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Contents

Monthly Volume 16 Number 3 March 27, 2024

EDITORIAL

MINIREVIEWS

ORIGINAL ARTICLE

Retrospective Cohort Study

Retrospective Study

World Journal of Gastrointestinal Surgery

Monthly Volume 16 Number 3 March 27, 2024

Contents

World Journal of Gastrointestinal Surgery

Monthly Volume 16 Number 3 March 27, 2024

Contents

ABOUT COVER

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ORIGINAL ARTICLE

Retrospective Cohort Study

Rescue from complications after pancreaticoduodenectomies at a low-volume Caribbean center: Value of tailored peri-pancreatectomy protocols

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Abstract

BACKGROUND

Pancreaticoduodenectomy (PD) is a technically complex operation, with a relatively high risk for complications. The ability to rescue patients from post-PD

complications is as a recognized quality measure. Tailored protocols were instituted at our low volume facility in the year 2013.

AIM
To document the rate of rescue from post-PD complications with tailored protocols in place as a measure of quality.

METHODS
A retrospective audit was performed to collect data from patients who experienced major post-PD complications at a low volume pancreatic surgery unit in Trinidad and Tobago between January 1, 2013 and June 30, 2023. Standardized definitions from the International Study Group of Pancreatic Surgery were used to define post-PD complications, and the modified Clavien-Dindo classification was used to classify post-PD complications.

RESULTS
Over the study period, 113 patients at a mean age of 57.5 years (standard deviation [SD] ± 9.23; range: 30-90; median: 56) underwent PDs at this facility. Major complications were recorded in 33 (29.2%) patients at a mean age of 53.8 years (SD: ± 7.9). Twenty-nine (87.9%) patients who experienced major morbidity were salvaged after aggressive treatment of their complication. Four (3.5%) died from bleeding pseudoaneurysm (1), septic shock secondary to a bile leak (1), anastomotic leak (1), and myocardial infarction (1). There was a significantly greater salvage rate in patients with American Society of Anesthesiologists scores ≤ 2 (93.3% *vs* 25%; $P = 0.0024$).

CONCLUSION
This paper adds to the growing body of evidence that volume alone should not be used as a marker of quality for patients requiring PD. Despite low volumes at our facility, we demonstrated that 87.9% of patients were rescued from major complications. We attributed this to several factors including development of rescue protocols, the competence of the pancreatic surgery teams and continuous, and adaptive learning by the entire institution, culminating in the development of tailored peri-pancreatectomy protocols.

Key Words: Pancreas; Complication; Rescue; Failure; Morbidity; Mortality; Pancreaticoduodenectomy

Core Tip: Pancreaticoduodenectomy is a technically complex operation, with a relatively high risk for complications. Conventional teaching suggests that these operations should only be done in high-volume centers. Rescue, defined as the proportion of patients who were salvaged after treatment of a major complication, is a recognized quality measure. We have shown that acceptable rescue rates can be achieved at low volume centers once there is attention to detail and protocols tailored to the hospital environment.

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INTRODUCTION

Pancreaticoduodenectomy (PD) remains the best therapeutic option for peri-ampullary malignancies[1,2]. As it is a technically complex operation, PDs should be performed by experienced teams who are facile with the operative steps and management of complications when they occur. The ability to rescue patients from succumbing to post-PD complications is recognized as a quality measure in modern practice[3-7].

Our facility in the Caribbean is a tertiary referral center where experienced pancreatic surgeons perform PD at low volumes. The primary aim of this study was to evaluate rescue rates after PD and to document short-term outcomes using tailored peri-pancreatic protocols.

MATERIALS AND METHODS

We secured ethics approval to collect data for this study from a pancreatic surgery unit in the Eastern Caribbean. A dedicated unit was established on January 1, 2013, staffed by pancreatic surgeons, anesthetists, and support staff.

In this study, we carried out an audit to identify all consecutive patients who underwent PD at this facility over one decade, from January 1, 2013 to June 30, 2023. Patients were identified from operating room registers. Then hospital records were retrieved to identify patients who experienced a major complication after PD. The following data were collected from these records: patient demographics, operative details, postoperative complications, and 30-d mortality.

The criteria to be eligible for inclusion were: Age > 18 years, PD during the specified study period, availability of hospital records, and documentation of a major complication. Patients were excluded if they underwent left-sided or total pancreatic resections, had missing or incomplete records, were transferred to other facilities for any reason, and experienced minor or no complications.

