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Name of Journal: *World Journal of Gastrointestinal Surgery*

Manuscript NO: 84960

Manuscript Type: ORIGINAL ARTICLE

Retrospective Cohort Study

Initial Suction Drainage Decreases Severe Postoperative Complications after Pancreatic Trauma: A Cohort Study

Initial Suction Drainage in Pancreatic Trauma

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Abstract

BACKGROUND

Few studies have addressed the question of which drain types are more beneficial for patients with pancreatic trauma (PT).

AIM

To investigate whether sustained low negative pressure irrigation suction drainage (NPI) is superior to closed passive gravity drainage (PG) in PT patients.

METHODS

PT patients who underwent pancreatic surgery were enrolled consecutively at a referral trauma center from January 2009 to October 2021. The primary outcome was defined as the occurrence of severe complications (Clavien–Dindo grade ≥ III_b). Multivariable logistic regression was used to model the primary outcome, and propensity score matching (PSM) was included in the regression-based sensitivity analysis.

RESULTS

In this study, 146 patients underwent initial PG drainage, and 50 underwent initial NPI drainage. In the entire cohort, the multivariable logistic regression model showed that the adjusted risk for severe complications was decreased with NPI drainage (14/50 [28.0%] vs. 66/146 [45.2%]; OR, 0.437; 95%CI, 0.203-0.940). After 1:1 PSM, 44 matched pairs were identified. The proportion of each operative procedure performed for pancreatic injury-related and other intra-abdominal organ injury-related cases was comparable in the matched cohort. NPI drainage still showed a lower risk for severe complications (11/44 [25.0%] vs. 21/44 [47.7%]; OR, 0.365; 95%CI [0.148-0.901]). A forest plot revealed that NPI drainage was associated with a lower risk of Clavien–Dindo severity in most subgroups.

CONCLUSION

This study, based on one of the largest PT populations in a single high-volume center, revealed that initial NPI drainage may be recommended as a safe and effective alternative for managing complex PT patients.

Key Words: Pancreatic Trauma; Drainage; Postoperative Complications; Clavien-Dindo; Propensity Score Matching

Li KW, Wang K, Hu YP, Yang C, Deng YX, Wang XY, Liu YX, Li WQ, Ding WW. Initial Suction Drainage Decreases Severe Postoperative Complications after Pancreatic Trauma: A Cohort Study. *World J Gastrointest Surg* 2023; In press

Core Tip: Few studies have addressed the question of which drain types are more beneficial for patients with pancreatic trauma (PT). A total of 196 PT patients were selected from 2009 to 2021, of which 146 patients underwent closed passive gravity (PG) drainage and 50 underwent low negative pressure irrigation suction (NPI) drainage. In the entire cohort, multivariate analysis showed that the risk for severe complications (Clavien– Dindo grade ≥ IIIb) was decreased with NPI drainage. After 1:1 propensity score matching between PG and NPI drainage, the results were consistent with multivariate analysis.

INTRODUCTION

Pancreatic trauma (PT) is relatively rare; however, injury to the pancreas can be challenging for even the most experienced trauma surgeon [1-3]. Significant morbidity and mortality are usually related to the cumulative effect of all injured organs [4]. Surgical management is nearly always adopted for PT in the emergency setting of abdominal trauma [5, 6].

Consensus regarding the necessity for drainage has been formulated in many management strategies for PT [7-9]. The rationale is to evacuate intra-abdominal exudate, pancreatic juice or blood that may accumulate after surgery and serve as an early warning sign of possible pancreatic fistula, anastomotic fistula and associated hemorrhage [8-10]. Moreover, peripancreatic drainage alone is an important therapeutic measure [11, 12]. The following two drain types are mainly placed for pancreatic surgery: closed passive gravity (PG) drainage and sustained low negative pressure irrigation suction (NPI) drainage. PG drainage applies no pressure, evacuating fluid by gravity alone with intra-abdominal pressure [13]. NPI drainage actively flushes the abdominal cavity with normal saline under low negative pressure [14, 15]. In fact, high-level evidence has not yet been provided to support the choice of drain type for PT [16].

Several issues related to drainage are considered counterproductive, which leads to constant evaluation of the roles of these methods [16, 17]. First, the drains can serve as a portal of entry for bacteria [18]. Second, fistula, hemorrhage, or hollow-organ perforation may be caused by mechanical pressure, suction or erosion around the anastomosis and fragile tissue [19]. It is of paramount importance to understand to what extent drains influence the development and severity of complications. Therefore, based on one of the largest PT populations in our high-volume center, we performed a retrospective study to investigate whether NPI is superior to PG drainage.

