DOI: 10.7860/JCDR/2022/52988.16484

Original Article

Pharmacology Section

A Prospective Observational Study on Prescribing Pattern and Outcome of Acute Stroke from a Tertiary Care Hospital in Bengaluru, India

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ABSTRACT

Introduction: Stroke is the most common cerebrovascular disorder and a second leading cause for death. Early diagnosis and treatment of stroke along with controlling of risk factors, post stroke infection and rehabilitation can enhance patient outcomes. Stroke is an important economic burden for the society, requiring increasing attention for more effective healthcare planning and resources allocation.

Aim: To determine the prescribing pattern, risk factors and outcome of acute stroke in a tertiary care hospital.

Materials and Methods: A prospective observational study was conducted in the Department of Medicine, at Kempegowda Institute of Medical Sciences Hospital and Research Centre, Bangalore, Karnataka, India, from January 2018-June 2019 for 18 months. After approval and clearance obtained from the Institutional Ethics Committee, 100 acute stroke subjects of either gender with or without co-morbidities were included in the study. Relevant information about the ongoing drug therapy, co-morbidities, personal and past history were obtained. The outcome of the stroke was assessed by Modified Rankin Scale (mRS). Chi-square test was used for categorical data, student t-test for continuous data and Analysis of Variance (ANOVA) test for temporal change in mean mRS.

Results: The mean age of the subjects in the study was 68.41±12.98 years. Ischaemic stroke (72%) was more common than haemorrhagic stroke (28%). Hypertension and diabetes were significantly associated with stroke with p-value of 0.04 and 0.02, respectively. Association of smoking and alcohol with stroke was significant with p-value of 0.01 and 0.001, respectively. The most commonly prescribed drugs were aspirin, clopidogrel and statins. The mean mRS at admission for both ischaemic and haemorrhagic stroke came down after 28 days with treatment and rehabilitation. At the end of 28th day Ischaemic Stroke showed better outcome than haemorrhagic stroke (p-value: 0.03).

Conclusion: Early diagnosis, lifestyle changes and combination drug therapy reduce complication of stroke and improve patients' outcome. Risk factors such as hypertension, diabetes mellitus, smoking and alcohol should be controlled. Antiplatelet agents, antihypertensive agents and statins are commonly prescribed for secondary prevention and treatment of stroke. Greater awareness is needed to reduce the burden of stroke.

Keywords: Haemorrhagic stroke, Ischaemic stroke, Modified rankin scale, Risk factors

INTRODUCTION

Stroke is the commonest cerebrovascular disorders, with the prevalence progressively increasing with age and elderly subjects are more prone for various stroke-related complications [1]. Globally it is the second leading cause of death after ischaemic heart disease and third most common cause of disability of DALYs (Disability Adjusted Life Years) after neurological disorders and ischaemic heart disease in developing countries [2]. The Global Burden of Diseases, Injuries and Risk factors study (GBD 2015) has shown that the cause of mortality has shifted from communicable diseases, maternal and nutritional causes towards non communicable diseases like stroke [3].

Majority of the Indian population doesn't have access to healthcare, therefore there is a need to put emphasis on population based stroke prevention strategies [4]. There is paucity of data available in India which could provide clear conclusion on the epidemiology, treatment and outcome of stroke in India [1,5].

Since stroke is a medical emergency and second leading cause for death and mortality, along with early diagnosis and treatment, secondary stroke prevention remains a top priority in treating patients after the first stroke, which mainly includes; controlling of risk factors (modifiable and non modifiable) with drugs and lifestyle measures, post stroke infection and rehabilitation to reduce the morbidity, mortality, and to improve the quality of life [5,6]. WHO addressed drug utilisation as a marketing, distribution, prescription and use of drug in a society considering its constituents medical, social and economic [7].

The current therapy for acute stroke designed to reverse or lessen the amount of tissue infarction include thrombolytics, anticoagulants, antiplatelet drugs, antihypertensives, lipid lowering agents, antibiotics, endovascular revascularisation, neuroprotection and rehabilitation. Proper management of risk factors and treatment of stroke leads to positive therapeutic outcome [8]. There are only few studies which address the risk factors, treatment and outcome of stroke in the hospital [1,5], hence, present study was taken up to address some of these issues. The study was carried out with the aim to determine the prescribing pattern, risk factors and outcome of acute stroke.

