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Complexity and experience grading to guide patient selection for minimally-invasive pancreatoduodenectomy: An ISGPS Consensus

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Abbreviation list

ASA	American Society of Anesthesiologists
BMI	body mass index
CBD	common bile duct
CI	Confidence interval
CR-POPF	clinically-relevant post-operative pancreatic fistula
CT	Computed tomography
DGE	delayed gastric emptying
ECOG	Eastern Co-operative Oncology Group
ERCP	Endoscopic retrograde cholangiopancreatography
FTR	failure to rescue
HJ	Hepaticojejunostomy
HPB	Hepato-pancreato-biliary
IQR	Inter-quartile range
ISGPS	International Study Group for Pancreatic Surgery
MIPD	minimally-invasive pancreatoduodenectomy
MPD	Main pancreatic duct
MRI	Magnetic resonance imaging

NAT	Neoadjuvant therapy
OR	Odds ratio
PD	Pancreatoduodenectomy
POPF	Post-operative pancreatic fistula
RCT	randomized controlled trial

Abstract

Objective: The ISGPS aims 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 towards appropriate patient selection according to adequate surgeon and center experience.

Methods: The 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 anatomical (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 (cut-offs 40 and 80) and center *annual* MIPD volume (cut-offs 10 and 30), all also incorporated in an A-B-C classification.

Conclusion: 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 outcome between centers and countries.

Introduction

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 has steadily paved the way for a systematic implementation of MIPD (1-4). Nevertheless, still less than 4.5% of PDs are performed minimally-invasive (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 following unplanned intraoperative conversions of MIPD when compared to successfully completed MIPD and upfront open PD (32). Numerous anatomical (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 two decades, the International Study Group for Pancreatic Surgery (ISGPS) has introduced several globally accepted consensus definitions and grading systems for post-pancreatectomy 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 guiding 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, amongst 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; prospective, randomized controlled trials; 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 (SGB, OS, RS, GM, CW, JW, CRF, TH, MGB, SVS), 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.

Results

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

Anatomical factors

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

Acknowledging the relevance of this anatomical factor, the ISGPS (36) has previously used the subclassification of MPD diameter sizes of <3mm, 3-8mm and >8mm based on the frequency with which occurrence of POPF was reported (50, 51). A recently developed scoring system (PD-ROBOSCORE) to predict severe post-operative complications after robotic MIPD, confirmed the significant impact of an MPD <4mm (OR 1.59; p<0.0001) (52). Interestingly, contrary to the above, three studies noted a higher risk of conversion with MPD diameter sizes >3mm (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 anatomical factors in decision making. Data on a protective role for robotic PD in mitigating CR-POPF, especially in high-risk patients, remains heterogenous with one study confirming this (56), while another not only finding 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 (CT) scans and magnetic resonance imaging (MRI) 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). While 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 (esp. 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 2.4-5.6% (60-63) for leaks and 2.6% for biliary strictures on long-term follow-up at a median of 13 months following 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 post-surgery with an HJ diameter of ≤8mm 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 (<10mm diameter), increased distance of the HJ (>10mm) from the hilar plate, and continuous suturing technique (66). Kendrick and Cusati (67) reported performing an end-to-side HJ with running (bile duct >5mm) or interrupted (bile duct ≤5mm) sutures for total laparoscopic PDs. Whilst a bile duct diameter >6mm is regarded as dilated on ultrasound, a diameter of 10mm can be confidently appreciated as dilated on computed tomography (CT) 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 8mm and 11mm 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 anatomical factors determining complexity of PD, in general, both open and MIPD. 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 >40mm (OR 2.7, 95% CI 1.0 to 6.8; p<0.041) and pancreato-biliary tumors (OR 2.2, 1.0 to 4.8; p<0.039), compared to ampullary/duodenal tumors, as risk factors for conversion in MIPD. Tumor size >2cm 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 preference for smaller, periampullary tumors (70-73). MIPD for uncinate process lesions adds technical complexity to the procedure (74, 75) and 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 six international associations of hepato-pancreato-biliary (HPB) surgery (2), arterial and venous tumor involvement were 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 multi-visceral (80) resections. Elective conversion in these cases should be considered good judgement rather than a complication and should be done according to the surgeon experience. 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. Whilst the focus of 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 were made based on consensus amongst 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 a 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]) following 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 post-operative outcomes and it may be prudent not to mix these notions; however, their inferences remain relevant in the context of 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 were identified. Whilst 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 (i.e. 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 >30kg/m^2 (p<0.02) were independently associated with FTR after a major PD complication. Age ≥75years has also been identified as an independent risk factor (OR 2.0, CI 1.0 to 4.1; p<0.043) for conversion in MIPD (39) and mortality following PD (41, 69, 90). This is possibly why MIPD has been reported to be performed more frequently in younger patients (43). The largest randomized controlled trial (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 cut-off of ≥30kg/m^2 whilst 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. Whilst, a BMI ≥25kg/m^2 for males and ≥30kg/m^2 for females has been noted to be significantly associated with severe post-robotic 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 post-operative 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 are agreed that, in general, the surgical management of patients older than 75years and / or with an ASA class of III, or more, should be approached cautiously. However, these factors do not impact on 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 an MIPD has not been sufficiently published in literature, although it has been documented for open PD following previous gastric bypass (95-98). The reason for this is likely due to such patients being excluded from enrolment in studies (73, 99). Recurrent attacks of cholangitis with stent exchanges and ERCP, or tumor-induced severe acute (necrotizing) pancreatitis are factors known to influence the technical complexity of PD, both open and MIPD. However, the literature on this is sparse and heterogenous precluding any meaningful derivations.

