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ORIGINAL ARTICLE

Stent Retriever Thrombectomy with Mindframe Capture LP in Isolated M2 Occlusions

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Abstract

Background and Purpose Mechanical thrombectomy is an effective recanalization technique in acute ischemic stroke patients with large vessel occlusions; however, it is unclear to what extent stent retriever thrombectomy may be applicable to occlusions of smaller peripheral cerebral vessels. The outcome of patients with isolated M2 occlusions treated with the Mindframe Capture low profile (LP) stent retriever was reviewed.

Material and Methods A retrospective review of prospectively collected data on all consecutive patients treated for isolated M2 occlusions between June 2013 and December 2017 using the Mindframe Capture LP was performed. Technical aspects of the recanalization procedure, recanalization rate, complication rate, and clinical outcome were analyzed.

Results Mechanical thrombectomy with the Mindframe Capture LP was performed in 38 patients (median age 79 years) with an isolated M2 occlusion. The median National Institutes of Health Stroke Scale (NIHSS) score on admission was 7.5 (interquartile range, IQR 5–12) and successful reperfusion modified Thrombolysis in Cerebral Infarction (mTICI 2b or 3) was achieved in 28 patients (74%). A compensated/adjusted modified Rankin Scale (mRS) 0–2 at 3 months was observed in 65% when taking pre-stroke disability into account. Symptomatic intracranial hemorrhage (sICH) occurred in 1 patient (2.6%). Asymptomatic intracranial hemorrhage (aICH) was noted in 8 patients (21%) and a small subarachnoid hemorrhage (SAH) in the immediate vicinity of the target vessel was apparent in 8 patients (21%).

Conclusion The Mindframe Capture LP is a technically effective thrombectomy device for the treatment of isolated M2 occlusions. The lower profile of the device is advantageous when targeting peripheral intracranial occlusions.

Keywords M2 occlusion · Acute ischemic stroke · Mechanical thrombectomy · Small intracranial vessel occlusion · Endovascular treatment

Introduction

A total of seven randomized controlled trials have shown a clear benefit of mechanical thrombectomy in patients suffering an acute ischemic stroke with a proximal intracranial artery occlusion [1–7]. While thrombectomy has become a mainstay in the treatment of large vessel occlusion and has been adopted in recent guidelines [8], its role in more peripheral occlusion sites remains unclear since affected patients have been excluded from randomized controlled trials; however, studies suggest that M2 occlusions may lead to significant morbidity and mortality [9]. A recently published meta-analysis and smaller trials suggested the potential benefit of endovascular treatment in patients with peripheral occlusions compared to intravenous thrombolysis with recombinant tissue plasminogen activator (IV rtPA) [10–12]. In general, distal thrombi are expected to cause smaller infarct volumes. Nevertheless, when impeding flow to eloquent areas they may cause significant clinical and functional impairment [13, 14]. The choice of the appropriate device is crucial when targeting peripheral vessels because the risk of peri-interventional complications may increase [15], which is associated with poorer clinical outcome. Complications include dissection, vessel perforation, vessel rupture or subarachnoid hemorrhage (SAH), and are

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mainly due to the smaller diameter and elongated course of the vessels. The Mindframe Capture low profile (LP) device (Medtronic, Minneapolis, MN, USA) is a small stent retriever designed specifically for use in more peripheral intracranial vessels.

The objective of this study was to retrospectively assess technical and clinical efficacy of the Mindframe Capture LP in all consecutive patients presenting with an isolated M2 occlusion.

