

Supplementary Online Content

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

eTable 1: POINT, ISTH and PRoFESS Hemorrhage Classifications

POINT	ISTH	PRoFESS
<p>Major Hemorrhage</p> <p>Hemorrhage that results in non-traumatic, symptomatic intracranial hemorrhage (intracerebral, subdural, subarachnoid, intraventricular, symptomatic hemorrhagic transformation of an ischemic stroke), intraocular bleeding causing loss of vision, need for transfusion of two or more units of red cells or equivalent amount of whole blood, need for hospitalization/prolongation of an existing hospitalization, or death.</p> <p>May include bleeding events related to surgical procedures.</p> <p>Minor Hemorrhage</p> <p>Hemorrhage that results in interruption or discontinuation of study drug but not classifiable as major hemorrhagic event; may include bleeding events related to surgical procedures but not those related to accidental trauma.</p>	<p>Major Bleeding in Non-Surgical Patients</p> <p>Fatal bleeding, <i>and/or</i></p> <p>Symptomatic bleeding in a critical area or organ, such as intracranial, intraspinal, intraocular, retroperitoneal, intraarticular or pericardial, or intramuscular with compartment syndrome, <i>and/or</i></p> <p>Bleeding causing a fall in hemoglobin level of 2 g/dL (1.24 mmol/L) or more, or leading to transfusion of two or more units of whole blood or red cells.</p> <p>Minor Bleeding</p> <p>All non-major bleeds considered minor bleeds; further divided into those that are clinically relevant and those that are not.</p> <p>Clinically Relevant Minor Bleed^a</p> <p>An acute or subacute clinically overt bleed that does not meet criteria for a major bleed but prompts a clinical response, in that it leads to at least one of the following:</p> <ul style="list-style-type: none"> • hospital admission for bleeding • physician-guided medical or surgical treatment for bleeding • change in antithrombotic therapy (including interruption/discontinuation of study drug) 	<p>Major Hemorrhage</p> <p>Hemorrhage that results in clinically significant disability, symptomatic intracranial hemorrhage, intraocular bleeding causing loss of vision, need for a transfusion of 2 or more units of red cells or equivalent amount of whole blood, or need for hospitalization.</p> <p>Life-threatening Hemorrhage</p> <p>Hemorrhage that was fatal or required use of intravenous inotropic medication to maintain blood pressure, surgical intervention, or transfusion of 4 or more units of red cells or equivalent amount of whole blood.</p> <p>Non-life-threatening Hemorrhage</p> <p>Hemorrhage classified as major hemorrhage but not as life-threatening.</p> <p>Minor Hemorrhage</p> <p>All non-major hemorrhages leading to interruption of therapy.</p>

Abbreviation: POINT, Platelet-Oriented Inhibition in New TIA and minor ischemic stroke; ISTH, International Society on Thrombosis and Hemostasis; PRoFESS, Prevention Regimen for Effectively Avoiding Second Strokes; g/dL, grams per deciliter; mmol/L, millimoles per liter.

^a Communication from the Scientific and Standardization Committee (SSC) of the International Society on Thrombosis and Hemostasis (ISTH), November 2015.

eTable 2: Baseline Characteristics for ITT Study Population by Major Hemorrhage Status

