Choice of access site and type of anticoagulant in acute coronary syndromes with advanced Killip class or out-of-hospital cardiac arrest

SUPPLEMENTARY DATA CONTENT

Supplementary table 1

Baseline characteristics in patients with or without hemodynamic or electrical vulnerability and according to the randomized access site

	VP			Non-VP			
	Radial access	Femoral access	*P*	Radial access	Femoral access	*P*	*P* for interaction
Number of patients	462	472		3735	3735		
Age, y	69.1 ± 11.9	69.9 ± 11.3	.26	65.2 ± 11.8	65.4 ± 11.8	.40	.44
≥ 75 y	176 (38.1)	191 (40.5)	.46	897 (24.0)	918 (24.6)	.57	.63
Men	321 (69.5)	316 (66.9)	.41	2805 (75.1)	2730 (73.1)	.048	.94
BMI, kg/m²	27.3 ± 4.8	27.0 ± 4.5	.28	27.1 ± 4.1	27.1 ± 4.1	.74	.22
Diabetes mellitus	156 (33.8)	144 (30.5)	.29	803 (21.5)	800 (21.4)	.93	.34
Insulin-dependent	44 (9.5)	50 (10.6)	.59	165 (4.4)	207 (5.5)	.025	.62
Current smoker	161 (34.8)	129 (27.3)	.013	1298 (34.8)	1299 (34.8)	.98	.019
Hypercholesterolemia	189 (40.9)	201 (42.6)	.60	1610 (43.1)	1691 (45.3)	.059	.89
Hypertension	325 (70.3)	325 (68.9)	.62	2300 (61.6)	2361 (63.2)	.15	.35
Previous myocardial infarction	89 (19.3)	101 (21.4)	.42	496 (13.3)	517 (13.8)	.48	.63
Previous PCI	77 (16.7)	89 (18.9)	.38	533 (14.3)	496 (13.3)	.21	.21
Previous CABG	20 (4.3)	24 (5.1)	.59	91 (2.4)	122 (3.3)	.031	.70
Previous TIA or stroke	25 (5.4)	42 (8.9)	.039	170 (4.6)	188 (5.0)	.33	.13
Peripheral vascular disease	64 (13.9)	70 (14.8)	.67	277 (7.4)	302 (8.1)	.28	.95
Renal failure	19 (4.1)	22 (4.7)	.68	27 (0.7)	37 (1.0)	.21	.65
Dialysis	1 (0.2)	1 (0.2)	1.00	3 (0.1)	3 (0.1)	1.00	.99
ST-segment elevation myocardial infarction	275 (59.5)	242 (51.3)	.011	1726 (46.2)	1767 (47.3)	.34	.0068
NSTE-ACS	275 (59.5)	242 (51.3)	.011	1726 (46.2)	1767 (47.3)	.34	.0068
NSTE-ACS, troponin positive	174 (37.7)	210 (44.5)	.034	1780 (47.7)	1722 (46.1)	.18	.015
Left ventricular ejection fraction, %	44.8 ± 11.3	44.0 ± 11.6	.31	52.1 ± 9.0	51.7 ± 9.1	.091	.53
Systolic blood pressure	130.6 ± 31.0	132.3 ± 30.3	.43	139.5 ± 24.6	139.7 ± 24.9	.73	.43
Heart rate	82.5 ± 21.4	82.0 ± 20.6	.72	75.5 ± 15.7	75.3 ± 16.1	.44	.86
eGFR	75.1 ± 27.6	73.5 ± 26.6	.39	85.3 ± 24.9	84.6 ± 25.1	.21	.65
eGFR<60 mL/min	151 (33.2)	154 (32.9)	.93	549 (14.8)	561 (15.1)	.68	.80

Data are expressed as No. (%) or mean ± standard deviation.

BMI, body mass index; CABG, coronary artery bypass graft; eGFR, estimated glomerular filtration rate; HF, heart failure; NSTE-ACS, non−ST-segment elevation acute coronary syndrome; OHCA, out-of-hospital cardiac arrest; PCI, percutaneous coronary intervention; TIA, transient ischemic attack; VP, hemodynamic/electrical vulnerable patients; KC, Killip class.

Supplementary table 2

Procedural characteristics in patients with or without hemodynamic or electrical vulnerability and according to the randomized access site

	VP			Non-VP			
	Radial access	Femoral access	*P*	Radial access	Femoral access	*P*	*P* for interaction
Number of patients	462	472		3735	3735		
Only radial access site	428 (92.6)	0 (0.0)	< .0001	3585 (96.0)	7 (0.2)	< .0001	-
Only femoral access site	0 (0.0)	455 (96.4)	< .0001	1 (0.0)	3641 (97.5)	< .0001	-
Both radial and femoral access site	34 (7.4)	17 (3.6)	.012	147 (3.9)	82 (2.2)	< .0001	.65
Other access site	0 (0.0)	0 (0.0)	-	2 (0.1)	5 (0.1)	.45	-
Crossover	34 (7.4)	17 (3.6)	.012	149 (4.0)	83 (2.2)	< .0001	.65
Coronary angiography completed	462 (100.0)	472 (100.0)	-	3733 (99.9)	3728 (99.8)	.18	-
Medications in the catheterization laboratory							
Aspirin	25 (5.4)	27 (5.7)	.84	197 (5.3)	232 (6.2)	.082	.70
Clopidogrel	32 (6.9)	38 (8.1)	.51	237 (6.3)	216 (5.8)	.31	.33
Prasugrel	38 (8.2)	21 (4.4)	.018	297 (8.0)	270 (7.2)	.24	.060
Ticagrelor	49 (10.6)	43 (9.1)	.44	332 (8.9)	352 (9.4)	.42	.32
Unfractionated heparin	225 (48.7)	214 (45.3)	.30	1807 (48.4)	1650 (44.2)	.00027	.81
GPI	77 (16.7)	73 (15.5)	.62	496 (13.3)	449 (12.0)	.10	.90
Planned GPI	52 (11.3)	53 (11.2)	.99	363 (9.7)	315 (8.4)	.053	.49
Bailout GPI	25 (5.4)	20 (4.2)	.40	133 (3.6)	134 (3.6)	.95	.42
Bivalirudin	196 (42.4)	177 (37.5)	.12	1507 (40.3)	1547 (41.4)	.35	.078
Post-PCI bivalirudin	92 (19.9)	89 (18.9)	.68	769 (20.6)	775 (20.7)	.86	.66
Intra-aortic balloon pump	41 (10.8)	40 (11.1)	.88	30 (1.0)	45 (1.5)	.084	.27
CABG after coronary angiography	20 (4.3)	28 (5.9)	.27	135 (3.6)	127 (3.4)	.62	.23
Completed PCI after coronary angiography	381 (82.5)	360 (76.3)	.019	2986 (79.9)	2997 (80.2)	.75	.021
At least 1 planned staged procedure	87 (18.8)	81 (17.2)	.51	680 (18.2)	660 (17.7)	.55	.67
Treated vessel(s)							
Left main coronary artery	57 (15.0)	27 (7.5)	.0014	94 (3.1)	91 (3.0)	.80	.010
Left anterior descending artery	222 (58.3)	177 (49.2)	.013	1454 (48.7)	1461 (48.7)	.97	.019
Left circumflex artery	99 (26.0)	102 (28.3)	.47	798 (26.7)	801 (26.7)	1.00	.50
Right coronary artery	90 (23.6)	127 (35.3)	.00049	1016 (34.0)	982 (32.8)	.30	.00030
Bypass graft	4 (1.0)	6 (1.7)	.54	16 (0.5)	29 (1.0)	.071	.86
≥ 2 vessels treated	85 (22.3)	68 (18.9)	.25	364 (12.2)	369 (12.3)	.89	.27
Overall stent length, mm	35.3 ± 20.9	34.0 ± 23.1	.48	31.4 ± 19.1	31.1 ± 19.1	.63	.55
Duration of procedure, min	58.1 ± 28.6	58.4 ± 28.5	.89	55.0 ± 28.5	53.4 ± 27.8	.025	.38

Data are expressed as No. (%) or mean ± standard deviation. CABG, coronary artery bypass graft; GPI, glycoprotein IIb/IIIa inhibitor; HF, heart failure; KC, Killip class; OHCA, out-of-hospital cardiac arrest; PCI, percutaneous coronary intervention; VP, hemodynamic/electrical vulnerable patients.

