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## Pancreaticoduodenectomy and placement of operative enteral access: Better or worse?<sup>☆</sup>



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### ABSTRACT

**Background:** It is unclear whether placement of operative enteral access (OEA) during pancreaticoduodenectomy (PD) correlates with decreased morbidity.

**Methods:** A retrospective chart review of patients undergoing PD with and without OEA placement between January 2016 and May 2018 was undertaken. Outcomes included length of stay (LOS), 30- and 90-day readmission, initiation of total parenteral nutrition (TPN), postoperative pancreatic fistula (POPF), delayed gastric emptying (DGE), and surgical site infection (SSI).

**Results:** 69 patients were evaluated; there was a trend toward decreased LOS for patients without OEA (9 vs. 7.5 days,  $p = 0.07$ ). There were no significant differences in initiation of TPN (9.1% vs 19.4%,  $p = 0.311$ ), POPF (21.2% vs 11.1%,  $p = 0.999$ ), DGE (24.2% vs 22.2%,  $p = 0.999$ ), organ/space SSI (12.1% vs 8.3%,  $p = 0.702$ ).

**Conclusion:** OEA placement at the time of PD is not necessarily associated with improved perioperative morbidity and outcomes, suggesting that OEA may not be necessary and should be considered on a case by case basis.

**Summary:** It is unclear whether placement of operative enteral access (OEA) during pancreaticoduodenectomy (PD) correlates with decreased morbidity. A retrospective review of patients undergoing PD with and without OEA placement between January 2016 and May 2018 was performed, demonstrating that there were no overall significant differences in postoperative complications and outcomes.

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### Introduction

Pancreaticoduodenectomy (PD) is considered the gold standard for operable pancreaticobiliary malignancy that involves the head of the pancreas, ampulla, mid-to distal common bile duct, and/or duodenum. While mortality has significantly improved over time and now ranges from 1 to 5%, the rate of perioperative complications remains as high as 30–60%,<sup>1,2</sup> despite advances in surgical

technology and management. Procedure-specific complications include delayed gastric emptying (DGE), postoperative pancreatic fistula (POPF) and organ/space infections, to name a few. It has been suggested that early reintroduction of postoperative nutritional supplementation can lead to improved wound healing, decreased rate of infectious complications, and overall improvement in clinical outcomes.<sup>2,3</sup> Recent studies have compared various methods of postoperative nutritional supplementation and associated benefits and risks.<sup>1,2,4,5</sup> Although the correlation between enteral nutrition and perioperative outcomes after PD are somewhat limited, it is generally accepted that early enteral nutrition is safe and tolerated after PD without significant impact on postoperative complications.<sup>3</sup> The aim of this study is to evaluate whether patients undergoing pancreaticoduodenectomy and concomitantly placed operative enteral access (OEA) would have less perioperative

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morbidity than patients with no enteral access placed during surgery.

## Methods

69 patients undergoing PD with or without OEA placement at a single institution from January 2016 to May 2018 were identified from a prospectively maintained database, which includes demographics, treatment, intraoperative data, pathology, and clinical outcomes. This study received institutional review board approval. The patient cohort was divided into two study groups of 33 consecutive patients who received OEA at the time of operation, followed by 36 consecutive patients who did not receive OEA at the time of operation. Data were obtained from institutional clinical, radiological, and pathological records. Additional factors that might affect postoperative outcomes, such as neoadjuvant therapy, as well as nutritional surrogates such as preoperative albumin and body mass index (BMI) were examined. Intraoperative variables including OEA placement, vascular reconstruction, and estimated blood loss (EBL) were collected. POPF, DGE, superficial- and organ/space surgical site infection (SSI), length of stay (LOS), readmission within 30 and 90 days of discharge and associated etiologies such as failure to thrive, and initiation of total parenteral nutrition (TPN) were compared between the two groups. POPF was stratified according to the updated 2016 definitions provided by the International Study Group on Pancreatic Surgery (ISGPS).<sup>6,7</sup> DGE was also stratified by ISGPS criteria from 2007.<sup>6,8</sup> Duration of initial nasogastric tube (NGT) placement and rate of re-insertion were recorded. Surgical site infections, as defined by the Center for Disease Control and Prevention guidelines, were classified into two categories: superficial incisional SSI, defined as an infection involving only the skin or subcutaneous tissue of the surgical wound and organ/space SSI, defined as an infection involving anatomical spaces and organs that were involved during the operation, with diagnosis made within 30 days of surgery.<sup>9</sup> Patients readmitted within 30 or 90 days of discharge were evaluated for nutrition-specific etiology for readmission, such as failure to thrive or feeding tube complications.

