VOLUME 5 | ISSUE 3

HJR

Neuro/Head and Neck Radiology ORIGINAL ARTICLE

Rescue intracranial stenting in the endovascular therapy of acute ischaemic stroke

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SUBMISSION: 25/2/2020 - ACCEPTANCE: 6/7/2020

ABSTRACT

Purpose: The present study aimed to evaluate the clinical and angiographic outcome of permanent intracranial stenting as rescue therapy for acute ischaemic stroke (AIS) after failed mechanical thrombectomy (MT). MT has become the standard therapy in AIS in patients with large vessel occlusion. However, failed MT has been reported due to an underlying intracranial atherosclerotic stenosis, residual adherent thrombi or dissection of the target vessel. In such cases, permanent stenting may be required to obtain sufficient recanalisation.

Material and Methods: We retrospectively reviewed collected records of patients treated with intracranial stents for AIS after failed MT in our department between 2013 and 2017. Clinical, angiographic and neuroimaging data were analysed. Neurological status was evaluated with the National Institutes of Health Stroke Scale (NIHSS) score on admission and with the modified Rankin Scale (mRS) score on discharge and after 3 months. The endpoints of this study were recanalisation, clinical outcome at 3 months, symptomatic intracranial haemorrhage (sICH) and mortality at 90 days.

Results: Forty patients underwent permanent intracranial stenting after failed MT for AIS. Seventeen stents were self-expanding and 23 drug-eluting, balloon-mounted stents. Twenty occlusions (50%) were located in the anterior circulation, whereas the remaining 20 were in the posterior circulation. Intravenous recombinant tissue plasminogen activator (rtPA) was administered to 50% of the patients prior to interventional therapy. Successful reperfusion (modified Thrombolysis In Cerebral Infarction 2b-3) was achieved in 37 patients (93%). A favourable clinical outcome with mRS≤2 after

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90 days was observed in 17 patients (42.5%). The overall mortality was 20% at 90 days. sICH occurred in one patient (2.5%). Post-procedural transcranial sonography revealed acute stent occlusions in 2/35 of patients (5.7%).

Conclusions: Our study suggests that acute permanent intracranial stenting after failed MT represents a feasible and effective treatment option and has a low risk of symptomatic haemorrhage.

KEY WORDS

Stroke; Thrombectomy; Intracranial stent; Acute stroke treatment

Introduction

Mechanical intra-arterial thrombectomy (MT) is one of the most powerful tools in the treatment of acute ischaemic stroke (AIS) due to large vessel occlusion (LVO). The recanalisation rate after MT is between 59% and 88% for anterior circulation proximal occlusions and up to 80% for posterior circulation occlusions [1-10]. Furthermore, a correlation between recanalisation rates and good clinical outcome has been shown, thus demonstrating recanalisation as a powerful predictor of clinical improvement. Following an otherwise successful MT, angiographic imaging after stent retrieval occasionally depicts luminal narrowing, which compromises sufficient blood flow, leading to immediate refractory reocclusion. There are numerous reasons for the failure of MT that are difficult to differentiate. Possible causes are underlying intracranial atherosclerotic stenosis, wall-adherent thrombus or high clot burden, and, in rare cases, intracranial dissection or vasospasms [11-13]. In some of these patients, additional angioplasty or even permanent stenting may be required to obtain sufficient recanalisation. Permanent acute intracranial stenting (ICAS) has been an early approach for endovascular treatment of LVOs; however, it was quickly replaced following the introduction of stent retriever thrombectomy as a first-line treatment [14, 15]. In the present study, we evaluated the clinical and angiographic benefits of ICAS as second-line therapy after failed MT.

Material and Methods

Patient population

From January 2013 to October 2017, 842 patients presenting with an AIS due to an extra- and/or intracranial artery occlusion were treated with various endovascular modalities at our center. Forty consecutive patients with failed MT (mTICI 0-1) due to reocclusion or flow compromising target vessel stenosis after MT who received acute intracranial stenting as rescue therapy were retrospectively analysed.

