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Whipple's Operation with a Modified Centralization Concept: A Model in Low-Volume Caribbean Centers

Cawich SO *et al.* Whipple's Operation

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Abstract

BACKGROUND

Conventional data suggest that complex operations, such as a pancreaticoduodenectomy (PD), should be limited to high volume centers. However, this is not practical in small, resource-poor countries in the Caribbean. In these settings, PDs have to be performed locally at low volumes. We discuss our viewpoint on improving outcomes for PDs in this setting.

AIM

In this paper, we review the evolution of the concept of the high-volume center. We discuss the feasibility of this concept and the incorporation of PD into low-volume and resource-poor countries, such as those in the Caribbean.

METHODS

This paper has two parts. First, we performed a literature review evaluating studies published on outcomes after PD in high volume centers. The data in the Caribbean is then examined and we discuss the incorporation of this operation into resource-poor hospitals with modifications of the centralization concept.

CONCLUSIONS

Most patients who require PD in the Caribbean do not have realistic opportunities to have surgery in high-volume centers in developed countries. In these settings, their only options are to have their operations in the resource-poor, low-volume settings in the Caribbean. However, post-operative outcomes may be improved, despite low-volumes, if a modified centralization concept is encouraged.

Key Words: Pancreas; Surgery; Pancreatectomy; Whipple's; Pancreaticoduodenectomy

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Core Tip: The published data generally support pancreaticoduodenectomies (PD) being reserved for high volume hospitals. However, this is not practical in resource-poor, low volume countries in the Caribbean. Nevertheless, we have documented good short-term outcomes after PD in this setting. In this paper we discuss a modified centralization concept used to incorporate PD into these low volume centers.

INTRODUCTION

Pancreaticoduodenectomy (PD) is a technically complex operation that is accompanied by high complication rates. Although post-operative morbidity has declined over the past 2-3 decades with better supportive care, 30-50% of patients still experience post-operative complications [1].

Due to PD's high-morbidity profile, specialized hospitals began to appear at the turn of the 21st century where hepatopancreatobiliary (HPB) services were concentrated. This drove the "high-volume center" concept in developed countries with large populations, and it was fueled by good outcome data emerging from these centers. A change in referral patterns followed, where patients with peri-ampullary lesions were sent to these experienced centers for multidisciplinary teams to perform PDs at high volumes. This was the birth of the era of service centralization and terminology evolved from "experienced centers" [2] to "high-volume centers" [3].

In this paper, we discuss our experience incorporating PD into this low-volume, resource-poor region.

DATA FROM HIGH-VOLUME CENTRES:

At the turn of the 21st century, published data emerged to show that high volume centers performed PDs with significantly reduced overall morbidity [1-8], thirty-day

mortality ^[1,8] readmission rates ^[3], cost ^[3,9], duration of hospital stay ^[3,9] and 5-year survival rates ^[1,8,10]. These data supported the principle of centralization – a concept that seemed predictable and intuitive on first glance.

¹ However, a closer look at the existing data revealed that there was no standardized definition of “high volumes”, with researchers applying ad-hoc definitions that ranged from as low as 2 PDs annually ^[6,8] to as high as 125 PDs annually ^[11]. We conducted a systematic literature search across the Pubmed, Medline and Google Scholar platforms seeking publications that defined “high-volume” hospitals, using the search terms: “high-volume”, “experienced”, “centers of excellence”, “referral centers” and “specialty centers”. The literature search was performed by two researchers and spanned the 27-year period from January 1, 1995 to December 31, 2021. All studies identified were retrieved and reviewed in detail by both researchers who extracted the following data: definition of high-volume center, mortality in low and high-volume centers and study population. We excluded studies that did not document these data, studies with missing data and duplicated studies. The results are outlined in table 1 ^[1-30]. Most studies demonstrated significant differences in 30-day mortality, but the definitions of “high volume” varied widely. Most papers in the literature quoted numbers ≥ 20 PDs per annum ^[1,3,4,9,16,17,25].

ARGUMENTS AGAINST REGIONALIZATION:

Although data accumulated to support service centralization in developed countries, the concept faced several challenges.

Unclear Definitions of “High Volume”

With the presumption that medical literature will soon adopt a standardized definition of “high volume” equating to ≥ 20 PDs per annum (table 1), there are few hospitals across the globe that would qualify as high-volume centers. This creates a logistic problem because it would be impractical for patients to be routed to few centers across the globe for PD. This is especially unrealistic in the Caribbean where many patients are

not able to afford care in developed countries. The region has some of the poorest countries in the Western Hemisphere and many patients in these territories do not have health insurance.

