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ORIGINAL ARTICLE

Recanalization is the Key for Better Outcome of Thrombectomy in Basilar Artery Occlusion

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Abstract

Purpose Patients with basilar artery occlusion (BAO) were excluded from previous randomized controlled trials (RCTs) of endovascular treatment (ET) for acute ischemic stroke, but are commonly treated in clinical practice. This study aimed at analyzing predictors of functional outcome of ET in patients with BAO to improve patient selection for ET.

Methods Consecutive patients with BAO who received ET over a 2-year time period were prospectively studied. Baseline characteristics, procedural and outcome data were evaluated. Outcome was assessed by the modified Rankin Scale (mRS) 90 days after stroke. Multivariate regression analyses were performed to identify predictors of outcome across the range of the mRS, of poor outcome (mRS 5–6) and independent outcome (mRS 0–2).

Results A total of 39 patients with BAO (median age: 75 years, 67% male) were included. Median baseline National Institutes of Health Stroke Scale (NIHSS) score was 24. Intravenous thrombolysis therapy (IVT) was administered in 56%. Successful recanalization assessed by a modified thrombolysis in cerebral infarction (TICI) score ≥2b was achieved in 82%. Independent outcome was observed in 30% of patients with successful recanalization, but in no patient with failed recanalization. Poor outcome was observed in 47% and 86%, respectively. Successful recanalization was associated with lower scores on the mRS at 90 days ($p = 0.035$), and failed recanalization was associated with an odds ratio of 13.6 for poor outcome ($p = 0.036$).

Conclusion Reperfusion is the major predictor of functional outcome in BAO in clinical practice. Failed recanalization resulted in a 13-fold increase of the risk of poor outcome. Successful recanalization is crucial to achieve a better functional outcome in BAO.

Keywords Reperfusion · Stroke · Intervention · Large vessel occlusion · Clinical practice

Introduction

Basilar artery occlusion (BAO) is one of the most devastating subtypes of stroke and is frequently associated with high morbidity and mortality rates despite recent advances in stroke care [1]. Several randomized controlled trials (RCT) demonstrated safety and efficacy of endovascular treatment (ET) in acute ischemic stroke caused by anterior circulation large vessel occlusions, while patients with BAO were excluded from these trials [2–6].

Different treatment approaches are available for BAO, such as intravenous thrombolysis (IVT) alone, intra-arterial thrombolysis, mechanical thrombectomy and a combination of these [7]. Superiority of one of these treatment options in BAO has not yet been established. The observational Basilar Artery International Corporation Study (BASICS) did not demonstrate superiority of ET over the other therapeutic strategies in patients with BAO, irrespective of stroke severity prior to treatment [8]. Results from RCTs on endovascular therapy in BAO to assess treatment effects and elucidate this issue are still lacking.

Owing to the consistent positive results in the RCTs for ET in large vessel occlusions of the anterior circulation, mechanical thrombectomy is nowadays widely adopted for

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patients suffering from BAO in clinical practice, as it was in the first ever reported case of interventional treatment of acute ischemic stroke almost 40 years ago in a patient with BAO [9]. At the same time, there is contradictory information on factors predicting functional outcome in BAO treated by endovascular therapy. The ENDOSTROKE registry identified the baseline National Institutes of Health Stroke Scale score (NIHSS), collateral status, and the use of magnetic resonance imaging (MRI) prior to ET as independent predictors of outcome whereas recanalization did not predict clinical outcome [10]. Other observational studies reported an association of better outcome with successful recanalization [11, 12]. A prospective study of all patients with BAO undergoing ET in this stroke center was carried out with the aim to improve the understanding of parameters affecting functional outcome after ET in BAO.

Methods

Patients

All consecutive patients suffering from BAO who received ET between July 2015 and June 2017 in this hospital were enrolled in a prospective observational study. Patients were either admitted directly to the center (mothership) or referred from external hospitals for ET (ship). The use of ET was indicated at the discretion of the treating neurologist and interventional neuroradiologist on a case by case basis considering all available patient variables. The use of IVT was applied prior to ET according to national guidelines and institutional protocols.

Clinical and Radiological Data

Baseline characteristics included demographical data, prestroke mRS, NIHSS on admission, prior anticoagulation, vascular risk factors, and information on stroke onset time. The presence of BAO was diagnosed either by computed tomography (CT) or magnetic resonance imaging (MRI) and confirmed by angiography of the brain. The recanalization result was defined by the modified thrombolysis in cerebral infarction score (mTICI) at the end of ET. All patients underwent follow-up brain imaging within 24 h after intervention. After ET, all patients were referred either to the stroke unit or to the intensive care unit.

