Prevalence of ear complaints in patients with severe chronic rhinosinusitis with nasal polyps*

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Dear Editor:

Patients with chronic rhinosinusitis (CRS) commonly have ear complaints (ECs) [1]. Reported prevalences in CRS-patients vary up to 61% [2, 3], and even higher (82%) in patients with nasal polyps (CRSwNP) with an indication for surgery [4]. These data, however, are not based on validated otologic surveys. Instead, the ear-related questions of the SinoNasal Outcome Test 22-items (SNOT-22) [5] are used. ECs are often overlooked as CRSwNP patients present primarily with nasal complaints, despite the impact on quality of life of this co-morbidity [2, 4]. With the advent of biological therapy for severe uncontrolled CRSwNP, comorbidities are increasingly appreciated including the rare but debilitating eosinophilic otitis media (EOM) [6].
This study investigates ECs, evaluated by otologic questionnaires, in a severe uncontrolled CRSwNP population. It also investigates the use of single SNOT-22 ear items as proxy for relevant ECs.

We determined the prevalence of ECs in a severe uncontrolled primary diffuse type 2 CRSwNP cohort of 368 patients with an indication for dupilumab therapy (12% with EOM [9]; Table S1). Patients filled in the following questionnaires: Dutch version of the Chronic Ear Survey (DCES; scoring range 13-71, higher scores indicate better functional health) [7], Otology Questionnaire Amsterdam (OQUA; scoring range 0-100 per domain, no total score) [8] and the SNOT-22 (scoring range 0-110). Cohort medians [interquartile range (IQR)] were 66 [62-69] for the DCES, 53 [41.25-64] for the SNOT-22 and OQUA domain medians ranged from 0-66.8. More information, such as baseline characteristics, ethics statement and data collection, can be found in the Supplementary Material.

Using the SNOT-22, we found that 78.5% had any degree of ear fullness, 59.6% had any degree of dizziness and 51.5% any degree of otalgia (Table S2). As such, total SNOT-22 ear domain scores of the overall cohort were 4 [2-7].
The severity of the single SNOT-22 ear items correlated well with the corresponding OQUA_VAS (VAS cut-off: 5; Figure S1). Through ROC analysis, cut-offs were defined to indicate relevant complaints (Figure S2; Table S3) and were ear fullness ≥3; ear pain ≥2; dizziness ≥3. Relevant ECs had a large overlap, with ear fullness being the most prevalent one (in 43.7% of the cases; Figure 1).
There was a moderate-strong correlation (Spearman's rho 0.67) between the degree of ear fullness from the SNOT-22 and the DCES scores. Patients with ear fullness above threshold consequently had significantly diminished DCES scores compared to those not reaching the threshold (respectively 62 [IQR 53-66] vs 68 [IQR 66-69], $p<0.001$; Table S1).
Of the EOM-patients, 95.3% had any degree of ear fullness, and 79% had ear fullness above threshold (Table S2). The median DCES of the EOM patients was significantly worse than in non-EOM (53 vs. 67, $p<0.001$). EOM was present in 23% of the patients with ear fullness above threshold (Table S1). Nevertheless, in patients without EOM, still 38.1% had relevant ECs based on the ear fullness (Table S2).

Limitations of this study are the following: Validation of the SNOT-22 ear fullness item as a screening tool in CRSwNP should ideally be tested in a larger cohort. The cut-offs are exploratory and internally derived. Also, otologic questionnaires are not commonly used in rhinology, their interpretation is limited due to missing validated cut-offs/MCIDs, and the OQUA [8] is officially meant for pre-/post-treatment evaluation instead of our cross-sectional approach. Selection bias is introduced as biological patients generally suffer from difficult-to-treat-CRSwNP. Finally, this is a descriptive study without data on otologic examination, underlying cause or therapeutic suggestions for the ECs.

