Original Article

Development, Validation, and Reliability of Functional Outcome Questionnaire on Toronto Extremity Salvage Score [TESS] to Thai Version for Patients with Bone and Soft-Tissue Sarcoma

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Objective: To develop and test the validity and reliability of the Thai version of the Toronto Extremity Salvage Score [TESS] questionnaire for patients with bone and soft-tissue Sarcoma.

Materials and Methods: The Thai version of the TESS was developed by translation, back translation, and review for consensus. Then the questionnaire's validity and reliability was tested in 140 patients (70 upper extremities and 70 lower extremities). The validity was tested in two aspects, by content validity and criterion validity. The content validity was done through a physician-rated scoring for content validity index [CVI]. The criterion validity was measured by comparing with the clinical-rated Musculoskeletal Tumor Society Score [MSTS] by Pearson's correlation coefficient (r). The reliability was tested in two aspects namely internal consistency by Cronbach's alpha coefficient and external consistency by intraclass coefficient [ICC].

Results: TESS was translated into a Thai version and tested in Thai patients. For upper extremity TESS, the mean score was 82.15±21.9. The validity was acceptable (CVI = 0.90, r = 0.612). The reliability was high (Cronbach's alpha = 0.975, ICC = 0.910). Regarding lower extremity TESS, the mean score was 87.99±14.39. The validity was acceptable (CVI = 0.95, r = 0.636). The reliability was high (Cronbach's alpha = 0.981, ICC = 0.810).

Conclusion: The Thai version of TESS was valid and reliable to evaluate functional outcome in Thai bone and soft tissue sarcoma patients.

Keyword: Toronto extremity salvage score [TESS], Functional outcome, Thai version, Sarcoma, Validity, Reliability

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Sarcoma is a rare cancer, found more commonly in the extremities. Advanced treatments of sarcoma have changed in the last four decades and improved the survival rate of the disease. The trend of ablative surgery and amputation has decreased overtime because the rate of limb salvage surgery has increased through the development of surgical technique, implant devices, radiographic imaging, and adjuvant chemotherapy. The limb salvage surgery has many alternative methods such as endoprosthesis, allograft, recycle tumor-bearing autograft, and rotationplasty. The number of sarcoma survivors is increasing due to advancement of successful treatment. The results of the treatment can be measured by functional outcome. Performance limitations can restrict the survivor's ability to participate fully in daily activities necessary for self-care, home management, or work. Evaluation of physical functioning in patients with cancer relies on a combination of clinical assessment of impairments and/or patient self-report of physical functioning. Self-report questionnaires can be valid measures of functional status and establish a baseline on which to formulate a treatment plan and to estimate treatment effects.

Enneking et al[1,2] reported an evaluation scale system for sarcoma patients, developed from the International Symposium on Limb Salvage [ISOLS] and modified by the Musculoskeletal Tumor Society [MSTS]. The last version was created in 1993. However,

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the MSTS evaluates the function outcome by the physician without patient input and patients' perception. Patient's perceptions of their health are recognized as important outcomes in evaluating the effectiveness of medical and surgical treatment.

Davis et al[3] developed the Toronto Extremity Salvage Score [TESS], the disease specific self-reported questionnaire, to evaluate the functional outcome of extremity sarcoma patients. Currently, the TESS is widely used as the standardized questionnaire for monitoring sarcoma patients by evaluating the musculoskeletal functional outcomes. It has been translated in different languages for other cross-cultural settings[4-8]. It provides reliability and validity in mailing and internet usage[9].

However, in Thailand, only the MSTS is commonly used to monitor the functional outcome of sarcoma patients. This test is designed to be completed by a clinician and does not include patient input and patient's perception. Consequently, it may affect the outcomes as the patient's perception is recognized as one of the main outcomes in evaluating the effectiveness of medical and surgical treatment. Therefore, to fulfill this gap, the present study aimed to develop the TESS questionnaire in Thai language-version and to evaluate the validity and reliability of this Thai version questionnaire.

