Circulation Reports
Circ Rep 2022; 4: 363–370
doi:10.1253/circrep.CR-22-0059

ORIGINAL ARTICLE
Ischemic Heart Disease

Correlation Between the Japanese Version of the High Bleeding Risk (J-HBR) Criteria and the PRECISE-DAPT Score, and Optimal J-HBR Cut-Off Score to Predict Major Bleeding

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Background: The correlation between the Japanese version of high bleeding risk (J-HBR) criteria and the Predicting Bleeding Complications in Patients Undergoing Stent Implantation and Subsequent Dual Antiplatelet Therapy (PRECISE-DAPT) score is unknown, as is the relationship of both risk scores with ischemic events.

Methods and Results: This study enrolled 842 patients who underwent percutaneous coronary intervention (PCI) between January 2016 and December 2020. The 2 bleeding risk scores at the time of PCI and the subsequent risk of bleeding and ischemic events over a 1-year follow-up were examined. The J-HBR score was significantly correlated with the PRECISE-DAPT score (r=0.731, P<0.001). However, 1 year after PCI, the J-HBR was not significantly associated with the incidence of major bleeding and ischemic events (log-rank, P=0.058 and P=0.351, respectively), whereas the PRECISE-DAPT score predicted both the incidence of major bleeding and ischemic events (log-rank, P=0.006 and P=0.019, respectively). According to receiver operating characteristic curve analysis, a J-HBR score ≥1.5 was significantly associated with a higher cumulative incidence of major bleeding, but not ischemic events (log-rank, P=0.004 and P=0.513, respectively).

Conclusions: The J-HBR score is highly correlated with the PRECISE-DAPT score. A J-HBR score ≥1.5 can identify high bleeding risk patients without an increased risk of ischemic events.

Key Words: Coronary artery disease; High bleeding risk; Percutaneous coronary intervention

The Predicting Bleeding Complications in Patients Undergoing Stent Implantation and Subsequent Dual Antiplatelet Therapy (PRECISE-DAPT) score[1] has been often used to assess high bleeding risk (HBR), and was cited by the Japanese Circulation Society (JCS) 2018 guidelines on the revascularization of stable coronary artery disease (CAD).[2] However, there are many scoring systems for bleeding risk in addition to the PRECISE-DAPT score. Recently, the Academic Research Consortium for HBR (ARC-HBR) criteria were developed to standardize the definition of HBR.[3] In addition to the ARC-HBR criteria, low body weight, frailty, chronic kidney disease requiring dialysis, heart failure, and peripheral vascular disease have been independently associated with bleeding in Japanese people.[4–6] Thus, the Japanese version of the HBR criteria (J-HBR) was developed.[7] Consequently, the evaluation of bleeding risk in the 2020 JCS guideline update on antithrombotic therapy in patients with CAD was based on the J-HBR score.[7]

However, the correlation between the J-HBR and conventional PRECISE-DAPT scores remains unknown. In addition, bleeding risk generally overlaps with ischemic risk,[5] and it is not known how either risk score relates to ischemic events. Thus, the aim of the present study was to examine the accuracy of the J-HBR and PRECISE-DAPT scores to predict major bleeding and ischemic events.

Received June 6, 2022; accepted June 7, 2022; J-STAGE Advance Publication released online June 30, 2022 Time for primary review: 1 day
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ISSN-2434-0790

