

Adaptation and psychometric evaluation of the simplified Chinese version of the Identification of Functional Ankle Instability questionnaire in Chinese-speaking patients with chronic ankle instability disorders

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Research article

Keywords: IdFAI; validation; cross-culture translation; psychometrics

Posted Date: August 15th, 2019

DOI: <https://doi.org/10.21203/rs.2.12959/v1>

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Version of Record: A version of this preprint was published at BMC Musculoskeletal Disorders on May 25th, 2020. See the published version at <https://doi.org/10.1186/s12891-020-03314-1>.

Abstract

Background: This study aimed to adapt the Identification of Functional Ankle Instability (IdFAI) questionnaire into simplified Chinese version and assess its reliability, validity, and responsiveness in Chinese-speaking patients with chronic ankle instability (CAI) disorders. **Methods:** The simplified Chinese version of the IdFAI (SC-IdFAI) questionnaire was developed in a five-step procedure of cross-cultural translation and adaptation. Three questionnaires, including the SC-IdFAI, Medical Outcomes Study Short-Form 36 (SF-36), and Foot and Ankle Ability Measure (FAAM), were administered to the recruited patients. Then, the Cronbach's alpha, intraclass correlation coefficient (ICC), standard error of measurement (SEM), minimal detectable change (MDC), Spearman's correlation coefficient (rs), effect size (ES), and standardized response mean (SRM) were calculated to evaluate the reliability, validity, and responsiveness of the SC-IdFAI questionnaire. **Results:** A total of 131, 119, and 86 patients with CAI successfully completed the first, second, and third rounds of the questionnaires, respectively. Good or excellent internal consistency and test–retest reliability were found in the overall scale and subscales of the SC-IdFAI questionnaire. Low values for SEM (1.346) and MDC (3.73) indicated that small clinical changes could be detected by the SC-IdFAI questionnaire. The correlations of SC-IdFAI with FAAM and SF-36 were generally in agreement with a priori hypotheses (85%, 34/40), suggesting good construct validity of the SC-IdFAI questionnaire. Moreover, good responsiveness was observed in the overall scale and subscales of the SC-IdFAI questionnaire. **Conclusion:** The SC-IdFAI questionnaire was reliable, valid, and responsive for evaluating Chinese-speaking patients with CAI and might prove to be an effective instrument.

Background

Chronic ankle instability (CAI) is one of the most common exercise-related injuries. Previous studies have shown that as high as 40% of ankle sprains develop to CAI [1,2]. The manifestations of CAI mainly include a sense of fear and instability on uneven ground, sore and pain of the joint after a long walk, and restricted ankle joint movement [3,4]. More than 23,000–27,000 ankle sprains are estimated to occur in the United States every day [5]. However, no reliable incidence of ankle sprains has been reported in China yet. Given the huge population base in China, the number of patients with CAI in China is also be very high. In recent years, increasing attention has been paid to ankle sprain and CAI with the implementation of the nationwide physical fitness campaign and increasing demands for higher quality of life in China.

A series of studies have been devoted to the development of patient-reported outcome measures (PROMs) since the 1980s [6]. PROMs data are collected mainly by asking the patients to complete the questionnaires independently. Through this method, massive information about the target patient group can be easily obtained. In addition, these data enable physicians to understand the disease severity in such patients and thus consequently develop appropriate treatment strategies correspondingly [7]. PROMs are an important part of both clinical practice and research because they are efficient, reliable, and inexpensive [8]. PROMs are classified into two major groups of scales according to their purpose: generic scale and specific scale. The generic scales mainly assess the gross conditions of various diseases in the patients. For instance, the Medical Outcomes Study Short-Form 36 (SF-36) is one of the most classic generic scales. However, the specific scales are used in specific patient groups, such as the Western Ontario Shoulder Instability Index for shoulder instability [9], the Foot and Ankle Ability Measure (FAAM) for different neuromusculoskeletal alterations in the foot/ankle [10], and the Ankle Instability Instrument (All), Cumberland Ankle Instability Tool (CAIT), and Identification of Functional Ankle Instability (IdFAI) for CAI [11].

Professional organizations, such as the National Athletic Trainers' Association, recommend the use of PROMs as a criterion to identify patients' perception of ankle instability for treatment decision-making in the management of CAI [12]. Seven PROMs have been developed to assess CAI before the IdFAI questionnaire, among which CAIT and All have been acknowledged as the two scales with the highest sensitivity and specificity. Therefore, the International Ankle Consortium has recommended the combination of CAIT and All for assessing CAI [11,13]. Matthew Donahue et al. further developed the IdFAI questionnaire in 2012, by merging CAIT and All. In general, the IdFAI questionnaire is a simple but effective tool

for assessing CAI [14]. When using only one scale for assessing CAI, the IdFAI questionnaire was reported to have the highest accuracy among all similar scales [15].

