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CLINICAL ARTICLE

Simplified Chinese Version of the Spinal Instability Neoplastic Score in Evaluating Patients with Metastatic Spinal Tumor: A Cross-Cultural Adaptation and Validation

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Objective: To translate the original English version of the Spinal Instability Neoplastic Score (SINS) into simplified Chinese, adapt it cross-culturally, validate its psychometric properties in measuring spinal instability in patients with metastatic spinal tumors in the Chinese mainland, examine the reliability and validity to demonstrate its accuracy and applicability in clinical practice.

Methods: Patients diagnosed with metastatic spinal disease between January 2016 and January 2020 were recruited. The number of participants was advised to be at least 50 for appropriate analysis of reliability, construct validity, as well as ceiling or floor effects, and recruitment of 100 patients was advised for internal consistency analysis. The study was conducted in two phases: first, the SINS was translated into simplified Chinese; second, the factor structure, internal consistency, test–retest reliability, validity, and floor and ceiling effects of the SC-SINS were assessed. The internationally recognized cross-cultural adaptation guidelines were followed. Internal consistency was evaluated with Cronbach's alpha. Test–retest reliability was examined among the patients with a 4-week interval. The validity of the Chinese version of SINS (SC-SINS) was assessed by examining its relationship with Kostuik classification. Principal component analysis was conducted to confirm the factor structure of each subscale.

Results: A total of 160 participants (88 males and 72 females) were enrolled. No major difficulties occurred in the forward and backward translations of SINS. The internal consistency of SC-SINS was excellent (Cronbach's $\alpha = 0.857$, ranging from 0.68 to 0.85). Test-retest reliability was also excellent with a value of 0.89, ranging from 0.86 to 0.95. Validity analyses indicated that the SC-SINS was positively and significantly correlated with Kostuik classification. The correlation between "Posterolateral Involvement of Spinal Elements" and "1-2 Partial Damage" was the highest with a correlation value of 0.792. The correlation between "Pain" and "1-2 Partial Damage" was the lowest with a value of 0.341. All items showed principal component coefficients greater than 0.4. The values of Factor 1 ranged from 0.523 to 0.681; Factor 2 ranged from 0.591 to 0.731; Factor 3 ranged from 0.501 to 0.754; Factor 4 ranged from 0.461 to 0.711; Factor 5 ranged from 0.513 to 0.701; and Factor 6 ranged from 0.501 to 0.668. In addition, neither floor nor ceiling effects were seen in the SC-SINS.

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Conclusion: The SC-SINS demonstrated high internal consistency and test–retest reliability, which has been proven valid and reliable to measure spinal stability in patients from the Chinese mainland with metastatic spinal tumor.

Key words: Cross-cultural adaptation; Reliability; Spinal instability; Spinal Instability Neoplastic Score; Vlidity

Introduction

The skeleton is the third most common site of metastatic cancer, and more than 70% of patients dying of cancers have pathological evidence of spinal metastases(1,2). Spinal metastasis may lead to mechanical pain, spinal cord compression, secondary paralysis, and dysfunction, which can negatively affect a patient's quality of life and survival(3). Spinal cord compression from epidural tumor often requires immediate treatment and surgery. In most of the spinal metastatic cases, the goal of surgery is to palliatively relieve pain, and to reduce the risk of spinal cord injury.

For spinal tumor surgery, apart from a thorough understanding of the tumor nature and prognosis, evaluating the stability of the lesion segment is also necessary for detailed surgical planning and outcome assessment. In 2010, the Spinal Oncology Study Group (SOSG) defined spinal instability as the "loss of spinal integrity as a result of a neoplastic process that is associated with movement-related pain, symptomatic or progressive deformity, and/or neural compromise under physiological loads"(4). In practice, if a vertebral body is not stabilized it will progressively fracture. At present, the Kostuik classification and Spine Stability Neoplastic Score (SINS) are widely used to classify and evaluate the spinal instability. Kostuik classification divides each vertebra into six columns to determine which lesion may cause mechanical instability and thus require surgical treatment. The six columns include the four columns of the cross section of the vertebral body and two columns at the back. It is suggested that spinal instability occurs when the tumor occupies three or more columns, and will be more severe when the tumor involves five or more columns. The evidence-based Spine Instability Neoplastic Score (SINS) was developed based on the best available literature and expertopinion consensus(5-7). As an adequate instrument to determine spinal instability, SINS allows easier consultation and communication among specialists treating spinal metastases. The system scores lesions on a scale from 0-18 using six variables: pain, location, bone lesion quality (lytic/blastic), alignment, vertebral body collapse, and posterolateral element involvement. Lesions are then described as stable (0-6), potentially unstable (7-12), or unstable (13-18). As with any scoring system, the utility of SINS is determined by its ability to accurately guide practice and to yield consistent results both across and within reviewers.

