Association of Gravity Drainage and Complications Following Whipple: An Analysis of the ACS-NSQIP Targeted Database

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Abstract

Background: The optimal type of operative drainage following pancreaticoduodenectomy (PD) remains unclear. Our objective is to investigate risk associated with closed drainage techniques (passive [gravity] vs. suction) after PD.

Methods: We assessed operative drainage techniques utilized in patients undergoing PD in the ACS-NSQIP Pancreas-Targeted database from 2016-2018. Using multivariable logistic regression to adjust for characteristics of the patient, procedure, and pancreas, we examined the association between use of gravity drainage and postoperative outcomes.

Results: We identified 9,665 patients with drains following PD from 2016-2018, of which 12.7% received gravity drainage. 61.0% had a diagnosis of adenocarcinoma or pancreatitis, 26.5% had a duct <3 mm, and 43.5% had a soft or intermediate gland. After multivariable adjustment, gravity drainage was associated with decreased rates of postoperative pancreatic fistula (odds ratio [OR] 0.804, 95% Confidence Interval [CI] 0.659-0.981, P= 0.031), delayed gastric emptying (OR 0.830, 95%CI 0.693-0.988, P= 0.036), superficial SSI (OR: 0.741, 95% CI: 0.572-0.959, P=0.023), organ space SSI (OR: 0.791, 95% CI: 0.658-0.951, P=0.012), and readmission (OR: 0.807, 95% CI: 0.679-0.958, P=0.014) following PD.

Conclusions: Gravity drainage is independently associated with decreased rates of CR-POPF, DGE, SSI, and readmission following PD. Additional prospective research will help determine which method is preferred.

Introduction

The approach to abdominal drainage after major abdominal surgery has evolved in recent decades. While many procedures employ selective drainage, drains are still commonly utilized after pancreatectomy.[1–6] Reasons commonly given for routine pancreatic drainage are early diagnosis of and management of pancreatic fistula, which is a potentially devastating complication.[7] Whether operative drains help prevent or manage complications remains debated. While some clinical trials addressing this question showed similar complications and mortality regardless of closed-suction drain usage, others were stopped early after showing increased mortality in patients without drains.[8–10] As a result, drain placement in pancreatectomy remains discretionary and subject to institutional and surgeon preference.

Regardless of the decision to utilize operative drains, the preferred method of closed drainage following pancreatectomy is poorly understood. Two of the most commonly utilized methods are suction and gravity drainage. The most commonly cited reason for using gravity drainage is avoiding suction near the pancreaticoenteric anastomosis, which may cause or contribute to the development of postoperative pancreatic fistula (POPF).[11–14] Supporting this argument are institutional series associating higher leak rates with prolonged suction drainage and decreased leak rates associated with gravity drainage.[12,13] In contrast, other authors have not demonstrated differences in POPF rates between closed-suction and

gravity drains in mixed cohorts of pancreatectomy.[15] However, the majority of these series have evaluated drain suction across small patient cohorts or diverse pancreatectomy procedures, rather than pancreaticoduodenectomy (PD) alone.

A better understanding of the relationship between drain suction and complications following PD is necessary to improve patient care. Therefore, in this study we sought to investigate the relationship between type of drainage and procedure-specific complications following PD. To do this, we used an international surgical registry to assess the relationship of drain suction and postoperative outcomes in a large cohort of PD patients.

Material And Methods

Ethics Approval and Consent to Participate

All data within this study was obtained from a registry comprised of de-identified information. As such, it was exempt from review by our University's Institional Review Board. Similarly, since no individual patient data was analyzed, individual patient consent was forgone.

Data Source

The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) is a clinical registry that collects pre-operative data and 30-day outcomes for patients undergoing surgical procedures from 713 hospitals around the world, of which 581 are located in the United States.[16] Details regarding data abstraction and validity have been reported elsewhere.[17] Beginning in 2014, the ACS-NSQIP offered procedure-targeted data collection for pancreatectomy procedures for select hospitals.[16] The procedure-targeted dataset includes 100% case capture for pancreatectomy procedures and additional preoperative, intraoperative, and postoperative variables. For this study we merged the pancreatectomy procedure-targeted dataset from 2016-18 with the contemporaneous ACS-NSQIP Participant User Data File.

