Real world efficacy of dupilumab in switchers versus biological naive CRSwNP patients

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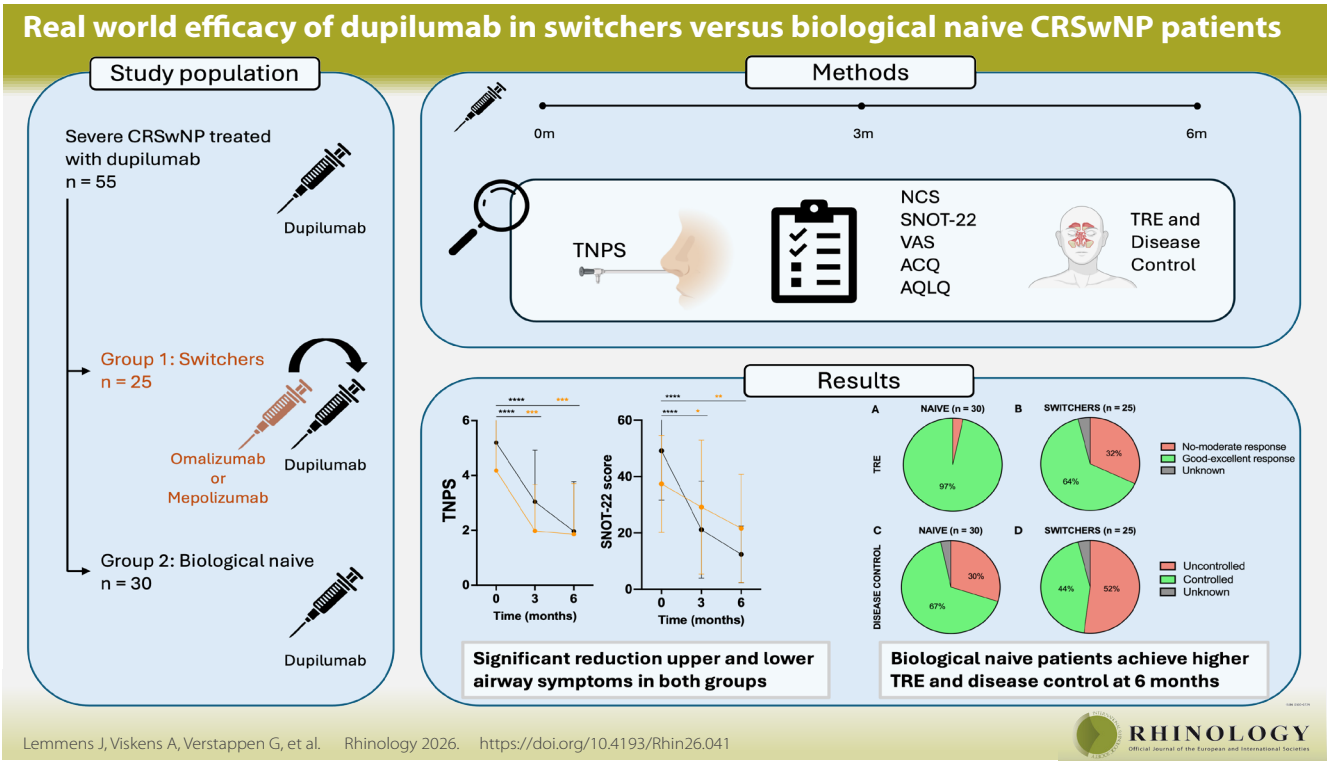

