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#### **ORIGINAL ARTICLE**

### WILEY

## Evaluation of the psychometric properties of the endoscopic endonasal sinus and skull base surgery questionnaire (EES-Q) in a prospective cohort study

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Ellen ten Dam, Department of Otorhinolaryngology-Head and Neck Surgery, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands. Email: e.ten.dam@umcg.nl **Objectives:** The patients' perspective on health has become increasingly important when assessing treatment outcomes. Recently, the Endoscopic Endonasal Sinus and Skull Base Surgery Questionnaire (EES-Q) was developed to determine the impact of endoscopic endonasal surgery on health-related quality of life (HRQoL). The aim of this study was to evaluate the test-retest reliability, construct validity and responsiveness of the EES-Q.

Design: Prospective cohort study.

**Setting:** University Medical Center Groningen, tertiary referral hospital, the Netherlands.

**Participants:** One hundred patients who underwent endoscopic endonasal surgery because of sinus or anterior skull base pathology.

**Main outcome measures:** Test-retest reliability, construct validity and responsiveness. **Results:** The EES-Q domains exhibited good test-retest reliability (ICC > 0.90). Construct validity was corroborated by significant positive and negative correlations between the EES-Q and the Sino-Nasal Outcome Test-22 (SNOT-22) and postoperative health status (P < 0.01) respectively. The correlation between the social EES-Q domain and the ability to move and perform usual activities (EuroQol-5D-3L [EQ-5D-3L]) was significant positive (P < 0.01). In patients with paranasal sinus pathology, the EES-Q was responsive to clinical change (Cohen's d = 0.6).

**Conclusion:** The EES-Q is a reliable and acceptable responsive disease-specific HRQoL instrument. The expected construct validity of the EES-Q is supported by the results in this study. Inconveniences in social functioning had the greatest negative impact on postoperative health status rating. This reflects the importance of a multidimensional HRQoL assessment after EES. The results indicate that the EES-Q is a promising disease-specific tool for the HRQoL assessment after endoscopic endonasal sinus or anterior skull base surgery.

### 1 | INTRODUCTION

The primary cause of morbidity in endoscopic endonasal surgery (EES) is nasal trauma.<sup>1</sup> Nasal blockage and altered sense of smell are common patient-reported postoperative complaints.<sup>2</sup> The nasal function is often only temporarily changed after EES. However, the effect of EES on the patient's overall well-being or health-related quality of life (HRQoL) should not be underestimated.<sup>3,4</sup> Generally, HRQoL is described in a physical, psychological and social domain. This means that EES affects nasal functioning, the patient's psychological well-being and performance of daily activities.<sup>3</sup>

When evaluating treatment outcomes, the patients' perspective has become increasingly important.<sup>3,6</sup> Because the surgeon's impression of a patient's well-being may be inaccurate, it is essential to use HRQoL instruments to evaluate the patient-reported postoperative HRQoL.<sup>7</sup> Existing EES instruments are, however, not fully tailored to the HRQoL concept. Instruments are unidimensional or do not specifically assess nasal morbidity.<sup>1,8,9</sup> Other instruments are devised for patients with chronic rhinosinusitis,<sup>10</sup> skull base tumors<sup>11</sup> or malignant pathology.<sup>8</sup> In an effort to bridge that gap, the Endoscopic Endonasal Sinus and Skull Base Surgery Questionnaire (EES-Q) was developed.<sup>2</sup> The EES-Q is a disease-specific instrument encompassing a physical, psychological and social domain with a total of 30 items. The EES-Q proves to be a comprehensive and suitable tool to evaluate HRQoL after endoscopic endonasal sinus or skull base surgery. Excellent internal consistencies of the EES-Q health domains have been demonstrated.<sup>2</sup>

The purpose of this study was to evaluate the psychometric properties of the EES-Q in patients undergoing endoscopic endonasal sinus or skull base surgery.

#### 2 | MATERIALS AND METHODS

#### 2.1 | Ethical considerations

Formal approval was obtained from the institutional ethical review board of the University Medical Center Groningen before commencing.

