Performance of PRECISE-DAPT score for predicting bleeding complication during dual antiplatelet therapy

***Sun Young Choi*, Moo Hyun Kim, Young-Rak Cho, Jong Sung Park, Kwang Min Lee, Tae-Ho Park, Sung-Cheol Yun**

Department of Biomedical Laboratory Science, Daegu Health College, Daegu, South Korea, Department of Cardiology, Dong-A University Hospital, Busan, Korea, Department of Clinical Epidemiology and Biostatistics, University of Ulsan College of Medicine, Asan Medical Center, Seoul, South Korea

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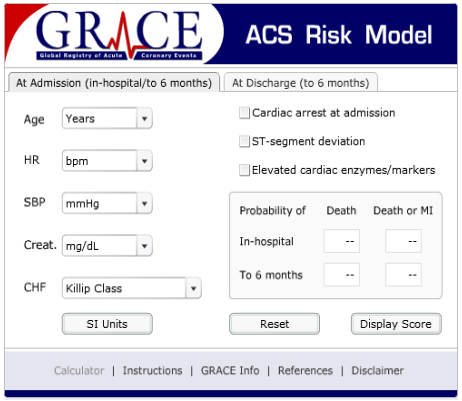
Risk Scores for Predicting Clinical Outcomes

PCI patients → **Risk assessment** → **Management**



Ischemic risk

Bleeding risk

Intensive antithrombotic Agents and invasive strategies

							Add to score
Gender	Male 0					Female +8	
Age (years)	<50 0	50-59 +3	60-69 +6	70-79 +9	≥80 +12		
Serum creatinine (mg/dl)	<1.0 0	1.0-1.2 +2	1.2-1.4 +3	1.4-1.6 +5	1.6-1.8 +6	1.8-≥2.0 +8 +10	
White blood cell count (giga/l)	<10 0	10-12 +2	12-14 +3	14-16 +5	16-18 +6	18-≥20 +8 +10	
Anemia	No 0					Yes +6	
Presentation	STEMI +6		NSTEMI - Raised biomarkers +2			NSTEMI - Normal biomarkers 0	
Antithrombotic medications	Heparin plus a GPI 0					Bivalirudin monotherapy -5	
	Total Score*						

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Baseline Risk of Major Bleeding in Non–ST-Segment–

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Emad Abu-
Pamela Lea
Marta Rodr
Santiago Ge
Belén Alvar
José Ramón

European Heart Journal Acute

ORIGINAL RESEARCH

American Heart Association | American Stroke Association

Incremental Value of the CRUSADE, ACUITY, and HAS-BLED Risk Scores for the Prediction of Hemorrhagic Events After Coronary Stent Implantation in Patients Undergoing Long or Short Duration of Dual Antiplatelet Therapy

Francesco Costa, MD; Jan G. Tijssen, PhD; Sara Ariotti, MD; Sara Giatti, MD; Elisabetta Moscarella, MD; Paolo Guastaroba, MSc; Rossana De Palma, MD; Giuseppe Andò, MD, PhD; Giuseppe Oreto, MD; Felix Zijlstra, MD, PhD; Marco Valgimigli, MD, PhD, FESC

Background—Multiple scores have been proposed to stratify bleeding risk, but their value to guide dual antiplatelet therapy duration has never been appraised. We compared the performance of the CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes With Early Implementation of the ACC/AHA Guidelines), ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy), and HAS-BLED (Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly) scores in 1946 patients recruited in the Prolonging Dual Antiplatelet Treatment After Grading Stent-Induced Intimal Hyperplasia Study (PRODIGY) and assessed hemorrhagic and ischemic events in the 24- and 6-month dual antiplatelet therapy groups.

Methods and Results—Bleeding score performance was assessed with a Cox regression model and C statistics. Discriminative and reclassification power was assessed with net reclassification improvement and integrated discrimination improvement. The C statistic was similar between the CRUSADE score (area under the curve 0.71) and ACUITY (area under the curve 0.68), and higher than HAS−BLED (area under the curve 0.63). CRUSADE, but not ACUITY, improved reclassification (net reclassification index 0.39, P=0.005) and discrimination (integrated discrimination improvement index 0.0083, P=0.021) of major bleeding compared with HAS-BLED. Major bleeding and transfusions were higher in the 24- versus 6-month dual antiplatelet therapy groups in patients with a CRUSADE score >40 (hazard ratio for bleeding 2.69, P=0.035; hazard ratio for transfusions 4.65, P=0.009) but not in those with CRUSADE score ≤40 (hazard ratio for bleeding 1.50, P=0.25; hazard ratio for transfusions 1.37, P=0.44), with positive interaction (P_{int}=0.05 and P_{int}=0.01, respectively). The number of patients with high CRUSADE scores needed to treat for harm for major bleeding and transfusion were 17 and 15, respectively, with 24-month rather than 6-month dual antiplatelet therapy; corresponding figures in the overall population were 67 and 71, respectively.

Conclusions—Our analysis suggests that the CRUSADE score predicts major bleeding similarly to ACUITY and better than HAS BLED in an all-comer population with percutaneous coronary intervention and potentially identifies patients at higher risk of hemorrhagic complications when treated with a long-term dual antiplatelet therapy regimen.

