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Prophylactic abdominal drain- Assessing the timing for avoidance based on fistula risk score in pancreaticoduodenectomy

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Abstract

Background: Pancreaticoduodenectomy is technically challenging surgery with high complications rate, often requiring surgical drains for potential complication management. However, the necessity and effectiveness of routine drainage remain debated.

Objectives: To evaluate the utility of the fistula risk score in guiding abdominal cavity drain placement decisions for pancreaticoduodenectomy patients.

Methods: A single-centered, descriptive study was conducted during 1st February 2022 to 31st January 2023 among 33 patients undergoing pancreaticoduodenectomy. Intraoperative decision-making regarding drain placement was guided by fistula risk scores. We closely monitored clinical outcomes, duration of hospital and intensive care unit stays, and other postoperative complications including clinically relevant post operative pancreatic fistula.

Results: Drain placement was avoided in seven (21.2%) patients with negligible or low fistula risk score, and only one (3.0%) patient required subsequent intervention. Biochemical leaks and clinically relevant postoperative pancreatic fistulas occurred in five (15.1%) and three (9.1%) respectively. No significant difference was observed in hospital and intensive care unit stay between drain and no drain group.

Conclusion: Abdominal drainage after pancreaticoduodenectomy should be tailored to individual risk profiles. Routine drainage may not be necessary for low-risk patients but effectively manages complications when required.

Key words: Drainage; Pancreatic fistula; Pancreaticoduodenectomy.

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INTRODUCTION

Pancreaticoduodenectomy (PD) is a technically challenging surgery with mortality rates reaching 5%.[1,2] Surgical drains are considered mandatory after pancreatic surgery, as they help manage leakage, hemorrhage, and prevent post-operative intra-abdominal collection.[3-5] Early detection and routine drainage of pancreatic fistulas and other fluid collections post-pancreatic surgery are crucial for reducing complications.[6] Intra-abdominal drains aid in early detection of post-surgical leaks and bleeding and removal of these collection.[7]

However, drains are a recognized risk for infections due to their role as foreign bodies, bacterial facilitators, and potential to convert non-infected sites into infectious

and can erode anastomoses causing intestinal leaks.[8,9] Clinical assessment and imaging are effective ways to detect postoperative complications, regardless of whether routine drainage is utilized.[10-12] Recent advances allow safer post-operative drain placement without routine intraperitoneal drainage.[13]

This study aims to evaluate the utility of the fistula risk score in guiding abdominal cavity drain placement decisions for PD patients.

METHODOLOGY

This study is a single-centered, descriptive cross-sectional study conducted in department of general and GI surgery, Kathmandu Medical College Teaching Hospital from 1st February 2022 to 30st January 2023. The ethical approval was taken from the institutional review committee of Kathmandu Medical College Teaching Hospital (Ref.: 1001202202). All patients undergoing PD, during the study period were enrolled in the study. The study population included all patients fulfilling the selection criteria, which included patients undergoing PD who were more than 18 years of age and consented to the study. The exclusion criteria included patients who had undergone previous pancreatic surgery and non-consenting to the study. We did a sample size calculation using our previous year's data for calculating prevalence.

Using the Cochrane Formula for sample size determination (n) = (Z2*p*q)/e2. Here, Z = 1.65 (taking 90% confidence interval); p = 0.5 (proportion of patients with drain placement after PD, taken 0.5 for maximum sample size); q = 1 – p = 0.5; e = 0.1 (margin of error 10%). Thus, sample size = 69. Now calculating the minimum adjusted sample size for finite population (N=40, we had only 44 patients undergoing PD during the study period among which drain was placed in only 40 patients), n= n/(1+ (n/N) = 26.86 (~27). The calculated sample size was 27. However, we included all 33 patients undergoing PD during the study period.