### Postoperative care

All patients underwent classical pancreaticoduodenectomy with retroperitoneal lymphadenectomy, and subsequent reconstruction with modified Blumgart pancreaticojejunostomy, single-layer, interrupted hepaticojejunostomy, followed by an antecolic, posteriorly-fashioned stapled gastrojejunostomy performed by a single surgeon. In the first cohort of patients (January 2016–March 2017), approximately 20 cm distal to the gastrojejunostomy, a 12-French feeding jejunostomy was placed in a Witzel fashion. Enteral feeding using the jejunostomy feeding tube was initiated on postoperative day one. Per protocol, NGT was maintained on negative suction until there was <500 mL of bilious output; thereafter, NGT was placed to gravity until output was <500 mL, and subsequently removed. After removal of NGT, the patient was initiated on a clear liquid diet, followed by advancement to a post-gastrectomy diet within 24 h. All patients were discharged with home enteral tube supplementation in addition to a limited post-gastrectomy oral diet.

The second cohort of patients underwent PD without OEA placement (March 2017–May 2018). NGT management was identical to the aforementioned description, and all patients were discharged home with post-gastrectomy oral diet. Any patients requiring nutritional supplementation were discharged with total parenteral nutrition.

## Statistical analysis

Descriptive, univariate, and multivariable analyses were performed using R Statistical Software (v 3.3.1, R Development Core Team, Auckland, New Zealand). Categorical variables were compared using chi-square test or Fisher exact test if the expected frequency for any cell was found to be < 5. Continuous variables were compared using two independent sample *t*-test or Mann-Whitney *U* test if normality assumption does not hold. Multivariable linear and logistic regressions were used to investigate the association outcomes and OEA adjusted for preoperative ECOG and vascular resection because differences were identified between these two groups at  $p < 0.1$ . A weakly informative prior was used to fix the non-convergence issue when there is complete separation in multivariable logistic regression<sup>10</sup> for 30-day mortality and 90-day mortality. In sensitivity analyses, we restricted our sample to those without vascular reconstruction. A  $p$ -value < 0.05 was used to determine statistical significance.

## Results

69 patients were identified and included in the analysis; 33 (47.8%) patients underwent PD with placement of OEA, whereas 36 (52.2%) patients underwent PD with no OEA. Baseline characteristics and demographics were comparable across groups (Table 1), with no differences with regards to median age (66 years vs. 64.5 years,  $p = 0.393$ ), sex (48.5% vs. 52.8%,  $p = 0.908$  males), and race ( $p = 0.768$ ). There were no preoperative differences in albumin levels of patients ( $3.68 \pm 0.56$  g/dL vs.  $3.59 \pm 0.63$  g/dL,  $p = 0.545$ ) or preoperative BMI ( $27.3$  kg/m<sup>2</sup> vs.  $26.2$  kg/m<sup>2</sup>,  $p = 0.914$ ). Diagnosis on final pathology ( $p = 0.670$ ), use of neoadjuvant systemic therapy ( $p = 0.999$ ), including those who received chemotherapy alone versus chemoradiation ( $p = 0.649$ ) were comparable in both groups. There was no difference in intraoperative blood loss between the groups, with a median EBL of 300 mL in both groups ( $p = 0.506$ ). Four patients underwent intraoperative vascular resection (12.1% vs 0%,  $p = 0.047$ ) in the OEA group.

