



ASSESSMENT OF CLINICAL OUTCOME AND THEIR RISK FACTORS IN PATIENTS WITH STROKE

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ABSTRACT

Globally, stroke is the second leading cause of mortality and disability. In India, 619000 in 9.4 million deaths were due to stroke. There is paucity of information regarding the factors affecting clinical outcome in stroke patients. This study aims to assess the risk factors associated with clinical outcomes in patients with stroke.

A prospective observational study was conducted in neurology unit of a tertiary care teaching hospital with a total of 80 patients over a period of six months. During the study period, the subjects were followed till discharge to assess the prescribing pattern and clinical outcomes. The clinical outcomes were assessed using modified ranking scale (mRS), Glasgow coma scale (GCS) and muscle power grading scale (MRC).

Among the study subjects, 48(60%) were male, 40(50%) were aged 60 years and above. Patients received an average of 10.38 drugs during hospital stay, in which 77 (96.25) were prescribed with atorvastatin and 35(43.75%) with heparin. A combination of aspirin-clopidogrel was received by 70(87.5%). Total of 49(61.25%) patients had a good clinical outcome at the time of discharge. Mortality rate during hospitalization was found to be 5%.

The study concludes that factors such as age of 60 years and above, family history, polypharmacy, co-morbidities and length of hospital stay contribute to a negative clinical outcome in stroke patients.

KEYWORDS : stroke, risk factors, clinical outcome

BACKGROUND

The World Health Organization (WHO) characterizes Stroke (CVA) as "rapidly developing clinical signs of focal or global disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin."¹ CVA is one of the common neurological diseases that cause a sudden interruption in the blood supply of the brain and consequently mild to severe neurological damages.² CVA is the second leading cause of death in individuals aged above 60 years.³ According to the studies, the annual incidence of stroke is estimated to 145/100,000.⁴ In Indian populations, it is estimated that stroke-related burden will be doubled by 2030.¹⁵

Clinically stroke is classified into ischemic or haemorrhagic stroke.⁵ Ischemic stroke is 'an episode of neurological dysfunction caused by focal cerebral, spinal, or retinal infarction, whereas haemorrhagic stroke is damage caused by bleeding into or around the brain.'⁷ Modifiable risk factors such as age, sex, family history, race/ethnicity and non-modifiable risk factors such as hypertension, diabetes, smoking, alcohol consumption, hyperlipidaemia and physical inactivity contribute to stroke. Progression of neurological damages in the brain may cause alteration of physical movement, loss of memory and reasoning and even death.^{8,9} Ischemic stroke requires multiple approaches of treatment such as thrombolytic, anticoagulants, antihypertensives, lipid-lowering agents and cerebral activators.¹⁰ While in hemorrhagic stroke, mannitol reduces intracranial pressure to prevent further brain damages.¹¹ Patient with stroke may be associated with multiple comorbidities and complications, which enhances the need of multiple drug therapy for long term. This may attribute to negative clinical

outcomes like severity of stroke, level of consciousness, physical disability and mortality are the commonly considered clinical outcomes of patients presented with stroke.¹² Early identification of stroke type, early diagnosis of hypertension and other risk factors, framing tobacco and smoking control strategies and enhancing patient's knowledge about the symptoms of stroke is essential to reduce complications and related mortality.^{5,13}

There is a lack of data regarding the clinical presentation, clinical outcomes and their risk factors in stroke patients.¹⁴ Hence, the current study aimed to assess the clinical outcomes and their risk factors in stroke patients.

METHOD

This prospective cross-sectional study was carried out in the Neurology department of a tertiary care teaching hospital in south India, over 6 months (December 2018- May 2019). Patients of either gender and aged 18-years and above, who were diagnosed with stroke through clinical and radiological evidence were enrolled in the study. Patients who were having hospital stay of less than 24 hours and those who were not willing to provide consent were not included in the study.

A total of 80 subjects were enrolled during the study period. "Pharm D" students collect the baseline patient's data in a suitably designed data collection form. Study subjects were followed till discharge or death for assessing their clinical outcomes. The factors influencing the negative clinical outcomes were assessed for their association. During hospitalization, patient's improved level of physical disability, consciousness and muscle power strength is considered to be good clinical outcome and were measured on a daily basis using mRS, GCS and MRC scales.

mRS scale: 'mRS scale is a six point disability scale with possible scores ranging from 0 to 6. Category of 6 implies those who expire.'

GCS: 'The GCS assesses a person based on their ability to perform eye movements (total score of 4), speak(score of 5), and move (score of 6) their body.' In total score of 15 implies the best response.

MRC: MRC is used to the assess the muscle strength in neurological deficit patients with scores ranging from 0 to 5. Zero score indicates no contraction'

Improved scores of patients from admission to discharge was considered as the improvement in clinical outcomes.

