

Development of a Self-reported Olfactory Dysfunction Questionnaire (SODQ) to screen olfactory disorders in China*

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Abstract

Background: The diagnosis of olfactory dysfunction is challenging given the negligence during routine physical examination, inconvenience of diagnosis in clinical practice, and the inattention to cross-cultural adaptability. The study aimed to develop and validate a simple and effective self-reported olfactory dysfunction questionnaire (SODQ) for the initial screening of clinical olfactory disorders in China.

Methods: A total of 121 subjects participated in the study; of these, 96 subjects completed the T&T olfactometer test and 12-item questionnaire, and 25 participants were retested using the SODQ after one week. The T&T olfactometer test examined the olfactory function and the questionnaire measured the ability to perceive common odors in daily life. We evaluated the factor structure, reliability, validity, and discriminative ability of the SODQ.

Results: The final version of the SODQ consisted of 10 items with one factor. Test-retest and internal consistency were excellent. Convergent validity of the questionnaire with the T&T olfactory test was high. Furthermore, the discrimination ability was high for the questionnaire with an area under the curve of 0.95 and a cut-off point of 22.

Conclusions: The SODQ is a brief, valid, and repeatable tool that has the potential to effectively screen for clinical olfactory disorders from a subjective perspective.

Key words: anosmia, hyposmia, reliability, ROC, validity

Introduction

Olfaction plays a pivotal role in the general quality of life (QOL) of humans, including avoidance of environmental hazards, food intake, and social communication^(1,2). However, olfactory disorders are frequently stated problems that affect approximately one in every five (19–25%) individuals^(3,4). Olfactory dysfunction can be an early indicator of neurodegenerative diseases and psychiatric disorders^(5–7). More recently, an impaired sense of smell has also been associated with COVID-19 as an early symptom of infection⁽⁸⁾. Therefore, the evaluation of olfactory dysfunction is extremely meaningful.

Psychophysical tests for evaluating olfactory function have been developed in the last 30 years. The T&T olfactory test⁽⁹⁾, Sniffin' Sticks test⁽¹⁰⁾, and the University of Pennsylvania Smell Identification Test⁽¹¹⁾ are the most common tools that are widely used in clinical practice and academic research owing to their good psychometric properties (reliability and validity)⁽¹²⁾. However, psychophysical tests may be time-consuming and costly in clinical practice⁽¹³⁾. Therefore, it is also important to screen olfactory dysfunction when psychophysical methods are not available. More recently, psychometric questionnaires and scales have been developed as a useful complementary technique⁽¹⁴⁾. Multi-

language versions of the Questionnaire of Olfactory Disorders (QOD) are now available in English⁽¹⁵⁾, Chinese⁽¹⁶⁾, and Korean⁽¹⁷⁾ owing to good validity and reliability⁽¹⁸⁾, but it addresses only the qualitative olfactory dysfunction (i.e., parosmia) and quality of life. The Self-Reported Mini Olfactory Questionnaire (Self-MOQ) was developed to screen for quantitative olfactory dysfunction (i.e., anosmia and hyposmia) in Germany. This includes five items suitable for daily situations such as “I do not perceive the smell of coffee and fresh bread.”⁽¹⁹⁾ The Self-Administered Odor Questionnaire (SAOQ) was developed in Japan to assess olfactory function in normal subjects, which showed high sensitivity to odor perception but the special odorants for the Japanese population, such as “soy sauce,” “steamed rice,” and “seaweed” makes general evaluation of olfaction problematic^(20,21). In China, there has been a long-time need for psychometric tools with established validity and reliability that screen for quantitative olfactory dysfunction. However, previously published questionnaires like the Self-MOQ and SAOQ are limited to local surveys, and there is no general agreement about cross-cultural adaptability. The primary aim of this study was to develop a simple and effective Self-reported Olfactory Dysfunction Questionnaire (SODQ) to evaluate olfactory function for the Chinese population. The questionnaire was developed to assess the ability to perceive day-to-day odors and validate its effectiveness by correlation with psychometric tests that have been developed for measurement of olfactory function. The secondary aim of this study was to obtain cut-off points of the questionnaire score using receiver operating characteristic (ROC) curves.

