

The quality control in pancreatic surgery



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AIM: Over the past decade, several centralization programs for major pancreatic surgery have been implemented in hospitals with high procedural volumes. Although the impact of this process was altogether positive, also possible negative effects have been evidenced, above all the lack of comprehensive coverage and access to specialized centers. In order to solve these problems, it was proposed the utilization of an outcome-based and not volume-based center selection. For this purpose the choice of an appropriate outcome assessment system is crucial.

MATERIAL OF STUDY: We retrospectively reviewed 74 patients undergoing pancreatoduodenectomy. The outcomes were evaluated utilizing the Accordion Severity Classification of Postoperative Complications.

RESULTS: The morbidity of 58 % and the mortality of 4 % were comparable with the ones reported in large series utilizing the same classification system.

CONCLUSIONS: The Accordion system is an effective method of quality control for pancreatic surgery both in high- and low-volume hospitals.

KEY WORDS: Minimum volumes, Pancreatic surgery, Quality control.

Introduction

There are many reports showing a volume-outcome association in major pancreatic surgery ¹⁻⁴.

On the basis of this evidence, different countries with different Health Care Funding Models are implementing specific volume-based programs in centralization of pancreatic complex surgical procedures ⁵⁻⁸.

The early appraisal of these experiences shows a trend for reduced post-operative mortality rate ^{5,7,8}, but also provides evidence of some criticalities like the inert implementation of the minimum volume regulation ⁶, the inconstant volume-outcome associations among high volume centres ^{9,10}, the increased burden for patients access to optimal care ¹¹.

In order to extend the state wide availability of services and programs for major pancreatic surgery, some authors hypothesized to involve in the regional health care delivery systems also low-volume hospitals achieving results comparable with national benchmark ^{12,13}. Selection of low-volume hospitals can be determined only through ongoing outcomes assessments. With the exception of defining and grading pancreatic fistula ¹⁴, in literature no consensus exists on how to report and quantify complications following pancreatic surgery. Recently, to the assessments of quality in pancreatic surgery, was adapted the Accordion System, a therapy-oriented severity

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TABLE I - *Contracted Accordion Classification - Definition of levels of severity* - <http://www.accordionclassification.wustl.edu>

Grade 1 - Mild Complications	Requires only minor invasive procedures that can be done at the bedside such as insertion of intravenous lines, urinary catheters, and nasogastric tubes, and drainage of wound infections. Physiotherapy and the following drugs are allowed: antiemetics, antipyretics, analgesics and electrolytes.
Grade 2 – Moderate Complications	Requires pharmacologic treatment with drugs other than such allowed for minor complications, for instance antibiotics. Blood transfusions and total parenteral nutrition are also included.
Grade 3 – Severe Complications	All complications requiring endoscopic or interventional radiologic procedures or re-operation as well as complications resulting in failure of one or more organ systems.
Grade 4 – Deaths	Postoperative Death.

grading system¹⁵, providing a standardized assessment of both large and small series. In order to verify the validity in the quality control for a low volume hospital, we have analysed the outcome of pancreatoduodenectomy (PD) performed in the Department of General and Thoracic Surgery of Trieste University during the last ten years.

Material of Study

A database of 74 consecutive patients, undergoing elective pylorus-preserving PD between September 2000 and September 2010 in the General and Thoracic Surgery Department of Trieste University, has been retrospectively analysed.

Patients' work up included blood analysis (bilirubin, AST, ALT, gamma-GT, FA serum levels dosage), abdominal US, Cholangio-MRI, abdominal CT and preoperative medical risk assessment. The indication for surgical treatment was a suspected or histological confirmed diagnosis of pancreatic, ampullary or extra hepatic bile ducts malignancy.

All the resections were undertaken by 3 expert surgeons. Patients were assigned to individual surgeons according to their expressed wishes. According to the surgeon's judgement, 46 (62%) patients underwent reconstruction with a PD, 28 (38%) with a pancreaticogastrostomy. All patients provided preoperative written informed consent before the procedure.

The studied outcomes included all negative events occurred after surgery. Data were obtained by reviewing medical records and were assessed using the Contracted Accordion Severity Grading System¹⁶ that classifies the complications severity depending on the treatment needed for their correction. An automated *Standard Table for reporting postoperative complications can be produced* on the website of the Washington University in St Louis (Table I).

