Treatment of acute middle cerebral artery occlusion with a Solitaire AB stent: preliminary experience

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ABSTRACT. We report our initial experience with a Solitaire AB neurovascular remodeling stent device in performing cerebral embolectomy in seven patients presenting to our institution with acute stroke who were resistant to iv thrombolytic drug treatment. The main inclusion criteria were: National Institutes of Health Stroke Scale (NIHSS) score ≥ 10 ; treatment performed within 8 h from the onset of symptoms and no large hypodensity on CT; and occlusion of a major cerebral artery on the CT angiogram. An admission and a post-interventional NIHSS score were calculated for all patients by two different neurologists. Efficacy was assessed radiologically by post-treatment thrombolysis in myocardial infarction (TIMI) scores and clinically by a 30-day Modified Rankin Scale (MRS) score. The mean duration of neurointerventional treatment was 84 min. All interventions were successful, with TIMI scores of 2 or 3 achieved in 100% of patients. There was one procedural complication in our series owing to a self-detached stent and one patient had a small asymptomatic basal ganglia haemorrhage. There was improvement of more than 4 points on the NIHSS score in 5 (72%) of the patients following treatment, of whom 4 (57%) had a 30-day MRS score of ≤ 2 . The use of a Solitaire stent in acute stroke was safe, time-efficient and encouraging; however, a larger sample size will be required to further evaluate the use of this device, which could benefit a significant number of stroke patients.

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Intravenous recombinant tissue plasminogen activator (iv r-tPA), which is used as therapy for acute ischaemic stroke, has been shown to improve 3-month outcome if given within the first 3 h of stroke onset; however, >50% of patients do not demonstrate a favourable clinical response [1]. There is evidence of a sustained effect of intra-arterial therapy (IAT) when patients are assessed 2 years after a stroke [2]. If drug therapy fails, mechanical clot retrieval seems warranted and is used as adjunctive therapy at our institution. In several series, mechanical clot disruption in conjunction with IAT has been shown to achieve higher rates of recanalisation [3–5]. We review seven patients presenting to our institution over a period of 4 months with acute stroke in whom a CT angiogram confirmed the presence of a thrombus. These patients were resistant to iv thrombolytic drug treatment and underwent partial to complete clot removal by means of a Solitaire AB neurovascular remodeling stent device (ev3 Neurovascular, Irvine, CA). Various mechanical clot retrieval devices are used in current medical practice; however, the use of a Solitaire stent is not emphasised in the current medical literature to the best of our knowledge.

Methods and materials

Between May 2009 and August 2009, seven patients presenting with acute thrombotic stroke underwent mechanical clot retrieval with the use of a Solitaire AB neurovascular remodeling device. Previously, this particular device had been used only for treatment of intracerebral aneurysms. Informed consent was obtained either from the patient or from the next of kin when it was not possible to obtain direct patient consent.

Clinical protocol

A neurological examination was performed at our stroke unit by an experienced neurologist on all patients presenting with acute stroke, and their post-interventional care was carried out in the intensive care unit of our institution. The main inclusion criteria for this study were: National Institutes of Health Stroke Scale (NIHSS) score ≥ 10 ; treatment performed within 8 h from onset of symptoms and no large hypodensity on CT; and occlusion of a major cerebral artery on the CT angiogram. An admission and a post-interventional NIHSS score were calculated on all the patients by two different neurologists. A 30-day Modified Rankin Scale (MRS) score was then recorded for the patients. Clinical follow-up and rehabilitative care through a multidisciplinary approach were undertaken in these patients.

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Imaging protocol

Prior to the intervention, all the patients underwent cranial CT and CT angiography, including cervical and intracranial views. Patients with intracranial/cervical carotid occlusion secondary to a thrombus were included in the intervention. The occlusions were present at the proximal middle cerebral artery (MCA M1 segment), at the M1/M2 junction of the MCA or at the terminal internal carotid artery (ICA). A four-vessel diagnostic cerebral angiogram was performed and the level of occlusion was localised prior to proceeding for neuro-intervention. Thrombolysis in myocardial infarction (TIMI) scores were recorded after the procedure. A post-procedural cranial CT scan was performed within 24 h and repeated at necessary intervals depending on the clinical status of the patient.

