Supplemental Online Content

Lee M, Byun S, Lim S, et al; TALOS-AMI Investigators. Dual antiplatelet therapy de-escalation in stabilized myocardial infarction with high ischemic risk: post hoc analysis of the TALOS-AMI randomized clinical trial. *JAMA Cardiol*. Published online December 20, 2023. doi:10.1001/jamacardio.2023.4587

This supplemental material has been provided by the authors to give readers additional information about their work.

eTable 1. Definitions of Outcomes

Clinical outcome	Definition
Cardiac death	Any death due to proximate cardiac cause (e.g. myocardial infarction, low-output failure, fatal arrhythmia), unwitnessed death and death of unknown cause, all procedure-related deaths including those related to concomitant treatment.
Vascular death	Any death caused by noncoronary vascular cause (e.g. cerebrovascular, pulmonary embolism, aortic rupture or dissection)
Cardiovascular death	Composite of cardiac or vascular death
Non-cardiovascular death	Any death which is not covered by cardiac or vascular death, such as infection, malignancy, pulmonary cause, suicide, or trauma.
Myocardial infarction	The definition of myocardial infarction was based on the 3rd Universal definition of Myocardial infarction.[1]
Stroke	Acute episode of neurologic dysfunction attributed to a central nervous system vascular cause, documented by imaging or autopsy
Ischemic stroke	Stroke caused by an infarction of central nervous system, documented by imaging
Ischemia-driven revascularization	Ischemia-driven revascularization was defined as any repeated CABG or PCI for a lesion with a diameter stenosis ≥50% by quantitative coronary analysis combined with either a corresponding positive functional study, ECG changes, typical ischemic symptoms, or abnormal IVUS (≤4 mm2 for non-LM lesions, ≤6 mm^2 for LM lesions), or fractional flow reserve ≤0.80.
Definite stent thrombosis	Angiographic confirmation of stent thrombosis[2] The presence of a thrombus that originates in the stent or in the segment 5mm proximal or distal to the stent and presence of at least 1 of the following criteria within a 48-hour time window: Acute onset of ischemic symptoms at rest New ischemic ECG changes that suggest acute ischemia Typical rise and fall in cardiac biomarkers (refer to definition of spontaneous MI) Nonocclusive thrombus, intracoronary thrombus is defined as a (spheric, ovoid, or irregular) noncalcified filling defect or lucency surrounded by contrast material (on 3 sides or within a coronary stenosis) seen in multiple projections, or persistence of contrast material within the lumen, or a visible embolization of intraluminal material downstream. Occlusive thrombus, TIMI 0 or TIMI 1 intrastent or proximal to a stent up to the most adjacent proximal side branch or main branch (if originates from the side branch). Pathological confirmation of stent thrombosis Evidence of recent thrombus within the stent determined at autopsy or via examination of tissue retrieved following thrombectomy.
Probable stent thrombosis	Clinical definition of probable stent thrombosis is considered to have occurred after intracoronary stenting in the following cases: Any unexplained death within the first 30 days Irrespective of the time after the index procedure, any MI that is related to documented acute ischemia in the territory of the implanted stent without angiographic confirmation of stent thrombosis and in the absence of any other obvious cause

Bleeding	The definition of bleeding was based on the Bleeding Academic Research Consortium (BARC) definition for bleeding.[3]
Type 2	Overt bleeding requiring intervention or hospitalization or evaluation (not meeting type 3, 4, or 5)
Type 3a	Overt bleeding + hemoglobin drop of 3 to <5g/dL, or Any transfusion
Type 3b	Overt bleeding + hemoglobin drop ≥5g/dL or bleeding requiring surgical intervention or vasoactive drug, cardiac tamponade
Type 3c	Intracranial hemorrhage or intra-ocular bleeding compromising vision
Type 5a	Probable fatal bleeding; no autopsy or imaging confirmation but clinically suspicious
Type 5b	Definite fatal bleeding; overt bleeding or autopsy or imaging confirmation
Net adverse clinical event	A composite of cardiovascular (CV) death, any myocardial infarction (MI), ischemic stroke, ischemia-driven revascularization, stent thrombosis, or Bleeding Academic Research Consortium (BARC) type 2, 3, or 5 bleeding

