Randomization and Follow-up of the Participants in the Modified Intention-to-Treat Population.

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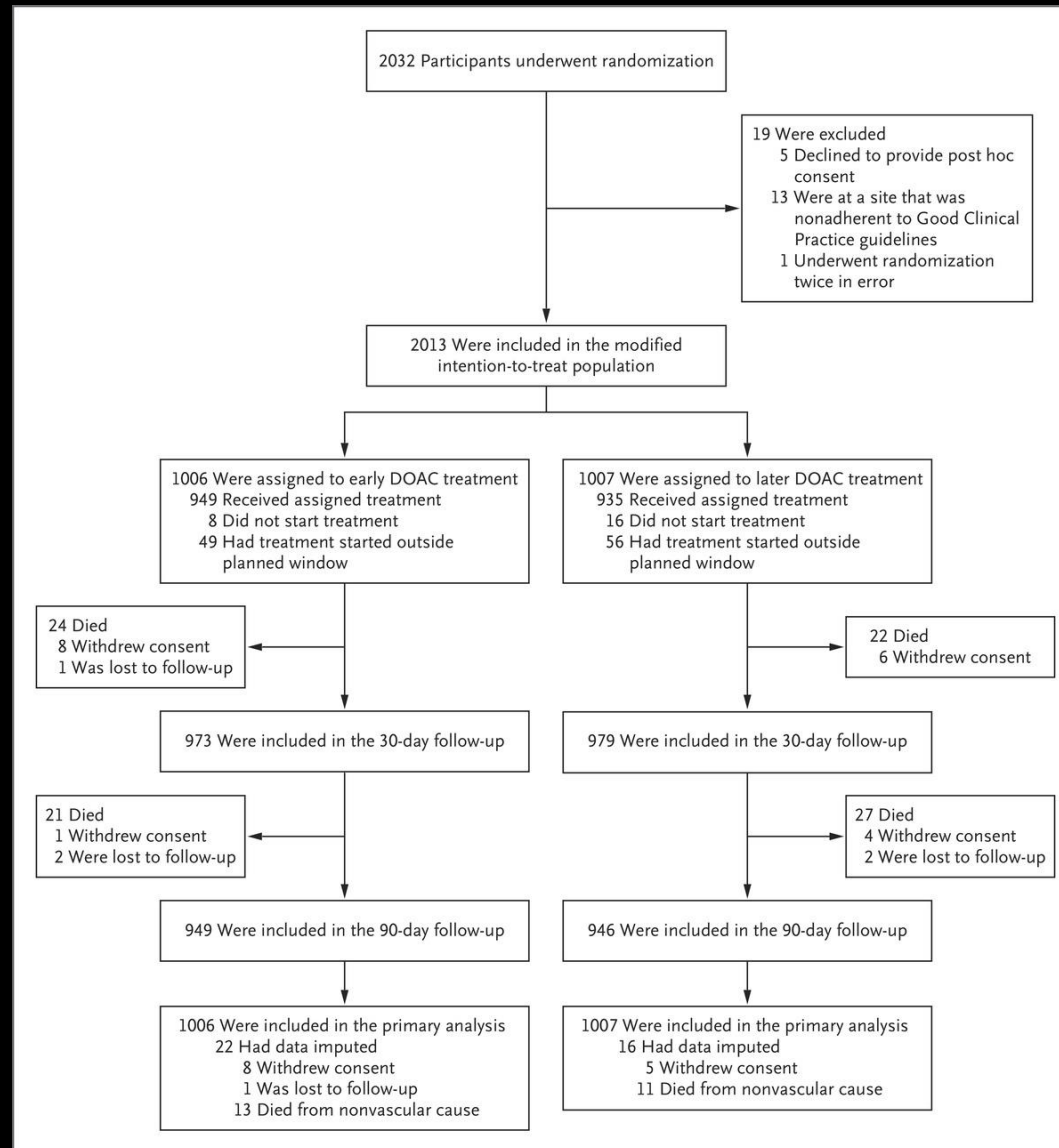
The Primary Composite Outcome and Its Components at 30 and 90 Days.

