# Discrepancy between self-reported and actual topical steroid use in CRS-patients with nasal polyps\*

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### **Dear Editor:**

Topical corticosteroids are standard therapy in chronic rhinosinusitis with nasal polyps (CRSwNP) and asthma, administered as nasal corticosteroids (NCS) and inhaled corticosteroid (ICS). Suboptimal adherence is associated with impaired health-related quality of life (1).

In the era of biologic treatment where up to two-third of CRSwNP-patients have asthma, referred to as "global airway disease" (GAD) – adherence remains underexplored. Adherence has significant implications for clinical practice as most countries requires ongoing use of topical corticosteroids as a criterium for initiating biologic treatment.

Few studies have assessed adherence to NCS in CRS, with reported rates from 18 to 81%  $^{(2)}$ . Fewer have investigated adherence to dual local corticosteroid therapy.

We included 136 adults with CRSwNP: 33% (CRSwNP-only, 77% with GAD) prior to their screening for biologic treatment in a cross-sectional study (Figure S1 and Table 1). CRSwNP was diagnosed according to EPOS criteria, asthma was diagnosed by symptoms and a positive bronchial challenge.

The following data were collected:

- Two self-reported adherence-rates for nasal douching (ND), NCS and ICS (if prescribed)
  - o "How many days in the last seven days did you take your medication as prescribed?" divided by seven and expressed as percent (3).
  - o Medication Adherence Report Scale-5 (MARS-5 ) $^{(4)}$ , with a score  $\geq$ 20 =  $\geq$ 80% adherence and 25 = 100% adherence.
- Objectively assessed adherence to NCS and ICS was conducted at 6- and 12-months prior to each patients screening visit using a Medication Possession Ratio (MPR).
  Defined as the number of redeemed daily doses divided by

the number of prescribed daily doses <sup>(5)</sup>. Data was collected from the Common Medication Card and the National Prescription Registry <sup>(6)</sup>. Adherence rates equal  $\geq$  80% were defined as acceptable.

Patients with CRSwNP-only reported 93% self-reported adherence to NCS and 76% had a reported MARS-5-NCS score  $\geq$  20. Patients with GAD reported a significantly higher adherence: 100% self-reported NCS adherence and 97% had a MARS-5-NCS score  $\geq$  20. Self-reported adherence to ND was similar in both groups (71%) (Table 1).

In contrast, objective adherence data showed 17% of the CRSwNP-only patients had a MPR ≥80%, over 12-months. Patients with GAD had a significantly higher, though still low, acceptable adherence rate 36% (p=0.049) (Table 1 and Table S1). Objective adherence to ICS among GAD patients, was 49.3%, with only 21% achieving a 12-month MPR ≥80% (Table 1). A statistically significant correlation was found between self-reported and objective assessed adherence (p=0.006) however, no significant correlations were observed for MARS-5 scores, or self-reported ICS adherence MPR (Figure S2).

Multivariate logistic regression analyses showed adherence to NCS was significantly lower in CRSwNP-only patients compared to those with GAD (OR=0.30 (CI 95% 0.09–0.83 p=0.029) (Table S2). No statistically significant associations were found for age, sex, education level in relation to NCS adherence (Table S2). Our study is strengthened by the inclusion of a large consecutive cohort of patients with free access to the health-care-system and low cost of NCS due to reimbursement. All patients had relevant prescriptions by their referral from ENTs or pulmonologists. Of note, patients can buy NCS over the counter, which could bias adherence estimates. Discrepancies in adherence may therefore

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Table 1. Characteristics of patients with global airway disease or CRSwNP only referred to a tertiary clinic (N = 136).

