A STUDY TO DETERMINE THE DRUG COMPLIANCE AMONG PEOPLE WITH EPILEPSY ATTENDING THE FOLLOW UP CLINIC OF SCTIMST

PROJECT REPORT

Submitted in partial fulfillment of the requirements

For the

Diploma in Neuro nursing

SUBMITTED BY

VINEETHA. J. R
Code No: 6209

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM, 695011

November 2011

CERTIFICATE FROM SUPERVISORY GUIDE

This is to certify that **Mrs. VINEETHA. J. R** has completed the project work on **" A study to determine the drug compliance among people with epilepsy attending the follow-up clinic of SCTIMST",** under my direct supervision for the partial fulfillment for the Diploma in Neuro Nursing of Sree Chitra Tirunal Institute for Medical Sciences and Technology. It is also certified that no part of this report has been included in any other thesis for processing any other degree by the candidate.

Saramma PP

Thiruvananthapuram
November 2011

Dr. Saramma PP, PhD
Senior Lecturer in Nursing
SCTIMST, Trivandrum

CERTIFICATE FROM THE CANDIDATE

This is to certify that the project on " **A study to determine the drug compliance among people with epilepsy attending the follow up clinic of SCTIMST",** is a genuine work done by me, under the guidance of Dr. Saramma PP, PhD, Senior Lecturer in Nursing, SCTIMST, Trivandrum. It is also certified that this work has not been presented to any other university for award of degree, diploma or other recognition.

Thiruvananthapuram
November 2011

Mrs. VINEETHA. J. R
Code No: 6209
SCTIMST
Thiruvananthapuram

APPROVAL SHEET

This is to certify that Mrs. VINEETHA JR bearing code no 6209 have been admitted to the Diploma in Neuro Nursing in January 2011 and she has undertaken the project entitled " **A STUDY TO DETERMINE THE DRUG COMPLIANCE AMONG PEOPLE WITH EPILEPSY ATTENDING FOLLOW UP CLINIC OF SCTIMST",** which is approved for the diploma in Neuro Nursing awarded by Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, as it is found satisfactory.

Place:

Date:

Examiners

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Guide

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(2) _____

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ABSTRACT

Objectives: Study to determine the drug compliance among the people with epilepsy attending the follow up clinic of SCTIMST and to determine the factors affecting drug compliance.

Method: In this study purposive sampling technique is used and study sample was 60 adult patients who attended the follow up clinic of SCTIMST. The total period of study was from September 2011 to November 2011.The data collection tool used for the study was a validated self prepared questionnaire to assess the drug compliance level among the people with epilepsy.

Result: The total number of sample was 60.The mean age of the participant was 31.95yrs.In this study 70% patients with complex partial seizure and 30% with Generalized tonic clonic seizure. Out of 60 patients 28 (46.67%) had no seizure in last one year. The most commonly used medication is Carbamazepine (37.12%). Out of 60 patients 50% patients used as mono therapy to control seizure, 37% patients had two medications, and 13% has three medications. In 60 patients 49 (81.67%) drug compliance level was good they never miss their medication, 16.67% patients occasionally miss their medication and complete irregular in only one (1.66%). The reasons for non-compliance were forgetfulness (81.82%), and side effects (68.33%). The major side effect reported was excessive sleep (25.93%). Out of 60 patients 93.33% of patients kept their appointments correctly. The study showed that there was no relationship between AED compliance and age (p=0.45), education (p=0.60), place of living (p=0.35), duration of illness (p=0.40), side effects p=0.52), and expenditure (p=0.40). However a significant relationship was found between history of noncompliance and current status of noncompliance (p=0.004).

Conclusion: In this study only 29 (48.33%) patients had a history of compliance i e before attending this institute. In SCTIMST, Comprehensive epilepsy care programme (R.Madhavan Nayar center for Comprehensive epilepsy care) educate and council the patients to improve the drug compliance level to prevent recurrence of seizures. Now drug compliance level is 81.67%. In spite of education and counseling the issue of non-compliance still remains a considerable obstacle to the more successful treatment of peoples with epilepsy.

KEY WORDS: Epilepsy, drug compliance, people with epilepsy, drug adherence.

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LIST OF ABBREVATIONS

AED	-	Antiepileptic drug
WHO	-	World Health Organization
ILAE	-	International League Against Epilepsy
OPD	-	Out Patient Department
GTCS	-	Generalized Tonic Clonic Seizure
CPS	-	Complex Partial Seizure
SCTIMST	-	Sree Chitra Tirunal Institute For Medical Sciences and Technology

CHAPTER 1

1.1 Introduction

Epilepsy is one of the most common neurological disorders. The word epilepsy is derived from Greek word means to “seize” or “take hold of”, indicating the persons having a seizure is possessed or at least out of control. Epilepsy and seizure affect more than 50 million people worldwide (epilepsy foundation, 2007 and WHO, 2007). The various consequences of epilepsy may be health related or social in nature. From health perspective, epilepsy has been associated with an increased risk of mortality and injury (Nei and Bagla, 2007).

Epilepsy is a chronic disorder of abnormal, recurrent, excessive and self-terminating discharge from neurons. Period between seizures can vary widely and can measure in minutes, hours, days, weeks, months or even years. However there is repetition of seizure activity at sometimes in the future, regardless of the interval (Hickey, 2003).

The majority of people with epilepsy in developed countries are able to manage their condition by using one or more pharmacological therapies with anti convulsant medication (sander, 2004). For almost all patients with epilepsy long-term drug therapy is the only practical way of form of treatments and many factors that affect adherence to pharmacological treatment can lead to lack of control over seizure and recurrence (Mc Donald, 2002).

Eighty percentages of people with epilepsy live in the developing world (Leonadi and Ustun, 2002) An individual with epilepsy suffers recurrent seizure unprovoked by acute brain insults or metabolic derangement. Seizures are characterized by a brief period of involuntary shaking. They may be partial, involving only one part of the body or generalized involving the entire body and they may be accompanied by loss of consciousness and lack of bowel or bladder

control. Some individuals continue to have frequent seizure with anti epileptic drugs. However more than 70% of patients, who are treated, achieve long-term remission or freedom from seizure, usually with in 5 years of diagnosis (De Boer, Mula and Sander, 2008). The majority of people with epilepsy have good prognosis if they receive appropriate treatment (Sander 2003, 2004 and Kwan, 2004). In the world wide, 60-90% of people with epilepsy receive no treatment or are inadequately treated (Scott, 2001).

The long term anti convulsant therapy has potential morbidity. There fore the possibility of discontinuing therapy should be balanced against the risk and danger of seizure recurrence (Marson, 2009). Patients who are on anti epileptic drug should follow a correct order of medication and check up but many people cannot follow the order and seizure can occur from anti epileptic drug withdrawal. (Gomes (b), 1998).

1.2 Background of the study

Epilepsy is one of the most common neurological conditions representing a heterogeneous collection of disorder that have in common a recurrence of seizures. About 1.25 to 2 million people in the united state has epilepsy. Approximately 30% of all epilepsy and 60% of all child hood epilepsies may have a significant genetic susceptibility (Hirose et al, 2000). Seizure is a single (finite) event of abnormal discharge in the brain and epilepsy is a chronic disorder with abnormal recurrent seizures and epileptic syndrome is an epileptic disorder characterized by a cluster of signs and symptoms customarily occurring together (Hickey, 2003). Epilepsy is considered as active if the patient has had seizure or had been treated with anti epileptic drug in the previous 5 years and remission of epilepsy is defined as a period of freedom from seizure, expressed for a specific time such as two, three or five years. In an epidemiological study in Kerala using a house-to-house survey involving the population of nearly 2, 50,000,it is estimated that there will be about 1,50,000 persons with active

epilepsy among the 30 million population of Kerala. Nearly 15, 000 new cases of epilepsy will occur annually among the Kerala population. Twenty percent of people with epilepsy would be resistant to anti epileptic drug treatment; accordingly there will be nearly 30,000 patients in Kerala (30 million populations) who are resistant to AEDs (Radhakrishnan, 1999)

1.2.1 Classification of epilepsy

The International League Against Epilepsy (ILAE) is the major contributor to established standardized classification and terminology for epileptic seizure and syndrome. The ILAE classification of epileptic seizure (commission on classification of and terminology of the ILAE 1981) is shown in Table 1 and the International League Against Epilepsy definition of epileptic syndrome (1989) is shown in Table 2.

In ILAE commission report on 2001 a proposed diagnosed scheme for people with epileptic seizure and with epilepsy. In this diagnostic scheme is divided in to five parts or axes. In axes 1- fetal terminology and phenomenology, axes II-seizure type, axes III-syndrome, axes IV-etiology and in axes v for impairment. The axes organized to facilitate a logical clinic approach to the development of hypothesis (Engel 2001). Revised terminology and concept for organization of seizure and epilepsy on the report of the ILAE commission on classification and terminology is done in 2009 (Berg et al, 2009).

Table 1.1. Classification of epileptic seizures

Partial (focal, local) seizures
Simple partial seizure (consciousness not impaired)
1.Focal motor (with and without jacksonian march)
2.Somatic sensory or special sensory symptoms
3.With automatic symptoms (e g. as epi gastric sensation, pallor, flushing.
4.With psychic symptoms (disturbance of higher cerebral function.
Complex partial seizure (with impairment of consciousness)
Beginning with as simple partial seizure and progressing to impairment of consciousness
With no other features
With features as in simple partial seizures
With automatism
With impairment of consciousness at onset
With no other features
With features as in simple partial seizure
With automatism
Partial seizure evolving to secondarily generalized seizure
Simple partial seizures evolving to generalized seizure
2. Complex partial seizure evolving to generalized seizure
Simple partial seizures evolving to complex partial seizure to generalized seizure
II. Generalized seizure (generalized bilateral without focal onset)
Absence seizure
Myo clonic seizure
Clonic seizure
Tonic seizure
Tonic-clonic seizure
Atonic seizure.
III. Unclassified epileptic seizure (include all seizure that cannot be classified due to inadequate or incomplete data.)

ILAE classification of epileptic seizure 1981

The International League Against Epilepsy defines epilepsy syndrome in1989 as shown in the Table 1.2

Table 1.2 Epilepsy and epilepsy syndrome

Epilepsy syndrome: A complex of signs and symptoms that define unique epilepsy condition Epilepsy disease: A pathologic condition with a single specific well-defined etiology Epileptic encephalopathy: A condition in which the epileptiform abnormalities themselves are believed to contribute to the progressive disturbances in cerebral function Benign epilepsy syndrome: A Syndrome characterized by epileptic seizure that are easily treated or require no treatment and remit with out sequelae Reflex epilepsy syndrome: A syndrome in which all epileptic seizure is precipitated by sensory stimuli Idiopathic epilepsy syndrome: A Syndrome that is only epilepsy with no underlying structured brain lesion or other neurologic signs or symptoms. Symptomatic epilepsy syndrome: A syndrome in which the epileptic seizure is the result of one or more identifiable structural lesion of the brain. Probably symptomatic epilepsy syndrome: Synonymous with but preferred to the term cryptogenic, used to define syndrome that are believed to be symptomatic, but no etiology has been identified.

1.2.2 Anti epileptic drugs (AEDs)

Treatment of epilepsy mainly involve anti epileptic medication. With the right anti epileptic drug up to 70% people with epilepsy could have seizure control. The first anti epilepsy drug to use to treat epilepsy was phenobarbitone in 1912.The AEDs is often complex, requiring several doses a day constantly for many years, sometimes for lifetime. About 70-80% people developing epilepsy

may expect to be rendered seizure free with AED therapy. Approximately 80% of patient benefit from AED therapy will be controlled with a single drug, and 10-15% with combination of two AEDs (Sander, 1993). The established or first generation AED includes Phenobarbital, Phenytoin, Primidone, Carbamazepine, Ethosuximide, and Valproic acid. The second generation AEDs includes Felbemate, Gabapentine, Lamotrigine, Levetiracetam, Oxcarbazipine, Tiagabaline, Topiramate, Vigibatrin and Zonisamide (Mc Auley and Anderson, 2002).

AEDs can be narrow or broad spectrum as shown in table 3. The narrow spectrum AEDs mostly work for specific type of seizure such as partial, focal, or absence, myoclonic seizures. The broad spectrum AEDs additionally has some effectiveness for a wide variety of seizures (partial plus absence myoclonic seizure) (Fisher 2009).

Table 1.3. Narrow and broad spectrum AEDs

Narrow spectrum	Broad spectrum
Phenytoin	Valproic acid
Phenobarbitone	Lamotrigine
Carbamazepine	Topiramate
Oxcarbazepine	Zonisamide
Gabapentine	Levetiracetam
Pregabalin	Clonazepam
Lacosamide	Rufinamide
Vigabatrin	

The success of anti epileptic drug therapy in the treatment of epilepsy is depending upon patient ability to take his or her prescribed treatment regimen. In a survey of 55 patients observed for an average of 14 weeks the over all rate of

compliance with dosing regimen was 75%. Compliance rates declined as the number of dose increased. Each day 86%, twice a day 80%, three times a day 76% and with a significant decrease to 53% in compliance for four times a day dosing. (Cremer and Mattson, 1995)

The high prevalence of inadequate compliance is the major contributor of the cost of medical care in every therapeutic area. The national council for patient information and education estimates that half of the 1.6 billion prescriptions written in the United States annually are not taken properly. Despite instruction and advice many patients do not take their drugs as prescribed. Few patients are willfully noncompliant. But many are negligent, the partial complier who take fewer dose than prescribed (Rosack, 2004)

1.3 Need and significance of study

Epilepsy is a major public health problem and 80% of the burden of epilepsy worldwide is borne by developing countries. In India 5 million persons with active epilepsy, most people reside in rural areas (Radhakrishnan, 2009). In an individual with epilepsy adherence to medication is crucial in preventing or minimizing seizure and there is cumulative impact on every day life. Non-adherence to AEDs can results in break through seizure many months or years after a previous episode (Baumann et al., 2004)

The reason for noncompliance are complex and multi layered, the patient can accidentally fail to adhere through forgetfulness, misunderstanding or intentionally due to their own expectation of treatment and side effect (Mitchell et al 2000). Non-compliance is directly associated with poor treatment outcomes in patient with epilepsy and therapeutic non compliance has been associated with excess urgent clinic visit and hospitalization. In adult epilepsy population poor AED adherence contribute to morbidity (Gopinath et al, 2000; Bassili et al, 2002;

Manjunath et al, 2009). The numerous incidence of break through seizures occurring only after missing doses.

The compliance rate is typically higher among patients with acute condition as compared with chronic condition. The compliance among patient with chronic condition is disappointingly low. The rate of compliance for patient is usually reported as the percentage of the prescribed dose of medication actually taken by a specific period. Non-compliance to medication regimen accounts for substantial worsening of disease (Osterberg, 2005).

In Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) Trivandrum a comprehensive epilepsy care program was initiated (Madhavan Nayar Center for Comprehensive epilepsy care) in 1998 for evaluation, medical, surgical and psychosocial management of persons with epilepsy. In SCTIMST epilepsy out patient clinic more than 120 patients are coming for follow up treatment weekly. For a period of seven month (from January to July) seven patients got admitted with status epilepticus and 25 patients got admitted with seizure disorders in ICU. The continuous medical therapy is needed for these patients. Missing of the drug will lead to recurrence of the seizures. So it is important to know the drug compliance among patient with epilepsy.

1.4 Statement of the problem

Study to determine the drug compliance among people with epilepsy attending the follow up clinic of SCTIMST.

1.5 Objectives

1. To determine the drug compliance among people with epilepsy attending the follow up clinic of SCTIMST.

2. To identify factors determining drug compliance in people with epilepsy attending the follow up clinic of SCTIMST.

1.6 Operational definition

People with epilepsy: A person who have affected with epilepsy and show the signs and Symptoms of epilepsy

Drug compliance: The reliability of patient in using a prescribed medication exactly as ordered by the physician, or the regular ingestion of medication, as prescribed.

Follow up clinic: It is out patient review clinic for therapeutic assessment and treatment.

1.7 Methodology

The survey approach is used in this study. The data will be collected from patient with epilepsy and their caregivers attending the OPD clinic in SCTIMST will be interviewed by using a structured questionnaire. The duration of study is Aug-November 2011.

Population	: people with epilepsy attending the OPD clinic in SCTIMST
Sample size	: 60
Setting	: Epilepsy OPD clinic in SCTIMST
Sampling technique	: purposive sampling

1.8 Tool

The investigator determines the rate of drug compliance among patient with epilepsy by interview schedule using a structured questionnaire.

1.9 Delimitation

The study is limited to people attending the epilepsy clinic in SCTIMST and sample size is 60

1.10 Organization of report

This chapter deals with introduction, background of the study, need and significance of study, statement of problem, objectives, operational definition, methodology and delimitations.

Chapter - II
REVIEW OF LITERATURE

2.1 Introduction

Review of literature can serve a number of important functions in the research process. It is the critical summary of research on a topic of interest, often prepared to put a research problem in context. Literature review help to lay the foundation for a study, and can inspire into the problem and help in selecting methodology, developing tool and also analyzing data. With these in view an intensive review of literature has been done.

The review of literature relevant to this study is presented in the following sections

2.2 Studies related to drug compliance among patient with epilepsy.
2.3 Studies related to factors influencing drug compliance among patient with epilepsy.
2.4 Studies related to strategies to improve patient drug compliance with epilepsy.

2.2 Studies related to drug compliance in-patient with epilepsy.

Modi et al (2011) conducted a study the pattern of non-adherence to anti-epileptic drug therapy in children with newly diagnosed epilepsy. In this prospective, longitudinal observational study of anti-epileptic drug adherence in consecutive cohort of 124 children (2-12 yrs.) with newly diagnosed epilepsy, The data collection period was 3 years. The study result was fifty eight percent of children with newly diagnosed epilepsy demonstrated persistent non-adherence during the first months of therapy. Group based trajectory models identified 5 differential adherence patterns. (Bayesian information criteria =-23611.8): severe

early non-adherence (13%; 95%, confidence interval (CI) 8%-20%), severe delayed non-adherence (7%; 95%, (CI) 3% -12%), moderate non-adherence (13%; 95% (CI) 8%-20%), mild non adherence (26%; 95%, (CI) 19%-34%) and near perfect adherence 42%; 95% (CI 33% -50%). The adherence pattern of most patients was established by the first month of therapy. Socio economic status was sole predictor of adherence n=115; p<. 001. The lower socio economic status associated with higher non-adherence. Few trajectory patterns were identified that captured the spectrum of non-compliance to anti-epileptic drug among children with newly diagnosed epilepsy; the patterns were significantly associated with socio economic status.

Modi et al (2010) conducted a study to describe the development and validation of pediatrics epilepsy medication self-management questionnaires (PEMSQ) for caregiver's of children 2-14 years. It was expected that PEMSQ scales would have internally consistent factors and moderate associations with adherence and seizure. The participants included 119 children with epilepsy and their primary caregivers seen at the new onset epilepsy clinic. The mean age =7.2 years, 36% female, 72% Caucasian who completed PEMSQ, demographic questionnaires and AEDs adherence was assessed. The final PEMSQ was 27 items with four scales (epilepsy and treatment knowledge expectation, adherence to medication and clinic appointment, barriers to medication adherence, belief about medication efficacy). No significant correlation was found between child age, socio economic status and pediatrics epilepsy self-management scale. Significant positive correlation were revealed between the time since diagnose and several self-management scale including epilepsy and treatment knowledge and expectation (r=0.25 p<. 01), belief about medication efficacy (r=0.32 p<0.001) and total self-managements (r=0.23 p<0.05). These data suggest that the longer a child has epilepsy, more their caregivers know about epilepsy and its treatment and more they believe medication will be effective. No significant gender p=0.49, race (e.g.: white verses minority status p=0.21), marital status (p=0.57), epilepsy type (p=0.58) difference found on pediatrics self-management

scales. Significant association was found between PEMSQ scale, adherence ($p<0.0001$) and seizure. The PEMSQ scale represents the first self-management measure validated for caregivers of children with epilepsy with clinic and research activity.

Zeber, Copeland and Pugh (2010) conducted a study to assess the variation in ant epileptic drug adherence among older patient with new onset epilepsy. The objective of this study was to analyze adherence to nine different AEDs. The patient over age 66 receiving care in the Veterans Health administration were eligible if they met criteria for new onset epilepsy with AED mono therapy of at least 3 months. . A cross sectional study design was used to assess adherence as defined by the medication possession ratio (MRP). The study population was 6373 patients, male (98%), white 79% and exempt from medication to disability status, nearly 40% had a prior psychiatric or dementia diagnosis. Nearly half of patients were poorly adherent with rate ranging from (42-63%). In multivariate models, patient on Phenobarbital, valproate and Gabapentine were significantly less likely to be adherent on both outcomes, while Lamotrigine and Levetiracetam were positively associated with adherence as per the MRP.

Faught et al (2008) conducted a study to assess impact of non-adherence to anti epileptic drug on health care utilization and cost. The objective of this study was to investigate whether non-adherence to AEDs is associated with increased mortality and secondary objective to examine whether serious clinical event including emergency visits. A retrospective open cohort design was employed using state Medicaid claims data from Florida, Iowa, and New Jersey during the period from January 1997 to June 2006. Patients aged >or=18 years with one or more neurologist visit with an epilepsy diagnosis and two or more pharmacy claims for AEDs were included. Medication possession ratio (MPR) was used to evaluate AED adherence with MPR >or= 0.80 considered adherent and <0.80 considered non adherent. The association of non-adherence with utilization outcomes [hospitalizations, inpatient days, emergency department (ED), and

outpatient visits] was assessed with Univariate and multivariate Poisson regressions. Quarterly per-patient inpatient, outpatient, ED, and pharmacy costs were calculated across non-adherent and adherent quarters for the younger than 65 population (under-65) and cost differences were computed. Adjusted incremental costs of non-adherence were estimated with multivariate Tobit regression models. A total of 33,658 patients were included (28,470 under-65), together contributing 388,564 treated quarters (26% non adherent). In multivariate analyses, AED non-adherence was associated with significantly higher incidence of hospitalizations [incident rate ratio (IRR) = 1.39, 95% confidence interval (CI) = 1.37-1.41], inpatient days (IRR = 1.76, 95% CI = 1.75-1.78), and ED visits (IRR = 1.19, 95% CI = 1.18-1.21). Non-adherence was associated with cost increases related to serious outcomes, including inpatient ($4,320 additional cost per quarter, 95% CI = $4,077-$4,564) and ED services ($303 additional cost per quarter, 95% CI = $273-$334), but lower costs for outpatient and pharmacy services, likely because of non-adherent behavior.

Manjunath, Davis and Candrillis (2009) conducted a study to assess the association of anti epileptic drug non-adherence with risk of seizure. This study evaluated the potential effect of anti epileptic drug non-adherence on the risk of subsequent seizure. Retrospective insurance claims from the United State were analyzed. The inclusion criteria were age 21-64 yrs diagnosis of epilepsy or non-febrile convulsions, 2 AED prescriptions, and insurance enrolled for 6 months pre and 60 days post AED initiation. Seizure was defined as s hospital or emergency admission associated with epilepsy or non-febrile seizure. The observation began 7 days post drug initiation, ending with the first of the following seizure, insurance, disenrollment, or 365 days post drug initiation. Adherence was measured using the medication possession ratio with MRP<0.8 defining non-adherence. Seizure risk was assessed using the extended Cox proportional hazard of 18,073 subjects identified, 2467(14%) had 1 seizure. Mean follow up was 133 days among subject with event 305 days for patient without event. Seizure risk

was 21% higher among non- adherers (hazard ratio 1.205, p=0.00027) than others.

Ettinger and Manjunath (2009) conducted a study to assess the prevalence and cost of non-adherence to anti epileptic drug in elderly patient with epilepsy. Retrospective insurance claims from the United States were analyzed to assess non-adherence to anti epileptic drugs (AEDs) and the association between AED non-adherence, seizures, and health care costs in elderly persons with epilepsy. Inclusion criteria were: age 65, epilepsy diagnosis between 1 January 2000 and 31 June 2006, 2 AED prescriptions, and insurance enrollment for 6 months pre- and 12 months post-AED initiation. Adherence was evaluated using the medication possession ratio (MPR), with MPR<0.8 defining non-adherence. Per-patient outcomes were evaluated over 12 months post-AED initiation. Of 1278 patients identified, 41% were non-adherent. Seizure, defined by epilepsy-related inpatient or emergency department admission, occurred in 12.1% of non-adherers versus 8.2% of adherers (P=0.0212). Non-adherers had higher inpatient ($872, P=0.001), emergency department (+$143, P=0.0008), other outpatient' and ancillary ($1741, P=0.0081), and total health care ($2674, P=0.0059) costs. AED adherence among elderly patients with epilepsy is sub optimal and associated with increased seizures and health care costs.

Brown, Sheeran and Reuber (2009) conducted a study to enhancing anti epileptic drug adherence. The study method was randomized control trial. This trial was designed to demonstrate whether implementation, intention, and intervention involving the completion of a simple self-administered questionnaire to improved AED adherence. Of the 81 patients with epilepsy who were randomized, 69 completed a month monitoring period with an objective measure of tablet taking by electronic registration of pill bottle opening, medication event monitoring system. The intervention participant showed improved adherence relative to control on three out comes i e dose taken in total (93.4% vs.79.1%) day on which correct dose was taken (88.7% vs.65.3%) and dose taken on schedules

78.8% vs. 55.3% (p=<0.01). The implementation intention intervention may be an easy to administer and effective means of promoting AEDs adherence.

Pooya (2005) conducted a study in drug compliance of children and adolescent with epilepsy. In this study patient with epilepsy under 18 years attending the clinic and their families were interviewed, total number of patient was 181 with epilepsy, mean age was 7-+4.6 years, the mean age of onset of this disease was 4.9-+4.2 years The sex ratio of the patient was 1.29. The etiology was specified in 21.5 % patient and idiopathic in 78.5% .The drug compliance was satisfactory in 72.3% and poor in 27% patients. The duration of disease didn't have a significant effect on compliance (2.4-+1.9). In-patient with poor compliance 2.2-+2.4 years with good compliance, p=0.576. Compliance was not significantly different in children and adolescents (p=0.07), parental smoking (p=0.115) parental education (p>0.05) living in urban versus rural areas (p=0.394) didn't significantly influence the compliance. The family size had significant effect on drug compliance; in this study drug compliance was satisfactory in almost three forth of the patient with epilepsy. There was no significant association between noncompliance and cause of epilepsy, duration of disease, socio economic status and number of drug used to treat the illness but paying attention to education for patients and parents, decreasing complexity of regime and younger possibly more motivated in small family, increased drug compliance.

Lusic and Titlic (2005) conducted a study to determine epileptic patient's compliance with prescribed medical treatment. In this study different demographic and clinical data, collected up on questionnaires completion from 146 patients suffering from epilepsy. In this study 62% subject the compliance level was recorded well, in 23% as satisfactory and remains 15% unsatisfactory. The possible predictors of the less perceive adherence to prescribed therapeutic regimen (p=0.05) was also assessed. The study revealed a tendency towards lower compliance level in patient age below 30. In spite of different experiment aimed to improve the regularity in taking the prescribed therapy, the issue of

noncompliance still possesses a considerable obstacle to the more successful treatment of epileptic patients.

Asawavichienjida (2003) conducted a study to compliance with treatment of adult epilepsy in Thailand .The method of study was all epileptics registered in clinic and their caregivers interviewed and examined. Of a total 93 epileptic registered, 83 with their caregivers were interviewed and examined. Out of 72 adults epileptics, 41 (56.9%) were 100 % complaint and factors found to be significantly associated with compliance were gender, house income and patient's health insurance p=<0.05.The majority reasons for noncompliance were misunderstanding (48.4%), forgetfulness 16.1% and economic problem 12.9. To improve patient compliance the real factors for noncompliance, which are unique to patient in a specific area, need to be identified.

AL-Faris and Abdulghani (2002) conducted a study to estimate the rate of drug compliance in epileptic patients; factors associated with drug compliance and determine the patient perceived reason for non-compliance with appointments. The method of study was prospective in which 147 epileptic children attended the neurology clinic. The patients were recruited in to the study after a detailed questionnaires and their compliance with appointments was monitored prospectively. Eighty six percent of patient stated that they were complying with AEDs and 53% of them didn't miss any appointments to the clinic. Children with grand mal and absence seizures were more likely to show adherence with their medications. The belief model factors associated with noncompliance were children encountering side effect, parents who were not satisfied with provided service, and forgetfulness. The researcher suggests that failure to keep the clinic appointments is an indicator of poor compliance.

Mitchell (2000) conducted a study to determine adherence to treatment among a group of children with epilepsy. The study subjects (4-13 year old) were enrolled in a longitudinal seizure study at the first visit to the seizure clinic,

attending at least 6 months and had at least two appointments. Interview, chart review and psychometric testing obtained baseline predictors including social and cultural (family environment) seizure history, previous treatment history, child behavior, cognitive function (IQ) and family stress. Four latent factors tapping these indicating of risk acculturative risk, seizure severity, behavior problems, family environment, and two measured variables IQ and life event were hypothesized. Family environment was associated significantly and positively with IQ ($r=0.25$, $p<0.05$) and negatively with life events ($r=0.24$, $p<0.05$). The families with higher acculturative risk and with higher life events reported greater adherence and seizure severity did not influence adherence.