We used standardized definitions from the International Study Group of Pancreatic Surgery[8,9] to define post-PD complications and the definition of pancreatic fistula proposed by the International Study Group on Pancreatic Fistula criteria[10,11]. The modified Clavien-Dindo classification[12] was used to classify post PD complications. Complications were further divided into medical and procedure-related complications using standardized classifications[13,14]. Procedure-related complications include pancreatic fistula, delayed gastric emptying, surgical site infection, organ space collection, post-pancreatectomy hemorrhage, anastomotic leaks, and bile leaks[13,14].

Rescue was defined as the proportion of patients who were salvaged after a major (Claviden-Dindo ≥ 3a) post-PD complication was treated[3]. Descriptive statistics were generated using SPSS version 16.0. The χ^2 and *t*-tests were used to compare rescue rates based on patient sex, patient age (≤ 55 years *vs* > 55 years), type of complication (medical *vs* procedure-related), Eastern Cooperative Oncology Group performance scores (ECOG 0-1 *vs* 2-4), and physical status using the American Society of Anesthesiologists' risk score (ASA 1-2 *vs* 3-5). $P < 0.05$ was considered statistically significant.

RESULTS

Over the study period, 113 patients underwent PDs at this facility. There were 71 males and 62 females at a mean age of 57.5 years (standard deviation [SD] ± 9.23; range: 30-90; median: 56). Major complications were recorded in 33 (29.2%) patients after PD. In the subgroup with major complications, there were 23 males and 10 females at a mean age of 53.8 years (SD: ± 7.9; range: 30-70; median: 53). Table 1 outlines the individual complications.

Twenty-nine patients who experienced major morbidity were salvaged after aggressive treatment of their complication. Therefore, the salvage rate at this facility was 87.9%.

Four (3.5%) patients died as a direct consequence of their complications, resulting in an FTR rate of 12.1%. The complications from which patients could not be rescued included: Post-pancreatectomy hemorrhage from a bleeding pseudoaneurysm, septic shock secondary to a bile leak, intra-abdominal collections from an anastomotic leak, and a cardiac insufficiency due to myocardial infarction.

There were seven major medical complications and six (85.6%) were rescued after treatment of the complication. There were 26 patients with procedure-related complications and 23 (88.5%) of these patients were rescued. There was no statistically significant difference in salvage rates for medical *vs* procedure-related complications ($P = 0.0391$).

We found that salvage rates were slightly higher in patients with age ≤ 55 years (89.5% *vs* 83.3%; $P = 0.743$) and ECOG scores ≤ 1 (91.3% *vs* 80%; $P = 0.361$), female sex (90% *vs* 87%; $P = 0.951$), although neither achieved statistical significance. Due to the retrospective nature of data collection, we could not evaluate the relationship between salvage rates and body mass index (BMI). However, there was a significantly greater salvage rate in patients with ASA scores ≤ 2 (93.3% *vs* 25%; $P = 0.0024$).

DISCUSSION

Rescue from salvageable complications requires early recognition and treatment of complications. Since PD is recognized to be a technically challenging procedure with high inherent complication rates[1-4], isolated analyses of morbidity and mortality are not the best quality measures[3,6,7]. Instead, interhospital variations in mortality bear a closer relationship to the rates of rescue or failure thereof[3-7].

At our center, PD was accompanied by 29.2% major morbidity and 3.5% mortality, which is on par with reports in the surgical literature[3,13-18]. More importantly, we were able to rescue 89% of patients from major complications. The failure rate (12.1%) was at the upper limit of that reported from high-volume centers, ranging from 5.4%[8] to 12.5%[19]. This means there may still be room for improvement in complication management at our center.

Prior data suggest that rescue rates are directly proportional to hospital case volume[3,6,7,20,21]. Although there is no consensus on what constitutes a high-volume center, most authors consider high-volume hospitals as those performing > 18 PDs annually[22-26]. van Rijssen *et al*[3] suggested that hospital volume > 40 per year was an an independent predictor of rescue. Therefore, with an annual volume of 11.3 PDs per year, our hospital does not qualify as high volume.

We found that the only factor that predicted rescue was the patients' physical status using the ASA risk score, in agreement with published data[3,27,28]. The surgical literature suggests that other factors predicting failure to rescue include patient-related factors, such as male sex[3], increasing age[3,27], high BMI[3], and co-morbidities[6,28,29]. Hospital-specific factors include understaffing[6,28,30], intensive care unit support[6,28,29], hospital technology status[3], nurse-to-patient ratio[6,28,29], and availability of interventional radiology[27].