#### 2.2 | Setting

Of the original cohort of 300 patients, 100 patients were selected.<sup>2</sup> Those 100 patients comply with the planned time period for the test-retest measure. In addition, they completed the 22-item Sino-Nasal Outcome Test (SNOT-22), the EuroQoI-5D-3L (EQ-5D-3L) and rated their postoperative health status 3 months postoperatively for the validity analysis.

#### 2.3 | Psychometric properties

#### 2.3.1 | Reliability

Reliability, referring to the extent to which an instrument is free of measurement error, was assessed by a test-retest design. Patients

#### **Keypoints**

- Multidimensional HRQoL assessment after endoscopic endonasal surgery is important.
- The endoscopic endonasal sinus and skull base surgery questionnaire (EES-Q) is a promising disease-specific tool for the HRQoL assessment after endoscopic endonasal sinus or anterior skull base surgery.
- The EES-Q is a reliable and acceptable responsive disease-specific HRQoL instrument and the expected construct validity of the EES-Q is supported by the results in this study.

completed the EES-Q three months postoperatively and again approximately 2 weeks later. For the retest measurement, the EES-Q was mailed to the patients 10 days after the 3-month postoperative assessment. Patients were asked to complete the instrument and send it back.

#### 2.3.2 | Validity

Validity, defined as the extent to which an instrument measures what it is supposed to measure, was evaluated by a specific variant of construct validity: convergent validity. This refers to the extent to which EES-Q scores relate to the following measures in a manner that is consistent with the theoretically derived hypothesis concerning the concept that is measured<sup>12,13</sup>: SNOT-22,<sup>10</sup> EQ-5D-3L<sup>14</sup> and the subjective postoperative health rating. The postoperative health status was rated as poor (1), moderate (2), good (3), very good (4), or excellent (5).

#### 2.3.3 | Responsiveness

Responsiveness, referring to the extent to which an instrument is able to detect and measure HRQoL changes after treatment,<sup>15</sup> was evaluated by comparing preoperative and 3-month postoperative EES-Q scores for both the patients with paranasal sinus and skull base pathology.

#### 2.4 | Instruments

# 2.4.1 | Endoscopic endonasal sinus and skull base surgery questionnaire

The EES-Q is a comprehensive, disease-specific instrument for patients undergoing endoscopic endonasal sinus or skull base surgery.<sup>2</sup> The EES-Q contains a physical, psychological and social domain, each with 10 items. Items are formulated as complaints or activities. Subjects are required to indicate which answer best fits the degree of inconvenience over the past 2 weeks on a five-point

#### TABLE 1 Descriptive statistics

Instrument	Domain	Mean (SD)
EES-Q	Physical	20.8 (18.9)
	Psychological	9.3 (15.4)
	Social	17.9 (23.5)
SNOT-22		19.1 (18.3)*
EQ-5D-3L		
Descriptive system		
	Mobility	20.8 (18.9)
	Self-care	9.3 (15.4)
	Usual activities	17.9 (23.5)
	Pain/discomfort	20.8 (18.9)
	Anxiety/depression	9.3 (15.4)
EQ-VAS		70.1 (14.8)*

The mean (SD) scores of the subdomains of the EES-Q, SNOT-22, and EQ-5D-3L at three months postoperatively are shown. EES-Q, Endoscopic Endonasal sinus and skull base Surgery Questionnaire; EQ-5D-3L, EuroQol five dimensions, three levels; EQ-VAS, EuroQol visual analogue scale; SD, standard deviation; SNOT-22, 22-item Sino-Nasal Outcome Test.

\*Completed by 99 patients instead of 100.

