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GUIDELINES

Practice guidelines on endoscopic surgery for qualified surgeons by the Endoscopic Surgical Skill Qualification System: Pancreas

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1 | REVIEW

This guideline is the English version of the Practice Guidelines on Endoscopic Surgery for qualified surgeons, originally published in Japanese in September 2019.

1.1 | History and insurance coverage of laparoscopic pancreatectomy

The first report on laparoscopic pancreatectomy was the laparoscopic pylorus-preserving pancreatoduodenectomy reported by Gagner et al. in 1994.[1] Laparoscopic distal pancreatectomy (LDP) was first reported by Cuschieri et al. in 1996.[2] Subsequently, laparoscopic spleen-preserving distal pancreatectomy,[3] laparoscopic pancreatic tumor enucleation,[3] and laparoscopic central pancreatectomy[4] were also reported. In Japan, reports of laparoscopic pancreatectomy have been appearing since about 1996. However, there have been fewer reports of laparoscopic surgery for the pancreas than for the gallbladder, stomach, or large intestine and its widespread use seems to be lagging.

In 2006, "laparoscopic-assisted distal pancreatectomy and enucleation" was approved for insurance coverage as an Advanced Medical Care for benign and minimally malignant tumors that do not require lymph node dissection. In 2012, "laparoscopic-assisted distal pancreatectomy" was approved for insurance coverage under the limited condition that "it does not generally require lymph node dissection." In 2016, with the change in limitations to "in principle,

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without combined resection of surrounding organs and vessels,", the expanded use of laparoscopic surgery for pancreatic body tail cancer was approved. In the same year, "laparoscopic pancreatoduodenectomy (LPD)" was covered by insurance under the limited condition that "in principle, the procedure does not involve combined resection of vascular or lymph node dissection." In addition, laparoscopic pancreatic tumor resection was covered by insurance in 2018, and the number of cases utilizing these procedures is expected to increase in the future. The following points should be noted when performing LDP and LPD:

1. The LDP and LPD must meet the facility criteria and be accredited by the chief of the relevant Regional Bureau of Health and Welfare or the branch manager of the Regional Bureau of Health and Welfare that has jurisdiction at the location of the authorized insurance medical institution.
2. In Japan, LPD and LDP have only been covered by insurance for a short period. Therefore, to ensure safety and to provide precise data on surgical outcomes, the Japan Society for Endoscopic Surgery, the Japanese Society of Hepato-Biliary-Pancreatic Surgery, and the Japanese Society for Endoscopic and Robotic Pancreatic Surgery have jointly organized a preregistration system for these procedures, in which prospective case registration has already started.
3. It should be noted that as of August 2018, LPD for malignant tumors is not covered by insurance and is currently being performed as clinical research, and the treatment is not covered by public insurance.

2 | CQ1: IS LDP RECOMMENDED?

LDP is mildly recommended for pancreatic tumors including pancreatic invasive ductal adenocarcinoma.

Recommended level 2 Evidence level C.

2.1 | Explanation

There are no RCTs comparing LDP with open distal pancreatectomy (ODP).

In comparing the respective impacts of LDP and ODP in relevant areas including cancer, it has been reported that there is no difference in perioperative mortality between the two operative procedures. In addition, LDP's significantly shorter postoperative hospital stay has been reported in many articles, including meta-analysis.[5-14] There are several reports, including meta-analyses, that LDP is more beneficial than ODP for complication rates,[9,13,14] incidence of pancreatic fistula,[8,13] and transfusion rates,[6,8,9,13] whereas others have reported that these are equivalent to each other.

LDP was associated with longer operative time than ODP in an extensive Japanese analysis using propensity score matching for benign and low-grade tumors. Still, there was no difference in perioperative mortality between the two groups. Furthermore, the incidence of pancreatic fistula, intraoperative blood loss, blood transfusion rate, and postoperative hospital stay with LDP were reported to be more beneficial than ODP.[8] Based on these evaluations, LDP may improve the complication rates and transfusion rates, including the incidence of pancreatic fistula and postoperative hospital stay compared with ODP. LDP is therefore recommended for benign or low-grade lesions.

In Japan, the LDP for pancreatic cancer is only covered by insurance at those facilities that meet the coverage criteria. There are five cancer-specific articles among the above reports, but all of them are from overseas. These reports indicate that postoperative hospital stay is significantly shorter with LDP.[5-7,9,11] Sulpice et al.[9] reported that LDP significantly improved the long-term prognosis compared with ODP, although selection bias cannot be denied; other reports, however, showed no difference in survival rates.[1–3,7] All of the reports indicated that LDP and ODP were equivalent in perioperative mortality.[5,6,9,11] Cochrane Review[5] reported no difference between LDP and ODP in terms of complication rate, incidence of pancreatic fistula, and positive margin rate. Stauffer et al.[2] reported with a single-center retrospective analysis that LDP was more beneficial than ODP for the number of lymph nodes dissected and the number of days until the start of postoperative chemotherapy. Based on these evaluations, LDP for pancreatic cancer is considered acceptable. However, since insurance coverage has only just started in Japan, analysis of short and long-term outcomes based on accumulated cases is needed in the future. In addition, the report is limited to observational studies only, and verification through prospective studies is desirable.

