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Routine prophylactic abdominal drainage versus no-drain strategy after distal pancreatectomy: A multicenter propensity score matched analysis

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A B S T R A C T

Background: /Objectives Postoperative pancreatic fistula (POPF) remains the most common complication after distal pancreatectomy (DP). Traditionally, surgical drains are placed routinely after DP, but some question its efficacy and postulate that the use of drains may convert a self-limiting postoperative collection into a POPF. This study aimed to compare outcomes between three institutions with varying drainage strategies.
Methods: The study is a retrospective propensity score-matched analysis of intraoperative prophylactic drain placement during DP (2010–2019). The primary outcome is major morbidity. Propensity score matching was used to obtain comparable groups.
Results: Overall, 963 patients after DP were included. One center did not place a surgical drain routinely, but decided to place a drain when unsatisfactory pancreatic closure occurred. Prophylactic abdominal drains were placed in 805 patients (84%) of which 74 could be matched to 74 patients without a drain. The rate of major morbidity (8% vs 19%, $p = 0.054$) and radiological interventions (5% vs 12%, $p = 0.147$) were non-significantly lower in the no-drain group as compared to the prophylactic drain group, respectively. The rates of POPF (4% vs 16%, $p = 0.014$) were lower in the no-drain group.
Conclusion: In this international retrospective multicenter study, a selective no-drain strategy after DP was not associated with higher rates major morbidity or radiological interventions as compared to routine prophylactic abdominal drainage. Although the rate of POPF was lower in the no-drain group, randomized trials should confirm the safety and outcome of a no-drain strategy after DP.

1. Introduction

Morbidity after distal pancreatectomy (DP) may reach up to 50% even in high-volume centers [1,2]. Postoperative pancreatic fistula (POPF) remains the most common complication after DP [3]. Traditionally, surgeons have left one or two prophylactic abdominal drains after DP, but this has become a topic of debate in recent years [4]. Some have suggested that routine drain placement after DP might even facilitate the development of a POPF or introduce bacteria in the initially sterile peripancreatic fluid. The omission of the prophylactic drainage would theoretically lead to fewer POPF, less infected collections, and even less post pancreatectomy hemorrhage (PPH) [5]. For patients at high risk of POPF, there might be an indication for drainage, however, the risk of developing POPF

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after DP has proven difficult to predict [6].

Evidence from randomized trials on omitting routine prophylactic abdominal drainage in pancreatic surgery is scarce. A recent systematic review identified a single randomized multicenter trial focused on prophylactic drainage after 344 DP, one propensity-score matched study and three retrospective studies [7]. The randomized trial did not stratify for high or low POPF risk, had different type of patients, indications, surgical techniques and perioperative management but found no differences between patients with and without routine prophylactic drainage [8]. The propensity-score matched study included data from 43 centers in the United States which placed no drain in 155 of 761 patients on indication and also used varying surgical techniques [9].

In preparation for the currently ongoing Dutch-Italian randomized PANDORINA trial [10], we performed the present multicenter retrospective study aimed to compare outcomes based after DP in one American center which routinely placed no drain versus two European centers who routinely placed drains.

2. Methods

2.1. Patient selection

This is a retrospective propensity score-matched analysis of perioperative prophylactic drain placement during DP, including patients from Mayo Clinic Florida, Amsterdam UMC, and University of Verona Hospital Trust (2010–2019). Patients were classified according to the placement of a perioperative prophylactic surgical drain. All consecutive patients from the three centers were included. Excluded were patients who had undergone pancreatoduodenectomy or if DP was performed for disconnected pancreatic duct syndrome.