Likert response scale: not at all (1), mildly (2), moderately (3), severely and (4) very severely (5).<sup>2</sup>

#### 2.4.2 | Sino-nasal outcome test-22

The SNOT-22 is a disease-specific HRQoL instrument validated for patients with chronic rhinosinusitis. Patients are asked to rate 22 items as they have been experienced over the past 2 weeks: 0 = no problem; 1 = very mild problem; 2 = mild or slight problem; 3 = moderate problem; 4 = severe problem; 5 = problem as bad as it can be. The theoretical range of the total score is 0-110, with lower scores implying a better HRQoL.<sup>10</sup>

#### 2.4.3 | EuroQol-5D-3L

The EQ-5D-3L is a validated, generic health measure consisting of a descriptive system with five domains (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) with three levels: no, some, and extreme problems. The visual analogue scale (EQ-VAS) records the respondent's self-rated overall health with endpoints of 0 (worst imaginable health state) and 100 (best imaginable health state). This information was used as a quantitative measure of health as judged by the individual respondents.<sup>14</sup>

#### 2.5 | Statistical analysis

Endoscopic endonasal sinus and skull base surgery questionnaire domain scores were computed by summing the 10-item scores of each domain. To obtain a domain score ranging from 0 (no inconvenience) to 100 (very severely inconvenience), ten points were subtracted from the total and the resulting domain scores were then multiplied by 2.5. The maximum number of missing answers was three items per subject for each domain. Test-retest reliability was determined by computing the intraclass correlation coefficient (ICC) with 95% confidence intervals (CI) using a one-way random model (with subjects as random component).<sup>12</sup> For construct validity, the correlation between the EES-Q and the SNOT-22,<sup>10</sup> the EQ-5D-3L<sup>14</sup> and the postoperative health status was calculated using Spearman's correlation coefficient  $\rho$ . The correlation strength was considered as: 0.00-0.19 "very weak," 0.20-0.39 'weak'; 0.40-0.59 "moderate"; 0.60-0.79 "strong": 0.80-1.00 "very strong."<sup>16</sup> Responsiveness was assessed by calculating the effect size Cohen's d. An effect size of >0.2, >0.5 or >0.8, respectively, was considered as a small, moderate or large improvement in HRQoL.<sup>13</sup> A P value < 0.05 was considered statistically significant. The calculations were performed with IBM SPSS Statistics version 22.0 (SPSS IBM, Inc, Armonk, NY).

#### 3 | RESULTS

#### 3.1 | Patient-reported scores

Three months postoperatively, the mean (SD) scores for the physical, psychological and social EES-Q domain were, respectively, 20.8 (18.9), 9.3 (15.4) and 17.9 (23.5). The patient-reported total SNOT-22 score was 19.1 (18.3). The mean (SD) EQ-VAS value was 70.1 (14.8; Table 1). Most patients had no problems in walking about (77%) or with self-care (96%) and were not anxious (89%). Patients did experience some degree of pain (41%) and had problems when performing usual activities (34%). Ninety-three of 100 patients rated their postoperative health status as poor (3%), moderate (31%), good (40%), very good (15%) or excellent (4%). The other seven postoperative health status ratings were missing. Patient characteristics are summarised in Table 2.

#### 3.2 | Reliability

High test-retest reliability was supported by ICC's of 0.96, 0.90 and 0.93 for the physical, psychological and social EES-Q domain, respectively (Table 3).

#### 3.3 | Validity

#### 3.3.1 | Sino-nasal outcome test-22

There were significant positive correlations (P < 0.01) between the EES-Q domain scores and the total SNOT-22 score (Table 4). The correlation with the total SNOT-22 score was very strong for the physical domain ( $\rho = 0.80$ ), strong for the psychological domain ( $\rho = 0.62$ ), and moderately strong for the social domain of the EES-Q ( $\rho = 0.50$ ).

