

## MINIMAL CLINICALLY IMPORTANT DIFFERENCE OF THE LYMPHEDEMA QUALITY OF LIFE SCALE IN UPPER LIMB LYMPHEDEMA AFTER BREAST CANCER SURGERY

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### ABSTRACT

*This study aimed to determine the minimal clinically important differences (MCID) for the Lymphedema Quality of Life Questionnaire (LYMQOL) in breast cancer-related lymphedema (BCRL). LYMQOL was used to evaluate quality of life (QoL) with four domains: function, body image, symptoms, and mood. All patients received a standardized three-week program of combined complex decongestive therapy. An anchored-based (response to a satisfaction question at post treatment) method was used to estimate MCIDs. The optimal cut-off points were calculated. The study included 67 patients with a mean age of  $54.3 \pm 9.73$  years and a BMI of  $32.6 \pm 6.80$  kg/m<sup>2</sup>. Significant statistical improvements were observed in all domains of the LYMQOL after treatment, including function ( $p=0.001$ ), body image ( $p=0.001$ ), symptoms ( $p<0.001$ ), and mood ( $p=0.012$ ) with the overall QoL score increasing from  $6.31 \pm 1.93$  to  $6.81 \pm 1.45$  ( $p=0.004$ ). The MCID values for LYMQOL were 0.31 for function, 0.5 for body image, 0.31 for symptoms, and 0.33 for mood, with corresponding MCID change percentages of 10.33%, 16.66%, 10.33%, and 11%, respectively. This study's MCID values for QoL provide valuable insights to enhance clinical decision-*

*making and improve patient outcomes in BCRL.*

**Keywords:** Minimal clinically important difference; Lymphedema Quality of Life questionnaire; Upper limb lymphedema; Breast cancer surgery; Quality of Life

### INTRODUCTION

Lymphedema is a localized tissue swelling caused by impaired lymphatic drainage leading to accumulation of lymphatic fluid in the interstitial space, and is classified as either primary (developmental) or secondary (acquired) (1). Breast cancer-related lymphedema (BCRL) is a significant healthcare burden, as it can develop within days and up to 11 years after surgery. Specifically, breast cancer operation including axillary lymph node dissection has a reported 30–50% incidence of upper limb lymphedema despite advancements in early detection, treatment, and adjuvant therapies (2). Complex decongestive therapy (CDT) is the universally accepted treatment for extremity lymphedema (3), encompassing manual lymphatic drainage (MLD), skin care, specialized exercises, compression and self-education. It is divided into Phase I (Decongestion) and Phase II (Maintenance), and

should be individualized to optimize effectiveness and minimize costs (4,5).

Lymphedema has a profound impact on patients' overall quality of life (QoL), affecting various aspects of their physical, emotional, and social well-being (1). A comprehensive assessment strategy for patients should encompass both objective and subjective methods to improve evaluation of BCRL (6).

Lymphedema Quality of Life Questionnaire (LYMQOL) is a widely used and validated tool for assessing health-related QoL in patients with lymphedema. However, the lack of responsiveness of LYMQOL presents a significant limitation since this responsiveness can be considered as longitudinal validity and refers to the degree to which an instrument is able to measure change in the construct to be measured (7,8). Before a health status measurement instrument can be applied in research or clinical practice, its reliability, validity, and responsiveness should be evaluated. As a key component of the COSMIN (Consensus-based Standards for the selection of health Measurement Instruments) framework, responsiveness reflects the extent to which changes align with a reference standard of clinical or health status (9,10).

Interpreting changes in scores on patient reported outcome instruments is a fundamental component of instrument development, as without clear interpretation guidelines, the clinical significance of statistically meaningful improvements observed within a treatment group can't be adequately determined (11). Understanding how patients perceive improvements and determine meaningful change is essential for guiding clinical decisions and optimizing treatment strategies (12). Minimal Clinically Important Difference (MCID) was the first metric introduced to assess whether changes in functional outcome scores are clinically meaningful rather than just statistically significant, defining the smallest change that a patient perceives as beneficial (13). The MCID of a patient-reported outcome measure can vary depending on the patients and clinical context, with distribution-based and anchor-based methods each having their strengths and limitations. Distribution-based methods

