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A Study on Thrombolysis Outcome in Acute Ischemic Patients

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ABSTRACT
Background: Stroke has been a major concern worldwide. Thrombolysis has brought a new direction for management in acute ischemic stroke. It has served as a catalyst for major changes in the management of acute stroke. It is at the forefront with good evidence of its efficacy within 4.5 hours of symptom onset.
Objectives : To determine demographic profile, co morbidities, clinic radiological profile, efficacy and safety of intravenous alteplase (0·9 mg/kg) in study population.
Methods and materials : We have taken data of acute ischemic stroke patients who underwent thrombolysis with alteplase. Data collection was retrospective and analysed from September 2019 to September 2021.Primary outcome was measured with NIH Stroke Scale (NIHSS) at admission and at discharge; and secondary outcome was measured with modified Rankin score (mRS) and NIHSS at three months.
Results: We collected data of consecutive 35 patients who received alteplase for thrombolysis. Mean age was 53±14.2 years with majority of them being males. Mean duration of hospital stay was eight days. Mean time of onset of symptoms to arrival to ED was 177.2 ± 62 min (range: 60–360). Primary outcome achieved 20 patients(57.14%) ,secondary outcome in 25 patients(71.42%) and poor outcome including death in the remaining 10 patients (28.57%).
Conclusions: Stroke thrombolysis is a safe and effective therapy in actual practice. Its role has helped in reduction of morbidity and mortality associated with acute ischemic stroke.
KEYWORDS: Alteplase, Thrombolysis, Acute ischemic stroke, Complications, NIHSS, mRS.

I. INTRODUCTION

Acute ischemic stroke is a significant concern in present decade in view of rising incidence. It is most common neurological condition and second leading cause of mortality in global ranking after coronary artery disease.1 Thrombolysis restore the cerebral blood flow in acute ischemic stroke and may lead to improvement and restoration of neurologic deficit. With introduction of Alteplase (tPA) for reperfusion therapy has caused a pioneer change in approach to stroke management. It was discovered in 19832 but its use for effective treatment in ischemic stroke was in 1995'3With the licensed time window upto 4.5 hours, National Institute of Neurological Disorders and Stroke (NINDS) has approved intravenous alteplase (recombinant tissue plasminogen activator) a thrombolytic agent for acute ischemic stroke.4,5 Administration of tPA is simple with a total dose of 0.9mg/kg body weight – initiated with 10 percent bolus followed by remaining dose over one hour infusion.6 Complications associated with it are bleeding manifestations like intracerebral haemorrhages and other systemic haemorrhages and, anaphylactic reactions. This study was done in view of assess the effectiveness of alteplase use in ischemic stroke, in correlation with risk factors and severity of stroke.

II. MATERIALS AND METHODS :

This is a retrospective analysis of all patients given intravenous alteplase therapy for acute ischemic stroke from September 2019 to September 2021.Ethical approval was obtained from standard institutional ethical committee. Standardized recommendation for inclusion and exclusion criteria was strictly followed. All patients above 18years presented with acute ischemic stroke in window period were taken for the study. Any prior history of haemorrhage, pregnancy, seizure disorder, bleeding disorder, persistent hypertension at arrival (SBP:185mm Hg or DBP:110mm Hg), NIHSS score of less than 4 at admission were excluded. Informed written consents were taken from all the patients or their relatives. Basic demographic information of the patients with acute

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ischemic stroke to emergency department, who have given informed consent, were collected. All the patients were thoroughly examined and computed tomography (CT) or magnetic resonance imaging (MRI) scan of brain, to rule out hematoma and magnetic resonance imaging stroke protocol to assess early infarct and any evidence of cerebral arterial occlusion was done. Thrombolysis was carried out in emergency department. Baseline risk factors, stroke characteristics, baseline NIHSS scores, mRS scores were collected. Follow up outcome assessed at discharge and 90 days was assessed by NIHSS score and mRS scale after 90days. Primary outcome was measured by improvement of NIHSS score by four or more than four points at the time of discharge. Secondary outcome was measured by mRS score of 0 or 1. Complications after thrombolysis like symptomatic intracranial haemorrhage, systemic haemorrhage, angioedema or any event related symptoms were noted. Simple statistics were used for descriptive analysis. Spearman correlation was used for qualitative correlation of discrete variables. Statistical analysis was done using SSPS version 20.