Supplementary table 3

Baseline characteristics in patients with or without hemodynamic or electrical vulnerability and according to the randomized antithrombin type

	VP			Non-VP			
	Bivalirudin	UFH	*P*	Bivalirudin	UFH	*P*	*P* for interaction
Number of patients	397	422		3213	3181		
Age, y	68.5 ± 12.1	70.0 ± 11.3	.067	65.1 ± 11.8	64.9 ± 11.8	.36	.043
≥75 y	145 (36.5)	171 (40.5)	.24	763 (23.7)	740 (23.3)	.65	.21
Men	283 (71.3)	290 (68.7)	.42	2448 (76.2)	2474 (77.8)	.13	.20
BMI, kg/m²	27.5 ± 4.9	26.7 ± 4.1	.013	27.1 ± 4.1	27.1 ± 4.1	.67	.014
Diabetes mellitus	125 (31.5)	127 (30.1)	.67	699 (21.8)	666 (20.9)	.42	.92
Insulin-dependent	36 (9.1)	41 (9.7)	.75	165 (5.1)	149 (4.7)	.40	.52
Current smoker	139 (35.0)	119 (28.2)	.036	1168 (36.4)	1183 (37.2)	.49	.027
Hypercholesterolemia	161 (40.6)	177 (41.9)	.69	1435 (44.7)	1381 (43.4)	.31	.47
Hypertension	277 (69.8)	283 (67.1)	.40	1987 (61.8)	1939 (61.0)	.47	.58
Previous myocardial infarction	74 (18.6)	91 (21.6)	.30	456 (14.2)	410 (12.9)	.13	.12
Previous PCI	66 (16.6)	83 (19.7)	.26	470 (14.6)	421 (13.2)	.11	.10
Previous CABG	20 (5.0)	20 (4.7)	.84	107 (3.3)	75 (2.4)	.019	.42
Previous TIA or stroke	26 (6.5)	30 (7.1)	.75	155 (4.8)	155 (4.9)	.93	.80
Peripheral vascular disease	52 (13.1)	65 (15.4)	.35	244 (7.6)	219 (6.9)	.27	.19
Renal failure	17 (4.3)	20 (4.7)	.75	31 (1.0)	27 (0.8)	.62	.58
Dialysis	1 (0.3)	0 (0.0)	.48	4 (0.1)	2 (0.1)	.69	-
ST-segment elevation myocardial infarction	249 (62.7)	268 (63.5)	.82	1763 (54.9)	1730 (54.4)	.70	.73
NSTE-ACS	148 (37.3)	154 (36.5)	.82	1450 (45.1)	1451 (45.6)	.70	.73
NSTE-ACS, troponin positive	134 (33.8)	143 (33.9)	.97	1300 (40.5)	1300 (40.9)	.74	.94
Left ventricular ejection fraction, %	44.0 ± 11.3	44.5 ± 11.5	.57	51.3 ± 9.0	51.8 ± 8.9	.031	.97
Systolic blood pressure	131.1 ± 30.7	130.0 ± 30.8	.61	139.5 ± 25.2	139.3 ± 24.9	.70	.65
Heart rate	81.9 ± 22.2	81.9 ± 20.0	.99	75.5 ± 15.9	75.0 ± 15.7	.17	.67
eGFR	75.4 ± 26.7	73.9 ± 27.8	.41	84.6 ± 24.7	85.8 ± 25.1	.051	.14
eGFR < 60 mL/min	117 (29.8)	144 (34.4)	.16	472 (14.8)	444 (14.1)	.42	.11

Data are expressed as No. (%) or mean ± standard deviation.

BMI, body mass index; CABG, coronary artery bypass graft; eGFR, estimated glomerular filtration rate; HF, heart failure; NSTE-ACS, non-ST-segment elevation acute coronary syndrome; OHCA, out-of-hospital cardiac arrest; PCI, percutaneous coronary intervention; TIA, transient ischemic attach; VP, hemodynamic/electrical vulnerable patients; KC, Killip class.

Supplementary table 4

Procedural characteristics in patients with or without hemodynamic or electrical vulnerability and according to the randomized antithrombin type

	VP			Non-VP			
	Bivalirudin	UFH	*P*	Bivalirudin	UFH	*P*	*P* for interaction
Number of patients	397	422		3213	3181		
Only radial access site	188 (47.4)	189 (44.8)	.46	1516 (47.2)	1526 (48.0)	.53	.36
Only femoral access site	182 (45.8)	208 (49.3)	.32	1585 (49.3)	1546 (48.6)	.56	.26
Both radial and femoral access site	27 (6.8)	25 (5.9)	.61	109 (3.4)	107 (3.4)	.95	.66
Other access site	0 (0.0)	0 (0.0)	-	3 (0.1)	2 (0.1)	1.00	-
Coronary angiography completed	397 (100.0)	422 (100.0)	-	3210 (99.9)	3178 (99.9)	1.00	-
Medications in the catheterization laboratory							
Aspirin	22 (5.5)	31 (7.3)	.29	210 (6.5)	222 (7.0)	.48	.45
Clopidogrel	31 (7.8)	42 (10.0)	.28	210 (6.5)	247 (7.8)	.056	.76
Prasugrel	30 (7.6)	29 (6.9)	.70	283 (8.8)	284 (8.9)	.87	.68
Ticagrelor	40 (10.1)	52 (12.3)	.31	360 (11.2)	325 (10.2)	.20	.16
Unfractionated heparin	31 (7.8)	400 (94.8)	< .0001	216 (6.7)	3073 (96.6)	< .0001	.051
GPI	22 (5.5)	129 (30.6)	< .0001	141 (4.4)	805 (25.3)	< .0001	.95
Planned GPI	0 (0.0)	105 (24.9)	< .0001	0 (0.0)	676 (21.3)	< .0001	-
Bailout GPI	22 (5.5)	24 (5.7)	.93	141 (4.4)	129 (4.1)	0.51	.74
Bivalirudin	375 (94.5)	5 (1.2)	< .0001	3068 (95.5)	9 (0.3)	< .0001	.0064
Post-PCI bivalirudin	183 (46.1)	1 (0.2)	< .0001	1554 (48.4)	2 (0.1)	< .0001	.25
Intra-aortic balloon pump	38 (10.6)	43 (11.2)	.79	38 (1.3)	37 (1.2)	.94	.81
CABG after coronary angiography	6 (1.5)	3 (0.7)	.33	18 (0.6)	14 (0.4)	.50	.51
Completed PCI after coronary angiography	367 (92.4)	397 (94.1)	.35	3032 (94.4)	3012 (94.7)	.57	.51
At least 1 planned staged procedure	73 (18.4)	71 (16.8)	.56	659 (20.5)	614 (19.3)	.23	.87
Treated vessel(s)							
Left main coronary artery	44 (12.3)	39 (10.2)	.36	99 (3.3)	86 (2.9)	.37	.78
Left anterior descending artery	209 (58.4)	190 (49.6)	.017	1477 (49.2)	1438 (48.3)	.53	.041
Left circumflex artery	84 (23.5)	116 (30.3)	.037	814 (27.1)	785 (26.4)	.54	.030
Right coronary artery	100 (27.9)	117 (30.5)	.43	997 (33.2)	999 (33.6)	.74	.53
Bypass graft	4 (1.1)	6 (1.6)	.75	28 (0.9)	17 (0.6)	.11	.25
≥ 2 vessels treated	74 (20.7)	78 (20.4)	.92	380 (12.6)	353 (11.9)	.36	.79
Overall stent length, mm	33.4 ± 20.8	36.0 ± 23.0	.12	31.3 ± 19.8	31.2 ± 18.5	.84	.36
Duration of procedure, min	55.8 ± 25.8	60.5 ± 30.6	.025	54.4 ± 27.5	53.9 ± 28.8	.51	.99

Data are expressed as No. (%) or mean ± standard deviation. CABG, coronary artery bypass graft; GPI, glycoprotein IIb/IIIa inhibitor, HF, heart failure; KC, Killip class; OHCA, out-of-hospital cardiac arrest; PCI, percutaneous coronary intervention; VP, hemodynamic/electrical vulnerable patients.

