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ORIGINAL ARTICLE

Delivery Assist Catheters

A new Device Class and Initial Experience in Mechanical Thrombectomy in Acute Ischemic Stroke Patients

Johannes A. R. Pfaff[1] · Ralf Siekmann[2] · Yogesh P. Shah[3] · Peter A. Ringleb[4] · Christian Ulfert[1] · Kai Koller[2] · Martin Bendszus[1] · Markus A. Möhlenbruch[1]

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Abstract

Purpose To report in vivo experience of a delivery assist catheter as ascending aid for a large-bore catheter for intracranial thromboaspiration.

Methods Retrospective data collection and analysis of stroke databases of two comprehensive stroke centers focusing on technical and angiographic parameters – primary endpoint defined as reaching the occlusion with a large-bore reperfusion catheter – from patients receiving endovascular stroke treatment using an AXS Offset™ delivery assist catheter (Stryker, Fremont, CA, USA) between May 2017 and November 2017.

Results Using the delivery assist catheter, a 6F catheter could be advanced to an intracranial occlusion for direct thromboaspiration in 30 (88.2%) out of a total of 34 patients (male: $n=14$ out of 34 [41.2%], age in years: mean [SD]: 75 [11], median baseline NIHSS [National Institutes of Health stroke scale]: 16 [interquartile range, IQR 12-21]). In 4 out of 34 (11.7%) cases the occlusion could not be reached with the aspiration catheter because of a preceding non-occlusive arteriosclerotic plaque ($n=1$, 2.9%) or because of severe elongation and tortuosity of the arterial access route ($n=3$, 8.8%). After thromboaspiration mTICI (modified thrombolysis in cerebral infarction) 2b-3 was reached in 14 out of 30 (46.7%) patients. In 21 out of 34 (61.8%) patients stent-retriever-maneuvers (median: 1 [IQR: 0-2]) were needed. In 28 out of 34 (82.3%) patients final mTICI 2b-3 could be achieved.

Conclusion Delivery assist catheters can be used as ascending aid for large-bore catheters for thromboaspiration in acute ischemic stroke, in particular to overcome vessel tortuosity and anatomic obstacles.

Keywords Thromboaspiration · Acute ischemic stroke · Large bore catheter · Anatomic obstacle · Vessel tortuosity

Abbreviations

AIS	Acute ischemic stroke
CT	Computed tomography
DSA	Digital subtraction angiography
ICA	Internal carotid artery
M1	Main branch of middle cerebral artery
mRS	Modified Rankin scale
mTICI	Modified thrombolysis in cerebral infarction
NIHSS	National Institutes of Health stroke scale
RCT	Randomized controlled trial
sICH	Symptomatic intracranial hemorrhage

✉ Markus A. Möhlenbruch
markus.moehlenbruch@med.uni-heidelberg.de

[1] Department of Neuroradiology, Heidelberg University Hospital, Im Neuenheimer Feld 400, 69120 Heidelberg, Germany

[2] Department of Neuroradiology, Klinikum Kassel, Kassel, Germany

[3] Department of Neurology, Klinikum Kassel, Kassel, Germany

[4] Department of Neurology, Heidelberg University Hospital, Heidelberg, Germany

Introduction

Mechanical thrombectomy using a first-line contact aspiration with large-bore reperfusion catheters is a fast and efficient alternative technique for retrieving clots in acute ischemic stroke due to large intracranial vessel occlusions [1–4]. Because of vessel tortuosity or other anatomic ob-

