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Research Article

Effect of Solitaire FR Stent Thrombectomy Combined with the Suction Thrombus on the Clinical Effect and Prognosis of Acute Middle Cerebral Artery Occlusion

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To determine the curative effect and prognosis of Solitaire FR stent thrombectomy integrated with the suction thrombus on the treatment of acute middle cerebral artery occlusion (AMCAO). Based on the treatment, patients suffering from AMCAO were separated into the Solitaire FR group (Solitaire FR stent + suction thrombus) and suction group (suction thrombus). Modified thrombolysis in cerebral infarction grading, National Institutes of Health Stroke Scale (NIHSS) score, modified Rankin Scale score, and safety performance were compared between the two groups. The operation time in the suction group was obviously shorter than the Solitaire FR group ($P < 0.05$). Significant differences were observed in the NIHSS scores 1 week and 4 weeks after the operation between the Solitaire FR group and the suction group ($P < 0.05$). The NIHSS scores 1 week and 4 weeks after operation were significantly lower than those before operation ($P < 0.05$). NIHSS scores 1 week after operation did not show obvious difference ($P > 0.05$). The Solitaire FR group showed obvious lower NIHSS scores than the suction group 4 weeks after surgery ($P < 0.05$). Statistically obvious difference in cerebral infarction grading of modified thrombolysis between the Solitaire FR group and the suction group were observed ($P < 0.05$). The recanalization rate of the Solitaire FR group was obviously higher than the suction group ($P < 0.05$). The difference in the monthly modified Rankin Scale score was obvious ($P < 0.05$). The good prognosis rate of the Solitaire FR group was obviously higher than the suction group ($P < 0.05$). No obvious differences in the incidence of internal bleeding, reocclusion, and 3-month postoperative mortality were observed ($P > 0.05$). These results showed that the treatment of the Solitaire FR stent + suction thrombus in AMCAO patients has a good thrombus recanalization rate and is helpful in improving the prognosis and safety performance.

1. Introduction

Acute middle cerebral artery occlusion (AMCAO) is the blockage of intracranial blood vessels caused by atherosclerotic thrombosis of large vessels and shedding of cardiac emboli, resulting in hypoxia and ischemic necrosis of brain tissue and neurological deficit [1]. If the blood supply cannot be restored in a short time, the brain tissue in the corresponding blood supply area will become edematous and necrotic. Especially, the acute occlusion of large intracranial vessels will cause serious symptoms and lead to poor clinical recovery [2]. Therefore, early diagnosis of AMCAO, opening of occluded blood vessels, avoiding irreversible damage to nerve cells, and preventing recurrence are the key measures for treatment [3]. Arterial and intravenous thrombolysis has been a commonly used method of vascular recanalization in the past, but its application is limited due to strict time window control, poor prognosis, and a high vascular reocclusion rate [4]. In recent years, stent mechanical thrombectomy, the suction thrombus, and stents combined with the suction thrombus have been used in the treatment of AMCAO. The therapeutic effect of thrombectomy is more advantageous than that of arterial and intravenous thrombolysis, and thrombectomy also prolongs the treatment time

window [5, 6]. The objective of the research was to compare the therapeutic effects of the Solitaire FR stent + suction thrombus and the suction thrombus on AMCAO.

2. Materials and Methods

2.1. General Datum. The clinical case data of 80 patients with AMCAO from Jan 2020 to Dec 2020 were selected as research subjects. Based on the therapeutic method for the first time, they were separated into the Solitaire FR group (Solitaire FR stent + suction thrombus; 27 males and 13 females) and the suction group (suction thrombus; 25 males and 15 females). The information of the patients was listed in Table 1, including age, time from onset to admission, hypertension, and so on. This study was approved by the Medical Ethics Committee of our hospital, and all patients gave informed consent.

2.1.1. Inclusion Criteria

① Age 40–80 years old;

② The time from onset to admission <8 hours;

③ There is obvious neurological dysfunction (language, limbs, consciousness, etc.), which is progressive and lasts for more than 1 hour;

④ The National Institutes of Health Stroke Scale (NIHSS) score is 6–35 points [7];

⑤ AMCAO was confirmed by emergency CTA or DSA on admission;

⑥ Angiography showed occlusion of the M1 segment of AMCAO;

⑦ No bleeding tendency.