Spine instability may have numerous negative effects on a person's functional ability and quality of life. The degree of spinal instability may vary greatly, which eventually may cause variances in results ranging from mechanical pain to paralysis. Therefore, quantification of spinal instability is necessary to determine and understand its impact on patients' perception of disability and assessment of clinical outcomes. Consequently, this would help clinicians in decision-making and in the management of these patients. SINS is the most commonly used system to evaluate spinal instability. However, SNIS is in the English language, hence it cannot be accurately understood and accepted by the population in the Chinese mainland. To the best of our knowledge, no reliable and simplified Chinese version of the SINS is available yet. Therefore, developing SINS in simplified Chinese language instead of developing a new comprehensive scoring system will allow clinicians and researchers to compare this score with different populations. It will permit clinicians and researchers to exchange information across cultural and linguistic barriers, and will help with the strategic surgical planning and assessment of clinical outcomes.

The objectives of this study are to: i) adapt and validate the Chinese version of SINS (SC-SINS), and ii) assess the properties, reliability, and validity of SC-SINS.

Methods

Participants

Patients diagnosed with spinal metastases between January 2016 and January 2020 were recruited in this study. The minimum number of participants was advised to be 50 for appropriate analysis of reliability, construct validity, as well as ceiling or floor effects, while recruitment of 100 patients was advised for internal consistency analysis(8). Inclusion and exclusion criteria were determined following the PICOS (Patient, Intervention, Comparison, Outcome, and Study design) principle. Patients diagnosed with spinal metastases and confirmed by pathology or positron emission tomography and computed tomography (PET-CT) were included in this study. Whereas, patients unable to understand the significance of this study, had communication difficulties, and those who reported a history of spinal surgery or whose spinal disease was caused by infection, ankylosing spondylitis, or systemic rheumatologic disease were excluded. Complete imaging results and available clinical data were mandatory for all patients. Complete imaging results included sagittal view, axial view and coronal view of magnetic resonance imaging (MRI). Clinical data included demographic characteristics, neurological function, tumor levels, pathology report, complications and surgical treatment. There are eight spine evaluators who have at least 6 years of education and

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the ability to read and speak Chinese. This study was approved by the Ethics Committee of Affiliated Hospital 2 of Nantong University (2016KW021) and The First Affiliated Hospital of Zhengzhou University (2019-KY-173), and all patients signed a written informed consent.

Instruments

Sins

SINS, a comprehensive classification system developed to diagnose neoplastic spinal instability, comprises six individual component scores (i.e. spine location, pain, lesion bone quality, radiographic alignment, vertebral body collapse, and posterolateral involvement of the spinal elements). The maximum and minimum scores are 18 and 0 respectively. The total scores are divided into three categories in terms of stability: stable (0–6 points), potentially unstable (7–12 points), and unstable (13–18 points). In addition, the SINS scores can also be analyzed as a binary indicator of surgical referral status: "stable" (0–6 points) or "current or unstable" (7–18 points). A surgical consultation is recommended for patients with SINS scores greater than 7(6).

Kostuik Classification

The Kostuik classification is used to classify the degree of tumor involvement of the spinal column. In this classification, the vertebral body is divided into six components (four columns of the cross section of the vertebral body and two columns at the back), and considered three categories of stability: stable (1-2 partial damages), relatively unsteady (3-4 partial damages), and absolutely unsteady (5-6 partial damages)(9,10).

Procedure

The study was conducted in two phases: first, the SINS was translated into simplified Chinese; second, the factor structure, internal consistency, test-retest reliability, validity, and floor and ceiling effects of the SC-SINS were assessed. The procedures followed the cross-cultural adaptation guidelines written by Beaton(11).