The study was approved by the local ethics committee (Hamburg, Germany; MC-039/16). Written informed consent was obtained from the patient or the proxy. Consent was waived if patients died before consent could be obtained or lacked the capacity to give consent and no proxy was available.

Procedural and Outcome Data

A total of six interventional neuroradiologists performed endovascular procedures on a 24/7 basis in accordance with institutional guidelines. Devices for ET were chosen according to the preference of the interventional neuroradiologist. Successful recanalization was defined as mTICI ≥ 2b. The time elapsed from symptom onset to groin puncture and from symptom onset to recanalization were recorded. Symptomatic intracerebral hemorrhage (sICH) was determined by an occurrence of ICH combined with a deterioration of at least 4 points on the NIHSS score or indications for surgery or death. The following periprocedural and posttreatment complications were documented until discharge: presence of vasospasm, dissections, bleeding and distal embolisms as well as recurrence of stroke, groin hematoma/pseudoaneurysm, myocardial infarction, pneumonia and ICH. Functional outcome was assessed by the mRS 90 days after stroke by face to face visit or a standardized telephone interview with the patients or caregiver. The assessors were blinded to patient variables including the results of ET.

Statistical Analysis

Standard descriptive statistics are reported as median and interquartile range (IQR) for continuous variables, and numbers and percentage for categorical variables. Correlation analyses were performed by Spearman's rank-order correlation tests. Predictors of functional outcome were calculated by ordinal regression analysis with the mRS score at 90 days as the dependent variable. Logistic regression analysis was applied to identify predictors of poor outcome (defined as mRS 5–6) and independent outcome (defined as mRS 0–2). The variables sex, IVT, ship, and successful recanalization (defined by mTICI 2b/3) and prestroke mRS (categorized to 0–1 and 2–5) were considered as dichotomous independent variables whereas age, baseline NIHSS and symptom onset-to-recanalization as continuous independent variables. Variables that were predictive at the level of $p < 0.1$ in univariate analysis were entered into the multivariate analysis. The resulting odds ratios (OR) with 95% confidence intervals (CI) and p values are presented and p values <0.05 were considered statistically significant. All tests were two-sided. The statistical analysis was performed using SPSS (version 25.0; IBM, Armonk, NY, USA).

Table 1 Baseline characteristics ($n = 39$)

Baseline characteristics (n = 39)	
Age (years)—median (IQR)	75 (61–82)
Male—n (%)	26 (67)
Risk factors—n (%)	
Arterial hypertension	31 (80)
Hyperlipidemia	5 (13)
Diabetes mellitus	8 (21)
Atrial fibrillation	11 (28)
Stroke etiology—n (%)	
Atrial fibrillation	11 (28)
Atherosclerosis	18 (46)
Dissection	1 (3)
Other	3 (8)
Undetermined	6 (15)
mRS before admission—median (IQR)	0 (0–1)
Baseline NIHSS—median (range)	24 (11–42)
Anticoagulation before admission—n (%)	5 (13)
Symptom onset unknown—n (%)	14 (36)
Wake up stroke	4 (10)
Unwitnessed stroke	8 (21)
Any timepoints not documented	2 (5)
Intravenous thrombolysis—n (%)	22 (56)
Ship—n (%)	23 (59)
Mothership—n (%)	16 (41)

mRS modified Rankin scale, *NIHSS* National Institutes of Health Stroke Scale

Table 2 Procedural and outcome parameters

Workflow times	
Symptom onset to groin puncture (min)—median (IQR) ($n = 24$)	272 (163–365)
Symptom onset to recanalization (min)—median (IQR) ($n = 21$)	323 (226–421)
Procedural and outcome parameters	
mTICI 2b/3—*n* (%)	32 (82)
Any ICH—*n* (%)	3 (8)
sICH—*n* (%)	2 (5)
mRS at 90 days ($n = 248$)—median (IQR)	5 (2.5–6)

mTICI modified thrombolysis in cerebral infarction score, *ICH* Intracerebral hemorrhage, *sICH* symptomatic intracerebral hemorrhage, *mRS* modified Rankin scale

Results

Patient Characteristics

A total number of 39 patients with BAO received ET in this center during the study period. Baseline characteristics are displayed in Table 1. A total of 23 patients (59%) were referred from external hospitals (ship), while 16 (41%) were admitted directly (mothership) to this center. Median age was 75 years (IQR 61–82 years) and 67% were male. The median NIHSS score on admission was 24 and 3 patients had a prestroke mRS >1. Of the patients, 22 (56%) underwent IVT prior to endovascular therapy, 13 patients (33%) were treated beyond 6 h, whereas in 4 patients (10%) the time elapsed from symptom onset to groin puncture was unknown due to wake up stroke and in another 3 patients (8%) the exact time points were not available.

