

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients

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ABSTRACT

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INTRODUCTION

Epilepsy represents a persistent neurological condition which causes individuals to experience uncontrollable seizures that occur without any external trigger. A seizure represents an abrupt increase in irregular brain activity which leads to temporary alterations in a person's movements and conduct and emotional state. Seizures can last only a few seconds when someone experiences a staring spell or a limb shows involuntary movements or they can become extreme when a person suffers full-body convulsions. A person who has a seizure does not automatically develop epilepsy because it requires specific medical criteria to be met. The diagnosis requires a minimum of two independent, non-febrile seizure episodes separated by an interval exceeding 24 hours.

The range of seizures extends from short attention breaks to complete body convulsions. Epilepsy affects millions of people worldwide, cutting across age, gender, and social status. The condition creates major disruptions to work, study activities, and protection of personal safety. Some people experience infrequent seizures while others face multiple daily episodes that disrupt their everyday activities.^[3]

The primary treatment for epilepsy uses medications as its main method of control. Anti-seizure drugs which doctors refer to as antiseizure medications (ASMs) function by

reducing excess brain activity which leads to decreased seizure occurrence and intensity. The treatment helps patients with epilepsy to achieve normal functioning but it does not provide a full cure. The correct medication selection requires doctors to consider seizure type which affects their choice of treatment for patients who have specific health conditions and need to avoid certain drug interactions. Some patients respond well to a single drug (monotherapy), while others may require a combination of medicine.^[5]

EPIDEMIOLOGY OF EPILEPSY

Worldwide epilepsy represents a leading global neurological burden, with an estimated prevalence ranging from 50 to 52 million people worldwide. The active epilepsy rate throughout the world shows that 0.5 to 0.7 percent of people during any moment experience the condition which different age groups and geographic areas show different prevalence levels. The majority of these cases occur in low-income and middle-income countries. The healthcare system in resource-limited regions faces extreme challenges because millions of new cases emerge each year to create additional patient demands.

The Indian population experiences epilepsy as a critical public health challenge which affects approximately 10 to 12 million people and creates one-sixth of the global epilepsy burden. Research studies show that the Indian

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population experiences epilepsy at a rate between 3 and 12 cases per 1000 people which results in approximately 0.3 to 1.2 percent of the population experiencing the condition at

TYPES OF EPILEPSY/SEIZURE

any given moment. The country reports new case rates that match this pattern because rural areas and underprivileged populations experience higher rates of new cases.

Type	Subtype	Description
Focal Seizures	Focal Aware Seizures	Seizures limited to one area of the brain with preserved awareness; may involve motor or sensory symptoms.
	Focal Impaired Awareness	Seizures start in one area, with impaired awareness; may involve automatisms (e.g., lip-smacking).
Generalized Seizures	Absence Seizures	Brief episodes of staring or loss of awareness; commonly seen in children.
	Tonic-Clonic Seizures	Involves loss of consciousness, stiffening of muscles (tonic), followed by rhythmic jerking (clonic).
	Myoclonic Seizures	Sudden, brief muscle jerks involving part or all of the body. ^[8]
	Tonic Seizures	Sudden stiffening of muscles, often affecting the back, arms, and legs.
	Atonic Seizures	Sudden loss of muscle tone, leading to falls ("drop attacks").
	Clonic Seizures	Repetitive, rhythmic muscle jerking, typically bilateral.

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Unknown Onset	Seizures of Unclear Origin	Seizures whose onset is unclear or not witnessed.
Epilepsy Syndromes	Lennox-Gastaut Syndrome	Severe epilepsy with multiple seizure types and intellectual disability.
	Juvenile Myoclonic Epilepsy	Characterized by myoclonic seizures, often after waking up, in teens or young adults.
	Dravet Syndrome	Rare genetic epilepsy beginning in infancy, resistant to treatment, with various seizure types. ^[9]

PATHOGENESIS

1.Neuronal Hyperexcitability

The main issue in epilepsy results from excessive neuronal activity which makes brain cells (neurons) more likely to experience uncontrolled firing. Neurons use electrical signals which their system regulates to communicate with each other. The epileptic condition results in disrupted neural equilibrium which leads to irregular and simultaneous neuronal discharges. Various factors including genetic mutations and brain injuries and chemical imbalances lead to a decreased threshold which enables abnormal brain activity to occur. Different types of epilepsy allow hyperexcitable neurons to initiate localized seizures or to expand their effects throughout the entire brain.

2.Imbalance Between Excitatory and Inhibitory Neurotransmitters

Seizures occur in epileptic patients due to malfunctioning neurotransmitter systems which fail to maintain proper balance between excitation and inhibition. Neurons increase their activity when glutamate, which functions as the primary excitatory neurotransmitter, produces its effects while gamma-aminobutyric acid (GABA) serves to inhibit neuronal activity. Epileptic conditions result from excessive glutamate activation together with insufficient GABA activation, which creates uncontrollable brain electrical activities. All genetic factors and brain injuries and infections and metabolic disturbances create an impact on this particular functional deficiency. The majority of anti-seizure drugs work by either strengthening GABA's ability to inhibit brain activity or decreasing glutamate's power to activate brain functions.

RISK FACTORS

Category	Specific Factors
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3.Ion Channel Dysfunction in Epilepsy

Sodium channels, potassium channels and calcium channels function as ion channels which manage the movement of charged ions through neuronal membranes. The genetic mutations together with acquired damage to these channels result in their malfunction which causes neurons to fire improperly in epilepsy. The excessive activity of sodium channels leads to prolonged neuronal activity which results in repetitive discharges that cause seizures. Lacosamide functions as a sodium channel stabilizer which prevents excessive neuronal firing through its mechanism of action. The study of ion channel dysfunction allows medical professionals to determine which anti-seizure medications will most effectively treat patients according to their specific epilepsy mechanisms.^[12]

4.Structural and NetworkAbnormalities

Seizures can occur because of structural or network-level brain abnormalities. Seizures develop when brain circuits become abnormal due to cortical malformations and tumors and strokes and infections and traumatic brain injuries. Genetically determined epilepsy develops hyperexcitable neuron networks which enable abnormal electrical activity to spread throughout the brain. The structural and network alterations in the brain enable abnormal circuits to sustain their discharge activity, which leads to treatment-resistant seizures. Advanced imaging techniques such as MRI and functional studies assist in detecting these alterations which establish the foundation for creating treatment procedures.^[13]

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Genetic Factors	- Mutations in genes affecting ion channels, neurotransmitter systems, or synaptic function.
	- Genetic syndromes such as Dravet syndrome, Lennox-Gastaut syndrome, and juvenile myoclonic epilepsy.
Structural Causes	- Congenital brain malformations (e.g., cortical dysplasia, heterotopia).
	- Brain tumors, stroke, traumatic brain injury, or neurodegenerative diseases (e.g., Alzheimer's disease).
Infections	- Central nervous system (CNS) infections like meningitis, encephalitis, neurocysticercosis, and brain abscess.
Immune-Mediated Causes	- Autoimmune encephalitis (e.g., anti-NMDA receptor encephalitis).
	- Inflammatory conditions like multiple sclerosis. ^[14]
Metabolic Disorders	- Hypoglycemia, hyperglycemia, hyponatremia, hypernatremia, hypocalcemia, or uremia.
Perinatal/Neonatal Factors	- Hypoxic-ischemic encephalopathy, birth trauma, or neonatal infections.
	- Maternal substance abuse or malnutrition.
Toxic or Drug-Induced	- Drug withdrawal (e.g., alcohol, benzodiazepines).
	- Toxic exposures (e.g., heavy metals, carbon monoxide).
Idiopathic	- Cases where no identifiable cause is found, often presumed to be genetic or functional. ^[15]

DIAGNOSIS 1. Clinical History and Seizure Description
The diagnosis process requires a comprehensive seizure history which includes information about when the seizures began and how long they lasted and what factors triggered the seizures and what symptoms appeared before and during and after the seizures. Eyewitness accounts provide essential information because patients often forget their episodes. The assessment process involves evaluating family history and head injuries and infections and other medical conditions to determine the patient's seizure type which will influence their treatment plan.

2. Neurological Examination

The neurological exam evaluates brain and nerve function through tests that measure reflexes and motor abilities and sensory perception and coordination and

mental processing. The results of the examination show structural brain damage or epilepsy symptoms which result from brain injuries or tumors or strokes.

3. Electroencephalography (EEG)

Scalp electrodes record the electrical activity of the brain through the EEG system. Seizure predisposition shows itself through abnormal patterns that include spike and sharp wave disturbances. The EEG test allows doctors to determine the type and location of the seizure while predicting its future development. A normal EEG test result does not exclude the possibility of epilepsy.

4. Imaging Studies

Neuroimaging identifies structural brain causes of epilepsy. MRI produces high-resolution brain scans that show detailed brain tissue information and enable the detection of tumors and malformations and scarring. CT

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is used in emergencies. The imaging process distinguishes between symptomatic epilepsy and idiopathic epilepsy while determining surgical and interventional treatment methods for patients who do not respond to medication.

5.Laboratory and Other Tests

Blood tests check for metabolic issues infections or electrolyte imbalances that may trigger seizures. Genetic testing identifies inherited epilepsy syndromes. Medical staff use cardiac monitoring to evaluate patients who experience fainting episodes. The combination of history examination, EEG and imaging tests enables accurate diagnosis and correct seizure classification and personalized treatment development.^[17]

TREATMENT 1.Anti-Seizure Medications (ASMs)

Anti-seizure medications (ASMs) function as the primary treatment for epilepsy. The common medications include levetiracetam and lacosamide and valproate and carbamazepine and lamotrigine. The initial treatment should use monotherapy because it leads to fewer side effects and simpler medication management but patients with treatment-resistant cases will require combination therapy. The selection of treatment depends on the specific seizure type of the patient and their current age and existing medical conditions and potential drug interactions.

2.Lifestyle and Self-Management

Individuals with epilepsy need both medication and self-management techniques which include lifestyle changes to control their condition. Seizure frequency decreases when people maintain their regular sleep patterns and practice stress management techniques and complete exercise routines while staying away from all known seizure triggers. Patients and doctors' benefit from seizure diary documentation because it enables them to identify seizure patterns and triggers which help in developing customized treatment plans.

3.Surgical Treatment

Patients who have drug-resistant epilepsy receive surgical treatment which works best for focal epilepsy because their seizures originate from particular brain areas. The surgical options available to patients include resection which involves removing the seizure focus and disconnection procedures. The team conducts pre-surgical evaluation through EEG tests and MRI scans and functional imaging assessments to find the exact location of the epileptogenic area.

LEVETIRACETAM

Levetiracetam was first developed in the 1990s as a novel anti-seizure medication and approved for clinical use in the early 2000s. The compound functions as a synthetic derivative of the neurotransmitter pyrrolidone which possesses a different molecular structure from existing anti-epileptic medications. The developers created the medication to deliver successful treatment results while generating fewer adverse effects and exhibiting no major drug interaction issues. Levetiracetam started its research process as a potential treatment for persistent epilepsy but now doctors use it as the main treatment for focal

seizures and as a supplementary treatment for generalized seizures. The medication has achieved rapid global usage because its pharmacokinetic properties and simple dosing method and wide-ranging treatment effectiveness make it suitable for both adult and pediatric patients.^[27]

Mechanism of Action

The neurotransmitter release process is controlled through the protein synaptic vesicle protein 2A (SV2A) which serves as a selective binding target for levetiracetam. The medication controls nerve cell activity through its SV2A brain protein effects which prevent excessive brain cell activity that causes seizures. The drug exhibits anti-epileptogenic effects which decrease the risk of seizures spreading throughout the body. The special mechanism of levetiracetam enables its simultaneous use with other anti-seizure treatments because it does not produce harmful drug interactions or increased toxicity.