Stage I: Forward Translation into Simplified Chinese

Each of the six components of SINS were translated into simplified Chinese independently by two bilingual native Chinese translators. One translator was a medical professional who knew the concepts related to the index well, while the other was a professional translator with no medical background and was blind to the objectives of this study.

Stage II: Synthesis of the Translations

The expert committee, consisting of translators, radiologist, and spinal surgeons specialized in spinal metastases discussed the translations and compared them with the original English version of SINS. After reaching a consensus, the forward translations were compiled into one single simplified Chinese version.

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Fig. 1 Male, 67 years old, Spinal metastasis of lung cancer, Location (Semirigid, 1 point), Pain (Yes, 3 points), Bone lesion (Lytic, 2 points), Radiographic Sal Alignment (*De novo* deformity, 2 points), Vertebral Body Collapse (<50% collapse, 2 points), Posterolateral Involvement of Spinal Elements (Unilateral, 1 points). Total point is 11, meaning unstable. So, this patient underwent surgery

Stage III: Backward Translation into English

Backward translation was then undertaken independently by another two professional bilingual translators, a radiologist, and a spinal orthopaedist. Both of them were not aware of the prior translation procedures. They independently and blindly translated back the simplified Chinese version into English. Each of the English translations was then compared with the original English version and checked for inconsistencies.

Stage IV: Expert Committee

The expert committee consolidated all the translations and discussed with all the translators, bilingual experts, and spinal surgeons. A consensus was reached on all discrepancies. Then the committee came into an agreement on the equivalence between the original version and the target version. Finally, the pre-final version of the SC-SINS was created.

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Stage V: Evaluation of the Pre-Final Version

The data of 28 patients were collected for pilot test by the evaluators. Each evaluator subsequently pointed out their difficulties in completing the classifications or understanding the purpose and meaning of each question. The expert committee discussed all the findings and then developed the final version of SC-SINS which was used for further psychometric testing. Figure 1 presented an example of a case with SC-SINS score.

Stage VI: Evaluation of the Final Version

A booklet of the final version of SC-SINS and an informed consent form were given to all participating patients who met the inclusion/exclusion criteria. We evaluated the internal consistency, test-retest reliability, and floor and ceiling effects of the final version. Each patient's demographic characteristics were recorded.

Table 1 Demographic and clinical characteristic	cs of the sample			
Characteristic Group	Pre-final group ($n = 28$)	Test–retest group ($n = 33$)	Validity group ($n = 160$)	
Age, years	59.5 ± 8.8	62.5 ± 9.5	60.5 ± 8.2	
Gender, Male/Female	12/16	18/15	88/72	
Disease duration, months	12.5 ± 4.8	15.2 ± 3.9	$\textbf{13.1}\pm\textbf{4.1}$	
BMI (kg/m ²)	$\textbf{23.7} \pm \textbf{1.8}$	$\textbf{22.5} \pm \textbf{2.1}$	22.8 ± 2.3	
Occupation, active/retired	16/12	17/16	73/87	
Primary tumor				
lung/breast	8	10	35	
liver/renal	6	3	29	
gastric/intestinal	6	8	28	
other	8	12	68	
Tumor stage, I-III/IV	20/8	22/11	110/50	
Frankel Score, A-C/D-E	15/13	16/17	85/75	
Segments involved, Single/multiple	14/14	19/14	78/82	
Visceral metastasis, yes/no	9/21	11/22	56/104	
Treatment, Surgical/Non-Surgical	17/11	18/15	91/69	
SINS Component				
Location				
Junctional	2	5	28	
Mobile spine	12	12	64	
Semirigid	12	11	56	
Rigid	2	5	12	
Pain				
Yes	20	22	132	
Occasional pain but not mechanical	7	9	19	
Pain-free lesion	1	2	9	
Bone lesion				
Lytic	9	14	68	
Mixed	11 15		72	
Blastic	8	4	20	
Radiographic Spinal Alignment				
Subluxation/translation present	3	6	13	
De novo deformity	11	9	27	
Normal alignment	14	18	120	
Vertebral Body Collapse				
>50% collapse	11	7	68	
<50% collapse	9	12	50	
No collapse with >50% body involved	4	11	18	
None of the above	4	3	9	
Posterolateral Involvement of Spinal Elements				
Bilateral	15	16	80	
Unilateral	11	15	70	
None of the above	2	2	10	

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Statistical Analysis

SPSS18.0 (Chicago, IL, USA) was used for statistical analysis. Data were expressed as the mean \pm standard deviation (SD). Values were reported with 95% confidence intervals (CIs) and a p-value less than 0.05 (p < 0.05) considered statistically significant.

