



Duct-to-Mucosa vs Invagination for Pancreaticojejunostomy after Pancreaticoduodenectomy: A Prospective, Randomized Controlled Trial from a Single Surgeon

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- BACKGROUND:** Pancreatic fistula (PF) is the most common significant complication after pancreaticoduodenectomy. Invagination and duct-to-mucosa anastomoses are anastomotic techniques that are commonly performed after pancreaticoduodenectomy. There are conflicting data on invagination vs duct-to-mucosa anastomoses about which is superior for minimizing the risk of PF. In addition, all previous studies involved multiple operating surgeons and failed to control for variation in surgeon expertise.
- STUDY DESIGN:** This was a randomized controlled study comparing the outcomes of PD between patients who underwent invagination vs those who had duct-to-mucosa anastomoses. All 132 patients were operated on between October 2012 and March 2015 by a single surgeon experienced in both procedures. Pancreatic fistula was the main end point.
- RESULTS:** Overall and clinically relevant rates of PF rate were 29.5% and 10.6%, respectively. Overall PF rates in the patients treated with invagination vs duct-to-mucosa anastomoses were 30.9% vs 28.5% ($p = 0.729$), respectively and the corresponding clinically relevant PF rates were 17.6% vs 3.1%, respectively ($p = 0.004$). Although the overall complication rates were similar in the 2 groups, severe complications were significantly more frequent in the patients treated with invagination ($p = 0.013$). Duct-to-mucosa anastomosis was also associated with shorter postoperative hospital stay (13 vs 15 days; $p = 0.021$). There was one perioperative death. Independent variables for the risk of PF were the diameter of the pancreatic duct (greater risk with smaller diameter), the underlying pathology, and male sex.
- CONCLUSIONS:** Both methods yield similar overall rates for PF, but the rate of clinically relevant PF is lower in patients treated with duct-to-mucosa anastomosis. Additional single-surgeon studies or multi-institution randomized trials controlling for comparable expertise in both procedures should be conducted to confirm these results. (J Am Coll Surg 2016;222:10–18. © 2016 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Pancreaticoduodenectomy (PD) is performed for a variety of benign and malignant disorders involving the head of the pancreas or the periampullary region, particularly

for tumors of the pancreas and ampulla of Vater. With advances in surgical technique and perioperative management, postoperative mortality and morbidity have been

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Abbreviations and Acronyms

| | |
|-------|---|
| ISGPF | = International Study Group on Pancreatic Fistula |
| PD | = pancreaticoduodenectomy |
| PF | = pancreatic fistula |
| PJ | = pancreaticojejunostomy |
| POD | = postoperative day |
| RCT | = randomized controlled trials |

reduced substantially. However, postoperative pancreatic fistula (PF) remains the most troubling complication. It is associated with infection and bleeding, both of which can be life threatening.

Evidence suggests that the PF rate can be as high as 20%, even in high-volume centers.^{1,2} The past few decades have seen many efforts to reduce this. These have included the use of perioperative somatostatin, intraoperative use of stents and fibrin glue, and improved anastomoses. To date, numerous anastomotic methods and modifications of them have been proposed to prevent PF. They include pancreaticogastrostomy and pancreaticojejunostomy (PJ).^{1,3-8} Some studies have suggested that pancreaticogastrostomy is superior to PJ.⁹ However, PJ remains the most frequently performed PD procedure, and it has the advantage that it is more physiological, in terms of where pancreatic juice is discharged into the digestive tract.

Invagination (also known as dunking technique) and duct-to-mucosa are 2 well-established anastomotic methods for PJ, and there is a long running debate as to which is better. There have been 6 randomized controlled trials (RCTs) addressing this topic.^{5,10-14} However, only 3 of them used the International Study Group on Pancreatic Fistula (ISGPF)'s definition of PF.^{10,12,14} A meta-analysis, which included some of these RCTs, found no significant differences in the PF rate between the 2 anastomotic methods.¹⁵

Although multicenter RCT is considered to be the gold standard for assessing drug efficacy, the situation is more complicated when it comes to assessing the superiority of surgical techniques. Outcomes can differ markedly according to the training and experience of the surgeon. In addition, patient factors, such as whether the procedure is being undertaken for a systemic disorder or for a purely localized pancreatic condition, can also affect outcomes. Patient, surgeon, and anastomotic method ("PF triangle") all affect the rate of PF after PD. To determine the influence of anastomotic method, it is necessary to control for the other 2 variables. The previously reported RCTs all involved more than one operating surgeon (Table 1). Therefore, we aimed to perform a rigorously designed

Table 1. Summary of the Number of Participants and the Number of Operating Surgeons in Previous Randomized Controlled Studies of Duct-to-Mucosa vs Invagination for Pancreaticojejunostomy after Pancreaticoduodenectomy

| First author | Year | Patients included, n | Operating surgeons, n |
|-------------------------|------|----------------------|-----------------------|
| Langrehr ⁵ | 2005 | 113 | >1 |
| Berger ¹⁰ | 2009 | 197 | 8 |
| Chou ¹¹ | 1996 | 93 | 5 |
| Han ¹² | 2009 | 64 | Unknown |
| Bassi ¹³ | 2003 | 144 | 3 |
| El Nakeeb ¹⁴ | 2015 | 100 | >1 |

study, controlling for the surgeon factors and randomizing the patient factors, to allow comparison between invagination and duct-to-mucosa PJ techniques in preventing PF and other adverse events.

METHODS

This was a single-center RCT designed to compare the rates of PF and other complications after duct-to-mucosa vs invagination for PJ. All surgical procedures were performed by the same surgeon (TL), who had 25 years experience doing hepatobiliary and pancreatic surgery and performed >450 Whipple procedures independently. That surgeon had performed both duct-to-mucosa and invagination techniques with comparable frequency (57% and 43%, respectively) before the study started. The study was approved by the Ethics Committee of the Second Affiliated Hospital, Zhejiang University School of Medicine, China, and registered at ClinicalTrials.gov (NCT01695447). Informed written consent was obtained from all participants.

Patients

The study was conducted between October 2012 and March 2015. Patients aged 18 to 80 years who required a PD for a variety of disorders, including pancreatic neoplasm, distal cholangiocarcinoma, and ampullary tumor, were eligible for inclusion, provided they were judged as being fit enough to undergo the planned procedures, and had a life expectancy of at least 3 months. Patients who required multiorgan and/or vascular resections were included. However, those for whom laparoscopic PDs were planned, or who had undergone previous abdominal operations, were excluded.

Patients were recruited if the need for PD was anticipated. If one anastomotic method was judged too difficult to perform, an alternative procedure was permitted, but the patient was then excluded from the trial before randomization. For other eligible patients, once the operating surgeon had intraoperatively assessed and confirmed

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