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# External validation of the Japanese difficulty scoring system for minimally-invasive distal pancreatectomies

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ABSTRACT

*Introduction:* Preoperative prediction of the difficulty of surgery would be useful for surgeons embarking on MIDP. A novel difficulty scoring system(DSS) was recently developed in Japan but has not been externally validated. This study aims to externally validate the DSS determine its association with important clinical outcome parameters.
*Methods:* Retrospective review of 90 patients who underwent MIDP from 2006 to 2018. The patients were stratified into 3 groups (low, intermediate and high difficulty) according to the DSS with some minor modifications.
*Results:* Difficulty of MIDP was classified as low in 45(50%), intermediate in 32(35.5%) and high in 13(14.4%). Comparison between the baseline characteristics across the 3 difficulty groups demonstrated a significant difference in the frequency of malignant tumors, larger tumor size, frequency of extended pancreatectomies and use of robotic assistance. There was statistically significant increase in operation time, blood loss and blood transfusion rate across the 3 groups from low to high difficulty.
*Conclusion:* The DSS correlated significantly with operation time, blood loss and blood transfusion rate. These findings support the validity of the system.



## Introduction

Cushieri et al. reported the first minimally-invasive distal pancreatectomy (MIDP) in 1996.[1] Subsequently, numerous studies reporting on MIDP have been reported from various regions throughout the world.[2–5] Although MIDP is recognized to be not as technically demanding as proximal pancreatic resections, it still remains a challenging procedure as evidenced by the high open conversion rates of 16–31% reported even from high volume specialized centers especially by early adopters during the learning phase.[6–8] Hence, a gradual stepwise adoption of MIDP is essential for the safe dissemination of MIDP.

Recently, a novel difficulty score system (DSS) for laparoscopic distal pancreatectomy was developed in Japan by Ohtsuka et al.[9] using an automatic linear modeling (LINEAR) statistical tool similar to that developed by Ban et al.[10] for laparoscopic liver resections. The DSS was developed based on clinical data of 80 patients who underwent MIDP at 4 high volume Japanese pancreatic surgery institutions. Its purpose was to quantify the degree of difficulty of MIDP to assist surgeons in teaching and learning MIDP. The parameters included in the DSS were type of operation, pancreatic resection line, proximity of tumor to major vessel, tumor extension to peripancreatic tissue and presence of left-sided portal hypertension. However, since its recent formulation, the DSS has not been externally validated.

In this study we aimed to validate the DSS and determine its association with important clinical outcome parameters such as morbidity, operation time, length of stay and blood loss in a cohort of patients who underwent various approaches of minimally-invasive distal pancreatectomies (MIDP). To our knowledge, this is the first study attempting to externally validate the novel DSS.

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## Materials and methods

All consecutive patients who underwent MIDP at a single institution from 2006 to 2018 were identified from a prospectively maintained surgical database. All patient data were subsequently obtained retrospectively from the patients' clinical, radiological and pathological records. Clinical data was collected from a prospective computerized clinical database (Sunrise Clinical Manager version 5.8, Eclipsys Corporation, Atlanta, Georgia) and patient's clinical charts whereas operative data were obtained from another prospective computerized database (OTM 10, IBM, Armonk, New York) consecutive patients were identified.

Clinicopathological data including relevant preoperative, intraoperative and postoperative outcomes such as patient demographics, presence of symptoms, history of abdominal surgery, American Society of Anaesthesiology (ASA) score, tumor size, tumor pathology, operation time, blood loss, blood transfusion, postoperative morbidity and postoperative hospitalization were recorded. All 30-day/in-hospital postoperative morbidities and mortalities were recorded. The postoperative complications were classified according to the Clavien-Dindo grading system.[11] Our operative technique for MIDP (laparoscopic or robotic) have been described previously.[12–15]