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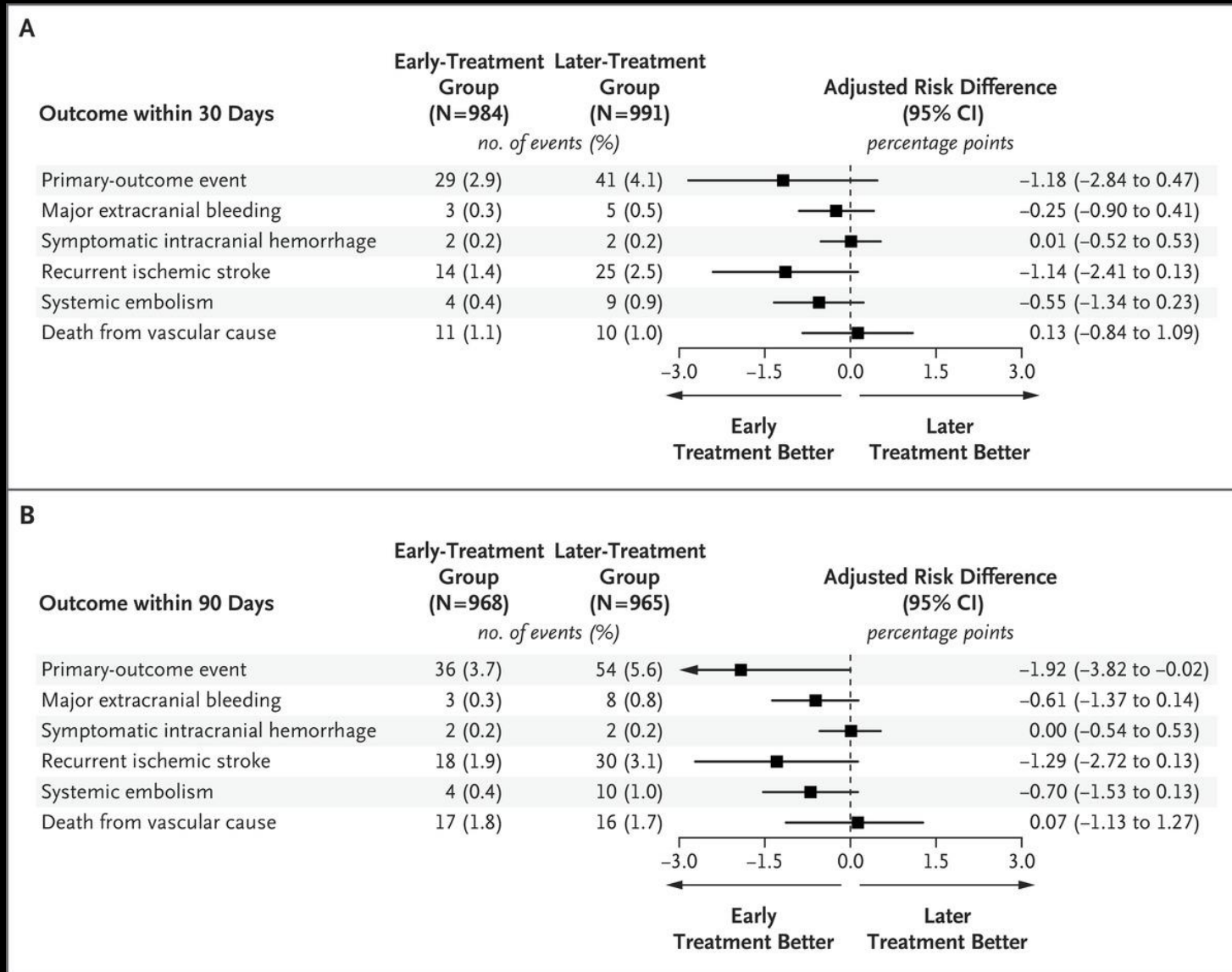
Characteristics of the Participants at Baseline.*

Table 1. Characteristics of the Participants at Baseline.*

Characteristic	Early-Treatment Group (N=1006)	Later-Treatment Group (N=1007)
Median age (IQR) — yr	77 (70–84)	78 (71–84)
Female sex — no. (%)	459 (45.6)	456 (45.3)
Region — no. (%)		
Central Europe	615 (61.1)	618 (61.4)
United Kingdom and Ireland	249 (24.8)	250 (24.8)
Israel	17 (1.7)	17 (1.7)
India	26 (2.6)	29 (2.9)
Japan	99 (9.8)	93 (9.2)
Medical history — no. (%)		
Ischemic stroke	128 (12.7)	140 (13.9)
Transient ischemic attack	45 (4.5)	51 (5.1)
Systemic embolism	19 (1.9)	31 (3.1)
Hypertension	690 (68.6)	673 (66.8)
Myocardial infarction	80 (8.0)	87 (8.6)
Diabetes	185 (18.4)	161 (16.0)
Median CHA_2DS_2-VASc score (IQR)†	5 (4–6)	5 (4–6)
Prestroke score on the modified Rankin scale — no./total no. (%)‡§		
0–2	889/1005 (88.5)	898/1006 (89.3)
3–5	116/1006 (11.5)	108/1007 (10.7)
Stroke severity according to infarct size — no. (%)		
Minor	378 (37.6)	374 (37.1)
Moderate	399 (39.7)	397 (39.4)
Major	229 (22.8)	236 (23.4)
NIHSS score — median (IQR)§		
At admission¶	5 (2–12)	5 (2–11)
At time of randomization	3 (1–6)	3 (1–6)
Initial treatment for stroke — no./total no. (%)¶		
Thrombolysis	391/986 (39.7)	377/987 (38.2)
Thrombectomy	207/986 (21.0)	232/987 (23.5)

