2 Challenges in Robotic and Minimally Invasive Pancreatic Surgery in the Year 2020

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2.1 Background

Robotic pancreatic surgery (RPS) is increasing in recent years [1]. No randomized controlled trial has demonstrated superiority when comparing robotic to laparoscopic pancreatic surgery (LPS).

Nevertheless, robotic technology may have an edge when performing complex, gastrointestinal, minimally invasive reconstructive tasks in narrow anatomical regions, such as minimally invasive esophagectomy, pancreatoduodenectomy, and deep rectal cancer surgery. Other advantages of RPS include extended triangulation possibilities and a 3D view of the operative field [1].

This chapter highlights the status of laparoscopic or robotic surgery for pancreatic cancer today. The specific data available for pancreatoduodenectomy for pancreatic head carcinoma and for distal pancreatectomy or pancreatic left resection for pancreatic carcinoma located on the left side of the mesenteric-portal axis will be taken into account. The indication for RPS should be identical to LPS. As RPS and LPS are a rather evolving procedures, the current experience of experts should be taken into account and modular approaches as well as well-selected cases should be chosen [2].

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2.2 Review of the Current Literature

2.2.1 Distal Pancreatic Resections

The clinical outcome quality of minimally invasive distal pancreatectomy was recently evaluated in a multicenter, randomized controlled clinical trial in the Netherlands [3]. This patient-blinded study, which was conducted in 14 national centers from 2015 to 2017, compared the time to functional recovery of patients who received either minimally invasive (n = 51) or open (n = 56) distal pancreatectomy (LEOPARD; NTR5689) without vascular involvement in a tumor confined to the left side of the pancreas. The primary endpoint, time to functional recovery, was significantly shorter with 4 days for minimally invasive versus 6 days for open pancreatectomy. The conversion rate was 8%. The overall complication rated as Clavien-Dindo

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≥ III was not significantly different, but there was less gastric emptying disorder and a better quality of life without increasing costs for minimally invasive distal pancreatectomy. Surgical quality control was performed prior to patient enrollment in the study, since only surgeons who had undergone >50 complex minimally invasive GI procedures, >20 distal pancreatectomy, and >5 minimally invasive distal pancreatectomies were accepted as surgeons within the clinical trial [4].

The results of the LEOPARD study (Dutch Pancreatic Cancer Group data, 17 centers; 2005–2016) were compared with the database of the American College of Surgeons' National Quality Improvement Program (ACS-NSQIP) (88 centers; 2014–2016). In this international cohort study, severe 30-day morbidity including mortality was evaluated according to the surgical procedure – either minimally invasive or open distal pancreatectomy. Of the 2921 ACS-NSQIP patients, 1562 (53%) received a minimally invasive distal pancreatectomy with 18% conversion rate and 1359 (47%) received an open distal pancreatectomy. The minimally invasive surgical technique was associated as an independent factor with reduced severe 30-day morbidity including mortality for distal pancreatectomy. [5]

In a retrospective analysis of the prospective database of the American College of Surgeons-National Surgical Quality Improvement Program, morbidity and mortality following minimally invasive (n = 166; 33.1%) versus open (n = 335; 66.9%) distal pancreatectomy in 501 patients with pancreatic ductal adenocarcinoma (PDAC) and distal pancreatectomy were investigated with preoperatively comparable comorbidity and pathological staging. Overall morbidity, transfusion administration, pneumonia rate, surgical wound infections, sepsis, and hospitalization time were lower with minimally invasive distal pancreatectomy. Mortality, pancreatic fistulas, and gastric emptying disorders were comparable. Accordingly, the short-term postoperative outcome from this large multi-institutional database for minimally invasive distal pancreatectomy in pancreatic cancer appears to be improved [6].