2.1.2. Exclusion Criteria

(1) Cerebral hemorrhage;

(2) NIHSS score ≥35 points;

(3) Brain CT examination showed fresh infarction;

(4) History of trauma or surgery within the past 3 months; mmHg, diastolic blood pressure >110 mmHg.

The research was approved by the hospital ethics association.

2.2. Methods. All patients have received the green channel for diagnosis and treatment after admission and priority to quickly improve various preoperative preparations, including electrocardiogram, blood routine, coagulation function, blood biochemistry, and head CT scan. AMCAO was diagnosed by CTA or DSA. The treatment was carried out after a comprehensive assessment. Before surgery, aspirin of 300 mg + clopidogrel of 300 mg was injected by nasal feeding to maintain stable blood pressure.

The treatment procedure of the Solitaire FR group was as follows: after administering local or general anesthesia, puncture the right femoral artery, following the placement of an 8 F femoral artery sheath. Intracranial angiography was performed to determine the occlusion site and thrombus length, and an appropriate stent was selected according to the data. Guide the microcatheter to the distal of the occlusion site through the guiding wire, and insert the protective sheath part into the *Y* valve. After being locked properly, the protective sheath was flushed with pressure to ensure that the liquid enters the protective sheath from the distal end and flows out from the proximal end. Loosen the *Y* valve, place the protective sheath on the front section of the microcatheter, top the inner wall, and fix the *Y* valve. Push the Solitaire FR stent (4 mm model or 6 mm model, EV3, USA) into the microcatheter. The microcatheter was advanced for an additional 10 cm, and the introducer sheath was removed. Continue to advance the Solitaire FR stent until its distal radiographic marker exceeds the thrombus, and midposterior segment of the stent was located in the thrombus. Then, the Solitaire FR stent was released with the guide wire fixed to keep the stent in place. The microcatheter was retracted proximally as slowly as possible to reduce thrombus cutting and avoid distal embolism. To ensure that the stent is fully released, the microcatheter tip must be withdrawn until the proximal radiographic landmark of the Solitaire FR stent is fully exposed. The stent was completely released and then kept in place for 5 min. Push the microcatheter forward with the fixed push guide wire, covering the proximal end of the Solitaire FR stent by 3-4 mm. Then, lock the *Y* valve at the end of the microcatheter so that it is integrated with the stent to maintain synchronous movement. Advance the guide catheter as far as possible, shorten the distance from the stent retraction to the guide catheter, close all channels of saline flush, and place a *Y* valve at the end of the guide catheter. The catheter is withdrawn as a whole. During the withdrawal process, the syringe at the end of the catheter is continuously sucked until the stent is withdrawn. If a second thrombectomy is required, the Solitaire FR stent should be placed in a protective sheath after cleaning, and the above steps should be repeated.

The treatment procedure of the suction group was as follows: after administering local or general anesthesia, puncture the right femoral artery, following the placement of an 8F femoral artery sheath. Using angiography to identify the occlusion site, the 8 F guide catheter (length 90 cm) was sent into the ACE suction catheter (Penumbra, USA) or the softer Tianxun intermediate catheter (Suzhou Zhongtian Medical Equipment Technology Co., Ltd.). Then, the ACE suction catheter or intermediate catheter was inserted and placed at the thrombus occlusion site. When the catheter is about to make contact with the thrombus, an initial negative pressure is given through a 50-ml syringe. After it touches the core of the thrombus, the catheter is connected to the suction pump to perform negative pressure suction for 90 s. If no blood flow is found in the suction system, slowly remove the catheter under negative pressure until the blood flow in the tube of the suction pump returns to normal.

Postoperative treatment: the patients were given treatment such as nutrition for cranial nerves, fluid expansion, blood vessel expansion, scavenging of oxygen free radicals, and improvement of circulation after operation. On the 2nd day after the operation, the CT scan of the brain was rechecked to detect any asymptomatic hemorrhage or

infarction. If there was no hemorrhage, clopidogrel (75 mg, qd), atorvastatin calcium (20 mg, qd), and antiplatelet aggregation drugs were administrated orally, and tirofiban hydrochloride was administrated by intravenous infusion (discontinuously for 6 h after operation). For patients with worsening conditions after the operation, brain CT was reviewed as soon as possible. A decompressive craniectomy needs to be performed if necessary.

