

図 1. がんの経過と精神症状

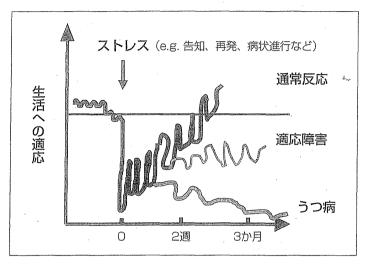


図 2. 悪い知らせに対する心理的反応

がん患者の13~20%にうつ病,15~25%に適応障害が認められている。また、がん治療が終了したがんサバイバーであっても再発不安などの精神的問題を多く抱えていることが示されている⁶⁷⁷.

1. 通常の心理反応(bad news 後の心理的衝撃)

がんの診断や治療中の再発などの悪い知らせを 受けた直後には、強い抑うつや不安、恐怖、苛立 ちなどが生じ、日常生活に大きな支障をきたすこ ともある.しかし、通常は2週間ほどで回復し、 日常の活動を再開することができるようになる. 2週間を経過しても回復が認められない場合に は、適応障害またはうつ病が疑われる(図2).

2. うつ病・適応障害

1)うつ病の診断

がん患者のうつ病(大うつ病性障害)を診断する場合も精神医学一般と同じく,アメリカ精神医学会の診断基準 DSM-5⁸⁾を使用する(表 1).

うつ病性障害の診断基準の項目でもある食欲低 下や睡眠障害,疲労感・気力減退,思考力・集中

表 1. うつ病の診断

以下の症状のうち、5つ以上が2週間続く 少なくとも1つは(1)抑うつ気分、または(2)興味·喜び の喪失である

- (1) 抑うつ
- (2) 興味・喜びの減退
- (3) 食欲減退·体重減少
- (4) 不眠·過眠
- (5) 焦燥・制止
- (6) 疲労感·気力減退
- (7) 無価値·罪責感
- (8) 思考力・集中力の減退
- (9) 希死念慮

力の低下は、がんに伴う身体症状やがん治療に伴う副作用として出現することも多い. これらの症状の扱いには検討が必要であるが、実地臨床では、抑うつを過小評価したことによる対応の遅れを防ぐために、上記の身体症状を含めてうつ病の診断をするのが一般的である.

2) 適応障害の診断

はっきりと確認できるストレス因に反応して気 分の落ち込みや不安などの症状が続き、日常生活 に著しい支障をきたしているが、うつ病の診断基 準は満たさない状態である⁸.

3) うつ病・適応障害のスクリーニング

抑うつを見逃さずに適切に対応するために、簡易で妥当性が検証されている精神症状スクリーニングも用いられる。つらさと支障の寒暖計、ワンクエスチョンインタビューは国立がん研究センター精神腫瘍学研究部のホームページよりダウンロードが可能である(http://pod.ncc.go.jp).

4) うつ病・適応障害の影響

うつ病や適応障害はそれ自体が強い精神的苦痛

であるだけでなく, QOLの全般的な低下や治療 アドヒアランスの低下, 意思決定に関する問題, 入院の長期化, 家族の精神的負担の増大, 予後の 増悪, 自殺などにも関連するといわれている. し たがって, 早期に患者の精神的問題に気づき, 適 切なアセスメントおよび治療介入を行うことが重 要である⁹.

5) 希死念慮

がんに罹患することは強い精神的苦痛となり、 がん患者から「早く死にたい」などの言葉が聞かれることも稀ではない、がん患者の自殺率は一般人口に比べて有意に高く、特にがんの診断から1年以内で高いことが知られている¹⁰⁾、最近の我が国の疫学研究では、がんの診断から1年以内の自殺の危険率は23.9(95% CI:13.8-41.6)と非常に高いが、1年後以降は非がん群とほぼ同率まで低下している¹¹⁾.

3. 再発不安

厚生労働省の「がんの社会学 | に関する合同研究 班は、我が国のがん患者およびがん体験者7.885 名を対象として、がん患者が抱える悩みの大規模 調査を行っているが、最も頻度が高い悩みは不安 などの心の問題(52.9%)であり、なかでも再発・ 転移への不安の占める割合が高く, 再発不安がが んサバイバーの中心的な問題であることが示され た12). 再発不安には、がんは手術などの治療によ り病巣を取り除いても再発の危険性が一定の割合 で存在すること、疼痛などの身体的要因のほか、 がん自体への不安の強さや治療選択への後悔など の感情も関与しているといわれており、結果とし て行動の制限や身体的不安の増強などが生じる. 再発不安は、日常生活における機能障害が強い場 合は適応障害と診断されるが, 精神医学的診断が つかないまま持続することも多い.

がんサバイバーシップにおける 精神的問題への介入

1. 基本となるアプローチ

多くのがん患者はもともと心理的健康度が高い

ため,基本的な支持的技法とともに,患者と医療者との信頼関係や良好なコミュニケーションそのものが精神療法として重要な役割を果たす.また,現実的な困難に遭遇しているがん患者に対しては,日常生活上の具体的なアドバイスを行うことも有効である.

2. うつ病・適応障害への介入

軽症のうつ病および適応障害の治療は精神療法であり、薬物療法は積極的には考慮しない. 中等症以上のうつ病では精神療法に薬物療法を併用するのが一般的である.

抑うつが強い場合や希死念慮を訴える場合は, 精神腫瘍科へのコンサルテーションを積極的に考 慮する.

