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Primary Endovascular Treatment of Acute Ischemic Stroke Using Stent Retrievers: Initial Egyptian Experience

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Abstract

Background—Several mechanical thrombectomy (MT) devices have been designed with the goal of improving the recanalization rates of major intracranial artery occlusions.

Objective—In this single-center experience, we analyzed the acute ischemic stroke (AIS) treatment with Primary MT; safety and efficacy and clinical results in our patients with large vessel occlusion (LVO).

Methods—During a five-year period (from September 2011 to July 2016), out of 996 patients who presented to our center with a diagnosis of AIS, 113 (11.4%) patients (55 men and 58 women) underwent primary mechanical recanalization within three hours from onset of signs and symptoms for anterior and 12 hours for posterior circulation (with computer tomography angiography/perfusion ELVO). Successful recanalization (thrombolysis in cerebral infarction 2b–3), good outcome (modified Rankin scale score 0–2) and overall mortality rate, and symptomatic intracranial hemorrhage [sICH: parenchymal hematoma Type 1 or Type 2; National Institutes of Health Stroke Scale (NIHSS) score increment ≥4 points] were prospectively assessed.

Results—The mean age of the patients was 62 ± 11.73 years, with a baseline mean admission NIHSS score of 16.7 ± 3.2. The mean time from onset to puncture (time to treatment) was 208.55 ± 53.49. Successful recanalization was achieved in 104 (92%) cases. Good outcome was observed in 89 (78.8%) patients, and mortality was 11.5% (n = 13). sICH occurred in five (4.4%) patients.

Conclusion—MT, within the first 4.5 hours, as primary treatment of acute LVO stroke provides high rate of recanalization and favorable clinical outcomes with low procedural complications.

Keywords

acute ischemic stroke; thrombectomy; thrombolysis; endovascular treatment; Egyptian

Introduction

Acute ischemic stroke (AIS) treatment is based on the concept that early recanalization of an occluded artery will lead to preservation of the time-sensitive penumbra, which theoretically leads to a better clinical outcome [1]. Intra-arterial (IA) pharmacological thrombolysis for AIS was first reported in 1983 [2]. The low efficacy of this approach led to the development of mechanical thrombectomy (MT) devices. MT was initially introduced as a complementary treatment to AIS therapy, in particular, when IA or intravenous (IV) thrombolysis is ineffectual [3]. The first of such devices, approved by the FDA in 2004, was the MERCI retrieval device (Concentric Medical, Inc.). This device appeared to be an improvement over pharmacological thrombolysis alone, but unfortunately it had practical deficiencies that prompted the search for a safer, clot retriever. Subsequently, in

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December 2007, the FDA approved the Penumbra endovascular suction device (Penumbra, Inc.) [4,5]. A commonality among various studies was that Penumbra caused fewer hemorrhagic complications than MERCI, likely due to a reduction in the mechanical trauma to the artery, but may result in worse neurological outcomes because of multiple thromboemboli sent distally [6]. The Solitaire-FR retrievable stent (ev3/Covidien), member of the newest line of ischemic stroke devices referred to as stent retrievers, was the first such device to be approved by the FDA (approved in March 2012). The stent received the Conformite′ Europe′ene mark in July 2009 for flow restoration in AIS as the Solitaire-FR device [7]. Shortly thereafter, in August 2012, the Trevo Pro Retriever received the FDA approval.

Evidence-based medicine extrapolated from recent randomized controlled trials (RCTs) reordered AIS management paradigm regarding large vessel occlusion (LVO) stroke patients who presented within the first 4.5 hours. Accordingly, those patients should receive IV Rtpa then arrange for MT within six hours. But what if, for any reason, those patients received primary mechanical recanalization within the first three hours [8,16,17,19].

In our single-center experience, we analyzed the results of primary MT during the standard three hours for ACS and within 12 hours for PCS for LVO in terms of safety and efficacy and clinical results.

Methods

From September 2011 to July 2016, out of 996 AIS patients presented to our center, we could identify 113 patients (55 men and 58 women), with a diagnosis of AIS who underwent primary mechanical recanalization (no IV thrombolytic was given), and were admitted to our tertiary university hospital within three hours from the onset of signs and symptoms for anterior and 12 hours for posterior circulation. Our stroke center is the first comprehensive stroke center playing the role of the hub for multiple spokes paradigm which developed the first prototype model of national stroke network in Egypt (www.egyptianstrokenetwork.com). The National Institutes of Health Stroke Scale (NIHSS) score was obtained at admission.

