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Clinical profile of patients with acute ischaemic stroke undergoing thrombolysis in a tertiary hospital- A retrospective observational study

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ABSTRACT

Background: Acute ischaemic stroke is one of the most important causes of morbidity and mortality in the Indian subcontinent. Intravenous thrombolysis has revolutionized the treatment of acute stroke and has shown good evidence of its efficacy in most patients.

Objectives: The primary objectives of the study were to study the clinical and demographic profile of stroke patients undergoing intravenous thrombolysis and to determine their functional outcome after three months.

Materials and Methods: The study was done by retrospective chart analysis of all patients with acute stroke in Neurology department undergoing intravenous thrombolysis over a one year period. Primary outcome was measured by assessing the Modified Rankin Scale after three months.

Results: A total of 56 patients underwent intravenous thrombolysis in the study period of which 68 percent were males. The average age of the study population was 62.4 years. The most common co-morbidities noted were hypertension followed by dyslipidemia, type 2 diabetes mellitus, coronary artery disease and chronic kidney disease among others. The average duration of the window period and door to needle time were 148.4 minutes and 66.3 minutes respectively. Intracranial haemorrhage was noted in seven patients (12.5%) of which six expired. Favourable outcome defined by MRS score of 0-2 was achieved in almost 68% of all patients undergoing thrombolysis.

Conclusions: Intravenous thrombolysis is an effective mode of treatment for acute stroke with favourable outcomes obtained in the majority of patients undergoing the same.

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1. Introduction

Stroke is a worldwide health problem. It is one of the most common causes of morbidity and mortality, in developed as well as in developing countries. WHO has defined stroke as 'rapidly developed clinical signs of focal disturbance of cerebral function, lasting more than 24 hours or leading to death, of mainly vascular origin'.¹ Stroke is the second most common cause of mortality in the world and third most common cause of disability globally.² Stroke is a global

health problem attributing to morbidity and mortality in both developing and developed nations worldwide.

Data regarding prevalence of stroke in India is less. However, it can be extrapolated from the Western data. Banerjee et al. in their study in 2001 found that the crude prevalence rate of stroke in India was 147/100,000 and the annual incidence rate was approximately 36/100,000.³ Overall prevalence of stroke ranges from 147-922/100,000 in various Indian studies.⁴

Stroke patients are at the highest risk of death in the first few weeks after the event, and about half (20-50%) of the victims die within the first month depending on the type,

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severity, age, comorbidities and effectiveness of treatment of complications.⁴ Stroke patients may end up with functional deficits resulting in disability and other poor neurologic sequelae.⁵ Adequate and prompt treatment is therefore of great importance.

Throughout the years, a variety of therapies have revolutionized acute stroke care including the usage of thrombolytic therapy, endovascular thrombectomy, and revascularization methods integrated with efficient neuroimaging, and appropriate clinical evaluation of patients.^{6,7}

Thrombolytic agents are drugs which act by leading to resolution of thrombi⁸ and clot lysis. They act by converting inactive plasminogen into plasmin which subsequently dissolves fibrin within the thrombus and causes its lysis. Alteplase was approved initially for intravenous thrombolysis.^{9,10} This was followed subsequently by Tenecteplase. The outcome of patients undergoing acute thrombolysis is assessed after a period of 3 months follow up. Positive outcome is assessed by the quality of life attained by the patients after discharge.¹¹ Attainment of a productive and independent life is an indicator of success of the treatment.¹² The Modified Rankin Scale(MRS) is the most widely used tool for assessment of the quality of life at follow up.

The present research was conducted with the objective to study the clinical profile of patients with acute ischemic stroke receiving intravenous thrombolysis with Alteplase. There are a few studies in the Indian setting looking at the efficacy of thrombolysis as an effective treatment of stroke. To fulfil this unmet need in the management of patients with stroke in developing countries with limited resources, we aim to conduct a retrospective study among patients with acute ischaemic stroke admitted to the Department of Neurology at MOSC Medical College, Kolenchery, Kerala, India to determine the clinic-epidemiological profile and outcome of patients with stroke undergoing thrombolysis.

