Complexity and Experience Grading to Guide Patient Selection for Minimally Invasive Pancreatoduodenectomy

An International Study Group for Pancreatic Surgery (ISGPS) Consensus

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Objective: To develop a universally accepted complexity and experience grading system to guide the safe implementation of robotic and laparoscopic minimally invasive pancreatoduodenectomy (MIPD).

Background: Despite the perceived advantages of MIPD, its global adoption has been slow due to the inherent complexity of the procedure and challenges to acquiring surgical experience. Its wider adoption must be undertaken with an emphasis on appropriate patient selection according to adequate surgeon and center experience.

Methods: The International Study Group for Pancreatic Surgery (ISGPS) developed a complexity and experience grading system to guide patient selection for MIPD based on an evidence-based review and a series of discussions.

Results: The ISGPS complexity and experience grading system for MIPD is subclassified into patient-related risk factors and provider experience-related variables. The patient-related risk factors include anatomic (main pancreatic and common bile duct diameters), tumor-specific (vascular contact), and conditional (obesity and previous complicated upper abdominal surgery/disease) factors, all incorporated in an A-B-C classification, graded as no, a single, and multiple risk factors. The surgeon and center experience-related variables include surgeon total MIPD experience (cutoffs 40 and 80) and center annual MIPD volume (cutoffs 10 and 30), all also incorporated in an A-B-C classification.

Conclusions: This ISGPS complexity and experience grading system for robotic and laparoscopic MIPD may enable surgeons to optimally select patients after duly considering specific risk factors known to influence the complexity of the procedure. This grading system will likely allow for a thoughtful and stepwise implementation of MIPD and facilitate a fair comparison of outcomes between centers and countries.

Key Words: outcomes, pancreaticoduodenectomy, quality

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An increasing use of laparoscopic and robotic minimally invasive pancreatoduodenectomy (MIPD) has been reported globally over recent years. The initial concerns raised by expert pancreatic surgeons have steadily paved the way for the systematic implementation of MIPD.[1–4] Nevertheless, still < 4.5% of pancreatoduodenectomies (PDs) are performed minimally invasive (MI).[5–7] The adoption of MIPD has been fostered through leadership in training the next generation of MI pancreatic surgeons[8,9] with an emphasis on expertise and appropriate patient selection.[10–12] Such an approach depends on an understanding of the value of surgical volume[13,14] and learning curves,[15–17] underpinned by adherence to the principles of pancreatic surgery[18,19] and a stringent evaluation of outcomes.[20–23]

Morbidity after (open or MI) PD remains relatively high,[24–28] even in centers of excellence.[29–31] One of the key determinants of perioperative outcomes for PD, which is especially evident in MIPD, is optimal patient selection.[1] Patient outcomes are significantly compromised after unplanned intraoperative conversions of MIPD when compared with successfully completed MIPD and upfront open PD.[32] Numerous anatomic,[30,33–38] tumor-specific,[30,39] and patient-specific (conditional)[39–43] factors have emerged, thus identifying subgroups of patients who tend to have worse outcomes after an operation. Just as important, is the technical capability of the surgeon, as well as the center volume, resources, and experience, which is essential for early detection and treatment of complications to avoid "failure to rescue" (FTR).[44,45]

Over the last 2 decades, the International Study Group for Pancreatic Surgery (ISGPS) has introduced several globally accepted consensus definitions and grading systems for postpancreatectomy complications[24–28,46] which have been well-accepted, widely cited, and broadly adopted in the literature. These have allowed important and accurate comparisons of outcomes across practitioners, institutions, and countries. The focus of this ISGPS undertaking is not to prescribe decision-making in terms of resectability but to assist surgeons, regardless of their experience, in appropriately selecting patients for MIPD, by providing an insight into the preoperative determination of the potential complexity of the procedure considering factors known to impact on the safe execution of MIPD as determined by the combined experience of the members of the ISGPS. This grading system will, thus, potentially help guide surgeons to determine which patients can be operated on, taking into account their own experience, as well as the institutional experience, and also help determine the need for additional resource allocation (maximal blood ordering schedules,[47] planning for vascular resections and reconstructions[48]), availability of senior surgeons, the need for more than one pancreatic surgeon being involved, having an experienced "rescue team," including an interventional radiologist, among others).

This study presents the ISGPS evidence and consensus-based complexity and experience grading system for laparoscopic and robotic MIPD. This objective grading system also acts as a framework for the standardization, reporting, and comparison of outcomes.

METHODS

A computerized search of the PubMed and Embase databases was undertaken in January 2023, using the following terms: "pancreatoduodenectomy," "pancreaticoduodenectomy," "minimally-invasive," and "laparoscopic," "pancreatic cancer," "pancreatic adenocarcinoma," "robotic," "complexity," "selection," "conversion," "outcomes." All levels of evidence were included and rated, according to the evidence level of individual studies defined by the recommendations of the Center for Evidence-Based Medicine, Oxford, UK (http://www.cebm.net/), in descending order: systematic reviews and meta-analyses of randomized controlled trials (RCTs), prospective, RCTs, systematic reviews of cohort studies, prospective/retrospective cohort studies, and existing consensus reports. Only studies published in English were included. Case studies, editorials, and conference abstracts were excluded. References of the included articles were checked to ensure no relevant studies had been missed. All relevant literature and a summary of the extracted data were reviewed by the ISGPS study subgroup (S.G.B., O.S., R.S., G.M., C.L.W., J.W., C.R.F., T.H., M.G.B., and S.V.S.), who then provided a first draft of the consensus definitions and statement.

Multiple revised drafts were circulated through electronic mail for critical analysis and further modifications. Numerous revisions were circulated, commented upon, and edited electronically by all the contributing members of the ISGPS who participated in this study. Eventually, a consensus was achieved across all members and approved for publication.

