

Technical Feasibility and Application of Mechanical Thrombectomy with the Solitaire FR Revascularization Device in Acute Basilar Artery Occlusion

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ABSTRACT

BACKGROUND AND PURPOSE: Acute BAO is a devastating neurological condition associated with a poor clinical outcome and a high mortality rate. Recanalization has been identified as a major prognostic factor for good outcome in BAO. Mechanical thrombectomy using retrievable stents is an emerging treatment option for acute stroke. First clinical trials using stent retrievers have shown promising high recanalization rates. However, these studies mainly included large artery occlusions in the anterior circulation with only a few or single cases of BAO. Therefore, the purpose of this study was to evaluate technical feasibility, safety, and efficacy of mechanical thrombectomy using retrievable stent in the treatment of acute BAO.

MATERIALS AND METHODS: Fourteen consecutive patients with BAO undergoing endovascular therapy using retrievable stents (Solitaire FR Revascularization Device) were included. Additional multimodal treatment approaches included thromboaspiration, intravenous and/or intra-arterial thrombolysis, and PTA/permanent stent placement. Recanalization rates after multimodal therapy and stent retrieval were determined. Clinical outcome and mortality were assessed 3 months after treatment.

RESULTS: Median patient age was 64.5 years (range 55–85). Median NIHSS score at presentation was 21 (range 5–36). Overall, successful recanalization (TICI 3 or 2b) was achieved in all patients (TICI 3 in 78.6%, 11/14). In 4 patients (28.6%), insufficient recanalization after stent retrieval was due to an underlying atherosclerotic stenosis. Additional deployment of a permanent intracranial stent was performed in 3 patients (21.4%) and PTA alone in 1 patient (7.1%), resulting in final TICI 3 in 1 patient and TICI 2b in 3 patients. Stent retrieval alone was performed in 4 patients (28.6%). Average number of device passes was 1.3 (range 1–3). Median procedure time to maximal recanalization was 47 minutes (range 10–252). No device-related complications or thromboembolic occlusion of a previously unaffected artery occurred. There was no symptomatic intracranial hemorrhage. At 3 months, good functional outcome (mRS 0–2) was observed in 28.6% (4/14); overall mortality was 35.7% (5/14).

CONCLUSIONS: A multimodal endovascular approach using retrievable stents in BAO has high recanalization rates, with very low complication rates. Underlying atherothrombotic stenotic lesions of the basilar artery may still necessitate additional permanent stent placement to achieve complete recanalization.

ABBREVIATIONS: BAO = basilar artery occlusion; mRS = modified Rankin Scale; PROACT = Prolyse in Acute Cerebral Thromboembolism study; PTA = percutaneous transluminal angioplasty; TICI = Thrombolysis in Cerebral Infarction; TIMI = Thrombolysis in Myocardial Infarction; TOAST = Trial of Org 10172 in Acute Stroke Treatment

Acute BAO is a devastating condition associated with poor clinical outcome and mortality rates approaching 90% in patients without treatment.^{1–4} Recanalization is the most important prognostic factor for good functional outcome in BAO.^{5–8} Recanalization rates with intravenous or intra-arterial thrombolysis are

approximately 53% and 65%, respectively, and chances of good outcome without recanalization are only around 2%.⁹ Mechanical thrombectomy using self-expanding retrievable stents is an emerging treatment option for acute stroke. It combines the fast and efficient flow restoration effect of an intracranial stent and the capability of definitive thrombus removal of a mechanical thrombectomy device. The Solitaire FR Revascularization Device (ev3, Irvine, California) is the first dedicated retrievable stent device for acute stroke treatment. At our institution, in January 2010, stent retrievers were added to our multimodal endovascular stroke treatment protocol. Recent data of our own have demonstrated that adding retrievable stents to a multimodal approach in acute ischemic stroke treatment reduces the time to recanalization and further increases the recanalization rate to over 90%.¹⁰

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However, most studies concerning the efficacy of stent retrievers have been performed in large vessel occlusions of the anterior circulation, including only a few or single cases of BAO.¹⁰⁻¹⁷ Furthermore, in the posterior circulation, proximal balloon occlusion for flow reversal during retrieval is not applicable. Therefore, the risk of distal thromboembolic events is potentially increased. Hence, clinical data and detailed analyses focusing on the impact of mechanical thrombectomy using stent retrievers in BAO are still sparse.^{14,15}

The purpose of this study was to evaluate the feasibility, safety, and efficacy of retrievable stents, with special focus on their application in the treatment of acute BAO.