There were no differences identified with regards to postoperative outcomes (Table 2). The overall incidence of POPF (8/33, 24.4% vs 8/36, 22.2%,  $p = 0.999$ ) and DGE (8/33, 24.2% vs 8/36, 22.2%,  $p = 0.999$ ) were not significant, and superficial (1/33, 3.0% vs 2/36, 5.6%,  $p = 0.999$ ) and organ/space (4/33, 12.1% vs 3/36, 8.4%,  $p = 0.702$ ) SSI were also not significant. When the incidence of POPF was stratified based on severity (grades A, B, C) as defined by ISGPS, there was also no difference in the severity of POPF ( $p = 0.152$ ). However, when the incidence of DGE was stratified based on severity (grades A, B, C) as defined by ISGPS, there was a significant difference in the severity of DGE between the two groups ( $p = 0.006$ ). Six patients were found to have grade B DGE, all in the OEA group. There were four patients with grade C DGE, all occurring in the non-OEA group. The median duration of initial NGT placement was found to be significant (3.5 days vs. 2.0 days,  $p = 0.034$ ). However, there was no difference in NGT re-insertion rate between the two groups ( $p = 0.665$ ). There was no difference in the incidence of initiating TPN for supplemental nutrition across groups (3/33, 9.1% vs 7/36, 19.4%,  $p = 0.311$ ).

There was a trend towards increased LOS in the group with OEA placement (9 days vs 7.5 days,  $p = 0.070$ ). There were no differences in 30-day ( $p = 0.728$ ) or 90-day ( $p = 0.999$ ) readmission, or 30-day ( $p = 0.225$ ) or 90-day mortality ( $p = 0.225$ ). However, significant differences between preoperative and postoperative BMI were identified at 30 days. In patients receiving OEA at the time of surgery, there was significantly less change in BMI ( $-5.06\% \pm 4.95\%$  vs  $-10.04\% \pm 5.44\%$ ,  $p < 0.001$ ) at 30 days. By 90 days, the percent

**Table 1**  
Baseline characteristics and perioperative variables.

	OEA PLACEMENT AT PD (N = 33)	NO OEA PLACEMENT AT PD (N = 36)	P VALUE
Age, median (iqr)	66 (55–71)	64.5 (57–71)	0.393
Gender, n (%)			0.908
Male	16 (48.5%)	19 (52.8%)	
Female	17 (51.5%)	17 (47.2%)	
Race, n (%)			0.768
Caucasian	20 (60.6%)	25 (69.4%)	
African american	9 (27.3%)	7 (19.4%)	
Others	4 (12.1%)	4 (11.1%)	
Preop albumin (g/dl), mean (sd)	3.68 ± 0.56	3.59 ± 0.63	0.545
Preop bmi (kg/m <sup>2</sup> ), median (iqr)	27.31 (23.48–30.74)	26.16 (24.63–29.8)	0.914
Preop ecog, n (%)			0.061
Ecog 0	16 (48.5%)	26 (72.2%)	
Ecog 1	15 (45.5%)	10 (27.8%)	
Ecog 2	2 (6.1%)	0 (0%)	
Diagnosis, n (%)			0.670
Pancreatic adenocarcinoma	19 (57.6%)	18 (50%)	
Cholangiocarcinoma	2 (6.1%)	5 (13.9%)	
Adenocarcinoma	2 (6.1%)	2 (5.6%)	
Adenocarcinoma	2 (6.1%)	2 (5.6%)	
Tumor	1 (3.0%)	4 (11.1%)	
Others	7 (21.2%)	5 (13.9%)	
Neoadjuvant therapy, n (%)	11 (33.3%)	13 (36.1%)	0.999
Chemo alone vs chemort, n (%)			0.649
Chemotherapy alone	2 (6.1%)	4 (11.1%)	
Chemoradiation	9 (27.3%)	9 (25%)	
Vascular reconstruction, n (%)	4 (12.1%)	0 (0%)	0.047
Estimated blood loss (ml), median (iqr)	300 (250–400)	300 (200–470)	0.506

loss in BMI were no longer significant between groups (−8.17% vs −8.94%,  $p = 0.210$ ).

Multivariable analyses utilizing linear and logistic regression methodology were performed to assess the association between OEA placement at the time of surgery and postoperative outcomes, including postoperative pancreatic fistula, delayed gastric emptying, superficial and organ/space surgical site infection (SSI), NGT re-insertion, initiation of TPN, and readmissions (Table 3). The multivariate models were adjusted for baseline characteristics and perioperative variables with  $p < 0.10$ , specifically patients who underwent vascular resection ( $p = 0.047$ ) and ECOG status ( $p = 0.061$ ). Within the controlled models, the results of multivariate analysis were found to have similar statistically significant findings with univariate analysis.

