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STUDY OF DRUG UTILIZATION PATTERN OF ANTIEPILEPTIC DRUGS AT TERTIARY CARE HOSPITAL

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Abstract:

Background: The World Health Organization (WHO) defined Drug Utilization Research (DUR) in 1977 as "The advertising, dissemination, prescription, and utilization of drugs in a society, with an exceptional accentuation on the subsequent medical, social and monetary results."

Objective: To analyse the drug utilization pattern of antiepileptic drugs (AEDs) for managing different epileptic seizures over one year**.**

Methods: This Prospective study was conducted on epileptic patients at Tertiary Care Hospital. Duration of study was from August 2022 to October 2023. Ethical clearance was obtained from the Institutional Ethical Committee**.**

Result: The most represented age groups are 21-30 years and 41-50 years, each comprising 22.0% of the study population. Males constitute 50.8% of the total population, while females account for 49.2%. Tonic clonic seizures are the most common, affecting 20.1% of the population. A majority of the participants, 62.4%, are receiving multiple drug therapy, as indicated by the 156 individuals in this category. Among the 156 patients receiving multiple drug therapy, a small fraction, 3.8% (6 patients), are prescribed just one additional drug. The most frequently used drug is Sodium Valproate, prescribed to 37.2% of the patients (93 individuals). Midazolam, the average number of antiepileptic drugs prescribed per prescription is 1.33, with a standard deviation of 0.48, and a p-value of 0.000 indicates a statistically significant result, suggesting a distinct prescribing pattern compared to other antiepileptic drugs. A significant portion of patients (54.4%) were prescribed a combination of two drugs, indicating this is the most common prescribing pattern.

Conclusion: sodium valproate emerged as the most frequently prescribed antiepileptic medicine, with a cumulative count of 128 prescriptions. Tonic clonic seizure was the commonest diagnosis. Majority of the study population was under polytherapy for epilepsy management. A detailed analysis indicated a relatively lower frequency of prescriptions for medications like midazolam and levetiracetam.

Keywords: Drug Utilization Pattern of Antiepileptic Drugs At Tertiary Care.

INTRODUCTION

The objective of the DUR is to promote rational drug consumption among populations. For individual patients, rational drug utilization refers to the prescription of a comprehensive documented medication in an appropriate dosage for an accurate indication, with the correct information, and at a reasonable cost. In the absence of facts regarding the endorsement and utilization of drugs, initiating a conversation on rational drug usage and suggesting strategies to enhance the inclination to promote drugs to executives becomes challenging. The historical performance of prescribers is crucial for any evaluation system.

Drug utilization studies serve as robust investigative instruments for determining the societal impact of medications.[1] They establish a robust socio-medical and health-economic foundation for making decisions on healthcare. It is a highly efficient approach for evaluating the prescribing behavior of doctors.[2,3] Drug utilization studies are crucial in guiding sensible drug prescription practices, thereby reducing the likelihood of side effects and enhancing patient adherence and overall quality of life.[4]

Epilepsy is a prevalent neurological disorder distinguished by the occurrence of repeated and unprovoked seizures. The occurrence and frequency of epilepsy exhibit significant variations across different geographical regions.[5] In the majority of affluent nations, the occurrence of this condition ranges from 50 to 100 cases per 100,000 individuals annually, with a frequency of approximately 5-8 cases per 1000 individuals.[6]

However, in underdeveloped countries, the prevalence has been shown to exceed 40 cases per 1000 individuals.[7] Furthermore, the prevalence of epilepsy within the population exhibits heterogeneity across different age cohorts.[8] Neurologists frequently encounter epilepsy as the second most prevalent chronic neurological disorder. The estimated number of individuals with epilepsy in India is 550,000.[9] There are three fundamental mechanisms of action that are shared throughout the five available antiepileptic medications (AEDs). The effects of these substances include the reduction of repeated firing caused by interference with sodium currents, the enhancement of β-amino butyric acid (GABA) neurotransmission, or the reduction of transient Ca++ currents.[10]

Population-based studies have revealed that a significant proportion, ranging from 19-24%, of individuals diagnosed with epilepsy employ poly-therapy in conjunction with AEDs.[11] Research on individuals with refractory epilepsy, including children and adults, revealed that 64% of participants employed poly-therapy by using two or more AEDs. Additionally, 35% of the adults experienced comorbid disorders connected to the central nervous system, which significantly increased the likelihood of interactions.[12]

