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Pharmacotherapy and treatment outcome in Acute Stroke patients - A prospective single centre study.

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Abstract

Global burden of stroke is increasing every year with higher risk of stroke because of increasing prevalence of risk factors like diabetes and hypertension.

Objective: This study was aimed to assess different types of stroke, associated risk factors, pharmacotherapy and treatment outcomes of stroke.

Methodology: This prospective, observational single-centered study was conducted at a tertiary care teaching hospital for a duration of 18 months. Severity and treatment outcomes were assessed using NIHSS and mRS scores respectively. Data was recorded and analysed using Z test, unpaired t test, Chi square test, repeated measures ANOVA and Pearson's correlation coefficient.

Results: Amongst 105 stroke patients, 63 patients had having ischemic stroke and 42 had haemorrhagic stroke. Past history of hypertension was present in 41 patients while 34 had both hypertension and diabetes mellitus type II. For the treatment of ischemic stroke commonly prescribed drugs were aspirin 75mg (35), clopidogrel 75 mg (10) and a combination of both (15).

Common drugs for hemorrhagic stroke were sodium valproate (21), mannitol (7) and furosemide (27). At admission the mean NIHSS score was 18.06 ± 7.21 (mean ± SD) while at discharge the score decreased to 6.55 ± 3.17 (mean ± SD). Mean mRS Score at discharge

was 2.77 which decreased to 1.27 at 1-month post treatment and 0.68 at 3 months.

Conclusion: Pharmacotherapy and early use of NIHSS and mRS scales proved valuable in assessing outcomes.

Keywords: Stroke, NIHSS Score, mRS Scores, Treatment Outcome

Introduction

Stroke is a second leading cause of death and third leading cause of DALY (Disability adjusted life years) in world. Stroke incidence and mortality are higher in Asian countries than in Western countries due to higher prevalence of hypertension and high serum cholesterol level in the Asian population.

According to Indian Stroke Association (ISA) the incidence in India ranges from 84- 262 per 100,000 populations in rural and 334 -424 per 100,000 in urban areas.[1,2]

There are two types of stroke i.e. ischemic stroke and hemorrhagic, ischemic stroke accounts for about 87 %. Further, hemorrhagic strokes are classified as intra cerebral (within the brain) or subarachnoid hemorrhage. The common risk factors for acute stroke are diabetes, hypertension, smoking and obesity. Treatment of co-morbidities improves outcome and prognosis in stroke patients. The past history of stroke in itself increases chances of developing a stroke[3].

Treatment of acute stroke, includes oral aspirin and intravenous r-tPA (recommended tissue type plasminogen activator) as the only two currently recommended treatment options. For hemorrhagic stroke decompression, surgery is recommended.

Management of stroke also depends on its severity and neurological deficit. One such scores for assessing stroke severity is National Institutes of Health Stroke Scale (NIHSS) which is also an indicator of prognosis. Additionally, Long-term efficacy of management can be measured by a disability scale like modified Rankin Scale (mRS).

The global burden of stroke is increasing every year and Indians are at high risk of stroke because of high prevalence of risk factors. Hence, this study was aimed to study different types of stroke, associated risk factors, co-morbidities, drugs used to treat them, complications like disability and treatment outcomes of stroke based on its medical management.

Materials and methods

After taking approval from Institutional Ethics Committee, civil hospital, Ahmadabad (EC/ Approval/ 157/2021) this prospective, observational single-centered study was conducted at a tertiary care teaching hospital for a duration of 18 months.

All newly diagnosed patients of acute stroke and those who gave written informed consent during the study period were enrolled and each patient was followed up daily till discharge, 1 month and 3rd month after discharge. Severity and treatment outcomes were assessed using NIHSS and mRS scores respectively.

Severity assessment was done using National Institute of Health Stroke Scale (NIHSS) which is a 11-item neurologic examination stroke scale used to evaluate the effect of acute cerebral infarction on the levels of consciousness, language, neglect, visual-field loss, extra-ocular movement, motor strength, ataxia, dysarthria, and sensory loss.

