

# Analysis of Factors Influencing the Complications of Solitaire AB Stent Mechanical Thrombectomy in Patients with Acute Intracranial Artery Occlusion

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**Abstract:** To investigate the influence factors of hemorrhage and stroke with retriever with Solitaire AB stent in patients with acute intracranial artery occlusion. **Methods:** A retrospective of 43 cases of patients with acute intracranial artery occlusion for endovascular treatment with Solitaire AB stent enrolled from March 2016 to June 2018 in our hospital, combining the characteristics of the patients of our city, through the clinical baseline data statistical analysis, complications screening of risk factors of complications. **Results:** There were 81.4% of patients who were dredged totally. The incidences of cerebral hemorrhage and infarction were 18.6% and 16.3%, cerebral hemorrhage group compared with control group, diabetes, blood pressure, revascularized time, NIHSS score, ASPECTS score had statistically significant differences, when infarction group compared with control group, age, opening time, ASITN\_SIR score and grade of mTICI had statistically significant differences. **Conclusion:** Mechanical thrombectomy with Solitaire AB stent in patients with acute intracranial artery occlusion, the occurred of complications associated with various clinical factors, and the occurrence of complications seriously affect the prognosis of patients, therefore, selecting the indications strictly, and adopt individualized treatment to reduce complications.

**Keywords:** acute ischaemic stroke; Solitaire AB stent; retriever; complications; influence factors

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## 1 Introduction

The sample survey showed that the incidence of stroke continued to increase, which has become the leading cause of disability and death in China<sup>[1]</sup>. It causes a heavy burden and intense suffering to society, families and individuals, in which ischemic stroke accounts for about 80%. Intravenous thrombolysis has been shown to be effective in early revascularization in patients with cerebral infarction, however, the time windows limits the number of patients to receive treatment in a very limited extent. With the continuous advancement of interventional therapy techniques and materials in cerebrovascular diseases, the deepening of the treatment in acute ischemic stroke from “time is the brain” to “mismatch is the brain” has made clear that mechanical thrombectomy is the main endovascular treatment of acute intracranial artery occlusion and can yield a significant benefit compared to standard medical treatment. In practice, a considerable number of patients with indications showed no significant improvement in their condition after receiving endovascular treatment and even serious complications such as hemorrhagic transformation. In this study, we combined the clinical characteristics of patients with acute ischemic stroke in this city to investigate the factors in affecting the prognosis of patients with acute intracranial artery occlusion treated with Solitaire AB stent and provide a reference to more individualized treatment.

## 2 Data and methods

### 2.1 General information

A total of 43 patients with acute ischemic stroke who underwent thrombectomy in the Department of Neurology, The Central Hospital of Guangyuan City

from March 2016 to June 2018 were enrolled. The time from onset till the femoral artery puncture was less than 6 hours, including 21 males (45.7%), 22 females (47.8%) with an average age of  $67.4 \pm 9.8$  years. Combined with other diseases and personal history, there were 31 patients with hypertension (67.4%), 20 patients with diabetes (43.5%), 5 patients with elevated blood lipids (11.6%), 8 patients with atrial fibrillation (18.6%), 8 patients with coronary heart disease (18.6%), 19 patients with smoking history (44.2%) and 12 patients with drinking history (27.9%). Computed tomography angiography (CTA) and digital subtraction angiography (DSA) showed intracranial artery occlusion, wherein 8 cases at internal carotid artery (17.4%), 29 cases at middle cerebral artery (43.5%), 3 cases at basilar artery (6.9%) and 2 cases at vertebral artery (4.7%).

## 2.2 Research methodology

### 2.2.1 Inclusion criteria

(1) Diagnostic criteria for acute ischemic stroke by referring to “China Acute Ischemic Stroke Diagnosis and Treatment Guide 2018”. (2) Age  $\geq 18$  years. (3) CTA or DSA shows intracranial artery occlusion. (4) National Institutes of Health Stroke Scale (NIHSS) score  $\geq 6$  points. (5) Alberta Stroke Program Early CT (ASPECTS) score  $\geq 6$  points. (6) No thrombolytic contraindications in the onset time window using recombinant tissue plasminogen activator (rt-PA) (4.5 hours) or urokinase (4.5-6 hours) for thrombolysis, direct bridging and thrombectomy.

