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ACUTE ISCHEMIC STROKE ENDOVASCULAR TREATMENT OF PATIENTS WITH LARGE VESSEL OCCLUSIONS

Arturs Balodis[1, 2#], Maija Radziņa[2], Evija Miglāne[3, 4], Ramona Valante[3], Andrejs Millers[3], and Kārlis Kupčs[2]

[1] Department of Doctoral Studies, Rīga Stradiņš University, Dzirciema iela 16, Rīga, LV-1007, LATVIA

[2] Institute of Diagnostic Radiology, Pauls Stradiņš Clinical University Hospital, Pilsoņu iela 13, Rīga, LV-1010, LATVIA

[3] Department of Neurology, Pauls Stradiņš Clinical University Hospital, Pilsoņu iela 13, Rīga, LV-1010, LATVIA

[4] Department of Neurology and Neurosurgery, Rīga Stradiņš University, Pilsoņu iela 13, Rīga, LV-1010, LATVIA

[#] Corresponding author; arturs.balodis@rsu.lv

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Mechanical thrombectomy as an active treatment method has recently been chosen for patients with large artery occlusions and thrombolysis beyond a time window. The aim of our study was to evaluate the results of endovascular treatment in patients with proximal vessel occlusion, compare this group with the intravenous thrombolysis group, and to identify possible criteria of active treatment. The prospective study included 81 patients hospitalised in the Pauls Stradiņš Clinical University Hospital due to acute ischemic stroke; 48 of them received mechanical thrombectomy and 33 — intravenous thrombolysis. Thrombectomy (TE) was performed using Solitaire FR stent retrievers. The NIHSS score was used for evaluation of early therapy results and mRS (modified Rankin Scale) was used for late therapy results. ASPECTS was used to define the lesion size using imaging on admission and after treatment. Median NIHSS on admission was higher in the TE group — 16 (range 12 to 19) than in the TL group — 12 (range 8 to 15) ($p < 0.05$). Ninety days after treatment, mRS (0–2) was seen in 67% of patients in the TE group ($n = 29$), and 34% of patients in the TL group ($n = 9$) patients ($p < 0.05$). Median ASPECTS was lower in TE group — 5, in comparison to the TL group — 7 ($p < 0.01$) Mortality frequency was higher in the TL group ($p > 0.05$). Frequency of symptomatic intracerebral haemorrhages was similar in the groups. Mechanical thrombectomy can achieve better late functional outcome than thrombolysis in a selected patients group.

Key words: *ischemic stroke, thrombectomy, thrombolysis, criteria of active treatment.*

INTRODUCTION

For the last 15 years, intravenous thrombolysis (TL) has been the only active treatment method for acute ischemic stroke within the first 4.5 hours from the onset of symptoms (Wahlgren *et al.,* 2007; Hacke *et al.,* 2008; Khatri *et al.,* 2009). Recent studies have shown that results of thrombolysis might be suboptimal in patients with large artery occlusion and if the length of thrombus exceeds 8 mm (Tomsick *et al.,* 2008; Riedel *et al.,* 2011). Several studies in 2013 presented mechanical thrombectomy (TE) as a new approach to ischemic stroke patients; the majority of these cases showed that thrombectomy did not have better outcome than thrombolysis (Broderic *et al.,* 2013; Ciccone *et al.,* 2013; Kidwell *et al.,* 2013). The studies were criticised for the lack of multimodal computed tomography (CT) examination protocols, the use of different thrombectomy devices and small patient groups. Several new studies published in 2015 showed superiority of thrombectomy over thrombolysis because of better patient selection for this treatment method (Berkhemer *et al.,* 2015; Compbell *et al.,* 2015; Goyal *et al.,* 2015). Thrombectomy as a treatment method for acute ischemic stroke was established in 2010 in Latvia. There have been few small previous studies characterising mechanical endovascular therapy, but there are no previous studies analysing and comparing both treatment methods in Latvia (Balodis *et al.,* 2015).

The aim of this study was to evaluate the results of endovascular treatment in patients with proximal vessel occlusion, compare results of this group with those from an intravenous thrombolysis group and to identify possible criteria of active treatment.