Digital clinical charts were reviewed for demographics and neurological status at admission. Patients were evaluated with the National Institutes of Health Stroke Scale (NIHSS) and modified Ranking Scale (mRS) scores on admission and discharge. The use of intravenous thrombolysis with recombinant tissue plasminogen activator (rtPA) was also reviewed. Computed tomography (CT) and CT angiography of the supra-aortic vessels were performed on admission to exclude intracranial haemorrhage (ICH) and to assess arterial occlusion. All patients with an ASPECT score >5 were included. CT perfusion was not a standard technique at our center during the study period. Angiographic images were reviewed retrospectively by two experienced interventional neuroradiologists for the location of the occlusion, revascularisation after MT, reason for stent deployment and procedure-related complications. Intracranial perfusion after MT was assessed with the modified Treatment in Cerebral Ischaemia (mTICI) score (30). The study was approved by the Ethics committee of Klinikum Bremen Mitte.

Interventional treatment

After clinical examination and diagnostic imaging, all patients with evidence of an intracranial artery occlusion were transferred to the angiography department. Patients with no contraindications for IV rtPA treatment and symptom onset within 4.5 h were treated with a body-weight-adapted dose of rtPA prior to the interventional treatment. Depending on the neurological status, patients

were treated under sedation or general anaesthesia.

All procedures were performed on a biplane angiography machine (*Philips Allura Xper FD20/15, Koninklijke Philips N.V., Netherlands*). Cerebral vessel access was established using a 6F 088 Neuron MAX Long Sheath 90/4 Straight (*Penumbra, Inc., Alameda, CA, USA*). For patients with anterior circulation vessel occlusion, the sheath was positioned in the distal portion of the internal carotid artery. For patients with basilar or vertebral artery occlusions, the guide sheath was advanced to the level of the distal V2 segment. All patients underwent MT prior to stent deployment. The Penumbra ACE 68 aspiration catheter (*Penumbra Inc, Alameda, CA, USA*) was used for clot extraction either alone or in combination with a stent retriever. The stent retrievers used were pReset (*Phenox, Bochum, Germany*), Catch+ (*Balt, Montgomery, France*), and Solitaire FR (*Medtronic, Minneapolis, MN, USA*). If persistent lumen narrowing (residual flow-limiting stenosis) or immediate reocclusion of an intracranial vessel was identified after three rounds of MT, a self-expanding or balloon-mounted stent was inserted to maintain vessel lumen patency. In cases of self-expanding stents, intracranial angioplasty was performed using a Trek or mini Trek balloon (*Abbott, Santa Clara, CA, USA*) in accordance with the target vessel size **(Fig. 1)**.

The decision to perform permanent stenting, the choice of intracranial stent as well as the periprocedural antithrombotic therapy were left to the discretion of the interventionist. The stents used in our patient collective included the drug-eluting coronary stents (DES) XIENCE Stent *(Abbott Vascular, Abbott Park, IL, USA)* and Coroflex Stent (*B. Braun Melsungen AG, Melsungen, Germany*); the bare metal balloon-mounted stent PHAROS Vitesse (*Micrus Endovascular, San Jose, CA, USA*); and the self-expanding stents LEO Baby Stent (*Balt, Montmorency, France*) and Enterprise Stent (*Codman Neurovascular, Raynham, MA, USA*).

Drugs administered during the procedure were weight-adjusted bolus of heparin (70 IU/kg) if no thrombolytic therapy was possible; 500 mg of acetylsalicylic acid (*Aspirin, Bayer Vital GmbH, Germany*) IV to all patients without a history of antiplatelet and/or anticoagulant therapy, in most cases followed by a loading dose (300 mg) of clopidogrel after the procedure; and weight-adjusted IV bolus of glycoprotein IIb/IIIa inhibitor (*Integrilin, GlaxoSmithKline AG*). After stent deployment, all patients received dual antiplatelet therapy consisting of 100 mg of aspirin per day plus 75 mg of clopidogrel per day for 3 or 12 months, depending on the stent type (12 months for DES), followed by lifelong aspirin.