### 2.2.2 Exclusion criteria

Combined with severe heart, lung, liver and kidney diseases, active bleeding, severe trauma and inability to cooperate.

### 2.2.3 Endovascular treatment method

According to whether the patients can choose local anesthesia or general anesthesia with individualized treatment, the pre-operative blood pressure should not exceed 180/105 mmHg, and the sheath should be placed immediately after the puncture of femoral artery. A DSA examination should be performed to determine the occlusion of the patients. The collateral circulation classification was performed by the Neuroradiology and Neuroradiology Society (ASITN\_SIR) collateral grading system<sup>[2]</sup> for the neuro interventional treatment. The collateral circulation/blood flow was divided into 5

levels. It was ranging from 0th level to 4th level, which were no collateral blood flow in the lesion area, slow collateral blood flow with continuous perfusion defects, rapid collateral flow with continuous perfusion defects, slow and complete blood flow, rapid and complete retrograde perfusion of blood flow. (1) Levels 2 to 4 were designated as good collateral circulation whereas (2) levels 0 to 1 were designated as poor collateral circulation. 6F common guiding catheter is in place, 0.014 micro-guide wire and micro-catheter are passed through the occlusion segment to deliver and release Solitaire AB stent. 6 mm or 4 mm of stent is selected according to the diameter of the blood vessels (4 mm stent was selected if diameter of the tube is  $< 3$  mm). After the micro-catheter was returned to the guiding catheter, the angiography was repeated. The modified thrombolysis in cerebral infarction (mTICI) was used to evaluate the blood vessel revascularization. Level 0 indicates no perfusion, level 1 indicates only a small amount of blood flow through the occlusion segment, level IIa indicates blood perfusion  $< 50\%$  at the ischemic area, level IIb indicates perfusion  $\geq 50\%$  at the ischemic area, level III indicates complete perfusion at the ischemic area while achieving mTICI level 2b/3 represents good reperfusion. After surgery, 100 mg/day of aspirin and 75 mg/day of clopidogrel were taken orally or infusion of tirofiban for 24 hours. Anti-platelet aggregation drugs were given after excluding the possibility of bleeding by reviewing head computed tomography (CT) after 24 hours of intravenous thrombolysis. After 3 months, the treatment was changed to monotherapy using a single drug.

## 2.3 Observation index

(1) Immediate post-operative angiography and 24 hours post-operative examination of head CT and magnetic resonance imaging (MRI) to assess revascularization. (2) 3 months post-operative mRS score 0 to 2 points to assess the prognosis of patients. (3) Statistics on the complications of cerebral hemorrhage, infarction of the new site and recurrent occlusion.

## 2.4 Statistical analysis

Statistical analysis was performed using SPSS 23.0. The data was expressed in percentage (%). The measurement data was expressed as mean  $\pm$  standard deviation. The risk factors affecting the occurrence of complications were analyzed by one-way ANOVA. The difference was statistically significant at  $P < 0.05$ .

### 3 Results

#### 3.1 Univariate analysis of the effects of endovascular treatment on the complications of acute ischemic stroke

There were 8 cases of cerebral hemorrhage occurred (18.6%) compared with patients without complications of cerebral hemorrhage. Age, gender, obesity, smoking and drinking histories, hypertension, coronary heart disease, diabetes, hyperlipidemia, atrial fibrillation, platelet count, intravenous thrombolysis rate, ASITN\_SIR score, mTICI score, occlusion site, stent size were not statistical significant ( $P>0.05$ ), whereas diabetes, blood pressure over 180/105 mm Hg, revascularization time, NIHSS score, ASPECTS score and cerebral

hemorrhage were statistically significant ( $P<0.05$ ). See Table 1.

Cerebral infraction included recurrent vascular occlusion of the primary vessel and infraction of the new site. A total of 7 cases occurred (16.3%) compared with patients without complications of cerebral infraction. Gender, obesity, smoking and drinking histories, hypertension, coronary heart disease, hyperlipidemia, atrial fibrillation, platelet count, intravenous thrombolysis rate, NIHSS score, ASPECTS score, occlusion site, stent size were not statistically significant ( $P>0.05$ ), whereas advanced age, time from onset till the femoral artery puncture, ASITN\_SIR score and mTICI score were closely related to the occurrence of cerebral infraction and the difference was statistically significant ( $P<0.05$ ). See Table 1.

