

Translation and validation of the traditional Chinese version of the Constipation Severity Instrument

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Abstract

Background: The Constipation Severity Instrument (CSI) is a well-validated measure for assessing constipation severity. At present, no translated traditional Chinese version of the scale is available. We aimed to develop a traditional Chinese version of the CSI and to validate the translated version.

Methods: The CSI questionnaire was translated into traditional Chinese language, followed by linguistic validation. It was tested on 45 constipated patients and 55 controls from colorectal outpatient clinics and volunteers. A retest was performed in a subgroup of 39 patients 2 weeks later. Convergent validation was assessed using the Cleveland constipation scoring system (CSS) and quality of life was assessed with the 12-item short-form health survey (SF-12). The reliability and validity were assessed using Cronbach's α coefficient, intraclass correlation coefficient (ICC), and the Spearman correlation test.

Results: Cronbach's α coefficient for the CSI total score and its three subscale scores were all above 0.93. Test-retest reliability was good for the CSI total score (ICC = 0.865) and its three subscale scores (ICC = 0.709–0.882). The constipated participants could be effectively differentiated from the controls based on the CSI total score and its three subscales. The convergent validation was good between the CSI and CSS (Spearman's $\rho = 0.711$, $p < 0.001$). The CSI score correlated negatively with the physical composite score and mental composite score of the SF-12 quality of life scale, indicating poorer quality of life in constipated patients.

Conclusion: We demonstrated the reliability and validity of the traditional Chinese version of the CSI, which could be a standardized tool for future studies on constipation.

Keywords: Constipation; Survey and Questionnaires; Validation Studies

1. INTRODUCTION

Constipation is one of the most common gastrointestinal complaints in the general population, with a prevalence of approximately 14% in the community.¹ It is speculated to be more common among women, elderly people, and people of lower socioeconomic status and also results in significant impairment in health-related quality of life.^{2,3} In Taiwan, a nationwide survey in elementary school students revealed the prevalence of constipation is 32.2%, which is higher than in other countries, and girls are more likely to have constipation.⁴ Besides, a lower intake of vegetables, fruits, soybean products, and eggs was significantly associated with childhood constipation in this study. Patients with constipation who seek help are initially assessed using self-report symptoms. However, for definition of the

disease and guidance of the treatment, several questionnaires were developed by experts. The Rome criteria were developed to assist the diagnosis of functional constipation, and the latest Rome IV criteria were published in 2016.⁵ However, these criteria have not been defined to assess severity. Several measures are available to assess the severity of constipation including clinician-rated scales and patient self-reported symptom-based questionnaires, most of which were developed in the English version. Due to the differences in expression and wording among various languages, translation and validation in other non-English language versions are important for questionnaires that are relied on the patient's self-reported symptom. Before using these translated questionnaires, reliability and validity should be confirmed.

Currently, the only published validated traditional Chinese questionnaire for constipation is the Chinese Constipation Questionnaire, which was developed by the University of Hong Kong for assessing constipation in 2005.⁶ This questionnaire is similar to the patient assessment of constipation symptom questionnaire,⁷ but it is composed of several Cantonese-specific characters. Although people in Hong Kong and Taiwan use traditional Chinese, some words and phrases are used differently. For people in Taiwan, translation and validation of a questionnaire for constipation in the traditional Chinese version are necessary for clinical practice.

The Constipation Severity Instrument (CSI) was developed in 2008 by Varma et al. at the University of California, San

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Francisco.⁸ This is a well-validated self-reported questionnaire and has the advantage of being easy to fill out completely.⁹ The CSI contains three subscales and 16 items with a total score ranged from 0 to 73 to evaluate symptoms and severity of constipation. It uniquely includes three subscales of obstructive defecation (six items), colonic inertia (six items), and pain (four items). Since constipation can be classified roughly as normal-transit constipation, slow-transit constipation, and disorders of defecatory,¹⁰ a potential benefit of the CSI is to differentiate subtypes of constipation and assist in clinical evaluation and management for constipated patients.¹¹ Besides, the questionnaire was recently recommended by the American Society of Colon and Rectal Surgeons for measurement of constipation severity.¹²

This study aimed to develop a traditional Chinese version of the CSI for Mandarin-speaking Chinese-writing Taiwanese and to determine the reliability and validity of the translated version. To the best of our knowledge, this version is the first translated and validated version of the CSI.

