STUDY OF PRESCRIPTION PATTERN OF ANTIEPILEPTICS DRUGS USED IN GSVM MEDICAL COLLEGE, KANPUR; A TERTIARY CARE HOSPITAL

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Abstract:
Introduction: Epilepsy is a chronic neurological disorder characterized by recurrent, unprovoked seizures that can significantly impact an individual's quality of life. Current evidence suggests that the prescription of AEDs can vary significantly based on factors such as the type of epilepsy, patient demographics, and the presence of comorbid conditions.
Aims & Objectives: The study aims to analyse prescription pattern of antiepileptic drugs used in Neuro medicine department of the tertiary care hospital, GSVM Medical College Kanpur, Uttar Pradesh.
Material & Methods: An observational, cross-sectional study was carried out in Department of Pharmacology in collaboration with the Department of Neurology, G.S.V.M Medical College, Kanpur. Prescriptions of study participants were collected and further studied. All basic details and prescribed drugs were collected and entered in predesigned proforma.
Results: It is observed that in 136 study subjects 'prescriptions, the total number of prescribed antiepileptic drugs in study prescriptions was found to be 479 and the average number of prescribed antiepileptics per prescription encounter was found 3.52. It was observed that four fifth (79.41%) drugs were prescribed in polytherapy form i.e. more than two drugs and one fifth (20.59%) antiepileptics prescribed as monotherapy for management of diagnosed epilepsy diseases/disorders in study patients. Out of the total prescribed antiepileptic drugs, the most commonly prescribed antiepileptic drug was Carbamazepine (31.94%) followed by sodium valproate (23.59%) and Levetiracetam (21.29%).
Conclusion: Overall, this study serves as a foundational assessment of AED prescribing practices at GSVM Medical College, Kanpur, and provides a basis for ongoing improvements in epilepsy management. By addressing the identified limitations and implementing the suggested recommendations, the institution can work towards optimizing patient care and aligning its practices with the latest advancements in epilepsy treatment

Keywords Prescription, Anti-epileptics Drugs, Tertiary care hospital

INTRODUCTION:

Epilepsy is a chronic neurological disorder characterized by recurrent, unprovoked seizures that can significantly impact an individual's quality of life. Epilepsy occurs in approximately 0.3–0.5% of the world's population, and its prevalence is estimated to be 5–30 individuals per 1000. [1] Approximately 80% of epilepsy patients reside in developing nations with limited resources. In India, the prevalence of epilepsy is estimated to range between 5.59 and 10 per 1000. [2]

The management of epilepsy primarily involves pharmacological intervention, and antiepileptic drugs (AEDs) are the cornerstone of treatment. The choice and effectiveness of these drugs are crucial for achieving seizure control, minimizing side effects, and improving patient outcomes. Eighty percent of epilepsy patients can be adequately controlled with one drug, and the risk of significant adverse effects and drug interactions increases when multiple drugs are prescribed.[3]

The study of a prescription pattern is a component of medical audit that helps prescribers to provide rational and cost-effective medical care along with cost analysis which will be beneficial to patients and society.[4] Rational use of drugs means that the right drugs should be prescribed for the right patient in an adequate dose for a sufficient duration and at a reasonable cost.[5]

In a tertiary care setting such as GSVM Medical College, Kanpur, a comprehensive understanding of the prescription patterns of antiepileptic drugs can provide valuable insights into the treatment approaches used in a specialized medical environment. The study of prescription patterns not only sheds light on the preferences and practices of healthcare providers but also helps in identifying trends, evaluating the adherence to clinical guidelines, and assessing the overall efficacy and safety of the prescribed regimens [6][7].

Current evidence suggests that the prescription of AEDs can vary significantly based on factors such as the type of epilepsy, patient demographics, and the presence of comorbid conditions [8]. Furthermore, with the advent of newer AEDs and ongoing research into their efficacy and safety profiles, it is essential to evaluate how these advancements are reflected in clinical practice. [9]

With this background this study aims to analyse prescription pattern of antiepileptic drugs used in Neuro medicine department of the tertiary care hospital, GSVM Medical College Kanpur, Uttar Pradesh with the following objectives

1. To find the demographic profile of epileptic patient.
2. To analyze the pattern of drug prescription among epileptic patients and the rationality of use of pharmacotherapy in epilepsy.