**Table 1. Analysis of factors influencing the complications of endovascular treatment in acute ischemic stroke**

Parameters	Complications (n=15)		Non-hemorrhagic (n=28)	P	
	Hemorrhage (n=8)	Infraction (n=7)		P1	P2
Age ( $\bar{x}\pm s$ )	66.4 $\pm$ 7.6	78.7 $\pm$ 4.4	64.9 $\pm$ 9.6		0.001
Gender, female, n (%)	4 (50)	2 (28.6)	16 (57.1)		
Obesity, n (%)	2 (37.5)	2 (28.6)	7 (25)		
Smoking history, n (%)	5 (62.5)	3 (42.9)	11 (39.3)		
Drinking history, n (%)	1 (12.5)	1 (14.3)	10 (35.7)		
Coronary heart disease, n (%)	1 (12.5)	1 (14.3)	6 (21.4)		
Hypertension, n (%)	6 (75)	6 (85.7)	19 (67.9)		
Diabetes, n (%)	7 (87.5)	4 (57.1)	9 (32.1)	0.015	
Hyperlipidemia, n (%)	1 (12.5)	0	4 (14.3)		
Platelet count<100, n (%)	2 (25)	3 (42.9)	10 (35.7)		
Atrial fibrillation history, n (%)	2 (25)	3 (42.9)	3 (10.7)		
Blood pressure during admission (diastolic pressure>100 or systolic pressure>180 mm hg), n (%)	4 (50)	1 (14.3)	3 (10.7)	0.036	
Time from onset till puncture, min ( $\bar{x}\pm s$ )	331.3 $\pm$ 19.6	324.3 $\pm$ 25.1	283.6 $\pm$ 38.6	0.004	0.022
Intravenous thrombolysis, n (%)	3 (37.5)	3 (42.9)	13 (46.4)		
General anesthesia, n (%)	7 (87.5)	6 (85.7)	24 (85.7)		
NIHSS score, ( $\pm s$ )	15.4 $\pm$ 4.4	13.6 $\pm$ 4.2	10.7 $\pm$ 2.9	0.037	
ASPECTS score $\leq$ 7 points, n (%)	4 (50)	3 (42.9)	2 (7.1)	0.020	
ASITN_SIR score, Level 2-4, n (%)	2 (25)	1 (14.3)	18 (64.3)		0.047
mTICI reaches 2b/3, n (%)	7 (87.5)	3 (42.9)	25 (89.3)		0.013
Thrombosis					
Internal carotid artery, n (%)	3 (37.5)	2 (28.6)	3 (10.7)		
Basilar artery, n (%)	2 (25)	1 (28.6)	4 (14.3)		
Vertebral artery, n (%)	0	2 (14.3)	6 (21.4)		
Middle cerebral artery, n (%)	3 (37.5)	2 (28.6)	15 (53.6)		
Stent size					
4 mm, n (%)	3 (37.5)	4 (57.1)	21 (75)		
6 mm, n (%)	5 (62.5)	3 (42.9)	7 (25)		
3 months post-operative mRS score 0–2 points, n (%)	1 (12.5)	3 (42.9)	18 (64.3)	0.029	

Note:  $P < 0.05$  is statistically significant.

### 3.2 Data analysis results

The results showed that the revascularization of mTICI reached 35 cases in level 2b/3. The revascularization rate was 81.4%, the incidence of cerebral hemorrhage was 18.6% and the incidence of cerebral infraction was 16.3%.

In term of complications of cerebral hemorrhage, it was statistically significant ( $P < 0.05$ ) in patients with diabetes mellitus, blood pressure over 180/105 mmHg, time from onset till femoral artery puncture, NIHSS score and ASPECTS score. In addition, the proportion of smoking history in the hemorrhagic transformation group [5 (62.5%)] was significantly higher than that in the non-hemorrhagic group [11 (39.3%)], while the ASITN\_SIR score at level 2-4 [2 (25%)] was significantly lower than that in the non-hemorrhagic group [18 (64.3%)]. Moreover, the difference in stent size was obvious [3 (37.5% vs 21 (75%)), but it was not statistically significant.

