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► **To cite this version:**

Nasreddine Nouri, Marc Ferrigno, Thomas Personnic, Fouzi Bala, Martin Bretzner, et al.. Real-World Thrombectomy Using the Sofia Catheter. *World Neurosurgery*, 2019, 122, pp.e1247 - e1251. <10.1016/j.wneu.2018.11.023>. <hal-03486483>

HAL Id: hal-03486483

<https://hal.science/hal-03486483v1>

Submitted on 20 Dec 2021

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Real-world thrombectomy using the Sofia catheter

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Key words: Thrombectomy; Stroke; Catheter

Real-world thrombectomy using the Sofia catheter

ABSTRACT

Background We aimed to study the safety and performance of real-world thrombectomy using the Sofia catheter in our comprehensive stroke center.

Methods We conducted a cohort study from a prospective clinical registry of consecutive stroke patients treated by mechanical thrombectomy (MT) between March 2016 and September 2017. Baselines clinical and imaging characteristics, recanalization rates, complications and clinical outcomes were analyzed.

Results: Among the 140 patients included, 54 were treated using aspiration first, 64 were treated using aspiration and stent-retriever straightaway and 22 were treated with Sofia as a rescue device. Successful recanalization (mTICI2b/3) was achieved in 82.1% patients and good outcome in 34.3%. Symptomatic intracranial hemorrhage occurred in 7.1% and mortality in 25%.

Conclusion: In our single center experience, thrombectomy using the Sofia as an intermediate or aspiration catheter provided high recanalization rates under the everyday conditions.

Introduction:

Mechanical thrombectomy (MT) with stent-retriever is the new standard of care for patients with anterior circulation acute ischemic stroke with large vessel occlusion (AIS-LVO) ¹. Recent studies reported high recanalization rates, shorter recanalization time and reduced cost using large bore aspiration catheters as first line recanalization device ^{2,3}. Other endovascular strategies have been described using a combined approach with a stent-retriever and a distal aspiration catheter ^{4,5}. The Sofia catheter (MicroVention Inc, Tustin, CA, USA) is an intermediate and aspiration catheter designed for the management of AIS -LVO. We aimed to assess the performance and safety of the SOFIA catheter in the setting of real-world thrombectomy in a single center comprehensive stroke center.

Methods:

Study design

We conducted a cohort study from the prospective clinical registry of consecutive stroke patients treated by MT in our comprehensive stroke center. The IRB approved the study on December 21st, 2010 (n° 10.677). Patients or their relatives gave their informed consent to participate.

Population

All AIS-LVO patients who underwent MT with the Sofia catheter between March 2016 and September 2017 at a single academic comprehensive stroke center were included for analysis. Eligibility criteria for IV thrombolysis (IVT) and MT were previously published ⁶. Upon admission, patients underwent brain MRI with intracranial time-of-flight MR-angiography (TOF-MRA) as first line imaging (or CT / CTA, if presenting a MR contraindication). A follow-up brain MRI was routinely performed 24 to 36 hours after treatment.

Endovascular Procedure

MT procedures were usually performed under conscious sedation, using a transfemoral approach. An initial diagnostic cerebral angiogram was performed to assess intracranial clot location (M1 or M2 - middle cerebral artery, intracranial internal carotid artery). A 6-French long introducer sheath (Flexor Shuttle Select, Cook, Bloomington, Indiana, USA) was placed in the internal carotid artery. The Sofia catheter was placed in contact with the clot in a wedge position over a 0.021'' microcatheter and a 0.014'' guidewire, the operator could choose between a 5-Fr or 6-Fr Plus Sofia catheter. Choice between Sofia 5F and Sofia Plus 6F catheters was based on operator's preferences, thrombus location and size of the target artery. As a consequence, the Sofia 5F catheter was preferred for cases of distal M1 or M2 occlusions, and the Sofia Plus 6F catheter for cases of ICA or proximal M1 occlusions. Clot removal was performed using contact aspiration as the first line treatment (aspiration first group, ADAPT) or in conjunction with a stent-retriever (aspiration & stent-retriever group, SOLUMBRA) depending on the operator's choice. Aspiration was always performed using a dedicated mechanical pump. In case of tandem occlusion, treatment of the extracranial ICA could involve balloon angioplasty or stenting.

