

## Original Article



# Bangla Version of Lymphedema Life Impact Scale Version 2: Reliability and Validity

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### Abstract

**Background:** The use of disease-specific scales would be more valuable for the evaluation of the effects of lymphedema. To manage accordingly, and maintain the optimum quality of life of lymphedema patient, a validated outcome measure is helpful.

**Objective:** To investigate the reliability and validity of Bangla Version of Lymphedema Life Impact Scale Version 2 (B-LLIS V2).

**Materials and Methods:** A structured process that included translation, verification, compromise assessment, reverse translation, feedback, and final correction. B-LLIS V2 reliability and validity were conducted on 52 lymphedema patients. The reliability was evaluated by performing internal consistency and test-retest analyses. Its validity was assessed by comparing the B-LLIS V2 with other scales implying Pearson's correlation.

**Results:** Internal consistency with Cronbach's alpha was 0.92 for total score and 0.79, 0.82, 0.80 and 0.78 for physical, psychosocial, functional, and infection respectively. The calculated overall tool score in Intra-class correlation co-efficient (ICC) for test-retest reliability was 0.94 and among subscales, the scores were 0.92, 0.95, 0.91 and 0.93 for physical, Psychosocial, functional, and infection respectively, which signified substantial reliability. The overall values of Pearson's correlation coefficient for the construct validity were 0.91, 0.78 and 0.86 against reference standard Bengali SF-36 Health Survey, Bangla version of the Boston Carpal Tunnel Questionnaire and Bangla Start Back Screening Tool, and they all were statistically significant.

**Conclusions:** B-LLIS V2 is a valid and reliable tool for the assessment of impairment due to lymphedema.

**Key words:** Lymphedema, Outcome measure, Quality of life, Validity

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### Introduction

The term "lymphedema" is often used to describe an overgrown limb regardless of the underlying etiology; 25% of referred patients with "lymphedema" do not have the disease.<sup>1,2</sup> Lymphedema is the swelling of soft tissues due to accumulation of lymph, the fluid carried in the vessels that accompany arteries and veins like the later possess smooth muscles and valves to aid in centripetal flow of lymph.

It is important to accurately determine if a patient has lymphedema so that, the individual is managed correctly.<sup>3</sup> However, treatment is started based on clinical signs. These are many and

include the color and temperature of the skin, the nature of implantation of hair. These signs, together with a history of the development of the edema, provide sufficient information to allow us to treat the patient appropriately. Lymphedema may present with swelling, pain, limited motility in the extremities, recurrent infections, functional disabilities, and psychosocial problems. As a result, the daily activities may become difficult with impaired quality of life (QoL).<sup>4,5</sup> Accurate information on health-related QoL outcomes among patients with lymphedema is critically needed to determine evidence-based decision making, indicating the impact of disease on survivors' lives. Due to the special symptoms and difficulties of the patients with

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lymphedema, it is important to use a questionnaire developed specifically for patients suffering from this chronic condition.<sup>6</sup> The Lymphedema Life Impact Scale version 2 (LLIS version 2) is a tool of condition specific outcome measure for lymphedema, developed to evaluate the physical, psychosocial, and functional effects of lymphedema. Unlike other scales used for the evaluation of lymphedema, it questions the incidence of infection, which is a frequent and important complication of lymphedema. The scale consists of 18 items in four subscales: physical (6 items), psychosocial (6 items), functional (5 items) and infection rate (1 item). Each item is scored from 0 to 4, with higher scores denoting greater severity. It can be used for any extremity lymphedema. The validity and safety studies of the original English version have been conducted by Weiss and Daniel.<sup>7</sup> This type of instrument needs to be translated in other languages so that, it can be applied in other countries and contexts. Bangladesh is one of the lymphatic filariasis endemic countries in the world and moreover, there are many cases of cancer related lymphedema.<sup>8,9</sup> In the present study, we aimed to investigate the validity and reliability of the Bangla version of the LLIS version 2 in Bangladeshi population.

## Materials and Methods

A total of 52 patients with lymphedema who were attended to, and referred from the other department to the outpatient department of the Physical Medicine and Rehabilitation of Khwaja Yunus Ali Medical College and Hospital, Enayetpur, Sirajganj and the National Institute of Cancer Research and Hospital between January 2021 and December 2021 were included. The patients were 18 years and older, having either upper or lower limb, bilateral or unilateral lymphedema, and able to read, speak, and comprehend in the Bangla language. The patients with any extremity insufficiency due to orthopedic or neurological reasons, and life-threatening or terminal illness were excluded.

