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LETTER

EUFOREA Comment on a Misleading Allergic Rhinitis Report [Letter]

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Dear editor

As members of the EUFOREA Allergic Rhinitis Expert Panel we look for new evidence of effectiveness and acceptability of rhinitis treatments, reflecting EUFOREA's ambition to optimize chronic respiratory disease therapy.[1] Having read "Patient Satisfaction and Sensory Attributes of Nasal Spray Treatments of Olopatadine Hydrochloride/Mometasone Furoate Monohydrate and Azelastine Hydrochloride/Fluticasone Propionate for Allergic Rhinitis in Australia – An Observational Real-World Clinical Study", published in Patient Preference and Adherence 2023:17,141–151[2] we wish to comment on its concept, conduct and conclusions.

The title "REAL-WORLD" is inappropriate for a skewed, paid, unbalanced patient population, collected via a commercial online portal. The patients studied do not correspond to real world practice in Australia.[3]

There is marked disparity between patient populations: that of Olopatadine Hydrochloride/Mometasone Furoate Monohydrate (OLO/MOM) was 44% female, versus 76% of the Azelastine Hydrochloride/Fluticasone Propionate (AZE/FLU) population. 77% of OLO/MOM were under 40 years of age versus 63% for AZE/FLU. There was no differentiation of non-allergic rhinitis (NAR) which is a co-factor in approximately 30% of allergic rhinitis (AR) patients, nor for any concomitant nasal structural abnormalities. NAR is associated with nasal hyper-reactivity and is more common in females. AZE/FLU nasal formulation is currently the only treatment with proven efficacy on nasal hyperreactivity (NHR).[4]

Nearly two thirds of those receiving OLO/MOM had a short disease duration of under 12 months vs 50% in the AZE/FLU group. Longer duration of disease involves priming: increased reactivity towards both allergic and non-allergic stimuli following allergen exposure.

There was also a significant difference in treatment background with more OLO-MOM subjects being treatment naive: 51% patients in the OLO/MOM group used less than 1 previous treatment (meaning zero) whereas 75.9% patients in the AZE/FLU group used 1 or more in the last 12 months (Table 1). To be prescribed AZE/FLU patients had to be dissatisfied with their previous treatment and were thus more likely to suffer from severe AR.

Self-determination of treatment, a positive influencer of health outcomes and satisfaction, occurred in 29.2% of the OLO-MOM group but in only 2.1% for AZE/FLU.

Thus there was significant bias in favour of OLO-MOM on several counts. Despite this the outcome which matters to patients, namely efficacy, was superior in the AZE/FLU users ($p< 0.01$**) and the duration of action was also significantly superior when re-scaled for importance. These results were not discussed in the Conclusions.

Another important omission was that of nasal irritation. OLO/MOM formulation has a pH of 3.7 with sucralose as a taste-masking agent. AZE/FLU has a pH of 5.9, without any taste-masking excipients. It is likely that a more acidic pH will cause more nasal irritation.[5] However, the authors did not discuss the results in this respect.

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Table 1 Treatment Background Information of Participants Using Olopatadine Hydrochloride and Mometasone Furoate Monohydrate (OLO/MOM), Participants Using Azelastine Hydrochloride and Fluticasone Propionate (AZE/FLU), and the Full Sample

Treatment Background (N = 426)	OLO/MOM n (%)	AZE/FLU n (%)	Total n (%)
No. of previous treatments in the last 12 months			
Less than 1	50 (51.0%)	79 (24.1%)	129 (30.3%)
Equal to or more than 1	48 (49.0%)	249 (75.9%)	297 (69.7%)
Type of Allergic Rhinitis			
Seasonal Allergic Rhinitis (SAR) only	36 (36.7%)	126 (38.4%)	162 (38.0%)
Perennial Allergic Rhinitis (PAR) only	23 (23.5%)	118 (36.0%)	141 (33.1%)
Both SAR and PAR	38 (38.8%)	79 (24.1%)	117 (27.5%)
Do not know/not sure	1 (1.0%)	5 (1.5%)	6 (1.4%)
Time on current treatment			
Less than 1 year	58 (59.2%)	164 (50.0%)	222 (52.1%)
≥ 1 year ≤ 2 years	24 (24.5%)	103 (31.4%)	127 (29.8%)
> 2 years ≤ 3 years	6 (6.1%)	34 (10.4%)	40 (9.4%)
> 3 years ≤ 4 years	2 (2.0%)	8 (2.4%)	10 (2.3%)
> 4 years ≤ 5 years	2 (2.0%)	8 (2.4%)	10 (2.3%)
More than 5 years	5 (5.1%)	8 (2.4%)	13 (3.1%)
Do not know/not sure	1 (1.0%)	3 (0.9%)	4 (0.9%)
Who recommended current treatment			
Doctor	61 (62.2%)	288 (87.8%)	349 (81.9%)
Pharmacist	29 (2.0%)	27 (8.2%)	56 (13.1%)
Self-managed	6 (29.6%)	7 (2.1%)	13 (3.1%)
Other	2 (6.1%)	6 (1.8%)	8 (1.9%)

Notes: Reproduced from Fifer S, Toh L, Barkate H, et al. Patient Satisfaction and Sensory Attributes of Nasal Spray Treatments of Olopatadine Hydrochloride/Mometasone Furoate Monohydrate and Azelastine Hydrochloride/Fluticasone Propionate for Allergic Rhinitis in Australia – An Observational Real-World Clinical Study. *Patient Prefer Adherence*. 2023;17:141–151.[2]

Abbreviations: AR, Allergic rhinitis; AZE/FLU, Azelastine Hydrochloride/Fluticasone Propionate; NAR, Non-allergic rhinitis; NHR, Nasal hyperreactivity; OLO/MOM, Olopatadine Hydrochloride/Mometasone Furoate Monohydrate.

Thus the paper which states that patient satisfaction is greater with OLO/MOM than with AZE/FLU is unrepresentative, biased and inaccurate since the most important outcomes: efficacy and duration of action were actually superior in the AZE/FLU treated patients.

Disclosure

GKS: Honoraria for articles, speaker and advisory boards: ALK, Bayer, GlaxoSmithKline, Haleon, Noucor, Sanofi-Regeneron, and Viatris. Chair of BSACI rhinitis guidelines, Scientific Chief Editor, Rhinology Section of Frontiers in Allergy, Board member and AR lead for EUFOREA, and Chair/ member Data Monitoring Committees on SLIT for ALK.

PKS: grants for investigator-initiated research from Hyloris, GSK and Sanofi. He has received honorarium for participating in GA2LEN and Viatris activities and advisory boards for the Nestle Nutrition institute and speaker activities for the latter and GSK. Grants from the Stafford Fox Foundation and the Australian Nation Health and Medical Research Foundation. He has shares in Valneva, a vaccine company. He has patents in detection and modification of TRP receptor dysfunction. He is a member of the EUFOREA rhinitis expert panel.

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