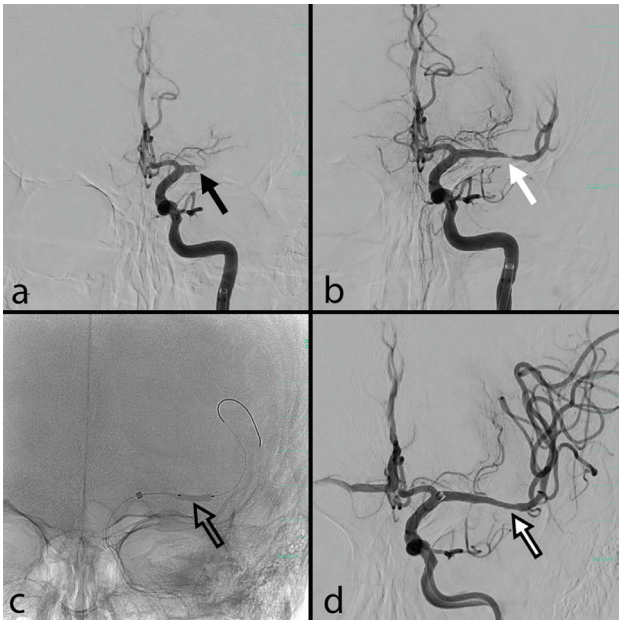


Fig. 1. *Thrombotic M1 occlusion (arrow) shown in a. Residual stenosis after otherwise successful thrombectomy (arrow in b). Fluoroscopic image of a balloon-mounted stent during inflation (arrow in c). Control angiogram after successful stent assisted angioplasty (arrow in d).*

Post-procedural CT and magnetic resonance imaging (MRI) scans were performed before discharge or in cases of clinical deterioration (i.e., increase in NIHSS score of >4). Stent patency after treatment was assessed by transcranial ultrasound and/or MR angiography when possible.

Definitions and statistics

Technical success was defined as safe and accurate stent placement and deployment as well as decreased luminal narrowing of at least 50%. An mTICI score of 2b or 3 was defined as a successful intracranial recanalisation. Good clinical outcome was defined as mRS≤2 at 3 months. Symptomatic intracranial haemorrhage was defined as haemorrhage with neurological deterioration.

Standard descriptive statistics were employed for all study endpoints. Fisher's exact test was performed to compare categorical variables. Variables were compared by an unpaired Student's t-test for continuous variables of normal distribution or the Mann-Whitney U test for continuous variables of non-normal distribution. Logistic re-

gression analysis was performed to identify independent predictors. All statistical analyses were performed with SPSS Version 22 (*SPSS Inc., Chicago, IL, USA*). The significance level was set at P=0.05.

Results

Forty patients (4.75% of patients who underwent MT) were treated with permanent intracranial stenting due to persistent occlusion or luminal tapering after successful MT (mTICI 0 or 1). Patients were divided into two groups depending on the stent location. Half of the stents (20/40) were located in the anterior circulation, whereas the remaining 50% were in the posterior circulation. The median age of the patient population was 69 years (range 46-89), with 10/40 (25%) of patients female. The median NIHSS score at admission was 12.6 (5-35). Prior to MT, 20/40 (50%) of the patients received IVT with a standard dose (0.9 mg/kg). The distribution of administered IVT was significantly higher in the group with an occlusion in the anterior circulation (14/20, 70%). Baseline characteristics of the patients are summarised in **Table 1**.

Medical treatment regimen

A bodyweight-adapted bolus of a competitive platelet glycoprotein IIb/IIIa receptor inhibitor (integrilin) was administered to 34 patients (85%) before stent placement. After successful stent implantation, 500 mg of aspirin was administered intravenously to 22 (55%) patients. Thirteen patients were on antiplatelet therapy prior to the stroke. A 300 mg loading dose of clopidogrel was given immediately to 15 (37.5%) patients after the procedure. All patients received dual platelet inhibition therapy comprising of 100 mg of aspirin and 75 mg of clopidogrel the day following the procedure for 3 months for patients with bare-metal stents and 12 months with DES.

Angiographic outcome

Eleven patients (27.5%) required general anaesthesia due to agitation, whereas the procedure was performed under mild sedation in the remaining 29 patients. Twenty-three (57.5%) of the deployed stents were drug-eluting.

Technical success was achieved in all cases. All stents were completely expanded. Angiographic runs showed no vessel perforation or wall dissection. Periprocedural in-stent thrombosis occurred in one patient immediately after deployment and was successfully treated with balloon angioplasty. Revascularisation (mTICI grades 2b or 3) was achieved in 37 (92.5%) cases. Due to distal embolisation, an mTICI 2a was achieved in two patients after the intervention. Recanalisation failed (mTICI 0) in one patient and was most likely due to a massive clot burden.

Follow-up vascular imaging via transcranial ultrasound and/or MRI was available in 35 (94.5 %) of 37 patients with recanalisation success. The stents were patent in 33 (94%) of the 35 patients. Asymptomatic early stent occlusions occurred in two patients (bare metal stents in both cases, Pharos & Enterprise).

