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Original Article

Mechanical thrombectomy of M2 occlusions with distal access catheters using ADAPT

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ABSTRACT

Background and purpose. – The direct aspiration first pass technique (ADAPT) using distal access catheters (DAC) has proven to be an effective and safe endovascular treatment strategy of acute ischemic stroke with large vessel occlusions (LVO). However, data about direct aspiration using DAC in M2 segment occlusions is limited.
We assess the safety and efficacy of DACs in acute M2 occlusions using ADAPT with large bore (5 French /6 French) aspiration catheters as the primary method for endovascular recanalization.
Materials and methods. – From January 2017 to July 2018, 52 patients with an acute ischemic stroke due to M2 occlusions underwent mechanical thrombectomy using ADAPT with DACs (SOFIA 5 French/Catalyst 6) as frontline therapy. Patient demographics, technical parameters and outcome data were recorded.
Results. – Median National Institutes of Health Strokes Scale (NIHSS) Score was 12 at admission. Successful revascularization to mTICI 2b-3 with ADAPT alone was achieved in 45 of 52 patients (86.5%) with mTICI 3 achieved in 32 patients (61.5%). Additional stent retrievers were used in 6 patients and led to an overall successful revascularisation of 92.3% (48/52). Median NIHSS at discharge was 4. 29 of 52 (55.8%) patients had a modified Rankin Scale (mRS) Score 0–2 at three months. Symptomatic intracranial hemorrhage did not occur.
Conclusion. – DACs can safely be used for mechanical thrombectomy of acute M2 occlusions by the ADAPT approach. Their use alone can be a high efficacious treatment of distal intracranial thromboembolic occlusions.

Introduction

The positive results of five randomized controlled trials comparing endovascular treatment (mainly with stent retrievers) to conservative treatment have dramatically changed the management of acute ischemic stroke in patients with large vessel occlusions. Consequently, mechanical thrombectomy with stent retrievers has become the preferred treatment option for patients who meet the relevant criteria [1–6]. Thromboembolic occlusion of smaller distal cerebral arteries may also lead to severe neurological deficits despite a smaller core infarct volume. The current American Heart Association guidelines recommend treating occlusions of the middle cerebral artery M2 segment with mechanical thrombectomy based on the data from recent studies that have shown effectiveness of endovascular treatment in the distal intracranial vasculature [7,8]. In the past few years, the neurointerventional community discussed intensively about the best thrombectomy technique for cerebral vessel occlusions. Recently, the ADAPT technique (a direct aspiration first pass technique for stroke thrombectomy) has proven to be effective, fast and safe in large vessel occlusions (LVO) using state-of-the art aspiration catheters [9–12]. However so far, there are only sporadic studies describing ADAPT as frontline therapy in the distal intracranial vasculature and most of them used catheters, similar but smaller in size than those catheters routinely applied in large caliber arteries like the distal internal carotid artery (ICA) and M1 segment [13–17].

The purpose of this study is to assess the safety and efficacy of the direct aspiration first pass technique in M2 occlusions using

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ADAPT	a direct aspiration first pass technique
DAC	distal access catheter
LVO	large vessel occlusion
NIHSS	National Institutes of Health Strokes Scale
mRS	modified Rankin Scale
ICA	internal carotid artery
TICI	Thrombolysis in Cerebral Infarction
IVT	intravenous thrombolysis
DSA	Digital Subtraction Angiography
tPa	tissue plasminogen activator
ICH	intracranial hemorrhage
IQR	interquartile range
ENT	embolization to new territory
SD	standard deviation

solely large bore (5 French and 6 French) distal access catheters (DAC) as the primary method for endovascular recanalization in acute stroke.

Methods

Patients

Approval of the local hospitals' institutional review boards of the three centers was obtained. All patients with acute ischemic stroke who underwent mechanical thrombectomy between January 2017 and July 2018 were retrospectively screened for M2 segment occlusions. The M2 segment was defined as the middle cerebral artery branches extending from the genu to the top of the Sylvian fissure and the circular sulcus [18]. If the anterior temporal artery arises from the horizontal M1 segment, it has not been considered a M2 branch [7]. Only patients who were treated with direct aspiration performed with an off-label distal access catheter in M2 branches as a frontline therapy were included to the study. Further inclusion criteria was a National Institutes of Health Stroke Scale (NIHSS) Score > 5 or aphasia if the score was < 5. If eligible, patients received intravenous thrombolysis (IVT) before intervention following the Guidelines of the German Society of Neurology. Exclusion criteria included evidence of intracranial hemorrhage or major established cerebral infarction in the affected M2-territory. Patient demographic data and clot location were recorded.

