ORIGINAL ARTICLE

The Indications for Laparoscopic Pancreatectomy

Results on 550 Patients in the German Laparoscopic Pancreas Registry in Comparison to Other Registries

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SUMMARY

Background: Laparoscopic pancreatectomy is not yet established as a routine procedure everywhere in Germany or in other countries. Few data are available on its short- and long-term outcomes.

Methods: From 2008 onward, a working group initiated by 10 centers and currently comprising 34 centers has gathered data on all cases of laparoscopic pancreatectomy. Procedures in which laparoscopy was converted to open surgery are also included.

Results: The registry now contains 550 data sets representing 267 cases of benign disease, 244 malignancies, and 39 borderline tumors. The most common procedure was laparoscopic left pancreatectomy, followed by resection of the head of the pancreas and tumor enucleation. The most common intra-operative complication was hemorrhage, with a frequency of 3%. The rate of conversion to open surgery was 35%; if minilaparotomies are excluded, the conversion rate was only 16%. 39% of patients developed a pancreatic fistula after surgery (usually grade A or B, with 1.5% grade C) and 3% underwent reoperation because of postoperative hemorrhage. The procedure-related mortality was 1.3%. 91% of the patients reported only very mild postoperative pain. 6.7% newly developed diabetes mellitus after the procedure.

Conclusion: The patient cohort in the registry consists of persons who were selected to undergo laparoscopic pancreatectomy by the participating hospital teams, and the data are thus inherently affected by selection bias. The operative procedures that they underwent reflect the current practice of laparoscopic pancreatectomy in Germany. The complication rates are similar to those of open surgery. Selection bias can be avoided only by a randomized trial.

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Laparoscopic procedures on many different organs have replaced open surgery over the past 20 years. This development has markedly reduced operative trauma, enhanced the preservation of bodily integrity, and shortened post-surgical recovery times (1). Resection of part or all of the pancreas is among the more complex procedures in visceral surgery, with a relatively high burden of complications; the use of laparoscopy in this area is motivated by the desire to lessen procedure-related trauma.

After the pioneering initial work of Gagner and Cuschieri in 1992, in which the procedures often involved assistance by hand, the use of laparoscopy in pancreatic surgery declined for a few years (2, 3). After the introduction of dedicated instruments for laparoscopic surgery, including ultrasonic scissors, sealing instruments, and special staplers, laparoscopy again became a viable concept for surgery on the pancreas.

The role of laparoscopy in pancreatic surgery was still a controversial topic in discussions at the annual meeting of the German Society for General and Visceral Surgery (*Deutsche Gesellschaft für Allgemein- und Viszeralchirurgie*, DGAV) in 2007. In 2008, surgeons with an interest in this area joined together to create a data registry. At the first consensus conference, held in 2011, criteria for the selection of especially suitable patients were determined and then published (4). Promising findings were already available from registries of laparoscopic pancreatic surgery in other countries (5, 6).

As stated in the IDEAL criteria (7), when a new technique is introduced, the outcomes after its use should be documented quantitatively so that its potential can be properly assessed. In particular, its advantages (e.g., easier recovery or less pain for the patient, with comparable final outcomes to those of standard technique) must be weighed against its disadvantages (e.g., the development of diabetes mellitus).

By the time the second consensus conference was held in 2013, the registry already contained information on 270 patients. It was decided then that the technique would be evaluated in accordance with the IDEAL criteria once data from 500 patients had been compiled. In the meantime, the number of

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TABLE 1

Patient cohort

	Female	Male
Sex distribution	59%	41%
Age at diagnosis	58.6	62.5
Body-mass index (mean)	25.8	25.9

TABLE 2

Reasons for conversion to open surgery in 550 operations that were begun with laparoscopic technique

Reason for conversion	Number	Percent
PPPD (minilaparotomy for reconstruction)	127	23.1
Adhesions	8	1.5
Hemorrhage	8	1.5
Carcinoma	7	1.3
No tumor found	5	0.9
Pancreatectomy	4	0.7
Bleeding splenic vein	3	0.6
Obesity	3	0.6
Tumor in head of pancreas	3	0.6
Hemorrhage >500 mL	2	0.4
Large tumor	2	0.4
Splenic hemorrhage	1	0.2
Necrotizing pancreatitis	1	0.2
Panacreatitis involving head of organ	1	0.2
Stapler malfunction	1	0.2
Injury to mesentery of transverse colon	1	0.2
Injury to spleen	1	0.2
Infiltration of celiac trunk	1	0.2
Atypical course of splenic artery	1	0.2
Atypical course of right hepatic artery	1	0.2
Splenic abnormality	1	0.2
Obesity	1	0.2
Pancreas torn in specimen removal	1	0.2
Severed common hepatic artery	1	0.2

PPPD, pylorus-preserving pancreaticoduodenectomy

participating centers has risen steeply to 34, and the laparoscopic pancreatic surgery registry now contains data on 550 patients. As far as we can tell from the published international literature, this is the largest such database anywhere in the world.

