Clinically Relevant Postoperative Pancreatic Fistula rates in two methods of pancreatico-jejunal anastomosis compared: Evolution of surgical technique in a single centre over time

Tommaso Zurleni (tzurleni@yahoo.it)
ASST Valle Olona, Hospital of Busto Arsizio https://orcid.org/0000-0002-3971-2297

Simone Olmetti
Ospedale di Busto Arsizio

Luca Marzoli
Ospedale di Busto Arsizio

Francesco Zurleni
Ospedale di Busto Arsizio

Research article

Keywords: pancreatico-jejunal anastomosis, pancreatic cancer, postoperative pancreatic fistula, pancreaticoduodenectomy, pancreatic surgery, duct-to-mucosa anastomosis

Posted Date: May 8th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-24483/v1

Abstract

Background:

Pancreaticoduodenectomy remains the gold standard for management of patients with pancreatic head and periampullary neoplasms. Despite the low mortality, overall morbidity remains high, principally due to the development of a clinically relevant postoperative pancreatic fistula (CR-POPF).

The aim of the present study is to compare rates of CR-POPF in two groups of patients treated with two different pancreaticojejunostomy techniques.

Methods:

Among 264 consecutive patients submitted to surgery for pancreatic neoplasm, 142 pancreaticoduodenectomies with end-to-side pancreaticojejunostomy were analysed. The first group of patients underwent a direct mucosa-to-mucosa anastomosis as described by Longmire and Traverso. In the second group, a duct-to-mucosa anastomosis with an outer seromuscolar and inner full thickness layer as described by Z'graggen, Shrikhande and Buchler was performed.

Results:

Mortality was 2,8% in the first group (2/71) and zero in the second. In group 1°, 48.5% of patients suffered one or more grade II-V Clavien-Dindo complications; in group 2°, complications were observed in 26,7% of patients. Clinically relevant POPF occurred in 12 patients in group 1° (17%) and in 4 patients in group 2° (5,6%).

Conclusions:

Changing pancreaticojejunostomy techniques may produce different outcomes. In our experience, a standardized duct-to-mucosa anastomosis, as performed in group 2, significantly reduced the rate of CR-POPF.

Background

Pancreaticoduodenectomy (PD) is considered the standard treatment for malignant and benign lesions of the pancreatic head and periampullary region. It is a technically challenging procedure requiring a high level of surgical experience with regard to resection and reconstruction.

Whereas the rate of mortality associated with PD has dramatically decreased in the last two decades to below 5%, the morbidity rate remains high, from 30–50%, indicating the complexity of pancreatic surgery [1]. The most important and potentially life-threatening complication after PD is the occurrence of a postoperative pancreatic fistula (POPF), traditionally perceived as the Achilles heel. From the literature, its

incidence varies from 2% to more than 20% [2–4]. In 2005, the International Study Group of Pancreatic Fistula (ISGPF) reached a consensus, defining a clinical system of 3 grades of POPF: A, B and C [5].

Afterwards, criticism was published until the International Study Group of Pancreatic Surgery (ISGPS) in 2017 introduced a new definition on the grading of POPF [6–8]. Grade A is now redefined as “biochemical leak”; grades B and C (clinically relevant POPF) are confirmed but defined more strictly: patients who required percutaneous drains are classified as grade B, while those classified as grade C are associated with organ failure, reoperation or death [8].

The aim of the present study is to compare the rate of clinically relevant POPF in two groups of patients before and after the introduction of a standardized technique of pancreaticojejunal anastomosis described by Z’graggen, Shrikhande and Buchler [9, 10].

Methods

Patients

From January 2000 to December 2015, of 264 consecutive patients (of which 37 were admitted for palliative or exploratory procedures), 227 underwent pancreatic surgery in our centre. These included 142 cephalic pancreatoduodenectomy (PD), 14 total duodenopancreatectomy, 3 central resection, 4 pancreaticojejunal derivation in pseudocyst, 38 distal pancreatectomy with or without splenectomy, and 26 multiorgan resection including corpo-caudal pancreatectomy for infiltrating neoplasia from stomach, colon and left kidney or retroperitoneal sarcoma.

None of the patients underwent neoadjuvant treatment.

Of the 142 PD, 71 consecutive patients underwent surgery before March 2009 (Group 1); the other 71 patients were enrolled from April 2009 (group 2) after introduction of a different technique for pancreatic anastomosis. The clinicopathological characteristics of the two groups are shown in Table 1.

