Safety and Efficacy of the Sofia (6F) PLUS Distal Access Reperfusion Catheter in the Endovascular Treatment of Acute Ischemic Stroke

Hussain Shallwani, MD[*¶]
Hakeem J. Shakir, MD[*¶]
Leonardo Rangel-Castilla, MD[*¶]
Jason M. Davies, MD, PhD[*¶‡‡]
Ashish Sonig, MD, MS, MCh[*¶]
Mithun G. Sattur, MD[‖]
Bernard R. Bendok, MD[‖]
Kenneth V. Snyder, MD, PhD[*§¶‖]
Adnan H. Siddiqui, MD, PhD[*‡¶#**]
Elad I. Levy, MD, MBA[*‡¶#]

[*]Department of Neurosurgery, Jacobs School of Medicine and Biomedical Sciences, University at Buffalo, State University of New York, Buffalo, New York; [‡]Department of Radiology, Jacobs School of Medicine and Biomedical Sciences, University at Buffalo, State University of New York, Buffalo, New York; [§]Department of Neurology, Jacobs School of Medicine and Biomedical Sciences, University at Buffalo, State University of New York, Buffalo, New York; [¶]Department of Neurosurgery, Gates Vascular Institute at Kaleida Health, Buffalo, New York; [‖]Department of Neurosurgery, Mayo Clinic Arizona, Scottsdale, Arizona; [#]Toshiba Stroke and Vascular Research Center, University at Buffalo, State University of New York, Buffalo, New York; [**]Jacobs Institute, Buffalo, New York; [‡‡]Department of Bioinformatics, Jacobs School of Medicine and Biomedical Sciences, University at Buffalo, State University of New York AND Jacobs Institute

Correspondence:
Elad I. Levy, MD, MBA,
University at Buffalo Neurosurgery,
100 High Street, Suite B4,
Buffalo, NY 14203
Email: elevy@ubns.com

Received, April 29, 2016.
Accepted, March 10, 2017.
Published Online, April 19, 2017.

BACKGROUND: Neuroendovascular intervention has become a key treatment option for acute ischemic stroke. The Sofia (6F) PLUS catheter was designed for neurovascular access for diagnostic or therapeutic interventions.

OBJECTIVE: To report the first series describing use of the Sofia PLUS intermediate/distal access reperfusion catheter in the treatment of acute ischemic stroke.

METHODS: In this retrospective study, 41 stroke cases were identified in which the catheter was utilized for thrombolysis/thrombectomy. Mean preprocedure National Institutes of Health Stroke Scale score was 16.5 ± 5.2 (range 4-29). Occluded vessels included the M1 segment, M2 segment, internal carotid artery terminus, cervical internal carotid artery, and basilar artery.

RESULTS: Successful positioning of the Sofia PLUS catheter near the occlusion site was achieved in 38 (92.7%) of 41 cases in which thrombectomy or thrombolysis was attempted using intraarterial tissue plasminogen activator, a direct aspiration first-pass technique, and/or stent retrieval. A postprocedure thrombolysis in cerebral infarction (TICI) score of 2b/3 was achieved in 37 of 41 cases. Of 15 cases where the Sofia PLUS was used for a direct aspiration first-pass technique, TICI 2b/3 was achieved in 11 (73.3%). In one case where intra-arterial tissue plasminogen activator was used as the only treatment modality, TICI 2a was achieved. No device-related or catheter-related complications were observed. The mean 7-d-postprocedure National Institutes of Health Stroke Scale score among the 39 survivors was 8.5 ± 7.3 (range 0-23).

CONCLUSION: Initial results with use of the Sofia (6F) PLUS for endovascular treatment of acute ischemic stroke have been encouraging. Experience with a larger series is warranted to further evaluate the safety and efficacy of this device and compare it with other reperfusion catheters.

KEY WORDS: Distal access catheter, Neuroendovascular, Sofia PLUS, Stroke

Neurosurgery 82:312–321, 2018 DOI:10.1093/neuros/nyx169 www.neurosurgery-online.com

Recent randomized controlled trials have shown significant improvement of patient outcomes when endovascular therapy and mechanical thrombectomy are used for the treatment of acute ischemic stroke.[1-6] It is no surprise then that the 2015 Focused Update of the 2013 American Heart Association/American Stroke Association Guideline for Early Management of Patients with Acute Ischemic Stroke recommends endovascular treatment with a stent retriever for patients who meet the relevant criteria.[5]

Novel tools are being rapidly developed, enabling interventionists to supplant traditional ways and apply newer technologies for better access to acutely occluded intracranial vessels. However, with respect to intermediate/distal

ABBREVIATIONS: ADAPT, a direct aspiration first-pass technique; **DSA,** digital subtraction angiography; **F,** French; **IA,** intraarterial; **ICA,** internal carotid artery; **MCA,** middle cerebral artery; **NIHSS,** National Institutes of Health Stroke Scale; **PCoA,** posterior communicating artery; **Sofia,** Soft torquable catheter Optimized For Intracranial Access; **TICI,** thrombolysis in cerebral infarction; **tPA,** tissue plasminogen activator

access and suction catheters used during acute stroke interventions, navigability of tortuous vessels may be an issue. These catheters may become lodged in the ophthalmic artery and the posterior communicating artery (PCoA) region of the supraclinoid internal carotid artery (ICA), thus hampering distal navigation. The Soft torquable catheter Optimized For Intracranial Access (Sofia) PLUS catheter (MicroVention Terumo, Tustin, California) is one such advancement that was designed to enable interventionists to obtain adequate distal access to intracranial lesions.

