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Closure and anastomosis of the pancreas using a four-needle threeloop suture device

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Abstract: Pancreatic juice can leak not only from the main pancreatic duct but also from unclosed ductal branches appearing on the pancreatic stump. We have developed a suture device consisting of three loops of suture attached to four small-curvature needles with the aim to maximize the area of pancreatic parenchyma to be ligated and reduce the number of punctures made on the pancreas during pancreatic closure or anastomosis. In pancreatojejunostomy, the dorsal wall of the jejunum and then the pancreatic parenchyma are sutured using the four needles. Following duct-to-mucosa anastomosis, the ventral jejunal wall is sutured, and the three threads are finally tied sequentially to complete the reconstruction following the Blumgart method. In distal pancreatectomy, the pancreatic stump is sutured from the dorsal aspect sequentially using the four needles, before or after the pancreatic transection. The three threads are then respectively tied on the ventral surface of the pancreas. This device was used in six pancreatoduodenectomies (including two minimally invasive procedures) and five distal pancreatectomies. A postoperative pancreatic fistula requiring additional drainage or repositioning of abdominal drains developed in two patients. No adverse events associated with this device were encountered. The four-needle three-loop suture device can be an alternative to conventional staplers or sutures for closure and anastomosis of the pancreatic stump.

Keywords: distal pancreatectomy, pancreatic fistula, pancreatic leak, pancreatic reconstruction, suture device, pancreaticoduodenectomy

Introduction

Despite advances in suturing techniques and surgical devices, there is no single method for closing and anastomosing the pancreatic stump to prevent development of postoperative pancreatic fistula (POPF). Among a variety of surgical techniques, Blumgart anastomosis (1) has become widely used as a safe and effective method of pancreatojejunostomy during pancreaticoduodenectomy (PD) (2). In distal pancreatectomy (DP), staple closure is the most common technique, especially in the minimally invasive setting. Hand-sewn suture closure can also be used to ensure adequate management of the pancreatic stump with closure of the main pancreatic duct (MPD) in complicated surgical procedures (3).

In our previous studies, fluorescence imaging using a chymotrypsin-activated probe showed that pancreatic juice could leak not only from the MPD stump but also from unclosed ductal branches located in the whole pancreatic raw surface and pinholes made by surgical instruments (4,5). These findings suggested that it would be reasonable to extend areas of pancreatic parenchyma to be ligated while minimizing injuries on the pancreas, leading to development of a new suturing device consisting of three loops of suture connected to four small-curvature needles (three-loop suture device). The methods for using the three-loop suture device in PD and DP are herein detailed with operative outcomes.

Materials and Methods

This study protocol was reviewed and approved by the Institutional Ethics Review Board of The University of Tokyo (approval number: 2021194NI) and performed in accordance with the guidelines of the Declaration of Helsinki. Informed consent was obtained from all patients.

Concept and design of the suture device

Previous studies aiming to develop intraoperative fluorescence imaging of pancreatic juice using a chymotrypsin-specific probe demonstrated that pancreatic juice could leak not only from the MPD stump but also from orifices of unclosed branches located widely on the pancreatic raw surface and/or pinholes made by suturing or stapler devices (Figure 1A, 1B). These findings inspired the author (T.I.) to design a new four-needle three-loop suturing device that maximizes areas of the pancreatic stump to be ligated with a minimum number of punctures on the pancreas (Figure 1C).

A prototype of this device was manufactured and clinically used in 2016. The updated version used in the present study consisted of three nonabsorbable threads (PTFE-coated polyester, U.S.P. 4-0 and 70 cm in length) and four small-curvature needles (1/5 circle and 3.0 cm in length). The ends of the first and second threads were attached to the second needle and those of the second and third threads were connected to the third needle, making three loops in a row (Figure 1D). The first and third threads were blue and the second thread was white, making it easy to differentiate the ends of each thread when ligated. In pancreatojejunostomy during PD, the dorsal wall (seromuscular layer) of the elevated jejunum and then the pancreatic parenchyma (from dorsal to ventral aspects) are sutured, usually from the cranial to caudal side, using the four needles of the abovedescribed suturing device in a sequential manner. Following duct-to-mucosa anastomosis of the MPD, the ventral seromuscular layer of the jejunum is sutured in sequence, the needles are removed by cutting the threads at their roots, and the three threads are then respectively tied to complete the anastomosis following the Blumgart method (Figure 2A). The above procedures can be followed in either laparoscopic or robot-assisted surgery.

