ALLAS—Bioimpedance spectroscopy (BIS) combined with immediate compression therapy, may be a more effective surveillance technique than standard tape measurement (TM) in detection and early treatment of subclinical lymphedema in breast cancer patients, according to an interim analysis of results from the randomized, prospective PREVENT clinical trial.

The interim results, presented at the 2019 American Society of Breast Surgeons annual meeting, showed post-treatment surveillance with BIS reduced absolute rates of progression requiring complex decongestive physiotherapy by about 10 percent when compared to TM (Abstract 581304). BIS was associated with a 67 percent relative reduction, and a 9.8 percent absolute reduction, in progression.

“Although not statistically significant, these results may support the concept of post-treatment surveillance with BIS to detect subclinical breast cancer-related lymphedema and initiate early intervention,” Sheila Ridner, PhD, RN, lead author and Professor of Nursing at Vanderbilt University School of Nursing, told a press briefing.

A total of 498 patients were evaluated, 15.8 percent of those in the BIS group (41 of 259) and 26.5 percent of those in the TM cohort (68 of 239) had an event that required intervention. In the latter group, 10 patients, or 14.7 percent, went on to develop clinical lymphedema requiring complex decongestive intervention, compared to 4.9 percent in the BIS group. The mean time to reach intervention thresholds was 9.3 months and 2.8 months, respectively.

“The bioimpedance device measures lymphatic fluid, and the tape measures much more than that,” said Ridner, a researcher at Vanderbilt-Ingram Cancer Center. “It takes more lymphatic fluid to make your whole arm volume change than it does to make the device pick up changes. The device is just more sensitive to changes in lymphatic fluid.”

TM assessment also includes fat, bone, soft tissue, and other fluids that may result from the trauma of cancer treatment, complicating interpretation, she explained. Moreover, TM assessment leaves more room for human error. By contrast, BIS relies on electrical current to interpret electrical signal through the body. The technology is similar to electronic monitors for body mass index, but much more refined. “I believe that this is a scientifically robust study. I expect that we will achieve similar results throughout the rest of the study and hope someday every breast cancer patient at risk will have access to this valuable tool,” said Ridner.

Methodology

Women in the study were recruited prior to undergoing mastectomy, and/or a range of lymph node-related breast cancer surgeries, and/or radiation. They were randomized to either the BIS or TM groups and, starting 90 days after their procedure, were regularly assessed and followed for a minimum of 1 year. The interim analysis was conducted after at least 500 trial participants had at least 12-months of follow-up after surgery.

Compression therapy was provided to all TM patients who experienced an increase in arm circumference of 5 percent or more, reflexive of subclinical lymphedema. In the BIS group, an increase of 6.5 L-DEX units from baseline, also indicating subclinical lymphedema, precipitated intervention. Therapy consisted of arm compression using a precisely fitted sleeve and chest gauntlet for 12 hours each day for 28 days. In both groups, clinical lymphedema was defined as a 10 percent increase in arm circumference with TM assessment.

Post-surgical inclusion criteria included stage I-III invasive breast cancer or ductal carcinoma in situ with at least one of the following: mastectomy, axillary treatment (axillary lymph node dissection, sentinel lymph node biopsy with greater than six nodes, axillary radiation), and taxane-based chemotherapy. Additional post-surgical exclusion criteria included bilateral breast surgery. Patients who triggered intervention (change from presurgical baseline ≥ 5% volume by TM; ≥ 6.5 L-Dex BIS) were prescribed a compression sleeve and gauntlet for 4 weeks and re-evaluated.

The median age of the subjects was 58.8 years, and 77 percent were Caucasian. The most common co-morbid conditions were cardiovascular in 44 percent of the women. In all, 56.7 percent were diagnosed were the norm. BIS is a relatively low cost, fast, and may save the significant expense of decongestive physical therapy if later required,” she said.

“It is possible that at 3 months post-surgery in some patients there remains a generalized, whole-arm inflammatory response that is identified by tape measure. Increased extracellular fluid may not be a major factor in that volume change,” according to the report.

Of statistical significance, more people in the tape group required intervention than in the BIS group, which was contrary to what many people thought would have happened in the study.

“One of the concerns about BIS in general was that it might generate false positives and we might psychologically distress people, but that was never my experience in the 15-16 years I’ve been working with the technology,” Ridner noted.

“Tape measure is the most commonly used method around the world even though it is fraught with error. To get accurate measurements for a research study, there is an incredible amount of training to teach all the sites in this international study how to measure the same way. I do annual fidelity oversight visits at every single site to make sure there has not been any slippage in the protocol.”

BIS is a painless and non-invasive procedure that entails running an electronic signal through the body. The technology is similar to electronic monitors for body mass index, but much more refined.

“Lymphedema significantly lowers quality of life and consistently ranks as the number one fear of breast cancer survivors,” noted Ridner. “It is possible that at 3 months post-surgery in some patients there remains a generalized, whole-arm inflammatory response that is identified by tape measure. Increased extracellular fluid may not be a major factor in that volume change,” according to the report.