Data Generalization

Healthcare personnel should exercise good judgement when interpreting the available data. Pawlik *et al* [31] made the point that volume-outcome relationships are one way to judge hospitals, but are non-informative about any specific hospital - apart those from which the data was collected. In other words, it cannot be used to generalize outcomes in every low or high-volume hospital. Thus, if a low-volume hospital published data to show good outcomes, it should trump simple volume data.

Additionally, there are many factors that may skew outcomes data: Firstly, within high volume centers, surgeons do not have equivalent experiences, case volumes or clinical outcomes [1,31,32,33,34]. Secondly, some high-volume centers may end up treating higher-risk cases while some community or teaching hospitals may treat more indigent patients, potentially skewing outcome data. Thirdly, volume-related data only provides information on patients who underwent PDs, but excludes any useful information on clinician judgement, expertise and decision making when choosing patients for surgery [31]. This critical aspect of care for patients with peri-ampullary carcinomas does not appear in any volume-based data.

Surgeon Volumes

To be able to complete a PD, surgeons must accrue experience through repetition of the operative steps. Some have argued that PD outcomes are less dependent on hospital volume and more dependent on the technical competence of the operating surgeon [1,2,5,7,13,35]. Numerous authors have demonstrated the association between increasing individual surgeon volume and improved PD outcomes [1,2,5,13,35]. Published data show that high-volume surgeons complete PD with significantly lower mean blood loss [12], shorter operating time [1] and greater nodal harvest [1] when compared to low-volume

surgeons. Nordback *et al* ^[13] also demonstrated that 86% of post-PD deaths were due to surgical or technical complications.

However, it is difficult to meaningfully interpret these data because ¹there is no standardized definition of a “high-volume surgeon”, with researchers applying ad-hoc definitions that range from as low as 3 PDs annually ^[13] to as high as 50 PDs annually ^[2,20,30]. We conducted a systematic literature search across the Pubmed, Medline and Google Scholar platforms seeking publications that defined: “high-volume” surgeons, using the search terms: “high-volume”, “experienced”, “subspecialty trained” and “specialized”. The literature search was performed by two researchers and spanned the 27-year period from January 1, 1995 to December 31, 2021. Table 2 outlines the results ^[1,2,3,13,35] and shows a large variation in the definition of “high volume surgeons”.

Schmidt *et al* ^[1] introduced the “experienced surgeon” concept being distinct from a high-volume surgeon. They defined an experienced surgeon as one who had performed >50 PDs in their career. In other words, they suggested that the cumulative experience was important unlike a high-volume surgeon which was time dependent. Schmidt *et al* ^[1] were able to demonstrate that, compared to their less-experienced colleagues, experienced surgeons performed more PDs with vein resections (96% *vs* 4%) and had significantly lower overall morbidity, pancreatic leak rates, operative blood loss and mean operating time. Importantly, they showed that experienced surgeons who currently performed PDs at low volumes had equivalent outcomes to high-volume surgeons.

Schmidt *et al* ^[1] suggested that a pancreatic surgeon needs to accrue 50 PDs before the improvement in technical operative skills begins to plateau. Tseng *et al* ^[36] suggested that in their experience, surgeons continued to acquire skills and technical expertise even when approaching 200 PDs. Although there is no consensus, and regardless of a time or case-load dependent definition, we believe that pancreatic surgeons continue to gain experience by developing operative maneuvers, recognizing avoidable pitfalls and learning how to get out of trouble when PDs don’t go smoothly. They also develop mature judgement that is important for appropriate patient selection.

We cannot downplay the importance of developing inter-personal relationships over time that facilitate better working relationships with colleagues in other specialties to enhance supportive post-operative care. These are lessons that can only be learned with proper surgical mentorship and accrued experience [1,37].

Combined Team Expertise:

Taking it a step further, PDs are quite unforgiving when complications arise. When they do, expert multidisciplinary care is required to prevent bad outcomes [7,37]. This includes input from intensivists, gastroenterologists, interventional radiologists, infectious disease specialists, nutritionists, among others. We agree with Sosa *et al* [3] that it is the “combined experience of the entire team of pancreatic care providers”, and not necessarily the hospital volume, surgeon volume or surgeon experience that make the difference in peri-operative outcomes. We also believe that is feasible to foster the growth of a multidisciplinary support team in low-volume institutions.