[1] Definitions adapted from Thygesen K. et al., Circulation. 2012;126(16):2020-35.
[2] Definitions adapted from Cutlip DE. et al., Circulation. 2007;115:2344-2351
[3] Definitions adapted from Mehran R. et al., Circulation. 2011;123(23):2736-47

eTable 2. Baseline Characteristics of AMI Patients With or Without High Ischemic Risk

	AMI with high ischemic risk (n=1,371)	AMI without high ischemic risk (n=1,326)	*P* value
Age, mean (SD), y	61.7 (11.3)	58.2 (11.1)	<0.001
Age ≥75y, No. (%)	200 (14.6)	121 (9.1)	<0.001
Female, No. (%)	259 (18.9)	195 (14.7)	0.004
BMI, mean (SD), kg/m2	24.6 (3.2)	24.5 (3.1)	0.33
Cardiovascular risk factors, No. (%)			
DM	731 (53.3)	0 (0.0)	<0.001
HTN	796 (58.1)	522 (39.4)	<0.001
Dyslipidemia	605 (44.1)	514 (38.8)	0.005
Current smoker	627 (45.7)	717 (54.1)	<0.001
Chronic kidney disease	305 (22.6)	0 (0.0)	<0.001
Past medical history, No. (%)			
Previous PCI	76 (5.5)	45 (3.4)	0.007
Previous CABG	2 (0.2)	2 (0.2)	1.000
Previous CVA	67 (4.9)	36 (2.7)	0.003
Clinical presentation, No. (%)			
STEMI	684 (49.9)	771 (58.1)	<0.001
NSTEMI	687 (50.1)	555 (41.9)	
LVEF <40%	124 (9.0)	72 (5.4)	<0.001
PRECISE-DAPT Score, mean (SD)	18.8 (10.7)	14.5 (8.3)	<0.001
Procedural characteristics, No. (%)			
Radial access	679 (49.5)	673 (50.8)	0.05
Femoral access	692 (50.5)	653 (49.2)	
Glycoprotein IIb/IIIa inhibitor	338 (24.7)	306 (23.1)	0.35
Infarct related artery (Culprit)			
LM	45 (3.3)	0 (0.0)	<0.001
LAD	577 (42.1)	742 (56.0)	
LCX	246 (18.0)	220 (16.6)	
RCA	502 (36.6)	362 (27.3)	
Multivessel PCI	678 (49.5)	0 (0)	<0.001
Total stent number, mean (SD)	1.3 (0.6)	1.1 (0.3)	<0.001
Total stent length, mean (SD), mm	32.4 (15.8)	26.9 (9.9)	<0.001
Stent diameter, mean (SD), mm	3.2 (0.4)	3.2 (0.5)	<0.001
Bifurcation PCI with 2 stents	15 (1.1)	0 (0.0)	<0.001
IVUS	352 (25.8)	288 (22.1)	0.02
OCT	36 (2.7)	46 (3.6)	0.19

Abbreviations: AMI, acute myocardial infarction; BMI, body mass index; CABG, coronary artery bypass graft; CVA, cerebrovascular accident; DAPT, dual antiplatelet therapy; HTN, hypertension; IVUS, intravascular ultrasonography; LAD, left anterior descending; LCX, left circumflex; LM, left main; LVEF, left ventricular ejection fraction; NSTEMI, Non-ST-segment elevation myocardial infarction; OCT, optic coherence tomography; PCI, percutaneous coronary intervention; PRECISE-DAPT, predicting bleeding complications in patients undergoing stent implantation and subsequent dual antiplatelet therapy; RCA, right coronary artery; SD, standard deviation; STEMI, ST-segment elevation myocardial infarction

