

Pattern of EEG Change after Treatment with High Dose Oral Prednisolone in Comparison to Low Dose ACTH among Children with West Syndrome in a Tertiary Care Hospital

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Abstract:

Background: West syndrome is a devastating epileptic encephalopathy of early infancy. The peak age of onset is 4-6 months, and the incidence of WS is 2–3 cases per 10,000 live births. In WS, the EEG is severely abnormal. Therefore, this study aimed to assess the EEG pattern before and after treatment of high-dose oral prednisolone compared to intramuscular ACTH in patients with West syndrome.

Methods: This prospective observational study was conducted in the Department of Paediatric Neurology, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh, from September 2021 to August 2022. We included 60 Patients with West syndrome and divided them into two groups: The experimental group (Patients who received oral prednisolone at a dose of 4 /kg/day for 2 weeks) and the Control group (Patients who received ACTH therapy 20 IU/day for 2 weeks).

Result: Initial EEG findings include classical hypsarrhythmia was found in 36.67% (11/ 30) in oral prednisolone group and 23.33% (7/30) in the ACTH group, the focal epileptiform discharge (6.67 % & 10%), Multifocal discharge was present (26.67% and 30.0%) and burst suppression was present (30% and 36.67%) in oral prednisolone group and ACTH group respectively. Electroencephalography response was found normal in 17/30 patients (56.67%) in the Oral prednisolone group and 11/30 (36.67%) in the ACTH group. EEG response after Oral prednisolone and IM ACTH therapy showed significant improvement (P -value <0.001).

Conclusion: Interictal EEG pattern changes were found in the patient with West syndrome during treatment with high-dose oral prednisolone and low-dose ACTH.

Keywords: West syndrome, Oral prednisolone, ACTH, Hypsarrhythmia, EEG

1. INTRODUCTION

West syndrome (WS) is a devastating form of epilepsy defined by a triad of infantile spasms, genetic (tuberous sclerosis complex), structural (malformation of cortical development), and previous CNS insult. [10] group clusters were

first described by Dr. West of England in 1841 which was observed in his infant son.[2] The incidence of WS is 2–3 cases per 10,000 live births and a lifetime prevalence rate of 1.5-2 per 10,000 children. [3,4]

WS affects infants between the ages of 6 and 12 months, with a peak onset of 4 to 6 months. It can be responsible for up to 20% of new-onset epilepsy cases in children under the age of 2 and up to 5% of all instances of childhood-onset epilepsy. [5] There are several possible prenatal, perinatal, and postnatal phases where infantile spasms (ISs) may originate. One of ISs' most frequent causes is hypoxic-ischemic encephalopathy, according to reports. Following the most frequently used classical terms, WS and IS, the term epileptic spasm has been included in the broad definition of "infantile spasm syndrome" (ISs), a condition in which various seizure types, EEG, and developmental features tend to occur simultaneously. [6] The most serious aspect of WS was the poor developmental outcome: 70% to 90% of children subsequently develop cognitive deficits (IQ<70), and 30% show symptoms of autistic spectrum disorder. [7] Numerous newborns with WS also experience focal seizures, which progress to Lennox-Gastaut syndrome, another kind of catastrophic epileptic encephalopathy. [8] Overall, the precise underlying etiology and therapeutic delay are frequently linked to the outcome of WS.[7-9] For a great majority (70%) of infants the cause for WS can include genetic (tuberous sclerosis complex), structural (malformation of cortical development), and previous CNS insult. [10].

The prenatal, perinatal, and postnatal stages may be the source of infantile spasms (IS). One of the most frequent causes of ISs is said to be hypoxic-ischemic encephalopathy. Hypoxic-ischemic encephalopathy was found in 10% of 127 out of 207 individuals with ISs with a confirmed etiological diagnosis, according to the "United Kingdom Infantile Spasms Study" (UKISS). Chromosome abnormalities and complex malformation syndromes were the next most common causes. [11]

Gibbs and Gibbs originally characterized the typical EEG pattern of the epileptic encephalopathy in West syndrome in 1952, referring to it as "hypsarhythmia." [12] Nevertheless, hypsarhythmia is not always present, nor is it always present throughout the illness. [13, 14] In addition to hypsarhythmia, several newborns had clusters of epileptic spasms (ES).[15] Thus, there are differences in

the EEG image of West syndrome. In most cases, hypsarhythmia goes away after a clinical episode of epileptic spasms. During the disease, another EEG pattern replaces or alters the interictal pattern.[1] Both the resolution of hypsarhythmia on EEG and the cessation of epileptic spasms should result from effective therapy for WS.

