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Contributo para a validação da versão portuguesa do instrumento de medição Lymphoedema Quality of Life (LYMQOL) Arm

Dossier Complementar

Projeto elaborado com vista à obtenção
do grau de Mestre em Fisioterapia
na Especialidade de Saúde da Mulher

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Índice

1. Introdução

Este dossier denominado "Dossier Complementar" encontra-se associado ao artigo "Contributo para a validação da versão portuguesa do instrumento de medição Lymphoedema Quality of Life (LYMQOL) Arm".

No presente dossier encontram-se todos os documentos complementares à compreensão do artigo, os quais caracterizam o processo de validação da versão portuguesa do referido instrumento.

De referir que o Dossier Complementar encontra-se organizado de acordo com o processo evolutivo da validação, iniciando-se com o artigo do autor que deu origem ao questionário que foi traduzido e adaptado, seguindo-se então o questionário original e respetiva pontuação. De seguida, apresentam-se os dois artigos de validação existentes até à data, do LYMQOL Arm, ambas validações para a população turca. Posteriormente apresenta-se a autorização do autor do estudo original para a realização do estudo de tradução e adaptação cultural para a população portuguesa. Apresenta-se seguidamente a aprovação deste trabalho de projeto pelo Conselho de Mestrado e Conselho Técnico Científico da Escola Superior de Saúde do Alcoitão e ainda o pedido de autorização e aprovações do Instituto Português de Oncologia de Lisboa Francisco Gentil, EPE, (IPOLFG) para a realização do estudo.

O dossier continua com a apresentação da versão portuguesa do LYMQOL Arm, ou seja o LYMQOL Braço, bem como o questionário EORTC QLQ C – 30 (European Organization for Research and Treatment of Cancer Quality Life Questionnaire Core 30), instrumento usado para testar a validade de construção do LYMQOL Braço, apresenta-se, também a autorização para uso do mesmo e a sua pontuação. Por último, surgem o termo explicativo do estudo, o consentimento informado e a ficha de dados sociodemográficos e clínicos, ou seja, os restantes documentos entregues aquando da recolha de dados aos sujeitos da amostra, além dos dois questionários referidos.

2. Artigo original do Lymphoedema Quality of Life LYMQOL

A QUALITY OF LIFE MEASURE FOR LIMB LYMPHOEDEMA (LYMQOL)

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Abstract

Background: This paper describes the validation of a 'condition-specific' quality of life (QoL) assessment tool for lymphoedema of the limbs (LYMQOL). *Aims:* To ascertain whether the tool could accurately assess QoL in this patient group. *Methods:* Face and content validity were assessed by patient questionnaires; criterion validity by comparison with European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Core 30 questions (EORTC QLQ-C30); internal validity by Cronbach's Alpha and split half-testing of each domain; reliability by the test-retest method; construct validity by comparing LYMQOL score with initial limb volume and responsiveness by measuring changes in score following treatment. *Results:* The tool was validated in a total of 209 patients. Face, content, criterion and internal validity were supported. However, there was no correlation between initial limb volume and LYMQOL score (construct validity), a finding which is similar to that from other studies. The validation of responsiveness was limited by the small numbers of responses at three and six months after the initial assessment. *Conclusions:* LYMQOL is a validated condition-specific QoL assessment tool which can be used for lymphoedema of the limbs both in clinical assessment and as an outcome measure. *Declaration of interest:* The authors are not aware of any conflicts of interest.

Key words

QoL assessment tool
Symptom
Body image/appearance
Function
Mood

The impact of lymphoedema on a patient's quality of life (QoL) has generally been underestimated. However, it is now clear that it can cause physical symptoms, impaired physical and social function and emotional effects (Moffatt et al, 2003).

A number of attempts have been made to define QoL (Higginson and Carr, 2001) and it is a very personal issue. However, in healthcare it usually incorporates physical and social health and functioning and psychological and emotional wellbeing (Bowling, 1997).

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This paper describes the validation of a condition-specific QoL measure for lymphoedema of the limbs (LYMQOL) which could be used routinely in clinical services.

QoL measures can be used to assess the impact of chronic oedema on the individual and also to demonstrate changes as a result of treatment (Keeley, 2008). They can be used as practical clinical tools influencing treatment decisions and measuring outcome, as well as in research studies assessing the effectiveness and cost-effectiveness of interventions (Higginson and Carr, 2001).

Health-related quality of life measures that have been used in studies of lymphoedema have been either 'general', e.g. Medical Outcome Study 36-item short form (SF-36) (Ware and Sherbourne, 1992), which assesses functional health status, or 'condition-specific', e.g. European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Core 30 questions (EORTC QLQ-C30) (Aaronson et al, 1993) and QLQ-BR23, a 23-question tool specifically for breast cancer (Sprangers et al, 1996). However, general health-related measures may not be as accurate or informative as condition-specific tools (Morgan et al, 2005).

In the recent literature, a number of lymphoedema/chronic oedema-specific QoL assessment tools have been reported. For some, the validation has been published, e.g. ULL-27 for upper limb lymphoedema (Launois and Alliott, 2000) and FLQA-L for lymphoedema of arms and legs (Augustin et al, 2005). For others, the tools have been used in studies without a formal validation being reported, e.g. Wesley Clinic Lymphoedema Scale (WCLS) or post mastectomy lymphoedema (Mirolo et al, 1995) and an un-named tool for

peripheral lymphoedema (Weiss and Spray, 2002).

This paper describes the validation of a condition-specific QoL measure for lymphoedema of the limbs (LYMQOL) which could be used routinely in clinical services. Interim stages of the validation process have been previously reported (Keeley et al, 2004).

Methods

Development of the tool

LYMQOL was developed by experienced healthcare professionals in the lymphoedema service in Derby, UK in consultation with service users. Separate tools were developed for arm and leg lymphoedema. The tools were designed as patient-completed questionnaires with a structure similar to the EORTC QLQ-C30 (*Appendices 1a and 1b*).

The questions cover four domains:

- Symptoms
- Body image/appearance
- Function
- Mood.

There is an overall QoL rating. The mood questions were taken from the previously validated EORTC QLQ-C30 with permission.

Scoring of LYMQOL

Each item in each domain was scored:

- Not at all = 1
- A little = 2
- Quite a bit = 3
- A lot = 4.

A total score for each domain was calculated by adding all scores together and dividing by the total number of questions answered. If fewer than 50% of the items were answered, the whole domain was scored as 0. The 'overall QoL' item was scored 0–10.

In some of the analyses, the domain scores were calculated as a percentage to facilitate comparison with other measures (see below).

Validation

The study was designed to measure (Fallowfield, 1990):

- Validity, i.e. is the scale measuring what it was designed to do?
- Reliability, i.e. to what extent can the scale be reproduced under different conditions?
- Responsiveness, i.e. is the scale sensitive enough to record significant changes following treatment?

Specific aspects of these elements were measured as follows.

Face validity

The subjective assessment of the presentation of the questionnaire and its relevance was measured using a short questionnaire that was given to patients who took part in the study (*Appendix 2*).

Content validity: does the content address all the important issues

This was assessed from the patient questionnaire and by a separate study (Veigas and Keeley, 2004). The study was a phenomenological interview of 22 patients. The main themes that emerged were loss, both actual and potential, relating to the individual's role, work, body image, self-esteem and embarrassment.

Criterion validity: how does the new measure compare with a 'gold standard' tool?

No such condition-specific tool was available at the time the study was carried out. Therefore, the results were compared with relevant sections of the EORTC QLQ-C30 in the first 50 patients, using the Spearman or Pearson correlation coefficient and intra-class correlation coefficient.

Internal validity

This includes:

- Internal consistency: by Cronbach's Alpha and split half-testing of each domain. The latter tests for homogeneity, i.e. the extent to which the questions relating to a particular domain measure only that and no other. Split half-testing was carried out in two ways, the first comparing first and second half items and the second comparing odd and even numbered items. The Spearman-Brown coefficient was used to test for similarities between the two halves
- Reliability: by the test re-test method in a subgroup of patients. The first measure was carried out at the initial assessment and the second before intensive treatment with bandaging, i.e. repeated in individual patients before any treatment had been given, and therefore it was unlikely that there would have been any significant change in QoL. Results were compared using Pearson's correlation coefficient.

Construct validity: to what extent does the tool test the theory it is measuring?

It was postulated that patients with more severe lymphoedema (i.e. larger limb volumes) would have a 'lower' QoL, i.e. higher scores in LYMQOL domains. Therefore, initial limb volume was compared with LYMQOL scores in each domain, using the paired T test.

Responsiveness: is the tool sensitive to change?

This was assessed by measuring changes in QoL scores following treatment, using the Pearson correlation coefficient.

Inclusion criteria:

- New patients presenting to the lymphoedema clinic in Derby who consented to take part
- Patients over 18 years of age with unilateral or bilateral swelling of upper or lower limbs.

Exclusion criteria:

- Those with active malignancy
- Those undergoing chemotherapy.

Data was collected as follows:

- First visit:
  - demographics, i.e. gender, age,
  - site of lymphoedema, cause of lymphoedema
  - LYMQOL score
  - Patient questionnaire
  - EORTC QLQ-C30 (first 50 patients)
  - Limb volume measurement.
- Follow-up at one week, one month, three months and six

months after treatment either with a compression garment or multilayer lymphoedema bandaging ± manual lymphatic drainage (MLD). This involved:

- LYMQOL score
- Limb volume measurement.

The study was approved by the Southern Derbyshire Local Research Ethics Committee (Reference No: SDLREC 0202/438).

Results

A total of 209 patients took part in the study, of which 78.7% were women. The mean age of participants was 58 years (SD 16.4 years). Bilateral leg swelling was the most frequently reported site of swelling (43.8%). Approximately one quarter of the sample reported unilateral arm swelling (26.8%) or unilateral leg swelling (27.7%). 1.5% of patients reported that a combination of arms and legs was swollen.

Face validity

Face validity was confirmed (*Table 1*). Patients found LYMQOL clear, easy to complete and not too long.

Content validity

There were 90 patient questionnaires returned. Although 92% of respondents felt that no questions could be left out, 20% felt that there were important areas missing. The main themes of these are shown in *Table 2*.

Criterion validity

The LYMQOL results for the domains 'function', 'symptoms', 'mood' and 'overall QoL' showed good correlation with those for comparable domains in the EOTC QLQ-C30 for both arm and leg questionnaires (*Tables 3 and 4*). There was no comparable domain in the EORTC QLQ-C30 for that of 'appearance' in LYMQOL, so no comparison could be made.

Internal validity

Internal consistency — Cronbach's alpha

Cronbach's alpha was >0.8 for all domains in both the arm and leg versions of LYMQOL, thus confirming internal consistency (*Tables 5* and *6*).

Table 1

Face validity. Response to questionnaires (n=90)

	Yes (%)	No (%) months
Was it easy to complete?	93	7
Was it too long?	1	99
Were the questions clear?	99	1

Deleting any of the items did not appear to increase the value of alpha by a large amount, i.e. did not improve internal consistency and therefore supported the reliability.

The small number in the 'symptom' domains included in the analysis reflects the relatively large number of incomplete responses in this domain.

Split half-testing of each domain

Reliability was adequate (≥0.8) or good (≥0.9) for each of the domains with the exception of 'symptoms' for LYMQOL (arm) when first and second halves were compared (*Tables 7* and *8*). This is likely to be because the questions in the first half are all part of Q11 and relate to the site and degree of pain. The second method of testing is therefore more appropriate for this domain. Reliability was found to be adequate or good for all of the domains tested.

Reliability

Reliability was supported using the test-retest method for 15 patients who had leg oedema (*Table 9*). This number is relatively small and reflects the fact that most patients were treated at the first clinic appointment and the test-retest method could only be used in those who returned for treatment at a later date. Nevertheless, there was good correlation between the mean scores for each domain at visit one and two, i.e. with no intervening treatment in this subgroup.

Construct validity

It was postulated that patients with more severe swelling, i.e. larger limb volume would have a 'lower' quality of life. Therefore, LYMQOL scores were compared with initial limb volume.

Table 2

Examples of comments on what was missed out

- Sensitivity of legs
- Redness and soreness
- Burning/hot feelings
- Effect of other conditions, e.g. previous knee injury
- Impact of cellulitis
- Embarrassment
- Effect of compression garment

There was no significant correlation between any of the domains of LYMQOL and the initial limb volume.

Responsiveness

Scores at the time of presentation were compared with those at one week and one month later to see how the questionnaire responded over time. Too few responses were received at later times after presentation to allow meaningful analysis.

There were no significant differences in scores after one week and one month for LYMQOL (arm) domains.

For LYMQOL (leg), the 'appearance' scores were significantly lower, i.e. improved at one week and one month, whereas the 'function', 'symptoms'

Table 3

Correlation between LYMQOL (arm) and EORTC QLQ-C30 domains

	n	correlation coefficient	p-value	ICC	p-value
Function	15	0.689	0.005	0.686	0.001
Symptoms	15	0.688	0.005	0.643	0.003
Mood	15	0.860	<0.001	0.868	<0.001
QoL	14	0.937	<0.001	0.941	<0.001

ICC=Intraclass correlation coefficient

Table 4

Correlation between LYMQOL (leg) and EORTC QLQ-C30 domains

	n	correlation coefficient	p-value	ICC	p-value
Function	23	0.690	<0.001	0.674	<0.001
Symptoms	25	0.788	<0.001	0.614	<0.001
Mood	26	0.805	<0.001	0.782	<0.001
QoL	24	0.644	0.001	0.632	<0.001

ICC=Intraclass correlation coefficient

Table 5

Cronbach's alpha for the domains of LYMQOL (arm)

	n	alpha
Function	28	0.882
Appearance	42	0.832
Symptoms	14	0.851
Mood	50	0.867

and 'mood' domains showed no difference. The 'overall QoL' scores were significantly higher, i.e. better at one week but no different at one month from presentation (*Table 10*), although the difference at one week was small and not likely to be of clinical significance.

Reducing the number of items

Although the LYMQOL tool is not particularly lengthy (38 items for arm; 40 items for leg), analysis was carried out to see if any items were 'redundant', i.e. were unnecessary and could be removed. This was achieved by examining internal correlations of items within each domain using Spearman's correlation coefficient (rho).

If two items have a high correlation, they may be measuring the same thing and, therefore, one could be removed in the development of a revised version of LYMQOL. From a statistical point of view, a correlation of ≥0.7 was applied as the 'cut off' for a significant value in determining whether a particular item could be considered superfluous.

Items with a poor correlation to the overall domain score may equally not contribute much to the domain as a whole. These could also be removed to shorten the tool without affecting its value.

However, in the application of this methodology, consideration has also to be given to whether the items are particularly relevant clinically. If LYMQOL is to be used as part of clinical assessment and outcome measurement, keeping some potentially 'redundant' items may be appropriate if they are of clinical importance.

Finally, consideration was given to whether some items were frequently 'not answered' by respondents and could therefore be omitted. This was particularly relevant to the 'symptom' domain where the number of complete responses was low (*Tables 5* and *6*).