Materials and methods

Participants

One hundred and forty-seven participants were recruited at the Department of Otolaryngology, Sun Yat-sen Memorial Hospital of Sun Yat-sen University, Guangzhou, China, from June to October 2020. The eligible patients were determined according to the following inclusion criteria: age >16 years; complaining of rhinologic symptoms (such as nasal obstruction, running nose, olfactory dysfunction, rhinalgia or facial pain); and can understand the olfactometer test and the questionnaire. After eliminating missing data of 26 participants, 96 participants (52 men and 44 women; mean age: 41 years, range: 16–75 years) completed the T&T olfactometer test and SODQ, and 25 participants (14 men and 11 women; mean age: 47.48 years, range: 23–67 years) who initially completed the SODQ were retested by this questionnaire. This study was approved by the Ethics Committee of Sun Yat-sen Memorial Hospital of Sun Yat-sen University (SYSEC-KY-KS-2019-175). All participants provided written informed consent.

Materials

T&T olfactometer test

Olfactory function was assessed by the T&T olfactometer test⁽⁹⁾. The standard olfactometer was made of five olfactory elements (β -phenyl ethyl alcohol, methyl cyclopentenolone, iso-valeric acid, γ -undecalactone, and skatole). For each odorant, an incremental series of concentrations (10-fold method: 10–2–105) was presented. The test based on the odor concentration aimed to detect the olfactory detection threshold (DT) and recognition threshold (RT). DT was defined as the lowest odorant concentration detectable by the subject, whereas RT was defined as the lowest concentration at which the odor can be identified. When the participant was unable to detect or recognize an odor at the highest concentration, the threshold was defined as the highest step plus one. The olfactory function was categorized into five classes according to the average RT value. An average value of <1 was considered normosmic, and values of 1.1–2.5, 2.6–4.0, 4.1–5.5, and >5.6 were indicative of mild hyposmia, moderate hyposmia, severe hyposmia, and anosmia, respectively.

SODQ

The SODQ was developed based on the literature review and clinical practice to identify appropriate items for inclusion. A 12-item version of the SODQ was originally developed. The items were self-statements and measured common odor perception problems in daily life (e.g., “I can’t smell the scent of the food when eating,” see Table 1). According to daily experience, participants could rate on a 4-point Likert scale ranging from 0 to 3 (0=“Totally disagree”; 1=“Partially disagree”; 2=“Partially agree”; 3=“Totally agree”). All participants completed the SODQ; 96 patients completed the questionnaire before the T&T olfactometer test, and the remaining 25 participants were retested using the SODQ after one week.

Data analysis

All analyses were carried out using SPSS, version 25.0 (IBM, Armonk, NY, USA). An exploratory factor analysis (EFA) was performed to evaluate the number of underlying dimensions. The principal components analysis (PCA) and orthogonal (varimax) rotations were analyzed in original items. The internal consistency of each item was calculated by Cronbach’s alpha coefficient. Test–retest stability of the SODQ was evaluated by Pearson’s correlation coefficient between the questionnaires completed twice by the 25 participants. Convergent validity was tested by the correlation between the SODQ score and the result of the T&T olfactometer test. Receiver operating characteristic (ROC) curve was performed to investigate the discrimination of SODQ. The discriminatory cut-off point was a point with high sensitivity and specificity, which can identify whether the participant with an olfactory disorder⁽²²⁾. For all statistical analyses, $p < 0.05$ was considered to indicate statistical significance.

Table 1. Subjective evaluation questionnaire of olfactory function.

Items	Totally disagree	Partially disagree	Partially agree	Totally agree
1. I can't smell the aroma of the food when eating.	0	1	2	3
2. I can't smell familiar fruits in supermarkets or fruit shops.	0	1	2	3
3. I can't smell the condiments such as vinegar or soy sauce in the kitchen.	0	1	2	3
4. I can't smell the food when it burns, but my family can smell it.	0	1	2	3
5. I can't smell the gas leak, but my family can smell it.	0	1	2	3
6. I can't smell the smell of pets, but my family can.	0	1	2	3
7. I can't smell the rancid smell when I pass the rancid trash can.	0	1	2	3
8. I can't smell the bad smell of the toilet.	0	1	2	3
9. I can't smell the coffee and fresh bread.	0	1	2	3
10. I can't smell the flowers in flower shop.	0	1	2	3
11. I can't smell the paint at the decoration site.	0	1	2	3
12. I can't smell the mowing.	0	1	2	3

Note: Items 6 and 12 were deleted in the final version of the SODQ.

