Upper and lower airways response to tezepelumab in asthma patients with / without comorbid nasal polyposis: a 6-months real-life perspective

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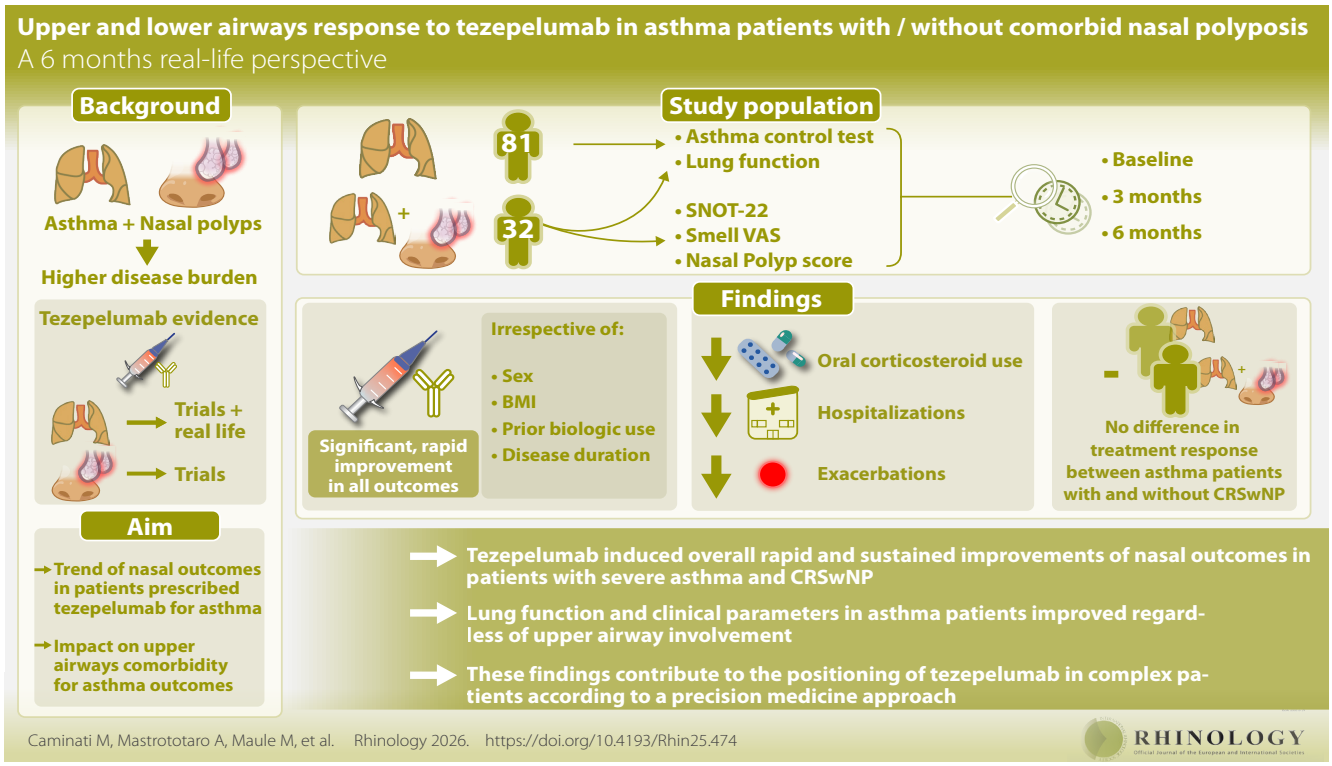

Abstract

Background: The efficacy of tezepelumab in chronic rhinosinusitis with nasal polyps (CRSwNP) has been demonstrated in clinical trials, but real-world evidence remains limited. Our study investigated the trend of CRSwNP outcomes in patients prescribed with tezepelumab for severe asthma and the impact of upper airways comorbidity on asthma outcomes over a 6 months follow-up. **Methods**: Data from 5 referral centres for severe asthma and CRSwNP were retrospectively analysed. Patient reported outcomes and objective measures related to nasal (SNOT-22, VAS, nasal polyp score) and bronchial (asthma control test, lung function) evaluation were assessed at baseline, 3 and 6 months after tezepelumab initiation. **Results**: Tezepelumab significantly and rapidly improved all the nasal outcomes and asthma-related parameters, irrespective of sex, body mass index, prior biologic use, or disease duration. Furthermore, significant reduction of oral corticosteroid use, hospitalizations and exacerbations were also observed. When comparing patients with and without CRSwNP, no differences were observed in term of treatment response. **Conclusions**: In patients with severe asthma and CRSwNP, tezepelumab demonstrated to induce in the real-life setting an overall rapid and sustained improvement of nasal outcomes, as well as of lung function and clinical parameters in asthma patients regardless of upper airway involvement. Although larger studies are needed, these findings contribute to the positioning of tezepelumab in the real-world clinical practice according to a precision medicine approach.