Using this approach, LYMQOL arm and LYMQOL leg were modified and the new versions contain 28 and 27 items respectively (*Appendix 3a, 3b*). The scoring system is also included in *Appendix 3a and 3b*.

The details of this modification process are included in *Appendix 4*.

Discussion

This paper has demonstrated the face validity, content validity, criterion validity and internal validity of LYMQOL.

The aim was to produce a condition-specific QoL tool for lymphoedema which could be used in routine clinical practice for assessment and as an outcome measure, as well as in research.

Table 6

Cronbach's alpha for the domains of LYMQOL (leg)

	n	alpha
Function	45	0.945
Appearance	78	0.874
Symptoms	12	0.917
Mood	100	0.875

Table 7

Spearman-Brown coefficients for split half-testing for LYMQOL (arm) domains

	n	1st/2nd half	Odd/even
Function	28	0.923	0.933
Appearance	42	0.853	0.830
Symptoms	14	0.642	0.859
Mood	50	0.801	0.871

Table 8

Spearman-Brown coefficients for split half-testing for LYMQOL (leg) domains

	n	1st/2nd half	Odd/even
Function	45	0.897	0.964
Appearance	78	0.835	0.936
Symptoms	12	0.887	0.964
Mood	100	0.855	0.923

As such, it is important that the tool is easy to use and not too lengthy. Although patients did not feel it was too long, and indeed suggested further items which should be added (*Table 2*), it was also clear that there was a degree of 'fatigue' in repeatedly completing the questionnaire during the course of the study, as the numbers responding decreased over time. Indeed, there were insufficient responses at three and six months to examine statistically.

On reviewing the issues raised in *Table 2*, it was felt that some could perhaps be addressed by existing items, e.g. impact on holidays covered by the item on leisure activities and embarrassment by the 'appearance' domain.

The question of the effect of comorbidity on the scores is more complex. For example, mobility may be affected by other conditions, e.g. arthritis, lung disease and neurological problems, rather than the lymphoedema itself. This needs to be considered when using the tool to assess individual patients, since treating the lymphoedema successfully may not necessarily result in an improvement in mobility (as measured by the 'function' domain) in these situations.

Taking the above into account, it was felt important to try to reduce the size of LYMQOL to make it more acceptable to users. This process was supported by the statistical analysis, which had demonstrated that some items were potentially redundant. The revised versions of LYMQOL should also address the problem of incomplete responses to the symptom domain (*Tables 5, 6, 7* and *8*). It seems that the issue here related to the 'sites of pain', particularly in LYMQOL (arm) as described in *Table 7* and, therefore, the revised version has been amended accordingly (*Appendices 3a, 3b* and *4*).

The decline in 'response rate' at three and six months may reflect patient 'fatigue', however it is also possible that not all patients received questionnaires to complete at these times if the research nurse was not present at the follow-up appointment. Regardless of this, a less frequent use, e.g. six-monthly or annually may be appropriate when LYMQOL is employed in routine clinical practice to fit in with follow-up assessment appointments.

Construct validity was not fully confirmed in that there seemed to be no significant correlation between initial limb volume and quality of life. Interestingly, other studies have reported a lack of relationship between improved QoL and a reduction in limb volume after treatment (e.g. Sitzia and Sobrido, 1997; Weiss and Spray, 2002). Thus, the initial construct that limb volume and quality of life are inversely related may be erroneous. Nevertheless, this could suggest that QoL measures may add a different dimension to patient assessment beyond the routine measurement of limb volume currently carried out by most lymphoedema services. Hence,

Table 9

Correlation of domain scores in LYMQOL (leg) at visits one and two without intervening treatment (n=15)

Domain	Correlation	p-value
Functional	0.543	0.036
Appearance	0.909	<0.001
Symptoms	0.861	<0.001
Mood	0.826	<0.001
Overall QoL	0.542	0.037

Table 10

Comparison of domain scores at presentation, 1 week and 1 month for LYMQOL (leg)

Domain	n	Mean (%)	SD	T-test	p-value
a) Appearance					
Presentation	76	45.2	26.1	3.109	0.003
One week	76	38.8	26.9		
Presentation	54	41.2	28.5	2.482	0.016
One month	54	34.0	27.9		
b) Overall QoL					
Presentation	74	63.1	20.3	-2.176	0.003
One week	74	66.9	18.3		
Presentation	49	63.1	17.6	-0.230	0.819
One month	49	63.7	20.9		

this strengthens the case for using a condition-specific QoL assessment tool as a clinical outcome measure.

Unfortunately, the data available in this study have not conclusively demonstrated the responsiveness of LYMQOL over time, although the 'appearance' scores of LYMQOL (leg) were significantly improved at one week and one month. This is largely due to the fact that few patients completed questionnaires at three and six months. More data is to be collected on this using the revised LYMQOL, but asking patients to complete questionnaires less frequently (six-monthly), with the aim of improving the response rate.

LYMQOL seems to be a potentially useful tool in assessing and monitoring patients with chronic limb oedema. One limitation in its use, however, is that it does not specifically address 'midline' oedema, e.g. trunk, genital and head and neck oedema.

A number of other condition-specific QoL tools for lymphoedema have been developed and reported. Only two other groups have published the validation of the tools — ULL-27 for upper limb lymphoedema (Launois and Alliott, 2000) and FLQA-L for lymphoedema of the arms and legs (Augustin et al, 2005).

The former is a 27-item tool specifically designed for upper limb lymphoedema. The latter is a 92-item questionnaire derived from a previously validated tool (FLQA vein questionnaire). LYMQOL represents an alternative to these, being a relatively short tool, covering both arm and leg oedema.

LYMQOL has not been designed for use in children, therefore it is not recommended for this age group. In addition, as described above, it does specifically address 'mid-line' lymphoedema. This is going to be the subject of future work

Key points

- The validation of LYMQOL, a quality of life assessment tool for limb lymphoedema is described.
- LYMQOL covers four domains: symptoms, body image/ appearance, function and mood, as well as an overall QoL score.
- As a result of the validation process, a revised version of LYMQOL has been produced and is available for use in the assessment of patients with lymphoedema and their response to treatment.data and monitoring of changes over time.

Conclusions

LYMQOL is a validated QoL assessment tool for use with people with limb lymphoedema. Further work is underway to confirm its responsiveness over time. Readers who are interested in using LYMQOL are invited to contact vaughan.keeley@derbyhospitals.nhs.uk for further information and to share experiences of its use. JL

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Appendix 2

Lymphoedema quality of life questionnaire responses

(1) Was it easy to complete?

If no, please say why:

.....

.....

(2) Was it too long?

(3) Were all the questions clear?

If no please record the relevant question numbers, and state why:

.....

.....

(4) Were there any important areas where your swollen limb(s) affects the quality of your life that were not covered?

If yes please comment:

.....

.....

(5) Were there any questions which you feel we could have left out?

If yes please give examples:

.....

.....

(6) Any other comments?

.....

.....

Appendix 1a

Lymphoedema Quality of Life Study (LYMQOL) ARM

If any of the items are not applicable to you, please write N/A in the relevant answer box(es).

(1) How much does your swollen arm affect the following daily activities?

	Not at all	A little	Quite a bit	A lot
a) occupation				
b) housework				
c) combing hair				
d) dressing				
e) doing up/undoing buttons				
f) writing				
g) eating				
h) washing				
i) cleaning teeth				
j) putting on make-up/shaving				

(2) How much does it affect your leisure activities/social life?				

Please give example(s) of this.

.....

.....

(3) How much do you have to depend on other people?				
(4) How much do you feel the swelling affects your appearance?				
(5) How much difficulty do you have finding clothes to fit?				
(6) How much difficulty do you have finding clothes you would like to wear?				
(7) Have you had difficulty wearing jewellery, e.g. wedding ring?				
(8) Does the swelling affect how you feel about yourself?				
(9) Does it affect your relationship with your partner?				
(10) Does it affect your relationships with other people?				
(11) Does your lymphoedema cause you pain?				
If so, do you have pain in the arm				
shoulder				
back				
neck				
elsewhere — if so, where?				
(12) Do you have any numbness in your swollen arm?				
(13) Do you have any feelings of 'pins and needles' or tingling in your swollen arm?				
(14) Does your swollen arm feel weak?				
(15) Does your swollen arm feel heavy?				
(16) Does your hand feel 'cold'?				
(17) Do you feel tired?				
In the past week				
(18) Have you had trouble sleeping?				
(19) Have you had difficulty concentrating on things, e.g. reading?				
(20) Have you felt tense?				
(21) Have you felt worried?				
(22) Have you felt irritable?				
(23) Have you felt depressed?				

(24) Overall, how would you rate your quality of life at present? Please mark your score on the following scale:

Poor	0	1	2	3	4	5	6	7	8	9	10	Excellent

Thank you for completing this form.

If you have any comments or queries about it, please discuss these with.....

Dr V L Keeley, Consultant

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Appendix 1b

Lymphoedema Quality of Life Study (LYMQOL) LEG

If any of the items are not applicable to you, please write N/A in the relevant answer box(es).

(1) Has your swollen leg(s) affected:				
	Not at all	A little	Quite a bit	A lot
a) your walking				
b) your ability to go up and down stairs				
c) your ability to bend, e.g. to tie shoelaces or cut toenails				
d) your ability to kneel				
e) your ability to stand				
f) your ability to get into/out of a car				
g) Your ability to get on/of public transport, e.g. trains/buses				
h) your ability to get up from a chair				
i) your ability to drive a car				
j) your occupation				
k) your ability to do housework				
(2) Does the swelling affect your leisure activities/social life?				

Please give example(s) of this.

.....

.....

(3) How much do you have to depend on other people?				
(4) How much do you feel the swelling affects your appearance?				
(5) How much difficulty do you have finding clothes to fit?				
(6) How much difficulty do you have finding clothes you would like to wear?				
(7) Do you have difficulty finding shoes to fit?				
(8) Do you have difficulty finding socks/tights/stockings to fit?				
(9) Does the swelling affect how you feel about yourself?				
(10) Does it affect your relationship with your partner?				
(11) Does it affect your relationships with other people?				
(12) Does your lymphoedema cause you pain?				
If so, do you have pain in the foot/feet				
leg/legs				
hip(s)				
back				
elsewhere — if so, where?				
(13) Do you have any numbness in your swollen leg(s)?				
(14) Do you have any feelings of 'pins and needles' or tingling in your swollen leg(s)				
(15) Does (do) your swollen leg(s) feel weak?				
(16) Does (do) your swollen leg(s) feel heavy?				
(17) Does (do) your swollen foot (feet) feel 'old'?				
(18) Have you had any leakage of fluid from your leg(s)				
In the past week				
(19) Have you had trouble sleeping?				
(20) Have you had difficulty concentrating on things, e.g. reading?				
(21) Have you felt tense?				
(22) Have you felt worried?				
(23) Have you felt irritable?				
(24) Have you felt depressed?				

(25) Overall, how would you rate your quality of life at present? Please mark your score on the following scale:

Poor	0	1	2	3	4	5	6	7	8	9	10	Excellent

Thank you for completing this form.

If you have any comments or queries about it, please discuss these with..... Dr V L Keeley, Consultant

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Appendix 3a

LYMQOL ARM-Scoring System
Lymphoedema Quality of Life Tool

The score for the individual responses are given below. If the item is not scored and left blank or not applicable this is scored with a 0. Domain totals are calculated by adding the individual scores and dividing the total by the number of questions answered. (If >50% of questions per domain are not answered this cannot be calculated and =0).
The four domains and their corresponding questions are: Function 1 (a–h), 2, 3;
Appearance 4, 5, 6, 7, 8; Symptoms 9, 10, 11, 12, 13, 14; and Mood 15, 16, 17, 18, 19, 20.
Overall quality of life (Q21) is scored as the value marked by the patient, between 0–10.

(1) How much does your swollen arm affect the following daily activities?

	Not at all	A little	Quite a bit	A lot
a) occupation	1	2	3	4
b) housework	1	2	3	4
c) combing hair	1	2	3	4
d) dressing	1	2	3	4
e) writing	1	2	3	4
f) eating	1	2	3	4
g) washing	1	2	3	4
h) cleaning teeth	1	2	3	4

(2) How much does it affect your leisure activities/social life?	1	2	3	4

Please give example(s) of this.

.....

.....

(3) How much do you have to depend on other people?	1	2	3	4
(4) How much do you feel the swelling affects your appearance?	1	2	3	4
(5) How much difficulty do you have finding clothes to fit?	1	2	3	4
(6) How much difficulty do you have finding clothes you would like to wear?	1	2	3	4
(7) Does the swelling affect how you feel about yourself?	1	2	3	4
(8) Does it affect your relationships with other people?	1	2	3	4
(9) Does your lymphoedema cause you pain?	1	2	3	4
(10) Do you have any numbness in your swollen arm?	1	2	3	4
(11) Do you have any feelings of 'pins and needles' or tingling in your swollen arm?	1	2	3	4
(12) Does your swollen arm feel weak?	1	2	3	4
(13) Does your swollen arm feel heavy?	1	2	3	4
(14) Do you feel tired?	1	2	3	4
In the past week	1	2	3	4
(15) Have you had trouble sleeping?	1	2	3	4
(16) Have you had difficulty concentrating on things, e.g. reading?	1	2	3	4
(17) Have you felt tense?	1	2	3	4
(18) Have you felt worried?	1	2	3	4
(19) Have you felt irritable?	1	2	3	4
(20) Have you felt depressed?	1	2	3	4
(21) (24) Overall, how would you rate your quality of life at present? Please mark your score on the following scale:	1	2	3	4

Poor	0	1	2	3	4	5	6	7	8	9	10	Excellent

Thank you for completing this form.

If you have any comments or queries about it, please discuss these with.....

Dr V L Keeley, Consultant

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Appendix 3b

LYMQOL LEG-Scoring System
Lymphoedema Quality of Life Tool

The score for the individual responses are given below. If the item is not scored and left blank or not applicable this is scored with a 0. Domain totals are calculated by adding the individual scores and dividing the total by the number of questions answered. (If >50% of questions per domain are not answered this cannot be calculated and =0).
The four domains and their corresponding questions are: Function 1 (a–f), 2, 3
Appearance 4, 5, 6, 7, 8, 9, 10; Symptoms 11, 12, 13, 14, 15 and Mood 16, 17, 18, 19, 20, 21.
Overall quality of life (Q22) is scored as the value marked by the patient, between 0–10.

(1) How much does your swollen leg affect the following daily activities?

If any items are not applicable, please write N/A in the relevant box(es)	Not at all	A little	Quite a bit	A lot
a) your walking	1	2	3	4
b) your ability to bend, e.g. to tie shoelaces or cut toenails	1	2	3	4
c) your ability to stand	1	2	3	4
d) your ability to get up from a chair	1	2	3	4
e) your occupation	1	2	3	4
f) your ability to do housework	1	2	3	4

(2) Does the swelling affect your leisure activities?	1	2	3	4

Please give example(s) of this.