All the data were transformed into Microsoft Excel 2017 and was analysed using SPSS statistical software. The independent variables were analysed by descriptive statistics. To determine the predictors of the clinical outcome regression analysis was performed with a confidential interval of 95% and $p < 0.05$.

RESULTS

In this study, a total of 80 hospitalized stroke patients were enrolled. Of them, 48 (60%) were males and half of the patients were aged within and above 60 years. The majority of the study patients were married 75 (93.75%) and 36 (45%) were from urban residence. Patient with a history of alcoholism 19 (23.75%), smoking 16 (20%) and 21(26.25%) gave the history of both an alcoholic and smoker. Nearly one-third of the patients 24 (30%) had a positive family history and 66 (82.5%) patients were taking a mixed diet. The majority of patients 23 (28.75%) were illiterate and 42 (52.5%) were unemployed. A summary of socio-demographics details presented in table 1.

Table 1: Socio-demographics of the study populations

Categories	Parameters	Total, n=80 (%)
Gender	Male	48 (60)
	Female	32 (40)
Age groups (Years)	<40	3 (3.75)
	41-50	7 (8.75)
	51-60	30 (37.5)
	>60	40 (50)
Residences	Rural	17 (21.25)
	Semi-urban	27 (33.75)
	Urban	36 (45)
Marital Status	Single	1 (1.25)
	Married	75 (93.75)
	Widow/ divorce	4 (5)
Social habits	Alcoholic	19 (23.75)
	Smoker	16 (20)
	Both alcoholic and smoker	21 (26.25)
Family history	Present	24 (30)
	Absent	56 (70)
Diet	Vegetarian diet	7 (8.75)
	Non- Vegetarian diet	7 (8.75)
	Mixed diet	66 (82.5)
Literacy status	Graduate & above	5 (6.25)
	High school or Diploma	13 (16.25)
	Middle school	20 (25)
	Primary school	19 (23.75)
	Illiterates	23 (28.75)
Employment status	Employed	39 (48.75)
	Unemployed	42 (52.5)

Accordingly, 74 (92.5%) were diagnosed with ischemic stroke ,74 (92.5%) patients were taking more than 5 drugs and 52 (65%) had hospitalized for ≤ 7 days. 55 (68.75%) patients were presented with comorbidities greater than three. Of them, 32 (40%) had hyperlipidaemia followed by 29 (36.25%)

hypertension, and 24 (30%) diabetes. Hemiparesis 65(81.25%), aphasia/dysphasia 41(51.25%) and slurred speech 24 (30%) were most observed sign and symptoms among enrolled patients. A summary of clinical characteristics of participants presented in table 2.

Table 2: Clinical characteristics of the study population

Categories	Clinical characteristics	Total, n=80 (%)
Type of stroke (diagnosis)	Ischemic stroke	74 (92.5)
	Haemorrhagic stroke	6 (7.5)
Polypharmacy	≤ 5	6 (7.5)
	> 5	74 (92.5)
No. of Comorbidities	≤ 3	23 (28.75)
	> 3	57 (71.25)
Length of hospital stay	≤ 7 days	52 (65)
	> 7 days	28 (35)
Clinical manifestations	Aphasia/ dysphasia	41 (51.25)
	Left side hemiparesis	33 (41.25)
	Right side hemiparesis	32 (40)
	Slurred speech	24 (30)
	General sensory loss	20 (25)
Comorbidities	Loss of memory	7 (8.75)
	Hyperlipidaemia	32 (40)
	Hypertension	29 (36.25)
	Diabetes mellitus	24 (30)
	Epilepsy	22 (27.5)
	Infections	13 (16.25)
Others	17 (21.25)	

During study period, an average of 10.38 drugs per patient was prescribed. Of them, 77 (96.25%) were prescribed with lipid lowering drugs followed by 44 (55%) were with anticoagulants and 70(87.5%) patients were prescribed with combination of aspirin and clopidogrel.

Two fourth of the patients (49, 61.25%) who had a stroke was discharged with a good clinical outcome, in which 36 (45%), 38(47.5%) and 32 (40%) patients showed improvement in level of disability, consciousness and muscle power respectively.

In another hand, 31(38.75%) were presented with negative clinical outcome, among them 26 (32.5%) patients were observed with having poor clinical outcome (no improvement in clinical outcomes), one patient observed as degenerative (worsening of clinical outcomes) and 4 (5%) patients died during the study period. Three- fourth of the died patients were stayed in the hospital for more than 7 days. Thirty-one ischemic stroke patients were observed with good treatment outcomes stayed for less than 5 days in the hospital respectively. A summary of clinical outcome concerning LOS presented in table 3.

