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Effectiveness of physiotherapy lymphedema management in limb circumference and shoulder mobility among women with breast cancer-related lymphedema

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ABSTRACT

Introduction: This study aimed to evaluate the effectiveness of physiotherapy lymphedema management (LM) in upper limb circumference (LC) and shoulder mobility and determine whether baseline muscle strength (MS) was associated with LC and shoulder mobility in women with breast cancer-related lymphedema.

Methods: This study analyzed 79 patients (mean age = 58.89 ± 10.22 years) who were categorized by age group (<60 and ≥60 years) and lymphedema stage (stages 1-2 and 3-4) and completed 8 sessions of LM. Key outcomes evaluated included shoulder flexor strength, LC, and shoulder flexion range of motion (ROM). Data were analyzed using a paired *t*-test and Pearson's correlation based on age group and stage of lymphedema.

Results: There was a significant reduction in LC by 12.56%, 16.41%, 9.60%, 22.84%, and 7.76% for all patients, those aged <60 years (n = 38), ≥60 years (n = 41), stage 1-2 (n = 41), and stage 3-4 (n = 38), respectively (all $p < 0.05$). Shoulder flexion ROM improved by 3.99% ($p < 0.05$), 3.06% ($p > 0.05$), 5.06% ($p < 0.05$), 2.95% ($p > 0.05$), and 5.5% ($p < 0.05$) for all patients, those <60 years, ≥60 years, stage 1-2, and stage 3-4, respectively. Baseline MS was significantly correlated with LC at pre- and post-treatment for all groups (r = –0.53-–0.92) ($p < 0.05$), except for the LC of those with stages 1-2 of lymphedema at post-treatment while baseline MS was significantly correlated with shoulder flexion ROM at pre- and post-treatment in all groups (r = 0.86-0.98), except for stages 1-2.

Conclusion: An 8 sessions of LM may effectively reduce lymphedema and improve shoulder mobility. MS may be associated with LC and ROM; thus, the LM protocol should include regular assessment of MS and incorporate progressive strengthening exercises at an early stage.

Keywords: Breast cancer; lymphedema; physiotherapy; malaysia

INTRODUCTION

Lymphedema is a condition characterized by localized tissue swelling due to the retention of lymphatic fluids in the interstitial compartment associated with impaired lymphatic drainage (1). Following breast cancer treatment, lymphedema can occur, normally known as breast cancer-related lymphedema (BCRL). BCRL may result in various issues such as pain, upper extremity disability, psychological distress, body image disturbance, sexuality impairment, lack of social support, and poor quality of life (2). BCRL is also a barrier to returning to work that may cause an economic burden (2,3). These issues could be associated with edema of the affected limb, skin changes such as hardening, pitting, and darkening, and feeling heaviness from the edema (4). The incidence of BCRL tends to increase after a few years of cancer treatment. According to prospective cohort research (5), the cumulative incidence of BCRL was 14% after 2 years, 30% after 5 years, and 41% after 10 years. Factors that contributed to a higher risk of lymphedema include those who had axillary radiotherapy, with obesity, who developed seroma, underwent chemotherapy infusions in the affected limb, and had advanced disease (5). While other literature suggests that *en bloc* dissection of the axillary lymph nodes but not the type of breast surgery increases the probability of BCRL development (6). Hence, early diagnosis and intervention for BCRL may be necessary to maintain functions, prevent complications, and promote a good quality of life.

Physiotherapy has long been recommended as one of the strategies for managing the symptoms related to BCRL. A systematic review that has included 13 RCTs of physiotherapy roles in treating BCRL highlighted that exercise and

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physiotherapy are essential during post-surgery to improve subjective and objective parameters and enhance the quality of life among breast cancer patients (7). In addition, a more classical systematic review suggested that decongestive therapy is only effective in reducing BCRL when combined with manual lymphatic drainage (MLD) and compression bandages (8), suggesting further study to determine its efficacy and to provide evidence for physiotherapy practice in treating lymphedema, especially in Malaysia.

Evidence is needed to support the effectiveness of physiotherapy management and become the basis for developing a standard operating procedure for lymphedema management (LM). Thus, this study aimed to determine the effectiveness of physiotherapy LM in upper limb circumference (LC) and shoulder flexion range of motion (ROM). Secondarily, this study also aimed to determine the relationship between baseline muscle strength (MS) with pretest, post-test, and changes in the LC and shoulder flexion ROM measures following 8 sessions of LM.