A further study, in the sense of a population-based retrospective cohort study, investigated perioperative factors with regard to differences between minimally invasive and open surgery. A total of 8575 open surgery procedures were compared to 382 minimally invasive distal pancreatectomies. This analysis revealed a low incidence of general perioperative complications (39.0% vs. 30.1%, $P < 0.001$) and less frequent postoperative bleeding events (20.6% vs. 13.6%, $P < 0.001$). Hospital length of stay was shorter in the minimally invasive group, so the authors conclude that minimally invasive distal pancreatectomy is associated with a more favorable complication profile and therefore minimally invasive distal pancreatectomy can be used as an alternative to open surgery [7].

In a retrospective, monocentric analysis of a high-volume center (n = 422 distal pancreatectomies from 2005 to 2014), the oncological outcome in 79 comparable patients with PDAC after laparoscopic (n = 33) or open (n = 46) distal pancreatectomy was investigated. Intraoperative and pathological variables were comparable, such as surgery time, duct size, glandular texture, tumor size, type of pancreatic closure, number of lymph nodes removed, tumor stage, and R0 status at the removal site. The 1-, 3- and 5-year survival and local recurrence and distant metastasis rates were comparable in both groups. Laparoscopic distal pancreatectomy was judged by the authors to be comparable to the open surgical technique in terms of oncological criteria [8].

Furthermore, the question arises to what extent the robot-assisted surgical technique offers advantages in the quality of results compared to laparoscopic distal pancreatectomy. Huang B. et al. have compared robot-assisted and laparoscopic distal pancreatectomy in adult patients with malignant, borderline malignant, and also benign disease. Primary endpoints were conversions to open surgery, transfusion rate, spleen preservation, surgery time, complications (pancreatic fistula), and length of hospital stay. A total of nine studies with a total population of 1167 patients were evaluated, including 929 patients undergoing laparoscopic and 238 patients under-

going robotic distal pancreatic left resection. Overall, there was no significant difference between laparoscopic and robotic pancreatic left pancreatic resection for any of these endpoints. However, despite the small number of robotic pancreatic left resections, the authors evaluated them as safe and effective compared to laparoscopic pancreatic left resection [9].

A retrospective analysis compared the quality of results between laparoscopic and robotic distal pancreatectomy. A total of 247 procedures were identified in a database analysis at a center in the USA (135 laparoscopic, 108 robot-assisted operations). It was shown that the surgery time was shorter in the laparoscopic group, but the proportion of spleen preservation was higher in the robotic group. There were no significant differences in the incidence of clinically relevant B/C fistulas, conversion rate (4.3% and 1.8%), and oncological 2-year outcome [10].

To summarize this paragraph, perioperative complications seem to be lower in minimally invasive distal pancreatic resected patients.

2.2.2 Complications in Minimal-Invasive Pancreatic Surgery

In a recent systematic review from 2020 with meta-analysis, the perioperative outcome quality of laparoscopic versus open elective pancreaticoduodenectomy for patients with benign or malignant pancreatic diseases was compared from three randomized controlled clinical trials with a total of 224 patients. Primary endpoints were 90-day mortality, complication rated as Clavien-Dindo $\geq$ III, and length of hospital stay. Secondary endpoints were pancreatic-specific outcome parameters such as postoperative pancreatic fistula, gastric emptying disorder, biliary fistulas, blood loss, re-operation, hospitalization, oncological outcome (R0-resection, number of removed lymph nodes), and surgery time. The meta-analysis showed only a significant difference in surgery time in favor of open pancreatoduodenectomy and less blood loss with the laparoscopic surgical technique. All other primary and secondary outcome parameters were not significantly different with overall moderate to low evidence levels. Based on these results, laparoscopic pancreaticoduodenectomy currently has no advantage over open surgery. In the future, the learning curve in the respective medical technology and the increasing implementation of robotic surgery must be taken into account when evaluating the quality of perioperative outcome. [11]

A retrospective monocentric analysis examined the perioperative outcome quality as well as pathological and oncological outcome parameters in a total of 1623 minimally invasive pancreaticoduodenectomies (1458 laparoscopic, 165 robot-assisted operations). It could be shown that robot-assisted surgery is more likely to be performed at high-volume and university facilities. There was no difference between laparoscopic and robotic surgery with regard to the investigated target parameters. Only the conversion rate was lower in the robot-assisted group (17.0% vs. 27.6%, $P = 0.003$). There was no statistically significant difference in resection status (R0/R1), number of lymph nodes examined, hospitalization time, 90-day mortality, and median overall survival (laparoscopic 20.7 months vs. robot assisted 22.7 months; log-rank $P = 0.445$) [12].

