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Comparative study on treatment of acute cerebral infarction between mechanical thrombectomy by micro catheter and thrombectomy by Solitaire AB stent

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Abstract

Background: Acute cerebral artery occlusion is a common disease with high morbidity and mortality. At present, the commonly used mechanical thrombectomy schemes are mechanical thrombectomy and stent thrombectomy. However, the clinical differences between the two methods is not fully understood. The present study aimed to evaluate the clinical effectiveness of Solitaire AB stent thrombectomy for acute cerebral infarction (ACI).

Methods: A retrospective study was carried out in 96 ACI patients admitted to our department from January 2017 to January 2020. According to the treatment they received, they were divided into group A (conventional microcatheter mechanical thrombectomy, n = 48) and group B (Solitaire AB stent thrombectomy, n = 48). All patients were followed up for 3 months. Their pre-and post-operative nerve function indices were compared between the 2 groups. The therapeutic effects were evaluated by thrombolysis in cerebral infarction scale system, Glasgow coma scale (GCS), National Institutes of Health Stroke Scale (NIHSS), and modified Rankin scale statistics.

Results: Two groups of patients with NIHSS scores postoperative 3 and 30 days decreased significantly compared with preoperation. NIHSS score of group A 3 and 30 days postoperation was significantly higher than group B ($P < .05$). Two groups of patients with GCS scores postoperative 3 and 30 days increased significantly compared with preoperation. GCS score of group A 3 and 30 days postoperation was significantly lower than group B ($P < .05$). Group B with vascular recanalization ratio postoperative 30 days was higher than group A, however with no significant differences ($P > .05$). Moreover, group B with outcomes (modified Rankin scale score $\leq$2 points) postoperative 3months was better than group A, however with no significant differences ($P > .05$).

Conclusion: Solitaire AB stent embolectomy shows similar efficacy as mechanical thrombectomy in the treatment of ACI patients.

Abbreviations: ACI = acute cerebral infarction, GCS = Glasgow coma scale, mRS = modified Rankin scale, NIHSS = National Institutes of Health Stroke Scale, TICI = thrombolysis in cerebral infarction.

Keywords: acute cerebral infarction, clinical efficacy, mechanical thrombectomy, Solitaire AB stent

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XD and GX contributed equally.

YS and LM contributed equally.

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The present study was approved by the ethic committee of Hebei Provincial People's Hospital of science and technology [No. HPHST-IRB-2017009].

All authors agreed the submission and the policy of the journal and copyright.

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All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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Highlights

- NIHSS score of group A 3 and 30 days postoperation was significantly higher than group B
- GCS score of group A 3 and 30 days postoperation was significantly lower than group B
- Group B with vascular recanalization ratio postoperative 30 days was higher than group A, however with no significant differences.
- Group B with outcomes (mRS score$\leq$2 points) postoperative 3 months was better than group A, however with no significant differences.

1. Introduction

Acute cerebral artery occlusion is a common disease with high morbidity and mortality, and vascular recanalization after occlusion is a prerequisite for a good clinical outcome. There are many treatment methods for vascular recanalization, including intravenous thrombolysis, arterial thrombolysis, and mechanical thrombectomy, but the clinical outcome of intravenous thrombolysis and arterial thrombolysis is not good.[1,2]

In recent years, intra-arterial mechanical therapy has gradually sprung up, such as destroying the thrombus of the occlusive segment or causing the embolus to deform and rupture through the arterial approach with the help of interventional equipment (guidewire, catheter, stent, etc). If necessary, interventional equipment can be used to remove the thrombus from the intracranial occlusive segment to restore and recanalize the occluded intracranial vessels.[3,4] At present, the commonly used mechanical thrombectomy schemes are mechanical thrombectomy and stent thrombectomy. Intra-arterial mechanical therapy is through the arterial approach, with the help of interventional equipment to destroy the occlusive thrombus or to break or deform the embolus or use interventional equipment to remove the embolus, to restore the perfusion of occluded intracranial vessels. Stent thrombectomy can directly remove most of the thrombus tissue from the body, restore the blood flow of the occlusive segment as soon as possible, and greatly reduce the dosage of thrombolytic drugs.[5]

To provide valuable therapeutic information for clinicians and patients, Solitaire AB stent thrombectomy and conventional microcatheter mechanical thrombectomy were used to evaluate the therapeutic effect of patients with acute cerebral infarction (ACI) in our hospital.

