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Is Aromatherapy Effective in Treating Emotional Instability in Women Undergoing Surgical Breast Procedures?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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Abstract

Objective: The objective of this selective EBM review is to determine whether or not “Is aromatherapy effective in treating emotional instability in women undergoing surgical breast procedures?”

Study Design: Systematic review of one single-site, randomized study, one randomized control trial, and one randomized, placebo-controlled study, all English language, one published in 2016 and two published in 2017.

Data Sources: Studies were published in peer-reviewed journals and researched via the PubMed Database.

Outcomes Measured: All of the articles analyzed the effectiveness of aromatherapy in treating emotional instability in women undergoing surgical breast procedures. Improved emotional instability was measured via the Speilberger State Anxiety Inventory for Adults (STAI), the EORTC QLQ-C30 questionnaire, or the STAI for Adults Self-Evaluation Questionnaire specifically Forms Y-1 and Y-2.

Results: Franco et al. found a statistically significant difference across all p-values in positive and negative attitudes before surgery in women using Lavender Fleur Oil and Unscented Oil. Tamaki et al. found that aromatherapy did not improve emotional functioning better than the comparison in women undergoing breast cancer surgery with only 81.4% of experimental patients showing improved emotional functioning as opposed to 76.5% of control patients, with a number needed to treat (NNT) of 21 and a p-value of 0.68. Trambert et al. found a statistically significant difference in anxiety in experimental patients using lavender aromatherapy as opposed to a placebo (p=0.032).

Conclusions: Due to the use of various patient questionnaires, the lack of blinding participants in one study, and the use of aromatherapy at different intervals during the perioperative time period, it is inconclusive whether or not aromatherapy is effective in treating anxiety in women undergoing surgical breast procedures.

Key Words: Aromatherapy and Breast Surgery
Introduction

Surgically correcting or altering any aspect of the fragile human body can be an overwhelming experience for many individuals. While the fear of surgery itself can be an emotionally taxing experience, there are so many other factors that influence the success of surgery such as an experienced medical team, individual coexisting comorbidities, and unexpected events. Therefore, emotions can play a significant role in an individual’s preparedness for a surgical procedure. Depending on the individual, a person can experience a great deal of emotional instability surrounding a major surgical operation.

One form of surgery that remains prevalent today and affects many women in the United States is breast surgery. Surgical breast procedures encompass a vast number of unique procedures, which may be required to eliminate breast cancer or may be elective to alter breast size. Examples of surgical breast procedures include, but are not limited to, breast biopsies, partial or complete mastectomies, breast reconstructions, or breast augmentations. While there is a wide spectrum of surgical breast procedures, not always from cancer alone, it is estimated that in the United States, 1 in 8 women will receive a breast cancer diagnosis in her lifetime.\textsuperscript{1,2} Furthermore, breast cancer remains the second most common cancer in women in the United States.\textsuperscript{1} Neither an exact number of total healthcare costs nor healthcare visits have been identified for surgical breast procedures due to the range of procedures available. However, one study completed in 2016 found that breast cancer treatment, which may include surgical breast procedures, ranged from $71,909 to $182,655 depending on the cancer stage.\textsuperscript{3} Similarly, approximately 266,120 new cases of invasive breast cancer and 63,960 cases of non-invasive breast cancer will be diagnosed in U.S. female patients in 2018,\textsuperscript{2} therefore contributing to costs and visits for future surgical breast procedures.
Surgical breast procedures, although invasive surgeries, may be diagnostic procedures to definitively rule in or rule out breast cancer, with one example being breast biopsies. Plastic breast surgery remains an elective procedure; however, it may still produce emotional instability due to the nature of the invasive procedure. Although these surgeries may take a major toll on an individual’s emotions, perioperative anxiety is a normal human reaction while enduring surgery and may also affect the healing process. Therefore, it is important to address methods to treat surgical emotional instability in an effective manner.

Perioperative emotional instability may be treated with medications such as benzodiazepines, relaxation techniques, establishing rapport, psychotherapy, music, or exercise. Additionally, one widely studied emotional therapy is aromatherapy. Aromatherapy is a form of alternative medicine that has been used for thousands of years. Aromatherapy uses herbs, flowers, and other plants to prepare essential oils that can be used homeopathically in various aspects of medicine. There is no current cure for emotional instability during surgical breast procedures, but rather approved medications and therapeutic techniques, as listed above, that treat the symptoms of emotional instability. Aromatherapy is a unique and intriguing natural treatment for emotional instability that is not only convenient, but easy to use as well. Although other natural remedies, such as yoga or relaxation techniques, are positive alternatives to medications, aromatherapy can be used in the pre-, intra-, and post-operative settings.