The results of laparoscopic surgery as determined from this registry, in terms of complication rates, surgical outcomes, and length of hospital stay, must be compared with results from other registries, e.g., those of Belgium and Spain (8).

Materials and Methods

Registry

In 2008, the registry for laparoscopic pancreatic surgery was established and was evaluated and approved by the Ethics Committee of the University of Ulm. The registry is a platform for the documentation of all laparoscopic procedures on the pancreas. Participation is voluntary; data are acquired by being entered onto a standardized form. The registry has been presented multiple times at major surgical congresses in Germany (e.g., the annual meetings of the societies for general surgery and visceral medicine), and these presentations were exploited as opportunities to acquire new participating institutions. All surgeons who perform laparoscopic pancreatectomy were invited to participate voluntarily in the registry. The registry has also been presented to DGAV working groups such as those for the liver, biliary pathways, and pancreas (*Chirurgische Arbeitsgemeinschaft Leber-Galle-Pankreas, CALGP*) and for minimally invasive surgery (*Chirurgische Arbeitsgemeinschaft Minimal-Invasive Chirurgie, CAMIC*). Subsequently, the presidents of these working groups recommended participation in the registry.

The progress of the registry was reported on once a year at the annual meetings of each of the two major German surgical societies (*Fachgesellschaft für Chirurgie, Deutsche Gesellschaft für Chirurgie*). Data on laparoscopic procedures that were converted to open surgery were also included. The data were acquired by entry onto standardized forms for the documentation of key pre-, intra-, and postoperative information (e.g., histopathology) and the patients' further course (e.g., length of hospital stay, pain score, and complications). Only complete data sets were accepted, with the further requirement that the data must pass a plausibility test.

The authors of the present review are from the four centers that have contributed the largest number of patients to the registry; all four centers have participated in the registry since its inception. The other highly active participating centers and surgeons are listed by name at the end of the article.

Results

The main features of the patient cohort are listed in *Table 1*. 267 patients (48.5% of the total) had benign lesions. These comprised mainly

- Serous cystadenomas (58/10.5%),
- Neuroendocrine tumors (47/8.5%),
- Intraductal papillary-mucinous neoplasia (43/7.8%),
- Mucinous-cystic neoplasia (36/6.5%),

- Chronic pancreatitis (35/6.4%), and
- Pseudocysts (16/2.9%).

Rarer benign lesions accounted for the remaining 32 cases.

39 patients (7.1%) had borderline tumors, which, in turn, were further broken down into neuroendocrine tumors (23/4.2%), intraductal oncocytic papillary neoplasia (IPMN) (11/2%), and mucinous-cystic tumors (5/0.9%).

244 patients (44.4%) had cancerous lesions. The most common type was ductal adenocarcinoma (110/20%), followed by neuroendocrine carcinoma (79/14.4%). Rarer entities included metastases of other types of cancer (12/2.2%) and the following:

- Carcinoma of the papilla of Vater (8/1.5%)
- Mucinous cystadenocarcinoma (6/1.1%)
- Adenocarcinoma on the background of intraductal papillary-mucinous neoplasia (6/1.1%)
- Acinar cell carcinoma (5/0.9%)
- Bile duct carcinoma (3/0.5%)
- Ampullary carcinoma (3/0.5%)
- Serous cystadenocarcinoma (2/0.36%)
- B-cell lymphoma (2/0.36%)
- Intestinal-type adenocarcinoma (2/0.36%)
- Solid pseudopapillary carcinoma (2/0.36%).

There was one case each (0.18%) of malignant pheochromocytoma, carcinoid of the ampulla of Vater, duodenal carcinoma, and carcinosarcoma.