By examining the types of AEDs prescribed, their combinations, and the factors influencing these choices, this research will contribute to a deeper understanding of epilepsy management in a specialized healthcare setting and may guide future treatment strategies.

MATERIAL & METHODS

An observational, cross-sectional study was carried out for one and half years (22ndfeb 2023- 30th June 2024) in Department of Pharmacology in collaboration with the Department of Neurology, G.S.V.M Medical College, Kanpur. Study population included patients who attended the outpatient clinic of the Neuro-medicine department, GSVM Medical College Kanpur (U.P) diagnosed with epilepsy.

Patients of either sex, above 18 years of age, diagnosed with epilepsy only and who are on prescription medication were included in the study while Patients below 18 years of age, patients critically ill patients, Immuno-compromised and those with concurrent major psychiatric illness and /or concurrent major medical illness were excluded from the study

Taking the prevalence of epilepsy in India as 5.05% [10] sample size came out to be 145 using Cochran's Formula, **Sample size n=Z^2 PQ/d^2** considering 10% non-response rate.

Prescriptions of study participants were collected and further studied. All basic details and prescribed drugs were collected and entered in predesigned proforma having the following sections;

Section A includes the patient's Name, Age, gender, education, occupation, income, accompanied attendant details, etc., and filled.

Section B Includes details of various drugs and their prescription pattern indicators were filled as follows
- The total number of drugs prescribed (generic brand) per prescription.
- The average number of antiepileptic drugs prescribed per visit.
- The average number of systemic antiepileptic (oral or i.v) drugs prescribed per visit.
- The patients who received monotherapy and polytherapy during the entire study.
- Distribution of antiepileptic drugs according to therapeutic class.

Statistical Analysis:
The data of the present study has been recorded and after its proper validation, checked for error; coding &data compilation, and segregation were done in MS Excel. Statistical Package for the Social Sciences (SPSS) software version 23.0 was used for statistical analysis. P value < 0.05 was considered statistically significant.

RESULTS
Of the total 145 study patients, 9 patients were lost to follow up and finally, 136 study subjects were considered in the study.

Table 1: Distribution of study patients by Age
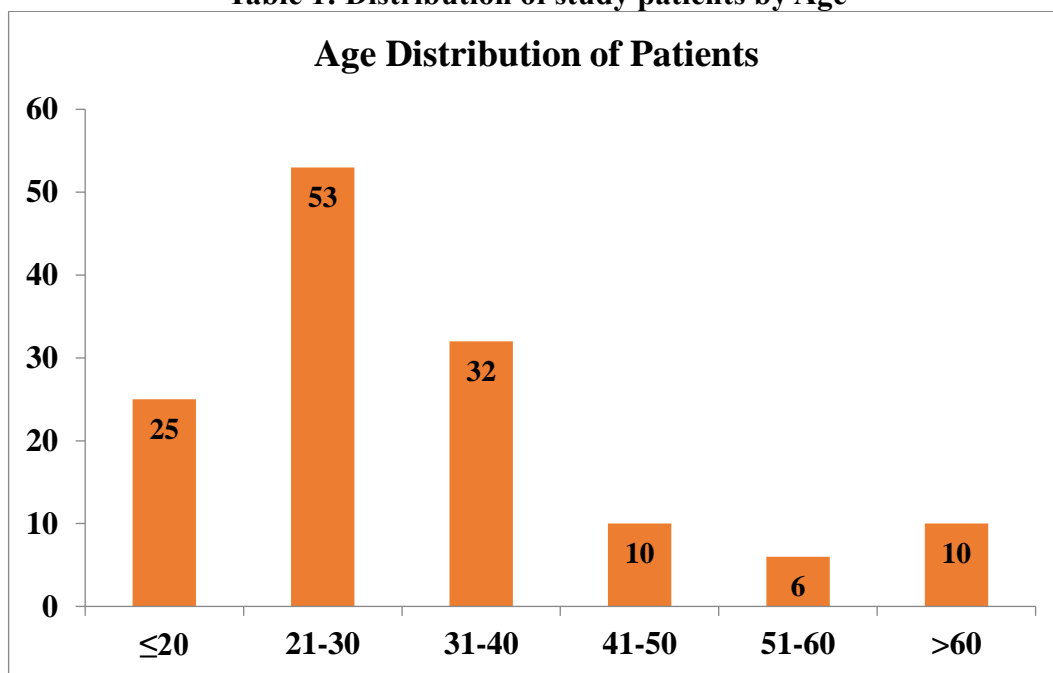
Majority of study participants were in middle age group of 21-30 years (39%) followed by 31-40 years (23.5%) There were 10 (7.4%) patients with age above 60 years and 10 (7.4%) with age between 41-50 years. The mean age± S.D.was found to be 32.15 ± 13.73 years