The procedures were classified according the recently proposed DSS with some modifications.[9] The key features of the DSS are summarized in Table 1. Procedures with a score of 1–3 were classified as a of low difficulty, 4–6 as of intermediate difficulty and 7–10 as of high difficulty. The 2 main modifications in this study was that patients with early/small pancreatic malignancies who underwent conventional distal pancreatosplenectomies were given the same score as for patients who underwent distal pancreatosplenectomy for benign disease. In our practice radical antegrade modular pancreatosplenectomy (RAMPS) was not routinely performed for all patients with pancreatic malignancy especially small early cancers. Secondly, patients who underwent spleen-saving distal pancreatectomy via the Warshaw technique were also given the same procedural score as having undergone distal pancreatosplenectomy for benign disease. In this study, we did not restrict the procedures to LDP but included all approaches of MIDP as we postulated that the DSS would be valid the various approaches.

### *Definitions*

Postoperative pancreatic fistula (POPF) was defined and graded according to latest International Study Group for Pancreatic Fistula system.[16] The previously defined grade A biochemical POPF[16] was reported but was no longer considered a morbidity. We defined a subtotal pancreatectomy was as when the transection of the pancreatic parenchyma was located at or to the right of the portal vein/splenic vein junction]. Extended pancreatectomy was defined according to the recent international study group definition which included any distal pancreatectomy with adjacent organ resection such as the stomach, colon, mesocolon or vascular resection due to local tumor involvement.[17]

All statistical analyses were performed using the computer program Statistical Package for Social Sciences for Windows, version 22.0 (SPSS Inc, Chicago, IL, USA). Analyses were performed using the Jonckheere-Terpstra test or Mantel Haenszel tests as appropriate. Spearman's Correlation was used to determine correlation between significant outcomes and the total difficulty score. Receiver operating characteristics (ROC) curve was used to calculate the C statistic. All statistical tests were 2-sided and $p < 0.05$ was considered statistically significant.

## Results

Ninety consecutive patients underwent MIDP at our institution during the study period. The clinicopathological features and perioperative outcomes of these patients are summarized in Tables 2 and 3. The approaches attempted was conventional laparoscopic in 66 (73.3%), robotic-assisted in 22 (24.4%) and hand-assisted in 2 (2.2%). Five (5.6%) patients had synchronous operations (non-cholecystectomies) such as colectomy or gastrectomy for other pathologies and 4 (4.4%) patient had extended pancreatectomies for locally advanced malignancies. Open conversion was required in 12 (13.3%) of patients. The median postoperative stay was 6 (range, 3–73) days and there were 19 (21.1%) readmissions within 30 days of discharge. Major morbidity occurred in 15 (16.7%) of patients including 1 (1.1%) reoperations for port site hernia. There were 19 (21.1%) clinically-significant grade B fistulas (no grade C) of which 14 (15.6%) required percutaneous drainage.

There was no 30-day mortality and 2 in-hospital mortalities. The 2 in-hospital mortalities occurred in a ASA 3 patients with high cardiac risk who underwent uneventful surgery for pancreatic malignancy but developed acute myocardial infarction and cerebral hemorrhage postoperatively and the other mortality occurred in a post-renal transplant patient who underwent laparoscopic pancreatectosplenectomy for worrisome risk intraductal papillary mucinous neoplasm with concomitant extended right hemicolectomy for synchronous colorectal cancers and gastric resection for gastrointestinal stromal tumor. The patient developed and eventually demised from sepsis due to nosocomial pneumonia.

