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Lymphedema Surveillance and Patient-Reported Anxiety: Comparison Between Volumetric Assessment and Bioimpedance Analysis

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Abstract

Background: Lymphedema is a complication of breast cancer therapy associated with substantial anxiety. We designed a prospective, randomized study to assess the psychosocial impact of different surveillance methods for lymphedema.

Methods and Results: In this open-label study of 38 women undergoing breast cancer surgery, we screened for lymphedema using traditional volumetric measurements (circumferential readings from the wrist to the axilla) versus bioimpedance spectroscopy (BIS) using electric current. The primary outcome measure was total anxiety measured by the Beck Anxiety Inventory, a 21-item questionnaire administered at preoperative, 6-week, 3-month, and 6-month postoperative visits (range 0–63 points). Outcome metrics were compared after adjustment for baseline anxiety. There were no differences in clinical characteristics or cancer therapies between groups, except for more reoperation for positive surgical margins in the BIS patients (5% vs. 32%, $p = 0.036$). Baseline anxiety, depression, and associated medical therapies were similar as well. Only one woman in each group developed lymphedema during the study. Anxiety was higher in the BIS group at baseline (mean Beck score 12.2 vs. 7.2, $p < 0.001$), but anxiety levels gradually declined by the end of the 6-month study in both groups, with no differences in adjusted anxiety scores between the two groups at any time point during follow-up (all $p = $ NS).

Conclusions: In this pilot study of women scheduled for breast cancer surgery, most subjects reported mild anxiety at baseline, and anxiety levels fell during continued lymphedema surveillance visits. There was no difference in patient-reported anxiety when surveillance was performed using standard volumetric versus BIS measurements.

Keywords: quality of life/anxiety, breast neoplasms, lymphedema, mastectomy

Introduction

Lymphedema is an accumulation of fluid related to insufficient drainage through normal lymphatic pathways in the body. The most common cause of lymphedema in the United States is breast cancer treatment, as surgery and radiation therapy frequently compromise lymphatic drainage and result in swelling of an upper extremity or the chest wall.[1]

Lymphedema is often cosmetically difficult to ignore, as a visible reminder of cancer treatment, and women who develop lymphedema have higher levels of psychological, social, sexual, and functional morbidity than their counterparts without lymphedema.[2] Furthermore, professional organizations have suggested that ''fear of lymphedema'' negatively impacts quality of life, and that arm swelling or edema is among the most feared side effects of breast cancer treatment.[3] Patients have reported that higher anxiety levels arise from limited physician knowledge about lymphedema, limited treatment options, potential changes in lifestyle due to physical limitations, and changes in interpersonal relationships.[4,5]

When screening for lymphedema, standard measurements of limb circumference are performed using a tape measure. More recently, bioimpedance spectroscopy (BIS) provides a

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more accurate estimate of limb fluid accumulation by measuring the time it takes for an electrical current to pass through the limb, thus allowing for earlier detection of subclinical lymphedema when compared with limb measurements alone.[6]

Despite this advancement in technology, the psychosocial impact of earlier testing, detection of subclinical fluid accumulation, or using an additional screening modality for postoperative surveillance for lymphedema has not been described. Given the high levels of anxiety accompanying the diagnosis of lymphedema in this population, it remains unclear whether increased monitoring with newer technology that gives clear ''normal vs. abnormal results'' may affect anxiety levels. Several professional organizations have advocated early detection efforts,[3] but early detection and treatment could actually provoke greater levels of patient anxiety—a concern for some clinicians resistant to preventative screening.

To address this gap in knowledge, we conducted a pilot study evaluating anxiety levels and trends over time among patients with traditional versus BIS screening during a longitudinal follow-up after breast cancer surgery. We hypothesized that lymphedema screening using BIS testing would decrease patient anxiety about lymphedema, due to the more objective nature of its results.

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Materials and Methods

Patient population

This study was approved by our institutional review board, and all participants provided written informed consent. Women scheduled for breast cancer surgery with planned axillary lymph node removal (either sentinel node biopsy or full axillary dissection) were eligible for study inclusion. Potential patients were identified by their surgeons and informed of the study, and written materials describing lymphedema screening procedures were provided to interested individuals. Those consenting to the study were then scheduled for visits with a certified lymphedema therapist at a single integrative medicine outpatient cancer center.