Figure 1: Pie diagram showing the distribution of subjects by Gender

Gender distribution of patients
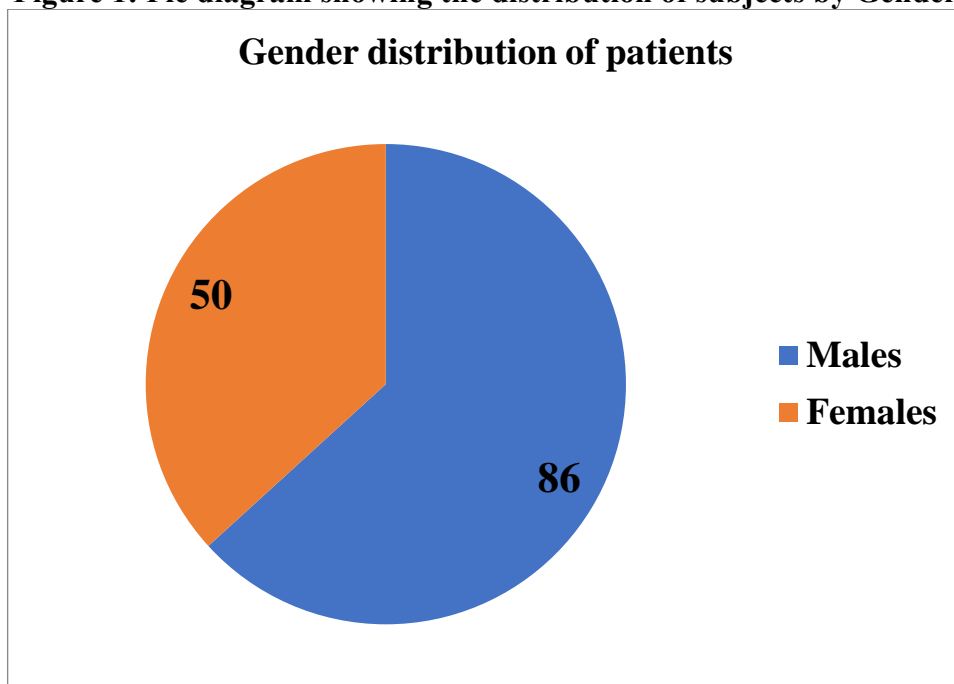
Majority of study participants were Males (63.2%) while females were (36.8%)

Table 2: Distribution of Diseases/Disorders among Study Patients

Disorders	Frequency (n-=136)	Percentage (%)
Generalized tonic-clonic seizure	120	88.3%
Complex partial seizure	7	5.1%
Absence seizure	4	2.9%
Miscellaneous	5	3.7%

The different diseases for which prescribed antiepileptic drugs in the study patients were considered. It was found that 120 (88.24%) subjects suffered from Generalized tonic clonic seizures with epilepsy disorders. Complex partial seizures were noticed in 7 (5.15%) study patients and Absence seizure was seen among 4(2.9%) subjects. Miscellaneous 5 (3.68%) subjects.