2. Materials and Methods

2.1. Study design

Retrospective analysis of medical records of patients with acute ischaemic stroke admitted in the Neurology department over a period of twelve months from the date of commencement of study.

2.2. Study period

One year from the start of the study.

2.3. Study setting

Department of Neurology, MOSC Medical College, Kolenchery.

2.4. Study population

Patients admitted with acute ischaemic stroke undergoing intravenous thrombolysis in mid-Kerala

2.5. Inclusion criteria

1. All cases (of age 18-80 years) with acute ischemic stroke receiving IV thrombolysis with rtPA-alteplase within four and half hours (window period) of onset of symptoms

2.6. Exclusion criteria

1. All cases of Acute ischaemic stroke not receiving IV thrombolysis
2. History of gastrointestinal bleeding in preceding three weeks
3. Stroke /Head injury in preceding 3 months

2.7. Study instruments

The Modified Rankin Scale (MRS) is a globally accepted and standardized outcomes rating scale for patients post-stroke. It is used to categorize the level of functional independence with reference to activities that were possible before the onset of the stroke.

The usual technique of performing the MRS is a guided interview which is carried out by asking the patient about their activities of daily living.

This is divided into five sections that include:

1. Whether the patient requires constant care
2. Basic ADL (Activities of Daily living)- Does the patient require assistance for basic routines like eating, going to the toilet, walking
3. Instrumental ADL – Is assistance essential for preparing a simple meal, looking after money, shopping
4. Whether the patient finds it difficult to participate in social functions and activities which they previously attended
5. The presence of common stroke symptoms like difficulty reading/writing, speaking or word finding, imbalance, blurred vision, numbness, dysphagia, or other symptoms due to stroke.

The administration of the MRS does not require any specialized equipment nor any formal training. The entire process will take only around 10-15 minutes.

2.8. Modified rankin scale

Score Disability

0- The patient has no residual symptoms.

1- The patient has no significant disability; able to carry out all pre-stroke activities.

2- The patient has slight disability; unable to carry out all pre-stroke activities but able to look after self without daily help.

3- The patient has moderate disability; requiring some external help but able to walk without the assistance of another individual.

4- The patient has moderately severe disability; unable to walk or attend to bodily functions without assistance of another individual.

5- The patient has severe disability; bedridden, incontinent, requires continuous care.

6- The patient has expired (during the hospital stay or after discharge from the hospital).

2.9. Statistical analysis

All the categorical variables will be summarized using frequency and percentage.

Quantitative variables will be summarized using mean and SD(Standard Deviation) if data follows normality assumption else using Median and IQR [Q 1 , Q 3]. Kolmogorov-Smirnov test and Shapiro test will be used to check the normality of the data. For this study, we have used McNemar test to find out the sample size. $P < 0.05$ will be considered as statistically significant and the entire analysis will be performed using SPSS and EZR software.

2.10. Study procedure

A detailed history of presenting complaints including exact time of onset was taken and a thorough clinical examination was done. Patients were assessed according to MRS score taken at the time of admission. All blood investigations, cardiac evaluation and imaging including plain CT and MRI were done and recorded. Patients were admitted in the neuro intensive care unit and intravenous thrombolysis was done using Alteplase after taking a proper informed consent.

A repeat scan was done after thrombolysis to rule out any hemorrhage workup for stroke was done including neck vessel doppler and an echocardiogram. Patients were discharged and routinely followed up. At the end of 3 months patients were reassessed by using Modified Rankin Score (MRS) to reflect the quality of life. This scoring is a measure of the improvement in quality of life in the post stroke time period.

3. Objectives

3.1. Primary objectives

1. To study the clinical and demographic profile of patients with acute ischaemic stroke undergoing intravenous thrombolysis.
2. To determine the effectiveness of IV thrombolysis (via MRS) and treatment outcomes in patients with acute ischemic stroke.

3.2. Secondary objectives

1. To estimate the door to needle time.
2. To estimate the incidence of complications of intravenous thrombolysis in patients receiving the treatment.