2.2. Drain placement strategies

There was a difference in routine drain management strategies after DP between the three centers. Two centers routinely placed a surgical drain at the pancreatic stump during DP. From these two centers, only patients with a drain were included. One center did not place a surgical drain routinely and decided during the operation to drain in case of an unsatisfactory staple line because of an open space on the staple line, or when additional stitches were needed. From this center, only patients without a drain were included. In the American center all patients were stapled, and the ‘stepwise graded compression’ technique and staple line reinforcement was used in all patients for pancreatic transection as described by Asbun et al. [11] In the Dutch center all patients were stapled and used the graded compression technique and staple line reinforcement in all patients performed after June 1th 2017. The Italian center used hand-sutures, stapling and ultrasonic shears and used the graded compression technique for all patients which were stapled. In none of the patients somatostatin analogues or hydrocortisone was used. The strategies of drain removal were comparable. The Dutch and the American center removed the operative drain when the drain amylase was lower than 3 times the upper serum limit on postoperative day 3. The Italian center removed the operative drain on postoperative day 3 when the amylase was lower than 5000 U/L on postoperative day 1. On day 5 the drain amylase was measured again and was removed when the drain amylase was lower than 200 U/L.

2.3. Definitions

Distal pancreatectomy was defined according to the International Study Group for Pancreatic Surgery (ISGPS) definition as a resection of the body and/or the tail of the pancreas, which may or may not include the spleen (including splenic vessels), lymphadenectomy, Gerota's fascia and elements of the transverse mesocolon without relevant vasculature. The ISGPS definitions were also used for delayed gastric emptying (DGE), and PPH [12–14]. For POPF, DGE, and PPH only the clinically relevant grade B/C complications were included. Postoperative complications were classified using the Clavien-Dindo classification reported until 90 days postoperative [15]. Major morbidity was defined as Clavien-Dindo grade III or higher reported until 90 days postoperative. Conversion was defined as any laparotomy or hand assistance for other reasons than trocar placement or specimen extraction [16].

Baseline characteristics collected were sex, age, body mass index (BMI, kg/m2), American Society of Anaesthesiologists (ASA) physical status, tumor location, tumor size (mm), the administration of neoadjuvant chemo- and/or radiotherapy, and the indication for surgery. Intraoperative outcomes were drain placement, operation time, blood loss (mL), and involvement of other organs or vascular structures (beyond spleen and splenic vessels). Postoperative outcomes included major complications, POPF [12], DGE [13], PPH [14], surgical site infection (SSI), length of hospital stay (LOS), date of drain removal, readmission, and 90-day mortality.

2.4. Outcomes

The primary outcome is major morbidity. Secondary endpoints are grade B/C POPF, PPH, DGE, re-intervention (surgery, endoscopy, or radiological), unplanned intensive care unit admission, length of hospital stay, readmission, and mortality.

2.5. Statistical analysis

The clinical, biological, and morphologic parameters were analyzed for the entire population to identify factors influencing the patient outcome. Categorical data are presented as percentages and frequencies and were compared using the Chi-square or Fisher's exact test as appropriate. Normally distributed continuous data are presented as means and standard deviations (SDs) and compared using the two independent samples *t*-test. Non-normally distributed continuous data are presented as medians and interquartile ranges (IQRs) and were compared using the Mann-Whitney *U* test. All analyses have been performed on the total cohort and the propensity-score matched cohort [17]. We used the standardized mean difference (SMD) to assess balance at baseline in both groups. Optimal balance on a parameter was considered when the SMD was on or below 0.1.

Patients with prophylactic abdominal drainage after DP (two centers) and without routine prophylactic drains (one center) were matched based on propensity score using nearest neighbor matching. A case-matching analysis achieved a comparison between the no-drain index group and the drain control group. The groups were randomly matched, 1:1 with a caliper width of 0.1 and an average treatment effect, with drain presence as the independent variable. Variables considered for propensity score estimation were chosen after the initial univariate analysis of the baseline and intraoperative parameters. The propensity score for the presence of

Table 1
Baseline characteristics of the full cohort, before PSM.

