A Novel Difficulty Classification for Perioperative Risk Assessment in High-level Hepatobiliary Pancreatic Surgeries

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Purpose : Although mortality and morbidity rate of high-level hepatobiliary pancreatic (HBP) surgery has been improved, which remains still high in some procedures. The difficulty of high-level HBP surgeries are varies depending on the surgical complexity, thereby perioperative outcomes can be variable. The aim this study was to establish a novel difficulty classification of high-level HBP surgeries and to assess its validity.

Methods : High-level HBP surgeries were classified into four groups, A to D, in order of increasing difficulty, based on the expert opinion. A total of 473 patients who underwent high-level HBP surgery from July 2014 to July 2021 in our hospital were classified into aforementioned four groups, and surgical and postoperative outcomes of which were compared.

Results : The numbers of patients in each difficulty group were as follows : A (n = 62), B (n = 278), C (n = 74) and D (n = 59). Operation time and blood loss showed a significant stepwise increase in the group A to D ($p < 0.001$ and $p < 0.001$ respectively). The duration of postoperative hospital stay also increased significantly from the group A to D ($p < 0.001$). The incidence of complications over Clavien-Dindo classification IIIa increased in group A to D significantly (35.5 % vs 35.3 vs 37.8 vs 54.2 % ; $p = 0.021$). However, the 90-day mortality rates did not differ within four groups (1.6 % vs 0.4 % vs 2.7 % vs 1.7 % ; $p = 0.394$).

Conclusions : The novel difficulty classification of high-level HBP surgeries can predict surgical risk in each surgical procedure. Further large-scale nationwide study should be warranted to confirm these results. *Shinshu Med J 72 : 19—29, 2024*

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Key words : High-level HBP surgery, classification, safety, education

I Introduction

The safety and efficacy of hepatobiliary pancreatic (HBP) surgery have improved dramatically in recent years, but the operative mortality rate remains higher than that of other gastrointestinal surgeries[1]. The Japanese Society of Hepato-Biliary-Pancreatic Surgery (JSHBPS) has established a board certification system for training surgeons able to perform high-level HBP surgeries safely and reliably[2)-4)]. The 90- and 30-day mortality rates at board-certified training institutions were 1.7 % and 1.3 %, respectively, in 2015, which were significantly lower than the rates in 2012[5]. However, the difficulty of high-level HBP surgeries varies depending on the complexity of each procedure, and the perioperative outcomes thus vary accordingly. For example, the 90-day mortality following extrahepatic bile-duct resection with bilio-enteric anastomosis in patients with congenital biliary

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dilatation was 0 %, compared with 10.3 % in patients with left trisectionectomy of the liver, even in certified institutions[5].

Advances in perioperative management and surgical techniques, together with changes in public awareness of medical safety, mean that perioperative death is becoming unacceptable, even after high-level HBP surgery. However, in order to produce expert surgeons able to carry out high-level HBP, it is necessary for them to accumulate experience in the appropriate surgeries safely and efficiently under appropriate instruction. Although several new difficulty classifications of liver resection have been reported[6)-8)], there is currently no classification that can act as an indicator of difficulty and risk for all high-level HBP surgeries. This study thus aimed to establish a novel difficulty classification for high-level HBP surgeries to provide an indicator for expert training and to aid the appropriate allocation of surgeons, and to evaluate its validity for difficulty assessment.

Ⅱ Material and Methods

A Classification of surgeries

A questionnaire survey was administered to six experts and three expert trainees for JSHBPS board certification in Shinshu University and its affiliated hospital in December 2021. Expert surgeon was defined as high-level HBP surgeon who certified by the JSHBPS. The surgeons were asked to evaluate and rank the difficulties of various high-level HBP surgeries on a scale of 1-10, where level 1 was "easiest" and level 10 was "most difficult". The survey specified that all resections were to be considered as open, rather than laparoscopic procedures[9]. All the surveys were anonymous. Based on the questionnaire, high-level HBP surgeries were classified into four groups, procedures with median score of 1 to 3 as level A : "easy", median score 4 to 6 as B : "moderate", median score 7 to 8 as C : "difficult", and median score 9 to 10 as D : "most difficult". The recommendation of surgeon's level for high-level HBP surgeries were also collected by the questionnaire ; for general surgeon, HBP trainee, HBP expert surgeon.