Meanwhile, infraction of the new site or recurrent vascular occlusion complications, statistical analysis showed that the age, NIHSS score, ASPECTS score  $\leq 7$  points, ASITN\_SIR score level 0-1 were statistically significant ( $P < 0.05$ ). In addition, the proportion of cerebral infraction in patients with diabetes [4 (57.1%)] was higher than that in the control group [9 (32.1%)]. Moreover, the proportion of patients with atrial fibrillation [3 (42.9%)] was higher than that in the control group [3 (10.7%)]. However, the differences between these two groups were not statistically significant.

The study showed that patients with complications of cerebral hemorrhage had a significant reduction in 3 months post-operative mRS scores at level 0-2 [1(12.5%) vs 18(64.3%)] ( $P = 0.029$ ), and the difference was statistically significant. Meanwhile, patients with complication of cerebral infraction with 3 months post-operative mRS scores at level 0-2 were also obviously reduced [3(42.5%) vs 18(64.3%)], but there was not statistically significant.

## 4 Discussion

Endovascular treatment in acute ischemic stroke has undergone evolution from arterial thrombolysis, bridged arterial thrombolysis to mechanical thrombectomy using stent retriever as well as the vascular stent formation and implantation during the bridging therapy

in mechanical thrombolysis and combined with special case of severe stenotic vascular disease. With the continuous advancement of interventional techniques and materials, DEFUSE-3 and DAWN-based studies have confirmed that by assessing ischemic penumbra with the aid of CTP, PWI, DWI and others can help to better define the mismatch between infarct core in clinical practice and hence prolong the intravascular treatment time window<sup>[3, 4]</sup>. Neovascular interventional techniques have achieved more and more obvious results in the treatment of acute cerebral infraction and the development prospects are very positive. However, some patients have more serious complications in clinical practice. Therefore, it is of great clinical value to investigate the prognostic factors of patients with acute intracranial artery occlusion treated by mechanical thrombectomy.

Previous clinical practice studies have shown<sup>[5]</sup> that even patients with acute cerebral infraction who meet the indications for endovascular treatment has successful revascularization within the time window. However, there is still a difference in clinical prognosis. A considerable number of patients have no significant improvement in symptoms, and some have a poor prognosis due to cerebral hyperperfusion. Our study showed that urinary disease, blood pressure over 180/105 mmHg during admission, time from onset till femoral artery puncture, NIHSS score and ASPECTS score were closely related to cerebral hemorrhage. Previous studies<sup>[6]</sup> have shown that increased vascular fragility in diabetic patients can lead to increased risk hemorrhagic transformation. Diabetes promotes mitochondrial dysfunction and accelerates endothelial cell death. Therefore, patients with acute intracranial artery occlusion have ischemia and hypoxia. The prognosis of patients with combined diabetes and cerebral ischemia is even worse and the risk of hemorrhagic transformation is also increased. This study also showed that intravascular treatment of diabetic cerebral hemorrhage after acute stroke is closely related. At present, there is disagreement about whether collateral circulation, acute intracranial artery occlusion and long revascularization time should actively undergo interventional vascular treatment. Some opinions<sup>[5]</sup> suggest that the prognosis will be poor if such patients are unable to be revascularized. Some experts have pointed out that such occluded arteries are often ineffective upon treatment. The symptoms of patients are unable to be improved but also may

significantly increase the risk of cerebral hemorrhage due to high perfusion. Good collateral circulation can significantly reduce the recurrent of hemorrhagic transformation after the endovascular treatment of blood vessels<sup>[7]</sup>. This study showed that the risk of hemorrhagic transformation was high in patients with low ASPECTS scores and long revascularization time. The ASITN\_SIR scores at level 2-4 showed that hemorrhagic transformation group was also significantly lower than those in non-hemorrhagic group. The ASPECTS and ASITN\_SIR scores reflected collateral circulation. For such patients, the inefficient rate of revascularization was high and even some patients have complications of cerebral hemorrhage which seriously affect the prognosis. Therefore, intravascular treatment of such patients should be carefully selected, and should be assessed with before surgery using CTP, DWI, PWI and other full imaging evaluation of the penumbra and core infarct area for predicting the risk. Previous literature has reported<sup>[8]</sup> the increased risk of intracerebral hemorrhage after treatment in patients with acute cerebral infarction received high blood pressure before thrombolysis or thrombectomy (diastolic blood pressure>100 mmHg, systolic blood pressure>180 mmHg. This study shows that pre-operative blood pressure is closely related to cerebral hemorrhage. At present, the post-operative hemorrhagic transformation in patients with acute stroke is mainly treated with surgical treatment and intracranial pressure control.