Gomes, Filbo and Neo (1998a) conducted a study to assess the anti epileptic drug intake adherence, the value of blood drug level measurement and the clinical approach. A pilot cross-sectional study was carried out at a neurologic outpatient clinic of a university hospital. Ninety-three patients AED blood concentration (Phenobarbital, Phenytoin, Carbamazepine) were analyzed from 24 patients. The variability of the AED blood level was measured (in the steady state period by means of the variation coefficient) and compared with the self-reported anti epileptic medication non-adherence, AED blood level according to the range (therapeutic or not), and the seizure control. It was not observed any strong correlation between the higher value of variability and the other three parameters of non adherence. The highest correlation was with the blood drug level (therapeutic or not). The evaluation of blood drug measurement alone, except in cases of extreme low adherence and variability of drug intake, was not enough for the recognition of incorrect drug intake, but the clinical markers and the self-reported adherence have to be also considered for this sort of evaluation

Gomes and Filbo (1998b) conducted a study to assess medication taking behavior and drug self-regulation of people with epilepsy. The method of study was a cross-sectional study, 45 consecutively seen patients answered a standardized questionnaire including questions about drug intake behavior. Both

genders were equally represented (22M x 23F). The mean age was 30.2 years. No specific characteristic was present in all patients. The self-reported non-use of the drug at any moment one week before (self-reported non-adherence) was 40.0%. Patients took the drug more than once in most cases (75.0%), and the only precipitating factor of seizures more frequently avoided was alcohol intake (66.7%). Forty-four percent said to be afraid of becoming addicted to the medicine, 61.4% reduced or stopped the medicine just to see what would happen, and 47.7% changed the prescription with the same purpose. There is no relationship among socio-demographic, behavior aspects or treatment characteristics, and self-reported non-adherence. The study conclusion was several patients' aspects do not seem to be strongly correlated with self-reported adherence. Nevertheless, drug self-regulation is probably related to the drug-intake behavior, and it is important for the physician to understand this parallel influence on treatment for a more realistic approach.

Pryse-Phillips et al (1982) conducted a study to determine compliance with drug therapy by epileptic patients who were attending the out patient clinic and who were receiving drug therapy for any form of seizure disorder. A structured clinical interview was conducted by student interviewer either in the clinic or by telephone. Fifty patients with epilepsy were randomly divided in to the three groups and given respectively, the oral information about the nature, purpose, appearances, functions and unwanted effects of their medications at an initial interview: the same information supplemented by its presentation in written form for the patient to take home; and the same information by telephone contact only. Compliance with anticonvulsant therapy was assessed by interview and by the drug levels. The amount of knowledge retained and the drug levels were measured again 4 weeks later. While no increase in serum level could be detected over the mean values in the first interview on reduction in level could be documented either, although the drug information sheets had listed both minor and serious side effects of the drug. The patient information scores improved significantly in all

three groups, but the combination of data presented at interview both orally and in written form was markedly superiorly to the other methods.

2.3 Study related to factors influencing drug compliance among patient with epilepsy

Buck and Jacoby (1997) conducted a study to assess the factors influencing drug compliance with anti convulsant therapy. The method of study is survey method. The data reported from the records from community based survey of epileptic patients. They were identified from the records of 31 general practices. Nine hundred and seventy five subjects aged over 16 or over were sent a postal questionnaire and 769 were returned, of which 73 was rejected because of unanswered questions. Out of 696 patients, 95% were taking AEDs (68% were on one type of drug i.e. mono therapy and 27% were on poly therapy). Of these 95% almost three quarter (72%) of patient said they never missed taking their medication. 15% missed less than once a month, 9% missed more than once a month. The 50% patient reported AEDs side effect (tiredness 80%, memory problem 71%, lack of concentration 65%, sleepiness 63%, depression 60%, and head ache 58%). The patient age was significantly associated with compliance; the older ones always had compliance to medication. The social class (p=0.09) and gender of the patient (p=0.04) were not significantly related to missing medication. There was no relation ship between whether or not patient missed taking their tablets and seizure frequency (p=0.6). Also patient on mono therapy reported a significant shorter duration of epilepsy than those on poly therapy p=0.00001). There was no significant relationship between compliance and number of times patient had seen their general practice p=0.02. The univariate analysis showed that factors associated with compliance were patient age, how important patient felt it was to take drug as prescribed, whether patient reported feeling of stigma, whether on mono therapy or poly therapy, whether patients reported side effect. The multivariate analysis showed that the strongest predictors of non-compliance were feeling it was not very or not at all important to take

AEDs as prescribed, being a teenager, being aged under 60 and being on mono therapy.

2.4 Study related to strategies to improve drug compliance among patient with epilepsy

Peterson (1984) conducted a study to improve patient drug compliance with anti convulsant therapy. In this study 53-hospital outpatient with epilepsy were randomly allocated to either a control group or an interventional group. The patients in the interventional group were subjected to a combination of compliance improving strategies, patient counseling, a special medication container, self recording of medication intake and seizure and mailed reminders to collect prescription refills and attend clinic appointments, Compliance with anticonvulsant therapy (as measured by plasma anticonvulsant levels and prescription refill frequencies), and seizure frequency, were evaluated in each patient prior to intervention and 6 months afterwards. Patient compliance and clinical control improved significantly in the intervention group patients. Seizure frequency was, on average, halved following intervention. Compliance and seizure frequency were unaltered in the control group. Intervention failed to improve clinic appointment keeping. Poor compliance with drug therapy commonly confounds the treatment of epilepsy. This study shows that compliance can be improved and seizure frequency lessened by strategies that are easily incorporated into the routine management of epileptic patients. Compliance with anticonvulsant therapy and seizure frequency was evaluated in each patient prior to intervention and 6 month afterwards. The patient compliance and clinical control of seizure improved significantly in the intervention group.

2.5 Summary

This chapter include introduction, studies related to drug compliance among patient with epilepsy, studies related to factors influencing drug

compliance among patient with epilepsy and study related to strategies to improve drug compliance.

Chapter - 3
METHODOLOGY

3.1 Introduction

Research methodology is the systematic way to solve the research problem. It include the step that researcher adopt to study his problem with the logic behind. It indicate the general pattern of organizing the procedure of gathering valid and reliable data for an investigation.

This chapter provides a brief description of the method adopted by the investigator to conduct this study. This chapter deals with research approach; study design, the sample and sampling technique. It further deals with the development and description of the tool, pilot study, data collection, procedure and plan of analysis.

3.2 Objectives of the study

The objectives of the study were

- To determine the drug compliance among people with epilepsy attending the follow up clinic of SCTIMST
- To identify factors determining drug compliance in people with epilepsy attending the follow up clinic of SCTIMST

3.3 Research approach

Survey method

3.4 Setting of the study

The study was conducted in the follow up clinic in epilepsy OPD in SCTIMST, Trivandrum. In SCTIMST the epilepsy follow up clinic is conducted

twice weekly i.e. on Wednesdays and Fridays. On each day more than 60 patients are attending the clinic.

3.5 Study population

People with epilepsy attending the OPD follow up clinic of SCTIMST, Trivandrum.

3.6 Sample and sampling techniques

Purposive sampling technique was used. The sample consisted of people with epilepsy attending the OPD clinic of SCTIMST. The sample size was 60. The duration of study was from August 2011 to November 2011.

3.7 Inclusion criteria

- Patient who were willing to participate
- Patients who have age above 18

3.8 Exclusion criteria

- Patient who do not understand Malayalam

3.9 Development of the tool

An extensive study and review of literature helped in the preparation of the tool. A self-prepared questionnaire was used as the tool for this study. Patient's medical records also were reviewed to collect data.

3.10 Description of the tool

Part I: This part contains identification data and this include patient name, age. Sex, marital status, place, diagnosis, number of

hospitalization, educational qualification, type of family, and job status.

Part II: This part include disease related aspects like questions about the family history of epilepsy, age at onset of epilepsy, duration of illness in years, type of seizure and frequency of seizure in last year.

Part III: This part contains questions about the medications and it use. These include 14 questions. It include name of drug type of drug therapy, frequency of medication, compliance to AEDs, history of noncompliance, if it is noncompliant reason, family remind to take your medicine, develop any side effect, is the prescribed medicine is easily available, monthly expenditure for the medicine and follow the regular clinical appointment.

3.11 Pilot study

Pilot study was done in September 2011. Ten patients were taken for the pilot study. The pilot study was conducted to find out the feasibility of the study.

3.12 Data collection

The data was collected from epilepsy follow up clinic in the SCTIMST. The period of data collection was August 2011 to November 2011.

3.13 Plan of analysis

The investigator developed a plan of analysis after pilot study. The data collected were coded, entered in excel sheet and analyzed by descriptive statistics using chi-squred test/ fisher exact scale by epi info version 3.5.1 and present in the form of bar diagram. Percentage would be used for describing the sample.

3.14 Summary

This chapter deals with methodology, study setting, and sampling and sampling technique, development and description of the tool, pilot study, data collection, and plan of analysis.

Chapter --4
ANALYSIS AND INTERPRETATIONS

4.1. Introduction

This chapter presents the analysis and interpretation of data collected from sixty patients with epilepsy attending the follow up clinic of SCTIMST. Sixty patients were selected for assessing the drug compliance level. Analyzing is a process of organizing and synthesizing data in such a way that research questions can be answered. The overall objective of analysis is to organize structure and elicit answers from the assessment.

Interpretation is the process of making sense of the result and examining the implication of finding within the broader content.

The finding of the study were analyzed and arranged under the following sections.

4.2 Distribution of sample according to demographic data.

4.3 Distribution of sample according to disease data.

4.4 Distribution of sample according to medication data.

4.5 Factors influencing drug compliance

4.2 Distribution of sample according to demographic data

4.2aDistribution of sample by diagnosis

Table 4.2.a Distribution of sample according to diagnosis

Diagnosis	Frequency	Percentage
GTCS	18	30
CPS	42	70
Total	60	100

The diagnosis of sample made by two types, GTCS and CPS. There were 18 (30%) patients with GTCS, 42 (70%) patients with CPS. The data given in the Table 4.2a shows that majority of patients were having CPS (70%). The same data is shown as the pie diagram in the figure 4.2a

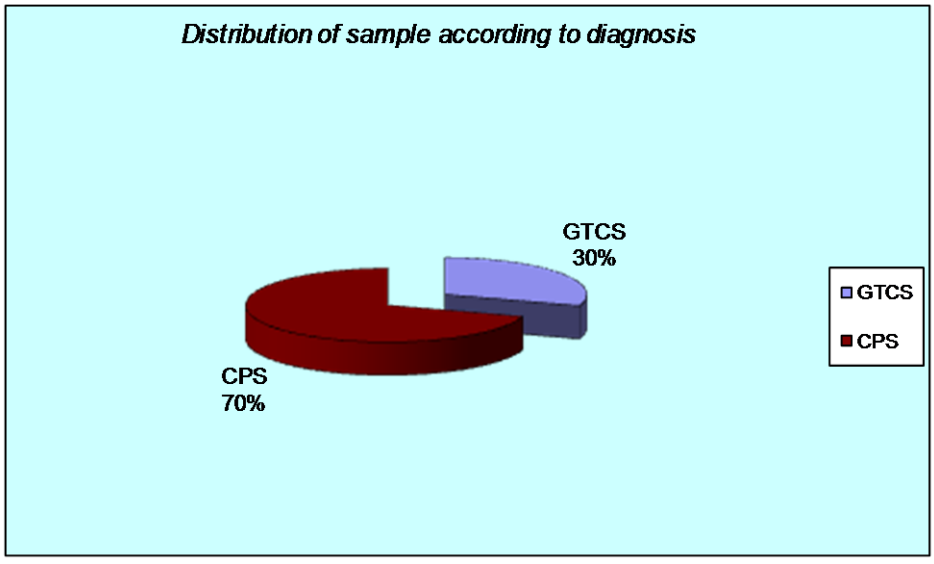


Fig 4.2a Pie diagram showing distribution of sample according to diagnosis

4.2b Distribution of sample according to number of hospitalization

Table 4.2b Distribution of sample according to number of hospitalization

Number of Hospitalization	Frequency	Percentage
No need for hospitalization	35	58.33
One time	24	40.00
Two times	1	1.67
Total	60	100

Table 4.2b shows the distribution of sample according to number of hospitalization. Thirty-five (58.33%) patients was didn't need hospitalization, and twenty-four (40%) required one-time hospitalization. The same data is shown in fig 4.2b

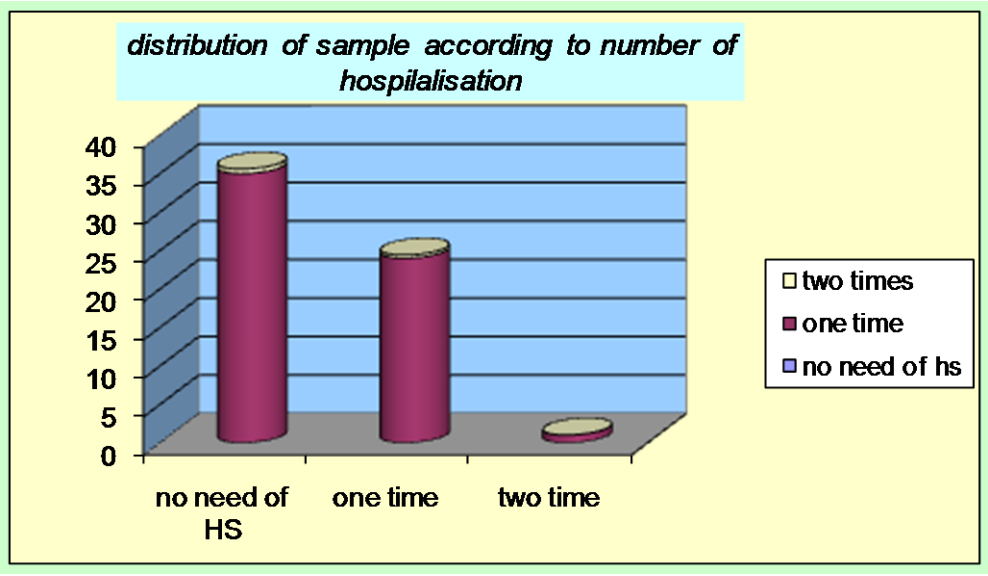


Fig 4.2b Bar diagram of sample by number of hospitalization

4.2c Distribution of sample according to age

The age of the sample ranged from 18-56 with a mean age of 31.95, standard deviation of 10.87, median age of 29 and mode 23.

Table 4.2c shows distribution of sample according to age

Age category	Frequency	Percentage
18-30	34	56.67
31-50	21	35.00
>50	5	8.33
Total	60	100

Age categories were made based on the age distribution of sample so as to have a minimum number under each class. The majority of patients belonged to age group 18-30, (56.67%). The same data is shown in Fig 4.2c.

