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#### ABSTRACT

Background: Medication adherence is defined by the World Health Organization as "the degree to which the person's behavior corresponds with the agreed recommendations from a health care provider". Poor adherence is considered a critical barrier to treatment success and remains one of the leading challenges to professionals. healthcare Adherence to antiepileptic drugs may be improved by using a number of interventions such as patient counseling, recording of medication intake and seizures, and mail reminders to refill the prescription and attend clinic appointments.

**Objectives**: To evaluate the impact of counseling on patient caretaker's knowledge and adherence to paediatric anti-epileptic drug therapy

**Methodology:** A prospective interventional study was carried out for a period of six months in department of paediatrics in Basaveshwara Medical College Hospital & Research Centre, Chitradurga.

**Results:** Total 66 patients were enrolled for the study, among them 34 were female and 32 were male patients. Majority of the patients falls between the age group of 1-5 years. In the first visit majority of patients were low adherent, after follow up it has been improved to moderate adherence and compliance. The medication adherence of the patients was improved after providing structured counselling along with specially designed patient information leaflet.

**Conclusion:** This study concludes that pharmacist provided patient education found to have positive impact on caretaker's knowledge on epilepsy and use of antiepileptic drugs. This may lead to better compliance and empowers caretakers to provide better patient care.

*Key words:* Medication adherence, Antiepileptic drugs.

#### **INTRODUCTION**

Epilepsy is a chronic condition that requires long-term management. Adherence to medication is essential for control of the symptoms and in preventing seizures. Pharmacists play a key role in the care of epileptic patients by educating patients on condition, appropriate their use of medication and the importance of compliance.<sup>[1]</sup>

Medication adherence is defined by the World Health Organization as "the degree to which the person's behavior corresponds with the agreed recommendations from a health care provider." <sup>[2]</sup>

About one in four patients do not adhere well to prescribed drug therapy. Following principles of evidence based medicine, clinicians use the most relevant and available evidence to guide decisions on drug therapy. Once the prescription is written, however, the fate of drug therapy is with the patient. Poor adherence is considered a critical barrier to treatment success and remains one of the leading challenges to healthcare professionals.<sup>[3]</sup>

Seventy percent of children will become seizure free with appropriate antiepileptic treatment. There are multiple reasons why patients have inadequate

seizure control and amongst others these include the lack of efficacy of medication for that particular type of epilepsy or even misdiagnosis.<sup>[4]</sup>

Non-adherent patients are more likely to frequently experience seizures which increases the overall cost of health care imposing a financial burden on the caregivers who meet the treatment costs. These patients are frequently hospitalized with prolonged lengths of stay and more emergency department visits. They are also likely to miss school or work because of the seizure effects or out of fear of seizure occurrence. Adherence to antiepileptic drugs may be improved by using a number of interventions such as patient counseling, use of a special medication container, selfrecording of medication intake and seizures, and mailed reminders to collect prescription refills and attend clinic appointments.<sup>[5]</sup> The major focus of this study is to improve the knowledge of patient caretakers and to assess the medication adherence of Paediatric patients over antiepileptic drug therapy.

#### MATERIALS AND METHODS

**Study design :** A prospective interventional study.

**Study site** : The study was conducted in Department of Paediatric in Basaveshwara Medical College & Hospital, Chitradurga.

**Study period :** The study was conducted over a period of six months from November 2017 to April 2018.

**Study subjects:** Patients who met the following criteria were enrolled.

#### Inclusion criteria:

- Patients who are admitted in paediatric department.
- Paediatrics treated with antiepileptic drugs.

#### **Exclusion criteria:**

• Subjects who are having febrile Convulsion

#### **Ethical approval:**

The study was approved by the Institutional Ethical Committee of Basaveshwara

Medical College Hospital & Research Centre, Chitradurga.

#### Sources of data:

- Medical records of in-patients
- Interview with patients and/or care takers.

