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Original Article

Prescription Pattern in the Management of Secondary Prevention of Stroke in Post Stroke Patients

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ABSTRACT

Background: To analyze the drug prescription pattern for secondary prevention of stroke, medication adherence, knowledge and awareness about the disease, direct medical cost involved in the treatment of stroke. **Methods:** A prospective interventional study was done on ischemic stroke patients for a period of 10 months in the outpatient department of stroke after obtaining ethical clearance. Medical prescriptions of all patients were checked as per the ASA guidelines. Educational interventions were given on lifestyle modifiable risk factors with the aid of booklets on stroke. All the patients were assessed for knowledge on stroke, medication adherence at baseline and post-intervention using validated questionnaires. Direct medical cost for treatment during the study was estimated. **Results:** The mean age of study patients was 59.69 ± 9.56 years and 67% were males. Disease knowledge, medication adherence improved significantly post-intervention (P<0.001). Among the various classes of drugs prescribed for secondary stroke prevention, antihypertensive medications constituted the largest class (81%) followed by antiplatelets and statins (68%). Out of 100 patients 99 were having $CHADS_2$ score ≥2, 67% were prescribed with antithrombotic medications who were having medium to high risk for secondary stroke. The mean medication cost for the treatment of stroke during the study period was 33,077.35 ± 10241.32 Rs. **Conclusion**: The data procured from this study highlights the importance of prescribing patients with anticoagulants rather than antithrombotic or combination of antithrombotic in those who are at medium to high risk for future strokes. Clinical pharmacist's contributions can provide better management in secondary prevention of stroke.

Key words: Anticoagulants, Clinical pharmacist, Medication adherence, Secondary prevention, Stroke.

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INTRODUCTION

Stroke the second leading cause of death and third leading contributor to disability-adjusted life-years in the world.[1,2] Among patients who survive an acute stroke, the risk of stroke recurrence is highest within the first few weeks, approximately 10% in the first year and 5% per year subsequently.[3] Even though advanced treatment for acute ischemic stroke is available nowadays, the number of effective and feasible treatments remains limited.[4,5] The economic impact of stroke will vary from different countries. For this reason, secondary prevention of ischemic stroke remains a major clinical and public health issue.[6] Recurrent stroke can be prevented to a great extent by adopting evident based treatment strategies, improving medication adherence and by management of modifiable risk factors. Various studies have proved the benefits of including a clinical pharmacist in the patient care team in improving medication adherence, management of hypertension and dyslipidemia which are the major modifiable risk factors targeted in secondary prevention of stroke.[7-9] Hence this study aimed to explore the impact of clinical pharmacist interventions in Indian population in secondary stroke prevention management and to assess the prescription pattern of medicines used for secondary stroke prevention.

MATERIALS AND METHODS

Participant selection

A Prospective interventional study was done for a period of 10 months in the out-patient (OP) department of stroke division, Amrita Institute of Medical Sciences and Research Centre, Kochi, a 1250 bedded tertiary care teaching hospital after approval of the institutional review board.

Inclusion Criteria

All stroke OP patients who satisfied the inclusion and exclusion criteria were selected for the study process. Stroke patients aged ≥18 years admitted under stroke department and discharged from stroke unit, including those who were started on oral anticoagulants were included.

Exclusion Criteria

Pregnant and breast-feeding patients, those with severe liver/renal insufficiency, those on long term follow up prior to the commencement of the study or patients and /or their caregivers unwilling to provide written informed consent were excluded.

Relevant medical data were obtained by personal interview of communication with patients and/or their caregivers, examination of electronic medical records and assessment using validated questionnaires.

Secondary stroke prevention

Patients were evaluated on their first visit after discharge (7±3 days) for baseline knowledge and awareness regarding the disease using locally prepared validated questionnaire and medication adherence using Morisky Medication Adherence 8-item scale.[10-12] and reassessed during follow up visit. The patients were provided with stroke education

booklets at their baseline visit and made them aware regarding the use of 'pill box'. From discharge onwards proper medication counseling was given and all the medications prescribed were checked at each visit. The direct medical cost was tabulated which includes consultation cost, medication cost, lab investigation cost at each visit.

One hundred prescriptions of all the patients were assessed and their prescription pattern was compared with standard guidelines of American Stroke Association. The risk of the patients for future stroke was assessed by $CHADS_2$ Score and CHADVASc score.