**Objective**

The objective of this selective EBM review is to determine whether or not “Is aromatherapy effective in treating emotional instability in women undergoing surgical breast procedures?”
Methods

In this selective evidence based medicine review, one single-site, randomized study, one randomized control trial, and one randomized, placebo-controlled study were selected, reviewed, and analyzed based on population, intervention, comparison groups, and outcomes measured. This investigation included a population of female patients undergoing surgical breast procedures. The intervention in these studies involved exposing the population to various scents of aromatherapy at various times during the perioperative period. The female patients undergoing breast surgery who received aromatherapy were compared to control groups receiving unscented aromatherapy, conventional perioperative care, or a visually similar placebo depending on the respective study. Regardless of the compared group, each study measured whether or not aromatherapy helped improve emotional instability including reduced anxiety and improved emotional functioning in the previously mentioned population.

The author of this review researched and found each study on the PubMed database by searching key words: aromatherapy and breast surgery. All studies were published in peer-reviewed journals and written in the English language. Each study was selected based on its relevance to the clinical question and that its respective outcome was one that was patient-oriented (POEMS). Each study could be included in this review if it was a randomized controlled trial published after 2007. Studies were excluded from this this review if it included male patients or any surgical procedures that did not involve the breast. All three studies used the p-value statistic. Other statistics reported include mean change from baseline, paired t-test, ANOVA, and NNT. The demographics and characteristics of each study are outlined in Table 1.
<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th># Pts</th>
<th>Age (yrs)</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>W/D</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Franco&lt;sup&gt;4&lt;/sup&gt; (2016)</td>
<td>Single-site, randomized study</td>
<td>93</td>
<td>≥18</td>
<td>-Patients ≥18                                                                      -American Society of Anesthesiologist (ASA) I-III status who were scheduled for an elective breast surgery</td>
<td>-History of pulmonary disease -Contact dermatitis with cosmetic fragrances -Significant lab abnormalities -Vulnerable populations such as pregnancy or cognitively impaired individuals</td>
<td>3</td>
<td>Women received two drops of 2% lavender fleur oil (LFO) into a plastic oxygen mask that was inhaled for 10 minutes.</td>
</tr>
<tr>
<td>Tamaki&lt;sup&gt;7&lt;/sup&gt; (2017)</td>
<td>Randomized Control Trial</td>
<td>162</td>
<td>≥18</td>
<td>-Breast cancer from Stage 0-Stage IIIc including the pts with neoadjuvant chemotherapy, endocrine therapy, and targeting therapy -Patient ≥18 -Eastern Cooperative Oncology Group performance status of 0 or 1 (0= pt fully active/able to carry on all pre-disease activities w/o restriction; 1= pt restricted in physically strenuous activity but is ambulatory and able to carry out work of a light of sedentary nature)</td>
<td>-Current uncontrolled medical conditions that could limit a patient’s ability to undertake study therapy</td>
<td>9</td>
<td>Patients either received a ylang-ylang, orange, or lavender aroma oil by their bedside for 9 hours before surgery.</td>
</tr>
<tr>
<td>Trambert&lt;sup&gt;8&lt;/sup&gt; (2017)</td>
<td>Randomized, placebo-controlled study</td>
<td>89</td>
<td>≥18 and ≤90</td>
<td>-Ability to read English -Consent at age 18-90 -Ability to complete STAI forms</td>
<td>-Non-English speaking -Pregnant or nursing women -Allergy to plants -Inability to breathe through nose -Sensitivity to odors -History of asthma, epilepsy, or seizure -Personal history of breast cancer</td>
<td>2</td>
<td>Aromatherapy tabs with combination of lavender sandalwood essential oils or orange and peppermint essential oils were placed on the front a patient’s gown through the entire image-guided biopsy procedure.</td>
</tr>
</tbody>
</table>
Outcomes Measured

The outcomes measured in this selective evidence based medicine review were based on patient questionnaires that were completed throughout aromatherapy treatment while undergoing surgical breast procedures and were patient-oriented outcomes. These outcomes were then analyzed appropriately to determine results.

Franco et al. utilized the Speilberger State Anxiety Inventory for Adults (STAI) to measure outcomes. Patients completed this 20-statement questionnaire to analyze their anxiety and answered each statement on a scale from 1 to 4, or “not at all” to “very much so”, respectively. These statements were further separated into positive and negative categories for analysis. According to the study, positive feelings included “calm, secure, at ease, satisfied, comfortable, self-confident, relaxed, content, steady and pleasant” while negative feelings included, “tense, jittery, strained, upset, frightened, nervous, indecisive, worried, confused, and presently worrying over possible misfortunes.” Questionnaires were completed in the preoperative holding area prior to aromatherapy administration as well as immediately following the aromatherapy treatment. Lower scores reflected less negative attitudes.