Table 1. Baseline Characteristics of the Study Population

	Overall (n=842)	J-HBR			PRECISE-DAPT score		
		High (n=569)	Low (n=273)	P value	High (n=431)	Low (n=411)	P value
Age (years)	70±12	74±10	62±11	<0.01	77±8	63±10	<0.01
Male sex	633 (75)	393 (69)	240 (88)	<0.01	292 (68)	341 (83)	<0.01
Body height (cm)	162±10	160±10	167±8	<0.01	159±9	166±9	<0.01
Body weight (kg)	61±13	57±13	69±12	<0.01	55±12	68±13	<0.01
BMI (kg/m²)	23±4	23±4	25±3	<0.01	22±4	24±4	<0.01
Diagnosis							
ACS	421 (50)	259 (46)	162 (59)		201 (47)	220 (54)	
STEMI	268 (32)	156 (27)	112 (41)		120 (28)	148 (36)	
NSTEMI	53 (6)	44 (8)	9 (3)	<0.01	39 (9)	14 (3)	0.046
UAP	100 (12)	59 (10)	41 (15)		42 (10)	58 (14)	
Stable CAD	421 (50)	310 (54)	111 (41)		230 (53)	191 (46)	
No. vessels	1.7±0.8	1.7±0.8	1.5±0.7	<0.01	1.8±0.8	1.6±0.8	<0.01
CTO	100 (12)	65 (11)	35 (13)	0.56	44 (10)	56 (14)	0.13
Approach							
Transradial	202 (24)	138 (24)	64 (23)		93 (22)	109 (27)	
Transfemoral	637 (76)	428 (75)	209 (77)	0.77	335 (78)	302 (73)	0.10
Transbrachial	3 (0.4)	3 (0.5)	0 (0)		3 (0.6)	0 (0)	
Coronary risk factor							
Obesity	250 (30)	132 (23)	118 (43)	<0.01	86 (20)	164 (40)	<0.01
Smoker	542 (64)	345 (61)	197 (72)	<0.01	256 (59)	286 (70)	<0.01
Hypertension	601 (71)	433 (76)	168 (61)	<0.01	331 (77)	270 (66)	<0.01
Diabetes	368 (44)	264 (46)	104 (38)	0.02	210 (49)	158 (38)	<0.01
Dyslipidemia	510 (61)	327 (57)	183 (67)	<0.01	237 (55)	273 (66)	<0.01
Familial hypercholesterolemia	14 (2)	10 (2)	4 (1)	0.76	7 (2)	7 (2)	0.94
Family history of CAD	104 (12)	65 (11)	39 (14)	0.24	49 (11)	55 (13)	0.37
Previous coronary intervention	131 (16)	94 (17)	37 (14)	0.27	74 (17)	57 (14)	0.19
Hemodialysis	56 (7)	56 (10)	0 (0)	<0.01	54 (13)	2 (0.5)	<0.01
Laboratory data							
WBC (/mL)	7,900±3,800	7,700±3,700	8,300±3,900	0.04	8,000±3,900	7,900±3,600	0.71
Hb (g/dL)	13±2	12±2	15±1	<0.01	12±2	14±2	<0.01
Platelet count (×10⁴/mL)	22±8	22±9	23±6	0.052	22±9	23±8	0.053
TG (mg/dL)	125±98	115±80	145±123	<0.01	105±55	145±124	<0.01
HDL-C (mg/dL)	45±13	45±14	45±12	0.61	44±14	46±13	0.14
LDL-C (mg/dL)	99±36	95±35	108±38	<0.01	92±34	107±37	<0.01
HbA1c (%)	6.4±1.2	6.5±1.2	6.4±1.2	0.72	6.4±1.1	6.5±1.2	0.89
Cr (mg/dL)	1.5±1.9	1.7±2.2	0.8±0.2	<0.01	2.0±2.4	0.8±0.5	<0.01
eGFR (mL/min/1.73 m²)	60±27	53±26	75±21	<0.01	45±23	76±21	<0.01
BNP (pg/mL)	233±508	322±596	48±91	<0.01	377±659	84±185	<0.01
Medication at hospital discharge							
Aspirin	774 (92)	509 (89)	265 (97)	<0.01	381 (88)	393 (96)	<0.01
Clopidogrel	557 (66)	416 (73)	141 (52)	<0.01	306 (71)	251 (61)	<0.01
Prasugrel	181 (21)	74 (13)	107 (39)	<0.01	66 (15)	115 (28)	<0.01
Oral anticoagulant	164 (19)	164 (29)	0 (0)	<0.01	99 (23)	65 (16)	<0.01
Statin	710 (84)	455 (80)	255 (93)	<0.01	331 (77)	379 (92)	<0.01
Ezetimibe	183 (22)	99 (17)	84 (31)	<0.01	59 (14)	124 (30)	<0.01
PCSK9 inhibitor	7 (0.8)	4 (0.7)	3 (1.1)	0.55	2 (0.5)	5 (1.2)	0.23
PPI or H_2 receptor blockers	801 (95)	531 (93)	270 (99)	<0.01	394 (91)	407 (99)	<0.01

Continuous variables are expressed as the mean±SD and were compared using Student's t-test. Categorical variables are expressed as n (%) and were compared using the Chi-squared test. ACS, acute coronary syndrome; BMI, body mass index; BNP, B-type natriuretic peptide; CAD, coronary artery disease; Cr, creatinine; CTO, chronic total occlusion; eGFR, estimated glomerular filtration rate; Hb, hemoglobin; HBR, high bleeding risk; HDL-C, high-density lipoprotein cholesterol; J-HBR, Japanese version of high bleeding risk criteria; LDL-C, low-density lipoprotein cholesterol; NSTEMI, non-ST-elevation myocardial infarction; PCSK9, proprotein convertase subtilisin/kexin type 9 serine protease; PPI, proton pump inhibitor; STEMI, ST-elevation myocardial infarction; TG, triglycerides; UAP, unstable angina pectoris; WBC, white blood cell count.

