Changes in Patient Reported Outcomes in Women with Breast Cancer in A Dual-Center Double Blind Randomized Controlled Trial Assessing the Effect of Acupuncture in Reducing Aromatase Inhibitor-induced Musculoskeletal Symptoms (AIMSS)

Ting Bao, Kelly Betts, Karineh Tarpinian, Ling Cai, Jeff Gould, Ming Tan, Claire Snyder, Kate Tkaczuk and Vered Stearns

tbao@umm.edu

Abstract #31
No Disclosure
Background

- Aromatase inhibitors (AIs) are the recommended primary adjuvant endocrine therapy in postmenopausal women with hormone-receptor-positive breast cancer.

- AIs have been associated with worsening of patient related outcomes (PROs) such as AIMSS, menopausal symptoms and depression.

- Acupuncture has been reported to alleviate such symptoms.
Hypothesis and Study Design

• Real acupuncture (RA) would improve PROs more than sham acupuncture (SA)

• To test this hypothesis, we designed a
  – Dual center
  – Randomized
  – Sham acupuncture controlled (non penetrating needle, non-acupoints, Park device)
  – Blinded trial
ELIGIBLE:
Women with stage 0-III breast cancer on AI-treatment ≥ 1 month who are having treatment-related musculoskeletal symptoms.

NO prior acupuncture treatment in the past year.

Acupuncture (n = 23)

Sham Acupuncture (n = 24)

Follow-Up

Acupuncture or Sham Acupuncture Treatment (8 weekly treatments total)

HAQ-DI and PROs Questionnaires, Hot Flash/Medications/Problems Diary (daily)

Research Blood Draw

Intention-to-treat analysis

Wilcoxon rank sum and signed-rank tests were used to make comparisons between and within group, respectively.
**PRO Questionnaires**

- Revised National Surgical Adjuvant Breast and Bowel Project (NSABP) menopausal symptoms questionnaire
- Center for Epidemiological Studies Depression Scale (CESD)
- Hospital Anxiety and Depression Scale (HADS)
- Pittsburgh Sleep Quality Index (PSQI)
- Hot Flash (HF) Daily Diary
- Hot Flash Related Daily Interference Scale (HFRDI)
- EuroQoL survey
Results

• Between May 2008 and July 2011, 51 patients were randomized, 47 patients were evaluable, 23 were randomized to real acupuncture group and 24 to sham acupuncture group.

• Baseline characteristics were balanced between the two groups with regard to age, race, BMI, type and duration of AI, and PROs baseline scores.
• No significant differences in improvement of the PROs between the two arms

• When compared to baseline, there were statistically significant improvements at wk 8 in CESD, hot flash weekly severity score, hot flash frequency, HFRDI and NSABP menopausal symptoms scores in RA arm; for EuroQoL, HFRDI and NSABP menopausal symptoms scores in SA arm
Hot flash weekly severity score at each time point
HF weekly severity score

Mean difference (SA–RA) and 95% CI
What caused the racial difference?

• Same baseline HF weekly severity scores (p=0.941)

• More non-AA patients took anti-hot flash medication

• AA patients respond better to RA and worse to SA than non-AA patients?
Limitations

- Small sample size
- Secondary end points
- Post hoc analysis
- Small number of AA patients
Conclusions

• Real and sham acupuncture were both associated with improvement in PROs in breast cancer patients taking AIs

• We detected no significant difference in the change of PROs between real and sham acupuncture

• Racial difference in response to acupuncture warrants further study
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