRAPARTIDAS PARA OS PARTICIPANTES

Benefícios previsíveis:

Riscos/incómodos previsíveis:

São dadas contrapartidas aos participantes:

· pela participação  Sim  Não  Não aplicável

· pelas deslocações  Sim  Não  Não aplicável

· pelas faltas ao emprego  Sim  Não  Não aplicável

· por outras perdas e danos  Sim  Não  Não aplicável

## CUSTOS / PLANO FINANCEIRO

Os custos da investigação são suportados por:

Investigador  Promotor  Serviço onde é realizado

Não aplicável

Outro: \_\_\_\_\_

Existe protocolo financeiro?  Sim  Não

## LISTA DE DOCUMENTOS ANEXOS

- Pedido de autorização ao Presidente do Conselho de Administração do Centro Hospitalar de São João (se aplicável)
- Pedido de autorização à Diretora da Faculdade de Medicina da Universidade do Porto (se aplicável)
- Protocolo do estudo
- Declaração do Diretor de Serviço onde decorre o estudo  
(sendo um estudo na área de enfermagem deve anexar também a concordância da chefia de enfermagem)
- Profissional de ligação
- Informação dos orientadores
- Informação ao participante
- Modelo de consentimento
- Instrumentos a utilizar (inquéritos, questionários, escalas, p.ex.): \_\_\_\_\_
- Curriculum Vitae abreviado (máx. 3 páginas)
- Protocolo financeiro
- Outros:

## COMPROMISSO DE HONRA E DECLARAÇÃO DE INTERESSES

Declaro por minha honra que as informações prestadas neste questionário são verdadeiras. Mais declaro que, durante o estudo, serão respeitadas as recomendações constantes da Declaração de Helsínquia (1960 e respetivas emendas), e da Organização Mundial da Saúde, Convenção de Oviedo e das "Boas Práticas Clínicas" (GCP/ICH) no que se refere à experimentação que envolve seres humanos. Aceito, também, a recomendação da CES de que o recrutamento para este estudo se fará junto de doentes que não tenham participado em outro estudo, nos últimos três meses. Comprometo-me a entregar à CES o relatório final da investigação, assim que concluído.

Porto, 9 de fevereiro de 2017

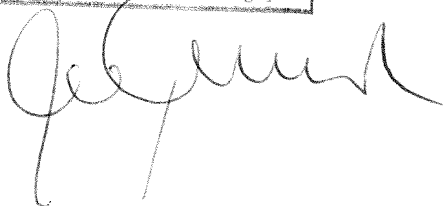
Nome legível: José Chen Xu

  
assinatura

Parecer da Comissão de Ética do Centro Hospitalar de São João/FMUP

Emitido na reunião plenária da CE de 21 / 04 / 17

A Comissão de Ética para a Saúde  
APROVA por unanimidade o parecer do  
Relator, pelo que nada tem a opor à  
realização deste projecto de investigação.





## Hernia

The World Journal of Hernia and Abdominal Wall Surgery

Editor-in-Chief: M. **Miserez**; R.J. **Fitzgibbons**

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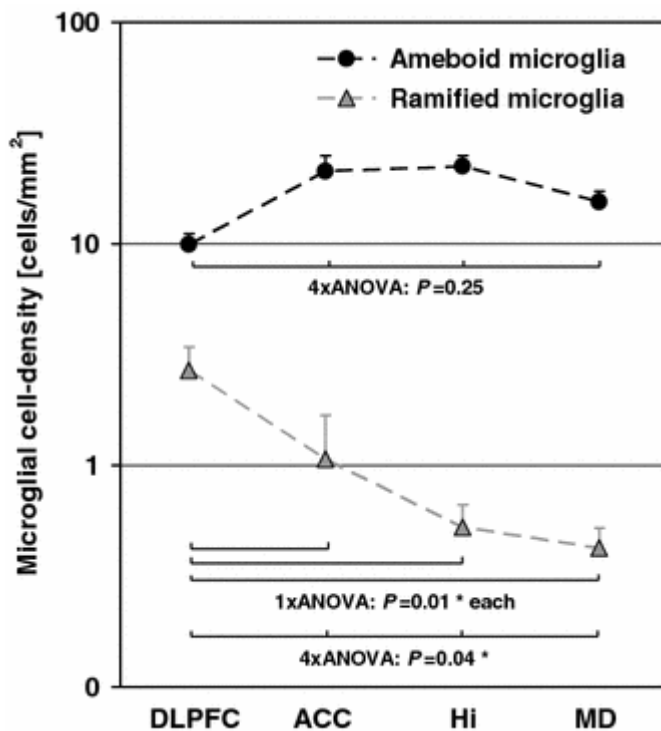
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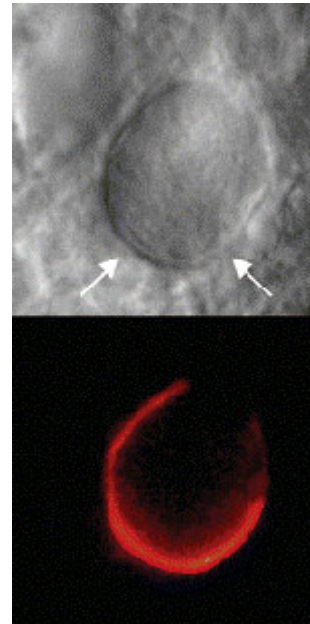
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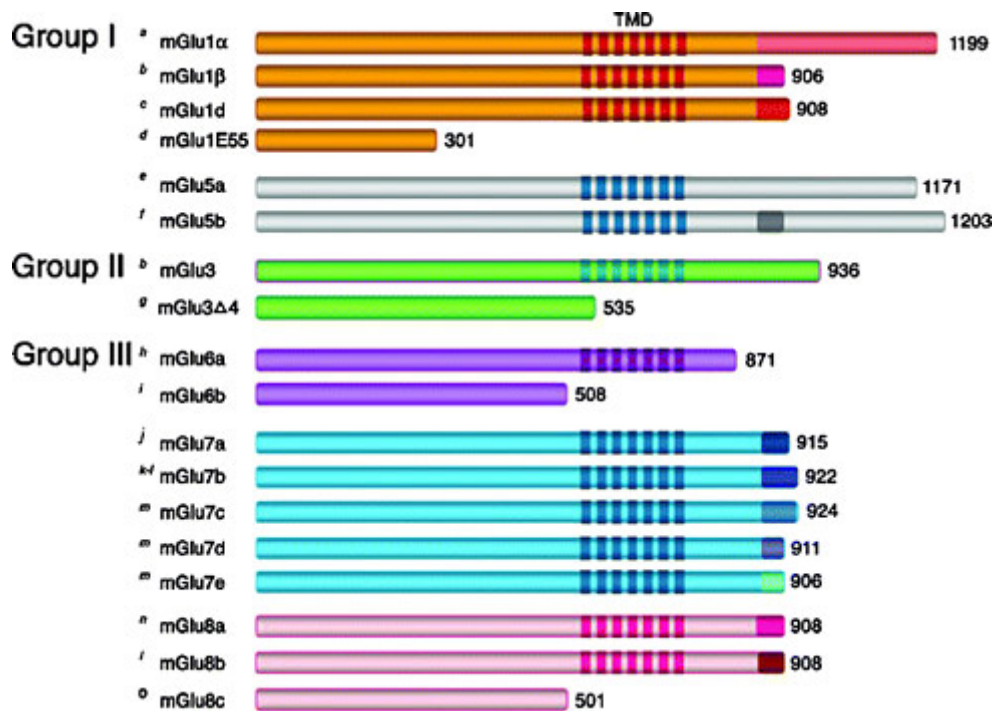
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## **APPENDIX**