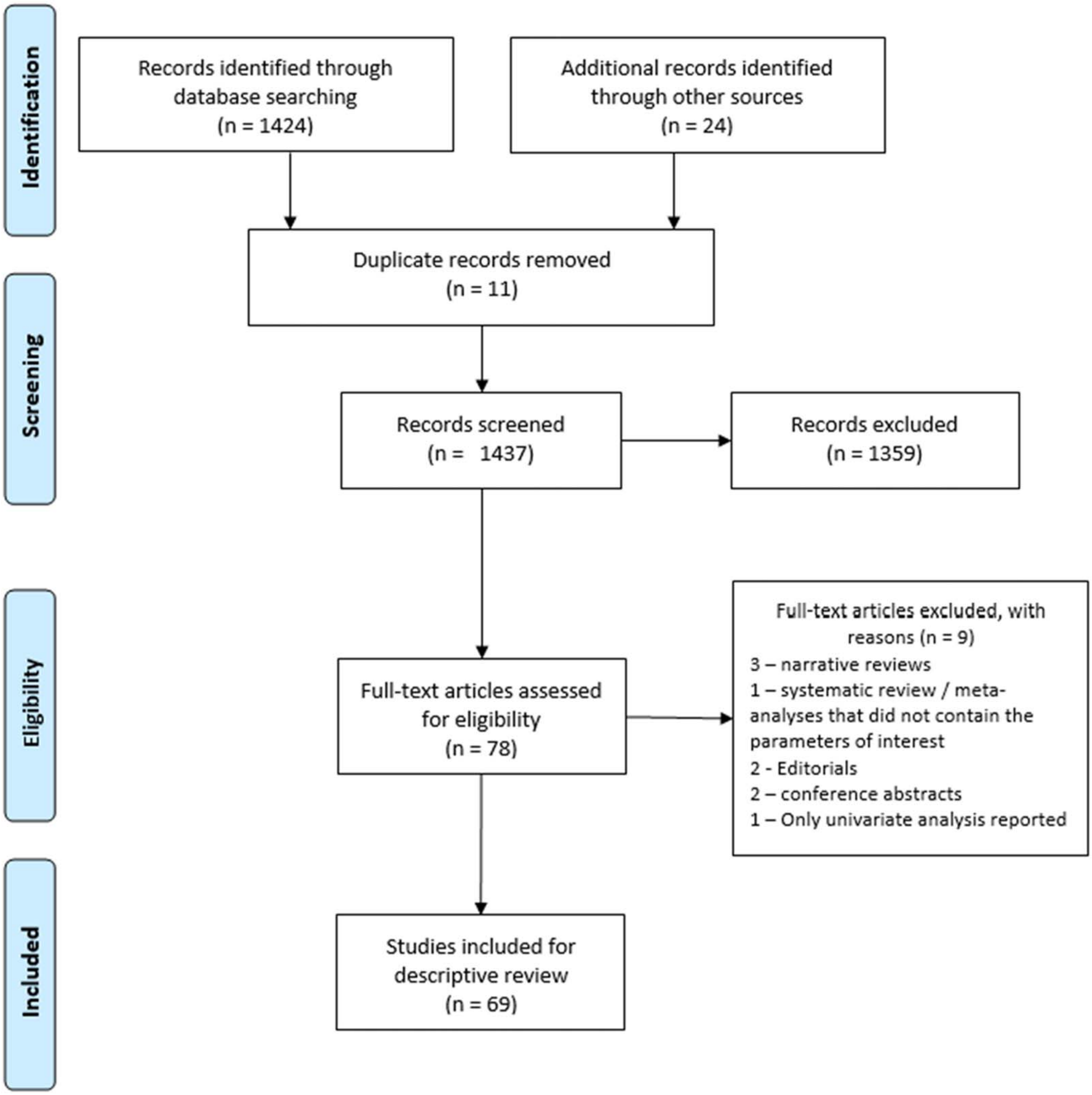

FIGURE 1. Search strategy.

RESULTS

The systematic review yielded 1448 studies, of which 69 were included for descriptive review (Fig. 1).

Anatomic Factors

Postoperative pancreatic fistula (POPF) remains one of the most harmful complications after pancreatic resection.[27] A main pancreatic duct (MPD) diameter of < 3 mm has been consistently associated with an increased risk of ISGPS grade B/C POPF.[49]

Acknowledging the relevance of this anatomic factor, the ISGPS[36] has previously used the subclassification of MPD diameter sizes of < 3 mm, 3 to 8 mm, and > 8 mm based on the frequency with which occurrence of POPF was reported.[50,51] A recently developed scoring system (PD-ROBOSCORE) to predict severe postoperative complications after robotic MIPD, confirmed the significant impact of an MPD < 4 mm [odds ratio (OR): 1.59; $P < 0.0001$].[52] Interestingly, contrary to the previous, 3 studies noted a higher risk of conversion with MPD diameter sizes > 3 mm.[53–55] The likelihood that vascular involvement, tumor size, tumor-associated inflammation, or even surgeon factors influenced the conversion rates is plausible and highlights the need to consider more than just anatomic factors in decision-making. Data on a protective role for robotic PD in mitigating clinically relevant (CR) POPF, especially in high-risk patients, remain heterogenous, with one study confirming this,[56] whereas another not only found no difference between open and robotic PD for CR-POPF in high-risk patients but a higher risk of CR-POPF in intermediate-risk patients.[57] A previous review of the evidence by the ISGPS[49] noted a significant impact of soft pancreatic texture on the development of POPF (OR: 4.24, 95% CI: 3.67–4.89; $P < 0.01$). Although some imaging modalities, including computed tomography scans and magnetic resonance imaging, are to some extent able to predict the texture of the pancreas by comparing its signal intensity relative to that of the spleen, liver, or muscle, prospective validation studies are currently lacking.[58] Although pancreatic texture is a natural component of the fistula risk score,[59] it does not necessarily impact the technical complexity of MIPD. There remains a paucity of focused studies on the technique of performance of hepaticojejunostomy (HJ) at the time of PD or the morbidity associated with it (especially the incidence of bile leak/stricture). This is likely related to the fact that morbidity related to the performance of HJ for reconstruction during PD is uncommon. The reported rates vary from 2.4% to 5.6%[60–63] for leaks and 2.6% for biliary strictures on long-term follow-up at a median of 13 months after PD.[64] In a large retrospective study of 443 patients who underwent open PD, Yamaki et al[65] noted a clinical HJ stenosis rate of 9%, a median of 7.2 months postsurgery with an HJ diameter of ≤8 mm at surgery being an independent risk factor on multivariate analysis.

