

Case Control Study

Efficacy of Solitaire AB stent-release angioplasty in acute middle cerebral artery atherosclerosis obliterative cerebral infarction

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Abstract

BACKGROUND

In both national and international studies, the safety and effectiveness of treatment with the Solitaire stent in patients with ischemic stroke caused by acute large vessel occlusion were good, and the disability rate was significantly reduced. However, there are currently only a few reports on the differences in endovascular treatment for different etiological classifications, especially in the anterior cranial circulation, aorta atherosclerotic stenosis, and acute thrombosis.

AIM

To investigate the efficacy of Solitaire AB stent-release angioplasty in patients with acute middle cerebral artery atherosclerosis obliterative cerebral infarction.

METHODS

Twenty-five patients with acute middle cerebral atherosclerosis obliterative cerebral infarction were retrospectively enrolled in this study from January 2017 to December 2019. The Solitaire AB stent was used to improve anterior blood flow to maintain modified cerebral infarction thrombolysis [modified thrombolysis in cerebral infarction (mTICI)] at the 2b/3 level or above, the stent was then unfolded and released.

RESULTS

All 25 patients underwent successful surgery, with an average recanalization time of 23 min. One patient died of cerebral hemorrhage and cerebral herniation after the operation. The National Institutes of Health Stroke Scale (NIHSS) scores immediately after surgery (7.5 ± 5.6), at 24 h (5.5 ± 5.6) and at 1 wk (3.6 ± 6.7) compared with the preoperative NIHSS score (15.9 ± 4.4), were significantly different ($P < 0.01$). One case of restenosis was observed 3 mo after surgery (the stenosis rate was 50% without clinical symptoms), the modified Rankin scale

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scores were 0 points in 14 cases (56%), 1 point in 4 cases (16%), 2 points in 2 cases (8%), 3 points in 3 cases (12%), 4 points in 1 case (4%), and 6 points in 1 case (4%).

CONCLUSION

In acute middle cerebral artery atherosclerosis obliterative cerebral infarction, when the Solitaire AB stent is unfolded and the forward blood flow is maintained at mTICI level 2b/3 or higher, stent release may be a safe and effective treatment method; however, long-term observation and a larger sample size are required to verify these findings.

Key Words: Stent angioplasty; Atherosclerosis obliterative; Acute cerebral infarction

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Core Tip: There are currently only a few reports on the differences in endovascular treatment for different etiological classifications, especially in the anterior cranial circulation, aorta atherosclerotic stenosis, and acute thrombosis. There are no relevant reports on the use of Solitaire stent mechanical thrombectomy or stent release angioplasty when used above level 2b/3 (modified thrombolysis in cerebral infarction).

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INTRODUCTION

In both national and international studies, the safety and effectiveness of treatment with the Solitaire stent in patients with ischemic stroke caused by acute large vessel occlusion were good, and the disability rate was significantly reduced[1,2]. However, there are currently only a few reports on the differences in endovascular treatment for different etiological classifications[3], especially in the anterior cranial circulation, aorta atherosclerotic stenosis, and acute thrombosis. There are no relevant reports on the use of Solitaire stent mechanical thrombectomy or stent release angioplasty when used above level 2b/3 [modified thrombolysis in cerebral infarction (mTICI)]. This study reports the outcome of 25 cases with acute middle cerebral artery atherosclerosis occlusive cerebral infarction using Solitaire AB stent-release angioplasty during endovascular treatment.

MATERIALS AND METHODS

Patient population

Twenty-five patients (14 males and 11 females, aged 44-80 years, with an average age of 64.6 ± 5.3 years) with acute middle cerebral artery atherosclerosis obliterative cerebral infarction were retrospectively included in this study from January 2017 to December 2019. The onset time was 1.5-7 h, and the average onset time was 4.5 h. Twenty-one cases (84%) had hypertension, 15 cases (60%) had diabetes, 22 cases (88%) had hyperlipidemia, 5 cases (20%) had peripheral atherosclerosis, 9 cases (36%) had coronary atherosclerotic heart disease, 18 cases (72%) had previous stroke or transient ischemic attack, 13 cases (52%) were smokers (continuous or cumulative smoking for 6 mo or more in their lifetime), and 9 cases (36%) consumed alcohol. Nineteen cases (76%) underwent intravenous thrombolysis combined with endovascular treatment, 6 cases (24%) underwent direct endovascular treatment (lesions may appear hyperintense on fluid-attenuated inversion recovery with increased diffusion-weighted imaging and decreased apparent diffusion coefficient values[4], all had magnetic resonance imaging diffusion weighted imaging-fluid attenuation inversion recovery mismatch), and had a femoral artery puncture time of 77 ± 8.2 min, the

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average recanalization time was 23 min, and the average operation time was 57 min.