In DP, the pancreatic stump is sutured from the dorsal to ventral aspects using the four needles in a sequential fashion, usually from the cranial to caudal side, before (Figure 2B) or after (Figure 2C) pancreatic transection. The three threads are then respectively

Use of three-loop suturing device in PD and DP

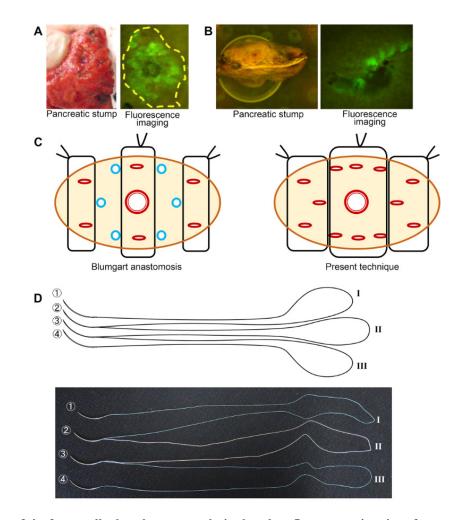


Figure 1. Design of the four-needle three-loop suture device based on fluorescence imaging of pancreatic juice. (A, B): Fluorescence imaging using a chymotrypsin-activated probe facilitates visualization of pancreatic juice leaking from (A) the whole raw surface of the pancreatic stump and (B) pinholes made by staples. (C): Device concept. In the conventional Blumgart anastomosis (left), pancreatic ductal branches located in the parenchyma between the ligations may remain unclosed (blue circles), and they can be closed with use of the three-loop suture device by maximizing the extent of ligations (right). (D): A drawing (above) and picture (below) of the four-needle three-loop suture device, which consists of four needles (1/5 curvature, φ 0.45 mm for the needles "1" and "4" and φ 0.6 mm for the needles "2" and "3") and three nonabsorbable threads (U.S.P. 4-0, I-III). Threads I (blue) and II (white) and threads II and III (green) are attached to needle "2" and "3", respectively, making three loops in a row.

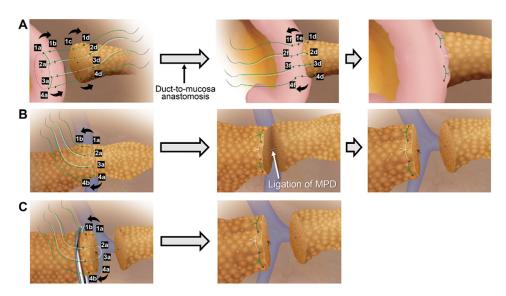


Figure 2. Methods of using the four-needle three-loop suture device in PD and DP. (A): In pancreatojejunostomy during PD, the first needle is used to suture the seromuscular layer on the posterior jejunal wall (1a to 1b) and then the pancreatic stump from the posterior to ventral aspects (1c to 1d). The remaining needles are respectively used in a similar manner (2a to 2d, 3a to 3d, and 4a to 4d). Following duct-to-mucosa anastomosis of the MPD, the seromuscular layer of the anterior jejunal wall is sutured with the first needle (1e to 1f), followed by caudal anastomoses with use of the remaining three needles. Finally, the needles are detached and the three loop threads are respectively ligated. (B): In DP, the future pancreatic remnant is sutured from the dorsal to ventral aspects using the four needles respectively (1a to 1b, 2a to 2b, 3a to 3b, and 4a to 4b), usually from the cranial side and caudal side. After gentle ligation of the three-loop suture device in DP. This device can also be used to reinforce the pancreatic stump after panchymal transection by suturing the pancreas, usually from the dorsal to ventral aspects, with the four needles. PD, pancreaticoduodenectomy; DP, distal pancreatectomy; MPD, main pancreatic duct.

tied on the ventral surface of the pancreas. During the pancreatic transection, the MPD can be identified and ligated independently.

Results and Discussion

During November 2018 and March 2021, the fourneedle three-loop suture device was used in six PDs (including one laparoscopy-assisted and one robotassisted procedure) and five open DPs with no additional resections on the remnant pancreas. The patients' demographic background characteristics and operative outcomes are summarized in Table 1. Seven patients had a normal soft pancreas without diabetes mellitus or obstruction of the MPD.

The amylase concentration in the drained abdominal fluids on postoperative day 3 ranged from 22 to 17,000 IU/L (median, 2,448 IU/L). International Study Group on Pancreatic Surgery (ISGPS) grade B POPF (6) developed in two (18%) patients (additional percutaneous puncture of abdominal fluid in one patient and drain repositioning for symptomatic fluid collection in one patient). No adverse events associated with use of the three-loop suture device were encountered.