Results

Olfactory outcomes

The olfactory function of 96 participants was tested and categorized by the T&T olfactometer test. The average score of DT and RT of the T&T olfactometer test was -0.53 ± 2.93 and 0.03 ± 3.09 , respectively. Based on the RT score, 73 participants (-1.62 ± 0.57) were normosmic, one had mild hyposmia (-0.2), two had moderate hyposmia (3.80 ± 3.11), four had severe hyposmia (4.95 ± 0.77), and 16 had anosmia (5.86 ± 0.28).

Exploratory factor analysis (EFA)

An EFA was performed on 121 participants. Item-total correlations were assessed with the original 12 items. The results showed a high degree of correlation between each item score and total score ($0.88 < r < 0.96$, $p < 0.01$).

The Kaiser–Meyer–Olkin Measure of Sampling Adequacy (KMO) and Bartlett test of sphericity were applied to determine whether the sample data were suitable for EFA. The KMO value was 0.95, with a significant result found in the Bartlett's sphericity test ($\chi^2 = 2494.23$, $df = 66$, $p < 0.01$). Principal component analysis and scree-plot inspection both identified a single factor (eigenvalue: 10.32), which explained 86.03% of the variance in the item scores. The factor solution was obtained based on the item's factor loadings. The results showed high common values (0.77 – 0.92) and factor-loading values (0.88 – 0.96). The scores for all factors were > 0.6 , indicating that despite the differences in expression, all items were related to the same potential dimension. To avoid verbosity, items with factor loading ≤ 0.9 were eliminated (items 6 and 12). Therefore, the final version of the SODQ includes 10 items with one factor.

Reliability and convergent validity

The reliability and validity of the final version of the questionnaire were analyzed. Twenty-five participants were retested with the SODQ after one week. Intraclass correlation coefficient revealed excellent test–retest reliability ($r = 0.98$, $p < 0.01$) (Figure 1). The correlation between the SODQ score and T&T olfactometer test score by 96 participants showed good convergent validity ($r = 0.82$, $p < 0.01$). Cronbach's alpha coefficient was 0.99 ($p < 0.01$) from the 121 final versions of the questionnaire, suggesting high internal consistency.

ROC analysis

Considering the small number of samples, all groups of olfactory function impairment were classified into one category, including 23 cases (DT = 4.09 ± 2.77 , RT = 5.26 ± 1.55). Analyses based on the ROC curve were performed to investigate the discrimination between olfactory impairment and normosmia in the final version of SODQ. The area under the ROC curve was 0.95 ($p < 0.01$) (Figure 2). The sensitivity and specificity values are highlighted for Youden's index of 0.87 and a score cut-off point of 22.

Relationship between the SODQ and T&T olfactometer test scores of the demographic variables

No significant correlation was found between the total score of SODQ and age ($r = 0.02$, $p = 0.80$). The scores of DT and RT of the T&T olfactometer test had no significant relationship with age (DT: $r = -0.02$, $p = 0.88$; RT: $r = 0.01$, $p = 0.91$). The independent samples t-test indicated that sex had no significant effect on the T&T olfactometer test threshold and SODQ score (all $p > 0.05$).

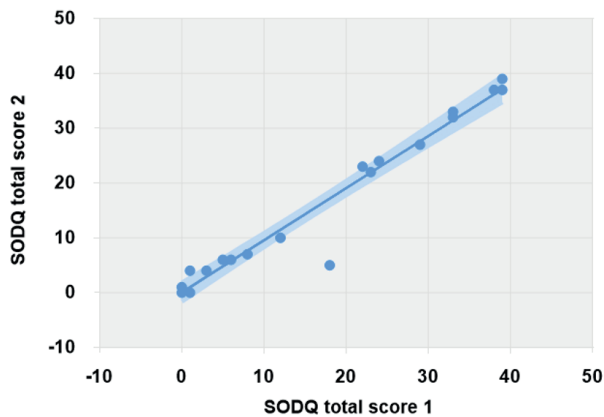


Figure 1. Relationship between SODQ total score 1 and SODQ total score 2 after 1 week. ($r=0.98$, $p<0.01$).

Discussion

In this study, we developed a simple and valid questionnaire—the SODQ—to assess the olfactory function of Chinese patients. The high psychometric properties of the SODQ were certified by the EFA and reliability and validity tests.