A number of scales are used in different patient groups in different countries. This has become necessary with the growing number of multicenter studies [6], which provide more meaningful results of randomized controlled trials [16]. When a reliable and valid scale is used in populations with different cultural backgrounds, testing the psychometric properties of the scale rather than simply translating the content is necessary to avoid the evaluation error caused by cultural differences [17,18]. The IdFAI questionnaire was originally developed in English and has been culturally adapted into four languages, including Korean, Brazilian, Persian, and Japanese, and validated [11,13,19,20]. However, a cross-cultural adaptation study of the IdFAI questionnaire has not been performed in Chinese, a language spoken by 1.2 billion people as a first language [21] and one of the six official languages of the United Nations [22].

Therefore, this study aimed to translate and adapt the IdFAI questionnaire into a simplified Chinese version (SC-IdFAI) and evaluate the reliability, validity, and responsiveness of the SC-IdFAI questionnaire in a cohort of native Chinese-speaking patients with CAI disorders.

Methods

2.1 Translation and cross-cultural adaptation

The original version of the IdFAI questionnaire was translated according to the principles reported in previous studies [23,24]. In brief, the translation included the following several steps. (1) Forward translation: Two native Chinese speakers highly familiar with the English language (one translator was an orthopedist in the hospital, while the other was a professional translator without any medical background) were asked to translate the IdFAI questionnaire into simplified Chinese version. (2) Discussion I: All the investigators discussed the two independently translated versions, and finally the two versions were merged into the preliminary version of the SC-IdFAI questionnaire. (3) Backward translation: Two native English speakers independently translated the preliminary version of the SC-IdFAI questionnaire into the English language. (4) Discussion II: The versions were discussed by the investigators again to address the discrepancies, ambiguities, and other language expression issues in the preliminary version of the SC-IdFAI questionnaire. Then the prefinal version of the SC-IdFAI questionnaire was obtained. (5) Pretesting: Twenty patients with CAI were asked to complete the prefinal version of the SC-IdFAI questionnaire. The questions reported by the 20 patients during the completion of the scale were also recorded. Afterward, a third discussion was conducted among the investigators to conduct the final, specific modifications to the questionnaire, and then the final version of the SC-IdFAI questionnaire was obtained.

2.2 Patients and data acquisition

The consecutive native Chinese-speaking patients with CAI treated in our hospital (the General Hospital of Western Theater Command) between February 2016 and March 2018 were recruited. The inclusion criteria were as follows: (1) patients aged >18 years, capable of signing for themselves; (2) Chinese native speakers who could independently read and complete the questionnaire; and (3) patients with a history of at least two severe ankle sprains who reported episodes of a feeling of ankle instability and/or "giving way" and/or chronic pain in the ankle during daily life or sports activity. The exclusion criteria were as follows: (1) patients with a history of previous surgery of musculoskeletal structures and fracture requiring realignment of either limb of the lower extremity; (2) patients with acute injury to the musculoskeletal structures of the other lower-extremity joints in the previous 3 months; and (3) patients with other chronic inflammatory diseases in the lower limbs, which might affect the ankle function. The patients who met all the eligibility criteria and volunteered to participate were included in the study. In addition, the number of included participants also met the sample size criteria of PROMs, as recommended by Terwee et al. [25]. In brief, the sample size for internal consistency analysis should be ≥ 100 , and the sample sizes for floor or ceiling effects, reliability, and validity analyses should be ≥ 50 . All the

participants carefully read and signed the informed consents. The study was approved by the Ethics Committee of the General Hospital of Western Theater Command.

The patients were asked to provide demographic information, such as sex, age, and weight, on the first day of enrollment and independently complete the following four questionnaires: SC-IdFAI, FAAM, SF-36, and CAIT-C (for another research) in a quiet meeting room. One week after the first filling-in, on the day before starting the physical therapy, they completed the SC-IdFAI questionnaire for the second time to evaluate the test–retest reliability of the scale. Patients having related treatment in the previous week were excluded. Finally, the patients who volunteered to receive the 8-week physiotherapies in the hospital were asked to complete the SC-IdFAI questionnaire for the third time to help in assessing the responsiveness.

2.3 Instruments

IdFAI is a scale specific to the assessment of patients with CAI. It was developed by Matthew Donahue et al. based on the CAIT and All [14]. It combines the advantages of both CAIT and All scales, and thus has its own specific advantages as follows: (1) the IdFAI questionnaire contains 10 questions, which are easily understood, and the patients need very short time to complete them; and (2) the questionnaire has very high accuracy in the assessment. Using the IdFAI questionnaire alone can result in higher accuracy than CAIT or All [15]. The IdFAI questionnaire consists of three subscales as follows: (1) factor 1, the history of ankle sprains (items 5, 6, 7, and 10); factor 2, the presence and severity of ankle instability (items 1, 2, 3, and 4); and factor 3, the functional performance in daily living and other physical activities (items 8 and 9). As the first question is a nonchoice question, the answer is not included into the total score, while the scores of the other nine questions are added to obtain the final score. The total score ranges from 0 to 37, with higher scores indicating poorer ankle functions. Generally, if the total score is >10, the patients are considered to have CAI [20].