Consensus statement

Obesity (i.e. WHO definition (100): BMI >30kg/m2) and previous (complicated) upper abdominal surgery/disease (e.g. gastric bypass, peritonitis, bowel perforation, and necrotizing pancreatitis) are important conditional factors determining complexity of MIPD.

Surgeon and center experience

Morbidity following PD remains high irrespective of the technical approach (i.e. 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 following 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 following PD was highlighted by Tseng *et al.* (101) more than a decade ago. The development of MIPD has reignited an appreciation in the value of surgeon and center annual volumes and experience on outcomes following 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 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 a first phase of 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 if 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 pre-emptive 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 three 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 nation-wide 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. Whilst the robotic approach was associated with a significantly longer operating time, there was lower blood loss (200 vs 500ml), wound infection rates (7.4 vs 12.2%) and hospital stay (11 vs 12days). This study, too, confirmed the importance of the 20-case cut-off with centers performing more than 20 robotic PDs annually having a significantly lower mortality (2.9 vs 7.3%; p=0.009) and conversion rate (6.3 vs 11.2%; p=0.03) when compared to centers performing less than 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 250mL; p =0.002] and 35.0%vs 3.3%; p<0.001], respectively), incidence of POPF after 40 MIPD (27.5% vs 14.4%; p=0.04), and operative time after 80 MIPD (581 vs 417 minutes [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 recognise 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 outcome of MIPD and should be considered when selecting patients for MIPD (**Figure 2**).

The ISGPS MIPD complexity and experience grading system (Table 1; Figure 2)

The ISGPS MIPD complexity and experience grading system is subclassified into patient-related (**Table 1a**) and surgeon and center-related (**Table 1b**) variables using a simple A-B-C classification. The patients-related variables encompass anatomical factors (main pancreatic duct and bile duct diameter), tumor-specific factor (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 realisation that a 3cm periampullary tumour could be located away from vessels and be amenable to a safe MIPD. On the other hand, a 2 cm lesion in contact with the superior mesenteric artery and vein would be a technically more difficult tumour to resect. The key difference being 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 appreciate that radiologically identified vascular contact of the tumor increases the complexity of pancreatic resection in upfront surgery, as well as post-neoadjuvant therapy (109), irrespective of contact with the vein or artery. Furthermore, neoadjuvant therapy does not downgrade the complexity if a tumour 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 to not further subdivide 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. Additionally, a recent objective matched pair cohort analysis (110) comparing male and female patients undergoing bariatric surgery found no difference in outcomes based on the sex of the patient. Future studies should assess the impact of BMI in different sexes of patients undergoing MIPD. Table 1b provides a sub stratification of surgeon total MIPD experience and the center 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 centers volume. In the absence of objective evidence, the ISGPS does not prescribe that an experience grade C surgeon alone must perform a complexity grade C MIPD. Rather, utilizing available evidence and experience, the ISGPS propose 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 as its validation.