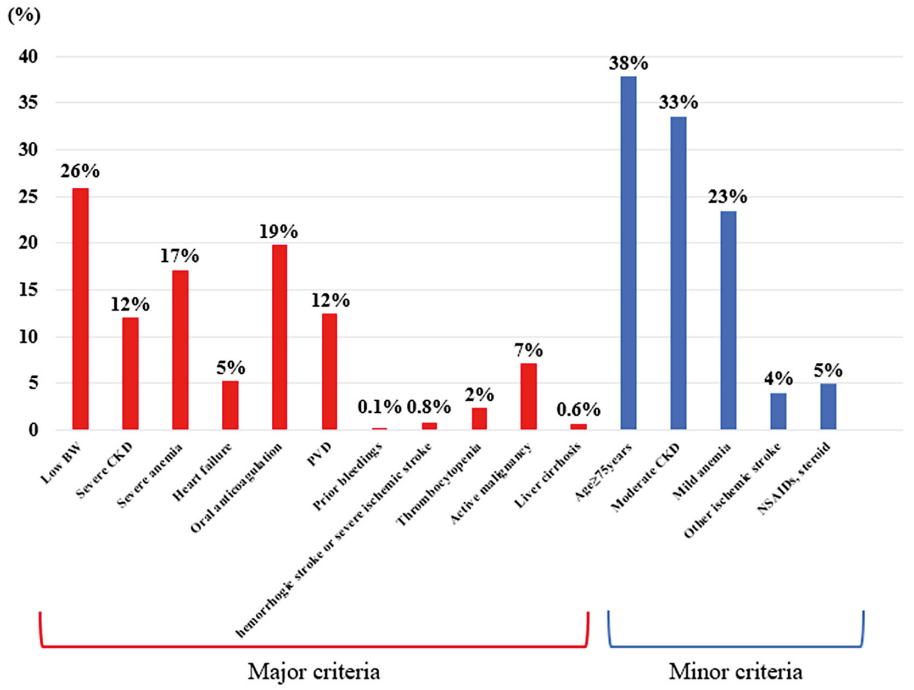

Figure 1. Prevalence of each criterion included in the Japanese version of high bleeding risk (J-HBR). BW, body weight; CKD, chronic kidney disease; NSAIDs, non-steroidal anti-inflammatory drugs; PVD, peripheral vascular disease.

Methods

This retrospective single-center study enrolled 842 consecutive patients who underwent percutaneous coronary intervention (PCI) in Niigata University Medical and Dental Hospital between January 2016 and December 2020. The 2 bleeding risk scores (J-HBR and PRECISE-DAPT) at the time of PCI were examined. Subsequent major bleeding (Bleeding Academic Research Consortium [BARC] Type 3 or 5)[8] or ischemic events (myocardial infarction and ischemic stroke) within 1 year after PCI were evaluated based on a review of medical records. Peri-PCI bleeding events from the access site were excluded. The ARC definition of myocardial infarction was used,[9] and ischemic stroke was defined as neurological symptoms lasting >24 h.

The J-HBR score consists of 14 major and 6 minor criteria.[7] This study did not capture data for several major criteria (i.e., frailty, chronic bleeding diathesis, and non-deferrable major surgery on dual antiplatelet therapy [DAPT]). Originally, patients who meet 1 major or 2 minor criteria were considered to be at high risk for bleeding. Therefore, we assigned 1 point for each major criterion and 0.5 points for each minor criterion and calculated a total score (J-HBR score), with J-HBR scores ≥1 defined as indicating a high risk for bleeding, or HBR(J). PRECISE-DAPT scores were calculated using an online calculator (http://www.precisedaptscore.com/predapt/webcalculator.html), with scores ≥25 defined as indicating a high risk for bleeding, or HBR(PD). The antithrombotic therapy after PCI depended on the JCS guidelines at the time.

This study was approved by the Ethics Committee of Niigata University, and all patients had the opportunity to opt out of the study.

Statistical Analysis

Continuous valuables are expressed as the mean±SD and were compared using Student's t-test. Categorical variables were compared using the Chi-squared test. The correlation between the J-HBR and PRECISE-DAPT scores was evaluated using Pearson correlation coefficients. Cumulative incidence was estimated using Kaplan-Meier estimates, and differences were assessed using the log-rank test. The risk of major bleeding and ischemic events was evaluated by crude and age-adjusted hazard ratios (HRs) and their 95% confidence intervals (CIs) using the Cox proportional hazards models. Two-sided $P<0.05$ was considered significant.

We calculated the area under the curve (AUC) for the receiver operating characteristic (ROC) curve to predict bleeding and ischemic status at the end of the 1-year follow-up. The optimal cut-off value of the J-HBR score for predicting major bleeding was determined as the point at which Youden's Index (sensitivity + specificity − 1) was maximal. Analyses were performed using SPSS version 27 (SPSS Inc., Chicago, IL, USA).

Results

Patient Characteristics at Baseline

The baseline characteristics of the patients are presented in **Table 1**. In the overall population, mean age was 70±12 years, and 75% of patients were male. In all, 421 (50%) patients underwent PCI for acute coronary syndrome (ST-elevation myocardial infarction [STEMI], non-STEMI, and unstable angina). The medications at hospital discharge were aspirin (92%), clopidogrel (66%), prasugrel (21%), and oral anticoagulants (19%). Based on the J-HBR score, 569 (68%) were classified as HBR(J), with a mean

