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Original Article / Özgün Makale

The Lymphedema Functioning, Disability, and Health Questionnaire for Lower Limb Lymphedema: Translation, reliability, and validation study of the Turkish version

Alt Ekstremite Lenfödeminde Lenfödem İşlevsellik, Özürlülük ve Yaşam Kalitesi Ölçeği: Türkçe versiyonunun çevirisi, geçerlik ve güvenirlik çalışması

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ABSTRACT

Background: This study aims to perform translation, reliability, and validation study of the Lymphedema Functioning, Disability, and Health Questionnaire for Lower Limb Lymphedema into the Turkish language.

Methods: A total of 50 patients (14 males, 36 females; mean age 50.3±12.9 years; range 21 to 70 years) diagnosed with lower limb lymphedema were asked to fill out the Turkish version of the original questionnaire two times, seven days apart. Internal consistency was tested using the Cronbach's alpha and the test-retest reliability was assessed by calculating the intra-class correlation coefficient. Construct validity was examined by comparing the results of the lymphedema questionnaire and Short Form-36 questionnaire.

Results: The test-retest reliability (range, 0.79 to 0.93) and the Cronbach alpha values (range, 0.79 to 0.94) of the lymphedema questionnaire total scores, physical function scores, mental function scores, general tasks/household scores, mobility scores, and life domains/social life scores were found to be excellent. Most of the Short Form-36 subscale (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, mental health) and the lymphedema questionnaire subscales were significantly correlated (range, 0.006 to 0.01). Only the lymphedema total scores were not correlated with any subscale of the Short Form-36.

Conclusion: The Turkish version of the Lymphedema Functioning, Disability, and Health Questionnaire for Lower Limb Lymphedema was found to be valid and reliable for patients with lower limb lymphedema.

Keywords: Lower limb lymphedema; Lymph-ICF-LL; reliability; validity.

ÖZ

Amaç: Bu çalışmada Alt Ekstremite Lenfödeminde Lenfödem İşlevsellik, Özürlülük ve Yaşam Kalitesi Ölçeği'nin Türkçe diline çevirisi, güvenirlik ve geçerlik çalışması yapıldı.

Çalışma planı: Alt ekstremite lenfödem tanısı konan toplam 50 hastadan (14 erkek, 36 kadın; ort. yaş 50.3±12.9 yıl; dağılım 21-70 yıl) original anketin Türkçe versiyonunu yedi gün arayla iki kez cevaplaması istendi. İç tutarlılık, Cronbach alfa kullanılarak test edildi ve test-tekrar test güvenirliği sınıf içi korelasyon katsayısı hesaplanarak değerlendirildi. Yapısal geçerliği, lenfödem anketi ve Kısa Form-36 anket sonuçları karşılaştırarak araştırıldı.

Bulgular: Lenfödem anketi toplam skoru, fiziksel fonksiyon skoru, ruhsal fonksiyon skoru, genel görevler/ev işi skoru, hareketlilik skoru ve yaşam alanları/sosyal yaşam skoru test-tekrar test güvenirliği (dağılım: 0.79-0.93) ve Cronbach alfa değeri (dağılım: 0.79-0.94) mükemmel bulundu. Kısa Form-36 alt ölçeğinin büyük bir kısmı (fiziksel işlevsellik, fiziksel-rol, bedensel ağrı, genel sağlık, canlılık, sosyal işlevsellik, duygusal-zihinsel sağlık rolü) ve lenfödem anketinin alt ölçekleri anlamlı düzeyde ilişkili idi (dağılım: 0.006-0.01). Yalnızca lenfödem toplam skoru, Kısa Form-36 alt ölçeklerinin hiçbiri ile ilişkili değildi.

Sonuç: Alt Ekstremite Lenfödeminde Lenfödem İşlevsellik, Özürlülük ve Yaşam Kalitesi Ölçeği'nin Türkçe versiyonu, alt ekstremite lenfödemli hastalar için geçerli ve güvenilir bulundu.

Anahtar sözcükler: Alt ekstremite lenfödemi; Lymph-ICF-LL; güvenirlik; geçerlik.