	All	Global airway disease	CRSwNP only	P-value <sup>2</sup>				
	(N=136) <sup>1</sup>	(n=105) <sup>1</sup>	(n=31) <sup>1</sup>					
Female, n (%)	50 (37%)	42 (40%)	8 (26%)	0.15				
Age, years [range]	48 [38-57]	49 [41-57]	42 [31-57]	0.12				
Education level, n (%)								
Primary education	26 (19%)	22 (21%)	4 (13%)	0.7				
Vocational education	35 (26%)	25 (24%)	10 (32%)					
Bachelor's or higher	68 (50%)	52 (50%)	16 (52%)					
Unknown and others	7 (5.1%)	6 (5.7%)	<4					
Burden of symptom CRSwNP and asthma								
Duration of disease	21.3 [15.3-23.7]	21.6 [15.4-23.6]	20.6 [14.2-23.6]	0.6				
Number of previous FESS	2.00 [1.00-3.00]	2.00 [1.00-3.00]	2.00 [1.00-3.00]	0.7				
SNOT-22	63 [47-76]	63 [47-76]	62 [52-74]	>0.9				
VAS CRSwNP <sup>3</sup>	85 [71-98]	86 [70-97]	81 [75-97]	>0.9				
FEV1 (L)1 <sup>4</sup>	3.34 [2.71-4.34]	3.24 [2.5-4.24]	3.54 [3.01-4.51]	0.062				
FeNO⁵	26 [15-49]	27 [16-53]	23 [14-31]	0.2				
ACQ-5 <sup>6</sup>	1.80 [1.00-2.80]	2.0 [1.00-3.40]	N/A	N/A				
ACT <sup>7</sup>	19 [14-22]	18 [12-22]	N/A	N/A				
VAS asthma <sup>8</sup>	60 [50-77]	[50-76]	N/A	N/A				
	Self-rep	oorted adherence score						
Self-reported NCS adherence (%)	100 [86-100]	100 [91-100]	93 [4-100]	0.003				
Unknown	2	1	1					
Self-reported ICS adherence (%)	100 [100-100]	100 [100-100]	N/A	N/A				
Unknown	32	1	N/A					
Self-reported ND <sup>9</sup> adherence	71 [18-100]	71 [29-100]	71 [0-95]	>0.9				
Unknown	26	19	7					
		MARS-5						
MARS-5: NCS <sup>10</sup>	24 [23-25]	24 [23-25]	23 [20-25]	0.015				
MARS-5: NCS ≥20, n (%)	123 (92%)	101 (97%)	22(76%)	<0.001				
Unknown	3	1	2					
MARS-5: ICS <sup>11</sup>	23 [22-25]	23 [22-25]	N/A	N/A				
MARS-5: ICS≥20, n (%)	118 (89%)	94 (90%)	N/A					
Unknown	3	1	N/A					
Objective adherence MPR -12 months								
MPR NCS <sup>12</sup> , 12 months	57.5 [25.2-95.8]	65.8 [32.3-97.0]	32.9 [8.6-51.2]	0.002				
MPR NCS, 12 months ≥80%, n (%)	42 (31%)	37 (36%)	5 (17%)	0.049				
Unknown	2	1	1					
MPR ICS <sup>13</sup> , 12 months	49.3 [24.7-74.0]	N/A	N/A	N/A				
MPR ICS, 12 months ≥80%, n (%)	22 (21%)	22 (21%)	N/A	N/A				
Unknown	31	0	N/A					

<sup>&</sup>lt;sup>1</sup> Median (IQR); n (%); <sup>2</sup> Wilcoxon rank sum test; Pearson's Chi-squared test; Fisher's exact test; <sup>3</sup> VAS of CRSwNP = patient-reported chronic rhinosinusitis severity (VAS); <sup>4</sup> FEV1 = forced expiratory volume in 1 second; <sup>5</sup> FeNO = fractional exhaled nitric oxide; <sup>6</sup> ACQ-5 = Asthma Control Questionnaire; <sup>7</sup> ACT = Asthma Control Test; <sup>8</sup> VAS of asthma = patient-reported asthma severity (VAS); <sup>9</sup> Self-reported ND = self-reported nasal douching; <sup>10</sup> MARS-5: NCS = Medication Adherence Report Scale-5, nasal steroid; <sup>11</sup> MARS-5: ICS = Medication Adherence Report Scale-5, inhaled steroid; <sup>12</sup> MPR NCS = Medication Possession Ratio, nasal steroid; <sup>13</sup> MPR ICS = Medication Possession Ratio, inhaled steroid.

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reflect desirability, recall bias, misunderstanding of prescriptions, or unregistered over-the-counter use. Over-the-counter use does not gain reimbursement, and the cost for the patients is substantially higher per doses, which could minimize that bias.

#### Conclusion

Fewer than one-third of patients with CRSwNP referred for biological therapy demonstrated acceptable adherence to NCS. Poor adherence was especially common in CRSwNP-only patients despite a high subjective disease burden. Over-the-counter availability might be a possible bias. Identifying and addressing corticosteroid adherence prior to biologic treatment remains essential in severe disease.

