Predictive factors for utilization of a low-volume center in pancreatic surgery: A nationwide study.

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Predictive factors for utilization of a low-volume center in pancreatic surgery: A nationwide study

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Abstract

Study objective: It has been demonstrated that mortality following pancreatectomy is correlated with surgical volume. However, up until now no French study has dwelt on relevant predictive factors in a low-volume center. The objective of this study is to analyze the clinical, socio-economic and medical density details characterizing patients according to an establishment's surgical volume and to analyze predictive factors for hospitalization in a low- volume center.

Patients and methods: All patients having undergone a pancreatectomy in France from 2012 to 2015 were included, using the PMSI data base. Establishments were classified as low, intermediate and high volume (<10, 11-19, ≥20 resections / year). The variables taken into account were clinical and socio-economic data, distance covered (from home to hospital) and urbanization.

Results: More than 12000 (12333) patients were included. Those having undergone surgery in a low-volume center were significantly older, with high Charlson comorbidity index (CCI); their socio-economic level was lower, and they more often resided in rural areas. The distances covered by patients operated in low-volume centers were significantly shorter than in high-volume centers (23 vs 61 km, $p<0.001$). In multivariate analysis, advanced age ($p=0.04$), $CCI \geq 4$ ($p=0.008$), short distance covered ($p<0.001$), low socio-economic level ($p<0.001$) and rurality ($p<0.001$) were predictive for pancreatectomy in a low-volume center.

Conclusion: Utilization of a low-volume center depends not only on clinical parameters, but also on socio-economic and environmental factors, which should be taken into account in view of improving postoperative course through more centralized organization of pancreatic surgery.

Keywords: pancreatectomy, low-volume center, PMSI, centralization

Essential points:

- Pancreatic surgery is a complex operation entailing appreciable morbi-mortality.
- Approximately 3000 pancreatic resections are carried out each year in France.
- Centralization of pancreatic surgery in high-volume centers would help to improve postoperative course.
- Utilization of a low-volume center is correlated with age, comorbidities, distance, socio-economic level and rurality.

Introduction

In France, approximately 3000 pancreatic resections are carried out every year. Pancreatic surgery is a complex operation, entailing non-negligible morbi-mortality (1). The mortality rate has significantly declined, and is currently lower than 5% in establishments considered as expert centers (2). And yet, even though fewer patients die, overall morbidity has remained high (1), ranging from 30% to 60% (3). Complications are detrimental to patient quality of life (4), have an economic impact (5,6) and affect survival after cancer surgery (7).

Numerous studies have suggested a reduction of postoperative mortality after complex surgery in high-volume centers (8–10). In France, two studies based on the *Programme de Médicalisation des Systèmes d'Information* (PMSI, medical information system program) (2,9) show a clear correlation between center volume and postoperative morbi-mortality after pancreatectomy. They studies confirm the results of numerous studies conducted in several European countries and the United States. The authors recommend centralization of pancreatic surgery in high-volume centers as a means of improving postoperative course (11,12). Moreover, there now exist positive examples concerning centralization of certain surgical procedures, and it has led to significant reduction of postoperative mortality rates and even, in some cases, to prolonged survival of patients operated for cancer (13,14).

Above all, it is imperative that centralization policies guarantee equitable access to care for the entire population. This is a major public health issue raising organizational as well as medico-economic questions. In this respect, the available studies show that elderly patients and/or those with comorbidities tend to undergo heavy-duty surgery in low-volume centers (15,16). These patients present the highest surgical risk and would benefit the most from surgery in a high-volume center (17). Other studies have reported disparities in socio-

economic status and distances covered (from home to hospital) according to surgical volume of hospital establishment (15,18–20).

While centralization should improve postoperative course after pancreatic surgery, it must not alter vulnerable persons' access to care. Comprehension of the factors liable to influence patient choice would contribute to effective organization of the centralization process. In France, however, we are lacking in data on patient characteristics according to the volume of the establishment where their pancreatic surgery was carried out.

The objective of this work is to analyze patients' clinical and socio-economic information according to surgical volume and to determine the predictive factors for utilization of a low-volume center.