Approved by the Food and Drug Administration in early 2015, the 6-French (F) Sofia PLUS catheter (Figure 1) is the second generation of the Sofia (5F) Distal Access Catheter and was designed for neurovascular access during diagnostic or therapeutic interventions.[7] The device has a 0.070-inch wide single lumen to enable aspiration, a flexible design with a steam-shapeable tip and torquable shaft to enable better navigation into vessels, and enhanced kink resistance to maintain catheter stability and facilitate deployment of treatment devices.[8] It comes in lengths of 125 cm and 131 cm to allow access to more distal vessels and is claimed to reach up to the M2 segment of the middle cerebral artery (MCA). However, the clinical application and success of this device are yet to be reported. We report the first series describing the use of the Sofia (6F) PLUS catheter with the intent and attempt to revascularize large-vessel occlusions in patients with acute ischemic stroke at 2 academic centers in the United States. The primary outcome of interest in this retrospective cohort study was the rate of success in obtaining distal access to the site of thrombus with this catheter. Secondary outcomes were the associated rates of recanalization of occluded vessels and periprocedural complications when the Sofia PLUS catheter was used for a direct aspiration first-pass technique (ADAPT) or along with a stent retriever.

METHODS

Study Population and Setting

This study was conducted after obtaining institutional review board approval. Ethics approval was received from the University at Buffalo Health Sciences Institutional Review Board (Project No. CR00000031) and Mayo Clinic Arizona (approval waived—1 case from this center). The approval included a Health Insurance Portability and Accountability Act waiver of patient authorization owing to the retrospective nature of and use of de-identified data in this study.

We identified 45 nonconsecutive cases, among a total of 86 cases, in which the Sofia (6F) PLUS catheter was utilized during acute stroke interventions performed between August 2015 and April 2016. In 4 of the 45 cases, thrombectomy was not required or not attempted; therefore, these cases were excluded from the study. The 41 remaining cases were included in our series as thrombectomy or thrombolysis of the clot was

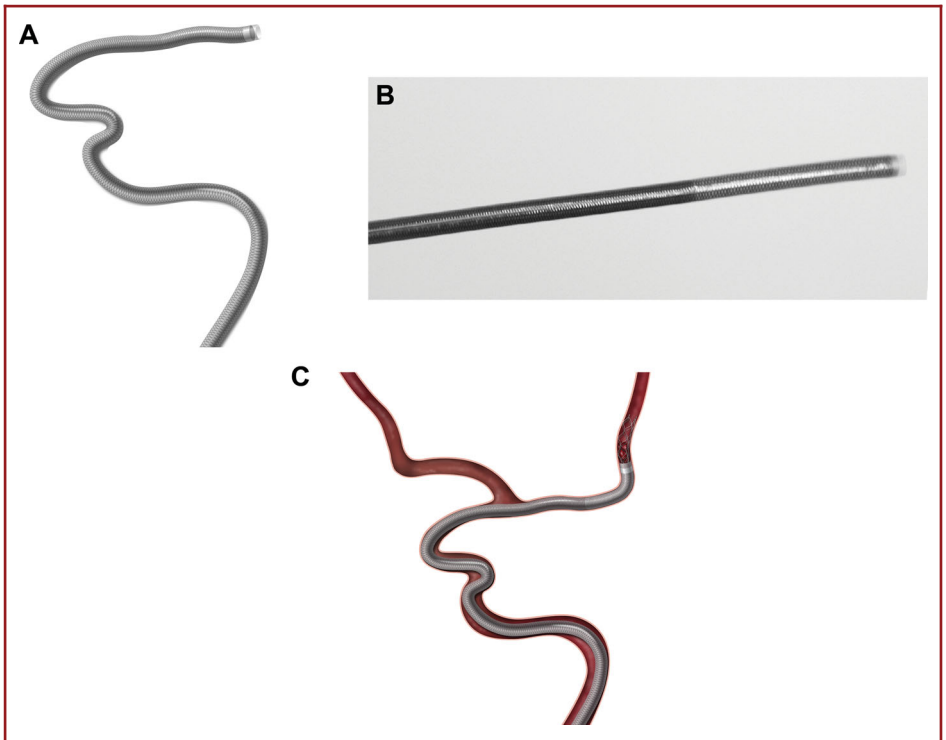

FIGURE 1. *Sofia PLUS catheter.* **A**, *Illustration of catheter tip.* **B**, *Photograph of catheter tip.* **C**, *Illustration of catheter with stent retriever deployed in a vessel. Images provided courtesy of MicroVention Terumo.*

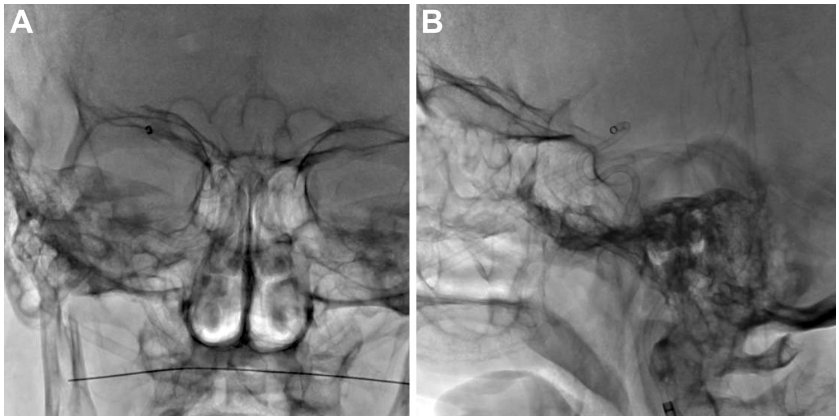

FIGURE 2. *Sofia PLUS catheter positioned in the M1 segment of middle cerebral artery.* **A**, *Anteroposterior view.* **B**, *Lateral view.*

attempted. The decision to use this catheter was made at the discretion of the interventionists participating in the study.

