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ORIGINAL ARTICLE

Low incidence of pancreatic fistula and well-preserved endocrine function with non-reconstructed small remnant pancreas after pancreaticoduodenectomy

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Abstract

Aim: Pancreatic reconstruction after pancreaticoduodenectomy (PD) that leaves a small remnant pancreas is often difficult. Pancreatic fistula is a major complication after PD, and fistulas are rare in patients with hard pancreas. However, the clinical impact of non-reconstructed small remnant after PD with hard pancreas is unknown.

Methods: We included all patients who underwent PD for pancreatic tumor without pancreatic reconstruction in two institutions supervised by one surgeon between January 2004 and March 2021. Their short- or long-term outcome after surgery was retrospectively analyzed.

Results: PD was performed in 774 patients, of whom 16 patients were without reconstruction (2.1%) with negative margins at the pancreatic stump. Pancreatic transection was performed above or to the left of the superior mesenteric artery, with a median remnant pancreas length of 3.7 cm (range, 1.3–10.0). A major complication (≥ Clavien–Dindo Grade IIIa) occurred in one patient (6%). Fistula of grade B occurred in one patient (6%). After a median follow-up of 44 months (95%CI, 10.6–77.3), insulin administration was unnecessary in 11 patients.

Conclusion: The preservation of a small pancreatic remnant without reconstruction after PD can be performed safely and may enable the keeping of pancreatic endocrine function for some selected patients with hard pancreas.

KEYWORDS
glucose tolerance, hard pancreas, non-reconstructed remnant pancreas, pancreatic fistula, pancreaticoduodenectomy

1 | INTRODUCTION

Pancreatic reconstruction is a standard procedure during pancreaticoduodenectomy (PD) or middle pancreatectomy. When tumor infiltration extends widely from pancreatic head to body/tail, the pancreas is divided on the left side of superior mesenteric artery (SMA) leaving a small remnant pancreas. Pancreatic reconstruction with small remnant pancreas is often challenging due to the deep anastomotic location and small main pancreatic duct.[1] Although total pancreatectomy is sometimes selected when the tumor spread is observed widely, the impact on the patients' quality of life due to the loss of pancreatic exocrine and endocrine function is considerable.[2] Furthermore, insulin replacement therapy, which is essential after total pancreatectomy due to the loss of insulin secretion, seriously diminishes the quality of life in affected patients.

While there have been a few case reports on PD without pancreatic reconstruction,[3,4] this study of 16 patients who underwent PD without reconstruction contains the largest number of patients to date to our knowledge. We hypothesized that preservation of a small pancreatic remnant could secure endocrine function and spare some patients the need for insulin self-injection therapy. To date, the clinical implications of preserving the pancreatic remnant has not been well investigated; however, Iizawa et al. reported that the volume of remnant pancreas after PD did not impact the incidence of new-onset or exacerbation of diabetes mellitus in contrast to exocrine pancreatic function.[5]

A major concern of foregoing pancreatic reconstruction is a risk of intractable pancreatic fistula. Once pancreatic fistula occurs, healing is complicated by the lack of a digestive drainage route. The texture of the remnant pancreas is a significant factor for developing pancreatic fistula. Toyama et al.[3] reported a case of a patient undergoing PD with non-reconstructed pancreatico-enterostomy due to total fat replacement of the remnant pancreas and an uneventful postoperative course without pancreatic fistula. The soft texture of the pancreas is widely accepted as a significant risk factor for pancreatic fistula.[6,7] It has been reported that exocrine function would be abolished in extremely small remnant and hard pancreas.[3,8] Therefore, we hypothesized that pancreatic reconstruction with hard and small remnant pancreas could be omitted. In our institution, non-reconstruction of pancreatico-enterostomy is indicated if the remnant pancreas fulfills the following criteria: (1) small remnant pancreas with a length of several centimeters, and (2) hard pancreas due to tumor obstruction.

