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COMPARATIVE ANALYSIS OF STANDARD VS HIGH DOSE STEROID VS VIGABATRIN IN TREATMENT OF INFANTILE SPASMS: A SHORT-TERM OUTCOME BASED STUDY

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Abstract

Objective: *To compare the short-term outcomes of standard-dose prednisolone, high-dose prednisolone and vigabatrin in children with infantile spasms.*

Study Design: *Quasi-experimental study*

Place and Duration of Study: *Department of Pediatric Neurology, The Children's Hospital, Lahore, from October 2024 to March 2025.*

Materials and Methods: *Sixty-six children aged 3-24 months with infantile spasms using non probability consecutive sampling were enrolled and allocated into three groups: standard-dose prednisolone (2 mg/kg/day), high-dose prednisolone (10 mg per dose four times daily) and vigabatrin (dose titrated up to 150 mg/kg/day). Outcomes were assessed on day 14 in terms of effectiveness (complete response) and adverse effects.*

Results: *Out of total 66 patients, the majority of the patients were males, younger than 12 months, had an illness duration longer than one month and were predominantly from urban areas. CNS infections were the most frequent underlying etiology among three groups. Developmental delay was observed in majority of patients. Effectiveness was achieved in 63.6% of children in the high-dose group compared to 27.3% in both the standard-dose group and vigabatrin group (p=0.017). Adverse effects were more common in steroid groups, including weight gain, hypertension, irritability, hyperglycemia, and infections. In contrast no adverse effects were observed in the vigabatrin group (p=0.230).*

Conclusion: *High-dose prednisolone was significantly more effective than standard-dose prednisolone and vigabatrin in achieving spasm resolution at day 14, with an acceptable adverse effect profile. Vigabatrin showed lower efficacy but was well tolerated.*

INTRODUCTION

Infantile spasms (IS) is a type of epilepsy affecting infants in their first year. It is characterized by short, sudden muscle contractions in the neck, torso, and arms, spasms occur in clusters up to 100 times daily. They often manifest in morning and during alertness, triggered by sudden noises or movements.[1,2] Infantile spasms primarily occur in infants aged three to 12 months, with an incidence of 4.5 per 1000 live births; peak onset age is four to seven months.[3]

Timely diagnosis and management of IS are often delayed, adversely impacting growth,

disrupting brain development, leading to developmental delays and cognitive deficits.[4] Infantile spasms are typically treated with adrenocorticotropic hormone (ACTH) or vigabatrin, to reduce spasms frequency. EEG serves as a reliable technique to diagnose IS. BASED score is a scoring system (0-5) used to detect EEG severity and assess response to therapy in patients of IS.[5]

Cessation of spasms is the primary treatment goal for IS, with EEG as an effective evaluation tool. Early treatment and spasm cessation are associated with better neurodevelopmental outcomes.[6] Delays in IS treatment are linked to poor outcomes, such as psychomotor regression and seizures in later life.[7,8] Corticosteroids and Vigabatrin effectively treat infantile spasms; however, their effectiveness and safety are controversial.[9,10]

In a study, clinical effectiveness was observed in 29.0% low-dose versus 58.1% high-dose steroid patients (p=0.026). Weight gain (12.9% vs. 22.6%), hypertension (3.2% vs. 9.7%), irritability (12.9% vs. 9.7%), and infection (12.9% vs. 19.4%) were comparable.[11] In another study, spasm cessation on day-14 was higher in the high-dose group (51.6% vs. 25%, p=0.03).[12] Vigabatrin alone resulted in spasms resolution in 33.3% of patients. Effectiveness was noted in 39.1% of patients after 14 days.[13,14]

Steroids are often an affordable choice of treatment of IS. High cost of vigabatrin and nonavailability of ACTH in Pakistan poses significant treatment challenges. In Pakistan, no trials have been done comparing low, high doses of prednisolone and vigabatrin in children with IS, so we aimed this research to compare the outcomes of these three regimens in our population.

