Real-world effectiveness of omalizumab in patients with chronic rhinosinusitis with nasal polyps (CRSwNP): findings from CHRINOSOR

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Dear Editor:

Omalizumab is a recombinant DNA-derived humanized monoclonal antibody targeting free immunoglobulin E. In the omalizumab phase III studies for chronic rhinosinusitis with nasal polyp (CRSwNP), a clinically relevant reduction of the nasal polyp score (NPS) was observed leading to improved SinoNasal Outcome Test-22 (SNOT-22) [(1)]. In the extension study, sustained or further improvement of symptoms and NPS reduction were observed up to 52 weeks [(2)]. Real-world data is needed to establish effectiveness in uncontrolled severe CRSwNP [(3)], but so far, data on long-term omalizumab treatment is sparse [(4,5)].

CHRINOSOR has been conceived to address such real-world research questions in CRS [(6–8)]. Relevant CRS outcome parameters were collected from medical records of 61 omalizumab treated CRSwNP patients (7 tertiary centres - 4 EU countries). Treatment response was assessed at 24 and 52 weeks compared to baseline, and according to EUFOREA 2021 criteria.

Baseline patient characteristics were summarized in Table S1. Significant improvements in SNOT-22 were observed at 24 weeks and 52 weeks of omalizumab compared to baseline ($p < 0.0001$; Figure 1B). A clinically relevant improvement in SNOT-22 (≥8.9 points) was reached in 70.4% and 76.3% of patients at 24

