

Safety and efficacy of mechanical thrombectomy with Solitaire in patients with acute ischemic stroke

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ABSTRACT

Background: Stroke is the third most common cause of death. Ischemic stroke accounts for 87% of all strokes. The standard treatment for acute ischemic stroke (AIS) is IV recombinant tissue plasminogen activator for patients who can reach the hospital within 4.5 h. A rapid and complete recanalization is a major factor in good clinical outcomes in the treatment of acute cerebral ischemia. Stent-based recanalization techniques are increasingly used in stroke caused by large vessel occlusion, with promising results. **Objective:** To evaluate the safety and efficacy of Solitaire stent retriever in recanalizing cerebral vessels in patients with AIS. **Materials and Methods:** We treated 16 patients of AIS with a mean age of 52.25 years, ranging from 16 to 76 years with Solitaire clot retrieval system from September 2011 to March 2013 at our stroke center. The anterior circulation strokes were treated within 6 h of stroke onset and the posterior circulation strokes were treated up to 24 h of stroke onset. Patients with intracerebral bleed and established large acute infarcts were excluded. **Results:** Out of the 16 patients of AIS treated with Solitaire clot retrieval system, good recanalization (thrombolysis in cerebral infarction 2 [TICI 2] and TICI 3) was achieved in 14/16 patients (87.5%) and no recanalization achieved in 2/16 (12.5%) patients. Clinical outcome was good (modified Rankin score 2 or less) in 10 out of 16 patients (62.5%). **Conclusion:** Mechanical clot retrieval with Solitaire appears to be safe and effective in acutely occluded large intracranial vessels.

Key words: Acute ischemic stroke, modified Rankin score, National Institutes of Health Stroke Scale, Solitaire, thrombectomy, thrombolysis in cerebral infarction

INTRODUCTION

Stroke is the third most common cause of death.^[1] Ischemic stroke accounts for 87% of all strokes.^[2] The standard treatment for acute ischemic stroke (AIS) is IV recombinant tissue plasminogen activator for patients who can reach the hospital within 4.5 h.^[3,4] A rapid and complete recanalization is a major factor in good clinical outcomes in the treatment of acute cerebral ischemia.^[5] Stent-based recanalization techniques with Solitaire and Trevo are increasingly used in acute ischemic stroke (AIS) due to large vessel occlusion. After the Solitaire Flow Restoration With the Intention for Thrombectomy trial,^[6] Solitaire flow restoration (FR) stent retriever received Food and Drug Administration

(FDA) approval for treatment of AIS in March 2012. We present our experience with Solitaire thrombectomy device in AIS. To the best of our knowledge, this is the largest series of patients treated by Solitaire for AIS in India.

MATERIALS AND METHODS

We treated 16 patients of AIS with a mean age of 52.25 years, ranging from 16 to 76 years with Solitaire clot retrieval system from September 2011 to March 2013 at our stroke center [Table 1]. Out of the 16 patients, 12 were males and 4 were females. The anterior circulation stroke was treated within 6 h of stroke onset and the posterior circulation stroke was treated up to 24 h of stroke onset. Computed tomography (CT) or magnetic resonance (MR) imaging performed in all patients after neurological examination and before instituting specific therapy. Patients undergoing CT scan (2/16) were examined with plain CT scan of the brain. The MR imaging (14/16) sequences included axial diffusion-weighted imaging [Figure 1a], fluid-attenuated inversion recovery, T2, 3D time-of-flight and susceptibility. The exclusion criteria

Access this article online	
Quick Response Code:	Website: www.ijns.in
	DOI: 10.4103/2277-9167.131998

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were intracerebral hemorrhage or an established large acute infarct (more than one-third of a vascular territory). Inclusion criteria were, National Institutes of Health Stroke Scale (NIHSS) score >7, anterior circulation stroke within 6 h and up to 24 h for posterior circulation stroke, occlusion of large intra cranial vessel. Patients with bleeding and coagulation disorders were excluded. All patients were treated under local anesthesia except two patients, where general anesthesia was used due to hemodynamic instability.

