Bioelectrical Impedance Self-Measurement Protocol Development and Daily Variation Between Healthy Volunteers and Breast Cancer Survivors with Lymphedema

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Abstract

Background: A significant percentage of breast cancer survivors are at risk for lymphedema for which lifelong self-care is required. Previous studies suggest that less than 50% of breast cancer survivors with lymphedema (BCS-LE) perform prescribed self-care tasks and that even wearing a compression sleeve, the most commonly reported self-care activity, is done irregularly. Reasons for poor self-care adherence include perceived lack of results from self-care (no available arm volume data) and perceived inability to manage the condition.

Methods and Results: A two-part pilot study was conducted to: 1) develop and determine the feasibility of a self-measurement protocol using a single frequency bioelectrical impedance device; and 2) examine daily variation in extracellular volume in healthy and lymphedematous limbs. Healthy and BCS-LE volunteers were recruited to refine and test a self-measurement protocol. Volunteers were trained in the use of the device and measured for 5 consecutive days in a laboratory setting. They were then given the device to use at home for an additional 5 consecutive days of self-measurement. All volunteers completed each scheduled home measurement. Daily variability in both groups was noted.

Conclusions: Home self-measurement using bioelectrical impedance is feasible, acceptable, and captures change. This has implications for both self-care support and for the possibility of incorporating self-measurement using bioelectrical impedance in future clinical trials examining effectiveness of lymphedema treatment.

Introduction

A SIGNIFICANT PERCENTAGE OF BREAST CANCER SURVIVORS (BCS) are at risk for lymphedema, a progressive side effect of breast cancer treatment.^{1–7} Once established, lymphedema is a chronic condition for which there currently is no cure.² Breast cancer survivors with lymphedema (BCS-LE) experience psychosocial and physical difficulties and a poorer quality of life than those without lymphedema.^{8–13} They also have a unique cluster of symptoms associated with lymphedema-alteration in limb sensation, loss of confidence in body, decreased physical activity, fatigue, and psychological distress.¹⁴ This cluster is present in individuals who have undergone professional limb volume reduction treatment and are purportedly self-managing the condition. Data from our previous studies suggest that less than 50% of BCS-LE actually perform prescribed self-care tasks and that even wearing a compression sleeve, the most common self-care activity, is

not done regularly.^{15,16} Reasons for poor self-care adherence include perceived lack of results from self-care (no available arm volume data) and feelings of inability to manage the condition.¹⁶ Poor adherence to prescribed self-care activities may partially explain the psychosocial and physical difficulties experienced by these individuals.^{8–13}

Lifelong lymphedema self-care is required to reduce exacerbations of swelling and infections, maintain arm function, and slow disease progression.¹⁷ Patients determine satisfaction with the outcomes associated with self-regulation behaviors (i.e., self-care) based on available information.¹⁸ Adequate information for successful self-regulation exists only when there is accessible information to engage two cognitive pathways, a subjective emotional pathway and an objective functional pathway (the pathway of interest in this study).^{18–20} We theorize that the lack of an objective self-measurement method for arm volume causes those with lymphedema to primarily engage the subjective pathway

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when making self-care decisions. This creates a barrier to self-care adherence by impeding the patient's ability to: 1) set measurable self-care goals (e.g., maintaining arm size); 2) have objective reinforcement for self-care; 3) make informed self-care decisions; and 4) determine satisfaction with self-care outcomes. Lack of objective data may also make it difficult to know when to seek treatment for increased swelling. Therefore, we conducted a pilot study to develop and test a home-based self-measurement protocol that could be used in future randomized clinical trials to support lymphedema self-care.

Due to their portability, water displacement, tape measurement, and bioelectric impedance analysis (BIA) are potentially viable self-measurement options. We undertook a review of each method prior to conducting the study to determine which would be used in our protocol. We determined that although water displacement has been the "gold standard" measurement method, it was less than ideal for home use as: 1) limbs with wounds cannot be assessed, 2) full limb extension may be difficult for some patients, and 3) spilled water could create a safety risk for falls in home settings.