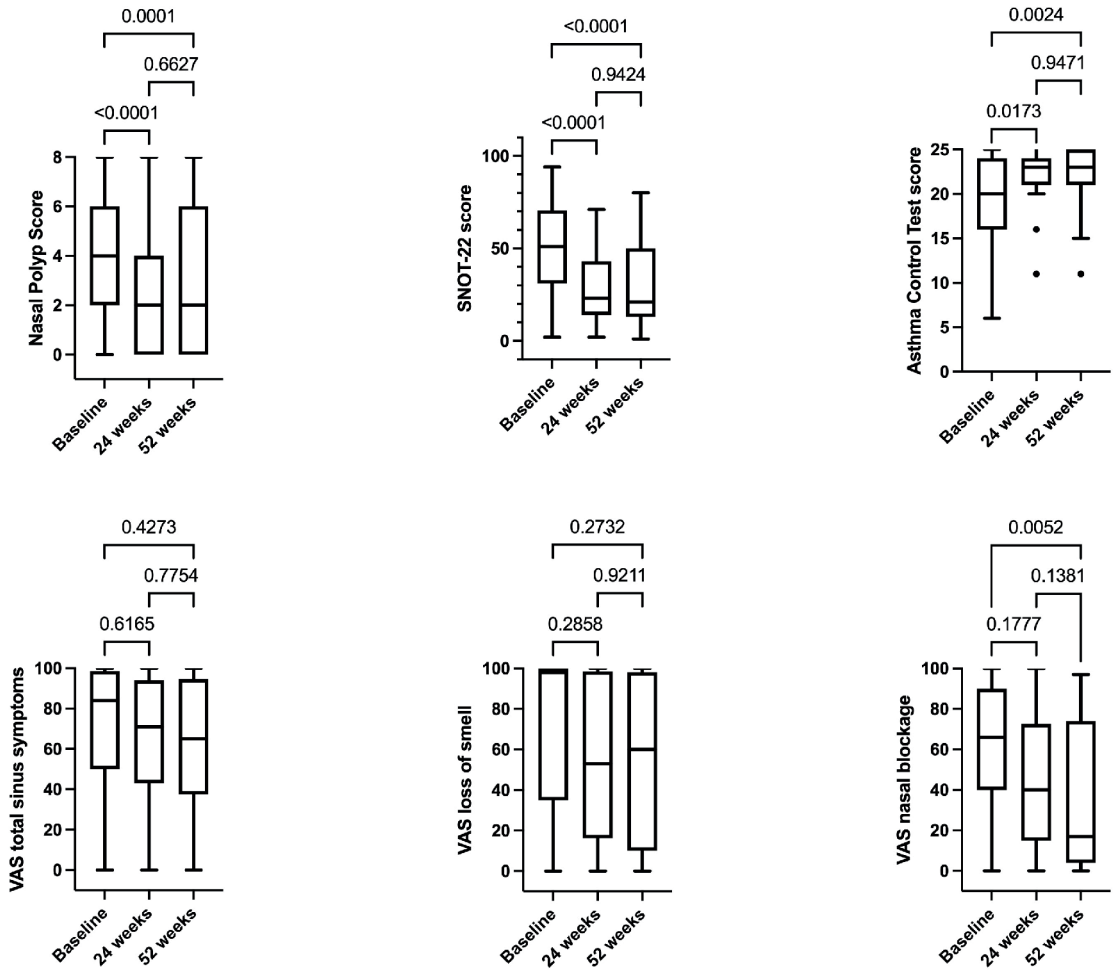

Figure 1. Effectiveness of omalizumab on, respectively, SNOT-22 score, NPS, ACT score, VAS symptoms at baseline, 24 weeks, and 52 weeks. A, Patient numbers of SNOT-22: 57, 56 and 39. B, Patient numbers of NPS: 60, 58 and 39. C, Patient numbers of ACT: 35, 29 and 19. D, Patient numbers of VAS total sinus symptoms: 25, 23 and 17. E, Patient numbers of VAS LoS: 25, 24 and 17. F, Patient numbers of VAS nasal blockage: 23, 21 and 15. Data are presented as Tukey box-and-whisker plots. Within-group comparison was performed by mixed effects model and Dunnett multiple testing comparison.

and 52 weeks, respectively (Table S2). Similarly, NPS significantly improved at 24 and 52 weeks compared to baseline ($p < 0.0001$; Figure 1A). An improvement of NPS by ≥1 point was achieved in 68.4% and 65.8% of patients at 24 and 52 weeks, respectively (Table S2). VAS total sinus symptoms and loss of smell were not statistically different at both timepoints, compared to baseline (Figure 1D-E). VAS nasal blockage showed a significant improvement at 52 weeks but not at 24 weeks compared to baseline ($p = 0.005$ and $p = 0.18$; Figure 1F). In patients with asthma, the asthma control test score significantly improved at 24 weeks ($p = 0.02$; Figure 1C), and 52 weeks ($p = 0.002$; Figure 1C) compared to baseline. The proportion of patients who reported systemic corticosteroids in the past year decreased after 52 weeks omalizumab (1/34, 2.9%) compared to baseline (43/60, 71.7%; $p < 0.0001$). At 24 weeks, 83.1% of patients fulfilled at least 1 EUFOREA 2021 responder criterion, which increased to 85.4% of patients at 52 weeks (Table S2). Assessing the more stringent composite EUFOREA 2021 criteria, 15.4% of patients met all criteria at 52 weeks compared to 10.0% at 24 weeks (Table S2). Of 61 included patients, 20 patients discontinued omalizumab before or at 52 weeks, all due to inadequate response.

Our study suggests that the effectiveness of omalizumab on NPS and SNOT-22 is already present at 24 weeks and sustained up to at least 52 weeks. The lack of further symptom improvement at 52 weeks suggests that the treatment effect may plateau after an initial period of improvement, although longer follow-up is needed to confirm this trend. On the other hand, significant improvements in VAS nasal blockage took longer and were only observed after 52 weeks. Therefore, decisions regarding therapy switch or discontinuation should not be made prematurely in individual patients. The lack of a control group and patient selection bias (academic), and patient loss to follow-up, may limit the generalizability of the results. While the safety of omalizumab in this CRSwNP cohort was not assessed on a structural basis,

the safety profile of this drug is acceptable given its long-term clinical use for allergic asthma [9].

Conclusion

Omalizumab offers relevant clinical benefits for patients with uncontrolled severe CRSwNP in a real-world setting, leading to meaningful improvements in both nasal blockage and overall quality of life, but not in smell. Studies including larger number of patients are required to confirm our findings.

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Authorship contribution

SFS, GMa, CB designed the study. GMo, CC, SR, SS, PVT, MW, AC, WJF, MdV, CH and SM recruited patients for the study. GMo, SFS, JdK and GB contributed to data analysis. GMo, SFS and JdK prepared the first draft of the manuscript. All authors critically revised the manuscript.

