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Endovascular Stroke Therapy Focused on Direct Clot Aspiration Using the SOFIA™ Catheter for Acute Ischemic Stroke

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ABSTRACT

AIM: To report our experience of mechanical thrombectomy using the SOFIA™ catheter, in terms of its effectivenessicacy and safety.

MATERIAL and METHODS: Acute ischemic stroke patients with large vessel occlusions who underwent mechanical thrombectomy, with the SOFIA™ aspiration catheter as the first-line approach, were retrospectively identified. For all patients, the data, including reperfusion success (modified Thrombolysis in Cerebral Infarction [mTICI]), procedural details, clinical status at the baseline and post-discharge at 90 days, and complications, were analysed.

RESULTS: During the study period (January 2017–July 2020), 73 patients underwent endovascular thrombectomy. The mean age and the baseline National Institutes of Health Stroke scores were 72 (41–83) and 16 (12–25), respectively. Successful reperfusion (mTICI≥2b–3) was obtained in 80.8 % (n=59) of the patients. Using ADAPT, a first-pass effect was achieved in 63.01% (n=46) of the patients. Rescue stent retriever (SRV) had to be utilized in 36.98% (n=27) of the patients; all presented with a favourable clinical outcome (modified Rankin score ≤0-2) at 90 days. The complication rate in the study was 13.7% (n=10).

CONCLUSION: The contact aspiration approach with SOFIA™ catheters as a first-line device appears to be fast, safe, and effective. Our results were comparable to the findings of other series. In the case of insufficient response on contact aspiration, we could easily modify the SOFIA™ catheter approach for an additional stent retriever rescue treatment.

KEYWORDS: Ischemic stroke, Thrombectomy, Direct aspiration first pass technique (ADAPT), SOFIA™ catheter

ABBREVIATIONS: AIS: Acute ischemic stroke, **ADAPT:** A direct aspiration first pass technique, **CTA:** Computed tomography angiography, **FPE:** First-pass effect, **ICA:** Internal carotid artery, **MCA:** Middle cerebral artery, **NIHSS:** National Institutes of Health Stroke Scale, **mRS:** Modified Rankin scale, **mTICI:** Modified thrombolysis in cerebral infarction, **rtPA:** Recombinant tissue plasminogen activator

INTRODUCTION

Recent prospective randomized acute stroke trials have consistently emphasized the beneficial role of mechanical thrombectomy (4,7,17). In general, mechanical thrombectomy is achieved by stent retrievers (SRV) or a direct aspiration first pass technique (ADAPT), including direct aspiration of clots at the first pass via large-bore aspiration catheters (8,14,18,20). After the publication of randomized trials comparing SRV and contact aspiration (ASTER; COMPASS), ADAPT is now considered a first-line strategy for mechanical thrombectomy (11,19). This approach

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appears to be fast and cost-effective. However, during mechanical thrombectomy, sometimes an additional SRV may be required if sufficient response cannot be accomplished by contact aspiration alone. As a highly effective distal aspiration catheter offering soft torque properties, SOFIA™ (MicroVention, Tustin, CA, USA) is a newer alternative. The distal inner lumen of the SOFIA™ catheter is 0.055" in 5 French (5F) and 0.070" in 6F Plus versions. Its hybrid design combined with a unique braid and coil construction optimizes intracranial access. Previous comprehensive studies have proved that SOFIA™ is a safe and effective catheter (8,13). Herein, we report our experience of thrombectomy using the SOFIA™ catheter at a single high-volume centre.

MATERIALS and METHODS

Study Design and Selection of Samples

In this study, we retrospectively analysed 95 patients with acute ischaemic stroke (AIS) who underwent endovascular thrombectomy between January 2017–July 2020. Ethical approval for the study was obtained from the Institutional Ethics Committee (20-1416). Twenty-two of the 95 patients were treated by SRV alone; thus, they were excluded from the study. The remaining 73 AIS patients, in whom mechanical thrombectomy was performed using first-line ADAPT with a SOFIA™ catheter, comprised the study group. In 27 -of the 73 patients, the SRV system had to be used because of insufficient response.

Data Collection and Outcome Assessment

The data, including demographic characteristics of the patient, the time of arrival, National Institutes of Health Stroke Score Scale (NIHSS), computed tomography (CT) findings, digital subtraction angiography (DSA) findings, treatment method, post-procedure DSA findings, modified Thrombolysis in Cerebral Infarction (mTICI) score, NIHSS scores post-procedure and at discharge, were evaluated. Control CT was performed in the 24th hour after the procedure, postoperatively, and at discharge. After the endovascular treatment, the successful reperfusion threshold was angiographically set at "mTICI ≥2b–3". TICI categories are detailed in Table I. Modified Rankin score (mRS) was evaluated at the third clinical follow-up. An mRS≤ 0–2 at 90 days was considered a favourable clinical outcome.