In a Dutch multicenter randomized study (LEOPARD-2), the safety profile of laparoscopic pancreatic head resection in periampullary carcinomas was investigated in a prospective setting [13]. The study design was a two-stage concept so that a phase II/III design could be run in parallel. The study initially focused on the description of a detailed safety profile of periampullary carcinoma resection. Interestingly, the primary endpoint of the phase II part was the postoperative elevation of the cytokine interleukin-6. Surgical complications (POPF, hemorrhage, etc.) were only considered as secondary endpoints.

As a result, the study was presented by the Data and Safety Monitoring Board and terminated with five deaths in the group of minimally invasive surgery in the 90-day postoperative period (10%).

Regarding the primary endpoints, the study cannot provide discriminatory results, as the total number of patients enrolled is too low. The authors conclude that the number of perioperative complications was worryingly high and unexpected, especially considering that only centers and surgeons with high expertise in both open and minimally invasive pancreatic surgery were included. As a result, the program for minimally invasive pancreatic head resections has been suspended at national level in the Netherlands. The authors speculate that the required qualifications of the surgeons may not have been sufficient and that an even longer training period is necessary to perform this type of surgery with a comparable quality of outcome as is currently possible with open surgery.

With regard to the development of clinically relevant fistulas, McMillan et al. have analyzed robot-assisted pancreatic head resections in comparison to the open procedure in a propensity matched analysis. A total of 152 open procedures were compared with the same number of robot-assisted operations. It was shown that the incidence of clinically relevant pancreatic fistulas (POPF grade B/C) was lower in the robot-assisted group than in open surgery (OR, 0.4 [95%CI, 0.2–0.7]; $P = 0.002$). In all other secondary endpoints, robotic procedures and open surgery were comparable and did not show significant differences (total complication rate (73.7%vs 66.4%; $P = 0.21$), median hospital stay (8 vs 8.5 days; $P = 0.31$), 30-day recovery (22.4% vs 21.7%; $P > 0.99$), 90-day mortality (3.3% vs 1.3%; $P = 0.38$)) [14].

Identical results could be shown by a likewise monocentric retrospective database analysis of the National Cancer Database (NCDB) from the USA. There was no difference in perioperative outcome parameters in the study, only the conversion rate was higher in the laparoscopic group than in the robot-assisted group (27% vs. 10%, $P < 0.001$) [15].

To summarize this paragraph, robotic surgery seems to lower conversion rates of minimally invasive pancreatoduodenectomies without any other quality differences when compared to open or laparoscopic surgery.

2.2.3 Oncological Outcomes

A propensity score-matched analysis investigated oncological overall survival in comparison between open and laparoscopic procedures in a monocentric retrospective analysis. A total of 1947 patients were identified, 605 of whom underwent laparoscopic surgery. A balanced group formation with 563 patients was achieved. In the 3-year survival rate, there was no difference between open and laparoscopic procedures (41.6% vs. 36.0%; hazard ratio 0.93, 95% confidence interval 0.77–1.12; $P = 0.457$). The time from surgery to the start of the first adjuvant chemotherapy was identical in both groups with 50 days, as well as the number of resected lymph nodes (median 12 lymph nodes in both groups). Furthermore, there was no difference in the 30-day and 90-day mortality rates. Therefore, the authors conclude that a minimally invasive procedure is an acceptable alternative to open surgery in terms of oncological outcome [16].

