



Research Article

VILWAPANCHANGA GHRITA IN THE MANAGEMENT OF PEDIATRIC INTRACTABLE  
EPILEPSY: A PRELIMINARY CLINICAL STUDY

Roshni Anirudhan<sup>1\*</sup>, Deepa Ravindranath<sup>2</sup>, Aswathy S<sup>3</sup>

<sup>1</sup>Professor & Head, Department of Kaumarabhritya, Government Ayurveda College, Thiruvananthapuram, Kerala.

<sup>2</sup>Medical Officer, Indian System of Medicine, Kerala, India.

<sup>3</sup>Specialist Medical Officer, National Ayush Mission, Department of Kaumarabhritya, Government Ayurveda College, Thiruvananthapuram, Kerala, India.

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ABSTRACT

**Background:** Drug-resistant epilepsy (DRE) in children remains a major clinical challenge, with limited efficacy of current pharmacological and non-pharmacological interventions. In Ayurveda, *Apasmara* is described as a condition analogous to epilepsy, with classical texts recommending *Vilwapanchanga Ghrita* as a key therapeutic formulation.

**Materials and Methods:** An open-label clinical study was conducted in 10 pediatric patients (2–12 years) diagnosed with intractable epilepsy. *Vilwapanchanga Ghrita*, prepared as per *Arogyakalpadruma*, was administered for two months, with a subsequent two-month follow-up. Outcome measures included seizure severity (Hague Seizure Severity Scale), frequency of impairment of consciousness, frequency of jerks or cramps, seizure duration, and safety profile. Statistical analyses were performed using paired t-test and Wilcoxon signed-rank test.

**Results:** A significant reduction in seizure severity was observed, with mean scores decreasing from  $43.0 \pm 2.58$  at baseline to  $32.5 \pm 1.84$  post-treatment ( $p < 0.001$ ), and sustained during follow-up. Frequency of impairment of consciousness and jerks/cramps also improved significantly ( $p < 0.01$ ). Median seizure duration reduced from 300 seconds (IQR 226.25–510.00) at baseline to 120 seconds post-treatment, and further to 47.5 seconds at follow-up ( $p = 0.005$ ). No adverse effects were reported; instead, caregivers noted improvements in digestion and reduction in recurrent respiratory infections.


**Conclusion:** *Vilwapanchanga Ghrita* demonstrated significant and sustained efficacy in reducing seizure severity, frequency, and duration in pediatric intractable epilepsy, with an excellent safety profile. These findings provide preliminary clinical validation for its classical use in *Apasmara* management and suggest potential as an adjunctive therapy. Larger randomized controlled trials are warranted.

INTRODUCTION

Epilepsy is a chronic neurological disorder characterized by recurrent, unprovoked seizures resulting from abnormal, excessive, and synchronous neuronal discharges in the brain.<sup>[1]</sup> The clinical spectrum of seizures is heterogeneous, ranging from brief lapses in awareness or myoclonic jerks to prolonged generalized convulsions.

Recurrent or uncontrolled seizures are associated with significant neurological morbidity and, in severe cases, may lead to irreversible structural and functional brain damage.

Globally, epilepsy is a major public health concern, affecting nearly 50 million individuals. In India, the pooled prevalence is reported to be 5.59 per 1000 population, with no significant differences across gender or geographic distribution<sup>[2]</sup>. Despite therapeutic advances, approximately 10–20% of patients, and up to 50% in specialized centers, develop drug-resistant epilepsy (DRE). These patients often do not respond adequately to newer antiepileptic drugs (AEDs), dietary regimens such as the ketogenic diet,

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surgical resection, or neuromodulatory strategies including vagus nerve stimulation. The modest success rates of these modalities, combined with adverse effects associated with long-term AED therapy, underscore the need to explore alternative or complementary strategies that are safe, effective, and particularly applicable in pediatric care.

Within Ayurvedic nosology, several conditions are described with clinical features resembling epilepsy, including *Apasmara*, *Sannipatika Mūrccha*, *Akshepaka*, *Apatanaka*, and *Apatantraka*. Among these, *Apasmara* is considered the closest correlate, encompassing recurrent seizures accompanied by impairment of memory, cognition, and consciousness. The pathogenesis of *Apasmara* is attributed to derangement of higher cerebral functions, resulting in compromised intellectual and psychological faculties. In children, inadequately controlled *Apasmara* is associated with developmental delays, reduced quality of life, and poor long-term outcomes, highlighting the need for timely and holistic management.