Overall, there was no significant difference between the outcomes of the anterior and posterior circulation. The successful recanalisation rate (mTICI≥2b) for occlusions in the anterior circulation was 90% (18/20), and the anterior stent patency at discharge was 100% (18/18). mTICI 2b-3 recanalisation was obtained in 19/20 (95%) of the posterior occlusions, and 15/17 (88%) of the posterior located stents were patent.

Clinical outcome

Secondary ICH occurred in one (2.5%) patient in the anterior circulation group within 24 h following implantation, and the patient died shortly after. Fifty percent of patients with an anterior stent achieved a good functional outcome of mRS≤2, which was maintained for 90 days. Twenty-five percent of patients with a posterior stent had an mRS of ≤2, improving to 35% at 90 days follow-up. The mortality rate at 90 days was equal in both groups (20%). An independent predictor of good outcome (mRS≤2) at 90 days was not found in both groups (**Tables 2 and 3**).

Discussion

This retrospective study describes a single-center experience of 40 consecutive patients who underwent permanent intracranial stenting as a rescue therapy after failed MT. Our findings suggest that ICAS represents a viable treatment option with high recanalisation rates (mTICI≥2b) of 92.5% and very good clinical outcome (42.5%) in the absence of increased sICH rates (2.5%).

Different factors have been implicated in the failure of thrombectomy, such as difficultly establishing anatomical access, vessel tortuosity especially in older patients, intracranial atherosclerotic disease, massive thrombus burden, wall-adhesive thrombus, resistant occlusion due to thrombus composition and length or rare vascular disorders such as vasculitis [16, 17]. Poor recanalisation after MT can also be caused by arterial dissection and distal

Table 1. Baseline characteristics of the study population.

Baseline characteristics	All patients (n=40)	Anterior circulation (n=20)	Posterior circulation (n=20)	P value
Median age (range)	69 (46-89)	68.5 (46-89)	71 (50-89)	0.588
Women [%(n)]	25 (10/40)	30 (6/40)	20 (4/20)	0.716
CV-Risk factors [%(n)]				
- Hypertension	65 (26/40)	65 (13/20)	65 (13/20)	0.629
- Diabetes	15 (6/40)	15 (3/20)	15 (3/20)	>0.05
- Nicotine	32.5 (13/40)	40 (8/20)	25 (5/20)	0.501
- Hyperlipidaemia	5 (2/40)	10 (2/20)	0 (0/20)	0.487
Antiplatelet Therapy	32.5 (13/40)	40 (8/20)	25 (5/20)	0.501
NIHSS [median(range)]	12.6 (5-35)	10.5 (5-22)	14.8 (5-35)	0.551
mRS [median(range)]	4 (1-5)	4 (1-5)	4.5 (3-5)	0.560
Stent site [%(n)]				
-Anterior:	50 (20/40)	70 (14/20)	-	
- M1	-	20 (4/20)	-	
- M2	-	10 (2/20)	-	
- ICA	-			
-Posterior:	50 (20/40)	-	60 (12/20)	
- VA V4	-	-	40 (8/20)	
- BA	-			
IVT [%(n)]	50 (20/40)	70 (14/20)	30 (6/20)	0.026

