Original Article

Mechanical Thrombectomy Using a Solitaire Stent in Acute Ischemic Stroke; Initial Experience in 40 Patients

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Objective : This study was conducted in order to demonstrate the initial experience of the Solitaire AB stent in mechanical intracranial thrombectomy.

Methods : We conducted a retrospective review of 40 consecutive patients who underwent intra-arterial Solitaire AB stent thrombectomy for treatment of acute ischemic strokes between October 2010 and November 2011. Demographic, clinical, and radiological presentations and outcomes were studied.

Results : Twenty six men and 14 women with a mean initial National Institutes of Health Stroke Scale (NIHSS) score of 14.1 (range, 8-26) and a mean age of 65.4 (range, 32-89) years were included in this study. Occlusion sites were as follows: internal carotid artery (n = 11), middle cerebral artery M1 (n = 22), M2 (n = 5), and basilar artery (n = 2). Successful revascularization was achieved in 36 (90%) patients. The mean NIHSS score was 11.6 (range, 1-23) at 24 hours after the procedure, and 42.5% of patients showed a modified Rankin scale score of $\leq$ 2 at 90 days. New occlusion by migrated emboli was observed in one (2.5%) case. Post-procedural intracerebral hemorrhage occurred in only one case (2.5%), with an all-cause mortality of two (5%).

Conclusion : The Solitaire AB device is a relatively safe and effective tool for use in performance of mechanical thrombectomy in patients with acute ischemic stroke.

Keywords   Acute ischemic stroke, Thrombectomy, Solitaire AB stent

INTRODUCTION

In acute ischemic stroke, achievement of reperfusion as soon as possible by recanalizing the occluded intracranial vessels is the most important priority.[4][10][14] However, intravenous infusion of recombinant tissue plasminogen activator (rTPA) has a relatively tight time limit and rates of recanalization are unsatisfactory.[13] Several intra-arterial methods have been introduced and recent studies have shown that mechanical thrombectomy can extend the time limit and make earlier and better recanalization possible.[2][3][6][9][11][12] Among thrombectomy techniques, there is a method using the fully retrievable, self-expanding Solitaire stent (ev3 Inc., Irvine, CA) which was initially used in stent-assisted embolization of intracranial aneurysms. Relatively quick and safe performance of thrombectomy using this stent, with satisfactory recanalization rates, has been documented.[1][7][8]

In this report, we analyzed the clinical and radiological outcomes of mechanical thrombectomy using the Solitaire AB stent (the Solitaire thrombectomy) in

40 patients with acute occlusion of intracranial arteries.

MATERIALS AND METHODS

Forty consecutive patients with acute intracranial artery occlusion underwent Solitaire thrombectomy in our department. Patients' data were collected from October 2010 through November 2011. Neurological evaluation (as per the National Institutes of Health Stroke Scale [NIHSS]) was performed before and after the procedure and at the time of discharge. Assessment of the modified Rankin Scale (mRS) was performed 90 days after treatment. The mRS of 0 to 2 was defined as a good neurological outcome and poor outcome was assumed when the mRS score was 3 to 6.

In order to rule out hemorrhagic stroke, all patients underwent evaluation with brain computed tomography (CT) on arrival. Then, magnetic resonance (MR) imaging with diffusion-weighted imaging (DWI), MR angiography, and perfusion-weighted imaging (PWI) was performed for assessment of occluded vessels and DWI-PWI mismatch. After the thrombectomy procedure, brain CT was performed routinely in order to rule out intracerebral hemorrhage (ICH). MR angiography with DWI was acquired 24 to 36 hours after the procedure. In one patient, these were replaced with brain CT and brain CT angiography because of his pacemaker.

The main inclusion criteria were (1) NIHSS score $\geq$ 8; (2) Thrombolysis in cerebral infarction (TICI) score of 0 to 1 in an accessible vessel; (3) DWI-PWI mismatch and no detection of ICH; and (4) arrival at the hospital within six hours of symptom onset. When intracranial artery occlusion was found on MR angiography, treatment with intravenous rTPA (0.9 mg/kg body weight) was started if symptom onset was within three hours. Patients who were refractory or ineligible for use of intravenous rTPA were then transferred to the angiosuite for treatment with Solitaire thrombectomy.