Among the types of laparoscopic procedure that were performed, left pancreatectomy was the most common (65%), followed by pylorus-preserving resection of the head of the pancreas (23%) and lesional enucleation (9%). Isolated segmental and pancreas-head resections were also performed, as well as five total pancreatectomies.

Laparoscopic left pancreatectomy

Laparoscopic left pancreatectomy was performed in 359 cases (65%) and was the most common procedure. The spleen was removed at the same procedure in 56% of these cases. Of the 201 cases in which preservation of the spleen was intended at the outset (e.g., in patients with benign diseases), the spleen was in fact preserved in 157 cases (78%). The mean duration of the procedure was 220 minutes, and the mean size of the resected pancreatic specimen was 9.0 cm (standard deviation, 3.5 cm).

The instrumentation used for dividing the pancreas is an important matter, as one of the goals of surgery is to prevent the postoperative development of a pancreatic fistula. The EndoGIA stapler was used in 59% of the patients, the Ligasure vessel sealer and divider in 25%, and the Ultracision Harmonic Ace Scalpel in 6%. No further information on laparoscopic instruments was entered into the registry.

Laparoscopic resection of the head of the pancreas

Laparoscopic resection of the head of the pancreas was the second most common type of procedure (127 cases, 23%). It was associated with 0% mortality within 60 days, as reflected by the data entered into the standardized questionnaire. The median length of hospital stay was 15 days (range, 7–59). Procedure-associated post-

TABLE 3

Intra- and postoperative complications

Complication	Number	Percent
Intraoperative		
Hemorrhage >500 mL	17	3.1
Injury to neighboring organs and structures	11	2.0
Cutaneous emphysema / rise in CO ₂	1	0.2
NSTEMI	1	0.2
Postoperative		
Pancreatic fistula	215	39.1
Pancreatic fistula after left-sided resection	147/359	40.9
Gastric emptying disturbance	65	11.8
Abscess	34	6.2
Postoperative hemorrhage without reoperation	27	4.9
Wound infection	19	3.5
Postoperative hemorrhage with reoperation	18	3.3
Pneumonia	11	2.0
Death (60 days)	7	1.3
Splenic infarction	6	1.1
Death (30 days)	5	0.9
Chyle fistula	4	0.7
Pleural effusion	3	0.6
Pulmonary embolism	3	0.6
Urinary tract infection	3	0.6
Cicatricial hernia	2	0.4
Biliary fistula	2	0.4
Colon perforation	2	0.4
Pancreatitis	2	0.4
ARDS	2	0.4
Circulatory failure	2	0.4
Renal infarction / renal failure	2	0.4
Suture line dehiscence	2	0.4
Colonic fistula	1	0.2
Diabetes mellitus due to resection of pancreatic tissue	1	0.2
SIRS/sepsis	1	0.2
Drain dislodged	1	0.2
Gastric perforation	1	0.2
Clostridium-difficile-associated colitis	1	0.2
Hemothorax	1	0.2

ARDS, acute respiratory distress syndrome; NSTEMI, non-ST-segment-elevation myocardial infarction; SIRS, systemic inflammatory response syndrome

operative complications were experienced by 97 patients.

Laparoscopic enucleation

In 48 cases, lesions were laparoscopically enucleated (9%). The mortality associated with these procedures was also 0%. The median length of hospital stay was

TABLE 4

Comparison of main types of surgical procedure

Operation (number performed)	Malignancies	Reop rate	Conversion rate	Hospital stay (median)	Morbidity	Mortality
Laparoscopic left pancreatectomy (359)	38%	11%	15%	13 days	57%	1.7%
Laparoscopically assisted PPPD (127)	75%	10%	100%*	15 days	76%	0%
Enucleation (48)	19%	12%	12%	11 days	47%	0%

* With procedure-related minilaparotomy for anastomoses.

PPPD, pylorus-preserving pancreaticoduodenectomy (= resection of the head of the pancreas); Reop, reoperation

11 days (range, 4–67). 23 patients had postoperative complications.

Intra- and postoperative course of laparoscopic pancreatectomy

In 16% of all patients—not counting those who underwent a laparoscopically assisted, pylorus-preserving pancreaticoduodenectomy (PPPD)—a laparoscopic procedure was converted intraoperatively to open surgery. The median time from the beginning of the procedure to the conversion was 135 minutes. The reasons given for conversion were:

- Spread of cancer (n = 7)
- No tumor found (n = 5)
- Splenic hemorrhage (n = 4)
- Necrotizing pancreatitis (n = 1)
- Pancreatitis (n = 1)
- Dysfunction of an EndoGIA stapler (n = 1)
- Adhesions (n = 8)
- Obesity (n = 3)
- Inflammation involving the head of the pancreas (n = 3)
- Pancreatectomy (n = 4)
- Iatrogenic injury of the mesentery of the transverse colon (n = 1).