Inclusion and exclusion criteria

Inclusion criteria: After the patients had undergone cranial computed tomography (CT) to exclude cerebral hemorrhage, the preoperative early CT scores of the Alberta Stroke Project were ≥ 6 points, which was confirmed by CT angiography (CTA), magnetic resonance angiography, or digital subtraction angiography (DSA) as intracranial brain middle artery occlusion; 18 years \leq age \leq 80 years; time from onset to femoral artery puncture < 8 h; National Institutes of Health Stroke Scale (NIHSS) scores ≥ 6 points.

Exclusion criteria: A past history of cerebral hemorrhage, history of intracranial aneurysm or bleeding tendency; preoperative modified Rankin scale (mRS) score ≥ 2 points; history of atrial fibrillation or cardiogenic embolism caused by atrial fibrillation; other endovascular treatments using non-stent-like embolization devices; combined with insufficiency or failure of important organs; life expectancy less than 6 mo; uncontrolled severe hypertension. This study was reviewed and approved by the Ethics Committee of Puai Hospital Affiliated to Tongji Medical College of Huazhong University of Science and Technology. All patients or their families signed an informed consent.

Methods

Preoperative management: Preoperative cranial CT excluded bleeding, and blood pressure was controlled below 180/105 mmHg after intensive blood pressure reduction, and patients within the intravenous thrombolysis time window were given recombinant tissue-type plasminogen activator (rt-PA). Intravenous thrombolytic therapy (0.9 mg/kg, 10% of the dose by intravenous bolus in 1 min, the remainder was given over 60 min to complete the infusion), patients who exceeded the intravenous thrombolytic time window were given clopidogrel 300 mg, and aspirin 100 mg orally or nasogastrically.

Surgical technique: The patient was placed in the supine position, 1% lidocaine local anesthetic and dexmedetomidine for sedation were administered *via* femoral artery puncture, an 8F arterial sheath was introduced, an 8F guiding catheter was selected, and a 0.014 inch micro-ribbon micro-catheter was passed through. After occlusion of the blood vessel, the micro-catheter was gradually withdrawn following withdrawal of the micro-guide wire, and the distal end of the occlusion site was determined by segmental radiography. The top of the Rebar 18 micro-catheter was placed at least 5 mm away from the occlusion, and the Solitaire AB stent (4 mm \times 20 mm, Medtronic) at the distal end was inserted to the top of the micro-catheter. The micro-catheter was then slowly withdrawn and the stent was unfolded. Five minutes after the stent was unfolded, DSA was performed to observe blood perfusion and the stent shape. If the distal forward blood flow was above 2b, observation was continued for 15 min, and then tirofiban was injected intravenously (8 μ g/kg, within 3 min) before the stent was released, and 0.15 μ g/kg/min was administered for 24 h after the operation[5]. Immediately after surgery, CT was performed to identify intracranial hemorrhage, and normal heparin saline was injected intravenously throughout the operation.

Postoperative management: Close postoperative monitoring in the intensive care unit included vital signs, strict control of blood pressure, and systolic blood pressure was maintained below 140 mmHg; low molecular weight heparin was injected subcutaneously as needed; postoperative dynamic review of head CT was performed to determine the presence of intracranial hemorrhage and new-onset infarction. The patients were treated with overlapping dual antiplatelet drugs (aspirin 100 mg/d and clopidogrel 75 mg/d) 4 h before stopping tirofiban, and were given long-term single antiplatelet drugs for 3 consecutive mo.

Efficacy and safety: Postoperative re-examination of head CT and CTA to determine the presence of intracranial hemorrhage, new infarction, and patency of cerebral blood vessels was performed. NIHSS scores were used to determine the patient's immediate recovery, at 24 h, and 1 wk after surgery. The mRS score was used to evaluate the prognosis of patients at 3 mo.

Statistical analysis

SPSS 22.0 was used for analysis; measurement data are expressed as mean \pm SD using the *t* test; and counting data are expressed as frequency or percentage. *P* < 0.05 was considered statistically significant.