All of the procedures were performed under local anesthesia by an endovascular neurosurgeon. When the patient required sedation (three out of 40), intravenous midazolam (Bukwang Pharm, Seoul, Korea) was administered. First, angiograms of the normal vessels were obtained for evaluation of the degree of leptomeningeal collaterals to the ischemic area. Then, the occlusion status and TICI scale of the occluded vessel were confirmed by taking angiography after locating the 7F or 8F guiding catheter (Guider XF Softip™, Boston Scientific, Plymouth, MN) to the proximal internal carotid artery (ICA) or vertebral artery (VA). To prevent occurrence of a new thromboembolic event during the procedure, a mixture of 2,000 IU of heparin and 0.9% normal saline 1,000 ml was administered continuously through the guiding catheter. Next, the microcatheter (Prowler SELECT™ PLUS, Codman Neurovascular, Raynham, MA) and microwire (Synchro™-14, Stryker Neurovascular, Fremont, CA) were introduced into the target vessel

Fig. 1. Initial gradient echo image of magnetic resonance image (MRI) shows a clot from the right middle cerebral artery (MCA) to the internal carotid artery (ICA) (A). Angiogram shows confirmation of occlusion segment length by manual injection of contrast through the microcatheter while withdrawing it (B) and simultaneous injection of contrast through the microcatheter and the guiding catheter (C). Cerebral angiogram after temporary deployment of a 5 x 30 mm Solitaire stent shows sufficient coverage and minimal flow restoration of the occluded segment by the stent (D). Cerebral angiogram after the thrombectomy shows complete recanalization of the right ICA occlusion (E).

and located at the distal portion of the occlusion site after passing the thrombus segment. Then, the microwire was removed and the total length of the thrombus was confirmed by manual injection of contrast through the microcatheter while withdrawing it or simultaneous injection of contrast through the microcatheter and guiding catheter before the withdrawal under roadmap condition (Fig. 1). The Solitaire stent was introduced into the microcatheter so that the device could be deployed to completely cover the occlusion segment. Deployment of the stent was maintained for at least two minutes before retrieval. The microcatheter and stent were gently withdrawn and the guiding catheter was pulled out of the sheath with the stent in it and the flushing was stopped. At the same time, an assistant applied negative pressure using a 50 cc syringe through the guiding catheter to prevent development of a new embolism by lost clots. When the subsequent angiogram showed a TICI score < 2, the procedure was repeated until a TICI score of ≥ 2 or 3 was achieved.

RESULTS

In this study, male was slightly dominant (65%), 18 (45%) patients had atrial fibrillation, and the proximal middle cerebral artery was the most common site of occlusion (55%). Intravenous rTPA was administered to 17 patients (Table 1). Of the 40 patients, revascula-

Table 1. Patient characteristics

Characteristic	
Number of patients	40
Demographic data	
Mean age (years) (range)	65.4 (32-89)
Sex (male : female) (%)	26 : 14 (65 : 35)
Atrial fibrillation (%)	18 (45)
Hypertension (%)	12 (30)
Coronary disease (%)	4 (10)
Intravenous rTPA	17 (42.5)
Site of occlusion	
ICA (%)	11 (27.5)
MCA M1 (%)	22 (55)
MCA M2 (%)	5 (12.5)
BA (%)	2 (5)

rTPA = recombinant tissue plasminogen activator, ICA = internal carotid artery, MCA = middle cerebral artery, M1, M2 = first and second segment of MCA, BA = basilar artery

Table 2. Radiological and clinical outcomes

Outcomes	
Success of recanalization (%)	
Complete recanalization (TICI 3)	15 (37.5)
Partial recanalization (TICI 2a/2b)	21 (52.5)
Recanalization failure (TICI 0/1)	4 (10)
NIHSS score, mean (range)	
Initial	14.1 (8-26)
After thrombectomy	12.5 (2-20)
24hrs later	11.6 (1-23)
At discharge	8.8 (0-24)
Improvement of clinical symptom (%)	
Complete improvement (NIHSS = 0)	4 (10)
Marked improvement (NIHSS ≥10 or NIHSS = 1)	9 (22.5)
mRS ≤ 2 at 90 days	17 (42.5)

NIHSS = National Institutes of Health Stroke Scale, TICI = thrombolysis in cerebral infarction, mRS = modified Rankin Scale

