ORIGINAL RESEARCH PAPER

Pharmacy

KEY WORDS:

# IMPACT OF PHARMACIST COUNSELLING IN PATIENTS WITH EPILEPSY – AN OBSERVATIONAL STUDY

**Dr. N. Senthil Kumar** Principal, JKKMMRF'S – Annai JKK Sampoorani Ammal College of Pharmacy- Erode, Namakkal District, Tamilnadu, India.

**D. Krishnarajan** Associate professor, Department of pharmacy practice, JKKMMRF'S – Annai JKK Sampoorani Ammal College of Pharmacy- Erode, Namakkal District, Tamilnadu, India.

**Rahiyanath.M .R*** Sixth year Doctor of Pharmacy, Department of pharmacy practice, JKKMMRF'S – Annai JKK Sampoorani Ammal College of Pharmacy - Erode, Namakkal District, Tamilnadu, India. *Corresponding Author

**Shemi Mol. S** Sixth year Doctor of Pharmacy, Department of pharmacy practice, JKKMMRF'S – Annai JKK Sampoorani Ammal College of Pharmacy - Erode, Namakkal District, Tamilnadu, India.

ABSTRACT

**OBJECTIVES:** To determine the effect of structural education program by a pharmacist in epilepsy patient.
**METHODS:** The prospective observational study include both inpatients and outpatients who all are taking antiepileptic drug (AEDs), followed for two months after counselling. The knowledge attitude and practice were analyzed using epilepsy self-management scale (ESMS).
**RESULT:** A convenient sample of 100 patients was studied on the basis of epilepsy self- management scale. The mean medication management score from pre counselling to post counselling shows an improvement of 17.1±5.5.The mean information management score from pre counselling to post counselling shows an improvement of 13.3±4.4. The mean safety management score from pre counselling to post counselling shows an improvement of 15.8±5.4. The mean seizure management score from pre counselling to post counselling shows an improvement of 10.5±4.2.The mean life style management score from pre counselling to post counselling which shows an improvement of 11.1±3.5. Total impact of counselling (5 sub scales) was found by calculating total mean score. 81.4±11.8 was the pre counselling score and post counselling score was 149.1±8.9. Which shows an improvement of 67.7±13.8. The total improvements of medication, information, safety, seizure, life style management in pre and post counselling were statistically very highly significant (P<0.001).
**CONCLUSION:** There was a significant improvement in the epilepsy self-management score of each patients post follow up. Therefore, it is highly recommended that pharmacists counselling have a key role in the education of patients with epilepsy.

## INTRODUCTION:

Epilepsy implies a periodic recurrence of seizures with or without convulsions. A seizure results from an excessive discharge of cortical neurons and characterized by changes in electrical activity. A convulsion implies violent involuntary contraction of the voluntary muscles.[1] About 50 million peoples around the world is affected by epilepsy. More than 85% are living in developing world.[2]

The management of epilepsy demands long term use of antiepileptic drugs (AEDs). The primary requirements are complete diagnosis, selection of suitable treatment and counselling appropriate to individual needs. [3] The epilepsy treatment is complex and may need use of antiepileptic drugs, a ketogenic diet and vagus nerve stimulation.[4] Treatment with antiepileptic drug are the primary choice.[5] Either monotherapy or polytherapy is used for treat chronic form of disease. [6, 7] The polytherapy with antiepileptic drugs may cause undesirable adverse drug interactions (ADRs) and drug interactions (DIs).[8]

Antiepileptic drug effectively control illness in majority of patients. [9] Yet more than 30% of patients do not reach complete seizure control. [10] The treatment failure is happening because of poor adherence to the AED therapy.[11] The medication adherence helps to prevent seizure occurrence. Factors that affect medication adherence are complex and multifactorial, are level of social support, family history, drug regimen and patient belief about the treatment effectiveness. [12] The medication adherence can be improved by proper counselling.