Patients and methods

The study population

Using the PMSI data base, we included all patients having undergone major pancreatic resection (cephalic duodenopancreatectomy (CDP), left pancreatectomy (LP), total pancreatectomy (TP) and central pancreatectomy (CP)) by laparoscopy or laparotomy between January 2012 and December 2015. Identification of the pancreatectomy procedures was carried out using the following CCAM codes: HNFA001, HNFA002, HNFA004, HNFA007, HNFA008, HNFA010, HNFA013, HNFC002, HNFC028. We excluded enucleations, bypass surgery and emergency procedures. The patients included had been operated for benign or malignant tumors, which were identified by the following CIM-10 diagnostic codes: C25,

C250, C251, C252, C253, C254, C254+0, C254+8, C257, C258, C259, C259+0, C259+8, C170, C240, C241, C249, D132, D136, D137. All patients less than 18 years of age, of foreign nationality or whose hospital stay contained coding errors were excluded (Figure 1).

Study variables

- Surgical volume

As was the case in a previous publication by our team (2), we used the discriminant threshold of 20 resections/year. In order to create several categories of centers, a second threshold (10 resections/year) was added, and the centers were consequently stratified by volume category as follows: low (<10 pancreatic resections /year), intermediate (10-19 pancreatic resections /year) and high (≥ 20 pancreatic resections /year).

- Clinical and socio-economic data

Data relative to age, sex, nutritional status, obesity, neoadjuvant chemotherapy, indication and surgical approach were taken into consideration. Patient comorbidities were evaluated according to the Charlson comorbidity index (CCI). The patients were stratified in three groups according to degree of surgical risk (0-2, 3 and ≥4).

Distance was calculated in kilometers "as the crow flies". Patients were localized in the centers of the geographic zone corresponding to the residence code entered in the PMSI data base. The hospital centers were situated according to their FINESS (national health facility register) identification numbers.

The **F**rench social **dep**rivation index (FDep) (21) was calculated on the municipal scale using population data taken from the 1999 census records of INSEE, the French national institute

for statistics and economic studies, and from taxable household incomes in 2001. In our work, the indicator quartiles standardized at the nationwide level between 0 (not disfavored) and 1 (disfavored) were taken into consideration.

Rurality was defined by a zone of residence containing fewer than 5000 inhabitants. The zones were situated according to the residence code entered in the PMSI data base.

Statistical analysis

The qualitative variables were expressed as percentages, and the quantitative variables as means. The qualitative variables were compared with each other using the Chi^2 and Pearson tests. Cross-tabulation of the quantitative and qualitative variables was studied using the Kruskal-Wallis tests. Predictive factors for utilization of a low-volume center were sought out. Bivariate analysis was carried out, after which a multinomial multilevel model was designed, explaining yearly per-center surgical volume divided into classes, with type of surgery, characteristics (age, sex…) patient comorbidities (CCI), distance covered between hospital and patient homes, social deprivation index (FDep) and rurality of residential community as explanatory variables.

All of the *p* values presented corresponded to a bilateral test, and the significance threshold was set at $p < 0.05$. The different statistical analyses were carried out using STATA 13 (StataCorp, College Station, TX).

Results

Description of the study population (Table 1)

From January 2012 to December 2015 in France, 12,333 patients underwent pancreatic resection for benign and malignant tumors. The annual average number of pancreatectomies was 3083.25, with a progressive increase during the study period (Figure 2). The population was consisted in 47.2% of women and 52.8% of men, with a sex ratio of 1.12. The majority of the patients were over 60 years of age (70.8%), and half of them (49.7%) were ranked 0-2 on the CCI. The main surgical intervention was CDP (68.9%), followed by TP (26.9%), and the main indication for pancreatectomy was pancreas adenocarcinoma (PAC) (74.8%).