METHODS

This retrospective analysis used secondary data from a pretest-posttest clinical intervention by physiotherapists for BCRL. This study design was selected as it provides data for auditing the current practice of physiotherapists in patients with BCRL. Data on female patients who completed breast cancer treatment (such as surgery, chemotherapy, and radiotherapy) within 1-2 years were obtained from their clinical records at the physiotherapy department of the National Cancer Institute (NCI), Putrajaya, Malaysia. The NCI is a tertiary health institution dedicated to cancer treatment that started its operation on September 2nd, 2013. Patients from all over the country who require specific cancer therapy are usually referred to this institute.

Data from January 2019 to December 2020 were retrieved from patients who completed eight sessions of LM. The patients included in the data analysis were (1) aged between 20 and 80 years old, (2) referred by a doctor for LM, and (3) completed eight sessions of LM. The patients were excluded if they had incomplete: (1) sociodemographic information; (2) measurements of LC, shoulder flexion ROM, and baseline MS.

The primary researcher of this study was a physiotherapist who has >3 years of working experience in the related field. The ethical approval for a study involving secondary data from human subjects was approved by the Research Ethics Committee of the Universiti Teknologi MARA and the Ministry of Health Malaysia. Since this study used secondary data, no informed consent was required; however, permission to obtain the data was granted by the Director of NCI.

Data such as age, ethnicity, marital status, level of education, occupation, stage of breast cancer, comorbidities, and body mass index were retrieved from each patient's file. The baseline MS was evaluated using the Medical Research Council Manual Muscle Testing scale (MMT) (9), for the shoulder flexor of the affected extremity. The testing was performed when patients were positioned in a supine lying to isolate other muscles. This procedure requires evaluating the muscle with the patients attempting to resist the resistance given by the therapist. The scoring for the MS was as follows: 0 = no muscle activation; 1 = trace muscle activation, such as a twitch, without achieving full ROM; 2 = muscle activation with gravity eliminated, achieving full ROM; 3 = muscle activation against gravity, full ROM; 4 = muscle activation against some resistance, full ROM; 5 = muscle activation against the assessor's full resistance, full ROM. The validity of the MMT had been reported in a previous study; however, the researchers highlighted its limitations in providing a valid and objective assessment of muscular strength, particularly in populations with musculoskeletal conditions (10). Nevertheless, it is noteworthy that MMT is commonly utilized in clinical practice due to its simplicity and efficiency.

The LC of the affected side was evaluated by a circumference measurement that was taken with an 8-meter tape (11), and the results were recorded in centimeters. This method was chosen as it allows a comprehensive assessment of LC at multiple points, providing a more detailed understanding of the distribution of tissue swelling or changes in the affected limb (12). The procedure involved measuring the arm at five different points, namely the metacarpophalangeal joints, the wrist, at 10-cm distal to the lateral epicondyle, the mid-point of the elbow (between the medial and lateral epicondyle), and 15-cm proximal to the lateral epicondyle. The assessor measured the circumference twice to maximize reliability and recorded the average value. The maximal circumference difference was used to calculate the difference between the affected and unaffected arms at the uppermost symptomatic arm location. These measurements were taken weekly during the treatment, but only the first measurement and after the 8th session of LM were included in the data analysis.

The shoulder flexion ROM was assessed using a 12-inch plastic goniometer (Standard BASELINE®, Model 12-1000, Fabrication Enterprises; White Plains, New York). The measurement was taken with the patient in supine lying with knees flexed, the palm facing medially, and thumbs up. The assessor stood at the side of the affected arm to perform the measurement, with the goniometer axis placed on the middle of the humeral head laterally, the stationary arm parallel with the trunk, and the moveable arm in line with the midline of the humerus. The patient was instructed to perform flexion (with elevation) of both shoulders to avoid compensatory movement of the affected side. The angle of maximum shoulder flexion measured by the goniometer was recorded in degrees (°). Measurements taken before the first and after the 8th session were included in the data analysis. The intrarater reliability for assessing shoulder flexion ROM using a goniometer has been reported to be excellent (ICC = 0.95, 95% CI = 0.89-0.98) (13).