Table 3: Drug prescription according to WHO drug indicators

WHO Indicators	Frequency	Inference
Total number of drugs per prescription encounters	859	6.32
Total number of antiepileptics prescribed per prescription encounters	479	3.52
Percentage of encounters with an injection prescribed	00	00
Average number of oral drugs per encounter	859	3.52
Percentage of drugs prescribed by generic name	366	76.41%
Percentage of drugs prescribed from the essential drugs list	292	60.9%

➢ **Total number of drugs prescribed per prescription:** It is observed that in 136 study subjects 'prescriptions, a total of 859 drugs were prescribed and the average number of prescribed drugs per prescription encounter was found 6.32.

➢ **Average number of anti-epileptic drugs prescribed per prescription:** The total number of prescribed antiepileptic drugs in study prescriptions was found tobe 479 and the average number of prescribed antiepileptics per prescription encounter was found 3.52.

➢ **Anti-epileptic drugs prescribed as Generic or Brand Name:** Out of a total of 479 prescribed antiepileptic drugs, 366(76.41%) drugs were prescribed by generic name in the study subjects and 113(23.59%) drugs were found according to brand name in the study.

Table 4: Distribution of antiepileptic therapy

| Therapy	Frequency (n = 136)	Percentage (%)
Monotherapy	28	20.59%
Polytherapy	108	79.41%

Out of the total study patients, 28(20.59%) prescribed antiepileptics as monotherapy for the treatment of diagnosed epilepsy disorders, and the rest 108 (79.41%) study prescriptions were found with polytherapy for their diagnosed epilepsy diseases/disorders.

Table 5: Distribution of anti-epileptic drugs prescribed

| No. of Antiepileptic drugs prescribed per prescription	Frequency	Percentage (%)
One	28	20.6%
Two	60	44.1%
Three	23	16.9%
Four	1	0.7%
Five or more	24	17.6%

It has been noticed that among 136 study patients, most of the prescribed two antiepileptic drugs, and found in 60(44.1%) study prescriptions followed by one (20.6%) and 5 or more in 24 (17.6%) patients with diagnosed epilepsy.

Figure 2: Distribution of drugs by class of Medication
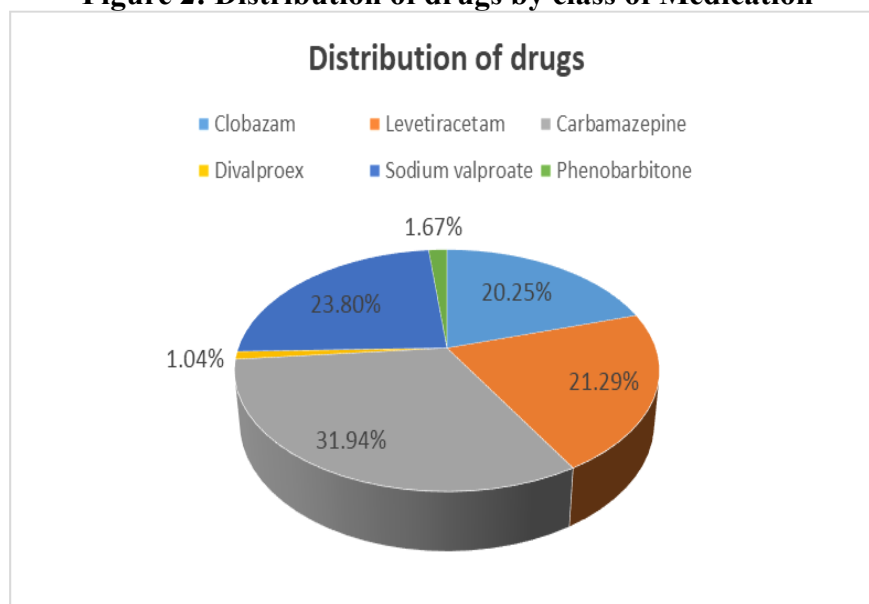
Out of the total prescribed antiepileptic drugs, the most commonly prescribed antiepileptic drug was Carbamazepine (31.94%) followed by sodium valproate (23.59%), Levetiracetam (21.29%), and Clobazam (20.25%) as common prescribing drugs in our study.