A significant number of patients stopped taking epilepsy treatment within one year in India due to poor knowledge in relation to the outcome after discontinuation.[13]

In this ambience, the pharmacist can plays an important role in monitoring patients with epilepsy and provide counselling regarding the medication, seizure, life style management.[14,15] Considering the intricacy of treating epilepsy and lack of knowledge of patients, this study aimed to educate the patients regarding the seizure management, medication management, life style management, safety management and information management and determine the impact of pharmacist counselling in this patients.

## ETHICAL CLEARANCE:

The ethical clearance for the study was obtained from the local institutional ethical committee.

## MATERIALS & METHODS:

The study was conducted in both inpatients and outpatients to provide counselling and assess the impact of pharmacist counselling in epilepsy patients using ESMS. Study design consist of questionnaires. Demographic data was obtained from all patients prior to initiation of therapy. ESMS consist of Medication management, Lifestyle management, Safety management, Seizure management, Information management. All patients were given a brief introduction regarding the study and the confidentiality of data.

Socio-demographic data were collected from the patient. Data about the history of illness and treatment were obtained from the medical records and seizure diary which is kept by the patient.

Prospective data including current medication, seizure frequency, compliance, age of onset of seizure, duration of seizure were collected at the time of interview. All data were entered in a pre-designed data collection form. The knowledge attitude and practice of patients are analyzed according EPILEPSY SELF

MANAGEMENT SCALE (ESMS) and counselling was given about the medication management, seizure management, safety management, information management and lifestyle management. An informed consent was obtained from all the patients. The improvements are recorded at the second visit.

**RESULTS:**

The epilepsy subjects were described according to their demographic profiles such as age, gender, educational status, precipitating factors, social histories, injuries during seizures, number of medications, number of dietary therapies, age at onset, last one year incidents, last six month incidents, primary care given during initial epilepsy occurrence, seizure duration, medications used and drug at registration.

**1. GENDER WISE DISTRIBUTION**

**Table 1: Gender wise distribution of epilepsy subjects (N=100)**

| Serial No | Gender | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | Male | 56 | 56.0 |
| 2 | Female | 44 | 44.0 |
| **Total** | | **100** | **100.0** |

Table 1 shows that majority of the study population were male which is 56 patients (56%) and 44 patients (44%) female.

**2. AGE WISE DISTRIBUTION**

**Table 2: Age wise distribution (N=100)**

| Sl No | Age group (years) | Frequency | Percentage (%) | Mean ±SD |
|---|---|---|---|---|
| 1 | 15-25 | 17 | 17.0 | 41.3±14.8 (Range= 65-16= 49 years) |
| 2 | 26-35 | 18 | 18.0 | |
| 3 | 36-45 | 21 | 21.0 | |
| 4 | 46-55 | 17 | 17.0 | |
| 5 | 56-65 | 27 | 27.0 | |
| **Total** | | **100** | **100.0** | |

Table 2 shows among the study population majority of the patients were from 56-65 years which is 27% of the population, followed by 36-45 years (21%), 26-35 years (18%) and the least were from the age groups of 15-25, 46-55 (17%). The mean age of them was 41.3±14.8 years with range of 15-65 years.

**3. EDUCATIONAL STATUS**

**Table 3: Educational status (N=100)**

| Serial No | Educational status | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | Illiterate | 23 | 23.0 |
| 2 | Primary | 22 | 22.0 |
| 3 | Secondary | 32 | 32.0 |
| 4 | Higher Secondary | 6 | 6.0 |
| 5 | Graduates | 17 | 17.0 |
| **Total** | | **100** | **100.0** |

Table 3 shows that most of the patients in the study population were secondary which is 32%of the study population followed by illiterate (23%), primary (22%), graduates (17%) and less number of population were Higher secondary (6%).

**4. SOCIAL HISTORY**

**Table 4: Social history of the epilepsy persons (N=100)**

| Serial No | Social history | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | No substance abused | 86 | 86.0 |
| 2 | Alcoholic | 9 | 9.0 |
| 3 | Alcoholic & Smoking | 4 | 4.0 |
| 4 | Smoking | 1 | 1.0 |
| **Total** | | **100** | **100.0** |

Table 4 shows among the total study population majority of the patients are no substance abused (86%), followed by alcoholic (9%), alcoholic and smoking (4%), smoking (1%).

