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Original research

SOFIA Aspiration System as first-line Technique (SOFAST): a prospective, multicenter study to assess the efficacy and safety of the 6 French SOFIA Flow Plus aspiration catheter for endovascular stroke thrombectomy

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ABSTRACT

Background Mechanical thrombectomy (MT) is the standard of care for acute ischemic stroke (AIS) patients with large vessel occlusion (LVO). The SOFAST study collected clinical evidence on the safety and efficacy of the 6 French SOFIA Flow Plus aspiration catheter (SOFIA 6F) when used as first-line treatment.

Methods This was a prospective, multicenter investigation to assess the safety and efficacy of SOFIA 6F used for first-line aspiration. Anterior circulation LVO stroke patients were enrolled. The primary endpoint was the final modified Thrombolysis in Cerebral Infarction (mTICI)≥2b rate. Secondary endpoints included first-pass and first-line mTICI≥2b rates, times from arteriotomy to clot contact and mTICI≥2b, and 90-day modified Rankin Scale (mRS)≤2. First-line and final mTICI scores were adjudicated by an independent imaging core lab. Safety events were assessed by an independent clinical events adjudicator.

Results A total of 108 patients were enrolled across 12 centers from July 2020 to June 2022. Median age was 67 years, median National Institutes of Health Stroke Scale (NIHSS) was 15.5, and 56.5% of patients received intravenous thrombolytics. At the end of the procedure, 97.2%, 85.2%, and 55.6% of patients achieved mTICI≥2b, ≥2c, and 3, respectively. With SOFIA 6F first-line aspiration, 87.0%, 79.6%, and 52.8% achieved mTICI≥2b, ≥2c, and 3, respectively. After the first pass, 75.0%, 70.4%, and 50.9% achieved mTICI≥2b, ≥2c, and 3, respectively. Median times from arteriotomy to clot contact and successful revascularization were 12 and 17 min, respectively. At 90 days, 66.7% of patients achieved mRS≤2.

Conclusions First-line aspiration with SOFIA 6F is safe and effective with high revascularization rates and short procedure times.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Endovascular thrombectomy (EVT) is an efficacious treatment for large vessel occlusion (LVO) strokes, and patient outcomes are sensitive to EVT devices and techniques.

WHAT THIS STUDY ADDS

⇒ This study demonstrates the superb efficacy and safety of first-line aspiration with the SOFIA 6F catheter for anterior circulation LVO stroke patients.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Future studies should investigate the performance of SOFIA 6F in comparison with other EVT devices.

INTRODUCTION

Endovascular thrombectomy (EVT) is the gold standard treatment for select acute ischemic stroke (AIS) atients with large vessel occlusions (LVOs).[1 2] In general, there are two main approaches to EVT: direct contact aspiration and stent-retriever with or without aspiration. To date, three large randomized controlled trials (ASTER,[3] COMPASS,[4] and the Penumbra Separator 3D trials[5]) have suggested clinical equivalency of first-line aspiration and stent-retrieval techniques; however, the percentage of excellent revascularization after the first pass was reported to be modest, suggesting that the development of better EVT devices are needed to further optimize patient care.

Patient outcomes following stroke thrombectomy are sensitive to the performance of neurothrombectomy devices. For instance, achieving excellent revascularization after the first pass, also termed the first-pass effect,[6] has been shown to be associated with favorable outcomes. Poor or suboptimal performance of thrombectomy devices to achieve successful reperfusion after each attempt introduces additional procedural risks (eg, vasospasm, vascular injury, longer procedure times), which may compromise patient outcomes.[7] In addition, repeated agitation and crossing of the occlusive thrombus may

