

Prospective, comparative, cohort study comparing the rhinogram, Sino-Nasal Outcome Test-20 and Heath-Related Quality of Life questionnaire

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Abstract

Background: Many outcome measures exist for rhinosinusitis. However, few are used in the clinical setting due to their long completion times.

Objective: To assess the validity, reliability and responsiveness of the rhinogram, compared with two validated rhinosinusitis outcome measures: the Sino-Nasal Outcome Test-20 and the Heath-Related Quality of Life questionnaire.

Methods: Fifty-one patients were entered into a prospective, comparative, cohort study using all three outcome measures one week pre-operatively and three months post-operatively. Outcome scores were then correlated using non-parametric Spearman's rank correlation and chi-square testing for the diagnostic criteria of all three outcome measures.

Results: Statistically significant correlations were found between all three outcome measures for all symptom scores, individually as well as combined ($p < 0.01$ for all calculations). Comparison of the diagnostic accuracy of the rhinogram, compared with the Sino-Nasal Outcome Test-20 and the Heath-Related Quality of Life questionnaire, showed statistical significance ($p < 0.05$; chi-square test).

Conclusion: The rhinogram is a reliable, valid and responsive rhinosinusitis outcome measure which can assist patient diagnosis and management in the clinical setting. Due to its quick completion time, this outcome measure could be used in rhinology out-patient clinics.

Key words: Rhinitis; Sinusitis; Outcome Assessment

Introduction

Rhinosinusitis, as defined by the 2005 European Academy of Allergy and Clinical Immunology (EAACI) position paper, is mainly diagnosed by careful history-taking and examination.¹ Unlike other types of pathology, such as otological disease, it has no objective measure, such as a hearing test. This has resulted in the development of validated outcome measures to assess the benefit of various rhinosinusitis treatments.

Validated outcomes research uses expanded measures of outcome, such as quality of life and health perception, rather than traditional clinical endpoints such as survival or complication rates.²

In 1992, Dr Paul Ellwood described outcomes management as a 'technology of patient experience', predicting that medicine would move toward systematic assessment of patients' experience of the health care system and their perception of treatment outcomes.³

Outcomes research requires identification and clear definition of the disease, as well as a clear

staging system for disease severity. One must acknowledge co-morbid conditions and establish the outcomes to be measured – disease-related and/or patient-related. Finally, instruments for measuring those outcomes must be tested for reliability, validity and responsiveness, using psychometric statistics.

There are many different validated outcome measures for rhinosinusitis.^{4–7} However, many are too time-consuming to complete in a busy out-patient clinic, and are mainly used as research tools. In 2004, Paul White described the rhinogram, a non-validated outcome measure.⁸ The rhinogram was intended as a standardised, disease-specific outcome measure which could be easily used in the clinic, providing immediate assessment of treatment benefits.

The current study comprised a prospective, comparative assessment of pre- and post-surgical rhinosinusitis, in which two validated outcome measures, the Health-Related Quality of Life questionnaire and the Sino-Nasal Outcome Test-20, were compared

TABLE I

QUESTION ITEMS: COMPARISON OF THE THREE QUESTIONNAIRES		
HRQL*	SNOT-20 [†]	Rhinogram [‡]
1 Facial pain, pressure, sinuses	1 Need to blow nose	1 Facial pain or pressure
1a Facial pain scale (0–10)	2 Sneeze	2 Headache
2 Blocked or stuffy nose	3 Runny nose	3 Nasal blockage
2a Blocked nose scale (0–10)	4 Cough	4 Post-nasal drip or discharge
3 Post-nasal drip	5 Post-nasal discharge	5 Reduced sense of smell
3a Post-nasal drip scale (0–10)	6 Thick nasal discharge	6 Overall effect on lifestyle
4 Thick nasal discharge	7 Ear fullness	
5 Runny nose	8 Dizzy	
6 Tired or fatigued	9 Ear pain	
7 Trouble sleeping	10 Facial pain or pressure	
8 Harder to concentrate	11 Difficulty falling asleep	
9 Harder doing normal things	12 Waking up at night	
10 Embarrassed	13 Lack of a good night's sleep	
11 Frustrated	14 Waking up tired	
12 Irritable	15 Fatigue	
13 Sad or depressed	16 Reduced productivity	
14 Think about nasal symptoms	17 Reduced concentration	
	18 Frustrated or restless or irritable	
	19 Sad	
	20 Embarrassed	

Scored: *0–4; [†]0–10; [‡]1–10. HRQL = Health-Related Quality of Life questionnaire; SNOT-20 = Sino-Nasal Outcomes Test-20

with the rhinogram, a non-validated outcome measure.^{8–10} The null hypothesis proposed no difference between the three outcome measures as regards reliability, validity and responsiveness to change.