Characteristic	N	Major Hemorrhage (N=33)	N	No Major Hemorrhage (N=4848)	p-value
Age (yr) – median (IQR)	33	74.0 (60.0-84.0)	4848	65.0 (55.0-74.0)	0.0043
Female sex – no. (%)	33	17 (51.5%)	4848	2178 (44.9%)	0.4482
Race – no. (%)	32		4706		0.2533
White		22 (68.8%)		3533 (75.1%)	
Black		7 (21.9%)		959 (20.4%)	
Asian		2 (6.3%)		142 (3.0%)	
Other		1 (3.1%)		72 (1.5%)	
Ethnicity – no. (%)	32		4616		0.4486
Not US Hispanic		29 (90.6%)		4329 (93.8%)	
US Hispanic		3 (9.4%)		287 (6.2%)	
Region – no. (%)	33		4848		1.0
United States		28 (84.9%)		4015 (82.8%)	
Outside United States		5 (15.2%)		833 (17.2%)	
Systolic blood pressure – median (IQR)	33	160.0 (138.0-173.0)	4844	159.0 (143.0-180.0)	0.6884
Diastolic blood pressure – median (IQR)	33	83.0 (70.0-91.0)	4844	87.0 (77.0-98.0)	0.0924
Medical history – no. (%)					
Congestive heart failure	33	0 (0.0%)	4841	126 (2.6%)	1.0
Atrial fibrillation	33	1 (3.0%)	4834	48 (1.0%)	0.2847
Ischemic heart disease	33	4 (12.1%)	4836	493 (10.2%)	0.7698
Hypertension	32	27 (84.4%)	4828	3346 (69.3%)	0.0818
Diabetes mellitus	33	9 (27.3%)	4839	1331 (27.5%)	0.9762
Current tobacco smoker – no. (%)	33	8 (24.2%)	4844	996 (20.6%)	0.6022
Taking aspirin at presentation – no. (%)	33	20 (60.6%)	4848	2794 (57.6%)	0.7304
Taking clopidogrel at presentation – no. (%)	33	1 (3.0%)	4847	89 (1.8%)	0.4601
Time to randomization (h) – mean (SD)	33	7.0 (3.1)	4847	7.3 (2.9)	0.5108
Time to randomization – no. (%)	33		4847		0.8685
< 6h		10 (30.3%)		1534 (31.7%)	
≥ 6h		23 (69.7%)		3313 (68.4%)	
Qualifying event – no. (%)	33		4848		0.3325
TIA		17 (51.5%)		2091 (43.1%)	
Ischemic stroke		16 (48.5%)		2757 (56.9%)	
Qualifying TIA baseline ABCD ² score – median (IQR)	17	5.0 (4.0-6.0)	2087	5.0(4.0-6.0)	0.6018
Qualifying ischemic stroke baseline NIHSS score – median (IQR)	16	2.0 (1.0-3.0)	2734	2.0 (1.0-2.0)	0.5120

Differences in baseline characteristics between the treatment groups were not significant with the exception of age, $p=0.0043$. Race is missing/unknown for $N=143$; ethnicity is missing/unknown for $N=233$. ABCD² scale score is given only for TIA group ($N=2108$ with 4 missing) and NIHSS score given only for ischemic stroke group ($N=2773$ with 23 missing).

Abbreviation: IQR, interquartile range; US, United States; SD, standard deviation; TIA, transient ischemic attack; ABCD², age/blood pressure/clinical features/duration of symptoms/diabetes; NIHSS, National Institutes of Health Stroke Scale.

eTable 3: Major and Minor Hemorrhages for ITT Study Population

Outcome	Clopidogrel plus aspirin (N=2432)		Aspirin (N=2449)		Hazard Ratio (95% CI)	P Value
	Patients with Event		Patients with Event			
	no.	%	no.	%		
Fatal Major Hemorrhage^a	3	0.1	2	0.1		
Major Hemorrhage	23	0.9	10	0.4	2.32 (1.10 – 4.87)	0.02
<u>Intracranial hemorrhage</u>	6	0.2	3	0.1		
Hemorrhagic stroke	5	0.2	3	0.1		
Symptomatic intracerebral hemorrhage	2	0.1	2	0.1		
Symptomatic hemorrhagic transformation of cerebral infarcts	2	0.1	1	0.0		
Other symptomatic intracranial hemorrhage (subarachnoid)	2	0.1	0	0		
<u>Other than intracranial hemorrhage^b</u>	17	0.7	7	0.3		
Upper GI hemorrhage	4	0.2	4	0.2		
Lower GI hemorrhage	7	0.3	1	0		
Hematuria	1	0.0	1	0.0		
Other ^c	5	0.2	1	0.0		
Minor Hemorrhage	40	1.6	13	0.5	3.12 (1.67 – 5.83)	<0.001

^a The five fatal major hemorrhages consist of 2 symptomatic intracerebral hemorrhages, 2 symptomatic hemorrhagic transformations, and 1 groin hemorrhage with cardiac arrest.

