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RHINOLOGY

Moroccan adaptation and validation of the rhinosinusitis quality-of-life survey

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Abstract The aim of this study was to validate the Moroccan translation and sociocultural adaptation of the RhinoQOL questionnaire. The questionnaires were translated into Moroccan and then translated back into English. The final version was administered twice to an asymptomatic control population ($n = 50$) and once to a patients with chronic rhinosinusitis (CRS) undergoing functional endoscopic sinus surgery (FESS) ($n = 99$). Both of the groups answered the questionnaire before and one year after surgery. The psychometric properties, reliability, validity with correlation to other clinical instruments and responsiveness to treatment, were analyzed. Univariate and multivariate analyses were performed. The test–retest reliability was excellent [intraclass correlation coefficient (ICC) >0.9], indicating a good reliability when administering the instrument on repeated occasions. The internal consistency was 0.80, 0.75 and 0.94 for the scores of the RhinoQOL sub-scales (frequency, bothersomeness, and impact, respectively). Firstly, our questionnaire was able to detect differences between patients with CRS and group of healthy volunteers ($p < 0.0001$) and secondly, it improved significantly after surgery ($p < 0.0001$), indicating a good responsiveness. A good correlation was found between the Moroccan version, the preoperative objective scores, and SNOT-22 and RSDI scores. The Moroccan RhinoQOL questionnaire appears to be culturally appropriate and psychometrically valid.

Keywords Moroccan language · Validation · Chronic rhinosinusitis · Endoscopic surgery · Quality of Life

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Abbreviations

RQLQ	Rhinoconjunctivitis quality of life questionnaire
SS	Sinusitis survey
F	Fairley's symptom questionnaire
CST	Chronic sinusitis type specific questionnaire
CSS	Chronic sinusitis survey
RSOM	Rhinosinusitis outcome measure
RSDI	Rhinosinusitis Disability Index
RSI	Rhinosinusitis Symptom Inventory
SNOT-20	Sinonasal Outcome Test-20
SNOT-16	Sinonasal Outcome Test-16
RSUI	Rhinitis Symptom Utility Index
SNAQ	Sinonasal assessment questionnaire
SN5	Five-item sinus and nasal quality of life survey
Col	Cologne questionnaire
SNOT-22	Sinonasal Outcome Test-22

Background

In today's world, chronic rhinosinusitis (CRS) represents a significant health, social and economic problem. The significance of CRS is believed to be rising in terms of both incidence and prevalence. It is comparable to diabetes and heart disease [1, 2]. In the United States, epidemiological data show that the CRS affects 14–15% of the adult, higher than other common chronic diseases like arthritis and hypertension. While in Europe, it has been reported to affect 5–15 % of urban populations [1]. A large European multicentre study has shown that CRS has an overall prevalence of 10.9% with substantial regional variation [3]. On the other hand, the socio-economical impact of CRS is significant in terms of healthcare costs, loss of work productivity and absenteeism [4]. The 2007 Medical Expenditure Panel

Survey suggests a national spending average on CRS approaching $8.6 billion per year [3]. Recently, the diagnosis of CRS was based on the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS 2012) [5]. It is defined as: inflammation of the nose and the paranasal sinuses characterized by two or more symptoms, one of which should be either nasal blockage/obstruction/congestion or nasal discharge (anterior/posterior nasal drip) ± facial pain/pressure, ± reduction or loss of smell; and either endoscopic signs of polyps and/or mucopurulent discharge primarily from middle meatus and/or edema/mucosal obstruction primarily in middle meatus and/or CT changes showing mucosal changes within the ostiomeatal complex and/or sinuses. CRS symptom must have been present for more than 12 weeks [5]. Furthermore, functional endoscopic sinus surgery (FESS) became the worldwide standard surgical procedure for CRS refractory to medical therapy and the success rate was between 67 and 97.5% [6]. Over the last two decades, disease-specific instruments which measure symptoms and health-related quality of life (HRQOL) have been develop to assess the impact of treatments for patients with CRS. There are numerous scoring systems to subjectively assess CRS impact and associated incapacity, including the Rhinosinusitis Outcome Measure (RSOM-31) [7], the Rhinosinusitis Disability Index (RSDI) [8], the Chronic Sinusitis Survey (CSS) [9], the Sinonasal Outcome Test (SNOT20 , SNOT22) [10, 11] and the Rhinosinusitis quality of life survey (RhinoQoL) [12, 13]. All this frequently used validated questionnaires are available only in English [14]. The RhinoQOL is one of the most frequently used tools for determining QOL outcomes in patients treated for CRS [12, 13]. It has been translated and validated in several languages, including French [15], and Portuguese [16] but not in Moroccan. There is a critical need for a standardized QOL measure adapted to this population. In the present study, we prepared a Moroccan Arabic version of the RhinoQOL and studied the reliability and validity of this version with the participation of Moroccan-speaking patients with CRS. Also, we reported the impact of preoperative factors on these outcomes for better surgical case selection.