Limb girth can be measured with a nonstretch tape, and findings can be used to estimate volume or assess girth changes.²¹ Our laboratory testing found that even in a controlled setting, trained research staff had difficulty holding a tape measure for self-measurement, and measurement error was high.

BIA has been validated in both human subjects and animal species.^{22–25} BIA has been shown to be more sensitive, reliable, and valid than tape measurement of the limb and has been used in multiple research studies.^{22–24} The FDA has approved a single frequency bioelectrical impedance analysis (SFBIA) device to measure lymphedema, the Impedimed L-Dex XCA.^{26,27} A lymphedema index (L-Dex) reading of greater than 10 is indicative of lymphedema.²⁷

The first author has used SFBIA in studies since 2002, and volunteers with breast cancer-related lymphedema have repeatedly asked to use these devices at home to monitor their arms.²⁸ Additionally, direct testing of the ability to self-measure using SFBIA was demonstrated by members of this research team in our laboratory. Therefore, due to participant requests to use the device for self-measurement, its demonstrated utility as a measurement method for arm lymphedema, and its ease of use compared to other methods, SFBIA was chosen as the proposed measurement method for this study. In this article, we report on a two-part pilot study to: 1) develop and determine the feasibility of a self-measurement protocol, and 2) examine daily variation in L-Dex values in healthy and lymphedematous limbs.

Materials and Methods

Based upon prior laboratory testing, the research team developed a preliminary self-measurement protocol before commencing with the study. This protocol was approved by both the Vanderbilt University Institutional Review Board (IRB) and the Vanderbilt-Ingram Cancer Center Scientific Review Committee. Written informed consent was obtained from all participants before enrollment in the study.

Recruitment

Eleven healthy volunteers were recruited to test the preliminary protocol and provide data regarding daily L-Dex readings in non-lymphedematous arms. Eleven BCS-LE vol-

unteers were then recruited to test a revised protocol and provide data regarding daily L-Dex readings representative of extracellular fluid in arms with the disease. Volunteers were recruited from an existing IRB approved registry of both BCS-LE and healthy women who had given permission to be contacted. To facilitate recruitment and retention, healthy volunteers drawn from the Vanderbilt community were paid \$5.00 each day they were in the study (up to \$50.00 total). Volunteers with lymphedema incurred travel expense to the campus for the 5 days of observed measurements and were paid \$7.50 per day (up to \$75.00 total).

All volunteers enrolled in this study met the following inclusion criteria: 1) age 21 or older; 2) no history of surgical procedures in arms or family history of primary lymphedema; 3) ability to stand upright; 4) no conditions that could cause swelling such as pregnancy, congestive heart failure, or liver failure; 5) no open sores on arms or known sensitivity to electrodes; 6) no pacemaker or internal defibrillator; and 7) not using laxatives or diuretics to lose weight. In addition to these criteria, volunteers with lymphedema had a history of breast cancer and diagnosis of lymphedema in one arm.

Data collection instruments

Demographic and medical history questionnaire. A self-report questionnaire was used to capture demographic and medical data.

Skin assessment. A skin assessment was completed by staff during the first study visit and by volunteers on the last day of the study. Findings were documented on a 20-item (e.g., open sore, cracked) standardized yes/no checklist.

Bioelectrical impedance. A SFBIA device manufactured by Impedimed (Mansfield, Australia) was used to measure extracellular fluid and provide L-Dex readings.²⁸

Protocol observation checklist and measurement log (lab and home versions). A checklist to guide evaluation of protocol understanding and volunteer adherence was used by staff. It was revised as needed to reflect changes in the protocol for Part Two of the study. L-Dex measurements were recorded on measurement logs. Date, time, and person completing the measurement were noted. Menstrual cycles, if applicable, were annotated.

Standardized post home measurement interview guide. Six questions were asked that addressed difficulty using the device, how those difficulties were handled, desirable changes to the protocol, tips for device use, whether volunteers would use the device and how often, and how much they would pay for it.

Willingness and Confidence Scale (Lymphedema Group). A self-report, 10-item survey that indicated willingness to incorporate self-monitoring into their self-care program and confidence in completion of self-measurement was completed only by volunteers with lymphedema.