All patients received LM, which included MLD, multi-layered bandaging, exercises, and patient education on self-management (Table 1). The self-management training at the end of each session encouraged patients to self-manage their condition and stay motivated in the long run. In this study, the intervention was given weekly for eight sessions within 2-month period, performed by a certified lymphedema therapist.

All data retrieved from the medical record files were copied to a data collection form designed for the study. Data

TABLE 1. Summary of the lymphedema management

Procedure	Description
Manual lymphatic drainage (Vodder approach) Duration: 45 min	1. Manual activation of lymph nodes (neck, superficial and deep abdomen, axilla, groin, thorax, back, lateral trunk) to promote the movement of the lymphatic fluid from the swollen arm. 2. Drainage with light hand motions (pump, scoop, stationary circle, rotary, and thumb circle) from proximal to distal regions.
Multi-layered bandaging (every night time, at least 8 h)	Bandaging according to the scheme: 1. Tubular bandage 2. Elastic gauze or Mollelast bandages to the fingers 3. Padding with foam 4. Multilayer bandaging with short-stretch bandages.
Exercises Duration: 20-30 min	1. Circulatory exercise for arm and hand I. Combination of handgrip with wrist flexion and extension: holding 5-10 s each position, repeat 15-30 times every h. II. Elbow flexion and extension: 15-30 times for each movement III. Shoulder flexion, extension, abduction-adduction, and rotation: 15-30 times for each movement 2. Stretching for the arm, triceps, and biceps: holding each movement to a point of slight tension, 4 times X 15 s. 3. Light resistance exercises using an elastic band for the upper limbs: Elbow flexion and extension, shoulder extension, flexion, abduction, and adduction. 4. Breathing exercises
Patient education on self-management	1. Skin and nail care 2. Self-manual lymphatic drainage 3. Self-bandaging 4. Home exercise program; as taught during the physiotherapy session

were then processed and analyzed using the IBM Statistical Package for the Social Science (SPSS version 26).

Descriptive analysis was used to describe the characteristics of the patients to provide the mean, standard deviations (SD), range (minimum-maximum), frequency, and percentage (%) of variables of interest. The paired *t*-tests were performed to determine the significant changes for all patients and each category based on age group (<60 and ≥60 years) and stage of lymphedema (stages 1-2 and 3-4). The percentage change for each category of the LC and shoulder flexion ROM was also presented. In addition, the relationships between baseline MS and the treatment outcomes (LC and shoulder flexion ROM) were measured using Pearson's correlation. The level of significance was set at $p < 0.05$.

RESULTS

A total of 79 patients who fulfilled the inclusion criteria were included in the data analysis. The characteristics of the patients are shown in Table 2. The patients were aged between 33 and 79 years, with a mean age of 58.89 ± 10.22 years. About 51.9% (n = 41) of the patients were aged ≥60 years old. The majority of the patients were Malays (70.9%), married (84.8%), and graduated from university (67.1%). Patients who were working accounted for about 39.2%. It was observed that 34.2% of the patients had some comorbidities. Most patients (51.8%) were diagnosed with stage 1-2 breast cancer. The mean for the baseline handgrip strength was 3.29 ± 1.20 kg.

TABLE 2. Characteristic of patients (n=79)

Characteristics	Mean±SD (range)	Frequency (%)
Age (years)	58.89±10.22 (33-79)	
Below 60		38 (48.1)
60 and above		41 (51.9)
Ethnicity		
Malay		56 (70.9)
Chinese		15 (19.0)
Indian		8 (10.1)
Marital status		
Single		7 (8.9)
Married		67 (84.8)
Divorced/Widowed		5 (6.3)
Level of education		
Primary		2 (2.5)
Secondary		24 (30.4)
University		53 (67.1)
Occupation		
Not Working		28 (35.5)
Working		31 (39.2)
Retired		20 (25.3)
Stage of BCRL		
Stage 1-2		41 (51.8)
Stage 3-4		38 (48.2)
Comorbid (HPT, DM)		
Yes		27 (34.2)
No		52 (65.8)
Body Mass Index (kg/m^2)	26.16±4.65 (16.9-42.5)	
Baseline muscle strength	3.29±1.20 (0-5)	

BCRL: Breast cancer-related lymphedema

Table 3 displays the changes in the LC and shoulder flexion ROM of the affected sides following 8 sessions of LM. In terms of effects on LC, all groups showed a significant reduction, with a general improvement of 12.56% (t = 4.103, $p = 0.001$). When comparing age groups, patients <60 years had a greater improvement than those ≥60 years (16.41% [t = 3.752, $p = 0.001$] vs. 9.60% [t = 2.256, $p = 0.030$]). The patients with stage 1-2 lymphedema also presented with a significantly higher improvement in LC than patients with stage 3-4 (22.84% [t = 3.889, $p < 0.001$] vs. 7.76% [t = 2.163, $p = 0.037$]).