Abstract

Background: Biologicals have revolutionized care for severe uncontrolled chronic rhinosinusitis with nasal polyps (CRSwNP). Currently, real-world efficacy (RWE) data of dupilumab in patients who switch to dupilumab after having no or minimal therapeutic response to either omalizumab or mepolizumab are lacking. No comparison has been performed between patients switching from omalizumab or mepolizumab to dupilumab and those receiving dupilumab as their first biological. **Aim**: 55 CRSwNP patients receiving dupilumab in the RELIBIO trial were divided into those who were biological naive (n = 30) and those who showed no to poor therapeutic response to 6 months therapy with either omalizumab or mepolizumab (n = 25), with evaluation of the following parameters at baseline and 6 months: SNOT-22 scores, nasal congestion scores (NCS), VAS scores for nasal obstruction, smell loss and postnasal drip, ACQ-5, AQLQ and total nasal polyp scores (TNPS). We determined disease control and therapeutic response evaluation (TRE) at 6 months for both groups using the EUFOREA/EPOS criteria. **Results**: Dupilumab showed significant improvements on all patient-reported outcome measures (PROMs) and TNPS in both groups. When comparing the efficacy between switchers and naive patients, dupilumab showed equal efficacy in both groups on SNOT-22, TNPS, NCS, VAS scores for smell loss, nasal blockage and postnasal drip, ACQ-5 and AQLQ. A good to excellent therapeutic response at 6 months was observed in 67% of switchers compared to 97% of the biological naive patients. Regarding disease control at 6 months, we observed 44% being controlled in the switchers and 67% in the biological naive group, with smell loss being the main reason for not being controlled. **Conclusion**: This prospective RWE study shows that dupilumab significantly reduced symptom severity and nasal polyp scores in CRSwNP patients at 6 months of therapy, also in those showing a minimal therapeutic response to mepolizumab or omalizumab. Patients in the biologic naive group showed a higher likelihood of achieving disease control.

Key words: chronic rhinosinusitis, nasal polyps, biologicals, dupilumab, type 2 inflammation

Introduction

Chronic rhinosinusitis (CRS) represents a chronic inflammatory condition of the nasal and paranasal mucosa, giving rise to typical symptoms such as nasal congestion, nasal discharge, postnasal drip, facial pain and/or reduced sense of smell [1]. CRSwNP has a predominant type 2 inflammatory endotype, with biologics having emerged as novel therapeutic options neutralizing typical type 2 mediators such as: IL-4, IL-5 and IgE [2]. Dupilumab, omalizumab and mepolizumab are currently registered and reimbursed for severe uncontrolled CRSwNP in most European countries. The safety and efficacy of these three biologicals have been validated in large phase III double blinded placebo controlled randomized trials [3–5]. Multiple indirect comparison studies have compared the efficacy of these different biologicals, with a recent first head-to-head comparison of real-world efficacy of dupilumab and omalizumab [6]. Reflecting on the outcomes of previous trials, dupilumab appears to be more effective than mepolizumab and omalizumab on the reduction of nasal polyp scores (NPS) [6–10] and patient-reported outcomes measures such as smell loss [10,11] and the SNOT-22 scores [8,10]. It remains however unknown to what extent patients who showed minimal therapeutic response to 6 months of therapy with either omalizumab or mepolizumab might still benefit from dupilumab.

A multicentre RWE study was launched across 9 rhinology centres in Belgium and investigated the real-world efficacy of dupilumab. The primary objective of this RWE study is to evaluate the efficacy of dupilumab in patients who showed no to poor response to mepolizumab or omalizumab following 6 months of therapy. Secondly, we compared the efficacy of dupilumab between switchers and biological naive patients at 6 months. We also determined the percentage of patients achieving disease control and the therapeutic response evaluation (TRE) at 6 months for both groups using the EUFOREA/EPOS criteria [12].

Materials and methods

Patient population

We performed a prospective RWE study to determine the efficacy of dupilumab in patients who had no or minimal response to either omalizumab or mepolizumab after 6 months of therapy, labelled as 'switchers', and in those who did not receive biologic therapy for the indication of CRSwNP or asthma before, labelled as 'biological naive' (Figure 1). Patients who met the reimbursement criteria for biological therapy were enrolled and followed up prospectively. Patients were excluded if they had received any other biologic therapy within 3 months prior to study initiation. A convenience sample of 55 patients was included as part of the RELIBIO (Real-life Evaluation of the Efficacy of Biologicals in Chronic Rhinosinusitis With Nasal Polyps) registry between September 27, 2022, and August 10, 2025 [13]. This registry was

