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Extending the use of the Endoscopic Endonasal Sinus and Skull Base Surgery Questionnaire in a cross-sectional study: Patients with chronic rhinosinusitis versus healthy controls

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Abstract

Objectives: There are several instruments to assess health-related quality of life (HRQoL) in chronic rhinosinusitis (CRS). Unfortunately, none of them evaluates all three health domains (physical, social and psychological) important to assess the overall well-being of the patient. The Endoscopic Endonasal Sinus and Skull Base Surgery Questionnaire (EES-Q) does assess all these elements. Initially, the EES-Q is validated to evaluate the impact of endoscopic endonasal surgery (EES) on HRQoL. The aim of this study is to assess whether EES-Q outcomes differ in patients with CRS compared with healthy individuals. Therefore, extending the use of the EES-Q for all CRS patients.

Design: Cross-sectional study.

Setting: Tertiary referral hospital.

Participants: One hundred patients with uncontrolled CRS (50% with nasal polyps) scheduled to receive EES. The questionnaire was completed preoperatively. Healthy control subjects (n = 100) without any history of sinusitis or a known current medical treatment at a hospital were included.

Main outcome measures: Mann–Whitney *U* test was performed to identify differences in EES-Q scores (domain scores and EES-Q score).

Results: The median EES-Q score in CRS patients (33.8) was significantly higher (p < 0.001) than in the control group (10.4). As well as the physical (52.5 vs. 16.4, p < 0.001), psychological (13.8 vs. 5.0, p < 0.001) and social (37.5 vs. 2.5, p < 0.001) domain scores.

Conclusions: With this study, we are extending the use of the EES-Q. It indicates that the EES-Q can be a valuable clinical tool to assess multidimensional HRQoL in all patients with CRS.

Gonneke E. Joustra and Marc C. den Heijer contributed equally to this study.

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KEYWORDS

chronic rhinosinusitis, EES-Q, known-groups validity, patient-reported outcome measure, quality of life

1 | INTRODUCTION

Chronic rhinosinusitis (CRS) is known to have an impact on Health-Related Quality of Life (HRQoL) comparable to or higher than other chronic diseases, such as asthma.¹ Several instruments evaluate HRQoL in CRS and contain important domains to measure HRQoL.¹⁻³ Today, the most widely used sinus-specific questionnaire to assess HRQoL in patients with CRS is the 22-item Sino-Nasal Outcome Test (SNOT-22).² Although the SNOT-22 thoroughly assesses sinonasal and general complaints, with only five questions about psychological and social complaints it does not sufficiently address all three health domains (physical, social and psychological) important to evaluate the overall well-being of the patient.^{4,5} Other questionnaires used to measure HRQoL in patients with CRS are the 36-item Short Form Health Survey Questionnaire (SF-36)¹ and the EuroQol-5Dimension-5Level (EQ-5D). Both of these adequately assess the general well-being of the patient, but they lack detail to evaluate sinonasal complaints.^{1,3,6}

Our research group developed and validated the Endoscopic Endonasal Sinus and Skull Base Surgery Questionnaire (EES-Q, appendix), a reliable and comprehensive instrument including physical, social and psychological domains and initially designed to assess HRQoL after endoscopic endonasal surgery (EES). For the development of the EES-Q 300 patients undergoing EES were included. Seventy-two items were generated based on existing instruments (e.g., SNOT-22), expert opinion and patient interviews. These items tested on construct validity, interpretability and internal consistency. The final version consists of 30 items with a high internal consistency (>0.80) for all three health domains.

Psychometric properties of the EES-Q were evaluated on 100 patients undergoing EES. This showed a good test-retest reliability, a significant construct validity and acceptable responsiveness.⁸

Since the EES-Q thoroughly assesses sinonasal complaints and was compared to the SNOT-22 during development, it could be a valuable instrument to evaluate HRQoL in all patients with CRS, not only after surgical intervention.

The aim of the current study is to determine whether EES-Q outcomes differ in patients with CRS compared to healthy individuals. This is a first step in extending the use of the EES-Q, to define and improve patient-centred health care focusing on all aspects of HRQoL of patients with CRS.