Procedures Part One: Healthy Group

Healthy volunteers completed 10 consecutive days of measurements. The first five measurements were done in an

observed laboratory setting, and the final five were at home. All laboratory measurements were made early in the morning. Volunteers were instructed not to exercise (including fast walking or going up stairs) or consume caffeine for 2 hours prior to the test, and to avoid alcohol intake for 12 hours prior to their lab appointments. During the first laboratory visit, demographic and medical history information was collected. Volunteers were given a written protocol to read. Staff then demonstrated measurement using the protocol. Volunteers then demonstrated self-measurement: programmed the device, prepped site for electrodes, applied electrodes, and conducted the measurement while lying supine on a massage table with arms extended and legs not touching (Fig. 1). Once volunteers demonstrated the ability to measure their arms with staff present in the lab, they were knowingly observed through a one-way mirror for ability to follow the protocol unassisted. The Protocol Observation Checklist was used by trained staff to determine if the volunteers were able to complete the major steps of the protocol. If problems were noted at any time during this initial observed self-measurement activity, or in any subsequent self-measurement activity, re-education and re-assessment took place.

FIG. 1. Demonstration of self-measurement.

For visits two through five, volunteers returned to the lab and demonstrated self-measurement while knowingly observed through the one-way mirror by study staff. The Protocol Observation Checklist was used to record the participant's ability to complete the major steps of the protocol. Volunteers provided feedback and consistently successfully demonstrated self-measurement while in the lab. On day five of lab measurement, those who achieved an observation checklist score of 90% or better were loaned a device for home use. They then continued to measure their arms every morning for five days.

All home measurements were made in the early morning, before eating or drinking and after voiding. Logs were kept that included time of day, results, and positive or negative comments about the measurement process. After five days, staff picked up the device and volunteers were interviewed using a standard interview guide to determine any perceived difficulties following the protocol and to solicit suggestions for protocol improvement.

Procedures Part Two: Lymphedema Group

The preliminary protocol was revised based upon feedback from the healthy volunteers. Study visits were then conducted with the lymphedema volunteers using the same procedures as reported in Part One. Additional information related to breast cancer and lymphedema diagnosis and treatment was obtained. The Willingness and Confidence Scale was completed at the end of the study.

Statistical analyses

Key outcomes of this investigation were estimates of adherence and efficacy that can be used to adequately power subsequent studies and development of a SFBIA self-measurement protocol for use by BCS-LE. Descriptive statistical summaries of the sample characteristics were generated. Tests of differences in characteristics between the two volunteer groups were conducted using Chi-Square Tests of Independence (nominal/ordinal categories) and independent *t*-tests (age, education). Due to the skewed nature of the distributions of time since lymphedema diagnosis and treatment values, median and minimum/maximum values summarize those variables. Qualitative responses to the interview were coded for difficulties with specific tasks (e.g., placing electrodes, operating device, etc.) and suggested improvements (e.g., order of tasks, font size) and used to modify the protocol.

Each volunteer's daily L-Dex values from the laboratory and home environments were summarized using median and respective coefficient of variability. These statistical summaries were then used to assess differences in central tendency and variability of values within and between the two. Group differences were tested using Mann-Whitney Tests. Associations between home and lab values were generated using Spearman Rho correlations.

Additional evidence for the successful implementation of SFBIA self-monitoring was defined as volunteers with lymphedema a) recording a minimum of three of five possible home readings and b) seven 'yes' responses on the Willingness and Confidence Scale. These data (met criteria or not) were summarized using frequency distributions.

Results

Participant characteristics

One healthy volunteer withdrew from the study due to lack of time to comply with study requirements, which resulted in $n=10$. All volunteers with lymphedema completed the study ($n=11$). The final sample ($N=21$) consisted of non-Hispanic females ages 31 to 66 years old. The volunteers with lymphedema tended to be less educated ($p=0.037$) and had lower levels of income ($p=0.033$) (Table 1). Median years since lymphedema diagnosis and initial treatment was approximately 7 years (Table 2).

Self-Monitoring Part One: Healthy Group

All healthy volunteers scored 90% or higher on the Protocol Observation Checklist and were given the SFBIA device for home measurement. They completed all 50 scheduled home measurements and, as instructed, documented all readings

with date and time of measurement. Some included notes on weather and measurement conditions they thought could impact readings.

