



Laparoscopic versus open distal pancreatectomy for benign and low-grade malignant lesions of the pancreas: a single-center comparative study

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Abstract

Purpose The purpose of the study was to compare the outcomes of laparoscopic distal pancreatectomy (LDP) and open distal pancreatectomy (ODP) for benign and low-grade malignant lesions to determine the safety and efficacy of LDP.

Methods This retrospective comparative study included 67 consecutive patients who underwent LDP ($n = 32$) and ODP ($n = 35$) for benign or low-grade malignant lesions of the pancreas from January 2012 to March 2017. Thirty-five patients who were eligible for LDP in the ODP group were carefully selected. The clinical outcomes were compared in an intention-to-treat analysis.

Results LDP was associated with significantly less operative blood loss (182 ± 232 vs. 505 ± 376 ml, $P < 0.001$) but a longer operation time (327 ± 89 vs. 173 ± 48 min, $P < 0.001$), than ODP. There were no significant differences between the 2 groups in the overall morbidity rates defined by Clavien–Dindo classification \geq grade II (13% vs. 11%), clinically relevant postoperative pancreatic fistula rates (6% vs. 9%), and lengths of postoperative hospital stay (11 vs. 11 days).

Conclusion The study showed that LDP was safe and feasible. LDP should be considered as the first-line treatment for benign and low-grade malignant lesions in the left side of the pancreas.

Keywords Laparoscopic distal pancreatectomy · Laparoscopic pancreatectomy: benign and low-grade malignant lesions

Introduction

With recent improvements in the laparoscopic technique and increasing surgical experience, laparoscopic pancreatectomy is being performed increasingly frequently. Since the first report of laparoscopic distal pancreatectomy (LDP) was published by Cuschieri et al. [1], LDP has become the most widely performed laparoscopic pancreatic surgery worldwide because of its acceptable technical feasibility and safety without complex anastomoses or reconstructions required for pancreas head resection. Several observational cohort studies have reported significant reductions in the intraoperative blood loss, blood transfusion, complications,

and hospital stay compared with open distal pancreatectomy (ODP) [2–9]. These results were confirmed by several systematic reviews of cohort studies in all pancreatic diseases [10–15].

Recently, the European Association for Endoscopic Surgery Clinical Consensus Conference stated with a high level of consensus from the scientific community that LDP is a feasible and safe alternative to ODP in the treatment of benign and malignant pancreatic lesions, providing advantages in terms of reduced blood loss and enhanced postoperative recovery that result in a shorter hospital stay than with ODP [16]. However, LDP for pancreatic ductal adenocarcinoma remains controversial, because it is technically more challenging than LDP for benign and low-grade malignant lesions of the pancreas with regard to en bloc resection, a clear resection margin, and lymph node dissection. Furthermore, its oncological safety in terms of the long-term results has not been proven, because no randomized study has been conducted. Nevertheless, LDP has been regarded as

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the standard procedure for benign and low-grade malignant lesions of the pancreas in Western countries.

Historically, laparoscopic pancreatic surgery was introduced later than laparoscopic surgery for other organs because of the anatomical complexity of the pancreas and the requirement of high surgical skill. Previous studies have been reported from only expert centers. In Japan, the government approved health insurance coverage for LDP for benign and low-grade malignant lesions of the pancreas in 2012. As the indication for LDP has been strictly limited, the number of procedures is small, even in high-volume centers of pancreatic surgery. A few reports of LDP in a small number of patients were published from single centers in Japan before health insurance covered LDP [3, 17, 18]. In our hospital, LDP for benign and low-grade malignant lesions was introduced in 2014.

In this retrospective case–control study, we compared the outcomes of LDP and ODP for benign and low-grade malignant lesions to determine the safety and efficacy of LDP at a single center in Japan in the current era.

Methods

Patient and study design

A prospectively accumulated database containing demographic information, perioperative parameters, and outcomes for all patients who underwent pancreatic resection has been maintained at the Hospital of the Kindai University Faculty of Medicine since January 2011. We introduced LDP for benign or low-grade malignant lesion of the pancreas in June 2014.

