Assessment of the extent of previous endoscopic sinus surgery using the ACCESS score in patients with chronic rhinosinusitis referred to tertiary care rhinologic clinics

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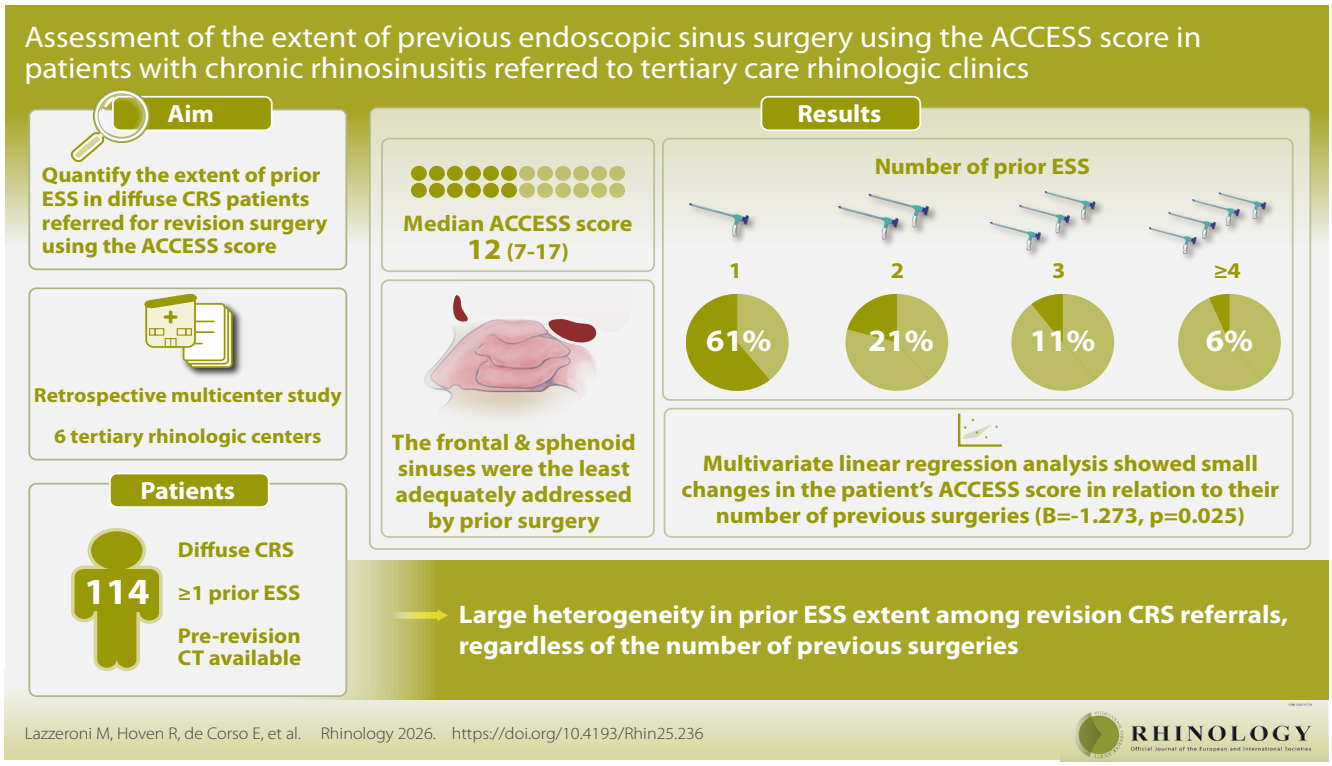