.....

.....

(3) How much do you have to depend on other people?	1	2	3	4
(4) How much do you feel the swelling affects your appearance?	1	2	3	4
(5) How much difficulty do you have finding clothes to fit?	1	2	3	4
(6) How much difficulty do you have finding clothes you would like to wear?	1	2	3	4
(7) Do you have difficulty finding shoes to fit?				
(8) Do you have difficulty finding socks/tights/stockings to fit				
(9) Does the swelling affect how you feel about yourself?	1	2	3	4
(10) Does it affect your relationships with other people?	1	2	3	4
(11) Does your lymphoedema cause you pain?	1	2	3	4
(12) Do you have any numbness in your swollen arm?	1	2	3	4
(13) Do you have any feelings of 'pins and needles' or tingling in your swollen arm?	1	2	3	4
(14) Does (do) your swollen leg(s) feel weak?	1	2	3	4
(15) Does (do) your swollen arm(s) feel heavy?	1	2	3	4
In the past week	1	2	3	4
(16) Have you had trouble sleeping?	1	2	3	4
(17) Have you had difficulty concentrating on things, e.g. reading?	1	2	3	4
(18) Have you felt tense?	1	2	3	4
(19) Have you felt worried?	1	2	3	4
(20) Have you felt irritable?	1	2	3	4
(21) Have you felt depressed?	1	2	3	4
(22) (24) Overall, how would you rate your quality of life at present? Please mark your score on the following scale:	1	2	3	4

Poor	0	1	2	3	4	5	6	7	8	9	10	Excellent

Thank you for completing this form.

If you have any comments or queries about it, please discuss these with.....

Dr V L Keeley, Consultant

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Appendix 4

LYMQOL Modifications after further analysis

LYMQOL arm:

Arm function: questions 1(a–j)–3

- Question 1e: doing up/undoing buttons demonstrated high correlations to dressing, eating and putting on make up and shaving, all were >0.7. This question was therefore removed as it was felt that this action was covered by these questions.
- Question 1j: Putting on make up/shaving was also highly correlated with writing, eating and washing, all >0.68. This question was also removed.
- Questions 1a and i: Occupation and cleaning teeth were poorly correlated to the other questions and the domain as a whole. Despite this it was decided that these questions should be kept. Despite a maximum of 37 participants answering Q1a it was felt to have clinical significance if recognised as a problem by the patient. Q1i was not omitted as it was felt that this activity required a level of dexterity and actions not covered by the other questions.

Arm appearance: questions 4–10

- On the whole the individual questions in this section were poorly correlated with each other; however, they were correlated to the domain as a whole. There were two questions that were not correlated to the domain 7 and 9: difficulty wearing jewellery and whether the swelling affects the relationship with their partner. Both of these questions were removed.

Arm symptoms: questions 11–17

- Question 11 asks whether the lymphoedema causes pain and the five subsequent questions detailed specific areas. It was felt that the presence of pain was the significant question and knowing the specific area did not add to this, as further questions regarding the presence of pain would be covered in a clinical assessment. These five questions have been removed from the modified version of LYMQOL.
- Question 16 asked whether the hand felt cold and this was poorly correlated with the other questions and also the domain as a whole. This question was therefore removed.

Arm mood: questions 18–23

- These questions were taken from the EORTC questionnaire and therefore have been previously validated. However, they have been taken from different domains in the EORTC. They are all correlated to the domain and therefore all remain in the modified version.

LYMQOL leg:

Leg function: questions 1(a–k)–3

- The majority of the questions correlated well with each other and the domain as a whole. There was one aspect, however, that did not demonstrate any significant correlations with any other aspect or to the domain. This was the ability to drive a car (1i). This has subsequently been removed in the modified version.
- Question 1j: The effect of the swelling on the patient's occupation did not demonstrate a high correlation with the other functional aspects but was correlated with the domain. Similarly to the arm LYMQOL, this was perceived as having clinical significance and was retained.
- As a result of the high correlations each question was reviewed and questions 1b (the ability to go up and down stairs), d (the ability to stand), f (the ability to get into/out of a car), g (the ability to get on/get off public transport) have been removed, as it was felt that these aspects were covered by the remaining questions.

Leg appearance: questions 4–11

- Similarly to the arm questionnaire, question 10, 'relationship with your partner' was poorly correlated and it was felt that this could be answered by the following question, relationship with others. Therefore this has been removed.

Leg symptoms: questions 12–18

- Once more the relationships demonstrated in the analysis of the arm questionnaire were mirrored in the leg questionnaire. The sub-questions relating to the areas of pain (12 a–e) and also the feeling of coldness (17) have been removed.
- Question 18, leakage of fluid was not correlated with any of other questions and did not add to the domain as a whole, therefore it been removed. This symptom can be addressed in the clinical assessment.

Leg mood: questions 19–24

- These questions were taken from the EORTC questionnaire and therefore have been previously validated. However, they have been taken from different domains in the EORTC. They are all correlated to the domain and some with each other (21, 22, 23 and 24 are all significantly correlated with each other) and therefore all remain in the modified version.

3. Versão original do LYMQOL Arm

LYMQOL ARM
Lymphoedema Quality of Life Tool

This questionnaire has been designed and validated for patients with chronic oedema/ lymphoedema of one or both arms to measure quality of life.
Please tick the box that best describes how you feel about each of the questions.

Name: é é é é é é é é é é é é é é é é é .. **Hospital Number:**é é é é é é é é

Date: é é é é é é é é é

(Q1)How much does your swollen arm affect the following daily activities?
If any of the items are not applicable to you, please write N/A in the relevant answer box(es).

	Not at all	A little	Quite a bit	A lot
a) occupation				
b) housework				
c) combing hair				
d) dressing				
e) writing				
f) eating				
g) washing				
h) cleaning teeth				

(Q2) How much does it affect your leisure activities/ social life?				

Please give examples of this .....

.....

(Q3) How much do you have to depend on other people?				

	Not at all	A little	Quite a bit	A lot
(Q4) How much do you feel the swelling affects your appearance?				
(Q5) How much difficulty do you have finding clothes to fit?				
(Q6) How much difficulty do you have finding clothes you would like to wear?				
(Q7) Does the swelling affect how you feel about yourself?				
(Q8) Does it affect your relationships with other people?				

	Not at all	A little	Quite a bit	A lot
(Q9) Does your lymphoedema cause you pain?				

(Q10) Do you have any numbness in your swollen arm?				
(Q11) Do you have any feelings of "pins & needles" or tingling in your swollen arm?				
(Q12) Does your swollen arm feel weak?				
(Q13) Does your swollen arm feel heavy?				
(Q14) Do you feel tired?				

In the past weeké .	**Not at all**	**A little**	**Quite a bit**	**A lot**
(Q15) Have you had trouble sleeping?				
(Q16) Have you had difficulty concentrating on things, e.g. reading?				
(Q17) Have you felt tense?				
(Q18) Have you felt worried?				
(Q19) Have you felt irritable?				
(Q20) Have you felt depressed?				

(Q21) Overall, how would you rate your quality of life at present?
Please mark your score on the following scale:

0 1 2 3 4 5 6 7 8 9 10
poor **excellent**

Thank you for completing this form.
If you have any comments or queries about it, please discuss these with é é é é é é é é é é ..

Dr V L Keeley, Consultant

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These questions are only a part of the QLQ-C30 Questionnaire.

4. Pontuação da versão original do LYMQOL Arm

LYMQOL ARM-*Scoring System*

Lymphoedema Quality of Life Tool

The score for the individual responses are given below. If the item is not scored and left blank or not applicable this is scored with a 0.

Domain totals are calculated by adding the individual scores and dividing the total by the number of questions answered. (If >50% of questions per domain are not answered this cannot be calculated and =0).

The four domains and their corresponding questions are: Function 1 (a-h), 2,3

Appearance 4,5,6,7,8 Symptoms 9,10,11,12,13,14 and Emotion 15,16,17,18,19,20.

Overall quality of life (Q21) is scored as the value marked by the patient, between 0-10.

(Q1)How much does your swollen arm affect the following daily activities?

If any of the items are not applicable to you, please write N/A in the relevant answer box(es).	**Not at all**	**A little**	**Quite a bit**	**A lot**
a) occupation	1	2	3	4
b) housework	1	2	3	4
c) combing hair	1	2	3	4
d) dressing	1	2	3	4
e) writing	1	2	3	4
f) eating	1	2	3	4
g) washing	1	2	3	4
h) cleaning teeth	1	2	3	4

(Q2) How much does it affect your leisure activities/ social life?	1	2	3	4

Please give examples of this .....

.....

(Q3) How much do you have to depend on other people?	1	2	3	4

	Not at all	**A little**	**Quite a bit**	**A lot**
(Q4) How much do you feel the swelling affects your appearance?	1	2	3	4
(Q5) How much difficulty do you have finding clothes to fit?	1	2	3	4
(Q6) How much difficulty do you have finding clothes you would like to wear?	1	2	3	4
(Q7) Does the swelling affect how you feel about yourself?	1	2	3	4
(Q8) Does it affect your relationships with other people?	1	2	3	4

	Not at all	**A little**	**Quite a bit**	**A lot**
(Q9) Does your lymphoedema cause you pain?	1	2	3	4

(Q10) Do you have any numbness in your swollen arm?	1	2	3	4
(Q11) Do you have any feelings of "pins & needles" or tingling in your swollen arm?	1	2	3	4
(Q12) Does your swollen arm feel weak?	1	2	3	4
(Q13) Does your swollen arm feel heavy?	1	2	3	4
(Q14) Do you feel tired?	1	2	3	4

In the past week….	**Not at all**	**A little**	**Quite a bit**	**A lot**
(Q15) Have you had trouble sleeping?	1	2	3	4
(Q16) Have you had difficulty concentrating on things, e.g. reading?	1	2	3	4
(Q17) Have you felt tense?	1	2	3	4
(Q18) Have you felt worried?	1	2	3	4

(Q19) Have you felt irritable?	1	2	3	4
(Q20) Have you felt depressed?	1	2	3	4

(Q21) Overall, how would you rate your quality of life at present?

Please mark your score on the following scale:

0 1 2 3 4 5 6 7 8 9 10

poor **excellent**

Thank you for completing this form.

If you have any comments or queries about it, please discuss these with ……..

Dr V L Keeley, Consultant

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5. Validação do LYMQOL Arm para turco por Bakar *et al.,* 2017

Original Article

Eur J Breast Health 2017; 13: 123-128
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Translation and Validation of the Turkish Version of Lymphedema Quality of Life Tool (LYMQOL) in Patients with Breast Cancer Related Lymphedema

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ABSTRACT

Objective: Breast cancer related lymphedema (BCRL) is a drastic situation that affects patients who have undergone breast cancer surgery. The impact of this condition on individuals' quality of life should be investigated in more detail to obtain better treatment results.

Materials and Methods: In total, 65 patients with BCRL participated in this study. Nottingham Health Profile (NHP) was used to evaluate the validity of associated domains in Lymphedema Quality of Life Tool (LYMQoL). Both the LYMQoL and NHP were filled out by BCRL patients. To evaluate its test-retest reliability, the LYMQoL was subsequently performed seven days following its initial application. Measurement properties such as internal consistency, test-retest reliability, criterion validity and factor structure were tested. The internal consistency was assessed via Cronbach's alpha; test-retest reliability was assessed by the intra-class correlation coefficient (ICC).

Results: Cronbach's alpha values ranged from 0.74 to 0.91 for the LYMQoL total and domain scores. Test-retest reliability was excellent (ICC=0.92-0.99). When the relation between LYMQoL and NHP was investigated, 'good' to 'very good' correlations were obtained (r=0.539-0.643, p<0.05) for all domains of LYMQoL. Exploratory factor analyses demonstrated a four-factor structure.

Conclusion: Turkish version of LYMQoL is a valid and reliable measurement tool to evaluate the quality of life in patients with BCRL.

Keywords: Validity, Reliability, Lymphedema Quality of Life Tool, Turkish version, Breast Cancer Related Lymphedema

Cite this article as: Bakar Y, Tuğral A, Ozdemir Ö, Duygu E, Üyeturk Ü. Translation and Validation of the Turkish Version of Lymphedema Quality of Life Tool (LYMQOL) in Patients with Breast Cancer Related Lymphedema. Eur J Breast Health 2017; 13: 123-128.

Introduction

Breast cancer is the most frequent cancer and the major reason of cancer related deaths among women in the world. Incidence in Turkey was 39/100.000 in 2010 and increased to 46/100.000 in 2013 (1, 2). Since the incidence of breast cancer among Turkish women is increasing, the number of women affected by complications of its treatment is increasing, as well. Breast cancer-related lymphedema (BCRL) is one of the most distressing complication of breast cancer treatment (3). BCRL can manifest directly after surgery or, in most cases, in the first two years after breast cancer treatment (4, 5). Systematic reviews suggest that more than one in five women who survive breast cancer will develop arm lymphedema (6). BCRL can be described as the excessive accumulation of protein-rich fluid in interstitial tissue of the arm, hand, and/or chest wall that can occur after breast cancer surgery or radiation therapy (7). This chronic and incurable condition causes physical and psychological disorders. Patients may develop symptoms such as heaviness, tightness, stiffness, impaired upper limb function and body image, which are all related with swelling (8). Apart from these symptoms, situations such as inability to find a proper outfit, to wear watch or ring trigger psychosocial problems that affect the quality of life (QoL) among breast cancer survivors. Breast cancer survivors with BCRL have a significantly lower QoL than patients without BCRL (9). Therefore, QoL is an important outcome measure in many breast cancer studies. In clinical settings, generic health-related quality of life (HRQoL) questionnaires are used due to lack of lymphedema-specific questionnaires specific questionnaires... along with cultural adaptation and validation studies are not exist yet. However, HRQoL questionnaires are incapable of evaluating both the symptoms and treatment outcome; therefore, they cannot evaluate problem specific conditions. Thus, the use of disease specific questionnaires has a role in this manner. Disease-specific HRQoL questionnaires such as Lymphedema Quality of Life (LYMQoL) are more likely to track changes more specifically in QoL in comparison with HRQoL measures. The LYMQoL is a comprehensive questionnaire designed to measure QoL in patients with BCRL.

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LYMQoL was developed by Keeley et al, which is a self-report questionnaire that assesses upper limb lymphedema symptoms and ability to perform common functional activities in patients with BCRL (10). The LYMQoL has been validated in the English and Dutch languages. However, validation of LYMQoL for upper limb lymphedema in the Turkish language has not been performed yet (11). The aim of this study was to translate the English version of LYMQoL to Turkish and to test the reliability and validity of the Turkish version of the questionnaire among patients with BCRL in Turkey.