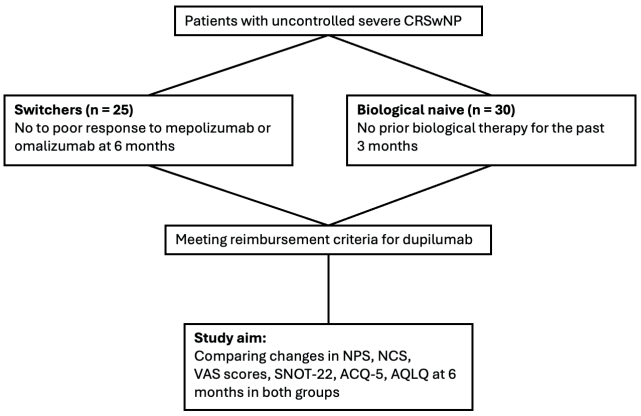

Figure 1. Flow chart.

conducted in 9 rhinology centres in Belgium: 5 University hospitals (UZLeuven, UZAntwerp, VUBrussels, ULiège and UCLouvain) and 4 non-academic medical centres (Aalst, Genk, Bruges, and Hasselt). Patients were included if they either had been switched from omalizumab or mepolizumab to dupilumab for 6 months or if they had received dupilumab as their first biological for 6 months. Ethical approval was provided by the medical ethical committee of the University Hospital of Leuven (S66646).

Baseline characteristics

Baseline characteristics such as age, gender, currently smoking, years since diagnosis of CRSwNP, comorbidities such as asthma, allergy and aspirin intolerance, eosinophils, total IgE, number of previous endoscopic sinus surgeries and presence of structural nasal pathology were documented.

Evaluation of patient reported outcome measures (PROMs)

Questionnaires were completed at treatment initiation, 3 and 6 months to assess upper airway symptoms, using the nasal congestion score (NCS), visual analogue scale (VAS) for smell loss, nasal blockage, postnasal drip, rhinorrhoea and facial pain and sinonasal outcome test-22 (SNOT-22) as well as lower airway symptoms, using the asthma control questionnaire-5 (ACQ-5) and asthma quality of life questionnaire (AQLQ)

Evaluation of total nasal polyp score (TNPS)

Nasal polyps were evaluated using the nasal polyp score (NPS), ranging from 0 (no polyps) to 4 (polyps extending to the floor of the nasal cavity) for each nostril, as proposed in the consensus meeting of Gevaert et al. [14]. Assessment of NPS was performed through nasal endoscopy. The sum of the NPS of both nasal cavities is defined as the TNPS.

Evaluation of therapeutic response (TRE) and disease control

The therapeutic response to dupilumab at 6 months was evaluated using the EUFOREA/EPOS criteria [2].

1. reduction in NPS by at least one unit,

Table 1. Baseline characteristics.

Baseline characteristics	Total	Switchers	Naive
Patients included (%)	55 (100%)	25 (45%)	30 (55%)
Age (mean ±SD)	53y (±13y)	52y (±14y)	54y (±13y)
Gender n (%)			
Male	29 (53%)	13 (52%)	16 (53%)
Female	26 (47%)	12 (48%)	14 (47%)
Smoker n (%)			
No	36 (71%)	17 (74%)	19 (68%)
Yes	2 (4%)	1 (4%)	1 (4%)
Ex-smoker	13 (25%)	5 (22%)	8 (28%)
Years with disease n (%)*			
<5 Years	14 (30%)	3 (16%)	11 (41%)
5-10 Years	6 (13%)	3 (16%)	3 (11%)
>10 Years	26 (57%)	13 (68%)	13 (48%)
Comorbidities n (%)			
Asthma*	32 (62%)	18 (75%)	14 (50%)
Aspirin intolerance (based on history)*	31 (40%)	4 (18%)	17 (60%)
Airborne allergies	27 (52%)	15 (65%)	12 (44%)
Number of sinus surgeries n (%)*			
0	11 (22%)	0 (0%)	11 (39%)
1	23 (45%)	11 (48%)	12 (43%)
2	9 (18%)	6 (26%)	3 (11%)
>2	8 (15%)	6 (26%)	2 (7%)
Structural nasal pathology n (%)*			
Septal deviation, valve pathology, septal perforation	3 (9%)	3 (13%)	0 (0%)
Biomarkers (mean ±SD)			
Total IgE (KU/L)	279 (±292)	274 (±250)	284 (±373)
Eosinophils (*10^9/L)	0,43 (±0,25)	0,49 (±0,29)	0,38 (±0,21)