Efficacy

Levetiracetam has demonstrated high efficacy in controlling both focal and generalized seizures. Clinical trials show that as monotherapy, it achieves seizure freedom in 40–60% of patients with focal epilepsy and it reduces seizure frequency when used as adjunctive therapy. The treatment shows effectiveness to both children and elderly patients and to individuals with treatment-resistant epilepsy. Studies suggest that levetiracetam acts quickly, with rapid onset of action, and maintains consistent seizure control over long-term use.

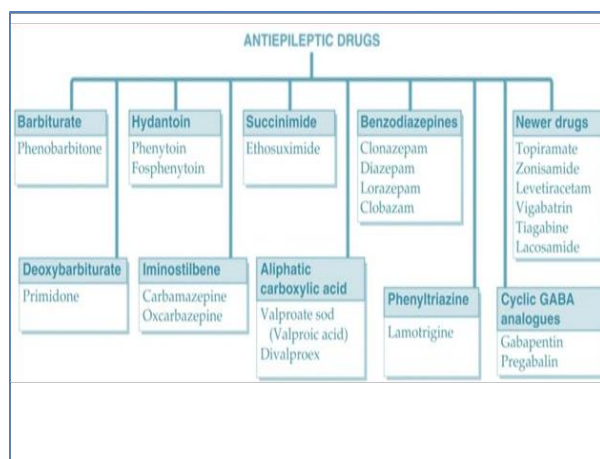
Safety and Tolerability

Levetiracetam provides better safety for patients because it produces fewer adverse effects than traditional anti-seizure drugs which were developed before it. The common side effects of the medication include fatigue and dizziness and headache and irritability and mild behavioral changes. Serious side effects occur infrequently but they can lead to mood disturbances and allergic reactions. The medication has minimal drug interactions which make it appropriate for patients who take multiple drugs. The drug remains safe for patients with liver dysfunction because it primarily excretes through the kidneys and undergoes minimal liver metabolic processes.

LACOSAMIDE

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Lacosamide is a new-generation anti-seizure medication



first developed in the early 2000s and approved for clinical use in 2008. The medication was created to achieve new treatment methods which also provided safe treatment results. Lacosamide began as a secondary treatment option for patients who experienced uncontrolled focal epilepsy but later received approval for use as a standalone treatment for focal-onset seizures. The compound functions as a synthetic amino acid derivative which shows fundamental structural differences from existing anti-seizure medications. The drug development process aimed to create a treatment which would succeed with patients who did not respond to standard medical treatments while maintaining minimal side effects and drug interaction possibilities.

Mechanism of Action

The mechanism of action for lacosamide involves its ability to enhance the sodium channels' slow inactivation process which results in hyperexcitable neurons becoming stable while their normal electrical activity remains intact. The mechanism functions by blocking repeated neuron discharges which lead to seizures while maintaining normal brain activity. Lacosamide operates differently from most sodium channel blockers because it does not interfere with fast inactivation which leads to a lower chance of neurotoxic effects. The medication demonstrates effectiveness against refractory epilepsy because of its ability to protect the brain and control the electrical activity of neurons

Efficacy

Lacosamide has shown effective results in decreasing seizure occurrences in both adult and pediatric patients who have focal epilepsy. The clinical trials show that the treatment results in more than 50 percent seizure decrease for 40 to 60 percent of patients with some patients achieving total seizure control. Lacosamide shows effectiveness for refractory epilepsy because patients can achieve results after they have already tried multiple treatment options and they can continue to benefit from the drug through extended use. The studies show that the drug starts working quickly and its drug absorption patterns are easy to predict which helps doctors to determine the correct dosage.

Safety and Tolerability

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RATIONALE FOR COMBINATION THERAPY

Patients who fail to control their seizures through monotherapy are treated with combination therapies that include both levetiracetam and lacosamide. The rationale for this combination arises from their opposing mechanisms of action which involve levetiracetam suppressing neurotransmitter release through its modulation of synaptic vesicle protein 2A and lacosamide blocking sodium channels to stop repeated neuronal firing. The combination produces its effects through different pathways which results in either additive or synergistic effects that enhance seizure control without causing significant extra side effects. This method enables personalized treatment for patients who experience refractory epilepsy and complex epilepsy conditions.^[1]

The drugs function together because their different mechanisms work with each other to reduce drug interactions. The combination treatment provides superior seizure management for patients who have focal or generalized epilepsy and do not respond to single-drug treatment. Their combined effect decreases hyperexcitability in various neuronal pathways which creates a scientific benefit for difficult-to- treat situations.^[36]

Efficacy

Clinical studies demonstrate that levetiracetam and lacosamide combination treatment leads to substantial seizure reduction in individuals diagnosed with pharmacoresistant epilepsy. The combination treatment results in better responder rates which show at least 50 percent reduction in seizures compared to the effects of each drug used separately. The treatment shows effectiveness for both focal and secondary generalized seizures which occur in adult and pediatric patients. The evidence shows that the treatment begins to work quickly while also providing better seizure management and fewer emergency seizures.

Safety and Tolerability of the Combination

The combination of levetiracetam and lacosamide is generally well-tolerated. The majority of adverse effects show mild symptoms which include fatigue and dizziness and headache and gastrointestinal discomfort. Behavior changes occur because of levetiracetam while patients with heart problems need cardiac monitoring for their lacosamide treatment.

QUALITY OF LIFE

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Epilepsy treatment methods directly enhance the quality of life for patients. People experience better daily life and greater independence because anti-seizure medications effectively decrease both the number of seizures and their intensity and the likelihood of sustaining injuries. Levetiracetam and lacosamide emerge as new medications because they produce fewer side effects and interact with other drugs at minimal levels while preserving cognitive and emotional functions. The combination therapy approach for treating refractory epilepsy provides patients with improved seizure control and increased life satisfaction. Effective treatment requires two components: the delivery of medical services and the adoption of healthy lifestyle practices and social support and counseling services.^[41]

FUTURE DIRECTIONS IN COMBINATION THERAPY FOR EPILEPSY

Future research on epilepsy treatment through combination therapy will use personalized treatment methods which target specific mechanisms to achieve better seizure control and enhanced patient life quality

LITERATURE REVIEW

1.Zhang Y, Wu P. 2025. Comparative study on efficacy and safety of levetiracetam and lacosamide in the treatment of epilepsy n this 2025 retrospective clinical study involving 82 epilepsy patients divided evenly into levetiracetam (LEV, n=41) and lacosamide (LCM, n=41) groups, treatment lasted 24 weeks. Both LEV and LCM significantly reduced seizure frequency and improved EEG scores, cognitive function, and quality of life compared to baseline, but LEV showed a slightly superior reduction in seizure frequency and greater improvements in cognitive outcomes than LCM. Adverse events differed between groups but were generally mild; both drugs were well tolerated with no serious safety signals. These results support both ASMs as effective options, with LEV showing modestly better efficacy.

2.Yang C. 2023. Effectiveness and safety of Lacosamide therapy for children with focal epilepsy: a real world study.

This 2023 real-world cohort study enrolled 92 children with focal epilepsy who received either lacosamide (LCM, n=46) or levetiracetam (LEV, n=46) and followed them for 12 months. There was no significant difference in mean seizure frequency at 1, 3, 6, 9, or 12 months between groups, though LCM had a superior 50% responder rate at 6 months. Both drugs maintained good safety and adherence; no serious adverse events were reported. The most commonly documented mild side effects were dizziness and somnolence, similar between groups. Overall, LCM showed comparable effectiveness and safety to LEV in pediatric focal epilepsy.

3.Salafica, G et al. 2025. Efficacy and safety of branded vs generic lacosamide in epilepsy: a retrospective real-world study

This 2025 observational study compared branded lacosamide (Vimpat) and generic (Stutan) in 60 adult epilepsy patients with focal or generalized seizures.

Patients were matched for baseline characteristics, and outcomes included seizure frequency reduction (responder rate $\geq 50\%$), adverse events, and dose adjustments. Although the branded group had a higher average dose

(275 ± 121 mg vs 168 ± 89 mg), both formulations showed comparable efficacy in seizure reduction (60.0% responder rate for Vimpat vs 43.3% for Stutan; $p=0.08$) and similar safety profiles. Most adverse reactions (minor dizziness, nausea, somnolence) were mild or moderate, reinforcing generic LCM as a valid and cost-effective alternative.

4.Xiong L, et al. 2024. Effectiveness and safety of Lacosamide in pediatric patients with epilepsy under four years: Results from a prospective cohort study in China.

A 2024 prospective Chinese cohort studied LCM in 109 children aged 1 month to 4 years receiving monotherapy or adjunctive therapy. Among 59 monotherapy patients, 75% achieved

$\geq 50\%$ seizure reduction and 56% were seizure-free at 12 months. In 50 adjunctive therapy patients, 51% had $\geq 50\%$ response and 36% achieved seizure freedom. LCM showed a high retention rate (70% monotherapy) and a favorable safety profile with 13.8% reporting adverse events, mainly somnolence. Lower baseline seizure frequency and younger age were associated with higher retention. The study supports LCM's effectiveness and safety in very young pediatric epilepsy patients.

5.Bhaumik S, Nemichandra SC, Sharma D, Gopinath M, Dave Y, Qureshi Z, Korukonda K, Kulkarni G. Real world observational study investigating clinical effectiveness and safety of lacosamide in epilepsy: ULTIMATE study.

In this 2025 multicenter retrospective cohort including 685 epilepsy patients, lacosamide (LCM) demonstrated significant seizure reduction and good tolerability when used as monotherapy and adjunctive therapy. Among focal onset seizure (FoS) patients receiving

LCM alone, 62.96% achieved $\geq 50\%$ responder rate at 12 weeks and 47.66% achieved seizure freedom ($P < 0.0001$). In primary generalized tonic-clonic seizures (pGTCS), 66.78% exhibited response and 52.16% showed seizure freedom. Combination therapy of LCM with levetiracetam (LEV) showed higher responder and freedom rates compared with LCM plus other ASMs, indicating added benefit of dual therapy. Adverse events were mild and led to few discontinuations, confirming LCM's effectiveness and safety profile.

6.Li C, et al. 2025. Antiepileptic Drug Combinations for Epilepsy: Mechanisms, Clinical Strategies, and Future Prospects.

Although not a single clinical trial, research strongly supports that combining levetiracetam (binding to SV2A to modulate neurotransmitter release) and lacosamide (enhancing slow inactivation of voltage-gated sodium channels) provides a broader spectrum of seizure inhibition than either alone. Mechanistic synergy enhances neuronal stabilization and reduces aberrant firing patterns. Clinical practice guidelines and real-world data from observational cohorts reinforce that LEV+LCM combinations improve responder rates and seizure freedom in refractory and polytherapy settings, with tolerability similar to monotherapy.

