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ORIGINAL ARTICLE - VASCULAR NEUROSURGERY - ISCHEMIA

Frontline contact aspiration thrombectomy using SOFIA catheter for acute ischemic stroke: period-to-period comparison with Penumbra catheter

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Abstract

Background Recent aspiration thrombectomy devices tend to have a more flexible distal tip and larger bore for easy target access and effective reperfusion. Here, this study primarily focused on the efficacy and safety of the SOFIA catheters when it was used as a frontline contact aspiration thrombectomy (CAT) tool for acute intracranial large vessel occlusion in comparison with the data from a period when the Penumbra catheter was used.

Methods The subjects comprised 189 patients who underwent CAT (90 with Penumbra Max family and 99 with SOFIA/SOFIA plus). Patients' data were retrospectively analyzed to evaluate overall clinical and angiographic outcomes and compared between the devices.

Results Baseline characteristics were similar between groups. But, intravenous alteplase was more frequently administered in the Penumbra group (43.3% vs. 29.3%, $p = 0.045$), while incidence of ICA occlusion was higher in SOFIA group (18.9% vs. 38.4%, $p = 0.013$). The modified thrombolysis in cerebral infarction 2b-3 of reperfusion was 94.4% for the Penumbra group and 92.9% for the SOFIA group ($p = 0.656$). The first-pass effect was more frequently achieved in the SOFIA group (20.0% vs. 39.4%, $p = 0.004$) and endovascular procedure time was significantly shorter (55.5 min vs. 36 min, $p < 0.001$). However, clinical outcomes did not differ significantly regarding mortality (11.1% vs. 6.1%, $p = 0.213$), hemorrhagic complications, and mRS 0–2 at 3 months (63.3% vs. 58.6%; $p = 0.504$).

Conclusion CAT using SOFIA may be safe and comparable to thrombectomy using the Penumbra reperfusion catheter. And, the SOFIA catheter could be advantageous for rapid reperfusion and first-pass effect without any significant complications.

Keywords Acute ischemic stroke · Contact aspiration thrombectomy

Abbreviations

AIS	Acute ischemic stroke
CAT	Contact aspiration thrombectomy
EVT	Endovascular thrombectomy
FPE	First-pass effect
LVO	Large vessel occlusion
SRT	Stent retriever thrombectomy

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Introduction

Several randomized controlled trials (RCTs) have shown the clinical benefit of endovascular thrombectomy (EVT) in patients with acute stroke due to intracranial large vessel occlusion (LVO) [1–5]. In these trials, patients were treated with stent retriever thrombectomy (SRT) in the majority of cases. In addition to SRT, contact aspiration thrombectomy (CAT) using a large-bore aspiration catheter is increasingly performed as one of the major EVT methods around the world [6, 7]. CAT has been shown to be safe and effective for

removal of clots in a recent RCT which compared CAT and SRT as a first-line thrombectomy [8].

In the beginning of CAT, the most common aspiration catheters used were Penumbra reperfusion catheters, from the original Penumbra 032/041/054 family to the Penumbra ACE 068. According to previous studies, improvement in aspiration devices resulted in better angiographic and clinical outcomes for CAT [7, 9–11]. Moreover, several new large-bore catheters, such as SOFIA, Arc, and Catalyst 6, have been introduced recently and have been used for CAT in clinical practice [12–14]. Nevertheless, to date, there have been only a few single-armed, small case series investigating the efficacy and safety of new aspiration catheters.

We originally used Penumbra reperfusion catheters as our frontline CAT device. Once the SOFIA catheter became available, the SOFIA catheter replaced the Penumbra catheter as our frontline CAT device. The aim of this study was to evaluate the efficacy and safety of the SOFIA catheters when it was used as a frontline CAT tool for acute intracranial LVO cases in comparison with the data from a period when the Penumbra catheter was used.

Materials and methods

Patients

The patients were retrospectively reviewed and selected from a prospectively collected institutional stroke registry between October 2015 and September 2017. The inclusion criteria for this study were as follows: (1) acute ischemic stroke (AIS) with occlusion of the intracranial internal carotid artery (ICA), middle cerebral artery (MCA) M1/M2, or basilar artery (BA); (2) arrival at our center within 6 h from symptom onset; and (3) EVT performed using the CAT technique with a Penumbra 3 MAX/ 4 MAX/5 MAX reperfusion catheter (Penumbra, Alameda, CA, USA) or SOFIA/SOFIA PLUS catheter (Soft torqueable catheter Optimized For Intracranial Access, MicroVention, Tustin, CA, USA). The study protocol and design were approved by the local Institutional Review Board.