As for the shoulder flexion ROM, generally, all patients had a significant improvement of 3.99% (t = 2.831, $p < 0.01$). When comparing the two age groups, those 60 years and above had a greater improvement than patients aged <60 (5.06% [t = 2.562, $p = 0.014$] vs. 3.06% [t = 1.515, $p = 0.138$]). Similarly, patients with stage 3-4 lymphedema showed a significantly higher percentage of improvement than patients with stage 1-2 (5.50% [t = –2.040, $p = 0.049$] vs. 2.95% [t = –1.939, $p = 0.060$]).

The relationships between baseline MS, LC, and shoulder flexion ROM are shown in Table 4. Analyses were performed using pre-treatment, post-treatment, and change values. The age group analysis for the relationship between baseline MS and LC at pre- and post-treatment revealed that all measures were negatively significantly correlated with high r values between –0.81 and –0.92 (all $p > 0.01$).

TABLE 3. Effects of lymphedema management on limb circumference and shoulder flexion ROM in all patients (n=79), based on age category and stage of lymphedema

Variables	Pre-treatment mean±SD	Post-treatment mean±SD	% of change	*t* (*p*-value)
Limb circumference (cm)				
All	3.74±3.20	3.27±3.23	12.56	4.103 (0.001)**
Age group (years)				
<60 (n=38)	3.36±3.12	2.81±3.13	16.41	3.752 (0.001)**
≥60 (41)	4.09±3.27	3.70±3.29	9.60	2.256 (0.030)*
Stage of lymphedema				
1-2 (n=41)	2.32±1.20	1.79±1.29	22.84	3.889 (<0.001)**
3-4 (n=38)	5.28±3.92	4.87±3.88	7.76	2.163 (0.037)*
Shoulder flexion ROM (º)				
All	139.56±66.09	145.13±66.29	3.99	2.831 (0.006)**
Age group (years)				
<60 (n=38)	154.87±54.32	159.60±53.68	3.06	1.515 (0.138)
≥60 (n=41)	125.37±73.20	131.71±74.29	5.06	2.562 (0.014)*
Stage of lymphedema				
1-2 (n=41)	172.56±21.77	177.80±14.05	2.95	–1.939 (0.060)
3-4 (n=38)	103.95±78.65	109.87±81.18	5.50	–2.040 (0.049)*

*significant at $p<0.05$, **significant at $p<0.01$, based on paired t-test. ROM: Range of motion, °=degree

TABLE 4. Relationship between baseline muscle strength with pre-treatment, post-treatment, and changes of limb circumference and shoulder flexion ROM

Variable	Baseline muscle strength		
	Pre-treatment r (*p*-value)	Post-treatment r (*p*-value)	Changes r (*p*-value)
Limb circumference (cm)			
All	−0.85 (0.001)**	−0.89 (0.001)**	0.18 (0.120)
Age group (years)			
<60	−0.92 (0.001)**	−0.92 (0.001)**	0.01 (0.959)
≥60	−0.81 (0.001)**	−0.89 (0.001)**	0.25 (0.113)
Stage of Lymphedema			
1-2	−0.53 (<0.001)**	0.25 (0.119)	0.10 (0.535)
3-4	−0.83 (<0.001)**	−0.90 (<0.001)**	0.20 (0.225)
Shoulder flexion ROM (º)			
All	0.92 (0.001)**	0.93 (0.001)**	0.05 (0.661)
Age group (years)			
<60	0.86 (0.001)**	0.89 (0.001)**	−0.05 (0.763)
≥60	0.94 (0.001)**	0.94 (0.001)**	−0.08 (0.625)
Stage of lymphedema			
1-2	0.01 (0.996)	−0.05 (0.761)	0.04 (0.799)
3-4	0.98 (<0.001)**	0.97 (<0.001)**	−0.12 (0.485)

**Pearson's correlation is significant at $p<0.01$. ROM: Range of motion, °=degree

While, when patients were categorized according to the stage of lymphedema, baseline MS was significantly correlated with LC at pre-treatment only ($p < 0.001$).