### *Validation of the DSS*

Tables 2 and 3 summarize the baseline demographic, clinicopathologic, perioperative and postoperative data of the patients

**Table 1**
Difficulty scoring system for distal pancreatectomy as proposed by Ohtsuka.

| Parameter | | Score |
|---|---|---|
| Type of operation | DP-S for benign disease [a] | +1 |
| | SPDP | +3 |
| | RAMPS | +4 |
| Pancreatic resection line | Portal vein | +1 |
| | Pancreatic tail | 0 |
| Tumor close to major vessel | Presence | +2 |
| | Absence | 0 |
| Tumor extension to peripancreatic tissue | Presence | +1 |
| | Absence | 0 |
| Left sided portal hypertension and/or splenomegaly | Presence | +5 |
| | Absence | 0 |

DP-S, distal pancreatosplenectomy; RAMPS, radical antegrade modular pancreatosplenectomy; SPDP, spleen-preserving distal pancreatectomy.
[a] In this study DP-S for malignancy and SPDP via Warshaw technique was given the score of +1.

**Table 2**
Comparison between the baseline demographic and perioperative data of patients who underwent MIDP according to the difficulty score.

| | Total | Low (1–3) | Intermediate (4–6) | High (7–10) | P-value |
|---|---|---|---|---|---|
| Number | 90 | 45 | 32 | 13 | NA |
| Male sex, n (%) | 39 (43.3) | 24 (53.3) | 11 (34.4) | 4 (30.8) | 0.071 |
| Median age (range), yrs | 61 (19–85) | 63 (22–80) | 51.5 (19–78) | 61 (21–85) | 0.175 |
| Symptoms, n (%) | 28 (31.1) | 13 (28.9) | 8 (25.0) | 7 (53.8) | 0.213 |
| Median BMI (range), kg/m | 23.1 (12.6–35.9) | 24.2 (15.9–32.4) | 22.6 (19.1–35.9) | 22.1 (12.6–24.4) | **0.026** |
| Previous abdominal surgery, n (%) | 23 (25.6) | 14 (31.1) | 5 (15.6) | 4 (30.8) | 0.543 |
| ASA score, n (%) | | | | | 0.229 |
| 1 | 15 (16.7) | 5 (11.1) | 7 (21.9) | 3 (23.1) | |
| 2 | 64 (71.1) | 33 (73.3) | 23 (71.9) | 8 (61.5) | |
| 3 | 11 (12.2) | 7 (15.6) | 2 (6.3) | 2 (15.4) | |
| MIS type, n (%) | | | | | **0.001** |
| Laparoscopic | 66 (73.3) | 39 (86.7) | 22 (68.8) | 5 (38.5) | |
| Hand-assisted | 2 (2.2) | 0 | 1 (3.1) | 1 (7.7) | |
| Robotic-assisted | 22 (24.4) | 6 (13.3) | 9 (28.1) | 7 (53.8) | |
| Malignant neoplasm, n (%) | 19 (21.1) | 8 (17.8) | 4 (12.5) | 7 (53.8) | **0.040** |
| Median tumor size, mm (range) | 30 (8–140) | 24 (8–100) | 43 (15–140) | 42 (10–69) | **0.003** |
| Type of DP, n (%) | | | | | **<0.001** |
| SPVPDP | 18 (20.0) | 7 (15.6) | 9 (28.1) | 2 (15.4) | |
| DPS/SPDP (Warshaw) | 64 (71.1) | 38 (84.4) | 23 (71.9) | 3 (23.1) | |
| RAMPS | 8 (8.9) | 0 | 0 | 8 (61.5) | |
| Subtotal (resection at/right of PV), n (%) | 24 (26.7) | 3 (6.7) | 12 (37.5) | 9 (69.2) | **<0.001** |
| Extended pancreatectomy, n (%) | 4 (4.4) | 0 | 0 | 4 (30.8) | **<0.001** |
| Concomitant surgery, n (%) | 5 (5.6) | 3 (6.7) | 0 | 2 (15.4) | 0.068 |
| Left-sided portal hypertension, n (%) | 7 (7.8) | 0 | 3 (9.4) | 4 (30.8) | **0.001** |
| Tumor extension to peripancreatic tissue, n (%) | 40 (44.4) | 7 (15.6) | 24 (75.0) | 9 (69.2) | **<0.001** |
| Tumor close to major vessel, n (%) | 42 (46.7) | 2 (4.4) | 27 (84.4) | 13 (100) | **<0.001** |