* IQR denotes interquartile range.
† The CHA_2DS_2-VASc score (an assessment of the risk of stroke among patients with atrial fibrillation according to congestive heart failure, hypertension, age >75 years, diabetes, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, and sex) ranges from 0 to 9, with 0 indicating no risk and 9 indicating a very high stroke risk.
‡ Scores on the National Institutes of Health Stroke Scale (NIHSS) range from 0 to 42, with 0 indicating no deficits and a higher score indicating more severe neurologic symptoms.
§ Scores on the modified Rankin scale range from 0 (no symptoms) to 6 (death).
¶ Data on NIHSS scores at admission were missing for 25 participants in the early-treatment group and 24 participants in the later-treatment group.

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Primary and Secondary Efficacy Outcomes.

Table 2. Primary and Secondary Efficacy Outcomes.

Outcome	Early-Treatment Group (N = 1006)	Later-Treatment Group (N = 1007)	Adjusted Odds Ratio (95% CI)*
	no./total no. (%)		
Primary outcome: composite outcome at 30 days	29/1006 (2.9)†	41/1007 (4.1)†	0.70 (0.44 to 1.14)‡
Secondary outcomes at 30 days			
Major extracranial bleeding	3/984 (0.3)	5/991 (0.5)	0.63 (0.15 to 2.38)
Symptomatic intracranial hemorrhage	2/984 (0.2)	2/991 (0.2)	1.02 (0.16 to 6.59)
Recurrent ischemic stroke	14/984 (1.4)	25/991 (2.5)	0.57 (0.29 to 1.07)
Systemic embolism	4/984 (0.4)	9/991 (0.9)	0.48 (0.14 to 1.42)
Vascular death	11/984 (1.1)	10/991 (1.0)	1.12 (0.47 to 2.65)
Nonmajor bleeding	30/984 (3.0)	27/991 (2.7)	1.13 (0.67 to 1.93)
Modified Rankin scale score ≤2§	624/997 (62.6)	626/1000 (62.6)	0.93 (0.79 to 1.09)
Secondary outcomes at 90 days			
Major extracranial bleeding	3/968 (0.3)	8/965 (0.8)	0.40 (0.10 to 1.31)
Symptomatic intracranial hemorrhage	2/968 (0.2)	2/965 (0.2)	1.00 (0.15 to 6.45)
Recurrent ischemic stroke	18/968 (1.9)	30/965 (3.1)	0.60 (0.33 to 1.06)
Systemic embolism	4/968 (0.4)	10/965 (1.0)	0.42 (0.12 to 1.21)
Vascular death	17/968 (1.8)	16/965 (1.7)	1.04 (0.52 to 2.08)
Death from any cause¶	45/994 (4.5)	48/995 (4.8)	0.93 (0.61 to 1.43)
Nonmajor bleeding	39/968 (4.0)	41/965 (4.2)	0.94 (0.59 to 1.47)
Modified Rankin scale score ≤2§	659/989 (66.6)	654/994 (65.8)	0.93 (0.79 to 1.09)
Any serious adverse event	132/947 (13.9)	157/993 (15.8)	

* The analyses were stratified according to or adjusted for age, NIHSS score at admission, and infarct size. The widths of the 95% confidence intervals (CIs) were not adjusted for multiple comparisons and should therefore not be used for inference about treatment effects.
† For the estimation of the primary outcome, data on 22 participants in the early-treatment group and 16 participants in the later-treatment group were imputed.
‡ The between-group risk difference for the primary outcome was −1.18 percentage points (−2.84 to 0.47).
§ The modified Rankin scale was analyzed with the use of ordinal logistic regression, and the incidences and percentages shown are the values of 2 or less.
¶ One death occurred at day 99 after randomization; therefore, it is not counted in the secondary outcomes.

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