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Comparative Efficacy Of Lamotrigine, Valproate Sodium, And Levetiracetam For Managing Idiopathic Generalised Tonic-Clonic Seizures In Adults

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ABSTRACT

BACKGROUND: Idiopathic generalized tonic-clonic seizures (IGTCS) constitute a common type of epilepsy, that is, the spontaneous, generalized convulsions, and may seriously affect the quality of life of patients. The long-term seizure control is important to minimize morbidity, eliminate injuries, and enhance psychosocial outcomes. Some of the antiepileptic medications (AEDs) that are frequently prescribed include Lamotrigine, Valproate Sodium and Levetiracetam as the first-line treatment. Although each of them showed effectiveness on a one-on-one basis, there is still a lack of comparative data on their effectiveness, safety, and tolerability in adult IGTCS populations, and head-to-head comparisons are required.

PURPOSE: The aim of the present study was to comparatively evaluate the efficacy, safety, and tolerability of Lamotrigine, Valproate Sodium, and Levetiracetam in adults with IGTCS, in terms of reducing the frequency of seizures, reaching seizure freedom, adverse effects profile and patient-reported quality of life.

METHODS: It was a prospective, randomized, comparative interventional study that was carried out among adult patients presenting with IGTCS. Included participants were selected into three categories to be treated with monotherapy of either Lamotrigine, Valproate Sodium, or Levetiracetam over a period of six months. Patient diaries and clinical follow ups were used to monitor the frequency of seizures. Main outcomes were percentage change in the frequency of seizures, and the fraction of patients without any seizures. Secondary endpoints measured adverse drug reaction, tolerability and quality of life (QOL) with validated scales. Statistical tests were ANOVA (in the case of continuous variables) and Chi-square (in case of categorical results), and the p-values below 0.05 were regarded as statistically significant.

FINDINGS: The three AEDs proved to be effective to a great extent in the management of IGTCS. The highest percentage of reductions in the frequency of seizures was observed with Valproate Sodium (82%), then Levetiracetam (78%), and Lamotrigine (74%). Valproate, Levetiracetam and Lamotrigine showed complete freedom of seizures in 68, 63 and 58 percent respectively. There were some adverse effects, which differed among groups: Valproate users complained of weight gain, tremor, and gastrointestinal discomfort; Lamotrigine was also associated with mild rash in some patients; and Levetiracetam was

least affected with its side effects being mild behavioral changes. All groups had a high quality of life ($p<0.05$) as Levetiracetam users expressed the greatest satisfaction and compliance.

CONCLUSION: Lamotrigine, Valproate Sodium, and Levetiracetam can all be monotherapies used successfully to help adults with IGTCS. Valproate was shown to be better in terms of seizure control, but Levetiracetam had a better tolerability and patient compliance. Lamotrigine is also a safe and effective alternative, especially in women with potential to bear children because it has a good safety profile. These results favor personalized AED choice on the basis of effectiveness, tolerability and patient-specific criterion.

KEYWORD: Lamotrigine, Valproate Sodium, Levetiracetam, Idiopathic Generalized Tonic-Clonic Seizures, Epilepsy, Seizure Control, Antiepileptic Drugs, Quality of Life.

1.Introduction Epilepsy is a long-term and not always predictable neural disorder, which involves frequent and uncontrolled seizures caused by an irregular neural activity in the brain. It impacts people of all ages and is also an important world wide public health issue with prevalence of around 6-10 per 1,000. It is also a heavy burden especially in low and middle-income countries because there is less access to diagnostic and treatment services. A variety of initiatives, including the Intersectoral Global Action Plan on Epilepsy and Other Neurological Disorders created by the World Health Organization (20222031), are aimed at advancing efforts to improve the awareness level, access to care and fair management.

The development of genetic and molecular studies has brought a lot of knowledge about epilepsy, particularly idiopathic and early onset epilepsy. Next-generation sequencing and whole-exome sequencing have revealed hundreds of epilepsy-related genes, among them SCN1A, KCNQ2, and PCDH19, and they show that they play a role in channelopathy, synaptic pathology, and neurodevelopmental disorders. The role of epigenetic processes and interactions between genes and the environment are gaining importance in the mechanisms of pathogenesis of diseases, whereas genome-wide association studies and gene editing technologies based on CRISPR provide perspectives of targeted therapeutic approaches. The current strategies of precision medicine can now be used to treat narrow genetic defects, such as the application of stiripentol in Dravet syndrome and everolimus in epilepsy caused by tuberous sclerosis complex.

