

Isolated Roux-en-Y loop for pancreatic and gastro-biliary anastomoses versus conventional single-loop jejunal reconstruction after pancreaticoduodenectomy: a randomized comparative study

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Background

Pancreaticoduodenectomy (PD) is the definitive treatment in managing malignant and selected benign pancreatic and periampullary lesions. Pancreatico-enteric anastomosis is the 'Achilles heel' of reconstruction. Postoperative pancreatic fistula (POPF) paves the way for other complications and increases their severity. Anastomotic diversion into two isolated loops may contribute to decrease these problems.

Patients and methods

Fifty-two patients underwent PD for different pancreatic and periampullary lesions. The patients were divided randomly into two groups: 26 patients each. Isolated pancreatic anastomosis was done using Roux-en-Y loop reconstruction for pancreatic and gastro-biliary anastomoses were performed in one group, while conventional single jejunal loop was used for pancreatic, biliary, and gastric anastomoses. Preoperative, operative, and postoperative data were recorded and analyzed.

Results

There was no significant statistical difference between study groups in demographic data, comorbidities, clinical presentation, or type and site of pathologies. There was a significant difference favoring the isolated loop group as regards the hospital stay, time for drain removal, and major complication rates ($P=0.007$, 0.020 , and 0.035 , respectively). POPF, biliary leakage, steatorrhea, postoperative hemorrhage, need for reoperation, delayed gastric emptying, intra-abdominal sepsis, time to resume oral fluids, and the postoperative mortality or morbidity within the first 30 postoperative days were reduced in the isolated loop group but the difference did not reach a statistical significance. While postoperative wound infection and pulmonary complications were less in the conventional groups but also the difference did not reach a statistically significant value.

Conclusion

Isolated Roux-en-Y loop pancreaticojejunostomy after PD is safe and easy. There was a reduction of POPF and biliary leak that did not reach a significant value, however, it decreased its related complications with significant reduction of hospital stay, time for drain removal, and major complication rates.

Keywords:

isolated Roux-en-Y loop, pancreaticoduodenectomy, pancreaticojejunostomy, postoperative pancreatic fistula

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Introduction

Pancreaticoduodenectomy (PD) is considered the appropriate management for selected patients with benign and malignant diseases of the pancreas and periampullary region [1,2]. It results in removal of important multiorgans in the upper intestinal tract and leads to secondary physiologic sequelae [3]. Based on the literature of the previous decades, there was a belief that it should be avoided due to its extremely high rates of morbidity (>70%) and mortality (>30%) [4]. Although the rates of

morbidity and mortality have been reduced significantly, still the pancreatico-enteric anastomosis is considered as the 'Achilles heel' of the modern-day single-stage PD. The postoperative pancreatic fistula (POPF) is responsible for up to 45% of complications [5]. Till 2005, there were 26 different definitions of

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POPF. This had its impact to hinder reliable comparisons of outcomes among surgeons in different clinical centers who had relied on different definitions of POPF. In 2005, an international working group of 37 pancreatic surgeons in the International Study Group of Pancreatic Fistula (ISGPF) met to reach a universally accepted objective definition of POPF. The POPF was defined as an abnormal communication between the pancreatic ductal epithelium with another epithelial surface containing pancreas-derived, enzyme-rich fluid. A consensus was agreed defining the POPF as fluid output of any measurable volume via an operatively placed drain with amylase activity more than three times the upper normal serum value. A clinical system of three different grades of POPF (grades A, B, and C) was proposed according to the complication-specific severity [6].

The POPF is challenging, even at high-volume centers, as it significantly increases the hospital bill, stay, and mortality. It has many odious sequelae like postoperative hemorrhage, intra-abdominal collection, delayed gastric emptying, and sepsis [7]. Over the last decades, a lot of scientifically backed technical renovation has been tried to decrease factors that may cause the poor results of a pancreatico-enteric anastomosis and higher incidence of POPF. Examples are using a trans-anastomotic stent, working under magnification, and using somatostatin analogs. There was more tendency to adhere to the basic principles of surgical reconstruction, including gentle pancreatic handling, careful and meticulous anastomosis, ensuring a satisfactory blood supply at the anastomotic areas, and absence of distal obstruction or tension [5,8]. One of the examples is implementation of double-loop reconstruction with isolated Roux-en-Y loops for pancreatic and biliary anastomoses. This was described for the first time in 1976 by Machado and colleagues, aiming to decrease the morbidity and mortality rates, then, it has afterward been applied by many surgeons in different variations [9,10].

