Research Article

Assessment of Prescribing Patterns and Health-Related Quality of Life in Cerebral Stroke Patients

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ABSTRACT

Background and objectives: Stroke was one of the major public health challenges, not only for neuroscience but the society in general. This study aimed to assess the Prescribing Patterns and Health-Related Quality of Life in Cerebral Stroke patients. Methods: This is a prospective observational study for 6 months where patients diagnosed with cerebral stroke, satisfying the inclusion criteria were recruited and were categorized into Ischemic and hemorrhagic stroke. A standardised data collection was prepared and symptoms, risk factors and the prescription pattern of various drugs used were recorded. Quality of Life assessment was done by the Short Form-36 questionnaire and paired t-test was used for determining any significance in the change detected before and after treatment. Results: Out of 150 patients' stroke was higher in males (63%). The weakness of limbs (32%) constitutes the major complaint. Major risk factors associated were hypertension (30%), diabetes mellitus (18%). Cognitive enhancers (16%), antiplatelets (14%) were the most prescribed class of drugs and in combination aspirin + clopidogrel was highly prescribed. The response score of all scales increased statistically (p-value < 0.0001) indicating improved Quality of life after treatment. Conclusion: Long term studies are further required to evaluate the benefit of combinational therapy over monotherapy and to develop standard guidelines for better management. Integration of the role of a pharmacist in the management of the disease is crucial and improves clinical outcomes of patients.

Keywords: Stroke, Symptoms, Risk factors, Prescribing pattern, Drugs, Quality of life

INTRODUCTION

Stroke is a term used to describe an abrupt onset of focal neurologic deficit that lasts at least 24 hours and is assumed to be of vascular origin. Stroke can be either ischemic or hemorrhagic in origin. Transient ischemic attacks (TIAs) are focal ischemic neurologic deficits lasting less than 24 hours and are usually less than 30 minutes[1].

Types of Strokes include: - Ischemic stroke, Hemorrhagic stroke (SAH / ICH) and Transient Ischemic Attack (TIA).[2-6]

The estimated adjusted prevalence rate of stroke range in rural and urban areas was 84-262 / 100,000 and 334-424 / 100,000, respectively and the incidence rate is 119-145 / 100, according to stroke factsheet 2012[7,8,9]. The third commonest cause of death worldwide after coronary heart disease (CHD) and cancer of all types was a stroke[10,11,12]. The mortality rate due to stroke in India was 22 times that of malaria and 1.4 times that of tuberculosis. Risk factors can be modifiable and non-modifiable. Smoking, alcoholism, atrial fibrillation, hyperlipidemia, hypertension, physical inactivity, obesity and postmenopausal hormone therapy constitutes modifiable risk factors whereas non-modifiable risk factors include old age, males and family history of stroke, race (African American, Asian, Hispanic). High blood pressure and diabetes are common risk factors among Indians[13,1,4,7,8].

Nowadays, the diagnosis of stroke is done by FAST examination which includes weakness of the face, arm, speech disturbance and essentially time. CT scan, MRI scan, PET and ultrasound were the other means of diagnosis[14,3,10]. Symptoms and physical findings most often include sudden onset of facial weakness, arm drift, and abnormal speech, severe headache[15].

For acute thrombotic stroke, proven treatments include IV thrombolysis within 3 hours of the onset of symptoms, use of aspirin within 48hours and decompressive surgery for malignant middle cerebral artery infarction[3]. Stroke can cause myriad of negative consequences on an individual's life ranging from institutionalization, loss of independence to cognitive and communication difficulties[16]. Stroke in young causes economic, social burdens on families and society and also deteriorates the quality of life of a person by its functional limitations[17,2]. The greater the morbidity and disability, the lesser the quality of life of stroke survivors[18].

Pharmacists are in a key role to provide pharmaceutical care to stroke survivors, review patients profile for risk factors, whenever necessary either to recommend or initiate appropriate drug therapy if indicated. To improve patient outcomes, integrating the pharmacist in the management of stroke patients and also educating them plays a vital role[4].

It would be better to review stroke preventive ways, as there will be a rapid increase in the burden of stroke in the coming years and restricted accessibility of stroke care in India. The present study aims to provide a broad review of gender differences, demographics, risk factors, symptoms, prescribing pattern and Health-Related Quality of Life (HRQoL) of cerebral stroke patients.

