

Application of retrievable Solitaire AB stents in the endovascular treatment of acute ischemic stroke

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ABSTRACT

Purpose: Retrievable stents are widely used in acute ischemic stroke (AIS); however, the results remain unclear in Chinese patients. This study aimed to explore the usefulness of Solitaire AB stents in AIS.

Materials and Methods: Seventy-three AIS patients treated with Solitaire AB stents for thrombectomy of large artery occlusion of anterior circulation in January 2014-June 2015 were retrospectively evaluated. Recanalization was assessed with the Thrombolysis In Cerebral Ischemia (TICI) scale. Clinical outcomes were assessed according to the National Institute of Health Stroke Scale (NIHSS) and the modified Rankin Scale (mRS). Operation-related complications were recorded. The main factors affecting successful recanalization with Solitaire AB were analyzed.

Results: The 73 patients enrolled included 39 males and 34 females (median age of 59 [31-78] years); 77 Solitaire AB stents were used. The initial recanalization rate with Solitaire AB as the first thrombectomy method was 53.42% (39/73; recanalization group). Among the 34 patients with failed stent retrieval, 32 underwent other treatments; the final arterial recanalization rate was 89.04% (65/73). Perioperative embolization events and symptomatic intracranial hemorrhage (sICH) occurred in 5 and 8 patients, respectively. The mean NIHSS score was 9.12 ± 3.86 one week after thrombectomy, significantly lower compared with admission values. In 31 patients (42.47%), NIHSS score decreased by >8 . Good functional independence (mRS score ≤ 2) was achieved in 39 patients (53.42%) at 90 days; 12 patients (16.44%) died. Compared with the recanalization group, the remaining patients showed lower AF and higher LAA percentages.

Conclusion: Solitaire AB stents are useful in the endovascular treatment of AIS.

Keywords: Acute ischemic stroke; Solitaire stent; Artery occlusion; Recanalization therapy; Intracranial hemorrhage

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INTRODUCTION

Stroke is the third cause of modality worldwide and the first in China, with a high disability rate; 60%-80% of all stroke cases are acute ischemic stroke (AIS). In the past, intravenous thrombolysis has been used as the standard treatment for AIS, and its efficacy has been confirmed by many clinical trials (1, 2). However, intravenous thrombolysis has a short time window, low a recanalization rate, and higher disability and mortality rates. Recently, the

application of various thrombectomy devices has helped endovascular intervention therapy develop very fast. With the publication of recent randomized, controlled trials of endovascular treatments for AIS (3-7), mechanical thrombectomy with stent retrievers has been recommended as the first-line method in patients with intracranial large artery occlusion (LAO) (8).

The Solitaire AB stent was approved by the FDA in 2012 for clinical use as a new generation of thrombectomy devices; the new retrievable stents have promoted immediate reperfusion in AIS, showing superior results in large vessel occlusion compared with other recanalization devices and techniques (9). The stent acts as a temporary intracranial bypass providing immediate flow restoration; when it is withdrawn, the thrombosis could be removed by trapping the thrombus into cells. In this study, patients with AIS due to LAO who received endovascular treatment were analyzed retrospectively to evaluate the therapeutic effects and safety of retrievable Solitaire stents.

