



ORIGINAL ARTICLE

Cross-cultural adaptation and validation of the Sinus and Nasal Quality of Life Survey (SN-5) into Brazilian Portuguese[☆]



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KEYWORDS

Quality of life;
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Abstract

Introduction: The concept of quality of life is subjective and variable definition, which depends on the individual's perception of their state of health. Quality of life questionnaires are instruments designed to measure quality of life, but most are developed in a language other than Portuguese. Questionnaires can identify the most important symptoms, focus on consultation, and assist in defining the goals of treatment. Some of these have been validated for the Portuguese language, but none in children.

Objective: To validate the translation with cross-cultural adaptation and validation of the Sinus and Nasal Quality of Life Survey (SN-5) into Portuguese.

Methods: Prospective study of children aged 2–12 years with sinonasal symptoms of over 30 days. The study comprised two stages: (I) translation and cross-cultural adaptation of the SN-5 into Portuguese (SN-5p); and (II) validation of the SN5-p. Statistical analysis was performed to assess internal consistency, test-retest reliability, and sensitivity, as well as construct and discriminant validity and standardization.

Results: The SN-5 was translated and adapted into Portuguese (SN-5p) and the author of the original version approved the process. Validation was carried out by administration of the SN-5p to 51 pediatric patients with sinonasal complaints (mean age, 5.8 ± 2.5 years; range, 2–12 years). The questionnaire exhibited adequate construct validity (0.62, $p < 0.01$), internal consistency (Cronbach's $\alpha = 0.73$), and discriminant validity ($p < 0.01$), as well as good

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test-retest reproducibility (Goodman-Kruskal gamma = 0.957, $p < 0.001$), good correlation with a visual analog scale ($r = 0.62$, $p < 0.01$), and sensitivity to change.

Conclusion: This study reports the successful translation and cross-cultural adaptation of the SN-5 instrument into Brazilian Portuguese. The translated version exhibited adequate psychometric properties for assessment of disease-specific quality of life in pediatric patients with sinonasal complaints.

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PALAVRAS-CHAVE

Qualidade de vida;
Estudos de validação;
Rinite;
Sinusite;
Saúde da criança

Adaptação e validação transcultural da *Sinus and Nasal Quality of Life Survey* (SN-5) para o português brasileiro

Resumo

Introdução: O conceito de qualidade de vida é subjetivo e de definição variável; depende da percepção do indivíduo quanto ao seu estado de saúde. Os questionários para qualidade de vida são instrumentos planejados para medir a qualidade de vida, mas a maioria foi desenvolvida em línguas diferentes do português. Os questionários podem identificar os sintomas mais importantes, serem focadas na consulta e ajudar na definição das metas terapêuticas. Alguns desses instrumentos foram validados para o idioma português, mas nenhum em crianças.

Objetivo: Validar a tradução com adaptação transcultural e validação do questionário SN-5 para o idioma português.

Método: Estudo prospectivo de crianças com idades entre 2 e 12 anos com sintomas sinasais com mais de 30 dias de duração. O estudo consistiu em dois estágios: (I) tradução e adaptação transcultural do SN-5 para o idioma português (SN-5p); e (II) validação do SN5-p. Foi realizada análise estatística para avaliação da consistência interna, confiabilidade de reteste e sensibilidade, bem como construto e validade discriminante e de padronização.

Resultados: O questionário SN-5 foi traduzido e adaptado para o idioma português (SN-5p) e o autor da versão original aprovou o processo. A validação foi realizada pela administração do SN-5p a 51 pacientes pediátricos com queixas sinasais (media de idade, $5,8 \pm 2,5$ anos; variação de 2–12 anos). O questionário exibiu validade de construto adequada (0,62, $p < 0,01$), consistência interna (alfa de Cronbach = 0,73) e validade discriminante ($p < 0,01$), além de boa reprodutibilidade de teste-reteste (gama de Goodman-Kruskal = 0,957, $p < 0,001$), boa correlação com uma escala analógica visual ($r = 0,62$, $p < 0,01$) e sensibilidade à mudança.

Conclusão: O presente estudo relata uma bem-sucedida tradução e adaptação transcultural do questionário SN-5 para o idioma português brasileiro. A versão traduzida exibiu propriedades psicométricas adequadas para avaliação da qualidade de vida específica para doenças em pacientes pediátricos com queixas sinasais.