Case 1: A 77-year-old female presented with painless jaundice and a pancreatic head mass (proven adenocarcinoma on endoscopic ultrasound-guided biopsy) without distant metastases. She had a BMI of 24kg/m^2 and was classified as ASA III on account of age and co-morbidities. She had undergone two uncomplicated lower segment caesarean sections. On imaging (**Figure 3**) her tumor was measured at 21x13mm with SMV contact <180^0. The MPD was 10mm and the CBD measured at 12mm. 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 experience Grade C, preferably operated on in a center and by a surgeon classified as experience level C.

Case 2: A 78-year-old male presented with vague abdominal symptoms, significant weight loss and a pancreatic head mass with no distant metastases. He had a BMI of 25kg/m^2 and was classified as ASA II on account of age and co-morbidities. He had undergone no previous abdominal surgery. On imaging (**Figure 4**) his tumor was measured at 15.1x13.5mm without vessel contact. The MPD was 6.4mm and the CBD 22.7mm. 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 (anatomical, 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 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 (minimally-invasive 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 a 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 acknowledgement of the difficult exposure of 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, five RCTs are available on laparoscopic MIPD vs open PD (4, 78, 94, 113-115). Furthermore, recently the two first RCTs including robotic MIPD were completed in Europe (EUROPA, DIPLOMA-2) and one in China (116-119). Whilst the first two RCTs (94, 113) of laparoscopic MIPD versus open PD showed some advantages of MIPD, concerns were raised after early termination of the third multi-center RCT (4) comparing laparoscopic MIPD versus open PD due to higher complication-related mortality after laparoscopic MIPD group in the absence of demonstrable advantages. Surgeon's and institutional experience appeared to have played a role on the outcomes of this study and are addressed in this ISGPS MIPD complexity and experience grading system. The fourth, and largest, RCT (78) in which the primary outcome of interest was 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 (IQR) postoperative length of stay. A single-center propensity matched analysis including 460 robotic PD patients inferred that such an approach could mitigate the clinical impact of pancreatic leaks post-PD (120). Another multi-center propensity-score matched analysis noted a significant lower clinically-relevant POPF rate (OR 0.4 95% CI 0.2-0.7; p<0.002) with robotic PD when compared to open when it was performed in high-volume, academic, pancreatic surgery specialty centers in a standardized fashion-by surgeons who had surpassed the robotic PD learning curve (121). However, the EUROPA trial (118) comparing open versus robotic PD noted that whilst 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 DGE (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 to 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 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 increases 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 anatomical 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 cut-offs 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 socio-economic disparities (126-128). Third, the coupling between complexity and experience should not be considered as an absolute treatment advice. This decision always should remain with the treating surgeon in discussion with the treating team, the patient and family.

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 amongst 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 co-morbidities and even surgeons with a high-volume experience working in low volume centres, 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 resourcing 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 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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Figure 1: Search strategy