Committee voting results

Recommend conducting (strong recommendation)	Suggest conducting (mild recommendation)	Suggest not conducting (mild recommendation)	Recommend not conducting (strong recommendation)	Abstention from voting
25.0%	75.0%	0.0%	0.0%	0.0%

3 | CQ2: IS LPD RECOMMENDED FOR BENIGN AND LOW-GRADE TUMORS?

> Laparoscopic pancreatoduodenectomy is mildly recommended for benign and low-grade tumors in facilities having abundant experience with this surgery.

Recommended level 2 Evidence level C.

3.1 | Explanation

In Japan, laparoscopic pancreatoduodenectomy is only covered by insurance at facilities that meet the coverage criteria. Therefore, coverage is generally limited to cases that do not involve combined resection of the vascular system and lymph node dissection.

To date, there are no RCTs comparing LPD with open pancreatoduodenectomy (hereafter OPD).

Articles comparing LPD and OPD, including meta-analyses articles, reported no difference in perioperative mortality between the two operative procedures[13,15-19] and also stated that the postoperative hospital stay after LPD is significantly shorter.[13,15-17,19] There are some reports that the transfusion rate is low in the LPD group,[13,19] but there are also reports that the transfusion rates of the two groups are comparable.[4] There are also several reports stating that the complication and the incidence rates of pancreatic fistula[13,17-19] are identical.

In view of these reports, LPD may have a perioperative outcome that is not inferior to OPD when performed at experienced surgical centers but should be performed with caution at surgical facilities that are in the early stages of its introduction or have only limited experience. However, even now, there are still a few articles that attempt to compare LPD and OPD, so further accumulation of cases is needed.

Committee voting results

Recommend conducting (strong recommendation)	Suggest conducting (mild recommendation)	Suggest not conducting (mild recommendation)	Recommend not conducting (strong recommendation)	Abstention from voting
12.5%	75.0%	0.0%	0.0%	0.0%

4 | FUTURE RESEARCH QUESTION

4.1 | LPD for pancreatic cancer

There are no randomized trials comparing OPD with laparoscopic pancreatoduodenectomy (LPD) for pancreatic cancer. Moreover, since LPD for pancreatic cancer is not currently covered by insurance in Japan as of August 2018, there are no reports comparing OPD and LPD specifically for pancreatic cancer in Japan.

There are several reports from overseas on retrospective studies comparing LPD and OPD.[15,16,19]

Croome et al.[19] reported no difference in overall survival (OS). The LPD group was superior to the OPD group in terms of progression-free survival (PFS), negative margin (R0 resection) rate, hospital stay, intraoperative blood loss, blood transfusion rate, and time until receiving postoperative chemotherapy. The incidence of pancreatic fistula, postoperative complications (Clavien–Dindo classification IIIb or higher), and operative duration (surgery time) times were similar.

Sharpe et al.[16] compared the OPD group ($n = 4037$) with the LPD group ($n = 384$) using the US National Cancer Database (NCDB) from 2010 to 2011, and reported that the LPD group was superior to the OPD group in terms of R0 resection rate, the number of dissected lymph nodes, readmission rate, and postoperative hospital days. There was no difference in 30-day postoperative mortality between the OPD and the LPD groups but multivariate analysis showed that LPD was significantly associated with 30-day postoperative mortality. A more detailed analysis showed that the 30-day postoperative mortality rate was significantly higher in the LPD group than in the OPD group in those surgical centers performing fewer than 10 LPDs for 2 years, but there was no difference between the two groups in those surgical centers performing more than 10 LPDs in 2 years.

Kantor et al.[15] compared the OPD group ($n = 7385$) with the LPD group ($n = 828$) using the NCDB from 2010 to 2013.

Although there was no difference in long-term prognosis (median survival) or perioperative mortality between the OPD and LPD groups, the 30-day postoperative mortality rate was significantly lower in those centers performing more than 20 LPDs/4 years than at those centers performing less than 20 LPDs/4 years. Moreover, the readmission rate was significantly lower in the LPD group than in the OPD group, and the hospital stay and the time to adjuvant chemotherapy tended to be shorter in the LPD group, although these differences were not statistically significant. On the other hand, there was no difference between the two groups in the R0 resection rate and the number of dissected lymph nodes.

Based on these reports, LPD may be equivalent to OPD in long-term and short-term prognosis and shortened postoperative hospital stay. However, in those centers still in the early stages of their introduction, the short-term postoperative mortality rate of LPD may be higher than that for OPD. In the future, after accumulating results from LPD for benign and low-grade diseases, high-quality evidence should be established through prospective clinical trials targeting only pancreatic cancer in Japan.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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