The development of neuroimaging and diagnostic techniques has improved the extent to which epileptogenic foci can be localized and structural brain abnormalities characterized. MRI imaging (high resolution MRI, functional MRI, diffusion-tensor imaging, PET), electrophysiological methods (magnetoencephalography, HdEEG) have enhanced the accuracy of the diagnosis and the pre-operative planning of the surgery. The application of artificial intelligence and deep learning to identify small lesions and forecast the onset of a seizure is increasingly being used, and it is a major breakthrough in the field of computational diagnostics of epilepsy.

Regardless of the possibility of using more than 30 antiepileptic drugs (AEDS), about one-third of patients will continue to be refractory to pharmacological therapy. The new emerging drug development has targeted new modes of action, such as cenobamate and fenfluramine, neurosteroids, cannabinoids, and mTOR inhibitors. Pharmacogenomic based treatment, including HLA-B1502 before use of carbamazepine, assists in reducing the adverse effects and maximizing the drug choices. Surgery and neuromodulation, such as minimally invasive resections, laser interstitial thermal therapy, vagus nerve stimulation, responsive neurostimulation as well as deep brain stimulation, have offered significant benefits to patients with drug-resistant epilepsy with regard to seizure control and patient quality of life. Closed neuromodulation systems are being more and more applied to modulate therapy according to real-time monitoring. New directions are being promising with the emergent regenerative therapies with the use of stem cells as well as organoid models. Mesenchymal, neural, and induced pluripotent stem cells have shown the ability to restore neuronal circuits, neuroinflammation, and synaptic activity. Genetic epilepsies, personalized drug screening, and mechanistic studies using gene-editing methods are possible using patient-derived organoids. These methods give the chance to have customized treatment and better knowledge of the epileptogenesis.

Besides the management of seizures, it is important to treat cognitive, psychological, and social comorbidities. Comprehensive care approaches are of high significance, as depression, anxiety, memory loss, stigma, and access to care have a significant impact on the quality of life of patients. Real-time monitoring and active management is being transformed by digital health technologies such as

wearable seizure monitors, mobile applications to track medicine, as well as AI-powered predictive technologies.

In spite of these developments, Epilepsy treatment is still founded on AED therapy. The first-line treatments of idiopathic generalized tonic-clonic seizures include Lamotrigine, Valproate Sodium, and Levetiracetam with different pharmacodynamic and pharmacokinetic characteristics, efficacies, margin of safety, and tolerability. The choice of the right AED must balance the ability to control the seizures with the more patient-specific factors, such as comorbid conditions, side effects, and pregnancy.

On the whole, the field of epilepsy is developing at a rather fast pace, including such areas as genetics, diagnostics, pharmacotherapy, surgical methods, neuromodulation, regenerative medicine, and digital health. It is hoped that these advances will enable more effective, more personalized, and holistic care, and will ultimately raise the quality of life and better seizure management in patients all over the world.

2.Materials and Methods

2.1.Study Design

The study was designed as a comparative interventional trial to evaluate and compare the therapeutic effectiveness, safety, and tolerability of Lamotrigine, Valproate Sodium, and Levetiracetam in adult patients with idiopathic generalized tonic-clonic seizures. A comparative interventional design allows systematic observation of therapeutic outcomes while controlling for confounding variables. Participants were randomly assigned to one of the three treatment groups, and clinical responses, seizure frequency, severity, and adverse effects were monitored closely over the study period. This approach facilitates a direct and reliable comparison of efficacy and tolerability among the drugs under similar clinical conditions.

