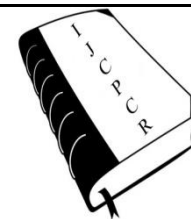




## International Journal of Current Pharmaceutical & Clinical Research



www.ijcpcr.com

### A PROSPECTIVE CROSS-SECTIONAL STUDY ON MEDICATION ADHERENCE AND IT'S FACTORS INFLUENCING IN EPILEPTIC PATIENTS IN A TERTIARY CARE HOSPITAL

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#### ABSTRACT

Non-Adherence in Epileptic patients is the biggest challenge that widespread globally. Though out of 70 million persons with Epilepsy worldwide, nearly 12 million reside in India; which contributes to roughly one-sixth of the global burden, the studies regard AED's adherence are very limited in India. **Aim and Objectives:** This study mainly sought to assess the level of adherence in epileptic patients and also to identify factors contributing to barriers to AED's adherence among adults as well as paediatrics. **Methodology:** A cross-sectional study of 150 in-patients (78 adults, 72 paediatrics) with Epilepsy and fulfilled the inclusion criteria were recruited from general medicine and paediatrics wards in a tertiary care centre. Data was collected by using a structured interview regard patient demographics, and questionnaires containing Morisky Medication Adherence Scale-8 (MMAS-8), Beliefs about Medicines Questionnaire (BMQ) and Pediatric Epilepsy Self-Management Questionnaire (PESMQ) were used to assess adherence as well as factors affecting it. **Result:** Approx. 71% of adult subjects showed poor adherence, where the factors that contributed to low adherence were negative beliefs towards medicines, lack of knowledge, long term therapy and forgetfulness. In paediatrics, 50% of subjects were good to high adherence and barriers observed were dislike of taste, the difficulty of swallowing medications. **Conclusion:** The factors that affecting adherence were individual beliefs, psychological percepts, lack of knowledge regard disease and medications, duration of therapy, lack of hope on medications, forgetfulness. To increase adherence rate, implementing strategies to improve awareness among subjects and caregivers regarding knowledge about Epilepsy and its complications associated with non-adherence, the significance of AED's in treating epilepsy and adherence assessments should routinely be performed.

**Key words:** AED's, MMAS, BMQ, PESMQ.

#### INTRODUCTION

Epilepsy is characterized by recurrent, unprovoked epileptic seizures and can affect people of all age groups. The overall estimated worldwide prevalence of epilepsy is 10/1000 population.<sup>[1]</sup> Approximately, 50 million people live with epilepsy all over the world, and nearly 75% belong to resource-poor countries with less

accessibility to proper healthcare facilities.<sup>[2]</sup> The management of epilepsy is complex as it involves avoidance of precipitating factors as well as suppression of recurrent seizure by prophylactic therapy with antiepileptic medication or surgery and also identification of goals and development of proper care plan as well.<sup>[3]</sup> The ultimate

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goal is freedom from seizure along with improvement in the quality of life<sup>[4]</sup> and this cannot be achieved if patient develops repeated seizures due to poor compliance to AED. Patients with good medication adherence to Antiepileptic drugs (AEDs) can prevent seizures in approximately 70% of adult patients with Epilepsy. However, AEDs non-adherence is highly prevalent, with estimates ranging from 20% to 80%<sup>[5]</sup>.

Medication adherence [MA] has been defined as the extent to which a patient follows the instruction for a prescribed medication by a physician and persistence as the duration of time from initiation to discontinuation of treatment<sup>[6]</sup>

Non-adherence to medication is one of the most serious impediments in clinical practice,<sup>[7]</sup> and this phenomenon in patients with Epilepsy can lead to loss of seizure control,<sup>[8]</sup> resulting in failure to achieve the treatment goal leading to increased risk of mortality, and a higher incidence of emergency department visits, hospital admissions, injuries, and fractures.