In various studies, it is found that seizure relapse after initial treatment is dependent on initial EEG findings.[16]

Therefore, in this study, we present the electroclinical features and evolution of patients with West syndrome to assess the EEG pattern before and after treatment of high-dose oral prednisolone compared to intramuscular ACTH.

2. METHODOLOGY

This was a prospective observational study conducted in the Department of Paediatric Neurology, IPNA, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh during the period from September 2021 to August 2022. In our study, we included 60 children with symptoms and signs of West syndrome attending the outpatient and inpatient Department of Pediatric Neurology at BSMMU. All studied children were divided into two groups: The experimental group: Participants treated with high-dose oral prednisolone therapy and the Control group: Participants treated with intramuscular ACTH therapy.

These are the following criteria to be eligible for enrollment as our study participants: a) Children aged 2 months to 2 years; b) Children with Epileptic spasms, and developmental arrest; c) Children with EEG changes specific for West syndrome; d) Parents of children who were willing to participate were included in the study And a) Children with status epilepticus;b) Children previously treated with either prednisolone or ACTH; c) Children with tuberous sclerosis; d) Children with known allergy/hypersensitivity to study drugs; e) Children with any history of acute illness (e.g.,renal or pancreatic diseases, ischemic heart disease, asthma, COPD etc.) were excluded from our study.

2.1. Drug Dosage

The experimental group received oral prednisolone therapy; the dose regimen for

oral prednisolone was 4 mg/kg/ day in divided doses given for 2 weeks during which patients were observed for side effects of steroid. The control group received intramuscular ACTH at a dose of 20 IU once daily in each alternate thigh for 2 weeks of therapy.

2.2. Data Collection Procedure

Participants were recruited through outpatient and inpatient clinics and were subjected to a comprehensive baseline evaluation, including a detailed medical history, neurological examination, CT, MRI, and EEG. Seizure frequency, before and after therapy, was assessed based on parents’ reports and seizure diary. Therapeutic response was assessed after 2 weeks of treatment. [17] Adverse effects were closely monitored and managed according to institutional protocols. Follow-up evaluations, including seizure frequency and EEG, were conducted after the completion of treatment. After the clinical resolution, prednisolone and ACTH were tapered over 2 weeks and stopped. In children with persisting spasms, oral prednisolone and ACTH were tapered gradually over 2 weeks, and other first-line anti-epileptic drugs were added. Hypsarrhythmia was characterized by an EEG with 0.5 to 3 Hz chaotic, asynchronous slow waves with voltages greater than 300 mV. Multifocal spikes and sharp and slow waves

may also be present. Intervals of attenuation can occur with and without clinical myoclonic activity or flexor spasms. ¹⁰ Modified hypsarrhythmia was described by one of the following criteria: a) Hypsarrhythmia with increased interhemispheric synchronization, b) Asymmetrical hypsarrhythmia, c) Hypsarrhythmia with a consistent focus on abnormal discharge, d) Hypsarrhythmia with episodes of attenuation, and e) Hypsarrhythmia comprises primarily high-voltage slow activity with little sharp-wave or spike activity.[18]

2.3. Statistical Analysis

All data were recorded systematically in preformed data collection form. Quantitative data was expressed as mean and standard deviation and qualitative data was expressed as frequency distribution and percentage. The comparison between groups was analyzed by unpaired t-test, chi-square (X²) test, fisher’s exact test, and paired T-test. A marginal homogeneity test was done to compare the EEG response before and after therapy. A p-value <0.05 was considered as significant. Statistical analysis was performed by using SPSS 23 (Statistical Package for Social Sciences) for Windows version 10. The study was approved by the Ethical Review Committee of Bangabandhu Sheikh Mujib Medical University.

3. RESULTS

Table I. Baseline characteristics of the study participants in two groups (N=60)

	Oral Prednisolone (n=30)	ACTH (n=30)	p-value
Age (months)			
Mean ± SD	12.06 ± 5.87	12.20 ± 5.83	1.000
Gender			
Male	18 (60.0)	20 (66.67)	0.841
Female	12 (40.0)	10 (33.33)	
Weight	8.18 ± 2.15	8.62 ± 8.64	0.755
Microcephaly	15 (50.0)	17 (56.67)	0.651
Birth-related history of the study participants			
Gestational age (weeks)			
Preterm	6 (20.0)	6 (20.0)	0.840
Term	22 (73.33)	23 (76.67)	
Post-term	2 (6.67)	1 (3.33)	
Prenatal history			
Fever/rash	1 (3.33)	1 (3.33)	0.734
HTN	3 (10.0)	6 (20.0)	
UTI	6 (20.0)	6 (20.0)	
Perinatal			
Asphyxia	21 (70.0)	22 (73.33)	0.203
Neonatal Jaundice	7 (23.33)	4 (13.33)	
Post-natal			
Neonatal sepsis	12 (40.0)	18 (60.0)	0.094

