Doctor of Nursing Practice
The University of Texas at El Paso

PROPHYLACTIC BIOIMPEDANCE SPECTROSCOPY FOR BREAST CANCER-RELATED LYMPHEDEMA
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Maria Marquez, MSN, APRN, FNP-BC
- Chairperson: Hector R. Morales, DNP, APRN, PMH-CNS-BC

UTEP | 500 W. UNIVERSITY AVE. EL PASO, TEXAS 79968

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Maria M. Marquez

School of Nursing: The University of Texas at El Paso

Doctor of Nursing Practice Program

DNP Chair: Hector R. Morales, DNP, APRN, PMH/CS-BC

DNP Quality Improvement Project

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Abstract

The purpose of this quality improvement project was to implement the standardized use of Bioimpedance Spectroscopy (BIS) for the early detection and management of breast cancer-related lymphedema (BCRL). BCRL is a common complication of breast cancer treatments resulting from damage to the lymphatic system. While three of every four patients that develop lymphedema typically do so within the first three years after treatment, this complication can develop at any time during or after therapeutic intervention. The National Comprehensive Cancer Network® Clinical Practice Guidelines and others suggest that bilateral baseline limb measurements should be performed on patients at high risk for developing post-treatment BCRL. Early detection and diagnosis of lymphedema are critical for its optimal management because while stages 0 and 1 are reversible, stages 2 and 3 are typically less responsive to treatment. Subclinical BCRL can be detected using BIS before, during, and after surgical procedures and chemoradiation therapy. Furthermore, this procedure can be repeated at regular intervals to monitor lymphedema. This QI project identified changes and improvements in which the use of BIS resulted in superior outcomes for breast cancer patients. One hundred and thirty-one charts were reviewed, and five participants were included in the QI project. The types of breast cancer ranged from Stage 1A, invasive ductal carcinoma (IDCA), hormone receptor positive, sentinel axillary lymph node biopsy (SLNB), axillary lymph node dissection (ALND), Stage 3B, and Stage 3A, triple negative receptor. BIS is an important modality that can be used to evaluate the effectiveness of clinical interventions and to manage pivotal outcomes in patients with BCRL.

Prophylactic Bioimpedance Spectroscopy for Breast Cancer-Related Lymphedema

Background Knowledge

As part of this Quality Improvement (QI) project, I identified an opportunity to improve clinical outcomes for breast cancer patients undergoing outpatient treatment at our center. Breast cancer-related lymphedema (BCRL) is a common complication of breast cancer treatment that results from damage to the lymphatic system. Lymphedema can be acute or chronic (NCCN Guidelines, 2021). While three of every four patients who ultimately develop lymphedema typically present within the first three years after treatment, this complication can develop at any time during or after therapeutic intervention. A recent study published in the *Annals of Surgical Oncology* reported that BCRL represents a significant source of lifelong morbidity among breast cancer survivors (Ridner, et al., 2019). In the United States alone, the annual cost of cancer-related lymphedema has been estimated at $7 billion. The costs of healthcare for breast cancer survivors who develop lymphedema within two years following cancer treatment have been estimated to be $120,00 higher than costs for those who remained free of this complication. These estimated costs included 112% higher annual out-of-pocket expenses and $3,325 additional costs per year due to loss of productivity (Dean, et al., 2019).

The use of Bioimpedance Spectroscopy (BIS) can facilitate subclinical detection and early intervention and thus a 95% reduction in the progression of lymphedema. BIS uses an electrical current to detect volume of extracellular fluid that is converted into a lymphedema index score (L-Dex) measurement with increased validity and sensitivity when compared to traditional modalities such as circumference measurements as well as having the ability to detect subclinical or stage 0 BCRL (Shah, et al., 2016). My Doctor of Nursing Practice (DNP) QI

project was designed to address early detection of BCRL using BIS as a critical change that might improve healthcare outcomes for my breast cancer patients. My practice setting includes patients 20 to 80 years of age diagnosed with breast cancer, including those who are pre- and post-treatment with chemoradiation therapy and surgery. This cohort includes patients at high-risk for developing lymphedema because of extensive axillary lymph node dissection (ALND) and/or sentinel lymph node biopsy (SNLB). These patients include those who have and have not been treated, radiation and/or taxane-based chemotherapy. My clinical cohort includes patients of all socioeconomic backgrounds and those who are primarily Spanish or English speaking.

As part of my 10-day reflective practice log, I performed a clinical needs assessment of my practice, reflected on my findings, and identified an opportunity to improve the care I currently provide to my patients. I learned that I was not taking a sufficiently proactive approach to the early detection and prevention of acute and chronic BCRL. Furthermore, I surveyed the 10 providers in my clinic and discovered lymphedema was routinely assessed by physical examination rather than by the methods suggested by the National Comprehensive Cancer Network® (NCCN) guidelines (i.e., version 3.2021 Survivorship: Lymphedema Principles). Among other principles, these guidelines suggest that pretreatment bilateral limb measurements should be performed on all patients to provide a baseline for survivors who might be at risk for developing treatment-related lymphedema. Early detection and diagnosis are critical for optimal management of this condition. Lymphedema diagnosed at stages 0 and 1 is frequently reversible, whereas stages 2 and 3 are typically less responsive to treatment (National Comprehensive Cancer Network, 2021). My current practice does not include an opportunity to prevent stage 0, subclinical lymphedema. Treatment is initiated at stage 1 when pitting edema is evident. My research suggested that BIS could be used to facilitate this type of evaluation, as it can be

performed before, during, and after breast surgery and chemoradiation therapy. BIS can be repeated at regular intervals (e. g., every three months) to monitor the development of lymphedema and the results of these studies can be used to direct therapeutic intervention and appropriate management.