The indications of LDP for benign and low-grade malignant pathology are as follows: (1) intraductal papillary mucinous neoplasm (IPMN) and mucinous cystic neoplasm without invasion to the parenchymal of the pancreas on preoperative imaging studies; (2) solid-pseudopapillary neoplasm; (3) non-functioning neuroendocrine neoplasm with a tumor size of ≤ 1.5 cm; (4) insulinoma with a tumor size of ≤ 2.0 cm; (5) symptomatic serous neoplasm or with a tumor size of ≥ 4.0 cm; (6) metastatic pancreatic tumor; and (7) chronic pancreatitis without severe inflammation. All neoplastic lesions were localized in the body and/or tail of the pancreas without distant and/or lymph node metastasis on preoperative imaging studies. Chronic pancreatitis with severe inflammatory lesion and/or pseudocyst, previous upper abdominal surgery including gastrectomy, left colectomy, and left nephrectomy, are considered contraindications for LDP.

Distal pancreatectomy was performed on a total of 149 patients at our hospital between January 2012 and March

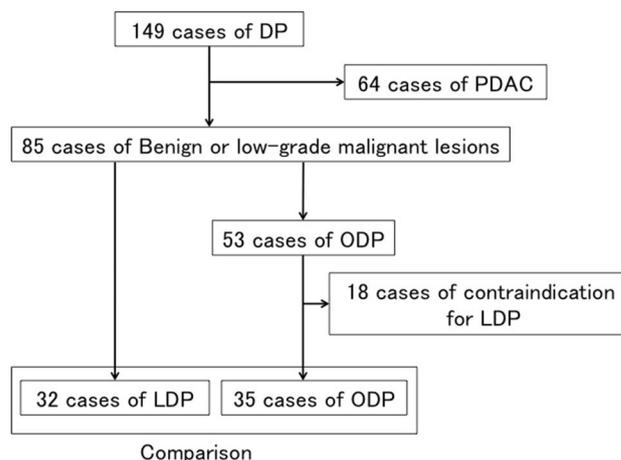


Fig. 1 Patient flow diagram. *DP* distal pancreatectomy, *PDAC* pancreatic ductal adenocarcinoma, *OPD* open distal pancreatectomy, *LDP* laparoscopic distal pancreatectomy

2017. The patient flow diagram is shown in Fig. 1. Of the 149 patients, 64 with pancreatic ductal adenocarcinoma were excluded from this study. During the study period, LDP and ODP for benign or low-grade malignant lesion were conducted in 32 patients (LDP group) and 53 patients, respectively. ODP was performed as a standard procedure between January 2012 and May 2014. LDP was performed consecutively between June 2014 and March 2017 by an experienced surgeon (I.M) who had performed the procedure in more than 40. ODP was performed by two experienced surgeons (T.Y. and I.M).

Medical records, including data on comorbidities, history of pancreatitis, previous surgeries, laboratory data, and preoperative imaging findings, of the 53 patients who underwent ODP were carefully reviewed by I.M. Of the 53 patients, 18 were considered to have contraindications for LDP, including chronic pancreatitis with a severe inflammatory lesion and/or pseudocyst ($n = 13$), a history of surgery ($n = 2$), IPMN with extensive tumor growth in the main pancreatic duct ($n = 2$), and ruptured mucinous cystadenoma ($n = 1$). These patients were excluded from the comparison. As a result, the ODP group included 35 patients who were considered to also be eligible for LDP. The clinicopathological and surgical outcomes were retrospectively compared between the LDP and ODP groups in an intention-to-treat analysis.

The patients provided their written informed consent before their surgery according to the rules and regulations of our institution. This study was performed in accordance with the Declaration of Helsinki and approved by the ethics review committee of Kindai University Faculty of Medicine (no. 29-045).

Surgical principles and procedures

LDP and ODP were performed with or without splenectomy. Distal pancreatectomy with splenectomy was planned for one or more of the following reasons: (1) potential lymph node metastasis of the pancreatic neoplasm and/or (2) technical difficulty in dissecting the distal pancreas from the splenic vessels as evaluated by preoperative imaging studies. All splenic conservations were planned with preservation of the splenic artery and vein. Splenic conservation while sacrificing the splenic vessels (Warshaw technique) was only performed when tumor dissection from the splenic vessels was deemed difficult intraoperatively.

