



## Drug Utilization Pattern and Role of Clinical Pharmacist in Medication Adherence of Stroke Patients in a Tertiary Care Hospital, South India: A Prospective Observational Study

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### ABSTRACT

Stroke comprises of a broad term encompassing many disorders of the blood vessels of the central nervous system that may result from either inadequate blood flow to the brain with subsequent infarction of the involved portion of the CNS or haemorrhages into the parenchyma or subarachnoid space of the CNS causing neurologic dysfunction. Stroke is one of the major cause of mortality worldwide. The objective of the study was to assess the drug utilization pattern (DUP) and to evaluate the impact of counseling on medication adherence for stroke patient admitted in the hospital. Dual antiplatelet therapy (69.4%) was mostly given over monotherapy (28.2%). CCB (28.2%) was the most commonly prescribed antihypertensive drug class and amlodipine (77.1%) was the major CCB given in this study. 96.5 prescriptions comply AHA/ASA guidelines. Unintentional reasons for nonadherence were been reported more frequently than intentional reasons prior to the counseling. The commonest reported unintentional reasons were Forgetfulness (96.0%), Confusion (80.0%) and intentional reasons are carelessness (92%), avoiding dosing schedule (78%). Medication adherence before and after counseling was compared and was found to be improved with a statistically significant ( $p < 0.01$ ). In our study most patients with hypertension, diabetes mellitus and hyperlipidemia were the victims of the stroke. An equal preponderance of both the gender was observed. Our study identified unintentional reasons for non-adherence were more common than intentional non-adherence.



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### INTRODUCTION

Stroke is the most common, life-threatening disease and is the major cause of morbidity and mortality worldwide especially in South Asian subcontinent [1, 2]. The impact of stroke can be short and long term, depending on which part of brain is affected and how quickly treatment is given. Stroke can cause permanent damage, including partial paralysis and impairment in speech, cognition and memory and the most common Risk factors are HTN, DM, DLP, smoking, alcohol, unhealthy diet etc. According to recent studies globally 1 in 4 adults over the age of 25 will have a stroke in their life-

time. Around 13.7 million people worldwide will be affected with stroke at this age and 5.5 million will die as a result. If appropriate action is not taken the annual death rate may increase to 6.7 million in every year.

The WHO defined Drug Utilization research as “the marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences and it aims to improve the rational drug use by identifying and reducing the drug and health related treatment costs, reducing the number of medication related problems and medication errors, improvising the health-related quality of life of the patient [3].

Medication adherence is defined as the extent to which a patient’s medication taking behavior coincides with the intention of health advice they has been given. It is one of the most important factors that determine the therapeutic outcomes especially in patients suffering from chronic illness.

The number of stroke patients admitted in this hospital is relatively high and majority of population in this locality having risk factors such as hypertension and DM. Non adherence to treatment and poor quality of life are prevalent in patient with stroke. Therefore, medication adherence plays a major role in preventing stroke incidence and reoccurrence.

Clinical pharmacist plays an important role in overcoming barriers contributing to the medication non-adherence and improving the Individual patient medication adherence for achieving the desired therapeutic outcome and also assessing risk factors to decrease the stroke occurrence and helps in secondary prevention of the disease.

The objective of present study was to assess drug utilisation pattern and to evaluate impact of counselling on medication adherence for stroke patients.

## METHODOLOGY

It is a prospective observational study conducted on stroke patients who admitted in Valluvanad hospital, Kerala, South India for a period of six months.

### Ethical Approval

The study protocol was approved by ethical committee of Valluvanad hospital, Ottappalam [108/KTN/VND/2021]

### Participants selection

Patients with ischemic and hemorrhagic stroke of both sex and agreeable to take part in the planned study was included. A total of 85 patients included in this study as per inclusion and exclusion criteria.

