

UNVEILING ADVERSE REACTIONS: A COMPREHENSIVE ASSESSMENT OF ANTI-EPILEPTIC DRUGS**¹Akshara K. R., ²Riya Varghese, ³Rex K. Roys and ⁴Dr. Elesy Abraham**^{1,2,3}Pharm D Intern, Department of Pharmacy Practice, Nazareth College of Pharmacy, Other P.O, Thiruvalla.⁴Principal, Nazareth College of Pharmacy, Other P.O, Thiruvalla.***Corresponding Author: Akshara K. R.**

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ABSTRACT

Epilepsy, a neurological condition affecting quality of life, is frequently not treated adequately despite its common occurrence. Those with epilepsy often face daily challenges. Detecting and treating epilepsy early can enable individuals to live symptom-free lives. A major issue with epilepsy management is the difficulty in identifying cases promptly and providing appropriate treatment. Another significant obstacle is patients' non-compliance with treatment. They may stop taking medication due to increased adverse effects or lack of perceived benefits from anti-epileptic drugs. Treatment for epilepsy can involve either using a single medication (monotherapy) or multiple medications (polytherapy). Monotherapy has traditionally been the preferred approach. However, many patients experience adverse effects when the drug dosage is increased or as the disease progresses, leading them to discontinue treatment altogether. Polytherapy has been advocated as a solution for managing epilepsy. It involves using multiple medications at the lowest effective doses to achieve the desired therapeutic effect. Our study, based on 563 patients, found that approximately half of them experienced some form of adverse drug reaction (ADR). Among the 282 patients who developed ADRs, 62% were on monotherapy, while the remaining 38% were on polytherapy. This indicates that monotherapy is more effective than polytherapy in reducing the incidence of adverse drug reactions.

KEYWORDS: Epilepsy, Seizure, Polytherapy, Monotherapy.**INTRODUCTION**

Epilepsy, a disorder of the central nervous system, disrupts normal brain activity, resulting in seizures or episodes of unusual behavior, sensations, or loss of awareness. This chronic condition affects around 50 million individuals globally and is not contagious. It is characterized by recurrent seizures, which can manifest as brief involuntary movements affecting specific body parts (partial seizures) or the entire body (generalized seizures), sometimes leading to loss of consciousness and control of bowel or bladder function. Seizure episodes stem from excessive electrical discharges in clusters of brain cells, which can occur in various brain regions. Seizures can range from momentary lapses of attention or muscle twitches to severe and prolonged convulsions, with frequencies varying from less than one per year to several per day.^[1]

Living with epilepsy presents numerous challenges that affect different aspects of daily life. Seizures can lead to accidents and injuries, while managing medication side effects poses additional difficulties. Moreover, individuals with epilepsy face an increased risk of depression and anxiety. Other consequences may involve

feeling self-conscious about experiencing seizures in public, losing the ability to drive, or becoming reliant on others for daily tasks.^[2]

Various medications, known as antiepileptics, are utilized for preventing and treating seizures, including status epilepticus and febrile seizures. Carbamazepine affects sodium channels and is used for partial seizures, with potential side effects such as gastrointestinal upset and rash. Clonazepam, a benzodiazepine, enhances GABA effectiveness, leading to sedation and mood changes. Gabapentin influences GABA transport and calcium channels, causing side effects like dizziness and fatigue. Lacosamide blocks sodium channels differently and can result in dizziness and memory issues. Lamotrigine, with mechanisms including glutamate release blocking, may cause dizziness and rash. Levetiracetam is frequently used due to its effectiveness and low cognitive issues but may lead to vertigo and irritability. Lorazepam, like clonazepam, is used for seizure clusters, while oxcarbazepine has fewer side effects but may lower blood sodium. Phenobarbital enhances GABA activity and can cause sedation and bone issues. Phenytoin modifies sodium channels and

may lead to unsteadiness and long-term cosmetic problems. Pregabalin, similar to gabapentin, is potent for seizures. Topiramate, a wide-spectrum AED, can cause cognitive problems and renal stones. Valproic acid is effective for generalized seizures but has numerous side effects including weight gain and birth defects. Vigabatrin blocks GABA metabolism and can cause vision loss. Zonisamide, akin to topiramate, has fewer cognitive issues but may cause glaucoma.^[3]

OBJECTIVES

To assess the adverse drug reactions of anti-epileptic drugs.