Clinical Trial Registration—URL: http://clinicaltrials.gov. Unique identifier: NCT00611286. (***J Am Heart Assoc.*** **2015;4: e002524 doi: 10.1161/JAHA.115.002524)**

Joint meeting of Coronary Revascularization

Derivation and validation of the predicting bleeding complications in patients undergoing stent implantation and subsequent dual antiplatelet therapy (PRECISE-DAPT) score: a pooled analysis of individual-patient datasets from clinical trials

Francesco Costa, David van Klaveren*, Stefan James, Dik Heg, Lorenz Räber, Fausto Feres, Thomas Pilgrim, Myeong-Ki Hong, Hyo-Soo Kim, Antonio Colombo, Philippe Gabriel Steg, Thomas Zanchin, Tullio Palmerini, Lars Wallentin, Deepak L Bhatt, Gregg W Stone, Stephan Windecker, Ewout W Steyerberg, Marco Valgimigli, for the PRECISE-DAPT Study Investigators*

Summary

Background Dual antiplatelet therapy (DAPT) with aspirin plus a $P2Y_{12}$ inhibitor prevents ischaemic events after coronary stenting, but increases bleeding. Guidelines support weighting bleeding risk before the selection of treatment duration, but no standardised tool exists for this purpose.

Methods A total of 14 963 patients treated with DAPT after coronary stenting—largely consisting of aspirin and clopidogrel and without indication to oral anticoagulation—were pooled at a single-patient level from eight multicentre randomised clinical trials with independent adjudication of events. Using Cox proportional hazards regression, we identified predictors of out-of-hospital Thrombosis in Myocardial Infarction (TIMI) major or minor bleeding stratified a long (12–24 months) or short (3–6 months) treatment in relation to baseline bleeding risk.

The PRECISE-DAPT as simple five-item score is a standardized tool for predicting out-of-hospital bleeding during DAPT.

Findings The PRECISE-DAPT score (age, creatinine clearance, haemoglobin, white-blood-cell count, and previous spontaneous bleeding) showed a c-index for out-of-hospital TIMI major or minor bleeding of 0·73 (95% CI 0·61–0·85) in the derivation cohort, and 0·70 (0·65–0·74) in the PLATO trial validation cohort and 0·66 (0·61–0·71) in the BernPCI registry validation cohort. A longer DAPT duration significantly increased bleeding in patients at high risk (score ≥25), but not in those with lower risk profiles ($p_{interaction}$=0·007), and exerted a significant ischaemic benefit only in this latter group.

Interpretation The PRECISE-DAPT score is a simple five-item risk score, which provides a standardised tool for the prediction of out-of-hospital bleeding during DAPT. In the context of a comprehensive clinical evaluation process, this tool can support clinical decision making for treatment duration.

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Costa F et al. Lancet (2017)

Table 1. Multivariable analysis for out-of-hospital TIMI major or minor bleeding

Characteristics	Hazard Ratio (95% CI)	p value
Age	1.34 (1.11-1.48)	0.005
Previous bleeding	4.14 (1.22-14.0)	0.023
White-blood-cell count	1.06 (0.99-1.13)	0.078
Hemoblobin at baseline	0.67 (0.53-0.84)	0.001
Creatinine clearance	0.90 (0.82-0.99)	0.004

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Costa F et al. Lancet (2017)

PRECISEDAPT

Home | WebCalculator | Disclaimer | About | Contact Us

Haemoglobin unit
- (•) g/dl
- ( ) mmol/L

Age (years)

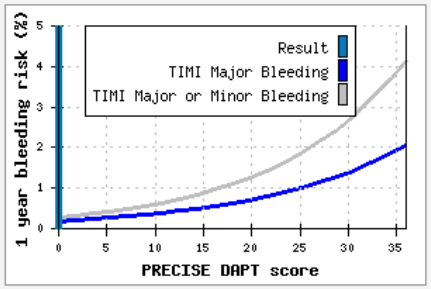
White blood cells unit
- (•) u/mcL
- ( ) 10^9/L

Creatinine Clearance (ml/min)

Prior Bleeding ☐

CALCULATE

RESET



RESULT:

Cluster of risk:

Score Calculated

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12 months risk of TIMI major or minor Bleeding

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12 months risk of TIMI Major Bleeding

Copy to clipboard

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European Journal of Cardio-Thoracic Surgery 53 (2018) 34–78
doi:10.1093/ejcts/ezx334 Advance Access publication 26 August 2017

2017 ESC focused update on dual antiplatelet therapy in coronary artery disease developed in collaboration with EACTS

The Task Force for dual antiplatelet therapy in coronary artery disease of the European Society of Cardiology (ESC) and of the European Association for Cardio-Thoracic Surgery (EACTS)

Change in recommendations

Before → 2017

- Pretreatment with $P2Y_{12}$ inhibitors when PCI is planned
- Liberal use of PPI to mitigate GI bleeding risk
- Elective surgery requiring discontinuation of the P2Y12 inhibitor after 1 month
- Ticagrelor interruption of 3 days prior elective surgery
- Dual therapy as an alternative to triple therapy when bleeding risk outweighs the ischaemic risk
- Discontinuation of antiplatelet treatment in patients treated with OAC should be considered at 12 months.
- Routine platelet function testing to adjust therapy

