

A STUDY ON TREATMENT WITH IV THROMBOLYSIS OF PATIENTS WITH ACUTE ISCHEMIC STROKE

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Abstract

Background: Stroke is a clinical syndrome characterized by loss of cerebral function due to tissue hypoxia. The WHO clinically defines stroke as the "Rapid development of clinical signs and symptoms of a focal neurological disturbance lasting more than 24 hours or leading to death with no apparent cause other than vascular origin". Ischemic strokes are the most common type, and cerebral thrombosis or embolism causes them. They account for 80%–85% of cerebrovascular accidents worldwide. Reperfusion treatments in the early hours can reduce the morbidity to be utilized. **Objective:** To analyse the outcome of patients selected for intravenous thrombolysis **Materials and Methods:** The details of patients admitted with acute ischemic stroke within the time window who were treated with IV thrombolytic therapy with Inj. Alteplase was analysed. This analysis was done regarding deficit at admission, complications, and deficit at discharge and after 3 months. **Result:** Of the 20 cases, The NIHSS was less than 15 in 11 patients and more than 15 in 9 cases. Only 5 patients achieved a primary outcome in this study. None had significant symptomatic intracranial haemorrhage. But 4 patients (20%) had a subtle asymptomatic haemorrhagic transformation. Mortality was observed in 2 cases due to mass effect. About 9 patients (45%) had a favourable outcome with an MRS scale of 0- 2 at 3 months **Conclusion:** The established benefits of rtPA vs a lesser number of haemorrhagic complications while using IV thrombolytics alteplase should be utilized whenever feasible for a relatively better functional status at 3 or 6 months.

INTRODUCTION

Stroke is a significant global health problem and a major cause of mortality and morbidity in developed countries and increasingly in low-middle income countries (LMICs), making stroke India's fourth leading cause of death and the fifth leading cause of disability.^[1,2] In a recent systematic review, consisting mainly of cross-sectional studies, the incidence of stroke in India was estimated to be between 105 and 152/100,000 people per year.^[3] Over the years, the utilization of IV thrombolytic therapy has increased across the country. Stroke is a major cause of mortality and morbidity, and thrombolysis has catalyzed major changes in managing acute ischemic stroke. Intravenous

alteplase (recombinant tissue plasminogen activator) is the only approved thrombolytic agent indicated for acute ischemic stroke.^[4]

Objective

This study was done to analyse the outcome of patients selected for intravenous thrombolysis and who were administered to analyse the outcome and complications in the management.

MATERIALS AND METHODS

This retrospective study was carried out from August 2021 to December in the government hospital of Kilpauk Medical College, a tertiary care hospital and referral centre hub. Within the time

frame, 20 patients were admitted with acute ischemic stroke and treated with IV thrombolytic therapy with Inj. Alteplase. These patients were received in the casualty and evaluated with investigations and imaging.

Then patients were shifted to the intensive medical care unit of the Medicine department. The patients were clinically assessed regarding the onset of symptoms, comorbidities, contraindications list and general examination with vital signs assessment and a detailed neurological assessment along with NIHSS. Neuroimaging was done with a CT scan to confirm that it is the case of ischemic stroke and, in some cases, with MR perfusion studies. Routine investigations, including sugars and coagulation profile reports, were collected before proceeding. A

cardiac evaluation with an echocardiogram was done as per requirement. IV antihypertensive (Inj. Labetalol) was given to lower

RESULTS

Out of 20 patients in the present retrospective study, 16 (80%) were males, while the remaining 4 (20%) were females. 18 (90%) patients had anterior circulation stroke, while 2 (10%) patients had posterior circulation stroke. National Institute of health stroke scale Score (NIHSS) was recorded at admission. The NIHSS was less than 15 in 11 patients and more than 15 in 9 cases.

Table 1: Demographic data of the study

		No. of patients	%
NIHSS Score	5-9	2	10
	10-15	9	45
	16-20	5	25
	21-25	3	15
	>25	1	5
Time of onset of symptoms to needle time	0-2 hours	1	5
	2-3 hours	4	20
	3-4.5 hours	15	75
Primary outcome	Yes	5	25
	No	15	75
Haemorrhagic transformation classification	Class 1a	2	10
	Class 1b	1	5
	Class 1c	1	5
	Class 2	0	0
	Class 3a	0	0
	Class 3b	0	0
	Class 3c	0	0
Haemorrhage complication	Class 3d	0	0
	Symptomatic intracranial haemorrhage	0	0%
	Asymptomatic haemorrhagic transformation	4	20%

Time from the onset of symptoms to needle time was recorded between 0-2 hours, 2-3 hours and 3-4.5 hours. Out of 20 patients, 19 (95%) patients had reached the hospital after 2 hours of acute ischemic stroke. The Primary outcome is a reduction of NIHSS by at least 4 points 24 hours after thrombolysis. Out of 20 patients, 5 (25%) patients showed a reduction of NIHSS by 4 points, so they achieved the primary outcome in the present study. None of the 20 patients showed significant symptomatic intracranial haemorrhage. 4 (20%) patients had a subtle asymptomatic haemorrhagic transformation, but all these patients had shown clinical improvement at the time of discharge. Four patients who were shown intracranial haemorrhage were supervised for any haemorrhage complication. All 4 patients were shown asymptomatic

haemorrhagic transformation. Among 2 deaths, one patient had bilateral ICA occlusion, and another had unilateral ICA and MCA occlusion. Despite treatment, both patients died due to significant mass effects [Table 1]. The NIHSS was calculated at the time of discharge. It was found that 5 (25%) patients had NIHSS between 6-10 and 11-15, while 4 (20%) patients had NIHSS between 0-5 and 16-20.

