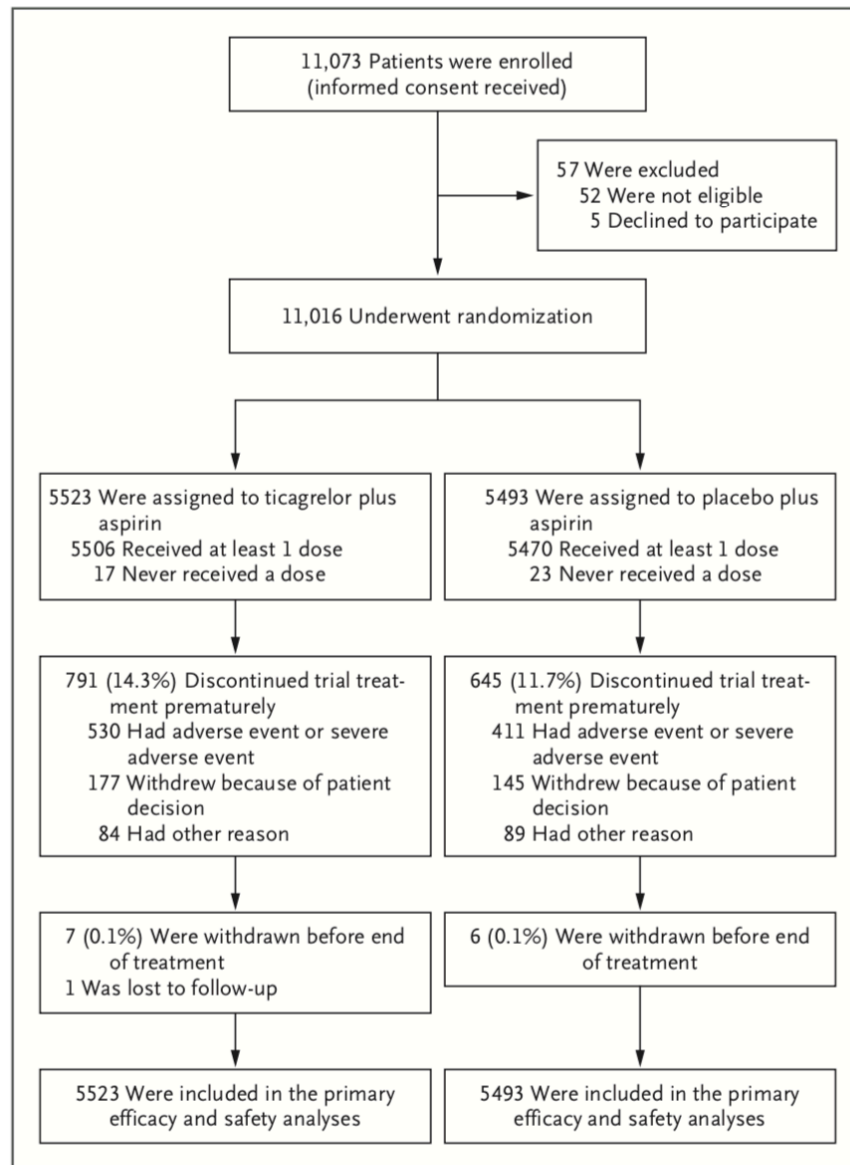


# Ticagrelor and Aspirin or Aspirin Alone in Acute Ischemic Stroke or TIA

S. Claiborne Johnston, M.D., Ph.D., Pierre Amarenco, M.D., Hans Denison, M.D., Ph.D., Scott R. Evans, Ph.D., Anders Himmelmann, M.D., Ph.D., Stefan James, M.D., Ph.D., Mikael Knutsson, Ph.D., Per Ladenvall, M.D., Ph.D., Carlos A. Molina, M.D., Ph.D., and Yongjun Wang, M.D., for the **THALES** Investigators\*

N Engl J Med 2020;383:207-17.