New recommendations 2017

- The occurrence of actionable bleeding while on DAPT should prompt reconsideration of type and duration of DAPT regimen.
- The decision for DAPT duration should be dynamic and reassessed during the course of the initially selected DAPT regimen.
- Discontinuation of $P2Y_{12}$ inhibitor therapy after 6 months when stenting ACS patients with PRECISE-DAPT ≥ 25
- 6-month DAPT regimen In patients with SCAD treated with drug-coated balloon
- Early administration of ticagrelor/ clopidogrel in NSTE-ACS with invasive approach
- Ticagrelor 60 mg b.i.d preferred over other oral P2Y12 inhibitors for DAPT continuation >12 months in post-MI

I IIA IIB III

New/revised concepts

Metallic stent and DAPT duration

Switch between $P2Y_{12}$ inhibitors

Risk scores to guide DAPT duration
- –PRECISE DAPT score
- –DAPT score

Specific profiling
- –Definition of complex PCI
- –Unfavourable profile for OAC and APT
- –Gender considerations and special populations

DAPT duration without stenting
- –Medical management
- –CABG or cardiac surgery

Anticoagulation and DAPT
- –Acute and chronic setting
- –Dosing regimen

European Journal of Cardio-Thoracic Surgery 53 (2018) 34–78
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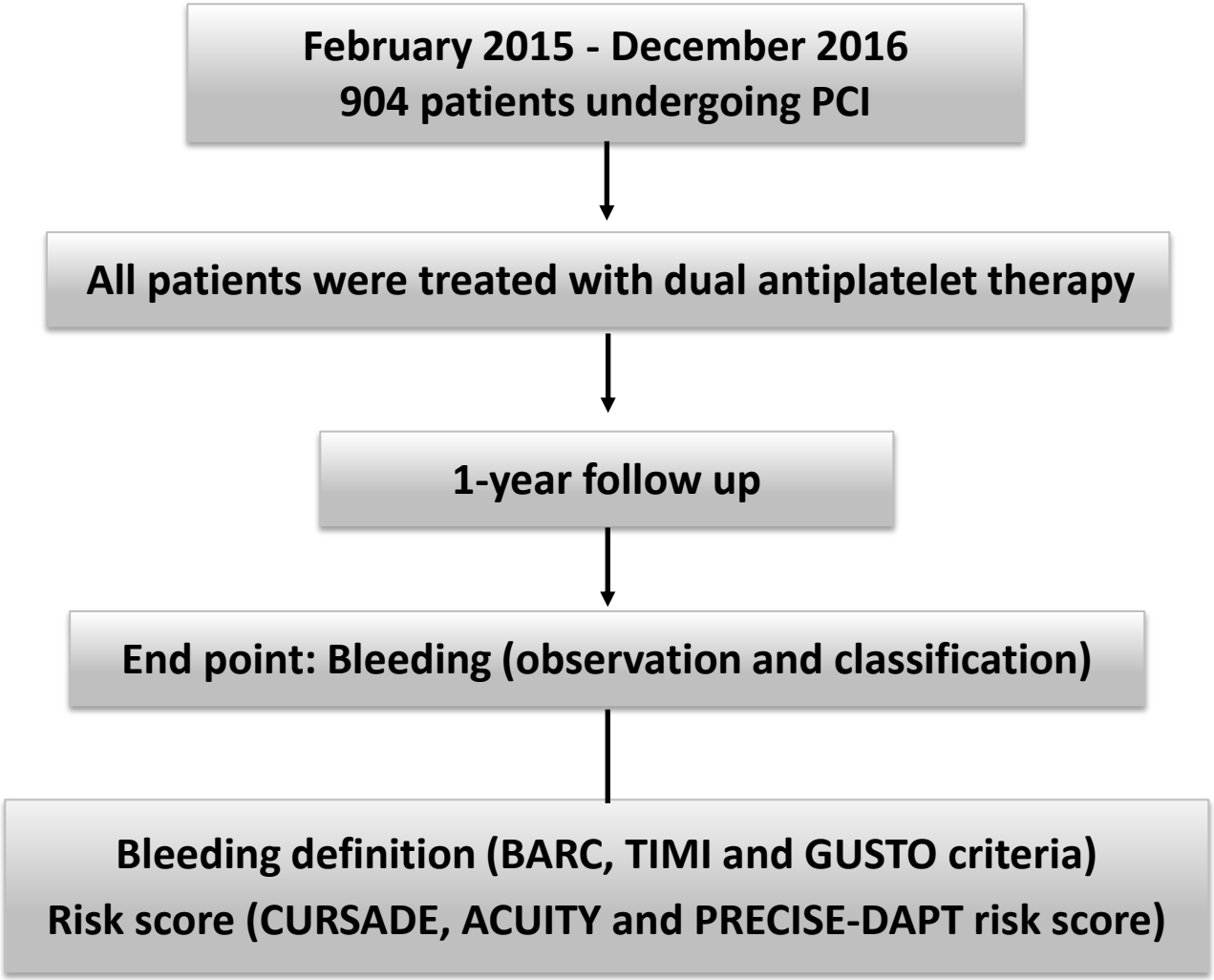
Purpose of the study

- Several risk scores have been proposed for the bleeding management of patients treated with DAPT.

- We sought to validate new PRECISE-DAPT score for bleeding risk in Korean patients treated with DAPT and compared the performance of CRUSADE, ACUITY and PRECISE-DAPT risk scores to predict bleeding complication.