Local Problem

The local problem addressed in this project is early diagnosis and treatment of lymphedema. My review of the pertinent literature suggested that BIS may be a valuable screening tool that can be used to facilitate early diagnosis and intervention, thus improving our chances of eliminating BCRL before it progresses to an irreversible state (Ridner, et al., 2022).

Intended Improvement

The changes and improvements made in addressing the processes and outcomes of the proposed intervention were overall positive. The process began with establishing rapport with the patient and her family at the initial encounter. Patients were provided with evidence-based literature which typically empowered and motivated them to take a proactive approach to their care. My ability to monitor subclinical BCRL via the use of BIS facilitates early intervention and significantly reduces the risk of chronic disease compared to monitoring efforts based on arm circumference determined by tape measure alone. Thus, BIS should be considered and available for screening for subclinical BCRL, especially for patients in high-risk populations (Shah, et al., 2021). According to the Institutional Review Board (IRB) application (discussed below), five patients met the criteria for enrollment. Inclusion criteria for the QI project are patients 20 to 80 years of age diagnosed with breast cancer, pre-treatment, post chemoradiation therapy, and post-surgical. The exclusion criteria were patients not meeting inclusionary criteria.

The Medical Director of our clinic and my collaborating physician were champions of this work and the intended QI that might result from the intervention proposed. We all agreed that this would be an excellent time to reconsider our current underutilization of BIS and to make appropriate changes to our clinical practice.

Methods

Ethical Issues

I completed the Collaborative Institutional Training Initiative (CITI) training course that was intended to foster ethical integrity when conducting a QI study. Ethical considerations for a QI project included a process for attaining IRB approval. The IRB process was completed through the IRBnet website, https://www.irbnet.org/release/home.html. The application was submitted to The University of Texas at El Paso IRB Office of the Vice President for Research and Sponsored Projects. The University of Texas at El Paso IRB determined that this QI project did not meet the definition of human subjects research under the purview of the IRB federal regulations and granted approval.

Setting

Elements and characteristics of the setting that were most likely to benefit from a change and/or improvement in my clinical practice are breast cancer survivors at risk for BCRL. My practice includes patients 20 to 80 years of age who have been diagnosed with breast cancer who are currently in pretreatment, active treatment with chemotherapy/radiation, or post-surgery phases. Monitoring with BIS will have the most impact on this patient cohort as current evidence suggests that early detection and intervention can significantly reduce the risk of developing chronic BCRL by 69% and 81% compared to that achieved by routine evaluation and measurements alone, particularly in high-risk patients (Shah, et al., 2021).

Planning the Intervention

The Texas Advanced Practice Registered Nurse scope of practice and the American Academy of Nurse Practitioners National Certification Board, which both protect public health by overseeing and ensuring safe nursing practices, permitted me to introduce BIS technology to better serve my patients. This problem was reviewed and documented in great detail during a ten-day reflective period. I reflected on every step of the advanced practice process used to care for breast cancer patients who were at risk for developing BCRL and looked for new areas of opportunity. My patient cohort included a large number of breast cancer survivors who had undergone lumpectomy, SLNB, ALND, active adjuvant taxane-based chemotherapy, neoadjuvant chemotherapy, and/or adjuvant radiation. As noted in the NCCN guidelines (version 3.2021), BCRL has emerged as an important clinical issue due to the frequency of treatment-related injury to the lymphatic system. For example, during my ten-day reflective period, I encountered one breast cancer survivor with severe, irreversible lymphedema (stage 3). It became apparent that I needed to take a more aggressive approach to early detection and prevention of BCRL with baseline measurements before and after treatment.

Before initiating this intervention, I trained myself on how to operate the BIS device, including preparation, performing the evaluation, viewing the measurements, and documenting the results. A self-test was performed before each patient trial to ensure that the device was functioning properly. BIS is an advanced modality in which bioimpedance measurements are used to assess fluid levels and tissue composition. This is achieved by sending a painless alternating electrical current through the patient's body. Impedance is a measure of the opposition to electrical flow measured in ohms that represents a combination of both resistance and reactance (i.e., factors that oppose the alternating current; ImpediMed, 2014). The outcome

of BIS is presented as a Lymphedema index score (L-Dex). BIS is a rapid, noninvasive, and cost-effective technique designed to aid clinical assessment by monitoring fluid content, in this case in the patient's arm. This modality is approximately four times more sensitive than any of the other commonly used methods for assessing lymphedema. The BIS device includes a tetrapolar set of leads that are attached to electrodes that adhere to the skin and measure current, voltage, and phase angle. These variables are then used to calculate the three critical bioimpedance parameters: impedance (Z), resistance (R), and reactance (Xc). These calculations are used to estimate impedance over a frequency range of 4–1000 kHz to generate a value defined as true bioimpedance (ImpediMed, 2014).