One formulation of particular relevance is *Vilwapanchanga Ghrita*, a medicated ghee preparation described in the *Arogyakalpadruma*, a classical pediatric treatise, in the context of *Apasmara chikitsa*<sup>[3]</sup>. It is prepared using all five parts of *Vilwa* (*Aegle marmelos* [L.] Correa) root, bark, leaves, flowers, and fruit -processed with *Panchagavya* (a traditional combination of cow dung juice, urine, milk, curd, and ghee). Preclinical studies have demonstrated the anticonvulsant potential of *Aegle marmelos*<sup>[4]</sup>. The ghee-based medium is pharmacologically significant, as its lipophilic nature may enhance transport of active constituents across the blood-brain barrier. In addition, *Panchagavya* itself is described in classical literature as *Apasmarahara* (antiepileptic) and has shown preliminary pharmacological activity supportive of this claim<sup>[5]</sup>. The synergistic properties of these components provide a scientific rationale for evaluating *Vilwapanchanga Ghrita* in epilepsy management.

Although modern research has increasingly explored herbal and dietary interventions in epilepsy, clinical data on classical Ayurvedic formulations remain limited. Most existing studies are preclinical or single-ingredient based, with a scarcity of evidence on polyherbal preparations tailored for pediatric populations. Notably, systematic clinical evaluation of *Vilwapanchanga Ghrita* is lacking, despite its documented traditional use in *Apasmara*. This research gap highlights the need for systematic clinical evaluation of such traditional formulations to validate their safety, efficacy, and therapeutic relevance in drug-resistant epilepsy.

The present study was therefore designed to assess the clinical efficacy of *Vilwapanchanga Ghrita* in children aged 2–12 years with intractable epilepsy. The primary objective was to evaluate its impact on seizure frequency and severity, with secondary aims of assessing its role in improving overall quality of life in pediatric epilepsy.

## Materials and Methods

### Study Drug: *Vilwapanchanga Ghrita*

The study drug was *Vilwapanchanga Ghrita*, prepared by processing *Panchagavya Ghrita* with *Vilwa* (*Aegle marmelos* [L.] Correa). Preclinical studies have demonstrated the anticonvulsant potential of *Panchagavya Ghrita* at a dose of 4000 mg/kg, showing protection against maximal electroshock-induced seizures in rats and potentiation of phenytoin and carbamazepine without altering their serum levels. These findings suggest its potential as an adjunct to conventional AEDs by improving efficacy, enabling dose reduction, and minimizing side effects.<sup>[5,6]</sup> Similarly, *Aegle marmelos* extract has shown significant anticonvulsant activity in pentylenetetrazole-induced epilepsy in zebrafish, with reversal of epilepsy-induced behavioral alterations and statistically significant improvements in oxidative stress markers (glutathione peroxidase, lipid peroxidation) and inflammatory mediators (TNF- $\alpha$ , IL-1 $\beta$ ).<sup>[7]</sup>

### Preparation of the Formulation

The raw materials were authenticated by Dravyaguna experts at the Government Ayurveda College, Thiruvananthapuram. Equal quantities (3072 g) of the root, bark, leaves, fruit, and flowers of *Vilwa* were taken. A decoction (*Kashaya*) was prepared by boiling 64 L of water with the plant material, reducing it to 16 L, and filtering. One liter of cow's ghee was taken, to which 250 g each of the *Panchangas* (root, seed, leaf, fruit, flower, bark) was added, along with the filtered decoction. The mixture was cooked over low flame with continuous stirring until *Mridupaka* stage was attained. Subsequently, 125 mL of cow dung juice and 250 mL of cow urine were incorporated and again processed to *Mridupaka*. Thereafter, 1250 mL of curd and 2 L of milk were sequentially added and further processed until the *Madhyamapaka* stage was achieved, characterized by subsiding froth and thread-like consistency of the sediment. The mixture was filtered through a sterile steel strainer, cooled, and stored in sterile 200 g bottles.

