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ORIGINAL RESEARCH ARTICLE

Bailout Intracranial Angioplasty or Stenting After Thrombectomy for Acute Large Vessel Occlusion: 1-Year Outcomes of ANGEL-REBOOT

Feng Gao, MD*; Xu Tong, MD*; Ming Wei, MD*; Xiaoxi Yao, MD*; Lei Li, MD*; Yuesong Pan, PhD; Baixue Jia, MD; Thanh N. Nguyen, MD; Ming Yang, MD; Dapeng Sun, MD; Ganghua Feng, MD; Guangxiong Yuan, MD; Chenghua Xu, MD; Zhengzhou Yuan, MD; Yue Wan, MD; Jing Wang, MD; Ping Jing, MD; Xinguang Yang, MD; Zhilin Wu, MD; Wei Hu, MD; Yuanfei Jiang, MD; Chaobin Wang, MD; Changming Wen, MD; Jianjun Tang, MD; Xiang Luo, MD; Yingchun Wu, MD; Ruile Shen, MD; Tuanyuan Zheng, MD; Yaxuan Sun, MD; Mingze Chang, MD; Yan Liu, MD; Yang Haihua, MD; Di Li, MD; Bo Yin, MD; Weihua Jia, MD; Dongjun Wan, MD; Guodong Xu, MD; Zaiyu Guo, MD; Dianjing Sun, MD; Yang Wang, MD; Jixin Duan, MD; Liyu Wang, MD; Guoqing Wang, MD; Liping Wei, MD; Gaoting Ma, MD; Xiaochuan Huo, MD; Dapeng Mo, MD; Ning Ma, MD; Zeguang Ren, MD; Liping Liu, MD; Xingquan Zhao, MD; Yilong Wang, MD, PhD; Jens Fiehler, MD; Yongjun Wang, MD, PhD; Zhongrong Miao, MD; on behalf of the ANGEL-REBOOT study group

BACKGROUND: The long-term benefits of bailout intracranial angioplasty or stenting (BAOS) after thrombectomy in patients with acute large vessel occlusion remain unclear. This study compared BAOS with standard therapy in patients with large vessel occlusion with unsuccessful recanalization (expanded Thrombolysis In Cerebral Infarction score 0–2a) or >70% residual stenosis after thrombectomy.

METHODS: ANGEL-REBOOT (Randomized Study of Bailout Intracranial Angioplasty Following Thrombectomy for Acute Large Vessel Occlusion) was a multicenter, open-label, blinded–end point, randomized trial conducted across 36 Chinese hospitals. Patients ≥18 years of age with anterior or posterior circulation large vessel occlusion within 24 hours of stroke onset were enrolled. After identification of thrombectomy failure or high-grade residual stenosis, patients were randomly assigned to the BAOS group (intervention) or the standard therapy group (control), in which thrombectomy was continued or terminated. The use of tirofiban was permitted in both groups during and after the procedure. In the intention-to-treat population, the primary outcome was analyzed using an assumption-free ordinal analysis (Wilcoxon-Mann-Whitney test) to compare the modified Rankin Scale scores (ordinal variable ranging from 0 to 6) between groups at 1-year follow-up, from which the generalized odds ratio was derived. Secondary outcomes included stroke recurrence in the treated artery and all-cause mortality within 1 year, analyzed using Cox proportional hazards models.

RESULTS: A total of 348 patients were randomly assigned (176 to the BAOS group and 172 to the standard therapy group) and followed for 90 days, from December 19, 2021, to June 2, 2023. Of these, 326 patients (166 in the BAOS group and 160 in the standard therapy group) completed the 1-year follow-up. Compared with standard therapy, BAOS significantly improved the 1-year modified Rankin Scale score distribution (generalized odds ratio, 1.34 [95% CI, 1.05–1.73]; P=0.02). Fewer stroke recurrences in the treated artery occurred in the BAOS group than in the standard therapy group (7 of 166 [4%] versus 21 of 160 [13%]; hazard ratio, 0.30 [95% CI, 0.13–0.71]; P=0.006). One-year mortality rates were similar between groups (25 of 166 [15%] versus 27 of 160 [17%]; hazard ratio, 0.87 [95% CI, 0.50–1.50]).

CONCLUSIONS: Among Chinese patients with large vessel occlusion with unsuccessful recanalization or high-grade residual stenosis after thrombectomy, BAOS was associated with reduced disability and stroke recurrence after 1 year compared with standard therapy.

REGISTRATION: URL: https://www.clinicaltrials.gov; Unique identifier: NCT05122286.

Key Words: angioplasty ■ intracranial atherosclerosis ■ thrombectomy

Correspondence to: Zhongrong Miao, MD, Interventional Neuroradiology, Department of Neurology, Beijing Tiantan Hospital, Capital Medical University, Beijing, China, Email zhongrongm@163.com, or Yongjun Wang, MD, PhD, China National Clinical Research Center for Neurological Diseases, Beijing, China. Email yongjunwang@ncrcnd.org.cn
*F. Gao, X. Tong, M. Wei, X. Yao, and L. Li contributed equally.
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Clinical Perspective

What Is New?

- Bailout intracranial angioplasty or stenting after thrombectomy provides significant long-term clinical benefits for patients with predominantly intracranial atherosclerotic disease–related large vessel occlusion, evidenced by improved functional outcomes scores on modified Rankin Scale at 1 year.
- This intervention also demonstrates durable benefits through a reduced rate of stroke recurrence in the treated artery within 1 year.

What Are the Clinical Implications?

- These findings offer clinicians substantial reassurance regarding the durable long-term efficacy of bailout intracranial angioplasty or stenting.
- These findings also confirm the critical role of bailout intracranial angioplasty or stenting in reducing the risk of stroke recurrence in the responsible vascular territory, highlighting its value in maintaining long-term stability of revascularization.