III. RESULTS :

A total of 35 patients were enrolled for the study. Out of 35,27(77.14%) were males and 8 (22.86%) were females. Mean age of study population was 53±14.42years . Mean age among males was 48.25 and among females was 62.12 Among risk factors, most prevalent were alcohol, smoking, hypertension and diabetes, seen in 15 patients (42.28%), 12 patients (34.42%), 10 (28.57%) and 11(31.42%) respectively. Other risk factors noted were dyslipidaemia in 8 patients (22.86%),4 patients (11.43%)had history of ischemic heart disease and 1 patient each (2.86%) had hypothyroidism, history. One patients had (2.86%) hyperhomocysteinemia. Three patients reported to develop acute ischemic stroke without any significant risk factors. Mean NIHS score at admission 12.63±4.55,at discharge 6.34±3.11 and three mont 3.23±2.97.mean mRS score at admission 3.69±.9,at one month 2.31±.76 and three month .93±.8. In my study mean systolic BP 136.66±23.27 and mean diastolic Bp 88.71±14.21. and mean RBS at admission 150.51±67.58**.** Speech was affected in 25 patients (71.42%) and 10 patients (28.57%) had no speech involvement. About 23 (65.71%) patients had left sided weakness and 12 (34.29%) had right sided weakness. Primary outcome achieved 20 patients(57.14%) ,secondary outcome in 25 patients(71.42%) and poor outcome including death in the remaining 10 patients (28.57%).

TABLE 1: age and sex distribution

	MALE	FEMALE	TOTAL
21-30	2	0	2
31-40	7	0	7
41-50	3	1	4
51-60	10	4	14
61-70	3	1	4
71-80	2	2	2
TOTAL	27	8	35

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GRAPH:1

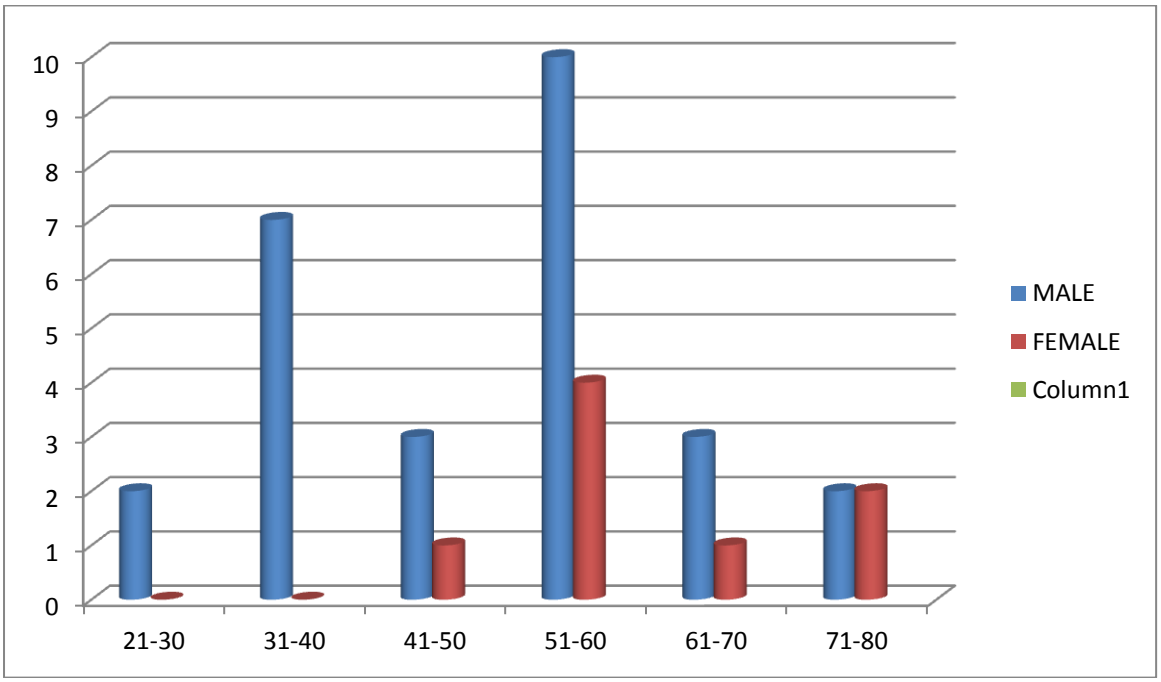

Table 2: Prevalence of Risk factors in the study population

Risk factor	Yes	No	Cumulative percentage(%)
Smoking	12	23	34.42
Alcohol	15	20	42.28
Dyslipidemia	8	27	22.86
Hypertension	10	25	28.57
Diabetes mellitius	11	24	31.42
RHD	4	31	11.43
Hyperhomocystienmia	1	34	2.86
Hypothyroidism	1	34	2.86
Not determined	3	32	8.57

Table 3:charcterstics of AIS

CHARACTERSTICS	
Age	53±14.2
RBS at admission	150.51±67.08
Systolic BP	136.66±23.27
Diastolic BP	88.71±14.21
NIHS score at admission	12.63±4.55
NIHS score 2 hrs after thrombolysis	10.71±5.93
NIHS score at discharge	6.34±3.11
NIHS score at three months	3.23±2.97
mRS score at admission	3.69±.9
mRS score at one month	2.31±.76
Mrs score at three months	.93±.8