Poster presented in the “XXXVIII Congresso Nacional de Cirurgia”, from 8<sup>th</sup> to 10<sup>th</sup> March 2018 in  
Lisbon, Portugal, organised by Sociedade Portuguesa de Cirurgia.

# Hérnia Incisional em Cirurgia Hepatobiliar e Pancreática – incidência e fatores de risco

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## INTRODUÇÃO

A ocorrência de hérnia incisional (HI) é uma das principais complicações da cirurgia aberta. Porém, a sua incidência em cirurgia hepatobiliar e cirurgia pancreática não é conhecida. Escassos artigos referem a incidência de HI em hepatectomia parcial e em pancreatite necrotizante. Os dados mostram que pode chegar até aos 42%. O objetivo deste estudo é a determinação da incidência de HI e os seus fatores de risco (FR).

## MÉTODOS

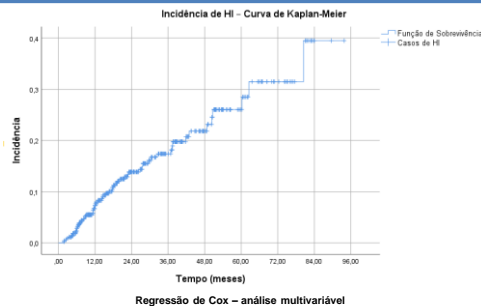
Inclusão de **654** doentes submetidos a cirurgia hepatobiliar ou pancreática aberta entre **janeiro 2010 e dezembro 2016** no **CHSJ**. Foram excluídos os casos de pancreatite aguda. Analisaram-se **34** variáveis para determinar os fatores de risco para HI.

Análise Estatística:

- Teste Mann-Whitney e  $\chi^2$  ou teste exato de Fisher;
- Curvas ROC - *threshold* nas variáveis contínuas;
- Curvas de Kaplan-Meier - incidência de HI;
- Método de Regressão Cox na análise univariável e multivariável - determinação FR independentes.

Hérnia incisional foi definida como descontinuidade na fáscia abdominal reportada no exame físico ou observada na tomografia computadorizada.

### Cirurgia Hepatobiliar



Variável	Hazard Ratio	Valor de p
IMC > 25.95 kg/cm <sup>2</sup>	2.694 (1.063-6.824)	0.037
Gordura Perirrenal > 14.65 mm	2.251 (1.028-4.931)	0.043

### Cirurgia Pancreática



Variável	Hazard Ratio	Valor de p
Altura > 167.5 cm	4.835 (1.181-19.798)	0.028
Gordura Subcutânea > 23.25 mm	3.692 (1.080-12.621)	0.037
Deiscência superficial	26.402 (4.114-160.43)	0.001
Infeção do local cirúrgico	6.698 (2.116-21.199)	0.001

## CONCLUSÃO

A altura, obesidade e complicações da ferida operatória são fatores de risco para IH em doentes submetidos a cirurgia pancreática, enquanto que a obesidade apresentou correlação independente com a incidência de hérnia incisional, sendo fator de risco no grupo submetido a cirurgia hepatobiliar. Os doentes submetidos a cirurgia pancreática apresentam uma incidência que vai até aos 12%; já o risco de HI é elevado nos doentes submetidos a cirurgia hepatobiliar – 27%. Sugere-se a incorporação de estratégias na prática clínica que permitam diminuir este número, nomeadamente nos doentes de alto risco.