Interim Analysis of the Lymphedema "PREVENT" Randomized Trial

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Disclosures

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Background

- Despite advances in breast conserving surgery, radiation protocols, and chemotherapy, breast cancer-related lymphedema remains a major source of morbidity and concern in the patient population.
- Prospective surveillance model gaining support
  - Research is needed to compare lymphedema risk reduction outcomes resulting from standard assessment method (tape measure) to those from bioelectrical impedance spectroscopy (BIS).
- Aim: To determine if subclinical detection of extracellular fluid accumulation via bioelectrical impedance spectroscopy (BIS) and subsequent early intervention reduce the rate of progression to CDP relative to rates seen using standard tape measurement (TM) .

Methods

- Design: international, multi-site, two-group (Tape Measure and Bioelectrical Impedance Spectroscopy), randomized controlled trial
- Population: newly diagnosed breast cancer patients
  - Stage I-III invasive breast cancer or DCIS with **at least** one of the following: mastectomy, axillary treatment (axillary lymph node dissection, sentinel lymph node biopsy with greater than 6 nodes, axillary radiation), taxane based chemotherapy
- Post surgical follow-ups
  - 3 months, 6 months, 12 months, 15 months*, 18 months, 21 months*, 24 months, 30 months and 36 months

*optional visit

Methods

- Trigger Points
  - Tape measure ≥ 5%-<10% volume change from pre-treatment baseline
  - BIS ≥6.5 L-Dex change from pre-treatment baseline
- Intervention
  - compression sleeve and gauntlet for 4 weeks, 12 hrs. a day
- Progression ≥ 10% volume change from pretreatment baseline as measured by tape measure

Interim Analysis-required when ≥ 500 patients completed 12 months of follow-up

		Tape Measurement	BIS
Total Sample	N=508	N=245	N=263
Sample for Potential Trigger	N=498	N=239	N=259
	n (%)	n (%)	n (%)
Triggered	109 (21.9%)	68 (28.5%)	41 (15.8%)
Progression	12 (11.0%)	10 (14.7%)	2 (4.9%)

Conclusions

- Interim results of post-treatment surveillance with BIS of lymphedema progression compared to tape measure demonstrate:
  - 10% absolute reduction
  - 67% relative reduction
- Interim results may support the concept of post-treatment surveillance using BIS for early detection of subclinical lymphedema coupled with early intervention.