

**STUDY ON IMPACT OF CLINICAL PHARMACIST INTERVENTION ON
MEDICATION ADHERENCE IN STROKE PATIENTS IN TERTIARY CARE HOSPITAL**

V. Prudhvi*, T. Sravani, U. Mounika, M. L. Prathyusha, N. Soujanya, A. M. S Sudhakar Babu

Department of Pharmacy Practice, AM Reddy Memorial College of Pharmacy, Petlurivaripalem, Narasaraopet, Guntur-522 601, Andhra Pradesh, India.

***Corresponding Author: V. Prudhvi**

Department of Pharmacy Practice, AM Reddy Memorial College of Pharmacy, Petlurivaripalem, Narasaraopet, Guntur- 522 601, Andhra Pradesh, India.

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ABSTRACT

Objective: The objective of this study was to evaluate the impact of pharmacist intervention on Risk factors and Medication adherence for patients with stroke. **Methodology:** This Study was conducted in the Neurology department of Lalitha Super Specialty Hospital, Guntur, and Andhra Pradesh. The procedure of the study was a prospective randomized interventional comparative design was conducted in the hospitalized patients. A Self-administered questionnaire was prepared using information and thorough review from the literature survey and factors used in previous studies. Questionnaire statistically it was validated by using Cronbach's α value which reported a good measure of 0.79 **Results & discussions:** A sample of 120 patients were enrolled into the study. 76 (63%) patients are male and 44 (37%) patients were female respectively. In this study unintentional reasons for non-adherence have been reported more frequently than intentional reasons before counselling causes of non-compliance. The most prevalent causes of non-compliance were forgetfulness (48.11%), too expensive (47%), confusion (42.45%), side effects (38.67%), Trouble reading pills (34.9%), Alter dosing schedule for convenience (31.13%), Don't care to take medication (30.18%), Trouble swallowing pills (30.18%), Stop to see it still need (20.75%), Think medication not effective (18.86%). The commonest reported reason for an intentional non adherence was forgetfulness. This test performed by using chi square (χ^2 test) test statistics. Chi square statistic value is 53.6251 this result is significant at $p < .05$ whose p value is < 0.00001 . **Conclusion:** The current study identified unintentional reasons for non-adherence to be more common than intentional non-adherence.

KEYWORDS: Stroke, Medication adherence, Cronbach alpha, Chi square test, Compliance, Noncompliance.**INTRODUCTION**

Stroke is a medical condition in which poor blood flow to the brain results in cell death. Stroke is one of the most common neurological disorders in clinical practice.^[1] According to WHO, it is the second commonest cause of death worldwide. It is forecasted that the deaths because the of stroke will rise to 6.5 million by 2015 and by 2020, stroke and coronary artery disease are expected to be the leading causes of losing life. Earlier Surveys on stroke in different parts of India shown that the prevalence of stroke varies in different regions of India and ranges from 40 to 270 per 1, 00,000 populations. Stroke is responsible for around 11% of all deaths worldwide.^[2] The causes of stroke are diverse hypertension are the most common.^[3]

Adherence can be summarized as "The extent to which a person's behaviour taking medication, following a diet, and/or executing lifestyle changes-corresponds with agreed recommendations from a healthcare provider"^[4]

Adherence to prescribed medication predicts outcome. In a 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. [5] 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.^[6-12]

OBJECTIVE**General objective**

To Assess the Risk factors, Medication adherence, cost burden associated with stroke disease in a tertiary care hospital.

Specific objectives

To evaluate the impact of Pharmacist counseling on medication adherence for patients with Stroke disease.

To collect the demographic data of selected patients of Stroke affected in South region.

To improve health and effectiveness of medication therapy by patient education.

To educate and promote awareness of the importance of adherence to stroke medication and outcomes to avoid non adherence.

METHODOLOGY

Study design

This was a prospective randomized interventional comparative study in which information was obtained on the risk factors, mediational adherence associated with stroke diseases by the administration of a structured interviewer-administered questionnaire. The study was carried out October-2017 to March-2018.

Study site

The study was carried out in tertiary care hospital of Guntur district.

