

Mechanical Thrombectomy and Final Infarct Volume in Medium or Distal Vessel Occlusion Stroke

A Post Hoc Analysis of a Randomized Clinical Trial

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 Supplemental content

IMPORTANCE Imaging-based end points may enhance the understanding of endovascular treatment (EVT) outcomes in patients with medium- or distal-vessel occlusion stroke.

OBJECTIVE To investigate the outcomes of endovascular treatment (EVT) in addition to best medical treatment (BMT) compared with BMT alone on the volume of brain tissue initially at risk preserved in patients with a medium or distal vessel occlusion stroke.

DESIGN, SETTING, AND PARTICIPANTS Post hoc imaging analysis of the Endovascular Treatment for Stroke Due to Occlusion of Medium or Distal Vessels (DISTAL) trial, a multicenter randomized clinical trial with blinded end point assessment conducted at 55 hospitals in 11 countries from December 2021 through July 2024, with clinical follow-up at 90 days. Patients with baseline perfusion imaging and follow-up imaging at 24 hours were included.

INTERVENTIONS EVT plus BMT compared with BMT alone.

MAIN OUTCOMES AND MEASURES Primary outcome was calculated as the difference in volume of tissue at risk and the final infarct volume divided by the tissue at risk (change in Vrel). We defined a Vrel of 0.8 or greater as a good imaging outcome, meaning that at least 80% of the brain tissue initially at risk was not infarcted at 24 hours. Additionally, the association between brain tissue preserved and clinical outcome at 90 days was investigated.

RESULTS From the 447 patients (252 [56.4%] male; median [IQR] age, 77.0 [68.0-84.0] years) included in this secondary analysis, 226 received EVT plus BMT and 221 received BMT alone. Median (IQR) time of the follow-up imaging was 22.9 (19.2-25.5) hours. Median (IQR) Time to maximum more than 6 seconds (Tmax6) volume was 34.0 (20.0-50.0) mL. Median follow-up infarct volume was 7.0 (1.0-22.9) mL. The median (IQR) change in absolute volume in the EVT plus BMT group was 23.6 (5.7-38.9) mL and 14.8 (0-30.3) mL in the BMT group. Median (IQR) change in Vrel was 0.8 (0.2-1.0) in the EVT plus BMT group and 0.6 (0-0.9) in the BMT group. Odds for reaching a change in Vrel of 0.8 or greater were higher in the EVT plus BMT group compared with BMT (adjusted odds ratio [aOR], 1.6; 95% CI, 1.1-2.3) and with successful reperfusion compared with no successful reperfusion (aOR, 2.5; 95% CI, 1.3-4.8). Patients with a change in Vrel of 0.8 or greater had a better clinical outcome at 90 days.

CONCLUSIONS AND RELEVANCE In this post hoc analysis of the DISTAL trial data, EVT plus BMT was associated with a higher likelihood of achieving a good imaging outcome compared with BMT alone. A good imaging outcome was associated with a better clinical outcome in both treatment groups.

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JAMA Neurol. 2026;83(6):537-543. doi:10.1001/jamaneurol.2026.0805
Published online April 20, 2026. Corrected on June 15, 2026.

Endovascular treatment (EVT) is beneficial in patients with an acute ischemic stroke due to large vessel occlusion (LVO).¹⁻³ However, recent randomized clinical trials failed to show a benefit of EVT plus best medical treatment (BMT) for medium or distal vessel occlusions (MDVO).^{4,5} Clinical scales such as the modified Rankin Scale (mRS) at 90 days might be too crude to capture a clinically relevant difference in patients with milder stroke deficits.^{6,7}

The aim of this post hoc analysis was to assess the association between EVT and imaging outcomes in patients with MDVO stroke. We estimated the association of EVT in addition to BMT compared with BMT alone on the volume of preserved brain tissue between baseline and follow-up imaging in the population of the Endovascular Treatment for Stroke Due to Occlusion of Medium or Distal Vessels (DISTAL) trial. We also investigated the association between successful reperfusion in the EV plus BMT group and imaging outcomes and the association between imaging outcome, treatment group, and clinical outcome at 90 days.

