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Clinical outcome in patients monitored by the NIHSS after mechanical thrombectomy in relation to time and cerebrovascular risk factors

Klinički ishod praćen primenom skale NIHSS kod bolesnika posle mehaničke trombektomije u odnosu na vreme i cerebrovaskularne faktore rizika

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Abstract

Background/Aim. Mechanical thrombectomy (MT) is an endovascular treatment that involves the extraction of thrombotic masses in the first hours of acute ischemic stroke (AIS) from the large blood vessels of the head and/or neck. The aim of the study was to determine the role of predictors (time and vascular risk factors) of the clinical outcome of patients with AIS monitored by the National Institute of Health Stroke Scale (NIHSS). **Methods.** The study included 134 patients diagnosed with occlusion of a blood vessel of the head and/or neck with a clinical picture of AIS who met the criteria for MT and in whom, upon admission to the hospital, existing vascular risk factors were observed. In relation to the time parameter from the onset of the clinical picture of AIS to the start of MT, the patients were divided into two groups. The first, the examined group, consisted of 85 (63.4%) patients in whom recanalization was initiated within the first four hours from the onset of symptoms, and the second, the control group, consisted of 49 (36.6%) patients in whom recanalization was initiated after the fourth hour. The results were monitored by the change of the NIHSS score at the time of discharge of the patient, on the 30th and 90th day, in relation to the NIHSS score on admission. **Results.** There was no statistically significant difference between the groups except for the variables endovascular treatment (EVT) and previous vascular event [cardiovascular disease (CVD)] ($p < 0.05$). A statistically significant correlation was found between improvement and the time when EVT was performed in relation to the onset of complaints ($\chi^2(1) = 4.756$; $p < 0.05$). A statistically significant correlation was also found between improvement and CVD ($\chi^2(1) = 4.756$; $p < 0.05$). **Conclusion.** The results of our study support MT as a promising stand-alone therapy for AIS. Clinical outcome monitored by the NIHSS after MT in relation to time and cerebrovascular risk factors shows that patients in whom EVT was performed in the first four hours have an improvement more often than patients in whom EVT was performed four hrs after the onset of symptoms. Likewise, patients without CVD were more likely to show improvement than patients with CVD.

Key words:
endovascular procedures; ischemic stroke; risk factors; time-to-treatment; treatment outcome.

Apstrakt

Uvod/Cilj. Mehanička trombektomija (MT) je endovaskularno lečenje koje uključuje uklanjanje trombotičnih masa iz velikih krvnih sudova glave i/ili vrata u prvim satima akutnog ishemijskog moždanog udara (AIMU). Cilj rada bio je da se utvrdi uloga prediktora (vreme i vaskularni faktori rizika) kliničkog ishoda obolelih od AIMU praćenih primenom skale *National Institute of Health Stroke Scale* (NIHSS). **Metode.** Ispitivanjem su obuhvaćena 134 bolesnika sa dijagnozom okluzije krvnog suda glave i/ili vrata sa kliničkom slikom AIMU, koji su zadovoljavali kriterijume za MT, a kod kojih su pri prijemu u bolnicu postojali faktori rizika od vaskularnih bolesti. U odnosu na period od nastanka kliničke slike AIMU do vremena početka MT, bolesnici su bili podeljeni u dve grupe. Prvu, ispitivanu grupu, činilo je 85 (63,4%) bolesnika kojima je rekanalizacija započeta u prva četiri sata od pojave simptoma, a drugu, kontrolnu grupu, 49 (36,6%) bolesnika kojima je rekanalizacija započeta posle četvrtog sata. Rezultati su praćeni na osnovu skora primenom skale NIHSS prilikom otpusta bolesnika, 30-og i 90-og dana, u odnosu na NIHSS rezultat pri prijemu bolesnika. **Rezultati.** Nije bilo statistički značajne razlike između grupa, osim za varijable endovaskularni tretman (EVT) i raniji vaskularni događaj [kardiovaskularna bolest (KVB)] ($p < 0,05$). Utvrđena je statistički značajna povezanost između poboljšanja i vremena kada je EVT

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urađen u odnosu na pojavu tegoba ($\chi^2(1) = 4,756$; $p < 0,05$). Nađena je statistički značajna povezanost i između poboljšanja i prisutva KVB ($\chi^2(1) = 4,756$; $p < 0,05$). **Zaključak.** Rezultati naše studije ukazuju na MT kao obećavajuću samostalnu terapijsku proceduru u lečenju AIMU. Klinički ishod posle MT praćen NIHSS skalom, u odnosu na vreme i cerebrovaskularne faktore rizika, pokazuje da bolesnici kod kojih je EVT urađen u prva četiri sata češće imaju poboljšanje od bolesnika kod kojih je EVT urađen posle četiri sata od pojave tegoba. Takođe, bolesnici bez KVB češće imaju poboljšanje od bolesnika sa KVB.