Evaluation and outcome data

All patients with symptoms of an acute stroke underwent a CT scan and a supraaortic and cerebral CT-angiography after a brief evaluation by a neurologist. This CT scan was repeated promptly after the intervention and again approximately 24 hours after symptom onset (or earlier if clinical deterioration occurred) to rule out a symptomatic intracranial hemorrhage according to the European Acute Stroke Study II classification [19].

For quantification of the neurological deficit, the NIHSS Scores were obtained at admission and at discharge and the modified Rankin Scale (mRS) Scores were noted at admission and after 90 days. A good functional outcome was defined as mRS Scores of 0–2. For outcome analysis of the interventional procedure, the following parameters were recorded for each patient: time from symptom onset to groin puncture, occlusion site, time from symptom onset to successful revascularisation defined as final Thrombolysis in Cerebral Infarction (TICI) score 2b or 3 within the affected territory, recanalization time defined as time from groin puncture to final angiogram after successful revascularisation, need of additional devices (i.e. stent retriever), procedure-related complications.

Endovascular procedure

All procedures were performed under general anesthesia. After femoral puncture a long sheath (Penumbra Neuron MAX or Terumo Destination) was placed in the cervical ICA of the affected side and Digital Subtraction Angiography (DSA) was performed to confirm the exact localization and the extent of the vessel occlusion. Using the ADAPT technique, an aspiration catheter, in our study a distal access catheter (Sofia 5 French, MicroVention, Tustin, CA, USA or Catalyst 6, Stryker Neurovascular, Freemont, CA, USA), was mounted over a 0.014 "microguidewire or over a 0.021" microcatheter and advanced to the level of the thrombus under roadmap assistance (Fig. 1 and 2). After positioning the aspiration catheter with the catheter tip in the proximal part of the clot, microguidewire and/or microcatheter were removed and the hemostatic valve at the DAC was disconnected to verify that there was no back flow of blood through the catheter (wedging position) (Figs. 1B and 2F). Then, aspiration was performed by using a 60 mL syringe (VacLok, Vacuum Pressure Syringe, Merit Medical Systems, Utah, USA) for at least 1–2 minutes. Next, the DAC was slowly removed under continuous aspiration. The DAC was slowly and gently withdrawn to the cavernous ICA or completely removed in case of a blocked catheter due to clot material. In the latter case additional manual suction was applied at the long sheath. Depending on the blood pressure and in consultation with our anesthetists, the procedures were performed under continuous intra-arterial infusion of nimodipine.

A control DSA was performed after each aspiration attempt. If sufficient recanalization ($\geq$ TICI 2b) was not achieved with ADAPT as a frontline therapy after not more than 3 failed aspiration attempts, an additional stent retriever was deployed by using the DAC approach and the so called Solumbra technique was conducted at the discretion of the operator. The Solumbra technique combines a stent retriever distal to the clot with an aspiration catheter at the proximal aspect of the clot. The stent retriever is pulled directly into the aspiration catheter while maintaining aspiration and both are removed together.

Statistical analysis

A median test was used to compare continuous variables. Continuous variables are reported as mean ± standard deviation and categorical variables are reported as *n* (%). Results were considered statistically significant with P-values < 0.05. Statistical analyses were performed using SPSS 20.0 (SPSS Inc., Chicago, IL, USA) and SAS 9.2 (SAS Institute, Cary, NC, USA).

Results

Patient characteristics and presentation

Patients' demographics, technical parameters of the thrombectomy procedure and outcome data are summarized in Table 1. From January 2017 to July 2018 52 patients with acute ischemic stroke underwent thrombectomy of an acute M2 occlusion with ADAPT as first intention. All patients had an isolated thrombus in the M2 segment of the middle cerebral artery. Intravenous tPa was administered in 30 patients (57.7%) before mechanical thrombectomy. Patients presented with a median NIHSS score of 12 (IQR: 8).

Technical outcomes

In all cases, the DAC could be navigated to the occlusion site in the M2 territory.