Materials and methods

Translation and cultural adaptation of the RhinoQOL

After getting the author's permission to translate and culturally adapt the questionnaire, it was translated according to standard procedures [17, 18]. The RhinoQOL was first translated independently by two translators into the Moroccan Arabic dialect. The draft was created and reviewed by two ENT specialists for medical viewpoint. Next, the questionnaire was re-converted into English by two independent English native-speakers. Translations were compared to each other to check that they had the same semantic value and to establish the final version of the questionnaire.

Assessment of reliability and validity

Study design and inclusion–exclusion criteria

The participants were prospectively recruited from the tertiary care center at the Department of ENT, 20 August Hospital, Ibn Rochd University Hospital (Casablanca, Morocco). The study included 99 patients with CRS, who underwent FESS between January 2013 and December 2014, when medical treatment failed. Informed written consent was obtained in advance from all patients included in this study, which was approved by the hospital's Ethics Committee. The diagnosis of CRS was defined by the EPOS [5]. Prior to enrollment, all subjects had previously failed to medical management defined as a minimum of a 3-week course of broad-spectrum antibiotics (amoxicillin 500 mg + clavulanate 125 mg twice a day), a minimum of a 3-month trial of topical nasal corticosteroid sprays (budesonide or fluticasone, 200 µg/day) and a 5-day trial of systemic steroid therapy (deflazacort, 1 mg/kg of weight per day). Treatment modality selection was not randomized or assigned for study purposes at any time point. The surgical procedures were performed along the guidelines described by Messerklinger and Stammberger with modifications from Wigand [19]. Postoperatively, all patients were given short course of antibiotic (amoxicillin–clavulanic acid 875 mg twice daily) for one week. Nasal saline douching was given for one month and topical nasal corticosteroid (Fluticasone 100 mcg both nostrils once daily) was started 15 days after surgery and continued if necessary. During follow-up, nasal suctioning was done, crusts were removed and nasal cavity was examined for any synechiae formation for 4 weeks. Enrollment criteria included: age ≥18 years; CRS with nasal polyps (CRSwNP) or without nasal polyps (CRSsNP) refractory to medical therapy and undergoing FESS; preoperative CT scan of the paranasal sinuses; and a postoperative follow-up of 1 year. Exclusion criteria were: patients with benign/malignant tumor; mucocèle; antrochoanal polyp; chronic diseases (diabetes, tuberculosis, HIV/SIDA) and patients with a follow-up time less than 1 year.

Control group

The control group comprised 50 healthy adult (older than 18 years) volunteers, with no history or current nasal sinus

disease, who were randomly selected prospectively in the same department. Scores of the control group were compared to scores obtained before surgery by the study group subjects who underwent FESS.

Test–retest study

All participants completed the Moroccan version of the RhinoQOL, the RSDI and the SNOT-22 questionnaires before surgery and one year after FESS. The test–retest reliability was carried out in patients with CRS, by employing RhinoQOL questionnaire twice, during routine visits of the patient before surgery. The retest examination was carried out after 15 days. Patients with acute change of symptoms due to common cold/respiratory tract infection during the period between completing the test–retest questionnaire were excluded from the study.

