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Short Communication

Mechanical thrombectomy in patients with stroke due to large vessel occlusion in the anterior circulation and low baseline NIHSS score

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We sought to verify the benefit of mechanical thrombectomy in patients with acute ischemic stroke due to large vessel occlusion in the anterior circulation and low National Institute of Health stroke scale score at presentation. The prospective database of our stroke center was screened for patients with acute ischemic stroke due to large vessel occlusion and a baseline National Institute of Health stroke scale score $\leq$5 that had undergone mechanical thrombectomy. Outcome measures were the modified Rankin Scale (mRS) score at 90 days, brain bleeding events and death at 90 days. Out of 459 patients, 17 (12 females, mean age 70 $\pm$ 14 years) with occlusion of M1 or M2 segment of middle cerebral artery and baseline National Institute of Health stroke scale score $\leq$5 underwent mechanical thrombectomy. Eight patients (47%) were treated within 6 hours from the onset, 5 (29%) were treated beyond 6 hours, and 4 (24%) were wake-up strokes. Effective mechanical thrombectomy was achieved in 16 patients (94%) and associated with excellent functional outcomes at 3 months (mRS 0–1) in 13 (76%). The asymptomatic brain-bleeding event was observed in one patient 4 days after effective mechanical thrombectomy concerning safety issues. One patient died 1 month after mechanical thrombectomy of a cause unrelated to stroke. Our findings favor a potential benefit of mechanical thrombectomy in patients with stroke due to large vessel occlusion and low National Institute of Health stroke scale score at presentation. These patients may also benefit from a prolonged time window for treatment.

Keywords

Acute ischemic stroke; Large vessel occlusion; National Institute of Health Stroke Scale; Mechanical thrombectomy

1. Introduction

Results from randomized trials have shown the superiority of mechanical thrombectomy (MT) over medical treatment (including intravenous thrombolysis—IVT) in patients with acute ischemic stroke (AIS) due to large vessel occlusion (LVO) [1–6]. Current guidelines recommend MT in AIS with causative occlusion of the internal carotid artery (ICA) or middle cerebral artery (MCA), a baseline National Institute of Health Stroke Scale (NIHSS) score of $\geq$6 and within 6 hours from onset of symptoms [7]. On the contrary, the benefit of MT in patients with AIS due to LVO in the anterior circulation and mild neurological symptoms at presentation (NIHSS score $\leq$5) remains unclear [8–12]. This issue is of particular interest as these patients may face later neurological deterioration that can limit the benefit of any subsequent recanalization treatment with the possible poor long-term functional outcome [12–14]. Here we present a retrospective and descriptive analysis of a case series of patients with AIS due to LVO and mild symptoms at presentation subjected to MT in our high-volume tertiary stroke center. We report data on the occlusion location, collateral status, time between the onset of symptoms and MT, recanalization rates, clinical outcome, procedural complications and safety measures.

2. Methods

In this observational retrospective study, we screened the prospective database of our high-volume tertiary stroke center for patients with AIS due to LVO that had undergone MT from 1 June 2016 to 30 June 2020. All patients were diagnosed with a comprehensive head and neck CT protocol that included a basal scan with determination of the Alberta Stroke Program Early CT (ASPECT) score [15] followed by multiphase CT angiography to define the site of occlusion and calculate the pial arterial filling score [16]. In addition, a CT perfusion protocol was also performed in patients with AIS in the anterior circulation admitted beyond 6 hours from

the onset or with unknown time of onset (wake-up strokes) to determine eligibility to MT in accordance with the advanced neuroimaging criteria [17–19]. Patients with an occlusion site other than the MCA, segment M1 or M2, or a pre-event modified Rankin Scale (mRS) score >1 were excluded. Of the remaining patients, those with an NIHSS score ≤5 at the groin puncture time were selected. A flow diagram of patient selection is provided in Fig. 1.