The Secondary outcome was measured as MRS Score after 3 months of IV thrombolysis [Table 2]. Regarding follow-up of patients after 3 months, 9 patients (45%) had a favourable outcome with an MRS scale of 0-2 and 2 (10%) patients with MRS 3. On the other hand, a less favoured outcome was observed in 4 (20%) patients with MRS 4 and 3 (15%) patients with MRS 5 at the end of 3 months.

Table 2: NIHSS at discharge

		No. of patients	%
NIHSS Score at discharge	0-5	4	20
	6-10	5	25

	11-15	5	25
	16-20	4	20
	>20	0	0
	Death	2	10
MRS score	0	2	10
	1	5	25
	2	2	10
	3	2	10
	4	4	20
	5	3	15
	6	0	0

DISCUSSION

The use of mechanical thrombectomy, IV thrombolytic treatment, or combined thrombectomy with thrombolytic treatment for acute ischemic stroke in the first few hours has been growing recently. In the present study, IV thrombolytic therapy, CT brain imaging, and in some cases, MRI brain and perfusion are used and treated as per the recommendations in the literature. The ECASS III.^[5] study examined the safety and efficacy of IV tPA given between 3 and 4.5 hours. The IV tPA group's sICH rate was noticeably higher. The mortality rate remained constant. However, the SITS-International Stroke Treatment Registry (SITS-ISTR).^[6] found no discernible difference between patients treated within the 3-hour and 3- to 4.5-hour time windows in terms of incidence of sICH, death, or functional independence (mRS<2). The updated pooled analysis of ATLANTIS, ECASS-I, and NINDS was updated with data from ECASS-II, ECASS-III, and EPITHET. The treatment effect size decreased as the time from stroke onset increased. Although the IV tPA group was significantly more likely to have sICH, there was no difference in mortality between the control and IV tPA groups for the 3- to the 4.5-hour time window.^[7] In response to the exclusion of older patients in prior stroke trials, the third International Stroke Trial (IST-3) was conducted. The study demonstrated a greater benefit for IV tPA in patients older than 80.^[8] In the Cochrane review, studies from 27 trials suggested that thrombolytic therapy given up to 6 hours after the onset of symptoms significantly reduced the likelihood of death or dependency (mRS 3-6) at 3 to 6 months after stroke, and patients older than 80 years of age benefited just as much as younger patients. There were no patients over the age of 80 in our study. But the benefits and complications were the same for people over and under 70.^[9] In our study, we utilized an MRI brain and perfusion study in 9 cases, of which 7 were with clear <4.5 hrs time window and 2 cases had early morning stroke with the deceptive onset time issue, which we took for IV thrombolytic treatment. There was no increase in sICH with better MRS at 3 months. Thomalla G et al. concluded that the outcome of IV-tPA therapy in an expanded time window of 6 hours in MRI-selected patients was better than in unselected patients from the pooled rtPA stroke trials.^[6] Schellinger PD et al.

compared MRI-based thrombolysis with CT-based thrombolysis. They concluded that MRI-based thrombolysis was more effective and safer than CT-based thrombolysis.^[10] Ogata T et al. reviewed data from two studies using alteplase in patients with acute stroke 3-6 hours after its onset in two groups of patients while using the outcome based on MRI and concluded that alteplase improved the reperfusion rates significantly.^[11] In the present study of 20 patients, the defined primary outcome of a significant reduction in the NIHSS stroke scale was seen in only 5 patients (25%), which is less than in other studies. Probably the lesser primary outcome of 9 patients with NIHSS > 15 and 10 patients with NIHSS 10-15 implies a larger area and larger vessel with lesser recanalisation using only IV thrombolytic therapy. In the present study, none of the patients showed any symptomatic intracerebral haemorrhage. The significant post-thrombolytic-related bleeding complication was also less as compared to other studies. The mortality in 2 patients was due to significant mass effect despite treatment and not due to haemorrhagic complications of thrombolytic therapy. Regarding improvement in neurological status, about 70% had improvement in NIHSS compared to admission NIHSS at the time of discharge. At the end of 3 months, it was observed that 9 (45%) patients had an MRS scale of 0-2, and 2 (10%) patients had an MRS scale of 3. These findings were considered a favourable outcome of the present study. There had been some betterment in improvement in morbidity at 3 months.

CONCLUSION

The goal of ischemic stroke management in the early hours is to improve reperfusion as soon as possible, making use of the facility as it is available and practical. As recommended months with fewer hemorrhagic consequences, IV thrombolytics such as alteplase should be utilised to get a comparatively better functional status during a recovery phase.

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