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Case report

Aspiration thrombectomy with off-label distal access catheters in the distal intracranial vasculature

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ABSTRACT

Background: As neurointerventionalists aim to treat occlusions in the ever more distal vasculature, off-label catheters (OLCs) have been adapted for aspiration thrombectomy. This may not be without its attendant risks. Recently issued, a letter from the FDA cautioned providers against using OLCs as substitutes for FDA-cleared aspiration thrombectomy catheters, especially in the distal vasculature. In light of this, we evaluated the efficacy and safety of OLCs used for aspiration thrombectomy in the distal vasculature at our institution.

Methods: We retrospectively queried all patients who underwent thrombectomy at our institution between January 1, 2016 and March 1, 2017. Patients were screened for: (1) occlusion location in the distal vasculature (M2 or more distal) and (2) direct thrombus aspiration attempt with an OLC. Demographic, clinical, and procedural data were recorded.

Results: Eight patients were included for analysis (Table 1). The median admission NIHSS was 17 (IQR 13–23.3). Occlusion locations included left M2 (6/8), right M2 (1/8), and left M3 (1/8). The OLCs employed included the Stryker Catalyst 6 (5/8), Penumbra Velocity (2/8), and the MicroVention Sofia Plus (1/8). Direct thrombus aspiration was successful in 50% (4/8) of cases, though final TICI 2b-3 was achieved in all patients. There were no instances of symptomatic intracranial hemorrhage. Median NIHSS at discharge was 5 (IQR 0.8, 15).

Conclusions: Aspiration thrombectomy with OLCs may be safe and effective in the distal vasculature. In light of the recent FDA warning regarding their use, further evaluation of OLCs in this capacity is warranted.

1. Introduction

Although large vessel occlusions of the distal vasculature are expected to involve a smaller vascular territory, the location of the infarction can cause significant morbidity and mortality [1]. Thrombolysis with intravenous tissue plasminogen activator (IV-tPA) is frequently ineffective, with recanalization rates of M2 occlusions reported at approximately 30%, and, as a result, endovascular intervention if often warranted [2]. Current guidelines recommend treating M2 occlusions with mechanical thrombectomy based on data from the STAR, SWIFT, and SWIFT PRIME studies [3,4]. Both stent retriever thrombectomy and manual aspiration thrombectomy have demonstrated effectiveness in the distal vasculature [4–8]. However, aspiration thrombectomy is of particular interest in these smaller vessels, as it may be associated with a lower rate of distal embolization and reduced vessel wall injury compared with stent retrievers [9–12].

As a result, neuroendovascular device manufacturers have continually developed improved catheter technologies to perform the procedure, including aspiration thrombectomy catheters (ATC), distal access catheters, and microcatheters. These newer-generation devices, with superior trackability and safety profiles compared with previous generations, have allowed operators to

Abbreviations: ATC, aspiration thrombectomy catheter; CT, computed tomography; CTA, computed tomography angiography; OLC, off-label catheter; FDA, Food and Drug Administration; IV-tPA, intravenous tissue plasminogen activator; NIHSS, National Institutes of Health Stroke Scale; TICI, thrombolysis in cerebral infarction.

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treat occlusions more safely and effectively. The superior technology has also allowed operators to reach distal occlusions untreatable with previous technology.

As neurointerventionalists aim to treat occlusions in vessels of smaller caliber and more distal location, they have turned to catheters with smaller diameters and improved trackability, including distal access catheters and microcatheters, to perform aspiration thrombectomy. Importantly, however, this adaptation of these catheters for aspiration thrombectomy is an off-label use. Unlike ATCs, which are FDA-cleared for aspiration thrombectomy, distal access catheters and microcatheters are only FDA-cleared for accessing the intracranial vasculature, and their adaptation to aspiration thrombectomy may not be without its attendant risks. These risks were recently emphasized in a letter to health care providers from the FDA cautioning operators that use of OLCs for direct aspiration thrombectomy may be associated with serious complications, especially in the distal vasculature [13]. They note that the design differences between OLCs and ATCs may lead them to perform differently and, thus, possess unique risk and safety profiles. In considering this FDA warning, we chose to retrospectively evaluate the performance and safety of OLCs for aspiration thrombectomy at our institution.