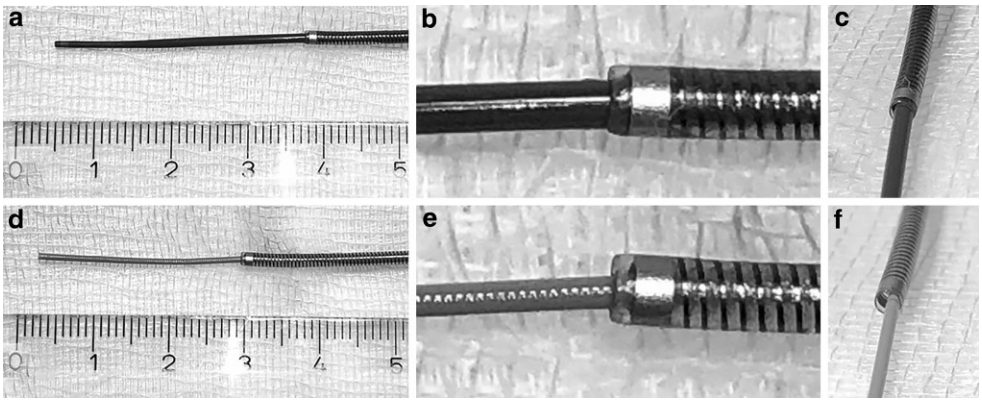

Fig. 1 **a** Shows an AXS Offset™ Delivery Assist Catheter (inserted through an AXS Catalyst 6 catheter) with its gradually progressing diameter at the distal tip. **b** Shows a direct and **c** an oblique close-up view of the distal tip of the AXS Catalyst 6 catheter with the inserted AXS Offset. **d**–**f** Show a Rebar™ 18 microcatheter inserted through an AXS Catalyst 6 catheter in comparable views. Please note that the shoulder between Rebar™ 18 microcatheter and the AXS Catalyst 6 catheter is markedly bigger (**e** and **f**) compared to when an AXS Offset™ Delivery Assist Catheter is inserted (**b** and **c**; scale in **a** and **d** in centimeters)

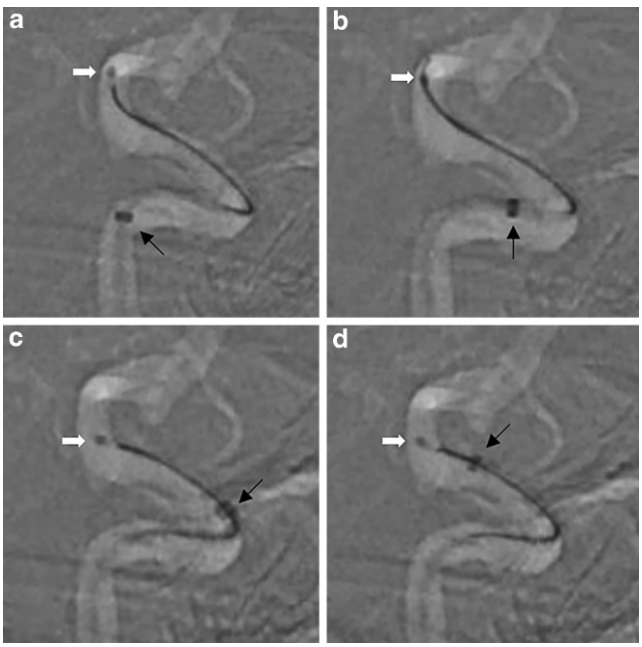

Fig. 2 **a**–**d** Show a lateral view of a right intracranial carotid artery (fluoroscopic images) with the tip of the delivery assist catheter in the carotid terminus (*white arrow*) and the aspiration catheter (the *black arrow* marks the tip of the AXS Catalyst 6 catheter) being advanced through the carotid siphon and past the origin of the ophthalmic artery (**c**)

stacles (e.g. origin of the ophthalmic artery), maneuvering and advancement of a large-bore reperfusion catheter towards the occlusion can be difficult or even impossible and imposes the risk of damaging the vasculature.

For an easier distal access, large-bore reperfusion catheters can be guided via a smaller inner catheter. This coaxial technique, however, creates a shoulder between the smaller inner catheter and the distal tip of the large-bore outer catheter: in some publications called a "ledge" effect. This shoulder still bears the risk of damaging the vessel wall and might cause dissection and subarachnoid hemorrhage. To decrease the shoulder between the two catheters, Takahira et al. used a compliant balloon catheter as inner catheter (positioned and inflated at the distal tip of the large-bore reperfusion catheter; [5]). With this so-called rocket technique, the coaxial system can be advanced to reach intracranial vessel occlusions. Potentially being inspired by the rocket technique, a delivery assist catheter has been developed as a new device to aid in the delivery of interventional devices, especially reperfusion catheters, in the neurovasculature. The purpose of this technical note is to report first in vivo experiences and the technical procedure during thromboaspiration in acute ischemic stroke patients.