Methods

A prospective, comparative, cohort study was planned. Patients with a diagnosis of rhinosinusitis who had failed medical therapy and had clear radiological disease were enrolled. A questionnaire plus covering letter was distributed to 51 consecutive patients in the pre-assessment clinic, one week prior to their elective

TABLE IIb

EAACI DIAGNOSTIC CRITERIA FOR RHINOSINUSITIS, SEVERITY SCALES			
Severity	HRQL	SNOT-20	Rhinogram
Mild	0–2 0–4*	0–2	1–5
Moderate or severe	3–4 5–10*	3–5	6–10

Data represent visual analog scores. *On scale of 0–10. HRQL = Health-Related Quality of Life questionnaire; SNOT-20 = Sino-Nasal Outcome Test-20

endoscopic sinus surgery. The questionnaires included the validated Sino-Nasal Outcome Test-20, the validated Health-Related Quality of Life questionnaire and the rhinogram. Three months after their operation, all patients were given the same questionnaires in the out-patient clinic, or by post. Of the 51 patients enrolled in the study, 50 completed both the pre- and post-operative questionnaires.

Health-Related Quality of Life questionnaire

This questionnaire assessed recent sinus and nasal symptoms within the previous week. It consisted of 14 questions (See Table I), with symptom prevalence ranked as: none of the time; a little of the time; some of the time; most of the time; and, finally, all of the time (scored zero to four). The first three questions were further subdivided to indicate how much patients were bothered by their symptoms, on a zero to 10 scale.

Sino-Nasal Outcome Test-20

This test assessed recent nose and sinus problems within the past two weeks, and considered the severity and frequency of each. It consisted of 20 questions (see Table I), with symptoms ranked as: no problem; very mild problem; mild or slight problem; moderate problem; severe problem; and, finally, problem as bad as it could be (scored zero to five).

Rhinogram

The rhinogram questionnaire assessed how nose and sinus problems had affected patients over the previous two weeks. It consisted of six questions (see

TABLE IIa

EAACI DIAGNOSTIC CRITERIA FOR RHINOSINUSITIS, AND CORRESPONDING QUESTIONNAIRE ITEMS

EAACI diagnostic criteria	HRQL	SNOT-20	Rhinogram
Blockage or congestion	2 Blocked or stuffy nose 2a Blocked nose scale (0–10)	1 Need to blow nose	3 Nasal blockage
Nasal or post-nasal discharge	3 Post-nasal drip 3a Post-nasal drip scale (0–10) 4 Thick nasal discharge 5 Runny nose	3 Runny nose 5 Post-nasal discharge 6 Thick nasal discharge	4 Post-nasal drip
Facial pain or pressure	1 Facial pain, pressure, sinuses 1a Facial pain scale (0–10)	10 Facial pain or pressure	1 Facial pain 2 Headache
Decreased smell	2 Blocked or stuffy nose 2a Blocked nose scale (0–10)		5 Reduced smell

EAACI = European Academy of Allergy and Clinical Immunology; HRQL = Health-Related Quality of Life questionnaire; SNOT-20 = Sino-Nasal Outcome Test-20