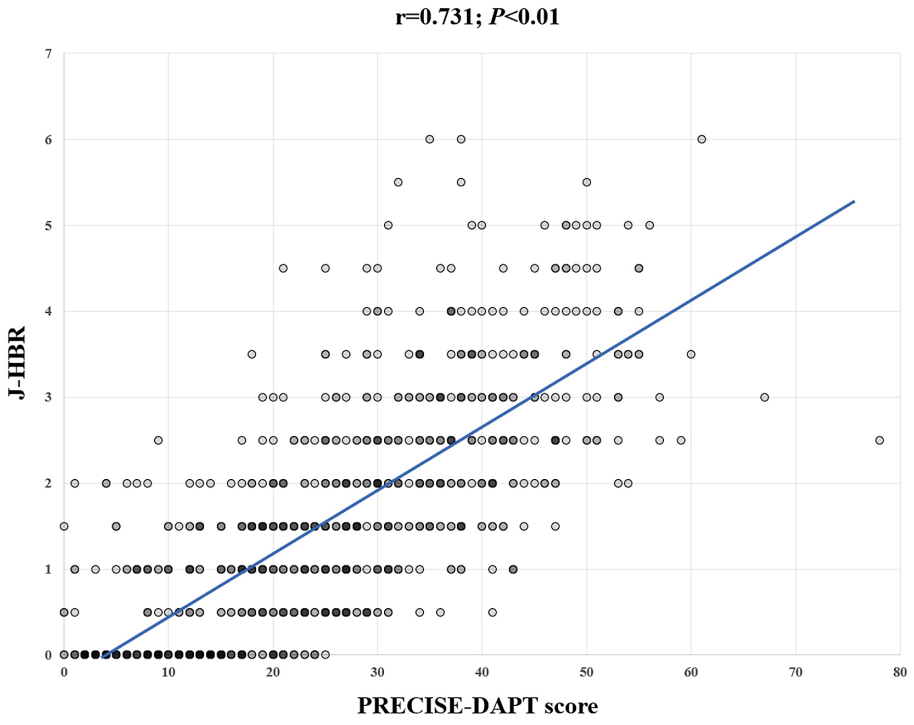

Figure 2. Correlation analysis between the Japanese version of high bleeding risk (J-HBR) criteria and the PRECISE-DAPT score.

J-HBR of 1.6±1.3. Compared with patients who were not classified as HBR(J), those classified as HBR(J) were significantly older (P<0.01), weighed less (P<0.01), were less likely to have acute coronary syndrome (P<0.01), were more likely to have a history of hypertension (P<0.01) and diabetes (P=0.02), as well as worse anemia (P<0.01) and renal dysfunction (P<0.01). The prevalence of all individual risk criteria of the J-HBR is shown in **Figure 1**. There was a high prevalence of older age (38%), low body weight (26%), chronic kidney disease (45%), anemia (40%), and the concomitant use of anticoagulants (19%) in this study population.

Conversely, based on the PRECISE-DAPT score, 431 (51%) patients were classified as HBR(PD), with a mean PRECISE-DAPT score of 25±14. Patient characteristics according to PRECISE-DAPT scores were comparable to those by the J-HBR score. **Figure 2** shows a positive correlation between the J-HBR and PRECISE-DAPT scores (r=0.731, P<0.01).

Clinical Outcomes

During the follow-up period, major bleeding was observed in 25 patients, including 11 cases of gastrointestinal bleeding and 7 cases of intracerebral hemorrhage. An ischemic event was observed in 17 patients, including 9 cases of myocardial infarction and 8 cases of ischemic stroke. In 1 patient, myocardial infarction after PCI was due to stent thrombosis. The cumulative incidence of major bleeding or ischemic events by the end of the 1-year follow-up after PCI according to HBR status is shown in **Figure 3**. Subjects classified as HBR(PD) had a significantly higher cumulative incidence of major bleeding and ischemic events than those not classified as HBR(PD) (log-rank, P=0.006 and P=0.019, respectively). However, there were no significant differences in the cumulative incidence of major bleeding and ischemic events according to HBR(J) status (log-rank, P=0.058 and P=0.351, respectively).

ROC Curve Analysis and Modified J-HBR Score

ROC curves for major bleeding and ischemic events based on J-HBR and PRECISE-DAPT scores are shown in **Figure 4**.

The AUCs for both the J-HBR (AUC 0.695; 95% CI 0.59–0.80) and PRECISE-DAPT (AUC 0.723; 95% CI 0.62–0.83) scores for major bleeding were significantly greater than 0.5. There was no significant difference between these AUCs (P=0.459). Conversely, the AUC of the J-HBR score for ischemic events was close to 0.5 (AUC 0.578; 95% CI 0.45–0.71) and lower than the AUC of the PRECISE-DAPT score (AUC 0.672; 95% CI 0.54–0.80), albeit not significantly (P=0.071). According to Youden's Index, the optimal cut-off value of the J-HBR score to predict major bleeding was 1.5. A J-HBR score of ≥1.5 was then used as "modified HBR(J) criteria" for high bleeding risk; 451 (54%) patients met the modified HBR(J) criteria.

Figure 5 shows the cumulative incidence of major bleeding or ischemic events based on modified HBR(J) status. The cumulative incidence of major bleeding was significantly higher in patients meeting the modified HBR(J) than in those who did not (log-rank, P=0.004). Conversely, there was still no significant difference in the incidence of ischemic events according to modified HBR(J) status (log-rank, P=0.513).