Significant difference ($p<0.05$) indicated with *, significance was calculated using Fisher's exact test for categorical variables and unpaired t-test for continuous variables.

2. no need for OCS/surgery,
3. improved sense of smell, defined as VAS score for smell loss lower than 5 cm,
4. improved quality of life, defined as SNOT-22 score lower than 40 and an improvement of at least 8.9 units and
5. reduction of the impact of comorbidities, defined as a reduction in ACQ-5 score by 0.5 points or having an ACQ-5 score lower than 0.75, after 6 months of dupilumab treatment.
6.

The TRE was defined by the number of fulfilled criteria: a good-to-excellent response corresponded to fulfilling 4–5 criteria, a moderate response 2–3 criteria, and a poor response 0–1 criterium.

Disease control was assessed according to the EUFOREA/EPOS criteria [12]: patients with a VAS score ≤5 cm for nasal blockage, rhinorrhoea, anosmia, post-nasal drip, and facial pain, and with a TNPS ≤2 (with maximum NPS 1 on each side) were classified as controlled. Patients who scored higher than 5 cm for at least one of those VAS scores and/or with NPS ≥ 2 on one side, were considered uncontrolled [12].

Evaluation of adverse events and treatment adherence

At each outpatient visit, patients were queried regarding need for antibiotics, oral corticosteroids, sinus surgery and adverse events. Additionally, adherence to the biological therapy, as well as to standard-of-care treatments such as nasal rinsing and intranasal corticosteroids, was assessed.