#### Study procedure:

- Demographics and medical history is collected from the interview with the patient caretaker and case or profile forms.
- Patients who satisfy the above study criteria will be included in the study. A prospective interventional study will be carried out in all the patients satisfying the inclusion criteria.
- A suitably designed data collection form will be prepared to collect the details of the patient from interview and case profile form.
- After obtaining informed assent, a selfdesigned questionnaire is given to the patient care taker before the counseling section along with Morisky Medication Adherence Scale 4 and the same questions are asked after 2 weeks through telephonic conversation and their responses are collected.

#### Statistical analysis:

- The data were entered in Microsoft excel and data were analyzed by SPSS software version 19.
- Categorical data were presented as frequency, percentage and quantitative data were analyzed by central tendency distribution.
- Student t test was used to compare the means of two variables.

#### RESULTS

#### **Details of subjects enrolled in the study:**

Total no of 74 subjects were enrolled in the study for  $1^{st}$  visit, out of which only 66 subjects were present in the  $2^{nd}$  visit. Hence we have selected the data of 66 subjects for further study analysis and remaining 8 subjects were excluded from the study.

Gender wise distribution of paediatric epileptic patients (n=66):

Out of 66 patients, 51.5% are females and 48.5% are males. The details are given in Table No.1

 Table No.1 Gender wise distribution of paediatric epileptic patients

Genders	Frequency	Percentage
Female	34	51.5
Male	32	48.5

Distribution of paediatric epileptic patients according to age groups

Out of 66 patients, maximum number of patients comes under 1-5 year and minimum number of patients comes under less than 1 year. The details are given in Table No.2

 Table No.2 Distribution of paediatric epileptic patients

 according to age groups

Age-groups in years	Frequency	Percentage
Less than 1-year	3	4.6
1-5 year	37	56
6-10 year	24	36.4
More than 10 years	2	3

## Distribution according to the education of the care taker

Out of 66 patient caretakers, 15.1% are graduates and 84.9% are non- graduates. The details are given in Table No.3

Table No.3 Distribution according to the education of the care taker

Education level	Frequency	Percentage
Non graduates	56	84.9
Graduate	10	15.1

## Distribution according to the occupation of the care taker

Out of 66 patients 62.1% are working and 37.9% are not working. The details are given in Table No.4

Table No.4 Distribution according to the occupation of the care taker

Occupations	Frequency	Percentage
Working	41	62.1
Not working	25	37.9

## Distribution according to the type of seizure diagnosis

Out of 66 patients, 42.6% were diagnosed as Generalised tonic clonic seizure, 18.1% patients were treated for simple seizure and followed by Status epilepticus 15.1%, Complex partial seizure 10.7% and Focal seizure 7.5%. Details are graphically represented in Figure No.1

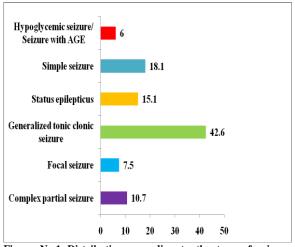


Figure No.1 Distribution according to the type of seizure diagnosis

#### Assessing the medication adherence by Morisky Medication Adherence- 4

Out of 66 patients, on first visit 30 have low adherence, 36 have medium adherence and none of the patient have high adherence. In  $2^{nd}$  visit, only 3 have low adherence, 39 have medium adherence and 24 have high adherence. The details are graphically represented in Figure No.2

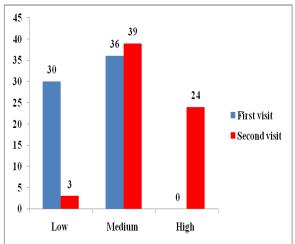


Figure No.2 Medication adherence by Morisky Medication Adherence-4

## Assessing the knowledge of patient caretaker

### **Response to question-1: Is Epilepsy a curable disease?**

In first visit out of 66 patients, only 5 patients answered correctly for the question "Is epilepsy a curable disease?" After giving

proper counseling and intervention the number has been increased (45).