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Meningitis	1 (3.33)	2 (6.67)	
Birth weight			
AGA	16 (53.33)	19 (63.33)	0.564
SGA	11 (36.67)	9 (30.0)	
LGA	3 (10)	2 (6.67)	
Seizure Profile			
Age of onset of spasm (months)	5.20 ± 3.22	4.64 ± 2.24	0.361
Type of spasm			
Flexor	16 (53.33)	14 (46.67)	0.243
Extensor	3 (10.0)	3 (10.0)	
Mixed	11 (36.67)	13 (43.33)	
Number of clusters/days	13.12 ± 11.72	17.25 ± 11.63	0.120
Character of spasm			
Symmetric	27 (90.0)	27 (90.0)	1.000
Asymmetric	3 (10.0)	3 (10.0)	
Development history before the spasm			
Age appropriate	7 (23.33)	7 (23.33)	0.785
Delayed	23 (76.67)	23 (76.67)	

Table I seizure profiles of the study subjects. Most of the study subjects were aged ≤12 months in both high-dose oral prednisolone and ACTH groups. Males were predominant in both groups. Perinatal asphyxia was the commonest cause found in both groups (70% in the oral prednisolone group and 73.33% in the ACTH group). There was no significant difference in age, gender, weight, and OFC

between the two groups. The mean age of onset of spasm was 5.20 ± 3.22 months and 4.64 ± 2.24 months in the high-dose oral prednisolone group and ACTH group respectively (P-value 0.361). The most prevalent type of spasm was flexor and mixed in the oral prednisolone group and the ACTH group. Character of spasm was symmetrical (90%) and Asymmetric (10%) in both groups.

Table II. Baseline EEG characteristics of the study participants in two groups (N=60)

	Oral Prednisolone (n=30)	ACTH (n=30)	p-value
Baseline EEG characteristics			
Background (abnormal)	30 (100.0)	30 (100.0)	
Classical hypsarrhythmia	11 (36.67)	7 (23.33)	0.633
Modified hypsarrhythmia			
Focal discharge	2 (6.67)	3 (10.0)	0.664
Suppression burst variant	9 (30.0)	11 (36.67)	0.446
Multifocal discharge	8 (26.67)	9 (30.0)	0.348
Frequency (mean ± SD)	4.87 ± 1.08	4.66 ± 0.92	0.371

Table II shows the EEG findings of the study subjects in two groups. Classical hypsarrhythmia was found in 36.67% of the oral prednisolone group and 23.33% in the ACTH group, focal epileptiform discharge was found (6.67 % & 10%), Multifocal

discharge was present (26.67% and 30.0%) and burst suppression was present (30% and 36.67%) in oral prednisolone group and ACTH group respectively. There was no significant difference in EEG findings between the two groups.

Table III. EEG characteristics after therapy of the patients in two groups (N=60)

EEG at two weeks	Oral Prednisolone (n=30)	ACTH (n=30)	p-value
Normal	17 (56.67)	11 (36.67)	0.070
Abnormal	13 (43.3)	19 (63.3)	
Background (abnormal)	15 (50.0)	17 (56.67)	0.651
Classic hypsarrhythmia	0 (0.0)	1 (3.33)	1.000
Modified hypsarrhythmia			
Focal discharge	12 (40.0)	21 (70.0)	0.041
Suppression burst variant	2 (6.67)	0 (0.0)	1.000
Multifocal discharge	5 (16.67)	5 (16.67)	1.000
Frequency (mean ± SD)	5.71 ± 0.92	5.26 ± 0.64	0.014

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Table III shows the EEG characteristics after therapy of the study participants between two groups. EEG was found normal in 17/30 patients (56.67%) in the Oral prednisolone group and 11/30 (36.67%) in the case of the

ACTH group. Abnormal EEG persisted in 43.3% of patients in the case of oral prednisolone therapy and 63.3% in the case of ACTH therapy.

