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REVIEW ON: THIN FLIM LAMOTRIGINE TREATMENT FOR CHILDHOOD EPILISY

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ABSTRACT

Epilepsy in childhood poses a significant challenge to healthcare providers and caregivers alike. necessitating effective and tolerable treatment options. Lamotrigine, an antiepileptic drug, has gained attention for its potential efficacy in managing childhood epilepsy. This review systematically examines the existing literature on thin film formulations of lamotrigine, specifically focusing on their use in treating Pediatric epilepsy. Inclusion criteria encompassed clinical trials, observational studies, and case series that investigated the use of thin film lamotrigine in Pediatric patients diagnosed with epilepsy. The synthesis of data includes an in-depth analysis of seizure outcomes, adverse events, pharmacokinetic profiles, and patient adherence to thin film lamotrigine therapy. Additionally, this review explores the practical aspects of thin film formulations, such as ease of administration, convenience, and overall patient and caregiver satisfaction. Lamotrigine is considered a broad-spectrum antiepileptic drug. It is an antiepileptic drug (AED) that is primarily used for the treatment of epilepsy and bipolar disorder. It works by stabilizing electrical activity in the brain and affecting the way nerves send messages to the brain.

KEYWORDS: Lamotrigine. Seizure. Anti-epileptics, Childhood epilepsy.

1. INTORDUCTION

1.1 Pediatric Epilepsy

Epilepsy is one of the most common chronic neurological disorders in childhood, characterized by recurrent, unprovoked seizures due to abnormal, excessive electrical activity in the brain. Pediatric epilepsy refers specifically to seizure disorders that begin in infancy, childhood, or adolescence. It is a highly heterogeneous condition, with diverse causes ranging from genetic mutations and developmental brain malformations to acquired insults such as infections, trauma, or perinatal injuries.[1]

Globally, epilepsy affects around 0.5–1% of children, with onset being most frequent in the first decade of life. The impact of pediatric epilepsy extends beyond seizures, often influencing cognitive, behavioral, and psychosocial development, making early diagnosis and appropriate management crucial. Advances in neuroimaging, electroencephalography (EEG), and genetic testing have significantly improved our understanding of epilepsy in children, leading to more precise classifications and tailored treatments.[2]

Management of pediatric epilepsy requires a multidisciplinary approach, including pharmacological therapy, dietary interventions, surgical options, and psychosocial support. With timely and effective intervention, many children achieve good seizure control and can lead fulfilling lives.[3]

Epilepsy is a neurological condition where the brain has bursts of irregular electrical activity. The defining feature of epilepsy is having seizures that are not caused by a short-term event like a fever or injury. It's the most common brain disorder affecting children in the United States Seizures can appear differently in each child, and not all involve shaking.[4]

For some children and youth living with epilepsy, the risk of Sudden Unexpected Death in Epilepsy (SUDEP) is an important concern. SUDEP refers to death in a person living with epilepsy whose death isn’t caused by another illness or injury. Parents and caregivers can lower their child’s risk of SUDEP by taking steps to keep seizures under control. Learn more about SUDEP.[5] Epilepsy in children can be caused by many different health problems like genetic disorders, brain injuries, strokes or brain tumors that change the structure or function of the brain. However, physicians often cannot find the reason why a child develops.[6]

Seizures manifest in various ways, from brief staring spells and confusion to unconsciousness and uncontrollable shaking, and are not caused by acute illnesses or injuries. While many children outgrow epilepsy, it can also be a lifelong condition requiring management with anticonvulsant medications, lifestyle changes, and in some cases, specialized diets or surgery.[7] Seizures happen when there is a sudden change in electrical activity in the brain. There are many different types of seizures, and each type affects people differently.

Someone who is having a seizure may stare, collapse, shake or become unaware of what's going on around them.[8]

1.2 Symptoms of Pediatric Epilepsy

Symptoms of epilepsy in children vary but commonly include brief staring spells, loss of consciousness, uncontrolled jerking or stiffening movements, and confusion or unresponsiveness. Other signs can be more subtle, such as repeated odd movements, falling, loss of bladder/bowel control, or sudden behavioral changes like fear, anxiety, or mumbling. A healthcare provider must be seen for a proper diagnosis, as these symptoms can also indicate other health conditions.

Common symptoms of pediatric epilepsy include

Staring spells: or becoming unresponsive and "blanking out" for a short time.

