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Quality of life, functional ability and physical activity in children and adolescents after lower extremity bone tumour surgery

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Chapter 7

CROSS CULTURAL VALIDATION OF THE ENGLISH VERSION OF
THE DUX QUESTIONNAIRE FOR LOWER EXTREMITY BONE TUMOUR
PATIENTS (BT-DUX): A DISEASE SPECIFIC MEASURE OF HEALTH
RELATED QUALITY OF LIFE

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Submitted

ABSTRACT

Background: The Dutch Bt-DUX questionnaire a disease specific quality of life instrument after surgery for lower extremity malignant bone tumours comprises four domains. Aim of the presented study was to culturally adapt and translate the Bt-DUX into the English (UK) language.

Procedure: The adaptation and translation process included forward translation, back-translation and a review of the back-translation by an expert committee. The internal consistency and validity of the translated questionnaire were examined in a sample of adolescents and young adults treated for lower extremity osteosarcoma in the United Kingdom. Assessments included, apart from the Bt-DUX, the Toronto Extremity Salvage Score (TESS), the Short Form (SF)-36 and the TNO-AZL Questionnaire for Adult's Quality of Life (TAAQOL).

Results: Seventeen patients (7 ♂, 10 ♀), median age 19.9 (range 16-25) years completed the questionnaires. The mean Bt-DUX score was 38.8 (range 23-78), with Cronbach's alpha being 0.95 Domain-total correlations ranged between 0.84 and 0.93 ($p < 0.01$). Correlations between Bt-DUX total score, the TESS, and the comparative TAAQOL and SF-36 scores were, with a few exceptions, statistically significant ($p < 0.05$).

Conclusion: Preliminary evidence suggests that the English Bt-DUX translation is a valid disease specific instrument for evaluating QoL of adolescents and young adults with lower extremity bone cancer.

INTRODUCTION

Malignant bone tumours like osteosarcoma and Ewing sarcoma appear most frequently in the long bones of the lower extremity. The highest incidence of these tumours is seen in the teenage years. The survival rates for children and adolescents with lower-extremity bone malignancies have improved significantly over the past decades. As result of the improved life expectancy, there has been a growing interest in functional outcome and Quality of Life (QoL) after surgery [1-2]. Most of the studies on the outcome of surgery have so far been mainly focused on basic daily activities or have used generic instruments for QoL. With the usage of these instruments a number of relevant issues, such as the patient's valuation of the cosmetic, functional and emotional impact of the disease and its surgical treatment, are not specifically taken into account.

These latter dimensions are included in a recently developed questionnaire DUX for lower extremity bone tumours in children and adolescents (Bt-DUX) [3]. The Bt-DUX questionnaire was constructed as a disease specific questionnaire, modelled upon the generic DUX 25 QoL questionnaire (short version of the Dutch Children TNO-AZL Quality of Life Questionnaire / DUCATQOL) [4]. The DUX 25 has been used in studies among children with celiac disease, juvenile chronic arthritis, langerhans cell histiocytosis, and siblings of paediatric cancer patients [5-9] and proved to be internally consistent and reproducible.

The scores on the Bt-DUX reflect patients' individual values for cosmetic, social, emotional and functional aspects of their life after the surgery. The Dutch version of the Bt-DUX was found to be a practically applicable instrument with a good internal consistency and validity and appeared to have added value regarding existing measures of QoL in patients undergoing surgery for malignant bone tumours of the lower extremity³.

To expand/facilitate the usage of the Bt-DUX, the aim of the present study was to perform a cross-cultural translation and adaptation of the original Dutch Bt-Dux into English (UK) and a preliminary validation among patients undergoing surgery for malignant bone tumours of the lower extremity in the United Kingdom.