#### 3.3.2 | EuroQol-5D-3L

There were significant positive correlations (P < 0.01) between the EES-Q domain scores and the EQ-5D-3L domains, except for the

#### **TABLE 2** Patient characteristics

	Pathology		
Characteristic n (%)	Paranasal sinuses (n = 72)	Anterior skull base (n = 28)	
Gender			
Male	39 (54.2)	17 (60.7)	
Female	33 (45.8)	11 (39.3)	
Mean (SD) age (in years)	50.9 (13.9)	58.4 (10.7)	
ASA			
I	21 (29.2)	6 (21.4)	
II	41 (56.9)	16 (57.1)	
III	10 (13.9)	3 (10.7)	
History of EES	46 (63.9)	8 (28.6)	
Diagnosis			
Pituitary adenoma	na	28 (100)	
Chronic rhinosinusitis	57 (79.2)	na	
Mucocele	7 (9.7)	na	
Inverted papilloma	4 (5.5)	na	
Other <sup>a</sup>	4 (5.5)	na	
Type of surgery			
Transsphenoidal approach	na	28 (100)	
Limited FESS <sup>b</sup>	18 (25.0)	na	
Extended FESS <sup>b</sup>	48 (66.7)	na	
Medial maxillectomy II-III	6 (8.3)	na	
Complications			
CSF leakage	na	1 (3.6)	
Nosebleed	2 (2.8)	na	
Other <sup>c</sup>	2 (2.8)	na	
Re-operation	2 (2.8)	1 (3.6)	

ASA, American society of anaesthesiologists; CSF, cerebrospinal fluid; EES, endoscopic endonasal surgery; FESS, functional endoscopic sinus surgery; na, not applicable; SD, standard deviation.

<sup>a</sup>Other includes planocellular carcinoma (2), low-grade adenocarcinoma (1), juvenile angiofibroma (1).

<sup>b</sup>FESS was divided into limited (infundibulotomy, ethmoidectomy, Draf I) and extended (sphenoidectomy, Draf II, Draf II).

<sup>c</sup>Other includes burn nasal vestibule (1), bradycardia during surgery (1).

domain "self-care" (Table 4). A strong correlation was observed between the social EES-Q domain and "performing usual activities" ( $\rho = 0.78$ ).

#### 3.3.3 | Postoperative health status rating

There were significant negative correlations (P < 0.01) between the EES-Q domain scores and postoperative health status rating (Table 4). The correlation with the postoperative health status was strong for the social domain ( $\rho = -0.66$ ), and moderately strong for the physical ( $\rho = -0.45$ ) and psychological domain ( $\rho = -0.58$ ).

TABLE 3 Test-retest reliability of the EES-Q

	Mean (SD)			
EES-Q	3 mo postop- eratively	3 mo + 2 wk postopera- tively	ICC	95% Cl
Physical	20.8 (18.9)	18.8 (18.2)	0.96	(0.94-0.97)
Psychological	9.3 (15.4)	8.5 (13.0)	0.90	(0.87-0.94)
Social	17.9 (23.5)	16.7 (21.8)	0.93	(0.89-0.95)

CI, confidence interval; EES-Q, Endoscopic Endonasal Sinus and Skull Base Surgery Questionnaire; ICC, intraclass correlation coefficient; SD, standard deviation.

#### 3.4 | Responsiveness

For patients with paranasal sinus pathology, there was a statistically significant decrease (P < 0.01, t = 3.3) in EES-Q score at three months postoperatively. The effect size is moderate (Cohen's d = 0.4; Table 5). For patients with anterior skull base pathology, the 3 months postoperative EES-Q score is almost equal to the preoperative EES-Q score (effect size 0).

#### 4 | DISCUSSION

#### 4.1 | Key findings

Our study demonstrates that the EES-Q is a reliable and acceptable responsive disease-specific HRQoL instrument for the HRQoL assessment of after endoscopic sinus or anterior skull base surgery. The construct validity of the EES-Q is supported by the results of this study. The impact of inconveniences in social functioning on postoperative health status rating reflects the importance of a multidimensional HRQoL assessment after EES.