B Patients and data collection

Patients who underwent high-level HBP surgery in Shinshu University Hospital from July 2014 to July 2021 were included in the study. The operations of 38.5 % was performed by expert surgeons. Data on the patients' basic characteristics, including age, sex, body mass index, American Society of Anesthesiologists physical status (ASA-PS), social history, and laboratory data were collected. Data on surgical and postoperative outcomes, including the type of surgical procedure, duration of operation, intraoperative blood loss, qualification of surgeon, surgeons' career, duration of postoperative hospital stay, postoperative complications, and 30- and 90-day mortalities were also collected and evaluated. Postoperative complications were defined and graded according to the Clavien-Dindo (CD) classification system[10]. All complications were recorded and complications above CD grade IIIa were defined as major complications. The patients were classified into the above four groups according to the surgical procedure carried out, and their surgical and postoperative outcomes were compared. To compare with similar patient's comorbidities' backgrounds, stratification was performed based on the ASA-PS and age. Liver transplantation donor operations were excluded from the analysis because it was difficult to reflect social responsibility and ethical issues in the difficulty score.

C Comparison of classification and perioperative outcomes

The perioperative outcomes of the patients in the four difficulty groups based on HBP surgeon opinion were compared to confirm the performance of the classification. Duration of operation, intraoperative blood loss, incidence of major postoperative complications, 30- and 90-day mortality rates, failure-to-rescue (FTR) rate, and duration of postoperative hospital stay were set as outcomes measurements. The FTR rate was defined as death in a patient with at least one postoperative complication[11]. The difficulty classification effect was tested by comparing the areas under the receiver operating characteristic (ROC) curves (AUCs).

D Statistical analysis

Continuous variables were compared using the

Table 1 Difficulty score of high-level HBP surgeries based on surgeon opinion and classification

Procedures	Median (IQR)	Classification
Hepatic segmentectomy : S3	3.00 (2.00–4.25)	A
Hepatic segmentectomy : S2	3.50 (3.00–4.25)	A
Hepatic segmentectomy : S5	3.50 (3.00–5.00)	A
Hepatic segmentectomy : S6	3.50 (2.75–5.00)	A
Extrahepatic bile duct resection for congenital biliary dilatation	4.00 (3.00–4.50)	A
Distal pancreatectomy with lymph node dissection (for pancreatic cancer)	4.00 (3.75–5.00)	A
Hepatic sectionectomy : posterior	5.00 (3.75–6.00)	B
Hepatic sectionectomy : S4	5.00 (4.00–6.00)	B
Duodenum-preserving pancreas head resection	5.00 (4.50–5.50)	B
Beger's operation	5.00 (4.00–5.50)	B
Hepatectomy with distal pancreatectomy	5.00 (3.00–6.00)	B
Hepatic segmentectomy : S7	5.50 (3.75–6.00)	B
S4a + S5 hepatectomy with extrahepatic bile duct resection	5.50 (4.00–6.00)	B
Pancreatoduodenectomy	5.50 (4.75–6.00)	B
Inferior pancreas head resection	5.50 (4.75–6.25)	B
Right or extended right hepatectomy	6.00 (4.75–6.25)	B
Left or extended left hepatectomy	6.00 (4.75–7.00)	B
Hepatic sectionectomy : anterior	6.00 (4.75–7.00)	B
Hepatic segmentectomy : S8	6.00 (4.75–6.00)	B
Total pancreatectomy	6.00 (4.50–6.25)	B
Middle segment pancreatectomy	6.00 (4.00–6.50)	B
Hepatic sectionectomy or less and pancreatoduodenectomy	6.50 (6.00–7.75)	B
Central bisectionectomy of the liver	7.00 (6.50–8.00)	C
Hepatic segmentectomy : S1	7.00 (5.50–8.00)	C
Liver transplantation donor operation	7.00 (6.50–7.25)	C
Pancreas-preserving duodenectomy	7.00 (6.50–7.50)	C
Ventral pancreatectomy	7.00 (7.00–7.00)	C
Right or extended right hepatectomy with extrahepatic bile duct resection	7.00 (5.25–7.25)	C
Left trisectionectomy of the liver	7.50 (6.25–8.00)	C
Right trisectionectomy of the liver	8.00 (6.50–8.00)	C
Left or extended left hepatectomy and pancreatoduodenectomy	8.00 (8.00–9.00)	C
Right trisectionectomy with extrahepatic bile duct resection	8.50 (7.75–9.00)	C
Liver transplantation recipient operation	9.00 (8.50–9.51)	D
Left trisectionectomy with extrahepatic bile duct resection	9.00 (7.75–10.00)	D
Right or extended right hepatectomy and pancreatoduodenectomy	9.00 (8.50–9.50)	D
Central bisectionectomy of the liver and pancreatoduodenectomy	9.00 (9.00–10.0)	D
Right trisegmentectomy of the liver and pancreatoduodenectomy	10.00 (10.00–10.00)	D
Left trisegmentectomy of the liver and pancreatoduodenectomy	10.00 (10.00–10.00)	D

Abbreviation : HBP, Hepatobiliary pancreatic ; IQR, interquartile range ; A, easy ; B, moderate ; C, difficult ; D, most difficult.