MATERIALS AND METHODS

Study design

Translation of the Bt-DUX into British-English took place at the departments of Paediatrics and Medical Psychology of the Leiden University Medical Center in the Netherlands between January and March 2010. Preliminary validation of the English version of the Bt-DUX took place among patients of the Royal Orthopaedic Hospital, Birmingham, United Kingdom between September 2010 and January 2011. This study was approved by the Research Ethics Committee of the Royal Orthopaedic Hospital, and written informed consent was obtained from the participants and/or their parents,

Translation, adaptation and validation

The methodology used was based on published guidelines for the process of cross-cultural adaptation of self-report measures [10,11]. The process of cross-cultural adaptation aims to produce equivalency of content between the source language (in this project Dutch) and the target language (English). The term “cross-cultural adaptation” encompasses a process that looks both at language and cultural adaptation issues in preparing the new version of the scale. The adaptation has several stages, which are reported in sequential order.

Stage I: Initial translation

The first stage in adaptation is the forward translation. At least two forward translations of the Bt-DUX (including instructions to users) were made from the original Dutch Bt-DUX. The two independent translations were produced by bilingual translators who had English as their mother tongue. The two translators had different backgrounds, to ensure the best possible translation. One translator was a physical therapist, knowledgeable about the type of concepts bone tumour patients and was therefore considered to be an “informed” translator. The other translator was a basic researcher, not aware of the concepts addressed, and was therefore considered to be a “naïve” translator.

The two translators each produced a written report of their translation. Comments were included to highlight challenging phrases or uncertainties along with the rationale for final choices. The questionnaire items and instructions were both translated independently without any discussion between translators initially.

Stage II: Synthesis of these translations

The two translations were compared and any discrepancies resolved in a discussion between the translators and the principal investigator (PB). Working from the original questionnaire as well as the two translated versions, a synthesis of these translations was produced, resulting in one common translation.

Stage III: Back-translation

Working from the common translated version of the questionnaire, and blinded to the original version, the questionnaire was then translated back into the original language by two bilingual persons with Dutch as their mother tongue. The two back-translators were neither aware nor informed of the concepts explored, and had no medical background.

Stage IV: Expert committee

An expert committee comprising a methodologist, two translators and the principal investigator reviewed all the versions and components of the questionnaire and, following discussion, reached consensus on the final wording and formatting to be used for the English language version of the Bt-DUX.

Stage V: Test of the adapted version

The preliminary validation of the adapted and translated Dux-Bt was performed among 17 patients from the UK. This part of the study had a cross-sectional design, requiring patient completion of the translated version of the Bt-DUX and the three other questionnaires on only one occasion.

Patient recruitment

Patients were identified from the database of the Royal Orthopaedic Hospital Oncology Service, Birmingham, UK. We selected all patients who underwent a surgical intervention due to a malignant bone tumour in the lower extremity between 2004 and 2009. Surviving patients were eligible if they were aged between 16 and 25 years at the time of the selection, if the malignant bone tumour (Osteosarcoma or Ewing's sarcoma) was located in the leg and the surgical intervention consisted of either limb sparing or ablative surgery. Patients were excluded if they could not complete the questionnaires unaided, if other medical conditions limit their participation in this study and those with mental impairment. The selected patients were invited to participate by their treating physician by sending them a letter, a patient information leaflet, an informed consent form, a set of questionnaires and a prestamped envelope. Six weeks after the questionnaire was sent, nonresponders received a telephone reminder from the local investigator (LB).

Assessments

Bt-DUX [3]. The Bt-DUX consists of 20 questions which cover the domains social, emotional, cosmetic and physical functioning. The answer categories are presented as abstract faces (smiley's) with their expressions ranging from very happy (1) to very sad (5) constituting a five-point Likert scale. Single item scores are recoded and added up resulting in a raw total score and four raw domain scores. The raw scores are then converted into a total score and four domain scores all ranging from 0-100, with the highest scores indicating better QoL.

TNO-AZL Adult's Quality of Life (TAAQOL) questionnaire [12]. For participants of 16 years and older and in the English language validated [13], generic health-related quality of life questionnaire, the TAAQOL was used. Health-related quality of life, as assessed by the TAAQOL, is defined as a person's health status, weighted by their emotional response to their health status problems. The TAAQOL consists of 45 questions divided into twelve scales (most of them four items each): gross motor functioning, fine motor functioning, cognition, sleep, pain, social contacts, daily activities, sex, vitality, happiness, depressive mood, and anger. The TAAQOL questionnaire measures the emotional impact of self-reported functional problems. Internal consistency of the scales was sufficient for research purposes [12].