### Inclusion criteria

1. Patients who are diagnosed and admitted with stroke
2. Above 18 years of age
3. Any gender
4. With or without comorbidities

### Exclusion criteria

1. Patients with incomplete case reports
2. Breastfeeding/ Pregnant ladies
3. Pediatrics
4. Outpatients
5. Who were not interested to participate

### Data collection

A Specially designed data collection form is used for the data collection. After direct interview with the patient, the questionnaire was filled out. Patient information leaflet also provided to the patient. The main purpose of this patient information leaflet is to improve the medication adherence of the patient.

### Statistical analysis

Categorical and quantitative variables were expressed as frequency (percentage) and mean  $\pm$  SD respectively. Wilcoxon Signed Rank Test was carried out to compare medication adherence between two intervals of time. For all statistical interpretations,  $p < 0.05$  was considered the threshold for statistical significance. Statistical analyses were performed by using a statistical software package SPSS, version 20.0.

## RESULTS

A total of 85 patients were enrolled in our study. Among these, 51.8% of participants were males and 48.2% were females. Table 1 showed that 29.4% were from age group 70-80 years followed by 28.2% from 60-70 years [Figure 1].

Majority of patients who participated in this study does not have any social history, only 17.6% were smokers, 3.5% were both smokers and alcoholic and 1.2% alcoholics. (Table 2)

Out of 85 patients most of the patients (81.2%) were hypertensive, followed by 57.6% diabetic and 29.4% were hyperlipidemia (Table 3).

**Table 1: Distribution of participants based on Age**

| Age in years | Number | %    |
|--------------|--------|------|
| 30 – 40      | 1      | 1.2  |
| 40 – 50      | 8      | 9.4  |
| 50 – 60      | 21     | 24.7 |
| 60 – 70      | 24     | 28.2 |
| 70 – 80      | 25     | 29.4 |
| 80 – 90      | 6      | 7.1  |

**Table 2: Distribution based on social history**

| Social history      | Number | %    |
|---------------------|--------|------|
| Smoking             | 15     | 17.6 |
| Alcoholic           | 1      | 1.2  |
| Smoking & alcoholic | 3      | 3.5  |
| Smoking & tobacco   | 1      | 1.2  |
| None                | 65     | 76.5 |

**Table 3: Distribution based on comorbidities**

| Comorbidities         | Number | %    |
|-----------------------|--------|------|
| HTN                   | 69     | 81.2 |
| DM                    | 49     | 57.6 |
| DLP                   | 25     | 29.4 |
| CAD                   | 11     | 12.9 |
| Seizure               | 3      | 3.5  |
| Renal impairment      | 2      | 2.4  |
| COPD                  | 4      | 4.7  |
| Asthma                | 2      | 2.4  |
| Pneumonia             | 1      | 1.2  |
| Hypothyroidism        | 1      | 1.2  |
| Folic acid deficiency | 9      | 10.6 |

**Table 4: Distribution of stroke subtype**

| Stroke subtype | Number | %    |
|----------------|--------|------|
| Ischemic       | 13     | 15.3 |
| Hemorrhagic    | 1      | 1.2  |
| Infarct        | 68     | 80.0 |
| TIA            | 3      | 3.5  |

**Table 5: Percentage distribution of thrombolytics**

| Thrombolytics | Number | %    |
|---------------|--------|------|
| Tenecteplase  | 13     | 15.3 |
| None          | 72     | 84.7 |

**Table 6: Distribution according to antiplatelet therapy**

| Antiplatelet drugs | Number | %    |
|--------------------|--------|------|
| Mono therapy       | 24     | 28.2 |
| Dual therapy       | 59     | 69.4 |
| Not given          | 2      | 2.4  |