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Introduction

The concept of quality of life is subjective and, therefore, variously defined. It is related to the individual's perception of his or her health status in the major domains or dimensions of life.^{1,2}

The main instruments used in assessment of quality of life are quality of life questionnaires. These instruments are intended to assess the various aspects and dimensions of a patient's life, including physical, psychological, social, role performance, pain, and sleep quality, in addition to specific symptoms.^{1–6}

Sinonasal symptoms and their correlative diseases, such as rhinitis and rhinosinusitis, account for a significant portion of visits to health care facilities. Rhinitis is estimated to affect approximately 500 million people worldwide.⁷ The

International Study of Asthma and Allergies in Childhood (ISAAC) revealed an upward trend for rhinitis prevalence in Brazilian children, with rates increasing from 10.3% to 17.4% among 6–7 year-olds and from 8.9% to 28.5% among 13 to 14 year-olds between 1996 and 2002.⁸ Rhinosinusitis affects approximately 31 million people every year in the United States alone, generating an annual cost of US\$6 million, and is one of the leading causes of antibiotic prescription and of absenteeism.^{9–11} Its prevalence is estimated at 14% in adults and 7.6% in the pediatric population.¹² Nationwide data are only available for the adult Brazilian population. Prevalence is estimated at 5.5% according to household surveys conducted in São Paulo.¹³

Several disease-specific questionnaires have been developed to characterize morbidity in patients with sinonasal disease, such as the Rhinitis Quality of Life Questionnaire¹⁴

and the Sino-Nasal Outcome Test-20 and -22 (SNOT-20 and -22).¹⁵ The Sinus and Nasal Quality of Life Survey (SN-5) was the first validated questionnaire for assessment of disease-specific quality of life related to sinonasal symptoms in pediatric populations.¹⁶ The SN-5 is a short, straightforward, and easily administered instrument. Since its validation, it has been employed in epidemiological studies¹⁷ and, particularly, in trials of clinical¹⁸ and surgical^{19,20} interventions.

Methods

This prospective, observational study was conducted at a hospital, between October 2013 and June 2014. Participation was voluntary, and all patients and their legal guardians provided written informed assent and consent respectively, as approved by the local research ethics committee (CAAE: 05955813.6.0000.5201).

Questionnaire

The SN-5 consists of a series of five questions to be answered by the patient's parents. Each item is scored on a seven-point scale designed to assess symptom frequency during the preceding four weeks. The items assess symptoms related to: (a) nasal obstruction; (b) sinus infection; (c) allergy symptoms; (d) emotional distress; and (e) activity limitations. At the end of the questionnaire, overall quality of life was assessed by means of a visual analog scale (VAS) from 0 to 10.¹⁶

Recruitment

The parents of children seen at the outpatient otorhinolaryngology clinic who met the inclusion criteria were invited to take part voluntarily. The inclusion criteria were: (a) child aged 2–12 years; (b) presence of one or more of the following symptoms for at least one month at the time of assessment: rhinorrhea or postnasal drip, nasal congestion, nasal obstruction, daytime cough, and halitosis; and (c) caregiver ability to read and understand the Portuguese language. The exclusion criteria were: (a) primary diagnosis of obstructive sleep apnea syndrome (OSAS) caused by tonsillar hyperplasia; (b) developmental delay or cognitive impairment and/or craniofacial abnormalities; (c) secondary chronic rhinosinusitis: fungus ball, invasive fungal disease, granulomatous diseases, vasculitides, isolated mucocele, malignant or benign sinonasal tumors, congenital abnormalities (e.g., primary ciliary dyskinesia, cystic fibrosis), and oronasal fistula; and (d) primary or secondary immune deficiency.

Cross-cultural adaptation

Cross-cultural adaptation of the original, English-language SN-5 (Fig. 1) into Portuguese (Fig. 2) followed a standardized process.²¹ The intermediate and final versions resulting from this process were sent to the author of the original instrument to ensure that the original meaning of the items was preserved.

Validation of the SN-5p

The Portuguese version of the instrument was administered at three time points, as in the original study: in person, at the initial patient encounter; by telephone, one week later; and again in person after four weeks. Test–retest reliability was assessed by means of the Goodman–Kruskal gamma coefficient (γ) between the results of the initial encounter and the one-week time points.

Statistical analysis

The minimum sample size was estimated at 45 patients, with a correlation coefficient of 0.20 as the outcome of interest. An alpha value of 5% ($p < 0.05$) was deemed significant for all statistical tests.¹⁶ Analyses were performed in PASW Statistics v. 18 (Chicago, IL, United States).