1) 支持的精神療法

受容, 傾聴, 支持, 肯定, 保証, 共感などを中心とした精神療法であり, がん患者に限らず, 精神医療において最も一般的な治療技法である¹³⁾. がん患者の抱えている感情の表出を促し, 先行きへの不安や抑うつ感, 孤独感などの思いを傾聴し, 批判や解釈することなく受容, 患者を支え続ける関わりを行う.

2) 薬物療法

中等度以上のうつ病では、選択的セロトニン再取り込み阻害薬(SSRI)、セロトニン・ノルアドレナリン再取り込み阻害薬(SNRI)、ノルアドレナリン作動性特異的セロトニン作動性抗うつ薬(NaSSA)などを、身体状態や抗がん剤との薬剤相互作用を考慮しながら使用する。抗うつ薬は効果発現まで2~4週間程度要することが多い。

軽症うつ病や適応障害に対してアルプラゾラム などの抗不安薬を使用することもあるが、依存が 生じないよう短期間の使用にとどめる必要があ る.

3. 再発不安への介入

がんサバイバーにおける再発不安に対する標準 的な治療法はなく,支持的精神療法のほか認知行 動療法的介入を中心にいくつかの治療技法が用い られている。その1つに問題解決療法があり,精 神症状発現の原因となっているストレス状況に対し、下記の5つのステップからなるプログラムを行うことで症状の軽減をはかる¹⁴⁾¹⁵⁾.

- (1) **問題の定義と明確化(第1段階)**: 患者にとっての日常生活上の「問題」のリストを作る.
- (2) 目標設定(第2段階): その「問題」に対する 達成可能で現実的な目標を設定する.
- (3) 解決策の生成(第3段階):設定された目標 に対する解決策のリストを作る.
- (4) 実行可能な解決策の選択:解決策のリストから複数の解決策を取り上げ、その解決策のメリット・デメリットについてのリストを作成する. 最もメリットが多く、デメリットが少ない解決策を実際に実行する解決策として選択し、実行計画を作成する.
- (5) 解決策の実行と評価:作成された実行計画書を実行してもらい、その結果について評価とフィードバックを行う.

がんサバイバーシップにおける ポジティブな心理変化

がんに罹患したことによる精神的苦痛は大きく、うつ病や適応障害などの病的な状態に陥るがん患者も少なくないが、一方で、危機的な状況に曝露されることにより、精神面に正の変化が起きることも知られるようになってきた、外傷後成長(post traumatic growth: PTG)は「危機的な出来事や困難な経験との精神的なもがき・闘いの結果生ずるポジティブな心理的変容の体験」と定義されば、がんサバイバーにおいても注目されている。

おわりに

がんサバイバー(がん患者)の体験する精神的問題とそれに対する介入方法について紹介した.がんに罹患すること自体が大きなライフイベントであり,がん治療中だけでなく,がん治療が終了した後であっても,新たな精神的問題を抱える可能性が高いがん患者では,継続的な精神的ケアが必要と思われる.

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ORIGINAL ARTICLE



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

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Abstract

Background Before this work a Japanese version of the Toronto Extremity Salvage Score (TESS), a disease-specific patient-completed questionnaire widely used to assess the physical function of patients with musculoskeletal tumors, had not been developed. The purpose of this study was cross-cultural adaptation and validation of the Englishlanguage version of the TESS to facilitate international comparisons of treatment results.

Methods The TESS was translated into Japanese, backtranslated into English, and reviewed by a committee to develop a consensus Japanese version of the TESS. One

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hundred and two patients were assessed by use of this Japanese version to examine its reliability and validity.

Results Test-retest reliability and internal consistency determined by using the intraclass correlation coefficient (0.941) and Cronbach's alpha test (0.978), respectively, were excellent. Factor analysis showed that the structure consisted of a three-item cluster; the Akaike information criterion (AIC) network also demonstrated that the items could be divided into three domains in accordance with their content. The Japanese version of the TESS correlated with the Musculoskeletal Tumor Society rating scale (r=0.811; P<0.001) and the Short Form-36 physical component summary (r=0.785; P<0.001).

Conclusions Our study suggested that the Japanese version of the TESS is a reliable and valid instrument for measuring patient-reported functional outcome for patients with lower extremity sarcoma, and that it enables international comparisons of treatment results. The spatial association of each item demonstrated by using the AIC network also suggested that the underlying structure of the TESS reflected its coverage of a wide range of physical functions.

Introduction

Functional outcome after musculoskeletal tumor surgery is usually evaluated by using clinical measures such as muscle strength or range of motion outcome, on the basis of a combination of symptoms and mobility, as specified in the Musculoskeletal Tumor Society (MSTS) rating scale [1] or the Toronto Extremity Salvage Score (TESS) questionnaire [2].

The TESS is a disease-specific, self-report questionnaire for patients with musculoskeletal tumors in the extremities. The intent of the TESS is to evaluate single-domain

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physical disability on the basis of patient reports of their functional status. Its purpose is to monitor and evaluate the physical function of individual patients and groups of patients over time and to measure change in function after different therapeutic intervention [2].