Treatment Protocol

The Sofia (6F) PLUS was used for clots located beyond the PCoA segment of the ICA wherein catheter navigability is vital to reach the "face" of the clot. It was used as an intermediate/distal access catheter as a part of a triaxial system introduced to aid in intracranial vessel access. The triaxial system comprised a microcatheter (Velocity [Penumbra, Inc, Alameda, California] or Marksman [Covidien/ev3, Irvine, California]), a Sofia PLUS catheter as the intermediate/distal access catheter, and a guide catheter positioned in the internal carotid artery.

The choice of anesthesia (general vs conscious sedation) was governed by institutional policy, surgeon's preference, and patient's consciousness and cooperativeness. Similarly, the use of a balloon guide catheter was at the discretion of the interventionist. During the interventions, the site of thrombus was approached using the microwire and microcatheter, and the Sofia PLUS catheter was navigated up until there was no blood return (Figure 2). Once the Sofia PLUS catheter was at the proximal end of the thrombus, the microcatheter and microwire were removed, without crossing the thrombus. The Sofia PLUS catheter was then used for direct aspiration (ADAPT), either manually with a syringe or along with an aspiration pump. Suction was applied for 3 min before the Sofia PLUS catheter was removed. In cases where stent retrievers were used, the microwire and microcatheter were used to cross the lesion, and the device was deployed and left for 3 to 5 min before being retrieved under direct aspiration (referred to as the "Solumbra" technique of mechanical thrombectomy[9]). The stent retriever was pulled back through the intermediate/distal access catheter to maintain distal access for repeated thrombectomy attempts if needed.

Data Sources/Assessment

Hospital electronic medical records and images from digital subtraction angiograms (DSA) from each case were assessed for the following data: age, sex, preoperative National Institutes of Health Stroke Scale (NIHSS) score, type of aortic arch, carotid tortuosity (defined subjectively based on the number of bends in the vessel), site of thrombus, side of thrombus, successful positioning at thrombus site, preintervention and postintervention thrombolysis in cerebral infarction (TICI) scores, time from groin puncture to first recanalization attempt, procedures (stenting, angioplasty, stent retriever, and/or aspiration thrombectomy), device used for thrombectomy (including Solitaire, Trevo, Penumbra), aspiration using the Sofia PLUS catheter, Sofia PLUS catheter-related complications, procedure-related complications, other complications, and postprocedure NIHSS scores. Statistical analysis was performed to calculate the frequencies of categorical variables and the mean, standard deviation, and range for numerical variables.

RESULTS

Descriptive Data

The series included 28 women and 13 men (Table). The mean age of these patients was 71.5 ± 14.9 yr (range 32-94 yr). The mean preprocedure NIHSS score was 16.5 ± 5.2 (range 4-29). Thirty-two patients had an occlusion in the M1 segment of the MCA, 6 patients had an M2 occlusion, 2 patients (cases 16 and 37) had an isolated ICA occlusion (1 cervical, 1 terminus), and 1 had a basilar artery occlusion (case 17). Twenty-two of the anterior circulation lesions were on the left side, whereas 18 presented on the right side. Two patients had tandem ICA occlusion (cases 27 and 40), 1 had ICA stenosis (in addition to the acute M2 occlusion) and underwent carotid stenting during the same procedure (case 23), and 1 had partial occlusion (case 32). All procedures were performed under conscious sedation except for cases 18, 21, 22, and 34.

Outcome Data

Distal Access

Of 41 cases in which thrombectomy or thrombolysis was attempted, successful positioning of the Sofia PLUS catheter near the occlusion site was achieved in 38 (92.7%). Case 6 had a type III aortic arch that could not be crossed, and the procedure was

TABLE. Demographic, Clinical, and Procedural Details and Complications of Cases in the Series