Material and Methods

Patient Population

A retrospective review of prospectively collected data of all patients with acute ischemic stroke undergoing endovascular therapy at this institution between June 2013 and December 2017 was performed. Inclusion criteria were: (1) acute ischemic stroke with an isolated M2 occlusion seen on initial computed tomography (CT) or magnetic resonance imaging (MRI); (2) National Institutes of Health Stroke Scale (NIHSS) ≥4, except for isolated aphasia or hemianopia; (3) time from symptom onset to groin puncture <6h—if presentation occurred after this time window, a perfusion study demonstrating relevant cerebral blood flow to cerebral blood volume (CBF/CBV) mismatch indicating penumbra and salvageable tissue; (4) mechanical thrombectomy performed with the Mindframe Capture LP device. Exclusion criteria were: (1) multiple intracranial occlusions in different territories; (2) proximal large vessel occlusion (proximal internal carotis artery [ICA], carotid T or M1) with additional downstream M2 occlusion; (3) patients with periprocedural thromboembolic complications occurring during a distinct neurointervention, e. g. aneurysm coiling requiring mechanical thrombectomy. Cases were reviewed by two board-certified neuroradiologists (T.D and P.M). The M2 segment was defined as extending from the bifurcation/trifurcation of the middle cerebral artery (MCA) to the circular sulcus of the insula, where the artery makes a right angle.

The radiological examinations were retrieved from the Picture Archiving and Communication System (PACS, R11.4.1, 2009; Philips, Best, Netherlands; Sectra, Linkoping, Sweden). Clinical data on the selected patients were obtained from the Stroke Registry, which lists all patients admitted to this hospital with the diagnosis of stroke. The data registered included the NIHSS scores, time from symptom onset to admission, procedure time, occlusion site on initial imaging, additional intravenous rtPA, type of anesthesia, periprocedural complications, symptomatic intracerebral hemorrhage and modified Rankin Scale (mRS) at 3 months. The decision to perform endovascular procedures was made on an individual basis after consultation with the neurologist and the interventionalist. The study was performed in accordance with the applicable ethical guidelines and with the permission of the institutional review board.

Device and Endovascular Intervention

The Mindframe Capture LP is a laser-cut stent attached to a nitinol push-wire, intended for mechanical thrombectomy in patients with acute ischemic stroke, and has been approved by the Food and Drugs Administration (FDA). It is compatible with 0.010 inch and 0.014 inch (in) microcatheters and comes with a diameter of 3 mm and 4 mm, each available in lengths of 20 mm or 30 mm, and a resulting effective clot capture length of 15 mm and 23 mm, respectively (Fig. 1). According to the manufacturer its use is recommended in vessels with a diameter ranging from 2.0 mm to 3.5 mm. For visualization it has one radiopaque marker on the proximal and two markers on the distal end. During the endovascular procedure the device is positioned across the blood clot for immediate restoration of the blood flow and is later removed with the clot anchored within the stent struts.

Selective intra-arterial digital subtraction angiography (DSA) was performed on a biplane, high-resolution angiographic system (Axiom Artis zee, Siemens, Erlangen, Germany) using Iopamiro 300 (Iopamidol, Bracco, Switzerland) for vessel opacification. Depending on the clinical status of the patient, the intervention was performed with the patient under general anesthesia or conscious sedation. After puncture of the common femoral artery an 8 or 9-French (Fr) sheath (Terumo Medical, Tokyo, Japan) was inserted to secure the access. For angiography of the supra-aortic vessels a JB3 catheter (Cook Medical, Bloomington, IN, USA) was advanced over a 0.035 inch hydrophilic guide wire (Terumo). After verification of the occlusion site, a balloon-guiding catheter (Table 1) was advanced into the proximal ICA. The thrombus was crossed with the microwire and microcatheter (Table 1). The microwire was removed and the position of the microcatheter tip distal to the thrombus was confirmed with contrast. The Capture LP device was delivered through the microcatheter and fully deployed across the blood clot by completely withdrawing the microcatheter. If the vascular architecture of the patient was deemed suboptimal for balloon catheter placement, i. e. torturous anatomy of the ICA, and depending on operator choice a distal access catheter (DAC; 5MaxACE, Penumbra, Alameda, CA, USA; AXS Catalyst, Stryker, Kalamazoo, MI, USA; Sofia, Microvention, Aliso Viejo, CA, USA; $N = 29/38$, 76%) was advanced over the push-wire of the Capture device into the occluded vessel for distal aspiration during retrieval. The Capture device was slightly