Antithrombotic protocol

IV r-tPA as per the patient's body weight was administered immediately by the neurologist on the clinical and imaging diagnosis of acute stroke. Only one patient in our study had a contraindication for iv r-tPA as he was within 8 h of surgery for prostate carcinoma. Additionally, these patients received intra-arterial r-tPA during the neurointerventional procedure with the dose varying between 4 mg and 20 mg, with a mean dose of 10.5 mg. Tirofiban, which is a fast-acting GB IIb/IIIa inhibitor that disaggregates platelet thrombi and improves cerebral perfusion, was administered in two patients in whom the Solitaire stent was completely detached. These two patients were then commenced on oral aspirin and clopidogrel the following day.

Solitaire AB neurovascular remodeling stent device (ev3) protocol

The interventions were performed by the femoral-approach. A 6-Fr guiding catheter was placed in the ICA. A diagnostic angiogram was performed to visualise the location of the clot.

The clot was passed with a Transend microwire (Boston Scientific, Natick, MA) and a Rebar 27 microcatheter (ev3) was navigated over the wire just distal to the clot. The microcatheter was left *in situ* and the microwire completely retrieved and replaced by the Solitaire stent. More than two-thirds of the stent was deployed within the clot by withdrawing the microcatheter over the stent and r-tPA was then administered through the microcatheter. The stent was then further retrieved within the microcatheter with only one-third of the distal stent within the thrombus. Following this, the entire system comprising the stent and the microcatheter were completely retrieved under negative suction from a 50-ml syringe at the level of the guiding catheter in an attempt to prevent shower emboli. On retrieval, the clot could be seen entangled within the meshwork of the stent (Figure 1). This procedure was repeated up to three times in three of the patients to optimise the results. Control angiography was performed following each retrieval. TIMI scores were measured following the

procedure. In one patient the stent completely self-detached owing to severe vessel tortuosity and deployed within the C6 segment of the right ICA. In another patient, the stent was left *in situ* within the proximal MCA (M1) to maintain the vessel patency and blood flow. The femoral sheath was removed following the procedure and the wound closed with an Angio-Seal (St. Jude Medical, Inc, St. Paul, MN) vascular closure device.

Illustrative case

A 76-year-old man presented with symptoms of dense left hemiparesis and left facial nerve palsy. Initial cranial CT and CT angiography performed within 40 min of onset of clinical symptoms showed normal brain parenchyma with a clot within the proximal right MCA (M1), which was confirmed by cerebral angiography. Using a Rebar 27 microcatheter, a Solitaire stent was deployed within the clot and 8 mg of intra-arterial r-tPA was administered. The stent and the microcatheter system were completely retrieved under negative suction pressure, leading to complete recanalisation of the vessels with a TIMI score of 3. The patient showed immediate improvement of more than 4 points on the NIHSS score following the procedure. A follow-up head CT scan demonstrated normal brain parenchyma. 4 weeks after the onset of stroke the patient was discharged without any significant neurological deficit. A MRS score (30 day) of 1 was achieved at discharge (Figure 2a-h).

Results

Patient and initial imaging characteristics

The clinical and imaging characteristics of all seven patients are shown in Table 1. The patients were admitted to our stroke unit between 50 min and 75 min after the onset of symptoms, with a mean of 63 min. Most of our patients presented with dense hemiparesis. In addition, patients had neglect, dysphasia, difficulty in swallowing and one patient had right facial nerve palsy. Another patient had been found unconscious. Three patients had normal brain parenchyma, whereas two

Figure 1. Thrombus seen entangled within the meshwork of the Solitaire AB stent (red arrows).

Figure 2. (a and b) Initial angiogram (Towne's and lateral views) demonstrating the occlusion of the M1 segment of the right middle cerebral artery (MCA) (black arrow). (c) Placement of the Rebar 27 microcatheter just distal to the clot (black arrow). (d and e) Deployment of the Solitaire stent within the thrombus (black arrow). (f) Administration of intra-arterial tissue plasminogen activator through the microcatheter with the stent *in situ* (black arrow). (g and h) Immediate post-treatment angiogram showing complete revascularisation of the previously occluded right MCA.

had background chronic small vessel disease and one showed signs of a previous lacunar stroke on admission cranial CT imaging. None of the patients had CT evidence of acute parenchymal damage, whereas one patient had subtle low density in the left frontoparietal region suggestive of ongoing ischaemia. The presence of a thrombus was confirmed by CT angiogram in all seven patients. Six patients had a thrombus occluding the

proximal middle cerebral artery (M1 segment). Of these, two patients had a thrombus extending from the M1 to C7 segment of the ICA; of these two patients, one had a coexisting critical ICA bifurcation stenosis which was treated with a hybrid carotid Cristallo stent (Invatec, Roncadelle, Italy) to restore the flow within the ICA during the procedure. Only one patient had thrombus within the M1/M2 junction of the MCA.