MATERIALS AND METHODS

Patient Population

AIS patients due to large artery occlusion of anterior circulation treated with Solitaire AB stents in the period between January 2014 and June 2015 in Henan Provincial People's Hospital were retrospectively reviewed. All patients underwent cranial CT (MRI) to exclude intracranial bleeding; Alberta Stroke Program Early CT (ASPECT) scores were used to evaluate the extent of infarction based on previously acquired non-enhanced CT or magnetic resonance imaging (MRI) data. Some patients might have multiple modes of imaging examinations for the evaluation of ischemic cerebral tissues. Patients eligible for IVT received IVT (rt-PA 0.9 mg/kg) before endovascular treatment. The inclusion criteria for endovascular treatment were consistent with the following conditions: 1) $18 \leq \text{age} \leq 80$ years; 2) time from symptom onset to puncture < 6 h; 3) exclusion of intracranial hemorrhage by cranial CT or MRI; 4) anterior circulation occlusion confirmed by CTA or MRA; 5) NIHSS score ≥ 6 ; 6) informed consent from the patients or their legal representatives. Exclusion criteria were: 1) known serious sensitivity to radiographic contrast agents or device materials; 2) known hereditary or acquired hemorrhagic diathesis; 3) severe cerebral stroke within 6 months; 4) ASPECT score < 6 ; 5) baseline NIHSS score > 30 ; 6) life expectancy of less than 90 days.

Thrombectomy procedure

Under conscious sedation or general anesthesia, a 6F or larger guide catheter was placed through the femoral artery, proximal to the target vessel, which was navigated with a 0.014-inch micro-guide wire (Boston USA) through the occlusion. A microcatheter was then advanced over the wire to the distal side of the occlusion. Selective microcatheter angiography was performed to confirm the occlusion site and distal blood flow. Under the optimal working angle, a 0.021-inch Rebar 18 microcatheter (ev3, Irvine, USA) was navigated to the distal occlusion over the micro-wire. Then, the microcatheter was exchanged with a Solitaire stent, whose size was selected according to occlusion site and length. The stent's distal marker was positioned at the proximal side of the microcatheter. Upon deployment of the stent, angiography was performed to observe blood flow. The device was left in place for 3-5 minutes before removal. Next, the stent and microcatheter were gently pulled back, and manual aspiration with a 50 ml syringe was performed during stent retrieval. Generally, the above steps were performed no more than five times. In a patient with tandem internal carotid and middle cerebral arterial occlusions, the first step was generally to establish endovascular access with balloon dilatation, stent implantation or forced suction thrombectomy, before attempting the recanalization of the intracranial occlusion. Patients with failed stent retrieval may receive other rescue treatments, and a stent might be considered for deployment. In patients with stent deployed, tirofiban (8 μ g/kg) should be injected intravenously within three minutes, followed by

continuous use at a dosage of 0.10 μ g/(kg /min) for 24h. CT was performed after intracranial bleeding, with low molecular weight heparin dripped intravenously during the whole procedure.

Postoperative management

Blood pressure was closely monitored; cranial CT or MRI was performed in the first 24 hours after the procedure to detect the presence of ICH. In patients with stent placement, dual anti-platelet drugs (aspirin 100 mg/d and clopidogrel 75 mg/d) were used for 3 months after the procedure. Then, single anti-platelet medicine (aspirin 100 mg/d) was administered. In patients with no stent deployment, long-term application of single anti-platelet (aspirin 100 mg/d) was required for the prevention of stroke recurrence.

Definitions and Statistical Analysis

The etiology of AIS with large artery occlusion was based on the TOAST classification system (10). Recanalization results were assessed by catheter angiography according to the Thrombolysis in Cerebral Ischemia (TICI) system, and successful recanalization was defined as TICI2a or 3. Improvement in neurologic function in one week after the procedure was defined as a decrease of 4 or more in the NIHSS score. Clinical outcome at 90 days was assessed according to the modified Rankin Scale (mRS), good functional independence defined as a mRS score of 0 to 2. Symptomatic intracranial hemorrhage (sICH) was defined as any type of hemorrhage on imaging studies and clinical deterioration of more than 4 points in the NIHSS score or a 1-point reduction in the level of consciousness with the NIHSS.

Data analysis was performed with the SPSS software (version 22.0; SPSS, Chicago). Continuous variables were presented as mean \pm SD. Baseline characteristics and clinical outcomes were compared between the two groups by the Fisher test for categorical variables and Student's t test for continuous ones. Two-sided $P < 0.05$ was considered statistically significant.