Endovascular procedure

The institutional criteria for EVT were as follows: (1) a baseline National Institute of Health Stroke Scale (NIHSS) score of 6 or more and pre-stroke modified Rankin Scale (mRS) score of 2 or less; (2) AIS corresponding to large arterial occlusion on CT angiography or MR angiography; and (3) ASPECTS of 6 or more in patients within 6 h from the last normal time, or no evidence of a well-developed parenchymal lesion on fluid-attenuated inversion recovery or T2-weighted imaging in patients within 6 h from the first-found abnormal time. All procedures were performed using a biplane angiography system under conscious sedation. EVT was performed by three experienced neurointerventionalists (Y-WK, D-HK, and Y-SK). Guide catheter was advanced to the accessible portion of target occlusion (anterior circulation: ipsilateral cervical ICA, posterior circulation: distal V2 segment of dominant vertebral artery) We used a 9 Fr balloon-tipped guide catheter (Optimo, Tokai Medical, Aichi, Japan) for anterior circulation stroke and a 6 Fr guide catheter (Envoy; Codman & Shurtleff, Raynham, Massachusetts or Chaperon; Microvention-Terumo, Irvine, CA, USA) for posterior circulation stroke. In period 1 (October 2015 to September 2016), CAT was performed using a Penumbra reperfusion catheter (5MAX/4MAX for anterior circulation occlusion and 3MAX for posterior circulation occlusion). In period 2 (October 2016 to September 2017), a SOFIA catheter was used (SOFIA or SOFIA PLUS for anterior circulation occlusion and SOFIA for posterior circulation occlusion). The SOFIA catheter was introduced as a distal access catheter, which has a soft and pliable distal portion though a large distal inner diameter (SOFIA 0.055″, SOFIA PLUS 0.070″). So, the SOFIA catheter could be advanced to just the proximal end of the occlusion following a coaxial system with a 0.021 microcatheter and 0.014 microwire. After target access with the SOFIA catheter, the microcatheter and microwire were removed and CAT was performed subsequently. If reperfusion was not achieved within three attempts, a rescue strategy with a stent retriever was performed.

Clinical and angiographic data

Clinical characteristics and demographic data were collected from the patients' medical record. The NIHSS was measured at admission, day 1, and day 7. The mRS was assessed at admission and 3 months; favorable clinical outcome was defined as an mRS score of ≤ 2. Successful reperfusion was defined as a modified thrombolysis in cerebral infarction (mTICI) score of 2b or 3 based on the final angiography after EVT [15]. The first-pass effect (FPE) was defined as complete revascularization at the first thrombectomy attempt without rescue treatment, and modified FPE was defined as mTICI 2b-3 of reperfusion at the first thrombectomy attempt without rescue treatment [16]. The mTICI grade was independently evaluated by an interventional neurologist (Y-WK) and neurologist (Y-HH) blinded to the clinical information. The brain CT was obtained after EVT and 24 h after EVT to evaluate hemorrhagic complications. Hemorrhagic complications were determined based on the European-Australasian Acute Stroke Study II classification [17]. Symptomatic intracranial hemorrhage was defined as any hemorrhage with an increase of ≥ 4 points in NIHSS score within 24 h.

Statistics

Statistical analysis was performed using SPSS 22.0 (IBM, Armonk, USA). The chi-squared test or Fisher exact test was used for categorical variables, and an independent *t* test or Mann-Whitney *U* test was used for continuous variables. Binary logistic regression analysis was used to identify independent predictors of favorable clinical outcome at 3 months. Variables with a *p* value less than 0.10 for favorable clinical outcome at 3 months in univariate analysis were analyzed with a binary logistic regression analysis. There were highly correlated variables including FPE, successful reperfusion, and time intervals, such as onset to reperfusion and groin puncture to reperfusion. Therefore, two models were included in binary logistic regression analysis from univariate analysis. In model 1 of binary logistic regression analysis, age, sex, use of intravenous rtPA, baseline NIHSS score, time from onset to reperfusion, successful reperfusion, and smoking were included as possible confounding factors. In model 2, time from onset to groin puncture and FPE (instead of time from onset to reperfusion and successful reperfusion) were analyzed. A *p* value of 0.05 was considered statistically significant.