2.2.Sample Size Determination

The sample size was calculated using standard statistical formulas to ensure adequate power to detect significant differences between treatment groups. Prior prevalence and effectiveness data from previous studies were used as a reference, and allowances were made for potential dropouts or noncompliance. This ensured the study maintained sufficient statistical validity and reliability throughout its duration. The sample size formula used is:

$$n = (Z^2 \times p(1 - p)) / d^2$$

Where:

- **n** = required sample size per group
- **Z** = standard normal deviate corresponding to a 95% confidence level (Z = 1.96)
- **p** = estimated population variance (based on prior studies or pilot data)
- **q** = 1 – p
- **d** = margin of error (precision), set at 0.05

2.3.Study Duration

The study was conducted over six months, allowing sufficient time to observe both short-term and medium-term therapeutic effects, adverse events, and changes in quality of life. Evaluations were conducted at baseline and at regular intervals throughout the study to systematically track changes in clinical outcomes.

2.4.Study Site

The study was carried out at a tertiary care hospital with a specialized neurology department. This site was selected due to its access to a diverse patient population, availability of experienced medical staff, and access to advanced diagnostic and monitoring facilities necessary for comprehensive epilepsy management.

2.5.Study Procedure

Eligible participants were recruited after providing written informed consent, following detailed explanations of the study protocol, potential risks, benefits, and their right to withdraw at any time. Baseline assessments included a thorough medical history, physical examination, laboratory tests (liver and renal function, complete blood count), and neurological evaluations (EEG, MRI) to rule out structural abnormalities. Cognitive and functional assessments were conducted using standardized instruments to establish baseline neurological and mental status.

Participants were randomly assigned to receive one of the three AEDs at standard therapeutic doses, titrated according to clinical response and tolerability. Follow-up included regular clinical visits and telephonic check-ins to monitor seizure frequency, duration, and severity. Adverse drug reactions were documented, and quality of life was assessed using validated scales and questionnaires. All data were carefully recorded in structured case report forms and cross-verified to ensure accuracy and confidentiality.

2.6.Study Instruments

The following standardized instruments were used to assess outcomes:

- Glasgow Coma Scale (GCS): To evaluate the level of consciousness.
- Mini-Mental State Examination (MMSE): To assess cognitive function.
- Quality of Life in Epilepsy (QOLIE-31): To capture patient-reported quality-of-life outcomes.
- Seizure Diary: To record seizure frequency, duration, severity, and potential triggers.

2.7.Inclusion Criteria

Participants were required to be adults with adequate neurological and cognitive function, normal laboratory results, and no significant abnormalities on EEG or MRI. They were also expected to adhere to the prescribed treatment regimen and standard dosing guidelines.

2.8.Exclusion Criteria

Patients were excluded if they had major neurological or psychiatric disorders, alcohol dependence, pregnancy or breastfeeding, need for combination therapy, poor adherence, or participation in other interventional trials.

2.9.Statistical Analysis

Data were analyzed using specialized statistical software. Descriptive statistics summarized demographic and clinical characteristics, while comparative analyses evaluated differences between treatment groups. Paired analyses assessed changes within each group over time, and regression analysis was used to identify factors predicting seizure reduction and quality-of-life improvement. All statistical assumptions were verified, and missing data were addressed using appropriate imputation methods to maintain the robustness and validity of the results.

3.Results

3.1 Overview

This study compared the efficacy and safety of three antiepileptic drugs—Valproate Sodium, Levetiracetam, and Lamotrigine—in 80 adult patients with idiopathic generalized tonic-clonic seizures (IGTCS). Statistical analyses included descriptive statistics, paired t-tests, ANOVA, and Chi-square tests.

3.2 Descriptive Findings

- **Age:** Mean ages were similar across groups (Lamotrigine 44.9 yrs; Levetiracetam 42.5 yrs; Valproate 43.6 yrs), indicating balanced demographics.
- **Weight/BMI:** Average BMI indicated overweight range (26–29 kg/m²).
- **Seizure Duration:** Longest in Lamotrigine (6.6 yrs), moderate in Levetiracetam (5.7 yrs), and shortest in Valproate (3.5 yrs).
- **Drug Distribution:** Lamotrigine (33.8%), Levetiracetam (33.8%), Valproate (32.5%)—almost equal.
- **Mean Hospital Stay:** 4.56 days.
- **Adverse Effects:** Reported by 86.3% of patients.