Conflict of interest

TB reports participation on advisory board from Sanofi, Astra Zeneca and GSK. CB: reports grants or contracts from GSK, Sanofi, Novartis, Galenus Health. GB: employee of Galenus Health. ZD: reports consulting fees and/or payment for lectures in the past 3 years: from Arcede, Biosion, Foresee Pharmaceuticals, Galenus Health, GlaxoSmithKline, Hippo-Dx, Pleuran, Sanofi-Genzyme and QPS-NL. Leadership role in EUFOREA (asthma expert panel chair 2020-2023), associate editorships at Springer (RESNI/MedNet 2011-2024), Respiratory Medicine (2004-ongoing) and Allergy (2018-2024). JED: reports grants (institution) from Astra Zeneca, Novartis, payment for lectures from Allergopharma, participation on advisory board from GSK, Astra Zeneca, Bencard. VH: payments for lectures from Novartis, participation to advisory boards of Sanofi, GSK and leadership role in EAACI. JK: partner and shareholder of Galenus Health. AS: employee of Novartis. GM: partner and shareholder of Galenus Health. SM: reports consulting fees from GSK, Sanofi, Novartis, Astra Zeneca, support for attending meetings from LoFarma, Sanofi, participation on advisory board from AstraZeneca, Sanofi, Novartis. SFS: employee of Galenus Health.
SS: reports grants, payment for lectures and participation on advisory board from Sanofi, Astra Zeneca and GSK. MW: reports grants from ALK-Abello, GSK, Regeneron, Astra Zeneca, Novartis, Sanofi, Takeda, consulting fees from ALK, Genzyme, Novartis, Stallergenes, Astra Zeneca, GSK, Sanofi, payment for lectures from ALK-Abello, Astra Zeneca, GSK, Leti Pharma, Sanofi, Allergopharma, Bencard Allergie, Infectopharm, Novartis, Stallergenes, Leadership role in DGAKI (executive committee). AA: speaker fees from GSK and advisory board member for AstraZeneca. MBr: reports grants, payment for lectures and participation on advisory boards from Sanofi, GSK, Astra Zeneca.
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This manuscript contains online supplementary material

SUPPLEMENTARY MATERIAL

Materials and Methods

Study design and population

This retrospective, observational, multicentre study was conducted in seven tertiary care centres across four European countries: Austria (Medizinische Universität Graz, Medizinische Universität Wien, Ordensklinikum Linz), Belgium (Cliniques Universitaires Saint-Luc), Germany (Universitätsklinikum Düsseldorf), and Spain (Bellvitge Hospital, Hospital Germans Trias i Pujol). To this end, we collected and analysed pseudonymized data of patients treated with omalizumab for CRSwNP between April 2017 and December 2024. Data were collected from (electronic) medical records at the start of omalizumab treatment (baseline), and clinical response was evaluated after 24 (± 8) weeks and 52 (± 8) weeks of treatment. The study received approval from the local institutional review boards and has been registered on clinicaltrials.gov (NCT04670172).

Inclusion and exclusion criteria

Out of 76 patients with uncontrolled severe CRSwNP who received omalizumab subcutaneously every 2 or 4 weeks according to national indications, 61 patients were included in the study. Omalizumab effectiveness was assessed at 24 and/or 52 weeks based on available data on at least one of the following measures: Nasal Polyp Score (NPS), Sino-Nasal Outcome Test (SNOT-22) and visual analogue scale (VAS). The 15 patients who were excluded from analysis lacked follow-up data on the above parameters at 24 and 52 weeks (due to loss to follow-up, pending follow-up visits, or missing recorded data, or as their available follow-up data fell outside the predefined time window of 24 weeks and 52 weeks (±8 weeks). However, patients previously treated with a biologic for asthma and/or CRSwNP before initiating omalizumab, were not excluded. All patients were permitted to continue their standard-of-care medical treatment.