As for the relationship between baseline MS and shoulder flexion ROM at pre- and post-treatment, all measures were positively correlated with high r values between 0.86 and 0.94 (all $p > 0.01$). The significant correlation between MS and shoulder ROM at pre- and post-treatment was only found in the patients with stage 3-4 lymphedema ($p < 0.001$).

There is no significant correlation between baseline MS with changes in the LC and shoulder flexion ROM in all patients, based on age groups and stage of lymphedema (all $p > 0.05$).

DISCUSSION

To the best of the authors' knowledge, this is the first retrospective report on the effectiveness of LM following breast cancer treatment in women with BCRL conducted in Malaysia. Based on the analysis, the effectiveness of LM in managing BCRL was observed in a significant proportion of women aged ≥60 years in the current study cohort. However, a cross-sectional study performed in 185 patients with BCRL revealed that younger people with lymphedema had more problems with daily functioning (14) while another study suggested that aging is related to the severity of BCRL (15), contrary to a systematic review that did not conclude age as a risk factor for lymphedema development (16). Due to the inconsistency in the previous literature, it is necessary to make comparisons between age group and severity of BCRL.

In terms of the effect of LM on LC, the current study demonstrated a significant reduction in LC regardless of age group (all $p < 0.05$), with a general improvement of

12.56%. This improvement is consistent with a systematic review that concluded LM, which combined MLD, exercise, compression therapy, and skin care, can achieve a 45-75% reduction in lymphedema volume (17). Consistently, a 1-month-long course to train women to professionally carry out self-administered complete decongestive therapy (CDT) showed limb volume decreased compared to the baseline with a median reduction of 8% (18).

Previous studies have reported varying findings regarding the effectiveness of MLD in reducing lymphedema volume. Specifically, a study comparing the effects of MLD and compression therapy revealed a significant decrease ($p < 0.001$) in lymphedema volume irrespective of treatment assignment (17). In addition, individuals with mild lymphedema receiving combined MLD and compression bandages experienced a significantly larger percentage reduction in volume compared to those receiving compression bandages alone (19). In contrast, another multicenter, randomized, single-blind trial concluded that MLD did not provide additional volume reduction in breast cancer patients (20).

In the current study, it is shown that the percentage of improvement in LC in patients <60 years was higher compared to those ≥60 years. According to a previous report, age would affect LM even though there is no relationship with lymphedema severity; however, the elderly group had a poor response that could be due to poor bandage compliance (21). In addition, lymphedema in the elderly is often complicated by comorbidities, diagnostic uncertainties, intervention complications, damage to the lymph systems resulting in fluid overload, causing further edema, as well as inactivity and muscle weakness that can lead to difficulty in managing the treatment (22). It was also noted in this study that those with stage 1-2 lymphedema showed a significantly higher percentage of improvement in the LC than those with stage 3-4. This could be because the early stages of lymphedema are predominantly characterized by interstitial fluid accumulation or mild tissue changes that cause tissue swelling, whereas advanced lymphedema is accompanied by adipose tissue hypertrophy, skin thickening, and tissue fibrosis (23). The findings of this study may support earlier literature that suggested CDT is an effective treatment modality for early-stage BCRL (24).

Surgery conducted near the shoulder joint may negatively affect the shoulder ROM due to pain and scarring from the healing tissues. A previous study found that the affected arm of women with BCRL typically presented with reduced shoulder ROM, particularly in abduction (25). However, the current practice, as reported in this study, only measures the shoulder flexion ROM. Fortunately, in this study, patients who received LM, which included exercises for the upper shoulder extremity, obtained a significant improvement of about 3.99% ($p < 0.001$) for the shoulder flexion ROM. When comparing age groups, the current study showed that those ≥60 years had a greater shoulder ROM improvement than the younger group. Contrary to the previous studies, patients who were under 65 years old had better improvement in the upper extremity (26). This may be due to the fact that baseline measure for shoulder flexion ROM for those <60 years was already higher than that for those ≥60 years, with a baseline mean of 154.87 (SD = 54.32) and 125.37 (SD = 73.20), respectively. In this study, those aged ≥60 years old were mainly retired and had more time to perform exercises than the younger ones, who may be working or busy with house chores. With regard to comparisons of shoulder flexion ROM, those with stage 3-4 had a significantly higher percentage of improvement. Those with stage 1-2 lymphedema had a smaller improvement as their baseline performances were almost full range (180°), leaving a smaller room for improvement. In contrast, those with stage 3-4 presented with a higher percentage of improvement as their baseline ROM was rather small; however, even after completing 8 sessions of treatment, the shoulder flexion ROM was still limited. This may suggest that those with a higher stage of lymphedema may require a longer duration of treatment.