Generally, factors affecting adherence to medication can range from socio-demographic factors, such as age, gender, level of education, affordability, number of drugs administered, social support, beliefs about medication, and side effects to medication.<sup>[9]</sup>

To increase MA in patients the health care professionals should follow methods like Level of prescribing, communication with patients during follow-ups by direct and indirect methods.<sup>[10,11]</sup> Importantly, no method is considered the gold standard.<sup>[12],[13],[14]</sup>

Direct observations include biochemical measurements, and the addition of computer chips into pills. An advantage of these direct measures is that they can assess the actual presence of the medication in the body. The disadvantages of these direct methods are that they are obtrusive, costly, and difficult to implement. Indirect measures mainly involve; pharmacy data, electronic pill box monitoring and self-report scales. These scales are most widely used and very easily applicable in assessing adherence to medication prescribed for a specific illness. In our study 8-Item MMAS: (Morisky Medication Adherence Scale)<sup>[15]</sup>, Belief about Medicines Questionnaire (BMQ) are used in adults and Pediatric Epilepsy Self- Management questionnaire (PESMQ) is specially used to measure pediatric anti epileptics adherence and also to assess barriers.

## AIM

The present study aims to assess medication adherence and factors affecting medication adherence.

## OBJECTIVES

- To measure AED'S medication adherence in epileptic patients.
- To assess beliefs about medications.

- To study barriers contribution in affecting medication adherence.

## STUDY DESIGN

Prospective Cross-sectional study.

## STUDY SITE

The study was conducted in Sri Venkateshwara Ramnarain Ruia Government General Hospital, tertiary care teaching hospital, in the department of General Medicine and Pediatrics.

## STUDY DURATION

This study was carried out for six months.

## STUDY POPULATION

- The sample size for the study was 150 patients

## STUDY MATERIALS

- Patient data collection proforma
- Informed consent form (ICF)
- Morisky medication adherence scale (MMAS)
- Belief about medicines questionnaire(BMQ)
- Pediatric epilepsy self-management questionnaire(PESMQ)

**The 8-Item MMAS:** (Morisky Medication Adherence Scale):

The MMAS-8 includes eight items (e.g., 'Did you take your medication yesterday?' or 'Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?') seven items of which are answered on a dichotomous (yes/no) and one on a 5 point rating scale.<sup>[14]</sup> If the score is less than 6 it is considered as poor adherence and if score is 8 considered as high adherence.

## Belief about Medicines Questionnaire (BMQ)

This questionnaire was developed in the UK and published by Robert Horne and Weinman (1999). Subjects answered the extent to which they agreed or disagreed with the statement on a five-point Likert scale, where 1 = strongly disagree, 2 = disagree, 3 = uncertain, 4 = agree and 5 = strongly agree, to investigate the participants' opinion for each item. The questionnaire was divided into two sections, measuring beliefs about medicines in general and beliefs about medicines in specific. In this evaluation, items in the specific section will relate to the 'antiepileptic drugs', where 5 items evaluate personal beliefs about the necessity of the medications for maintaining or improving health, against 5 items evaluating concerns about the potential adverse effects of taking them. The general section consists of the overuse sub scale for overuse of medicines by physicians and the Harm-Benefit or General-Harm sub scale for assessing beliefs about harmful effects caused by medicines. The scores for each item in a sub

scale were summed to give a total score which ranged from 5 to 25 for specific necessity and specific concern, 4 to 20 for general harm and general overuse sub scales. The higher scores indicated stronger beliefs in the specific category represented by the scale.

**Pediatric Epilepsy Self- Management Questionnaire: PESMQ**

In this questionnaire there were a core set of items that included the assessment of communication with healthcare providers, barriers and facilitators of treatment adherence, beliefs about medications, expectations regarding treatment, and comfort with the treatment regimen. Likert scale was used on the questionnaire: “Strongly disagree” to “Strongly agree” or “never” to “always” score ranging from 1-5. PESMQ is a 27 item questionnaire consisting of four scales.

