

Bioimpedance Spectroscopy Monitoring Reduces Long-term Clinical Lymphedema Risk

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San Antonio Breast Cancer Symposium: December 6th – 10th, 2022

Background

- A prospective surveillance model (PSM) of care can reduce the risk of breast cancer related lymphedema (BCRL).
- Bioimpedance spectroscopy (BIS) devices can identify sub-clinical BCRL (sBCRL). A recent randomized controlled trial (RCT) demonstrated the benefit of a PSM model of care using BIS over tape measure (TM) but it did not look at the long-term risk following intervention.
- This work reports the actuarial risk of clinical lymphedema for those who have triggered an intervention for sBCRL by either BIS or TM.

Materials and Methods

- Eight hundred seventy-nine (n=879) women with breast cancer were randomized to lymphedema screening with either BIS (n=442) or TM (n=437). Following consent, patients underwent baseline pre-surgical measurements with BIS (L-Dex U400, ImpediMed) and volume (circumference) measurements (Gulick II tape) and randomized after surgery. Both the TM and BIS arms underwent planned post-operative assessments at 3, 6, 12, 18, 24, 30, and 36 months as well at the end of any intervention.
- Patients with a BIS change from baseline of ≥ 6.5 L-Dex units or TM volume change ≥ 5 and $<10\%$ above pre-surgical baselines "triggered" for sBCRL from the basis of this study. Triggered patients underwent 4-weeks of wearing a class two (23–32 mmHg) compression sleeve and gauntlet for 12 hours per day.
- TM volume change $\geq 10\%$ was considered clinical BCRL (cBCRL) for all patients who triggered by either BIS or TM. The cumulative incidence of cBCRL was calculated via the Kaplan-Meier method and compared by the Log-rank test.

Results

Two hundred nine [209, (23.8%)] women triggered an intervention and completed treatment for sBCRL [BIS: 89 (20.1%), TM: 120 (27.5%)]. The median follow-up for the women who triggered was 32.2 months (IQR 17.0 – 33.9) with 30 women (14.4%) women developing cBCRL [BIS: 7 (7.9%), TM: 23 (19.2%)]. There was a significant difference in risk between the groups over the follow up interval (log rank test $P = 0.021$; **Figure 1**) with the cumulative risk in the BIS group being lower compared to the TM group (Hazard Ratio = 0.38, 95%CI 0.19 – 0.79). The 2-year actuarial risk of cBCRL for triggered patients undergoing lymphedema screening by BIS was 5.0% versus 15.7% for TM screening ($P = 0.021$, HR = 0.30); the corresponding 3-year rates of cBCRL were 10.3% and 21.2% ($P = 0.031$, HR = 0.40), respectively (**Figure 2**).