Clinical data collection

Basic demographic characteristics, including vascular risk factors and vascular history, were prospectively collected. Initial stroke severity was evaluated using the National Institutes of Health Stroke Scale (NIHSS) by stroke neurologists upon admission. Times of symptom onset, groin puncture and recanalization were recorded. The etiology of stroke was determined using the TOAST classification⁷. Symptomatic intracerebral hemorrhage (sICH) was defined according to ECASS-2 criteria⁸. Scores on the modified Rankin scale (mRS) were assessed at 3-months by a stroke neurologist through formal, structured in-person

interview⁹. For patients who did not undergo the visit with the neurologist, a mRS score was obtained by telephone contact with the patient or a close relative.

Imaging data collection

All images were reviewed by neuroradiologists blinded to clinical data. The extent of ischemia was estimated using DWI-ASPECT scores on baseline imaging. Intracerebral hemorrhage (ICH) on day-1 imaging was analyzed according to the ECASS criteria adapted to MRI⁸⁻¹⁰. Clot location (M1-MCA, M2-MCA, or intracranial ICA, tandem or extracranial ICA) was assessed on conventional angiography images and reports. Recanalization was rated on the basis of findings on post procedural conventional angiography using the modified Thrombolysis In Cerebral Ischemia (mTICI) scale. Successful recanalization was defined as a grade of 2b (50 to 99% reperfusion) or 3 (complete reperfusion) on the mTICI scale¹¹. First pass effect was defined as a complete mTICI3 recanalization of the downstream territory after a single pass of a device and no use of rescue therapy. Procedure-related adverse events were recorded.

Outcomes

The primary end-points were the rate of successful recanalization of the target intracranial artery (mTICI 2b or 3), complete recanalization (mTICI3), and the incidence of procedure related complications within 24 hours after the procedure. Secondary outcomes were the rate of good functional outcome at 3 months (defined as a mRS score of 0 to 2 or similar to the prestroke mRS¹²), sICH and mortality.

Statistics

Continuous variables were expressed as mean (standard deviation, SD) or as median (interquartile range, IQR) in cases of non-normal distribution. Normality of distributions was assessed using histograms and the Shapiro-Wilk test. Categorical variables were expressed as frequencies (percentages). Statistical analyses were performed using SPSS version 25 (SPSS Inc., Chicago, IL, USA).

Results:

Population

Among the 405 anterior-circulation AIS patients treated by MT during the study period, we identified 140 consecutive patients treated with the Sofia catheter. Patients demographics and basic clinical baseline characteristics are reported in **Table 1**. Overall, the median age was 73 years (IQR, 60 - 83), 52.9% were female (74/140), 77.9% (109/140) had a pre-stroke mRS 0-1, median initial NIHSS was 19 (13 to 24), and 99/140 (70.7%) patients had an ASPECT score 6 -10 on initial imaging. The intracranial occlusion site was M1-MCA in 78/140 (55.7%), M2-MCA in 24/140 (17.1%), intracranial ICA in 20/140 (14.3%), tandem occlusion in 15/140 (10.7%), and extracranial ICA in 3/140 (2.1%) patients. IV thrombolysis was administered to 96/140 (68.6%) patients prior to MT. Mean time from stroke recognition to groin puncture was 242 min (SD, 75) and 39 patients (27.9%) patients were admitted for a wake-up stroke. The following aspiration catheters were employed: Sofia 5 Fr (71.4%, n=100) and Sofia Plus 6 Fr (28.6%, n=40).

Primary outcomes

Angiographic outcomes are presented in **Table 2**. Successful recanalization (mTICI \geq 2b) was achieved in 82.1% (115/140) of patients. Complete recanalization (mTICI 3) was achieved in 69/140 (49.3%) patients, with a 31.4% (44/140) first pass effect. The Sofia was successfully

advanced in contact with the clot in 98.0% (137/140). Median time of procedure was 32 min (20 to 51) in patients treated with Sofia as first line device.

The ADAPT technique was experienced in 54/140 (38.6%) patients. Successful recanalization was achieved with this strategy in 42/54 (77.8%) after a median procedural time of 29 min (range 9 to 60). However, a stent-retriever was judged necessary in 12/54 (22.2%) of these patients because of insufficient recanalization after first-line direct aspiration.