MATERIALS AND METHODS

This study is based on the Bernese stroke registry. Since 1992, data for all patients with stroke treated by endovascular means are prospectively recorded in our stroke data base. From this prospectively collected cohort, we retrospectively analyzed all patients with acute ischemic stroke with BAO undergoing endovascular stroke treatment between January 2010 and August 2011. All patients were evaluated on admission by a stroke neurologist and assessed with the NIHSS score. Inclusion criteria for endovascular stroke treatment were as follows: 1) diagnosis of BAO was established; 2) baseline NIHSS score was ≥ 4 or hemianopia was present; 3) hemorrhage on cranial CT or MR imaging was excluded; 4) BAO, as observed on DSA, correlated with the neurologic deficit; 5) symptom duration was not >24 hours; and 6) no individual clinical or premorbid conditions or laboratory findings advised against recanalization.

Multimodal treatment consisted of a combination of 1) thromboaspiration, 2) intravenous and/or intra-arterial thrombolysis, 3) mechanical thrombectomy, and 4) PTA/stent placement. Intravenous thrombolysis with rtPA (full dose 0.9 mg/kg) was administered as bridging therapy in patients referred within 4.5 hours from symptom onset. A loading dose of 10% was given in these patients. Intra-arterial urokinase (Urokinase Medac; Medac, Wedel, Germany) was used up to a dose of 1,000,000 IU within the first 6 hours after symptom onset.

Endovascular Treatment

An 8F sheath was placed in the femoral artery, and a 4-vessel diagnostic DSA was performed to assess vessel occlusion and collateral flow to the affected vessel territory. After confirmation of vessel occlusion, the largest possible guide catheter to allow safe catheterization, a 6–8F guide catheter (Guider Softip; Boston Scientific, Natick, Massachusetts), was introduced into the dominant or most accessible vertebral artery.

For thromboaspiration, the guide catheter was advanced distally in the vertebral artery. Then an aspiration catheter (5.1F Vasco35+ASPI, Balt, Montmorency, France, or 5.2F DAC, Concentric Medical, Mountain View, California) was advanced to the occlusion site. Aspiration was performed by 2 lockable 60-mL syringes connected to the guide and aspiration catheters. The aspiration catheter was removed during continuous aspiration of both catheters.

Intra-arterial thrombolysis was performed via a microcatheter (2.8F Renegade Hi-Flo, Boston Scientific; or 2.3F Prowler Select

Plus, Cordis, Miami Lakes, Florida) for 30–60 minutes by placing the catheter tip into the occluding thrombus. Follow-up angiograms were performed every 20–30 minutes to assess patency.

Mechanical thrombectomy was performed using the Solitaire FR Revascularization Device (ev3). All retrievable stents used measured 4 mm in diameter and 20 mm in length. First, the thrombus was passed with the microwire (SilverSpeed 14; ev3) and the microcatheter (2.3F Prowler Select Plus) and a distal angiogram was performed to confirm proper localization in the target cerebral artery. The Solitaire FR was placed through the microcatheter and deployed by retracting the microcatheter through the occlusion site under fluoroscopic control. Once fully deployed, a control angiogram was obtained to assess immediate recanalization effect. According to the results of previous animal and clinical studies,^{10,18} the device was left in place for 5 minutes to allow the clot to become embedded in the stent before the microcatheter was then advanced to partially resheath the proximal connection site of the stent to the pusher wire. The Solitaire FR and the microcatheter were retrieved simultaneously during aspiration with a 60-mL syringe at the guide catheter. If this failed or recanalization was insufficient, the device was cleaned and reinserted. A maximum of 3 retrieval attempts was allowed per device.

In cases where no sufficient recanalization was achieved, despite various recanalization attempts, placement of an intracranial stent (Wingspan; Boston Scientific) and/or PTA was applied to reduce the risk of delayed reocclusion.

Control angiograms were performed after each revascularization attempt to assess the recanalization results and thromboembolic events in a previously unaffected vessel territory. The extent of recanalization was classified according to the TICI grading scale.¹⁹ TICI grades 3 and 2b were rated as sufficient recanalization, whereas TICI grades 2a to 0 were rated as insufficient recanalization.

All endovascular procedures were performed under general anesthesia. Postprocedure patients were observed for at least 24 hours in an intensive care unit, and CT or MR imaging was performed if clinical worsening occurred to rule out intracranial hemorrhage. The NIHSS score was assessed at day 1 by a stroke neurologist. Clinical outcome was assessed at 3 months by a stroke neurologist according to the mRS.²⁰ An mRS score of 0–2 was defined as good and an mRS score of 3–6 was defined as poor functional outcome. Stroke etiology was classified according to TOAST criteria.²¹ The following time points were recorded for analysis: onset of symptoms, first angiogram, and achievement of final recanalization result. Time intervals from symptom onset to the first angiogram and procedure time to final recanalization (time to recanalization) were calculated.

