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# Improved Pancreaticoduodenectomy Outcomes after Starting a Specialized Community Hospital Pancreatic Surgery Program

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## ABSTRACT

Background: Recent trends in centralization of pancreatic surgery happened as a response to improved outcomes in tertiary care institutions. The volume-outcome relationship is true for high volume hospitals and surgeons. Obstacles to patient travelling to high volume institutions and widespread quality care in community hospitals led to establishing a quality specialized pancreatic surgery program in the community.

Methods: Two pancreatic surgery specialists relocated their program from a tertiary care center to a community hospital. Results of the first sixty-two pancreaticoduodenectomy and total pancreatectomy procedures were studied.

Results: One hundred and seventeen pancreatic surgery cases were analyzed, sixty-two pancreaticoduodenectomy and total pancreatectomy cases were included. Patient demographics were not different in regard to the median age (67 vs. 62 years), gender (65 vs. 62% males), median BMI (26.2 vs. 26 kg/m$^2$), or American Society of Anesthesiologists class, in between the two hospitals. There was a significant decrease in the operative time (350 vs. 281 minutes, p=0.0001), estimated blood loss (409 vs. 156 milliliters, p=0.003), and length of hospital stay (7.2 vs. 5.2 days, p=0.0001). Most patients were operated on for a diagnosis of malignancy (74.2%), and the R0 resection rate was better at the community hospital reaching 95.2%. Transfusions, delayed gastric emptying and leaks tended to be better at the community hospital but did not reach statistical significance.

Conclusion: With dedicated institutional support and careful program design, complex procedures such as PD can be successfully relocated to the community where superior results can be achieved.

## KEYWORDS

Pancreaticoduodenectomy, Whipple, Enhanced recovery, Community hospital.

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## Introduction

Pancreatic surgery is one of the most complex disciplines among abdominal surgeries. Pancreaticoduodenectomy (PD) remains the golden standard procedure to treat diseases of the peri-ampullary area but continues to pose challenges even to experienced pancreatic surgeons due to its complexity. For a long time after its introduction, PD was associated with very high rates of morbidity reaching 60% and mortality reaching 20% [1-3]. Improvement in outcomes resulted from emerging advances in technology and optimized perioperative management of complex surgeries. It has been shown that pancreatic surgery, specifically PD, has a volume-outcome formula, where improved mortality and better outcomes were obtained in high volume centers when performed by high volume surgeons [4-7]. This correlation led to centralization or regionalization of pancreatic surgery to major tertiary care centers, further advocated for by the Leapfrog initiative [8-10]. It is still debatable as to whether hospital volume or surgeon volume or system processes are responsible for this effect [11,12]. In consequence, emerging reports from community hospitals demonstrated acceptable PD safety and outcomes [13,14].

A multispecialty surgical group in northern Virginia decided to expand into complex hepatopancreatobiliary surgery and hired a fellowship-trained pancreatic surgeon to partner with their fellowship-trained transplant and pancreatic surgeon. A specialty pancreatic surgery program was created and operated at two hospitals. One is a tertiary care hospital and the other, a sister community hospital both belonging to the same healthcare system. The aim of this study is to examine the outcomes of pancreatic surgery and specifically those of PD, for two high volume surgeons who improved their outcome after migrating their program to a community hospital.

## Methods

Data was retrospectively collected from a prospectively-maintained database at the division of hepatopancreatobiliary surgery at Virginia Surgery Associates (Fairfax, VA). Medical records of patients who underwent pancreatic surgery with the two pancreatic surgery specialists of the group (GY and TRS), were identified and reviewed. Patients demographics, preoperative, intraoperative and postoperative parameters were analyzed. Data from August 2016 to December 2018 was collected, just after 60 consecutive PD were performed. We elected to stop at the 60 PD limit as to adhere to the published learning curve threshold [15,16]. During this period, a total of 117 pancreatic surgeries were performed at two different institutions, a tertiary care center (TCC), and a community hospital (CH), under the umbrella of the same healthcare system. Pancreatic procedures reviewed include PD, total pancreatectomy (TP), distal pancreatectomy and pancreatic drainage procedures. We only included PD(n=60) and TP, (n=2), in our final analysis, for a total of 62 consecutive procedures.