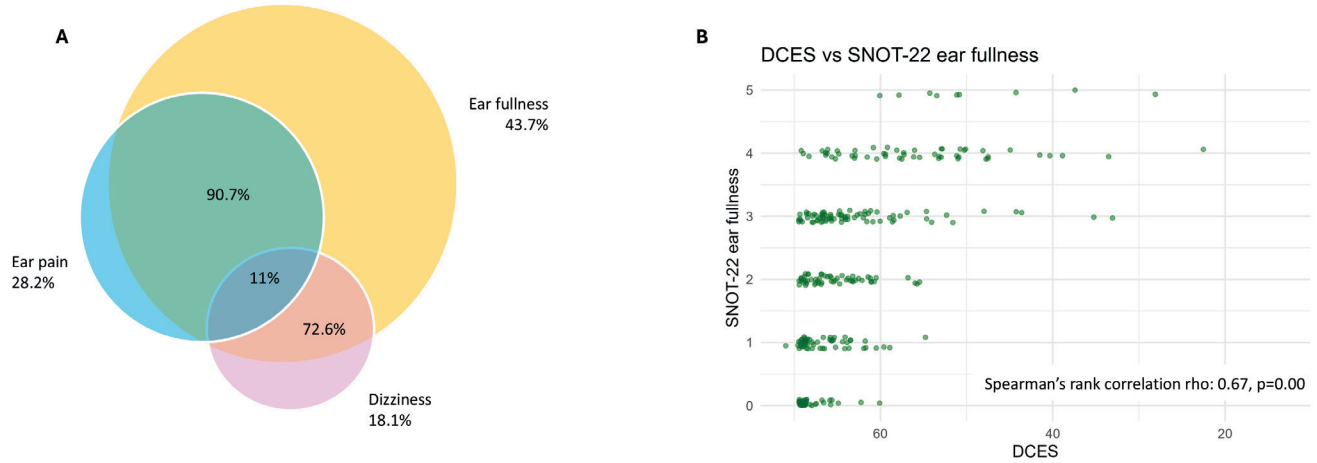

Figure 1. (A) Prevalence of ear complaints according to the SNOT-22 ear items and cut-offs (n=368) including overlap between complaints. (B) Scatter plot of SNOT-22 ear fullness vs. the DCES scores including correlation coefficients. NB: the x-axis is reversed as high DCES scores indicate good functional health.

Conclusion

Ear complaints in severe uncontrolled CRSwNP are prevalent. We propose the SNOT-22 ear fullness item as screening tool for ear complaints, to be validated in other studies.

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Abbreviations

CRSwNP: Chronic rhinosinusitis with nasal polyps; SNOT-22: SinoNasal Outcome Test 22-items; OQUA: Otology Questionnaire Amsterdam; DCES: Dutch version of the Chronic Ear Survey; EOM: Eosinophilic Otitis Media; VAS: Visual Analogue Scale.

Authorship contribution

WF and SR: conceptualization, methodology, resources, supervision, and writing—review and editing. HE: original draft, data curation, formal analysis, and visualization. All other authors: review and editing.

Conflict of interest

WF is an advisory board member of Sanofi, GSK, and Dianosic. SR has acted as a consultant and/or advisory board member for Sanofi, GSK, and Novartis. MC has acted as a consultant and/or advisory board member for Sanofi, GSK, ALK, Mylan, and Medtronic. AR has acted as a consultant and/or advisory board member for Sanofi. JJO The department of Otorhinolaryngology and Head/Neck Surgery of the Amsterdam UMC has received research funding from Sanofi, GSK, and Novartis. HE, IJK, IK, GA, LB, RS and RH have no conflict of interest to declare.

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Collaborators

*PolyREG Consortium: the members of the PolyREG Consortium have enrolled patients to the study through the Nasal Polyp Register (PolyREG) database: a national, Dutch, real-time cohort database for CRSwNP patients treated with biologics. Demographics and specific clinical parameters are collected at baseline and follow-up visits in the participating medical centers. This cohort is still expanding with participating centers throughout The Netherlands. The members and centers currently include: R.W.H. Smits (Maasstad hospital), F.C.A. Timmer (Amphia hospital), M. E. Cornet (Alrijne hospital), A.B. Rinia (Isala hospital), I.J. Kleiss (Rijnstate hospital), I. Krebbers (Maastricht University Medical Center), G.F.J.P.M. Adriaensen (Amsterdam UMC), L.B.L Benoist (Amsterdam UMC), D.R. Hoven (Amsterdam UMC), S. Reitsma (Amsterdam UMC), W.J. Fokkens (Amsterdam UMC).

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This manuscript contains online supplementary material

SUPPLEMENTARY MATERIAL

Materials and Methods

Ethics statement

Assessment of the institutional Medical Ethical Review Committee of the PolyREG registry deemed it not to be subject to the Dutch Medical Research Involving Human Subjects Act (MREC ID: W21_030#21.034). Informed consent was obtained from all patients.