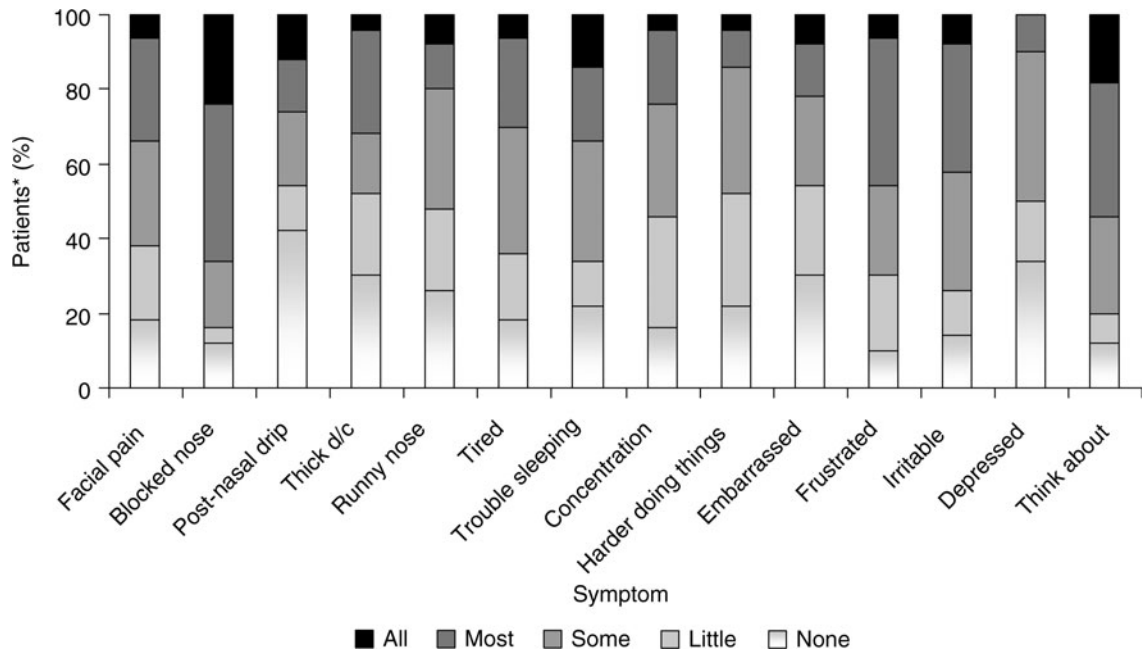


FIG. 1

Heath-Related Quality of Life questionnaire: pre-operative results. *n = 50. D/c = discharge

Table I), with responses ranked from ‘no problem’ to ‘severe problem’ on a scale from one to 10.

Diagnosis of rhinosinusitis

The EAACI position paper on rhinosinusitis and nasal polyps set out diagnostic criteria for rhinosinusitis. Rhinosinusitis was clinically defined as: inflammation of the nose and the paranasal sinuses characterised by two or more symptoms (i.e. blockage or congestion, discharge (anterior or post-nasal drip), facial pain or pressure, and/or reduction or

loss of smell) and endoscopic signs (i.e. polyps, mucopurulent discharge from the middle meatus, and/or oedema or mucosal obstruction primarily in the middle meatus) and/or computed tomography changes (i.e. mucosal changes within the ostiomeatal complex and/or sinuses).

Rhinosinusitis can be further divided into mild, or moderate or severe, disease. This is based on a 10-mm visual analogue scale (VAS), where 0–4 mm = mild disease, and 5–10 mm = moderate or severe disease. Our questionnaire results were used

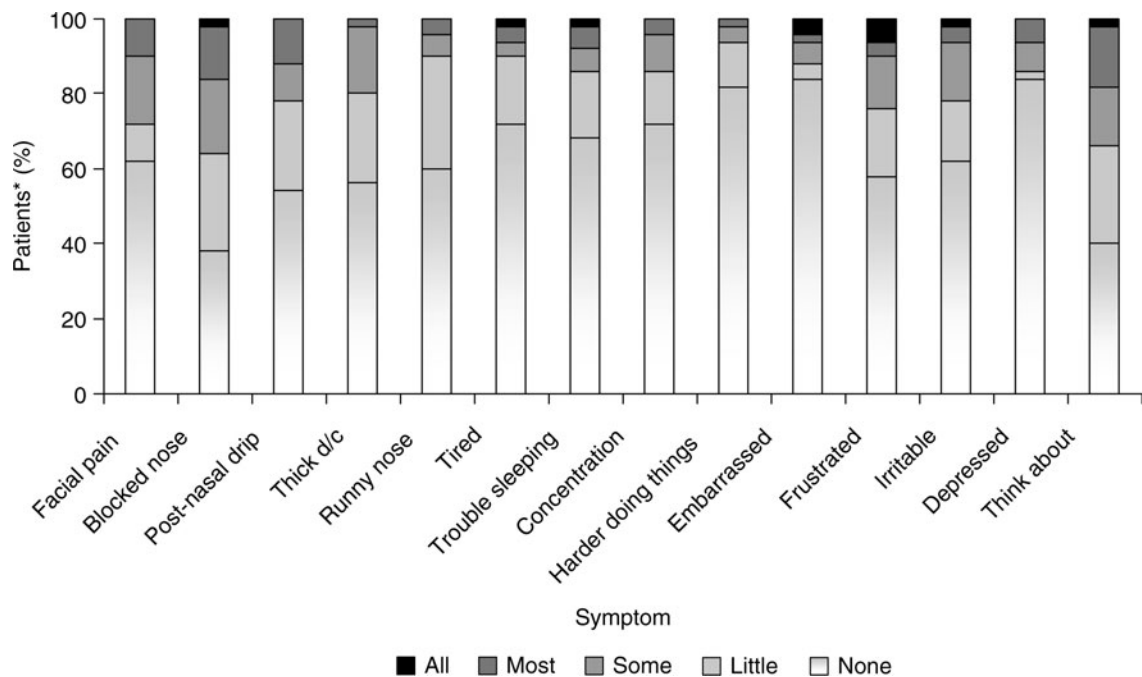


FIG. 2

Heath-Related Quality of Life questionnaire: post-operative results. *n = 50. D/c = discharge