Case no.	Age	Sex	Preop NIHSS	Type of aortic arch	Carotid tortuosity (subjective)	Thrombus site	Side of thrombus	Successful positioning at thrombus site	TICI-pre	TICI-post	Time from groin puncture to first recanalization attempt (min)	Procedures (stenting; angioplasty; stent retriever and/or aspiration thrombectomy)	Other device used for thrombectomy (e.g., Solitaire; Trevo; Penumbra)	Aspiration using Sofia PLUS	Catheter-related complications	Procedure-related complications	Other complications	Post-procedure NIHSS
1	73	F	6	Type II	Moderate	M1	Right	Yes	0	3	33	Stent retriever + aspiration	Solitaire	Yes	No	No	No	4
2+	69	F	20	Type III	Minimal	M1	Right	Yes	0	3	20	Aspiration	NA	Yes	No	No	No	5
3	65	M	18	Type I	Minimal	M1	Left	Yes	0	2b	37	Stent retriever + aspiration	Solitaire	Yes	No	No	Hemorrhagic conversion	14
4+	57	M	20	NAv	Severe	M1	Left	Yes	0	3	13	Aspiration	NA	Yes	No	Distal embolism (L-ACA occlusion—reperfused using Solitaire and Sofia Plus)	Death—respiratory Arrest	NA—Expired
5+	87	F	20	Type III	Severe	M1	Right	Yes	0	3	17	Aspiration	NA	Yes	No	No	No	2
6	85	F	23	Type III	Severe	M1	Left	No—type III aortic arch	0	0	24	Aborted—could not access vessels beyond aortic arch	NA	NA	NA	No	Death	14
7+	54	F	17	Type I	Moderate	M1	Right	Yes	0	3	18	Aspiration	NA	Yes	No	No	No	0
8	75	F	11	Type III	Minimal	M1	Right	No—could not be navigated beyond the ophthalmic artery	0	3	19	Stent retriever + aspiration	Solitaire	Yes	No	No	No	7
9+	87	M	13	Type III	Severe	M1	Right	Yes	0	3	41	Aspiration	NA	Yes	No	No	No	3
10	86	F	13	NAv	Severe	M1	Left	Yes	0	3	30	Stent retriever + aspiration	Solitaire	Yes	No	No	No	5
11	86	F	16	Type II	Severe	M2	Right	Yes	0	3	41	Stent retriever	Trevo	No	No	No	No	8
12	82	F	16	Type I	Severe	M1	Right	Yes	0	3	28	Stent retriever + aspiration	Trevo—2 passes	Yes	No	No	No	14

TABLE ***Continued.***

Case no.	Age	Sex	Preop NIHSS	Type of aortic arch	Carotid tortuosity (subjective)	Thrombus site	Side of thrombus	Successful positioning at thrombus site	TICI-pre	TICI-post	Time from groin puncture to first recanalization attempt (min)	Procedures (stenting; angioplasty; stent retriever and/or aspiration thrombectomy)	Other device used for thrombectomy (e.g., Solitaire; Trevo; Penumbra)	Aspiration using Sofia PLUS	Catheter-related complications	Procedure-related complications	Other complications	Post-procedure NIHSS
13	56	M	8	Type I	Minimal	M1	Left	Yes	0	3	30	Stent retriever + aspiration	Trevo	Yes	No	Vasospasm of ICA	No	1
14+	57	F	10	NAv	Severe	M1	Left	Yes	1	2b	39	Aspiration; stent retriever + aspiration; angioplasty + stent (M1)	Solitaire; Gateway Balloon + Multi-link Mini-Vision stent	Yes	Solitaire not pulled in	No	No	11
15+	94	F	16	Type II	Moderate	M2	Left	Yes	0	3	49	Aspiration	NA	Yes	No	No	Atrial flutter	17
16	56	M	9	Type I	Minimal	ICA-T	Left	Yes	0	3	39	Stent + angioplasty for carotid dissection; stent retriever + aspiration	Wallstent + aviator balloon; Trevo	Yes	No	Dissection + vasospasm of ICA	No	1
17	82	F	20	NAv	NA	Basilar	NA	Yes	0	3	30	Stent retriever + aspiration	Trevo - 2 passes (failed); then Solitaire	Yes	No	No	No	1
18	67	F	15	Type I	Moderate	M1	Left	Yes	0	3	22	Stent retriever + aspiration	Trevo	Yes	No	No	No	10
19+	32	M	19	Type I	Minimal	M1	Left	Yes	0	2b	14	Aspiration	NA	Yes	No	No	No	3
20	85	F	14	Type II	Severe	M1	Right	Yes	0	3	47	Stent retriever + aspiration	Solitaire	Yes	No	Right retroperitoneal hematoma and pseudoaneurysm formation	No	16
21	87	F	18	NAv	Moderate	M2	Left	Yes	0	2a	19	IA-TPA	NA	NA	No	No	No	20
22	85	M	12	Type II	Minimal	M2	Right	Yes	0	3	22	Stent retriever + aspiration	Solitaire	Yes	No	No	No	1