These four scales make up a total Self-Management score. Finally, the total Self-Management scale is a compilation of the 4 core scales. All scores are

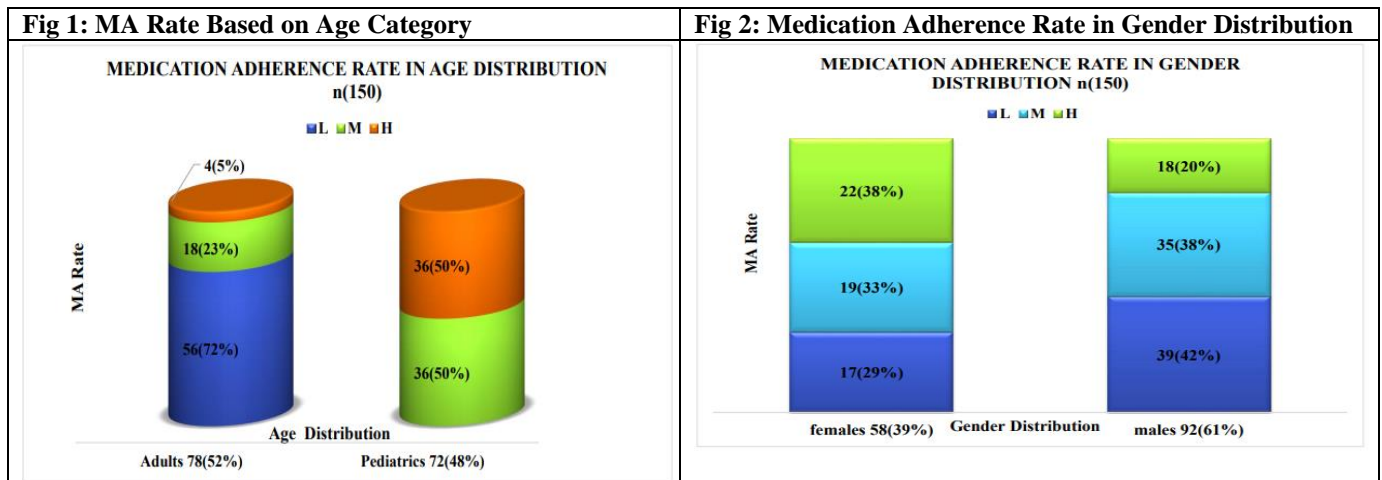
based on raw values, which are added together to make up the score for a particular scale. Items on the Barriers to Medication Adherence scale are reverse scored for consistency. Scores range from 8–40 for the Epilepsy and Treatment Knowledge and Expectations, Adherence to Medications and Clinic Appointments, and Barriers to Medication Adherence scales. Scores ranged from 3–15 for the Beliefs about Medication Efficacy and 27 – 135 for the total Self-Management Scale. Higher scores represent better self- management.

**RESULTS**

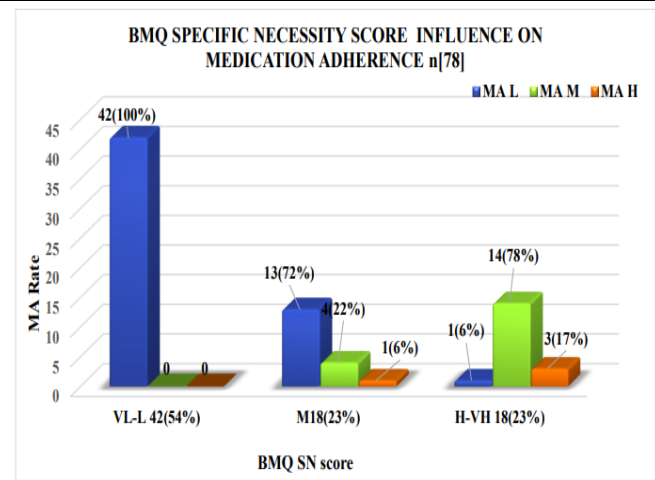
The table 1 shows that in age 52% were adults and 48% were pediatrics and on gender distribution 39% were females and 61% were males. By seizure onset 87% are generalized and 13% were focal. 45% subjects had co morbidities and 55% alone epilepsy. 47% subjects were in mono therapy, 46% in dual therapy and 7% in multi therapy.

