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Endovascular treatment of acute basilar artery occlusion: Tama-REgistry of Acute Thrombectomy (TREAT) study

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ABSTRACT

Objective: The effectiveness of mechanical thrombectomy (MT) for acute basilar artery occlusion (ABAO) remains unknown. We evaluated the feasibility, safety, and efficacy of endovascular treatment for ABAO.
Methods: We retrospectively investigated patients with ABAO who underwent MT, using modern stent retrievers and an aspiration device, between January 2015 and December 2017 at 12 comprehensive stroke centers. Functional outcomes and 90-day mortality were analyzed as primary outcomes.
Results: Forty-eight patients were included. Good outcome (modified Rankin Scale mRS 0–2) was achieved in 20/48 patients and the all-cause 90-day mortality rate was 25%. Successful recanalization (modified Thrombolysis In Cerebral Infarction [mTICI] grade 2b and 3) was achieved in 47/48 patients. National Institutes of Health Stroke Scale, posterior circulation Alberta Stroke Program Early CT Score (pc-ASPECTS), DWI Brain Stem Score, mTICI (3 > 2b), and intracranial hemorrhage were significantly different between good and poor functional outcome groups. The occlusion site of BA was significantly different between patients with moderate outcome (mRS 0–3) versus others. We found that age, pc-ASPECTS and mTICI were significantly associated with functional outcomes in the logistic regression model.
Conclusion: MT with stent retrievers and an aspiration device for ABAO results in high successful recanalization and good outcomes. Further studies are required to confirm our results.

1. Introduction

Acute basilar artery occlusion (ABAO) is a devastating disease characterized by high morbidity and mortality rates [1,2]. With conventional treatment (with antiplatelets and anticoagulation alone), the fatality rate was reportedly 40% and moderate outcomes (modified Rankin Scale [mRS] 0–3) were achieved in 21% of patients [2]. In patients with severe disease (with coma, locked-in syndrome, or

Abbreviations: ABAO, acute basilar artery occlusion; BASICS, Basilar Artery Intervention Cooperation Study; BSS, Brain Stem Score; CTA, computed tomography angiography; DWI, diffusion-weighted image; IAT, intra-arterial therapy; ICH, intracranial hemorrhage; IVT, intra-venous therapy; LVO, large vessel occlusion; MRA, magnetic resonance angiography; MT, mechanical thrombectomy; mTICI, modified Thrombolysis In Cerebral Infarction; OTR, onset to recanalization; pc-ASPECTS, posterior circulation Alberta Stroke Program Early CT Score; RCT, randomized clinical trials; rtPA, recombinant tissue plasminogen activator; TREAT, Tama-REgistry of Acute Thrombectomy

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tetraplegia), the fatality rate was 54% and moderate outcomes were achieved in only 7.6% of patients [1].

In 2015, multiple clinical trials proved the effectiveness of mechanical thrombectomy (MT) for large vessel occlusion (LVO) in the anterior circulation [3–7]. The results of the five randomized clinical trials (RCTs) suggested that intra-arterial therapy (IAT), particularly MT using modern stent retrievers, in addition to intra-venous therapy (IVT), specifically recombinant tissue plasminogen activator (rtPA), was superior to IVT alone [3–7]. However, with regard to the posterior circulation, the evidence for MT remains unclear due to a lack of RCT data. In the prospective registry from the Basilar Artery Intervention Cooperation Study (BASICS), there was no difference in functional outcomes between IAT and IVT [1]. One of the main reasons for the lack of distinction between groups by BASICS was due to the MT device used. In particular, modern stent retrievers were not available during the study period. Therefore, limited data are available regarding the effectiveness of MT for LVO in the posterior circulation.

The objectives of the present study were to evaluate the feasibility and effectiveness of endovascular treatment for ABAO, and to identify influencing factors of functional outcome using region-wide registry data of stroke centers in suburban Tokyo, Japan.