2.3. Observation Indicators

2.3.1. Data Collection. The data of the Solitaire FR group and the suction group were collected, including age, gender, BMI, time from onset to admission, comorbidities, systolic blood pressure, diastolic blood pressure, and operation time.

2.3.2. Neurological Function. NIHSS was calculated to appraise the neurological function of the Solitaire FR group and suction group 1 week and 4 weeks after the operation. The low score indicates good neurological function.

2.3.3. Vascular Recanalization. Modified thrombolysis in cerebral infarction grading (mTICIG) data were calculated to assess the recanalization of blood vessels: grade 0, no blood perfusion at the distal end of the occluded vessel; grade 1, blood flow through but little perfusion of distal branches; grade 2a, the reperfusion area of the occluded vascular distribution area <50%; grade 2b, the reperfusion area of the occluded vascular distribution area >50%; grade 3, complete recanalization of occluded vessels; the success criteria for recanalization were mTICIG 2b and 3 [8].

2.3.4. Prognosis. The modified Rankin Scale score (mRSS) of clinical prognosis was calculated to appraise the prognosis of patients 3 months after the operation. The mRSS less than or equal to 2 indicates that the patient has a good prognosis. The mRSS of 3–6 indicates that the patient has a poor prognosis [9].

2.3.5. Safety Performance. The incidence of surgical complications (such as subarterial layer, new embolism, and vascular rupture), postoperative subarachnoid hemorrhage, symptomatic intracranial hemorrhage, reocclusion, and postoperative death in patients were counted.

2.4. Statistical Analysis. Statistical analysis was calculated by SPSS 21.0. Data were expressed by $\overline{x} \pm s$. An independent t-test was performed for comparison between the Solitaire FR group and the suction group. Multiple time points were compared using the variance of repeated measure data analysis, and if there are differences between the groups, the independent sample t-test is performed to compare the differences at each time point. If there is a time difference, the LSD-t test is performed for pairwise comparison. The χ^2 test or Fisher's exact test was calculated, and the Mann–Whitney test was used in the comparison of grade data. $P < 0.05$ indicated that the differences were obvious.

3. Results

3.1. Comparison of Baseline Characteristics and Operation Time. No obvious difference was observed in baseline characteristics between the Solitaire FR group and the suction group ($P > 0.05$) (Table 1). Operation time of the suction group was obviously shorter when compared to the Solitaire FR group ($P < 0.05$), which is illustrated in Table 1.

3.2. Comparison of NIHSS Scores before and after Operation. There were obvious variances in NIHSS scores between the Solitaire FR group and the suction group 1 week and 4 weeks after operation ($P < 0.05$). There was no obvious variance in the NIHSS score at 1 week after operation ($P > 0.05$). The NIHSS score in the Solitaire FR group at 4 weeks after operation was lower compared to the suction group ($P < 0.05$), which is illustrated in Table 2 and Figure 1.

3.3. Comparison of the Vascular Recanalization Rate. There was an obvious difference for mTICIG between the Solitaire FR group and the suction group ($P < 0.05$); the recanalization rate of the Solitaire FR group was obviously higher when compared to the suction group ($P < 0.05$), which is illustrated in Table 3.

3.4. Comparison of Clinical Prognosis 3 Months after Operation. There was an obvious difference in mRSS scores between the Solitaire FR group and the suction group 3 months after operation ($P < 0.05$). The good prognosis rate in the Solitaire FR group was obviously higher than the suction group ($P < 0.05$), which is illustrated in Table 4.

3.5. Comparison of Surgical Complications. There was no obvious variance for surgical complications between the Solitaire FR group and the suction group ($P > 0.05$), which is illustrated in Table 5.

