Efficacy of mechanical thrombectomy in stroke patients with large vessel involvement

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Abstract

Ischemic stroke is a common disease worldwide and leads to a significant rate of mortality and disability in patients every year, and imposes high costs on the health care system. The aim of this study was to evaluate the efficacy of the invasive method of mechanical thrombectomy for rapid intervention in ischemic stroke patients with large vessel involvement. Patients suspected of having a stroke, who were referred to Imam Hossein Hospital, were examined, and the diagnosis of stroke was confirmed. In the next stage, patients' MRS index was measured and the possibility of emergency thrombectomy was evaluated in patients. Patients who underwent thrombectomy were considered as the case group and the other patients were contemplated as the control group; then, the cases of the two groups were evaluated and compared. The mean age of patients was 66.63 ± 12.26 years. the use of emergency thrombectomy in the study group significantly reduced the MRS index of patients after 90 days ($p < 0.001$), while a significant increase in the mean scores of the MRS index was seen in patients receiving pharmacological treatments. Also, there was no significant difference in terms of gender between the group of patients undergoing thrombectomy and the group receiving other treatments ($p = 0.375$). Emergency mechanical thrombectomy significantly reduces disability in stroke patients in the long term and can be a good alternative to conventional drug treatments..

Key Words: Stroke; thrombolytic therapy; embolectomy.

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Stroke is the lack of blood supply to an area of the brain resulting in the loss of some neurological functions.[1] Ischemia is a decrease in blood supply to an organ or part of the body that reduces the transfer of oxygen and nutrients to tissues and thus impairs organ function, and it can be caused by atherosclerosis, blood clots, vasoconstriction, embolism, low blood pressure, and tumors. One type of ischemia is cerebral ischemia,[2,3] which includes three etiologies: thrombosis, embolism, and decreased systemic blood flow (the most common problems of blood flow to the brain and other organs). Stroke has many symptoms, the most obvious of which are hemiparesis and hemiplegia (weakness or paralysis of one-half of the body).[3,4] The World Health Organization (WHO) claims that according to current trends and in line with forecasts, the incidence of ischemic stroke will increase significantly over the next 5 years. The economic burden of stroke is $9 billion annually in the United Kingdom and $38 billion in the United States, and this enormous economic burden is increasing.[5] Similar to myocardial infarction, removing the constriction of cerebral arteries in the acute phase of a stroke can improve the symptoms and prognosis of these patients. Numerous clinical trials have shown that intravenous injection of tissue plasminogen activator (tPA) in the first three hours after the onset of symptoms results in a better 90-day prognosis in patients with ischemic stroke compared with controls.[6] On the other hand, during the past three decades, thrombectomy methods have gradually evolved and found their way into the acute treatment of ischemic strokes. Preliminary studies could not show the superiority of mechanical thrombectomy over intravenous tPA injection in these patients. However, subsequent studies have shown that mechanical thrombectomy with stent retrievers is quite effective in the acute treatment of strokes caused by the involvement of the large vessels of the brain.[7] Studies have shown that the use of thrombolysis in the first 4-5 hours along with mechanical thrombectomy in the first 6

hours after the onset of symptoms is more effective in the treatment of obstruction of large anterior arteries, in comparison with the use of thrombolysis alone.[8] Considering the importance of effective therapeutic interventions in reducing mortality and disability due to stroke and also reducing the economic burden caused by this disorder, if the use of mechanical thrombectomy would be associated with better clinical results, performing mechanical thrombectomy and equipping the centers with the necessary facilities can lead to significant clinical improvements in the in long-term and reduce the rate of disability and mortality due to stroke in communities. Therefore, the aim of this study was to investigate the effect of mechanical thrombectomy in stroke patients with large vessel involvement.

Material and Methods

Ethical considerations

Participation in the current study was voluntary and written consent was obtained from patients or their companions before entering the study. The participation of cases in the study did not lead to deprivation of the patients from standard treatment and did not incur additional costs for them. Before the start of the research, all necessary permissions for this study were obtained from the relevant ethics committees, and all patient information would remain completely confidential to the researcher. Registration code of this study is IR.SBMU.MSP.REC.1400.092, which was registered at the meeting of the ethics committee of the research vice-chancellor of the medical school on May 22, 2021.

