URTICARIA, ANGIOEDEMA

AN INVESTIGATOR-BLIND RANDOMISED CONTROLLED TRIAL COMPARING THE EFFECTIVENESS, SAFETY AND TOLERABILITY OF LEVOCETRIZINE AND BEPOTASTINE IN CHRONIC URTICARIA

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Introduction: Chronic Urticaria (CU) is common and distressing dermatoses where search for newer agents with improved effectiveness and tolerability-profile is a felt-need. Bepotastine, a second-generation antihistamine with added effect on suppression of eosinophil migration has prospect in management of CU

Aims: To assess and compare effectiveness, safety and tolerability of Bepotastine versus Levocetrizine in CU.

Methods: Single-center, investigator-blind, randomized, active-controlled, parallel group phase IV trial (CTRI REF/2018/04/019692) conducted on adult patients of CU of either sex. Patients were randomized into receiving either bepotastine besilate 10mg tablet twice daily or levocetirizine 5 mg tablet once daily with fortnightly follow-up for 6 weeks(End-of-treatment visit) and then monthly for 3 months with medication taken at 'on-demand' basis(Test-of-cure visit). Primary outcome measures were Urticaria Activity Score 7(UAS7) and Urticaria Total Severity Score (TSS). Routine hematological and biochemical tests and treatment-emergent adverse events were monitored for safety. Calculated sample size was 70.

Results: Thirty patients on bepotastine group and 29 patients on levocetirizine group were analyzed by modified-intention-to-treat. Study groups were comparable at baseline with respect to demography and severity of CU. UAS7 and TSS reduced significantly ($P<0.001$, Friedman's ANOVA) in both treatment groups from 1st Follow-up visit and 2nd Follow-up visits ($P<0.05$, Post Hoc Dunn's test) for UAS7 and TSS respectively. At Test-of-cure visit UAS 7 (0.733±1.17 vs 1.07±1.28) and TSS (5.10±4.06 vs 7.07±4.48) was less with

bepotastine than levocetirizine, though not statistically significant (P=0.188 and 0.073 respectively, Mann-Whitney test). Sedation was found to be significantly more (P<0.001, Fischer's exact test) with Levocetrizine than Bepotastine (73.3% vs 17.2%).

Conclusion: Bepotastine offers a new option in the treatment of CU with comparable effectiveness as the gold-standard i.e., Levocetirize; but the side-effect profile is low with bepostastine.