Based on the previous data, the current study has been designed aiming to evaluate the value of isolated Roux-en-Y loops for pancreatic and gastro-biliary anastomoses, where the term 'isolated' Roux-en-Y loop always means isolation of the pancreatic anastomosis.

Patients and methods

This is a clinical comparative prospective study that has been performed on 52 patients, recruited from the

Outpatient Surgery Clinic at Faculty of Medicine, Menoufia University, and planned to have PD from January 2015 to January 2022. The study was approved by the authors' institution ethical and research committees and a written informed consent was obtained from all patients to be included in the study.

Patient selection

The inclusion criteria to this study were patients with pancreatic, duodenal, or distal common bile duct lesions who were candidates for PD. However, patients with metastatic or locally advanced irresectable tumors, those who were unfit for operation due to major comorbidities (severe malnutrition, uncontrolled cardiac or respiratory condition, and poor hepatic functions with impaired coagulopathy) were excluded from the study. Exclusion criteria also included patients with previous gastro-enteric or bilio-enteric anastomosis for any other indication.

All the included patients have been subjected routine preoperative assessment in the form of routine laboratory tests and echocardiography. The tumors were staged and assessed for resectability by computed tomography scan abdomen (pancreatic protocol). Endoscopic retrograde cholangiopancreatography was performed for biliary drainage in patients with obstructive jaundice (serum bilirubin levels of >10mg/dl or when this was associated with high liver enzymes) [more than threefold the normal level (i.e. >120 IU/ml)] [7].

All patients have been subjected to classic PD, then the patients were randomly divided after resection, by closed-envelope method, into two equal groups, 26 patients each, based on the reconstruction techniques. The first group was the conventional (control) group in which gastric, biliary, and pancreatico-enteric anastomoses were accomplished by single loop (pancreaticojejunostomy). While in the other group pancreatico-enteric continuity was restored by isolated Roux loop pancreaticojejunostomy.

Operative details

PD was done by the standard method with mobilization of duodenum and head of pancreas. Partial pancreatectomy was performed left to the superior mesenteric vein and distal antrectomy with no pyloric preservation (Fig. 1).

In the conventional group, the transected jejunal loop was brought through a defect in the transverse mesocolon and anastomosed to the pancreatic

remnant, followed (40 cm downstream) sequentially by a standard hepaticojejunostomy and finally gastrojejunostomy (Fig. 2). While in the isolated

Figure 1

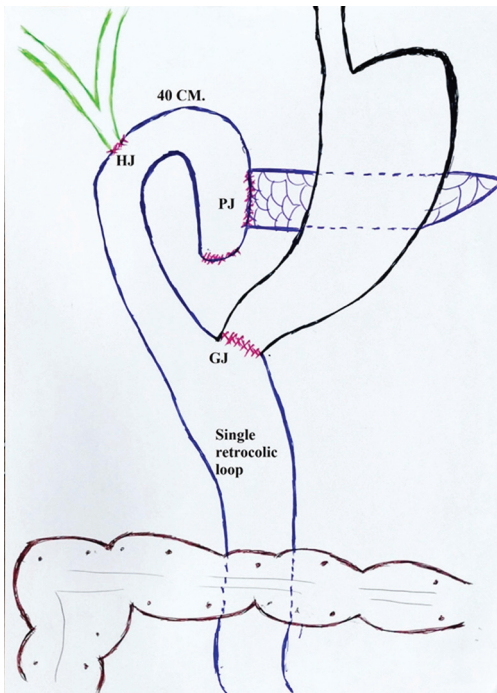


Pancreaticoduodenectomy and preparing the field for anastomoses.

loop group, the transected jejunum was brought through the mesocolon, to be anastomosed in an end-to-side fashion to the pancreatic remnant. A separate antecolic Roux jejunal loop was fashioned for the hepaticojejunal anastomosis by dividing the jejunum about 50–60 cm distal to the pancreatic anastomosis, and the gastro-jejunal anastomosis was performed 30 cm downstream from the hepaticojejunostomy. Finally, the pancreatic loop was implanted in this efferent loop 20 cm distal to the gastro-jejunal anastomosis (Figs 3–6).