2. METHODS

The study was initiated after receiving approval from the ethical committee of the Taipei Veterans General Hospital (IRB no. 2018-05-012CC). Madhulika G. Varma provided consent for the translation of the CSI questionnaire into traditional Chinese and for its use at the Taipei Veterans General Hospital. All participants provided written informed consent before the test.

The original English version of the CSI was translated into traditional Chinese by a native translator with good command of the English language and then back-translated. The translated version was compared with the initial one, revised as needed, and subsequently submitted for expert review by 11 gastroenterologists and colorectal surgeons. After incorporating the revision suggestion by these experts, a pilot study was arranged in 10 participants including medical staff, nursing students, and non-medical expertise people. The final version was reached following the incorporation of the feedback from these participants.

From June 2018 to August 2018, 100 participants including 45 constipated patients and 55 healthy controls took part in the study. The participants were recruited from colorectal outpatient clinics and volunteers in the hospital. They were all more than 20 years of age, Taiwanese habitant, and can read and write Mandarin in Traditional Chinese Character fluently. Those who had symptoms of fecal incontinence or received treatment for constipation were excluded. They were initially screened using both subjective complaints of constipation and Rome IV criteria for functional constipation.⁵ Then, the participants were assigned to a constipated or controlled group according to ROME IV diagnostic criteria. The severity of constipation was surveyed using the Cleveland constipation scoring system (CSS) by Y.J. Tsai and Y.T. Lan. The participants were then asked to complete the translated version of the CSI and the Chinese version of the 12-item short-form health survey (SF-12v2) (with the license agreement from Optum).^{13,14}

The CSS is a widely accepted standard scoring system for the evaluation of constipated patients.¹⁵ It was developed in 1996 in Cleveland clinics for assessing the constipation severity and was correlated with objective physiologic studies including colonic transit time, anal manometry, cindefecography, and electromyography. It is a physician rating scale by interview and consists of eight questions, with a score range from 0 to 30. Each question has a scoring range from 0 to 4 with the exception of "assistance for defecation," which is 0–2. A total score of more than 15 was defined as constipation.

The CSI comprises 16 items that evaluate constipation symptoms, frequency, stool consistency, straining, and aids for evacuation. They are grouped into three subscales including obstructive

defecation (six items, scores 0–29), colonic inertia (six items, scores 0–28), and pain (four items, scores 0–16). The total score of CSI (scores 0–73) is created by summation of the three subscales. A higher score represents more severity of constipation.

The SF-12 is a validated self-report measure to evaluate general health status and quality of life. Physical component summary (PCS) and mental component summary (MCS) that range from 0 to 100 can be calculated. A better quality of life specific to better physical or mental status could be reflected by a higher score.

2.1. Reliability

Reliability of the translated CSI was evaluated by measuring internal consistency and test–retest coefficients. The internal consistencies of each subscale and total score were tested using Cronbach's α coefficient. Good internal consistency was considered if Cronbach's α coefficient was between 0.7 and 0.95.¹⁶

We used the test–retest method to evaluate the tool's stability over time. Thirty-nine participants were randomly selected to fill out the CSI questionnaire again at a 2-week interval in the same clinics after the initial interview. No new treatment was given between test and retest. The intraclass correlation coefficient (ICC) was calculated for each subscale to evaluate the correlation between the two measurements. ICC > 0.70 was considered good.¹⁷

2.2. Convergent validity

We used CSS to establish the convergent validity of the translated CSI. Spearman's correlation was calculated to evaluate the correlation between the two measures.

2.3. Discriminant validity

The CSI and CSS scores between the constipated group and control group were evaluated using the t test.

2.4. Relationship to quality of life

To evaluate the relationship of CSI with quality of life, we administered the traditional Chinese version of the SF-12v2, a validated questionnaire for multidimensional quality of life.^{13,14} Both the MCS and PCS scores of this questionnaire were used for analysis. Analysis of validity of the translated CSI with respect to the SF-12 was made using Spearman's rank correlation coefficient.

2.5. Statistical analysis

Participants' baseline characteristics, including age, gender, education level, and work status were collected. The participants were divided according to ROME IV criteria for constipation. The demographic data between the two groups were checked with the Pearson Chi-square test to identify any possible confounding factors. The Reliability tests included internal consistency with Cronbach's α coefficient and test–retest reliability with the interclass coefficient. The validity test included discriminant validity by test the scores between the constipated and control group with the Pearson Chi-square test, and convergent validity by test the scores between CSI and CSS with Spearman's rank coefficient. The relation between CSI and life quality was tested by CSI scores and MCS and PCS of SF-12 by Spearman's rank correlation coefficient. Data management was done using SPSS software, version 22 (IBM Corp. Armonk, NY, USA).