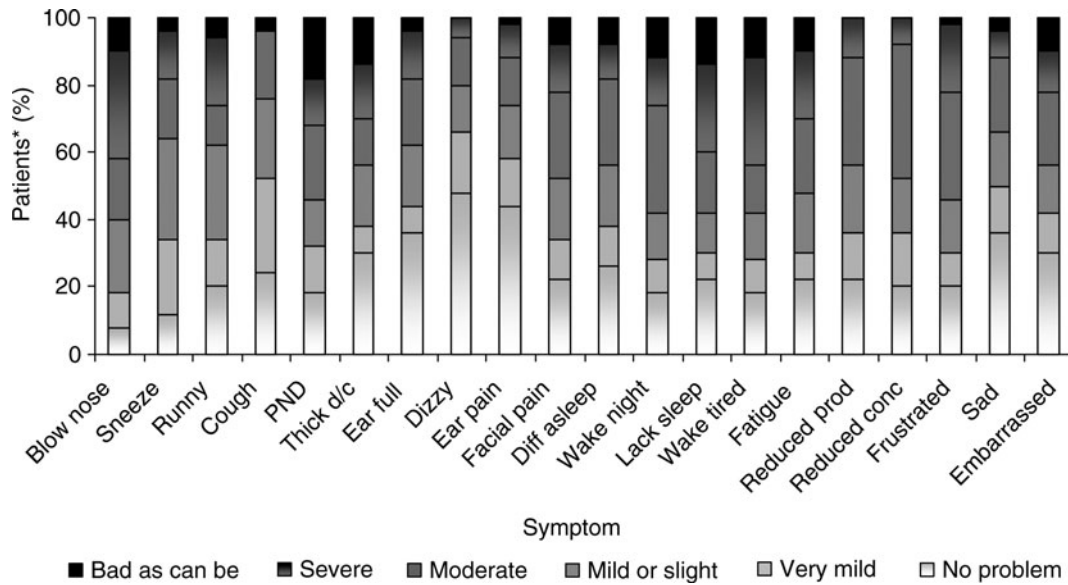


FIG. 3

Sino-Nasal Outcome Test-20: pre-operative results. *n = 50. PND = post-nasal discharge; d/c = discharge; full = fullness; diff = difficulty; prod = productivity; conc = concentration

to determine the number of patients with clinically defined rhinosinusitis, both pre- and post-operatively. The values were then subdivided into mild disease or moderate or severe disease, by allocating similar values to the VAS within each question (see Tables IIa and IIb).

Statistics

A power calculation was performed to enable recruitment of enough patients to ensure a power of 80 per cent (acceptable type two error) with a significance level of 5 per cent (acceptable type one error). All information was then entered into an Excel spreadsheet. Similar variables in the two validated

questionnaires and the non-validated rhinogram were compared against each other using Spearman's rank correlation statistical analysis for non-parametric ordinal data. Diagnostic criteria were tabulated and analysed using the chi-square test.

Results

Fifty-one patients were enrolled into the study, comprising 22 men and 29 women, with a mean age range of 55 years (range 27–78 years). Fifty patients completed the study and provided full data sets for all three questionnaires on two separate occasions (see Figures 1 to 6).

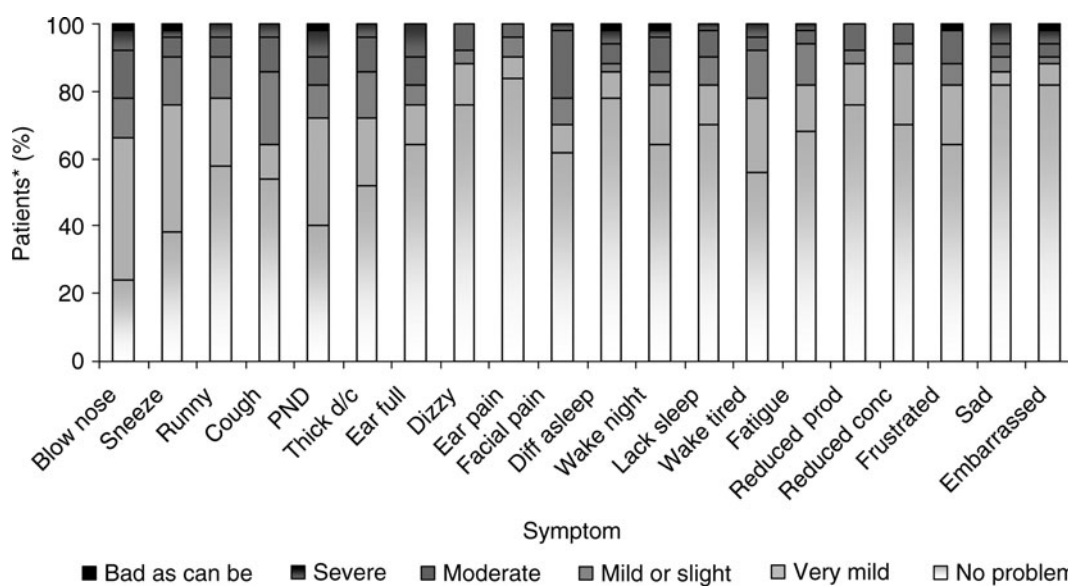


FIG. 4

Sino-Nasal Outcome Test-20: post-operative results. *n = 50. PND = post-nasal discharge; d/c = discharge; full = fullness; diff = difficulty; prod = productivity; conc = concentration