Methods

Patient Selection

The DISTAL trial was an investigator-initiated, international, randomized, 2-group, assessor-blinded trial investigating whether EVT plus BMT compared with BMT alone is superior for reduction of disability and dependency in patients with an acute ischemic stroke due to isolated MDVO.⁴ The trial protocol (available in [Supplement 1](#)) was approved by Ethikkommission Nordwest- und Zentralschweiz and locally at each institution and has been published previously.⁸ Written informed consent was obtained from all the participants or their legally authorized representatives either at the time of enrollment or post hoc (emergency consent procedures), according to country-specific requirements. In this post hoc analysis we included patients from the DISTAL trial with baseline perfusion imaging (computed tomography [CT] or magnetic resonance imaging [MRI]) and available follow-up imaging (CT or MRI at 24 hours). We excluded 59 patients with no available perfusion scans at baseline, 8 with missing follow-up images, and 29 with other incompatibility issues (eFigure 1 in [Supplement 2](#)).

Perfusion Postprocessing and Segmentation

Perfusion data were processed using RapidAI commercial software (Rapid CTP, iSchemaView, Inc; hereafter referred to as AI software).^{9,10} The area corresponding to the Tmax6 threshold was automatically segmented and extracted as a binary segmentation. The segmentations were manually corrected for artifacts (lesion of the contralateral side or other nonocclusive territories). If perfusion volumes could not be processed by automated software (eg, perfusion raw data not available) we manually segmented the available perfusion maps (using Syngo.via; Siemens Healthineers) and calculated volumes using 3D Slicer.¹¹ For the follow-up images, the available MRI or native CT were segmented and volumes were calculated. We segmented the infarct volume at follow-up with algorithmic meth-

Key Points

Question What is the outcome of endovascular treatment (EVT) in addition to best medical treatment (BMT) compared with BMT alone on the volume of brain tissue at risk preserved in patients with a medium or distal vessel occlusion stroke?

Findings In this post hoc analysis of a randomized clinical trial including 447 patients, the likelihood of achieving a good imaging outcome was higher in the EVT plus BMT group compared with the BMT alone group. The good imaging outcome was associated with less dependency and disability at 90 days in both treatment groups.

Meaning These findings suggest that imaging-based end points may improve the assessment of the treatment outcomes of EVT in patients with medium- or distal-vessel occlusion stroke.

ods and manually corrected in case of discrepancies. Hemorrhages were included in the volumetric analysis and incorporated into the total stroke volume as infarcted tissue. The segmentations and visual corrections were made by 2 blinded neuroradiology fellows (A.A. and E.C.) and were corrected by an experienced neuroradiologist (M.-N.P.). Segmentation examples are available in the [Figure](#). Perfusion details are reported in eTable 1 in [Supplement 2](#).

Volumetric Analysis

We measured the tissue at risk volume in mL at baseline using Tmax6 and the infarct volume on follow-up imaging at 24 hours. To measure the volume of the manually segmented and/or corrected images, we summed the number of segmented pixels and multiplied it by the pixel size. When the perfusion did not need corrections, we used the automatically calculated volume directly from the AI software map. We calculated the absolute (Vabs) and the relative (Vrel) difference in volume of tissue at risk and the final infarct. We used the relative values to minimize the influence of the outliers (very large volumes) and standardize by the baseline volume at risk. Change in Vabs (mL) = volume of tissue at risk (baseline perfusion) – volume of infarct (24 hours follow-up) and change in Vrel = change in Vabs ÷ volume of tissue at risk (baseline perfusion). In the 14 cases that had a Tmax6 of 0 and developed an infarct at follow-up, we set the relative difference to –1 to address the issue of infinite values.

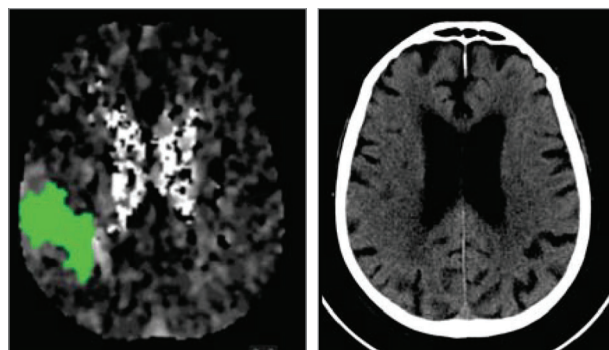
Statistical Analysis

Statistical analysis was performed using R version 4.4.1 (R Project for Statistical Computing). Baseline, treatment, and outcome data are described by treatment group as median with IQR for continuous variables and counts with frequencies for categorical variables. *P* values were derived for the fixed effects in the regression models and all tests were 2-sided with significance set at *P* > .05.