Table 1
Clinicopathological characteristics

	Group 1° (%)	Group 2° (%)	p-value
N° of patients	71	71	
Sex (M/F)	36/35	38/33	0.74
Age	65	66	
ASA ≥ 2	65 (92)	65 (92)	1
Malignant disease	66 (93)	65 (92)	0.75
Pancreas	36 (51)	50 (70)	
Ampullar	25 (35)	14 (20)	
Distal biliary duct	5 (7)	6 (8)	
Others	5 (7)	1(1.4)	
Benign disease	5 (7)	6 (8)	
Type of resection			0.35
PD classic Whipple	18 (25)	23 (32)	
PPPD Pylorus preserving PD	53 (75)	48 (68)	
Vascular resection	3 (4)	12 (17)	0.026
Pancreatic duct diameter < 3 mm	15 (21)	18 (25)	0.55
Pancreatic texture	Not routinely collected	Not routinely collected	
Preoperative biliary drainage (PBD)	28 (39)	37 (52)	0.13
T tube Kehr	65 (91)	5 (7)	< 0.001
Internal p-j stent	34 (47)	1 (1.4)	< 0.001

Surgery

All patients underwent open surgical procedure.

In group 1, a pancreaticojejunostomy described by Longmire and Traverso [11] "*as a direct mucosa-to-mucosa anastomosis of the pancreatic duct to the jejunum*" was performed. Posterior and anterior layers were constituted of 4.0 interrupted stitches and mucosa to mucosa with 6.0 poliglicolic monofilament splinted in 47% of cases with an internal stent.

Then, an end-to-side hepaticojejunostomy was splinted (91% of cases) with a T tube inserted through the bile duct.

The surgical technique of Group 2° was previously described by Z'graggen, Shrikhande and Buchler "*as end to side duct to mucosa anastomosis with an outer seromuscolar and inner full thickness layer"* [9, 10]. The cut end of the left hemipancreas was mobilized for 2 cm to allow the placement of a posterior external suture. All stitches were monofilament absorbable PDS 5 – 0 (C-1, 13 mm 3/8c, visi-black, or TF 13 mm 1/2c) for interrupted single sutures. The first step was the placement of at least three ductal sutures, first anterior and then posterior, including the cut edge of the pancreas remnant; the ductal stitches were retained with clamps and organized in order.

The anastomosis consisted of two posterior row, external and inner sutures, and two anterior, inner and external sutures. External posterior suture was performed with interrupted suture every 4–5 mm placed from the dorsal pancreatic capsule and parenchyma to the jejunum end-to-side; all stitches were retained and organized, and the knots were gently tied. The jejunum was then opened on its antimesenteric side, next to the mesentery, and the mucosa was sutured on the cut edge of the pancreas with interrupted sutures with integration of previously posterior placed ductal sutures; all knots were tied after completion of the inner posterior suture. The anterior inner suture between the anterior cut edge of pancreas and the opened jejunum was performed utilizing the previously placed anterior ductal suture. The second row of anterior suture covered the inner suture line without tension and invaginated the anterior cut edge into the jejunum by 1 cm.

Then, an end-to-side hepaticojejunostomy with interrupted single sutures PDS 5.0 was performed.

In selected cases, we used the round ligament as a patch around the PJ anastomosis, as described by Iannitti et al. [12].

In both group 1° and 2°, surgical loupes were routinely used at 2.5 × magnification for pancreaticojejunal anastomosis; in two cases, a microscope at 12.5 × was used.

Digestive continuity was restored by an ante-colic duodenal/gastro-jejunostomy in classic Whipple with a Braun anastomosis or a Roux-en-Y in five patients. One (or two) 4 × 10 mm fluted flat drainages were placed behind the pancreatic and biliary anastomosis, and the postoperative secretion was routinely monitored with respect to amylase contents. A nutritional jejunostomy was placed 20 cm next to the last jejunal anastomosis and utilized from the second postoperative day [13].

In case of cancer, lymph node dissection along the hepatoduodenal ligament, common hepatic artery, vena cava, superior mesenteric vein and the right side of the superior mesenteric artery was a standard part of the procedure. Octreotide was started during the induction of anaesthesia and given for some days after operation (three doses of 0.1–0.2 mg per day subcutaneously).