eTable 3. Outcomes by High Ischemic Risk

	AMI with high ischemic risk (n=1,371)	AMI without high ischemic risk (n=1,326)	HR (95% CI)	*P* value
Primary ischemic outcome	63 (5.0)	35 (2.8)	1.74 (1.15-2.63)	0.01
BARC type 2, 3 or 5 bleeding	53 (4.1)	56 (4.5)	0.91 (0.63-1.33)	0.64
Net adverse clinical events	112 (8.7)	86 (6.9)	1.26 (0.95-1.67)	0.11
Composite of cardiovascular death, myocardial infarction, or stroke	40 (3.1)	25 (2.0)	1.54 (0.94-2.54)	0.09
All cause death	15 (1.2)	6 (0.5)	2.41 (0.93-6.20)	0.07
Cardiovascular death	8 (0.6)	4 (0.3)	1.93 (0.58-6.40)	0.29
Myocardial infarction	23 (1.8)	9 (0.7)	2.47 (1.14-5.33)	0.02
Ischemic stroke	6 (0.5)	10 (0.8)	0.58 (0.21-1.59)	0.29
Ischemia-driven revascularization	50 (4.0)	21 (1.7)	2.30 (1.38-3.83)	0.001
Stent thrombosis	5 (0.4)	1 (0.1)	4.82 (0.56-41.25)	0.15
BARC type 2 bleeding	36 (2.8)	41 (3.3)	0.85 (0.54-1.32)	0.46
BARC type 3 or 5 bleeding	23 (1.8)	20 (1.6)	1.11 (0.61-2.02)	0.74

Abbreviations: AMI, acute myocardial infarction; BARC, bleeding academic research consortium; HR, hazard ratio; MI, myocardial infarction
Data are shown as number (% of Kaplan-Meier estimates)

eTable 4. Ischemic Outcomes Stratified by High Ischemic Risk Features

	Number of events (%)		*P* value
Diabetes mellitus	**No (N=1966)**	**Yes (N=731)**	
Primary ischemic outcome	63(3.2)	35(4.8)	0.06
Composite of cardiovascular death, myocardial infarction, or stroke	43(2.2)	22(3)	0.26
Cardiovascular death	9(0.5)	3(0.4)	1.00
Myocardial infarction	19(1)	13(1.8)	0.11
Ischemia-driven revascularization	42(2.1)	29(4)	0.01
Chronic kidney disease	**No (N=2392)**	**Yes (N=305)**	
Primary ischemic outcome	80(3.3)	18(5.9)	0.03
Composite of cardiovascular death, myocardial infarction, or stroke	50(2.1)	15(4.9)	0.01
Cardiovascular death	7(0.3)	5(1.6)	0.01
Myocardial infarction	24(1)	8(2.6)	0.02
Ischemia-driven revascularization	59(2.5)	12(3.9)	0.13
Multivessel PCI	**No (N=2019)**	**Yes (N=678)**	
Primary ischemic outcome	64(3.2)	34(5)	0.03
Composite of cardiovascular death, myocardial infarction, or stroke	45(2.2)	20(2.9)	0.31
Cardiovascular death	8(0.4)	4(0.6)	0.51
Myocardial infarction	22(1.1)	10(1.5)	0.42
Ischemia-driven revascularization	46(2.3)	25(3.7)	0.05
Number of lesions treated ≥3	**No (N=2244)**	**Yes (N=453)**	
Primary ischemic outcome	75(3.4)	23(4.8)	0.14
Composite of cardiovascular death, myocardial infarction, or stroke	49(2.2)	16(3.4)	0.14
Cardiovascular death	10(0.5)	2(0.4)	1.00
Myocardial infarction	20(0.9)	12(2.5)	0.008
Ischemia-driven revascularization	52(2.3)	19(4)	0.05
Total stent length >60 mm	**No (N=2244)**	**Yes (N=453)**	
Primary ischemic outcome	76(3.4)	22(4.9)	0.13
Composite of cardiovascular death, myocardial infarction, or stroke	50(2.2)	15(3.3)	0.18

Cardiovascular death	10(0.4)	2(0.4)	1.00
Myocardial infarction	21(0.9)	11(2.4)	0.01
Ischemia-driven revascularization	53(2.4)	18(4)	0.07
Number of stents implanted ≥3	**No (N=2380)**	**Yes (N=317)**	
Primary ischemic outcome	80(3.4)	18(5.7)	0.05
Composite of cardiovascular death, myocardial infarction, or stroke	51(2.1)	14(4.4)	0.02
Cardiovascular death	10(0.4)	2(0.6)	0.64
Myocardial infarction	22(0.9)	10(3.2)	0.003
Ischemia-driven revascularization	57(2.4)	14(4.4)	0.04
Left Main PCI	**No (N=2653)**	**Yes (N=44)**	
Primary ischemic outcome	95(3.6)	3(6.8)	0.21
Composite of cardiovascular death, myocardial infarction, or stroke	62(2.3)	3(6.8)	0.09
Cardiovascular death	12(0.5)	0(0)	1.00
Myocardial infarction	29(1.1)	3(6.8)	0.01
Ischemia-driven revascularization	68(2.6)	3(6.8)	0.11
Bifurcation PCI	**No (N=2682)**	**Yes (N=15)**	
Primary ischemic outcome	97(3.6)	1(6.7)	0.43
Composite of cardiovascular death, myocardial infarction, or stroke	64(2.4)	1(6.7)	0.31
Cardiovascular death	12(0.4)	0(0)	1.00
Myocardial infarction	31(1.2)	1(6.7)	0.16
Ischemia-driven revascularization	70(2.6)	1(6.7)	0.33

