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Achieving Good Perioperative Outcomes After Pancreaticoduodenectomy in a Low-Volume Setting: A 25-Year Experience

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Perioperative mortality following pancreaticoduodenectomy has improved over time and is lower than 5% in selected high-volume centers. Based on several large literature series on pancreaticoduodenectomy from high-volume centers, some defend that high annual volumes are necessary for good outcomes after pancreaticoduodenectomy. We report here the outcomes of a low annual volume pancreaticoduodenectomy series after incorporating technical expertise from a high-volume center. We included all patients who underwent pancreaticoduodenectomy performed by a single surgeon (ADC.) as treatment for periampullary malignancies from 1981 to 2005. Outcomes of this series were compared to those of 3 high-volume literature series. Additionally, outcomes for first 10 cases in the present series were compared to those of all 37 remaining cases in this series. A total of 47 pancreaticoduodenectomies were performed over a 25-year period. Overall in-hospital mortality was 2 cases (4.3%), and morbidity occurred in 23 patients (48.9%). Both mortality and morbidity were similar to those of each of the three high-volume center comparison series. Comparison of the outcomes for the first 10 to the remaining 37 cases in this series revealed that the latter 37 cases had inferior mortality (20% versus 0%; $P = 0.042$), less tumor-positive margins (50 versus 13.5%; $P = 0.024$), less use of intraoperative blood transfusions (90% versus 32.4%; $P = 0.003$), and tendency to a shorter length of in-hospital stay (20 versus 15.8 days; $P = 0.053$). Accumulation of surgical experience and incorporation of expertise from high-volume centers may enable achieving satisfactory outcomes after pancreaticoduodenectomy in low-volume settings whenever referral to a high-volume center is limited.

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During the 1960s and 1970s, early mortality rate after pancreaticoduodenectomy (PD) varied between 20% and 40%.[1,2] Since the 1980s, significant advances in the selection of patients and in surgical technique, associated with the refinement of perioperative care and standardization of postoperative care, have contributed to an important improvement in the outcomes after PD.[3–6]

Recently, evidence has suggested that better perioperative results expressed by a mortality rate lower than 5% are achieved by hospitals and surgeons with a high annual volume (HV) of PDs.[7–11] This relationship between HV and excellence in results has led to an increasing regionalization of PD.[12] However, morbidity remains high in a large number of series.[13–16]

In the United States, a reassessment in pancreatic surgery training has been triggered.[17] Parsa *et al*[18] noticed that from 1990 until 1997, the average of PDs performed by each general surgery resident in the United States was less than three. Moreover, publications regarding the learning curve in PDs are scarce.[19,20]

Although HV positively influences the outcomes after PD, we hypothesize that HV might not be an obligation for successful outcomes on this procedure. The present study analyzes the outcomes of a 25-year low–annual volume (LV) series on PD.

Patients and Methods

After institutional board approval, we reviewed the charts of 47 consecutive patients who underwent PD as a potentially curative treatment for malignant periampullary tumors during the study period (January 1981 to December 2005). All operations were performed by a single surgeon (ADC) since his first PD as a staff surgeon. In order to avoid heterogeneity of the study population, patients who underwent PD for benign tumors (n = 3) and pancreatic trauma (n = 1) were not included in this study. The procedures were performed at 6 hospitals (4 community hospitals and 2 university teaching hospitals) in the municipality of Porto Alegre, Brazil. All hospitals had the necessary structure to shelter high-complexity operations, except that the availability of an interventional radiologist was limited before 2002.

Demographic data obtained, respecting patient confidentiality, were: age, sex, presence of jaundice, location of tumor, type of operation, en bloc resection of other organs, intraoperative blood transfusion, pathologic diagnosis, status of the tumor margins, length of hospital stay, morbidity, perioperative mortality, and late survival. The margins analyzed included: main bile duct, pancreatic neck, stomach/duodenum, and retroperitoneal margins (uncinate process and resected tissue next to the anterior and lateral right side of the superior mesenteric artery). Perioperative mortality was considered when it occurred in the first 90 postoperative days. Morbidity included all surgical and clinical postoperative complications.

Selection of all patients to PD was performed according to the following criteria: (1) absence of disseminated tumor disease in the abdominal computed tomography (CT) scan and/or in the exploratory laparotomy; (2) absence of superior mesenteric vessel involvement in the abdominal CT scan and laparotomy following the surgical approach to assess the resectability of the malignant periampullary tumors; and (3) acceptable clinical status for undergoing a major operation, selected by the routine preoperative assessment for major operations and Karnofsky performance scale equal to or higher than 80.

