Common Scents: Using a Placebo-Controlled Research Study to Drive Practice

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Disclosure

- There are no disclosures related to this study.
- Beekley Medical™ supplied the aromatherapy tabs. Beekley Medical had no input to the design, conduct or outcome of the study.

Atlantic Health System
Carol G. Simon Cancer Center

Morristown Medical Center
Morristown, NJ

6,612 employees: 1,800 nurses
1,588 physicians
198 medical residents
40,828 admissions
86,385 emergency visits
419,118 outpatient visits
2,066 breast biopsies

ANCC Magnet Recognition® at Morristown Medical Center

In 1983, MMC was one of 41 original hospitals in the US recognized by the American Academy of Nursing as a top hospital for recruiting and retaining well qualified nurses, a precursor to the Magnet designation.
Research Team

- **Renee Trambert**, MPH, RN, CN-‐BN
  - Principal Investigator
  - Nurse Navigator
  - Carol W. and Julius A. Rippel Breast Center

- **Paul Friedman**, DO
  - Medical Director
  - Carol W. and Julius A. Rippel Breast Center

- **Betty Wu**, RN, CN-‐BN
  - Nurse Navigator
  - Carol W. and Julius A. Rippel Breast Center

- **Carol W. and Julius A. Rippel Breast Center**

- **Diana Caruso**, RT
  - Nurse Navigator
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- **Nimisha Mehta**, MD
  - Chief Radiology Resident
  - Department of Radiology
  - Carol W. and Julius A. Rippel Breast Center

- **Mildred Ortu Kowalski**, PhD, RN, NE-‐BC
  - Nurse Researcher
  - Morristown Medical Center

Carol W. and Julius A. Rippel Breast Center

Research Process

- Research Question
- Putting team together
- PICO: Defining the population and intervention to be studied
- Literature Search
- Incorporation of the Nurse Theorist
- Design: objectives, comparison, variables, statistical analyses, sample size
- Recruitment Plan
- Writing the Protocol
- Developing Forms
- Brochure for Recruitment
- Resources
- IRB Approval
- Initiation
- Statistical consult
- Findings
- Dissemination
Background

Approximately 232,340 women will be diagnosed with breast cancer in the USA this year.

Breast biopsy is the standard diagnostic procedure for diagnosis.

Biopsies are anxiety provoking for patients.

Aromatherapy

- For centuries aromatherapy has been used to reduce anxiety.
- This study uses a unique deliver system to measure the reduction of anxiety using aromatherapy.

Common Scents: Anticipated Aromatherapy Effects

<table>
<thead>
<tr>
<th>Aroma</th>
<th>Documented effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lavender</td>
<td>Calming</td>
</tr>
<tr>
<td>Sandalwood</td>
<td>Anti-depressant, calming</td>
</tr>
<tr>
<td>Orange</td>
<td>Calming, sedative effect</td>
</tr>
<tr>
<td>Peppermint</td>
<td>Relieves nausea, combats fatigue</td>
</tr>
<tr>
<td>Placebo</td>
<td>Anticipated benefit may be realized</td>
</tr>
</tbody>
</table>

ACS, 2014; Alankar, 2009; Setzer, 2009
Research Question

- Biopsies are anxiety provoking for patients
- Culture of Healing
- “How can nurses reduce anxiety for people having breast biopsies?”

Roy Adaptation Theory

The nursing theory used at MMC. A systematic and holistic nursing theory. Incorporates physical, emotional, social and spiritual nature of beings. Charges nurses with helping patients adapt to stressors.