Patients on oral anticoagulants were given additional educational interventions and booklets on oral anticoagulation. Ischemic stroke in patients with atrial fibrillation were assessed using $CHADS_2$ as well as CHA_2DS_2-VASc score. Bleeding risk in patients on oral anticoagulants were assessed using HAS-BLED score. The safety and effectiveness of oral anticoagulants including newer oral anticoagulant dabigatran prescribed to the patients were evaluated by monitoring the ADRs and by the occurrence of secondary stroke respectively.

Determinant measures

Various patient level factors were studied *viz.*

i) Demographic characteristics - Age, sex, ethnicity, and education level.

ii) Co-morbidities and prescriptions recorded prior to the stroke event: previous hypertension, diabetes, lipidemia, heart related problems, previous stroke, or transient ischemic attack (TIA) events and prior prescriptions of antiplatelet drugs, anticoagulant drugs, antihypertensive drugs, and lipid lowering drugs.

iii) Lifestyle - Obesity, smoking, alcohol addiction etc.

iv) Patients disability status upon discharge was assessed by using specific scale.

Statistical Analysis

The medication cost for both patients taking warfarin and dabigatran was calculated each time. For patients on warfarin, the cost for doing INR test was also included. The data were tabulated using Microsoft excel and statistical analysis was done using Statistical package for the Social Sciences (SPSS) software version 21. The significance was compared using Z test and Wilcoxon signed rank test.

RESULTS

Out of 100 ischemic stroke patients selected, 67% were males and the mean age of study patients was 59.69 ± 9.56 years.

Table 1 and 2 shows the $CHADS_2$ and CHA_2DS_2-VAScscore of patients in the study sample respectively. 99% patients were found to have $CHADS_2$ score ≥ 2 points and 99% had CHA_2DS_2-VAScscore ≥ 2 points. The general pattern of prescription of drugs for the secondary prevention of stroke is shown in Table 3. 68% of study population was prescribed with antiplatelet drugs, 47% with anticoagulants, 81% with antihypertensives, 68% with stains for secondary stroke prevention. The knowledge and awareness of patients regarding stroke improved significantly post-intervention. Only 2% of the patients were aware of the sudden warning signs of stroke at baseline and it improved to 98% post-intervention. The responses of our study patients to various questions on knowledge and awareness regarding stroke is shown in Table 4.

The medication adherence of patients improved significantly post-intervention (p<0.001) (Figure 1) and the direct medical cost for the treatment of study patients during the study period was estimated and is shown in Table 5.

Bleeding risk in patients on oral anticoagulants was assessed using HAS-BLED scoring. HAS-BLED scoring of patients on oral anticoagulants

Table 1: $CHADS_2$ score of patients in the study sample (*n*=100).

$CHADS_2$ Score	% of annual stroke risk*	No. (%) of patients
0	1.9	1 (1)
1	2.8	0 (0)
2	4.0	3 (3)
3	5.9	32 (32)
4	8.5	56 (56)
5	12.5	8 (8)
Mean score		3.66
SD		0.755

* The chances for future stroke can be predicted by calculating $CHADS_2$ score. Standard values representing % of annual stroke risk in the study patients.

Table 2: CHA_2DS_2-VASc score of patients in the study sample (*n*=100).

CHA_2DS_2-VASc score	No. (%) of patients
0	0
1	1
2	35
3	12
4	23
5	21
6	3
7	4
8	1
9	0
Mean	3.58
SD	1.519

Additional risk factors like vascular disease, female sex, age 64-75 are considered in CHA_2DS_2-VASc score

Table 3: General pattern of prescription of drugs for the secondary prevention of stroke.

Drug categories	No. (%) of patients	Percentage of medications(n=504)
• Antiplatelets*	68(68%)	13.42
• Aspirin	34(34%)	6.746
• Clopidogrel	9(9%)	1.78
• Aspirin and Clopidogrel	25(25%)	4.96
• Anticoagulants*	47(47%)	9.32
• Warfarin	37(37%)	7.34
• Dabigatran	10(10%)	1.98
• Antihypertensives	81 (81%)	20.23
• Calcium channel blockers	49 (49%)	9.72
• Angiotensin receptor blockers	25(25%)	4.96
• Beta blockers	12(12%)	2.38
• Alpha blockers	11(11%)	2.18
• Diuretics	5(5%)	0.99
• Dyslipidemics		
• Statins	68(68%)	13.49

The general prescription pattern of drugs for secondary stroke prevention in the study group is described and the highly prescribed class of drug is Antihypertensive. This prescription pattern was compared with the standard guidelines.

