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ARTICLE

Comparison of Direct Aspiration With SOFIA Distal Access Catheter and Solitaire Retrievable Stent-Induced Thrombolysis for the Treatment of Acute Ischemic Stroke

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Abstract

Aims/Background Direct aspiration with soft torqueable catheter optimized for intracranial access (SOFIA) distal access catheter and Solitaire retrievable stent-induced thrombolysis are two commonly used interventional therapy methods in acute ischemic stroke (AIS). Despite their distinctive advantages, these surgical methods need to be further studied and compared to help with treatment selection. Therefore, this study aims to analyze the distinct effects of SOFIA distal access catheter direct aspiration and Solitaire retrievable stent-induced thrombolysis in the treatment of AIS.

Methods The clinical data of 312 patients with AIS admitted to The Quzhou Affiliated Hospital of Wenzhou Medical University from January 2019 to March 2024 were collected and analyzed retrospectively. All patients were treated with thrombectomy stents. According to different types of stents utilized, 150 patients treated with SOFIA distal access catheter direct aspiration were grouped under the SOFIA group, while 162 patients treated with Solitaire retrievable stent-induced thrombolysis were categorized in the Solitaire group. The success rate and recanalization rate following thrombolysis were compared between the two groups. The scores of National Institutes of Health Stroke Scale (NIHSS), Glasgow Coma Scale (GCS) and modified Barthel Index (MBI) before and 3 months after treatment were compared. The complications, recurrence rate and mortality of the two groups were compared 3 months after operation.

Results There was no statistically significant difference in the success rate of mechanical thrombectomy between the two groups after treatment ($p > 0.05$), while the recanalization rate in the SOFIA group was significantly higher than that in the Solitaire group ($p < 0.05$). After treatment, the NIHSS scores of the two groups of patients were lower than before treatment, while the scores of GCS and MBI were higher than before treatment ($p < 0.05$), but there was no significant difference in these scores between the two groups ($p > 0.05$). Symptomatic intracranial hemorrhage, subarachnoid hemorrhage, arterial perforation, distal thrombosis or emboli occurred in both groups after treatment, without significant differences between the two groups ($p > 0.05$). The recurrence rate in the SOFIA group was significantly lower than that in the Solitaire group after 3 months of follow-up ($p < 0.05$), and there was no significant difference in mortality between the two groups ($p > 0.05$).

Conclusion The SOFIA distal access catheter direct aspiration shows significant efficacy in the treatment of AIS by improving the vascular recanalization rate of AIS and reducing the recurrence rate.

Key words: acute ischemic stroke; aspiration; thrombectomy; mortality rate

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Introduction

Stroke is ranked one of the top causes of disability and mortality worldwide, including China, posing a significant threat to patients' health and lives (Barthels

and Das, 2020). Acute ischemic stroke (AIS) accounts for nearly 80% of all stroke cases, and usually manifests as sudden neurological dysfunction, such as limb weakness, speech disorder, visual disorder, etc., with intracranial and extracranial vascular occlusions being the primary causes (Klepanec et al, 2020). The main treatment strategy for AIS is swift opening of the occluded intracranial vessels and blood flow restoration to minimize the area of infarcted brain tissue. In the past, pharmacological intravenous thrombolysis was commonly used for treating AIS, but this technique is accompanied by suboptimal rates of vessel recanalization and outcomes (Vannucchi et al, 2020). Mechanical thrombectomy has increasingly been adopted in recent years and has become the standard treatment protocol for AIS, with the Solitaire retrievable stent being the most frequently used device, often employed as the second-generation thrombectomy stent (Caranfa et al, 2018). The adoption of direct-aspiration thrombectomy in clinical practice primarily lies in its rapid recanalization feature, due to the advancements in clinical technology, with the soft torqueable catheter optimized for intracranial access (SOFIA) distal access catheter being widely utilized. The SOFIA catheter has a smaller outer diameter and more flexible distal design than the conventional catheters, allowing it to pass more easily through tortuous vascular paths to reach the site of occlusion, significantly increasing revascularization rates and reducing procedure time and complexity (Roh et al, 2022). Quzhou Affiliated Hospital of Wenzhou Medical University has employed SOFIA distal access catheter for direct-aspiration treatments in recent years, having been able to attained successful outcomes in certain cases. However, there are few clinical comparative studies regarding its efficacy and safety in the literature. Thus, this study aims to explore the clinical value of the SOFIA distal access catheter through a retrospective analysis.