Mann-Whitney *U* test and categorical variables were compared using χ^2 and Fisher's exact tests. One-way analysis of variance (ANOVA) was used for comparisons among the four groups. Trends in perioperative outcomes with a stepwise increase from groups A to D were evaluated using the Cochran-Armitage trend test for categorical variables and Jonckheere-Terpstra trend test for continuous variables. The classification was validated by ROC curve analysis and AUCs. To identify independent risk factors for postoperative major complication, multivariable analyses were performed along with logistic regression analysis with covariates with a cutoff P value = 0.10. Results are expressed as odds ratios with 95 % confidence intervals. All statistical analyses were performed using IBM SPSS version 27 (IBM Corp., Armonk, NY, USA). The threshold for significance was $P < 0.05$.

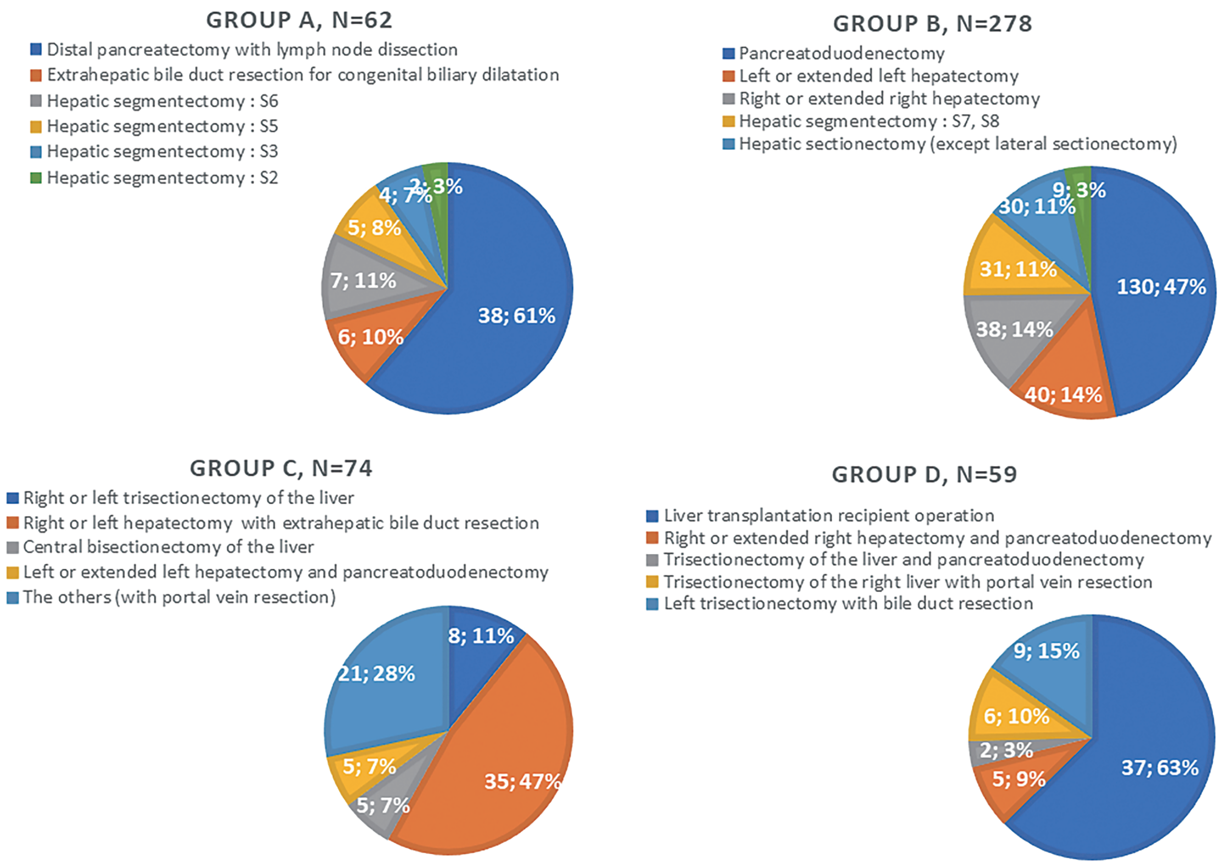

Fig. 1 Numbers and proportions of patients in each high-level HBP surgery group. Distal pancreatectomy accounted for most patients (61 %) in group A, pancreaticoduodenectomy accounted for the highest percentage in group B (48 %), hepatectomy with extrahepatic bile duct resection and trisesectionectomy were the main surgeries in group C, and liver transplant receipt accounted for most patients (74 %) in group D.