RESULTS

All 25 patients underwent successful surgery, with an average recanalization time of 23 min (the recanalization time refers to the time from femoral artery puncture to blood flow recanalization). The NIHSS score immediately after surgery was (7.5 ± 5.6), at 24 h (5.5 ± 5.6), and at 1 wk (3.6 ± 6.7). Compared with the preoperative NIHSS score (15.9 ± 4.4), the scores after surgery were significantly different ($P < 0.01$) (Figure 1). One patient died due to cerebral hemorrhage and herniation after the operation. One patient had restenosis 3 mo after surgery (the stenosis rate was 50% without clinical symptoms), the mRS score was 0 points in 14 cases (56%), 1 point in 4 cases (16%), 2 points in 2 cases (8%), 3 points in 3 cases (12%), 4 points in 1 case (4%), and 6 points in 1 case (4%).

DISCUSSION

Mechanical thrombectomy has become the standard and preferred treatment for acute large vessel occlusion[6-8]. The Solitaire AB stent is composed of a self-expanding nickel-titanium alloy. It is a laser engraved open-loop stent with a diameter of 4-6 mm and a length of 15-30 mm. It is installed on a 0.016 inch push guide-wire. It can be electrolytically removed and an NDS-2 release device is used to release the stent. The Solitaire AB stent has the best radial force to reduce residual stenosis[9], is a representative third-generation intravascular mechanical thrombectomy device and its strong thrombectomy ability has been demonstrated in clinical trials[10-13].

In the treatment of acute ischemic large vessel occlusion, the Solitaire AB stent is mainly used for mechanical thrombus removal alone or in combination with an intermediate catheter, and there are few clinical studies on direct release. The results of a Chinese study on intracranial arterial stenosis and occlusion showed that the incidence of intracranial atherosclerosis in patients with ischemic stroke or transient ischemic attack in China was 46.6%, and the symptoms in patients with intracranial atherosclerotic stenosis were more severe in those with acute anterior circulation large vessel occlusion caused by large atherosclerotic stenosis, and mechanical thrombus removal with a retrievable stent alone was often difficult to achieve blood vessel recanalization, and hospital stay was longer[14]. The risk of re-occlusion caused by thrombosis was very high. Often used as a remedy after other therapeutic measures have failed[15-17], mechanical thrombus removal alone cannot relieve stenosis of the target vessel before stent implantation[18]. There are also rare reports of Solitaire stent retention *in situ* after thrombectomy[19].

Researchers at home and abroad agree that the purpose of mechanical thrombus removal is to obtain blood flow reperfusion, and not only to achieve recanalization of blood vessels. Reperfusion is the key to improving prognosis. In all current endovascular treatment trials, whether stent thrombectomy or aspiration studies, the modified cerebral infarction thrombolytic classification mTICI 2b/3 is often used as the standard for evaluating effective reperfusion[20-22]. In clinical work, for patients with acute occlusion of intracranial middle cerebral artery atherosclerotic stenosis, if the anterior blood flow was maintained above mTICI 2b/3 after the Solitaire AB stent was unfolded, repeated thrombus removal may easily lead to re-occlusion of the blood vessels, thereby affecting patient prognosis. Possible reasons for this are mechanical thrombectomy injury caused by blood platelet aggregation, lipid core exposure leading to platelet activation and aggregation, *in situ* stenosis not relieved, blood flow was slowed, and embolus clearance decreased, which can cause re-occlusion[1]. Repeated operations also caused surgery-related complications; thus, the number of mechanical thrombectomies was generally ≤ 3 times[23]. A total of 25 patients were investigated in this study. According to their previous medical history and clinical characteristics, the "micro-catheter first pass effect" proposed by Yi *et al*[24], preliminarily determined that the responsible vascular disease was acute occlusion based on atherosclerotic stenosis. After opening the Solitaire AB stent, the forward flow was maintained at mTICI level 2b/3 or above, and the operation was successful in all 25 patients. The average recanalization time was 23 min. The operation time was short, the operation relatively simple, and the complications related to the operation were significantly reduced. There were significant differences in NIHSS scores immediately (7.5 ± 5.6), at 24 h (5.5 ± 5.6) and at 1 wk (3.6 ± 6.7) after surgery compared with the preoperative NIHSS score (15.9 ± 4.4) ($P < 0.01$), and one patient died of cerebral hemorrhage and cerebral hernia after surgery. The patients were followed up for 3 mo after the operation and restenosis occurred in 1 case (stenosis rate 50% without clinical

