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Original research article

Single-center experience of stent retriever thrombectomy in acute ischemic stroke

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ARTICLE INFO

Article history:
Received 31 May 2016
Accepted 14 September 2016
Available online 23 September 2016

Keywords:
Ischemic stroke
Endovascular treatment
Mechanical thrombectomy
Stent retriever device
Intra-arterial thrombolysis

ABSTRACT

Background and purpose: Recently, positive data from several randomized controlled trials (RCTs) of endovascular therapy for acute ischemic stroke (AIS) has emerged. The aim of this retrospective study is to present our clinical experience in cerebral vessel occlusion treatment using retrievable intracranial stents.

Methods: Forty-three consecutive patients with ischemic stroke (median age 75, range 22–87) treated by stent retriever thrombectomy (Solitaire™ FR) between January 2013 and December 2015 were identified. We retrospectively assessed Thrombolysis in Cerebral Infarction (TICI) scale (2b–3 considered as successful recanalization), clinical outcome using modified Rankin scale (mRs) at 3 months (regarding score 0–2 as good clinical outcome), device-related complications and symptomatic intracranial hemorrhage (sICH; parenchymal hematoma Type 1 or 2 and National Institutes of Health Stroke Scale [NIHSS] score increment ≥4 points) rate.

Results: The mean NIHSS score on admission was 16.4 (median 16). The mean time from onset to groin puncture (time to treatment) was 290 min (median 254 min). Successful recanalization was achieved in 30 (69.8%) cases. The mean time from onset to successful reperfusion or procedure termination (time to reperfusion) was 394 min (median 375 min). Good outcome was observed in 17 (39.5%) patients and mortality was 27.9% ($n = 12$). We found 2 (4,7%) sICHs, one (2,3%) thromboembolic event in different vascular territory and one (2,3%) groin hematoma.

Conclusion: Stent retriever thrombectomy for the treatment of ischemic stroke is safe, provides high rate of recanalization and good clinical outcomes in the setting of large vessel occlusion.

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Abbreviations: AIS, acute ischemic stroke; rt-PA, recombinant tissue plasminogen activator; NIHSS, National Institutes of Health Stroke Scale; mRS, modified Rankin scale; EVT, endovascular treatment; DSA, digital subtraction angiography; TICI, thrombolysis in cerebral infarction; LVO, large vessel occlusion; IVT, intravenous thrombolysis; RCTs, randomized controlled trials; sICH, symptomatic intracranial hemorrhage.

http://dx.doi.org/10.1016/j.pjnns.2016.09.001
0028-3843/

1. Introduction

The main goal of therapy in acute ischemic stroke (AIS) is based on the ''flow-restoration hypothesis''. It assumes that reopening (recanalization) of the occluded artery and recovering blood flow (reperfusion) prevents salvageable brain tissue from irreversible damage (infarction). Confirmingly, recanalization is strongly associated with improved functional outcomes and reduced mortality [1]. Current standard treatment method, aiming at restoration of cerebral blood flow, is intravenous thrombolysis (IVT) with recombinant tissue plasminogen activator (rt-PA). It has been proven to provide significant beneficial effect [2]. However, intravenous rt-PA use is limited by narrow therapeutic time window (<4.5 h) and several important contraindications (i.e., coagulopathy, recent major surgery, active bleeding). Furthermore, acute recanalization rates in patients with large vessel occlusion (LVO) of the main cerebral artery treated by IVT are as low as 20% [3,4]. Only 10–15% of internal carotid artery (ICA) and 30–50% of proximal medial cerebral artery (MCA) occlusions recanalize, which corresponds with poor clinical outcomes [5–7]. What's important LVO is responsible for approximately one-third to one-half of AIS [8]. Ultimately, there is a significant proportion of patients that are either ineligible or relatively resistant to systemic thrombolysis.

Constraints in IVT use have led to investigation of other revascularization methods. Over the past years endovascular treatment (EVT), comprising of intra-arterial rt-PA delivery and mechanical clot-retraction, continued to rapidly evolve. In early randomized controlled trials (RCTs) it provided higher recanalization rates, although failed to show superiority over standard medical treatment [5,9,10]. Several limitations of those trials have been widely described, such as no pre-procedural vascular imaging selection, older generation devices used or significant time to treatment delay [11]. More recently, various RCTs proved remarkable clinical outcomes improvement among patients treated with EVT comparing to standard treatment. Newer devices, i.e., stent retrievers, predominantly used among those trials, presented even greater recanalization rates and minimized procedure duration [12–16]. Gathering of data from conducted RCTs has led to development of clinical guidelines with highest-level of evidence recommendations in Europe [17] and United States [18].