Methods

Inclusion Criteria

The individuals meeting inclusion criteria of this study are as follows:

(a) Diagnosed with AIS characterized by acute anterior circulation large vessel occlusion via computed tomography (CT), magnetic resonance imaging (MRI), or digital subtraction angiography (Chinese Society of Neurology and Cerebrovascular Group, 2018);

(b) Aged $\geq$18 years old;

(c) With an onset-to-admission time $<$6 hours;

(d) Having given informed consent (of the patients or the next of kins).

Exclusion Criteria

The individuals meeting exclusion criteria of this study are as follows:

(a) With cerebral and external vascular tandem lesions;

(b) With bilateral arterial occlusion;

(c) With cerebral artery dissection;

(d) With intracranial hemorrhage as detected by CT examination;

(e) With tortuosity of the arteries, which prevented mechanical thrombectomy;

(f) With arteriovenous malformation;
(g) With serious diseases of heart, liver, kidney and other systems;
(h) With malignant tumor.

General Data

A total of 312 patients with AIS admitted to the Quzhou Affiliated Hospital of Wenzhou Medical University from January 2019 to March 2024 were selected as the study subjects, and the patients were divided into two groups according to surgical methods used. In the SOFIA group, 150 patients were treated with SOFIA distal access catheter direct aspiration, whereas in the Solitaire group, 162 patients were treated with Solitaire retrievable stent-induced thrombolysis. The present study conformed to the ethical principles outlined in the Declaration of Helsinki and was approved by the Medical Ethics Review Committee of the Quzhou Affiliated Hospital of Wenzhou Medical University (Ethics Batch number: Ethics Review 2022 Study No. 102).

Treatment Protocol

Mechanical thrombectomy was performed in all patients within the treatment time window.

In the SOFIA group, after a femoral artery puncture angiography was performed to determine the location of vascular occlusion. The 8F guiding catheter was inserted into the blood vessel near the lesion, the microcatheter was introduced, and the microcatheter was placed in the distal end of the lesion vessel, so that the head end of the microcatheter was in the true lumen of the distal end of the lesion vessel. SOFIA distal access catheter was introduced along the catheter (Model: DA6125ST, Shenzhen Tengkang Medical Equipment Co., Ltd., Shenzhen, China). The SOFIA distal access catheter was placed at the diseased thrombus with a microcatheter and a guide wire, and then negative pressure suction was performed at the end of the SOFIA distal access catheter with a syringe. Following the suction, the catheter was withdrawn.

In the Solitaire group, the Solitaire AB stent (Model: SAB-4-20, Antaimed [Beijing] E-commerce Co., Ltd., Beijing, China) was placed in the diseased vascular occlusion segment, then slowly withdrawn and opened, and the stent was completely withdrawn after standing for 3 to 5 minutes.

Observational Indicators

The observational indicators recorded and measured in this study includes:

(a) General information about the two groups, including gender, age, weight, body mass index, duration of illness to hospitalization, history of diabetes, history of hypertension.

(b) Success rate and recanalization of simple mechanical thrombectomy in the two groups: Recanalization rate = (Complete recirculation + Partial recirculation)/Total cases × 100%.

(c) The scores of National Institutes of Health Stroke Scale (NIHSS), Glasgow Coma Scale (GCS) and modified Barthel Index (MBI) of the two groups before

Table 1. Comparison of general information between the SOFIA and Solitaire groups.