Technical factors predictive of biliary stricture and cholangitis after robotic PD include preoperative radiotherapy, small duct size (<10 mm diameter), increased distance of the HJ (>10 mm) from the hilar plate, and continuous suturing technique.[66] Kendrick and Cusati[67] reported performing an end-to-side HJ with running (bile duct >5 mm) or interrupted (bile duct ≤5 mm) sutures for total laparoscopic PDs. While a bile duct diameter >6 mm is regarded as dilated on ultrasound, a diameter of 10 mm can be confidently appreciated as dilated on computed tomography scans.[34] A recent population-based study of health in Pomerania, examined the upper reference (>95th percentile) of common bile duct (CBD) diameter limits on magnetic resonance imaging.[68] In the study, they found 8 mm and 11 mm to be the upper reference limits for CBD diameters in patients <65 years and ≥65 years, respectively.

Consensus Statement

Small MPD and CBD diameters are important anatomic factors determining the complexity of PD, in general, both open and MI. These critical factors may become less relevant as surgeons negotiate learning and proficiency curves over time. Although pancreatic texture is highly relevant it cannot be reliably determined in the preoperative setting and is therefore not included.

Tumor-specific Factors

Large tumor size and pancreatic cancer were identified as factors considered to be contraindications, or raising technical concerns, for MIPD resections in a worldwide survey.[2] Lof et al[39] identified tumor size >40 mm (OR: 2.7, 95% CI: 1.0–6.8; $P < 0.041$) and pancreatobiliary tumors (OR: 2.2, 95% CI: 1.0–4.8; $P < 0.039$), compared with ampullary/duodenal tumors, as risk factors for conversion in MIPD. Tumor size >2 cm was significantly associated with a risk of a positive resection margin in a large national cohort of open and laparoscopic MIPD from the United States.[69] The largely unknown impact of size and tumor location in MIPD is probably due to the careful patient selection during its evolutionary phase with a preference for smaller, periampullary tumors.[70–73] MIPD for uncinate process lesions adds technical complexity to the procedure[74,75] and a significantly higher risk of CR-POPF. One study noted that robotic MIPD performed for uncinate process tumors was associated with a significant risk of severe complications (OR: 1.69; $P < 0.0001$).[52]

Neoadjuvant therapy (NAT) has been considered an exclusion criterion for MIPD in the past.[73,76–78] However, Sharpe et al[69] were unable to find a significant impact of NAT (chemotherapy and/or chemoradiotherapy) on 30-day mortality in a large national audit from the United States.

In a worldwide survey exploring the opinions of members of 6 international associations of hepato-pancreato-biliary surgery,[2] arterial and venous tumor involvement scored the highest when considering contraindications and technical concerns for MIPD. Vascular resections are generally avoided when selecting patients for MIPD,[69] although the feasibility has been demonstrated in experienced hands.[79] Lof et al[39] noted in their study that the majority of conversions from MIPD to open were due to increased complexity of the procedure because of vascular ($P < 0.001$) or adjacent organ ($P < 0.001$) involvement, potentially influencing the surgical outcome negatively. Other studies have also corroborated a higher risk of conversion in procedures that involved vascular[54,80] and multivisceral[80] resections. Elective conversion in these cases should be considered good judgment rather than a complication and should be done according to the surgeon's experience. The borderline resectable tumor is a risk factor for technical difficulty in robotic MIPD (OR: 1.98; $P < 0.0001$).[52] The importance of variant vascular anatomy on the outcomes of MIPD is also well appreciated.[81] The presence of a hepato-mesenteric trunk has been identified as an important risk factor for severe post-robotic MIPD complications.[52] Key to the evaluation of this aspect when developing the grading was the delineation of technical and oncological aspects of MIPD. While the focus of the review of this aspect was not to prescribe decision-making in terms of resectability,[18,82,83] there remain tumor-specific factors that play a role in the complexity of PD, especially MIPD. Hence, while all relevant factors were considered in the first instance, the final decision on those to be included in the grading system was made based on consensus among all members.

Consensus Statement

Vascular tumor contact is the most relevant tumor-specific factor determining resectability[18,82,83] and, therefore, adds technical complexity to MIPD.

Conditional Factors

Conditional factors and performance status are important determinants in the outcome after pancreatic resection, as demonstrated by Katz et al[84] when they included marginal performance status patients in type C of the MD Anderson borderline resectable categories.[85,86] This important determinant of outcome encompassing functional status [including age and body mass index (BMI)] after PD[63] has also been incorporated into the international consensus definition and criteria for borderline resectable pancreatic ductal adenocarcinoma in 2017.[87] Admittedly, these classifications were not intended to segregate postoperative outcomes and it may be prudent not to mix these notions; however, their inferences remain relevant in the context of the complexity of MIPD. The Eastern Co-operative Oncology Group/ECOG performance score[88] has been shown to impact MIPD outcomes in elderly patients.[40] However, no further evidence correlating ECOG status with peri-PD outcomes, patient selection, or FTR was identified. While an ECOG score >1 was significant on univariate analysis in a nationwide study in the Netherlands (OR: 2.09; CI: 1.02–4.26; $P < 0.04$) for mortality after a major complication (ie, FTR) in PD,[89] it was not significant ($P < 0.26$) on multivariable analysis. In the same study,[89] age >75 years ($P < 0.001$) and BMI >30 kg/m^2 ($P < 0.02$) were independently associated with FTR after a major PD complication. Age 75 years or older has also been identified as an independent risk factor (OR: 2.0, CI: 1.0–4.1; $P < 0.043$) for conversion in MIPD[39] and mortality after PD.[41,69,90] This is possibly why MIPD has been reported to be performed more frequently in younger patients.[43] The largest RCT for MIPD to date, from China, excluded patients over the age of 75 years.[78] Numerous studies have confirmed the impact of age on the increased risk of intraoperative conversions in MIPD.[54,55,80,91]