Materials and Methods

The present study was approved by the Research Ethical Committee of the Royal Thai Army Medical Department, and informed consent was obtained from all participants before beginning the study. One hundred forty primary bone and soft tissue sarcoma patients (70 upper extremity and 70 lower extremity) treated and followed-up with the author's department between 2012 and 2015 were included in this study. Inclusion criteria were above 18 years, postoperative definitive surgery for at least 12 months, no local recurrence of the disease, and literate in Thai language. Exclusion criteria were cognitive impairment, benign lesion or malignant skeletal metastasis, or sarcoma at trunk, head, or neck location. The background (demographic and clinical) data of participants were completed by the investigators in case medical records, and every eligible participant completed a self-administration questionnaire of the final version of Thai version of TESS at our clinic. The participants were given a second visit to complete the self-administration TESS questionnaires, which was one month later for test/retest reliability.

Questionnaire translation process and cross-cultural adaptation

We used the guidelines for the process of cross-cultural adaptation of self-report measures as reference protocol[10]. Initially, the original TESS was translated by two independent English experts leading to the two Thai versions of TESS. These two preliminary Thai translations were synthesized and committed to be the first consensus Thai version of TESS. Some items were adapted to be appropriate for Thai culture. The back translation was done from Thai to English and reviewed by the committee to achieve the pre-final Thai version of TESS. Pre-final Thai version of TESS was tested as a pilot questionnaire by the patients to measure quality of the content. This TESS was submitted for appraisal to the adaptation process of the final Thai version of TESS.

The final Thai version of TESS was tested for validity and reliability. The validity was measured in content validity and criterion validity. The content validity was about appropriateness, relevance, and comprehensiveness of questionnaire to evaluate if the instrument could adequately probe the specific domains that are required and if there was any difference with Thai culture. We verified the content validity index [CVI][11] of Thai version of TESS by five orthopedic oncologists content experts. The criterion validity (concurrent validity) was measured by comparing with the clinical-rated MSTS score, which was evaluated by physician on six parameters. Each parameter was rated from 0 to 5 points (full score = 30) and summed. Finally, the scores were converted to percentage, as gold standard, to compare with TESS score. Finally, the reliability was measured by internal and external consistency (test/retest reliability).

Statistical analysis

The demographic and clinical characteristics of patients were presented in descriptive statistics. The CVI was reported as agreement of content experts. To evaluate criterion validity of TESS with MSTS, Pearson's correlation coefficient was used. For the reliability, Cronbach's alpha coefficient was calculated for internal consistency and the test-retest reliability for external consistency were evaluated by intraclass coefficient [ICC]. All data was analyzed by Stata/SE for Window version 9.2 (StataCorp LP, College Station, TX).

Results

The final Thai version of TESS was developed

and a few items in questionnaire were adapted because some activities were not usually performed in Thai daily life. The pre-final Thai version of TESS used CVI for content validity, was considered high, 0.90 for upper extremity and 0.95 for lower extremity. No patients found the TESS, Thai version, difficult to understand and all patients answered the questionnaire. The average time for answering the TESS was 10 minutes. The demographic and clinical data are shown in Table 1.

Validity and reliability

The CVI for Thai version of TESS were 0.9 in upper extremity and 0.95 for lower extremity. Pearson's correlation coefficient was used to evaluate criterion validity by compare between MSTS score as gold standard and Thai version of TESS, which was considered accepted at 0.612 for upper extremity and 0.636 for lower extremity. Cronbach's alpha was used to evaluate internal consistency, which was considered accepted, 0.975 for upper extremity and 0.981 for lower extremity. The ICC was calculated to evaluate external consistency and considered accepted, 0.910 for upper extremity and 0.810 for lower extremity. The summery of statistic values for psychometric test are shown in Table 2.