The patient's ability to answer questions and perform activities are scored by an observer. Ratings for each item are scored on a 1 to 5-point scale, with 0 being normal. Modified Rankin Scale (mRS) was used to quantify functional outcome. It is a 7-grade scale which measures functional independence and gait stability of

patient. Modified Rankin Scale (mRS) comprises seven levels, from 0 to 6, with higher scores indicating greater disability and where 0 and 1 is generally considered a good outcome with individuals assuming complete functional independence while score more than 1 is considered as a poor outcome with an individual assuming functional dependence and score of 6 denotes an individual who is deceased.

All the necessary details like demography, past history, family history, past medication history, investigations and treatment given for stroke, along with details of adverse drug reactions were collected. Data was recorded in a predesigned case record form, entered in Microsoft Excel ® 2013 and analyzed using appropriate statistical tests like Z test, unpaired t test, Chi square test, repeated measures ANOVA and Pearson's correlation coefficient.

Results

This prospective, observational single-centered study was conducted at a tertiary care teaching hospital with the aim to study different types of stroke, associated risk factors, co-morbidities, drugs used to treat them, complications like disability and treatment outcomes. A total of 105 patients were enrolled in the study whose mean age was 59.38±15.34 (mean ± SD) years.

As observed in table 1, seventy-nine (75%) patients belonged to age group of 50 or more (75.23%) and male to female ratio was 3:1. Forty-six patients (43.08%) were illiterate while 59 (56.19%) patients had education of primary level or higher.

Amongst 105 stroke patients, 63 (60%) patients were provisionally diagnosed as having ischemic stroke and 42 (40%) patients were diagnosed as hemorrhagic stroke. Past history of hypertension was present in 41 (39.04%) patients while 34 (32.38%) had hypertension and diabetes mellitus type II both Forty (38.09%) patients had history of addiction to smoking (23, 57.5%), alcohol (6, 15%) or both (11, 27.5%) (Table 1).

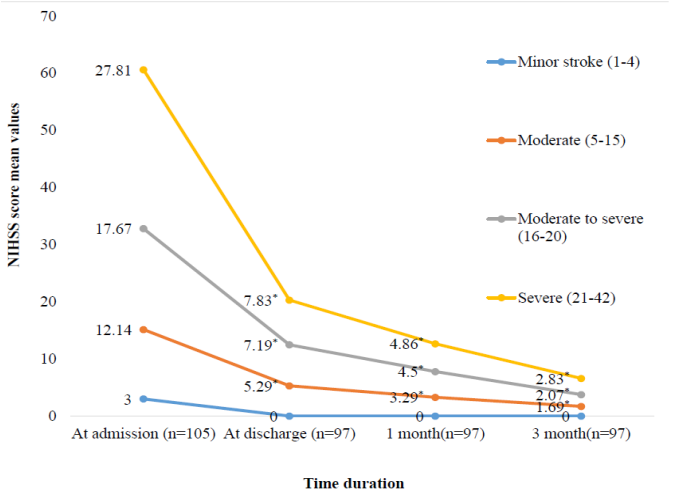
Table 1: Details of patients with ischemic and hemorrhagic stroke

Parameter	Subgroups	Number of patients with ischemic stroke (n=63)	Number of patients with hemorrhagic stroke (n=42)	Total number of patients (n=105)
Age	18-34	1	6	7
	35-50	14	5	19
	51-65	28	14	42
	66-80	15	16	31
	>80	5	1	6
Gender	Male	52	27	79
	Female	11	15	26
Presenting complaints	Weakness-hemiplegia/paraplegia	35	8	43
	Slurring of speech	26	6	32
	Altered sensorium	2	13	15
	Drowsiness	7	1	8

Past history of disease and concomitant illness	Hypertension	33	8	41
	Hypertension + diabetes mellitus type II	27	7	34
	COPD	10	4	14
	Ischemic heart disease	4	2	6
	Tuberculosis	2	2	4
History of addiction	Smoking	14	9	23
	Alcohol consumption	2	4	6
	Smoking + Alcohol consumption	3	8	11