Utilizing a BMI cutoff of ≥30 kg/m^2 while assessing risk factors for conversion in MIPD (laparoscopic and robotic), Lof et al[39] were unable to identify it as a risk factor on multivariable analysis. However, Chao et al[42] noted obesity to be an independent risk factor for major complications (OR: 5.983; CI: 1.394–25.682; $P = 0.001$) during the implementation of robotic MIPD. While, a BMI ≥25 kg/m^2 for males and ≥30 kg/m^2 for females has been noted to be significantly associated with severe postrobotic PD complications (OR: 2.39; $P < 0.0001$),[52] another study confirmed that although obese patients are at risk for increased postoperative complications regardless of approach, robotic PD may mitigate wound infection (OR: 0.3; $P < 0.001$) and grade B/C pancreatic fistula (OR: 0.34; $P < 0.001$) rates.[92] BMI is a risk factor for open and MIPD, although there remain theoretical advantages of MIPD in obese patients, especially in relation to postoperative recovery. However, the latter does not take away the overall relevance of high BMI in influencing the technical complexity of MIPD.

Similarly, the role of the American Society of Anesthesiologists (ASA) physical status score has been evaluated to determine its capability of predicting complications, mortality,[93] and conversion in MIPD.[39] In general, there is a lesser likelihood of patients with ASA class III undergoing MIPD,[43] with studies often excluding these patients with a poor performance status.[72,94] Two studies found that an ASA class of III-IV was associated with an increased risk of conversion to open PD.[39,55] An ASA class ≥3 is associated with a significant risk of severe complications after robotic MIPD (OR: 1.59; $P < 0.0001$).[52] The authors agreed that, in general, the surgical management of patients older than 75 years and/or with an ASA class of III, or more, should be approached cautiously. However, these factors do not impact the technical complexity of PD, open or MIPD.

All surgeons would agree that previous abdominal upper abdominal operations could impact the performance of a subsequent PD. However, the impact of previous open surgery on the complexity and risk of conversion when performing a MIPD has not been sufficiently published in the literature, although it has been documented for open PD after a previous gastric bypass.[95–98] The reason for this is likely due to such patients being excluded from enrollment in studies.[73,99] Recurrent attacks of cholangitis with stent exchanges and endoscopic retrograde cholangiopancreatography, or tumor-induced severe acute (necrotizing) pancreatitis, are factors known to influence the technical complexity of PD, both open and MI. However, the literature on this is sparse and heterogeneous, precluding any meaningful derivations.

Consensus Statement

Obesity (ie, WHO definition:[100] BMI >30 kg/m^2) and previous (complicated) upper abdominal surgery/disease (eg, gastric bypass, peritonitis, bowel perforation, and necrotizing pancreatitis) are important conditional factors determining the complexity of MIPD.

Surgeon and Center Experience

Morbidity after PD remains high irrespective of the technical approach (ie, MIPD vs open). Variations in mortality between centers are largely explained mainly by differences in case selection, surgeon experience, and FTR, rather than the incidence of major complications.[89] The initial outcomes of patients after PD, thus, are not only determined by the surgeon and surgical team's technical capabilities intraoperatively but also the ability (of the team and center) to deliver high-quality care in the postoperative setting.

The relevance of the surgical learning curve to outcomes after PD was highlighted by Tseng et al[101] more than a decade ago. The development of MIPD has reignited an appreciation of the value of surgeon and center annual volumes and experience on outcomes after PD.[1,4] The Miami International evidence-based consensus[1] noted that the learning curve case load differed between open, laparoscopic, and robotic MIPD. In laparoscopic MIPD, learning curve related improvements in outcome were seen after 10 to 50 procedures. For robotic MIPD, 20 to 40 procedures were considered necessary to overcome the learning curve. Furthermore, the Miami guidelines advised a minimum annual center volume of 20 MIPD since mortality was worse in the case of lower annual volume. Based on an appreciation of the evolution of a surgeon through "phases" which relate to the above parameters, Muller *et al*[102] noted that the number of procedures to surpass the first phase of the learning curve was 30$^{20–50}$ for open PD, 39$^{11–60}$ for laparoscopic MIPD, and 25$^{8–100}$ for robotic MIPD ($P = 0.521$). The authors defined the first phase of the learning curve as the period when the surgeon learns to carry out a surgical procedure under supervision and with the help of an experienced surgeon. They surmised that at the end of the phase, the surgeon should acquire competency and be able to perform a specific procedure without supervision. However, while the concept of a learning curve is somewhat intuitive, pragmatically, this concept remains nebulous since it does not specifically factor in the time over which the prescribed cases were undertaken. As highlighted by Tseng et al,[101] a surgeon continues to improve over the course of their career by appreciating the nuances of the procedure and being preemptive rather than reactive, seeking feedback, and adopting important concepts, such as standardization of technique[61] aimed at improving their operative outcomes.

The Miami guidelines annual center volume threshold of 20 MIPD has since been confirmed by others.[103,104] A retrospective study analyzing the outcomes of the initial 100 consecutive patients undergoing MIPD for malignant and benign tumors of the head of the pancreas and periampullary area at 3 centers found that 61 PD were needed to achieve a plateau of the operative time for the laparoscopic approach, 32 for the hybrid approach, and 68 for the robotic approach.[105] A Dutch nationwide propensity-score matched analysis[106] comparing robotic PD performed at 8 centers versus open PD performed at 18 centers between 2014 and 2021 found no difference in major morbidity, mortality, and CR-POPF between the two approaches. While the robotic approach was associated with a significantly longer operating time, there was lower blood loss (200 vs 500 mL), wound infection rates (7.4% vs 12.2%), and hospital stay (11 vs 12 days). This study, too, confirmed the importance of the 20-case cutoff with centers performing more than 20 robotic PDs annually having significantly lower mortality (2.9% vs 7.3%; $P = 0.009$) and conversion rate (6.3% vs 11.2%; $P = 0.03$) when compared with centers performing <20 robotic PDs.