**Table 1: Characteristic Distribution in Subjects**

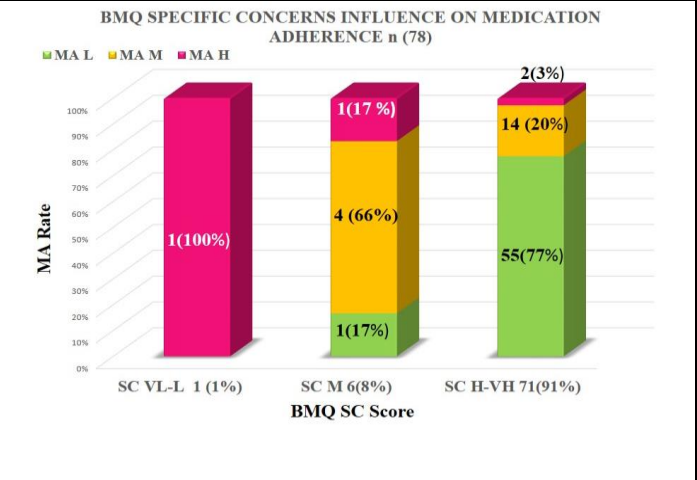
CHARACTERISTICS	LOW MA	MODERATE MA	HIGH MA
<b>AGE</b>			
Adults[78]	56	18	4
Pediatrics[72]	0	36	36
<b>GENDER</b>			
F[58]	17	19	22
M[92]	39	35	18
<b>SEIZURE ONSET</b>			
Generalized[131]	52	49	30
Focal[19]	4	4	11
<b>COMORBIDITIES</b>			
Present[68]	29	21	18
Nil[82]	27	32	23
<b>AED'S THERAPY</b>			
Mono[71]	19	24	28
Dual[69]	32	26	11
Multi[10]	5	2	3



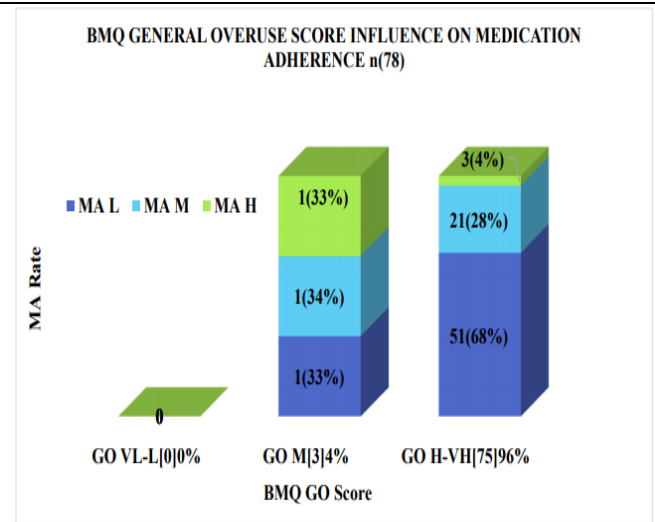
**Fig 3: BMQ Specific Necessity Score Influence On Medication Adherence**



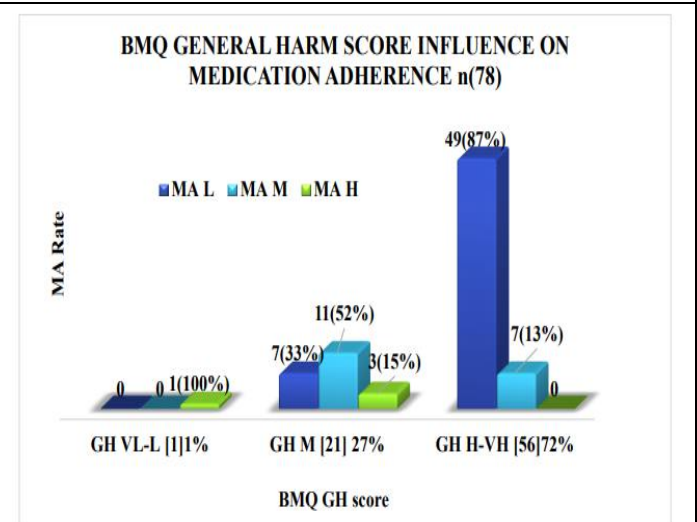
**Fig 4: BMQ Specific Concerns Influence On Medication Adherence**