Ⅲ Results

A Difficulty scores for high-level HBP surgeries

The median and interquartile range (IQR) of the score for each high-level HBP surgery based on HBP surgeon opinion is shown in **Table 1**. Based on these opinions, the high-level HBP surgeries were classified into four groups. Surgical procedures with portal vein, inferior vena cava, or hepatic vein reconstruction were assigned as 1-rank-up group of difficulty classification based on HBP surgeon opinion.

B Patient characteristics

Among 496 patients who underwent high-level HBP surgeries in Shinshu University Hospital during 2014 to 2021, 22 patients who underwent liver transplantation donor operation were excluded. A total of 473 patients were therefore enrolled in this study. The numbers and proportions of patients undergoing each high-level HBP surgery are shown in **Fig. 1**. In the entire cohort, 62 patients underwent group A, 278 group B, 74 group C, and 59 group D surgeries.

The background characteristics of the patients are shown in **Table 2**. Stratification was performed by ASA-PS ≤ 2 and age ≥ 57-year-old, to compare the similar patients' backgrounds. There was no significant difference in sex ($P=0.553$) or body mass index ($P=0.717$) among the four groups, whereas age ($P=0.015$) was still difference among four groups. The preoperative rates of comorbid diabetes mellitus, hypertension, cardiovascular or pulmonary diseases were similar in all four groups.

C Surgical and postoperative outcomes

The surgical and postoperative short-term outcomes are summarized in **Table 3**. Operation time (median : 375 min vs 526 min vs 652 min vs 794, respectively ; $P<0.001$), blood loss (300 ml vs 405 ml vs

Table 2　Characteristics of patients who underwent high-level HBP surgeries for ASA-PS ≤ 2 and age ≥ 57

Parameters	Group A (n = 51)	Group B (n = 224)	Group C (n = 65)	Group D (n = 29)	P value
Age, year[a]	70 (68–76)	72 (66–78)	72 (66–78)	68 (63–72)	0.015[b]
Sex, male	30 (58.8)	146 (65.2)	44 (67.7)	16 (55.2)	0.553[c]
BMI, kg/m[2a]	21.7 (20.4–23.8)	22.1 (19.8–24.5)	22.5 (20.4–24.7)	22.1 (19.7–22.9)	0.717[b]
Preoperative comorbidity					
Diabetes mellitus	17 (33.3)	65 (29.0)	15 (23.1)	4 (13.8)	0.458[c]
Hypertension	26 (51.0)	128 (57.1)	33 (50.8)	11 (37.9)	0.243[c]
Cardiovascular disease	6 (11.8)	12 (5.4)	2 (3.1)	2 (6.9)	0.189[c]
Pulmonary disease	2 (3.9)	12 (5.4)	8 (12.3)	2 (6.9)	0.213[c]
Social history					
Smoking	21 (41.2)	126 (56.3)	38 (58.5)	15 (51.7)	0.119[c]
Drinking	30 (58.8)	149 (66.5)	44 (67.7)	20 (69.0)	0.779[c]

Note : Values in parentheses are percentages unless indicated otherwise.
Abbreviation : BMI, body-mass index ; ASA-PS, American Society of Anesthesiologists physical status.
[a]Median (IQR)
[b]Kruskal-Wallis test.
[c]Pearson's chi-square test.