Results

Of 189 enrolled patients, 90 patients received EVT with a Penumbra reperfusion catheter (Penumbra group) and 99 patients with a SOFIA catheter (SOFIA group). The baseline characteristics in each group are summarized in Table 1. The median age, baseline NIHSS score, and proportion of females were not different between group. Although median time from symptom onset to door did not differ statistically (155.5 min vs. 184 min, $p = 0.374$), intravenous rtPA was more commonly administered in Penumbra group (43.3% vs. 29.3%, $p = 0.045$). The incidence of stroke risk factors, including hypertension, diabetes, dyslipidemia, coronary diseases, smoking, and atrial fibrillation, were not different between groups. Regarding location of target occlusion, the Penumbra group showed a higher proportion of MCA occlusion (57.8% vs. 35.3%). ICA and BA occlusion were more frequent in the SOFIA group (18.9% vs. 38.4%).

Angiographic and clinical outcomes are summarized in Table 2. Final reperfusion without rescue use of a stent retriever was achieved in 70% of patients in the Penumbra group and in 69.7% of patients in the SOFIA group, and their final

Table 1 Baseline characteristics

Variables	Penumbra ($n = 90$)	SOFIA (n = 99)	*p* value
Age, median (IQR)	70 (60.75–76.0)	71 (63–78)	0.276
Female	29 (32.2%)	42 (42.4%)	0.148
NIHSS, median (IQR)	16 (9.75–21.0)	16 (11.0–21.0)	0.540
Intravenous rtPA	39 (43.3%)	29 (29.3%)	0.045
Hypertension	45 (50.0%)	50 (50.5%)	0.945
Diabetes	28 (31.1%)	23 (23.2%)	0.223
Dyslipidemia	34 (37.8%)	51 (51.5%)	0.058
Atrial fibrillation	42 (46.7%)	59 (59.6%)	0.075
Coronary diseases	11 (12.2%)	18 (18.2%)	0.256
Smoking	28 (31.1%)	26 (26.3%)	0.461
Occlusion location			0.013
ICA	17 (18.9%)	38 (38.4%)	
ICA with tandem lesion	13 (14.4%)	12 (12.1%)	
MCA M1	41 (45.6%)	31 (31.3%)	
MCA M2	11 (12.2%)	4 (4.0%)	
Basilar artery	8 (8.9%)	13 (13.1%)	
Multiple	0	1 (1.0%)	
Stroke etiologies			0.127
LAA	29 (32.2%)	23 (23.2%)	
CE	43 (47.8%)	64 (64.6%)	
UE-NE	13 (14.4%)	8 (8.1%)	
UE ME, IE or OE	5 (5.6%)	4 (4.0%)	

CE cardioembolism, *ICA* internal carotid artery, *IE* incomplete evaluation, *IQR* interquartile range, *LAA* large artery atherosclerosis, *MCA* middle cerebral artery, *ME* multiple etiology, *NE* negative etiology, *NIHSS* National Institute of Health Stroke Scale, *OE* other etiology, *rtPA* recombinant tissue plasminogen activator, *UE* undetermined etiology

successful reperfusion rates were similar between groups (98.4% vs. 98.6%, $p = 0.976$). In addition, the SOFIA group revealed a significantly higher rate of FPE (20.0% vs. 38.4%, $p = 0.004$) and modified FPE (24.4% vs. 47.5%, $p = 0.001$). Median time from groin puncture to final reperfusion in the SOFIA group was significantly shorter than the Penumbra group (55.5 min vs. 36 min, $p < 0.001$). However, the rates of final successful reperfusion were similar between groups (94.4% vs. 92.9%, $p = 0.656$). In the safety profile, there were no differences in the rates of downstream distal embolization (14.4% vs. 11.1%, $p = 0.492$) and embolization in uninvolved territory (2.2% vs. 2.0%, $p > 0.999$) during EVT. And, three symptomatic intracranial hemorrhages occurred in each group (3.3% vs. 3.0%, $p > 0.999$). The mortality rates were similar between groups. Favorable clinical outcomes at 3 months were achieved in 63.3% in the Penumbra group and in 58.6% in the SOFIA group.