Results

There were 29 females and 45 males; the age range was 47-88 years (mean 66.97 years).

Regarding co-morbidities 35 patients had a body mass index (BMI) greater than 25 (47%), 20 (27%) had a history of arterial hypertension, 18 (24%) of cardiovascular disease, 16 (22%) of diabetes mellitus.

The postoperative histological diagnosis was pancreatic cancer in 37 patients (50%), carcinoma of the ampulla of Vater in 16 (22%), cancer of the distal biliary tract in 5 (7%), neuroendocrine tumour in 4 (5%), pancreatic cystic tumour in 4 patients (5%), chronic pancreatitis in 8 (11%).

Mean postoperative length of stay in hospital was 29.3 days (range 9 to 150 days).

The overall postoperative complication rate following PD was 58.1% (43 cases), the mortality rate 4.05% (3 cases). In the remaining 28 patients (37.8%) postoperative course was uneventful.

Using the Accordion Classification System, the detailed grading of complications is as follows:

– Grade 1, Mild complication: 12 (16.2%), of whom 7 pancreatic fistulas, 3 pleural effusion, 1 hospital acquired pneumonia and 1 pulmonary oedema.

– Grade 2, Moderate complication: 17 (22.9%), of whom 6 pancreatic fistulas, 4 hospital acquired pneumonias, 3 intra-abdominal bleeding, 1 intra-abdominal abscess, 1 septicaemia, 1 pulmonary embolism and 1 atrial fibrillation.

– Grade 3, Severe complications: 14 (18.9%), of whom 4 pancreatic fistulas, 4 intra-abdominal haemorrhage, 1 pancreatitis, 1 biliary ducts stenosis, 1 septicaemia, 1 pulmonary embolism, 1 pulmonary oedema and 1 ascitis.

– Grade 4, Postoperative Death: 3 patients (4.05%). The underlying complications were 1 pancreatic fistula with sepsis, 1 acute coronary event and 1 acute pulmonary oedema.

Discussion and comment

An empirical association between hospital procedural volume and mortality in high risk surgery has been evidenced since 1979¹⁷. In the field of major pancreatic resection this association has been showed in 1996 by a study performed in the 39 hospitals of Maryland State¹⁸ and then confirmed in the USA by Birkmeyer J.D.¹, in Netherland by Gouma D.J.² and in Italy by Balzano G.³. A recent meta-analysis of 14 cohort studies¹⁹ found that hospital volume is clearly related to lower postoperative mortality rates and to higher long-term survival. The superior outcomes achieved in high volume centers can be explained with the specific expertise of the attending medical (surgeon, anaesthetist, endoscopist, interventional radiologist) and nursing staff, because of the large number of procedures involved. However, also technological advances, progress in the field of perioperative care, improvements in the hospital's culture of safety are most likely to have contributed to enhance operative outcomes. These results have led to the deduction that a high-risk procedure like PD can benefit from concentration in high-volume centers. Therefore, during the last decade, in countries with different health care funding and delivery models, there was a considerable interest in developing pancreatic surgery centralization programs.

Several recent studies have attempted to define and characterize the effects of the pancreatic surgery centralization on the outcomes and on the structure of patient care. The analysis of the Leapfrog Group data⁵ shows that, during the last 10-years period, the postoperative mortality rate of the PD decreased from 7.3% to 5.9% and that a large portion of these results is explained by higher hospital volumes. Likewise the impact of centralizing pancreatic cancer surgery in the South of the Netherlands exhibits a positive feedback⁸, the postoperative mortality rate fell from 24.4% to 3.6% and was zero in the last year of the study. Moreover, in the health care network of Western part of the Netherlands, a centralization program of pancreatic surgery has been implemented and it resulted in improved clinical outcomes⁴. However, the fall in 30-days mortality from 8% to zero happened in the first stage of the program, after the introduction of quality standards and before the mandatory referral of pancreatic surgery to two high-volume hospitals.

Although trends toward centralization of complex pancreatic surgery are encouraging, several Authors provided the evidence of some questions about critical points: the inert implementation of the minimum volume regulation⁶, the inconstant volume-outcome correlations among high-volume center^{9,10}, the increased burden for patients access to optimal care¹¹, the lack of local expertise¹² that is crucial when the need for surgery occur in emergency.

