

Efficacy and Tolerance of Bepotastine Besilate in Chronic Urticaria

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Abstract

Background: Urticaria or hives is a common skin condition usually resolves within a few hours and always by 24 hours. It is mediated by aberrant release of histamine and other inflammatory mediators from mast cells and basophils¹. The therapeutic approach should be based on elimination or avoidance of the cause or trigger/stimulus, symptomatic drug treatment by reducing mast cell mediator release and inducing tolerance. Oral Bepotastine besilate is non-sedative, selective H1-R antagonist. **Aim:** To study the efficacy and tolerance of oral Bepotastine besilate in respect of wheal, pruritus, sedation and effectiveness in chronic urticaria patients. **Methodology:** All adult Patients attended out-patient department of our dermatology department, who had a history of wheals, erythema more than 6 weeks with pruritis were included. Pregnant and lactating women were excluded. After clinical diagnosis Oral bepotastine 10 mg twice daily was started and response (pruritus, wheals, drug effectiveness and sleepiness) was assessed by urticaria activity score (UAS), Medication effective score (MAS), Sedation scale in a predesigned performa on day 0,14 and 28. **Results:** The majority of patients showed significant improvement in pruritus and wheal scores as compared to baseline, starting from end of the second week visit. Among 45 patients; 38 had no sedation and 7 had mild drowsiness. Nine patients achieved complete relief. **Conclusion:** Bepotastine 10 mg twice daily is well tolerated, effective and non-sedative antihistamine drug for the treatment of chronic urticaria.

Keywords: Bepotastine; Pruritis; Chronic Urticaria; Antihistamine.

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INTRODUCTION

Pruritis is the most common symptom in many skin conditions such as chronic urticaria, eczema, atopic dermatitis, xerosis, psoriasis and skin infections. In case of urticaria, result in redness (erythema), wheals and sometimes angioedema [2]. Patient's quality of life (QoL) hampered due to its unpleasant sensation and scratching over body such as sleeplessness, anxiety and many systemic diseases. Bepotastine besilate is a new selective histamine H1-receptor antagonist, a second-generation antihistamine which are non sedative. As it has faster onset of action and it maintains its efficacy over the time. It is also a mast cell stabilizer and leukotrienes inhibitor [3]. In Japan, oral Bepotastine 10 mg tablet was approved for allergic rhinitis in year 2000 and for urticaria/ pruritus in year 2002, and in India in year 2017, it was approved for the treatment of allergic rhinitis and itching associated with cutaneous disorders. In our study, the efficacy and tolerance of oral Bepotastine besilate in form of wheal, pruritus, sedation

and effectiveness were assessed by urticaria activity score (UAS), Medication effective score (MAS)-scoring was done in form of relief, similarly sedation scale in form of degree of sleepiness was done in all 45 patients on day 0,14 and 28.

METHODOLOGY

All adult Patients attended out-patient department of our dermatology department, who had a history of wheals, erythema more than 6 weeks with pruritis were included. Pregnant and lactating women were excluded from study. Total 45 patients (Figure-1) were selected by clinical diagnosis then oral Bepotastine 10 mg twice daily started. No other oral and topical medication except moisturizer in few cases, was given under this study protocol, patients were followed up on day 14 and day 28.

Urticaria Activity Score (UAS) assessed pruritis and wheal on a 4-point defined rating scale by scoring from 0 to 3 on day 0, 14 and 28.

In UAS wheals were score as score-0 no wheals (none), score-1 having <20 wheals/24 hour(mild), score-2 having 20-50 wheals/24 hour (moderate) and score- 3 is > 50 wheals/24 hour or large confluent areas were involved (intense).

In UAS pruritus were scored from 0 to 3 as none, mild, moderate and severe respectively according to the severity.

In medication effectiveness scale (MES) on day 14 and day 28 we assessed all 45 patients in form of how much they got relief and score 0 to 4 , score-0 when they got complete relief, score-1 marked relief, score-2 moderate relief, score-3 slight relief, score- 4 no relief.

Similarly Sedation scale was used to see the degree of the sleepiness and to decide about further

continuation of oral bepotastine or stopped by seeing improvement in quality of life at 2 weeks and 4 week.

The patients adherence for treatment were rating at end of treatment on a 5-point scale of Excellent, Very Good, Good, Average and Poor. This study was initiated after ethics committee approval and after taking patient consent.