Abstract

Background: Despite optimal medical and surgical therapy, many patients suffering from chronic rhinosinusitis (CRS) experience continuous inflammation for which revision surgery can be indicated. The present work was set out to investigate the extent of prior endoscopic sinus surgery (ESS) performed in CRS patients referred to tertiary rhinologic centers for revision surgery in Western countries. **Methods**: A retrospective multicenter study was conducted including patients with any (pheno)type of diffuse CRS, who had undergone at least one prior ESS. All patients had a sinus computed tomography (CT) scan performed before their revision surgery which was used to retrieve the Amsterdam classification of completeness of ESS (ACCESS) scores, which range from 0 (sinuses functionally opened) to 24 (no sinus opening). **Results**: 114 patients from 6 different centers were included. The median ACCESS score was 12 (7-17). Most patients had only one previous ESS (70/114, 61%), while 24 (21%) had 2 previous surgeries, 13 (11.4%) patients had three, and 7 (6%) patients had four or more. Median ACCESS scores by number of previous ESS were: 13 (6-16) for one prior surgery, 12 (7-18) for two, 10 (8-13) for three, and 6 (3-13) for four or more surgeries. Multivariate linear regression analysis showed small changes in the patient's ACCESS score in relation to their number of previous surgeries. **Conclusions**: Our study underscores a large heterogeneity in extent of prior ESS among patients referred to tertiary rhinologic centers for diffuse CRS, regardless of the number of previous surgeries

Key words: CRS, ESS, revision surgery, ACCESS

Introduction

Chronic rhinosinusitis (CRS) is an inflammatory condition of the nasal cavity and paranasal sinuses that presents with debilitating symptoms. It has significant impact on the patient's quality of life [1] and induces relevant societal costs [2]. The EPOS2020 guidelines classify CRS into primary and secondary CRS according to the possible underlying disease (such as immunological or genetic disorders) and based on disease localization (localized/unilateral versus diffuse/bilateral). Primary diffuse CRS is further specified according to the dominant underlying inflammatory endotype, pragmatically distinguished as type2 versus non-type2 [3, 4]. For localized disease, surgical intervention is often warranted [3, 4]. For diffuse disease, which does not have its pathoetiology linked to anatomical abnormalities, medical treatments such as nasal irrigations, local or systemic corticosteroids, and antibiotics are indicated to attain disease control [3, 4]. When these conservative treatments fail, endoscopic sinus surgery is usually advised in diffuse CRS [3]. The aim of (primary) surgical treatment for most CRS phenotypes is to create a functionally opened cavity that allows the paranasal sinuses to be adequately drained and to receive topical nasal medications [3, 5].

However, a minority of patients have poor disease control despite previous ESS followed by appropriate medical treatment and are subsequently referred for revision surgery [6-9]. A widely acknowledged definition of revision surgery and its correct indications are still lacking [10-12]; indeed, establishing the timing, goals and extent of revision surgery was included in the research needs of EPOS2020 [3]. Revision surgery typically involves targeting residual ethmoidal cells, lateralized middle turbinates, synechiae, regrown polyps or inadequately opened ostia [13]. Over the years there have been contrasting reports on the appropriate extent of ESS for CRS, with some [14-17] suggesting that more comprehensive ESS leads to better outcomes with sustained control, while others [18, 19] suggest that comprehensive ESS only exposes patients to the risk of iatrogenic complications. However, the most recent systematic review with meta-analysis shows that indeed, more extensive surgery leads to better outcomes [14].

Recently, "reboot surgery" has again been proposed, representing an aggressive surgical approach to the paranasal sinuses that involves not only opening the natural ostia but also removing the entire sino-nasal mucosa [20, 21]. Yet, most of these studies were observational, non-randomized studies that presented variable concepts of surgical radicality and different follow up periods, and therefore, their results are difficult to compare [15, 16, 18, 22, 23]. To address these issues, the Amsterdam classification of completeness of ESS (ACCESS) was devised [24], providing a standardized tool for quantification of the extent of previous surgery. More recently, other classifications of the extent of surgery for CRS have been proposed to address this controversial topic, such as the Lamella Ostium Extent Mucosa (LOEM) system [25] and the Completion of Surgery Index [26] (CoSI).

While ACCESS score, CoSI and LEOM are three different approaches to describe surgical completeness, the CoSI attributes heavy emphasis on frontal sinus surgery, with the maximum scores being attainable only with a Draf 3 procedure, due to the implications for adequate access for topical therapy delivery to the sinuses. Similarly, it defines complete surgery for the maxillary and sphenoid sinuses by an opening of the ostia greater than 70%. The LEOM classification system, instead, is independent of any radiological assessment and is only based on the descriptions of surgical procedures. The imaging-based ACCESS score focuses on the functional completeness of surgery, regardless of the surgical techniques used, representing a versatile and pragmatic tool for routine clinical assessment and future research.