Nonstandard Abbreviations and Acronyms

ANGEL-REBOOT	Randomized Study of Bailout Intracranial Angioplasty Following Thrombectomy for Acute Large Vessel Occlusion
ASPECTS	Alberta Stroke Program Early CT Score
BAOS	bailout angioplasty or stenting
EQ-5D	EuroQol–5 Dimensions
eTICI	expanded Thrombolysis In Cerebral Infarction
ICAD	intracranial atherosclerotic disease
LVO	large vessel occlusion
mRS	modified Rankin Scale
sICH	symptomatic intracranial hemorrhage

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Unsuccessful recanalization or reocclusion after thrombectomy is associated with poor outcomes in patients with acute ischemic stroke attributable to large vessel occlusion (LVO).[1,2] In patients with acute LVO, intracranial atherosclerotic disease (ICAD) is a major contributor to unsuccessful recanalization or reocclusion after thrombectomy.[2,3] Several observational studies have supported bailout intracranial angioplasty or stenting (BAOS) after thrombectomy as a viable therapeutic option that can not only restore recanalization but also prevent early reocclusion, thereby improving the clinical outcomes of ICAD-related LVO.[3–5] However, a recently published randomized trial of BAOS after thrombectomy for acute LVO (ANGEL-REBOOT [Randomized Study of Bailout Intracranial Angioplasty Following Thrombectomy for Acute Large Vessel Occlusion]) conducted across multiple centers in China reported that BAOS did not improve functional status at 90 days and was associated with an increased risk of symptomatic intracranial hemorrhage (sICH) and iatrogenic arterial dissection.[6]

A 90-day follow-up may represent too short a time frame to detect the potential benefits of BAOS in patients with ICAD-related LVO. The effect may become more apparent over a longer duration, particularly in patients with persistent high-grade stenosis, in whom BAOS could alleviate hypoperfusion or reduce the risk of stroke recurrence, thereby supporting functional recovery. Therefore, the aim of this extended follow-up analysis of ANGEL-REBOOT was to evaluate the long-term (1-year) clinical benefit of BAOS in patients with acute ischemic stroke LVO in the anterior or posterior circulation who experienced unsuccessful recanalization (defined as an expanded Thrombolysis In Cerebral Infarction [eTICI] score of 0–2a) or had high-grade residual stenosis (>70%) after thrombectomy.

METHODS

Data Sharing

Individual, deidentified participant data used in these analyses will be shared on request from any qualified investigator after approval of a protocol and signed data access agreement through the trial steering committee.

Study Design

ANGEL-REBOOT was an investigator-initiated, multicenter, prospective, open-label, adaptive, randomized controlled, phase 3 clinical trial with blinded outcome assessment conducted at 36 tertiary hospitals across 19 provinces in China (Tables S1 and S2; Figures S1 and S2).[6] Before initiating patient enrollment, all participating hospitals obtained ethics approval from their local institutional review boards. The trial was registered at ClinicalTrials.gov (URL: https://www.clinicaltrials.gov; Unique identifier: NCT05122286) and has been completed. The study protocol, available in the Supplemental Material, was amended during the trial to include follow-up assessments up to 1 year after randomization. Members of the ANGEL-REBOOT steering and executive committees designed the extended follow-up trial, analyzed the data, prepared the manuscript, and made the decision to submit the manuscript for publication.

Participants

The trial design and protocol, including detailed inclusion and exclusion criteria, have been reported previously.[6,7] Inclusion criteria consisted of ≥18 years of age, no substantial prestroke

disability (defined by a modified Rankin Scale [mRS] score of 0–2), presentation with a National Institutes of Health Stroke Scale score ≥6 within 24 hours resulting from anterior or posterior circulation LVO, and unsuccessful recanalization (eTICI score 0–2a) after 3 thrombectomy attempts or high-grade residual stenosis (>70%) after 1 to 3 thrombectomy attempts. All patients or their legal representatives provided written informed consent to participate in the trial.

Funding for the extended follow-up trial became available in November 2022, when the enrollment percentage in ANGEL-REBOOT had reached ≈60% of the anticipated sample size. Therefore, around one-third of patients had already completed their 90-day follow-up assessment. However, the 1-year follow-up time point had not yet been reached for any patient. For the remaining patients enrolled in ANGEL-REBOOT after November 2022, the extended follow-up duration was included in the updated informed consent. For patients originally enrolled in the trial who had not initially provided consent for extended follow-up, verbal consent was obtained by telephone after reinvitation.

Randomization and Masking

An interactive web response system using the minimization method (covariate-adaptive randomization with a 1:1 ratio) assigned patients on the basis of baseline characteristics to balance weighted values across treatment groups. Covariates included in the randomization algorithm were stroke severity (defined by a baseline National Institutes of Health Stroke Scale score <16 or ≥16), onset-to-puncture time (<6 hours or 6–24 hours), and occlusion site (anterior or posterior circulation). The study was open-label; however, outcome assessments at 90 days and 1 year were performed in a blinded manner by assessors unaware of treatment allocation.

Procedures

Stent retriever, contact aspiration, or a combination of both was recommended as the first-line approach for thrombectomy. All thrombectomy devices were used in accordance with their intended purpose and the operating instructions approved by the National Medical Products Administration of China.

If a patient was allocated to standard therapy (control group), the decision to continue or terminate the thrombectomy procedure, as well as the use of alternative thrombectomy devices or techniques, was left to the discretion of the neurointerventionalist. If a patient was allocated to BAOS (intervention group), any balloon or stent approved by the National Medical Products Administration could be used. The choice between angioplasty and stenting was made by the treating team on the basis of clinical judgment. After balloon angioplasty or stent placement, additional thrombectomy was permitted as a rescue measure in cases of in situ thrombosis, distal embolization, or embolization in new territories; such actions were not considered protocol violations.

In both treatment groups, tirofiban (5 mg diluted in 100 mL of normal saline) was recommended during and after the procedure for patients with high-grade residual stenosis after thrombectomy, regardless of their eTICI score. During the procedure, a bolus dose of tirofiban (0.5–0.6 mg) could be administered intra-arterially, intravenously, or by both routes at a rate of 1 mL/min. After the procedure, intravenous tirofiban was recommended to be continued at a rate of 0.1 μg/kg per minute for 24 hours. Oral antiplatelet therapy was overlapped with intravenous tirofiban for 4 hours, after which tirofiban infusion was discontinued. If no intracranial hemorrhage was observed, all patients received dual antiplatelet therapy consisting of aspirin (100 mg/day) and clopidogrel (75 mg/day) or ticagrelor (180 mg/day) for 3 months, followed by lifelong monotherapy with aspirin, clopidogrel, or ticagrelor. Thromboelastography or *CYP2C19* genotype testing were used to assess for clopidogrel resistance. In patients with clopidogrel resistance, clopidogrel was replaced with ticagrelor. Statin therapy was also administered. Vascular risk factors (eg, hypertension, diabetes, and smoking) were managed with appropriate medications or lifestyle modification in accordance with the Chinese Stroke Association guidelines.[8]