^b Three of these patients had 2 hemorrhagic events each.

^c Other consists of 1 uterine fibroids, 1 vitreous hemorrhage, 1 implantation of a loop recorder, 1 gallbladder hematoma, and 1 groin hemorrhage with cardiac arrest. One patient had a traumatic arm hemorrhage due to a fall adjudicated as a major hemorrhage; according to the protocol, this should not have qualified as a major hemorrhage since it was due to accidental trauma.

Abbreviation: GI, gastrointestinal.

eTable 4. Baseline Characteristics of Patients with Major Hemorrhages in the ITT Study Population by Treatment Group

Characteristic	N	Clopidogrel plus Aspirin (N=23)	N	Aspirin (N=10)
Total events		24		12
Events on treatment		22		7
Total patients		23		10
Patients on treatment		21		6
Time to hemorrhage (days) – median (IQR)	23	29.5 (2.6 – 51.8)	10	19.8 (6.5 – 46.8)
Age (yr) – median (IQR)	23	74.0 (63.0-84.0)	10	68.0 (49.0-82.0)
Female sex – no. (%)	23	12 (52.2%)		5 (50.0%)
Race - no. (%)	22		10	
White		17 (77.3%)		5 (50.0%)
Black		4 (18.2%)		3 (30.0%)
Asian		1 (4.6%)		1 (10.0%)
Other		0 (0.0%)		1 (10.0%)
Ethnicity - no. (%)	22		10	
Not US Hispanic		19 (86.4%)		10 (100.0%)
US Hispanic		3 (13.6%)		0 (0.0%)
Region – no. (%)	23		10	
United States		20 (87.0%)		8 (80.0%)
Outside United States		3 (13.0%)		2 (20.0%)
Systolic blood pressure – median (IQR)	23	162.0 (140.0-173.0)	10	154.0 (138.0-181.0)
Diastolic blood pressure – median (IQR)	23	73.0 (68.0-92.0)	10	88.0 (83.0-91.0)
Medical history – no. (%)				
Congestive heart failure	23	0 (0.0%)	10	0 (0.0%)
Atrial fibrillation	23	1 (4.4%)	10	0 (0.0%)
Ischemic heart disease	23	4 (17.4%)	10	0 (0.0%)
Hypertension	22	20 (90.9%)	10	7 (70.0%)
Diabetes mellitus	23	6 (26.1%)	10	3 (30.0%)
Current tobacco smoker – no. (%)	23	5 (21.7%)	10	3 (30.0%)
Taking aspirin at presentation – no. (%)	23	14 (60.9%)	10	6 (60.0%)
Taking clopidogrel at presentation – no. (%)	23	1 (4.4%)	10	0 (0.0%)
Time to randomization (h) – mean (SD)	23	7.5 (3.4)	10	8.1 (2.2)
< 6h		8 (34.8%)		2 (20.0%)
≥ 6h		15 (65.2%)		8 (80.0%)
Qualifying event – no. (%)	23		10	
TIA		12 (52.2%)		5 (50.0%)
Ischemic stroke		11 (47.8%)		5 (50.0%)
Qualifying TIA baseline ABCD ² score – median (IQR)	12	5.0 (4.5-6.0)	5	5.0 (4.0-5.0)
Qualifying ischemic stroke baseline NIHSS score – median (IQR)	11	2.0 (0.0-3.0)	5	2.0 (2.0-3.0)

Differences in baseline characteristics between treatment groups were not significant: smallest p-value was for diastolic blood pressure with a p-value of 0.1081. Race is missing/unknown for N=1. Ethnicity is missing/unknown for N=1. ABCD² scale score is given only for TIA group (N=17) and NIHSS only for ischemic stroke group (N=16).