Table 3: Clinical outcomes

MRS Scaling	Type of Stroke	Length of hospital stay			
		1-5 days	6-10 days	11-15 days	> 15 days
Improved	Haemorrhagic	2	1	1	0
	Ischemic	31	9	3	2
Not improved	Haemorrhagic	0	2	0	1
	Ischemic	7	9	7	0
Degeneration	Haemorrhagic	0	0	0	0
	Ischemic	0	1	0	0
Death	Haemorrhagic	0	0	1	0
	Ischemic	0	1	1	1

Multiple regression analysis used to identify the association of negative clinical outcome of the enrolled patients during the study. The major three risk factors identified which significantly associated with negative clinical outcomes were polypharmacy [OR 9.33 (95% CI, 2.56-33.92), $p < 0.0007$], comorbidities more than three [OR 2.95 (95% CI, 1.11-7.40),

p<0.028] and hospital stay more than 7 days [OR 1.63 (95% CI, 0.26-2.51), p<0.014].

Table 4: Risk factors associated with negative outcomes

Risk Factors	Treatment outcomes		Odds Ratio (OR)	95% CI		P Value *
	Impr oved	Not improved		Lower limit	Upper limit	
Gender						
Male	30	18	0.06	0.94	4.91	0.068
Female	19	13	1			
Age distribution						
<40	2	1	1			
41-50	4	3	0.16	0.018	1.419	0.1002
51-60	20	10	0.08	0.185	1.115	0.085
>60	23	17	1.06	0.513	2.883	0.046*
Both alcoholic and smoker	9	12	1.33	0.491	3.615	0.571
Family history						
Present	17	7	0.30	0.114	0.812	0.017
Absent	33	23	1			*
Polypharmacy level						
≤5	3	3	1	2.564	33.925	0.000
>5	46	28	9.33			7*
No. of comorbidities						
≤3	15	8	1	1.116	7.404	0.028
>3	34	23	2.975			*
Length of hospitalization						
≤ 7 days	33	19	1	0.262	2.519	0.014
> 7 days	16	12	1.63			*

DISCUSSION

Our study was performed to assess the clinical outcome and the predictors for negative clinical outcome in hospitalized stroke patients. The majority of the patients in the study was in the age group of sixty and above, which is similar to other studies where the mean age was ranged from 60-65 in India, and thus the age was considered as one of the non-modifiable risk factors in stroke patients.^{15,16} Our study showed that males were more prone to stroke than females which were similar to other studies.^{17,18} social habits like alcoholism and smoking maybe contribute to stroke, which was observed lower than the study by PN. Sylaja et al.¹⁹ The rate of comorbidities such as hyperlipidaemia, hypertension, and diabetes mellitus may attribute to a high prevalence of CVA. This was similar to that of studies conducted in Ethiopia,⁵ Iran,²⁰ Thailand.²¹ In our setting, aphasia/ dysphasia, hemiparesis and Slurred speech were the most common symptoms associated while admission. While the study by Ginenus Fekadu et al showed that headache was the most observed symptoms in stroke patients followed by aphasia, hemiparesis and facial palsy.⁸This discrepancy may be due to the difference in the sociodemographic, geographical factors and other patient dependent factors in different settings.

The findings of this study also revealed that the most prescribed category of drugs was antiplatelet, lipid-lowering drugs followed by anticoagulants. This was inconsistent with that of a study by Subransu Sekhar Jena et al in which the most utilized drug was antihypertensive followed by hyperlipidemic.⁶ This variation may due to the difference in risk factors and comorbidities in different settings. Aspirin and clopidogrel was the most commonly seen combinational drug of choice in our study. This data were in line with the study reported by Muthaliar M R.et al.²²

Clinical outcome assessment showed that the majority of the subjects does not show any improvement in their clinical

wellbeing. This is consistent with another study done by Amita Mukhopadhyay, et al.²³ Regarding the clinical outcome of stroke patients, the death rate was found to be 5 %. The rate is relatively lower than other studies by Sennay A. Gebremariam et al (12%)²⁴ and Eyob Alemayehu Gebreyohannes et al (12.5%).²⁵ This change could be due to the difference in clinical and treatment pattern. Similarly, in our study 61.25% of stroke patients had good outcomes, the findings are in- line with other previous studies where 55%²⁶ and 59.2%⁵ of stroke patients had good outcome. The regression analysis showed that clinical outcome was significantly associated with factors such age, family history, polypharmacy, number of comorbidities and length of hospital stay.

CONCLUSION

In our study, Atorvastatin and combination of aspirin-clopidogrel were the most common choice of drug prescribed in patients with ischemic stroke. Half of the patients were achieved good clinical outcome during the study period and age, family history, polypharmacy, number of comorbidities and length of hospital stay were found as the risk factors associated with negative clinical outcomes.

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