2. Methods

Institutional review board approval was obtained for this retrospective review. All patients with acute ischemic stroke who underwent mechanical thrombectomy between January 1, 2016 and March 1, 2017 were screened for inclusion from a prospectively acquired database. Only patients who had direct aspiration performed with an off-label distal access catheter in the distal vasculature (M2 or more distal) were included for analysis. The OLCs used at our institution included the Catalyst 6 distal access catheter (Stryker Neurovascular, Freemont, CA, USA), Sofia Plus distal access catheter (MicroVention, Tustin, CA, USA), and Velocity microcatheter (Penumbra, Alameda, CA, USA). Demographic data, occlusion location, catheter type, thrombectomy procedure details, postoperative complications, admission/discharge NIHSS scores, and final TICI revascularizations scores were collected from the medical record. A successful revascularization attempt was defined as an improvement in TICI score as a result of the aspiration pass. Symptomatic intracerebral hemorrhage (sICH) was defined as a grade 2 parenchymal hematoma associated with neurologic deterioration ($\geq$4 point increase in NIHSS score).

3. Results

A total of 110 patients had thrombectomy within the study timeframe. Of these, 35 had occlusions located in the distal vasculature (M2 or more distal). Eight of these patients had aspiration thrombectomy performed with an OLC and, thus, met the inclusion criteria for the study (Table 1). The median age of the cohort was 71.5 years (IQR 60.8, 79.5), 6 (75%) were female, and median 123 admission NIHSS was 17 (IQR 13–23.3). There were 6 patients (75%) with left M2 occlusions, 1 (12.5%) with a right M2 occlusion, and 1 (12.5%) with a left M3 occlusion. The majority, 62.5% (5/8), were primary lesions, while the remaining 3 were distal embolizations that had occurred during a thrombectomy procedure. The Catalyst 6 (Stryker) was used in 5 cases, the Velocity (Penumbra) in 2 cases, and the Sofia Plus (MicroVention) in 1 case. Direct aspiration with these devices was successful in 50% (4/8) cases. All patients had a final reperfusion of TICI 2b-3. There were no instances of device complications during the direct aspiration attempt with any of these devices. No patients developed symptomatic intracranial hemorrhage (sICH), though a small intraparenchymal bleed was noted on routine postoperative imaging in one patient, who remained asymptomatic. All 8 patients had some degree of neurologic improvement and median NIHSS at discharge was 5 (IQR 0.8, 15).

4. Case illustrations

4.1. Patient 1

The patient is an 84-year-old female with a past medical history of paroxysmal atrial fibrillation off anticoagulation who was brought to the ED 4.5 h after the onset of difficulty speaking. On examination, she was found to be lethargic and not following commands (NIHSS 16). A CT head demonstrated subtle evidence of left frontal acute ischemic stroke (ASPECTS 9). Given symptom onset greater than 4.5 h, tPA was not administered. A CTA of the head and neck was performed, demonstrating a left M2 occlusion (Fig. 1). Given her examination, favorable ASPECTS, and left M2 occlusion on CTA, she was brought for mechanical thrombectomy.

Angiography demonstrated a left superior division M2 occlusion (Fig. 2A & B). Given this location, the Catalyst 6 distal access catheter was chosen for aspiration thrombectomy. The Catalyst 6 tracked smoothly over a microguidewire to the proximal interface of the thrombus (Fig. 3). Suction was activated through the Catalyst 6 and the thrombus aspirated directly into the catheter. Subsequent angiography demonstrated full reperfusion (Fig. 2C & D). The patient was discharged home from the hospital on postprocedure day 3 with a NIHSS of 1.

4.2. Patient 3

The patient is an 86-year-old female with a past medical history of atrial fibrillation and prior left frontotemporal infarct who presented to the ED after collapsing on the floor of her apartment with altered mental status and right sided weakness. Upon arrival to the ED, her exam included right-sided hemiparesis, left gaze deviation, and altered mental status amounting to an NIHSS of 24. CT head demonstrated left frontotemporal encephalomalacia and

Table 1
Patient and Treatment Characteristics.

Patient	Admission NIHSS	Occlusion location	Primary or distal Embolus	Catheter type used	Successful aspiration attempt	Final TICI score	NIHSS discharge	Device complication	Postoperative sICH	Postoperative aICH
1	16	LM2	Primary	Stryker catalyst 6	Yes	3	1	No	No	No
2	18	LM2	Distal embolization	Microvention Sofia Plus	Yes	2C	2	No	No	No
3	24	LM2	Primary	Stryker catalyst 6	Yes	3	14	No	No	No
4	23	LM2	Primary	Stryker catalyst 6	No	2B	18	No	No	No
5	9	LM3	Primary	Penumbra velocity	No	3	0	No	No	No
6	14	LM2	Distal embolization	Stryker catalyst 6	No	2B	8	No	No	No
7	10	RM2	Primary	Penumbra velocity	No	3	0	No	No	No
8	25	LM2	Distal embolization	Stryker catalyst 6	Yes	2B	22	No	No	Yes

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