METHODOLOGY

This quasi-experimental study was conducted at the Department of Pediatric Neurology, The Children's Hospital, Lahore, from October 1st, 2024, to March 31st, 2025, after approval from the Hospital's Ethical Committee. Children aged between 3 and 24 months who presented with epileptic spasms were included. Inclusion criteria comprised children having spasms with a frequency of at least one cluster per day, with or without EEG-confirmed hypsarrhythmia, modified hypsarrhythmia, or multifocal discharges assessed using the BASED score. Children were excluded if they had evidence of active tuberculosis, active systemic illness, severe acute malnutrition (defined as visible wasting or mid-upper arm circumference <11.5 cm), were already taking steroids, had severe hypertension, or had an inborn error of metabolism (screening done on basis of developmental regression, refractory seizures, family history and relevant investigations like ABGs, BSR, Anion gap, Serum electrolytes, Urine for ketones, Ammonia and Lactate) to avoid etiological heterogeneity. Etiological diagnosis was recorded in all cases keeping in view thorough history, clinical examination and relevant investigations if required.

A total of 66 children were enrolled using non-probability consecutive sampling. The sample size was calculated with a 95% confidence level, 80% power of the test, and taking the expected percentage of clinical effectiveness (complete response) as 29.0% in the standard-dose and 58.1% in the high-dose, resulting in 22 children per group.[11] After obtaining written informed consent from parents, eligible children were allocated into three groups. Children in the standard-dose prednisolone group received prednisolone at 2 mg/kg/day, administered in three divided doses for 14 days. Children in the high-dose prednisolone group received prednisolone at a fixed dose of 10 mg per dose, four times daily, irrespective of weight, for 14 days. Children in the vigabatrin group received vigabatrin starting at 50 mg/kg/day for one day, increased to 100 mg/kg/day for the next three days, and escalated to 150 mg/kg/day if spasms persisted.

Outcomes were evaluated for effectiveness and adverse effects. Effectiveness was defined as complete response with spasm resolution with or without BASED score of ≤2 for ≥48 hours after 14 days of treatment. Primary outcome was categorized as complete (spasm freedom ≥48 hours), partial (>50% reduction), or no response (<50% reduction) on Day 14, with or without BASED score of ≥3. Adverse effects (secondary outcome) included weight gain, hypertension, irritability, hyperglycemia, infections, and blurred vision. Education of

parents regarding seizure burden and response was given. Seizure burden was documented by frequency of spasms by the parents. Data were collected via structured proforma, including demographic variables, history, physical examination, EEG findings, and diagnosis. Parents were reminded 2-3 days before the 14-day follow-up. EEG findings were noted prior to treatment and on follow-up visit by 2 expert pediatric neurologists independently. At follow-up, outcomes were assessed, blood pressure measured, weight assessed electronically, and irritability evaluated through parent questioning. Infections were identified based on clinical assessment and validated by investigations (CBC, urinalysis, chest X-ray). The management of different adverse effects was done according to established guidelines without compromising treatment continuity. Further treatment of patients was done according to UK protocol of IS.

Data input and analysis were conducted utilizing SPSS version 25. Quantitative parameters like age, systolic blood pressure, diastolic blood pressure, and weight were expressed as mean values accompanied by their standard deviations. Qualitative factors such as gender, residency status, underlying causes, treatment effectiveness, and adverse reactions were reported in terms of frequencies and proportions. To account for potential confounding variables, stratification was carried out based on age, gender, residency, and etiology. Following stratification, group comparisons were made using the Chi-square test. Statistical significance was defined as a p-value of ≤0.05.

RESULTS

The majority of the patients in all the groups were males (63.6%). In Group A (standard dose prednisolone), 72.7% were males and 27.3% were females, while in Group B (high dose prednisolone), 59.1% were males and 40.9% were females, and the same distribution was observed in Group C (vigabatrin). Regarding age groups, most of the patients were younger than 1 year (54.5%). In Group A, 54.5% were ≤12 months and 45.5% were >12 months with a mean age of 12.56±5.96 months as compared to 11.29±4.77 months in Group B and 14.40±6.35 months in Group C.