Implementation of Centralization

Although data accumulated to support centralization, there was reluctance to route patients to high-volume centers, even in the developed countries where data proved better outcomes. Fong *et al* [4] reported that there were only 10-12 high-volume pancreatic surgery centers in the entire United States, but over 1000 Low-volume centers performing PDs. Glasgow [9] reported that 88% of patients in California had PDs at hospitals that performed <2 cases per year. Many hospitals continued to perform PDs at low volumes [4,8,9,31,38]. Table 3 outlines the proportion of PDs performed by low-volume hospitals in developed countries.

Similarly, although there were data to support better outcomes by high-volume surgeons [1,2] and experienced surgeons [1], many PDs were not performed by these surgeons. There are numerous examples: Leiberman *et al* [2] documented that 67% of all the resections in New York State were done by low-volume surgeons who had done <9 PDs; Sosa *et al* [3] showed that 47.3% of PDs in Maryland, USA were performed by low-

volume surgeons performing <1 PD per year; and Nordback *et al* [13] reported that on average, PDs in Finland were performed by surgeons who only performed 2.1/year/hospital and 0.7/year/surgeon.

Negative Effects of Centralization:

Finally, there is existing data to show that healthcare inequity has developed in hospitals that adopted the centralization principle. There is clear data to show that patients are significantly less likely to have PD in a high-volume center if they are non-white (table 4) [3,16,17,24,39], female [17] or did not have private insurers (table 5) [24]. Eppsteiner [35] also documented that across the United States, patients were significantly more likely to have their pancreatic resections by high-volume surgeons if they were male, white raced, and a resident of a high-income zip code.

CARIBBEAN EXPERIENCE:

The age standardized incidence of pancreatic adenocarcinoma in the Caribbean is 4.4 per 100,000 population [40]. However, only 3 of 17 Caribbean countries have populations >200,000 persons. Therefore, few patients develop peri-ampullary lesions and qualify for PD annually. Peri-ampullary malignancies remain the most common indication for PD in the Caribbean, but most patients are not able to access high-volume centers in developed countries because of travel restrictions, lack of social support, financial limitations and/or lack of health insurance. Therefore, local hospitals are often their only options for PD.

After three specialized HPB centers were established in the Caribbean in 2011, general surgeons readily gave up performing major hepatectomies but they have been reluctant to give up PDs. We previously reported that 98% of hepatectomies are now performed by subspecialty trained HPB surgeons [41], but a review of unpublished data from the same database between 2013 and 2020 showed that 80% of attempted PDs were performed by HPB teams (Table 6).

As a surrogate marker of technical expertise, we used the same database to tally the number patients who had PD attempted and those who had PDs completed. The HPB surgeons completed 94% of attempted PDs, but general surgeons performed palliative bypasses in all 18 cases. Schmidt *et al* [1] suggested that vein reconstruction was a surrogate marker for surgeon experience. In this database, HPB surgeons were more likely to perform vein reconstruction during PD compared to general surgeons (26% *vs* 0). This suggests that the specialty surgeons were experienced, although none were high-volume surgeons using conventional criteria in table 1. Published data documented that only 12.8 PDs were performed annually at the busiest specialized HPB center in the Caribbean [42]. Nevertheless, we believe that outcomes can be improved using a modified centralization concept, with attention to the following five points:

Leadership

Surgical leaders must recognize that the concept of centralization is a significant deviation from “cultural norms” in the Caribbean and general surgeons are bound to resist this change. We must also recognize that it is not feasible to send all patients across the region to referral centers. Even if this was feasible, it would be undesirable because it would develop services in a handful of institutions but it would not be beneficial to the entire population at large.

Therefore, an astute leader could instead offer to operate at lower-volume centers assisted by general surgeons. In this way, they could identify and change hospital-based practices and processes. This has several potential advantages: better trained staff, diligence in care administration, development of critical care pathways and improved proficiency of the less experienced facility and their staff to care for critical patients. We agree with Pawlik *et al* [31], Billimora *et al* [8], Gasper *et al* [20], Hashimoto *et al* [44] and Ravaioli *et al* [55] that we should strive to identify specific elements of patient care in specialized hospitals that lead to better outcomes and introduce them in less-experienced facilities.

Fostering Team Spirit

We have already made the point that PDs are technically complex and unforgiving operations. Complications will occur once sufficient cases are attempted – and, regardless of surgeon skill and experience, it is the multidisciplinary team effort that will save patients. Therefore, it is important to pay attention to the pre- and post-operative care pathways.

