Translation and Validation Assessment of the Chinese Version of the Chronic Sinusitis Survey

Pa-Chun Wang, MD, MSc; Chih-Jaan Tai¹, MD, MSc; Chia-Chen Chu², MSc; Shu-Cheng Liang², MSc

Background: The Chronic Sinusitis Survey (CSS) is a valid, disease-specific measure for evaluating the health status and treatment effectiveness of adults with chronic rhinosinusitis (CRS). In this study, we developed a Chinese version of the CSS (CCSS) which provides the psychometric properties of the Chinese CSS.

Methods: The CSS was translated into Chinese using a parallel model. The CCSS was administered to 198 patients in a prospective manner, and was validated in order to establish its reliability and validity.

Results: The CCSS demonstrated good test-retest reliability (correlation coefficient = 0.6~0.89, \( p = 0.0001 \)) and internal consistency (Cronbach's \( \xi \) =0.76). The CCSS results were significantly correlated with bodily pain (BP), general health (GH), role-emotional (RE), and mental health (MH) subscales of the Chinese (Taiwan) version of the generic 36-item Short-Form Health Survey (TSF-36). The standardized response mean for the CCSS total score was 0.75, indicating good sensitivity to clinical change.

Conclusions: This validation study demonstrates that the performance characteristics of the CCSS meet the criteria for a valid measure. The CCSS is a valid tool to evaluate adults with CRS among Mandarin-speaking populations.


Key words: chronic rhinosinusitis, outcomes, Chronic Sinusitis Survey.

Reporting subjective outcomes based on patient-oriented surveys is a widely accepted methodology among sinus surgeons.¹² The Chronic Sinusitis Survey (CSS) is a validated outcomes measure for evaluating health impacts and treatment effectiveness in adults with chronic rhinosinusitis (CRS).¹³ The CSS has been used to identify quality-of-life consequences of CRS such as sinus-related symptoms and medical resource utilization associated with CRS.⁴⁻⁷ While treatment effectiveness in CRS has been established through conventional studies, the patient-based CSS enables physicians to understand the effects of CRS and how intervention affects the functioning and well-being of the patients from patients' point of view.⁸⁻¹⁰ The need for quality-of-life instruments is global. There is no validated Chinese language quality-of-life instrument to evaluate patients with CRS.

From the Department of Otolaryngology, Cathay General Hospital, Taipei; ¹Department of Otolaryngology, China Medical College Hospital, China Medical College, Taichung; ²Department of Public Health, China Medical College, Taichung, Taiwan.

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Address for reprints: Dr. Pa-Chun Wang, Department of Otolaryngology, Cathay General Hospital. 280, Sec.4, Jen-Ai Road.,106, Taipei, Taiwan, R.O.C. Tel.: 886-2-27082121 ext.5036; Fax: 886-2-27074949; E-mail: drtony@tpts4.seed.net.tw
Rather than design a new instrument, we believe that having a common tool available in both English and Chinese will make it possible to combine data from various centers worldwide for analysis. A uniform CRS outcomes measure will provide cross-cultural quality-of-life information and provide a way to compare treatment effectiveness under different healthcare systems. The aims of this study were to translate and validate a Chinese version of the Chronic Sinusitis Survey (CCSS). The performance characteristics of a quality-of-life measure include its reliability and validity.

METHODS

Chronic sinusitis survey

The CSS (Table 1) was developed by the Clinical Outcome Research Unit of the Massachusetts Eye and Ear Infirmary, is a 6-item, duration-based survey that evaluates sinus-related symptoms and medication usage associated with CRS on a Likert scale, i.e., every question has 5 response options. The CSS generates a total score and 2 subscale scores (symptom score and medication score). The symptom subscale score (CSS-S) reflects sinus-related symptoms such as headaches, nasal drainage, and nasal congestion directly related to CRS. The medication subscale score (CSS-M) is reflective of medical resource (antibiotics, nasal spray, and antihistamines) utilization for the treatment of CRS. Survey total and subscale scores are normalized on a 0 (worst) to 100 (best) scale based on published algorithms.\(^{(b)}\)

Instrument translation

The development of the CCSS followed the standard forward step, backward step, and pretest step for instrument translation.\(^{(9)}\) Authorization to translate was obtained in advance. The CSS was first translated into Mandarin Chinese and then back into English iteratively by 2 bilingual otolaryngologists until the 2 versions were considered completely interchangeable (Table 2). A bilingual lay panel consisting of 3 individuals with different backgrounds was then used to measure comprehensibility, test translation alternatives, highlight unexpected errors, and reveal inappropriate items.

Study population

One hundred and ninety-eight consecutive adult patients with a diagnosis of CRS were prospectively enrolled. In compliance with the 1997 AAO-HNS Rhinosinusitis Task Force definition, chronic rhinosinusitis was defined as an infectious condition of the nose and sinuses of at least 3 months’ duration characterized by various nasal symptoms.\(^{(10)}\) Diagnosis was made based on symptoms consistent with CRS (e.g., purulent rhinorrhea, headaches, etc.). All patients underwent bone-window sinus computerized tomography to confirm the mucosal change within the sinuses.