Study Flow



Various Bleeding Definition

TIMI Bleeding Criteria

Major	**Any intracranial bleeding Clinically overt signs of hemorrhage that is associated with a drop in Hb of ≥5 g/dL**
Minor	**Any clinically overt sign of hemorrhage (including imaging) that is associated with a drop of Hb 3 to <5 g/dL**
Minimal	**Any clinically over sign of hemorrhage (including imaging) that is associated with a drop in Hb <3g/dL**

GUSTO Bleeding Criteria

Severe	**Intracerebral hemorrhage Resulting in substantial hemodynamic compromise requiring treatment**
Moderate	**Bleeding that requires blood transfusion but does not result in hemodynamic compromise**
Mild	**Bleeding that does not meet above definition**

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European Heart Journal (2011) 32, 1854–1864

Various Bleeding Definition

BARC Bleeding Criteria

Type 1	Bleeding that is not actionable and does not cause the patient to seek hospitalization, or treatment
Type 2	Actionable sign of bleeding - Medical intervention, Hospitalization, Requiring evaluation
Type 3	Type 3a - Transfusion or Hemoglobin level (3 ~ 5 g/dL) Type 3b - Intervention or Hemoglobin level (≥5 g/dL) Type 3c - Intracranial hemorrhage
Type 4	CABG-related bleeding – Excepted
Type 5	Fatal bleeding

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European Heart Journal (2011) 32, 1854–1864

Risk scores for predicting bleeding

	CRUSADE	ACUITY	PRECISE-DAPT
Age		O	**O**
Sex	**O**	O	
Diagnosis		O	
Diabetes mellitus	**O**		
Current smoking		O	
Antithrombotic medication		O	
CHF	**O**		
VHD	**O**		
Heart rate	**O**		
Systolic BP	**O**		
Creatinine		O	
Creatinine clearance			**O**
GFR	**O**		
Hematocrit	**O**		
Hemoglobin			**O**
White blood cell		O	**O**
Previous bleeding			**O**

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Baseline Characteristics

Variables	Overall (n=904)
Age, year	**65.5 ± 10.5**
Female, n (%)	271 (30.0)
BMI, kg/m^2	24.4 ± 3.2
Diagnosis, n (%)	
Angina	**593 (65.6)**
NSTEMI	**261 (28.9)**
STEMI	**50 (5.5)**
Prior antiplatelet therapy, n(%)	472 (52.2)
Risk factor, n (%)	
Diabetes mellitus	384 (42.5)
Hypertension	595 (65.8)
Dyslipidemia	516 (57.1)
Current smoking	240 (26.5)
Past history, n (%)	
Prior MI	219 (24.2)
Prior PCI	369 (40.8)
Prior Stroke	93 (10.3)