The purpose of our study is to present our clinical experience in endovascular treatment of acute ischemic stroke using stent retriever devices. The use of this treatment method is limited in Poland owing to shortage of endovascular treatment facilities and lack of state funding. Local literature on this topic is insufficient as well [19]. Our effort is to fill this information gap.

2. Materials and methods

2.1. Patients

Between January 2013 and December 2015 1,342 patients were diagnosed with AIS at our Stroke Unit (Department of Neurology, Clinical Voividship Hospital No. 2, Rzeszów, Poland). Two hundred eighty-two (21.3%) were treated with IVT. Fifty-four (4%) had an LVO proved by CT angiography and was qualified for EVT (Table 1). Among those, there were two cases of recanalization after IVT shown by pre-procedural digital subtraction angiography (DSA) and in the other two we failed to catheterize the aimed vessel due to anatomical difficulties. Seven patients had intra-arterial rt-PA administered as the only method of endovascular treatment. Therefore, in this study we retrospectively reviewed the records of forty-three consecutive patients (median age 75, range 22–87) treated with stent retriever thrombectomy. All procedures was conducted with the Solitaire FR device. In 38 (88%) cases it was used as the only technique and the other 5 (12%) had additional intra-arterial rt-PA applied. Only one (2.3%) patient was transported from another hospital to perform endovascular procedure at our Department.

Table 1 – Interventions among 1,342 patients with AIS treated at our Department.

AIS (n = 1342)	n (%)
IVT	287 (21.3)
Patients initially qualified for EVT[a]	54 (4)
Intra-arterial rt-PA only	7 (0,5)
Mechanical thrombectomy only	38 (2.8)
Intra-arterial rt-PA + mechanical thrombectomy	5 (0.4)

[a] Explanation in text.
Abbreviations: *AIS*, acute ischemic stroke; *IVT*, intravenous thrombolysis; *rt-PA*, recombinant tissue plasminogen activator.

2.2. Procedure

All subjects had initial non-contrast CT imaging and clinical evaluation by neurologist as part of our standard algorithm and, if eligible, had IVT administered (n = 28; 65%). Noninvasive vascular imaging by CT angiography was performed in each case. When LVO (occlusion of internal carotid artery [ICA] terminus, first segment of middle cerebral artery [MCA-M1], second segment of middle cerebral artery [MCA-M2], basilar artery [BA], posterior cerebral artery [PCA], vertebral artery [VA]) was confirmed, further inclusion and exclusion criteria were assessed (Tables 2 and 3). Exceptions from the predefined criteria were allowed at the discretion of endovascular treatment team (experienced vascular neurologist and neuroradiologist).

Two (4.7%) patients had EVT conducted despite mild neurological deficit measured by National Institutes of Health Stroke Scale (NIHSS score <6) and one (2.3%) was functionally dependent before stroke onset (modified Rankin scale [mRS] score 3) due to prior lower limb amputation. In a single case (2.3%) MCA-M3 occlusion was the aim of treatment. Once (2.3%) EVT was proceeded after performing emergency cesarean section in a woman at 35 weeks gestation. In each particular subject risk in relation to potential benefit were carefully evaluated.

Twenty-seven (62.8%) procedures were performed under general anesthesia. In patients with anterior circulation occlusion we used 8F sheath introducer (Super Arrow-Flex; Teleflex, Limerick, Pennsylvania) and 8F balloon catheter

Table 2 – Inclusion criteria for the mechanical thrombectomy.

Inclusion criteria	Patients treated without meeting criterion *n* (%)
The clinical diagnosis of acute ischemic stroke (exclusion of cerebral hemorrhage on CT scan)	
Age ≥18	
NIHSS ≥6	2 (4.7%)
Capability to start treatment before 8 h (or 15 h for posterior circulation occlusion) from onset of symptoms	
Angio-CT confirmed large vessel occlusion (terminal ICA, MCA-M1, MCA-M2, VA, BA, PCA)	1 (2.3%)
No improvement or exclusion from systemic thrombolysis	
mRS ≤2 before treatment	1 (2.3%)
Consent to treatment	

Table 3 – Exclusion criteria for the mechanical thrombectomy.