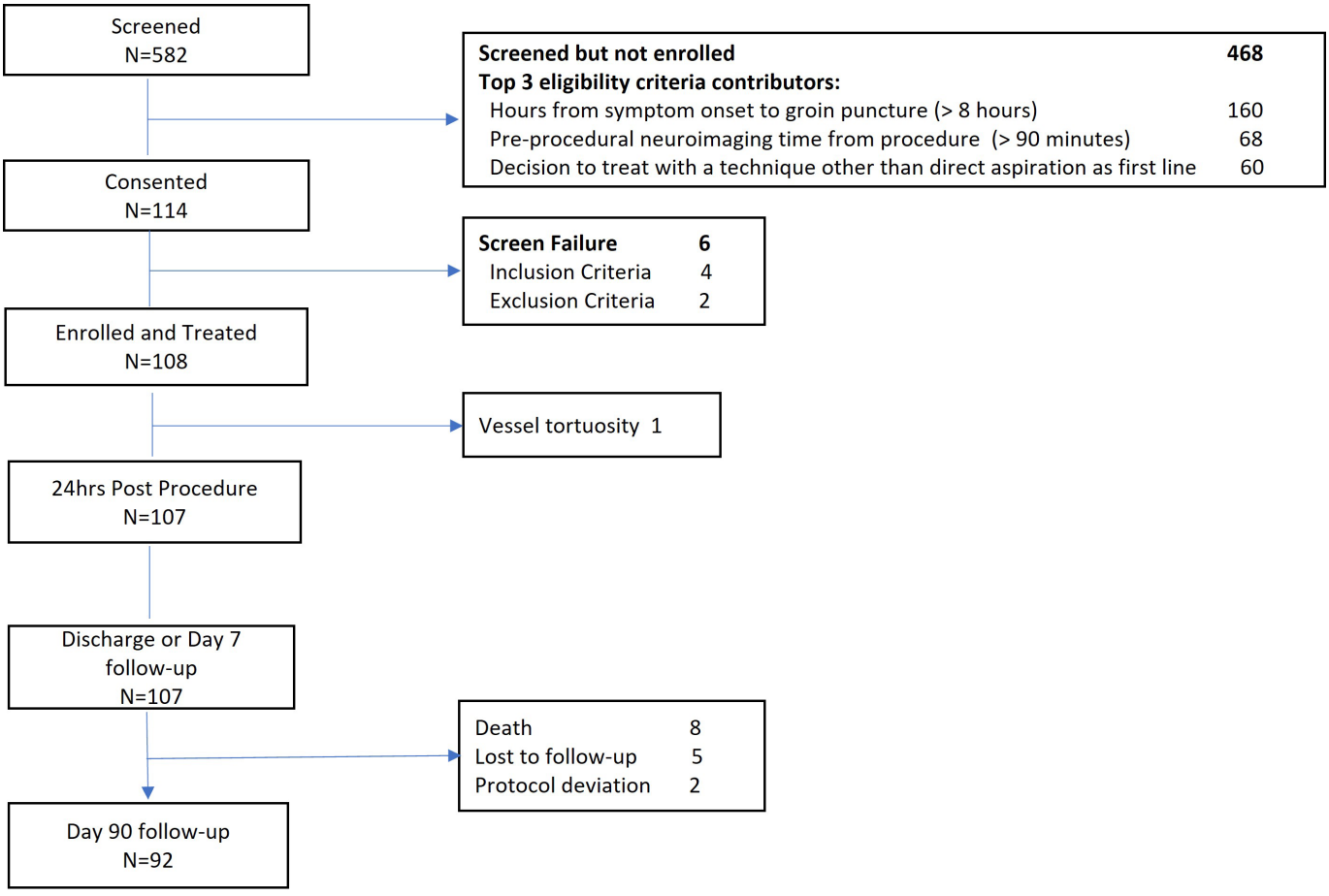

Figure 1 Study accountability flow chart.

lead to clot fragmentation and distal embolism that may not be amenable to further intervention, resulting in suboptimal angiographic outcomes.[8] Recent studies have suggested that the efficacy of EVT may be diminished for patients requiring multi-pass procedures,[9] further highlighting the need for better devices with high rates of successful revascularization within as few attempts as possible.