Abbreviations: PCI, percutaneous coronary intervention

eTable 5. Outcomes by High Ischemic Risk and Antiplatelet Strategy (Per-Protocol)

	AMI with high ischemic risk (n=1,219)				AMI without high ischemic risk (n=1,161)				
	De-escalation group (n=616)	**Active control group (n=603)**	**HR (95% CI)**	***P* value**	**De-escalation group (n=592)**	**Active control group (n=569)**	**HR (95% CI)**	***P* value**	***P* value for interaction**
Primary ischemic outcome	28 (4.6)	29 (4.8)	0.93 (0.55-1.56)	0.78	12 (2.0)	16 (2.8)	0.71 (0.34-1.51)	0.38	0.57
BARC type 2, 3 or 5 bleeding	17 (2.8)	30 (5.0)	0.55 (0.30-0.99)	0.05	16 (2.7)	34 (6.0)	0.44 (0.25-0.81)	0.01	0.64
Net adverse clinical events	43 (7.0)	58 (9.6)	0.71 (0.48-1.05)	0.08	26 (4.4)	47 (8.3)	0.52 (0.32-0.84)	0.01	0.33
Composite of cardiovascular death, myocardial infarction, or stroke	15 (2.4)	20 (3.3)	0.73 (0.37-1.42)	0.61	8 (1.4)	14 (2.5)	0.54 (0.23-1.29)	0.17	0.61
All-cause death	6 (1.0)	8 (1.3)	0.73 (0.25-2.09)	0.55	4 (0.7)	1 (0.2)	3.81 (0.43-34.09)	0.23	0.18
Cardiovascular death	3 (0.5)	5 (0.8)	0.58 (0.14-2.43)	0.46	2 (0.3)	1 (0.2)	1.90 (0.17-20.99)	0.60	0.40
Myocardial infarction	10 (1.6)	12 (2.0)	0.80 (0.35-1.85)	0.60	1 (0.2)	7 (1.2)	0.14 (0.02-1.10)	0.06	0.12
Ischemic stroke	1 (0.2)	3 (0.5)	0.33 (0.03-3.16)	0.34	5 (0.8)	4 (0.7)	1.20 (0.32-4.46)	0.79	0.33
Ischemia-driven revascularization	24 (3.9)	22 (3.7)	1.05 (0.59-1.87)	0.87	5 (0.8)	11 (1.9)	0.43 (0.15-1.24)	0.12	0.15
Stent thrombosis	3 (0.5)	2 (0.3)	1.44 (0.24-8.62)	0.69	0 (0.0)	1 (0.2)	-	-	0.99
BARC type 2 bleeding	12 (2.0)	22 (3.7)	0.53)0.26-1.07)	0.07	13 (2.2)	25 (4.4)	0.49 (0.25-0.96)	0.04	0.90
BARC type 3 or 5 bleeding	8 (1.3)	11 (1.8)	0.71 (0.28-1.76)	0.46	4 (0.7)	13 (2.3)	0.29 (0.10-0.90)	0.03	0.23

Abbreviations: AMI, acute myocardial infarction; BARC, bleeding academic research consortium; MI, myocardial infarction

eTable 6. Major Post-Hoc Study of Randomized Controlled Trials Investigating De-Escalation Antiplatelet Strategy in ACS/AMI Patients Who Underwent Complex PCI or Had High Ischemic Risk