Key words: tezepelumab, TSLP, chronic rhinosinusitis with nasal polyps, severe asthma

Introduction

Chronic rhinosinusitis with nasal polyps (CRSwNP) is an inflammatory condition, which affects approximately 2% to 4% of the general population. Its clinical manifestations, including loss of smell, nasal obstruction, thick nasal discharge, and facial pressure, heavily impact on quality of life of affected patients [1,2]. CRSwNP represents a common and relevant comorbidity in severe asthma patients, affecting at least half of them and significantly increasing the overall disease burden [3]. In fact, individuals suffering from both the conditions experience more severe sinonasal symptoms, more extensive inflammation in the lower airways, more compromised pulmonary function, and a decreased health-related quality of life (HRQoL) when compared to individuals with asthma or CRSwNP only [4]. The pathobiological evidence sustains the hypothesis of asthma and CRSwNP as clinical expressions of the same inflammatory condition driven by type 2 (T2) and epithelial cells and cytokines, mainly including eosinophils, IL-4, IL-5, IL-13 and TSLP [5,6]. That background paved the way to the investigation of anti-T2 cytokines compounds already approved for severe asthma in patients affected by CRSwNP. So far, omalizumab, dupilumab and mepolizumab, respectively targeting IgE, IL 4/-13 receptor and IL 5, have been marketed for nasal polyps' indication [7].

Recently, the WAYPOINT phase 3 clinical trial, enrolling adult patients with severe, uncontrolled CRSwNP, explored the efficacy and safety of tezepelumab, an anti-TSLP monoclonal antibody already approved and marketed for severe uncontrolled asthma [8]. The active arm resulted in significantly greater benefit in terms of nasal polyp size, nasal congestion severity, sinonasal symptoms, as well as a reduced need for nasal-polyp surgery and systemic glucocorticoid use, compared to placebo.

The use of tezepelumab as a treatment option for CRSwNP has not yet been licensed so far; consequently, real-life data related to that indication are scarce.

Our study aimed to explore in a real-life setting the trend of CRSwNP outcomes in patients prescribed with tezepelumab for severe asthma and the impact of upper airways comorbidity on asthma outcomes by comparing the same population and a subgroup of asthma patients without CRSwNP.

Materials and methods

Study population and design

We conducted a real-life multicentre observational retrospective study including 5 Italian referral centres for severe asthma. Consenting severe asthma patients consecutively referring to the participating centres and prescribed with tezepelumab for severe asthma between March and November 2024 were enrolled. Severe asthma diagnosis followed the GINA recommendations definition [9], and eligibility to tezepelumab treatment was evaluated according to the current regulatory criteria [10]. For CRSwNP diagnosis, the European Position Paper on Rhinosinusitis and Nasal Polyps 2020 was considered as the reference [11].

Outcome measures

CRSwNP and asthma were assessed at baseline and 3 and 6 months after tezepelumab initiation. Objective evaluations as well as patient reported outcomes were selected as detailed below.

Nasal outcomes

Nasal evaluation included nasal polyp score (NPS) [12], SNOT22 [13,14], and visual analogue scale (VAS) [15] for olfactory dysfunction. NPS is an endoscopic scoring system based on a 0-4 points range per nostril according to the polyp's size. SNOT 22 comprises 22 customised questions for the patients exploring the severity of symptoms and their impact on Quality of Life in patients with nasal polyps. The validated Italian version of SNOT-22 was administered [14]. When analysing the results, a specific focus was deserved to the first 12 items, investigating the physical symptoms of CRSwNP. VAS is another patient reported outcome measure which assesses the entity of specific symptoms on a scale from 0 to 10. The loss of smell was evaluated through VAS.