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Lymphedema is a serious and potentially debilitating condition which occurs, when the transport capacity of the lymphatic system falls below the lymphatic load, resulting in the accumulation of protein-rich lymph fluids in the subcutaneous tissues.[1] It can be a grossly disfiguring condition, usually affecting a limb, which causes discomfort and pain, and can be complicated by recurrent infections often requiring hospital admission.[2] Recurrent infections can cause permanent lower limb lymphedema, particularly in susceptible patients. In addition, lympadenectomy for neoplasms with lymph node metastasis and radiotherapy of the inguinal region are also causes of permanent lymphedema.[3] Untreated limbs can become huge, which is referred to as elephantiasis. Sufferers often report the psychological impact of the condition to be considerable.[4]

Lower limb lymphedema results in many symptoms such as decreased mobility of the limb, pain, tissue fibrosis, and associated skin changes. It is also associated with psychosexual dysfunction and impaired quality of life.[5-7] In general, the activity level of a lymphedema patient is lower, compared to a healthy individual of the same age.[8]

Patients with lower limb lymphedema report other problems in functioning, besides swelling, associated with their lymphedema.[9] A comprehensive evaluation should include other problems in functioning associated with the development of lymphedema. There are many tools which can measure the quality of life, but not specific to lower limb lymphedema.[10-12]

There is an International Classification, Disability and Health (ICF)-based and compact tool which can be used to evaluate functional problems associated only with lower limb lymphedema. The Lymphedema Functioning, Disability, and Health Questionnaire for Lower Limb Lymphedema (Lymph-ICF-LL) is a tool which assess impaired function, activity limitations, and participation restrictions in patients with primary or secondary lower limb lymphedema.[13]

In the present study, we aimed to perform translation, reliability, and validation study of the Lymph-ICF-LL into the Turkish language in patients with lower limb lymphedema.

PATIENTS AND METHODS

The Lymph-ICF-LL was translated into Turkish and culturally adapted in accordance with stages recommended by Beaton et al.[14] The patients were diagnosed with lower limb lymphedema by cardiovascular surgeons through lymphoscintigraphic measurements. All patients had chronic lower limb lymphedema of Stage I-II of the clinical classification. Stage I refers to an early accumulation of fluid relatively high in protein content and subsides with limb elevation. Stage II refers to that limb elevation no longer reduces tissue swelling and pitting is manifest. Later in Stage II, pitting is less evident as tissue fibrosis supervenes.[15] Inclusion criteria were as follows: unilateral or bilateral lower limb lymphedema for a duration of at least three months, age between 18 and 75 years, and the ability to reply to visual or verbal instructions. Exclusion criteria were as follows: lymphangitis, cellulitis, heart failure, chronic venous diseases, and musculoskeletal problems. Based on these criteria, a total of 50 patients (14 males, 36 females; mean age 50.3±12.9 years; range 21 to 70 years) were included in the study.

The study was approved by the institutional Ethics Committee. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

The Lymph-ICF-LL questionnaire

The scale consists of 28 questions with five domains: physical function, mental function, general tasks/household, mobility, and life domains/social life. Each question is scored on an 11-point scale. The patients are asked to score their average impairments in function, activity limitations, and participation restrictions due to lower limb lymphedema during the past two weeks. The questionnaire is a self-assessment tool and takes about five min to complete.

The Short-Form 36 (SF-36) Quality of Life scoring system questionnaire

The SF-36 scale was used to establish a health profile in the present study and comprises of eight scaled scores: each scale is directly transformed into a scale from 0 to 100 to identify the patient's physical and mental state. The correlation between the SF-36 and Lymph-ICF-LL was evaluated.[16]

The English version of the Lymph-ICF-LL was adapted for Turkish use according to the established guidelines for cross-cultural adaptation of self-reported questionnaires. The guideline includes five steps: In the first step, the English translation of the Lymph-ICF-LL was translated into Turkish by two independent Turkish native speakers who are fluent in English. In the second step, both translations were assembled by two translators and a team of experts. In the third step, the Turkish translation of the Lymph-ICF-LL was translated back into English

by two individuals who were bilingual native English speakers. In the fourth step, all translations were reviewed by an Expert Committee including forward and back translators. In the fifth step, the pre-final versions of the Turkish Lymph-ICF-LL were tested with 15 patients with lymphedema to evaluate the accuracy of wording and understanding of the test items in an outpatient physiotherapy department. The interviewer defined and recorded any problems occurring during the filling out of the pre-final Turkish Lymph-ICF-LL questionnaire. Considering these issues, a final version of the Turkish Lymph-ICF-LL was established. The questions were found to be understandable by all patients and there were no ambiguities.

