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Original research

Mechanical thrombectomy by Solitaire stent for treating acute ischemic stroke: A prospective cohort study

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HIGHLIGHTS

- Data of mechanical thrombectomy with the 3rd generation stent are from Chinese.
- Mechanical thrombectomy without the balloon guide catheter.
- The 3rd generation stents combined with some other tools were used in this study.

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ABSTRACT

Background: Acute ischemic stroke (AIS) is a worldwide serious health problem. Intravenous (IV) thrombolysis with recombinant tissue plasminogen activator (rt-PA) is the standard treatment; however, only a small number of patients benefit from it due to the strict application restrictions. Recently, more and more evidence prove mechanical thrombectomy is an effective and safe therapy of AIS.

Patients and methods: From December 2010 to March 2015, 83 patients who underwent mechanical thrombectomy were collected as a sample pool. All patients met the following criteria: National Institutes of Health Stroke Scale (NIHSS) score $\geq$10, treatment performed within 6 h from the onset of symptoms, no large hypodensity on CT or multimodal MRI, and angiography revealed occlusion of a major cerebral artery. Recanalization rates were assessed immediately post-procedure by follow-up angiography according to the thrombolysis in cerebral infarction score criteria. Assessment of the modified Rankin Scale was performed 90 days after treatment.

Results: The mean age of patients was 63.3 years, and NIHSS scores 19.12 $\pm$ 4.60 at presentation. The vessel occlusions occurred in the middle cerebral artery (68.7%), distal internal carotid artery (7.2%), internal carotid artery with tandem middle cerebral artery occlusion (14.5%), basilar artery (2.4%), and vertebral artery (7.2%). Successful recanalization (TICI 3/2b) was achieved in 56 of 83 patients (67.5%). At 90-day follow-up, good clinical outcome (mRS $\leq$ 2) was achieved in 33 of 83 patients (39.8%), while 20 patients died (24.1%).

Conclusions: This study revealed mechanical thrombectomy with Solitaire stent device was an effective and safe therapy, which achieved a high rate of angiographic recanalization and independent outcome accompanied by a low mortality rate.

1. Introduction

Acute ischemic stroke is a worldwide health problem and associated with high morbidity and mortality rates. In recent years, intravenous (IV) thrombolysis with recombinant tissue plasminogen activator (rt-PA) has become the standard treatment for acute ischemic stroke [1]. However, only a small percentage of acute

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ischemic stroke patients received rt-PA because of the narrow time window and other restrictions such as a history of intracranial hemorrhage, coagulation abnormalities, et, al [2,3]. Moreover, intravenous alteplase appears to be less effective while opening proximal occlusions of the major intracranial arteries, which account for more than one third of cases of acute anterior-circulation stroke [4].

To improve the outcome of acute ischemic stroke, intra-arterial treatment was developed as a potentially effective therapy. Endovascular mechanical thrombectomy has shown advantages over intravenous thrombolysis treatments for proximal lesions, including more rapid achievement of recanalization, enhanced efficacy in treating large-vessel occlusions, potentially lower risks of hemorrhagic complication, a longer therapeutic window and higher recanalization rate [5]. Recent studies indicated that rapid thrombectomy treatment after stroke onset resulted in higher reperfusion rate, better functional recovery and similar safety compared with IV rt-PA treatment [6–8]. Mechanical approaches have shown great potential of replacing locally applied thrombolytic agents as first-line therapy [9].

Here we report our experience of mechanical thrombectomy using Solitaire stent device in Chinese patients. We also compare our results to other main trails in recent years.

2. Patients and methods

This work is in line with the STROBE criteria [10].

This study had been approved by Ethics Committee of The First People's Hospital of Changzhou, Soochow University. From December 2010 to March 2015, 83 patients underwent mechanical thrombectomy using Solitaire stent. All the patients met the following criteria: National Institutes of Health Stroke Scale (NIHSS) score $\geq$ 10, treatment performed within 6 h from the onset of symptoms, no large hypodensity on CT or multimodal MRI, and angiography revealed occlusion of a major cerebral artery.

On admission, a stroke neurologist examined all patients. The baseline NIHSS score, a clinical measure of neurologic deficit with a range from 0 (no deficit) to 42 (maximum possible deficit), was used to identify patients. Patients with a NIHSS score of 10 or more have a greater than 80% likelihood of a major arterial occlusion [11]. Cranial CTA or multimodal MRA were obtained prior to every intervention to confirm the diagnosis of large vessel occlusion and to rule out intracranial hemorrhage (ICH). Interventional treatment was initiated within 6 h from onset of stroke symptoms. The “time of symptom onset” was defined as the acute onset of symptoms as observed by the family members. The “door time” was defined as the time when the patient arrived at the emergency room and the “needle time” was the time groin puncture was performed.