Study design and sample size

This descriptive clinical study included all patients with acute ischemic stroke who were referred to Imam Hossein Hospital in Tehran between 2018 and 2020. In this study, samples were selected using simple random sampling method. According to a study by Lapergue, et al.,[9] considering the first type error of 0.05% and the power of 0.2%, the number of samples was calculated to be 100, but due to dissatisfaction of some patients and after considering the inclusion/exclusion criteria, the sample size was reduced to 61 people. The sample size was obtained from the following equation:

$$n = \frac{Z^2 P(1-P)}{d^2}$$

Inclusion and exclusion criteria

Complete satisfaction, age between 18 to 70 years, diagnosis of acute ischemic stroke according to clinical symptoms, MRI and CT-Angiography, hospitalization, and lack of drug addiction were the inclusion criteria.
Exclusion criteria included patient dissatisfaction and the presence of symptoms of hemorrhagic factors.

Procedure

After obtaining the necessary permits, All patients who were referred to Imam Hossein Hospital in Tehran from 2018 to 2020 with suspected symptoms of acute stroke were included in the study. These patients were examined by a neurology resident and a Brain CT-scan was performed, and after rejecting hemorrhagic factors, the diagnosis of acute ischemic stroke was confirmed. If the golden time for thrombectomy was not passed in these patients (12 hours), after explaining the study procedure and obtaining informed consent, the patients were transferred to the intervention unit for mechanical thrombectomy. Other patients, in whom the golden time of thrombectomy was passed and thrombectomy had no indication, or those who were not satisfied with participating in the study were monitored as the control group. In patients who were included in the study with a possible diagnosis of acute ischemic stroke, CT-Angiography was initially requested and then patients were sent to the angiography suit for receiving thrombectomy treatment. At this stage, patients underwent penumbra aspiration thrombectomy and received the necessary care. In the next step, the MRS index of these patients was evaluated and recorded, and the resulting data were statistically compared with the data obtained from the control group who did not receive mechanical thrombectomy treatment.

Statistical Analysis

Qualitative data were reported as number and percentage, as well as mean and standard deviation. In statistical studies to compare the studied groups, if the conditions for using parametric statistical tests were met, Independent Samples T-Test, Paired Samples T-Test, and Chi-Squared were used; if the conditions were not met, non-parametric equivalents of Fischer Exact Test, Mann Whitney U Test, and Wilcoxon Sign Rank Test were used. All statistical analyzes in this study were performed using IBM SPSS statistical analysis software version 23.0.

Results

In this study, a total of 61 patients were studied and the cases were divided into two study groups. The first group included 30 patients who underwent thrombectomy and the second group consisted of 31 patients who did not meet the criteria for thrombectomy and received other treatments. In terms of gender, the first group consisted of 15 men (50%) and 15 women (50%) and the second group consisted of 19 men (55.9%) and 12 women (44.4%). There was no significant difference in terms of gender between the group undergoing thrombectomy and the group receiving other treatment ($p = 0.375$). The mean age of patients was 66.63 ± 12.26 years. The findings of the Independent Samples T-Test demonstrated that there was no significant difference in the mean age of patients of the two groups ($p = 0.077$).
The results of this study showed that there was a significant difference between the two groups in terms of changes in the MRS index ($p < 0.001$). This means that in the cases that underwent thrombectomy, the MRS index

Table 1. *Evaluation of changes observed in patients before and after interventions*

	Group	Initial MRS	90th day MRS	Changes
	Thrombectomy	4.67 ± 0.95	3.57 ± 1.90	**-1.10 ± 1.53**
	Non-Thrombectomy	4.90 ± 0.30	5.71 ± 0.93	**0.81 ± 0.91**
	All patients	4.79 ± 0.71	4.66 ± 1.83	**0.13 ± 1.57**

Tests of Within-Subjects Contrasts

Source	MRS	Type III Sum of Squares	df	Mean Square	f	Sig.	Partial Eta Squared
MRS	Linear	.657	1	.657	.829	.366	.014
MRS * Group	Linear	27.706	1	27.706	34.951	.000	.372
Error(MRS)	Linear	46.769	59	.793			