Supplementary table 5

Clinical outcomes at 30 days in patients with or without hemodynamic or electrical vulnerability

	VP (HF and/or OHCA)	HF (KC > 1)	OHCA	Non-VP	Rate ratio (95%CI)*	*P* *
Number of patients	934	808	168	7470		
Coprimary composite endpoint of all-cause mortality, MI or stroke	147 (15.7)	140 (17.3)	15 (8.9)	651 (8.8)	1.87 (1.55-2.25)	< .0001
Coprimary composite endpoint of all-cause mortality, MI, stroke, or BARC 3 or 5	162 (17.3)	153 (18.9)	18 (10.7)	734 (9.9)	1.84 (1.54-2.19)	< .0001
Composite of all-cause mortality, MI, stroke, urgent TVR, definite stent thrombosis	163 (17.5)	154 (19.1)	18 (10.7)	747 (10.1)	1.82 (1.52-2.17)	< .0001
All-cause mortality	79 (8.5)	78 (9.7)	6 (3.6)	78 (1.1)	8.51 (6.21-11.66)	< .0001
Cardiovascular death	76 (8.1)	75 (9.3)	6 (3.6)	67 (0.9)	9.51 (6.83-13.24)	< .0001
Noncardiovascular death	2 (0.2)	2 (0.3)	0 (0.0)	5 (0.1)	3.40 (0.66-17.50)	.1201
Myocardial infarction	70 (7.7)	64 (8.2)	9 (5.5)	559 (7.5)	1.03 (0.80-1.33)	.8299
Stroke	9 (1.0)	9 (1.2)	1 (0.6)	23 (0.3)	3.27 (1.51-7.04)	.0014
Ischemic	7 (0.8)	7 (0.9)	0 (0.0)	16 (0.2)	3.66 (1.51-8.88)	.0021
Hemorrhagic	2 (0.2)	2 (0.3)	1 (0.6)	6 (0.1)	2.77 (0.56-13.63)	.1906
Uncertain origin	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	2.66 (0.11-65.25)	1.0000
Transient ischemic attack	6 (0.7)	6 (0.8)	0 (0.0)	12 (0.2)	4.13 (1.55-10.97)	.0020
Urgent target vessel revascularization	18 (2.0)	13 (1.7)	8 (4.9)	71 (1.0)	2.12 (1.26-3.56)	.0037
Definite stent thrombosis	15 (1.7)	11 (1.4)	5 (3.1)	42 (0.6)	2.97 (1.65-5.36)	.0001
Acute definite stent thrombosis	7 (0.8)	5 (0.6)	2 (1.2)	26 (0.3)	2.21 (0.96-5.10)	.0562
Subacute definite stent thrombosis	9 (1.0)	7 (0.9)	3 (1.8)	16 (0.2)	4.75 (2.10-10.78)	< .0001
Definite or probable stent thrombosis	24 (2.7)	20 (2.6)	5 (3.1)	56 (0.8)	3.58 (2.22-5.78)	< .0001
Acute definite or probable stent thrombosis	10 (1.1)	8 (1.0)	2 (1.2)	28 (0.4)	2.93 (1.42-6.05)	.0022
Subacute definite or probable stent thrombosis	16 (1.8)	14 (1.9)	3 (1.8)	28 (0.4)	4.85 (2.62-8.97)	< .0001
Bleeding	147 (16.2)	128 (16.4)	27 (16.4)	814 (11.0)	1.53 (1.28-1.84)	< .0001
Type 1	60 (6.7)	47 (6.1)	16 (9.7)	414 (5.6)	1.20 (0.91-1.58)	.1918
Type 2	52 (5.7)	47 (6.0)	8 (4.8)	290 (3.9)	1.50 (1.11-2.02)	.0076
Type 3abc	25 (2.8)	23 (3.0)	5 (3.0)	111 (1.5)	1.88 (1.22-2.91)	.0038
Type 3a	18 (2.0)	17 (2.2)	2 (1.2)	53 (0.7)	2.84 (1.66-4.86)	.0001
Type 3b	6 (0.7)	5 (0.6)	2 (1.2)	54 (0.7)	0.92 (0.40-2.14)	.8485
Type 3c	1 (0.1)	1 (0.1)	1 (0.6)	5 (0.1)	1.66 (0.20-14.15)	.6373
Type 4	2 (0.2)	2 (0.3)	0 (0.0)	9 (0.1)	1.87 (0.40-8.68)	.4149
Type 5ab	12 (1.3)	12 (1.6)	0 (0.0)	17 (0.2)	5.89 (2.81-12.35)	< .0001
Type 5a	10 (1.1)	10 (1.3)	0 (0.0)	10 (0.1)	8.37 (3.48-20.11)	< .0001

Type 5b	2 (0.2)	2 (0.3)	0 (0.0)	7 (0.1)	2.37 (0.49-11.44)	.2676
Type 3 or 5	37 (4.1)	35 (4.5)	5 (3.0)	127 (1.7)	2.44 (1.69-3.52)	< .0001
Type 3 or 5 related to access site	11 (1.2)	10 (1.3)	2 (1.2)	48 (0.7)	1.90 (0.98-3.66)	.0517
Type 3 or 5 not related to access site	26 (2.9)	25 (3.2)	3 (1.8)	79 (1.1)	2.76 (1.77-4.29)	< .0001
Type 2, 3 or 5	89 (9.8)	82 (10.5)	13 (7.9)	412 (5.6)	1.83 (1.45-2.31)	< .0001
Type 2, 3 or 5 related to access site	37 (4.1)	33 (4.2)	6 (3.6)	229 (3.1)	1.34 (0.94-1.90)	.1014
Type 2, 3 or 5 not related to access site	55 (6.1)	51 (6.6)	8 (4.9)	186 (2.5)	2.50 (1.85-3.38)	< .0001
Major bleeding	13 (1.4)	12 (1.6)	3 (1.8)	51 (0.7)	2.12 (1.15-3.91)	.0133
Minor bleeding	16 (1.8)	15 (1.9)	2 (1.2)	41 (0.6)	3.27 (1.83-5.85)	< .0001
Major or minor bleeding	29 (3.2)	27 (3.5)	5 (3.0)	92 (1.3)	2.65 (1.74-4.03)	< .0001
Severe bleeding	12 (1.3)	11 (1.4)	3 (1.8)	40 (0.5)	2.49 (1.31-4.75)	.0041
Moderate bleeding	14 (1.6)	14 (1.8)	0 (0.0)	45 (0.6)	2.60 (1.42-4.73)	.0012
Mild bleeding	120 (13.3)	102 (13.1)	24 (14.6)	734 (9.9)	1.38 (1.13-1.68)	.0014
Severe or moderate bleeding	26 (2.9)	25 (3.3)	3 (1.8)	85 (1.2)	2.55 (1.64-3.96)	< .0001
Composite of surgical access site repair or blood products transfusion	26 (3.0)	23 (3.1)	4 (2.4)	89 (1.2)	2.44 (1.58-3.78)	< .0001
Surgical access site repair	2 (0.2)	1 (0.1)	1 (0.6)	17 (0.2)	0.98 (0.23-4.23)	.9742
Blood products transfusion	25 (2.9)	22 (3.0)	4 (2.4)	80 (1.1)	2.61 (1.67-4.10)	< .0001

Unless otherwise indicated, data are expressed as No. (%). BARC, bleeding academic research consortium; CI, confidence interval; KC, Killip class; OHCA, out-of-hospital cardiac arrest; MI, myocardial infarction; TVR, target vessel revascularization; VP, hemodynamic/electrical vulnerable patients.

*Rate ratio and *P* for comparison of VP vs non-VP.