The reasons for conversion are listed in greater detail in Table 2.

As for intraoperative complications, hemorrhage beyond the amount typically expected (500 mL per procedure) was documented in 3.1% of patients. Further complications, occurring in one patient each, were iatrogenic injuries to the mesentery of the transverse colon, the splenic vein, the common bile duct, and the diaphragm. The spleen was injured intraoperatively in four cases.

As for postoperative complications, postoperative hemorrhage not requiring reoperation arose in 27 patients (4.9%), and postoperative hemorrhage leading to reoperation arose in 17. Thirty-nine percent of all patients developed a pancreatic fistula (mostly grade A and B fistulae, with 8 grade C fistulae in the entire patient cohort). 5.5% of patients developed an abscess, and 1.1% developed a splenic infarct. Seven patients died for reasons related to the procedure (1.3%); 3.5% had a postoperative wound infection. A more detailed listing of all intra- and postoperative complications is given in Table 3.

The median length of hospital stay was 14 days (range, 4–93 days).

As for postoperative pain, 91% of the patients had a Visual Analog Score (VAS) less than 4. Diabetes mellitus was already present preoperatively in 15.6% of all patients and newly arose postoperatively in a further 6.7% of all patients.

TABLE 5

Comparable publications

First author / year (ref. no.)	Country	Centers	Percentage of laparoscopies	Percentage of cancer	Intraoperative blood loss	Conversion rate	POPF	Mortality
Mabrut JY et al., 2005 (8)	Belgium	25	(127/127) – 100%	13%	n.a.	13.4%	14%	n.a.
Weber SM et al., 2009 (6)	USA	9	(219/219) – 100%	n.a.	n.a.	n.a.	23%	0%
Jayaraman Set al., 2010 (20)	USA	1	(107/343) – 31%	17%	150 mL	n.a.	15%	n.a.
Song KB et al., 2011 (21)	South Korea	1	(359/359) – 100%	10%	n.a.	n.a.	7%	0%
Zhou ZQ et al., 2014 (22)	South Korea	1	(246/246) – 100%	10.4%	378 mL	n.a.	237%	0%
Croome KP et al., 2014 (23)	USA	1	(108/322) – 34%	100%	492 mL	n.a.	11%	2%
Song KB et al., 2015 (24)	South Korea	1	(137/1 661) – 8%	75%	592 mL	n.a.	29.9%	1%
Lee SY, et al., 2015 (25)	USA	1	(131/805) – 16%	100%	262 mL	31%	8%	0%
Siech M, Strauss P et al., 2017	Germany	34	(550/550) – 100%	44.4%	2.7% >500 mL	15.6%	39.0%	0.9%

n.a., data not available; POPF, postoperative pancreatic fistula

The three most common types of laparoscopic surgery are compared in *Table 4*. The 57–76% morbidity mentioned in the table may seem very high at first but is accounted for by the conscientious recording of cases of grade A pancreatic fistula or grade A gastric emptying disturbance, both of which are generally clinically irrelevant conditions.

Discussion

This German-language registry, which now contains data on 550 patients, is currently the world's largest database on laparoscopic pancreatic surgery. The 34 participating centers are to be commended for their unprecedented collaboration and mutual solidarity under the aegis of the German Society for General and Visceral Surgery.

We are well aware that the registry data presented here are not free of bias. The advantages and disadvantages of clinical registry studies in comparison to prospective randomized controlled trials are well known: even though the latter are now considered the gold standard for testing a new technique, the former are much better at reflecting the overall current care situation in the geographical region of interest (9). Further advantages of registry studies are the following:

- No prior restriction on the number of patients
- Heterogeneous patient group
- Heterogeneous conditions and centers
- Open inclusion
- Safety and goal-directedness
- Choice of either a prospective or a retrospective design.

The registries in other countries that are known to us from the published literature consist of data derived from no more than 3–9 centers per registry.