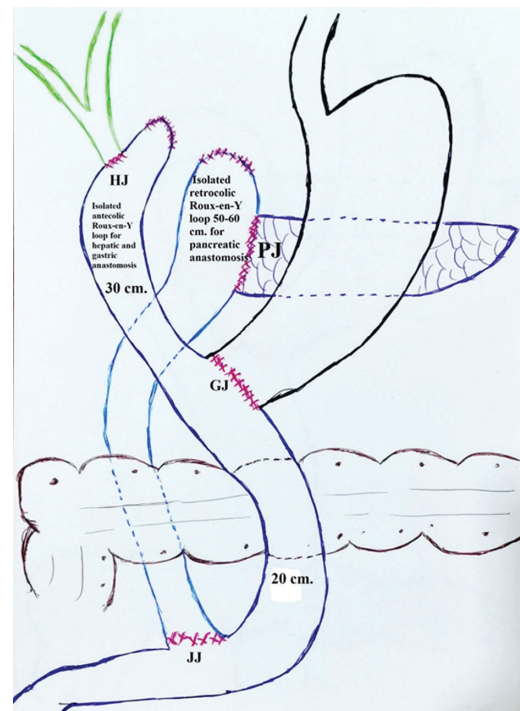
All the jejuno-pancreatic anastomoses were hand-sewn and constructed in an end-to-side fashion with two layers. The inner layer was a sutured duct to the mucosa using 5/0 vicryl-interrupted sutures in a radial manner, and the outer layer was sutured between the pancreatic capsule and the jejunal seromuscular layer using 3/0 proline-interrupted sutures. Ductal stents, fibrin glue, and omental wrapping were not used in all cases. The biliary continuity was restored by end-to-side hepaticojejunostomy using interrupted 4/0 vicryl sutures, while the gastrointestinal anastomosis was accomplished in an end-to-side fashion using 3/0 vicryl continuous sutures in two layers.

Figure 2



Single retrocolic loop used in conventional (control) group showing pancreaticojejunosomy (PJ) followed 40 cm down-stream sequentially by a standard hepaticojejunostomy (HJ) and finally gastrojejunostomy (GJ). All anastomoses are fashioned in end-to-side manner.

Figure 3



Isolated Roux-en-Y loops, where there is an isolated 50–60 cm reterocolic loop for pancreaticojejunosomy (PJ), and another antecolic loop for standard hepaticojejunostomy (HJ) and finally 30 cm downstream gastrojejunostomy (GJ) then the isolated pancreatic loop joins it by jejunojejunosomy (JJ) 20 cm downstream after the GJ.

Figure 4



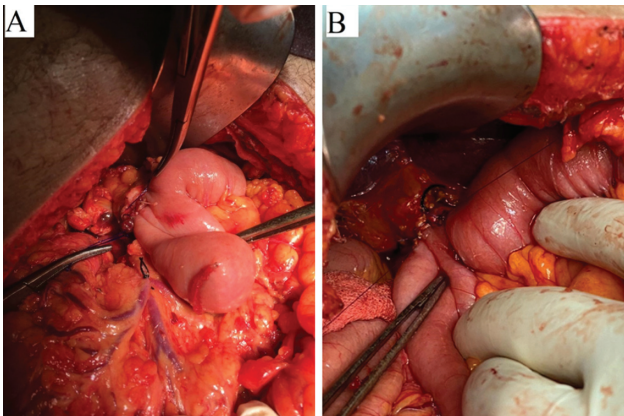
Preparing the double Roux-en-Y Loop loops, one isolated Roux-en-Y Loop for pancreaticojejunostomy (PJ) and the other for hepaticojejunostomy (HJ) and gastrojejunostomy (GJ).