RESULTS

From January 2010 to August 2011, 14 patients (6 women, median age 64.5 years, range 55–85 years) with BAO were treated by endovascular means. The median NIHSS score on admission was 21 (range 5–36). In our sample, 57.1% of patients had hypertension, 14.3% had diabetes, 14.3% were current cigarette smokers, 57.1% had hypercholesterolemia, 21.4% had atrial fibrillation,

21.4% had coronary artery disease, and 21.4% had a history of previous stroke or TIA.

The occlusion site was the proximal basilar artery in 2 (14.3%) patients, the mid-basilar artery in 1 (7.1%) patient, the distal basilar artery in 10 (71.4%) patients, and the proximal to distal basilar artery segments in 1 (7.1%) patient. Stroke etiology, according to TOAST criteria, was large vessel disease in 5 (35.7%), cardioembolic in 6 (42.9%), and undetermined in 3 (21.3%) patients. Five patients (35.7%) received intravenous rtPA as bridging therapy before endovascular treatment. Seven patients (50%) received intra-arterial thrombolysis (median dose 550,000 IU, range 100,000–1,000,000 IU). Thrombus aspiration prior to using a stent retriever was performed in 4 patients (28.6%). Mechanical thrombectomy without adjunctive thrombolytic therapy was performed in 4 patients (28.6%). Delivery of the Solitaire FR was technically feasible in all patients. All patients were treated with the Solitaire FR 4 × 20 mm, with an average number of passes of 1.3 (range 1–3), until achieving maximal recanalization (1 retrieval attempt in 12 patients, 3 retrieval attempts in 2 patients). Immediate flow restoration after stent deployment was observed in 78.6% (11/14). Overall, TICI 3 or 2b recanalization grade was achieved in all patients. After stent retrieval, recanalization grade was TICI 3 in 10 patients (71.4%). In 4 patients (28.6%), recanalization grade after stent retrieval was insufficient due to an underlying atherosclerotic stenosis. Additional deployment of a permanent intracranial stent was performed in 3 patients (21.4%; predilation in 2 patients, postdilation in 1 patient) and PTA alone in 1 patient (7.1%). These resulted in a final recanalization grade of TICI 3 in 1 patient and TICI 2b in 3 patients.

The median time from symptom onset to first angiogram was 414 minutes (range 176–1440 minutes) and median procedure time to recanalization was 47 minutes (range 10–252). No thromboembolic occlusion of a previously unaffected artery was found at control angiography after stent retrieval. No device-related adverse events were observed.

There were 3 (21.4%) asymptomatic postprocedure hemorrhages according to the PROACT II criteria,²² but no clinically symptomatic intracranial hemorrhage occurred.

Median NIHSS score after 24 hours was 8 (range 1–36). Of the total sample, 35.7% of patients (5/14) improved by >9 points on the NIHSS scale after 24 hours. Mortality was 35.7% (5/14). Four of the 9 surviving patients (28.6%) had favorable clinical outcomes after 3 months (mRS 0–2) and 5 (35.7%) had poor outcomes (mRS 3–5).

DISCUSSION

The introduction of retrievable stents to the armamentarium of endovascular ischemic stroke treatment increased recanalization rates up to 80%–94%.^{10–12,15–17} Recent preliminary clinical studies examined the treatment effect of retrievable stents in large vessel occlusions, mainly in the anterior cerebral circulation (ICA and MCA occlusions), including only a few or a single acute BAO. Therefore, only very limited data and detailed analyses of the treatment effect of stent retrievers in acute BAO are available in the literature.

Roth et al¹² included 8 acute BAOs in their series of 20 intracranial vessel occlusions treated with the Solitaire FR. Recanaliza-

tion was successful in all BAOs, defined as a TICI score >2, with a mean number of device passes of 1.75. Symptomatic intracranial hemorrhage occurred in 1 patient. Good functional outcome (mRS 0–2) was achieved in 50% of patients (4/8) and mortality was 37.5% (3/8). Miteff et al¹⁷ presented 10 acute BAOs in their series, totaling 26 patients treated using the Solitaire FR. Presumed etiology of BAO was cardioembolic in 4, dissection in 3, atherosclerosis in 1, iatrogenic in 1, and unknown in 1 patient. TIMI 2 or 3 recanalization grade was achieved in all patients (TIMI 3 in 33.3%, 3/10 patients), with more than 3 device passes needed in 50% of cases. Good functional outcome (mRS 0–2) was observed in 20% of patients (2/10), and mortality was 33.3% (3/10). The largest number of acute BAOs treated thus far with the Solitaire FR was reported by Costalat et al,¹⁵ who included 16 acute BAOs in their series of 50 patients with large vessel occlusion stroke. Successful recanalization (defined as TICI 3) was achieved in 81% (13/16), with a mean of 2.1 passes. One patient experienced a symptomatic intracranial hemorrhage, and symptomatic embolic events occurred in 2 patients. An mRS of 0–2 at 3 months was observed in 44% (7/16), with a mortality rate of 25% (4/16). The recanalization results of the present study are in line with these previous data, confirming the capability of achieving very high recanalization rates in the setting of a multimodal approach.

