Journal of Medicine in Scientific Research

Volume 1 | Issue 1 Article 2

Subject Area:

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Recommended Citation

El-Bassiouny, Ahmed; Khalaf, Magdy; and Adly, Romany (2018) "Technical aspect of mechanical thrombectomy of acute ischemic stroke," *Journal of Medicine in Scientific Research*: Vol. 1: Iss. 1, Article 2.
DOI: https://doi.org/10.4103/JMISR.JMISR_4_18

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Original Article

Technical aspect of mechanical thrombectomy of acute ischemic stroke

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Abstract

Background and purpose

Mechanical thrombectomy was recently reported of having the potential to treat acute ischemic stroke. However, few comparative studies on neurothrombectomy devices are reported. This study aims to compare two retrievable stent systems according to their safety and effectiveness in patients with acute ischemic stroke.

Patients and methods

In this study, the clinical, radiological, and functional outcomes of 20 patients with acute ischemic stroke are compared prospectively. Patients were treated with either Trevo retriever (TR) or Solitaire stent (ST) according to the neurointerventionalist preference. Successful recanalization was defined as thrombolysis in cerebral ischemia grade 2a to 3.

Results

Revascularization was achieved in seven (70%) patients in the ST group and six (60%) in the TR group. The rate of symptomatic intracerebral hemorrhage was 20% in the ST group and 30% in the TR group. One (10%) patient died during the first week in the TR group and one (10%) patient in the ST group. The rate of good outcome was 60 and 70% for TR and ST groups, respectively.

Conclusion

Our study showed no significant differences between both stent retrievers. Moderately high recanalization rates are possible with both; however, larger series may depict safety-related variations.

(1) A picture of thrombus removed by stent from the first pass.
(2) Digital angiography anteroposterior view showed complete occlusion of left middle cerebral artery.
(3) Digital angiography anteroposterior view after mechanical thrombectomy showed recanalization of left middle cerebral artery.

Keywords: Solitere, stent, stroke, thrombectomy, Trevo

Introduction

The second most common cause of death is stroke worldwide, and it is a frequent cause of adult disability in developed countries [1].

There was a statistically significant decrease (42%) in stroke incidence rates in high-income countries. However, in low-income to middle-income countries, stroke incidence rates have increased by more than 100% and currently exceed those in high-income countries [2].

The standard treatment for acute ischemic stroke with intravenous tissue plasminogen activator (t-PA) has been recommended as thrombolytic therapy when a patient qualifies. It has been shown that intravenous t-PA is clinically useful within 4.5 h after onset of stroke symptoms, after which the likelihood of neurological and functional recovery decreases. Because of the short therapeutic window for intravenous t-PA, and because of the extensive set of other clinical eligibility

Access this article online

Quick Response Code:

Website: www.jmsr.eg.net

DOI: 10.4103/JMISR.JMISR_4_18

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How to cite this article: Khalaf M, El-Bassiouny A, Adly R. Technical aspect of mechanical thrombectomy of acute ischemic stroke. J Med Sci Res 2018;1:8-12.

criteria for administration, patients with limited acute ischemic stroke qualify for the intervention on presentation [3].

Almost 50% of patients treated with t-PA alone in the National Institutes of Neurologic Disorder and Stroke (NINDS) trial had achieved mostly full recovery. However, subgroup analyses of the NINDS data showed that patients with severe strokes had only an 8% likelihood of achieving clinically significant improvement with t-PA. The unfortunate outcome in these patients has inspired the search for acute stroke treatments that are more effective than t-PA [4].