TABLE *Continued.*

Case no.	Age	Sex	Preop NIHSS	Type of aortic arch	Carotid tortuosity (subjective)	Thrombus site	Side of thrombus	Successful positioning at thrombus site	TICI-pre	TICI-post	Time from groin puncture to first recanalization attempt (min)	Procedures (stenting; angioplasty; stent retriever and/or aspiration thrombectomy)	Other device used for thrombectomy (e.g., Solitaire; Trevo; Penumbra)	Aspiration using Sofia PLUS	Catheter-related complications	Procedure-related complications	Other complications	Post-procedure NIHSS
23	55	F	12	Type I	NAv	ICA stenosis + M2	Left	Yes	0	3	44	Angioplasty + atent; stent retriever	Wallstent (x2) + Aviator balloon; Solitaire	No	No	No	No	9
24	75	M	19	Type III	Minimal	M1	Right	Yes	0	3	47	Stent retriever + aspiration	Solitaire	Yes	No	No	No	21
25	73	F	29	Type III	Moderate	M1	Left	Yes	0	3	16	Stent retriever + aspiration; angioplasty for ICAD-related stenosis (M1)	Solitaire; Gateway Balloon	Yes	No	No	No	15
26	75	F	20	Type III	Moderate	M1	Left	Yes	0	3	16	Stent retriever + aspiration	Solitaire	Yes	No	Vasospasm of ICA	No	23
27	59	M	14	Type III	Minimal	ICA-T + M1	Right	Yes	0	3	25	Stent retriever + aspiration	Solitaire	Yes	No	Vasospasm of ICA	No	1
28	68	F	23	Type I	Moderate	M1	Left	Yes	0	3	26	Stent retriever + aspiration (both sites treated simultaneously)	Solitaire	Yes	No	No	No	0
29+	83	M	21	Type II	Minimal	M1	Left	Yes	0	3	33	Aspiration	NA	Yes	No	No	No	7
30	56	F	13	Type I	Minimal	M2	Left	Yes	0	3	21	Stent retriever + aspiration	Solitaire Platinum	Yes	No	No	No	0
31	78	F	16	NAv	Moderate	M1	Left	Yes	0	3	15	Stent retriever + aspiration	Trevo	Yes	No	No	No	1
32	52	M	17	Type III	Moderate	ICA-C + M1	Left	Yes	0	3	26	Stent retriever + aspiration (M1 only)	Solitaire Platinum	Yes	No	No	No	22
33+	92	F	19	Type III	Severe	M1	Right	Yes	0	2b	28	Aspiration	NA	Yes	No	No	No	22

TABLE ***Continued.***

Case no.	Age	Sex	Preop NIHSS	Type of aortic arch	Carotid tortuosity (subjective)	Thrombus site	Side of thrombus	Successful positioning at thrombus site	TICI-pre	TICI-post	Time from groin puncture to first recanalization attempt (min)	Procedures (stenting; angioplasty; stent retriever and/or aspiration thrombectomy)	Other device used for thrombectomy (e.g., Solitaire; Trevo; Penumbra)	Aspiration using Sofia PLUS	Catheter-related complications	Procedure-related complications	Other complications	Post-procedure NIHSS
34	55	F	19	Type I	Severe	M1	Right	Yes	0	2b	43	Stent retriever + aspiration	Solitaire Platinum	Yes	No	No	Superficial thrombophlebitis of R-Arm	1
35	57	F	4	Type I	Minimal	M1	Right	Yes	0	2a	14	Aborted—contrast extravasation	NA	NA	No	Contrast extravasation	No	6
36+	61	F	18	Type I	Severe	M1	Right	No—could not be navigated beyond the ophthalmic artery	0	3	21	Aspiration; stent retriever + aspiration	Solitaire Platinum	Yes	No	No	Hemorrhagic conversion	10
37+	71	F	24	NAv	Severe	ICA	Left	Yes	0	3	72	Aspiration; stent retriever + aspiration	Solitaire	Yes	No	No	No	12
38+	89	F	25	NAv	Severe	M1	Left	Yes	0	2a	16	Aspiration	NA	Yes	No	Contrast extravasation	Death—respiratory Arrest	NA—Expired
39	86	M	21	Type I	Severe	M1	Left	Yes	0	3	15	Stent retriever + aspiration	Solitaire	Yes	No	No	No	15
40+	89	F	16	Type II	Slight	ICA-C + M1	Right	Yes	0	3	28	Aspiration (ICA-C); stent retriever + aspiration (M1)	Solitaire	Yes	No	No	No	2
41+	50	M	12	Type III	Severe	M1	Right	Yes	0	3	24	Aspiration	NA	Yes	No	Distal embolism (R-ACA—reperfused with stent retriever and Sofia Plus)	No	8

ACA, anterior cerebral artery; ICA, internal carotid artery; ICA-T, ICA terminus; ICA-C, ICA cervical; ICAD-intracranial atherosclerotic disease; NA, not applicable; NAv, not available; L, left; TICI, thrombolysis in cerebral infarction (pre- and postthrombectomy).

Device manufacturers: 5Max ACE, Penumbra, Inc.; Aviator balloon, Cordis; Gateway balloon, Boston Scientific; Multi-link Mini-vision stent, Abbott Vascular; Sofia PLUS, MicroVention Terumo; Solitaire, Medtronic; Trevo, Sprinter balloon, Medtronic; Stryker Neurovascular; Wallstent, Boston Scientific.

+For these cases, ADAPT with the Sofia PLUS catheter was the initial method of thrombectomy.

aborted after multiple attempts. In cases 8 and 36, the catheter could not be navigated beyond the ophthalmic artery to the site of the occlusion.

Recanalization

Fifteen patients underwent ADAPT with the Sofia PLUS catheter as the initial method of thrombectomy; successful recanalization (TICI 2b/3) was achieved in 11 (73.3%) of these cases. Three of them (cases 14, 36, and 37) subsequently underwent thrombectomy with a stent retriever (Solitaire; Medtronic, Dublin, Ireland), and a TICI score of 2b/3 was achieved with a single pass. The Solumbra technique was applied in a total of 27 patients. A single patient (case 21) received intra-arterial (IA) thrombolytic therapy alone because she presented within the 6-h window and had a left MCA occlusion.