Study Period

06 Months.

Study Population & Sampling

A sample of 120 subjects was drawn in order to yield 5% accuracy at the 90% confidence level. Initially a total of 150 sample size was collected and estimated to be the sample size and due to non-response factor and communication errors it was settled down to 120. The estimated prevalence rate was derived from the study. Since, knowledge of the cause of a disease is one of the most important factors in the control of the disease, the knowledge that 'Stroke was caused by risk factors smoking, alcohol, hypertension, diabetes mellitus was taken as the prevalence rate for the purpose of calculating the sample size.

Study Criteria

Inclusion criteria

1. Population who were 18 years or older of rural areas who are interested to participate.
2. Stroke patients undergoing treatment in selected neurology care center of Guntur district.

Exclusion criteria

1. The patients below 18 years old.
2. The patients who were non respondent to the study.
3. The pregnant patients.

Study Tools

A Self-administered questionnaire was prepared using information and thorough review from the literature survey and factors used in previous studies and it was validated by faculties in department of pharmacy practice and who expertise as a physician in Neurology care center. It consists of 11 questions.

1. Do you forget to take your medications regularly?

The intention of this question is to enquire whether the patient is taking medications regularly and to evaluate the patient behavior towards the medication.

2. Do you miss any of your prescribed doses in the past 2 weeks?

The intention of this question is to enquire whether the patient has missed any of their prescribed doses in the medication during the past two weeks.

3. Do you stop taking your medication, if you feel better or if your symptoms are under control?

The intention of this question is to enquire whether the patient stop medication when the patient feels or believed by themselves that they are relieved symptomatically or whether the patient stop medication when their symptoms are in control.

4. Do you feel worse while you are on your medication do you stop taking them?

The intention of this question is to enquire whether the patient stop medications when they feel worse while taking medication due to the occurrence of side effects like headache, vertigo etc.

5. Do you take your medication at the prescribed time?

The intention of this question is to enquire whether the patients administering medication at the right time.

6. Do you often feel difficult in remembering your medication?

The intention of this question is to enquire whether the patients is able to remember their medication daily or how often they feel difficulty in remembering medication.

7. Do you carry your medications with you regularly?

The intention of this question is to enquire whether the patient is able to carry their medications with them regularly where ever they go Example: office, tours.

8. Do you take your medication only if you are sick?

The intention of this question is to enquire whether the patient administer medication only if when they feel sick or with signs and symptoms.

9. Do you feel at times being careless to take your medications?

The intention of this question is to enquire whether the patient is active at the time when the medication is to be taken.

10. Do you believe that taking medication regularly can control your disease?

The intention of this question is to enquire whether the patient believe that taking medication regularly can control their disease this helps in evaluating the patient attitude towards medication can be known.

11. Are you afraid of being addicted to your medication by taking it regularly?

The intention of this question is to enquire whether the patient is afraid of being taking their medication regularly at proper time.

Score ranges 0-1, where affirmative answers get no score with a higher score representing a high level of adherence. (The adherence score was given accordingly < 3 -poor, 4-7: Medium, 8-11 are considered as high level of adherence).

Questionnaire Validation

Two physicians with experience in Neurology Department were asked to evaluate the clarity, relevance and conciseness of items included in the questionnaire (limitations on questionnaire was a feedback which was rectified by eliminating). Statistically it was validated by using Cronbach's α value which reported a good measure of. 0.79

$$\alpha = \frac{K}{K-1} \left(1 - \frac{\sum_{i=1}^K \sigma_{Y_i}^2}{\sigma_X^2} \right)$$

Interviewers

The interviews were carried out by the students of the project members by telephone communication and through direct interview. The interviewers were familiarized with the questionnaire and trained in the proper manner of questioning as well as being familiarized with the operational definitions in order to maintain the uniformity of interpretation and explanation for the benefit of the illiterate and non-English speaking respondents. It was stressed that the interviewers write the responses as stated by the respondents and not their own interpretation of what was stated. The interviewers were also trained not to show bias or emotion during the interview. Non-respondents were not replaced for the purpose of the survey. A brief introduction about the purpose and nature of the study and assurance about confidentiality were explained to the respondents prior to the interview. The interview for each respondent lasted 10 to 15 minutes on average.