Methods

For this retrospective analysis patient data from stroke databases from a maximum care facility and a university hospital both with 24 h/7 day neurological and neuroradiological attendance were used. Patients with acute ischemic stroke who received mechanical thrombectomy using a delivery assist catheter between May 2017 and November 2017 were included in this analysis. In all patients, direct thromboaspiration as primary recanalizing maneuver was intended. Additional maneuvers using a stent-retriever were allowed at the discretion of the treating neurointerventionalist. Intravenous thrombolytic drugs were administered and dosed at the discretion of the treating neurologist following national and international guidelines.

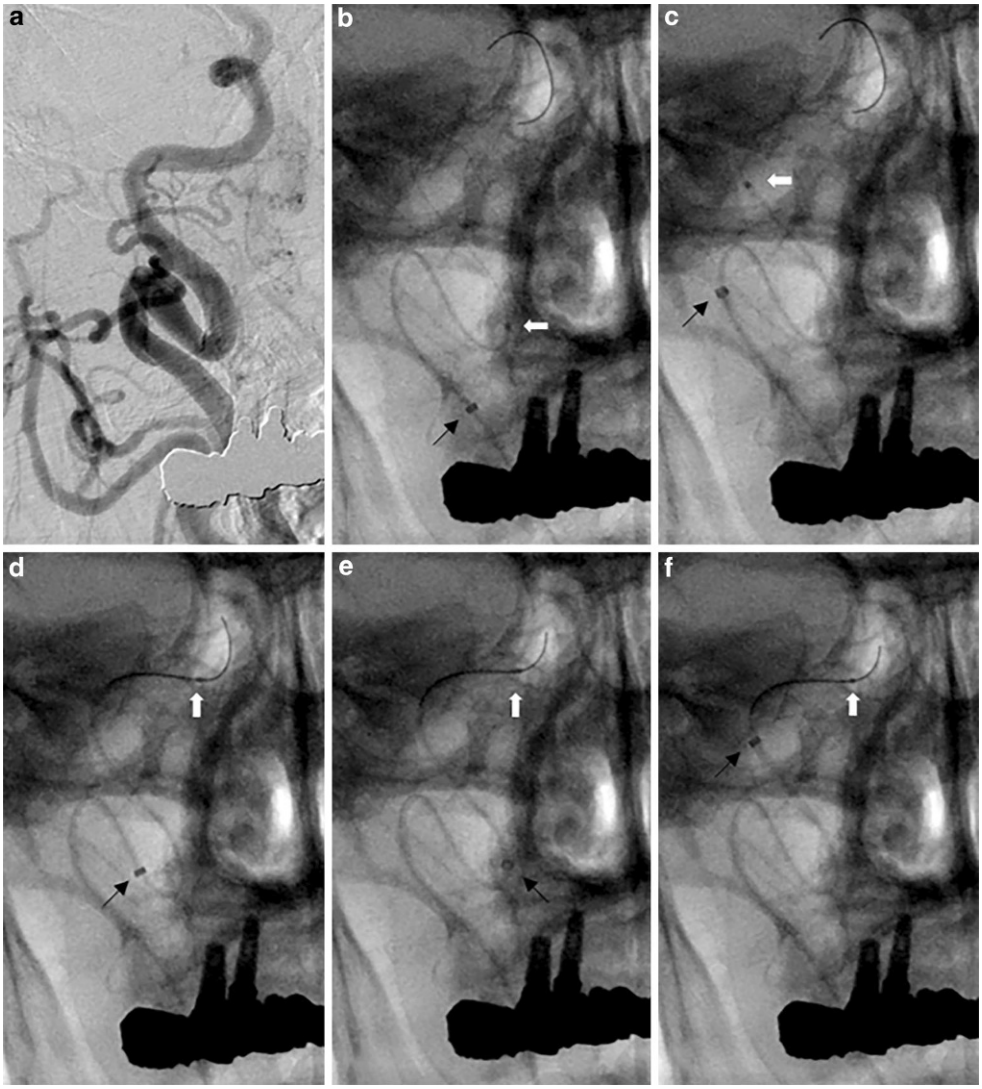

Fig. 3 **a** Shows an angiographic image (posteroanterior view) of a tortious, elongated right cervical carotid artery, **b**–**f** show the advancing coaxial system within the carotid artery (the *white arrow* points to the radiopaque marker of the AXS Offset delivery assist catheter, the *black arrow* marks the radiopaque marker of the AXS Catalyst 6 catheter)

Delivery Assist Catheter

In all cases reported in this article, an AXS Offset™ Delivery Assist Catheter (Stryker Neurovascular, Fremont, CA, USA) was used. The AXS Offset is a CE label marked single lumen device developed to assist in accessing distal vasculature for placement of a reperfusion catheter. The distal part of the device is highly flexible and has a 2 cm long microcatheter-like distal tip with a radiopaque marker: outer diameter 2.7 F (0.91 mm), inner diameter: 0.021 inches (0.53 mm) which gradually broadens to a 28 cm long broader part: outer diameter: 3.8 F (1.3 mm). The proximal section of the delivery assist catheter is semi-rigid and has an outer diameter of 3.0 F (1.0 mm). Overall intravascular working length of the device is 150 cm, which is preceded by a luer fitting on the catheter hub for attachment of accessories. The device is used with a steerable micro-guidewire. The AXS Offset is hydrophilically coated on the outer surface to reduce friction during maneuvering in the vessel (Fig. 1).

Operative Technique