MATERIALS AND METHODS

This prospective observational study was done in the Department of Medicine, KIMS Hospital and Research Centre, Bangalore, Karnataka, India, from January 2018-June 2019. Approval and clearance were obtained from the Institutional Ethics Committee (IEC) (KIMS/IEC/D-03/2017) before starting the study. Written informed consent was obtained from all the study subjects or their legal representatives (in case patient was not in a position to respond) after fully explaining the study procedure to their satisfaction. Anonymity, confidentiality and professional secrecy was maintained for all the study subjects. Subjects were categorised into ischaemic stroke and haemorrhagic stroke based on diagnosis by the physician.

Inclusion criteria: Study subjects of either gender aged >18 years with acute stroke of vascular origin, with or without co-morbid conditions such as hypertension, diabetes mellitus, ischaemic heart disease etc. receiving medications for stroke, recurrent stroke and willing to give written informed consent were included in the study.

Exclusion criteria: Old cases of stroke admitted for co-morbidities, neurological deficit due to non vascular and other causes, and patients with age <18 years, pregnant and lactating women were excluded from the study.

Sample size calculation: A total of 100 consecutive patients with acute stroke of vascular origin diagnosed and confirmed by the physician were included. Sample size was calculated using prevalence from previous study p=1.9% [9] using the formula

$N=Z_{1-\alpha/2}^{2}\ p\ (1-p)/d^{2}$

sample size calculated was 63.8 for statistical significance and better evaluation, sample size taken was 100.

Study Procedure

Risk factors for stroke like co-morbidities, smoking, alcohol, past history of stroke was recorded. A detailed present and past medical (cases diagnosed and treated earlier for stroke) history and personal (including smoking and alcohol intake) was recorded from all the study subjects. The available medical records of the subjects were thoroughly scrutinised to obtain relevant information about the co-morbid conditions, previous and ongoing drug therapy. The details of the ongoing pharmacotherapy including the route, number of drugs, the therapeutic class, dose and frequency was documented. Co-morbidities included hypertension, diabetes, ischaemic heart disease which are the major risk factors for stroke. The duration of co-morbidities was also studied. Concomitant medications for co-morbid conditions or intercurrent illnesses were also recorded. The outcome of the therapy was assessed at admission and after 28 days of admission by mRS [10]. In patients discharged before 28 days; the outcome was assessed through personal telephonic enquiry.

The mRS is a six point disability scale used for evaluating recovery from stroke [10]. It includes scores from 0-6.

0- No symptoms at all, 1- No disability despite some symptoms, 2- slight disability but does not require assistance, 3- Moderate disability but can walk, 4- Moderately severe disability, 5- Severe disability, usually bedridden, 6- Dead

The risk factors, treatment therapy and outcome were compared between ischaemic and haemorrhagic stroke.

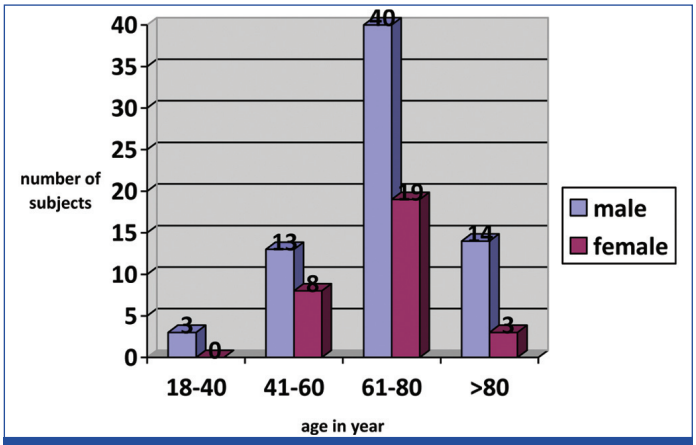
STATISTICAL ANALYSIS

The data collected was analysed using descriptive statistics, namely mean±standard deviation. The results were also depicted in the form of tables and graphs. Statistical Package for the Social Sciences (SPSS) version 20.0 was used for the analysis of data and Microsoft Word and MS Excel to generate graphs and tables. Chi-square test was used for categorical data, student's t-test for continuous data and ANOVA test for temporal change in mean mRS. A p-value <0.05 was considered significant.

RESULTS

The age and gender distribution in the study subjects is shown in [Table/Fig-1]. The mean age was 68.41±12.98 years. Majority of the subjects (59%) were in the age group of 61-80 years, and only 3% were below 40. Among the study subjects 70% (n=70) of the subjects were males and 30% (n=30) were females.

In present study 72 subjects suffered from ischaemic and 28 from haemorrhagic stroke. Hypertension was the most common co-morbidity present in the study subjects. The association of hypertension and diabetes mellitus with the stroke was significant 0.041 and 0.024 respectively [Table/Fig-2].