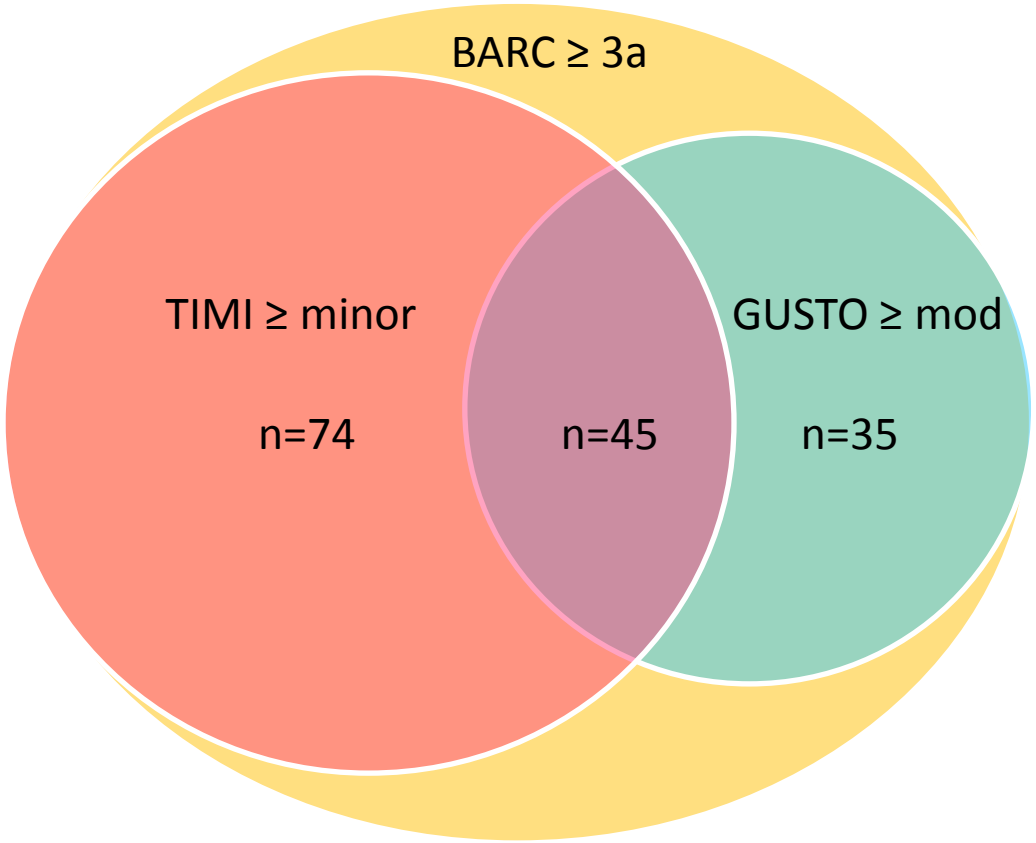
Baseline Characteristics

Variables	Overall (n=904)
Heart rate, bpm	75.1 ± 15.4
Systolic BP, mmHg	130.1 ± 22.7
LVEF, %	58.9 ± 11.0
Total cholesterol, mg/dl	163.8 ± 40.7
HbA1c, %	6.6 ± 1.3
White blood cell count (10^6/mL)	7.9 ± 3.0
Platelet count, 10^{3ul}	211.2 ± 62.1
Haemoglobin, g/dl	12.8 ± 2.0
eGFR, mL min^{-1}, 1.73 m^{-2}	76.1 ± 26.1
P2Y12 Inhibitors, n (%)	
Clopidogrel	**858 (94.9)**
Prasugrel	**39 (4.3)**
Ticagrelor	**7 (0.8)**
Bleeding risk scores	
CRUSADE	31.0 ± 14.2
ACUITY	12.3 ± 6.8
PRECISE-DAPT	22.0 ± 12.9

Characteristics of Bleeding Events

Characteristics	1-year bleeding n = 154 (17%)
Hematoma, or oozing	17
Blood transfusion	68
Gastrointestinal bleeding	12
Hemoglobin drop (Hb ≥3g/dL)	63
Brain hemorrhage	4
Tamponade	1
Ecchymosis, or Bruise	3

Incidence of 1-year bleeding events according to three bleeding definition



BARC ≥ 3a (n=154)

TIMI ≥ minor (n=119)

GUSTO ≥ moderate (n=80)

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Mean Value of Three Different Scores according to Three Bleedings Definition

Variables	BARC ≥ 3a 1-year bleeding (n=154)	TIMI ≥ minor 1-year bleeding (n=119)	GUSTO ≥ mod 1-year bleeding (n=80)
CRUSADE score	43.7 ± 14.7	41.0 ± 14.0	47.1 ± 15.4
ACUITY score	18.7 ± 6.3	17.6 ± 6.3	19.1 ± 6.5
PRECISE-DAPT score	34.4 ± 12.5	31.7± 11.8	37.1± 12.6

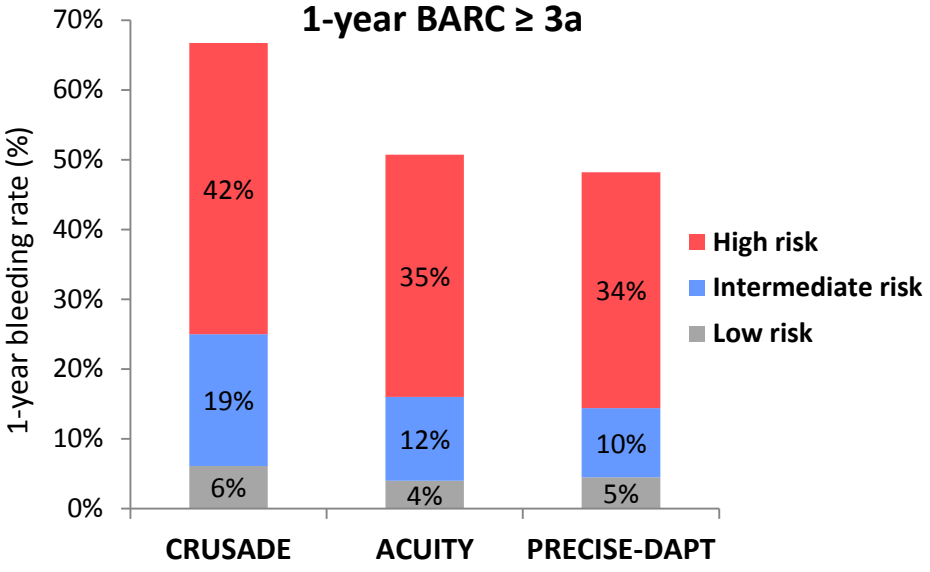
1-year bleeding events according to type of DAPT

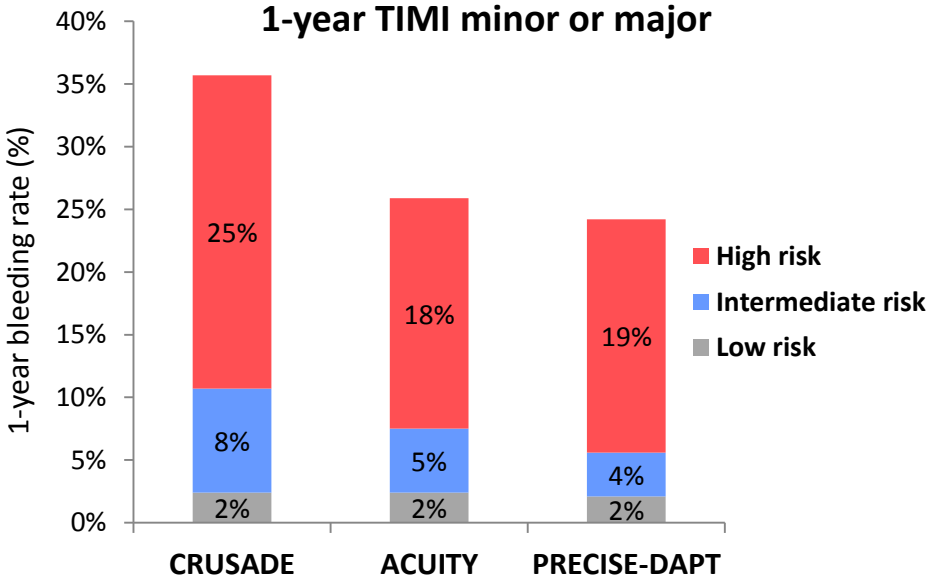
	Clopidogrel	New P2Y12 inhibitor	p value
BARC ≥ 3a	144	10	0.495
TIMI minor or major	111	8	0.477
GUSTO ≥ moderate	76	4	0.615