Figure 6



Gastrojejunostomy (GJ) then the isolated pancreatic loop joins it by jejunojejunostomy (JJ).

Figure 5



(a, b) Isolated Roux-en-Y Loop for pancreaticojejunostomy (PJ) showing the PJ anastomosis.

After checking for good hemostasis and the integrity of the accomplished anastomoses, two large-bore soft drains were inserted to drain the performed anastomoses.

Postoperative management and follow-up

All patients were admitted to the ICU for at least 1 day and then transferred to the ward. The drains and nasogastric tube output were recorded daily. The amylase level in serum and drainage fluid were

recorded daily from the third postoperative day and afterward. Patients resumed oral feeding starting from the fourth postoperative day, except there was a cause to hinder the oral feeding, for example, development of POPF. Patients started by oral fluids followed by a soft diet once patients were able to tolerate oral feeding. The drains were removed when their output dropped below 30 ml/day and the amylase concentration was less than twice the serum concentration. Based on its importance and effect on other outcomes, we considered the POPF as the primary outcome of the study. We adopted the modified ISGPF for POPF where we considered occurrence of POPF if the drained fluid has an amylase level reaching triple fold its serum level. However, other complications were considered the secondary outcome.

Follow-up abdominal ultrasound was performed routinely to all patients and ultrasound-guided percutaneous drainage was requested in patients who demonstrated localized abdominal collection. Follow-up was conducted after discharge at 1 week, 2 weeks, 1 month, 3 months, and 6 months at the outpatient clinic and if symptoms developed between follow-up visits.

Statistical analysis of the collected data

Sample size was calculated by GPower software (GPower ApS with headquarters at Samsøvej 31, 8382 Hinnerup, Denmark) [11], and has been

estimated to be 20 participants in each group (40 in both groups) based on a previous study by Casadei *et al.* [12]. Data were collected, tabulated, and statistically analyzed by an IBM-compatible personal computer with SPSS Statistical Package, Version 23 (SPSS Inc. Released 2015. IBM SPSS Statistics for Windows, Version 23.0; IBM Corp., Armonk, New York, USA). Data were expressed in number, percentage, mean, and SD. Student's *t* test was used for comparison of quantitative variables between two groups of normally distributed data, while Mann–Whitney's test was used for not normally distributed ones. χ^2 test was used to study the association between qualitative variables. Whenever any of the expected cells were less than five, Fisher's exact test was used. A two-sided *P* value of less than 0.05 was considered statistically significant.

Results

The study included 52 patients divided equally into the two study groups, 26 patients each. There was no statistically significant difference between the two groups regarding the demographic data or preoperative clinical presentations as shown in Table 1. Comparing the two groups regarding pathological data revealed that there was no statistically significant difference such as location of the tumor or its pathological type, or regarding operative data as the diameter of the pancreatic duct and pancreatic texture. Although the extra maneuver in the isolated loop group had consumed longer operative time and resulted in more blood loss than the conventional group, however, it did not reach a statistically significant level with *P* values 0.219 and

Table 1 Patient's demographics and preoperative variables

Characters	Conventional group (N=26)	Isolated loop group (N=26)	<i>P</i> value
Age (years)	57.30±6.04	56.23±7.35	0.567
Range	41.0–67.0	36.0–67.0	
Sex [<i>n</i> (%)]			
Male	15 (57.7)	16 (61.5)	0.777
Female	11 (42.3)	10 (38.5)	
Complaint [<i>n</i> (%)]			
Obstructive jaundice	14 (53.8)	16 (61.5)	
Pain	7 (26.9)	6 (23.1)	0.865
Weight loss	5 (19.2)	4 (15.4)	