<table>
<thead>
<tr>
<th>Focal Stimuli</th>
<th>Contextual Stimuli</th>
<th>Residual Stimuli</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety – related to breast biopsy</td>
<td>Family history of breast cancer</td>
<td>Age, race, insurance, educational level, marital status factors</td>
<td>Will aromatherapy enhance adaptation to anxiety associated with breast biopsy?</td>
</tr>
<tr>
<td>Primary Stressor</td>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Aromatabs®

- Small foam-like tab (1 in X 1 ½ inches) on a larger cardboard backing (2 inch X 2 ½ inches)
- Hypo-allergenic adhesive backing
- Tab is placed on the gown, by the shoulder
- MDS information was provided to the IRB
- Beekley Manufacturer provided the tabs and matched placebo. They had no input in the design, conduct or outcome of the study.
Literature Review

- Librarians: Janina Kaldan, Library Manager
  Yi Zhou, Librarian
  Kelly Heeney, Library Technician

- Shinn-Lathrope Health Science Library at Morristown Medical Center

- Multiple databases: CINAHL, Pubmed, EBSCO

- Mary Loughran was used as a resource because of her previous research experience with aromatherapy

- Beekley Manufacturer

Key Findings from Lit Review

- Anxiety is one of the most common problems patients face before an image-guided core biopsy

- Methods to reduce anxiety and enhance adaptation are paramount to nursing care

- Reduced anxiety may improve patient’s outpatient hospital experience

- Documented results include reduced anxiety and improved mood with aromatherapy

- Aromatherapy has been shown effective in a variety of clinical settings

- Delivery is challenging

  - Aromatabs are easy, convenient delivery system

PICO Question

Population: Females, 18 – 90 years, no prior personal history of breast cancer, having breast biopsy at the Carol W. and Julius A. Rappel Breast Center of the Carol G. Simon Cancer Center at MMC

Intervention: Aromatherapy Tab using a unique delivery system

Comparison: Three groups of aromatherapy including: Lavender Sandalwood, Orange/Peppermint compared to a Matched Control Delivery System

Outcome: Reduction of Anxiety as measured by the State-Trait Anxiety Inventory for adults Self-Evaluation Questionnaire (Spielberger, 1977)

Adapted from Cincinnati's Children's Hospital
https://www.cincinnatichildrens.org/assets/0/78/176/4711/4715/fca30651‐b07c‐43be‐a28a‐80e171e7cca4.pdf; accessed 09/02/2013
Study Objectives

- To explore the use of aromatherapy, via aromatherapy tabs, to reduce anxiety during image-guided breast biopsy.
- To investigate the effects of lavender/sandalwood (Group A) or the effect of orange/peppermint (Group B) aromatherapy, compared to a matched placebo (Group C), in the reduction of anxiety and related physiological changes in women.
- To evaluate differences in anxiety and vital signs with the aromatherapy tabs versus placebo.

Outcome

Will aromatherapy enhance adaptation to anxiety associated with breast biopsy?

Anxiety as measured by Spielberger State Trait Inventory

State Anxiety Inventory (STAI)

- The STAI measures state anxiety
- Difference between state and trait anxiety
- Validity and Reliability of the instrument well established
  - Validity – over 5000 tests
  - Reliability – test/re-test, correlation
- Licensed though Mind Garden™
- The State Anxiety Inventory Scale = 20 questions
- The Trait Anxiety Inventory Scale = 20 questions
- Paper and pencil
State Trait Anxiety Inventory Scale (STAI) – State Scale

State Trait Anxiety Inventory Scale (STAI) – Trait Scale

Define Population

- All women scheduled for an image guided core biopsy at MMC meeting eligibility criteria
- Consentig women between the ages of 18-90
- Exclusion:
  - Allergy to plants, seasonal allergies, problems breathing through nose, history of asthma, history of seizures
  - Women who had a history of breast cancer
  - Women who were pregnant
  - Non-English speaking
  - Cognitively or decisionally impaired
Sample Size

- N = 87
- Based on alpha level of 0.05, power = 80%, and a medium effect size
- The effect size is estimated from a post-operative study (Fayazi, et al, 2011). Showed an eight point difference in anxiety.