Out of 75 patients of stroke who had past history of hypertension, 29 patients never took any medication for hypertension, 8 patients had discontinued the treatment while 21 patients were taking medication irregularly. Most common antihypertensive was amlodipine (41 patients). Out of 34 patients of diabetes, 30 patients were on metformin and other 4 patients were not on any medication. Out of 75 patients 10 patients had abnormal triglyceride above 150mg/dl, 15 patients had HDL level below 60 mg/dl and 17 patients had LDL level above 100 mg/dl. At admission the mean NIHSS score was 18.06 ± 7.21 (mean ± SD) while at discharge the score decreased to 6.55 ± 3.17 (mean ± SD). Further, after 1 month of discharge, it further decreased to 4.07±2.62 (mean ± SD) while after 3 months it decreased to 2.08 ± 2.22 (mean ± SD). This improvement in score (decrease shows improvement) at discharge, at 1st month and at 3 months was found to be statistically significant as compared to baseline. (ANOVA, figure 1).

Figure 1: NIHSS score in patients of stroke



*p<0.05, statistically significant as compared to baseline by using repeated measures ANOVA

The average time from symptom onset to initiation of treatment was 16.26 ± 6.6 hours (mean ± SD). During hospitalization, every patient received an average of 10.73 drugs for a mean duration of 5.09 ± 2.35 days. For the treatment of ischemic stroke during hospital stay, most commonly prescribed drugs were anti platelet i. e, aspirin 75mg in (35), clopidogrel 75 mg (10) and a combination of both in 15 patients. Lipid lowering agents i.e. atorvastatin (10-20 mg) was prescribed to 19 (30.16%) patients; LMWH 0.6 cc was prescribed in 29

(46.6%) patients. For treatment of hemorrhagic stroke, during hospital stay most common drugs prescribed were sodium valproate in 21 (50%) patients, mannitol in 7 (16.67%) patients and furosemide in 27 (64.29%) patients. Common concomitant drugs prescribed during hospitalization were ceftriaxone, pantoprazole and ondansetron in 102 (97.14%), 102 (97.14%) and 101 (96. 19%) patients respectively. (Table 2)

Table 2: Drugs prescribed in patients of stroke during hospital stay.

Type of stroke	Drug group	Drug name	Route	Dose	Frequency	Duration of treatment (Mean±SD) (days)	Number of patients	% of patient
ISCHEMIC (n=63)	Anti platelets (n=60)	Tablet Aspirin	PO	75 -150 mg	OD	7 ± 4.5	35	55.56
		Tablet Clopidogrel	PO	75 mg	BD	7.5±4.2	10	15.87
		Tablet Aspirin + clopidogrel	PO	75 + 75 mg	OD	7.5±4.2	15	23.81
	Antiepileptic (n=19)	Injection Sodium valproate	IV	200 mg	BD	5.2 ± 3.6	19	30.16
	Anti diabetic drugs (n=23)	Injection Insulin	SC	According to RBS	BD	5.3 ± 2.7	23	36.51
	Anticoagulant (n=29)	Injection LMWH	SC	0.6 CC	BD	4.7 ± 3.1	29	46.03
	Diuretics (n=12)	Injection Mannitol	IV	300 CC	BD	6.23 ± 5.1	12	19.04
	Dyslipidemic drugs (n=19)	Tablet Atorvastatin	PO	10-20 mg	HS	7 ± 5.8	19	30.16
	Bronchodilator (n=8)	Tablet Theophylline	PO	100 mg	TDS	6 ± 2.9	8	12.7
HEMORRHAGIC (n=42)	Antiepileptic (n=21)	Injection Sodium valproate	IV	200 mg	BD	5.2 ± 3.6	21	50
	Antidiabetic Drugs (n=17)	Injection Insulin	SC	According to RBS	BD	5.3 ± 2.7	17	40.48
	Diuretics (n=34)	Injection Furosemide	IV	40 mg	BD	5.33 ± 4.6	27	64.29
		Injection Mannitol	IV	300 CC	BD	6.23 ± 5.1	7	16.67

As shown in table 3, out of 105 patients of acute stroke, level of consciousness, orientation, gaze, visual field, facial movements, limb ataxia, language, articulation and extinction increased in 95 patients at time of discharge as compared to baseline and it was statistically significant by paired t test ($p<0.05$) while responses to commands, motor functions and sensory functions increased in 92 patients after 1 month of discharge and it was statistically significant as compared to baseline by paired t test ($p<0.05$).

Table 3: Analysis of responses of each tested item scores of NIHSS.