Table 2 Pathological and operative details

Variables	Conventional group (N=26) [<i>n</i> (%)]	Isolated loop group (N=26) [<i>n</i> (%)]	<i>P</i> value
Site			
Pancreatic head	18 (69.2)	19 (73.1)	0.802
Duodenum	7 (26.9)	5 (19.2)	
Distal CBD	1 (3.8)	2 (7.7)	
Pathology			
Malignant	20 (76.9)	18 (69.2)	0.892
Benign	2 (7.7)	2 (7.7)	
Borderline	4 (15.4)	6 (23.1)	
Pancreatic duct diameter			
≤3 mm	11 (42.3)	12 (46.2)	0.780
>3 mm	15 (57.7)	14 (53.8)	
Texture of pancreas			
Soft	11 (42.3)	10 (38.5)	0.777
Firm	15 (57.7)	16 (61.5)	
Operative time (min)			
Mean±SD	283.26±31.71	296.80±45.42	
Median	286.50	298.50	0.219
Range	216.0–365	200.0–398.0	
Blood loss (ml)			
Mean±SD	690.15±281.82	743.23±264.46	
Median	655.0	775.0	0.487
Range	240.0–1220.0	250.0–1450.0	

0.487 for operative time and blood loss, respectively, as shown in Table 2.

The postoperative course of the included patient is summarized in Table 3. Postoperative data can be categorized into three main categories. In the first category, there was a statistically significant difference between the two study groups favoring the isolated loop group over the conventional group, namely, duration of hospital stays ($P=0.007$) and duration to remove the drain ($P=0.035$). Last, the postoperative complications were grouped based on the Clavien–Dindo classification of surgical complications [13]. GIII and above (serious) postoperative complications have occurred in two (7.7%) patients in the isolated loop group compared with eight (30.8%) patients in the conventional group with P value of 0.035.

In the second category, there was reduction of the incidence of some postoperative data and complications favoring the isolated loop group over the conventional group, but it did not reach a statistically significant value. These have been shown in time to resume oral fluids, POPF, delayed gastric emptying, intra-abdominal sepsis, biliary leakage, steatorrhea, postoperative hemorrhage, need for reoperation, postoperative mortality, and number of

patients with morbidity within the first 30 days. On the other hand, the third category comprises a reduction of the incidence of some postoperative complications like postoperative wound infection and postoperative pulmonary complications favoring the conventional group over the isolated loop group, with still no statistically significant difference.

Discussion

Although there are a lot of advances in perioperative care and management in addition to modifications in surgical techniques, still the morbidity rates record high percentages reaching as high as 30–50% even in high-volume centers. The bile reflux into the pancreatic duct is a known inductor of acute pancreatitis, especially in the presence of sepsis. Biliary secretions activate the pancreatic enzymes and augment the effect of proteolytic enzymes with their hazardous effect on enteric anastomosis after PD. The isolated pancreaticojejunostomy Roux loop provides the advantage of preventing the mixing of pancreatic juice with the bile and intestinal content with consequent limiting of activation of pancreatic secretion by bile and the resultant better and faster anastomotic healing even in the presence of fistula or anastomotic dehiscence [10,14–17]. This study was a trial to evaluate the isolated pancreaticojejunostomy

Table 3 Postoperative course and complications

Variables	Conventional group	Isolated loop group	P value
Hospital stay (days)			
Mean±SD	11.53±4.05	9.53±4.01	0.007*
Median	10.0	8.0	
Range	7.0–22.0	6.0–23.0	
Time to resume oral fluids (days)			
Mean±SD	7.96±3.56	6.70±2.73	0.300
Median	7.0	7.0	
Range	4.0–19.0	4.0–15.0	
Time to remove the drain (days)			
Mean±SD	14.23±4.95	11.88±4.69	0.020*
Median	13.0	10.0	
Range	9.0–28.0	8.0–24.0	
POPF [n (%)]	5 (19.2)	3 (11.5)	0.703
Delayed gastric emptying [n (%)]	5 (19.2)	3 (11.5)	0.703
Wound infection [n (%)]	6 (23.1)	7 (26.9)	0.749
Intra-abdominal sepsis [n (%)]	4 (15.4)	2 (7.7)	0.668
Biliary leakage [n (%)]	6 (23.1)	3 (11.5)	0.465
Pulmonary complications [n (%)]	4 (15.4)	5 (19.2)	0.714
Hemorrhage [n (%)]	2 (7.7)	0	0.490
Reoperation [n (%)]	3 (11.5)	1 (3.8)	0.610
Steatorrhea [n (%)]	7 (26.9)	2 (7.7)	0.140
Patient with serious complications [n (%)]	8 (30.8)	2 (7.7)	0.035*
Patients with post-operative morbidity within 30 days [n (%)]	10 (38.5)	9 (34.6)	0.773
Postoperative mortality within 30 days [n (%)]	2 (7.7)	1 (3.8)	0.552