Availability of Data and Materials

All data analyzed in this study originated from the ACS-NSQIP Participant User Data File. This data may be obtained by requresting the Participant User Data Files from the American College of Surgeons at https://www.facs.org/quality-programs/acs-nsqip.

Study Population and Variables

We identified all adults undergoing PD that also received operative drain placement from 2016-18 in ACS-NSQIP participating hospitals with pancreatectomy-targeted data collection using relevant Current Procedural Terminology (CPT) codes. We excluded patients undergoing emergency surgery, patients with open drainage systems or missing data regarding drainage.

Available patient characteristics included age, gender, race, American Society of Anesthesiologists (ASA) class, diabetes, and administration of neoadjuvant chemotherapy or radiation. Operative data included surgical approach (open vs. minimally-invasive), wound classification, prophylactic antibiotic usage, wound protector usage, operative duration, pancreatic duct diameter, gland texture, vascular reconstruction, type of pancreatico-enterostomy, red blood cell transfusion on postoperative day (POD) 0, and pancreatic pathology.

Postoperative outcomes

The primary outcome of this study was clinically relevant POPF (CR-POPF) in accordance with the updated International Study Group on Pancreatic Fistula (ISGPF) definition from 2016.[18] As ACS-NSQIP does not specifically code pancreatic fistula according to this definition, the variable CR-POPF was created using available registry data as previously described in the literature.[19] In brief, patients defined as having a "pancreatic fistula" or those with a drain amylase > 300 U/dL on or after POD 3 were considered to have a CR-POPF if they met any of the following criteria: (1) drain in place for > 14 days with prolonged hospital stay > 21 days; (2) postoperative percutaneous drain placed, or (3) presence of organ space surgical site infection (SSI), reoperation, sepsis, shock, or multisystem organ failure.[19]

Secondary outcomes of interest included delayed gastric emptying (DGE), percutaneous drain placement, reoperation, readmission, prolonged length of stay (LOS), mortality, and surgical site compilations including superficial, deep, or organ space SSI, sepsis and septic shock. Delayed gastric emptying was defined by NSQIP as no oral intake by POD 14, or nasogastric/gastric drainage or replacement after POD 7. Prolonged length of stay was defined as a LOS > 75th percentile. Mortality was defined as death within 30 days of surgery or prior to discharge. For all infectious outcomes, a complication was documented if it occurred within 30 days of the operation and was not documented as present on admission.

Statistical analysis

Student’s t-test, Chi-square, or Fisher’s exact tests were used as appropriate to evaluate univariable associations between primary and secondary outcomes and the type of operative drainage (suction vs. gravity). We then assessed the influence of drainage type on CR-POPF and secondary outcomes using multivariable logistic regression, adjusting for patient demographics, comorbidities and operative differences across groups. Patient and operative characteristics associated with CR-POPF and secondary outcomes were identified using stepwise logistic regression with backwards selection to ensure appropriate model fit. Candidate variables in the model included patient age, gender, race, smoking, diabetes, year of procedure, ASA classification ≤ 2, wound classification ≥ 3, neoadjuvant chemotherapy, neoadjuvant radiation, surgical approach, vascular reconstruction, pancreas reconstruction, surgical pathology, pancreatic gland texture, and pancreatic duct size, and POD 0 transfusion. For modeling purposes, minimally invasive procedures that converted to open were considered open surgery. For the final analysis and in accordance with previous literature evaluating pancreatic fistula risk,[19] surgical pathology was dichotomized as "adenocarcinoma or pancreatitis" or "other," and pancreatic gland texture was dichotomized as "hard" or "intermediate/soft."[20] As the estimated blood loss of the operation was

not available, associations with this variable were tested using the administration of a red blood cell transfusion on POD 0.