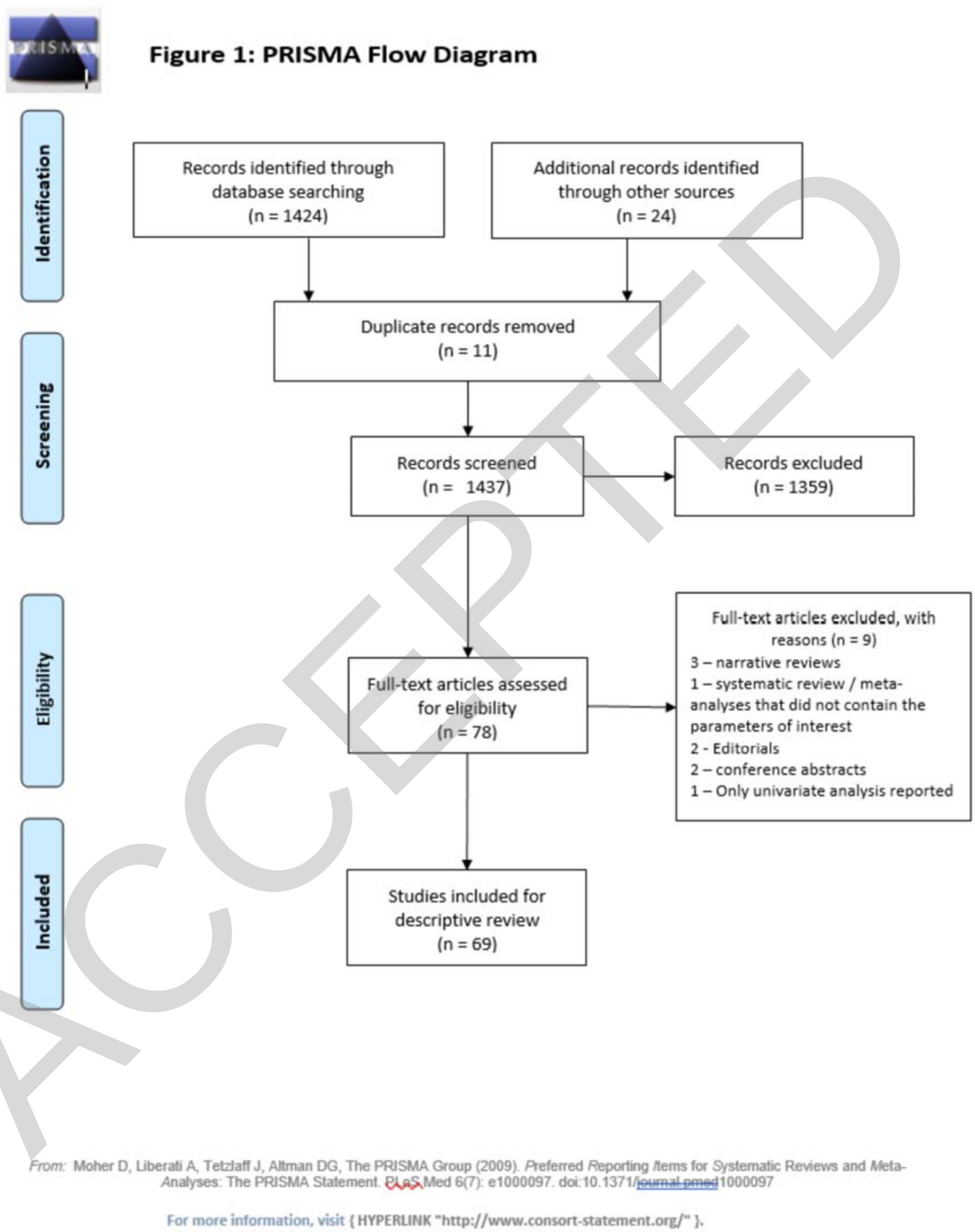

Figure 2: Proposed ISGPS grading system for complexity vs experience of MIPD surgeon and center