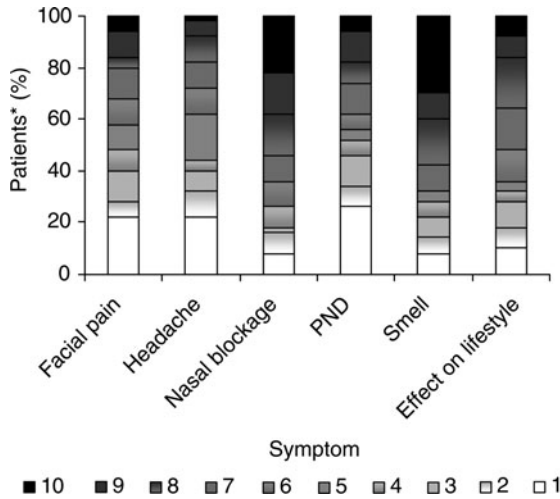


FIG. 5

Rhinogram: pre-operative results. *n = 50. PND = post-nasal discharge

Questionnaire correlations

Rhinogram outcomes were compared with similar outcomes in the Heath-Related Quality of Life and Sino-Nasal Outcome Test-20 questionnaires, as shown in Tables III and IV, respectively. Good correlation was found between the rhinogram and both the Heath-Related Quality of Life questionnaire and the Sino-Nasal Outcome Test-20. Figures 7 to 10 give examples of this correlation, for one of the variables tested.

Rhinosinusitis diagnosis

The presence of two or more symptoms (as determined by each questionnaire) as well as clinical

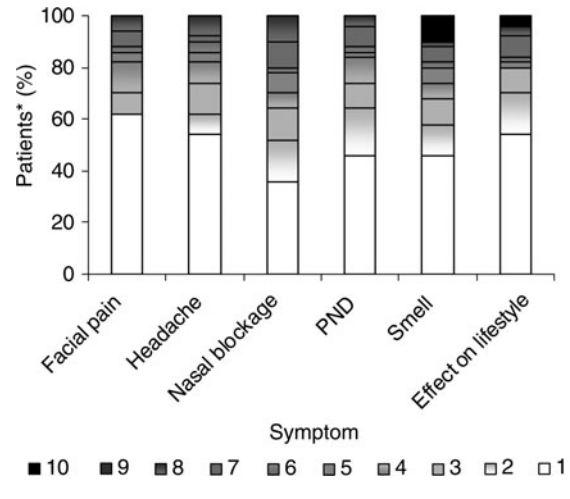


FIG. 6

Rhinogram: post-operative results. *n = 50. PND = post-nasal discharge

findings was diagnostic of rhinosinusitis, as shown in Tables IIa and IIb. Rhinosinusitis diagnostic results are shown in Tables V to VIII. The data for each of the three questionnaires appeared very similar, with no significant differences between the data sets (chi-square test). This suggests that the data generated by the three questionnaires did not differ significantly, when the same diagnostic criteria were applied to each questionnaire.

Discussion

Chronic rhinosinusitis can significantly affect patients' quality of life.¹ Numerous sinonasal outcome scoring systems exist, indicating the lack of a single, accepted system for the evaluation of