After entering the lesser sac through the gastrocolic ligament, LDP was initiated at the superior border of the pancreas. The common hepatic and splenic arteries were separated from the upper border of the pancreas. The inferior border of the pancreas was dissected. Subsequently, a sufficient window was created at the isthmus between the anterior surface of the portal vein and the posterior part of the pancreas. In case of LDP with splenectomy, first, the splenic artery and, then, the vein were divided. The pancreas was transected with a triple row stapler with bioabsorbable material (Endo GIA Reinforced Reload with Tri-Staple™ Technology; COVIDIEN, North Haven, CT, USA). In case of splenic conservation, the splenic artery and vein were skeletonized from the isthmus toward the hilum of the spleen. In case of ODP, all pancreas transections and stump closures were performed with scalpel and in a hand-sewn manner, respectively, as published elsewhere recently [19]. The level of pancreatic transection was decided at the point of the minimum surgical margin to preserve as much of the parenchyma of the pancreas as possible.

Definition of postoperative complications

Postoperative complications were evaluated by a modified Clavien grading system [20]. Postoperative pancreatic fistula (POPF) was defined by the classification system of the International Study Group on Pancreatic Fistula (ISGPF) as an amylase level in the fluid collected on the third postoperative day (POD) > threefold the serum amylase level [21]. POPF was classified into one of the three categories—biochemical leak, grade B, or grade C—according to the ISGPF clinical criteria. The amylase levels in the drainage fluid on POD 3 were measured in all patients. The diameter of the main pancreatic duct and thickness of the pancreas at the resection site were estimated and measured by preoperative multidetector row CT with 1-mm thickness based on the distance from the left edge of the portal vein measured intraoperatively.

Statistical analyses

Categorical variables were presented as proportions, and continuous variables were presented as the mean and standard deviation, except for the day of starting oral intake and the postoperative hospital stay (expressed as the median and range). The distributions were tested with the Shapiro–Wilk statistic. The means between two groups were compared using Student's *t* test when the data distribution was normal and the Mann–Whitney rank sum test if continuous variables were skewed. Proportions were compared using the Chi-square test or Fisher's exact test when the expected values in any of the cells of the contingency table were below 5. All analyses were performed using the JMP software program, ver. 12.0 for Macintosh (SAS Institute, Inc, Cary, NC, USA).

Results

Patient and clinicopathologic characteristics

The clinicopathologic characteristics are presented in Table 1. Most of the characteristics were comparable between the LDP and ODP groups. There were no significant differences in the age, sex, performance status, body mass index, diabetes, white blood cell count, or serum albumin level between the two groups. The serum hemoglobin level was significantly lower in the LDP group than in the ODP group (12.7 ± 1.5 vs. 13.8 ± 1.5 g/dl, $P < 0.001$). The tumor characteristics were comparable between the two groups. There were no significant differences between the groups in the final pathology, malignant status, lesion size, lesion site, diameter of the main pancreatic duct, or thickness of the pancreas at the transection line.

Planned procedures and conversion to other procedures in the LDP group

LDP with splenectomy was planned in 17 of the 32 patients. Of these, three patients were converted to a hand-assisted procedure because of bleeding from the splenic vein or spleen. Fourteen of the 17 patients underwent planned LDP with splenectomy. The completion rate of planned LDP with splenectomy was 82.3% (14/17). Spleen-and-vessel-preserving LDP was planned in 15 patients. Of these, the procedure was converted to the Warshaw operation in three patients and to LDP with splenectomy in one patient because of difficulty dissecting the splenic vein and tumor and/or difficulty controlling bleeding. Eleven of the 15 patients underwent planned spleen-and-vessel-preserving LDP. The completion rate of planned spleen-and-vessel-preserving LDP was 73.3%. As a result, spleen conservation was achieved in 14 (93.3%) of 15 patients.