2. Methods

2.1. Patient selection

The Tama-REgistry of Acute Thrombectomy (TREAT; UMIN-CTR: UMIN000026888) is a regionwide, multicenter, retrospective observational registry launched in 2015 to investigate the outcome of revascularization therapy for all LVO cases in the Tama district in the western part of suburban Tokyo [8]. During the inclusion period of this study, modern stent retrievers and aspiration devices were available for use. We retrospectively analyzed data collected from 12 comprehensive stroke centers in the region of Tama (1160 km^2). This area is densely populated (4.3 million people). Details concerning the aims and structure of TREAT have been described elsewhere [8]. The period of the current study was from January 2015 to December 2017. All patients with ABAO for whom endovascular revascularization therapy was performed, and in whom ABAO was subsequently confirmed by computed tomography angiography (CTA), magnetic resonance angiography (MRA), or conventional contrast angiography, were included. In this study, we wanted to examine patients who developed ischemic stroke outside of a hospital setting; hence, patients who developed a stroke during hospitalization for other reasons were excluded. No limits were placed on patient age, National Institute of Health Stroke Scale (NIHSS) score, time from onset, or pre-treatment activity. Each stroke center had full responsibility for patient selection.

Study approval was obtained from the institutional review board of each stroke center. Each participant provided informed written consent for participation.

2.2. Revascularization therapy

Each center could decide the strategy for revascularization and select the devices deemed most appropriate for treatment. Guiding catheters could be used with or without a balloon. MT devices were second-generation stent retrievers, such as the Solitaire (Covidien, Irvine, CA, USA), or Trevo (Stryker, Fremont, CA, USA), and the Penumbra System (Penumbra, Oakland, CA, USA) was used as the aspiration device. Other than MT devices, balloon angioplasty or local fibrinolytic therapy and stenting could be used as IAT. Similarly, no restrictions were placed on the anesthesia method, anti-thrombotic therapy, equipment used, or post-operative care.

2.3. Endpoints

The primary outcomes of the current study were functional outcomes and all-cause mortality at 90 days. Functional outcome was defined by the mRS. A good outcome had a mRS score of 0–2, while a score of 0–3 was a moderate outcome. The secondary outcome was the analysis of background characteristics and treatments between the good and poor functional outcomes groups, and identification of factors influencing functional outcome. Background characteristics and treatments were age, gender, NIHSS score, the posterior circulation Alberta Stroke Program Early CT Score (pc-ASPECTS) assessed by diffusion-weighted imaging (DWI) [9], DWI Brain Stem Score (BSS) [10], etiology of occlusion, site of basilar artery (BA) occlusion, use of rtPA, type of revascularization devices used, number of passes required, modified Thrombolysis In Cerebral Infarction (mTICI) grade [11], time from onset to recanalization (OTR), and any intracranial hemorrhage (ICH). The definition of the occlusion site was proximal (proximal to the anterior inferior cerebellar artery), or middle (between the anterior inferior and superior cerebellar arteries) and distal (distal to the superior cerebellar artery) [12]. Successful recanalization was defined as mTICI 2b and 3. Symptomatic intracranial hemorrhage (sICH) was defined as any hemorrhagic transformation seen on the post-procedural CT scan and associated with a decline of > 4 points in the NIHSS score within 72 h or leading to another surgical procedure.

2.4. Statistical analysis

We compared the background characteristics and treatments between the good and poor functional outcomes groups. Continuous variables were compared between the groups using a *t*-test or Mann-Whitney *U* test, and categorical variables were analyzed using chi-square or Fisher's exact tests, as appropriate. We performed a logistic regression analysis for influencing factors to outcome and adjusted for the following factors: age, NIHSS, tPA, pc-ASPECTS, mTICI and OTR. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated. The threshold for significance was $p < .05$. We calculated the area under the receiver operator characteristic (AUROC) curves for pc-ASPECT to predict 90-day functional outcome and used the Youden index as the cutoff predictive value.

All statistical analyses were conducted using IBM SPSS version 23.0 for Windows (IBM Corp., Armonk, NY, USA).