Asthma outcomes

Asthma assessment relied on clinical, functional and inflammatory variables including number of exacerbations, number of hospitalizations due to asthma relapse, use and dose of oral steroids, asthma control test (ACT) [16], pre- and post-bronchodilator (BD) forced expiratory volume in 1 second (FEV1) and blood eosinophil count (BEC). ACT is a patient reported outcome measure including 5 questions assessing asthma symptoms severity and their impact on daily life.

The variation of asthma related variables over the treatment course were comparatively analysed in patients with and without CRSwNP.

Statistical analysis

Baseline characteristics of included patients were described using percentages and frequency rates for categorical variables and medians with interquartile range for continuous ones. Differences in those characteristics at baseline were assessed through chi-squared and Fisher's exact test or Mann–Whitney U non-parametric test, as appropriate.

Linear mixed-effects model (LMER) for longitudinal data with individual by centre as nested random effect was used to estimate the evolution of sino-nasal outcome measurements (SNOT-22, VAS, NPS) over time (baseline, three and six months) adjusted by sex, biologic therapy switch, disease duration and body mass index. The same model was used adding an interaction term between time and CRSwNP (yes/no) to explore differences in response to therapy considering spirometry outcomes (Fev1%, FVC%) and clinical respiratory outcomes (ACT, OCS dosage, eo-

Table 1. Sociodemographic and clinical characteristics of the study population by Chronic Rhinosinusitis with Nasal Polyps (CRSwNP).

	Overall (n=113)	No-CRSwNP (n=81)	CRSwNP (n=32)	p-Value
Sex				
female	75 (66,4%)	54 (66,7%)	21 (65,6%)	0.998
male	38 (33,6%)	27 (33,3%)	11 (34,4%)	
Age (years)	56.5	55.7	56.9	0.691
Median (IQR)	(48.9-64.2)	(47.9-64.1)	(51.0-64.8)	
Body mass index (kg/m²)	27	27	28	
Median (IQR)	(24-31)	(24-32)	(24-31)	0.565
Smoking				
Ex	9 (8,0%)	9 (11,1%)	0 (0,0%)	**0.018**
No	86 (76,1%)	56 (69,1%)	30 (93,8%)	
Yes	18 (15,9%)	16 (19,8%)	2 (6,3%)	
Allergic rhinitis				
No	55 (48,7%)	44 (54,3%)	11 (34,4%)	0.089
Yes	58 (51,3%)	37 (45,7%)	21 (65,6%)	
Dermatitis				
No	108 (95,6%)	76 (93,8%)	32 (100,0%)	0.352
Yes	5 (4,4%)	5 (6,2%)	(0,0%)	
ASA hypersensitivity				
No	91 (80,5%)	72 (88,9%)	19 (59,4%)	**<0.001**
Yes	22 (19,5%)	9 (11,1%)	13 (40,6%)	
Urticaria				
No	111 (98,2%)	79 (97,5%)	32 (100,0%)	0.916
Yes	2 (1,8%)	2 (2,5%)	0 (0,0%)	
Gastroesophageal reflux disease				
No	69 (61,1%)	47 (58,0%)	22 (68,8%)	0.401
Yes	44 (38,9%)	34 (42,0%)	10 (31,3%)	
Bronchiectasis				
No	96 (85,0%)	72 (88,9%)	24 (75,0%)	0.117
Yes	17 (15,0%)	9 (11,1%)	8 (25,0%)	
Switch				
No	48 (42,5%)	38 (46,9%)	10 (31,3%)	0.191
Yes	65 (57,5%)	43 (53,1%)	22 (68,8%)	
Disease duration (years)	23.6	23.1	25.8	0.224
Median (IQR)	(14.3-34.5)	(13.3-34.3)	(19.2-34.3)	

Rhinitis was diagnosed according to ARIA (Allergic Rhinitis and its Impact on Asthma) guidelines (Bousquet et al, J Allergy Clin Immunol. 2020;145(1):70-80.e3.)

sinophilic count, hospitalizations, relapses). Results of the adjusted model were presented as predictions with 95% confidential interval (95%CI). All analyses were performed with the software R v4.3. A p-value <0.05 was considered significant.