Finally, as part of my overall reflection on this issue, I reviewed the electronic charts in the outpatient cancer treatment center and became aware of the current practice standards. This action was the catalyst that influenced my decision to pursue this QI project to improve my approach to lymphedema screening and prevention.

Review of Patients and Development a of PICOT question

The review of patient data was recorded for 10 days of practice and was organized by the nursing process that includes assessment, diagnosis, treatment/intervention, and follow-up. A PICOT (patient, intervention, current practice, outcome, and time) question was generated based on my identification of the major diagnosis associated with recurrent complaints and ineffective interventions. Specifically, I studied and reviewed patient diagnoses of chronic lymphedema and assessed what interventions might be implemented during the acute phases of this condition. My findings were similar to those of Disipio et al., (2013) who reported the need for an improved understanding of the prevention and management strategies that might be used to reduce the individual and public health burden of this disabling and distressing clinical issue. The patient

population was a crucial indicator in the development of the PICOT question. The outpatient cancer center provides treatment for a high volume of breast cancer patients; thus, a convenience sample for the QI project included patients from 20 to 80 years of age who were diagnosed with breast cancer and developed lymphedema. Based on the review process, the PICOT question was formulated as follows:

P: Patients ages 20 to 80 diagnosed with breast cancer who developed lymphedema.

I: Prophylactic Bioimpedance Spectroscopy for Breast Cancer-Related Lymphedema

C: Treatment of BCRL after diagnosis.

O: Reduction of chronic BCRL.

T: Six weeks.

Planning the Study of the Intervention

I adapted evidence-based practice in the clinical setting by utilizing a translational framework provided by Lewin's Organizational Theory of Change and the three-step change model (1951) that includes Unfreezing, Change, and Refreezing. In collaboration with the Medical Director and my collaborating physician, I identified a need for prophylactic use of BIS for BCRL. The first step, or Unfreezing, involved a change in the methods used for detection and treatment of lymphedema after diagnosis. The introduction of new technology prompted disturbances to the organization's status quo. This disequilibrium was the driving force needed to overcome resistance from stakeholders who questioned the clinical value of this QI. This initiative permitted me to focus on strategic planning to strengthen the reinforcement of the planned change. The Change step permits trial and error regarding the use of preventative BIS. This procedure was performed during routine follow-up visits. Meanwhile, I observed decreased levels of resistance to change among the various stakeholders involved (Refreeze). Evaluation of

BIS evidence-based practice revealed the need to improve the services that I currently provide for survivors of breast cancer. Early detection, diagnosis, intervention, and prevention while the condition remains in a reversible state are key components of optimal BCRL management. BIS can be performed before, during, or after breast cancer treatment and repeated every three months or at regular intervals up to 36 months. While the organization will revert to the original status quo if it fails to acknowledge the normality of new behavior (Manchester et al., 2014), the ongoing availability of BIS, its reinforcement through routine use, and the recognition of its important role in preventing BCRL will most likely lead to its sustained use in my clinical setting.

The plans for assessing how well the intervention was implemented began with the selection of a QI model. The Plan-Do-Study-Act (PDSA) cycle for evidence-based QI projects is a four-stage problem-solving model that can be used for rapid improvement and/or carrying out change (SlideModel, 2022) as follows:

Plan. I was the central provider during this stage. I completed the American Academy of Nurse Practitioners National Certification Board for the State of Texas Professional and Individual Scope of practice and generated a detailed 10-day reflective practice log covering events that transpired over 10 working days. I reflected on every step of the advanced practice and processes involved in caring for patients and reviewed areas for potential practice improvement. A review of patients was generated and organized by diagnosis and treatment. Insight was gained from my extensive review of the assessments, diagnoses, interventions, and follow-ups. Three potential practice problems were organized into PICOT questions. The DNP Chair approved the final PICOT question selected (see above), and a literature review was initiated. A minimum of six publications with high-quality evidence (levels 9–12) supported the

PICOT question. The publications presenting the three highest levels of evidence were well-summarized and supported the PICOT question. The translational frameworks (Lewin's Organizational Theory of Change and QI Model PDSA Cycle Evidence-Based Practice QI) were presented together with the anticipated outcome and local impact of the completed DNP QI Project. The worksite supervisor signed the DNP QI Proposal and provided a signed work letter on department letterhead. Once DNP Chair approval was received, an IRB QI application was submitted. The IRB provided me with a letter that stated that this QI project did not come under the auspices of human subjects research. I also reviewed my January 2022 schedule and collected initial BIS measurements performed on breast cancer patients at risk for BCRL.