The mean time from groin puncture to first revascularization attempt was 28 ± 13 min (range 13-72 min). A postprocedure TICI score of 2b/3 was achieved in 37 of the 41 (90.2%) cases of attempted thrombolysis or thrombectomy. In 3 cases, thrombectomy was aborted due to inadequate access (case 6) or procedural complication (cases 35 and 38). A postprocedure TICI score of 2a was achieved in case 21, in which IA tissue plasminogen activator (tPA) was used as the only treatment modality. Likewise, a postprocedure TICI score of 2a was achieved with mechanical thrombectomy in cases 35 (ie, after thrombectomy was attempted but aborted) and 38. In 2 cases (cases 14 and 25), mechanical thrombectomy was followed by angioplasty for intracranial atherosclerotic disease-related stenosis or residual thrombus; a TICI score of 2b and 3 was achieved at the end of procedure, respectively. At 7-d postprocedure, the mean NIHSS score among the 39 survivors in this series was 8.5 ± 7.3 (range 0-23).

Procedural Complications

Fragmentation of clot with embolization to a different vascular territory occurred in 2 patients (cases 4 and 41); this complication was managed with the Solumbra technique of mechanical thrombectomy in which a Sofia PLUS catheter was placed in the proximal A1 segment while a stent retriever was deployed across the clot and then retrieved under aspiration. There were 7 other procedure-related complications including 4 instances of vasospasm (cases 13, 16, 26, and 27) of the cervical ICA. The vasospasm was at the proximal cervical ICA and was associated with the large guide catheter (Neuron MAX [Penumbra Inc] or Cook Shuttle [Cook Medical, Bloomington, Indiana]), not the Sofia PLUS catheter. All vasospasm responded to verapamil infusion. One patient had a retroperitoneal hematoma and pseudoaneurysm formation (case 20) managed during the patient's hospital stay. Case 16 presented with an iatrogenic proximal carotid artery dissection that was subsequently stented prior to mechanical thrombectomy. In 2 cases (cases 35 and 38), contrast extravasation was seen during the procedure, and therefore the procedure was terminated. In case 35, the microrun after crossing the clot with the microcatheter showed some contrast extravasation before thrombectomy was attempted; the microcatheter was subsequently withdrawn, and extravasation was confirmed with low contrast imaging using biplane angiography. In case 38, there was some contrast extravasation seen on the postthrombectomy intracranial run; TICI 2a revascularization had been achieved. The devices were subsequently withdrawn, and the procedure was ended. None of the aforementioned complications were related to the use of the Sofia PLUS catheter.

DISCUSSION

Recent major trials have shown that mechanical thrombectomy leads to lower mortality and significant improvement in clinical outcomes if used in a select group of patients with large-vessel occlusion within an appropriate timeframe.[1-6] This emphasizes the growing demand for device improvements that would enhance a well-trained interventionist's ability to access the occlusive lesion in an acute setting and provide prompt treatment. In this paper, we report our experience with the Sofia PLUS catheter, which was designed to enable the interventionist to achieve adequate distal access.

Older patients have increased tortuosity of vessels, including the aortic arch, common carotid artery, and ICA. Similar to the first-generation Sofia (5F) catheter,[10] the Sofia (6F) PLUS catheter possesses characteristics of softness and flexibility that can assist in navigation across tortuous vessels without causing any endothelial damage. A stable distal access catheter provides a platform for other devices (eg, microcatheter and stent retrievers) to be positioned and deployed at the thrombus and for subsequent thrombus retrieval. In our series, we were able to achieve good distal access in 38 of 41 (92.6%) cases in which the Sofia PLUS catheter was used for thrombectomy or thrombolysis. One patient (case 6) had significant tortuosity of the proximal common carotid artery that prevented access. In 2 other patients (cases 8 and 36), the catheter could not be navigated beyond the ophthalmic artery. With a 92.6% success rate of distal access to the site of thrombus, the Sofia PLUS catheter has shown promising results in this initial case series. Moreover, with the mean time to first recanalization attempt being 28 ± 13 min, the Sofia PLUS catheter seems to be useful in overcoming tortuous anatomy at the aortic arch, cervical carotid artery, and the internal carotid artery siphon within a relatively short time.

Turk et al[11] first described the ADAPT in 2013. Large-bore catheters were positioned over the thrombus, and aspiration was applied using a syringe or a Penumbra aspiration pump (Penumbra, Inc). They reported a 75% success rate, with complete recanalization in 57% of cases. Subsequently, 5Max and 5Max ACE catheters (Penumbra, Inc) were used with the technique, and successful recanalization (TICI 2b/3) was noted in 75% and 82% of the cases, respectively.[12] However, Kowoll et al[13] reported a lower success rate of only 56% when the 5Max ACE was used with aspiration alone for thrombectomy. Successful

recanalization was achieved with the Sofia 5F distal access catheter when aspiration alone was used for thrombectomy.[10,14] Kabbasch et al[14] reported a success rate of 67% with first-line aspiration, with greatest success achieved for lesions in middle cerebral artery. In the present series, the use of the ADAPT for thrombectomy resulted in a success rate of 73.3% (11 of 15 cases), when the Sofia PLUS catheter was used for first-line aspiration.

Distal access catheters can be used for concomitant aspiration to increase revascularization rates with stent retrievers and prevent distal embolization of debris.[9,10,15] When stent retrievers were used along with the Sofia PLUS catheter for mechanical thrombectomy, a 100% revascularization rate was achieved in our series; only 2 of the 27 such cases required more than 1 pass to achieve a TICI score of 2b/3.