may lack clinical relevance and generalizability, while anchor-based methods depend on the choice of anchor question and are prone to recall bias (14). Distribution-based approaches often fail to bridge the gap between statistical variance and clinical meaningfulness; thus, they establish thresholds that represent measurement precision instead of patient benefit (15). The determination of the MCID is highly sensitive to the chosen methodology. As highlighted by a recent study, different calculation methods yield heterogeneous values. While distribution-based methods provide very small sufficient thresholds only for detecting minimal statistical shifts. They fail to capture the patient's perspective of a truly important change (16). Therefore, the calculation of MCID with anchor-based methods allows for more accurate reflection of meaningful changes in patient outcomes.

The reviews conducted up until 2022 (7, 17) indicate that responsiveness remains an area in need of further studies and more recent studies have also been unable to address this gap. For instance, recent studies on the translation and cultural adaptation of the LYMQOL, including of the German (18) and Indonesian versions (19) have also not addressed responsiveness at all. In the Italian translation study of LYMQOL, the minimal detectable change (MDC) values ranged from 0.40 scale points for body image to 0.81 for mood (20). However, it has been shown that MDC does not consistently approximate the anchor-based MCID. It was recommended that investigators use the anchor-based approach to ascertain the MCID of health-related outcome measures (21). To the best of our knowledge, this is the first study to calculate the MCID of LYMQOL in BCRL. Therefore, this study aimed to determine the MCID for LYMQOL in BCRL.

## *MATERIALS AND METHODS*

### *Study Design*

This prospective cohort study was carried out in compliance with the principles of the Declaration of Helsinki. The study was ap-

proved by the Ethics Committee of Bilkent City Hospital (approval number: TABED 1/90/2024, approval date: 13.03.2024) and informed consent was obtained from all individual participants included in the study.

### *Participants*

Female patients aged 18 years or older who had been diagnosed with unilateral breast cancer and had undergone breast cancer-related surgery were included in the study. All participants developed ipsilateral BCRL in the operated upper extremity and were diagnosed with BCRL at Bilkent City Hospital between April and September 2024. The assessment and diagnosis of BCRL were performed by a physical medicine and rehabilitation physician with more than 15 years of clinical experience in lymphedema management. Diagnosis was established through clinical evaluation in accordance with the International Society of Lymphedema (ISL) criteria. Participants included both patients who were newly diagnosed with BCRL at the time of enrollment and those who had received a BCRL diagnosis within a maximum of three months prior to study inclusion. Exclusion criteria included male sex, bilateral breast cancer, cognitive or mental impairment, failure to complete baseline pre-intervention patient-reported outcome questionnaires, presence of distant metastases, orthopedic or neurological disorders affecting the upper extremity, prior participation in cancer rehabilitation programs, previous upper extremity surgery unrelated to breast cancer, and a BCRL diagnosis established more than three months prior to study inclusion. A total of 71 patients with a confirmed diagnosis of BCRL were assessed for study eligibility. Two patients were excluded due to missing data and two due to cognitive impairment, resulting in a final study population of 67 participants.

### *Treatment*

All patients underwent CDT (MLD, skin care, compression therapy, and exercises) five days a week for three weeks (15 sessions) at

the Bilkent City Hospital Oncological Rehabilitation Lymphedema Clinic. The treatment protocol was conducted by the same physiotherapist for all participants. MLD treatment was administered to the neck, abdomen, and affected extremity in sequence. The affected extremity received MLD therapy following a proximal-to-distal approach. After each MLD session, skincare was provided using pH 5.5 creams, followed by the application of short-stretch bandaging. Lastly, remedial exercises were performed.

### *Assessment*

Demographic and clinical characteristics of patients, including age, body mass index (BMI), dominant hand, affected extremity, type of surgery, and lymphedema stage were recorded. The lymphedema stage of the patients was determined using ISL criteria. According to this classification, if the difference between the extremities was between 5% and 20%, it was classified as stage 1, between 20% and 40% as stage 2, and greater than 40% as stage 3 (22). The assessments were performed prior to treatment and 3 weeks following treatment, with the same clinician responsible for both the assessments and the treatment.