Exclusion criteria
Glucose <50 mg% or >400 mg%
Hemorrhagic diathesis or coagulation factors deficit
International Normalized Ratio (INR) >3
The use of heparin within 48 h before treatment and Activated Partial Thromboplastin Time (APTT) prolonged more than twice the upper laboratory limit
Thrombocytopenia < 30,000/mm^3
Radiological evidence of significant mass effect with the midline shift or ischemic injury involving more than one third of the MCA territory
Concomitant myocardial infarction or severe infection (sepsis, infectious endocarditis)
A history of stroke within previous 30 days
Systolic >185 mmHg and diastolic blood pressure >110 mmHg despite intensive treatment
Pregnancy[a]
History of radiographic agents allergic reaction
Predicted life expectancy ≤3 months for the reason other than current stroke

[a] One (2.3%) patient was treated despite being pregnant at the stroke onset.

(Cello balloon guide catheter; Fuji Systems Corp., Tokyo. Japan) to gain ICA access. Microcatheter (Rebar 18 or 027, Covidien, Irvine, California, USA) was then advanced for the Solitaire 2 FR device (size 4 mm × 30 mm, 4 mm × 20 mm or 4 mm × 15 mm) over a hydrophilic guidewire (X-pedion 10 or 14, Covidien, Irvine, California, USA) to cross the thrombus. After contrast injection, clot length and vessel diameter were assessed to introduce adequately sized Solitaire stent. The device was unsheathed partially within, partially distal to the thrombus and held in position for 5 min. Angiographic run was then performed to determine revascularization status. Before system removal, balloon catheter was inflated at the level of upper ICA. Suction was applied through the guide catheter during thrombus evacuation. The procedure was repeated until successful recanalization (TICI 2b, 3) or fifth device pass (predefined upper limit). When residual distal vessel occlusion was confirmed, further endovascular treatment was applied at the discretion of endovascular treatment team. In case of posterior circulation vessel occlusion ordinary guide catheter instead of balloon catheter was used.

We employed intra-arterial thrombolysis in case of technical difficulties due to vessel tortuosity, distal vessel occlusion (M2 or M3 portion of MCA) or mechanical clot removal failure. A follow-up CT scan between 24 and 36 h after procedure was performed in all cases.

2.3. *Imaging and clinical assessment*

Assessment of recanalization was based on Thrombolysis in Cerebral Infarction (TICI) score, with grades 2b and 3 regarded as being successful. We calculated time to treatment as the time between onset of symptoms to groin puncture. The time to reperfusion was defined as the time to successful reperfusion or the end of the procedure in cases for which it was not achieved.

Patients were evaluated applying NIHSS on admission, 24 h and 7 days after treatment. Subjects who died had no NIHSS score assigned and were not included in analyses of such scores. Functional outcomes at 3 months were determined during outpatient follow-up or by telephone interview with the patient, proxy or health care provider. The mRS score was used (≤2 considered as good clinical outcome). We investigated patients records in search for procedural complications, such as: vessel dissection or perforation, remote vascular territory embolization, groin hematoma and symptomatic intracranial hemorrhage (sICH; parenchymal hematoma Type 1 or parenchymal hematoma Type 2 with NIHSS score increment ≥4 points).

3. Results

Forty-three patients (median age 75, range 22–87) were diagnosed with AIS proved to be caused by intracranial LVO and were treated with stent retriever thrombectomy. Among those, 44 procedures were performed (in one case there was simultaneous anterior cerebral artery [ACA] and MCA occlusion). Twenty-eight (65.1%) subjects had prior IVT administered and 5 (11.6%) received additional intra-arterial rt-PA. The

Table 4 – Localization of vessel occlusions.

Location (*n* = 44)	*n* (%)
ICA terminus	6 (13.6)
M1	23 (52.3)
M2	7 (15.9)
M3	1 (2.3)
ACA	1 (2.3)
BA	4 (9.1)
PCA	2 (4.6)

Abbreviations: ICA, internal carotid artery; M1, first segment of middle cerebral artery; M2, second segment of middle cerebral artery; M3, third segment of middle cerebral artery; BA, basilar artery; PCA, posterior cerebral artery