Data analysis

The responses in the recording form were manually checked for errors and omission. Standardized codes were used to simplify the coding process and analysis. Data were analyzed using Statistical Package for Social Sciences (SPSS) software Version 11.0. Data analysis was done based on the objectives of the study. Data screening was done to determine associations or correlations between variables. Chi square test was used to compare differences in proportions for categorical variables and Chi square test & Student paired t test for trend was used to compare trends for selected ordinal independent variables. A p value less than 0.05 was considered to be statistically significant.

Study variables

Outcome variable

The main outcome variable in this study was attitudes of the respondents towards those affected by stroke. The responses to hypothetical statements on attitudes were framed on own in taking follow up with questionnaires based on +1,-1 values.

Independent variables

Two groups of independent variables were measured in relation to the attitudes towards stroke medication adherence.

(i) Socio-demographic characteristic of the respondents: The age, gender, habits like smoking, alcohol, family history were considered and risk factors were evaluated.

(ii) Mediating Variables: General medications of stroke, comorbid diseases along with questionnaires for analyzing medication adherence were included and score was given. The responses to questions under the knowledge and attitudes sections were analyzed individually and as aggregated scores.

Minimizing errors

The steps taken to minimize errors in data collection and data entry were as follows:

1. The interviewers were familiarized with the questionnaire and adequately trained to complete the required responses to minimize interviewer bias.
2. A weekly assessment of completed questionnaires was carried out by a single coordinator and feedback provided to the interviewers.
3. Regular supervision of interviewers was carried out during the course of data collection.
4. Random checks on the accuracy of the responses were carried out by the coordinator by re-visiting the housing units of the respondents and reviewing the questionnaire with them.
5. Accuracy of data entry was assessed by a 10 % reassessment of data entry and cross checks with the hard copy of the data.

Ethical issues

The following ethical issues were considered in the design of the study:

1. The participants were briefed regarding the nature, objectives and method of study and their voluntary participation acquired.
2. Participants were reserved the right to withdraw from the study at any point of time.
3. Total confidentiality with regard to the identification of the participants and information volunteered was assured at all times during and after survey.

RESULTS AND DISCUSSION

To the best of our knowledge, this is our first study in south India that evaluates risk factors, medication adherence associated with stroke disease in a tertiary

care hospital of Guntur district, Andhra Pradesh. The results were obtained after 6 months duration study in the neurology department of tertiary care hospital. A total of 120 patients enrolled into the study & the data was analyzed using Microsoft excel 2010.

Gender distribution of the Participants

Out of 120 patients, males are more prone to the disease than females with the data representing in the figure: 1. 76 (63%) patients are male and 44 (37%) patients were female respectively.

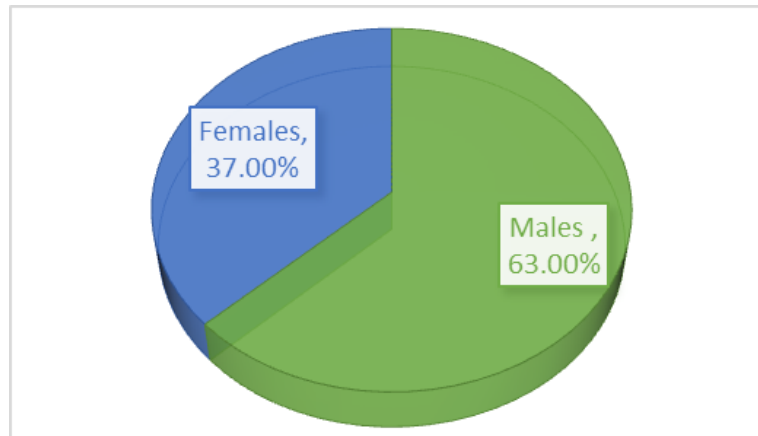


Fig 1: Gender Distribution of the Participants.

Age based demographic details of the stroke patients

21 to 90Y Age groups were considered under the study. From the collected data, more no. of patients lie in the

age range of 61-70Y were observed. The following data denoting the no. of patients belonging to their respective age groups in the table 01 and Fig: 2

Table 1: Age based demographic details of the stroke patients.