Table 1. Demographic and clinical data

Characteristic	Upper extremity (n = 70)		Lower extremity (n = 70)	
Age (years), mean ± SD		45.00±18.97		40.09±19.06
Gender				
Male		37 (52.9)		30 (42.9)
Female		33 (47.1)		40 (57.1)
Tissue type, n (%)				
Soft-tissue sarcoma		38 (54.3)		27 (38.6)
Bone sarcoma		32 (45.7)		43 (61.4)
Location, n (%)				
	Shoulder	15 (21.4)	Pelvis/hip	9 (12.9)
	Arm	10 (14.3)	Thigh	18 (25.7)
	Elbow	10 (14.3)	Knee	26 (37.1)
	Forearm	10 (14.3)	Leg	10 (14.3)
	Wrist/hand	25 (35.7)	Foot/ankle	7 (10.0)
Tumor staging (Enneking), n (%)				
IA (low grade, intracompartment)		4 (5.6)		0 (0.0)
IB (high grade, extracompartment)		6 (8.6)		8 (11.4)
IIA (low grade, intracompartment)		6 (8.6)		7 (10.0)
IIB (high grade, extracompartment)		52 (74.4)		50 (71.4)
III (distant metastasis)		2 (2.8)		5 (7.1)
Type of surgery, n (%)				
Amputation		16 (22.9)		5 (7.1)
	Forequarter	31.25%	Hip disarticulation	0.00%
	Shoulder disarticulation	25.00%	Hemipelvectomy	20.00%
	Below elbow amputation	43.75%	Above knee amputation	20.00%
			Below knee amputation	60.00%
			Ankle disarticulation	0.00%
			Foot/toe amputation	0.00%
Limb salvage surgery		54 (77.1)		65 (92.9)
- No reconstruction, resection alone		44.44%		47.70%
- Arthrodesis		0.00%		0.00%
- Rotationplasty		0.00%		0.00%
- Autograft		11.11%		3.10%
- Allograft		21.42%		26.20%
- Recycling tumor-bearing autograft		14.20%		10.80%
- Composite graft		0.00%		4.60%
- Tumor endoprosthesis		7.10%		7.75%
MSTS score, mean ± SD		82.15±21.95		84.39±18.80
TESS, mean ± SD				
1st		95.25±4.91		87.99±14.39
2nd		94.23±6.73		85.47±15.10

MSTS = Musculoskeletal Tumor Society; TESS = Toronto Extremity Salvage Score

Table 2. Validity and Reliability statistic values of Thai version of TESS

Statistic values	Upper extremity	Lower extremity	Reference value
Validity			
Content validity (CVI)	0.90	0.95	CVI ≥0.8, acceptable
Criterion validity (Pearson's correlation)	0.612	0.636	r ≥0.9, excellent 0.7≤ r <0.9, good 0.5≤ r <0.7, acceptable 0.3≤ r <0.5, poor r <0.3, unacceptable
Reliability			
Internal consistency (Cronbach's alpha)	0.975	0.981	α ≥0.9, excellent 0.7≤ α <0.9, good 0.6≤ α <0.7, acceptable 0.5≤ α <0.6, poor α <0.5, unacceptable
External consistency (ICC)	0.910	0.810	ICC ≥0.9, excellent 0.7≤ ICC <0.9, good 0.6≤ ICC <0.7, acceptable 0.5≤ ICC <0.6, poor ICC <0.5, unacceptable

CVI = content validity index; ICC = intraclass coefficient

Discussion

For treatment of bone and soft tissue sarcomas, the limb sparing surgery is performed increasingly nowadays. The consequence after treatment can be measured by functional outcome. MSTS is usually the standard measurement to evaluate functional outcome, which is evaluated by the physician. The TESS self-report questionnaire was developed to evaluate functional outcome, based on patient's report of his/her function, and is widely used in many nations. However, the TESS is an English questionnaire. Some questions were not appropriate for Thai patient, so we developed the Thai version TESS for use in Thai patients.

We performed the standard method of translation of questionnaire development from the original English version TESS; translation into Thai, back translation to English, cultural adaptation, and expert committee agreement to achieve a final Thai version of TESS, which was finally tested by psychometric analysis. In the developmental process of the Thai version of TESS, some items were adapted to the Thai culture. As example, in upper extremity Thai version of TESS questionnaire, "Cutting food while eating" was changed to "Having the meal with spoon and fork" because in Thai culture, they did not use a knife while having a meal. As another example, in the lower extremity Thai version of TESS questionnaire "Getting in the bath tub" was changed to "Walk over the door step", because bathing in a tub is rarely done in Thai culture. Both items were replaced with the equivalent meaning of extremity actions. The short response time of Thai version of TESS represented the easy of understanding of the questionnaire.