MATERIALS AND METHODS

A prospective, cross-sectional cohort study was conducted on 81 patients with acute ischemic stroke, who were hospitalised in the Pauls Stradiņš Clinical University Hospital (PSKUS), in the period from January 2013 till December 2014. The study was approved by the Ethics Committee of Rīga Stradiņš University. Patients were divided into two groups. The first group included patients who received thrombectomy with or without intravenous thrombolysis (TE group) and the second consisted of patients who received only intravenous thrombolysis (TL group). The TE group consisted of 48 patients, 32 patients received only thrombectomy, and 16 patients received combined therapy — thrombectomy with thrombolysis. Thrombectomy was performed within 8 hours from onset of symptoms. All the thrombectomies were performed using stent retrievers *Solitaire FR*. The TL group consisted of 33 patients who received thrombolysis with intravenous t-PA within 4.5 hours from symptom onset.

Multimodal computed tomography, including non-contrast CT, CT angiography (CTA) and CT perfusion (CTP), was performed for all patients. The area detectable on CTP surrounding necrosis is the potentially viable hypoperfused brain tissue, called penumbra. Additionally, digital subtraction angiography (DSA) was performed for patients who received combined therapy. Successful revascularisation was evaluated with the use of the Thrombolysis in Cerebral Infarction (TICI) scale. The scale ranges from 0 (no perfusion) to 3 (full perfusion). Complete revascularisation was evaluated as a TICI score of 2b to 3.

To evaluate the neurological status on admission, the National Institutes of Health Stroke Scale (NIHSS) was used. Lesion size at admission was estimated from computed tomography imaging using the Alberta Stroke Programme Early CT score (ASPECTS). A more detailed explanation of ASPECTS is shown in Figure 1.

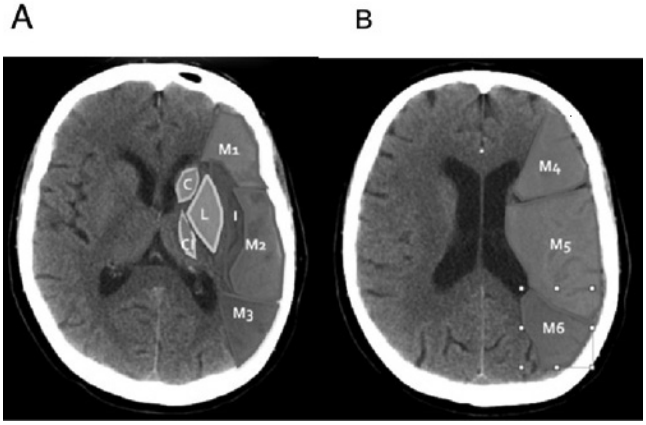

Fig. 1. ASPECTS score. **A:** The level at the basal ganglia, C, caudate nucleus, I, insula, IC, internal capsule, L, lentiform nucleus, M1, anterior cortex of MCA, M2, lateral cortex of MCA, M3, posterior cortex of MCA. **B:** Supraganglionic level. M4, anterior cortex of MCA, M5, lateral cortex of MCA, M6, posterior cortex of MCA. 10 point system: normal = 10 points, each lesion – 1 point.

Table 1

INCLUSION AND EXCLUSION CRITERIA OF THE PATIENTS

Groups	Inclusion criteria	Exclusion criteria
Thrombectomy and combined therapy (TE) I/v thrombolysis (TL)	- ASPECTS score ≥ 5 - Good, poor collaterals - CT native, CT angiography, CT perfusion - Time window TE group till 8 hours, TL group 4.5 hours - ACI proximal and distal, ACM M1, M2 segment occlusion	- ASPECTS score < 5 - Malignant collaterals - Not performed CT angiography or CT perfusion - Time window TE group > 8 hours, TL group > 4.5 hours - ACM M3, M4 segment oclussion

ACI, Arteria carotis interna; ACM, Arteria cerebris media; M1, middle cerebral artery from the origin to bifurcation; M2, middle cerebral artery from bifurcation to origin of cortical branches; M3, middle cerebral artery opercular branches; M4, middle cerebral artery branches emerging from the Sylvian fissure to the convex surface of the hemisphere.

Early results of applied therapy were evaluated also using ASPECTS and NIHSS at 24 hours after the treatment. Late therapy results were evaluated using the modified Rankin Scale (mRS) at discharge from hospital and 90 days after therapy. Collaterals were analysed using validated classification and were divided into two groups: good and poor (Tan *et al*., 2009).

Patients who died during hospitalisation were not included in this study because they did not meet the inclusion criteria; the majority of them had malignant collaterals, large core (necrosis) area and had an ASPECTS score less than 5. Inclusion and exclusion criteria are shown in Table 1.

Mortality was analysed at 90 days after therapy.