Endpoint

The aim of the present study was to compare rates of clinically relevant POPF using the last classification proposed by ISGPS [8] in two groups of patients, before and after introduction of a different technique for pancreaticojejunal anastomosis. Morbidity and mortality were also evaluated.

Statistical analysis

Statistical analysis was done by addressing differences in categorical variables between the two groups with Chi square test for 2 × 2 contingency tables. Fisher's exact test was used when the number of an observed value was < 5. For continuous variables, a two-tailed t-test was used, and P values < 0.05 were considered statistically significant.

Statistical analyses were performed using MedCalc for Windows, version 11.6 (MedCalc Software, Ostend, Belgium).

Results

Results were retrospectively analysed in terms of postoperative mortality and morbidity (Table 2).

Mortality was defined as death within 30 days or in hospital, irrespective of the duration of stay. The definition of CR-POPF was based on the consensus classification of the International Study Group of Pancreatic Surgery (ISGPS) [8]; for the delayed gastric emptying (DGE) and Postpancreatectomy haemorrhage (PPH), we referred to ISGPS classification [14, 15].

Mortality:

In group 1°, the mortality rate was 2,8% (2/71). One patient died of perioperative haemorrhagic shock, and the second died three months after PD after delayed sentinel haemorrhage from POPF C, reoperation with total pancreasectomy, discharge and readmission for uncontrolled diabetes and herpes virus disease. Zero mortality was observed in group 2°.

Morbidity:

As reported by a grading system applied to pancreaticoduodenectomy [16], we also assessed grade II-V Clavien-Dindo morbidity from one or more complications; 34/70 patients (48,5%) in group 1° and 19/71 patients (26,7%) in group 2° had these complications.

A total of 40 complications occurred in group 1° and 22 in group 2°. Uneventful postoperative course (grade 0-I Clavien-Dindo) occurred in 51,5% and 73,7% of patients, respectively, in the two groups.

Wound infection, urinary tract infection, pneumonia and cholangitis were included as complications when there was the need for antibiotic treatment and/or when hospital stay was prolonged because of these complications, according to Clavien-Dindo classification [16, 17].

Clinically relevant POPF occurred in 12 patients in group 1° (17%) and in 4 patients in group 2° (5,6%), p = 0.06. For POPF B (10 in group 1° and 3 in group 2°), an intraoperative drain was left for more than 3 weeks, except for one patient in the first group, for whom interventional drainage was used.

Two patients had POPF C in group 1°; both underwent reoperation for sentinel bleeding from stump erosion of the gastroduodenal artery in post operative day (POD) 7 and POD 20, and one of these patients died.

In group 2°, one case of POPF C (1,4%) was observed. Because of multiorgan failure, the patient was admitted to the Intensive care unit (ICU) and then discharged after 7 days.

PPH occurred in five patients (7%) in group 1°: two grade B and three grade C; 2 early and 3 delayed haemorrhage; and 1 intraluminal (treated with blood transfusions) and 4 extraluminal. Four subjects were submitted to re-laparotomy, in two cases for sentinel haemorrhage and POPF C. In group 2°, PPH occurred in two patients (2,8%): one grade B and one grade C; one early submitted to re-laparotomy, and one had delayed intraluminal haemorrhage treated with angiography and embolization.

Five patients suffered from DGE in both groups (7%); one DGE C case in group 2° was re-operated at POD 25 with Roux-en-Y. Prolonged enteral nutritional support through routinely placed jejuneostomy was performed and well tolerated; prolongation of hospital stay did not cause any delay of adjuvant therapy, as the patient was classified as TNM stage I.

Operative time was significantly higher in the second group.

Table 2
Morbidity and mortality

	Group 1° (%)	Group 2° (%)	p-value
Mortality (30 day in hospital)	2/71 (2.8%)	0/71	0.496
Morbidity II-IV Clavien-Dindo pts	34 (48.5%)	19 (26.7%)	0.009
Morbidity II-IV Clavien-Dindo n°	40	22	0.002
POPF B	10 (14.2%)	3 (4.2%)	
POPF C	2 (2.8%)	1 (1.4%)	
CR-POPF total	12 (17%)	4 (5.6%)	0.06
PPH B-C	5 (7%) 2B, 3C	2 (2.8%) 1B, 1C	0.44
DGE B-C	5 (7%) 4B, 1C	5 (7%) 3B, 2C	1
Biliary leakage	1 (1.4%)	1 (1.4%)	1
Cardiopulmonary	5 (7%)	4 (5.6%)	1
Infection (bile, wound, abscess)	11 (15.7%)	5 (7%)	0.18
Khyle leak	1 (1.4%)	1 (1.4)	1
Reoperation	4 (5.7%)	2 (2.8%)	0.68
Operative time mean (SD) min	366.9 (SD ± 60.1)	400.4 (SD ± 55.2)	P < 0.001
Blood loss mean (SD) ml	1040 (SD ± 1230)	1020 (SD ± 1270)	P = 0.92
LOS (length of stay-days) mean (SD)	25 (SD ± 11.6)	18 (SD ± 9)	P < 0.001