3.6. Comparison of Safety Performance. No obvious difference was observed for subarachnoid hemorrhage, symptomatic intracranial hemorrhage, reocclusion, and postoperative mortality between the Solitaire FR group and the suction group 3 months after operation ($P > 0.05$), which is illustrated in Table 6.

3.7. Typical Cases. A 69-year-old male patient admitted to our hospital on Oct 31, 2020, due to sudden left limb weakness was selected as the typical case. No hemorrhage was found on the CT scan, the right middle cerebral artery (MCA) showed hyperdense signs (Figure 2(a)), and right carotid angiography demonstrated occlusion of the right MCA (Figures 2(b) and 2(c)). The images during operation

Table 1: Comparison of baseline characteristics [($\overline{x} \pm s$), n (%)].

Projects	Solitaire FR group (40)	Suction group (40)	t/χ^2	P
Age	66.88 ± 9.66	66.65 ± 8.96	0.110	0.912
BMI (kg/m^2)	22.33 ± 5.46	23.48 ± 5.05	0.978	0.331
Time from onset to admission (h)	4.40 ± 1.06	4.22 ± 0.80	0.857	0.394
Male	27 (67.50)	25 (62.50)	0.220	0.639
Hypertension	26 (65.00)	29 (72.50)	0.524	0.469
Diabetes	9 (22.50)	10 (25.00)	0.069	0.793
Coronary heart disease	4 (10.00)	6 (15.00)	0.457	0.499
Hyperlipidemia	13 (32.50)	11 (27.50)	0.238	0.626
Smoking	21 (52.50)	22 (55.00)	0.050	0.823
Blood pressure (mmHg)	140.15 ± 19.79	136.95 ± 15.57	0.804	0.424
Diastolic blood pressure (mmHg)	78.80 ± 11.20	78.40 ± 8.45	0.180	0.857
Operation time (h)	2.87 ± 0.60	2.01 ± 0.72	5.803	<0.001

Table 2: Comparison of NIHSS at different times [($\overline{x} \pm s$), points].

Group	n	NIHSS score			Statistics	P
		Preoperative	One week after surgery	Four weeks after surgery		
Solitaire FR group	40	17.55 ± 8.11	6.78 ± 2.11	4.55 ± 1.28	$F_{\text{between groups}} = 70.563$	<0.001
Suction group	40	16.35 ± 6.83	6.95 ± 1.45	5.48 ± 1.41	$F_{\text{time}} = 81.919$	<0.001
t		0.716	0.420	3.089		
P		0.476	0.676	0.003		

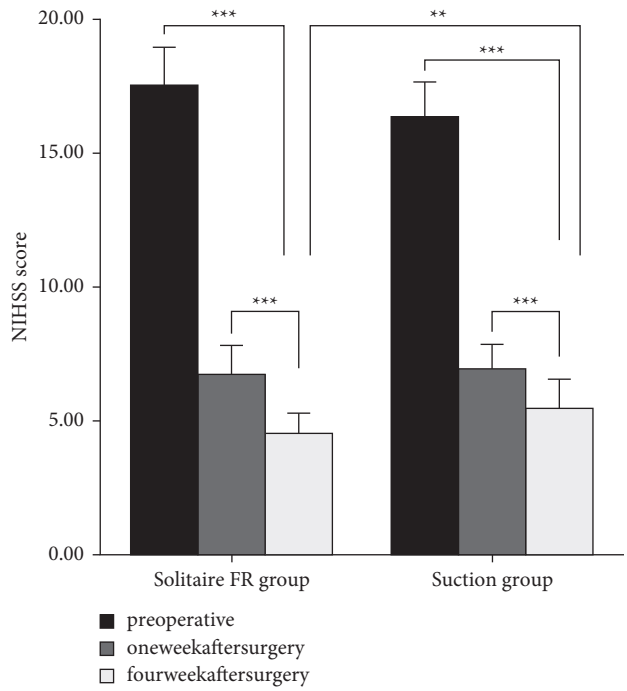


Figure 1: Comparison of NIHSS before and after operation. $^{**}P < 0.01$, $^{**}P < 0.001$.

and after operation were shown in Figures 2(d)–2(j), respectively.