	No drain after DP (n = 158)	Drain after DP (n = 805)	Total DP (n = 963)	p-value
Female n, %	99 (62.7%)	445 (55.3%)	544 (56.6%)	0.020
Age mean, SD	63.1 (±14.0)	60.1 (±13.8)	60.6 (±13.9)	0.018
BMI mean, SD	27 (±5)	26 (±5)	26 (±5)	0.002
ASA 3/4, n, %	101 (63,0%)	195 (24,2%)	296 (30,8%)	<0.001
Laparoscopic n, %	146 (92.4%)	336 (41.7%)	482 (50.1%)	<0.001
EBL (mL) median, IQR	109 (±180)	265 (±422)	235 (±390)	<0.001
Operation time median, IQR	167 (±86)	274 (±97)	254 (±104)	<0.001
Conversion n, %	7 (4.4%)	57 (7.1%)	64 (6.6%)	0.220
Venous resection n, %	0 (0.0%)	10 (8.1%)	10 (9.6%)	0.009
Arterial resection n, %	2 (1.3%)	7 (0.9%)	9 (0.9%)	0.486
Colon resection n, %	6 (3.8%)	43 (5.3%)	49 (5.1%)	0.419
Splenectomy n, %	136 (86.1%)	699 (86.8%)	835 (86.4%)	0.798

DP: distal pancreatectomy; ASA: American Society of Anesthesiologists classification; EBL: estimated blood loss in milliliter.

a drain after DP was generated based on a statistical difference on univariate analysis, such as $p < 0.05$ (Table 1). The variables included were age, BMI, ASA score, EBL, operation time, minimally invasive approach, and vascular resection. The two propensity-score matched cohorts were compared using a Chi-square test for categorical variables and independent-samples t-tests for continuous variables. Multivariate logistic regression analysis was used on the pre-matched cohort.

3. Results

Overall, 963 patients fulfilled the eligibility criteria, 158 patients without a drain, and 805 patients with a routinely placed prophylactic drain. Baseline characteristics are shown in Table 1. From the center with selective drain strategy, the rate of intraoperative draining was 26%. Outcomes of the full cohort are shown in Table 2 and in additional table A given per center. Propensity score matching was possible in 74 (46.8%) patients from the no-drain group with 74 (9.2%) patients from the drain group. In baseline characteristics of the matched cohort (Table 3), no differences in age, sex, BMI, and ASA score were seen. No differences were seen between the groups concerning estimated blood loss, operation time, conversion rate, extended resections, and colon resections. The rate of splenectomy was higher in the no-drain group (n = 66, 89% versus n = 47, 64%, SMD = 0.69).

The rate of major morbidity was (non-significantly) less in the no-drain group (8% vs. 19%, $p = 0.054$) as shown in Table 4. The rates of grade B/C POPF (4% vs. 16%, $p = 0.014$) and readmission (4% vs. 15%, $p = 0.025$) were lower in the no-drain group. Length of stay (LOS) was shorter in the no-drain group (3 vs. 7 days, $p < 0.001$). In the pre-matched cohort, the LOS differed significantly between the drain and no drain patients from the center with selective drain strategy (3 vs. 6 days, $p < 0.001$).

No significant differences were observed in the rates of ICU admission (9% vs. 4%, $p = 0.190$), reoperation (1% vs. 3%, $p = 0.560$), grade B/C PPH (5% vs. 4%, $p = 0.699$), surgical site infection (1% vs. 0%, $p = 0.551$), and radiological intervention (5% vs. 12%, $p = 0.147$) between the no-drain and drain groups, respectively. Mortality within 90 days was 0 in the no-drain versus 1 (1%) in the drain group ($p = 0.316$).

In the univariable analysis, perioperative drain placement was associated with major morbidity. In the multivariable analysis on the entire cohort prior to matching, only routine drain placement was significantly associated with major morbidity (OR 3.222, CI 1.096–9.464 $p = 0.034$) as shown in Table 5.

4. Discussion

This international propensity score-matched multicenter retrospective cohort study found that not placing a prophylactic surgical drain after DP in selected patients was not associated with higher rates of major morbidity or higher rates of radiological reintervention. On the other hand, the rates of POPF, and readmission, and the hospital stay appeared favorable as compared to routine abdominal drainage, although randomized trials will have to confirm the non-inferiority of a no-drain strategy.

As opposed to pancreatoduodenectomy, the role of prophylactic peritoneal drainage following distal pancreatectomy has received

Table 2
Outcomes of the full cohort, before PSM.