Data collection and outcome measures

Baseline demographic data, including patients' age, gender, body mass index (BMI) and smoking status, were recorded. Disease history was documented, including the use of systemic corticosteroids (SCS) in the past year, the number of endoscopic sinus surgery (ESS) procedures, and prior biologic treatments targeting type 2 disease. The presence of physician-diagnosed comorbidities, such as N-ERD, asthma, and allergies, was also recorded. Clinical outcomes were assessed at baseline and during follow-up visits. The NP size was evaluated endoscopically during the visit using the NPS, ranging from 0 to 4 per side, with a total score ranging from 0 to 8. Disease-specific health-related quality of life was assessed using SNOT-22, which has a total score of 110, with higher scores indicating a greater impact on quality of life [(1)]. Asthma control was evaluated using the Asthma Control Test (ACT), with a maximum score of 25, in which higher scores (20-25) reflect good asthma control [(2)]. Chronic rhinosinusitis (CRS) symptom severity was assessed using a VAS ranging from 0 mm (no bothersome symptoms) to 100 mm (extremely bothersome symptoms), assessing total sinus symptoms, loss of smell, and nasal blockage. Laboratory markers, including blood eosinophil counts (cells/mm^3) and serum total immunoglobulin E (IgE) levels (IU/mL), were also measured.

Evaluation of treatment response

Assessment of the clinical response to omalizumab was performed according to EUFOREA 2021 criteria [(3)]. Since nasal congestion scores and loss of smell scores are not routinely assessed in the real-world clinical practice at included centres, VAS nasal blockage and VAS loss of smell were analysed as part of a standardized evaluation of symptoms by VAS as described above. At 24 weeks, patients were considered to show a clinically relevant response to biologics if at least one score had improved, i.e.: VAS loss of smell (≥20 mm change compared to baseline), VAS nasal blockage (≥20 mm change compared to baseline), VAS total sinus symptoms (≥20 mm change compared to baseline), NPS (≥1 change compared to baseline), SNOT-22 (≥8.9 change compared to baseline) [(3)]. At 52 weeks, patients were considered to have a beneficial composite treatment response if all of the following criteria were fulfilled, i.e.,: VAS nasal blockage (<50 mm), VAS total sinus symptoms (<50 mm), NPS (<4), SNOT-22 score (<30) [(3)].

Statistical analyses

Sample size calculations were performed for NPS and SNOT-22 scores based on historical data of the previous omalizumab phase 3 (combined POLYP 1 and 2 as well OLE) trials [(4,5)]. Calculations assumed a one-sided significance level of 0.0025 and a minimum of 80% power to detect treatment effects at 24 and 52 weeks compared to baseline. For NPS, a minimum of 17 patients at 24 weeks (effect size (Cohen's d) = 0.73) and 14 patients at 52 weeks (effect size = 0.81) were required. For SNOT-22, the corresponding minimum sample sizes were 7 and 5 patients, assuming effect sizes of 1.33 and 1.65 at 24 and 52 weeks, respectively. Given the large effect sizes and a within-subject design with n=61 patients, the statistical power exceeds 99.9% for all endpoints. Sample size and power calculations were performed with R (v4.4.1 (2024-06-14, R Foundation for Statistical Computing, Vienna, Austria) in RStudio (v2024.09.0+375) using the pwr (v1.3-0) library. Normality was assessed using the Shapiro-Wilk

test. Within-group comparisons of outcome parameters were conducted using a mixed-effects model (restricted maximum likelihood without data imputation for missing values) with Dunnett's multiple comparison test. The Geisser-Greenhouse correction was applied. Missing data were reported for each outcome parameter in the figure legends. Proportions of patients were compared using the chi-square test. Data are presented as Tukey box-and-whisker plots. Statistical analyses were performed using GraphPad Prism 10 (Boston, MA, USA). A p-value of < 0.05 was considered statistically significant.

Results

Effect of omalizumab on type 2 inflammatory markers

Omalizumab significantly reduced BEC at both 24 weeks (335.0 cells/mm^3 [200.0–485.0]; $p = 0.002$; Figure S1A) and 52 weeks (250.0 cells/mm^3 [100.0–400.0]); $p = 0.0007$; Figure S1A) compared to baseline (400.0 cells/mm^3 215.0–507.5]). In contrast, serum total IgE levels increased significantly after 24 weeks (450.0 IU/mL [206.3–745.5]; $p = 0.01$; Figure S1B), but no significant increase was observed at 52 weeks (377.0 IU/mL [278.0–758.0]; $p = 0.30$; Figure S1B) of treatment compared to baseline (193.0 IU/mL [99.0–365.3]).