Mean weight was highest in Group C at 9.08±2.55 kg, compared to 8.20±2.51 kg in Group A and 7.55±1.98 kg in Group B. Mean systolic blood pressure was comparable across groups with 85.91±7.65 mmHg in Group A, 84.09±6.29 mmHg in Group B, and 87.05±7.34 mmHg in Group C. Mean diastolic blood pressure was also similar among groups. Regarding duration of illness, the majority in each group had illness duration of more than one month (65.1%). In terms of residence, most children were from urban areas across all groups (60.6%). Etiologically, hypoxic ischemic encephalopathy was the most common in Group B (45.5%), while CNS infections were more frequent in Group C (36.4%) with CNS infection being overall common among three groups (31.8%). Developmental delay was present in the majority of patients in all groups (86.3%), especially in Group B with 95.5%. Mean first EEG BASED score was highest in Group B (2.68±1.78) and lowest in Group A (2.23±1.77), while mean second EEG BASED scores showed reduction in all groups after treatment. TABLE 1 shows variable distribution among three groups.

The primary outcome at day 14 showed complete response in 27.3% of Group A, 63.6% of Group B, and 27.3% of Group C patients, with a p-value of 0.040 indicating significant difference. Partial response was noted in 40.9% of Group A, 18.2% of Group B, and 54.5% of Group C patients, while no response was observed in 31.8% of Group A, 18.2% of Group B, and 18.2% of Group C patients.

Overall effectiveness defined as complete response was significantly higher in Group B (63.6%) compared to Group A (27.3%) and Group C (27.3%), with a p-value of 0.017. Regarding adverse effects, no adverse effects were reported in 68.2% of Group A, 68.2% of Group B, and all patients in Group C. Weight gain was observed in 4.5% of Group A and 9.1% of Group B patients, hypertension (>95th centile for age) in 9.1% of Group A, infection in 4.5% of Group A and Group B, each, irritability in 9.1% of both Group A and Group B, and hyperglycemia(≥200mg/dl) in

4.5% of Group A and 9.1% of Group B patients. No adverse effects were noted in Group C patients. The differences in adverse effects among groups were not statistically significant (p-value=0.230). TABLE 2 shows the comparison of outcome variables among the three groups.

Complete response was generally higher in the high-dose group, especially among females and children aged ≤12 months, where the differences were statistically significant. For other variables like gender (male), age >12 months, residence, and different etiologies, differences in effectiveness among groups were not significant. TABLE 3 shows the stratified analysis of treatment efficacy based on different variables among the groups.

Table-1: Comparative analysis of distribution of different variables among groups

Variable	Subcategory	Group A (Standard dose)	Group B (High dose)	Group C (Vigabatrin)
Gender	Male	16 (72.7%)	13 (59.1%)	13 (59.1%)
	Female	6 (27.3%)	9 (40.9%)	9 (40.9%)
Age Group	≤12 months	12 (54.5%)	14 (63.6%)	10 (45.5%)
	>12 months	10 (45.5%)	8 (36.4%)	12 (54.5%)
	Mean ± S.D (months)	12.56 ± 5.96	11.29 ± 4.77	14.40 ± 6.35
Weight (kg)	Mean ± S.D (kg)	8.20 ± 2.51	7.55 ± 1.98	9.08 ± 2.55
Systolic BP (mmHg)	Mean ± S.D (mmHg)	85.91 ± 7.65	84.09 ± 6.29	87.05 ± 7.34
Diastolic BP (mmHg)	Mean ± S.D (mmHg)	63.83 ± 4.86	62.73 ± 4.81	65.45 ± 5.32
Duration of Illness	≤1 month	7 (31.8%)	8 (36.4%)	8 (36.4%)
	>1 month	15 (68.2%)	14 (63.6%)	14 (63.6%)
	Mean ± S.D (months)	1.54 ± 0.80	1.75 ± 0.91	1.76 ± 0.82
Residence	Rural	8 (36.4%)	9 (40.9%)	9 (40.9%)
	Urban	14 (63.6%)	13 (59.1%)	13 (59.1%)
Etiology	HIE	6 (27.3%)	10 (45.5%)	4 (18.2%)
	Brain Malformation	0 (0.0%)	1 (4.5%)	2 (9.1%)
	CNS Infection	6 (27.3%)	7 (31.8%)	8 (36.4%)
	Neurocutaneous Syndrome	3 (13.6%)	2 (9.1%)	4 (18.2%)
	Unknown	7 (31.8%)	2 (9.1%)	4 (18.2%)
Developmental Status	Normal	5 (22.7%)	1 (4.5%)	3 (13.6%)
	Delayed	17 (77.3%)	21 (95.5%)	19 (86.4%)
EEG Score (BASED)	1st EEG (Mean ± S.D)	2.23 ± 1.77	2.68 ± 1.78	2.27 ± 1.98