4. Results

1. A total of 56 patients in total were recruited in this study.
2. Of these, 38 were male(67.9%) and 18 (32.1%) were female

4.1. Age group

1. The maximum age group in the patients studied falls in the range of 61-75 years of age with 55.35 % of study population in this group
2. The least common age group seen is the age group above 75 yrs comprising 5.35 % of the study population.
3. The mean age of presentation is 62.38 years, with a standard deviation of 10.714 (Table 3)

4.2. Risk factors

1. The study population who had a number of risk factors including hypertension and Diabetes was about 70 %.
2. 27% had only a single risk factor known to be associated with stroke.
3. 3% had no associated risk factors for stroke.

Among these comorbidities, the most common were hypertension (66.1%), followed by dyslipidemia (58.9%), type 2 diabetes mellitus (41.1%), coronary artery disease (10.7%), and chronic kidney disease (5.4%), along with hypothyroidism, polycythemia and systemic vasculitis.

4.3. Blood pressure at admission

1. Most of the representative population had a blood pressure in the range of BP $< 185/110$ mmHg-almost 82%
2. 18% of them had high BP found to be greater than 185/110mmHg. These patients required administration of blood pressure medications before start of thrombolysis.
3. The mean (standard deviation) systolic blood pressure at admission was 159.39 (23.655) mm Hg, and the mean (standard deviation) diastolic blood pressure at admission was 89.04 (8.928) mm Hg.

4.4. Time of presentation-window period

1. The window period in the study was defined as patients who presented within 4.5 hours of onset of symptoms

2. Among them 71.4 % presented within 3 hours of onset.
3. Remaining 28.6 % presented in the extended window period of between 3 and 4.5 hours.
4. Mean window period noted was 148 minutes.

4.5. Door to needle time

This was defined as the time taken from arrival in the ER to the time the thrombolysis is started in the ICU.

25 cases, which make up 44.6% of the total, had a door to needle time of 60 minutes or less and 3 (55.4%) cases had a door to needle time exceeding 60 minutes.

The mean door to needle time noted was 66 minutes.

4.6. Imaging done

All patients had either CT/CT angiogram or MRI/MR Angiogram done.

48 % of patients had CT done while 52 % had MRI done

Perfusion studies were done only in a few patients due to time constraints.

NIHSS (National institute of health stroke scale) AT ADMISSION.

Most of the cases had NIHSS at admission between 5 and 9- 62%.

8 Percent had NIHSS greater than 9

30 Percent had NIHSS less than 5

Mean NIHSS was noted to be 6

4.7. Stroke distribution

From this study we found that 44 (78.6%) cases specifically involved the anterior circulation, 10 (17.9%) cases associated with the posterior circulation and 2 (3.6%) cases affected both the anterior and posterior circulations. Aphasia was present in 13 patients (23.2%) and 43 patients (76.8%) had no language disorder.

4.8. Complications

Out of 56 patients, complications arose during their hospital stay in 11 cases, accounting for 19.6% of the total. Within this, 7 patients, which is equivalent to 63.6% of 11, faced the complication of intracranial hemorrhage. Notably, 6 of these 7 cases resulted in intracranial hemorrhage with a fatal outcome. One case (10.4%) exhibited symptoms of hematemesis and dysuria another one case (10.4%) developed an intramuscular hematoma in the right forearm. One case (10.4%) experienced a recurrence of stroke two weeks after the initial event.

4.9. MRS at admission and 3 months

The Modified Ranking Scale (MRS) was utilized for assessing disability both upon admission and at the time of discharge . In the scoring at admission, 25% of the study population achieved an MRS score of ≤ 2 ,

while the remaining 75% had an MRS score exceeding 2(Table 1). Similarly, upon discharge, 67.9% of the patients were categorized as having an MRS score of ≤ 2 , with the remaining 32.1% having an MRS score greater than 2.(Figure 1)

MRS Score of 0-2 is considered a favourable outcome.

At discharge, 68% of patients had an MRS score of between 1 and 2 denoting good outcome following thrombolysis.

Only 21 percent of patients had MRS more than 2 -Poor outcome.