In terms of the correlation between MS and LC, the current study showed that the higher the baseline MS, the smaller the LC (Table 4). A strong muscle can generate a pumping effect that enhances lymphatic drainage, which may contribute to the observed relationship between MS and LC (27). Unlike treating lymphedema with MLD, which relies on passive forces, MS can produce active forces or skeletal muscle pumping. This, in turn, stimulates the contraction of lymphatic vessels and enhances the drainage of lymphatic fluid, thereby limiting vascular permeability and contributing to improved outcomes (28).

The current study also found a significant correlation between MS and shoulder flexion ROM ($p > 0.01$), except for patients with stage 1-2 lymphedema. This explained that the higher the baseline MS, the better the shoulder flexion ROM. There is limited study to support the current finding; however, one study suggested that strengthening exercise using a resistance band five times a week for 8 weeks in conjunction with intensive CDT for 1 or 2 weeks, depending on severity, may improve upper extremity function as measured by the disabilities of arm, shoulder, and hand (DASH) questionnaire (29). Greater shoulder muscular strength was significantly associated with better functional well-being in breast cancer survivors who performed Qigong training (30). However, the current protocol of LM, as reported in this study, did not include any progressive strengthening exercises except for light exercises with an elastic band, and there were no follow-up measures of upper limb strength. A systematic review found that the early introduction of a combination of stretching and strengthening or strengthening alone was valuable in avoiding deterioration in shoulder mobility (31). Therefore, this exclusion may be one of the weaknesses of LM that needs to be considered in future practice, given the small changes in the outcomes. Another finding suggested that breast cancer survivors can perform resistance exercise training at high enough intensities to elicit strength gains without triggering changes to lymphedema status (32).

This study was conducted in a single center only, and the same protocol of LM was given to all patients. However, this current study presents a few limitations. The technique for measuring LC lacks evidence to support its validity, which needs to be determined in future studies. In addition, in the current assessment of shoulder mobility, only shoulder flexion ROM was included, as other movements have not been the priority of the management. This is because most

patients complained of having difficulties with activities of daily living involving flexion movement. Shoulder flexion alone may not reflect the overall upper extremity functions. However, the value of comparing the affected and unaffected arms should be acknowledged to provide a more comprehensive understanding of the overall shoulder function and identify any compensatory movements or asymmetries between the arms. A comparison between the arms could indeed help identify the relationship between global ROM and the ROM in the affected arm. Thus, a more reliable functional tool should be incorporated into the management, such as performing the DASH outcome measure to analyze patient upper extremity function (33). In addition, MS measurement was only conducted during the first assessment using MMT in the current LM protocol. Most current studies use handgrip strength to represent the upper limb muscle function of women with BCRL (34-36).

Future studies should include more specific and objective ROM and strength measures to determine whether LM provides overall well-being for the upper limb. The evidence suggested in this study is important for the lymphedema therapist as it can implement new actions or improve the existing clinical practice in terms of patient assessment and treatment.

CONCLUSION

The effects of the LM, as reported in this current study, indicated that 8 sessions of LM showed a significant improvement in the LC and shoulder mobility as measured by the flexion ROM. The findings also revealed that MS might influence LC and shoulder flexion ROM outcomes. However, progressive strengthening exercises were not part of the treatment in the LM procedures.

Based on the findings of this study, it is recommended that the protocol of the LM requires a comprehensive review. It is suggested that measurements of LC, shoulder ROM (flexion, abduction, rotation, extension), and MS be conducted as routine assessments as part of the management of BCRL. In addition, valid outcome measures should be used for all the measurements to determine the cost-effectiveness of the treatment.

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DECLARATION OF INTERESTS

Authors declare no conflict of interests.

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