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RESEARCH ARTICLE

EPALRESTAT AND METHYL COBALAMINE COMPOSITE (EPINEURON) IN HERPETIC NEURALGIA

[1, *]Dr. Avinash Shankar, Dr. Shubham, Dr. Abhishek Shankar, Dr. Amresh Shankar and Dr. Anuradha Shankar

[1,5]R A. Hospital & Research Centre, Warisaliganj (Nawada), Bihar, India
[2]Department of Pediatrics, VMMC&H, New Delhi
[3]Department of Oncology, AIIMS, Delhi
[4]Bihar Health Services, Patna

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ABSTRACT

Herpes zoster, an agonizing blister forming disease caused by Varicella zoster virus 1,2,3and analgesics even opioids fails cease agony of pain , local; anesthetics only provide transient pain relief 4,5,6 and accidental observation of complete relief of neurological pain with a composite Epineuron (Epalrestat and methylcobalamine), intended to evaluate the composite in management of Herpetic neuralgia. 124 patients of Herpes zoster involving various body part, without any associated other disease were evaluated comparatively for pain relief and safety margin. A composite Epineuron SR (Epalrestat 150mg and Methyl cobalamine 1500µg) daily with Famciclovir oral and Acyclovir as topical application in trial group, while placebo and Antiviral drug in control group. All patients taking trial drug had marked relief in agony of pain in mean duration of 24±4 hrs, blister healing in 9±2 days, complete pain relief in 14±4 days and all had excellent clinical recovery without any effect or alteration in hematological, hepatic and renal parameters with 100% compliance.

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INTRODUCTION

Herpes zoster is caused by the Varicella zoster virus (Goh, 1997; Kost and Straus, 1996; Bader, 2013) which presents with agonizing bullae or blister in the distribution of particular nerve root and agonizing unbearable pain remain most encumbrance ,commonly practiced medications are antiviral oral and topical application ,though relieve blisters but fails to ensure pain relief even with anti inflammatory analgesic adjunction, accidental observation of prompt relief of herpes neuralgia non responsive to even narcotic analgesic and phenytoin sodium , anticonvulsant agents (e.g., gabapentin and pregabalin), opioids, tricyclic antidepressants (e.g., nortriptyline)prompted for evaluation of the composite in herpes neuralgia (Zareba, 2005; Livengood, 2000; Cohen, 2013; Yawn and Gilden, 2013). Thus a study was planned µto evaluate Epalrestat and Methylcobalamine composite in alleviation of agony of pain and burning sensation in Herpes zoster at various site of the body .

Corresponding author: Dr. Avinash Shankar
R A. Hospital & Research Centre, Warisaliganj (Nawada), Bihar, India.

MATERIAL AND METHODS

Design of study

Comparative clinical evaluation of therapeutic response and safety profile of Epilrestat and Methyl Cobalamin Composite in Herpes Neuralgia.

Material

Patients of herpes zoster presenting with blister on the involved nerve root region, attending medical OPD of RA. Hospital and Research Centre, Warisaliganj (Nawasa) Bihar were selected as per following index

- Patient without any associated disease like hypertension, Diabetes mellitus or any other existing neurological disorders.
- Female not carrying pregnancy or feeding their children
- Patients not taking any drug, history of any drug interaction either to Epalrestat or Methylcobalamine or both or hypersensitivity to any drug.
- Very morbid patients
- Children below 15 yrs

Methods

Selected patients were thoroughly interrogated regarding disease onset, therapy taken and their response, examined and interrogated for basic hematological, hepatic and renal parameters to evaluate post therapy safety profile of the trial drug. Patients illness severity were graded on the basis of

- Blister size and its number
- Agonizing pain status
- Associated disease
- Lag period in seeking medicare
- Therapeutics taken and their response

Degree of severity of the presenting patients was indexed as per following

Grade I: Blisters without agonizing pain
Grade II: Blisters with mild pain
Grade III: Increasing blister numbers and size with agonizing pain

Selected patients were classified in to two equal groups and are advocated the following regime

Group A: Antiviral drug (Oral & Local),
Analgesics and Methyl Cobalamine + Placebo
Group B: Antiviral drug(Oral & Local),
Analgesic and anti inflammatory + Trial drug-

Among antiviral drug Famciclovir as oral and Acyclovir ointment as topical application been used.