### *Lymphedema Quality of Life Questionnaire*

LYMQOL is a reliable and valid condition-specific QoL assessment tool developed by Keeley and colleagues in 2010. It can be used both in clinical assessments and as an outcome measure to detect impact of limb lymphedema on patients' QoL (23). The 20 items in the questionnaire covers four domains – symptoms, body image/appearance, function, and mood. Each item was scored as follows: not at all = 1, a little = 2, quite a bit = 3, a lot = 4. The total score for each subcategory is determined by summing item scores and dividing the sum by the number of questions answered. Higher scores reflect a lower QoL. The final question assesses overall QoL and is rated on a scale from 0 to 10, with higher scores indicating a better QoL. The Turkish version of

the LYMQOL, with established validity and reliability, was used in this study. The internal consistency and reliability of the Turkish version of the LYMQOL were found to be good, with Cronbach's alpha ranging from 0.88 to 0.90 and test-retest intra-class correlation-coefficient ranging from 0.45 to 0.71. External construct validity was also strongly supported (24).

#### *Anchor Question:*

Patients were asked one anchor question post-intervention to determine clinically meaningful changes in LYMQOL. The anchor question to calculate MCID was: "How would you describe your condition compared to before treatment, considering your QoL specifically related to BCRL?" Responses were scored on a 5-point global scale- "Much Worse" or "Worse," or "No Change (Same)," or "Better," or "Much Better."

#### *Statistical analysis*

The study aimed for a power of 80% and an alpha error rate of 0.05, with the expected area under the curve (AUC) being 0.70 based on previous research and using the MedCalc (Belgium) sample size calculation tool, the minimum required sample size was determined to be 62 patients. This calculation was based on discrimination performance rather than anchor-based assumptions. No additional inflation was applied given the minimal amount of data missing. Demographic and clinical characteristics of the patients, including age, body mass index (BMI), dominant hand, involved side, type of surgery, and lymphedema stage, were reported using descriptive statistics. Continuous variables were presented as mean  $\pm$  standard deviation (SD) and range (minimum–maximum), while categorical variables were expressed as frequencies and percentages. The Wilcoxon signed-rank test was used to compare pre-treatment and post-treatment scores from the LYMQOL.

#### *Minimal Clinically Important Differences*

The MCID was determined using receiver

operating characteristic (ROC) curve analysis, with the optimal cutoff point identified between the unchanged and better groups (25). AUC of 0.7 was considered acceptable (26). In clinical contexts where avoiding false-positive classification of meaningful improvement is prioritized, greater emphasis on specificity may be warranted. Therefore, in the present study, the cut-point was selected by prioritizing specificity to provide a more conservative and clinically meaningful estimate of the MCID (27). Considering that the domain score ranges from 1 to 4, the total change score was defined as 3 (maximum score minus minimum score), and percentage values were calculated.

#### *RESULTS*

*Table 1* shows demographic and clinical characteristics of patients included in the study. A total of 67 patients were included with a mean age of  $54.3 \pm 9.73$  years (range: 35–78) and BMI of  $32.6 \pm 6.80$  kg/m<sup>2</sup>. The majority of patients (83.6%) were right-handed and the effected extremity was also on the right in 52.2%. In terms of surgical interventions, 43.3% of patients underwent lumpectomy, 19.4% had a simple mastectomy, and 37.3% underwent a modified radical mastectomy. With respect to axillary surgery, 24 patients underwent axillary lymph node dissection while 38 patients underwent sentinel lymph node biopsy. Most patients (58.2%) were classified as Stage 2 lymphedema, while 22.4% and 19.4% were in Stage 1 and Stage 3, respectively. Following treatment, 38 patients reported feeling better about QoL specifically related to BCRL, while 29 patients reported no change in their condition. None of the patients indicated deterioration or expressed feeling much better about QoL specifically related to BCRL. *Table 1* presents a comparison of pre-treatment and post-treatment scores from LYMQOL. *Table 2* shows MCID values for each domain. The MCID values for the LYMQOL subdomains ranged from 0.31 to 0.5 with percentage changes in MCID for each component at 10.33% for function, 16.66% for body image, 10.33% for symptoms, and 11% for mood. The AUC value for all subdomains was  $>0.7$  and