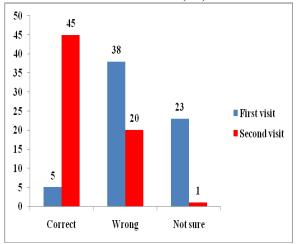


Figure No.3 Response to question-1: Is Epilepsy a curable disease?

### **Response to question-2: Is Epilepsy a type of the seizure?**

In first visit, among 66 caretakers 23 were responded correctly for the question "Is Epilepsy a type of the seizure?" After giving proper counselling the number has been increased to 62.

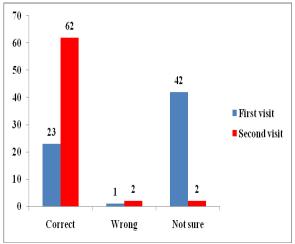


Figure No.4 Response to question-2: Is Epilepsy a type of the seizure

#### Response to question-5: Seizure comes when your child misses taking seizure medication.

Out of 66 patients, 52 had seizure when they miss taking seizure medication.

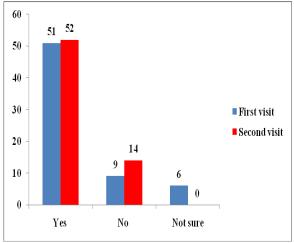


Figure No.5 Response to question-5: Seizure comes when your child misses taking seizure medication

#### Response to question-6: You can bring the child to see other doctors but you must inform them your child is on seizure medication(s).

On first visit out of 66 patients, 47 answered correctly for the question "You can bring the child to see other doctors but you must inform them your child is on seizure medication(s)" and by second visit 55 answered correctly

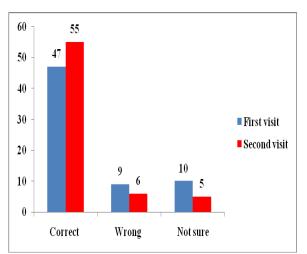
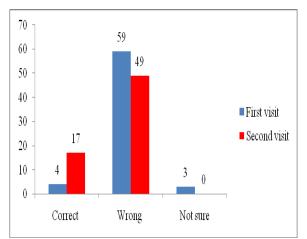


Figure No.6 Response to question-6: You can bring the child to see other doctors but you must inform them your child is on seizure medication(s).

# Response to question-7: If your child missed a dose(s) of the medication(s), you should ignore the missed dose and double the next dose.

Out of 66 patients, in first visit 4 patients responded correctly for the question "If your child missed a dose(s) of the medication(s), you should ignore the missed dose and

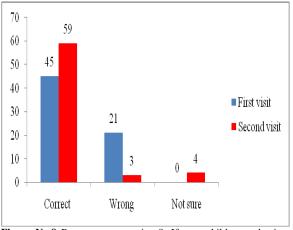
double the next dose" and in second visit 17 answered correctly



**Figure No.7** Response to question-7: If your child missed a dose(s) of the medication(s), you should ignore the missed dose and double the next dose

#### Response to question-8: If your child stops having seizures while taking the seizure medication(s), will you stop the medication(s).

After giving proper intervention about the medication the patient's knowledge about the medication has improved and it shows a positive impact on adherence of medication. On first visit 45 showed positive responses, by on second visit 59 were responded positively.

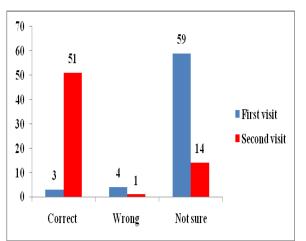


**Figure No.8** Response to question-8: If your child stops having seizures while taking the seizure medication(s), will you stop the medication(s).

Response to question-9: If your child is having a convulsive seizure (whole body is stiff and jerking uncontrollably) turn the child's body to recovery position

### (body, lying on the side, head tilted upward).

Among 66 patients, most of the patients were unaware about the seizure first aid and after giving proper counseling 51 patients improved their knowledge



**Figure No.9** Response to question-9: If your child is having a convulsive seizure (whole body is stiff and jerking uncontrollably) turn the child's body to recovery position (body, lying on the side, head tilted upward).