Figure 3: Distribution of prescribed anti-epileptics incurred
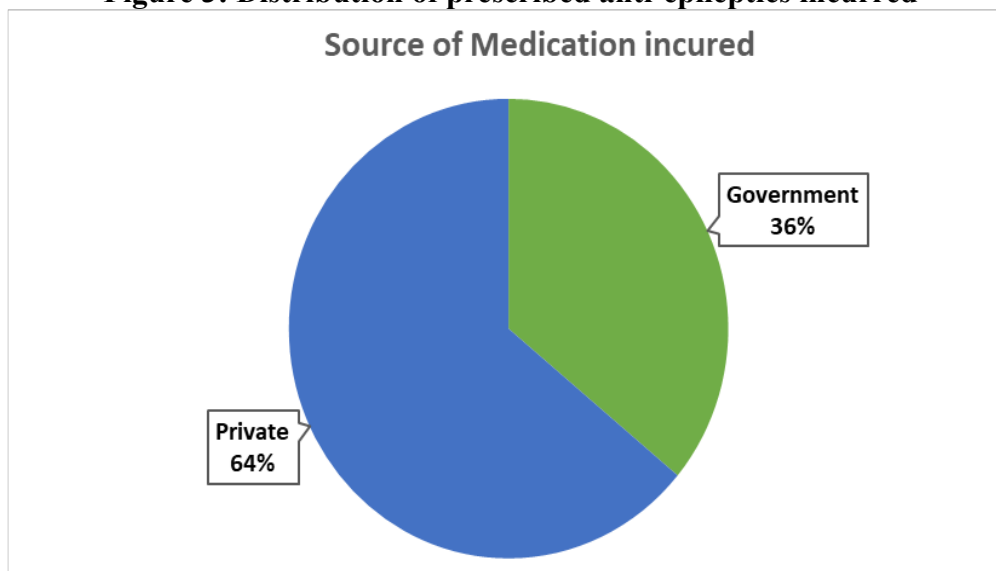
Out of the total study patients, 49(36%) subjects were prescribed antiepileptics diagnosed with epilepsy from government supply, and 87 (64%) were incurred anti-epileptics drugs from private shops.

DISCUSSION
According to various studies by Caprio A and Hauser WA [11], Hanssen Y et al. [12], and Lim SH and Tan EK [13], the incidence of epilepsy has a bimodal distribution with a peak in the first decade and a second peak in the elderly and our result is in accordance with it. Our study shows predominance of male epileptic patients (63.2%) than female patients in our study. Murthy NV et al. [14] showed males were more frequently faces with epilepsy than females. however that T.Badwaik et al [15] study found females were more than males in their study exposed to antiepileptic drugs, which counter to our study findings.

In our study, Most frequent diagnosis in our study was epilepsy without any co-morbidity diagnosis who were suffered from GTCS (88.24%) for which anti epileptics drugs were prescribed. Other were Complex partial seizure (5.15%), Miscellaneous (3.68%) and Absence seizure (2.9%) in patients. It tells that epilepsy due to co-morbidities are less in our study. Generalized tonic colonic (GTC) seizure was the most common type of epilepsy. These result are similar to studies from Akinsulore A et al. [16] and Murthy NV et al [14]

Junny Sebastian et al. [17] also seen hypertension as most common comorbidity in epileptic Patients. Study from Germany found cerebrovascular accident, dementia, and intra cerebral hematoma as a most common comorbidity. [18]

In present study on considering therapeutic regimen and analyzing prescriptions of 136 epileptic patients considering various indicators of drug pattern prescription as per WHO it was found that total 859 drugs were prescribed and average number of prescribed drugs per prescription encounter was found 6.32. The total number of prescribed antiepileptic drugs in study prescriptions was found 479 and the average number of prescribed anti-epileptics per prescription encounter was found 3.52. Although presently there are above 20 antiepileptic drugs which are available for clinical use today.