Internal Consistency

Internal consistency reliability was evaluated using Cronbach's alpha (α) coefficient for each domain(12). High Cronbach's α indicates high correlations among the items. Cronbach's $\alpha \ge 0.70$ was considered satisfactory. In addition, the item-total correlations of each item were calculated. Levels of agreement for α were graded according to the recommendations of Landis and Koch. A value of 0.00 to 0.20 considered slight agreement; 0.21 to 0.40, fair agreement; 0.41 to 0.60, moderate agreement; 0.61 to 0.80, substantial agreement; and 0.81 to 1.00, almost perfect agreement(13).

Test-Retest Reliability

The test-retest reliability was assessed by comparing the results of the first and final SC-SINS scales. Intra-class correlation coefficient (ICC) was calculated with two-way random-effects ANOVA to quantify the test-retest reliability (14,15). We reassessed 60 patients for the second time. The sequence of SC-SINS was rearranged to reduce the memory error. A 4-week interval was designed between the two tests. ICC values ranged from 0 to 1, and a higher value indicated higher repeatability. An ICC above 0.7 could be accepted as

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good and below 0.4 as poor reliability(16). The correlation values were as follows: 0-0.20, poor; 0.21-0.40, fair; 0.41-0.60, moderate; 0.61-0.80, very good; 0.81-1.0, excellent.

Validity

To assess criterion-related validity, we examined construct validity. We evaluated the relationship between the SC-SINS and Kostuik classification using the Pearson correlation coefficients. Correlation values of 0.81-1.0 was considered excellent, 0.61-0.80 very good, 0.41-0.60 good, 0.21-0.40 fair, and 0-0.20 poor.

Structural Factor Analysis

We used factor analysis to evaluate the factor structure of the SC-SINS, and to confirm the subscales. Since the original SC-SINS indicated that the items were distributed across six subscales, we used principal component analysis rotation to confirm the factor structure of each subscale, rather than exploratory factor analysis. Item loadings on each factor equal to or greater than 0.4 were considered satisfactory (14).

Results

Translation and Cross-Cultural Adaptation

No major difficulties occurred during the forward and backward translations of SINS. The minor variances in few items caused due to cultural differences were minimized by adapting them cross-culturally and some modifications were made as well. In section 2 (Pain), "occasionally, not

	ltem	Item-total Score Correlation ($n = 160$)			
SC-SINS		R	Р	Cronbach's alF Item Deleted (n = 160)	ICC Values (n = 33)
Location	Q1	0.79	<0.0001	0.925	0.96 (0.94–0.99)
	Q2	0.85	< 0.0001	0.936	0.95 (0.93-0.97)
	Q3	0.77	< 0.0001	0.893	0.97 (0.94-0.99)
	Q4	0.74	<0.0001	0.914	0.93 (0.90-0.95)
Pain	Q1	0.71	<0.0001	0.818	0.87 (0.83-0.92)
	Q2	0.68	<0.0001	0.826	0.93 (0.91-0.94)
	Q3	0.79	<0.0001	0.825	0.90 (0.85-0.95)
Bone lesion	Q1	0.76	< 0.0001	0.876	0.89 (0.85-0.92)
	Q2	0.75	< 0.0001	0.899	0.93 (0.90-0.95)
	Q3	0.81	< 0.0001	0.902	0.91 (0.88-0.94)
Radiographic spinal alignment	Q1	0.71	< 0.0001	0.893	0.88 (0.84-0.92)
	Q2	0.73	< 0.0001	0.816	0.84 (0.81-0.90)
	Q3	0.81	< 0.0001	0.825	0.89 (0.83-0.92)
Vertebral body collapse	Q1	0.71	< 0.0001	0.796	0.86 (0.81-0.90)
	Q2	0.73	< 0.0001	0.897	0.88 (0.83-0.91)
	Q3	0.72	< 0.0001	0.814	0.84 (0.81-0.87)
	Q4	0.81	< 0.0001	0.907	0.85 (0.81-0.87)
Posterolateral involvement of spinal elements	Q1	0.72	<0.0001	0.796	0.87 (0.83-0.92)
	Q2	0.76	<0.0001	0.858	0.88 (0.86-0.90)
	Q3	0.71	< 0.0001	0.826	0.91 (0.89-0.94)