Age, sex, occupation, height, weight, additional diseases, history of cancer, swelling in the affected extremity, tightness, heaviness, stiffness, pain, and numbness were questioned. The location, etiology, and stage of lymphedema were recorded. The circumference measurements of the affected and ipsilateral extremity were made. The points of measurement were determined as the metacarpophalangeal joint, the wrist, the 10 cm distal and the proximal parts of the elbow in the upper extremity, and metatarsophalangeal joint, the ankle, the 10 cm distal and the proximal parts of the knee in the lower extremity. The differences between the extremities were recorded in cm. Permission of the author of the LLIS Version 2 scale was obtained for translation into Bangla. As the first step, the scale was translated into Bangla independently by two researchers who had specialty in Physical medicine and Rehabilitation and one translator who had advanced experience in the English language. The translations included differences in some words, although they referred the same meaning. Therefore, a synthesis of the most appropriate matches in the Bangla and those fitting

best in English was made. The final adaptation was performed via comparison of the original English scale to the Bangla scale. For pilot testing, cognitive debriefing was performed with 10 patients. During a cognitive debriefing interview, participants were asked to identify any words that were difficult to understand and explain in their own words the meaning of each sentence in the questionnaire. This procedure evaluated the feedback about how clearly the questions of the scale was understood and how they could be better expressed. The final version of the scale was constructed based on these feedbacks. All the patients included in the study, filled out the LLIS Version 2 scale under the guidance of a supervisor in the hospital setting.

For the reliability analysis, the internal consistency and the test-retest reliability were measured. To evaluate the internal consistency, the Cronbach's alpha values were calculated for the total scale and for the subscales. A Cronbach's alpha coefficient of  $>0.7$  was accepted as internally consistent. The test retest reliability was evaluated using the intra class correlation coefficient (ICC). The content validity of the Bangla version of LLIS Version 2 (B-LLIS version 2) was assessed by Index of content validity (ICV), which was done through calculation of responses by the 3 experts for each question. Each expert rated each item as 1 (agree), 0 (undetermined) or -1 (disagree). The ICV of each item was then calculated using summation of scores from each expert divided by the number of experts. The Construct validity was attained to see validity, by comparing the Bengali Short Form-36 (SF-36) Health Survey, Bangla version of the Boston Carpal Tunnel Questionnaire (B-BCTQ) and Bangla Start Back Screening Tool (B-SBST) with Bangla version of LLIS Version 2 (B-LLIS version 2) by examining Pearson correlation coefficient in between.<sup>10-12</sup> A p value of  $\leq 0.05$  was considered statistically significant. The statistical analysis was performed using the IBM SPSS version 22.0 software.

A written informed consent was obtained from each participant. The study protocol was approved by Institutional Review Board of Khwaja Yunus Ali Medical College, Sirajganj. The study was conducted in accordance with the principles of the Declaration of Helsinki.

## Results

The majority of the study population were female. In the upper extremity, lymphedema was present 90.6% in female and 9.4% in male patients and in the lower extremity it was 95% in female and 5% in male patients. In the upper extremity lymphedema group, 6.2% of the patients had primary lymphedema and 93.8% had secondary lymphedema and, for the lower extremity the value were 15% and 85% respectively. Among the patients with upper extremity lymphedema, the etiology of secondary lymphedema included breast cancer in 87.5% patients and, in the lower extremity it was Carcinoma pelvic region in 40% patients. The demographic and clinical characteristics of the patients displayed in Table I.