We used a web-driven randomization algorithm to randomly assign patients to traditional versus BIS lymphedema screening groups. At the initial (baseline) visit, each subject completed the anxiety assessment before being informed of her assignment to traditional versus BIS screening. All patients were evaluated by the lymphedema therapist before surgery, and then, follow-up measurements were performed at 6 weeks, 3 months, and 6 months postoperatively. At each screening visit, all patients were assessed for their current lymphedema risk behaviors, as outlined by the National Lymphedema Network.[7] Patients were counseled regarding lymphedema symptoms and risk reduction strategies, after which the therapist performed screening procedures based on group (traditional vs. BIS).

Limb measurements

Traditional screening involved circumferential measurements of both arms at each study visit using a tape measure, every 4 cm from the wrist to the axilla, after which a standardized computer algorithm calculated limb volume in milliliters. Significant changes were defined as >3% volume increase when compared with the contralateral limb, including a 1%–3% allowance for limb dominance, without other clear explanations (as recommended by definitions from the International Society of Lymphology).[8]

BIS measurements involved the placement of adhesive electrodes on each wrist and the right ankle, followed by connection of the electrodes to the BIS machine (L-Dex U-400; ImpediMed Ltd, Carlsbad, CA). The L-Dex uses a painless electrical impulse to measure impedance of flow, and thus, asymmetry in the extracellular lymphedema volume between the two upper limbs.[6,9–13] This tool compares readings with normative data to determine if significant asymmetry exists, or if the current reading is >2 standard deviations from the baseline reading for that individual.

Measurement of anxiety

To evaluate anxiety levels, all patients were asked to fill out the Beck Anxiety Inventory® (BAI), a standardized 21-item questionnaire (range 0–63 points, with 63 being the state of maximal anxiety), and a validated screening tool for distress used in prior studies of patients with breast and other cancers,[14,15] including serial measurements over time.[16] This questionnaire was administered at the baseline preoperative visit and then at each lymphedema screening visit.

The BAI puts emphasis on somatic symptoms of anxiety, for example, symptoms such as ''heart pounding or racing'' or ''fear of the worst happening,'' and are rated 0–3 according to their frequency of occurrence during the past week. The other BAI questions are ''numbness or tingling,'' ''feeling hot,'' ''wobbliness in legs,'' ''unable to relax,'' ''dizzy or lightheaded,'' ''unsteady,'' ''terrified,'' ''nervous,'' ''feelings of choking,'' ''hands trembling,'' ''shaky,'' ''fear of losing control,'' ''difficulty breathing,'' ''fear of dying,'' ''scared,'' ''indigestion or discomfort in abdomen,'' ''faint,'' ''face flushed,'' and ''sweating, not due to heat.'' According to the severity scores of the BAI, anxiety can be characterized as minimal (0–7), mild (8–15), moderate (16–25), and severe (26–63).[17]

Statistical approach

Baseline patient characteristics, treatment strategies, and breast cancer outcomes were compared using chi-square for categorical and *t*-test for continuous variables, or nonparametric alternatives as appropriate. Psychosocial history, along with medical therapies for anxiety and depression, were evaluated as well. BAI values were then compared between the two groups for each follow-up visit, after adjusting for baseline anxiety scores. *p*-Values ≤ 0.05 were considered statistically significant. All analyses were performed with SAS software (version 9.2; SAS Institute, Cary, NC).

Results

Of the 38 patients who completed the study, mean age was 59 years, 39% underwent lumpectomy, and 61% underwent total mastectomy. Two-thirds of the patients had sentinel node biopsy only, while the remaining third required full axillary lymph node dissection. Baseline demographic, clinical, and cancer outcome characteristics were similar between those randomized to traditional and BIS surveillance groups (Table 1), except for a larger number of patients undergoing reoperation for positive surgical margins in the BIS