#### 4.2 | Strengths of the study

HRQoL instruments should meet three measurement criteria: reliability, validity and responsiveness.<sup>12</sup> For the EES-Q, excellent internal consistency was already demonstrated with Cronbach's a exceeded 0.80 for all domains, which is adequate for clinical purposes.<sup>2,17</sup> The high testretest correlations (ICC > 0.90 for all domains) provide evidence of instrument stability. Convergent validity was demonstrated by applying the SNOT-22.10 A strong positive correlation did appear between the physical EES-Q domain and the SNOT-22. This is not surprising, since both instruments contain five identical items: "blocked nose," "need to blow nose," "facial pressure," "waking up tired," and "sense of taste/ smell." An increase in level of complaints was associated with a higher SNOT-22 score, implying poorer HRQoL. The correlation between the social EES-Q domain and the SNOT-22 was moderately strong. This can be explained by the absence of domains in the SNOT-22. Actually, the social EES-Q domain may only cover the item "reduced productivity" of the SNOT-22. No correlation was found between the EES-Q domains and the self-care domain of the EQ-5D-3L.<sup>14</sup> Indeed, 96% of the patients

**TABLE 4**Construct validity(Spearman's rho correlation coefficients)of the EES-Q

		EES-Q		
Instrument	Domain	Physical	Psychological	Social
SNOT-22		0.80*	0.62*	0.46*
EQ-5D-3L	Mobility	0.29*	0.31*	0.50*
	Self-care	0.00	0.09	0.15
	Usual activities	0.35*	0.43*	0.78*
	Pain/discomfort	0.45*	0.43*	0.37*
	Anxiety/depression	0.40*	0.49*	0.44*
Postoperative health rating		-0.45*	-0.58*	-0.66*

EES-Q, Endoscopic Endonasal Sinus and Skull Base Surgery Questionnaire; EQ-5D-3L, EuroQol five dimensions, three levels; SNOT-22, 22-Item Sino-Nasal Outcome Test. \*P < 0.01.

#### TABLE 5 Responsiveness of the EES-Q Mean (SD) for patients with paranasal sinus and anterior skull base pathology 3 mo Mean (SD) preoperatively postoperatively difference t Cohen's d PS group 75.9 (44.0) 49.0 (47.9) 26.9 (66.1)\* 3.3 0.4 (n = 72)SB group 50.5 (41.5) 49.6 (51.2) 0.9 (60.4) 0.1 0.0 (n = 28)

PS group, paranasal sinus group; SB group, skull base group. \*P < 0.01

reported no problems with self-care. This confirms the elimination of "grooming" (ie bathing, dressing) during the EES-Q development.<sup>2</sup> A strong positive correlation was observed between the social EES-Q domain and the domain "carrying out usual activities" of the EQ-5D-3L. Inconveniences in social functioning were associated with the largest decrease in postoperative health status rating, while the correlation between physical functioning and postoperative health status was only moderately strong. A possible explanation could be that subjective impairment in carrying out activities is the indirect effect of physical complaints, which results in a choice to function at a lower level.<sup>18</sup> In addition, when asked which features of life make the most important contribution to quality of life, relatively "healthy" individuals (our study participants) are likely to say "my social and family life, my work."<sup>12</sup>

The importance of using multidimensional HRQoL instruments is highlighted in this study. As far as we know, the EES-Q is the first disease-specific outcome measure evaluating all three HRQoL domains after EES. This multidimensionality makes the EES-Q a practical instrument. The advantage of using the EES-Q is that it circumvents the need to use a generic HRQoL instrument as a supplement to evaluate all different HRQoL aspects relevant for patient undergoing endoscopic endonasal sinus or skull base surgery.

#### 4.3 | Comparisons with other studies

The present study confirms that patients with anterior skull base pathology have, compared to patients with paranasal sinus pathology, a better sinonasal HRQoL preoperatively.<sup>4,5</sup> As in the studies of McCoul et al,<sup>19,20</sup> we demonstrates that EES does not have a detrimental long-term effect on HRQoL in patients with anterior skull base lesions. As expected, the HRQoL is decreased in the early post-operative period after which the HRQoL improves.<sup>19,20</sup> Three months postoperatively, a the EES-Q score of the anterior skull base patients was almost equal to the preoperative EES-Q score. Therefore, in anterior skull base patients the postoperative improvement in HRQoL (responsiveness) can't be as great as in paranasal sinus patients.