Supplementary table 6

Clinical outcomes at 30 days of TRA vs TFA in patients with or without hemodynamic or electrical vulnerability

	VP						Non-VP						
	Radial access	Femoral access	Risk difference (%)	NNT/NNH	Rate ratio (95%CI)	*P*	Radial access	Femoral access	Risk difference (%)	NNT/NNH	Rate ratio (95%CI)	*P*	***P* for interaction**
Number of patients	462	472					3735	3735					
Coprimary composite endpoint of all-cause mortality, MI or stroke	69 (14.9)	78 (16.5)	−1.6 (−6.3 to 3.1)	63	0.89 (0.64-1.25)	.51	300 (8.1)	351 (9.5)	−1.4 (−2.6 to −0.1)	73	0.85 (0.72-0.99)	.039	.77
Coprimary composite endpoint of all-cause mortality, MI, stroke, or BARC 3 or 5	73 (15.8)	89 (18.9)	−3.1 (−7.9 to 1.8)	33	0.82 (0.59-1.13)	.22	337 (9.0)	397 (10.7)	−1.6 (−3.0 to −0.3)	62	0.84 (0.72-0.97)	.022	.89
Composite of all-cause mortality, MI, stroke, urgent TVR, definite stent thrombosis	74 (16.0)	89 (18.9)	−2.8 (−7.7 to 2.0)	35	0.83 (0.60-1.14)	.25	345 (9.3)	402 (10.9)	−1.5 (−2.9 to −0.2)	66	0.85 (0.73-0.98)	.030	.91
All-cause mortality	35 (7.6)	44 (9.3)	−1.7 (−5.3 to 1.8)	57	0.80 (0.51-1.25)	.32	31 (0.8)	47 (1.3)	−0.4 (−0.9 to 0.0)	233	0.66 (0.42-1.04)	.068	.55
Cardiovascular death	34 (7.4)	42 (8.9)	−1.5 (−5.0 to 2.0)	65	0.81 (0.51-1.28)	.37	26 (0.7)	41 (1.1)	−0.4 (−0.8 to 0.0)	249	0.63 (0.39-1.03)	.065	.46
Myocardial infarction	36 (7.8)	34 (7.2)	0.6 (−2.8 to 4.0)	-170	1.07 (0.66-1.73)	.78	263 (7.1)	296 (7.9)	−0.9 (−2.1 to 0.3)	113	0.88 (0.74-1.05)	.15	.46
Stroke	5 (1.1)	4 (0.9)	0.2 (−1.0 to 1.5)	-426	1.25 (0.34-4.66)	.74	11 (0.3)	12 (0.3)	−0.0 (−0.3 to 0.2)	3735	0.91 (0.40-2.07)	.83	.69
Transient ischemic attack	2 (0.5)	4 (0.9)	−0.4 (−1.4 to 0.6)	241	0.50 (0.09-2.72)	.41	3 (0.1)	9 (0.2)	−0.2 (−0.3 to 0.0)	623	0.33 (0.09-1.23)	.083	.71
Urgent target vessel revascularization	11 (2.4)	7 (1.6)	0.9 (−0.9 to 2.7)	-111	1.59 (0.61-4.11)	.34	38 (1.0)	33 (0.9)	0.1 (−0.3 to 0.6)	-747	1.15 (0.72-1.84)	.55	.55
Definite stent thrombosis	8 (1.8)	7 (1.6)	0.2 (−1.4 to 1.9)	-402	1.15 (0.42-3.18)	.79	22 (0.6)	20 (0.5)	0.1 (−0.3 to 0.4)	-1868	1.10 (0.60-2.02)	.76	.94
Acute definite stent thrombosis	5 (1.1)	2 (0.4)	0.7 (−0.5 to 1.8)	-152	2.52 (0.49-13.08)	.25	16 (0.4)	10 (0.3)	0.2 (−0.1 to 0.4)	-623	1.60 (0.73-3.54)	.24	.62
Subacute definite stent thrombosis	4 (0.9)	5 (1.1)	−0.2 (−1.4 to 1.1)	517	0.80 (0.21-2.99)	.74	6 (0.2)	10 (0.3)	−0.1 (−0.3 to 0.1)	934	0.60 (0.22-1.65)	.31	.73
Definite or probable stent thrombosis	14 (3.1)	10 (2.2)	0.9 (−1.1 to 2.9)	-110	1.41 (0.62-3.17)	.41	28 (0.8)	28 (0.8)	0.0 (−0.4 to 0.4)	.	1.00 (0.59-1.69)	1.00	.49
Acute definite or probable stent thrombosis	7 (1.5)	3 (0.7)	0.9 (−0.4 to 2.2)	-114	2.36 (0.61-9.18)	.20	17 (0.5)	11 (0.3)	0.2 (−0.1 to 0.4)	-623	1.55 (0.72-3.31)	.26	.59
Subacute definite or probable stent thrombosis	9 (2.0)	7 (1.6)	0.5 (−1.2 to 2.1)	-215	1.28 (0.48-3.45)	.62	11 (0.3)	17 (0.5)	−0.2 (−0.4 to 0.1)	623	0.64 (0.30-1.38)	.25	.28
Bleeding	59 (13.1)	88 (19.3)	−5.9 (−10.5 to −1.2)	17	0.64 (0.46-0.90)	.010	292 (7.9)	522 (14.1)	−6.2 (−7.6 to −4.8)	16	0.54 (0.46-0.62)	< .0001	.35
Type 1	26 (5.8)	34 (7.5)	−1.6 (−4.7 to 1.6)	63	0.76 (0.45-1.27)	.29	142 (3.8)	272 (7.4)	−3.5 (−4.5 to −2.4)	29	0.51 (0.42-0.63)	< .0001	.16

Type 2	22 (4.9)	30 (6.5)	−1.6 (−4.5 to 1.3)	63	0.72 (0.41-1.27)	.26	105 (2.8)	185 (5.0)	−2.1 (−3.0 to −1.3)	47	0.56 (0.44-0.71)	< .0001	.41
Type 3abc	8 (1.8)	17 (3.8)	−1.9 (−3.9 to 0.2)	53	0.47 (0.20-1.08)	.069	45 (1.2)	66 (1.8)	−0.6 (−1.1 to −0.0)	178	0.68 (0.46-0.99)	.044	.43
Type 3a	7 (1.6)	11 (2.4)	−0.8 (−2.6 to 0.9)	123	0.63 (0.24-1.64)	.34	21 (0.6)	32 (0.9)	−0.3 (−0.7 to 0.1)	340	0.65 (0.38-1.13)	.13	.96
Type 3b	1 (0.2)	5 (1.1)	−0.8 (−1.9 to 0.2)	119	0.20 (0.02-1.71)	.10	22 (0.6)	32 (0.9)	−0.3 (−0.7 to 0.1)	373	0.69 (0.40-1.18)	.17	.25
Type 3c	0 (0.0)	1 (0.2)	−0.2 (−0.6 to 0.2)	472	0.34 (0.01-8.32)	1.00	2 (0.1)	3 (0.1)	−0.0 (−0.1 to 0.1)	3735	0.67 (0.11-3.98)	.65	.44
Type 4	1 (0.2)	1 (0.2)	0.0 (−0.6 to 0.6)	-21806	1.00 (0.06-16.11)	1.00	4 (0.1)	5 (0.1)	−0.0 (−0.2 to 0.1)	3735	0.80 (0.21-2.97)	.74	.89
Type 5ab	4 (0.9)	8 (1.8)	−0.8 (−2.3 to 0.6)	121	0.50 (0.15-1.67)	.25	9 (0.2)	8 (0.2)	0.0 (−0.2 to 0.2)	-3735	1.12 (0.43-2.91)	.81	.30
Type 5a	3 (0.7)	7 (1.6)	−0.8 (−2.1 to 0.5)	120	0.43 (0.11-1.66)	.21	6 (0.2)	4 (0.1)	0.1 (−0.1 to 0.2)	-1868	1.50 (0.42-5.31)	.53	.18
Type 5b	1 (0.2)	1 (0.2)	0.0 (−0.6 to 0.6)	-21806	1.01 (0.06-16.18)	1.00	3 (0.1)	4 (0.1)	−0.0 (−0.2 to 0.1)	3735	0.75 (0.17-3.34)	.70	.85
Type 3 or 5	12 (2.7)	25 (5.5)	−2.7 (−5.2 to −0.2)	37	0.47 (0.24-0.95)	.031	53 (1.4)	74 (2.0)	−0.6 (−1.1 to 0.0)	178	0.71 (0.50-1.01)	.059	.30
Type 3 or 5 related to access site	2 (0.4)	9 (2.0)	−1.5 (−2.8 to −0.1)	68	0.22 (0.05-1.03)	.035	14 (0.4)	34 (0.9)	−0.5 (−0.9 to −0.2)	187	0.41 (0.22-0.76)	.0038	.46
Type 3 or 5 not related to access site	10 (2.2)	16 (3.6)	−1.2 (−3.3 to 0.9)	82	0.62 (0.28-1.38)	.24	39 (1.1)	40 (1.1)	−0.0 (−0.5 to 0.4)	3735	0.97 (0.63-1.51)	.90	.33
Type 2, 3 or 5	34 (7.5)	55 (12.1)	−4.3 (−8.0 to −0.5)	23	0.60 (0.39-0.93)	.021	156 (4.2)	256 (6.9)	−2.7 (−3.7 to −1.6)	37	0.60 (0.49-0.73)	< .0001	.99
Type 2, 3 or 5 related to access site	8 (1.8)	29 (6.3)	−4.4 (−6.9 to −1.9)	23	0.27 (0.12-0.59)	.0005	61 (1.6)	168 (4.5)	−2.9 (−3.6 to −2.1)	35	0.36 (0.27-0.48)	< .0001	.51
Type 2, 3 or 5 not related to access site	26 (5.8)	29 (6.4)	−0.5 (−3.5 to 2.5)	194	0.90 (0.53-1.53)	.69	96 (2.6)	90 (2.4)	0.2 (−0.5 to 0.9)	-623	1.07 (0.80-1.42)	.67	.58
Major bleeding	4 (0.9)	9 (2.0)	−1.0 (−2.5 to 0.5)	96	0.44 (0.14-1.44)	.16	22 (0.6)	29 (0.8)	−0.2 (−0.6 to 0.2)	534	0.76 (0.43-1.32)	.32	.42
Minor bleeding	5 (1.1)	11 (2.4)	−1.2 (−2.9 to 0.4)	80	0.45 (0.16-1.31)	.13	19 (0.5)	22 (0.6)	−0.1 (−0.4 to 0.3)	1245	0.86 (0.47-1.59)	.63	.30
Major or minor bleeding	9 (2.0)	20 (4.4)	−2.3 (−4.5 to −0.1)	44	0.45 (0.20-0.98)	.040	41 (1.1)	51 (1.4)	−0.3 (−0.8 to 0.2)	373	0.80 (0.53-1.21)	.29	.19
Severe bleeding	4 (0.9)	8 (1.8)	−0.8 (−2.3 to 0.6)	121	0.50 (0.15-1.66)	.25	19 (0.5)	21 (0.6)	−0.1 (−0.4 to 0.3)	1868	0.90 (0.48-1.68)	.75	.39
Moderate bleeding	5 (1.1)	9 (2.0)	−0.8 (−2.4 to 0.7)	121	0.55 (0.18-1.65)	.28	19 (0.5)	26 (0.7)	−0.2 (−0.5 to 0.2)	534	0.73 (0.40-1.32)	.29	.66
Mild bleeding	49 (10.9)	71 (15.6)	−4.4 (−8.7 to −0.2)	23	0.67 (0.46-0.97)	.034	257 (6.9)	477 (12.9)	−5.9 (−7.2 to −4.5)	17	0.52 (0.44-0.61)	< .0001	.22

