

Validation of Korean Version of 'Questionnaire to Characterize Lymphedema in Women Treated for Breast Cancer'

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Objective: Lymphedema is one of the common complications that compromise the quality of life after the treatment of breast cancer. Bio-impedance, perometer, circumferential upper limb measurement and self-report are known as an appropriate tool to assess the lymphedema. Self-report method is simple, less expensive, accurate measure. Since the Korean version of lymphedema questionnaire is absent, the investigation of the reliability and validity of Korean version of 'Questionnaire to Characterize Lymphedema in Women Treated for Breast Cancer' is required.

Methods: The cross-culture translation of 'Questionnaire to Characterize Lymphedema in Women Treated for Breast Cancer' was done by guideline by Dorcas. The translated questionnaire was applied to 91 breast cancer patients (mean age=48.4±8.9) before treatment. Questionnaire assessment of degree and presence of the lymphedema was compared with measurement of circumference, at above and below 10 cm of both epicondyles. Lymphedema was categorized as no lymphedema (circumference difference less than or equal to 1 cm), mild lymphedema (circumference difference larger than 1 cm to less than or equal to 2 cm), and moderate/severe lymphedema (circumference difference larger than 2 cm). The questionnaire composed of 2 major questions. Question number 1 asked patients whether they feel a difference between upper extremities. Question number 2 asked how they notice the difference between their arms, forearms, and hands. Questionnaire was analyzed with 2 methods. On method 1, the summation of score equal or larger than 4 was considered moderate/severe (the score was assigned as - very slight, you are the only person who would notice this: 1, noticeable to people who knows you well, but not to strangers: 2, Very noticeable: 3). On method 2, any sites 'noticeable to people who knows you well but not to strangers' was considered moderate/severe. If the summation of scores were 0, when the patient chose the question number 1 as 'no', the patient was considered as no lymphedema. The follow up questionnaire was done after the lymphedema treatment when they visited an outpatient.

Results: Total of 46 patients followed up with questionnaire. Weighted kappa analysis was used to confirm the reliability and validity of Questionnaire compared with actual measurement. On initial questionnaire method 1, kappa was 0.717. On method 2, kappa was 0.752. On follow up questionnaire, kappa was 0.586 by method 1. On method 2, kappa was 0.622.

Conclusion: The Korean version of 'Questionnaire to Characterize Lymphedema in Women Treated for Breast Cancer' showed validity and reliability in women treated for breast cancer. It showed excellent agreement with actual measurement before and after the treatment. The method 2 was more agreeable to the actual measurement, before and after the treatment.

Key Words: Lymphedema • Questionnaire • Breast cancer • Women • Validation

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INTRODUCTION

The lymphedema is one of the most important complications after breast cancer treatment, which can compromise a quality of life of the patient severely [1]. It is a chronic condition that requires lifelong attention. Complication such as lymphedema, which would require long term management, reduces the quality of life. The lymphedema affects not only patients' physical health but also emotional well-being and adjustment to life [2].

The recent data show that 3-15% of women who had sentinel lymph node biopsy [3,4] and up to 49% of women who took axillary lymph node dissection [5].

Lymphedema is characterized by the accumulation of extracellular fluid. The mechanism is known that the excessive protein-rich fluid accumulates in regional interstitial space. The lymphatic stasis enhances the accumulation of protein and metabolites such as macromolecular protein and hyaluronan. In chronic phase, the number of fibroblasts, adipocyte, and keratinocyte in edematous tissues increases. The collagen deposition and connective tissue overgrowth in the edematous skin and subcutaneous tissues [6].

Aggressive decongestive lymphatic therapy is the mainstream of most management recommendations. Decongestive lymphatic therapy can reduce the limb circumferences, which produces long-term benefits due to the acceleration of lymph transport in the edematous limb and the removal of accumulated protein [7,8]. However, long-standing lymphedema is hard to remove, since the matured connective tissues and collagen entangle each other. Probably, the surgery and liposuction are management tools left in long-standing lymphedema, yet the effect of them are unsure [9]. Consequentially, the early intervention is essential in management of lymphedema.

The lymphedema is measured by several methods. Measuring the circumference of the limb is a common practice. Usually, the unaffected limb is used comparing the differences between the limbs. If the circumferential differences between the limbs are more than 2 cm or 10%, the patient considered to have the lymphedema [10].

The measurement of limb circumference can be calculated into the volume, by assuming that the limbs are either cylindrical or truncated cone geometry. Measuring the bio-impedance of limbs and using perometer are also investigated and proved to be adequate measurements. These tools usually take time and need special instruments. And since these measurements are hos-

pital-based and costly, the easy and less expensive measurement tool is needed.