Our stroke imaging protocol that includes non-contrast brain computer tomography (CT), which was evaluated for signs of early ischemic changes as defined by the Alberta stroke program early CT score (ASPECTS) [9], followed by CT angiography of intracranial and extracranial (neck) arterial system, and CT perfusion (CTP) imaging was performed on every patient enrolled in the study [12]. In general, the decision about the bridging therapy in patients with LVO stroke was made by the neurologist.

Our inclusion criteria for primary MT are as follows: patients with major vessel stroke (NIHSS ≥10; large vessel—internal carotid artery (ICA), middle cerebral artery (MCA), or vertebral artery (VA)/basilar artery occlusion) with contraindication for IV thrombolysis, e.g., patients after recent surgery or acute myocardial infarction, patients on anticoagulant therapy suffered stroke during hospitalization, and patients with BA occlusion or any obstacle hindering the IV-rtpa delivery within the three hours. Demarcated ischemic lesion on the non-contrast brain CT scan and no tissue at risk (ischemic penumbra) on the CTP were exclusion criteria in our treatment protocol.

Postprocedural neurological examination (NIHSSscore) was performed for all patients 24 hours after the procedure. Complete post-procedural neurological recovery was defined as NIHSS 0 or 1, whereas significant neurological improvement was defined as ≥4 NIHSS point reduction [33]. Modified Rankin scale (mRS) was available for all patients at one- and three-month period of follow-up; a favorable outcome was defined as mRS ≤2 after stroke [14]. Overall mortality rate during the first three months after the procedure was recorded.

All intracranial hemorrhages were classified using the definition of the European Cooperative Acute Stroke Study [11]. Symptomatic intracranial hemorrhage (sICH) was defined as ≥4 NIHSS point decline within 24 hours with any blood identified on the 24-hour brain CT scan (petechial bleeding, hematoma, or subarachnoid hemorrhage) or any intracranial hemorrhage that ended with the death of the patient (occurred in five patients) [14].

Revascularization Protocol

The percutaneous IA MT was performed by one skilled interventional neurologist. All procedures were performed under general anesthesia protocol. Using a transfemoral approach, an 8F sheath introducer (Super Arrow-Flex; Teleflex, Limerick, Pennsylvania) and 8F balloon catheter (Merci balloon guide catheter; Stryker, Natick, MA, USA) were placed in the ICA or VA, and an angiogram was performed to locate the occluding clot. A heparinized saline solution was continuously perfused through the catheter during the procedure. When the carotid siphon and terminal ICA appeared very tortuous, a 4.3F or 5F intermediate catheter was advanced

through the guiding catheter to increase system stability and to be used as another hub for aspiration.

With the balloon of the guide catheter deflated, a 014-inch guide wire and a microcatheter were advanced (through the guiding catheter or the intermediate catheter when used) within the occluded intracranial vessel passing through the clot. The following are the different kinds of devices used: clot retrievers (Catch+ device, Balt Extrusion, Montmorency, France) and stent retriever devices (Solitaire, ev3 Inc., Irvine, CA, USA; Trevo, Concentric Medical). After successful recanalization of the proximal occlusion, if distal occlusion in M2–M3 branches was observed, IA tPA was used as an adjuvant therapy to complete recanalization. The selection of the device used was taken exclusively by the operator.

Our angiographic result was evaluated on the basis of three-grade thrombolysis in cerebral infarction (TICI) scale as follows: 0 = no perfusion, 1 = penetration with minimal perfusion, 2 = partial perfusion (2a: less than two thirds of the entire vascular territory; 2b: complete but slower filling of all of the expected vascular territory), and 3 = complete perfusion without flow constraint [10]. TICI 2b or TICI 3 flow was considered a successful recanalization of the treated artery. Time to puncture (from symptom's onset to puncture) and procedure duration were analyzed.

Procedure-related adverse events were defined as perforation, treated vessel dissection, or embolization of a previously uninvolved territory. Clinically significant procedure-related adverse events were defined as a procedure-related adverse event with decline of neurological clinical picture (NIHSS ≥4 compared with the NIHSS before the procedure) or death related to the procedure [15].