Table 1. Patient Characteristics According to Lymphedema Surveillance Method

Clinical variable	*Volumetric* (n = *19*)	*Bioimpedance* (n = *19*)	p
Age, years	60 ± 10	58 ± 12	0.62
Body mass index, kg/m^2	30 ± 5	29 ± 6	0.41
Caucasian race	16 (84)	16 (84)	1.00
Type of breast cancer			0.66
Ductal carcinoma *in situ*	2 (11)	4 (21)	
Invasive ductal	12 (63)	11 (58)	
Invasive lobular	5 (26)	4 (21)	
Left-sided breast cancer	12 (63)	13 (68)[a]	0.73
Recurrent disease	3 (16)	4 (21)	0.68
Stage of disease			0.49
0–1	10 (53)	9 (47)	
2	5 (26)	8 (42)	
3–4	4 (21)	2 (11)	
Type of resection			0.50
Lumpectomy	8 (42)	6 (32)	
Mastectomy	11 (58)	13 (68)	
Side of resection			1.00
Ipsilateral breast only	11 (58)	11 (58)	
Bilateral resection	8 (42)	8 (42)	
Lymph node evaluation			0.18
Sentinel node biopsy	14 (74)	10 (53)	
Full axillary dissection	5 (26)	9 (47)	
Positive lymph node status	7 (37)	8 (42)	0.74
Reoperation for positive margins	1 (5)	6 (32)	0.036
Subsequent chemotherapy	11 (58)	11 (58)	1.00
Subsequent radiation therapy	10 (53)	12 (63)	0.51
Subsequent endocrine therapy	15 (79)	14 (74)	0.70
Development of lymphedema during the study	1 (5)	1 (5)	1.00

All values are reported as *n* (%) for categorical variables and mean ± standard deviation for continuous variables.
[a]One patient in the bioimpedance group had bilateral breast cancer.

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group. Two patients were diagnosed with lymphedema during the study (one in each measurement group).

When evaluating anxiety, 16% of patients had a chart history of anxiety, and 21% were taking antianxiety medications at baseline. As seen for the demographic and clinical characteristics, diagnoses of anxiety and depression, along with medical therapies for anxiety or depression, were similar for both groups (Table 2).

Baseline anxiety was higher in the BIS group (mean Beck score was 12.2 vs. 7.2, $p < 0.001$) (Fig. 1). However, anxiety levels gradually declined in both groups by the end of the 6-month study (mean BAI scores in the traditional volumetric measurement group were 7.5, 7.4, 7.8, and 4.8, and mean scores in the BIS group were 12.2, 8.8, 10.1, and 5.5 (Fig. 2). After adjusting for baseline anxiety levels, there were no differences in anxiety scores between the two groups at any of the follow-up time points (all p = NS).

Table 2. Baseline Psychological History of Enrolled Patients

Psychological variable	*Volumetric* (n = *19*), n (%)	*Bioimpedance* (n = *19*), n (%)	p
Chart history of anxiety	3 (16)	3 (16)	1.00
Chart history of depression	1 (5)	4 (21)	0.15
Currently taking anxiolytic medication	4 (21)	4 (21)	1.00
Currently taking antidepressant	2 (11)	4 (21)	0.37

Discussion

In this pilot study evaluating women scheduled for breast cancer resection, we found that baseline anxiety levels were in the mild to moderate range, with gradual improvement during the 6-month postoperative period. Levels of anxiety were not affected by the method of lymphedema surveillance (traditional vs. using bioimpedance measurements). The higher baseline anxiety score in the BIS group may have been related to the greater number of patients requiring re-excision, but the anxiety measurements were collected before women knew their assigned lymphedema screening group, and ultimately there was no significant difference in anxiety during postoperative recovery after adjusting for baseline anxiety levels.

Prior studies

Anxiety among breast cancer patients has been evaluated in previous studies. Among 303 women with a recent diagnosis of breast cancer studied by Kissane et al., 36.7% had