Material and Methods

Instrument

The LYMQoL was designed as a disease-specific HRQoL measure by Keeley in 2010 (10). Its questions can be gathered under four domains being function, appearance, symptoms and mood. It consists of 21 questions. The last question 'overall quality of life' scale investigates the general QoL. Item scoring in each domain is as follows: Not at all=1, A little=2, Quite a bit=3, A lot=4. The total score for each domain is calculated by adding up all the scores together and dividing it by the total number of questions answered. If fewer than 50% of the items were answered, the whole domain is scored as 0. The LYMQoL total score and each domain score have a range between 1 and 4. Higher scores indicate lower quality of life. The last question about the 'overall quality of life' item is scored through 0 to 10. Higher scores indicate a better overall QoL (8).

Translation and constitution of the Turkish version of LYMQoL

After permission was granted for translation and use of LYMQoL from the copyright holder Keeley the standard translation method was followed, which was established by previous studies (12). The English version was first translated independently to Turkish by two native Turkish speakers (a physiotherapist specialized in lymphedema and a professional translator). A panel consisting of these two translators and one bilingual author (Y.B) critically reviewed the translations to reveal the first draft of Turkish version of LYMQoL. Two other bilingual speakers who did not know the original questionnaire translated this draft back to English. The discrepancies among the original version and the translated versions were analyzed by the panel (consisting of all five members). Semantic and conceptual equivalences were discussed, and a draft version of the questionnaire was developed. In the next step, the Turkish LYMQoL was firstly tested on a sample of 20 Turkish female patients with BCRL as a pilot study. The aim was to detect problems with the questionnaire such as wording, terminology, instructions, items and whether the questionnaire was understandable or not. After completion of the questionnaire, an interview was held with patients to investigate the understandability of each item. They were asked to comment on items and offer recommendations for improvement. All patients reported that the questionnaire was easily understandable, readable and culturally relevant. No problematic items were observed in the Turkish translated version of LymQoL.

Nottingham health profile

Nottingham Health Profile (NHP) was used to measure the generic HRQoL. NHP is a self-administered questionnaire which is used to evaluate perceived health problems. NHP includes 38 questions with assigned individual score under six domains as energy level, pain, emotional reaction, sleep, social isolation, and physical abilities. The sum of maximum scores for all domains is 100. For the calculation of final score in each domain, variation in the number of items per domain was estimated by computing the percentage score (i.e., each sum was multiplied by 100 and divided by the number of items in the domain). Possible scores ranged from 0 (indicating all "no" answers in that domain or absence of distress) to 100 (all "yes" answers indicating maximal distress). Lower NHP scores indicate a better QoL. The reliability and validity of Turkish NHP was demonstrated (13).

Study sample

Eighty-seven women with BCRL were recruited to the study between June 2016 and December 2016 at the lymphedema outpatient clinic in School of Physical Therapy and Rehabilitation in Abant Izzet Baysal University. BCRL was diagnosed by the medical oncologist and patients were also evaluated by the circumference measurement method in which the diagnostic criteria was chosen as having a circumferential difference of 2 cm or above in their arms compared to the contralateral arm. The sample size for this study comprised of patients who were referred to the lymphedema outpatient clinic for being informed and learning treatment options about BCRL. The inclusion criteria for this study were as follows: having BCRL, 18 years of age or older, able to read, speak, and understand Turkish, being a volunteer to be recruited in this study. Patients with acute infection, lymphangitis, breast cancer recurrence, ongoing chemotherapy, radiotherapy, history of trauma, thrombosis in upper limbs and having open wounds in the affected limb were excluded from the study. All patients were asked to fill in the LYMQoL and NHP questionnaires. Then, they were asked to refill the LYMQoL one week later. This study was approved by the local ethics committee. (31 May 2016; number 2016/98). Written informed consent was taken from the participants after oral and written information was given to them.

Reliability

The reliability of LYMQoL was evaluated by means of the internal consistency and test-retest analysis. Internal consistency measures the consistency of responses across the questionnaire and the subscales. Internal consistency was determined by using Cronbach's alpha coefficient. Commonly accepted values for Cronbach's alpha are described as excellent ($a>0.9$), good ($0.9>a>0.7$), acceptable ($0.7>a>0.6$), poor ($0.6>a>0.5$) and unacceptable ($a<0.5$) (14). Test-retest reliability was tested by administering a questionnaire to the patient on two separate times without any substantial changes in her symptoms. Retest analysis was done after seven days. It was calculated by using intraclass correlation coefficient (ICC). Correlation coefficient power was categorized as poor (<0.40), fair to good (0.40-0.75), and excellent (>0.75). A correlation coefficient of 0 indicates no reliability, whereas a value of 1 indicates excellent reliability (15).

Validity

Criterion validity means the degree to which an instrument measures what it is intended for. The criterion validity of the LYMQoL was determined by calculating Pearson's correlation coefficient between the patients' LYMQoL and the NHP scores. The Pearson's r correlation coefficient is used for the criteria of poor (r<0-0.20), fair (r=0.21-0.40), moderate (r=0.41-0.60), good (r=0.61-0.80), and excellent (r>0.81-1) (16).

Factor analysis

The main purpose of factor analysis is to reduce items into smaller groups, which are called factors. Factors contain correlated variables and are typically quite similar in terms of content. Exploratory factor analysis allows the researcher to determine the underlying domains or factors that exist in a set of data (17).

Statistical analysis

Descriptive analyses were used to calculate means and standard deviations of the demographic variables. The distribution was determined by the normality tests. 'Overall quality of life', total score of LYMQoL and differences between baseline and last measurements in four domains were compared via the Wilcoxon Signed Rank Test. Internal consistency was assessed by Cronbach's alpha coefficient between items. Test-retest reliability of each item was investigated via the Kappa coefficient while test-retest reliability, which consisted of four domains' total scores, was assessed with the (ICC). Pearson correlation analysis was used for correlations between values of total scores of LYMQoL and NHP for the investigation of the validation of LYMQoL questionnaire. Exploratory factor analysis was used to investigate the structure of questionnaire. Within this analysis, the Kaiser-Meyer-Olkin test was used to investigate whether factor analysis was appropriate for data structure or not. The factor structure was assessed with maximum likelihood extraction and Varimax rotation (18).The internal consistency was assessed by using Cronbach's alpha coefficient. Alpha values ≥0.7 are considered as satisfactory. Test- retest reliability was assessed using (ICC). Criterion validity was assessed by Pearson's correlation coefficient. Correlation coefficient was categorized as poor (0-0.20), fair (0.21-0.40), moderate (0.41-0.60), good (0.61-0.80), and excellent (0.81-1). The statistical significance level accepted as $p<0.05$. PASW (SPSS Institute, Chicago, IL, USA. versiyon 18) was used for the statistical analyses.

Results

In total, 87 patients with BCRL were screened for participation in the study. Ten patients were excluded from the study due to their inability to meet inclusion criteria. Six participants had acute infection, 2 of them had active metastasis and 2 of them had no ability to read and write. The second evaluations were missed in 12 participants. Thus, this study was started and completed with 65 participants in total with an attrition rate of 25% (22/87).The mean age was 50.6±12.45 years. Forty-nine patients (75.4%) had unilateral arm lymphedema. Demographic characteristics and clinical features of the patients are shown in Table 1.

Cronbach's Alpha value of the total score of LYMQoL and domains (Functional Aspects, Appearance/Body image, Symptoms, Mood/Emotions) were recorded as 0.91, 0.76, 0.79, 0.70 and 0.94, respectively. These values indicated that the questionnaire has 'good to excellent' internal consistency. Test-retest ICC value (95% confidence interval) of each domain varied between 0.92 and 0.99, $p<0.001$ (Table 2). According to the ICC values, it was shown that the LYMQoL had excellent test-retest results.

The LYMQoL correlated very well with the 'overall quality of life' and NHP as having a good criterion validity of the LYMQoL in this population. The 'overall quality of life' had negative correlation with all the domains of LYMQoL. The p values were found significant in all parameters except for correlation between Energy Level (EL) of NHP and symptoms domain of LYMQoL. The p values of 'overall quality of life' and NHP total scores were all significant (Table 3).

The floor and ceiling effects were determined by calculating the rate of participants in which lowest and highest scores in each item most The floor-ceiling effect was calculated for the first measurement of questions within LYMQoL and possibility of participants who replied to "1" in 15th question was much more when compared to other ques-

Table 1. Demographic characteristics and clinical features of the patients (n=65)

	Minimum	Maximum	X±SD
Age (years)	24	75	50.6±12.45
Height (m)	1.48	1.78	1.60±0.06
Weight (kg)	45	103	71.0±14.06
BMI (kg/m2)	15.76	41.98	27.82±5.79
Lymphedema duration (year)	1	18	4.32±3.06

BMI: body mass index; X±SD: mean±standard deviation

Table 2. Reliability of Lymphedema Quality of Life Questionnaire (LYMQoL) (n=65)

LYMQoL Domain	ICC (95% CI)	p
Functional Aspects	0.99 (0.983-0.994)	<0.001
Appearance/Body image	0.99 (0.983-0.994)	<0.001
Symptoms	0.98 (0.982-0.993)	<0.001
Mood/Emotions	0.99 (0.986-0.995)	<0.001
Total LYMQoL	0.99 (0.993-0.997)	<0.001

ICC: intra-class correlation coefficient p<0.05

Table 3. Criterion validity of Lymphedema Quality of Life Questionnaire (LYMQoL)

	NHP		Energy Level		Pain		Emotional Reactions		Social Isolation		Sleep		Physical Activity'		Overall Quality of Life'	
LYMQoL Domains	r	p	r	p	r	p	r	p	r	p	r	p	r	p	r	p
Functional Aspects	0.539	0.000	0.328	0.008	0.559	0.000	0.329	0.007	0.310	0.013	0.322	0.009	0.446	0.000	-0.642	0.000
Appearance/Body image	0.541	0.000	0.405	0.001	0.503	0.000	0.309	0.012	0.272	0.030	0.412	0.001	0.367	0.003	-0.655	0.000
Symptoms	0.543	0.000	0.153	0.224	0.562	0.000	0.481	0.000	0.388	0.002	0.468	0.000	0.337	0.006	-0.571	0.000
Mood/Emotion	0.555	0.000	0.311	0.012	0.580	0.000	0.403	0.001	0.345	0.005	0.412	0.001	0.317	0.010	-0.535	0.000
Total LYMQoL	0.643	0.000	0.365	0.003	0.646	0.000	0.446	0.000	0.382	0.002	0.484	0.000	0.421	0.000	-0.707	0.000

r: pearson correlation coefficient p<0.05; NHP: Nottingham Health Profile

Table 4. Factor analysis loadings of the LYMQoL

	Factors			
Item	1	2	3	4
1.Affect daily activities	.679	.208	.133	.273
2. Affect leisure activities	.624	.276	.504	.253
3. Depend on the other people	.912	.276	.123	-.055
4. Affect appearance	.227	.876	.267	-.147
5. Difficulty finding clothes to fit	.301	.610	.305	-.343
6. Difficulty finding clothes to wear	.369	.764	.186	-.311
7. Affect feel about yourself	-.036	.594	.535	.071
8. Affect relationship with other people	.296	.587	.233	.520
9. Cause you pain	-.002	.150	.731	.244
10. Numbness in your swollen arm	.200	.056	.866	-.261
11. Feelings pins and needles	.119	.016	.817	.063
12. Feel weak	-.011	.203	.376	.157
13. Feel heavily	.132	.240	.448	.352
14. Feel tired	-.222	-.147	.720	.215
15. Trouble sleeping	-.250	.048	.198	.795
16. Difficulty concentrating on things	.210	.406	.036	.788
17. Feel tense	.205	.195	.048	.851
18. Feel worried	.270	.219	.101	.861
19. Feel irritable	.146	.211	.172	.848
20. Feel depressed	.211	.186	.140	.855

tions, while the replies "4" were much higher in number than others in the 5th question.

When exploratory factor analysis was conducted with items within the questionnaire, considered...as...appropriate-Olkin test value was found 0.781. It was considered appropriate to conduct a factor analysis with the questionnaire due to value is above 0.50. Besides, the sphericity test resulted in the conclusion that the correlation matrix did not have a spherical structure ($p<0.0001$). This result shows that correlations were significant between items of questionnaire and the factor analysis was suitable. Furthermore, it was deduced that it was not necessary to eliminate any items from questionnaire since all the diagonal elements were above the value of 0.50 in anti-image matrix. After factor loadings were gained, they were rotated with the Varimax rotation method; factor loadings were obtained and finally, four significant factors were achieved in the Turkish version of LYMQoL and the factor structures were the same as in the original version. The same items appeared in the same factors. We selected four factors which explained 74.9% of the total variance, each accounting for 44.3%, 13.9%, 10.7% and 6.1% of the total variance, respectively. Factor loadings constituted in the study and factor names are shown in Table 4.

Discussion and Conclusion

During the data collection period, there were no validated Turkish versions of any lymphedema questionnaires. Thus, the aim of this study was to translate the original version of the LYMQoL to Turkish for Turkish-speaking patients with BCRL and to evaluate its validity and reliability. The results of the current study showed that the Turkish version of LYMQoL was a reliable, internal consistent and valid questionnaire for determining the HRQoL in patients with BCRL.

Breast cancer related lymphedema is a chronic condition which can occur after removal of axillary lymph nodes and radiotherapy. Some women with BCRL can fall into depression and think that this condition is much worse than breast cancer itself when they figure out that lymphedema is a chronic disease and only its symptoms could be brought under control (19). In this situation, attention should be paid on quality of life of women with BCRL (20). Velonovich et al (21) showed that lymphedema-related symptoms (swelling, heaviness, firmness, pain, hardness, reduced extremity mobility etc.) have negative impact on physical and functional well-being and these affect the QoL negatively. Ridner et al (22) stated that patients who have more symptoms and more need for self-care have a lower QoL. Yet, the generic HRQoL measurements which are used often do not provide detailed information in comparison with disease-specific HRQoL questionnaires since they can only show the picture of general deficit (23). For instance, the volume of the lymphedematous extremity cannot completely reflect the effect of disease of an individual. The social and psychological problems, which are primarily caused by the disease, and the patient's well-being are ignored. The effect of the disease on daily life is reflected better by the evaluation of disease-specific HRQoL. Thus, evaluation of disease-specific HRQoL is important for the determination of both the patient's situation and effectiveness of the administered treatment (23). The LYMQoL is a specific questionnaire which assesses the QoL in BCRL patients (10). In this study, LYMQoL was translated and validated for Turkish-speaking patients with BCRL. Patients answered the Turkish version of LYMQoL without any difficulties.

In version studies, for test-retest analyses, various time intervals were selected between test-retest periods. In the original version of LYMQoL, the time interval between test-retest was one week, and in the Dutch version for lower limb lymphedema it was two weeks. It was reported that no significant differences were found between two days and two weeks of test-retest time intervals. In the present study, the time interval between test-retest was selected as seven days based on the report of Marx et al (24).