Procedural and Outcome Data

In patients with known time of symptom onset the median time interval from symptom onset to groin puncture was 272 min (163–365 min) and the median time elapsed from symptom onset to recanalization was 323 min (226–421 min) (Table 2). A successful recanalization (TICI 2b/3) was achieved in 32 patients (82%). In 22 patients (56%) a stent-retriever was the only device applied, in 6 patients (15%) an aspiration catheter alone achieved reperfusion (see Online Resource 1, Table e1). In five cases (13%) both stent-retriever and aspiration catheters were required to treat the vascular occlusion. In one patient (3%) an intra-arterial thrombolysis was performed. In two patients (5%) full reperfusion was detected in angiography prior to any ET procedure. In three subjects (8%) target occlusion could not be reached due to highly elongated and tortuous vessels.

Periprocedural complications occurred in two patients (5%) with perforation of the basilar artery accompanied by sICH. Up to discharge 19 patients (49%) suffered from complications, which comprised recurrence of stroke, ICH, pneumonia and others (e.g. urosepsis, cardiac decompensation accompanied by pulmonary edema, cardiac decompensation resulting from endocarditis and delirium, see Online Resource 1, Table e2). In three patients (8%) ICH was detected, two of which (5%) were considered symptomatic and occurred during the intervention. In three patients (8%) a percutaneous transluminal angioplasty with stent implantation was required. Of the patients, 2 were lost to follow-up, thus, functional outcome at 90 days was available for 37 patients (95%). See Fig. 1a for the distribution of scores on the mRS at 90 days. Independent outcome was achieved in 9 patients (24%), while 20 patients (54%) had a poor outcome and 10 patients (26%) had died at 90 days.

Outcome According to the Recanalization Result—a Comparative Analysis

Of the 30 patients where successful recanalization was achieved, 9 (30%) reached an independent outcome, while poor outcome was observed in 14 (47%) (Fig. 1b). In