The present study aims to assess the average extent of ESS performed in CRS patients referred to tertiary centers for revision surgery in Western countries, to evaluate demographic and radiological characteristics in these patients, and to determine the factors influencing advanced or limited surgical extent.

Materials and methods

Study design

Retrospective multicenter cohort study, including patients with any (pheno)type of diffuse chronic rhinosinusitis as defined per the EPOS2020 guidelines [3], who had undergone at least one prior sinus surgery (consisting of a minimum of uncinectomy and anterior ethmoidectomy according to the referring surgeons) and were subsequently referred to tertiary centers for revision surgery due to lack of disease control.

The tertiary rhinological centers that contributed to this study were: 1) Amsterdam UMC, Amsterdam, The Netherlands, 2) University of Cincinnati College of Medicine, Cincinnati, USA, 3) Department of Otorhinolaryngology, Head & Neck Surgery, Aristotle University of Thessaloniki, AHEPA Hospital, Thessaloniki, Greece, 4) Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy, 5) Department of Otolaryngology-Head and Neck Surgery, Guy's and St. Thomas' Hospitals, London, United Kingdom and 6) Department of Otolaryngology-Head and Neck Surgery, Stanford University, Stanford, USA. Each center was asked to provide up to 20 patients.

Data collection

Patients' general demographic characteristics were collected such as age, sex, classification of diffuse CRS (primary or secondary, endotype prevalence (type 2 or non-type 2)), physician-reported diagnosis of comorbidities such as asthma and non-steroidal anti-inflammatory drug (NSAID)-exacerbated

Table 1. Baseline characteristics and outcomes of the full group and according to the center of origin.

		Full Group	Amsterdam	Cincinnati	London	Rome	Stanford	Thessaloniki
Number of patients		114	20	20	14	20	20	20
Number of previous surgeries		1 (1-2)	2 (1-3)	1 (1-1)	1 (1-2)	1 (1-2)	1 (1-2)	1 (1-2)
Total LM score		16 (9-20)	20 (16-22)	10 (4-14)	18 (15-21)	19 (17-20)	9 (6-15)	15 (10-21)
Total ACCESS score		12 (7-17)	14 (8-15)	7 (4-13)	15 (3-20)	11 (8-14)	16 (12-18)	9 (4-14)
Age		51 (41-63)	51 (38-61)	57 (49-65)	50 (43-56)	50 (41-59)	43 (35-55)	60 (47-68)
Sex	Female	42 (37%)	10 (50%)	7 (35%)	4 (28.6%)	4 (20%)	11 (55%)	6 (30%)
	Male	72 (63%)	10 (50%)	13 (65%)	10 (71.4%)	16 (80%)	9 (45%)	14 (70%)
Asthma		61 (54%)	14 (70%)	13 (65%)	8 (61.5%)	14 (70%)	6 (30%)	6 (30%)
NERD		19 (17%)	7 (35%)	1 (5%)	5 (35.7%)	2 (10%)	3 (15%)	1 (5%)
Type of diffuse CRS	Primary	105 (92%)	20 (100%)	19 (95%)	14 (100%)	19 (95%)	14 (70%)	19 (95%)
	Secondary	9 (8%)	0 (0%)	1 (5%)	0 (0%)	1 (5%)	6 (30%)	1 (5%)
Endotype of primary diffuse CRS	Type-2	72 (87%)	18 (90%)	/	9 (81%)	19 (100%)	7 (50%)	19 (100%)
	Non type-2	11 (13%)	2 (10%)	/	2 (19%)	0 (0%)	7 (50%)	0 (0%)

Data are presented as median (IQR) for continuous variables or counts n (%) for categorical variables. ACCESS: Amsterdam Classification of Completeness of Endoscopic Sinus Surgery; LM score: Lund-Mackay Score; CRS: Chronic Rhinosinusitis; N-ERD: Nonsteroidal anti-inflammatory drug exacerbated respiratory disease.

respiratory disease (N-ERD), and number of previous surgeries. Type 2 inflammation was defined according to the EPOS/EUFOREA update on indication and evaluation of Biologics in Chronic Rhinosinusitis with Nasal Polyps [27]: by a blood eosinophils cut-off ≥150 cells/mL, total IgE ≥100 kU/L or tissue eosinophils ≥10 / HPF.