Table 4: Response of study patients to Knowledge and awareness questionnaire.

SL. No.	Questions	% of patients giving correct responses		Z-value
		Pre-intervention	Post-intervention	
1.	What do you understand by the term 'stroke'?	3%	94%	48.49**
2.	What are the warning signs of stroke?	2%	98%	33.20**
3.	Which hemisphere of the brain is affected by stroke?	4%	96%	70.00**
4.	Which is the most common form of stroke?	0%	98%	43.05**
5.	What is a hemorrhagic stroke?	2%	97%	16.54**
6.	Name a risk factor for hemorrhagic stroke?	12%	88%	21.34**
7.	What should you do if you find a person having symptoms of stroke?	18%	100%	15.65**
8.	Is there a chance for second stroke after the first one?	29%	100%	14.81**
9.	How can one prevent the recurrence of stroke?	24%	95%	31.27**
10.	Man or woman who is at high risk for stroke?	7%	98%	25.87**
11.	Smoker or ex-smoker who is at high risk for stroke?	13%	100%	7.33**
12.	Name a modifiable risk factor of stroke?	26%	72%	17.64**
13.	How can one prevent the extent of brain damage due to stroke?	12%	90%	48.99**
14.	Which is the most powerful blood thinning drug used in prevention of stroke?	0%	96%	48.49**

** Significant at 0.01 level, P<0.001indicates a significant difference in the knowledge score of study patient group before and after intervention.

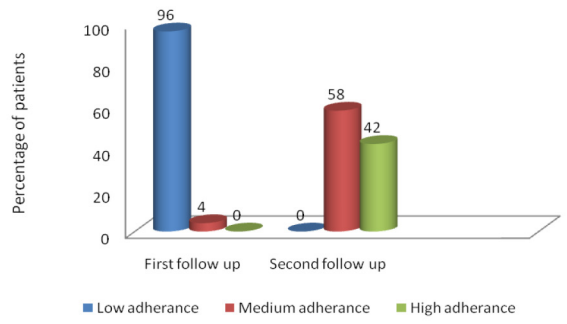

Figure 1: Medication adherence of study patients as per MMAS-8 Scale (*n*=100).

Table 5: Direct medical cost estimation for stroke treatment in study patients (*n*=100).

Parameters	Total cost (Rs)	Mean cost (Rs)
Consultation cost for first visit	20,000	200±0.00
Cost of medications during hospital stay	3,74,275.76	3,742.76±934.71
Lab cost during hospital stay	13,57,920	13,579.2±3465.86
Consultation cost for follow up after discharge	40,000	400±0.00
Cost of medications for 10 months after discharge	11,79,179	11,791.79±358.67
Lab cost for 10 months after discharge	3,36,360	3,363.60±758.95
Grand total	33,07,734.76	33,077.35±10241.32

The mean medical cost calculated by taking in to account of consultation cost, medical cost and lab costs during the study period are listed.

both Warfarin and Dabigatran was assessed and 100% of the study patients taking either warfarin or dabigatran had a HAS-BLED score ≤ 2.

DISCUSSION

In our study we found a significant improvement in the stroke risk by the control of modifiable risk factors. This was achieved by the regular medical follow up along with clinical pharmacist's interventions in making the patients aware regarding the disease signs and symptoms, management of modifiable risk factors, improving medication adherence. About 8% of the people who had a primary stroke are likely to have stroke recurrence soon.[13] So, prevention of stroke recurrence will play a key role in improving the overall health as well as economic burden of the patients.

Out of 100 patients selected for the study 67% were males and the remaining females which was like the group of patients in the study conducted by Pandian *et al.*[14] The mean age group of our patients (59.69±10.15years) compares well with the above-mentioned study group (59.7±14.1years).

The chances for future stroke can be predicted by calculating $CHADS_2$ score. Patients having $CHADS_2$ score 2 or more will have high risk for future stroke.[15] Ninety nine percent of our study patients had $CHADS_2$ score ≥2 (Table 2). The additional risk factors that are expressed in the CHA_2DS_2-VASc have been proposed to complement the $CHADS_2$ score.[16] Additional risk factors like vascular disease, female sex, age 64-75 are considered in CHA_2DS_2-VASc score. So, this scoring truly identifies patients at higher risk for future stroke when compared to $CHADS_2$ score. $CHADS_2$ score ranges from 0-6 and CHA_2DS_2-VASc score ranges from 0-9. In both scoring, patients having a score ≥2 are grouped in high risk category.