Outcomes

Trained assessors, masked to treatment allocation and imaging findings, collected outcome data using a standardized questionnaire,[9,10] preferably administered in person or, if not feasible, by telephone. The primary outcome of this trial, mRS score at 90 days, has been previously published.[6] In this article, we report an extended follow-up analysis of ANGEL-REBOOT, with 1-year functional status as the primary outcome. Functional status was as assessed using the mRS, an ordinal scale ranging from 0 to 6 (with 0 indicating no symptoms and 6 indicating death, at which higher scores reflect greater disability). Secondary outcomes (all assessed at 1-year follow-up) included stroke recurrence in the treated artery (defined by imaging evidence, particularly diffusion-weighted imaging, of new infarcts in the treated vascular territory, combined with clinical evaluation showing new or worsening neurological deficits, after excluding nonvascular causes such as tumors, infections, or stroke mimics); functional independence (mRS score of 0–2); independent ambulation (mRS score of 0–3); patient-reported quality of life (ie, EuroQol–5 Dimensions [EQ-5D] questionnaire); mortality; reocclusion of the treated artery (defined by follow-up computed tomographic angiography or magnetic resonance angiography within 36 hours for all patients, or within 1 year in those with recurrent stroke, showing an arterial occlusive lesion grade of 0 or 1[11]); and revascularization of the treated artery (including thrombectomy, angioplasty, and stenting).

Statistical Analysis

Because of the lack of previous research data, reliable information on the distribution of ordinal mRS scores in both groups was unavailable. Therefore, sample size estimation was based on a dichotomous end point (good outcome defined as mRS score 0–2 at 90 days rather than 1 year). Based on observational data from patients with atherosclerotic stenosis or refractory occlusion receiving BAOS therapy after thrombectomy, the assumed good outcome rates were 40% in the BAOS group and 25% in the standard therapy group.[2,3,12,13] Using a group-sequential design (O'Brien-Fleming method, 2 interim analyses), 156 patients per group (312 overall) were required to detect a 15% between-group difference with 80% power at a 2-sided α=0.05. Accounting for a 10% dropout rate, the final planned sample size was 174 patients per group (348 overall).

A statistical analysis plan was developed before data set lock for the 1-year outcomes and was approved by the trial

steering committee and the data and safety monitoring board (Supplemental Material). Analyses were performed in the intention-to-treat population, with patients analyzed according to their originally assigned treatment groups, regardless of the treatment actually received. Additional sensitivity analyses were conducted in the per-protocol population and in models using multiple imputation under the assumption of missing-at-random for the outcome. Multiple imputation was conducted using 5 replications and the Markov chain Monte Carlo method to account for missing primary and secondary outcome data.[14]

For the primary outcome, an assumption-free ordinal analysis (the Wilcoxon-Mann-Whitney test) was used to calculate the generalized odds ratio and its 95% CI, assessing the overall shift in the distribution of mRS scores. The primary outcome was also analyzed in prespecified subgroups on the basis of clinical and imaging characteristics. For binary secondary outcomes (mRS scores of 0–2 and 0–3), a generalized linear model based on the negative binomial distribution was used to calculate and report relative risks with corresponding 95% CIs. For the continuous secondary outcome (EQ-5D score), a generalized linear model based on the Gaussian distribution was applied, and the β-coefficient with 95% CI was reported. For time-to-event secondary outcomes (stroke recurrence, reocclusion, revascularization of the treated artery, and mortality), a Cox proportional hazards regression model was used, with proportionality confirmed. Hazard ratios and 95% CIs were reported. We further used the Fine and Gray regression model for a subdistribution function treating death as a competing event for stroke recurrence.[15] As specified in the statistical analysis plan, analyses adjusted for covariates used in the randomization algorithm (baseline National Institutes of Health Stroke Scale score, occlusion site, and onset-to-puncture time) were also performed. Center effects were not included in the model because of the relatively small sample sizes at individual sites.

All statistical analyses were performed using SAS software (version 9.4) with 2-sided hypothesis testing and a significance threshold of P=0.05. Because no prespecified multiplicity adjustment was applied to secondary outcomes or subgroup analyses, only point estimates and 95% CIs are reported. The widths of these CIs have not been adjusted for multiplicity; therefore, definitive conclusions about treatment effects for secondary outcomes or subgroup analyses should not be drawn from these intervals.

RESULTS

Between December 19, 2021, and March 17, 2023, a total of 706 patients were screened for eligibility, and 348 were enrolled in the current trial. Of these, 176 patients were randomly assigned to receive BAOS, and 172 to receive standard therapy after thrombectomy. No patient withdrew from the trial or was lost to follow-up for the primary outcome at 90 days. Thirteen patients (10 in the BAOS group and 3 in the standard therapy group) were excluded from the per-protocol analyses because of major protocol violations or treatment crossover. In the BAOS group, reasons for exclusion were as follows: 5 had baseline ASPECTS (Alberta Stroke Program Early CT Score) or posterior circulation ASPECTS <6; 2 had >3 thrombectomy attempts; 1 had occlusion in the M2 segment of the middle cerebral artery; and 2 had crossover treatment. In the standard therapy group, reasons for exclusion were as follows: 1 had posterior circulation ASPECTS <6; 1 did not have confirmed LVO; and 1 had crossover treatment. A total of 9 patients developed sICH within 36 hours after the procedure (8 in the BAOS group and 1 in the standard therapy group). None of the patients with hemorrhage were excluded from the study, and all completed the 1-year follow-up observation (detailed data are provided in Table S3).

At the time of initiation of the extended follow-up trial, 220 patients had already been enrolled in the original trial. An additional 128 patients were subsequently enrolled and prospectively followed for up to 1 year after randomization. Of the 220 previously enrolled patients, 118 (54%) had completed the 90-day follow-up evaluation, and none had reached the 1-year follow-up time point. These patients were reinvited to participate in the extended follow-up trial. A total of 22 patients were lost to follow-up at the 1-year time point (10 in the BAOS group and 12 in the standard therapy group). Data for the primary outcome were available for 326 of 348 patients (94%) at the 1-year follow-up, which was completed on March 30, 2024, including 166 in the BAOS group and 160 in the standard therapy group (Figure 1). A comparison of baseline characteristics and 90-day outcomes between patients with and without missing data for the 1-year mRS outcome is provided in the appendix (Table S4). Among the 326 intention-to-treat patients with available 1-year follow-up data, the median age was 62 years, and 75% were men. The median National Institutes of Health Stroke Scale score at baseline was 12 (interquartile range, 9–16). Demographic and clinical characteristics at baseline, as well as secondary prevention and ongoing care during the 1-year follow-up period, were generally similar between the 2 groups (Table 1; Table S5). At the 90-day and 1-year follow-ups, mortality rates in the BAOS group were 11% (19 of 176) and 15% (25 of 166), respectively, compared with 10% (17 of 172) and 17% (27 of 160) in the standard therapy group.