Cronbach's Alpha value of the total score of LYMQoL was recorded as 0.91 and the ICC values were recorded in the range of 0.92 and 0.99. According to the results, the Turkish version of LYMQoL has an excellent internal consistency and test-retest reliability. Keeley et al (10) did not report the ICC value for the test-retest reliability and Cronbach's Alpha value of total LYMQoL, while they indicated only Cronbach's Alpha values for the domains of LYMQoL. The internal consistency of the English version of the LYMQoL was reported to be in the range of 0.83-0.88. Similar findings were obtained in the Turkish version of LYMQoL. In this study, the Cronbach's Alpha values of the domains of LYMQoL were in the range between 0.70-0.79. For criterion validity in the English version, the correlation was investigated ..between..the...domains of EORTC QLQ-C30 and LYMQoL. It was reported that a good correlation was found. During the study process, NHP was used for criterion validity due to the absence of a Turkish lymphedema-specific HRQoL questionnaire since it is widely used in Turkish population and it also has relatively good readability and comprehensibility. 'Good' to 'very good' correlations were found between domains of the Turkish version of the LYMQoL and the

NHP total scores (0.539-0.643) and as expected, negative correlations were found between LYMQoL and 'overall quality of life' (-0.535, -0.707). Based on these findings, the Turkish version of the questionnaire appears to have 'good' to 'very good' validity. It was thought that if Turkish disease specific HRQoL questionnaire had been used, it could was obtained for criterion validity. There is already only one specific questionnaire translated into Turkish, the Lymphedema Functioning, Disability and Health Questionnaire (Lymph-ICF) (25). Nevertheless, this questionnaire could not be used since it was published while we were in the data collection period. When investigating the factor analyses, four domains existed in the original questionnaire. It was seen that the Turkish version has four domains in the factor analysis that was conducted, as well. Besides, the floor-ceiling effect analyse was not done in the original questionnaire whereas it was also applied to the Turkish version of the LYMQoL in our study. In the 5th item, "Difficulty finding to clothes", the possibility of "4: A lot" answer was much higher than the other answers; while in the 15th item, "Trouble sleeping" the answer "1: Not at all" was much more common than the others. These were expected results since difficulty with finding clothes is natural in lymphedema patients because of their severe swelling as it was investigated in the 5th item "Trouble sleeping", which was also less in proportion. This can be explained with the generally painless characteristic of lymphedema. We could not evaluate the responsiveness of the questionnaire due to the lack of treated patient population because most patients who referred to the outpatient clinic had no insurance for treatment costs. Keeley et al (10) assessed the responsiveness of the questionnaire one week and one month after the treatment; yet they stated that there were no significant differences although improvement was observed with the treatment in the resulting LYMQoL scores. They also concluded that was occurred due to the small sample size. Patel et al (26) stated that LYMQoL was a condition-specific instrument that could be used to track changes in the QoL throughout a lymphedema treatment. They also noted that the use of LYMQoL indicated that some domains improved earlier than others. In a similar manner, Terumi Iuchi et al (27) stated that improvements in QoL could be evaluated by using the LYMQoL measure regarding the Complex Decongestive Therapy.

There is a number of questionnaires that evaluate disease-specific HRQoL in upper limb lymphedema such as Wesley Clinic Lymphedema Scale (WCLS) (28), Upper Limb Lymphedema-27 (ULL-27) (29), Lymph-ICF (25). However, all of these questionnaires have disadvantages in their own way. There is no responsiveness analysis of Lymph-ICF even though the Turkish version was published this year (30) and the scoring system is not completely understood by patients (25). Wesley Clinic Lymphedema Scale is a questionnaire derived from the questionnaire Functional Living with Cancer. Yet, the words "disease" and "cancer" were replaced with "lymphedema" in WCLS. Furthermore, no validity and reliability studies currently exist. Thus, it is not appropriate for evaluating lymphedema. In the original version of the LYMQoL, it was indicated that the questionnaire could not evaluate the trunk, genital, head and neck lymphedema, which was considered a limitation (10). This limitation is not specific to LYMQoL only as all the questionnaires mentioned above cannot evaluate the lymphedema separately from the extremity.

A measurement tool should not take a long time for both the clinician and patient. Additionally, it should be easy to use. 93% of patients indicated that they completed the original version of LYMQoL easily and 99% indicated that the items were easily understandable, only 1% of patients indicated that the questionnaire was too long (10). In our point of view, LYMQoL is short and compact and these could be assumed as the most important advantages as compared to other questionnaires. Our patients remarked that the questionnaire was easily understandable and they spent five minutes on average to complete the questionnaire. As shown in the pilot study, no incomprehensible questions were found. Since questions were found understandable by patients, no changes were necessary to take into consideration. During the data collection process, no negative situations were observed in the light of feedbacks received from our patients. We believe that more detailed and specific questions about lymphedema such as compression and infection-related questions should have been included in original questionnaire based on our clinical experiments.

In conclusion, the Turkish version of LymQoL is a disease specific HRQoL questionnaire for BCRL patients and it is appropriate to use in the Turkish population. Because it is short and easy-to-apply, it can be recommended as a clinical outcome measure for disease-specific HRQoL evaluation in patients with BCRL. As a future study, the responsiveness of Turkish LYMQoL for BCRL patients in the Turkish population should be investigated. Besides, another disease specific Turkish HRQoL tool should be used regarding criterion validity.

Ethics committee approval: All the procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Abant Izzet Baysal University Ethics Committee (31 May 2016; number 2016//98).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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6. Validação do LYMQOL Arm para turco por Borman *et al*., 2018

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Original Article

The reliability and validity of Lymphedema Quality of Life Questionnaire-Arm in Turkish patients with upper limb lymphedema related with breast cancer

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ABSTRACT

Objectives: This study aims to adapt Lymphedema Quality of Life Questionnaire-Arm (LYMQOL) into Turkish and to test its reliability and validity in Turkish patients with upper limb lymphedema related with breast cancer.

Patients and methods: Between June 2015 and November 2015, the Turkish LYMQOL-Arm was obtained using forward-backward translation method and administered to a total of 135 female patients (mean age 51.8±9.8 years; range, 31 to 82 years) with upper limb lymphedema with European Organization for Research and Treatment of Cancer-QoL Breast Cancer-specific version (EORTC QLQ-BR23) and Functional Assessment of Cancer Therapy-Breast-4 (FACT-B+4) questionnaires. A test-retest interval of seven-days was used to assess the reliability. The validation studies were carried-out by means of construct-validity using Spearman's rank correlation-coefficient. Internal consistency and test-retest-reliability were assessed using Cronbach's alpha and intra-class correlation-coefficient (ICC), respectively.

Results: 135 patients completed the questionnaire with upper limb lymphedema related with breast cancer completed the questionnaires. The mean lymphedema duration was 21.1±28.7 (median: 6) months. Internal consistency and reliability of the Turkish LYMQOL-Arm was good with Cronbach's alpha (0.88-0.90) and test-retest ICC (0.45-0.71). External construct validity was highly confirmed by expected correlations with comparator scales, EORTCQLQ-BR23 and FACT-B+4 ($p<0.01$).

Conclusion: The Turkish version of the LYMQOL-Arm is a valid and reliable tool for evaluating QoL in female patients with upper limb lymphedema related with breast cancer.

Keywords: Lymphedema Quality of life Questionnaire-Arm; lymphedema; quality of life; validity; Turkish.

Breast cancer is the most frequent cancer among women in Turkey.[1] Cancer treatments comprising resection of lymph nodes and/or radiation therapy can damage lymph drainage pathways causing accumulation of lymph fluid in the interstitial tissue of related limbs and body areas, known as secondary lymphedema.[2,3] In recent years, more effective screening modalities and advances in therapeutic procedures have resulted in significant improvements in the survival of cancer patients.[4] The long-term side effects and treatment-related adverse effects during the survivorship may impair the quality of life (QoL) of the patients. Lymphedema has been described as one of the most significant survivorship complications after the surgical treatment of breast cancer.[4-6]

Lymphedema may have severe consequences in terms of patients' functional and psycho-social aspects of life. Accurate information on health-related QoL outcomes among patients with lymphedema is critically needed to determine evidence-based decision making and indicate the impact of disease on survivors' lives.[1,5,6] A number of questionnaires has been presented to assess the QoL in cancer patients

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with lymphedema. Generic instruments comprising; European Organization for Research and Treatment of Cancer QoL Breast Cancer (EORTC-QLQ-30), its specific version for breast cancer (EORTC-QLQ-BR23), the World Health Organization Quality of Life (WHOQOL)-BREF, Functional Assessment of Cancer Therapy-Breast (FACT-B) as well as Short Form-36 (SF-36) or Nottingham Health Profile (NHP) have been used in previous studies.[7-10] In recent years, there has been more interest in developing lymphedema-specific QoL instruments. Due to the specific symptoms and difficulties of the patients with lymphedema, it is important to use a questionnaire specifically developed for patients suffering from this chronic condition. However, few are developed to measure specific QoL in patients with lymphedema. The Upper Limb Lymphedema-27 (ULL-27),[11] Lymphedema Quality of Life Inventory (LyQLI),[12] Lymphedema Functioning, Disability and Health Questionnaire (Lymph-ICF),[13] and Lymphedema Life Impact Scale (LLIS)[14] were specifically designed and validated for assessing health related-QoL in patients with upper limb lymphedema. However, we are impressed with the short and simple questionnaire named Quality of Life measure for Limb Lymphedema (LYMQOL) developed by Keeley et al.[15] It consists of two questionnaires: for upper and lower lymphedema LYMQOL-Arm and LYMQOL-Leg. We are surprised to find very little published translated versions in the literature.

The LYMQOL is a disease specific patient reported outcome measure developed in the United Kingdom (UK), consisting of 28 perceived items. The Turkish language is spoken by nearly 85 million individuals worldwide. Previously several generic questionnaires comprising EORTC-QLQ-30, its specific version for breast cancer-EORTC-QLQ-BR23,[7] SF-36,[16] and FACTB-4[17] have been translated to Turkish and validated for breast cancer patients. However, no specific instrument for lymphedema has been tested for validity and reliability in Turkey. In this study, we aimed to translate and validate the LYMQOL-Arm for Turkish breast cancer patients with lymphedema.

PATIENTS AND METHODS

In this study, we conducted a descriptive and methodological study for validation of the LYMQOL-Arm among Turkish patients with breast cancer-related lymphedema (BCRL). The study was conducted at Lymphedema Unit, Physical Medicine and Rehabilitation Department of a university hospital, between June 2015 and November 2015. A total of 135 female patients (mean age 51.8±9.8 years; range, 31 to 82 years) were included. The study was approved by the Clinical Research Ethics Committee of the University School of Medicine. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

The BCRL patients with having mental incapacity, having psychiatric diagnoses requiring medications, patients with other types of cancer, those younger than 18 years and older than 65 years were not included. Patients were excluded, if they were illiterate or involved in intensive lymphedema treatment during the test period. All patients completed their chemotherapy and radiotherapy sessions and did not have active malignancy. The diagnosis of BCRL was verified by bilateral volumetric measurements depending on the circumferential measurements.[18] Circumferential measurements were performed by a standard 1 cm retractable tape at 4 cm intervals along the arm and converted to an approximate arm volume using the truncated cone formula to enable estimation of volume. The presence of lymphedema was assessed by inter-limb volume difference (>10%) based on the serial circumferential measurements in both affected and non-affected extremities.[19] Also, the circumferential measurements of second finger base and metacarpophalangeal areas were recorded for patients with hand edema. Lymphedema was defined as an increase in hand circumference at any level by 1.5 cm or more compared to the contralateral side.[20]

The demographic properties (age, sex, education, and marital status, occupation, Body Mass Index) and clinical characteristics (duration of lymphedema, involvement side, treatments, type of surgery, grade of lymphedema) were recorded.

Translation and cross-cultural adaptation

After obtaining written permission from the researcher who developed the LYMQOL, the forward-backward translation method was initiated. Four steps were used in the linguistic validation of the questionnaire. Two lecturers graduated from departments of foreign languages of Bilkent University and two lymphedema specialists, competent who were fully bilingual in both Turkish and English, participated in the translation process. One of the lecturers translated the English version into Turkish to produce an understandable and conceptually equivalent translation. The back translation of the Turkish version into source language was done by the second lecturer who was blind to the purpose of

translation. The original form and the one translated form from Turkish to English were compared by the two lecturers, and the final form of the Turkish version was prepared. Finally, the two lymphedema specialists, who were fully competent in both languages, controlled and revised the lecturers' final Turkish version to obtain the Turkish version used in this study. To avoid misunderstanding and to obtain difficulties in understanding, the instrument was given as a pretest to 30 patients with BCRL. Face-to-face interviews with the patients showed that all the indices were clear and the instrument was understandable. We made no cross-cultural validation in the translation, as feedback from the pretest study group did not identify any concerns. The Turkish version of LYMQOL-Arm was answered by the patients themselves. One lymphedema specialist was in the interview room to help the patients in case they needed assistance, which was the case only in a few patients with difficulty in reading. The scale was completed by each patient twice with one-week interval.

Questionnaires

The LYMQOL-Arm has been developed to assess the impact of lymphedema of the arms on the QoL of the patients. It consists of four domains with 28 items. These domains are symptoms, appearance, function, and mood. The answers were evaluated on a four-point Likert scale (1= not at all 2= a little, 3= quite a bit, 4= a lot). Each item received a score between 1 and 4, with higher scores indicating a worse QoL. Domain totals were calculated by adding the individual scores and dividing the total by the number of questions answered (If >50% of questions per domain were not answered this cannot be calculated *and =0). If the item was not scored and left blank or not applicable, this was scored with a 0. The four domains and their corresponding questions are: Function 1 (a-h), 2,3, Appearance 4,5,6,7,8 Symptoms 9,10,11,12,13,14 and Emotion 15,16,17,18,19,20. Overall QoL (Q21) is scored as the value marked by the patient, between 0-10. Previous reports indicated that the LYMQOL-Arm was easy to complete with clear face validity and good internal consistency.[15]

Patients with BCRL were also administered the Functional Assessment of Cancer Therapy-Breast-4 (FACT-B+4)[21] and EORTC-BR23[22] QoL tools, for comparisons with the new instrument. They were chosen as criterion standards, since they are suggested for QoL studies for lymphedema patients and their Turkish versions have previously been evaluated for test-retest reliability and validity.[10,16]

The European Organization for Research and Treatment of Cancer QoL Breast Cancer-specific Version (EORTC QLQ-BR23) is a 23 item self-administered cancer specific questionnaire designed to measure QoL in breast cancer population at various stages and with patients with differing treatment modalities. The assessment is comprised of eight domains (body image (BRBI), sexual functioning (BRSEF), sexual enjoyment (BRSEE) and future perspective (BRFU); symptom scales-arm symptoms (BRAS), breast symptoms (BRBS), systemic therapy side effects (BRST) and upset by hair loss (BRHL).[23] The EORTC-QLQ-BR23 is found effective and suggested in clinical studies for assessing breast cancer-specific QoL.[22]

The FACT-B+4 questionnaire was developed by adding a four-item Arm subscale to the well-validated FACT-B (Functional Assessment of Cancer Therapy–Breast)[21] and was been translated and field-tested in Turkish subjects. The 40 items in FACT-B+4 evaluated patients' physical, social, emotional and functional well-being; specific breast cancer concerns; arms symptoms; as well as their overall QOL. Previous reports indicated excellent reliability, internal consistency and sensitivity to change among patients with BCRL.[17,21]

Procedure

The participants completed the LYMQOL-Arm, FACT-B and EORTC BR23 concurrently, while the LYMQOL-Arm was completed for patients twice with seven-day intervals.