Variables from the stepwise regression model with coefficient p-values < 0.05 were then used in a second multivariable model including drainage type. In our model assessing drainage on CR-POPF, the variables duct size (< 3 mm, ≥ 3 mm, or unknown), firm gland texture, surgical pathology, and POD 0 transfusion were forced into the model regardless of significance. To account for missing data, particularly within variables above known to influence the risk of CR-POPF, we performed multiple sensitivity analyses. First, the analysis was performed only using observations with complete data for surgical pathology, gland texture, duct size, and POD 0 transfusion. Second, multiple imputation was used to account for the missing data within each variable. As the results of both analyses were qualitatively identical to the primary analysis, only the results of the primary analysis are presented here. Statistical analyses were performed using SAS v9.4 (SAS Institute Inc., Vary, NC, USA). For all statistical tests, P values are 2 tailed, and alpha is set at 0.05.

Results

A total of 9,665 PD patients received operative drainage between 2016 and 2018 at ACS-NSQIP targeted pancreatectomy participating hospitals. Demographic, operative, and pathologic characteristics, according to type of drainage, are shown in Table 1. Of 9,665 patients with operative drains, 1,224 (12.7%) had drains to gravity. Patients with closed-suction drains were more likely to have ASA classification 3 or 4 (78.1% vs. 74.3%, p = 0.002), received neoadjuvant chemotherapy (22.3%, vs. 18.4%, P = 0.002), and radiation (9.2% vs. 6.2%, P = 0.001), underwent more vascular resections (17.3% vs 13.8%, p = 0.003) and more frequently had duct-mucosa pancreaticojejunostomy reconstructions (89.1% vs 86.8%, p = 0.015).

Table 1
Patient characteristics and operative details

Variable	Suction (N = 8,441)		Gravity (N = 1,224)		P-value
	Number	Percent	Number	Percent	
Age (median, [IQR])	67 [59, 73]		67 [58, 73]		**0.048**
Female	3,891	46.1%	598	48.9%	0.070
Race					0.293
White	6,284	74.4%	894	73.0%	
Unknown/other	2,157	25.6%	330	27.0%	
Smoking					**0.048**
Yes	1,461	17.3%	184	15.0%	
No	6,980	82.7%	1,040	85.0%	
Diabetes					0.146
Yes	2,207	26.2%	344	28.1%	
No	6,234	73.8%	880	71.2%	
Operation year					**< 0.001**
2016	2,581	30.6%	498	40.7%	
2017	2,853	33.8%	378	30.9%	
2018	3,007	35.6%	348	28.4%	
ASA class					**0.002**
1 or 2	1,845	21.9%	315	25.7%	
3 or 4	6,596	78.1%	909	74.3%	
Wound class					**< 0.001**
1 or 2	6,802	80.6%	1038	84.8%	
3 or 4	1,639	19.4%	186	15.2%	
Neoadjuvant chemotherapy					**0.002**
Yes	1,884	22.3%	225	18.4%	

Variable	Suction (N = 8,441)		Gravity (N = 1,224)		P-value
	Number	Percent	Number	Percent	
No	6,557	77.7%	999	81.6%	
Neoadjuvant radiation therapy					**0.001**
Yes	777	9.2%	76	6.2%	
No	7,664	90.8%	1,148	93.8%	
Approach (combined categories)					**0.013**
Open	7,925	93.9%	1,171	95.7%	
Minimally invasive	516	6.1%	53	4.3%	
Pancreatic duct diameter					**< 0.001**
< 3 mm	2,254	26.7%	324	26.5%	
≥ 3 mm	4,697	55.6%	615	50.2%	
Unknown	1,490	17.7%	285	23.3%	
Pancreatic gland texture					**< 0.001**
Soft/intermediate	3,890	46.1%	533	43.5%	
Hard	2,797	33.1%	336	27.5%	
Unknown	1,754	20.8%	335	27.4%	
Pancreatic Pathology					0.264
Adenocarcinoma or Pancreatitis	5,010	59.4%	747	61.0%	
Other or Unknown	3,431	40.6%	477	39.0%	
Transfusion on POD0					**0.001**
Yes	1,169	13.8%	127	12.1%	
No	7,272	86.2%	1,097	83.9%	
Pathologic Detail					–
Pancreatic adenocarcinoma	4,614	55.4%	687	56.9%	
Ampullary carcinoma	683	8.2%	88	7.3%	
Duodenal carcinoma	255	3.1%	32	2.7%	