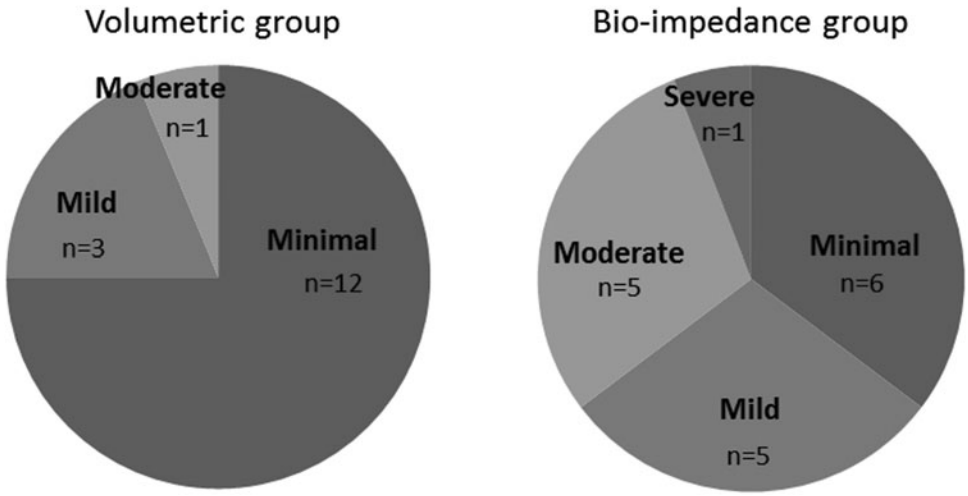

FIG. 1. Baseline anxiety levels according to the BAI. BAI, Beck Anxiety Inventory.

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mood disorders while anxiety disorders affected 8.6% of the patients.[18] In a cohort of 715 women who underwent breast cancer surgery, Saboonchi et al. noted that over a third (37.7%) had anxiety at baseline, with this proportion decreasing to 26.7% at 4 months, and then no further change from 4 to 12 months.[19] These authors concluded that distress following breast cancer surgery is a transient, nonpathologic response.

Similarly, Stafford et al. studied 66 women with breast cancer and 39 with gynecologic cancer.[20] Rates of anxiety and depression were highest at the time of initial diagnosis, and both decreased at 8 and 40 weeks postdiagnosis. In contrast, Kyranou et al. noted among 396 breast cancer patients that higher preoperative anxiety, poorer physical health, decreased sense of control, and more feelings of isolation predicted worse anxiety scores over time.[21] Unlike the Saboonchi and Stafford cohorts, these investigators found that moderate levels of anxiety persisted in women for 6 months following surgery.

Our study results mirror those of the Saboonchi and Stafford studies, as our quantitative anxiety assessments demonstrated gradual reductions in anxiety over time after surgical resection. Some variance between the proportions of patients with anxiety could be related to items on the specific questionnaires used in these studies. For example, the Hospital Anxiety and Depression Scale (HADS) delves into symptoms of depression along with anxiety, whereas the BAI focuses more on somatic symptoms related to anxiety. In 31 Iranian patients with postmastectomy lymphedema studied by Abbasi et al., there were much higher rates of psychological symptoms at baseline,[22] likely related to the use of the HADS tool and its greater inclusion of depression symptomatology. Nonetheless, these authors also found gradual reduction in anxiety over time, in a similar manner as our study. Since our goal was to focus on the impact of education and screening on anxiety, rather than a quantitative assessment of baseline anxiety or depression, our lower levels of anxiety could simply be a reflection of patient selection, or the use of the less-sensitive BAI tool.

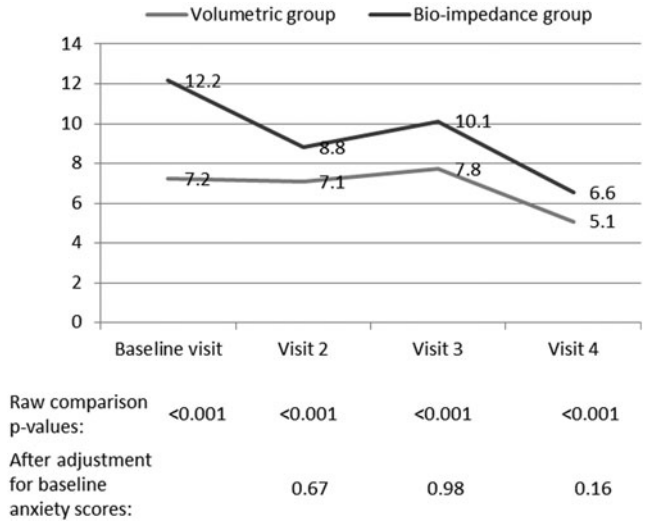

FIG. 2. Comparison of BAI scores over time.