Table 4:Base line NIHS Score

Base line NIHS score	No
0-5	2
6-14	20

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15-24	13
>25	0

Table 5:characterstics of patients in the group of favourable and unfavourable outcome

	Favorable	Unfavorable
No	20	15
Age	48.25±11.95	59.33±15.37
Window period	152.75±50.51	155±15.37
Mean NIHS scoe at admission	13.4±4.54	11.6±4.52
Mean RBS	150.05±69.62	151.13±65.94
Systolic BP	133.33±22.89	138.05±24.99
Diastolic BP	86±12.67	90.05±15.9

Table 6 :Spearman correlation of number of risk factors and mRS scores after three months (showed no significant correlation) (mRS – modified Rankin Scale) **Correlations**.

		Number risk factor	Mrs score
Number risk factor	a.correlation coefficient	1.000	.13863
	b.sig.(2-tailed)		.42708
	N	35	35
mRS score	a.correlation coefficient	.13863	1.000
	b.sig.(2-tailed)	.42708	
	N	35	35

Table 7: mRS scores at admission and after three months were quantified. (mRS – modified Rankin Scale)

Grade	mRS on admission	mRS after three month
0	0	8
1	0	17
2	4	2
3	9	2
4	16	0
5	6	0
6	0	0 ,one reffered and 5 deaths

Table 8: Chi – square correlation between window period and mRS scores after three months.

mRS 3 month	Window period <2.5 hrs	Window period >2.5 hrs	Total
<2	15(15.43) (.01)	12(11.57)(.002)	27
>1	3 deaths, 2(4.57)(.04)	1 death,2(3.43)(.05)	8
Total	20	15	35

The chi square statistic is 0.1215.the p value is.7273.not significant at p<.05

Table 9: Correlation of NIHSS scores at admission with mRS scores after three months (showed significant association with value less than 0.05)

Chi-Square Test

mRS score	NIHS score <15	NIHS score >15	total
≤1	**20**	**5**	**25**
≥ 2	4	6	10

The chi-square statistic is 5.303. The p value is .021. significant at p<.05

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Table 10: Complications in the study population

Complication	Number	Cumulative percentage
No complication	29	82.86%
GI bleed	1	2.86%
Intra cerebral bleed	5	14.48%

IV. DISCUSSION

Thrombolysis has played a major role in outcome of ischemic stroke. Early intervention has helped in improving morbidity and quality of life. In our study the mean age was 53±14.42 years which was smaller to that study done by Volans.P.et.al7 which showed a mean age of 69 years and 64.9+/-12 done by Werner Hacke et.al8 . A study done by Sussane S et.al, showed mean age of 58 years.9 The mean SBP in our study was 136.66±23.27 mm of Hg and DBP is 88.71±14.21 which was identical with the study done by Werner Hacke et.al which showed a SBP of 152.6+/-19.2 and DBP of 84.4+/-13.510 . The study also assessed the mean duration of hospital stay of 8 days which resembles the study done by Thorkild Terkelson et.al which showed a mean duration of days of 9days (thrombolysed patients) and 13 days(Nonthrombolysed patients)11 . Mean window period was 177.2 minutes, which was higher compared to the study done by Akansha et.al 76.8min12. It was lesser compared to a study done by Victor et al.13 which showed mean window period time of 580 minutes. In the window period, we assessed those who are arriving within 2.5hours and between 2.5 to 4.5 hours and correlated with mRS scores. No significant association has been noted among the two groups. Mean NIHSS score at admission observed was 12.63±4.55.It was lesser compared to a study done by Jagini et.al.14 and also to a study done by Vikram Huded et al.15. Mean mRS after three months was .99±.8 . Primary outcome was achieved in 57.14%% which was lesser compared to 65% done in a study by Padma et al. 16 Secondary outcome was reached in 71.42% which was higher compared to a largest single centre stroke study done by Jan Sobesky et.al which showed only 53%.17 and German stroke study which showed only 35%18. Complications were noted in 17.14% which was lower compared with two studies done in Kolkata which 20% and 16.1% respectively and 14.28% percent mortality which was higher compared to a study done by Fischer et al.19In our study.

Limitations of the study

Though patients noted to have better outcome with alteplase, sample size was small and restricted to a regional geographical area.

V. CONCLUSION

Here we have assessed the utility of alteplase in ischemic stroke in our study population. Predominantly males were noted with mean window period of two hours. Alteplase has reached the primary and secondary outcome in maximum patients, which helped in moulding the morbidity with least complications noted in our study. NIHSS and mRS scoring scales have played a major role in assessing the morbidity and outcome in our study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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