Patients on prior biologics

Eleven of the 61 patients treated with omalizumab had previously received other biologic therapy (all dupilumab) for CRSwNP and/or asthma. Of these, 8 patients switched due to insufficient response, while 3 patients switched because of side effects, including psoriasis (skin lesions), flushing, and lung problems.

Discontinuation, switches, and adverse events of omalizumab

Of the 61 patients included, 20 patients discontinued omalizumab therapy before or at 52 weeks, all due to inadequate response. Two of these patients were on dupilumab as prior biologic. Among those who discontinued, 5 patients switched to alternative treatment modalities, such as surgery or systemic corticosteroids, or were lost to follow-up, while 15 patients switched to another biologic. Specifically, 14 patients switched to dupilumab, and one patient switched to mepolizumab. The details regarding prior biologic use, therapy discontinuation, and switching are summarized in Figure S2. One patient reported a local reaction at the injection site.

Analysis of omalizumab responders in discontinued patients

At 24 weeks, 78.9% of the patients who discontinued omalizumab before or at 52 weeks, fulfilled at least 1 criterion to qualify as responder based on these 24 weeks responder criteria, whilst 80.0% qualified as responder at 52 weeks. At 24 and 52 weeks none of the patients met all 4 qualifying criteria for responders at 52 weeks. However, the number of patients with outcomes at 52 weeks was too low due to discontinuation, to meaningfully assess treatment response at that timepoint. Evaluation of treatment response at 24 weeks in the 20 discontinued patients showed similar response rates compared to the 41 patients who continued omalizumab until the end of the study period (78.9% versus 85.0% in the patients who continued until at least 52 weeks; $p = 0.56$).

Discussion

Our results confirm and extend the findings of the POLYP 1 and 2 studies, which showed that omalizumab significantly reduced NP size and improved related symptoms in patients with CRSwNP. Comparison of our results with those from the phase 3 clinical (POLYP 1 and 2) studies confirms the effectiveness of omalizumab, i.e,: a reduction of NPS at 24 weeks of 1.6 versus 1.1 and 0.9 in POLYP 1 and 2 (POLYP co-primary endpoint), a reduction in SNOT-22 at 24 weeks of 21.6 versus 24.7 and 21.5 in POLYP 1 and 2 (POLYP secondary endpoint), a NPS improvement ≥ 1 and ≥ 2 at 24 weeks of 68.4% and 49.1% versus 44.4% and 31.3% for POLYP (study 1 and 2 combined). The at least equal or even better results compared to the phase 3 studies (POLYP 1+2) of omalizumab may be related to the less structured and less stringently selected patients in our real-world setting. In addition, direct comparison between our real-world study and POLYP 1 and 2 should be interpreted in the light of differences in baseline patient characteristics, with higher prevalence of comorbidities (comorbid asthma 78.3% versus 59.7, N-ERD 42.4% versus 29.8%), a different treatment history (prior ESS 90.0% versus 57.6%, SCS use past year 72.9% versus 26.9%), combined with a lower disease burden (mean NPS of 3.9 versus 6.3 and mean SNOT-22 of 50.9 versus 59.5). Other real-world studies in CRSwNP previously also demonstrated significant improvements in SNOT-22 scores and NPS with omalizumab [6–8].

Asthma control has not been assessed in POLYP 1 and 2 studies, nor in the real-world studies with omalizumab for CRSwNP as primary indication, so far. We observed a significant improvement of ACT already at 24 weeks, which was sustained up to 52 weeks. These improvements in ACT in patients with comorbid asthma further highlights the systemic benefits of omalizumab, given its known role in reducing type-2 inflammation across multiple organ systems.

Biologic switching and discontinuation patterns observed in this study offer insights into real-world treatment decisions. The overall discontinuation rate due to insufficient clinical response (32.8% at 52 weeks) highlights the fact that not all patients respond to biologic therapies, reinforcing the importance of reliable predictors of treatment response to optimize management strategies. Patients who switched from omalizumab to other biologics (dupilumab and mepolizumab) or alternative therapies (e.g., sinus surgery, systemic corticosteroids) did so