In this retrospective study, we investigated the short- and long-term outcomes after PD with non-pancreatic reconstruction leaving a small pancreatic remnant.

2 | PATIENTS END METHODS

2.1 | Patients

Prospectively maintained databases were searched to identify patients who had undergone PD for pancreatic tumor without pancreatic reconstruction between January 2004 and December 2018 at the Cancer Institute Hospital (CIH); and between January 2019 and March 2021 at the Juntendo University Hospital (JUH). These study periods corresponded to periods when the corresponding author (A.S.) headed the division of hepatobiliary-pancreatic surgery at the respective institutes. All the analyses conducted in this study were performed in accordance with the ethical guidelines for clinical studies at both institutions and were approved by the respective Institutional Review Boards (#1323 in CIH and #E21-0029 in JUH).

2.2 | Surgical procedure

Subtotal stomach preserving PD was the standard procedure during the study period. Our standardized surgical procedure of PD has been described previously.[9] The surgeon decided on the need of pancreatic reconstruction during the operation. PD without pancreatic reconstruction was indicated when the remnant pancreas was hard due to tumor obstruction and several centimeters long. The pancreatic stump was checked through intraoperative rapid pathological diagnosis. Non-reconstructed pancreatic stump was closed by a running suture using 4-0 non-absorbable monofilament thread (PROLENE®; ETHICON, Inc., Somerville, NJ, USA) after ligation of the main pancreatic duct (MPD) if possible. At least one drain was placed near the pancreatic stump. The drain was removed on postoperative day 4 or later if drain fluid amylase levels were less than three times the normal upper limit of institutional serum amylase on postoperative day 3.[10]

2.3 | Follow-up

Patients were followed up at 3-month intervals for up to 3 years after surgery. Patients underwent a physical examination, laboratory tests including HbA1c and CT scan if necessary. All patients having undergone PD routinely took antacid drugs and pancreatic exocrine enzyme. We prescribed 1200 mg/day of Excelase® combination capsules or granules (Meiji Seika, Japan) from 2004 through 2011 and changed to 1800 mg/day with pancrelipase (Lipacreon® Capsules, Viatris, Japan) after 2011.[11] Patients with preoperative diabetes mellitus were followed up by their primary care doctor or diabetes specialist in parallel. Patients suspected of having new-onset diabetes mellitus were referred to the specialist.

2.4 | Measurement of pancreatic parameters

Remnant pancreatic volume was measured by CT volumetry taken 3 months after operation. Serial transverse enhanced CT scan images were obtained at 1.0 to 5.0 mm intervals. Each slice of the remnant pancreas parenchyma was traced, and the corresponding area was analyzed using a three-dimensional image analysis system (SYNAPSE VINCENT®, Fujifilm, Japan). The distance between transection line of pancreas and SMA, and the length of remnant pancreas were also

measured using the same CT scan. The size of the main pancreatic duct at the stump was measured intraoperatively and recorded in surgical records.

2.5 | Exacerbation of diabetes mellitus

Patients having any medication for diabetes mellitus or with HbA1c greater than or equal to 6.5% in preoperative laboratory tests were classified as having preoperative diabetes mellitus. Patients without preoperative diabetes mellitus were considered as having new-onset diabetes mellitus if they required postoperative diabetes medication. Exacerbation of diabetes mellitus was defined as the postoperative necessity of additional diabetes medication or escalation of insulin therapy in patients with preoperative diabetes. The administration of insulin during postoperative management alone was not classified as new-onset or exacerbation of diabetes mellitus.

New-onset or exacerbation of diabetes was defined as the need for continued insulin administration after discharge.