Endovascular Treatment Procedure

Treatment decisions for patients with AIS were made by the stroke team (neurologist, interventional neuroradiologist, neurosurgeon). In selected patients, whose duration of symptoms was less than 4–5 hours, intravenous recombinant tissue plasminogen activator (rt-PA) was used, provided the patients and who had no history of anticoagulant use, and had their a baseline CT showed ing ed no evidence of haemorrhage, and pre-treatment blood pressure wasof <185/110.

In accordance with our institutional anaesthesia protocol, we usually performed the procedure under local anaesthesia. However, in rare circumstances, it was converted to general anaesthesia. In all cases, we initially performed mechanical thrombectomy using the ADAPT technique with the SOFIA™ catheter. First, a 6-8F guide catheter was placed in the internal carotid artery (ICA). Second, the SOFIA™ catheter was introduced and moved until the occlusion. To provide backup support and pass-through the occluded segment, we used either a 0.021–0.027" microcatheter or a standard 0.014" micro-guidewire (Synchro 14, Stryker, Fremont, California, USA). Occasionally, we could pass through the thrombotic occlusion using the SOFIA™ catheter alone. Once the SOFIA™ catheter was coaxially through the thrombotic segment, negative aspiration was initiated manually using a 50cc syringe. While maintaining negative aspiration, the SOFIA™ catheter was slowly withdrawn. If on control angiography, results were not satisfactory, additional attempts were made. In some cases, where thrombo-aspiration failed, the procedure was repeated using SRV.

Statistical Analysis

The continuous parameters with normal distribution were compared using Welch's t-test, and those with non-normal distribution were compared using the Mann-Whitney U test. Categorical variables were compared using Fisher's exact probability test. SPSS 18.0 Software version was used for all statistical analysis. The statistical significance was set at a α value of 0.05 and a p-value of <0.05.

Table I: Modified Thrombolysis in Cerebral Infarction (mTICI) Categories

Category	Definition
Grade 0	no flow, no recanalization/perfusion
Grade 1	minimal recanalization (<20%)
Grade 2	partial recanalization
Grade 2 a	perfusion of <50% of the MCA distribution
Grade 2b	partial perfusion with incomplete distal branch filling of > 50–99% or complete filling but the filling is slower than normal
Grade 3	full perfusion with filling of all distal branches, including M3, M4, normal flow

RESULTS

In this study, a total of 73 patients underwent thrombo-aspiration; mechanical thrombectomy with the SOFIA™ aspiration catheter was used as the initial treatment method. Of the 73, 40 patients Forty(54.8%) were male and their median age was 72 (range, 41–83) years. The occluded segments were localized in the following regions: anterior circulation (n=68; 93.2%), posterior circulation (n=5; 6.8%), M1 segment of the middle cerebral artery (MCA; n=A)35; 47.9%), MCA M2 (n=7; 9.6%), L-type of ICA terminus occlusion (n=in 26; 35.6 %), and basilar artery (n=5; 6.8%). The median baseline NIHSS score was 16 (range, 12–25), and the median Alberta Stroke Program Early CT (ASPECT) score was 7 (range, 6–9).

Comparison of baseline characteristics (Table II) between the "ADAPT" group and "ADAPT+SRV" group revealed no significant differences. Eligible patients received rt-PA (n=11, 15%) as a bridging therapy. Revascularization outcomes, procedural timings, complications as well as clinical outcomes are summarized in Table III. The mean time from symptom onset to groin puncture was 182 (± 65) min. The mean procedure time from groin puncture to recanalization was 42 (± 3.23) min for all patients; it was 32 (13–76) min in the "thrombo-aspiration alone" group and 48 (36–236) min in the "ADAPT+SRV" group. In 46 patients (63.01%), direct contact aspiration with the SOFIA™ catheter alone provided a reperfusion score of mTICI≥2b–3. While in 27 patients (36.98%), SRV had to be performed because of insufficient aspirate on using ADAPT technique; successful perfusion could be achieved by adding SRV to thrombo-aspiration with the SOFIA™ catheter. Successful reperfusion rate (mTICI≥2b-3) was 94.4% in all ADAPT patients.

Diagnostic angiography revealed an mTICI score of 0 and 1 in 67 patients (91.8%) and 5 patients (8.2%), respectively. After the thrombectomy, a perfusion grade of mTICI≥2b–3 was established in 62 (85%) patients. The procedural complications were observed in 10 (13.7%) patients: embolization of new territory (ENT), vessel perforation, and inferior trunk dissection of the M2 segment of MCA were observed in three (4.1%), six (8.2%) and one (1.4%) patients in the ADAPT+SRV group.