Table IV. Response to therapy according to baseline EEG abnormalities in two groups (N=60)

Response to therapy	Oral Prednisolone (n=30)	ACTH (n=30)	p-value
Classical hypsarrhythmia			
Response	10 (90.9)	5 (71.43)	0.365
No response	1 (9.09)	2 (28.57)	
Focal discharge			
Response	2 (100.0)	2 (66.67)	0.361
No response	0 (0.0)	1 (33.33)	
Multifocal discharge			
Response	7 (77.78)	8 (72.73)	0.483
No response	2 (22.22)	3 (27.27)	
Suppression burst variant			
Response	6 (75.0)	7 (77.78)	0.659
No response	2 (25.0)	2 (22.22)	

Table IV shows the response to therapy in the case of EEG variants of West syndrome. Classical hypsarrhythmia responded 90.9% in the case of Oral prednisolone therapy and 77.78% in the case of ACTH therapy. The p-value was 0.365. Focal discharge improved by 100% & 66.67% in the case of oral

prednisolone and ACTH group respectively. Multifocal discharge improved by 77.78% in the case of the Oral prednisolone group and 72.73% in the case of the ACTH group. The suppression burst variant improved by 75% & 71.43% in the case of the Oral prednisolone and ACTH group respectively.

Table V. EEG response before and after therapy (N=60)

EEG	Oral Prednisolone (n=30)			ACTH (n=30)		
	Before therapy	After therapy	p-value	Before therapy	After therapy	p-value
Normal	0	19 (63.33)	<0.001	0	13 (43.33)	<0.001
Abnormal	30 (100.0)	11 (36.67)		30 (100.0)	17 (56.67)	

Table V shows the EEG response before and after therapy. EEG status significantly

improved in both the Oral prednisolone and ACTH groups, P value <0.001.

Table VI. Response to therapy according to development history before spasm in two groups (N=60)

Response to therapy	Oral Prednisolone (n=30)	ACTH (n=30)	p-value
Age appropriate			
Response	6 (20.0)	5 (16.67)	1.000
No response	1 (3.33)	2 (6.67)	
Delayed			
Response	17 (56.67)	14 (46.67)	0.154
No response	6 (20.0)	9 (30.0)	

Table VI shows the response to therapy according to the development status of the

study participants before spasm in two groups. Patients with age-appropriate development

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showed a response of 20% in the Oral prednisolone group and 16.67% in the case of the ACTH group. Patients with delayed development history before spasm showed a

response of 56.67% in the case of the oral prednisolone group and 46.67% in the case of the ACTH group. No statistically significant difference was found in both groups.

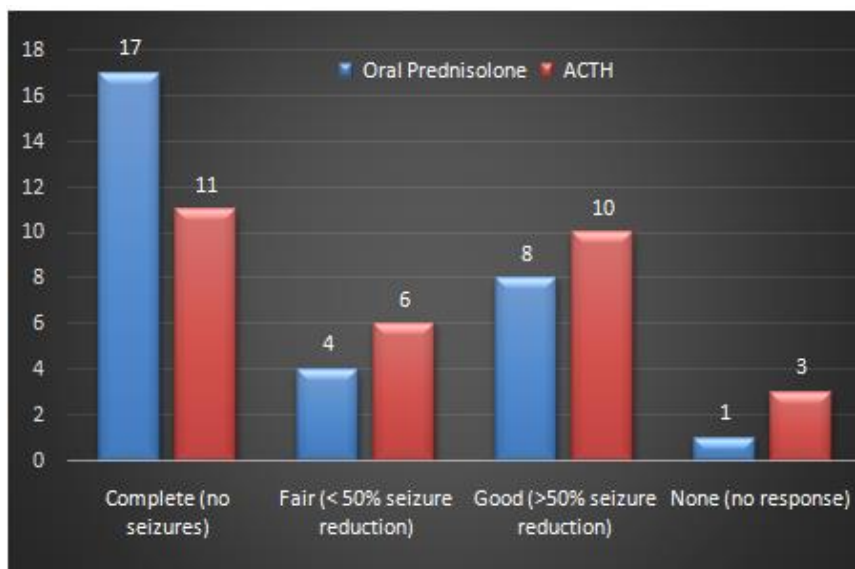


Figure 1. Bar diagram of response to therapy of the patients in two groups

Figure 1 shows the response to therapy between two groups. No seizures were found in 56.67% of the Oral prednisolone group and 36.67% in the ACTH group. Good response to the treatment was found in 33.33% of patients in the ACTH group and 26.67% in the Oral

prednisolone group. No responses were 3.33% in high-dose oral prednisolone and 6.67% in the ACTH group. No statistical significance was detected between the two groups.