2.6 | Clinical variables

We analyzed short- or long-term outcomes after surgery. Short-term outcomes included postoperative hospital stay, postoperative pancreatic fistula proportion, and other major complications. Long-term outcomes included disease-free survival (DFS), overall survival (OS), and diabetic condition. DFS was defined as the interval between surgery and recurrence or death. OS was defined as the interval from surgery to the time of the last follow-up visit or death. Postoperative complications were classified according to Clavien–Dindo classification and pancreatic fistula was defined and classified according to the criteria of International Study Group of Pancreatic Surgery (ISGPS). R0 resection was defined as no tumor cells within a margin of <1 mm.[12,13]

2.7 | Statistical analysis

Continuous data were expressed as median (range) or median (95% CI) where appropriate, and qualitative data were expressed as number (%). Survival curves were calculated with Kaplan–Meier analysis. All statistical analyses were conducted using SPSS software, version 26.0 (Chicago, IL, USA).

3 | RESULTS

3.1 | Patient demographics

Out of 774 consecutive patients undergoing PD for pancreatic tumor during the study period, 16 patients (2.1%) underwent PD without pancreatic reconstruction (14 patients at CIH and two patients at JUH). Patient demographics are summarized in Table 1. Of these 16 patients, 13 patients had pancreatic ductal adenocarcinoma (PDAC) and three patients had invasive intraductal papillary mucinous neoplasm (IPMN). Among the patients with IPMN, two patients were diagnosed as mixed type IPMN and the rest as branch duct type IPMN. Although six patients (37.5%) had a medical history of preoperative diabetes mellitus, none received insulin injection therapy.

TABLE 1 Patient demographics.

Age, years	65.5 (43–73)
Sex, *n* (%)	
Male	10 (63%)
Female	6 (38%)
Diagnosis, *n* (%)	
PDAC	13 (81%)
IPMC	3 (19%)
Medical history of DM, *n* (%)	
Present	6 (38%)
Absent	10 (63%)

Note: Data are presented as median (range) unless otherwise indicated.
Abbreviations: DM, diabetes mellitus; IPMC, intrapapillary mucinous carcinoma; PDAC, pancreatic ductal adenocarcinoma.

3.2 | Surgical procedure

Details of the surgical procedure are summarized in Table 2. Pancreatic transection was performed above or to the left of the SMA, with a median remnant pancreas length of 3.7 cm (range, 1.3–10.0) and a median distance between transection line of pancreas and SMA of 3.0 cm (range, 0–5.0). Figure 1 shows a representative photo and scheme after resection. In 11 of 16 patients (69%), the pancreas was divided at the preoperatively planned transection line. The remaining five patients (31%) underwent PD without pancreatic reconstruction mainly due to the additional resection of the pancreas due to positive pancreatic surgical margins identified through intraoperative frozen sections. The texture of the remnant pancreas was hard in all patients. In three of 16 patients (18.8%), the main pancreatic duct could not be detected on the cut surface, and their pancreatic stump was closed by a running suture without ligation of the main pancreatic duct. MPD on the pancreatic stump could be detected in 13 of 16 patients (81.2%).

3.3 | Short-term outcomes

Short-term outcomes are summarized in Table 3. Overall postoperative complications (≥ Clavien–Dindo Grade I) were observed in nine out of 16 patients (56%), and a major complication (≥ Clavien–Dindo Grade IIIa) occurred in one patient (7%) who underwent reoperation

due to anastomotic failure of hepaticojejunostomy. No patient died within 90 days of surgery (Clavien–Dindo Grade V) in this series. One patient (6%) suffered a pancreatic fistula. This patient developed a fistula classified as grade B by ISGPS criteria and was successfully treated by conservative drain management. Post-pancreatectomy acute pancreatitis did not occur in any patients.[14] In three out of 16 cases, transient elevation of serum amylase was observed without any impact on the postoperative course.[15] Microscopically curative resection (R0) was achieved in 12 of 16 patients (75%). Regarding the pancreatic stump, a negative surgical margin was achieved in all 16 patients. All positive margins were located within the dissection margins.

TABLE 2 Details of surgical procedure.