Statistical analysis

For the reliability and validity studies, the sample size is determined as at least five-fold of item numbers. Based on these data, 135 patients were required to study. A total of 20% of these patients was evaluated for retest procedure.[24] Descriptive analyses were performed to calculate means and standard deviations and median of the demographic variables.

For test-retest reliability, 65 patients completed the questionnaires, as a second time within seven days, at the same time of day, during a non-treatment period. Intra-class correlation coefficients (ICC) with one-way random effects model, were used to determine test-retest reliability of the scores on five domains of LYMQOL and of the score on each question separately. Cronbach alpha coefficients were used to determine internal consistency of the entire questionnaire and of each domain. As recommended, the internal consistency of a magnitude of ≥0.70 was sought. The Cronbach alpha was determined as high correlation,

if values in range of 0.80 to 0.95 were obtained, where a value >0.95 indicated excessive internal consistency.

Confirmatory factor analysis was used to show the convenience of factor structure to the original scale. Construct validity was tested by convergent-divergent validity approach comparing the correlation of the similar scales of the LYMQOL-Arm and EORTC-BR23 and FACT-B4. It was expected that conceptually related scales would correlate better with the functioning scales of the LYMQOL and vice versa. We used the Pearson correlation coefficient for normally distributed scores and the Spearman correlation coefficient for the other scores. The correlation coefficients are interpreted as follows: <0.4 was weak, 0.4-0.74 was moderate, 0.75 to 0.9 was strong, and >0.9 was very strong.[24] Statistical analysis was performed using the SPSS version 15.0 statistical software (SPSS Inc., Chicago, IL, USA). A p value of <0.05 was considered statistically significant.

RESULTS

Of 135 patients with BCRL, 65 completed test 1 and 2 for LYMQOL-Arm for test-retest analyses. The time between test 1 and 2 was within seven days. The demographic and clinical characteristics of the patients are shown in Table 1. All patients underwent breast cancer surgery. A great number of them were married and housewives. A number of participants (65%) were

Table 1. Demographic and clinical characteristics of patients (n=135)

	n	Mean±SD	Median	Min-Max
Age (year)		51.8 ±9.8		31-82
Marital status				
Unmarried	18			
Married	110			
Divorced/widowed	7			
Education				
Primary school	49			
Secondary school	15			
Lycee	36			
University	35			
Occupation				
Housewife	86			
Retired	21			
Officer	23			
Self-employer	5			
Involved side				
Right	70			
Left	65			
Body Mass Index (kg/m^2)		29.2± 5.4		19.2-45.1
Duration of lymphedema (months)		21.1±38.7	6	0.2-164
Dominant hand				
Right	128			
Left	7			
Surgery	135			
Modified radical mastectomy	98			
Lumpectomy	7			
Simple mastectomy	30			
Lymphedema stage				
1	39			
2	84			
3	2			
Treatment				
Surgery	135			
Chemotherapy	128			
Radiation therapy	96			
Hormone therapy	97			
Time since surgery (month)		41.4±44.5		0.75-164

SD: Standard deviation; Min: Minimum; Max: Maximum.

Table 2. Internal consistency and test-retest reliability of the Turkish LYMQOL-Arm instrument (n=65)

	Test-retest		Consistency
LYMQOL-Arm scores	ICC	95% CI	Cronbach alpha
Function	0.611	0.373-0.773	0.880
Appearance	0.665	0.449-0.808	0.881
Symptom	0.714	0.521-0.838	0.886
Mood	0.451	0.165-0.666	0.853
Overall	0.627	0.379-0.790	0.900

LYMQOL: Lymphedema-Quality-of-Life-Questionnaire; * p<0.001. ICC: Intra-class correlation-coefficient.

high school or university graduated. Radiation therapy and chemotherapy were completed prior to entry into the study. The median duration of lymphedema was six months.

Reliability

The internal consistency (based on a Cronbach alpha score of (0.85-0.90) and test-retest reliability (based on an intra-class correlation coefficient of 0.45-0.74 of the LYMQOL-Arm were found to be high (p<0.001; Table 2). The test-retest reliability of the symptom, appearance, and mood scores was strong and the function and overall scores were moderate to strong.

Confirmatory factor analysis

The confirmatory factor analysis was applied to the factor structure. Specifically, we expected a best-fit model with the following indices: a Satorra-Bentler scaled chi-square (S-Bχ^2)/degrees of freedom ratio (CMIN/DF) of 2.0 or less; a Trucker Lewis Index (TLI) of 0.90 or higher; a Comparative Fit Index (CFI) of 0.90 or higher; a Goodness-of-Fit Index (GFI) of 0.90 or higher; a Incremental Fit Index (IFI) of 0.90 or higher and a low root mean square error of approximation (RMSEA) of 0.08 or less. These values were calculated as CMIN/df: 1.733, RMSEA: 0.074, GFI: 0.782, IFI: 0.904, CFI: 0.902, TLI: 0.888. Accordingly, this factor structure was found to be acceptable.

Construct (convergent-divergent) validity

Table 3 shows an overview of inter-scale Spearman correlation coefficients between the different domains of LYMQOL-Arm and the EORTC-BR23 and FACT-B4. All patients completed the three questionnaires. All domains of LYMQOL-Arm had the strongest correlation with the expected domains of EORTC-BR23 (future, systemic complications, breast symptoms, arm symptoms). Concurrently, all sub-scores of LYMQOL-Arm had strongest correlations with the corresponding domains of FACT-B4. By means of divergent validity, no correlation between

Table 3. Correlation between the EORTC-BR23 and FACT-B4 questionnaires and the LYMQOL-Arm questionnaire (construct validity)

	LYMQOL-Arm function	LYMQOL-Arm appearance	LYMQOL-Arm symptom	LYMQOL-Arm mood	LYMQOL-Arm overall
FACT-B4 physical	-0.440**	-0.407**	-0.504**	-0.530**	0.471**
FACT-B4 social	-0.100	-0.173*	-0.102	-0.161	0.239**
FACT-B4 emotion	-0.356**	-0.377**	-0.354**	-0.512**	0.487**
FACT-B4 function	-0.282**	-0.363**	-0.296**	-0.363**	0.450**
FACT-B4 arm symptom	-0.318**	-0.395**	-0.371**	-0.430**	0.341**
EORTC-body image	-0.320**	-0.347**	-0.248**	-0.403**	0.370**
EORTC-sexual function	0.026	-0.034	-0.022	-0.017	0.192*
EORTC-sexual satisfaction	0.116	0.086	0.008	-0.064	0.095
EORTC-future	-0.255**	-0.320**	-0.214*	-0.406**	0.203*
EORTC-systemic completed	0.279**	0.284**	0.287**	0.390**	-0.335**
EORTC-breast symptoms	0.341**	0.331**	0.373**	0.429**	-0.215*
EORTC-arm symptoms	0.612**	0.637**	0.602**	0.561**	-0.389**
EORTC-hair loss	-0.092	0.106	-0.096	0.214	-0.102

EORTC: European Organization for Research and Treatment of Cancer; FACT-B4: Functional-Assessment-of-Cancer-Therapy-Breast-4; LYMQOL: Lymphedema-Quality-of-life-Questionnaire; * p<0.05; ** p<0.01.

sexuality and hair loss domains of EORTC-BR23 and domains of LYMQOL-Arm (except correlation between overall score) was detected (Table 3).

DISCUSSION

Lymphedema research has gained acceleration recently. Breast cancer-related lymphedema is an important argument to assess and monitor different therapeutic approaches and has a significant impact on QoL.[3,4,8,10,16] A systematic review investigated the quality and appropriateness of patient-reported outcome instruments and indicated that lymphedema-specific QoL instruments had strong psychometric properties and offered greater reliability and validity for use in BCRL survivorship researches.[10] As it is well-known, the perceived health status and QoL show variability in BCRL patients with different ethnic origins. In addition, factors such as socioeconomic status, as well as number and quality of medical services vary from country to country and affect the perception of QoL.[3,8,10,16,17] Until now, there is no validated Turkish patient-reported QoL instrument for lymphedema patients. The LYMQOL is a relatively short instrument for patient-reported outcome measures that evaluates QoL in lymphedema patients and was originally developed in the UK.[15] The transcultural validation of LYMQOL was reported previously only for Dutch patients,[25] but was used in several studies.[26-29]

In this study, we tested the reliability and validity of LYMQOL-Arm in Turkish BCRL patients. In our study, there was a strong correlation between all items of the Turkish LYMQOL questionnaire, which demonstrates good internal consistency. We found that all subscales of Turkish LYMQOL had good internal consistency and test-re-test reliability. The Turkish version was reliable and internally consistent for the total questionnaire and subclass domains. (Cronbach alpha: 0.90). The reliability of the Turkish LYMQOL was good to excellent for patients with BCRL. Similar to van de Pas et al.[25] who tested the validity of Dutch LYMQOL, we found Cronbach alpha coefficients higher than the recommended level of 0.70. Our results were comparable with findings from the original validation study in UK patients with BCRL.[15] In the reliability analysis of the present study, the Cronbach alpha values of all subscales of LYMQOL-Arm were satisfactory which were consistent with other validation studies.[11-14,25]

The test re-test correlation coefficient measured by ICC showed the stability of LYMQOL-Arm in the Turkish sample. Our results were quite similar to those reported by van de Pas[24] who found test-retest reliability to be excellent and internal consistency to be good. In the original study, Keeley et al.[15] showed an internal consistency using Cronbach alpha scores ranging from 0.83 to 0.88 across all domains of the instrument in patients with upper limb lymphedema. Better than the original study internal consistency in this present study was observed to be between 0.85-0.90 which can be explained by the use of more specific breast-cancer QoL questionnaire (EORTC-BR23) rather than EORTC-30, as suggested in previous studies.[22]

In the present study, we used EORTC-QLQ-BR23 and FACT-B+4 for validity analysis. The EORTC QLQ-BR23 is a health-related QoL instrument that has been designed for patients with different stages of breast-cancer.[23] The FACT-B+4 was recommended by the Breast Cancer Edge Task force to assess QoL in patients with BCRL.[21] The Turkish LYMQOL-Arm showed significant correlation with FACT-B+4 and EORTC-BR23. Construct validity was tested in two ways and provided good results in our patient group. There was a good convergence between functional, symptom, appearance, mood scales of LYMQOL-Arm and domains of FACT-B+4 and EORTC-BR23. Symptom, function appearance and mood domains of LYMQOL-Arm had strong to moderate correlations with the expected domains of FACT-B+4 and EORTC-BR23. None of the domains (except overall score) of LYMQOL-Arm correlated with sexuality and hair loss scores in EORTC-BR23 questionnaire.

The results of this validity study can be compared favorably to those of other prior studies.[15,25,30,31] In the original study Spearman's correlation coefficients between the common scores of the LYMQOL and EORTC-30 ranged from-0.68 to 0.93 were relatively close to the range of correlations found in our study.[15] Similar to some previous studies, a more significant correlation was observed between the LYMQOL-Arm and FACT-B+4 scores supporting the external validity of the LYMQOL.[30,31]

By means of divergent validity, the LYMQOL scores were weakly correlated or showed no correlation with perceived sexuality and hair loss domains of EORTC-BR-23, as we predicted. The low or lack of correlation of some domains of EORTC-BR23 (sexuality and hair loss) with the LYMQOL subscale scores indicates that these are specific problems that may not affect the QoL in Turkish lymphedema patients. The relationship between breast cancer and sexual life

in Turkish patients was investigated previously and shown that sexual life has far less importance than survival.[5] Demirci et al.[7] demonstrated that sexuality was not an important factor for QoL in breast cancer patients living in Turkey. These issues can be explained by several reasons such as sociocultural status of the Turkish women, body image, pain, fear of recurrence. Another explanation may be that the instruments measure different aspects, LYMQOL concerns the lymphedema, others the QoL-related breast cancer and treatments.[5-7,15,21,32]

There is an unmet need for a specific instrument like LYMQOL to establish patients' QoL aspect for lymphedema and to measure and monitor improvement in the treatments. Appropriate translation of lymphedema-specific QoL tools into local language to meet the needs of the community is important. To the best of our knowledge, our study is the first to investigate the Turkish validity of a specific QoL measure for lymphedema patients in Turkey. Nonetheless, the study may have potential limitations. First, it was a cross-sectional study with the lack of responsiveness data. Therefore, further studies are needed for responsiveness of this tool. Another limitation was the exclusion of patients with psychiatric diagnoses and elderly. These patients were excluded based on the perception that they were unable to have a full comprehension of all questions. These selection criteria might have caused some limitations in the generalizability of our results for all BCRL patients.

In conclusion, the Turkish translated version of LYMQOL-Arm is a valid and reliable tool for the assessment of the QoL in patients with BCRL. The Turkish BCRL patients found the Turkish version of LYMQOL-Arm questionnaire to be easy to understand. Based on our study results, we recommend the use of LYMQOL-Arm in Turkish BCRL patients in further clinical researches and suggest the investigation of the responsiveness of this questionnaire.

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Declaration of conflicting interests

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7. Autorização do autor do instrumento original LYMQOL Arm

---------- Forwarded message ----------
From: **KEELEY, Vaughan (DERBY TEACHING HOSPITALS NHS FOUNDATION TRUST)** <vaughan.keeley@nhs.net>
Date: 2017-03-06 12:37 GMT+00:00
Subject: LYMQOL
To: "ft.joanavieira@gmail.com" <ft.joanavieira@gmail.com>
Cc: "RICHES, Katie (DERBY TEACHING HOSPITALS NHS FOUNDATION TRUST)" <katie.riches@nhs.net>

Dear Joana,
Thank you very much for your e mail.
I'm delighted to hear that you would like to translate and validate LYMQOL in Portuguese. Are you going to translate both the arm and leg versions?
My colleague, Katie Riches will send you an electronic version and our registration form.
We would be very keen to hear how you get on and would be grateful to receive a copy of any publications you have from this please.
Please pass on my best wishes to Dr Duarte. I enjoyed working with him very much.
Kind regards
Vaughan Keeley

Good morning Dr. Keeley,
My name is Joana Vieira and I'm a Women's Health master student at Alcoitão School of Health.
Your contact was given to me by my master thesis supervisor, Dr. Nuno Duarte, the portuguese physiotherapist who colaborated with you on European partership for postgraduate lymphology training - Medical School of Hannover.
For my master thesis, I would like to translate and validate the "Lymphoedema Quality of Life Questionnaire" for the portuguese population, therefore, I would like your authorization to do so.