RESULTS

Seventy three patients (39 males, 34 females) with AIS were treated with Solitaire AB stents during the study period. Their demographic and clinical features are shown in Table 1.

For occlusion site, middle cerebral artery occlusion (MCA) was found in 35 cases (47.95%), with intracranial internal carotid artery (ICA) occlusion in 26 cases (35.62%), and tandem internal carotid artery and middle cerebral arterial (TIM) occlusion in 12 cases. Concerning the etiology of large artery occlusion, large artery atherosclerosis (LAA) was present in 33 cases (45.21%), with cardioembolism (CE) in 31 cases (42.47%) and stroke of undetermined etiology in 9 cases (12.33%).

Table 1 Demographic and clinical features of the included patients.

Characteristics	All patients (n=73)	Recanalization (n=39)	No-recanalization (n=34)	P
Age, y	58.72	58.42±3.75	59.06±5.23	1.000
Male sex	39(53.42%)	18(46.15%)	21(61.76%)	0.241
Hypertension	43(58.90%)	20(51.28%)	23(67.64%)	0.233
Diabetes	16(21.92%)	6(15.38%)	10(29.41%)	0.168
Hyperlipidemia	19(26.03%)	9(23.08%)	10(29.41%)	0.599
Atrial fibrillation	28(38.35%)	22(56.41%)	6(17.65%)	<0.001
LAA	33(45.21%)	10(13.70%)	23(67.64%)	<0.001
Admission NIHSS score	17.08	17.09±4.34	17.06±3.69	1.000
Prior IVT	8(10.96%)	5(12.82%)	3(8.82%)	0.716
Embolization	5(6.85%)	4(10.26%)	1(2.94%)	0.363
sICH	8(10.96%)	4(10.26%)	4(11.76%)	1.000
90d mRS (0-2)	39(53.42%)	21(53.84%)	18(52.94%)	1.000
Mortality rate	12(16.44%)	6(15.38%)	6(17.65%)	1.000