Distance between transection line of pancreas and SMA, *n* (%)	
<2 cm	1 (6%)
≥2 cm, <4 cm	9 (56%)
≥4 cm	6 (38%)
Volume of remnant pancreas, mL	5.5 (1–29)
Length of remnant pancreas, cm	3.7 (1.3–10.0)
MPD, mm	2 (2–8)
Combined vascular resection	
PV resection, *n* (%)	
Yes	11 (69%)
No	5 (31%)
SA resection, *n* (%)	
Yes	1 (6%)
No	15 (94%)
CA resection, *n* (%)	
Yes	1 (6%)
No	15 (94%)

Note: Data are presented as median (range) unless otherwise indicated.
Abbreviations: CA, celiac axis; MPD, main pancreatic duct; PV, portal vein; SA, splenic artery; SMA, superior mesenteric artery.

3.4 | Long-term outcomes and status of diabetes mellitus

Table 4 summarizes long-term outcomes. Median follow-up time was 44.0 months (95%CI, 10.7–77.3). Median RFS was 14 months (95%CI, 7.7–20.3) and median OS was 66 months (95%CI, 10.5–121.5). Local recurrence was detected in three of 16 patients (18.8%). Six patients developed new onset of diabetes mellitus, and another four patients experienced an exacerbation of diabetes. Of the former, three patients and of the latter, two patients required insulin injections. In summary, among the entire cohort of 16 patients, five patients required insulin therapy, seven required some medication for diabetes and four were free from any diabetes medication. During the postoperative follow-up period, aggravation of dilatation of the remnant MPD was found in only one patient without recurrence. CT findings of the representative case without aggravation of dilation of the MPD were shown in Figure 2.

3.5 | Pathological findings at the stump

A representative microscopic photograph of the pancreatic stump of one patient is shown in Figure 3, where preservation of Langerhans' islet cells was confirmed by positive synaptophysin staining, despite the elimination of acinar cells with negative bcl-10 staining. The microscopic photograph of the case with pancreatic fistula is shown in Supplementary Figure. The presence of acinar cells on the pancreatic stump was confirmed by positive staining for bcl-10.