One study investigated the agreement of each measurements including self-report. The concordance correlation between the measurements was high. Even though the level of correlation between self-report and other measurements was modest to high (Pearson's r ranges from 0.65 to 0.71), the correlation was statistically significant. Consequently, the questionnaire is cost-effective measurement of the lymphedema and reflects the status of edema of the patients [11].

In Korea, there is no valid questionnaire for assessing the lymphedema. Therefore, through this study, we investigated the reliability and validity of Korean version of Questionnaire to Characterize Lymphedema in Women Treated for Breast Cancer'.

METHODS

1. The Process of Cross-culture Translation of 'Questionnaire to Characterize Lymphedema in Women Treated for Breast Cancer' [12].

The translation was conducted by the guideline from 'Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures' by Beaton et al. [13] The translation process consists of 5 stages. On first stage, two translators conduct translation into Korean, (T1 and T2). On second stage, two translations synthesized into one questionnaire (T-12) and resolve any discrepancies with translators' reports. On third stage, two English first-language naïve to outcome measurement back translates the T-12 (BT1 and BT2). On stage 4, expert committee reviews all the reports, reach consensus on discrepancies and produce Pre-final version. On stage 5, the pretesting of pre-final version was conducted. The translation process of 'Questionnaire to Characterize Lymphedema in Women Treated for Breast Cancer' followed the guideline by Dorcas. The final version of translated questionnaire was used in this study.

2. The measurement of circumference of limbs

The circumferences were measured on 10 cm below of lateral elbow epicondyle and 10 cm above of lateral elbow epicondyle. The difference of circumference was used to identify the lymphedema. If the difference is smaller or equal to 1 cm, the patient considered to have no lymphedema. If the difference is larger than 1 cm

and smaller than or equal to 2 cm, the patient considered to have mild lymphedema. If the difference is larger than 2 cm, the patient considered to have moderate to severe lymphedema.

If they had lymphedema, they were advised to have lymphedema treatment. And if they agree to take treatment, they took conventional lymphedema treatment for 2 weeks, including manual lymph drainage, compression stockings and if needed, bandages. After the treatment, they filled up the questionnaire again.

The second measurements took place only to whom had lymphedema treatment, after the 1 month of first measurement. The difference of limb circumference between first and second measurement was then divided by the first circumference measurement expressed as the ratio. The ratio was used in analyzing the correlation between the questionnaire and circumference measurement.

The circumferences were measured by two qualified clinicians. Every result was recorded in electric medical records as they measure the circumferences.

3. The Questionnaire

The questionnaire consists of 2 main questions. On first question, we asked whether the patient feels the difference between their upper limbs. If the patient answers yes, the second question asked the patients that how much they feel the difference between the limbs. The degree of difference was asked such. (1) Very slight, that the patient is the only person who would notice this, (2) Noticeable to people who know the patient well but not to strangers, (3) Very noticeable. And the question asked on 3 parts of upper limbs, upper arm, arm and hand.

4. The Interpretation of Questionnaire

The original method of questionnaire was used interpreting the initial assessment. The questions were scored from 1 to 3. If the patient chooses the question 'Very slight, that the patient is the only person who would notice this', the score is 1. If the patient chooses 'Noticeable to people who know the patient well but not to strangers', the score is 2. If the patient chooses 'Very noticeable', the score is 3. On Method 1, the summation of the scores is larger or equal to 4, the patient considered to have moderate to severe lymphedema. If the patient answers the first question as 'No', she considered to have no lymphedema. If the summation of lymph-

phedema is 1 to 3, she considered have mild lymphedema. On Method 2, if the patient answers that 'Very noticeable' on any sites, she considered to have moderate to severe lymphedema. If the patient answers the first question as 'No', she considered to have no lymphedema. And if the patient answers the first question as 'Yes' and pick the second's answer other than 'Very noticeable', the patient considered to have mild lymphedema.

5. Statistical Analysis

The data were analyzed by SPSS Statistics 18.0. The agreement of first assessment of circumference and questionnaire were analyzed by Kappa. If the value of Kappa is less than 0.20, it was considered to have poor agreement. The value between 0.20 and 0.40 was considered to have fair agreement. If the value is between 0.40 and 0.60, 0.60 and 0.80, 0.80 and 1.00, the evaluation was considered to have moderate, good and very good agreement.

The changes between first and second assessment of circumference, expressed in ratio between changes of circumference and first circumference measurement, were compared with questionnaire result, Method 1 and 2. The Spearman's correlation coefficient was used in analyzing correlation between questionnaire and circumference measurement. If the p-value is lower than 0.05, it was considered to have statistical significance. If the Spearman's correlation coefficient was close to 1, it was considered to have positive correlation. If the Spearman's correlation coefficient was close to -1, it was considered to have negative correlation.