Here, mechanical thrombectomy was performed using ADAPT and/or stent retriever. The SOFIA™ catheter was successfully guided to the thrombo-embolus area of thrombotic occlusion in 94% of the patients (Figure 1A-E, 2A-E).

The "ADAPT" with SOFIA™ catheter group had a significantly shorter endovascular procedure time than the "ADAPT+SRV" group (24 min [13–76] *vs.* 58 min [36–236]). Forty-four (81%) patients produced outcome data, 63.3% of whom had a favourable clinical outcome at 60–90 days of follow-up (mRS≤ 0-2) while 41% had a poor result (mRS≥3-5). In-hospital mortality was observed in 15% (n=11) of the patients.

Table II: Patient Baseline Characteristics (n=73)

Characteristic	All (n=73)	SOFIA alone	SOFIA + SRV	p	Test
Age (mean)(yr)	72 (41-83)	73 (41-79)	71 (48-83).	0.3	Mann-Whitney
Men *n/N* (%)	40/73 (54.8%)	22/46 (49%)	14/27 (52%)	0.8	Fisher's exact
ASPECTS (median)	7 (6-9)	7 (7-9).	7 (6-8)	0.6	Mann-Whitney
Baseline NIHSS median (range)	16 (range 12-23)	17 (13-23)	16 (12-20)	0.5	Mann-Whitney
Intravenous rtPA	22/73 (33%)	13/46 (30%)	9/27 (36%)	0.8	Fisher's exact
Onset to groin puncture (median)	182(± 65 min)	189 (± 66)	178 (± 66)	0.6	Unpaired t-test

Table III: Procedural Data, Complication and Outcomes

Outcomes	All (n=73)	SOFIA alone	SOFIA + SRV	p	Test
Procedure time, median (range)	42 min (± 3.23)	24 min (13-76)	58 min (36-236)	**0.0001**	Mann-Whitney
mTICI≥2b/3.	62/73 (85%)	28/46 (61%	20/27 (74%)	0.4	Fisher's exact
sICH *n/N* (%)	7/73 (9.6%)	0/46 (0%)	7/27 (26%)	**0.04**	Fisher's exact
ENT *n/N* (%)	3/73 (4.1%)	1/46 (2%)	2/27 (7%)	0.8	Fisher's exact
NIHSS at discharge median (range)	8 (2-15)	7 (2-14)	8 (4-15)	0.8	Mann-Whitney
mRS≤ 0-2 at discharge	22/73 (30%)	12/46 (27%)	9/27 (34%)	1	Fisher's exact
mRS≤ 0-2 90 days, *n/N* (%)	33/73 (46%)	20/46 (43%)	14/27 (52%)	0.8	Fisher's exact
Mortality *n/N* (%)	11/73 (15%)	7/46 (15%)	4/27 (15%)	1	Fisher's exact

