RESEARCH LETTER

One-Year Outcomes After Endovascular Treatment for Large Acute Ischemic Stroke: The TESLA Randomized Clinical Trial

Previous clinical trials demonstrated 90-day benefits for endovascular therapy in acute ischemic stroke with large-core infarcts, but protocols relied on advanced multimodal perfusion imaging.[1-4] Selection based on noncontrast computed tomography (NCCT) is an alternative that could broaden access to mechanical thrombectomy.[5] In the Thrombectomy for Emergent Salvage of Large Anterior Circulation Ischemic Stroke (TESLA) randomized clinical trial, which used an NCCT-alone selection strategy and compared endovascular therapy with medical management (MM) alone for patients with large-core infarcts, the primary outcome assessed at 90 days did not meet the criterion for statistical superiority.[6] Because recovery or decline after large-core stroke may extend beyond 90 days, this article presents the prespecified 1-year secondary efficacy and safety outcomes.

Supplemental content

Methods | TESLA was a multicenter, open-label, blinded end point randomized clinical trial conducted at 47 US stroke centers.[6] Eligible patients were aged 18 to 85 years, presenting within 24 hours of last known well with a National Institutes of Health Stroke Scale score of 6 or higher, internal carotid artery or middle cerebral artery occlusion, Alberta Stroke Program Early Computed Tomography Score (ASPECTS) of 2 to 5 on baseline NCCT, and premorbid modified Rankin Scale (mRS) score of 0 to 1. Participants were randomized 1:1 to undergo intra-arterial thrombectomy (IAT) plus best MM vs MM

Table. One-Year Outcomes in the Thrombectomy for Emergent Salvage of Large Anterior Circulation Ischemic Stroke (TESLA) Trial

Characteristic/outcome	No. (%)		Effect estimate (95% CI or CrI)	*P* value/posterior probability[a]
	Intra-arterial thrombectomy (n = 144)	Medical management (n = 133)		
Primary 1-year end point				
Utility-weighted mRS score, mean (SD)	3.65 (0.22)	2.78 (0.17)	MD: 1.18 (0.42 to 1.93)	Posterior probability: .999
Secondary functional end points				
mRS 0-2 (functional independence)	34 (23.6)	9 (6.8)	RD: 16.8% (8.7% to 25.0%)	<.001
mRS 0-3 (independent ambulation)	51 (35.4)	24 (18.0)	RD: 17.4% (7.2% to 27.6%)	<.001
mRS ordinal shift			cOR: 1.82 (1.16 to 2.86)	.005
Categorical mRS distribution				
0 (Complete recovery)	9 (6.3)	0		
1	9 (6.3)	3 (2.3)		
2	16 (11.1)	5 (3.8)		
3	17 (11.8)	15 (11.3)		
4	21 (14.6)	31 (23.3)		
5 or 6 (Severe disability/death)	72 (50.0)	78 (58.6)		
All-cause mortality at 1 y	62 (43.1)	62 (46.6)	RD: −3.5% (−15.3% to 8.2%)	.42
EQ-5D-5L index score, mean (SD) [total No.]	60.3 (28.7) [79]	49.3 (24.2) [66]	MD: 10.0 (5.0 to 21.0)	.003
Sensitivity models on 1-y utility-weighted mRS, mean (SD) [total No.]				
Per-protocol population	3.69 (0.24) [117]	2.90 (0.20) [110]	MD: 1.17 (0.32 to 2.02)	Posterior probability: .996
Core-lab ASPECTS adjudicated	3.45 (3.72) [125]	2.08 (2.78) [107]	MD: 1.37 (0.53 to 2.22)	.002
Multivariable analysis[b]	3.29 (3.70) [144]	2.09 (2.80) [131]	MD: 1.09 (0.37 to 1.81)	.003
Last observation carried forward	3.32 (3.64) [152]	2.28 (2.94) [147][c]	MD: 1.04 (0.28 to 1.79)	.007
Tipping-point analysis[d]	3.11 (3.68) [152]	2.33 (3.18) [148]	MD: 0.79 (0.01 to 1.57)	.05

Abbreviations: ASPECTS, Alberta Stroke Program Early Computed Tomography Score; cOR, common odds ratio; CrI, credible interval; EQ-5D-5L, European Quality of Life 5 Dimensions, 5 Levels; MD, mean difference; mRS, modified Rankin Scale; RD, risk difference.

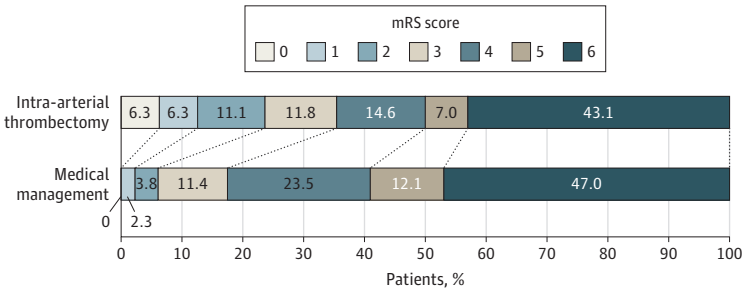
[a] *P* values for continuous end points were derived from the Wilcoxon rank-sum test; binary end points were evaluated using rate differences, with 95% CIs calculated by normal approximation and compared using χ^2 or Fisher exact tests. *P* values for secondary end points were exploratory and unadjusted for multiplicity.