In Germany the Federal Joint Committee introduced in year 2004 a compulsory minimum volume standard for

five surgical interventions including complex pancreatic surgery. The accompanying research carried out by the "Institut für Gesundheitssystemforschung" showed no reduction in the number of hospitals performing pancreatic intervention between 2004 and 2006 when the minimum volume was doubled. Furthermore 10% to 60% of the hospitals failed to comply with the minimum volumes²⁰. Another study issued from the same institution⁶ reports that in 2006, in spite of the increasing of minimum volume to 10 pancreatectomies, the patients' travel to reach the hospital didn't increased, showing an unchanged number of hospitals providing the procedure. Also in USA regionalization it has been difficult to implement, as the number of Leapfrog sites is low in rural areas²¹.

The reliability of procedural volume as single standard of quality is questioned for the inconstant volume-outcome association in high volume centers¹⁰. Also The S.H. et al.¹², in 2009, noted a significant disparity in perioperative outcomes among surgical centers across the United States. These individual hospital differences were likely to be accounted for different reasons than hospital volume. In addition to these variability in high volume centres outcomes, several studies from low-volume and community-based hospitals have reported excellent results and suggest that in low volume hospitals complex pancreatic procedures can be safely performed: guideline oriented patients' assessment selection, presence of a surgeon with adequate training, ICU availability are the means of achieving results comparable to large-volume hospital²¹⁻²³.

High volume cut-off is under debate. Numerous studies indicate that the improvements in outcomes increase with the increase of case volume^{3,18}. Regarding individual surgeon volume, improvement in measured outcomes goes on during the whole operative career, independently from the amount of PD performed²⁴. A recent large observational study demonstrated that the volume cut-off in pancreatic resections is arbitrary, as yielding varying "high-volume" definition are predicated by statistical necessity²⁵. Regarding this point, a sensitivity analysis determined that a volume cut-off of 31 pancreatic resections per year was the optimal cut-off level²⁶ and if this cut-off is used in the centralization programs implementation, could raise the risk to preclude the patient from being admitted to a center of excellence. For this reason the currently used cut-off is 10/11 cases/year, but the "Institut für Gesundheitssystemforschung" supports the opportunity to reduce the minimum volume for complex pancreatic surgery down to 5 cases/year, in order to avoid "occasional surgery" without impact on access to care²⁰.

Furthermore, several studies have documented that historical results are a better outcome predictors than hospital procedural volumes and Geraedts M. asserted that: «there are both good hospitals with low volumes and bad hospitals with high volumes⁹».

It's necessary to consider, that mandatory referral to institutions with high procedural volume may create excessive barriers in obtaining specialized care and leave patients far from supportive networks¹². Financial and geographical burdens hit mostly patients who are uninsured or reside in rural areas. This negative impact differs on the basis of national topography and health care funding²⁷. In a recent study Bilimoria K.Y. et al.¹¹ emphasized the USA national failure to operate on early stage pancreatic cancer, evidencing that more than half of patients with resectable cancer failed to receive surgery. This problem mostly concerns people not referred to National Cancer Institute (NCI) institutions or other high-volume centers.

As the availability of services affects their use, in Germany the Federal Joint Committee provides for exceptions to minimum volume in the case of emergencies or of staffing realignments, for surgical training, or to guarantee extensive coverage. In the large scale study of Teh S.H. et al¹² on 103, 222 cases, independent predictors for outcome were age of the patient, comorbidities and hospital volume. The post-complication mortality was related to the age and co-morbidities, so the Authors propose a selective policy, by referring the older patients with co-morbidities to high-volume centers and low risk patients to low-volume hospitals meeting the national benchmark that is derived from NCI-designated cancer centers.

Schell M.T. et al.¹³, from the California State University, on the basis of the positive experience matured in a health care system with one tertiary high volume and three low volume affiliated hospitals, suggested that the best way to improve access to complex surgical procedures for the majority of the population in the United States is to develop specific programs in selected low volume centers. determine how to answer for the country-wide availability of services and programs for pancreatic cancer treatment, Teh SH et al.¹² recommended outcome-based rather than volume-based referrals. It's true that this choice may impact on the regional health care delivery systems, involving also low-volume hospitals achieving national benchmark.