The distribution of mRS scores at the 1-year follow-up (Figure 2; Table 2) favored the BAOS group over the standard therapy group (median mRS score, 2 [interquartile range, 0–4] versus 3 [interquartile range, 1–4], respectively; generalized odds ratio, 1.34 [95% CI, 1.05–1.73]; P=0.02). Similar findings were observed in the per-protocol and multiple imputation analyses (Table 2; Tables S6 and S7).

Of the 290 patients who were alive at 90 days and completed the 1-year follow-up, 89 (31%) demonstrated a ≥1-point improvement in mRS score (64 of 147 [44%] in the BAOS group and 25 of 143 [18%] in the standard therapy group; Table S8). Among these, 28 patients (24

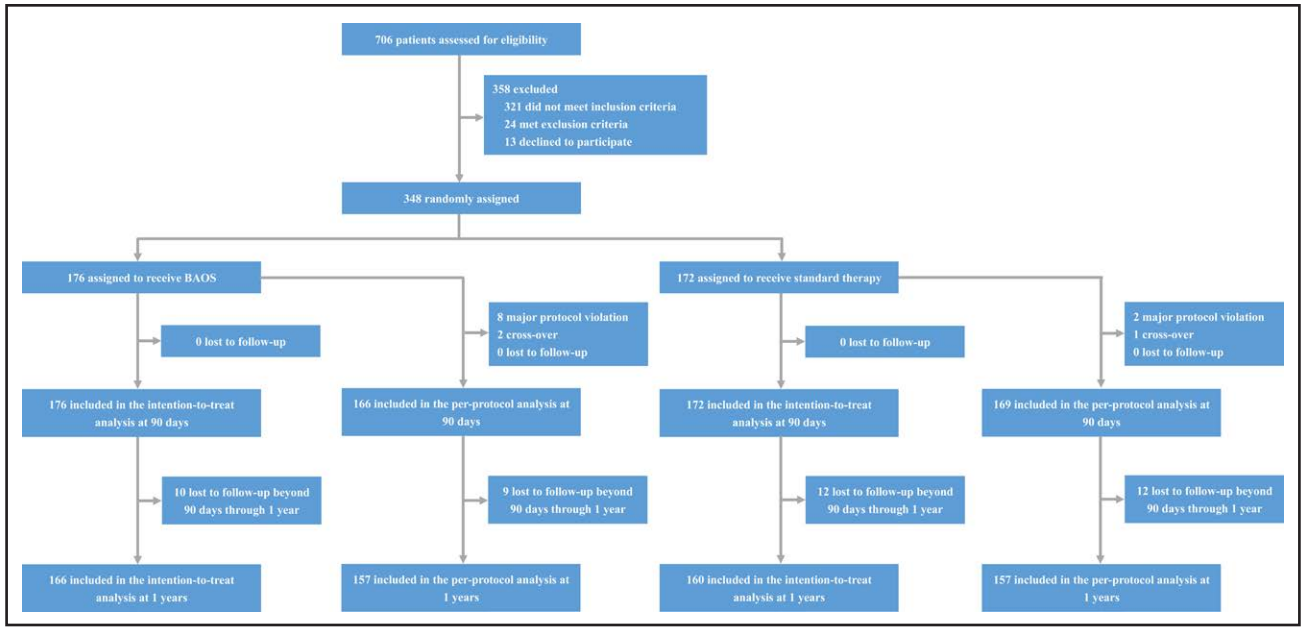

Figure 1. Trial profile.
BAOS indicates bailout angioplasty or stenting.

in the BAOS group and 4 in the standard therapy group) had an mRS score of 3 to 5 at 90 days and improved to 0 to 2 at 1 year. Thus, a significantly higher rate of mRS 0 to 2 at 1 year was observed in the BAOS group compared with the standard therapy group (112 of 166 [67%] versus 75 of 160 [47%]; relative risk, 1.44 [95% CI, 1.16–1.72]; $P<0.001$). A summary of baseline characteristics by transition status from 90-day to 1-year follow-up is provided in Table S9.

Regarding other secondary outcomes, the BAOS group had a significantly lower rate of stroke recurrence in the treated artery within 1 year (7 of 166 [4%] versus 21 of 160 [13%]; hazard ratio, 0.30 [95% CI, 0.13–0.71]; $P=0.006$; Table 2; Figure S3). Similar findings were observed in the adjusted model, competing risk model, and other sensitivity analyses (Table 2; Tables S6 and S7). This may be attributed to the fact that patients in the BAOS group underwent intracranial angioplasty or stenting, with post-treatment residual stenosis rates of ≥70% and ≥80% observed in 6% (10 cases) and 5% (9 cases), respectively. In contrast, the standard therapy group had residual stenosis rates of ≥70% and ≥80% in 77% (123 cases) and 33% (52 cases) of patients, respectively (Table S10). Moreover, at 90 days, the EQ-5D quality of life score was 5 points lower in the BAOS group than in the standard therapy group, whereas at 1 year, it was 5 points higher in the BAOS group. However, neither difference was statistically significant (Table 2; Tables S6 and S7). Rates of mortality, reocclusion, and revascularization of the treated artery within 1 year were similar between treatment groups (Table 2; Tables S6 and S7).

We did not find any significant difference in the treatment effect of BAOS on the basis of sex, age, occlusion site, stroke severity, onset-to-puncture time, or reperfusion status before randomization, although patients with refractory occlusion had a point estimate of treatment effect <1 (Figure 3). However, this subgroup was small (n=19), resulting in a wide CI.