Inadequate patient compliance with pharmaceutical regimens is a prevalent factor contributing to heightened rates of death. The annual direct expenses incurred by the U.S. health care system due to non-compliance have been estimated to range from $100 billion to $289 billion. Numerous researches have been conducted to investigate the present state of

medication adherence, its determinants, its correlation with patient outcomes, and strategies for enhancing it. Hence, the identification of precise and uniform metrics for assessing medication adherence holds significant significance.[13] It is imperative to conduct a thorough assessment of the potential risks and benefits associated with the prescription of antiepileptic medication, as well as engage in a comprehensive conversation with the patient regarding the advantages and potential adverse effects of the treatment. The majority of individuals with epilepsy will achieve seizure-free status by the administration of suitable antiepileptic drug (AED) therapy, after which they will undergo evaluation by primary care providers.[14]

Conducting a study on drug utilization patterns antiepileptic drugs at a tertiary care hospital in India is essential for several reasons. It facilitates the evaluation of prescribing methodologies, patient characteristics, and treatment results pertaining to antiepileptic medications, so aiding healthcare professionals in enhancing therapeutic approaches, reducing unfavorable occurrences, and enhancing patient well-being.

MATERIAL AND METHODS

This Prospective study was conducted on epileptic patients at Tertiary Care Hospital. Duration of study was from August 2022 to October 2023. Ethical clearance was obtained from the Institutional Ethical Committee**.**

Sample size: All the epileptic patients who attended OPD and admitted in wards for treatment during above duration of period.

Inclusion criteria:

- Patients of both gender and all age group receiving antiepileptic treatment.
- Newly diagnosed and old patients receiving treatment for epilepsy.
- Patients attended OPD for follow-up treatment as well as patients admitted in ward for treatment of acute epilepsy.

Exclusion criteria:

- Patients with secondary epilepsy due to head injury, cerebral palsy, stroke, metabolic disorders.
- Patients not willing to participate in the study were excluded from our study.
- Patients diagnosed as pre eclampsia and eclampsia with seizures.
- Patients on herbal therapy for treatment of epilepsy.
- Epileptic patients taking drug treatment for nonepileptic disorder.

Data collection:

- The Dose and Formulation of drug.

- Duration and frequency of drug.
- Details of drug use.
- Drug prescribing indicators.

Assessment of core indicators:

- Average number of antiepileptic drugs prescribed per prescription
- Percentage of drugs prescribed by generic name out of total drugs prescribed
- Percentage of drugs prescribed from essential drug list out of total drugs prescribed
- Percentage of drugs prescribed from hospital formulary list out of total drugs prescribed
- Percentage of fixed drug combinations prescribed out of total drugs prescribed
- Percentage of injections prescribed out of total drugs prescribed

RESULTS

The data shows that the most represented age groups are 21-30 years and 41-50 years, each comprising 22.0% of the study population. Following closely is the 51-65 age group, which accounts for 23.6%, making it the largest single group. Individuals aged 31-40 make up 14.4% of the population, while those in the 1-14 age group represent 13.2%. The 15-20 age category is less represented, with only 3.6% of the population. Finally, the least represented age group is those over 65 years, making up just 1.2% of the total. Overall, the data indicates a relatively balanced distribution among the various adult age categories, with a notable drop-off in representation among the youngest and oldest age groups.

Table 1. Percentage distribution of study population – according to age

Age category	Frequency	Percentage (%)
1-14 yrs.	33	13.2
15-20 yrs.	9	3.6
21-30 yrs.	55	22.0
31-40 yrs.	36	14.4
41-50 yrs.	55	22.0
51-65 yrs.	59	23.6
>65 yrs.	3	1.2
Total	250	100.0

Males constitute 50.8% of the total population, while females account for 49.2%. This nearly equal distribution indicates a well-balanced representation of both genders in the study, with a slight predominance of males. The total number of participants is 250, with 127 males and 123 females, reflecting a comprehensive inclusion of both genders in the analysis.