**Table 7: Distribution of dual antiplatelet therapy**

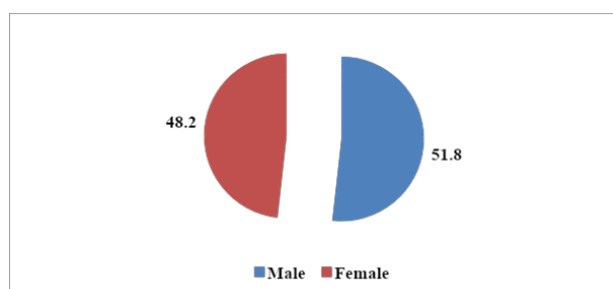
| Dual therapy                    | Count | %    |
|---------------------------------|-------|------|
| Aspirin/Clopidogrel: 325/150 mg | 22    | 37.3 |
| Aspirin/Clopidogrel: 150/75 mg  | 34    | 57.6 |
| Aspirin/Clopidogrel: 325/75 mg  | 3     | 5.1  |

**Table 8: Percentage distribution of anticoagulants**

| Anticoagulants    | Count | %    |
|-------------------|-------|------|
| Enoxaparin sodium | 38    | 44.7 |
| None              | 47    | 55.3 |

**Table 9: Percentage distribution of Antihypertensive**

| Antihypertensive         | Count | %    |
|--------------------------|-------|------|
| ACEI                     | 1     | 1.2  |
| Beta blocker             | 5     | 5.9  |
| CCB                      | 24    | 28.2 |
| ARB                      | 11    | 12.9 |
| Diuretics                | 5     | 5.9  |
| Alpha adrenergic blocker | 1     | 1.2  |
| CCB +BB                  | 9     | 10.6 |
| CCB + ARB + Diuretic     | 2     | 2.4  |
| CCB + Diuretic           | 3     | 3.5  |
| ARB + Diuretic           | 2     | 2.4  |
| CCB + Adrenergic blocker | 2     | 2.4  |
| CCB + ARB                | 4     | 4.7  |
| Vasodilator              | 1     | 1.2  |

**Figure 1: Distribution of participants based on gender**

The results reveals that 80% of the patients were diagnosed with having an infarct type of stroke,

15.3% patient having ischemic stroke, 3.5% patients having transient ischemic attack and 1.2% of patient having hemorrhagic stroke. (Table 4)

Table 5 indicated that, out of 85 patients only 15.3% were thrombolysed with Tenecteplase within the critical period explained in the guideline. Remaining 84.7% patients were not received thrombolytic therapy.

Majority of patients (69.4%) received dual therapy of anti-platelets and 28.2% were received monotherapy. (Table 6). In dual antiplatelet therapy Aspirin/ Clopidogrel were in the dose (150/75mg) 57.6% followed by (325/150mg) 37.3%. (Table 7)

**Table 10: Percentage distribution of Antihypertensive**

|                          | Drugs                 | Count      | %     |
|--------------------------|-----------------------|------------|-------|
| ACEI                     | Enalapril             | 1          | 100.0 |
| Beta blocker             | Labetalol             | 8          | 42.1  |
|                          | Metoprolol            | 5          | 26.3  |
|                          | Atenolol              | 4          | 21.1  |
|                          | Nebivolol             | 1          | 5.3   |
|                          | Bisprolol             | 1          | 5.3   |
|                          | CCB                   | Amlodipine | 37    |
|                          | Clinidipine           | 7          | 14.6  |
|                          | Nifedipine            | 2          | 4.2   |
|                          | Verapamil             | 2          | 4.2   |
| ARBS                     | Telmisartan           | 19         | 90.5  |
|                          | Losartan              | 2          | 9.5   |
| Diuretics                | Mannitol              | 9          | 64.3  |
|                          | Mannitol + Nicorandil | 1          | 7.1   |
|                          | Lasilactone           | 1          | 7.1   |
|                          | Furosemide            | 3          | 21.4  |
| Alpha adrenergic blocker | Clonidine             | 2          | 50.0  |
|                          | Moxonidine            | 2          | 50.0  |
| Vasodialator             | Nicorandil            | 1          | 100.0 |