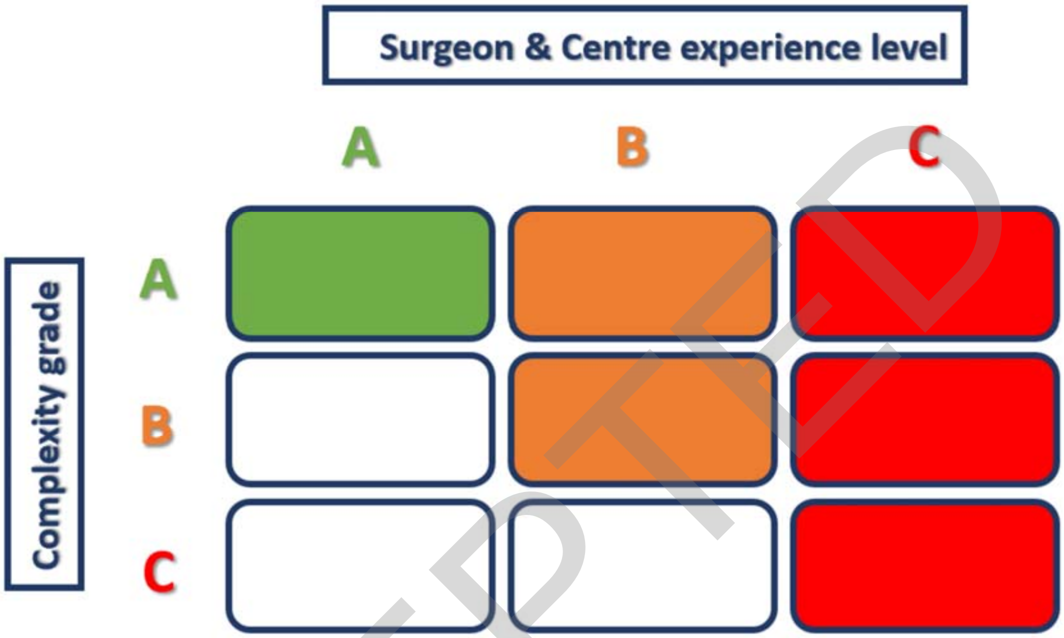

Figure 3: Case 1 – Contrast-enhanced computed tomography images demonstrating a pancreatic head mass measuring 21x13mm (A) with superior mesenteric vein (SMV) contact <180^0 (D). The main pancreatic diameter (MPD) was 10mm (B) and the common bile duct (CBD) measured at 12mm (C).