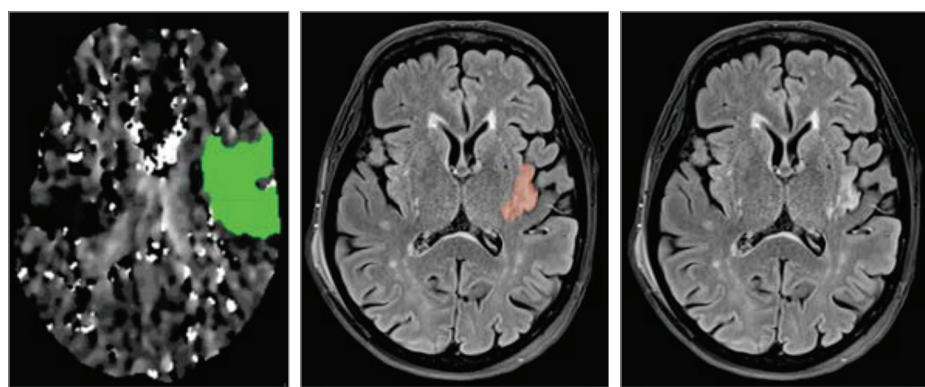
To assess the change in Vrel, we used a hurdle model. Change in Vrel is a continuous variable with a skewed distribution and a ceiling at 1, indicating the perfect outcome with no brain tissue loss. After consulting expert opinion, we defined change in Vrel of 0.8 or more as a good imaging outcome, meaning more than 80% of the initial brain at risk was

Figure. Brain Image Examples of Volume Measurements in 2 Different Cases

A CT Tmax6 map and follow-up CT for first case



B CT Tmax6 map and follow-up MRI with and without segmentation for second case



A, No infarct on follow-up images, with relative difference in volume of tissue, 1 and absolute difference in volume of tissue, 23 mL. Image at left, CT RapidAI Tmax6 map with a lesion volume of 23 mL; image at right, follow-up CT with no infarct. B, Case presenting infarct signs on the follow-up images, with Tmax6 threshold automatically segmented without manual corrections; relative difference in volume of tissue, 0.69 and absolute difference in volume of tissue, 25 mL. Image at left, RapidAI Tmax6 map with a lesion volume of 36 mL; middle image, follow-up MRI with a segmentation and a lesion volume of 11 mL; image at right, follow-up MRI without the segmentation. CT indicates computed tomography; MRI, magnetic resonance imaging; Tmax, time to maximum (measure of delayed perfusion on perfusion imaging).

not infarcted after 24 hours. The model consisted of 2 components. First, a logistic regression estimated the probability of achieving change in Vrel of 0.8 or less. The fixed effect of interest was the treatment group (as randomized). The model was adjusted for predefined covariates age, sex, National Institutes of Health Stroke Scale (NIHSS) on admission, occlusion location, and intravenous thrombolysis. Results were presented as adjusted odds ratios (aOR) with 95% CIs. Second, for patients with change in Vrel less than 0.8, a linear regression was applied to the log-transformed values of change in Vrel ($1 - \text{change in Vrel}$). The fixed effect of interest was again treatment group, and the same adjustments as the first model were applied. Results were presented as adjusted regression coefficients (β) with 95% CIs. The same model was repeated in the patients in the EVT plus BMT group with successful reperfusion (ie, modified thrombolysis in cerebral infarction [mTICI] $\geq 2b$) compared with no successful reperfusion (ie, mTICI 0-2a) as variable of interest.

The association between brain tissue preserved, treatment group, and mRS at 90 days was assessed by fitting a mixed-effects ordinal regression model for outcome mRS at 90 days with categories 5 and 6 collapsed after accepting the proportional odds assumption with the Brant test. The fixed effect of interest was the interaction between treatment group and change in Vrel (≥ 0.8 vs < 0.8). The model was adjusted for the covariates mentioned previously plus prestroke mRS. We report the adjusted common odds ratio (acOR) with 95% CI.