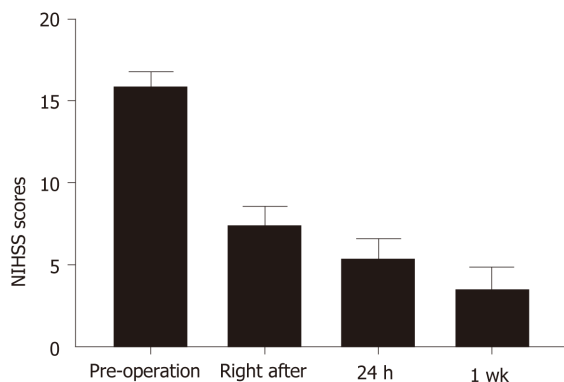


Figure 1 National Institutes of Health Stroke Scale scores immediately after surgery (7.5 ± 5.6), at 24 h (5.5 ± 5.6), and at 1 wk (3.6 ± 6.7) compared with the pre-operative National Institutes of Health Stroke Scale score (15.9 ± 4.4), were significantly different ($P < 0.01$). NIHSS: National Institutes of Health Stroke Scale.

symptoms). The mRS score was 0 points in 14 cases (56%), 1 point in 4 cases (16%), 2 points in 2 cases (8%), 3 points in 3 cases (12%), 4 points in 1 case (4%), and 6 points in 1 case (4%). **Figure 2** and **3** both show DSA of the patients undergoing surgery and CTA images of reexamination 3 d and 3 mo after surgery. The stents were in good shape and the distal vessels were unobstructed. Duan *et al*[25] reported that 44 cases of complicated intracranial atherosclerotic stenosis were treated by balloon angioplasty and Solitaire AB stent implantation in the non-acute stage. The technical success rate was 100%, and the residual stenosis rate after stent implantation was 0%-40% (average $15\% \pm 12.94\%$), the incidence of 30-d surgery-related complications was 9.09%, the average follow-up was 25.5 mo, and the recurrence rate of ischemic events at related sites was 4.55%. Therefore, it is believed that balloon angioplasty and implantation of Solitaire AB stents for the treatment of complex intracranial artery atherosclerotic stenosis is safe, effective, and has a high technical success rate, relatively few perioperative complications, and good follow-up prognosis[25]. The Solitaire AB stent has been permanently implanted to restore distal flow after failure of mechanical thrombectomy, and a number of studies have shown that the Solitaire AB stent may be a safer device for intracranial stenosis[26-28]. A recent study by Chang *et al*[29] retrospectively analyzed 591 patients with acute anterior circulation and great vessel occlusion. Among them, 148 patients who failed mechanical thrombus removal and recanalization were grouped and analyzed according to whether or not stents were implanted. The results showed that the stent implantation rate was 64.6%. Patients with failed thrombus removal were recanalized, and the clinical prognosis after recanalization was similar to that of mechanical thrombectomy, suggesting that rescue stent placement was safe and effective after thrombectomy failure. Stent implantation as the preferred treatment for acute ischemic stroke with large vessel occlusion remains controversial[30]. The major problem facing intravascular opening is how to achieve recanalization in the shortest time and avoid iatrogenic injury[31].

For patients with acute anterior circulation large vessel occlusion caused by intracranial aortic atherosclerosis stenosis, the Solitaire AB stent was unfolded and the anterior blood flow was maintained at mTICI level 2b/3 to release the stent, which can avoid repeated mechanical thrombus removal causing pulling back damage to the vascular intima[32] and repeated mechanical pulling back leads to re-occlusion of the blood vessel. Also, the time for salvage stent placement is shortened. The operation was relatively simple, the operation time was short, and the damage to the blood vessel was small. The operation cost was relatively low, creating favorable conditions for obtaining a good prognosis, and it was a clinically beneficial technique. Due to the relatively small number of cases, a larger sample size is still needed to confirm these findings, and the restenosis and long-term effects after stent release require further investigation.

CONCLUSION

In conclusion, Solitaire AB stent-release angioplasty may be safe and effective in the treatment of acute middle cerebral artery atherosclerotic occlusive cerebral infarction.