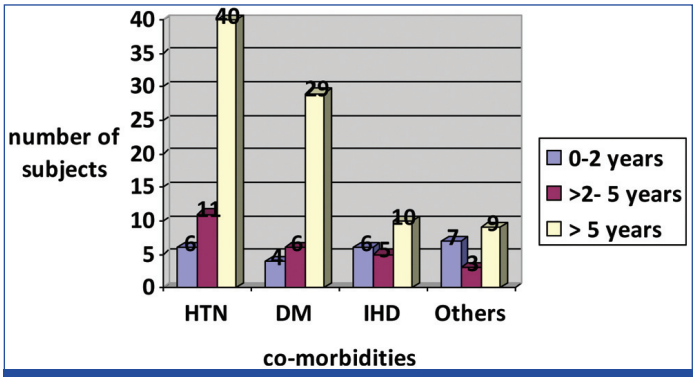


[Table/Fig-1]: Age and gender distribution (N=100).

Co-morbidities	IS n (%)	HS n (%)	p-value
HTN	40 (55.55)	17 (60.71)	0.041227
DM	29 (40.27)	10 (35.71)	0.024117
IHD	18 (25)	3 (10.71)	1.079
Others*	17 (23.61)	2 (7.14)	2.74

[Table/Fig-2]: Risk factors: co-morbidities.
*Others- COPD, Hypothyrodism, BPH, Liver disease
Chi-square test, p<0.05 statistically significant; IS: Ischaemic stroke; HS: Haemorrhagic stroke; HTN: Hypertension; DM : Diabetes mellitus; IHD: Ischaemic heart disease; Not all patients had risk factors and one patient can have multiple risk factors

Majority of the hypertensive (40%), diabetic (29%) and ischaemic heart disease patients (10%) presented with history for more than five years [Table/Fig-3].



[Table/Fig-3]: Duration of co-morbidities.

History	IS, n (%)	HS, n (%)	p-value
Smoking	38 (52.77)	8 (28.57)	0.0101
Alcohol	28 (38.88)	4 (14.28)	0.0012
Past stroke present	5 (6.94)	2 (7.14)	1

[Table/Fig-4]: Risk factors: personal history.
Chi-square test; p<0.05; statistically significant; Not all patients had risk factors and one patient can have multiple risk factors

Smoking and alcohol were significantly associated with increasing the risk of stroke 0.01 and 0.001 respectively. Seven subjects (ischaemic-5, haemorrhagic-2) had past history of stroke [Table/Fig-4].

[Table/Fig-5] shows the temporal changes in mean mRS at admission and on 28th day. A total of five (ischaemic-four, Haemorrhagic-one) deaths occurred in the study.

[Table/Fig-6] shows change in mRS from admission to 28th day. The baseline mRS at the time of admission between ischaemic stroke and haemorrhagic stroke was comparable. The outcome was based on improvement in mRS score from baseline to at the end of 28th day. At the end of 28th day ischaemic stroke showed better outcome than haemorrhagic stroke (p-value-0.03).

mRS	Ischaemic stroke (n=72)	Haemorrhagic stroke (n=28)
At the time of admission Score Mean (S.D)	3.56 (1.83)	4.14 (1.88)
mRS 0 (0%)	0	0
mRS 1 (%)	0	0
mRS 2 (%)	14 (19.44)	2 (7.14)
mRS 3 (%)	22 (30.55)	5 (17.85)
mRS 4 (%)	17 (22.66)	8 (28.57)
mRS 5 (%)	19 (26.38)	13 (46.42)
mRS 6 (%)	0	0
28th day Score Mean (SD)	2.75 (2.01)	3.67 (2.1)
mRS 0 (%)	2 (2.77)	0
mRS 1 (%)	12 (16.66)	2 (7.14)
mRS 2 (%)	18 (25)	3 (10.71)
mRS 3 (%)	15 (20.83)	7 (25)
mRS 4 (%)	13 (18.05)	9 (32.14)
mRS 5 (%)	8 (11.11)	6 (21.42)
mRS 6 (%)	4 (5.55)	1 (3.57)

[Table/Fig-5]: Temporal changes in mean modified rankin score at admission and on 28th day after admission.

Day	Ischaemic stroke Mean±SD (p-value)	Haemorrhagic stroke Mean±SD (p-value)	p-value (IS vs. HS)
Admission	3.56±1.83	4.14±1.88	0.13
28th Day	2.75±2.01 (p=0.34)	3.67±2.1 (p=0.35)	0.03*

[Table/Fig-6]: Change in mRS score from admission to 28 days and p-value between IS and HS.