The TESS was originally developed in English, and two different language versions have been validated in non-English speaking countries [3, 4]. However, to our knowledge, a Japanese version of the TESS had not been developed and validated. In this study therefore, our purpose was to translate and cross-culturally adapt the TESS into Japanese, and to validate this version for use by patients with musculoskeletal tumors in the lower extremities. We also attempted to identify the latent structure of the TESS by means of a novel statistical approach using factor analysis and the Akaike information criterion (AIC) [5, 6] by evaluating a sufficient number of patients.

Patients and methods

Cross-cultural adaptation

This study was approved by the institutional review board of each hospital. Cross-cultural adaptation of the TESS into Japanese was performed in accordance with published guidelines [7, 8]. Briefly, the English version of TESS was separately translated by three native Japanese bilingual translators (two with medical backgrounds). Subsequently, the two translators with the medical backgrounds and two musculoskeletal oncologists analyzed and compared the three translations and combined them into a single translation. After uniform agreement was reached among the three forward translators, this version was back-translated into the original language (English) by two professional bilingual translators who were unaware of the original English version. A pre-final consensus version that required only minor amendments was reached by the collective of health and language professionals, and forward and back-translators. Then, final formatting of the Japanese version of the TESS was completed.

Validation study

Patients and data collection

Patient recruitment was undertaken in accordance with four eligibility criteria:

- 1. intermediate or malignant bone or soft tissue tumors in a lower extremity or the pelvic girdle on the basis of the 2013 World Health Organization classification [9];
- 2. age 12-85 years;

- 3. a minimum time of 6 months after definitive surgery, including limb salvage surgery and amputation; and
- 4. no local recurrence or distant metastasis after definitive surgery.

We asked patients who had visited four outpatient clinics between August 2014 and December 2014 and met these criteria to participate in the study; 102 agreed to participate. The clinical and demographic characteristics of participants are listed in detail in Table 1. The patients and/or their families were informed that the data obtained would be submitted for publication, and gave their consent.

Instruments

The TESS is a self-administered questionnaire designed specifically to assess physical function for patients aged 12–85 years with musculoskeletal tumors [2]. The questionnaire contains 30 questions about daily activities including mobility, dressing, and working. Each question has response options, namely "impossible to do", "extremely difficult", "moderately difficult", "a little bit difficult", "not at all difficult" or "this task is not applicable for me (which is chosen if the item is not a usual activity for that individual)". The final score range is 0–100 points with higher scores indicating better function.

The Short Form-36 (SF-36) Health Survey is the most widely used questionnaire for comprehensive evaluation of health-related quality of life (HRQOL). It measures health in eight multi-item categories covering functional status, well-being, and overall evaluation of health [10]. In this validation study, the SF-36v2 (4-week recall) was used. Patients were asked to rate their responses on a 3, 5, or 6-point Likert scale. For each category, item scores were calculated, summed, and converted to a scale ranging from 0 (worst health) to 100 (best health) [10].

The MSTS rating scale is the most widely used physician-completed scale [1]. This score is based on analysis of factors pertinent to the patient as a whole and of those specific to the affected lower limb; these include pain, function, emotional acceptance, use of any external support, walking ability, and gait alteration. Each of these factors is assigned a value of 0–5 points (maximum overall score, 30 points) on the basis of established criteria.

Psychometric characteristics of the Japanese version of TESS

Floor and ceiling effects To assess floor and ceiling effects, the proportion of answer frequencies with the worst (1) and best possible (5) value on the 5-point Likert scale was calculated for each of the 30 survey items. Scores with floor or



Table 1 Descriptive characteristics of the study population

Characteristic	No. of patients (%)
Overall	102 (100)
Age, years; mean (SD)	48.3 (range 14-82) (17.8)
Sex	
Male	49 (48)
Female	53 (52)
Time from surgery, months; mean (SD)	54.0 (range 7–229) (51.3)
Tumor location	
Soft tissue	64 (63)
Thigh	38 (37)
Knee	6 (6)
Inguinal region	5 (5)
Pelvis	4 (4)
Buttock	4 (4)
Lower leg	4 (4)
Foot	3 (3)
Bone	38 (37)
Femur	20 (20)
Pelvic bone	13 (13)
Tibia	5 (5)
Histologic diagnosis	The second secon
Soft tissue	
Myxoid liposarcoma	14 (14)
Atypical lipomatous tumor/well differentiated liposarcoma	10 (10)
Undifferentiated pleomorphic sarcoma	8 (8)
Synovial sarcoma	8 (8)
Myxofibrosarcoma	6 (6)
Leiomyosarcoma	3 (3)
Others	15 (15)
Bone	e de la companya de
Osteosarcoma	17 (17)
Chondrosarcoma	8 (8)
Giant cell tumor of bone	6 (6)
Undifferentiated high-grade pleomorphic sarcoma of bone	4 (4)
Others	3 (3)
Type of surgery	
Ablative surgery	3 (3)
Amputation	2 (2)
Rotation plasty	1 (1)
Limb salvage surgery	99 (97)
Resection only	68 (67)
Resection + biological reconstruction	14 (14)
Resection + prosthesis	12 (12)
Curettage	5 (5)

SD standard deviation

ceiling effects may not detect patient improvement or deterioration because they are already at the lower or upper end of the scale. When >15 % of the participants obtained the highest or lowest score, an effect was noted.

Internal consistency Internal consistency of the TESS was assessed by use of Cronbach's alpha, because it provides a measurement of the strength of the relationship among the items in the questionnaire.