Table 3　Surgical and postoperative outcomes in patients who underwent high-level HBP surgeries for ASA-PS ≤ 2 and age ≥ 57

Parameters	Group A (n = 51)	Group B (n = 224)	Group C (n = 65)	Group D (n = 29)	P value
Surgical outcomes					
Operation time, min[a]	375 (304–441)	526 (409–612)	652 (562–709)	794 (644–962)	<0.001[b]
Blood loss, ml[a]	300 (150–560)	405 (250–650)	700 (500–1200)	900 (550–4000)	<0.001[b]
Transfusion	6 (11.8)	35 (12.6)	26 (40.0)	18 (62.1)	<0.001[c]
Expert surgeon	8 (15.7)	64 (28.6)	37 (56.9)	22 (75.9)	<0.001[c]
Surgeons' career, year[a]	19 (6–35)	23 (5–35)	29 (17–35)	29 (20–25)	<0.001[c]
Postoperative outcomes					
Morbidity	37 (72.5)	181 (80.8)	55 (84.6)	27 (93.1)	0.028[c]
Major complication ≥ CD grade IIIa	20 (39.2)	87 (38.8)	28 (43.1)	15 (51.7)	0.285[c]
Postoperative hospital stay, day[a]	15 (11–39)	20 (13–38)	24 (18–40)	35 (23–49)	<0.001[b]
30-day mortality	0 (0)	0 (0)	0 (0)	0 (0)	–
90-day mortality	1 (2.0)	1 (0.5)	2 (3.1)	0 (0)	0.732[c]
30-day failure to rescue	0 (0)	0 (0)	0 (0)	0 (0)	–
90-day failure to rescue	1 (2.8)	1 (0.6)	2 (3.6)	0 (0)	0.814[c]

Note : Values in parentheses are percentages unless indicated otherwise.
Abbreviation : CD grade, Clavien-Dindo classification grade.
[a]Median (IQR)
[b]Jonckheere-Terpstra trend test.
[c]Cochran-Armitage trend test.

700 ml vs 900 ml, respectively ; $P<0.001$), intraoperative transfusion rate (11.8 % vs 12.6 % vs 40.0 % vs 62.1 %, respectively ; $P<0.001$), expert surgeon rate (15.7 % vs 28.6 % vs 56.9 % vs 78.9 %, respectively ; $P<0.001$) and surgeons' career (19 years vs 23 years vs 29 years vs 29 years, respectively ; $P<0.001$) showed significant stepwise increases with increasing difficulty. The duration of postoperative hospital stay was also significantly associated with the degree of difficulty (median : 15 days vs 20 days vs 24 days vs 35 days, respectively ; $P<0.001$). A trend test of the incidence of morbidity was significant increased with increasing

Table 4 Comparison of surgical and postoperative outcomes in patients who underwent group C and D high-level HBP surgeries between non-expert surgeons versus expert surgeons

Parameters	Non-expert (n=48)	Expert (n=85)	*P* value
Surgical procedures			0.113
Right or left trisectionectomy of the liver	1 (2.1)	7 (8.2)	
Right or left hepatectomy with extrahepatic bile duct resection	12 (25.0)	23 (27.1)	
Central bisectionectomy of the liver	3 (6.3)	2 (2.4)	
Left or extended left hepatectomy and pancreatoduodenectomy	1 (2.1)	4 (4.7)	
Liver transplantation recipient operation	14 (29.2)	23 (27.1)	
Right or extended right hepatectomy and pancreatoduodenectomy	0 (0)	5 (5.9)	
Trisectionectomy of the liver with pancreatoduodenectomy	0 (0)	2 (2.4)	
Trisectionectomy of the liver with portal vein resection	0 (0)	6 (7.1)	
Trisectionectomy of the liver with extrahepatic bile duct resection	1 (2.1)	8 (9.4)	
The others (with portal vein resection)	16 (33.3)	5 (5.9)	
Surgical outcomes			
Operation time, min[a]	711 (625-958)	689 (579-831)	0.065
Blood loss, ml[a]	1025 (650-3410)	850 (540-1420)	0.139
Transfusion	29 (60.4)	46 (54.1)	0.504
Postoperative outcomes			
Morbidity	43 (89.6)	70 (82.4)	0.442
Major complication ≥ CD grade IIIa	19 (39.6)	41 (48.2)	0.368
Postoperative hospital stay, day[a]	28 (18-38)	28 (20-50)	0.320
30-day mortality	1 (2.1)	0 (0)	0.361
90-day mortality	1 (2.1)	2 (2.4)	1.000
30-day failure to rescuer	1 (2.3)	0 (0)	0.381
90-day failure to rescuer	1 (2.3)	2 (2.9)	1.000

Note : Values in parentheses are percentages unless indicated otherwise.
Abbreviation : CD grade, Clavien-Dindo classification grade.
[a]Median (IQR)

difficulty (72.5 % vs 80.8 vs 84.6 vs 93.1 %, respectively ; $P=0.028$). However, major complications ≥ CD grade IIIa and 90-day mortality rates did not differ among the four groups (39.2 % vs 38.8 % vs 43.1 % vs 51.7 %, respectively ; $P=0.285$ and 2.0 % vs 0.5 % vs 3.1 % vs 0 %, respectively ; $P=0.732$) and there were no significant differences in 30- or 90-day FTR rates among the four groups (30-day : 0 %, 0 %, 0 %, and 0 % ; 90-day : 2.8 % , 0.6 % , 3.6 % , and 0 % , respectively) **(Table 3)**.