[Table/Fig-7] summarises the prescribing pattern in subtypes of stroke. The most commonly used neuroprotective agent was citicoline [Table/Fig-8] shows the concomitant medicines prescribed to the patients who suffered from co-morbidities. Antihypertensives were the most common prescribed drugs.

[Table/Fig-9] shows the drug prescribed as fixed dose combination. Most commonly used combination was aspirin and clopidogrel. Antiplatelet drugs are used to reduce cardiovascular mortality.

DISCUSSION

In the present study, majority of the subjects (59%) were in the age group of 61-80 years, and only 3% were below 40. This was in similar line with studies like Jaladi H, Rakesh B and Pasha SA et al., where patients in the age group of 61-80 years constituted 57.14% and 44.75% respectively [11,12]. The prevalence of stroke in old age group indicates the burden of stroke in elderly population. This may be due to the increase risk factors like Cardiovascular Disease, Hypertension, Diabetes mellitus, ischaemic heart disease etc. with advancing age [5]. Among the study subjects 70% of the subjects were male. The higher incidence of stroke in males can be attributed to reasons like prevalence of Hypertension, Diabetes Mellitus, smoking and alcoholism in males and also better awareness about health and economic independence compared to females, which was consistent with studies of Lai CL et al., and Miah M et al., which had incidence in male of 58.9% and 61.7 % respectively [13,14]. Smoking damages blood vessels leading to their blockage, increasing the risk of stroke by about 50% [11]. Both active and passive smoking should be avoided [15].

In present study, majority (72%) suffered from ischaemic stroke than haemorrhagic (28%). Study conducted by Konduru S et al., showed similar result of 85% of ischaemic stroke [5]. On the contrary, study

Therapeutic class	Drugs prescribed	Dosage	Frequency	ROA	Ischaemic stroke n (%)	Haemorrhagic stroke n (%)
Anticoagulants	tPA (Alteplase)	0.9 mg/kg	OD	IV	1 (1.38)	0
	LMWH	20 mg	OD	SC	21 (29.16)	3 (10.71)
	Acenocoumarol	4 mg	OD	Oral	1 (1.38)	0
Antiplatelets	Aspirin	75 mg	OD	Oral	65 (90.27)	3 (10.71)
	Clopidogrel	75 mg	OD	Oral	55 (76.38)	1 (3.57)
Neuroprotective agents	Citicoline	500 mg	BD	Oral	47 (65.27)	6 (21.42)
	Cerebroprotein	90 mg	BD	Oral	4 (5.55)	1 (3.57)
Antioedema	Mannitol	100 mL	TID	IV	16 (22.22)	24 (85.71)
	Glycerol	20 mL	6 hrly	IV	9 (12.5)	22 (78.57)

[Table/Fig-7]: Use of anticoagulants, antiplatelets, anti oedema and neuroprotective agents in subtypes of stroke.
OD: Once daily; BD: Twice daily; TID: Thrice daily; IV: intravenous, SC: Subcutaneous; ROA: Route of administration

Class			Dosage	Frequency	ROA	Ischaemic stroke n (%)	Haemorrhagic stroke n (%)
1. Anti hypertensives	CCBs	Amlodipine	5 mg	OD	Oral	24 (33.33)	7 (25)
		Cilnidipine	5 mg	OD	Oral	4 (5.55)	2 (7.14)
	ARBs	Losartan	50 mg	OD	Oral	6 (8.33)	3 (10.71)
		Telmisartan	20 mg	OD	Oral	3 (4.16)	2 (7.14)
		Cardesartan	4 mg	OD	Oral	1 (1.38)	0
	Diuretics	Furosemide	40 mg	OD	IV	12 (16.66)	5 (17.85)
		Hydrochlorothiazide	12.5 mg	OD	Oral	3 (4.16)	2 (7.14)
	β-blockers	Metoprolol	50 mg	OD	Oral	5 (6.94)	3 (10.71)
		Labetalol	50 mg	OD	Oral	1 (1.38)	2 (7.14)
2. Lipid lowering agents		Statin	10 mg	OD	Oral	Oral	19 (67.85)
		Fenofibrate	200 mg	OD	Oral	Oral	0
3. Antiepileptic		Phenytoin	100 mg	BD	Oral	Oral	12 (42.85)
		Levetiracetam	500 mg	OD	Oral	Oral	2 (7.14)
4. Antidiabetic		Insulin- As per glucose level		BD	SC	14 (19.44)	5 (17.85)
		OHA	-	BD	Oral	11 (15.27)	4 (14.28)
		Insulin+OHA	-	BD	SC, oral	4 (5.55)	1 (3.57)