MATERIALS AND METHODS

We performed a retrospective cohort study of consecutive patients who had undergone pancreatic surgery at a tertiary trauma referral center between January 2009 and October 2021 in our PT database. The study was approved by the Institutional Review Board (IRB) of Jinling Hospital (Approval No. 2021DZGZR- YBB- 009). Informed consent was waived by the IRB because of the retrospective nature of the study. This study was conducted in accordance with the principles of the Declaration of Helsinki. The exclusion criteria were as follows: early death (<48 h) after admission; Glasgow Coma Scale ≤ 8; Abbreviated Injury Scale score = 6 for any area of the body; nonoperative treatment; pregnancy status; and previous history of malignancy, immune system or hematological diseases.

Operative and drainage management

Pancreatic injuries are classified into 5 grades (I -V) according to the Organ Injury Scale (OIS) proposed by the American Association for the Surgery of Trauma (AAST) in 1990. For low-grade PT (I -II), drainage alone was performed after complete exposure of the pancreas. For high-grade PT (III-V), distal pancreatectomy with or without splenectomy was usually adopted for grade III injury; debridement/resection of the area of injury, closure of the proximal stump and distal Roux-en-Y pancreaticojejunostomy or drainage alone was implemented for grade IV injury; one-stage damage control drainage and subsequent definitive operative or pancreaticoduodenectomy were utilized for grade V injury.

After distal pancreatectomy, a drain was inserted *via* the left flank and was placed near the pancreatic remnant; the other drain was placed in the left subphrenic area, but only when splenectomy was performed. Similarly, a drain was inserted *via* the left flank and was placed between the pancreaticojejunostomy and pancreatic remnant after middle pancreatectomy. After pancreatoduodenectomy, a drain was inserted *via* the right flank and placed posterior to the biliary anastomosis, extending to the proximal margin of the pancreatic remnant. The other drain was inserted *via* the left flank and was placed posterior to the stomach, extending to the posterior surface of the pancreatic anastomosis in proximity to the contralateral drain. In addition, individualized operative management was performed, and drains were placed as appropriate after careful assessment for other intra-abdominal organs.

The two drain types adopted are shown in **Figure 1**. The decision regarding which drain type to place was made on a case-by-case basis and according to the surgeon's preference. Drains were routinely kept in situ for at least postoperative day (POD) 7 to 10. CT scans were performed every other week postoperatively. Once pancreatic fistula grade B/C or gastrointestinal fistula was confirmed by fistulography, the duration of drain placement was prolonged. For these patients, PG drainage was replaced by NPI drainage through the sinus tract for irrigation to minimize erosion of the surrounding tissue by the digestive juice. A controlled pancreaticocutaneous fistula or enterocutaneous fistula was created by retaining the catheter in situ until the fistula healed spontaneously. When necessary, CT-guided percutaneous drainage procedure was performed in patients with local pancreatic complications after failed initial drainage and/or new-onset gastrointestinal fistula and localized intra-abdominal abscess requiring source control, and then replaced with NPI drainage following the guidewire.

We regularly replaced the catheter to maximize the effect of sustained irrigation drainage and reduce the size of the tube by degrees as appropriate. Two replacement strategies are employed for management of NPI drainage in clinical practice: 1) planned replacement for prophylactic drainage, 2) on-demand replacement for therapeutic drainage. If patients not develop pancreatic fistula grade B/C or gastrointestinal fistula and the volume of drainage fluid is decreasing, prophylactic NPI drainage is planned to be replaced every 3 days. For patients with pancreatic fistula grade B/C or gastrointestinal fistula, on-demand replacement is adopted due to the role of NPI has been convert to therapeutic drainage. Retaining the catheter in situ to a create controlled pancreaticocutaneous fistula or enterocutaneous fistula when there is a large volume of drainage fluid. In addition, on the basis of the nature of drainage fluid and the irrigation and drainage fluid in and out volume per unit time to judge whether catheter blockage occurred. If blockage occurs, replace it promptly. Moreover, in the presence of a decreasing volume of drainage fluid and no evidence of intra-abdominal infection, we switching the NPI drainage from on-demand to planned replacement.

We adhered to the following drain removal policy: lack of infection-induced systemic inflammatory response syndrome; pancreatic fistula defined by the ISGPF was absent or grade A; the evidence provided by CT excluded intra-abdominal abscess or undrained fluid collections; drained fluid was less than 20 mL per day and turned clear, and lack of any gastrointestinal fistula. Additional management methods included the administration of antibiotics, supplemental parenteral or enteral nutrition, reinterventions (reoperation, endoscopic, or interventional radiological procedures), and organ function support.

