Patient Preference and Adherence

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RESPONSE TO LETTER

EUFOREA Comment on a Misleading Allergic Rhinitis Report [Response to Letter]

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Dear editor

Thank you for the opportunity to respond to the Letter to the Editor regarding our manuscript titled "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". It is evident that Scadding et al are well aware and appreciate the value of patient-centred care in empowering the patient in their care and treatment decisions. Whilst clinical trial data is the cornerstone of evidence-based medicine, it may not always reflect real-world care and outcomes. Understanding the patient voice, including satisfaction with treatments via studies such as this one, is equally important to inform shared decision making which may contribute to better compliance and treatment adherence, and in turn positively impact patients' quality of life. As such, we reiterate the primary focus of the study was to assess the level of satisfaction with, and importance of, treatment attributes of the two combination corticosteroid and antihistamine nasal sprays for allergic rhinitis (AR) available in the Australian environment from the patients' perspective. The study was not an objective efficacy study and as stated in the manuscript, no efficacy outcomes were measured.

We contend that this study adds important information directly from the patients using the medicines, to the body of evidence in this area. Limitations of the study, including concerns around sampling raised by Scadding et al, were all disclosed in the manuscript, and do not invalidate the important information received directly from patients using the medicines in question.

We respond in further detail below.

1. The appropriate use of "real-world" terminology and the importance of amplifying the patient voice.

Real-world studies offer a complementary lens to clinical trials by examining the impact of medical treatments or healthcare strategies in real-world settings from various data sources.[1] This includes studies with prospective observational self-reported data from patients outside a controlled environment to understand treatment satisfaction and patient choice. Based on these factors, we consider the use of "real-world" terminology in our manuscript title appropriate. The method of recruitment through convenience sampling was fully disclosed in the Materials and Methods section (p. 142, para 4). Real-world studies are important in amplifying the patient voice – qualitative research found that patients with AR have strong opinions about treatment satisfaction but do not often share this with their healthcare professional.[2,3] Therefore, while clinical evidence paints one part of the picture, patient voice (assessed through subjective ratings in this study) is also important to understand and should be elevated.

2. Disparities in patient populations such as gender, age, time on treatment, treatment background, and self-determination of treatment.

The manuscript was transparent in disclosing all demographic and background differences between OLO/MOM and AZE/FLU user groups, summarised in the Results (p. 145, para 1) and in Tables 1 and 2 (p. 145 and 146 respectively). Due to convenience sampling and OLO/MOM being in the market for a shorter period compared to AZE/FLU, there was a smaller number of participants using OLO/MOM that could lead to uneven representation on some background

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characteristics. This was discussed and acknowledged as limitations of the study (p. 150, para 1). While we acknowledge that there is uneven representation in both groups, it is crucial to note that our study was designed to assess patient satisfaction and treatment attributes from a subjective perspective. We believe that the study's primary focus on patient-reported satisfaction ratings allows us to capture the unique perspectives of individuals using these nasal sprays, irrespective of the demographic differences.

Importantly it is unclear how such differences could confound results for patient satisfaction of AR treatment. The implied assumption that these confounders would be inherently linked to differences in treatment satisfaction lacks evidence-based support and is unsubstantiated.

For example, whilst a smaller proportion of participants using OLO/MOM reported more than 1 AR treatment in the past 12 months compared to participants using AZE/FLU (49% for OLO/MOM; 75.9% for AZE/FLU), the argument that patients had to be dissatisfied with their previous treatment and thus more likely to suffer severe allergic rhinitis (AR) to be prescribed AZE/FLU, somehow skewing the results is an interesting hypothesis which is not supported by the subgroup analysis observations. Looking specifically at the subgroup of patients who used 1 treatment only in the past 12 months, we found a similar trend to that observed in the whole sample, with participants using OLO/MOM reporting a higher treatment satisfaction index (TSI M = 75.35, SE = 1.82) than participants using AZE/FLU (TSI M = 62.92, SE = 1.46), noting that no statistical analyses were performed for these subgroups (n = 129; 38.76% OLO/MOM, 61.24% AZE/FLU, described on p.148).

3. Concerns about the assessment and discussion of AR treatment efficacy.

The key focus of the study was to understand patient satisfaction and importance of AR treatment attributes, particularly sensory attributes; the study was not an objective efficacy study. As stated in the manuscript, "treatment efficacy" was not assessed as no efficacy outcomes were measured (p. 143, para 4). Rather, participants were asked to assess the importance and level of satisfaction with regards to AR symptom control. These results were therefore not indicative of how efficacious these treatments are. Comments on efficacy associated with nasal hyper-reactivity do not contribute to our answering of our research questions, nor does it conflict our findings on the efficacy domain. Therefore, we fail to understand the relevance of this comment.

The finding that participants using AZE/FLU scored higher on AR symptom control for satisfaction and importance compared to OLO/MOM, and that both groups regarded this highly, was reported in the Results (p. 146, para 3–4) and Discussion (p. 149, para 2). This was not in the Conclusions as the main outcome was overall satisfaction (Treatment Satisfaction Index; TSI), and the focus of the paper was on sensory attributes. Of note, the attributes chosen for this study have previously been utilised and reported in other peer reviewed publications studying monotherapy nasal sprays.[4–9] By incorporating such attributes, the study aims to build upon the existing body of evidence while also capturing the patient perspective on combination corticosteroid and antihistamine nasal sprays.

4. Clarification of inaccuracies.

Regarding the comment on pH formulation affecting nasal irritation, we are unaware of any published data specific to OLO/MOM to support this claim. Of note in our study, irritation to nose was a domain in the ABWS. Within that domain, participants using OLO/MOM were still more satisfied (and regarded this as more important) than participants using AZE/FLU ($p = 0.001$ and $p = 0.004$ respectively). This was reported in the Results (p. 146, para 3) and in Table 3.

Scadding et al also state that OLO/MOM contains sucralose as a taste-masking agent. This is incorrect as OLO/MOM marketed in Australia as Ryaltris does not contain sucralose. Interested readers can consult the Australian TGA approved Ryaltris Product Information for the full list of excipients.[10]

Summary

This real-world observational study is methodologically sound and the limitations raised have been transparently acknowledged in the manuscript. The study's findings shed light on the diverse factors that impact patient satisfaction with AR medications, underscoring the significance of incorporating patient feedback into the shared decision-making process to enhance patient outcomes. We respectfully ascertain that this study, through elevating the Australian AR patient voice, is a valuable addition to the existing evidence base and offers an often under-represented perspective that can greatly benefit healthcare professionals in their clinical practice.

Disclosure

SF and LT are from CaPPRe who were contracted by CSL Seqirus to design the experiment, provide data management, conduct the analysis and write the manuscript involved. The authors report no other conflicts of interest in this communication.

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