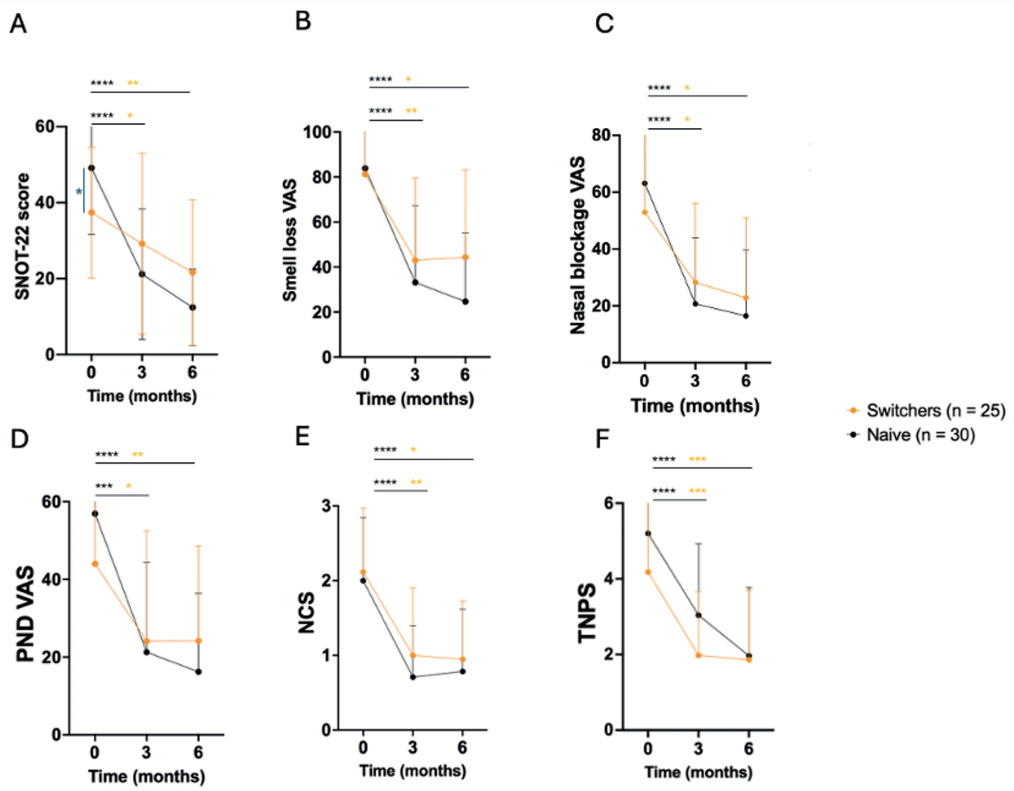

Figure 2. SNOT-22, VAS scores, NCS and TNPS. (A) SNOT-22 reduction of switchers compared to naive patients. (B) VAS smell loss reduction of switchers compared to naive patients. (C) VAS nasal blockage reduction of switchers compared to naive patients. (D) VAS postnasal drip reduction of switchers compared to naive patients. (E) NCS reduction of switchers compared to naive patients. (F) TNPS reduction of switchers compared to naive patients. Data are shown as mean ± 95% CI, significance was calculated by using mixed effect analysis with Tukey's multiple comparisons test, ****: P<0.0001, ***: P <0.001, **: P < 0.01, *: P < 0.05.

Data analysis

We analysed the changes in NCS, TNPS, VAS, SNOT-22, ACQ-5 and AQLQ at 3 months and at 6 months, compared to baseline using GraphPad Prism VI for Macintosh Version 10.6.0 (GraphPad Software Inc., San Diego, CA, USA). Comparisons of baseline characteristics between switchers and biological naive patients were performed using Fisher's exact test for categorical variables and unpaired t-test for continuous variables. Differences between NCS, TNPS, VAS, SNOT-22, ACQ-5 and AQLQ at baseline, 3 months and 6 months were analysed using mixed-effect model with Tukey's multiple comparisons test. Results were regarded as statistically significant if $p < 0.05$.

Results

Baseline characteristics

55 patients were included in this study: 25 patients had been treated with omalizumab (n = 5) or mepolizumab (n = 20) with poor therapeutic response after 6 months, after which they were switched to dupilumab based on clinical criteria and meeting the national reimbursement criteria of dupilumab. 30 patients were treated with dupilumab from the beginning (biological naive) (Figure 1). In general, the average age was 53 years. In more than half of the patients the disease had been going on for more than 10 years. Concomitant asthma was present in 62% of patients, history of aspirin intolerance in 40%, and airborne allergy in 52%. Overall, 78% of patients had undergone at least one prior sinus surgery. There was no significant difference in gender nor smoker status. Structural nasal pathology was identified in 13% of the switchers, whereas it was absent in the biological naive group. There was no significant difference in biomarkers. Average IgE was 279 KU/L, average eosinophil count was 0.43 x 10^9/L. Baseline characteristics are listed in Table 1.

Comparing efficacy on upper airway parameters (TNPS, NCS, SNOT-22) in switchers vs biological naive patients

We observed a significant improvement on all upper airway symptoms (TNPS, NCS, SNOT-22) in both groups (Figure 2). The mean SNOT-22 at baseline was 37 (CI 30 to 45) and 49 (CI 42 to 56) for switchers and naive patients, respectively, and decreased with 15 (CI 7 to 24, p = 0.0017) and 37 (CI 30 to 44) for switchers and naive patients, respectively. There was a significant difference between baseline values of the SNOT-22 score in both groups. The mean difference in SNOT-22 score at baseline between both groups was 12 (CI 3 to 22, p = 0.0119) (Figure