mainly due to limited therapeutic effect. These discontinuation rates are higher than observed in POLYP 1 (3.7% of randomized) and 2 (4.7%) [4]. Viskens et al reported discontinuation of 26% at 24 weeks in patients treated with omalizumab in the real-world setting [9], whereas Tat reported a discontinuation of 5.9% over a median 9-month follow up [10]. Analysis of biologic description data in US at 52 weeks showed an overall biologic discontinuation of 30.7% [11]. Recently, Cai et al reported a low number (0.7%) of discontinuations due to adverse effects in a meta-analysis of real-world omalizumab data [12]. Although a rapid improvement of NPS and SNOT-22 score was demonstrated in this study, a significant effect on VAS nasal blockage was only observed after 52 weeks. Moreover, no significant improvement in VAS loss of smell was noted at 24 and 52 weeks. In many patients with CRSwNP, anosmia is one of the more persistent and bothersome symptoms for patients with CRSwNP, correlating with the severity of the disease and affecting their quality of life [13]. The limited effect on olfactory function may explain the subjective dissatisfaction with therapy and the desire to change the therapeutic agent. Only few other real-world studies on omalizumab also looked into olfactory function [9,10,14,15]. Viskens et al. reported a median VAS of approximately 60/100mm is reached in most studies after 24, which is in line with our findings [9]. Another study found a decrease in VAS impaired smell from 100 to 20mm, but only included 17 CRSwNP patients from Turkey [10]. Overall, it seems that the extent of effect of biologics on olfactory functions is larger for dupilumab than for omalizumab in CRSwNP [16,17].

Omalizumab acts by binding to free IgE, preventing its interaction with mast cells and basophils, thereby reducing the release of inflammatory mediators. This is because omalizumab forms stable IgE-drug complexes, which prolong IgE's half-life in circulation while inhibiting its biological activity. Therefore, serum total IgE levels typically increase after omalizumab treatment, rather than decrease. This is in contrast to dupilumab use for CRSwNP, which typically decreases IgE levels by inhibiting IL-4 signalling – a key pathway in IgE production - and in contrast to mepolizumab, which generally does not affect serum total IgE levels, as it primarily targets eosinophils by blocking IL-5 [18,19]. The elevation in serum total IgE can be seen early on during omalizumab treatment and persists throughout therapy, without clinical relevance. However, free (biologically active) IgE levels are significantly reduced, leading to clinical benefits in CRSwNP and other type 2 inflammatory diseases [20].

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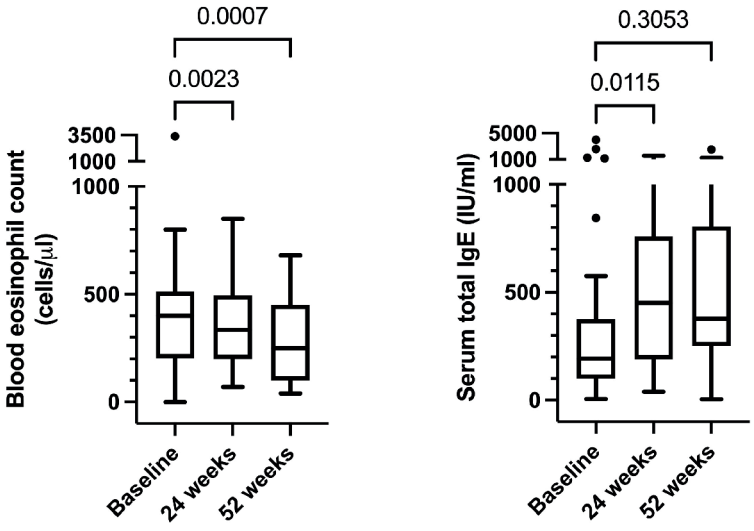


Figure S1. Effect of omalizumab on blood eosinophil counts and serum total IgE at baseline, 24 weeks, and 52 weeks. A, Patient numbers of BEC: 46, 36 and 21. B, Patient numbers of serum total IgE: 56, 35 and 22. Data are presented as Tukey box-and-whisker plots. Within-group comparison was performed by mixed effects model and Dunnett multiple testing comparison.

