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Results of a randomized controlled trial comparing closed-suction drains versus passive gravity drains after pancreatic resection☆,☆☆

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ABSTRACT

Background: This dual-center, randomized controlled trial aimed to compare 2 types of intra-abdominal drains after pancreatic resection and their effect on the development of pancreatic fistulae and postoperative complications.

Methods: Patients undergoing pancreatic resection were randomized to receive either a closed-suction drain or a closed, passive gravity drain. The primary endpoint was the rate of postoperative pancreatic fistula. A secondary endpoint was postoperative morbidity during follow-up of 3 months. The planned sample size was 223 patients.

Results: A total of 294 patients were assessed for eligibility, 223 of whom were randomly allocated. One patient was lost during follow-up, and 111 patients in each group were analyzed. The rate of postoperative pancreatic fistula (closed-suction 43.2%, passive 36.9%, $P = .47$) and overall morbidity (closed-suction 51.4%, passive 40.5%, $P = .43$) were not different between the groups. We did not find any differences between the groups in reoperation rate ($P = .45$), readmission rate ($P = .27$), hospital stay ($P = .68$), or postoperative hemorrhage ($P = .11$). We found a significantly lesser amount of drain fluid in the passive gravity drains between the second and fifth postoperative days and also on the day of drain removal compared with closed-suction drains.

Conclusion: The type of drain (passive versus closed suction) had no influence on the rate of postoperative pancreatic fistulae. The closed-suction drains did not increase the rate of postoperative complications. We found that the passive gravity drains are more at risk for obstruction, whereas the closed-suction drains kept their patency for greater duration.

Introduction

Although the mortality of pancreatic resection has decreased to <5% in major centers of experience, the morbidity remains substantial.[1] One of the most ominous complications is postoperative pancreatic fistula (POPF). Although in most cases POPF is not life threatening, POPF prolongs hospital stay, requires additional treatment modalities and interventions, and increases the cost of treatment.[2,3]

Several methods have been studied in the past to decrease the rate of POPF, including pharmacologic treatment with octreotide or other analogues of somatostatin[4] in an attempt to decrease pancreatic exocrine secretions and various technical interventions directed at the pancreatic remnant such as pancreatic stenting.[1] The use of octreotide remains controversial, and none of the studied techniques proved consistently to be superior.

The use of intra-abdominal drains is another method that has been studied recently in an attempt to decrease morbidity and POPF rates.[5–7] Recent studies have reported that the use or routine avoidance of intra-abdominal drains, the type of drain, and the time of extraction can influence the rate of POPF formation.[8]

Intra-abdominal drains have long been used in surgery,[9] but the controversy over whether drains should be used remains in both urgent and elective abdominal surgery.[10] Many recent studies have

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reported that drain placement does not add any additional benefit to the patient after selected abdominal operations (eg, appendectomy, cholecystectomy, hepatectomy, colectomy, gastrectomy).[11] Indeed, the use of drains might even be harmful to patients because they can slow recovery and the restoration of bowel movements and thereby prolong hospital stay. Drains may even cause further postoperative complications, such as retrograde intra-abdominal infection or even hollow-organ perforation.[11,12] Also, as a result of the artificial access to the peritoneal cavity, there can be an inflammatory response to the drain as a foreign body, increased pain as a result of the drain, or the loss of fluid and electrolytes.[8] Prolonged duration of intra-abdominal drainage also interferes with the enhanced recovery after surgery programs.[13]

In pancreatic surgery the main role of drains is to prevent the formation of intra-abdominal fluid collections; moreover, it helps with early diagnosis of a pancreatic leak, biliary leak, or postoperative hemorrhage.[14,15] Keeping the drain in place for a greater period can be part of conservative treatment of POPF, such as by creating a controlled pancreaticocutaneous fistula until the fistula is healed completely.[5,16]

The use and management of drains in pancreatic surgery has attracted attention recently.[8] Although drains had previously been considered mandatory after pancreatic resection, a new approach in pancreatic resection without routine drain placement emerged with the first pilot study of Jeekel et al[17] in 1992. Three randomized studies and a number of retrospective or cohort studies have been published since. The results of the randomized controlled trials are contradictory.[9,18,19] A recent study by McMillan et al[20] found that selective drain placement according to the risk-stratification might be an optimal solution. When drains are used, early removal is recommended.[14]