**5. PRECIPITATING FACTORS**

**Table 5: Precipitating Factors (N=100)**

| Serial No | Precipitating Factors | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | Previous head injury | 24 | 24.0 |
| 2 | Stress | 11 | 11.0 |
| 3 | Chronic alcoholism | 5 | 5.0 |
| 4 | Brain tumor | 3 | 3.0 |
| 5 | Neurological problem | 2 | 2.0 |
| 6 | Pregnancy | 2 | 2.0 |
| 7 | Edema in the brain | 1 | 1.0 |
| 8 | Unknown | 52 | 52.0 |
| **Total** | | **100** | **100.0** |

Table 5 shows that the data's related to precipitating factor collected and recorded. Majority of the population (52%) were unaware of the precipitating factor. The highest reported precipitating factor was previous head injury (24%), followed by stress (11%), chronic alcoholism (5%), Brain tumor (3%), neurological problem, pregnancy (2%) and the least was edema in the brain (1%)

**6. AGE OF ONSET**

**Table 6: Age of onset (N=100)**

| Sl No | Age group (years) | Frequency | Percentage (%) | Mean ±SD |
|---|---|---|---|---|
| 1 | < 15 | 22 | 22.0 | 30.3±17.3 (Range= 65-05= 60 years) |
| 2 | 15 – 25 | 18 | 18.0 | |
| 3 | 26 – 35 | 20 | 20.0 | |
| 4 | 36 – 45 | 14 | 14.0 | |
| 5 | 46 – 55 | 15 | 15.0 | |
| 6 | 55 – 65 | 11 | 11.0 | |
| **Total** | | **100** | **100.0** | |

Table 6 shows that majority of the population (22%) age of onset of epilepsy was less than 15 years followed by 26 to 35 years (20%), 15 to 25 years (18%), 46 to 55 years (15%), 36 to 45 years (14%) and in the least population (11%) the onset was in 56 to 65 years.

**7. DURATION OF SEIZURE EPISODES**

**Table7: Duration of seizure episodes (N=100)**

| Sl No | Seizure duration (Minutes) | Frequency | Percentage (%) | Mean ±SD |
|---|---|---|---|---|
| 1 | < 5 | 14 | 14.0 | 6.7±2.8 (Range= 15-02=13 minutes) |
| 2 | 5 – 10 | 50 | 50.0 | |
| 3 | > 10 | 36 | 36.0 | |
| **Total** | | **100** | **100.0** | |

Table 7 shows that 50% of study population, seizure duration was 5-10 minutes followed by >10 minutes (36%) and 14% population had a duration of less than 5minutes.

**8. PRIMARY CARE TAKEN DURING SEIZURE EPISODE**

**Table 8: Primary care taken during seizure episode (N=100)**

| Serial No | Primary care initial at Episode | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | Send hospital immediately | 44 | 44.0 |
| 2 | Taking rest | 33 | 33.0 |
| 3 | Holding the key | 19 | 19.0 |
| 4 | Massaging Head, Limbs, Hand | 3 | 3.0 |
| 5 | Taking medication | 1 | 1.0 |
| **Total** | | **100** | **100.0** |

Table 8 shows majority of the patient were taken to the hospital (44%), followed by 33% population took rest, 19% were used the key, 3% were massaging head, limbs, hand, and 1% took medication.

**9. INJURIES DURING THE SEIZURE**

**Table 9: Injuries during seizures (N=100)**

| Serial No | Injuries during seizures | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | Tongue bite | 18 | 18.0 |
| 2 | Injury in the hand | 5 | 5.0 |
| 3 | Injury in the knee | 4 | 4.0 |

| | | | |
|---|---|---|---|
| 4 | Burn | 2 | 2.0 |
| 5 | Nil | 71 | 71.0 |
| **Total** | | **100** | **100.0** |

Table 9 shows that major population of study population didn't have any injuries during the seizure (71%). The major injury happen was tongue bite (18%) followed by injury in the hand (5%), injury in the knee (4%) and the least was burn (2%).