PROCEDURE

Patients suitable for endovascular recanalization with Solitaire were immediately transferred to angiogram suite from the imaging (CT/MR) room. The angiogram was

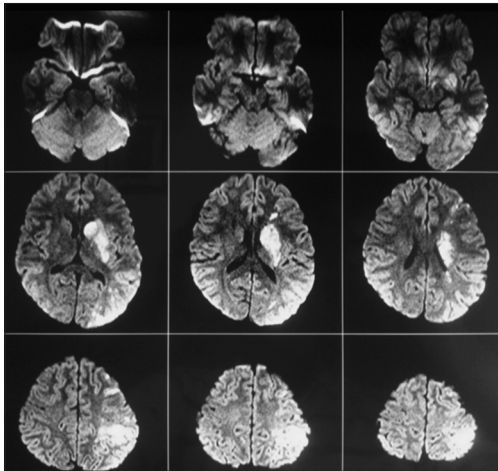


Figure 1a: Diffusion-weighted imaging showing diffusion defects in left middle cerebral artery territory

performed through right common femoral arterial 6F access (Philips Allura single plane cath lab). Informed consent was obtained in all patients. In one patient, the thrombectomy was done through trans-brachial route due to severe aorto-iliac disease. 3000 IU of heparine was given intravenously after the femoral access to all patients except one, who has received IV recombinant tissue plasminogen activator (rtPA) prior to thrombectomy. The occluded vessel was identified [Figure 2a, b, and 1b] and mechanical thrombectomy was done with Solitaire (Covidien, Plymouth, USA). Both Solitaire FR (4/16) and Solitaire AB (12/16) were used for thrombectomy.

The thrombectomy was done by placing a 6F envoy guiding catheter (Codman Neuro, USA) into the cervical portion of the internal carotid artery (ICA). A combination of Rebar 18 microcatheter (Covidien, Plymouth, USA) [Figure 2c] with Xpedition 14 microwire (Covidien, Plymouth, USA) was navigated and the thrombus was crossed. The wire was removed and a check angiogram with Rebar was performed to ensure that the catheter was

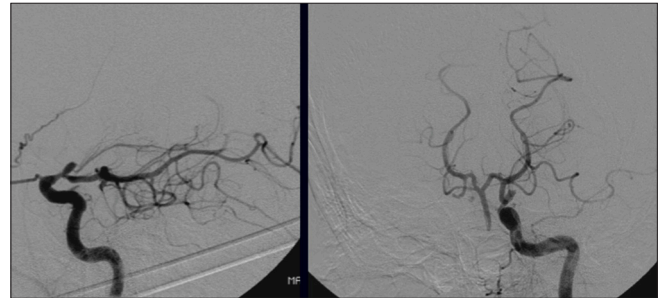


Figure 1b: Left internal carotid artery terminus occlusion

Table 1: Details of patient treated by Solitaire for AIS

Age	Sex	Time of stroke onset in hours	NIHSS	Angiogram finding	TICI pre-procedure	No. of passes (Solitaire)	Time for recanalization in minutes	TICI post-procedure	Hemorrhage	mRS 90 days
Male	16	2	14	ICA occlusion	0	4	105	0	–	2
Male	65	4	14	MCA occlusion	0	2	35	3	–	0
Male	32	5.5	18	ICA occlusion	0	2	45	3	–	3
Male	42	6	20	MCA occlusion	0	3	52	2	+	3
Male	49	4.5	13	BA occlusion	0	2	44	3	–	0
Male	68	3.5	12	MCA occlusion	0	1	28	3	–	0
Female	42	18	20	BA occlusion	0	4	75	2	–	6
Male	48	1.5	18	MCA occlusion	0	3	65	3	–	0
Female	34	4	15	MCA occlusion	0	1	34	3	–	0
Female	58	4.5	18	ICA occlusion	0	3	70	3	–	2
Male	65	5	19	MCA occlusion	0	3	110	3	–	6
Male	33	6	19	ICA occlusion	0	4	115	0	–	3
Female	66	5.5	18	MCA occlusion	0	3	56	1	–	4
Male	72	5	15	MCA occlusion	0	2	45	3	–	1
Male	76	4.5	14	MCA occlusion	0	3	75	3	–	0
Male	44	2.5	15	MCA occlusion	0	2	32	3	–	0