Figure 1: Kaplan-Meier Curves

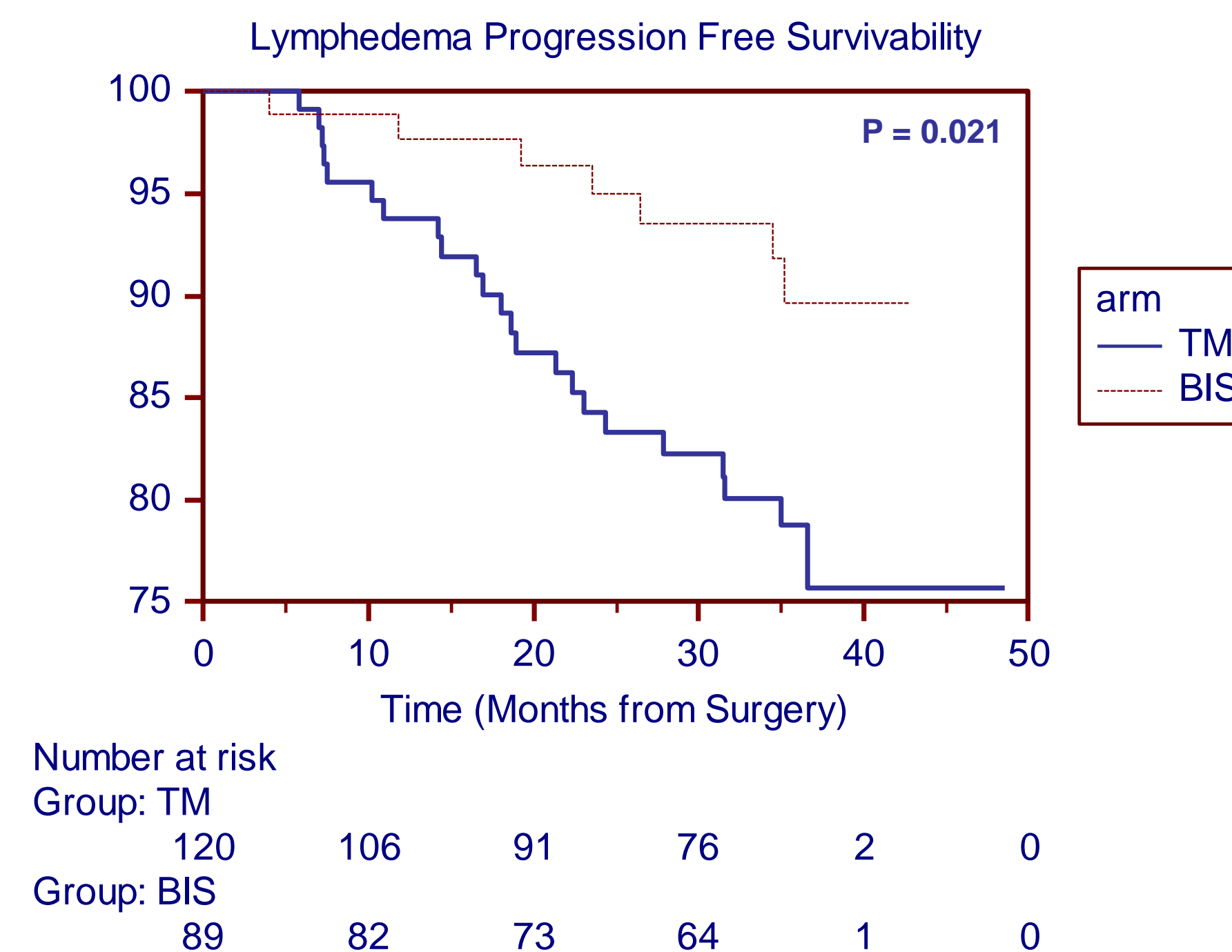
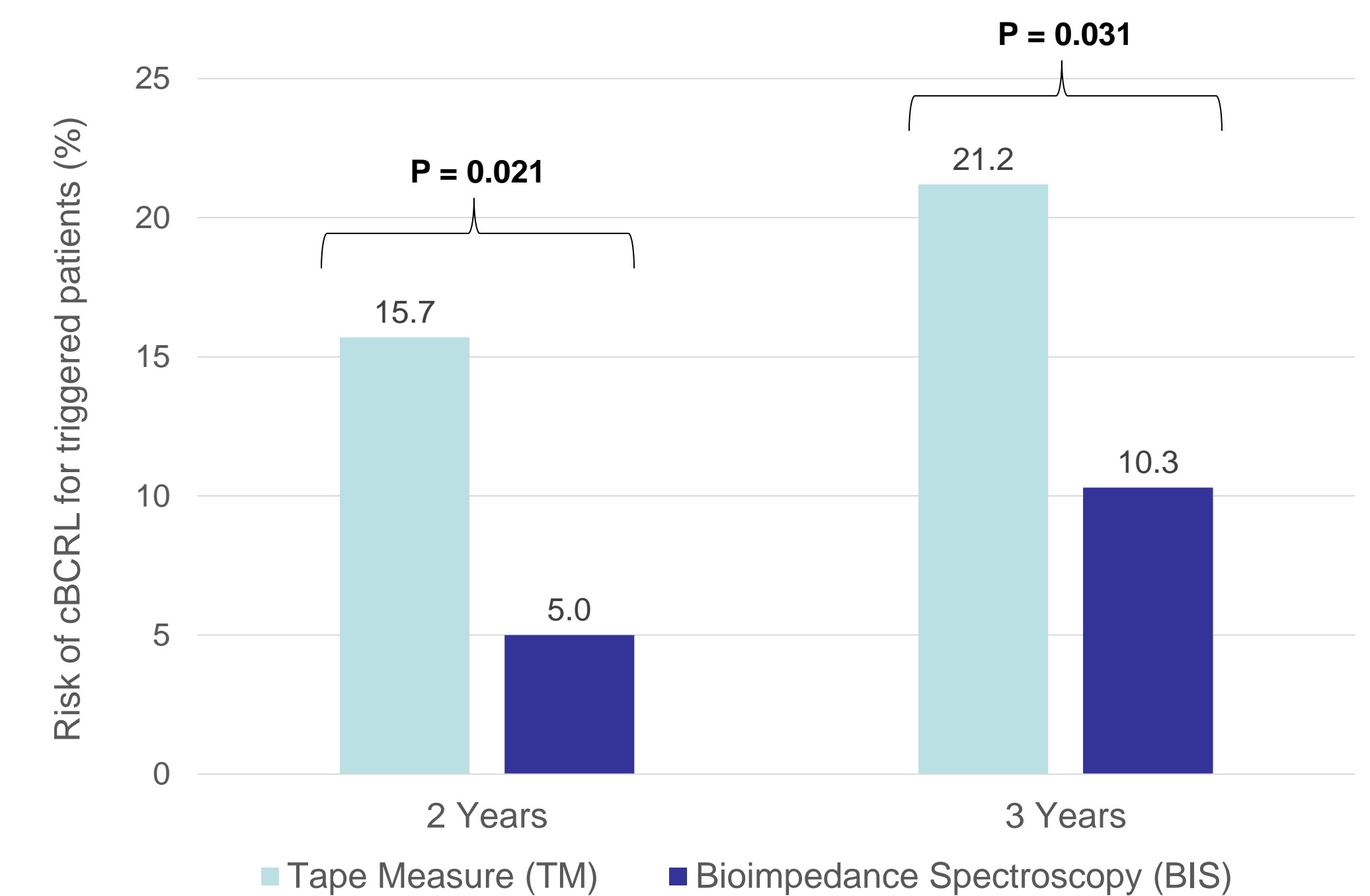


Figure 2: Risk of cBCRL at 2 and 3 Years



Conclusions

BIS monitoring for sBCRL with subsequent intervention provides significantly lower risks of cBCRL. The lower triggering rates with BIS highlight its better discrimination of true sBCRL compared to TM and support its use for post-treatment surveillance to detect sBCRL and initiate early intervention. These data suggest that monitoring for sBCRL with BIS and subsequent intervention does not just delay the inevitable progression to cBCRL, but rather prevents it over the duration of the study.