3. Results

3.1. Patient selection and baseline characteristics

During the study period, 586 patients were retrospectively registered in TREAT. Among the 586 patients, there were 64 (10.9%) patients with ABAO. Of these, 14 patients whose events developed on an in-patient basis were excluded. Two patients were lost to follow-up. Thus, 48 patients, with available 90-day functional outcomes, were included in this study. Patient numbers for the mRS before stroke were as follows: mRS 0 (32), mRS 1 (5), mRS 2 (6), mRS3 (2), mRS 4 (2), and mRS 5 (1). Table 1 presents the baseline characteristics of the patients included in the study. (See Table 1.)

3.2. Outcomes

A good outcome (mRS 0–2) was achieved in 20/48 (41.7%) patients. All-cause mortality affected 12/48 (25%) patients. A moderate outcome (mRS 0–3) was achieved in 26/48 (54.2%) patients at 90 days (Fig. 1). Successful recanalization was attained in 47/48 (98.0%) patients. Hemorrhagic complications occurred in 11/48 (22.9%) patients: subarachnoid hemorrhage occurred in 3 patients, intracranial hemorrhage occurred in 1 patient, and hemorrhagic infarction occurred in 7 patients. sICH occurred in 2/48 (8.3%) patients.

Table 1
Demographic and clinical characteristics of patients.

	Good outcome	Poor outcome	P
Variables	*N* = 20	*N* = 28	
Age	68 (58.5–75.8)	82 (72.3–86.5)	< 0.01
Gender, male	16 (80.0)	19 (67.9)	0.35
NIHSS	12 (6.85–25.5)	25 (21.5–32.3)	< 0.01
pc-ASPECTS	7.5 (6.3–9.0)	6.0 (4.0–7.0)	< 0.01
BSS	1 (0–2)	2 (1–3)	0.04
Etiology			0.49
Cardiogenic	13 (65.0)	22 (78.6)	
Atheroma	6 (30.0)	4 (14.3)	
Dissection	1 (5.0)	1 (3.6)	
Others, unknown	0	1 (3.6)	
Occlusion site of BA			0.45
Proximal	3 (15.8)	9 (32.1)	
Mid	8 (42.1)	9 (32.1)	
Distal	8 (42.1)	10 (35.7)	
tPA	8 (40.0)	13 (46.4)	0.66
First device			0.42
Stent retriever	14 (70.0)	19 (67.9)	
Aspiration system (Penumbra)	5 (25.0)	7 (25.0)	
Balloon PTA	1 (5.0)	0	
Others	0	2 (7.1%)	
mTICI			0.04
3	17 (85.0)	14 (50.0)	
2b	3 (15.0)	13 (46.4)	
0–2a	0	1 (3.6)	
Number of Pass	1 (1–2)	1 (1–2)	1.0
Time from onset to recanalization (m)	281 (216–617)	340 (260–575)	0.50
Transferred from another hospital	8 (40.0)	6 (21.4)	0.16
Hemorrhagic complication	1 (5.0)	10 (35.7)	0.01

Data are presented as n (%) or median (interquartile).
NIHSS: National Institutes of Health Stroke Scale; pc-ASPECTS: posterior circulation Alberta Stroke Program Early CT Score; BSS: Brain Stem Score; BA: basilar artery; tPA: recombinant tissue plasminogen activator; PTA: percutaneous transluminal angioplasty; mTICI: modified Thrombolysis In Cerebral Infarction; ICH: intra cranial hemorrhage.

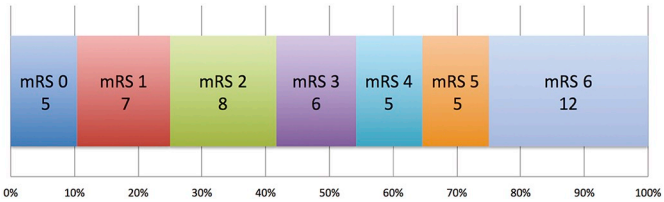

Fig. 1. Functional outcome at 90 days.