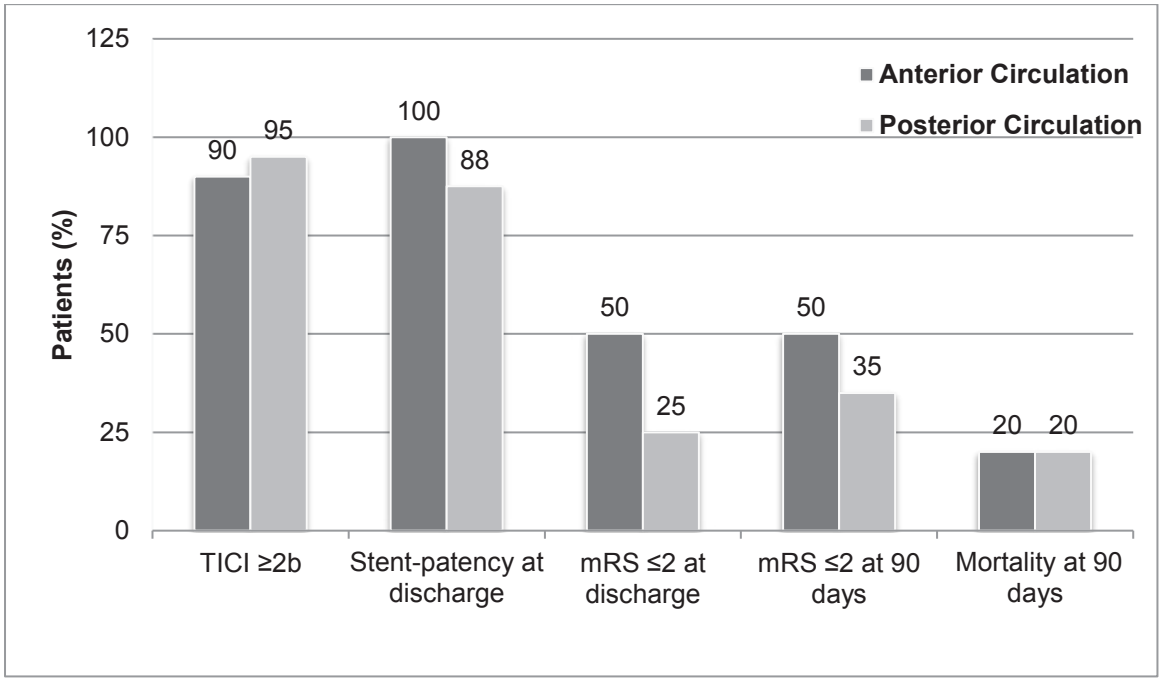
embolisation due to thrombus fragmentation. However, in this study, we analysed a special subgroup of cases in which an immediate reocclusion of the target vessel occurred after successful thrombectomy. According to our experience, these patients benefit from additional acute intracranial stent placement.

Wareham et al. analysed eight studies from a combined international cohort from Europe, Asia, and North America with 160 patients reporting outcomes after failed endovascular thrombectomy in the anterior circulation with acute implantation of self-expandable stents [18]. Recanalisation (mTICI ≥2b) was achieved in 71% of patients, whereas clinical independence was attained at 3 months in 43% of patients. The mortality rate and sICH were 21% and 12%, respectively. These findings are very similar to those of the HERMES study, in addition to our own, suggesting that acute stenting improves the recanalisation grade and clinical outcome [19]. Moreover a recently published meta-analysis of Maingard et al. demonstrated superiority for acute stenting over non stenting after failed MT showing improvement in clinical outcomes without corresponding risk of sICH [20].

In the present study, the sICH rate (2.5%) was significantly lower than in previously reported studies. This may be partially due to the different types of glycoprotein IIb/IIIa inhibitors applied to our patients (eptifibatide *vs.* tirofiban or abciximab in other studies). A recently published meta-analysis of nine randomised controlled trials suggested that the safety of eptifibatide is slightly superior to tirofiban in patients with acute coronary syndrome without a significant difference in efficacy [21]. Another possible explanation for the lower rate of haemorrhagic complications may be the lower mean NIHSS score on admission in our study population (NIHSS of 12.6 *vs.* NIHSS of 17 in the HERMES and Wareham meta-analyses).

The antithrombotic regimen is a major concern after acute intracranial stenting. In patients who had previous-

Table 2. Comparison of results on the interventional and clinical outcomes between anterior and posterior circulation.



ly received IV rtPA, additional antithrombotic agents may increase the risk of haemorrhagic complications [22-25]. However, acute stent thrombosis can occur in the absence of antithrombotic drugs [26, 27]. According to the literature on coronary interventions, most thrombotic events occur within hours of the acute-stenting procedure. Therefore, antithrombotic drugs must be administered during the intervention [28, 29].

In our study, 85% of the patients received an IV bolus of glycoprotein IIb-IIIa receptor inhibitor immediately after stent placement. Furthermore, half of the patients also received 500 mg of aspirin intravenously shortly before or during treatment. sICH occurred in only one patient. This particular patient did not receive rtPA, antiplatelet and/or anticoagulant therapy before the stroke. The antithrombotic therapy during and immediately after stent deployment was a combination of 500 mg of aspirin, integrilin bolus and a loading dose of clopidogrel via nasogastric tube. An identical regimen was also administered to an additional 10 patients without evidence of bleeding complications during follow-up examinations. Therefore, there was no correlation between an antithrombotic regimen and sICH in our study. Furthermore, 95% of patients received post-procedural antiplatelet therapy, which correlated with a significant increase in the rate of haemorrhagic complications or mortality compared to MT alone [2]. A recent multicenter study comprising 210 patients with both anterior and posterior LVOs reported a higher haemorrhage risk in the anterior circulation, which is concordant with our experience [30].