Fistula risk score (FRS) was calculated preoperatively in all the patient, which includes four variables - Gland texture, pathology (site of tumor), pancreatic duct diameter, and intraoperative blood loss and individual points is given to each variable with a minimum of zero and a maximum of 10 points proposed by M Callery et al.[14] and evaluated as 4 ranges of score (negligible risk 0 points; low risk, 1 to 2; intermediate risk, 3 to 6; high risk ,7 to 10).

Post-operative pancreatic fistula (POPF) was described as "any measurable volume of drain fluid on or after postoperative day 3 with amylase level >3 times the upper limit of normal serum amylase" according to International Study Group of Pancreatic Surgery (ISGPS) 2016 update.[15] Post pancreatectomy acute pancreatitis (PPAP) was described as "acute inflammatory condition of the pancreatic remnant beginning within the first 3 postoperative days after a partial pancreatic resection with sustained elevated serum amylase for ≥48 h postoperatively, radiological findings consistent with acute pancreatitis, and associated clinically relevant features" according to ISGPS 2016 update. Pancreatic resection was done using bipolar cautery device and cut surface margin was checked with use of Indocyanine green (ICG) for vascularity. The pancreatoenteric anastomosis was done using polydioxanone 5-0 sutures using the Blumgart technique and the decision on whether to place a drain or not was taken intraoperatively.

Informed written consent was obtained from all patients for the utilization of their data for research purposes. Only experienced consultant Hepato-pancreato-biliary (HPB) surgeons who have done more than 50 PD were performing the surgery. Decision on whether to place the drain or not was taken intraoperatively based on FRS score (If FRS ≤4, drain was omitted, and if FRS ≥5 drain was placed). Ultrasonography was done on regularly during hospital stay to rule out any pockets of collection and for early intervention if required. The patient's demographic profile, intraoperative blood loss, texture of the pancreas, and size of the pancreatic duct was noted. Use of abdominal drain or not, any post-operative intervention required (like pigtail drain insertion), the incidence of clinically relevant delayed gastric emptying (CR-DGE) graded as B and C by ISGPS which is defined as nasogastric tube required >7 days, reinserted after post-operative day 7, or unable to tolerate solid diet by 14th post-operative day. Clinically relevant postoperative pancreatic fistula (CR-POPF) as defined as grade B and C by the ISGPS, the complication of Clavien–Dindo Grade III or higher, any re-intervention required were noted. Pre-operative albumin levels and body mass index (BMI) are not considered but are recognized as potential confounding factors with increased risk of CR-POPF in patients with high BMI and low albumin. The primary outcome of this study is to determine the need for a drain post-surgery in patients with a low FRS and secondary outcomes include determination of post-operative complications including length of intensive care unit (ICU) and hospital stay, CR-DGE between low and high FRS patients. To reduce potential bias, pre-operative computed tomography (CT) scans was done in all patients for evaluation of anatomy of pancreas,

duct size and same surgical technique was applied in all patients. Days of ICU stay, days of hospital stay, and histopathological report were also recorded in self-structured questionnaire (proforma) during the hospital stay or during follow-up of patients. Continuous data were presented as mean, proportion and percentage of categorical data were analyzed with statistical package for social science (SPSS) 26 version.

RESULTS

In one-year period from 1st February 2022 to 30st January 2023, total 33 patients were included in study. Demographic information of the patients is presented in table 1.

The mean blood loss was 500 ml (300-800 ml), however record regarding blood loss was not satisfactorily recorded in most of the patients. Pancreatic texture was firm in 24 (72.7%) patients and soft in 9 (27.3%). The mean pancreatic duct diameter was 5 mm (3-8 mm). Intra-peritoneal drain was placed after surgery in 26 (78.8%) patients and was avoided in 7 (21.2%) patients (Table 2).

The patient's fistula risk score was negligible in 4 (12.1%) patients, low in 16 (48.5%) and moderate in 13 (39.4%) patients with no having high risk. The median FRS was 3 for patients with drain and 2 for without drain (Table 3).