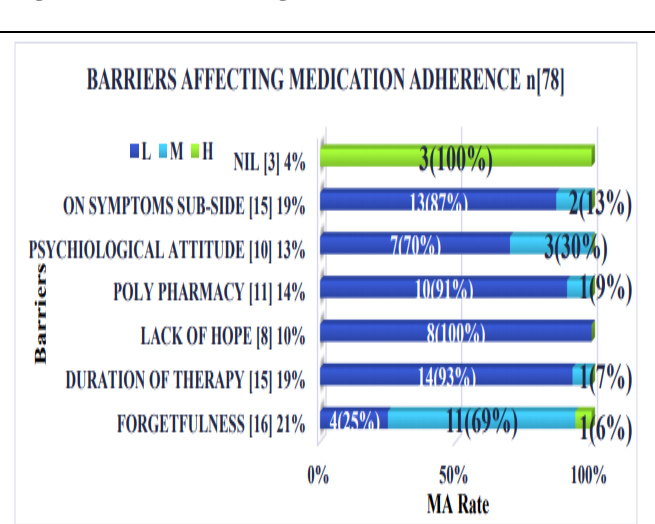
**Fig 5: BMQ General Overuse Score Influence On Medication Adherence**



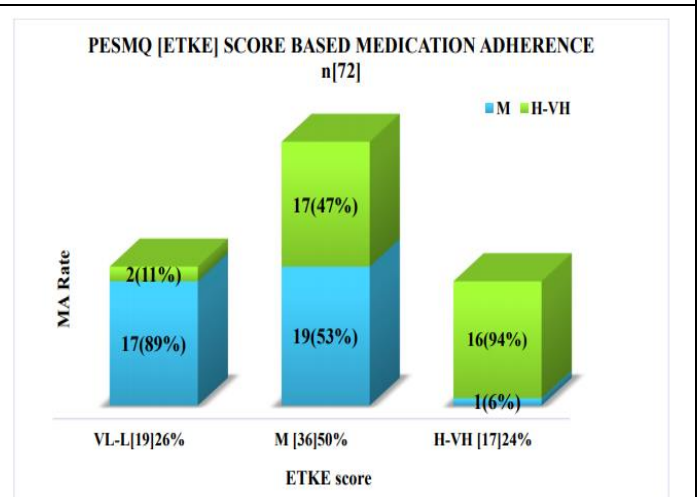
**Fig 6: BMQ General Harm Score Based Medication Adherence**