Reliability For patients from whom informed consent was obtained, we gave a second copy of the TESS for completion at their home 2–5 weeks after the first completion, for test–retest reliability analysis. The second questionnaire included a question asking if the difficulty had changed since completion of the first questionnaire, and only subjects reporting no change were included in the reliability analysis. The reproducibility (test–retest reliability) of the TESS was assessed by calculating the intraclass correlation coefficient (ICC). The ICC was calculated between the responses to the first (test) and the second questionnaire (retest) for each item in the TESS and for the total score.

Validity Construct validity refers to the extent to which a score measures what it is supposed to measure. Factor analysis is a powerful method for analyzing data to reveal the underlying cluster of a set of measurements. Factor analysis using the principal axis factoring method was performed to examine the latent structure of the TESS as a measure of construct validity. We used the scree plot and parallel analysis to identify the point where the curve starts to become level. We attempted to identify the major dimension of factors in the TESS data represented by groupings of items after sorting of the score matrix. Repeated varimax rotations were performed to dimensionally separate data clusters. This process resulted in a spatial representation of the relationships among the items. The factor loading pattern was also extracted. In addition to this conventional method, the correlation among items of the TESS was evaluated by using the AIC network to examine the latent structure of the construct validity of the TESS; this is a graphic modeling method used to assess the relationship among items and was developed by use of the Syntax language in SPSS software (version 10.0J; SPSS, Chicago, IL, USA) [5, 6]. The Japanese Institute of Statistical Mathematics has developed computer software in Fortran, called the "Categorical Data Analysis Program" (CATDAP-2), to conduct crosstable analyses involving all combinations of questionnaire items. This software simultaneously searched for the best subset and categorization of explanatory variables (items) and automatically indicated matching combinations by using the AIC [11, 12].

Criterion validity was assessed by comparison of the Japanese version of the TESS with the SF-36 and the MSTS rating scale. Correlations were evaluated by use of Spearman's correlation coefficient.

Statistical analysis

All statistical analysis was conducted by use of IBM SPSS version 18.0 (IBM SPSS, Armonk, NY, USA). Scores are reported as mean values \pm standard deviation. The threshold for significance was P < 0.05.

Results

Translation and cross-cultural adaptation

For the cross-culturally adapted TESS, some Japanese words normally expressed in Kanji (the Chinese characters used in the Japanese writing system) were changed to the Japanese characters of the Kana syllabary Hiragana to facilitate easier reading by patients at all educational levels. No major problems were reported by the three forward translators, because questions that involved short and simple sentences regarding simple activities were used in the original TESS. In addition, no major problems with the comprehensibility of the cross-cultural adaptation were noted during the back-translation and pretesting phase.

Questionnaire content

The mean score for the TESS was 86.7. Of the 102 patients included in the study, 100 (98 %) completed the first questionnaire. For each of two subjects in the first questionnaire, only one item was missing, sitting (Q20) and sexual activities (Q25). Participating in my usual sporting activities (Q30; 35.3 %), participating in sexual activities (Q25; 34.3 %), and driving (Q17; 32.3 %) were most frequently chosen as "not applicable".

Floor and ceiling effects

No substantial floor effect was observed for the Japanese version of the TESS; a ceiling effect was noted for the best score (100 points) for 17 patients (16.7 %).

Internal consistency and reliability

The overall Cronbach's alpha was 0.978, suggesting high internal consistency. The Pearson correlation coefficients between one item and the total score (excluding that item) ranged from 0.523 to 0.907.

A summary of the test-retest data is presented in Table 2. The detailed test-retest data for each item are given in Appendix 1 (which can be seen by downloading the file in the Supplementary Material). The overall ICC value was 0.941, indicating adequate reproducibility of the TESS. On the basis of the individual questionnaire items, rising from a chair (Q12), sitting (Q20), and standing upright (Q22) were the least reliable, with ICC values of 0.514, 0.624, and 0.676, respectively. Participating in sexual activities (Q25) and participating in my usual sporting activities (Q30) were the most reliable, with ICC values of 0.961 and 0.913, respectively.

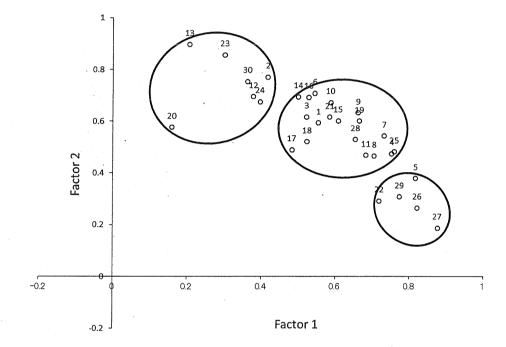


Table 2 Summary of test-retest data for the total score of the Japanese version of the TESS

	TESS s	corea			ICC_p	95 % CI	Cronbach's alphac	
	Min	Max	Mean	SD				
Test	26.7	100	86.7	16.5	0.941	0.913-0.960	0.978	
Retest	23.3	100	86.6	17.4			47 -	

SD standard deviation, ICC intraclass correlation coefficient, CI confidence interval

Fig. 1 Factor plotting of the TESS after varimax rotation



Validity

The appropriate number of dimensions was considered to be two from the scree plot (data not shown). The plotting factor for the TESS after varimax rotation is shown in Fig. 1. On the basis of the factor-loading pattern, we separated the TESS items into three domains: the first and second groups loading only factor 1 or 2, respectively, and third group loading both factors (Appendix 2, which can be seen by downloading the file in the Supplementary Material). This result indicated the presence of an underlying set of clusters that reflected the multidimensional and interrelated structure of the TESS. However, spatial relationships between these domains, on the basis of the calculated groupings regarding the TESS, were required for further analysis.