Trial drug constitutes

Epalristat 150mg and Methyl cobalamine 1500µgm
Dose schedule of trial drug : 1 tab daily every 24 hrs

Each patients were give a follow up card to enter the response and on completion response was graded as per following index:

Clinical response was graded as

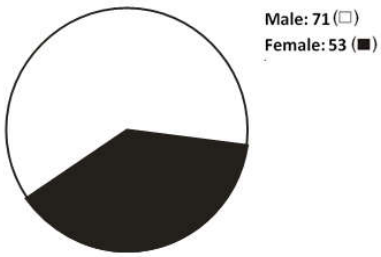
Fair: Mild suppression of pain,
Good: Pain relief till its effect
Excellent: Prompt relief with adjuvant and progressive relieve without drug adjunction and No recurrence of pain even after 14 days of drug withdrawal

Observations: Selected patients were of age group of 10-60 yrs ,out of which 11 were of age <20yrs while 14 of age >50 yrs, majority (46)patients were of age group 40-50 yrs. (T-1)

Table 1. Distribution of patients as per age and sex

Age group (in yrs)	Number of patients		
	Male	Female	Total
10-15	02	04	06
15-20	04	01	05
20-25	5	03	08
25-30	06	04	10
30-35	07	06	13
35-40	12	10	22
40-45	11	09	20
45-50	15	11	26
>50	09	05	14

Table 2. Pie diagram showing sex wise composition



Male female preposition was 71:53 (Table-2: pie diagram)

50% patients were having herpetic lesion in chest and thigh though patients with herpetic lesion on other site of the body were also included in the study (T-3).

Patients Name: Age/sex
Address:
Diagnosis:
Basic Data:
Blood pressure: Temperature: Blood sugar
Hematology Hepatic Renal
Hb% Serum bilirubin Blood urea
WBC SGOT Serum creatine
RBC SGPT Urine albumin
Parameters Follow up days

	2	4	6	8	10	12	14	16	18	20
Blister:										
Increasing										
Decreasing										
unaltered										
Pain agony:										
Increasing										
Decreasing										
Unaltered										

Other associated presentation if any

Help line: 09279380432, 9308304090

Patients signature Parent /Attendant signature

Dated:

On 21st day of therapy patients were duly examined and evaluated for hematological, hepatic and renal status to ascertain the clinical efficacy and safety status.

As per clinical index of severity 105 patients were of grade III severity and 19 were of Grade II severity (Table-4: Bar diagram). All patients taking the trial drug shows excellent

clinical response without any alteration in hematological, hepatic and renal parameters (T-5).

Table 3. Distribution of patients as per distribution of lesion

Involved site /area	Number of patients		
	Male	Female	Total
Chest:			
Right side	12	11	23
Left side	11	10	21
Abdomen:			
Right side	04	03	07
Left side	03	03	06
Skull:			
Right side	08	95	13
Left side	05	05	10
Face:			
Right side	03	02	05
Left side	03	00	03
Neck			
Right side	02	02	04
Left side	03	02	05
Groin			
Right side	04	02	06
Left side	05	03	08

Table 4. Bar diagram showing distribution of patients as per grade of severity

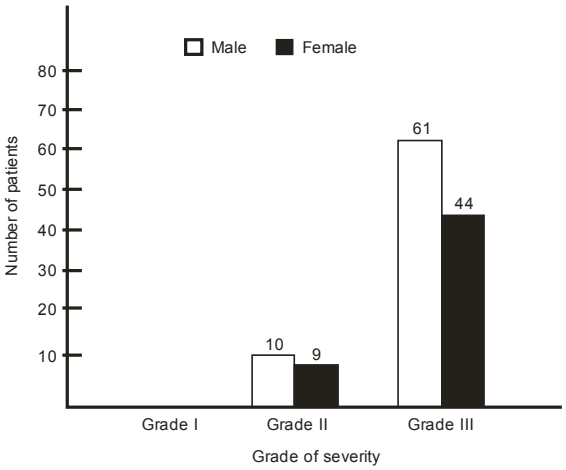


Table 5. Showing pre and post therapy hemato, hepato renal status

Particulars	Pre therapy		Post therapy	
	Male	Female	Male	Female
Hematological status:				
Hemoglobin:				
>10gm %	71	53	71	53
<10gm%	-	-	-	-
Hepatic:				
Serum bilirubin:				
>1mg%	-	-	-	-
<1mg%	71	53	71	53
SGOT:				
>30IU	-	-	-	-
<30 IU	71	53	71	53
SGPT:				
>30 IU	-	-	-	-
<30 IU	71	53	71	53
Renal:				
Blood urea:				
>26mg%	-	-	-	-
<26mg%	71	53	71	53
Creatinine:				
>1.5mg%	-	-	-	-
<1.5mg%	71	53	71	53
Urine:				
Albumin:				
Present	-	-	-	-
Absent	71	53	71	53
RBC:				
Present	-	-	-	-
Absent	71	53	71	53