Binary logistic regression was performed to identify predictive factors for favorable clinical outcomes (Table 3). With highly correlated variables, representative variables considering clinical relevance were included. In model 1, male sex (odds ratio [OR] 2.872, 95% confidence interval [CI] 1.381–5.974, $p = 0.005$), low baseline NIHSS score (OR 0.894, 95% CI 0.840–0.952, $p < 0.001$), successful reperfusion (OR 6.066, 95% CI 1.448–25.414, $p = 0.014$), and time from onset to reperfusion (OR 0.998, 95% CI 0.997–1.000, $p = 0.017$) were significant predictors of favorable clinical outcomes. In model 2, male sex (OR 3.011, 95% CI 1.409–6.433, $p = 0.004$), low baseline NIHSS score (OR 0.878, 95% CI 0.822–0.937, $p < 0.001$), and FPE (OR 5.671, 95% CI 2.374–13.548, $p < 0.001$) were predictors of favorable clinical outcomes.

Discussion

The main findings of this study were that CAT using SOFIA catheters revealed comparable angiographic and clinical outcomes compared with CAT using Penumbra reperfusion catheters. Regarding angiographic outcomes, the SOFIA group revealed a higher incidence of FPE and a faster reperfusion time. This result might be associated with the larger diameter of the SOFIA catheters. A large catheter diameter has some advantages. First, theoretically, the aspiration force of a catheter is

Table 2 Details of endovascular treatment and clinical outcomes

Variables	Penumbra ($n = 90$)	SOFIA ($n = 99$)	p value
Time intervals, median (IQR), min			
Onset to door	155.5 (48.25–404.25)	184 (66.5–415)	0.374
Door to groin puncture	72.5 (57–88.25)	74 (62–88.25)	0.469
Groin puncture to reperfusion	55.5 (34.75–92.25)	36 (20–73)	< 0.001
Guide catheterization to reperfusion	36.5 (16.75–67)	19 (5–51)	0.004
Onset to reperfusion	280 (195.5–508.5)	311 (168.5–563)	0.874
MT strategy			0.964
CAT only	63 (70.0%)	69 (69.7%)	
Switching to Stent retriever	27 (30.0%)	30 (30.3%)	
First-pass effect	18 (20.0%)	39 (39.4%)	0.004
Modified first-pass effect	22 (24.4%)	47 (47.5%)	0.001
Successful reperfusion	85 (94.4%)	91 (92.9%)	0.656
Downstream distal embolization	13 (14.4%)	11 (11.1%)	0.492
Embolization in uninvolved territory	2 (2.2%)	2 (2.0%)	> 0.999[a]
Hemorrhagic complication			0.621
Parenchymal hematoma	6 (6.7%)	4 (4.0%)	
Subarachnoid hemorrhage	0 (0.0%)	1 (1.0%)	
Mixed	1 (1.1%)	2 (2.0%)	
Symptomatic ICH	3 (3.3%)	3 (3.0%)	> 0.999[a]
NIHSS 1D, median (IQR)	6 (2.0–14.0)	8 (2–15.0)	0.259
NIHSS 7D, median (IQR)	2 (1.0–3.0)	2 (1.0–3.0)	0.743
mRS 0–2 at 3 months	57 (63.3%)	58 (58.6%)	0.504
Mortality	10 (11.1%)	6 (6.1%)	0.213

CAT Contact aspiration thrombectomy, *ICH* intracranial hemorrhage, *IQR* interquartile range, *mRS* modified Rankin Scale, *MT* mechanical thrombectomy, *NIHSS* National Institute of Health Stroke Scale

[a] Fisher's exact *T* test

Table 3 Binary logistic regression analysis for favorable clinical outcome at 3 months

Variables	Odds ratio (95% CI)	*p* value
Model 1		
Age (/1 year)	0.987 (0.958–1.018)	0.402
Sex (female)	0.348 (0.167–0.724)	0.005
Intravenous rtPA	1.299 (0.599–2.817)	0.509
Baseline NIHSS	0.894 (0.840–0.952)	<0.001
Time from onset to reperfusion (/minute)	0.998 (0.997–1.000)	0.017
Successful reperfusion	6.066 (1.448–25.414)	0.014
Smoking	1.418 (0.435–1.418)	0.435
Model 2		
Age (/1 year)	0.988 (0.958–1.020)	0.471
Sex (female)	0.332 (0.155–0.710)	0.004
Intravenous rtPA	1.610 (0.727–3.564)	0.241
Baseline NIHSS	0.878 (0.822–0.937)	<0.001
Time from onset to groin puncture (/minute)	0.999 (0.998–1.001)	0.255
First-pass effect	5.671 (2.374–13.548)	<0.001
Smoking	1.517 (0.624–3.689)	0.358