RhinoQOL questionnaire

The RhinoQOL questionnaire is aimed at patients with CRS. It is characterized by analyzing the rhinologic signs and its ability to assess the impact of CRS on the different areas of diurnal and nocturnal QOL. The RhinoQOL is a brief and easy-to-use rhinosinusitis-specific questionnaire with strong psychometric characteristic [12, 13]. This instrument included 17 items, divided in 3 domains: symptom frequency (5 items: Q1–Q5), symptom bothersomeness (3 items: Q1a–Q3a), and symptom impact (9 items: Q6–Q14). For the symptom frequency and impact questions, the patient has five possible responses graduated as follows: (0 = 'never', 1 = 'a few times', 2 = 'some of the time', 3 = 'most of the time', 4 = 'always'). While for the symptom bothersomeness questions, the answers are ranging from 0, meaning "not bothered at all", to 10, meaning "bothered a lot", for each of its three items. The psychometric evaluation was performed separately for RhinoQOL symptom frequency, bothersomeness, and impact scales. The result for each sub-scale score ranges from 0 to 100 with higher scores indicating better health status. Therefore, the final symptom frequency, final symptom bothersomeness and final symptom impact scores are measured as follows: [100 − (Frequency * 5)]; [100 − (Bothersomeness * (10/3))] and [100 − (Impact * (100/36))], consecutively.

Statistical procedure

Descriptive statistics were drawn up on the data; the mean was found for quantitative variable and the percentage for qualitative variable. All the statistical analysis was carried out using statistical package SPSS 20.0. The normal distribution was assessed using Shapiro–Wilk test and skewness kurtosis z values. We analyzed the internal consistency and test–retest reliability of the Moroccan version of the RhinoQOL. Coefficient alpha index (Cronbach's alpha) is used to represent and evaluate internal consistency for ordinal responses. The minimum acceptable value is 0.7 [20]. For the RhinoQOL questionnaire test–retest reliability analysis, the statistical test used was the intraclass correlation coefficient (ICC) between the RhinoQOL scores: at time 1 (RhinoQOL preoperative 1) and time 2: 2 weeks after (RhinoQOL preoperative 2). Construct validity is the degree to which the RhinoQOL measures the theoretical construct that is intended to measure, and includes convergent and discriminant or divergent validity. Convergent validity was assessed by comparing the scores of three questionnaires (RhinoQOL, SNOT-22 and RSDI) in the two populations: patients with CRS and healthy volunteers. A convergent validity was assessed because we desired to see how closely the RhinoQOL was related to other specific rhinologic questionnaires (SNOT-22 and RSDI). Discriminant validity, which is the ability to discriminate between known groups, was determined by comparing two groups: patients with CRS and healthy volunteers. The unpaired Mann–Whitney U test was used to determine if the questionnaire could detect a difference between healthy volunteers and patients with CRS. Concurrent validity was assessed by comparing the preoperative RhinoQOL score (at time 1) with two preoperative objective scores: endoscopic Lund–Kennedy and CT scan Lund–Mackay scoring systems. The responsiveness of the questionnaire was assessed by comparing the RhinoQOL scores before and after surgery to detect if there are significant clinical changes after surgical intervention. Responsiveness can also be assessed by measuring the magnitude of the effect, which is the mean value of the scores' variation divided by the standard deviation of the initial values. By convention, an effect magnitude between 0.2 and 0.5 is considered a mild improvement; between 0.5 and 0.8, moderate improvement; and greater than 0.8, a great improvement in quality of life [21]. Stepwise method was chosen for multiple regression models. A p value under 0.05 (5%) was considered statistically significant for all analyses.

Results

Translation and cultural adaptation

Appendix shows the Moroccan version of RhinoQOL questionnaire. Patients and healthy subjects did not encounter any difficulties in filling out the Moroccan translation of the questionnaire. The mean time required to complete the questionnaire was approximately 5.5 min (range 5–6 min).