Do. This stage focused on the implementation of the project. Evidence-based educational material was provided to potential candidates who met the criteria as outlined in the IRB application. These materials motivated these patients to take an active role in their care. I obtained baseline L-Dex measurements on each of these patients; the reference scores for this value are -10 to +10. Patients with baseline scores ≥10 were diagnosed immediately with subclinical (stage 0) lymphedema and provided with treatment. Patients with scores within the reference range were asked to return in one week for follow-up testing. If no lymphedema was detected at the one-week follow-up (i.e., L-Dex < 6.5 points over the original baseline), patients were asked to return for another follow-up visit in four weeks. By contrast, patients with scores that were ≥6.5 points over their original baseline were diagnosed with subclinical (stage 0) lymphedema at that time. These patients were managed with a four-week at-home intervention that included compression garments and referral for their appropriate fitting. All patients with stage 0 lymphedema were also asked to return to the clinic in four weeks. If the L-Dex score at follow-up was the same or higher, a referral for ongoing therapy was made (Shah et al., 2016).

Secondary therapy may include outpatient lymphedema therapy with specialized therapists who offer one-on-one expert care at several locations including The Hospitals of Providence, University Medical Center, Paloma Wellness and Rehabilitation, and Manual Physical Therapy Specialists. A post-treatment surveillance follow-up visit at three months was recommended for all patients. An L-Dex score was documented together with vital signs.

Before undergoing a BIS examination, patients were asked to remove their socks and all metal jewelry and devices. I confirmed that the patient was not pregnant and did not have any implanted electronic devices. I also ascertained that we were not in the presence of a strong electromagnetic field. Patients were then asked to lay in a supine position and both right and left arms were examined. The arms remained uncrossed with legs apart to avoid short-circuiting the electrical path. The skin was prepared to facilitate contact with the electrode and avoid measurement inconsistencies by gently rubbing the contact sites with alcohol wipes to remove excess oil. I applied the adhesive side of each electrode to the skin at placement sites that have been standardized for unilateral arm measurements. Single dual-tab electrodes were placed on the right hand, the left hand, and the right foot. I placed the proximal ends of two electrodes (one on each hand) with the green line on the midline of the ulnar styloid process with the distal end extending toward the fingers. I placed the proximal end of the third electrode with the green line between the medial and lateral malleolus with the distal end extending toward the toes. I then obtained a baseline measurement by confirming unilateral measurement parameters as shown on the screen; three measurements are needed to calculate a single result. I then connected one lead to each electrode via their attached alligator clips according to the color-coding displayed on the BIS screen. After each measurement was performed, the device displayed the impedance on the raw results screen. The results are displayed as black dots in a plot of resistance (R) *versus*

reactance (X). A best-fit curve is calculated and displayed as a solid blue line within this graph. High-quality data generate a semicircular pattern (ImpediMed, 2014).

Study: The results of this analysis in terms of the reduction of chronic BCRL as determined by BIS were determined. I also evaluated what went wrong and/or what was learned. The use of BIS led to improvements in the early detection of BCRL. For example, one patient presented with a baseline measurement (L-Dex) of 15.8 and was diagnosed with subclinical (stage 0) lymphedema at that time. The patient was diagnosed with a triple negative receptor left breast cancer, stage 3A, who was undergoing neoadjuvant chemoimmunotherapy. A four-week at-home intervention was implemented that included compression garments and a referral for fitting; the patient was asked to return to the clinic in four weeks. The post intervention L-Dex score were 3.8 and 3.3 on her left and right arms, respectively. This approach was worth the investment as it facilitated earlier detection of BCRL on routine follow-up visits. I reported specific positive trends in L-Dex scores. There were no unmanageable side effects. I also learned that it was important to coordinate these efforts so that the patients did not need to schedule appointments at two separate locations. The plan was overall a success.

Act: I plan to implement BIS as the standard of care for breast cancer patients at risk of developing BCRL. I also recognize that there is always an opportunity for further improvement. For example, our entire organization may need to be more focused on modern technology, as all providers, researchers, educators, and staff can benefit from sustained and successful practice change (Roush, et al., 2020). Improvements achieved and lessons learned as part of this QI project are shared with others in our organization. I will be taking steps to sustain this QI by bringing this to the attention of corporate management. My goal is to have BIS incorporated into

routine care practice for the breast cancer community. My long-term plans for additional improvement involve iterative PDSA cycles as needed.

Literature Review

Shah, et al. (2016) reported that the use of BIS facilitated earlier detection of BCRL with increased sensitivity and supported surveillance screening for early intervention. A related meta-analysis concluded that BIS monitoring for early intervention significantly reduces the risk of developing chronic BCRL, including 69% and 81% reductions when compared to control and circumference measurement techniques, respectively. This was particularly evident in patients who had undergone a mastectomy, ALND, regional node irradiation (RNI), or taxane-based chemotherapy who are at an increased risk of developing BCRL. In these cases, BIS can aid in the assessment of stage 0 lymphedema and trigger early intervention (Shah et al., 2021). Bioimpedance-based measurement techniques can be used for clinical diagnosis by quantifying the extent of abnormal fluid accumulation (Silva, et al., 2019). A randomized control trial (RCT) compared tape measure (TM) and BIS measurements for BCRL surveillance screening of newly diagnosed patients with the intent of identifying and treating subclinical BCRL to improve patient outcomes. The results of this RCT included statistically significant results, leading the authors to suggest that BIS screening might be used as a standard approach to BCRL surveillance. BIS provides the benefits of precise identification and thus facilitates the early use of compression therapy compared to the conventional TM approach (Ridner, et al., 2022). BIS is considered a reliable and sensitive modality that can be used to detect early changes in interstitial fluid (O'Toole et al., 2013). A secondary analysis of a randomized parent study in which patients were followed for 24 months with frequent BIS assessments during the 15-month post-surgical period revealed statistically significant L-Dex scores leading to early detection of stage 0

lymphedema (Ridner, et al., 2020). Similarly, Boyages et al., (2021) published the results of an RCT that compared the risk of developing subclinical BCRL in patients treated with ALND and RNI as detected by BIS and TM methods. The use of BIS resulted in superior detection of subclinical BCRL compared to TM, thus supporting its use in post-treatment surveillance aimed at early detection and intervention.