The final issue regarding drain management is the choice of the type of drain. Not much attention has been paid to this question.[21] There are 2 basic types of abdominal drains: passive gravity drains and closed-suction drains. The majority of authors prefer various modifications of closed-suction drains because they believe this system is more effective. Some surgeons, however, believe that the negative pressure of the drain may pose potential hazards to the patients, increase the risk of POPF, or lead to delayed hemorrhage. Diener et al[5] stated that the role of different types of drain remains unclear. Strobel and Buchler[6] also noted that the best type of drainage remains unknown. Various types of drains have been studied retrospectively in other operative procedures.[8] The situation in pancreatic surgery is different because the pancreaticoenteric anastomosis is not watertight in most cases, as indicated by an increased amylase level on the first postoperative day (POD).[22] Therefore more attention must be paid to the choice of the type of drain used in pancreatic resection to prevent the clinically important types B and C POPFs.[8]

Methods

This dual-center, randomized controlled trial was conducted between November 2013 and April 2016. The aim of this study, called the DRAPA (DRAins in PAncreatic surgery) trial, was to compare closed-suction drains versus the passive gravity drains after pancreatic resection and to study the effect of the drains on the development of POPF and other postoperative complications.

The primary endpoint of this study was the rate of POPF as defined by the International Study Group for Pancreatic Fistula.[23] A secondary endpoint was postoperative morbidity, including wound infection, intra-abdominal collections, delayed gastric emptying, postoperative hemorrhage, pneumonia, abdominal wound dehiscence, cardiac events, and neurologic complications, as defined previously.[21] The postoperative complications were graded according to Clavien-Dindo definition modified by DeOliveira for pancreatic surgery.[24,25]

Study population and eligibility criteria

The DRAPA trial took place in 2 participating centers: University Hospital Hradec Králové and University Hospital Olomouc, both in the Czech Republic. All patients who were scheduled for pancreatic resection at one of the 2 participating centers were screened and assessed for eligibility. Patients undergoing a nonstandard pancreatic resection or a procedure associated with known greater morbidity were excluded from the study to achieve a homogeneous study group.

Inclusion criteria were (1) patients scheduled for pancreatoduodenectomy or distal pancreatectomy, (2) aged 18 years or older, and (3) signed informed consent provided.

Exclusion criteria were (1) pancreatic resection not performed; (2) total pancreatectomy, central pancreatectomy, or enucleation; (3) multivisceral resection; (4) laparoscopic procedure; (5) resection of the portal vein and reconstruction with a graft; and (6) lack of compliance, informed consent not provided, or refusal to participate

Sample size calculation

The sample size calculation was based on the expected rate of POPF from our previous experience because there were no preexisting valid data comparing closed-suction drain and closed passive-gravity drains in pancreatic surgery. The POPF rate in the closed passive gravity drain group was expected to be 35% based on previous studies.[3] The POPF rate in the closed-suction drain group was expected to be half (17.5%) that of the passive gravity drains. The sample size calculation was based on difference of two independent proportions with respect to the primary endpoint, which was the POPF rate. With an α of 5% and a β of 20%, a sample size of 97 patients per group was necessary to detect a difference between the groups. With an expected dropout rate of 15%, we planned to enroll 223 patients to the study.

Study treatment

The operative procedures were standardized in both participating institutions and have been described previously.[21] Briefly, a standard resection of the pancreatic head with the duodenum and a standard lymphadenectomy were performed followed by the reconstruction phase. Pancreatojejunostomy was performed in end-to-side fashion. We used either a duct-to-mucosa 2-layer anastomosis or an invaginating 1-layer anastomosis according to the surgeons' preferences. No stents were used. No additional manipulation, such as fibrin glue or reinforcement with a mesh, was performed. For distal pancreatectomy, the main pancreatic duct was occluded with a figure of 8 stitch and the pancreatic remnant was then oversewn with interrupted stitches. In the pancreatoduodenectomy, 2 drains were placed—1 anterior and 1 posterior to the pancreatico-enteric anastomosis. In distal pancreatectomy, 1 drain was placed near the pancreatic remnant. A second drain was placed in the left subphrenic area but only when splenectomy was performed.

In the patients assigned to the closed, passive-gravity drainage group, passive tube drains with a diameter of 8.7 mm (PFM Medical, Köln, Germany) were used. In the patients assigned to the closed-suction drain group, BLAKE Silicone drains with diameter 6.3 mm (Ethicon, Somerville, NJ) were used. Drains exited the abdominal wall through a separate stab incision and were fixed with a stitch to the skin. The volume of fluid was measured every 24 hours and noted in the patient's record form. Amylase activity in

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