Additionally, the group C and D high-level HBP surgeries which by non-expert surgeons were compared with expert surgeons **(Table 4)**. There was trend that the operation time was longer in non-expert surgeon group, however, there was not any significant difference between two groups about morbidity and mortality. 30-day mortality and 30-day FTR was only in non-expert surgeon group.

D Independent preoperative prognostic factors for major complications

The results of univariate and multivariate analyses of the preoperative risk factors for major postoperative complications are shown in **Table 5**. The cut-off value for age was determined by ROC curve analysis, and age ≥ 57 years was considered positive. In multivariate analysis, age ≥ 57 years (odds ratio : 2.152, 95 % confidence interval : 1.286-3.600 ; $P=0.004$) and difficulty classification D (odds ratio : 2.836, 95 % confidence interval : 1.318-6.103 ; $P=0.008$) were independent risk factors for major postoperative complications.

E Performance of difficulty classification

Surgical difficulty was indicated by operation time, blood loss, postoperative complications, and duration of postoperative hospital stay. To develop the ROC

Table 5 Uni- and multivariate analysis of the preoperative risk factors for postoperative major complications

	Univariate		Multivariate	
Variables	Odds ratio	*P*	Odds ratio	*P*
Age				
≥ 57 years[a]	1.667 (1.038-2.675)	<0.001	2.152 (1.286-3.600)	0.004
<57 years[a]	1.000 (reference)		1.000 (reference)	
Sex				
Male	0.892 (0.640-1.243)	0.499		
Female	1.000 (reference)			
Body-mass index				
≥ 25 kg/m^2	0.832 (0.516-1.341)	0.450		
<25 kg/m^2	1.000 (reference)			
Smoking				
Yes	1.033 (0.713-1.496)	0.864		
No	1.000 (reference)			
Drinking				
Yes	1.088 (0.740-1.601)	0.667		
No	1.000 (reference)			
Hypertension				
Yes	0.924 (0.634-1.344)	0.678		
No	1.000 (reference)			
Diabetes mellitus				
Yes	1.092 (0.711-1.678)	0.687		
No	1.000 (reference)			
Pulmonary disease				
Yes	0.788 (0.330-1.836)	0.591		
No	1.000 (reference)			
Heart disease				
Yes	0.734 (0.293-1.836)	0.508		
No	1.000 (reference)			
ASA-PS				
≥ 3	0.683 (0.389-1.200)	0.185		
1-2	1.000 (reference)			
Difficulty classification				
D	1.288 (0.999-1.660)	0.051	2.836 (1.318-6.103)	0.008
C	1.095 (0.766-1.546)	0.606	1.066 (0.526-2.160)	0.860
B	0.982 (0.559-1.765)	0.982	0.986 (0.563-1.005)	1.796
A	1.000 (reference)		1.000 (reference)	
Expert surgeon				
Yes	1.065 (0.737-1.538)	0.738		
No	1.000 (reference)			

Note: Values in parentheses are 95 % confidence intervals.
Abbreviation: ASA-PS, American Society of Anesthesiologists physical status.
[a]The cut-off value was determined using Receiver Operating Characteristic curve analysis.

curves, we converted the continuous variables of operation time, blood loss, and duration of postoperative hospital stay into dichotomous variables based on their median values. An operation time ≥ 530 min, blood loss ≥ 450 ml, and postoperative hospital stay ≥ 20 days were set as positive values, while lower values were set as negative values. The AUC for operation time was 0.739 ($P<0.001$), for blood loss was 0.690 ($P<0.001$), for morbidity was 0.575 ($P=0.024$), and for postoperative hospital stay was 0.649 ($P<$