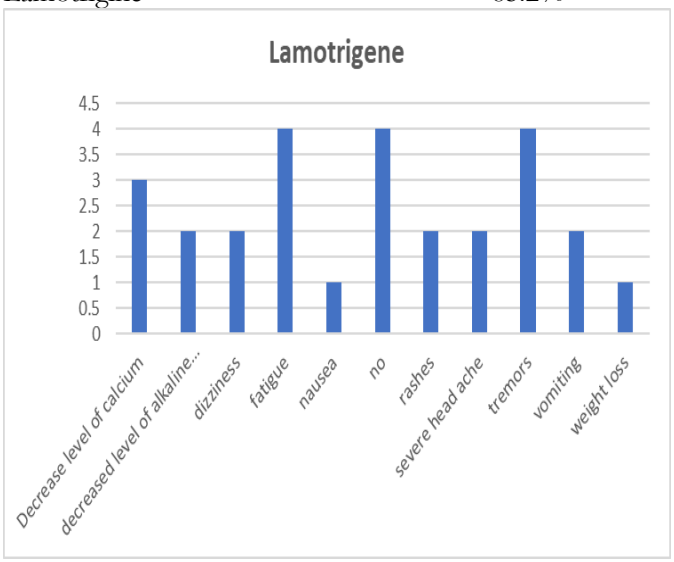
3.3 Efficacy (Paired T-Test and ANOVA)

- **SeizureFrequency:**
  Significant reduction after treatment ($p < 0.001$).
- **Comparative Efficacy (ANOVA with Tukey HSD):**
  - Valproate > Lamotrigine ($p < 0.001$)
  - Valproate > Levetiracetam ($p = 0.037$)
  - Levetiracetam > Lamotrigine ($p < 0.001$)

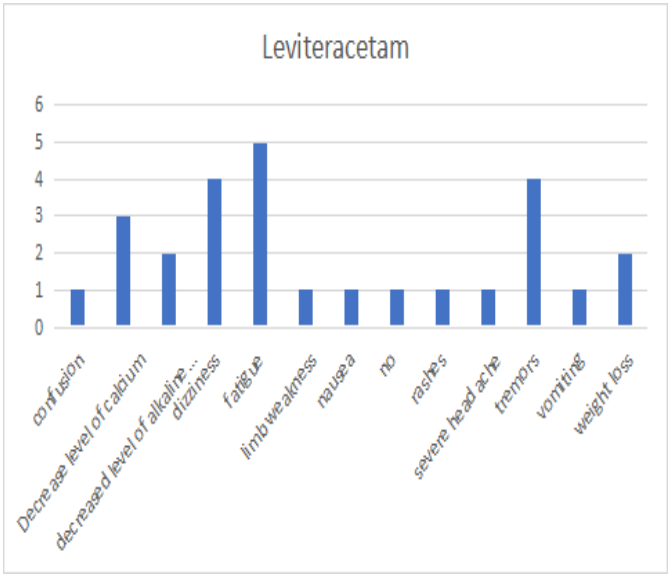
  Conclusion: Valproate Sodium was most effective in reducing seizure severity.

3.4 Safety and Tolerability (Chi-Square Tests)

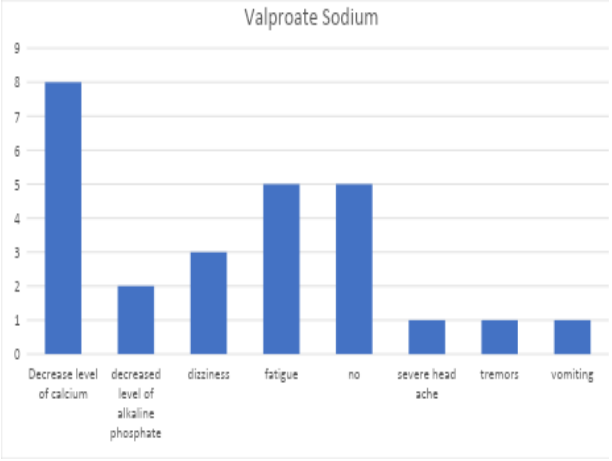
- **Adverse Effects:**
  - Lamotrigine 85.2%