Variable	Suction (N = 8,441)		Gravity (N = 1,224)		P-value
	Number	Percent	Number	Percent	
Neuroendocrine	550	6.6%	88	7.3%	
IPMN-invasive	188	2.3%	17	1.4%	
Distal cholangiocarcinoma	273	3.3%	24	2.0%	
Malignant Other	419	5.0%	50	4.1%	
Chronic pancreatitis	288	3.5%	51	4.2%	
IPMN-noninvasive	534	6.4%	96	7.9%	
Mucinous cystic neoplasm	59	0.7%	5	0.4%	
Serous cystadenoma	78	0.9%	14	1.2%	
Solid pseudopapillary neoplasm	43	0.5%	7	0.6%	
Benign Other	342	4.1%	49	4.1%	
Pancreatic reconstruction					**0.015**
Pancreaticojejunal duct-to-mucosal	7,521	89.1%	1,062	86.8%	
Pancreaticojejunal invagination or pancreaticogastrostomy	920	10.9%	162	13.2%	
Vascular reconstruction (any)	1,457	17.3%	169	13.8%	**0.003**
T stage					–
T0/Tis	110	1.3%	8	0.7%	
T1	899	10.9%	125	10.4%	
T2	1,777	21.5%	272	22.7%	
T3	3,629	43.8%	502	41.8%	
T4	381	4.6%	47	3.9%	
Tx/Unknown	1,484	17.9%	246	20.5%	
N stage					–
N0	2,689	32.7%	369	31.0%	
N1	4,029	49.1%	573	48.2%	
Nx/Unknown	1,493	18.2%	248	20.8%	

Variable	Suction (N = 8,441)		Gravity (N = 1,224)		P-value
	Number	Percent	Number	Percent	
M stage					–
M0/Mx	5,381	70.2%	615	61.6%	
M1	145	1.9%	28	2.8%	
Unknown	2,136	27.9%	356	35.6%	

Results from the univariable analysis of postoperative drain management and outcomes are displayed in Table 2. SSIs were more frequent in the closed-suction drain group, particularly superficial SSI (7.3% vs 5.6%, P = 0.033) and organ space SSI (14.9% vs 12.4%, P = 0.022). Unplanned readmission (17.6% vs 14.1%, P = 0.008) and DGE (16.6% vs 14.0%, P = 0.019) were also more common in the closed-suction group. Length of stay was similar between groups. Notably, no significant differences in rates of CR-POPF, percutaneous drain placement, reoperation, sepsis or mortality were observed.

Table 2
Univariable associations between drain management and outcomes for the entire cohort

Outcome	Suction (N = 8,441)	Gravity (N = 1,224)	P-value
CR-POPF	1,053 (12.5%)	129 (10.5%)	0.053
Mortality	158 (1.9%)	14 (1.1%)	0.072
Surgical site infection (SSI)			
Superficial	617 (7.3%)	69 (5.6%)	**0.033**
Deep incisional	83 (1.0%)	7 (0.6%)	0.161
Organ-space	1,257 (14.9%)	152 (12.4%)	**0.022**
Any SSI	1,801 (21.3%)	210 (17.2%)	**0.001**
Sepsis	570 (6.7%)	72 (5.9%)	0.253
Reoperation	475 (5.6%)	54 (4.4%)	0.081
Unplanned readmission	1,486 (17.6%)	173 (14.1%)	**0.008**
Delayed gastric emptying	1,403 (16.6%)	171 (14.0%)	**0.019**
Percutaneous drain placement	1,047 (12.4%)	153 (12.5%)	0.924
Prolonged length of stay*	2,318 (27.8%)	313 (25.9%)	0.165
*Greater than or equal to 12 days			
(CR-POPF: Clinically Relevant Post-operative Pancreatic Fistula; SSI: Surgical Site Infection)			