4. Discussion

4.1. Advantages of the Solitaire FR Stent + Suction Thrombus in the Treatment of AMCAO. When using the traditional metal stents for thrombectomy, the mesh of the stent is incarcerated, and the thrombus will wrap around the mesh during the stent pulling process [10]. However, due to the metal properties, traditional metal stent can easily cause mechanical damage, arterial dissection, and vascular reocclusion, resulting in the final failure of the operation [11]. The Solitaire stent is a second-generation thrombectomy device (self-expanding), which is recyclable and has the characteristics of good vascular adherence, a flexible delivery system, and fewer complications [12]. The Solitaire FR stent is a kind of a nickel-titanium memory alloy stent specially used for thrombectomy. The appropriate size (4 mm and 6 mm) can be selected according to the diameter of the responsible vessel and the length of the thrombus. Stop pushing and confirm the cause of obstruction. Forced pushing may damage the device or vessels [13]. It is worth noting that after the stent is released, it should be kept in place for 5 minutes to open the occluded artery, which can quickly supply blood to the distal end and improve ischemic tolerance. Fresh blood contains plasmin, which is the best thrombolytic agent. The degree of tightness between the thrombus and the device improves the success rate of thrombectomy [14]. There is a balloon at the head end of the matching guide tube, which can block the forward blood flow after the balloon is inflated during the retraction process, and the speed should be as slow as possible at the beginning of the retraction process to prevent possible locking of the instruments with surrounding structures. When the blood vessel is significantly reduced in diameter or particularly tortuous, the withdrawal speed should be slightly slowed down to reduce the possibility of thrombus escape [15]. Some scholars have found that the Solitaire FR stent within 4.5 hours of onset can effectively improve the brain tissue perfusion cause by ischemic stroke, resulting in better prognosis of an

Table 3: Comparison of vascular recanalization rates between the solitaire FR group and the suction group [($\overline{x} \pm s$), n (%)].

Group	n	mTICIG					Recanalization rate (%)
		0	1	2a	2b	3	
Solitaire FR group	40	0 (0.00)	0 (0.00)	0 (0.00)	14 (35.00)	26 (65.00)	100
Suction group	40	1 (2.50)	2 (5.00)	4 (10.00)	20 (50.00)	13 (32.50)	82.50
Z/χ^2				3.309			5.636
P				0.001			0.018

Table 4: Comparison of clinical prognosis 3 months after operation [n (%)].

Group	n	mRSS							Good prognosis rate (%)
		0	1	2	3	4	5	6	
Solitaire FR group	40	7 (17.50)	18 (45.00)	5 (12.50)	4 (10.00)	3 (7.50)	2 (5.00)	1 (2.50)	75.00
Suction group	40	2 (5.00)	12 (30.00)	7 (17.50)	6 (15.00)	6 (15.00)	2 (5.00)	5 (12.50)	52.50
Z/χ^2					−2.682				4.381
P					0.007				

Table 5: Comparison of surgical complications [n (%)].

Groups		New embolism	Ruptured blood vessel	Arterial dissection	Procedural complications (%)
Solitaire FR group	40	4 (10.00)	2 (5.00)	2 (5.00)	20.00
Suction group	40	2 (5.00)	2 (5.00)	1 (2.50)	12.50
χ^2					0.827
P					0.363