Another major concern after ICAS is early stent occlusion, an event associated with a poor functional outcome. In a study published by Forbig et al., approximately one-third of patients had an early occlusion or high-grade in-stent stenosis despite antithrombotic therapy [31]. In the present study, the reocclusion rate 48 h after the procedure was 5.7% (two patients). Both stents were bare metal and deployed in the posterior circulation. Furthermore, both occlusions were asymptomatic. The multicenter study of Chang et al. postulated that stent patency is strongly associated with the use of glycoprotein IIa/IIIb inhibitors but not with antiplatelet therapy [27]. However, a recent study published by Kim et al. found suboptimal angioplasty to be a predisposing factor for acute reocclusion within the first 48 h, and is associated with a 28-fold increase in the reocclusion rate [32]. Surprisingly, neither heparin nor glycoprotein IIb/IIIa was administered in the studied population, and 6 of the 46 patients experienced

Table 3. Statistical comparison of results between anterior and posterior circulation.

Results	Anterior circulation	Posterior Circulation	P value
Recanalisation rate TICI≥2b (n)	18/20	19/20	>0.05
Stent patency at discharge (n)	18/18	15/17	>0.05
mRS at discharge (n)	10/20	5/20	0.105
mRS at 90 days (n)	10/20	7/20	0.341
Mortality at discharge (n)	2/20	4/20	>0.05
Mortality at 90 days (n)	4/20	4/20	>0.05

acute reocclusion after angioplasty with or without stent deployment. Therefore, the occlusion causes and predictors of stent patency remain obscure.

Stent occlusion may also be related to a specific stent device. So far, the majority of rescue stenting studies reported on their experience with bare-metal stents. However, in our population, most of the deployed stents were drug-eluting. DES has been known to be effective for reducing the risk of in-stent restenosis due to its controlled local release of antiproliferative agents compared to BMS in coronary stenting and secondary stroke prevention [33-36].

However, there is a lack of information on DES in acute stroke therapy. Several potential impacting factors play a role in stent-decision making, such as vessel size, occlusion site, lesion morphology and length, operator-related factors, as well as institution-related factors (for example, stent-size availability). In our experience, both occluded stents were bare metal, most likely indicating a correlation. However, the result was not statistically significant due to the small sample. Balloon-mounted, drug-eluting stents were used in a previous study on 60 patients with acute LVO, with an acute/subacute in-stent-stenosis rate of 7% reported, which is comparable to our findings [37].

Fifty percent of the vessel occlusions were distributed in the anterior circulation. In the present study, clinical outcomes in the anterior circulation were slightly superior to posterior circulation LVO stroke patients. However, considering that patients with posterior circulation occlusions usually have a worse outcome, the above statement should not be considered significant.

Among the limitations of this study are its retrospective design, the small sample size of patients treated with acute ICAS, and single-arm and single-center nature of the study. Furthermore, the decision of stent deployment and antithrombotic therapy depended on the preference of the interventionalist.

Conclusions

Intracranial stent deployment in patients with AIS due to LVO, refractory to stent-retriever or aspiration thrombectomy, increases recanalisation rates and improves the favourable outcome of stroke patients without increasing the sICH or mortality rates compared to MT patients. Administration of antithrombotic drugs, even in combination with IV tPA, did not increase the rate of sICH. DES may reduce early stent occlusion. Further prospective and randomised trials are required to examine whether this technique represents the best treatment strategy for refractory reocclusions. In addition, future studies should focus on establishing an optimal antithrombotic regimen and stent device. **R**

Funding

This project did not receive any specific funding.

Ethical approval

Ethics committee of Klinikum Bremen Mitte.

Conflict of interest

The authors declared no conflicts of interest.

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Boutchakova-Meyer M, Papanagiotou P, Alexandrou M, Meyer L, Kastrup A, Roth C. Rescue intracranial stenting in the endovascular therapy of acute ischaemic stroke. *Hell J Radiol 2020*; 5(3): 11-19.