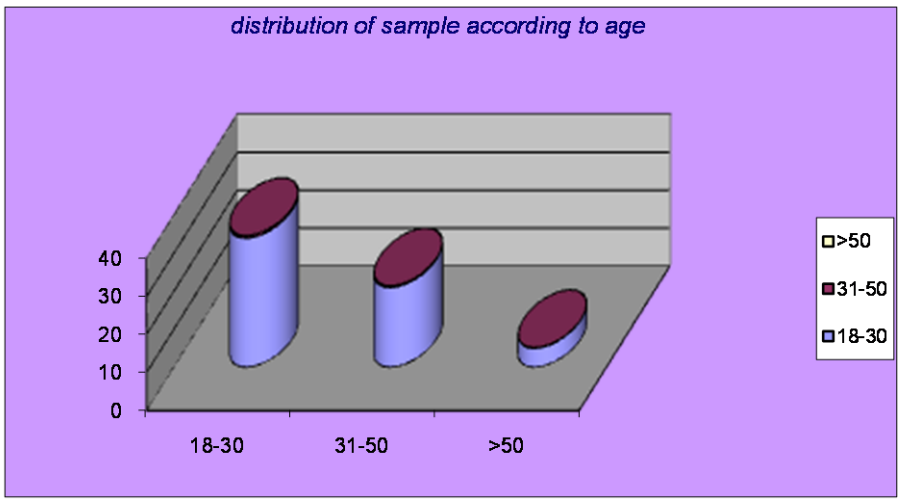


Fig 4.2c Bar diagram of sample by age group

4.2d Distribution of sample according to sex

Table 4.2d shows the distribution of sample according to sex. There were (58.33%) male in sample and (41.67%) in females

Table 4.2d Distribution of sample according to sex

Sex	Frequency	Percentage
Male	35	58.33
Female	25	41.67
Total	60	100

The same data is shown in Fig 4.2d

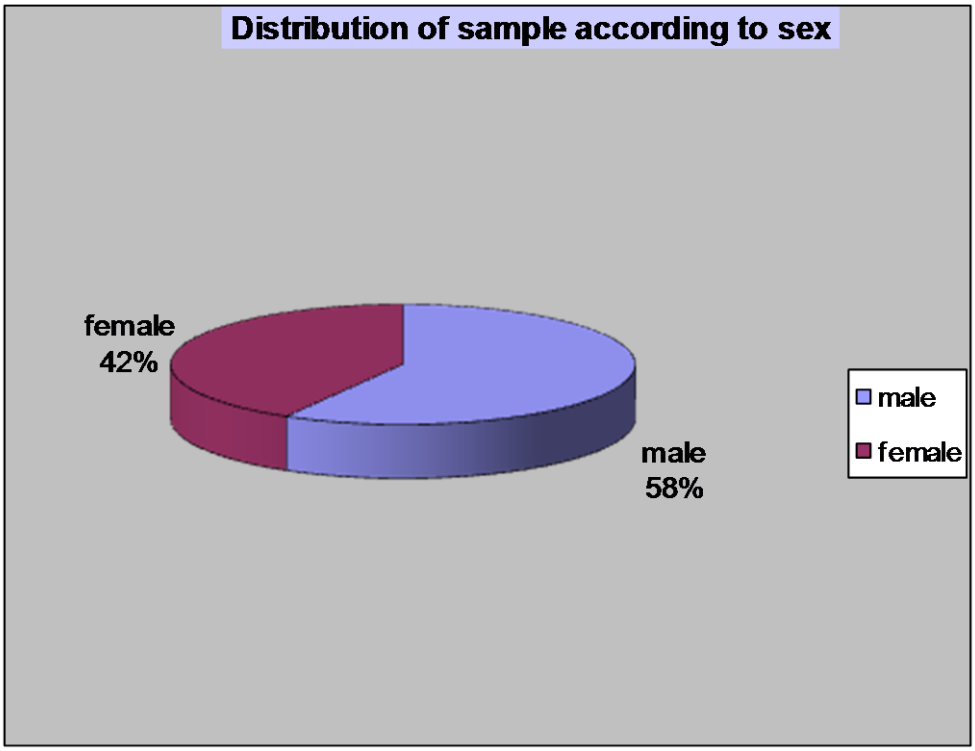


Fig 4.2d Pie diagram of sample by sex

4.2e Distribution of sample according to marital status

Table 4.2e shows that the majority of samples were unmarried (55%).The same data is shown in the Fig 4.2e

Table 4.2e distribution of sample by marital status

Marital status	Frequency	Percentage
Unmarried	33	55
Married	27	45
Total	**60**	**100**

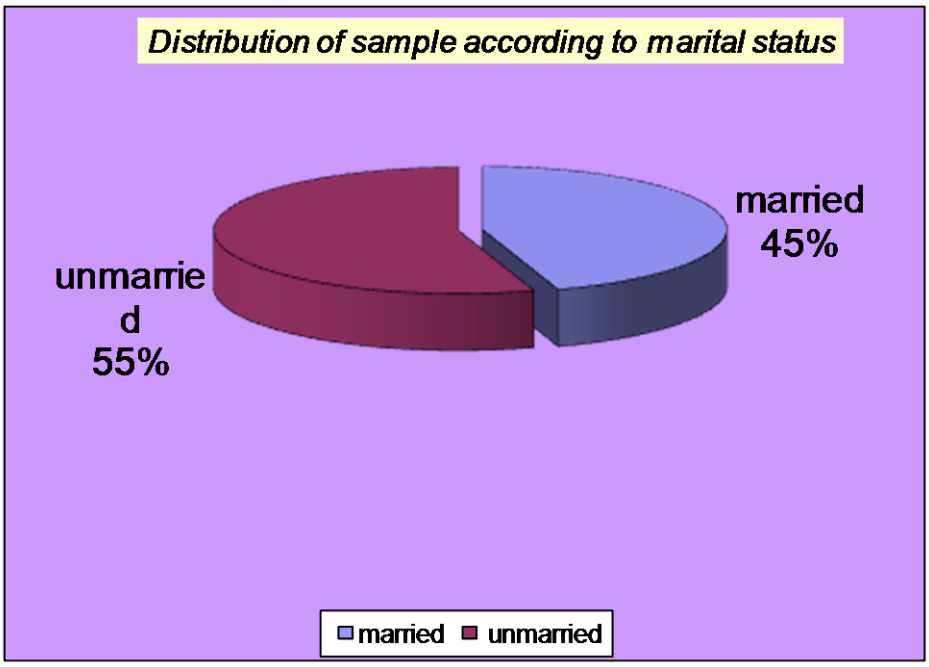


Fig 4.2e Pie diagram of sample by marital status.

4.2f Distribution of sample according to place of living

Table 4.2f shows the distribution of sample according to place of living. The majority of people belonged to rural area (55%).

Table 4.2.f Distribution of sample according to place of living

Place	Frequency	Percentage
Urban	27	45
Rural	33	55
Total	60	100

The same data is shown in Fig 4.2f.

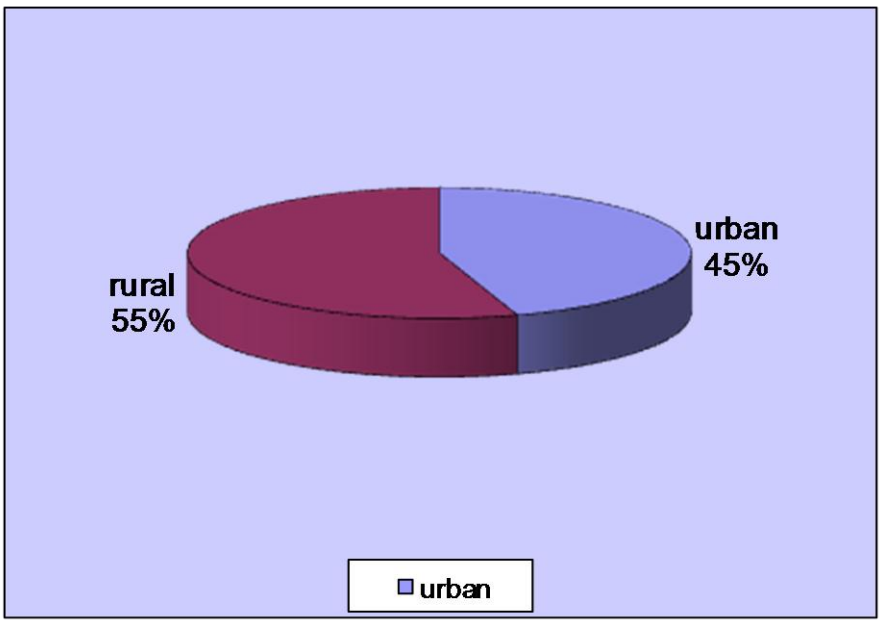


Fig 4.2f pie diagram of sample by place of living

4.2g Distribution of sample according to educational status

Table 4.2g Distribution of sample according to educational status

Educational Status	Frequency	Percentage
School	32	53.33
Plus two	15	25.00
Graduate	10	16.67
Post graduate	03	05.00
Total	60	100

Table 4.2g shows that the majority of sample had school education (53.33%), only five percentages had post graduate education (5%). The same data is shown in the Fig 4.2g.

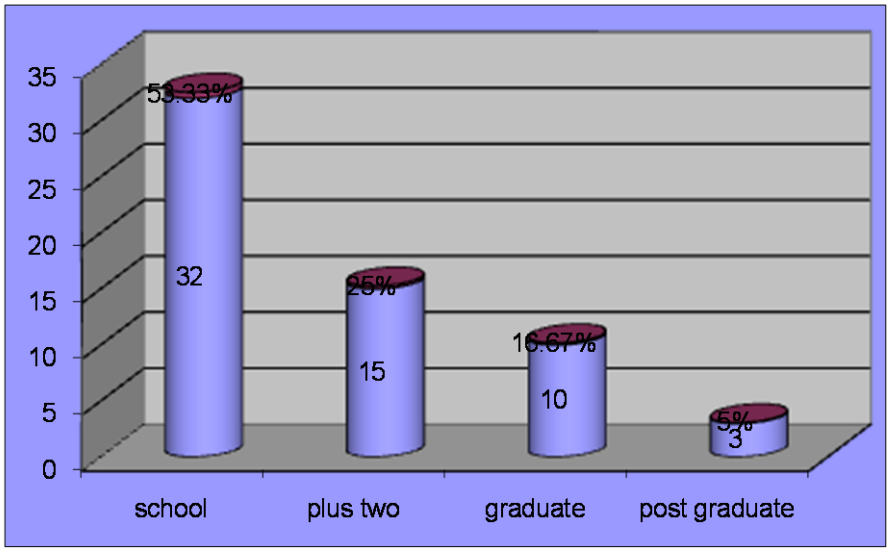


Fig 4.2g Bar diagram of sample by educational status

4.2h Distribution of sample according to type of family

Type of family	Frequency	Percentage
Nuclear family	40	66.67
Joint family	20	33.33
Total	60	100

Table 4.2h Distribution of sample according to type of family

Table 4.2h shows that the majority of samples were from nuclear family (66.67%) and remaining belonged to joint family (33.33%). The data is shown in the figure 4.2h.

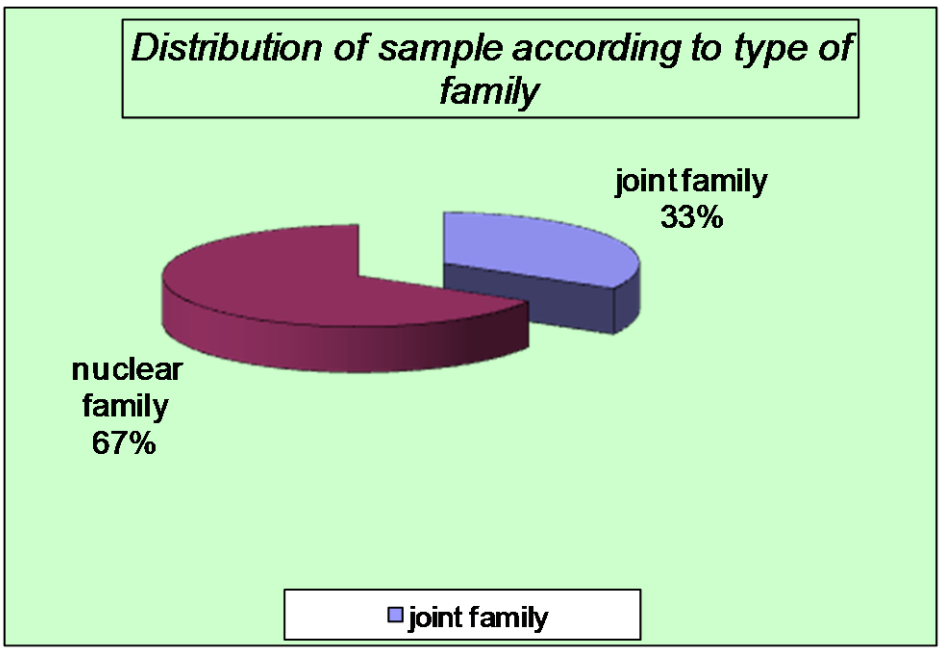


Fig 4.2h Pie diagram of sample according to type of family.

4.2i Distribution of sample according to employment status

Table 4.2i Distribution of sample according to employment status

Employment status	Frequency	Percentage
Unemployed	34	56.67
Employed	26	43.33
Total	60	100

Table 4.2i shows that the majority of samples were unemployed (56.67%)). The same data is shown in the Fig 4.2i.

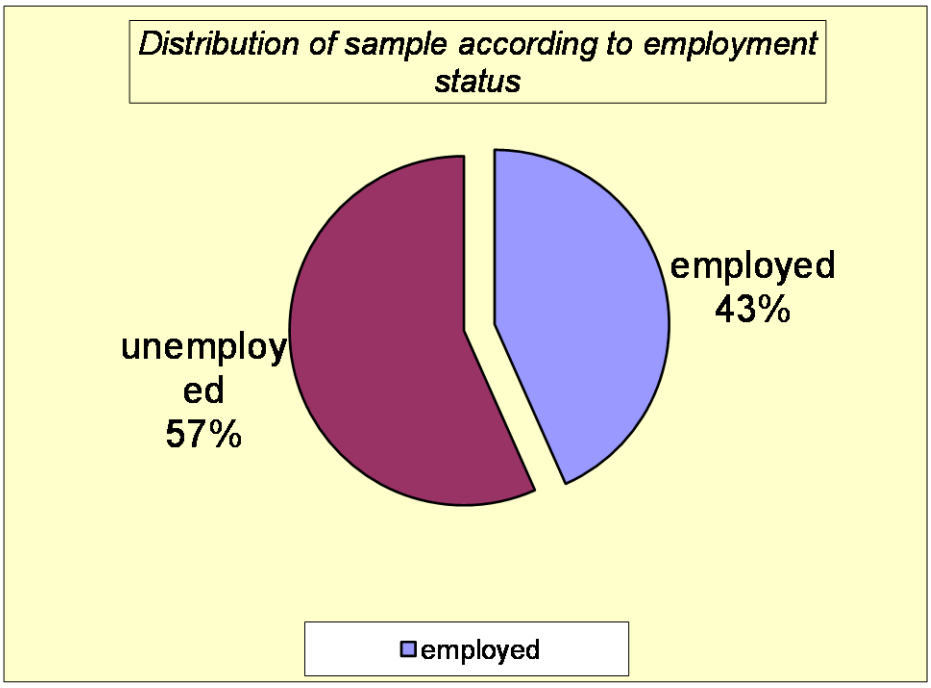


Fig 4.2i Pie diagram of sample according to employment status

4.3 Distribution of sample according to disease data

4.3a Distribution of sample according to family history of epilepsy

Table 4.3a Distribution of sample according to family history of epilepsy

Family history of epilepsy	Frequency	Percentage
Absent	50	83
Present	10	17
Total	60	100

Table 4.3a shows that the majority of sample didn't have family history of epilepsy (84%) and only seventeen percentages had family history of epilepsy. The same data is shown in the Fig 4.3a.