2. Material and methods

2.1. Study subjects

A retrospective study was carried out in 96 patients with ACI, aged from 43 to 80 (61.6$\pm$9.8) years, who were selected for complete thrombectomy of the blood vessel from January 2017 to January 2020. According to the method of operation, these patients were divided into 2 groups: microcatheter mechanical thrombectomy group (group A, n=48) and Solitaire AB stent thrombectomy group (group B, n=48). Group A included 27 males and 21 females, aged from 43 to 79 years old (mean age 62.37$\pm$9.7years). Group B included 26 males and 22 females, aged from 44 to 79 years old (mean age 60.85$\pm$10.0 years). The clinical manifestations of the patients were limb hemiplegia, language disorder, sensory disturbance, consciousness disorder, eye movement disorder and so on. During the operation, digital subtraction angiography confirmed that there were 52 cases of main artery of middle cerebral artery occlusion, 27 cases of the distal part of the internal carotid artery occlusion, 6 cases of the anterior cerebral artery and 11 cases of the main artery of vertebrobasilar artery occlusion.

Inclusion criteria: Age >18 years, clinical diagnosis of acute ischemic stroke, with clinical symptoms and focal neurological deficits corresponding to suspected occlusion of vascular innervation area. The onset time of the anterior circulation is within 8 hours, and the posterior circulation department is extended to within 24 hours of the onset. Mechanical thrombectomy for progressive cerebral infarction can be extended under the guidance of imaging as appropriate. The onset time was less than 4.5 hour, and the patient had poor venous thrombolysis and bridged the artery for thrombectomy. Head CT excludes intracranial hemorrhage, low-density brain parenchyma changes < 1/3 of the middle cerebral artery area, and posterior circulation low-density shadow ranges <1/3 of the brain stem and unilateral cerebellar hemisphere. Digital subtraction angiography in the head and neck before operation revealed occlusion of large intracranial vessels. The patient or his immediate family members understand and sign the informed consent form.

Exclusion criteria: Patient has a history of intracranial hemorrhage in the last 3 weeks. Arteriovenous malformations or aneurysms did not undergo surgical treatment. Known history of contrast agent allergy. Blood glucose <2.8 mmol/l or >22.0 mmol/l. Acute bleeding constitution, coagulation factor deficiency disease, international standardized ratio > 1.7 or platelet count $< 100 \times 10^{*}9$/L. The expected survival time was less than 90 days and patients with severe liver and kidney dysfunction.

Note: The inclusion criteria and exclusion criteria refer to the 2015 Chinese Guidelines for Intravascular Treatment of Ischemic Stroke.

2.2. Treatment

Group A: Routine treatment, namely microcatheter mechanical thrombus fragmentation, cerebral angiography confirmed diagnosis, injection of heparin 4000 IU, plus heparin 1500–2000 IU, into 6F guide catheter through arterial duct sheath every 1 hour, the pro great microcatheter system was sent to the proximal end of vascular occlusive segment by coaxial catheter technology under the guidance of "Road Map" technology, and the guidewire was slowly passed through the thrombus segment. Under the guidance of the microcatheter, the microcatheter was passed through the occlusive segment and withdrew from the microwire, and the distal blood vessels and blood flow of the thrombus were confirmed by the microcatheter angiography. The guidewire and catheter were used to break the thrombus mechanically, and the microcatheter was placed in the thrombus segment for contact thrombolysis. Urokinase 10–20 $\times$ 10^4U was injected into segments with a constant speed pump at a speed of 1 $\times$ 10^4U/min. In the process of thrombolysis and thrombolysis, microcatheter angiography was used to understand the artery recanalization and blood flow, as well as whether there was secondary cerebral embolism caused by thrombus shedding.

Group B: The right femoral artery of the patient was punctured by the Seldinger method after satisfactory local anesthesia, and a 6F catheter sheath was placed. After cerebral artery occlusion was confirmed by whole cerebral angiography, the 6F supporting catheter was sent to the right vertebral artery. The microcatheter was guided by a microwire to put the microcatheter into the occlusive segmental artery, and the distal end of the catheter passed through the thrombus. Microcatheter angiography confirmed the condition of the distal vascular bed and the range of thrombus. The Solitaire AB-type 4 mm × 20 mm thrombectomy stent was placed into the occlusive artery through the microcatheter, and the distal end of the stent was released in the normal artery. After the stent was opened for 2 minute, the stent and the microcatheter were withdrawn. If necessary, thrombectomy could be performed many times. Arterial thrombolysis, balloon dilatation or stent implantation were used after reexamination.