Tested items title	Baseline	Discharge	1 month	3 month
1A- level of consciousness	1.07	0.02*	0*	0*
1B- Orientation	0.98	0.02*	0*	0*
1C- Responses to commands	0.99	0.97	0.02#	0
2- Gaze	0.98	0.05*	0*	0*
3- Visual fields	0.9	0.09*	0.02*#	0.02*#
4- Facial movements	1.07	0.2*	0.04*#	0.01*#!
5- Motor functions (arm)	1.9	0.89	0.12#	0.06#!
6- Motor functions (leg)	1.97	1.09	0.6#	0.16#!
7- Limb ataxia	1.07	0.9*	0.64*#	0.16*#!
8- Sensory	0.97	0.89	0.89#	0.02#!
9- Language	0.97	0.12*	0.02*#	0*
10- Articulation	0.87	0.07*	0*	0*
11- Extinction/inattention	0.9	0.02*	0*	0*

*Statistically significant as compared to baseline

#Statistically significant as compared to discharge

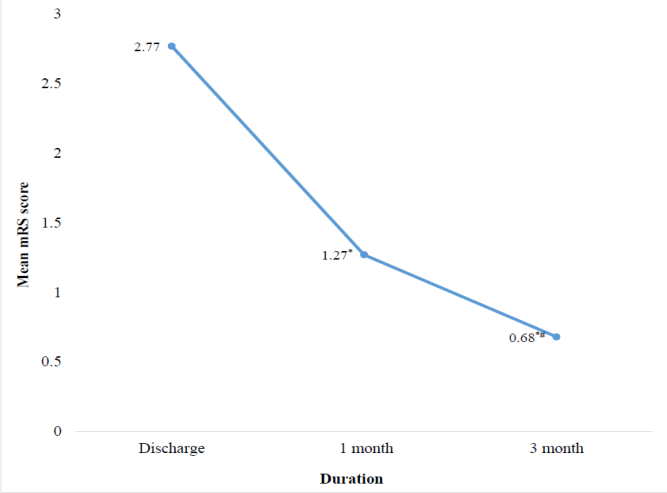
!Statistically significant as compared to 1 month after discharge

Statistical significance was observed by applying unpaired t test; $p<0.05$ considered statistically significant Modified Rankin Scale (mRS) was used to measure stroke outcome and functional impact in patient's post-stroke. Total 8 (7.62%) patients died before discharge. Hence, analysis of 97 patients was done for outcome. The mean mRS score at discharge was 2.77 which decreased to 1.27 at 1 month post treatment and 0.68 at 3 months ($p<0.05$, on both occasions; repeated measures ANOVA). After 1 month of post stroke, total 13 (13.40%) patients had score 0 while 42 (43.29%) patients had score 1, 40 (41.24%) patients had score 2 and 2 (2.06%) patients had score 3. After 3 months of post stroke, scores improved and 26 (26.8%) patients had score 0 while 68 (70.10%) patients had score 1 and only 3 (3.09%) patients had score 2. The improvement in mRS score (less the value of mRS score more is improvement) at 1 month as well as 3 months after discharge improved significantly as compared to discharge representing an improvement in functional outcome of patients [repeated measure ANOVA ($p<0.00034$)]. (figure 2)

Total 8 (7.62%) patients died before discharge. The mean age of the dead patients was 66.62 ± 14.54 (Mean ± SD) years; out of which six were male and 7 patients were of hemorrhagic stroke. Mean NIHSS score for dead

patients was 36.25; average time taken from symptom onset to admission was 14.37±7.8 hours and average days of hospitalization were 3.5±1.8 days.

Figure 2: Functional outcome of acute stroke patients according to mRS (n=97)



*Statistically significant as compared to discharge

#Statistically significant as compared to 1 month after discharge

Further, patients with mRS score 0 and 1 were considered as having good outcome (without any complication) while patients with mRS score >1 as poor outcome (with complication). After 3 months of discharge, 96 patients had good stroke outcome while 1 patient had poor outcome. It was observed that in patients with increased stroke severity the mean duration of hospital stays also increased; however, this was not statistically significant. [Pearson coefficient (r - 0.787, p - 0.2).

