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Study of clinical outcome and quality of life of patients undergoing intravenous thrombolysis for acute ischemic stroke in tertiary care center

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Abstract

Background: Modern management of stroke includes rapid assessment, protocol wise approach, thrombolysis for acute ischemic stroke, early specialist management and appropriate monitoring. The aim of present study is to assess the clinical outcome and improvement in quality of life of patients undergoing intravenous thrombolysis for acute ischemic stroke in tertiary care center. **Material and Methods:** Present study was single-center, prospective, descriptive study, conducted in patients of age 19-80 years, either gender, admitted as diagnosed case of acute ischemic stroke, underwent thrombolysis. **Results:** In present study, among 30 patients, majority were from 51-60 years age group (43.3 %), male patients were 63.33 %. Majority presented within 3 hours (76.67 %), had multiple risk factors (56.67 %), blood pressure at the time of admission < 185/110 mm Hg (90 %), did not required intravenous anti-hypertensives for acute control of blood pressure (83.33 %) & had normal capillary blood glucose levels at the time of presentation (63.33 %). The NIHSS score at the time of admission was in the range of 10-22 in majority of cases (76.67 %) as compared to score in range of 5-9 (23.33 %), mean score at presentation was 12.60 ± 4.17. After 24 hrs of admission the NIHSS score was in the range of 5-9 in majority cases (70 %) as compared to score in range of 10-22 (30 %), mean score was 7.83 ± 5.299. The primary outcome (i.e.) reduction of NIHSS by 4 points from the initial score is present in 60% of the study population. **Conclusion:** Use of intravenous thrombolysis in patients presenting with acute ischemic stroke within the window period of 4.5 hours is beneficial for the patient, and there is a great improvement in quality of life which is assessed after 3 months.

Keywords: intravenous thrombolysis, acute ischemic stroke. NIHSS, Modified Rankin Score

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Introduction: Institution of intra-venous thrombolysis as treatment modality for acute ischemic stroke has revolutionised the field of Neuromedicine in the past few years.[1] The concept of thrombolysis and various endovascular interventions for acute stroke has opened the doors of the field of Interventional Neurology. The better availability of Neuro-imaging services has enhanced the decision-making capacity for using acute thrombolysis.[1,2]
Like myocardial infarction, acute ischemic stroke (AIS) is equivalent to "Brain Attack". It should be treated as acute emergency and top priority to be given during triage. Preventing the rapid loss of neurons due to ischemic insult, and preserving the ischemic penumbra from permanent damage is the corner stone of the thrombolytic therapy in AIS.[3] Effective treatment with proper response is very important in prevention of complications and improving the quality of life of the patient.[3,4]
Modern management of stroke includes rapid assessment, protocol wise approach, thrombolysis for acute ischemic stroke, early specialist management and appropriate monitoring.[5] Thrombolysis is a key intervention for patients presenting early within window period of 4.5 hours. Long term outcome of the therapy is to improve physical quality of life and reduction of dependency on others.[6] The aim of present study is to assess the clinical outcome and improvement in quality of life of patients undergoing intravenous thrombolysis for acute ischemic stroke in tertiary care center

Material And Methods
Present study was single-center, prospective, descriptive study, conducted in department of internal medicine, at Govt. Stanley Medical college. Chennai, India. Study duration was of 6 months (March 2018 to August 2018). Study approval was obtained from institutional ethical committee.
Inclusion criteria

- Patients of age 19-80 years, either gender, admitted as diagnosed case of acute ischemic stroke, underwent thrombolysis with characteristics such as
- ✓ Onset of symptoms to time of drug administration < 4.5hrs,
- ✓ Measurable neurological deficit (impairment of language, motor function, cognition and/gaze, vision or neglect)
- ✓ Score for stroke severity >4 on the NIHSS score
- Willing to participate in present study

Exclusion criteria

- Age >80 yrs
- Minor stroke (NIHSS<4) / major stroke(NIHSS>22)
- Prior use of antiplatelet / GI bleed in preceding 21 days
- Stroke /TIA/Head injury in preceding 3months
- Myocardial infarction in preceding 3 months
- Major surgeries in preceding 14 days
- Radiologically demonstrable stroke with ASPECT score <6