Internal consistency reliability was estimated by calculation of Cronbach's alpha and inter-item and item-total correlations, and was considered acceptable if >0.70 .

Test–retest reliability of the SN-5 questionnaire was assessed by means of Spearman's correlation coefficient, comparing responses to the initial questionnaire to the responses of patients who did not exhibit any change in overall quality of life score as assessed on the VAS.

Discriminant validity was assessed by means of the difference in SN-5 scores between two groups: patients in the study group and 25 patients seen at the study clinic for other reasons and with no sinonasal complaints (control group). The Mann–Whitney U test was used for this comparison.

The sensitivity to change of the instrument was assessed by calculation of the mean effect size.⁶

Results

The Portuguese version of the SN-5 (SN-5p) was administered to a group of patients with sinonasal complaints between October 2013 and June 2014. Overall, 51 participants met the inclusion criteria, of whom 28 (54.9%) were male and 23 (45.1%) were female. The mean age was 5.82 ± 2.51 years (range, 2–12 years).

The SN-5p was administered to the selected patients and, after assessment of applicability, was not found to require modification of any items.

The internal consistency of the SN-5p, as measured by Cronbach's alpha, was 0.73 (total scale). Item-item and item-total correlation analysis showed adequate construct validity.

Discriminant validity was statistically significant (median [interquartile range]) = 0.20 [0.20] vs. 3.40 [1.80], $U = 752.5$, $p < 0.01$; Fig. 3). Test–retest reproducibility one week after initial interview was adequate ($\gamma = 0.957$, $p < 0.001$). Significant correlation was observed between the VAS and the SN-5p, as assessed by Spearman's coefficient ($r = 0.62$, $p < 0.01$) (Fig. 4). The effect size was 2.03.

Table 1 shows the change in SN-5 scores between the first encounter and the last time point of assessment (four weeks later). Significant improvement in all symptoms was observed after administration of proposed treatments ($p < 0.001$), which indicates that the SN-5 is able to measure clinical improvement.

Instructions: Please help us understand the impact of sinus and/or nasal problems on your child's quality of life by checking one box [x] for each question below. Thank you.

SINUS INFECTION: Nasal discharge, bad breath, daytime cough, post-nasal drip, headache, facial pain or head banging. How often a problem for your child during the past 4 weeks?

- None of the time
- Hardly any time at all
- A good part of the time
- A small part of the time
- Most of the time
- Some of the time
- All of the time

NASAL OBSTRUCTION: Stuffy or blocked nose, nasal congestion, reduced sense of smell, trouble breathing with mouth closed. How often a problem for your child during the past 4 weeks?

- None of the time
- Hardly any time at all
- A good part of the time
- A small part of the time
- Most of the time
- Some of the time
- All of the time

ALLERGY SYMPTOMS: Sneezing, itchy nose/eyes, need to rub nose/eyes, or watery eyes. How often a problem for your child during the past 4 weeks?

- None of the time
- Hardly any time at all
- A good part of the time
- A small part of the time
- Most of the time
- Some of the time
- All of the time

EMOTIONAL DISTRESS: Irritable, frustrated, sad, restless, or trouble sleeping. How often a problem for your child during the past 4 weeks because of nose or sinus illness?

- None of the time
- Hardly any time at all
- A good part of the time
- A small part of the time
- Most of the time
- Some of the time
- All of the time

ACTIVITY LIMITATIONS: Missed school/daycare, lost time with family/friends, unable to do projects. How often a problem for your child during the past 4 weeks because of nose or sinus illness?

- None of the time
- Hardly any time at all
- A good part of the time
- A small part of the time
- Most of the time
- Some of the time
- All of the time

OVERALL, HOW WOULD YOU RATE YOUR CHILD'S QUALITY OF LIFE AS A RESULT OF NOSE OR SINUS PROBLEMS?
(Circle one number)

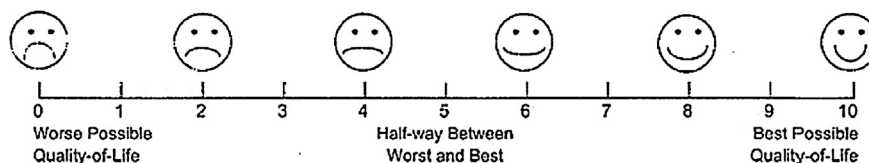


Figure 1 Questionnaire English-language SN-5.

Table 1 Median and interquartile range sinonasal complaint scores on initial and final assessment.