Table 2. Percentage distribution of study population – according to type of seizures

Type of seizures	Frequency	Percentage
Tonic clonic seizure	50	20.1 %
Complex partial seizure	45	18.1 %
Myoclonic seizure	34	13.7 %
Tonic seizure	19	7.6 %
Atonic seizure	33	13.3 %
Absence seizure	32	12.9 %
Simple partial seizure	36	14.5 %
Total	250	100.0 %

Tonic clonic seizures are the most common, affecting 20.1% of the population. This is followed by complex partial seizures, which are experienced by 18.1% of the participants. Simple partial seizures account for 14.5%, making them the third most prevalent type. Myoclonic seizures are reported by 13.7% of the population, and atonic seizures by 13.3%. Absence seizures are present in 12.9% of the cases. The least common type is tonic seizures, affecting 7.6% of the population. Overall, the data indicates a diverse range of seizure types within the study group, with tonic clonic seizures being the most frequent and tonic seizures the least.

Table 3. Percentage distribution of study population – according to monotherapy and multiple drugs

Monotherapy	Frequency	Percentage
No	156	62.4 %
Yes	94	37.6 %
Total	250	100.0 %

A majority of the participants, 62.4%, are receiving multiple drug therapy, as indicated by the 156 individuals in this category. In contrast, 37.6% of the participants, or 94 individuals, are undergoing monotherapy. This indicates that in the study population, a greater proportion of individuals are being treated with a combination of drugs rather than a single medication.

Table 4. Percentage distribution of study population – according to multiple drug

No of drugs prescribed	Multi drug therapy	
	No of patients	Percentage
2	84	56%
3	66	44%

Among the 156 patients receiving multiple drug therapy, a small fraction, 3.8% (6 patients), are prescribed just one additional drug. The majority, accounting for 56% (84 patients), are treated with two drugs. Additionally, 44% (66 patients) are on a regimen involving three drugs. This indicates that within this group, the most common therapeutic approach involves the use of two medications. A substantial portion also requires a three-drug regimen, while the prescription of only one additional drug is relatively rare. Overall, the data underscores the prevalent use of multi-drug combinations, particularly two-drug regimens, in managing the patients within this study population. This indicates that they are being treated with more than one medication.

Table 5. Percentage distribution of study population – according to antiepileptic drug used

Drug used	Frequency	Percentage
Midazolam	27	10.8%
Phenytoin	34	13.6%
Levetiracetam	43	17.2%
Sodium valproate	93	37.2%
Carbamazepine	43	17.2%
Phenobarbitone	10	4.0%
Total	250	100

The most frequently used drug is Sodium Valproate, prescribed to 37.2% of the patients (93 individuals). Both Levetiracetam and Carbamazepine are each used by 17.2% of the population (43 patients each). Phenytoin is administered to 13.6% of the patients (34 individuals). Midazolam is used by 10.8% of the population (27 patients). The least commonly used drug is Phenobarbitone, prescribed to 4.0% of the patients (10 individuals). Overall, the data highlights that Sodium Valproate is the most commonly used medication in this study population, while Phenobarbitone is the least commonly used.

Table 6. Percentage distribution of study population – according to routes of drug administrations

D1 Drug Usage:

- The only drug used as D1 is Midazolam, with 59 instances, representing 100% of the total usage for D1. All cases of D1 drug usage are covered by Midazolam, indicating a strong preference or protocol for this drug in the given context.

D1 Route:

- For the administration route of D1 drugs, 17 instances (28.8%) are intravenous (IV), and 42 instances (71.2%) are oral. This suggests a preference for oral administration for D1 drugs, although a significant portion is still administered intravenously.

Category	D1 Drug used and route	Counts	Percentage
D1 drug used	Midazolam	59	100
D1 route	IV	17	28.8%
	Oral	42	71.2%

Table 6(a): Drug 1-Midazolam

D2 Drug Usage:

- Phenytoin is the only drug used as D2, with 69 instances, making up 100% of D2 drug usage. This indicates exclusive use of Phenytoin for D2 drugs.

D2 Route:

- For D2 drugs, 42 instances (60.9%) are administered intravenously, while 27 instances (39.1%) are oral. This shows a tendency towards IV administration for D2 drugs, though oral administration is also notable.

Category	D2 Drug used and route	Counts	Percentage
D2 drug used	Phenytoin	69	100
D2 route	IV	42	60.9%
	Oral	27	39.1%

Table 6 (b): Drug 2-Phenytoin

D3 Drug Usage:

- Levetiracetam is the sole drug used as D3, with 98 instances, accounting for 100% of the total D3 drug usage. This reflects an exclusive use of Levetiracetam for D3 drugs.