**TABLE 1**  
**Demographic and Clinical Characteristics of Study Patients and Comparison**  
**Between Pre-treatment and Post-treatment Outcomes**

	<b>n (%)</b>	<b>Mean±SD</b>	<b>Min-Max</b>
Age	67	54.33±9.73	35-78
Body Mass Index (kg/m <sup>2</sup> )	67	32.59±6.80	21.91-55.56
Dominant hand			
Right	56 (83.6%)		
Left	11 (16.4%)		
Effected Extremity			
Right	35 (52.2%)		
Left	32 (47.8%)		
Surgery			
Lumpectomy	29 (43.3%)		
Simple mastectomy	13 (19.4%)		
Modified radical mastectomy	25 (37.3%)		
Lymphedema stage			
1	15 (22.4%)		
2	39 (58.2%)		
3	13 (19.4%)		
	<b>Pre-treatment (mean±SD)</b>	<b>Post- treatment (mean±SD)</b>	<b>p value*</b>
<b>Lymphedema Quality of Life Questionnaire</b>			
Function Domain	1.96±0.77	1.73±0.70	0.001*
Body Image Domain	2.11±0.90	1.87±0.81	0.001*
Symptoms Domain	2.40±0.79	2.01±0.72	0.000*
Mood Domain	2.08±0.79	1.80±0.71	0.012*
Overall	6.31±1.93	6.81±1.45	0.004*

\*Wilcoxon test

the ROC curves for each domain are shown in *Figures 1-4*.

### DISCUSSION

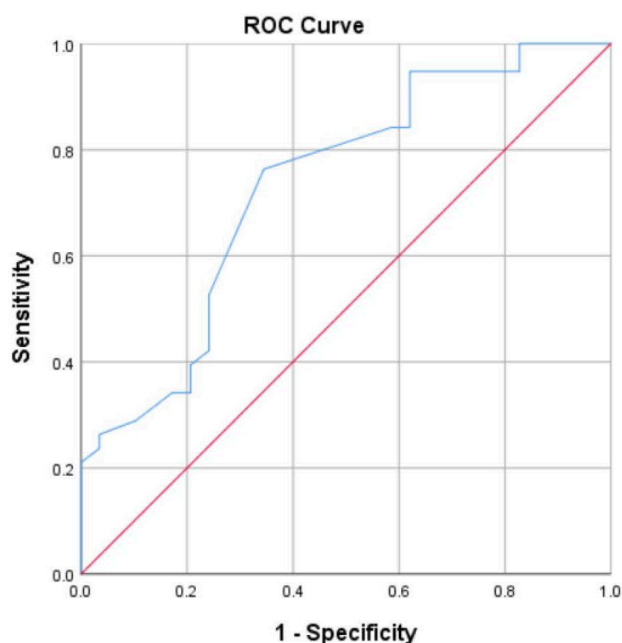
Patient progress assessment is a crucial component of clinical practice, and it is vital to establish meaningful threshold change values for outcome tools. These values help in making informed decisions about a patient's condition and ensure that results are commu-

nicated clearly and effectively. This study used an anchor-based method to define MCID for the LYMQOL scale. Our findings suggest that the MCID threshold reflects the minimal improvement that a patient perceives as meaningful, thereby enhancing the ability to interpret score changes on an individual basis in clinical practice.

Patients prioritize clinical significance over statistical significance. Patient-centered outcome measures are designed to assess

**TABLE 2**  
**Minimal Clinically Important Difference (MCID) of Lymphedema**  
**Quality of Life Questionnaire**

Lymphedema Quality of Life Questionnaire Domain	MCID	Area Under Curve	Percentage change over time	Significance	95% Confidence interval	Sensitivity/ Specificity
Function	0.31	0.732	10.33 %	p=0.001	0.610-0.854	0.474/ 0.759
Body image	0.50	0.703	16.66%	p=0.005	0.578-0.828	0.395/ 0.931
Symptoms	0.31	0.784	10.33%	p<0.001	0.672-0.897	0.658/ 0.862
Mood	0.33	0.758	11%	p<0.001	0.641-0.875	0.533/ 0.897