Fig. 1 Close-up view of Mindframe Capture low profile (LP) attached to the nitinol push-wire; device diameter 4 mm and total stent length of 20 mm and 15 mm effective capture length

pulled back until partially resheathed within the distal tip of the DAC and both were then withdrawn together through the guiding catheter while maintaining constant suction by manual aspiration. Successful reperfusion was defined as a modified Thrombolysis in Cerebral Infarction (mTICI) score of 2b–3 on the last angiogram (illustrative case see Fig. 2 and 3).

Results

Mechanical thrombectomy of an isolated M2 occlusion using the Mindframe Capture LP device was performed in 38 patients with acute ischemic stroke (median age: 79 ± 17.3 years; 18 women; Table 1). A total of 36 patients presented with an isolated M2 occlusion on initial CT or MRI. An additional two patients with a M1 occlusion on initial imaging receiving IV rtPA showed distal migration of the thrombus to a M2 segment on first DSA and were also included. The median NIHSS score on admission was 7.5 (interquartile range, IQR 5–12). In total 19 (50%) patients underwent a bridging thrombolysis with intravenous rtPA prior to mechanical thrombectomy. The average diameter of the target vessel was 1.69 mm (range 1.3–2.5 mm). Mindframe Capture LP was used as the first line technique in 33 patients. In 3 patients, the Mindframe Capture LP was applied after failed superselective intra-arterial thrombolysis with urokinase (500,000 U). Urokinase has been the drug of first choice for intra-arterial thrombolysis at this institution for 20 years and several publications have shown that its application yields comparatively high recanalization rates with low rate of intracranial hemorrhage (<5%) [16–20]. In 1 patient each, the Mindframe Capture was used as second-line regimen after failed primary thrombectomy with a Solitaire 4/20 (Covidien/ev3, Irvine, CA) or after a failed first pass aspiration technique (ADAPT) attempt. Overall, successful reperfusion (mTICI 2b–3) was achieved in 28 patients (74%). A DAC was used for additional distal aspiration during retrieval of the Capture LP device in 29 patients (76%) with similar rates of good reperfusion with and without DAC (78% vs. 72%). In 3 patients with residual peripheral clot fragments in M4/5 branches in the downstream territory after thrombectomy, intra-arterial thrombolysis with urokinase (250,000 U) was performed without immediate blood flow restoration on the last angiographic run. No iatrogenic embolization into a previously unaffected territory occurred. Rupture of an M2 branch occurred during retrieval of the Capture LP device in 1 patient and was successfully coiled. Extracranial complication during access occurred in 2 patients in whom an ICA dissection not requiring further treatment was reported. Emergency ICA stenting in the acute setting was performed in two patients due to high grade symptomatic stenosis at the origin. The mean time interval from symptom onset to admission was 164 ± 150 min and the mean procedure duration was 62 ± 33 min.

Intracranial hemorrhage (ICH) was classified according to the European-Australasian Acute Stroke Study (ECASS II) classification [21]. Symptomatic intracranial hemorrhage (sICH), defined as parenchymal hematoma causing mass effect with clinical deterioration (increase in NIHSS score ≥4), occurred in 1 (2.6%) patient. Asymptomatic ICH (aSIH) was observed in 8 patients (21%); hemorrhagic infarction (HI) type 1 and type 2 in 4 and 3 patients, respectively, and parenchymal hematoma (PH) type I in 1 patient. Small SAH visible on gradient echo (GE) MRI in the immediate vicinity of the target vessel was apparent in 8 patients (21%). Of the patients two were lost to follow-up. Overall, good clinical outcome (mRS 0–2) was observed in 19 patients (53%); however, if the functional dependency before the event was taken into consideration (prestroke mRS >2: mRS 3 in 2, mRS 4 in 7 patients) a compensated/adjusted mRS 0–2 was observed in 70% of patients. There was no significant difference in the rate of good clinical outcome (39% and 67%, $P = 0.181$) or aSIH (35% vs. 50%. $P = 0.512$) in patients with and without thrombolysis. Of the patients 6 died within the 3-month follow-up period, 1 patient due to sICH, the remaining