The Post Home Measurement Interview identified requests that images be included in the written protocol instructions as those would be more helpful than text instructions. Some stated the protocol format was difficult to follow and that information should be included on the care of the device. Volunteers thought instructions for testing the device prior to measurement would be helpful. Some felt it was difficult to keep the electrodes in contact with the skin and that the lead wires got tangled frequently.

Positive feedback suggested the device was simple to use and easy to maintain. Most felt that measurements were easier and quicker at home than in the lab and that training had prepared them well for home use of the device. This group of healthy volunteers estimated that they would be willing to pay approximately \$400 out of pocket for such a device.

TABLE 1. SAMPLE CHARACTERISTICS BY GROUP

	Total (N=21)	Healthy volunteers (N=10)	Breast cancer survivors with lymphedema (N=11)	P value
Race	N (%)	N (%)	N (%)	0.706
Caucasian	13 (61.9)	7 (70.0)	6 (54.5)	
African American	6 (28.6)	2 (20.0)	4 (36.4)	
Asian	2 (9.5)	1 (10.0)	1 (9.1)	
Marital status				0.550
Married	11 (52.4)	4 (40.0)	7 (63.6)	
Single	6 (28.6)	3 (30.0)	3 (27.3)	
Other	4 (19.1)	3 (30.0)	1 (9.1)	
Current employment				0.088
Full time	14 (66.7)	9 (90.0)	5 (45.5)	
Part time	1 (4.8)	1 (10.0)	0 (0.0)	
Retired	3 (14.3)	0 (0.0)	3 (27.3)	
Unemployed	1 (4.8)	0 (0.0)	1 (9.1)	
Other	2 (9.5)	0 (0.0)	2 (18.2)	
Residence				0.283
City	20 (95.2)	9 (90.0)	11 (100.0)	
Country	1 (4.8)	1 (10.0)	0 (0.0)	
Insurance				0.565
Private	16 (76.2)	8 (80.0)	8 (72.7)	
Government	2 (9.6)	0 (0.0)	2 (18.2)	
Other	3 (14.3)	2 (20.0)	1 (9.1)	
Yearly household income				0.033
\$10,001 to \$20,000	3 (15.8)	0 (0.0)	3 (33.3)	
\$20,001 to \$30,000	1 (5.3)	1 (10.0)	0 (0.0)	
\$30,001 to \$40,000	3 (15.8)	3 (30.0)	0 (0.0)	
\$40,001 to \$50,000	2 (10.5)	2 (20.0)	0 (0.0)	
\$50,001 to \$60,000	3 (15.8)	0 (0.0)	3 (33.3)	
Over \$60,000	7 (36.8)	4 (40.0)	3 (33.3)	
Education				0.037
Grades 1–12	2 (9.5)	0 (0.0)	2 (18.2)	
Grades 13–16	15 (71.4)	6 (60.0)	9 (81.8)	
Grades >16	4 (19.0)	4 (40.0)	0 (0.0)	
Menstrual status				0.122
Pre-menopausal	7 (33.3)	5 (50.0)	2 (18.2)	
Post-menopausal	14 (66.7)	5 (50.0)	9 (81.8)	
Age	Mean (SD) 52.3 (9.7)	Mean (SD) 48.5 (11.6)	Mean (SD) 55.7 (6.3)	0.088

All volunteers were female and non-Hispanic.

TABLE 2. LYMPHEDEMA DISEASE AND TREATMENT SUMMARIES, LYMPHEDEMA GROUP (N=11)

	Median [Min, Max]
Years since lymphedema diagnosis at baseline	7.2 [1.6, 14.7]
Years since initial lymphedema treatment at baseline	7.2 [1.5, 14.7]
Lymphedema location	N (%)
Left	6 (54.5)
Right	5 (45.5)
Lymphedema grade	
Grade I	4 (36.4)
Grade 2	7 (63.6)
Initial lymphedema treatment type	
Complex decongestive therapy by therapist	9 (81.8)
Compression sleeve	2 (18.2)
Current location of lymphedema treatment	
Home only	8 (72.7)
Home and as needed outpatient physical therapy clinic	1 (9.1)
Home and as needed private massage therapist	1 (9.1)
None	1 (9.1)
Current lymphedema treatment type	
Compression Sleeve	3 (27.3)
Complex decongestive therapy and pump	1 (9.1)
Pump and compression sleeve	1 (9.1)
Arm elevation and medication	1 (9.1)
Other	2 (18.2)
None	3 (27.3)