The 6 French SOFIA Flow Plus aspiration catheter (SOFIA 6F) is a single-lumen catheter that has received Food and Drug Administration (FDA) 510(k) clearance and is designed to remove thrombus from the vasculature using continuous aspiration. To further assess the clinical safety and efficacy of the SOFIA 6F aspiration catheter for the treatment of LVO strokes, we conducted the SOFAST (SOFIA Aspiration System as first-line Technique) study and report the results herein.

METHODS

SOFAST was a prospective, multicenter, single-arm, open-label, post-market study to assess the efficacy and safety of SOFIA 6F when used as the first-line, aspiration-only treatment for patients with acute large vessel ischemic stroke in the anterior cerebral circulation. The study was conducted across 12 centers in the United States from July 2020 to June 2022, and was compliant with all applicable regulations. Sites were responsible for ensuring institutional review board (IRB) approval of the study protocol and informed consent prior to subject enrollment as well as for continuing IRB review. Sites were also responsible for the reporting of protocol deviations and adverse events (AEs) in accordance with protocol and IRB guidelines throughout the study. IRB approval was obtained at all investigational sites (protocols are detailed in Ethics Approval section).

Patient inclusion and exclusion criteria

Patients with AIS due to an LVO for whom groin puncture could be achieved within 8 hours of stroke symptom onset or last known well time were eligible. Ischemic stroke patients presenting for acute stroke treatment were screened. Patients were enrolled only if they satisfied all eligibility criteria for the study. Informed consent was initially acquired by each study site from the patient or their legally authorized representative prior to EVT procedures, with a later revision of the protocol allowing consent up to 48 hours after treatment. Screening logs were maintained by the sites to document reasons for ineligibility of patients not enrolled (online supplement).

Key inclusion criteria included: age 21 to 85 years, premorbid modified Rankin Scale[10] (mRS) of 0 to 1, National Institutes of Health Stroke Scale (NIHSS) of at least 5 at the time of intervention, and imaging-confirmed LVO (distal internal carotid artery through the middle cerebral artery bifurcation) within 90 min prior to arteriotomy. Patients with carotid artery stenosis or dissection requiring stenting, presence of large territory infarction, inability to establish femoral artery access, or chronic/pre-existing vascular occlusion in the symptomatic territory were excluded. Patients with large infarcts (Alberta Stroke Program Early CT Score (ASPECTS) less than 6, core volume greater than 50 cc, or involvement of more than one-third of the middle cerebral artery (MCA) vascular territory) were also excluded.

Study intervention

Per protocol, all eligible patients underwent EVT for AIS with SOFIA 6F as the first-line aspiration treatment. SOFIA 6F was used with the Gomco aspiration pump and Microvention tubing kit per the Instructions for Use (IFU) indication. Introduction of SOFIA 6F into the neurovasculature via femoral arterial access was a prerequisite for study enrollment. The decision to perform EVT procedures under general anesthesia or conscious sedation was made per institutional protocols at each participating site. The use of balloon guide catheters was at the discretion of the treating physician. Investigators and study sites were encouraged to complete three passes with SOFIA 6F prior to crossing over to their choice of other FDA-cleared or approved thrombectomy devices.

Study endpoints

The primary endpoint of the study was the proportion of subjects achieving mTICI[11 12] ≥2b at the end of the procedure.

Secondary endpoints included mTICI≥2b outcomes following first-line aspiration using SOFIA 6F, mTICI≥2b outcomes after the first aspiration pass with SOFIA 6F, number of passes to mTICI≥2b revascularization, time from arteriotomy to initial clot contact, time from arteriotomy to successful revascularization (mTICI≥2b), and functional independence (mRS≤2 at day-90). Safety-related secondary endpoints included symptomatic intracerebral hemorrhage (sICH) within 24 hours post-EVT, all-cause mortality at day-90, procedure-related serious adverse events (SAEs), embolization to new territory (ENT), and vasospasm involving the accessed vascular tree. The number of patients who crossed over to other thrombectomy devices, overall adverse events (AEs), SAEs, and the numbers of device-related SAEs, dissections, and perforations were also tabulated.