Feasibility

- Out of 21 counties in NJ, Morris County is 2nd highest annual incidence rate of breast cancer (147.8), second only to Hunterdon County 150.3 (2005-2009 rate period).
- MMC = 1478 breast biopsies/year
  - 673 ultrasound guided core biopsies annually
  - 547 stereotactic guided core biopsies a year
  - 258 MRI guided core biopsies a year
- Recruitment rate of approximately 10 cases/month
- Plan was September 30, 2013 to June 30, 2014
- Actual was September 30, 2013 to June 23, 2014
- Duration of enrollment was 9 months
Planned Analysis

- Description of the characteristics of the sample
- Comparison of State Anxiety Score between pre and post-biopsy
- Comparison of BP, P, R between pre and post-biopsy
- Effect of intervention on reducing anxiety
- Detect any difference between groups
  - Lavender versus Placebo
  - Orange versus Placebo
  - Lavender versus Orange
IRB Approval

- Nursing Research Council approval
- Submit Institutional Review Board Documents: Protocol, Consent Form, Information Forms, STAI Survey Forms, Brochure, MSD Sheets, application, sub-investigator forms, CV, CITI training certification
- Full IRB review – PI present for questions at meeting
- Approved via letter
- Use of Stamped Consent Form

Data Entry, Coding and Analysis

- Demographic variables collected were: age, marital status, education, insurance type
- Clinical variables: BP, P, R
- Psychosocial: State and trait anxiety inventory (Spielberger)
- Time of procedure, time of tab placement, group, day of week

Data Collection Form
Coding

Statistical Analyses

- Descriptive statistics are provided for the study sample.
  - Continuous variables are summarized using average and standard deviation or median (range)
  - Proportions are used for categorical variables.
- The three groups are compared in terms of baseline demographic and clinical factors using ANOVA/Kruskal-Wallis test or the Chi-square test
- The change in the State score (post – pre) was compared in the three groups using the Kruskal-Wallis test
  - Pairwise comparisons between groups were made using the Mann-Whitney U test
- The three groups were also compared in terms of the change (post-pre) in BP (systolic and diastolic), pulse and respiratory using the Kruskal-Wallis test

Findings

- Demographics
- State Pre and Post
- Physiological Measures Pre and Post
- Compare groups
### Demographics N=87

<table>
<thead>
<tr>
<th>Variable</th>
<th>Lavender</th>
<th>Orange</th>
<th>Placebo</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) Mean ± SD</td>
<td>52.4 ±10.6</td>
<td>50.3 ±10.5</td>
<td>47.5 ±8.9</td>
<td>0.21</td>
</tr>
<tr>
<td>White Race %</td>
<td>90%</td>
<td>83%</td>
<td>96%</td>
<td>0.26</td>
</tr>
<tr>
<td>Private Insurance %</td>
<td>93%</td>
<td>96%</td>
<td>93%</td>
<td>0.83</td>
</tr>
<tr>
<td>Education %</td>
<td></td>
<td></td>
<td></td>
<td>0.24</td>
</tr>
<tr>
<td>College</td>
<td>56%</td>
<td>56%</td>
<td>44%</td>
<td>0.74</td>
</tr>
<tr>
<td>Graduate or post-graduate</td>
<td>28%</td>
<td>37%</td>
<td>41%</td>
<td>0.54</td>
</tr>
<tr>
<td>Type of Biopsy %</td>
<td>62%</td>
<td>47%</td>
<td>68%</td>
<td></td>
</tr>
<tr>
<td>MRI</td>
<td>7%</td>
<td>7%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>Stereotactic</td>
<td>90%</td>
<td>83%</td>
<td>96%</td>
<td></td>
</tr>
<tr>
<td>Ultrasound</td>
<td>31%</td>
<td>47%</td>
<td>29%</td>
<td></td>
</tr>
</tbody>
</table>