BIS can be used for early detection and intervention as L-Dex scores ≥6.5 above baseline clearly indicate subclinical (stage 0) lymphedema that can be managed with a four-week at-home intervention and follow-up. Plans were made to evaluate the effectiveness of this change by arranging for repeated tests at regular intervals with routine follow-up visits as standard practice.

Evidence-based guidelines from the National Lymphedema Network suggest the value of BIS-based diagnostic therapeutics for the early detection of BCRL (Shah, et al., 2016). RCT, systematic reviews, meta-analysis, randomized prospective trials, secondary assessments of a randomized parent study, and NCCN guidelines support the collection of bilateral pretreatment values as baseline measurements. The effects of the intervention were evaluated based on L-Dex scores obtained at the initial and first follow-up (i.e., one-week post-baseline measurements) as well as at four-week post-intervention follow-up visits. Instruments that have been identified as valid and reliable include BIS, water volumetry, TM, and perometry. Of these, BIS can detect alterations in the extracellular fluid (ECF) in stage 1 lymphedema which supports established internal validity. A systematic review and meta-analysis focused on the external validity of this modality for the detection of unilateral arm lymphedema after breast cancer indicated a clear need for improved understanding of contributing risk factors, prevention, and management strategies that can be used to reduce the individual and public health burden of this disabling and distressing clinical problem (Disipio, et al., 2013).

Methods of Evaluation

Data collection began on January 18, 2022, and ended on March 2, 2022. Chart reviews were conducted and the screening process of breast cancer patients at risk for developing BCRL was initiated. As part of this screening process, I considered gender, age, stage of disease, diagnosis, and treatment type. One hundred and thirty-one charts were reviewed, and five participants were included in the QI project. Baseline measurements were obtained using BIS. Instruments and procedures used to assess the effectiveness of implementation, contributions of the intervention, and anticipated outcomes were outlined in the IRB application. After performing baseline measurements, patients were asked to return to the clinic in one week for a second assessment. At this visit, patients with a change in L-Dex score ≥6.5 were provided with a four-week at-home intervention that included the use of compression garments; a referral for fitting was also provided. Patients undergoing this at-home intervention were asked to return four weeks later for a follow-up assessment. Of note, patient #3 presented with a baseline score of 15.8, which suggested subclinical lymphedema; an intervention was made at that time. This patient was then asked to return in four weeks for a follow-up assessment.

Three measurements are required to calculate a result. After each measurement, the device displayed the measured impedance in the raw results screen. The L-Dex score includes measured bioimpedance parameters over a range of frequencies (4–1000 kHz) and results in 256 data points. These bioelectrical parameters are then used to determine the L-Dex score for the at-risk limb. These values can be compared to those obtained for the unaffected limb. Unilateral L-Dex scores >10 and scores ≥6.5 over baseline values were considered as early signs of lymphedema. The screen device also permits the operator to view previous results to determine whether L-Dex scores are increasing or decreasing over time. The results are displayed as black

dots in a plot of resistance (R) *versus* reactance (X). Best fit curves are calculated from these data points and displayed as a solid blue line. High-quality data results in a semicircular pattern. BIS is a valid and reliable technique that is four times more sensitive at detecting BCRL than any other commonly used modality (ImpediMed, 2014).

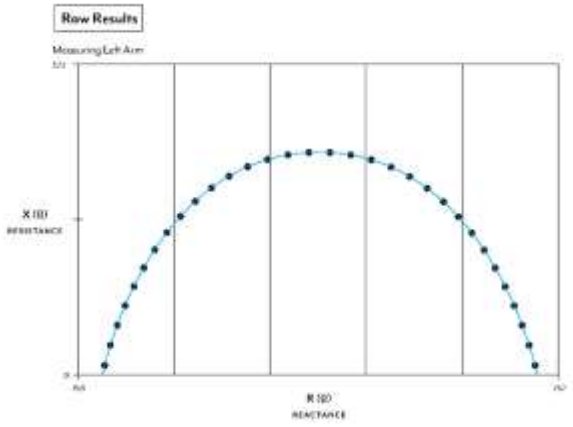
Analysis

BIS analysis was performed on five patients. The impedance data shown in the raw results screen was reviewed to ascertain the quality and validity of each measurement. The final results (measured in Ohms) are shown as black dots in a plot of resistance (R) *versus* reactance (X). A semi-circular best fit curve was calculated for each measurement confirming the collection of high-quality data. These results were used to calculate L-Dex scores based on the ratio of the impedance determined for the at-risk limb versus the uninvolved limb. Figure 1 is an example of BIS data presented as a reactance *versus* resistance curve (ImpediMed Oncology, 2021).