	TALOS-AMI	TWIILIGHT[4]	Global Leaders[5]	STOPDAPT-2[6]	TICO[7]	HOST-REDUCE-POLYTECH-ACS[8]
Population	1371 AMI patients with high ischemic risk (Clinical risk factor + Complex PCI)	2342 CAD patients (64% ACS) with high ischemic risk (clinical risk factor + Complex PCI	4570 CAD patients (49% ACS) with Complex PCI	509 CAD patients (32% ACS) with Complex PCI	1473 ACS (68% AMI) patients with high ischemic risk (Clinical risk factor + Complex PCI)	705 ACS (42% AMI) patients with Complex PCI
Definition of Complex PCI	multivessel PCI, ≥3 lesions treated, total stent length >60 mm, ≥3 stents implanted, left main PCI, or bifurcation PCI with ≥2 stents	3 vessels treated, ≥3 lesions treated, total stent length >60 mm, bifurcation with 2 stents implanted, atherectomy device use, left main PCI, surgical bypass graft or chronic total occlusion as target lesions	multivessel PCI, ≥3 stents implanted, ≥3 lesions treated, bifurcation PCI with ≥2 stents, or total stent length >60 mm	3 vessels treated, ≥3 stents implanted, ≥3 lesions treated, bifurcation with 2 stents, >60 mm total stent lengths, and target of chronic total occlusion	≥3 stents implanted, total stent length >60 mm, complex procedures (chronic total occlusion, left main occlusion, or bifurcation plaques remedied using the 2-stent technique)	≥3 stents implanted, ≥3 lesions treated, bifurcation PCI, total stent length ≥60 mm, left main PCI, heavy calcification
Timing of de-escalation	1 month after PCI	3 months after PCI	1 month after PCI	1 month after PCI	3 months after PCI	1 month after PCI
Method of de-escalation	Unguided de-escalation with clopidogrel for 11 months	Ticagrelor monotherapy for 12 months	Ticagrelor monotherapy for 11 months	Clopidogrel monotherapy for 11 months	Ticagrelor monotherapy for 9 months	Prasugrel dose de-escalation for 11 months

Antiplatelet strategy of the control arm	DAPT with ticagrelor for 12 months	DAPT with ticagrelor for 15 months	DAPT with ticagrelor (ACS) or clopidogrel (stable CAD) for 12 months	DAPT with clopidogrel for 12 months	DAPT with ticagrelor for 12 months	DAPT with prasugrel for 12 months
Ischemic outcome	CV death, MI, ischemic stroke, ischemic-driven revascularization, stent thrombosis	CV death, MI, or ischemic stroke	All-cause death, any stroke, any MI, any revascularization	CV death, MI, definite stent thrombosis, ischemic or hemorrhagic stroke	All-cause death, MI, stent thrombosis, stroke, and target vessel revascularization	CV death, nonfatal MI, stent thrombosis, and repeat revascularization
Experimental arm	4.7%	3.6%	9.4%	1.7%	3.3%	5.3%
Control arm	5.3%	4.8%	11.9%	3.0%	4.5%	6.0%
Bleeding outcome	BARC 2,3,5	BARC 2,3,5	BARC 3,5	TIMI major and minor	TIMI major	BARC 2,3,5
Experimental arm	3.2%	4.2%	1.8%	0%	2.8%	1.8%
Control arm	4.9%	7.7%	2.0%	2.3%	3.7%	6.9%
Follow up duration	12 months	15 months	12 months	12 months	12 months	12 months

Abbreviations: ACS, acute coronary syndrome; AMI, acute myocardial infarction; BARC, bleeding academic research consortium; CAD, coronary artery disease; CV, cardiovascular, DAPT, dual antiplatelet therapy; MI, myocardial infarction; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial infarction.

