Bousquet et al. Clinical and Translational Allergy 2013, 3(Suppl 2):P42
http://www.ctajournal.com/content/3/S2/P42

Clinical and Translational Allergy

POSTER PRESENTATION Open Access

A new efficacy parameter (complete/near complete symptom relief) in allergic rhinitis management: results with a new therapy MP29-02*

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From 9th Symposium of Experimental Rhinology and Immunology of the Nose (SERIN 2013)
Leuven, Belgium. 21-23 March 2013

Background

It is unclear what constitutes a clinically-meaningful response for allergic rhinitis (AR) outcomes. In a recent survey [1] most experts defined control as being "hardly troubled at all" by each symptom. We propose a new criterion of ≤1 point remaining in each nasal symptom score (Max AM+PM score for each symptom=6) of the reflective total nasal symptom score (rTNSS) to stringently test efficacy and provide an endpoint meaningful to physicians and patients. This criterion has been termed complete/near-to-complete symptom control. Any treatment providing this level of control (patients will feel "cured") should have considerable socioeconomic impact.

Objective

To compare the proportion of patients achieving ≤1 point remaining in each of the 4 symptoms of the rTNSS (congestion, itching, rhinorrhoea & sneezing) and the time taken to achieve this response in patients treated with MP29-02* (a novel intranasal formulation of azelastine hydrochloride [AZE] and fluticasone propionate [FP]), FP, AZE or placebo (PLA) nasal sprays.

Methods

610 patients (≥12 years old) with moderate-to-severe seasonal AR were randomized into a double-blind, placebo-controlled, 14 day parallel-group trial to receive MP29-02*, commercially-available AZE or FP nasal sprays or PLA nasal spray (all 1 spray/nostril bid; total daily dose [AZE: 548μg, FP: 200μg]). The primary outcome was change from baseline in rTNSS over 14-days. Time to achieve ≤1 point remaining in each nasal symptom (AM + PM) of the rTNSS was assessed post-hoc by Kaplan-Meier estimates and log rank tests.

Results

17.8% of MP29-02* patients (1 out of 6) achieved this response versus 8.3%, 9.2% and 7.8% of those treated with AZE, FP and PLA, respectively. MP29-02* patients achieved this response up to 7 days faster than AZE (p=0.0152) and up to 8 days faster than either FP (p=0.0262) or PLA (p=0.0094). Neither AZE nor FP differed from PLA for this parameter.

Conclusion

MP29-02* provides faster and more complete symptom control than first-line therapies for AR. One out of 6 moderate to severe AR patients achieved complete/near-to-complete and uniform symptom relief days faster than either FP or AZE. MP29-02* is the drug of choice for AR treatment since it was the only therapy to rapidly provide such a level of symptom control. This endpoint should become a new standard in assessing the efficacy of current and novel AR therapy.

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Published: 16 July 2013

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doi:10.1186/2045-7022-3-S2-P42
Cite this article as: Bousquet *et al.*: A new efficacy parameter (complete/near complete symptom relief) in allergic rhinitis management: results with a new therapy MP29-02*. *Clinical and Translational Allergy* 2013 **3**(Suppl 2): P42.