The median drain amylase in patients at POD 3 and POD 5 were 1955 U/L (163-3675 U/L) and 495 U/L (142-2640 U/L). The histopathological reports showed that 16 (48.5%) patients had carcinoma head of the pancreas, 10 (30.3 %) had distal cholangiocarcinoma, 6 (18.2%) had ampullary tumor and 1 (3%) had duodenal carcinoma (Table 4).

The median ICU stay was 3 days (2-5 days), mean hospital stay was 8 days (5-16 days), re-intervention (intra peritoneal pigtail catheter drainage) was required in 1 patient in whom drain was not placed initially. Biochemical leak was noted in 5 (15.1%) patients and Cr-

POPF was seen in 3 (9.1%). Cr-DGE was noted in 8 (24.25%) cases. Four patients required readmission, two for surgical site infection (SSI) and two for post-operative intraperitoneal bleeding and GI bleeding. There was mortality in two of these readmitted patients because of pseudo-aneurysm bleed; patients underwent angiographic intervention (coiling of GDA pseudoaneurysm) but both could not be saved (Table 5).

Table 1: Demographic profile of the patients

Variables	n (%)
Age	
Mean ± SD: 58.38 ± 15.73 years	
Range: 34-84 years	
Sex	
Male	20 (60.6%)
Female	13 (39.4%)
ECOG performance status	
ECOG 0-1	25 (75.8%)
ECOG >1	8 (24.2%)

Table 2: Intra-operative findings

Parameters	n (%)
Pancreatic texture	
Soft	9 (27.3)
Firm	24 (72.7)
Pathology	
Pancreatic adenocarcinoma	16 (48.5)
Ampullary, duodenal, cystic, islet cell	17 (51.5)
Duct size (in mm)	
≥5 mm	13 (39.4)
4 mm	10 (30.3)
3 mm	9 (27.3)
2 mm	1 (3)
Estimated blood loss (in ml)	
<= 400 ml	9 (27.3)
401-700 ml	19 (57.6)
701-1000 ml	4 (12.1)
>1000 ml	1 (3)
Drain avoided	7 (21.2)
Drain placed	26 (78.8)

Table 3: Fistula risk score

Risk score	n (%)
Negligible	4 (12.1)
Low	16 (48.5)
Moderate	13 (39.4)

Table 4: Histo-Pathology Report

Site of Carcinoma	n (%)
Carcinoma Head of pancreas	16 (48.5)
Distal cholangiocarcinoma	10 (30.3)
Ampullary carcinoma	6 (18.2)
Duodenal carcinoma	1 (3)

Table 5: Post-operative parameters

Parameters	Value	Remark
ICU stay	3 (2-5 days)	
Total hospital stay	8 (5-16 days)	
Timing of drain removal	10 (7-20 days)	
Biochemical leak	5 (15.1%)	
CR-POPF	3 (9.1%)	
CR-DGE	8 (24.25%)	
Clavien–Dindo Grade III or higher	3 (9%)	
Requirement of re-intervention	1 (3)	Pigtail drain placed for intraperitoneal collection
Readmission	5 (15.1)	Two for SSI, one for intra-abdominal collection and two for post-operative hemorrhage
Mortality	2 (6)	Pseudoaneurysm bleeding

DISCUSSION

In our study, we adopted a strategy of not placing drains in 7 out of 33 patients who underwent PD. Among these patients, only 1(14% of the no-drain group) required a subsequent intervention, in which a pigtail drain was inserted to manage an intraperitoneal collection. The decision to place drains was made during the surgery, and patients with a low-FRS were considered for the no-drain group. Biochemical leakage occurred in 15% of the patients, and 9% developed CR-POPF, all of which were managed conservatively by maintaining the existing drain.

Despite advancements in surgical techniques and surgeon expertise, postoperative pancreatic fistula (POPF) continues to be a significant source of postoperative complications and even mortality. To assess the risk of POPF in patients undergoing PD, surgeons worldwide employ the Fistula Risk Score. In our hospital, we have been utilizing the FRS for risk assessment in patients, allowing us to make informed decisions about omitting drain placement in cases where the risk of POPF is negligible or low.