AIS – Acute ischemic stroke; NIHSS – National institutes of health stroke scale; TICI – Thrombolysis in cerebral infarction; ICA – Internal carotid artery; MCA – Middle cerebral artery; BA – Basilar artery; mRS – Modified rankin score

in a thrombus-free distal vessel lumen. A 4 mm × 20 mm Solitaire was loaded through the hub of the Rebar and navigated into the distal lumen under fluroscopic guidance. The Solitaire was deployed [Figure 2d and 1c]

across the thrombus by retracting the Rebar over the Solitaire. Angiogram was done to ensure blood flow to the distal vascular territory. The Solitaire was left *in situ* for 5 min. The Solitaire was recaptured by approximately

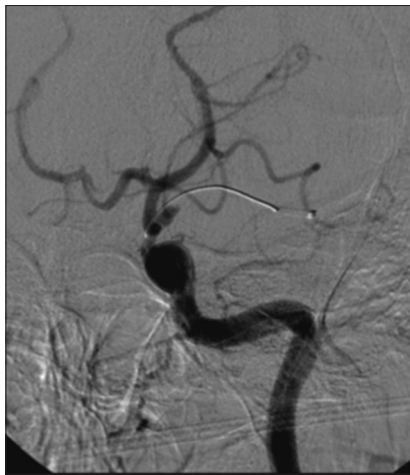


Figure 1c: Solitaire across the occlusion



Figure 1d: Partial recanalization



Figure 1e: Complete recanalization



Figure 2a: Right middle cerebral artery occlusion anteroposterior view



Figure 2b: Right middle cerebral artery occlusion lateral view

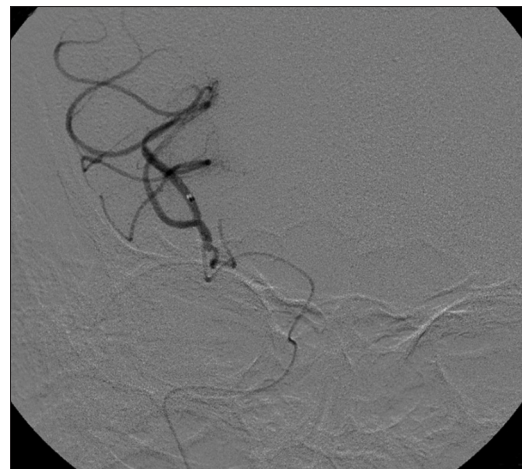


Figure 2c: Rebar microcatheter across the occlusion



Figure 2d: Solitaire across the occlusion



Figure 2e: Complete recanalization

30% of its length and withdrawn. During withdrawal of the Solitaire, blood was constantly aspirated from the side port from the guiding catheter with a 50cc syringe. An angiogram was done to assess the recanalization of the occluded segment. If the recanalization was not complete [Figure 1d], the same procedure was repeated. A complete recanalization was recorded as thrombolysis in cerebral infarction (TICI 3) [Figure 2e and 1e]. At the end of the procedure, clot fragmentation, clot migration to unaffected vessels, extravasation at the site of occlusion or wire perforation in distal vessels were specially looked into.

After the thrombectomy, CT scan of the brain was done in all patients. Patients without hemorrhage were started with double antiplatelet medication and shifted to intensive care unit. Patients were evaluated with modified Rankin score (mRS) score at 30 and 90 days after the procedure.