AIM AND OBJECTIVES AIM:

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients

To evaluate and compare the efficacy, safety, and tolerability of Levetiracetam and Lacosamide when used as monotherapy or in combination therapy in patients with epilepsy.

➤ **OBJECTIVES**

➤ **PRIMARY OBJECTIVES**

- To compare seizure-control efficacy among:
 1. Levetiracetam monotherapy
 2. Lacosamide monotherapy
 3. Levetiracetam + Lacosamide combination therapy.

➤ **SECONDARY OBJECTIVES**

To observe the frequency and types of adverse effects in each treatment group.

To analyze the relationship between treatment type and adverse events.

To evaluate treatment adherence across monotherapy and combination therapy.

To identify demographic or clinical factors associated with increased adverse events. ○ To assess the impact of therapy on quality of life, mood, and daily functioning.

To document any dose adjustments, discontinuations, or therapy changes due to adverse effects

METHODLOGY

STUDY SITE:

The study was conducted at the Department of Neurology, Citi Neuro Centre, Banjara Hills, Hyderabad, Telangana.

STUDY DESIGN:

This study was conducted as an ambispective observational study, incorporating both retrospective and prospective data.

STUDY DURATION:

The study was conducted over a 6-month period.

STUDY POPULATION

The study included a total of 80 patients with epilepsy.

STUDY CRITERIA:

INCLUSION CRITERIA:

Diagnosed Epilepsy of any age group

Receiving levetiracetam or lacosamide as monotherapy or as combination therapy.

Able and willing to provide informed consent.

TREATMENT GROUPS

Patients were assigned to one of three treatment groups:

Lacosamide Monotherapy – 100mg, 150 mg and 200 mg.

–

Levetiracetam Monotherapy – 750 mg, 1000 mg and 1500 mg.

Combination Therapy (Lacosamide + Levetiracetam)

–

DATA COLLECTION

EXCLUSION CRITERIA:

Who already have psychiatric disorders unrelated to epilepsy.

Pregnant and breastfeeding women.

Inability to communicate or give informed consent.

Chronological age, sex distribution, seizure phenotypes, disease duration, comorbidities, and hereditary predisposition was recorded. Patients underwent longitudinal observation for 4 months to document seizure frequency, treatment adherence, adverse effects, and quality of life. Causality of adverse occurrences was determined via the Naranjo scale, and all changes in medication dose or therapy were noted to evaluate safety and effectiveness systematically. –

DATA COLLECTION TOOLS

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1. Case Report Form (CRF):

CRFs were used to systematically record individual biometric profiles, comprehensive clinical anamnesis, seizure type, treatment details, and follow-up information. This ensured uniform data capture for both prospective and retrospective patients, facilitating accurate analysis and comparison across treatment groups.

2. NHS3 Scale (National Hospital Seizure Severity Scale):

Seizure activity was determined using the NHS3 scale, with potential values spanning a numerical continuum from 0 to 27. Elevated numerical outputs indicate increased clinical severity. This scale helped quantify clinical severity and monitor treatment effectiveness over time.

3. Naranjo Scale (Adverse Drug Reaction Assessment):

Adverse drug reactions (ADRs) were evaluated using the Naranjo scale (score 0–13): ≥ 9 = definite, 5–8 = probable, 1–4 = possible, 0 = doubtful. This standardized tool allowed objective assessment of the likelihood that a drug caused a reported reaction.

4. QOLIE-31 (Quality of Life in Epilepsy-31) Scale:

Quality of life was measured with QOLIE-31, a scale spanning from zero to one hundred, with ascending scores reflecting better well-being. It assessed multiple domains, including emotional health, cognitive function, seizure worry, and daily functioning, to evaluate treatment impact on patients' lives.

OUTCOME MEASURES

5. Treatment adherence in monotherapy and combination therapy.

Reduction in seizure frequency from baseline.

Impact on quality of life. Documentation of dose adjustments, discontinuations, or therapy changes due to adverse

Responder rate (patients achieving $\geq 50\%$ seizure reduction). effects.

Occurrence, type, and severity of adverse effects.

Association of demographic and clinical factors (age, gender, seizure type, comorbidities) with outcomes.

Relationship between drug dose and adverse effects.

COMPLETE STUDY PROCESS

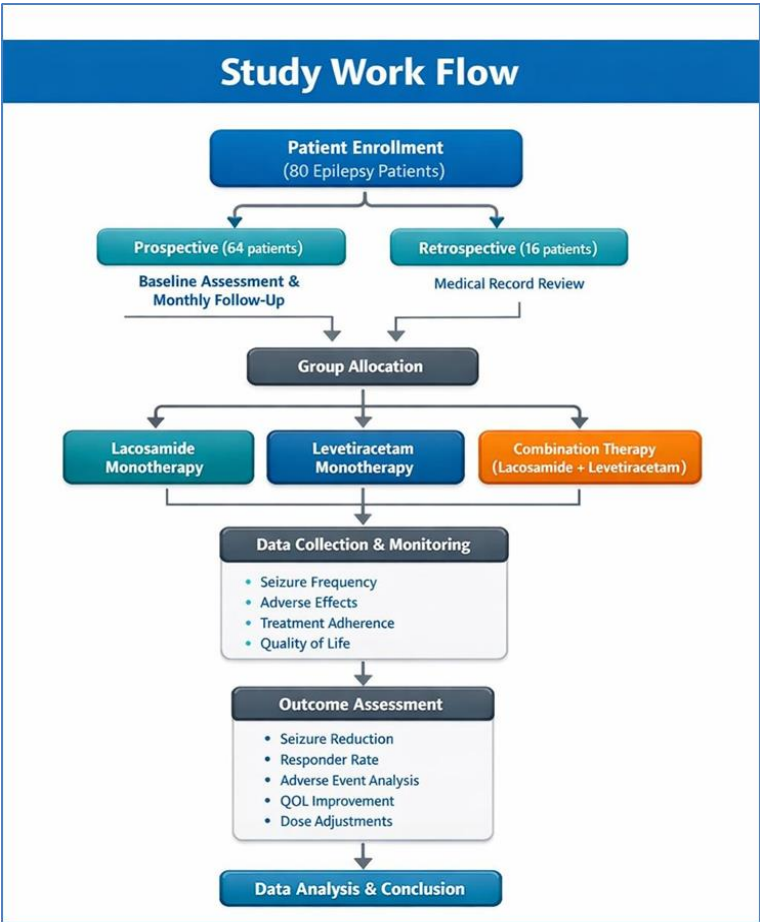
The study included 80 epilepsy patients, with 64 enrolled prospectively and 16 retrospectively. For prospective patients, baseline assessments of seizure frequency, type, severity, functional well-being, and overall health were

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done, and clinical follow-up was performed for four months to track seizure reduction, side effects, treatment adherence, and dose adjustments. Retrospective patients' medical records were reviewed to collect similar information, including seizure patterns, previous treatments, adverse effects, and demographic and clinical details. All patients received either levetiracetam or lacosamide as monotherapy, or a combination of both, using standard dosing. Outcomes from each study groups were analyzed together to evaluate treatment effectiveness, safety, and impact on daily functioning.

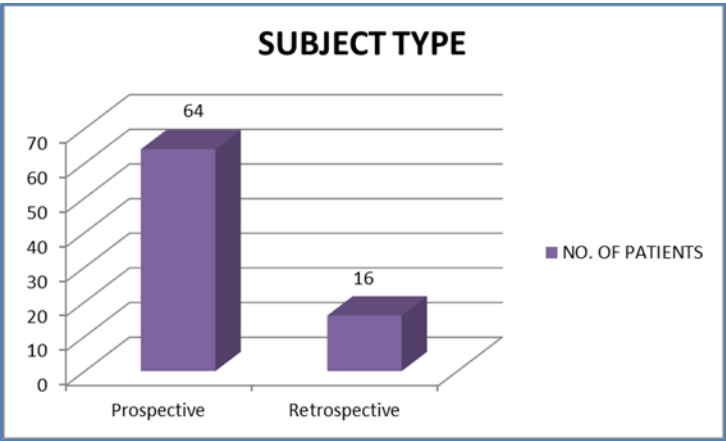
DATA ANALYSIS

Statistical evaluation was executed using SPSS version 25. Descriptive statistics such as frequency, percentage, mean, and standard deviation were employed to summarize demographic and clinical data. Inferential statistics including Chi-square test were applied to investigate degree of association between various categorical classifications, while t-test was used for comparison of two means and ANOVA for more than 2 means. A p-value of <0.05 was considered statistically significant.



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SUBJECT TYPE	NO. OF PATIENTS	PERCENTAGE(%)
Prospective	64	80.00%
Retrospective	16	20.00%



STUDYWORKFLOW

RESULTS

SUBJECT TYPE Table 1: SUBJECT TYPE

A total of 80 epilepsy patients were included in the study. Among them, 64 patients (80.00%) were enrolled prospectively and followed throughout the study period to assess treatment outcomes. The remaining 16 patients (20.00%) were included retrospectively based on previously recorded medical data of epilepsy patients receiving antiepileptictherapy.

Figure 1: Subject Type

AGE CATEGORY > GENDER
Table 2: AGE CAGETORY
Table 3: GENDER

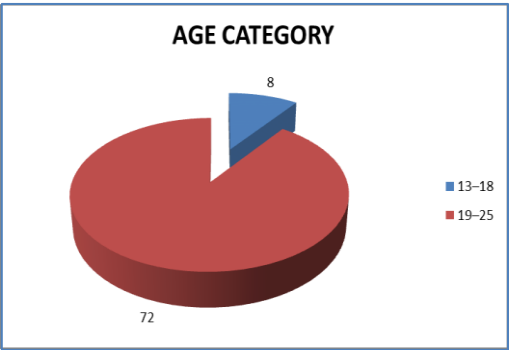
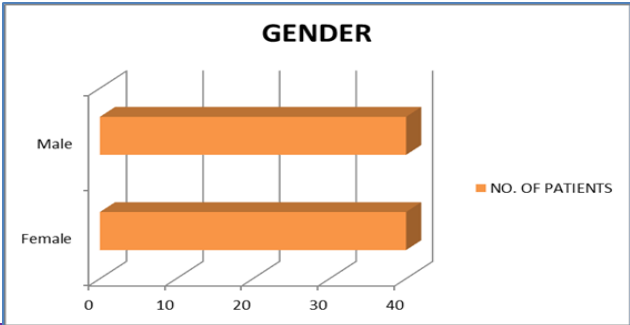


Figure2: Age Category

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GENDER	NO. OF PATIENTS	PERCENTAGE (%)
Female	40	50.00%
Male	40	50.00%

AGE CAGETORY	NO. OF PATIENTS	PERCENTAGE (%)
13–18	8	10.00%
19–25	72	90.00%

A total of 80 epilepsy patients were categorized based on age. Among ➤ A total of 80 epilepsy patients were included in the them, 8 patients (10.00%) belonged study with an equal distribution of gender. Among to the 13–18 years age group, while them, 40 patients (50.00%) were female and 40 the majority of patients, 72 patients (50.00%) were male. This equal representation (90.00%), were in the 19–25 years of both genders helps in minimizing gender-related bias age group. This indicates that most while evaluating the treatment outcomes of participants included in the study were antiepileptic therapy.

young adults receiving antiepileptic ➤ Figure 3: Gender treatment.