FAAM is a region-specific scale designed specifically for the assessment of the feet and ankle functions [26]. FAAM contains two subscales, namely activities of daily living (ADL) and sports. The ADL subscale contains 21 questions, while the sports subscale contains 8 questions. The score for each question ranges from 0 to 4. Thus, the range of the total score of the ADL subscale and sport subscale is 0–84 and 0–32, respectively, with higher scores indicating better functions. Although FAAM is region-specific, and not a disease-specific scale, previous studies already demonstrated that FAAM had high validity when used in patients with CAI [27]. SF-36 is a versatile scale for assessing the quality of life, which contains 35 questions in the 8 subscales. The first four subscales can be categorized as “physical subscales,” which mainly assess the physiological functions of the patients, while the latter four subscales can be categorized as “mental subscales,” which mainly assess the mental status of the patients. Each subscale of the SF-36 scale has a specific scoring method, while the final score is converted into centesimal grade. The higher score of the SF-36 scale indicates the better mental status of functions [28]. Both these scales have been translated into Chinese versions and demonstrated to have high validity, reliability, and responsiveness [29,30].

2.4 Psychometric assessments and statistical analysis

The validity, reliability, and responsiveness of the SC-IdFAI questionnaire were assessed to evaluate whether it could be applied in native Chinese-speaking patients with CAI.

The reliability of the SC-IdFAI questionnaire was mainly assessed from three aspects, namely internal consistency, test–retest reliability, and measurement error. Internal consistency was described as the degree of interrelatedness among the items [31], which was assessed by calculating the Cronbach’s α value of the scale. The scale was considered with acceptable, good, and excellent internal consistency when the Cronbach’s α value was >0.7, 0.8, and 0.9, respectively [25]. However, not all the higher Cronbach’s α values indicated better validity. For instance, Cronbach’s α values >0.95 generally indicated question redundancy in the scale [32]. In addition, the Cronbach’s α value was also calculated after the questions in the SC-IdFAI questionnaire were omitted one by one to assess the influence of each question on the α value, which was

also a method to assess the internal consistency [25,33]. For assessing the test–retest reliability of the SC-IdFAI questionnaire, the patients were asked to answer the questions twice, with an interval of 1 week, and then the answers were compared. The intraclass correlation coefficient (ICC), which was derived from a two-way analysis of variance in a random-effects model, was used to assess the test–retest reliability. The test–retest reliability of the scale was considered acceptable, good, and excellent when the ICC was >0.7, 0.8, and 0.9, respectively [34]. The measurement error is the systematic and random error of a patient’s score that is not attributed to true changes in the construct to be measured [35]. Moreover, it was analyzed using the standard error of measurement (SEM) and calculated according to the following formula: $SD \times \sqrt{1 - ICC}$, where SD is the standard deviation of the scores from all patients at the first assessment [36]. The minimal detectable change (MDC) reflected the minimal individual change in the score that could be interpreted as a real change. It was calculated as $SEM \times 1.96 \times \sqrt{2}$ at an individual level and $SEM \times 1.96 \times \sqrt{2} / \sqrt{n}$ at the group level [36]. The Bland–Altman plots were further depicted to observe the systematic error between the first two investigations [37].

The validity of the SC-IdFAI questionnaire was mainly assessed from two aspects, namely content validity and construct validity. The content validity was assessed by the comprehensiveness and the relevance of the items [38]. The response rate of the questions, ceiling/floor effects, and patients’ feedback were the three indicators for assessing the comprehensiveness. If the response rates of all the questions were >95%, the ceiling/floor effects of all the subscales were <15%, and the patients did not report difficulties in understanding the scale, the scale was considered to be of good comprehensiveness [25,39]. Moreover, an expert of rehabilitation medicine and two experts of osteology were invited to help in judging whether the items of the SC-IdFAI questionnaire were relevant for the construct to be measured and for the patients with CAI [38]. The criterion validity of the SC-IdFAI questionnaire could not be assessed as no gold standard was available. So, the construct validity was assessed by the method of hypotheses testing. The construct validity is the extent to which the scores on a scale are consistent with hypotheses based on the assumption that the scale validly measures a specific construct [32]. In this study, FAAM and SF-36 were selected as the control scales for SC-IdFAI. Most of the questions in the SC-IdFAI questionnaire assessed the physical conditions, but not mental conditions, of the patients with CAI. Therefore, it was hypothesized that the results of the SC-IdFAI questionnaire highly correlated with the physical subscales of the SF-36 (physical functioning, role physical, bodily pain, and general health), as well as FAAM, but poorly correlated with the mental subscales of the SF-36 (vitality, social functioning, role emotional, and mental health). In addition, FAAM was a region-specific scale specifically designed for the patients with ankle injuries, while SF-36 was a generic scale with wide applicability. Therefore, although FAAM was not a disease-specific scale designed specifically for the patients with CAI, the contents of FAAM should be closer to IdFAI than to SF-36. Thus, it was further hypothesized that the correlation between SC-IdFAI and FAAM should be higher than that with any subscales of SF-36. The detailed contents of the hypotheses between the scales are shown in table 4. Based on these hypotheses, the Spearman’s correlation coefficient (r_s) of SC-IdFAI with SF-36 and FAAM was analyzed, using the first answers from the patients in the scales. Then, the construct validity of the SC-IdFAI questionnaire was assessed according to the consistency between the data and the hypotheses. Good construct validity was based on meeting the criterion for at least 75% (30/40 or more) of stipulated a priori hypotheses [35]. The correlations were judged as poor ($r_s = 0-0.2$), fair ($r_s = 0.2-0.4$), moderate ($r_s = 0.4-0.6$), good ($r_s = 0.6-0.8$), or excellent ($r_s = 0.8-1.0$) [40].