2.3. Observation and evaluation of efficacy

National Institutes of Health Stroke Scale (NIHSS) and GSC scales were used to evaluate the severity of stroke before, 3 days and 30 days after the operation. The higher the NIHSS score or the lower the Glasgow coma scale (GCS) score was, the more serious the neurological impairment was. The recanalization of a cerebral artery after thrombolysis and thrombectomy was evaluated by thrombolysis in cerebral infarction (TICI). TICI grade III was complete recanalization, grade II was partial recanalization, and grade 0-I defined as cerebral hypoperfusion was vascular recanalization failure. The modified Rankin scale (mRS) score at postoperative 3 months evaluates the postoperative clinical prognosis of the patient. If the mRS is less than or equal to 2 points, the patient's prognosis is good.

2.4. Statistics

Means with standard deviation were calculated for the numeric variables. SPSS 25.0 was used to perform the statistical analysis. Independent sample *t* test or Chi-square test was employed for intergroup comparison. A value of $P < .05$ was considered statistically significant.

3. Results

• Comparison of baseline data between 2 groups

Comparison of clinical baseline data of the 2 groups of patients is presented in Table 1. The differences in gender, age, cerebral artery lesion characteristics were not statistically significant.

• Comparison of recanalization between 2 groups Patients in group A accounted for 35.41% of TICI grade III, 47.91% of TICI grade II, 16.67% of TICI grades 0 to I, and TICI III in group B Grade accounted for 54.17%, TICI grade II 39.58%, TICI grade 0~I 6.25%, there was no statistically significant difference between the 2 groups of TICI grades (Table 2).

• Comparison of NIHSS scores between 2 groups after the operation

NIHSS scores of the 2 groups at 3 and 30 days after operation were significantly lower than those before the operation, whereas GCS scores were significantly higher than those before operation. However, there was no significant differences in preoperative NIHSS scores and GCS scores between the 2 groups ($P > .05$, Table 3). Moreover, the NIHSS score of group B was significantly lower than that of group A at 3 and 30 days after the operation, whereas the GCS score was significantly higher than that of group B ($P < .05$, Table 3).

• Comparison of mRS scores between 2 groups Three months after surgery, the prognosis rate of patients in group A was 66.67% (32/48), in group B 77.08% (37/48), the difference between the 2 groups was not statistically significant (Table 4).

4. Discussion

ACI is a common disease in clinical neurosurgery, which occurs rapidly and is the main cause of disability in middle-aged and

Table 1

Basic characteristics of all patients.

Group		Group A (n = 48)	Group B (n = 48)	χ^2/Z/*t*	*P*
Age	< 50	6	8	0.357	.836
	50–70	29	27		
	> 70	13	13		
Gender	Male/female	27/21	26/22	0.042	.837
Distribution of obliterans	Middle cerebral artery	27	25	0.501	.919
	Internal carotid artery	12	15		
	Anterior cerebral artery	3	3		
	Vertebrobasilar artery	6	5		

Table 2

Comparison of recanalization between 2 groups.

Group	0~I	II	III	Recanalization rate (II + III)
Group A (n = 48)	8 (16.67%)	23 (47.91%)	17 (35.41%)	40 (83.33%)
Group B (n = 48)	3 (6.25%)	19 (39.58%)	26 (54.17%)	45 (93.75%)
t	4.537			2.567
P	.103			.109

Table 3

NIHSS scores and GCS scores between the 2 groups.

Group		Group A (n = 48)	Group B (n = 48)	*t*	*P*
NIHSS scores	Before operation	16.74 ± 1.86	16.65 ± 2.16	0.280	.836
	3 d after operation	10.82 ± 1.25	9.57 ± 1.36	4.691	.000
	30 d after operation	5.92 ± 1.16	5.35 ± 0.97	2.656	.009
GCS scores	Before operation	7.67 ± 1.17	7.93 ± 1.11	−1.104	.272
	3 d after operation	11.52 ± 1.74	12.29 ± 1.56	−2.267	.026
	30 d after operation	15.59 ± 1.90	16.56 ± 2.29	−2.274	.025

Table 4

Comparison of mRS scores and prognosis between 2 groups.

Group	Before operation	90 d after operation	Good rate (≤2 points)
Group A (n = 48)	5.45 ± 0.53	1.91 ± 0.31	32 (66.67%)
Group B (n = 48)	5.49 ± 0.60	1.84 ± 0.25	37 (77.08%)
t	−0.395	1.117	1.288
P	.694	.267	.256

elderly people. It not only seriously threatens the physical and mental health of patients but also brings a heavy economic burden to society and families. At present, there are many methods for clinical treatment of ACI, such as intravenous thrombolysis[6] and mechanical thrombolysis,[7] but the time window of intravenous thrombolysis is relatively short.[8] Some out-of-hospital patients have far exceeded the time window of intravenous thrombolysis from onset, admission, diagnosis to the beginning of treatment.[9,10] And some foreign scholars have shown that the effect of intravenous thrombolytic therapy for patients with macro-vascular occlusion or relatively serious conditions is not good, and the vascular recanalization rate is only 13% to 18%.[11] Urokinase is a commonly used thrombolytic drug. Its main component can directly act on the endogenous fibrinolytic system in patients and can catalyze and cleave it into plasmin. Patients in group A of this project were treated by microcatheter mechanical thrombectomy with urokinase. We hope to make the patients obtain better postoperative results.