Nonpharmacological technologies have settled for the treatment of acute ischemic stroke, such as devices for mechanical thrombectomy. Mechanical thrombectomy is a technique that attempts to remove as much of the clot as possible. MERCI Retriever (Concentric Medical, Mountain View, California, USA) was the first to be approved by the Food and Drug Administration (FDA) in 2005. Moreover, it is constituted by a set of catheters that allow the flow to be proximally blocked and the clot to be approached and captured with a guide wire with a 'corkscrew'-like tip. The next device was the PENUMBRA System to be approved (Penumbra, Alameda, California, USA). It is currently in use in many centers. It was designed to perform revascularization using a technique of aspiration followed, if necessary, by direct extraction of the thrombus if any remained. As technology advances, creation of the catheter with large lumens able to aspirate even voluminous thrombus becomes possible. More recently, stent-retriever devices, which encapsulate the thrombus, have been developed; this allows a fast restoration of the blood flow and increases the efficacy of thrombolytic substances. There is currently an increasing number of companies providing this technology: Solitaire (ev3, Plymouth, Minnesota, USA), Trevo (Concentric Medical), Aperio (Acandis), and Revive (Codman Endovascular, Asia Pacific). It is crucial that the clot removal be done under proximal flow arrest promoted by a balloon-guided catheter. The new generations of aspiration catheter and stent retrievers can perform faster and better than MERCI [5].

The use of a catheter (during angiography) to directly deliver a clot disrupting or retrieval device to thromboembolism that is occluding a cerebral artery is considered as mechanical treatments. Most devices are used in cerebral vessels that are 2–5 mm. Mechanical thrombectomy devices can remove a clot in a matter of minutes, whereas pharmaceutical thrombolytic, even those delivered intraarterially, may take as long as 2 h to dissolve a thrombus. The most recently developed devices, known as retrievable stents or stent retrievers, have shown higher recanalization rates and better outcomes than those with the older Merci retriever [6].

The Trevo stent-retriever (TR) received US FDA clearance in 2012 after a randomized, multicenter trial showed superior revascularization and patient's outcome with this device compared with Merci retriever [7].

The solitaire stent-retriever system also received FDA clearance in 2012 after showing better outcomes, better revascularization, and an absence of symptomatic intracranial hemorrhage with this device compared with the Merci retriever in randomized, multicenter studies [8].

Therefore, this study is aimed at determining efficacy and safety of mechanical thrombectomy in the treatment of acute ischemic stroke and compared outcome between the TR and Solitaire stent-retriever (ST) systems.

Patients and methods

A prospective study was designed comparing the clinical, radiological, and functional outcomes of 20 consecutive patients with acute ischemic stroke. Patients were treated either with TR or ST according to the neurointerventionalist preference and according to site and length of the occluded segment. In all cases, the devices were used as monotherapy. Figure 1 from neurointervention cath lab of el mataria teaching hospital (our work).

Details of procedure

All procedures were performed under our institutional mild sedation protocol (propofol intravenous dose of 0.5–1 mg/kg may be repeated every 5 min under precautionand mechanical ventilators standby). Some cases needed general anesthesia. During a transfemoral approach, a 6-Fr guiding catheter was placed in the internal carotid artery (ICA), and an angiogram was performed to locate the occluding clot. A heparinized saline solution was continuously perfused through the catheter during the procedure.

A 0.014-inch guide wire (Transend, Stryker Neurovascular USA) and a 0.018-inch microcatheter (Rebar, Medtronic USA), through the guiding catheter, were advanced passing through the clot within the occluded intracranial vessel. Once the microcatheter with its distal end was positioned a few millimeters beyond the distal aspect of the clot, the guide wire was exchanged by the TR or ST embolectomy device. The device was held in place when 3 mm was out of the microcatheter. Then the microcatheter was slowly pulled back to deploy the TR or ST device over the clot.

At that point, a contrast injection through the guiding catheter could show contrast filling of some distal branches previously occluded. The stent was kept deployed for 3 or 5 min to allow the clot to be embedded in the stent mesh. Then we gently withdrew the microcatheter and the embolectomy device through the guide catheter. Under continuous proximal aspiration with a 50-cc syringe to create a reverse flow. The procedure could be repeated up to six passes when recanalization failed. The procedure was terminated when recanalization was achieved or according to the treating physician criteria.

Vascular recanalization was defined as thrombolysis in cerebral ischemia (TICI) grade 2a, 2b, or 3. Established device-related complications, namely, vascular perforation, arterial dissection, or embolization, were systematically collected. Symptomatic intracranial hemorrhage was defined as a hemorrhagic

transformation on the 24-h computed tomography (CT) scan related to the deterioration in the patient's clinical condition in the judgment of the clinical investigator. The dramatic clinical improvement was defined as a greater than or equal to 10-point decrease in the National Institutes of Health Stroke Scale (NIHSS) at 24 h.