Independent imaging and safety adjudication

The final and first-line mTICI scores were adjudicated by an independent imaging core lab.

Neurological and procedure- or study device-related AEs, as determined by the sites, were documented and monitored from the time of enrollment through the final follow-up visit, on which any ongoing AEs were documented as still ongoing. All neurological AEs, procedure- or study device-related AEs, and study device malfunctions/technical events were reviewed and adjudicated by an independent Clinical Events Adjudicator (CEA) to determine relatedness.

Sample size calculation and statistical analysis

The target sample size was 107 subjects. This sample size was calculated based on a primary endpoint performance goal predicated on the literature-reported results of five randomized controlled trials on EVT, which averaged a 70% rate of successful revascularization, with adequate (>80%) power.[13] The primary endpoint analysis was performed based on the full analysis set (FAS) which is the equivalent of the intention-to-treat (ITT) population. Secondary endpoint results were summarized using counts, percentages, and two-sided 95% binomial confidence intervals for binary outcomes, and descriptive statistics with two-sided 95% confidence intervals for continuous parameters.

RESULTS

A total of 582 patients were prospectively screened; informed consent was obtained for 114 patients, and 108 patients were enrolled and treated across 12 centers (figure 1). The top three reasons for study exclusion among screened patients were time

Table 1 Patient characteristics

Characteristic	Value (% (n) or median (IQR))
Demographics	
Age (years)	67 (53.5–72.5)
Women	50.0 (54)
Medical history	
Hypertension	75.0 (81)
Diabetes	19.4 (21)
Dyslipidemia	61.1 (66)
Atrial fibrillation	38.0 (41)
Current smoking	17.6 (19)
Cardiac disease	37.0 (40)
Previous ischemic stroke	16.7 (18)
Previous TIA	11.1 (12)
Intracranial atherosclerotic disease	9.3 (10)
Antiplatelet use	4.6 (5)
Anticoagulant use	10.2 (11)
Current stroke event	
Systolic blood pressure (mmHg)	138 (124–156.5)
Diastolic blood pressure (mmHg)	79.0 (89.0–68.5)
NIHSS	15.5 (10-20)
Pre-morbid mRS	
0	80.6 (87)
1	19.4 (21)
ASPECTS score	9 (8-10)
Core infarct volume* (cc)	19 (7–30)
Left-sided stroke	50.9 (55)
Site of occlusion	
Internal carotid artery	13.0 (14)
Middle cerebral artery – M1	72.2 (78)
Middle cerebral artery – M2	14.8 (16)
Time metrics	
Symptom onset to hospital arrival (min)	164.5 (80.5–239.5)
Symptom onset to arteriotomy (min)	217.0 (140.5–298)
mTICI prior to treatment	
0	88.0 (95)
1	8.3 (9)
2a	3.7 (4)
Procedural details	
Intravenous tPA	56.5 (61)
General anesthesia	61.1 (66)
Balloon guide catheter use	26.9 (29)
First-line (SOFIA 6F) device details	
Subjects who used one SOFIA 6F device	100 (108)
Subjects who used two SOFIA 6F devices	6.5 (7)
Number of devices used	1.0 (1–1)

N=108 unless otherwise specified.
*Data available for 55 subjects.
ASPECTS, Alberta Stroke Program Early CT Score; IQR, interquartile range; mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale; TIA, transient ischemic attack; tPA, tissue plasminogen activator.