Table 6. Graph showing number of patients having relief in pain and blister healing among trial group

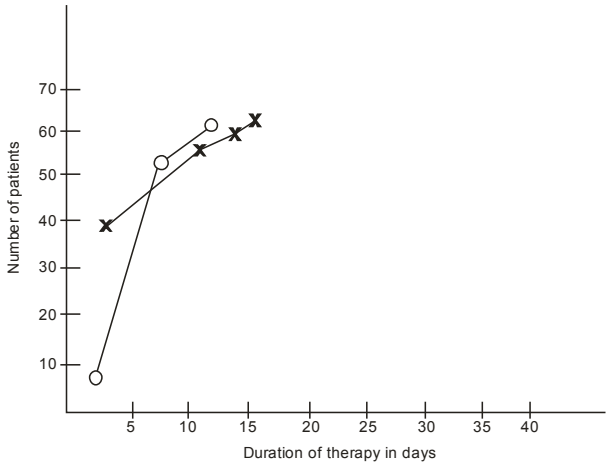


Table 7. Graph showing duration required for relief in pain agony

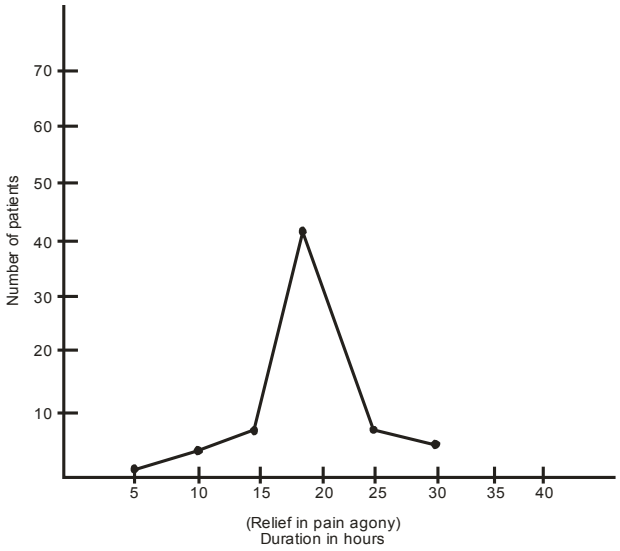


Table 8. Showing outcome of the therapy

Particulars	Group A	Group B
Pain agony:		
Ulaltered	48	-
Markedly relieved	02	60
Momentry relief	10	02
Increased	04	-
Blister size:		
Markedly regressed	02	62
Unaltered	54	-
Increased	06	-
Associated post therapy symptom:		
Urinary discomfort	09	-
Lethargy	50	-
Neuropsychiatric change	03	-
Response grade:		
Fair	02	-
Good	-	-
Excellent	-	62

All taking Epineuron SR had marked regression in blister healing while 06 cases of control group had exacerbation of blister (Table 6). All the patients on Epineuron SR (Epalrestat and Methylcobalamin composit) had marked relief in agonizing pain in 60(62) where as majority 52(62) of control group remained without any relief of pain though 4(62) had increase in pain agony (Table 7). The mean duration required in achieving healing of blister and relief of pain is 9±2 and 14±4days respectively. All cases of group B show excellent clinical response whether only 2 of control group show fair clinical response. No patients of group B presented with any associated presentation while patients of control group presented with various presentation during therapy or post therapy period (Table 8).

DISCUSSION

Herpes zoster caused by Varicella zoster virus , is known for its agonizing neurological pain and commonly prescribed analgesics, opioids and topical application of local anesthetic [10-21]only provide transient pain relief but agonizing withdrawal with sleeplessness night are very common . In present study patients taking Epineuron SR daily along with antiviral drug both oral and local show marked and effective relief of both pain and blister healing without any alteration in hematological, hepatic and renal parameters with 100% compliance as compared to control group patients. This marked clinical response can be explained as Epalrestat maintains neural sheath a lipoprotein myelin sheath by restricting or reducing intracellular sorbitol accumulation and improves motor and sensory nerve conduction velocity (Ramirez *et al.,* 2008) while Methylcobalamin, DNA synthesizer regulate fatty acid synthesis and energy production increases availability and effectiveness of Noradrenalin, 5 Hydroxy tryptamin in the descending inhibitory nociceptive system, promotes neuro synthesis and neuro protection, eases neuralgic pain (Jurna, 1998; Sun *et al.,* 2005).

Conclusion

All patients of Herpes zoster presents with agonizing neurological pain ,not responding to analgesics even opioid and transient relief with local anesthetic spray or gel application, taking Epineuron SR orally along with other antiviral and analgesics had complete relief and excellent clinical response with safety profile and compliance as compared to control group.

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