Complaint	Initial	Final	Change	p
Sinus infection	5 (3)	2 (3)	-2 (1)	<0.001
Nasal obstruction	6 (6)	1 (0)	-3 (5)	<0.001
Allergy symptoms	4 (3)	1 (2)	-2 (3)	<0.001
Emotional distress	3 (2)	1 (1)	-2 (1)	<0.001
Activity limitations	2 (2)	1 (1)	0 (1)	<0.001
VAS	6 (3)	9 (2)	3 (2)	<0.001
SN-5	3.4 (2)	1.8 (1)	-1.6 (2)	<0.001

VAS, visual analog scale; SN-5, Sinus and Nasal Quality of Life Survey.

Discussion

Assessment of quality of life in pediatric patients usually poses a challenge. Those who should be the most reliable informants – patients themselves – may be unable to express their perceptions of quality of life as clearly as adults can. Parents have their own perceptions of their children's quality of life, but from a standpoint that may be biased by their own experiences, by the concern they wish to convey to

the clinician, and by their affectional bonds with the child. These facts clearly demonstrate the unique challenges of quality of life assessment in pediatric patients and the need to raise awareness of the translation, cross-cultural adaptation, and validation of the SN-5 instrument in Portuguese (Fig. 2).

Several questionnaires exist for the assessment of overall quality of life in pediatric patients, such as the *Autoquestionnaire de Qualité de Vie Enfant Imagé* (AUQEI),²² but these instruments do not provide precise information as compared with questionnaires containing items designed to assess a specific disease. One of the first pediatric health-related quality of life (HRQoL) questionnaires was the TNO AZL Child Quality Of Life (TACQOL) questionnaire, developed in 1992. Thus far, few attempts had been made to develop instruments specifically for the assessment of pediatric patients.²³

One of the first such publications in the field of otorhinolaryngology was a 1998 French questionnaire devised to assess the cumulative effect of recurrent child ear, nose, and throat infections on parents' quality of life during the winter season.²⁴

It has been demonstrated that deterioration of quality of life in patients with sinonasal complaints can lead to several disturbances, including impairment of the activities of

Instruções: Por gentileza, ajude-nos a entender o impacto dos problemas nasais ou dos seios da face na qualidade de vida de sua criança, marcando uma das alternativas (x) para cada pergunta abaixo. Agradecemos sua participação.

SOBRE SINUSITE: Secreção nasal, mau hálito, tosse durante o dia, gotejamento pós-nasal (secreção descendo pela garganta), dor de cabeça, dor na face ou ficar batendo na cabeça.

Com que frequência isso foi um problema para sua criança nas últimas 4 semanas?

- | | | |
|--|--|---|
| <input type="checkbox"/> Nenhuma vez | <input type="checkbox"/> Raramente | <input type="checkbox"/> Várias vezes |
| <input type="checkbox"/> Poucas vezes | <input type="checkbox"/> Algumas vezes | <input type="checkbox"/> Quase o tempo todo |
| <input type="checkbox"/> Algumas vezes | | <input type="checkbox"/> O tempo todo |

SOBRE OBSTRUÇÃO NASAL: Nariz obstruído ou entupido, congestão nasal, dificuldade para sentir cheiro, dificuldade para respirar com a boca fechada.

Com que frequência isso foi um problema para sua criança nas últimas 4 semanas?

- | | | |
|--|--|---|
| <input type="checkbox"/> Nenhuma vez | <input type="checkbox"/> Raramente | <input type="checkbox"/> Várias vezes |
| <input type="checkbox"/> Poucas vezes | <input type="checkbox"/> Algumas vezes | <input type="checkbox"/> Quase o tempo todo |
| <input type="checkbox"/> Algumas vezes | | <input type="checkbox"/> O tempo todo |

SOBRE SINTOMAS DE ALERGIA: Espirros, coceira no nariz/olhos, necessidade de esfregar nariz/olhos, ou olhos lacrimejando.

Com que frequência isso foi um problema para sua criança nas últimas 4 semanas?

- | | | |
|--|--|---|
| <input type="checkbox"/> Nenhuma vez | <input type="checkbox"/> Raramente | <input type="checkbox"/> Várias vezes |
| <input type="checkbox"/> Poucas vezes | <input type="checkbox"/> Algumas vezes | <input type="checkbox"/> Quase o tempo todo |
| <input type="checkbox"/> Algumas vezes | | <input type="checkbox"/> O tempo todo |

SOBRE PROBLEMAS EMOCIONAIS: Irritação, frustração, tristeza, agitação, dificuldade para dormir.