All patients had a sinus computed tomography (CT) scan performed before their revision surgery and the ACCESS and Lund-Mackay (LM) scores for all patients were obtained from authors of the tertiary referring center of provenance. The ACCESS score indicates the extent of previous surgeries and ranges from 0 to 24, with higher scores corresponding to less functionally opened sinus ostia and therefore lower invasiveness of previous surgeries [24].

Statistical analysis

Normality of data was assessed through visual inspection of the distribution, Q-Q plots and the Shapiro-Wilk test. Continuous variables were reported as medians and interquartile ranges if non-normally distributed, or as means and standard deviations if normally distributed. Categorical variables were reported as frequencies and valid percentages in case of missing values.

The primary aim of the present study was to assess the ACCESS scores of patients requiring revision surgery for chronic rhinosinusitis. The correlation between the total ACCESS scores and number of previous surgeries was assessed through Spearman test. The influence of various factors, such as age, sex, comorbidities, total LM score, number of previous surgeries and referring hospital on the total ACCESS score was then evaluated separately by means of univariate linear regression. For sites, dummy variables were created. Variables with a $p < 0.2$ were then included in a multivariate linear regression model. Due to the low number of patients with 4, 5, or 6 previous surgeries, these patients were grouped together (≥4 surgeries) for the analyses. Stepwise, all variables with a p-value of ≥0.05 were deleted until all remaining parameters were significant. All statistical analysis were performed with SPSS software (version 28.0.1.1).

Ethics statement

This study is in line with the Helsinki declaration and its later amendments. Each center received permission to participate in the present study from their local institutional review boards. Informed consent for this retrospective study was waived from the local Institution Review Boards.

Results

Demographics

Baseline characteristics of the study cohort are reported in Table 1. The present retrospective, multicenter study included 114 diffuse CRS patients from 6 different tertiary centers located in Amsterdam, Rome, Stanford, Cincinnati and Thessaloniki, which provided 20 patients each, and London 14 patients. After a median of 1 (interquartile range: 1-2) previous surgery, patients had a median ACCESS score of 12/24 points. Most patients (N=70 [61%]) had only one ESS before referral, while 24 (21%) had 2 previous ESS, 13 (11.4%) patients had three, and 7 (6%) patients

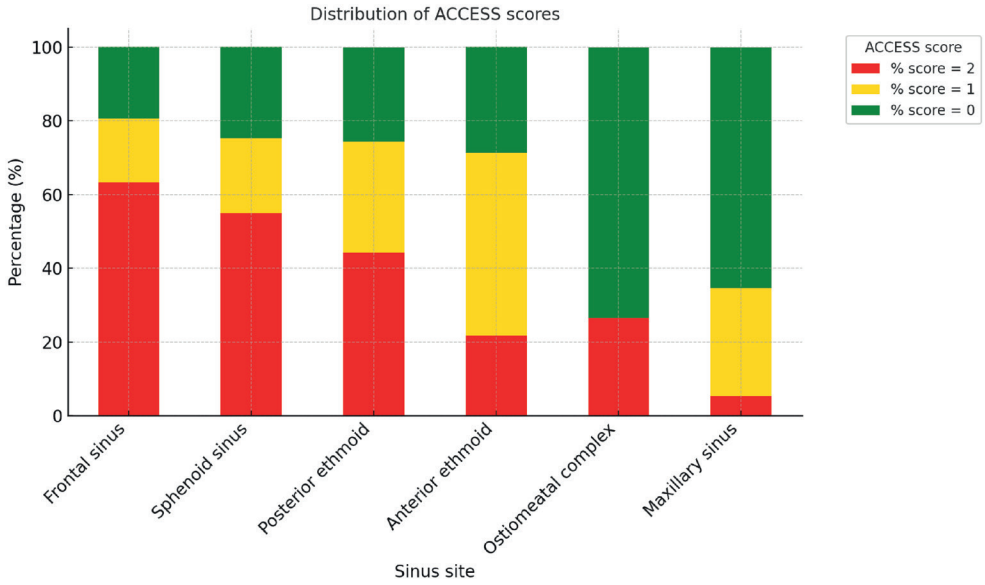

Figure 1. Bar chart showing the distribution of the ACCESS score across the different sinus sites. The frontal and sphenoid sinuses were most frequently untouched, while the maxillary sinus and ostiomeatal complex were typically adequately opened.

had four or more surgeries.