In our series, no procedural deaths or complications were directly related to use of the 6F Sofia Plus. The fragmentation observed in 2 patients (cases 4 and 41) is a phenomenon that is uncommon when the ADAPT is performed;[11,12] the fragmented thrombus was subsequently managed using the Sofia PLUS catheter and a stent retriever.

In patients with tandem occlusions, concomitant stenting of the carotid artery and mechanical thrombectomy of the intracranial occlusion is a feasible and safe alternative.[16-20] The use of the Sofia PLUS catheter in cases of tandem stenosis or occlusion in our series provided good distal access for stent-retriever thrombectomy and was not associated with any complications.

CONCLUSION

Use of the Sofia (6F) PLUS distal access catheter in endovascular treatment of acute ischemic stroke has shown encouraging initial results. Although this catheter is not free of shortcomings, its success, safety, and efficacy are promising. Additional studies are warranted to further evaluate the efficacy of this device compare to other similar reperfusion catheters available in the antistroke toolbox.

Disclosures

Dr Bendok has a research grant from MicroVention. Dr Levy is a shareholder with ownership interest in Intratech Medical Ltd, Blockade Medical LLC, and NeXtGen Biologics; is the principal investigator for the Covidien US SWIFT PRIME Trials; has received honoraria from Covidien; is a consultant for Pulsar and Blockade Medical; is on the Advisory Board for Stryker, NeXtGen Biologics, and MEDX, and receives financial support from Abbott for carotid training sessions. Dr Siddiqui has the following research grants, not directly related to this submission: The National Institutes of Health (co-investigator: NINDS 1R01NS064592-01A1, Hemodynamic induction of pathologic remodeling leading to intracranial aneurysms), The National Institutes of Health (co-investigator: NIBIB 5 R01 EB002873-07, Micro-Radiographic Image for Neurovascular Interventions), The National Institutes of Health (co-investigator: NIH/NINDS 1R01NS091075 Virtual Intervention of Intracranial Aneurysms); he has financial interests in Hotspur, Intratech Medical, StimSox, Valor Medical, Blockade Medical, Lazarus Effect, Pulsar Vascular, and Medina Medical, is a consultant for Codman & Shurtleff, Covidien Vascular Therapies, GuidePoint Global Consulting, Penumbra, Stryker, Pulsar Vascular, MicroVention, Lazarus Effect, Blockade Medical, Reverse Medical, and W.L. Gore & Associates; he is on National Steering Committees for Penumbra-3D Separator Trial, Covidien-SWIFT PRIME Trial, MicroVention-FRED Trial, the Speaker's Bureau for Codman & Shurtleff, Inc, and the Advisory Board of Codman & Shurtleff, Covidien Neurovascular, ICAVL, and Medina Medical; he has received honoraria from Penumbra and Toshiba Medical Systems. The other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article. Dr Snyder is on the Speaker's Bureau of the Toshiba and Jacobs Institute.

REFERENCES

1. Berkhemer OA, Fransen PS, Beumer D, et al. for the MR CLEAN Investigators. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med*. 2015;372(1):11-20.
2. Campbell BC, Mitchell PJ, Kleinig TJ, et al. for the EXTEND-IA Investigators. Endovascular therapy for ischemic stroke with perfusion-imaging selection. *N Engl J Med*. 2015;372(11):1009-1018.
3. Goyal M, Demchuk AM, Menon BK, et al. for the ESCAPE Trial Investigators. Randomized assessment of rapid endovascular treatment of ischemic stroke. *N Engl J Med*. 2015;372(11):1019-1030.
4. Jovin TG, Chamorro A, Cobo E, et al. for the REVASCAT Investigators. Thrombectomy within 8 hours after symptom onset in ischemic stroke. *N Engl J Med*. 2015;372(24):2296-2306.
5. Powers WJ, Derdeyn CP, Biller J, et al. American Heart Association/American stroke association focused update of the 2013 Guidelines for the Early management of patients with acute ischemic stroke regarding endovascular treatment a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2015;46(10):3020-3035.
6. Saver JL, Goyal M, Bonafe A, et al. for the SWIFT PRIME Investigators. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. *N Engl J Med*. 2015;372(24):2285-2295.
7. Food and Drug Administration, Department of Health & Human Services. K150366. Sofia 6F PLUS/Distal Access Catheters. March 27, 2015. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf15/K150366.pdf Accessed August 22, 2016.
8. MicroVention Terumo. Sofia PLUS International Brochure, 2015. Available at: http://scovas.nl/wp-content/uploads/2014/12/SOFIA-PLUS-Intl-Brochure-Final.pdf Accessed August 22, 2016.
9. Dumont TM, Mokin M, Sorkin GC, Levy EI, Siddiqui AH. Aspiration thrombectomy in concert with stent thrombectomy. *J Neurointerv Surg*. 2014;6(4):e26.
10. Stampfl S, Kabbasch C, Muller M, et al. Initial experience with a new distal intermediate and aspiration catheter in the treatment of acute ischemic stroke: clinical safety and efficacy. *J Neurointerv Surg*. Epub 2016;8(7):714-718.
11. Turk AS, Spiotta A, Frei D, et al. Initial clinical experience with the ADAPT technique: a direct aspiration first pass technique for stroke thrombectomy. *J Neurointerv Surg*. 2014;6(3):231-237.
12. Turk AS, Frei D, Fiorella D, et al. ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy. *J Neurointerv Surg*. 2014;6(4):260-264.
13. Kowoll A, Weber A, Mpotsaris A, Behme D, Weber W. Direct aspiration first pass technique for the treatment of acute ischemic stroke: initial experience at a European stroke center. *J Neurointerv Surg*. 2016;8(3):230-234.
14. Kabbasch C, Mohlenbruch M, Stampfl S, Mpotsaris A, Behme D, Liebig T. First-line lesional aspiration in acute stroke thrombectomy using a novel intermediate catheter: Initial experiences with the SOFIA. *Interv Neuroradiol*. epub 2016;22(3):333-339.
15. Chueh JY, Puri AS, Wakhloo AK, Gounis MJ. Risk of distal embolization with stent retriever thrombectomy and ADAPT. *J Neurointerv Surg*. 2016;8(2):197-202.
16. Cohen JE, Gomori JM, Rajz G, Itshayek E, Eichel R, Leker RR. Extracranial carotid artery stenting followed by intracranial stent-based thrombectomy for acute tandem occlusive disease. *J Neurointerv Surg*. 2015;7(6):412-417.
17. Cohen JE, Gomori M, Rajz G, et al. Emergent stent-assisted angioplasty of extracranial internal carotid artery and intracranial stent-based thrombectomy in acute tandem occlusive disease: technical considerations. *J Neurointerv Surg*. 2013;5(5):440-446.

