

Aspiration Thrombectomy with Off-Label Distal Access Catheters in the Distal Intracranial Vasculature

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Introduction

As occlusions in the distal cerebral vasculature are increasingly targeted for removal, distal access catheters (DACs) have been adapted for off-label aspiration thrombectomy. Although of potential utility in this area of the vasculature, DACs may carry additional risks. The FDA recently published a letter to providers that urges caution when using DACs for aspiration thrombectomy, emphasizing that DACs are distinct from aspiration thrombectomy catheters (ATCs), which are FDA cleared for this purpose. They made particular mention that the risks of off-label aspiration thrombectomy with DACs may be accentuated in the distal vasculature. In light of this, we evaluated the efficacy and safety of distal access catheters used for aspiration thrombectomy in the distal vasculature at our institution.

Methods

Using a prospectively acquired and maintained database all patients who underwent thrombectomy at our medical center between January 1, 2014 and March 1, 2017 were retrospectively screened for inclusion in the study. Patients were screened for: 1) occlusion location in the distal vasculature (M2 or more distal) and 2) direct thrombus aspiration attempt with a distal access catheter. Data including occlusion location, catheter type, postoperative complications, admission/discharge NIHSS scores, and final TICI revascularizations scores were recorded.

Patient	Age	Sex	Admission NIHSS	Occlusion Location	Primary or Distal Embolus	Catheter Type Used	Successful Aspiration Attempt	Final TICI Score	NIHSS Discharge	Device Complication	Postoperative aTCH	Postoperative sTCH
1	84	F	16	LM2	Primary	Stryker Catalyst 6	Yes	3	1	No	No	No
2	54	M	18	LM2	Distal Embolization	Microvention Sofia Plus	Yes	2C	2	No	No	No
3	86	F	24	LM2	Primary	Stryker Catalyst 6	Yes	3	14	No	No	No
4	72	F	23	LM2	Primary	Stryker Catalyst 6	No	2B	18	No	No	No
5	63	M	9	LM3	Primary	Penumbra Velocity	No	3	0	No	No	No
6	47	F	14	LM2	Distal Embolization	Stryker Catalyst 6	No	2B	8	No	No	No
7	71	F	10	RM2	Primary	Penumbra Velocity	No	3	0	No	No	No
8	78	F	25	LM2	Distal Embolization	Stryker Catalyst 6	Yes	2B	22	No	No	Yes

Results

The analysis included 8 patients. 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 distal access catheters employed included the Stryker Catalyst 6 (5/8), Penumbra Velocity (2/8), and the Sofia Plus (1/8). Direct thrombus aspiration was successful in 50% (4/8) 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 off-label distal access catheters may be safe and effective in the distal vasculature. In light of the recent FDA warning regarding off-label use, further evaluation of distal access catheters in this capacity is warranted.

First Author	Year	N	NIHSS Admission (IQR or SD)	Catheter Type	Additional Treatment Method	Aspiration Success Rate	Final TICI 2B/3 Rate	NIHSS Discharge (IQR or SD)	Postoperative sTCH	Postoperative aTCH	Other Complications
Park	2016	32	10.9 (5.1)	Penumbra 4MAX	N/A	27/32 (84%)	27/32 (84%)	4.3 (4.0)	0/32 (0%)	3/32 (9%)	0/32 (0%)
Vargas	2016	35	14.1 (6.9)	Penumbra 3MAX, 4MAX, 5MAX, 5MAX ACE	7/35 (20%)	26/35 (77%)	34/35 (97%)	NR	1/35 (3%)	0/35 (0%)	1/35 (3%) (Dissection of ICA)
Kim	2016	25	15 (8-17)	Penumbra 041 or 4MAX	5/25 (20%)	16/25 (64%)	18/25 (72%)	2 (1-6)	1/25 (4%)	3/25 (12%)	3/25 (12%) (Distal Embolization)

Catheter	Type	Distal Inner Diameter, Inches (mm)	Distal Outer Diameter, French (mm)	Working Length (cm)	Additional Characteristics
Penumbra ACE68	ATC	0.068 (1.73)	6 (2)	132	- coil winding geometry - flexible distal shaft - 16 transition zones - atraumatic tip - beveled tip - compatible with the Penumbra System for aspiration
Penumbra ACE64	ATC	0.064 (1.63)	5.75 (1.92)	132	- 14 transition zones - nitinol reinforced distal lumen - compatible with the Penumbra System for aspiration
Penumbra ACE60	ATC	0.06 (1.52)	5.4 (1.8)	132	- 12 transition zones - nitinol reinforced distal lumen - compatible with the Penumbra System for aspiration
Penumbra 5MAX	ATC	0.054 (1.37)	5.0 (1.67)	132	- tracking technology permits access over microguidewire only - compatible with the Penumbra System for aspiration
Penumbra 4MAX	ATC	0.041 (1.04)	4.3 (1.43)	139	- tracking technology permits access over microguidewire only - compatible with the Penumbra System for aspiration
Penumbra 3MAX	ATC	0.035 (0.89)	3.8 (1.27)	153	- tracking technology permits access over microguidewire only - compatible with the Penumbra System for aspiration
Stryker Catalyst 6	DAC	0.06 (1.52)	5.4 (1.8)	132	- atraumatic tip - kink-resistant nitinol-reinforced shaft - 15 transition zones - supportive stainless steel reinforced proximal shaft - 14cm flexible distal zone
MicroVention Sofia Plus	DAC	0.07 (1.78)	6.3 (2.1)	125/131	- hybrid braid and coil design - soft distal tip - steam shapable tip
Penumbra Velocity	DAC	0.025 (0.64)	2.6 (0.87)	160	- compatible with the Penumbra ACE catheter family, 5MAX, and 4MAX - compatible with the Penumbra System for aspiration

Learning Objectives

By the conclusion of this session, participants should be able to 1) identify the differences between an aspiration thrombectomy catheter and a distal access catheter, 2) understand the FDA safety concerns of using DACs for aspiration thrombectomy, especially in the distal vasculature, and 3) recognize that DACs may, in fact, be safe for this aspiration thrombectomy.