MATERIALS AND METHODS

Study design

Retrospective Descriptive Cross-Sectional Study.

Study Site

The study was conducted at Believers Church Medical College Hospital (BCMCH), Thiruvalla.

Study duration

6 months (December 2022 – May 2023)

Sample Size

Sample size of 563 patients.

Statistical formula for calculating sample size:

$$[Z^2 * p * (1-p)/e^2] / [1 + (Z^2 * p * (1-p)/e^2 * N)]$$

Where, P = Standard Deviation

N = Population Size

e = Margin of error

Z = 95% Confidence interval of Z

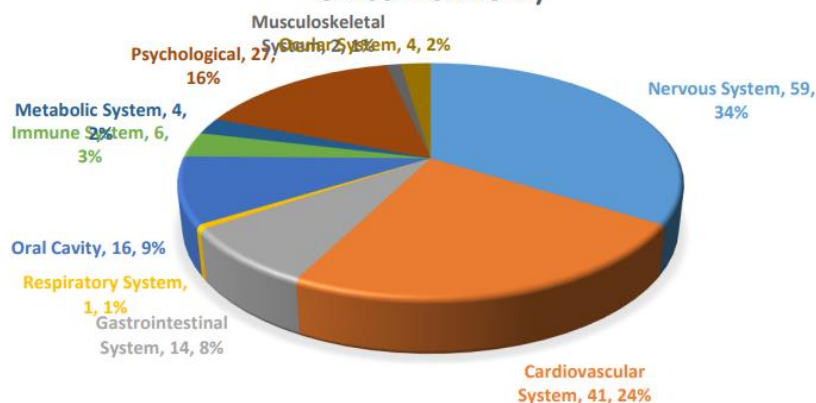
Study Approval

The study was approved by the Institutional Review Board of Believers Church Medical College Hospital, Thiruvalla.

RESULTS AND DISCUSSION

ADR Distribution in Monotherapy (System wise classification)

ADR DISTRIBUTION IN MONOTHERAPY (SYSTEM WISE CLASSIFICATION)



STUDY CRITERIA

The study will be carried out by considering the following criteria.

Inclusion criteria

- Patients diagnosed with epilepsy, taking anti epileptic drugs for at least one year.

Exclusion criteria

- Patients below 18 years, Pregnant population, Lactating women.

Source of Data

- Data were collected from medical records and Patient drug charts.
- Patient Data was obtained by follow up through Telemedicine department.

STUDY PROCEDURE

The proportion of adverse drug reactions were analyzed through a retrospective descriptive study conducted in epileptic patients in the medicine department. The medical records and patient drug chart were analyzed and telephone interviews were conducted for follow up data on further events. The medical records with incomplete information on drugs were excluded from data collection.