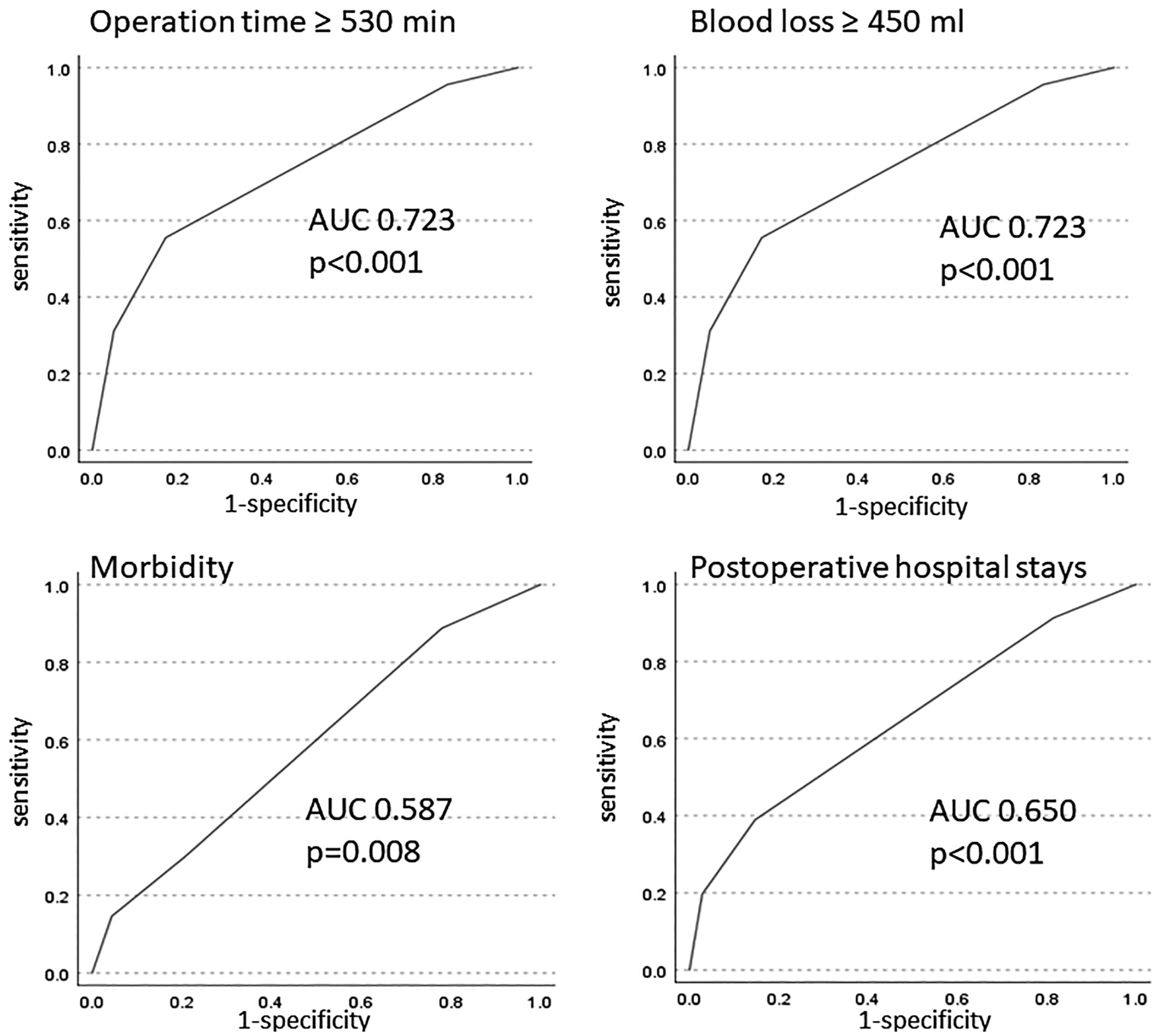

Fig. 2 Receiver operating characteristic curves for performance of difficulty classification according to operation time, blood loss, morbidity, and postoperative hospital stay.

0.001) **(Fig. 2)**.

Ⅳ **Discussion**

Although the safety of high-level HBP surgeries has increased, the 90-day mortality rate differs widely depending on the surgical procedure[5]. Attempts to provide benchmark values to help standardize surgical outcomes for some high-level HBP surgeries have been reported[12)13]. These procedures are recognized as HBP surgeries with high degrees of difficulty and complexity, which require surgeons to undergo theoretical, gradual, and efficient education and training systems to become proficient and thus improve the safety of these procedures, based on a simple and accurate system for classifying the difficulty or complexity of the different types of HBP surgery. Several complexity classifications of liver resection have been reported to stratify surgical and postoperative outcomes, including operation time, blood loss, and morbidity[8)7)14]. Lee et al.[6)9] showed the complexities of various liver resections using expert opinions and formed a new classification, followed by studies targeting the difficulty classification of liver resection. However, there is currently no difficulty classification system covering all high-level HBP surgeries, including not only liver resections, but also biliary and pancreatic surgeries. To the best of our knowledge, the present study is the first to attempt to establish a difficulty classification system aimed at improving the safety of high-level HBP surgeries and the efficacy of expert training.