Table 1 Patient characteristics

	LDP (<i>n</i> = 32)	ODP (<i>n</i> = 35)	<i>P</i> value
Age (years)	63 ± 14	58 ± 17	0.232
Sex (male/female)	9/23	15/20	0.207
Performance status (0/1/2)	27/5 /0	30/4/1	0.467
Body mass index (kg/m ²)	22.5 ± 3.6	22.9 ± 3.9	0.664
Diabetes	6 (19%)	7 (20%)	0.897
Serum hemoglobin (g/dl)	12.7 ± 1.5	13.8 ± 1.5	<0.001
White blood cell count (10 ³ /μl)	5.4 ± 1.5	5.5 ± 1.2	0.704
Serum albumin (g/l)	4.3 ± 0.4	4.3 ± 0.4	0.633
Final pathology			0.670
Intraductal papillary mucinous neoplasm	9 (28%)	8 (23%)	
Mucinous cystadenoma	4 (13%)	10 (29%)	
Neuroendocrine neoplasm	9 (28%)	4 (11%)	
Solid-pseudopapillary neoplasm	2 (6%)	2 (6%)	
Serous cystadenoma	1 (3%)	2 (6%)	
Others	7 (22%)	9 (26%)	
Benign/malignant	23/9	27/8	0.621
Lesion size (mm)	38 ± 17	36 ± 23	0.426
Lesion site (body/tail)	7/25	11/24	0.545
Diameter of the main pancreatic duct (mm)	1.9 ± 1.2	2.3 ± 1.5	0.249
Thickness of the pancreas (mm)	14.7 ± 4.5	16.3 ± 4.0	0.145

Categorical variables are described as numbers, and continuous variables are described as the mean and standard deviation

LDP laparoscopic distal pancreatectomy, ODP open distal pancreatectomy

A comparison of the operative data and postoperative complications

Operative data are shown in Table 2. There were no significant differences in operative procedure with or without splenectomy, combined resection of other organs, or pancreatic texture between the two groups. The operation time was significantly longer in the LDP group than in the ODP group (327 ± 89 vs. 173 ± 48 min, *P* < 0.001). Intraoperative blood loss was significantly lower in the LDP group than in the ODP group (182 ± 232 vs. 505 ± 376 ml, *P* < 0.001).

Postoperative outcomes and complications are shown in Table 3. Overall mortality was 0 in both groups. Overall morbidity defined as Clavien–Dindo classification ≥ grade II developed in 4 patients (13%) in the LDP group and 4 (11%) in the ODP group. Severe complications (grade IIIa) developed in 2 patients (6%) in the LDP group and 3 (9%) in the ODP group. No patient in either group developed ≥ grade IIIb complications. There was no significant difference in the morbidity rate between the two groups. Regarding clinically relevant POPF defined by the ISGPF classification system, 1 patient (3%) in the LDP group and 3 (9%) in the ODP group

Table 2 Operative data

	LDP (<i>n</i> = 32)	ODP (<i>n</i> = 35)	<i>P</i> value
Operative procedure			0.07
DP with splenectomy	18 (56%)	12 (34%)	
Spleen-preserving DP	14 (44%)	23 (66%)	
Combined resection of other organs	3 (9%)	1 (3%)	0.121
Operation time (min)	327 ± 89	173 ± 48	<0.001
Blood loss (ml)	182 ± 232	505 ± 376	<0.001
Blood transfusion	3 (9%)	1 (3%)	0.253
Pancreatic texture (soft/hard)	29/3	33/2	0.569

Categorical variables are described as numbers, and continuous variables are described as the mean and standard deviation

LDP laparoscopic distal pancreatectomy, ODP open distal pancreatectomy, DP distal pancreatectomy

Table 3 Postoperative outcomes and complications

	LDP (n=32)	ODP (n=35)	P value
Mortality	0 (0%)	0 (0%)	1.000
Morbidity	4 (13%)	4 (11%)	0.809
Clavien–Dindo classification			0.756
II	2 (6%)	1 (3%)	
IIIa	2 (6%)	3 (9%)	
IIIb	0 (0%)	0 (0%)	
IV	0 (0%)	0 (0%)	
V	0 (0%)	0 (0%)	
Pancreatic fistula, ISGPF grade			0.914
None or BL	31 (97%)	32 (91%)	
B	1 (3%)	3 (9%)	
C	0 (0%)	0 (0%)	
Delayed gastric emptying	1 (3%)	0 (0%)	0.964
Intra-abdominal abscess	2 (6%)	3 (9%)	0.917
Postoperative hemorrhage	0 (0%)	0 (0%)	1.000
Wound infection	2 (6%)	0 (0%)	0.434
Reoperation	0 (0%)	0 (0%)	1.000
Oral intake (POD)	3 (2–13)	4 (2–7)	0.410
Hospital stay (POD)	11 (5–113)	11 (7–27)	0.696
Readmission	1 (3%)	2 (6%)	0.937