Age Range(Y)	21-30	31-40	41-50	51-60	61-70	71-80	81-90	Total
No. of Patients	4	9	18	30	39	13	7	120

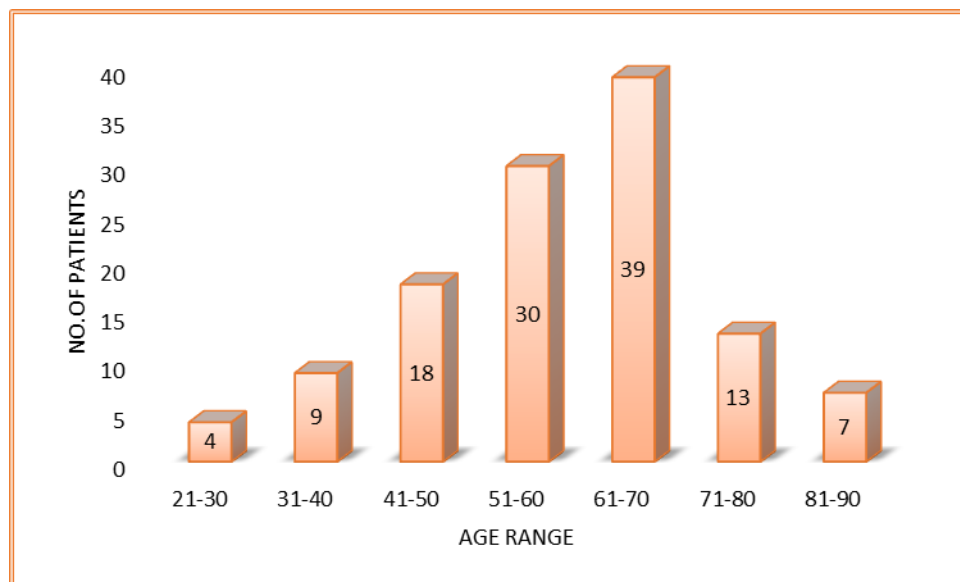


Fig 2: Age wise Range distribution of Participants.

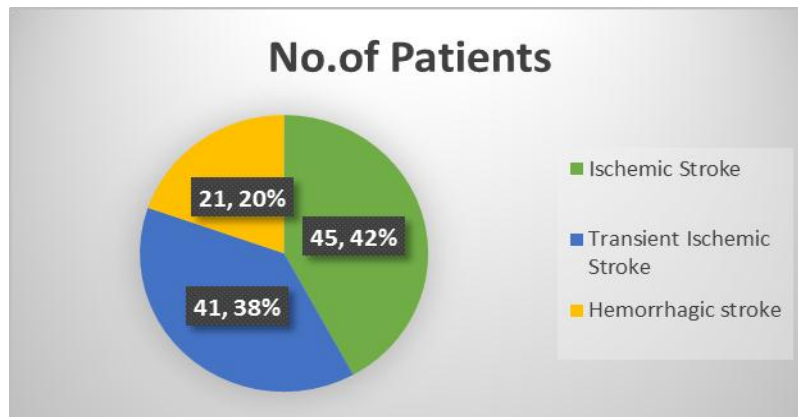
Out of 120 patient's data, based on the range of age, the number of patients are 4, 9, 18, 30, 39, 13, and 7, respectively with the age range of 21-30, 31-40, 41-50, 51-60, 61-70, 71-80, 81-90.

Distribution of frequency of patients in Types of stroke

The data was also used to analyze the types of stroke which were observed during this study with following distribution of frequency in the table 02 and Fig: 3.

Table 2: Distribution of frequency of patients in Types of stroke.

Types of Stroke	Ischemic Stroke	Transient Ischemic Stroke	Hemorrhagic stroke
No. of Patients	45	41	21
Percentage of Patients	37.5%	34.16%	17.5%

**Fig 3: Distribution of frequency of patients in Types of stroke.**

Out of 120 patients received data, 34.16% patients having transient ischemic attack and 37.5% patients having Ischemic Stroke and 17.5% patients having Hemorrhagic stroke are reported.