The *Toronto Extremity Salvage Score (TESS)* [14] is a valid and reliable disease-specific measure developed to evaluate physical disability in patients treated for extremity sarcoma. The self-administered questionnaire includes 30 items on activity limitations in daily life, such as restrictions in body movement, mobility, self-care and performance of daily tasks and routine. The degree of physical disability is rated from 0 (not possible) to 5 (without any problem). The raw score is converted to a score ranged from 0 to 100 points, with higher scores indicating no functional limitations.

The *Short Form-36 (SF-36)* [15] is a validated, self administered measure of Health Related Quality of Life. The SF-36 evaluates eight health concepts; physical functioning, role limitations because of physical and emotional problems, bodily pain, general health, vitality, social functioning and mental health. Each scale score ranges from 0 (worst health state) to 100 (best health state). These eight health concept scales can be converted into two

summary scores; a physical component summary scale (PCS) and a mental component summary scale (MCS), standardized to a score with a mean of 50 and a standard deviation of 10, with scores above and below 50 indicating above and below average functioning, respectively [16].

Analysis

Descriptive statistics were used for the patient's clinical demographic as well as the clinical variables. All variables were examined to ascertain the data distribution and to assess normality. Possible floor or ceiling effects of the Bt-DUX were determined by using the frequency distributions of the Bt-DUX total score and subscale scores. Floor or ceiling effects are considered to be present if >15% of the respondents achieved the lowest or highest possible score, respectively [17]. The clinimetric properties of the English Bt-DUX were evaluated in accordance with the methods employed with the original Dutch Bt-DUX, by computing the internal consistency, and the construct and discriminant validity [17]. Internal consistency of the Bt-DUX was determined by calculating Cronbach's α and by computing the correlation between the four domain scores and the total Bt-DUX score (domain-total correlation). A Cronbach's α value of 0.85 or higher is in general considered as good [18-19]. Depending on a normal or skewed distribution of the data, construct validity of the Bt-DUX was determined by calculating Pearson or Spearman correlation coefficients between the Bt-DUX and the measures of quality of life (previously selected subscales of the TAAQOL and SF-36) and functional ability domain (TESS). Discriminate validity was evaluated by determining the ability of the Bt-DUX to discriminate between patients with worse and better functional status, as defined according to the median value of the TESS.

RESULTS

The translation process

Due to the short and simple sentences in the original Bt-DUX, the forward translators did encounter few difficulties in relation to the terms used. For the vast majority of the items the process was easy. An example where literal translation was difficult was the Dutch word "conditie". An appropriate English translation was found in the words "fitness level".

In addition, few discrepancies were noted between the two back translations and the original version of the instrument, indicating that the synthesis of the 2 forward translations was substantially accurate. The final panel discussion involving participants from different medical and language backgrounds gave an opportunity to refine the final language versions of the scales, in some cases favouring versions that were felt to be closer to what English patients might say in their language over an exact word-for-word translation from the English to the target language.

The preliminary validation

Patient characteristics.

Seventy-one patients who underwent surgery for a malignancy of the lower extremity were identified from the registries of the Royal Orthopaedic Hospital and fulfilled the inclusion criteria. Of these patients, seven patients had died before the evaluation, the health status of seven patients did not allow participation; three lived abroad or were lost to follow-up and thirty-seven patients did not respond to the invitation to participate in the study before the end of the research period.

Finally, the study sample consisted of seventeen patients (see Table I). Their median age was 19.9 years (range 16-25) and median time since surgery 3.4 years (range 1.6-5.9). Limb-salvage surgery was performed in 15 (88%) of the patients, amputation in 2 (12%).

Table II shows the results of the Bt-DUX and the other measures of quality of life and functional ability. Figure 1 shows the median scores and the distribution of Bt-DUX total and domain scores. None of the patients reached the maximum total Bt-DUX total score. The numbers (proportions) of patients with a maximum score for the subscales were 1 for the emotional and 1 for the cosmetic domain score, respectively. None of the patients reached the minimum score for the Bt-DUX total or domain scores. According to these results, the Bt-Dux had no floor or ceiling effects.