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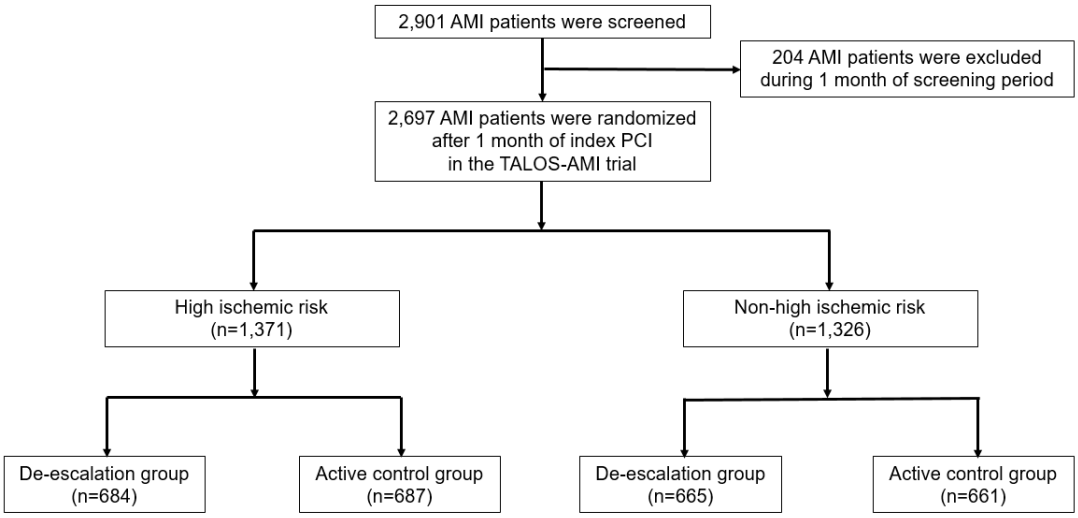
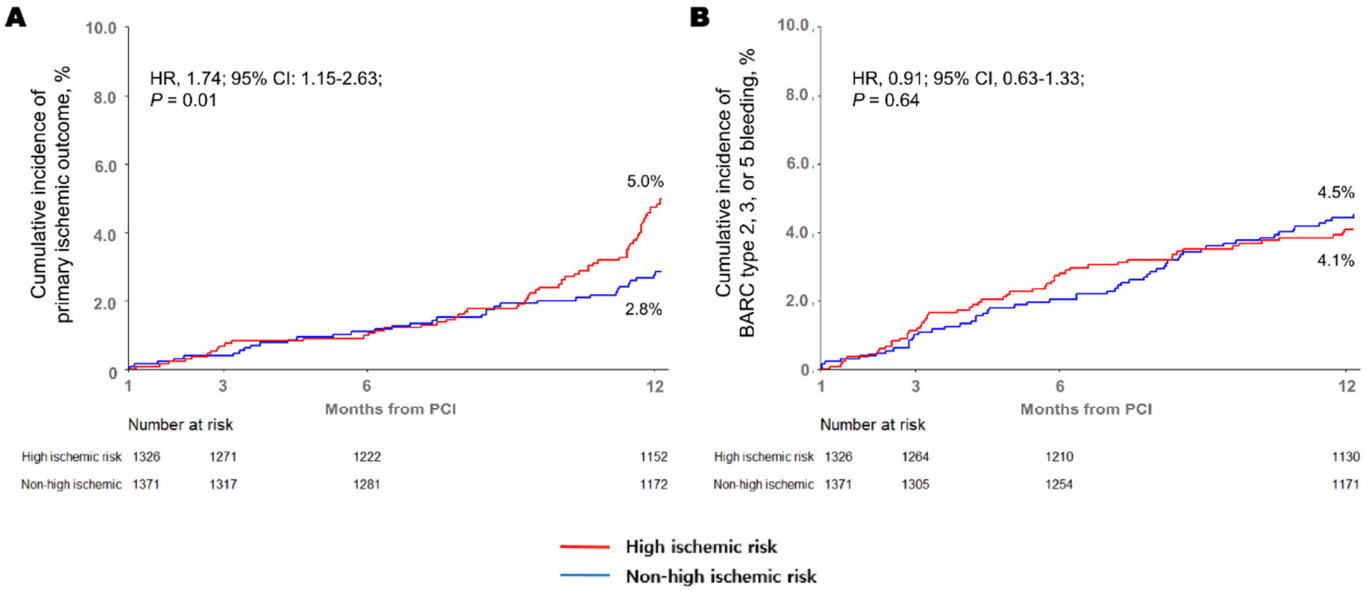
eFigure 1. Patient Flow Diagram of the Present Study



Abbreviations: AMI, acute myocardial infarction; PCI, percutaneous coronary intervention; TALOS-AMI, Ticagrelor versus Clopidogrel in Stabilized Patients with Acute Myocardial Infarction.