Because CT may underestimate the follow-up infarct volume at 24 hours compared with MRI, we performed a sensitivity analysis investigating the potential association between the follow-up imaging modality and the primary analysis. For statistical purposes, we additionally performed sensitivity analyses using alternative change in Vrel thresholds of 0.6 and 1.0. Details of the additional sensitivity analyses are described in eTables 2 and 3 in [Supplement 2](#).

Results

A total of 447 patients (252 [56.4%] were male; median [IQR] age, 77.0 [68.0-84.0] years) with baseline perfusion imaging and follow-up imaging at 24 hours met the inclusion criteria for this post hoc analysis. Prestroke mRS was 0 to 2 in 413 cases (92.6%) and median (IQR) NIHSS on admission was 6.0 (5.0-9.0) in the BMT group and 6.0 (4.2-9.0) in the BMT plus EVT group. Baseline and treatment characteristics, as well as outcomes are presented in [Table 1](#) and imaging outcomes are presented in [Table 2](#). Follow-up imaging was performed at a median (IQR) of 22.9 (19.2-25.5) hours after randomization. The most common baseline modality was CT (412 cases [92.2%]), and 435 of the perfusion scans (97.3%) were analyzed with RapidAI. Follow-up imaging consisted of CT in 320 cases (71.6%).

Table 1. Characteristics of the Patient Population of the Post Hoc Analysis

Characteristic	Patients, No. (%)		
	Overall (N = 447)	BMT (n = 221)	BMT plus EVT (n = 226)
Age, median (IQR), y	77.0 (68.0-84.0)	78.0 (68.0-84.0)	77.0 (68.0-83.0)
Sex			
Female	195 (43.6)	99 (44.8)	96 (42.5)
Male	252 (56.4)	122 (55.2)	130 (57.5)
Prestroke mRS			
0-1	362 (81.2)	171 (77.7)	191 (84.5)
2	51 (11.4)	28 (12.7)	23 (10.2)
3-4	33 (7.4)	21 (9.5)	12 (5.3)
NIHSS on admission, median (IQR)	6.0 (5.0-9.0)	6.0 (5.0-9.0)	6.0 (4.2-9.0)
Absence of infarct signs in the baseline imaging	416 (94.3)	202 (92.7)	214 (96.0)
Occlusion site			
A1	1 (0.2)	1 (0.5)	0
A2	13 (2.9)	3 (1.4)	10 (4.4)
A3	14 (3.1)	5 (2.3)	9 (4.0)
M1	1 (0.2)	0	1 (0.4)
M2	205 (45.9)	96 (43.4)	109 (48.2)
M3	113 (25.3)	64 (29.0)	49 (21.7)
M4	3 (0.7)	0	3 (1.3)
No occlusion	1 (0.2)	1 (0.5)	0
P1	24 (5.4)	10 (4.5)	14 (6.2)
P2	56 (12.5)	31 (14.0)	25 (11.1)
P3	16 (3.6)	10 (4.5)	6 (2.7)
IVT	289 (64.7)	147 (66.5)	142 (62.8)
Time LSW to randomization, median (IQR), h	4.2 (2.3-9.8)	4.4 (2.4-10.7)	3.9 (2.3-9.0)
Time LSW to imaging, median (IQR), h	3.7 (1.6-9.4)	3.7 (1.7-10.3)	3.6 (1.6-9.1)
Time LSW to puncture, median (IQR), h	NA	NA	5.2 (3.0-11.0)
Time imaging to puncture, median (IQR), min	NA	NA	69.0 (53.8-93.2)
Time admission to puncture, median (IQR), min	NA	NA	85.5 (64.2-111.0)
General anesthesia	NA	NA	96 (49.0)
No. of EVT passes, median (IQR)	NA	NA	1.0 (1.0-2.0)
Final mTICI (core-lab) (%)	NA	NA	
mTICI0	NA	NA	23 (12.0)
mTICI1	NA	NA	1 (0.5)
mTICI2a	NA	NA	17 (8.9)
mTICI2b	NA	NA	35 (18.3)
mTICI2c	NA	NA	49 (25.7)
mTICI3	NA	NA	66 (34.6)
Successful reperfusion	NA	NA	150 (78.5)
Vessel perforation	NA	NA	7 (3.6)
mRS at 90 d, median (IQR)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	2.0 (1.0-3.0)
mRS at 90 d			
0	NA	39 (17.8)	28 (12.4)
1	NA	42 (19.2)	53 (23.5)
2	NA	42 (19.2)	51 (22.6)
3	NA	44 (20.1)	39 (17.3)
4	NA	22 (10.0)	21 (9.3)
5-6	NA	30 (13.7)	34 (15.1)