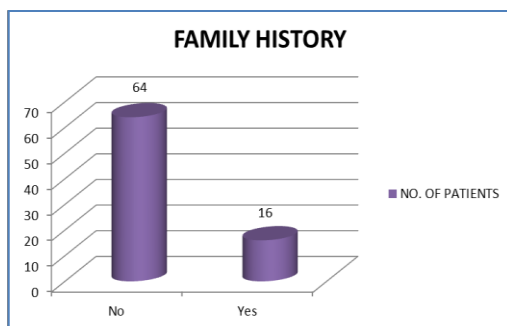
EDUCATIONAL STATUS

FAMILY HISTORY ➤

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➤ **Table 4: FAMILY HISTORY**

FAMILY HISTORY	NO. OF PATIENTS	PERCENTAGE (%)
No	64	80.00%
Yes	16	20.00%



➤ Among the 80 epilepsy patients, 64 patients (80.00%) had no family history of epilepsy, while patients (20.00%) reported positive family history. indicates that most patients in the study did not have a hereditary predisposition to epilepsy.

Figure 4: Family History

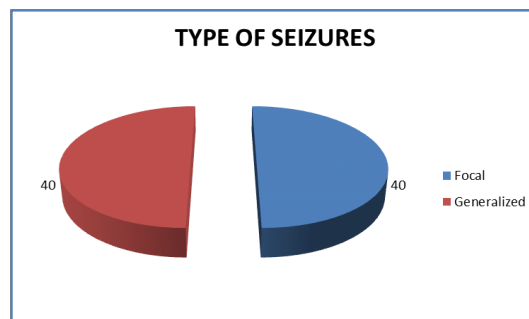
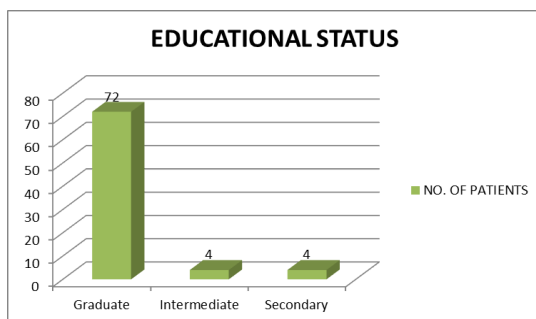


Table 5: EDUCATIONAL STATUS

EDUCATIONAL STATUS	NO. OF PATIENTS	PERCENTAGE (%)
Graduate	72	90.00%
Intermediate	4	5.00%
Secondary	4	5.00%

A total of 80 epilepsy patients were categorized according to their educational status. Among them, 72 (90.00%) were graduates. Additionally, 4 patients (5.00%) had completed intermediate education and 4 patients (5.00%) had secondary level education. This indicates that most study participants had attained a higher level of education.

Figure 5: Educational Status

TYPE OF SEIZURES

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients

Table 6: TYPE OF SEIZURES➤

TYPE OF SEIZURES	NO. OF PATIENTS	PERCENTAGE (%)
Focal	40	50.00%
Generalized	40	50.00%

Out of the total 100 patients included in the study, 64 patients (64%) did not report any additional comorbid conditions, whereas 36 patients (36%) had one or more comorbidities along with diabetes. The findings indicate that although the majority of the participants had only T2DM without other associated diseases, a considerable proportion of patients were affected by additional health conditions. The presence of comorbidities in diabetic patients may increase their vulnerability to infections and complications, particularly respiratory illnesses.

Figure 6: Type Of Seizures

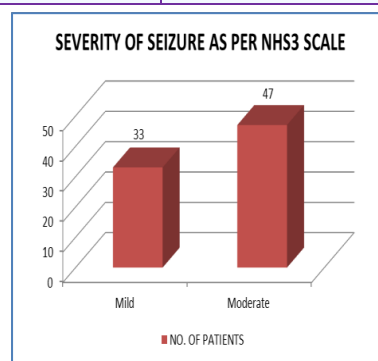
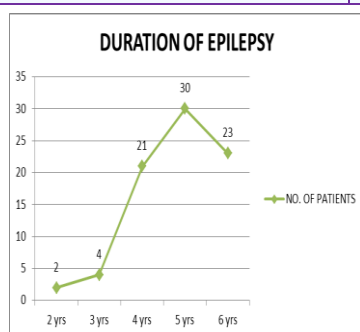
DURATION OF EPILEPSY

Table 7: DURATION OF EPILEPSY ➤ SEVERITY OF SEIZURE AS PER NHS3 SCALE

DURATION OF EPILEPSY	NO. OF PATIENTS	PERCENTAGE (%)
2 yrs	2	2.50%
3 yrs	4	5.00%
4 yrs	21	26.25%
5 yrs	30	37.50%
6 yrs	23	28.75%

Table 8: SEVERITY OF SEIZURE AS PER NHS3 SCALE

SEVERITY OF SEIZURE	NO. OF PATIENTS	PERCENTAGE (%)
Mild	33	41.25%
Moderate	47	58.75%



that most patients had chronic epilepsy with Figure 7: Duration Of Epilepsy longer duration.

TYPE OF TEATMENT GIVEN

Table 9: TYPE OF TREATMENT GIVEN

TREATMENT GIVEN AND DOSE

Table 10: TREATMENT GIVEN AND DOSE

The severity of seizures assessed using the NHS3 scale showed that a higher proportion of patients experienced moderate severity seizures, accounting for 47 patients

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Among the epilepsy patients, the duration of (58.75%), while 33 patients (41.25%) had mild severity seizures. This indicates that most patients in the study illness varied across individuals, with the majority population had moderately severe seizure presentations at having a longer disease history. Most patients, baseline, highlighting the clinical need for effective 30, had epilepsy for 5 years, followed by 23 antiepileptic treatment to achieve better seizure control and patients with a duration of 6 years. Additionally, improve patient outcomes.

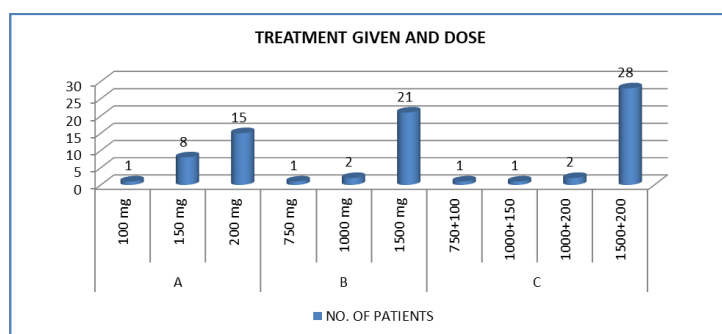
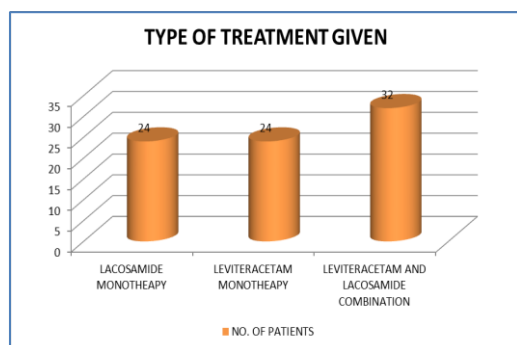
21 patients had a duration of 4 years, while only a few patients had shorter durations of 3 years (4

Figure 8: Severity Of Seizure as per NHS3 Scale patients) and 2 years (2 patients). This indicates

TREATMENT GIVEN	DOSE	NO. OF PATIENTS	PERCENTAGE (%)
A	100 mg	1	1.25%
	150 mg	8	10.00%
	200 mg	15	18.75%
B	750 mg	1	1.25%
	1000 mg	2	2.50%
	1500 mg	21	26.25%
C	750+100	1	1.25%
	1000+150	1	1.25%
	1000+200	2	2.50%
	1500+200	28	35.00%

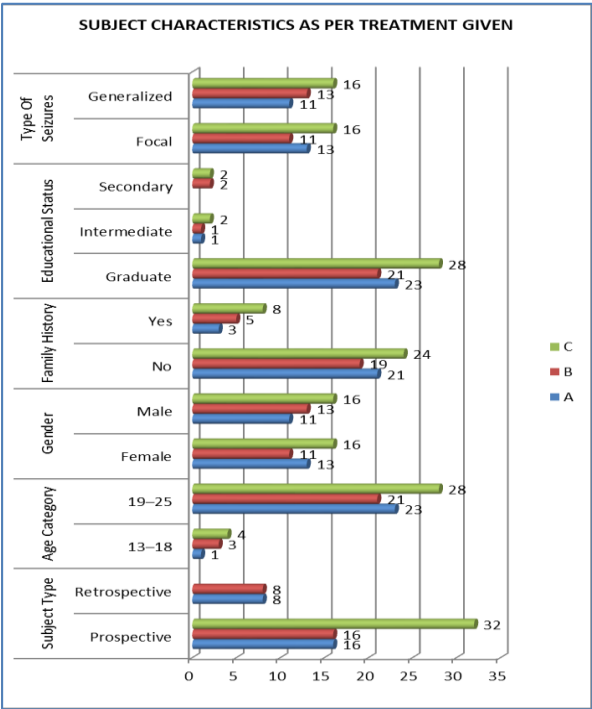
TYPE OF TREATMENT GIVEN	NO. OF PATIENTS	PERCENTAGE (%)
LACOSAMIDE MONOTHEAPY (A)	24	30.00%
LEVITERACETAM MONOTHEAPY (B)	24	30.00%
LEVITERACETAM AND LACOSAMIDE COMBINATION (C))	32	40.00%

Among the epilepsy patients, different dosing



Among the 80 epilepsy patients, 24 patients (30.00%) patterns were observed across treatment groups. received lacosamide monotherapy, 24 patientsIn the lacosamide group (A), most patients (30.00%) were treated with levetiracetamreceived 200 mg (18.75%), followed by 150 mg monotherapy, and 32 patients (40.00%) received a(10.00%). In the levetiracetam group (B), the combination of levetiracetam

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients



SUBJECT CHARACTERISTICS		A	B	C
Subject Type	Prospective	16	16	32
	Retrospective	8	8	0
Age Category	13–18	1	3	4
	19–25	23	21	28
Gender	Female	13	11	16
	Male	11	13	16
Family History	No	21	19	24
	Yes	3	5	8
Educational Status	Graduate	23	21	28
	Intermediate	1	1	2
	Secondary		2	2
Type Of Seizures	Focal	13	11	16
	Generalized	11	13	16

and lacosamide. Thismajority received 1500 mg (26.25%). In the indicates that combination therapy was morecombination group (C), most patients received commonly utilized compared to individual1500 mg + 200 mg (35.00%), indicating monotherapy regimens in the study population. preference for higher dose combination therapy.