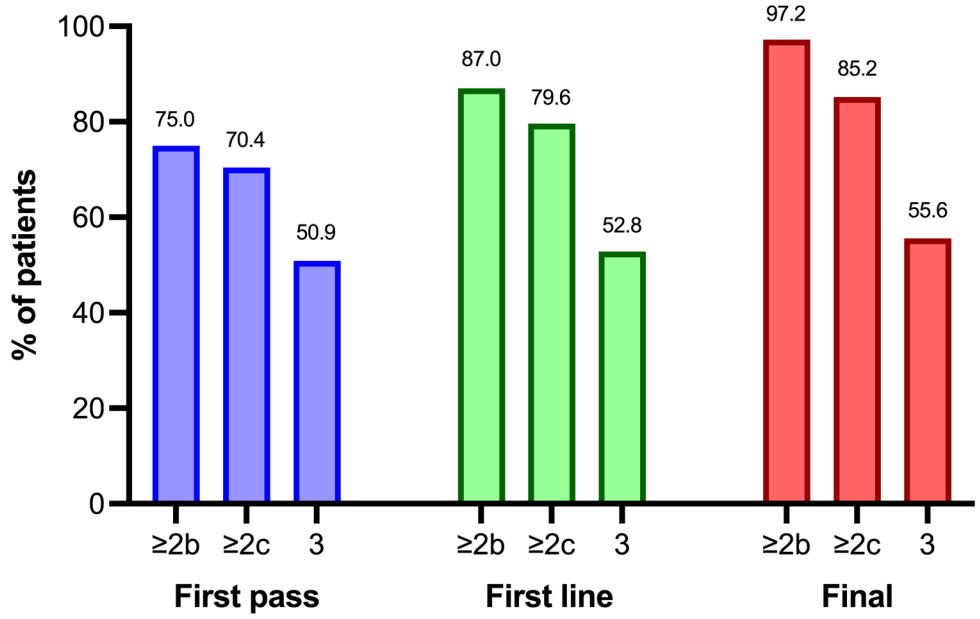

Figure 2 Angiographic outcomes measured by proportion of patients achieving modified Thrombolysis in Cerebral Infarction (mTICI) score thresholds following first-pass and first-line (within three attempts) with the SOFIA 6F aspiration catheter and at the end of the procedure.

from stroke symptom onset to arteriotomy >8 hours (n=160), time from preprocedural neuroimaging to EVT procedure >90 min (n=68), and decision to treat with a technique other than direct aspiration as first-line (n=60) (figure 1). A full account of reasons for non-enrollment of each screened patient is presented in online supplemental materials. The SOFIA 6F device was used for first-line aspiration for all enrollees. A total of 27 major deviations were noted in 24 patients; 12 (in 12 patients) were due to the use of a pump other than the Gomco aspiration pump required per protocol, 11 (in 11 patients) were due to non-compliance with study eligibility criteria, and 4 (in 4 patients) were related to not following procedures per protocol.

Some 107 of 108 patients (99.1%) completed discharge or day 7 follow-up; for the remaining subject, the study device could not reach the clot due to vessel tortuosity, but the patient was still included in the FAS/ITT population. A total of 92 of 108 patients (85.2%) completed the study with 90-day follow-up; 8 patients (7.4%) died prior to study completion, 5 (4.6%) were lost to follow-up, and 2 (1.9%) did not complete the study for other reasons (figure 1).

Patient characteristics

Median age was 67 (IQR 53.5–72.5) years, and 54 patients (50.0%) were female. Some 41 patients (38.0%) had atrial fibrillation, and 10 (9.3%) had intracranial atherosclerotic disease. Other details for medical comorbidities are outlined in table 1.

For the index stroke event, median NIHSS was 15.5 (IQR 10–20), median ASEPCTS was 9 (IQR 8–10), and median core infarct volume was 19.0 cc (IQR 7–30 for the 55 patients with available data). Fourteen patients (13.0%) harbored an internal carotid artery occlusion, 78 had an M1 occlusion (72.2%), and 16 (14.8%) had an M2 occlusion. Sixty-one patients (56.5%) were treated with intravenous thrombolytics, and all patients had an mTICI score of less than 2b prior to endovascular treatment. Other details for stroke and procedural characteristics are outlined in table 1.