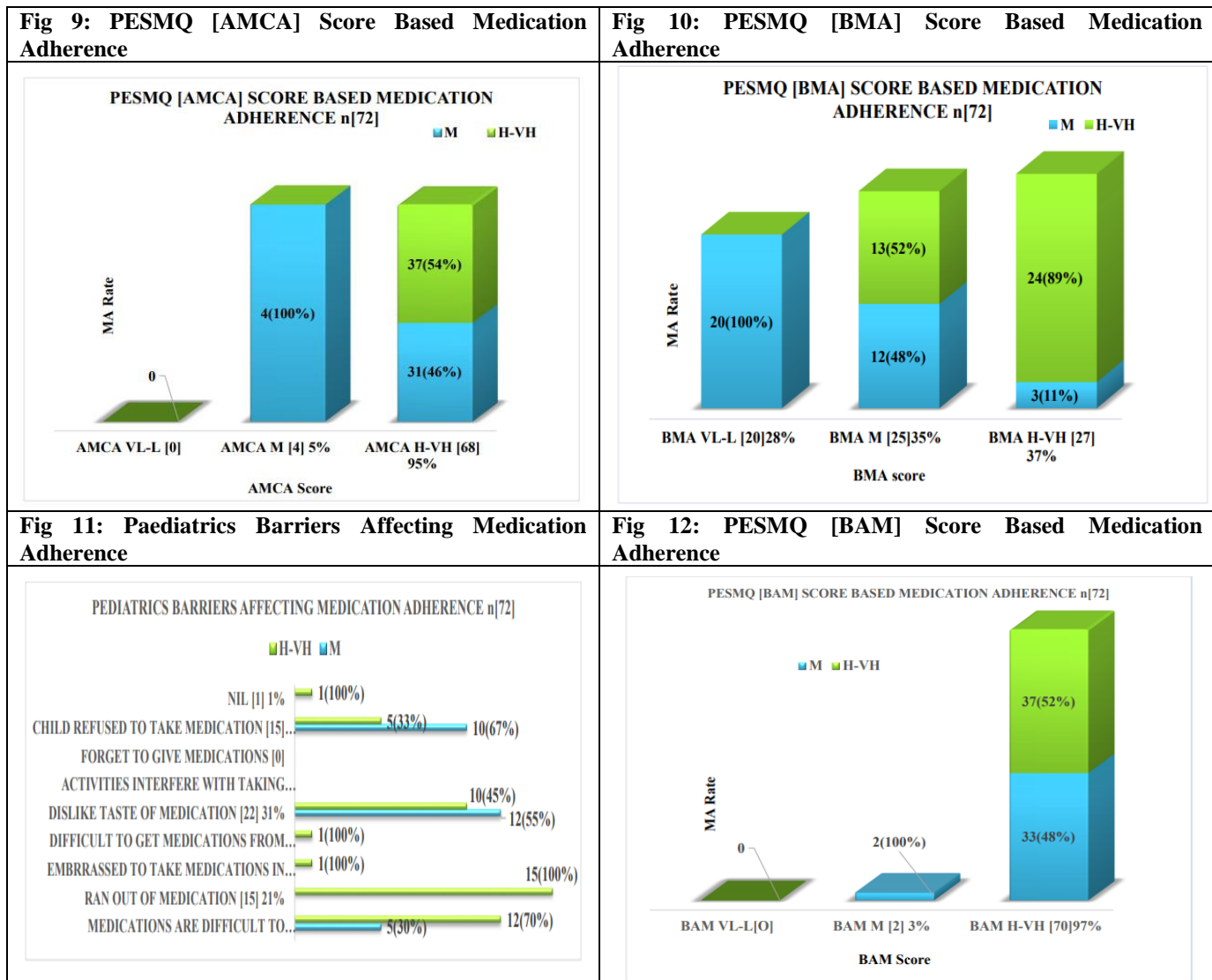


**Fig 7: Barriers Affecting Medication Adherence**



**Fig 8: PESMQ [ETKE] Score Based Medication Adherence**





The above fig 1: shows that out of 78 adults, MA was found to be low in 56(72%) subjects and in pediatrics out of 72 pts, none of the patients had low adherence. The above fig 2: shows that MA was greater in females i.e. 22(38%) when compared to males 18(20%). The above fig 3: shows that 42 (54%) sub. had a low score in SN showed 100% low MA rate, whereas with moderate and high score were 18 (23%) sub. in each contributing to low MA rate were 13(72%) and 1(6%) respectively. The above fig 4: shows that 71 (91%) sub. had a high score in SC showed 77% of high MA rate, whereas only 1 (1%) sub. with low score showed high MA rate and 6(8%) sub. scored moderately had poor and high MA rate of 1(17%) in each. The above fig 5: shows that 75(96%) were having high score in GO with 51(68%) low adherence, where 0% low score and in 3(4%) sub. with moderate score were 1(33%) in low, moderate and in high MA respectively. The above fig 6: shows that sub. with VL-L score in GH were 1(1%) had high adherence, where 21(27%) sub. with moderate

score were 7(33%) low, 11(52%) moderate and 15(3) in high MA and 56(72%) who had H-VH score were 49(87%) low, 7 (13%) moderate.