### **Abbreviations**

CRS = Chronic rhinosinusitis; CRSwNP = Chronic rhinosinusitis with nasal polyps; GAD = Global airway disease; ENT = Ear, nose and throat department; ENTs = Ear, nose and throat specialists; ICS = Inhaled corticosteroid; MARS-5 = Medication Adherence Report Scale-5; MPR = Medication Possession Ratio; ND = Nasal douching; NCS = Nasal corticosteroid.

### **Authorship contribution**

CH: Writing – original draft; KEJH, KA, CSU, BAE, RH, VB: Writing – review & editing; All authors approved the final version.

### **Conflict of interest**

Outside the submitted work and unrelated to this. CH has received unregistered research grants from GSK and Sanofi. KEJH has received personal fees from AstraZeneca, Chiesi, GSK, Sanofi and TEVA. KA has received personal fees from GSK, Sanofi, and AstraZeneca. CSU has received personal fees for lectures, being on advisory boards etc. from AstraZeneca, Berlin-Chemie Menarini, Boehringer Ingelheim, Novartis, GSK, Sanofi, TEVA, Orion Pharma, TFF Pharmaceuticals, Pfizer, Chiesi, Covis Pharma, Takeda, Hikma Pharmaceuticals, Novo Nordisk and Roche. VB has received personal fees from AstraZeneca, GSK, TEVA, Sanofi Genzyme, MSD, Chiesi, Boehringer-Ingelheim, Novartis, ALK-Abello, Mundipharma, BIRK NPC and Pharmaxis.

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### **SUPPLEMENTARY MATERIAL**

### **Materials and Methods**

### Study design

This cross-sectional study was conducted among patients diagnosed with chronic rhinosinusitis with nasal polyps (CRSwNP) or global airway disease (GAD), who were referred to the Department of Otorhinolaryngology (Ear, Nose, and Throat, ENT) at Copenhagen University Hospital – Rigshospitalet. Between November 2022 and December 2023, eligible patients were consecutively enrolled in the National Registry for Global Airway. All included patients were referred by ENT specialists, pulmonologist or other ENT departments for potential for imitation of biologic treatment for CRSwNP. The study was approved by the Danish Scientific Ethical Committee (H-21020685) and the Capital Region of Copenhagen's Data Privacy Center (P-2021-193). All patients provided informed consent to participate, and the study was conducted in accordance with the Declaration of Helsinki.

#### Inclusion and exclusion criteria

All patients referred with CRSwNP or GAD for possible biologic treatment, were evaluated for inclusion for this study. Exclusion criteria were inability to respond to questionnaires, language difficulties, and/or non-Danish residents without a Danish civil registration number.

### **Data and definitions**

Data were collected from the national registry, from November 2022 – December 2023. A total of 153 patients were screened, of whom 21 were deemed not eligible due to questionnaire non-completion (n = 7), language difficulties (n = 6), or absence of a Danish civil registration number (n= 9). Consequently, 136 participants were included in the study and completed the following

questionnaires prior their screening visit in the period.

Adherence to NCS and ICS was objectively assessed using the Medication Possession Ratio (MPR), a widely applied and validated method for measuring adherence in research (1,2). MPR is based on prescription refill data and reflects the proportion of days within a given period covered by dispensed medication <sup>(1,2)</sup>. While MPR provides an objective estimate of medication supply coverage it does not capture actual intake or dosing frequency <sup>(1-3)</sup> (e.g., whether NCS or ICS were taken once or twice daily). MPR was calculated as the number of redeemed daily doses divided by the number of prescribed daily doses over 6- and 12-month period prior to each patient's screening, using data from the Danish Common Medication Card and the National Prescription Registry. An adherence rate ≥ 80% was defined as acceptable.

#### **Statistics**

Descriptive statistics were used for continuous and categorical variables, presented as either number (%) or median (interquartile range, IQR), as appropriate. Medians were compared using Wilcoxon-Mann-Whitney and categorical values using chi squared or Fishers Exact for variable with small counts (i.e. <5) values). Linear regressions were performed to investigate the correlation between self-reported adherence measures (self-reported adherence score, MARS-5-NCS/ICS) and objective adherence measures (calculated MPR calculated based on redeemed prescriptions). A multivariate logistic regression, adjusted for age, sex, education level and GAD, was used to explore predictors of good adherence. A p-value ≤0.05 was considered statistically significant. All analyses and graphics were performed using R version 4.3.2 (The R Foundation, AU).