HRs for major bleeding and ischemic events according to HBR status based on J-HBR and PRECISE-DAPT scores are presented in **Table 2**. Using the original J-HBR score cut-off value (i.e., ≥1.0), HBR(J) was not significantly

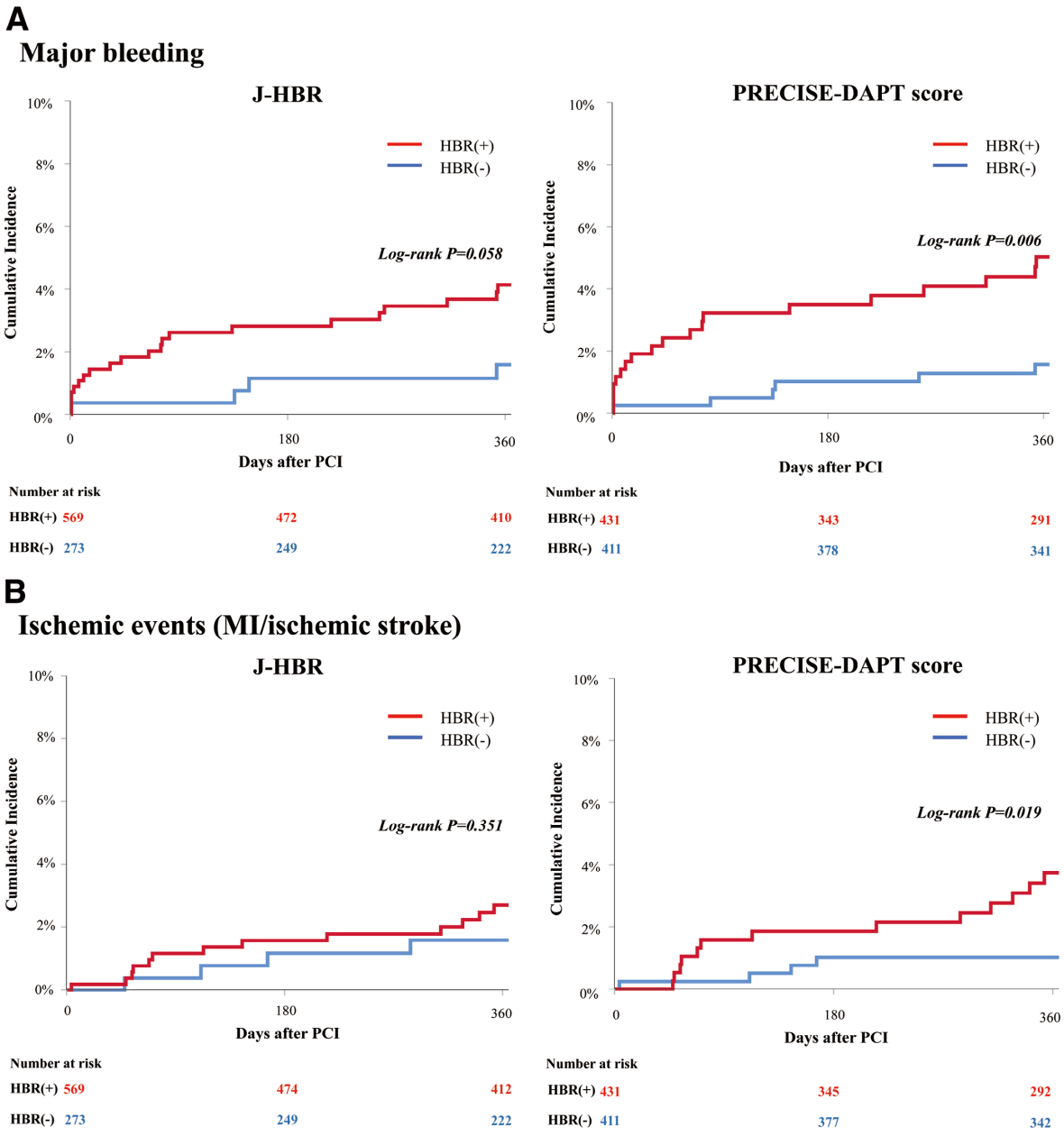

Figure 3. Kaplan-Meier curves of (**A**) major bleeding and (**B**) ischemic events (myocardial infarction [MI] and ischemic stroke) according to high bleeding risk (HBR) status based on the Japanese version of high bleeding risk (J-HBR) criteria and the PRECISE-DAPT score. The presence of HBR (HBR(+)), was defined as a J-HBR score ≥1.0 and a PRECISE-DAPT score ≥25. PCI, percutaneous coronary intervention.