### Study Design

This was an experimental, therapeutic, interventional study employing a pre-post test design.

## Study Setting and Duration

The trial was conducted in the Department of Kaumarabhritya, Government Ayurveda College, Thiruvananthapuram. The intervention period was two months, followed by a two-month post-intervention follow-up. The overall duration of the study, including recruitment and follow-up, was 18 months.

## Study Population

Children of both sexes, aged 2–12 years, with a diagnosis of intractable epilepsy were included.

## Inclusion criteria

- Age 2–12 years
- ≥5 seizure episodes per month despite regular AED use

## Exclusion criteria

- History of status epilepticus
- Severe recurrent respiratory tract infections
- Clinical evidence of neurodegenerative disorders

## Sample Size and Sampling Technique

Ten consecutive children meeting the eligibility criteria were enrolled during the recruitment period.

## Intervention

Participants received *Vilwapanchanga Ghrita* in age-appropriate doses, administered twice daily with lukewarm water for two months, as an add-on to their existing AED regimen:

- 2–6 years: 5 mL twice daily
- 7–12 years: 10 mL twice daily

A one-hour gap was maintained between AEDs and ghrita administration to minimize potential drug interactions. Dietary restrictions included avoidance of fermented, aerated, and alcoholic beverages; foods with pungent, bitter, excessively hot, or astringent tastes; and preparations containing additives or coloring agents. Parents were instructed to administer food only after the child regained appetite, ensuring complete digestion of the medication.

## Outcome Assessment

Data were collected through caregiver-maintained seizure diaries, parental interviews, and direct clinical observation at three time points: Baseline (before intervention), Post-treatment (after two months) and Follow-up (after four months).

## Subjective parameters

1. Seizure severity as assessed with Hague Seizure Severity Scale (HSSS)
2. Seizure associated Impairment of Consciousness
3. Seizure associated Frequency of Jerks or Cramps

## Objective parameters

### 1. Duration of Seizures in seconds

The Hague Seizure Severity Scale was used as the primary outcome tool. The HSSS is a validated, parent-reported scale designed for pediatric epilepsy, measuring 13 seizure-related parameters (ictal and postictal features). Each item is scored on a 4–5 point scale, with total scores ranging from 13 (least severe) to 54 (most severe). The dependent variables included changes in seizure frequency, duration, and severity, as reflected in HSSS cumulative scores.

## Statistical Analysis

Data were analyzed using descriptive statistics (mean, median, standard deviation, percentages) and appropriate graphical representations. The Wilcoxon Signed-Rank test, a non-parametric equivalent of the paired t-test suitable for small samples and ordinal data, was applied to compare pre- and post-intervention outcomes.

## Ethical Considerations

The study protocol was approved by the Institutional Ethics Committee (IEC), Government Ayurveda College, Thiruvananthapuram (Letter No. AVC-IEC 052018/2014, dated 20.05.2014). Informed written consent was obtained from parents after explaining study objectives, procedures, and rights of voluntary withdrawal. Patient confidentiality was strictly maintained. The formulation was prepared under expert supervision and considered safe based on longstanding departmental clinical experience.

## Observation and Results

### Demographic Characteristics

Among the 10 enrolled participants, 50% (n=5) were aged between 2–6 years, and 50% (n=5) were between 7–12 years. A male predominance was observed, with 90% of participants being boys. Socioeconomic distribution revealed that 40% (n=4) of children were from lower-income families, 40% (n=4) from middle-income, and 20% (n=2) from upper-income groups.

Perinatal history showed that 70% (n=7) were term babies, 10% (n=1) near-term, and 30% (n=3) preterm. Birth weight distribution indicated that 40% (n=4) had low birth weight (<2.5 kg), 50% (n=5) were within 2.5–3.5 kg, and 10% (n=1) weighed >3.5 kg.

Epilepsy onset was reported during the neonatal period in 50% (n=5), between 28 days–6 months in 10% (n=1), between 6 months–2 years in 30% (n=3), and between 2–6 years in 10% (n=1). No cases had onset between 6–10 years or 10–12 years. At baseline, 90% had poor seizure control, while 10% demonstrated moderate control.