Categorical variables are described as numbers, and continuous variables are described as the median and range

LDP laparoscopic distal pancreatectomy, *ODP* open distal pancreatectomy, *ISGPF* the International Study Group of Pancreatic Fistula, *POD* postoperative day

developed grade B fistula. No patients developed grade C POPF. There was no significant difference in the occurrence rate of POPF between the two groups. There were also no significant differences in the development of other complications, including delayed gastric emptying, intra-abdominal abscess, postoperative hemorrhage, and wound infection. No patient in either group required reoperation. Readmission was required in 1 patient (3%) in the LDP group and in 2 patients (6%) in the ODP group. The difference was not significant. There were no significant differences in the time to oral intake or duration of postoperative hospital stay between the two groups.

Discussion

In our study, the LDP group showed a significantly longer operation time but less intraoperative blood loss than the ODP group. There were no differences in the overall morbidity or POPF rates between the two groups, nor was there any marked difference in the duration of the postoperative hospital stay between the two groups.

Recent meta-analyses comparing LDP and ODP have shown the superiority of LDP in terms of intraoperative blood loss, patient recovery, and hospital stay [10–15]. Overall, all studies showed that LDP was favorable. However, the results regarding the operation time, transfusion rate, spleen preservation rate, morbidity rate, and POPF rate were inconsistent. These discrepancies may have been due to significant potential selection biases. Several case-matched comparative studies of LDP versus ODP from a single center have been reported [5–7, 22]. However, the number of matched variables was only 3 or 4 in each study, and the variables only included the age, sex, body mass index, American Society of Anesthesiologists score, tumor size, and histology. When surgeons plan the operation (LDP or OPD), many other factors should be considered, such as severe adhesion and/or inflammation and extension of the tumor. In our study, we carefully selected the control (ODP) group by examining the patients' medical records and imaging studies; the control (ODP) group consisted of patients who were eligible for LDP. The baseline characteristics of the patients in the LDP and ODP groups were, therefore, well matched in our study.

Recently, the first multicenter patient-blinded randomized control study of minimally invasive distal pancreatectomy versus ODP (LEOPARD) was reported by the Dutch Pancreatic Cancer Group [23]. According to their report, minimally invasive distal pancreatectomy reduced the time to functional recovery compared with ODP. We were unable to show the data of the time to functional recovery in the present study because of inadequate data collection. In our study, the length of the postoperative hospital stay did not differ markedly between the two groups. Our results are, therefore, not in agreement with those of the previous reports, probably due to the low rate of morbidity in the two groups and the small number of subjects in our study. Our results showed that LDP was associated with a reduced intraoperative blood loss and increased operation time, but did not reduce the morbidity rate compared with ODP. These results were in accordance with those of the LEOPARD trial.

Of note, our study showed low rates of morbidity and POPF. The Clavien–Dindo grade \geq III complication rate was 6% after LDP vs. 9% after ODP. POPF grade B was seen in 3% of patients after LDP versus in 9% after ODP. No patient in either group developed POPF grade C. The major complication and POPF rates have recently been reported as 8–38% and 11–39% for LDP and ODP, respectively [7–9, 23]. The outcomes of the patients in our study, therefore, tended to be better than those of the previous studies. In the LDP group, the pancreas was transected with a triple row stapler with bioabsorbable material. Kawai et al. [24] conducted a multicenter single-arm prospective study to evaluate the safety and efficacy of this stapler during distal pancreatectomy. They reported that clinically relevant POPF occurred in 13 (12.4%) of 105

patients. In the ODP group, we did not use a stapler for pancreas transection because of our institutional policy and efforts to ensure cost effectiveness. We previously developed a novel technique for preventing POPF using transpancreatic mattress sutures with Vicryl mesh around the stump during ODP [19]. In our initial series of 26 consecutive patients, no patient developed clinically relevant POPF using this method. Both the newly developed stapler device and stump closure technique might have improved the surgical outcome had they been applied.