The proportion of patients operated in low, intermediate and high-volume centers was 29%, 19% and 52% respectively. The majority of the centers were low-volume (74.9%) (Figure 3). Patients with high CCI ($\geq$4) were more often operated in low and intermediate than in high-volume centers (34.3% and 36% vs 29.4% respectively, $p<0.001$). On the same token, patients over 60 were most often treated in a low-volume center (low = 73.5%, intermediate = 73.1% and high = 68.5%; $p<0.001$). Finally, the proportion of neo-adjuvant treatment was higher in the high (9.9%) than in the low (3.5%) and the intermediate centers (6.3%) ($p<0.001$).

Study of distances covered and patient socio-economic parameters according to surgical volume (Table 2)

In our series, the average distance covered by patients on their way to or from a center was 44.8 km. Among the patients having utilized a high-volume center, 38.8% had traversed a distance exceeding 56 km. Conversely, only 6.9% of the patients operated in low-volume centers had covered as many kilometers. Average FDep was 0.56. The most deprived patients ([0.68-1.00]) tended to utilize low-volume (20.8%) rather than high-volume centers

(19.6%) (p = 0.020). As regards rurality, 34.3% of the patients having undergone pancreatic surgery inhabited a rural area. There was no statistical difference between the three surgical volume groups (p = 0.133).

Predictive factors for utilization of a low-volume center (Table 3)

We carried out a multivariate analysis to determine the predictive factors for utilization of a low-volume center. When we used high-volume centers as a reference, our results showed that utilization of a low-volume center was correlated with age, CCI, distance, FDep and rurality. Indeed, the likelihood of pancreatic center in a low-volume center increased proportionally with age, particularly in patients over 80 years old (OR 2.162 [1.511-3.094], p<0.001). In addition, CCI $\geq$ 4, low socio-economic level and rurality were associated with utilization of a low-volume center. The probability of utilizing a low-volume center was inversely proportional to distance.

Discussion

We are reporting in this work on a French study pertaining to more than 12000 patients having undergone pancreatectomy. With the objective of centralizing pancreatic surgery in high-volume centers, we analyzed factors predictive for utilization of a low-volume center. Our results show that age, comorbidities, socio-economic level, rurality and distance covered are correlated with surgical volume. These results are congruent with those of the literature from other countries.

The study of the German register published by Krautz *et al* and pertaining to 60000 patients found that those operated in low-volume centers were older and tended to have more comorbidities (16). Several relevant studies have also been conducted in the United States.

After having analyzed more than 129,000 pancreatectomies using the American NIS data base, Bliss *et al* concluded that utilization of low-volume (<5 resections/year) or intermediate (5-18 resections/year) centers was correlated with more comorbidities and lower private insurance coverage and, logically, with more unfavorable economic status (15). Stitzenberg *et al* dealt with the impact of cancer surgery centralization on the distances covered by patients. Their study revealed, among other findings, a 40% increase in median distance in cases involving utilization of a high-volume center (19). In addition, Jindal *et al* observed a 77% decrease in 30-day mortality when pancreatectomy was carried out in a center necessitating lengthy travel (20). Lastly, Kagendan *et al* demonstrated that patients residing in rural areas and those with low income had less access to optimal management in pancreatic cancer treatment (18).

Our results suggest that the issue of centralization goes beyond sheerly medical consideration, and that it necessitates overall, policy-based solutions. Several European countries have adopted a medical centralization system, and the results have been favorable. In the Netherlands, for example, centralization policies were implemented starting in 2005, and through collaboration with low-volume centers, they helped to bring about a reduction in postoperative mortality (22) and improved survival of patients having undergone cancer-related operations (23). And in Germany since 2004, operating centers are required to carry out at least 10 pancreatic resections a year (24).

In France, since 2007 there exists a minimum threshold of 30 cancer-related digestive resections a year; it entitles centers to carry out oncologic digestive surgery (25). Decided upon by the French national cancer institute (INCA), this threshold presents several salient limitations. First of all, it was determined arbitrarily, without being preceded by any targeted

study, and its relevance is correspondingly reduced. More precisely, present-day data suggest that this threshold remains below thresholds specific to a given type of cancer or resection (2,17). Moreover, application of this threshold in current practice is problematic insofar as approximately 30% of the centers in France maintain surgical practice without having the necessary volume of activity (26). Lastly, by including only digestive surgery for cancer, the threshold remains restrictive; it fails to take into account a certain number of complex, “heavy duty”, functionally challenging operations for benign pathologies.