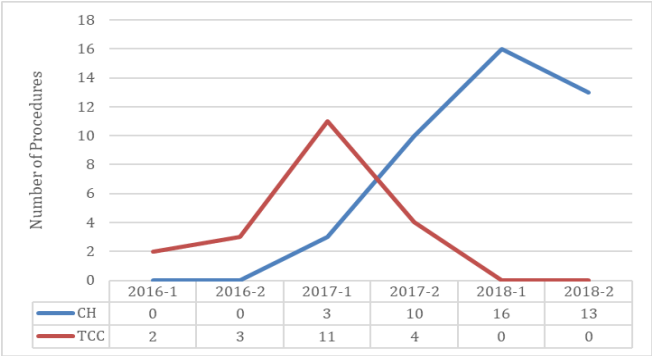
The two surgeons started the program at the TCC, which has a large general surgery residency program, in August of 2016. Procedures there were done by one of the two surgeons assisted by a fifth-year general surgery resident. In April 2017, which is approximately eight months into the program, and based on the community requirements, both surgeons began performing these procedures at the CH. One surgeon performed the procedure and the other surgeon acted as the assistant, residents were not part of the CH setting. By the end of 2017, all pancreatic surgeries were performed at the CH and this decision was mainly outcomes-driven.

All PD were done though an upper midline incision. The steps of the procedure were performed in the same way consistently. These steps have been published by Christians et. al. [17] The pancreatic reconstruction part of the procedure was done with end-to-side, duct-to-mucosa retrocolic pancreaticojejunostomy with interrupted absorbable sutures, and anterior and posterior layers following the modified Blumgart technique. The biliary anastomosis was done in an end-to-side fashion using interrupted absorbable sutures and the gastrojejunostomy was constructed in a two-layer, handsewn, antecolic, end-to-side fashion. We performed the standard PD procedure without sparing the pylorus. The post-operative care plan was standardized after a limited number of cases and an enhanced recovery post-PD recovery pathway was used. A multimodality pain pathway protocol was developed with the help of the anesthesia department at both hospitals. Patients were regularly admitted to monitored hepatobiliary unit surgical beds post-operatively with specially trained nursing staff and did not get admitted to the intensive care unit unless indicated.

Standard post-PD complications were measured using published guidelines from the International Study Group on Pancreatic Surgery and the Pancreas Club calculators [18-20]. Patient outcomes were compared using standard statistical methods, we compared outcomes of surgeries done at the TCC (n=20), to the outcomes of surgeries done at the CH (n=40) after approval from the institutional review board as an outcomes study. Statistical analysis was done using GraphPad Prism (Lajolla, CA) and p-value $<0.05$ was considered significant.

## Results

From August 2016 to December 2018, a total of 117 pancreatic surgeries were done at both hospitals. The pancreatic surgery program was initiated August of 2016 at the TCC. In April of 2017, the program expanded to the nearby CH. The sixtieth PD was performed in December of 2018. The quarterly number of cases done initially picked up at both hospitals until August of 2017 where all procedures were done exclusively at the CH (Figure 1).




| | 2016-1 | 2016-2 | 2017-1 | 2017-2 | 2018-1 | 2018-2 |
|---|---|---|---|---|---|---|
| CH | 0 | 0 | 3 | 10 | 16 | 13 |
| TCC | 2 | 3 | 11 | 4 | 0 | 0 |

**Figure 1:** Pancreaticoduodenectomy and total pancreatectomy procedures done at the Tertiary Care Center (TCC), and the Community Hospital (CH) between August of 2016 and December of 2018.