Table I. Clinical and demographic characteristics of 17 patients who underwent surgery for a malignant bone tumour of the lower extremity.

	No. (%)	Mean (SD)	Median (Range)
Gender			
Female	7 (41%)		
Male	10 (59%)		
Age (years)			
At evaluation		20.0 (2.4)	19.9 (16.3-24.7)
At surgery		16.2 (2.7)	15.6 (11.5-20.3)
Follow-up		3.7 (1.4)	3.4 (1.7-6.0)
Type of surgery			
Endoprosthesis	13 (77%)		
Autograft	2 (12%)		
Amputation	2 (12%)		
Morphology			
Osteosarcoma	15 (88%)		
Ewing's sarcoma	2 (12%)		
Tumour location			
Femur	11 (65%)		
Tibia / Fibula	6 (35%)		

Table II. Measures of quality of life and functional ability in 17 patients after malignant bone tumour surgery of the leg.

		Mean (SD)	Median (Range)
Bt-DUX	Total	57.7 (20.2)	64.4 (23-89)
	Social	68.2 (21.1)	75.0 (20-95)
	Emotional	66.2 (20.8)	75.0 (30-100)
	Cosmetics	56.3 (23.9)	57.5 (20-100)
	Physical	38.4 (21.1)	42.5 (10-85)
TAAQOL	Gross motor	56.1 (23.7)	56.3 (19-94)
	Cognitive	63.6 (29.1)	62.5 (6-100)
	Social functioning	89.2 (18.1)	100 (38-100)
	Daily activities	64.2 (28.8)	62.5 (0-100)
	Vitality	36.3 (16.9)	41.7 (0-75)
SF-36	PCS	20.4 (22.2)	11.7 (0-64)
	MCS	45.7 (17.9)	48.2 (0-64)
TESS		76.7 (16.9)	77.5 (28-95)

SF-36: Short Form 36; **PCS:** Physical component summary score; **MCS:** Mental component summary score

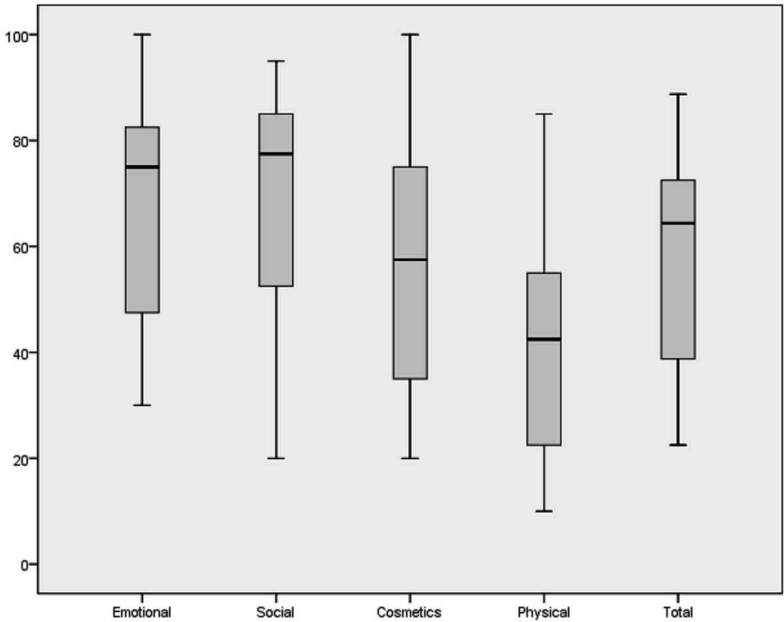


Figure 1. Median scores and distribution of the Bt-DUX total and domain scores.

The median score of 77.5 (range 28-95) for the TESS, indicates moderate functional limitations. The median scores of the SF-36 were 11.7 (range 0-64) for the Physical Component Summary Scale and 48.2 (range 0-64) for the Mental Component Summary scale. The median TAAQOL domain scores varied between 41.7 and 100.