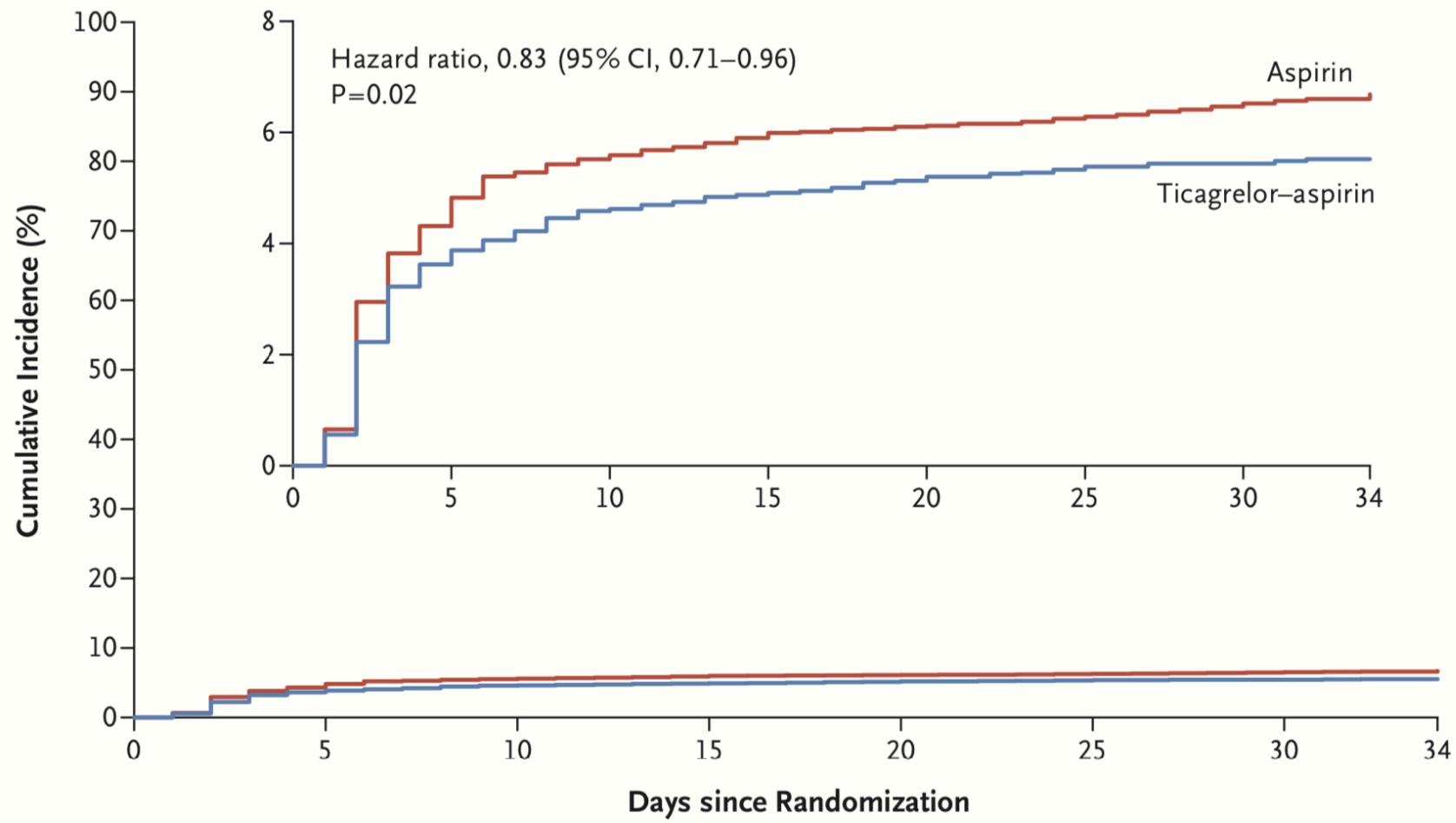


**Figure 1. Enrollment, Randomization, and Treatment.**

Discontinuations of the trial treatment owing to an adverse event or severe adverse event included discontinuations because of an outcome event.

