One-Year Outcome After Endovascular Treatment for Acute Basilar Artery Occlusion

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BACKGROUND AND PURPOSE: The BASILAR registry, a nationwide prospective nonrandomized study conducted in China, enrolled consecutive patients with acute basilar artery occlusion receiving endovascular treatment or conventional-treatment from January 2014 to May 2019. This article aimed to report the results of clinical follow-up at one year among these patients.

METHODS: The primary outcome was the modified Rankin Scale at one year, assessed as a common odds ratio using ordinal logistic regression analysis adjusted for prespecified prognostic factors. Secondary outcomes included the modified Rankin Scale-based outcome group at one year (0–1, 0–2, or 0–3) and all-cause death.

RESULTS: Of the 829 patients enrolled in the original BASILAR registry, one-year data were available for 785 patients (94.7%). The distribution of outcomes on the modified Rankin Scale favored endovascular treatment over conventional-treatment (adjusted common odds ratio, 4.50 [95% CI, 2.81–7.29]; \( P < 0.001 \)). The cumulative one-year mortality rate was 54.6% in the endovascular treatment group versus 83.5% in the conventional-treatment group (adjusted odds ratio, 4.36 [95% CI, 2.69–7.29]; \( P < 0.001 \)).

CONCLUSIONS: The beneficial effect of endovascular treatment on functional outcome at one year in patients with acute basilar artery occlusion is similar to that reported at 90 days in the original study.

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GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: basilar artery ■ endovascular procedures ■ ischemic stroke ■ prognosis ■ therapy
Study Design
Our study population was enrolled from the BASILAR registry. Detailed methodology for the BASILAR registry, the 90-day outcomes, and the study protocol have been published previously. This study was performed in accordance with the Declaration of Helsinki and was approved by the local institutional ethics review board. We reported our study according to the RECORD (Reporting of Studies Conducted Using Observational Routinely-Collected Health Data) statement, as detailed in the Supplemental Material.

Patients
After the 90-day follow-up assessment, we invited eligible patients who were still alive to take part in the extended follow-up study. Patients (or a legal representative if they were unable to communicate) who wished to participate in the extended follow-up study provided informed consent by telephone. The detailed inclusion and exclusion criteria are shown in the Supplemental Material.

Outcome Measures
The primary outcome was the score on the modified Rankin Scale (mRS) at one year. The mRS is an ordinal scale that ranges from 0 (no symptoms) to 6 (death). Secondary outcomes included the mRS-based outcome group at one year (where 0–1 was defined as an excellent outcome, 0–2 as a good outcome indicative of functional independence, and 0–3 as a favorable outcome) and all-cause death during the one-year period following treatment.

Statistical Analysis
We analyzed the shift towards the improvement of mRS using ordinal logistic regression, and other outcomes using binary logistic regression, adjusting for confounders of age, sex, National Institutes of Health Stroke Scale (NIHSS) score, posterior circulation Acute Stroke Prognosis Early CT Score, onset to imaging diagnosis time, history of diabetes and ischemic stroke, intra-venous thrombolysis, and location of occlusion. Propensity score matching was performed to maintain homogeneity between groups. Besides, sensitivity analysis was performed on outcomes using multiple imputation for missing data. All statistical analyses were performed using SPSS software version 23.0 (IBM Corp., Armonk, NY). Further details are provided in the Supplemental Material.

RESULTS
Study Population
A total of 785 (94.7%) patients had one-year follow-up data and were included in the primary analysis for functional outcome (Table; Tables I and II and Figure I in the Supplemental Material).

Primary Outcome
The adjusted common odds ratio (OR) was 4.50 (95% CI, 2.81–7.29; P<0.001) for optimal distribution of outcomes on the mRS with EVT compared with conventional treatment (Figure; Table III in the Supplemental Material).

Secondary Outcomes
Patients in the EVT group were more likely than patients in the conventional-treatment group to have an excellent outcome (22.6% versus 7.6%; adjusted OR, 3.21 [95% CI, 1.69–6.56]), good outcomes (30.9% versus 10.0%; adjusted OR, 4.15 [95% CI, 2.32–7.83]), and favorable outcomes (35.6% versus 11.8%; adjusted OR, 4.54 [95% CI, 2.61–8.28]). The cumulative one-year mortality rate was significantly higher in the conventional-treatment alone group than in the EVT group (83.5% versus 54.6%; P<0.001; absolute difference: 28.9% [95% CI, 22.1%–35.7%]), with an adjusted OR of 4.36 (95% CI, 2.69–7.29; Table III and Figure II in the Supplemental Material).

Propensity Score Matching Analysis
After 1:1 propensity score matching analysis, the baseline characteristics between the 2 groups were evenly distributed (Table IV in the Supplemental Material). A total of 154 patients who had EVT were eligible for the matched-pairs analysis using the multivariate method. The score on the mRS at one year, the primary functional outcome, was significantly lower in the EVT group than in the conventional-treatment group (6 [interquartile range, 2–6] versus 6 [interquartile range, 6–6], P<0.001; Table IV in the Supplemental Material; Figure). Compared with the conventional-treatment group, patients in the EVT group had a higher proportion of excellent outcomes (20.1% versus 8.4%; P=0.003), good outcomes (29.9% versus 11.0%; P<0.001), and

Nonstandard Abbreviations and Acronyms
| Abbreviation | Description |
|--------------|-------------|
| BAO          | basilar artery occlusion |
| BASICS       | Basilar Artery International Cooperation Study |
| BASILAR      | Assessment of Endovascular Treatment for Acute Basilar Artery Occlusion via a Nationwide Prospective Registry |
| BEST         | Basilar Artery Occlusion Endovascular Intervention Versus Standard Medical Treatment |
| EVT          | endovascular treatment |
| mRS          | modified Rankin Scale |
| NIHSS        | National Institutes of Health Stroke Scale |
| OR           | odds ratio |
| RECORD       | Reporting of Studies Conducted Using Observational Routinely-Collected Health Data |
favorable outcomes (34.4% versus 12.3%; \( P < 0.001 \)). Mortality within one year was significantly higher in the conventional-treatment alone group than in the EVT group (59.1% versus 81.8%, \( P < 0.001 \)).