Results

Sample characteristics

Overall, 113 patients were enrolled. Table 1 summarizes the main characteristics of the study population, by concomitant CRSwNP, detected in 28.3%. Most of the subjects were female (n=75, 66.4%), and the median age was 56 years (IQR 48.9-64.2). Respiratory and extra-respiratory comorbidities were equally distributed among the two subgroups, excluding ASA hypersensitivity whose frequency was higher in CRSwNP patients.
In terms of biologic treatment prior to tezepelumab, 65 subjects (57.5%) were switching from another compound, with no difference according to the coexisting CRSwNP.
The baseline assessment related to upper airways impairment is described in Table S1. Comparable lung function parameters in asthma patients with and without nasal polyps were observed, whilst higher blood eosinophils were detected in CRSwNP patients, who however experienced less asthma exacerbations prior to tezepelumab initiation, compared to subjects with asthma only.

CRSwNP outcomes

Both total score of SNOT22 and the first-12 items score showed a statistically significant decrease from baseline to the last considered follow-up 6 months after starting tezepelumab, from 37.0 (95%CI 30.5-43.4) to 19.5 (95%CI 11.8-27.4, p<0.001) and from

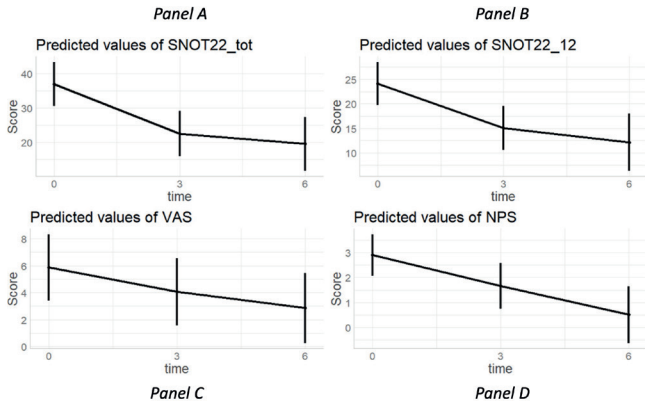

Figure 1. Trends of sino-nasal outcomes over tezepelumab treatment course. SNOT= Sinonasal Outcome Test; VAS= Visual Analogic Scale; NPS= Nasal Polyp Score. 3 and 6 refer to the three- and six-months follow-ups.

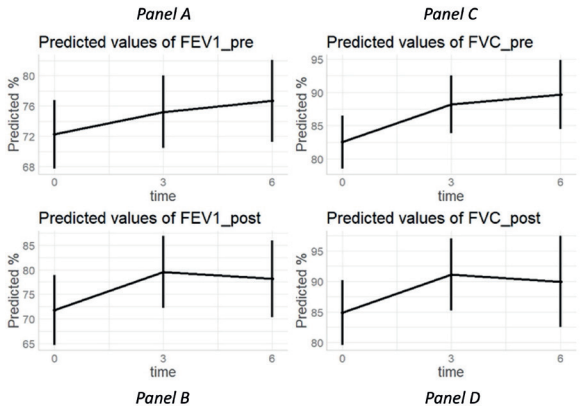

Figure 2. Overall trends of lung function parameters over tezepelumab treatment course. Pre and post refer to bronchodilation test. 3 and 6 refer to the three- and six-months follow-ups.

24.1 (95%CI 19.7-28.5) to 12.2 (95%CI 6.3-17.0, p<0.001, Figure 1, Panel A and B), respectively. Similarly, VAS and NPS scores decreased over time from 5.9 (95%CI 3.4-8.3) and 2.9 (95%CI 2.13.7) at baseline to 2.9 (95%CI 0.3-5.5, p<0.001) and 0.5 (95%CI 0.0-1.6, p<0.001) respectively after 6 months of treatment (Figure 1, Panel C and D)