The AIC calculation for the TESS yielded 841 (= $_{30}$ C₂ + $_{30}$ C₃) minimum distance assortments (i.e., degree of independence for the two-item groupings). On the basis of the spatial association of the calculation of each item (AIC

network), we were able to separate the questionnaire items in the TESS into three domains according to their content, although confounding relationships among the items were noted (Fig. 2).

A summary of the criterion validity data for the TESS as compared with other widely accepted scoring systems is given in Table 3. There were moderate to strong correlations between the TESS and the MSTS rating scale, SF-36 physical component summary, physical functioning, role-physical, bodily pain, social functioning, and role-emotional, however, no correlations were noted between the TESS and the mental component summary, general health, vitality, and mental health.

Discussion

The reliability, internal consistency, and validity of the Japanese version of the TESS were comparable with those of

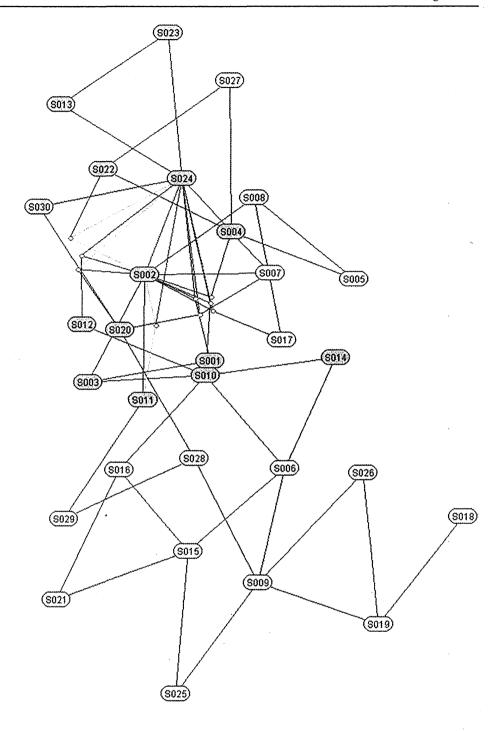


^a The total score of 100 points, best score; 0, worst score

^b The ICC ranges from 0.00 (no agreement) to 1.00 (perfect agreement) and describes the consistency of repeated assessments when no real change has occurred for a subject within the assessment period

^c This estimate can vary between 0.00 (no correlation) and 1.00 (perfect correlation), where a good correlation (e.g., alpha >0.90) among the items indicates strong internal consistency

Fig. 2 AIC network showing the three domains of the TESS: (1) items related to simple movements or activities not requiring appreciable strength or endurance (the *upper left region*, *blue* items); (2) items related to more advanced activities requiring muscle strength, endurance, or coordination represented by locomotion and work (the *lower right region*, *white* items); and (3) sporting activities (Q30; the edge of the *upper left region*, a *pink* item)



the original version of the TESS and other language versions [2–4]. In addition to development of the Japanese version of the TESS, in this study we used a large patient cohort for validation of the TESS. It is the first to clearly present additional information on the lower extremities regarding a ceiling and/or floor effect, to determine validity by use of factor analysis, and to use an AIC network to evaluate the TESS with regard to the lower extremities.

In development of the Japanese version of the TESS we used the previously published guidelines that take linguistic

and cross-cultural bias into account [7, 8]. In our translation process, we encountered only one major linguistic or cultural discrepancy. The high incidence of "not applicable" with regard to the question on sexual activity may have been the result of cultural background, because many people avoid volunteering information about their sexual behavior in an open manner; a more euphemistic expression may be preferred in the translation.

Although no previous data are available about floor and ceiling effects in the TESS, a ceiling effect was observed



Table 3 Criterion validity

Reference score	Mean	SD	Spearman's correlation coefficient ^a	95 % CI	P value
SF-36 (physical component summary)	44.7	16.5	0.785	0.697 to 0.850	< 0.001
SF-36 (mental component summary)	52.8	9.1	-0.106	-0.294 to 0.090	0.296
SF-36 (physical functioning)	48.6	19.2	0.781	0.692 to 0.847	< 0.001
SF-36 (role physical)	44.4	13.4	0.703	0.589 to 0.790	< 0.001
SF-36 (bodily pain)	50.7	9.1	0.466	0.299 to 0.606	< 0.001
SF-36 (general health)	51	9.4	0.214	0.020 to 0.392	0.031
SF-36 (vitality)	51.1	8.9	0.327	0.142 to 0.490	0.001
SF-36 (social functioning)	47.6	12.2	0.568	0.420 to 0.687	< 0.001
SF-36 (role emotional)	46.8	12.4	0.467	0.300 to 0.606	< 0.001
SF-36 (mental health)	51.7	9	0.148	-0.048 to 0.333	0.140
ISOLS (total)	82.3	20.4	0.811	0.732 to 0.869	< 0.001
ISOLS (pain)	4.6	0.8	0.393	0.215 to 0.546	< 0.001
ISOLS (function)	4.1	1.3	0.731	0.625 to 0.810	< 0.001
ISOLS (emotional acceptance)	3.8	1.3	0.449	0.279 to 0.592	< 0.001
ISOLS (support)	4.2	1.7	0.625	0.490 to 0.731	< 0.001
ISOLS (walking)	4.2	1.1	0.688	0.570 to 0.778	< 0.001
ISOLS (gait)	4.1	1.2	0.723	0.615 to 0.804	< 0.001