Table 2. *Investigation of the observed differences between the two groups*

Tests of Between-Subjects Effects

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	2707.524	1	2707.524	1396.842	.000	.959
Group	43.164	1	43.164	22.269	.000	.274
Error	114.361	59	1.938			

decreased by an average of 1.1 units after 90 days, while in the cases that received other treatments, the MRS index increased by about 0.8 units after 90 days (Table 1). By examining the effects of interventions on both groups, and according to Table 2 and Figure 1, it was found that there was no correlation between the time of onset of symptoms and MRS ($p = 0.459$). Also, the rate of decrease in the MRS index was not related to age ($p = 0.094$). But the rate of 90-day MRS in patients showed a significant correlation with age ($r = 0.354$ and $p = 0.05$).

Discussion

Stroke is one of the most important causes of death and disability worldwide, especially in the elderly, and accounts for a large part of the burden on the health system each year.[8] Similar to myocardial infarction, removing the constriction of cerebral arteries in the acute phase of stroke can improve the symptoms and prognosis of patients.[9,10] In strokes, the initial damage is generally irreversible, but it accounts for a small portion of the final damage, and if the tissue ischemia is not compensated well with timely and effective measures, ischemia and necrosis would be observed in a larger area of the brain and the secondary damage leads to further serious injuries to the patient.[11,12] In the treatment of stroke, the main goal is to prevent this secondary injury and control tissue ischemia with different approaches. Different pharmacological methods and surgical interventions are used today to control and limit stroke injury.[13] Mechanical thrombectomy is one of the invasive methods used in ischemic stroke that has been considered by researchers today. Numerous studies have shown the usefulness of mechanical thrombectomy in the treatment of ischemic strokes with thrombotic or embolic origins, and some studies indicate its superiority over the classical method of thrombolysis.[14,15] In a 2012 study, Kissela et al. examined the demographic characteristics of stroke in a large population (1.3 million) between 1993 and 2005.[16] According to the data of this study, the average age of incidence of stroke during these years was decreased from 71.2 to 69.2 years and the number of strokes under the age of 55 years was increased significantly during these years. In our study, the mean age of patients who met the requirements for mechanical

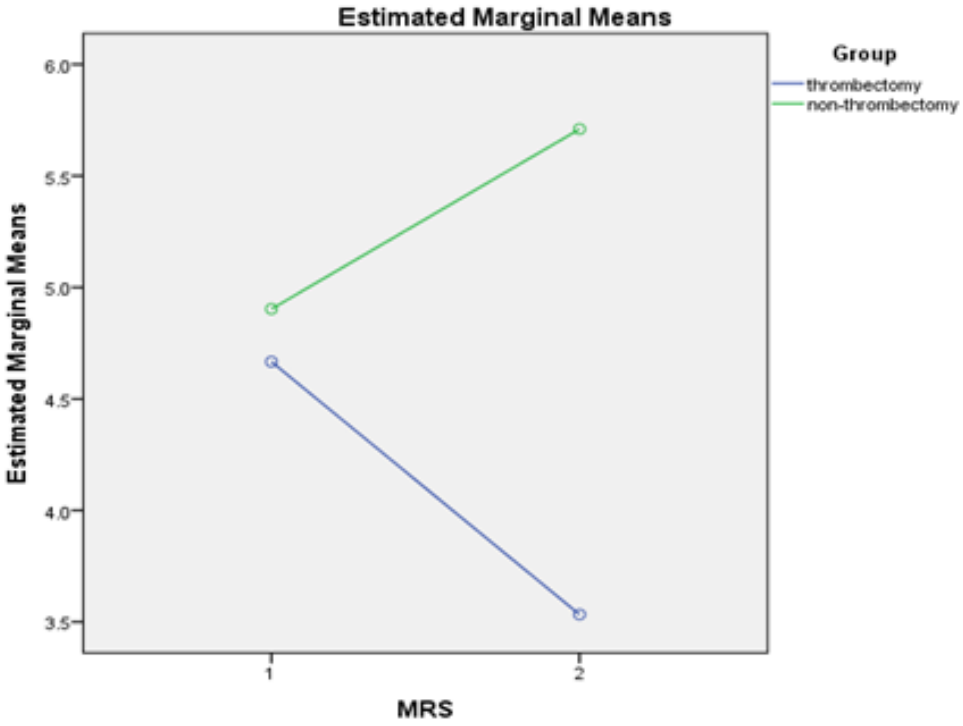

Fig 1. *Shows status of changes in MRS index based on interventions in case and control groups*