Factor	SOFIA group (n = 150)	Solitaire group (n = 162)	t/χ^2	p
Gender (n)			0.439	0.508
Male	74 (49.33)	86 (53.09)		
Female	76 (50.67)	76 (46.91)		
Age (years)	63.82 ± 5.72	63.41 ± 5.37	0.653	0.514
Weight (kg)	51.23 ± 4.29	50.81 ± 4.38	0.855	0.393
Body mass index (kg/m^2)	22.51 ± 2.33	22.72 ± 2.18	0.822	0.411
Onset-to-admission duration (h)	3.47 ± 0.28	3.43 ± 0.27	1.284	0.200
History of diabetes (n)	27 (18.00)	23 (14.20)	0.837	0.360
History of hypertension (n)	30 (20.00)	45 (27.78)	2.580	0.108

Note: Data are expressed as either n (%) or mean ± SD, depending on data type. SOFIA, soft torqueable catheter optimized for intracranial access.

and 3 months after treatment: (i) The NIHSS includes 11 aspects, with a total of 42 points; a higher score indicates a worse deterioration of the neurological function (Lyden et al, 2001); (ii) The GCS encompasses four aspects: eye-opening response, language response, limb movement, and coma degree (Jain and Iverson, 2023), with a total score of >15 indicating normal condition; a lower score indicates worse cognitive condition; (iii) The MBI has a total score is 100, whose points can be stratified in different levels of ability: 100 points for normal self-care ability, 61–99 points for mild loss of self-care ability, 41–60 points for moderate loss of self-care ability, ≤40 points for severe loss of self-care ability; a higher score indicates the stronger self-care ability (Yuan et al, 2023).

(d) Incidence of postoperative complications of the two groups within 3 months post-operation.

(e) Recurrence rate and mortality rate in two groups, measured at 3 months after discharge and follow up conducted via outpatient review or telephone.

Statistical Methods

SPSS 18.0 statistical software (SPSS Inc., Chicago, IL, USA) was used to analyze the data. The categorical data are expressed as counts and percentages. The Chi-square (χ^2) test was used for analyzing differences between groups. Continuous data are expressed as mean ± standard deviation. Normality of these data was tested using the Kolmogorov-Smirnov test. Independent samples t-test was utilized for between-group comparisons while paired samples t-test was employed for inter-group comparisons. $p < 0.05$ was considered statistically significant.

Results

Comparison of General Information

There were no statistically significant differences between the two groups in terms of gender, age, weight, body mass index, onset-to-admission duration, history of diabetes, and history of hypertension ($p > 0.05$) (Table 1).

Table 2. Comparison of success and recanalization rates following simple mechanical thrombectomy between the SOFIA and Solitaire groups.

Group	Success rate, *n* (%)	Recanalization, *n* (%)			
		Complete recanalization	Partial recanalization	Non-reperfusion	Recanalization rate
SOFIA group (*n* = 150)	89 (59.33)	84 (56.00)	56 (37.33)	10 (6.67)	140 (93.33)
Solitaire group (*n* = 162)	94 (58.02)	54 (33.33)	73 (45.06)	35 (21.60)	127 (78.40)
χ^2	0.055				14.081
p	0.815				0.000

Comparison of Success and Recanalization Rates Following Simple Mechanical Thrombectomy

After treatment, there was no significant difference in the success rate of simple mechanical thrombectomy between the two groups ($p > 0.05$), and the recanalization rate of the SOFIA group was significantly higher than that of the Solitaire group ($p < 0.05$) (Table 2).

Comparison of NIHSS, GCS and MBI Scores Before and After Treatment

The post-treatment NIHSS scores were lower than the pre-treatment scores, whereas the opposite trends were observed in the GCS and MBI scores ($p < 0.05$), but there were no significant differences in these scores between the two groups ($p > 0.05$) (Table 3).

Comparison of Postoperative Complications

Postoperative complications such as symptomatic intracranial hemorrhage, subarachnoid hemorrhage, arterial perforation, and distal thrombus or embolus occurred in the two groups, but no statistically significant difference between the two groups was detected ($p > 0.05$) (Table 4).

Comparison of Recurrence and Mortality Rates

The follow-up data of all patients at 3 months after discharge revealed that subjects in the SOFIA group faced significantly lower recurrence rate compared to their counterparts in the Solitaire group ($p < 0.05$). There was no significant difference in the mortality rate between the two groups ($p > 0.05$) (Table 5).