	2nd EEG (Mean ± S.D)	0.83 ± 1.38	1.32 ± 1.33	0.94 ± 1.29

Table-2: Comparison of outcome variables among different groups

Outcome Variable		Group-A (Standard Dose)	Group-B (High Dose)	Group-C (Vigabatrin)	p-value
Primary Outcome at Day 14	Complete Response	6 (27.3%)	14 (63.6%)	6 (27.3%)	0.040
	Partial Response	9 (40.9%)	4 (18.2%)	12 (54.5%)	
	No Response	7 (31.8%)	4 (18.2%)	4 (18.2%)	
Effectiveness (Complete Response)	Yes	6 (27.3%)	14 (63.6%)	6 (27.3%)	0.017
	No	16 (72.7%)	8 (36.4%)	16 (72.7%)	
Adverse Effects	Nil	15 (68.2%)	15 (68.2%)	22 (100%)	0.230
	Weight Gain	1 (4.5%)	2 (9.1%)	0 (0%)	
	Hypertension	2 (9.1%)	0 (0%)	0 (0%)	
	Infection	1 (4.5%)	1 (4.5%)	0 (0%)	
	Irritability	2 (9.1%)	2 (9.1%)	0 (0%)	
	Hyperglycemia	1 (4.5%)	2 (9.1%)	0 (0%)	

Table-3: Stratification of efficacy (complete response) among groups with respect to different variables

Variable	Category	Response	Group-A (Standard dose)	Group-B (High dose)	Group-C (Vigabatrin)	p-value
Gender	Male	Yes	4 (25.0%)	6 (46.2%)	3 (23.1%)	0.359
		No	12 (75.0%)	7 (53.8%)	10 (76.9%)	
	Female	Yes	2 (33.3%)	8 (88.9%)	3 (33.3%)	**0.030**
		No	4 (66.7%)	1 (11.1%)	6 (66.7%)	
Age group	≤12 months	Yes	3 (25.0%)	12 (85.7%)	3 (30.0%)	**0.003**

		No	12 (75.0%)	2 (14.3%)	7 (70.0%)	
	>12 months	Yes	3 (30.0%)	2 (25.0%)	3 (25.0%)	0.958
		No	7 (70.0%)	6 (75.0%)	9 (75.0%)	
Residence	Rural	Yes	2 (25.0%)	6 (66.7%)	3 (33.3%)	0.177
		No	6 (75.0%)	3 (33.3%)	6 (66.7%)	
	Urban	Yes	4 (28.6%)	8 (61.5%)	3 (23.1%)	0.089
		No	10 (71.4%)	5 (38.5%)	10(76.9%)	
Etiology	HIE	Yes	2 (33.3%)	7 (70.0%)	1 (25.0%)	0.195
		No	4 (66.7%)	3 (30.0%)	3 (75.0%)	
	Brain malformation	Yes	0 (0.0%)	1 (100.0%)	1 (50.0%)	0.386
		No	0 (0.0%)	0 (0.0%)	1 (50.0%)	
	CNS infection	Yes	0 (0.0%)	3 (42.9%)	1 (12.5%)	0.122
		No	6 (100.0%)	4 (57.1%)	7 (87.5%)	
	Neurocutaneous	Yes	1 (33.3%)	1 (50.0%)	1 (25.0%)	0.829
		No	2 (66.7%)	1 (50.0%)	3 (75.0%)	
	Unknown	Yes	3 (42.9%)	2 (100.0%)	2 (50.0%)	0.354
		No	4(57.1%)	0(0.0%)	2 (50.0%)	