The above fig 7: shows that barriers to MA observed in subjects were 21% forgetfulness, 19% each on duration of therapy and on symptoms subside, 10% lack of hope on medications, 14% too many medications, 13% psychological attitude, and 4% were not affected by these factors. The barriers that contributed to highest poor adherence rate were seen in lack of hope, duration of therapy and on symptoms sub-side. The above fig 8: shows that 17(24%) sub. with high ETKE score having 16(94%) of H-VH MA rate, 36(50%) sub. with moderate score showed 17(47%) high adherence rate and 19(26%) with low score were having high MA rate of 11%. The above fig 9: represents that 4(5%) moderate AMCA score subjects were with predominantly moderate MA rate and 68(95%) with H-VH score having 54% high MA. The above fig 10: represents that 20(28%) sub. with low BMA

score were having 100% moderate MA rate, 25(35%) were with moderate score had 13(52%) high MA rate and 27(37%) sub. with high BMA score had 89% of high MA rate. The above fig 11: represents barriers affecting children were 31% taste dislike, 24% medications are difficult to swallow and 1% embarrassed to take medications in front of others and barriers affecting CGs were 21% ran out of medications, and 1% didn't affected by any of these factors. The above fig 11: shows that 2(3%) sub. with moderate BAM score had moderate MA and 70(97%) sub. had higher BAM score were having 52% of high MA rate.

## DISCUSSION

Adherence to antiepileptic drugs is crucial in improving seizure control and overall treatment outcome in epileptic patients. However, maintaining good adherence to antiepileptic drugs remained the most important challenge in the globe, particularly in developing countries.<sup>[16]</sup>

Although poor adherence is considered to be one of the significant causes of non-responsiveness to AED therapy, this has not been studied extensively in India. Hence in this study, we assessed the extent of AED adherence, as well as the factors influencing AED adherence among patients with epilepsy (PWE).

Assessment of medication adherence and its contributing factors helps design programs for future intervention. Therefore, our study investigated the rate of non-adherence and its contributing factors among epileptic patients.<sup>[17, 18]</sup> MA, beliefs and barriers were assessed by using MMAS-8 and BMQ in adults, and PESMQ in pediatrics were used.

In this study, 150 subjects (sub) were analyzed regarding their MA and its factors influencing. Out of which 78(52%) sub were adults (54 male [M] Pt's, 24 female [F] Pt's) and 72(48%) sub were pediatrics (38 M Pt's, 34 F Pt's). By seizure onset 87% were generalized seizures and 13% were with focal seizures. 45% of sub had co morbidities and 55% alone with epilepsy. 47% sub. were in monotherapy, 46% in dual therapy and 7% in multi-therapy.

By assessing MA prevalence rate with respect to age, among adults 56 (72%) pt's out of 78 patients were Non-adherent (NA). None of the pediatric patients were in low adherence as their parents were generally involved in medication administration. This study clearly indicates that low medication adherence was found more in adults where 72% were NA. Considering gender, MA was found to be more in females i.e. 22(38%) when compared to males 18(20%). This states that females were more health conscious than males.

By this we came to a conclusion that the adherence rate variation in between gender and age groups were due to beliefs about medications, being depressed or anxious, poor medication self-administration management,

uncontrolled recent seizures, poor physician-patient relationship and perceived social support.

The other approach which successfully explained a great portion of medication non adherence among patients with epilepsy was behavioral factors, beliefs and barriers to MA. Several studies have successfully shown good correlation between beliefs about medicines and MA. Belief about medicines is important for one's life which determines the level of adherence.

Many individual factors affecting adherence in adults were studied by using BMQ and the results showed that sub. were having higher score in SC (i.e., 71 [91%] out of 78 sub.) than in SN( i.e.,18[23%] out of 78). Considering SN and SC majority of sub. had high score in SC i.e. negative beliefs which contributed for poor adherence.

In GO, GH scales; high score in this category shows belief towards medications regarding over usage and side effects/harmful effects. Considering GO, 96% (75 out of 78 sub.,) showed strong belief towards physicians over usage of medicines. Considering GH, 56(72%) sub. scored high, indicating negative beliefs. Those subjects who scored high in both GO and GH had predominantly low medication adherence.