Responsiveness is the ability of a scale to detect a change over time in the construct to be measured [38]. In this study, the responsiveness of SC-IdFAI was evaluated by comparing the scale results before (the first-time filing) and 9 weeks after administering physiotherapeutics (the third-time filing). The effect size (ES) and standardized response mean (SRM) were the two indices to evaluate the responsiveness. SRM was defined as the mean change between the two time points divided by the SD of this change. ES was defined as the mean change between pretreatment and 9-week posttreatment results divided by the SD of the pretreatment SC-IdFAI score [41]. ES and SRM were considered large if >0.80, moderate if between 0.51 and 0.80, and small if <0.50 [42].

The Statistical Package for the Social Sciences, version 20.0 (SPSS, IL, USA), was used for statistical analysis. The mean values were reported with SD. The ICC values were reported with 95% confidence intervals. A *P* value of 0.05 or less was considered statistically significant.

Results

3.1 Patients

A total of 161 patients with CAI (including 104 males and 57 females) who received treatments in our hospital between February 2016 and March 2018 and met the eligible criteria were invited. Of these, 132 (82.0% of those invited, including 86 males and 46 females) volunteered to participate in this study. All these patients completed the first survey using the scales. One week later, 119 patients (including 81 males and 38 females) completed the SC-IdFAI questionnaire for the second time during re-examination in the hospital or on being contacted by telephone calls or e-mails. Among the 13 patients not completing the second SC-IdFAI questionnaire, 9 were excluded for receiving related treatments 1 week before (using analgesics or unclear physiotherapy), while the other 4 could not be contacted. In addition, 86 of the patients (including 62 males and 24 females) received regular physiotherapy in our hospital and completed the third SC-IdFAI questionnaire after all the treatments were completed (8 weeks later). Therefore, 132 patients were assessed for internal consistency, measurement error, and validity of the SC-IdFAI questionnaire, 119 patients for the test–retest reliability, and 86 patients for the responsiveness of the SC-IdFAI questionnaire. The detailed demographic data of the patients who initially participated in the study are shown in Table 1.

3.2 Translation and cross-cultural adaptation process

The forward translation, backward translation, and cross-cultural adaptation of the IdFAI questionnaire were all conducted smoothly. As the SC-IdFAI questionnaire was concise and easy to understand, the contexts of the questionnaire were not substantially modified. Twenty patients with CAI (including 10 male and 10 female) completed the prefinal version of the SC-IdFAI questionnaire in the pretesting, with no feedbacks regarding difficulty in understanding or misunderstanding in the questionnaire reported.

3.3 Reliability

The overall Cronbach's *a* value of the SC-IdFAI questionnaire was 0.902, suggesting that the scale had excellent internal consistency. The Cronbach's *a* value of the three subscales of the SC-IdFAI questionnaire was 0.897, 0.808, and 0.721, respectively, suggesting that the subscales had acceptable or good internal consistency. In addition, Table 2 also shows the Cronbach's *a* values of the SC-IdFAI questionnaire after omitting the questions one by one, as well as the correlation coefficient between the questions and the corresponding scores of the SC-IdFAI questionnaire. No evident increase in the Cronbach's *a* value of the SC-IdFAI questionnaire was identified after the questions were omitted one by one.

The overall ICC value of the SC-IdFAI questionnaire was 0.936, suggesting that the scale had excellent test–retest reliability. The ICC value of the three subscales of the SC-IdFAI questionnaire was 0.907, 0.881, and 0.876, respectively, suggesting that the subscales had good or excellent test–retest reliability (Table 3). In addition, the Bland–Altman plots also showed that in the first two surveys, the SC-IdFAI questionnaire and the three subscales had no evident system errors (Figure 1), indicating that the SC-IdFAI questionnaire had good test–retest agreement.

The SEM value of SC-IdFAI was 1.346. Therefore, the MDC reflecting the minimal individual and group (this study) change in score that could be interpreted as a real change was 3.73 and 0.32, respectively. The SEM and MDC of the three subscales are also displayed in table 3.