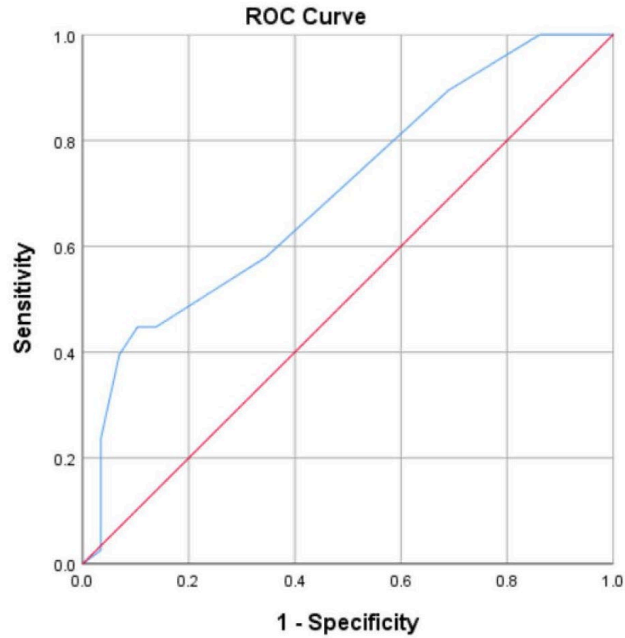


**Fig. 1.** Receiver Operating Characteristic (ROC) curve for the LYMQOL function subdomain.

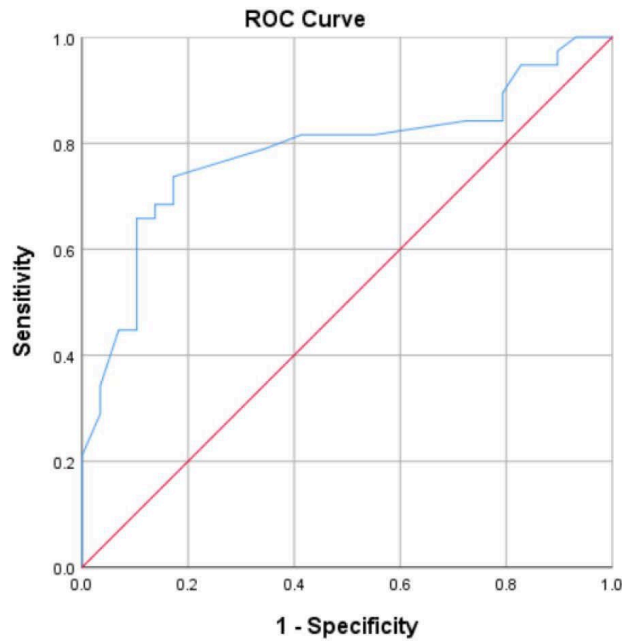
"clinical" relevance with the MCID serving as a crucial metric to determine meaningful changes in patient health status (28). Recently the concept of MCID has become a significant issue with numerous systematic reviews conducted especially in the orthopedic field (29-31). Although the MCID has been calculated for the Lymphedema Functioning, Disability, and Health Questionnaire which focuses on

functionality, there is a gap regarding MCID calculations related to lymphedema where clinical benefit is critical and directly impacts QoL and treatment response.

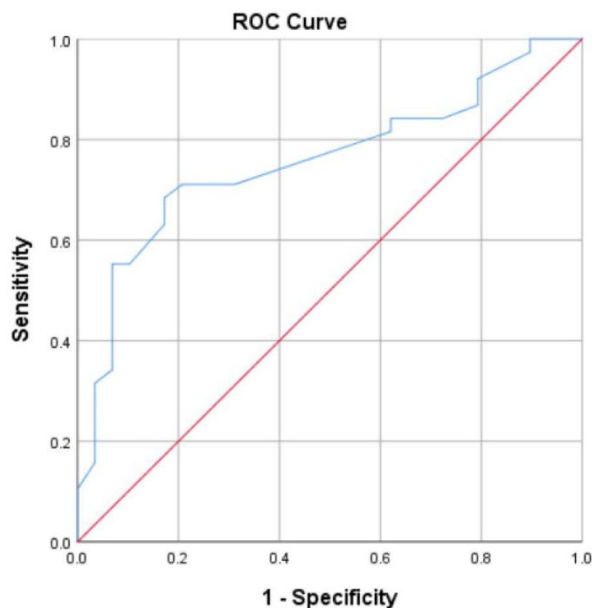
QoL is a multidimensional concept that encompasses various aspects of an individual's well-being. Lymphedema, a common consequence of breast cancer treatment, remains a significant concern due to its detrimental