Ključne reči:
endovaskularne procedure; moždani udar, ishemijski; faktori rizika; vreme do početka lečenja; lečenje, ishod.

Introduction

Acute stroke is defined as a focal or global disorder of brain function that occurs suddenly and is the consequence of a disorder of cerebral circulation or a condition in which the blood flow is not sufficient to meet the metabolic needs of neurons for oxygen and glucose [1]. Stroke is the second leading cause of death and the third leading cause of disability in the world [2, 3].

Modern acute treatment, secondary prevention measures, and prognosis largely depend on the pathophysiological mechanisms of acute ischemic stroke (AIS) formation. More than one-third of ischemic strokes are caused by embolization.

Mechanical thrombectomy (MT) is an endovascular treatment (EVT) that involves the extraction of thrombotic masses in the first hours of AIS from the large blood vessels of the head and/or neck. In 2015, five randomized controlled trials [4–8] reported the superiority of MT compared to medical therapy in stroke patients due to large vessel occlusion, leading to its adoption as the standard of care for this subset of patients. The time frame for MT application has become increasingly variable. Recently, the DAWN trial demonstrated that the period for MT can be extended up to 24 hrs in selected cases of large vessel occlusion [9, 10].

Previous studies suggest that the benefit was the greatest with the time from the onset of symptoms to arterial puncture for thrombectomy under 2 hrs and became insignificant after 7.3 hrs [11].

The aim of this study was to determine the degree of efficiency, outcome, and adverse events of MT administration in patients with a clinical picture of AIS and existing vascular risk factors, in whom MT was initiated in the shortest possible period of time.

Methods

The research was conducted as an observational, clinical, nested cohort, single-center, case-control study.

Selection of patients

Patient data was obtained retrospectively from medical records in concordance with the Helsinki Declaration and with the approval of the local Ethics Committee (No. 3/3116, from June 30, 2021). The patients who were included in the study were treated at the Special Hospital for Cerebrovascular Diseases “Sveti Sava” in Belgrade, Serbia, from March 1, 2014, until December 31, 2020; they were diagnosed with blood vessel occlusion of the head and/or neck and had a clinical picture of AIS. The patients also had to meet the criteria for MT.

The sample in this research comprised 134 patients, male and female aged 18 and above, who met the aforementioned inclusion and MT criteria; existing vascular risk factors were observed upon admission to the hospital.

Since the time from the onset of symptoms to EVT was defined as the main variable of the study, we divided the patients into two groups. The first group consisted of 85 (63.4%) patients in whom EVT started within the first four hrs from the onset of the first symptoms of the clinical picture of AIS, and the second, i.e., the control group, consisted of 49 (36.6%) patients in whom EVT was started after the fourth hour from the onset of symptoms.

Treatment of patients

Anamnesis and/or heteroanamnesis were taken; a neurological examination and scoring with the National Institute of Health Stroke Scale (NIHSS) and a somatic examination were performed for all patients with a clinical picture of AIS. The following data was taken from the patients: sex, age, smoking history, presence of associated diseases defined as vascular risk factors [previous cerebrovascular disease (CVD), hypertension arterialis (HTA), atrial fibrillation (AF), diabetes mellitus (DM), hyperlipoproteinemia (HLP)].

All of the selected patients underwent computerized tomography (CT) of the endocranium without contrast and CT angiography of the blood vessels of the neck and head, standard laboratory analyses, and X-ray of the lungs [12–14].

The decision on the intervention was made in consultation between the neurologist, neuroradiologist, and interventional neuroradiologist. Digital subtraction angiography and MT [15] were performed after the decision. The results were monitored by the change in NIHSS score at the time of discharge of the patients, on the 30th and 90th day after EVT, in relation to the NIHSS score on admission of the patients [16].

The NIHSS for neurological deficits in stroke was used. The scale assesses 11 parameters: state of consciousness, bulbar movements, visual field width, facial motor skills, hand motor skills, leg motor skills, limb ataxia, sensibility, speech, dysarthria, and the phenomenon of neglect. The scores in the NIHSS range from 0 to 42 points [17].

An increase in the score indicates an increase in neurological deficit (0–4 mild, 5–15 moderate, 16–20 moderately severe, > 20 severe neurological deficit) [18–20].