Additional sensitivity analyses were performed (Supplementary Tables 1–3), restricting our sample to those without vascular reconstruction as the four patients who underwent vascular reconstruction belonged to the OEA cohort. The two deceased patients in the study group both had vascular reconstruction. Therefore, we were not able to evaluate mortality rate. For other outcomes, the point estimates and confidence intervals were similar for all outcomes except NGT duration, for which we did not find significant association with OEA in the main analysis.

## Discussion

Despite continued advances and ongoing changes in surgical technique and perioperative management, the morbidity

**Table 2**  
Postoperative outcomes.

	OEA PLACEMENT AT PD (N = 33)	NO OEA PLACEMENT AT PD (N = 36)	P VALUE
PANCREATIC FISTULA, N (%)	8 (24.2%)	8 (22.2%)	0.999
POPF GRADE, N (%)			0.152
GRADE A (BIOCHEMICAL LEAK)	1 (3%)	4 (11.1%)	
GRADE B	5 (15.2%)	4 (11.1%)	
GRADE C	2 (6.1%)	0 (0%)	
DELAYED GASTRIC EMPTYING, N (%)	8 (24.2%)	8 (22.2%)	0.999
DGE GRADE, N (%)			0.006
GRADE A	2 (6.1%)	4 (11.1%)	
GRADE B	6 (18.2%)	0 (0%)	
GRADE C	0 (0%)	4 (11.1%)	
DURATION OF NGT (DAYS), MEDIAN (IQR)	3.5 (2–4)	2 (2–3)	0.034
NGT RE-INSERTION, N (%)	3 (9.1%)	2 (5.6%)	0.665
SUPERFICIAL SSI, N (%)	1 (3.0%)	2 (5.6%)	0.999
DEEP SSI, N (%)	4 (12.1%)	3 (8.3%)	0.702
INITIATION OF TPN, N (%)	3 (9.1%)	7 (19.4%)	0.311
LENGTH OF STAY (DAYS), MEDIAN (IQR)	9 (8–13)	7.5 (7–11.25)	0.070
30-DAY BMI % CHANGE, MEAN (SD)	−5.06 ± 4.95	−10.04 ± 5.44	<0.001
90-DAY BMI % CHANGE, MEDIAN (IQR)	−8.17 (−11.58 to −2.74)	−8.94 (−16.72 to −6.39)	0.215
30-DAY READMISSION, N (%)	5 (15.2%)	4 (11.1%)	0.728
90-DAY READMISSION, N (%)	3 (9.1%)	4 (11.1%)	0.999
30-DAY MORTALITY, N (%)	2 (6.1%)	0 (0%)	0.225
90-DAY MORTALITY, N (%)	2 (6.1%)	0 (0%)	0.225

**Table 3**  
Multivariate regression analysis.

	Patients with OEA placement during PD (Reference Group: Patients without OEA)	
	Estimate (95% CI)	p value
Length of Stay (days)	0.86 (−1.44–3.16)	0.459
NGT Duration (days)	1.19 (0.07–2.32)	0.038
30-Day BMI % Change	4.77 (2.00–7.43)	0.001
90-Day BMI % Change	3.27 (−2.02–8.55)	0.221
	OR (95% CI)	p value
Pancreatic Fistula	1.00 (0.28–3.53)	0.994
Delayed Gastric Emptying	1.13 (0.33–3.82)	0.851
Superficial SSI	0.66 (0.03–7.69)	0.743
Organ/Space SSI	0.70 (0.08–4.90)	0.723
NGT Reinsertion	0.76 (0.03–9.30)	0.833
Initiation of TPN	0.25 (0.03–1.25)	0.124
30-Day Readmission	1.68 (0.38–7.85)	0.486
90-Day Readmission	1.09 (0.19–5.75)	0.911
30-Day Mortality	0.56 (0.05–62.2)	0.755
90-Day Mortality	0.56 (0.05–62.2)	0.755