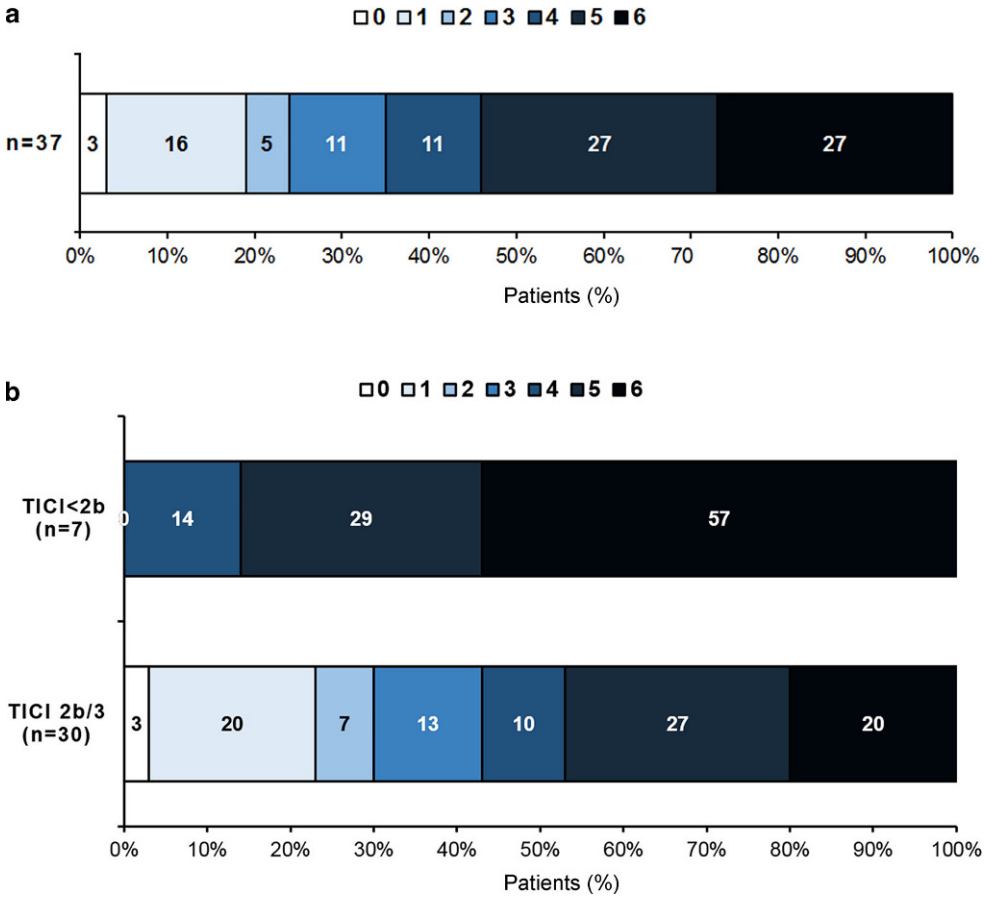

Fig. 1 **a** Distribution of the mRS scores at 90 days ($n=37$) within the entire study population. **b** Distribution of the mRS scores at 90 days in patients with successful (TICI 2b/3) compared to patients with unsuccessful (TICI <2b) recanalization. *The diagrams were created by Microsoft Excel, exported as a graphic file and edited by the graphics software Jasc Paint Shop Pro 7.02*

contrast, none of the seven patients with failed recanalization reached an independent outcome, while six (86%) had a poor outcome. In the group of patients with successful recanalization the mRS 90 days after stroke was significantly positive correlated with the baseline NIHSS score (r = 0.475, $p=0.008$), whereas in patients with futile ET the correlation analysis showed no significant result (r = –0.418, $p=0.35$).

Outcome Predictors

In univariate ordinal regression analysis, age, baseline NIHSS score and successful recanalization were predictors of outcome. In multivariate analyses, only successful recanalization remained as a significant predictor of lower scores on the mRS at 90 days (OR 5.7; 95% CI 1.1–29.2, Table 3).

In univariate and multivariate logistic regression analyses, higher baseline NIHSS scores and failed recanalization were independent predictors of poor outcome. Failed recanalization was associated with an OR for poor outcome of 13.6 (95% CI 1.2–153.9). Univariate logistic regression analyses revealed age and baseline NIHSS score to be predictors of independent outcome. In multivariate analyses, no significant predictor of independent outcome remained.

Discussion

In this prospective observational study of patients with BAO treated by ET in a real-world setting, the recanalization result was identified as the most significant predictor of func-

Table 3 Predictors of clinical outcome (multivariate regression analyses)

	Odds ratio (95% CI)	*P* value
Ordinal regression analyses (lower mRS scores at 90 days)		
Successful recanalization (TICI 2b/3)	5.7 (1.1–29.2)	*0.035**
Logistic regression analyses (poor outcome mRS 5–6)		
Baseline NIHSS	1.1 (1.0–1.1)	*0.029**
Unsuccessful recanalization (TICI <2b)	13.6 (1.2–153.9)	*0.036**

CI confidence interval, *mRS* modified Rankin scale, *mTICI* modified thrombolysis in cerebral infarction score, *NIHSS* National Institutes of Health Stroke Scale
*significant

tional outcome at 90 days after stroke. Successful recanalization was associated with lower scores on the mRS at 90 days reflecting better functional outcome. At the same time, failed recanalization was a significant predictor of poor outcome, i.e. death or bedridden. This study demonstrates that in clinical practice high rates of successful recanalization (82%) can be achieved in patients suffering from BAO. However, approximately one in four patients had an independent outcome, while half of the patients had a poor outcome. Thus, recanalization appears to be a prerequisite for a better functional outcome as none of the patients with failed recanalization had a mRS score of less than 4 at 90 days. However, recanalization alone does not ensure a good clinical result, as also in patients with successful recanalization only 30% of patients achieved an independent outcome. This may be explained by differences in the vascular architecture between the anterior and posterior circulation and in the neuroanatomy of the adjacent brain regions. The occlusion of small perforating arteries in thromboembolic BAO may persist even with clot removal and recanalization of the basilar artery or poorer collateral supply may result in brainstem infarction despite recanalization. Finally, even small brainstem infarctions from perforating artery stroke are often accompanied by persisting impairment, while perforating artery stroke in the anterior circulation frequently has a good outcome [13]. This may also explain the overall high mortality rate (26%) and rate of poor outcome (mRS 5–6, 54%) in this study cohort suffering from BAO, while the overall rate of independent outcome was low (mRS 0–2, 24%). However, it is noteworthy that the study population was characterized by an older patient group (median age 75 years) with highly severe stroke reflected by a high NIHSS score (median baseline NIHSS score 24) which may also be one reason for the worse outcome in this patient group.