Data were analysed using Microsoft Excel and SPSS 20. Linear data were tested for normality using Shapiro–Wilcoxon and Kolmogorov–Smirnov tests, if the p value was less than 0.05, the data were not considered to be normally distributed. Median and interquartile range was used for linear data characteristics. The Mann–Whitney test was used to compare median data in thrombectomy and thrombolysis groups. Spearman's correlation analysis was used to evaluate relationships between two linear data groups. The Chi-Square test was used for conclusive statistics. A p value less than 0.05 was considered as statistically significant.

RESULTS

Neurological status was evaluated within both groups using NIHSS on admission. Median NIHSS on admission was significantly higher ($p < 0.05$) in the TE group — 16 (range 12 to 19) than in the TL group — 12 (range 8 to 15).

Early treatment results were evaluated using NIHSS: median NIHSS after the treatment was significantly lower ($p < 0.01$) in the TE group — 4 (range 2 to 7), compared to 7 (range 2 to 16) in the TL group.

Median NIHSS after therapy was significantly lower ($p < 0.05$) in the TL group among patients with good collaterals — 4, compared to 15 in patients with poor collaterals; there was no significant difference in the TE group ($p > 0.05$).

Mortality at 90 days was 11% in the TE group (n = 4) and 29% in the TL group (n = 8), with no significant difference between groups ($p > 0.05$). The number of complications (intracerebral haemorrhage) was equal in both groups (TE 9 patients, TL 9 patients). Baseline and neurological status characteristics are shown in Table 2.

Median ASPECTS values were significantly lower ($p < 0.01$) in the TE group — 5 (range 4–6), corresponding to larger size stroke than in the TL group — 7 (range 5–8).

There was a negative significant Spearman's correlation between the ASPECTS score at 24 hours follow-up and computed tomography NIHSS score at discharge negative, showing higher NIHSS values in larger size stroke (lower ASPECTS score), ($r_s = –0.63$, $p < 0.01$) in TE group and ($r_s = –0.44$, $p < 0.05$) in TL group. Radiological investigation characteristics are shown in Table 3.

Table 2

BASELINE AND NEUROLOGICAL STATUS CHARACTERISTICS

	Endovascular/ combined therapy (n = 48)	I/V thrombolysis (n = 33)
Age, years		
Median	71	74
Interquartile range	64–75	64–79
NIHSS score admission		
Median	16	12
Interquartile range	12–19	8–15
NIHSS score after therapy		
Median	4	7
Interquartile range	2-7	2-16
mRS after therapy		
Median	3	4
Interquartile range	0–5	0–5
mRS (0–2)	16	7
%	33	21
mRS 90 days		
Median	2	3
Interquartile range	1–3	1–3
mRS 90 days (0–2)		
N	29	9
%	60	27
Missing	5	7
Time from stroke onset to treatment (min)		
Median	300	190
Interquartile range	255–340	180–215
Time from stroke onset until hospitalization (min)		
Median	130	100
Interquartile range	84–182	75–120

NIHSS, National Institutes of Health Stroke Scale; mRS, modified Rankin Scale

Patients were also analysed by occlusion site. More proximal occlusions (*Arteria carotis interna*, ACI) had higher median NIHSS score values and higher median mRS values among therapy groups (TE vs TL (NIHSS 4 vs. 10, mRS 3 vs. 5) at discharge. There was a significant functional improvement (mRS improvement by 1–2 values) in both treatment groups, particularly for the TE group in intracranial ACM (*Arteria cerebris media*) proximal and ACI occlusions ($p = 0.05$), shown in Table 4.

Patients with a mRS score of 0, 1 or 2 are rated as functionally independent. There was a significant difference between treatment groups ($p < 0.05$) in patients with functional independence at 90 days (mRS 0–2) — in the TE

Table 3

RADIOLOGICAL CHARACTERISTICS

	Endovascular/ combined therapy (n = 48)	I/V thrombolysis (n = 33)
ASPECTS core		
Median (range)	8	9
Interquartile range	6–9	6–10
ASPECTS penumbra		
Median	5	7
Interquartile range	4–6	5–8
ASPECTS 24 h		
Median	8	7
Interquartile range	6–9	4–9
Successful reperfusion, N (%)	44 (91%)	
Complications:		
i/c haemorrhage, N(%)	9 (19%)	9 (27%)
Combinated group, N (%)	4 (25%)	
Collaterals		
Good N (%)	38 (79%)	19 (58%)
Poor N (%)	10 (21%)	14 (42%)