associated with the risk of either major bleeding (crude HR 2.69; 95% CI 0.92–7.85; P=0.069) or ischemic events (crude HR 1.69; 95% CI 0.55–5.20; P=0.357), whereas HBR(PD) was significantly associated with the risk of both major bleeding (crude HR 3.34; 95% CI 1.34–8.37; P<0.01) and ischemic events (crude HR 3.52; 95% CI 1.15–10.81; P=0.028) (**Table 3**). Using the modified cut-off value for J-HBR score (i.e., ≥1.5), the modified HBR(J) was significantly associated with the risk of major bleeding (crude HR 3.81; 95% CI 1.43–10.15; P=0.007), even after adjusting for age (age-adjusted HR 3.47; 95% CI 1.20–10.06; P=0.022); these HRs are comparable to those for the association of HBR(PD) with the risk of major bleeding (crude HR 3.52 [95% CI 1.15–10.81; P=0.028] and age-adjusted HR 3.86 [95% CI, 1.02–14.54; P=0.046]). However, the modified HDR(J) was still not significantly associated with the risk of ischemic events (crude HR 1.38; 95% CI 0.53–3.62; P=0.515).

Discussion

The main findings of this study are as follows. First, there was a good correlation between the J-HBR and PRECISE-

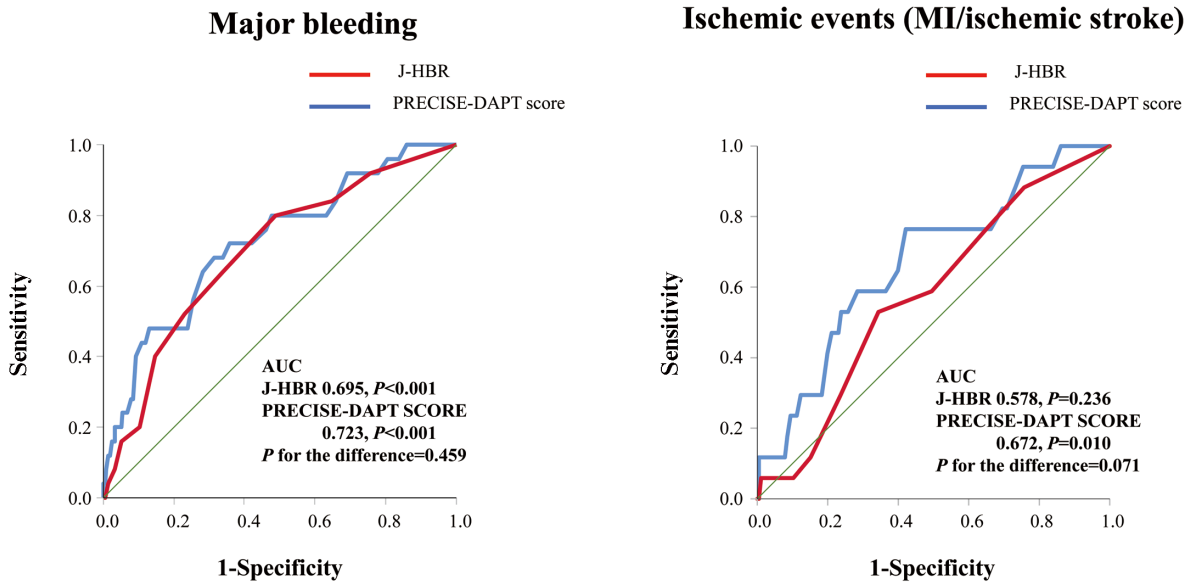

Figure 4. Receiver operating characteristic curves for the incidence of major bleeding and ischemic events (myocardial infarction [MI] and ischemic stroke) according to high bleeding risk (HBR) status based on the Japanese version of high bleeding risk criteria (J-HBR) and PRECISE-DAPT score. The optimal cut-off value on the J-HBR for predicting major bleeding events based on Youden's Index was 1.5. AUC, area under the curve.