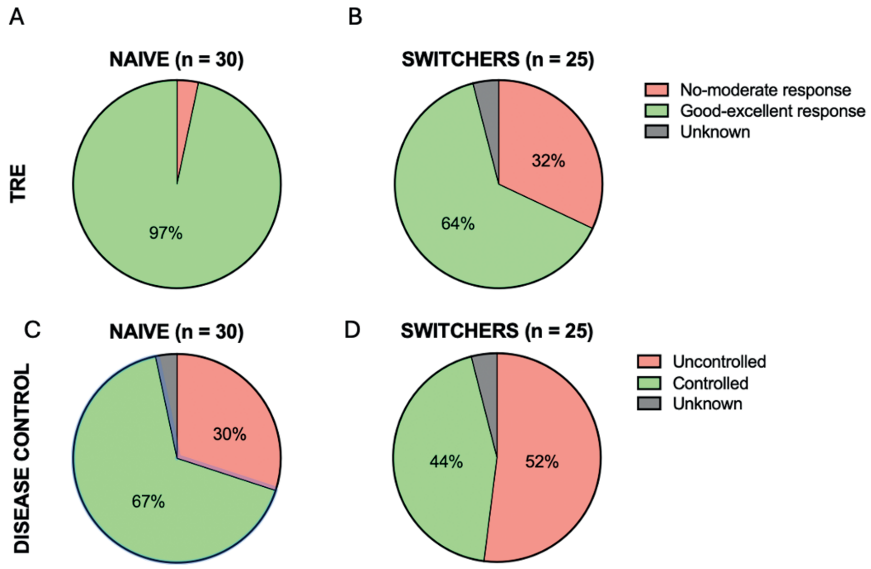

Figure 3. TRE and disease control. (A) Therapeutic response evaluation of switchers at 6 months. (B) Therapeutic response evaluation of naive patients at 6 months. (C) Disease control of switchers at 6 months. (D) Disease control of naive patients at 6 months.

2). The mean TNPS at baseline was 4.2 (CI 3.2 to 5.2) and 5.2 (CI 4.6 to 5.8) for switchers and naive patients, respectively, and decreased with 2.4 (CI 1.2 to 3.6, p = 0.0002) and 3.4 (CI 2.6 to 4.2, p < 0.0001) for switchers and naive patients, respectively. The mean NCS at baseline was 2.1 (CI 1.8 to 2.6) and 2.0 (CI 1.7 to 2.3) for switchers and naive patients, respectively, and decreased with 1.1 units (CI 0.2 to 1.9, p = 0.0142) and 1.3 (CI 0.8 to 1.7, p < 0.0001) for switchers and naive patients, respectively.

Comparing efficacy on lower airway parameters (ACQ-5, AQLQ) in switchers vs biological naive patients

We observed a significant improvement on lower airway symptoms (ACQ-5 and AQLQ) in both groups (Figure 2). The mean ACQ-5 at baseline was 1.3 (CI 0.6 to 1.9) and 1.4 (CI 1.7 to 2.3) for switchers and naive patients, respectively, and decreased with 0.6 (CI 0.0 to 1.2, p = 0.0487) and 1.0 (CI 0.5 to 1.4, p < 0.0001) for switchers and naive patients, respectively. The mean AQLQ at baseline was 6.0 (CI 5.7 to 6.4) and 5.9 (CI 5.6 to 6.3) for switchers and naive patients, respectively, and improved with 0.3 (0.0 to 0.7, p = 0.0489) and 0.6 (CI 0.3 to 0.9, p = 0.0003) for switchers and naive patients, respectively.

Disease control and TRE

At 6 months, 44% (11/25) and 67% (20/30) of switchers and biological naive patients, respectively, were controlled according to the EUFOREA/EPOS criteria (Figure 3). The effect of dupilumab on smell loss in both groups is illustrated in Figure 4.
Regarding TRE at 6 months, 67% of switchers (16/24) and 97% of biological naive patients (29/30) showed a good to excellent therapeutic response (Figure 3). The 2 main unmet criteria in the switched group were lack of improvement in smell loss and SNOT-22 scores. Persistent smell loss was observed in 44% of switchers (11/25), with these patients failing to reach a VAS smell score below 50. Additionally, 24% (6/25) did not meet the combined SNOT-22 criterion of a score < 40 with a ≥ 8.9-point improvement. In half of these patients (3/6), the total score fell below 40 but the required improvement threshold was not reached.

