

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

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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 İzzet 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 ($\alpha > 0.9$), good ($0.9 > \alpha > 0.7$), acceptable ($0.7 > \alpha > 0.6$), poor ($0.6 > \alpha > 0.5$) and unacceptable ($\alpha < 0.5$) (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 ($r < 0.20$), 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)

LYMQoL Domains	NHP		Energy Level		Pain		Emotional Reactions		Social Isolation		Sleep		Physical Activity'		Overall Quality of Life'	
	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

Item	Factors			
	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 be 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 analysis 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 İzzet 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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