MATERIALS AND METHODS

Study site and design

A prospective observational study was carried out over hospitalized cerebral stroke patients from July to December 2019 at Sivaranjani super speciality hospital. It is a tertiary care hospital specialized in neurology department which treats the patients in Bhimavaram town and nearby areas regarding various neurological disorders. Every day 100 to 150 patients were treated either in inpatient (IPD) or outpatient department (OPD).

Study criteria

Inclusion criteria

- Male and female patients of age ≥ 20 years

- Patients who are diagnosed with cerebral stroke (Ischemic, Hemorrhagic and TIA)

- Patients who are willing to give consent form to participate in the study

Exclusion criteria

- Children, Pregnant women, patients who are having a seriously debilitating condition like End-stage renal disease, HIV, Cancer

- Patients with disabilities before the incident of stroke due to various other diseases

Study procedure

Data collection

An approval of ethical clearance has been obtained from the Institutional Ethical Committee before the initiation of the study. Subjects who met the inclusion criteria (150) were enrolled for the study. Details regarding the socio-demographics, past medical and medication history and current medications were obtained by patient or care giver interview and by observing case notes and captured in valid data collection form, patient's health-related quality of life information was measured by using SF-36 questionnaire.

Data Analysis / Statistics

Descriptive statistics of demographic and clinical variables included percentages, mean and standard error of the mean (S.E.M). Mean scores before and after treatment and mean changes were calculated for the domains of SF-36. A paired t-test was used to determine if the change detected from the before and after treatment was significant. The probability value of ≤ 0.05 was set as significant and ≤ 0.001 as highly significant. All statistical analysis was performed using Graph Pad Prism version 8.3.0 (San Diego, California, USA).

Ethical consideration

The study was carried out from July 2019 to December 2019 after due permission from the Institutional Ethics Committee (Ref No: SVCP/IEC/16/12; dated: 29/07/2019) and after getting consent (in written form) from all the participating subjects.

RESULTS

**Demographics: Table 1:** Demographical characteristics of participants

Category	Type	No. of patients	Percentage (%)	Mean ± S.E.M
Gender	Male	109	63	60 ± 1
	Female	41	37	60 ± 2
	Total	150	100	60 ± 1
Age group	21 - 30	4	2	-
	31 - 40	6	4	-
	41 - 50	25	17	-
	51 - 60	46	31	-
	61 – 70	40	27	-
	71 - 80	24	16	-
	>80	5	3	-
Type of Stroke	Ischemic	132	88	-
	Hemorrhagic	12	8	-
	TIA	6	4	-

A total of 150 patients was enrolled in our study. 63% were males and 37% were females. Patients ageing ≥ 20 years were enrolled and among them most of the patients were in the age group of 51-60 (31%), followed by 61-70 (27%), 41-50 (17%), 71–80 (16%) and least were noted in the age group of 21–30 (2%) with a mean age group of 60 ± 1 (Mean ± S.E.M) (Table 1).

Risk factor

This study revealed that, out of 150 patients the risk factor of hypertension is about 30%, diabetes mellitus is about 18% followed by alcohol 16%, smoking 13%, history of stroke (old CVA) 10%, obesity 5%, hyperlipidemia 3%, head injury 2%, CAD 2% and seizures 1%. Hypertension and diabetes mellitus were the most common risk factors for the cause of cerebral stroke (Figure 1).
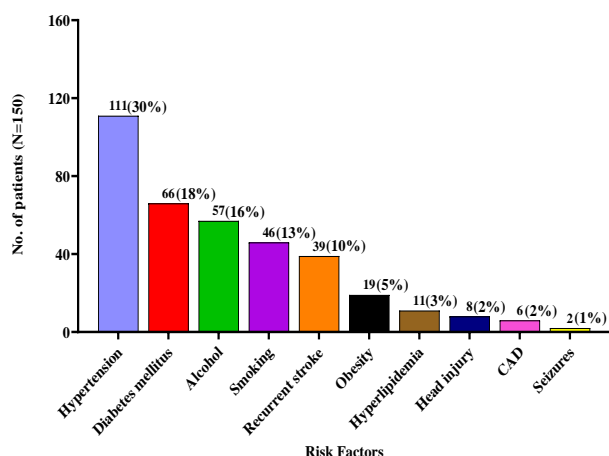
Figure-1: Distribution of study population based on risk factors