SD standard deviation, CI confidence interval

in this study. However, considering the heterogeneity of diagnoses and the diverse range of treatments for patients undergoing musculoskeletal tumor surgery, variable levels of physical function can be expected. In cases involving less invasive surgery, for example resection without bone involvement, the treatment does not usually significantly affect functional outcome. Further studies stratified by use of such uniform variables as age, site and tumor size, extent and type of tissue resected during surgery, and reconstructive techniques are required to resolve the problem of population heterogeneity.

We attempted to reveal the latent structure of the TESS in this study by using factor analysis and the AIC network. On the basis of the factor-loading pattern in the factor analysis and the results of the AIC network analysis, we were able to separate questionnaire domains that were differently related to specific components. With regard to the AIC network, especially, we were able to identify the underlying domains according to the nature or intensity of the activities. In addition, this underlying structure reflected the TESS coverage of a wide range of physical functions.

As a result of increased life expectancy there has recently been growing interest not only in functional outcome after surgery but also in HRQOL. It seems mandatory that other important domains, including body image, mental status, or social activities, are taken into account in evaluation of the HRQOL of patients with musculoskeletal tumors. There was good correlation between the TESS, the

MSTS rating scale, and the physical domains of SF-36, because the TESS specifically focuses on basic daily activities. Our results suggested it did not reflect the mental status of patients, however; correlation between the TESS and the mental domains of SF-36 were low. Development of such a disease-specific measure to evaluate HRQOL for patients with musculoskeletal tumors is awaited.

Several limitations of our study should be noted. First, although it is difficult to prove, the two different methods used for completion of the second questionnaire in our study, by appointment or by mail, could have affected reliability; ICC were adequately high, however. Second, assessment of the responsiveness of the Japanese version of the TESS was not performed, because this study is part of a recently initiated study focusing on the function and HRQOL of patients with musculoskeletal tumors. Future research examining the responsiveness of the Japanese version of the TESS over the recovery period after surgery would further demonstrate its validity.

In conclusion, the Japanese version of the TESS is a reliable and valid measure of outcome that provides a valuable basis for all clinical studies focused specifically on patient opinion of their physical function after musculoskeletal tumor surgery. Our findings with regard to the validity of the TESS, especially the spatial association of each item demonstrated by use of the AIC network, also suggest that the underlying structure of the TESS reflects its coverage of a wide range of physical functions.



^a The strength of the correlation was categorized in accordance with the absolute value of the correlation coefficient as follows: <0.20 (very weak); 0.20–0.39 (weak); 0.40–0.59 (moderate); and ≥0.60 (strong)

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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日本語版 Toronto Extremity Salvage Score 下肢の開発 — 言語的妥当性を担保した翻訳版の作成*

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産業**国際**はじめに 医型国際的

近年、リハビリテーションや整形外科のように機能の改善をめざす分野や心理学の分野においては、臨床所見や検査所見のみならず、患者の視点に立った患者立脚型評価尺度を用いて治療効果判定を行うことの重要性が強調されている。また骨・軟部腫瘍の手術では、広範囲に及ぶ組織欠損による四肢の機能低下とそれに起因する日常生活動作(activities of daily living:ADL)の低下が問題となり、患者の状態を評価する際には適切な評価尺度を使用して総合的に評価することが重要である.

現在、骨・軟部腫瘍における疾患特異的な患者立脚型評価尺度は Toronto Extremity Salvage Score(TESS)が唯一使用可能である。TESS は骨・軟部腫瘍患者の術後の身体機能を多面的にとらえ、総合的に評価するために Davis らにより開発された自記式の英語版の質問票であり、原発巣が上肢および上肢帯に存在する場合の評価法と下肢および下肢帯に存在する場合の評価法に分かれている。上肢は 29 個、下肢は 30 個の ADL に関する質問からなる。質問項目のうち 11 個は上肢、下肢に共通である。1996 年に計量心理学的な妥当性の検証がなされ公表された¹⁾、英語版のほかにポルトガル語など複数の言語で言語的妥当性が確認された翻訳版が作成されており、これまで広く使用されている^{2,3)}。しかし、わ

が国においては言語的な妥当性が確認された翻訳版はないのが現状である.

わが国においても TESS—下肢を治療評価に使用可能にすべく, 英語の原作版を日本語に翻訳しその言語的妥当性を検討したので報告する.