Higher hospital volume of MIPD has been associated with a lower risk of 30-day mortality (OR: 0.98; $P < 0.0001$).[69] It has been determined that the volume-outcome relationships in pancreatic surgery persist in centers performing ≥40 PDs annually when assessing for both mortality and survival.[107] When analyzing the learning curve of the pancreatic surgery team, Boone et al[15] found statistical improvements in estimated blood loss and conversions to open surgery occurred after 20 MIPD (600 vs 250 mL; $P = 0.002$ and 35.0% vs 3.3%; $P < 0.001$, respectively), the incidence of POPF after 40 MIPD (27.5% vs 14.4%; $P = 0.04$), and operative time after 80 MIPD (581 vs 417 min; $P < 0.001$). The same team recently reported that operating room time for robotic MIPD plateaued after 240 procedures.[76] They[108] have further gone on to demonstrate that not only operating room time, but also conversion rates and estimated blood loss decreased across generations (defined as (1) no mentorship or curriculum, (2) mentorship but no curriculum, and (3) mentorship and curriculum) without a concomitant rise in adverse patient outcomes. Thus, it is important to recognize that a proficiency-based curriculum coupled with mentorship will allow for the safe introduction of less experienced surgeons to robotic PD without compromising patient safety.

Consensus Statement

Surgeon experience and annual center volume are crucial factors for patient outcomes of MIPD and should be considered when selecting patients for MIPD (Fig. 2).

The International Study Group for Pancreatic Surgery Minimally Invasive Pancreatoduodenectomy Complexity and Experience Grading System

The ISGPS MIPD complexity and experience grading system is subclassified into patient-related and surgeon and center-related (Table 1 and 2) variables using a simple A-B-C classification. The patient-related variables encompass anatomic factors (MPD and bile duct diameter), tumor-specific factors (vascular contact), and conditional factors (BMI and previous complicated upper abdominal surgery/disease). The authors acknowledge tumor size as an important determinant of outcomes of PD. However, after much deliberation, the decision was made to exclude it from the grading system. The rationale for this decision was based on the realization that a 3 cm periampullary tumor could be located away from vessels and be

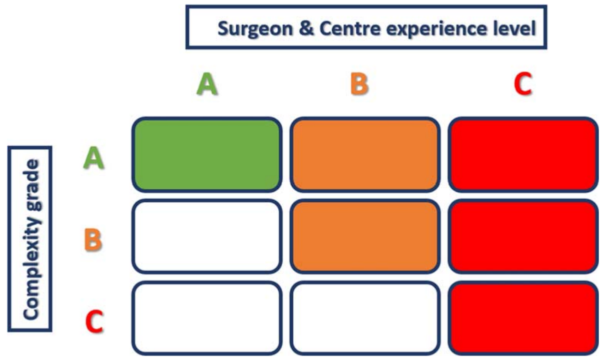

FIGURE 2. Proposed ISGPS grading system for complexity versus experience of MIPD surgeon and center. Surgeons and centers with an experience level A can safely undertake MIPD in patients with a complexity grade A. Evidence is lacking for grade B and C. Surgeons and centers with an experience level B can safely undertake MIPD in patients with complexity grades A and B. Evidence is lacking for grade C. Surgeons and centers with an experience level C can safely undertake MIPD in patients of any complexity grade.

amenable to a safe MIPD. In contrast, a 2 cm lesion in contact with the superior mesenteric artery and vein would be a technically more difficult tumor to resect. The key difference is the impact of "vascular contact." Despite its exclusion from the grading system, tumor size remains a factor that may influence an individual surgeon's decision on their approach to PD. The use of the term "vascular contact," as opposed to "stage III borderline resectable disease"[82] within the proposed classification system is intentional. The ISGPS appreciates that radiologically identified vascular contact of the tumor increases the complexity of pancreatic resection in upfront surgery, as well as post-NAT,[109] irrespective of contact with the vein or artery. Furthermore, NAT does not downgrade the complexity if a tumor initially had vascular contact. Hence, the presence of any degree of vascular contact has been classified under the highest grade, namely grade C. In the context of BMI, due consideration was given to the differing patterns of intra-abdominal fat between males and females appreciating the male pattern of fat distribution to be more surgically challenging. However, the rationale for not further subdividing BMI by sex was based on a few factors, including the common experience of females who possess an intra-abdominal male pattern of fat distribution and vice versa. In addition, a recent objective-matched pair cohort analysis[110] comparing male and female patients undergoing

TABLE 1. ISGPS MIPD A-B-C Complexity Grading System

	Risk factors
Anatomical	Main pancreatic duct diameter ≤3 mm
	Common bile duct diameter ≤5 mm
Tumor	Vascular contact*
Conditional	Obesity (kg/m^2) ≥30
	Previous complicated upper abdominal surgery/ disease†

*Any degree of vascular contact means a complexity Grade C.
†Gastric bypass, peritonitis, bowel perforation, necrotizing pancreatitis. This does not include: cholecystitis, appendicitis, diverticulitis, uncomplicated abdominal surgery.

A = no risk factor present
B = one risk factor present
C = two to five risk factors present*

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TABLE 2. ISGPS MIPD A-B-C Experience Grading System

	Center annual MIPD volume	Surgeon total MIPD experience†
Experience Level A	< 10	< 40
Experience Level B	10-30	41-79
Experience Level C	>30	≥80

*Since both surgeon and center experience are required for optimal outcome, the lowest score counts, e.g. a surgeon who has performed 50 MIPDs in total and works in a center that performs < 10 MIPDs per year is classified as Experience level A.