According to American stroke association (ASA) guidelines for long term secondary prevention of stroke antiplatelets, anticoagulants, blood pressure lowering medications and lipid lowering drugs are given to patients.[17] All our study patients received medications for secondary prevention of stroke. This was contradictory to the study done by Volpato[18] where majority of patients were discharged without antithrombotic medications. In that study about 40% of the patients who had a previous stroke were neither receiving antiplatelets nor

anticoagulants, but in our patients 68% were prescribed with antiplatelets who had an ischemic stroke, while the remaining 47 patients were given oral anticoagulants, 34 of these patients were given oral anticoagulants for stroke prevention in atrial fibrillation. More study patients could have been subjected to anticoagulation, but the confounding factors may be bleeding risk and old age, also the decision to start anticoagulants is solely doctor's decision in our health system. 15 patients were taking both anticoagulants and antiplatelets. Four among them were taking clopidogrel along with warfarin as they had undergone valve replacement surgery and the remaining were taking aspirin along with warfarin as they had coronary artery disease. All patients who had a previously treated hypertension as well as newly diagnosed one were taking appropriate class of antihypertensive medication as prescribed. Patients with dyslipidemia (total cholesterol levels are high) were prescribed with appropriate dose of statins to reduce the risk of stroke and cardiac complications. All patients who had uncontrolled diabetes were treated with oral hypoglycemic drugs and with insulin injections. All were educated regarding the lifestyle, dietary modification that can be followed to reduce the modifiable risk factors.

The knowledge of our study patients regarding the disease improved significantly (P<0.001) post-intervention as compared to the baseline. This might be due to education given to the patients regarding the warning signs, risk factors of stroke, importance of early hospitalization and stroke rehabilitation measures etc. by clinical pharmacists. Our study had positive correlation with other studies conducted by Kothari *et al.*[19] and Croquelois *et al.*[20] where the patients/caregivers had low knowledge regarding the warning signs and risk factors of stroke. Proper adherence to medications is very vital for secondary prophylaxis of stroke. Most patients had low medication adherence at baseline. Forgetfulness, fear about adverse drug effects, ignorance about the consequences of non-adherence may be the reasons for low adherence. Pharmacist led educational interventions can improve medication adherence.[21] The mean adherence scores of patients improved significantly in the second follow up visits (P<0.001). This might be due to patient counseling and patient education by clinical pharmacists.

HAS-BLED scoring was done to identify the bleeding risk of patients on oral anticoagulants. Patients having HAS-BLED score ≤ 2 have low bleeding risk and they can be prescribed antithrombotic medications safely. A score ≥3 indicates high risk for bleeding and these patients require review and monitoring of therapy.[22] Traditional anticoagulant warfarin and newer anticoagulant dabigatran were used in our patients. As per our study results none of the patients on warfarin and dabigatran were having a high risk for bleeding at baseline.

On comparing newer anticoagulant Dabigatran with warfarin, number of patients using dabigatran (10) was less as compared to patients using warfarin (37) in our study where as in the non-inferiority trial conducted by Conolly[23] comparing dabigatran and warfarin the total number of patients included was 18,113 and the follow up period was 2 years. Nevertheless, we compared the bleeding episodes in the two groups, and it was found to be non-significant (P =0.284). As per our study dabigatran was not superior (P=0.161) to warfarin (13.51%) in preventing stroke recurrence which was in contradiction to the study obtained by Miller[24] where it was found that newer anticoagulants were effective in reducing the risk for stroke and systemic embolism than warfarin. Another cohort study by Banerjee[25] shows that when the risk for stroke and bleeding are high dabigatran, rivaroxaban and apixaban had a better clinical benefit than warfarin.

CONCLUSION

Educational interventions by clinical pharmacists can contribute to better disease knowledge and improved medication adherence. As per the American Stroke Association guidelines the prescription pattern should be made rational according to the patient characteristics and $CHADS_2$ score. The data procured from this study highlights the importance of prescribing patients with anticoagulants rather than antithrombotic or combination of antithrombotics in those who are at medium to high risk for future strokes. Antithrombotic or oral anticoagulants play an important role in preventing recurrence of cardio-embolic stroke. Clinical pharmacist's contributions can provide better management in secondary prevention of stroke.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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