Internal consistency

The internal consistency of total and domain scores of the Bt-DUX appeared to be good. Cronbach's α was 0.95 for the total Bt-DUX, 0.79 for the emotional, 0.89 for the cosmetics, 0.82 for the social and 0.85 for the physical function domain scores. The domain-total correlations were good, with Spearman correlation coefficients varying between 0.84 and 0.93 ($p < 0.01$). The inter-domain correlation was moderate to good, with Spearman correlation coefficients varying between 0.64 and 0.87 ($p < 0.01$).

Construct validity

Table III shows the relationship between Bt-DUX total and domain scores with TESS scores and corresponding TAAQOL and SF-36 scores. Spearman correlation coefficients between the Bt-DUX total score and the selected TAAQOL domains were moderate and with exception of the correlation between the vitality (TAAQOL) and emotional (Bt-DUX) scales, statistically significant. The Spearman correlation coefficients ranged from 0.59 to

Table III. Spearman correlation coefficients between the domain and total Bt-DUX scores and measures of quality of life and functional ability 17 patients after malignant bone tumour surgery of the leg.

	Bt-DUX				
	Total	Social	Emotional	Cosmetics	Physical
TAAQOL					
Gross motor	.70**	.52*	.57*	.58*	.81**
Social	.63**	.59*	.60*	.42	.54*
Daily activities	.35	.36	.31	.17	.60*
Vitality	.40	.38	.35	.50*	.40
Positive emotions	.79**	.73**	.65**	.77**	.58*
SF-36					
Physical functioning	.40	.21	.38	.19	.51*
Social functioning	.64**	.49*	.57*	.59*	.50
Vitality	.48	.45	.39	.42	.48
General health	.59*	.46	.63**	.57*	.49
PCS	.50*	.34	.40	.27	.70**
MCS	.42	.59*	.40	.47	.13
TESS	.49	.39	.42	.33	.70**

*. Correlation is significant at the 0.05 level; **. Correlation is significant at the 0.01 level; PCS: Physical component summary score; MCS: Mental component summary score.

0.81 ($p < 0.05$). Especially the gross motor and positive emotional domain correlated strongly with the Bt-DUX. Except for the vitality (TAAQOL) and emotional (Bt-DUX) scales, the associations between the Bt-DUX and the matching health concept scales of the SF-36 were moderately strong and significant with Spearman correlation coefficients ranging from 0.49 to 0.70 ($p < 0.05$).

The Bt-DUX physical domain scores was moderately strongly associated with functional limitations as measured with the TESS ($r = 0.70$; $p < 0.01$).

Discriminant validity

Table IV illustrates the discriminating properties of the Bt-DUX total score and the four domain scores regarding two categories of the TESS (division made according to the median TESS score). It was found that the Bt-DUX and all of its domain scores were higher in the patients with better TESS scores, these differences were statistically significant ($p < 0.05$) for the total, emotional and physical domain scores of the Bt-DUX, but not for the social and cosmetics domains.

DISCUSSION

This English translation of the Bt-DUX, a 20-item, disease-specific and self-administered questionnaire for assessing quality of life after bone cancer surgery of the leg, demonstrate good internal consistency, construct and discriminant validity, with the results being comparable to the results of the original Dutch language version [3].

The process of translating and back-translating the Dutch Bt-DUX was carried out based on published guidelines for the process of cross-cultural adaptation of self-report measures [10,11]. This is an easy and well-described way to perform a cross-cultural adaptation. If the steps are carefully followed, the cross-cultural adaptation is consistent in the content

Table IV Bt-DUX total and domain scores in groups of patients with worse and better functional (TESS) status.

	TESS scores				
	Worse functional status (TESS ≤ 77.5) N= 9		Better functional status (TESS > 77.5) N= 8		p-value
	Mean (SD)	Median (Range)	Mean (SD)	Median (Range)	
Total Bt-DUX	45.9 (20.4)	38.8 (23-78)	69.4 (12.1)	67.5 (48-89)	0.03 *
Social	59.4 (24.0)	60.0 (20-90)	78.1 (12.3)	80.0 (55-95)	0.11 ns
Emotional	55.6 (20.8)	50.0 (30-90)	78.1 (13.6)	75.0 (55-100)	0.04 *
Cosmetics	45.0 (23.8)	35.0 (20-85)	67.5 (19.3)	67.5 (40-100)	0.07 ns
Physical	23.1 (15.1)	22.5 (10-55)	53.8 (13.8)	52.5 (40-80)	0.003 **

* $p < 0.05$, ** $p < 0.01$; differences between worse and better functional status (Mann-Whitney test); Worse and better functional status corresponds with less than or greater than the median value (77.5) of the TESS.

and face validity between the source and target versions of the questionnaire. Therefore, it should follow that if the original version was reliable and valid, the translation should be as well.