DISCUSSION

Information on long-term outcomes is valuable for both clinical practice and health care policy decisions. In this study, we report 1-year clinical follow-up results of patients enrolled in ANGEL-REBOOT. In contrast to the previously published 90-day findings, the extended follow-up analysis demonstrated that BAOS, in patients with predominantly ICAD-related LVO after thrombectomy, led to improved functional recovery compared with standard therapy as measured by the mRS at 1 year. No significant differences in the treatment effects of BAOS were observed across prespecified subgroups. Compared with the standard therapy group, the common odds ratio for an improved mRS score in the BAOS group was 0.86 (95% CI, 0.59–1.24) at 90 days, versus a generalized odds ratio of 1.34 (95% CI, 1.05–1.73) at 1 year. Mortality rates within 1 year did not differ between the 2 groups.

The benefit of BAOS compared with standard therapy at 1 year was observed not only in the overall distribution of mRS scores but also across other secondary outcomes. The proportion of patients who were functionally independent (mRS score of 0–2) in the BAOS group increased from 55% at 90 days to 67% at 1 year. In contrast, in the standard therapy group, this

Table 1. Baseline Characteristics of the 326 Patients Included in the 1-Year Outcomes Analysis, According to Treatment Assignment

Baseline variables	BAOS (n=166)	Standard therapy (n=160)	*P* value
Age, y	62 (55–69)	63 (55–69)	0.94*
Sex§			0.95†
Female	42 (25)	41 (26)	
Male	124 (75)	119 (74)	
Medical history			
Hypertension	108 (65)	106 (66)	0.82†
Diabetes	35 (21)	33 (21)	0.92†
Dyslipidemia	8 (5)	5 (3)	0.43†
Coronary heart disease	13 (8)	16 (10)	0.49†
Atrial fibrillation	4 (2)	6 (4)	0.48†
Previous stroke or TIA	34 (20)	34 (21)	0.87†
Prestroke mRS score ≥1	7 (4)	8 (5)	0.74†
Cigarette smoking	79 (48)	78 (49)	0.83†
Wake-up stroke	22 (13)	28 (18)	0.29†
Mode of stroke onset			0.36‡
Maximal deficit at onset	97 (58)	106 (66)	
Progressive stroke	66 (40)	51 (32)	
Fluctuating symptoms without full recovery	3 (2)	3 (2)	
Systolic blood pressure, mm Hg	147 (131–163)	149 (135–162)	0.65*
NIHSS score	12 (9–16)	12 (8–16)	0.39*
ASPECTS‖	8 (7–9)	8 (7–9)	0.25*
Intravenous alteplase pretreatment	44 (27)	36 (23)	0.40†
Occlusion site			0.42†
Intracranial internal carotid artery	35 (21)	27 (17)	
Middle cerebral artery M1	89 (54)	95 (60)	
Vertebrobasilar junction	20 (12)	13 (8)	
Basilar artery	21 (13)	24 (15)	
Type of anesthesia			0.12†
Local only	67 (40)	72 (45)	
Local plus sedation	13 (8)	21 (13)	
General	86 (52)	67 (42)	
Onset-to-puncture time, min	512 (286–750)	514 (301–798)	0.42*
Puncture-to-recanalization time, min#	85 (56–172)	86 (50–139)	0.25*
First-line thrombectomy			0.65†
Stent-retriever	26 (16)	20 (13)	
Aspiration	10 (6)	8 (5)	
Stent-retriever plus aspiration	130 (78)	131 (82)	
Reason for rescue treatment			0.20†
eTICI 0–2a after 3 passes	61 (37)	48 (30)	
High-grade stenosis after 1–3 passes	105 (63)	112 (70)	
Underlying ICAD	156 (94)	151 (94)	0.88†
Periprocedural use of tirofiban	156 (94)	156 (98)	0.12†

Values are n (%) or median (interquartile range). BAOS indicates bailout angioplasty or stenting; eTICI, expanded Thrombolysis In Cerebral Infarction; ICAD, intracranial atherosclerotic disease; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; and TIA, transient ischemic attack.

*Wilcoxon rank-sum test.

†χ^2 test.

‡Fisher exact test.

§Sex was self-reported.

‖ASPECTS (Alberta Stroke Program Early CT Score) for anterior circulation stroke; posterior circulation ASPECTS for posterior circulation stroke.

#For patients with recanalization failure, this refers to the time from puncture to the end of the procedure.

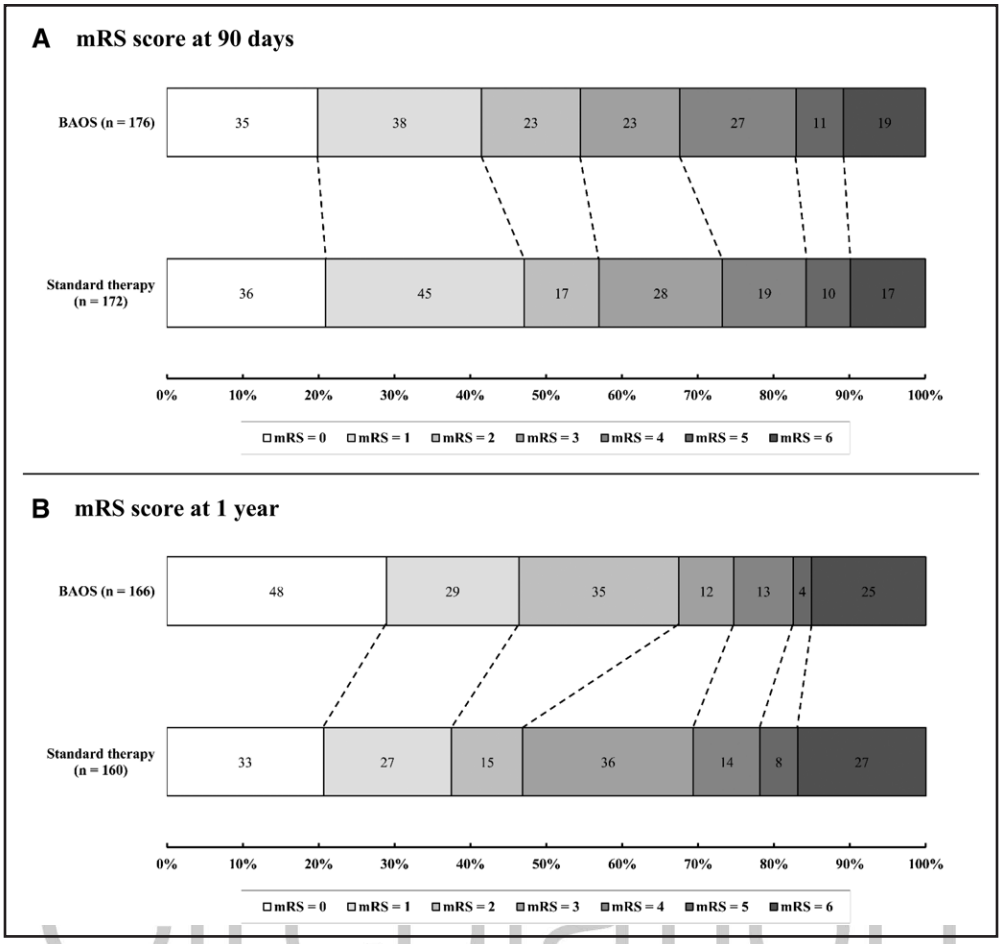

Figure 2. Modified Rankin Scale scores at 90 days and 1 year according to treatment assignment.
A, Modified Rankin Scale (mRS) score at 90 days. **B**, mRS score at 1 year. BAOS indicates bailout angioplasty or stenting.