RESULTS

Sixteen patients of AIS with large vessel occlusion were treated with Solitaire. Four of them were females and 12 were males. The patients were in the age group of 16-76 years with the mean age of 52.25 years. The youngest patient was of 16 years and had protein S deficiency. Rest of the patients had atherosclerotic arterial disease. All patients were treated within 6 h of stroke onset except one. One patient was treated at 18 h after the stroke onset. She was treated after a detailed discussion of the risk and outcome of such treatment beyond 6 h of stroke. The average time of presentation for anterior circulation stroke (14/16) was 4.25 h. The NIHSS score of patients treated ranged from 12 to 20 with a mean score of 16.3. One of the patient received rtPA on arrival at 2.5 h following the stroke. He was subjected to thrombectomy at 5 h, as his condition

did not improve. All patients chosen for thrombectomy had TICI 0 score prior to intervention. Most of the patients needed more than one pass of Solitaire ranging from 1 to 4 times with a mean passage of 2.6 times. Both Solitaire AB (13/16) and Solitaire FR (3/16) were used for thrombectomy. The procedure time for recanalization ranged from 28 min to 115 min with a mean procedure time of 61.5 min. The middle cerebral artery (MCA) isolated occlusions could be recanalized faster than the ICA occlusions with an average time for recanalization for MCA at 49 min compared to ICA occlusion, which took an average time of 83.7 min. We could achieve complete recanalization (TICI 3) in 11 patients, partial recanalization in three patients and no recanalization in two patients. All the patients were evaluated with mRS score at 30 and 90 days. Good clinical outcome (mRS of 2 or less) was achieved in 10 patients (62.5%). One patient had an asymptomatic cerebral hemorrhage with no significant change in NIHSS score.

DISCUSSION

The approved treatment for AIS is thrombolysis with rtPA with in 4.5 h of stroke onset. IV rtPA achieves early recanalization (TICI 2 and TICI 3) in only 30-50% of patients and even lower recanalization rates in proximal large vessel occlusions (MCA, basilar artery, and carotid terminus).^[4,7] The earlier IVT can be administered, the more benefit can be expected. Intra-arterial thrombolysis might even be effective when patients are treated within 6 h.^[8] It remains unknown whether the time window for recanalization therapy in patients with basilar artery occlusion (BAO) can be longer than in patients with arterial occlusions in the anterior circulation.^[9] White matter, which is relatively more abundant in the brain stem than in other parts of the brain, might be more resistant to ischemia than other brain tissue. Furthermore,

penumbral tissue might be preserved for a longer period of time as a result of better collaterals in the posterior than in the anterior circulation. Case reports suggest that patients with BAO can recover from recanalization therapy beyond 8 h after symptom onset.^[10] Many different methods have been employed to recanalize a large vessel occlusion resulting in AIS. Several studies have demonstrated the efficacy of a combined intravenous and endovascular approach in the treatment of AIS compared with intravenous therapy alone.^[11,12] Endovascular clot retrieval with Merci, Solitaire, Trevo and thrombo aspiration with penumbra has shown promising results in different studies and proven superior to IV rtPA alone. Solitaire FR has gained momentum as a tool for mechanical thrombectomy after its approval by FDA in 2012. Many centers started using Solitaire for mechanical thrombectomy even before its approval. We treated 16 patients with Solitaire and achieved good clinical outcome in 10 of them.

Recanalization

Successful recanalization is associated with good clinical outcomes after adjustments for age, sex and stroke severity.^[13] We had successful recanalization (TICI 2 and TICI 3) in 14 (87.5%) of our patients, similar to the rates reported by Koh *et al.*^[14]

In two patients with ICA occlusion, recanalization was unsuccessful after repeated attempts. In one of them, we tried balloon angioplasty after repeated attempts with solitaire but finally flow could not be established. The procedure was abandoned. Patient was managed medically. He improved partially with mRS score of 3 at the end of 3 months.

The other patient had extensive thrombus with extension of thrombus from ICA to MCA. The entire clot could be removed, but there was a critical stenosis of the MCA leading to repeated slow flow distally with occlusion. The MCA was stented acutely with detachment of Solitaire. But, the MCA occluded immediately. The procedure had to be stopped and patient managed medically. He improved partially with mRS 3 at the end of 3 months.