2 | METHODS

2.1 | Participants

A total of 100 patients with CRS, (50% with nasal polyps) were included in this study. All patients in this study have CRS defined by

Key Points

- There is a growing interest in the use of questionnaires for patient monitoring, disease screening, counselling for treatment and for clear communication between the physician and the patient.
- To the best of our knowledge, there is currently no health-related quality of life (HRQoL) instrument available to thoroughly evaluate all three health domains in all chronic rhinosinusitis (CRS) patients.
- The endoscopic endonasal sinus and skull base surgery questionnaire (EES-Q) does assess all three health domains, and initially was only validated for assessment after endoscopic endonasal surgery.
- The results of this study show that the EES-Q distinguishes between healthy individuals and CRS patients in a tertiary referral hospital.
- This is the first step in extending the use of the EES-Q for all CRS patients with or without surgical intervention.

the European Position Paper on Rhinosinusitis and Nasal Polyps and were scheduled to receive EES. $^{\circ}$ The questionnaire was completed preoperatively. Control subjects (n=100) without any history of sinusitis were included. All control subjects are healthy, working adults not receiving any medical treatment from a specialist at a hospital. These were persons from the personal network of the authors without any involvement to this research. They were asked to participate and complete the questionnaire anonymously. All participants are aged ≥ 18 years and fluent in the Dutch language.

2.2 | Study design

From our prospective cohort study at a tertiary referral centre, we took a cross-sectional sample. To minimise the risk of selection bias, 50 chronic rhinosinusitis with nasal polyps (CRSwNP) and 50 chronic rhinosinusitis without nasal polyps (CRSsNP) patients were enrolled consecutively. No selection was made based on the degree of their complaints or other comorbidities. For this study, it was essential to have an equal number of patients in these two groups. In each group, patients were enrolled consecutively until a group of 50 was reached. All study subjects were invited to participate in this study. Participants received the EES-Q by e-mail and were asked to complete the questionnaire. The maximum number of missing answers was three per subject per domain. In accordance with our previous study on the

evaluation of the psychometric properties of the EES-Q 100 participants per group was considered an adequate number.⁸

2.3 | Health-related quality of life instrument—EES-Q

The EES-Q is a patient-reported outcome measure encompassing physical, social and psychological domains. A total of 30 items (10 per domain) describe activities or complaints with a five-point Likert response scale ranging from not at all (1), (mildly (2), moderately (3), severely (4)) to very severely (5) to indicate the degree of inconvenience.⁷ A higher score indicates a worse HRQoL.

2.4 | Statistical analyses

Descriptive statistics were used to summarise patient characteristics. To obtain an easily interpretable score, the sum of scores in one domain was recalculated into a *domain score* ranging from 0 (not at all) to 100 (very severe inconvenience). *Domain scores* were calculated by summing the 10-item score of each domain, subtracting 10 points from this total and multiplying this by 2.5. *Domain scores* were corrected for the missing answers by adjusting the subtracted value and the multiplication factor accordingly. The maximum number of missing answers is three per subject per domain.⁸ The *EES-Q score*, ranging from 0 (not at all) to 100 (very severe inconvenience), was calculated by summing the three *domain scores* and dividing the total score by three. Median (*Mdn*) and interquartile range (IQR) were calculated to indicate the HROOL in all three health domains.

To identify differences in EES-Q scores (*domain scores* and *EES-Q score*) between healthy controls and CRS patients a Mann–Whitney *U* test was performed. A *p* value <0.05 was considered statistically significant. All statistical analyses were performed with IBM SPSS Statistics version 22.0 (SPSS IBM, Inc.).

3 | RESULTS

Two hundred participants were enrolled in this study (Table 1). Fifty subjects suffered from CRSwNP, 50 from CRSsNP and the remaining

TABLE 1 Patient characteristics

Characteristic	Value (n = 200, %) all participants	Value (n = 100, %) CRS patients	Value (n = 100, %) healthy controls
Age, mean (±SD) in years	43.3 (±15.3)	50.2 (±14.9)	36.3 (±12.5)
Sex			
Male	93 (46.5%)	49 (49%)	44 (44%)
Female	107 (53.5%)	51 (51%)	56 (56%)

Abbreviation: CRS, chronic rhinosinusitis.

100 were healthy controls. The mean age of all the participants was 43.3 ± 15.3 years and 53.5% were female.

The total group of CRS patients was on average 50.2 ± 14.9 years of age and 51% was female. Seventy-four (74%) patients previously underwent EES, at least 1 year prior to inclusion in this study. The mean age of the patients with CRSwNP was 48.7 ± 15.5 years and 32 were females (64%). The CRSsNP patients had a mean age of 51.7 ± 14.1 years of which 19 were female (38%).

The healthy control group was 36.3 ± 12.5 years of age and included 56 females (56%). None of them underwent EES in the past.

Data of questionnaire answers were not normally distributed, as conformed by the Shapiro–Wilk test and Kolmogorov–Smirnov test (p < 0.001 for all answers). Mann–Whitney U test was therefore used for analyses between the groups.