Table 1 Baseline characteristics of patients undergoing thrombectomy with the Mindframe Capture LP device for an isolated M2 occlusion

Characteristics	Patients with isolated peripheral M2 occlusion (*n* = 38)
Age (years, median, IQR)	79 (63–84)
Sex, female	18 (47%)
Admission NIHSS (median, IQR)	7.5 (5–12)
ASPECT (median, IQR)	8 (7–9)
IV rtPA	19 (50%)
Guiding catheter	8-Fr guider (*n* = 21) (55%)
	8-Fr/9-Fr Merci BGC (*n* = 14 or 3) (45%)
Distal access catheter (DAC)	*n* = 29 (76%)
Microcatheter	SL-10/Echelon 10 (*n* = 12)
	Prowler Select (*n* = 24)
	Headway 17 (*n* = 2)
Good reperfusion (mTICI 2b–3)	28 (74%)
Symptom onset to admission (mean ± SD)	164 ± 150 min
Procedure time	62 ± 33 min
Anesthesia:	
(A) conscious sedation	(A) *n* = 19
(B) general anesthesia	(B) *n* = 19
Periprocedural complications	1 (2.6%) M2 branch rupture
Asymptomatic intracranial hemorrhage	*8 (21%)*
	HI1 (*n* = 4)
	HI2 (*n* = 3)
	PH1 (*n* = 1)
Subarachnoid hemorrhage	8 (21%)
Symptomatic intracranial hemorrhage	1 (2.6%) with PH 2
Mortality	6/33 (18%)
mRS (0–2) at 3 months	
Overall	18/33 (55%)
Adjusted (considering pre-stroke disability)	18/26 (69%)

IQR interquartile range, *SD* standard deviation, *HI* hemorrhagic infarction defined as non-space-occupying petechial bleeding in punctuate (type I) or confluent (type II) configuration, *PH* parenchymal hematoma with mass effect occupying <30% (type I) and >30% (type II) of the infarct zone, *BGC* balloon guiding catheter, *NIHSS* National Institutes of Health Stroke Scale, *ASPECT* Alberta stroke program early CT score, *IV rtPA* intra-venous recombinant tissue plasminogen activator, *mTICI* modified Thrombolysis in Cerebral Infarction, *mRS* modified Rankin Scale

patients as a result of cardiopulmonary comorbidities in the subacute postischemic period within a few days after the stroke.

Discussion

The experience gained at this single center suggested that the Mindframe Capture LP device is effective for thrombectomy in M2 occlusions. The device may be deployed through a microcatheter as small as 0.010 inch, which allows better navigability in vessels with tortuous anatomy and small caliber. In contrast, the most widely used stent retriever (SR) devices, such as Solitaire (Covidien/ev3) or Trevo XP Retriever (Stryker Neurovascular, Mountain View, CA, USA) have diameters of 6 mm and 4 mm, respectively, and require microcatheters with an inner diameter ranging from 0.018 inch to 0.027 inch, which may be a drawback when trying to navigate peripheral territories. The diameter of the MCA, superior, and inferior trunk averaged 2.41 ± 0.82 mm, 1.71 ± 0.73 mm and 1.60 ± 0.58 mm, respectively [22]. Considering the decreasing diameter and thinner vessel walls, when targeting more peripheral segments gentle manipulation is essential to prevent vessel perforation. Furthermore, the more elongated course of the peripheral vessels might increase the mechanical force applied during thrombectomy.