Table 1. English Version of the Chronic Sinusitis Survey

<table>
<thead>
<tr>
<th>1. During the past 8 weeks, how many weeks have you had:</th>
<th>2. During the past 8 weeks, how many weeks have you taken:</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Sinus headaches, facial pain, or pressure</td>
<td>a. Antibiotics</td>
</tr>
<tr>
<td>0 weeks 1-2 weeks 3-4 weeks 5-6 weeks 7-8 weeks</td>
<td>0 weeks 1-2 weeks 3-4 weeks 5-6 weeks 7-8 weeks</td>
</tr>
<tr>
<td>b. Nasal drainage or postnasal drip</td>
<td>b. Nasal sprays prescribed by your doctor</td>
</tr>
<tr>
<td>0 weeks 1-2 weeks 3-4 weeks 5-6 weeks 7-8 weeks</td>
<td>0 weeks 1-2 weeks 3-4 weeks 5-6 weeks 7-8 weeks</td>
</tr>
<tr>
<td>c. Nasal congestion or difficulty breathing through your nose</td>
<td>c. Sinus medications in pill form (such as antihistamines, decongestants)</td>
</tr>
<tr>
<td>0 weeks 1-2 weeks 3-4 weeks 5-6 weeks 7-8 weeks</td>
<td>0 weeks 1-2 weeks 3-4 weeks 5-6 weeks 7-8 weeks</td>
</tr>
</tbody>
</table>

Table 2. Chinese Version of the Chronic Sinusitis Survey

<table>
<thead>
<tr>
<th>1. 过去8周内，您患病的周数是：</th>
<th>2. 过去8周内，您服用的周数是：</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. 颞压，面部疼痛，或疼痛</td>
<td>a. 抗生素</td>
</tr>
<tr>
<td>0周 1-2周 3-4周 5-6周 7-8周</td>
<td>0周 1-2周 3-4周 5-6周 7-8周</td>
</tr>
<tr>
<td>b. 鼻腔溢液或鼻后滴液</td>
<td>b. 鼻喷雾剂由您医生开的</td>
</tr>
<tr>
<td>0周 1-2周 3-4周 5-6周 7-8周</td>
<td>0周 1-2周 3-4周 5-6周 7-8周</td>
</tr>
<tr>
<td>c. 鼻塞或鼻塞在你的鼻子里</td>
<td>c. 罂粟碱，去充血药等 (如{a. 抗生素， nasal spray, and antihistamines})</td>
</tr>
<tr>
<td>0周 1-2周 3-4周 5-6周 7-8周</td>
<td>0周 1-2周 3-4周 5-6周 7-8周</td>
</tr>
</tbody>
</table>
Survey forms
At entry into this study, all patients received the self-administered CCSS and the research-validated Chinese (Taiwan) version of the Medical Outcome Study 36-Item Short-Form Health Survey (SF-36). Permission to use the SF-36 was obtained from the Medical Outcomes Trust of Boston, MA, USA. The SF-36 is a widely used, generic quality-of-life measure with 8 domains of general health including: physical function (PF), role functioning-physical problems (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role functioning-emotional problems (RE), and mental health (MH). Scores were tabulated according to published algorithms from 0 (worst) to 100 (best) (Table 3).

Reliability of the CCSS
One hundred and eighty-four patients with CRS awaiting surgical scheduling and without known interval clinical change from treatment were retested with the CCSS after a 2- to 4-week interval. Spearman rank order correlation coefficients were used to determine the test-retest reliability for individual items, subscales, and total survey scores. Cronbach α correlation coefficients were used to calculate the internal consistency of the CCSS.

Validity of the CCSS
The CCSS was assessed for convergent validity through correlations to validated SF-36 results. Patients with major systemic comorbidity were excluded from the validity test; in total, 131 complete sets of the CCSS and SF-36 were obtained from 198 patients.

Responsiveness of the CCSS
Sixty-nine of 131 patients used in the validity test were again tested with the CCSS 6 months after standard functional endoscopic sinus surgery. Sinus infections in these patients were all successfully controlled as determined by their physicians based on post-operative endoscopic findings at the 6-month postoperative evaluation. Longitudinal sensitivity to clinical change was calculated as the standardized response mean (SRM = response mean/response standard deviation), according to methodology described by Liang et al.

CCSS population norm
One hundred and forty-six consecutive healthy adults presenting to the same institution but without a history of nose complaints or sinus surgery were administered the CCSS to establish a normative sample.

Data management
All data were stored in an Access 7.0 database (Microsoft, Redmond, WA). Analyses were conducted using the SAS software package (SAS Institute, Cary, NC).