Table 1. Patient and initial imaging characteristics

Patient	Age/gender	Symptoms-to-admission interval (min)	Clinical presentation	Admission cranial CT findings	CT angiogram/angiography findings
1	81/male	50	Dense left-sided hemiparesis, neglect and difficulty in swallowing	Normal brain parenchyma	Proximal right MCA (M1) occlusion
2	64/male	75	Right hemiparesis, dysphasia and neglect	Chronic small vessel ischaemic changes only	Thrombus at left M1/M2 junction
3	81/male	70	Found unconscious and had neurological signs localising to the right	Old lacunar infarct in left frontal region with normal brain parenchyma	Critical stenosis of left ICA bifurcation. Proximal M1 occlusion
4	83/male	60	Dense right hemiparesis, aphasia and right facial nerve palsy	Normal brain parenchyma	T-occlusion with clot extending from M1 to C7 segment of ICA
5	63/male	80	Dense right hemiparesis and dysphasia	Subtle low density in left frontoparietal region	Clot extending from M1 to C7 segment of ICA
6	76/male	45	Left-sided hemiparesis	Chronic small vessel ischaemic changes only	Proximal right MCA (M1) occlusion
7	40/male	60	Dense right hemiparesis, dysphasia and neglect	Normal brain parenchyma	Proximal left MCA (M1) occlusion

ICA, internal carotid artery; MCA, middle cerebral artery.

Clinical and post-procedural imaging characteristics

The clinical and post-procedural imaging characteristics are shown in Table 2. The time to treatment after the onset of symptoms ranged between 60 min and 280 min, with a mean value of 160 min. The duration of neurointerventional treatment was between 40 min and 145 min, with a mean value of 84 min. The NIHSS score on admission was between 11 and 23, with a mean value of 19. There was an improvement of more than 4 points on the NIHSS in 5 patients following treatment. Complete angiographic revascularisation with a TIMI score of 3 was achieved in 4 patients and a score of 2 was achieved in the remaining 3 patients. These three patients had improved revascularisation compared with the initial angiogram but had one absent MCA bifurcation branch on the post-procedure angiogram. All three patients had three passes with the Solitaire stent prior to abandoning the procedure. The four patients who achieved a TIMI score of 3 had only one pass with the Solitaire stent system. One patient with a TIMI score of 3 showed normal brain parenchyma within 48 h on post-procedure cranial CT imaging. Of the remaining two patients with a TIMI score of 3, one showed only a small infarct in the basal ganglia region and one showed a small infarct in the insular cortex with no evidence of any bleeding. Only 1 patient with a TIMI score of 3 demonstrated a right MCA infarct and bleeding in the region of the basal ganglia. This was the patient with extreme vessel tortuosity in whom the procedure was complicated because of a self-detached Solitaire stent within the C7 segment of the ICA. 2 patients with a TIMI score of 2 had a left MCA infarct with areas of preserved cortex in the left superior frontoparietal region, probably because of partial revascularisation of the MCA following the procedure. Another patient with a TIMI score of 2

had a small infarct in the left parietal region. 4 patients had a 30-day MRS score of ≤ 2 . The patient who had complications because of the self-detached stent had a 30-day MRS score of 4.

Discussion

Endovascular mechanical embolectomy is an effective means of achieving revascularisation in patients with acute ischaemic stroke, including patients whose treatment is started late and those with iv tPA failure [6]. Various mechanical clot retrieval devices have been used recently in conjunction with iv and intra-arterial thrombolysis for effective treatment of acute embolic stroke. Use of such mechanical devices is limited owing to the technical challenges of the procedure, cost-effectiveness, training issues and the question of real-time prognostic benefit to the patient.

The Solitaire AB neurovascular remodeling device is the only self-expanding stent initially designed for bridging the neck of aneurysms that allows for multiple retrieval, even after full deployment for adjustment and superior placement [7]. Its open-slit, closed-cell design gives the Solitaire AB an optimal radial force with good kink resistance and also maximises the opportunity for trapping the clot [7]. These properties have led to its use in acute stroke, in which the thrombus within the cerebral vessels is trapped within the struts of the stent, which can then be retrieved under negative suction pressure.