†Surgeon experience - The experience of the senior Surgeon participating in the procedure counts.

bariatric surgery found no difference in outcomes based on the sex of the patient. Future studies should assess the impact of BMI on different sexes of patients undergoing MIPD. Table 2 provides a substratification of the surgeon's total MIPD experience and the center's annual MIPD volume into 3 levels. Figure 2 is a visual representation of the complexity of procedures that would be best undertaken by a surgeon considering their total volume and the center's volume. In the absence of objective evidence, the ISGPS does not prescribe that an experienced grade C surgeon alone must perform a complexity grade C MIPD. Rather, utilizing available evidence and experience, the ISGPS proposes the use of the complexity grading system to enable surgeons to preoperatively identify complex procedures. This system may provide a clear opportunity for surgeons and centers to undertake more complex MIPDs as their experience increases, ensuring that the quality performance indicators for pancreatectomy are met[111] and without compromising patient outcomes.

Case Vignettes

The following examples are provided to enable the reader to understand the application of the proposed system and not its validation.

Case 1: A 77-year-old woman presented with painless jaundice and a pancreatic head mass (proven adenocarcinoma on endoscopic ultrasound-guided biopsy) without distant metastases. She had a BMI of 24 kg/m^2 and was classified as ASA III on account of age and comorbidities. She had undergone two uncomplicated lower-segment cesarean sections. On imaging (Fig. 3), her tumor was measured at 21×13 mm with superior mesenteric vein contact < 180 degrees. The MPD was 10 mm, and the CBD measured at 12 mm. The patient was deemed to have a borderline resectable tumor but refused neoadjuvant chemotherapy and was hence, planned for upfront surgery.

As per the proposed ISGPS experience grading system, the presence of vascular contact would result in this patient being an experienced grade C, preferably operated on in a center and by a surgeon classified as experience level C.

Case 2: A 78-year-old man presented with vague abdominal symptoms, significant weight loss, and a pancreatic head mass with no distant metastases. He had a BMI of 25 kg/m^2 and was classified as ASA II on account of age and comorbidities. He had undergone no previous abdominal surgery. On imaging (Fig. 4), his tumor was measured at 15.1×13.5 mm without vessel contact. The MPD was 6.4 mm, and the CBD 22.7 mm. The patient was deemed to have a resectable tumor and hence, planned for upfront surgery.

As per the proposed ISGPS experience grading system, the patient would be a grade A, preferably operated on by a surgeon in a center classified as experience level A, B, or C.

DISCUSSION

The ISGPS MIPD complexity and experience grading system aims to provide a conceptual framework that incorporates patient-related variables (anatomic, tumor-specific, and conditional) and surgeon and center-related volume (total and annual) with the overarching desire to guide the safe and wider implementation of MIPD and facilitate future research. This proposed system is expected to be refined in the coming years with accumulating evidence.

The ISGPS MIPD complexity and experience grading system acknowledges the good outcomes of MIPD when performed in selected patients by surgeons and teams with appropriate surgical experience and annual volume. This undertaking builds on the efforts of several surgeons within the ISGPS who have worked towards systematic adoption of MIPD globally through structured training of the next generation of MIPD surgeons.[8,9] These efforts had an emphasis on technical expertise and appropriate patient selection,[10–12] an understanding of the value of surgical volume[13,14] and learning curves,[15,16] underpinned by adherence to the principles of pancreatic surgery[18,19] and a stringent evaluation of outcomes.[20–23] Center volume is an important determinant of PD outcomes irrespective of the approach (MI or open). This has been previously acknowledged in the Miami International evidence-based consensus.[1] Experienced surgical teams can detect and expertly manage complications early by the timely recognition of clinical and biochemical signs and the judicious use of imaging supplemented by critical care and interventional radiology support. This has likely translated into reduced 90-day mortality in high-volume centers regardless of the surgical approach.[37] A minimum of at least 20 MIPD procedures per year have been associated with lower postoperative mortality.[104] The present ISGPS grading system, thus, acknowledges this intricate relationship between the selection of patients appropriate for MIPD and center volume.

The initial concerns raised by expert pancreatic surgeons regarding MIPD have included the acknowledgment of the difficult exposure of the pancreas in the retroperitoneum, intimate proximity to major vascular structures, complex technical nature and high complication profile of operations,[112] ability (or lack thereof) to adhere to oncologic principles, and challenges in training surgeons to perform these relatively low-volume, complex operations.[2] Currently, 5 RCTs are available on laparoscopic MIPD versus open PD.[4,78,94,113–115] Furthermore, recently, the 2 first RCTs, including robotic MIPD, were completed in Europe (EUROPA, DIPLOMA-2) and 1 in China.[116–119] While the first 2 RCTs[94,113] of laparoscopic MIPD versus open PD showed some advantages of MIPD, concerns were raised after early termination of the third multicenter RCT[4] comparing laparoscopic MIPD versus open PD due to higher complication-related mortality after laparoscopic MIPD group in the absence of demonstrable advantages. Surgeons and institutional experience appeared to have played a role in the outcomes of this study and are addressed