Severe or moderate bleeding	9 (2.0)	17 (3.8)	−1.7 (−3.8 to 0.4)	60	0.53 (0.23-1.18)	.11	38 (1.0)	47 (1.3)	−0.2 (−0.7 to 0.2)	415	0.81 (0.52-1.24)	.32	.36
Composite of surgical access site repair or blood products transfusion	8 (2.0)	18 (4.0)	−2.1 (−4.2 to 0.0)	48	0.44 (0.19-1.01)	.047	34 (0.9)	55 (1.5)	−0.6 (−1.1 to −0.1)	178	0.62 (0.40-0.94)	.025	.48
Surgical access site repair	0 (0.0)	2 (0.4)	−0.4 (−1.0 to 0.2)	236	0.20 (0.01-4.15)	.50	4 (0.1)	13 (0.3)	−0.2 (−0.5 to −0.0)	415	0.31 (0.10-0.94)	.029	.44
Blood products transfusion	8 (2.0)	17 (3.8)	−1.9 (−3.9 to 0.2)	53	0.47 (0.20-1.08)	.069	33 (0.9)	47 (1.3)	−0.4 (−0.8 to 0.1)	267	0.70 (0.45-1.09)	.11	.40

Unless otherwise indicated, data are expressed as No. (%). BARC, bleeding academic research consortium; CI, confidence interval; MI, myocardial infarction; NNT/NNH, number needed to treat/harm; TVR, target vessel revascularization; VP, hemodynamic/electrical vulnerable patients.

Supplementary table 7

Clinical outcomes at 30 days of bivalirudin vs unfractionated heparin in patients with or without hemodynamic or electrical vulnerability

	VP						Non-VP						
	Bivalirudin	UFH	Risk difference (%)	NNT/NNH	Rate Ratio (95%CI)	*P*	Bivalirudin	UFH	Risk difference (%)	NNT/NNH	Rate Ratio (95%CI)	*P*	*P* for interaction
Number of patients	397	422					3213	318					
Coprimary composite endpoint of all-cause mortality, MI or stroke	61 (15.4)	76 (18.0)	−2.6 (−7.7 to 2.5)	38	0.84 (0.59-1.19)	.33	313 (9.8)	316 (10.0)	−0.2 (−1.7 to 1.3)	520	0.98 (0.83-1.15)	.80	.43
Coprimary composite endpoint of all-cause mortality, MI, stroke, or BARC 3 or 5	63 (15.9)	89 (21.1)	−5.2 (−10.5 to 0.1)	19	0.73 (0.52-1.02)	.064	345 (10.8)	361 (11.4)	−0.6 (−2.1 to 0.9)	164	0.94 (0.81-1.10)	.45	.17
Composite of all-cause mortality, MI, stroke, urgent TVR, definite stent thrombosis	64 (16.1)	89 (21.1)	−5.0 (−10.3 to 0.3)	20	0.74 (0.53-1.04)	.079	351 (11.0)	367 (11.6)	−0.6 (−2.2 to 0.9)	163	0.94 (0.81-1.10)	.45	.20
All-cause mortality	24 (6.0)	48 (11.4)	−5.3 (−9.2 to −1.5)	19	0.51 (0.31-0.84)	.0070	35 (1.1)	35 (1.1)	−0.0 (−0.5 to 0.5)	9125	0.99 (0.62-1.58)	.97	.056
Cardiovascular death	23 (5.8)	47 (11.1)	−5.3 (−9.1 to −1.6)	19	0.50 (0.30-0.83)	.0063	30 (0.9)	30 (1.0)	−0.0 (−0.5 to 0.5)	10646	0.99 (0.60-1.65)	.97	.060
Myocardial infarction	39 (10.0)	28 (6.9)	3.2 (−0.6 to 7.0)	-31	1.46 (0.88-2.41)	.14	271 (8.5)	277 (8.8)	−0.3 (−1.6 to 1.1)	366	0.97 (0.81-1.15)	.71	.13
Stroke	3 (0.8)	6 (1.6)	−0.7 (−2.1 to 0.7)	150	0.50 (0.13-2.01)	.32	10 (0.3)	10 (0.3)	−0.0 (−0.3 to 0.3)	31939	0.99 (0.41-2.38)	.98	.41
Transient ischemic attack	2 (0.5)	3 (0.8)	−0.2 (−1.3 to 0.9)	483	0.68 (0.11-4.06)	.67	3 (0.1)	6 (0.2)	−0.1 (−0.3 to 0.1)	1050	0.50 (0.12-1.98)	.31	.79
Urgent target vessel revascularization	12 (3.1)	6 (1.5)	1.6 (−0.4 to 3.6)	-62	2.07 (0.77-5.53)	.14	40 (1.3)	29 (0.9)	0.3 (−0.2 to 0.8)	-300	1.37 (0.85-2.21)	.19	.46
Definite stent thrombosis	9 (2.3)	6 (1.5)	0.8 (−1.0 to 2.7)	-118	1.54 (0.55-4.35)	.41	27 (0.8)	15 (0.5)	0.4 (−0.0 to 0.8)	-271	1.79 (0.95-3.37)	.067	.81
Acute definite stent thrombosis	4 (1.0)	3 (0.7)	0.3 (−1.0 to 1.6)	-337	1.37 (0.31-6.14)	.68	16 (0.5)	10 (0.3)	0.2 (−0.1 to 0.5)	-545	1.59 (0.72-3.51)	.25	.86
Subacute definite stent thrombosis	5 (1.3)	4 (1.0)	0.3 (−1.1 to 1.7)	-321	1.28 (0.34-4.78)	.71	11 (0.3)	5 (0.2)	0.2 (−0.1 to 0.4)	-540	2.19 (0.76-6.30)	.14	.53
Definite or probable stent thrombosis	11 (2.9)	13 (3.3)	−0.3 (−2.6 to 2.0)	323	0.87 (0.39-1.94)	.73	34 (1.1)	22 (0.7)	0.4 (−0.1 to 0.8)	-273	1.54 (0.90-2.63)	.11	.24
Acute definite or probable stent thrombosis	4 (1.0)	6 (1.5)	−0.4 (−1.9 to 1.1)	241	0.69 (0.19-2.44)	.56	18 (0.6)	10 (0.3)	0.2 (−0.1 to 0.6)	-407	1.79 (0.82-3.88)	.14	.20