Patients with one previous ESS had a median (IQR) ACCESS score of 13 (6-16), those with two previous surgeries had a score of 12 (7-18), those who had already received three previous surgeries had a score of 10 (8-13), and those with four or more previous surgeries had a score of 6 (3-13). There were only 3 patients in total with an ACCESS score of 0: one had undergone one previous ESS and two had received three previous surgeries

Most of the included patients presented with primary diffuse CRS (N=105 [92%]). Among the patients affected by secondary diffuse CRS (N=9 [8%]), 6 [5%] came from Stanford.

The median ACCESS and LM scores of patients with primary diffuse CRS were 12 (6-16) and 16 (9-20) and in secondary diffuse CRS were 17 (9-19) and 11 (10-18) respectively, however no statistically significant differences were found between the two groups. Among patients with primary diffuse CRS the median ACCESS and LM scores were 12 (7-16) and 17 (14-21) respectively for those with type-2 endotype, while for non-type-2 patients 14 (12-18) and 9 (8-18). Also, in this case no statistically significant differences were found between the groups. Regarding the surgical completeness of the individual sinuses, the frontal and sphenoid sinuses were the most frequently untouched, with an ACCESS score of 2 in 63% and 55% of the sinuses respectively as shown in Figure 1.

Factors influencing the extent of previous surgeries

The Spearman correlation analysis showed no association between total ACCESS score and number of previous surgeries (p=0.218).

In the univariate linear regression analysis variables such as N-ERD, total LM score, type of diffuse CRS, and endotype of CRS did not meet the required significance thresholds to be included in the multivariate analysis. Other factors such as sex, age, asthma, number of previous surgeries were found to have p values <0.2 (Table 2) and where therefore selected for the stepwise multivariate analysis. The influence of the patients' center was also evaluated in the multivariate analysis. While not all centers showed sufficient significance levels, they were all included in the model to avoid biased coefficient estimates and ensure proper adjustment for institutional variability [28, 29]. The multivariate analysis showed a moderate correlation between the predictors (number of previous surgeries and site) and the total ACCESS score (R=0.446). The model explained 19.9% of the variance (R2=0.199), with an adjusted R2 of 0.153 and a standard error of 5.903.

The number of previous surgeries was found to be significantly associated with lower ACCESS scores (B=-1.273 95% CI -2.380: -0.165, p=0.025), as visually represented in Figure 2; likewise, patients from Cincinnati exhibited a significantly lower ACCESS score (B=-5.341 95% CI -9.122: -1.560, p=0.006). Age, sex and asthma did not show significant associations with the total ACCESS score.

Differences between centers

Patients from Cincinnati had the lowest total ACCESS scores with a median of 7 (4-13), consistent with the significant association found in the multivariate analysis. Patients from Cincinnati and Stanford also showed lower LM scores with medians of 10 (4-14) and 9 (6-15) respectively. Other patient characteristics such as age, asthma and N-ERD prevalence appeared homogeneous among the different centers.

Table 2. Results of univariate and multivariate linear regression analysis used to identify factors associated with the total ACCESS score.

Univariate analysis		
Parameter	**Model R^2**	**p-value**
Sex	0.031	0.064
Asthma	0.033	0.054
NERD	0.000	0.962
Age	0.016	0.184
Type of CRS	0.012	0.244
Number of previous surgeries	0.021	0.127
Total LM score	0.007	0.378
Multivariate model		
Parameter	**Model R^2**	**B-coefficient (95% CI)**
Number of previous surgeries, Site	0.199	
Constant		14.882 (11.489:18.275)
Number of previous surgeries		-1.273 (-2.380: -0.165)
Cincinnati		-5.341 (-9.122: -1.560)
London		-0.538 (-4.620: 3.545)
Rome		-0.750 (-4.451: 2.951)
Stanford		3.113 (-0.665: 6.892)
Thessaloniki		-3.259 (-6.981: 0.468)

ACCESS: Amsterdam Classification of Completeness of Endoscopic Sinus Surgery; LM score: Lund-Mackay Score; CRS: Chronic rhinosinusitis; N-ERD: Nonsteroidal anti-inflammatory drug exacerbated respiratory disease; CI: confidence interval. The univariate analysis shows the impact of each factor through the R2 and p values. In the multivariate model, only the significant ($p<0.05$) unstandardized regression coefficients (B) are reported along with their 95% confidence interval. Amsterdam was chosen as the reference category for comparisons between centers and therefore it is not included in the analysis to avoid multicollinearity.