The overall number of adverse events in this study was low, with a single occurrence of vessel rupture in the setting of a calcified thrombus, which in general have low recanalization rates [23]. A Capture Mindframe LP 3 × 15 mm was deployed across the clot, which was localized in a proximal

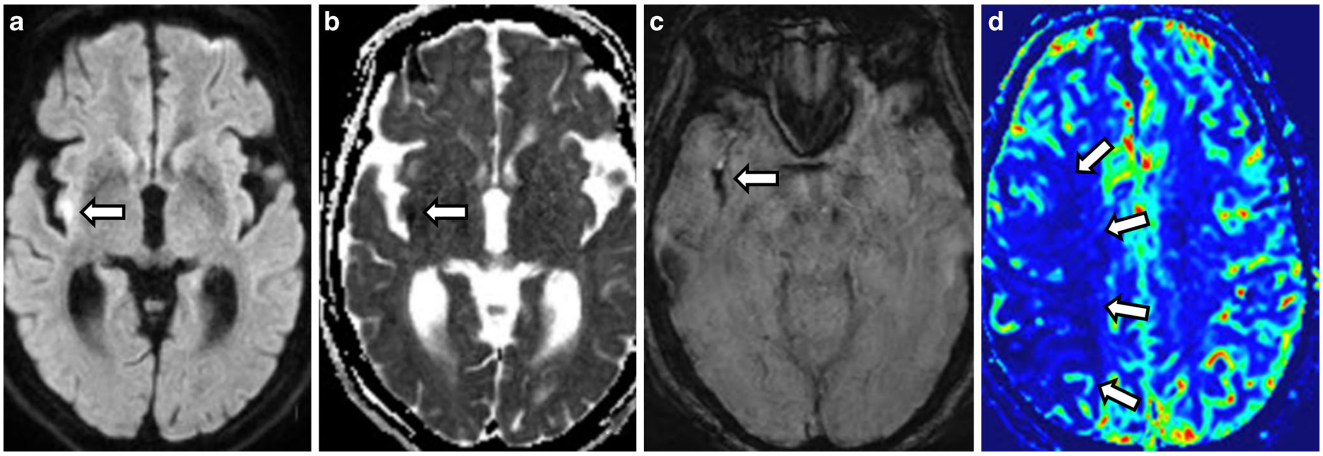

Fig. 2 Magnetic resonance imaging (MRI) study showing representative images in the axial plane in a 77-year-old patient presenting with left-sided hemiparesis (National Institutes of Health Stroke Scale of 5 on admission). **a** Diffusion weighted imaging (DWI), b-1000 showing a small hyperintense area in the insular region on the right (*arrow*) with corresponding signal loss in the **b** apparent diffusion coefficient (ADC) map. **c** Susceptibility weighted imaging (SWI) shows a susceptibility artifact from thrombotic material in the inferior trunk of the MCA. **d** Perfusion study showing a large area with reduced cerebral blood flow (CBF) in the posterior part of the middle cerebral artery (MCA) territory. Due to the large perfusion-diffusion mismatch, the patient was transferred to the angio suite for mechanical thrombectomy (see Fig. 3)