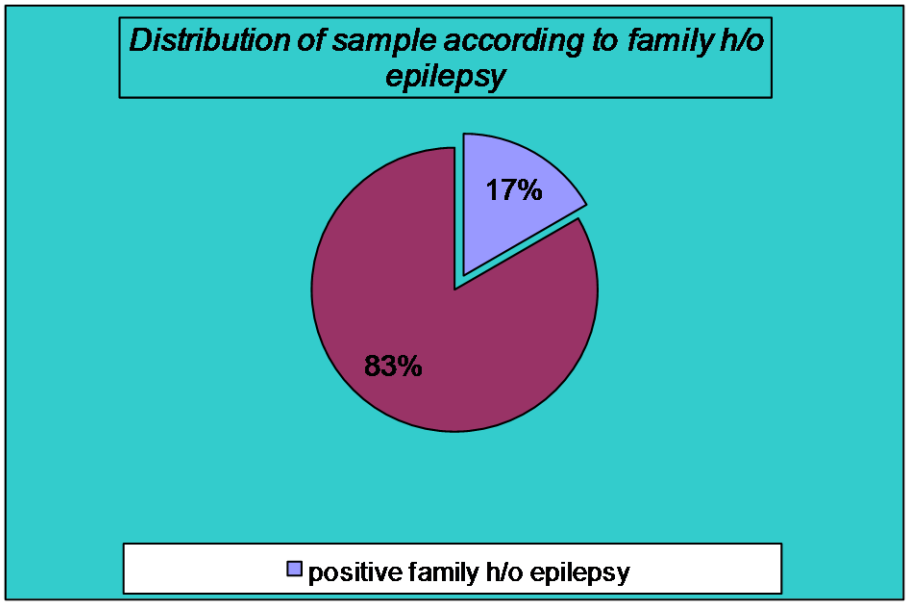


Fig 4.3a Pie diagram of sample by family history of epilepsy.

4.3b Distribution of sample according to age of onset of epilepsy

Table 4.3b Distribution of sample according to age of onset of epilepsy

Age	Frequency	Percentage
0-5 years	12	20.00
5-8 years	17	28.33
>18 years	31	51.67
Total	60	100

Table 4.3b shows that the majority of sample had age of onset of disease as >18 (51.67%) and less number of sample in age of 0-5 years 12 (20%). The same data is shown in the Fig 4.3b.

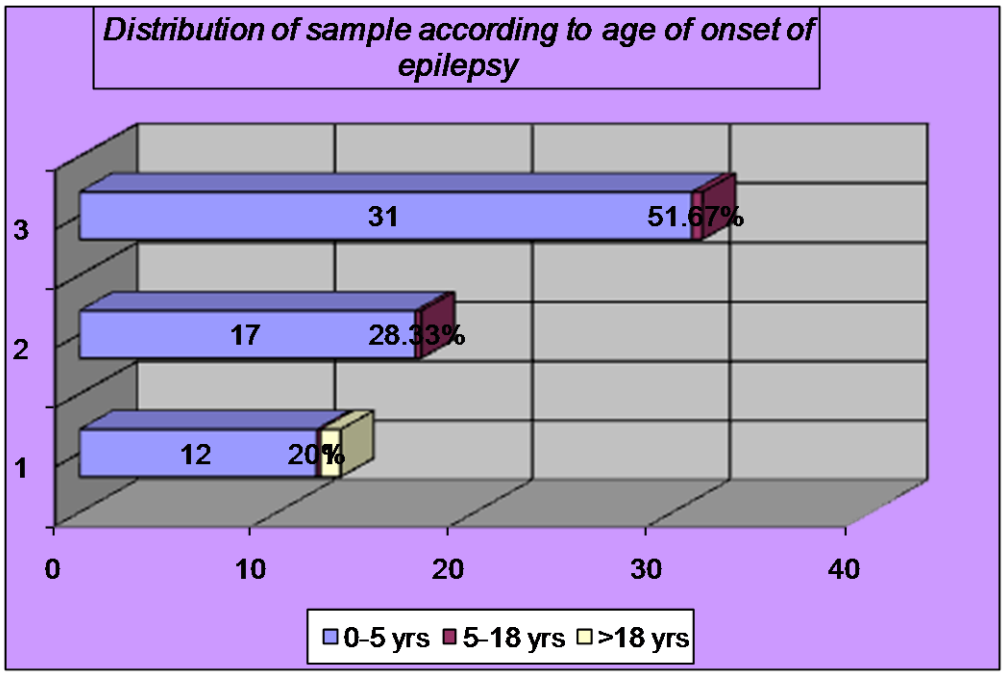


Fig 4.3b Bar diagram of sample by age of onset of epilepsy.

4.3c Distribution of sample according to illness in years

Table 4.3c Distribution of sample according to illness in years

Illness in years	Frequency	Percentage
1-10 yrs	27	45.00
11-20 yrs	20	33.33
21-30 yrs	10	16.67
31-40 yrs	2	3.33
> 40 yrs	1	1.67
Total	**60**	**100**

s

Table 4.3c shows that the majority of sample had duration of illness 1-10 yrs (45%), five percentage of sample had duration of illness more than 30 years. The duration of illness ranged from 1-46 yrs. The mean duration of illness is 13.96yrs and standard deviation is 9.84, median is 11yrs and mode is 9yrs.

The same data is shown in the Fig 4.3c.

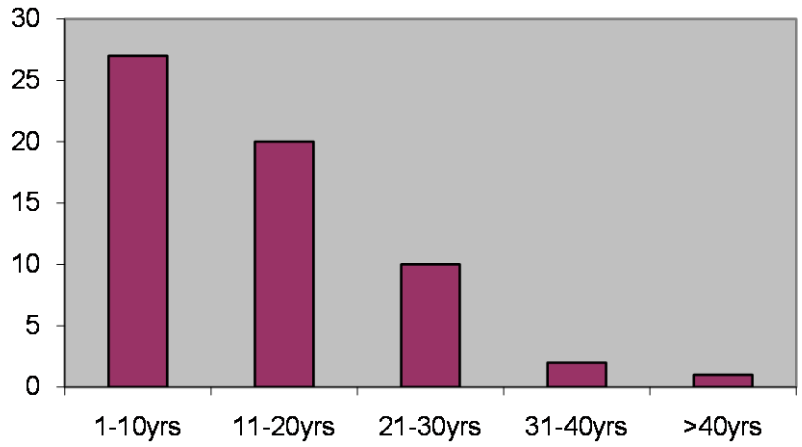


Fig 4.3c Bar diagram of sample according to illness in years.

4.3d Distribution of sample according to type of seizure

Table 4.3d Distribution of sample according to type of seizure

Type of seizure	Frequency	Percentage
Generalized seizure	20	33.33
Partial seizure	35	58.34
Multiple type	05	8.33
Total	60	100

Table 4.3d shows that the majority of sample had partial seizures (58.34%), thirty-three percentages had generalized seizure (33.33%) and eight percentages had multiple type seizures. The same data is shown in the Fig 4.3d.

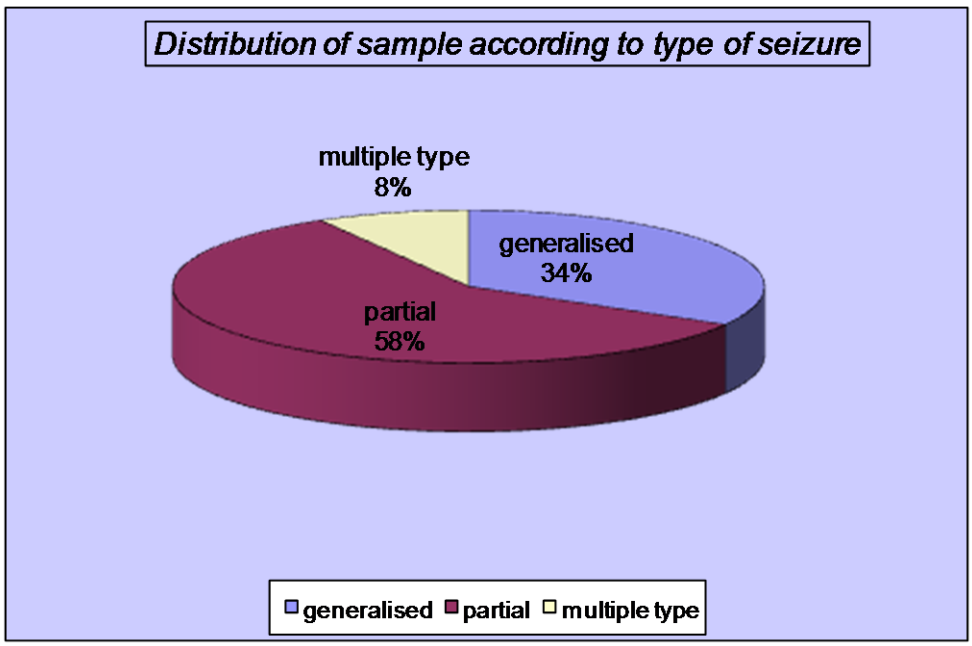


Fig 4.3d pie diagram of sample according to type of seizure.

4.3e Distribution of sample according to frequency of seizure

Frequency of seizure in one yr	Frequency	Percentage
No seizure	28	46.67
Weekly	01	01.66
Two weekly	03	05.00
Monthly	06	10.00
Two- three monthly	04	06.67
Six monthly	03	05.00
Once a year	13	21.67
Any other	02	03.33
Total	60	100

Table 4.3e Distribution of sample according to frequency of seizure.

Table 4.3e shows majority of sample were seizure free in the previous year (46.67%). The data is shown in the Fig 4.3e.

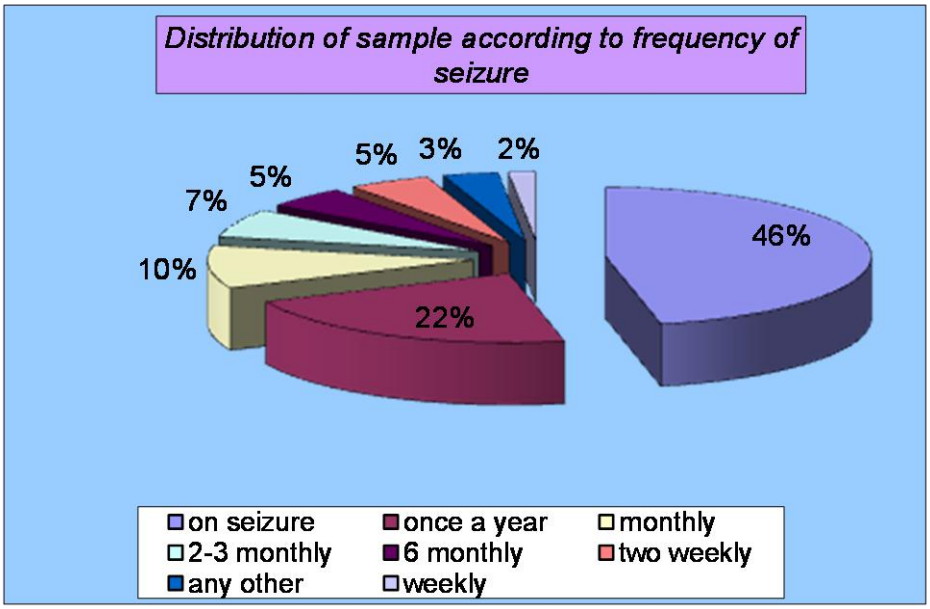


Fig 4.3e Pie diagram of sample by frequency of seizure.

4.4 distribution of sample according to medication data

4.4a Distribution of sample according to number of AEDs

Table 4.4a distribution of sample according to type of AEDs

No of AEDs	Frequency	Percentage
Mono therapy	30	50
Two AEDs	22	37
Three AEDs	08	13
Total	60	100

Table 4.4a shows that the majority of sample was on mono therapy (50%), thirty-seven percentages were on two AEDs and thirteen percentages were getting three AEDs. The commonly used medication is Carbamazepine (mono therapy and poly therapy). The second common mono therapy medication is Sodium valproate. The most common combination therapy medication is the Carbamazepine and clobazem. The same data is shown in the Fig 4.4a

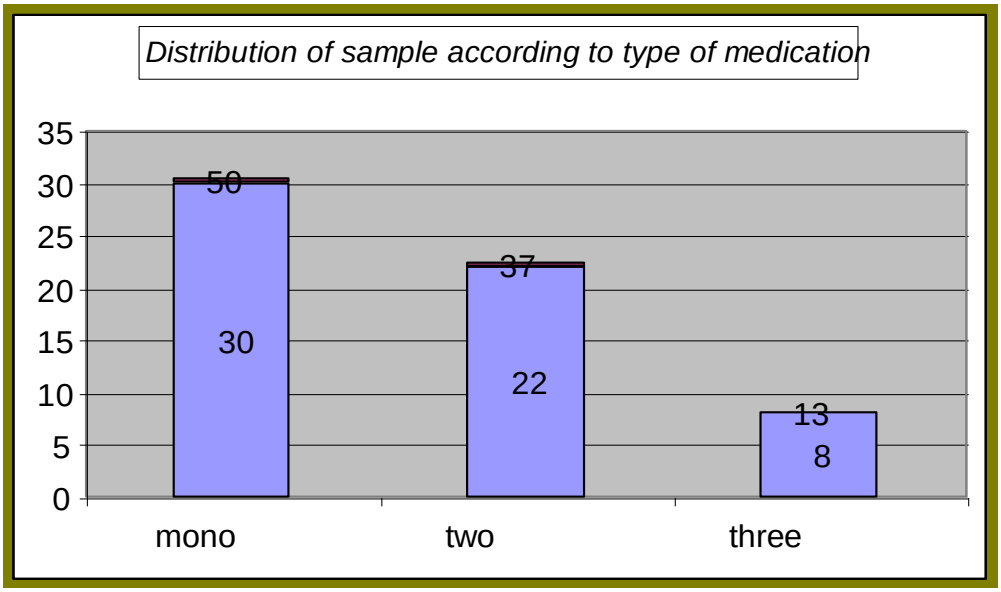


Fig 4.4a Bar diagram of sample according to number of AEDs

4.4b Distribution of sample according to frequency of medication

Table 4.4b Distribution of sample according to frequency of medication

Frequency of medication	Frequency	Percentage
Once a day	06	10
Two times a day	48	80
Three times a day	06	10
Total	60	100

Table 4.4b shows that the majority of samples were receiving AEDs two times a day (80%). Ten percentages each were receiving AEDs once or thrice daily. The same data is shown in the Fig 4.4b.