D3 Route:

- All instances (87 cases) of D3 drug administration are oral, making up 100% of the routes used for D3 drugs. This indicates a uniform preference for oral administration of Levetiracetam.

Category	D3 Drug used and route	Counts	Percentage
D3 drug used	Levetiracetam	98	100%
D3 route	Oral	98	100%

Table 6 (c): Drug 3-Levetiracetam

D4 Drug Usage:

- Sodium Valproate is the only drug used as D4, with 128 instances, representing 100% of the D4 drug usage. This signifies exclusive use of Sodium Valproate for D4 drugs.

D4 Route:

- For D4 drugs, 34 instances (26.8%) are intravenous, and 93 instances (73.2%) are oral. This shows a preference for oral administration, although a substantial portion is still administered intravenously.

Category	D4 Drug used and route	Counts	Percentage
D4 drug used	Sodium valproate	128	100
D4 route	IV	35	26.8%
	Oral	93	73.2%

Table 6 (d): Drug 4-Sodium Valproate

D5 Drug Usage:

- Carbamazepine is the only drug used as D5, with 93 instances, making up 100% of the D5 drug usage. This reflects exclusive use of Carbamazepine for D5 drugs.

D5 Route:

- All 93 instances of D5 drug administration are oral, accounting for 100% of the routes used for D5 drugs. This indicates a consistent preference for oral administration of Carbamazepine.

Category	D5 Drug used and route	Counts	Percentage
D5 drug used	Carbamazepine	93	100%
D5 route	Oral	93	100%

Table 6 (e): Drug 5-Carbamazepine

D6 Drug Usage:

- Phenobarbitone is the only drug used as D6, with 13 instances, representing 100% of the D6 drug usage. This signifies exclusive use of Phenobarbitone for D6 drugs.

Category	D6 Drug used and route	Counts	Percentage
D6 drug used	Phenobarbitone	13	100%
D6 route	Oral	13	100%

Table 6(f): Drug 6-Phenobarbitone

The prescribing patterns of antiepileptic drugs reveal significant variations among different medications. For Midazolam, the average number of antiepileptic drugs prescribed per prescription is 1.33, with a standard deviation of 0.48, and a p-value of 0.000 indicates a statistically significant result, suggesting a distinct prescribing pattern compared to other antiepileptic drugs. In contrast, Phenytoin has a notably higher average of 2.94 antiepileptic drugs per prescription, with a standard deviation of 0.34. Levetiracetam also shows a relatively high average of 2.33 drugs per prescription, accompanied by a standard deviation of 0.57. Sodium Valproate prescriptions typically include an average of 1.86 antiepileptic drugs, with a standard deviation of 0.65. For Carbamazepine, the average number of drugs per prescription is 2.05, with a standard deviation of 0.21. Phenobarbitone prescriptions average 2.10 antiepileptic drugs, with a standard deviation of 0.32. These figures underscore

the diverse prescribing practices for different antiepileptic medications, reflecting the complexity of treatment strategies tailored to patient needs.

Table 7. Average number of drugs prescribed per hospital formulary

		Frequency	Percent
Drug prescribed per hospital formulary	1	48	19.2%
	2	136	54.4%
	3	66	26.4%
	Total	250	100

A significant portion of patients (54.4%) were prescribed a combination of two drugs, indicating this is the most common prescribing pattern. A smaller percentage, 26.4%, received three-drug combinations, reflecting more complex therapeutic needs. Meanwhile, 19.2% of prescriptions involved only a single drug, possibly for patients with simpler medical conditions. This distribution suggests that the majority of patients required moderate polypharmacy, with fewer requiring either minimal or extensive medication regimens.

Table 8. Core indicators assessment:

Indicators	Percentage
Average number of drugs prescribed per prescription	2.07%
Percentage of drugs prescribed by generic name out of total drugs prescribed	93.53%
Percentage of drugs prescribed from hospital formulary list out of total drugs prescribed	100%
Percentage of fixed dose combination prescribed out of total drugs prescribed	62.4%
Percentage of injections prescribed out of total drugs prescribed	66.8%
Prescription with antiepileptic FDC	80%
Total no. of drugs prescribed	100%

Table 8 shows average number of drugs prescribed per prescription: On average, each prescription includes 2.07 drugs. This metric reflects the complexity of treatment regimens and the common practice of prescribing multiple medications concurrently.