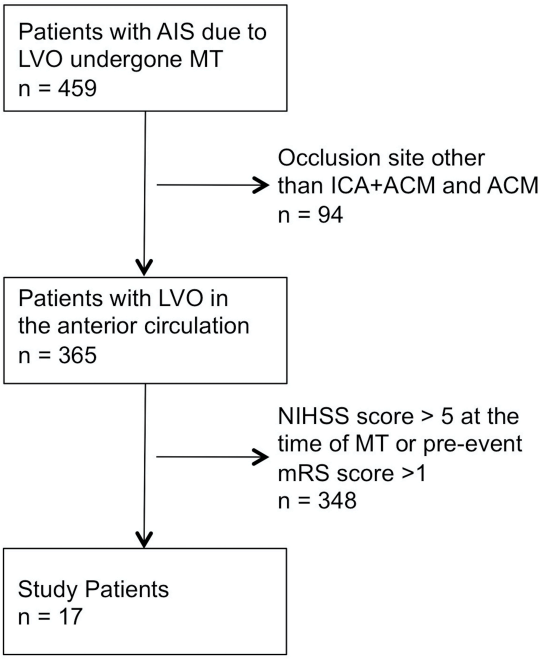

Fig. 1. Flow chart of the patient inclusion criteria.

When applicable, administration of intravenous tissue plasminogen activator (tPA) was performed before MT according to standard protocols and at the discretion of the treating physicians. An endovascular treatment option aimed to re-establish the occluded vessel's patency and avoid possible clinical deterioration had appropriately been discussed with each eligible patient and/or family member. Flow restoration at the end of each procedure was graded using the modified Treatment In Cerebral Infarction (mTICI) scale [20]. Clinical outcome was measured through the mRS score at 90 days. Two expert neuroradiologists reviewed all baseline CTs, multiphase CTAs and angiographic data, blinded to clinical outcome. Safety data were (1) brain bleeding events following reperfusion therapies, assessed by CT or MRI scan after 24–96 hours and defined according to the Heidelberg Bleeding Classification [21], and (2) death within 90 days after stroke.

3. Results

Out of 459 patients, 17 (12 females, mean age 70 ± 14 years) with occlusion of M1 or M2 segment of MCA and NIHSS score ≤5 at presentation underwent MT. The median [IQR] baseline NIHSS score was 3 [2–5]. The Median [IQR] ASPECT score was 9 [9–10]. The Median [IQR] pial arterial filling score was 5 [4–5], meaning good collateral [16]. IVT preceded MT in 2 patients. Eight patients (47%) were treated within the 6-hour time window, 5 (29%) were treated beyond 6 hours from the onset, whereas 4 (24%) were wake-up strokes. MT was conducted under general anesthesia or mild sedation, and the treatment strategy (stent-retriever versus thromboaspiration or a combination of both) was at the discretion of the neuro interventionist. Successful recanalization (mTICI score 2b–3) was achieved in 16 patients (94%), whereas only one had an mTICI score of 0. No procedural complications were recorded. A representative case is shown in Fig. 2. Effective MT was associated with excellent functional outcomes at 3 months (mRS 0–1) in 13 patients (76%). One patient in whom MT was ineffective (mTICI score = 0) experienced early neurological worsening (≥4 NIHSS points increase from baseline) and had a significant disability at 3 months (mRS score = 4). Concerning safety issues, an asymptomatic brain-bleeding event in the form of parenchymal hematoma type-2 was observed in one patient 4 days after effective MT and led to a poor long-term clinical outcome (mRS score = 5). One patient died 1 month after MT of acute coronary syndrome. Relevant demographic, baseline clinical and imaging data and outcome measures are reported in Table 1 (Ref. [15]).

4. Discussion

The appropriateness of MT in patients with AIS due to LVO and a low NIHSS score at presentation is currently debated since conclusive evidence is still ahead to be clarified. Indeed, the limited number of randomized patients with a low baseline NIHSS score in the main MT trials has hampered the possibility of addressing this issue [22]. Skepticism may arise from the risks of an invasive procedure not being counterbalanced by the possible benefits in patients presenting with a so-called 'minor stroke'. However, the definition of 'minor' stroke may vary considerably. It cannot simply be based on an NIHSS score cutoff value without considering the type of symptoms (disabling or non-disabling) and the association with a long-term effect favorable outcome [23]. Following this consideration, setting an NIHSS score threshold for MT eligibility may also appear arbitrary. Nonetheless, current guidelines recommend MT in patients with a baseline NIHSS score ≥6, an ASPECT score ≥6 and a pre-stroke mRS score of 0–1 [7, 24]. On the other hand, MT is considered reasonable only in patients with a baseline NIHSS score ≤5 but who have a pre-stroke mRS score >1, a causative occlusion of ICA or proximal MCA (M1 segment), and ASPECT score <6 and in whom treatment can be initiated within 6 hours from onset (class IIb recommendation) [7].