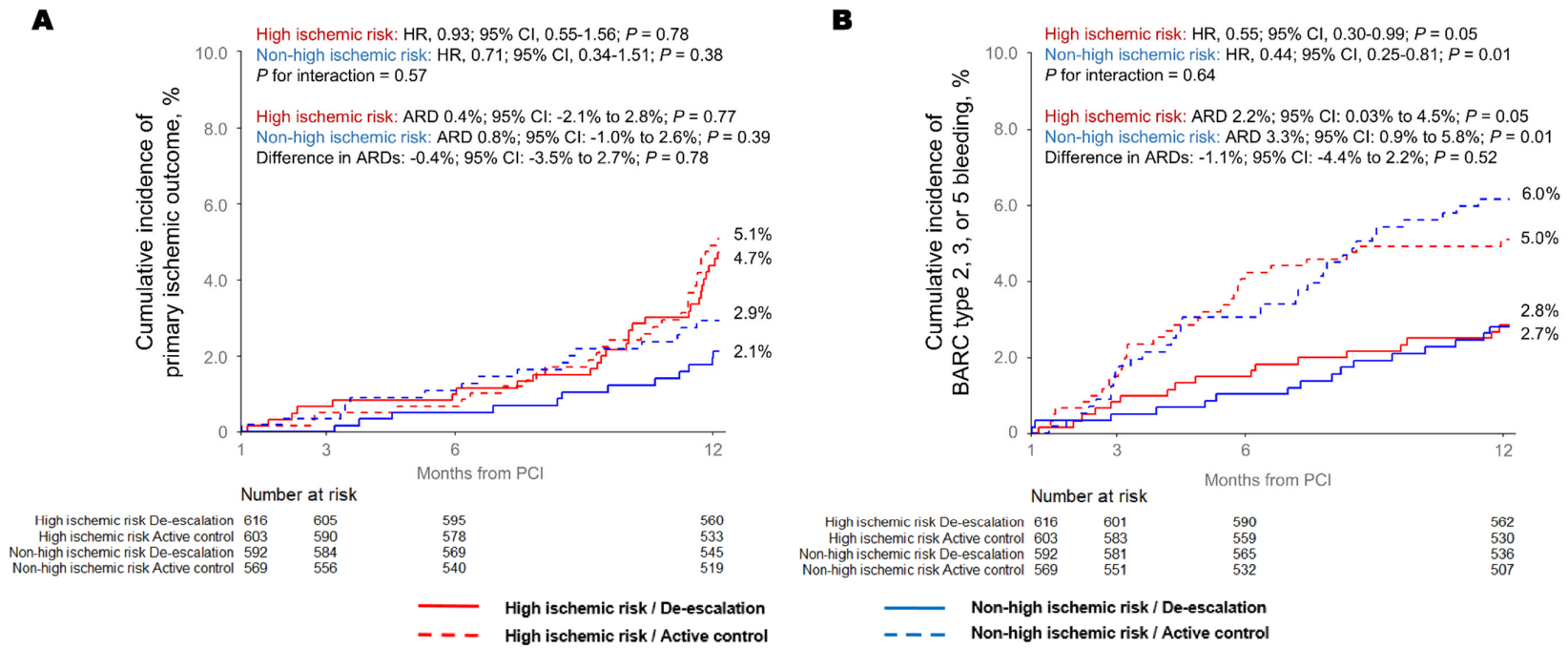
eFigure 2. Impact of High Ischemic Risk in Stabilized Post-Myocardial Infarction Patients



Patients with high ischemic risk had a significantly higher risk of primary ischemic outcomes than those without (A). The incidence of BARC type 2, 3 or 5 bleeding was comparable between the two groups (B).

Abbreviations: BARC, Bleeding Academic Research Consortium; PCI, percutaneous coronary intervention.