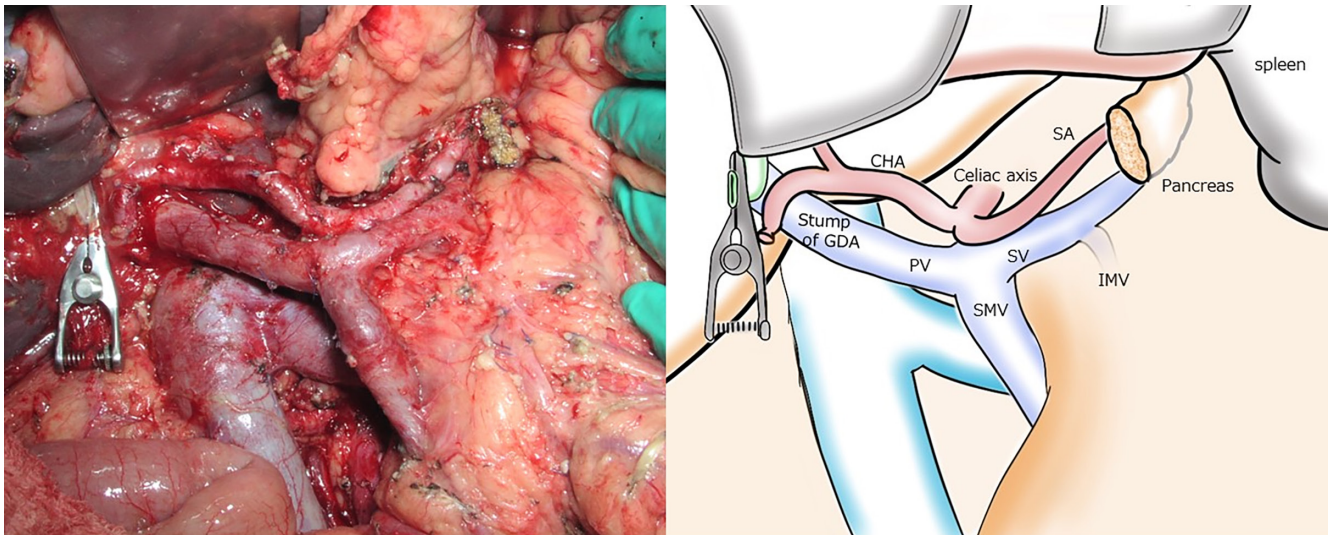

FIGURE 1 Positive synaptophysin staining revealed Langerhans' islet cells. In contrast, no acinar cells were stained by bcl-10 in the same slide.

TABLE 3 Short-term outcomes.

Operation time, min	554 (440–751)
Intraoperative blood loss, mL	801 (280–1670)
Transfusion, *n* (%)	
Yes	1 (7%)
No	14 (93%)
Postoperative hospital stay, days	21 (14–33)
Postoperative complication[a], *n* (%)	
Grade 0	6 (40%)
Grade 1	2 (13%)
Grade 2	6 (40%)
Grade 3a	0
Grade 3b	1 (7%)
Grade 4	0
Grade 5	0
Pancreatic fistula[b], *n* (%)	
No	15 (94%)
Grade B	1 (6%)
Grade C	0
Surgical margin, *n* (%)	
R0	12 (75%)
R1	4 (25%)

Note: Data are presented as median (range) unless otherwise indicated.

[a]Classified according to Clavien–Dindo criteria.

[b]Classified according to criteria of International Study Group for Pancreatic Surgery.

TABLE 4 Long-term outcomes.

Follow-up, months	44.0 (10.7–77.3)
Recurrence-free survivals, months	14.0 (12.4–15.6)
Overall survivals, months	66.0 (10.5–121.5)
Recurrence, *n* (%)	10 (63%)
Site of recurrence, *n* (%)	
Local	3
Liver	1
Lung	6
Peritonium	0
Others	1
Status of postoperative DM, *n* (%)	
None	4 (25%)
New-onset DM	6 (38%)
Stable DM	2 (13%)
Exacerbation of DM	4 (25%)
Necessity of insulin treatment for DM, *n* (%)	
Yes	5 (31%)
No	11 (69%)
Episode of hypoglycemia, *n* (%)	
Yes	3 (19%)
No	13 (81%)

Note: Data are presented as median (95% CI) unless otherwise indicated.

Abbreviation: DM, diabetes mellitus.

4 | DISCUSSION

Here we show that PD without pancreatic reconstruction leaving small and hard remnant pancreas could be safely performed and pancreatic endocrine function was well-preserved. Despite non-reconstruction, the incidence of pancreatic fistula was as low as 6% (1/16) in the present study, which was comparable to previous studies that reported an incidence of clinically relevant pancreatic fistula after PD for hard pancreas ranging from 3.5% to 6.2%.[1] Regarding pancreatic endocrine function, 11 of 16 (69%) patients continued to enjoy insulin-free life. Our report is the largest case series of PD without pancreatic reconstruction. Although the sample size of the present study was small, long-term survival outcomes were not diminished.

We consider that PD preserving the small remnant pancreas without pancreato-enterostomy can be an alternative to total pancreatectomy for patients with extremely small and hard pancreas. In our study, the median volume and length of the remnant were 5.5 mL and 3.4 cm, respectively. Despite the extremely small remnant, long-term pancreatic endocrine function was well-preserved. Indeed, the initiation of insulin therapy was avoided in 69% of patients in the present study. Since all patients undergoing total pancreatectomy need insulin injection therapy, which leads to a reduced quality of life, this procedure is worth considering. A previous report showed that islet cells in the hard pancreatic body/tail were well-preserved even after severe fibrosis and vanishing of acinar cells in patients with pancreatic head cancer. Previous reports using an exocrine pancreas-insufficient pig model showed acinar fibrotic atrophy but with little effect on islet cells after ligation of the pancreatic duct.[16,17] Iizawa et al. reported that the volume of remnant pancreas after PD did not influence the new occurrence or exacerbation of diabetes mellitus, contrary to its effect on exocrine function.[5] These findings support our hypothesis of the clinical implications of preserving a small remnant pancreas with hard texture. As supportive evidence for preserved endocrine function in hard pancreas with diminished exocrine function, Figure 1 depicts microscopic findings of a pancreatic stump.