Demographic statistics: ANOVA/Kruskal-Wallis test or the Chi-square test

### Baseline Measures: Vital Signs and State/Trait Anxiety Scores

<table>
<thead>
<tr>
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<th>Orange</th>
<th>Placebo</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic BP median (range)</td>
<td>118 (99-148)</td>
<td>118 (91-146)</td>
<td>118 (91-146)</td>
<td>0.25</td>
</tr>
<tr>
<td>Diastolic BP median (range)</td>
<td>70 (56-101)</td>
<td>70 (53-96)</td>
<td>70 (53-96)</td>
<td>0.20</td>
</tr>
<tr>
<td>Pulse median (range)</td>
<td>74 (54-87)</td>
<td>70 (60-100)</td>
<td>72 (55-133)</td>
<td>0.32</td>
</tr>
<tr>
<td>Respirations median (range)</td>
<td>16 (12-24)</td>
<td>16 (12-20)</td>
<td>16 (12-20)</td>
<td>0.51</td>
</tr>
<tr>
<td>State median (range)</td>
<td>48 (22-66)</td>
<td>43 (22-73)</td>
<td>43 (23-66)</td>
<td>0.34</td>
</tr>
<tr>
<td>Trait median (range)</td>
<td>37 (23-61)</td>
<td>32 (20-64)</td>
<td>30 (23-59)</td>
<td>0.30</td>
</tr>
</tbody>
</table>

### Outcome Measures: Vital Signs and State Anxiety Scores

<table>
<thead>
<tr>
<th>Variable</th>
<th>Lavender</th>
<th>Orange</th>
<th>Placebo</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in Systolic median (range)</td>
<td>0 (-13, 14)</td>
<td>0 (-13, 13)</td>
<td>0 (-13, 13)</td>
<td>0.003</td>
</tr>
<tr>
<td>Change in Diastolic median (range)</td>
<td>0 (-13, 13)</td>
<td>0 (-13, 13)</td>
<td>0 (-13, 13)</td>
<td>0.003</td>
</tr>
<tr>
<td>Change in Pulse median (range)</td>
<td>0 (-13, 13)</td>
<td>0 (-13, 13)</td>
<td>0 (-13, 13)</td>
<td>0.003</td>
</tr>
<tr>
<td>Change in State median (range)</td>
<td>-0.2 (0.6, 4)</td>
<td>-0.3 (0.4, 4)</td>
<td>-0.4 (0.2, 4)</td>
<td>0.003</td>
</tr>
</tbody>
</table>

The change in the State score (post – pre) was compared in the three groups using the Kruskal-Wallis test. Pairwise comparisons between groups were made using the Mann-Whitney U test.
Change in State Score by Aromatherapy Group

Results

- A reduction in anxiety as measured by the STAI was observed between pre and post biopsy in all groups.
- Reduction in anxiety was observed most in Lavender, then Orange, and least in Placebo.
- Lavender showed a statistical difference compared to placebo.
- Lavender and Orange were statistically different.
- Orange did not show a statistical difference compared to placebo.

Conclusions

- This study showed that Aromatabs are an effective nursing intervention to reduce anxiety in women having image guided breast biopsies, thus, promoting adaptation.
- Results led to the development of a procedure at MMC for aromatherapy using Aromatabs.
- Patients without a preference for scent should be offered the lavender aroma, based on the findings of this study.
- The Roy Adaptation Theory provided a useful guide for this nursing study.
Anxious Patient

- Anti-anxiety Meds
  - alprazolam
  - diazepam
  - benzodiazepine

Procedure
- Delayed or Canceled

Can escalate to:
- Panic Attack
- Vasovagal Response

Using Common “Scents”

- Identify Patient’s Feelings
- Justify Patient’s Feelings
- Act as a Sounding Board
- Support Adaptation

Future implications and research

- A similar study using Aromatabs during breast biopsy is planned at Overlook Medical Center, Summit, NJ.
- Research in areas including the ED and the pain center are being explored.
- Future studies should be expanded to other populations:
  - Women with a personal history of breast cancer
  - Spanish speaking patients
  - Men.
Dissemination

- Poster of concept within the Medical Center
- 2015 Magnet Conference Podium
- Planned Written Publication

Tips for Your Research Journey

1. Think of real issue/problem that will enhance patient experience
2. Find a mentor where you work
3. Be passionate about your research and find others who are like yourself
4. Process is always longer than you think, but worth the effort
5. Realize the changes you make can affect the world in your little corner
6. Research drives our patient practice
Thank you

- Women’s Foundation at Morristown Medical Center
- Beekley Medical for the donation of supplies
- Ms. Stephanie Chiu and Dr. Rami Bustami
- Supportive staff at the Carol W. and Julius A. Rippel Breast Center at Morristown Medical Center
- Special thanks to the women who participated in this study

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