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Table 3 Pearson Correlation Coefficient of the SC-SINS with Kostuik Classification				
Factors	1–2 Partial Damage	3–4 Partial Damage	5–6 Partial Damage	
Location	0.741	0.572	0.523	
Pain	0.341	0.623	0.499	
Bone lesion	0.451	0.622	0.381	
Radiographic Spinal Alignment	0.381	0.546	0.381	
Vertebral Body Collapse	0.541	0.712	0.689	
Posterolateral Involvement of Spinal Elements	0.792	0.672	0.598	

consistently, no severe pain, and it was tolerable" were added as the explanations.

In pilot trial, 28 participants were enrolled. Among the 28 participants (12 males and 16 females), 17 received surgical treatment and 11 received non-surgical treatment. Table 1 presents summarized demographic and clinical data of the participants. Among the 28 participants, 13 mistakenly considered that the items were asking about the severity of pain before or after surgery. After consulting with the expert committee, we revised the pre-final SC-SINS and emphasized "pain" to refer to the preoperative pain for patients undergoing surgical treatment. Finally, the simplified Chinese version of the SINS was produced.

Demographic and Clinical Characteristics of the Sample

A total of 160 participants (88 males and 72 females) were enrolled in the final test. No significant differences were observed in the mean age, gender, duration, and BMI of the pre-final, test-retest, and validity groups. As per Frankel Score (A-C) the number of participants were 16, 17, 73 in the three groups, respectively. Pathologically, of the primary tumors, most of them were in lung, breast, liver, renal, gastric, intestine. The demographic data of the participants in each group and descriptive statistics have been shown in Table 1.

Internal Consistency

The internal consistency of SC-SINS was found to be excellent (Cronbach's $\alpha = 0.857$). All the item-total correlation scores were moderate to high, ranging from 0.68 (Pain, item 2) to 0.85 (Location, item 2). Following elimination of one item, the value of Cronbach's α did not increase by more than 0.1 for each item, which indicates that all items were relevant to this population. Table 2 demonstrates the results

SC-SINS	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6
Factor 1 Location						
Q 1–1	0.681					
Q 1–2	0.584					
Q 1–3	0.523					
Q 1–4	0.546					
Factor 2 Pain						
Q 2–1		0.591				
Q 2–2		0.676				
Q 2–3		0.731				
Factor 3 Bone lesi	on					
Q 3–1			0.613			
Q 3–2			0.681			
Q 3–3			0.754			
Factor 4 Radiogra	ohic Sal Alignment					
Q 4–1				0.565		
Q 4–2				0.461		
Q 4–3				0.711		
Factor 5 Vertebral	Body Collapse					
Q 5–1					0.513	
Q 5–2					0.626	
Q 5–3					0.619	
Q 5–4					0.701	
Factors 6 Posterol	ateral Involvement of Spin	al Elements				
Q 6–1						0.668
Q 6–2						0.592
Q 6–3						0.501

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of the Cronbach's α , item-total correlation scores, and Cronbach's α if the item was deleted.

Test-Retest Reliability

Thirty-three randomly selected patients were included in the retest session and the interval between the two tests was 4 weeks. The scores for the retest were found to be similar with those in the first test. All the ICC values were high, ranging from 0.86 (Radiographic spinal alignment) to 0.95 (Location). The mean ICC values of total SC-SINS was 0.89 (95% *CI*: 0.87–092), indicating excellent test–retest reliability (Table 2).

Validity

Validity analyses indicated that the SC-SINS was positively and significantly correlated with Kostuik classification (P < 0.0001). The six components of the SC-SINS were also significantly associated with the three components of the Kostuik classification (all p values <0.0001). In Table 3 it has been shown that the correlation between "Posterolateral Involvement of Spinal Elements" and "1-2 Partial Damage" was the highest with a correlation value of 0.792. The correlation between "Pain" and "1–2 Partial Damage" was the lowest with a value of 0.341.