Approval for data collection of interventional procedures was given by the institutional review board. Patient consent for study inclusion was obtained from the patients or their legal representatives.

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. The distribution of quantitative variables were tested for normality using the Kolmogorov Shapiro–Wilk test and the D'Agstino test, also Histogram and QQ plot was used for vision test. Numerical data are presented as mean ± standard deviation or median with interquartile range. Changes in clinical outcome were analyzed from the baseline to post-procedural follow-up by a paired samples *t* test. Significance of the obtained results was judged at the 5% level.

Results

The demographic characteristics, risk factors, and clinical results of the patients included in our study are presented in Table 1, while procedural and radiological characteristics of the study patients are presented in Table 2.

One hundred and thirteen consecutive patients presented with AIS and treated with primary MT during a five-year period (from September 2011 to July 2016) were analyzed.

The mean age of the patients was 62 ± 11.73 years; the females constituted 51.3% of our patients. Among the study patients, 53.98% had hypertension, while 75.2% of our group had diabetes mellitus and dyslipidemia. Among our study population, 59.3%, 46%, and 33.6% had ischemic heart disease, atrial fibrillation, and peripheral vascular disease, respectively. Among our patients, 33.6% experienced transient ischemic attack (Table 1).

The NIHSS score upon admission was 16.7 ± 3.2. Post-procedural neurological examination (NIHSS score) performed in all patients, 24 hours after the procedure, was 6.4 ± 4.1. Favorable outcome was defined as mRS ≤2 after stroke (78.8% of our patients) [15]. Overall, mortality rate during the first month after the procedure was 11.5% (Table 1).

Among our patients, 29.2% had their occluded artery in MCA-M1. MCA-M2 and anterior cerebral artery occlusions constitute 10.6% and 0.9%, respectively. Carotid occlusion was detected in 38.9% of our cohort, while postcirculation stroke was found in 20.3% of our patients. Exuberant collaterals were found in 23% of our patients. Recanalization of the occluded artery was achieved in 112 (99.1%) patients.

The flow was completely restored (TICI 3) in 60 (53.1%) occluded arteries. In additional 52 (459 %) patients, the flow was partially restored (TICI 2a in 2b): TICI 2a in 8 (7%) and 2b in 44 (38.9 %) patients. In one patient (0.9 %), TICI 1 flow was restored. No patient presented was with TICI 0. Successful recanalization (defined as TICI 2b and 3) was achieved in 104 (92%) patients.

CTP ASPECT mismatch was detected in 79.6% of patients. Solitaire AB (ev3, Irvine, CA, USA) was used as a stent retriever in 28.3% of patients. Trevo (Stryker Neurovascular, Fremont, CA, USA) was used in 37.2% of our cases, while the catch thrombectomy device (Balt, Montmorency, France) was used in 18.6% of patients.

Table 1. Demographic and clinical characteristics of the patients of the studied Cohort

	Patients
Age	62 ± 11.73
Female	58 (51.3)
HTN	61 (53.98)
DM	85 (75.2)
Dyslipidemia	85 (75.2)
IHD	67 (59.3)
AF	52 (46)
PVD	38 (33.6)
TIA	38 (33.6)
Initial NIHSS	16.7 ± 3.2
NIHSS score change	10.3 ± 3.8
24 post-NIHSS	6.4 ± 4.1
mRS	1.5 ± 1.7
Favorable outcome (mRS ≤ 2)	89 (78.8)
Mortality	13 (11.5)
Periprocedural complications	75 (66.3)
Symptomatic intracranial hemorrhage	5 (4.4)
Asymptomatic hemorrhage	24 (21.2)

HTN: hypertension, DM: diabetes mellitus, IHD: ischemic heart disease, AF: atrial fibrillation, PVD: peripheral vascular disease, TIA: transient ischemic attack, NIHSS: National Institutes of Health Stroke Scale, mRS: modified Rankin scale.