Discussion

A standardized approach to the pancreatic anastomosis and a consistent practice of a single technique appear to be related to decreased postoperative complications [18].

The ISGPS in 2010, improving uniformity and standardization in pancreatic anastomosis (PA), formulated a new classification that incorporates factors related to the pancreatic remnant, such as pancreatic duct size, length of mobilization, and gland texture, as well as factors related to the pancreatoenteric anastomosis. The use of duct-to-mucosa anastomosis or invagination (dunking) of the remnant into the jejunum, the use of a stent (internal or external) across the anastomosis, and the use of intraperitoneal drains were other important issues discussed [19].

In 2017, an ISGPS position statement failed to provide definitive, consistent and convincing level 1 evidence that any PA technique was better than the others. Pancreaticojejunostomy (PJ) remains the

most common type of reconstruction, practised by 88.7% of surgeons. [20]

Another issue of interest concerns the placement of trans-anastomotic stents. [21] Some authors reported that a normal soft pancreas does not require a stenting tube [22–24]. Ductal stents in pancreatic anastomosis were frequently used (47%) in our group 1° and in only one patient in group 2°. A biliary T-tube was inserted in 91% of patients in group 1° and rarely (7%) in group 2°, with the rationale that the diversion of biliary secretions away from pancreatic drainage may avoid activation of pancreatic enzymes and therefore protect the healing process of the PJ [25]. Other authors subsequently suggested reconstruction on dual loop (Roux-en-Y) [26, 27].

The use of routine drains at the site of the anastomosis has been widely debated [28, 29]; a randomized, prospective, multicenter trial demonstrated an increase number of complications and mortality in PD without intraperitoneal drainage [30]. Nevertheless, drains may provide access for bacteria, potentially leading to super infected fluid, bile, chyle, and pancreatic juice collections [31]. Lastly, a recent dual-centre randomized trial indicated that selective drainage might be a better concept; abandoning intraperitoneal drains did not increase the reintervention rate, mortality, and overall morbidity. Moreover, the clinically relevant POPF rate was lower in the no-drain group (CR-B/C 11,9% vs 5,7%)[32].

Furthermore, management decisions involve the postoperative day of drain removal. Even the timing of drain removal is still under discussion. In a report on 1.507 patients with PD, drain removal occurred at median POD 7 [6]; in contrast, in patients with a low risk of pancreatic fistula, intra-abdominal drains can be safely removed on POD 3 or POD 1 after standard pancreatic resections [33–35]. A prolonged period of drain insertion was associated with a higher rate of postoperative complications with increased hospital stay and costs [36, 37]. We routinely used drains in group 1° patients without POPF, removing the drain on POD 7; in low risk group 2° patients, we removed drain earlier, on POD 3.

Preoperative biliary drainage (PBD) does not have a beneficial effect on postoperative outcome; intraoperative bile samples had demonstrated that contamination of bile was significantly increased in patients who underwent stenting, as recently reported [38]. The increase of postoperative overall complications and wound infections urges precise indications for preoperative biliary drainage [39, 40]. Our experience showed many infections (biliary and wound) in patients with preoperative biliary drainage (nearly half of patients).

Vascular resection, especially performed in group 2°, did not increase the complication rate of our patients, as other authors reported, but justified a small increase in operative time and blood loss [41, 42]. Mortality rates (30 days or in hospital) varied in most recent publications between 2% and 4% [2, 3, 43, 44, 45]. Volume-outcome relationships in pancreaticoduodenectomy are well established, but an optimal volume remains to be determined. Mortality at 90 postoperative days was most favourable in > 40 PDs/year centers compared with 5–19 PDs/year centres (4,3% vs 8,9%) [46]. In our centre, the volume of pancreatic resection was lower (14.6 /year) but with high volume of major oncological surgery; our mortality rate of 30 days or in hospital was 2,8% (2/71) in group 1° and zero in group 2°(0/71). Morbidity

rates after pancreaticoduodenectomy remain high, between 30–50%, as documented in several studies [1, 3, 4, 32, 44, 45, 47].

