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

Pa-Chun Wang, MD, MSc; Chih-Jaan Tai[1], MD, MSc; Chia-Chen Chu[2], MSc; Shu-Cheng Liang[2], 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 £\=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.
(Chang Gung Med J 2002;25:9-15)

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

Reporting subjective outcomes based on patient-oriented surveys is a widely accepted methodology among sinus surgeons.[1,2] The Chronic Sinusitis Survey (CSS) is a validated outcomes measure for evaluating health impacts and treatment effectiveness in adults with chronic rhinosinusitis (CRS).[3] 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¡f point of view.[7,8]

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; [1]Department of Otolaryngology, China Medical College Hospital, China Medical College, Taichung; [2]Department of Public Health, China Medical College, Taichung, Taiwan.
Received: Jun. 13, 2001; Accepted: Sep. 3, 2001
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.[3]

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

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

Table 2. Chinese Version the Chronic Sinusitis Survey

¡u″C'˝» ˜u″‰ <d″ ¡v//¶‴

/@¡Bƒb„L#ƴK> <P·`• //¡Aƒ‡ƒh/ > <P·`–zƒ‡¡G
a. » ˜u/ _“” Y h¡B^C>–flk h'¸ £″ƒ•P ?
❶ 0¶g ❷ 1-2¶g ❸ 3-4¶g ❹ 5-6 ¶g ❺ 7-8¶g
b. <y» fi '¸» fi >¸<y ?
❶ 0¶g ❷ 1-2¶g ❸ 3-4¶g ❹ 5-6 ¶g ❺ 7-8¶g
c. » “ ¶º•P' ¸˜—o¥¸» /1'I§l§x^1 ?
❶ 0¶g ❷ 1-2¶g ❸ 3-4¶g ❹ 5-6 ¶g ❺ 7-8¶g

/G¡Bƒb„L#ƴK> <P·`• //¡Aƒ‡ƒh/ > <P·`–z·¿¤˜¥¸¡G
a. §¥fl
❶ 0¶g ❷ 1-2¶g ❸ 3-4¶g ❹ 5-6 ¶g ❺ 7-8¶g
b. ´¥˝#B⁄£‴”» ..Q fl ?
❶ 0¶g ❷ 1-2¶g ❸ 3-4¶g ❹ 5-6 ¶g ❺ 7-8¶g
c. ‟v ł» ˜u ^D”” fl˜˜“« (ƒp§ † ´·fi ¡B#¥Rƒ fl)?
❶ 0¶g ❷ 1-2¶g ❸ 3-4¶g ❹ 5-6 ¶g ❺ 7-8¶g

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 (TSF-36).[11] Permission to use the TSF-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).[12-15] Scores were tabulated according to published algorithms from 0 (worst) to 100 (best) (Table 3).[16]

Table 3. SF-36 Subscale and Definition

Subscale	Definition
Physical functioning (PF)	Limitation of physical activities such as walking, bathing, and strenuous sports
Role-physical (RP)	Problems with work or other daily activities as a result of physical health
Bodily pain (BP)	Intensity of bodily pain or limitations due to pain
General health (GH)	Perception of current health and health outlook
Vitality (VT)	Level of energy
Social functioning (SF)	Extent of health problems interferes with normal social activities
Role-emotional (RE)	Problems with daily activities as a result of emotional issues
Mental health (MH)	Mental health screening

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.[17]

Validity of the CCSS

The CCSS was assessed for convergent validity through correlations to validated TSF-36 results. Patients with major systemic comorbidity were excluded from the validity test; in total, 131 complete sets of the CCSS and TSF-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.[18]

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 varied from 0.6 to 0.89. The test-retest reliability of subscores and the total score were high; the correlation coefficients for CCSS-S and CCSS-M subscores and total score were 0.84, 0.67, and 0.82

Table 4. Spearman Correlation Coefficients for Test-retest Reliability of the Chinese Version of the Chronic Sinusitis Survey

		CCES	
Individual items	No.	*Spearman r*	*p*
1a	184	0.69	0.0001
1b	184	0.83	0.0001
1c	184	0.76	0.0001
2a	184	0.66	0.0001
2b	184	0.89	0.0001
2c	184	0.60	0.0001
Subscale			
CCSS-S	184	0.84	0.0001
CCSS-M	184	0.67	0.0001
Total survey	184	0.82	0.0001

CCSS-Chinese version of the Chronic Sinusitis Survey.
CCSS-S (symptom subscale)-items 1a, 1b, 1c; CCSS-M (medication subscale)-items 2 a-c; total survey-items 1 a-c; 2 a-c