In our study total 14 categories of were prescribed as antiepileptics drugs as either monotherapy or polytherapy among study epileptic patients for diagnosed illnesses. It was observed that four fifth (79.41%) drugs were prescribed in polytherapy form i.e. more than two drugs and one fifth (20.59%)

antiepileptics prescribed as monotherapy for management of diagnosed epilepsy diseases/disorders in study patients. These results are not in conjuncture with other study by Arulkumaran KSG et al. [19] where they found that most of the patients (≥50%) were prescribed single drug.

According to Guidelines mention that medical management of newly diagnosed epileptic patients should start with monotherapy. Polytherapy should be considered when failure of two attempts of monotherapy.[20]This may be due to the fact of failing of monotherapy or using polytherapy by a physician at once in severe or life-threatening situations. Failing of monotherapy may also result from a lack of adherence resulting from no proper counseling about their medication to rural patients with epilepsy are noncompliant, and this is the most common reason for treatment failure.[21]

Out of the total prescribed antiepileptic drugs, the most commonly prescribed antiepileptic drug was Carbamazepine (31.94%) followed by sodium valproate (23.59%) and Levetiracetam (21.29%). Similar findings were seen in another study by Thomas SV et al. [22] mentioned that carbamazepine was prescribed most commonly. Although studies Pathak S et al. [23], and Landmark CJ, et al. [24] mention that sodium valproate was the most commonly drug prescribed followed by phenytoin or other drugs which is the second most common drug prescribed in our study. Mani KS et al. [25]. Phenobarbitones are not commonly used most likely due to the side effect of cognitive impairment, often with sedation in adults and hyperactivity in young children similar to our study. These findings are due to the existence of wide variations in prescribing behavior and the preference of treating neurologists in prescribing antiepileptic drugs. The reason for discrepancies may be due to factors like availability, affordability, place of practice type of epilepsy, etc.

In present study, out of a total of 479 prescribed antiepileptic drugs, number of antiepileptic drugs prescribed by generic name and according to essential list of medicines is low via 366 (76.41%) drugs prescribed by generic name and 292(60.9%) antiepileptic drugs according to essential list of medicines. Drugs introduced before the 1990's are called older and after the 1990's are newer antiepileptic drugs. According to Guidelines for the Management of Epilepsy in India, 2013 shows that newer antiepileptic drugs and their discovery have not altered treatment regimens. [26] Five new drugs for epilepsy such as lamotrigine, gabapentin, oxcarbazepine, and topiramate have been licensed in India within the past 10 years as "add-on" treatments. Recently, lamotrigine and oxcarbazepine have been licensed for monotherapy in partial seizures [27]. So far, no studies have shown that the newer drugs have superior anticonvulsant efficacy than older ones but have favorable side effects. Less use in our settings may also bedue to the higher cost of these agents compared to older ones. In our study,we found and Levetiracetam as newer antiepileptics and older ones include Carbamazepine, Phenytoin, Valproate, Clobazam, and Phenobarbital.

It has been noticed that among 136 study patients, most of them were prescribed at least two antiepileptic drugs (44.1%) and 5 or more antiepileptic drugs 17.6% of patients with diagnosed epileptic disorders. 20.6% of prescriptions were found with only one antiepileptic drug in our study. some of the main advantages of monotherapy as mentioned in such studies was that patients enjoyed effective seizure control, had fewer side effects, and incurred lower costs of therapy. [28] In addition, monotherapy improves compliance due to fewer neurotoxic side effects and medication convenience [29]

Out of the total epileptic patients, around one-third (36%) were got prescribed antiepileptics from government supply while almost two-thirds (64%) incurred anti-epileptics drugs from other shops. This leads to an unusual financial crisis for the patients for management of epileptic patients. Unlike other developed countries patients with epilepsy in this country receive treatment frequently from tertiary care centers [30].