Figure 1

Results of Bioimpedance Spectroscopy

Raw Results Impedance, Resistance, Reactance



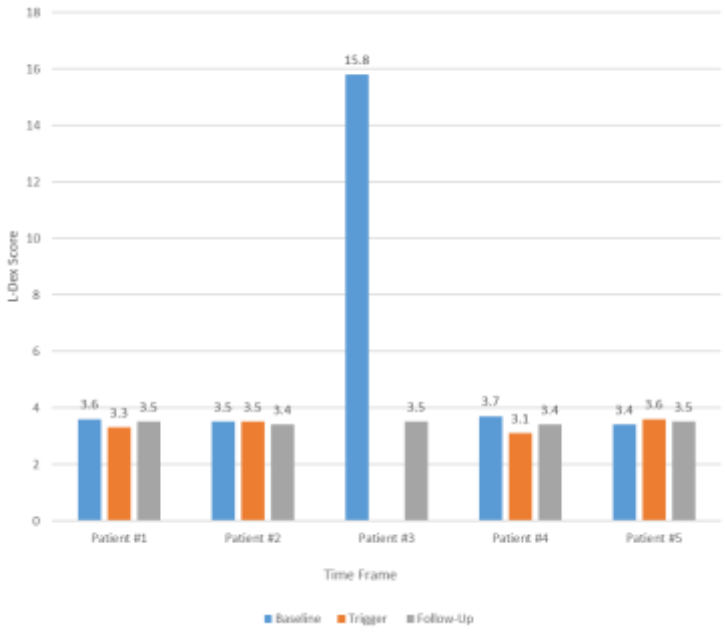
The average baseline L-Dex score for the five patients enrolled in my QI project was 5.98. The average L-Dex score for the four patients seen at one-week follow-up was 3.3. The average L-Dex score on the second follow-up visit was 3.4. BIS measurements at baseline as well as at one-week and five-week follow-up visits for all participants are shown in Figure 2.

Results

A rigorous review of the literature provided evidence that supported the clinical QI project in which BIS would be used for early detection and ongoing monitoring for BCRL. This methodology was used to improve the detection of subclinical (stage 0) lymphedema and thus to reduce the risk of developing chronic BCRL (Shah et al., 2021). The project was performed at an outpatient cancer treatment center located in central El Paso, Texas. Physical resources were readily available to support this QI. This center is part of a for-profit company with an established organizational hierarchy, philosophy, values, and expectations. Historically, efforts to promote change have been predominantly research-based. Structures and patterns of care that provided context for this BIS intervention for five patients at risk for developing BCRL adhered to the standards of practice for the state of Texas and the American Academy of Nurse Practitioners National Board Certification regulatory boards. The results of the intervention are discussed in the paragraphs that follow.

Figure 2

Bioimpedance Spectroscopy Measurements for each participant



Patient #1

Patient #1 who was first seen on January 18, 2022, is a 48-year-old female who underwent a left breast lumpectomy and SLNB. Her ALND was negative (4/4 lymph nodes). Her tumor was hormone-receptor-positive with a low Oncotype Dx score, indicating a <1% likelihood of benefitting from chemotherapy. She began adjuvant radiation therapy on March 2, 2022; once this has been completed, she will be treated with adjuvant hormonal therapy. The baseline L-Dex scores were 3.8 and 3.5 on her left and right arms, respectively. She returned to the clinic one week later (January 26, 2022) for a follow-up assessment post-surgery. At this time, her L-Dex scores were 3.4 (left arm) and 3.3 (right arm). At her four-week follow-up visit on February 23, 2022, her L-Dex scores were 3.5 (left arm) and 3.6 (right arm). No lymphedema

was detected either visually or objectively based on the L-Dex data. She will remain on post-treatment surveillance. Final determination: outcomes met.

Patient #2

Patient #2 was seen on January 24, 2022, while undergoing cycle 8 of taxane-based chemotherapy. She is a 70-year-old female who was status post a left breast lumpectomy and SLNB. Her ALND was positive (9/16 lymph nodes) which is associated with a high risk (>30%) of distant recurrence. She began adjuvant radiation therapy on March 17, 2022, followed by treatment with a hormonal blocking agent. Baseline lymphedema measurements (L-Dex scores) while on active taxane-based chemotherapy were 3.5 and 3.5 in her left and right arm, respectively. She returned to the clinic one week later on January 31, 2022, for a follow-up assessment. At that time, her L-Dex scores remained unchanged. She presented for a follow-up visit four weeks later on March 2, 2022, upon completion of chemotherapy; her L-Dex scores at that time were 3.5 (left arm) and 3.4 (right arm). No lymphedema was detected either visually or objectively based on the L-Dex data. She will remain on post-treatment surveillance. Final determination: outcomes met.