Table 2. Procedural and radiological characteristics of the study patients

Occluded artery	Patients
MCA-M1	33 (29.2)
Carotid-T	17 (15)
Total carotid	27 (23.9)
Basilar	21 (18.6)
PCA-P2	2 (1.7)
MCA-M2	12 (10.6)
ACA	1 (0.9)
Collaterals	
No	4 (3.5)
Some	12 (10.6)
Most	71 (62.8)
All	26 (23)
TICI	
1	1 (0.9)
2a	8 (7)
2b	44 (38.9)
3	60 (53.1)
CTP ASPECT mismatch	90 (79.6)
Stent type	
Trevo	42 (37.2)
Solitaire	32 (28.3)
2 Stents	18 (15.9)
Catch +	21 (18.6)
Bridging	71 (62.8)
Adjunctive method	
None	11 (9.7)
rTPA	8 (7)
Single aspiration	19 (16.8)
Double aspiration	71 (62.8)
rTPA Plus double aspiration	4 (3.5)
Puncture to recanalization time	85.88 ± 25.33
Onset to puncture time	208.55 ± 53.49

MCA: middle cerebral artery, PCA: posterior cerebral artery, ACA: anterior cerebral artery, CTP: computed tomography perfusion, ASPECT: Alberta stroke program early CT score, TICI: thrombolysis in cerebral infarction.

Adjunctive methods during MT in the form of rt-PA, single aspiration, double Aspiration, or rt-PA plus double aspiration were used in 90.3% of cases. Puncture to recanalization time was 85.88 ± 25.33 min, while the onset to puncture time was 208.55 ± 53.49 min.

Discussion

Egypt is the most populous nation in the Middle East and North Africa countries and the second most populated in the African continent, with 92.75 million people as an estimate. The country is considered by the WHO as a lower middle-income country with an overall expenditure on health per capita of $309 (4.9% of gross domestic product) [14]. Although no active national registry national or triage system for stroke in Egypt exists, there are only small community-based studies on stroke prevalence and incidence. If the incidence and prevalence rates reported in these limited local data can be generalized, then the number of new onset strokes in Egypt per year may be around 1,50,000–2,10,000 with a crude prevalence rate of 963/1,00,000 inhabitants [34]. Timely recanalization is a proven prognosticator of good outcome in AIS. It was the intent of our study to present our initial experience with intracranial stent retriever devices on a cohort of acute stroke patients undergoing endovascular therapy accepted during a 3- to 8-hour endovascular treatment window. Five-year results of primary mechanical recanalization in patients with AIS were analyzed in this study. During this five-year period, 113 patients were managed with primary MT. Recanalization procedures in our stroke patients significantly increased in the last two years of our study (≃2-fold), as reported in other studies [14].

Five recently published RCTs (MR CLEAN [16], ESCAPE [17], EXTEND-1A [18], SWIFT PRIME [19], and REVASCAT [20]) have proved the vusefulness of endovascular AIS treatment in six hours timeframe for LVO stroke without delaying administration of IV-rTPA if accessible. In our cohort, we used second-generation MT devices (stent retrievers), which were predominantly used among those trials, as a primary option for recanalization of LVO within three hours in a group of patients. Unlike previous reports (IMS III [21] and MR RESCUE [22]), where almost exclusively IA recombinant tissue plasminogen activator (rt-PA) and first-generation devices had been used, successful recanalization rates as high as 99.1% (versus 25–41%) were obtained [23]. It corresponds well with our data of 92% patients with TICI scale 2b/3 scores. The recanalization rates in our study are comparable with Roth *et al*. [24] who reported a successful TICI 2b/3 revascularization rate of 90.2% (20/22) in 22 consecutive patients with acute cerebral artery occlusions using the Solitaire. Our study group

was heterogeneous including 23 (20.4%) posterior, apart from 90 (79.6%) anterior circulation occlusion cases with successful recanalization (TICI 3 or 2b) obtained in 100% of cases with posterior circulation stroke. In agreement with our results, a series of 14 acute BAOs treated with the Solitaire FR, successful recanalization (TICI 3 or 2b) was obtained in 100% (TICI 3 in 78.6%, 11/14) of patients, with a mean of 1.3 passes [25]. These data suggest that mechanical stent retriever thrombectomy may be very effective in regaining vessel patency in the settings of posterior circulation occlusion.

Improvement of the neurological outcome is clearly observed. The mean NIHSS score after the procedure (6.4 ± 4.1) was highly significantly lower than the baseline NIHSS (16.7 ± 3.2) ($p < 0.0001$). Primary mechanical revascularization with thrombectomy is an important factor that has contributed to our favorable clinical outcome.