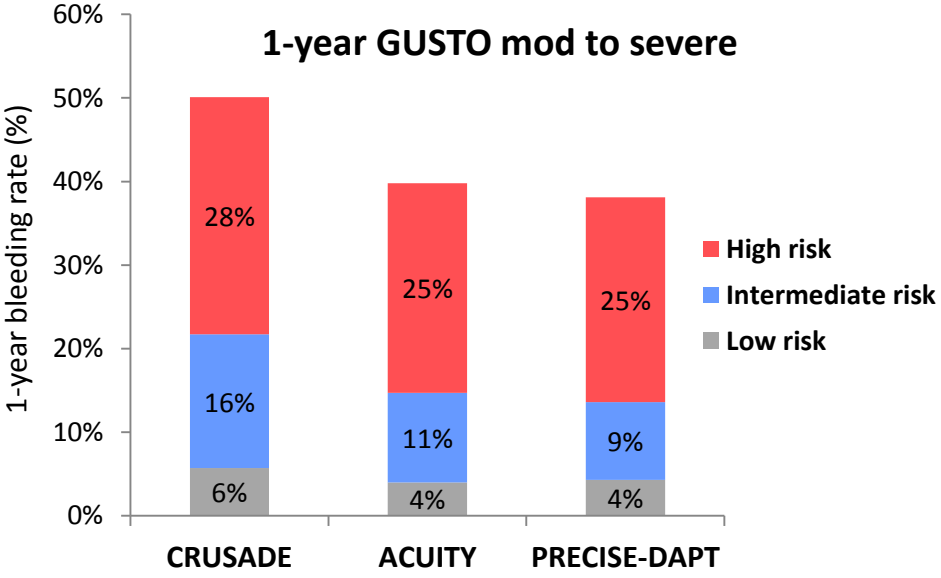
DAPT compliance rate between bleeding and non-bleeding group

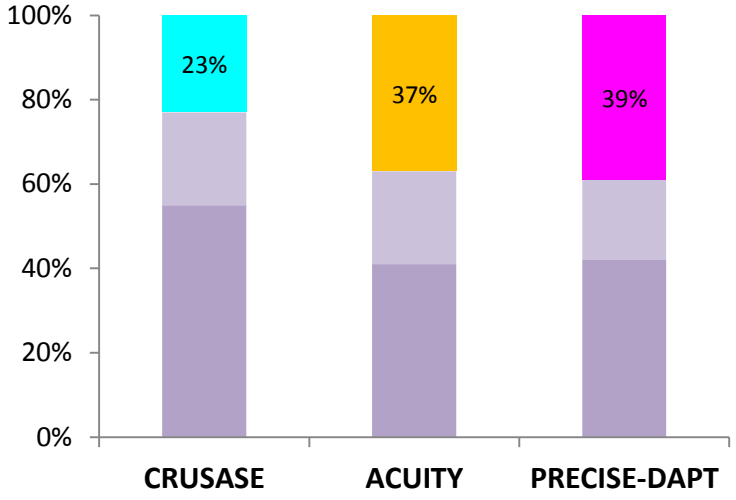
	1 month DAPT	6 month DAPT	12 month DAPT	P value
Bleeding group	55%	38%	18%	<0.001
Non-bleeding group	98%	89%	80%	

Distribution of CRUSADE, ACUITY and PRECISE-DAPT risk scores for 1-year bleeding by risk categories