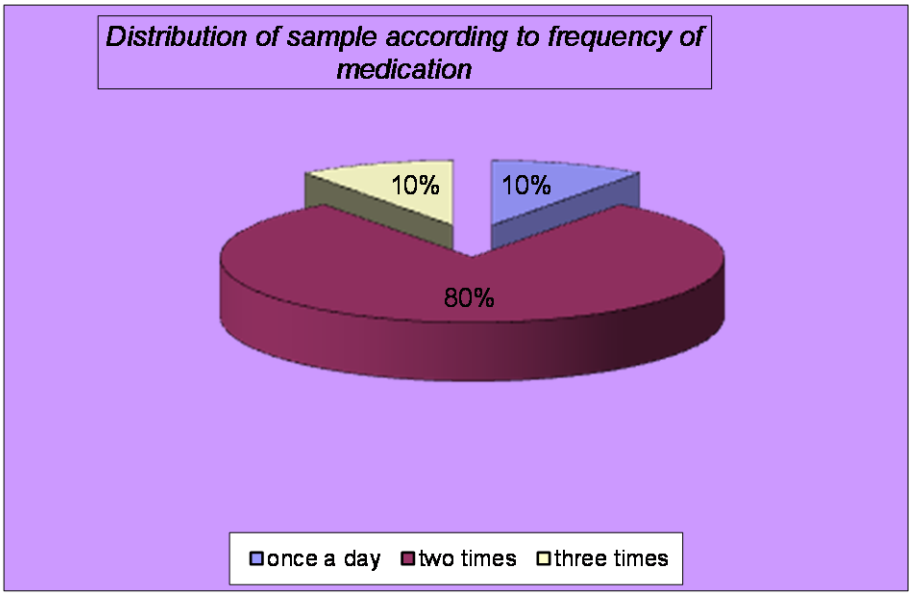


Fig 4.4b Pie diagram of sample by frequency of medication.

4.4c Distribution of sample according to drug compliance

Drug compliance	Frequency	Percentage
Never miss	49	81.67
Occasionally miss	10	16.67
Irregular	01	01.66
Total	60	100

Table 4.4c Distribution of sample according to drug compliance level

Table 4.4c shows that majority of sample were compliant, and never miss their medication (81.67%), only one patient was irregular in taking AEDs. The same data is shown in the Fig 4.4c.

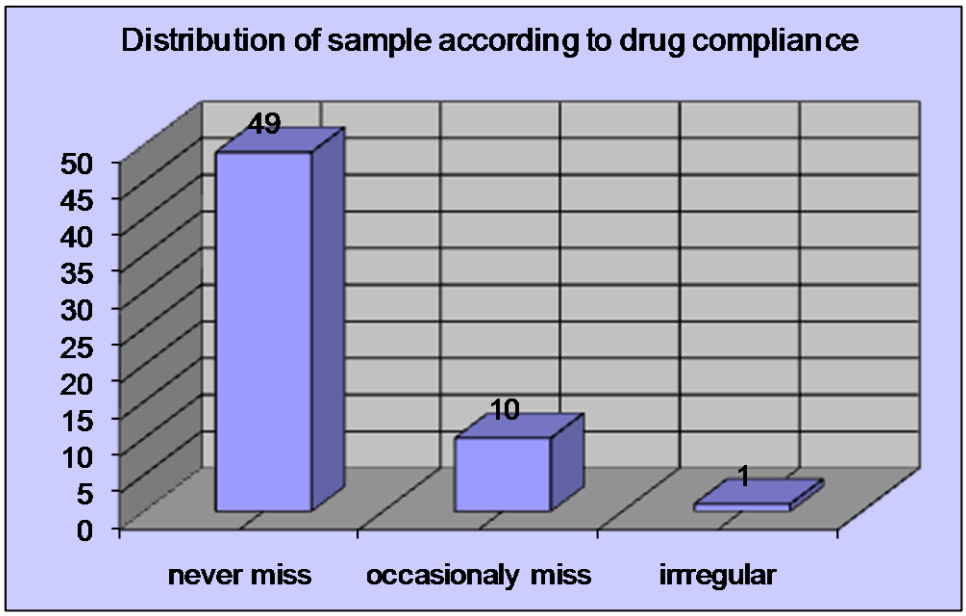


Fig 4.4c Bar diagram of sample by drug compliance level

4.4d Distribution of sample according to reason for drug noncompliance

Table 4.4d Distribution of sample according to reason for drug compliance

Reason for non compliance	Frequency	Percentage
Side effects	1	09
Forgetful ness	9	82
No specific reason	1	09
Total	11	100

Table 4.4c shows that out of eleven patients who were non compliant, the reason for non compliant was forgetfulness (82%). The one patient, who was irregular in drug didn't give any specific reason for the same. The same data is shown in the Fig 4.4d.

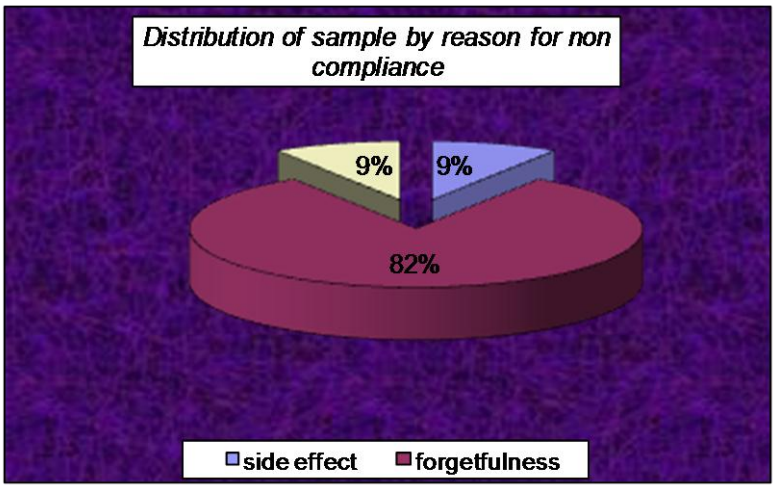


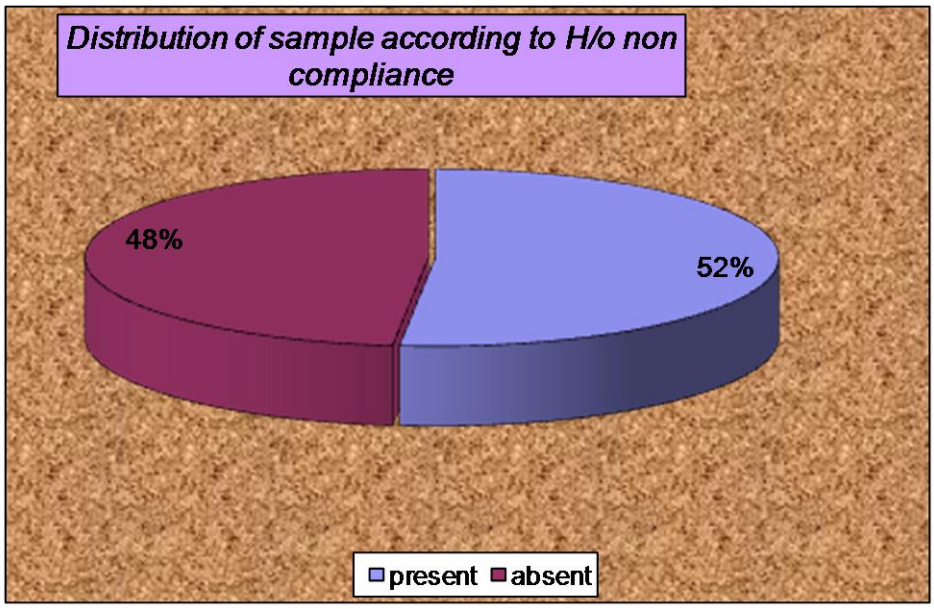
Fig 4.4d Pie of sample according to reason for non compliance

4.4e Distribution of sample according to history of non-compliance

Table 4.4e Distribution of sample according to history of non-compliance

H/o non compliance	Frequency	Percentage
Present	31	51.67
Absent	29	48.33
Total	60	100

Table 4.4e shows that more than fifty percentage of sample had history of noncompliance. The same data is shown in the Fig 4.4e.



4.4e Pie diagram of sample according to history of non-compliance

4.4f Distribution of sample according to side effects developed.

Table 4.4f Distribution of sample according to side effects developed

Side effect developed	Frequency	Percentage
Present	41	68.33
Absent	19	31.67
Total	60	100

The table 4.4f shows that majority of sample-developed side effects (68.33%) The same data is shown in the Fig 4.4f.

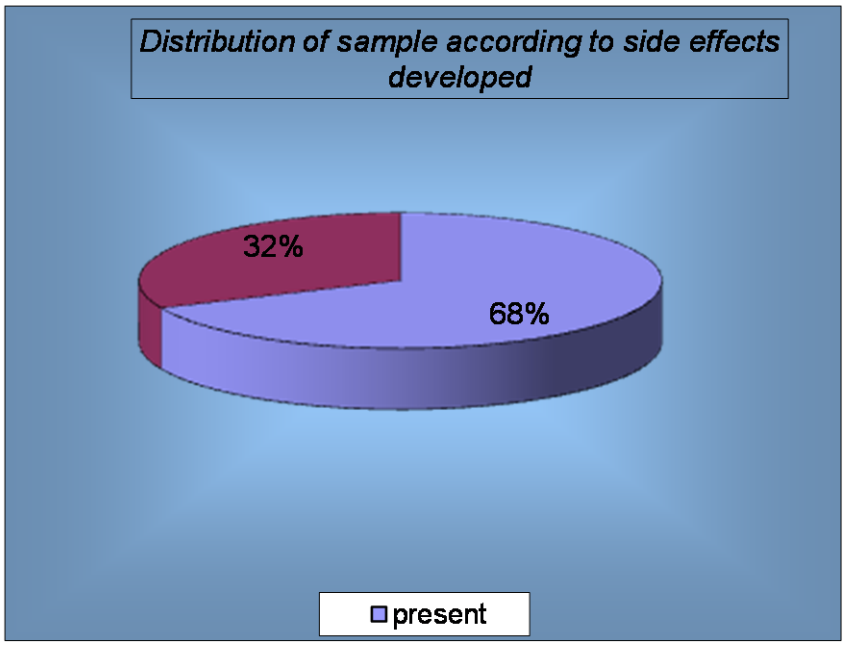


Fig 4.4f Pie diagram of sample by side effects developed

4.4g Distribution of sample according to type of side effects

Table 4.4g Distribution of sample according to type of side effects

Type of side effects	Frequency	Percentage
Excessive sleep	14	34.15
Fatigue /tired ness	12	29.27
Loss of memory	9	21.96
Affects learning	5	12.19
Behavioral changes	1	02.43
Total	41	100

Table 4.4g shows that majority of sample had excessive sleep 34.15% and only one patient reported behavioral problem The same data is shown in the Fig 44g.

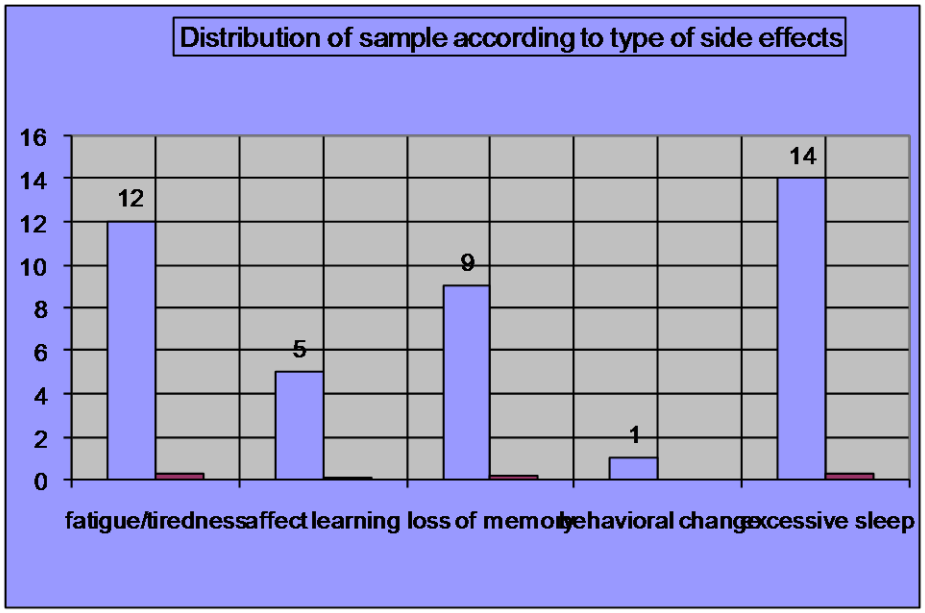


Fig 4.4g Bar diagram of sample by type of side effects

4.4h Distribution of sample according to side effects affecting work

Table 4.4h Distribution of sample according to side effects affecting work

Side effects affecting work	Frequency	Percentage
Yes	08	13.33
No	52	86.67
Total	60	100

Table 4.4h shows that side effects were not problematic for majority of sample (86.67%).The same data is shown in the Fig 4.4h

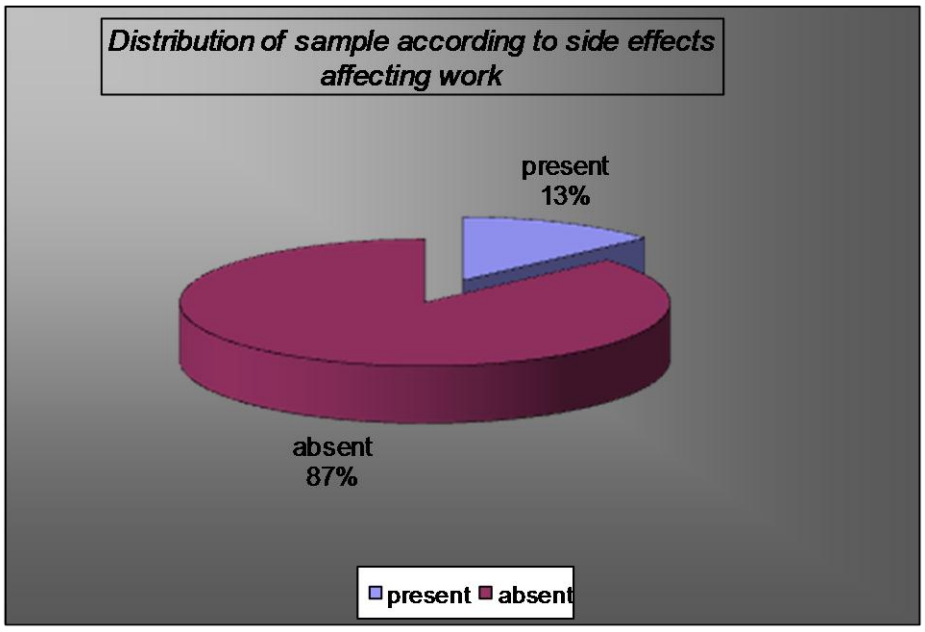


Fig 4.4h Pie diagram of sample by side effects affecting work

4.4i Distribution of sample according to easy availability of medicine

Table 4.4i Distribution of sample according to easy availability of medicine

Easy availability of medicine	Frequency	Percentage
Available	55	91.67
Not available	03	05.00
Some times available	02	03.33
Total	60	100

Table 4.4i shows that the majority of sample had easy availability of medicine (91.67%), five percentages had problem with availability of AEDs the same data is shown in the figure 4.4i.