Table 1 Complications after 113 pancreaticoduodenectomies

Overall morbidity	52 (46%)
Minor morbidity	19 (16.8%)
Pneumonia	3
Deep vein thrombosis	3
Delayed gastric emptying - grade A	2
Post-pancreatectomy hemorrhage - grade A	4
Superficial surgical site infection	5
Bile leaks - grade A	2
Major morbidity	33 (29.2%)
Major medical complications	
Renal failure	1
Respiratory complications	1
Cardiac complications	3
Systemic sepsis	2
Major procedure-related complications	
Delayed gastric emptying - grade B/C	3
Bile leak - grade B/C	5
Organ space collection	2
Anastomotic dehiscence	1
Post-operative pancreatic fistula	10
Post-pancreatectomy hemorrhage - grade B/C	5
30-d mortality	4 (3.5%)

Our results suggest that rescue is not necessarily related to case volumes alone. It is a much more complex issue that requires a multidisciplinary team approach, appropriate hospital equipment, and diligence on the part of the care team. In our setting where a new pancreatic service was being formed, we appreciated that a surgeon-led drive was necessary to ensure that the facility focused on recognized factors contributing to good outcomes, such as quaternary training for hepato-pancreato-biliary teams[31], trained nursing teams[32], development of care pathways[32], multidisciplinary approach to care[1,2], tailored centralization pathways[33], and continuous hospital learning[32]. We took a holistic approach, by creating peri-pancreatic protocols that are tailored to our resource-poor system, as summarized in Table 2.

We also needed to compensate for institutional deficiencies. For example, after we recognized that optimal care could not be delivered on the general wards in our setting, all our patients were admitted to the intensive care unit for the first 72 h. Post-operative surveillance was also inconsistent at our facility, so we compensated by scheduling members of the surgical team to physically review the patients on a 4-h rotation for the first 36 h post PD. This allowed early identification of complications and facilitated the early activation of rescue protocols. In this regard, we agree with van Rijssen *et al*[3] that failure to rescue was partly due to slow escalation of care[3], inadequate recognition and communication of patient deterioration to a senior colleague[30,34-36], lack of established protocols or support of team members[3], hierarchy[3], and understaffing[3].

It is important to recognize that the attending surgeon has less control in the post-operative period. It is the diligence of the nursing and support staff that allows complications to be recognized early, the experience of junior medical staff that allows appropriate steps to be taken and seniors to be notified, and the quality of care from the entire care team that will determine whether a patient is rescued. Team leaders/attending surgeons must recognize that they need cooperation from all categories of hospital staff and, many times, this is an exercise in diplomacy. To do this, attending surgeons must rely on charisma power (the ability to influence behavior through force of character) instead of coercive power (influencing others through fear or the ability to punish subordinates)[37].

It is also important for the surgeon to be able to adapt to their working environment. For example, we understood early that our facility battled with unavailability of intensive care unit space, paucity of blood products, shortage of consumables, and inconsistent supply of drugs, among others. Recognizing that these would have a negative impact on patient recovery, we emphasized good interdisciplinary relationships and the surgical team took the responsibility to ensure that everything needed was available prior to surgery. This was an example of continuous, adaptive learning by the entire institution[1,12,32], culminating in the development of the tailored peri-pancreatectomy protocols[32]. We firmly believe that this holistic approach has contributed to the good outcomes in this resource-poor, low-volume facility.