During the last decade, significant experience and knowledge regarding mechanical thrombectomy has been gained. The importance of thrombus aspiration through either a microcatheter [8, 9] or a guiding catheter [10, 11] has been mentioned in the current medical literature. The microsnare (Amplatz Goose neck, ev3)

Table 2. Clinical and post-procedural imaging characteristics

Patient	NIHSS score on admission	Time to Rx (min)	Duration of treatment (min)	No. of passes with Solitaire	Post-treatment TIMI score	Post-Rx NIHSS score	Follow-up post-treatment CT (<48 h)	30 day MRS score
1	18	120	100	1	3	16	Right MCA infarct and bleeding in the region of the right basal ganglia	4
2	14	180	145	3	2	9	A small infarct in the left parietal region. No bleeding seen	2
3	23	210	65	1	3	13	Infarct in left basal ganglia but no bleeding seen	2
4	22	210	90	1	3	9	Small left insular infarct	2
5	20	280	70	3	2	15	Left MCA infarct with areas of preserved cortex in left superior frontoparietal region	3
6	15	60	40	1	3	4	Normal brain parenchyma.	1
7	20	60	80	3	2	18	Left MCA infarct with areas of preserved cortex in left superior frontoparietal region	4

NIHSS, National Institute of Health Stroke Scale; TIMI, thrombolysis in myocardial infarction; MRS, Modified Rankin Scale; MCA, middle cerebral artery; Rx, treatment (time from symptom onset to treatment).

device is useful for removal of solid clots but is not so effective in retrieving fresh clots [12]. This device is also known to cause vasospasm and vessel dissection. Reported recanalisation rates for loop-shaped tools, a corkscrew-shaped nitinol coil (Merci Retriever, Concentric Inc., CA) and a nitinol basket are in the range of 50% [13].

In phase 1 of the Mechanical Embolus Removal in Cerebral Ischemia (MERCI) trial, which included 28 patients, successful recanalisation with mechanical embolectomy was achieved in 12 (43%) patients, with additional intra-arterial tPA in 18 (64%) patients [14]. 12 asymptomatic and no symptomatic intracranial haemorrhages occurred [14].

In the Multi MERCI trial, treatment with the L5 Retriever resulted in successful recanalisation in 75 of 131 (57.3%) treatable vessels and in 91 of 131 (69.5%) vessels after adjunctive therapy (intra-arterial tPA, mechanical) [15]. Overall, favourable clinical outcomes (MRS score 0–2) occurred in 36% of patients and mortality was 34%; both outcomes were significantly related to vascular recanalisation [15]. Symptomatic intracerebral haemorrhage occurred in 16 patients (9.8%); 4 (2.4%) of these were parenchymal haematoma type II [15]. Clinically significant procedural complications occurred in 9 (5.5%) patients [15].

Other devices currently used include a distally closed, self-expanding nitinol cage, the Catch device (Balt Extrusion, Montmorency, France), which has shown some promising results [16]. The more recent Penumbra Clot Retrieval System has also shown encouraging results in a recent pivotal study, with 81.6% of the treated vessels being successfully revascularised to give a TIMI score of 2 or 3 [17]. The procedural events were reported in 12.8% of patients, of whom 2.4% had events that were considered serious [17]. A total of 28% of patients were found to have intracranial haemorrhage on 24-h CT, of whom 11.2% were symptomatic [17]. All-cause mortality was 32.8% at

90 days with 25% of the patients achieving an MRS score of ≤ 2 [17].

There are various articles in the current medical literature discussing the benefits of iv, intra-arterial and mechanical treatments in acute stroke. Jahan and Vinuela [18] have reviewed the major iv and intra-arterial thrombolysis trials and also the mechanical strategies being developed to treat patients with acute ischaemic stroke.

The use of the Solitaire stent is well known in stent-assisted embolisation of cerebral aneurysms. Liebig et al [19] reported on the usage of the Solitaire stent in acute vessel occlusions at the ABC-WIN meeting of the World Federation of Interventional and Therapeutic Neuro-radiology in January 2009.

Owing to its above-mentioned properties we have used this device in seven patients with acute stroke. Although the sample size was limited, we had very encouraging initial results with the use of the Solitaire stent. Overall, recanalisation including a TIMI score of 2 or 3 was achieved in 100% of our initial 7 patients. There was one procedural complication in our series owing to a self-detached stent and one patient had a small asymptomatic basal ganglia haemorrhage. There was an improvement of more than 4 points on the NIHSS score in 5 (72%) of the patients following treatment; 4 (57%) of the patients had a good outcome with a 30 day MRS score of ≤ 2 .

Although our findings are encouraging, a larger sample size will be required to further evaluate the use of this device, which could benefit a significant number of patients presenting with acute thrombotic stroke.

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