Participant characteristics

Consecutive series of 120 adults having a CRS and 50 healthy volunteers were recruited. Only 99 patients completed the study, whereas 21 patients were excluded because they were lost to follow-up (17%). For the patients with CRS, 44 (44.4%) were male, and 55 (55.6%) were female. Mean age was 38.63 ± 12.83 years (range 13–73 years). Fifty-four patients suffered from CRSwNP. Eight patients had undergone previous surgery. Asthma was reported by 20 patients, and aspirin sensitivity was present in 10.1%. Seven patients presented Widal's syndrome. The overall mean of Lund–Mackay scoring and Lund–Kennedy scoring was 13.85 (SD 8.17) and 6.89 (SD 3.75), respectively. For the healthy volunteers, the mean age was 35.16 ± 13.29 years and the sex ratio was 0.85 (23 male and 27 female). There was no significant difference, in age and gender, between patients with CRS and control groups.

Reliability

Internal consistency was high, with a Cronbach's alpha value superior to 0.7 for all sub-scales at initial and retest examination. Also, the test–retest reliability was excellent (Table 1).

Validity

A high statistically significant correlation was observed between the RhinoQOL, SNOT-22 and RSDI scores (Table 2). For the concurrent validity, comparisons were made between the RhinoQOL and the objectives findings for nasal cavities. First, the correlation was obtained between the symptom frequency $r = -0.494$, symptom impact $r = -0.718$ and symptom bothersomeness $r = -0.470$ scores and the Lund–Kennedy endoscopic scores. Next, the correlation between the symptom frequency, symptom impact and symptom bothersomeness scores and the CT scan Lund–Mackay scores showed Spearman $r = -0.523$, $r = -0.687$ and $r = -0.443$, respectively. The two preoperative objective scores were highly correlated with the RhinoQOL ($p < 0.001$).

Discriminant validity revealed that each sub-scale of the RhinoQOL was able to highly discriminate between patients with CRS and healthy volunteers. It was [48.59 (Interquartile range (IQR) = 30) versus 88.50 (IQR = 10), Mann–Whitney U test, $p < 0.0001$], [35.07 (IQR = 44) versus 93.00 (IQR = 8), Mann–Whitney U test, $p < 0.0001$] and [48.62 (IQR = 27) versus 94.60 (IQR = 17), Mann–Whitney U test, $p < 0.0001$] for the frequency, impact and bothersomeness scores, consecutively.

Responsiveness at 1 year

Scores on each scale at baseline, and 1-year postoperative follow-up are shown in Table 3. Scores increased significantly from baseline to 1-year postoperative follow-up on all sub-scale scores, indicating clinical improvement. Furthermore, at 1 year, the effect size in all patients was superior to 0.8. This indicates high sensitivity to change for all three RhinoQOL sub-scales (Table 3).

Predictive factors

The multivariate logistic regression model examined 11 predictive factors that may affect QOL improvement: age, gender, prior sinus surgery, asthma, ASA intolerance, nasal polyp status, Lund–Kennedy endoscopic score, Lund–Mackay CT scan score, and the three RhinoQOL sub-scales. Of the various predictors proposed in the study, first for symptom frequency scale, preoperative symptom frequency score ($b = -0.887$, $p < 0.05$) and nasal polyposis ($b = -9.650$, $p < 0.05$) had a negative significant impact on the QOL outcomes; these two factors were thought to indicate a poor prognosis after FESS. Two other factors including preoperative symptom impact score [B coefficient (b) = 0.253, $p < 0.05$] and ASA intolerance ($b = 7.614$, $p < 0.05$) had a positive relationship with the absolute change value of QOL score and thought to have a good prognosis after FESS. This model was able to explain 59.6% of the change in symptom frequency score ($R^2 = 0.596$ and adjusted $R^2 = 0.579$). There was no collinearity within our data [variance inflation factors (VIF) <10, tolerance statistics <0.1]. Secondly, according to symptom bothersomeness scale, nasal polyps ($b = -8.856$,

Table 1 Cronbach's alpha scores and test–retest reliability for the RhinoQOL and its sub-scales

RhinoQOL	Cronbach's alpha (α)			ICC
	Preoperative 1	Preoperative 2	Postoperative	
Symptoms frequency	0.804	0.791	0.776	0.992
Symptoms impact	0.943	0.938	0.961	0.998
Symptoms bothersomeness	0.755	0.726	0.724	0.995