Successful revascularization in the M2 territory to mTICI 2b-3 with the ADAPT technique alone was achieved in 45 of 52 patients

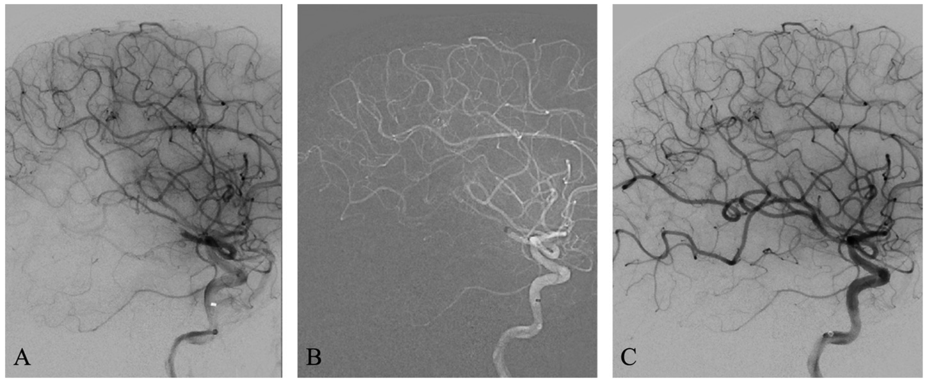

Fig. 1. Elderly female patient with a left M2 occlusion. DSA left internal carotid artery injection, lateral view, showing left M2 occlusion before thrombectomy (A). Road map in lateral projection. Position of the Catalyst 6 DAC with the catheter tip in the proximal part of the clot. There is no need to pass the thrombus with the microwire/-catheter system (B). Final angiogram of the left ICA, lateral view, showing successful recanalization of the left M2 branch after one aspiration attempt with a mTICI score of 3 (C).

Table 1
Patients' demographics, technical parameters and outcome data.

Characteristics	Value
Age (years), mean (range)	76.1 (52–96)
Sex, female/male	27/25
Average delays (min), mean (± SD)	
Time from symptoms' onset to groin puncture	227 (± 127.2)
Time from symptoms' onset to successful recanalization	289 (± 131.1)
Time from groin puncture to successful recanalization	63 (± 37.6)
Unknown time of symptom onset, number	1
Number of passes, median (IQR)	1 (1)
IVT	30 (57.7)
NIHSS score at admission, median (IQR)	12 (8)
NIHSS score at discharge, median (IQR)	4 (5.5)
mRS score at 90 days, median (IQR)	2 (2)
mRS 5–6	9
mRS 3–4	14
mRS 0–2	29
Angographic outcome after ADAPT alone, TICI	
0	0
1	5 (9.6)
2a	2 (3.9)
2b	13 (25)
3	32 (61.5)
Final angiographic outcome, TICI	
0	0
1	2 (3.9)
2a	2 (3.9)
2b	14 (26.9)
3	34 (65.4)
Type of DAC	
Sofia 5F	50 (96.2)
Catalyst 6	2 (3.9)
Complications	
Symptomatic ICH	0
Asymptomatic ICH	2 (3.9)
Vasospasm	2 (3.9)
Vessel dissection	0

Results are shown as number (%) of patients unless stated otherwise.
SD: standard deviation; IQR: interquartile range; IVT: intravenous thrombolysis; NIHSS: National Institutes of Health Stroke Scale; mRS: modified Rankin scale; ADAPT: a direct aspiration first pass technique; TICI: Thrombolysis in Cerebral Infarction; DAC: distal access catheter; ICH: intracranial hemorrhage.

(86.5%) with a median of 1 (IQR: 1) aspiration attempts. 32 of 52 (61.5%) patients were revascularized to mTICI 3. 61.5% (32/52) of the M2 occlusions were treated with one aspiration attempt, 17.3% (9/52) required two attempts and 7.7% (4/52) were successfully treated with three attempts. In 7 patients (13.5 %), only a contact aspiration did not recanalize the M2 branch and the Solumbra technique was additionally used in 6 of those cases after 2 or 3 failed aspiration attempts, achieving successful recanalization in 3 patients (1 patient with mTICI 2b and 2 patients with mTICI 3) and partial recanalization in another case (mTICI 2a). In one case the vessel remained occluded despite several thrombectomy attempts with ADAPT and the Solumbra technique (mTICI 1). In 1 patient, the aspiration led to a partial recanalization (mTICI 2a) and the Solumbra technique did not improve the final angiographic outcome. In another case, the procedure was aborted after unsuccessful aspiration of the M2 occlusion without the additional use of a stent retriever due to sharp angle of the vessel proximal to the occlusion (mTICI 1). The overall successful reperfusion rate of the M2 thrombectomies was 92.3% (48/52) using ADAPT as first-line treatment and in combination with a stent retriever using the Solumbra technique when thromboaspiration solely was unsuccessful.