Response to question-10: When your child is having seizure Put a spoon or finger into the child's mouth to prevent him or her from biting his/her own tongue.

To the below mentioned question, 8 patients showed positive response on first visit. On second visit out of 66, 42 were showed positive response

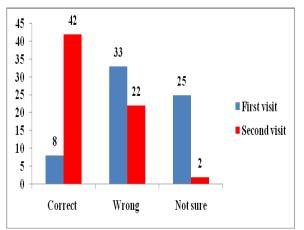


Figure No.10 Response to question-10: When your child is having seizure Put a spoon or finger into the child's mouth to prevent him or her from biting his/her own tongue.

## Response to question-11: After the seizure let your child sleep for at least 1 hour.

Out of 66 caretakers, 56 were positively answered on first visit for the question "After the seizure let your child sleep for at least 1 hour." On second visit out of 66 caretakers, 63 answered correctly.

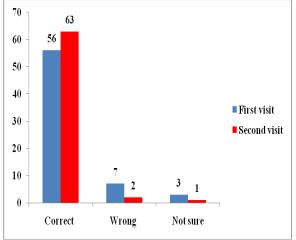


Figure No.11 Response to question-11: After the seizure let your child sleep for at least 1 hour.

# Response to question-12: Whether you should bring your child to seek medical attention immediately after occurrence of seizure?

Out of 66 caretakers, 55 were responded positively to the question "Whether you should bring your child to seek medical attention immediately after occurrence of seizure?" and in second visit it increased to 64 caretakers.

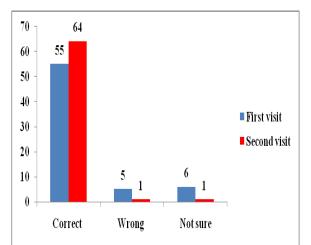


Figure No.12 Response to question-12: Whether you should bring your child to seek medical attention immediately after occurrence of seizure?

## **Response to question-13: Children with seizure may swim alone.**

Out of 66 caretakers, 23 were showed positive response on first visit. On second visit 52 showed positive responses.

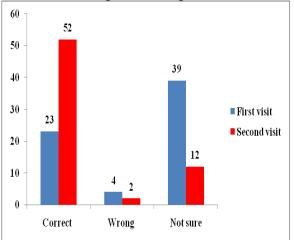


Figure No.13 Response to question-13: Children with seizure may swim alone.

## Assessing the effectiveness of antiepileptic therapy

## Response to question-14: Does the symptom get reduced after taking medication?

On first visit, for 44 patients the symptoms get reduced after taking medication. On second visit it has been increased to 66.

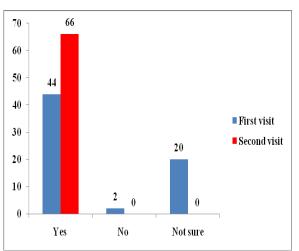


Figure No.14 Response to question-14: Does the symptom get reduced after taking medication?

## **Response to question-15: Whether your child shows any seizure symptoms during the treatment?**

Out of 66 patients, on first visit 59 patients doesn't show any seizure symptoms during

### the treatment. In second visit it increased to 64.

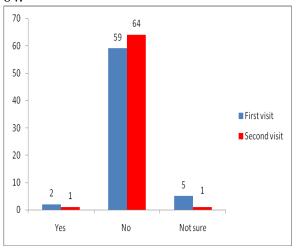
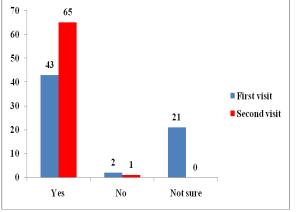
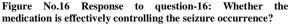


Figure No.15 Response to question-15: Whether your child shows any seizure symptoms during the treatment?