A prospective randomized study compared the open versus robotic pancreatic corpus resection with the primary target criterion of hospitalization time. A total of 107 patients were randomized and 50 vs. 50 patients were evaluated in the intention-to-treat analysis. Hospital stay in the minimally invasive group was shorter (15.6 vs. 21.7 days, $P = 0.002$), surgery time was shorter, blood loss was less, and the occurrence of clinically relevant pancreatic fistulas was less frequent. The authors conclude that the robot-assisted technique is superior to open surgery in all primary and secondary endpoints [17].

In a meta-analysis of all studies published by the end of 2017, the clinical outcome quality after robotic pancreatoduodenectomy and distal pancreatectomy was examined in comparison to the respective open surgical technique. A total of 15 non-randomized, controlled studies with 3690 patients (11 studies on robot-assisted vs. open pancreatoduodenectomy, 4 studies on robot-assisted vs. open pancreatic left resection) were included in the analysis. There was no significant difference between robot-assisted vs. open pancreatic ductectomy in terms of lymph node status, postoperative complications (pancreatic

fistula, p.o. voiding disorder), re-operation rate, hospitalization time, and mortality. Robot-assisted pancreatoduodenectomy required significantly longer surgery time, while blood loss, wound infections, and R1 status at the weaning margin were significantly lower than with open surgery.

Compared to open distal pancreatectomy, the robot-assisted procedure resulted in a lower overall complication rate, less blood loss, shorter hospital stay, and also a lower number of removed lymph nodes. There was no significant difference in spleen preservation, R1 status, mortality, and especially pancreatic fistulas.

The authors evaluate robot-assisted pancreatic surgery as a safe and possible alternative to open surgery in terms of perioperative, clinical outcome quality, subject to the lack of randomized controlled trials [18].

Comparable results (12 studies; a total of 2186 patients, 705 of them with minimally invasive and 1481 pancreatoduodenectomy) provided a systematic review with meta-analysis of minimally invasive (robot-assisted or laparoscopic) pancreatoduodenectomy compared to the open surgical method [19].

In a systematic review of published papers in the period 2000–2016, total robotic pancreaticoduodenectomy is compared to open pancreaticoduodenectomy in different diseases. A total of 13 non-randomized controlled studies with 692 robotic pancreatoduodenectomies were included in this review. The incidence of complications (biliary fistula, pancreatic fistula, postoperative bleeding), reoperations as well as mortality were comparable, but especially for complications due to missing data from large series, the results were not considered representative. The number of conversions (6.5–7.8% on average) to open surgery as well as surgery time decreased over time as the number of robotic pancreaticoduodenectomies increased. Lymph node status was comparable, but the number of R1 resections was shifted in favor of robotic pancreatoduodenectomy, most likely a selection bias. The authors conclude that robotic pancreatoduodenectomy is safely feasible in high-volume centers, but no data on long-term oncological survival and cost-effectiveness of this surgical technique are available [20].

In a retrospective non-inferiority propensity scored-matched analysis, the influence of the surgical method on the R-status after pancreatic head resections was investigated. A total of 20 robot-assisted procedures were compared to 24 open surgery procedures. In the robotically operated group, the R1 rate was 55.0% compared to 41.7% in the open surgery group ($P = 0.38$), and no difference was found in the secondary endpoints (number of lymph nodes examined, number of blood transfusions, adjuvant chemotherapy, overall survival, disease-free survival). With regard to the R0/R1 rate, the robot-assisted technique does not appear to be inferior to open surgery [21].

To summarize this paragraph, the evidence of minimally invasive pancreatoduodenectomy is still limited. When performed in high-volume centers, the procedure seems to safely achieve comparable long-time oncological outcomes.

2.3 Conclusions

The indication for RPS should be identical to LPS. As RPS and LPS are still rather evolving procedures, experiences of experts should be taken into account and modular approaches as well as well-selected cases should be chosen to safely perform the procedures without quality compromises.

If an RPS or LPS of a pancreatic carcinoma is performed, it should be reported to national and international registries such as the laparoscopic pancreatic surgery register of the German Society of General and Visceral Surgery (http://www.dgav.de/studoq/weitere-register.html).

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