Study was explained to patient's relatives in local language & written consent was taken for participation & study. The detailed history of the patients was recorded and patients underwent a detailed clinical examination. Patients were assessed according to NIHSS (National Institute of Health Stroke Scale) score at the time of admission. Early routine investigations including imaging with non-contrast CT scan were done.
Patients were thrombolysed using intra venous Alteplase 0.9 mg/kg (10% of dose as bolus and 90% over hour). After administration of intravenous thrombolytics, patients were observed in ICU. Reassessment of patient was done after 24 hours to look for primary

outcome i.e., decrease in NIHSS score by ≥4 indicating good prognosis in that patient. Repeat CT is done to rule out any bleeding complications.
After stabilizing the patient, they were started on routine stroke management with anti-platelets and rehabilitation therapy. Patients were discharged and routinely followed up. At the end of 3 months patients were assessed by using Modified Rankin Score. Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Statistical analysis was done using descriptive statistics.

Results

In present study, among 30 patients, majority were from 51-60 years age group (43.3 %) & least were from under 40 years (6.67 %). The mean age of presentation was 54.77 ± 8.86 years. Among the patients, male patients were 63.33 % & female patients were 36.67 %.

Table 1: Age & gender distribution

Characteristics	No. of patients	Percentage
Age groups (in years)		
≤ 40	2	6.67
41-50	9	30
51-60	13	43.33
61-80	6	20
Mean age (mean±SD)		
Gender		
Male	19	63.33
Female	11	36.67

In present study, majority presented within 3 hours (76.67 %), had multiple risk factors (56.67 %), blood pressure at the time of admission < 185/110 mm Hg (90 %), did not required intravenous anti-hypertensives for acute control of blood pressure (83.33 %) & had normal capillary blood glucose levels at the time of presentation (63.33 %). The mean capillary blood glucose at presentation was 166 ± 54.425 mg/dl.

Table 2: General characteristics

Characteristics	No. of patients	Percentage
Time of presentation (window period)		
≤ 3 hrs	23	76.67
3- 4.5 hrs	7	23.33
RISK FACTORS		
Nil	6	20
Single	7	23.33
Multiple	17	56.67
Blood pressure at the time of admission		
<185/110 mmHg	27	90
≥ 185/110 mmHg	3	10
Need for anti-hypertensive		
Yes	5	16.67
No	25	83.33
Capillary blood glucose at the time of admission		
Normal	19	63.33
High	11	36.67

In CT scan on admission, 16.7% presented with early CT changes while 83.3% presented with normal CT. The mean ASPECT SCORE was 9.60 ± 0.932. In CT scan after 24 hours of admission 50% the study population had ischemic changes, 43,33 % normal CT & 6.67 % had hemorrhage.

Table 3: CT scan findings

CT scan findings	No. of patients	Percentage
AT ADMISSION		
Early changes	5	16.67
Normal	25	83.33
AFTER 24 HOURS		
Ischemic changes	15	50
Normal	13	43.33
Hemorrhage	2	6.67

The NIHSS score at the time of admission was in the range of 10-22 in majority of cases (76.67 %) as compared to score in range of 5-9 (23.33 %), mean score at presentation was 12.60 ± 4.17. After 24 hrs of admission the NIHSS score was in the range of 5-9 in majority cases (70 %) as compared to score in range of 10-22 (30 %), mean score was 7.83 ± 5.299. The primary outcome (i.e.) reduction of NIHSS by 4 points from the initial score is present in 60% of the study population.

Table 4: NIHSS (National Institute of Health Stroke Scale) score

NIHSS	No. of patients	Percentage
At the time of admission		
5-9	7	23.33
10-22	23	76.67
AFTER 24 HOURS		
5-9	21	70
10-22	9	30
Primary outcome: (reduction in NIHSS score by 4)	18	60

In present study, 6.67 % had minor bleeding manifestations & 6.67 % had skin rashes. 86.67 % had no complication after the therapy. No one had major bleeding manifestations.

Table 5: Complications

Complication	No. of patients	Percentage
Minor bleeding manifestations	2	6.67
Skin rashes	2	6.67
No complication	26	86.67

In present study, Modified Rankin Score was 1 in majority patients (30 %), followed by score of 0 &2 (23.33 % each) & score of 3 (10 %). The mean score was 1.70 ± 1.557

Table 6: Modified Rankin Score

Modified Rankin Score	No. of patients	Percentage
0	7	23.33
1	9	30
2	7	23.33
3	3	10
4	2	6.67