2.1. Endovascular procedure

All interventions were performed by consultant neurointerventionalists Ya Peng and his colleagues on a biplane system (Artis Zee Biplane; Siemens, Erlangen, Germany) under local or general anesthesia. The choice of general anesthesia or conscious sedation for each particular procedure was at the operator's discretion. Using transfemoral access, a 6F sheath (TERUMO RadifocusTM Introducer, Tokyo, Japan) was placed into the right femoral artery. An intravenous bolus of 3000 IU of heparin was administered. Conventional cerebral angiography showed the location of the occlusion and collateral circulation. A 6-Fr guiding catheter was placed in internal carotid artery (ICA) or vertebral artery (VA). A Rebar 18 microcatheter (eV3, Irvine, California, USA) was navigated through the thrombus with microwire. The 4 mm $\times$ 20 mm Solitaire stent (eV3, Irvine, California, USA) was deployed in the clot and allowed to wait for 2 or 3 min. The entire system, comprised of the stent and the microcatheter, were completely retrieved while the assistant produced suction by placing a large syringe at the ‘Y’ valve of the guiding catheter, allowing the thrombus to be successfully removed. After retrieval, the clot typically could be seen entangled within the meshwork of the stent. Control angiography was performed following each retrieval until success. DynaCT (Artis ZeeBiplane; Simens, Erlangen, Germany) was immediately performed to evaluate the presence of any intracranial hemorrhage. The femoral sheath was removed and the wound closed with an Angio-Seal (St. Jude Medical, Inc, St. Paul, MN) vascular closure device. The thrombolyses in cerebral infarction (TICI) scores were estimated from angiographic runs before and after the procedure. Assessment of angiographic images was performed in consensus by 2 experienced neuroradiologists. Concurrent endovascular interventions, such as intra-arterial thrombolysis and detachment of stent or balloon angioplasty after Solitaire stent thrombectomy, were attempted in some of cases. Tirofiban, which is a fast-acting GB IIb/IIIa inhibitor that prevents platelet aggregation and improves cerebral perfusion was administered in 4 cases of stent-assisted angioplasty administered intravenously at an initial dose of 0.4 mg and continued at 0.1 μg/kg/min for 24 h. In one case, vasospasm was found in the M1 segment of the middle cerebral artery (MCA). After injecting 90 mg papaverine, the vessel spasm was successfully relieved.

The extent of recanalization was assessed immediately post-procedure by follow-up angiography. Following the procedure all patients were managed in the neuro critical care unit by an experienced team of neuro-intensivists. Thrombolysis in Cerebral Infarction scores were used to evaluate the extent of pre-procedure clot burden, the post-intervention residual clot burden, and the success rate of the procedure. Most cases of this group got a CT and MRI scan on day 1 and an MRA on day 3 to evaluate infarction, hemorrhage and patent of lesion artery. The patient outcomes were assessed by certified examiners at discharge (NIHSS) and the three-month follow-up (mRS).

2.2. Statistics

The mean value, standard error and percent value were calculated by the *Microsoft Excel* 2007, and Chi-square test performed by SPSS (Version 17.0).

3. Results

There were altogether 83 patients in our series. The mean patient age was over 60 years (range 21–85), and male patients accounted for 60.2% of the pool. Detailed characteristics of stroke patients are presented in Table 1. One 21-year-old male patient was

Table 1
Patient characteristics.

Age, years mean±(SD) (range)	63.34 ± 13.70 (21–85)
Sex (male: female) — no. (%)	1.52: 1 (60.2: 39.8)
Atrial fibrillation — no. (%)	40 (48.2)
History of hypertension — no. (%)	49 (59.0)
Blood Pressure, mmHg mean±(SD) (range)	
Systolic	144.71 ± 27.46 (70–192)
Diastolic	83.65 ± 13.83 (50–120)
History of diabetes — no. (%)	13 (1)
Serum glucose,mmol/l mean±(SD) (range)	8.33 ± 3.98 (3.9–27.1)
TG > 2.02 mmol/l — no. (%)	22 (26.5)
Triacylglycerol, mmol/l mean±(SD) (range)	1.86 ± 1.10 (0.68–6.06)
TC > 5.7 mmol/l — no. (%)	13 (15.7)
Cholesterol, mmol/l mean±(SD) (range)	4.40 ± 0.90 (2.19–6.89)
High homocysteine — no. (%)	2 (2.4)