However, to date, a growing body of evidence is available on the feasibility of MT in patients with stroke due to LVO and a low NIHSS score away from the criteria mentioned above. In real-world practice, such an option is usu-

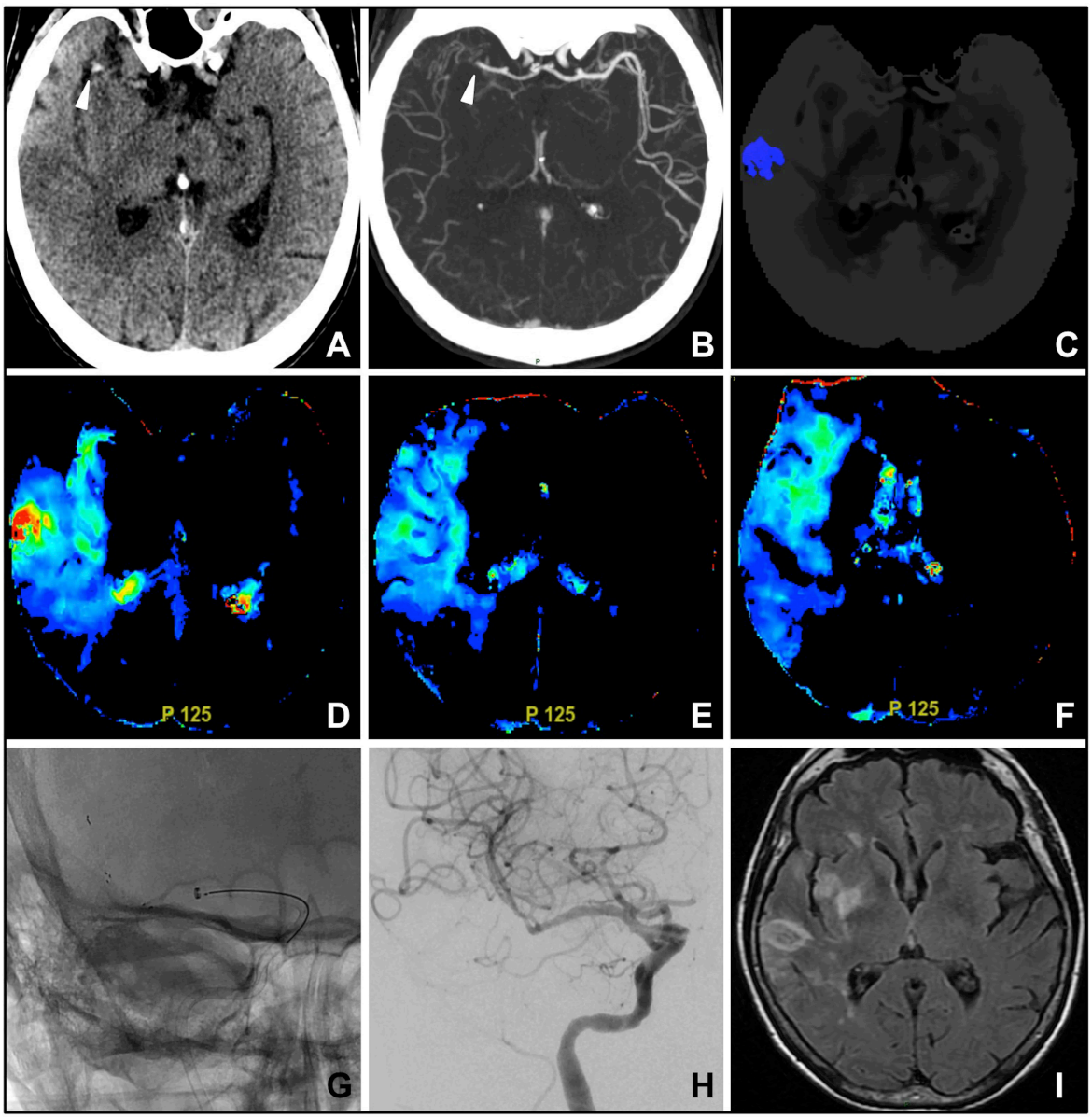

Fig. 2. Representative cases. Axial non-contrast CT image (A) showing a hyperdense vessel sign (arrowhead) and a small core of infarction in the right temporal lobe. The CTA (B) shows the M1 segment (arrowhead) occlusion and prominent collateral circulation. The $T_{max16s-25s}$ map confirms the small temporal lobe core of infarction (C), while the $T_{max9.5s-25s}$ maps. (D–F) show the extended area of ischemic penumbra in the fronto-insular and temporal lobes. Mechanical thrombectomy using a combination of stent-retriever and a 6F distal aspiration catheter (G) leads to complete recanalization of the vessel (H). The follow-up RMN study shows the pre-treatment temporal ischemic core and two small not-symptomatic new ischemic lesions in the right insula and caudate nucleus (I).

ally considered after careful evaluation of case-by-case clinical and radiological features and assessing risks and benefits. This comes along also with the increasing expertise of interventionists on MT and a better safety profile of the last-generation thrombectomy devices [25].

Here we report the experience of our high-volume stroke center on MT in patients with anterior circulation AIS and a baseline NIHSS to score $\leq$5, showing a high rate of effective recanalization and excellent neurological outcome at 3 months. Our results are in line with the evidence that MT has a beneficial effect on clinical outcomes across the entire baseline NIHSS severity range, with no substantial deviation from more comprehensive studies concerning safety issues [22].