3. RESULTS

3.1. Sociodemographic characteristics of the participants

The mean age of the 100 participants was 36.8 ± 12.4 years, ranging from 20 to 73 years. Up to 80% of the participants were women, 88% had a university or higher level of education, and 82% were working. We divided the participants into

Table 1
Sociodemographic data of the participants

	Constipation, N = 45 (%)	Control, N = 55 (%)	<i>p</i>
Age	40.0 ± 13.7	34.3 ± 10.6	0.02*
Sex			0.13
Male	6 (13)	14 (25)	...
Female	39 (87)	41 (75)	...
Education			0.27
University and above	37(82)	51(93)	
Senior high school	6	3	...
Junior high school	1	0	...
Elementary school	1	1	...
Have a job			0.01*
Yes	32 (71)	50 (91)	...
No	13 (29)	5 (9)	...

*Statistically significant difference.

constipation and control groups according to the patient’s subjective report and ROME IV criteria. There were 45% of participants in the constipation group. The constipated group was significantly older than the control group (*p* = 0.02). The number of patients with jobs was statistically significantly different between the two groups (*p* = 0.01) (Table 1).

3.2. Reliability

We evaluated the test–retest reliability of our version of the questionnaire with ICC. Thirty-nine participants were randomly selected for retest. The ICC value for the total score was 0.87, with 0.71 for the obstructive defecation domain, 0.88 for the colonic inertia domain, and 0.80 for the pain domain. These values were considered good and confirmed the reliability over time (Table 2). Internal consistency was examined using Cronbach’s α coefficient. The CSI total score and all three subscales revealed excellent results (Table 2).

3.3. Discriminant validity

The total CSI score and the score for all three subscales showed a statistically significant difference between constipation and control groups (*p* < 0.01) (Table 3).

3.4. Convergent validity

We chose the CSS for convergent validity to the CSI. The Spearman’s rho coefficient between the CSI total score and CSS total score was 0.71 (*p* < 0.01; Table 4). The CSI total score and all three subscales showed a statistically significant correlation with the CSS total score.

3.5. Relationship to quality of life

We evaluated the relationship between the CSI and quality of life using the validated traditional Chinese version of the SF-12. The CSI total score, subscale of obstructive defecation, and colonic

Table 2
Internal consistency and test–retest reliability

	Cronbach’s			α
	Test	Retest	ICC	
CSI total score	17.00 ± 12.60	18.13 ± 11.76	0.87 (0.76–0.93)	0.95
Obstructive defecation	9.00 ± 5.87	9.69 ± 4.67	0.71 (0.51–0.84)	0.94
Colonic inertia	5.20 ± 5.37	5.26 ± 5.69	0.88 (0.79–0.94)	0.94
Pain	2.87 ± 3.54	3.23 ± 3.50	0.80 (0.65–0.89)	0.93

CSI = Constipation Severity Instrument; ICC = intraclass correlation coefficient.

Table 3
Discriminant validity of the CSI, CSS, and SF-12

	Constipation	Control	<i>p</i>
CSI total score	29.78 ± 11.90	9.35 ± 6.22	<0.01*
Obstruction defecation	14.40 ± 5.24	5.25 ± 3.04	<0.01*
Colonic inertia	11.07 ± 6.08	3.04 ± 3.13	<0.01*
Pain	4.29 ± 4.22	1.13 ± 2.42	<0.01*
CSS	8.07 ± 4.20	1.66 ± 1.95	<0.01*
SF-12 PCS	53.58 ± 7.07	54.68 ± 6.90	0.20
SF-12 MCS	43.21 ± 9.04	47.48 ± 8.88	0.01*

CSI = Constipation Severity Instrument; CSS = Cleveland constipation scoring system; MCS = mental component summary; PCS = physical component summary; SF-12 = 12-item short form health survey.

*Statistically significant difference.

Table 4
Convergent validity

	Spearman’s ρ for the CSS total score	<i>p</i>
CSI total score	0.71	<0.01*
Obstructive defecation	0.69	<0.01*
Colonic inertia	0.64	<0.01*
Pain	0.35	<0.01*

CSI = Constipation Severity Instrument; CSS = Cleveland constipation scoring system.

*Statistically significant difference.

inertia were inversely correlated with the MCS of the SF-12, but not the PCS of the SF-12. On the other hand, the subscale of pain was negatively correlated with the PCS of the SF-12, but not the MCS of the SF-12. We also evaluated the correlation between the CSS and SF-12 and found that only MCS had a negative correlation with the CSS total score (Table 5).