Other difficulties may be encountered during the centralization process. The first of them has to do with the surgeon himself, whose activity may as a result be limited, with easily imaginable deleterious consequences from a professional (lessened peer recognition, lower salary…) as well as psychological standpoint (lowered self-esteem, loss of self-confidence…). Secondly, centralization would necessitate overall reorganization of our health care system, the objective being to ensure optimal patient management. It would require not only the restructuring of existing establishments, but also the creation of new high-volume centers that would respond to increased need for care, and the incremental cost would be appreciable. Thirdly and finally, centralization could have a negative impact on the patient by significantly increasing the distances to be covered, lengthening waiting time prior to surgery, and eventually lowering overall quality of management.

Centralization of pancreatic surgery must necessarily involve surgeons and patients alike. Public awareness of the issue could facilitate the centralization process in France. Ideally, centralization would not be considered by surgeons in low-volume centers as privation of activity, but rather as an opportunity for collaboration with expert centers in a cohesive medical network designed to guarantee improved patient management. Lastly,

centralization of pancreatic surgery in France would seem crucial to improvement of postoperative course. It will need to effectively integrate all the parameters liable to influence patient choice, the objective being to guarantee equitable access to care within a reasonable time frame (27).

The limitations of our study should be taken into account when interpreting our results. First of all, its retrospective nature is a potential source of bias. Moreover, we used the PMSI data base, of which the reliability is directly correlated with coding quality. That much said, the reliability of coding in the PMSI data base has been enhanced, and since the financing of health care establishments is premised on the coding of medical procedures, it is regularly monitored by the French health ministry. In addition, we are now in possession of recent evidence illustrating the reliability of PMSI data (28–30). As regards our utilization of FDep, it is liable to induce bias insofar as deprivation is calculated in geographical terms and represents a reflection of overall socio-economic level. On another score, "as the crow flies" distance estimates do not precisely translate the distances actually covered by patients. And yet, notwithstanding the above limitations, our article is the first French study to analyze by means of robust methodology predictive factors for pancreatic surgery in low-volume centers.

Conclusion

In conclusion, pancreatic surgery is a complex procedure entailing appreciable morbi-mortality. There currently exists a significant difference in morbi-mortality according to surgical volume, difference that leads us to think that centralization of pancreatectomies has become a vital necessity. That much said, centralization must imperatively integrate

parameters including socio-economic level, rurality and distance covered, the objective being to guarantee high-quality patient care within a reasonable time frame.

The authors have no ties of interest to declare.