One patient presented with an unknown time of symptom onset. In the other patients, the average delay between symptoms' onset and groin puncture was 227 min (± 127.2), the mean recanalization time was 63 min (± 37.6) and the average time between symptoms' onset and revascularisation was 289 min (± 131.1).

In three patients, a tandem lesion with a stenosis of the proximal internal carotid artery required balloon angioplasty and stent implantation to reach the intracranial vasculature and the M2 occlusion.

No complications occurred while attempting to reach the clot with the DAC. Vessel perforation or dissection following direct aspiration in the M2 branches was not observed. Symptomatic intracranial hemorrhage (ICH) was seen in 0% patients with M2 occlusions. 2 patients showed an asymptomatic small ICH on post-interventional CT and 2 patients developed mild vasospasms during the stroke procedures, which were treated with intra-arterial nimodipine.

Clinical outcomes

The median NIHSS of the patients improved from 12 (IQR: 8) at admission to 4 (IQR: 5,5) at discharge ($P < 0.05$). The mRS score improved significantly from a median of 5 (IQR: 1) at admission to a median of 2 (IQR: 2) at 90 days ($P < 0.05$). Favorable clinical outcome (mRs 0–2) at 3 months follow-up was noted in 29 of 52 patients (55.8%).

Discussion

Our retrospective study of 52 patients with M2 occlusion undergoing aspiration thrombectomy with large bore (5 French and 6