Endoscopic retrograde cholangiopancreatography or preoperative biopsy was not performed routinely. Until 1991 only standard PD technique was used. Starting in 1992, the preferential technique was pylorus-preserving PDs. Total PD with splenectomy was performed when tumor extension to the body and/or tail of the pancreas was detected. Patients were followed-up through access to the hospital record, check-up at the physicians' office, or through telephone calls.

The primary end point for this study was perioperative mortality. Secondary end points were morbidity, length of hospital stay, use of intraoperative blood transfusion, and the rate of positive margins.

Perioperative morbidity and mortality for this series were compared with those from each one of three literature series from HV centers. Also, outcomes of the first 10 patients were compared with those of the remaining 37 patients in this series. The division into two groups of patients was

according to a period when the surgeon visited an international HV PD center, which happened after he performed the first 10 PDs in this series. Following this observation, the practices of the referral HV center were adapted to local LV centers in Brazil. These included a thorough evaluation of the CT scan and consultation with a radiologist whenever necessary. Also incorporated were less invasive ways of treatment of postoperative complications, including percutaneous drainage of fluid collections by an interventional radiologist whenever available. Performance of intraoperative frozen sections of the surgical specimen with progression to total PD whenever multifocal pancreatic adenocarcinoma was identified also was learned from that HV center and incorporated into our practice.

All analyses were performed by using SPSS 16.0 for Windows software (Chicago, Illinois). Survival curves were estimated by the Kaplan-Meier method. Mortality and morbidity in this series were compared with the results of each of the three HV tertiary centers through χ^2 Pearson tests. Comparisons between two groups regarding margin, transfusion, morbidity, and perioperative mortality were performed using Fisher exact test. Mann-Whitney test was used for comparison of the hospitalization period between two groups. P values < 0.05 were considered statistically significant.

Results

A total of 47 PDs were performed during the 25-year study period (fewer than 2 PDs on average per year). Mean patient age was 59 years (range, 18–80 years). Twenty-four patients were male. A total of 44 patients (93.6%) presented with jaundice.

A total of 44 partial PDs (93.6%) and 3 total PDs (6.4%) were performed. Pylorus-preserving PD was performed on 29 patients (61.7%), and standard PD technique was performed on 18 patients (38.3%). Wedge resection of the right lateral margin of the portal vein was necessary in 2 patients (4.3%), en bloc splenectomies in 3 patients (6.4%), and en bloc total gastrectomy in 1 patient (2.1%). Pancreaticojejunostomy with the use of a stent was performed in all 44 partial PDs. Hepaticojejunostomy was performed in all patients and a T-tube was used in 32 patients (68%). Gastrojejunostomy/duodenojejunostomy was precolic in all cases. Suction drains were placed near the pancreatic and biliary anastomosis in all patients. Somatostatin-analogues were not used prophylactically.

Table 1 Postoperative complications (35 complications in 23 patients)

Postoperative complication[a]	Incidence of each specific complication, n (%)
Pancreatic fistula	6 (13.6)
Gastroparesis	6 (13.6)
Respiratory infection	4 (8.5)
Intra-abdominal abscess	3 (6.4)
Biliary fistula	3 (6.4)
Postoperative hemorrhage	3 (6.4)
Wound infection	3 (6.4)
Acute renal insufficiency	2 (4.25)
Respiratory insufficiency	2 (4.25)
Necrohemorrhagic acute pancreatitis	1 (2.1)
Upper digestive hemorrhage	1 (2.1)
Prolonged jaundice	1 (2.1)
Total no. of events	35

[a]Some patients had more than one complication.

Overall perioperative mortality was 2 patients (4.3%). Twenty-three patients had postoperative complications (morbidity = 48.9%). The most frequent complications were pancreatic fistula and gastroparesis (Table 1). Reoperation was necessary in 9 patients (19.1%), being due to hemorrhage (n = 3), pancreatic fistula (n = 3), abscess (n = 1), necrosis of the remaining pancreas (n = 1), and invasive infection of the surgical wound with evisceration (n = 1).