Patient demographics, indications for the procedures and the procedures performed are shown in Table 1. There was no significant difference between the two hospitals in regard to: patient median age (76 vs. 62 years), median body mass index (26.2 vs. 26 kg/m$^2$), gender (65 vs. 62% males), or American Society of Anesthesiologists (ASA) class. Additionally, indications and procedure types did not differ.

**Table 1:** Demographic and preoperative data.

| | | TTC | CH | p value |
|---|---|---|---|---|
| Number of Procedures | | 20 | 42 | |
| Age (Median, Years) | | 67 | 62 | 0.11 |
| Male Gender | | 13(65%) | 26(62%) | 0.52 |
| BMI (kg/m$^2$) | | 26.2 | 26 | 0.89 |
| ASA Class | 1 | 0 | 1 (2.4%) | 0.54 |
| | 2 | 4 (20%) | 6 (14.3) | |
| | 3 | 14 (70%) | 23 (54.8%) | |
| | 4 | 2 (10%) | 12 (28.5%) | |
| Type of Procedure | PD | 19 (95%) | 41 (97.6%) | 0.54 |
| | TP | 1 (5%) | 1 (2.4%) | |
| Indication of Procedure | Malignancy | 15 (75%) | 31 (73.8%) | 0.58 |
| | Pre-malignancy | 2 (10%) | 6 (14.3%) | |
| | Pancreatitis | 3 (15%) | 5 (11.9%) | |

Intraoperative variables and post-operative outcomes are shown in Table 2. Twenty patients were operated on at the TCC and forty-two at the CH. When procedures were performed at the CH, there was a significant decrease in operative time of the procedure (350 and 281 minutes, p<0.01) and estimated blood loss (409 and 156 ml, p<0.01). Intraoperative blood transfusions were reduced from 10% to zero, and post-operative transfusions from 10% to 2.4%, however these results did not reach statistical significance. There was no difference in pancreatic duct diameter and pancreatic gland texture between patients. These features are known to increase the complexity of the reconstruction after PD and are known risk factors for post-operative pancreatic leaks [21].

Overall delayed gastric emptying was reduced from 20% to 4.8%, Grade A from 15 % to 2.4% and Grade B from 5% to 2.4%. These results approached but did not reach statistical significance (p=0.08). There was no Grade C delayed gastric emptying in this study. Pancreatic leak rates were similar between the two hospitals; there was one Grade B leak and one Grade C leak at the TCC, versus two grade B and no Grade C leaks at the CH. Intra-abdominal infections, which included any abscesses or fluid collections that needed to be treated with antibiotics or percutaneous drains and these included the pancreatic leaks, did not differ between the two hospitals, (10% and 7.1%). Most patients were admitted to the regular hepatobiliary unit surgical beds, a small number of patients needed to be admitted to the intensive care unit, 15% at the TCC versus 7.1% at the CH. Reasons for intensive care unit admission included the needs for continuous infusion drips that were not permitted on the surgical floor. Examples included insulin drips from total pancreatectomy patients and anti-arrhythmia cardiac drips for atrial fibrillation patients. Only one patient at the TCC needed the intensive care unit for hemodynamic instability requiring pressor support. Rates of deep vein thrombosis, pulmonary emboli were basically null. Only one patient at the CH had a post-operative urinary tract infection requiring antibiotics. Rates of R0 resection were high and similar between the two hospitals (90% and 95.2%). One of the main post-operative outcomes that reached clinical significance was the length of hospital stay and that was reduced from 7.2 to 5.2 days (p <0.01) for patients that had their surgery at the CH. There was no statistical significance in terms of 30-day hospital readmissions between the two hospitals, however it was little increased at the CH (10% and 16.7%, p=0.71).

There was only one reoperation and that one case was also the only 30-day mortality case in the whole study. Most of the cases were done for a malignancy diagnosis as evidenced by the final pathology of resected specimen (Table 3).