Patient #3

This patient was first seen on January 24, 2022. She is a 67-year-old female who presented at this time for a treatment review and coordination visit to address pretreatment and surgery. She had been previously diagnosed with aggressive triple-negative cancer of the left breast and had undergone neoadjuvant chemotherapy to shrink the tumor. Chemoimmunotherapy was scheduled to begin on February 18, 2022. Baseline BIS measurements taken at this time revealed L-Dex scores of 15.8 in the left arm and 15.6 in the right arm. She was managed with a four-week-at-home intervention using compression garments; a referral for fitting was made at

this visit. BIS measurements performed four weeks later March 2, 2022, revealed L-Dex scores of 3.8 and 3.3 in the left and right arms, respectively. No lymphedema was detected based on observation, vital signs, and objective data. She will remain on post-treatment surveillance. Final determination: outcomes met.

Patient #4

Patient #4 was a 63-year-old female who had undergone a left breast lumpectomy with ALND. She was first seen on January 26, 2022, after the completion of adjuvant radiation and was followed by adjuvant hormonal therapy. Her history was notable for a low Oncotype Dx score indicating a <1% likelihood of benefitting from chemotherapy. Her baseline BIS measurements on January 26, 22 were 3.7 (left arm) and 3.7 (right arm). She returned to the clinic one week later for a first follow-up assessment; her L-Dex scores at that time were 3.3 and 3.0 (left and right arms, respectively). She returned to the clinic on March 2, 2022, for a four-week follow-up visit. Her L-Dex scores at this visit were 3.5 (left arm) and 3.5 (right arm). No lymphedema was detected based on objective data. She will remain on post-treatment surveillance. Final determination: outcomes met.

Patient #5

Patient #5 was seen in the office on January 26, 2022, for treatment review and coordination. She was a 62-year-old female diagnosed with hormone-receptor-positive breast cancer who was on neoadjuvant dose-dense taxane-based chemotherapy to shrink the tumor for a better surgical outcome. Her baseline pre-chemotherapy L-Dex scores were 3.6 and 3.3 in her left and right arms, respectively. She returned to the clinic one week later on February 2, 2022, for a follow-up assessment. Her L-Dex scores at that time were 3.6 and 3.6 (left arm and right arm, respectively). She returned to the clinic on March 2, 2022, after two cycles of

chemotherapy. Her L-Dex scores at that time were 3.4 (left arm) and 3.6 (right arm). No lymphedema was documented with objective data. She will remain on post-treatment surveillance. Final determination: outcomes met.

The initial plan evolved over time. Nonetheless, our findings suggest that BIS was highly effective when used for the early detection, management, and treatment of BCRL. Current data support surveillance screening for early detection and management of BCRL; sensitive diagnostic modalities such as BIS are more effective at detecting subclinical BCRL compared to traditional techniques, thereby facilitating early intervention (Shah et al., 2016). Results from published RCT studies suggest that BIS screening should be standard of care for BCRL surveillance. The use of this technique facilitates precise detection of this complication and identifies patients who are likely to benefit from compression therapy (Ridner et al., 2022). Unfortunately, one RCT focused on the detection of BCRL by arm circumference measurements both with and without BIS in patients with stage I–III breast cancer was terminated due to the departure of the Principal Investigator (Clinical Trials, 2018).

Discussion

Summary

The results of my study suggest that BIS is a practical and cost-effective method that can be used to diagnose secondary lymphedema that develops in response to the treatment of neoplastic disease. BIS can provide measurements of extracellular volumes within individual body segments that may develop lymphedema. This test can be performed both before and after treatment and can provide a quantitative assessment of the degree of fluid accumulation (Silva et al., 2019). The results of an RCT that focused on the risk of developing subclinical BCRL based on the extent of the ALND, SLNB, and in patients who have or have not undergone radiation

therapy concluded that BIS provided superior post-treatment surveillance and was more effective at detecting subclinical lymphedema (Boyages et al., 2020). Breast cancer patients who underwent surgery or radiation to the axillary, supraclavicular, or cervical regions are at increased risk for the development of lymphedema. Baseline pretreatment measurements of both limbs can be performed at regular intervals as part of routine follow-up visits to facilitate early detection and diagnosis for optimal lymphedema management. Of note, while stage 0 and stage 1 BCRL are reversible, stages 2 and 3 are less responsive to treatment and typically irreversible (National Comprehensive Cancer Network, 2021). My findings suggest that BIS can be introduced as a standardized interventional approach for early detection and management to reduce the incidence of chronic BCRL. All five patients who were managed with BIS had positive outcomes. Patient #3 had the most dramatic response to this approach. This patient presented with baseline L-Dex scores of 15.8 and 15.6 (left and right arm, respectively), which suggested subclinical (stage 0) lymphedema. The patient was managed with a four-week at-home intervention using compression garments. Follow-up L-Dex scores were 3.8 (left arm) and 3.3 (right arm) were within the normal range of values, suggesting dramatic improvement. The patient presented no additional difficulties and has been scheduled for post-treatment surveillance (Texas Breast Specialist, 2020). Thus, the overall goal of this project has been met, as the QI project has identified a clear benefit for a specific breast cancer population.