Table 3 displays mutlivariable associations between patient, and disease characteristics and the primary outcome, CR-POPF, in the final logistic regression model. After adjusting for relevant patient and treatment characteristics, including surgical pathology, pancreatic gland texture and duct size, and transfusion on POD0, use of closed-suction drainage systems is independently associated with risk of CR-POPF (adjusted Odds Ratio 1.24, 95% Confidence Interval 1.020–1.518, P = 0.031). Other characteristics significantly associated with risk of CR-POPF in the model include small pancreatic duct size, soft pancreatic gland texture, surgical pathology other than PDAC or pancreatitis, white race, Diabetes, neoadjuvant chemotherapy and radiation, minimally invasive surgery, pancreatic reconstruction other than duct-mucosa pancreaticojejunostomy, and BMI.

Table 3
Multivariable Associations between drain management and CR-POPF

Variable	AOR	95% CI		P-value
		Lower	Upper	
Closed-Suction Drainage	1.244	1.020	1.518	**0.031**
Pancreatic Duct Size				
> 3 mm	Ref	Ref	Ref	Ref
< 3 mm	1.370	1.118	1.678	**0.0024**
Unknown	1.431	1.238	1.653	**< .0001**
Pancreatic Gland Texture				
Hard	Ref	Ref	Ref	Ref
Soft/Intermediate	1.919	1.517	2.429	**< .0001**
Unknown	2.806	2.323	3.390	**< .0001**
Pathology Other than PDAC or Pancreatitis	1.579	1.379	1.809	**< .0001**
POD 0 Transfusion	1.087	0.896	1.317	0.3969
Female	0.660	0.580	0.751	**< .0001**
White Race	1.188	1.033	1.368	**0.0159**
Diabetes	0.762	0.653	0.889	**0.0005**
Neoadjuvant Chemotherapy	0.689	0.551	0.862	**0.0011**
Neoadjuvant Radiation	0.641	0.443	0.930	**0.0190**
Minimally Invasive Surgery	0.739	0.556	0.984	**0.0383**
Pancreatic Reconstruction other than Duct to Mucosa Pancreaticojejunostomy	1.255	1.044	1.508	**0.0155**
BMI	1.035	1.024	1.045	**< .0001**
(CR-POPF: Clinically Relevant Post-operative Pancreatic Fistula; PDAC: Pancreatic Ductal Adenocarcinoma; POD: Post-operative Day)				

The adjusted rates of postoperative outcomes for suction and gravity drainage are displayed in Fig. 1, while the corresponding odds ratios for gravity drainage are shown in Table 4. After adjusting for patient and operative risk factors, the rates of CR-POPF (7.9% vs 6.4%, P = 0.031), delayed gastric emptying (16.1% vs 13.7%, P = 0.036), any SSI (22.4% vs 17.7%, P < 0.001), superficial SSI (9.1% vs 6.9%, P = 0.023), organ space SSI (14.2 vs 11.8, P = 0.012), and readmission (20.8% vs 17.4%, P = 0.014) were lower in the gravity drainage group as compared to the closed-suction group. No adverse outcomes were more

common in the gravity cohort. The odds of experiencing CR-POPF were statistically significantly lower in patients receiving gravity drainage (Adjusted Odds Ratio [AOR] 0.804, 95% confidence interval [CI]: 0.659–0.981), as were the odds of DGE (AOR: 0.830, 95% CI: 0.693–0.988), any SSI (AOR: 0.741, 95% CI: 0.631–0.870), superficial SSI (AR: 0.741, 95% CI: 0.572–0.959), organ space SSI (AR: 0.791, 95% CI: 0.658–0.951), and readmission (AOR: 0.807, 95% CI: 0.679–0.958).