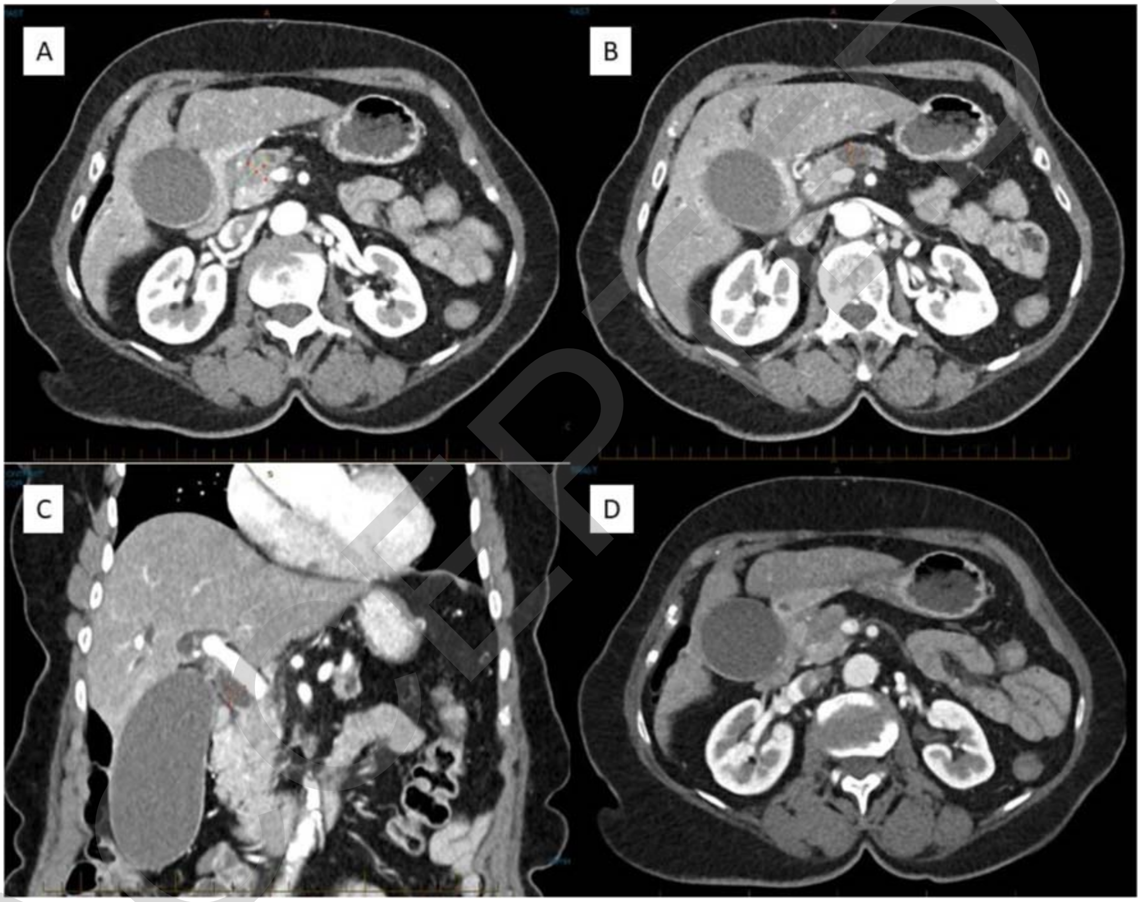

Figure 4: Case 2 – Contrast-enhanced computed tomography images demonstrating a pancreatic head mass measuring 15.1x13.5mm without vessel contact (A). The main pancreatic diameter (MPD) was 6.4mm (B) and the common bile duct (CBD) measured at 22.7mm (C).

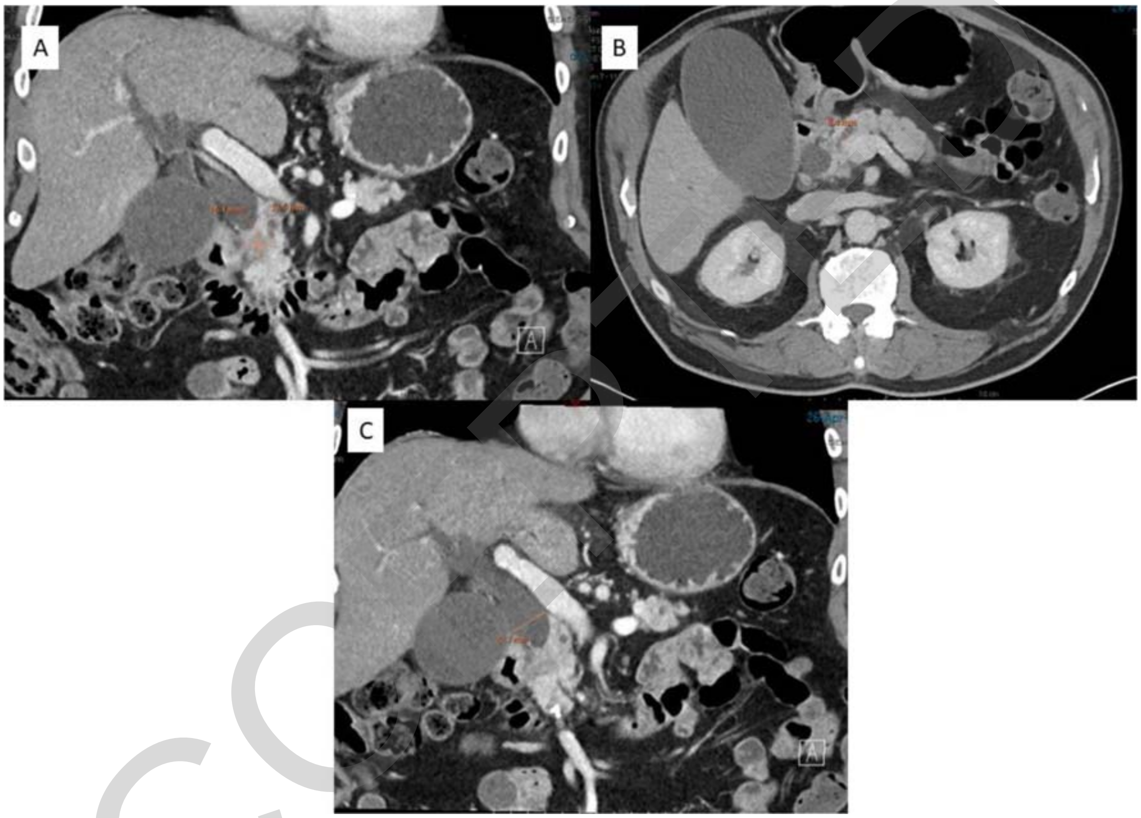

Table 1a: ISGPS MIPD A-B-C experience grading system

	Risk factors
Anatomical	**Main pancreatic duct diameter** ≤3mm
	Common bile duct diameter ≤5mm
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*

Table 1b: 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