Prior to beginning Part Two of the study, the protocol was revised and reformatted into sections to be easier to follow and more visually appealing. An introduction with "Helpful Hints" (Table 3) was developed to accompany a color photo step-by-step guide to measurement. More detailed instructions with color-coded highlighting that corresponded to wire lead colors, storage and care instructions, and the study phone number were also added. The device quality control testing procedure was also outlined with a photo included.

Self-Monitoring Part Two: Lymphedema Group

As in Part One, all volunteers with lymphedema scored 90% or higher on the Protocol Observation Checklist and were given the SFBIA device for home measurement. They completed all 55 of their scheduled home measurements and documented all readings with dates and times. Some made notes about salt intake, nasal congestion, activity, and therapy that they thought could impact readings. One noted increased swelling on waking that receded during the day and thought measurements in the early morning at home were higher than they had been in the lab for that reason.

TABLE 3. INTRODUCTION TO SELF-MEASUREMENT PROTOCOL

Helpful Hints about Using the L-Dex Bioimpedance Measurement Machine

- Try to take measurements at the same time each day. First thing in the morning, after you go the rest room and before you eat or drink anything is best.
 - a. No exercise 2 hours prior to taking measurements. This includes walking up stairs.
 - b. No caffeine 2 hours prior to taking measurements.
 - c. No alcohol 12 hours prior to taking measurements.
 - d. Always use the bathroom before doing measurements.
- Take measurements immediately after removing compression garment if you wear one.
- Make sure that electrodes are stored in a zipped pack to keep from drying out.
- When attaching the alligator clip, do not push into the gel.
- Make sure to double check placement of the wire leads prior to measurement.
- Make sure the device is not in close proximity to a cell phone during use.
- Lay flat when doing measurements; no pillow.
- If you need to, place a rolled towel between your legs, or between your arms and body to prevent limbs touching during the measurement.
- Take slow deep breaths before each measurement, but relax while measuring.

TABLE 4. WILLINGNESS AND CONFIDENCE SCALE, LYMPHEDEMA GROUP (N=11)

Questions*	Yes responses N (%)
I am confident I can use the device at home to measure my arm.	11 (100)
I am able to wipe the skin on my hands, wrist and one foot with an alcohol swab in the right places.	11 (100)
I can put the electrodes on my skin in the right places.	11 (100)
I can program the device to measure my arms.	11 (100)
I can push the button to measure my arms.	11 (100)
I can put the clips on the electrodes and then switch them to the other arm.	11 (100)
I am able to read the numbers on the device and record them on paper.	11 (100)
I am willing to contact the study team by telephone or by email if I need help using the device at home.	11 (100)
I am willing to use the device to measure my arm at home without help.	11 (100)
I am willing to use the device to measure my arm at home with help if I needed it.	11 (100)

*Choices given: yes, no, unsure.

Feedback included comments that the electrodes would not stay adhered to the skin and that the process was tedious with too many steps. Many felt five consecutive days of measurement were excessive and unnecessary. Some complained that the device would not allow them to save their information, which forced them to enter it with each use.

Positive feedback praised the device and protocol as easy to use once completed a few times. Reference cards included with the device were also found to be very useful. Upon seeing higher readings, at least one participant thought she should have completed more self-care even though she was busy. All reported an increased awareness of the need to care for their lymphedema. None developed signs of infection or skin irritation during their time in the study.

All eleven volunteers with lymphedema answered "yes" to all ten items on the Willingness and Confidence Scale (Table 4), which indicated that this was an acceptable and feasible method for arm self-measurement. This group was willing to pay \$125 out of pocket for this device.

Daily comparisons of L-Dex values

Figure 2 displays the individual L-Dex values over the entire ten-day study period. Table 5 summarizes those val-

FIG. 2. Individual L-Dex values over 10-day study period.