	No drain after DP (n = 158)	Drain after DP (n = 805)	Total DP (n = 963)	p-value	OR no drain vs drain
POPF B/C n, %	7 (4.4%)	182 (22.6%)	189 (19.6%)	<0.001	0.196 (0.094–0.41)
DGE B/C n, %	0 (0.0%)	21 (2.6%)	21 (2.2%)	0.040	1.027 (1.015–1.038)
PPH B/C n, %	4 (2.5%)	65 (8.1%)	69 (7.1%)	0.014	0.314 (0.116–0.848)
Surgical site infection n, %	6 (3.8%)	62 (7.7%)	68 (7.1%)	0.715	0.876 (0.702–1.148)
Radiological intervention n, %	8 (5.1%)	95 (11.8%)	103 (10.7%)	0.012	0.429 (0.213–0.865)
Reoperation n, %	1 (0.6%)	50 (6.2%)	51 (5.3%)	0.004	0.102 (0.014–0.732)
Readmission n, %	8 (5.1%)	91 (11.3%)	99 (10.2%)	0.018	0.447 (0.222–0.903)
Clavien-Dindo ≥3 n, %	11 (7.0%)	171 (21.2%)	182 (18.9%)	<0.001	0.328 (0.183–0.588)
ICU admission n, %	8 (5.1%)	62 (7.7%)	70 (7.3%)	0.243	1.004 0.992–1.014)
Hospital stay Median, IQR	3 (±2)	11 (±11)	9 (±10)	<0.001	
Mortality 90 d n, %	0	7 (0.9%)	7 (0.7%)	0.239	1.009 (1.002–1.015)

ICU: intensive care unit; POPF: post-operative pancreatic fistula; DGE: delayed gastric emptying; PPH: post pancreatectomy hemorrhage.

Table 3
Baseline characteristics after PSM.

	No drain after DP (n = 74)	Drain after DP (n = 74)	SMD
Female n, %	46 (62.2%)	47 (63.5%)	0.01
Age mean, SD	60.3 (14.6)	59.4 (15.8)	0.04
BMI mean, SD	26 (4)	26 (5)	−0.01
ASA 3/4, n, %	29 (39.2%)	36 (48.7%)	0.17
Laparoscopic n, %	66 (89.2%)	62 (83.8%)	0.15
EBL (mL) Median, IQR	50 (50–100)	100 (100–150)	−0.09
Operation time Median, IQR	182 (159–213)	180 (170–205)	−0.01
Conversion n, %	4 (5.4%)	10 (13.5%)	0.27
Venous resection n, %	0 (0.0%)	2 (2.7%)	0.23
Arterial resection n, %	1 (1.4%)	0 (0.0%)	0.29
Colon resection n, %	6 (8.1%)	1 (1.4%)	0.33
Splenectomy n, %	66 (89.2%)	47 (63.5%)	0.69

ASA: American Society of Anesthesiologists classification; EBL: estimated blood loss in milliliter.

Table 4
Outcomes after PSM.

	No drain after DP (n = 74)	Drain after DP (n = 74)	p value	Total (148)	
ICU admission n, %	7 (9.5%)	3 (4.1%)	0.190	10	6.76%
POPF B/C n, %	3 (4.1%)	12 (16.2%)	0.014	15	10.14%
DGE B/C n, %	0 (0.0%)	0 (0.0%)	1.0	0	0.0%
PPH B/C n, %	4 (5.4%)	3 (4.1%)	0.699	7	4.73%
Surgical site infection n, %	1 (1.4%)	0 (0.0%)	0.551	1	0.68%
Radiological intervention n, %	4 (5.4%)	9 (12.2%)	0.147	13	8.78%
Reoperation n, %	1 (1.4%)	2 (2.7%)	0.560	3	2.03%
Readmission n, %	3 (4.1%)	11 (14.9%)	0.025	14	9.46%
Hospital stay Median, IQR	3 (2–5)	7 (5–9)	<0.001	5	44352
Mortality 90 d n, %	0 (0.0%)	1 (1.4%)	0.316	1	0.68%
Clavien-Dindo ≥3 n, %	6 (8.1%)	14 (18.9%)	0.054	20	13.51%

POPF: post-operative pancreatic fistula; DGE: delayed gastric emptying; PPH: post pancreatectomy hemorrhage; SSI: surgical site infection; IAA: intra-abdominal abscess; LOS: length of hospital stay.