At present, the effective methods for clinical treatment of AIS are mechanical thrombectomy and stent thrombec-tomy.[12] The former is that Pro great microcatheter and micro-guide wire are coated with a hydrophilic coating, and the inner surface of the catheter is coated with lubricant. The latter belongs to nickel-titanium alloy, can be completely recovered from the self-expanding stent, has both open mesh and closed mesh design, one side is open, the other side is connected with a recoverable system, and has strong stability and stent adhesion.[13] Solitaire AB stent thrombectomy can accurately place the stent in the thrombus segment and release the stent, and the stent can be completely covered in the thrombus segment according to the length of the thrombus segment, and the thrombus can be removed repeatedly through the Solitaire AB stent.[14] Most of the thrombus tissue was directly removed from the body so that the blood flow in the occlusive segment could be restored as quickly as possible, which not only shortened the recanalization time of blood vessels, but also reduced the use of thrombolytic drugs. Kim et al[15] have reported that mechanical thrombectomy with the Solitaire stent as a first-line treatment can produce unfortunate results that will require additional procedures, but a large number of studies have reported that intra-arterial thrombectomy with the SolitaireABdeviceappearstobesafe and effective.[16–18]

Within the TICI classification, TICI 2b has been historically considered successful recanalization.[19] This study showed that there was no significant difference in the constituent ratio of TICI grade between the 2 groups, indicating that the 2 thrombectomy methods could achieve good recanalization of an occlusive artery in patients with ACI. NIHSS score may serve as a predictor of successful recanalization. Recanalization is relatively easier in mild stroke than in those with severe stroke.[20] Here, the NIHSS scores of the 2 groups at 3 days and 30 days after the operation were significantly lower than those before operation, but there was no significant difference in NIHSS scores at the same time point between the 2 groups, suggesting that the 2 methods of thrombus breaking can effectively improve the neurological deficit of the patients. A better 90-day outcome is defined as an mRS score of 0 to 2.[21] In this study, 3 months after the operation, there was no significant difference in the rate of good prognosis between the 2 groups, which confirmed that both methods could effectively improve the prognosis of patients with AIS. All these results are consistent with those reported in the literature.[22,23]

Our hospital summed up the following points for attention in the course of treatment.[1] The diameter of the vascular matching stent should be selected, because there are many bends of the internal carotid artery, so using Navien guide tube can reduce the walking distance of stent combined with thrombus, reduce the risk of thrombus detachment and improve the efficiency of vascular recanalization.[2] Accurate judgment should be made according to the location of the thrombus and appropriate length should be selected to ensure that the effective segment of the stent

covers the thrombus and the middle and posterior segment of the effective segment is used for thrombectomy.[3] Angiographic confirmation should be carried out in time in the course of treatment, and slow speed should be ensured at the beginning of treatment.

5. Conclusion

In summary, Solitaire AB stent thrombectomy, the effect of thrombectomy in patients with ACI is similar to that of conventional mechanical thrombectomy, which provides another reliable treatment for patients, and the operation method should be reasonably selected according to the condition of patients. The study also has some limitations, the number of cases included in this study may be less, and further random, large sample size in-depth studies are needed to obtain more evidence of evidence-based medicine.

Author contributions

XLD and GDX conducted most of the experiments and wrote the manuscript; YXS, LM, TTH, NY, and NM conducted the experiments and analyzed the data, GDX designed the study and revised the manuscript. All authors have read and approved the manuscript.

Data curation: Yaxue Song, Liang Ma.
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Writing - original draft: Xiaoli Dong, Guodong Xu.

Correction

When originally published, the funding information was missing from the footnote and this has now been added.

Several changes were also made to the author contributions. "RY, HG, GX, NY, and TW conducted the experiments and analyzed the data" was changed to "YXS, LM, TTH, NY, and NM conducted the experiments and analyzed the data". Data curation was changed from Nan Yin to Yaxue Song and Liang Ma. Formal analysis was changes from Xiaoli Dong and Jing Xu to Tiantian Hyo and Nan Yin. Visulaization was changed from Hao Guo to Nan Meng. Writing - original draft was changed from Rui Yang to Xiaoli Dong and Guodong Xu.

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