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Tables

Table 1: Patient characteristics

	Overall population: n=12 (N=12,333)	Low volume (N=3598)	Intermediate volume (N=2315)	High volume (N=6420)	
Sex					
Male	6511 (52.8%)	1877 (52.2%)	1262 (54.5%)	3372 (52.5%)	0.124
Female	5822 (47.2%)	1721 (47.8%)	1053 (45.5%)	3048 (47.5%)	
Age					
< 40 years	454 (3.7%)	96 (2.7%)	72 (3.1%)	286 (4.5%)	< 0.001
40-49 years	859 (7.0%)	221 (6.1%)	161 (7.0%)	477 (7.4%)	
50-59 years	2287 (18.5%)	637 (17.7%)	390 (16.8%)	1260 (19.6%)	
60-69 years	4217 (34.2%)	1235 (34.3%)	790 (34.1%)	2192 (34.1%)	
70-79 years	3653 (29.6%)	1130 (31.4%)	726 (31.4%)	1797 (28.0%)	
≥ 80 years	863 (7.0%)	279 (7.8%)	176 (7.6%)	408 (6.4%)	
CCI					
0-2	6127 (49.7%)	1695 (47.1%)	1045 (45.1%)	3387 (52.8%)	< 0.001
3	2250 (18.2%)	668 (18.6%)	437 (18.9%)	1145 (17.8%)	
≥ 4	3956 (32.1%)	1235 (34.3%)	833 (36.0%)	1888 (29.4%)	
Obesity					
No	11382 (92.3%)	3323 (92.4%)	2159 (93.3%)	5900 (91.9%)	0.032
Yes	951 (7.7%)	275 (7.6%)	156 (6.7%)	520 (8.1%)	
Malnutrition					
Non	8626 (69.9%)	2662 (74.0%)	1676 (72.4%)	4288 (66.8%)	< 0.001
Yes	3707 (30.1%)	936 (26.0%)	639 (27.6%)	2132 (33.2%)	
Surgical procedure					
CP	126 (1.0%)	14 (0.4%)	18 (0.8%)	94 (1.5%)	< 0.001
CDP	8498 (68.9%)	2546 (70.8%)	1635 (70.6%)	4317 (67.2%)	
LP	3314 (26.9%)	970 (27.0%)	587 (25.4%)	1757 (27.4%)	
TP	395 (3.2%)	68 (1.9%)	75 (3.2%)	252 (3.9%)	
Neo-adjuvant treatment					
No	11425 (92.6%)	3471 (96.5%)	2170 (93.7%)	5784 (90.1%)	< 0.001
Yes	908 (7.4%)	127 (3.5%)	145 (6.3%)	636 (9,9%)	
Indication					
Duodenal cancer	536 (4.3%)	170 (4.7%)	102 (4.4%)	264 (4.1%)	< 0.001
Cholangiocarcinoma	1482 (12.0%)	515 (14.3%)	266 (11.5%)	701 (10.9%)	
PAC	9227 (74.8%)	2664 (74.0%)	1762 (76.1%)	4801 (74.8%)	
Benign tumor	1088 (8.8%)	249 (6.9%)	185 (8.0%)	654 (10.2%)	

CCI: Charlson comorbidity index, CP: central pancreatectomy, CDP: cephalic duodeno-pancreatectomy, LP: left pancreatectomy, TP : total pancreatectomy, PAC: pancreatic adenocarcinoma

Table 2: Study of patient socio-economic parameters according to surgical volume

	Overall population (n = 12,137)	High volume (n = 6355)	Intermediate volume (n = 2254)	Low volume (n = 3528)	p
Distance					
Mean (sd)	44.8 (74)	61.5 (83.9)	30.9 (56.9)	23.4 (54.7)	p < 0.001
Median (Q1-Q3)	19.6 (6.1-56.5)	39.3 (10-83.3)	14.3 (5.5-37)	10.3 (3.8-24.3)	
< 6 km n(%)	3034 (25%)	1119 (17.6%)	617 (27.4%)	1298 (36.8%)	
[6 km-19 km[n(%)	3034 (25%)	1192 (18.8%)	711 (31.5%)	1131 (32.1%)	
[19 km-56 km[n(%)	3034 (25%)	1581 (24.9%)	597 (26.5%)	856 (24.3%)	
>= 56 km n(%)	3035 (25%)	2463 (38.8%)	329 (14.6%)	243 (6.9%)	
FDep					
Mean (sd)	0.56 (0.14)	0.56 (0.15)	0.56 (0.14)	0.57 (0.14)	p = 0.025
Median (Q1-Q3)	0.59 (0.49-0.66)	0.59 (0.49-0.66)	0.58 (0.48-0.66)	0.59 (0.49-0.66)	
[0.00 – 0.53[n(%)	4024 (33.2%)	2074 (32.6%)	802 (35.6%)	1148 (32.5%)	
[0.53 – 0.62[n(%)	3252 (26.8%)	1717 (27%)	579 (25.7%)	956 (27.1%)	
[0.62 – 0.68[n(%)	2484 (20.5%)	1320 (20.8%)	474 (21%)	690 (19.6%)	
[0.68 – 1.00] n(%)	2377 (19.6%)	1244 (19.6%)	399 (17.7%)	734 (20.8%)	
Rurality n(%)	4167 (34.3%)	2233 (35.1%)	746 (33.1%)	1188 (33.7%)	p = 0.133

sd : Standard deviation, Q1 : Quartile 1, Q3 : Quartile 3, FDep : French deprivation index