Uncontrolled muscle movements, such as stiffening of the body, jerking or twitching of arms and legs, or repetitive motions.

- Loss of consciousness, making the child seem to pass out.
- Loss of control of bowel or bladder.
- Sudden falls: for no apparent reason.
- Not responding: to words or noises.
- Appearing confused or in a haze: after a seizure.

Absence seizure (formerly known as petit mal seizure)

 Moments of intense starting or zoning out.

- A Temporary lack of awareness.
- Repetitive motion like blinking or lip smacking.

Tonic-conic Seizure (formerly known as grand mal seizure)

- Loss of consciousness.

- Suffering of muscles (tonic phase).
- Possible loss of bladder or bowel control.

Complex partial seizure

- Altered consciousness or awareness repetitive behaviors Automating such as lip smacking or hand rubbing.
- Confusion or disorientation after the seizure.

Simple Partial seizure

- Focal or localization sum depending on the part of the brain attended.
- Motor symptoms, Sensory symptoms, Autonomic symptoms or psychic symptoms.

Myoclonic seizure

- Sudden brief muscle jerks.
- Can affected specific muscle group of the entire body.

If a child appears to be having seizure or epilepsy, it is imperative that they be evaluated by medical professional in order to receive an accurate diagnosis. A comprehensive medical history, a neurological examination, and a number of diagnostic procedures including electroencephalography (EEG), brain imaging (MRI or CT scans), and blood tests, are usually the foundation for an accurate diagnosis.[8-10]

1.3 Cause of Pediatric Epilepsy

Epilepsy in Children - First Aid for Free Causes of epilepsy in children include structural abnormalities, like brain malformations or tumors; genetic conditions passed down through families or occurring as new mutations; infections such as meningitis; metabolic disorders; traumatic brain injury; and factors occurring before or during birth, such as oxygen deprivation.

In about half of cases, the underlying cause remains unknown.

Common Causes of Childhood Epilepsy

Structural Brain Abnormalities

Congenital conditions

- Brain defects present at birth or malformations during early development.

- Genetic abnormalities, structural brain malformations, and metabolic disorders, such as congenital disorders of glycosylation.
- These conditions lead to abnormal electrical signals in the brain, resulting in recurring seizures that can manifest from birth or early childhood.[11]

Abnormal blood vessels

- Issues with the brain's blood supply can lead to seizures.
- Abnormal blood vessels are a known structural cause of epilepsy, particularly arteriovenous malformations (AVMs) and cavernous malformations.
- These conditions involve a tangle or abnormal connection of blood vessels in the brain, which can lead to brain hemorrhages and seizures.[12]

Genetic mutations

- Gene changes can cause epilepsy, even without a family history infection.
- The Role of Genetics in Epilepsy: What Patients Should Know ...Genetic mutations can cause epilepsy by altering nerve cell excitability and brain function, leading to recurrent seizures
- These mutations can be inherited or occur spontaneously and affect genes controlling ion channels (like sodium and potassium channels)[11]

Metabolic Disorders

- Certain metabolic conditions present at birth, such as phenylketonuria (PKU), can increase the risk of epilepsy.□

  Metabolic disorders in childhood epilepsy are inherited conditions where a genetic defect causes a faulty enzyme or cofactor, leading to the accumulation of toxic substances or a deficiency in essential products, often affecting the brain and resulting in seizures along with other symptoms like developmental delays and hypotonia.□
- Diagnosis requires specialized tests, but can lead to targeted treatments such as dietary changes or cofactor supplementation, which can significantly improve outcomes in specific cases.[13]

Medications or drugs

Certain medications or illegal drugs can also be a cause. Unknown Causes In many cases, the specific cause of epilepsy cannot be identified, even with medical tests. Some medication to the treatment of childhood epilepsy.[14,15]

- Lamotrigine
- Levetiracetam
- Topiramate
- Carbamazepine
- Clobazam
- Valproate
- Zonisamide
- Clonazepam
- Brivaracetam
- Gabapentin

Febrile seizure

Seizure known as febrile seizure. Particularly in young children, may be associated with a higher chance of developing in the future.