Patients and data collection

The PolyREG is a real-world, prospective cohort and consists of patients aged ≥18 years old with severe CRSwNP with an indication for biological therapy, initiated on December 3rd 2019 [1-5]. Demographic data, clinical data related to CRSwNP and data on otologic symptoms were collected. Additional use of nasal medication was not collected in the PolyREG database.

CRSwNP-related data

Sniffin' Sticks Identification Test (12 pens; SSIT-12) [6], total endoscopic Nasal Polyp Score (NPS; total score 0-8, higher= worse), disease-specific quality of life 22-item Sinonasal Outcome Test (SNOT-22; total range 0-110 and item-range 0-5, higher=worse) [7], Asthma Control Test (ACT; range 5-25; >19 indicates well controlled asthma) [8, 9].

Otologic evaluation

Validated questionnaires in the Netherlands to evaluate chronic ear symptoms: the Dutch Chronic Ear Survey (DCES) [10] and the Otology Questionnaire Amsterdam (OQUA) [11].

- DCES [10]: standardized and validated questionnaire for chronic ear symptoms containing 13 items. Total scores range is 13-71; higher scores indicate better disease control. No MCID is available.
- OQUA [11]: standardized and validated questionnaire for a complete impression of severity and impact of ear symptoms. Contains 34 items divided over 9 domains. Does not accommodate sum (total) scores; the domain scores should officially be interpreted before/after treatment and between symptoms. For calculations of each domain score, we refer to Kraak et al. [11] with the correction that the impact score is 0-4 instead of 1-5 (so de denominator is 36 instead of 45 to get a total score between 0-100), and question 10-14 are scored 5->1 instead of 1->5.

The SNOT-22 also addresses three otologic symptoms (ear fullness, ear pain and dizziness), but has not been validated to analyze and interpret these individual item scores. Therefore, we correlate them to a validated measure: the corresponding symptom-specific VAS score derived from the OQUA.
No evaluation of otoscopy, audiometry or tympanometry was performed.

Statistical analysis

Mean values with standard deviation (SD) were calculated for normally distributed data. Medians and interquartile ranges (IQR) were calculated for non-normally distributed data. Percentages were calculated for categorical data.
The association between single SNOT-22 ear item scores and the corresponding OQUA-VAS was visualized with scatter plots and the Spearman's correlation coefficient rho was calculated. OQUA_VAS cut-off values were set at 5 [12, 13]. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated. We also performed a Receiver Operating Characteristic (ROC) curve analysis and calculated the Area Under the Curve (AUC) and Youden index. We chose the optimal SNOT-22 ear item scores based on these analyses. Statistical significance was assumed for p-values ≤0.05. SPSS Statistics version 28 and R version 4.3.2 were used.

Results

Table S1. Baseline characteristics and measurements of biological-naive CRSwNP-patients eligible for dupilumab.