Presenting complaints

Majority of patients reported to have weakness of limbs (32%), slurred speech (15%), hemiparesis (7%), giddiness (6%), difficulty walking (6%), other minor complaints such as headache (5%), hemiplegia (5%), deviation of mouth (5%), tingling sensation (5%), altered sensorium (5%), and miscellaneous (9%) including pain (4%), blurred vision (2%), facial palsy (2%), tremors (1%) (Figure 2).
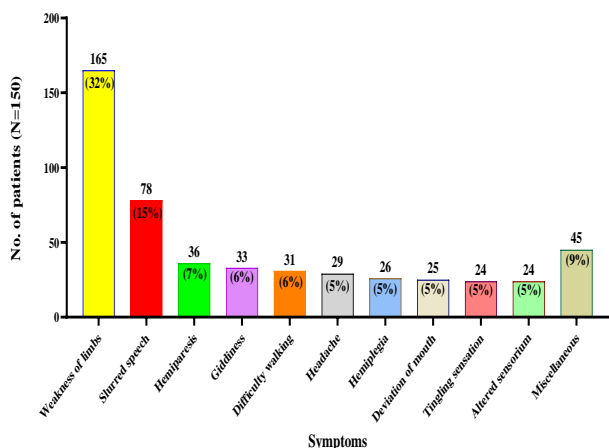
Figure-2: Prominent presenting complaints in study population

Medications

Table 2: Distribution of medications prescribed to the patients

S.no	Class of drugs	Percentage (%)
1	Cognitive Enhancers	16
2	Antiplatelets	14
3	PPIS	14
4	Dyslipidemics	12
5	Antihypertensives	12
6	Anticoagulants	8
7	Analgesics	7
8	Antidiabetics	7
9	Multivitamins	3
10	Antiepileptics	3
11	Antidepressants	2
12	Antibiotics	2

Study results revealed that cognitive enhancers (16%) as supportive therapy are most commonly present in every prescription followed by antiplatelets (14%), PPIs (14%), dyslipidemics (12%), antihypertensives (12%), anticoagulants (8%), analgesics (7%), antidiabetics (7%), antiepileptics (3%), antidepressants (2%) and antibiotics (2%).

Table 3: Core monotherapy prescribed

S. No	Drugs	Percentage (%)
1	Atorvastatin	43
2	Enoxaparin Sodium	31
3	Clopidogrel	10
4	Amlodipine	7
5	Mannitol	4
6	Rosuvastatin	3
7	Aspirin	2

Mostly used core single drug was atorvastatin (43%) followed by enoxaparin sodium (31%), clopidogrel (10%) and least prescribed was aspirin (2%).

Table 4: Core combination therapy prescribed

S.no	Drugs	Percentage (%)
1	Aspirin + Clopidogrel	86
2	Antiplatelet + Statin	14

Majorly prescribed combination drug was aspirin + clopidogrel (86%) and least prescribed was atorvastatin + aspirin, atorvastatin + clopidogrel, rosuvastatin + clopidogrel constituting antiplatelet + statin (14%) (Table 4).

Health related quality of life

Table 5: Comparison of mean scores of SF-36 scales before and after treatment

SF-36 scale (Q. No)	Treatment	N	Mean ± S.E.M	*P* value
Physical functioning (Q: 3-12)	Before	150	56.4 ± 6.0	0.0001 (HS)
	After	150	78.9 ± 5.0	
Role limitation due to physical health (Q: 13-16)	Before	150	28.2 ± 1.0	0.0001 (HS)
	After	150	82.0 ± 0.9	
Role limitation due to emotional problems (Q: 17-19)	Before	150	38.4 ± 0.6	0.0001 (HS)
	After	150	73.3 ± 0.4	
Energy/Fatigue (Q:23,27,29,31)	Before	150	56.8 ± 9.0	0.0001 (HS)
	After	150	73.9 ± 6.0	
Emotional wellbeing (Q: 34, 25, 26, 28, 30)	Before	150	62.6 ± 8.0	0.0001 (HS)
	After	150	79.2 ± 6.0	
Social functioning (Q:20,32)	Before	150	54.1 ± 2.0	0.0001 (HS)
	After	150	79.4 ± 0.3	
Pain (Q:21,22)	Before	150	62.9 ± 0.6	0.0001 (HS)
	After	150	85.4 ± 2.0	
General health (Q:1, 33-36)	Before	150	51.7 ± 9.0	0.0001 (HS)
	After	150	70.1 ± 5.0	
Health change (Q: 2)	Before	150	29.9 ± 0.0	0.0001 (HS)
	After	150	70.7 ± 0.0	

HS: Highly-significant.