Further, there was no statistical significance found on comparing variables like age, gender, education, severity, mean length of hospital stay, risk factors, types of stroke and average time from symptom onset to hospital admission on patient's outcome (chi square test). The level of education was directly related with time taken from symptom onset to hospitalization (statistically significant, un-paired t test, p<0.01). where illiterate patients took 18.22± 6.8 hours to reach hospital from symptom onset while those having education of primary level or higher took 14.29 ± 6.7 hours.

Out of 105 acute stroke patients, 21 (20%) patients developed adverse drug reactions which was hyponatremia (n=21) having possible association with the suspected drugs i.e. injection mannitol in 12 (57.14%) patients and injection pantoprazole in 9 (42.86%). All the ADRs were mild in severity and not preventable.

Discussion

The present study was undertaken to study different types of stroke, associated risk factors, co-morbidities, drugs used to treat them, complications like disability, functional and neurological and treatment outcomes. In the present study, the mean age of enrolled patients was 59.38±15.34 (Mean ±SD) years with 42 (40%) patients in age group 51-65 years. Males were affected more as compared to females with the ratio 3:1which was similar to previous studies by Ginenus Fekadu et al and Gedefa B et al[4, 6]. High prevalence of stroke in older patients could probably be due to the presence of different cardiovascular co-morbidities like hypertension withaging being the most robust non-modifiable risk factor for incident stroke, doubling every 10 years after 55 years of age.[5]

Patients with the lowest education level have high cumulative incidence rates of mortality, stroke-specific mortality, and cardiovascular events due to lack of awareness regarding the risk factors and consequences regarding diseases as was found in 43.08% patients who were illiterate in the present study.

Total 63 patients had ischemic stroke (60%) which was more as compared to hemorrhagic stroke (n=42, 40%) in

our study which is similar to other documented studies.[7]

A high prevalence of hypertension amongst middle age population contributes to increased ischemic stroke.[8]

There is strong association between smoking and stroke risk, with current smokers having at least a two- to four fold increased risk of stroke compared with lifelong nonsmokers. In the present study 23 (21.9%) patients had history of smoking which is similar to other documented studies.[9]

About 40% of patients in the present study had past history of hypertension in our study which was similar to another study where in 40.66 % patients of stroke had hypertension.[10] Hypertension increases intraluminal pressure leading to alteration in endothelium and smooth muscle function in intracerebral arteries increasing stress on the endothelium leading to damage of arteries and accelerated atherosclerosis. About one-third (34, 32.4%) patients had past history of both hypertension and diabetes mellitus type II. Concomitant hypertension with diabetes mellitus type II increases the risk for primary and secondary stroke.

In the present study out of 75 patients of hypertension, 58 (77%) patients were either on no medication, or non-compliant which was similar with the study conducted by Gedefa B et al, 2017 wherein also 73.8% patients were non-compliant to anti-hypertensives.[6]

Non-compliance to medication leads to uncontrolled hypertension which increases the risk of hemorrhagic stroke. NIHSS scores have a strong prognostic value for long-term functional outcome after stroke and it is also responsive to meaningful clinical change. NIHSS reflects cerebral dysfunction by assessing several clinical items and is responsive to meaningful clinical change. In the present study, mean NIHSS severity score decreased at discharge,1 month and 3 months after discharge as compared to baseline which was found to be statistically significant ($p<0.05$). This was similar with the study conducted by Khaled Z et al, 2022[11]

where strong and significant correlation was observed between the scores of NIHSS at admission and discharge on outcome of patient. These findings suggest that the severity of neurological deficit as detected by NIHSS predicts the functional outcomes in acute stroke patients and vice versa.

In the present study, illiterate patients took highest time to reach hospital from onset of symptoms while patients with post graduate degree took the lowest time to reach hospital from onset of symptoms (statistically significant, $p<0.01$). It was found that as the level of education increases in patients there was decrease in time from symptom onset to hospitalization.

Mean length of hospital stay in the present study was 5.09 ± 2.35 days (3 to 7 days) which was comparable to previous studies which is dependent on stroke severity.[7,12] Henceforth, in severe patient's hospital stay was 5.1 ± 2.38 days (Mean±SD) while patients with minor stroke stayed for 2 ± 1.4 days (Mean±SD) reflecting increased morbidity with delayed recovery.