Before selecting a patient for PD, there should be rigorous pre-operative evaluation [8,44,45], medical optimization [8], anaesthetic assessment [8,44] and tumour board discussion [46]. Mature surgeon judgment also has a large impact on the patient that makes it to the operating table. All of these factors affect peri-operative outcomes.

When complications develop in the post-operative phase, it is often not the surgeon who comes to the rescue. They rely on multidisciplinary support from a variety of specialties for around-the-clock emergency care [8,47,48,49,50,51]. It goes without saying that these services should be developed concurrently and we should strive for good interpersonal relationships across disciplines.

Critical Assessment of the healthcare environment

It is clear that the healthcare environment in the Caribbean differs significantly from those in developed countries. We have provided data showing that local subspecialty surgeons are experienced, but they have repatriated to resource-poor settings with many challenges: scarce blood products, lack of readily available specialized equipment, high competition for ICU/HDU beds, an undersupply of consumables and infrequent operating lists.

One is forced to realize that the environment is not always conducive to observing best practice recommendations [41]. In order to maintain quality service delivery, surgeons must perform a critical appraisal of their local facility and understand the pitfalls in their environment. Tailored processes of care would then have to be devised that suit the local healthcare environment. We agree with Sosa *et al* [3] who suggested that, instead of focusing on transforming a facility to a high-volume hospital, effort

would be better spent on developing a systematic approach to handle these patients by developing critical pathways to enhance the performance of the entire health care delivery team.

Developing Partnerships

While the traditional concept of centralization according to hospital volume or surgeon experience may not be practical in the Anglophone Caribbean, we have seen improved outcomes after introducing a partnership concept. In this concept, patients need not be channeled solely to referral centers. Instead, most Caribbean countries are sufficiently small for staff to move from referral centers to less experienced facilities, bringing with them experience, knowledge and select equipment for safe operations to be performed. Similarly, Ravaioli *et al* [55] published data to show that their institutions benefited from partnerships between high and low-volume facilities.

With this approach, we found that general surgeons still felt useful and were willing to cooperate with sub-specialists. They benefited because they received oversight from subspecialty surgeons, felt empowered to communicate about complications and increased their skillsets. Other authors have made similar suggestions to transfer mechanisms to improve outcomes into lower-volume hospitals where most patients receive their care [8,31,55].

Regular Audit

Over the years that the HPB units have been implemented in the Caribbean setting, we have prioritized data collection because we recognize that this is the way to objectively evaluate our clinical practices. The value of this exercise ultimately lies in improvement in outcomes after PD for the population as a whole, but changes in outcomes will not be fully evident until regular audits are carried out. This is the only way to create tangible benefits for the healthcare system. Regular review of the data also allows us to better

understand the challenges in the local healthcare system, ultimately facilitating the development of clinical care pathways and effective use of limited resources.

Knowledge of Population Based Data

It is important for surgeons to be knowledgeable about the characteristics of the population they work with. For example, it has been shown that persons of Caribbean descent harbor greater-than expected HPB anatomic variations [52]. If a surgeon has not anticipated and/or identified these variants, they can be easily injured and create significant complications. An example is a replaced right hepatic artery coursing behind the pancreatic head. This is prone to injury during PD and can lead to hepatic ischemia and mortality. In Caribbean populations, a replaced right hepatic artery coursing behind the pancreatic head is present in 18% of unselected individuals – significantly greater than published reports in medical literature [52].

Ultimately, there seems to be emerging consensus in the recent medical literature that hospital volume, surgeon volume and hospital teaching status are only proxies for not-yet-fully understood processes of care delivery [53-55]. These vary between facilities, but include staffing level, tumour board meetings, surgeon skill, care pathways, available technology and support services. Instead of focusing on these proxies, physicians should focus on specific hospital-based outcomes data and find directed ways to improve the quality of care in your hospital despite volume, surgeon, teaching or financial status of the facility.

CONCLUSION

Despite low case volumes, cultural resistance to subspecialty care, financial barriers and resource-poor environments, we have been able to maintain acceptable short-term outcomes after PDs. We advocate developing an intimate knowledge of your health care system to identify processes that will facilitate good outcomes. In our setting we used a modified centralization concept, with attention to creating partnerships with

experienced staff, fostering teamwork, appropriate staff training, development of care pathways, regular audits and knowledge of population-based data.

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