TABLE III
HEATH-RELATED QUALITY OF LIFE QUESTIONNAIRE VS RHINOGRAM

HRQL	Rhinogram	Pre-op		Post-op	
		Corr coeff	p	Corr coeff	p
Facial pain	Facial pain	0.72	<0.0001	0.87	<0.0001
Facial pain scale	Facial pain	0.74	<0.0001	0.86	<0.0001
Facial pain or headache	Headache	0.68	<0.0001	0.73	<0.0001
Facial pain scale	Headache	0.74	<0.0001	0.72	<0.0001
Blocked nose	Nasal blockage	0.76	<0.0001	0.68	<0.0001
Blocked nose scale	Nasal blockage	0.87	<0.0001	0.69	<0.0001
Blocked nose	Smell	0.56	<0.0001	0.35	0.0141
Blocked nose scale	Smell	0.59	<0.0001	0.46	0.0007
PND	Nasal discharge or PND	0.67	<0.0001	0.67	<0.0001
PND scale	Nasal discharge or PND	0.67	<0.0001	0.62	<0.0001
Thick discharge	Nasal discharge or PND	0.46	0.0008	0.45	0.0012
Runny nose	Nasal discharge or PND	0.65	<0.0001	0.49	0.0003
Tired or fatigue	Effect on lifestyle	0.53	<0.0001	0.75	<0.0001
Trouble sleeping	Effect on lifestyle	0.53	<0.0001	0.49	0.0003
Hard to concentrate	Effect on lifestyle	0.63	<0.0001	0.62	<0.0001
Harder doing normal things	Effect on lifestyle	0.68	<0.0001	0.55	<0.0001
Embarrassed	Effect on lifestyle	0.51	0.0002	0.58	<0.0001
Frustrated	Effect on lifestyle	0.65	<0.0001	0.70	<0.0001
Irritable	Effect on lifestyle	0.42	0.0022	0.77	<0.0001
Sad or depressed	Effect on lifestyle	0.58	<0.0001	0.69	<0.0001
Think about symptoms	Effect on lifestyle	0.35	0.0145	0.63	<0.0001

HRQL = Health-Related Quality of Life questionnaire; pre-op = pre-operative; post-op = post-operative; corr coeff = correlation coefficient; PND = post-nasal discharge

TABLE IV
SINO-NASAL OUTCOME TEST-20 VS RHINOGRAM

SNOT-20	Rhinoqram	Pre-op		Post-op	
		Corr coeff	<i>p</i>	Corr coeff	<i>p</i>
Facial pain	Facial pain	0.85	<0.0001	0.89	<0.0001
Blow nose	Nasal blockage	0.63	<0.0001	0.72	<0.0001
PND	Nasal discharge or PND	0.63	<0.0001	0.78	<0.0001
Runny nose	Nasal discharge or PND	0.66	<0.0001	0.50	0.0002
Thick discharge	Nasal discharge or PND	0.62	<0.0001	0.51	0.0001
Difficulty falling asleep	Effect on lifestyle	0.54	0.0001	0.37	0.0066
Wake at night	Effect on lifestyle	0.41	0.0044	0.44	0.0012
Lack of sleep	Effect on lifestyle	0.50	0.0003	0.40	0.0033
Wake tired	Effect on lifestyle	0.46	0.0012	0.57	<0.0001
Fatigue	Effect on lifestyle	0.48	0.0006	0.65	<0.0001
Reduced productivity	Effect on lifestyle	0.67	<0.0001	0.60	<0.0001
Reduced concentration	Effect on lifestyle	0.75	<0.0001	0.65	<0.0001
Frustrated	Effect on lifestyle	0.68	<0.0001	0.83	<0.0001
Sad	Effect on lifestyle	0.68	<0.0001	0.63	<0.0001
Embarrassed	Effect on lifestyle	0.49	0.0005	0.50	0.0002

SNOT-20 = Sino-Nasal Outcome Test-20; pre-op = pre-operative; post-op = post-operative; corr coeff = correlation coefficient; PND = post-nasal discharge

chronic rhinosinusitis outcomes.⁴⁻⁷ Some outcome questionnaires contain numerous items and may take significant time to complete, precluding routine clinical use. Extraction of data from VAS assessments may also be problematic.

The Sino-Nasal Outcome Test-20 was based on the Sino-Nasal Outcome Test-16. One of the faults in this outcome measure is that it does not query loss of smell. The EAACI position paper on rhinosinusitis has suggested that this symptom be assessed when diagnosing rhinosinusitis (and it is thus included in the rhinoqram). However, the Sino-Nasal Outcome Test-20 is nevertheless a validated outcome measure, and was used in the National Comparative Audit of Surgery for Nasal Polyposis and Chronic Rhinosinusitis.¹⁰ It has been described as easy to use, and as reliable, valid and responsive.

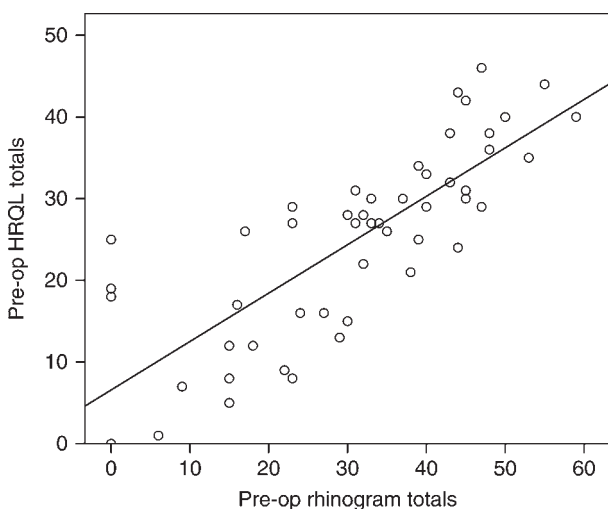


FIG. 7

Pre-operative (pre-op) total outcome scores (on the questionnaires): correlation between Health-Related Quality of Life questionnaire (HRQL) and rhinoqram. R sq linear = 0.623.