For the treatment of ischemic stroke out of 63 patients, antiplatelets like aspirin and clopidogrel were prescribed in 60 patients while hypolipidemic drug like atorvastatin was prescribed in 19 (30.16%) patients. Antiplatelets are recommended for secondary prevention in patients of ischemic stroke. In the present study, anticoagulants like LMWH was prescribed in 29 (46.6%) patients which might have been prescribed for prevention of venous thromboembolism as was observed by Fekadu et al. 2019[4]

where heparin was the most common anticoagulant. Anticoagulants are prescribed to prevent first or

recurrent stroke, especially among patients with cardio embolism due to arterial fibrillation and large artery atherosclerosis disease. However, a review by the panel of the Stroke Council of American Heart Association found no strong evidence for effectiveness of anticoagulants in treating acute ischemic stroke. Hence a review of treatment in the present study is warranted.

For the treatment of hemorrhagic stroke as per guidelines surgical evacuation of hematoma based on size and other symptomatic treatment for prevention of seizure and secondary infections, surgical interventions were not performed in the present study as those requiring surgical interventions were directly admitted to neurosurgery departments. Common drugs prescribed in patients of hemorrhagic stroke (42) were sodium valproate (21) mannitol (7) and furosemide (27). Valproate is used prophylactically for prevention of seizure. However, a study by F Angriman et al. 2019[13]. suggests that antiepileptic drugs as primary prevention among adult patients with spontaneous intracerebral hemorrhage is not associated with improved neurological function during long-term follow-up. Additionally, study done by David S et al. 2019[14] has suggested that osmotic diuretics such as mannitol decrease the intracranial pressure in the subarachnoid space as was observed in the present study which was also prescribed in the present study.

Modified Rankin Scale (mRS) is used to quantify functional outcome in individuals suffering from a neurological event. In the present study, improvement in the mean mRS score after 3 months of discharge as compared to time of discharge was found to be statistically significant. This suggests an improvement in functional performance of the enrolled patients and effective post stroke management as was also observed by Payam SA et al. 2020[15] in which mean mRS scores significantly improved at time of discharge and 3 months after the treatment.

In the present study, 26 severe patients stayed for 5.1 ± 2.38 days while 42 patients with moderate to severe stroke stayed for 5±2.35 days. Thirty-five patients with moderate stroke stayed for 5.08 ± 2.4 days while 2 patients with minor stroke stayed for 2 ± 1.4 days. Hence, as severity increased number of days of hospital stays also increased. This is in alignment with study done by Ji-Ho kang et al. 2016[16] suggests that severity of stroke is a direct predictor for length of hospital stay.

Out of 105 patients, 21 (20%) patients developed hyponatremia as an ADR which is similar to study done by Moiz Ehtesham et al. 2019[17] in which hyponatremia is a common electrolyte imbalance. Suspected drugs were injection mannitol in 12 (57.14%) patients and injection pantoprazole in 9 (42.86%).

In our set up as patients presented late, thrombolytic therapy was not given which was the major drawback of the present study and so treatment outcome with thrombolysed patients could not be assessed or compared. Additionally, not a single patient underwent surgical treatment for hemorrhagic stroke because patients requiring surgery were directly transferred to the neurosurgery department. In the present study, during hospital stay regular rehabilitation was not done, which might be a reason for delayed recovery in the enrolled patients.

This study has its strengths which include its study design with regular and comprehensive follow up throughout the hospital stay and even after 1 and 3 month of discharge with evaluation of functional and neurological outcome. Present study also used mRS

score which is a standard tool for assessing functional outcome in acute stroke patients.

Conclusion

On the basis of this study, routine use of severity and outcome scales like NIHSS and mRS might help in better management of patients as they will help in quantifying disease severity and judge treatment outcome. Further, it can be recommendations for organizing campaigns for awareness about modifiable risk factors like hypertension and diabetes mellitus along with warning signs and symptoms of stroke might help the patients to identify the stroke symptoms early and decrease the time to reach hospital because onset-to-admission delay remains the main exclusion criterion for thrombolysis as was observed in the present study, which hastens functional improvement. Community outreach and awareness interventions at the primary care level for adherence to treatment of risk factors like hypertension and diabetes mellitus can help mitigate stroke.

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