Table 4

OCCLUSION LOCATION AND OUTCOME CHARACTERISTICS

		TE and combined therapy (n = 46)		TL (n = 32)	
		Median (n)		Median (n)	
		Discharge	90 days	Discharge	90 days
ACM M2	NIHSS	3 (1)		6 (11)	
	mRS	3 (1)		4 (11)	
	90 days mRS		1 (1)		2 (6)
	Mortality		0		4
ACM M1	NIHSS	3 (29)		7 (17)	
	mRS	3 (9)		4 (17)	
	90 days mRS		2 (24)		3 (10)
	Mortality		3		2
ACI	NIHSS	4 (16)		10 (4)	
	mRS	3 (16)		5 (4)	
	90 days mRS		2 (14)		2 (2)
	Mortality		2		2

See abbreviations after Table 1. NIHSS, National Institutes of Health Stroke Scale

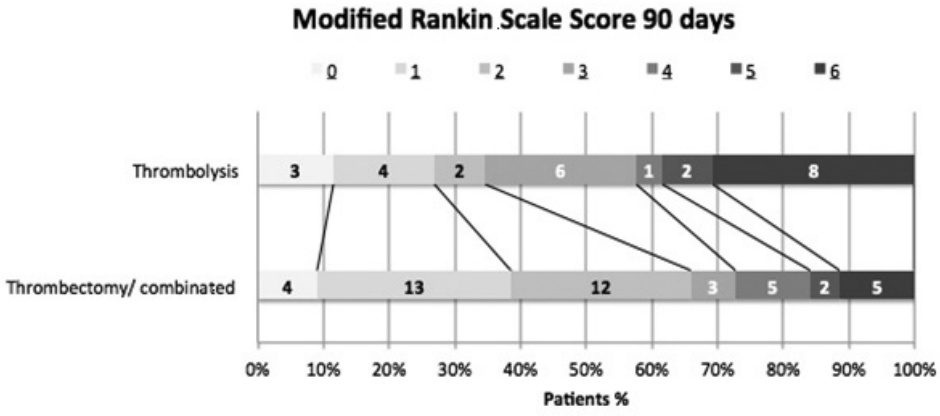

Fig. 2. Distribution of mRS (modified Rankin Scale) score 90 days after treatment in TE and TL groups. mRS range from 0 to 6 with 0 no symptoms, 1, no clinically significant disability; 2, slight disability but can live without assistance; 3, moderate disability; 4, moderately severe disability (unable to walk unassisted); 5, severe disability; and 6, death.

group 67% (n = 29) and in the TL group 34% (n = 9). Distribution of the mRS scores 90 days after treatment within TE and TL groups are shown in Figure 2.

DISCUSSION

Thrombectomy as a new treatment method was criticised in several trials published in 2013 which showed that there is no better functional outcome comparing thrombectomy with thrombolysis (Broderic *et al.* 2013), as the modified Rankin score of 2 or less at 90 days did not significantly difference between groups — 40.8% with endovascular therapy and 38.7% with intravenous t-PA. Thrombectomy is a new treatment method that has been performed relatively rarely in early multicenter trials without the necessary multimodal vascular imaging technologies prior to endovascular intervention, which may affect results. Our study showed significant difference between treatment groups (thrombectomy 67% vs. thrombolysis 34%) in favour of endovascular and combined therapy, which can be a result of the more recent stent retriever system use and adequate pretreatment imaging. Our data correspond to similar results published by Campbell *et al.* (2015), where the TE group had a higher rate of functional independence after 90 days (mRS 0–2) — thrombectomy 71% vs. thrombolysis 40%.

Thrombectomy as a treatment method can be effective in situations when thrombolysis cannot be performed because of time limitations or contraindications.

Our study showed that patients who received thrombectomy were hospitalised with significantly higher median NIHSS than in the TL group (TE – 10 patients vs. TL – 4 patients). This may be explained by the higher proportion of ACI occlusion in the TE group, which leads to larger lesion size and more severe neurological impairment. Thrombectomy was also performed for those patients who did not receive thrombolysis because of a limited time window.

Successful recanalisation was performed in 91% of our TE patients, while other trials show lower recanalisation rates (65–81%, depending on occlusion site) (Broderick *et al*., 2013), which can be explained by procedure technical reasons. All of our patients received thrombectomy by using stent retrievers *Solitaire FR*, while other previous trials used first generation thrombectomy devices, such as a *Merci Retriever* (Kidwell *et al.,* 2013).