Com que frequência isso foi um problema para sua criança nas últimas 4 semanas?

- | | | |
|--|--|---|
| <input type="checkbox"/> Nenhuma vez | <input type="checkbox"/> Raramente | <input type="checkbox"/> Várias vezes |
| <input type="checkbox"/> Poucas vezes | <input type="checkbox"/> Algumas vezes | <input type="checkbox"/> Quase o tempo todo |
| <input type="checkbox"/> Algumas vezes | | <input type="checkbox"/> O tempo todo |

SOBRE LIMITAÇÕES DAS ATIVIDADES: Falta na escola/creche, perdeu momentos com família/amigos, incapacidade para realizar tarefas do dia-a-dia.

Com que frequência isso foi um problema para sua criança nas últimas 4 semanas?

- | | | |
|--|--|---|
| <input type="checkbox"/> Nenhuma vez | <input type="checkbox"/> Raramente | <input type="checkbox"/> Várias vezes |
| <input type="checkbox"/> Poucas vezes | <input type="checkbox"/> Algumas vezes | <input type="checkbox"/> Quase o tempo todo |
| <input type="checkbox"/> Algumas vezes | | <input type="checkbox"/> O tempo todo |

DE MODO GERAL, COMO VOCÊ AVALIARIA A QUALIDADE DE VIDA DE SUA CRIANÇA POR CAUSA DE PROBLEMAS NASAIS OU DOS SEIOS DA FACE? (faça um círculo em um dos números)

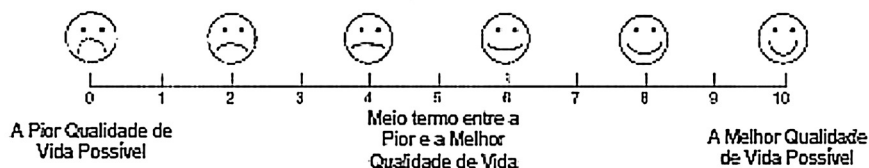


Figure 2 Questionnaire Portuguese-language SN-5.

daily living and issues at work and at school, particularly in patients with symptoms classified as moderate to severe.⁷ The patient's involvement in the proposed treatment and the need for a broader assessment of how and to which extent a given disease or medical intervention affects quality of life are essential factors in any healthcare setting.¹ Measurement of quality of life can help screen and monitor patients with altered clinical status, demonstrate population perceptions of different health problems, and measure the outcomes of medical interventions.¹

Sinonasal complaints and their correlative diseases, such as rhinitis and rhinosinusitis, account for a significant portion of visits to health care facilities. Patients with these

complaints can present with symptoms such as sneezing, nasal discharge, itching, nasal obstruction, facial pain, and coughing, as well as fatigue, mood disorders, and cognitive disturbances.

The need for a disease-specific quality of life questionnaire to assess the impact of sinonasal symptoms in children has been met by the development and validation of the SN-5 instrument. The SN-5 was selected for translation because it is easily and quickly administered.¹⁶ The cross-cultural adaptation process is essential in that it ensures that the overall meaning of the original instrument is preserved. Most questionnaires are developed and validated in the English language.²⁵ A poor translation can produce an

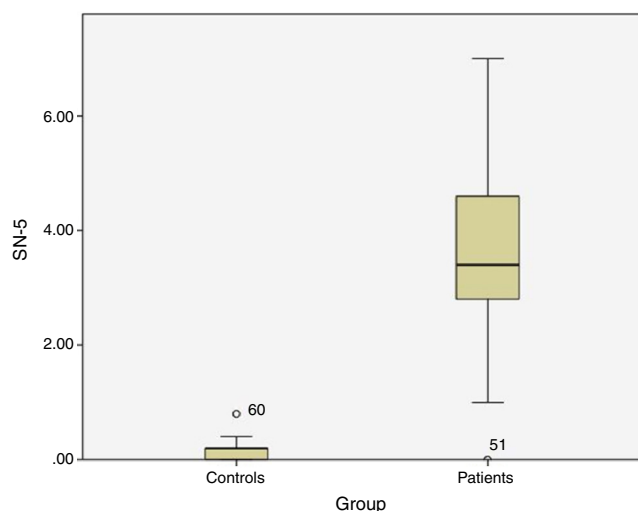


Figure 3 Discriminant validity. SN-5, Sinus and Nasal Quality of Life Survey.