The transition of the patient's score from greater to lesser stroke severity on the scale at the time of discharge and/or on the 30th and 90th day after EVT was defined as an improvement in the patient's neurological status.

Statistical analysis

We used descriptive statistical parameters in the statistical data processing (frequencies, percentages, mean value, median, standard deviation, and range). The normal Q-Q plot and histogram graphs, as well as the Kolmogorov-Smirnov test, were used to test the match of sample distributions of numerical data with the normal distribution. Statistical significance was determined by Student's *t*-test and ANOVA for samples with normal distribution and by Mann-Whitney and Kruskal-Wallis tests for samples without normal distribution. Other statistical tests (e.g., correlation) were used according to the results of the basic exploratory analysis. The independent influence of the examined independent and confounding variables on quality of life outcomes was examined using univariable linear and logistic regression. The simultaneous influence of the selected significant variables was examined using a multivariable linear and logistic regression model. The statistical significance of the probabilities of the investigated differences in the values of the variables between the study groups was assumed to be $p < 0.05$. All statistical analyses were performed using the standard program package SPSS v20.0.

Results

Table 1 shows the demographic and stroke risk factors of the patients who participated in this study.

The division of patients into NIHSS groups on different time points and according to stroke severity are presented in Table 2.

A fatal outcome occurred in 29 (21.6%) of the total number of 134 patients who underwent EVT. More precisely, a fatal outcome occurred in 12 patients in whom EVT was initiated within the first 4 hrs from the onset of the first complaint and in 17 patients in whom EVT was initiated 4 hrs after the onset of the first complaint. These patients were not statistically monitored in this study.

After statistical processing of demographic data, vascular risk factors, and time, and in relation to the change of the NIHSS score, improvement was observed in 80 patients (Table 3).

There was no statistically significant difference between the groups, except for the EVT and CVD variables ($p < 0.05$), based on the results of the Chi-square test of independence and the *t*-test for independent samples.

Based on the results of the Chi-square test of independence, it can be concluded that there was a statistically significant relationship between improvement and the time when EVT was performed in relation to the onset of complaints ($\chi^2_{(1)} = 4.756$; $p < 0.05$).

In the group of 25 patients who showed no improvement, EVT was performed in 13 patients within the first four hrs from the onset of symptoms. On the other hand, in the group of 80 patients who showed improvement, EVT was performed in 60 patients within the first four hrs from symptom occurrence.

Table 1

Demographic data of the 134 examined patients with acute ischemic stroke

Parameter	Values
Gender	
female	63 (47.0)
male	71 (53.0)
Age, years	65.87 ± 12.752
Smoker	
yes	26 (19.4)
no	101 (75.4)
former	7 (5.2)
Hyperlipoproteinemia	
yes	41 (30.6)
no	93 (69.4)
Hypertension arterialis	
yes	107 (79.9)
no	16 (11.9)
de novo	11 (8.2)
Diabetes mellitus	
yes	24 (17.9)
de novo	6 (4.5)
no	104 (77.6)
Atrial fibrillation	
yes	29 (21.6)
no	79 (59.0)
de novo	26 (19.4)

All values are expressed as numbers (percentages) except for age which is shown as mean ± standard deviation.

Additionally, based on the results of the Chi-square test of independence, it can be concluded that there was a statistically significant relationship between improvement and CVD ($\chi^2(_1) = 4.756$; $p < 0.05$).

In the group of 25 patients who did not show improvement, CVD was present in 12 (48%) patients, whereas in the group of 80 patients whose condition improved, CVD was present in 20 (25%) patients.

In addition to the above, logistic regression was performed to evaluate the influence of these two factors (CVD and EVT) on the probability that a patient undergoing MT would show an improvement. The model is statistically significant ($\chi^2(_2) = 8.740$; $p < 0.05$), which means that the model differentiates well between patients whose health condition improved and those whose health condition did not improve. The model explains 12% of the variance in patient classification and correctly classifies 77.1% of cases.

Based on the results presented in Table 4 it can be concluded that both variables (EVT and CVD) made a unique statistically significant contribution to the model.

The odds ratio (OR) for CVD was 2.735, indicating that subjects without CVD were 2.735 times more likely to show improvement than patients with CVD (Figure 1).

The OR for EVT was 0.366, which showed that people who underwent EVT within the first four hrs were 2.735 times more likely to have an improvement than those who underwent EVT four hrs after the onset of symptoms (Figure 2).