Procedures were performed within 6 h of symptoms onset. Successful recanalization was defined as TICI grade 2a to 3. Functional outcome was defined as NIHSS less than five after 1–3 months.

Clinical and radiological assessment

Clinical data were prospectively retrieved for each patient, including demographic, detailed history of preexisting vascular risk factors, and medication history.

All patients underwent a standard neurological examination, ECG, blood pressure, and blood workup, namely, coagulation studies, complete blood count, and basic metabolic panel at admission. The NIHSS at baseline and 24 h assessed stroke severity. All patients were selected and treated according to our institutional protocol (which include, age 30–80 years, onset <6 h, and no any contraindication to anticoagulant or femoral cannulation). Patients were evaluated radiologically with cranial CT scan (ASPECT score presence of any sign of large vessels and exclude hemorrhage) or multiparametric MRI.

A CT scan was routinely performed between 24 and 36 h after treatment or before if any neurological worsening (≥4-point increase in NIHSS score) occurred.

All patients underwent primary thrombectomy with either the TR or the ST within the first 6 h of symptoms onset.

In all cases, the patients or their relatives had signed the informed consent form before the procedure.

Statistical analysis

Descriptive and frequency statistical analysis was obtained, and comparisons were made using SPSS (SPSS Inc., Chicago, Illinois, USA).

Results

During the study period, 20 patients were treated. Ten patients were treated with the ST and 10 patients with the TR. Baseline clinical characteristics were similar between the two groups and are summarized in Table 1. Mean age was 55.9 ± 11.9 years for the ST and 56.1 ± 12.3 years for TR. Median baseline NIHSS score was 18.4 for the ST and 19.5 points in the TR. The time from symptom onset to procedure initiation (groin puncture) had a mean time of 3.95 ± 1.499 h for the ST group, and 3.60 ± 1.713 h for TR. On the first angiogram, in the TR group, the occlusion site was identified in the middle cerebral artery (MCA) in seven patients and the ICA in three patients. Regarding the ST group, the angiogram showed occlusion in eight patients in the MCA and two in the ICA. Six patients were performed under general anesthesia after induction of sedation failed.

Outcome analysis is summarized in Table 2. Briefly, revascularization was achieved in seven (70%) patients in the ST group and six (60%) patients in the TR group ($P = 0.923$). The maximum recanalization was achieved by a median number of three passes (2–4) for both groups. No distal embolization, arterial ruptures, or dissections were observed. Rate of symptomatic intracerebral hemorrhage was 20% for ST versus 30% for TR ($P = 0.356$). One (10%) patient died during the first week in the ST and one (10%) in the TR group ($P = 0.760$). There was one (10%) patient with dramatic clinical improvement in the ST group and one (10%) patient in the TR group ($P = 0.760$).

Discussion

In patients with acute stroke, early arterial recanalization is closely associated with early clinical recovery and a favorable outcome [9]. In this perspective, endovascular therapy will undoubtedly play a significant role shortly. Through this small

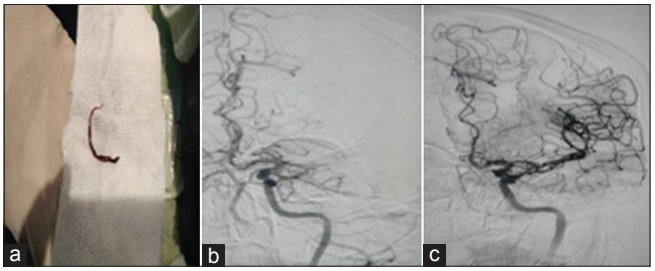

Figure 1: (a) A Picture of thrombus removed by stent from the first pass. (b) Digital angiography AP view showed complete occlusion of LT middle cerebral artery (MCA). (c) Digital angiography AP view after mechanical thrombectomy showed recanalization of Lt MCA.