CI confidence interval, *NIHSS* National Institute of Health Stroke Scale, *OR* odds ratio, *rtPA* recombinant tissue plasminogen activator

proportional to its cross-sectional area [18]. Therefore, a large diameter catheter can generate a more intense aspiration force. Second, the contact area between a thrombus and a catheter is also large. This is an important factor for conducting aspiration force through a catheter. These advantages might contribute to the strong wedging and extracting of a thrombus, which may result in a higher incidence of FPE and modified FPE and a faster reperfusion time.

Despite the above-mentioned advantages, delivery of the SOFIA catheter to the target occlusion might be relatively challenging in cases with multiple intracranial atherosclerosis and acute angulation in the ophthalmic ICA. To overcome this obstacle, new aspiration devices have common features, including a soft and flexible distal portion of the catheter. Furthermore, the distal portion of the SOFIA can be shaped using a mandrel. These factors might be associated with improvement in trackability. In this study, we were commonly faced with these obstacles, which could be overcome with a coaxial system and shaping of the distal portion of the SOFIA catheter.

In addition, the SOFIA catheter could be used as a thrombectomy device for posterior circulation occlusive stroke. Considering the diameter of a vertebral artery, we have tried a 6 Fr guide catheter, such as Chaperon (MicroVention, Tustin, CA, USA) or Envoy (Cordis, Miami, FL, USA) in posterior circulation stroke. Under use of a 6 Fr guide catheter, Penumbra reperfusion catheters cannot be introduced due to a large proximal outer diameter (0.080″), except the 3Max reperfusion catheter (proximal outer diameter; 0.062″). But, the SOFIA catheter can be applied with a 6 Fr guide catheter due to a 0.068″ proximal and distal outer diameter. Comparing the Penumbra 3Max reperfusion catheter and SOFIA catheter, the SOFIA catheter has a larger distal inner diameter. Therefore, a more forceful CAT can be performed. Although this study included a small number of posterior circulation occlusive stroke cases, the median endovascular procedure time was faster in the SOFIA group (19.5 min vs. 8.0 min).

With CAT, 22.8% to 45.2% of cases required rescue treatment, as reported in previous studies [7, 8, 11, 19, 20]. Our result was comparable to previous studies, and the incidence of rescue use of a stent retriever was similar between groups (30.0% vs. 30.3%, $p = 0.964$). The authors speculate that a similar rate of rescue treatment between groups may be associated with similar stroke etiologies. The rescue use of a stent retriever could be associated with difficult angiographic cases, such as atherosclerotic occlusion and impaction of a hard thrombus [21–24]. With atherosclerotic occlusion, the contact area between an atheroma and an aspiration catheter is relatively small. Therefore, an atheroma cannot be extracted by CAT, and CAT might play a limited role in the removal of a local thrombus or blood clot around the atheroma. To overcome this disadvantage, early identification of the complex situation is important. And rapid application of the rescue treatment, including using a stent retriever, angioplasty with or without stenting, and intra-arterial glycoprotein IIb/IIIa inhibitors, have to be considered [25–29]. For the impaction of a hard thrombus, aspiration force might be insufficient to extracting a thrombus. But, a stent retriever might be advantageous because thrombus capture by engagement of struts of a stent retriever can be stronger than aspiration.

Clinical outcomes between groups were not statistically different, though reperfusion was faster in the SOFIA group. In this study, the SOFIA group included a higher incidence of ICA occlusion than the Penumbra group. Based on a systematic review of endovascular treatment, ICA occlusion was associated with a worse clinical outcome compared with MCA occlusion [30, 31]. This study also reports similar results with 59.8% favorable clinical outcomes with ICA occlusion and 68.4% with MCA M1 occlusion. And, in patients with reperfusion failure, poor clinical outcomes also were more frequent with ICA occlusion than with MCA occlusion. In addition, time from symptom onset to final reperfusion was not statistically different despite faster reperfusion in the SOFIA group. Therefore, clinical outcomes might not be affected by differences in angiographic outcomes.