**Table I:** Demographic and clinical characteristics of the participants

	Upper extremity group			(n=32)	Lower extremity group			(n=20)
	n	%	median	Min - max	n	%	median	Min - max
Age (year)	32		52	29 - 73	20		54	31 - 80
Gender								
Female	29	90.6			19	95		
Male	3	9.4			1	5		
BMI			30	18 - 45			32	22 - 53
<b>Etiology</b>								
<b>Primary lymphedema</b>	2	6.2			3	15		
<b>Secondary lymphedema</b>	30	93.8			17	85		
Breast cancer	28	87.5						
Obesity	2	6.25			2	10		
Trauma					3	15		
Carcinoma of pelvic region					8	40		
Filariasis					4	20		
<b>Lymphedema stage</b>								
Stage 1	2	6.3			3	15		
Stage 2	27	84.4			16	80		
Stage 3	3	9.3			1	5		

Abbreviations: BMI-body mass index

**Reliability**

Internal consistency with Cronbach’s alpha ( $\alpha$ ) reliability for Bangla version of LLIS version 2 was 0.92 in total score and 0.79 in physical, 0.82 in psychosocial, 0.80 in functional, and 0.78 in infection subscale. Alpha should be >0.7, which was standard for all scores.<sup>13</sup>

The calculated overall tool score in Intra-class correlation co-efficient (ICC) for test-retest reliability for B-LLIS version 2 was 0.94 and, the scores were 0.92, 0.95, 0.91 and 0.93 in subscales Physical, Psychosocial, functional and infection respectively, which signified substantial reliability (Table II).<sup>12</sup>

**Table II:** Reliability co-efficient for the domains of Bangla version of LLIS Version 2

Domains	Cronbach’s $\alpha$	ICC	95% CI	P
Physical	0.79	0.92	0.89-0.96	<0.001
Psychosocial	0.82	0.95	0.92-0.98	<0.001
Functional	0.80	0.91	0.87-0.93	<0.001
Infection	0.78	0.93	0.89-0.95	<0.001
Total	0.92	0.94	0.91-0.96	<0.001

Abbreviations: ICC- Intra-class correlation co-efficient, CI-confidence interval

**Validity**

The calculated Index of content validity (ICV) showed 100% content validity of the final B-LLIS version 2. Whereas, the construct validity of Bangla version of LLIS version 2 was examined by Pearson’s correlation co-efficient between the scales and found negative correlation indicating positive association among them. The overall tool scores were 0.91, 0.78, 0.86 against reference standard the Bengali Short Form-36 (SF-36), B-BCTQ and, B-SBST. All of the items were statistically significant ( $p<0.001$ ) (Table III).

**Table III:** Construct validity of the Bangla version of LLIS version 2

Validity comparing tool	Pearson’s correlation co-efficient	p-value (Overall)
Bengali SF -36	0.91	<0.001
B -BCTQ	0.78	<0.001
B -SBST	0.86	<0.001

Abbreviations: Bengali SF-36 - Bengali Short Form-36 (SF-36) Health Survey, B-BCTQ - Bangla version of the Boston Carpal Tunnel Questionnaire, B-SBST - Bangla Start Back Screening Tool  
The correlation is significant at 0.01 level.

The final Bangla version of LLIS version 2 after the assessment of reliability and validity showed in Figure 1.

## বাংলা “লিম্ফেডেমা লাইফ ইমপ্যাক্ট স্কেল” সংস্করণ ২

**Bangla Lymfedema Life Impact Scale version 2**

রোগীর নামঃ

মূল্যায়নঃ

দশম সাক্ষাৎঃ

বিশতম সাক্ষাৎঃ

ত্রিশতম সাক্ষাৎঃ

(নিম্নের সমস্যা বা উপসর্গগুলো লিম্ফেডেমা আক্রান্ত ব্যক্তির বলে থাকেন। দয়া করে বলুন যে, গত এক সপ্তাহে এই সমস্যাগুলো আপনার লিম্ফেডেমার সাথে কতটুকু সম্পর্কিত ছিল। সমস্যার যে পর্যায়টা আপনার সাথে মিলে যায় সেটাতে গোল চিহ্ন দিন।)