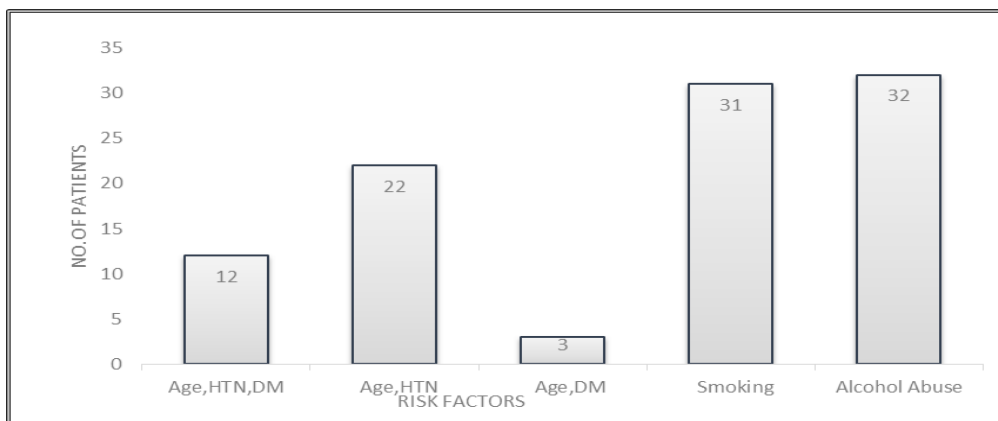
Hypertension, Diabetes mellitus, Smoking and Alcohol consumption in the respective area of South India. The results were attained in the table 03 as follows and representing in the Fig: 4.

Frequency of Risk factors distribution of stroke patients

Frequency of risk factors distribution of stroke patients has been studied considering factors like Age,

Table 3: Frequency of Risk factors distribution of stroke patients.

Risk factors	Age, HTN, DM	Age, HTN	Age, DM	Smoking	Alcohol Abuse
No. of Patients	15	26	4	37	38
Percentage (%)	12.5	21.67	3.33	30.83	31.6

**Fig 4: Frequency of Risk factors distribution of stroke patients.**

There are various risk factors for provoking stroke which include: Age, HTN, DM, Smoking, Alcohol consumption. According to the data obtained, out of 120 subjects Age, HTN along with DM may be the reason for the stroke in 15 patients; Age, HTN may be the reason in 26 patients; Age, DM may be the reason in 4 patients; Smoking may be the reason for stroke in 32, Alcohol consumption may be the reason for stroke in 39 patients.

Reasons for Non-Adherence

The most prevalent causes of non-compliance were expensive medications(49.05%), forgetfulness(48.11%), confusion(42.45%), side effects(38.67%), trouble reading pills(34.9%), altering dosing schedule for convenience(31.13%), don't care to take medication(30.18%), trouble swallowing pills(30.18%), stop to see if still needed(20.75%), fasting(19.81%),

think medication not effective(18.86%). The most common reason for intentional non-adherence was side effects(38.67%) and the most common reason for unintentional non-adherence was expensive medication.

Unintentional reasons for non-adherence were found to be more common than intentional non-adherence. The majority(n=77) of the subjects (49.3%) reported two reasons, 36.3% reported three reasons, 11.6% reported four reasons and 2.59% five reasons for non-adherence.

Intentional Non-Adherence

Table 4: Reasons for intentional Non-Adherence.

Reasons	Side effects	Think medication not effective	Don't care to take medication	Stop to see if still needed	Alter dosing schedule for convenience	Fasting
No. of Patients	41	20	32	22	33	21
Percentage (%)	38.67	18.86	30.18	20.75	31.13	19.81

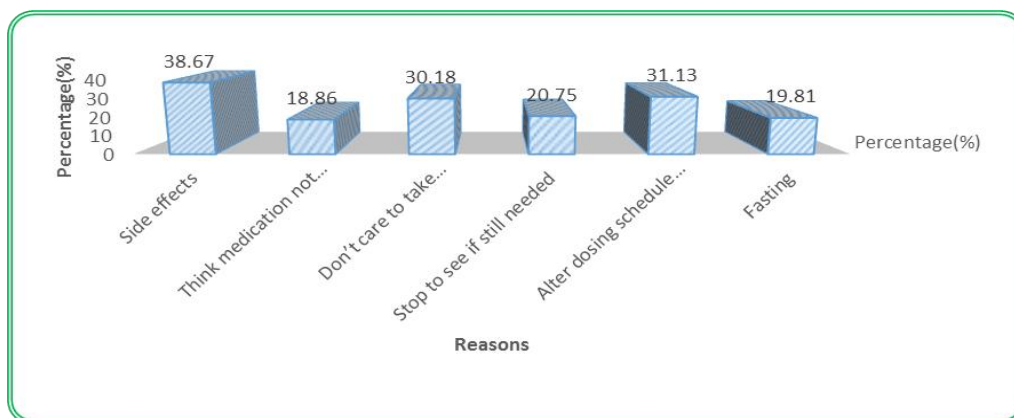


Fig 5: Reasons for intentional Non-Adherence.