Table 3. Data from the procedure

	Mean (range)
Time from onset of symptom to groin puncture (min)	215.8 (60-417)
Time from groin puncture to recanalization (min)	85.3 (8-160)
Number of runs needed for recanalization	2.9 (1-9)

rization was achieved in 36 (90%) (TICI grades 2a/2b and 3). The mean initial NIHSS score was 14.1 (range, 8-26), and the mean NIHSS score was 11.6 (range, 1-23) at 24 hours after the procedure. In 13 patients (32.5%), NIHSS scores showed improvement of more than 10 or were 0-1 at the time of discharge. At 90 days, 42.5% (17 of 40) of patients showed a good neurological outcome (mRS 0-2) (Table 2). The average time from symptom onset to groin puncture and groin puncture to recanalization were 215.8 minutes (range, 60-417 minutes) and 85.3 minutes (range, 8-160 minutes) respectively. The average number of times of thrombectomy up to maximal recanalization was 2.9 (range, 1-9); one thrombectomy in 15 cases (37.5%), while more than two in 21 cases (62.5%) in cases of successful recanalization (Table 3).

In one case, new occlusion occurred during withdrawal of the stent by migrated emboli but showed near complete resolution after infusion of 250,000 IU of urokinase (Fig. 2) and post-procedural ICH, which was asymptomatic, occurred in only one case (2.5%). There was no occurrence of technical failure or procedure-related complications such as arterial rupture or dissection, groin complication requiring surgery, or
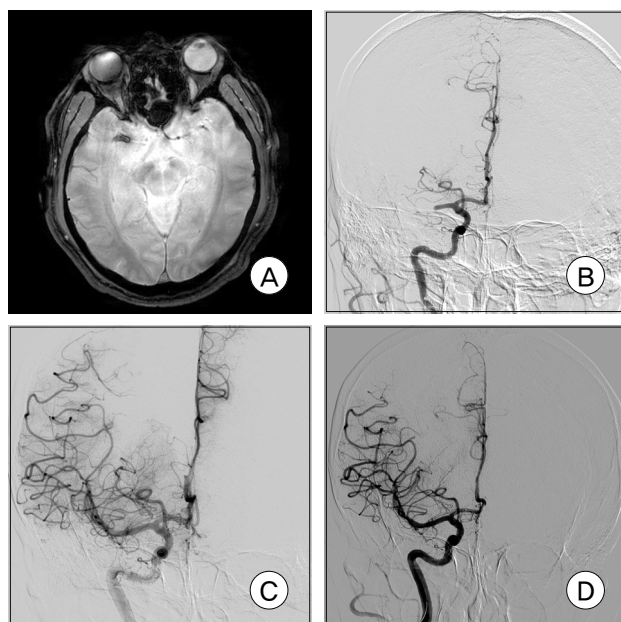
Fig. 2. Initial gradient echo image of magnetic resonance image (MRI) shows a clot in the right middle cerebral artery (MCA) (A). Initial angiogram in the anteroposterior plane shows right MCA M1 occlusion (thrombolysis in cerebral infarction grade 0) (B). After retrieval of the Solitaire AB stent, angiogram shows nearly complete recanalization of the right MCA and a newly observed occlusion in the previously uninvolved distal right anterior cerebral artery (ACA) (C). Cerebral angiogram after intra-arterial mechanical clot disruption and injection of Urokinase (250,000 IU) shows nearly complete recanalization of the right ACA (D).
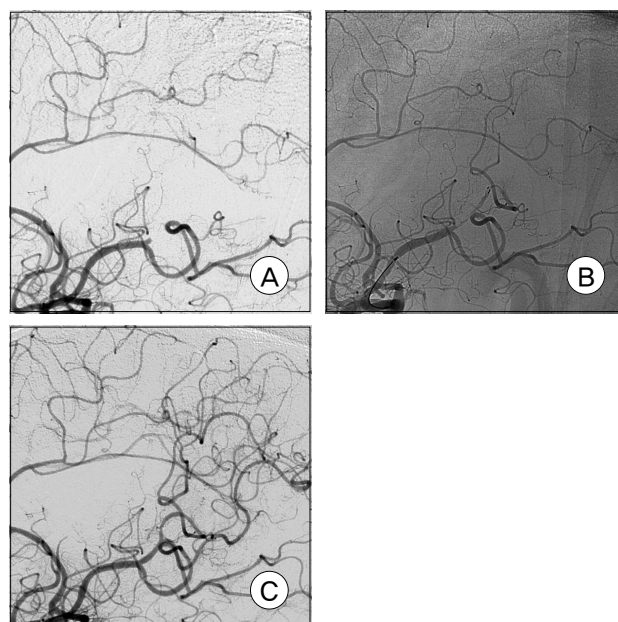