Our results clearly demonstrate that the SODQ has excellent psychometric properties. First, the reliability coefficient provides strong evidence that SODQ is internally consistent (0.99) and stable over time (0.98). Second, the SODQ exhibited adequate convergent validity as evidenced by the correlation with the questionnaire score and the score of the T&T olfactometer test (0.80). Third, the results of this study also indicated that based on the sensitivity and specificity of the test, discrimination between the olfactory impairment (hyposmia or anosmia) and normosmia are high (sensitivity=87%; specificity=96%) when combined with the area under the ROC curve, indicating a high degree of diagnostic accuracy. The optimal cut-off score for the ROC curve was 22, which distinguishes between normosmia and presence of olfactory disorders.

The development of this questionnaire complements those of earlier studies with respect to psychophysical tests and cultural adaptability issues. As the items in the SODQ are very common and daily in life, it may also have good cross-cultural adaptability. Although the current research is aimed to develop SODQ for the Chinese, we expect that it may also be applied in other countries in the future. Besides, the use of this questionnaire may be to improve our convenience in diagnosing olfactory dysfunction in future clinical applications. Previous evidence suggested that a questionnaire tool may play an important role in the large-scale preclinical diagnosis and evaluation of patients with olfactory dysfunction during treatment⁽²³⁾. The questionnaire has been especially effective during the COVID-19 pandemic, as it could combine subjective tools and psychophysical tests to mutually complement detection of olfactory disorders⁽²⁴⁾. Taken together, these advantages indicate that the questionnaire can

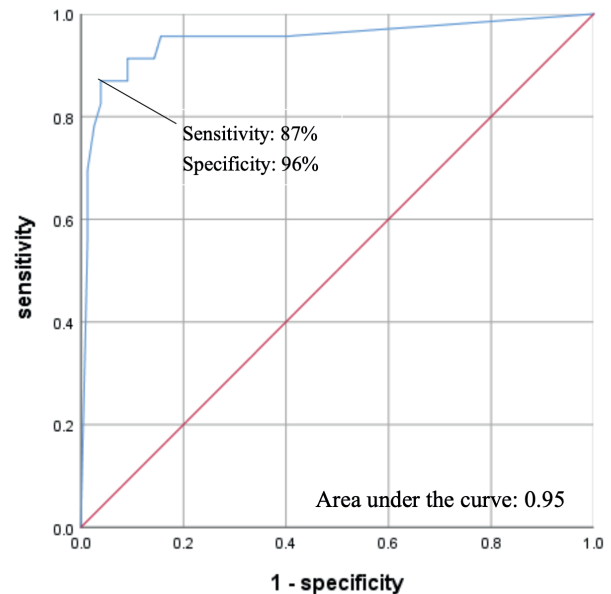


Figure 2. Receiver-operating-characteristic (ROC) curve.

play a great role in clinical primary screening and other future applications.

In our results, no significant correlation was found between age and olfactory performance. The finding was inconsistent with previous studies, which suggested that the olfactory performance was related to age^(10,19). Oleszkiewicz and colleagues found that olfactory performance decreased significantly after 60 years old⁽²⁵⁾. Therefore the reason for the inconsistent results may be that most of the patients were less than 60 years old ($n=87$, 90.6%) in our study.

A limitation of this study is its small sample size and all participants being recruited from a single center. A larger sample size from more clinics may likely improve the accuracy of the questionnaire. In addition, we did not perform the visual analogue scale (VAS) to score the sense of smell of the patients as subjective tool in this study. We will use the VAS before the smell test in the future studies.

Conclusion

Our study offers strong evidence that the SODQ is a useful and reliable application tool. We are hopeful that based on these results the SODQ can be applied in routine clinical practice to detect olfactory disorders in Chinese patients. However, we believe that this questionnaire method will still work best only in combination with psychological physical measurements.

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Authorship contribution

LQZ and XL designed the study and formulated the research question. XL conducted the data collection examination. LQZ and JYH analyzed the data. JYH and XL wrote the first draft of the manuscript. XL, JYH, JWH, PT and LQZ contributed to the interpretation and discussion of the results and commented on

the draft. All authors have read and approved the final manuscript.

Conflict of interest

The authors declare no conflict of interest.

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