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reported vs.objectively assessed adherence to inhaled corticosteroids in asthma. Asthma Res Pract. 2021;7(1):1–9.

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Table S1. Adherence rates for 136 patients with global airway disease or CRSwNP only, referred to a tertiary care clinic. Medication possession ratio (MPR) was calculated over a six-month period prior to the screening visit.

	AII N=136 ¹	Global airway disease N=105 ¹	CRSwNP only N=31 <sup>1</sup>	P-value <sup>2</sup>		
Objective adherence MPR (6 months)						
MPR NCS <sup>3</sup> (%), 6 months	57.5 [19.2-106.4]	63 [23.0-115.1]	35.6 [1.9-61.4]	0.009		
MPR NCS, 6 months ≥80%	46 (34%)	40 (38%)	6 (20%)	0.061		
Unknown	2	1	1			
MPR ICS 4(%), 6 months	49.3 [24.7 – 74.0]	49.3 (24.7, 74.0)	N/A			
MPR ICS, 6 months ≥80%	26 (25%)	26 (25%)	N/A	>0.9		
Unknown	31	0	N/A			

<sup>&</sup>lt;sup>1</sup> Median (IQR); n (%), <sup>2</sup> Wilcoxon rank sum test; Pearson's Chi-squared test; Fisher's exact test, <sup>3</sup> MPR: Medication Possession Ratio, nasal steroid, <sup>4</sup> Medication Possession Ratio, inhaled steroid

Table S2. Multivariate logistic regression analysis of the associations between age, sex, education level, comorbidity, and adherence to NCS.

	Odds Ratio	95% Confidence Interval	p-value
Sex			
Male (ref)	_	_	_
Female	0.52	0.22, 1.16	0.12
Age	0.99	0.96, 1.02	0.4
Education level			
Primary (ref)	_	_	_
Vocational	0.85	0.28 – 2.58	0.8
BSc+	0.73	0.26 – 2.04	0.5
Unknown/Other	0.00	_	>0.9
Comorbid Asthma			
Yes (ref)	_	_	_
No	0.30	0.09 – 0.83	0.029

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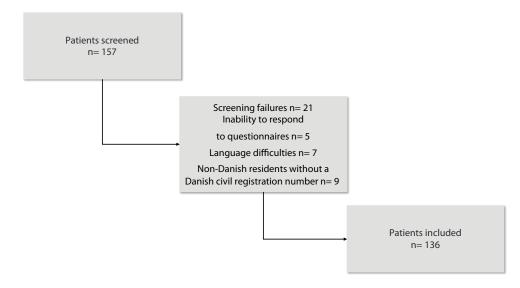


Figure S1. PRISMA flow diagram, overview of the participating patients.

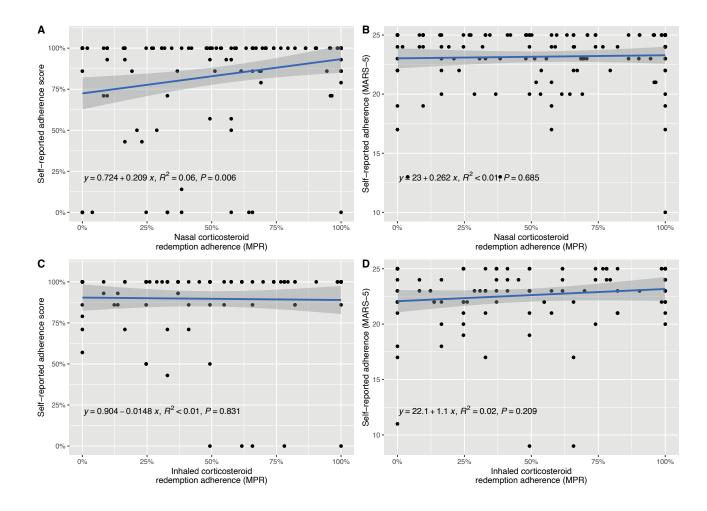


Figure S2. Univariate linear regressions between subjective and objective adherence measures: (A) self-reported adherence (%) versus medication possession ratio (MPR) for nasal corticosteroids (NCS); (B) Medication Adherence Report Scale-5 (MARS-5) versus NCS MPR; (C) self-reported adherence (%) versus MPR for inhaled corticosteroids (ICS); and (D) Medication Adherence Report Scale-5 (MARS-5) versus ICS MPR, in 136 patients with chronic rhinosinusitis referred to a tertiary care clinic.