It is clear that the participating centers selected patients for laparoscopic pancreatic surgery whom they considered to be highly suitable for the procedure (sample criteria: thin patient, small and easily accessible tumor). The percentage of laparoscopic operations among all pancreatic procedures in each participating hospital was 5–20%, which, of course, implies that 80–95% of the procedures were conventional open surgery. In our patient cohort, just as in the cohorts of earlier publications (8), left pancreatectomy was performed more often by laparoscopy. This is due to selection bias, as resections of the head of the pancreas predominate in conventional pancreatic surgery (10). Tumors located in the left side of the pancreas are less common, and this would make a randomized controlled trial difficult to perform, as the small group of candidates for left pancreatectomy would have to be subdivided into two separate, even smaller treatment groups (one for laparoscopic and one for open surgery).

Malignant tumors of the pancreas account for a higher percentage of the lesions resected laparoscopically in the German registry than in a comparable Belgian study (8). The reason is that, as surgeons become more experienced in the minimally invasive technique, it is increasingly used for malignant tumors as well. This is confirmed by a trend over time in the German registry: in 2011,

only 20% of the laparoscopic procedures were performed in patients with malignant disease (4), but, in the meantime, this figure has risen to 44.4%.

As shown in *Table 5*, extensive case series of pancreatectomies are now available from multiple industrialized countries. In some of them, the morbidity and mortality associated with laparoscopic pancreatic surgery are low and comparable to those associated with conventional resection. In 2015, Adam et al. reported on a series of 7061 patients—a subset of the National Cancer Database (11), which comprises 75% of newly diagnosed cases of cancer in the USA—among whom 983 (14%) underwent laparoscopic pancreaticoduodenectomy. The conversion rate was 30%. The mortality of laparoscopic surgery was 4.8%, compared to 3.7% for open pancreaticoduodenectomy. Thus, in this study, the procedure was found to be widely applicable, though still associated with a somewhat higher mortality than conventional surgery. The German-language registry, in contrast, revealed no difference in mortality. This may be due to the numerical predominance of left pancreatectomies in the registry, with right-sided resections only recently being performed at an appreciable rate. Two current publications by Sulpice et al. and Riviere et al. show no clear superiority of either technique (laparoscopic vs. conventional surgery) for left-sided resections (12, 13).

The registry data can also be compared with those of the Initiative for Quality in Medicine (*Initiative Qualitätsmedizin*, IQM), a consortium of 387 hospitals jointly pursuing objective quality control. The mortality among the 4845 cases reported to the IQM in 2015 was 8.3% (14). The 1.3% mortality documented by the German registry is markedly lower. On the other hand, the 39% rate of postoperative pancreatic fistula formation in the German registry is higher than the 30% rate reported in the literature (15).

The reported rates of newly arising diabetes mellitus after conventional Whipple procedures vary from 10% to 37% (16, 17). This value rises to as high as 60% after surgery for chronic pancreatitis (10). The much lower rate of 6.7% observed in the German registry cohort may be due to selection bias.

Laparoscopic pancreatectomy is not yet listed as a standard procedure in the German S3 guideline that was issued in October 2013 (18). In the guideline, it is recommended that all laparoscopic resections should be documented in a registry such as the one presented in here, so that new therapeutic techniques can be adequately assessed. We endorse this recommendation.

The quantifiable advantages of laparoscopic pancreatic surgery, particularly laparoscopic left pancreatectomy, for patients in comparison to conventional procedures include a low complication rate—in particular, a low rate of wound infections (19)—along with low mortality and shorter hospital stays. As the next step in the objective evaluation of laparoscopic pancreas surgery, according to the principles of evidence-based medicine, these conclusions derived from registry data will have to be tested in prospective randomized controlled trials.

KEY MESSAGES

- The lively interest aroused by the registry and the large-scale participation in it indicate that laparoscopy is now increasingly being taken into consideration as a useful technique for pancreatic surgery.
- The most common laparoscopic operation on the pancreas is left pancreatectomy, but resections of the head of the pancreas are increasingly being performed laparoscopically as well.
- Laparoscopy is also increasingly used to resect malignant tumors.
- Pancreatic fistula arises after laparoscopic surgery on the pancreas at approximately the same rate as after conventional surgery. The low mortality, low infection rates, low pain scores, and rarity of newly developed diabetes mellitus after surgery are highly encouraging.
- In the near future, these findings should be put to the test in a randomized controlled trial.

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Conflict of interest statement

The authors declare that no conflict of interest exists.

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