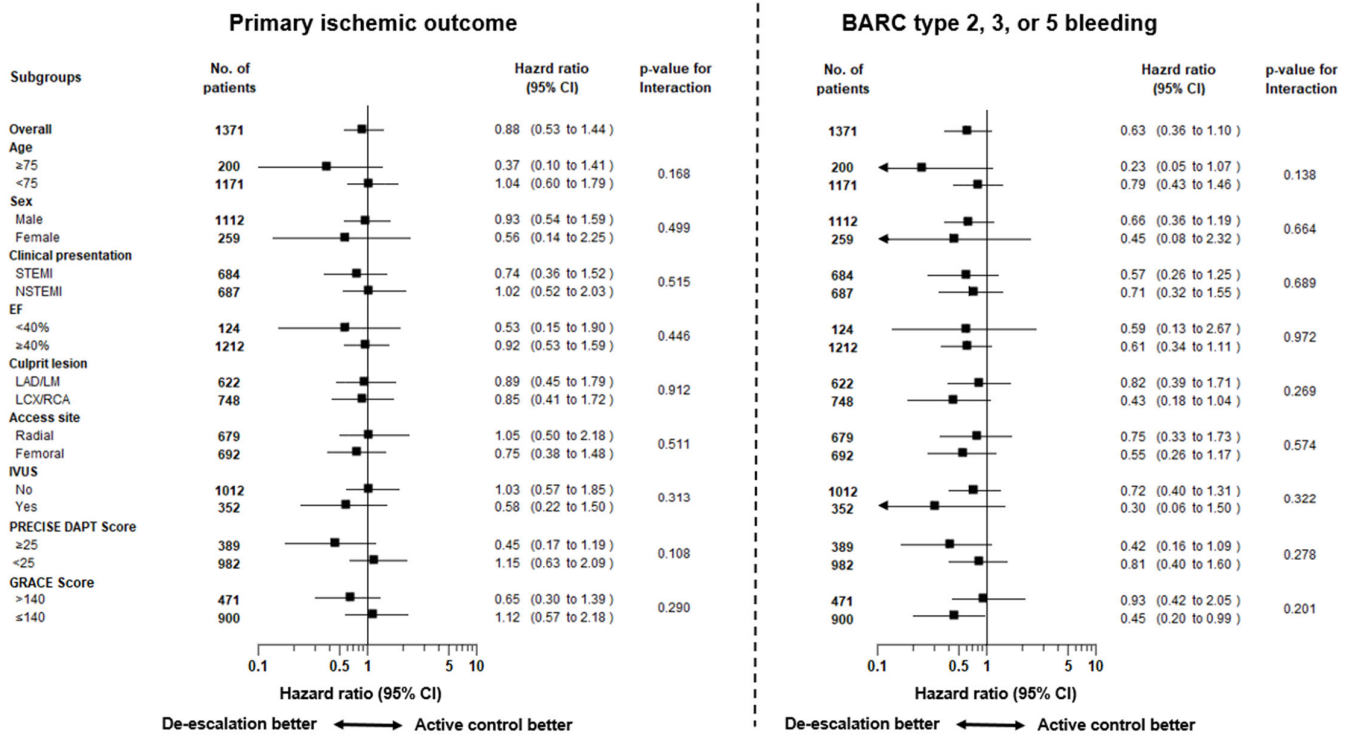
eFigure 3. Clinical Outcomes of the Antiplatelet Strategy (Per-Protocol)



In the per-protocol analysis, there was no significant difference in the primary ischemic outcomes between the de-escalation and ticagrelor-based dual-antiplatelet therapy strategies in patients with high ischemic risk (A). With regard to BARC type 2, 3 or 5 bleeding, the de-escalation strategy significantly lowered the risk in both patients with and without high ischemic risk, demonstrating consistent results (B).

Abbreviations: ARD, absolute risk difference; BARC, Bleeding Academic Research Consortium; PCI, percutaneous coronary intervention.

eFigure 4. Subgroup Analysis in Patients With High Ischemic Risk



The treatment effect of the de-escalation versus ticagrelor-based dual-antiplatelet therapy strategy on the primary ischemic outcome and BARC type 2, 3 or 5 bleeding were consistent in subgroups classified by clinical and procedural characteristics.

Abbreviations: BARC, Bleeding Academic Research Consortium; EF, ejection fraction; GRACE, Global Registry of Acute Coronary Events; IVUS, intravascular ultrasonography; LAD, left anterior descending; LCX, left circumflex; LM, left main; NSTEMI, non-ST-segment elevation myocardial infarction; PRECISE-DAPT, predicting bleeding complications in patients undergoing stent implantation and subsequent dual antiplatelet therapy; RCA, right coronary artery; STEMI, ST-segment elevation myocardial infarction.

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