Table 4
Adjusted odds ratios (AOR) for gravity drainage and outcomes

Outcome	AOR	95% CI		P-value
		Lower	Upper	
CR-POPF	0.804	0.659	0.981	**0.031**
Biochemical Leak	0.919	0.693	1.219	0.556
Delayed gastric emptying	0.830	0.693	0.988	**0.036**
Percutaneous drain placement	1.024	0.851	1.233	0.800
Any surgical site infection (SSI)	0.741	0.631	0.870	**< 0.001**
Superficial SSI	0.741	0.572	0.959	**0.023**
Organ-space SSI	0.791	0.658	0.951	**0.012**
Sepsis	0.956	0.664	1.105	0.233
Reoperation	0.794	0.594	1.062	0.120
Readmission	0.807	0.679	0.958	**0.014**
Mortality	0.640	0.368	1.112	0.113
(CR-POPF: Clinically Relevant Post-operative Pancreatic Fistula; SSI: Surgical Site Infection)				

Discussion

This analysis of the ACS-NSQIP Procedure-Targeted database demonstrates that among patients with operative drain placement after PD, closed suction drainage is independently associated with higher rates of CR-POPF (7.9 vs. 6.4%), DGE (16.1 vs. 13.7%), SSI (22.4% vs. 17.7%) and readmission (20.8% vs. 17.4%). Given the sparse literature on this subject and the mechanistic plausibility of the association, the results of this study raise important questions about the type of operative drainage utilized following PD and warrant further investigation.

Few studies have been published comparing gravity and closed-suction drainage in pancreas surgery, and much of the literature to date suffers from substantial limitations. In the single-institution retrospective study by Schmidt and colleagues, gravity drainage was associated with lower rates of POPF (14% vs. 3%), but also correlated with higher volume surgeons, raising concerns about gravity drainage

acting as a surrogate for procedure volume.[13] Though multiple authors have recently published results suggesting no differences in outcomes between drainage methods following pancreatectomy,[15, 21] neither study differentiated between types of pancreatectomy operations. As numerous reports have revealed substantial differences in drain usage and POPF rates between PD and distal pancreatectomy, this suggests that PD and distal pancreatectomy should be studied as two distinct operations.[9, 10] Previous randomized trials evaluating drainage type were limited by small sample size or showed rates of CR-POPF higher than those typically seen in US hospitals,[21] while previous registry studies have used the ACS-NSQIP definition of CR-POPF, which is recognized to have significant limitations.[15, 19] Our study addresses the limitations of prior work by using a large, validated, international surgical registry of pancreas surgery to increase sample size, studies a selected population of PD procedures only, and utilizes a rigorous definition of CR-POPF.[20] In contrast to recent research, the results herein suggest a consistent small but significant association between closed-suction drainage and higher rates of multiple complications following PD.

In pancreas surgery, much of the literature evaluating operative drainage is focused on addressing whether drains are necessary at all, and results remain conflicted. In one of the earliest trials addressing this issue, Conlon et al found no differences in overall morbidity or mortality in patients undergoing PD or distal pancreatectomy regardless of drain usage. In that study, POPF rates were higher in the drained group, suggesting either a detection bias or promotion of fistula formation in drained patients.[8] These results were later supported by findings from Witzigmann and colleagues in the pancreatic drainage (PANDRA) trial, but contradicted by Van Buren et al, who found higher mortality rates in PD patients without operative drains.[9, 22, 23] However, these studies had multiple inherent limitations. Similar to above, considering that the risk associated with operative drainage is procedure-dependent, the inclusion of all partial pancreatectomy patients by Conlon and colleagues may have influenced results.[8–10] The PANDRA trial also suffered from protocol violations and randomization issues.[22] In the later study, the definition of POPF differed from that set forth by the ISGPS and operative drains were used in approximately 15% of cases performed by surgeons who were classified as routinely omitting drains.[20, 23] Given the lack of consensus in the literature, and the potential for severe morbidity from an uncontrolled pancreatic leak, operative drains are placed in the majority of pancreatectomy cases.[7]