proportion decreased from 57% to 47% over the same period. At 1 year, the EQ-5D score was 5 points higher in the BAOS group, although this difference was not statistically significant. Given the significantly higher rate of postprocedural high-grade (>70%) stenosis in the standard therapy group compared with the BAOS group, this difference likely contributed to the higher incidence of stroke recurrence in the standard therapy group.[16–18] Similar to elective balloon angioplasty or stent placement in patients with symptomatic ICAD and high-grade stenosis,[19–21] the use of BAOS after thrombectomy reduced the degree of stenosis, thereby improving cerebral perfusion and potentially lowering the risk of long-term stroke recurrence. Therefore, patients in the BAOS group demonstrated improved functional recovery. Compared with the standard therapy group, the risk of stroke recurrence in the treated artery within 1 year was significantly lower in the BAOS group (4% versus 13%). Because secondary prevention and ongoing care were similar between 2 groups during the 1-year follow-up, the observed reduction in stroke recurrence is likely attributable to the BAOS intervention, representing another important finding of this study.

To our knowledge, this is the first trial to demonstrate a 1-year benefit of BAOS in patients with predominantly ICAD-related LVO and either unsuccessful recanalization or high-grade residual stenosis after thrombectomy. Our findings complement the long-term outcome analyses of several thrombectomy trials, including MR CLEAN (Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands), REVASCAT (Endovascular Revascularization With Solitaire Device Versus Best Medical Therapy in Anterior Circulation Stroke Within 8 Hours), MR CLEAN-LATE (Multicenter Randomised Clinical Trial of Endovascular Treatment of Acute Ischemic Stroke in the Netherlands for Late Arrivals), SELECT2 (Randomized Controlled Trial to Optimize Patient Selection for Endovascular Treatment in Acute Ischemic Stroke), and TENSION (The Efficacy and Safety of Thrombectomy in Stroke With Extended Lesion and Extended Time Window),[22–26] which predominantly enrolled patients with embolism-related LVO and did not address those with ICAD-related LVO or a high risk of stroke recurrence after thrombectomy. In our study, ≈30% of patients with continued follow-up beyond 90 days experienced

Table 2. Primary and Secondary Outcomes and Treatment Effects

Outcome variables	BAOS (n=166)	Standard therapy (n=160)	Effect estimate	Unadjusted analysis		Adjusted analysis*	
				Effect size (95% CI)	*P* value	Effect size (95% CI)	*P* value
Primary outcome							
mRS score at 1 y	2 (0–4)	3 (1–4)	Generalized OR†	1.34 (1.05–1.73)	0.02	NA‡	NA‡
Secondary outcomes							
Stroke recurrence of the treated artery within 1 y	7 (4)	21 (13)	HR§	0.30 (0.13–0.71)	0.006	0.30 (0.13–0.70)	0.005
			HR‖	0.25 (0.10–0.63)	0.003	0.19 (0.05–0.74)	0.02
mRS score of 0–2 at 1 y	112 (67)	75 (47)	RR	1.44 (1.16–1.72)	< 0.001	1.47 (1.17–1.78)	< 0.001
mRS score of 0–3 at 1 y	124 (75)	111 (69)	RR	1.08 (0.93–1.22)	0.28	1.08 (0.93–1.22)	0.28
EQ-5D score at 1 y	90 (55–100)	85 (40–95)	β coefficient	4.60 (–3.22 to 12.41)	0.11	4.46 (–2.92 to 11.83)	0.24
Mortality within 1 y	25 (15)	27 (17)	HR	0.87 (0.50–1.50)	0.61	0.80 (0.46–1.39)	0.44
Reocclusion of the treated artery within 1 y#	30 (18)	24 (15)	HR	1.22 (0.71–2.08)	0.48	1.28 (0.75–2.18)	0.36
Reocclusion of the treated artery within 36 h	27 (16)	21 (13)					
Reocclusion of the treated artery beyond 36 h through 1y	3 (2)	3 (2)					
Revascularization of the treated artery within 1 y**	3 (2)	4 (3)	HR	0.72 (0.16–3.23)	0.67	0.72 (0.16–3.21)	0.66

Values are n (%) or median (interquartile range). BAOS indicates bailout angioplasty or stenting; EQ-5D, EuroQol–5 Dimensions; NA, not available; and RR, relative risk.

*Adjusted for baseline National Institutes of Health Stroke Scale score, occlusion site, and onset-to-puncture time.

†The generalized odds ratio (OR) was calculated using the Wilcoxon-Mann-Whitney test, reflecting the odds of a 1-point improvement in the modified Rankin Scale (mRS) score at 1 year.

‡The Wilcoxon-Mann-Whitney test does not allow for adjustment for covariates.

§The hazard ratio (HR) was calculated using the Cox proportional hazards model.

‖The HR was calculated using the competing risk model.

#Defined as computed tomography angiography or magnetic resonance angiography follow-up performed within 36 hours for all patients or within 1 year for patients with recurrent stroke, showing an arterial occlusive lesion grade of 0 or 1.

**Revascularization included thrombectomy, angioplasty, or stenting procedures.

at least a 1-point improvement in their functional status on the mRS at 1 year. In contrast to the aforementioned studies, in which both the interventional and medical groups generally demonstrated recovery gains between 90 days and 1 year, the recovery trajectories in our trial diverged. The standard therapy group exhibited lower odds of favorable outcomes at 1 year, most likely because of a higher rate of stroke recurrence associated with residual high-grade stenosis at the end of the procedure. Despite the higher degree of residual stenosis in the standard therapy group immediately after the procedure, the rates of reocclusion and revascularization within 1 year were similar between groups. These findings collectively underscore a delayed yet clinically meaningful benefit associated with BAOS beyond the conventional 90-day time frame, particularly in reducing stroke recurrence in ICAD-related LVO with high-grade residual stenosis.