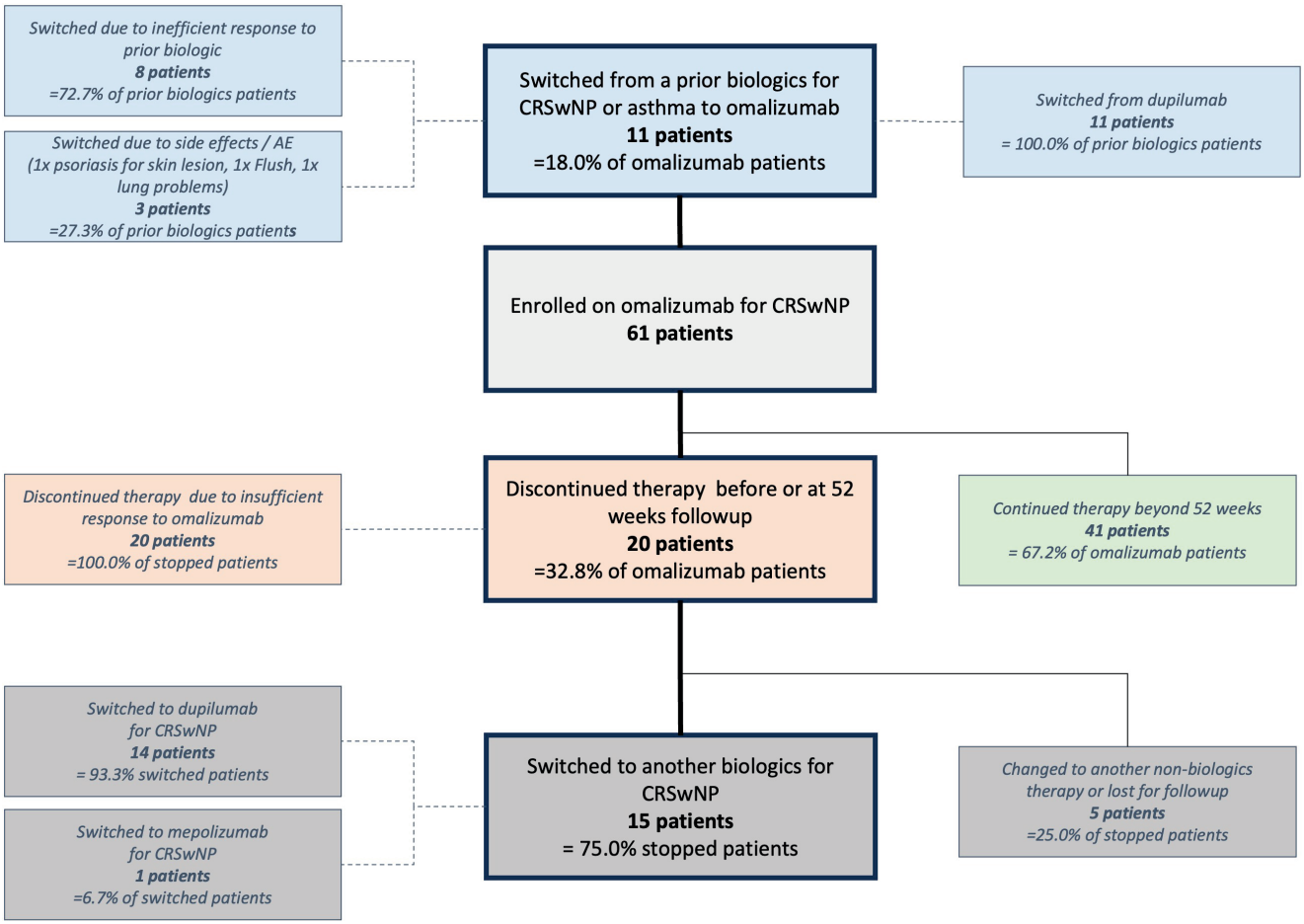


Figure S2. Prior biologic use, discontinuation and switches after omalizumab treatment.

Table S1. Patient characteristics.