Detachment of a permanent stent in a major intracranial vessel during acute ischemia has been proposed^[15,16] with fair results. Egashira *et al.*^[17] also have described stenting of an intracranial vessel in acute stroke, once the clot retrieval fails with stent retriever. However, we did not have a desirable result in our patient.

Basilar artery occlusion remains one of the most devastating subtypes of ischemic stroke with poor clinical outcome. Self-expanding retrievable stents in

acute BAO have higher recanalization rate without procedural complications and good clinical outcome in one-third of patients.^[18] Two patients with BAO had good recanalization with TICI 3 and TICI 2. But one patient succumbed to death.

Clinical outcome

Clinical outcome was evaluated at 3 months by mRS scale. Good clinical outcome was defined as mRS 2 or less. Ten out of 16 patients (62.5%) had good clinical outcome ICA (2/4), MCA (7/10), basilar artery (1/2). Good clinical outcome was seen in 70% of MCA occlusions compared to 50% for ICA occlusion. The MCA occlusion post-thrombectomy outcome is comparable with the outcome of RECAST study.^[19] In AIS, good outcome following successful recanalization is time dependent.^[20] Patients with faster recanalization with less number of passes with Solitaire had a good outcome.

Complications

The major complications with Solitaire thrombectomy are clot fragmentation with distal clot migration in the same or different territory, re-occlusion of recanalized vessel, wire perforation, cerebral hemorrhage, and dissection of vessels. We had complications in three of our patients. One patient had asymptomatic intracerebral hemorrhage post-thrombectomy. The other patient had clot fragmentation with slow flow in the same territory. The third patient had recurrent occlusion following repeated recanalization.

Hemorrhage

Symptomatic hemorrhage was defined as an increase of the NIHSS ≥ 4 .^[15] There are reports of symptomatic hemorrhage ranging from 2% to 6% in patient post-thrombectomy^[20,21] with poor outcome. One patient had asymptomatic cerebral hemorrhage following thrombectomy in the territory of recanalization.

Mortality

Two (2/16) patients died (12.5%). One of them had BAO presenting to us at 18 h of stroke onset with an infarct. We recanalized the basilar artery with TICI 2 without any hemorrhage. The patient developed cerebral edema on day 4, decompression craniotomy was planned but the patient coned to death before the surgery.

The other patient had associated severe cardiovascular comorbidity with ejection fraction of 30%. He had severe aorto-iliac disease with occlusion of both iliac arteries and had renal insufficiency with raised creatine level. The patient was intubated prior to the procedure. The Solitaire clot extraction for this patient had to be done through

trans-brachial arterial approach. Complete clot extraction with Thrombolysis in cerebral infarction (TICI) score of 3 achieved. Patient was extubated 2 days after the procedure. He died 7 days after the procedure. Mortality in our series is consistent with the study of Koh *et al.* (11%).^[14]

CONCLUSION

In the last few years interventional management of AIS has steadily improved. Especially after FDA approval of Solitaire in 2012, many stroke centers in India and abroad have attempted acute stroke management with clot retrieval devices such as Solitaire, Trevo, Merci, etc. Mechanical clot retrieval with Solitaire appears to be safe and effective in acutely occluded large intracranial vessels. Early the recanalization achieved, better the clinical outcome in patients with AIS.

Ours is a retrospective analysis of patient data from a single center. In our experience Solitaire thrombectomy is a safe prompt and effective procedure. Our results are consistent with other published series using the Solitaire FR or other “stent retriever” devices.^[16,22] However, our sample size is small and results needs to be validated by large, prospective, randomized trials.

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How to cite this article: Narayana RV, Pati R, Dalai S. Safety and efficacy of mechanical thrombectomy with Solitaire in patients with acute ischemic stroke. *Indian J Neurosurg* 2014;3:25-30.

Source of Support: Nil, **Conflict of Interest:** None declared.