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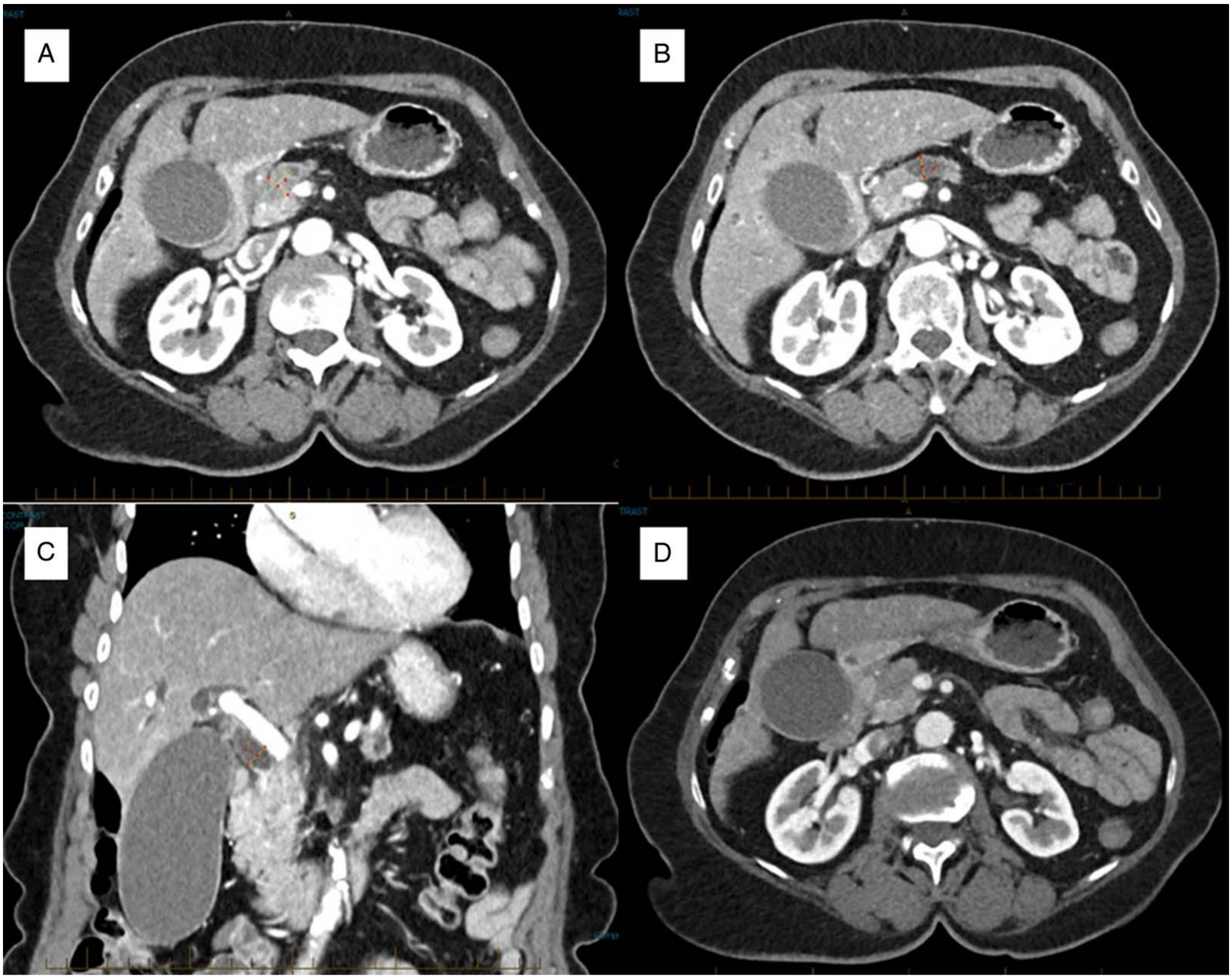

FIGURE 3. Case 1—Contrast-enhanced CT images demonstrating a pancreatic head mass measuring 21×13 mm (A) with SMV contact <180 degrees (D). The MPD was 10 mm, and (B) the CBD measured at 12 mm (C). CT indicates computed tomography; SMV, superior mesenteric vein.

in this ISGPS MIPD complexity and experience grading system. The fourth and largest RCT,[78] in which the primary outcome of interest was the postoperative length of stay, benefit was clinically marginal despite extensive procedural expertise with laparoscopic MIPD. The most recent RCT[114] comparing short-term outcomes of laparoscopic MIPD versus open PD performed by experienced surgeons in high-volume specialized institutions noted no difference in the rates of complications of the Clavien-Dindo grades III-IV, comprehensive complication index, and median (interquartile range) postoperative length of stay. A single-center propensity-matched analysis including 460 patients who underwent robotic PD inferred that such an approach could mitigate the clinical impact of pancreatic leaks post-PD.[120] Another multicenter propensity-score matched analysis noted a significantly lower CR-POPF rate (OR: 0.4 95% CI: 0.2–0.7; $P < 0.002$) with robotic PD when compared with open when it was performed in high-volume, academic, pancreatic surgery specialty centers in a standardized manner-by surgeons who had surpassed the robotic PD learning curve.[121] However, the EUROPA trial[118] comparing open versus robotic PD noted that while there was no difference in the comprehensive complication index (the primary endpoint), a 23% conversion rate was seen with robotic PD, which also had higher POPF (38 vs 21%), bile leak (17 vs 9%) and delayed gastric emptying (34 vs 6%) rates. The ChiCTR2200056809 trial[119] comparing short-term outcomes of open versus robotic PD performed by surgeons who have passed their learning curve noted a 2.5-day reduction in hospital stay with the use of robotic PD (11 vs 13.5; $P = 0.029$).

The international community of pancreatic surgeons has repeatedly highlighted the need for appropriate patient selection for MIPD[1,122] and adequate surgical procedural training.[12,123] Longer operative duration, high conversion rates, inferior oncological outcomes, and increased mortality after MIPD have been reported in low-volume centers.[13,16] Patient outcomes are significantly compromised following unplanned intraoperative conversions of MIPD when compared with successfully completed MIPD and upfront open PD.[32] These outcomes and the high risk of bias in the available evidence[20] have been flagged as matters of concern, highlighting the fact that such forays into MIPD could ultimately disadvantage patients and their disease outcomes in the early phases of a surgeon's learning curve. The ISGPS complexity and experience grading system took into consideration the evolving paradigms in PD, with young surgeons today beginning to adopt robotic or