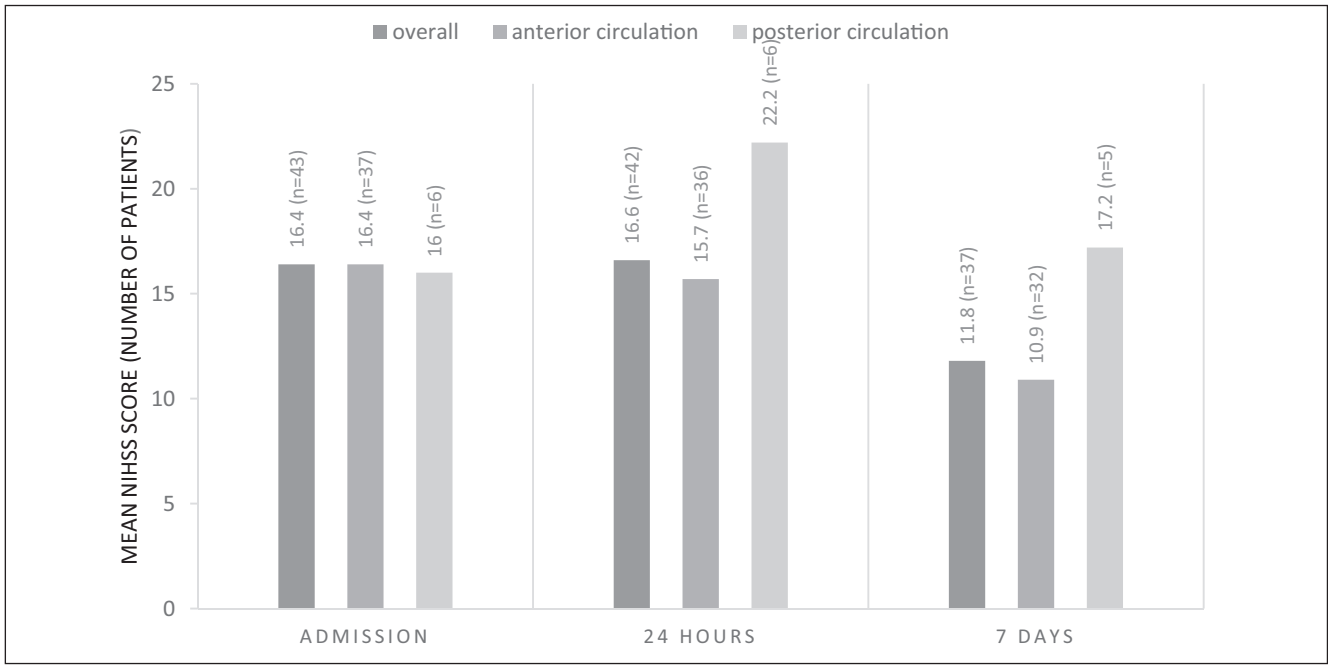

Fig. 1 – The mean NIHSS score at admission, 24 h and 7 days after treatment.

distribution of vessel occlusion localization is shown in Table 4. Thirty-seven patients had the pattern of anterior and six of posterior circulation obstruction. Early ischemic changes were found on the pretreatment CT scan in 16 (37.2%) cases.

The mean time to treatment was 290 min (range 120–885, median 254 min) and mean time to reperfusion equaled 394 min (range 170–1045, median 375 min). Successful recanalization was achieved in 30 (69.8%) cases. Eleven (25.6%) attempts failed to obtain recanalization (TICI 0). The mean duration of procedure was 103 min (range 35–215, median 95 min).

The mean values of NIHSS score on admission, at 24 h and 7 days of treatment are shown in the Fig. 1. One patient died before the 24-h and other seven before the seventh day evaluation. The mean NIHSS score assessed both at 24 h and seven days after treatment was higher in the posterior, than anterior circulation LVO subgroup (22.2 vs 15.7 and 17.2 vs 10.9, in the order given). On admission it was 16 and 16.4, respectively. The overall mortality at the discharge was 18.6% ($n = 8$).

At 3 months good clinical outcome (mRS ≤2) was achieved in 17 (39.5%) cases and mortality rate was 27.9% ($n = 12$). When comparing posterior to anterior circulation occlusion cohort, functional independence was achieved in 50% vs 37.8% and mortality in 33.3% vs 27% of patients, respectively. Distribution of mRS scores is shown in the Fig. 2.

We found 2 (4.7%) cases of sICH, one (2.3%) thromboembolic event in the other vascular territory (ACA embolization during MCA occlusion treatment) and one (2.3%) groin hematoma that did not require surgical intervention. The overall periprocedural complication rate was 9.3% ($n = 4$).