In this study, high-level HBP surgeries were classified into four groups based on expert HBP surgeon opinion. This methodology of difficulty classification based on expert opinion was also adopted in previous studies, and allowed the perceived difficulties of various surgical procedures to be quantified and reflected in a classification[6)9)]. In the present study, the surgical difficulty levels were well-balanced among surgeons and the results were in line with the 90-day mortality rates in Japan according to the National Clinical Database. However, it is also necessary to confirm if the established difficulty classification is appropriate. Although the current sample size was too small to determine if this difficulty classification was appropriate based on the mortality rate, surgical difficulty can also be represented by operation time and blood loss[15)]. Operation time and blood loss showed significant stepwise increases in groups A to D in the present study, in line with increasing subjective difficulty. Differences in surgical outcomes, such as operation time and blood loss, among different difficulty levels has been used to evaluate the accuracies of difficulty scoring systems for patient[16)17)] and of the complexity classification of liver resection procedures[7)]. Furthermore, Kawaguchi et al.[8)] and Jang et al.[7)] evaluated the accuracy of classification systems for reflecting surgical difficulty using ROC curve analyses of operation time and blood loss. In line with these studies, ROC curve analysis showed good performance in the current novel difficulty classification for differentiating these surgical outcomes. These findings suggest that this novel difficulty classification accurately reflected the complexity of the surgical procedures.

Postoperative outcomes, such as mortality, morbidity, and the incidence of major complications, have also been used as important indicators for evaluating the validity of classification systems. In the present study, the morbidity rate of any complications increased in line with increasing difficulty ($P = 0.028$). In contrast, however, the mortality rates were similar in all four groups, possibly due to the low mortality rate in the study population. Furthermore, the concept of FTR rate[11)] has been presented as an indicator for evaluating postoperative outcomes. Endo[18)] highlighted the differences in the performance of hepatopancreatoduodenectomy, as an extremely difficult surgical procedure, among certified levels of institution by focusing on FTR. In the present study, there were no significant differences in 30- and 90-day FTR rates among groups A to D. This may suggest that patients were rescued by the appropriate treatment of complications, given that the incidence of major complications tended to increase gradually with increasing difficulty, while the FTR rates were similar among all four groups. However, the small sample size of the entire cohort and limited number of events means that it is difficult to draw a definitive conclusion from these results. FTR may thus be an indicator for evaluating outcomes in relation to difficulty group, as well as a useful indicator of institutional and operator criteria for each level of high-level HBP surgery.

This study had several limitations. First, this was a retrospective study with a small sample size, making it difficult to reach definitive conclusions. Second, this was a single-center study, which did not consider institution and surgeon levels based on the JHBPS board certification system. Third, the surgical procedure points were not adjusted according to the surgeon's experience, because of the small number of surgeons who completed the questionnaire. Finally, based on our institutional characteristics, three quaters of group D was liver transplantation recipient operation and it might contain bias. However, more-experienced surgeons may tend to evaluate the same surgical procedure as being easier than less-experienced surgeons[6)9)]. The perceived difficulty scores derived from surgeons' opinions should thus be adjusted according to the individual surgeon's background characteristics, including their experience, certification, and affiliation[6)9)].

Despite these drawbacks, we believe that our findings will be of interest to HBP surgeons, given that, to the best of our knowledge, this represents the first report of a novel difficulty classification of high-level HBP surgeries able to predict the surgical risk associated with each surgical procedure. Moreover, this classification is also considered useful for the education of surgeons. Factors related to a surgeon's career, such as years of experience, number of cases handled, and certification, need to be collected to evaluate this difficulty classification. In this study, the number of years in the surgeons' careers was recorded, and there was a significant stepwise increased with increasing difficulty. These results suggest that the classification provides a valid basis for selecting surgeons based on difficulty.

In conclusion, we established a novel difficulty classification for high-level HBP surgeries based on surgeon opinion. This classification may provide an indicator of difficulty and complexity, which will aid the appropriate allocation of surgeons and the efficient and safe training of experts. Further large-scale nationwide studies are needed to confirm these results.

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The authors declare that they have no conflict of interest.

Informed consent was obtained from all individual participants included in the study.

This study protocol was approved by the Ethics Committee of Shinshu University School of Medicine (registration number : 5358) and was conducted in accordance with the principles of the Declaration of Helsinki.

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