Percentage of drugs prescribed by generic name out of total drugs prescribed: Approximately 93.53% of all prescribed drugs are generics. This high percentage indicates a strong

adherence to prescribing generic medications, which are typically more affordable and widely accessible.

Percentage of drugs prescribed from hospital formulary list out of total drugs prescribed: All drugs (100%) are prescribed from the hospital formulary list. This suggests adherence to institutional prescribing guidelines and formulary restrictions.

Percentage of fixed dose combination (FDC) prescribed out of total drugs prescribed: Fixed dose combinations constitute 62.4% of all prescribed drugs. FDCs are formulations that combine two or more active pharmaceutical ingredients in a single dosage form, often used to simplify treatment regimens and improve patient adherence.

Percentage of injections prescribed out of total drugs prescribed: Injections account for 66.8% of all prescribed drugs. This indicates a significant use of injectable medications in the treatment protocols, possibly reflecting the need for immediate therapeutic effects or specific clinical conditions requiring parenteral administration.

Prescription with antiepileptic FDC: 80% of prescriptions include antiepileptic fixed dose combinations. This high percentage underscores the frequent use of FDCs in managing epilepsy, aiming to optimize treatment outcomes and simplify dosing regimens for patients.

Out of the total 250 prescriptions analyzed:

- **Yes**: 80.3% of prescriptions (200 out of 250) include antiepileptic FDCs.
- **No**: 19.7% of prescriptions (50 out of 250) do not include antiepileptic FDCs

DISCUSSION

In our present study the most represented age groups are 51-65 years (23.6%), followed by 21-30 years and 41-50 years, each at 22.0%. Based on the findings of **Sharvani et al.**[15], the majority of patients in medicine units were within the age range of 36 to 60 years. Epilepsy shows a bimodal distribution, with a significant increase in cases during childhood and a second peak in the elderly.[16]

In the current study, the proportion of males is 50.8% and females constitute 49.2% of the total sample size of 250 participants. This suggests a somewhat balanced gender distribution, with a small male predominance observed, with 127 males and 123 females. **T. Badwaik et** colleagues observed a higher prevalence of antiepileptic drug exposure among girls compared to males in their study.[17]

It was observed that tonic clonic seizures had the highest prevalence rate at 20.1%, followed by complex partial seizures at 18.1% and simple partial seizures at 14.5%. Myoclonic seizures (13.7%), atonic seizures (13.3%), and absence seizures (12.9%) exhibit lower prevalence rates, with tonic seizures being the least frequent (7.6%). The presented data illustrates a wide array of seizure types, with tonic clonic seizures being the most prevalent.

The findings presented in this study align with previous research conducted by **Akinsulore et al.**[18] and **Murthy et al.**[19], who similarly identified tonic clonic seizures as a prominent diagnostic category.

The findings of our current study indicate that a significant proportion (62.4%) of the study group is undergoing multiple medication therapy, whilst 37.6% are receiving monotherapy. These findings indicate that combination therapy is more frequently employed compared to monodrug treatment. Additionally, a separate study revealed that 35.83% of the participants were receiving monotherapy, while 64.16% were undergoing multi-drug therapy, which involved the use of two or more antiepileptic medications.

Monotherapy is favored in epilepsy management for its reduced risk of adverse reactions and drug interactions. It simplifies treatment, improves adherence, and allows for better assessment of medication effectiveness, ultimately enhancing seizure control and patient quality of life.[20]

Since the 1990s, second-generation AEDs like lamotrigine and levetiracetam have been common, with new third-generation AEDs such as lacosamide recently introduced. These newer AEDs have better safety profiles and fewer side effects. Monotherapy with these AEDs is often preferred due to their effectiveness and improved tolerability.[21]

Since the early 1980s, polytherapy has been used for refractory epilepsy to achieve synergistic effects or reduce toxicity by combining smaller doses of multiple drugs instead of higher doses of a single medication.[22] Further trials resulted in a modification of this approach by confirming monotherapy as the primary treatment modality.[23] In the case of these individuals, polytherapy is not only deemed appropriate, but also considered normative treatment.[24]

In a study conducted by **Deckers et al.,**[25] comparedthat CBZ and VPA combination therapy had better outcomes than CBZ monotherapy, though not statistically significant, and faced criticism for pharmacokinetic interactions without proven synergy.