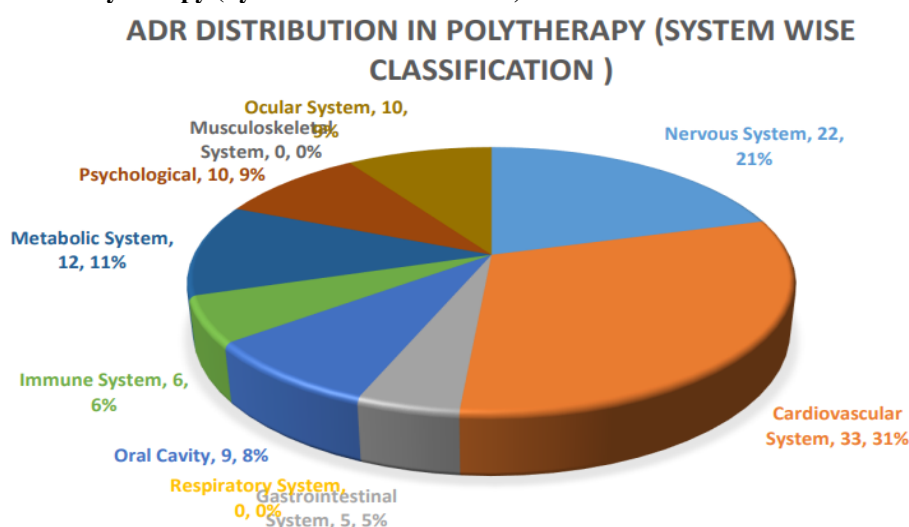
DATA ANALYSIS

The data was entered in Microsoft Excel – 2021. The results were analysed as tabular form and percentages (Descriptive Analysis).

The above chart represent the frequency distribution of ADR in monotherapy in a system wise manner. ADRs in the nervous system have the highest frequency count of 59, indicating that this system is the most commonly affected by ADRs. Common ADRs in the nervous system include headache, tremor, insomnia, and slurred speech. ADRs in the cardiovascular system have a frequency count of 41, which is lower than the nervous system but still significant. Common ADRs in the cardiovascular system include tachycardia, syncope, and bradycardia. ADRs in the gastrointestinal system have a frequency count of 14, indicating that this system is less commonly affected by ADRs than the nervous and cardiovascular systems. Common ADRs in the gastrointestinal system include constipation, nausea, and vomiting. ADRs in the respiratory system have a frequency count of 1, indicating that this system is the least commonly affected by ADRs. ADRs in the

respiratory system include dyspnea. ADRs in the oral cavity have a frequency count of 16. Common ADRs in the oral cavity include oral lesions and dry mouth. ADRs in the immune system have a frequency count of 6. Common ADRs in the immune system include allergies and rashes. ADRs in the metabolic system have a frequency count of 4. Common ADRs in the metabolic system include weight gain and weight loss. ADRs in the psychological system have a frequency count of 27. Common ADRs in the psychological system include depression, mood swings, and aggression. ADRs in the musculoskeletal system have a frequency count of 2. Common ADRs in the musculoskeletal system include muscle weakness and osteoporosis. ADRs in the ocular system have a frequency count of 4. Common ADRs in the ocular system include blurred vision, double vision, and flashes of light.

ADR Distribution in Polytherapy (System wise classification)



The nervous system has the highest frequency of ADRs.^[22] The most common ADRs in this system are likely to be related to the central nervous system, such as dizziness, headache, and drowsiness. The cardiovascular system has the second-highest frequency of ADRs.^[33] The most common ADRs in this system are likely to be related to changes in heart rate and blood pressure. The gastrointestinal system has the third-highest frequency of ADRs.^[5] The most common ADRs in this system are likely to be related to nausea, vomiting, and diarrhea. The oral cavity has a frequency of 9 ADRs. The most common ADRs in this system are likely to be related to dry mouth, oral ulcers, and taste alterations. The immune system has a frequency of 6 ADRs. The most common ADRs in this system are likely to be related to allergic reactions. The metabolic system has a frequency of 12 ADRs. The most common ADRs in this system are likely to be related to changes in blood sugar levels, weight gain, and weight loss. The psychological system has a frequency of 10 ADRs. The most common ADRs in this system are likely to be related to changes in mood, such as depression and anxiety. The ocular system has a

frequency of 10 ADRs. The most common ADRs in this system are likely to be related to changes in vision, such as blurred vision and dry eyes.

CONCLUSION

The study aimed to determine the prevalence of adverse drug reactions among patients undergoing treatment with antiepileptic drugs at a tertiary care hospital, comparing those on polytherapy versus monotherapy. Headache and syncope were the most commonly reported adverse reactions. Levetiracetam, from the Pyrrolidine drug class, was the most frequently prescribed medication. Patients primarily fell within the age groups of 18-28 and 58-68, with males more affected than females, especially among those on polytherapy. The cardiovascular system was the most affected. The study suggests the importance of providing patients with proper counseling and awareness to enhance their quality of life.

LIST OF ABBREVIATIONS

ADR: Adverse Drug Reaction

GABA: Gamma-aminobutyric acid

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