4. Discussion

Mechanical clot retrieval has lately become highest level of evidence-based method of AIS treatment in carefully selected

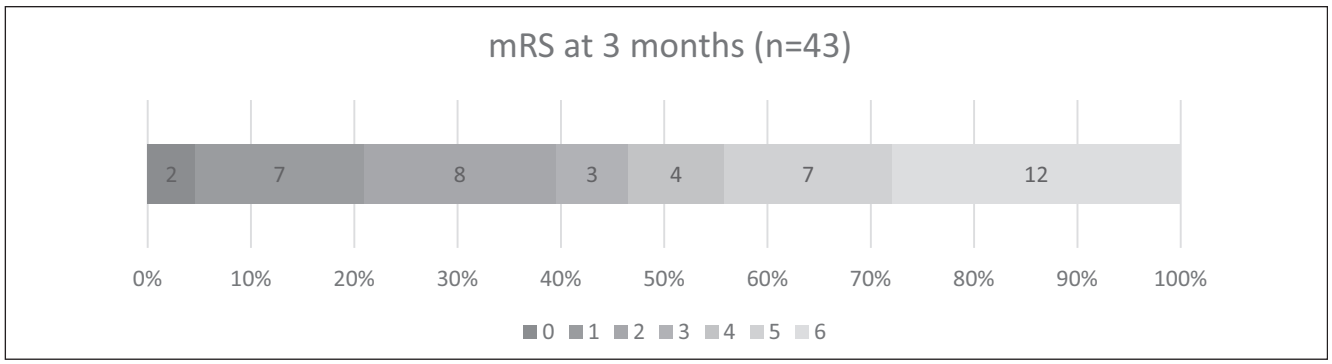

Fig. 2 – Distribution of mRS scores at 3 months after treatment.

patients with LVO [17,18]. Treatment of our cohort was, however, conducted before the European EVT guidelines emergence and the patient qualification process differed substantially from the currently recommended. Nonetheless, satisfying recanalization rates and clinical outcomes were achieved.

Five recently published RCTs (MR CLEAN [12], ESCAPE [13], EXTEND-1A [14], SWIFT PRIME [15], REVASCAT [16]) have proved benefits of endovascular AIS treatment in the setting of anterior circulation LVO. Similarly to our case series second-generation mechanical thrombectomy devices (stent retrievers) were predominantly used among those trials. In contrast to previous reports (IMS III [5] and MR RESCUE[9]), where almost exclusively intra-arterial rt-PA and first-generation devices had been employed, successful recanalization rates as high as 59% to 88% (vs 25% to 41%) were obtained [17]. It corresponds well with our results of 69.8% patients with TICI scale 2b/3 scores. Our cohort was, however, more heterogeneous including 6 (14%) posterior, apart from 37 (86%) anterior circulation occlusion cases. Those patients were a priori excluded from previously mentioned trials. Nonetheless, some evidence from single-center studies concerning posterior circulation LVO exists. It has shown recanalization rates over 75% following basilar artery thrombectomy using newer generation devices [20,21]. In this series, successful recanalization was achieved in 83% ($n = 5$) of patients with either BA or PCA occlusion. These data suggests that mechanical stent retriever thrombectomy may be very effective in regaining vessel patency in the settings of posterior circulation occlusion.

Good clinical outcomes (mRS ≤2) at 3 months was observed in 17 of 43 (39.5%) cases. These results are satisfying comparing to 33% in the endovascular arm of MR CLEAN study. However, when referring to the meta-analysis by Campbell et al. that pooled data from 4 recent RCTs predominantly using Solitaire device (ESCAPE, EXTEND-1A, SWIFT PRIME, REVASCAT), higher proportion (54%) of patients in the treatment arm was observed to be functionally independent (mRS 0–2) [22]. There are several features of our patient and procedural characteristics that might contribute to the difference in clinical results. Firstly, the prestroke function eligibility criterion was less strict (0–2 mRS) than in the ESCAPE, SWIFT PRIME and REVASCAT studies (0–1 mRS or Barthel score of >90–100), whereas EXTEND-1A, obtaining the highest rate (71%) of good clinical outcomes, allowed only 4.5-h treatment window. Besides, lower portion of our cohort had IVT conducted (65% vs 80.5%). We used no specific pretreatment patient selection based on CT perfusion or ASPECTS score (Alberta Score Program Early CT Score), which could led to treatment of subjects with initial worse prognosis. Moreover, there was longer median time from stroke onset to arterial access (254 vs 225 min). The higher median time to recanalization (375 vs 274 min), caused mainly by procedure length (median 95 vs 38) is also worth noting. The reasons for procedure elongation were mainly residual distal occlusion treatment and limited anesthesiologist availability.