Clinical implications

Patients with lymphedema report anxiety in addition to physical impairments, as lymphedema is known to impact emotional well-being regardless of the quantifiable amount of physical edema present.[23] The possibility of developing lymphedema has been shown to cause fear and anxiety among breast cancer survivors.[24] Asdourian et al. report that the paucity of high-level evidence and the conflicting nature of the existing literature on predictive factors for breast cancer-related lymphedema contribute significantly to patient distress and anxiety.[25] Interestingly, Ridner et al. noted that an individual's perceived difference in limb size may more greatly influence the total number of lymphedema symptoms experienced, and symptom-related distress, rather than the actual measured extracellular fluid volume.[24] Although this concern probably did not affect our overall study results, as only one patient in each surveillance group developed lymphedema, we noted a consistent downward trend in anxiety over time, as noted in the prior studies discussed above.

Future disease-specific studies of lymphedema and its psychosocial impact could involve both quantitative limb volume measurements and also patient perceptions of limb

volume, as suggested by the Ridner study. Of note, the L-Dex used in our study has gradually moved toward a next-generation device (SOZO by ImpediMed), where patients stand on a scale while being measured and thus adjust for changes in overall body weight while evaluating limb volume. Whether this approach may affect anxiety levels during postoperative lymphedema surveillance remains unclear.

Study limitations

Although this study randomly assigned patients to a specific lymphedema screening method, our analyses will have the same limitations as any other observational study at a single medical practice. Nonetheless, many of the previous publications on this topic were undertaken with a similar study design, and often among relatively small numbers of patients as well. As noted earlier, our study used the BAI, with its greater focus on physical symptoms of anxiety, and this approach may not have been as sensitive for identifying emotional distress when compared with other psychological tools. Other studies of cancer-related anxiety and distress have used the aforementioned HADS tool,[20,26] the Depression Anxiety Stress Scales,[27] or the Spielberger State-Trait Anxiety Inventory.[21]

Current National Cooperative Cancer Network (NCCN) guidelines (version 3.2017)[28] recommend screening for anxiety, depression, and distress among patients with breast cancer, given the known psychological impact of this diagnosis and its associated treatment. Of note, the NCCN anxiety screening includes questioning for symptoms such as feeling restless or on edge, difficulty concentrating, irritability, sleep disturbance, and a variety of questions about panic, including palpitations, sweating, trembling or shaking, fear of losing control, and fear of dying. One can see that there is considerable overlap between the NCCN screening questions and the questions asked in the BAI, suggesting that the use of BAI for measuring anxiety in our study was similar to questions recommended by contemporary guidelines. Nonetheless, additional research in this area may benefit from a disease-specific anxiety tool to differentiate between anxiety that is generalized, related to breast cancer overall, or specifically focused on the fear of developing lymphedema. Of note, our quantification techniques for calculating limb volumes were those recommended at the time our study was launched, but newer studies of serial limb volume measurements have identified more accurate volume estimates.[29] Although unlikely to change the findings from our study, future evaluations of lymphedema surveillance and anxiety should incorporate the newest calculation techniques, according to recommendations from standardized guidelines.

Conclusions

Anxiety related to the potential diagnosis of lymphedema does not appear to be affected by the method of perioperative surveillance after breast cancer surgery. In this pilot study of patients referred for lymphedema assessment around the time of breast cancer resection, most subjects reported minimal or mild anxiety at baseline, and we found no significant difference in patient-reported anxiety according to lymphedema surveillance method. Further studies should evaluate whether anxiety differs according to the presence versus absence of lymphedema screening after breast cancer surgery.

Author Disclosure Statement

S.A.S. has received compensation for educating sales representatives on lymphedema for ImpediMed, the company manufacturing the L-DEX device, although ImpediMed had no role in the development of the study, performance of the study, or preparation of the article. J.M.S. has served on the speaker's bureau or as a consultant for various pharmaceutical companies manufacturing cardiovascular or diabetes medications, none of which was related to the topic of this study. D.M.R. had no disclosures to report.

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