Discussion

AIS, a neurological disorder with high incidence, disability, and mortality rates, has seen a rising incidence in China in recent years due to the accelerated aging process and changes in lifestyle habits (Diana et al, 2021). Before the emergence of new treatment approaches, conservative drug treatment is often adopted in AIS treatment. However, this treatment method is only effective for small vessel occlusions and frequently falls short in completely dissolving larger or more structurally

Table 3. Comparison of NIHSS, GCS and MBI scores before and after treatment between the SOFIA and Solitaire groups.

Group	NIHSS score		GCS score		MBI score	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
SOFIA group (n = 150)	21.35 ± 1.92	13.26 ± 1.01[a]	6.77 ± 0.47	11.02 ± 1.12[a]	58.49 ± 4.98	71.97 ± 5.89[a]
Solitaire group (n = 162)	21.54 ± 1.84	13.08 ± 1.28[a]	6.68 ± 0.52	10.86 ± 1.03[a]	59.00 ± 5.07	72.81 ± 6.12[a]
t	0.892	1.372	1.599	1.315	0.895	1.233
p	0.373	0.171	0.111	0.190	0.371	0.218

Note: [a]$p < 0.05$ compared with before treatment. All score data are expressed as mean ± SD.
Abbreviations: GCS, Glasgow Coma Scale; MBI, modified Barthel Index; NIHSS, National Institutes of Health Stroke Scale.

Table 4. Comparison of postoperative complications between the SOFIA and Solitaire groups.

Groups	Symptomatic intracranial hemorrhage, n (%)	Subarachnoid hemorrhage, n (%)	Arterial perforation, n (%)	Distal thrombus or embolus, n (%)	Total count and rate, n (%)
SOFIA group (n = 150)	12 (8.00)	6 (4.00)	3 (2.00)	3 (2.00)	24 (16.00)
Solitaire group (n = 162)	18 (11.11)	3 (1.85)	3 (1.85)	6 (3.70)	30 (18.51)
χ^2	0.867	0.630*	0.101*	0.313*	0.345
p	0.352	0.427	0.751	0.576	0.557

Note: * Calibration χ^2 test is conducted.

Table 5. Comparison of recurrence and mortality rates between the SOFIA and Solitaire groups.

Group	Recurrence rate, *n* (%)	Mortality rate, *n* (%)
SOFIA group (*n* = 150)	6 (4.00)	0 (0.00)
Solitaire group (*n* = 162)	16 (9.88)	3 (1.85)
χ^2	4.104	1.197*
p	0.043	0.274

Note: * Calibration χ^2 test is conducted.

complex thrombi, thereby limiting the efficacy of pharmacological therapy (Jolugbo and Ariëns, 2021). Jiang et al (2018) found that intravenous thrombolysis with alteplase can improve neurological function in patients with AIS; however, this treatment is not without adverse reactions. Meanwhile, Zhuang (2018) found that endovascular intervention significantly increased the rate of vascular recanalization, promoted recovery of neurological function, and improved prognosis and quality of life in patients with acute internal carotid artery occlusion, when compared to the intravenous thrombolysis mode.

The microcatheter was placed in the occluded area of the blood vessel by mechanical thrombus extraction, and the proximal balloon catheter was used to assist suction when the stent was withdrawn, to remove the thrombus and restore the blood vessel smooth (Munoz et al, 2023). The Solitaire stent is a closed-loop, self-expanding Nitinol stent design form. Due to its overlapping cross-section design, it can be attached in multiple planes, so it can easily grasp blood vessels, and improve the flexibility and wall adhesion of the stent. However, a study has shown that after the successful implementation of mechanical thrombectomy, the blood vessel may still not be opened or be blocked again after opening (Duffy et al, 2019). SOFIA distal access catheter has the characteristics of a large internal cavity and fast flow rate, which bestow it with a high recanalization rate (Russo et al, 2023). In this study, a SOFIA distal access catheter was used in AIS patients. Compared with the Solitaire retrievable stent, the SOFIA distal access catheter has a stronger suction force and is easier to operate, which help save the time spent in stent placement and release, allowing for a shortened treatment time and improved recanalization rate. Complications are crucial events that deserve our attention after treatment. In this study, the number of complications after SOFIA distal access catheter treatment was lower because of the technique's ability in direct aspiration of thrombus, thereby reducing the risk of thrombus destruction and thrombus escape seen in treatment using the Solitaire stent (Bilgin et al, 2021). However, there were no significant differences in the number of complications between the two groups, probably due to small sample size.