The SOLUMBRA technique was used as the first line strategy in 64/140 (45.7%) patients. It resulted in successful recanalization in 54/64 (84.4%) patients after a median procedural time of 39 min (22 to 61). The first pass effect was 37.0% with the ADAPT technique and 26.6% with the SOLUMBRA technique.

The Sofia catheter was used as a rescue device in 22/140 (15.7%) patients after failed attempt (2 passes or more) of stent-retriever thrombectomy. It resulted in successful recanalization in 19/22 (86.4%) patients.

Procedure-related complications occurred in 23/140 patients (16.4%): 11 (7.9%) groin puncture hematoma, 3 (2.1%) iatrogenic ICA dissection, 2 (1.4%) intracranial perforation, 1 (0.1%) direct carotido-cavernous fistula, and 6 (4.3%) cases of distal emboli in a new territory.

Secondary outcomes

mRS scores were available for all patients (no missing data). In the overall population, 48/140 (34.3%) patients achieved good functional outcome at 3 months, and 35/140 (25.0%) patients died. Symptomatic intracranial hemorrhage (sICH) occurred in 10/136 (7.1%) patients who underwent day-1 follow-up imaging.

Discussion

The dramatic increase in the number of patients treated by MT since the publication of MR CLEAN ¹³ in 2014 has been associated with the development of new recanalization devices, such as large bore aspiration catheters, which require rigorous evaluation of safety and efficacy. In the ASTER trial ², contact aspiration with the Penumbra system has proven non inferiority compared with stent retriever but only a few studies have evaluated MT with the Sofia reperfusion catheter ¹⁴⁻¹⁶. In our single comprehensive stroke center, we aimed to assess safety and efficacy of this novel reperfusion catheter in the setting of real-world clinical practice.

The Sofia catheter reached the clot in all but 3 cases (98% success), which is in accordance with the literature ¹⁵ and highlights the trackability of the device, allowing an easy access to the occlusion site.

Overall, we showed a 82.1% rate of successful recanalization. Three recent retrospective case series of stroke patients treated with the Sofia catheter ¹⁴⁻¹⁶ exhibited 96.5% (n=85), 86.9% (n=115), and 90.2% (n=41) rates of successful recanalisation which appear to be slightly higher than our findings (**Table 3**). However, these studies did not include stroke patients with tandem occlusion which are considered as more challenging cases with lower successful recanalization rates ¹⁷.

Our study showed 34.3% patients with good outcome at 3 months and 25.0% of mortality. These results are similar to outcomes reported in MR CLEAN ¹⁸ (32.6% mRS 0-2 and 21% death) despite larger selection criteria. In our center as we included 22% of patients with prestroke mRS ≥ 2 , and 29% of patients of low ASPECTS scores (0-5).

We observed 3 cases of iatrogenic ICA dissections that occurred in 2/3 patients with severe vascular tortuosity. The 2 cases of intracranial artery perforations were concomitant with removal of a stent retriever pinched in the aspiration catheter. In one of the two cases, patient died within 24 hours. Thrombus migration in a new vascular territory occurred in 4.3% of

cases, which seems lower than previously reported in recent trials (6% in EXTEND-IA ¹⁹ , 15.6% in MR CLEAN ¹⁸). A iatrogenic direct carotid-cavernous fistula occurred in a patient with severe vascular tortuosity treated with a stent-retriever and a 6-Fr Sofia Plus catheter. It remained asymptomatic.

The limitations of this study include the monocentric design and the absence of independent core-lab assessing the clinical and imaging features. Since this is a non-randomized study, we acknowledge selection bias in the comparison between the 2 techniques (ADAPT vs SOLUMBRA) which remains descriptive. However, this is the largest case series of stroke patients treated with the Sofia catheter, with data extracted from a prospective hospital based registry.

Conclusion:

Thrombectomy with the Sofia as an aspiration or intermediate catheter appeared to be safe and provided high recanalization rates. Our single center experience showed some evidence for safety and efficacy of the Sofia catheter in the treatment of AIS-LVO patients.