The rate of clinically relevant postoperative pancreatic fistula (CR-POPF) in PJ continues to range between 10% and 15% [48–52]. In a recent, multicenter, multinational report of > 4000 pancreaticoduodenectomies, CR-POPFs occurred in 11.1% of all cases [53]. In 2016, from the Heidelberg centre, there was a proposal to assign all patients undergoing interventional drainage as POPF grade B. Among 1889 PD, the clinically relevant POPF rate was 8,9% (4,8% B and 4,1% C) [7]. Then, 11 years after the 2005 Consensus, ISGPS redefined grade A postoperative pancreatic fistula as “biochemical leak”. Grade B POPF requires a change in the postoperative management: drains should be left in place for more than 3 weeks or repositioned through endoscopic or percutaneous procedures. Grade C POPF refers to those conditions that require reoperation or lead to single or multiple organ failure or death [8].

The decrease in CR-POPF from 17–5.6% in our experience is probably due to standardization and meticulous attention to technical details. The use of fine monofilament sutures with fine needles could also reduce tissue damage, improving postoperative outcomes.

Certainly the absence of routine detection of pancreatic texture constituted a lack of the study.

The inability to tolerate a solid diet by POD 7 should be considered as DGE, occurring in 14% – 21% of patients after PD with prolonged hospitalization [1, 3, 4, 45]. The consensus definition of DGE after pancreatic surgery without mechanical obstruction was reached in 2007 by ISGPS and classified into Grades A, B and C [17]. As others author reported, in PPPD we always performed a dilatation of the pylorus with farabeuf until calibration to 26 mm [54].

PPH occurs in 1–8% of all pancreatic resection and represents from 11–18% of overall mortality [45, 47, 55]. In the literature, it was defined on the basis of 3 criteria: time of onset (early PPH occurring in the first 24 hours and late PPH occurring after 24 h postoperative), location (intra or extraluminal), cause and severity. In 2007, ISGPS proposed classifying PPH as A, B and C [15].

Reoperation is life-threatening: its rate was reported to be between 2,7% and 8% [1, 3, 7, 48, 56]. In our experience, the overall reoperation rate was (5,7%) in group 1° and 2,8% in group 2°. Mortality for all reoperations was 16,6% (1/6).

Several authors reported operation time, blood loss and length of stay as features of surgery [32, 45, 48]. In our experience, operative time was longer in group 2° ($P < 0,001$), perhaps for more time to perform pancreaticojejuneal anastomosis and probably due to vascular resection. Length of stay was decreased in group 2° ($P < 0,001$) because of lower numbers of complications, especially POPF.

Conclusion

In conclusion, the comparison between two groups of patients with different pancreatico-jejuneal anastomosis showed a lower rate of clinically relevant POPF and lower morbidity, mortality and length of

stay in the second group of patients.

Although it is a long period of study observation, it seems that the reduction of fistulas is mainly dependent on the type of anastomosis rather than other factors.

We consider this technique to be safe and reproducible by other surgeons through an educational surgical program.

The standardization of technical surgical details and careful perioperative care are crucial aspects, in our experience.

Furthermore, we believe, like Traverso, that "*surgery alone is not sufficient"* for pancreatic cancer [57]. The goal is to avoid morbidity, as the best candidate for adjuvant treatment will be that patient who has no delay in postoperative recovery.

List Of Abbreviations

CR-POPF Clinically relevant postoperative pancreatic fistula

PD Pancreaticoduodenectomy

ISGPF International Study Group of Pancreatic Fistula

ISGPS International Study Group of Pancreatic Surgery

PPPD Pylorus preserving pancreaticoduodenectomy

PBD Preoperative biliary drainage

PDS Polydioxanone

PPH Postpancreatectomy haemorrhage

DGE Delayed gastric emptying

POD Post operative day

TNM Tumor nodes metastasis

ICU Intensive care unit

PA Pancreatic anastomosis

PJ Pancreaticojejunostomy

Declarations

Ethical approval and consent to partecipate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This retrospective study did not need the approval of the ethics committee. Written informed consent was obtained from all patients before surgery.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request

Competing interests

The authors declare that they have no competing interests.

Funding

No funding has been received for this study.