associated with PD continues to be as high as 30–60%.<sup>1,3,4</sup> It has been suggested that the early initiation of postoperative nutrition can be associated with improvement in overall perioperative outcomes.<sup>1–3,11</sup> It is understood that early initiation of oral diet after major upper gastrointestinal surgery may lead to improvement in postoperative gut function.<sup>13</sup> In patients undergoing PD, early initiation of oral diet has shown favorable outcomes, such as shorter LOS, over those receiving enteral and parenteral support.<sup>11</sup> However, it is unclear whether early postoperative nutrition alone or supplemental nutritional alimentation constitutes the ideal method for reintroduction of postoperative nutrition.

Not all patients undergoing PD are able to initiate an oral diet in the early postoperative period, owing to multiple factors and morbidities with PD, including POPF and DGE, to name a few. Though not standardized, to mitigate these issues, some surgeons place operative enteral access at the time of PD in order to provide early and consistent postoperative nutrition. Ultimately, the decision to place OEA at the time of PD is at a surgeon's discretion.<sup>2,4</sup> The placement of OEA is not without its own inherent risks, including superficial or organ/space SSI, biliary drainage causing excoriation and irritation to the patient's skin. OEA may, in fact, be associated with inferior outcomes, suggested by a potential increased incidence of DGE.<sup>2</sup> Moreover, in an analysis of patients undergoing PD using the National Surgical Quality Improvement Program (NSQIP), overall morbidity was worse in patients receiving OEA, including postoperative complications such as deep SSI, pneumonia, acute renal failure and sepsis.<sup>1</sup> Adjuvant total parenteral nutrition (TPN) use has its own attendant risks and this has been well documented, including increased rates of perioperative complications and infection.<sup>12</sup>

Within our institution, extensive discussions were held amongst patients and providers, nutritionists, family members, and ancillary staff regarding barriers to expedited recovery, and recurring themes included the difficulty of managing the feeding tube in the inpatient and outpatient setting, as well as the psychosocial component of managing tube feedings for both patients and their families. For this reason, in 2017, at the considerations of patients and our multidisciplinary team, the decision was made to omit routine OEA placement during PD. This study evaluated whether the routine omission of OEA during PD would be associated with detrimental outcomes as compared to those patients who received OEA during PD over a similar timeframe.

The omission of OEA at the time of surgery did not result in any

difference in post-operative morbidity and outcomes such as superficial or organ/space SSI, DGE, or POPF. OEA was associated with a significantly longer NGT duration of 3.5 days as compared to 2 days in the cohort without OEA. There was no difference in NGT reinsertion rates after they had been removed. It was also noted that those patients who did not receive OEA had a trend towards shorter LOS (7.5 days vs 9 days,  $p = 0.070$ ). There were no significant differences in 30- and 90- day readmission and mortality rates; however, given the small size of the study, it is notable that the two mortalities in the study cohort belonged to the OEA group. It was noted that only one of the readmissions in the OEA group were admitted for feeding tube-related complaints. Interestingly, in the OEA omission group, two patients were readmitted within 30 days for failure to thrive, requiring inpatient hospitalization for the initiation of TPN. Moreover, while there was no difference in the incidence of POPF overall, when stratified by severity, there was almost twice the incidence (21% vs 11%) of clinically relevant (grades B/C) POPF in the OEA cohort. This would seem ironic given the patients with OEA were started with early enteral supplementation, as a prior series conducted from 1999 to 2007 showed that early enteral supplementation was associated with reduced occurrence of POPF. This study, however, was limited by routine practice of monitoring drain amylase levels coming about in 2005.<sup>3</sup> Although these observations were not statistically significant, there might be some clinical implication associated with higher incidence of postoperative events with OEA placement at PD.