Table 5. Spearman Correlation Coefficients between the Chinese Version Chronic Sinusitis Survey and TSF-36

	CCSS-S		CCSS-M		TOTAL	
TSF-36	r	p	r	p	r	p
PF	0.15	NS	0.10	NS	0.18	NS
RP	0.10	NS	0.14	NS	0.13	NS
BP	0.30	<.001	0.27	<.001	0.29	< 0.001
GH	0.22	<.05	0.17	NS	0.20	< 0.05
VT	0.12	NS	0.11	NS	0.11	NS
SF	0.09	NS	0.05	NS	0.10	NS
RE	0.28	<.05	0.21	<.05	0.24	< 0.05
MH	0.24	<.05	0.13	NS	0.20	< 0.05

Abbreviations: NS: not significant; CCSS-S: symptom subscale; CCSS-M:medication subscale; Total: total survey score; PF: physical functioning; RP: role-functioning-physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning; RE: role-functioning-emotional; MH: mental health

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 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 0.11~0.44), GH ($r = 0.20$, $p < 0.05$, 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.[18]

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 CSS (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.[3]

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).[3] Internal consistency for the CCSS total score (Cronbach's £\=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).[3,17,19]

Correlations of the CCSS with the validated TSF-36 general health measure was used as a test of convergent validity.[20] 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.[3] 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).[18] 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

1. Kennedy DW, Wright ED, Goldberg AN. Objective and subjective outcomes in surgery for chronic sinusitis. Laryngoscope 2000;110(suppl.):29-41.
2. Hoffman SR, Mahoney MC, Chmiel JF, Stinziiiano GD, Hoffman KN. Symptom relief after endoscopic sinus surgery: an outcomes-based study. Ear Nose Throat J 1993;72:413-20.
3. Gliklich RE, Metson R. Technique for outcomes research in chronic sinusitis. Laryngoscope 1995;105:387-90.
4. Gliklich RE, Hilinski JM. Longitudinal sensitivity of generic and specific health measures in chronic sinusitis. Qual Life Res 1995;4:27-32.
5. Gliklich RE, Metson R. The health impact of chronic sinusitis in patients seeking otolaryngologic care. Otolarygol Head Neck Surg 1995;113:104-9.
6. Glilich RE, Metson R. Effect of sinus surgery on quality of life. Otolaryngol Head Neck Surg 1997;117:12-7.
7. Metson RB, Gliklich RE. Clinical outcomes in patients with chronic sinusitis. Laryngoscope 2000;110:24-8.
8. Gliklich RE, Metson R. Economic implications of chronic sinusitis. Otolaryngol Head Neck Surg 1998;118:344-9.
9. Approaches to instrument translation: issues to consider. Medical Outcomes Trust Bulletin 1997;5:2.
10. Lanza DC, Kennedy DW. Adult rhinosinusitis defined. Otolaryngol Head Neck Surg 1997;117:S1-S7.
11. Lu JF, Tseng HM, Gandek B. Feasibility of the SF-36 Health Survey in Taiwan Chinese population: some cultural implications. Presented at the SF-36 mini-seminar, Jan 29, 2000, Taipei, Taiwan.
12. Ware JE, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36): I. Conceptual framework and item selection. Med Care 1992;30:473-83.
13. McHorney CA, Ware JE, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health construct. Med Care 1993;31:247-63.
14. Ruta DA, Abdalla MI, Garratt AM, Coutts A, Russell IT. SF 36 health survey questionnaire: I. Reliability in two patient based studies. Qual Health Care 1994;3:180-5.
15. Brazier JE, Harper R, Jones NMB, O'Cathain A, Thomas KJ, Usherwood T, Westlake L. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. Br Med J 1992;305:160-4.
16. Ware JE. Validity: norm-based interpretation. In: Ware JE, ed. SF-36 Health Survey Manual and Interpretation

Guide. Boston, Mass: Nimrod Press, 1993;10:1-10:38.
17. Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika 1951;16:297-334.
18. Liang MH, Fossel AH, Larson MG. Comparisons of five health status instruments for orthopedic evaluation. Med Care 1990;28:632-42.
19. Cohen J. Statistical Power Analyses for the Behavioral Sciences. 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates, 1988:109-44.
20. Nunnally JC. Psychometric Theory. 2nd ed. New York, NY: McGraw-Hill, 1978:86-116.