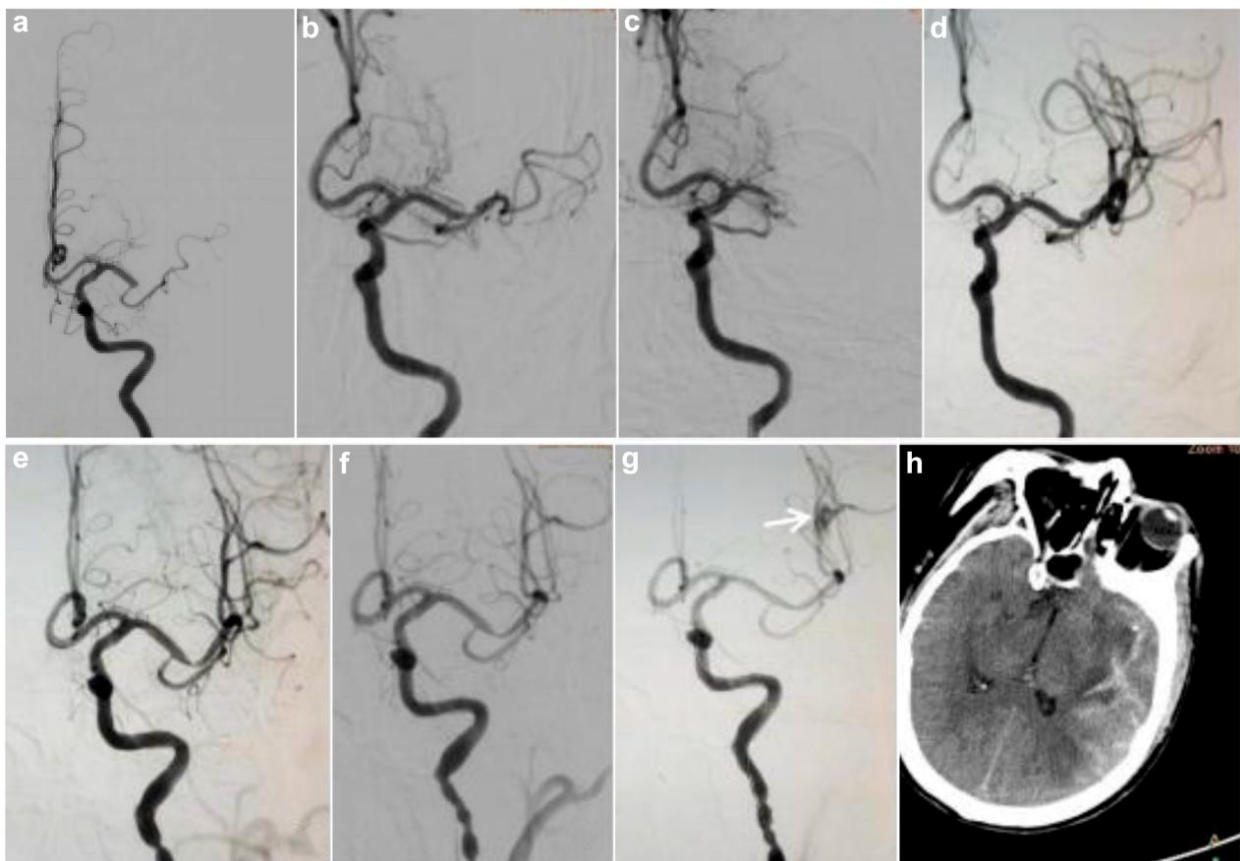


Figure 1. A 56 year old man suffered a sudden attack of right hemiplegia and aphasia 5h ago; the NIHSS score was 18, and MRA showed occlusion of the LMCA. (a) DSA showed occlusion of the LMCA; (b) the occlusion was partially recanalized after Solitaire retrieval in combination with penumbra aspiration; (c) the artery was still occluded after second thrombectomy with Solitaire stent; (d) TIC1 2b was achieved after third stent retrieval; (e) TIC1 1 was obtained during the observation; (f) an Enterprise stent was deployed in the site of stenosis; (g) extravasation contrast was observed after balloon dilatation; (h) postoperative CT showed subarachnoid hemorrhage (SAH). The mRS score of the patient at 90d was 2.

Compared with patients who had successful recanalization with Solitaire AB as the first thrombectomy method (recanalization group), the no-recanalization group had a lower percentage of AF in etiology ($P<0.001$) and significantly higher percentage of LAA ($P<0.001$).

A total of 8 cases (10.96%) received intravenous thrombolysis before stent thrombectomy. A total of 77 Solitaire AB stents were used in the 73 patients; thrombectomy with the Solitaire stent was performed 1 to 4 times. The initial recanalization rate merely with Solitaire AB as the first thrombectomy method was 53.42%. Of the remaining 34 patients with failed first thrombectomy with Solitaire stent, 32 received additional rescue treatments. The rescue treatments included stent deployment in 29 cases, thrombus aspiration in 14 cases, balloon dilatation in 12 cases, and intra-arterial thrombolysis in 6 cases. The final recanalization rate for the whole cohort of patients was 89.04%. The time from groin puncture to arterial recanalization ranged from 30 to 132 minutes (75.52 ± 26.83).

During thrombectomy, distal embolization occurred in 5 patients, among whom 4 received intra-arterial tirofiban. Symptomatic intracranial hemorrhage (sICH) occurred in 8 patients. In one patient, sICH was caused by micro-guidewire perforation of the vessel (Figure 1); bleeding was stopped following acute pressure decrease and anticoagulation injection of protamine. The mean NIHSS score was 9.12 ± 3.86 one week after thrombectomy, which was significantly ($P < 0.001$) lower compared with the value at admission; in 31 patients (42.47%), the NIHSS score decreased by > 8 . Clinical good functional independence ($mRS \leq 2$) was achieved in 39 patients (53.42%) at 90 days' follow-up. A total of 12 patients died during the study period.