However, despite the high recanalization success, favorable clinical outcome was limited. This finding might be attributable to the small sample size of the study. On the other hand, especially in basilar artery occlusions, other factors have been noted as predictors for outcome, such as high initial NIHSS score at presentation, younger age, time span from onset to recanalization, and thrombus extent and location,^{3,5,6,23–27} which may influence clinical outcome in addition to recanalization success.

The main causes of acute BAOs are atherothrombotic occlusions, due to local thrombosis on the ground of a high-grade stenosis, and embolic occlusions, due to cardiac or arterio-arterial thromboembolism. Atherothrombotic lesions are found in around 26%–36% of patients with acute BAO and are more often localized at the vertebrobasilar junction and up to the midbasilar segment. Embolic occlusions account for around 30%–35% of acute BAOs. These occur more often in the distal segment of the basilar artery and are reported to recanalize easier.^{3,8,23,27–29} Remarkably, all 4 patients in this study, where insufficient recanalization after stent retrieval was achieved, had an underlying high-grade atherosclerotic basilar artery stenosis. This observation might be attributable to several findings. First, thrombi occurring on the surface of ulcerated atherosclerotic plaques are usually more adhesive than embolic thrombi and therefore more difficult to extract. Second, only partial recanalization after stent retrieval on the grounds of a high-grade atherothrombotic lesion has a higher risk of reocclusion than a completely recanalized vessel. Reocclusion rates after intra-arterial thrombolysis have been reported to be 10%–30%.^{30,31} Furthermore, the Solitaire FR does not provide enough radial outward force during its temporary deployment to overcome a high-grade atherosclerotic stenosis. However, the radial force was sufficient to achieve an immediate flow restoration effect by compressing the thrombus against the vessel wall in most patients (11/14). In several studies, PTA and permanent intracranial stent placement were performed in addi-

tion to thrombolysis and thrombectomy as an on-demand or rescue procedure, with higher recanalization rates than intravenous or intra-arterial thrombolysis alone, ranging from 70%–94%.^{23,25,26,32} Therefore, PTA and/or permanent intracranial stent implantation at the site of the stenosis is still a treatment option when partial recanalization is achieved with a stent retriever.

In cases of thromboembolic BAO, thrombus load can be comparatively large and therefore resistant to thrombolytic therapy. Different thrombolytic agents at higher dosages have to be administered to dissolve the clot, possibly increasing the risk of hemorrhage.³³ The use of stent retrievers has the advantage of being able to immediately remove larger clot volumes in case of a cardioembolic occlusion.

Currently, proximal temporary balloon occlusion using a balloon-guide catheter in the ICA is recommended in anterior circulation strokes to avoid embolization or shearing off of thrombus fragments during stent retrieval. However, these guidelines are inconsistently followed in published series, and there are limitations to this approach in the posterior circulation, where a bilateral proximal vertebral artery occlusion with 2 balloon-guide catheters via a bifemoral approach would be necessary to achieve flow control.^{34,35} This renders the procedure more time consuming and complicated. Instead, we attempted to use the largest possible guide catheter allowing safe catheterization of the vertebral artery to achieve flow reduction and to enable effective aspiration during retrieval. With this technique, no thromboembolic events in previously unaffected arteries occurred in this series.

In the present study, no device-related complications occurred and no signs of vessel dissection or perforation were observed on control angiographies. Furthermore, no symptomatic intracranial hemorrhage was encountered after treatment. Only 3 patients with asymptomatic hemorrhages, according to the PRO-ACT II criteria,²² were observed on routine posttreatment imaging. This low hemorrhage rate compares favorably with the rates of symptomatic intracranial hemorrhage reported in other stent-retriever studies (0% to 17%)^{10,11,15,16} and with acute BAO treatment (0% to 19%).^{8,9,23,24,26,36,37}

This study has inherent limitations due to the retrospective design and the small number of patients. Furthermore, the application of a multimodal approach might confound the treatment effect of mechanical thrombectomy. Therefore, definitive conclusions about the efficacy of stent retrievers in the treatment of acute BAO cannot be derived from this small study population and further clinical studies are needed.

CONCLUSIONS

Our preliminary study suggests that a multimodal endovascular approach using retrievable stents in BAO has high recanalization rates with very low complication rates. Underlying atherothrombotic stenotic lesions of the basilar artery may still necessitate additional permanent stent placement to achieve complete recanalization.

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