*POPF, postoperative pancreatic fistula.

Table 4 Comparison of different studies results with the results of the current study

References	Technique	No. of patients	Hospital stays Days	POPF n (%)	Bile leak n (%)	Morbidity n (%)	Mortality n (%)	Conclusions
Machado et al. [10]	Isolated Roux-en-Y loops PJ	15	20	2 (13.3)	-	-	0	This technique reduced morbidity and death rates
Yeo et al.[34]	Conventional PJ	72	17.7±1.5	8 (11)	3 (4)	31 (43)	1 (exclude)	PG is equal to conventional PJ with no superiority for any over the other
	PG	73	17.1±1.6	9 (12)	1 (1.36)	36 (49)	0	
Kaman et al.[14]	Isolated loop PJ	60	17.75 ±6.30	6 (10)	7 (12)	29 (48)	5 (8.3)	No significant difference in reduction of POPF between both groups
	Single loop PJ	51	17.50 ±6.02	6 (12)	2 (4)	23 (45)	4 (7.8)	
Casadei et al. [12]	Isolated loop PJ	18	17.0±6.9	2 (11.1)	-	6 (33.3)	0	The isolated Roux loop is safe and easy with similar results as conventional one with significant reduction in hospital stay length
	Single loop PJ	20	32.0 ±PG 16.6	3 (15.0)	-	4 (20.0)	1 (5)	
Fernandez-Cruz et al.[35]	PPPD – with Conventional PJ	55	12±2	10 (18)	1 (2)	24 (44)	0	The PPPD-GP is safe and is associated with lower complication rate than PPPD-PJ
Fragulidis et al. [18]	PPPD-PG with gastric partition	53	16±3	2 (4)	0	12 (23)	0	
	Isolated loop PJ (short loop +invaginated duct anastomosis)	32	16.4±1.8	6 (18.75)	1 (3.1)	19 (59)	1 (3.1)	
	Isolated loop PJ (short loop+duct to mucosa anastomosi)	31	15.9±1.9	3 (10)	1 (3.1)	13 (42)	1 (3.1)	
	Isolated loop PJ (long loop +invaginated duct anastomosis)	30	10.6±2	3 (10)	0	10 (33)	0	Using a long isolated jejunal loop with duct-to mucosa Pancreaticojejunostomy decreased the pancreatic leakage rate after pancreaticoduodenectomy
Ballas et al.[25]	Isolated loop PJ (long loop+duct to mucosa anastomosis)	39	10.3±2.5	0	0	9 (23)	0	
	Isolated loop PJ	46	14.6±5.5	2 (4.3)	-	18 (39.1)	1 (2.2)	The isolated Roux loop, is equally safe alternative for single loop with similar results, and more studies are required to further clarify its efficacy
Wellner et al. [36]	Single loop PJ	42	19.5 ±10.1	3 (7.1)	-	13 (30.9)	1 (2.3)	
	Conventional PJ	57	17 (10–60)	1 (1.7)	1 (1.7)	-	1 (1.7)	PG and PJ as reconstruction techniques have similar results, with shorter time associated with PG technique
	PG	59	15 (7–135)	1 (1.7)	1 (1.7)	-	1 (1.7)	
Ke et al.[2]	Isolated loop PJ	107	18.7±1.8	17 (16)	2 (2)	49 (46)	0	Isolated loop PJ didn't significantly lower the rate of POPF It decreased fistula severity, duration of stay, and hospital bill (Continued)