Regarding *Doshic* vitiation, 70% exhibited *Kapha–Vata* dominance and 30% *Kapha–Pitta* dominance. Identified triggering factors included sleep



deprivation (20%), mental stress (10%), cold climate (20%), photic stimulation (10%), post-waking state (20%), hunger (10%), and loud sound (10%); no triggers were identified in 10% of participants.

Polytherapy was common: 30% were on two AEDs, 40% on three AEDs, and 30% on four AEDs. Seizure types included generalized tonic-clonic seizures (20%), West syndrome (20%), severe myoclonic epilepsy of childhood (10%), complex partial epilepsy (10%), mesial temporal lobe sclerosis (10%), tonic seizures (10%), atonic seizures (10%), and myoclonic epilepsy (10%).

## Parameters and Gradation

### Subjective Parameters

#### 1. Seizure Severity

- Tool: Hague Seizure Severity Scale (HSSS)
- Description: A validated parent-reported tool assessing 13 seizure-related parameters (ictal + post-ictal).
- Scoring:
  - Each item scored 0–4/5 (depending on domain).
  - Total score range: 13 (least severe) – 54 (most severe).
  - Interpretation: Higher score = greater severity.

#### 2. Impairment of Consciousness during seizures

- Tool: Caregiver observation & seizure diary.
- Gradation (frequency scale): Always (present in > 80% seizures), Usually (present in > 50% seizures), Sometimes (present in <50% seizures), Never (absent /present in <20% seizures)

#### 3. Frequency of Jerks/Cramps associated with seizures

- Tool: Caregiver observation & seizure diary.

- Gradation: Always, Usually, Sometimes and Never.

### Objective Parameters

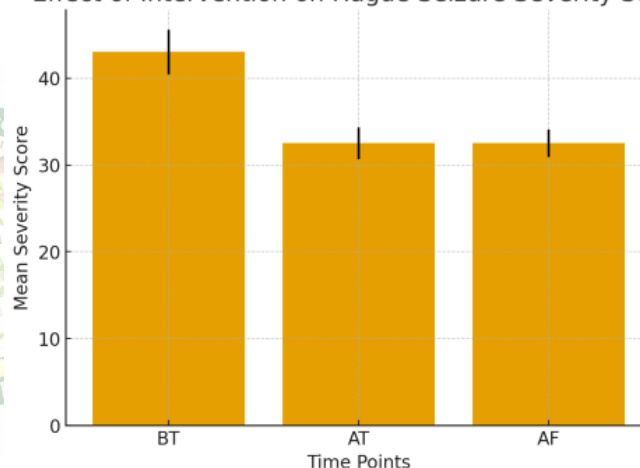
#### 1. Duration of Seizures

- Tool: Seizure diary + direct observation.
- Gradation: Recorded in seconds.
- Analysis: Reported as median with interquartile range (IQR) due to non-normal distribution.

### Seizure Severity

The Hague Seizure Severity Scale demonstrated a highly significant reduction in mean severity scores after two months of treatment, from  $43.0 \pm 2.58$  at baseline to  $32.5 \pm 1.84$  ( $p < 0.001$ ). This improvement persisted during the follow-up period, with mean scores remaining at  $32.5 \pm 1.58$ . (Table 1). Wilcoxon signed-rank testing confirmed significant reductions between baseline and post-treatment ( $p = 0.002$ ), and between baseline and follow-up ( $p = 0.002$ ), with no significant difference between post-treatment and follow-up ( $p = 0.508$ ).

Effect of Intervention on Hague Seizure Severity Scale



**Table 1: Effectiveness of treatment on change in overall seizure severity**

	N	Overall seizure severity score		Paired comparison	Paired differences		Paired samples t test	
		Mean	Sd		Mean	Sd	t	p
BT	10	43	2.582	BT - AT	10.5	1.716	19.35	<0.001
AT	10	32.5	1.841	AT - AF	0	0.667	0	1
AF	10	32.5	1.581	BT - AF	10.5	1.509	22	<0.001

### Impairment of Consciousness

Before treatment, impairment of consciousness was “always” present in 70% of participants. Post-treatment, this decreased to 10%, with most shifting to “sometimes” (50%) or “usually” (30%). At follow-up, results were sustained, with only minor variations. (Table 2). Statistical analysis revealed significant improvements from baseline to post-treatment ( $p = 0.006$ ) and from baseline to follow-up ( $p = 0.010$ ). No significant difference was found between post-treatment and follow-up.