Evaluation of adverse events and treatment adherence

No severe adverse events were reported during the first 6 months of treatment with dupilumab. None of the patients needed oral corticosteroids due to uncontrolled CRSwNP. Five of the 55 patients underwent endoscopic sinus surgery: three in the switched group and two in the biological naive group. No missed injections were reported.

Discussion

This RWE study on 55 patients confirms the efficacy of dupilumab in patients with severe uncontrolled CRSwNP, including those who switched from omalizumab or mepolizumab. Switchers and biological naive patients both showed significant improvements in patient-reported outcomes, TNPS, and substantial portion of patients with disease control after 6 months. Dupilumab did not show decreased efficacy in patients who had been treated with omalizumab or mepolizumab before on all outcome parameters. Interestingly, switchers showed lower percentages of patients achieving disease control and excellent TRE compared to biological naive patients. This observation seems mainly due to persisting smell loss, which may or may not be reversible with anti-inflammatory or targeted therapy.
Several mechanisms may underlie the persistence of smell loss

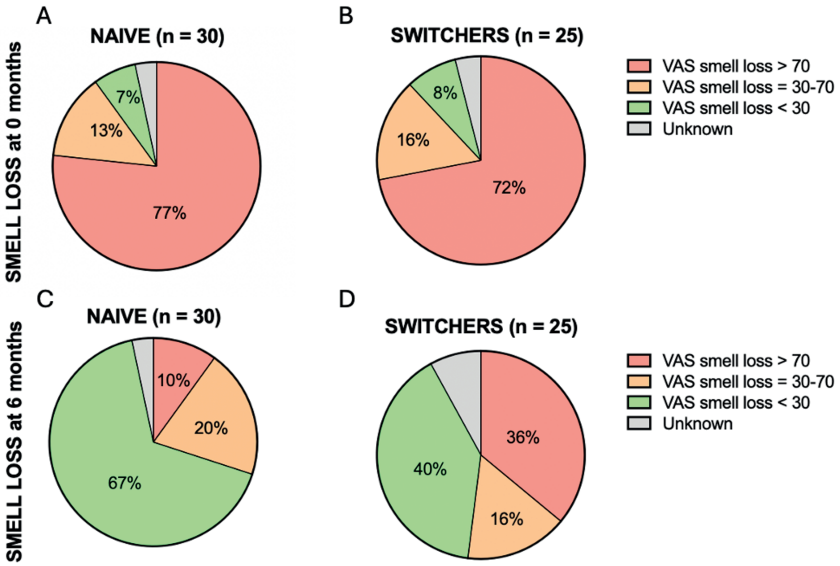

Figure 4. Smell loss. (A) Reported smell loss in biological naive patients at 0 months. (B) Reported smell loss in switchers at 0 months. (C) Reported smell loss in biological naive patients at 6 months. (D) Reported smell loss in switchers at 6 months.

despite biologic therapy.

Dupilumab blocks IL-4 and IL-13 signalling, whereas mepolizumab and omalizumab target IL-5 and IgE, respectively. The broader inhibition of type 2 inflammation by dupilumab may explain its overall superior performance across most CRSwNP symptoms. Nevertheless, olfactory dysfunction may not be solely driven by active type 2 inflammation. In patients with longstanding disease, chronic inflammation may have led to structural changes of the olfactory epithelium or central neural adaptation, limiting reversibility even when inflammatory pathways are adequately suppressed. Furthermore, smell loss in some patients may be multifactorial, involving mechanisms beyond those directly addressed by current biologic therapies [15].

Moreover, it is also important to point out that the results we obtained might be an underestimation of the efficacy of dupilumab in switchers given the fact that baseline SNOT-22 scores were lower in the switchers than in the biological naive patients, undoubtedly reflecting the history of previous biologic therapy with minor or moderate effects [13].