»{^ /// "'　¡u"C'˚» ˜u"¢„w«Æ‰ ‹d"　¡V

/ ' ‚s　„§fi[1]　ƒ¶¤¸flu[2]　–†Q‹F[2]

> I ‹"G　"C'˚» ˜u"¢„w«Æ‰ ‹d"　(Chronic Sinusitis Survey, CSS) ‹O/@¥ ‚g†¸>p ˙»{^ ""fiefiffiSfi '˚ ¤ ¡A¥¸¤ ·œ¶qƒ¤ƒ~"C'˚» /¸» ˜u"¢flf/H •–d"<"p¥H/¸¤ "v łfi˜flq¡C¥»‹ª¤s–N ¡u"C'˚» ˜u"¢„w«Æ‰ ‹d"　¡V/'¥H//˜¶¡A¤ˆ·£¥X¤ †¸>p»{^ …˘ ¡C

/Ł 'k G　¥»‹ª¤s–N　¡u"C'˚» ˜u"¢„w«Æ‰ ‹d"　¡V¥H¥>ƒ … ƒ¡/'¥H//˜¶¡C/// "'/§　¡u"C'˚» ˜u"¢„w«Æ‰ ‹d"　¡V¥H«e´/'˚/Łƒ¡ „/' 198ƒWflf/H¡A†¸>p»{^ ¸·œƒ„ ¤ /§«H« (reliability) ¡B̃fi« (validity) ¡C

† "G G　‹ª¤s¯ª¥ /// "'　¡u"C'˚» ˜u"¢„w«Æ‰ ‹d"　¡V¤ªƒ‡¤}ƒn/§·œ, -ƒA·œ, fi˜« (‹ ˆ «Y..˘ =0.6~0.89, p› ¨=0.0001) /¸/"‡¡/@>P'˚ (Cronbach ƒ>¨ =0.76) ¡C/// "'　¡u"C'˚» ˜u"¢„w«Æ ‰ ‹d"　¡V–O/ »P/// "'　¡uSF-36 ª¯Ø •–d ¤‰ ‹d　¡V(Mandarin Chinese (Taiwan) version Medical Outcome Study 36-Item Short-Form Health Survey, TSF-36) /§¤>¯Øflk h (bodily pain, BP) ¡B ª¯Ø •–d (general health, GH) ¡B–¡" ¥\fl ¤/ƒ (role functioning-emotional, RE) /¸/ †z •–d (mental health, MH) ƒ‡¯ª ‹ ˆ ¡C/// "'　¡u"C'˚» ˜u"¢„w«Æ‰ ‹d " ¡V`'/ /§..–•˙/˜/˜ ‡¥>§¡>¨　(standard response mean, SRM) ‹ 0.76 ¡A" ¥ ¤ „ flf/H/§ `{§ ¯ /˜ƒ‡« ƒn/§– •P« ¡C

† ‰G　/// "'　¡u"C'˚» ˜u"¢„w«Æ‰ ‹d"　¡V""»{^ ·œ, †"G¯ª¥ ¤ †¯ƒX/@¥ ƒ‡fi˜ ¤ ' ¶•¤ª ‡˘/§†¸>p ˙flS‰Ł¡Cƒ„/// "'　¡u"C'˚» ˜u"¢„w«Æ‰ ‹d"　¡V–N¥i¥¸¥H ßƒ ¤˘¥¸/// /§ƒ¤ ƒ~"C'˚» /¸» ˜u"¢–w" "" •–d"<"A¡C

("ˆ' ´ »x　2002;25:9-15)

^ ` ƒr¡G　"C'˚» /¸» ˜u"¢¡A„w«Æ¡A"C'˚» ˜u"¢„w«Æ‰ ‹d" ¡C

Œfi" ƒX´ |　ƒ » ‡ ‹ "[// Œ´ ˆ˜ ˙ |/‰ƒ@‰ˆ¥" ˙¤ţ¡F　[1]// Œ´ ˆ˜ ˙ |" ‡]´ |　ƒ » ‡ ‹ ¡F　[2]‰ˆ¥",p¥ ¥` •«O/pt ¤ / /Ø·`¡G¥ˆ Œ　90ƒ¬6/º13/Ø¡F– ¤ ¥Z, ¡G¥ˆ Œ　90ƒ¬9/º3/Ø¡C

fl`¤œ' ƒL¥»‡B¡G/ ' ‚s´ fiv¡A Œfi" ƒX´ |　ƒ » ‡ ‹ ¡C¥X¥_¥«　106/fl•R, ¥|‹q　280 „¡C　Tel.: (02)27082121 ´ 5036; Fax: (02)27074949; E-mail: drtony@tpts4.seed.net.tw