Illustrates the association between MRS scores at the three-month and several factors, including the window period in hours, NIHSS scores at admission, BP at admission, and MRS scores at admission. Our analysis revealed a significant association between NIHSS scores at admission and MRS scores at admission with MRS scores at discharge ($p < 0.05$).(Table 2)

4.10. Value less than 0 05 is statistically significant

NIHSS-National Institute of Health Stroke Scale,BP-Blood Pressure,MRS-Modified Rankin Scale

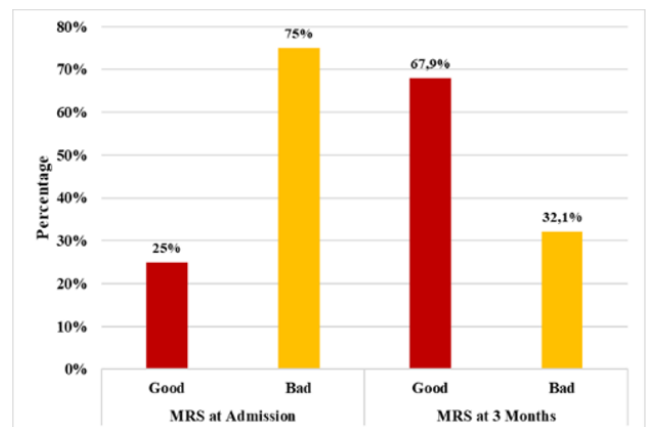


Figure 1: Modified ranking score at admission and discharge percentages

5. Discussion

Thrombolysis has played an important role in influencing the outcome of ischemic stroke. Early intervention has helped in improving morbidity and quality of life in stroke patients.

The clinical profile of patients in our study was analysed and compared with various studies done previously.

A total of 56 patients were enrolled in this study of which 68 % was male and the rest females.

Another similar study on stroke patients done by Boehme AK et al.¹³ shows the gender distribution as predominant in males as is common in most demographic studies.

Table 1: MRS scores at admission and after 3 months

Variable (N = 56)		N (%)
MRS at 3 Months	Good (≤ 2)	38 (67.9%)
	Bad (> 2)	18 (32.1%)
MRS at Admission	Good (≤ 2)	14 (25%)
	Bad (> 2)	42 (75%)

Table 2: Association between the MRS Score after three months and other variables

		MRS at 3 Months		P - value
		Good (≤ 2) (38)	Bad (> 2) (18)	
Window Period (Hrs)	<3	25 (65.8%)	15 (83.3%)	0.175 (Pearson Chi-square Test)
	3 – 4.5	13 (34.2%)	3 (16.7%)	
NIHSS at Admission	<5	17 (44.7%)	0	<0.001* (Fisher’s Exact Test)
	5 – 9	3 (7.9%)	1 (5.6%)	
	>9	18 (47.8%)	17 (94.4%)	
BP at Admission	<185/110	33 (86.8%)	13 (72.2%)	0.263 (Fisher’s Exact Test)
	≥185/110	5 (13.2%)	5 (27.8%)	
MRS at Admission	Good (≤ 2)	13 (34.2%)	1 (5.6%)	<0.001* (McNemar Test)
	Bad (> 2)	25 (65.8%)	17 (94.4%)	

Table 3: Descriptive variables of patients undergoing thrombolysis

Age(years)	62.38 ± 10.714	63 (56, 71.5)
SBP at the time of admission (mmHg)	159.39 ± 23.655	160 (140, 180)
DBP at the time of admission (mmHg)	89.04 ± 8.928	90 (80, 94.5)
Window Period (min)	148.39 ± 141.941	120 (90, 187.5)
Door to Needle Time (min)	66.43 ± 32.484	67.5 (35, 90)

SBP-Systolic blood pressure, DBP-Diastolic blood pressure, SD-Standard Deviation

In our study the mean age was 62 years which was lesser in comparison to a similar study done by Volans.P et al¹⁴ which showed a mean age of 69 years and another study done by Werner Hacke et.al¹⁵ that showed a mean age of 64.9 years. An Indian study done by Ramasamy et al,¹⁶ showed mean age of 59 years which was consistent with our results.