Table 5
Multivariate analysis for complications Clavien Dindo ≥3.

	Odds ratio	95% CI	p-value
Female	0.812	0.570–1.157	0.250
Age. in years	1.008	0.994–1.022	0.271
BMI	1.029	0.992–1.066	0.123
ASA score	0.891	0.638–1.244	0.497
Operative drain	3.222	1.096–9.464	0.034
Splenectomy	0.862	0.291–0.734	0.067

CI: confidence interval; BMI: body mass index; ASA: American Society of Anesthesiologists classification.

less attention. A recent systematic review identified one multicenter randomized trial, one propensity-score matched multicenter study, and three retrospective non-matched studies on routine prophylactic abdominal drainage after DP [7]. This illustrated the need for further randomized studies and propensity-score matched multicenter studies. The retrospective single-center study by Paulus et al. included patients after only open DP over a 14-year period and found no differences between patients with and without prophylactic drainage [5]. In a larger study analyzing all pancreas resections, Correa et al. included 350 patients undergoing DP between 2006 and 2011, of whom a total of 196 patients did not have drainage [18]. The results of Correa et al. are comparable for major morbidity, the need for percutaneous drainage, reoperation, and hospital readmission. However, blood loss and operative time were significantly higher in those who received a drain suggesting that there may have been surgeon bias toward draining patients at higher risk of complications [18]. Behrmann et al. compared a drain and a no-drain group consisting of 116 propensity score-matched patients after DP. The rates of major morbidity and the need for therapeutic intervention postoperatively did not differ between the groups [9]. In the only randomized trial on this topic, Van Buren et al. reported that the rates of major morbidity, grade B/C POPF, and radiological interventions did not differ significantly between the groups [8]. However, the Van Buren RCT reported readmission rates in the drain and no drain groups of 24 and 22% respectively. The main shortcoming of this trial is the lack of risk stratification. Therefore, it is unclear whether a selected group of patients may benefit from still receiving a surgical drain. As to be expected, the no-drain group had a higher rate of intra-abdominal fluid collections in this randomized trial, but this did not increase the rate of postoperative radiological interventions.

The main rationale for the prophylactic use of drains in pancreatic surgery is to drain pancreatic fluid collections with the intention of reducing the rates of POPF, infection, and PPH. However, it is debatable to what extent a prophylactic drain succeeds in doing so after DP [5]. Adding a drain may convert a self-limiting collection after DP into an actual POPF. Nevertheless, in patients with a high risk of POPF, the risk of delayed drainage of a POPF may potentially outweigh the risk of a drain. However, this theory cannot be tested in the Van Buren trial since no risk stratification was applied. In their defense, as opposed to PD [19,20], a fistula risk score for DP is still lacking and currently patients can therefore not be defined as high risk.

Current study showed a lower readmission rate of 4.1% in the no drain group when compared to 22% in the no drain group of the Van Buren RCT. This can partially be explained because drains were only omitted when the staple line was judged as satisfactory by the surgeon. However, since the drain rates of the drain groups were 15% in current study and 24% in the Van Buren RCT, this advocates for a more sophisticated POPF risk prediction.

The unadjusted POPF rates differed per center. In the American center, this rate was 8.6% in the no drain group and 24.5% in the drain group. The POPF rates were 20.8% and 33.3% in the Italian and the Dutch center respectively [11].