Table 3 : Predictive factors for utilization of a low-volume center

	Haut volume	Low volume center ise			
		OR	**95% IC**	**p overall**	**p / Hifh**
Sex				-	
Female	Reference	Reference	1		-
Male		0.931	[0.834 – 1.039]		0.204
Age				0.041	
< 40 years	Reference	Reference	1		-
40-49 years		1.560	[1.088 – 2.235]		0.016
50-59 years		1.865	[1.351 – 2.573]		< 0.001
60-69 years		2.004	[1.467 – 2.737]		< 0.001
70-79 years		2.178	[1.591 – 2.983]		< 0.001
≥ 80 years		2.162	[1,511 – 3.094]		< 0,001
CCI		0.235			
0-2	Reference	Reference	1		-
3		1.075	[0.925 – 1.250]		0.344
≥ 4		1.184	[1.046 – 1.341]		0.008
Distance				< 0.001	
< 6 km	Reference	Reference	1		-
[6 km-19 km[		0.354	[0.295 – 0.424]		< 0.001
[19 km-56 km[		0.058	[0.045 – 0.073]		< 0.001
>= 56 km		0.006	[0.004 – 0.008]		< 0.001
FDep				0.001	
[0.00 – 0.53[	Reference	Reference	1		-
[0.53 – 0.62[		2.231	[1.783 – 2.791]		< 0.001
[0.62 – 0.68[		2.692	[2.112 – 3.432]		< 0.001
[0.68 – 1.00]		3.488	[2.739 – 4.442]		< 0.001
Rural	Reference	2.860	[2.368 – 3.455]		< 0.001

OR : Odds Ratio, CI: Confidence interval, CII: Charlson comorbidity index, FDep: French deprivation index

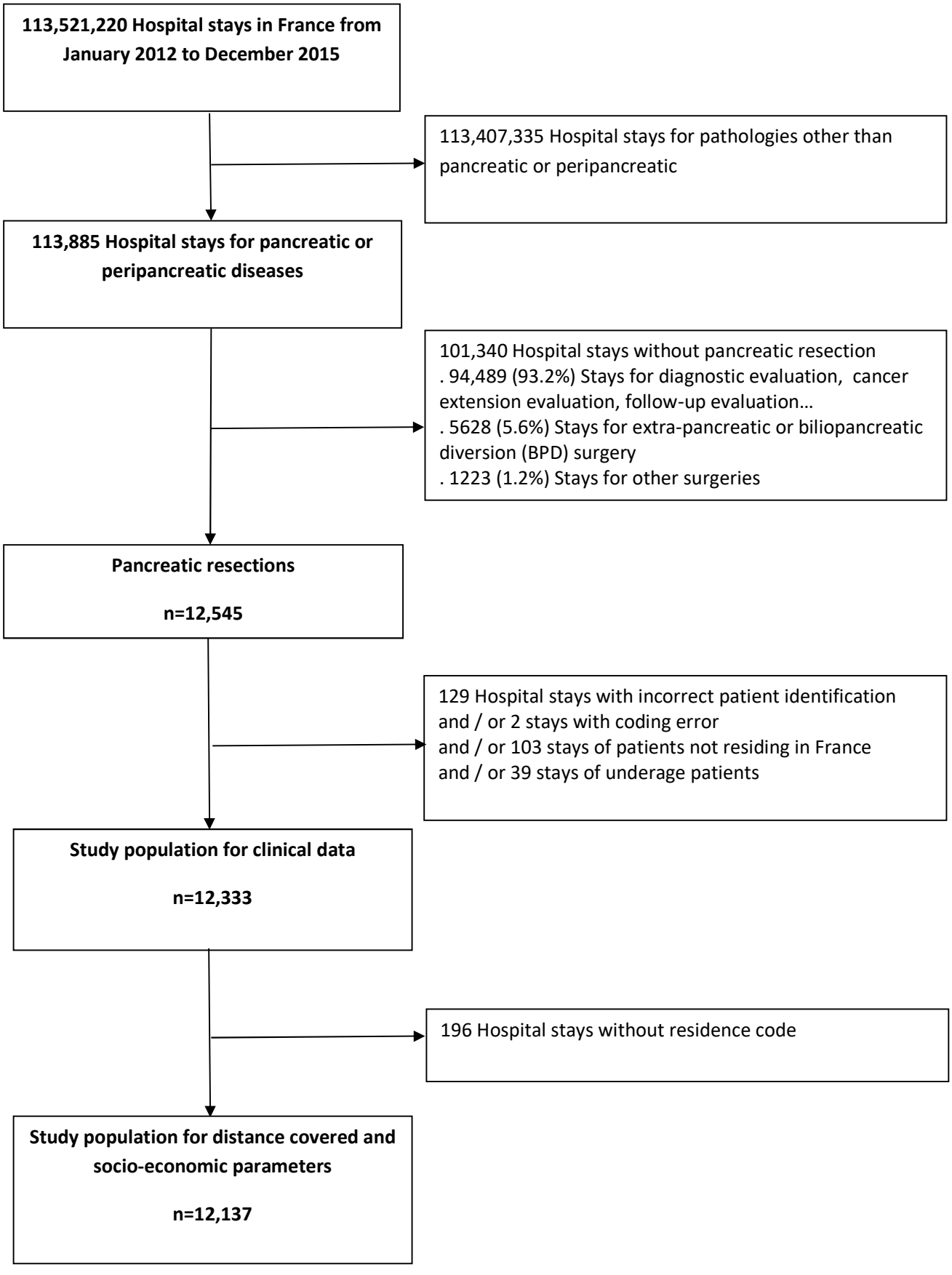
Figure legends:

Figure 1: Study flow diagram.

Figure 2: Distribution of included patients according to year of surgery.

Figure 3: Distribution of patients and centers according to volume.

Figure 1 : Study flow diagram



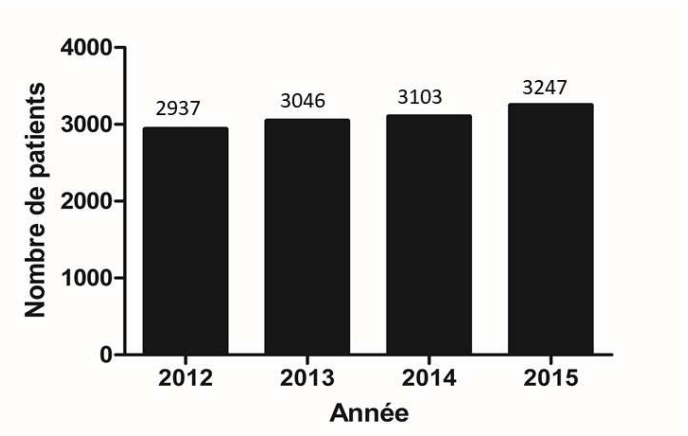


Figure 2: Distribution of included patients according to year of surgery;

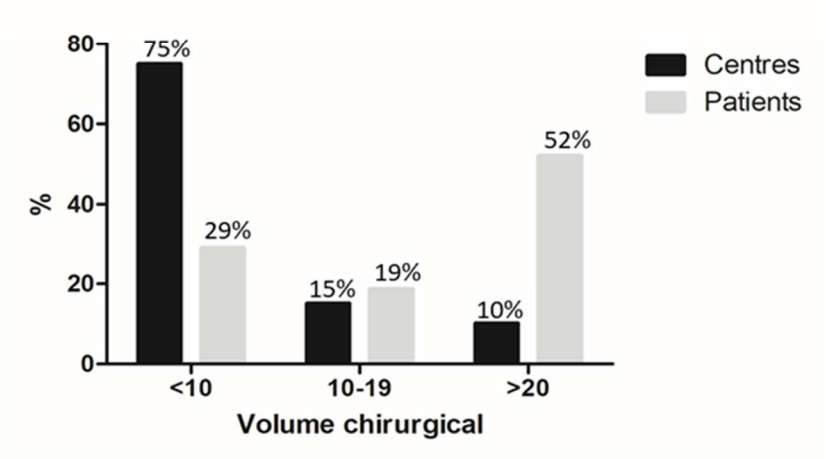


Figure 3: Distribution of patients and centers according to volume