A trial by **Kwan and Brodieet al** [26] found that after two failed monotherapy attempts, combination therapy showed better seizure control in drug-resistant epilepsy.A 20-year follow-up study showed that while monotherapy maintained a steady 60% seizure freedom rate, polytherapy nearly tripled its effectiveness, with seizure freedom increasing from 3% to 8.4%.[27]

Stephen and colleagues[121,122] conducted a study of 1,617 and 2,379 epilepsy patients in 2000 and 2010 found that about 20% were on polytherapy with two to four antiseizure medications (ASMs).Previous studies suggest potential synergy in dual combinations like valproic acid with lamotrigine and levetiracetam with carbamazepine.[28]

The present survey revealed that sodium valproate was the most often given antiepileptic medication, with a total of 128 prescriptions. Currently, there are more than 20 antiepileptic medicines that are readily accessible for therapeutic application. Our hospital utilized only six

distinct antiepileptic medications. A study conducted in India by **Thomas SV et al (2001)**[29] found that Carbamazepine was the most prescribed medication, while other studies show sodium valproate as the most common, followed by phenytoin.[30]

In **1966, Meunier and colleagues** conducted the first human trial of valproic acid (VPA) showed it significantly reduced seizures with minimal side effects in 12 patients with refractory epilepsy. By 1978, the FDA approved VPA for treating absence seizures.[31]

Sodium valproate is often considered more effective than phenytoin for treating generalized onset seizures, including tonic-clonic, absence, and myoclonic seizures.[32]Phenytoin is believed to be better for focal seizures than sodium valproate, though this lacks conclusive trial evidence, with support for valproate being mainly anecdotal.

In the present study, a majority of the patients showed a preference for injectable medications over oral treatments in managing epilepsy. **Phenytoin** was given more frequently via the intravenous (IV) route, with 60.9% of administrations being IV. In contrast, **Phenobarbitone, Carbamazepine, and Levetiracetam** were all prescribed 100% orally, making them the drugs most commonly administered via the oral route. Established epilepsy treatment can be administered orally, via nasogastric tube, or parenterally if immediate control or intravenous formulations are required.[33]

In our study, the average number of antiepileptic drugs per prescription was 2 (56%). Unlike previous research where most patients (≥50%) received monotherapy, 64.16% of patients here were treated with two or more medications.[34]

Furthermore, our investigation revealed that the mean number of medications prescribed per hospital formulary was 2, accounting for 54.4% of the total. Nevertheless, **Chandrarathna et al.**[35] found a mean of 6 medications, exceeding WHO's ideal, likely due to comorbidities in a tertiary care setting.

In our study, fixed-dose combinations are commonly used, with 80.3% of prescriptions including an antiepileptic FDC.

According to WHO criteria, FDCs require clinical justification, offering clear therapeutic benefits over individual drugs, such as improved efficacy, safety, or patient compliance. The combination must be backed by strong clinical evidence. For epilepsy, this applies to patients with specific seizure types[36] The WHO stresses that FDCs should have balanced dosages, ensuring each drug contributes effectively, with a safety profile that avoids more adverse effects than when used alone.[136]

FDCs simplify complex treatment protocols, especially in chronic conditions like epilepsy, by combining multiple medications into one dosage form. This reduces pill burden, improves patient compliance, and helps prevent disease progression or complications.[37]

FDCs are tailored for specific patient groups, considering disease progression, patient characteristics, and treatment logistics, making them a logical choice in modern pharmacology.

Combining levetiracetam and sodium valproate in an FDC improves seizure control and simplifies treatment for better adherence.

CONCLUSION

Our healthcare facility employed a limited selection of six unique antiepileptic drugs. The findings of the survey indicate that sodium valproate emerged as the most frequently prescribed antiepileptic medicine, with a cumulative count of 128 prescriptions. Tonic clonic seizure was the commonest diagnosis. Majority of the study population was under polytherapy for epilepsy management. A detailed analysis indicated a relatively lower frequency of prescriptions for medications like midazolam and levetiracetam.

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