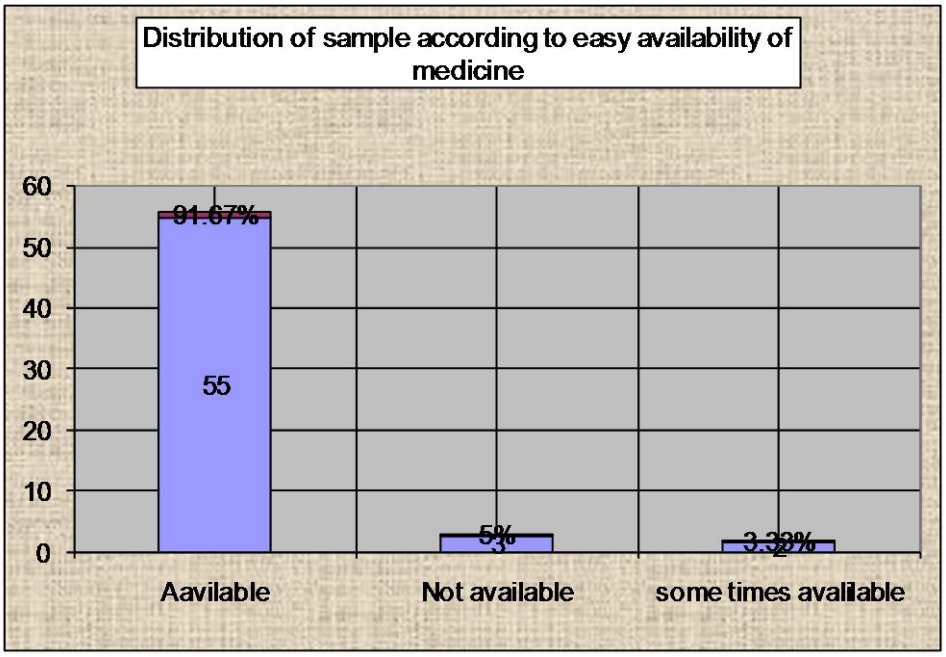


Fig 4.4i Bar diagram of sample by easy availability of medicine

4.4j Distribution of sample according to monthly expenditure of medicine

Table 4.4j Distribution of sample according to monthly expenditure of medicine

Monthly expenditure in Rs	Frequency	Percentage
Rs 100-400	34	56.67
Rs 401-1000	22	36.67
Rs 1001-3000	04	6.66
Total	60	100

The Table 4.4j shows that the majority of people had monthly expenditure in Rs 100-400 ranges (56.67%). The mean expenditure was 484.18, stdev 517.62, median 400, mode 500 and range 100 to 3000. The same data is shown in the Fig 4.4j.

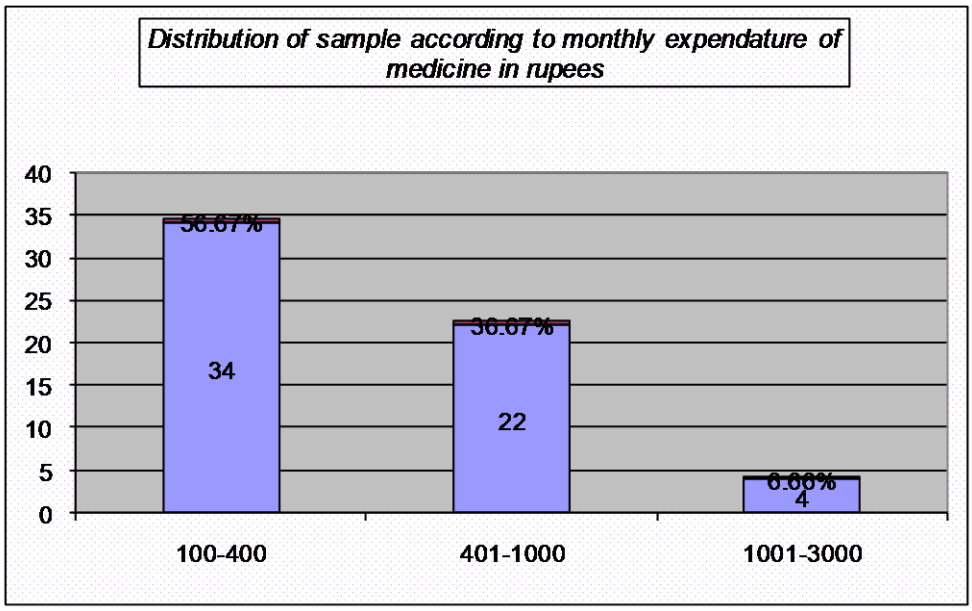


Fig 4.4j bar diagram of sample by monthly expenditure of medicine

4.4k Distribution of sample according to family member reminding to take medicine

Table 4.4k distribution of sample according to family member reminding to take medicine

Family member reminds to take medicine	Frequency	Percentage
Yes	39	65
No	21	35
Total	60	100

The table 4.4k shows that majority of sample (60%) were reminded to take their medication by family members. The same data is shown in the Fig 4.4k

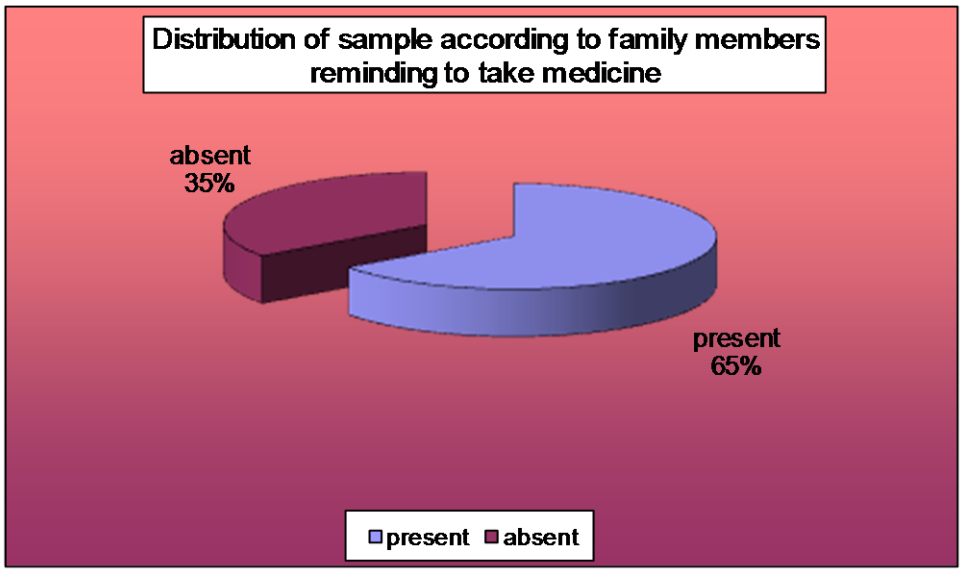


Fig 4.4k pie diagram of sample by family members reminds to take medicine

4.4L Distribution of sample according to follow up regularity

Table 4.4L Distribution of sample according to follow up regularity

Follow up regularity	Frequency	Percentage
Regular	56	93.33
Irregular	4	6.67
Total	60	100

The table 4.4L shows that the majority of sample kept regular follow up visits (93.33%). The same data is shown in the fig 4.4L.

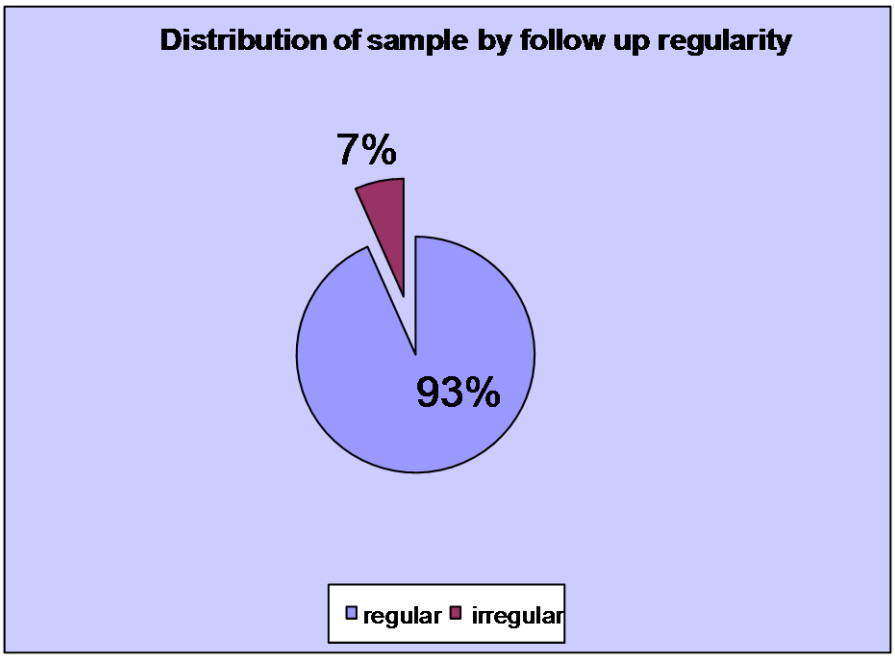


Fig 4.4L Pie diagram of sample by follow up regularity

4.5 Factors influencing drug compliance

Table 4.5 factors influencing drug compliance

Variables	Compliant Frequency (%)	Non compliant Frequency (%)	Total (%)	P-value
Age < 29	26 (83.9)	5 (16.1)	31 (100)	
> 29	23 (79.3)	6 (20.7)	29 (100)	0.45
Education: school	26 (81.3)	6 (18.8)	32 (100)	
> School	23 (82.1)	5 (17.9)	28 (100)	0.60
Place: urban	21 (77.8)	6 (22.2)	27 (100)	
Rural	28 (84.8)	5 (15.2)	33 (100)	0.35
Duration of illness				
<10 yrs	22 (78.6)	6 (21.4)	28 (100)	0.40
>10 yrs	27 (84.4)	5 (15.6)	32 (100)	
History of non compliance				
Present	21 (67.7)	10 (32.3)	31 (100)	
Absent	28 (96.6)	1 (03.4)	29 (100)	0.004
Side effects				
Present	33 (80.5)	8 (19.5)	41 (100)	0.52
Absent	16 (84.2)	3 (15.8)	19 (100)	
Expenditure of medicine				
<400	29 (84.4)	5 (15.6)	32 (100)	
>400	22 (78.6)	6 (21.4)	28 (100)	0.40

The Table 4.5 shows relationship between selected background variables and AED compliance. These include patient age, education, place of residence, duration of illness, history of noncompliance, side effects and expenditure of medicine by chi-squred test/ fisher exact test. There was no relationship between AED compliance and

age (p=0.45), education (p=0.60), place of living (p=0.35), duration of illness (p=0.40), side effects p=0.52), and expenditure (p=0.40). However a significant relationship was found between history of noncompliance and current status of noncompliance (p=0.004).

4.6 Summary

This chapter contains distribution of sample according to demographic data, disease data and medication data and factors affecting drug compliance.

The Table 4.5 shows relationship between selected background variables and AED compliance. These include patient age, education, place of residence, duration of illness, history of noncompliance, side effects and expenditure of medicine by chi-squred test/ fisher exact test. There was no relationship between AED compliance and age (p=0.45), education (p=0.60), place of living (p=0.35), duration of illness (p=0.40), side effects p=0.52), and expenditure (p=0.40). However a significant relationship was found between history of noncompliance and current status of noncompliance (p=0.004).

4.6 Summary

This chapter contains distribution of sample according to demographic data, disease data and medication data and factors affecting drug compliance.

Chapter 5
SUMMARY, CONCLUSION, DISCUSSION AND RECOMMENDATIONS

5.1 Introduction

A brief account of the study is given in this chapter, which cover objectives, findings of the study and possible application of result. Recommendation for future research and suggestion for improving the present study are also presented.

5.2 Summary

This study was conducted with the objectives to determine the drug compliance among people with epilepsy attending the follow up clinic of SCTIMST and to identify the factors affecting the drug compliance. A review of related research literature helped the investigator to get a clear concept about the topic undertaken, as well as to develop tools, methodology of the study and decide plan of data analysis.

The study was conducted in the epilepsy follow up clinic of SCTIMST; the size of the sample was 60. The duration of study was from August 2011 to November 2011.A self-prepared questionnaire was used for collecting data; it included identification data, clinical data and medication data. The data was analyzed and interpreted using descriptive and inferential statistics.

5.3 Objectives of the study

* To determine the drug compliance among people with epilepsy attending the follow up clinic of SCTIMST.
* To determines the factors influencing the drug compliance among people with epilepsy attending the follow up clinic of SCTIMST.

5.4 Limitation

The study was limited to people attending the epilepsy follow up clinic in SCTIMST and sample size was only 60.

5.5 Major findings of the study

The total number of participants was 60. The mean age of participant was 31.95yrs. In this study 70% patients were with Complex partial Seizure and 30% with Generalized Tonic-clonic seizure. The types of seizures were Partial seizure (58.34%), Generalized seizure (33.33%), and multiple type (8.33%). The patient's illness in years range from 1 to 46 yrs and mean illness in years of epilepsy is 13.96 yrs. Out of 60 patient 28 (46.67%) had no seizure in last one year and patients with positive family history of epilepsy was only 10 (16.67%).

The most common drugs prescribed were Carbamazepine 37.12%, Phenobarbital 13.41% and valproic acid 11.34%. Out of 60 patients 50% were on mono therapy to control seizure, 37% patient had two medications and only 13% had three medications to control seizure. The most common combination of medication used was Carbamazepine + clobazem.