Abbreviations: A1/A2/A3, segments of the anterior cerebral artery; BMT, best medical treatment; EVT, endovascular therapy; IVT, intravenous thrombolysis; LSW, last seen well; M1/M2/M3/M4, segments of the middle cerebral artery; mRS, modified Rankin scale; mTICI, modified thrombolysis in cerebral infarction; NA, not applicable; NIHSS, national institutes of health stroke scale; P1/P2/P3, segments of the posterior cerebral artery.

Volumetric Analysis Results

Median (IQR) Tmax6 volume was 34 (20-50) mL. Median follow-up infarct volume was 7 (1.0-22.9) mL. Median (IQR)

change in Vrel was 0.8 (0.2-1.0) in the EVT plus BMT group and 0.6 (0-0.9) in the BMT group. Overall, the median (IQR) change in Vabs was 18.8 (1.5-36.0) mL. The median (IQR)

Table 2. Delta Analysis and Outcomes

	Overall (N = 447)	BMT (n = 221)	BMT+EVT (n = 26)
Modality baseline (%)			
Other	5 (1.1)	0	5 (2.2)
RAPID	405 (90.6)	203 (91.9)	202 (89.4)
RAPID MRI	30 (6.7)	15 (6.8)	15 (6.6)
Syngo	7 (1.6)	3 (1.4)	4 (1.8)
Modality follow-up (%)			
CT	320 (71.6)	153 (69.2)	167 (73.9)
MRI DWI	16 (3.6)	9 (4.1)	7 (3.1)
MRI FLAIR	107 (23.9)	55 (24.9)	52 (23.0)
MRI T2	4 (0.9)	4 (1.8)	0
Time point of follow-up image median IQR, h	22.9 (19.2 to 25.5)	22.7 (19.8 to 25.5)	23.2 (17.9 to 25.5)
Volume Tmax 6, median (IQR), mL	34.0 (20.0 to 50.0)	31.0 (17.0 to 47.0)	36.0 (22.0 to 53.5)
Volume follow-up infarct, median (IQR), mL	7.0 (1.0 to 22.9)	8.6 (1.6 to 26.4)	5.1 (0.7 to 19.8)
Absolute difference in Vabs, median (IQR), mL	18.8 (1.5 to 36.0)	14.8 (0.0 to 30.3)	23.6 (5.7 to 38.9)
Relative difference in Vrel, median (IQR)	0.7 (0.1 to 1.0)	0.6 (0.0 to 0.9)	0.8 (0.2 to 1.0)
Randomization (BMT plus EVT over BMT alone)	1.566 (1.064 to 2.309) ^a	NA	0.042 (-0.172 to 0.257) ^b
EVT group; final mTICI (2b-3 over 0-2a)	2.461 (1.298 to 4.767) ^c	NA	-0.105 (-0.464 to 0.255) ^d

Abbreviations: BMT, best medical treatment; CT, computed tomography; DWI, diffusion-weighted imaging; FLAIR, fluid-attenuated inversion recovery; EVT, endovascular therapy; MRI, magnetic resonance imaging; mTICI, modified thrombolysis in cerebral infarction; T2, T2-weighted magnetic resonance sequence; Tmax, time to maximum (measure of delayed perfusion on perfusion imaging); Vabs, absolute difference in volume; Vrel, relative difference in volume.

^a Logistic regression, aOR (95% CI); $P = .01$.

^b Linear regression, adjusted β (95% CI); $P = .70$.

^c Logistic regression, aOR (95% CI); $P = .006$.