The most common histologic type was the ductal pancreatic adenocarcinoma (Table 2), and margins were negative in 37 patients (78.7%). One-year survival rate of the overall cohort was 74.5%. Five-year survival rate of the entire cohort was 21% (38.5% for ampullary cancer and 6.9% for pancreatic adenocarcinoma).

When comparing mortality and morbidity of our series with those of 3 HV tertiary centers we did not identify any statistically significant differences (Table 3). Overall morbidity also was similar to those of all 3 HV center comparison groups (Table 3).

Table 2 Histologic types of malignant pancreatic and periampullary tumors in 47 patients

Histologic types	n (%)
Ductal pancreatic adenocarcinoma	29 (61.7)
Ampullary adenocarcinoma	13 (27.6)
Bile duct adenocarcinoma	02 (4.2)
Duodenal adenocarcinoma	01 (2.1)
Cystic papillary neoplasia	01 (2.1)
Lymphoma	01 (2.1)
Total	47 (100)

Table 3 Comparison of morbidity and mortality between present series and other series from tertiary high–annual volume centers

Series	JH[a]	MGH[b]	IU[c]	Present
No. of cases	1423	489	516	47
Morbidity, % (*P*)[d]	38 (0.169)	37 (0.108)	43 (0.434)	48.9
Mortality, % (*P*)[e]	1 (0.090)	1.1 (0.062)	3.9 (0.898)	4.3

IU, Indiana University; JH, Johns Hopkins; MGH, Massachusetts General Hospital, Harvard.

[a]Winter *et al*.[16]

[b]Balcom *et al*.[24]

[c]Schmidt *et al*.[26]

[d]*P* value obtained from comparison of morbidity in the in the present series to that in our series.

[e]*P* value obtained from comparison of mortality in the in the present series to that in our series.

In the present series, there were 2 perioperative deaths among the first 10 patients (20% perioperative mortality), and mortality was null for the second group of 37 patients ($P = 0.042$; Table 4). Negative margins were achieved in 5 of the first 10 patients operated on (50%), and in 32 of the last 37 patients (86.5%; $P = 0.024$). Intraoperative blood transfusion was required in 21 patients (44.7%). Of the first 10 patients, 9 needed a blood transfusion, whereas 12 of the last 37 patients (32.4%) required a transfusion ($P = 0.003$). Average of length hospital stay of the 47 patients was 16.85 days, with a median of 11 days (range, 3–45 days). The first 10 patients had a 20-day average of stay, and the other 37 patients had a 15.8-day average of stay ($P = 0.053$). There was no statistical significance regarding morbidity when comparing both groups of patients ($P = 0.999$). Two reoperations were necessary among the first 10 patients (20%), and 7 were necessary among the second group of 37 patients (18.9%; $P = 0.784$).

Discussion

Although PD is a high-risk, complex surgical procedure, evidence has demonstrated that better operative results, expressed by perioperative mortality below 5%, have been obtained by several hospitals and surgeons with an HV of PDs.[7–11] The number of necessary cases to define a center and a surgeon as HV in PDs is different in several studies, with HV centers being characterized on average as those with more than 20 operations per year and HV surgeons as those performing more than 11 operations per year.[8–11] Several authors defend that the determining factor in reduction of mortality after PD is the HV, relegating the experience of a well-trained surgeon as secondary.[8–12,21]

None of the hospitals in our study had an annual average volume of PDs above 20 resections per year (data not shown). Also, mean annual volume of the surgeon (fewer than 2 PDs per year) was far lower than 11 annual resections. These volumes characterize this as both a hospital and a surgeon LV series.[7–9,12,22,23] A mortality rate of 4.3% and a morbidity rate of 48.9% are similar to those in the 3 HV comparison literature series and are within the standards of excellence obtained by HV PD centers.[14,16,20,24–26] Our data also reveal a tendency toward uniform good results, because for the last consecutive 37 patients, operated on during the last 14 study years, there were no perioperative deaths. As has occurred with several series of HV tertiary centers, the most frequent postoperative complications here were pancreatic fistula and gastroparesis.[27] The limited availability of an experienced interventional radiologist for draining fluid collections after PD for the first 38 patients might have

Table 4 Comparison of postoperative results between the two groups of the present series