To date, the BASICS registry has published the largest study on different treatment options in BAO but failed to show any difference in outcome between patients treated by endovascular thrombectomy, other intra-arterial treatment approaches or patients solely treated by IVT [8]. A potential drawback was the lack of randomization of patients enrolled in the study so that selection bias is likely. Another explanation could be that in most of the cases older devices were probably used whereas nowadays advanced intervention techniques are commonly applied as in the RCTs. In line with this hypothesis, a single center analysis demonstrated that ET with advanced techniques (e.g. stent-retriever systems) in BAO leads to better outcomes than other intra-arterial treatment [14]. To date, few studies and meta-analyses have shown that endovascular therapy with stent retrievers in BAO might be an effective treatment option achieving high rates of good clinical outcome while being safe with low incidences of procedure-related complications and sICH [15–17]. However, it remains unclear if a RCT of patients with BAO would yield a different result than in the BASICS registry when using these new techniques.

Compared to the findings in the ENDOSTROKE registry, in which most cases were treated with new stent-retriever devices, this study population showed a lower rate of good clinical outcome (24% vs. 34%), while mortality was higher in ENDOSTROKE (35% vs. 26%). When comparing the baseline characteristics, the present population was older (median age 75 years vs. 71 years) and had a higher baseline NIHSS score (median 24 vs. 20). However, an impact of age on clinical outcome was not observed in multivariate regression analyses in this study sample, which is in contrast to the findings of other studies [16, 18, 19], while a higher baseline NIHSS score did predict poor outcome, as in the ENDOSTROKE study, and thus, could at least partially explain the results.

Interestingly, in contrast to the findings of the ENDOSTROKE study, the recanalization result strongly predicted clinical outcome in this study. Successful recanalization was associated with a 5.7-fold higher likelihood of better functional outcome at 90 days reflected by lower scores on the mRS in ordinal regression analysis. Similarly, several previous case series revealed successful recanalization as a strong predictor of good outcome 3 months after stroke [11, 12, 20, 21].

When comparing the outcome results of patients with successful recanalization and those in which ET remained futile in this study sample, it is noteworthy that none of the patients with an unsuccessful ET achieved independent or moderate outcome while rates of poor outcome and mortality were high. A failed recanalization lead to a 13.6-fold higher risk of poor outcome 3 months after stroke in this patient cohort. In contrast, the group of patients in which ET was successful, one third achieved a good outcome (mRS 0–2). Whereas in patients with futile ET the mRS 90 days after stroke showed no correlation with the baseline NIHSS score, in the group of patients with successful recanalization the mRS was significantly positively correlated with the NIHSS score on admission.

Taken together these results indicate that endovascular reperfusion therapy with successful recanalization is crucial to avoid poor outcome and attain at least the possibility of a good outcome in patients with acute basilar artery occlusion.

Limitations

This study has several limitations that have to be acknowledged. At first, the study lacks a patient group suffering from BAO without ET serving as a control group. In addition, the study was performed in a single institution and a low patient number was included in the study, hence, the

findings have to be considered with caution. Nevertheless, this study is an observational study comprising prospectively enrolled BAO patients treated by ET in the real-world and, thus, can further help to improve the decision-making process of treating individual patients suffering from BAO in clinical practice since results from RCTs are still lacking.

Conclusion

In this study sample the recanalization result was the only strong independent predictor of clinical come, underlining the utmost importance of successful recanalization, which can be achieved by ET in patients with BAO. Therefore, in the face of the current paucity of data from RCTs of ET in BAO, this study supports the recommendation to treat patients with BAO by ET adjunct to standard medical care in clinical practice. Nevertheless, the high rate of poor outcome despite ET in BAO warrants further efforts to improve the treatment of BAO.

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Compliance with ethical guidelines

Conflict of interest M. Deb-Chatterji, F. Flottmann, H. Leischner and C. Brekenfeld declare that they have no competing interests. A. Alegiani reports fees as speaker from Bayer Vital. J. Fiehler reports personal fees from Cerenovus, Penumbra, Route 92 Medical, grants and personal fees from Acandis, Medtronic, Microvention. C. Gerloff reports fees as speaker and/or scientific advisory board member from Actitor Biotech, Amgen, Bayer Healthcare, Boehringer Ingelheim, Prediction Biosciences, Sanofi Aventis. G. Thomalla reports personal fees from Acandis, grants and personal fees from Bayer, personal fees from Boehringer Ingelheim, personal fees from Bristol-Myers Squibb/Pfizer, personal fees from Daichi Sankyo, personal fees from Stryker, outside the submitted work.

Ethical standards This study, conducted on human subjects, was approved by the local ethics committee (Hamburg, Germany; MC-039/16) and was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All patients or their proxies, as appropriate, gave written informed consent prior to inclusion in the study. Consent was waived if patients died before consent could be obtained or lacked the capacity to give consent and no proxy was available.

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