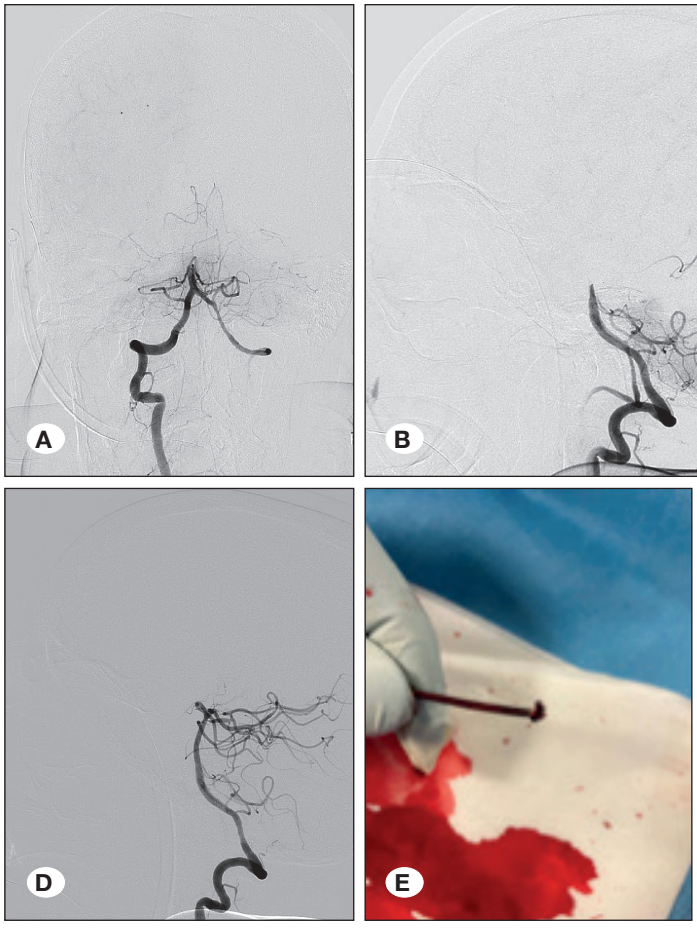

Figure 1: Pre-treatment angiography shows total occlusion of the basilar artery. Angiogram and illustration of the procedure show the occlusion site **(A, B).** Immediate post-procedural angiography shows complete (TICI 3) revascularization **(C, D).** The whole clot retrieved from the occlusion by SOFIA aspiration catheter **(E).**

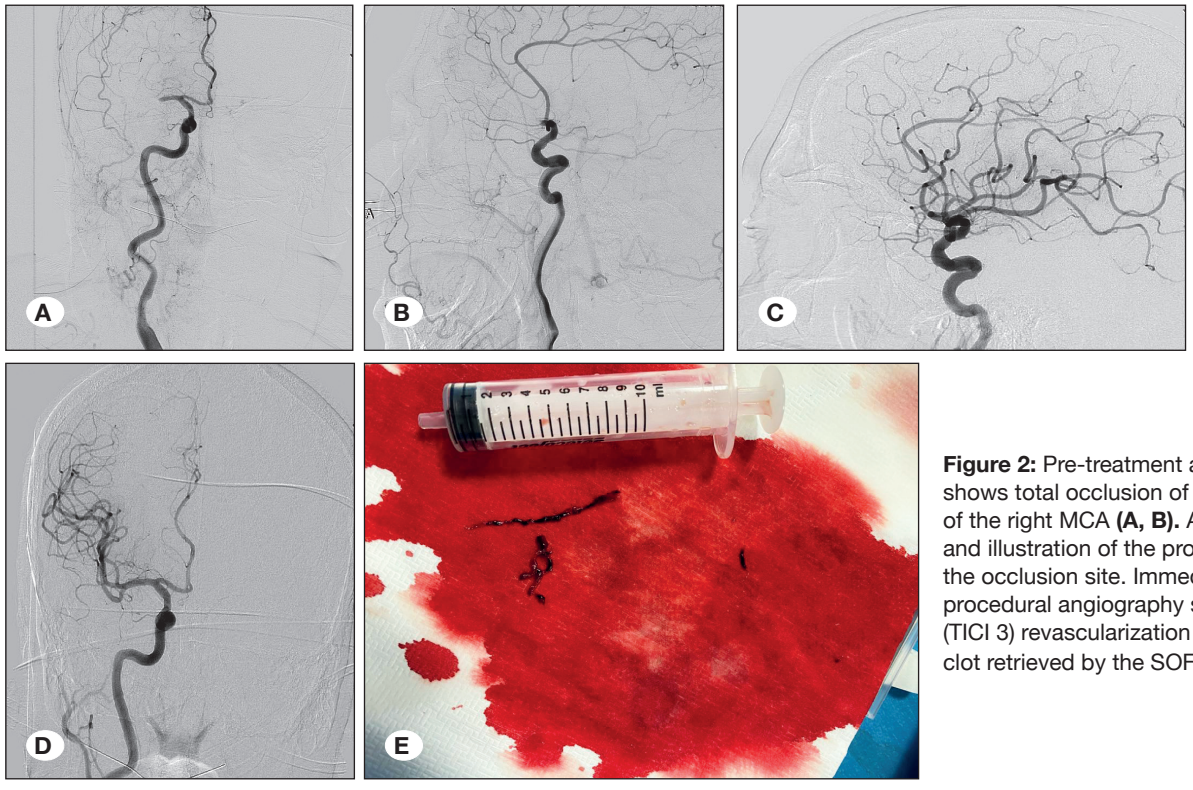

Figure 2: Pre-treatment angiography shows total occlusion of the M1 segment of the right MCA **(A, B).** Angiogram and illustration of the procedure show the occlusion site. Immediate post-procedural angiography shows complete (TICI 3) revascularization **(C, D).** A large clot retrieved by the SOFIA™ catheter **(E).**

DISCUSSION

Recently, mechanical thrombectomy for AIS, caused due to large vessel occlusion, has garnered a lot of attention. Several randomized trials (1,4,7,17) have reported better clinical outcomes with thrombectomy than intravenous thrombolytics.