[b] Performed while adjusting for baseline site-adjudicated ASPECTS, age, and presence of diabetes.

[c] One participant withdrew consent after 24 hours and did not have any follow-up mRS.

[d] Assuming that 8 of 8 participants lost to follow-up in the intra-arterial thrombectomy group vs 8 of 15 in the medical management group had a 1-year utility-weighted mRS of 0 (severe disability/death).

Figure. Horizontal Stacked Bar Chart of 1-Year Functional Outcomes



Proportion of patients across mRS categories (ranging from 0 [no symptoms] to 6 [death]) within the intention-to-treat population with complete 1-year data (intra-arterial thrombectomy, n = 144; medical management, n = 133).

mRS indicates modified Rankin Scale.

alone. All patients provided informed consent. The trial protocol was previously published.[6] TESLA followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

The primary 1-year end point was the mean utility-weighted mRS score (range, 0-10; higher scores indicate preferable functional states), calculated via standard utility multipliers.[7] Prespecified secondary end points assessed at 1 year included functional independence (mRS 0-2), independent ambulation (mRS 0-3), mRS ordinal shift, European Quality of Life 5 Dimensions, 5 Levels (EuroQol EQ-5D-5L) index score (range, 0-100; higher scores indicate better quality of life),[8] and all-cause mortality.

Analyses evaluated the intention-to-treat population with 1-year data and a per-protocol cohort. The main outcome used a baseline ASPECTS-adjusted bayesian model; a posterior probability of .975 or greater defined statistical superiority.

Exploratory frequentist secondary analyses used χ^2 or Fisher exact tests for categorical variables, Wilcoxon rank-sum tests for continuous distributions, and a proportional odds model for ordinal shift. Sensitivity analyses (eMethods in Supplement 1) included per protocol; core-lab ASPECTS adjudication; multivariable adjustment for age, diabetes, and site-adjudicated ASPECTS; last observation carried forward; and tipping-point analysis. A 2-sided $P < .05$ indicated statistical significance. Analyses were performed using SAS version 9.4 (SAS Institute).

Results | Of 302 randomized patients, 300 were included in the intention-to-treat cohort (152 IAT; 148 MM).[6] Complete 1-year functional data were available for 144 patients in the IAT group and 133 in the MM group; 23 individuals were lost to follow-up or withdrew consent. Among the 277 participants, baseline profiles were balanced, although the IAT group was slightly younger (median [IQR] age, 66 [54-74] vs 68 [59.5-76.5] years) and had a higher proportion of diabetes (28.5% vs 16.8%).

The primary 1-year end point, mean utility-weighted mRS score, was higher in the IAT vs MM group (3.65 vs 2.78), a bayesian adjusted mean difference of 1.18 points (95% credible interval, 0.42-1.93; posterior probability of superiority, .999) (**Table**).

Functional independence was 23.6% (34 of 144) in the IAT group vs 6.8% (9 of 133) in the MM group (risk difference [RD], 16.8% [95% CI, 8.7%-25.0%]; $P < .001$; risk ratio, 3.49 [95% CI, 1.74-7.00]). Independent ambulation occurred in 35.4% of the IAT vs 18.0% of the MM cohort (RD, 17.4% [95% CI, 7.2%-27.6%]; $P < .001$). Ordinal mRS shift favored IAT over MM (common odds ratio, 1.82 [95% CI, 1.16-2.86]; $P = .005$) (**Figure**).

The mean (SD) EQ-5D-5L score was 60.3 (28.7) in the IAT vs 49.3 (24.2) in the MM group ($P = .003$). All-cause mortality at 1 year was 43.1% in the IAT vs 46.6% in the MM group (RD, -3.5% [95% CI, -15.3% to 8.2%]; $P = .42$).

Sensitivity analyses for the primary outcome (Table) confirmed the direction of the primary findings.

Discussion | This extended follow-up of the TESLA trial demonstrated that mechanical thrombectomy for large anterior circulation infarcts selected by NCCT resulted in improved functional outcomes and higher patient-reported quality of life at 1 year compared with MM alone.

Although functional independence in the IAT group numerically increased between 90 days and 1 year, it declined in the MM group, which may reflect the severe natural history of untreated large-core tissue decay, delayed deconditioning, unmeasured rehabilitation intensity difference between groups, or baseline imbalances, such as age.

These exploratory observations complement the 12-month data reported in the SELECT2 and TENSION trials, supporting that early large-core reperfusion may facilitate prolonged neuroplastic remodeling up to 1 year post stroke.[9,10]

Limitations include potential performance bias from unblinded postprocedural rehabilitation intensity and asymmetric 1-year attrition. These findings are exploratory and descriptive because the preplanned primary 90-day end point of the trial was neutral, and secondary end points were not adjusted for multiplicity.[6] External validity to lower-resource regions remains unestablished given that the trial occurred within highly optimized US stroke networks. Nevertheless, these descriptive data suggest longer-term benefit associated with thrombectomy in large-core stroke, indicating that an NCCT-alone selection paradigm warrants further study as a lower-barrier strategy for global stroke systems.

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