Several studies have showed that good collaterals have an impact on treatment outcomes (Shi *et al.,* 2010). Our study showed that good collaterals are more important within the TL group, but without significant impact on thrombectomy results. This can be explained by the fact that patients with malignant collaterals were excluded from this study and recanalisation was achieved in patients with good and poor collaterals.

This study also showed that carefully selected patients for TE can achieve a better outcome, however, both treatment methods were equally safe and combined therapy did not show a significant raise of haemorrhagic complications. Intracerebral haemorrhages were detected in both groups, as observed in the MR CLEAN study (Berkhemer *et al.,* 2015). Higher mortality 90 days after treatment was detected in the TL group — 29% (11% in the TE group), which can be explained by poorer recanalisation rate in patients with ACI occlusions and TL (results showed in Table 4). Similar results with higher mortality in a TL group — 19% than in a TE group — 10% were published by (Goyal *et al.,* 2015).

There were some limitations of our study. Our study groups were small, and the TE group had more patients. Another limitation was that the TE group consisted of patients who received only thrombectomy and patients who received combined therapy with thrombolysis, which might have affected the results. Unequal distribution of patients — the majority of patients included in TE group had proximal ACI occlusion — affected the median NIHSS on admission.

In conclusion, our study results show that mechanical thrombectomy can achieve better late clinical outcome than thrombolysis in a selected patient group. Treatment results as well as the clinical outcome are related to the use of the latest stent retriever systems. Our results show that the pretreatment multimodal computed tomography examination is vital for patient selection for active treatment.

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AKŪTA CEREBRĀLA INFARKTA ENDOVASKULĀRA ĀRSTĒŠANA PACIENTIEM AR MAĢISTRĀLO ARTĒRIJU OKLŪZIJĀM

Trombektomija kā aktīvas ārstēšanas metode akūta cerebrāla infarkta gadījumā arvien biežāk tiek lietota pacientiem ar maģistrālo asinsvadu oklūzijām. Pētījuma mērķis bija novērtēt trombektomijas rezultativitāti pacientiem ar maģistrālo asinsvadu oklūzijām priekšējā smadzeņu cirkulācijā, salīdzināt rezultātus ar trombolīzes grupu, kā arī atklāt iespējamos papildus kritērijus aktīvas terapijas pielietošanai. Pētījumā tika iekļauts 81 pacients ar akūtu cerebrālu infarktu, kuri tikuši stacionēti Paula Stradiņa Klīniskajā universitātes slimnīcā, 48 no pacientiem tika veikta trombektomija, 33 — trombolīze. Trombektomijas tika veiktas, izmantojot *Solitaire FR* ierīci. Neiroloģiskā statusa novērtēšanai sākotnēji un agrīno rezultātu novērtēšanai tika izmantota *NIHSS* skala, *mRS* skala tika lietota vēlīno neiroloģisko rezultātu novērtēšanai, izrakstoties un pēc 90 dienām. *ASPECTS* skala tika lietota smadzeņu bojājuma apjoma novērtēšanai ar attēldiagnostiku, iestājoties un pēc terapijas. Mediānā NIHSS vērtība iestājoties bija augstāka pacientiem trombektomijas grupā — 16 (izkliede no 12 līdz 19), trombolīzes grupā — 12 (izkliede no 8 līdz 15) ($p < 0,05$). Trombektomijas grupā 90 dienas pēc terapijas pacienti ar maznozīmīgu neiroloģisku defektu — mRS (0–2) sastādīja 67% (n = 29), savukart trombolīžu grupā tikai 34% (n = 9) ($p < 0,05$). Mediānās ASPECTS vērtības bija zemākas trombektomiju grupā — 5 (izkliede no 4 līdz 6), trombolīžu — 7 (izkliede no 5 līdz 8) ($p < 0,01$). Mirstība bija augstāka trombolīžu grupā ($p > 0,05$). Mūsu pētījuma rezultāti liecina, ka ar mehānisku trombektomiju var sasniegt labāku vēlīno klīnisko iznākumu, nekā lietojot intravenozu trombolīzi pacientiem ar maģistrālo asinsvadu oklūziju. Ārstēšanas rezultāti, kā arī klīniskais iznākums ir saistīts ar jaunākās paaudzes trombektomijas ierīces izmantošanu. Agrīnai multimodālai datortomogrāfijas izmeklēšanai ir ļoti svarīgi, lai pacienti tiktu atlasīti aktīvai ārstēšanai.