In validity analysis, content validity by five experts was very high. When compared with the result of MSTS score in criterion validity, the Pearson's correlation of upper extremity and lower extremity were 0.612 and 0.636, respectively, that parallel to the Saraiva et al's study[4]. These results provided evidence for validity of Thai version of TESS. The Cronbach's alpha coefficient showed the high internal consistency. The ICC 0.910 and 0.810 of upper and lower extremity questionnaire, respectively, showed the high level of test-retest reliability that is similar to other studies[4-8]. These statistic results of psychometric analysis demonstrated that the Thai version of TESS met the validity and reliability to use in evaluation of functional outcome.

In comparison between TESS and MSTS, many studies showed that TESS is superior to MSTS in functional outcome measurement because each item of TESS could evaluate activity of daily living. Furthermore, patients were able to comment about the necessary activities for their living. MSTS can evaluate overall functional impairment and have advantages to evaluate especially in pain, emotional, and acceptance of treatment. Therefore, Thai version TESS and MSTS should be used together in functional outcome evaluation.

Conclusion

The result of the present study suggest that Thai version of TESS is appropriate to be used in bone and

soft tissue sarcomas to evaluate functional outcome in Thai patient for clinical follow-up, comparing and predicting outcome of each treatment option.

What is already known on this topic?

The TESS is a disease-specific measure, a single domain of physical disability, based on patients' reports of their function. The TESS was developed as a measure of physical function and is the gold standard method for evaluation in functional outcome of musculoskeletal oncology. The original TESS is an English-language questionnaire but it is widely used in different languages and across cultures.

What this study adds?

The validated Thai version TESS will benefit both clinical and research setting in musculoskeletal oncology of Thailand. In clinical setting, TESS score will reflect functional outcome and refer to quality of life of sarcoma patients after treatment. It can compare the results among different treatments. In research setting, this score can be used as a parameter for evaluation of treatment outcome and provide generalizability in research of musculoskeletal oncology field.

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Potential conflicts of interest

None.

References

1. Enneking WF. Modification of the system for functional evaluation of surgical management of musculoskeletal tumors. In: Enneking WF, editor. Limb salvage in musculoskeletal oncology. New York: Churchill-Livingstone; 1987:626-39.
2. Enneking WF, Dunham W, Gebhardt MC, Malawar M, Pritchard DJ. A system for the functional evaluation of reconstructive procedures after surgical treatment of tumors of the musculoskeletal system. Clin Orthop Relat Res 1993;(286):241-6.
3. Davis AM, Wright JG, Williams JI, Bombardier C, Griffin A, Bell RS. Development of a measure of physical function for patients with bone and soft tissue sarcoma. Qual Life Res 1996;5:508-16.
4. Saraiva D, de Camargo B, Davis AM. Cultural adaptation, translation and validation of a functional outcome questionnaire (TESS) to Portuguese with application to patients with lower extremity osteosarcoma. Pediatr Blood Cancer 2008;50:1039-42.
5. Saebye C, Safwat A, Kaa AK, Pedersen NA, Keller J. Validation of a Danish version of the Toronto Extremity Salvage Score questionnaire for patients with sarcoma in the extremities. Dan Med J 2014;61:A4734.
6. Kim HS, Yun J, Kang S, Han I. Cross-cultural adaptation and validation of the Korean Toronto Extremity Salvage Score for extremity sarcoma. J Surg Oncol 2015;112:93-7.
7. Ogura K, Uehara K, Akiyama T, Iwata S, Shinoda Y, Kobayashi E, et al. Cross-cultural adaptation and validation of the Japanese version of the Toronto Extremity Salvage Score (TESS) for patients with malignant musculoskeletal tumors in the lower extremities. J Orthop Sci 2015;20: 1098-105.
8. Xu L, Sun M, Sun W, Qin X, Zhu Z, Wang S. Cross-cultural adaptation and validation of the Chinese version of Toronto Extremity Salvage Score for patients with extremity sarcoma. Springerplus 2016;5:1118.
9. Clayer M, Davis A. Can the Toronto Extremity Salvage Score produce reliable results when used online? Clin Orthop Relat Res 2011;469:1750-6.
10. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976) 2000;25:3186-91.
11. Lynn MR. Determination and quantification of content validity. Nurs Res 1986;35:382-5.
12. Nunally JM. Psychometric theory. New York: McGraw-Hill; 1978.