18. Gao F, Joyce Lo W, Sun X, Xu X, Miao Z. Combined use of stent angioplasty and mechanical thrombectomy for acute tandem internal carotid and middle cerebral artery occlusion. *Neuroradiol J*. 2015;28(3):316-321.
19. Maurer CJ, Joachimski F, Berlis A. Two in one: endovascular treatment of acute tandem occlusions in the anterior circulation. *Clin Neuroradiol*. 2015;25(4):397-402.
20. Puri AS, Kuhn AL, Kwon HJ, et al. Endovascular treatment of tandem vascular occlusions in acute ischemic stroke. *J Neurointerv Surg*. 2015;7(3):158-163.

Acknowledgments

The authors thank Chandan Krishna MD from the Department of Neurosurgery at Mayo Clinic Arizona for assistance with data collection; and Paul H. Dressel BFA for preparation of the illustrations and Debra J. Zimmer for editorial assistance (both from University at Buffalo Neurosurgery).

COMMENTS

The authors are to be applauded for their early embrace and application of the Sofia PLUS catheter for mechanical thrombectomy cases. Their review demonstrated a 92.7% success in reaching target 38/41 cases with the Sofia catheter and a 73.3% TICI 2b/3a successful revascularization rate. In 2 remarkable cases, they were also able to position the Sofia PLUS catheter into the A1 and retrieve distal fragmented emboli. In only 3/41 cases could they not navigate to target due to type III aortic arch anatomy, and likely carotid siphon tortuosity unable to pass beyond the ophthalmic artery. In stroke cases access is the name of the game. Safe, efficient, and rapid revascularization as demonstrated in this well written paper determines success. Technological advances in catheter design has led to a significant improvement in reaching the target. There are no frustrations as great as not being able to reach an acute thrombus in a timely fashion with a patient in crisis. Anatomic challenges from vascular access in the groin to the distal intracranial circulation has been a daunting challenge in selected patients. At each twist and turn of the patient's vasculature we lose the ability to control and navigate our intracranial devices, thwarted in our advance to target this results in "mission-failure". This becomes more concerning especially as we approach targets beyond ICA and the M1 segment. The ability of the authors to demonstrate success with revascularization using the Sofia PLUS catheter should be taken notice by all neurointerventionalists and occupy a selected place in their stroke tool box. It should also inspire industry engineers to continue design improvements in distal access catheters and the stability of our working platforms. Our recent experience has mirrored these results and my only regret has often been not utilizing the Sofia PLUS catheter earlier in during revascularization. The use of pre-thrombectomy CTA evaluation of the proximal arch to target anatomy may help select those cases best treated with use of the Sofia PLUS catheter however currently in the majority of cases this is not identified until during the early stages of the revascularization procedure.

Rocco A. Armonda
Bethesda, Maryland

The authors reported their experiences of utilizing Sofia PLUS 6F intermediate catheters in acute endovascular treatment of selected patients suffering from large intracranial vessel occlusion (LVO). Excellent revascularization rate was reported with low risks of complications comparable with ones published in literature. This work is a nice addition to the ever-growing body of knowledge in endovascular treatment of acute ischemic stroke.

The ability to advance large bore intracranial catheters to the sites of LVO rapidly, safely, and easily has become one of the most important factors in success of LVO intervention, second only to the optimal patient selection process. In this series, in 15 out of 41 cases, the Sofia PLUS catheters can be navigated to the LVO sites without microcatheter/microwire crossing the thrombi. The 6F 0.070-in catheter can be even advanced into proximal A1 segment for successful thrombectomy. The authors' technical prowess and the devices' capability probably equally contributed to such impressive success.

We have very similar results in applying advanced intracranial large bore catheters in conjunction with stent-retrievers, achieving nearly 90% revascularization of LVOs in carefully selected patients. With such encouraging technological advancement, it is more pressing for the neurointerventional community to address the optimal LVO patient selection process, and to develop rational and economical technique algorithm in performing these life-saving and quality-of-life improving procedures.

Y. Jonathan Zhang
Houston, Texas