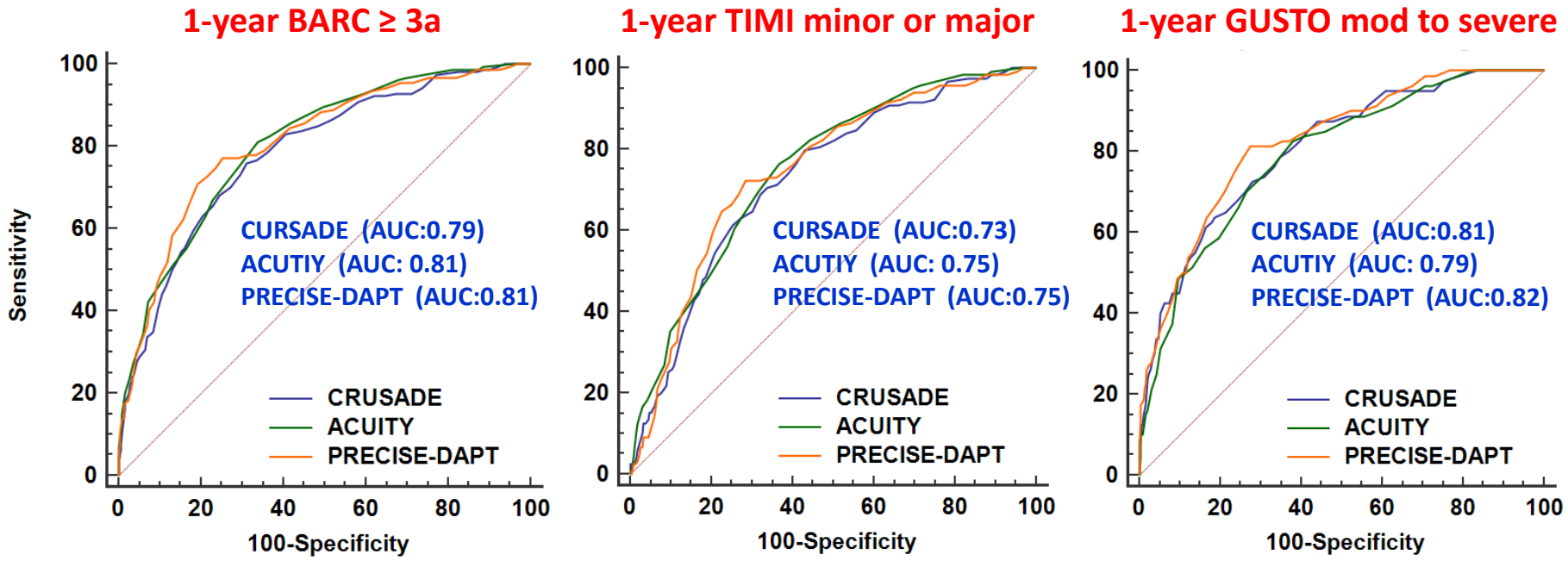
Predictive Performance of Risk Scores Categories for 1-year Bleeding according to the Different Bleeding Definition

	BARC ≥ 3a		TIMI minor or major		GUSTO moderate or severe	
	Hazard Ratio (95% CI)	p-value	Hazard Ratio (95% CI	p-value	Hazard Ratio (95% CI	p-value
CRUSADE score		<0.001		<0.001		<0.001
Low (≤30)	Reference		Reference		Reference	
Mod (31-40)	3.24 (2.19-5.41)		3.00 (1.91-4.69)		3.23 (1.88-5.56)	
High (>40)	**8.17 (5.41-12.3)**		**5.70 (3.59- 9.03)**		**10.1 (5.83-17.6)**	
ACUITY score		<0.001		<0.001		<0.001
Low (<10)	Reference		Reference		Reference	
Mod (10-14)	3.04 (2.02- 4.57)		2.81 (1.75-4.50)		1.97 (1.11-3.49)	
High (>14)	**9.71 (6.77- 13.9)**		**7.07 (4.69-10.6)**		**7.28 (4.44-11.9)**	
PRECISE-DAPT		<0.001		<0.001		<0.001
Low (≤17)	Reference		Reference		Reference	
Mod (18-24)	2.13 (1.39-3.26)		2.25 (1.38-3.68)		1.47 (0.81-2.67)	
High (>24)	**8.35 (5.86-11.9)**		**6.45 (4.32-9.64)**		**8.23 (5.06-13.4)**	

Predictive Performance of Risk Scores for 1-year Bleeding according to the Different Bleeding Definition

	CRUSADE score		ACUITY score		PRECISE-DAPT	
	AUC (95% CI)	p-value	AUC (95% CI)	p-value	AUC (95% CI)	p-value
1-year BARC bleeding						
BARC 3a	0.79 (0.76-0.81)	<0.001	0.81 (0.78-0.84)	<0.001	0.82 (0.79-0.84)	<0.001
BARC ≥ 3a	**0.79 (0.76-0.81)**	**<0.001**	**0.81 (0.78-0.83)**	**<0.001**	**0.81 (0.78-0.84)**	**<0.001**
BARC ≥ 3b	**0.69 (0.66-0.72)**	**<0.001**	**0.69 (0.66-0.72)**	**<0.001**	**0.68 (0.65-0.71)**	**0.001**
1-year TIMI bleeding						
Minor	0.73 (0.70-0.76)	<0.001	0.76 (0.73-0.78)	<0.001	0.76 (0.73-0.78)	<0.001
Minor or Major	**0.73 (0.70-0.76)**	**<0.001**	**0.75 (0.72-0.78)**	**<0.001**	**0.75 (0.72-0.78)**	**<0.001**
Major	**0.69 (0.65-0.72)**	**<0.001**	**0.68 (0.65-0.71)**	**0.001**	**0.67 (0.64-0.70)**	**0.002**
1-year GUSTO bleeding						
Mod or severe	**0.81 (0.78-0.83)**	**<0.001**	**0.79 (0.76-0.82)**	**<0.001**	**0.82 (0.80-0.85)**	**<0.001**

ROC Curves of Risk Scores for Predicting 1-year Bleeding according to the Different Bleeding Definition



Variables	1-year BARC ≥ 3a		1-year TIMI minor or major		1-year GUSTO mod to severe	
	z statistics	p value	z statistics	p value	z statistics	p value
CRUSADE vs. ACUITY	1.14	0.256	1.01	0.315	0.68	0.498
CRUSADE vs. PRECISE DAPT	1.47	0.141	0.94	0.350	0.86	0.388
ACUITY vs. PRECISE DAPT	0.38	0.708	0.16	0.876	2.13	0.034