#### 4.4 | Drawbacks

The Anterior Skull Base QoL Questionnaire (ASBQ)<sup>8</sup> is a frequently used instrument to study the effect of EES on HRQoL. This instrument was not included in our construct validity analysis because the ASBQ is validated for use in open skull base surgery. Moreover, it does not specifically assess nasal morbidity, which is one of the key sources of morbidity after EES.<sup>1,4</sup> In addition, the ASBQ is not designed for benign pathology, yet pituitary adenomas are among the most common types of benign tumours treated by neurosurgeons. De Almeida et al<sup>11</sup> developed the Skull Base Inventory (SBI) to differentiate between HRQoL for different skull base tumours and their surgical treatment (endoscopic vs open approaches). Although the SBI contains a few items assessing nasal morbidity, many more items are related to endocrine fluctuations after pituitary surgery. Aim of our study was to develop

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and validate a disease-specific HRQoL instrument to assess the impact of EES on nasal morbidity. A limitation of our study could be that only the SNOT-22<sup>10</sup> and EQ-5D-3L<sup>14</sup> are used for the construct validity analysis. However, since there is no "gold standard" available for comparison with the EES-Q, together with the mentioned limitations of the ASBQ<sup>8</sup> and SBI,<sup>11</sup> we choose to use the SNOT-22.<sup>10,21</sup> The SNOT-22 has not been validated for skull base pathology or sinonasal neoplasms but is a widely used instrument focusing on nasal morbidity, also in skull base studies.

We choose to evaluate the psychometric properties of the EES-Q with a subgroup of 100 patients of the original cohort, instead of a separate cohort, because it is appropriate to evaluate the EES-Q in this manner. In addition, a separate cohort might have caused delay in collecting the data and the possibility to evaluate the psychometric properties. Our choice for 100 participants in this study is because for the type of analysis we performed this number is sufficient to reach precise estimates for the statistical coefficients. This can be observed in Table 3 were the confidence intervals of the ICC's are quite narrow. This is largely due to the fact the three EES-Q domains are constructed as scores based on 10 summated items.

Of the 100 patients used in this study, 28 patients were diagnosed with a pituitary adenoma. In the development and the construction of the EES-Q, appropriate item selection was performed.<sup>2</sup> Therefore, the content of the EES-Q (ie the domains and the items) reflects the complaints that may arise after EES, regardless of the underlying diagnosis or the extent of surgery.<sup>2</sup> Patients undergoing EES may have different underlying pathology, however they are all operated by the endoscopic endonasal approach. We assume the EES-Q is suitable for the evaluation of HRQoL in all patients undergoing EES, however, further research is necessary to confirm this.

#### 4.5 | Clinical applicability

In our hospital, the EES-Q is used for HRQoL monitoring in all patients undergoing EES. In the future, it could be used to evaluate the impact of the extent of EES (eg, limited versus extended endoscopic sinus surgery, or anterior skull base reconstruction with or without nasoseptal flap harvesting). Similarly, the tool could be used to compare symptom severity between different patient groups (eg, chronic rhinosinusitis versus pituitary adenoma). Follow-up studies evaluating HRQoL one year after EES for different pathologies are forthcoming.

#### 5 | CONCLUSION

The EES-Q is a reliable and acceptable responsive disease-specific HRQoL instrument. The expected construct validity of the EES-Q is supported by the results in this study. The EES-Q is the first disease-specific outcome measure that evaluates all three HRQoL domains relevant for patients undergoing EES. The impact of inconveniences in social functioning on postoperative health status rating reflects the importance of a multidimensional HRQoL assessment after EES.

The results indicate that the EES-Q is a promising disease-specific tool for the HRQoL assessment after endoscopic endonasal sinus or anterior skull base surgery.

#### CONFLICT OF INTEREST

None.

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