**Table 2:** Post-operative outcomes.

| | TTC, n=20 | CH, n=42 | p value |
|---|---|---|---|
| Operative Time (Min) | 350 | 281 | 0.0001 |
| Estimated Blood Loss (ml) | 409 | 156 | 0.003 |
| Intraoperative Blood Transfusion | 2 (10%) | 0 (0%) | 0.1 |
| Nerve Block | 0 (0%) | 42 (100%) | 0.0001 |
| PD Diameter (mm) | 3.6 | 3.5 | 0.91 |
| Gland Texture (Soft %) | 11 (55%) | 22 (52%) | 0.53 |
| Delayed Gastric Emptying | | | 0.08 |
| Grade A | 3 (15%) | 1 (2.4%) | |
| Grade B | 1 (5%) | 1 (2.4%) | |
| Grade C | 0 (0%) | 0 (0%) | |
| Post-operative Blood Transfusion | 2 (10%) | 1 (2.4%) | 0.24 |
| Pancreatic Leak | | | 0.58 |
| Garde B | 1 (5%) | 2 (4.8%) | |
| Grade C | 1 (5%) | 0 (0%) | |
| Intra-abdominal Infection | 2 (10%) | 3 (7.1%) | 0.65 |
| ICU Stay Requirement | 3 (15%) | 3 (7.1%) | 0.37 |
| R0 Resection | 18 (90%) | 40 (95.2%) | 0.58 |
| DVT/PE/UTI | 0 (0%) | 1 (2.4%) | 1 |
| Length of Hospital Stay (Days) | 7.2 | 5.2 | 0.0001 |
| 30-day Readmission | 2 (10%) | 7 (16.7%) | 0.71 |
| Reoperation | 1 (5%) | 0 (0%) | 0.32 |
| 30-day Mortality | 1 (5%) | 0 (0%) | 0.32 |

**Table 3:** Pathology results.

| Diagnosis | No. of Cases | Percentage |
|---|---|---|
| Malignant Pathology | 46 | 74.2 |
| PDAC | 33 | 53.2 |
| PNET | 6 | 9.7 |
| AAC | 2 | 3.2 |
| DAC | 3 | 4.8 |
| CCA | 1 | 1.6 |
| GCA | 1 | 1.6 |
| Premalignant Pathology | 7 | 11.3 |
| IPMN | 7 | 11.3 |
| Benign Pathology | 9 | 14.5 |
| Pancreatitis | 8 | 12.9 |
| Adenoma | 1 | 1.6 |

## Discussion

Pancreatic surgery outcomes have been widely studied; definitions and guidelines have been nationally and internationally published [1,18,19,22,23]. It has become evident that volume-quality relationship applies to complex abdominal surgeries. High-volume centers and high-volume surgeons obtain better overall outcomes after PD [5,6,10,24-26]. These trends advocated for centralization of complex abdominal surgeries to high-volume tertiary care centers, nationally and internationally [25,27-30]. Several obstacles to centralization were met during this process, which were country and state-specific. In general, these were related to the following: feasibility of access to cancer care, disparity between patient groups, commercial insurance variability and changing government health policies [9,31].

In the face of centralization concerns, multiple community hospitals and surgeons at smaller institutions started publishing their results, showing comparable feasibility and safety in undergoing complex surgeries [11,13,32,33]. An ongoing debate exists now as to the nature of the defining denominators of superior outcomes in high-volume institutions [34]. A gray area exists when high-volume surgeons operate at low-volume hospitals, or low-volume surgeons operate at high-volume hospitals [35]. Surgeon experience remains the backbone on which pancreatic surgery programs rely [12,36]. There is a growing but stable trend in achieving acceptable and comparable outcomes in community hospitals adopting pancreatic surgery. This is largely due to high-volume experienced surgeons migrating to community hospitals, and thus altering these institutions' status into high-volume hospitals [11,13,32,37].