Figure 9: Type of Treatment Given

Figure 10: Type of Treatment Given

SUBJECT CHARACTERISTICS AS PER TREATMENT GIVEN
Table 11: SUBJECT CHARACTERISTICS AS PER TREATMENT GIVEN

Among the study population, prospective subjects were equally distributed in all treatment groups, while retrospective subjects were present only in the monotherapy

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients

TIME POINT	MEAN SEIZURE FREQUENCY	STD.DEV	T TEST VALUE	P VALUE
Baseline	7.5	0.5	NA	NA
1 Month	5.5	0.5	Baseline to 1 month : 13.8564	Baseline to 1 month : 0.000
2 Month	4.5	0.5	Baseline to 2 month : 6.9282	Baseline to 2 month : 0.000
3 Month	3	0.1	Baseline to 3 month : 14.6969	Baseline to 3 month : 0.000
4 Month	2	0.1	Baseline to 4 month : 46.71	Baseline to 4 month : 0.000

groups. The majority of patients in all groups belonged to the 19–25 years age category. Gender distribution was nearly equal across groups. Most patients had no family history of epilepsy. Graduates formed the majority in all groups, and both focal and generalized seizures were evenly distributed across treatment groups.

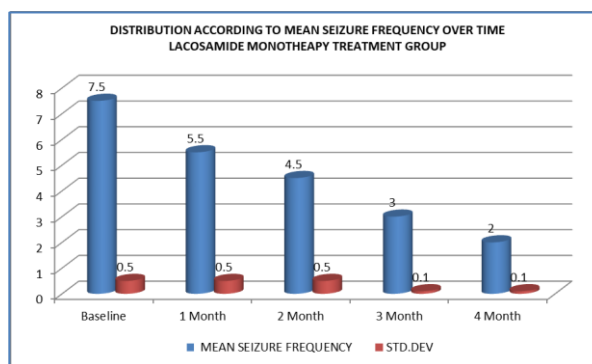


Figure 12: Distribution According to Mean Seizure

Figure 11: Subject Characteristics as Per Treatment Given

EFFICACY OUTCOMES

MEAN SEIZURE FREQUENCY OVER TIME (BASELINE VS 4 MONTH) – LACOSAMIDE MONOTHERAPY TREATMENT GROUP

Table 12: DISTRIBUTION ACCORDING TO MEAN SEIZURE FREQUENCY OVER TIME LACOSAMIDE MONOTHERAPY TREATMENT GROUP

Among patients receiving lacosamide monotherapy, a clear and steady reduction in seizure frequency was observed over the 4-month follow-up period. The mean seizure frequency decreased from 7.5 at baseline to 5.5 in the first month, and continued to decline to 4.5, 3, and finally 2 by the fourth month. The

statistical analysis using the t-test demonstrated highly significant results at all time points ($p < 0.001$).

Frequency Over Time

Lacosamide

Monotherapy

Treatment Group

MEAN SEIZURE FREQUENCY OVER TIME (BASELINE VS 4 MONTH) – LEVETIRACETAM MONOTHERAPY TREATMENT GROUP

Table 13: DISTRIBUTION ACCORDING TO MEAN SEIZURE FREQUENCY OVER TIME LEVETIRACETAM MONOTHERAPY TREATMENT GROUP

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients

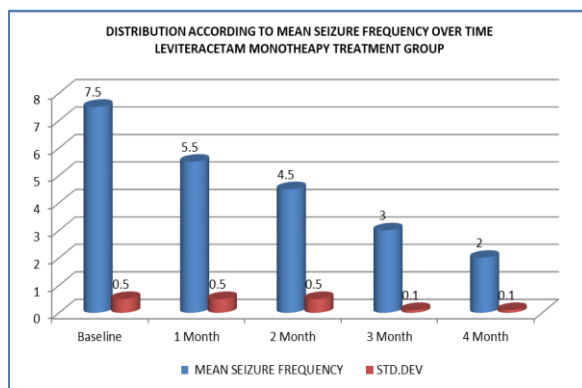


Figure 13: Distribution According to Mean

TIME POINT	MEAN SEIZURE FREQUENCY	STD.DEV	T TEST VALUE	P VALUE
Baseline	7.5	0.5	NA	NA
1 Month	5.5	0.5	Baseline to 1 month : 13.8564	Baseline to 1 month : 0.000
2 Month	4.5	0.5	Baseline to 2 month : 6.9282	Baseline to 2 month : 0.000
3 Month	3	0.1	Baseline to 3 month : 14.6969	Baseline to 3 month : 0.000
4 Month	2	0.1	Baseline to 4 month : 34.641	Baseline to 4 month : 0.000

Among patients receiving levetiracetam monotherapy, a consistent and gradual reduction in seizure frequency was observed over the 4-month follow-up period. The mean seizure frequency decreased from 7.5 at baseline to 5.5 in the first month, followed by 4.5 in the second month, 3 in the third month, and further reduced to 2 by the fourth month. The statistical analysis showed highly significant results at all time points ($p < 0.001$).

Seizure Frequency Over Time
Levetiracetam Monotherapy Treatment Group

Overall, levetiracetam monotherapy demonstrated effective seizure control and

contributed to improved patient outcomes over time.

COMPARISON OF MEAN SEIZURE REDUCTION AMONG 3 TREATMENT GROUPS

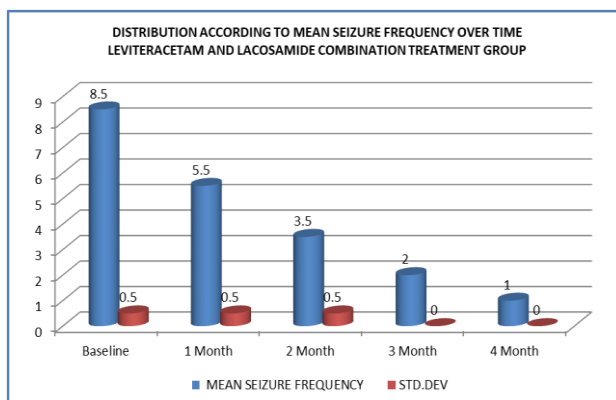
Table 15: COMPARISON OF MEAN SEIZURE REDUCTION AMONG 3 TREATMENT GROUPS

TIME POINT	A	B	C
Baseline	7.5	7.5	8.5
1 Month	5.5	5.5	5.5
2 Month	4.5	4.5	3.5
3 Month	3	3	2
4 Month	2	2	1
Baseline Vs 4 month change	5.5	5.5	7.5
ANOVA F STATISTIC	153.6		
P VALUE	0.000		

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients

MEAN SEIZURE FREQUENCY OVER TIME (BASELINE VS 4 MONTH) – LEVITERACETAM AND LACOSAMIDE COMBINATION TREATMENT GROUP

Table14: DISTRIBUTION ACCORDING TO MEAN SEIZURE FREQUENCY OVER TIME LEVITERACETAM AND LACOSAMIDE COMBINATION TREATMENT GROUP



TIME POINT	MEAN SEIZURE FREQUENCY	STD.DEV	T TEST VALUE	P VALUE
Baseline	8.5	0.5	NA	NA
1 Month	5.5	0.5	Baseline to 1 month : 24.0000	Baseline to 1 month : 0.000
2 Month	3.5	0.5	Baseline to 2 month : 16.000	Baseline to 2 month : 0.000
3 Month	2	0	Baseline to 3 month : 16.97	Baseline to 3 month : 0.000
4 Month	1	0	Baseline to 4 month : 40.0	Baseline to 4 month : 0.000

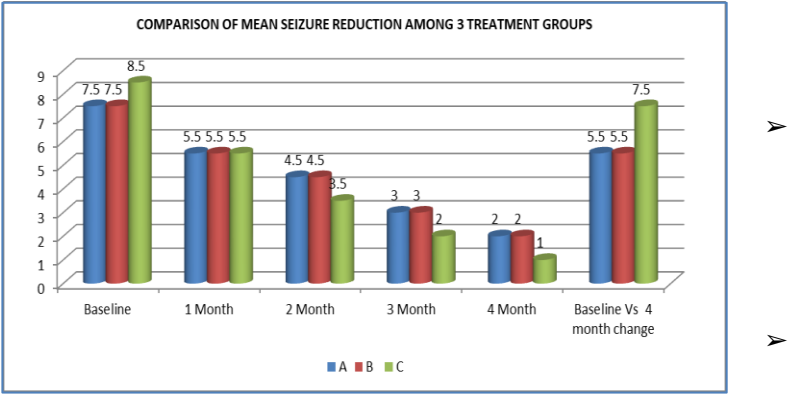
Among patients receiving the combination of levetiracetam and lacosamide, a marked and rapid reduction in seizure frequency was observed over the 4-month follow-up period. The mean seizure frequency decreased from 8.5 at baseline to 5.5 in the first month, followed by a sharper decline to 3.5 in the second month, 2 in the third month, and further reduced to 1 by the fourth month. This indicates a faster and greater

Figure 14: Distribution According to Mean Seizure Frequency Over Time Levetiracetam and Lacosamide Combination Treatment Group

improvement compared to monotherapy groups. The statistical analysis showed highly significant results at all time points ($p < 0.001$). Overall, combination therapy demonstrated superior efficacy in controlling seizures and improving clinical outcomes.

- The comparison of mean seizure frequency among the three treatment groups demonstrates a clear difference in efficacy over the 4-month follow-up period. At

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients

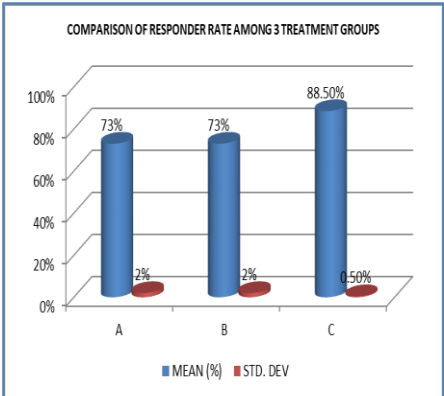


baseline, all groups had comparable seizure frequencies, with slightly higher

Figure 15: Comparison Of Mean Seizure Reduction Among 3 Treatment Groups

values observed in the combination therapy group. Over time, all groups showed a progressive reduction in seizure frequency, indicating that each treatment was effective in controlling seizures. However, the extent of reduction varied significantly among the groups. Both lacosamide (A) and levetiracetam (B) monotherapy groups showed a similar reduction of 5.5 seizures from baseline to the fourth month. In contrast, the combination therapy group (C) exhibited a greater reduction of 7.5 seizures, indicating superior efficacy. By the fourth month, the mean seizure frequency in the combination group was reduced to 1, compared to 2 in both monotherapy groups. The ANOVA test revealed a highly significant difference among the three groups ($F = 153.6$, $p < 0.001$). These findings clearly suggest that the combination of levetiracetam and lacosamide provides better seizure control compared to either drug used alone, supporting the primary objective of the study.

COMPARISON OF RESPONDER RATE AMONG 3 TREATMENT GROUPS
Table 16: COMPARISON OF RESPONDER RATE AMONG 3 TREATMENT GROUPS



RESPONDER RATE	A	B	C
MEAN (%)	73 %	73 %	88.5 %
STD. DEV	2 %	2 %	0.5 %
ANOVA F STATISTIC	926.168		
P VALUE	0.0000		

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients

Responder rate was used in this study to evaluate the proportion of patients achieving a clinically meaningful reduction in seizure frequency. Patients who achieved a $\geq 50\%$ reduction in seizure frequency from baseline after 4 months of treatment were classified as responders, while those with $< 50\%$ reduction or no improvement were considered non-responders.