**10. SEIZURE EPISODES IN LAST 6 MONTHS (BEFORE BASE LINE)**

**Table 10: Seizure episodes in last 6 months (before base line) (N=100)**

| Sl No | Number of seizures | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | 1 Times | 9 | 9.0 |
| 2 | 2 Times | 5 | 5.0 |
| 3 | 3 Times | 9 | 9.0 |
| 4 | 4 Times | 3 | 3.0 |
| 5 | 5 Times | 3 | 3.0 |
| 6 | >5 Times | 1 | 1.0 |
| 7 | Nil | 70 | 70.0 |
| **Total** | | **100** | **100.0** |

Table 10 shows 70% of the population did not have any seizure episodes in past 6 months. Among 9% of the population had 2 episodes of seizure, 5% had 3 episodes of seizure, 9% had 4 episodes of seizure, episodes of seizure were 5 times and 6 times among 3% of study population and 1% population had episodes of seizure 7 times.

**11. HISTORY OF SEIZURE EPISODES IN LAST ONE YEAR (BEFORE BASE LINE) (N=100)**

**Table 11: History of seizure episodes in last one year (before base line) (N=100)**

| Serial No | Number of seizure | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | 1 Times | 2 | 2.0 |
| 2 | 2 Times | 12 | 12.0 |
| 3 | 3 Times | 9 | 9.0 |
| 4 | 4 Times | 15 | 15.0 |
| 5 | 5 Times | 5 | 5.0 |
| 6 | 6 Times | 4 | 4.0 |
| 7 | 7 Times | 23 | 23.0 |
| 8 | > 7 Times | 2 | 2.0 |
| 9 | Nil | 28 | 28.0 |
| Total | | 100 | 100.0 |

Table 11 shows the number of seizures during the last one year. The nil was 28%.The maximum was 7 times as 23%. The next to that was 4 times as 15%. 2 times as 12%, 3 times as 9%, 4 times as 15%, 5 times as 5%,6 times as 4%, 7 times as 23% and more than 7times as 2%.

**12. DISTRIBUTION OF MEDICATION**

**Table 12: Distribution of number of medications (N=100)**

| Serial No | Number of Medications | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | Mono therapy | 43 | 43. |
| 2 | Dual therapy | 49 | 49.0 |
| 3 | Triple therapy | 8 | 8.0 |
| **Total** | | **100** | **100.0** |

Table 12 shows that most of the prescription (49%) contains two AED's followed by one drug (43%) and least was more than two drugs (8%)

**13. DRUG THERAPY**

**Table 13: Distribution of drug among monotherapy (N=43)**

| Serial No | Drugs administered | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | Levetiracetam | 27 | 62.79 |
| 2 | Phenytoin | 11 | 25.58 |
| 3 | Carbamazepine | 1 | 2.32 |
| 4 | Divalproex sodium | 1 | 2.32 |
| 5 | Lamotrigine | 1 | 2.32 |
| 6 | Lorazepam | 1 | 2.32 |
| 7 | Gabapentin | 1 | 2.32 |
| **Total** | | **43** | **43** |

Table 13 shows that majority of the patients were on Levetiracetam (63.79%) followed by 25.58% (Phenytoin) and 2.32% population received Carbamazepine, Divalproex sodium, Lamotrigine, Lorazepam and Gabapentine.

**14. DISTRIBUTION OF DRUG AMONG DUAL THERAPY (N=49)**

**Table 14: Distribution of drug among dual therapy (N=49)**

| Sl no | Drug Name | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | Levetiracetam + Phenytoin | 28 | 57.14 |
| 2 | Levetiracetam + Sodium Valproate | 13 | 26.53 |
| 3 | Levetiracetam + Lamotrigine | 6 | 12.24 |
| 4 | Levetiracetam + Lorazepam | 1 | 2.04 |
| 5 | Phenytoin + Lorazepam | 1 | 2.04 |

Table 14 shows that majority of the patients were on Levetiracetam + Phenytoin (57.14%) followed by Levetiracetam + Sodium Valproate (26.53%) followed by Levetiracetam + Lamotrigine (12.24%) followed by Levetiracetam + Lorazepam (2.04%) followed by Phenytoin + Lorazepam (2.04%).