Subacute definite or probable stent thrombosis	7 (1.8)	9 (2.3)	−0.4 (−2.3 to 1.5)	271	0.79 (0.29-2.13)	.64	16 (0.5)	12 (0.4)	0.1 (−0.2 to 0.4)	-828	1.32 (0.63-2.80)	.46	.41
Bleeding	57 (14.6)	80 (19.9)	−4.6 (−9.7 to 0.5)	22	0.72 (0.50-1.02)	.062	336 (10.6)	408 (12.9)	−2.4 (−3.9 to −0.8)	42	0.80 (0.69-0.93)	.0036	.56
Type 1	24 (6.2)	33 (8.3)	−1.8 (−5.2 to 1.7)	56	0.74 (0.43-1.26)	.26	172 (5.4)	213 (6.7)	−1.3 (−2.5 to −0.2)	74	0.79 (0.65-0.97)	.026	.80
Type 2	26 (6.6)	23 (5.7)	1.1 (−2.2 to 4.4)	-91	1.17 (0.66-2.07)	.59	128 (4.0)	134 (4.2)	−0.2 (−1.2 to 0.7)	437	0.94 (0.74-1.21)	.65	.50
Type 3abc	6 (1.5)	18 (4.5)	−2.8 (−5.0 to −0.5)	36	0.34 (0.13-0.85)	.015	43 (1.4)	60 (1.9)	−0.5 (−1.2 to 0.1)	183	0.71 (0.48-1.05)	.084	.14
Type 3a	3 (0.8)	14 (3.5)	−2.6 (−4.5 to −0.7)	39	0.22 (0.06-0.76)	.0083	24 (0.8)	27 (0.9)	−0.1 (−0.5 to 0.3)	982	0.88 (0.51-1.53)	.65	.039
Type 3b	2 (0.5)	4 (1.0)	−0.4 (−1.6 to 0.7)	225	0.51 (0.09-2.80)	.43	16 (0.5)	32 (1.0)	−0.5 (−0.9 to −0.1)	197	0.49 (0.27-0.90)	.019	.97
Type 3c	1 (0.3)	0 (0.0)	0.3 (−0.2 to 0.7)	-397	3.19 (0.13-78.08)	.48	3 (0.1)	2 (0.1)	0.0 (−0.1 to 0.2)	-3279	1.49 (0.25-8.90)	.66	.44
Type 4	0 (0.0)	0 (0.0)	0.0 (0.0 to 0.0)	.			1 (0.0)	3 (0.1)	−0.1 (−0.2 to 0.1)	1583	0.33 (0.03-3.18)	.31	
Type 5ab	2 (0.5)	9 (2.2)	−1.6 (−3.2 to −0.1)	61	0.23 (0.05-1.05)	.038	4 (0.1)	12 (0.4)	−0.3 (−0.5 to −0.0)	396	0.33 (0.11-1.02)	.044	.70
Type 5a	1 (0.3)	8 (2.0)	−1.6 (−3.0 to −0.3)	61	0.13 (0.02-1.02)	.021	4 (0.1)	6 (0.2)	−0.1 (−0.3 to 0.1)	1559	0.66 (0.19-2.34)	.52	.16
Type 5b	1 (0.3)	1 (0.2)	0.0 (−0.7 to 0.7)	-6701	1.02 (0.06-16.53)	.99	0 (0.0)	6 (0.2)	−0.2 (−0.3 to −0.0)	530	0.08 (0.00-1.42)	.015	.062
Type 3 or 5	8 (2.1)	27 (6.7)	−4.4 (−7.1 to −1.7)	23	0.30 (0.13-0.66)	.0015	47 (1.5)	71 (2.3)	−0.8 (−1.4 to −0.1)	130	0.65 (0.45-0.95)	.023	.073
Type 3 or 5 related to access site	2 (0.5)	9 (2.2)	−1.6 (−3.2 to −0.1)	61	0.23 (0.05-1.05)	.038	19 (0.6)	26 (0.8)	−0.2 (−0.6 to 0.2)	442	0.72 (0.40-1.31)	.28	.15
Type 3 or 5 not related to access site	6 (1.5)	18 (4.5)	−2.8 (−5.0 to −0.5)	36	0.34 (0.13-0.85)	.016	28 (0.9)	45 (1.5)	−0.5 (−1.1 to −0.0)	184	0.62 (0.38-0.99)	.042	.25
Type 2, 3 or 5	34 (8.7)	50 (12.4)	−3.3 (−7.4 to 0.8)	30	0.69 (0.44-1.07)	.098	172 (5.4)	203 (6.4)	−1.0 (−2.2 to 0.1)	97	0.83 (0.68-1.02)	.084	.44
Type 2, 3 or 5 related to access site	16 (4.1)	20 (5.0)	−0.7 (−3.5 to 2.1)	141	0.82 (0.42-1.59)	.55	89 (2.8)	117 (3.7)	−0.9 (−1.8 to −0.0)	110	0.75 (0.57-0.99)	.040	.81
Type 2, 3 or 5 not related to access site	20 (5.1)	31 (7.8)	−2.3 (−5.6 to 1.0)	43	0.66 (0.37-1.16)	.14	83 (2.6)	89 (2.8)	−0.2 (−1.0 to 0.6)	466	0.93 (0.69-1.25)	.61	.29
Major bleeding	5 (1.3)	6 (1.5)	−0.2 (−1.7 to 1.4)	616	0.85 (0.26-2.79)	.79	12 (0.4)	28 (0.9)	−0.5 (−0.9 to −0.1)	197	0.42 (0.22-0.83)	.010	.32

Minor bleeding	3 (0.8)	13 (3.3)	−2.3 (−4.2 to −0.5)	43	0.23 (0.07-0.83)	.014	17 (0.6)	23 (0.8)	−0.2 (−0.6 to 0.2)	516	0.73 (0.39-1.37)	.33	.10
Major or minor bleeding	8 (2.1)	19 (4.7)	−2.5 (−4.9 to −0.1)	40	0.43 (0.19-0.98)	.038	29 (0.9)	51 (1.6)	−0.7 (−1.2 to −0.2)	143	0.56 (0.36-0.89)	.012	.56
Severe bleeding	5 (1.3)	4 (1.0)	0.3 (−1.1 to 1.7)	-321	1.28 (0.34-4.76)	.72	12 (0.4)	25 (0.8)	−0.4 (−0.8 to −0.0)	242	0.48 (0.24-0.95)	.030	.18
Moderate bleeding	1 (0.3)	12 (3.0)	−2.6 (−4.3 to −0.9)	39	0.08 (0.01-0.65)	.0024	19 (0.6)	21 (0.7)	−0.1 (−0.5 to 0.3)	1453	0.90 (0.48-1.67)	.73	.011
Mild bleeding	51 (13.1)	63 (15.8)	−2.1 (−6.8 to 2.6)	48	0.83 (0.56-1.21)	.32	308 (9.7)	366 (11.6)	−1.9 (−3.4 to −0.4)	52	0.82 (0.70-0.96)	.014	.99
Severe or moderate bleeding	6 (1.6)	16 (4.0)	−2.3 (−4.5 to −0.1)	44	0.38 (0.15-0.97)	.035	31 (1.0)	46 (1.5)	−0.5 (−1.0 to 0.1)	208	0.67 (0.42-1.05)	.080	.28
Composite of surgical access site repair or blood products transfusion	5 (1.6)	18 (4.5)	−3.0 (−5.2 to −0.8)	33	0.28 (0.10-0.75)	.0072	31 (1.0)	50 (1.6)	−0.6 (−1.2 to −0.1)	165	0.61 (0.39-0.96)	.031	.15
Surgical access site repair	0 (0.0)	2 (0.5)	−0.5 (−1.1 to 0.2)	211	0.21 (0.01-4.36)	.50	5 (0.2)	10 (0.3)	−0.2 (−0.4 to 0.1)	630	0.50 (0.17-1.45)	.19	.34
Blood products transfusion	5 (1.6)	17 (4.3)	−2.8 (−4.9 to −0.6)	36	0.30 (0.11-0.81)	.011	26 (0.8)	47 (1.5)	−0.7 (−1.2 to −0.1)	150	0.55 (0.34-0.88)	.012	.27

Unless otherwise indicated, data are expressed as No. (%).