In contrast, the non-validated rhinoqram questionnaire was created with the aim of providing a quick assessment of chronic rhinosinusitis suitable for clinic use. It uses a pre-printed sheet (analogous to the pro forma used for pure tone audiograms) which is retained in patients' medical records (see Figure 11). The rhinoqram can be administered on subsequent clinic visits and simple comparisons made. Allowing the patient to compare successive rhinoqrams may also be helpful in demonstrating clinical improvement.

The rhinoqram is a concise method for recording disease progression and response to treatment. It concentrates on symptomatology, although it briefly addresses quality of life issues in one question. It does not allow the addition of supplementary items felt by the patient to be important, as do quality of life measures.⁹ There are numerous robust sinonasal-

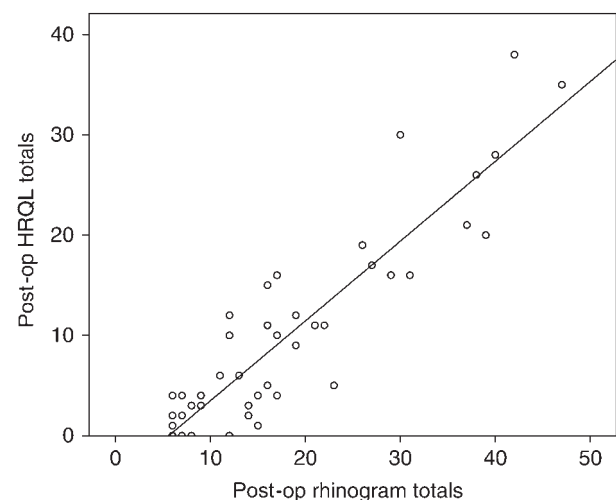


FIG. 8

Post-operative (post-op) total outcome scores (on the questionnaires): correlation between Health-Related Quality of Life questionnaire (HRQL) and rhinoqram. R sq linear = 0.836.

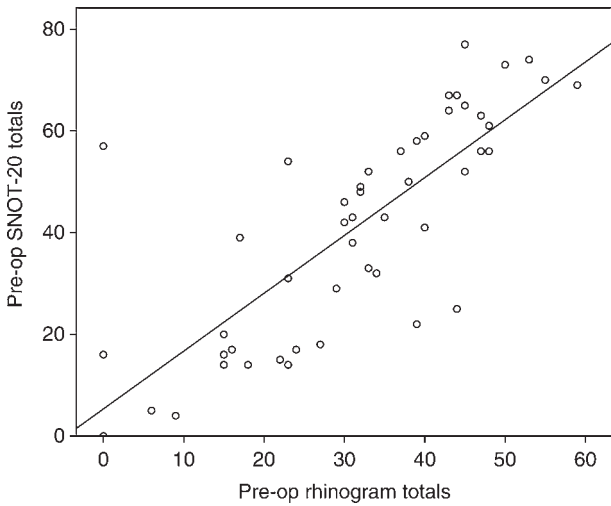


FIG. 9

Pre-operative (pre-op) total outcome scores (on the questionnaires): correlation between Sino-Nasal Outcome Test-20 (SNOT-20) and rhinogram. R sq linear = 0.628.

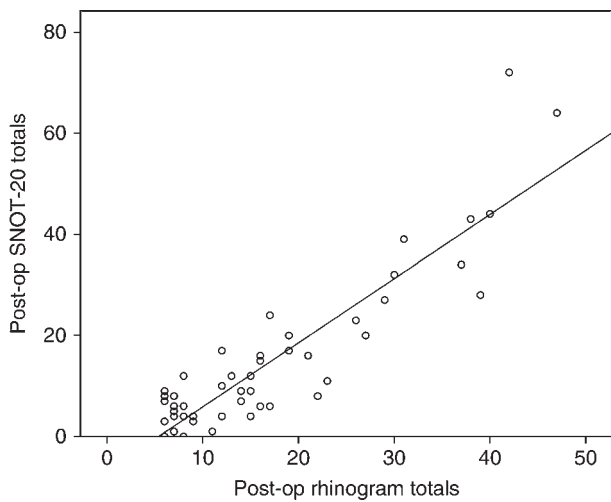


FIG. 10

Post-operative (post-op) total outcome scores (on the questionnaires): correlation between Sino-Nasal Outcome Test-20 (SNOT-20) and rhinogram. R sq linear = 0.808.