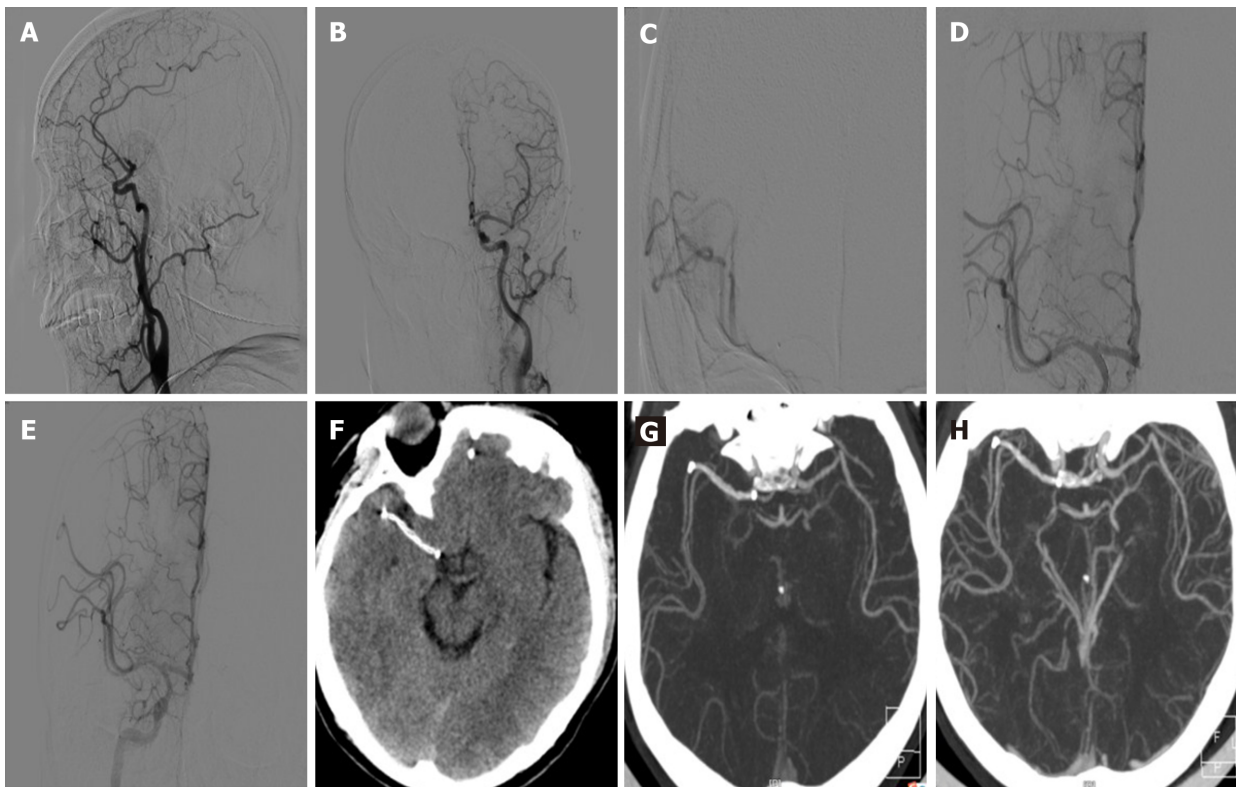


Figure 2 A 54-year-old male was admitted to the hospital with numbness and weakness in his left limb for 1 h. His admission National Institutes of Health Stroke Scale (NIHSS) score was 14 points, rt-PA intravenous thrombolysis after bridging endovascular treatment was performed, and immediately after surgery his NIHSS score was 2 points. The modified Rankin scale score was 0 points after 3 mo. A: Digital subtraction angiography lateral view shows proximal occlusion of the right middle cerebral artery; B: Left internal carotid artery angiography shows that the left anterior middle cerebral artery blood circulation was unobstructed; C: Micro-catheter angiography confirmed that the far end of the right middle cerebral artery was unobstructed; D: The Solitaire AB stent (4 mm × 20 mm) was unfolded (before being released) and the distal blood flow modified thrombolysis in cerebral infarction was above 2b/3; E: The distal blood flow was maintained after 15 min. The Solitaire AB stent was released; F: Immediately after surgery, there was no bleeding observed on head computed tomography (CT), and the shape of the stent was visible; G: Three days postoperatively, CT angiography (CTA) showed that the Solitaire AB stent was in good shape and the distal blood flow was smooth; H: The 3-month re-examination by CTA showed that the stent was in good shape and the distal blood flow was smooth.

