Real-world evidence in Rhinology

DOI:10.4193/Rhin25.906

When going through the table of contents for this issue of Rhinology, I noticed a few titles containing "real-world" or "real-life". Real-world evidence, real-life evidence, real-world experience, et cetera, all refer to data obtained from day-to-day practice. This means: outside the strict boundaries of randomized-controlled trials. This suggests: data from patients that we all encounter in our outpatient clinics. Patients with their own unique stories, comorbidities, preferences, and (disease-related) experiences. Obviously, real-world evidence is a valuable contribution to our knowledge, next to data from clinical trials. We should not forget, however, that it also has its limitations. Most importantly, real-world studies generally lack a control group or placebo comparison, meaning that the therapeutic effects found are usually larger than in strictly controlled trials. The difference of a certain disease marker (e.g., a SNOT-22 score) between baseline and follow-up encompasses both the treatment and placebo effects. We know that in chronic rhinologic conditions, such as allergic rhinitis or chronic rhinosinusitis, this placebo effect can be quite significant. On multiple occasions I have heard the Editor-in-Chief of Rhinology proclaim: "The best thing we can do for our patients is to include them in a trial!". The increased care and attention patients receive from study teams (doctors and nurses), and the increased focus on adherence to (auxiliary) therapy can have a substantial effect on patient well-being, and, thus, study outcomes.

The first publication in Rhinology that I could find carrying "real-life" in its title stems from 2001 by Wilson et al. [1]. It reports on the use of leukotriene receptor antagonist therapy in patients with chronic rhinosinusitis (roughly half of them had nasal polyps) in a single institution, showing some beneficial effects but not on olfactory dysfunction. Now, 24 years later, we have seen a vast increase in the number of papers describing real-world data, especially since the advent of biological therapy for chronic rhinosinusitis with nasal polyps (meaning primary diffuse type2 disease). Space here is too limited to reference them all [2-6], and more follow with every issue of our Journal.

With biological therapy, we now have powerful tools to help improve the sense of smell of our patients, as shown in this issue by Patel et al. This contrasts the effects of leukotriene receptor antagonist therapy described by Wilson et al., who reported their single-institution data on 32 patients. In the current issue, Mortuaire et al. report from a cohort of 752 patients from 6 different sites in 5 European countries. As such, biological therapy has not only revolutionized the treatment of chronic rhinosinusitis with nasal polyps, but it has also deeply strengthened our international collaborations. Exciting times are still ahead, as the armamentarium of biological therapy still increases. A very small but wonderful detail in this respect is that the last author of the aforementioned paper of Wilson et al., is now the first author of the phase III WAYPOINT trial on tezepelumab for chronic rhinosinusitis with nasal polyps [7].

I wish you much joy and insight when reading the articles from the current issue of Rhinology!

Sietze Reitsma, Associate Editor
Amsterdam, the Netherlands

References

1. Wilson AM, White PS, Gardiner Q, et al. Effects of leukotriene receptor antagonist therapy in patients with chronic rhinosinusitis in a real life rhinology clinic setting. Rhinology. 2001 Sep;39(3):142-6.
2. Bidder T, Sahota J, Rennie C, et al. Omalizumab treats chronic rhinosinusitis with nasal polyps and asthma together-a real life study. Rhinology. 2018 Mar 1;56(1):42-45.
3. Kassem F, Cohen-Confino R, Meir-Shafrir K, et al. Mepolizumab for eosinophilic chronic sinusitis with nasal polyposis: real-life experience. Rhinology. 2021 Feb 1;59(1):110-112.
4. Haxel BR, Hummel T, Fruth K, et al. Real-world-effectiveness of biological treatment for severe chronic rhinosinusitis with nasal polyps. Rhinology. 2022 Dec 1;60(6):435-443.
5. Boscke R, Heidemann M, Bruchhage KL. Dupilumab for chronic rhinosinusitis with nasal polyps: real-life retrospective 12-month effectiveness data. Rhinology. 2023 Jun 1;61(3):203-213.
6. Kiricsi A, Bella Z, Kraxner H, et al. Real-life effectiveness of dupilumab in chronic rhinosinusitis with nasal polyps. Results from eight Hungarian centres with 12-month follow-up. Rhinology. 2024 Aug 1;62(4):410-420.
7. Lipworth BJ, Han JK, Desrosiers M, et al. Tezepelumab in adults with severe chronic rhinosinusitis with nasal polyps. N Engl J Med. 2025 Mar 27;392(12):1178-1188.