Relation to Other Evidence

I identified substantial literature supporting early intervention and treatment of BCRL. The most significant benefit results from an approach involving monitoring of high-risk patients, including those who have undergone ALND, RNI, and taxane-based chemotherapy (Shah et al., 2016). Shah et al., (2016) published the results of two randomized trials focused on the outcomes

of early intervention with physiotherapy, exercise, and manual lymphatic drainage; however, both studies were small with a very short follow-up period. Shah et al., (2020) also published a meta-analysis study that compared BIS to arm circumference measurements and reported that patients monitored with BIS were significantly less likely to develop BCRL when compared to background rate (i.e., no monitoring) or monitoring with the TM method. The results also suggested that BIS monitoring was associated with reductions in the annual incidence of BCRL in high-risk populations (i.e., 40% post-mastectomy and 50% post-ALND).

Early detection can be used to identify patients who might benefit from early interventions such as compression garments, thereby preventing the development of chronic BCRL. There is substantial evidence in the literature indicating that active monitoring of BCRL significantly reduces the likelihood of progression to chronic BCRL (Shah et al., 2021). One recent systematic review reported that bioimpedance-based techniques could be used to detect extracellular fluid volumes both before and after treatment. Furthermore, a report that used the Cochrane tool identified seventy-five studies with a high risk of bias and two studies with uncertain risk. The domains with the highest risk of bias were those related to the size of the study cohort which did not result in security regarding the statistical evaluation. Nonetheless, despite these issues, the authors of this systematic review concluded that BIS was a valid and effective modality that could be used to evaluate the composition of interstitial volumes both before and after treatment and to direct clinical follow-up of patients at risk for developing lymphedema (Silva et al., 2019). Results from another study provided data suggesting the need for long-term (24 months) surveillance with frequent assessments every three months up to 15 months postoperatively. Ridner et al. (2020) reported that BIS was beneficial for the early identification of subclinical lymphedema based on statistically significant L-Dex scores. Further

studies will be needed to obtain insight into contributing risk factors and the optimal prevention and management strategies that might be used to reduce the individual and public health burden associated with this disabling complication (DiSipio et al., 2013). Similarly, Bundred et al., (2015) reported a modest correlation in a study in which multi-frequency bioimpedance was compared with perometry for the early detection of BCRL post-axillary node clearance (ANC) and suggested that further study of these modalities was needed.

Limitations

Limited investment in modern technology can limit the number of BIS screenings available to patients compared to current technology; in this case, the use of BIS may be more cumbersome and less cost-effective. However, the number of participants will most likely increase if BIS screening becomes standard of care. The reinforcement of preventative BIS use and the observed reduction in the number of patients who develop chronic BCRL will most likely increase the sustainability of this new practice unless the organization fails to acknowledge and normalize this new behavior. Efforts to minimize study limitations include improving practice fidelity with evidence-based practice and the introduction of BIS. The effect of constraints on the interpretation and application of BIS-based interventions prompted disturbances to the status quo of our current practice. However, there remains a driving force directed at overcoming resistance from stakeholders, providers, educators, and researchers who question the clinical value of this QI effort.

Interpretation

Efforts to address the possible reasons for differences between anticipated and observed outcomes begin with a comparison of research-focused expectations as opposed to those that result in practice-focused clinical settings. While research-focused results rely on the

interpretation of carefully controlled studies, a practice focus reports the results of real-world outcomes. Translation of research-focused evidence into nursing and healthcare practice can be challenging. Interprofessional collaboration is imperative if one hopes to promote the sustainability of a given practice change. Modifications directed at improving future performance are among the ways to acknowledge the normality of any new behavior. The impact of early detection is one of the driving factors promoting the increased use of BCRL screening. Recent guidelines that support early detection and intervention have focused on subclinical (stage 0) lymphedema; detection of this complication at this reversible stage can result in a reduction in rates of chronic BCRL. BIS is a valuable, practical, and cost-effective screening tool that can be used for early detection of BCRL and will help to prevent and manage the devastating effects of this potentially chronic disability (Kaufman et al., 2017).

Conclusions

Lymphedema is a disabling condition and a major post-surgical complication experienced by breast cancer patients. BCRL is one of the most feared consequences of survivorship as it serves as a constant reminder of their cancer diagnosis and its treatment (Dean et al., 2018). Chronic lymphedema is preventable if it is caught early on in its development. The use of BIS presents an opportunity for detection, intervention, and reversal of this disabling condition before the onset of fibrosis (Mayrovitz et al., 2009). BIS provides caregivers with an L-Dex score that can be used for the reliable diagnosis of subclinical (stage 0) lymphedema. The L-Dex score is a validated metric for lymphedema detection; a baseline score >10 or an increase ≥ 6.5 over a baseline value indicates the need for clinical intervention. Evidence-based clinical diagnostic outcomes from BIS are superior to those provided by commonly used conventional methodologies. Current evidence supports the use of BIS as a standardized clinical approach as it

has sufficient sensitivity and specificity to detect subclinical lymphedema (Dylke et al., 2016). Many nurses are undertaking QI projects that will have an impact on the clinical and financial operations of their organizations. BCRL is a profoundly important clinical issue with a tremendous impact on cancer survivors. Implementation of preventative strategies using BIS will ultimately reduce the cost of care, provide early recognition and prevention of chronic BCRL, decrease hospital length of stay, and improve care coordination and critical patient outcomes.

Other Information

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