ICC intraclass correlation coefficient, *RhinoQOL* rhinosinusitis quality of life survey

Table 2 Correlation between the Moroccan RhinoQOL score and other scores (SNOT-22 and RSDI)

Disease-specific QOL	SNOT-22, *r* (*p*)	RSDI, *r* (*p*)	Symptoms frequency, *r* (*p*)	Symptoms impact, *r* (*p*)
SNOT-22	–	–	–	–
RSDI	0.786 (<0.001)	–	–	–
Symptoms frequency	−0.842 (<0.001)	−0.697 (<0.001)	–	–
Symptoms impact	−0.921 (<0.001)	−0.705 (<0.001)	0.679 (<0.001)	–
Symptoms bothersomeness	−0.865 (<0.001)	−0.747 (<0.001)	0.920 (<0.001)	0.714 (<0.001)

SNOT-22 22-item Sino-Nasal Outcome Test, *RSDI* Rhinosinusitis Disability Index, *RhinoQOL* rhinosinusitis quality of life survey, *r* Spearman correlation coefficient

Table 3 Mean change in QOL scores after FESS

Disease-specific QOL	Preoperative 1 (mean ± SD)	Postoperative (mean ± SD)	Absolute Δ (mean ± SD)	*p*	Effect size
SNOT-22	56.37 ± 22.581	29.27 ± 21.079	27.10 ± 14.396	<0.001	1.20
RSDI	77.60 ± 21.077	38.16 ± 21.801	39.43 ± 17.252	<0.001	1.87
RhinoQOL					
Symptoms frequency	48.59 ± 18.476	79.90 ± 15.269	31.31 ± 16.438	<0.001	1.69
Symptoms impact	35.07 ± 22.729	64.14 ± 26.445	29.07 ± 15.539	<0.001	1.28
Symptoms bothersomeness	48.62 ± 18.177	79.09 ± 15.422	30.47 ± 15.837	<0.001	1.68

SNOT-22 22-item Sino-Nasal Outcome Test, *RSDI* Rhinosinusitis Disability Index, *RhinoQOL* rhinosinusitis quality of life survey, *SD* standard deviation, Δ absolute change value of RhinoQOL, SNOT-22 and RSDI scores (between preoperative 1 and postoperative), *FESS* functional endoscopic sinus surgery, *QOL* quality of life, *Effect size*: (Mean preoperative 1 − Mean 6-month)/SD baseline

$p < 0.05$) and preoperative symptom bothersomeness score ($b = -0.866$, $p < 0.005$) were able to predict a poor prognosis after surgery. On the other hand, preoperative symptom impact score ($b = 0.232$, $p < 0.05$) was a positive preoperative predictor. This model was able to explain 54.2% of the change in symptom bothersomeness score ($R^2 = 0.542$ and adjusted $R^2 = 0.527$). There was no collinearity within our data (VIF < 10, tolerance statistics <0.1). Lastly for symptom impact scale, there were no factors retained for clinically significant improvement.

Discussion

Actually, the use of disease-specific questionnaires adds valuable information to scientific knowledge. There are over 15 known disease-specific sinonasal outcome questionnaires in English (Abbreviations) [1]. But, to be of use in other countries and cultures, these questionnaires require rigorous translation and revalidation [22]. Until now, it has not been possible to measure CRS patients' symptom severity and health-related QOL in a Moroccan context because of the lack of a Moroccan standardized questionnaire. Among these specific rhinologic questionnaires, RhinoQOL showed strong psychometric characteristics than other questionnaires, and it is already validated in the English [12, 13], Portuguese [16], and French languages [15]. This was the main reason for choosing RhinoQOL for validation in Moroccan language. In this study, the original English version of the RhinoQOL was translated into the Moroccan language, and a validation study was conducted using this Moroccan version to assess its feasibility, reliability and validity. Results indicate that this questionnaire has good internal consistency and construct validity compared to the original instrument. The internal consistency of the Moroccan RhinoQOL was analyzed in our study. It refers to the way in which the items relate to each other within an instrument. In our study, Cronbach's alpha was superior to 0.7 at initial and retest examinations suggesting good internal consistency within the Moroccan version (Table 1). These findings are very similar to those presented by other authors [12, 13, 15, 16]. In all studies, the Cronbach's α coefficient of the frequency and bothersomeness was slightly lower than the impact sub-scale, because the main patient complaint was the nasal obstruction (Table 4). Test–retest reliability reflects stability over time with repeated testing. It is evaluated by correlating initial test and subsequent retest scores [2]. In this study, it was assessed by measuring intraclass correlation coefficient (ICC) between the RhinoQOL scores at time 1 (RhinoQOL preoperative 1) and at time 2 (15 days after: RhinoQOL preoperative 2) for the same population with CRS. The ICC considers not only the strength of the correlation but also systematic variations; therefore, it is more rigorous than Pearson correlation coefficient r [23]. In the present study, we analyzed the capacity of the