The reliability and validity of the final Turkish version of the Turkish Lymph-ICF-LL were tested in 50 patients with lower limb lymphedema. All patients completely filled out the Turkish version of the Lymph-ICF-LL and the Turkish version of the SF-36 at the first visit. In the second visit which was performed seven days after, the patients re-filled out the Lymph-ICF-LL questionnaire.

Statistical analysis

The IBM SPSS software version 21.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. The reliability of the Lymph-ICF-LL scale was performed using the Intra-class Correlation Coefficient Type 2:1 (ICC [2:1]) test-retest methodology in the full sample recorded at the baseline and seven days following a period of off-treatment. Internal consistency of the Lymph-ICF-LL was assessed using the Cronbach alpha. Internal consistency was considered acceptable, when the Cronbach alpha was >0.7. The Pearson's correlation coefficients were used to evaluate the construct validity, as the Lymph-ICF-LL and SF-36 scores were continuous variables and were normally distributed. Correlation coefficients were rated as follows: strong correlation r>0.75; moderate r=0.50-0.74; and poor ≤0.49.[17] A p value of ≤0.05 was considered statistically significant.

RESULTS

The questionnaires were filled out by all patients. Demographic and clinical characteristics of the patients are shown in Table 1. The affected side was unilateral lower limb in 24 patients (48%) and bilateral lower limb in 26 patients (52%). Based on the clinical assessment, 32 patients (64%) were diagnosed with primary lymphedema, while 18 patients (36%) were diagnosed with secondary lymphedema.

The test-retest stability with a seven day interval showed that the difference between the two measurement periods was not statistically significant (p>0.05). The results of reliability analyses are presented in Table 2. The test-retest reliability (ICC range, 0.79 to 0.93), Cronbach alpha values (range: 0.79 to 0.94) of the

Table 1. Demographic and clinical characteristics of the patients (n=50)

Characteristics	n	%	Mean±SD	Range
Age (year)			50.3±12.9	21-70
Body mass index (kg/m^2)			19.75±7.5	19.7-48.8
Gender				
Male	14	28		
Female	36	72		
Affected side of lymphedema				
Unilateral lymphedema (right/left)	24	48		
Bilateral lymphedema (both)	26	52		
Duration of lymphedema (month)			92.86±34.9	7-600
Stage				
Stage I	7	14		
Stage II	43	86		
Type of lymphedema				
Primary	32	64		
Secondary	18	36		
Localization of lymphedema				
Foot + cruris + thigh	10	20		
Foot + cruris	34	68		
Foot	6	12		

SD: Standard deviation.

Table 2. Test-retest reliability and internal consistency of Lymph-ICF-LL

	T_1	T_2			
Lymph-ICF-LL score	Mean±SD	Mean±SD	ICC	%95 CI	*p*
Physical function	41.5±28.8	40.7±27.0	0.93	0.87-0.97	0.001
Mental function	45.9±30.5	42.5±30.7	0.91	0.82-0.96	0.001
General tasks/household	91.9±48.9	89.6±42.3	0.79	0.56-0.90	0.001
Mobility	72.1±34.5	73.2±36.0	0.89	0.77-0.94	0.001
Life domains/social life	61.5±25.4	58.9±28.3	0.78	0.78-0.90	0.001
Lymph-ICF-LL total	57±13.1	55.5±13.4	0.83	0.65-0.92	0.001

Lymph-ICF-LL: Functioning, Disabilty and Health Questionnaire; SD: Standard deviation; ICC: Intraclass correlation coefficient; CI: Confidence interval; T_1: First test; T_2: Second test.