Angiographic and clinical outcomes

Overall, 97.2% of patients (105 of 108; 97.5% binomial CI: 95.2% to 100.0%) in the FAS/ITT population achieved mTICI 2b or better revascularization at the end of the thrombectomy procedure (figure 2 and table 2), meeting the established primary endpoint performance goal. Some 85.2% and 55.6% of patients achieved mTICI≥2c and mTICI 3 revascularization at the end of the thrombectomy procedure, respectively (figure 2 and table 2). Following first-line aspiration using SOFIA 6F, 87.0%, 79.6%, and 52.8% of patients achieved mTICI≥2b, ≥2c, and 3 revascularization, respectively (figure 2 and table 2). After the first pass with SOFIA 6F, 75.0%, 70.4%, and 50.9% of patients achieved mTICI≥2b, ≥2c, and 3 revascularization, respectively (figure 2 and table 2). With first-line aspiration using SOFIA 6F, 75.0% of patients (81/108) required only one thrombectomy pass, 9.3% of patients (10/108) required two passes, and 2.8% of patients (3/108) required three passes to achieve mTICI≥2b revascularization (table 2).

Median time from arteriotomy to initial clot contact was 12.0 min (IQR 7–16 min; table 2), and median time from arteriotomy to successful revascularization (mTICI≥2b) was 17.0 min (IQR 11–22 min; table 2). Some 18.5% of patients (20/108) crossed over to other devices during the thrombectomy procedure (table 2). It is important to note that 13 of these 20 patients had achieved mTICI≥2b revascularization with first-line treatment with SOFIA 6F prior to device crossover. Balloon guide catheters were used in 26.9% of patients (29/108).

Some 72 of 108 patients (66.7%) were functionally independent (mRS 2 or less) at day-90. Distribution of mRS at 90 days among study subjects is presented in the online supplemental materials.

Safety outcomes

sICH within 24 hours after EVT occurred in one patient (0.9%). All-cause mortality at day-90 was reported in 7.4% of patients (8/108), none of which were study device-related. Three of 108 patients (2.8%) experienced a total of four procedure-related SAEs. Two events were deemed possibly related to the procedure

Table 2 Study outcomes

Study outcome	Value (% (n) or median (IQR))
Efficacy: Primary endpoint	
Final mTICI≥2b	97.2 (105)
Efficacy: Secondary endpoints	
mTICI≥2b following first-line aspiration with SOFIA 6F	87.0 (94)
mTICI≥2b after first pass with SOFIA 6F	75.0 (81)
Number of passes to achieve mTICI≥2b revascularization with first-line aspiration treatment with SOFIA 6F	
1	75.0 (81)
2	9.3 (10)
3	2.8 (3)
90-day functional independence (mRS≤2)	66.7 (72)
Time metrics	
Arteriotomy to clot contact (min)	12 (7–16)
Arteriotomy to mTICI≥2b revascularization (min)	17 (11–22)
Efficacy: Other outcomes	
Final mTICI score	
≥2c	85.2 (92)
3	55.6 (60)
mTICI score following first-line aspiration with SOFIA 6F	
≥2c	79.6 (86)
3	52.8 (57)
mTICI score after first-pass with SOFIA 6F	
≥2c	70.4 (76)
3	50.9 (55)
Crossover to other devices*	18.5 (20)
Safety: Secondary endpoints [events]	
Procedure-related SAEs	2.8 (3) [4]
All-cause mortality at 90 days	7.4 (8) [8]
Vasospasm involving accessed vascular tree	9.3 (10) [10]
Embolization to new territories (ENTs)	0 (0) [0]
sICH within 24 hours of procedure	0.9 (1) [1]
Safety: Other outcomes [events]	
Overall AEs	36.1 (39) [63]
Overall SAEs	15.7 (17) [23]
Vessel perforation	0.9 (1) [1]
Vessel dissection	0.9 (1) [1]