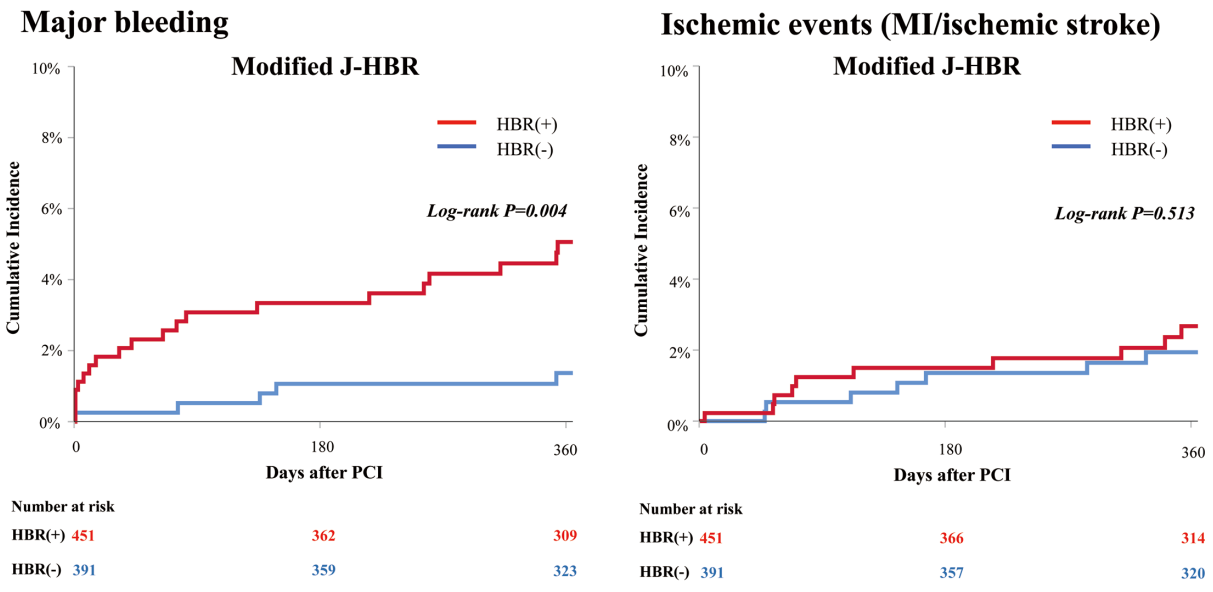

Figure 5. Kaplan-Meier curves of major bleeding and ischemic events (myocardial infarction [MI] and ischemic stroke) according the modified Japanese version of high bleeding risk criteria (J-HBR), in which a score ≥1.5 is taken to indicate high bleeding risk. PCI, percutaneous coronary intervention.

DAPT scores. At 1 year after PCI, the J-HBR score did not differ significantly according to the incidence of major bleeding and ischemic events, but the PRECISE-DAPT score was a good predictor of the incidence of both major bleeding and ischemic events. According to ROC curve analysis, the best J-HBR score cut-off value for the incidence of major bleeding may be 1.5. Using the modified J-HBR criterion (i.e., J-HBR score ≥1.5) identified patients at HBR without an increased risk of ischemic events.

Originally, the PRECISE-DAPT score was often used to assess HBR.[1] However, there have been many scoring systems for bleeding risk, in addition to the PRECISE-DAPT

Table 2. HRs for Bleeding and Ischemic Events According to the J-HBR and PRECISE-DAPT Score

	HR (95% CI)	P value	HR (95% CI)	P value
Original cut-off	J-HBR score ≥1.0		PRECISE-DAPT Score ≥25	
Major bleeding events				
Crude	2.69 (0.92–7.85)	0.069	3.34 (1.34–8.37)	0.01
Age-adjusted	2.18 (0.68–6.93)	0.188	3.27 (1.09– 9.84)	0.035
Ischemic events (MI/ischemic stroke)				
Crude	1.69 (0.55–5.20)	0.357	3.52 (1.15–10.81)	0.028
Age-adjusted	1.34 (0.39–4.62)	0.643	3.86 (1.02–14.54)	0.046
Modified cut-off	J-HBR score ≥1.5			
Major bleeding events				
Crude	3.81 (1.43–10.15)	0.007		
Age-adjusted	3.47 (1.20–10.06)	0.022		
Ischemic events (MI/ischemic stroke)				
Crude	1.38 (0.53–3.62)	0.515		
Age-adjusted	1.06 (0.36–3.14)	0.91		

CI, confidence interval; HR, hazard ratio; J-HBR, Japanese version of high bleeding risk criteria; MI, myocardial infarction.

score, and the ARC-HBR was developed to standardize the definition of HBR.[3] In addition to the ARC-HBR criteria, low body weight, frailty, chronic kidney disease requiring dialysis, heart failure, and peripheral vascular disease have been independently associated with bleeding in Japanese people.[4–6] Thus, the J-HBR was developed.[7] As a result, the evaluation of bleeding risk in the 2020 JCS guideline update on antithrombotic therapy in patients with CAD was based on J-HBR.[7] Patients defined as HBR based on the PRECISE-DAPT score (i.e., a score ≥25) have a >1% risk of Thrombosis in Myocardial Infarction (TIMI) major bleeding 1 year after PCI.[1] Conversely, patients defined as HBR based on the ARC-HBR criteria have a >4% risk of BARC 3 or 5 bleeding or a >1% risk of intracranial hemorrhage at 1 year after PCI.[3] The event rate for patients defined as HBR based on the J-HBR has not been specified.

The J-HBR consists of 14 major and 5 minor criteria. There was a high prevalence of older age, low body weight, chronic kidney disease, anemia, and concomitant use of anticoagulants in the present study. Similarly, in a previous report, Miura et al found that the prevalence of older age, chronic kidney disease, anemia, and concomitant use of anticoagulants was higher than that of other criteria.[10] In contrast, the PRECISE-DAPT score is calculated taking into consideration hemoglobin, age, white blood cell count, creatinine clearance, and a history of bleeding. Creatinine clearance, in turn, is calculated taking into consideration sex, age, body weight, and serum creatinine. These factors (i.e., age, body weight, hemoglobin, and renal function) are similar to those used to calculate the J-HBR score. Therefore, we believe that both bleeding risk criteria (i.e., PRECISE-DAPT and J-HBR) assessed almost the same factors. Consequently, there was good correlation between the 2 risk scores, and the ROC curves for major bleeding were similar in the present study. Thus, the assessment of bleeding risk should focus on age, body weight, anemia, renal function, and concomitant use of anticoagulants, which are considered in the J-HBR.