The mean value of physical functioning before treatment is 56.4 and after treatment is 78.9. The difference in means is highly statistically significant (P<0.0001). The mean role limitation due to physical health pre-treatment is 45.7 and post-treatment was 82.0. The difference in means is highly statistically significant (P<0.0001). The mean role limitation due to emotional problem pre-treatment is 43.6 and post-treatment is 73.3. The difference in means is highly statistically significant (P=0.0001). The mean energy/ fatigue pre-treatment is 56.8 and post-treatment are 73.9. The difference in means is highly statistically significant (P=0.0001). The mean Emotional wellbeing pre-treatment is 62.6 and post-treatment is 79.2. The difference in means is highly statistically significant (P=0.0001). The mean social functioning pre-treatment is 54.1 and post-treatment is 79.4. The difference in means is highly statistically significant (P=0.0001). The mean pain score pre-treatment is 62.9 and post-treatment is 85.4. The difference in means is highly statistically significant (P=0.0001). The mean general health score pre-treatment is 51.7 and post-treatment is 70.1. The difference in means is highly statistically significant (P=0.0001). The mean health change pre-treatment is 47.7 and post-treatment is 70.7. The difference in means is highly statistically significant (P=0.0001). The response score of all scales increased significantly (p < 0.0001), which indicates the improvement in Quality of life of stroke survivors after treatment (Table 5).

Table 6: Mono Vs Multiple therapy health score change

Domain	Monotherapy	Combination
Physical functioning (Q: 3-12)	24.7	18.5
Role limitation due to physical health (Q: 13-16)	55.9	53.0
Role limitation due to emotional problems (Q: 17-19)	17.2	39.8
Energy/Fatigue (Q:23,27,29,31)	16.6	18.7
Emotional well being (Q: 34, 25, 26, 28, 30)	14.5	27.4
Social functioning (Q:20,32)	21.5	26.8
Pain (Q:21,22)	19.7	23.6
General health (Q:1, 33-36)	17.9	18.4
Health change (Q: 2)	35.7	42.7

Multiple therapies using patients have an improvement in the quality of life in all domains compared to monotherapy

patients except in the domains of physical functioning and role limitation due to physical health where monotherapy using patients have shown best results than combination therapy (Table 6).

DISCUSSION

The present study is done to assess the symptoms, risk factors, prescribing pattern of drugs and to evaluate their impact on the quality of life of cerebral stroke patients admitted in a tertiary care hospital, Bhimavaram.

The total number of patients enrolled under this study group were N = 150, the distribution of males (63%) is greater than females (37%). The observation is in agreement with the findings of the study conducted by Jithin kc et al (2016) and Mathew E et al (2017) where males are affected more than females. Which can be attributed due to a) Estradiol has potent effects on endothelia that promote dilation of blood vessels and blood flow, whereas testosterone has opposite effects. This indicates women are protected by endogenous estrogens b) Males are more prone to HTN and DM than females c) Smoking[12,19].

The data from this study shows that major type stroke observed in our patients was Ischemic (88%) followed by Hemorrhagic (8%) and TIA (4%) which was in accordance with study by Prathyusha B et al (2014) and Vurumadla S et al (2015)[4,13].

Most patients in our study presented with complaints of weakness of limbs (32%), slurred speech (15%), hemiparesis (7%), giddiness (6%), difficulty walking (6%) etc., Similarly, in the study by Dc RAL et al (2010) in Mississippi chiropractic practice patients presented with complaints of unilateral arm weakness and slurred speech, other complaints included episodic loss of vision, dysphagia, dysphonia, and same-sided leg weakness[15]. Contrastingly the study results of Vurumadla S et al (2015) showed that symptoms like slurred speech, followed by weakness on the right side in 97 (65%) patients, headache in 88 (59%) patients, change in a speech in 87 (58%) patients, weakness on the left side in 58 (39%) patients and deviation of mouth in 48 (32%) patients[13].