The rationale behind placing an intraperitoneal drain after pancreatic resections is to allow for early detection of complications like pancreatic fistulae or biliary leaks and to facilitate the drainage of the postoperative fluid collections.[16] But, in an RCT by Conlon KC et al., complications were significantly higher in the drain group (including POPF, intra-abdominal collection, and abscess) compared to the no-drain group, while hospital stay length, mortality, and wound-related issues were similar in both groups, suggesting no advantage of prophylactic drain placement after pancreaticoduodenectomy.[17]

Clinically relevant fistulae following PD are associated with risk factors such as soft pancreatic parenchyma, pancreatic duct diameter of 3 mm or less, presence of ampullary, duodenal, cystic, or islet cell pathology, and intraoperative blood loss exceeding 1,000 ml.[18] Therefore, in our study, we assigned patients with larger pancreatic duct sizes (>5mm), firm pancreas, lower blood loss (<400 ml), to the no-drain group, while the drain was retained in patients with opposite findings.

Sergio Pedrazzoli's extensive systematic review, spanning 25 years and encompassing data from 60,739 patients, revealed a wide range of findings. The reported incidence of CR-POPF ranged from as low as 1% to as high as 36%, while the incidence of the more severe grade C POPF varied from less than 1% to over 9%.[19] These findings are similar to our study findings of approximately 9% CR-POPF, however, we did not note any grade C POPF during our study. We adopted a practice of internal stenting for all cases during the pancreatojejunostomy procedure. Our study revealed that the duration of ICU and hospital stays did not exhibit any significant differences between the drain and no-drain groups.

Our study, despite its limited sample size, underscores the potential utility of FRS in guiding the omission of drains following PD for patients with negligible or low FRS risk, in line with findings from other studies.[20] However, our study has several limitations, including its single-center setting, the absence of a robust comparison group, and potential selection bias due to the exclusive inclusion of patients with negligible or low FRS in the no-drain group.

We recommend that subsequent research in this domain should be performed to explore the precise guidelines for drain necessity, the selection of drainage method,

and the ideal timing for their extraction. Furthermore, conducting extensive multi-center studies will be instrumental in providing a holistic comprehension of how abdominal drainage affects postoperative results.

CONCLUSION

The use of abdominal drainage following PD should be customized based on each patient's individual risk profile. Routine drainage may not be required for low-risk patients and might not prevent complications but rather aid in their efficient management when necessary. Abdominal drainage can often prove effective in handling complications like biochemical leaks and CR-POPF. Whenever required postoperatively drain can be place with the help of intervention radiologist.