Fig. 3. Initial angiogram shows partial occlusion of the middle cerebral artery (MCA) inferior branch in a patient with a progressed MCA superior branch territory infarction on a diffusion-weighted magnetic resonance image (A). Cerebral angiogram after deployment of a Solitaire stent on the MCA inferior branch shows partial flow restoration in the occluded segment (B). Angiogram shows nearly complete recanalization in the MCA inferior branch (C).

blood transfusion. However, there were two cases of stent breakage. Three patients underwent decompressive craniectomy for aggravated brain edema. Two (5%) patients who died after aggravation of brain swelling had refused to undergo further treatment, such as decompressive craniectomy.

DISCUSSION

Efficacy of the Solitaire thrombectomy

In the MERCI trial study, Smith WS et al.[12] reported a recanalization rate in myocardial infarction (TIMI) grade 2/3 of 69%; the average NIHSS score improved by more than 10 or 0 at 24 hours after the procedure in 26% of cases, and 36% of patients had a favorable neurological outcome (the 90-day mRS ≤ 2). In the Penumbra pivotal study, the recanalization rate (TIMI 2/3) was 81.6%, and NIHSS score improved by more than 10 or 0-1 at the time of discharge in 27%, and the 90-day mRS ≤ 2 was 25%.[9] Roth C et al.[11] reported a recanalization rate of the Solitaire thrombectomy of 90.9%, improvement of NIHSS score more than 10 was 63.6% at the time of discharge, and the 90-day mRS ≤ 2 was 50%. The recanalization rate of the Solitaire thrombectomies performed in our hospital was 90%, the average NIHSS score improved by more than 10 or 0-1 at discharge in 32.5%, and 42.5% (17 of 40) of patients had a good neurological outcome (the 90-day mRS ≤ 2). Compared to the MERCI or Penumbra series, our Solitaire thrombectomy showed a better recanalization rate and clinical results and showed outcomes similar to those reported by other institutes. We think that the immediate restoration of flow after temporary stent deployment (Fig. 1D, 3B) and curtailment of the reperfusion time is one of the most important merits of the Solitaire thrombectomy.

Most previous studies on mechanical thrombectomy deal mainly with occlusion of large intracranial ves-

sels (ICA, BA, MCA M1).[1)9)11)] In this study, Solitaire thrombectomies were performed and recanalization was successful for five distal MCA occlusions (Fig. 3). Despite the closed cell type structure, a Solitaire stent was found to be effective in curved and narrow distal vessels which have been thought to be very dangerous and ineffective for thrombectomy with the other modalities.[5)] Based on these results, application of the Solitaire thrombectomy not only to large vessels but also to MCA M2 or a more distal vessel where microcatheter can reach if the stent can pass through can be recommended.

Safety of the Solitaire thrombectomy

The Solitaire thrombectomy is a relatively safe method. Occurrence of symptomatic ICH was reported in 9.8% of patients in the MERCI trial, 11.2% in Penumbra and 9% in the Roth C report.[9)11)12)] However, in our series, only one case showed asymptomatic ICH (2.5%). We have not experienced any type of vascular injury, such as arterial rupture/dissection, or clinically significant complications. Compared to other mechanical thrombectomies, use of a Solitaire stent exerted less tension on the vessel wall and less damage to the perforating artery, resulting in a lower incidence of ICH.

However, one of the concerns in use of the Solitaire thrombectomy is new embolic occlusion of an uninvolved artery, like our third case (Fig. 2). A balloon-guiding catheter, which is not available in this country, might be most effective for preventing this event. Instead, we stopped the heparinized saline flushing and aspirated through the guiding catheter using a 50 cc syringe during withdrawal of the stent into the guiding catheter. We then removed the guiding catheter with the stent in it in every thrombectomy and no further new embolic occlusion in an uninvolved artery was observed.