Table 2

Stroke severity classification of patients according to the National Institute of Health Stroke Scale (NIHSS)

NIHSS on different time points	Patients, n	Median	IQR
On admission (n = 134)			
mild deficit	5	4	3–4
moderate deficit	63	13	9–14
moderately severe deficit	52	19	17–20
severe deficit	14	23	21–23
On discharge (n = 108)			
mild deficit	41	2	1–3
moderate deficit	59	9	6–13
moderately severe deficit	8	17	17–19
After 30 days (n = 105)			
mild deficit	55	0	0–2
moderate deficit	42	10	7–13
moderately severe deficit	8	17	17–19
After 90 days (n = 105)			
mild deficit	57	0	0–2
moderate deficit	40	10	7–14
moderately severe deficit	8	17	17–19

n – number of patients; IQR – interquartile range.

Table 3

Risk factors associated with improvement following endovascular treatment

Parameter	Improvement		*p*-values
	no (n = 25)	yes (n = 80)	
Gender, female	12 (48)	35 (44)	0.709
Age, years	68.56	64.43	0.162
Smoker, yes/no/former	2 (8)/22 (88)/1 (4)	17 (21)/58 (73)/5 (6)	0.270
Hyperlipoproteinemia	10 (40)	20 (25)	0.147
Hypertension arterialis, yes/no/*de novo*	20 (80)/4 (16)/1 (4)	63 (79)/10 (13)/7 (9)	0.690
Diabetes mellitus, yes/no/*de novo*	6 (24)/17 (68)/2 (8)	13 (16)/64 (80)/3 (4)	0.425
Atrial fibrillation, yes/no/*de novo*	7 (28)/17 (68)/1 (4)	18 (23)/48 (60)/14 (18)	0.238
Endovascular treatment [#]	13 (52)	60 (75)	**0.029**
Cardiovascular diseases	12 (48)	20 (25)	**0.029**

[#] – the first 4 hrs from the onset of symptoms.

All values are given as numbers (percentages) except for age for which the unit is average number.

Table 4

Odds ratio for EVT and CVD

Parameter	B	S.E.	Wald	df	Sig.	Exp(B)	95% CI for Exp(B)
EVT	1.006	0.488	4.245	1	0.039	2.735	1.050–7.123
CVD	-1.006	0.488	4.245	1	0.039	0.366	0.140–0.952
Constant	0.880	0.420	4.388	1	0.036	2.412	

EVT – endovascular treatment; CVD – cardiovascular diseases; CI – confidence interval.

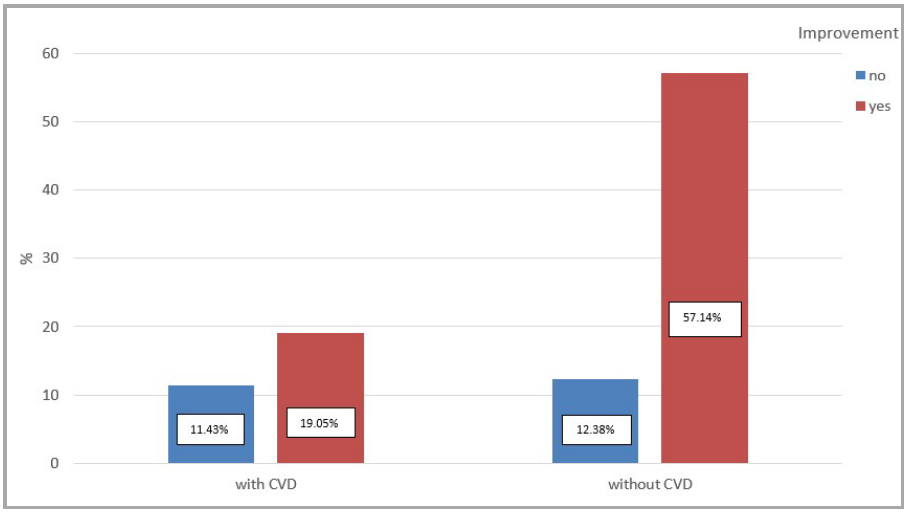

Fig. 1 – Improvement in patients with and without cardiovascular diseases (CVD).