3.4 Validity

No missing questions were found in the recovered questionnaires of SC-IdFAI in the formal survey. The mean score and SD of the overall SC-IdFAI was 24.57 ± 7.83 . No ceiling effect (1.52%–2.27%) or floor effect (0%) was found for the overall scale and the three subscales of the SC-IdFAI (Table 3). In addition, no patient reported difficulties or misunderstandings about the contents while completing the SC-IdFAI questionnaire. The experts of rehabilitation medicine and osteology all acknowledged that the information obtained by the questions was sufficient to assess the health-related quality of life in patients with CAI, and thus no omission or addition of questions was suggested. These findings demonstrated that the SC-IdFAI questionnaire had good content validity.

Table 4 shows the data for the assessment of the construct validity of the SC-IdFAI questionnaire. The correlations of the SC-IdFAI questionnaire with both the subscales of FAAM were moderate or good ($r_s = 0.575-0.776$). In addition, the correlations of the SC-IdFAI questionnaire with the physical subscales of SF-36 were all poor or moderate ($r_s = 0.295-0.551$), while the correlations with the mental subscales of SF-36 were poor, fair, or moderate ($r_s = 0.035-0.404$). These findings were generally in agreement with a priori hypotheses (85%, 34/40), suggesting that the SC-IdFAI questionnaire had good construct validity.

3.5. Responsiveness

Finally, the results of the 86 patients with CAI who completed the SC-IdFAI questionnaire before and after physiotherapy (9-week interval) were used, and the ES and SRM were calculated to assess the responsiveness. As shown in Table 3, the overall ES and SRM of SC-IdFAI were 1.123 and 1.554, respectively. The ES and SRM of the subscales, except for the subscale factor 1, were also higher than 0.8. These findings demonstrated that the SC-IdFAI questionnaire had good responsiveness.

Discussion

PROMs are essential tools for clinical studies. Investigators can use such scales to quantitatively assess the functions and status of the patients, and compare the results of the scales with other similar studies, which can guide the increasing number of multicenter clinical studies [6]. Currently, in China, several clinical studies are conducted and published every year, which are associated with not only the large patient samples but also the attention and support from the government [43]. Therefore, validated PROMs were desperately needed in China, as they could not only help the massive patients to receive a more accurate diagnosis and appropriate treatments but also support the increasing clinical studies in China. To date, however, no Chinese version of the disease-specific scale is available for massive patients with CAI in China. The IdFAI questionnaire has been acknowledged as the most accurate and simple specific scale for assessing CAI, following CAIT and AII. The IdFAI questionnaire has already been translated into four languages and has shown good reliability and validity in several independent studies [11, 13, 14, 19, 20]. Therefore, translating the IdFAI questionnaire into the Chinese language was valuable.

This study had several limitations. First, the sample was limited in size and might not fully represent the Chinese population. Second, the IdFAI questionnaire was translated into simplified Chinese, which is the official language in China. However, China is a multiethnic country, with a lot of minorities having their own languages. Therefore, the cultural differences among the ethnicities should be considered when using the scale. Finally, some participants were excluded and some lost to follow up, but the overall sample appeared to be adequately powered based on the results.

In this study, translation and cross-cultural adaptation were smoothly conducted. A lot of attention was paid to the translation of the phrase “giving way,” as the understanding of this phrase was critical for the patients to complete the scale correctly. Therefore, this phrase has been explained in detail at the conspicuous position at the start in the original version of the scale. However, no official Chinese word for “giving way” exists. After carefully reading the explanations of this phrase in the original scale, a slang word in Chinese (Da ruan tui) could well reflect the meaning of this phrase. To

prevent the incorrect answering of the questions from some patients due to the misunderstanding of this slang word, this word was explained using the official Chinese language at the beginning of the questionnaire so that it is clearly visible. No patients reported any content that could not be understood in the following pretesting and formal survey.

The SC-IdFAI questionnaire had excellent internal consistency (Cronbach's $\alpha = 0.902$). The Cronbach's α value of the SC-IdFAI questionnaire was slightly higher than those of the Brazil (0.87), Japanese (0.87), and Korean versions (0.89), but slightly lower than those of the original (0.96) and Persian versions (0.95). However, Cronbach's α value higher than 0.95 generally suggests the existence of redundant questions in the scale. Therefore, not all the higher Cronbach's α values suggested a better scale [32]. The three subscales of the SC-IdFAI questionnaire also had an acceptable or good internal constancy (Cronbach's $\alpha = 0.725$ – 0.882), which were generally in agreement with other previous studies [11,14,19]. The findings also showed that omitting any of the questions would not evidently increase the Cronbach's α value of the SC-IdFAI questionnaire (0.880–0.904). However, the findings in the Korean version showed that omitting question 8 increased the Cronbach's α value of the IdFAI-K questionnaire [20]. The investigators speculated that the results could be associated with the facts that professional athletes were included as the study participants, while question 8 was "Following a typical incident of your ankle rolling over, how soon does it return to normal." Thus, the inclusion of professional athletes could substantially affect the answers to this question. In contrast, the participants in this study and other previous studies were all general population but not professional athletes, which could induce the differences with the Korean version. The three subscales of the SC-IdFAI questionnaire also had good or excellent test–retest reliability (ICC = 0.876–0.936), which was in agreement with the findings reported by previous studies. In addition, the 1-week interval of the test–retest reliability was assumed to be appropriate, as 1 week was sufficient for the patients to forget the exact answers they provided for the first survey, while the functions and daily lives of the patients would not change evidently within 1 week. In addition, 1 week was also the time for some patients to wait for the first physiotherapy. Therefore, they would not receive other treatments in this time interval (those who received other treatments were excluded after the completing the second survey), and thus could prevent the related biases. The MDC (I) and MDC (G) values of the SC-IdFAI questionnaire was 3.73 and 0.32, respectively. The scores of the two scales higher than 3 would suggest the real differences in the ankle functions of the two subjects. Low values for MDC indicated that small clinical changes could be detected not only at the group level but also at the individual level by SC-IdFAI.