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Cancer patients, survivors, caregivers, health care professionals, and innovators can submit ideas that could help improve the lives of those touched by cancer. Ideas can be in the form of support tools, educational efforts, technology solutions, and more. The C Prize is open to any idea that can have an impact, especially if it’s simple. The idea should focus on one of three submission categories:

- **Cancer Health Disparities**: Ideas to reduce the unequal burden of cancer care, with a focus on tools and resources that reach underserved populations in the U.S. and abroad.
- **Cancer Survivorship**: Ideas to address survivorship challenge and concerns.
- **Cancer Care Journey**: Ideas to help improve the patient experience, ease decision-making, and navigate everyday care.

Based on the evaluation of an expert judging panel, the 2019 C Prize finalists will be announced in September 2019. Each of the finalists will win one of the four prizes. Three finalists will compete for the Grand Prize, with the runners-up awarded the two Innovation Prizes. The other finalist will be selected as the Emerging Ideas Prize winner, a first for the program. Judges will consider ideas for the Emerging Ideas Prize if they have high potential impact for patients and caregivers but need additional work and cultivation before implementing.

Finalists will present ideas in front of a panel of judges and audience during a live pitch event in October 2019, featuring judges including celebrity entrepreneur Bill Rancic and 2017 C Prize winner Hernâni Oliveira.

Entries will be accepted through July 15, 2019, and will be evaluated on the submitted idea’s feasibility, originality, creativity, potential impact, and the entrant’s vision for how to reach people who might benefit from their idea. Entrants are not required to have an established business or finished product to apply. Entrants are encouraged to submit an optional, short video about their experience with cancer and their innovative idea. The video should not exceed 2 minutes in length and may be filmed on a smartphone.

All winners will be provided with access to tools and resources to help them develop and advance their idea.

According to the 2018 C Prize Grand Prize Winner, Ebele Mbanugo, EdD, winning the prize has brought her one step closer to launching her program that fights the social stigma around breast cancer in Nigeria. “I encourage anyone with a creative solution, whether big or small, that can improve cancer care to apply to this challenge. One good idea has the potential to impact the lives of many people who are affected by cancer,” Mbanugo said.

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Kurt Samson is a contributing writer.

**LYMPHEDEMA**

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with stage I breast cancer, while 39 percent had stage II/III disease at baseline. The clinical trial was launched in June 2014 and will follow a total of 1,201 patients for 3 years post-surgery. To date, 200 patients have completed the full protocol.

**Commentary**

Lymphedema represents a significant morbidity for patients who experience it, said Julie A. Margenthaler, MD, Professor of Surgery at Washington University School of Medicine in St. Louis. “This study demonstrates that bioimpedance spectroscopy can identify early signs of lymphedema so that interventions can be taken to prevent progression. This is an important step in improving the lives of our breast cancer survivors.”

Carla Fisher, MD, Associate Professor of Surgery and Medical Director of Breast Surgery Oncology at Indiana University of Medicine, identified some of the current barriers to broader use of BIS in this population. “Access to the devices and cost have been a barrier,” she told *Oncology Times*.

“TM is easy to perform and does not cost anything other than the cost of the tape measure. If the two measurements are equivalent, then it is absolutely appropriate for physical therapists and physicians to use TM. This study is the first step in indicating that BIS may be more effective, and therefore the cost barrier is less important,” she said.

“We don’t know exactly how advanced lymphedema typically gets before a breast cancer patient is aware of swelling, and this is why we are proactively working on measurements that will detect changes. It does appear, however, that by detecting these changes prior to awareness will help decrease clinically significant lymphedema in the long run.”

Kurt Samson is a contributing writer.

**MAMMOGRAM GUIDELINES**

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specificity of actionable recommendations for each group, and suggestions for patient discussion and shared decision-making. The guides also take into account specific breast cancer subtypes found to be more common among certain racial and ethnic groups and encourage enhanced surveillance for earlier diagnosis and treatment.

The guidelines also acknowledge racial disparities in outcomes. For example, African-American women face a disproportionately high risk of breast cancer mortality, which is at least partly explained by differences in stage distribution as well as tumor biology, according to the statement.

“The age distribution of breast cancer is younger, and the stage distribution is more advanced in African-American women. Population-based breast cancer mortality rates are higher among African-American women, and population-based incidence rates of triple-negative (estrogen receptor-negative, progesterone receptor-negative, HER2/neu non-amplified) breast cancer are two-fold higher among African-American women.”

Taylor also noted that, while most health insurers cover some of the recommended strategies, such as risk assessment and 3D mammograms before age 50, the ASBrS specifically did not restrict guidelines to currently covered procedures.

“We have refined documentation of disparities in breast cancer burden related to associations between racial/ethnic identity, age, and breast tumor subtype. These issues, as well as shifting population demographics and increasing diversity in the U.S., elevate the screening mammography debate in discussions of strategies to achieve health equity,” the guidelines state.

“Changes in our understanding of breast cancer epidemiology justify re-evaluation of these trials in the context of contemporary recommendations for mammographic screening, despite the paucity of data these trials provide regarding screen-detected tumor biology and diverse patient populations.”

Kurt Samson is a contributing writer.