DISCUSSION

Infantile spasms represent a severe form of epileptic encephalopathy that manifests in infancy, characterized by epileptic spasms, abnormal brain wave patterns known as hypsarrhythmia on electroencephalogram and developmental regression or stagnation. Typically manifesting between the ages of three to twelve months, prompt intervention is essential to enhance seizure management and long-term neurodevelopmental outcomes. Treatment modalities encompass a range of options, including hormonal therapies like ACTH and prednisolone, as well as vigabatrin.[10]

This study demonstrated that the administration of high-dose prednisolone yielded significantly superior outcomes in achieving spasm freedom in comparison to standard-dose prednisolone and vigabatrin, with complete response rates of 63.6%, 27.3%, and 27.3% correspondingly (p=0.017). These results align with a prior research endeavor conducted in Pakistan by Basit et al., wherein the utilization of high-dose prednisolone (10 mg four times daily) resulted in a complete response rate of 58.1% versus 29.0% in the low-dose cohort (p=0.026), with no notable variance in adverse effects observed between the groups.[11]

Chellamuthu observed a greater therapeutic effectiveness of high-dose prednisolone at 51.6% in contrast to standard-dose prednisolone at 25% (p=0.03). Moreover, comparable incidences of adverse events were noted across both dosage groups.[12]

In a meta-analysis done in Taiwan, no significant difference was observed between steroids and ACTH in remission of spasms (p=0.32).[15] Furthermore, Shaojun Li, as documented in the meta-analysis of randomized controlled trials demonstrated equal efficacy of steroids and ACTH in treating IS, similarly, showing superior efficacy of high dose steroid compared to low dose steroid in achieving spasm freedom.[16] A comprehensive meta-analysis conducted by O'Callaghan has substantiated the superiority of hormonal

treatments over vigabatrin.[17] In a similar study, electroclinical response occurred in 64% of infants with IS within two weeks with high dose steroid regime.[18]

In our study, vigabatrin achieved a complete response rate of 27.3%. This is comparable to previous reports such as Hancock et al. who found efficacy rates between 35% and 33% in general infantile spasms populations,[19,20] while Pellock et al. noted approximately 35% response rate outside of tuberous sclerosis.[21] In research conducted by Knupp, administration of steroid therapy results in a swifter alleviation of spasms in contrast to vigabatrin, potentially impacting cognitive prognoses over an extended duration.[22]

The implications of these findings are important for treatment protocols in resource-limited settings where ACTH is often unavailable. High-dose oral prednisolone provides an accessible, cost-effective, and effective alternative. Although adverse effects such as weight gain, hypertension, and hyperglycemia were more frequent in steroid groups, they were generally manageable.

This study had limitations including a small sample size and short follow-up duration limited to 14 days, which precluded assessment of relapse rates, long-term seizure control, and neurodevelopmental outcomes. The non-randomized design may also introduce selection bias. Future studies should include randomized controlled trials with larger cohorts and long-term follow-up to assess cognitive and developmental outcomes.

CONCLUSION

In conclusion, high-dose prednisolone was significantly more effective than standard-dose prednisolone and vigabatrin in achieving short-term spasm resolution in children with infantile spasms, with an acceptable safety profile. Vigabatrin, while well tolerated, showed lower efficacy. High-dose prednisolone should be considered as a practical and effective first-line therapy in settings where ACTH is not accessible.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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No funding was required as treatment was available at The Children's Hospital, Lahore.

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