As a standardized approach a guide catheter was placed within the proximal parent artery. A reperfusion catheter (AXS Catalyst 6, Stryker Neurovascular) was then introduced followed by the introduction of the AXS Offset device. As a next step, the delivery assist catheter was advanced distally to the tip of the reperfusion catheter to reduce the shoulder between the two catheters. Being guided via a 0.014 inch guidewire (Traxcess®, MicroVention, Irvine, CA, USA or Transend™ EX SOFT TIP, Stryker), this coaxial system was then advanced together towards the intracranial occlusion in a "thrombus-no-touch" technique (i.e. caution was taken so that the thrombus was not penetrated or manipulated with the microwire or the deliv-

Table 1 Baseline clinical and therapeutic characteristics as well as radiological findings of patients receiving mechanical thrombectomy

Patient characteristics		$n = 34$
Baseline clinical characteristics		
Age (years), mean (SD)		75 (11)
Male (%)		14 (41.2)
Initial NIHSS, median (IQR)		16 (12–21)
Intravenous rtPA (%)		16 (47.1)
Unknown time of symptom onset (%)		14 (41.2)
Radiological findings before mechanical thrombectomy		
ASPECTS, median (IQR)		9 (8–10)
Occlusion site[b]	Intracranial ICA (excluding carotid T; %)	1 (2.9)
	Carotid T (%)	7 (20.6)
	M1 (%)	22 (64.7)
	M2 (%)	2 (5.9)
	Occlusion site right (%)	15 (46.9)[a]
	Basilar artery (%)	2 (5.9)

ASPECTS Alberta Stroke Program Early Computed Tomography Score, *ICA* internal carotid artery, *M1* main trunk of middle cerebral artery, *M2* segment arising distal to the main trunk of the middle cerebral artery, *NIHSS* National Institutes of Health Stroke Scale, *rtPA* recombinant tissue plasminogen activator, *IQR* interquartile range, *SD* standard deviation

[a]Percentage with respect to anterior circulation ischemic stroke

[b]On digital subtraction angiography (DSA) images before the first thrombectomy maneuver

ery assist catheter). To avoid penetrating the thrombus, the guidewire and delivery assist catheter could be placed in the anterior cerebral artery. Unlike with the rocket technique, where the balloon catheter needed to be deflated prior to the final step, the reperfusion catheter could be gently slid over the delivery access catheter and be navigated directly to the proximal surface of thrombus. Finally, the delivery assist catheter was removed from the reperfusion catheter and suction applied to the reperfusion catheter for thrombus aspiration. Examples of the operative technique are shown in Fig. 2 (maneuver to pass the ophthalmic artery) and in Fig. 3 (advancing the coaxial system in a severely elongated cervical carotid artery).