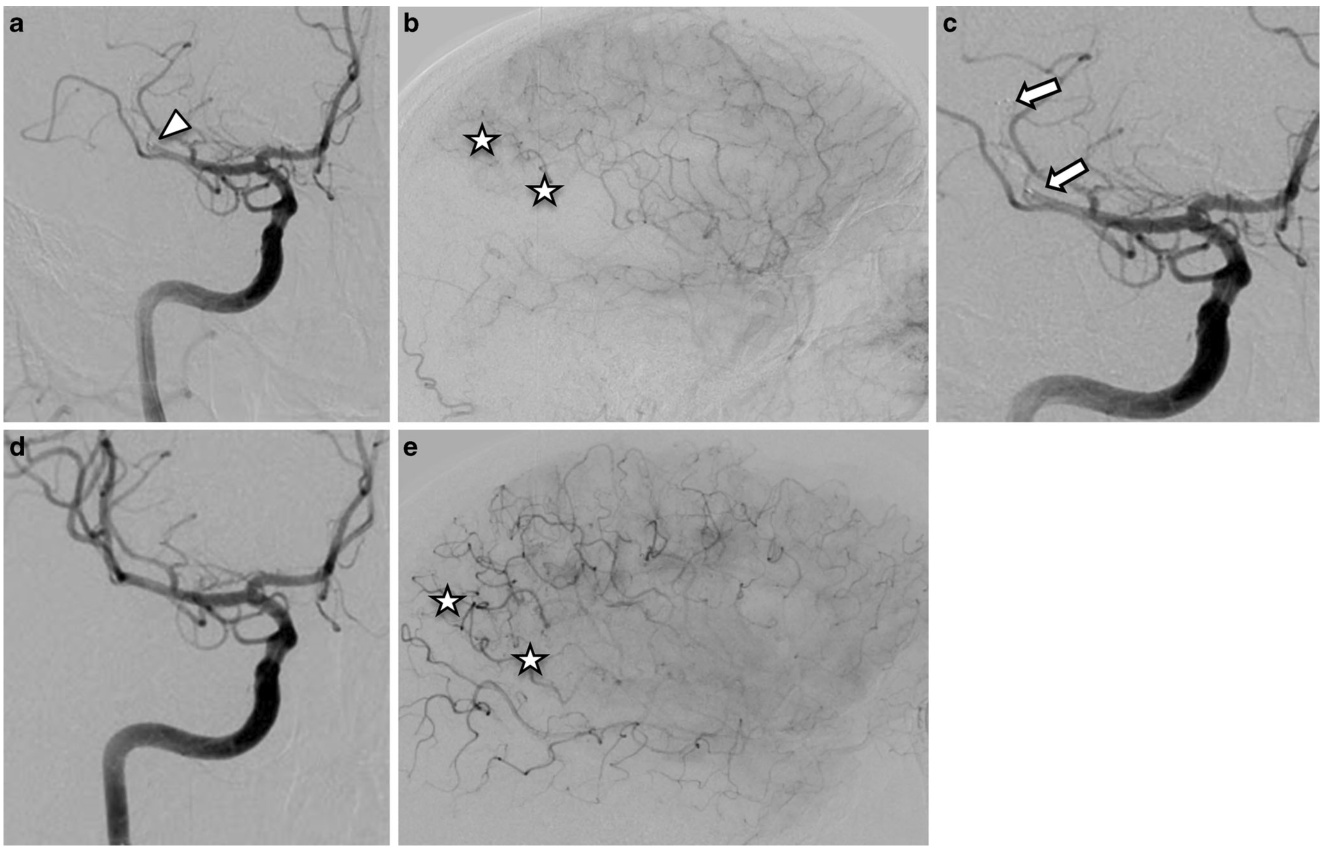

Fig. 3 Same patient as in Fig. 1. Baseline digital subtraction angiography (DSA) images in the posterior anterior (PA) projection in the early arterial phase **a** showing occlusion of the inferior trunk of the right middle cerebral artery (MCA) (*arrow head*) with a large perfusion deficit in the post-central region on the lateral projection (*asterisk*) in the capillary phase (**b**). **c** Deployed Mindframe Capture LP device in the inferior trunk—arrows indicating the proximal and distal markers. Control DSA after thrombectomy in the PA projection in the arterial phase (**d**) and lateral projection in the capillary phase (**e**) showing restoration of blood flow in the previously occluded M2 segment with normal parenchymal blush in the post-central region (*asterisk*) modified Thrombolysis in Cerebral Infarction (mTICI 3)

M2 branch. During device recovery, sudden loss of resistance occurred and a control run demonstrated active contrast extravasation from a distal M2 branch which was immediately occluded with two coils. The postinterventional CT scan demonstrated extensive SAH and contrast in the Sylvian fissure, and the patient died a few days later due to cardiac decompensation. As shown previously, calcified thrombi seem to pose higher resistance to the thrombectomy device and are associated with low reperfusion rates and high morbidity [23].