DPS, distal pancreatectosplenectomy; NA, not applicable; RAMPS, radical antegrade modular pancreatosplenectomy; SPDP, spleen preserving distal pancreatectomy; SPVPDP, spleen preserving vessel preserving distal pancreatectomy.
$p < 0.05$ (statistically significant).

across the 3 difficulty groups. There were 45 (50%) procedures classified as low difficulty, 32 (35.5%) as intermediate and 13 (14.4%) as high difficulty. Comparison between the baseline demographic of patients who underwent MIDP across the 3 groups demonstrated that there was a statistically-significant lower BMI, increased proportion of robotic assisted procedures, increased frequency of extended pancreatectomies and larger tumor size across the 3 groups. Not surprisingly there was also a significant increase in the frequency of subtotal pancreatectomies, left-sided portal hypertension, tumor extension to peripancreatic tissue and tumor close to the major vessels as these parameters were part of the difficulty scores.

Comparison of perioperative outcomes across the 3 difficulty groups demonstrated a significantly longer operation time, increased blood loss and increase in blood transfusion rate. There was no significant difference in other perioperative outcomes such as postoperative morbidity, readmission rate and postoperative stay. There was significantly weak positive correlation between the operation time with the total difficulty score, 0.419, $P < 0.001$ and the estimated blood loss with the total difficulty score, 0.368, $P < 0.001$. The C-statistic for blood transfusion rate with the DSS was 0.715, $P = 0.035$.

## Discussion

The DSS for laparoscopic distal pancreatectomies was proposed recently by Ohtsuka et al. to aid in the safe stepwise adoption of laparoscopic distal pancreatectomy.[9] This was based on a cohort of

**Table 3**
Comparison between the perioperative and oncologic outcomes of patients who underwent MIDP according to the difficulty score.

| | Total | Low | Intermediate | High | P-value |
|---|---|---|---|---|---|
| Open conversion, n (%) | 12 (13.3) | 6 (13.3) | 5 (15.6) | 1 (7.7) | 0.753 |
| Median operating time (range), min | 285 (85–775) | 225 (85–515) | 330 (140–685) | 385 (210–775) | **<0.001** |
| Median blood loss (range), ml | 175 (25–2000) | 100 (25–1000) | 200 (50–1200) | 300 (50–1400) | **0.009** |
| Intraoperative blood transfusion, n (%) | 10 (11.1) | 3 (6.7) | 3 (9.4) | 4 (30.8) | **0.035** |
| Postoperative morbidity, n (%) | 30 (33.3) | 15 (33.3) | 10 (31.3) | 5 (38.5) | 0.837 |
| Major morbidity (Clavien-Dindo grade > 2) | 15 (16.7) | 8 (17.8) | 6 (18.8) | 1 (7.7) | 0.515 |
| Biochemical pancreatic fistula, n (%) | 29 (32.2) | 15 (33.3) | 10 (31.3) | 4 (30.8) | 0.830 |
| Grade B/C pancreatic fistula, n (%) | 19 (21.1) | 10 (22.2) | 7 (21.9) | 2 (15.4) | 0.657 |
| Pancreatic fistula requiring percutaneous drainage, n (%) | 14 (15.6) | 8 (17.8) | 6 (18.8) | 0 | 0.245 |
| Reoperation, n (%) | 1 (1.1) | 0 | 0 | 1 (7.7) | 0.060 |
| 30-day mortality, n (%) | 0 | 0 | 0 | 0 | 1.000 |
| 90-day mortality, n (%) | 2 (2.2) | 2 (4.4) | 0 | 0 | 0.3203 |
| Median postoperative stay (range), d | 6 (3–73) | 6 (3–73) | 6 (3–22) | 6 (4–26) | 0.504 |
| Readmission, n (%) | 19 (21.1) | 8 (17.8) | 8 (25.0) | 3 (23.1) | 0.531 |

$p < 0.05$ (statistically significant).