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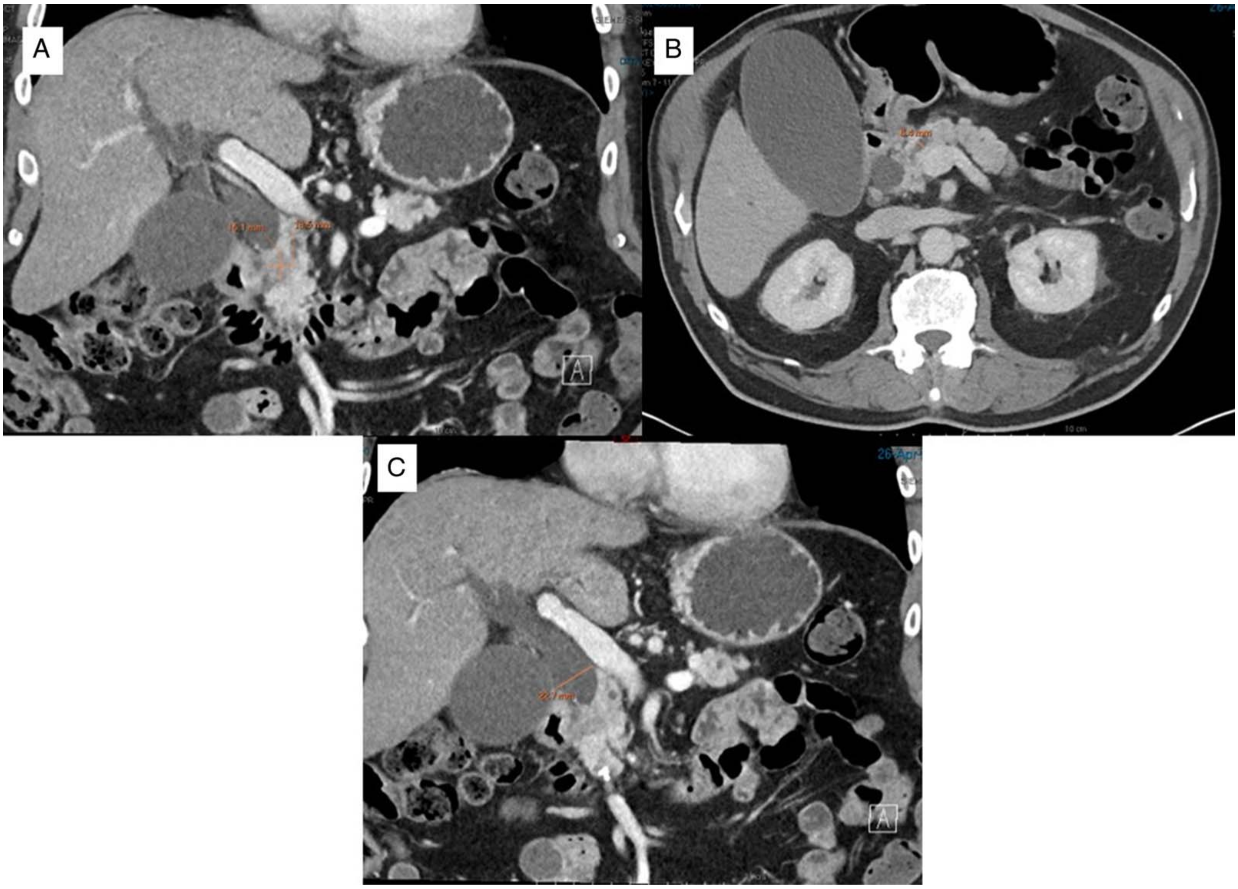

FIGURE 4. Case 2—Contrast-enhanced CT images demonstrating a pancreatic head mass measuring 15.1 × 13.5 mm without vessel contact (A). The MPD was 6.4 mm, and (B) the CBD measured at 22.7 mm (C). CT indicates computed tomography.

laparoscopic surgery often without having necessarily "evolved" through what would be perceived as the orthodox step up from open to laparoscopic to the robotic approach. Any grading system guiding patient selection in MIPD must, therefore, not necessarily focus on either a purely laparoscopic or robotic approach.

The variability in PD has also been reported in open surgery. In a study from the Heidelberg group, which classified PD based on technical difficulty and surgical extent, the validation of the classification considering morbidity and mortality confirmed an increase in morbidity (including pancreas-specific complications) and mortality with increasing complexity.[30] This analysis was performed on patients who underwent open PDs in one of the highest-volume pancreatic centers in the world. The technical complexity and resultant morbidity and mortality of PD increase when a venous resection is added, and even more so if an arterial resection is required. Thus, in the grading system, any vascular contact was regarded as significant. Factors such as the anatomic variants of the uncinate process, the type and course of the first jejunal vein,[124,125] the presence of accessory or replaced vessels (replaced right hepatic artery or common hepatic artery from the superior mesenteric artery) and their relationship with the bile duct,[81] the presence of a peribiliary inflammation secondary to a biliary metal stent can contribute to the complexity of the surgical dissection during MIPD. However, in the absence of strong evidence to objectively determine their impact, they have not been included in the grading system. After the prospective validation of the current grading system, we hope to have more data to support our conclusions.

Some limitations should be considered when using the ISGPS MIPD complexity and experience grading system. First, not all complexity risk factors used are based on strong evidence. Based on further evidence, the proposed risk factors could be expected to be altered. Second, the cutoffs on surgical experience and center volume are also based on preliminary evidence and may also be subject to change in future years. The transiency of such a grading system in the evolution of MI pancreatic surgery would appear less likely. We postulate this given the universality of the learning curve of PD regardless of the approach, open or MI, with the former continuing to remain the preferred approach globally unrelated to global socioeconomic disparities.[126–128] Third, the coupling between complexity and experience should not be considered as absolute treatment advice. This decision should always remain with the treating surgeon in discussion with the treating team, the patient, and the family.

CONCLUSIONS

We believe that the ISGPS MIPD complexity and experience grading system may potentially serve as a foundation to foster a safe and measured attitude towards the wider adoption of MIPD among surgeons. Ethical and practical considerations of access to MIPD are relevant in the era of evidence-based medicine but the primary intention of this ISGPS grading system is to advocate for the safe uptake of MIPD by informing surgeons with less experience or those treating patients with multiple comorbidities and even surgeons with a high-volume experience working in low-volume centers, to be mindful of the challenges that they will likely face. It will help pancreatic surgeons to safely select patients for MIPD based on their experience and capability to guide resources in terms of the presence of a second/senior surgeon and having experienced rescue teams available. The ISGPS complexity grading will also allow a stratified reporting of the outcome of MIPD. Future studies prospectively validating the ISGPS grading system would be encouraged to confirm its value. Furthermore, future cohort studies should use the ISGPS grading system to facilitate objective comparison of outcomes.

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