Out of 106 patients, reasons for intentional non-adherence were side effects, Think medications 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 38.67%(41), 18.86%(20), 30.18%(32), 20.75%(22), 31.13%(33), 19.81%(21) respectively.

Non-Intentional Non-Adherence

Table 5: Reasons for Non-Intentional Non-Adherence.

Reasons	Forgetfulness	Confusion	Expensive	Trouble swallowing pills	Trouble reading pills
No. of Patients	51	45	52	32	37
Percentage (%)	48.11	42.45	49.05	30.18	34.9

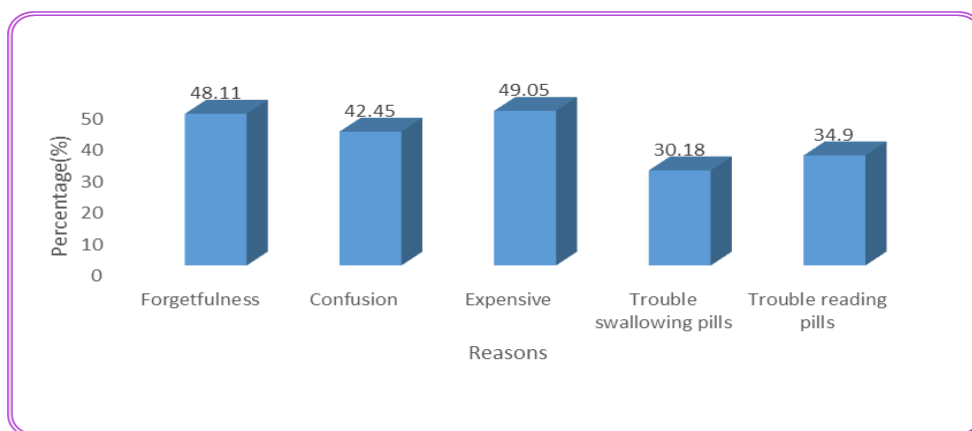


Fig 6: Reasons for Non-Intentional Non-Adherence.

In 106 patients, reasons for non-intentional adherence were forgetfulness, confusion, expensive, trouble

swallowing pills, trouble reading pills the reasons were reported are 48.11%,42.45%,49.05%,30.18%,34.9%.

Frequency of Drug therapy design in stroke patients

Most of the patients were prescribed with Triple regimen therapy (41.66%) followed by Double regimen therapy

(35%), Single regimen therapy (14.16%) and quadruple regimen therapy (9.16%) tabulated in table 06 representing in Fig: 7.

Table 6: Frequency of Drug therapy design in stroke patients.

Drug Therapy Design	Quadruple	Triple	Double	Single
No. of Patients	11	50	42	17
Percentage (%)	9.16	41.6	35	14.16