Our trial has several limitations. First, a selection bias may have been introduced because of missing 1-year follow-up data in 6% (22 of 348) of the patients. However, patients with or without missing outcome data at 1 year had similar clinical characteristics and functional outcomes at 90 days (Table S4), a finding that does not support nonrandom loss to follow-up. Therefore, under the missing-at-random assumption, sensitivity analyses using multiple imputation for missing data yielded results similar to the complete-case analysis, suggesting a limited effect of this bias. Second, the open-label (PROBE [prospective, randomized, open-label, blinded end point]) design may have introduced differential bias in postacute medical management, potentially influencing the observed differences in 1-year outcomes. However, both patient groups received comparable levels of postacute medical care throughout the 1-year follow-up period, which reduces the likelihood of a meaningful bias from this factor. Third, we did not assess patient-reported outcomes, such as cognitive, psychological, or social functioning outcomes. These were not collected because patients with severely disabling strokes often experience communication difficulties, cognitive impairments, or physical limitations that hinder accurate self-reporting. Fourth, adverse event monitoring was conducted only up to 90 days, and data on adverse events other than stroke

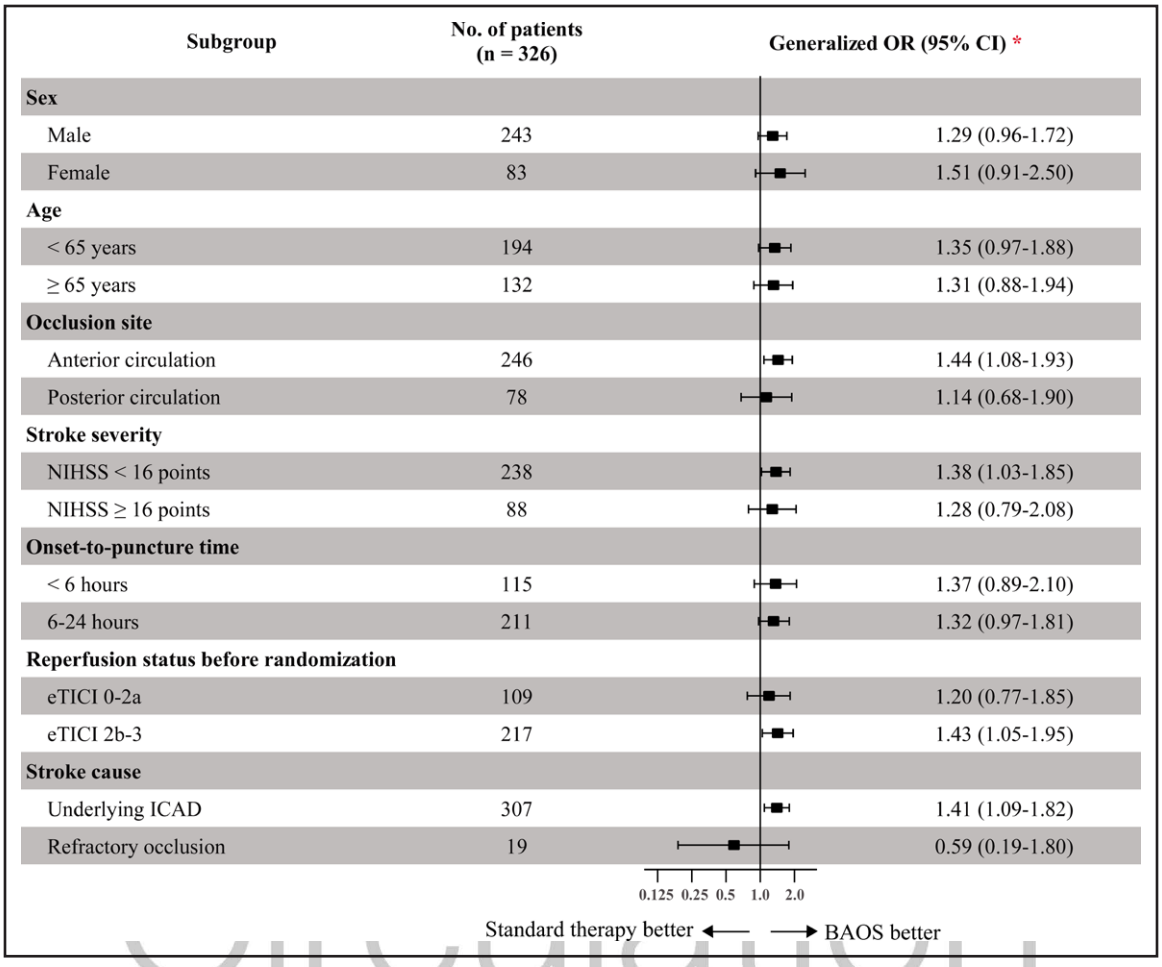

Figure 3. Treatment effects on the overall distribution of modified Rankin Scale scores in prespecified subgroups.
*The generalized odds ratio (OR) was calculated using the Wilcoxon-Mann-Whitney test, reflecting the odds of a 1-point improvement in the modified Rankin Scale score at 1 year. BAOS indicates bailout intracranial angioplasty or stenting; eTICI, expanded Thrombolysis in Cerebral Infarction; ICAD, intracranial atherosclerotic disease; and NIHSS, National Institutes of Health Stroke Scale.

recurrence were not collected. We also did not gather information on the cause of death beyond 90 days, or on the type and duration of rehabilitation received by individual patients. Fifth, the trial was conducted exclusively at tertiary hospitals in China, where high standards of secondary prevention and ongoing care are expected. Therefore, the generalizability of these long-term outcomes to other health care settings remains uncertain. Sixth, no correction for multiple testing was performed. Therefore, analyses of secondary outcomes should be considered exploratory and not used for definitive hypothesis testing. Moreover, the trial was not powered to detect differences in treatment effects across subgroups. In addition, the number of patients with sICH within 36 hours after treatment was higher in the BAOS group than in the standard therapy group (8 versus 1). All 9 patients with sICH completed the 1-year follow-up; however, because of the limited number of events, we were unable to perform a statistically meaningful comparative analysis of the 1-year outcomes between the 2 groups in patients with sICH.