Observation Endpoints

The primary observation endpoint of this analysis was the feasibility of placement of a reperfusion catheter at the proximal surface of the thrombus for thrombus aspiration. Secondary endpoints included periprocedural complications, reperfusion results, as per modified thrombolysis in cerebral infarction (TICI) and favorable early neurological recovery at discharge: modified Rankin scale ≤ 2 or National Institutes of Health Stroke Scale (NIHSS) = 0 or ΔNIHSS ≥ 10.

Ethical Approval and Statistical Analysis

According to the guidelines of the local ethics committees, no approval was necessary for this anonymous retrospective analysis, which was conducted in accordance with the Declaration of Helsinki. Data are shown as mean with standard deviation (SD) or median with interquartile range (IQR), as appropriate. All statistical analyses were performed using IBM SPSS Statistics 21.0.0.0 (Armonk, NY, USA).

Results

Overall 34 patients, male: $n = 14$ (41.2%), age mean (SD): 75 years (11 years) met the inclusion criteria for this retrospective analysis. Initial median NIHSS was 16 (interquartile range, IQR 12–21) and most often occlusions of the M1 segment of the middle cerebral artery, 22 out of 34 (64.7%), were treated. Further baseline clinical characteristics and radiological findings before mechanical thrombectomy are shown in Table 1.

In 30 out of 34 (88.2%) patients the primary endpoint could be reached and a total of 45 direct thrombus aspiration maneuvers were performed. In 4 out of 34 (11.7%) patients, however, the thrombus could not be reached by the reperfusion catheter and a stent-retriever was needed as the primary thrombectomy maneuver. Severe elongation and tortuosity of the arterial access route ($n = 3$, 8.8%) and a preceding non-occlusive arteriosclerotic stenosis ($n = 1$, 2.9%) were identified as the reason why the occlusion could not be reached with the aspiration catheter. In the three latter cases, the aspiration catheter was not long enough to reach the proximal surface of the clot. Stent-retriever maneuvers, either as primary thrombectomy maneuver or as additional maneuver after thromboaspiration, were performed in 21/34 (61.8%) patients. In 28/34 (82.3%) patients a good reperfu-

Table 2 Procedural aspects, interventional complications and early outcome parameters following mechanical thrombectomy

Procedural aspects		$n = 34$
Treatment under general anesthesia (%)		20 (58.8)
No. of direct aspiration maneuvers, median (IQR; min-max; mean)		1 (1–2, 0–4, 1)
Reperfusion result after aspiration maneuvers	mTICI 0–1 (%)	12 (40)[c]
	mTICI 2a (%)	4 (13.3)[c]
	mTICI 2b (%)	6 (20)[c]
	mTICI 3 (%)	8 (26.7)[c]
No. of stent-retriever maneuvers, median (IQR; min-max; mean)		1 (0–2, 0–4, 1)
Final reperfusion result	mTICI 0–1 (%)	3 (8.8)
	mTICI 2a (%)	3 (8.8)
	mTICI 2b (%)	12 (35.3)
	mTICI 3 (%)	16 (47.1)
Interventional complications		
Vasospasm (%)		0
Emboli into a new territory (%)		1 (2.9)
Dissection (%)		0
Vessel perforation (%)		1 (2.9)
Device-related complication (%)		0
Early outcome parameters		
Favorable early neurological recovery[a] (%)		11 (32.4)
In-house mortality (%)		6 (17.6)
Incidence of any kind of intracranial hemorrhages on follow-up NCCT (%)		13 (38.2)
Symptomatic intracranial hemorrhage (%)		3 (8.8)[b]