DISCUSSION

Although the final revascularization rate after rescue therapy increased to 89.04% in this study, the recanalization rate at the first thrombectomy with Solitaire stent was 53.42%, which is lower than the values of 58%-88% reported in other clinical trials of stent retrievers (3-7). Over 40% of the patients enrolled needed a rescue treatment after failed Solitaire stent retrieval. In a prospective multicenter study by Pereira et al, the primary revascularization rate with a Solitaire stent was 79.2% for a final revascularization rate after rescue therapy of 88.1% (11).

In the current study, the effectiveness of stent retrievers in treating acute intracranial atherosclerotic disease (IAD) related occlusion was limited compared with occlusion due to CE. Intracranial atherosclerosis and cardioembolism are two major reasons for ischemic stroke. In Asian individuals, the primary reason for acute ischemic stroke is atherosclerosis disease with a rate of 30%-50%, which is higher than that found in Western countries (12). The proportion of cases with IAD-related occlusion in this study (45.2%) was overtly higher than those reported for non-Asian populations. In a French study, only 5.5% of patients treated with stent retrievers showed intracranial stenosis (13). Deployment of Solitaire stents can achieve early flow restoration; however, atherosclerotic intracranial lesions with high-grade residual stenosis may resist the retracting

movement, and the risk of re-occlusion is high. Cardiogenic thrombi may be softer than atherosclerotic ones, and the Solitaire stent system can be superior in treating thrombi of a cardiogenic origin, which was confirmed in the present study.

Acute arterial reocclusion is a significant factor that impacts final recanalization, especially in patients with a high-grade residual stenosis (14). Glycoprotein-IIb/IIIa inhibitors can be used in endovascular treatment to prevent reocclusion and increase the odds of recanalization (15). In addition, local intra-arterial glycoprotein IIb/IIIa inhibitors were also used as a rescue treatment in early reocclusion in this study. Our results indicate that stent placement is highly effective for the treatment of refractory occlusion after failed Solitaire retrieval. Intracranial stent placement rapidly recanalizes occluded vessels; several trials depending on small samples used stent placement as complementary treatment after other endovascular methods had failed, and achieved a high rate of recanalization with an encouraging prognosis (16). Sauvageau E et al used stent placement as a rescue treatment after unsuccessful recanalization with the MERCI retriever, and achieved a 90% recanalization rate (17). Baek JH et al reported a more favorable outcome in the stenting group than in the non-stenting group for stentriever-failed occlusion without increased sICH and mortality rates (18). However, additional treatment with glycoprotein IIb/IIIa inhibitors or stent placement may also increase the risk of fatal intracranial hemorrhage according to previous studies (19, 20), although this phenomenon did not occur in the present study.

This study had some limitations. First, it was a retrospective study performed at a single hospital. Secondly, the sample size was small, with no control group included. In addition, the small cohort was further divided into subgroups with smaller numbers of patients, making it hard to draw definite conclusions from this study. Nevertheless, this work described the performance of stent retriever-based thrombectomy for intracranial large artery occlusion in the Chinese population.

The Solitaire AB stent retrieval can achieve early flow restoration of large artery occlusion of anterior circulation. The efficiency of stent retrieval differs between acute arterial occlusions due to intracranial atherosclerotic disease (IAD) and those caused by cardioembolism. Angioplasty is an efficient rescue treatment in patients with failed stent retrieval.

REFERENCES

1. Clark WM, Albers GW, Madden KP, et al. The rtPA (alteplase) 0- to 6-hour acute stroke trial, part A (A0276g) : results of a double-blind, placebo-controlled, multicenter study. Thrombolytic therapy in acute ischemic stroke study investigators. *Stroke* 2000; 31: 811-816.
2. Torbey MT, Jauch E, Liebeskind DS. Thrombolysis 3 to 4.5 hours after acute ischemic stroke. *N Engl J Med* 2008; 359: 2839; author reply 2841.