**Sensitivity Analysis**

The missing outcome data for the 44 patients were handled using multiple imputation. The pooled effect on the primary outcome after multiple imputation (adjusted common OR, 4.04 [95% CI, 2.58–6.32]; Table V in the Supplemental Material) was similar to the result of the main analysis of the primary outcome.

**Subgroup Analyses**

The treatment effect remained consistent in almost all prespecified subgroups, which were defined according to baseline characteristics (Figure III in the Supplemental Material). No significant interactions (effect modifications) were observed between the prespecified subgroups and treatment at one year.
DISCUSSION

The results of this extended follow-up evaluation of the BASILAR registry showed that EVT in patients with acute BAO resulted in functional recovery similar to the originally reported results at 90 days. The OR for better scores on the mRS in the EVT group than in the conventional-treatment group was 4.50 at one year, compared with an OR of 3.08 at 90 days. The percentage of patients in the EVT group who experienced a favorable outcome (ie, a mRS score of 0 to 3) at one year (35.6%) was also similar to the results at 90 days (32.0%).

Although the above results were similar, notable differences were observed between the 2 time points. First, during the extended follow-up period, the mortality rate in EVT group was much lower than that of conventional-treatment group, and the absolute difference became greater than the difference between the 2 groups at 90 days. Second, the percentages of patients with mRS of 0 to 1, 0 to 2, and 0 to 3 at one year were higher than those percentages at 90 days in both treatment groups. The absolute difference in the percentages of patients with mRS of 0 to 2 and 0 to 3 at one year became greater than that of the 2 groups at 90 days.

Recently, the BEST (Basilar Artery Occlusion Endovascular Intervention Versus Standard Medical Treatment) trial and the BASICS (Basilar Artery International Cooperation Study) trial have evaluated the efficacy and safety of EVT in addition to best medical treatment among patients with acute BAO. Although the BEST showed EVT had no benefit over best medical treatment in prespecified intention-to-treat analysis, the per-protocol and as-treated analyses demonstrated better outcomes following EVT. This result may be related to the higher clinical severity of patients who were selected for inclusion in the BEST trial (median baseline NIHSS score 32 [interquartile range, 18–38] in the intervention group versus 26 [interquartile range, 13–37] in the control group). In the BASICS trial, the results were underpowered to show a statistically significant benefit of EVT in patients treated within 6 hours of...
the estimated time of acute BAO. The subgroup analysis showed significantly better outcomes with EVT for patients with moderate-to-severe stroke (NIHSS scores ≥10). Notably, the 2 studies have suggested that the treatment effect size of EVT versus best medical treatment alone is significantly higher in patients presenting with severe deficits than those with mild deficits. Compared with the 2 trials, the BASILAR study enrolled a higher proportion of patients with moderate-to-severe deficits (88.78%), probably resulting in a significant treatment effect that was evident at 90 days and sustained at 1 year.

We found the prior efficacy of EVT over conventional treatment was consistent in patients treated within 6 hours and those over 6 hours, suggesting that EVT might be reasonable even after 6 hours of onset. This was different from the BASICS prospective registry, which showed no evidence of benefit of intraarterial therapy than intravenous thrombolysis beyond 6 hours after onset, possibly associated with the outdated EVT devices and overall negative results. Several multicenter cohorts have detected the effects of onset to treatment time on prognosis of EVT in patients with acute BAO. Although the rates of favorable outcome decreased when treatment beyond 6 hours after onset, they failed to conclude that patients could not benefit from EVT, due to the lack of conventional-treatment control. Furthermore, these data, ranging from 23.6% to 35%, was obviously higher than the 7% in the conventional treatment group reported in the BASICS prospective registry and in our study. Future clinical trials beyond 6 hours time window are needed.

Our study was a prospective observational study with all the inherent limitations of a nonrandomized study. Propensity score matching or multivariate analyses can never adjust completely for systematic differences between treatment groups, which is the aim of randomization in clinical trials. Moreover, the study was powered to detect an effect at 90 days but did not take into account loss to follow-up during the one-year follow-up period; however, a sensitivity analysis in which missing outcomes were imputed by means of model-based multiple imputation showed results that were similar to those of the main analysis of the primary outcome, which shows a limited bias effect. Furthermore, all participating hospitals of the BASILAR registry were EVT-capable stroke centers, the generalizability of the findings among more diverse hospitals is uncertain.

CONCLUSIONS
In conclusion, the beneficial effect of EVT in patients with acute BAO shown at 90 days was sustained for at least 1 year.

ARTICLE INFORMATION
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Disclosures
None.

Supplemental Materials
Expanded Methods
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RECORD Checklist

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