3.1 | Health-related quality of life

3.1.1 | Control versus (vs.) CRS patients

The EES-Q score (p < 0.001) as well as the physical (p < 0.001), psychological (p < 0.001) and social (p < 0.001) domain scores were significantly higher for the CRS patients compared with the control group (Table 2).

The EES-Q score reported by the CRS patients (Mdn=33.8) was higher (p < 0.001) than the score reported by the control group (Mdn=10.4) (Table 3, Figure 1). Within the physical domain the CRS patients (Mdn=52.5) scored higher (p < 0.001) than the control group (Mdn=16.4) (Table 3, Figure 1). Also, the CRS patients (Mdn=13.8) scored higher (p < 0.001) than the control group (Mdn=5.0) in the psychological domain (Table 3, Figure 1). As well as within the social domain: CRS patients (Mdn=37.5) scored higher (p < 0.001) than the control group (Mdn=2.5) (Table 3, Figure 1). For all individual questions, the median score was higher in the CRS group (Figure 2).

3.1.2 | Control versus CRSwNP

CRSwNP patients scored a significantly higher EES-Q score (p < 0.001), related to the physical (p < 0.001) and social (p < 0.001) domain scores in comparison with the control group. Within the psychological domain the CRSwNP patients score higher than the control group (p = 0.076) (Table 2).

The EES-Q score reported by the CRSwNP patients (Mdn = 29.2) was higher (p < 0.001) than the score reported by the control group (Mdn = 10.4). The CRSwNP patients (Mdn = 56.3) scored higher (p < 0.001) than the control group (Mdn = 16.3) within the physical domain. As in the social domain: CRSwNP patients (Mdn = 28.8) scored higher (p < 0.001) than the control group (Mdn = 2.5). Within the psychological domain, a higher (p = 0.076) score for the CRSwNP patients (Mdn = 7.5) compared with the control group (Mdn = 5.0), is not statistically significant (Table 3).

TABLE 2 Unpaired analysis (Mann-Whitney *U* test)

	Score	Category	N	U	r	р
Control versus CRS patients	EES-Q	Control	100	1405	0.62	<0.001
		CRS ^a	100			
	Physical domain	Control	100	885	0.71	<0.001
		CRS ^a	100			
	Psychological domain	Control	100	3490	0.24	<0.001
		CRS ^a	100			
	Social domain	Control	100	2162	0.50	<0.001
		CRS ^a	100			
Control versus CRSwNP patients	EES-Q	Control	100	746	0.57	<0.001
		CRSwNP ^a	50			
	Physical domain	Control	100	328	0.71	<0.001
		CRSwNP	50			
	Psychological domain	Control	100	2062	0.14	0.076
		CRSwNP ^a	50			
	Social domain	Control	100	1156	0.45	<0.001
		CRSwNP ^a	50			
Control versus CRSsNP patients	EES-Q	Control	100	659	0.60	<0.001
		CRSsNP ^a	50			
	Physical domain	Control	100	558	0.63	<0.001
		CRSsNPa	50			
	Psychological domain	Control	100	1429	0.35	<0.001
		CRSsNP ^a	50			
	Social domain	Control	100	1007	0.50	<0.001
		CRSsNP ^a	50			

 $\it Note$: The bold values are to emphasise the statistical significant $\it p$ -values.

Abbreviations: CRS, chronic rhinosinusitis; CRSsNP, chronic rhinosinusitis without nasal polyps; CRSwNP, chronic rhinosinusitis with nasal polyps; EES-Q, Endoscopic Endonasal Sinus and Skull Base Surgery Questionnaire.

TABLE 3 Median (IQR) scores

	Median (IQR) score						
	EES-Q	Physical domain	Psychological domain	Social domain			
Patients	33.8 (22.5-50.8)	52.5 (37.5-70.0)	13.8 (5.0-29.4)	37.5 (15.0-56.9)			
CRSwNP	29.2 (20.0-47.5)	56.3 (37.5-72.5)	7.5 (1.88-22.5)	28.8 (10.0-52.5)			
CRSsNP	39.2 (24.6-51.5)	51.3 (34.4-65.0)	17.5 (6.88-39.4)	44.7 (15.0-65.6)			
Control	10.4 (3.5-21.5)	16.3 (7.5-27.5)	5.0 (0-16.9)	2.5 (0-21.9)			

Abbreviations: CRSsNP, chronic rhinosinusitis without nasal polyps; CRSwNP, chronic rhinosinusitis with nasal polyps; EES-Q, Endoscopic Endonasal Sinus and Skull Base Surgery Questionnaire; IQR, interquartile range.