RESULTS
Study population
The mean age for the 198 patients at entry was 40.1 ± 14.6 years (range, 18-84), and 53.5% were male. Smoking was reported in 18.7% of cases, while 47.4% had concurrent allergic rhinitis. All patients had CRS; other systemic comorbidities such as hypertension, diabetes, chronic heart failure, asthma, depression, and recent acute myocardial infarction were reported in 67 cases.

Reliability of the CCSS
The test-retest reliability (Table 4) of individual items, subscores, and total survey scores were high; the correlation coefficients for CCSS-S and CCSS-M subscores and total score were 0.84, 0.67, and 0.82.
respectively. The performance consistency correlation coefficients among individual items and grouped items are tabulated in Table 4.

Cronbach α correlation coefficients for internal consistency were calculated as 0.67 for the CCSS-S subscale, 0.75 for the CCSS-M subscale, and 0.76 for the total survey.

Validity of the CCSS

Subscale scores for the TSF-36 were tabulated according to published algorithms. Representing different aspects of general health, the TSF-36 is divided into 8 subscales. The 8 subscale scores of the TSF-36 were compared with the CCSS-S, CCSS-M subscale scores and the total score on the CCSS and correlation coefficients were derived (Table 5). Overall, the CCSS symptom and medication subscores demonstrated significant correlations with the BP and RE TSF-36 subscale scores. The CCSS total score correlated well with BP (r = 0.29, p < 0.001, 95% CI 0.15–0.42), RE (r = 0.24, p < 0.05, 95% CI 0.13–0.57), and MH (r = 0.20, p < 0.05, 95% CI 0.11–0.35) TSF-36 subscale scores.

Responsiveness of the CCSS

Of the 69 patients who underwent clinically successful surgery, the mean change in the CCSS total score was 24.2; 32.4. The standardized response mean for the CCSS total score was 0.75, indicating a moderate responsiveness or sensitivity to clinical change.17

CCSS normative data

The mean age of the normative population was 35.1; 12.4 years (range, 18-75) with 57.2% male and 42.8% female. Normative CCSS data yielded an average total score of 96.3; 8.0, a symptom subscore of 94.5; 11, a medication subscore of 97.9; 7.9.

DISCUSSION

Understanding quality-of-life issues in health and disease is a global concern. Outcomes data collected from various health care systems can enhance our understanding of the impact of a disease and its treatment effectiveness. In the past, there was no Chinese instrument available to assess quality-of-life outcomes for patients with chronic rhinosinusitis. In this study, we demonstrate the Chinese version of the CCSS (CCSS) to be a valid, disease-specific health measure that can be used to evaluate adult patients with CRS among Chinese-speaking populations.

Development of the CCSS followed the standard forward, backward, and pretest steps for instrument translation. We used a parallel model approach in this study to establish a basis for cross-national comparability in the original validation stages of the CSS.13
The CCSS demonstrated robust test-retest reliability for individual test items, subscales, and for total score. However, as expected, some individual items may not overcome cultural differences despite extensive translation efforts. For example, the lowest correlation was detected on item 2c regarding tablet form of medication. Patients were obviously not sure about what medicine their physicians had prescribed to them. Yet, despite this anomaly, the test-retest reliability for the symptom and medication subscales and for total score are all comparable to the reported correlation coefficients of the English language version of the CSS (which range from 0.69 to 0.82). Internal consistency for the CCSS total score (Cronbach’s $\xi=0.76$) exceeded the recommended level of 0.7 commonly used to establish a reliable measure for population studies and is comparable to that of English version of the CSS (0.73). Correlations of the CCSS with the validated TSF-36 general health measure was used as a test of convergent validity. The CCSS total survey score showed significant correlations with several subscales of the TSF-36, including BP, GH, RE, and MH. The level of correlations between the CCSS and TSF-36 were in part consistent with those between the CSS and SF-36. These weak but significant correlations also imply that CRS might have mild but important impacts on a patient’s general health.

Responsiveness, or sensitivity to longitudinal change is the ability of a health instrument to detect clinical change over time. The CCSS demonstrated a good standardized response mean (0.75), indicating moderate responsiveness to clinical change. (A value of 0.2 or less is poor, 0.5 is moderate, and 0.8 or greater indicates excellent responsiveness). Hence, the CCSS meets the criteria for a sensitive instrument that can be used in clinical studies of CRS therapies.

All outcomes measures should provide a definition of normal functioning. The normative CCSS provides an important domestic benchmark for understanding what is considered "normal" functioning and therefore what the goals of therapy are. In conclusion, the CCSS is a valid, reliable, and sensitive outcomes measure. Validation demonstrated only minor language effects; the statistical properties of the CCSS are compatible with those of English version of the CSS. The CCSS is a validated equivalent of the CSS that can be used to measure quality-of-life outcomes in CRS among billions of adults in Chinese-speaking populations.

REFERENCES

Chronic Sinusitis Survey (CSS) (reliability): $\alpha = 0.6-0.89$, $p = 0.0001$ (Cronbach $\alpha = 0.76$) (validity).