Study variables and outcomes

Data analyzed included demographics, vital signs, injury parameters, operative procedures, type and location of drains, complications, reinterventions, bacterial culture information of drainage fluid samples, mortality and length of stay (LOS). The primary outcome was the occurrence of severe complications defined as Clavien– Dindo grade III_b-V during hospitalization. Further details on the definitions of outcome variables are provided in **Table S1**.

Statistical analysis

Student's *t* tests and Wilcoxon rank sum tests were used to compare normal or nonnormal continuous variables, respectively. Chi-square and Fisher's exact tests were used to compare categorical variables. A multivariate logistic regression model was applied to evaluate the association between the primary outcome and different drain types. Variables with $P < 0.2$ in the univariate test were included in the multivariate analysis.

To study effect modification by different drainage methods and to adjust for confounding factors, we performed sensitivity analysis based on propensity score matching (PSM). The PG group was matched 1:1 with the NPI group using their propensity scores with the nearest neighbor matching algorithm without replacement (the caliper was set at 0.2). A standardized mean difference (SMD) of less than 10% indicates appropriate balance. A univariable logistic regression model was adopted to estimate the OR and corresponding 95%CI for the primary outcome. Prespecified subgroup analyses were performed in the matched cohort to determine whether the effect of drainage varied across stratification factors of covariates. R version 4.0.3 was used for statistical analysis.

RESULTS

Patient Characteristics

Two hundred thirteen PT patients were managed by operative management with drain placement during the study period. Of these, 196 patients met the inclusion criteria: 146 (74.5%) PG vs. 50 (25.5%) NPI drainage. The screening process is shown in **Figure 2.** The patients' preoperative demographics, clinical characteristics and injury parameters are summarized in **Table 1**. In the entire cohort, the NPI group had less duodenum injury and more concomitant vascular injury ($P < 0.05$). For the time from trauma to operation, delayed operative treatment (≥24 h) occurred more frequently in the NPI group (46.0% vs. 20.5%, $P = 0.001$).

PSM with a 1:1 ratio resulted in 88 patients (PG 44, NPI 44). Before PSM, 13 of 15 baseline characteristics were unequally distributed between the two groups; following PSM, all of the variables reached an SMD < 0.10 (**Figure S1**), suggesting that the two matched cohorts were well balanced. In the matched cohort, the pancreatic injury grades and the extent of injury to intra-abdominal organs exhibited approximately proportional distributions ($P > 0.05$) (**Table 1**). Moreover, the proportion of each operative procedure performed for pancreatic injury-related and other intra-abdominal organ injury-related cases was comparable in the matched cohort (**Table 2**).

Primary outcome

In the entire cohort, the incidence of severe complications in the NPI group was significantly lower than that in the PG group (14/50 [28.0%] vs. 66/146 [45.2%], $P = 0.033$) (**Table 3**). In univariate logistic regression analysis, ISS, abdominal AIS, isolated pancreatic injury, and different drain types were associated with severe complications ($P < 0.05$) (**Table S2**). Notably, the NPI group was significantly less likely to develop severe complications (OR, 0.471; 95%CI, 0.235-0.947; $P = 0.035$). In multivariate analysis, the adjusted risk for severe complications was decreased in the NPI group (aOR, 0.437; 95%CI, 0.203-0.940; $P = 0.034$) (**Figure 3**). After PSM, the results of the sensitivity analysis were consistent with those of the multivariate analysis (OR, 0.365; 95%CI [0.148-0.901]; $P = 0.029$) (**Figure 3**).

Secondary outcomes

Among the matched cohort, no significant difference in in-hospital mortality was observed between the two groups. The drainage period in the NPI group was lower than that in the PG group (median [IQR], 35.0 [20.0-54.75] vs. 47.0 [30.0-68.0] days; $P = 0.009$). The proportion of underwent CT-drainage in the NPI group still significantly lower

(15.9% vs. 34.1%, P = 0.042). Moreover, The NPI group was associated with lower incidence of pancreatic fistula grade B/C, lower incidence of gastrointestinal fistulas, lower reoperation rate, and shorter LOS ($P < 0.05$) (**Table 3**). The POD 7 infection rate of drainage fluid in the NPI group was significantly lower (11/36 [30.6%] vs. 27/43 [62.8%], P = 0.004) (**Table S3**). With regard to the qualitative microbiological analysis, the incidence of G+ bacterial infection was higher in the NPI group (7/11 [63.6%] vs. 5/27 [18.5%], P = 0.017) (**Table S4**). In this prespecified subgroup analysis, the difference in the rate of the primary outcome between the PG and the NPI group was greater among patients without concomitant vascular injury (**Figure 4**). We detected no significant interaction with treatment for the other baseline factors ($P > 0.10$ for all comparisons).