The most important issue in the present study is whether or not the reconstruction of pancreatic duct is necessary. The present study shows the feasibility of PD without pancreatic reconstruction in patients with small and hard pancreatic remnant. Nakagawa et al. reported the superiority of the proximal subtotal pancreatectomy (PSTP) compared with total pancreatectomy in regard to endocrine function and they concluded that PSTP could be a good alternation for total pancreatectomy especially in patients with malnutrition.[18] In their study, invaginated pancreaticojejunostomy was performed for all PTSP patients. Despite the same concept of the preservation of small remnant pancreas, the difference between their and our study was the presence

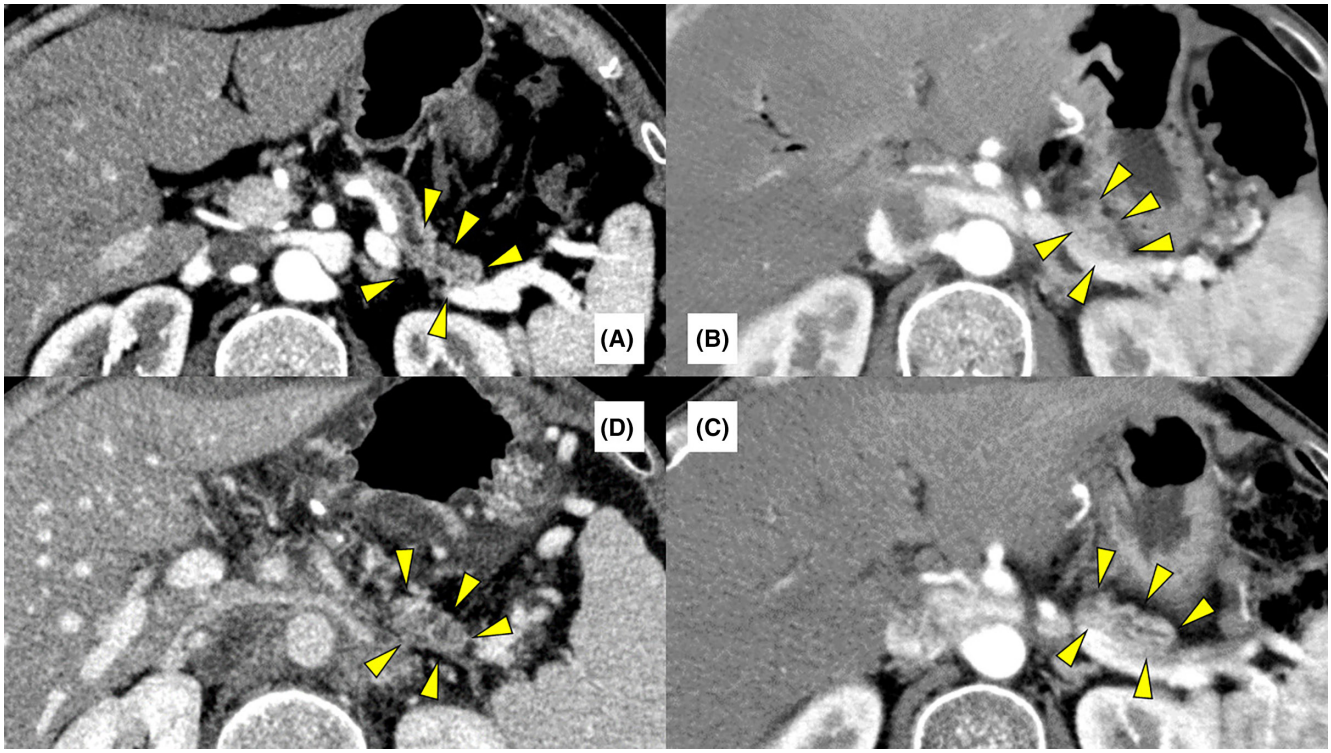

FIGURE 2 CT findings of the remnant pancreas in the representative case. There was no aggravation of MPD dilation in the 3 years following pancreatectomy. (Arrow heads: remnant pancreas) (A) Preoperative findings. (B) One year after pancreatectomy. (C) Two years after pancreatectomy. (D) Three years after pancreatectomy.

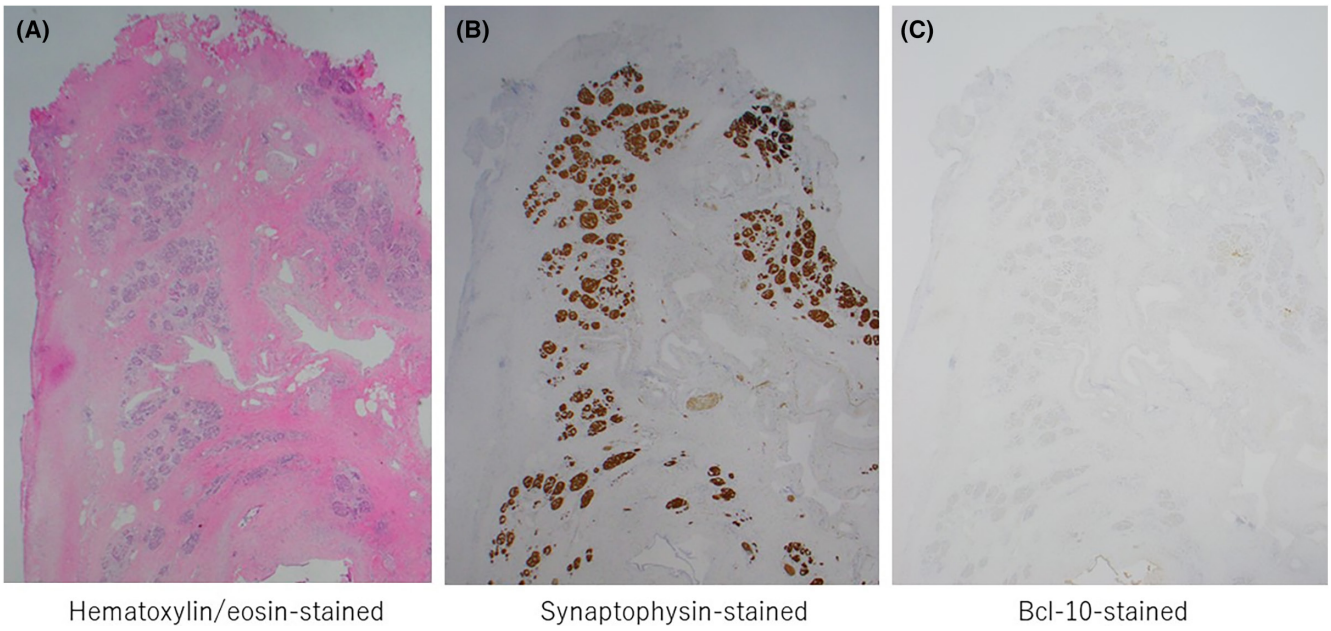

FIGURE 3 Pancreatic transection was performed to the left of the SMA. There is an end-to-side anastomosis of the SMV to the PV. GDA, gastroduodenal artery; IMV, inferior mesenteric vein; LGA, left gastric artery; LHA, left hepatic artery; PV, portal vein; RHA, right hepatic artery; SA, splenic artery; SMA, superior mesenteric artery; SMV, superior mesenteric vein; SV, splenic vein.