**15. DISTRIBUTION OF DRUG AMONG TRIPLE THERAPY (N= 8)**

**Table 15: Distribution of drug among triple therapy (N=8)**

| Sl no | Drug Name | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | Levitiracetam + Phenytoin + Lamotrigine | 4 | 50 |
| 2 | Levitiracetam + Phenytoin + Lorazepam | 2 | 25 |
| 3 | Levitiracetam + lamotrigine + Lorazepam | 2 | 25 |

Table 15 shows that majority of patients were on Levitiracetam + Phenytoin + Lamotrigine (50%) followed by Levitiracetam + Phenytoin + Lorazepam (25%) followed by Levitiracetam + lamotrigine + Lorazepam (25%).

**16. DETAILS OF DIETARY SUPPLEMENTS**

**Table 16: Details of dietary therapies (N=100)**

| Serial No | Dietary supplements | Frequency | Percentage (%) |
|---|---|---|---|
| 1 | Vitamins | 15 | 15 |
| 2 | Folic acid | 10 | 10 |
| 3 | Minerals | 7 | 7 |
| 4 | Not given | 68 | 68 |
| **Total** | | **100** | **100** |

Table 16 shows that dietary supplements were provided vitamins 15%, folic acid 10%, minerals 7% and 68% were not provided with dietary supplements.

**17. EFFECTIVENESS OF STRUCTURED EDUCATION PROGRAMME**

**Table 17: Effectiveness of structured education programme (N=100)**

| Management | Pre Counselling | | Post Counselling | | Improvements | | "t" | df | Sig |
|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | | | |
| Medication | 23.0 | 5.2 | 40.1 | 4.9 | 17.1 | 5.5 | 30.819 | 99 | P<0.001 |
| Information | 14.4 | 4.5 | 27.7 | 5.3 | 13.3 | 4.4 | 29.938 | 99 | P<0.001 |
| Safety | 16.8 | 4.2 | 32.6 | 3.3 | 15.8 | 5.4 | 29.297 | 99 | P<0.001 |
| Seizure | 15.1 | 4.4 | 25.6 | 2.2 | 10.5 | 4.2 | 24.807 | 99 | P<0.001 |
| Life Style | 12.1 | 2.9 | 23.2 | 2.7 | 11.1 | 3.5 | 31.800 | 99 | P<0.001 |
| Total | 81.4 | 11.8 | 149.1 | 8.9 | 67.7 | 13.8 | 49.129 | 99 | P<0.001 |

Table 17 shows the impact of counselling in epileptic patients. The mean medication management score of pre counselling was 23.0±5.2 and the post counselling mean medication value was

40.1± 4.9. Which shows an improvement of 17.1±5.5.
The mean information management score of pre counselling was 14.4±4.5 and the post counselling mean information management value was 27.7±5.3. Which shows an improvement of 13.3±4.4.

The mean safety management score of pre counselling was 16.8±4.2 and the post counselling mean safety management value was 32.6±3.3.which shows an improvement of 15.8±5.4.

The mean seizure management score of pre counselling was 15.1±4.2 and the post counselling mean seizure management value was 25.6±2.2. Which shows an improvement of 10.5±4.2.

The mean life style management score of pre counselling was 12.1±2.9 and post-test counselling mean life style value was 23.2±2.7. Which shows an improvement of 11.1±3.5.

Total impact of counselling (5 sub scales) was found by calculating total mean score. 81.4±11.8 was the pre counselling score and post counselling score was 149.1±8.9. Which shows an improvement of 67.7±13.8. The total improvements of medication, information, safety, seizure, life style management in pre and post counselling were statistically very highly significant (P<0.001).

A similar study conducted by Chen et. al,in Singapore among 55 caregivers also reported that post-counseling knowledge score was significantly higher than pre-counseling score (14.7 v/s 10.4).