Table 4 RhinoQOL data of our study and other authors

	RhinoQOL sub-scales	English study [10, 11]	Portuguese study [14]	French study [13]	Moroccan study
Cronbach's alpha (α)	Symptoms frequency	0.68	0.77	0.57	0.80
	Symptoms impact	0.89	0.88	0.83	0.94
	Symptoms bothersomeness	0.57	0.56	0.67	0.75
Intraclass correlation coefficient	Symptoms frequency	0.57	–	–	0.992
	Symptoms impact	0.67	–	–	0.998
	Symptoms bothersomeness	0.66	–	–	0.995
Effect size	Symptoms frequency	1.9	1.07	0.9	1.69
	Symptoms impact	2.4	0.88	1.1	1.28
	Symptoms bothersomeness	2.0	1.39	0.7	1.68

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questionnaire to produce different scores between CRS patients and the control group with the Mann–Whitney test, which showed significant difference between the two groups ($p < 0.0001$). Then the Moroccan version of RhinoQOL can differentiate between patients with CRS and healthy participants. Moreover, the RhinoQOL demonstrated strong correlation with the other specific rhinologic questionnaires (SNOT-22 and RSDI). Also, there was good correlation with the Lund–Mackay scores and the Lund–Kennedy endoscopic scores, although in many studies, results show a lack of correlation between patient-rated measures of symptom severity in CRS and objective measures [5]. All previous studies have reported that the magnitude of the surgery effect was moderate or high, which was considered a great improvement in QOL. The Moroccan version of the RhinoQOL has an excellent responsiveness after surgery. The magnitude of the effect of the surgery after 1 year was considered high ($r > 0.8$) (Tables 3, 4). Multiple study was found that patients with nasal polyposis had worst QOL evolution after surgery. Several authors have described nasal polyps to have a significant negative impact on QOL of patients and less improvement after surgery [24]. While preoperative symptom impact score was found to have a positive significant impact in both symptom bothersomeness scale and symptom frequency scale outcomes after FESS. Moreover, it is surprising that preoperative frequency scale and preoperative bothersomeness scale can predict a negative significant outcome after FESS in symptom frequency scale and symptom bothersomeness scale successively. The strength of this study are the prospective nature of data collection, the use of a properly adapted and validated assessment instrument (RhinoQOL), a low rate of lost patients, the use of control group, the follow-up of one year and the standardized translation and public involvement ensured the appropriate cultural adaptation. This study has several minor limitations that should be acknowledged. First, the patient population with CRS was obtained from a tertiary care center. Second, the sample size was small and the study of both CRS categories (with and without nasal polyps). Finally, due to the absence of a group that compares surgery to medical therapy, there was no evaluation of the score for medical treatment.

Conclusion

Research on QOL is gaining more weight within otolaryngology. The use of a reliable outcome measure is a necessity in all research. The Moroccan version of the RhinoQOL is a valid instrument for assessing patients with CRS. It demonstrated good internal consistency, reproducibility, validity, and responsiveness. It was found to be responsive to clinical change, and also useful to measure the outcome of FESS.

Compliance with ethical standards

Informed written consent was obtained in advance from all patients included in this study, which was approved by the hospital's Ethics Committee. This manuscript is not a research involving human participants and/or animals

Conflict of interest The authors declare that they have no competing interests.

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