NCCT non-contrast-enhanced computed tomography, *mTICI* modified thrombolysis in cerebral infarction, *NIHSS* National Institutes of Health stroke scale, *ECASS* European Cooperative Acute Stroke study

[a]Improvement of stroke symptoms at hospital discharge: modified Rankin Scale (mRS) = 0–2 or ΔNIHSS $\geq$ 10 (SWIFT trial criteria [13]) or NIHSS = 0

[b]According to the ECASS III classification [14]

[c]Measure provided for patients for patients in whom aspiration thrombectomy was performed

sion result according to mTICI 2b-3 was achieved. In one case (2.9%) a microwire perforation of the callosomarginal artery occurred while the microwire was positioned in the anterior cerebral artery and the coaxial system was advanced. This caused an angiographically self-limiting, clinically silent subarachnoid hemorrhage. Furthermore, in one patient (2.9%) emboli into a new territory occurred. No complications, such as dissections, vasospasm or device-related complications were observed. Favorable early clinical outcome was observed in 11/34 (32.4%) patients and 3/34 (8.8%) patients experienced a symptomatic intracranial hemorrhage. Further information concerning early outcome parameters is listed in Table 2.

Discussion

This article presents the first in vivo experiences of the new device class delivery assist catheter used for assistance in placement of a large-bore reperfusion catheter for direct thromboaspiration in acute ischemic stroke. Primary local thromboaspiration is a safe and rapid technique to remove thrombi and recanalize vessels without the additional use of stent-retrievers [2]. Unfortunately, anatomic obstacles and tortuosity of the vascular access route can make it impossible to navigate a large-bore reperfusion catheter to the intracranial occlusion and imposes the risk of damaging the vasculature. Microcatheters can be used as an inner guiding sheath for a reperfusion catheter. This coaxial system, however, results in a shoulder between the inner and outer catheter, which still bears the risk of vessel wall damage, especially at the outer curvature of vessel.

In order to reduce the shoulder between inner and outer catheters, the so-called rocket technique was developed [5]. Takahira et al. [5] successfully used a compliant balloon microcatheter as inner catheter to aid a 5 F reperfusion catheter to reach an intracranial occlusion. This technique, however, has several limitations. First, by using a balloon catheter at the tip of the reperfusion catheter, the reperfusion catheter or the balloon catheter itself can be damaged. Second, due to the rigidity of the system, advancing an inflated balloon catheter might cause vasospasm. Third, this technique requires experience from the neurointerventionalist. Most importantly, secondary to the complex handling (i. e. prepa-

ration of a balloon catheter), this technique might increase the time from groin puncture to reperfusion.

In all cases included in this analysis, the combination of an AXS Catalyst 6 and an AXS Offset™ Delivery Assist Catheter was used. As an alternative to the delivery assist catheter, a regular microcatheter could have been used; however, according to calculations based on manufacturer specifications, the shoulder between the standard microcatheter (Rebar™ 18 microcatheter, ev3 Neurovascular, Irvine, CA, USA) and an AXS Catalyst 6 would be at least 0.755 mm, if the microcatheter would be advanced more than 3 cm from the catheter tip but could be 0.855 mm, if the microcatheter tip would only be advanced distally to the tip of the reperfusion catheter. By using the AXS Offset™, the shoulder would be at most 0.755 mm, if only the tip of the delivery assist catheter would be advanced; however, when the olive-shaped, broader part of the delivery assist catheter protrudes the tip of the reperfusion catheter, the shoulder is reduced to 0.365 mm. This represents a reduction of the shoulder by 51.7% compared to the minimum shoulder when a Rebar 18 microcatheter is used.

Compared to the rocket technique, a major advantage of the delivery assist catheter is that preparation and introduction is comparable to a normal microcatheter, i. e. there is no need for preparation of a balloon. In our experience, maneuvering of the delivery assist catheter in the neurovasculature appeared to be less rigid compared to a 2.1 F balloon-microcatheter.