DISCUSSION

Few comparative studies have focused on the potential differences in the postoperative outcomes related to drain types for PT patients. Most Western countries recommended closed suction drainage, but conclusive evidence is lacking [7-9, 20]. The Memphis group found that closed suction drainage reduced septic complications, while sump drainage caused retrograde infections *via* catheters [21]. However, it is difficult to derive robust results from this study due to the heterogeneity of study participants, injury parameters, and operative procedures. In this study, we evaluated the severity of complications for different drain types after PT and revealed that NPI drainage is superior to PG drainage.

The reduced Clavien–Dindo severity for NPI drainage may be attributed to several factors. First, NPI drainage can effectively remove residual infection within intra-abdominal or between intestinal loops through continuous and active irrigation with sterile normal saline, thereby reducing the incidence of abscess, systemic inflammation or sepsis [22]. Second, NPI drainage can rapidly drain collected pancreatic juice by a low negative pressure system to reduce accumulation and diffusion and can dilute the accumulated fluid collection with irrigating sterile normal saline to minimize erosion and impairment to other tissues, thus preventing mild pancreatic leakage from developing a serious pancreatic fistula and avoiding hemorrhage and the formation of gastrointestinal fistulas. Jiang H *et al* verified that pancreatic fistula grade C in patients with NPI drainage was significantly less common than in patients with passive drainage after pancreaticoduodenectomy [15]. Under the dual effects, NPI drainage could achieve significant clinical benefits for patients. PG drainage generally relies on the pressure difference and gravity, which may not obtain adequate drainage and predisposes to catheter blockage. In this study, the incidence of catheter blockage was 9.6% (14/146) in the PG group, whereas it did not occur in the NPI group.

More importantly, postoperative digestive tract fistulas often contribute to various other complications, such as hemorrhage, sepsis, multisystem organ failure, and even death. These complications mandate reinterventions such as percutaneous drainage or reoperation [23]. Nevertheless, resection and anastomoses should not be considered suitable procedures due to the edematous and friable nature and adhesions adjacent to the fistula site. Fistulography is performed to evaluate the possibility of conservative treatment. For patients able to be treated conservatively, we uniformly adopted NPI drainage. The outer cannula can prevent both aspiration damage to surrounding tissues and blockage of the inner suction cannula. The patency provided by NPI drainage is a fundamental principle in the formation of a stable and controlled pancreaticocutaneous or enterocutaneous fistula, which is beneficial for facilitating the formation of the fistula tract [24].

In the matched cohort, the incidence of gastrointestinal fistulas and reoperation rate were higher in the PG group. Sixteen patients required reoperation for one or more intra-abdominal complications: intra-abdominal hemorrhage grade B/C in 10 patients, small intestinal fistulas in 3, colonic fistulas in 5, pancreatic fistula grade C in 2, and infectious pancreatic necrosis in 2. Correspondingly, 7 patients required reoperation in the NPI group: intra-abdominal hemorrhage grade B/C in 1 patient, gastric fistula in 1, colonic fistulas in 3, and pancreatic fistula grade C in 3. For patients who underwent CT-guided percutaneous drainage, the proportion in the NPI group was significantly lower than that in the PG group. From the above, it can be determined that patients in the NPI group could receive less invasive reinterventions. Our previous study also found that 74 of 88 gastric and small intestinal fistulas (84.1%) and 21 of 72 colonic fistulas (29.2%) caused by acute pancreatitis could be cured by NPI drainage [25]. Some studies have shown that negative pressure contributes by causing local tissue and vascular damage in the area near the drain [26]. However, Cecka *et al* found that the rates of pancreatic fistula, hemorrhage and overall morbidity were not different between closed suction and PG drainage after pancreatic resection [17]. According to the results of our study, low negative pressure did not raise the above concerns.

The overall mortality rate was 9.6% (19/196): 18 patients died of sepsis and related multiple organ failure. Similarly, the Western Trauma Association (WTA) Multicenter Trials Group on Pancreatic Injuries found that the mortality was 9.1% (79/872) in PT patients who underwent surgery [11, 12]. In our matched cohort, no significant differences in mortality were observed. These patients might benefit from good control of the infected source, and most digestive tract fistulas usually heal spontaneously over time [27]. In addition, the improvement of care capacity for severe trauma, parenteral and enteral nutritional support, and effective anti-infection treatment also played important roles.