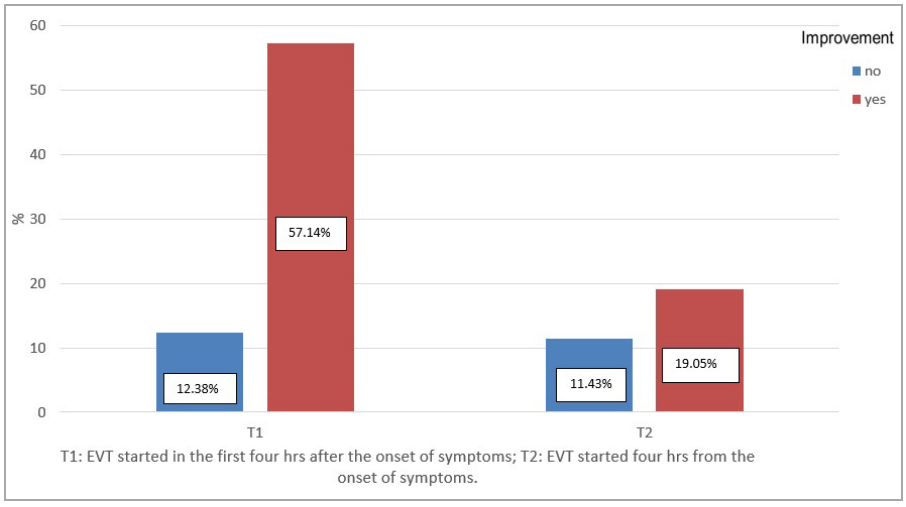

Fig. 2 – Patient improvement over time after endovascular treatment (EVT).

Discussion

The aim of this study was to determine whether the time of onset of MT and the absence of cerebrovascular risk factors are predictors of better clinical outcomes.

Of the 134 patients included in the study, 29 (21.6%) ended fatally, namely, 12 patients in whom EVT was initiated within the first 4 hrs from the onset of the first complaints and 17 patients in whom EVT was initiated 4 hrs after the onset of the first complaints. A high percentage of fatal outcomes was recorded in the group of patients who underwent an endovascular procedure 4 hrs after the onset of symptoms [1, 21].

Previous studies have shown that among patients with AIS treated with MT, those with DM showed worse outcomes than those without DM [22].

One study confirmed that HTA is associated with a poor outcome three months after MT in patients with AIS. However, the causal relationship between HTA and poor outcomes remains undetermined, and further research is needed to determine whether AIS patients undergoing MT benefit from intensive blood pressure control [23].

Another study showed that patients with AF responded significantly better to EVT than those without AF. Intracranial atherosclerotic diseases in patients without AF that were particularly refractory to EVT may contribute to the difference in functional outcomes between the two groups [24].

Based on statistical analysis, this study found that factors such as sex, age, smoking, HTA, HLP, AF, and DM were not statistically significant.

Only the time of MT onset and the existence of an earlier cerebrovascular event in the patient were shown to be statistically significant variables. In earlier studies, time was also shown to be a significant independent variable [25–28]. Some data show that the outcome of MT is better if MT is performed at night, as stated in the given study, because AIS at that time occurred in slightly younger patients [29].

Eighty patients experienced significant improvement of the clinical picture after their stroke severity score lowered on the NIHSS. In 60 (75%) patients, EVT was performed in the first 4 hrs after the onset of symptoms

In the group of 25 patients in whom there was no improvement, EVT was performed in 13 (52%) patients.

Furthermore, in the group of patients with significant improvement, a previous cerebrovascular event was present in only 20 (25%) subjects.

In the group of 25 patients with no improvement, an earlier cerebrovascular event was recorded in 12 (48%) patients.

Although other factors such as HLP, HTA, DM, and AF were monitored under the assumption that they would prove statistically significant, almost no group difference was observed in patients with and without improvement.

This showed that the time of onset of MT and earlier cerebrovascular traumas greatly influence the outcome of recovery and the clinical picture of patients. It was observed that patients in whom EVT was performed in the first 4 hrs from the onset of symptoms have 2.735 more frequent improvement compared to patients in whom EVT was performed in later hours. Furthermore, patients who did not have previous cerebrovascular traumas had 2.735 times more frequent improvement than those who did.

Conclusion

Application of MT in patients with initially lower NIHSS score gives a better outcome of the clinical picture in terms of neurological findings and reperfusion. Clinical outcome monitored by the NIHSS after MT in relation to time and cerebrovascular risk factors shows that people in whom EVT was performed in the first four hrs had an improvement of 2.735 times more often than patients in whom EVT was performed four hrs after the onset of symptoms. Patients without CVD were 2.735 times more likely to improve than patients with CVD.

Considering the results of our study, we believe that CVD and EVT affect the clinical outcome of patients after MT. A small number of patients were included in this study, so we cannot say with certainty that other risk factors known for the occurrence of AIS do not affect the clinical outcome of patients after MT.

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