In this study, the mean score of the SC-IdFAI questionnaire was slightly higher than that of the other versions (14.3–20.38) [11,19], suggesting that the severity of the CAI was relatively higher in the patients. In addition, the ceiling effect of SC-IdFAI was 1.52%, but not 0 as shown in other versions, suggesting that very few patients obtained a full score in the scale, but the percentage of the patients was far lower than 15%. The three experts also confirmed that the items of the SC-IdFAI questionnaire were relevant for the construct to be measured and for the patients with CAI. No missing questions were found in the recovered SC-IdFAI questionnaire. These findings and the good feedback from the patients suggested that the SC-IdFAI questionnaire had good content validity.

The studies on the Korean version of the IdFAI questionnaire also assessed the criterion validity of the scale [20]. However, according to the COnsensus-based Standards for the selection of health status Measurement Instruments (COSMIN) checklist, the "criterion validity" was defined as the degree to which the scores of a PROMs instrument are an adequate reflection of a "gold standard" [38]. The COSMIN checklist is a consensus-based checklist to evaluate the methodological quality of studies on the measurement properties of health status measurement instruments based on an international Delphi study in 2010. The criterion used should be considered as a reasonable "gold standard," but the Delphi panel reached a consensus that no gold standards exist for PROMs instruments [38]. Therefore, the criterion validity of the scale could not be assessed. The methods used in the Korean version were more likely for assessing the construct validity of the scale. Besides, the studies on other versions of the IdFAI questionnaire did not assess the construct validity of the scale using the "hypotheses testing" recommended by the COSMIN checklist [11,13,14,19,20]. Such studies only calculated the correlation coefficient of the translated IdFAI questionnaire with other control scales. However, no clearly

quantified indexes exist for the eligibility of the “construct validity” of the translated IdFAI. Therefore, it was speculated that proposing a series of hypotheses according to the COSMIN checklist first and then assessing whether the results were in agreement with the hypothesis would more correctly assess the construct validity of the scale, as this method had predefined indicators. In this study, the hypotheses testing method was used. The results showed that the correlations of SC-IdFAI with FAAM and SF-36 were generally in agreement with a priori hypotheses (85% of the hypotheses), suggesting that the SC-IdFAI questionnaire had good construct validity.

The responsiveness was not assessed in the original and other versions of the scale [11,13,14,19,20], despite the importance of the responsiveness, as it is an important indicator reflecting whether this scale could be used in prospective clinical studies. The findings of this study showed that the SC-IdFAI questionnaire had good responsiveness, suggesting that the scale could sensitively detect the functional changes in the patients after receiving systemic physiotherapies.

Conclusions

In summary, the IdFAI questionnaire was successfully translated and adapted into simplified Chinese version. It was also confirmed that this version was easy to understand, with high reliability, validity, and responsiveness. Therefore, this study suggested that the SC-IdFAI questionnaire could be used in the future clinical studies and clinical practices to assess the functions of the Chinese patients with CAI, thereby helping the physicians and investigators to better obtain the required data.

List Of Abbreviations

IdFAI: the Identification of Functional Ankle Instability questionnaire

AI: Ankle Instability Instrument

CAIT: Cumberland Ankle Instability Tool

CAI: Chronic ankle instability

SF-36: Medical Outcomes Study Short-Form 36

FAAM: Foot and Ankle Ability Measure

SEM: Standard error of measurement

MDC: Minimal detectable change

PROMs: patient reported outcome measures

WOSI: Western Ontario Shoulder Instability Index

NATA: National Athletic Trainers' Association

ES: Effect size

ICC: Intra-class correlation coefficient

SRM: Standardized response mean

Declarations

Ethics approval and consent to participate

All patients involved in the present study had thoroughly read and signed the informed consent. This study was approved by the ethics committee in the General Hospital of Western Theater Command.

Consent for publication

Not applicable

Availability of data and materials

The data are contained within the manuscript and the datasets supporting the conclusion of this article are available from the corresponding author upon reasonable request.

Competing interests

All the authors declare that they have no financial competing interests and non-financial competing interests concerning this article.