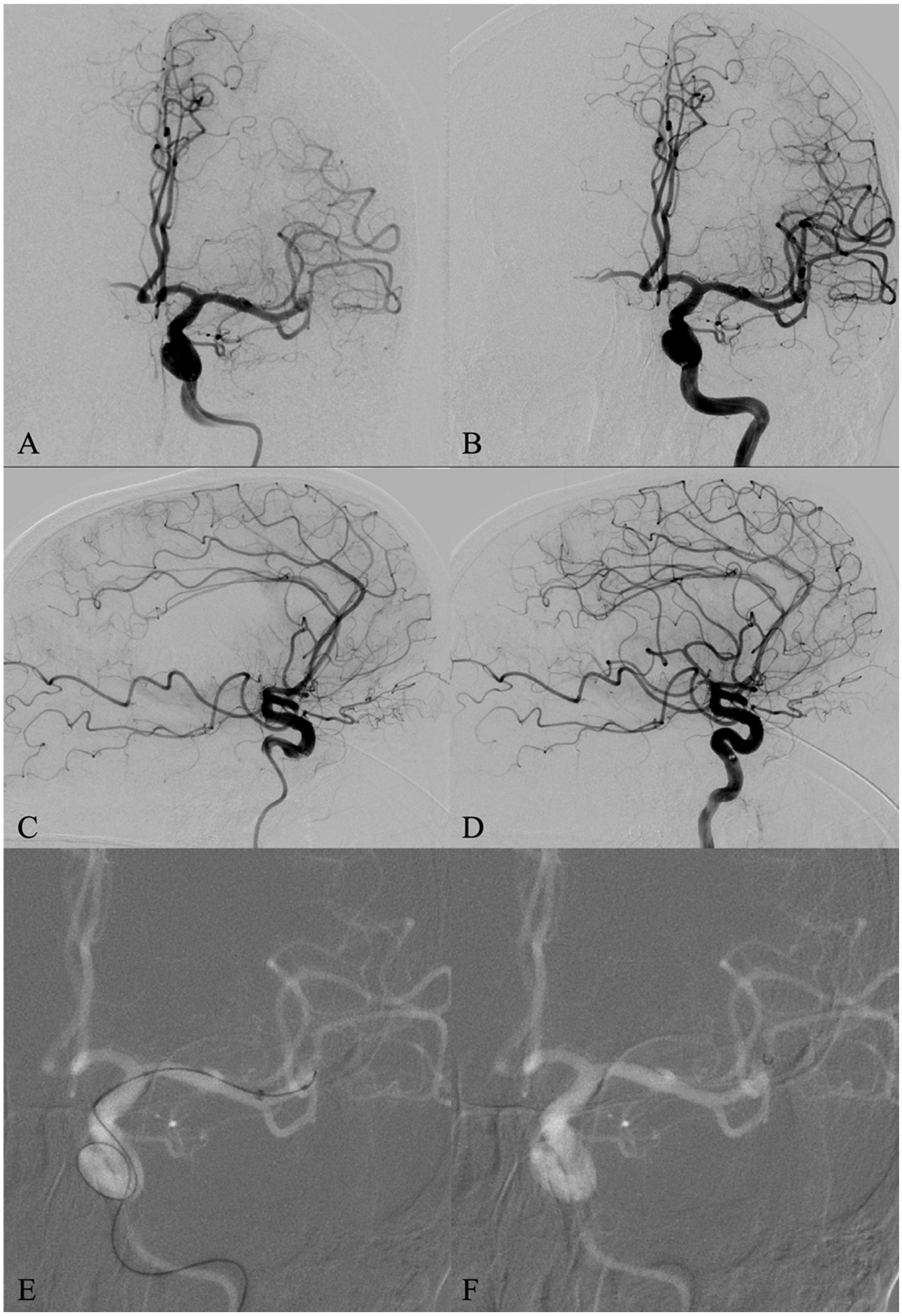

Fig. 2. Elderly male patient with a left M2 occlusion. DSA left internal carotid artery injection, anteroposterior (ap) view (A, B) and lateral view (C, D) showing occlusion of the left middle cerebral artery in the M2 segment before treatment (A, C) and after successful single pass aspiration with revascularization to a mTICI score of 3 (B, D). Roadmaps in ap projections (E, F). Position of the Sofia 5 French DAC within the proximal part of the clot without the need to pass the thrombus with the microwire/-catheter system (F).

French) aspiration catheters led to a number of interesting findings: First, we experienced no technical issues in achieving contact between the thrombus and the aspiration catheter. Second, revascularisation rates were high with over 80% of patients achieving TICI 2b/3 and over 60% of patients achieving TICI 3. Furthermore, there were no major complications such as vessel perforation or dissection. Finally, rates of good functional outcome were high with over 50% of patients having mRS 0–2 at 3 months. Therefore, we come to the conclusion that modern large bore aspiration catheters are safe and effective in treatment of M2 occlusions.

Although the five randomized stroke trials are mainly focused on LVOs from M1 and ICA occlusion, studies and post-hoc analyses following these trials suggest that endovascular treatment is also safe and effective for occlusions of the M2 segment compared to best medical treatment [7,8]. In recent years, ADAPT has been introduced to facilitate thrombectomy procedures by direct contact aspiration of the thrombus and has been successfully and safely used for proximal LVOs with high recanalization rates and also good clinical outcome [9,10]. However, in most of the retrospective studies focused on distal intracranial occlusions, stent retrievers were mainly used to recanalize the target vessel with heterogeneous reperfusion rates [7,8,20,21]. Comparison of results of contact aspiration and the use of stent retrievers in M2 occlusions is also limited and only retrospectively analyzed with no statistically significant differences in complications and good functional outcome [22,23]. The post-hoc analysis of the ASTER randomized trial (contact aspiration versus stent retriever for successful revascularisation) did not show significant differences on reperfusion and clinical outcome between contact aspiration and stent retriever as a first-line strategy in isolated M2 occlusions [24]. The results of this analysis were similar to those of two recently published meta-analyses comparing reperfusion rates of stent-retrieval and contact aspiration for M2 occlusions [25,26]. Grossberg et al., along with these data, demonstrated comparable efficacy of recanalization with both newer generation aspiration catheters and smaller stent retrievers for thrombectomy of distal intracranial occlusions [27].