or absence of pancreatic reconstruction. Although the volume of remnant pancreas was relatively low in our study (5.5 mL vs. 4.4 mL in median), the frequency of PF was same between the studies (Grade B PF occurred in one of 16 patients in both studies). Moreover, the report by Nakagawa et al. could not show the clear advantages regarding with exocrine function in PTSP group compared with total pancreatectomy group despite the presence of pancreatico-jejunostomy. In our procedure, pancreatic exocrine

function is assumed to be totally abolished. However, deterioration of the quality of life can be minimized by pancreatic exocrine replaced therapy (PERT). Moreover, the pancreatic exocrine function of most patients after PD with hard pancreatic remnant is assumed to be highly exhausted,[16] yet the clinical impact of exhaustion of pancreatic exocrine function is limited.

In the present study, one patient developed pancreatic fistula after PD without reconstruction. This patient was diagnosed as mixed type IPMN. Previous reports showed that pancreatic fistula was more frequent after PD in patients with IPMN than those with PDAC,[19,20] probably due to less frequent pancreatic atrophy derived from obstructive pancreatitis in IPMN than PDAC. Nakahodo et al. confirmed pathologically that considerable numbers of acinar cells remained in more than 70% of patients who underwent surgery for IPMN despite the presence of atrophic change in all patients.[21] Looking back at this case, invagination pancreatico-enterostomy, which does not need the duct-to-mucosa anastomosis, should be chosen for this patient rather than no reconstruction. Additionally, we consider that the indication of non-reconstruction should be considered carefully in patients with IPMN.

The present study has several limitations. First, the study comprised of a relatively small sample size of 16 patients and was retrospective in nature. However, to our best knowledge the present study is the largest sample size to date, with previously only some case reports addressing the clinical implication of preserving a small remnant pancreas without reconstruction after PD. Second, the present study could not address the applicability of our criteria for selecting the procedure, which were small remnant pancreas of several centimeters in length and of hard texture. It remains unclear how large the pancreas should be preserved to maintain satisfying pancreatic endocrine function or how large the pancreas could be preserved safely without reconstruction due to the small sample size of the present study. However, in the single case that experienced postoperative pancreatic fistula in the present study, the presence of acinar cells at the pancreatic stump was observed. Hence, the potential utility of intraoperative pathological examination to ascertain the presence or absence of acinar cells at the pancreatic stump might be a valuable criterion for assessment. It is possible to confirm the presence or absence of acinar cells through intraoperative pathological diagnosis. Currently, we perform this procedure only after confirming the absence of acinar cells. Although we consider that the present study could provide the minimum evidence to support the efficacy and feasibility of this procedure, further accumulation of experience of this procedure, for example through a multicenter study, would be necessary to address the applicability of patient selection criteria.

In conclusion, the preservation of a small pancreatic remnant without reconstruction after PD can be performed safely and may allow for the preserving of pancreatic endocrine function in selected patients. As such, this procedure might be an alternative to total pancreatectomy.

AUTHOR CONTRIBUTIONS

A.S. developed the main concept of this study and took responsibility of the operation as the head of the division of hepatobiliary-pancreatic surgery at the respective institutes. M.M. and R.Y. designed the research and wrote the article. Y.F. and M.T. were responsible for acquisition of clinicopathological data. A.O., Y.O., Y.I., Y.M., and Y.T. carried out part of the operation.

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None.

CONFLICT OF INTEREST STATEMENT

Akio Saiura, one of the co-authors, is an editorial board member of *Annals of Gastroenterological Surgery*.

ETHICS STATEMENTS

Approval of the research protocol: This study conformed to the Declaration of Helsinki on Human Research Ethics standards and was approved by the Ethics Committee of JUH (Approval No. E21-0029) and CHI (Approval No. 1323).

Informed Consent: N/A.

Registry and Registration Number: N/A.

Animal Studies: N/A.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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