Overall asthma outcomes

Figure 2 summarizes the lung function assessment over the treatment course. Both pre and post bronchodilatation FEV1 % of predicted increased from 72.2 [95%CI 67.7-76.8] and 71.8 [95%CI 64.7-78.9] respectively at baseline to 75.2 [95%CI 70.4-80.0, p=0.075] and 79.5 [95%CI 72.2-86.8, p<0.001] at 3 moths and to 76.7 [95%CI 71.2-82.1, p=0.038] and 78.1 [95%CI 70.3-85.9, p=0.003] after 6 months (Figure 2, Panel A and B). Both pre and post bronchodilatation FVC % of predicted increased from 82.5 [95%CI 78.5-86.5] and 84.9 [95%CI 79.6-90.2] at baseline to 88.2 [95%CI 83.8-92.5, p=0.003] and 91.1 [95%CI 85.2-97.0, p=0.005] at 3 months, and to 89.7 [95%CI 84.5-94.8, p=0.003] and 88.0 [95%CI 82.5-97.4, p=0.114] after 6 months (Figure 2, Panel C and D). When considering patients reported outcomes, ACT scores increased from 14.7 (95%CI 11.7-17.8) at baseline to 21.9 (95%CI 18.7-25.2, p<0.001) and 21.2 (95%CI 16.1-24.3, p=0.062) after 3 and 6 months of biological therapy, respectively (Figure 3, Panel A). Figure 3, Panel B also describes OCS daily dose decrease, from 5.9 mg (95%CI 3.1-8.6) to 2.3 (95%CI -0.5-5.1, p=0.002) and 1.8 (95%CI -1.3-4.8, p=0.001) at the 3rd and 6th month. Eosinophilic count trajectory (Figure 3 Panel C) showed a decreasing trend without achieving statistical significance 3 (p=0.276) and 6 months (p=0.413) after the treatment initiation. Both hospitalizations and asthma relapses declined significantly after 3 (p<0.001, p<0.001) and 6 (p=0.004, p<0.001) months (Figure 3, Panel D and E).

Asthma outcomes in patients with vs without CRSwNP

When comparing asthma outcomes in terms of functional, clinical and inflammatory parameters in patients with and without CRSwNP, the overall variation of each considered parameter over the treatment course did not show any significant difference (Figure 4 and 5). More in detail, variation of pre and post bronchodilatation FEV1 % of predicted was comparable in the two subgroups at any timepoint (t3: p=0.095, t6p=0.193 and t3: p=0.222, t6: p=0.153, respectively) (Figure 4, Panel A and B). No differences were found in both FVC pre (t3: p=168, t6: p=0.339) and post (t3: p=0.718, t6: p=0.388) trends based on CRSwNP coexistence (Figure 4, Panel C and D). A similar ACT improvement was also observed regardless the upper airways comorbidity (t3: p=0.627, t6: p=0.968) (Figure 5, Panel A), as well as a comparable steroid sparing effect when considering the OCS daily use in both subgroups (t3: p=0.418, t6: p=0.205) (Figure 5, Panel B).

Blood eosinophil count variation did not significantly differ regardless of the presence of upper airways comorbidity, with CRSwNP patients having over time significantly higher eosinophils (p=0.012) (Figure 5, Panel C).

Of note, patients with CRSwNP showed lower value over time of both hospitalization (p=0.018) and relapses (p<0.001). Those without CRSwNP had a higher decline in number of relapses (from 4.0, 95%CI 3.7-4.3 at t0 to 0.2, 95%CI -0.1-0.6 at t3) after three months of therapy compared to those without (from 2.7, 95%CI 2.2-3.2 at t0 to 0.1, 95%CI -0.4-0.7 at t3 p=0.007) (Figure 5, Panel D and E).

Discussion

Our findings demonstrated a rapid and significant improvement in sinonasal outcomes under tezepelumab therapy in severe asthma patients with concomitant CRSwNP. In addition, a com-

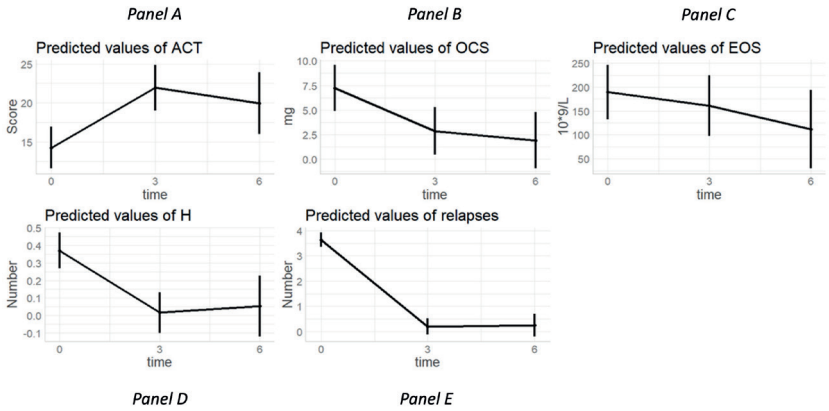

Figure 3. Overall trends of patient reported outcomes and clinical parameters over tezepelumab treatment course. EOS= blood eosinophils; H= number of hospital admissions due to asthma worsening; OCS=oral corticosteroids (expressed as mg/die). 3 and 6 refer to the three- and six-months follow-ups.