Funding

1. National Natural Science Foundation of China, 81701625.
2. Health and Family Planning Commission of Sichuan Province, 18PJ474.
3. Department of Science and Technology of Sichuan Province (CN) Project, 2019YJ0278.
4. Department of Science and Technology of Sichuan Province (CN) Project, 2017SZ0128.
5. Sichuan Cadre Health Committee Office, 2017-1302.
6. Department of Science and Technology of Sichuan Province (CN) Project, 2018SZ0187

Author's contributions

All authors have read and approved the manuscript

WW, JS, YT, WZ and ZL made substantial contributions to this article (conception and design, acquisition of data, analysis and interpretation of data).

QX has been involved in drafting the manuscript and analysis of data.

MW has been involved in drafting the manuscript.

Acknowledgments

We appreciate for the cooperation all the volunteered patients and the staff working in the outpatient center and in-patient department had given us.

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Tables

Table 1. Demographic and clinical characteristics of participants

Characteristics	Number (%) or Mean \pm SD
Age (years)	26.5 \pm 5.7
Range	18 - 47
Age groups	
\leq 20	23 (17.4%)
21 - 30	81 (61.4%)
31 - 40	25 (18.9%)
\geq 41	3 (2.3%)
Gender	
female	46 (34.8%)
male	86 (65.2%)
Affected side	
right	98 (74.2%)
left	34 (25.8%)
bilateral	
BMI (Kg/m ²)	23.4 \pm 4.9

MI: body mass index

Table 2. The internal consistency of SC-IdFAI

Items	Corrected Item: total correlation ^a	Cronbach's α ^b
Overall scale	1.000	0.902
Factor 1	0.882	0.897
Item 5	0.780	0.885
Item 6	0.815	0.880
Item 7	0.743	0.891
Item 10	0.782	0.884
Factor 2	0.725	0.808
Item 2	0.605	0.899
Item 3	0.585	0.904
Item 4	0.678	0.892
Factor 3	0.813	0.721
Item 8	0.690	0.894
Item 9	0.759	0.887

^aCalculated by the Spearman's correlation coefficient of the subscales or items with total score.

^bThe Cronbach's α of each item is calculated the alpha value of overall scale if this item was deleted.

SC-IdFAI: Simplified Chinese version of the Identification of Functional Ankle Instability questionnaire.

α /ceiling effects, test-retest reliability, measurement error and responsiveness of SC-IdFAI.

	Floor effect ^a	Ceiling effect ^a	ICC (CI range)	SEM	MDC (I) ^b	MDC (G) ^c	ES	SRM
Overall scale	0 %	1.52 %	0.936	1.346	3.73	0.32	-1.123	-1.554
Factor 1	0 %	2.27 %	(0.909-0.955) 0.907	0.886	2.46	0.21	-0.531	-0.683
Factor 2	0 %	1.52 %	(0.869-0.935) 0.881	0.668	1.85	0.16	-1.221	-1.347
Factor 3	0 %	2.27 %	(0.833-0.916) 0.876	0.466	1.29	0.11	-1.472	-1.100
			(0.827-0.912)					

patients with the worst (floor effect) and the best (ceiling effect) score at an individual level; at the group level.

ified Chinese version of the Identification of Functional Ankle Instability questionnaire; ICC: Intraclass correlation coefficient; CI: Coefficient of measurement; MDC: Minimal detectable change; ES: Effect size; SRM: Standardized response mean.

Construct validity of the SC-IdFAI

a	C-IdFAI subscales				
	Overall Scale	Factor 1	Factor 2	Factor 3	Hypotheses
Action	-0.776 (<0.001) ^b	-0.668 (<0.001) ^b	-0.575 (<0.001) ^b	-0.738 (<0.001) ^b	≥ Moderate, and better than SF-36 with SC-IdFAI
	-0.775 (<0.001) ^b	-0.644 (<0.001) ^b	-0.636 (<0.001) ^b	-0.669 (<0.001) ^b	
	-0.412 (<0.001) ^b	-0.395 (<0.001) ^c	-0.295 (0.001) ^c	-0.344 (<0.001) ^c	
-0.551 (<0.001) ^b	-0.511 (<0.001) ^b	-0.405 (<0.001) ^b	-0.424 (<0.001) ^b		
-0.482 (<0.001) ^b	-0.441 (<0.001) ^b	-0.359 (<0.001) ^c	-0.422 (<0.001) ^b		
Balance	-0.549 (<0.001) ^b	-0.529 (<0.001) ^b	-0.323 (<0.001) ^c	-0.511 (<0.001) ^b	≤ Poor, and worse than physical subscales of SF-36 and SC-IdFAI
	-0.372 (<0.001) ^b	-0.404 (<0.001) ^c	-0.155 (0.075) ^b	-0.278 (0.001) ^b	
	-0.242 (0.005) ^b	-0.173 (0.047) ^b	-0.230 (0.008) ^b	-0.107 (0.223) ^b	
Functional	0.035 (0.694) ^b	0.066 (0.455) ^b	-0.048 (0.586) ^b	0.050 (0.568) ^b	
	-0.137 (0.119) ^b	-0.116 (0.186) ^b	-0.083 (0.345) ^b	-0.141 (0.108) ^b	

the Spearman's correlation coefficient (r_s) of the overall scale and subscales of the SC-IdFAI with FAAM and SF-36.