The median conversion rate to open surgery during LDP has been reported as 11.2% (range 0–17.4%) [12]. However, most studies fail to mention reasons for conversion in detail. In our study, 3 patients (9.3%) required conversion from LDP to a hand-assisted procedure. We planned LDP with splenectomy in 17 cases and spleen-and-vessel-preserving LDP in 15 cases; the completion rates of these planned procedures were 82.3% (14/17) and 73% (11/15), respectively. Spleen-preserving LDP with preservation of splenic vessels has advantages over the Warshaw operation in terms of postoperative outcomes, particularly splenic infarction [16]. Therefore, we attempt spleen-and-vessel-preserving LDP whenever possible but convert to the Warshaw operation in case of bleeding or difficulty during dissection. Of the 15 patients in whom we planned to perform spleen-and-vessel-preserving LDP, 3 were converted to the Warshaw operation, and 1 underwent LDP with splenectomy because of spleen infarction during the operation. The spleen preservation rate was ultimately 93.3% (14/15).

Spleen-preserving DP is technically challenging comparing to DP with splenectomy. Our exclusion criteria for spleen preservation include a tumor extensively attached to the splenic vessels. In our study, the rate of spleen preservation was not significantly different between the two procedures, but was higher in the ODP group. One of the reasons for this might be, because it is technically easier to preserve the spleen in ODP than in LDP. Unfortunately, as this study was retrospective, we were unable to determine the precise rate of spleen preservation in an intention-to-treat basis analysis in the ODP group. Of note, spleen preservation was indicated only for lesions with no risk of lymph node metastasis. Another potential reason for the discrepancy may be the indications of spleen preservation for IPMN. In the ODP group, spleen preservation was performed in five of eight patients; in contrast, only two of nine patients underwent spleen-preserving DP in the LDP group. In the early period of the study, we aggressively preserved the spleen in patients with IPMN. However, making a precise preoperative diagnosis of minimally invasive cancer, which potentially has lymph node metastasis, remains difficult. Therefore, we changed the surgical indication for IPMN to spleen resection with D1 lymph node dissection in the later period of the study.

Our study had several limitations, including its retrospective design and the small number of patients enrolled. Although we attempted to match the baseline characteristics of the patients, selection bias may still have existed. However, the surgical procedure was standardized in both groups. LDP was performed by one surgeon, and ODP was performed by two surgeons. The quality of life, pain score, and costs were not evaluated in this study. In a recent randomized controlled trial, minimally invasive distal pancreatectomy was associated with a better quality of life without increasing costs compared with ODP [23].

In this study, all LDP procedures were performed by an experienced pancreatic surgeon to minimize selection bias. Although LDP has been regarded as the standard procedure for benign and low-grade malignant lesions of the pancreas in Western countries, the previous studies were notably reported from only expert centers. The learning curve of LDP is known to be slow and steep. Because the number of patients with pancreatic disease in Asian countries is smaller than those with diseases of other organs, such as gallbladder, gastric, and colorectal system, surgeons have few chances to perform LDP even in high-volume centers of pancreatic surgery. However, as the surgical procedure is standardized with the accumulation of surgical experiences, we expect that LDP will be performed more widely as the first-line treatment in Japan.

In conclusion, LDP significantly reduced the intraoperative blood loss, but increased the operation time in patients with benign or low-grade malignant lesions of the pancreas compared with ODP. No significant differences were found in the overall morbidity, POPF rate, or duration of hospital stay. With the increasing patient demand for LDP for tumor eradication due to the cosmetic impact of surgical wounds, LDP should be considered as the first-line treatment for benign and low-grade malignant lesions in the left side of the pancreas.

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Compliance with ethical standards

Conflict of interest The authors have no conflicts of interest to disclose.

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