Kim BJ et al¹⁷ in a study looked at the prevalence of risk factors associated with stroke and concluded that multiple risk factors were present in most cases, which was in keeping with our study. About 70 % of our study population had multiple risk factors like hypertension, diabetes, dyslipidemia, chronic kidney disease and cardiac illness. 27% had only a single risk factor, the most common being hypertension as is seen in most other studies. 3% of the study population had no pre-existing risk factors which emphasises the fact that stroke can occur without any major contributing factors in many patients.

82 % of the study population in our study presented with a BP <185/110 mmHg and 18 % with BP >185/110 requiring prior administration of agents before thrombolysis. The mean SBP is 159 mmHg and mean DBP is 89 mmHg which correlates well with other studies including the study done by Qureshi AI et al.¹⁸

In this study, the mean time period from onset of symptoms to presentation in ER -Window time- was 148

minutes. This was lesser compared to the window period time in studies including Jagini et al¹⁹ and Ramasamy et al.⁷² percent of cases presented within 3 hours while the rest presented in the extended window period of 3 to 4.5 hours.

The door to needle time-time taken from the arrival in ER to the start of the lysis was found to be a mean of 66 minutes. This was comparable with other studies including Jagini et al.¹⁹

Delay in decision making by patient relatives and also delays in shifting of patient contributed to cases with prolonged door to needle time.

In a similar study done by Jagini et al, most of the cases had a mean NIHSS ranging from between 10 and 22(almost 80%). The mean NIHSS was found to be about 13.5. In our study 62 % of them are in the range of score 5-9, with mean NIHSS of only 6. This could be because of early presentation in most of our patients.

Most of the cases- almost 80 percent- were found to involve the anterior circulation.

MRI was done in more than 50 percent of cases which is high compared to other studies.

The complications after the thrombolysis are very less in most of the patients (87%). A small proportion suffered intracranial hemorrhage-12.5% -which is higher than studies done by Sandercock et al²⁰ in which the

Table 4: Descriptive variables of thrombolysis patients

Variable (N = 56)	N (%)	
Age	30 – 45 years	4 (7.1%)
	46 – 60 years	18 (32.1%)
	61 – 75 years	31 (55.4%)
	> 75 years	3 (5.4%)
Sex	Male	38 (67.9%)
	Female	18 (32.1%)
Comorbidities (Yes = 54 (96.4%))	Type 2 Diabetes Mellitus	23 (41.1%)
	Hypertension	37 (66.1%)
	Coronary Artery Disease (CAD)	6 (10.7%)
	Dyslipidaemia (DLP)	33 (58.9%)
	Chronic Kidney Disease (CKD)	3 (5.4%)
	Atrial Fibrillation (AF)	2 (3.6%)
	Old stroke	2 (3.6%)
	Hypothyroidism	1 (1.8%)
	Chronic Liver Disease (CLD)	1 (1.8%)
	Old Traumatic Brain Injury (TBI)	1 (1.8%)
	Manic depressive disorder	1 (1.8%)
	Systemic Vasculitis	1 (1.8%)
	Polycythaemia	1 (1.8%)
Window Period (Hrs)	<3	40 (71.4%)
	3 – 4.5	16 (28.6%)
Blood Pressure at the time of admission	<185/110	46 (82.1%)
	≥185/110	10 (17.9%)
Door to Needle Time (min)	≤ 60	25 (44.6%)
	> 60	31 (55.4%)
Circulation	Anterior	44 (78.6%)
	Posterior	10 (17.9%)
	Anterior and Posterior	2 (3.6%)
Aphasia	Present	13 (23.2%)
	Absent	43 (76.8%)
NIHSS at Admission	<5	17 (30.4%)
	5 – 9	35 (62.5%)
	>9	4 (7.1%)
MRC Power grade at Admission	0.2 – 0.8	24 (42.9%)
	0/5	13 (23.2%)
	4+/5	2 (3.6%)
	Normal	17 (30.4%)
MRS at Admission	1	1 (1.8%)
	2	13 (23.2%)
	3	16 (28.6%)
	4	18 (32.1%)
	5	8 (14.3%)
MRS at 3 Months	1	18 (32.1%)
	2	20 (35.7%)
	3	12 (21.4%)
	Expired	6 (10.7%)
Imaging	CT	27 (48.2%)
	MRA	11 (19.6%)
	MRI	18 (32.1%)
Complication (Present = 11 (19.6%))	Intracranial haemorrhage (death 6 (10.7%))	7(12.5%)
	Hematemesis and dysuria	1 (1.8%)
	Intramuscular hematoma on right forearm	1 (1.8%)
	Recurrence of stroke after 2weeks	1 (1.8%)
	Worsening of motor power	1 (1.8%)