The POD 7 infection rate of drainage fluid in the NPI drainage was significantly lower; however, the incidence of infectious complications (abscess and sepsis) was not significantly different between the two drain types. This may be attributed to antibiotic administration and the application of percutaneous drainage. We speculate that the higher incidence of G+ bacterial infection with NPI drainage may be related to the open nature of the drain or retrograde migration of bacteria. Although subgroup analyses were prespecified, this study was not adequately powered to assess the benefit of treatment. Patients without concomitant vascular injury appeared to benefit more from NPI drainage than those with vascular injury. Nevertheless, with the limitations of a relatively small sample size and retrospective nature, caution should be exercised in the interpretation of these results.

Our study has several limitations. First, as an observational study, the analyses are subject to selection bias, and residual unmeasured confounding may persist despite adjustment for a variety of known patient variables using PSM to approximate randomization. Second, conducting the study at a single high-volume center limits generalizability. Third, the volume, microbiology and amylase concentration of drainage fluid trends over time and drainage catheter removal time were not included in our data; however, they may also reflect the potential differences between the two drain types.

CONCLUSION

In conclusion, we compared the incidence of severe postoperative complications between PG and NPI drainage and found that NPI drainage was associated with decreased Clavien–Dindo severity. These findings suggest that initial NPI drainage may be recommended as a safe and effective alternative for managing complex PT patients. Further randomized controlled trials are warranted to validate these results.

ARTICLE HIGHLIGHTS

Research background

Consensus regarding the necessity for drainage has been formulated in many management strategies for pancreatic trauma (PT).

Research motivation

Few studies have addressed the question of which drain types are more beneficial for PT patients.

Research objectives

To investigate whether sustained low negative pressure irrigation suction drainage (NPI) is superior to closed passive gravity drainage (PG) in PT patients.

Research methods

We performed a retrospective cohort study of consecutive patients who had undergone pancreatic surgery at a tertiary trauma referral center between January 2009 and October

2021 in our PT database. The primary outcome was defined as the occurrence of severe complications (Clavien–Dindo grade ≥ III_b). Multivariable logistic regression was used to model the primary outcome, and propensity score matching (PSM) was included in the regression-based sensitivity analysis.

Research results

In this study, 146 patients underwent initial PG drainage, and 50 underwent initial NPI drainage. In the entire cohort, the multivariable logistic regression model showed that the adjusted risk for severe complications was decreased with NPI drainage (14/50 [28.0%] vs. 66/146 [45.2%]; OR, 0.437; 95%CI, 0.203-0.940). After 1:1 PSM, 44 matched pairs were identified. The proportion of each operative procedure performed for pancreatic injury-related and other intra-abdominal organ injury-related cases was comparable in the matched cohort. NPI drainage still showed a lower risk for severe complications (11/44 [25.0%] vs. 21/44 [47.7%]; OR, 0.365; 95%CI [0.148-0.901]).

Research conclusions

Iinitial NPI drainage may be recommended as a safe and effective alternative for managing complex PT patients.

Research perspectives

Further randomized controlled trials are warranted to validate these results.

Footnotes

Institutional review board statement: This study protocol was approved by the Institutional Review Board (IRB) of Jinling Hospital (No. 2021DZGZR- YBB- 009).

Informed consent statement: This is a retrospective study, and patients were not required to give informed consent for the study because the analysis used anonymous clinical data that were obtained after each patient agreed to treatment by written consent.

Conflict-of-interest statement: All authors read and approved the final manuscript and declared no conflicts of interest.

Data sharing statement: The original anonymous dataset is available upon request from the corresponding author at dingwei_nju@hotmail.com.

Figure Legends

Figure 1 Sketch map of the NPI drainage and PG drainage systems.

Figure A is NPI drainage. A cranial margin closed the outer silicone cannula with a diameter between 24F and 30F, and multiple side apertures with diameters of 3-5 mm were arranged along the cannula (Part a). A 12F urinary catheter and the cranial margin are connected to Part a with silk thread for continuous irrigation with sterile normal saline at a rate of 100 to 125 mL/h after surgery (Part b). An inner silicone cannula without side aperture was placed into Part a, with approximately half the diameter of Part a, for connecting to a low negative pressure (-10 kPa to -20 kPa) system [28] (Part c). **Figure B** is PG drainage. PG drainage is defined as a latex catheter drain that maintains a pathway for fluid to follow from the surgical site by gravity, which is connected to a liquid storage bag maintained at atmospheric pressure.

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