The inter-rater reliability of the measurements of limb circumferences was analyzed by using intraclass correlation. If the intraclass correlation coefficient was more than .80, it was considered to have significant agreement between the assessors.

RESULTS

1. Subjects

Ninety-one patients (mean age=48.4±8.9) were recruited for the study before the treatment of lymphedema. Fifty-six patients had lymphedema on their right upper extremities, 35 on their left upper extremities. After the lymphedema management, 46 patients (mean age=50.5±9.4) took follow up assessment. Among them, 21 patients had lymphedema on their right upper extremity, 25 on their left upper extremity (Table 1).

All the patients had unilateral breast cancer. They took either modified radical mastectomy or breast conserving operation, with lymph node dissection or sentinel node biopsy.

2. The Measurements

On circumference measurement, among 91 patients, 17 were normal, 45 were mild lymphedema, 29 were moderate to severe lymphedema. By the questionnaire, on Method 1, 14 were normal, 42 were mild lymphedema, 35 were moderate to severe lymphedema. On Method 2, 14 were normal, 42 were mild lymphedema, 35 were moderate to severe lymphedema (Table 2).

The kappa value of Method 1 was 0.72 (95% CI=0.59-0.84). The kappa value of Method 2 was 0.75 (95% CI=0.63-0.87) (Fig. 1).

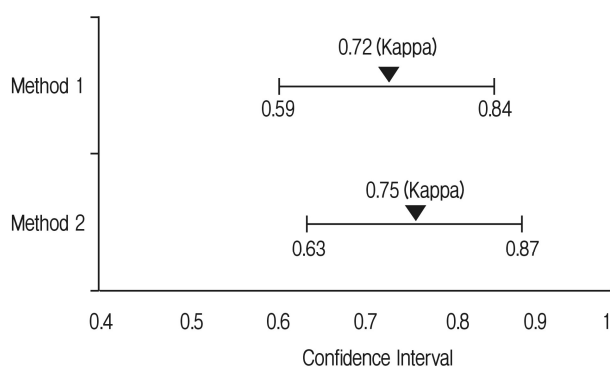


Fig. 1. Kappa Values of Method 1 & 2, initial assessment.

Table 1. Baseline characteristics of patients

	Before the Treatment	After the Treatment
Patient number (n)	91	46
Age (years)	48.4±8.9	50.5±9.4
Affected side (Rt/Lt)	56/35	21/25

Values are mean±standard deviation.

Table 2. Agreement between questionnaire results and circumference measurement before the treatment, Method 1 and 2

	Method 1			Method 2		
	Normal	Mild	Mod/Severe	Normal	Mild	Mod/Severe
Circumference						
Normal	12	2	3	12	2	3
Mild	2	37	6	2	38	5
Mod/Severe	0	3	26	0	2	27

Mod/Severe: moderate to severe.

The circumference measurement and questionnaire was correlated significantly on both Method 1 and 2. The Spearman's correlation coefficient of Method 1 was 0.58. On Method 2, the Spearman's correlation coefficient was 0.64 (Fig. 2).

3. The intraclass correlation

The intraclass correlation coefficient was .89 (95% CI: .82-.93) (Table 3) between two qualified clinicians.

DISCUSSION

There are not enough studies for lymphedema assessment by the means of questionnaire. As far as in our knowledge, there is only one questionnaire that has the validity and reliability. And yet, the Korean version of lymphedema questionnaire has not been developed. As previously mentioned, the early detection of lymphedema is essential, considering the price that undetected patients should pay later on. So, the validity and reliability of Korean version of lymphedema questionnaire was necessary.

The 'Questionnaire to Characterize Lymphedema in Women Treated for Breast Cancer' is questionnaire that its validity and reliability is solid. In that study, they investigated the agreement between circumference of the limb and the result from the questionnaire. They distinguished the lymphedema into 3 degrees (No lymphedema, mild lymphedema and moderate to severe lymphedema). The circumference difference was used to identify whether lymphedema was present and distinguish the degree of lymphedema. When the difference is shorter than or equal to 1 cm, the patient was considered to have no lymphedema. When the difference is larger than 1 cm and shorter than or equal to 2 cm, the patient was considered to have mild lymphedema. When the difference is larger than 2 cm, the patient considered to have moderate to severe lymphedema.