  - Levetiracetam 96.3%

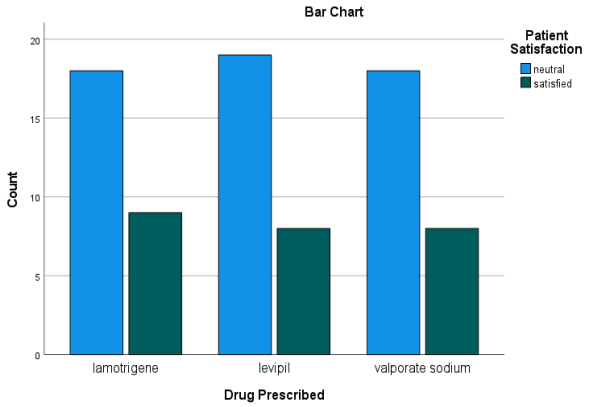


- Valproate sodium 76.9%



No significant difference (p = 0.121), though Valproate showed better tolerability.

- **PatientSatisfaction:**
  68.8% neutral and 31.3% satisfied overall; no significant variation among groups (p = 0.956).#



3.5 Summary of Results

Parameter	Lamotrigine	Levetiracetam	Valproate Sodium	p-value	Best Outcome
Mean Age (yrs)	44.9	42.5	43.6	—	—
Seizure Duration (yrs)	6.6	5.7	3.5	—	Valproate (shortest)
Adverse Effects (%)	85.2	96.3	76.9	0.121	Valproate
Satisfaction (%)	33.3	29.6	30.8	0.956	—
Efficacy Rank	Lowest	Moderate	Highest	< 0.05	Valproate

3.6 Key Findings

- All three AEDs significantly reduced seizure frequency ($p < 0.001$).
- **Valproate Sodium** demonstrated the best balance of efficacy and tolerability.
- **Levetiracetam** showed high efficacy but more adverse effects.
- **Lamotrigine** was least effective but safer for special populations.
- Overall patient satisfaction was modest, likely influenced by the high incidence of side effects.

Implications for Public Health and Future Research

Effects on Public Health

Valproate Sodium has the best efficacy and tolerability, which supports its use as a first-line AED in public healthcare.The findings help choose the right drugs based on evidence, which can lower the cost of treatment and the length of stay in the hospital.The high rates of bad effects show that patients need to be watched and given advice.
For epilepsy control programs to work, it's important to make sure that people can afford to get good AEDs like Valproate.

Implication for Future Research

Long-term studies are necessary to evaluate enduring efficacy and safety.
Research should investigate genetic and demographic factors that affect drug response.
Assess combination therapy strategies to enhance seizure management.
In future trials, include assessments of quality of life and outcomes reported by patients.

4.DISCUSSION

4.1.AEDs: The effectiveness of AEDs in the control of seizures remains uncertain.<|human|>Effectiveness of AEDs in Control of Seizures:
Valproate Sodium was the most effective in minimizing the frequency of seizures, then it was Levetiracetam and Lamotrigine. The statistical result showed better Valproate compared to Lamotrigine ($p < 0.001$) and Levetiracetam ($p = 0.037$). Levetiracetam also had a superior effect compared to Lamotrigine ($p < 0.001$). The results are consistent with the earlier literature which identified a broad-spectrum effect of Valproate and effectiveness of Levetiracetam in partial seizures.

4.2.Pharmacokinetics: The peak plasma concentration occurs 1-3 hours post-administration of a 150 mg dose.<|human|>Adverse Effects and Tolerability:The highest rates were reported in 86.3% of the patients with the highest incidence of Levetiracetam (96.3%), Lamotrigine (85.2%), and Valproate (76.9%). The trend is not statistically significant, but it indicates that new AEDs may not necessarily improve the tolerability. The frequent side effects were neuropsychiatric side effects due to Levetiracetam, rash due to Lamotrigine, and weight gain or tremors due to Valproate.

4.3.Patient Satisfaction:
There were no significant differences in patient satisfaction by the three groups of drugs ($p = 0.956$). This shows that treatment perception is determined by other factors other than seizure control like side effects, dosing convenience and psychological response.

4.4.Duration of Hospitalization and Seizure:
Mean inpatient stay was 4.56 days, and this was not different throughout the groups. The history of seizure duration was the shortest in valproate users (mean 3.49 years), and they may stabilize faster.

4.5.Comparative Insights:
The study gives an empirical, cross-sectional comparison of Lamotrigine, Levetiracetam and Valproate Sodium in terms of seizure management, tolerability, patient experience, BMI, and hospitalization pattern. Some of the key observations are that they have high level of adverse effects, there is a weak correlation between seizure control and satisfaction, and variations between populations in the BMI and response to treatment.