With the use of the delivery assist catheter the thrombus side was accessible for placement of a large-bore reperfusion catheter in 30/34 (88.2%) cases for direct thromboaspiration. This is within the range of previous publications (80–91.8%; [3, 6]). In all patients where the reperfusion catheter could be placed at the occlusion side, thrombi could be captured by direct thrombus aspiration. Compared to the literature, however, there are some differences with respect to the reperfusion success of aspiration thrombectomy maneuvers. While successful recanalization rates after direct thromboaspiration only varied between 56 and 78% in previous publications [2, 3, 7, 8], aspiration alone was deemed sufficient in only 13/34 (38.2%) cases, meaning that the majority of patients in this cohort would have had to undergo additional thrombectomy maneuvers using a stent-retriever. This finding, however, is probably not linked to the performance of the aspiration catheter, which has been proven to be successful in direct thromboaspiration [9] or the performance of the delivery assist catheter. It is more likely to be influenced by many factors such as the histological composition of the thrombus [10], the duration of the occlusion, a possible underlying arteriosclerotic stenosis of the vessel and the neurointerventionalist's experience with direct thromboaspiration and the decision about how many aspiration attempts should be made before additional devices are used.

Using a delivery assist catheter as an aid in endovascular stroke treatment was not associated with an increased periprocedural risk in this case series. Although a vessel perforation with a microwire was experienced while it was used to guide the coaxial system towards the intracranial occlusion, this event could have happened with other microcatheters or a balloon catheter as well. Complications directly caused by the delivery assist catheter or other complications, such as dissections or vasospasm were not observed. The latter finding is of particular interest since vessel dissections secondary to the advancement of a large bore catheter for intracranial thromboaspiration or vasospasm are not uncommon (up to 2.6%) [2, 3, 11]. These observations could be due to the safety profile of the procedure or the device; however, it might be secondary to the limited number of patients within this analysis and needs to be further evaluated.

The AXS Offset™ device, as the first representative of the new device class delivery assist catheter, has several limitations. First of all, the thin, most distal part of the device is relatively long. This means that there is a 2 cm long section where there is a shoulder between the inner and outer catheters. This might become relevant, for example, in cases with proximal occlusions of the middle cerebral artery or a terminal internal carotid artery (ICA) occlusion. While trying to avoid penetration of the thrombus with the microwire or the delivery assist catheter in such cases, the broader part of the delivery assist catheter ends in the cavernous or paraophthalmic segment of the ICA and has therefore a limited guiding effect for the reperfusion catheter. Second, as per directions for use, the AXS Offset™ must not be used with stents, stent-retrievers, coils or other (liquid) embolic agents. Although it was not necessary to use a stent, coil or other embolic agent in this patient cohort, it was frequently necessary to perform stent-retriever maneuvers. In these cases, additional material (microcatheter) and a limited additional time was needed for preparation of the stent-retriever placement. These circumstances contribute to the ongoing discussion whether local thromboaspiration should be chosen as a first line thrombectomy attempt or if alternative techniques, such as the SAVE technique [12], should be favored instead.

Limitations to the analysis include the retrospective design and a certain degree of selection bias to the patient population since other patients were treated within the observation period in whom the delivery assist catheter was not (intended to be) used; however, all cases in which the delivery assist catheter was used in the centers during the observation period were included in this analysis. Since this article is focused on the technical procedure using a delivery assist catheter, a control group of patients in whom

a microcatheter was used as an alternative ascending aid for a large-bore catheter was omitted.

Conclusion

Delivery assist catheters are a possible alternative to overcome vessel tortuosity and anatomic obstacles, such as the origin of the ophthalmic artery, when large-bore reperfusion catheters are intended to be used for direct intracranial thromboaspiration in acute ischemic stroke. Compared to a standard microcatheter, delivery assist catheters have the advantage of reducing the shoulder between the large-bore catheter and therefore might be less traumatic. The latter, however, needs to be confirmed in a larger patient population.

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