ক	শারীরিক উদ্বেগ	যদি ফোলা এবং উপসর্গ দুই অঙ্গের সমান থাকে তাহলে তাদেরকে একইভাবে মূল্যায়ন করুন, তা না হলে শুধুমাত্র খারাপতর অঙ্গকেই মূল্যায়ন করুন				
১	আমার লিম্ফেডেমার সাথে সম্পর্কিত ব্যথার পরিমাণ হোল	০ কোন ব্যথা নাই	১	২	৩	৪ প্রচণ্ড ব্যথা
২	আমার লিম্ফেডেমার সাথে সম্পর্কিত অঙ্গ ভারীতার পরিমাণ হোল	০ কোন ভারীতা নাই	১	২	৩	৪ প্রচণ্ড ভারী
৩	আমার লিম্ফেডেমার সাথে সম্পর্কিত চামড়াতে অঁটসাঁট ভাবের পরিমাণ হোল	০ কোন অঁটসাঁট ভাব নাই	১	২	৩	৪ প্রচণ্ড অঁটসাঁট ভাব
৪	আমার ফোলা অঙ্গ(সমূহ) এর আকার মনে হচ্ছে	০ স্বাভাবিক	১	২	৩	৪ প্রচণ্ড বড়
৫	আমার ফোলা অঙ্গ(সমূহ) এর নড়াচড়ায় লিম্ফেডেমার প্রভাব	০ স্বাভাবিক	১	২	৩	৪ প্রচণ্ড সংকুচিত
৬	আমার ফোলা অঙ্গ(সমূহ) এর শক্তি	০ স্বাভাবিক	১	২	৩	৪ প্রচণ্ড দুর্বল

খ	মনো-সামাজিক উদ্বেগ					
৭	লিম্ফেডেমা আমার শারীরিক প্রতিচ্ছবিতে প্রভাব ফেলে (আমার মতে আমাকে দেখতে কেমন লাগে)	০ একদমই না	১	২	৩	৪ পুরোপুরি
৮	লিম্ফেডেমা আমার সামাজিক মেলামেশায় প্রভাব ফেলে	০ কোন প্রতিবন্ধকতা নাই	১	২	৩	৪ সম্পূর্ণ প্রতিবন্ধকতা তৈরি করে
৯	লিম্ফেডেমা আমার পরি/সঙ্গীসহ সাথে অন্তরঙ্গ মেলামেশায় প্রভাব ফেলে (প্রয়োজ্য না হলে ০ দিন)	০ কোন প্রতিবন্ধকতা নাই	১	২	৩	৪ সম্পূর্ণ প্রতিবন্ধকতা তৈরি করে
১০	লিম্ফেডেমা আমাকে শেষ করে দিচ্ছে (মানে হোল- লিম্ফেডেমার কারণে আমার নিরাশ ও বিষণ্ণ লাগে বা রাগ লাগে)	০ কখনোই না	১	২	৩	৪ সর্বসময়
১১	লিম্ফেডেমার কারণে আমার সবসময় অন্যের সাহায্যের উপর নির্ভর করতে হয়	০ একদমই না	১	২	৩	৪ পুরোপুরি
১২	আমি আমার লিম্ফেডেমার ব্যবস্থাপনা জানি	০ ভালো জানি	১	২	৩	৪ একদমই জানি না

গ	সক্ষমতার উদ্বেগ	০	১	২	৩	৪
১৩	লিম্ফেডেমা আমার নিজের যত্ন নেয়ার ক্ষমতায় প্রভাব ফেলে (যেমনঃ খাওয়া, কাপড়চোপড় পরা, পরিষ্কার-পরিচ্ছন্নতা)	কোন প্রতিবন্ধকতা নাই				সম্পূর্ণ প্রতিবন্ধকতা তৈরি করে
১৪	লিম্ফেডেমা আমার দৈনন্দিন কর্মক্ষমতায় (ঘরের এবং কাজের ক্ষেত্রে) প্রভাব ফেলে	কোন প্রতিবন্ধকতা নাই				সম্পূর্ণ প্রতিবন্ধকতা তৈরি করে
১৫	লিম্ফেডেমা আমার পছন্দের অবসরকালীন কর্মতৎপরতায় প্রভাব ফেলে	কোন প্রতিবন্ধকতা নাই				সম্পূর্ণ প্রতিবন্ধকতা তৈরি করে
১৬	লিম্ফেডেমার কারণে জামাকাপড় বা জুতার সঠিক মাপে প্রভাব ফেলে	সঠিক মাপমত হয়				পরতে পারি না
১৭	লিম্ফেডেমা আমার ঘুমের বিঘ্ন ঘটায়	কোন বিঘ্ন ঘটায় না				পুরোপুরি বিঘ্ন ঘটায়

  