Baseline characteristics	Entire cohort (n=368)	With ear complaints (SNOT-22 ear fullness ≥3)	Without ear complaints (SNOT-22 ear fullness <3)	p-value Patients with vs. without ear complaints
Mean age (years)	51.5 ± 13.4	50.4 ± 13	52 ± 13.4	0.30#
Sex (female)	38.7%	44.5%	34.4%	0.17^
Disease duration (years)	12 [7-20]	12 [7-20]	12 [7-20]	0.61
No. of ESS	2 [2-4]	2 [2-4]	2 [1-4]	0.30
EOM	12%	23%	4.6%	<0.001^
Asthma	74.6%	79.6%	71.7%	0.17^
N-ERD	25.6%	32.1%	22.9%	0.02^
Allergic rhinitis	49.2%	50.7%	49.5%	0.59^
Median blood IgE (x10^9/L)	119 [49.3-251]	119.5 [44.9-251.5]	121 [51.2-258.5]	0.82
Median blood eosinophils (x10^9/L)	0.46 [0.31-0.68]	0.49 [0.33-0.72]	0.43 [0.31-0.65]	0.25
SSIT-12	3 [3-5]	3 [3-5]	3 [3-5]	0.21
Bilateral NPS	6 [5-6]	6 [4-6]	6 [5-6]	0.59
ACT (only asthma patients)	18 [14-21]	17 [13.25-20]	19 [15-21]	0.48
SNOT-22 [0-110]	53 [41.25-64]	62 [52-73]	46 [34-57.25]	<0.001
SNOT-22 ear domain [0-15]	4 [2-7]	7 [5-9]	2 [0-3]	<0.001
DCES [13-71]	66 [62-69]	62 [53-66]	68 [66-69]	<0.001
With EOM Without EOM	53 [41-61] } 0,001 67 [63-69]	48 [39-54] 64 [59-67]	65.5 [62.25-68] 68 [66-69]	
OQUA [0-100 per domain]				
Domain 'ache'	1.4 [0-10.2]	9.6 [2-30.8]	0.2 [0-2.2]	<0.001
Domain 'pressure'	6.9 [0.2-22.6]	26.8 [10.5-48.7]	0.7 [0-6.6]	<0.001
Domain 'itching'	4 [0.2-20.25]	18.6 [3.4-39.9]	0.9 [0-8.8]	<0.001
Domain 'tinnitus'	4.8 [0-39.8]	24.6 [1.8-71.6]	1.9 [0-12]	<0.001
Domain 'hearing loss'	2.7 [0-17.2]	15.5 [2.4-38.3]	0.2 [0-0.4]	<0.001
Domain 'discharge'	0 [0-1]	0.4 [0-3.2]	0 [0-0.4]	<0.001
Domain 'loss of taste'	66.8 [17.6-90.8]	73.6 [31.3-100]	62.4 [12-89.3]	0.02
Domain 'dizziness'	3.1 [0-12]	6 [0.5-20.1]	2.3 [0-8.1]	0.001
Domain 'impact'	5.6 [0-19.4]	19.4 [11-43.1]	0 [0-8.3]	<0.001

Data presented as mean ± standard deviation, median [interquartile range] or frequency (%). P-values are calculated with the Mann-Whitney U test, except for: # Independent t-test; ^ Chi^2 test. SNOT-22: 22-item SinoNasal Outcome Test; NPS: nasal polyp score; SSIT-12: Sniffin' Sticks Identification Test 12 pens; ACT: Asthma Control Test; N-ERD: non-steroidal anti-inflammatory drugs-exacerbated respiratory disease; IgE: immunoglobulin E; ESS: endoscopic sinus surgery; EOM: eosinophilic otitis media; DCES: Dutch Chronic Ear Survey; OQUA: Otology Questionnaire Amsterdam.

Table S2. frequencies of scores of single SNOT-22 ear items in CRSwNP study cohort (n=344).

	Ear fullness			Dizziness			Ear pain		
Item score	% of total	% of EOM cohort	% of non-EOM cohort	% of total	% of EOM cohort	% of non-EOM cohort	% of total	% of EOM cohort	% of non-EOM cohort
0	21.5	4.7	24.1	40.4	37.2	41.1	48.5	14	53.8
>0	78.5	95.3	75.9	59.6	62.8	58.9	51.5	86	46.2
0	21.5	4.7	24.1	40.4	37.2	41.1	48.5	14	53.8
1	18.3	7	20.1	23.3	23.3	22.7	23.3	23.3	23.4
2	16.6	9.3	17.7	18.3	16.3	18.7	11.9	11.6	11.7
3	22.1	11.6	23.4	13.4	20.9	12.4	11.6	25.6	9.4
4	17.2	46.5	12.7	4.7	2.3	5	4.7	25.6	1.7
5	4.4	20.9	2	-	-	-	-	-	-

SNOT-22: 22-item SinoNasal Outcome Test; CRSwNP: chronic rhinosinusitis with nasal polyps; EOM: eosinophilic otitis media [14].

Table S3. Cut-off analysis for single SNOT-22 ear items (n=330).