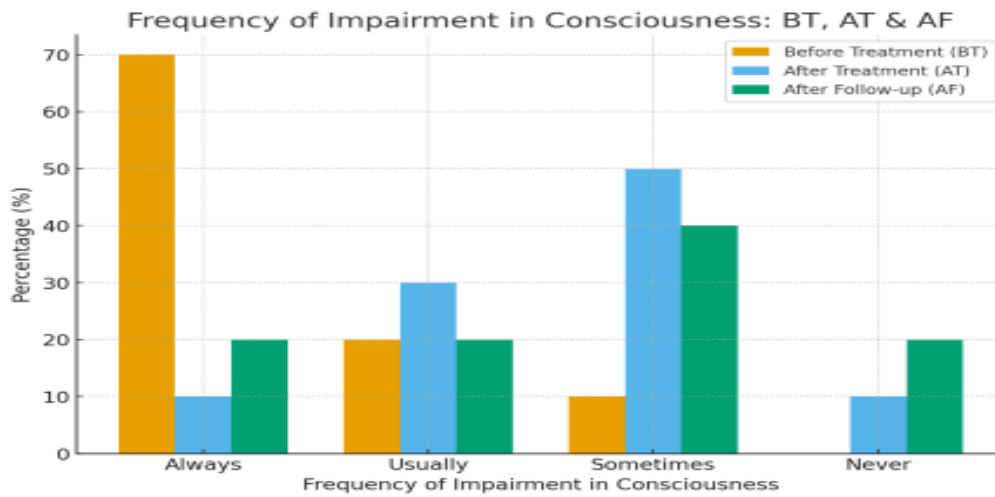


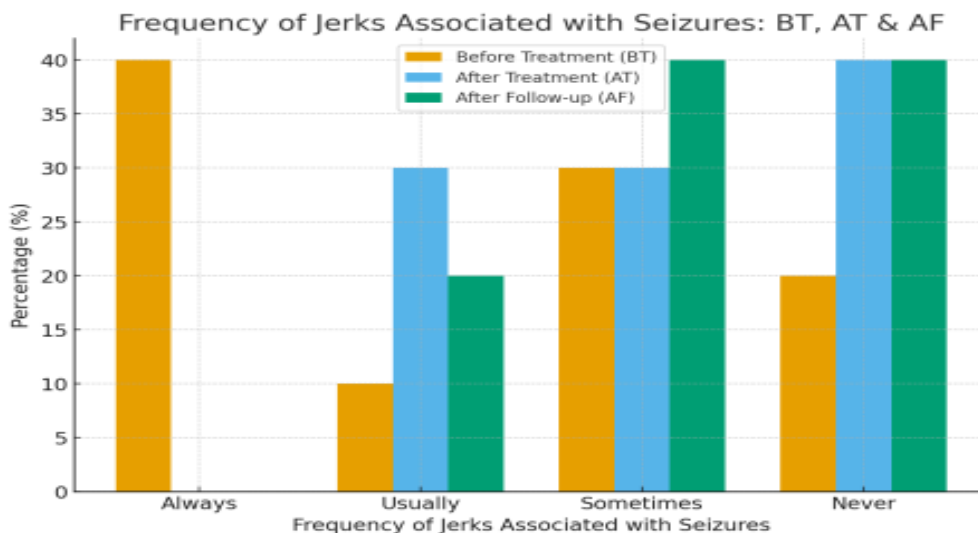
Table 2: Percentage reduction in Frequency of impairment of consciousness

Frequency	Before treatment		After treatment		After follow up	
	N	%	N	%	N	%
Always	7	70.0	1	10.0	2	20.0
Usually	2	20.0	3	30.0	2	20.0
Sometimes	1	10.0	5	50.0	4	40.0
Never	0	0	1	10.0	2	20.0
Total	10	100	10	100	10	100

Paired comparison	Wilcoxon signed rank test	
	Z	p
AT - BT	3.051	0.002
AT - AF	2.000	0.046
BT - AF	2.333	0.02

### Frequency of Jerks or Cramps

At baseline, 40% of participants experienced jerks “always,” 10% “usually,” 30% “sometimes,” and 20% “never.” Following treatment, the “always” category reduced to 0%, while 40% reported “never.” At follow-up, these results were largely maintained. Wilcoxon signed-rank testing demonstrated significant reductions from baseline to post-treatment ( $p = 0.011$ ) and baseline to follow-up ( $p = 0.014$ ), while no significant difference was observed between post-treatment and follow-up.