การพัฒนาและทดสอบความเที่ยงตรงความแม่นยำของแบบสอบถาม Toronto Extremity Salvage Score [TESS] เพื่อประเมินผลลัพธ์ของการทำหน้าที่ทางกายภาพในผู้ป่วยมะเร็งชนิดปฐมภูมิของกระดูกและเนื้อเยื่อเกี่ยวพัน

พฤษพงศ์ ศรีสวัสดิ์, วิทวัส เกษรารัตน์, สุทธิพัฒน์ ไพโรจน์บริบูรณ์, ภูวดล วีรพันธ์, ทิพชาติ บุณยรัตนพันธุ์, สุพิชัย เจริญวารีกุล, ทวี ทรงพัฒนศิลป์, สหชาติ พิพิธกุล

วัตถุประสงค์: เพื่อพัฒนาแบบสอบถาม Toronto Extremity Salvage Score [TESS] ฉบับภาษาไทย เพื่อประเมินผลลัพธ์ทางกายภาพในผู้ป่วยมะเร็งชนิดปฐมภูมิของกระดูกและเนื้อเยื่อเกี่ยวพัน และทำการทดสอบความเที่ยงตรงและแม่นยำ

วัสดุและวิธีการ: กระบวนการแปล ประกอบด้วย การแปลเป็นภาษาไทย การแปลกลับเป็นภาษาอังกฤษ การปรับปรุงแบบสอบถามให้เหมาะสมกับวัฒนธรรมไทย และการสรุปผลโดยผู้เชี่ยวชาญทางภาษากับศัลยแพทย์ออร์โธปิดิกส์ด้านมะเร็งกระดูกและเนื้อเยื่อเกี่ยวพัน แบบสอบถามฉบับภาษาไทยที่ได้จะถูกนำไปประเมินความเที่ยงตรงและแม่นยำโดยผู้ป่วย 140 ราย (รยางค์บน 70 ราย และรยางค์ล่าง 70 ราย) ที่ได้รับการรักษาด้วยการผ่าตัด การทดสอบความเที่ยงตรงโดยวิธีการทางด้านเนื้อหา CVI และวิธีการเปรียบเทียบกับ MSTS ด้วยค่าสถิติ Pearson's correlation coefficient (r) และทดสอบความแม่นยำ โดยทำการทดสอบความมั่นคงภายในด้วยค่าสถิติ Cronbach's alpha coefficient และความมั่นคงภายนอกด้วยค่าสถิติ intraclass coefficient [ICC]

ผลการศึกษา: แบบทดสอบ TESS ได้ถูกพัฒนาเป็นภาษาไทย และได้ทำการทดสอบในผู้ป่วยชาวไทย โดยในกลุ่มรยางค์บน คะแนน TESS เฉลี่ย 82.15±21.9 ผลการทดสอบความเที่ยงตรงอยู่ในระดับที่ยอมรับได้ (CVI = 0.90, r = 0.612) และผลความแม่นยำอยู่ในระดับสูง (Cronbach's alpha = 0.975, ICC = 0.910) และสำหรับรยางค์ล่างคะแนน TESS เฉลี่ย 87.99±14.39 คะแนน และผลการทดสอบความเที่ยงตรง อยู่ในเกณฑ์ที่ยอมรับได้ (CVI = 0.95, r = 0.636) และผลการทดสอบความแม่นยำอยู่ในระดับสูง (Cronbach's alpha = 0.981, ICC = 0.810)

สรุป: จากผลการศึกษาแสดงให้เห็นว่า แบบสอบถาม TESS ฉบับภาษาไทย มีความเที่ยงตรงและแม่นยำในการประเมินผลลัพธ์ทางกายภาพในผู้ป่วยชาวไทยที่เป็นมะเร็งของกระดูกและเนื้อเยื่อเกี่ยวพัน