Recommendations
1. **Standardize Prescription Protocols**: Develop and implement standardized guidelines for prescribing antiepileptic drugs based on the latest evidence and best practices. This can help in ensuring consistency in treatment and improving patient outcomes.
2. **Review and Update Formulary**: Periodic review and update the hospital formulary to include newer AEDs and to ensure the availability of effective and cost-efficient medications.
3. **Enhance Patient Monitoring and Follow-up**: Implement a robust system for monitoring patients' response to AEDs, including side effects, drug interactions, and therapeutic efficacy. Regular follow-up visits and adjustments to therapy based on patient feedback can optimize treatment outcomes.
4. **Data Collection and Analysis**: Establish a comprehensive database to collect and analyze prescription data, including patient demographics, drug types, dosage, and outcomes. This can help in identifying trends, evaluating the effectiveness of different AEDs, and making data-driven decisions.
5. **Promote Rational Drug Use**: Educate healthcare providers on the principles of rational drug use, including selecting the appropriate AED based on the type of epilepsy, patient characteristics, and cost-effectiveness.
6. **Patient Education and Involvement**: Enhance patient education programs to inform patients about their condition, treatment options, and the importance of adherence to prescribed therapies. Engaging patients in their treatment plan can improve adherence and overall treatment success.
7. **Patient-Centric Approach**: Ensure that treatment plans are tailored to individual patient needs, considering factors such as comorbid conditions, potential drug interactions, and patient preferences.

Implementing these recommendations can help optimize the use of antiepileptic drugs, improve patient outcomes, and enhance the overall quality of care in GSVM Medical College, Kanpur.

Limitations
1. **Limited Generalizability**: The findings from a single tertiary care hospital may not be generalizable to other healthcare settings, including primary care or different geographic regions. Differences in patient demographics, healthcare infrastructure, and prescribing practices could limit the applicability of the results to other institutions.
2. **Sample Size and Selection Bias**: The study may be limited by the number of patients included in the analysis. If the sample size is small or not representative of the entire population treated at the hospital, the results may not accurately reflect the overall prescribing patterns.
3. **Lack of Long-Term Data**: The study might only capture a snapshot of prescribing patterns at a specific point in time. Without long-term data, it is difficult to assess trends, changes over time, or the impact of evolving treatment guidelines.
4. **Confounding Variables**: Factors such as patient comorbidities, disease severity, and socio-economic status might influence prescribing patterns but may not be fully controlled for, potentially confounding the results.
5. **Subjectivity in Prescription Data**: The subjective nature of clinical decision-making may lead to variations in how prescriptions are recorded and interpreted. Different clinicians may have different approaches to documentation and treatment decisions.
6. **Limited Scope of Drug Analysis**: The study might focus only on a subset of antiepileptic drugs or specific types of epilepsy, potentially overlooking other important aspects of treatment and drug use.

CONCLUSION
Based on the study's results, several recommendations for enhancing AED prescribing practices have been proposed. These include standardizing protocols, improving clinician education, and ensuring

regular monitoring and follow-up. The study identifies potential gaps and inconsistencies in AED prescribing practices. This includes areas where adherence to guidelines could be improved and where patient outcomes could be optimized through better-tailored treatment plans. Overall, this study serves as a foundational assessment of AED prescribing practices at GSVM Medical College, Kanpur, and provides a basis for ongoing improvements in epilepsy management. By addressing the identified limitations and implementing the suggested recommendations, the institution can work towards optimizing patient care and aligning its practices with the latest advancements in epilepsy treatment. Future research, incorporating a broader range of data and considering long-term trends, will be essential for continuously refining and enhancing AED prescribing practices.

Financial support and Sponsorship
Nil

Conflicts of Interest
There are no conflicts of interest

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