	Omalizumab (n=61)
Age, mean +/- SD	49.2 ± 15.1
Male – female, %	44.3 – 55.7
BMI, mean +/- SD	26.0 ± 5.6
Smoking status (never - ex - current), %	81.4 – 7.0 – 11.6
Allergy, %	47.5
Asthma, %	78.3
N-ERD, %	42.4
# ESS procedures (0 - 1 - 2 - 3 - >3), %	10.0 – 35.0 – 23.3 – 11.7 – 20.0
SCS courses past year (0 – 1 – 2 – 3 - >3), %	55.6 – 22.2 – 7.4 – 7.4 – 7.4
Blood eosinophils, median (IQR)	400 (215-508)
Serum total IgE, median (IQR)	193 (99-365)
SNOT-22, median (IQR)	51.0 (32.0-70.0)
NPS, median (IQR)	4.0 (2.0-6.0)
ACT, median (IQR)	20.0 (16.0-23.5)

SD: standard deviation, N-ERD: non-steroidal anti-inflammatory drug exacerbated respiratory disease, ESS: endoscopic sinus surgery, SCS: systemic corticosteroids, VAS: visual analogue scale, SNOT-22: sinonasal outcome test-22, NPS: nasal polyp score, ACT: asthma control test, IQR: interquartile range.

Table S2. Omalizumab effectiveness based on EUFOREA 2021 criteria.

	Applied criteria	% responders at 24 weeks	% responders at 52 weeks	% change 52 versus 24 weeks
Responder defined as one of these five criteria to be met	Diff SNOT-22 ≥8.9	70.4% (38/54)	76.3% (29/38)	5.9%
	Diff NPS ≥1	68.4% (39/57)	65.8% (25/38)	-2.6%
	Diff VAS TSS ≥20	33.3% (7/21)	50.0% (8/16)	16.7%
	Diff VAS NB ≥20	50.0% (10/20)	46.7% (7/15)	2.3%
	Diff VAS LoS ≥20	45.5% (10/22)	50.0% (8/16)	4.5%
At least one of these 5 criteria met		83.1% (49/59)	85.4% (35/41)	2.3%
Responder defined as all of these four criteria to be met	SNOT-22 <30	58.9% (33/56)	61.5% (24/39)	2.6%
	NPS <4	69.0% (40/58)	64.1% (25/39)	-4.9%
	VAS TSS <50	26.1% (6/23)	29.4% (5/17)	3.3%
	VAS NB <50	52.4% (11/21)	66.7% (10/15)	14.3%
	VAS LoS <50	45.8% (11/24)	47.1% (8/17)	1.2%
Additional criterion	VAS LoS <50	45.8% (11/24)	47.1% (8/17)	1.2%
All these 4 criteria met		10.0% (2/20)	15.4% (2/13)	5.4%

VAS: visual analogue scale, SNOT-22: sinonasal outcome test-22, NPS: nasal polyp score, TSS: total sinus symptoms, NB: nasal blockage, LoS: loss of smell.

Real-world effectiveness of omalizumab in patients with chronic rhinosinusitis with nasal polyps (CRSwNP)

Findings from CHRINOSOR

Study population

CRSwNP treated with omalizumab

52-week follow-up

BL 24W 52W

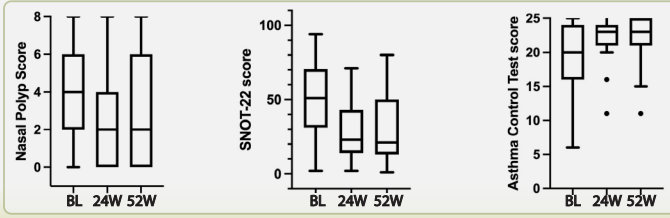
Study centres

7 centres in 4 EU countries

Omalizumab offers relevant clinical benefits for patients with uncontrolled severe CRSwNP in a real-world setting

EUFOREA 2021 Criteria at **24 weeks**	% Meeting criteria
Diff SNOT-22 ≥8.9	*70.4%*
Diff NPS ≥1	*68.4%*
Diff VAS TSS ≥20	*33.3%*
Diff VAS NB ≥20	*50.0%*
Diff VAS LoS ≥20	*45.5%*
≥1 of these 5 criteria met	*83.1%*

EUFOREA 2021 Criteria at **52 weeks**	% Meeting criteria
Diff SNOT-22 <30	*61.5%*
Diff NPS <4	*64.1%*
VAS TSS <50	*29.4%*
VAS NB <50	*66.7%*
All 4 of these criteria met	*15.4%*



Effectiveness of omalizumab on NPS, SNOT-22 and ACT is already present at 24 weeks and sustained up to at least 52 weeks

Bartosik T, Seys SF, de Kinderen J, et al. Rhinology 2026. https://doi.org/10.4193/Rhin25.514

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