Favorable clinical outcome (mRS ≤2) at three months was found in 89 of 113 (78.8%) cases. Our results showed more functionally independent cases when compared with the endovascular arm of MR CLEAN study (33%) or a series done by Wiącek *et al*. [26] (39.5%). A meta-analysis done by Campbell *et al*. [27] that pooled data from four recent RCTs predominantly using Solitaire device, higher proportion (54%) of patients in the treatment arm was observed to be functionally independent (mRS 0–2). While our data are satisfying compared with EXTEND-1A, it obtained the highest rate. Our favorable clinical outcome results can be attributed to our specific pretreatment patient selection based on CTP or ASPECTS score, which led to treatment of subjects with initial good prognosis, most importantly achievement of the higher rate of documented recanalization. Moreover, there was modest mean time from stroke onset to arterial access (208.55 ± 53.49 min) and mean procedure length (85.88 ± 25.33 min), which is also worth noting. This sheds light on the importance of time to reperfusion, being a known important predictor for a good clinical outcome [28,29].

In our cohort, mortality during three months was 11.5% ($n = 13$), and was lower than detected in the intervention arm of MR CLEAN study (21%). However, in comparison (median age 63 vs. 68, interquartile range 53–70 vs. 55–76), our cohort could have had initial better prognosis [30]. There was no statistically significant difference in mortality among subjects evaluated 0–2a compared with 2b–3 at the post-treatment TICI score assessment ($p = 0.045$, Fisher's exact test), differently from a case series done by Wiącek *et al*. [26] who observed a significantly higher mortality in the same subjects (53.9% vs. 16.7%, $p = 0.02$, Fisher's exact test). Our mortality rate (11.5%) is also lower than the overall mortality rate (27.9%) of the above-mentioned series done by Wiącek *et al*. [26].

The efficacy of MT shown in MR CLEAN study was demonstrated to be time dependent in subsequent report [31]. There was no statistically significant treatment benefit when time to reperfusion exceeded six hours and 19 min. Based on this and other [32] reports, recommendation of treating within six hours of symptom onset was proposed in current guidelines [23]. In our cohort, time to puncture (208.55 ± 53.49) did not exceed four hours and 35 min (under six hours). This factor can explain our high favorable clinical outcomes with higher rates of functional independence (mRS ≤2) at three months, improvement of the early neurological outcome as well as lower mortality rates (11.5%). Benefit from MT conducted after six hours of stroke onset still needs further study [23].

Overall complication rate in our series was 30% ($n = 34$). We detected sICH in 4.4% ($n = 5$) of cases, which is consistent with 5.7% shown in the MT meta-analysis by Badhiwala *et al*. [33]. Lower sICH rate (2.5%) was observed by Campbell *et al*. [18] in Solitaire thrombectomy meta-analysis. The fact that all procedures were performed by a single skilled interventional neurologist (O.M.) has made a major contribution to our modest incidence of procedural complications. The incidence is comparable with the rates reported in [15]. This retrospective study provides single-center experience of primary MT with the stent retriever devices. Results from this study are consistent with the evidence from recently published RCTs, confirming the efficacy and safety of this method in AIS treatment [16–20]; however, to our knowledge it is the first to study the safety and efficacy of Primary MT in AIS treatment within a 3-hour time onset. Postprocedural time is also crucial for the best possible clinical outcome as well as close monitoring for 24 hours in our neurointensive care unit postoperatively. The primary limitation of this study is the only use of stent retriever devices, which proved to be more efficient in reducing time to recanalization. Although a relatively small number study that does not permit to draw adequate conclusions, it rather confirms data from large RCTs in the clinical settings. In addition, it has no a randomized, controlled design; therefore, it has the limitations of case series methodology. Furthermore, a prospective study is required with a larger group of patients.

Conclusion

Primary MT for the treatment of acute LVO provides high rate of recanalization and favorable clinical out-

come with low procedural complications. Our single-center experience could provide valuable information in implementing the infrastructure of stroke care network regarding the effectiveness and safety of the procedure for intracranial LVO subset of acute stroke patients. Furthermore, multicenter studies with a randomized and prospective design will be necessary to verify the results.

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