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REFERENCES

1. Romano G, Agrusa A, Galia M, et al. Whipple's pancreaticoduodenectomy: Surgical technique and perioperative clinical outcomes in a single center. Int J Surg. 2015; 21: S68–71. [PubMed | Full Text | DOI]
2. Büchler MW, Wagner M, Schmied BM, Uhl W, Friess H, Z'graggen K. Changes in morbidity after pancreatic resection: toward the end of completion pancreatectomy. Arch Surg. 2003; 138(12):1310–4; discussion 1315. [PubMed | Full Text | DOI]
3. Shrikhande S V, Barreto SG, Shetty G, et al. Post-operative abdominal drainage following major upper gastrointestinal surgery: single drain versus two drains. J Cancer Res Ther. 2013; 9(2):267–71. [PubMed | Full Text | DOI]
4. Kyoden Y, Imamura H, Sano K, et al. Value of prophylactic abdominal drainage in 1269 consecutive cases of elective liver resection. J Hepatobiliary Pancreat Sci. 2010; 17(2):186–92. [PubMed | Full Text | DOI]
5. Iwata N, Kodera Y, Eguchi T, et al. Amylase concentration of the drainage fluid as a risk factor for intra-abdominal abscess following gastrectomy for gastric cancer. World J Surg. 2010; 34(7):1534–9. [PubMed | Full Text | DOI]
6. Wang Q, Jiang Y-J, Li J, et al. Is routine drainage necessary after pancreaticoduodenectomy? World J Gastroenterol. 2014; 20(25):8110–8. [PubMed | Full Text | DOI]
7. Reid-Lombardo KM, Farnell MB, Crippa S, et al. Pancreatic anastomotic leakage after pancreaticoduodenectomy in 1,507 patients: a report from the Pancreatic Anastomotic Leak Study Group. J GastrointestSurg Off J SocSurg Aliment Tract. 2007; 11(11):1451–8; discussion 1459. [PubMed | Full Text | DOI]
8. Puleo FJ, Mishra N, Hall JF. Use of intra-abdominal drains. Clin Colon Rectal Surg. 2013; 26(3):174–7. [PubMed | Full Text | DOI]
9. Fisher WE, Hodges SE, Silberfein EJ, et al. Pancreatic resection without routine intraperitoneal drainage. HPB Off J IntHepatoPancreato Biliary Assoc. 2011; 13(7):503–10. [PubMed | Full Text | DOI]
10. Liu HP, Zhang YC, Zhang YL, Yin LN, Wang J. Drain versus no-drain after gastrectomy for patients with advanced gastric cancer: Systematic review and meta-analysis. Dig Surg. 2011; 28(3):178–89. [PubMed | Full Text | DOI]
11. Albanopoulos K, Alevizos L, Linardoutsos D, et al. Routine abdominal drains after laparoscopic sleeve gastrectomy: a retrospective review of 353 patients. Obes Surg. 2011; 21(6):687–91. [PubMed | Full Text | DOI]
12. Shimoike N, Akagawa S, Yagi D, et al. Laparoscopic gastrectomy with and without prophylactic drains in gastric cancer: a propensity score-matched analysis. World J SurgOncol. 2019; 17(1):144. [PubMed | Full Text | DOI]
13. Cinat ME, Wilson SE, Din AM. Determinants for successful percutaneous image-guided drainage of intra-abdominal abscess. Arch Surg. 2002; 137(7):845–9. [PubMed | Full Text | DOI]
14. Callery MP, Pratt WB, Kent TS, Chaikof EL, Vollmer CM Jr. A prospectively validated clinical risk score accurately predicts pancreatic fistula after pancreatoduodenectomy. J Am Coll Surg. 2013; 216:1–14. [PubMed| Full Text | DOI]
15. Bassi C, Marchegiani G, Dervenis C, et al. International Study Group on Pancreatic Surgery (ISGPS) The 2016 update of the International Study Group (ISGPS) definition and grading of postoperative pancreatic fistula: 11 Years After. Surgery. 2017;161:584–591. [PubMed | Full Text | DOI]

16. Zaghal A, Tamim H, Habib S, et al. Drain or No Drain Following Pancreaticoduodenectomy: The Unsolved Dilemma. Scand J Surg. 2019; 109(3):228–37. [PubMed | Full Text | DOI]
17. Conlon KC, Labow D, Leung D, et al. Prospective randomized clinical trial of the value of intraperitoneal drainage after pancreatic resection. Ann Surg. 2001; 234(4):484–7. [PubMed | Full Text | DOI]
18. Pratt WB, Callery MP, Vollmer CMJ. Risk prediction for development of pancreatic fistula using the ISGPF classification scheme. World J Surg. 2008; 32(3):419–28. [PubMed | Full Text | DOI]
19. Pedrazzoli S. Pancreatoduodenectomy (PD) and postoperative pancreatic fistula (POPF): A systematic review and analysis of the POPF-related mortality rate in 60,739 patients retrieved from the English literature published between 1990 and 2015. Medicine (Baltimore). 2017; 96(19):e6858. [PubMed | Full Text | DOI]
20. Seykora TF, Maggino L, Malleo G, et al. Evolving the Paradigm of early drain removal following Pancreatoduodenectomy. J GastrointestSurg Off J SocSurg Aliment Tract. 2019; 23(1):135–44. [PubMed | Full Text | DOI]