with the Hypothesis

with the Hypothesis

ified Chinese version of the Identification of Functional Ankle Instability questionnaire; FAAM: Foot and ankle ability measure; ADL

36: Short-Form 36

Figures

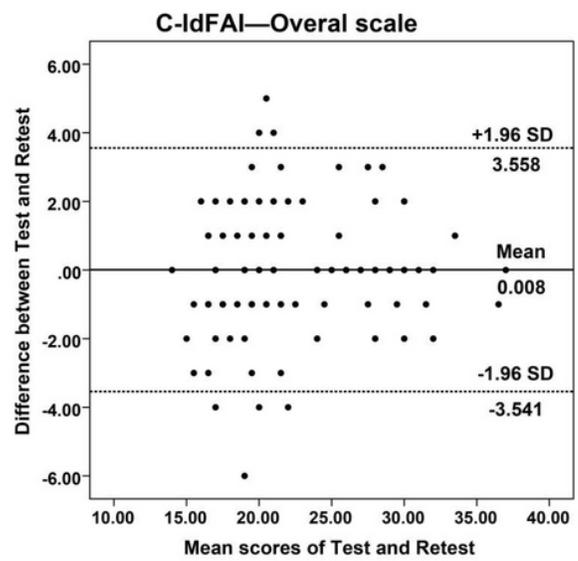
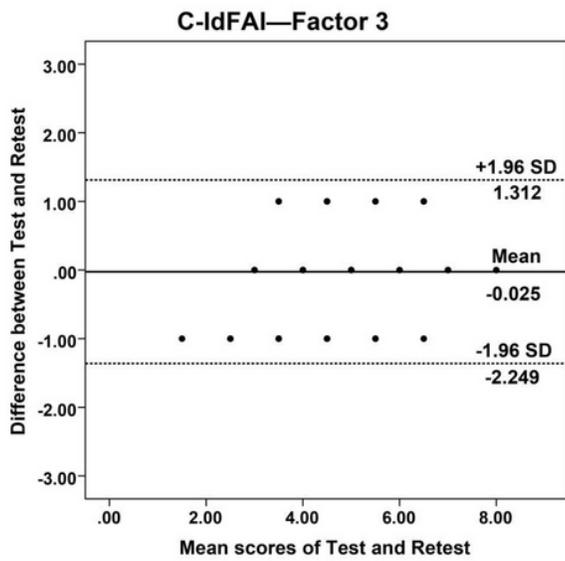
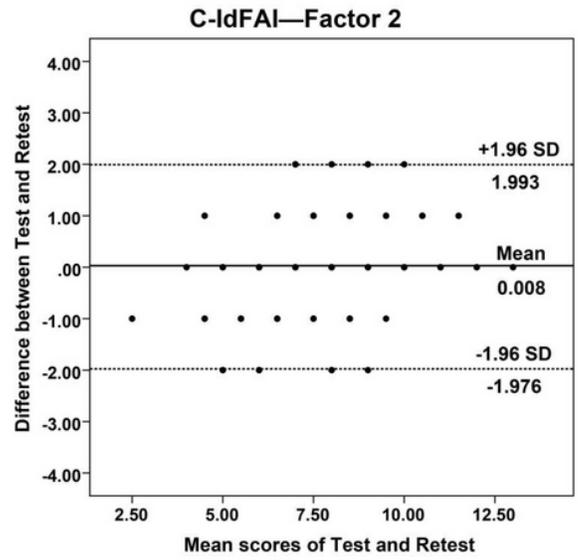
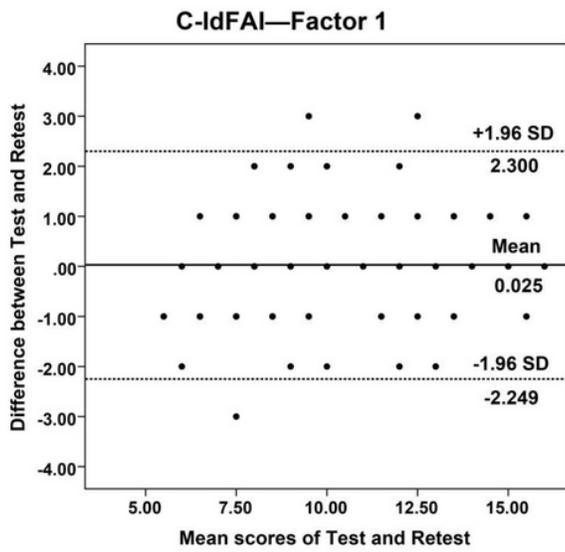


Figure 1

Bland–Altman plots also showed that in the first two surveys, the SC-IdFAI questionnaire and the three subscales had no evident system errors