The concept of the four-needle three-loop suture device is application of uniform pressure on the whole area of the pancreatic stump by making three ligations following four punctures on the pancreas. In the present series consisting of 11 pancreatic resections, this device could be used as designed with an acceptable incidence of POPF (18%, ISGPS grade B) and no device-associated adverse events, albeit the efficacy of this technique in preventing POPF should be fully evaluated by further comparative studies. The key factor for successful utilization of the three-loop suture device is to tie the threads gently with adequate force, feeling the texture of the pancreas and intestines. Too-tight ligations may cause ischemia of the pancreatic remnant, whereas too-lax threads (especially on the dorsal aspect of the pancreas) will lead to leakage of pancreatic juice.

Closure of the pancreas in DP using the four-needle three-loop suture device has potential advantages over stapler-based techniques in that this procedure can be used in a wider range of surgical situations; e.g., when there is limited space for stapler insertion, a thick/ irregular pancreatic shape and fragile texture, a proximal transection around the pancreatic head, and the need to obtain intact specimens of the pancreatic stump for precise evaluation of surgical margins. Using this device for ligation of the future pancreatic remnant prior to parenchymal division makes the transection plane bloodless and ensures identification and ligation of the MPD, which may lead to decreasing risk of POPF in some particular conditions (7). The present technique can also be applied to coverage of the pancreas by suturing the pancreatic stump with mesh (8,9), the round ligament (10), or the seromuscular layer of the jejunum (11). According to a recent meta-analysis focusing on DP, patch closure using the round ligament led to the lowest incidence of clinically relevant POPF (12).

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Table 1.	

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No.	Age (y) / Sex	Age (y) / Sex Preoperative diagnosis	DM or MPD obstruction	Surgical procedure	Maximum amylase level in abdominal drainage on POD3 (IU/L)	POPF (ISGPS grade)	Other complications	Postoperative hospital stay (days)
-	29/F	Mucinous cystic neoplasm		Open DP	2,448	B		19
2	73/F	Metastatic tumor	DM	Open DP	10,938			12
33	63/F	Neuroendocrine tumor		Laparoscopy-assisted PD	4,949			14
4	74/M	Pancreatic adenocarcinoma	DM	Open DP	349			6
5	73/F	Serous cystic tumor		Open DP	16,000			10
9	74/M	Pancreatic adenocarcinoma		Open DP with gastric wall resection	2,255		DGE	22
7	57/F	Pancreatic adenocarcinoma		Open PD with portal vein resection	135		DGE, epileptic seizure	34
8	83/M	Distal bile duct cancer		Open PD	7,027		1	28
6	75/M	Ampullary cancer		Open PD	205			23
10	46/F	Pancreatic adenocarcinoma		Open PD	22			18
11	61/M	Intraductal papillary mucinous neoplasm MPD obstruction	MPD obstruction	Robot-assisted PD	17,000	B*		15
F, female;]	M, male; DP, dist:	F, female; M, male; DP, distal pancreatectomy; PD, pancreaticoduodenectomy; DM, diabetes mellitus; MPD, main pancreatic duct; POD, postoperative day; POPF, postoperative pancreatic fistula; ISGPS, International Study Groun on Pancreatic Sturvery: DGF delayed eastric emptying *Additional addining devinence or adjustment of addominal drains under X-ray fluxocconv	ctomy; DM, diabetes litional abdominal dra-	mellitus; MPD, main pancreatic duct; inace or adjustment of abdominal drains	POD, postoperative day; PC	OPF, postoperative	pancreatic fistula; ISGP	S, International

A meta-analysis focusing on PD demonstrated that Blumgart anastomosis was associated with a decreased risk of grade B/C POPF (2). Use of the three-loop suture device for Blumgart anastomosis is reasonable because it reduces the number of pancreatic punctures used in conventional techniques from six to four, thus decreasing the risk of bleeding and pancreatic juice leakage due to needle trauma. The reduction of pancreatic punctures enabled by this device would also be beneficial in Blumgart anastomosis during laparoscopic and robot-assisted PD (13,14), although the current thread length (70 cm) should be shortened to 20 to 30 cm to facilitate manipulation during minimally invasive procedures. Furthermore, the three-loop suture device may be useful in pancreaticogastrostomy using matless sutures (15).

The four-needle three-loop suture device recently became commercially available in Japan (PANC LOOP, KONO SEISAKUSHO Co., Ltd., Chiba, Japan). This device has potential to be widely used for closure and anastomosis of the pancreatic stump as a safe and effective alternative to conventional staplers or sutures.

In conclusion, the four-needle three-loop suture device can be an alternative to conventional staplers or sutures for closure and anastomosis of the pancreatic stump.

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Conflict of Interest: T.I. has served as a consultant to SONY Corporation and KONO SEISAKUSHO Co., Ltd., Chiba, Japan. None of the other authors have actual or potential conflicts of interest regarding the submission of this article. A part of this study was presented at the 32nd Meeting of Japanese Society of Hepato-Biliary-Pancreatic Surgery (24 February 2021).

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