Characteristic	Ticagrelor–Aspirin Group (N=5523)	Aspirin Group (N=5493)
Age — yr	65.2±11.0	65.1±11.1
Female sex — no. (%)	2108 (38.2)	2171 (39.5)
Race — no. (%)†		
White	2973 (53.8)	2948 (53.7)
Black	21 (0.4)	32 (0.6)
Asian	2353 (42.6)	2339 (42.6)
Other	176 (3.2)	174 (3.2)
Geographic region — no. (%)		
Asia or Australia	2373 (43.0)	2356 (42.9)
Europe	2814 (51.0)	2803 (51.0)
North America	12 (0.2)	11 (0.2)
Central or South America	324 (5.9)	323 (5.9)
Median blood pressure (IQR) — mm Hg		
Systolic	150.0 (135.0–163.0)	149.0 (134.0–163.0)
Diastolic	84.0 (79.0–91.0)	84.0 (78.0–91.0)
Median BMI (IQR)‡	25.9 (23.3–29.0)	25.7 (23.2–28.9)
Current smoker — no. (%)	1504 (27.2)	1428 (26.0)
Hypertension — no. (%)	4298 (77.8)	4222 (76.9)
Type 1 or type 2 diabetes mellitus — no. (%)	1589 (28.8)	1557 (28.3)
Previous ischemic stroke — no. (%)	901 (16.3)	914 (16.6)
Previous TIA — no. (%)	275 (5.0)	240 (4.4)
Use of agent before event — no. (%)		
Aspirin	754 (13.7)	679 (12.4)
Clopidogrel	75 (1.4)	75 (1.4)
Time from symptom onset to randomization <12 hr — no. (%)	1812 (32.8)	1776 (32.3)
Qualifying event — no. (%)		
Ischemic stroke	5032 (91.1)	4953 (90.2)
TIA	491 (8.9)	540 (9.8)
ABCD <sup>2</sup> score in patients with qualifying TIA — no. (%)§		
≤5	60 (1.1)	71 (1.3)
6–7	431 (7.8)	469 (8.5)
NIHSS score in patients with qualifying ischemic stroke — no. (%)¶		
≤3	3359 (60.8)	3312 (60.3)
>3	1673 (30.3)	1641 (29.9)