3.1.3 | Control versus CRSsNP

Compared with the control group CRSsNP patients reported a significantly higher EES-Q score (p < 0.001) as well as for the physical (p < 0.001), psychological (p < 0.001) and social (p < 0.001) domain scores (Table 2).

The EES-Q score reported by the CRSsNP patients (Mdn = 39.2) was higher (p < .001) than that reported by the

control group (Mdn=10.4). CRSsNP patients (Mdn=51.3) reported a higher (p<.001) score compared with the control group (Mdn=16.3) in the physical domain. The psychological domain score is higher (p<.001) for patients with CRSsNP (Mdn=17.5), compared with the control group (Mdn=5.0). The social domain score reported by CRSsNP patients (Mdn=44.7) is also higher (p<.001) compared with the control group (Mdn=2.5) (Table 3).

^aHighest mean rank.

3.2 | Missing items

The number of missing items was 11 (0.18%). Six patients reported (a) missing item(s) in one domain. One patient reported a missing item in two domains. The EES-Q was completed on paper by the patient and they were asked to send it back. We could not find any patterns in the missing items. Therefore, we assumed data to be missing at random.

4 | DISCUSSION

To thoroughly evaluate HRQoL, insight into physical, psychological and social complaints is necessary.^{4,5} To the best of our knowledge,

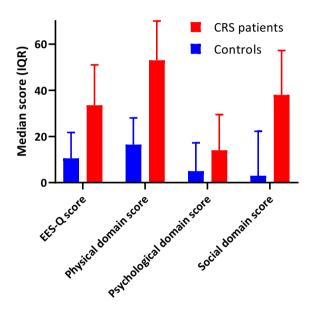


FIGURE 1 Endoscopic Endonasal Sinus and Skull Base Surgery Questionnaire score and domain scores, chronic rhinosinusitis patients versus controls

there is currently no validated instrument for CRS available that fully meets all these requirements. The EES-Q does adequately assess all three health domains, but currently, it only is validated for EES. Therefore, this study aimed to evaluate the ability of the EES-Q to discriminate between CRS patients and healthy individuals. This is the first step in extending the use of the EES-Q to all CRS patients with or without surgical intervention.

4.1 | Key findings

The CRS patients scored a significantly higher overall EES-Q score as well as higher scores in all three health domains separately. For all individual questions, the median score was higher in the CRS group. To have a heterogeneous CRS group, 50 patients with, and 50 patients without nasal polyps were included. In subgroup analyses, both groups scored significantly higher than the healthy control group. CRS patients report worse HRQoL in our instrument compared with healthy individuals.

Our study shows that CRS patients score remarkably worse on psychosocial issues than healthy individuals. Given CRS is associated with anxiety (17%–32%)^{10–12} and depression (11%–49%),^{12–14} mental health should be properly assessed. Since poor mental health is associated with increased healthcare-seeking behaviour with uncertain benefits,¹⁵ it is important to address all aspects of disability together to maximise the opportunity of improvement. In our study, the group with CRSwNP scores worse than the healthy individuals, it is however the only subgroup without statistical significance. A worse score for CRSsNP compared to CRSwNP is in line with other studies.^{12,14} The explanation for a worse psychological domain score in the CRSsNP could be found in less hospital visits or extra surgical treatment (e.g., nasal polypectomy).¹²

The EES-Q assesses the psychological as well as the social domain and is designed to be broken down into subscales.⁷

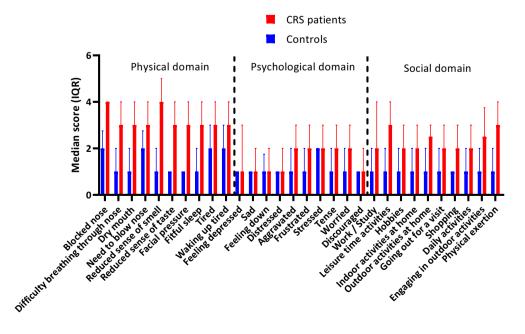


FIGURE 2 Individual questions, chronic rhinosinusitis patients versus controls

4.2 | Comparison to other studies

The SNOT-22 is a disease-specific questionnaire, including 22 questions generalised into three subcategories: physical problems, functional limitations and emotional consequences.² However, the SNOT-22 was not developed for subgroup analysis and the social and psychological domains are not addressed sufficiently. The SNOT-22 is frequently complemented by a generic HRQoL instrument to properly assess overall HRQoL of the patient.¹⁶ Emphasising the need and importance of a single HRQoL instrument including all three health domains.