Table 1: Baseline characteristics between the two groups

Characteristics	ST group	TR group	Significance (*P*)
Age (mean±SD)	55.90±11.939	56.10±12.333	0.097
NIHSS at onset (mean±SD)	18.40±3.502	19.50±3.504	0.690
Time from onset to catheterization lab (mean±SD) (h)	3.95±1.499	3.60±1.713	0.607
Occluded vessels [*n* (%)]			
MCA	8 (80)	7 (70)	
ICA	2 (20)	3 (30)	

ICH, intracerebral hemorrhage; MCA, middle cerebral artery; NIHSS, National Institutes of Health Stroke Scale; ST, Solitaire stent-retriever; TR, Trevo stent-retriever.

Table 2: Outcomes

	ST group	TR group	*P*
Number of trials (mean±SD)	2.60±1.174	2.60±1.174	0.756
Revascularization TICI (2-3) [*n* (%)]	7 (70)	6 (60)	0.923
NIHSS after 24 h (mean±SD)	6.40±4.195	6.30±4.668	0.454
Symptomatic ICH [*n* (%)]	2 (20)	3 (30)	0.356
Mortality [*n* (%)]	1 (10)	1 (10)	0.760
Immediately improvement [*n* (%)]	1 (10)	1 (10)	0.760

ICH, intracerebral hemorrhage; NIHSS, National Institutes of Health Stroke Scale; ST, Solitaire stent-retriever; TICI, thrombolysis in cerebral ischemia; TR, Trevo stent-retriever.

comparative study of two neurotrombecthomy devices, we compared the use of the concentric TR system and the EV3 ST in a cohort of patients with acute stroke undergoing endovascular therapy. Both groups of patients showed no significant changes in baseline characteristic regarding age, clinical variables, and time to procedure. In general, both devices could be safely deployed. They timely and efficiently induce recanalization in patients with severe stroke with a proximal intracranial occlusion, leading to a significant functional recovery in more than half of the patients. None of the devices presented any malfunction or were fractured during the procedures leading to failure to deploy the device, perforation, dissection, thrombus formation, or hemorrhage (including symptomatic and asymptomatic intracerebral and subarachnoid hemorrhage from vessel injury and another bleeding). The observed rates of recanalization and good clinical outcome in the present study are comparable to previously published results [10]. The recanalization rates in the ST group were slightly superior to the TR, but again, this was not statistically significant and in line with the recently published results from the SWIFT trial that showed a 68.5% recanalization rate using the ST [11]. Subjectively, our experience using the TR showed it to be smoother navigating the vessels. On the contrary, its closed distal end is intended to minimize the possible damage to the arterial wall when deployed and pulled out. Moreover, its high flexibility allows easy navigation up to distal M2/M3 MCA branches. On the contrary, the ST has a more rigid body and is somewhat more aggressive to navigate but carries a higher radial force and has the theoretical advantage over the TR of allowing immediate recanalization of the vessel upon deployment [12]. These features might make the ST more suitable for proximal occlusions with a high burden of clot such as terminal ICA occlusions. In our study, however, the time from groin puncture to recanalization and the number of passes to recanalization were similar for both groups. The small number of patients give further comparisons according to occlusion location. The time to recanalization appears similar to previous results, reflecting the relative ease of use of both stent retrievers [13]. This is important in the setting of acute stroke where restoring flow as soon as possible is essential [14]. The major limitation of our study is that selection of the device was not randomized. However, baseline characteristics of the patients were well balanced regarding stroke severity and occlusion location. Finally, this is a small study, so the results should be interpreted cautiously.

Conclusions

Our study suggests that there was no difference between the two devices. Moderately high recanalization rates are possible with both; however, larger series may depict safety-related variations. Randomized comparative studies between different devices are necessary to help neurointerventionalists in their decisions.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Appendix

TICI score

(1) Grade 0: no perfusion.
(2) Grade 1: penetration with minimal perfusion.
(3) Grade 2: partial perfusion.
    (a) Grade 2a: only partial filling (less than two-thirds) of the entire vascular territory is visualized.
    (b) Grade 2b: complete filling of all of the expected vascular territory is visualized, but the filling is slower than normal.
(4) Grade 3: complete perfusion.