**Table 3: Percentage reduction in Frequency of Jerks or cramps**

Q4	BT		AT		AF	
	N	%	N	%	N	%
Always	4	40.0	0	0	0	0
Usually	1	10.0	3	30.0	2	20.0
sometimes	3	30.0	3	30.0	4	40.0
Never	2	20.0	4	40.0	4	40.0
Total	10	100	10	100	10	100

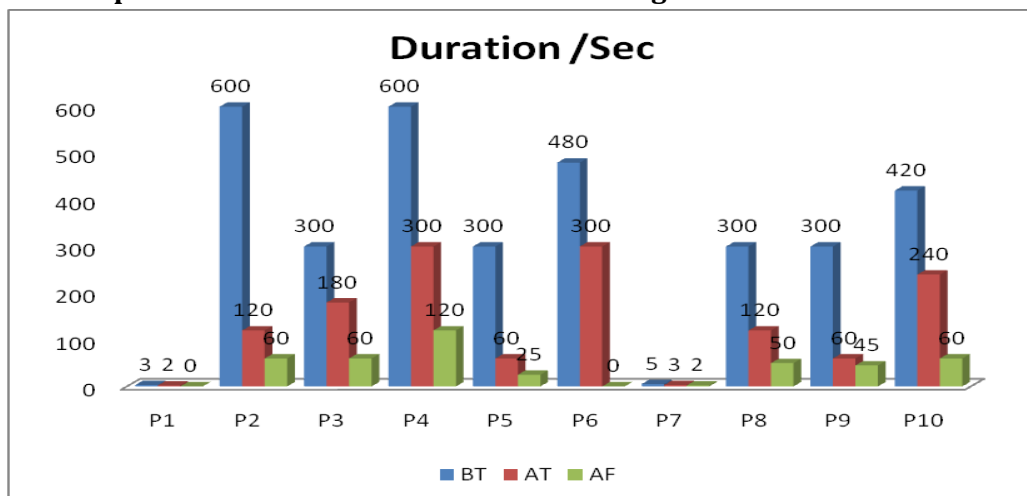
Wilcoxon signed rank test		
Paired comparison	Z	p
AT - BT	2.53	0.011
AT - BF	1.000	0.317
BT - BF	2.46	0.014

### Duration of Seizures

Median seizure duration decreased significantly from 300 seconds (IQR: 226.25–510.00) at baseline to 120 seconds (IQR: 45.75–255.00) post-treatment, and further to 47.5 seconds (IQR: 1.50–60.00) at follow-up. (Table 4). Statistical testing showed highly significant reductions across all comparisons (BT-AT, AT-AF, BT-AF;  $p = 0.005$  for all).

**Table 4: Effectiveness of treatment on change in duration of seizure**

Period of assessment	N	Duration in Seconds	Paired comparison	Wilcoxon signed rank test	
		Median Inter quartile range		Z	p value
BT	10	300.00 226.25 -510.00	BT-AT	2.812	0.005
AT	10	120.00 45.75 -255.00	AT-AF	2.805	0.005
AF	10	47.50 1.50 -60.00	BT-AF	2.807	0.005

**Graph 1: Effectiveness of treatment on change in duration of seizure**

### Safety Profile

No adverse effects were observed during the treatment or follow-up phases. Additionally, caregivers reported improvements in digestion and a reduction in recurrent respiratory tract infections.

### Discussion

Drug-resistant epilepsy (DRE) remains one of the most formidable challenges in pediatric neurology, with a substantial proportion of children failing to achieve seizure control despite polytherapy, ketogenic diet, surgical interventions, or neuromodulation.<sup>[8]</sup>

Persistent seizures not only increase the risk of neuronal injury but also compromise cognitive, psychosocial, and overall quality-of-life outcomes. The present study explored the efficacy of *Vilwapanchanga Ghrita* as an adjunctive intervention in intractable pediatric epilepsy, demonstrating meaningful clinical benefits across multiple outcome domains.