Best regards,

Joana Vieira

NHSmail provides an email address for your career in the NHS and can be accessed anywhere
For more information and to find out how you can switch, visit www.nhsdigital.nhs.uk/nhsmail

****
****

8. Aprovação do trabalho de projeto pelo Conselho de Mestrado e Conselho Técnico-Científico da Escola Superior de Saúde do Alcoitão

Gmail

Carla Marques <csvmarques@gmail.com>

Aprovação Trabalhos de Projeto e Relatório de Estágio - 9ªa edição Mestrado

Ana Isabel Correia Matos Ferreira Vieira <isabel.fvieira@essa.scml.pt> 29 de outubro de 2018 às 18:06
Para: "ftfabiopinheiro@gmail.com" <ftfabiopinheiro@gmail.com>, ANA RITA SOUSA DE REZENDES <anaritarezendes@gmail.com>, MANUEL JOÃO VIDEIRA DA SILVA BARBOSA DE ALMEIDA <m.jvsb.almeida@gmail.com>, ANA MARGARIDA DA ROSA NETO <anamneto4@hotmail.com>, CARLA SOFIA VAZ MARQUES <csvmarques@gmail.com>, SARA LUÍSA BARÃO VAZ <sarabaraovaz@hotmail.com>, INÊS ALEXANDRA RODRIGUES LOPES <neslopes@gmail.com>, CATARINA ALEXANDRA SEQUEIRA SOBRAL <Catarina_sobral433@hotmail.com>, MARLENE JESUS CASTELHANO SANTINHO <santinho.mjc@gmail.com>
Cc: "Patricia Almeida (patriciamdalmeida@gmail.com)" <patriciamdalmeida@gmail.com>, "Fatima Sancho (mfsancho1@gmail.com)" <mfsancho1@gmail.com>, Fátima Sancho <mfsancho@clix.pt>, António Manuel Fernandes Lopes <antoniomf.lopes@essa.scml.pt>, Rui Soles Gonçalves <ruisolesgoncalves@gmail.com>, Maria Lapa Capacete Rosado <maria.rosado@essa.scml.pt>, Nuno Duarte <nmfbduarte@netcabo.pt>, José Manuel Fernandes Esteves <josem.esteves@essa.scml.pt>

Caros estudantes,

Caros orientadores,

Informo que as propostas dos Trabalhos de Projeto e Relatório de Estágio (contratos de aprendizagem), assim como dos respetivos orientadores, relativos à 9ª edição do Mestrado em Fisioterapia e entregues até à data, foram aprovados em sede de Conselho de Mestrado e de Conselho Técnico-Científico.

Trabalhos de Projeto

Fábio Pinheiro

Título: Força de Preensão Manual e Função Cognitiva: Caracterização de uma População Idosa a Viver na Comunidade

Orientador: Professora Doutora Maria da Lapa Rosado

Ana Rita Sousa de Rezendes

Título: Tradução e Adaptação da Lower Extremity Functional Scale para a população portuguesa

Co-orientadores: Professor Doutor Rui Soles Gonçalves (ao abrigo do Protocolo da ESSA com o CEISUC) e Professor José Manuel Esteves

Manuel João Videira da Silva Barbosa de Almeida

Título: Reabilitação do joelho pós-meniscectomia: A influência do biofeedback eletromiográfico num programa de fisioterapia

Orientador: Professor José Manuel Esteves

Ana Margarida da Rosa Neto

Título: Prática de atividade física em idosos saudáveis: avaliação de um programa estruturado de exercícios

Orientador: Professora Doutora Maria da Lapa Rosado

Carla Sofia Vaz Marques

Título: Contributo para a validação para o português europeu do instrumento de medição Limb Lymphoedema Quality of Life “LYMQOL ARM” - membro superior)

Co-orientadores: Professor Doutor Rui Soles Gonçalves (ao abrigo do protocolo da ESSA/CEISUC) e Professor Doutor Nuno Bento Duarte

9. Pedido de autorização ao Instituto Português de Oncologia de Lisboa Francisco Gentil

Exmo Sr. Presidente do Conselho de
Administração do Instituto
Português de Oncologia de Lisboa
Francisco Gentil EPE
Sr. Dr. Francisco Ramos

Lisboa, 25 de junho de 2018

Assunto: Realização de estudo de investigação

Carla Sofia Vaz Marques, fisioterapeuta, encontrando-se a frequentar o Mestrado em Fisioterapia, na área de especialização na Saúde da Mulher – 9ª edição, na Escola Superior de Saúde do Alcoitão, Santa Casa da Misericórdia de Lisboa, vem por este meio solicitar a V Exª autorização para a realização de um estudo de investigação na instituição que superiormente dirige, nos moldes referidos no Anteprojeto de Investigação (cópia em anexo).

O estudo tem como titulo "**Contributo para a validação para o português europeu do instrumento de medida Limb Lymphoedema Quality of Life "LYMQOL ARM"**

O estudo tem como objetivo contribuir para a validação para o português europeu do instrumento de medida Limb Lymphoedema Quality of Life "LYMQOL ARM". Será realizado através do processo de avaliação das características métricas de fiabilidade e validade de construção.

Os orientadores do projeto são o Sr. Professor Doutor Rui Soles Gonçalves e o Sr. Professor Doutor Nuno Duarte, que exerce funções no serviço de Medicina Física e Reabilitação deste Instituto. Ambos se apresentam disponíveis para qualquer esclarecimento.

Agradecendo antecipadamente a atenção dispensada, apresenta os melhores cumprimentos.
Pede deferimento,

10. Aprovação do Conselho de Investigação do IPOLFG

Conceicao Costa

De: Ana Miranda
Enviado: segunda-feira, 15 de outubro de 2018 12:07
Para: Conceicao Costa
Cc: Helena Correia
Assunto: RE: Submissão de Projeto de Investigação de Carla Marques - UIC/1216

Bom Dia Conceição,
Considero que estão respondidas as questões que coloquei e corrigido o aspecto que referi quanto à recepção dos questionários.

Com os meus cumprimentos

Ana da Costa Miranda
RON – Registo Oncológico Nacional
SNS SERVIÇO NACIONAL DE SAÚDE RON Registo Oncológico Nacional

Rua Prof. Lima Basto
1099-023 Lisboa
Telef: 217229852
http://ron.min-saude.pt

De: Conceicao Costa
Enviada: segunda-feira, 15 de outubro de 2018 11:58
Para: Ana Miranda
Cc: Helena Correia
Assunto: FW: Submissão de Projeto de Investigação de Carla Marques - UIC/1216

Dra. Ana Miranda,

No seguimento do seu parecer (em anexo para confirmar) com pedido de esclarecimentos, reencaminho as respostas da investigadora para avaliação final.
Muito obrigada e cumprimentos,

Conceição Costa

De: Carla Marques [mailto:csvmarques@gmail.com]
Enviada: sexta-feira, 12 de outubro de 2018 10:11
Para: Conceicao Costa
Assunto: Re: Submissão de Projeto de Investigação de Carla Marques - UIC/1216

Assunto: Projecto de investigação intitulado **"Contributo para a validação para o português europeu do instrumento de medida Limb Lymphoedema Quality of Life "LYMQOL ARM"** – UIC/1216.

Cara Dra. Conceição Costa,

Venho por este meio enviar esclarecimento das questões colocadas relativamente ao projeto de investigação, conforme solicitado.

- O instrumento EORTC QLQ C-30 vai ser usado como medida concorrente para testar a validade de construção do LYMQOL, ou seja, para avaliar até que ponto as pontuações obtidas por subescalas dessas medidas (que meçam constructos similares) se relacionam.

- A dimensão da amostra é de 100 utentes.
Dos 100 utentes avaliados, 50 serão reavaliados para determinação de teste da reprodutibilidade (também designada de fiabilidade teste-reteste).
Todos os questionários serão codificados para permitir a futura alocação do questionário com o indivíduo a avaliar (o código será colocado nos questionários e ficha de caracterização da amostra, permitindo que não existam dados que possam identificar o indivíduo no cabeçalho do questionário).

- Será corrigido no projeto a questão da morada para o envio dos questionários preenchidos em casa pelos 50 utentes.
A morada será a do Serviço de Medicina Física e Reabilitação do IPOLFG, A/C do Responsável pela Investigação na Instituição/Fisioterapeuta Coordenador.

Caso seja necessário mais algum esclarecimento, estou ao dispor.

Grata,
Com os melhores cumprimentos,
Carla Sofia Marques

Conceicao Costa <CONCOSTA@ipolisboa.min-saude.pt> escreveu no dia quinta, 11/10/2018 à(s) 13:57:

Assunto: Projecto de investigação intitulado **"Contributo para a validação para o português europeu do instrumento de medida Limb Lymphoedema Quality of Life "LYMQOL ARM"** – UIC/1216.

Dra. Carla Marques,

No âmbito da submissão do estudo mencionado em epígrafe, junto envio o parecer do Conselho de Investigação com pedido de esclarecimentos.

Ficando aguardar uma resposta da sua parte, apresento os melhores cumprimentos,

Conceição Costa

De: Carla Marques [mailto:csvmarques@gmail.com]
Enviada: segunda-feira, 16 de julho de 2018 11:00
Para: Conceicao Costa
Cc: Nuno Duarte; Rui Soles Gonçalves
Assunto: Submissão de Projeto de Investigação de Carla Marques

Dra. Conceição Costa,

Sou Carla Sofia Vaz Marques, uma aluna do Mestrado de Fisioterapia em Saúde da Mulher, da Escola de Saúde do Alcoitão.

Pretendo realizar um estudo de investigação com a colaboração do Instituto Português de Oncologia de Lisboa Francisco Gentil (IPOLFG). Tenho como orientadores o Dr. Rui Gonçalves e o Dr. Nuno Duarte, Fisioterapeuta coordenador do Serviço de Medicina Física e Reabilitação do IPOLFG.

O Dr. Nuno Duarte facultou-me o seu endereço eletrónico, bem como a lista dos documentos necessários para a submissão do projeto de investigação ao IPOLFG, que se encontram em anexo. São eles:

- Carta de pedido de autorização dirigida ao Conselho de Administração;
- Formulário de Submissão de projectos de investigação (UIC.MOD.104.2);
- Minuta relativa ao envio do relatório final do estudo á UIC (UIC.MOD.103.1);
- Autorização do Director do Serviço onde está prevista a realização do estudo (UIC.MOD.101.1);
- *Curriculum Vitae* (resumido) do investigador;
- Protocolo do estudo;
- Consentimento Informado e termo explicativo do estudo
- Formulários de recolha de dados (CRF´s)

Caso seja necessário mais algum documento ou informação, estou ao dispor,

Grata,

Com os melhores cumprimentos,

Carla Sofia Marques

IPOLFG, EPE	Parecer do Conselho de investigação	UIC
	INSTITUTO PORTUGUÊS DE ONCOLOGIA DE LISBOA FRANCISCO GENTIL, EPE Unidade de Investigação Clínica	

Tipo de Projecto: Ensaio Clínico ☐ Estudo Observacional ☒
Investigação Básica ☐ Estudo Laboratorial ☐

Título: **Contributo para a validação para o português europeu do instrumento de medida Limb Lymphoedema Quality of Life "LYMQOL ARM – UIC/1216**

Promotor/ Entidade financiadora: **Escola Superior de Saúde de Alcoitão**

Investigador Responsável: Carla Vaz Marques

Serviços participantes Serviço de Medicina Física e Reabilitação

PARECER DO CONSELHO DE INVESTIGAÇÃO:

O Estudo é muito pertinente, pois trata-se da validação de uma escala para avaliação da qualidade de vida em mulheres com linfedema, problema frequente em mulheres tratadas para cancro da mama, e que permite avaliar a qualidade do tratamento subsequente para esta morbilidade., subsequente ao tratamento do tumor. Os objectivos estão bem definidos e o método de analise também.

Não é claro o motivo do preenchimento de questionários que já estão validados (QLQ-C 30), o da saúde mental ainda se compreende pois permite determinar o cumprimento de um dos critérios de inclusão.

Gostaria de ver esclarecida a **dimensão da amostra**, pois na pag 8 escrevem 100 doentes, na pagina 14 todas as doentes que aceitem participar e na página seguinte referem que o segundo questionário será entregue a 50 doentes, **devidamente codificado** – gostaria de ver esclarecida **esta frase**.

Não me parece adequado que os inquéritos para preenchimento em casa, sejam enviados para casa do investigador.

Considero que é de aprovar a realização deste estudo após esclarecimento das questãoes acima colocadas

Data: 2018-10-11

Assinatura:

Pelo Conselho de Investigação

11. Aprovação do Conselho de Ética do IPOLFG

IPOLFG, EPE	Apreciação e Votação de Parecer	CE
	INSTITUTO PORTUGUÊS DE ONCOLOGIA DE LISBOA FRANCISCO GENTIL, EPE Comissão de Ética	

Apreciação do Parecer

Data da Reunião: 06-12-2018

Título do Projeto: "Contributo para a validação para o português europeu do instrumento de medida *Limb Lymphoedema Quality of Life* "LYMQOL ARM" - UIC/1216

A Presidente da Comissão de Ética para a Saúde (CES) do Instituto Português de Oncologia de Lisboa Francisco Gentil, EPE, apreciou a fundamentação do perito sobre o pedido de realização do projeto acima identificado.

Resultado da Votação:

Parecer: Favorável (fundamentação em anexo)

Data: 10-12-2018

A Presidente da Comissão de Ética para a Saúde
do IPOLFG-EPE

Dra Filomena Pereira

Recebi no dia
14/12/2018
E. Costa

Parecer da Comissão de Ética sobre o projecto de investigação intitulado **"Contributo para validação para o português europeu do instrumento de medida Limb Lymphoedema Quality of Life "LYMQOL - ARM"** - UIC/1216

Trata-se de um estudo de Investigação básica, observacional, constituindo Investigadora Principal a licenciada em Fisioterapia Carla Marques, que se encontra a frequentar o Mestrado em Fisioterapia - 9º Edição do Mestrado - ramo de especialização em Saúde da Mulher - na ESSA. Sob orientação do Centro de Estudos e Investigação em Saúde da Universidade de Coimbra (CEISUC) e co-orientação do Doutor Nuno Duarte do Serviço de Medicina Física e Reabilitação do IPOLFG, sendo este o Serviço devidamente autorizado pela respectiva Directora, onde decorrerá o projecto apresentado em epígrafe.

Com o objectivo de traduzir e adaptar culturalmente para a realidade portuguesa o instrumento LYMQOL - Lymphema Quality of Life, que avalia a qualidade de vida em doentes com linfedema, será realizado um teste de compreensão a um conjunto de 100 indivíduos maiores de 18 anos que apresentem linfedema, unilateral ou bilateral do membro superior pós cirurgia do cancro da mama tratados no IPOLFG. Serão utilizados também neste estudo, os questionários de caracterização da qualidade de vida nos indivíduos com cancro, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ C-30), que servirão de medida concorrente para testar a validade de construção do LYMQQOL ARM, i.e., para avaliar até que ponto as pontuações obtidas por subescalas dessas medidas se relacionam.