	1	2	3	4	5	6	7	8	9	10
Facial pain/pressure	█	█	█	█	█	█	█	█		
Headache	█	█	█	█	█					
Nasal blockage	█	█	█	█	█	█	█	█	█	
Post-nasal drip, discharge	█	█	█	█	█					
Reduced sense of smell	█	█	█	█	█					
Overall effect on lifestyle	█	█	█	█	█	█	█	█	█	

FIG. 11

Sample completed rhinogram.

TABLE V

RHINOSINUSITIS DIAGNOSTIC RESULTS: PRE-OP HRQL VS RHINOGRAM

Rhinosinusitis	Pre-op HRQL	Pre-op rhinogram	χ^2
None	2	3	1.64*
Mild	8	4	
Mod or severe	40	43	

Data represent the outcome questionnaire scores unless otherwise stated. *For significance at 0.05 level, chi-square should be ≥ 5.99 . Pre-op = pre-operative; HRQL = Health-Related Quality of Life questionnaire; mod = moderate

TABLE VI

RHINOSINUSITIS DIAGNOSTIC RESULTS: POST-OP HRQL VS RHINOGRAM

Rhinosinusitis	Post-op HRQL	Post-op rhinogram	χ^2
None	17	16	1.24*
Mild	18	14	
Mod or severe	15	20	

Data represent the outcome questionnaire scores unless otherwise stated. *For significance at 0.05 level, chi-square should be ≥ 5.99 . Post-op = post-operative; HRQL = Health-Related Quality of Life questionnaire; mod = moderate

TABLE VII

RHINOSINUSITIS DIAGNOSTIC RESULTS: PRE-OP SNOT-20 VS RHINOGRAM

Rhinosinusitis	Pre-op SNOT-20	Pre-op rhinogram	χ^2
None	5	3	1.76*
Mild	7	4	
Mod or severe	37	43	

Data represent the outcome questionnaire scores unless otherwise stated. *For significance at 0.05 level, chi-square should be ≥ 5.99 . Pre-op = pre-operative; SNOT-20 = Sino-Nasal Outcome Test-20; mod = moderate

TABLE VIII

RHINOSINUSITIS DIAGNOSTIC RESULTS: POST-OP SNOT-20 VS RHINOGRAM

Rhinosinusitis	Post-op SNOT-20	Post-op rhinogram	χ^2
None	14	16	0.74*
Mild	18	14	
Mod or severe	18	20	

Data represent the outcome questionnaire scores unless otherwise stated. *For significance at 0.05 level, chi-square should be ≥ 5.99 . Post-op = post-operative; SNOT-20 = Sino-Nasal Outcome Test-20; mod = moderate

specific outcome measures which address such questions, but at the expense of increased questionnaire completion time. Our aim was to validate a straightforward, concise rhinosinusitis outcome measure which could be easily recorded and referred to within the patient's medical notes.

Patients attending a busy out-patient clinic often do not have time to fill out lengthy questionnaires. The rhinogram removes this problem. On average,

the Sino-Nasal Outcome Test-20 and the Health-Related Quality of Life questionnaires require over 5 minutes each for completion, compared with under a minute for the rhinogram. The rhinogram has the added benefit that it can be completed in the clinic room with the doctor, rather than in the waiting room. This would reduce the burden on the nursing staff and the patient prior to the consultation.

- **Rhinosinusitis, as defined by the 2005 EAACI position paper, is mainly diagnosed by careful history-taking and examination**
- **Unlike other types of pathology, such as otological disease, rhinosinusitis does not have an objective measure, such as a hearing test; thus, validated outcome measures are used to assess treatment benefits**
- **This paper assessed the validity, reliability and responsiveness of the rhinogram compared with two validated outcome measures: the Sino-Nasal Outcome Test-20 and the Health-Related Quality of Life questionnaire**
- **The rhinogram is a reliable, valid and responsive rhinosinusitis outcome measure which can assist patient diagnosis and management in the clinical setting**

Rhinosinusitis may be managed conservatively as well as surgically. This study compared the results of the Sino-Nasal Outcome Test-20 and the HRQL, both of which have been validated, against the rhinogram. The study could be criticised on the grounds that the Health-Related Quality of Life questionnaire has previously been validated only in medically managed patients, and that, while our rhinogram results correlated significantly with our Health-Related Quality of Life results, we examined only patients undergoing surgical treatment. Therefore, we cannot conclude that the rhinogram is valid in medically managed patients.

Conclusion

This study was performed prospectively to evaluate the reliability, validity and responsiveness of the rhinogram compared with two other, known, validated

outcome measures, through direct correlation of results. Our findings show that the rhinogram is statistically acceptable for use as a disease-specific outcome measure for patients with rhinosinusitis. Our initial null hypothesis was proven. Hopefully, these results will facilitate the routine clinical use of the rhinogram when managing chronic rhinosinusitis patients.

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