Based on this criterion, both lacosamide (A) and levetiracetam (B) monotherapy groups showed a mean responder rate of 73%, indicating that a majority of patients responded well to single-drug therapy. In contrast, the combination therapy group (C) demonstrated a higher responder rate of 88.5%, reflecting superior effectiveness in achieving seizure control. The low standard deviation in the combination group suggests consistent outcomes among patients.

COMPARISON OF QUALITY OF LIFE (QOL) AMONG 3 TREATMENT GROUPS

Table 17: COMPARISON OF QUALITY OF LIFE (QOL) AMONG 3 TREATMENT GROUPS

The comparison of quality of life (QoL) among the three treatment groups shows a significant improvement over the 4-month study period. At baseline, all groups had nearly similar QoL scores, around 50%, indicating moderate impairment in daily functioning due to epilepsy. After 4 months of treatment, QoL improved in all groups, reflecting the positive impact of seizure control on patients' overall well-being.

In the lacosamide (A) and levetiracetam (B) monotherapy groups, QoL scores increased to 77.29% and 77.08% respectively, showing

The ANOVA analysis revealed a highly significant difference among the

three groups ($F = 926.168$, $p < 0.001$), confirming that the higher responder rate observed in the combination therapy group is statistically significant. These findings indicate that combination therapy provides better clinical response compared to monotherapy in epilepsy management.

Figure 16: Comparison Of Responder Rate Among 3 Treatment Groups

TIME POINT		A	B	C
Baseline	QOL MEAN (%)	50.12	50.75	49.62
	STD. DEV	1.012	1.330	0.992
4 Month	QOL MEAN (%)	77.29	77.08	91.62
	STD. DEV	1.13	1.52	1.16
Baseline Vs 4 month change	QOL MEAN (%)	-27.16	-26.33	-42.0
	STD. DEV	0.47	0.47	0.5
ANOVA F STATISTIC		9621.8		
P VALUE		0.0000		

comparable improvement. However, the combination therapy group (C) demonstrated a much greater increase in QoL, reaching 91.62%, indicating a higher level of patient satisfaction and better daily functioning.

The mean change in QoL from baseline was higher in the

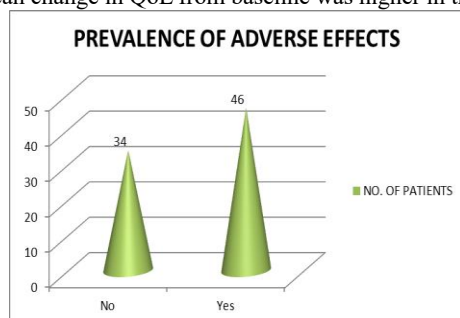
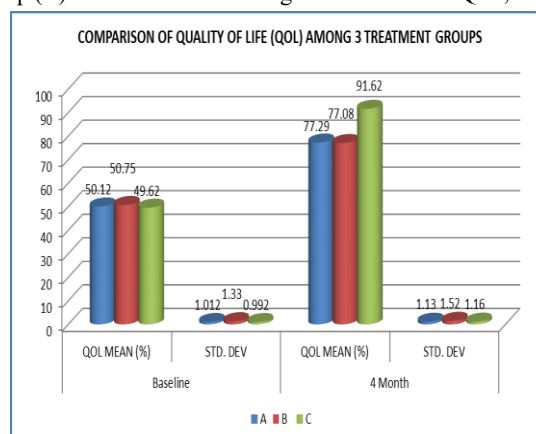


Figure 17: Comparison Of Quality of Life (QOL) Among 3 Treatment Groups



combination group (42.0%) compared to monotherapy groups (27.16% and 26.33%). The ANOVA test showed a highly significant difference among the groups ($F = 9621.8$, $p < 0.001$), confirming that the improvement in QoL is significantly

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients

SAFETY OUTCOMES superior

PREVALENCE OF ADVERSE EFFECTS

Table 18: PREVALENCE OF ADVERSE EFFECTS quality of life out

greater with combination therapy. These findings suggest that better seizure control with combination therapy translates into

ADVERSE EFFECT	NO. OF PATIENTS	PREVALENCE
No	34	42.50%
Yes	46	57.50%

Among the study population, the prevalence of adverse effects was observed in 46 patients (57.50%), while 34 patients (42.50%) showed no adverse effects. This indicates a higher prevalence of side effects among patients receiving antiepileptic therapy, emphasizing the need for careful monitoring of drug safety and patient

Figure 18:Prevalence of Adverse Effects tolerability during treatment.

PREVALENCE OF ADVERSE EFFECTS AMONG 3 TREATMENT GROUPS

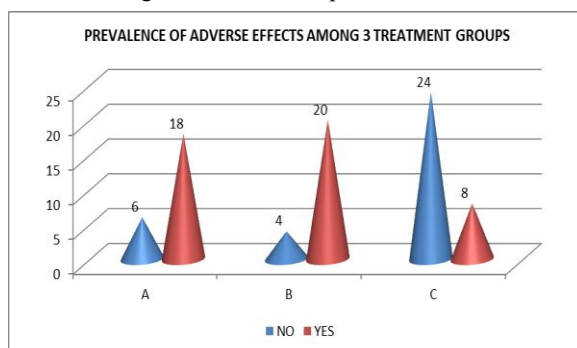
Table 19: PREVALENCE OF ADVERSE EFFECTS AMONG 3 TREATMENT

ADVER SE EFFE CT	A	B	C	CHI SQAUR E VALUE	P VALUE
NO	6	4	24	23.393	0.000
YES	18	20	8		
PREVALENCE	22.50%	25.00%	10.00%	NA	NA

GROUPS

Among the three treatment groups, the prevalence of adverse effects was higher in the monotherapy groups compared to the combination group. Lacosamide (A) showed a prevalence of 22.50%, while levetiracetam (B) had a slightly higher prevalence of 25.00%. In contrast, the combination therapy group (C) demonstrated a much lower prevalence of adverse effects at 10.00%. The Chi-square analysis revealed a highly significant difference among the groups ($\chi^2 = 23.393$, $p < 0.001$), indicating that the reduced prevalence of adverse effects in the combination group is statistically significant. These findings suggest that combination therapy is better tolerated compared to monotherapy.

Figure 19:Prevalence of Adverse Effects Among 3 Treatment Groups



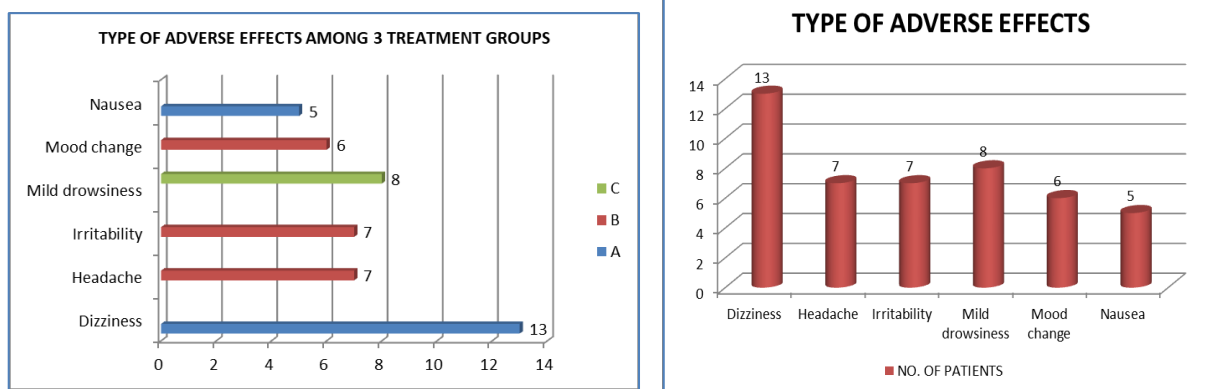
➤ TYPE OF ADVERSE EFFECTS ➤ TYPE OF ADVERSE EFFECTS AMONG 3
TREATMENT GROUPS ➤ Table 20: TYPE OF ADVERSE EFFECTS ➤ Table 21: TYPE OF
ADVERSE EFFECTS AMONG 3 TREATMENT GROUPS

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients

TYPE OF ADVERSE EFFECT	NO. OF PATIENTS	PREVALENCE
Dizziness	13	28.26%
Headache	7	15.22%
Irritability	7	15.22%
Mild drowsiness	8	17.39%
Mood change	6	13.04%
Nausea	5	10.87%

Among the reported adverse effects, dizziness was the most common, observed in 13 patients (28.26%). This was followed by mild drowsiness in 8 patients (17.39%). Headache and irritability were reported equally in 7 patients each (15.22%), while mood changes were seen in 6 patients (13.04%). Nausea was the least common adverse effect, observed in 5 patients (10.87%). This indicates that most adverse effects were mild to moderate in nature.

Figure 20: Type of Adverse Effects



Among the different treatment groups, the pattern of adverse effects varied distinctly. In the lacosamide group (A), dizziness (13 patients) and nausea (5 patients) were commonly reported. In the levetiracetam group (B), headache (7 patients), irritability (7 patients), and mood changes (6 patients) were observed. In contrast, the combination group (C) showed only mild drowsiness (8 patients) as the reported adverse effect. This indicates that monotherapy groups experienced a wider range of adverse effects, whereas the combination therapy group had fewer and milder adverse effects, suggesting better tolerability.

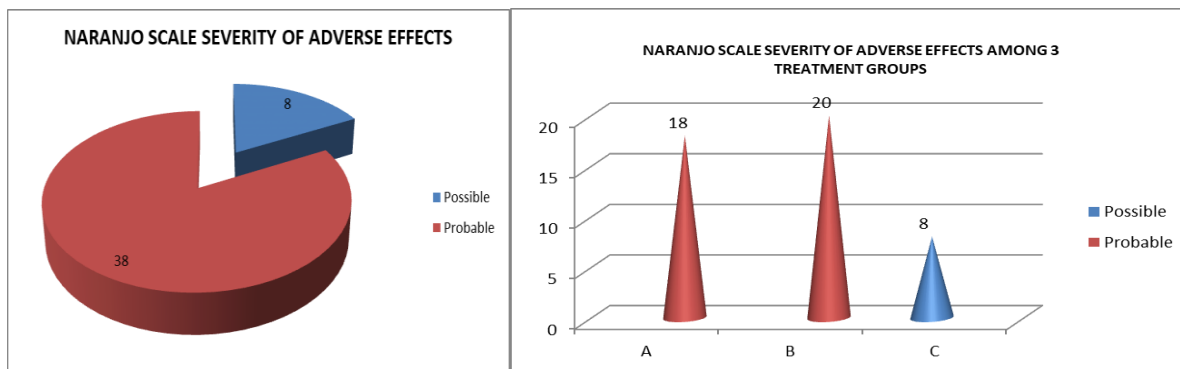
Figure 21: Type of Adverse Effects Among 3 Treatment Groups

NARANJO SCALE SEVERITY OF ADVERSE EFFECTS

Table 22: NARANJO SCALE SEVERITY OF ADVERSE EFFECTS

NARANJO SCALE SEVERITY	NO. OF ADVERSE EFFECTS	PERCENTAGE (%)
Possible	8	17.39%
Probable	38	82.61%

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients



Among the reported adverse effects, the majority were classified as probable according to the Naranjo scale, accounting for 38 cases (82.61%), indicating a strong likelihood of association with the treatment drugs. The remaining 8 cases (17.39%) were categorized as possible, suggesting a lower level of certainty. This reflects a significant drug-related contribution to the observed adverse effects.