The benefit of EVT shown in MR CLEAN study was demonstrated to be time dependent in subsequent report [23]. There was no statistically significant treatment effect when time to reperfusion exceeded 6 h and 19 min. Based on this and other [7,24] analyses, recommendation of treating as early as possible, until it can be initiated within 6 h of symptom onset, was proposed in current guidelines [17,18]. In this case series we managed to obtain time to reperfusion under 6 h in only 49% ($n = 21$) of patients. This subgroup shown trend to better outcomes with higher rates of functional independence (0–2 mRS) after 3 months (47,6% vs 31,8%, $p = 0.36$, Fisher's exact test) and lower mortality rates (13.6% vs 40.9%, $p = 0.09$) comparing to longer time to reperfusion cohort, although both failed to reach statistical significance. If there is a group of patients that could benefit from EVT conducted after 6 h of stroke onset still needs investigation [17].

In our EVT qualification protocol waiting period after IVT initiation was advocated to verify absence of early clinical improvement. Since reperfusion delay was confirmed to worsen clinical outcomes, new recommendation to abandon observation time and immediately proceed with mechanical thrombectomy appeared [17,18]. This treatment lag could influence our study results.

In this series mortality during 3-months observation equaled 27.9% ($n = 12$), and was higher than detected in the intervention arm of MR CLEAN study (21%). However, being older (median age 75 vs 68, interquartile range 61–80 vs 55–76), our cohort could have had initial poorer prognosis [25]. There was significantly higher mortality among subjects evaluated 0–2a comparing to 2b-3 at the post-treatment TICI score assessment (53.9% vs 16.7%, $p = 0.02$. Fisher's exact test). Analyzing the death causes, two (16.7%) patients died of symptomatic cerebral hemorrhage, one (8.3%) due to subsequently diagnosed malignancy, one (8.3%) of pulmonary embolism and three (25%) of pneumonia. Three (25%) deaths were a result of malignant cerebral infarction and there was no stated cause in 4 (33.3%) cases.

Overall complication rate in our series was 9.3% ($n = 4$). We detected symptomatic intracranial hemorrhage in 4.7% ($n = 2$) of cases, which is consistent with 5.7% shown in the mechanical EVT meta-analysis by Badhiwala and colleagues [26]. Lower sICH rate (2.5%) was identified by Campbell et al. in Solitaire thrombetomy meta-analysis [22]. We also observed one (2.3%) periprocedural thromboembolic event in the remote vascular territory. The ACA was occluded with the fragment of thrombotic material lost during device withdrawal. There was, however, no functional impairment at 3 months noted in this patient (mRS score 0). In one (2.3%) subject groin hematoma that was successfully treated conservatively arose.

Our retrospective study provides single-center experience of mechanical thrombectomy with the stent retriever device (Solitaire FR). Results of this case series are consistent with the evidence from recently published RCTs, confirming the safety and efficacy of this method in AIS treatment [12–16]. We, nonetheless, present more heterogeneous cohort including patients with posterior circulation and distal portions of MCA (M2, M3) occlusions, with broader time to treatment window, and unselected by means of advanced imaging techniques (CT perfusion) or ASPECTS score. Clearly, some of our qualification criteria require modification (treatment window) and other (BA, PCA, MCA M2, MCA M3 occlusions, CT early ischemic changes, minor neurological deficit) need to be validated by further RCTs.

This relatively small case series does not permit to draw adequate conclusions, but rather confirms data from large RCTs in the clinical settings. It has the limitations attributed to case series methodology.

5. Conclusions

Stent retriever thrombectomy for the treatment of acute large vessel occlusion provides high rate of recanalization and good clinical outcomes with acceptable complication rates. It's efficacy decreases with the treatment delay. Our single-center experience proves the technical feasibility of the procedure.

Conflict of interest

None declared.

Acknowledgment and financial support

None declared.

Ethics

The work described in this article has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans; Uniform Requirements for manuscripts submitted to Biomedical journals.

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