In the USA the benchmark can be derived from Nationwide Inpatient Sample Data. Birkmeyer JD et al²⁸ assessed postoperative mortality rates for 63,860 patients over 65 years of age undergoing resection for lung, oesophageal, gastric, pancreatic, bladder or colon carcinoma. They found that in-hospital mortality for pancreatic resections was 4,1% in NCI Cancer Centers and 7,1% in High volume non NCI hospitals. In the interval between these two values we can identify the USA national benchmark.

For a variety of reasons, while mortality results an objective outcome parameter, morbidity is only poorly defined and the complications are now presented in different inhomogeneous formats. Indeed, with the exception of the pancreatic fistula¹⁴, the quantifica-

tion of every single complication in pancreatic surgery is complex and includes multiple subjective criteria. Recently, DeOliveira M.L. et al.¹⁵ proposed the utilization of the Accordion Severity Classification of Postoperative Complications (ASCPC) in the pancreatic surgery assessment, a therapy-oriented severity grading system that can secure an appropriate retrospective analysis of complication even utilizing nursing notes. Furthermore, it can provide a standardized assessment of both large and small series because of its wide range of accommodation. In fact, the ASCPC can be expanded to assess a large range of complications described in major studies and can be contracted in smaller studies. The contracted system classifies the complication in four levels headed by self evident terms (mild, moderate, severe complication and death), as a result of unification of the grades three, four and five in the level of "severe" complications.

The ASCPC allows reporting postoperative complications utilizing an automated tabular format that is available at a George Washington University website. The complications' reporting is standardized and it facilitates comparison between data coming from multiple studies allowing the development of a quantitative measurement of postoperative morbidity. The automated standard format should also aid the author to avoid omissions in data implementation and in creating a standard menu item, and facilitate the reader in data processing.

Conclusions

In last ten years period several volume-based centralization programs of pancreatic carcinoma treatment in centers with focused expertise are being developed around the world. The assessment of results showed an improvement on surgical outcomes, but in the meantime suggests a lack in availability of specialized care for all the citizens. In order to rationalise health care funding and reduce disparity in referral for complex surgical care, Teh S.H. et Al.¹² published "A plea for Outcome-Based and Not Volume-Based Referral Guidelines".

The absence of consensus on quantifying pancreatic surgery complications makes hard an outcome-based accreditation of low- volume centres.

In our series of 74 PD both incidence and severity of postoperative complications resulted comparable with those reported in a large series by DeOliveira M.L. et Al.¹⁵. Also the in-hospital mortality fits the benchmark of the USA National Cancer Institute.

In our opinion, the ASCPC allows to report and quantify morbidity after pancreatic surgery and can solve the problem on how to perform a quality assessment both in high and low-volume hospitals. An effective method of ongoing control of selected centres may help to increase regional networks and reduce disparity in referral for complex surgical care.

Riassunto

OBIETTIVO: Negli ultimi dieci anni in alcuni paesi con sistemi sanitari diversi è stata avviata l'implementazione di programmi di centralizzazione della chirurgia pancreatica maggiore negli ospedali ad alto volume di attività specifica. Mentre l'impatto di questa riorganizzazione è stato nel complesso positivo, sono stati evidenziati anche possibili effetti negativi, in particolare la mancata copertura territoriale e la disparità nell'accesso alle cure specializzate.

Allo scopo di risolvere questi problemi è stato proposto di selezionare gli ospedali di riferimento in base ai risultati e non al volume di attività. A questo scopo diviene cruciale la scelta di un adeguato sistema di valutazione dei risultati.

MATERIALE E METODO: Abbiamo analizzato retrospettivamente una serie di 74 pazienti sottoposti a duodenocefalopancreasectomia. I risultati sono stati valutati utilizzando il sistema di classificazione delle complicanze "Accordion".

RISULTATI: Abbiamo evidenziato una incidenza di complicanze del 58% e una mortalità del 4 % che sono comparabili per incidenza e gravità con quelle riportate in casistiche più ampie valutate utilizzando lo stesso sistema di classificazione.

CONCLUSIONI: Il sistema "Accordion" è un metodo efficace di controllo di qualità in chirurgia pancreatica sia negli ospedali ad alto volume, sia in quelli a basso volume.

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