ঘ	সংক্রমণের হার	০ বার	১ বার	২ বার	৩ বার	৪ বারের বেশী
১৮	গত বছর আমার ফোলা অঙ্গে সংক্রমণের কারণে মুখে এন্টিবায়োটিক খেতে হয়েছিল অথবা হাসপাতালে ভর্তি হতে হয়েছিল					

বৈকল্যের শতকরা হিসাব নির্ণয়ে "লিম্ফেডেমা লাইফ ইমপ্যাক্ট স্কেল" এর ফলাফল প্রক্রিয়াঃ

- ১ থেকে ১৭ নম্বর প্রশ্নের ফলাফলের যোগফল (১৮ নম্বর প্রশ্নের ফলাফল অন্তর্ভুক্ত করবেন না) বের করুন
- যোগফলকে উত্তর দেয়া মোট প্রশ্ন সংখ্যা দিয়ে ভাগ করুন
- ২৫ দিয়ে গুন করুন

(প্রথম বার কোন প্রশ্নের উত্তর না দিলে পরবর্তীতেও ওই প্রশ্ন ফাঁকা রেখে যান)

Figure 1: Bangla Lymphedema Life Impact Scale version 2

## Discussion

The lymphedema is a chronic condition that can cause many impairments, limitations of activity, and infections that interfere the QoL. So, there is an obligation to record and compiling of the functional outcomes and impairment scoring for the rehabilitation recompense, and it is expected having both of a lymphedema-specific outcome measure and the one for estimation of the impairment level. Here, 0 means 'no impairment' and 4 means 'severe impairment'. The question regarding infection scoring 0 for 'no episodes of infection' and 4 to 4+ for 'episodes of infection in the past year'.<sup>7</sup> The Bangla version of LLIS version 2 is owning the same requisites that are provided by the original one.

The appraisal properties for a critically claiming tool are easily administrable, reproducible, valid, reliable and responsive to clinical evolution.<sup>14</sup> The B-LLIS version 2 (Figure1) takes roughly 10 minutes to be completed, so it doesn't impose any strain to the patients and researchers. Reliability and validity are the essence of the quality assessment. A reliable instrument gives the same result on diverse occasions. Test-retest and internal consistency are two main established points of reliability as a measurement tool in the evaluation of patient.

In this study, we have strived to translate the original version of

the LLIS version 2 into Bangla for native Bangladeshi patients with lymphedema and to evaluate its validity and reliability. It is showed in the results that the Bangla version of LLIS version 2 is a reliable, internally consistent, and valid questionnaire in Bangladeshi patients with the lymphedema. Here the Cronbach's alpha value has been taken >0.7 for the complete scale and each of the subscale. Furthermore, the total alpha value of the scale, which has been 0.92 (>0.9), indicated a ideal internal consistency of the scale which has been almost identical as Turkish version of LLIS (Cronbach's alpha, 0.91).<sup>15</sup>

For the test-retest reliability of the scale, the statistical difference between the measurements at two different time points need to be compared. Thus, the ICC should be determined. An ICC value of >0.75 denotes a good, and a value of >0.9 denotes a perfect reliability. This study has presented that all the values of the scale and subscales have been >0.9 showing a ideal reliability and the overall ICC is (0.94) in this study, which is similar to that of Turkish (0.99) and Persian (0.96) version of LLIS.<sup>15,16</sup>

The construct validity of Bangla version of LLIS version 2 has been examined by Pearson's correlation coefficient. For the evaluation of the construct validity, the outcomes of the newly developed scale are compared to those of the previous scales,

and the relationship between them has been analyzed. A significant correlation has been found between the LLIS version 2 and its subscales with validated Bangla version of Physical function subscale (PF-10) of SF-36, Bangla version of Boston carpal tunnel questionnaire (B-BCTQ) for the upper extremity lymphedema group and Bangla STaRT Back Screening Tool (SBST) for the lower extremity lymphedema group.

The main limitation of the present study is the low number of male participants. However, considering the pathophysiology of lymphedema and clinical findings, there is no reason to suggest a difference in the lymphedema-related problems between sexes.

## Conclusion

The Bangla B-LLIS version 2 was successfully validated in Bangladeshi population. It could be useful for the clinicians, researchers in this region for the complete and effective management of Lymphedema of the any extremities and, can be adopted by the different programs running in Bangladesh on lymphedema like Bangladesh Lymphatic Filariasis Elimination Programme. The disability certificate providers can use this tool also.

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