**Table 11: Percentage distribution of antihyperlipidemic drugs**

| Antihyperlipidemic | Count | %    |
|--------------------|-------|------|
| Rosuvastatin       | 82    | 96.5 |
| Atorvastatin       | 2     | 2.4  |
| Fenofibrate        | 1     | 1.2  |

**Table 12: Percentage distribution of compliance of treatment with AHA/ASA**

| AHA/ASA | Count | Percent |
|---------|-------|---------|
| Yes     | 82    | 96.5    |
| No      | 3     | 3.5     |

**Table 13: Distribution of medication adherence**

| Medication adherence | Before |      | After |      | Z#   | P      |
|----------------------|--------|------|-------|------|------|--------|
|                      | Count  | %    | Count | %    |      |        |
| Poor                 | 33     | 38.8 | 0     | 0.0  | 5.02 | p<0.01 |
| Medium               | 32     | 37.6 | 32    | 37.6 |      |        |
| High                 | 8      | 9.4  | 53    | 62.4 |      |        |
| NA                   | 12     | 14.1 | 0     | 0    |      |        |

**Table 14: Distribution based on reason for non-adherence**

| Reason for non-adherence | Count | %    |
|--------------------------|-------|------|
| Intentional              | 4     | 4.7  |
| Non intentional          | 32    | 37.6 |
| Both                     | 46    | 54.1 |
| None                     | 3     | 3.5  |

**Table 15: Distribution of intentional non-adherence**

| Reason for intentional non-adherence | Count | %    |
|--------------------------------------|-------|------|
| Side effect                          | 10    | 20.0 |
| Think medication not effective       | 18    | 36.0 |
| Carelessness                         | 46    | 92.0 |
| Stop to see if still needed          | 25    | 50.0 |
| Avoid dosing schedule                | 39    | 78.0 |
| Fasting                              | 4     | 8.0  |

**Table 16: Percentage distribution of non intentional non-adherence**

| Reason for nonintentional non-adherence | Count | %    |
|---|-------|------|
| Forgetfulness                           | 72    | 96.0 |
| Confusion                               | 60    | 80.0 |
| Expensive                               | 13    | 17.3 |
| Trouble swallowing                      | 15    | 20.0 |
| Trouble reading                         | 16    | 21.3 |

In our study 38(44.7%) out of 85 patients are treated with Enoxaparin sodium (Tables 8 and 9).

Table 10 showed that the most commonly prescribed Antihypertensives are CCB (28.2%) and ARB (12.9%) followed by combination of CCB+BB (10.6%). Overall 77.1% patients were treated with amlodipine (CCB), 90.5% patients with Telmisartan (arbs), 64.3% patients with Mannitol (Diuretics), 100% patients with Enalapril (ACEI), 42.1% patients with labetalol (BB), 50% patients with both clonidine and moxonidine (Alpha adrenergic blocker) and 100% patients with Nicorandil (Vasodialator).

In our study, Rosuvastatin (96.5%) is primarily used for hyperlipidemia and only 2.4% of patients received Atorvastatin (Table 11).

Out of 85 patients enrolled 96.5% of patients' treatments were followed according to AHA/ASA guideline (Table 12).

Table 13 showed that. From the structured interviewer-administered questionnaire we found that out of 85 patients 38.8% of them show poor medication adherence, 37.6% show medium medication adherence respectively only 9.45% have high medication adherence before counselling. Medication adherence score increases to 62.4%, 37.6% have medium adherence and none of the patient (0%) shows poor medication adherence after counselling ( $z=5.02$ ,  $p<0.01$ ) (Table 14).

Unintentional reasons (37.6%) for non-adherence were found to be more common than intentional non-adherence (4.7%) and the majority ( $n=46$ ) of the subjects 54.1% reported both reasons.

Table 15 showed that, the reasons for inten-

tional medication non-adherence were includes side effects, think medications were not effective, don't care to take medications, stop to see if still needed, Alter dosing schedule for convenience, fasting the results were reported as 20%, 36%, 92%, 50%, 78% and 8% respectively.