MRS-Modified Rankin Scale

MRC -Medical Research Council

NIHSS-National Institute of Health Stroke Scale

occurrence of hemorrhage is 7.7% but less than a study by Fisher et al.²¹ This could be due to an older study population in this study. There were 6 deaths due to symptomatic intracranial hemorrhage. There were no cases of anaphylaxis reported.

Modified Rankin Score was done in our study to assess the disability and quality of life at the end of 3 months. A score of between 0-2 is considered as a good outcome which provides independent life to the patients following a stroke. A significant reduction in mRS score at the end of 3 months is considered as the primary outcome of this study. The overall score of mRS in the range of 0-2 -good outcomes- in our study is 68.8 %. This correlates well with a similar study done by Jagini et al who stated that 76.9% had favourable outcome at the end of 3 months as assessed by MRS scale. This was higher as compared to a largest single centre stroke study done by Jan Sobesky et al²² which showed only 53%. and German stroke study²³ which showed only 35%.

Significant association was found between NIHSS score at admission and MRS at 3 months. Patients having higher NIHSS scores were found to have a poorer long term outcome. There was no significant association seen between blood pressure at admission and window period with long term outcome.

Significant association was found between MRS score at admission and at 3 months thereby confirming the beneficial effects of thrombolytic therapy.

5.1. Inference

This study shows a significant improvement in patient outcomes following therapy. 68% of the patients showed improvement in their quality of life at the end of 3 months. This signifies that the use of intravenous thrombolysis in patients presenting with acute ischemic stroke within the window period of 4.5 hours is beneficial in the long term for the patient. Complications of this therapy are very rare and occurrence of major life threatening complications like intracranial bleed is a rare event. This study promotes the widespread use of intravenous thrombolysis as an effective therapy for acute ischaemic stroke.

6. Conclusions

This study looked at 56 patients over the last one year presenting in the window period who underwent intravenous thrombolysis.

1. The age group that was most prevalent in our study population was 61-75yrs with 55.5 % and least is >75 years with 5.35 %.
2. Males are more commonly affected (68%) as compared to females.
3. 72% of patients presented within the window period of <3hrs and 28% in the extended window of 3-4.5 hrs.

4. Mean window period was 148 minutes. This value was smaller compared with various other similar studies. This could be due to increased awareness in the general public.
5. Door to needle time found to be 66 minutes. The ideal time according to international standards is less than one hour. The delay could be secondary to time needed for decision making by patient attenders. No significant association was seen between window period and final outcomes.
6. Presence of multiple risk factors was seen in most patients included in the study (70%).
7. The mean NIHSS at the time of admission in our study group was 6. Higher NIHSS scores were found to correlate with poorer outcomes.
8. 87.5% had no significant complications, 12.5 % had intracranial hemorrhage. This value is higher compared to similar studies. Patient selection could be a factor in this.
9. 6 patients died due to symptomatic intracranial hemorrhage
10. A good outcome as defined by an MRS score of 0-2 at the end of 3 months was achieved in 68% of patients. The good outcome is at par with similar studies.

Overall, the study proves that intravenous thrombolysis is an effective treatment for acute ischaemic stroke with good outcomes seen in more than two thirds of patients. Better patient selection could lead to lesser incidence of complications.

7. Limitations of study

The main limitations of the study are the small sample size and the short follow up of the patients

8. Source of Funding

None.

9. Conflict of Interest


None.

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