日本語版 TESS―下肢を作成するにあたって、まず原作者¹⁾から許可を得た、その後、言語的妥当性を担保した翻訳版を作成する際に標準的に用いられる手順に従って日本語版 TESS―下肢を作成した(図 1)^{4~6)}、適宜、骨・軟部腫瘍の専門医や英語のネイティブスピーカーを交え、原作版と翻訳版の内容的な整合性を確認しながら日本語訳を検討した。

1. 順翻訳および逆翻訳

まず日本語を母国語とする3名の翻訳者が、原作である英語版の質問票を日本語に翻訳し、各々の翻訳案を検討した後に日本語翻訳第一案として一つの翻訳案にまとめた、その後、骨・軟部腫瘍を専門とする医師との協議を行い、日本語翻訳第二案を作成した(順翻訳)、次に2名のバイリンガル(うち1名は英語を母国語とする翻訳者)が日本語翻訳第二案を英語に翻訳し、その内容について骨・軟部腫瘍専門医を含めた検討を行い、日本語翻訳第三案(日本語暫定版)を作成した(逆翻訳)

Key words: musculoskeletal tumor, self-reported questionnaire, Toronto Extremity Salvage Score, Japanese version

- * Development of the Japanese version of the Toronto Extremity Salvage Score : translation and linguistic validation
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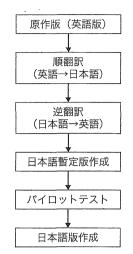


図 1. 日本語版 TESS-下肢作成の手順

2. パイロットテスト

日本語暫定版の文章表現や質問内容の妥当性を検討するために、当院において個別面談方式によるパイロットテストを行った。面談は診断・治療に関与していない第三者の医師および看護師が実施した。

個別面談は下肢の悪性骨・軟部腫瘍で患肢温存手術を受け、経過観察中である3名を対象に行った。回答終了後、①質問票の全体的な印象(説明文は明確でわかりやすいか、質問数や回答に要する時間は適当か)、②質問文・回答肢についての印象(質問文や回答肢はわかりやすく適切であるか)について意見を求めた。

.周恩圖圖圖圖 結果 图图圖圖圖

原作版と日本語版の対応を表1に示す.

1. 順翻訳および逆翻訳(日本語暫定版の作成)

日本語暫定版を作成するまでに検討した主な内容を以下に示す.

説明文(序文)の翻訳において、"activity"は直訳すると「活動」であるが、日本語としての自然さやわかりやすさを重視して、「動作」と翻訳した.

回答肢の翻訳では"extremely"は直訳すると「極度に」、"moderately"は直訳すると「中等度に、中程度に」となるが、「疾患特異的・患者立脚型慢性腰痛症機能評価尺度(Japan Low back pain Evaluation Questionnaire: JLEQ)」「や「疾患特異的・患者立脚型変形性膝関節症機能評価尺度(Japan Knee Osteoarthritis Measure: JKOM)」®の原作版と英語版の対応にならって、"extremely difficult"は「ひどく困難」、"moderately difficult"は「中程度困難」と翻訳した.

また、回答肢 "888. This task is not applicable for me." における "task" は直訳すると「仕事」であるが、日本語としての自然さやわかりやすさを重視して、説明文 (序文) における "activity" と同様に、「動作」と翻訳した.

質問文は "Q1) Putting on a pair of pants is:"や "Q2) Putting on shoes is:"のように、日常生活における単純動作について質問するための、比較的平易で短い表現が多く使われていたため、翻訳のうえで困難はなかった。"Q11) Getting out of bed is:"は直訳すると、「ベッドから外に出てくることは」であるが、日本語としての自然さやわかりやすさを重視して、「ベッドから起き上がることは」と意訳した。

2. パイロットテスト

下肢の悪性骨・軟部腫瘍のため患肢温存手術を受け、 経過観察中である日本語を母国語とする成人3(男性3) 例を対象に調査を行った.いずれの患者も質問内容をよく理解しており、回答にも問題はなかった.文章表現も わかりにくいところはなく、回答しやすい質問票である との意見であった.

3. 日本語版の作成

上記の結果をふまえて日本語暫定版を修正し、言語的 妥当性の担保された「日本語版 TESS—下肢」の最終版 を確定した(図 2).

TESS一下肢は骨・軟部腫瘍に対する患肢温存術のための自記式の評価尺度であり、英語を母国語とする国では広く用いられている。われわれは TESS一下肢が日本でも使用できるようにするために日本語翻訳版を作成した。

他言語で作成された質問票を翻訳する際には、文化的背景や言語的な違いを考慮し、原作版との内容的な整合性を担保しながら、日本人にも違和感なく受け入れられるように適切な表現を使用する必要がある⁹. われわれは質問票の翻訳版の言語的妥当性を担保するために用いられる標準的な手順に従って日本語版を作成し、作成過程では適宜、専門医およびネイティブスピーカーと協議を行い、臨床的・言語的な視点から翻訳案を検討しながら日本語訳の言語的な精度を高めていった.