Table 2
Logistic regression analysis for prediction of the influencing factors for good functional outcome.

	OR	*P*-value
Age	1.14 (1.03–1.27)	0.01
NIHSS	1.06 (0.97–1.17)	0.21
tPA	1.06 (0.08–13.77)	0.96
pc-ASPECTS	0.45 (0.24–0.85)	0.01
mTICI	16.2 (1.24–212)	0.03
OTR	1.00 (0.99–1.01)	0.95

In the analysis of background characteristics and treatments between the good and poor functional outcomes groups, there were significant differences for age ($p < .01$), NIHSS score ($p < .01$), pc-ASPECTS score ($p < .01$), BSS ($p = .04$), mTICI (2b < 3) ($p = .04$), and hemorrhagic complication. ($p = .01$). Regarding pc-ASPECTS, 75% of patients with a good outcome had a score of > 7 points, while no patients had a score below 5. The AUROC for pc-ASPECT analyses to predict 90-day functional outcome was 0.80 (95% CI, 0.67 to 0.92, $p = .001$). The pc-ASPECT threshold that was best associated with 90-day functional outcome was 7 as estimated by the Youden index (75% sensitivity, 67% specificity). When the occlusion site was divided into two groups (proximal vs. middle and distal), the group with occlusion in the middle and distal regions had a moderate outcome (mRS 0–3) significantly more often ($p = .02$) (Table 3). In the logistic regression analysis, age (OR 1.14, 95% CI 1.03 to 1.27), pc-ASPECTS (OR 0.45, 95% CI 0.24 to 0.85) and mTICI (OR 16.21, 95% CI 1.24 to 212) were significantly associated with functional outcome (Table 2).

Table 3
Relationship between occlusion site and moderate functional outcome.

	mRS 0–3	mRS 4–6	P
Variables	*N* = 25	*N* = 22	
Occlusion site of BA			0.02
Proximal	3 (12.0)	9 (40.9)	
Middle, distal	22 (88.0)	13 (59.1)	

Data are presented as n (%).

4. Discussion

In this study, > 40% of patients with ABAO for whom MT was performed achieved a good outcome, and nearly 55% achieved a moderate outcome. Successful recanalization was achieved in 98% of patients.

In a literature review of MT for ABAO published after 2010, there were six articles in which the patient number exceeded 30 [13–18]. The average percentage of patients in whom a good outcome was achieved was 40.8% (range: 34%–56%), and the average successful recanalization rate was 84.8% (range: 62%–100%). The good outcome rate was similar in the current study, and the successful recanalization rate was superior to that of previous reports. In the present study, each participating center was entrusted with device selection. There was no significant difference in study outcomes between the devices utilized, especially between stent retrievers and aspiration devices, and high recanalization rates were achieved irrespective of the device utilized. Historically the outcome in patients with ABAO was considered to be devastating. MT was shown to be as effective for patients with ABAO as for those with occlusion in the anterior circulation.

Regarding the analysis of background characteristics and treatments between the good and poor functional outcomes groups, there were significant differences in age, severity of the symptom (NIHSS), area of infarction (pc-ASPECTS, BSS), perfect recanalization rate (mTICI 2b < 3), and hemorrhagic complication. in the current study. OTR was not related to outcome. In five of six previously reported articles, age and NIHSS were related to functional outcome [13–16,18]. On the other hand, OTR was related to functional outcome in only three reports [14,17,18]. In the HERMES study, a meta-analysis of pooled data from 1287 patients in five RCTs of MT for LVO of the anterior circulation, OTR was significantly related to a good outcome [19].

It remains unclear why OTR was not associated with outcome in our patients with ABAO. Delay of OTR may be one reason. Uno et al. [14] reported on the outcome of MT for 34 patients with ABAO, and found that OTR was significantly related to outcome: a median OTR was 178 min for a good outcome, which was shorter than the OTR found in the present study. Giorgianni et al. [18], in a study of 102 patients with ABAO, also reported a significant relationship between outcome and OTR. However, their median OTR was 315 min for a good outcome, which was longer than in our study. Shorter OTR may not necessarily be associated with the outcome in patients with ABAO as compared to LVO of the anterior circulation. OTR was not significantly related to functional outcome in the current study, even after adjustment with a logistic regression analysis.