Despite the demonstrated correlation between the J-HBR and PRECISE-DAPT scores, the J-HBR score was not able to predict major bleeding 1 year after PCI, whereas the PRECISE-DAPT score could. In addition, the J-HBR score was not able to predict ischemic events 1 year after PCI, but the PRECISE-DAPT score could.

Table 3. Sensitivity and Specificity of Each High Bleeding Risk Score for Predicting Major Bleeding Events at 1 Year

	Sensitivity (%)	Specificity (%)
J-HBR score ≥1.0	84	32.9
J-HBR score ≥1.5	80	47.2
PRECISE-DAPT score ≥25	76	49.6

J-HBR, Japanese version of high bleeding risk criteria.

In the CREDO-Kyoto Registry Cohort-3, Natsuaki et al reported that the cumulative incidence of major bleeding and ischemic events 1 year after PCI in J-HBR-positive patients was 14.0% and 6.9%, respectively.[11] In the present study, the cumulative incidence of major bleeding and ischemic events 1 year after PCI was 4.2% and 2.7%, respectively, which is lower than that in the CREDO-Kyoto Registry Cohort-3. Although the characteristics of the study populations were similar between the present study and the CREDO-Kyoto Registry Cohort-3, the small number of patients in the present study may have resulted in the apparent differences in bleeding and ischemic events. Furthermore, the patients in the present study were enrolled from 2016 to 2020, whereas those in the CREDO-Kyoto Registry were enrolled from 2011 to 2013. Furthermore, differences in antithrombotic therapy (e.g., direct oral anticoagulants and prasugrel), the duration of antithrombotic therapy, and advances in PCI strategies (especially stents) may have affected the event rate. Patients undergoing PCI in more recent years may not have as high event rate as those in the CREDO-Kyoto Registry.

There are many common factors between the bleeding and thrombotic risk factors, such as severe renal dysfunction, atrial fibrillation, peripheral vascular disease, anemia, old age, and heart failure.[5] Previous reports indicated that patients with HBR had a higher incidence of thrombotic events than those without HBR.[11–14] In particular, the PRECISE-DAPT score has been well correlated with other ischemic risk prediction scores, such as $CHADS_2$-VASC,[15] PARIS-thrombotic score.[16] This means that patients with

HBR according to the PRECISE-DAPT score are also at high risk of ischemia. This makes it difficult to decide whether it is better to reduce the dose of antithrombotic drugs to avoid the risk of bleeding or to continue them to prevent infarction.

The findings of this study suggest that the original J-HBR may have low screening potential to identify patients at high risk of major bleeding. In the present study, based on the J-HBR, 68% of patients were at HBR. Previous studies in the Japanese population have reported that 55–64% of patients meet the HBR criteria.[10,11] This means that more than half the patients who undergo PCI in Japan meet the HBR criteria, resulting in low screening potential. In fact, many patients in daily practice may have HBR, and it would be useful to identify those at higher risk. In the present study, the ROC curve indicated that the best J-HBR cut-off score to predict major bleeding was 1.5. According to the modified J-HBR, a J-HBR score ≥1.5 may identify patients with HBR without an increased ischemic risk. In the PRECISE-DAPT score, patients with HBR also had high ischemic risk. Therefore, unlike the PRECISE-DAPT score, the modified J-HBR may identify HBR patients without increased ischemic risk, possibly providing a rationale for an early reduction in antithrombotic therapy.

Study Limitations

This study has some limitations. First, the study had a small sample size and was a single-center study. Second, data on some J-HBR major criteria (i.e., frailty, chronic bleeding diathesis, and non-deferrable major surgery on DAPT) were not available or were potentially underestimated due to the retrospective study design. Third, unlike previous reports,[10,11] bleeding events from access sites were excluded in this study. In Niigata University Medical and Dental Hospital, we often perform PCI from the transfemoral artery approach (76%) and access site bleeding depends on not only a patient's bleeding risk, but also on lesion characteristics and the PCI strategy. Fourth, we do not have detailed data on DAPT duration because most of the patients were followed up outside Niigata University Medical and Dental Hospital. Finally, the duration of antithrombotic therapy in the present study differed from the current guidelines. Therefore, further research is needed to investigate the topic and provide generalizable results.

Conclusions

There was a good correlation between the J-HBR and PRECISE-DAPT scores, but the original J-HBR may have low specificity in identifying HBR patients. According to the ROC curve, a J-HBR score ≥1.5 can identify HBR patients without increased ischemic risk at 1 year after PCI.

Acknowledgments

None.

Sources of Funding

This study did not receive any specific funding.

Disclosures

T.I. is a member of *Circulation Reports*' Editorial Team. The remaining authors have no conflicts of interest to declare.

IRB Information

This study was approved by the Ethics Committee of Niigata University (Reference no. 2020-286).

Data Availability

Data will not be shared so as not to compromise the privacy of the research participants.

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