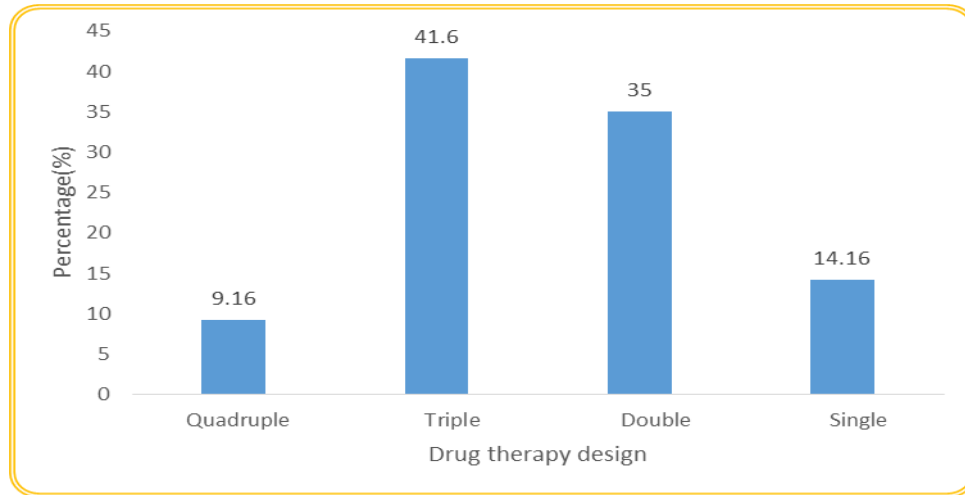


Fig 7: Frequency of Drug therapy design in stroke patients.

In a total data, based on the drug therapy design, 9.16% patients receiving quadruple regimen, 41.6% patients receiving triple regimen, 35% patients receiving double regimen, 14.16% patients receiving single regimen.

NOTE: Through this study, Aspirin (70%) was reported to be most preferable drug for treating the stroke disease. This was followed by piracetam (67.5%), Statins (46.3%), Clopidogrel (5.3%), Heparin (8.33%), Tirofiban (11.6%).

The study finally focusses on assessing the risk factors, medication adherence, associated with stroke disease patients which was attained to an optimum best with 88.33% overall patients are non-compliance to medication before counselling and 61.66% patients were compliance after counselling. The scale used to measure the non-compliance has been found to have an internal consistency with Cronbach's alpha value of 0.7906.

Table 7: Data distribution of Adherence in stroke patients before & after counseling.

Intervention	Before Counselling			After Counselling		
	POOR	MEDIUM	HIGH	POOR	MEDIUM	HIGH
Level of Adherence						
No. of Patients	62	44	14	18	58	44
Percentage (%)	51.66	36.66	11.66	15	48.3	36.6

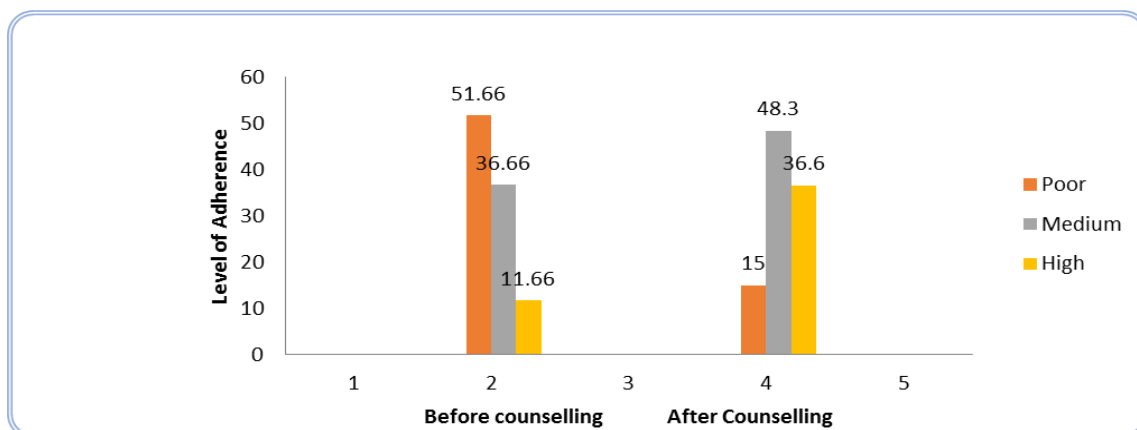


Fig 8: Data distribution of Adherence in stroke patients before and after counseling.