The unique collateral arterial network of the vertebro-basilar system may be another reason why OTR was not associated with outcome in this study. In general, the time window for recanalization of ABAO is longer than that of the anterior circulation [20]. Reflux from the posterior communicating artery (Pcom) to the upper BA is a specific feature of ABAO, while leptomeningeal anastomosis between the posterior inferior cerebellar artery, anterior inferior cerebellar artery, and superior cerebellar artery territory, and backflow to the basilar artery are further characteristics [20]. The development of these networks varies across patients and determines the way that ischemia spreads. RCTs of LVO of the anterior circulation have evaluated the core ischemic lesion and penumbra, and these were incorporated in our inclusion criteria [3–7]. In terms of the ischemic area, the pc-ASPECTS was significantly associated with functional outcome in this study. Regarding pc-ASPECTS, 75% of patients with a good outcome had a score of > 7, but no patients scored below 5. The pc-ASPECT threshold was 7.

An undeveloped collateral network might make the time window for achieving a good outcome shorter and the pc-ASPECTS worse than for those who have a developed network. In terms of the mTICI grade, the successful recanalization rate exceeded 90%, due to the use of modern MT devices, and successful recanalization is a precondition for a good outcome. In this study, a perfect recanalization rate (mTICI 3) was significantly associated with functional outcome. In patients with mTICI 3, a larger collateral network might be rescued than in patients with mTICI 2b.

In a case series, Parks et al. reported that patients with a distal occlusion had a more favorable outcome [21]. If the occlusion site was proximal, a collateral network via the anterior inferior cerebellar artery and superior cerebellar artery to the BA would be important to maintain perforated arteries of the BA in addition to reverse flow from the Pcom. When we categorized the occlusion site into two categories (proximal vs. middle and distal), the latter location was significantly related to a moderate outcome (mRS 0–3). We speculate that a shorter OTR is necessary for patients with ABAO whose collateral networks are undeveloped. On the other hand, OTR may clearly influence functional outcome for those who have developed one. Uno et al. reported that a cerebral blood flow/cerebral blood volume mismatch was related to functional outcome in patients who underwent MT for ABAO [14]. In future, the ischemic penumbra and collateral arterial network should be evaluated in patients with ABAO, as in patients with LVO of the anterior circulation.

The current study had several limitations. First, the study design was retrospective and observational. Second, as the study was multicentric, there was no standardization of patient selection and treatment procedures. Especially, age, severity of symptoms, onset time to admission, and evaluation of the ischemic region might be restricted for inclusion in future studies. Third, the sample size was fairly small, and a larger sample size might provide better statistical power for accurate analysis. Fourth, a longer period of observation, such as 6 months or more, might be more appropriate to evaluate outcome. In future, high-quality RCTs will be necessary to confirm the effectiveness of MT for patients with ABAO.

5. Conclusion

In this study, MT achieved a good outcome in > 40% of patients with ABAO, and the all-cause mortality was 25%. A very high rate of recanalization was achieved by MT. Our findings indicate that MT for patients with ABAO may be feasible and effective for improving functional outcome. Further studies are necessary to establish in which subgroup of patients with ABAO MT is effective.

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Declaration of conflicting interests

Dr. Hirano has received honoraria from Bayer, Boehringer-Ingelheim, Bristol-Myers Squibb, Daiichi-Sankyo, Otsuka Pharma, Pfizer, and Sanofi. Dr. Matsumaru has received honoraria from Medtronic, Stryker, and Johnson & Johnson. Dr. Shiokawa has received research grants from AbbVie GK and ONO Pharmaceutical Co., Ltd. The other authors report no conflicts.

Appendix A

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