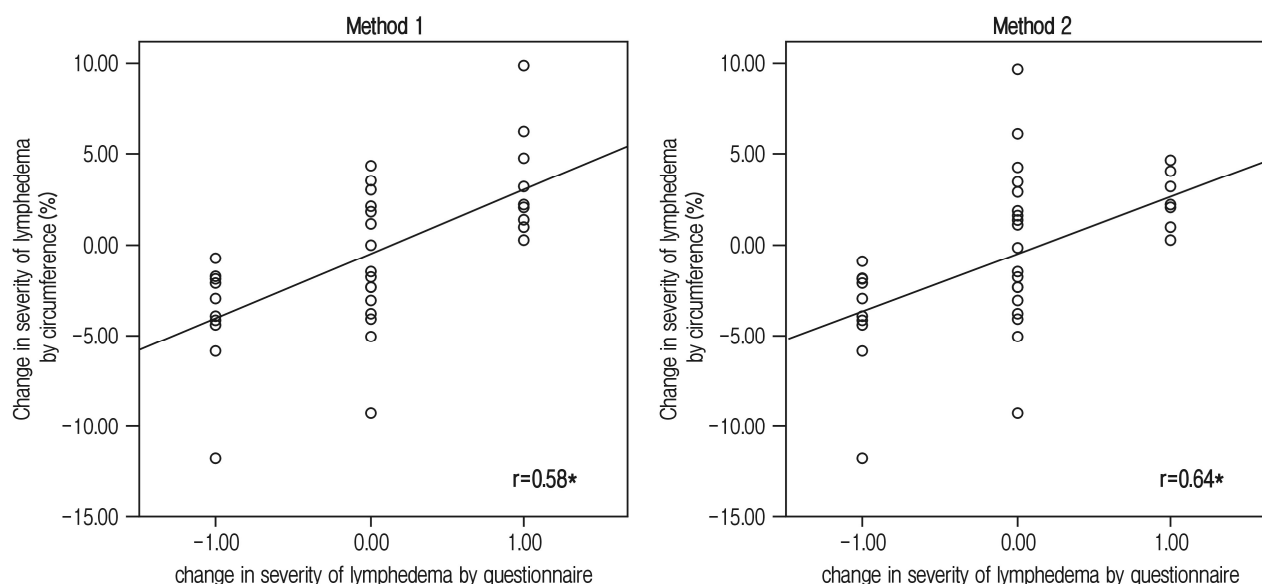


Fig. 2. Spearman's Correlation Coefficient between Questionnaire Results' Change and Circumference Measurement Change after the Treatment, Method 1 and 2. * $p < 0.05$ by Spearman's Correlation.

Table 3. The Inter-rater agreement of circumference measurements

	Total (n=64)
	ICC (95% CI)
The circumference measurements	0.89* (0.82-0.93)

ICC: Intraclass correlation coefficient, CI: Confidence interval.

* p -value < 0.01 .

They used 2 methods in interpreting the questionnaire result. They score the each question from 1 to 3. On method 1, when the summation of the score is larger than or equal to 4, the patient was considered to have moderate to severe lymphedema. When the score is 1 to 3, the patient was considered to have mild lymphedema. When the score was 0, the patient was considered to have no lymphedema. On method 2, when the patient picks the item, which score is '3', the patient was considered to have moderate to severe lymphedema. When the patient answers that she felt no difference between their upper limbs, the considered to have no lymphedema.

The Korean version of 'Questionnaire to Characterize Lymphedema in Women Treated for Breast Cancer' showed statistically significant agreement and reliability in women treated for breast cancer. This study investigated two scoring system in assessing the severity of lymphedema. In the initial assessment, the value of Kappa was higher in Method 2 (Kappa=0.72 vs. 0.75). The

Spearman's correlation showed statistical significance for patients who had lymphedema management, in both methods. However, the Spearman's r -value of each method was higher in Method 2 (Spearman's $r=0.58$ vs. 0.64). In general, Method 2 showed higher relationship between degrees of lymphedema and questionnaire. It is understandable, since the way of determining the degree of lymphedema by circumference measurement - determining the degree by only one site of measurement - is similar to that of Method 2. The inter-rater reliability of circumference measurement was high between two assessors (ICC=0.89).

We investigated the reliability of the questionnaire after the management of lymphedema. The translated questionnaire was reliable after the management. The after the management, not all patients showed decrease in circumference, but even that situation, the questionnaire reflected the changes of lymphedema.

CONCLUSION

The reliability and validity of the questionnaires in lymphedema did not be evaluated enough worldwide. In Korea also, there was no validated lymphedema questionnaire. Through this study, the questionnaire that has validity and reliability was translated with solid translation method. The translated questionnaire was tested

for the agreement from the circumference measurement. And changes in circumference of the limbs were compared with changes in questionnaire.

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