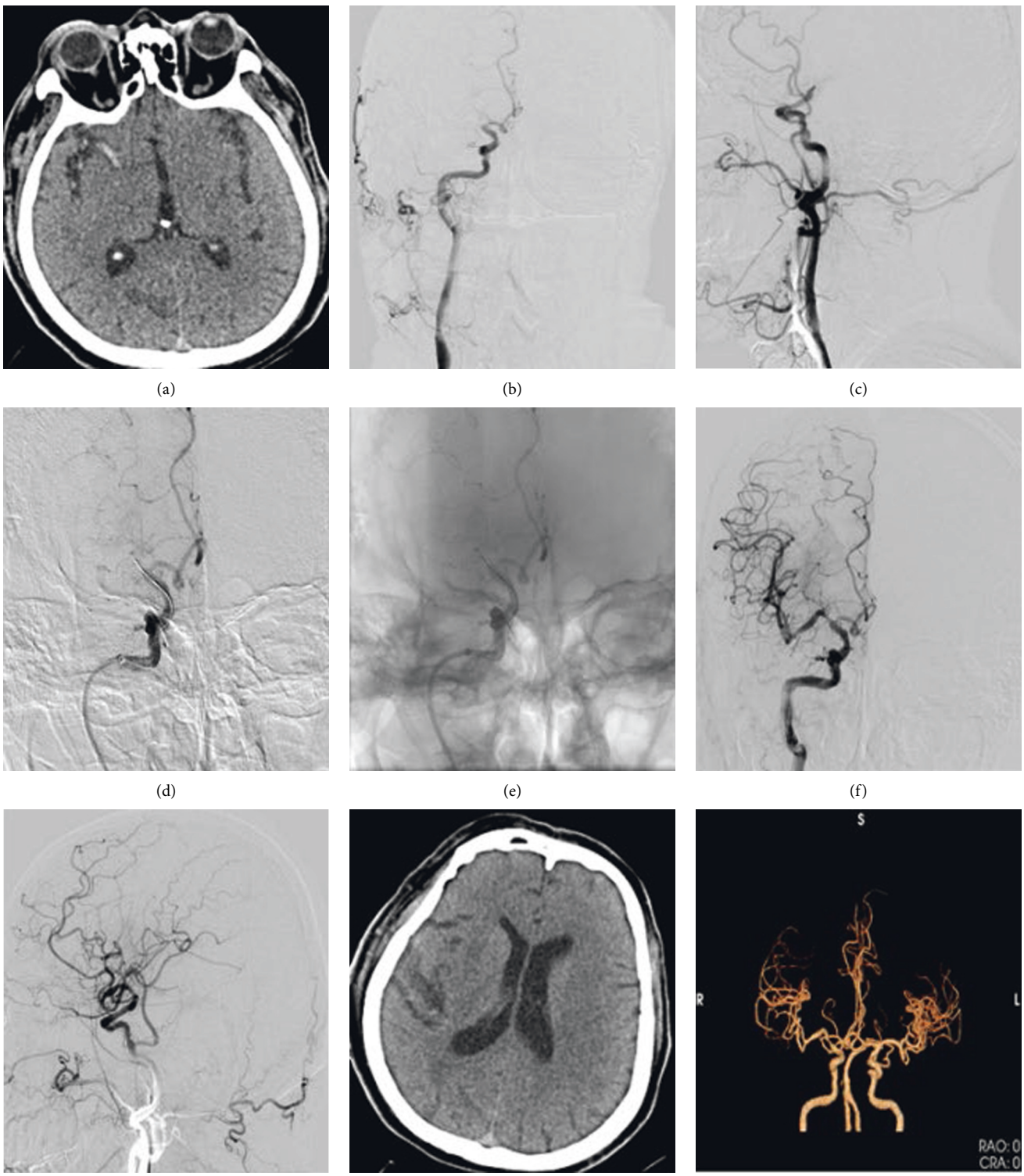
Table 6: Comparison of safety performance 3 months after operation [n (%)].

Group		Subarachnoid hemorrhage	Symptomatic intracranial hemorrhage	Reocclusion	3-month postoperative mortality
Solitaire FR group	40	1 (2.50)	2 (5.00)	1 (2.50)	1 (2.50)
Suction group	40	1 (2.50)	1 (2.50)	2 (5.00)	5 (12.50)
Fisher		—	—	—	—
P		0.474	1.000	1.000	0.203

early neurological function [16]. The Penumbra thrombus suction system was approved by the US FDA in December 2007 and launched in 2008. It mainly contacts the proximal surface of the thrombus and gently sucks the thrombus in the intracranial blood vessels [17]. In the present research, the vascular recanalization rate in the suction group and Solitaire FR group was 82.5% and 100%, respectively, r indicating that the Solitaire FR stent + suction thrombus for AMCAO has advantages in vascular recanalization.