A significant reduction was observed in seizure severity, as reflected by the Hague Seizure Severity Scale (HSSS). Mean scores decreased from  $43.0 \pm 2.58$  at baseline to  $32.5 \pm 1.84$  post-treatment, with improvements persisting during follow-up ( $p < 0.001$ ). Furthermore, seizure-associated impairment of consciousness and frequency of jerks showed marked improvements, shifting patients from the “always” to “sometimes” or “never” categories. Median seizure duration also declined substantially, from 300 seconds to 47.5 seconds by follow-up. Importantly, these effects were sustained beyond the active treatment phase, suggesting that the intervention may induce stable neuromodulatory or neuroprotective effects.

From an Ayurvedic standpoint, *Apasmara* (epilepsy) is conceptualized as a disorder of *Dosha dushti* at the level of *Majja Dhatu* and higher cerebral functions.<sup>[9,10]</sup> The observed improvements can be explained through the pharmacological and therapeutic attributes of *Vilwapanchanga Ghrita*. The formulation combines *Vata-Kapha Shamana* action, *Amapacana* (detoxification), and *Srotoshodhana* (channel cleansing) with *Rasayana* (rejuvenative) properties.<sup>[11]</sup> Its lipophilic base enhances transmembrane absorption and facilitates blood–brain barrier penetration, a critical factor for central nervous system efficacy.

Modern pharmacological insights support these mechanisms. *Aegle marmelos* (*Vilwa*) has documented anticonvulsant, antioxidant, hepatoprotective, and immunomodulatory properties,<sup>[12,13]</sup> which may synergistically reduce seizure activity and improve systemic resilience. Additionally, the ketogenic potential of medicated ghee could contribute to seizure reduction, paralleling the established benefits of ketogenic diets in refractory epilepsy.<sup>[14]</sup> The inclusion of *Pancagavya* provides *Ksharatva* (disintegrative quality), aiding in the clearance of *Srotorodha* (channel obstruction), traditionally implicated in seizure pathophysiology.<sup>[15,16]</sup>

Another critical observation was the improvement in digestion and reduction of recurrent respiratory infections reported by caregivers. These findings reinforce the *Rasayana* and immunomodulatory actions of the intervention, highlighting its systemic benefits beyond seizure control.<sup>[13,15]</sup> Considering the oxidative stress and cumulative toxic load from long-term antiepileptic polytherapy, the hepatoprotective and antioxidant

actions of the formulation may also mitigate iatrogenic adverse effects, thereby improving overall tolerability.<sup>[17]</sup>

The findings of this pilot study are encouraging but must be interpreted with caution due to limitations, including small sample size, absence of a control arm, and reliance on caregiver-reported outcomes for some measures. Despite these constraints, the consistent improvements across seizure severity, consciousness, jerks, and duration, along with the absence of adverse events, suggest a promising role for *Vilwapanchanga Ghrita* as a safe and potentially effective adjunct in pediatric epilepsy.

Future research should focus on larger, controlled clinical trials, pharmacokinetic profiling of bioactive compounds, and mechanistic studies exploring antioxidant, anti-inflammatory, and neuroprotective pathways. Such integrative approaches may establish a stronger evidence base for Ayurveda-inspired interventions in epilepsy and contribute to bridging traditional knowledge with contemporary neuroscientific research.

## Conclusion

1. *Vilwapanchanga Ghrita* as an adjunct to antiepileptic drugs demonstrated significant reductions in seizure severity, duration, impairment of consciousness, and seizure-associated jerks in children with intractable epilepsy.
2. The intervention was well tolerated, with additional benefits including improved digestion and reduced frequency of respiratory infections, highlighting its systemic *Rasayana* and immunomodulatory potential.
3. These findings support the role of integrative Ayurvedic approaches in pediatric epilepsy management, warranting validation through larger, controlled clinical trials.

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**\*Address for correspondence**

**Dr Roshni Anirudhan**

Professor & Head,  
Department of Kaumarabhritya,  
Government Ayurveda College,  
Thiruvananthapuram, Kerala, India  
Email: [dranjuvimal@gmail.com](mailto:dranjuvimal@gmail.com)

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