Endovascular treatment in patients with AIS due to LVO in the anterior circulation and mild neurological symptoms is of particular interest as they constitute a variable, but not negligible, percentage of total patients [8–12]. Despite LVO, in these patients, lack of symptoms is sustained by deploying a robust leptomeningeal collateral network [26], as confirmed in our cohort of patients with a median pial arterial filling score showing overall good collaterally. As these pa-

Table 1. Summary of demographic, clinical, imaging and procedural data.

Sex (females/ total patients)	12/17
Mean age, years ± SD	70 ± 14
Median NIHSS score at the time of groin puncture [IQR]	3 [2–5]
Median ASPECT score at admission [IQR]	9 [9–10]
Site of arterial occlusion	
MCA, M1 segment, patients/total (%)	10/17 (56%)
MCA, M2 segment, patients/total (%)	7/17 (44%)
Median pial arterial filling score [IQR]	5 [4–5]
Intravenous thrombolysis, patients/total (%)	2/17 (12%)
Onset-to-groin time	
Onset-to-groin time ≤6 hours, patients/total (%)	8/17 (47%)
Median onset-to-groin time [IQR] minutes	222 [202–240]
Onset-to-groin time >6 hours, patients/total (%)	5/17 (29%)
Median onset-to-groin time [IQR] minutes	565 [440–840]
Unknown onset-to-groin time (wake-up stroke), patients/total (%)	4/17 (24%)
mTICI score 2b–3, patients/total (%)	16/17 (94%)
3-month mRS score 0–1, patients/total (%)	13/17 (76%)
Brain-bleeding events	
Asymptomatic hemorrhagic transformation*, patients/total (%)	2/17 (12%)
Symptomatic parenchymal hematoma type-2*, patients/total (%)	1/17 (6%)
Death at 3 months, patients/total (%)	1/17 (6%)

SD, standard deviation; IQR, interquartile range; NIHSS, National Institute of Health Stroke Scale; ASPECT, Alberta Stroke Program Early CT score; MCA, middle cerebral artery; mTICI, modified treatment in cerebral infarction; mRS, modified Rankin Scale; * defined according to von Kummer and Colleagues [15].