Abbreviation: IQR, interquartile range; US, United States; SD, standard deviation; TIA, transient ischemic attack; ABCD², age/blood pressure/clinical features/duration of symptoms/diabetes; NIHSS, National Institutes of Health Stroke Scale.

eTable 5. Baseline Characteristics of Patients with Major Hemorrhages in the As-Treated Study Population by Treatment Group

Characteristic	N	Clopidogrel plus Aspirin (N=21)	N	Aspirin (N=6)
Total number of events		21		6
Total patients		21		6
Time to hemorrhage (days) – median (IQR)	21	21.2 (2.6 – 51.3)	6	11.5 (6.5 – 23.4)
Age (yr) – median (IQR)	21	74.0 (67.0-84.0)	6	64.5 (46.0-82.0)
Female sex – no. (%)	21	11 (52.4%)	6	4 (66.7%)
Race – no. (%)	20		6	
White		16 (80.0%)		3 (50.0%)
Black		3 (15.0%)		2 (33.3%)
Asian		1 (5.0%)		0 (0.0%)
Other		0 (0.0%)		1 (16.7%)
Ethnicity – no. (%)	20		6	
Not US Hispanic		18 (90.0%)		6 (100.0%)
US Hispanic		2 (10.0%)		0 (0.0%)
Region – no. (%)	21		6	
United States		18 (85.7%)		5 (83.3%)
Outside United States		3 (14.3%)		1 (16.7%)
Systolic blood pressure – median (IQR)	21	162.0 (142.0-173.0)	6	175.0 (160.0-189.0)
Diastolic blood pressure – median (IQR)	21	73.0 (68.0-92.0)	6	90.0 (87.0-104.0)
Medical history – no. (%)				
Congestive heart failure	21	0 (0.0%)	6	0 (0.0%)
Atrial fibrillation	21	1 (4.8%)	6	0 (0.0%)
Ischemic heart disease	21	3 (14.3%)	6	0 (0.0%)
Hypertension	20	18 (90.0%)	6	4 (66.7%)
Diabetes mellitus	21	6 (28.6%)	6	3 (33.3%)
Current tobacco smoker – no. (%)	21	5 (23.8%)	6	1 (16.7%)
Taking aspirin at presentation – no. (%)	21	12 (57.1%)	6	3 (50.0%)
Taking clopidogrel at presentation – no. (%)	21	1 (4.8%)	6	0 (0.0%)
Time to randomization (h) – mean (SD)	21	7.5 (3.6)	6	8.5 (1.4)
Time to randomization – no. (%)	21		6	
< 6h		8 (38.1%)		0 (0.0%)
> 6h		13 (61.9%)		6 (100.0%)
Qualifying event – no. (%)	21		6	
TIA		11 (52.4%)		4 (66.7%)
Ischemic stroke		10 (47.6%)		2 (33.3%)
Qualifying TIA baseline ABCD ² score – median (IQR)	11	5.0 (5.0-6.0)	4	5.0 (4.5-5.5)
Qualifying ischemic stroke baseline NIHSS score –median (IQR)	10	2.0 (1.0-3.0)	2	1.5 (1.0-2.0)