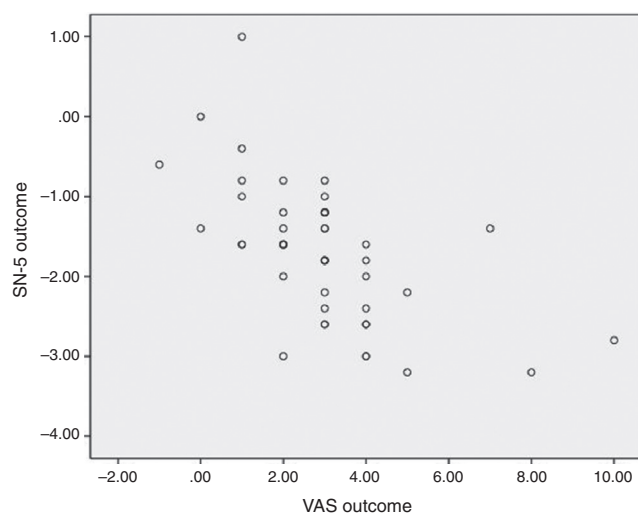


Figure 4 Scatter plot. VAS, visual analog scale; SN-5, Sinus and Nasal Quality of Life Survey.

instrument that is not equivalent to the original, and this lack of equivalence limits comparison of responses obtained in different populations. The process of cross-cultural adaptation of the SN-5 employed a detailed, systematic procedure for formal assessment of semantic equivalence, as published elsewhere.²¹

After its development, the SN-5p underwent a series of semantic validation procedures, which are important and necessary as a means of ensuring conceptual equivalence with the original instrument. The overall impression of the SN-5p was positive, confirming the relevance of its items to assessment of quality of life in pediatric patients, its proper understanding, and the adequacy of the item scoring scale.

The internal consistency reliability of the total scale, as measured by Cronbach's alpha coefficient, was adequate (0.76). Cronbach's alpha is an important measure because it assesses the extent to which questionnaire items correlate among themselves and with the overall results of the

study; it usually represents a measure of item reliability. The original, English-language version of the instrument¹⁶ had a Cronbach's alpha of 0.62. Therefore, the coefficient obtained for the Portuguese version suggests good reliability and shows that the several questionnaire items designed to measure the same construct yielded similar results, which is a finding relevant to the applicability of the instrument.

The SN-5p exhibited test-retest reliability, with a Goodman-Kruskal gamma of 0.957 ($p < 0.001$). This statistic suggests good reproducibility of the questionnaire when it was re-administered to patients one week after the first encounter.

When the SN-5p is administered to the same individual repeatedly over time, changes in score usually provide indirect estimates of an overall change in quality of life, with direct estimates of clinical change reported by the caregiver. Translation and validation of the SN-5p provides clinicians and investigators with a useful, user-friendly instrument that meets a pressing need in view of the high prevalence of sinonasal complaints in the pediatric population. Indirect changes in health status can be measured as changes in score, as obtained through completion of the instrument after an intervention, and this can be used clinically to evaluate the quality of life of pediatric patients with sinonasal disease. The size of the change in score reflects the degree of change in quality of life experienced by the individual.

Total SN-5p scores also correlated well with VAS scores, with a coefficient of 0.62 ($p < 0.001$). This demonstrates the extent to which VAS scores correspond to the overall clinical picture of the patient and that questionnaire items are in fact consistent with the phenomena of interest, providing evidence of the reliability of the questionnaire.

Analysis of discriminant validity between the control and patient groups [median [interquartile range] = 0.20 [0.20] vs. 3.40, $U = 752.5$, $p < 0.01$] demonstrated good ability of the questionnaire to discriminate between individuals with and without sinonasal symptoms.

Effect sizes revealed that the instrument was sensitive to change, as demonstrated by the ratio of mean scores and their standard deviations. The effect size of 2.02 suggests adequate sensitivity to longitudinal changes.

The overall impression of the SN-5p was positive, confirming the relevance of its items to assessment of quality of life in pediatric patients, its proper understanding, and the adequacy of the item scoring scale.

Conclusion

The SN-5p was successfully translated and cross-culturally adapted into Brazilian Portuguese, and the translated version exhibited adequate properties. The questionnaire was effective in assessing the quality of life of pediatric patients with sinonasal complaints, and can be used for this purpose both in the clinical setting and in future research.

Conflicts of interest

The authors declare no conflicts of interest.

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