## DISCUSSION

Drug utilization pattern and the impact of counselling on medication adherence for stroke patient admitted in the hospital were assessed in the study. The present study results suggested that overall our patients were from the age group above 50 years, which shows that age is a major non-modifiable risk factor for stroke. The studies conducted by Prudhvi et al. and Pasha et al. also found that the majority of stroke patients were in the age range of 61-70 years. [4, 5]. According to stanford health care, the age of occurrence of stroke is above 65 years. Our data perfectly aligns with this. Women are more prone to get events of stroke but less likely to recover compared to men. Current study show gender has equal preponderance in the occurrence of stroke. However, in contrast, studies conducted by Reeves shows [6].

In our study population, very less number of patients were alcoholic and smokers. Research done by Lee et al observed that in their study practices of sedentary lifestyle along with alcohol consumption and smoking showed a higher risk of cerebral infarction and stroke [7]. Stroke is a disease of multifactorial etiology that may develop as an end state in patients with vascular conditions and other comor-

bidities. Chronic arterial hypertension is the most significant modifiable risk factor for stroke. A persistent high blood pressure is the most dangerous condition which can either burst the blood vessel or clog the microvessels easily. Other comorbidities commonly observed are Diabetes Mellitus, and Dyslipidemia. Persistent and uncontrolled levels of blood sugar over time will lead to atherosclerosis and in later stage to stroke. Similarly, dyslipidemia is the most predominant cause for ischemic stroke. Because a high LDL cholesterol level causes fatty deposits in the arteries leading to atherosclerosis. So treatment of elevated BP during acute stroke must balance the theoretical risk of worsening the stroke. So modification of the risk factors remains the principal aspect of care for stroke prevention [8].

The present study revealed that majority of patients diagnosed with infarct type of stroke. It was observed that infarct type of stroke is commonly associated with patients diagnosed with an atheroma or embolus. Also, it is associated with patients who have a history of heart disease, heart attacks etc. As per ASA/AHA guidelines commonly used therapeutic regimens are Thrombolytics, Antiplatelets, Anticoagulants, Antihypertensive and Dyslipidemics. Other symptomatic treatments are also given. From the existing knowledge risk of recurrent ischemic stroke events in the first 30 days was found to be high. Antiplatelets modify the risk of further stroke events and reduce the rate of death in this acute period and in the long term. Antiplatelet agents are indicated when the cause of the ischemic stroke is determined to be non-cardioembolic. There are two options of antiplatelet therapy, mono and dual therapy respectively. Dual antiplatelet therapy is more beneficial compared to monotherapy, it reduces the risk of recurrent stroke, which is major challenge in stroke patients and MACE compared to aspirin monotherapy. In the present study, majority of patients were treated with dual antiplatelets. Meta-analysis of randomised control trial conducted by Bhatia et al concluded that DAPT with Aspirin and Ticagrelor or clopidogrel given within 24 hours of high-risk TIA or non-cardioembolic mild to moderate stroke effectively reduces the risk of recurrent stroke and MACE compared with Aspirin monotherapy [9]. From the Systematic Review and Meta-Analysis of Randomized Controlled Clinical Trials conducted by Trifan et al Compared with monotherapy, the use of dual antiplatelet treatment (DAPT) after stroke decreases the risk of recurrent stroke or transient ischemic attack (TIA), or the composite outcome of stroke, TIA, acute coronary syndrome, and death from any cause, but increases the risk of major

hemorrhage [10].

It is well established that dual antiplatelet agents are more beneficial compare to monotherapy as it reduces the risk of stroke recurrence and limit MACE. Himaja et al, Pasha et al, Harsshene et al in their study were also found that dual antiplatelet (aspirin+clopidogrel) therapy is given to most patients than monotherapy [5, 8, 11]. Enoxaparin sodium was the most prescribed anticoagulant. Anticoagulants are used to prevent recurrent stroke, especially among patients with cardioembolism due to arterial fibrillation and large-artery atherosclerotic disease. They are also termed as blood thinners, helps to prevent the formation of blood clots which may further leads to stroke recurrence.