Table 2 Caribbean peri-pancreatic surgery protocols

Pre-operative	Multidisciplinary care	All patients presented at a weekly multidisciplinary team meeting to review images and consensus decision making
	Patient consultation	Patient evaluated by attending surgeon to relay multidisciplinary team decisions
	Pre-operative counseling	Verbal information during pre-operative consultation
		Ensure patient receives a written pamphlets with information
	Patient education	Refer to AHPBA Caribbean Chapter video resources
		Part one of informed consent process as outpatient
	Medical clearance	Pre-operative cardiopulmonary exercise testing
		Evaluation and clearance from cardiology/pulmonology teams
		Pre-operative consultations with anesthesia team in patients with borderline fitness as a condition for acceptance for surgery
	Prehabilitation	Patients encouraged to discontinue smoking
		Discuss exercise regime pre-operatively
		Pre-operative chest physiotherapy
		Supervised exercise regime with physical trainer
	Fasting guidelines	Discourage prolonged fasting
		Encourage a carbohydrate-rich drink on the morning of surgery
	Biliary decompression	Appropriate decompression, as decided by multidisciplinary team
		Ensure standard blood tests are available within 48 h of surgery
	Supportive care	Ensure ICU bed is reserved prior to surgery
		Ensure ≥ 2 units of packed cells are available in the operating room
Intra-operative	Pre-operative anesthesia	Avoid routine sedatives prior to surgery
		Regional block and/or rectal sheath blocks prior to surgery
	Surgical team	Two experienced HPB surgeons operate together
		Dedicated nursing team
		Dedicated anesthetic team
	Prevention of intra-operative hypothermia	Close monitoring to maintain normothermia
		Active warming devices
		Pneumatic compression device available
	Peri-operative fluid management	Patients receive intra-operative restricted goal directed fluid therapy
		Ensure warmed fluids
	Specialized equipment	Ensure specialty equipment is available: Omni-Tract®, staplers
	Peri-operative tasks	Administer thrombo-prophylaxis at induction
		Administer prophylactic antibiotics at induction
		Place central line, urinary catheter, arterial lines prior to surgery
Post-operative	Escalation	Follow rescue protocols and inform attending surgeon if there is any deviation from expected post-operative course
	Ambulation	Patients encouraged to ambulate on the same day post-operatively
	Post-operative review	Surgical team rostered to physically review patient on 4 hourly shifts for 1st 36 h
	Fluid balance	Ensure adequate urine output of 0.5-1 mL/kg/h
		Ensure appropriate intravenous fluid regime is being followed
	Respiratory	Encourage coughing
		Encourage use of incentive spirometer

	Ensure physiotherapist input
Analgesia	Stepwise multimodal pain management to minimize opioid administration
Tubes	Consider early removal of urinary catheter
	Consider early removal of nasogastric tubes
	Drain evaluation at post-operative day 3
Post-operative diet	Consider early oral fluid intake, once clinically appropriate
Thrombo-prophylaxis	Ensure pneumatic compression device is being used
	Ensure prophylactic low molecular weight heparin is being administered

AHPBA: Americas Hepato-Pancreato-Biliary Association; HPB: Hepato-pancreato-biliary; ICU: Intensive care unit.

CONCLUSION

This paper adds to the growing body of evidence that volume alone should not be used as a marker of quality for patients requiring PD. Despite low volumes at our facility, we demonstrated that 87.9% of patients were rescued from major complications. We attributed this to several factors including development of rescue protocols, the competence of the pancreatic surgery teams and continuous, adaptive learning by the entire institution, culminating in the development of tailored peri-pancreatectomy protocols.

ARTICLE HIGHLIGHTS

Research background

Peri-operative outcomes differ between institutions due to a variety of factors. This can affect the way individual hospitals manage complications, and also their mortality rates after pancreaticoduodenectomies (PDs).

Research motivation

Our facility in the Caribbean is a low-volume center with numerous challenges. Tailored peri-pancreatic protocols were devised specifically to compensate for challenges at our facility. These have not been evaluated prior to this study.

Research objectives

The ability to rescue patients from post-PD complications is as a recognized quality measure. This study sought to document the rate of rescue from post-PD complications with tailored protocols in place as a measure of quality.

Research methods

A 10-year retrospective audit was performed to evaluate rescue rates in patients who experienced major post-PD complications. Standardized definitions from the International Study Group of Pancreatic Surgery were used to define post-PD com-plications and the modified Clavien-Dindo classification was used to classify post-PD complications. All data were examined with SPSS version 18.0.

Research results

There were 113 patients who underwent PDs and 33 experienced major morbidity. Twenty-nine (87.9%) patients were salvaged after aggressive treatment of their complication. There was a significantly greater salvage rate in patients with American Society of Anesthesiologists scores ≤ 2 (93.3% *vs* 25%; $P = 0.0024$).

Research conclusions

Despite low volumes and multiple hospital challenges, we were able to achieve acceptable rescue rates after post-PD complications. We attributed this to several factors including development tailored peri-pancreatectomy protocols.

Research perspectives

This adds to existing data that volume alone should not be used as a quality measure. It encourages further research with larger numbers since this early research shows encouraging results.

FOOTNOTES

Author contributions: Cawich SO, Dixon E, Sukla PJ, and Shrikhande SV designed the research; Cawich SO, Mohammed F, Pearce NW, and Francis W performed the research; Deshpande R, Pearce NW, Johnson S, and Bujhawan J contributed data analytic tools; Cawich SO,

Mohammed F, Deshpane R, Pearce NW, and Johnson S analyzed the data; Cawich SO, Dixon E, Sukla PJ, and Shrikhande SV wrote the paper; Cawich SO, Dixon E, Sukla PJ, Shrikhande SV, Deshpande R, Mohammed F, Pearce NW, Francis W, Johnson S, and Bujhawan J checked the manuscript for scientific accuracy.

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