Factor Analysis

Table 4 represents the summarized results of the factor analysis of all the SC-SINS items. All items showed principal component coefficients greater than 0.4. The values of Factor 1 ranged from 0.523 to 0.681; Factor 2 ranged from 0.591 to 0.731; Factor 3 ranged from 0.613 to 0.754; Factor 4 ranged from 0.461 to 0.711; Factor 5 ranged from 0.513 to 0.701; and Factor 6 ranged from 0.501 to 0.668. In addition, neither floor nor ceiling effects were seen in the SC-SINS.

Discussion

In this study, the SINS has been successfully cross-culturally adapted into a simplified Chinese version(SC-SINS), and the SC-SINS d emonstrated high accuracy and applicability in patients with spinal metastatic tumor in the simplified Chinese speaking population.

Adaptation and Validation of SC-SINS

The recent years have witnessed a sharp increase in the quantity and quality of clinical research in the field of neoplasia in China. However, till now there is no "gold standard" scoring system that could be used to score spinal stability, hence the doctors' views on spinal stability vary greatly. Therefore, valid scoring system is urgently needed to support the clinical researchers involved in studying spinal metastases in China. SINS is a valuable tool to quantify patients' spinal stability and conduct data analysis. This study successfully described the process of cross-cultural adaptation, structural validity, reliability, and construct validity of SINS among Chinese-speaking subjects. Furthermore, the unidimensional scaling using the newly developed SC-

SINS displayed satisfactory reliability and construct validity in patients with metastatic spinal tumor.

Following the recommended guidelines, the translation and cross-cultural adaptation were successfully done. The comprehensibility of the translated items was then reconfirmed. Hence, the SC-SINS could help clinicians and researchers to measure the spinal stability, compare the data with the patients of other nations, and be involved in cross-national studies. Furthermore, the SC-SINS was easy to understand and simple to use. After minor modifications, no item was difficult for participants to understand, and all items were answered in pretest and formal study, which supported good acceptability of SC-SINS. No significant floor or ceiling effects were also found in SC-SINS.

Properties, Reliability, and Validity of SC-SINS

In this study, the Cronbach's α value was similar to that reported in most other previous studies. In one study, Xu et al. reported that Cronbach's α was 0.831(9). Pennington *et al.* indicated that the reliability for SINS score was near perfect with a value of 0.815(17). Fox et al. also reported that total SINS scores showed near perfect with a value of 0.990(18). In addition, Arana et al. reported that the agreement was perfect with ICC = 0.96(19). In this study, the item-total correlation scores ranged from moderate to high (ranging from 0.68 to 0.85), and when a single item was deleted, the deletion did not increase the Cronbach's α by more than 0.1. Those findings suggested greater homogeneity of all sections and each section was well correlated to the SC-SINS. Item 1, a question based on objective fact, had the highest ICC value (Location, ICC = 0.85), which indirectly revealed the success of crosscultural adaptation. However, item 2 presented the lowest ICC value (Pain, ICC = 0.68). One possible explanation might be that the feeling of pain is subjective, which may be perceived by different patients in different ways and the change in the pain intensity might change with the different types of treatments. Furthermore, the test-retest reliability was excellent in this study. The ICC value of our study reached 0.89, which is higher than that in the abovementioned studies. Item 3, another subjective item, presented the lowest ICC value (Radiographic spinal alignment, ICC = 0.86), which could be attributed to the change caused by different body positions or other situations.

Limitations

The study has few limitations too. First, the participants in this study could not represent the entire Chinese population with metastatic spinal tumor. The patients recruited in this study were from two institutions only. Hence, enrollment of participants from multiple institutions could provide better sampling and improve the generalizability. However, the variability of this study was enough to demonstrate responsiveness. Second, the clinical experiences of the evaluators may affect the accuracy. Different understanding of systems may lead to a deviation in the results. Skilled spinal tumor surgeons should have been invited as evaluators to minimize bias, because they may make an agreement more easily than unskilled surgeons(20). Orthopaedic Surgery Volume 14 • Number 8 • August, 2022

Conclusions

The cross-cultural adaption of SINS into simplified Chinese version was successful. The SC-SINS demonstrated high internal consistency and test-retest reliability.

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The SC-SINS has been proven valid and reliable to measure spinal stability in patients from the Chinese mainland with metastatic spinal tumor.

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