Discussion

In our current data set, most patients were referred after one previous ESS and, when referred, patients with previous ESS had a median ACCESS score of 12. This is congruent with an infundibulotomy (-4 points), adequate access of the maxillary sinuses (-4 points) and complete anterior ethmoidectomy (or partial anterior and posterior ethmoidectomies; -4 points) bilaterally, which is the surgical extent to which most of the referred patients were operated on (Figure 1). However, the ACCESS scores of our patients showed a high variability, as underscored by Figure 2, with some patients being referred after 1 previous ESS and a total ACCESS score ranging between 0-23. This situation doesn't change much when we consider the group that had revision surgery; the groups of patients with more than one previous ESS had a slightly lower median ACCESS score, but a comparable range. The optimal extent of ESS for CRS, especially bilateral diffuse type 2 CRS, is still debated. One of the main goals of surgery for CRS is granting topical access to medical therapies to the sinuses [30, 31], the surgical completeness through which this can be achieved remains controversial since the available evidence on the topic suffers from major biases deriving from small sample sizes, non-randomized designs and short follow up periods [15, 22, 23].

Our results highlight the important role of tertiary care centers in delivering comprehensive ESS when disease control isn't reached after initial limited intervention(s). According to the latest guidelines by the American Academy of Otolaryngology - Head and Neck Surgery [32], surgeons managing CRS with polyps, osteitis or bony erosion should perform sinus surgery that includes full exposure of the sinus cavity and removal of diseased tissue, or refer the patient to a surgeon who can perform this extent of surgery. Indeed, the ACCESS scores of the included patients suggest that referring centers often did not address the frontal and sphenoid sinuses adequately, and it is in this regard that tertiary centers play a critical role by performing more extensive, tailored surgeries aiming to achieve disease control.

The present study has some limitations. Firstly, the observational, retrospective design of the study intrinsically carries risk of selection bias that might impact the representativeness of the included patients [33]. The relatively small number of patients that the different centers have provided might not reflect the variability of presentation of CRS. The total ACCESS score of the included patients did not follow a normal distribution, yet we showed that only with parametric models after correction for site there is a small influence of the number of previous surgeries on the ACCESS scores. Furthermore, patients were not necessarily enrolled consecutively at each center, which may introduce an additional degree of selection bias. Therefore, caution should be paid regarding the reliability of our model's predictive power.

As a multicenter study, inter-center variability needs to be taken into account due to the possible variability in surgical techniques (the patients were operated in secondary hospitals), disease assessment criteria (European guidelines have been considered for the classification of CRS [3, 27], but the study included patients from two American centers) and post-operative management.

Moreover, even though multiple potential confounders were assessed in our analysis (patients age, sex and comorbidities), residual confounding factors were not accounted for, such as the timeframe between surgery and disease relapse with referral to the tertiary center. Lack of disease control in CRS cannot always be explained simply as a result of insufficient/incomplete surgery [34], nor can it be prevented by complete surgery, asses-