Table 3. Construct validity: correlation analysis between the Turkish versions of the Lymph-ICF-LL and SF-36

	Lymph-ICF-LL					
SF-36 domain	Physical function	Mental function	General tasks-Household	Mobility	Life domains-social life	Total score
SF(PF)	-0.49**	-0.10	0.34	-0.33	0.31	0.27
SF(RP)	-0.50**	-0.28	0.44*	0.43*	0.37*	0.04
SF(BP)	-0.53**	-0.24	0.22	0.13	0.40	-0.12
SF(GH)	-0.30	-0.25	0.21	0.37*	0.20	0.03
SF(VH)	-0.22	-0.29	0.21	0.52**	0.25	0.13
SF(SF)	-0.39*	-0.42 *	0.20	0.29	0.35	-0.12
SF(RE)	-0.25	-0.20	0.41*	0.42*	0.28	0.15
SF(MH)	-0.43*	-0.50**	0.08	0.23	0.32	-0.17

Lymph-ICF-LL: Functioning, Disabilty and Health Questionnaire; SF-36: Short Form 36; PF: Physical functioning; RP: Role limitations due to physical function; BP: Bodily pain; GH: General health perceptions; VH: Vitality; SF: Social function; RE: Role-emotional; MH: Mental health; * $p<0.05$; ** $p<0.01$.

Lymph-ICF-LL total score, physical function scores, mental function scores, general tasks/household scores, mobility scores, and life domains/social life scores were found to be excellent.

Table 3 shows the results of validity analyses. Most of the SF-36 subscale (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health) and the Lymph-ICF-LL subscales were found to be significantly correlated (range, 0.006 to 0.01). Only the Lymph-ICF-LL total score was not found to be correlated with any subscale of the SF-36.

DISCUSSION

This study shows that the Turkish version of the Lymph-ICF-LL is a valid and reliable tool to assess impaired functions, activity limitations, and participation restrictions of patients with primary or secondary lower limb lymphedema. The original Dutch version of the Lymph-ICF-LL has been also shown to be a valid and reliable instrument for patients with primary or secondary lower limb lymphedema.

In our study, all of the patients found the questions easily understandable, readable, and culturally relevant and, therefore, there was no need to change any item. In their study, Ferreira et al.[18] translated the questionnaire to a Brazilian Portuguese version and some of the questions were found to be difficult to understand which still requires validation with various samples of the local population.[18]

In another study, the Cronbach alpha values of the original version were 0.96 for the total score of the Lymph-ICF-LL and 0.89 to 0.97 for the scores of the various domains.[13] In the present study, similar alpha values were found (range, 0.79 to 0.97). These results indicate that the Turkish version of the Lymph-ICF-LL is reliable and may be applicable in clinical research and practice in lower limb lymphedema by all specialists.

In addition, the test-retest indicated that the subscales were adequate for excellent reliability, and the Lymph-ICF-LL questionnaire as a whole had a very good reliability. In the original version, test-retest reliabilities were also very strong (ICC>0.90) for the

total scores of the questionnaire and for the scores of the physical function, general tasks/household activities, and mobility domains.[13] The test-retest variability was strong (ICC=0.79 to 0.93) for the scores of the mental function and life domains/social life domains. This may be due to the fact that the first and second Lymph-ICF-LL were conducted at different times. The time interval between repeated measurements is also an important factor in the determination of test-retest reliability. The reliability tends to be higher when an interval of ≤7 days is used, since short test-retest intervals can elicit similar responses.[14] Therefore, a seven day interval was chosen for the retest assessment to minimize the possibility of the participants' remembering the questions. We consider that patients with conditions of lower limb lymphedema would not change over this period.

In this study, the SF-36, a well-established questionnaire, was used, as it is a widely used generic health-related quality of life instrument both in Turkey and worldwide.[16]

Furthermore, for the concurrent validity, the Pearson's correlation coefficients of the subscales of the Lymph-ICF-LL and SF-36 were computed. Franks et al.[19] reported that, of all non-specific questionnaires (i.e., SF-36, Modified Barthel Index, Short-Form McGill Pain Questionnaire, and EuroQol instrument), the SF-36 appeared to be the most appropriate for use with lower limb lymphedema patients. Relative to the Lymph-ICF-LL (r=0.37 to 0.53), there was a similar correlation between the coefficients of the original version. This confirms that the SF-36 measures additional aspects of health, and provides more comprehensive, but less specific, information about the patient's overall health than condition-specific questionnaires. As expected, the SF-36 and Lymph-ICF-LL have similar items due to the SF-36 being a generic quality of life scale.

On the other hand, there are some limitations to this study. First, in the recent literature, there is no other report of validation of the Lymph-ICF-LL. Second, we were unable to divide the patients into two groups as primary and secondary lower limb lymphedema to measure the effects of lymphedema. We believe that further studies are required to confirm our findings.