BARC, bleeding academic research consortium; CI, confidence interval; MI, myocardial infarction; NNT/NNH, number needed to treat/harm; TVR, target vessel revascularization; UFH, unfractionated heparin; VP, hemodynamic/electrical vulnerable patients.

Supplementary table 8

Sensitivity analysis of main clinical outcomes at 30 days analyzed with Cox regression analysis and competing risk for both TRA vs TFA and bivalirudin vs unfractionated heparin in patients with or without hemodynamic or electrical vulnerability

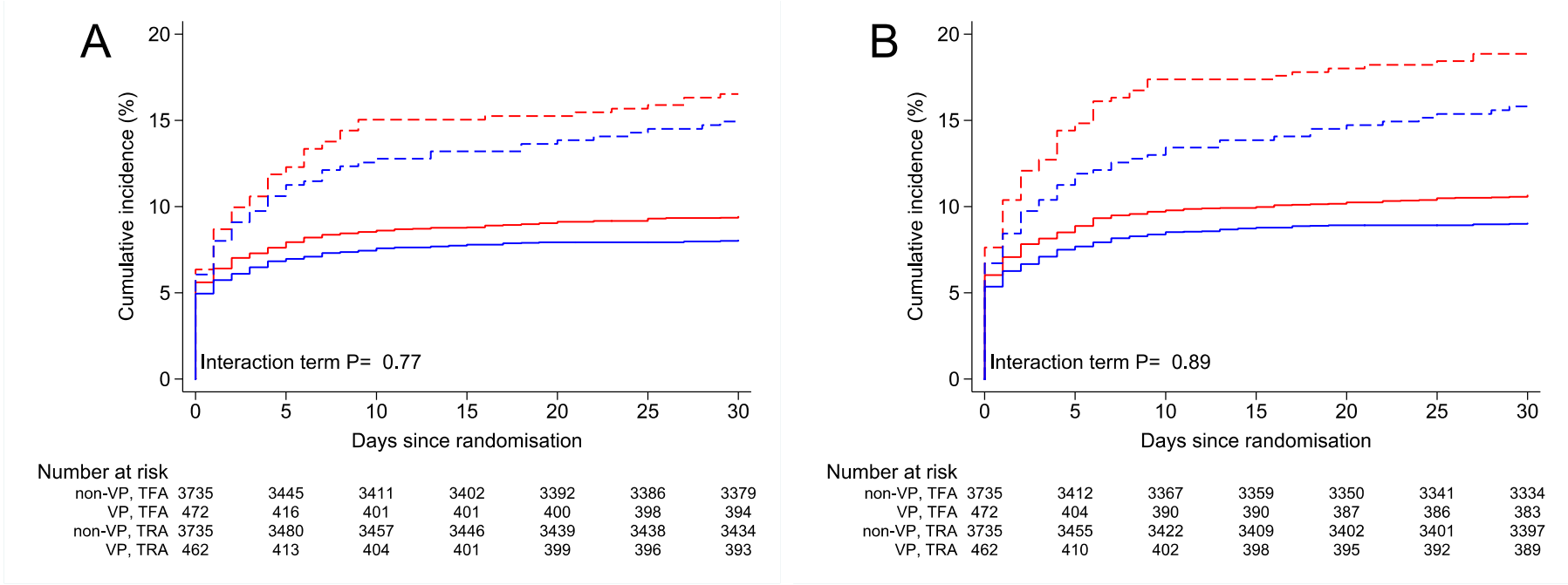
	VP		non-VP		*P* for interaction
Cox regression analysis					
Access site	Hazard ratio (95%CI)	*P*	Hazard ratio (95%CI)	*P*	
Coprimary composite endpoint of all-cause mortality, MI or stroke	0.90 (0.65-1.23)	.50	0.85 (0.73-0.99)	.036	.75
Coprimary composite endpoint of all-cause mortality, MI, stroke, or BARC 3 or 5	0.82 (0.61-1.12)	.21	0.84 (0.73-0.97)	.020	.91
All-cause mortality	0.80 (0.52-1.24)	.32	0.66 (0.42-1.04)	.070	.55
Antithrombin					
Coprimary composite endpoint of all-cause mortality, MI or stroke	0.84 (0.61-1.17)	.32	0.98 (0.84-1.14)	.80	.43
Coprimary composite endpoint of all-cause mortality, MI, stroke, or BARC 3 or 5	0.74 (0.54-1.01)	.059	0.94 (0.82-1.09)	.44	.17
All-cause mortality	0.52 (0.32-0.84)	.0076	0.99 (0.62-1.58)	.97	.057
Adjusted Cox regression analysis*					
Access site					
Coprimary composite endpoint of all-cause mortality, MI or stroke	0.92 (0.64-1.32)	.64	0.87 (0.74-1.02)	.078	.48
Coprimary composite endpoint of all-cause mortality, MI, stroke, or BARC 3 or 5	0.82 (0.59-1.15)	.26	0.87 (0.75-1.00)	.054	.88
All-cause mortality	0.77 (0.45-1.31)	.34	0.75 (0.45-1.23)	.25	.82
Antithrombin					
Coprimary composite endpoint of all-cause mortality, MI or stroke	0.86 (0.61-1.22)	.40	0.96 (0.82-1.12)	.63	.69
Coprimary composite endpoint of all-cause mortality, MI, stroke, or BARC 3 or 5	0.74 (0.53-1.03)	.073	0.92 (0.80-1.07)	.30	.33
All-cause mortality	0.46 (0.26-0.80)	.0063	0.93 (0.56-1.53)	.77	.084
Competing risk analysis (for death)					
Access site	*Sub-hazard ratio (95%CI)*	*P*	*Sub-hazard ratio (95%CI)*	***P***	
MI	1.07 (0.67-1.70)	.78	0.89 (0.75-1.04)	.14	.45
Stroke	1.67 (0.40-6.99)	.48	0.91 (0.40-2.07)	.83	.47

BARC 3 or 5	0.50 (0.25-0.99)	.047	0.71 (0.50-1.01)	.060	.36
Antithrombin					
MI	1.44 (0.89-2.32)	.13	0.97 (0.82-1.14)	.70	.12
Stroke	0.34 (0.07-1.66)	.18	0.99 (0.41-2.38)	.98	.25
BARC 3 or 5	0.26 (0.11-0.60)	.0016	0.65 (0.45-0.95)	.024	.048