The long-term clinical benefit of BAOS after thrombectomy in patients with predominantly ICAD-related LVO is evident not only in improved functional outcomes (as assessed by mRS score at 1 year), but also in a reduced rate of stroke recurrence in the treated artery within the same period. These findings offer clinicians substantial reassurance regarding the durable long-term efficacy of BAOS and confirm its crucial role in reducing the risk of stroke recurrence in the treated artery, underscoring its value in maintaining revascularization stability over the long term.

ARTICLE INFORMATION

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Affiliations

Interventional Neuroradiology (F.G., X.T., L. Li, Y.P., B.J., M.Y., Dapeng Sun, D.M., N.M., Z.M.) and Department of Neurology (L.L., X.Z., Yilong Wang, Yongjun Wang), Beijing Tiantan Hospital, Department of Neurosurgery, Beijing Chaoyang Hospital (Yang Wang), Department of Neurology, Xuanwu Hospital (G.M.), and Neurological Disease Center, Beijing Anzhen Hospital (X.H.), Capital Medical University, Beijing, China. Department of Neurosurgery, Tianjin Huanhu Hospital, China (M.W.). Department of Neurology, The First People's Hospital of

Chenzhou, China (X. Yao, G.F.). China National Clinical Research Center for Neurological Diseases, Beijing, China (Y.P., Z.R., Yilong Wang, Yongjun Wang). Departments of Radiology and Neurology, Boston Medical Center, MA (T.N.N.). Department of Emergency, Xiangtan Central Hospital, China (G.Y.). Department of Neurology, The First People's Hospital of Taizhou, China (C.X.). Department of Neurology, The Affiliated Hospital of Southwest Medical University, Luzhou, China (Z.Y.). Department of Neurology, The Third People's Hospital of Hubei Province, Wuhan, China (Y. Wan). Department of Neurointerventional Radiology, Beijing Fengtai You'anmen Hospital, China (J.W.). Department of Neurology, Wuhan Central Hospital, China (P.J.). Department of Neurology, Sun Yat-Sen Memorial Hospital, Sun Yat-Sen University, Guangzhou, China (X.Y.). Department of Neurointerventional Radiology, YunFu People's Hospital, China (Z.W.). Department of Neurology, The First Affiliated Hospital of USTC, Division of Life Sciences and Medicine, University of Science and Technology of China, Hefei, China (W.H.). Department of Neurology, Tai'an Hospital of Chinese Medicine, China (Y.J.). Department of Neurology, Beijing Liangxiang Hospital, China (C. Wang). Department of Neurology, Nanyang Central Hospital, China (C. Wen). Department of Neurology, Shanghai Neuromedical Center, China (J.T.). Department of Neurology, Tongji Hospital, Tongji Medical College of HUST, Wuhan, China (X.L.). Department of Neurology, Ordos Central Hospital, China (Y. Wu). Department of Neurology, The First Affiliated Hospital of Henan University of Science and Technology, Luoyang, China (R.S.). Department of Neurology, JiuJiang First People's Hospital, China (T.Z.). Department of Neurology, Shanxi Provincial People's Hospital, Taiyuan, China (Yaxuan Sun). Department of Neurology, Xi'an Third Hospital, The Affiliated Hospital of Northwest University, China (M.C.). Department of Neurology, JingJiang People's Hospital, The Seventh Affiliated Hospital of Yangzhou University, JingJiang, China (Y.L.). Department of Neurology, Beijing Daxing People's Hospital, China (H.Y.). Department of Neurointerventional Radiology, Dalian Municipal Central Hospital, Dalian Medical University, China (D.L.). Department of Neurosurgery, The Second Affiliated Hospital of Wenzhou Medical University, China (B.Y.). Department of Neurology, Beijing Shijingshan Hospital, China (W.J.). Department of Neurology, The 940th Hospital of Joint Logistics Support Force of Chinese People's Liberation Army, Lanzhou, China (D.W.). Department of Neurointerventional Radiology, Hebei Provincial People's Hospital, Shijiazhuang, China (G.X.). Center for Neurology, Tianjin TEDA Hospital, China (Z.G.). Department of Neurointerventional Radiology, Yantai Mountain Hospital of Yantai City, China (Dianjing Sun). Department of Neurosurgery, Changsha Hospital of Traditional Chinese Medicine, China (J.D.). Department of Neurointerventional Radiology, Beijing Shunyi Hospital, China (L.W.). Department of Neurology, Binzhou People's Hospital, China (G.W.). Department of Neurology, Luoyang Central Hospital, China (L.W.). Department of Diagnostic and Interventional Neuroradiology, University Medical Center Hamburg-Eppendorf, Hamburg, Germany (J.F.).

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Author Contributions

Study concept and design: Drs Gao, Tong, Fiehler, Yongjun Wang, and Miao. Critical revision of manuscript for intellectual content: Drs Gao, Tong, L. Li, Pan, Nguyen, and Fiehler. Study conduct: Drs Gao, Tong, M. Wei, Xiaoxi, L. Li, B. Jia, M. Yang, Dapeng Sun, Feng, G. Yuan, C. Xu, Z. Yuan, Y. Wan, J. Wang, Jing, X. Yang, Z. Wu, Hu, Jiang, C. Wang, Wen, Tang, Luo, Y. Wu, Shen, Zheng, Y. Sun, Chang, Y. Liu, H. Yang, D. Li, Yin, W. Jia, D. Wan, G. Xu, Guo, Dianjing Sun, Yang Wang, Duan, L. Wang, G. Wang, L. Wei, G. Ma, Huo, Mo, and N. Ma. Study supervision: Drs Ren, L. Liu, Zhao, Yilong Wang, Fiehler, Yongjun Wang, and Miao. Statistical analysis: Dr Pan.

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Disclosures

Dr Nguyen reports advisory board participation for Aruna Bio and Brainomix and is an associate editor of *Stroke*. Dr Fiehler reports related interests (managing director and stock holder of Eppdata and chair of an imaging core laboratory) and unrelated interests (consultant for Acandis, Cerenovus, Medtronic, Medina, Microvention, Penumbra, Phenox, Stryker, and TE Medical, and stock holder of Tegus Medical and Vastrax). The other authors declare no competing interests.

Supplemental Material

Appendix
Methods
Tables S1–S12
Figures S1–S3

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