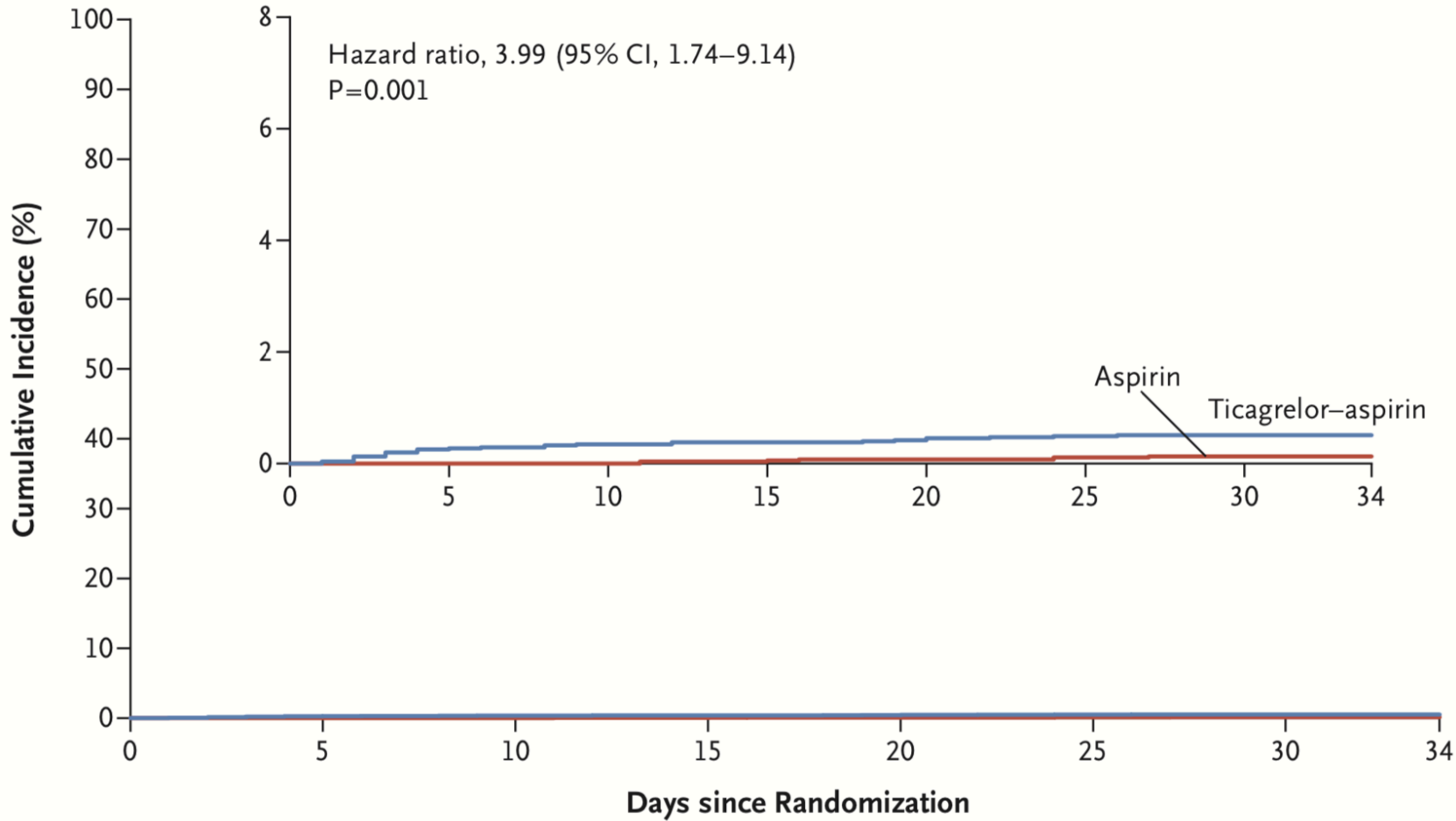
# A Probability of Stroke or Death



## No. at Risk

Ticagrelor-aspirin	5523	5314	5257	5241	5227	5215	5209	1091
Aspirin	5493	5253	5181	5159	5146	5138	5126	1135

**B Probability of Severe Bleeding**



**No. at Risk**

Ticagrelor-aspirin	5523	5495	5471	5467	5463	5457	5456	1146
Aspirin	5493	5486	5464	5459	5454	5451	5450	1216

Outcome	Ticagrelor–Aspirin Group (N=5523)		Aspirin Group (N=5493)		Hazard Ratio (95% CI)	P Value
	Patients with Event	Event Rate†	Patients with Event	Event Rate†		
	no. (%)	%	no. (%)	%		
<b>Primary outcome</b>						
Stroke or death	303 (5.5)	5.4	362 (6.6)	6.5	0.83 (0.71–0.96)	0.02
Stroke	284 (5.1)	5.1	347 (6.3)	6.3	0.81 (0.69–0.95)	
Death	36 (0.7)	0.6	27 (0.5)	0.5	1.33 (0.81–2.19)	
<b>Secondary outcomes</b>						
Ischemic stroke	276 (5.0)	5.0	345 (6.3)	6.2	0.79 (0.68–0.93)	0.004
Overall disability‡	1282 (23.8)	NA	1284 (24.1)	NA	0.98 (0.89–1.07)	0.61
<b>Safety outcomes</b>						
Severe bleeding	28 (0.5)	0.5	7 (0.1)	0.1	3.99 (1.74–9.14)	0.001
Intracranial hemorrhage or fatal bleeding	22 (0.4)	0.4	6 (0.1)	0.1	3.66 (1.48–9.02)	0.005
Fatal bleeding	11 (0.2)		2 (<0.1)			
Intracranial hemorrhage	20 (0.4)	0.4	6 (0.1)	0.1	3.33 (1.34–8.28)	0.01
Hemorrhagic stroke	10 (0.2)		2 (<0.1)			
Moderate or severe bleeding	36 (0.7)	0.6	11 (0.2)	0.2	3.27 (1.67–6.43)	<0.001
Premature permanent discontinuation of trial treatment owing to bleeding	152 (2.8)	2.9	32 (0.6)	0.6	4.80 (3.28–7.02)	<0.001