Figure 22: Naranjo Scale Severity of Adverse Effects

NARANJO SCALE SEVERITY OF ADVERSE EFFECTS AMONG 3 TREATMENT GROUPS

Table 23: NARANJO SCALE SEVERITY OF ADVERSE EFFECTS AMONG 3 TREATMENT GROUPS

NARANJO SCALE SEVERITY	A	B	C
Possible	0	0	8
Probable	18	20	0

Among the three treatment groups, the severity of adverse effects based on the Naranjo scale showed a distinct pattern. In both lacosamide (A) and levetiracetam (B) monotherapy groups, all reported adverse effects were classified as probable, indicating a strong association with the drugs. In contrast, in the combination therapy group (C), all adverse effects were categorized as possible, suggesting a lower certainty of drug-related causality. This indicates that adverse effects in the

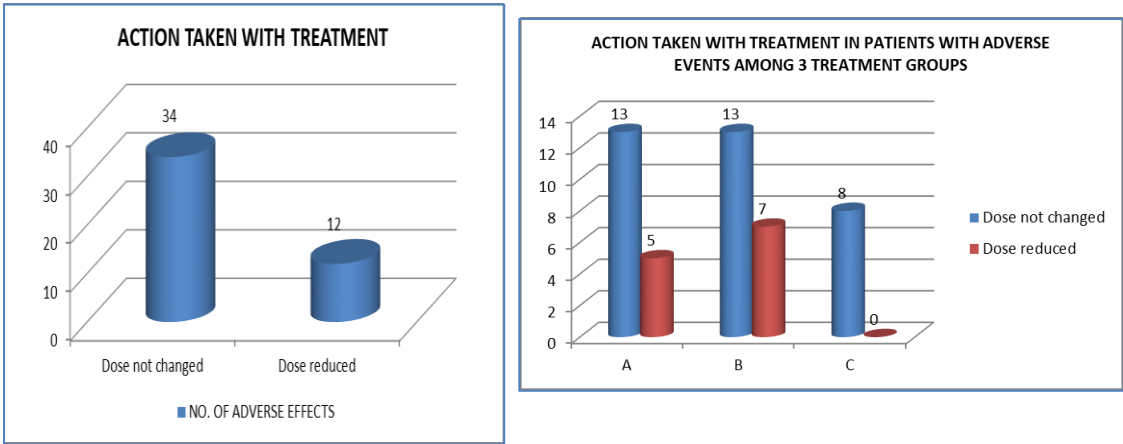
Figure 23: Naranjo Scale combination group were less likely to be strongly Severity of Adverse linked to the medications, reflecting better safety Effects Among 3 Treatment Groups and tolerability compared to monotherapy groups.

ACTION TAKEN WITH TREATMENT IN PATIENTS WITH ADVERSE EVENTS

Table 24: ACTION TAKEN WITH TREATMENT IN PATIENTS WITH ADVERSE EVENTS

ACTION TAKEN WITH TREATMENT	NO. OF ADVERSE EFFECTS	PERCENTAGE (%)
Dose not changed	34	73.91%
Dose reduced	12	26.09%

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients



Among the patients who experienced adverse effects, the majority did not require any change in their treatment regimen, with 34 cases (73.91%) continuing on the same dose. However, in 12 cases (26.09%), the dose was reduced to manage the adverse effects. This indicates that most adverse events were mild and manageable without major modification of therapy.

Figure 24: Action Taken with Treatment in Patients with Adverse Events

ACTION TAKEN WITH TREATMENT IN PATIENTS WITH ADVERSE EVENTS AMONG 3 TREATMENT GROUPS

Table 25: ACTION TAKEN WITH TREATMENT IN PATIENTS WITH ADVERSE EVENTS AMONG 3 TREATMENT GROUPS

ACTION TAKEN WITH TREATMENT	A	B	C
Dose not changed	13	13	8
Dose reduced	5	7	0

Among the three treatment groups, most patients with adverse effects continued their treatment without any dose modification. In the lacosamide (A) and levetiracetam (B) groups, 13 patients each had no change in dose, while dose reduction was required in 5 and 7 patients respectively. In contrast, in the combination therapy group (C), all patients continued without dose reduction, indicating better tolerability and milder adverse effects.

Figure 25: Action Taken with Treatment in Patients with

Evaluating The Efficacy Of Levetiracetam And Lacosamide As Monotherapy And Levetiracetam+ Lacosamide Combination Therapy Among Epilepsy Patients

TREATMENT GROUP	DOSE	NO ADVERSE EFFECT	ADVERSE EFFECT	CHISQUARE VALUE	P VALUE
A	100 mg	0	1	0.355	0.837
	150 mg	2	6		
	200 mg	4	11		
B	750 mg	0	1	1.885	0.389
	1000 mg	1	1		
	1500 mg	3	18		
C	750+100	1	0	1.333	0.721
	1000+150	1	0		
	1000+200	1	1		
	1500+200	21	7		

RECOVERED STATUS	NO. OF ADVERSE EFFECTS	PERCENTAGE (%)
RECOVERED	46	100 %

RECOVERED STATUS IN PATIENTS WITH ADVERSE EFFECTS

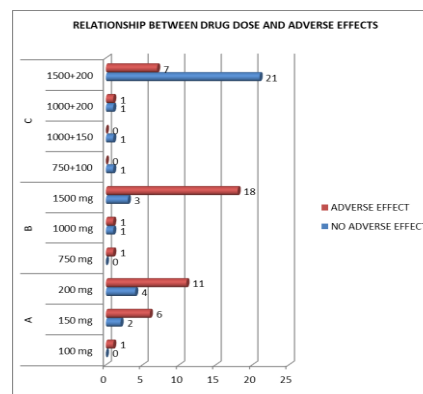
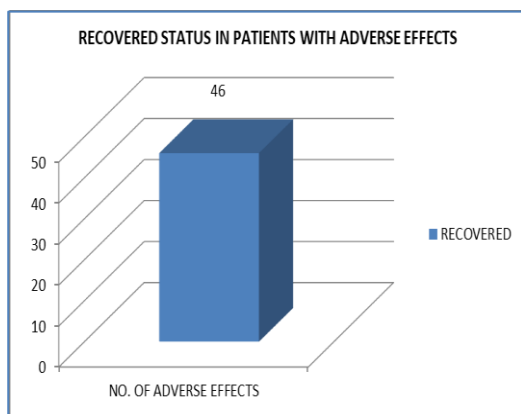
Table 26: RECOVERED STATUS IN PATIENTS WITH ADVERSE EFFECTS

RELATIONSHIP BETWEEN DRUG DOSE AND ADVERSE EFFECTS

Table 27: RELATIONSHIP BETWEEN DRUG DOSE AND ADVERSE EFFECTS

Among the patients who experienced adverse effects, all cases (46, 100%) showed complete recovery. This indicates that the adverse effects observed during the study were fully reversible and effectively managed. It also suggests that the treatments used were generally safe, with no long-term complications related to adverse events.

Figure 26: Recovered Status in Patients with Adverse EffectsFigure 27: Relationship Between



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Drug Dose and Adverse Effects

The relationship between drug dose and occurrence of adverse effects was analyzed across the three treatment groups. In the lacosamide group (A), adverse effects were slightly more common at higher doses, particularly at 200 mg; however, the association was not statistically significant ($\chi^2 = 0.355$, $p = 0.837$). Similarly, in the levetiracetam group (B), a higher number of adverse effects were observed at the 1500 mg dose compared to lower doses, but this difference was also not statistically significant ($\chi^2 = 1.885$, $p = 0.389$).

In the combination therapy group (C), most patients receiving the higher dose combination (1500 mg + 200 mg) did not experience adverse effects, with only a few cases reported. Lower dose combinations showed minimal or no adverse effects. The statistical analysis again indicated no significant association ($\chi^2 = 1.333$, $p = 0.721$).

Overall, although there is a trend suggesting increased adverse effects with higher doses in monotherapy groups, the lack of statistical significance indicates that dose variation did not have a strong impact on the occurrence of adverse effects in this study.

ASSOCIATION OF AGE, GENDER, SEIZURE TYPE WITH ADVERSE EFFECTS

Table 28: ASSOCIATION OF AGE, GENDER, SEIZURE TYPE WITH ADVERSE EFFECTS

Figure 28: Association Of Age, Gender, Seizure Type with

VARIABLES		NO ADVERSE EFFECT	ADVERSE EFFECT	CHI SQUARE VALUE	P VALUE
AGE CATEGORY	13–18	4	4	0.204	0.651
	19–25	30	42		
GENDER	FEMALE	13	27	3.27	0.07
	MALE	21	19		
TYPE OF SEIZURES	FOCAL	13	27	3.27	0.07
	GENERALIZED	21	19		

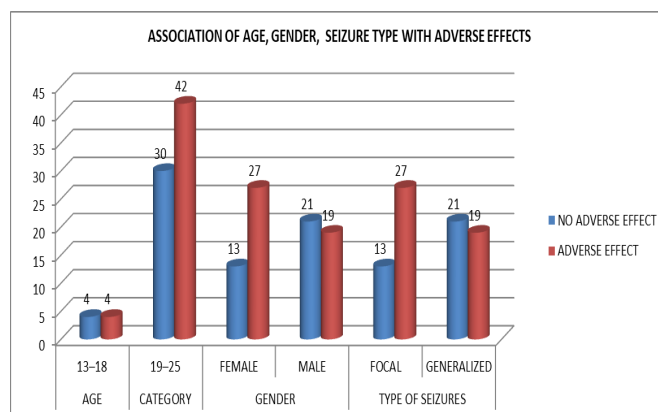
Adverse Effects

The association between age, gender, and type of seizures with the occurrence of adverse effects was analyzed. Age category did not show a statistically significant association ($\chi^2 = 0.204$, $p = 0.651$), indicating that both age groups experienced adverse effects similarly. Gender also did not show a significant association ($\chi^2 = 3.27$, $p = 0.07$), although females had a relatively higher number of adverse effects compared to males. Similarly, the type of seizures was not significantly associated with adverse effects ($\chi^2 = 3.27$, $p = 0.07$). However, patients with focal seizures showed a higher frequency of adverse effects compared to those with generalized seizures.

Overall, these findings suggest that age, gender, and seizure type did not significantly influence the occurrence of adverse effects in this study population.

DISCUSSION

STUDY DESIGN AND SUBJECT DISTRIBUTION



The present study included 80 epilepsy patients, with 80% enrolled prospectively and 20% retrospectively. This higher proportion of prospective subjects improves the reliability of

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outcome assessment, as patients were followed continuously to observe treatment response. These observations correlate with the research conducted by Brodie et al., which emphasized that prospective longitudinal frameworks facilitate a more robust appraisal of antiepileptic drug (AED) efficacy

AGE DISTRIBUTION AND YOUNG ADULT PREDOMINANCE

In this study, 90% of patients were aged 19–25 years, indicating a strong predominance of young adults. This demographic trend is consistent with the data presented by Beghi et al., which identified a significantly increased incidence of epilepsy within younger age cohorts. Similarly, Hauser et al. observed that epilepsy commonly begins in adolescence and early adulthood.