N=108 unless otherwise specified.
*Providers were encouraged to perform three SOFIA 6F aspiration passes prior to crossing over to other endovascular thrombectomy devices; 10 patients crossed over to another device prior to undergoing three SOFIA 6F aspiration attempts.
AE, adverse event; IQR, interquartile range; mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; SAE, serious adverse event; sICH, symptomatic intracerebral hemorrhage.

(seizure, hemorrhagic transformation), one event was deemed definitely related to the procedure (acute kidney injury), and one event was deemed possibly related to both study device and procedure (new ischemic stroke or stroke due to re-occlusion of large vessel following EVT). Details regarding these events are presented in table 2.

Procedural vasospasm involving the accessed vascular tree occurred in 10 patients (9.3%). There was one case of carotid artery dissection (non-flow limiting, at the site of the balloon guide catheter) and one case of cerebral artery perforation (MCA M2 segment) unrelated to the study device. There were no cases of embolization to new territories (ENTs).

DISCUSSION

In this prospective, multicenter, single-arm, post-market investigation to assess the efficacy and safety of SOFIA 6F when used as a first-line treatment for patients with acute large vessel ischemic stroke, we demonstrate high rates of mTICI≥2b (97.2%) revascularization by end of procedure, meeting the primary study endpoint performance goal. High rates of mTICI≥2b (87.0%) and ≥2c (79.6%) revascularization were achieved following first-line treatment with SOFIA 6F. Furthermore, SOFIA 6F achieved high rates of successful revascularization after the first pass (75.0% for mTICI≥2b and 70.4% for ≥2c), favorable day-90 functional outcomes (66.7%), as well as low rates of procedure-related SAEs (2.8%), sICH within 24 hours (0.9%) and all-cause mortality at day-90 (7.4%). There were no cases of ENTs. Overall, our study results demonstrate that EVT via aspiration with SOFIA 6F is effective and safe when used as a first-line technique for patients with large vessel AIS.

First-pass effect, defined as mTICI 2c or better after a single thrombectomy attempt, is a stringent and clinically important metric to evaluate the performance of EVT devices as well as a strong independent predictor of patient outcomes.[6] In the SOFAST study, we demonstrated a 70.4% rate of mTICI 2c or better after the first pass with SOFIA 6F aspiration, which was higher than what was reported in previous studies using other devices and techniques. For instance, the TIGER trial,[14] the COMPLETE registry,[15] and the ARISE II studies[16] reported lower rates of first-pass effect compared with SOFIA 6F (41.4%, 41.5%, and 40.1%, respectively). Revascularization beyond the first pass is also an important determinant of outcomes,[17] and SOFIA 6F aspiration performed well in achieving high rates of mTICI≥2c (85.2%) revascularization by end of procedure.

Another important performance metric of EVT procedures is the time from arteriotomy to successful revascularization, which is another important predictor of patient outcomes.[18] In the SOFAST study, the SOFIA 6F aspiration catheter was able to contact the clot at a median time of 12 min from groin puncture, and patients achieved mTICI 2b or better revascularization at a median time of 17 min from groin puncture. Our study reported a shorter time to successful revascularization than the durations reported in the COMPASS[4] (aspiration arm), Penumbra Separator 3D[5] (aspiration arm), TIGER,[14] COMPLETE,[15] ARISE II,[16] SEER,[19] and STRATIS[20] studies (22, 39, 24, 27, 35, 38, and 37 min, respectively), suggesting that the flexible and atraumatic distal end of the SOFIA 6F catheter offers easy and rapid distal navigation for EVT procedures.