Table VII. Adverse effects of the drugs (N=60)

Adverse effect	Oral Prednisolone (n=30)	ACTH (n=30)	p-value
Hypertension	7 (23.33)	13 (43.33)	0.108
Weight gain	17 (56.67)	16 (53.33)	0.346
Irritability	18 (60.0)	20 (66.67)	0.396
GIT upset	11 (36.67)	13 (43.33)	0.809
Others	10 (33.33)	18 (60)	1.000

Table VII shows that 60% of the Oral prednisolone group and 66.67% of the ACTH group had irritability, followed by weight gain (56.67% & 53.33%) and GIT upset (36.67% and 43.33%) in oral prednisolone and ACTH

4. DISCUSSION

This prospective observational study assessed the EEG changes before and after treatment with high-dose oral prednisolone compared to intramuscular (IM) ACTH and evaluated the response to therapy according to baseline EEG abnormalities in patients with West syndrome.

In the present study, the average age of the study children was 12.06 ± 5.87 months in the oral prednisolone group and 12.20 ± 5.83 months in the ACTH group. Males were the predominant gender in both groups. Other two

group respectively. Other less frequent adverse effects showed were cushingoid appearance and increased appetite. No significant difference was noted.

studies by Khreisat et al also found male predominance. [19] Fatema et al also show the mean age of onset being 5.65 months with slight male preponderance (58.5% vs. 41%). [20] The typical age of onset of WS is between 3 and 12 months of age (peak at 5 months) and males predominate (60%-70%). [21]

In this study, initial EEG findings include classical hypsarrhythmia was found in 36.67% (11/30) in oral prednisolone group and 23.33% (7/30) in the ACTH group, the focal epileptiform discharge (6.67% & 10%),

Multifocal discharge was present (26.67% and 30.0%) and burst suppression was present (30% and 36.67%) in oral prednisolone group and ACTH group respectively. Keshave et al also found hypsarrhythmia more common in their study.[22]

In this study, EEG change after oral prednisolone therapy and intramuscular ACTH therapy among study children were compared. EEG status improvement of 56.67% (after receiving high dose oral prednisolone) and 36.67% in the ACTH group. Abnormal EEG persisted in 43.3% of patients in the Oral prednisolone group and 63.3% in the ACTH group. That was no hypsarrhythmia present in the Oral prednisolone group and one patient was present with hypsarrhythmia in the ACTH group. Other EEG patterns were Focal discharge, multifocal discharge and suppression burst variant. One study by Chellamuthu et al showed that complete resolution of EEG abnormalities occurred in 56.3% of patients the in high-dose oral prednisolone group which is almost equal to our study. [23] Another study done by Sher and Sheikh reviewed 26 patients and showed resolution of hypsarrhythmia occurs in 65% of cases in the ACTH group, in our study ACTH response was 32.5% which is lower than the previous study.[24]

When we saw the individual EEG responses of the study participants, we found that hypsarrhythmia improved in 90.9% of patients, focal discharge improved by 100%, multifocal discharge improved by 77.78% and suppression burst variants improved by 75% among patients in the oral prednisolone group. In the ACTH group more patients were improved in the suppression burst variant (77.78%).

When we compared the EEG response in both groups before and after therapy we found significant improvement in both groups, p-value <0.001. A study done by Wanigasinghe et al. showed that the prednisolone group showed a significantly greater improvement in severity than that of the ACTH group (7.95 ± 2.76 vs 6.00 ± 2.61 ; $p < 0.01$). This study is the first randomized clinical trial to show the superiority of prednisolone over ACTH for treating West syndrome from the perspective of improving hypsarrhythmia (EEG response). [25]

In the present study, complete responses were found in 56.67% of the Oral prednisolone group and 36.67% in the ACTH group. Chellamuthu et al found that the low-dose prednisolone group had a complete response in 25% of cases in comparison to 51.6% in the high-dose prednisolone group ($p = 0.03$). [23]

In this study, 60% of the Oral prednisolone group and 66.67% of the ACTH group had irritability, followed by weight gain (56.67% & 53.33%) in the Oral prednisolone & ACTH group respectively. Chellamuthu et al showed weight gain and cushingoid facies were the most common adverse effects in their study participants. [23]

5. CONCLUSION AND RECOMMENDATIONS

The findings from this study show that high-dose oral prednisolone and low-dose ACTH therapy were equally effective for the treatment of West syndrome, but the prednisolone group showed a significantly greater improvement in EEG pattern than that of the ACTH group. Furthermore, interictal EEG pattern changes were found in the patients with West syndrome during treatment with high-dose oral prednisolone and low-dose ACTH.

So further study with a prospective and longitudinal study design including a larger sample size needs to be done to validate the findings of our study.

LIMITATIONS OF THE STUDY

This study was a single-center study. The sample size was small due to the short study period, so it doesn't represent the whole community. After evaluating those children, we did not follow up with them for the long term and did not know other possible interference that may happen in the long term with these children.

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee

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