Reclassification Analysis

Comparison	Event	Bleeding Correctly Reclassified, P (n1)	No Bleeding Correctly Reclassified, P (n2)	NRI	p	IDI	p
CRUSADE vs. ACUITY	BARC ≥ 3a	0.36(56)	0.40(300)	-0.04	0.68	0.01	0.45
	TIMI ≥ minor	0.31(37)	0.41(319)	-0.10	0.33	-0.00	0.75
	GUSTO ≥ moderate	0.55(44)	0.38(312)	0.17	0.14	0.03	0.00
CRUSADE vs. PRECISE	BARC ≥ 3a	0.38(58)	0.35(262)	0.03	0.77	0.01	0.23
	TIMI ≥ minor	0.31(37)	0.36(284)	-0.05	0.61	-0.00	0.89
	GUSTO ≥ moderate	0.50(41)	0.34(280)	0.16	0.17	0.03	0.00
ACUITY vs. PRECISE	**BARC ≥ 3a**	**0.60(93)**	**0.11(80)**	**0.70**	**0.00**	**0.00**	**0.67**
	TIMI ≥ minor	**0.50(59)**	**0.06(47)**	**0.56**	**0.00**	**0.00**	**0.82**
	GUSTO ≥ moderate	**0.70(57)**	**0.15(120)**	**0.85**	**0.00**	**0.01**	**0.13**

PRECISE-DAPT score vs. Simplified PRECISE-DAPT

- **Age**
- **Hemoglobin**
- ~~**WBC**~~
- **Creatinine clearance**
- **Prior bleeding**

PRECISE-DAPT score vs. Simplified PRECISE-DAPT

	PRECISE-DAPT		PRECISE-DAPT alternative	
	AUC (95% CI)	p-value	AUC (95% CI)	p-value
1-year TIMI bleeding				
Minor	0.76 (0.73-0.78)	<0.001	0.75 (0.72-0.78)	<0.001
Major	0.67 (0.64-0.70)	0.002	0.68 (0.65-0.71)	0.001
Minor or Major	0.75 (0.72-0.78)	<0.001	0.75 (0.72-0.77)	<0.001
1-year GUSTO bleeding				
Mod or severe	0.82 (0.80-0.85)	<0.001	0.83 (0.80-0.85)	<0.001
1-year BARC bleeding				
BARC 3a	0.82 (0.79-0.84)	<0.001	0.81 (0.79-0.84)	<0.001
BARC ≥ 3a	0.81 (0.78-0.84)	<0.001	0.81 (0.78-0.83)	<0.001
BARC ≥ 3b	0.68 (0.65-0.71)	0.001	0.69 (0.66-0.72)	0.001

Summary

- We have compared the new PRECISE-DAPT score and other bleeding scores (CRUSADE and ACUITY scores) for the prediction of out-of-hospital bleeding in Korean patients treated with DAPT, regardless of the bleeding definition.

- The CRUSADE, ACUITY, and PRECISE-DAPT scores showed good calibration and discrimination for 1-year bleeding during DAPT after coronary stenting

Conclusion

- **The PRECISE-DAPT score is a simple five-item risk score that represents a standardized tool for the prediction of bleeding in Korean patients receiving DAPT, regardless of bleeding definition.**

Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Performance of PRECISE-DAPT Score for Predicting Bleeding Complication During Dual Antiplatelet Therapy

Sun Young Choi, PhD
Moo Hyun Kim, MD
Young-Rak Cho, MD
Jong Sung Park, MD
Kwang Min Lee
Tae-Ho Park, MD
Sung-Cheol Yun, PhD

BACKGROUND: Dual antiplatelet therapy (DAPT) helps prevent ischemic events after coronary stenting but comes with an increased risk of bleeding. Several risk scores have been proposed for the management of patients receiving DAPT, but no standardized tool exists for the purpose. We sought to compare the performance of the new PRECISE-DAPT, CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes with Early Implementation of the American College of Cardiology/American Heart Association Guidelines), and ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) scores for the prediction of bleeding in Korean patients receiving DAPT.

METHODS AND RESULTS: Nine hundred and four consecutive patients who underwent stent implantation received DAPT. One-year bleedings were assessed using TIMI (Thrombolysis in Myocardial Infarction), GUSTO (Global Use of Strategies to Open Occluded Arteries), and Bleeding Academic Research Consortium. Bleeding events occurred in 154 patients (17.0%) by Bleeding Academic Research Consortium type ≥3a criteria, 119 patients (13.2%) by the TIMI minor or major criteria, and 80 patients (8.8%) by the GUSTO moderate or severe criteria. In the C statistic analysis, CRUSADE, ACUITY, and PRECISE-DAPT scores showed high area under the curve values for 1-year bleeding (area under the curve 0.73, 0.75, and 0.75 for TIMI minor or major bleeding; area under the curve 0.81, 0.79, and 0.82 for GUSTO moderate to severe; and area under the curve 0.79, 0.81, and 0.81 for Bleeding Academic Research Consortium type ≥3a, respectively). The discriminate ability of PRECISE-DAPT was similar to CRUSADE and ACUITY in bleeding complications. However, the PRECISE-DAPT score was better at reclassifying the risk of 1-year bleeding compared with ACUITY for the 3 bleeding criteria.