4. DISCUSSION

The original CSI questionnaire was developed by Varma et al. in 2008 for assessing constipated patients. It provided evidence of construct validity, content validity, criteria validity, internal reliability, and test–retest reliability.⁸ The results of this study showed that the translated version of the CSI had good test–retest reliability, good convergent validity, and was inversely related to the quality of life. The required sample sizes for setting power of 0.95 and α of 0.05 calculated with G*power 3.1.9.5 software according to data from the original study for CSI total score and obstruction defecation, colonic inertia, and pain subscales were 12, 12, 22, and 32, respectively.¹⁸ Our sample population was bigger than the required size and provided reliable statistical power.

Table 5
Relationship to quality of life

	PCS	<i>p</i>	MCS	<i>p</i>
CSI total score	–0.17	0.09	–0.32	0.01*
Obstructive defecation	–0.12	0.25	–0.36	<0.01*
Colonic inertia	–0.07	0.52	–0.23	0.02*
Pain	–0.35	<0.01*	–0.18	0.08
CSS	–0.06	0.571	–0.22	0.03*

CSI = Constipation Severity Instrument; CSS = Cleveland constipation scoring system; MCS = mental component summary; PCS = physical component summary.

*Statistically significant.

CSI is unique to other constipation scales by its measurement of the emotional effect of constipation.⁹ The subscales of the CSI describe symptoms grouped by their pathophysiology (i.e., obstructive defecation, colonic inertia, and pain). Diagnosing these subtypes of constipation without any further testing and providing a direction of treatment might be possible. Our study showed the same result of the constipated participants who achieved a higher score at the CSI total score and all three subscales as the original version.

The SF-12 has a traditional Chinese version and has been validated.¹⁴ The study of the original CSI questionnaire used a short-form 36 health survey (SF-36) to evaluate the relationship of CSI score and quality of life. It revealed that CSI total score and obstructive defecation subscale score were inversely associated with the SF-36 PCS and MCS. This result indicates that higher levels of constipation were related to lower levels of quality of life. Colonic inertia was inversely correlated with the MCS alone, and the pain was inversely associated with only the PCS, which were the same in our study.⁸ Although our study used SF-12 for validation, the impact of constipation on quality of life was still confirmed. Different subscales of CSI seemed to have different impacts on the mental or physical component. We found that the PCS in constipated patients in our study was higher than that in a previous review study.² The mean PCS was 47.5 in the review study and 53.58 in our study. This result may be attributed to less severity of constipation symptoms in our constipated group. Compared to Varma's original study,⁸ of our constipated patients reported lower total CSI scores at all three subscales (total score: 41 vs 29, OD/CI/Pain: 19/14/6 vs 14/11/4) and may result in higher PCS and better quality of life.

The limitation of our study is that we did not evaluate the socioeconomic status of our participants, and we did not recruit a matched control sample to decrease the discrepancy between the two groups. This version of CSI discriminated well between those participants with and those without constipation and demonstrated excellent convergent validity. We used self-report and ROME IV criteria for functional constipation to define the presence of constipation. A previous study showed that the prevalence of constipation decreased while using ROME II or ROME III criteria as the definition.¹ The study for ROME IV criteria validation revealed increased sensitivity for functional constipation if permitting overlapping irritable bowel syndrome with constipation.¹⁹ Therefore, we chose the latter definition and self-report to increase our sensitivity to constipation. All participants were recruited from our colorectal unit, including volunteers, and patients from admission, or outpatients in colorectal clinics. Participants who agreed to participate completed their questionnaire in a quiet room with on-hand support if any questions arise. We assessed the whole questionnaire after the participants completed it and then asked them to complete the missing questions immediately. This method provided a higher completion rate with a more accurate response from the participants. The retest questionnaires were performed in the same manner; therefore, a high completion rate was achieved. Because the CSI score is a summation score, which is highly relied on the completion rate. Any skipped item will result in a failure of calculation. How to ensure a high completion rate in daily clinical practice will be investigated in the future.

In conclusion, the CSI is unique to the existing measures of constipation severity because of its subscales. The use of the CSI to measure constipation severity could provide useful information for evaluation, treatment strategies, and perhaps even

clinical outcomes of different types of constipation. This study reports the reliability and validity of the traditional Chinese version of the CSI questionnaire, which is suitable for use as a standardized tool in clinical and research settings for patients with constipation and providing a basis for comparing various constipated population and assessing the treatment effects.

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