It is important to note that most of the retrospective studies focusing on ADAPT as a frontline therapy in these small distal intracranial vessels were performed with aspiration catheters with relatively small inner diameters, mainly the Penumbra 3MAX (0.035“) and 4MAX (0.041“) catheters [14–17]. Reports on use of larger bore catheters such as the 5MAX (0.054“) in proximal M2 segments are only sporadic [14]. To our knowledge, our retrospective study provides the largest reported number of patients performing the ADAPT technique with large bore distal access catheters as a frontline stroke therapy in M2 occlusions. In this cohort of patients, we only used large-bore catheters/DAC with an inner diameter of 0.055“(SOFIA 5F) and 0.060” (AXS Catalyst 6). The safety and efficacy data for the SOFIA 5F catheter in stroke interventions have already been reported [28]. In many of our cases, the SOFIA 5 F was advanced solely over a microguidewire to reach the clot interface which may reduce procedural duration. So far, there is only little data published about the AXS Catalyst 6 catheter with only one series of five M2 occlusions treated with direct aspiration [13]. This catheter, in our opinion, also provides balance between good trackability in tortuous intracranial anatomy and large inner diameter.

We achieved TICI 2b-3 in 45 of 52 patients (86.5%) with aspiration alone. Our results differ considerably to the results published by Chartrain et al. with only 50% successful aspiration with distal access catheters in M2 and M3 segments. However, this case series is limited by the small sample size of only 8 patients of whom two failed aspirations were performed with a Velocity catheter (Penumbra; inner diameter 0.025“) [13]. Park and colleagues used the smaller 4MAX catheter for M2 aspiration thrombectomy and achieved aspiration results comparable to our results with TICI 2b-3 in 27 of 32 patients (84%) [29], whereas Vargas et al. reported slightly lower recanalization results with TICI 2b-3 in 77.1% of cases in their series of 35 patients with distal intracranial vessel occlusions treated with 5MAX, 4MAX or 3MAX catheters [14].

In a comparative study of aspiration and stent retriever thrombectomy, Kim et al. found successful reperfusion (TICI 2b-3) with the 4MAX catheter after aspiration in only 16 of 25 patients (64%) [22]. Interestingly, the recanalization outcome with the 3MAX reperfusion catheter for frontline aspiration therapy in distal intracranial arteries varies considerably between two recently published studies and our aspiration results are comparable to the cohort of patients with M2 occlusions treated by Altenbernd et al. (83.9%) and considerably superior to the reperfusion rates published by Premat et al. (59.5%) [15,16]. Noteworthy, in comparison to those smaller reperfusion catheters, for aspiration thrombectomy with distal access catheters there is no need of an additional intermediate catheter placed more proximally to provide better support to the system. This might reduce procedural time until the first aspiration attempt.

If recanalization attempts with the ADAPT technique fail, a stent retriever can easily be navigated through the DAC and the Solumbra technique or any other technique with stent retriever can be performed as a bailout therapy. In our cohort of patients, stent retrievers were additionally used in 6 patients and led to a successful recanalization in 3 cases with a final overall successful reperfusion rate of 92,3% (48/52 patients). According to the authors' opinion, ADAPT and Solumbra are not competitors in stroke intervention but should rather be seen as complementary thrombectomy techniques that can easily be combined. Some authors believe, that particularly in very challenging distal catheterizations with extremely tortuous vessels, stent retrievers might be useful because the trackability of the delivery microcatheter is more suitable [15]. Further, M2 occlusions after a sharp vessel angulation can be very ambitious for the ADAPT technique and the clot might no be reached by the aspiration catheter.