The SOFAST study had excellent safety outcomes including low rates of procedure-related SAEs (2.8%), sICH within 24 hours post-procedure (0.9%), and all-cause mortality at day-90 (7.4%). Further, there was only one reportable SAE that was possibly related to SOFIA 6F, whereas none were deemed definitely related to SOFIA 6F. In addition, there were no cases of ENTs, which is a known complication of EVT procedures as reported for other studies (3.7%, 3.0%, 2.6%, 2.8%, and 6.6% for ASTER,[3] COMPASS,[4] TIGER,[14] COMPLETE,[15] and ARISE II,[16] respectively). These results support the favorable safety profile of the SOFIA 6F device in EVT procedures to treat LVOs.

It is important to recognize that clinical outcomes of EVT procedures are sensitive to the performance of neuroendovascular devices. While landmark trials in 2015 demonstrated an overwhelming benefit of EVT over medical management for select patients with large vessel ischemic strokes,[13] earlier studies

failed to show significant benefit,[21 22] partially due to suboptimal devices and techniques. Currently, there is an abundance of aspiration and stent-retriever devices routinely used for EVT. Overall, the results demonstrated in the SOFAST study establish SOFIA as a safe and effective EVT device, trending favorably with respect to results historically reported in the literature for other thrombectomy devices and techniques.

Limitations

This study has several limitations. As a single-arm study, SOFAST did not compare the SOFIA 6F device directly with other devices or techniques. While angiographic outcomes were evaluated independently at an imaging core lab and adverse events were adjudicated independently by a clinical events adjudicator, clinical (mRS) outcomes were collected by individuals who could not be blinded to the treatment device and their evaluations may thus be subject to bias. Informed consent was obtained after the thrombectomy procedure for a subset of patients; therefore, it is possible that the enrolled cohort may have been subject to selection bias and enriched with patients with more favorable outcomes. The study only included patients with anterior circulation LVOs and those presenting within 8 hours of stroke onset; thus, the performance of the SOFIA 6F device for posterior circulation occlusions or extended-time windows remains unknown and requires further investigation. Our study also excluded elderly patients above the age of 85 years; the elderly population is an important subset of LVO stroke patients,[23] and angiographic results have been shown to impact clinical outcomes.[24] Finally, a subset of patients (18.5%) crossed over to another neurothrombectomy device, which may have confounded the final angiographic and clinical outcomes; however, favorable first-pass and first-line angiographic outcomes prior to device crossover suggest that this crossover did not substantially affect the study outcomes.

CONCLUSIONS

The SOFAST study – a prospective, multicenter, post-market study – demonstrated that first-line aspiration with the SOFIA 6F device is a safe and effective EVT technique yielding high rates of revascularization and short procedure times.

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Contributors DG conceived the study idea, had a major role in administering the study, and is the guarantor of the study. DG and HC wrote the manuscript. SZ, DHS, LM, KK, TRM, SR, AAS, HHW, GT, CS, YL, and DF collected the data. All authors approved the final manuscript.

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Patient consent for publication Consent obtained from parent(s)/guardian(s).

Ethics approval This study involves human participants and institutional review board (IRB) approval was obtained at all investigational sites: University of Maryland (Protocol #: HCR-HP-00088121), Stony Brook (Protocol #: IRB2020-00153_MODCR004), Dignity Health/Mercy San Juan Medical Center (Protocol #: 1738462-16), Augusta University (Protocol #: 1280374), The Toledo Hospital/ProMedica Toledo Hospital (Protocol #: 1306964), Ascension Borgess (Protocol #: WMed-2020-0637), St. Vincent Hospital and Health Center/Goodman Campbell (Protocol #: MOD00005106), SSM Health Care St. Louis (Protocol #: 21-01-2014), Northwell Health (Protocol #: 1306964), Cleveland Clinic (Protocol #: 20-1091), Geisinger Clinic (Protocol #: 2020-0130), and Swedish Health Services (Protocol #: 1306964). Participants gave informed consent to participate in the study before taking part.

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