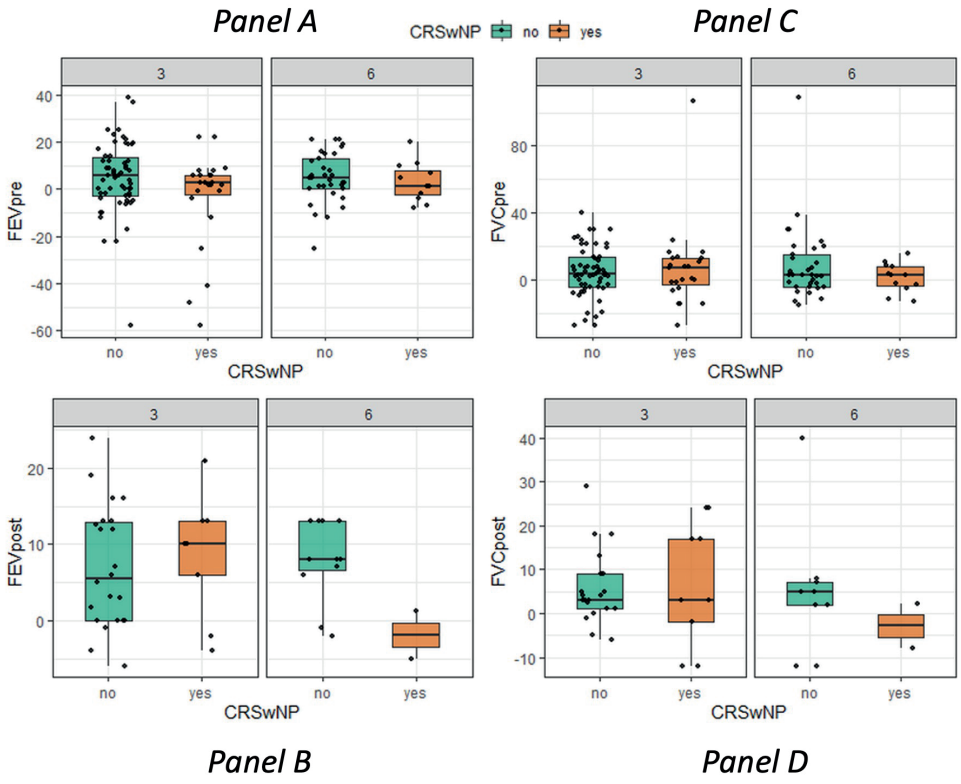

Figure 4. Comparative analysis of lung function assessment in patients with and without chronic rhinosinusitis with nasal polyps (CRSwNP) at each follow-up time point. Pre and post refer to bronchodilation test. 3 and 6 refer to the three- and six-months follow-ups.

parable treatment response in terms of functional, clinical and inflammatory outcomes related to asthma could be described in patients with and without upper airways involvement. The impact of tezepelumab on nasal polyps has been recently explored within the randomized clinical trials setting. A post hoc analysis of NAVIGATOR [17] reported a significant reduction of SNOT-22 total score already after 28 weeks from the treatment start, in patients with a concomitant history of nasal polyps. A more detailed analysis of NAVIGATOR data was recently published on 165 asthma patients with coexisting CRSwNP and documented a sustained improvement in treated subjects in terms of SNOT-22 total score throughout the 52-week study period when compared to placebo [18]. Of note, active treatment impacted on all five SNOT-22 domain scores (sleep, nasal, function, ear/facial, and emotion) and on the five SNOT-22 item scores which are considered more clinically relevant, including smell/taste, nasal blockage, reduced productivity, waking up tired, and cough. More recently, the results of WAYPOINT trial, specifically desig-