However, in our opinion, it might be an advantage to avoid the deployment of a stent retriever in small vessels. Mostly, it is not necessary to pass the thrombus before aspiration lowering the risk of embolic complications compared to the usage of a stent retriever [30]. Moreover, even small stent retrievers dedicated for the use in distal intracranial vessels were associated with relatively high vasospasm rates of 62.5% in a case series with the Trevo 3×20 devices [31] and of 19.5% in a study with the Catch Mini stent retriever [32]. Interestingly, we experienced only two mild vasospasms (3.9%) after sole aspiration, which were easily solved with intra-arterial Nimodipine. The most feared and precarious complication of mechanical thrombectomy is a symptomatic ICH. ADAPT has been reported to cause less symptomatic intracranial hemorrhage than the Solumbra technique, probably due to a lower propensity for endothelial damage without the use of a stent retriever [33]. Stent retriever passes beginning in M2 branches increase the risk of traction injury to smaller perforators with resultant iatrogenic subarachnoid hemorrhage [34]. Bhogal et al. published a large series of 106 acute M2 occlusions treated with stent retriever and experienced symptomatic ICH following thrombectomy in 4.7% of cases [35]. In contrast, several studies on ADAPT in distal middle cerebral artery occlusions report either no or only 1 symptomatic ICH in their respective cohort of patients [13–17,22,29,33]. In these studies thromboaspiration was predominantly performed with the 3MAX or 4MAX catheters. A recently published study on distal intracranial occlusions treated either with thromboaspiration or stent retriever based thrombectomy reported a 4% rate of parenchymal hematoma. Interestingly, these hematomas followed exclusively distal occlusions treated with stent retriever. No post-procedural parenchymal hematoma after thromboaspiration was described [27]. Phan et al. also showed a higher incidence of symptomatic ICH after stent retrieval compared to thromboaspiration [25]. These data substantiate our experience as we did not observe any parenchymal hematoma or symptomatic intracranial hemorrhage in our patients treated with aspiration alone. Asymptomatic ICH is more commonly reported than symptomatic ICH in the previous M2 thrombectomy studies with thromboaspiration or stent retrieval, with rates ranging mainly from 0% to 12% [13–17,22,29]. Relatively high rates of asymptomatic ICHs after stent retrieval were noted in a series of patients published by Bhogal et al. (26%) and in a study on the Mindframe Capture low profile stent retriever (21%) [35,36]. We encountered 2 post-thrombectomy asymptomatic ICHs (3.9%) after thromboaspiration.

Embolization to new territory (ENT) may occur with all types of mechanical thrombectomy devices. However, several studies indicate a lower ENT rate with aspiration alone (0–6%) than with stent retrievers (0–13.3%) [11,15,31,37,38]. In their meta-analysis on contact aspiration versus stent retriever thrombectomy, Phan et al. report higher rates of procedural complications after stent retrieval in terms of distal embolization and vessel dissection/perforation, even though the differences were not significant [25]. Our study results support this hypothesis as we observed no ENT, distal embolization or vessel dissection after ADAPT in M2 branches. In addition to these technical advantages, aspiration thrombectomy is more cost-effective and requires fewer resources than stent retriever based thrombectomy (e.g. in combination with a DAC) [39].

Our study is limited by its retrospective design and by the small number of patients. Further, only patients who underwent thrombectomy of M2 occlusions with a direct aspiration first pass technique as a frontline therapy were included. Thus, there has not been a consecutive enrollment of patients with M2 occlusions. M2 occlusions that were intentionally treated with the Solumbra technique as the frontline therapy were excluded. The respective treatment strategy was based upon the neurointerventionalist's discretion and therefore might lead to a selection bias. None of the angiographic or clinical outcomes were core lab adjudicated. Prospective studies are needed to compare contact aspiration using catheters with different inner diameters in distal intracranial vessels and to further and more precisely evaluate the ADAPT technique compared to stent retrievers.

Conclusions

The results of this retrospective analysis in 52 patients with M2 occlusions treated using the ADAPT technique as a frontline therapy suggest that large bore DACs can be safely navigated to the site of M2 occlusions for the purpose of thromboaspiration in acute ischemic stroke. Their use alone can be a high efficacious treatment of distal intracranial thromboembolic occlusions.

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Author statement

Dominik Grieb: developed the project; acquired, analyzed and interpreted data for the work; designed the study; drafted the manuscript and approved the final manuscript as submitted.

Martin Schlunz-Hendann: acquired, analyzed and interpreted data for the work; revised the manuscript and approved the final manuscript as submitted.

Waleed Brinjikji: analyzed and interpreted data for the work; critically revised the manuscript and approved the final manuscript as submitted.

Katharina Melber: acquired, analyzed and interpreted data for the work; revised the manuscript and approved the final manuscript as submitted.

Bjoern Greling: acquired, analyzed and interpreted data for the work; revised the manuscript and approved the final manuscript as submitted.

Heinrich Lanfermann: analyzed and interpreted data for the work; critically revised the manuscript and approved the final manuscript as submitted.

Friedhelm Brassel: conceptualized the study, analyzed and interpreted data for the work; critically revised the manuscript and approved the final manuscript as submitted.

Dan Meila: developed and supervised the project; analyzed and interpreted data for the work; critically revised the manuscript and approved the final manuscript as submitted.

All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Disclosure of interest

The authors declare that they have no competing interest.

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