Acknowledgements

Not applicable

Author contributions

TZ, SO and FZ designed the study, TZ, SO and LM contribuited to data acquisition and analysis, TZ, SO and FZ were involved in interpretation of data and writing of the paper, FZ and TZ critically revised the manuscript.

All authors have read and approved the manuscript.

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Figures

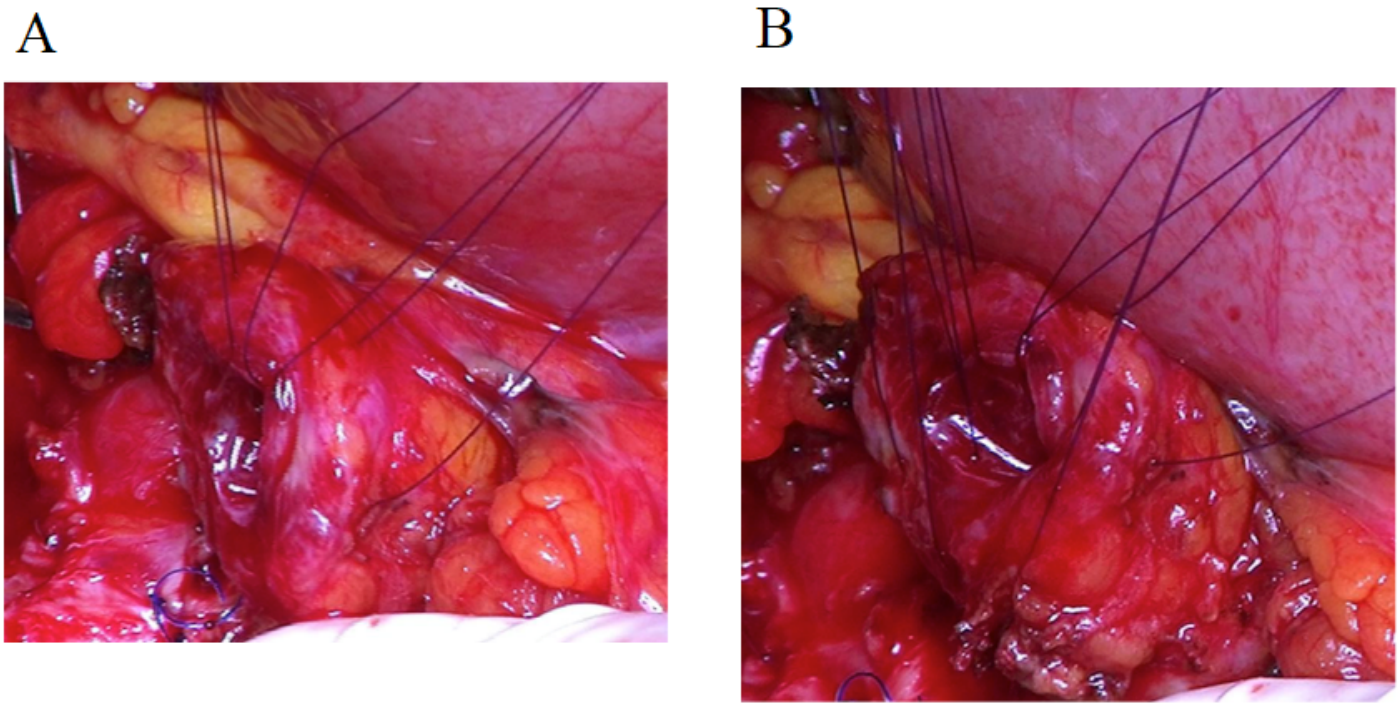

Figure 1

a: Anterior ductal sutures. b: Posterior ductal sutures.