Other barriers most commonly affecting MA were forgetfulness, too many medications, duration of therapy, lack of hope, psychological attitude and on symptoms sub-side many patients tends to cut-back medication without physician consultation mainly in epilepsy due to lack of knowledge about disease and medications importance to be in adherence.

The barriers to MA observed in our subjects were 21% forgetfulness, 19% duration of therapy, 10% lack of hope on medications, 14% too many medications, 13% psychological attitude, 19% on symptoms sub-side were having poor to moderate MA and 4% were not affected by these factors were in high MA. Though forgetfulness is leading barrier, in our subjects we observed that the factors that most contributed to low MA predominantly were lack of hope, duration of therapy, on symptoms sub-side and too many medications.

PESMQ was specific questionnaire specially designed to analyze knowledge [ETKE], adherence [AMCA], barriers [BMA], and believes [BAM] in pediatric patients and/or care givers (CG). The score in each category ultimately gives the final MA rate.

By analyzing with ETKE scale, 26% (19 sub. out of 72 sub) subject's care givers were having low knowledge regarding epilepsy and AED's were showed predominantly moderate MA. 50% (36 out of 72 sub.) those who had a good knowledge were having predominantly higher MA.

It shows that though majority scored low in knowledge were assessed to have moderate MA, by providing awareness regarding disease and knowledge

about medication importance it'll be easy to increase adherence effectively in pediatrics.

In AMCA scale was used to analyze adherence and also regular follow-ups of sub. 95% (68 out of 72) Sub/CG were with good -high rate with AMCA. Sub./CG with good follow- ups to checkup showed mod-high adherence and those with high rate to AMCA Sub./CG were had a high MA. This shows that in pediatrics care givers are taking more effort in attending regular follow-ups and administration of medicines.

The BMA scale assess the factors that affecting MA in Pt's which included with children as well as their care givers, only 28%(20) were scored low and 50%(36) showed high MA rate.

When pediatric barriers were individually analyzed, 30% sub. MA affected with dislike parameter, 24% complained swallowing difficulties, other barriers like child refusing to take medications, ran out of medications were 21% each, remaining barriers contribute to 2%, and 1% of subjects claimed that no barriers affecting their MA. Though barriers were complained in pediatrics when coming to MA, barriers seemed to be doesn't actually affects it, as in them parents/CG involved in medication administration, taste dislike and child refusing to take medication barriers didn't much affect the MA.

The BAM assess believes of sub. /CG the higher the score the higher the positive beliefs towards therapy. 3% subjects had moderate score had moderate MA and 97% had good-high score showed predominantly high MA. This clearly shows that the CG in pediatrics has positive beliefs regard usage of medications whereas in adults the results were contrast.

Hence MA is known to have a profound effect on the quality of life and increased awareness of the patient's beliefs about medicines is needed and that health care providers should encourage patients to express their views about medicines in order to stimulate concordance and

adherence to medication. Assessment of MA and its contributing factors will helpful in designing programs for future interventions to improve MA for AED's.

## CONCLUSION

Apart from diagnosing Epilepsy and planning drug regimen, adherence to AED's has been a major challenge to achieve seizure control globally. In this study we observed that subjects and care givers (in paediatrics) individual beliefs, psychological percepts, lack of knowledge regard disease and medications, duration of therapy, lack of hope on medications, forgetfulness are prominently affecting medication adherence. By this study we concluded that in order to overcome this problem and to increase adherence rate, implementing interventions that raise awareness among subjects as well as in care givers regarding knowledge about epilepsy and it's complications associated with non-adherence, significance of AED's in treating epilepsy and regular monitoring of medication adherence should be done.

## ABBREVIATIONS

AED's: Anti epileptic drugs

MMAS-8: Morisky Medication Adherence Scale-8

BMQ : Beliefs about Medicines Questionnaire

PESMQ: Pediatric Epilepsy Self-Management Questionnaire

MA: Medication adherence

SN: Specific necessity

SC: Specific concern

GH: General harm

GO: General overuse

ETKE: Epilepsy and treatment knowledge and expectations

AMCA: Adherence to medications and clinic appointments

BMA: Barriers to medication adherence

BAM: Beliefs about medication efficacy

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