Considering that operative drains remain heavily utilized, recent literature has focused on selecting patients for drain omission or identifying patients in whom drains can be safely removed early.[20, 24, 25] Several risk scores are available to stratify patients according to risk of CR-POPF, and many surgeons use these scores to select patients for drain omission.[20, 24, 25] Similarly, several postoperative drain management algorithms employing drain amylase levels are routinely used to identify patients in whom drains can be safely removed.[26, 27] However, neither the fistula risk calculations nor drain management algorithms published to date account for drainage type. Our study shows an association between gravity drainage and decreased CR-POPF after PD. These results suggest that the type of drainage should be considered in the management of PD patients with operative drains.

This study has several limitations. First, the ACS-NSQIP Procedure-Targeted database likely lacks variables that may further influence CR-POPF rates after PD, and as with any clinical registry there is residual confounding in these assessments. For example, while it is possible that many individual surgeons do not alternate use of suction and gravity drainage and the type of drainage employed is correlated with individual surgeons, surgeon specific data is not available for analysis. However, the ACS-NSQIP Procedure-Targeted database is currently the largest and most reliable contemporaneous clinical registry available to answer this research question, and the multivariable models used herein included patient, pancreas and procedure-specific variables (components of the FRS) widely accepted to influence risk of POPF. In addition, these results must be interpreted in the context of patient selection and institutional culture, which is known to influence outcomes following PD. A second and similar limitation of this study is that results may not be generalizable to institutions not participating in ACS-NSQIP. However, the institutional cohort of NSQIP is diverse, and includes a broad range of hospitals: critical access, community, and tertiary academic referral centers, urban and rural, for-profit and not-for-profit. Finally, this is a retrospective analysis and causation cannot be inferred from our results. While the associations reported herein should only be considered hypothesis generating, the consistency of the associations and the biologic plausibility of the mechanism warrant further investigation.

This is one of the largest studies to date addressing the question of preferred type of operative drainage following PD. Closed-suction drainage was consistently associated with higher rates of multiple pancreatectomy-specific complications. Additional prospective and (ideally) randomized research is needed to address this question both for PD patients and those undergoing distal pancreatectomy. In the context of disparate results from clinical trial data, these results challenge the prevailing practice of closed-suction drainage. If closed-suction drainage is found to contribute to formation of POPF, the results could have important implications for operations beyond PD that involve delicate or technically difficult anastomoses.

Declarations

Ethics Approval and Consent to participate: This study was ruled exempt by the IRB and utilizes deidentified data from an international multiinstitutional dataset. No individual consent for participation is required, as no individual data is included, and no human subjects were involved in the conduct of this study.

Consent for publication: This study uses an international multi-institutional deidentified dataset, so no additional consent for publication is required, as no human subjects were involved in the conduct of this study.

Availability of data and materials: This registry database is available to all participating members of the ACS NSQIP collaborative, and can be requested here: https://www.facs.org/quality-programs/acs-nsqip.

Competing Interests: All authors have no conflicts of interest, financial or otherwise, to disclose.

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Author Contributions: BNR was responsible for the initial concept of this study. VKS was responsible for the statistical analysis. CA, JCP, RWK, and BNR provided content expertise. BRH and ZHE drafted the manuscript with the assistance of BNR. All authors read, edited, and approved of the manuscript prior to submission, and are accountable for the accuracy and integrity of the work.