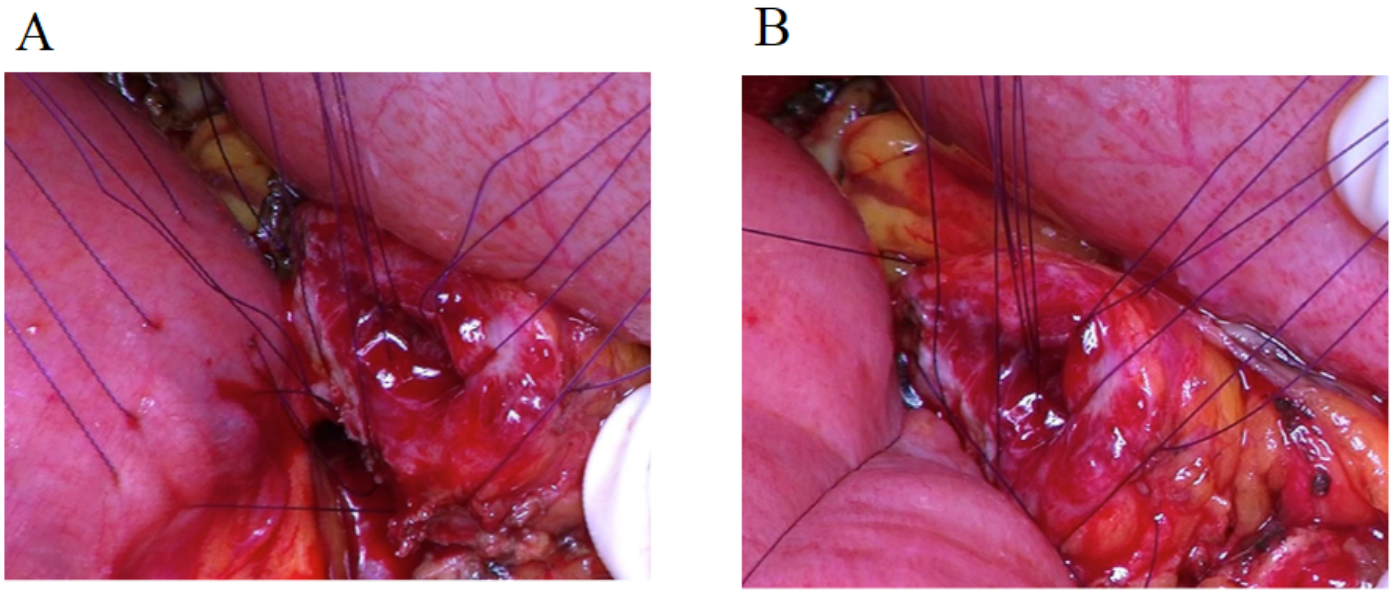

Figure 2

a: Posterior outer layer. b: Posterior outer layer completed.

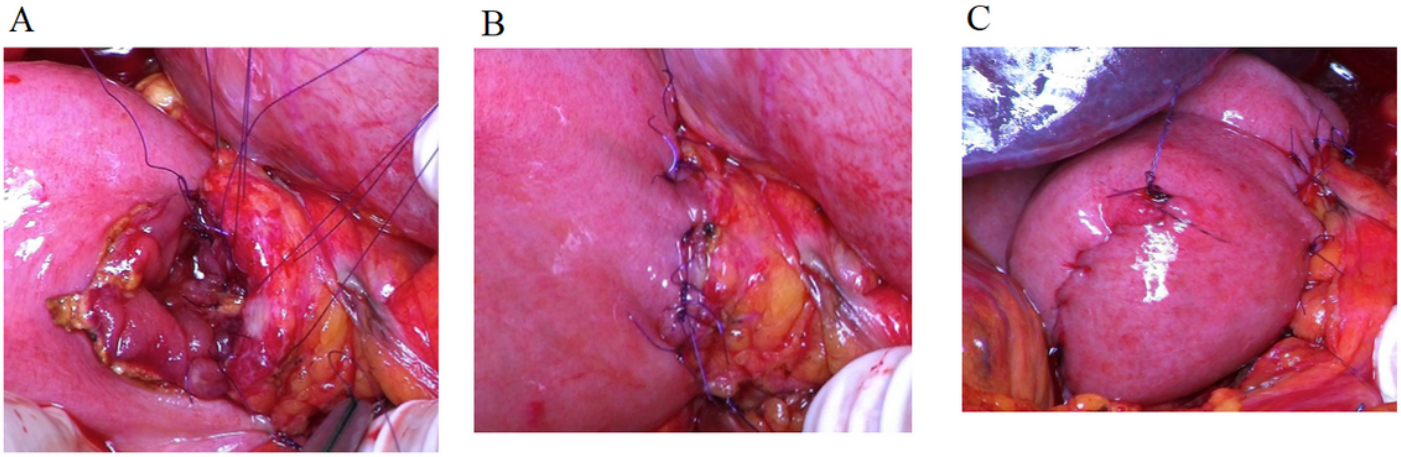

Figure 3

a: Posterior inner layer. b: Anterior inner layer. c: Completed anastomosis with anterior outer layer.