このような過程を経て原作版と同じ臨床的な概念を有し、かつ言語的に妥当な TESS—下肢の日本語訳が完成した. 今後, より適切な質問票とするためには必要に応

	表 1. 英語版 TESS(原作版)と日本語版 TESS の比較					
———— 名称	Toronto Extremity Salvage Score (TESS) —lower extremity	日本語版 TESS—下肢				
説明文	The following questions ask about your ability to perform activities that are common to every day life. Considering the amount of difficulty you have performing the activity due to the current problem you are having with your leg, please answer the questions by choosing the answer that best describes your ability to do the activity over the past week.	なたにできるかどうかについての質問です.現在,あなたの脚に問題があるためにその動作をすることが難しい場合は、困難の程度を考えて、この1週間にその動作を行ったときのあなたの能力にもっとも近い回答を1つ選				
質問文 回答肢	1) Putting on a pair of pants is: 1. impossible to do. 2. extremely difficult. 3. moderately difficult. 4. a little bit difficult. 5. not at all difficult. 888. This task is not applicable for me.	 ブボンをはくことは 不可能である ひどく困難 中程度困難 少し困難 まったく困難はない 888. この動作は私には当てはまらない 				
質問文	 2) Putting on shoes is : 3) Putting on socks or stockings is : 4) Showering is : 5) Light household chores such as tidying and dusting 	2) 靴をはくことは3) 靴下やストッキングをはくことは4) シャワーを浴びることは5) 片付けやほこりとりなど負担の少ない家事をするこ				
	includes both a job outside the home and as a homemaker.)	とは 6) 園芸や庭仕事をすることは 7) 食事を準備したり出したりすることは 8) 買い物に行くことは 9) 掃除機をかけたり,家具を動かすなど負担のかかる家事をすることは 10) 浴そうに入ったり、浴そうから出たりすることは 11) ベッドから起き上がることは 12) 椅子から立ち上がることは 13) ひざまずくことは 14) 床においてあるものを拾いあげることは 15) 階段を降りることは 16) 階段を降りることは 17) 車を運転することは 18) 家の中を歩くことは 19) 屋外を歩くことは 20) 座ることは 21) 丘や斜面を昇ったり降りたりすることは 22) まっすぐ立つことは 23) ひざまずいた状態から立ち上がることは 24) 車に乗り込んだり、車から降りたりすることは 25) 性行為をすることは 26) 仕事でいつもしている作業を終わらせることは(仕事には家の外に働きにでることと家事の両方が含まれます)				
質問文(総合評価)回答肢	 28) Participating in my usual leisure activities is: 29) Socializing with friends and family is: 30) Participating in my usual sporting activities is: 1) Considering all the activities in which I participate in daily life, I would rate the ability to perform these activities during the past week as: 1. impossible to do. 2. extremely difficult. 3. moderately difficult. 4. a little bit difficult. 5. not at all difficult. 	28) いつもの趣味の活動に参加することは 29) 友人や家族との付き合いは 30) いつもしているスポーツ活動に参加することは 1) 日常生活の中で行っているすべての活動を考えて回答してください. この1週間において, これらの活動を行う能力を評価すると 1. 不可能である 2. ひどく困難 3. 中程度困難 4. 少し困難 5. まったく困難はない				

名称	Toronto Extremity Salvage Score (TESS) —lower extremity	日本語版 TESS一下肢
質問文 (総合 評価)	2) I would rate myself as being:	2) 自分で自分自身を評価すると
回答肢	 completely impaired severely impaired moderately impaired mildly impaired not at all disabled 	 完全に障害されている 重度の障害がある 中等度の障害がある 軽度の障害がある 障害は全くない
質問文	Please comment below on any activities you find difficult to perform or on any other difficulties you experience due to the problem you currently have in your leg that you feel are important and have not been asked about in this questionnaire.	あなたが行うのが困難だと思うことがある場合, または, あなたの脚に現在問題があるために経験した困難で, あなたが重要と感じているにもかかわらず, このアンケートで質問されていないことが他に何かあれば, どんなことでも下に記入してください.
回答 説明文	(Free comment) Please check to make sure that you have answered all the questions. Thank you for taking the time to answer these questions.	(フリーコメント) すべての質問に回答しているかを確認してください. 質問への回答にお時間をいただき、ありがとうございました.

トロント患肢温存スコア(日本語版TESS)-下肢

(Toronto Extremity Salvage Score-Lower extremity)

渓の質問は冒葉生活のなかでよく。行われている動作があなたにできるかどうかについての質問です。現在、あなたの酮に問題があるためにその動作をすることが難しい場合は、菌鰈の程度を考えて、この1週間にその動作を行ったときのあなたの能力にもっとも違い固答を1つ選んでください。

1) ズボンをはくことは

- 1___未可能である
- 2___ひどく菌難
- 3____节程度函難
- 4___歩し菌難
- 5___まったく歯難はない

888___この動作は、私には当てはまらない

2) 靴をはくことは

- 1____木可能である
- 2____ひどく菌難
- 3___节程度菌難
- 4___歩し菌難
- 5___まったく函難はない

888___この動作は、私には当てはまらない

図 2. 日本語版 TESS-下肢

整形外科 Vol. 67 No. 3 (2016-3)

じて日本語の表現について検討を加え、質問票としての精度をさらに高めていくことが重要である。また本質問票を臨床で使用するためには十分な症例数での計量心理学的な検討が必要である。今後はこのような計量心理学的な特性についても検討を加え、日本語版 TESS—下肢を普及していく予定である。

関連 まとめ 調整

- 1) 日本でも TESS―下肢を使用可能にするため、原作者から許可を得たうえで原作版を日本語に翻訳した.
- 2)翻訳版質問票の言語的妥当性を担保するために用いられる標準的な手順に従い日本語版を作成した.
- 3) 言語的な検討に引き続き計量心理学的な検討を行う予定である.

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骨転移診療ガイドライン

面 南江堂

●編集 日本臨床腫瘍学会

■A4判・90頁 2015.3. ISBN978-4-524-26534-3 定価(本体 2,500 円+税) 日本臨床腫瘍学会編集による、がんの骨転移における診療ガイドライン. 腫瘍内科、整形外科、泌尿器科、放射線科、リハビリテーション科など、骨転移診療にあたる各科の医師・医療スタッフにより 26 の Clinical Question について解説、総説では、骨転移の病態・診断・治療とケアの要点を整理.

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