Virginia Surgery Associates is a private general surgery group in Northern Virginia. The group has been serving the community since 1978. In the last decade, the group made the decision to expand into surgical subspecialties in its covered area. Consequently, the hepatopancreatobiliary subdivision was created when they recruited a fellowship-trained pancreatic surgeon (GY) to partner with their fellowship-trained transplant surgeon. Procedures were initially performed at the high-volume TCC that is the base for a large general surgery residency program, where pancreatic surgeons served as teaching faculty. Community needs and referral trends allowed the group and its pancreatic surgeons to extend the pancreatic surgery program to a smaller sister community institution. Outcomes at the CH program eventually led to the full migration of the program to that institution. In less than two years, the program became a high-volume program and met all national benchmarks in pancreatic surgery [38]. The program outcomes were feasible, reproducible, safe and comparable to outcomes from major institutions [1,7,27]. At this early point in the program, the team was able to decrease operative time, operative blood loss, and length of hospital stay in a significant fashion. Although other outcomes results did not reach statistical significance, they did reach clinical significance. These include the overall decrease in rates of pancreatic leaks, which is "the Achilles heel" of the PD procedure. In addition to the overall decrease in: delayed gastric emptying, intra-abdominal infections, and ICU stay, there was a noteworthy improved rate of R0 resections reaching an excellent 95% in the CH setting.

These noteworthy improvements cannot be solely attributed to surgeon volume. Initiating the program at the CH was implemented only after a detailed and thorough plan was constructed in conjunction with the administration of the CH. Previously, the CH had in place its established cancer center as well as its own tumor boards and multidisciplinary teams. Furthermore, twenty-four-hour interventional radiology and interventional gastroenterology coverage was already in place, and the requirements for experienced cytological and pathological care were met. In fact, the pathology departments in both hospitals are administered by the same group.

Intraoperatively, the program was assigned a dedicated consistent team of specialty anesthesiologists and operating room personnel. An enhanced recovery pathway was used by the anesthesia team to reduce intraoperative volume and narcotic use. A multimodality pain pathway was implemented, this was started with a peripheral nerve block performed immediately after induction, again, performed by the same consistent anesthesia team.

A post-operative enhanced recovery pathway was also used on the surgical floor. This followed published international guidelines with some modifications that will be separately published by our group [39]. The planned hospital stay after a PD was reduced to 5 days and was accomplished in the majority of cases at the CH. All patients were discharged home on a full liquid diet and diets were advanced on an outpatient basis.

In addition, post discharge care provided was also highly advanced and detailed. The group's nurse navigator performed daily post discharge care via phone calls and a weekly follow up office visit. The group's pancreatic surgeons were available around the clock for direct communication with patients. The pancreatic surgeons were also available for patient hospital rounding on daily basis, including weekends.

This study has many limitations due its nature. It is meant to publish the improved outcomes of a new pancreatic surgery program in the Northern Virginia community area. Limitations include small patient numbers, different characteristics of both hospitals, the retrospective nature of the study, even though the patient database was prospectively maintained. The strict adherence to the enhanced recovery pathway was mainly applied at the CH and was not very strictly followed at the TCC, as it was first introduced at that hospital, and it needed TCC staff and residents some time to apply it. One bias is the use of peripheral nerve blocks (PNB) with long-acting liposomal agents at the CH, the procedure was not used at the TCC. There are mixed reviews whether or not nerve blocks help, we believe they do in our cohort and may have partly contributed to better short-term surgical outcomes. Procedures were performed by a surgeon and a senior resident at the TCC. Both surgeons assisted each other performing these cases at the CH without the use of trainees or surgical assistants. A high degree of standardization was achieved once the program relocated to the CH.

Regionalization of complex procedures allows improved outcomes if patients can travel to high-volume institutions. However, high-volume surgeons are taking advantage of the widespread dissemination of healthcare and building high-volume programs in the community. As evidenced by the results in this study; with dedicated institutional support and careful program design, complex procedures such as PD can be successfully relocated to the community where superior results can be achieved.

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