tients have higher odds of not receiving MT, they possibly face worsening their clinical condition upon failure of the leptomeningeal network [12]. In a recent single-center retrospective study, an unfavorable clinical evolution was documented in a fifth of patients with stroke due to LVO and mild symptoms that could be limited by rescue MT [12]. The potential benefit of MT has been proposed in a retrospective study also when performed before neurological deterioration. Indeed, MT in patients with baseline NIHSS scores ≤5 resulted in a higher rate of patients with functional independence (mRS score 0–2) at 90 days than patients initially undergoing best medical therapy and eventually receiving MT upon neurological worsening. In addition, no significant issues regarding safety were reported [27]. Conceptually similar results have been described in other exploratory and intention-to-treat analyses [11, 28–30]. Following this line of evidence, it has been proposed that MT can be considered in patients with an NIHSS score ≤5 but with disabling symptoms, using specific care to keep hemorrhagic rates below those reported in randomized clinical trials [31].

On the other hand, a recent multicenter retrospective study has failed to demonstrate significant differences in terms of functional outcome between MT and best medical therapy (including IVT) in patients with a baseline NIHSS score ≤5, regardless of the site of occlusion (internal carotid artery and M1 segment vs. M2 segment) and degree of stroke severity at admission (NIHSS score 0–3 vs. 4–5) [8]. In another retrospective, observational study, intended bridging therapy with IVT followed by MT was not superior in terms of clinical outcome compared to IVT alone. It was associated with higher odds of both symptomatic and asymptomatic intracranial bleeding events. However, when the study population was analyzed based on occlusion, bridging therapy resulted in significantly higher-excellent neurological outcomes in patients with proximal occlusion (ICA and MCA/M1 segment) than IVT alone [32].

Given that the persistence of a minimal neurological impairment in patients with LVO is due to the recruitment of efficient leptomeningeal collaterals, these patients may also benefit from a prolonged time window for MT [11, 12, 17, 19, 26, 27, 33] as they can maintain a small ischemic core and a significant amount of salvageable brain tissue beyond 6 hours from onset (the so-called "slow progressors") [34, 35]. Indeed, in our series, 9 out of 17 patients (53%) were treated beyond the initial 6 hours from onset. The sum of these observations also underlines the relevance of extending a multimodal vessel imaging protocol to all patients with AIS despite their baseline NIHSS score. Indeed, although an NIHSS score threshold can be set to yield a high sensitivity for detecting LVO, this diagnostic approach would inevitably miss a relevant number of patients harboring a large area of at-risk tissue and who would be otherwise good candidates for MT [36].

The main limitations of our report derive from being a retrospective observational study. The results should be viewed as preliminary from the small sample size and to be

used with caution in real-world clinical practice. In consideration of the sparse evidence available to date, it is expected that open randomized controlled trials, such as the MOSTE (MinOr Stroke Therapy Evaluation) study of the IN EXTREMIS trial (https://www.inextremis-study.com), will clarify whether MT is beneficial also in patients with LVO and a low baseline NIHSS score.

5. Conclusions

The efficacy of MT in patients with AIS due to LVO and low NIHSS score at presentation has been insufficiently studied in the main randomized clinical trials. Our findings favor a potential benefit of MT also in this category of patients. Nonetheless, this issue still remains open for clarification and the need for an unambiguous recommendation in clinical practice is urgent.

Abbreviations

MT, mechanical thrombectomy; IVT, intravenous thrombolysis; AIS, acute ischemic stroke; LVO, large vessel occlusion; ICA, internal carotid artery; MCA, middle cerebral artery; NIHSS, National Institute of Health Stroke Scale; ASPECT, Alberta Stroke Program Early CT; mRS, modified Rankin scale; tPA, tissue plasminogen activator; mTICI, modified Treatment In Cerebral Infarction; IQR, interquartile range.

Author contributions

AMA, IV and AB conceived and designed the experiments; GF, RM, FD, DG, ABA, RG, CR and LS performed the treatments; FC, GFR and AMA analyzed the data; PC, GDM and AP supervised the study. AMA and AB wrote the paper.

Ethics approval and consent to participate

This work is part of a nonprofit study protocol approved by Fondazione Policlinico Universitario A. Gemelli IRCCS, Roma, Institutional Ethics Committee: protocol number 6410/20, ID 3004. Informed consent for participation in the study was obtained in patients who were neurologically able to give it; for the other patients, the informed consent was obtained from a legal representative.

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Conflict of interest

The authors declare no conflict of interest.

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