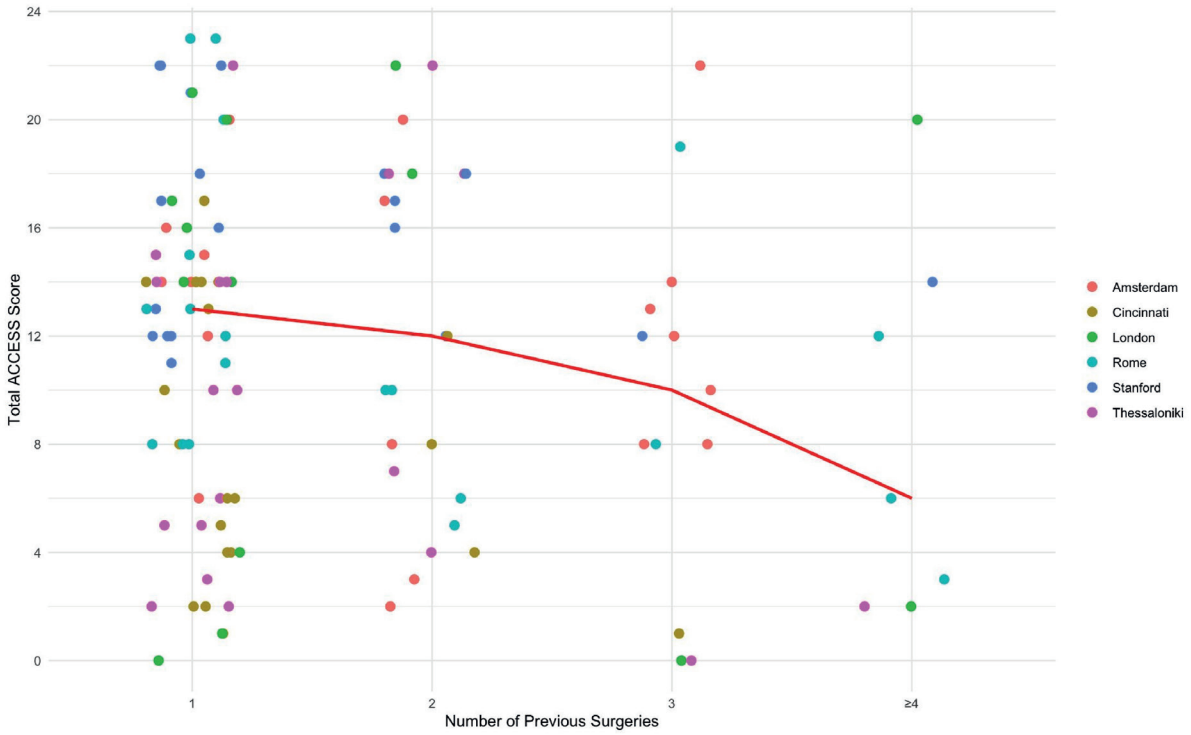

Figure 2. Scatter plot to show the relationship between the number of previous surgeries and the total ACCESS score. The red line connects the median ACCESS scores of the individual group of patients divided according to the number of surgeries; it highlights a decreasing trend in the median ACCESS scores as the number of surgeries increases.

sable through functionally opened ostia that can be quantified through standardized scores. As underlined by the EPOS2020 guidelines [3], most phenotypes of diffuse CRS are driven by systemic, chronic inflammation that sustains the disease's locoregional activity despite medical or surgical treatment.
Lastly, patients who had undergone multiple ESS were not followed up longitudinally with multiple CT scans, therefore, any progressive changes in their ACCESS score between surgeries could not be assessed.

Conclusion

This study confirms the usefulness of the ACCESS score to quantitively compare previous surgeries in CRS patients. As such, our study highlights a large variation in prior surgical extent among patients referred to tertiary rhinologic centers for diffuse CRS, regardless of the number of previous surgeries. Further research with larger sample sizes is necessary to confirm our results. Future studies should also investigate if this variability in outcomes also applies to surgical procedures performed in tertiary centers, and whether this impacts disease outcomes.

Author contributions

ML: Data curation; Formal analysis; Investigation; Methodology; Roles/Writing - original draft. RH, EdC, CM, ASe, ASa, JC, CH, BRC, ZP, PC: Data curation; Validation; Writing - review & editing. WF: Supervision; Project administration; Conceptualization; Writing - review & editing. SR: Conceptualization, Project administration; Validation; Supervision; Writing - review & editing.

Conflict of interest

ML, RH, AS, BRC and PC have no conflict of interest to declare. CM received lecture fees and participations in experts board meeting of GSK and Sanofi. EdC received lecture fees and participations on expert board meeting of GSK, Novartis, Sanofi, Firma and AstraZeneca. ARS has been involved in research funding and advisory board participation for Sanofi/Regeneron and GSK. JC reports honoraria for consultancy from GSK. CH is an advisory board member of AstraZeneca, BioInspire Technologies, Dianosic, GlaxoSmithKline and Sanofi. Z. M. Patel has served as an advisor/consultant for Medtronic, Optinose, Dianosic, Wyndly, and Mediflix, and holds equity in Olfera Therapeutics and SoundHealth. 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. The department of Otorhinolaryngology and Head/Neck Surgery of the Amsterdam UMC has received research funding from Sanofi, GSK, and Novartis.

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