The current findings should be interpreted in the light of some limitations. First, selection bias is present because of the study's retrospective character and selective drain placement. To minimalize this bias, a propensity score-matched analysis was executed, including blood loss and operative time [17]. However, pancreatic texture and neo-adjuvant therapy were not included in the propensity score-matching. Therefore, our results must be interpreted carefully. Our study does not provide definitive evidence for better outcome in all patients after DP with a no-drain strategy. Second, data from three different centers were included, which will have introduced heterogeneity. Most studies compare outcomes between patients with and without drains. However, the current design was specifically chosen in order to minimize this bias since the participating centers had different strategies for drain placement. The heterogeneity may also include differences in surgical technique. However, as several randomized trials have shown that different surgical approaches to transect the pancreas, use patches, or stapler reinforcement all have no impact on the risk of overall complications and POPF after distal pancreatectomy, we expect this additional bias to be of lesser importance [21–24]. Third, all no-drain patients were derived from one center, which introduces a bias due to inhomogeneous perioperative and postoperative management. To minimalize this bias, the pre-matched LOS were given for the selective drain center and these were found to be significantly different. Fourth, as POPF, chyle leak, or PPH can be detected by monitoring surgical drain production's color and biochemical analysis, there may be an underestimation of these variables in the no drain group. However, the clinical impact of such potential under registration is unclear considering the lower number of radiological interventions, reoperations, and major morbidity in the no-drain group. Fifth, not all strategies regarding drain placement after DP were assessed in this study. For instance, an early removal strategy in patients with low drain amylase levels may also reduce the rate of POPF and overall complications [16,25–27]. The timing of exact day of drain removal was not available as a variable in this study. Sixth, in the Italian center, in a portion of the patients the transection of the pancreas was done with ultrasonic shears or when stapled, without staple line reinforcement. Although this can lead to heterogeneity, both techniques were not found to have a significant effect on outcomes in two randomized trials [21,24].

In conclusion, a no-drain policy in selected patients after DP does not seem to increase morbidity or the rate of radiological reinterventions. The present retrospective study suggests that such an approach could even be associated with favorable rates of POPF and readmission when compared to routine prophylactic drainage. Pragmatic multicenter randomized trials on routine prophylactic drainage versus a no-drain strategy with stratification for fistula risk such as the currently ongoing Dutch-Italian randomized PANDORINA trial [10] are now required. Such a study should also focus on the existence of specific subgroups or indications for prophylactic drainage after DP.

Additional table A
Outcomes of the full cohort per center, before PSM

	Total						No drain						Drain					
	Mayo (n = 243)		Verona (n = 580)		Amsterdam (n = 140)		Mayo (n = 157)		Verona (0)		Amsterdam (1)		Mayo (86)		Verona (580)		Amsterdam (139)	
POPF B/C n, %	23	9.5%	124	21.4%	24	17.1%	7	4.5%	0	0.0%	0	0.0%	16	18.6%	124	21.4%	24	17.3%
DGE B/C n, %	2	0.8%	12	2.1%	7	5.0%	0	0.0%	0	0.0%	0	0.0%	2	2.3%	12	2.1%	7	5.0%
PPH B/C n, %	8	3.3%	58	10.0%	3	2.1%	4	2.5%	0	0.0%	0	0.0%	4	4.7%	58	10.0%	3	2.2%
Surgical site infection n, %	12	4.9%	0	0.0%	1	0.7%	6	3.8%	0	0.0%	0	0.0%	6	7.0%	0	0.0%	1	0.7%
Radiological intervention n, %	20	8.2%	53	9.1%	30	21.4%	8	5.1%	0	0.0%	0	0.0%	12	14.0%	53	9.1%	30	21.6%
Reoperation n, %	3	1.2%	42	7.2%	6	4.3%	1	0.6%	0	0.0%	0	0.0%	2	2.3%	42	7.2%	6	4.3%
Readmission n, %	17	7.0%	53	9.1%	29	20.7%	8	5.1%	0	0.0%	0	0.0%	9	10.5%	53	9.1%	29	20.9%
Clavien-Dindo ≥3 n, %	31	12.8%	90	15.5%	61	43.6%	11	7.0%	0	0.0%	0	0.0%	20	23.3%	90	15.5%	61	43.9%
ICU admission n, %	28	11.5%	34	5.9%	8	5.7%	8	5.1%	0	0.0%	0	0.0%	20	23.3%	34	5.9%	8	5.8%
Hospital stay Median, IQR	4	3	11	11	6	4	3	2	0	0	3	2	6	5	11	11	6	4
Mortality 90 d n, %	2	0.8%	3	0.5%	2	1.4%	0	0.0%	0	0.0%	0	0.0%	2	2.3%	3	0.5%	2	1.4%

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