Table 4 (Continued)

References	Technique	No. of patients	Hospital stays Days	POPF n (%)	Bile leak n (%)	Morbidity n (%)	Mortality n (%)	Conclusions
Topal <i>et al.</i> [37]	Conventional PJ	109	19.1±1.6	19 (18)	3 (3)	52 (48)	0	Pancreaticogastrostomy is better than pancreaticojejunostomy in decreasing the rate of POPF
	Conventional PJ	167	18 (14–25)	33 (19.7)	–	115 (69)	8 (5)	
	PG	162	19 (14–25)	13 (8)	–	108 (67)	4 (3)	
El Nakeeb <i>et al.</i> [7]	Isolated loop P	45	8 (5–41)	9 (20)	4 (8.88)	14 (31.1)	3 (6.66)	Isolated Roux loop PJ did not lower rate the POPF to a significant level It decreased the postoperative steatorrhea. and allowed for early oral feeding
	PG	45	9 (4–34)	10 (22.2)	6 (13.3)	17 (37.8)	4 (8.88)	
Machado and Machado[15] Li <i>et al.</i> [24]	Isolated loop PJ	214	9.7±4.1	42 (19.6) from which 38 (17.7) grade A	2 (1)	68 (32)	0	Isolated loop PJ decreases the severity of POPF with decreasing its complications Similar results were seen in both groups with no significant superiority for any group over the other
	Isolated loop PJ	43	21.3 ±13.4	10 (23.2) from which 6 (14) grade A	2 (4.65)	22 (51.2)	1 (2.32)	
Aghalarov <i>et al.</i> [9]	Conventional PJ	43	23.2 ±12.7	11 (25.6) from which 9 (21) grade A	1 (2.32)	25 (58.1)	1 (2.32)	The modified single loop was faster than the isolated loop and safer POPF is reduced but didn't reach a significant level but it decreased its related complications
	Isolated loop PJ	25	19±10	6 (24)	0	25 (100)	0	
Current study	Single loop PJ	50	35±14	13 (26)	4 (8)	46 (92)	4 (8)	Reduction of POPF in isolated loop group but didn't reach a significant level but it decreased its related complications Significant reduction of hospital stay, time for drain removal and major complications rate
	Modified single loop PJ	50	21±9	13 (26)	2 (4)	49 (98)	0	
	Isolated Roux-en-Y Loops PJ	26	9.53 ±4.01	3 (11.5)	3 (11.5)	9 (34.6)	1 (3.8)	
	Conventional PJ	26	11.53 ±4.05	5 (19.2)	6 (23.1)	10 (38.5)	2 (7.7)	

PG, pancreaticogastrostomy, single loop; PJ, conventional pancreaticojejunostomy; PJ, PPD, pylorus-preserving pancreatoduodenectomy; POPF, postoperative pancreatic fistula.

Roux loop after PD in decreasing postoperative complications.

Fragulidis *et al.* [18] in their study evaluating the optimum length for the isolated jejunal loop documented in a comparison between a short loop (20–25 cm) versus long loop (40–50 cm). They concluded that there was a statistically significant reduction in the incidence of POPF, morbidity, and hospital stay duration favoring the long-loop group. Longer Roux loop can decrease the biliary reflux, hence lower incidence of POPF. The same has been reported by other authors such as Tani *et al.* [19] and El Nakeeb *et al.* [7] who used a 40-cm loop length, while Ke *et al.* [2] and Clemente *et al.* [20] used a 60-cm isolated loop length. In the current study, the same principle has been followed where the isolated Roux jejunal loop length was 50–60 cm. Even in the conventional group, the hepaticojejunostomy was performed 40 cm downstream from the pancreaticojejunostomy so that the long-loop methods have been performed for both groups. Moreover, the suturing technique of pancreaticojejunostomy, either duct to mucosa or invagination techniques, has been demonstrated to have an impact on the integrity of the anastomosis and incidence of POPF. Although Li and Hua [21] did not document significant changes between both techniques regarding the incidence of POPF, meanwhile, other reports have stratified the indication of either technique. Hosotani *et al.* [22] concluded that duct-to-mucosa anastomosis might be the procedure of choice, however, invagination pancreaticojejunostomy could be more suitable with a smaller pancreatic duct or soft pancreas. On the other hand, Fragulidis *et al.* [18] and Binziad *et al.* [23] have demonstrated a statistically significant reduction in the incidence of POPF favoring the duct-to-mucosa method over the invagination method. In the current study, duct-to-mucosa anastomosis method in an end-to-side fashion has been performed in all cases.