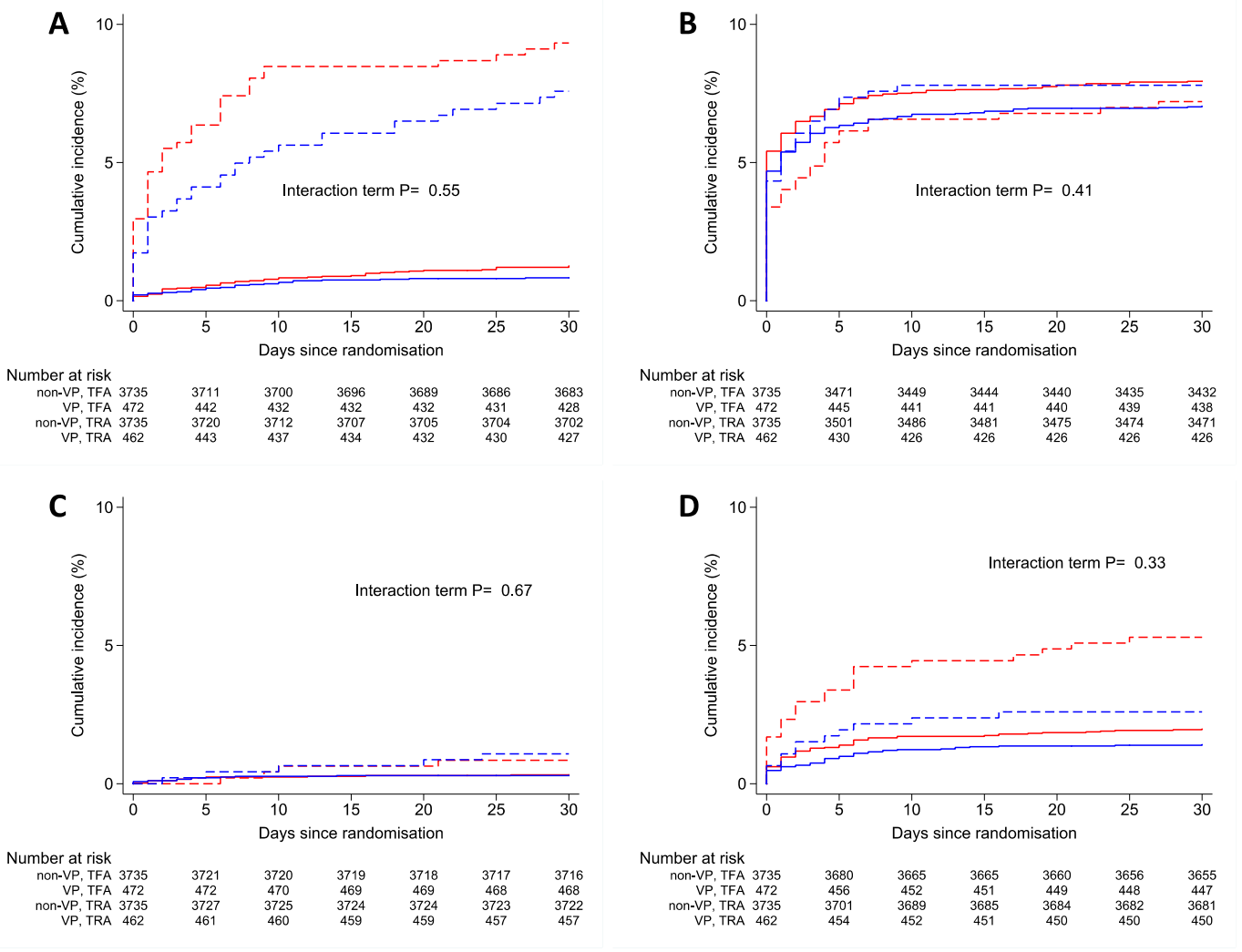
*Multivariable adjustment included the following variables: age, sex, BMI, diabetes, smoking, hypercholesterolemia, hypertension, previous MI, previous TIA/stroke, peripheral arterial disease, renal failure, clinical presentation as STEMI, left main treated, multivessel treatment.

BARC, bleeding academic research consortium; CI, confidence interval; MI, myocardial infarction; VP, hemodynamic/electrical vulnerable patients.

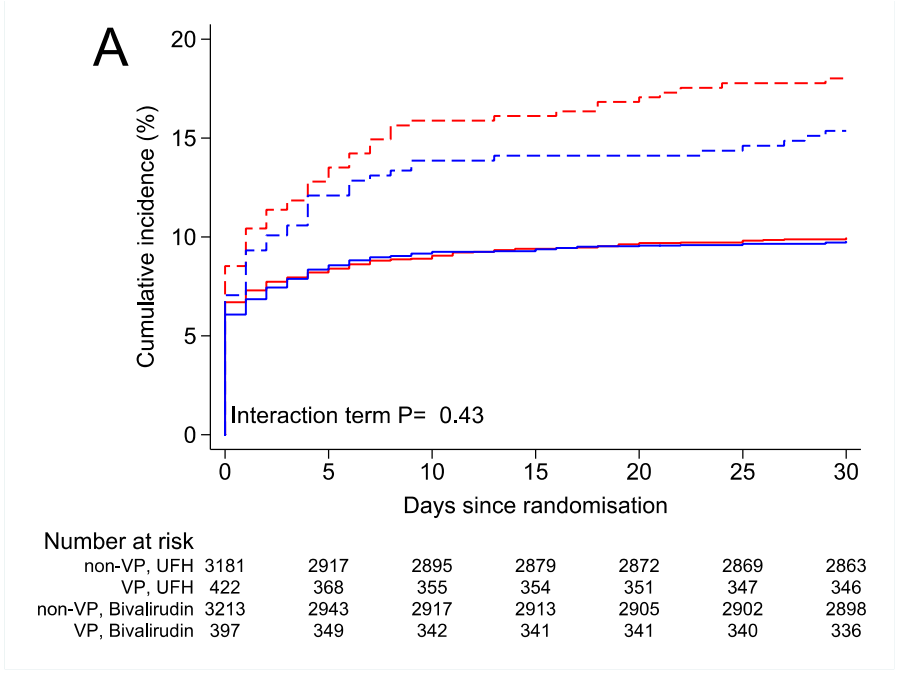
Supplementary figure 1. Coprimary composite access-related outcomes at 30 days in VP and non-VP.
Panels A and B show the cumulative incidence of the coprimary outcome of MACE and NACE respectively. Blue indicates radial access (TRA), red indicates femoral access (TFA), the continuous line indicates non-VP, and the dashed line indicates VP.

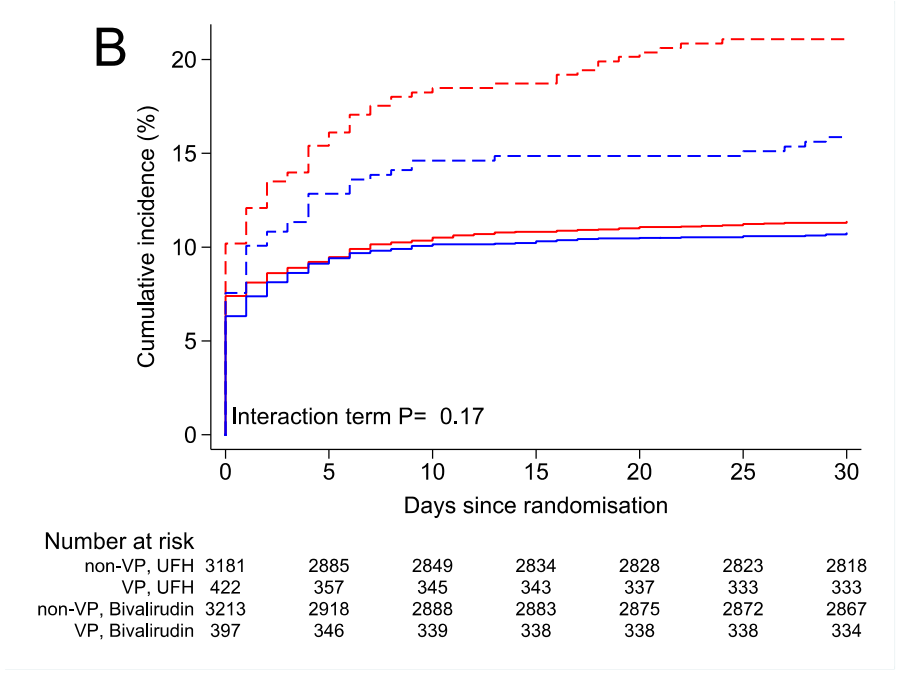


Supplementary figure 2. Components of coprimary composite access-related outcomes at 30 days in VP and non-VP.
Panels show the cumulative incidence of the coprimary outcome of all-cause death (A), myocardial infarction (B), stroke (C), and BARC 3 or 5 bleeding (D). Blue indicates radial access (TRA), red indicates femoral access (TFA), the continuous line indicates non-VP, and the dashed line indicates VP.



Supplementary figure 3. Coprimary composite antithrombin-related outcomes at 30 days in VP and non- VP.
Panels A and B show the cumulative incidence of the coprimary outcome of MACE and NACE respectively. Blue indicates bivalirudin, red indicates UFH, the continuous line indicates non-VP, and the dashed line indicates VP.





Supplementary figure 4. Components of coprimary composite antithrombin-related outcomes at 30 days in VP and non-VP.
Panels show the cumulative incidence of the coprimary outcome of all-cause death (A), myocardial infarction (B), stroke (C), and BARC 3 or 5 bleeding (D). Blue indicates bivalirudin, red indicates UFH, the continuous line indicates non-VP, and the discontinuous line indicates VP.