Regarding the safety profile, there were no statistically significant differences between groups. Our study showed 3.3% symptomatic ICH in the Penumbra group and 3.0% in the SOFIA group. Parenchymal hematoma type 2 occurred in 2.2% of patients in the Penumbra group and 2.0% in the SOFIA group. Our results were comparable to the outcomes of previous studies about contact

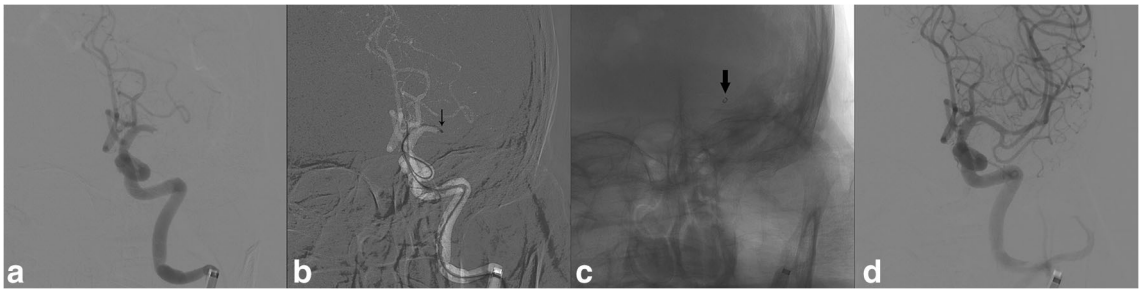

Fig. 1 Sequential angiographic images of contact aspiration thrombectomy. Cerebral angiography reveals an occlusion in the left middle cerebral artery (**a**). After delivery of microcatheter to the proximal end of occlusion without passing through the occlusion (**b**). Sofia catheter also reach to the proximal end of occlusion (**c**). Complete reperfusion of the middle cerebral artery is achieved (**d**)

aspiration [8, 11, 19, 20]. The authors speculated that these results might be associated with thrombectomy strategy. Although the thrombectomy devices used were different between groups, both groups underwent contact aspiration thrombectomy. Theoretically, in stent retriever thrombectomy, resistance between a vessel and a stent retriever might exist. Mechanical stretch during retrieval might result in benign SAH [32]. However, resistance between a vessel and a thrombus only exists in contact aspiration strategy. And endothelial cell damage was reportedly minimal in contact aspiration thrombectomy compared with stent retrievers in a vitro model study [33]. In this study, embolization in an uninvolved territory occurred in 2.2% of patients in the Penumbra group and in 2.0% in the SOFIA group, which was a lower incidence than in previous studies. We believed our CAT technique and the use of a balloon guide catheter (except with posterior circulation occlusive stroke) could help prevent distal embolization in uninvolved territories. Our CAT technique is slightly different from a direct aspiration first pass technique [33]. During aspiration catheter delivery to a target occlusion, we do not permit a pass through the thrombus with a microcatheter and microwire (Fig. 1). This may prevent clot fragmentation or migration. And, arresting antegrade blood flow using a balloon guide catheter during thrombus retrieval also can minimize the incidence of embolization [21].

However, this study has some limitations. First, this was a retrospective and single center result. The authors' center has a long history with aspiration thrombectomy, and all the participating neurointerventionalists also have over 300 cases of endovascular thrombectomy experience. Considering the learning curve effect on endovascular treatment, it may be limited to generalize these findings to other stroke centers with less experience in this thrombectomy strategy [34]. Second, the good outcomes of this study compared with previous studies may be associated with selection bias, because our neurointerventionalists choose the initial thrombectomy strategy based on initial radiological images. Third, the CAT device used in period 1 was not the newer version in Penumbra's ACE family of reperfusion catheters (the Penumbra 3/4/5MAX was used); thus, there may be different results when SOFIA is compared with the newer version of the Penumbra ACE reperfusion catheter.

Conclusions

Our findings suggest that CAT using a SOFIA/SOFIA plus catheter may be safe and effective and comparable to using a Penumbra reperfusion catheter. And, the SOFIA/SOFIA plus catheter could be advantageous for rapid reperfusion and FPE without any significant difference in complications.

Compliance with ethical standards

Conflict of interests All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge, or beliefs) in the subject matter or materials discussed in this manuscript.

Ethical approval For this type of study, formal consent is not required.

Informed consent This article does not contain any studies with human participants performed by any of the authors.

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