Patients with peripheral occlusions have been excluded from large randomized controlled trials; however, subgroup analyses and smaller trials suggest benefits of mechanical thrombectomy. In a recent meta-analysis on mechanical thrombectomy of M2 occlusions including 630 patients, good reperfusion (mTICI 2b–3) was achieved in 78% of the patients, a good outcome at 3-month follow-up was reported in 62% [24]. In a multicenter retrospective cohort study including 522 patients, of whom 288 received endovascular treatment (EVT), the rate of good outcomes was higher for patients who underwent EVT (62.8%) than for those who received medical management (35.4%).[12] Several recently published retrospective studies have shown good results using a stent retriever specifically designed for peripheral occlusions. Haussen et al. reported good reperfusion (mTICI 2b–3) in 6 patients (75%) after thrombectomy of distal intracranial occlusions using the Trevo XP ProVue Retriever 3 × 20 mm (Baby Trevo) [25]. Cerejo et al. reported on 9 patients treated with the Capture Mindframe LP, 8 of whom achieved mTICI 2b–3 (89%) [26]. Dorn et al. noted good reperfusion in 14 of 15 patients (93.3%) after mechanical thrombectomy in isolated M2 occlusions treated with Solitaire FR 4 × 20 mm, with 60% achieving functional independence (mRS 0–2) at 90 days [27]. Hofmeister et al. [28] reported good reperfusion in 32 out of 41 patients (78%) treated with Catch mini (Balt Extrusion, Montmorency, France). Bhogal et al. reported good outcome at 90d (mRS 0–2) in 54.6% of 106 patients undergoing mechanical thrombectomy mostly with the pREset stent (Phenox, Bochum, Germany) [29, 30].

The number of sICH observed in this study is in line with the figures published in the literature. Symptomatic ICH was reported in 5% of patients in the meta-analysis by Chen et al. [24] and in the multicenter study by Sarraj et al., respectively [12]. The rate of aICH in this study population is higher than reported by Chen et al. (10%) or by Sarraj et al. (5.2%). It is assumed that the routine workflow, which includes postinterventional MRI after 24 h with highly sensitive gradient echo images, leads to a higher detection rate, even of small amounts of blood products. A similar number of SAH was reported on follow-up CT scans by Yoon et al. (12/74; 16%) [31].

It is assumed that SAH and small PH are triggered by angiographically occult bleeding caused by injury of small perforating arteries arising in the vicinity of the occluded vessel segment. The perforators are exposed to excessive forces during thrombectomy due to stretching and may be sheared off leading to extravasation. The relatively high radial force of the Capture device may explain its propensity to produce SAH as it has a tendency to straighten the physiological loops of the peripheral cortical branches. Other devices with less radial force, such as the Catch mini or the ERIC (Microvention, Tustin, CA, USA) may be interesting alternative options [28, 32]. Due to the small size the bleeding remains angiographically occult but may be detected with highly sensitive gradient echo MRI. This underlying mechanism was previously described by Yoon et al. [31] The more peripheral vessels with smaller calibers are likely to be more fragile and susceptible to the tensile forces applied. Other mechanisms that may cause PH due to disruption of the blood–brain barrier include contrast neurotoxicity, exogenous plasminogen activators and reperfusion injury after successful thrombectomy.

Complete reperfusion mTICI3 has been associated with higher rates of good clinical outcome as compared to mTICI 2b [33, 34]. Thus in thrombectomy of large vessel occlusions with residual peripheral emboli in the M2 segment the Mindframe Capture LP may be a device to keep in mind when addressing residual peripheral emboli.

It is acknowledge that these results were derived retrospectively and from a single center and therefore have limitations inherent to this study type, especially the lack of a control group, and the relatively small number of patients.

Conclusion

The Mindframe Capture LP is an effective device for thrombectomy in small caliber intracranial vessels of the anterior circulation, including the M2 segment. The lower profile of the device and its delivery microcatheter provide better navigability and may thus be advantageous when targeting peripheral intracranial occlusions.

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