^d Linear regression, adjusted β (95% CI); $P = .57$.

change in Vabs was 23.6 (5.7-38.9) mL in the EVT plus BMT group and 14.8 (0-30.3) mL in the BMT group. The odds for reaching a good imaging outcome were higher in the EVT plus BMT group compared with BMT (aOR, 1.57; 95% CI, 1.06-2.31) and in patients with successful reperfusion compared with patients without successful reperfusion (aOR, 2.46; 95% CI, 1.30-4.77). The population with change in Vrel 0.8 or greater had a better clinical outcome at 90 days compared with patients with less brain tissue preserved (acOR, 2.35; 95% CI, 1.41-3.92) and lower odds of 3-month mortality (acOR, 0.29; 95% CI, 0.13-0.61), independent of treatment allocation. The primary and secondary analysis outcomes are presented in Table 2. eTable 5 in [Supplement 2](#) shows the adjusted models and eFigure 2 in [Supplement 2](#) shows clinical outcomes. Our sensitivity analysis showed that CT might provide lower follow-up infarct volumes, but follow-up modality had no association with the results of the primary analysis (eTables 2 and 3 in [Supplement 2](#)).

Discussion

In our post hoc analysis of a randomized clinical trial, EVT plus BMT was associated with greater brain tissue preservation, with a higher median change in Vrel, and with significantly higher odds of achieving a good imaging outcome compared with BMT alone. Successful reperfusion in the EVT plus BMT group was also associated with better imaging outcomes. Good imaging outcome was associated with better clinical outcomes at 90 days in both groups. Sensitivity analyses suggested that CT follow-up may underestimate infarct volumes but did not

change our primary findings. The baseline characteristics in our post hoc analysis were in line with those in the DISTAL trial, despite our reduced sample size due to the imaging requirements. The median age was 77 years, the distribution of pre-stroke functional status (mRS 0-2) was 92.6%, and median NIHSS on admission was 6 in both studies, indicating similar stroke severity at baseline.

The recent MDVO trials, which have failed to show a benefit of EVT plus BMT for MDVO stroke, used as outcomes only clinical end points.^{4,5,7,12} This post hoc analysis emphasizes the value of imaging-based end points, such as change in Vrel, in assessing the treatment effect in MDVO trials. As there are continuous discussions about the role of mRS as an end point in mild strokes, our post hoc analysis provides an alternative end point for MDVO strokes.^{13,14} This imaging end point is easily quantifiable and can be objectively measured, thus providing a surrogate for clinical end points such as the mRS. As subtle changes in clinical function and especially in neurocognitive behavior are not easily measured, quantifying the preserved brain tissue in addition to dedicated clinical outcomes, such as the utility weighted mRS or the Canadian Outcome Scale for Minor Stroke score can be a feasible goal in MDVO trials in the near future.^{7,15}

Imaging end points have also been investigated in the LVO population supporting the clinical relevance of infarct volume as an imaging surrogate. Specifically, the recent secondary analyses of the Highly Effective Reperfusion Evaluated in Multiple Endovascular Stroke Trials collaboration shows that in LVO cases, each 10-mL increase in final infarct volume was associated with a 5% decrease in the odds of achieving functional independence (mRS 0-2).¹⁶ The absence of improved

functional outcomes in the EVT plus BMT group despite reduced change in Vrel may be explained by procedure-related complications, particularly the high rate of subarachnoid hemorrhage, potentially offsetting the benefit of salvaged brain tissue. Our findings contribute to the ongoing debate on selection criteria for future MDVO trials, as patient selection based on larger baseline Tmax6 volumes may have greater potential for significant lesion reduction with successful reperfusion. An imaging-driven approach may better capture the true therapeutic window and potential for tissue salvage in MDVO. Combined with recent advances in MDVO-specific devices and techniques, these insights support the design of future, more focused trials that use imaging end points to more accurately evaluate the benefits of EVT plus BMT in MDVO.¹⁷

Imaging modality plays a critical role in accurately assessing infarct evolution after stroke intervention. Several studies have shown that CT underestimates the follow-up infarct volume compared with MRI.¹⁸⁻²⁰ In line with the available literature, our sensitivity analysis showed that CT might provide lower follow-up infarct volumes, but follow-up modality had no association with the results of the primary analysis. This can be relevant for centers without MRI availability, as follow-up MRI may provide more precise volumetric data and a better estimation of the clinical outcome of the patients.