5	1	3.33
6	1	3.33

Discussion

Acute ischemic stroke (AIS) is one of the major health problems causing mortality and long-term morbidity and disability worldwide. Neural tissue is very sensitive to ischemic insult and causes permanent disability once the treatment is delayed. Neuro imaging plays an important role in management of AIS.[7] CT and MRI form the backbone of clinical assessment of acute ischemic stroke. There are many other clinical conditions that may mimic AIS. They are intracranial hemorrhage, seizure, sepsis, cardiogenic syncope, migraine, dementia, nonischaemic spinal cord pathologies, peripheral neuropathy, transient global amnesia, and brain abscess or tumor. Modern imaging techniques are useful in establishing the diagnosis with a high degree of certainty in the very rapid time.[7]

In study done by Boehme AK et al.,[8] noted the gender distribution as predominant in males. In our study also showed male predominance in the patients undergoing thrombolysis. Male comprises of 63% of patients undergoing thrombolysis. Kim BJ et al.[8] noted that the presence of multiple risk factors is more common in patients suffering from acute ischemic stroke. About 57% of the study population had multiple risk factors like hypertension, diabetes, dyslipidemia, smoking, alcoholism and cardiac illness. 23% had single risk factor the most common being hypertension. 20% of the study population had no pre-existing risk factors. This signifies that even in the absence of significant risk factors, acute ischemic stroke can occur. 90% of the study population presented with a BP <185/110 mmHg and 10% with BP >185/110. The mean SBP is155mmHg and mean DBP is 91mmHg which correlates well with the study done by Qureshi AI,.[10]

Bruno A et al.,[11] stated that the mean blood glucose at the time of presentation is about 170mg/dl and about 40% of the patients had high blood sugar levels at the time of presentation. In our study the mean blood sugar level is 166 mg/dl and 37% of patients needed correction of blood glucose levels before thrombolysis

Jagni SP et al.,[12] in his study had maximum number of cases with NIHSS at the time of admission in the range of 10-22 (80%) and the mean NIHSS at admission was 13.5. In our study 77% of them are in the range of score 10-22, with mean NIHSS was 12.60 ± 4.174. This value closely correlates with above study hence statistically significant.

Of the CT brain taken at the time of admission 87.3% were normal. 16.7% had early CT changes. The ASPECT score of those with early CT changes were maximum of 10 and minimum of 7. The mean score is 9.60 ± 0.9. This data correlates well with the study done by Pexman JH et al.,[13] The CT brain taken after 24 hours had ischemic changes in about 50% of cases and 7% had haemorrhagic changes. 43% showed no significant changes. This correlates closely with the data by study of Latchaw RE et al.,[14] which had 56 % of ischemic changes and 6 % had haemorrhagic changes.

The primary outcome of the study is the reduction of NIHSS by ≥4 by 24 hours from the time of admission. Jagni et al.,[12] showed that 57.7% showed significant reduction of NIHSS by 4. Our study showed 60% of cases with positive primary outcome which closely correlates with the above study which is statistically significant.

The complications after the thrombolysis are mostly nil (87%). Only a small proportion suffered minor bleeding manifestations (7%) and skin manifestations by(6%). This correlates with the data from the study by Sandercock et al.,[15] in which the occurrence of hemorrhage is 7.7%. There were no patients in our study who had life threatening major bleeding manifestations or other major complications.

Modified Rankin Score is done to assess the disability and physical quality of life at the end of 3 months. The score of 0-2 is considered as the good outcome which provides independent life to the patients suffering. The better the mRS score the quality of life after stroke will be better. The full outcome of therapy is the significant reduction in mRS score at the end of 3 months which is considered as secondary outcome of this study. The overall score of mRS in the range of 0-2 in our study is 76.6%. This correlates well with the data by Jagni et al.,[12] who stated that 76.9% had favourable outcome at the end of 3 months. This value is statistically significant and many studies show similar outcome.

There is substantial and desirable decrease in NIHSS score 4 in about 60% and 77% showed improvement in their quality of life at the end of 3 months. As per the recent 2018 ASA/AHA guidelines the patients are to be carefully selected and prompt treatment with intravenous thrombolysis is of great use to the patient in preventing permanent disability affecting the quality of life of the patient in the forthcoming years.[3] This ultimately reduce the burden of the society in the form of rehabilitation of lives of people and helps them to lead an independent and dignified life.

Conclusion

Use of intravenous thrombolysis in patients presenting with acute ischemic stroke within the window period of 4.5 hours is beneficial for the patient, and there is a great improvement in quality of life which is assessed after 3 months. Complications of this therapy are also limited and occurrence of major life-threatening complications like intracranial bleed is very less.

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