Declarations of interest: None

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Table 1: Patients demographics and baseline characteristics

Characteristics	Overall (n=140)
Demographics and medical history	
Age, yr, median (IQR)	73 (60 to 83)
Pre stroke mRS 0-1	109 (77.9%)
Female	74 (52.9%)
Hypertension	92 (65.7%)
Diabetes	39 (27.8%)
Hypercholesterolemia	62 (44.2%)
Former or current smoking	56 (40.0%)
Current stroke event	
Admission NIHSS, median (IQR)	19 (13 to 24)
Wakeup stroke	39 (27.9%)
ASPECTS 6 – 10	99 (70.7%)
Intracranial Occlusion site	
- M1-MCA	78 (55.7%)
- M2-MCA	24 (17.1%)
- Intracranial ICA	20 (14.3%)
- Tandem occlusion	15 (10.7%)
- Extracranial ICA	3 (2.1%)
Stroke etiology	
- TOAST 1 (atherosclerosis)	10 (7.1%)
- TOAST 2 (embolism)	70 (50.0%)

- TOAST 3 (other known cause) 11 (7.8%)
- TOAST 4 (unknown) 49 (35.0%)

Revascularization procedures

IV thrombolysis prior MT	96 (68.6%)
Conscious sedation	140 (100%)
Onset to puncture, min, mean (SD)	242 (75)

Values are number (%), mean (SD) or median (IQR).

Abbreviations: ICA, internal carotid artery ; IVT, intravenous thrombolysis ; MT, mechanical thrombectomy ; MCA, middle cerebral artery; IQR, interquartile range

Table 2: Procedural characteristics and angiographic outcomes

	Overall	ADAPT	SOLUMBRA	Rescue
Population	140	54 (38.6%)	64 (45.7%)	22 (15.7%)
Occlusion sites				
<i>M1-MCA</i>	78 (55.7%)	28 (51.9%)	36 (56.3%)	14 (63.6%)
<i>M2-MCA</i>	24 (17.1%)	15 (27.8%)	8 (12.5%)	1 (4.5%)
<i>Intracranial ICA</i>	20 (14.3%)	7 (13.0%)	9 (14.1%)	4 (18.2%)
<i>Tandem</i>	15 (10.7%)	3 (5.6%)	10 (15.6%)	2 (9.1%)
<i>Extracranial ICA</i>	3 (2.1%)	1 (1.9%)	1 (1.6%)	1 (4.5%)
Outcomes				
<i>mTICI 3</i>	69 (49.3%)	25 (46.3%)	30 (46.9%)	14 (63.6%)
<i>mTICI 2b-3</i>	115 (82.1%)	42 (77.8%)	54 (84.4%)	19 (86.4%)
Time of procedure, min median (IQR)	32 (20-51)	29 (9-60)	39 (22-61)	NA
First pass effect	44 (31.4%)	20 (37.0%)	17 (26.6%)	NA

Values are number (%) or median (IQR).

Abbreviations: ICA, internal carotid artery ; MCA, middle cerebral artery; IQR, interquartile range; mTICI, modified thrombolysis in cerebral infarction.

Table 3: Safety profiles of the Sofia catheter in stroke treatment

Study	Catheter	Anterior circulation	TICI 2b/3	Successful placement	Complications
<i>This study</i> <i>n=140</i>	Sofia 5F	100%	82.1%	91.8%	Embolus (4.3%)
	Sofia 6F Plus				sICH (7.1%) Dissection (2.1%) Perforation (1.4%)
<i>Möhlenbruch et al.</i> <i>n=85</i>	Sofia 6F Plus	94.1%	96.5	91.8%	Embolus (4.7%) sICH (4.7%)
<i>Stampfl et al.</i> <i>n=115</i>	Sofia 5F	84.3%	86.9%	96%	Embolus (2.6%)
<i>Shallwani et al.</i> <i>n=41</i>	Sofia 6F Plus	97.5%	90.2%	92.7%	Embolus (4.8%) Dissection (2.4%) Perforation (7.3%)

sICH: Symptomatic intracranial Hemorrhage, Embolus : Thrombus migration to a new vascular territory, Dissection : cervical artery dissection, Perforation : intracranial artery perforation.