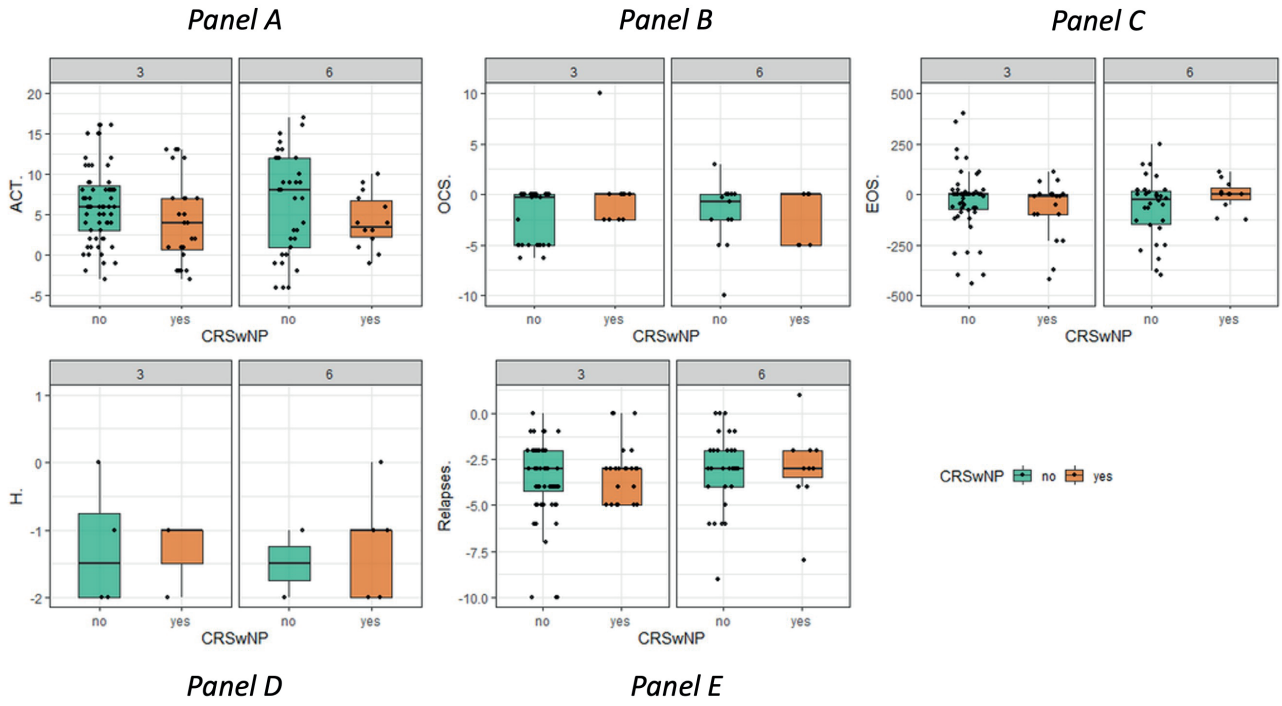

Figure 5. Comparative analysis of patient reported outcomes and clinical parameters in patients with and without chronic rhinosinusitis with nasal polyps (CRSwNP) at each follow-up time point. EOS= blood eosinophils; H= number of hospital admissions due to asthma worsening; OCS=oral corticosteroids (expressed as mg/die). 3 and 6 refer to the three- and six-months follow-ups.

ned to explore the effect of tezepelumab on CRSwNP, confirmed a significant reduction of nasal polyps' size, nasal congestion and sinonasal symptoms severity, and decrease nasal-polyp surgery rate and systemic glucocorticoids use in treated patients versus placebo [8].

Tezepelumab is currently licensed as a treatment option for severe uncontrolled asthma [10] but not yet for CRSwNP patients, and the real-life data on that population are limited to case series. The real-world evidence related to tezepelumab in severe asthma is increasingly growing but still not including patients concomitantly suffering from CRSwNP or not specifically focusing on upper airways involvement [19-23]. Our study firstly provides a specific focus on the upper-airways disease response to tezepelumab from a larger population in the real-life setting. Both patients reported outcomes and objective evaluations related to CRSwNP were investigated in subjects prescribed with tezepelumab for severe asthma. We observed a rapid and sustained reduction in both the total and first-12 item scores of the SNOT22 questionnaire. In addition, similar trends could be described when looking at VAS and NPS scores, the last parameter supporting with an objective evaluation the patients reported outcomes trend. Interestingly, no significant differences were observed in any of the SNOT22, VAS, or NPS scores when stratifying by sex, treatment switch or BMI, supporting the relevance of tezepelumab in effectively targeting both upper and lower airways impairment across various patient subgroups and regardless potentially relevant patient characteristics.