The first-pass effect (FPE), by definition, refers to complete recanalization with a single thrombectomy device pass. According to Zaidat et al., FPE is a strong prognostic factor for a favourable clinical outcome (22). For achieving FPE, (contact aspiration and SRV are the competing techniques in terms of clinical efficacy and safety. Sometimes, an SRV procedure may be added to contact aspiration as a rescue approach. However, two techniques should be used together, when necessary, to improve the patient's prognosis.

In the case of a large vessel occlusion, thrombectomy for a prompt and effective recanalization desired. Large bore distal aspiration catheters are attractive alternatives for contact aspiration during mechanical thrombectomy. SOFIA™ is a newly approved distal aspiration catheter with encouraging results. SOFIA™ 6F Plus catheters are specially designed for aspiration thrombectomy. They have a unique design with excellent navigability, torque, and tractability. A larger inner lumen (diameter 0.070") than its competitors provides it with more aspiration power, which that enables easy aspiration of large and multiple clots, enhancing fast and efficient recanalization and reperfusion of the vessel (21).

Contact aspiration with the SOFIA™ catheter has the potential advantages of being faster (less procedural time) and more cost-effective in comparison to the other mechanical thrombectomy procedures. In this study, the procedural time (groin puncture to recanalization) for the "ADAPT" with SOFIA™ group was 32 (13–76) min, which was comparable to that observed in previous literature (19). (In our cohort, on an average, three attempts were made using ADAPT. Although several catheters which can be utilized for contact aspiration, evidence indicates that the use of distal aspiration catheters with larger lumen may result in shorter reperfusion times, higher FPE, and a lower rate of SRV rescue treatment (2).

In the recently published randomized trials, ASTER and COMPASS (11, 19), similar rates of FPE were reported with both contact aspiration and SRV. In our study, FPE was achieved in 12 out of the 44 patients who underwent thromboaspiration with SOFIA™; these results were in agreement withto the findings reported previously in the literature (11,22).

In terms of the location of the thrombotic occlusion, we agreed were in consensus with the earlier parallel literature (8,13). Thrombotic occlusion in the anterior circulation (93.2%) was more common than in the posterior circulation (6.8%). Similar to other studies, we also had a higher first-attempt success rate in the case of MCA occlusions (8). The rate of symptomatic intracranial haemorrhage was 9.6% in our study, which was similar to that observed previously parallel (9,16).

All symptomatic intracranial haemorrhages occurred in the "ADAPT+SRV" group, indicating the complexities associated with an extended approach. In this study, ENT occurred in 4.1% of the patients, a rate similar to that stated in the literature (2,10,11,16).

Successful reperfusion is a significant predictor of a favourable outcome following thrombectomy for acute large-vessel occlusions (12,15). The mTICI score was developed from the TICI score, which was first proposed in 2003 by Higashida et al. (6), to evaluate pre- and post-MT cerebral perfusion on cerebral angiography (36). Recent controlled trials indicate that thrombectomy is a safe and efficient endovascular procedure; it is technically successful as long as an mTICI score of 2b–3 reperfusion is achieved (5). Here, we also could achieve reperfusion grades (mTICI≥2b–3) similar to that observed in previous studies on the SOFIA™ 5F-6F contact aspiration method (8,21).

In our study, the groin puncture-to-recanalization time in the "ADAPT+SRV" group (48 [36–236] min) was longer – min than in the "ADAPT" group (32 [13–76] min). Kowoll et al. and Kabbasch et al. reported similar findings (8,10). (Despite a delay in recanalization in the ADAPT+SRV group, we found similar rates of favourable clinical outcomes (mRS≤0–2 at 90 days) in both the "ADAPT" group and "ADAPT+SRV" group (49% *vs*. 57%).

Limitations

Retrospective design, single centre experience were major limitations of the present study. In addition, the sample size was relatively small. The patients were not consecutively enrolled and no randomisation was done. A mMajor proportion of the cases were anterior and posterior circulation occlusions.

CONCLUSION

The SOFIA™ catheter is a highly efficient, safe, and effective thrombectomy device. High rates of successful reperfusion could be achieved with a first-line thrombectomy strategy using SOFIA™ catheters. These may serve as a backup device whenever the procedure needs to be extended with an SRV system.

AUTHORSHIP CONTRIBUTION

Study conception and design: IA

Data collection: BS, MHS, BA

Analysis and interpretation of results: BS, AK

Draft manuscript preparation: IA, BS

Critical revision of the article: ED, GO

Other (study supervision, fundings, materials, etc...): ED, BS, AK

All authors (IA, BS, AK, ED, BA, MHS, GO) reviewed the results and approved the final version of the manuscript.

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