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Figures

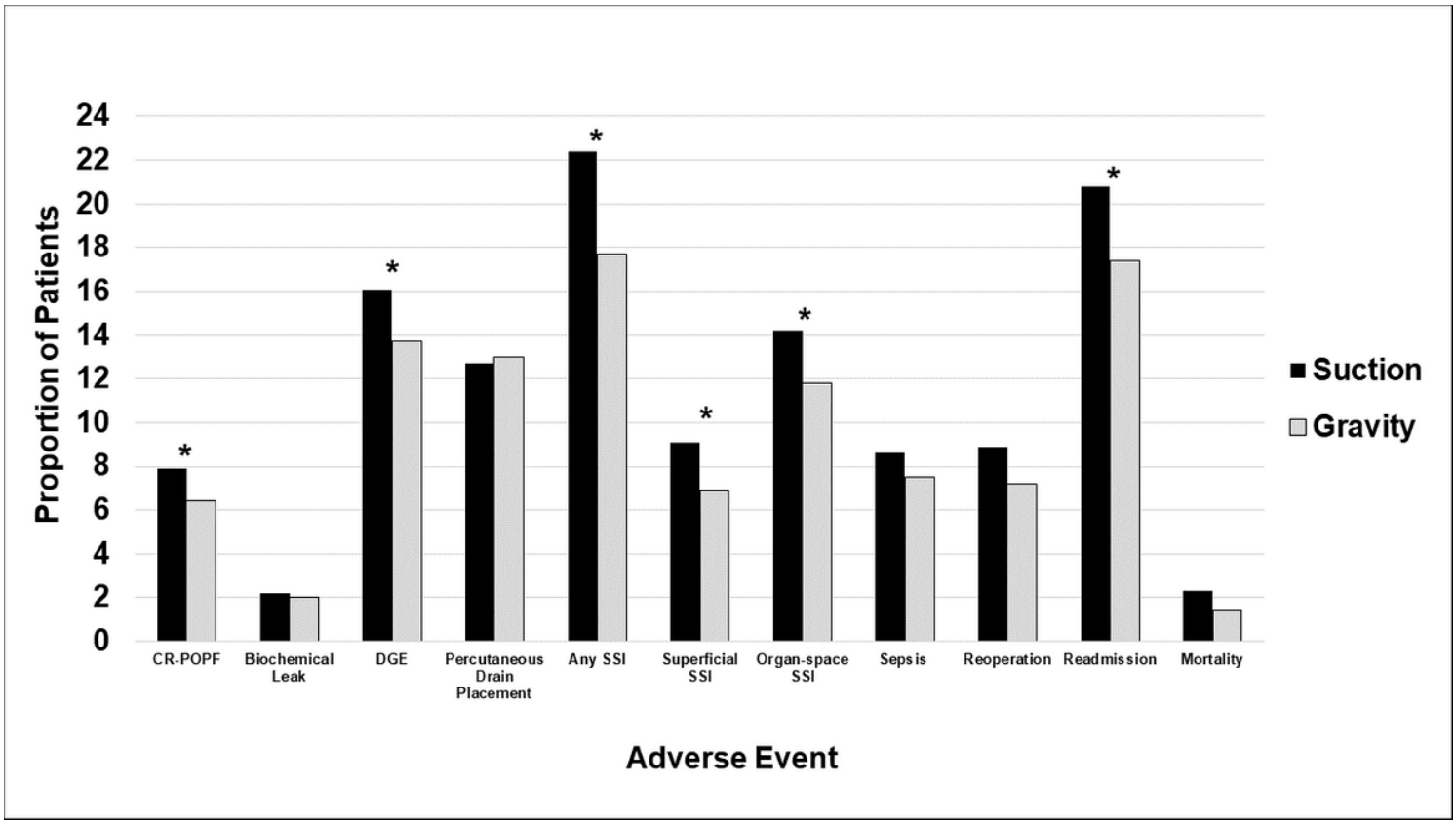

Figure 1

Adjusted rates of postoperative outcomes following pancreaticoduodenectomy. (Significant differences with P-values <0.05 are indicated with an asterisk; CR-POPF: Clinically Relevant Post-operative Pancreatic Fistula; DGE: Delayed Gastric Emptying; SSI: Surgical Site Infection).