	Total 47 patients (1891–2005)	First 10 patients (1981–1991)	Last 37 patients (1992–2005)	*P* value
Blood transfusion, n (%)	21 (44.7)	9 (90)	12 (32.4)	0.003
Negative margins, n (%)	37 (78.7)	5 (50)	32 (86.5)	0.024
In-hospital stay, mean, d	16.85	20	15.8	0.084
Morbidity, % (n)	48.90	50 (5)	48.6 (18)	0.999
Mortality, n (%)	2 (4.3)	2 (20)	0	0.042

contributed to explain our high rates of reoperation.[28]

Compared with those obtained by HV tertiary centers, our results allow us to question the concept of an HV hospital and an HV surgeon as necessary predictive factors for good operative outcomes after PD. According to Riall *et al*,[29] because there are significant variations in the results even among HV services, the measure of hospital volume is not reliable as the only parameter to assess the quality and the results in pancreatic surgery. Thus, although HV is generally associated with better results in several PD series, in several of those studies the clinical significance of those findings might be complicated by methodology bias.

Differences in the patient care, infrastructure, and trained allied staff between HV and most LV centers also may explain part of the relationship observed between volumes and results,[30] meaning that not the center volume but the differentiated conditions offered by HV centers compared with most LV centers would be responsible for superior outcomes after PD.[31] Also in accordance with our LV satisfactory outcomes, Joseph *et al*[32] claim that rather than volume, a good hospital structure is the decisive factor associated with a lower mortality rate in PD.

Some consider experience and technical expertise as being the most important factors in obtaining good results following PD.[3,33] Afsari *et al*[13] and Sarr[34] state that achievement of good results is associated with the quality and adequate training of the surgeon, along with an optimized hospital structure, independent of the volume. In a recent study, Schmidt *et al*[26] compared the outcomes of a PD series of 19 different surgeons. Analyzing 1003 consecutive PDs, those authors concluded that the experience of the surgeon is a predictive factor for good outcomes, independently of the annual volume.

The few previous series with excellent outcomes in PDs performed in LV hospitals by LV surgeons are not single-surgeon series, and they comprise series performed over short periods of time.[13,33,35,36] Our study differs from other previous reports with excellent results in LV centers in the fact that this is a single-surgeon experience of an individual starting on his first case as a staff surgeon and spanning a long time period (25 years). We also demonstrate the incorporation of expertise acquired at an international HV center to different hospitals, both community and university hospitals.

The improvement from 20% toward zero mortality in this series was associated with the improvement of several outcome measures, enabling us to make few inferences. First, the surgeon's acquired experience with the first 10 patients might have influenced the improvement in results, translating into a learning curve. Second, improvement in results followed an observation period at an international HV PD center, with adaptation of acquired knowledge and practices to well-equipped Brazilian LV hospitals. The acquired knowledge comprised learning radiologic criteria for better patient selection for PD. Visiting an HV center also aided improvement of operative skills for performing PD, specifically by learning aspects of safe vascular control, vascular resection, and vascular reconstructions. Also acquired at the HV center was the knowledge to identify multifocal pancreatic adenocarcinoma by intraoperative inspection, intraoperative ultrasound, and intraoperative frozen section of the specimen margins, leading to performance of total PD whenever necessary, which has resulted in a lower rate of tumor-positive margins. Multidisciplinary approach also was an important piece of knowledge acquired from that HV center, especially concerning a team approach for patient selection for resection, and for early diagnosis and treatment of postoperative complications. Consultation with a radiology team for percutaneous drainage of postoperative fluid collections also was incorporated after visiting a HV center. This incorporation of expertise might have contributed to lower tumor-positive margins, blood transfusion rate, and postoperative mortality in the last 37 patients of this series.[34,37,38]

Limitations of the present study involve a small number of patients (n = 47) when compared with large HV series. Also, HV hospitals tend to receive patients with larger tumors and to perform more vascular reconstructions that LV hospitals. However, the last 37 PDs in this study involved 2 patients with portal vein resections and also 3 total PDs with splenectomy without any operative mortality. It is hard to compare case mix populations from different institutions, but a frequency of 5 of 37 complex PDs (13.5%) in the latter era of this series seems to be comparable with a population of HV centers.

In conclusion, HV PD centers should be preferred over LV settings, because HV settings usually enable excellent results after PD. However, for several reasons, including economic and insurance limitations, referral to an HV center may not be feasible. In such instances, incorporation of expertise from HV

centers may enable well-trained LV surgeons to perform PD safely at well-equipped LV hospitals. Accumulated experience and incorporation of expertise may lead to excellent outcomes after PD.

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