GENDER DISTRIBUTION AND ITS CLINICAL RELEVANCE

Our investigation demonstrated a balanced sex distribution (comprising an equal 1:1 ratio of males to females), thereby mitigating potential gender-based confounding variables during the clinical appraisal of therapeutic interventions. This is consistent with a study by

Kotsopoulos et al., which reported nearly equal epilepsy prevalence among genders. However, some studies like Christensen et al. observed slight male predominance

FAMILY HISTORY AND GENETIC INFLUENCE

Only 20% of patients had an identifiable hereditary predisposition, suggesting that the vast majority of seizure manifestations within this cohort were sporadic or non-familial in origin. These results are congruent with the observations of Ruth Ottman et al., whose research identified a negligible degree of hereditary correlation across a broad spectrum of seizure disorders. However, a study by Ingo Helbig et al. underscored more pronounced genomic correlations within particular epileptogenic syndromes, particularly in early-onset and familial epilepsies.

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particular epileptogenic syndromes, particularly in early-onset and familial epilepsies

SEIZURE TYPE DISTRIBUTION

Within the present investigation, the distribution of seizure semiology was uniform, with 40 patients (50%) having focal seizures and 40 patients (50%) having generalized seizures. This equal distribution indicates that both seizure types are equally important in clinical practice and require careful management. Focal seizures arise from a specific area of the brain, while generalized paroxysms are characterized by widespread electrical discharge involving bilateral cerebral hemispheres, which typically manifests with more pronounced clinical presentations. Similar patterns were observed in a study by Robert S. Fisher et al., where seizure classification showed varied but balanced presentations.

DURATION OF EPILEPSY AND CHRONIC NATURE

Data regarding the chronicity of the condition in this cohort indicates a prevalence of protracted disease duration, with 30 patients (37.5%) having epilepsy for 5 years and 23 patients (28.75%) for 6 years. Only a small number had shorter durations.

This highlights that epilepsy is a chronic neurological condition requiring long-term management. Long disease duration can affect psychological health, social interactions, and treatment response. Similar findings were reported by Markku Sillanpää et al., who showed that epilepsy often persists for many years.

SEVERITY OF SEIZURES

Within the scope of this investigation, seizure severity assessment using the NHS3 scale showed that 47 patients (58.75%) had moderate seizures, while 33 patients (41.25%) had mild seizures. This indicates that a majority of patients were experiencing clinically significant symptoms requiring active treatment. The preponderance of the cohort exhibited clinically manifest symptoms that mandated active clinical management. A study by Löscher et al. reported that moderate [64,65] to severe epilepsy demonstrates a high prevalence within non-treated demographic groups. In parallel, Emilio Perucca emphasized the critical clinical necessity for timely and potent therapeutic initiation in this specific patient subset.

TREATMENT PATTERN OBSERVED

Combination therapy was used in 32 patients (40%), while lacosamide and levetiracetam monotherapy were each used in 24 patients (30%). This shows a preference toward combination therapy in this study. Combination therapy is often used when single drugs are not sufficient. A study by Martin Brodie et al. showed that combining antiepileptic drugs can improve seizure control in patients who do not respond to monotherapy. Another study by Kaminski also supported the use of polytherapy in difficult-to-treat epilepsy cases. [66,67,68]

LACOSAMIDE EFFECTIVENESS

In the lacosamide group, seizure frequency reduced from a mean of 7.5 at baseline to 2 at 4 months ($p < 0.001$). This shows a strong improvement in seizure control over time, with patients experiencing a gradual reduction month by month. A pivotal randomized controlled trial by Elinor Ben-Menachem et al. elucidated that the administration of lacosamide as an add-on therapy yielded a statistically significant diminution in seizure frequency among adult cohorts presenting with focal-onset seizures when evaluated against placebo. This was evidenced by profound median percentage decreases and superior clinical responder indices across the therapeutic dosage spectrum for lacosamide doses (400 mg and 600 mg per day) versus placebo. These observations align with the broader body of clinical evidence, reinforcing the conclusion that lacosamide represents a viable and efficacious pharmacological intervention for

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achieving seizure stabilization in individuals with focal epilepsy. [69,70]

LEVETIRACETAM EFFECTIVENESS

Within the cohort receiving levetiracetam, a statistically significant decrement in paroxysmal frequency was observed, declining from a baseline mean of 7.5 to 2.0 at the four-month follow-up interval ($p < 0.001$). This indicates consistent improvement with treatment. Levetiracetam is widely used due to its good safety profile and effectiveness in reducing seizures. In pivotal clinical trials, the administration of levetiracetam elicited a marked reduction in focal seizure manifestations when evaluated against placebo. Furthermore, clinical responder indices—defined by a $\geq 50\%$ attenuation in seizure burden—were found to be notably more robust in comparison to placebo-controlled cohorts among individuals with focal epilepsy. Long-term studies also show sustained seizure reduction and good tolerability with levetiracetam in adults with partial seizures.

LACOSAMIDE AND LEVETIRACETAM COMBINATION THERAPY EFFECTIVENESS

Combination therapy reduced seizures from a mean of 8.5 to 1 and showed a greater reduction (7.5) compared with monotherapy (5.5) in this study, indicating better effectiveness. Patients receiving combination therapy manifested a more rapid and clinically profound recovery trajectory throughout the therapeutic duration compared to cohorts managed via monotherapeutic regimens. Notwithstanding the paucity of high-evidence randomized controlled trials (RCTs) directly evaluating dual-therapy versus monotherapy, clinical consensus favors the implementation of rational polytherapy. This approach is particularly substantiated for individuals demonstrating therapeutic failure or suboptimal paroxysmal stabilization on a single-agent regimen.

RESPONDER RATE ANALYSIS

Responder rate was highest in combination therapy (88.5%) compared with monotherapy (73%). This means more patients achieved significant seizure reduction, and a higher responder rate indicates better treatment success. Although high-quality randomized trials directly comparing responder rates of combination therapy versus monotherapy are limited, clinical evidence and expert reviews indicate that a substantial proportion of patients exhibiting an insufficient response to monotherapeutic interventions may attain superior clinical outcomes through the strategic utilization of rational antiseizure polypharmacy. This is particularly relevant for the enhancement of paroxysmal suppression in individuals categorized as having pharmacoresistant or refractory epilepsy. [75,76]

QUALITY OF LIFE

Within the current investigation, baseline health-related quality of life (HRQoL) metrics were statistically equivalent among all therapeutic cohorts, with lacosamide (A) at 50.12%, levetiracetam (B) at 50.75%, and combination therapy (C) at 49.62%, indicating moderate impairment in daily functioning due to seizures. Following a four-month treatment duration, a clinically meaningful enhancement in QoL parameters was identified across all study arms: A increased to 77.29%, B to 77.08%, and C to 91.62%. The combination therapy group showed the greatest improvement (42.0% change), suggesting that better seizure control with combined levetiracetam and lacosamide therapy more effectively enhances patient well-being compared to monotherapy. A study by Gilliam et al. showed similar improvement in quality of life with effective treatment. Another study by Boylan et al. also supported this finding. [77,78,79]

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PREVALENCE OF ADVERSE EFFECTS

In this study, 46 patients (57.5%) experienced adverse effects, while 34 patients (42.5%) did not. This data reflects that a considerable percentage of the study population encountered mild-to-moderate treatment-emergent adverse events (TEAEs) during the course of antiepileptic pharmacotherapy. These observations align with the findings of Perucca et al., who noted that while adverse sequelae are prevalent, they typically remain clinically manageable within standard epilepsy care. Another study by Zaccara et al. confirmed that adverse effects occur in more than half of patients on antiepileptic drugs, yet most are reversible. These results underscore the imperative for persistent clinical surveillance to facilitate therapeutic optimization while concurrently mitigating potential iatrogenic risks. [80,81]

TYPE, SEVERITY AND NARANJO SCALE ASSESSMENT OF ADVERSE EFFECTS

The primary treatment-emergent adverse events (TEAEs) identified were vertigo (28.26%), mild somnolence (17.39%), headache (15.22%), irritability (15.22%), mood changes (13.04%), and nausea (10.87%) with the majority categorized as mild-to-moderate in clinical intensity. Previous studies highlighted that dizziness and somnolence are the most frequent side effects of antiepileptic therapy.

These comparisons demonstrate that the Such comparative metrics illustrate that the adverse effect profile within this investigation is consistent with established longitudinal datasets, bolstering the generalizability of our safety outcomes, supporting the generalizability of safety outcomes. Adverse effects in this study were evaluated using the Naranjo scale, where 38 cases (82.61%) were probable, and 8 cases (17.39%) were possible drug-related effects. In the combination therapy group, the causality of adverse sequelae was appraised utilizing the Naranjo Nomogram; within the combination therapy arm, all documented events were classified as "possible," reflecting a diminished level of causal certainty. [85,86,87,88]

MANAGEMENT AND RECOVERY OF ADVERSE EVENTS

Most patients with adverse effects (73.91%) continued treatment without dose modification, while 26.09% required dose reduction. Importantly, all 46 patients recovered completely, suggesting mild and manageable adverse events. This is consistent with findings by Brodie et al., where adverse effects were generally reversible with dose adjustments or monitoring. Another study by Biton et al. reported that structured follow-up allowed safe continuation of therapy in patients experiencing mild side effects.

Ultimately, these results underscore the imperative for vigilant clinical surveillance and proactive dose titration to effectively attenuate the impact of adverse sequelae and optimize the overall safety of antiepileptic pharmacotherapy. [89,90]

CONCLUSION

In this study of 80 epilepsy patients, both levetiracetam and lacosamide monotherapy significantly reduced seizure frequency from a mean of 7.5 at baseline to 2 at 4 months ($p < 0.001$). Combination therapy was more effective, reducing mean seizure frequency from 8.5 to 1, demonstrating a superior therapeutic response of 88.5%, which notably exceeded the

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73% observed in those receiving single-agent therapy. Psychosocial well-being indices showed significant enhancement. monotherapy groups increased from ~50% to ~77%, while combination therapy improved from 49.6% to 91.6%, demonstrating the greatest overall benefit in daily functioning.

Adverse effects were reported in 46 patients (57.5%), most commonly dizziness (28.3%), mild drowsiness (17.4%), headache (15.2%), and irritability (15.2%). The clinical severity of these events was categorized as low-to-intermediate grade.; 73.9% of affected patients continued therapy without dose modification, and all recovered completely. Notably, combination therapy had

fewer adverse events (10%) than lacosamide (22.5%) or levetiracetam (25%) monotherapy, indicating good tolerability.

Overall, the study confirms that levetiracetam and lacosamide are effective and safe in monotherapy, while combination therapy provides superior seizure control, higher responder rates, and a more pronounced amelioration in patient-reported functional outcomes with manageable adverse effects. These findings support individualized treatment strategies and rational polytherapy for individuals suffering from pharmaco-resistant or refractory seizure disorders.

REFERENCE

N/A