## **Response to question-16: Whether the medication is effectively controlling the seizure occurrence?**

On first visit 43 patients got control of seizure occurrence. On second visit the number has been increased by 65.





#### **Overall statistics (paired-t-test statistics)**

From the table below it is very well clear that by the II visit, the knowledge of the patients caretaker has improved and it is proved by paired t test with P value <0.001 at 95% confidence interval.

 Table No.5 Comparison of mean score (Comparison of the knowledge of patient caretakers)

Visit	Mean	SD	SEM	T -value	p-value
	score				
First visit	4.20	1.33	0.16	15.93	0.001 (sig)
Second visit	8.44	1.74	0.21		_
t = 15.93					

P- value: The two-tailed P value is less than 0.001 at 95% confidence interval by conventional criteria; this difference is considered to be extremely statistically significant.

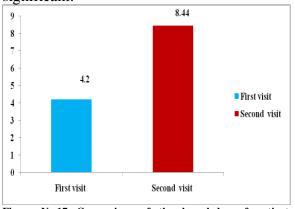


Figure No.17 Comparison of the knowledge of patient caretakers

#### DISCUSSION

Epilepsy is a disorder of the brain characterized by an enduring predisposition to generate epileptic seizures and by the neurobiological, cognitive, psychological, and social consequences of this condition. It is one of the commonest chronic neurological disorders affecting all people worldwide with no geographical or social boundaries.<sup>[5]</sup>

Adherence to therapies is a primary determinant of treatment Success. <sup>[2]</sup> Medication adherence is defined as the extent to which a patient medication taking behavior coincides with the intension of health advice he/ she has been given. It is one of the most important factors to determine the therapeutic outcome.

In this study 66 patients were enrolled, out of them 34 were female and 32 were male and majority of patients were in age group of 1-5 years. The current study reports that females were more prone to epilepsy than males. A similar report was found with the study Bhojan C *et al.*, which reported that females are slightly more likely to develop epilepsy than males. Age categorization of the current study was similar to a study conducted by Rasheed N *et al.*, which reported that seizures and epilepsy affect children and infants more than any other age group.

When we analyzed the educational status of the care taker, 42(63.6%) were educated up to SSLC and remaining 24 (36.4%) were educated PUC and above, which showed a similarity to the study conducted by Baldoni AO et al., where 70.2 % completed elementary school and 13.4 % completed their higher secondary and above.

In this present study the knowledge of patient caretakers regarding epilepsy and the effectiveness of therapy were assessed by 16 self-designed questionnaires which is collected from 66 caregivers and it shows positive response. Similar study was conducted by Chen C et al on The impact of pharmacist's counseling on pediatric patients caregiver's knowledge on epilepsy and its treatment in a tertiary hospital and concluded that Twenty-seven completed questionnaire sets (A, B and C) were collected from 55 caregivers who received the intervention (response rate = 49 %) between September 2010 and May 2011. Average post-counseling knowledge score was significantly higher than pre-counseling scores.<sup>[1]</sup>

In the present study the medication adherence was assessed and performed by modified morisky 4 item Medication adherence scale. Similar study was conducted by Gabr WM et al., on Adherence to medication among outpatient adolescents with epilepsy and results shows that assessment of medication adherence by Morisky medication adherence scale and found that there is significant improvement in the medication adherence of patient. This clearly showed that there was a good improvement in medication adherence behavior of diseased patients from low to high by patient counselling with the use of PILs.

#### CONCLUSION

With the results obtained, the following conclusions are made:

The female patients were more prone than male patients. Majority of patients were seen in the age group of 1-5 years. In the first visit majority of patients were low adherent, after follow up it has been improved to moderate adherence and compliance. The improvement in medication adherence has been observed descriptively and statistically. This study concludes that pharmacist provided patient education found to have positive impact on caregiver's knowledge on epilepsy and use of antiepileptic drugs. This may lead to better compliance and empowers caregivers in the care of the child.

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