Improvement in Medication Adherence

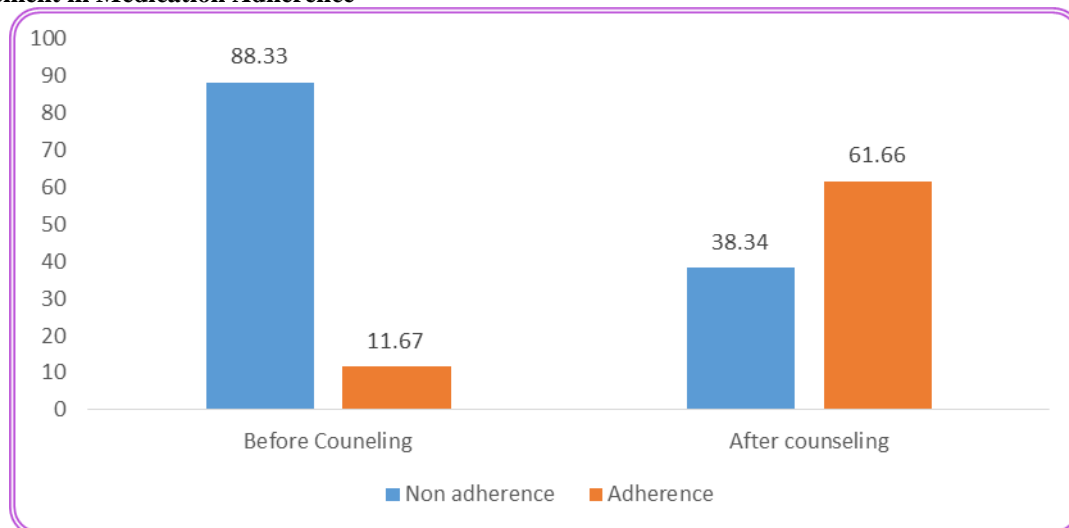


Fig 9: Diagrammatic representation of Level of Adherence showing improvement.

Before Counselling, 88.33% of patients were non-adhere to medications while 11.67% of patients were adhere to medications by SDPQ. After Counselling, the final result stating that 38.34% patients belonging to non-adhere medications and 61.66% patients adhere to medications by our counselling and follow-up.

This test performed by using chi square (χ^2 test) test statistics. Chi square statistic value is 53.6251 this result is significant at $p < .05$ whose p value is <0.00001 . & by using student paired t-test considering the P-value 0.68 with 95% confidence interval. By conducting pharmacist patient counselling on medication adherence for patients with stroke which gives 95% confidence interval value of $P=0.68$ which gives more confidence to conclude that pharmacist interventions improves medication adherence in stroke patients.

SUMMARY

1. The main aim of this study is to evaluate risk factors, medication adherence associated with stroke disease in a tertiary care hospital.
2. The general objective of the study is to assess the risk factors, medication adherence associated with stroke disease.
3. A self- designed questionnaire was prepared and a prospective randomized interventional comparative study was conducted on a sample of 120 patients with stroke disease.
4. The questionnaire was validated by using Cronbach's alpha and the value was found to be 0.07906.
5. The patients of 18yrs or older of rural areas and patients undergoing treatment in selected neurology care center were included in the study.
6. The patient demographic data was collected and were questioned regarding the medication adherence and the individual patient score was given.

7. From the data collected before counselling the patients who were non adherent to the medication was found to be 83.33 and the patients who were adherent were found to be 11.67.
8. The patient was counselled regarding the importance of medication adherence and educated to overcome the barriers of non -adherence to achieve desired therapeutic outcome.
9. The patients were communicated through telephone and a direct follow up of six months was done.
10. The patient who received continuous follow up are questioned again to assess the medication adherence before and after counselling.
11. From the data collected after the counselling the patients who were non adherent was found to be 38.34 and the patients who were adherent was found to be 61.66.
12. From the above study out of 120 patients the provoking risk factors for stroke observed are age, hypertension, diabetes mellitus, smoking and alcohol.
13. By using chi square (χ^2 test) test statistics. Chi square statistic value is 53.6251 this result is significant at $p < .05$ whose p value is <0.00001 .
14. By using student paired T-test the P value was found to be 0.68. Based on this value the study concluding the main role of pharmacist intervention in improving the patient medication adherence.

CONCLUSION

The main aim of this study is to evaluate risk factors, medication adherence associated with stroke disease was achieved successfully. This study concludes the importance of the pharmacist intervention 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 the risk factors to decrease the risk

ratio of stroke occurrence and helps in the secondary prevention of the disease.

The present study shows that participants (patients) who attended the interactive educational intervention session on evaluation of risk factors, medication adherence associated with stroke disease was much satisfied, and considered more effective and valuable.

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