Dash D et.al conducted a study to found out impact of health education on drug adherence and self-care in people with epilepsy with low education. This randomized controlled study conducted in 180 patients reported that in the epilepsy health education group, the pre-test mean score was 6.58 whereas the post-test mean score 7.53; the difference was significant. The mean scores for the control group's pre-test and post-test were 6.46 and 6.58 respectively, which were not significantly different.

## 7. CONCLUSION

Specialized counselling given by pharmacists to entire population results in a positive impact on patients knowledge on epilepsy and the use of AEDs. The improvements such as medication, information, safety, seizure, life style and total from pre counselling to post counselling were statistically very highly significant (P<0.001). It made the patients more adherent to AED therapy. This lead to better compliance and empowers in the care of patients.

There was a significant improvement in the epilepsy self-management score of each patients post follow up. Therefore, it is highly recommended that pharmacists counselling have a key role in the education of patients with epilepsy.

## REFERENCE:


1. Barbara G. Wells, Joseph T. Dipiro, Terry L. Schwinghammer, Cecily V. Dipiro, Pharmacotherapy handbook, 7th edition, Published by MC Graw hill, P;577
2. World Health Organization. Epilepsy in the WHO Eastern Mediterranean region: bridging the gap. http://www.emro.who.int/dsaf/dsa1039.pdf. 2010 Accessed: January 23, 2011
3. Smith D, Chadwick D. The management of epilepsy, Journal of Neurology, Neurosurgery & Psychiatry 2001; 70: ii15-ii21
4. Asconape JJ. The selection of antiepileptic drugs for the treatment of epilepsy in children and adults. Neurolclin. 2010 Nov; 28(4):843 52.doi:10.1016/j.ncl.2010.03.026
5. Chen AH. Update on pediatric epilepsy. AdvPediatr. 2011;58(1):259-276. Review.doi: 10.1016/j.yapd.2011.03.001
6. Abasolo-Osinaga E, Abecia-Inchaurregui LC, Etreandia-Ikobaltzeta I, Burgos-AlonsoN, Garcia-del PozoJ. A pharmacoepidemiological study of antiepileptic drug consumption (1992-2004). Rev Neurol. 2008;46(8):449-453.
7. Johannessen SI, Johannessen Landmark C. Antiepileptic drug interaction-principles and clinical implications. Curr Neuropharmacol.2010;8(3):254-267.
8. Thomas Sv, Koshy S, Nair CR, Sarma SP. Frequent seizures and polytherapy can impair quality of life in persons with epilepsy. Neurol India. 2005:53(1):46-50.
9. Shinnar S, Berg AT. Does antiepileptic drug therapy prevent the development of "chronic" epilepsy? Epilepsia 1996;37:701-8.
10. Devensky O. Patients with refractory seizures. N ENGL J Med 1999;340:1565-70.
11. Waleed M. Sweileh, Manal S. Ihbesheh, IkhlasS.Jarar, Adham S. Abu Taha, Ansam F. Swalha, Sa'ed H. Zyoud, Raniah M. Jamous, Donald E. Morisky. Aelf-reported medication adherence and treatment satisfaction in patients with epilepsy, Epilepsy &Behavior 21(2011):301-305
12. Dilorio C, Hennessy M, Manteuffel B. Epilepsy self-management: a test of a theoretical model. Nurs res 1996;45(4):211-217
13. Das K, Banerjee M, Mondal GP, Devi LG, Singh OP, Mukherjee BB. Evaluation of socio-economic factors causing discontinuation of epilepsy treatment resulting in seizure recurrence: a study in urban epilepsy clinic in India. Seizures 2007; 16(7):601-7
14. Ratanajamit C, Kaewpibal P, Setthawacharavanich S, Faroongsarng D. Effect of pharmacist participation in the health care team on therapeutic drug monitoring utilization for antiepileptic drugs, J Med Assoc Thai. 2009;92(11):1500-1507
15. McAuley JW, Casey J, Long L. An evaluation of pharmacist's knowledge of women's issues in epilepsy. Epilepsy Behav.2009;14(1):243-246. doi:10.1016/j.yebeb.2008.10.018.