**Fig. 2.** Receiver Operating Characteristic (ROC) curve for the LYMQOL body image subdomain.



**Fig. 3.** Receiver Operating Characteristic (ROC) curve for the LYMQOL symptom subdomain.



**Fig. 4.** Receiver Operating Characteristic (ROC) curve for the LYMQOL mood subdomain.

effects on QoL. It has been shown to impact physical health, psychological well-being, and emotional stability (32). Specifically, lymphedema negatively affects patients' QoL by altering body image, lowering self-esteem, inducing feelings of weakness, increasing fear and anxiety regarding disease progression, imposing financial burdens, and reducing limb functionality (33). The multidimensional nature of QoL requires a comprehensive assessment approach. The LYMQOL questionnaire includes subdomains such as body image and function, allowing for a more detailed evaluation (23). The presence of these subdomains enabled us to calculate separate MCID values for each, ensuring a more precise interpretation of the impact of lymphedema on different aspects of patients' well-being.

The assessment of health-related QoL in lymphedema has always been an important area of research. A 2022 study aimed at reviewing the literature categorized the relevant QoL scales into general ( $n=16$ ), disease-specific ( $n=11$ ), and lymphedema-specific categories ( $n=12$ ), identifying LYMQOL as the most frequently utilized scale with 29 included studies; however, its responsiveness was not reported

(7). A comparable study systematically reviewed 19 studies to assess the psychometric properties of QoL scales related to lymphedema in patients with BCRL (17). Only two of the included studies examined responsiveness: one for the Upper Limb Lymphedema Quality of Life scale (34) and the other for the Lymphedema Functioning, Disability, and Health Questionnaire for Upper Limb Lymphedema (Lymph-ICF-UL) (35). Williams et al. demonstrated responsiveness using effect size and calculated the estimate of the minimal important change based on one-half standard deviation; however, they recommended that future studies investigate the MCID (34). In the study by Devrize and colleagues, MCID was calculated for the Lymph-ICF-UL. The MCID for Lymph-ICF-UL ranged from 5% to 14%, across different categories such as physical function, mental function, household activities, mobility activities, and life and social activities (35). The specific domains and their corresponding values differ, suggesting variations in how different outcome measures reflect different clinical improvements.

Limitations of our study include the short follow-up period. The study included 67 parti-

participants, exceeding the power analysis requirement of 62; however, this sample size may still be considered relatively small. Larger sample sizes are typically observed in retrospective studies involving calculating MCID in surgical interventions. However, there is an increasing need for MCID in studies focused on conservative treatments. Our study is important as it contributes valuable data from a non-surgical perspective. One of the biggest criticisms of MCID is that it changes greatly based on the patient's baseline clinical status. Higher MCID levels were observed in patients with worse baseline clinical status, while MCID lost significance in patients with high baseline clinical values (36). In this context, the absence of high baseline values in our study strengthens its validity.

Caution is essential when interpreting and applying these MCID values, especially given the inherent limitations of the global rating of change scale (GRCS). The GRCS (and the MCID values derived from it) may be influenced by subjective retrospective assessments of change (e.g., due to recall bias or the patient's ability to understand the context of improvement). However, in our view, recall issues were unlikely to pose a significant problem, as the treatment duration was relatively short (3 weeks) and included periodic discussions about the patients' health status. The short treatment duration may also have prevented patients from reporting being "much worse," "worse," or "much better," thus allowing for the analysis of the entire study population.

### CONCLUSIONS

By providing MCID values for QoL across various domains, this study offers valuable insights that can enhance clinical decision-making and improve the evaluation of patient outcomes, ultimately contributing to better patient care in BCRL.

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### CONFLICT OF INTEREST

All authors declare no financial conflict of interest exist.

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