The data of our study regarding risk factors of cerebral stroke in our patients showed that hypertension (30%) is the major cause followed diabetes mellitus (18%), alcohol (16%) and smoking (13%). A study conducted by Vurumadla S et al (2015) shows similar results where the most common risk factors associated with the stroke was hypertension in 102 (68%) patients, followed by dyslipidemia in 81 (54%) patients, diabetes mellitus in 51 (35%) patients and heart disease in 49 (33%) patients[13].

A thorough screening was made into all the prescriptions of our study participants where cognitive enhancers (16%) as supportive therapy are mostly present in every prescription followed by antiplatelets (14%), PPIs (14%), dyslipidemic agents (12%), antihypertensives (12%), anticoagulants (8%), analgesics (7%) for pain and antidiabetics (7%) for patients with elevated blood sugar levels, for post-stroke seizures and depression drugs such as antiepileptics and antidepressants were given respectively, for hospital born infection prophylaxis antibiotics (2%) were given, similar results were obtained in the study of Jithin kc et al (2016) where the patients are prescribed with antiplatelets, anticoagulant, antihypertensive, statins, and antidiabetics, antidepressants, antiepileptics, multivitamins, and laxatives, GI protectants[19].

A study conducted by Konduru SST et al (2017) shows that the most frequently used drugs were antiplatelet (clopidogrel) - 70 (21%), psychostimulant (citicoline) – 67 (20%) and dyslipidemic (atorvastatin) – 56 (16%). Similarly, in our study mostly used core single drug was atorvastatin (43%) followed by enoxaparin sodium (31%), clopidogrel (10%) and least prescribed was Aspirin (2%)[22].

Our study results show that majorly prescribed combination drug was aspirin + clopidogrel (86%) and least prescribed was atorvastatin + aspirin, atorvastatin + clopidogrel, rosuvastatin + clopidogrel combining 14%. A study conducted by Konduru SST et al (2017) shows aspirin + clopidogrel was the major prescribed combination therapy in stroke patients which favours our study[22].

A study by Rajan B et al (2019) said that QoL showed significant improvements in all physical, psychological and social domains by the end of the 6th month of followup, the results were similar with our study where response score of all scales increased significantly (p < 0.0001), which indicates the improvement in Quality of life of stroke survivors after treatment[9]. Whereas Mahran S et al (2015) study says that low mean scores of all the nine domains of SF-36 were found which is opposite to our study result. This may be due to poor adherence of patients regarding their medications and lifestyle modifications designed by their physicians, stringent implementation of awareness and counselling regarding the effectiveness of treatment should be implemented[21].

Patients taking mono and combination therapy are assessed for their health score before and after therapy and the change in score was noted and compared. Multiple therapies using patients have an improvement in the quality of life in all domains compared to monotherapy patients except in the domains of physical functioning and role limitation due to physical health where monotherapy using patients have shown best results than combination therapy. Although clopidogrel-aspirin therapy seems to have substantially reduced the risk of stroke in the patients in comparison with aspirin-alone therapy, there is still a large proportion of patients at high risk of stroke despite clopidogrel treatment. Wang Y et al (2015) study shows that there was a slight benefit in patients taking combined therapy compared with monotherapy which is similar to the findings in our study[20].

CONCLUSION

Cerebral stroke is a multi-factorial health problem, and its prevalence and risk factors have changed considerably within the past century. The study finds the higher prevalence of cerebral stroke among males and in the age group of 51-60 years with major risk factors constituting hypertension, DM. The weakness of limbs, slurred speech and hemiparesis were the most commonly reported symptoms. Antiplatelets (clopidogrel), dyslipidemic agent (atorvastatin) and anticoagulants (enoxaparin sodium) were mostly prescribed single drugs along with cognitive enhancers and gastro protectives; in multiple therapy aspirin + clopidogrel constitutes major proportion. There was a statistical improvement in the health-related quality of life in cerebral stroke patients by the course of treatment and self-care. Prevalent cerebrovascular risk factors (hypertension, DM) increased the risk of getting a stroke, thereby identifying and managing them priorly with rational use of treatment decreases the worsening of the disease and co-morbidities. Long term studies are further required to evaluate the benefit of combinational therapy over monotherapy and to develop standard guidelines for better management. Integration of the role of a pharmacist in the management of the disease is crucial and improves clinical outcomes of patients.

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