After mechanical thrombectomy for acute ischemic stroke, vascular reocclusion and new localized embolism are also common complications of endovascular treatment and are associated with worsen clinical symptoms. Irreversible damage will occur after 5-6 minutes of neuronal ischemia. Therefore, even if the blood flow is revascularized, some patients still have severe sequela of cerebral infarction or recurrent infarction that is cannot be revascularized again. In a study of multimodal CT<sup>[9]</sup> score prediction for unvascularization, the ASPECTS score was used to analyze CT, CTA and CTP. Among the 150 patients included, the results showed that CTA ASPECTS score, cerebral blood volume ASPECTS score and collateral circulation can be used as grading predictions for the probability of unvascularization. This study showed that the age, NIHSS score, aspect score, ASITN\_SIR score were closely related to the occurrence of cerebral infarction after thrombectomy.

The proportion of cerebral infarction combined with atrial fibrillation and diabetes was also significantly higher than that of the control group. The ASPECTS and ASITN\_SIR scores reflect the circumstances of collateral circulation, and the relationship of patients with good collateral compensation and survival time of the ischemic penumbra. In addition, it is concerned that the atherosclerotic of the elderly patients is becoming more severe. During the thrombectomy process, the embolus may be displaced and the fragmentation may cause embolization of the distal secondary and adjacent blood vessels. Therefore, patients with acute cerebral infarction are screened by assessing the collateral circulation. Patients with advanced age and poor assessment of basic arterial conditions should have used a protective device such as an intermediate catheter to reduce the risk of embolization. In addition, the use of IIb/IIIa receptor antagonists with less reocclusion after surgery is closely related to clinical treatment decision making.

There is much evidence shows that stent diameter is an important factor affecting the efficacy of endovascular treatment<sup>[10]</sup> and the current guidelines have not yet reached a consensus on the size of the stent. A recent multicenter study showed no significant difference in efficacy and safety between patients with different diameter of Solitarie retractable stents in the treatment of acute intracranial artery occlusion. In the application of 4 mm diameter stent in patients with atherosclerotic occlusion, the operation time is shorter, the number of thrombectomy is lesser and the revascularization rate is higher<sup>[11]</sup>. There was no significant difference in the diameter of the stent and the complications in this study. It may also due to the small number of patients included in the study. The NIHSS score during admission was an independent predictor of clinical outcome in patients with acute ischemic stroke<sup>[12]</sup> and a good assessment of the severity of neurological damages. This study showed that the NIHSS score was closely related to cerebral hemorrhage and cerebral infarction complications after thrombectomy treatment.

#### **4.1 Specificity of Guangyuan area in Sichuan**

In this study, the proportion of patients with cerebral infarction with platelet count less than  $100 \times 10^9/l$  was 34.9% higher. Based on their medical history, it is speculated that this may be related to the low recovery treatment rate of intravenous thrombolysis in cerebral infarction hyperacute phase in the city. All patients had no significant hemorrhage tendency

before admission. Therefore, endovascular intervention has important clinical significance. This study also showed no significant relationship between platelet counts and prognosis, hemorrhage complications, recurrent infarction after revascularization or ineffective revascularization in patients with reduced thrombocytopenia and no significant hemorrhage tendency. However, due to the low sample size, a large sample survey is required to confirm the prevalence of thrombocytopenia in patients with cerebral infarction in the city. For the case of platelet aggregation in thrombocytopenia, the safety of endovascular treatment and possibility of thrombolysis therapy with informed consent will benefit patients with cerebral infarction in the city.

## 5 Conclusions

Neurointerventional techniques for the treatment of acute intracranial artery occlusion can greatly improve the prognosis of patients. However, it should be strictly regulated by screening through the uncontrollable factors and resolving the controllable factors. According to the specific case analysis, individualized treatment plan is adopted to reduce complications. In addition, the platelet count is low and there is no clear hemorrhage tendency in patients with cerebral infarction in Guangyuan City. For the tolerance to platelet aggregation, thrombolysis and endovascular treatment, further investigation is required in a large sample size. Interventional therapy for acute cerebral infarction is still in its developmental stage. The time window of interventional therapy is still the current research hot topic. Patients will further benefit from the advancement of technology and the continuous improvement of intravascular interventional devices.

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