4.2. Therapeutic Effects. The results of the research showed that NIHSS scores of the Solitaire FR group and suction group 1 week and 4 weeks after the operation were significantly different. No obvious difference was observed in the weekly NIHSS score. The NIHSS score in the Solitaire FR group was obviously lower than the suction group 4 weeks after operation. mRSS of the Solitaire FR group and suction group was compared, and variance was obvious at 3 months after surgery ($P < 0.05$). The Solitaire FR group demonstrated a significantly higher good prognosis rate than the suction group. In the suction group, it is suggested that the Solitaire FR stent + suction thrombus can effectively improve the neurological function and short-term prognosis of AMCAO patients.

4.3. Security. A retrospective study using mechanical thrombectomy in the treatment of cerebral embolism found that a 1-hour extension of the endovascular procedure was connected with a higher incidence of complications [18]. According to the hospital's own medical conditions, an emergency plan for endovascular treatment is formulated; careful operation, standardized operation, and perioperative management are strengthened so as to reduce related complications. In the present research, no obvious difference was observed for the incidence of surgical complications, subarachnoid hemorrhage, symptomatic intracranial hemorrhage, reocclusion, and 3-month postoperative mortality between the Solitaire FR group and the suction group of patients, indicating that the two methods of vascular recanalization are similar in safety performance. Subarachnoid hemorrhage and symptomatic intracranial hemorrhage are common serious complications after AMCAO treatment, and they are also the biggest risks after Solitaire FR stent thrombectomy. The longer the time window, the higher the

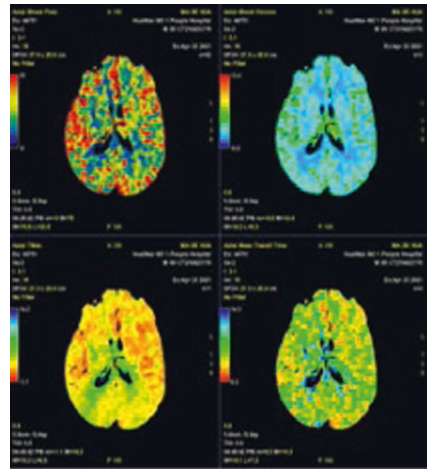


(a) (b) (c)

(d) (e) (f)

(g) (h) (i)

Figure 2: Continued.



(j)

Figure 2: The images of the patient before and after the Solitaire FR stent + suction thrombus. Note: (a) the right MCA can be seen with a high density sign on head CT; (b) and (c) preoperative anteroposterior and lateral carotid angiography demonstrated occlusion of the right MCA; (d) and (e) angiography shows intraoperative thrombectomy stent Solitaire FR 4 mm × 20 mm in place; (f) and (g) postoperative anteroposterior and lateral right carotid angiography shows M1 severe stenosis of the segment, considering thrombosis on the basis of in situ stenosis, the final mTICIG 3; (h) 24 h postoperative, the head CT review showed cerebral infarction in the right basal ganglia, no bleeding; (i) 3 months after surgery, severe stenosis of the lateral MCA M1 was observed but no obvious abnormality in CTP; (j) CTP showed the nidus to be basically normal 3 months after operation.

probability of bleeding [19, 20]. In order to reduce postoperative bleeding, the following points should be paid attention to: (1) patients with low-density changes in the brain CT scan before surgery should be closely monitored; (2) perioperative management should be strengthened, and blood pressure and blood sugar should be actively controlled, which could cause hypoxia in the blood vessel wall, making it more likely to develop necrotic lesions and aggravating the risk of postoperative bleeding. Treatment is initiated to control intracranial pressure and intracranial hemorrhage.

5. Conclusions

In this study, we explored the curative effect and prognosis of Solitaire FR stent thrombectomy integrated with the suction thrombus on the treatment of AMCAO. Statistical analyses revealed that modified thrombolysis in cerebral infarction grading, NIHSS score, modified Rankin Scale score, and safety performed better in the AMCAO patients treated by solitaire FR stent thrombectomy plus the suction thrombus than those in the patients only treated by the suction thrombus. These results showed that the treatment of the Solitaire FR stent + suction thrombus in AMCAO patients has a good thrombus recanalization rate, which is helpful to improve prognosis and safety performance. However, the sample size of the research is limited, so multicenter and prospective research including larger samples are needed for further verification.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

Acknowledgments

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