Febrile seizures are generalized seizures, typically in children between the ages of 6 months and 5 years, that occur with a fever greater than 100.4°F (38°C) not associated with a central nervous system (CNS) infection, a known seizure-provoking etiology (eg, electrolyte imbalance, hypoglycemia, or substance abuse).[16]

2. LAMOTRIGENE

Lamotrigine is a medicine used to treat epilepsy. It can also help prevent low mood (depression) in adults with bipolar disorder. Seizures are bursts of electrical activity in the brain that temporarily affect how it works. Lamotrigine slows these electrical signals down to stop seizures. Lamotrigine is available on prescription. It comes either as tablets you swallow, or tablets you chew or dissolve in water to make a drink.

OBJECTIVE

- Identify both approved and off-label indications for lamotrigine.
- Summarize the potential drug-drug interactions for lamotrigine.
- Describe interprofessional team strategies for improving care coordination and communication to use lamotrigine to enhance patient outcomes.

2.1 Indication

Lamotrigine can be used to treat the following partial seizures, primary generalized tonic-clonic seizures, bipolar I disorder maintenance and Lennox-Gastaut syndrome. Off-label uses include treating acute bipolar depression, fibromyalgia, schizophrenia, and unipolar depression. This activity covers lamotrigine, including mechanism of action, pharmacology, adverse event profiles, eligible patient populations, contraindications, monitoring, and highlights the interprofessional team's role in managing lamotrigine therapy. Explain the mechanism of action of lamotrigine.

2.2 Mechanism of action

The mechanism of action for lamotrigine is not entirely understood. It is a triazine, and research has shown that lamotrigine selectively binds and inhibits voltage-gated sodium channels, stabilizing presynaptic neuronal membranes and inhibiting presynaptic glutamate and aspartate release. Researchers have not demonstrated that lamotrigine has significant effects on other neurotransmitters such as serotonin, norepinephrine, or dopamine. There is a theory that lamotrigine may interact with voltage-activated calcium-gated channels, contributing to its broad range of activity. In vitro studies have also shown that lamotrigine inhibited dihydrofolate reductase, potentially contributing to concerns for its teratogenicity. Lamotrigine follows first- order kinetics with a half-life of 29 hours.

Lamotrigine likely acts by inhibiting sodium currents by selective binding to the inactive sodium channel, suppressing the release of the excitatory amino acid, glutamate.

The mechanism of action of lamotrigine in reducing anticonvulsant activity is likely the same in managing bipolar disorder. Studies on lamotrigine have identified its binding to sodium channels in a fashion similar to local anasthesia which could explain the demonstrated clinical benefit of lamotrigine in some neuropathic pain states.[18-20]

2.3 Administration

The administration of lamotrigine (brand name Lamictal) involves a careful, slow, and gradual dose escalation due to the risk of serious skin rashes, including Steven Johnson syndrome. The specific dosage and titration schedule depend on the patient's condition and whether other medications are being taken.[18]

Methods of Administration

Lamotrigine is taken orally and is available in different formulations:

Standard tablets: Should be swallowed whole with water. Do not crush, chew, or divide them Extended-release (XR) tablets: These are taken once daily and must be swallowed whole. Do not crush, chew, or divide them Orally disintegrating tablets (ODT): Place the tablet on your tongue and allow it to dissolve completely before swallowing, with or without water.

Chewable dispersible tablets: Can be swallowed whole, chewed, or dissolved in a liquid, such as a teaspoon of water or diluted fruit juice. If chewing, follow with a small amount of liquid.[20]

For seizure

A "seizure of childhood epilepsy" is an abnormal burst of electrical activity in a child's brain that causes different symptoms, from brief staring spells to violent convulsions, depending on the type of seizure and affected brain area. While a single seizure isn't epilepsy, epilepsy is diagnosed after a person has two or more unprovoked seizures. Childhood epilepsy is treat by the antiseizure. lifestyle adjustments, and in some cases, diet, surgery, or devices.[20,21]

2.4 Types of Seizures

Absence seizure: Brief staring spells where the child seems to "blank out" or daydream

Generalized tonic clonic (grand mal) seizure: Involve the whole body, including stiffening muscles, convulsions, and loss of alertness.

Focal (partial) seizure: Symptoms vary, depending on where the seizure starts, and can include twitching, numbness, or unusual movements.[22]

2.5 Adverse Effects

Lamotrigine can cause a range of side effects, from common mild symptoms to rare but life-threatening reactions, such as severe skin rashes. The risk of side effects often depends on the dosage and how quickly it is increased, especially during the first few weeks of treatment.