Strengths and Limitations

Strengths of this post hoc analysis include its randomized, multicenter design, the large sample size, and the novel use of imaging end points. Limitations include the retrospective design, the heterogeneity in follow-up imaging modality, and the low median NIHSS score at baseline, which could limit generalizability to more severe strokes cases. Future research should focus on the standardization of imaging end points in stroke trials to improve consistency and comparability across studies. There is also a need to validate change in Vrel as a reliable imaging marker in other cohorts. Additionally, further investigation is required to determine thresholds for meaningful brain tissue salvage that can guide treatment decisions, patient selection, and outcome prediction.

Conclusions

In this post hoc analysis of the DISTAL trial data, EVT plus BMT was associated with a higher likelihood of achieving a good imaging outcome compared with BMT alone. Good imaging outcomes were associated with a better clinical outcome in both treatment groups. Imaging-based end points can enhance understanding of EVT efficacy, even in patients with low NIHSS scores.

ARTICLE INFORMATION

Accepted for Publication: March 2, 2026.

Published Online: April 20, 2026.

doi:10.1001/jamaneurol.2026.0805

Correction: This article was corrected on June 15, 2026, to fix an error in the Abstract Results.

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Administrative, technical, or material support: Christodoulou, Heit, Müller, van Es, Van den Bergh, Aebischer.

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Conflict of Interest Disclosures: Dr Anastasiou reported receiving grants from Gottfried and Julia Bangert-Rhyner-Stiftung, Medtronic, Stryker

Neurovascular, Phenox GmbH, Rapid Medical, and Penumbra. Dr Albers reported receiving personal fees from iSchemaView consulting outside the submitted work. Dr Heit reported receiving personal fees from MicroVent, Medtronic, and iSchemaView during the conduct of the study. Dr Staals reported receiving personal fees from Medtronic outside the submitted work. Dr van Zwam reported receiving personal fees paid to institution from Bayer HealthCare Pharmaceuticals, Stryker, Terumo Neuro, Nicolab, Penumbra, and Philips; and personal fees from J&J Neuro outside the submitted work. Dr Tsvigoulis reported serving as data and safety monitoring board (DSMB) chair for the DISTAL trial. Dr Dobrocky reported serving as consultant for MicroVent and as advisory board member for OM Pharma. Dr Hajdu reported serving as consultant for Siemens Healthineers AG. Dr Fischer reported receiving research support from the Swiss National Science Foundation, State Secretariat for Education, Swiss Heart Foundation, Swiss Brain League, Horton Foundation, Medtronic, Stryker, Rapid Medical, Penumbra, Phenox, and Boehringer Ingelheim; consultant fees paid to institution from Medtronic, Bayer, Boehringer Ingelheim, Boston Scientific, CSL Behring, Merck, Siemens, and Takeda outside the submitted work; serving as a member of a clinical event committee of the COATING study (Phenox); serving as a member of the DSMB of the TITAN, RESCIND, LATE_MT, IN EXTREMIS, and RapidPulse trials; and serving as president of the Swiss Neurological Society and president-elect of the European Stroke Organisation. Dr Psychogios reported receiving grants from Swiss National Science Foundation and Bangert-Rhyner-Stiftung; grants paid to institution from Medtronic Inc, Rapid Medical Inc, Penumbra Inc, Siemens Healthineers AG, Stryker Neurovascular Inc, and Phenox GmbH during the

conduct of the study; receiving speaker fees paid to institution from Stryker Neurovascular Inc, Medtronic Inc, Penumbra Inc, Acandis GmbH, Phenox GmbH, Rapid Medical Inc, and Siemens Healthineers AG; and serving as sponsor and primary investigator of the DISTAL, SPINNERS, and ICARUS trials. No other disclosures were reported.

Funding: Support for the study was provided by a grant from the Swiss National Science Foundation.

Role of the Funder/Sponsor: The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Group Information: A full list of the DISTAL investigators appears in [Supplement 3](#).

Data Sharing Statement: See [Supplement 4](#).

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