The mean scores of the TESS, TAAQOL and SF-36 as found in the present study are comparable to those found in other studies, suggesting that our population is representative for adolescent and young adult patients' shortly after surgery due to a malignant bone tumour in the leg.

In this study, the discriminating properties of the Bt-DUX were studied by comparing Bt-DUX scores between two groups of patients with different levels of physical function as classified by the TESS score. The discriminating properties of the Bt-DUX with respect to different surgical interventions, age or gender still has to be determined.

A limitation of this study is the small number of patients included. However, there is a strong similarity between the results of internal reliability, construct and discriminant validity in both studies, supporting the conclusions concerning the validity of the English version of the Bt-DUX.

Moreover, the adaptation into the English language followed a standard protocol used for many scales [12] yet it could be argued that validity of the adapted version could have been further enhanced by undertaking additional qualitative interviews with patients in the United Kingdom. It is possible that there are country-specific nuances to quality of life after bone tumour surgery that could have been identified under such an approach. Another limitation of this study is the inclusion of only patients between 16 and 25 and the recruitment of patients from only one health care setting. Finally, there was a strong difference with the original Dutch study in the distribution of the surgical interventions, with no rotationplasty or allograft reconstructions presenting the present study population. Therefore, the generalizability of the results of this study is limited.

In summary, the results of this preliminary validation of the English version of the disease specific Bt-DUX is encouraging. However, its validity among larger populations English patients and different age groups, its ability to discriminate between different gender and surgical intervention groups, and its sensitivity to changes in a larger, prospective study still have to be determined. The Bt-DUX has now been translated from Dutch into the English language, more translations in different languages will be necessary to enhance comparison between study results of different countries.

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APPENDIX

Identificationnummer: <input type="text"/>	Birth date: <input type="text"/>
Study: <input type="text"/>	Date: <input type="text"/>






Bt-DUX











Questionnaire for Children and Adolescents after Bone Tumor Surgery
 © LUMC Physical Therapy / Medical Psychology
 WP Bekkering / HM Koopman











Explanation:

We would like to know how you have been feeling lately.
 For each question, circle the face which best fits how you feel.
 Each question has 5 faces from which you can choose.

This is an example.

<p>If you were very happy or satisfied, then colour in the happy face</p> 
<p>If you were very sad or disappointed, then colour in the sad face</p> 
<p>If you felt as yourself, then colour in the neutral face</p> 
<p>If you were a little bit happy, then colour in the somewhat happy face</p> 
<p>If you were a little bit sad, then colour in the somewhat sad face</p> 

How have you felt lately?	
1	When I think about how my leg looks after the operation, I feel ... 
2	Things with me are ... 
3	When I think about how it looks when I walk, I feel ... 
4	When I think about the possibilities I have to play sports, I am ... 
5	When I think about finding a boyfriend/girlfriend, I feel ... 
6	When I think about how others look at me, I feel ... 
7	When I think about the people at my school / work, I feel ... 
8	When I think about my life now, I feel ... 
9	When I think about making new friends, I feel ... 
10	When I think about my ability to play sports, I feel ... 

How have you felt lately?	
11	When I think about how I look now, I feel ... 
12	When I think about the possibilities that I have at school or at work, I feel ... 
13	When I think about other people, I feel ... 
14	When I think about things that I am able to do now, I am ... 
15	When I think about myself, I feel ... 
16	When I think about my fitness level, I feel ... 
17	When I think about things that I am not able to do, I am ... 
18	When I think about my health, I feel ... 
19	When I think about my friends, I feel ... 
20	When I think about the future, I feel ... 

This is the end of the questionnaire.

Thank you for your assistance!