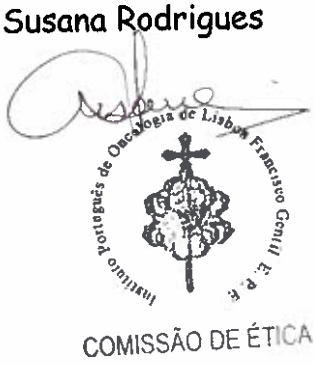
Na folha de Informação ao Doente participante e Formulário de Consentimento Informado estão devidamente enunciados os objectivos do estudo, a salvaguarda da confidencialidade e do anonimato dos dados e variáveis recolhidos. Sendo claro e explicito quanto à natureza do estudo, faz referencia de modo inequívoco à participação voluntária, à decisão de não participar ou de poder sair do estudo a qualquer momento sem que exista qualquer compromisso ou repercussão sobre os cuidados a ministrar. A concretização do presente projecto não implica a realização de despesa adicional para o IPOLFG.

Entende pois esta Comissão de Ética, nada ter a opôr ao prosseguimento do projecto de investigação mencionado em epígrafe, que comprometa o tratamento, salvaguarda e segurança dos doentes envolvidos no estudo.

IPOLFG-EPE, 04/12/2018

A Comissão de Ética,

Susana Rodrigues



12. Autorização final da Unidade de Investigação Clínica do IPOLFG

161967

INSTITUTO PORTUGUÊS DE ONCOLOGIA DE LISBOA FRANCISCO GENTIL, E.P.E.

Unidade de Investigação Clínica

NOTA DE SERVIÇO

De: Unidade de Investigação Clínica
Conceição Costa

Data: 18/12/2018

Para: Dr. João Freire
Vogal Executivo do Conselho de Administração

N.º : 163/2018

Assunto: Projecto de investigação intitulado **"Contributo para a validação para o português europeu do instrumento de medida Limb Lymphoedema Quality of Life "LYMQOL ARM" - UIC/1216.**

Obtidos os pareceres favoráveis do Conselho de Investigação e Comissão de Ética, junto envio para autorização final o estudo mencionado em epígrafe.

Com os melhores cumprimentos,

AUTORIZO
19/12/2018

Conceição Costa
Unidade de Investigação Clínica

João Geraldes Freire
Vogal do Conselho de Administração

13 DEZ. 2018

13. Instrumento de medida LYMQOL Braço (versão portuguesa)

LYMQOL BRAÇO
Instrumento de Qualidade de Vida no Linfedema

Este questionário foi construído e validado para medir a qualidade de vida de doentes com edema crónico/linfedema de um ou de ambos os braços (membro superior).
Marque, por favor, a resposta que melhor descreve como se sente relativamente a cada uma das perguntas.

(P1) Sente que o braço inchado afeta as seguintes atividades da vida diária?
Se algum dos pontos não se aplicar ao seu caso, por favor, assinale na coluna N/A.

	Nada	Um pouco	Bastante	Muito	N/A
a) exercer a sua profissão					
b) tarefas domésticas					
c) pentear-se					
d) vestir-se					
e) escrever					
f) comer					
g) lavar-se					
h) lavar os dentes					

	Nada	Um pouco	Bastante	Muito
(P2) Sente que o braço inchado afeta as suas atividades de tempos livres / vida social?				

Por favor, dê exemplos .....

.....

	Nada	Um pouco	Bastante	Muito
(P3) Sente que tem de depender de outras pessoas?				
(P4) Sente que o inchaço do braço afeta a sua aparência?				
(P5) Sente dificuldade em encontrar roupa que lhe sirva?				
(P6) Sente dificuldade em encontrar roupa que gostaria de vestir?				
(P7) Sente que o inchaço do braço afeta a ideia que tem de si?				
(P8) Sente que o inchaço do braço afeta a sua relação com outras pessoas?				
(P9) Tem dor no seu braço inchado/linfedema ?				
(P10) Sente alguma dormência no seu braço inchado?				

	Nada	Um pouco	Bastante	Muito
(P11) Sente picadas ou formigueiro no seu braço inchado?				
(P12) Sente fraqueza no seu braço inchado?				
(P13) Sente o seu braço inchado pesado?				
(P14) Sente-se cansado/a?				

Durante a última semanaé .

	Nada	Um pouco	Bastante	Muito
(P15) Teve dificuldade em dormir?				
(P16) Teve dificuldade em concentrar-se, por exemplo, para ler o jornal ou ver televisão?				
(P17) Sentiu-se tenso/a?				
(P18) Teve preocupações?				
(P19) Sentiu-se irritável?				
(P20) Sentiu-se deprimido/a?				

(P21) Como classificaria, em geral, a sua atual qualidade de vida?
Escolha um valor na seguinte escala:

0 1 2 3 4 5 6 7 8 9 10
Péssima **Ótima**

Obrigado por ter preenchido este questionário.

14. Instrumento de medida EORTC QLQ C – 30 (versão portuguesa)

EORTC QLQ-C30 (version 3)

Gostaríamos de conhecer alguns pormenores sobre si e a sua saúde. Por favor, responda você mesmo/a a todas as perguntas fazendo um círculo à volta do número que melhor se aplica ao seu caso. Não há respostas certas nem erradas. A informação fornecida é estritamente confidencial.

Escreva as iniciais do seu nome: |_|_|_|_|
A data de nascimento (dia, mês, ano): |_|_| |_|_| |_|_|_|_|
A data de hoje (dia, mês, ano): 31 |_|_| |_|_| |_|_|_|_|

		Não	Um pouco	Bastante	Muito
1.	Custa-lhe fazer esforços mais violentos, por exemplo, carregar um saco de compras pesado ou uma mala?	1	2	3	4
2.	Custa-lhe percorrer uma grande distância a pé?	1	2	3	4
3.	Custa-lhe dar um pequeno passeio a pé, fora de casa?	1	2	3	4
4.	Precisa de ficar na cama ou numa cadeira durante o dia?	1	2	3	4
5.	Precisa que o/a ajudem a comer, a vestir-se, a lavar-se ou a ir à casa de banho?	1	2	3	4

Durante a última semana :

		Não	Um pouco	Bastante	Muito
6.	Sentiu-se limitado/a no seu emprego ou no desempenho das suas actividades diárias?	1	2	3	4
7.	Sentiu-se limitado/a na ocupação habitual dos seus tempos livres ou noutras actividades de lazer?	1	2	3	4
8.	Teve falta de ar?	1	2	3	4
9.	Teve dores?	1	2	3	4
10.	Precisou de descansar?	1	2	3	4
11.	Teve dificuldade em dormir?	1	2	3	4
12.	Sentiu-se fraco/a?	1	2	3	4
13.	Teve falta de apetite?	1	2	3	4
14.	Teve enjoos?	1	2	3	4
15.	Vomitou?	1	2	3	4

Por favor, passe à página seguinte

Durante a última semana :	**Não**	**Um pouco**	**Bastante**	**Muito**
16. Teve prisão de ventre?	1	2	3	4
17. Teve diarreia?	1	2	3	4
18. Sentiu-se cansado/a?	1	2	3	4
19. As dores perturbaram as suas actividades diárias?	1	2	3	4
20. Teve dificuldade em concentrar-se, por exemplo, para ler o jornal ou ver televisão?	1	2	3	4
21. Sentiu-se tenso/a?	1	2	3	4
22. Teve preocupações?	1	2	3	4
23. Sentiu-se irritável?	1	2	3	4
24. Sentiu-se deprimido/a?	1	2	3	4
25. Teve dificuldade em lembrar-se das coisas?	1	2	3	4
26. O seu estado físico ou tratamento médico interferiram na sua vida familiar?	1	2	3	4
27. O seu estado físico ou tratamento médico interferiram na sua actividade social?	1	2	3	4
28. O seu estado físico ou tratamento médico causaram-lhe problemas de ordem financeira?	1	2	3	4

Nas perguntas que se seguem faça um círculo à volta do número, entre 1 e 7, que melhor se aplica ao seu caso

29. Como classificaria a sua saúde em geral durante a última semana?

1	2	3	4	5	6	7
Péssima						Óptima

30. Como classificaria a sua qualidade de vida global durante a última semana?

1	2	3	4	5	6	7
Péssima						Óptima

15. Autorização para uso do EORTC QLQ C – 30

Gmail Carla Marques <csvmarques@gmail.com>

Your request for an EORTC-questionnaire Request ID : 56540

1 mensagem

no-reply@eortc.be <no-reply@eortc.be> 11 de outubro de 2018 às 13:03
Para: csvmarques@gmail.com

Dear Carla Marques,

Thank you for registering on the EORTC Quality of Life Group website.

Your registration to obtain permission to use our tools has been approved. During the registration process you agreed to our terms and conditions regarding the academic use of our questionnaires. You can review the terms and conditions here.

Please find below the links to the requested tools:

QLQ-C30 Core Questionnaire - Portuguese

Scoring Manuals:

EORTC

http://www.eortc.org

http://qol.eortc.org

NOTE:
This email was automatically generated. Since this email is an automatic notification, we are unable to receive replies. Please do not respond to this email address.

http://www.eortc.be/signatures/signature_stats_525x166_2018.jpg

Disclaimer |

16. Termo explicativo do estudo

TERMO EXPLICATIVO DO ESTUDO

Contributo para a validação para o português europeu do instrumento de medida Limb Lymphoedema Quality of Life "LYMQOL ARM"

Investigador: Carla Sofia Vaz Marques, Fisioterapeuta

Ex.mo Senhor (a),
No âmbito do Mestrado em Fisioterapia, ramo de Saúde da Mulher, o autor está a realizar um estudo que mede a qualidade de vida do indivíduo com linfedema do membro (s) superior (es), e gostaria de o (a) convidar a participar.
Este documento descreve o estudo. Por favor, leia-o atentamente.

Objetivo do estudo?
Contribuir para a validação para o português europeu do instrumento de medida Limb Lymphoedema Quality of Life "LYMQOL ARM", ou seja adaptar o questionário de qualidade de vida do indivíduo com linfedema do membro(s) superior(es), a fim de tornar possível a sua utilização em Portugal.

O que será pedido se participar?
Será pedido que preencha dois questionários diferentes acerca da qualidade da vida. Um de âmbito geral e o outro mais relacionado com o linfedema do membro (s) superior (es). Será ainda necessário que preencha uma ficha com os seus dados pessoais e clínicos.
Poderá ser pedido que responda novamente ao questionário específico relacionado com a qualidade de vida e o linfedema, e o coloque no correio (será, para isso disponibilizado o questionário e um envelope já com selo).

Vantagens em participar?
A escolha de participar ou não no estudo é voluntária. O presente estudo não acarreta qualquer risco, não trazendo também qualquer vantagem direta para os que nele participam. Caso o utente não consinta a sua participação no estudo ou o abandone, a qualidade dos cuidados prestados pelo Instituto Português de Oncologia de Lisboa, não será em nada afetada.
Ao participar neste estudo, possibilitará conhecer-se a perceção do utente sobre o impacto que lhe causaram o diagnóstico e a terapêutica. Tem, também, o poder de contribuir para a melhoria da prestação dos cuidados de saúde.

Existe algum custo na participação?
Esta participação não envolve quaisquer encargos financeiros da sua parte.

Uso dos meus dados pessoais?
Todo o material recolhido no estudo será codificado e tratado de forma confidencial,
sendo conservado sob a responsabilidade dos investigadores, estando os resultados à disposição, a pedido dos interessados. As leis de proteção de dados pessoais serão observadas.

Quem posso contactar, caso queira esclarecer alguma dúvida?
Em caso de dúvida que tenha relativamente ao estudo e à sua participação no mesmo poderá contactar através de endereço eletrónico.

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b) Responsável pela investigação na instituição/ fisioterapeuta coordenador Nuno Duarte: nduarte@ipolisboa.min-saude.pt

Agradecemos desde já a sua colaboração e vontade em participar.

17. Consentimento informado do estudo

CONSENTIMENTO INFORMADO

Título do estudo: **Contributo para a validação para o português europeu do instrumento de medida Limb Lymphoedema Quality of Life "LYMQOL ARM"**

Declaro ter lido em documento anexo todos os procedimentos relativos ao estudo e compreendido todas as informações verbais que me foram fornecidas pelo/a investigador/a.

Declaro que o objetivo do estudo e os procedimentos envolvidos me foram devidamente explicados, tendo compreendido tudo o que me foi dito.

Aceito que os meus dados sejam utilizados para os objetivos descritos no estudo, tendo-me sido garantido que os mesmos serão tratados confidencialmente, omitindo o meu nome e protegendo a minha imagem. Foi-me garantida a possibilidade de, em qualquer altura, recusar participar neste estudo sem qualquer tipo de consequências.

Desta forma, aceito participar neste estudo e permito a utilização dos dados que de forma voluntária forneço, confiando nas garantias de confidencialidade e anonimato que me são dadas pelo/a investigador/a. Foi-me entregue uma cópia do termo explicativo do estudo e da folha de consentimento informado.

Nome do participante: … … … … … … … …... … … … …... … … … … … … …

Assinatura: … … … … … … … … …... … … … Data: ……. /……. /……...

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Declaro que o participante foi informado da natureza, dos objetivos do estudo e sobre os seus possíveis benefícios e riscos, utilizando uma linguagem compreensível e apropriada. O participante afirmou ter compreendido a minha explicação.

Nome da pessoa que obteve o consentimento: … … … … … … … …... … … … …...

18. Ficha de dados sociodemográficos e clínicos

Dados Sociodemográficos e Clínicos

Data:_____/_____/_____

Nome:_____

1. Idade: _____anos

2. Género: ☐ Masculino ☐ Feminino

3. Nº de anos de escolaridade concluídos _____

4. Profissão:_____

5. Estado civil: ☐ Solteiro/a ☐ Casado/a ☐ Divorciado/a ☐ Viúvo/a ☐ União de facto

6. Peso: ____ kg

7. Altura: ____ cm

8. Membro superior dominante: ☐ Direito ☐ Esquerdo

9. Localização do Linfedema:_____

☐ Direito ☐ Esquerdo ☐ Direito e Esquerdo

10. Diagnóstico histológico: _____

11. Terapias realizadas:

☐ Cirurgia:_____; Data de realização:___/___/_____

☐ Radioterapia; Data de realização:___/___/_____

☐ Quimioterapia; Data de realização:___/___/_____

☐ Hormonoterapia; Data de realização:___/___/_____

☐ Imunoterapia; Data de realização:___/___/_____

☐ Outras terapias; Data de realização:___/___/_____

12. Início do linfedema (nº de anos ou meses): ____anos ____meses

13. Comportamento do edema ao longo do dia: ☐ Constante ☐ Pior de manhã ☐ Pior ao fim do dia

14. Número de episódios de infeções subcutâneas: _____