RESULTS

The majority of patients showed significant improvement (decrease) in pruritis scores as well as wheal score as compared to baseline starting from end of the first week visit (Figures 2 and 3). After oral intake maximum patients got symptomatic relief within one hour. The average pruritus score reduced to '0' by the 3rd week; while average wheal score reduced to '0' by the 2nd week. According to medication effectiveness scale 9 patients achieved complete relief. 38 patients had no sedation, while 7 patients experienced mild drowsiness (Figure-5); according to subjective sedation scale. None of the patients spontaneously reported any adverse events.

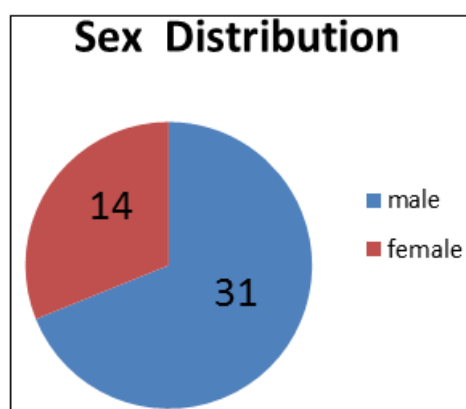


Fig-1:Distribution by Sex

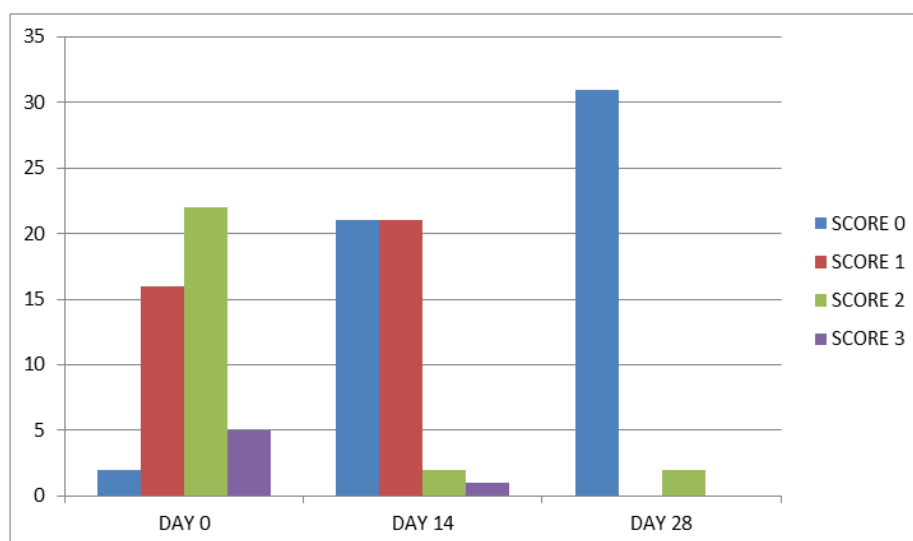


Fig-2: Urticaria Activity Score – Wheals

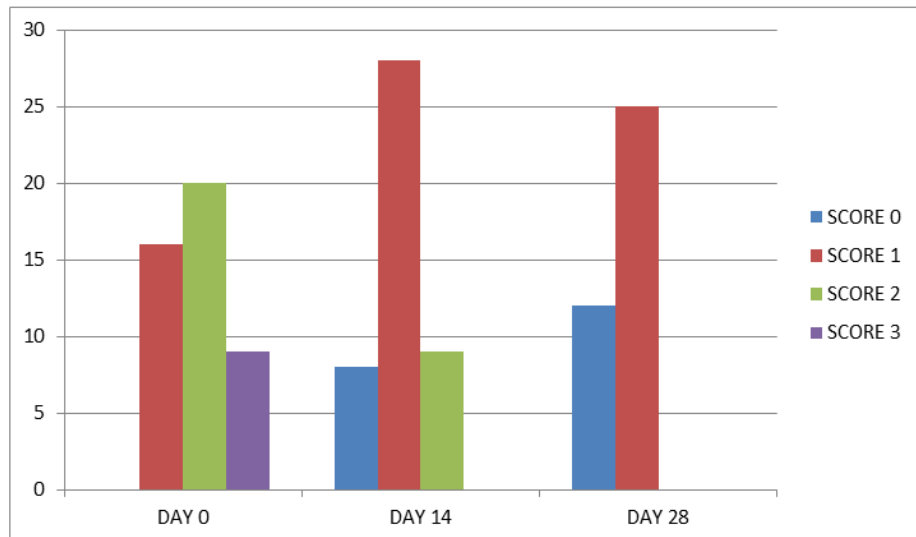


Fig-3: Urticaria Activity Score – Pruritus

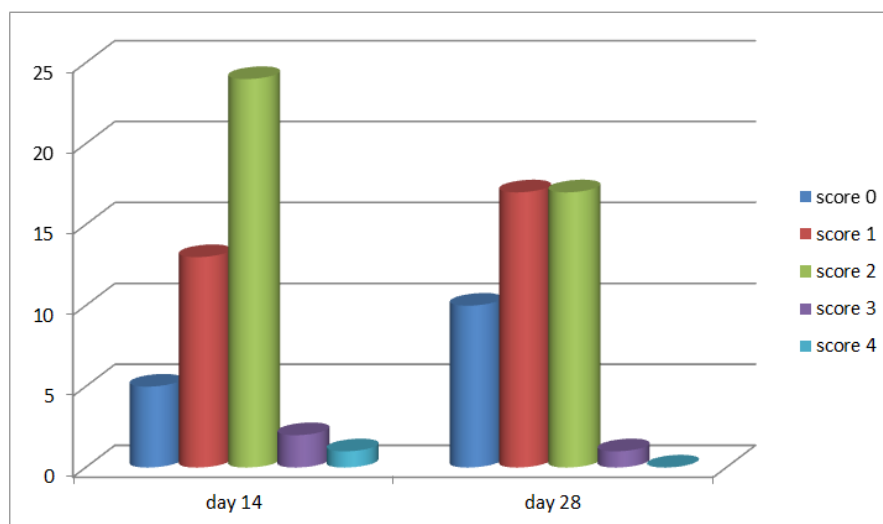


Fig-4: Medication Effectiveness Scale

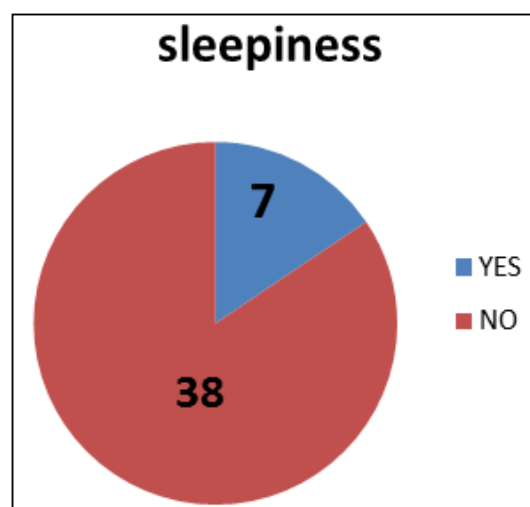


Fig-5: Sleepiness

DISCUSSION

Urticaria is a common skin condition that affects population with a lifetime prevalence of up to 22%. Chronic urticaria is thought to be mediated by aberrant release of histamine and other inflammatory mediators from mast cells and basophils [1]. Mast cell activation may either be through autoimmune, allergic, or idiopathic mechanisms.

Bepotastine is a non-sedating second generation antihistamine. It is a highly selective H1 receptor antagonist and mast cell stabilizer with minimal to no activity against other receptors such as H3, adrenergic, serotonin, muscarinic, and benzodiazepine [1]. It has a dose dependent long lasting effect. Ishibashi *et al.*, showed that Bepotastine 10 mg twice daily inhibited histamine induced erythema and wheals to a significantly greater extent than placebo and maintained the effect for at least 12 h [4]. Takahashi *et al.*, showed that 20 mg/day of bepotastine caused lesser subjective sedation and psychomotor impairment at 2 h than olopatadine 10 mg, fexofenadine 120 mg, and cetirizine 10 mg/day. The US Food and Drug Administration designated pregnancy category of bepotastine is Category C and the drug should be avoided during pregnancy [5]. It should be used only if the potential benefit justifies the potential risk to the fetus. Had an effect on itching within 1 or 1.5 h of administration, and it provided sustained improvement in pruritus and all other symptoms of chronic urticarial (wheals, frequency of episodes).

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