The study showed that the NIHSS scores of the two groups after treatment were significantly lower than before treatment, and the GCS and MBI scores were significantly higher than before treatment, but there were no significant differences between the two groups. This finding supports that the two treatment schemes have a significant positive effect on the recovery of the patient's body function and nor-

mal life. The recurrence rate of the SOFIA group was significantly lower than that of the Solitaire group after 3 months of follow-up, indicating that the SOFIA distal access catheter outperformed the Solitaire retrievable stent in terms of treatment effect, which may be related to the reduction of the operation time of the SOFIA distal access catheter and the reduction of the damage to the blood vessels (Han et al, 2023). Due to the limitations of the study duration and other conditions, the sample of patients included in this study is small; therefore, the findings generated from this study may not be generalizable to different healthcare settings or different patient populations. The rather short follow-up time may undermine the accuracy of the study results. Thus, future studies need to adopt a much extended follow-up duration to monitor specific postoperative complications over a longer period of time. In terms of cost-effectiveness, the SOFIA distal access catheter may have an advantage in overall treatment costs by virtue of the simpler operation and shorter procedure time. Although the implementation of treatment involving Solitaire retrievable stent may require more complex procedures and longer surgery times, its widespread market presence and extensive usage could influence its pricing. Specifically, the single-use cost of the SOFIA catheter may be lower than that of the Solitaire stent; however, considering the retrievability of the stent, the cost incurred for the long-term usage of the Solitaire stent can be regarded as more economical. Additionally, the use of the SOFIA catheter may reduce the risk of surgical complications, potentially lowering additional medical expenses associated with treating and controlling the complications. However, economic analyses in this regard need to be further validated using broader clinical data and long-term follow-up results.

Conclusion

In conclusion, direct aspiration with SOFIA distal access catheter has a significantly positive effect on AIS patients, by improving the vascular recanalization rate, reducing the risk of complications, and protecting nerve function.

Key Points

- There was no significant difference in the success rate of mechanical thrombectomy between direct aspiration with SOFIA distal access catheter and Solitaire retrievable stent-induced thrombolysis.
- SOFIA distal access catheter direct aspiration has a higher recanalization rate compared to Solitaire retrievable stent-thrombolysis.
- SOFIA distal access catheter direct aspiration and Solitaire retrievable stent-thrombolysis showed no significant difference in functional scores and postoperative complications.
- SOFIA distal access catheter direct aspiration has a lower recurrence rate compared to Solitaire retrievable stent-induced thrombolysis.

Availability of Data and Materials

All data generated or analyzed during this study are available from the corresponding author upon reasonable request.

Author Contributions

RCZ and YMX was responsible for the conception, data summarization and writing of the paper. YPL and RCL was responsible for the data collection and organization. AW was responsible for the design of the paper and the guidance of feasibility analysis. YQS was responsible for the collection of the data and statistical analysis. YBL was responsible for the analysis of the results of the paper's data and interpretation. YMX was responsible for the quality control and review of the article as a whole and for supervising and managing the management. All authors contributed to important editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

The study conformed to the ethical principles outlined in the Declaration of Helsinki and was approved by the Medical Ethics Review Committee of the Quzhou Affiliated Hospital of Wenzhou Medical University (Ethics Batch number: Ethics Review 2022 Study No. 102). The patients or the next of kins included in the study signed the informed consent form.

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Conflict of Interest

The authors declare no conflict of interest.

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