Additionally, there was no difference in overall DGE between the two groups. However, when stratifying DGE by severity, the OEA cohort had a higher incidence of grade B DGE. We believe this may have been a byproduct of the feeding tube itself where the inflated balloon serves to secure feeding tube placement as well as prevent biliary excoriation onto the skin. In doing so, however, this may have actually caused a partial functional obstruction of the efferent limb of the gastrojejunostomy contributing to gastroparesis symptoms. In patients who did not have OEA placed at the time of surgery, it was noted that this cohort had a higher incidence of grade C DGE. The definition of grade C DGE states that patients have prolonged NGT duration or persistent postoperative nausea, or they were started on additional supplementary TPN due to poor caloric intake.<sup>8</sup> The cohort of patients with omitted OEA that were noted to have grade C DGE did not have higher rates of prolonged nausea or vomiting, or higher rates of NGT reinsertion; rather, they had difficulty with caloric intake, requiring the initiation of TPN. This is supported by similar rates of NGT reinsertion across both groups.

What is notable, however, is the significant weight loss, manifested by change in BMI at 30 days (−9.6% vs. −5.4% change in BMI,  $p = 0.001$ ). Those patients that had OEA had decreased percentage of weight loss experienced in the first 30 days after surgery. However, by 90 days, there was no difference in BMI change (−8.2% vs −8.9%,  $p = 0.215$ ). This may be secondary to the OEA cohort receiving enteral feeds in the immediate post-operative period, leading to a decreased loss in BMI at 30 days postoperatively as compared to the non-OEA group. By 90 days, we suspect that the cohort without supplemental OEA feeds were able to consume adequate caloric intake comparably to the OEA cohort group.

These findings suggest a few things. In patients with OEA omitted at surgery, there are no differences in postoperative complications when it comes to critical complications such as organ/space infection, DGE and POPF. While there was no statistical difference between overall rates of DGE between the two groups, subset analysis suggests a higher rate of grade C DGE, attributable to poor oral intake or inability to obtain daily caloric requirements. From a clinical perspective, while readmission rates were no different, in the OEA omission group, patients were readmitted with failure to thrive requiring initiation of TPN; in patients

receiving OEA at the time of surgery, they did not have to be admitted for additional caloric support since they were sent with home enteral feeds.

Similar to the findings observed in this study, Waliye et al. published their retrospective study analyzing outcomes after routine OEA placement during PD and found that feeding tubes were associated with a statistically significant increased occurrence of DGE, extended LOS and longer duration to tolerating oral intake.<sup>2</sup> Meanwhile, Padussis et al. performed a retrospective study in 2012 utilizing the NSQIP database to examine complication rates of PD with OEA placement as compared to PD without OEA placement. They found that feeding tube placement was associated with overall increased morbidity, including deep SSI, acute renal failure and sepsis. Unfortunately, this study was limited as the NSQIP database did not include data on procedure-specific complications such as POPF and DGE.<sup>5</sup>

There are several limitations to our study. This was a retrospective study and the small sample size within this dataset prevents the broad generalization of these data to all patients undergoing PD, as our study is limited to a single center, with PD conducted by a single surgeon. Further, our study likely suffers from unintentional bias; for example, while patient demographics were similar across both groups, it was noted that a higher number of patients with preoperative ECOG 1 and 2 received OEA, while a greater number of patients with ECOG 0 did not receive OEA. Though this is neither statistically significant, nor a true selection bias as OEA was placed consecutively in our patient population, this suggests an inherent bias within our study towards placing OEA in patients who are less functionally “fit”. Given the limited study sample size, we were unable to perform propensity matching. However, in an effort to overcome the biases, we performed multivariate analyses, which demonstrated no additional independent associations between OEA and postoperative outcomes. We do suspect that if we were to examine a larger comparative cohort, the data would potentially provide more insightful conclusions with regards to postoperative complications. Additional future directions include a well-designed multicenter prospective randomized study in order to generate the power necessary to eliminate bias and determine significant conclusions. In this current scenario, however, we believe that the omission of OEA is associated with a trend towards shorter hospital length of stay without difference in morbidity and 30- or 90-readmission rates.

## Conclusions

OEA placement at the time of PD and the early introduction of nutritional supplementation is not necessarily associated with

improved postoperative morbidity and 30- or 90-day mortality. It appears that the use of OEA may be associated with longer hospital stay and possibly increased clinically relevant postoperative events, suggesting that OEA may not be necessary during PD and should be considered on a case by case basis.

## Conflicts of interest and source of funding

Dr. Kwon is a paid consultant for Ethicon, Inc.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.amjsurg.2018.11.024>.

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