It is quite logical that adding extra maneuver to the operative procedure in the isolated loop group will result by default into a longer operative time and could be associated with more operative blood loss. In the current study, operative time was longer with slight increase in blood loss in the isolated loop group, but the difference was not statistically significant. These have been also documented in many studies as regard blood loss [2,7,9,12,14,24]. Whereas other authors documented that the time difference between the groups reached a statistically significant value favoring the conventional group [7,9,14,24–26].

POPF is the main accused factor for morbidity as it can lead to sepsis, intra-abdominal abscesses, or even lethal hemorrhage caused by pancreatic juice autolytic activity that can lead to mortality [1,24,27–32]. Also, for this reason, in this study, we considered the POPF as the primary outcome of the study, while other complications were considered the secondary outcome.

Although there was a consensus by ISGPF to define the POPF with its three grades, there were some gray zones and unclear areas that needed a new revision again from the same ISGPF. Having the same definition for the POPF, but grade A is no longer considered a true pancreatic fistula or a real complication and called a 'biochemical fistula' or biochemical leak in the literature. The biochemical leak has by definition no clinical impact and implies no deviation for the normal postoperative sequelae, therefore, it does not affect the normal postoperative length of stay. While grade B is present if there is persistent drainage more than 3 weeks, clinically relevant change in management of POPF, percutaneous or endoscopic drainage, need for angiographic procedures for bleeding, or signs for infection without organ failure. Last, grade C is present if the patient is reoperated, organ failure occurred, or the patient died [33]. Based on the described updated criteria, POPF has been considered in the current study when at least grade B was documented. It has been observed to have less incidence in the isolated loop group compared with the conventional group, however, the difference did not show a statistical significance. Similar results were documented by many other authors [2,7,9,12,14,24,25], however, Ke *et al.* [2] reported that the difference has reached a statistically significant level with grade A and grade B types. Although Casadei *et al.* [12] and Ballas *et al.* [25] documented a reduction in the incidence of the POPF with isolated loop, they have reported an increase in the incidence of overall complications, in contrast to the current study that documented less incidence in overall morbidity within the first 30 postoperative days for this group.

Some authors such as Aghalarov *et al.* [9], Casadei *et al.* [12], and Ke *et al.* [2] have documented significant decrease in hospital stay and bill favoring the isolated loop group. This matches with the results of the current study that was an indirect indicator of the lower incidence of serious complications as well. While other authors reported that hospital stay was shorter in the isolated loop group but did not reach a statistically significant difference [7,14,25,27].

Table 4 summarizes the results of POPF, biliary leak, hospital stays, and mortality rate comparing the results of the current study with other similar studies. A lot of variations have been observed in the results of different studies in spite of reduction of the incidence of POPF in most of them in the isolated loop group. This could be contributed to previous nonstandardization of the definition for POPF or due to specific differences in preoperative demographic data or morbidities of the patients.

In the current study, there was higher incidence postoperative wound infection and pulmonary complications in the isolated loop group compared with the conventional group, but the difference did not reach a statistically significant value. Similar results were documented by many other authors [2,7,12,14,24,25]. This could be explained by the longer operative duration, increased handling of viscera, and more blood loss even with compensation.

Conclusion

Isolated Roux-en-Y loop pancreaticojejunostomy after PD is a safe and easy maneuver with nonsignificant prolongation of operative time or blood loss. There is reduction of POPF and biliary leak but with a nonsignificant difference. But it can significantly decrease its related complications with significant reduction of hospital stay.

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Conflicts of interest

There are no conflicts of interest.

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