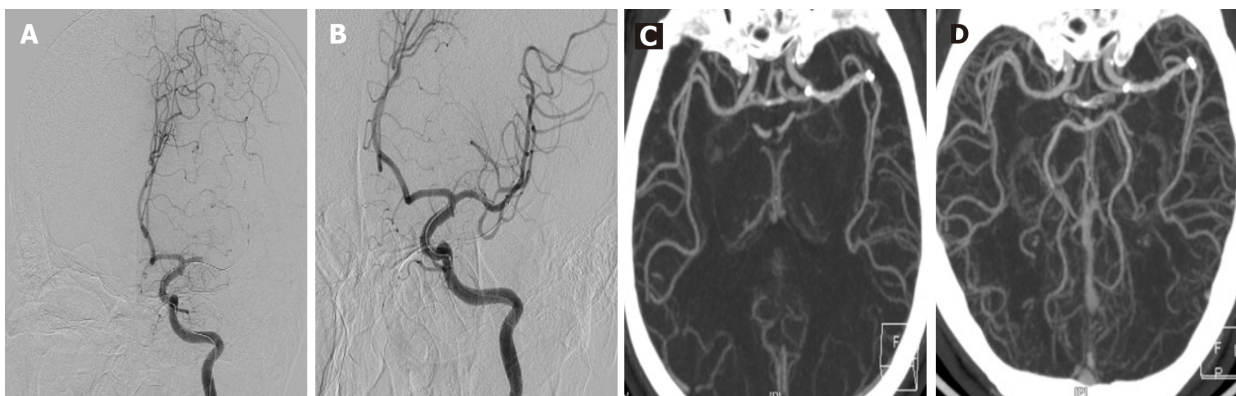


Figure 3 A 53-year-old male was admitted to the hospital with numbness of the right limb for 5.5 h, aggravation, and weakness for 1.5 h. The National Institutes of Health Stroke Scale (NIHSS) score was 10 points. The patient exceeded the intravenous thrombolysis time window and received emergency endovascular treatment. The NIHSS score immediately after the operation was 2 points. The modified Rankin scale score was 0 points after 3 mo. A: Left internal carotid angiography showed that the proximal left middle cerebral artery was occluded, part of the pial branch was compensated, and the micro-guide wire passed the stenosis; B: The Solitaire AB stent was unfolded (before being released) and the distal blood flow modified thrombolysis in cerebral infarction level was 2b/3. After 15 min observation, the stent was released; C: Computed tomography angiography (CTA) 3 d postoperatively showed that the Solitaire AB stent (4 mm × 20 mm) was in good shape and the distal blood flow was smooth; D: CTA 3 mo after surgery showed that the stent was in good shape and the distal blood flow was smooth.

ARTICLE HIGHLIGHTS

Research background

In recent years, the application of various intravascular thrombectomy devices has led to the rapid development of intravascular therapy, the Solitaire AB is a recyclable stent and its efficacy has been confirmed in several large clinical trials. Stent thrombectomy in the treatment of aortic occlusion was rapidly recommended as the standard treatment for acute great artery occlusion by domestic and international guidelines. However, the etiology of acute aortic occlusive cerebral infarction is complex, and at present, there is relatively little research on different treatment strategies for different etiologies and pathogenesis.

Research motivation

Aimed at the characteristics of intracranial atherosclerotic occlusion as the main pathogenesis of acute cerebral infarction in domestic patients, targeted treatment is required.

Research objectives

To analyze the safety and efficacy of Solitaire AB stent-release angioplasty in patients with acute middle cerebral artery atherosclerosis obliterative cerebral infarction.

Research methods

To observe the effect of Solitaire AB stent release in 25 patients with acute middle cerebral artery atherosclerotic cerebral infarction enrolled in a retrospective study.

Research results

The operation was successful in all 25 patients, the mean recanalization time was 23 min, the National Institutes of Health Stroke Scale scores decreased significantly at different time points after surgery, and the proportion of patients with a 3 mo modified Rankin scale score ≤ 2 was 80%.

Research conclusions

For patients with acute anterior circulation occlusion caused by intracranial aortic artery atherosclerosis, after Solitaire AB stent opening if the forward flow can maintain the level of modified thrombolysis in cerebral infarction 2b/3, stent release may be safe and effective.

Research perspectives

From the perspective of clinical practice, according to the main causes of acute aortic occlusion in China, targeted treatment methods should be adopted.

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