Severe skin reactions: The FDA has issued a black box warning for lamotrigine regarding life-threatening rashes, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). These rashes, which can appear as flu-like symptoms followed by painful blistering or

peeling skin, require immediate medical attention and may lead to hospitalization or death. The risk is higher in children, patients taking valproate, or if the dosage is increased too quickly.[23,24]

Irregular Heart Rhythm: Lamotrigine can cause abnormal heart rhythms (arrhythmias), which may lead to sudden death. Individuals with pre-existing heart conditions, including heart failure, may be at a higher risk.[25]

2.6 Common Side Effects

The following side effects are generally less severe and may subside as you continue treatment:

- Dizziness and drowsiness
- Headache
- Nausea, vomiting, dia, or stomach pain
- Blurred or double vision
- Problems with balance or coordination
- Trouble sleeping or agitation
- Tremors or shaking
- Runny or stuffy nose
- Pain weakness[26]

The most serious side effect of lamotrigine includes a spectrum of skin rashes, including SJS. If a patient reports a rash, discuss the nature of it to determine whether they need to be examined. Asian populations may be at increased risk for serious skin rashes.

2.7 Dosing Considerations

Dosing for lamotrigine is highly dependent on the child's age, weight, and whether other AEDs are being taken.

- **Slow titration**: To minimize the risk of serious side effects like a severe rash, the dose must be slowly increased over several weeks.
- **Drug interactions**: Concomitant use of other medications, especially valproate and enzyme-inducing AEDs like carbamazepine, significantly affects the necessary lamotrigine dosage.
- **Maintenance dose**: Once the appropriate maintenance dose is established, it often remains stable for a long time.[27]

2.7 TOXYCITY

Lamotrigine toxicity in children can range from mild side effects to severe, life-threatening events, particularly in cases of accidental overdose. Children appear more susceptible to central nervous system (CNS) toxicity and serious skin reactions than adults.

If lamotrigine overdose is suspected, seek immediate medical attention. In a hospital setting, treatment is focused on supportive care.

Airway support: Critical in cases involving respiratory depression or severely altered mental status.

Seizure control: Benzodiazepines are the first-line treatment for seizures and abnormal motor activity.

Gastrointestinal decontamination: Activated charcoal may be administered if the ingestion was recent and the patient's airway can be protected. This helps prevent further absorption of the drug.

Cardiac management: In cases of severe cardiac abnormalities, intravenous sodium bicarbonate or lipid emulsion therapy may be used.

Lamotrigine toxicity manifests with ataxia, vertigo, and diplopia, which can be symptoms of vertebrobasilar insufficiency.[27,28]

2.8 Thin Film Formulation

Thin film formulation refers to a type a drug delivery system was a thin layer of the active pharmaceutical ingredient (API) is coated onto a substance. These formulations are designed to provide controlled release, improved bioavailability, and enhance patient compliance. Lamotrigine is an antiepileptic drug commonly use in the treatment of epilepsy and bipolar disorder. While traditional oral; dosage form like tablets and capsule are widely used, researches explore alternative formulation to address challenge such as poor solubility, Erratic absorption, and variable bioavailability associated with certain drug.[29,30]

Advantages of thin film formulation include.

Improved bioavailability

Thin film can enhance the solubility of poorly water-soluble drugs, leading to better absorption and increase bioavailability.

Rapid Dissolution

It dissolves quickly upon contact with saliva, allowing for rapid drug release and rapid action.

Ease of Administration

Thin film typically thin flexible and easy to administrated, making them suitable for patient who may have difficulty swallowing traditional dosage form.

Taste Masking

Thin film can be formulated mask the taste of the drug, improve patient acceptability Especially in the case of pediatric or geriatric population.[31,32]

3. CONCLUSION

A promising development in improving patient adherence is the introduction of thin film Formulation, especially when it comes to the difficult paediatric population. Thin are a better option than regular medication because of their case of administration, Lower dosage frequency, better flavour, and lessened stigma. The potential; of thin film Formulation to improve patient outcomes in the paediatric healthcare is highlighted by this Variable taken together. It's important to remember that medical science is a dynamic field, and thing may have changed since I last updated. To obtain up to date information on the latest research and development concerning thin film lamotrigine or other treatment for paediatric epilepsy, one can refer to relevant research institution, clinical trial databases Or recent scientific literature

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