TABLE 5. L-Dex* VALUES BY GROUP AND SETTING

	Healthy Volunteers (N=10)	Breast Cancer Survivors with Lymphedema (N=11)	P value
<i>Laboratory</i>			
L-Dex			
Median	1.96	14.96	0.029
25 th –75 th IQR	–0.34–2.89	2.05–39.84	
Minimum	–8.08	0.02	
Maximum	4.66	106.78	
L-Dex CV**			
Median	0.56	0.21	0.024
25 th –75 th IQR	0.32–0.71	0.11–0.43	
Minimum	0.28	0.09	
Maximum	0.94	1.59	
<i>Home</i>			
L-Dex Mean			
Median	0.90	18.88	0.004
25 th –75 th IQR	–1.75–2.22	3.10–38.90	
Minimum	–5.62	–3.58	
Maximum	5.96	103.94	
L-Dex CV			
Median	0.70	0.20	0.004
25 th –75 th IQR	0.28–0.78	0.11–0.31	
Minimum	0.15	0.04	
Maximum	0.96	0.56	

*Lymphedema index, based on impedance ratios of affected to nonaffected limbs; **Coefficient of variability.

ues. As expected, the L-Dex values reported by volunteers with lymphedema were statistically significantly higher than those of the healthy volunteers, both in the lab and at home ($p < 0.05$). In both environments the variability of the readings for the group with lymphedema (relative to their

FIG. 3. Variability in L-Dex readings within groups by setting.

respective mean values) was statistically greater than the respective variability within the group of healthy volunteers ($p < 0.05$) (Table 5 and Figure 3). Correlations between individual mean L-Dex values in the lab and home were strong in both groups (HV: $r_s = 0.86$, $p = 0.002$, BCS-LE: $r_s = 0.99$, $p < 0.001$). However, correlations between the variability estimates were much higher in the BCS-LE group than they were in the healthy group (HV: $r_s = 0.29$, $p = 0.425$, BCS-LE: $r_s = 0.87$, $p < 0.001$).

Discussion

Though the healthy volunteers were somewhat younger, both groups were able to master the self-measurement protocol quickly. None of the volunteers were older than 70; therefore, it is unclear if individuals of more advanced age with co-morbidities such as arthritis could conduct self-monitoring. Further testing of the protocol in older individuals is indicated.

The varying educational and income levels noted in the lymphedema group did not result in any difficulties following the protocol. This suggests that the device can be used across educational and socio-economic levels when individuals receive hands-on training, as was done in this study. Volunteers with lymphedema reported feeling confident in the use of the device. The 100% completion rate for home measurement supports that self-monitoring with SFBIA is psychologically acceptable and physically feasible in this population.

Interestingly, the healthy volunteers were willing to pay more for the device than the volunteers with lymphedema. This was possibly related to the higher number of people with full-time jobs and overall better health in the healthy volunteer group. Alternatively, expenses related to lymphedema treatment may reduce the amount of money comfortably available for purchase of supplemental devices to those with the disease. Regardless of the reason, to make the device economically feasible, it would need to be made available for self-monitoring at a price point that is acceptable to the individual, private consumer. That price point would seem to be notably less than the current cost of the device to researchers.

To the best of our knowledge, this is the first study to compare daily variations in L-Dex readings between volunteers with and without lymphedema. Both groups had daily variations, however, taken in the context of each individual's mean L-Dex values, the variations were less among those individuals in the lymphedema group. This suggests that further investigation of these variations is likely warranted.

Conclusions

Home self-measurement using SFBIA is feasible, acceptable, and captures change. This has implications for both self-care support and the possibility of incorporating self-measurement using SFBIA in future clinical trials examining effectiveness of lymphedema treatment. Based upon findings that volunteers with lymphedema felt daily measurements were too burdensome and examination of patterns in the variation of daily L-Dex values amongst that group when compared to healthy volunteers, we believe that self-measurement every 3 days by BCS-LE is feasible and may be beneficial. We are further testing the use of SFBIA for lymphedema self-measurement in an on-going randomized clinical trial.

Author Disclosure Statement

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