We have experienced stent breakage in two of 40 cases during withdrawal. They were thought to have severe stenosis before occlusion. Therefore, one must keep in mind that stent breakage is always possible in the Solitaire thrombectomy.

CONCLUSION

These initial results suggest that a self-expanding and fully retrievable Solitaire stent may be a safe and efficient tool for recanalization of acute ischemic stroke due to intracerebral artery occlusion that was refractory or ineligible for use of intravenous tissue plasminogen activator.

REFERENCES

1. Castano C, Dorado L, Guerrero C, Millan M, Gomis M, Perez de la Ossa N, et al. Mechanical thrombectomy with the Solitaire AB device in large artery occlusions of the anterior circulation: a pilot study. Stroke. 2010 Aug;41(8):1836-40.

2. Furlan A, Higashida R, Wechsler L, Gent M, Rowley H, Kase C, et al. Intra-arterial prourokinase for acute ischemic stroke: the PROACT II study: a randomized controlled trial. Prolyse in Acute Cerebral Thromboembolism. JAMA. 1999 Dec;282(21):2003-11.

3. Kelly ME, Furlan AJ, Fiorella D. Recanalization of an acute middle cerebral artery occlusion using a self-expanding, reconstrainable, intracranial microstent as a temporary endovascular bypass. Stroke. 2008 Jun;39(6): 1770-3.

4. Khatri P, Abruzzo T, Yeatts SD, Nichols C, Broderick JP, Tomsick TA. Good clinical outcome after ischemic stroke with successful revascularization is time-dependent. Neurology. 2009 Sep;73(13):1066-72.

5. Krischek Ö, Miloslavski E, Fischer S, Shrivastava S, Henkes H. A comparison of functional and physical properties of self-expanding intracranial stents [Neuroform3, Wingspan, Solitaire, Leo(+), Enterprise]. Minim Invasive Neurosurg. 2011 Feb;54(1):21-8.

6. Levy EI, Ecker RD, Horowitz MB, Gupta R, Hanel RA, Sauvageau E, et al. Stent-assisted intracranial recanalization for acute stroke: early results. Neurosurgery. 2006 Mar;58(3):458-63.

7. Menon BK, Kochar P, Ah-Seng A, Almekhlafi MA, Modi J, Wong JH, et al. Initial experience with a self-expanding retrievable stent for recanalization of large vessel occlusions in acute ischemic stroke. Neuroradiology. 2012 Feb;54(2):147-54.

8. Park H, Hwang GJ, Jin SC, Jung CK, Bang JS, Han MK, et al. A retrieval thrombectomy technique with the Solitaire stent in a large cerebral artery occlusion. Acta Neurochir (Wien). 2011 Aug;153(8):1625-31.

9. Penumbra Pivotal Stroke Trial Investigators. The penumbra pivotal stroke trial: safety and effectiveness of a new generation of mechanical devices for clot removal in intracranial large vessel occlusive disease. Stroke. 2009 Aug;40(8):2761-8.

10. Rha JH, Saver JL. The impact of recanalization on ischemic stroke outcome: a meta-analysis. Stroke. 2007 Mar;38(3):967-73.

11. Roth C, Papanagiotou P, Behnke S, Walter S, Haass A,

Becker C, et al. Stent-assisted mechanical recanalization for treatment of acute intracerebral artery occlusions. Stroke. 2010 Nov;41(11):2559-67.

12. Smith WS, Sung G, Saver J, Budzik R, Duckwiler G, Liebeskind DS, et al. Mechanical Thrombectomy for Acute Ischemic Stroke: Final Results of the Multi MERCI Trial. Stroke. 2008 Apr;39(4):1205-12.

13. Tomsick T, Broderick J, Carrozella J, Khatri P, Hill M, Palesch Y, et al. Revascularization results in the interventional management of stroke II trial. AJNR Am J Neuroradiol. 2008 Mar;29(3):582-7.

14. Zaidat OO, Suarez JI, Sunshine JL, Tarr RW, Alexander MJ, Smith TP, et al. Thrombolytic therapy of acute ischemic stroke: correlation of angiographic recanalization with clinical outcome. AJNR Am J Neuroradiol. 2005 Apr;26(4):880-4.