Smell loss was the main factor causing lower percentages of patients achieving disease control and excellent TRE in the switchers. Dupilumab showed greater potential than omalizumab or mepolizumab for CRSwNP patients in term of general symptom burden and quality of life [6,16]. However, clinically, it is important to inform patients that, if omalizumab or mepolizumab did not sufficiently relieve smell loss, there is a significant chance that smell loss will be persistent even after treatment with dupilumab.

The findings of this RWE study are interesting and relevant for our communication with patients. Indirect comparison studies and meta-analyses on dupilumab consistently showed good efficacy. For example, in the systematic review by Wu et al. summarizing the efficacy and safety of dupilumab, omalizumab and mepolizumab in patients with CRSwNP, dupilumab ranked highest in terms of NPS and SNOT-22 score reduction [17]. Peters et al. demonstrated that dupilumab significantly outperformed omalizumab in reducing NPS, NCS, and smell loss at 24 w [18]. Chen et al. conducted a network meta-analysis including six studies with ≥52 w follow-up and reported that dupilumab had superior efficacy compared to both mepolizumab and omalizumab in reducing NPS, NCS, SNOT-22 and VAS scores [19]. Another network meta-analysis including 19 studies was performed by Wang et al. and found that dupilumab outperformed the other biologicals in reducing TNPS, NCS and SNOT-22 [20]. However, these analyses are limited by heterogeneity of patient characteristics among included studies and differing inclusion criteria. There have been head-to-head trials comparing biologicals in asthma patients with comorbid CRSwNP. For example, a study performed by Rosso et al. suggested that asthma patients with unsatisfactory upper airway control on omalizumab or mepolizumab may benefit from switching to dupilumab, improving control in the upper and lower airways [21]. A Canadian RWE study showed that 16% of CRSwNP patients switch from omalizumab or mepolizumab to dupilumab, but without evaluation of efficacy in the switchers vs biological naive patients [22].

Our data cannot be compared to other studies given the approach and unique situation in Belgium with first registration and reimbursement of omalizumab and mepolizumab, followed by dupilumab. We anticipated an attenuated response to

dupilumab in switchers due to multiple reasons like more severe inflammation and/or mixed endotype [23], irreversible smell loss due to viral or iatrogenic reasons, nasal obstruction due to structural pathology, or gastroesophageal reflux associated postnasal drip. The reasons why less patients in the switchers group achieve control and excellent therapeutic responses are multifactorial, including different reasons as mentioned in our previous work [24].

The strength of this study lays in the fact that it is a RWE study on the efficacy of dupilumab in switchers, a group underrepresented in previous studies, and performed in a multicentre context. Furthermore, this study uses the EUFOREA/EPOS criteria of control and therapeutic response, with the use of multiple PROMs enhancing the external validity. However, it is important to consider that the sample size remains modest. Larger cohorts in different countries may reveal more important outcomes in relation to prediction of outcomes of any biological therapy. Of note, a follow-up of 6 month is solid, but some literature data suggest further improvement up to one year with dupilumab (25). Larger studies covering a time frame of more than 6 months are needed to provide more data on long-term effects of dupilumab in both switchers and biological naive patients. Lastly, there is a selection bias, as the switchers group consists of patients with more severe disease, i.e. more surgeries, longer disease duration, more structural nasal pathology compared to the biological naïve group.

Conclusion

This observational trial in 55 CRSwNP patients on dupilumab shows good efficacy of dupilumab in CRSwNP patients, regardless of whether patients have been administered mepolizumab or omalizumab before. Biological naive patients benefit from higher rates of disease control and therapeutic response compared to switchers. Given the high cost of biologicals and the disease burden of CRSwNP, optimizing the choice of the first biological is of critical importance.

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Author contributions

PH: conceptualization, methodology, review and editing, supervision; JL, ASV: Data Collection, statistical analysis, writing, original draft preparation, review and editing; GV, CC, SH, VH, BV, WL, FR, KS, OV: data collection, review and editing; All authors have read and agreed to the published version of the manuscript.

Conflict of interest

FR is the recipient of grants for educational events and/or advisory boards by Sanofi, GSK and Novartis.

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