80 MIDPs performed at 4 expert Japanese centers.[9] In the original study, the DSS only correlated significantly with operation time. There was no statistically significant correlation between the DSS and other important clinical parameters such as blood loss, postoperative morbidity and hospital stay. This in our opinion was not surprising as the 80 cases were mainly performed by experienced surgeons who had overcome their learning curve and had likely optimized their individual outcomes especially in terms of open conversion and operative blood loss. Furthermore, the DSS was designed to determine technical difficulty of the procedure which may not necessarily correlate with morbidity and hence, length of stay. This is especially with regards to MIDP whereby the most common complication is the postoperative pancreatic fistula which is mainly determined by the texture of the pancreatic parenchyma.[18] Hence, conversely many "easy" MIDP for benign/premalignant tumors which are frequently associated with a soft pancreas may be associated with a higher postoperative pancreatic fistula rate as compared to technically-challenging pancreatectomies for malignant tumors which is more frequently associated with a firm pancreas.

In our present study, the operation time, estimated blood loss and blood transfusion rate increased significantly with an increasing difficulty. These parameters are well-accepted as indicators of operative difficulty.[19–23] There was a statistically significant weak positive correlation between estimated blood loss and operation time with the total difficulty score. The C-statistic for blood transfusion rate and the DSS was also statistically significant at 0.715. Hence, we successfully validated the DSS in our cohort of MIDP. Although formulated in patients who underwent conventional laparoscopic distal pancreatectomies, we postulated and have demonstrated that the DSS can applicable to the various approaches of MIDP. Open conversion rate is a frequently well-accepted indicator of operative difficulty. However, similar to the findings of the original study, we did not find a significant difference in the open conversion rates across the 3 difficulty groups. In fact, there tended to be a non-significant lower conversion rate in the high versus low difficulty group (13.3% vs 7.7%). This observation in our series is likely due to confounding factors such as more experienced surgeons performing difficult cases and possibly due to the significantly increase use of robotic assistance for the high difficulty group.

There are several potential important clinical applications of the DSS. Firstly, it can used as a guide to be build a curriculum[19] useful for surgeons embarking on MIDP in a stepwise manner from easy to difficult procedures. Secondly, it may also be used to guide clinicians in selecting appropriate cases for surgery taken into account factors such as patient fitness for surgery and disease prognosis.[9]

This study is associated with several limitations. Firstly, due to the retrospective nature and modest sample size, it may be subjected to various biases and statistical Type 1 or 2 errors. Secondly, some of the parameters in the original DSS were modified as described in our methodology to fit our patient cohort. According to the original DSS,[9] patients who underwent conventional distal pancreatosplenectomy for pancreatic malignancies could not be classified. This is likely because most Japanese surgeons propose that RAMPS be routinely performed for all pancreatic malignancies. However, in our practice as in many other centers, RAMPS is only selectively performed and we not infrequently performed conventional distal pancreatosplenectomy especially for small pancreatic malignancies. The Warshaw procedure for splenic preservation is also occasionally performed in our center and routinely by others.[24] Based on our experience, both these procedures were similar in difficulty to conventional pancreatosplenectomy for benign disease and hence our decision to assign the same difficulty score of "+1". Thirdly, we included patients who underwent various approaches of MIDP and not just conventional laparoscopy as formulated in this study. In our opinion, these minor modifications to the DSS is advantageous as it potentially allows wider application of the DSS to other institutions around the world.

In conclusion, this study demonstrated that the DSS for MIDP correlated significantly with operation time, blood loss and blood transfusion rate. These findings support the validity of the system. Further prospective studies in larger cohort of patients are needed to corroborate these findings.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjsurg.2019.03.012.

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