The effect of blocking TSLP-related cascade in severe asthma patients is robustly sustained by randomized clinical trials and an increasing amount of real-world evidence [19-24]. It is also well known that when CRSwNP coexists with asthma the overall burden is more impactful in terms of disease control and evolution [3]. Whether the presence of upper airways involvement does condition the response to biologic in asthma patients has been poorly and indirectly investigated so far. Some data come from a post-hoc analysis of the NAVIGATOR trial describing comparable results in terms of asthma exacerbations, lung function, patients reported outcomes and inflammation biomarkers regardless of the medical history of nasal polyps [17,18]. In our real-life investigation we addressed the issue by comparatively exploring the overall variation of asthma outcomes during the study time frame in patients with and without CRSwNP. According to our findings, no significant differences between the two subgroups could be detected in terms of functional, clinical and inflammatory outcomes, suggesting that upper airways impairment is not a "contraindication" for the use of tezepelumab in asthma comorbid asthma patients and can be considered a primary target of the drug. Of note, the higher baseline blood eosinophil count observed in CRSwNP patients did not seem to exert any impact on the asthma outcome trajectories over the treatment course. This finding does not fully align with NAVIGATOR results, demonstrating an even better response in asthma patients

with higher blood eosinophils at baseline [17]. However, the poor relevance of blood eosinophilia as a predictor of better response to tezepelumab has been previously highlighted. In fact, a recently published post-hoc analysis of tezepelumab asthma trials demonstrated a relevant decrease of asthma exacerbations co-occurring with respiratory infections regardless of the baseline eosinophilia [25]. Similar findings were described when focusing on asthma patients with fungal sensitizations [26], suggesting that in specific populations, including CRSwNP patients, tezepelumab efficacy is independent of circulating eosinophils before the treatment initiation. Which is not irrelevant in the biologic selection process according to a precision medicine approach. The retrospective design, and the relatively small study population size should be acknowledged when considering the strength of our data. In particular, the CRSwNP patient's subgroup does not match the asthma only one in terms of numerosity, which might hamper the comparative analysis. In addition, the follow-up duration is relatively short, which represents of course a limitation but at the same time highlights the rapid onset of treatment response at both upper and lower airways level. However, to the best of our knowledge we conducted the first real-life study specifically designed for exploring the upper airways subjective and objective outcomes and the potential impact of nasal impairment on asthma-related treatment response.

Conclusion

Although our findings need to be confirmed in larger studies, they initially provide real word evidence supporting the positioning of tezepelumab according to a precision medicine approach.

Author contributions

AM and MC were involved in study conception or design. AM, RV, MM were involved in the acquisition of data. AM, MC, BR contributed to data analysis or interpretation. All authors were involved in drafting the work and/or revised it critically for important intellectual content.

Conflict of interest

All authors reported no financial interests or potential conflicts of interest related to this study.

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SUPPLEMENTARY MATERIAL

Table S1. Baseline values of the sinonasal, spirometry and clinical respiratory outcomes of the study population .
(CRSwNP= Chronic Rhinosinusitis with Nasal Polyps).

	Overall (n=113)	No CRSwNP	CRSwNP (n=32)	p-Value
SNOT-22				
Median (IQR)			43 (36-58)	
VAS				
Median (IQR)			8 (6-8)	
NPS				
Median (IQR)			3 (3-6)	
FEV1% pre				0.668
Median (IQR)	74 (56-86)	73 (52-86)	76 (56-94)	
FEV1% post				0.157
Median (IQR)	78 (53-89)	74 (49-87)	82 (67-89)	
FVC pre				0.513
Median (IQR)	82 (72-93)	82 (72-90)	82 (72-98)	
FVC post				0.010
Median (IQR)	86 (75-95)	83 (65-90)	92 (82-99)	
ACT				0.074
Median (IQR)	14 (11-18)	14 (10-18)	15 (12-20)	
OCS dosage				0.572
Median (IQR)	5.0 (0.0-6.3)	5.0 (0.0-11.9)	3.8 (0.0-5.0)	
Eosinophilic count				0.002
Median (IQR)	130 (10-280)	100 (0.3-213)	280 (105-410)	
Hospitalizations				0.023
Median (IQR)	0 (0-0)	0 (0-1)	0 (0-0)	
Relapses				0.005
Median (IQR)	3 (3-5)	4 (3-5)	3 (2-3)	