In conclusion, according to the results of this study, the Turkish version of the Lymphedema Functioning, Disability, and Health Questionnaire for Lower Limb Lymphedema is a valid and reliable tool and can be applied in clinical research and practice for lower limb lymphedema.

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Declaration of conflicting interests

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REFERENCES

1. Warren AG, Brorson H, Borud LJ, Slavin SA. Lymphoedema: a comprehensive review. Ann Plast Surg 2007;59:464-72.
2. Badger C, Seers K, Preston N, Mortimer P. Antibiotics / anti-inflammatories for reducing acute inflammatory episodes in lymphoedema of the limbs. Cochrane Database Syst Rev 2004;2:CD003143.
3. Öz BS, Sargın M, İyem H, Bolcal C, Mataracı İ, Akay HT, et al. The incidence and factors influencing lymphedema in lower extremities. Turk Gogus Kalp Dama 2006;14:304-7.
4. Morgan PA, Franks PJ, Moffatt CJ. Health-related quality of life with lymphoedema: a review of the literature. Int Wound J 2005;2:47-62.
5. Ryan M, Stainton MC, Slaytor EK, Jaconelli C, Watts S, Mackenzie P. Aetiology and prevalence of lower limb lymphoedema following treatment for gynaecological cancer. Aust N Z J Obstet Gynaecol 2003;43:148-51.
6. Pusic AL, Cemal Y, Albornoz C, Klassen A, Cano S, Sulimanoff I, et al. Quality of life among breast cancer patients with lymphoedema: a systematic review of patient-reported outcome instruments and outcomes. J Cancer Surviv 2013;7:83-92.
7. Kandoth C, Schultz N, Cherniack AD, Akbani R, Liu Y, Shen H, et al. Integrated genomic characterization of endometrial carcinoma. Nature 2013;497:67-73.
8. Courneya KS, Karvinen KH, Campbell KL, Pearcey RG, Dundas G, Capstick V, et al. Associations among exercise, body weight, and quality of life in a population-based sample of endometrial cancer survivors. Gynecol Oncol 2005;97:422-30.
9. Williams AF, Franks PJ, Moffatt CJ. Lymphoedema: estimating the size of the problem. Palliat Med 2005;19:300-13.
10. Weiss J, Daniel T. Validation of the Lymphedema Life Impact Scale. (Llis): a condition-specific measurement tool for persons with lymphedema. Lymphology 2015;48:128–38.
11. Augustin M, Bross F, Foldi E, Vanscheidt, W, Zschocke I. Development, validation and clinical use of the FLQA-I, a disease-specific quality of life questionnaire for patients with lymphoedema. Vasa 2005;34:31-5.
12. Devoogdt N, Van Kampen M, Geraerts I, Coremans T, Christiaens MR. Lymphoedema Functioning, Disability and Health questionnaire (Lymph-ICF): reliability and validity. Phys Ther 2011;91:944-57.
13. Devoogdt N, De Groef A, Hendrickx A, Damstra R, Christiaansen A, Geraerts I, et al. Lymphoedema Functioning, Disability and Health Questionnaire for Lower Limb

Lymphoedema (Lymph-ICF-LL): reliability and validity. Phys Ther 2014;94:705-21.

14. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976). 2000;25:3186-91.
15. Bernas MJ, Witte CL, Witte MH. The diagnosis and treatment of peripheral lymphedema Draft Revision of the 1995 Consensus Document of the International Society of Lymphology Executive Committee for Discussion at the September 3-7, 2001, XVIII International Congress of Lymphology in Geno. Lymphology 2001;34:84-91.
16. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473-83.
17. Fabrigar LR, Wegener DT, MacCallum RC, Strahan EJ. Evaluating the use of exploratory factor analysis in psychological research. Psychol Methods 1999;4:272.
18. Ferreira KR, Carvalho RB, Andrade MF, Thuler LC, Bergmann A. Translation and Cross-Cultural Adaptation of the Lymphoedema Functioning, Disability and Health Questionnaire for Lower Limb Lymphoedema into Portuguese Language. Rev Bras Ginecol Obstet 2016;38:88-96.
19. Franks PJ, Moffatt CJ, Doherty DC, Williams AF, Jeffs E, Mortimer PS. Assessment of health-related quality of life in patients with lymphoedema of the lower limb. Wound Repair Regen 2006;14:110-8.