3. Berkhemer OA, Fransen PS, Beumer D, et al. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med* 2015; 372: 11-20.
4. Campbell BC, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. *N Engl J Med* 2015; 372: 1009-1018.
5. Goyal M, Demchuk AM, Menon BK, et al. Randomized assessment of rapid endovascular treatment of ischemic stroke. *N Engl J Med* 2015; 372: 1019-1030.
6. Jovin TG, Chamorro A, Cobo E, et al. Thrombectomy within 8 hours after symptom onset in ischemic stroke. *N Engl J Med* 2015; 372: 2296-2306.
7. Saver JL, Goyal M, Bonafe A, et al. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. *N Engl J Med* 2015; 372: 2285-2295.
8. Mulder MJ, van Oostenbrugge RJ, Dippel DW. Letter by Mulder et al Regarding Article, "2015 AHA/ASA Focused Update of the 2013 Guidelines for the Early Management of Patients With Acute Ischemic Stroke Regarding Endovascular Treatment: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association". *Stroke* 2015; 46: e235.
9. Grech R, Pullicino R, Thornton J, et al. An efficacy and safety comparison between different stentriever designs in acute ischaemic stroke: a systematic review and meta-analysis. *Clin Radiol* 2016; 71: 48-57.
10. Adams HP, Jr., Bendixen BH, Kappelle LJ, et al. Classification of subtype of acute ischemic stroke. Definitions for use in a multicenter clinical trial. TOAST. Trial of Org 10172 in Acute Stroke Treatment. *Stroke* 1993; 24: 35-41.
11. Pereira VM, Gralla J, Davalos A, et al. Prospective, multicenter, single-arm study of mechanical thrombectomy using Solitaire Flow Restoration in acute ischemic stroke. *Stroke* 2013; 44: 2802-2807.
12. Wong LK. Global burden of intracranial atherosclerosis. *Int J Stroke* 2006; 1: 158-159.
13. Gascou G, Lobotesis K, Machi P, et al. Stent retrievers in acute ischemic stroke: complications and failures during the perioperative period. *AJNR Am J Neuroradiol* 2014; 35: 734-740.
14. Hwang YH, Kim YW, Kang DH, et al. Impact of Target Arterial Residual Stenosis on Outcome After Endovascular Revascularization. *Stroke* 2016; 47: 1850-1857.
15. Sanak D, Kuliha M, Herzig R, et al. Prior use of antiplatelet therapy can be associated with a higher chance for early recanalization of the occluded middle cerebral artery in acute stroke patients treated with intravenous thrombolysis. *Eur Neurol* 2012; 67: 52-56.
16. Levy EI, Siddiqui AH, Crumlish A, et al. First Food and Drug Administration-approved prospective trial of primary intracranial stenting for acute stroke: SARIS (stent-assisted recanalization in acute ischemic stroke). *Stroke* 2009; 40: 3552-3556.
17. Sauvageau E, Samuelson RM, Levy EI, et al. Middle cerebral artery stenting for acute ischemic stroke after unsuccessful Merci retrieval. *Neurosurgery* 2007; 60: 701-706; discussion 706.
18. Baek JH, Kim BM, Kim DJ, et al. Stenting as a Rescue Treatment After Failure of Mechanical Thrombectomy for Anterior Circulation Large Artery Occlusion. *Stroke* 2016; 47: 2360-2363.
19. Kellert L, Hametner C, Rohde S, et al. Endovascular stroke therapy: tirofiban is associated with risk of fatal intracerebral hemorrhage and poor outcome. *Stroke* 2013; 44: 1453-1455.
20. Dorado L, Castano C, Millan M, et al. Hemorrhagic risk of emergent endovascular treatment plus stenting in patients with acute ischemic stroke. *J Stroke Cerebrovasc Dis* 2013; 22: 1326-1331.