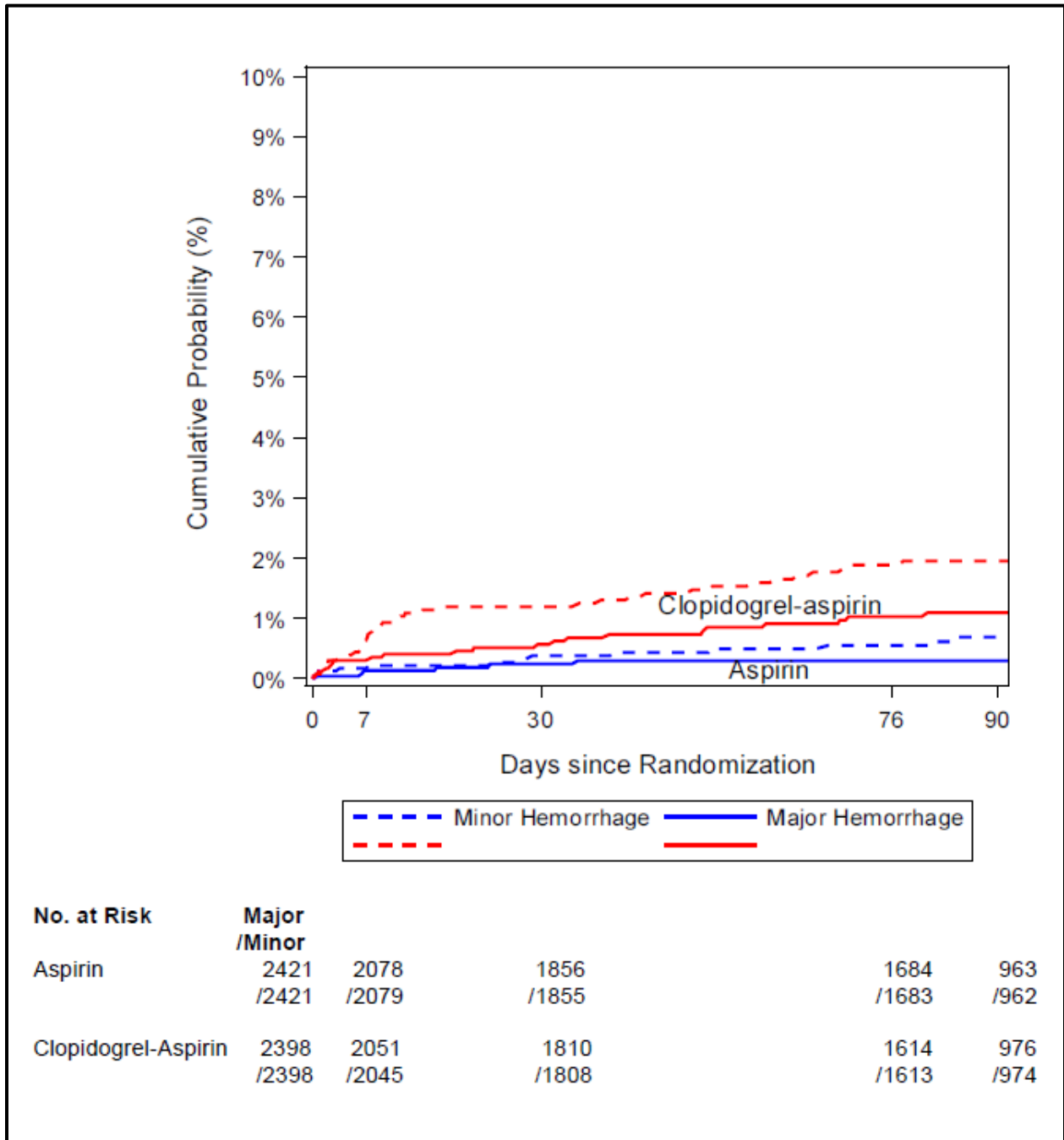
Differences in baseline characteristics between treatment groups were not significant at $p \leq 0.1$ except for diastolic blood pressure with a p-value of 0.09. Race is missing/unknown for N=1. Ethnicity is missing/unknown for N=1. ABCD² scale score given only for TIA group (N=15); NIHSS score given only for ischemic stroke group (N=12).

Abbreviation: IQR, interquartile range; US, United States; SD, standard deviation; TIA, transient ischemic attack; ABCD², age/blood pressure/clinical features/duration of symptoms/diabetes; NIHSS, National Institutes of Health Stroke Scale.

eTable 6: Bleeding Details for Minor Hemorrhages for the As-Treated Study Population

	Clopidogrel plus aspirin (N=2398)	Aspirin (N=2421)	Total
Asymptomatic intracerebral hemorrhage	1 (0.04%)	1 (0.04%)	2
Other asymptomatic intracranial hemorrhage	3 (0.12%)	1 (0.04%)	4
Conjunctival hemorrhage	0 (0.00%)	1 (0.04%)	1
Cutaneous	13 (0.54%)	1 (0.04%)	14
Epistaxis	3 (0.12%)	2 (0.08%)	5
Gastrointestinal	12 (0.50%)	4 (0.17%)	16
Genitourinary	3 (0.12%)	3 (0.13%)	6
Gum bleeding	1 (0.04%)	0 (0.00%)	1
Oral	2 (0.08%)	0 (0.00%)	2
Total	38	13	51

eFigure1. Kaplan Meier Curve of Major and Minor Hemorrhage in the As Treated Study Population



eAppendix. POINT Investigators

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