4.6.Regional Relevance:
The results can be especially relevant to South Asian groups as genetic, nutritional, and health determinants, which may affect AED effectiveness and tolerability, can be used as a localized reference point in clinical decision-making.

5.CONCLUSION

The current study provides the multiplex analysis of comparative efficacy, safety profile, and patient satisfaction related to three antiepileptic drugs (AEDs) that are frequently prescribed Lamotrigine, Levetiracetam, and Valproate Sodium. This study was undertaken in a real-life clinical environment to fill the gap between data provided by clinical trials and the real life experience with a patient with the ultimate aim to guide informed individualized approaches to managing epilepsy.
The results demonstrate that the three AEDs all play a role in statistically significant decrease in frequency of seizures, which supports their clinical importance in the treatment of epilepsy. But there was considerable variation among the treatment groups in the level of seizure control. Valproate Sodium turned out to be the best medication, whose effect was better in reducing seizures than Lamotrigine and Levetiracetam. The other study cohort also showed that Lamotrigine performed the least in seizure control compared to Levetiracetam, which outperforms the former.
Although Valproate is better in terms of efficacy, its use was characterized by a moderately high rate of adverse effects. Interestingly, Levetiracetam was the one that had the most cases of adverse effects with 96.3%cases reported by users of the drug. They consisted of a range of neuropsychiatric symptoms with the need to be carefully followed. Although Lamotrigine was not as useful in managing seizures, it had a relatively better side effects profile in certain situations. Nevertheless, the incidence of adverse effects did not differ between the three drug clusters, which did not provide any statistically significant difference and indicated that the problem of tolerability is common among AED classes and can be different in individual cases.
Among the more vivid results of the given study, the absence of statistically significant correlation between the prescribed drug and patient satisfaction should be mentioned. Most of the respondents said that they were neutral about their treatment irrespective of the kind of drug they were given. This lack of alignment between clinical and subjective satisfaction highlights the relevance of adding patient-reported outcomes and quality-of-life indicators into standard epilepsy care.
Other parameters such as BMI, the length of stay in hospital, and the history of seizures depicted some slight but significant patterns. The highest BMI was reported in patients on Levetiracetam whereas a shorter duration of seizures was reported in patients on Valproate. The mean length of stay (4.56 days) was actually the same in all drug groups and so the

need of inpatient stabilization was the same regardless of the AED used.

The research is also a source of new knowledge as it presents population specific data especially to the South Asian population. Since the majority of the current literature on AED is founded on Western populations, the results obtained in this paper provide useful localized information, which can be used to inform clinical practices in low-socioeconomic and genetic settings.

To sum up, Valproate Sodium is a very useful antiepileptic medication that is comparatively better tolerated than thought and must be prescribed when it is a first-line choice and provided that it is clinically justified. Although efficacious, levetiracetam has a high potential in adverse effects and thus should be carefully monitored. Even though Lamotrigine is linked to fewer serious side effects, it may be a better choice when used as an adjunct therapy, or in patients that have particular types of seizure that do not respond well to other medications.

The results of this research are indicative of the fact that an individual approach towards managing epilepsy is crucially needed which extends well beyond controlling seizures in patients to the extent of tolerability, preferences and quality of life. These findings should be confirmed by further longitudinal and multicenter research to broaden the perspective on the performance of AED in different populations.

6.DECLARATION

6.1.Ethical approval and consent to participate

The Institutional Ethics Committee approved this study (IEC Approval No. ECR/288/Indt/TN/2018/RR-21/115, dated 15.11.2024). All participants were informed about the study, and written informed consent was obtained prior to participation.

6.2.Data and Material Availability

All the data used to generate and analyse in the presented study are available from the corresponding author upon reasonable request.

6.3.Conflicts of interest

The authors declare that there are no competing interests.

6.4.Contribution of the Authors

All the three authors (Author 1, Author 2, and Author 3) participated equally in the design of study, collection of data and writing the manuscript. The research was directed by the senior author and the manuscript was critically revised by him. Prior to the final manuscript, all authors read and accepted its version.

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