5. Antimicrobials	Ceftriaxone	1000 mg	BD	IV	32 (44.44)	11(39.28)
	Cefpodoxime	200 mg	BD	oral	13 (18.05)	3 (10.71)
	Cefoperazone+sulbactam	1500 mg	BD	IV	17 (23.61)	7 (25)
	Levofloxacin	500 mg	BD	oral	6 (8.33)	0

[Table/Fig-8]: Concomitant medications.
OD: Once daily; BD: Twice daily; IV: Intravenous; SC: Subcutaneous

Fixed drug combination	Number of subjects
Aspirin+Clopidogrel	24
Aspirin+Clopidogrel+Atorvastatin	15
Temisartan+Hydrochlorthiazide	5
Glimepiride+Metformin	2

[Table/Fig-9]: Fixed drug combination.

done at St. Paul's Teaching Hospital showed haemorrhagic stroke was the most common type of stroke accounting for 61.3% of cases with majority of patients being in the 56-70 year age group [16]. The outcome was assessed by mRS for the temporal changes in mean mRS at admission and on 28th day. The baseline mRS at the time of admission between ischaemic stroke and haemorrhagic stroke was comparable. At the end of 28th day ischaemic stroke showed better outcome than haemorrhagic stroke (p-value - 0.03). The p-value of mean change in mRS in each type of stroke was however non significant. 37% patients had good outcome (mRS: 0-2) while 63% patients had poor outcome (mRS: >2). A total of 5% (ischaemic -4%, haemorrhagic -1%) deaths occurred in present study. This was in line with study in Ethiopia where 59.18% were discharged after showing good outcome and death was 13.3% [16]. In contrast, the overall hospital mortality among hospitalised stroke patients was only 4.9% in a study in Germany [3]. This difference may be due to variation in healthcare systems in different countries [3].

In present study only one subject received tPA. It is recommended that stroke patients arrive at the hospital within three hours of symptom onset in order to receive treatments such as tPA, to minimise long-term effects and even prevent death [17,18]. Even though thrombolysis is useful in acute stroke most of the patients don't receive that because of delay in reaching the hospital within the window period. The anticoagulants prescribed were Low Molecular Weight Heparin (LMWH) (24%), acecoumarol (1%). Antiplatelets are the most prescribed drugs and similar observations were made in many other studies [11,12]. The most common antiplatelet used were aspirin and clopidogrel. The antiplatelet drugs have proved to be effective in prevention of ischaemic attacks in patients with history of coronary heart disease, Peripheral Artery Disease (PAD) and stroke. Also, studies have shown their efficacy in decreasing the mortality rate and recurrent strokes [19, 20]. The most common used neuroprotective agents were citicoline and cerebroptein. Neuroprotectives are given to increase the functional outcome but only few patients continue it for long term due to high cost [21]. Antiedema drugs are mainly used in haemorrhagic stroke to reduce oedema and prevent rising of Intra Cranial Tension [21]. IV Mannitol (ischaemic- 16, haemorrhagic - 24) was prescribed initially for 5 days followed by syrup glycerol (ischaemic-9, haemorrhagic-22) orally [22]. The drug treatment strategy involved with choosing medication like thrombolytics, anticoagulants, antihypertensive (angiotensin changing enzyme inhibitors, angiotensin II receptor blockers, and diuretics), blood lipid lowering agents (statins), antiplatelet medication (aspirin and clopidogrel), and cerebral activators [23]. It is also suggested to select a route and dosage form of medication to own the best therapeutic effects to manage stoke [23].

Limitation(s)

Short duration of follow-up (28 days). Since stroke is a chronic disease, it takes longer time to show significant outcome. Follow-up for atleast 3-6 months may be needed to achieve and assess precise response. A randomised controlled design would have helped us in better comparing the efficacy of different drugs used in the treatment.

CONCLUSION(S)

The findings suggest combination drug therapy reduces complication of stroke and improve patients' outcome. Risk factors such as hypertension, diabetes mellitus and smoking should be controlled. Antiplatelet agents, antihypertensive agents and statins are commonly prescribed for secondary prevention and treatment of stroke. The rationality is of utmost importance because the irrational use will cause misuse, underuse or overuse of medicines. Greater awareness is needed to reduce the burden of stroke.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Oct 27, 2021
- Manual Googling: Apr 04, 2022
- iThenticate Software: May 19, 2022 (16%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Oct 25, 2021**
Date of Peer Review: **Jan 02, 2022**
Date of Acceptance: **Apr 04, 2022**
Date of Publishing: **Jun 01, 2022**