Out of 60 patients 49(81.67%) never missed their dose of anti epileptic drugs. Ten (16.67%) patients occasionally missed their AEDs and only one (1.66%) patient was completely non compliant. The reason for non-compliance was forgetfulness (81.82%) and side effects (9.09%). Thirty-nine (65%) patients family reminded them to take their medication. Thirty-one (51.67%) patients had history of non-compliance. Forty one patients (68.33%) reported side effects, excessive sleep (34.15%), fatigue and tiredness (29.27%), and loss of memory (21.96%). The monthly expenditure of medicine ranged from Rs. 100 to 3000 with a mean monthly expenditure Rs.487.56.fifty six (93.33%) of patients kept appointments correctly.

The study showed that there was no relationship between AED compliance and age (p=0.45), education (p=0.60), place of living (p=0.35), duration of illness (p=0.40), side effects p=0.52), and expenditure (p=0.40). However a significant relationship was found between history of noncompliance and current status of noncompliance (p=0.004).

In this study only 29 patients (48.33%) patients had a history of compliance i e before attending this institute. In SCTIMST, Comprehensive epilepsy care programme (R.Madhavan Nayar center for Comprehensive epilepsy care) educates and council the patients to improve the drug compliance level to prevent recurrence of seizures. Now drug compliance level is 81.67%. In spite of education and counseling the issue of non-compliance still remains a considerable obstacle to the more successful treatment of peoples with epilepsy.

5.6 Recommendation for future study

The following recommendations were made for the future research.

1. Similar study can be repeated in other patients with chronic disease like Chronic Heart Failure

2. Similar study can be repeated by increasing the size of the sample.

5.7 Discussion

There are many studies related to different aspects of drug compliance among patients with epilepsy. The present study emphasized to assess the self reported drug compliance level and factors affecting drug compliance among patients with epilepsy using self prepared questionnaires. This study showed that 81.67% patient reported drug compliance. The most common used medication was Carbamazepine as mono therapy or in combination with clobazem as poly therapy. Forty-one patients (68.33%) reported drug side effects. The most commonly reported side effect was excessive sleep (34.15%).

Asawavichienjida (2003) reported a compliance rate of 57%; Pooya (2005) reported as compliance rate of 72.37% both are lower than the present study (81.67%). Cacerces (2006) conducted a study to determine the noncompliance with pharmacological therapy in epileptic patients. The rate of non-compliance was 67.2%, which is much higher than the present study (18.33%). Lusic and Tittic (2005) reported higher compliance level (62%) and satisfactory compliance (23%) had and 15% had unsatisfactory compliance level (15%).

In this study out of 60 patients 81.67% had good compliance level; they never miss their medication at any time. 10 (16.67%) of patients occasionally miss their medication.

5.8 Conclusion

Based on the findings of the study the following conclusions were drawn. Majority of patients (81.67%) self reported drug compliance level was good. The reason for non-compliance was forgetfulness in 81.82%. Sixty-eight percentages of patients reported side effects; in that majority of people reported excessive sleep (34.14%). The study shows that there was no relationship between AED compliance and age (p=0.45), education (p=0.60), place of living (p=0.35), duration of illness (p=0.40), side effects p=0.52), and expenditure (p=0.40). However a significant relationship was found between history of noncompliance and current status of noncompliance (p=0.004).

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INFORMED CONSENT

I hereby agree to participate the research study "A *study to determine the drug compliance among people with epilepsy"* conducted by Mrs. Vineetha J R Ist year Diploma in Neuro Nursing of SCTIMST, Trivandrum. I understand that there will not be any change in the nature of care that I receive and data given by me will be kept confidential and will be used only for research purpose.

Signature of patient,

Name:

Place:

Date:

Drug compliance Questionnaire For Interview Schedule

IDENTIFICATION DATA

1. Name

Diagnosis:

No of hospitalization: 0, 1, 2, 3

2. Age

3. Sex (1.male, 0. female)

4. Marital status (1. married, 2.unmarried, 3. widow.4 widower)

5. Place of residence (1.urban, 2.rural)

6. Educational qualification (1. school, 2.Higher secondary, 3. Graduate, 4.post graduate)

7. Occupation (1. employed, 2. unemployed)

8. Type of family (1. joint, 2. nuclear)

9. Clinical Data

9.1 Any family history of epilepsy (1. yes, 0.no)

Age at which you were diagnosed to have epilepsy? (1. 0-5, 2. 5-18, 3. more than 18)

Duration of illness in years…

Types of seizure (1.Generalized, 2.Focal, 3.Unclassified, 4. Multiple types.)

Frequency of seizure in last years (1. Daily, 2.weekly, 3.two weekly, 4.monthly, 5.2-3 monthly, 6. Quarterly, 7. Six monthly, 8. Once a year, 9.not occur, 10. Any other)

10.<u>Data regarding drug Intake</u>

10.1 Name of AEDs in present treatment (1.PB, 2.CBZ, 3.PHT, 4.VAP, 5.LTG, 6.TPM, 7.CLB, 8.OXCBZ 9. ZSMD, 10.GP, 11.LEPL)

10.2 Types of drug therapy (1. mono therapy, 2. poly therapy)

10.3 How frequently do you take your medicine? (1. Once a day, 2. Twice a day 3. >/ = Three times a day)

10.4 Compliance to AEDs (1.never miss, 2. occasionally miss, 3. Irregular)

10.5 If non-compliant, reason? (1. Fear about side effects, 2.forgets. 3. cost factor, 4.beliefs, 5. Lack of benefits, 6.Any other)

10.6 Any previous history of non-compliance? (1.yes, 0.no). If yes what was the cause?

10.7 Does the family remind you to take your medicine? (1.yes, 0.no)

10.8 When you are not getting seizure for 2-3 months will you stop taking your medication? (1.Yes, 0. no)

10.9 Did you develop any side effects? 1.yes, 0. No

10.10 If yes, what was it? (1. Drowsiness 2.Fatigue, 3. Imbalance or in co ordination 4.Cognitive deficit, 5. Forgetfulness, 6. Mood changes, 7.Any other)

10.11 Do side effects affecting work? (1. Yes, 0.no)

10.12 Is the prescribed medicine easily available (1.Yes, 0.no,3. sta)

10.13 Monthly expenditure for the medicine?

10.14 Do you follow the regular clinic appointment? (1.yes, 0. no)

സമ്മതപത്രം

അപസ്മാര രോഗിയുടെ മരുന്നുകളുടെ ഉപയോഗത്തെക്കുറിച്ച് പഠിക്കുന്നതിന് തിരുവനന്തപുരം ശ്രീ ചിത്ര തിരുനാൾ ആശുപത്രിയിലെ ഒന്നാം വർഷ ഡിപ്ലോമ ന്യൂറോ നേഴ്സിംഗ് വിദ്യാർത്ഥിനിയായ വിനീത ജെ.ആർ. നടത്തുന്ന പഠനത്തിൽ സഹകരിക്കാൻ ഞാൻ സമ്മതിക്കുന്നു. എപ്പോൾ വേണമെങ്കിലും ഈ പഠനത്തിൽ നിന്ന് എനിക്ക് പിന്തിരിയാമെന്നും എന്റെ സഹകരണമോ, നിസ്സഹകരണമോ എനിക്ക് ലഭിക്കുന്ന ശുശ്രൂഷയെ ബാധിക്കുകയില്ലെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. ആയതിനാൽ സ്വമനസ്സാലെ ഞാൻ ഈ പഠനത്തിന്റെ ഭാഗമാകാമെന്ന് സമ്മതിക്കുന്നു.

ഒപ്പ്

വിവരം നൽകുന്ന വ്യക്തിയുടെ പേര്

സ്ഥലം:
തീയതി:

അപസ്മാര രോഗികളുടെ മരുന്നുകളുടെ ഉപയോഗത്തെക്കുറിച്ചുള്ള അഭിമുഖസംഭാഷണത്തിന്റെ ചോദ്യാവലി

വ്യക്തിവിവരം

Diagnosis :
Number of Hospitalization 0 1 2 3

1. പേര്
2. വയസ്സ്
3. 1. ആൺ 0. പെൺ
4. വിവാഹിത, അവിവാഹിത, വിധവ, വിഭാര്യൻ
5. താമസ സ്ഥലം
   1. നഗരം ☐ 2. ഗ്രാമം ☐
6. വിദ്യാഭ്യാസ യോഗ്യത
   1. സ്കൂൾ വിദ്യാഭ്യാസം ☐ 2. പ്ലസ് ടു ☐
   3. ബിരുദം ☐ 4. ഉന്നത ബിരുദം ☐
7. ഏത് തരത്തിലുള്ള കുടുംബമാണ്
   1. കൂട്ടുകുടുംബം ☐ 2. അണുകുടുംബം ☐
8. ജോലി
   1. ഉണ്ട് ☐ 0. ഇല്ല ☐

9. അസുഖത്തെക്കുറിച്ചുള്ള വിവരങ്ങൾ

9.1 കുടുംബത്തിൽ ആർക്കെങ്കിലും അപസ്മാരം ഉണ്ടായിരുന്നോ?

1. ഉണ്ട് ☐ 0. ഇല്ല ☐

9.2 താങ്കൾക്ക് എത്രാമത്തെ വയസ്സിലാണ് അപസ്മാരം കണ്ടുപിടിച്ചത്?

1. 0-5 വയസ്സ് ☐ 2. 5-18 വയസ്സ് ☐ 3. 18 വയസ്സ് കഴിഞ്ഞ് ☐

9.3 എത്ര വർഷമായി ഈ അസുഖം ഉണ്ട്?

9.4 ഏത് വിധത്തിലുള്ള അപസ്മാരമാണ് ഉണ്ടാകുന്നത്?

1. ശരീരം മൊത്തമായി ☐ 2. ഭാഗികമായി ☐
3. തരംതിരിക്കാൻ പറ്റാത്തത് ☐ 4. വിവിധ തരങ്ങളിൽ ☐

9.5 കഴിഞ്ഞ വർഷം നിങ്ങൾക്ക് എത്ര തവണ അപസ്മാരം വന്നു?

1. ദിവസവും ☐ 2. ആഴ്ചയിൽ ☐
3. രണ്ടാഴ്ചയിലൊരിക്കൽ ☐ 4. മാസത്തിലൊരിക്കൽ ☐
5. രണ്ട് മൂന്ന് മാസത്തിനിടയിൽ ☐ 6. നാല് മാസത്തിനിടയിൽ ☐
7. ആറ് മാസത്തിനിടയിൽ ☐ 8. വർഷത്തിലൊരിക്കൽ ☐
9. വന്നിട്ടില്ല ☐ 10. മറ്റ് ഏതെങ്കിലും ☐

10. <u>മരുന്നിന്റെ ഉപയോഗത്തെക്കുറിച്ചുള്ള വിവരം</u>

10.1 നിങ്ങൾ കഴിക്കുന്ന മരുന്നിന്റെ പേര് എന്താണ്?

1. PB ☐ 2. CBZ ☐ 3. PHT ☐ 4. VAP ☐ 5. LTG ☐
6. TPM ☐ 7. CLB ☐ 8. Oxcarb ☐ 9. ZSMD ☐ 10. GP ☐ 11. Lamp

10.2 എത്ര തരത്തിലുള്ള മരുന്നാണ് നിങ്ങൾ കഴിക്കുന്നത്?

1. ഒരു തരം മരുന്ന് ☐ 2. രണ്ട് തരം മരുന്ന് ☐
3. രണ്ടോ അതിൽ കൂടുതലോ ☐

10.3 എത്ര നേരമാണ് മരുന്ന് കഴിക്കുന്നത്?

1. ഒരു നേരം ☐ 2. രണ്ട് നേരം ☐
3. മൂന്ന് നേരമോ അതിൽ കൂടുതലോ ☐

10.4 താങ്കൾ കൃത്യസമയത്തിന് മരുന്ന് കഴിക്കാറുണ്ടോ?

1. ഒരിക്കലും മുടങ്ങാറില്ല ☐ 2. വല്ലപ്പോഴും ☐
3. മിക്കവാറും മുടങ്ങാറുണ്ട് ☐

10.5 കൃത്യസമയത്ത് മരുന്ന് കഴിക്കുന്നില്ല എങ്കിൽ അതിന്റെ കാരണം എന്താണ്?

1. മരുന്നിന്റെ ദൂഷ്യഫലങ്ങൾ ☐ 2. മറവി ☐
3. മരുന്നിന്റെ വില ☐ 4. തെറ്റിദ്ധാരണ ☐
5. സന്നികുറയാത്തതു കൊണ്ട് ☐ 6. മറ്റേതെങ്കിലും ☐

10.6 താങ്കൾ മുൻപ് എപ്പോഴെങ്കിലും മരുന്ന് കൃത്യമായി കഴിക്കാതെ ഇരുന്നിട്ടുണ്ടോ?

1. ഉണ്ട് ☐ 0. ഇല്ല ☐

ഉത്തരം ഉണ്ട് എന്നാണെങ്കിൽ അതിന്റെ കാരണം എന്താണ്?

10.7 താങ്കളുടെ വീട്ടുകാർ മരുന്നു കഴിക്കുവാൻ ഓർമ്മിപ്പിക്കാറുണ്ടോ?

1. ഉണ്ട് ☐ 0. ഇല്ല ☐

10.8 രണ്ടുമൂന്നുമാസം താങ്കൾക്ക് അപസ്മാരം ഉണ്ടായില്ലെങ്കിൽ മരുന്ന് നിർത്തുമോ?

1. ഉണ്ട് ☐ 0. ഇല്ല ☐

10.9 താങ്കൾക്ക് മരുന്നിന്റെ ദൂഷ്യഫലങ്ങൾ എന്തെങ്കിലും ഉണ്ടായിട്ടുണ്ടോ?

1. ഉണ്ട് ☐ 0. ഇല്ല ☐

10.10 മരുന്നിന്റെ ദൂഷ്യഫലങ്ങൾ ഉണ്ടായിട്ടുണ്ട് എങ്കിൽ എന്തായിരുന്നു അത്?

1. തളർച്ച ☐ 2. ക്ഷീണം ☐
3. നിയന്ത്രണമില്ലായ്മ ☐ 4. പഠനത്തിന് ബുദ്ധിമുട്ട് ☐
5. മറവി ☐ 6. സ്വഭാവത്തിൽ വരുന്ന മാറ്റം ☐
7. മറ്റേതെങ്കിലും ☐

10.11 മരുന്നിന്റെ ദൂഷ്യഫലങ്ങൾ നിങ്ങളുടെ ജോലിയെ ബാധിച്ചിട്ടുണ്ടോ?

1. ഉണ്ട് ☐ 0. ഇല്ല ☐

10.12 താങ്കൾ കഴിക്കുന്ന മരുന്ന് വിപണിയിൽ എപ്പോഴും ലഭ്യമാണോ?

10.13 മരുന്നിനുവേണ്ടി ഒരു മാസം ഏകദേശം എത്ര തുക ചിലവാക്കും?

10.14 താങ്കൾ കൃത്യമായി പരിശോധനയ്ക്ക് വരാറുണ്ടോ?

12/12/14