It is the well-known fact that Hypertension is the most significant modifiable risk factor for the stroke. Hypertensive patients with a history of cerebrovascular accident are at particularly high risk of recurrence therefore management of hypertension is the primary concern in stroke patients. Drug utilisation Studies conducted by Himaja et al, Mary jose et al, Sekhar Jena et al concluded that the percentage of antihypertensives were 100%, 78.6%, 69.9% respectively. [8, 12, 13]. Scientific research sounds that calcium ion overload is the pathway of cell death after stroke, so the mechanism of CCBs makes them applicable in the treatment of stroke. The antiatherosclerotic properties of CCBs may be useful in preventing the atherothrombotic type of stroke. Feng et al conducted a systematic review and meta-analysis of early diagnosis and treatment of hypertensive stroke under calcium channel blockers concluded CCBs can effectively prevent the recurrence of stroke, more quickly recover cognitive function, and lower blood pressure better [14]. Statin therapy is initiated in stroke patients for reducing the risk of dyslipidaemia in stroke patients along with cardiovascular diseases. The current study result showed a similar trend to study done by Ellangovan et al, where the use of statins had significantly increased in recent years due to its neuroprotective effect by regulating cerebral perfusion and improves endothelial function [1].

Patient counselling by the pharmacist have a significant role in improving medication adherence. A poor compliance which was observed at the initial time of study was improved using bedside patient counselling and with the provision of patient information leaflet. Wilcoxon Signed Rank Test was carried out to compare medication adherence between two intervals of time. For all statistical interpretations,  $p < 0.05$  was considered the threshold for sta-

tistical significance. population-based sample of 1,00,000 patients under the age 65 with Diabetes, Hypertension, Hypercholesterolemia, and Hospitalization rates as well as healthcare costs were significantly lower for patients with high medication adherence. Stroke events were almost twice as high in non-adherent study participants and remained independently predictive of adverse events after adjusting for baseline disease severity and known risk factors [4]. A systematic review conducted Basaraba et al, concluded pharmacist improve the use of evidence-based therapies, reduce stroke risk through control of modifiable risk factors and improve medication adherence [15].

Unintentional reasons or non-adherence were found to be more common than intentional non-adherence. Prudhvi et al, in their study also concluded that unintentional reasons for nonadherence were common than intentional adherence [4].

## CONCLUSION

In our study, the most commonly diagnosed case is cerebral infarction compared to ischemic stroke and hemorrhagic stroke. Researchers emphasise that the main reason leading to cerebral infarction is underlying cardiovascular disorder. It is clearly manifested in our study that patients with uncontrolled blood pressure, diabetes mellitus and hyperlipidaemia were the victims of the stroke. It is well documented that the incidence of stroke is higher in woman than man. But however in our study an equal preponderance of both the genders were observed. Few decades ago the approximate age of first attack of stroke was observed above 70 years. In our study majority of the patients who had the first attack of stroke was at the age of 60. This directly manifest that our modern lifestyle has a direct correlation on the incidence of the disease. As stroke is a condition of multifactorial etiology, both modifiable and non-modifiable factors plays a vital role. Modifiable factors like cessation of smoking and alcohol consumption along with dietary modification plays a critical role in the prevention and progression of the disease. However, non-modifiable risk factors also have to be considered cautiously. As medication adherence is the key for overall long-term health and well-being, measures have taken to assess the compliance of the patients towards usage of medications using an interviewer administered questionnaire. The current study identified unintentional reasons for non-adherence were more common than intentional non-adherence. A poor compliance which was observed at the initial time of study was improved using bedside patient coun-

seling and with the provision of patient information leaflet. Also, it was observed that the treatment given for stroke patients aligns well with the AHA/ASA guidelines.

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## Conflict of Interest

The authors declare that there is no conflict of interest.

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