CRS has a high socioeconomic burden, with indirect costs (a result of lost days at work and reduced productivity while at work) accountable for the greater part. $^{17-22}$ Wahid et al. 22 estimated the annual healthcare cost of CRS to be £ 16.8 billion in the UK. Total costs of care for CRSwNP in the Netherlands are estimated to be ε 1.9 billion per year. 20 This emphasises the importance of adequately assessing the psychological and social domain. To gain more insight on the (indirect) cots or other social effects of CRS.

The SF-36 is a generic HRQoL questionnaire containing 36 questions, divided into eight domains. The overall well-being of a patient is assessed, and a comparison can be made between various chronic illnesses, but it lacks detail to capture sinonasal symptoms.¹

The EQ-5D is a general health-related multi-attribute utility instrument designed to allow direct conversion into health utility values.³ The survey contains five general domains and a visual analogue scale to document a patient's overall health status at a given point in time. However, it too does not focus on sinonasal complaints and is developed primarily to complement other instruments.²³

With the use of the EES-Q, the HRQoL can be easily monitored (per domain). It can be used regularly and trends can be followed. The EES-Q is a single questionnaire that can be quickly completed (3–5 min) in the outpatient setting by the patient independently, and is easily interpretable.

4.3 | Missing data/limitations

The amount of missing items was very low (0.18%). The authors decided not to impute values for missing data as this small number does not suggest any risk of bias.

The study was conducted in a tertiary referral centre where most CRS patients are referred for revision surgery because of their uncontrolled CRS. Although this may not be a reflection of the total CRS population, we consider these patients useful because of their proven CRS. We are planning a subsequent study in a secondary referral hospital to confirm these results in a broader population.

In our study, the group of CRS patients is significantly older (50.2 \pm 14.9) than the control group (36.3 \pm 12.5). The reason for this difference is found in the age of the authors and their personal network. CRS is known to affect all ages, although the prevalence increases between 40 and 65 years of age. ^{17–19} Some studies suggest worse HRQoL for younger patients. ^{18,19,24} The control group is aimed to be a representative reflection of the working population, who do not receive any medical

treatment from a specialist at a hospital. Furthermore, the EES-Q links the psychological and social complaints to the physical complaints. The authors see no reason why age is an influencing factor, when a patient is socially limited because of physical complaints caused by CRS, for example. Taking all this into account, we do not expect the difference in age to be a confounder. Nevertheless, it will be taken into account in future studies.

The EPOS2020 steering group has suggested a new classification by endotype dominance: type 2 or non-type 2 CRS. At the time of data, collection this new classification was not yet known. As classification according to nasal polyps is still widely accepted, the authors chose to keep this classification for this article. In our population, four patients with cystic fibrosis and two patients with granulomatosis with polyangiitis were included. We see this as a result of consecutive inclusion without selection on level of complaints or other comorbidities and could therefore be a normal representation of the tertiary CRS population. Subanalyses on these groups are not possible because of the small numbers and would be beyond the scope of this current study.

4.4 | Future directions

There is a growing trend to thoroughly assess the impact of chronic diseases in our Western society. There is also a growing interest in the use of questionnaires for patient monitoring, disease screening, counselling for treatment and for clear communication between the physician and the patient. Our future goal is to determine whether the EES-Q will be suitable to assess these points, and to improve patient-centred health care. Additional research is in progress to confirm these results in a secondary referral hospital.

5 | CONCLUSION

This study demonstrates that tertiary CRS patients (prior to surgery) score significantly higher in the EES-Q score, as well as the physical, psychological and social domain scores, compared with healthy individuals. This indicates a worse HRQoL for our CRS patients, and suggests that the EES-Q can be a valuable clinical tool to assess HRQoL in all patients with CRS. The EES-Q is already validated for endoscopic endonasal surgery. With this study, we are extending the use of the EES-Q.

AUTHOR CONTRIBUTIONS

Gonneke E. Joustra: concept and design, statistical analysis, manuscript writing. Marc C. den Heijer: concept and design, data collection, manuscript writing. Karin M. Vermeulen: data analysis support, review manuscript. Robert A. Feijen: concept and design, review manuscript. Astrid G. W. Korsten-Meijer: concept and design, review manuscript.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data supporting the findings of this study are available upon request from the authors. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

Local institutional review board approval was obtained before commencing. Written information was provided and informed consent was obtained (RR 202000103). For the control group, data were collected anonymously with no identification information. For the CRS group, patient characteristics were collected from patient records and were pseudonymised added to the database.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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