thrombectomy was significantly lower than other patients, because naturally and pathologically physical complications increases with age while tolerance of invasive processes, including thrombectomy, decreases. In a 2020 study, Qureshi et al. examined the efficacy of endovascular thrombectomy in patients with ischemic stroke in the United States. In this large study, which investigated 23.375 patients who underwent mechanical thrombectomy, it was observed that in patients with acute stroke with thromboembolic causes who underwent thrombectomy during the clinical trial, the rates of mortality and moderate to severe disability were significantly lower compared to the control group.[17] In 2018, Kamal et al. evaluated the efficacy of mechanical thrombectomy in patients with stroke. In this study, studies published by other researchers were analyzed. The combined findings demonstrated that endovascular treatment in cases of stroke reduces the morbidity and mortality of patients.[18] In another study conducted by Lambrinos et al. in 2016, published evidence related to effectiveness of mechanical thrombectomy in the treatment of patients with acute ischemic stroke was reviewed. They stated that the use of mechanical thrombectomy, with or without thrombolytic therapies, significantly increases the success rate of treatment in patients with acute ischemic stroke.[19] In this study, in terms of improvement, there was no statistically significant difference between patients who received mechanical thrombectomy as well as thrombolytic therapy and patients who received thrombectomy alone.[19]

In our study, the MRS index was used to measure the involvement of patients and monitor their clinical course in both groups. The results demonstrated that the mean rate of MRS was reported to be in the range of 4 to 5 in all groups, which indicates moderate to severe disability in patients of both groups. According to the results of our study, it seems that there is a considerable difference in terms of the course of treatment between patients who underwent mechanical thrombectomy and other patients. Accordingly, data of 90-day changes in patients by type of treatment were analyzed using the Repeated Measures ANOVA test. The results showed that patients who underwent mechanical thrombectomy had relative improvements over time, and their MRS index decreased significantly, while in patients who only received drug treatment, the disease status worsened and their MRS index increased significantly. These findings are consistent with the findings of the studies by Qureshi et al. and Lambrinos et al.[18,19] The results of this study also demonstrated a significant difference in the process and the final result of treatment between thrombectomy patients and other patients, which indicated the superiority of mechanical thrombectomy over drug treatment. It is important to note that, given that the group of patients receiving medical treatment may have had worse clinical and general health conditions than patients receiving thrombectomy, the data obtained should be interpreted with caution. However, the findings of this study were in line with the findings of Wahlgren et al.[20] and Jovin et al.,[21] who concluded that mechanical thrombectomy is highly effective in the treatment of

ischemic stroke with large vessel involvement, thus our findings are in agreement with well documented previous studies. Limitations of our study are due to the operational and time constraints of the researchers, and uniqueness of the study. Thus, it was not possible to access a larger statistical population. Furthermore, according to the principles of ethics in research, it was not possible to deprive patients of receiving standard treatment, and therefore, it was not possible to define an ideal control group for this study.

In conclusion, emergency mechanical thrombectomy leads to changes in patients' clinical course and reduces their general disability in the long term, in comparison to drug treatments. Therefore, if the stroke patient's clinical condition would be favorable for invasive measures, it seems that mechanical thrombectomy can be an effective co-therapy to conventional drug treatments.

List of acronyms

CT - computerized tomography
df - degree of freedom
Eta - effect size index
F - F-test
MRI - magnetic resonance imaging
MRS – modified rankin scale
MRS *- modified rankin scale in $p<0.05$
Sig. - significant
tPA - tissue plasminogen activator
WHO - World Health Organization

Contributions of Author

All authors contributed to the design and implementation of the research, to the analysis of the results, and to the writing of the manuscript. All Auhthors approved the final edited typescript.

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Conflict of Interest

The authors declare no conflict of interests.

Ethical Publication Statement

The author confirms that he has read the Journal's position on the issues involved in ethical publication and states that this report is consistent with those guidelines.

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