Ear fullness	Ear pain	Dizziness
Optimal cut-off: 2.5 --> 3 (Youden-index: 0.60) Sens: 0.90 Spec: 0.70 PPV: 0.48 NPV: 0.96	Optimal cut-off: 1.5 --> 2 (Youden-index: 0.74) Sens: 0.90 Spec: 0.84 PPV: 0.44 NPV: 0.98	Optimal cut-off: 2.5 --> 3 (Youden-index: 0.65) Sens: 0.76 Spec: 0.89 PPV: 0.44 NPV: 0.97
Cut-off 2 (closest 1.50) Sens: 1.00 Spec: 0.52 PPV: 0.39 NPV: 1.00	Cut-off 3 (closest 2.50) Sens: 0.76 Spec: 0.94 PPV: 0.65 NPV: 0.96	Cut-off 2 (closest 1.50) Sens: 0.85 Spec: 0.70 PPV: 0.25 NPV: 0.98
Cut-off 4 (closest 3.50) Sens: 0.61 Spec: 0.91 PPV: 0.68 NPV: 0.89	Cut-off 4 (closest 3.50) Sens: 0.29 Spec: 0.99 PPV: 0.86 NPV: 0.91	Cut-off 4 (closest 3.50) Sens: 0.32 Spec: 0.99 PPV: 0.73 NPV: 0.93

SNOT-22: 22-item SinoNasal Outcome Test; Sens: sensitivity; Spec: specificity; PPV: positive predictive value; NPV: negative predictive value.

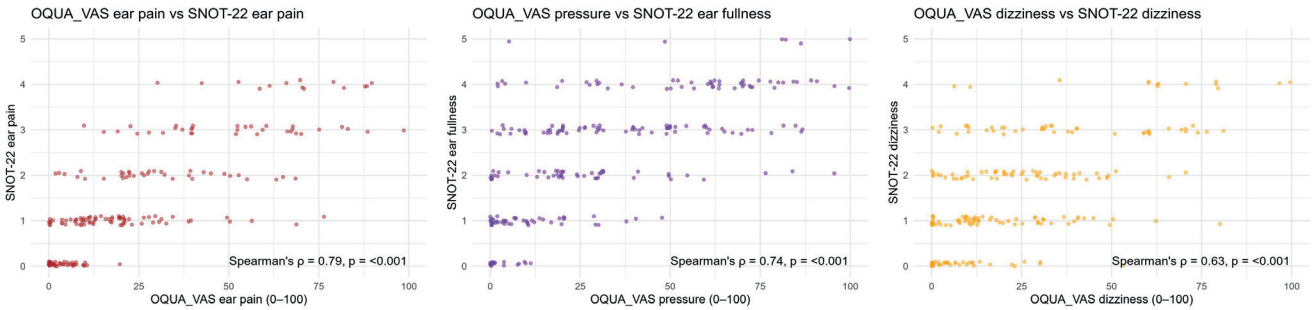

Figure S1. Scatter plots of OQUA_VAS scores vs. single SNOT-22 ear items. OQUA: Otologic Questionnaire Amsterdam; SNOT-22: 22-item SinoNasal Outcome Test; VAS: visual analogue scale.

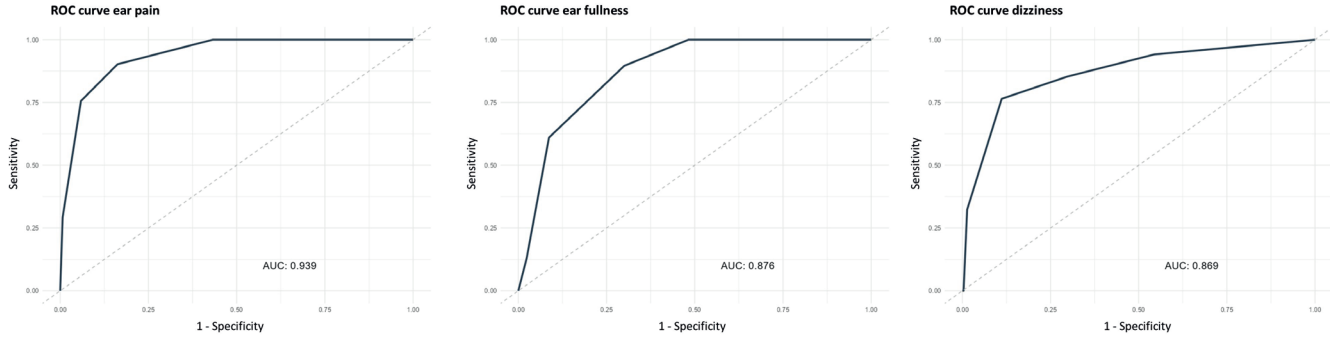

Figure S2. ROC curves including AUC of single SNOT-22 ear items. ROC: Receiver Operating Characteristic; AUC: Area Under the Curve.

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