Tamaki et al. assessed outcomes using the EORTC QLQ-C30 questionnaire, Version 3.0 of the European Organization for Research and Treatment of Cancer Study Group on quality of life. According to the study, the questionnaire includes five functional scales to assess quality of life including “physical functioning, role functioning, emotional functioning, cognitive functioning, and social functioning.” Higher scores on functioning scales were indicative of better functioning and quality of life. Patients subjectively completed these questionnaires three times, once at the moment of hospitalization as a baseline assessment, once on the day of surgery, and once on the first post-operative day.
Trambert et al. evaluated anxiety using the STAI for Adults Self-Evaluation Questionnaire with STAI Form Y-1 (state anxiety) and Form Y-2 (trait anxiety). Patients completed the appropriate questionnaire forms prior to and immediately following their image-guided biopsy; however, the STAI Form Y-2 (trait anxiety) was not completed following the biopsy due to its irrelevance to “situational changes.” According to the study, scores ranging from 21 to 39 reflected mild anxiety, scores ranging from 40 to 59 reflected moderate anxiety, and scores greater than 59 with a cut off of 80 reflected severe anxiety; therefore, a decrease in trait scores meant improvement in anxiety.

**Results**

In the Franco et al. study, 93 female patients that were undergoing breast surgery were randomized to either lavender fleur oil (LFO) or unscented oil (UO) aromatherapy groups. Female patients were randomized into groups to receive either lavender fleur oil (n=45) or unscented oil (n=45). Therefore, the unscented oil remained the control group. In this study, patients remained blinded to their group selection. Two drops of the respective oils were placed in each patient’s plastic oxygen mask for 10 minutes preoperatively. Prior to beginning the study, female patients were given a patch to adhere to their skin to determine whether or not they would have an allergic reaction to the oils. None of the women had an allergic reaction; therefore, the study proceeded as planned. However, after the study began, two women did not tolerate the oxygen mask and one woman was arranged to have surgery earlier than expected; therefore, 90 patients officially completed the study and appropriate allocation took place after the three women withdrew. Similarly, two women were double assigned to groups; therefore, only 43 patients were analyzed in the LFO group upon completion of the study. Aside from tolerability, there were no safety concerns or adverse events noted in this study.
Franco et al.\textsuperscript{4} compared the STAI answers for LFO and UO groups using the paired $t$ test. The STAI questionnaire was separated into 10 positive questions and 10 negative questions for individual analysis. Although the data were analyzed using the paired $t$ test, Franco et al.\textsuperscript{4} presented the results via the $p$-value. $P$-values were considered statistically significant if the values were less than 0.05/8 or equal to or less than 0.006 due to the number of comparisons made.\textsuperscript{4} See Table 2 for $p$-value comparisons between positive and negative question analysis. Mean change from baseline was also used to calculate the change based on negative question analysis prior to and after aromatherapy. This was done based on the fact that a decrease in negative feelings reflected feeling less frightened, or worried. See Table 2 for mean change from baseline values. Although small treatment effects were observed, a change was noted in both aromatherapy scents.

Table 2: Calculations for Mean Change from Baseline and Efficacy of Aromatherapy to Improve Preoperative Anxiety as Measured by Franco et al.\textsuperscript{4} 2016

<table>
<thead>
<tr>
<th></th>
<th>Positive Questions p-value</th>
<th>Negative Questions p-value</th>
<th>Mean change from Baseline for Negative Questions Pre and Post Aromatherapy (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lavender Fleur Oil</td>
<td>$p = 0.001$</td>
<td>$p = 0.0007$</td>
<td>0.5 [2.0 to 1.5]</td>
</tr>
<tr>
<td>Unscented Oil</td>
<td>$p = 0.003$</td>
<td>$p &lt; 0.0001$</td>
<td>0.3 [1.8 to 1.5]</td>
</tr>
</tbody>
</table>

*Statistically significant $p \leq 0.006$

Tamaki et al.\textsuperscript{7} studied 162 women undergoing breast cancer surgery. Female patients were randomly assigned to experimental or control groups. The experimental group received either a ylang-ylang, orange, or lavender aroma while the control group received conventional perioperative care as per protocol. Nine women withdrew from the study after not completing the appropriate EORTC QLQ-C30 questionnaire. Women were not blinded in the aromatherapy experimental group and chose their aromas resulting as ylang-ylang (n=9), orange (n=42), and lavender (n=41). Aroma oils were placed at the patient’s bedside from 9:00 in the evening before surgery until 6:00 in the morning on the day of surgery.\textsuperscript{7} The EORTC QLQ-C30 was completed
when arriving to the hospital, at 7:00 in the morning on surgery day, and on the morning of the first postoperative day. No adverse events were reported during this study from either group.

Tamaki et al. analyzed the EORTC QLQ-C30 data using ANOVA to calculate mean scores between the experimental and control groups. After the surgery on the first postoperative day, 81.4% of the experimental group (83 patients) reported good emotional functioning as opposed to average or poor. Similarly, 76.5% of the control group (39 patients) reported good emotional functioning. Together these compared groups produced a p-value of p=0.68, which is not statistically significant. RBI was calculated at 0.064, ABI was calculated at 0.049, and NNT was calculated to be 21. Detailed calculations can be seen in Table 3. This is not significant due to the fact that 21 individuals would have needed to be treated in order for one more patient to see a benefit with aromatherapy as compared to the control group not receiving treatment.

**Table 3: Calculations for Treatment Success and Efficacy of Aromatherapy to Improve Emotional Functioning as Measured by Tamaki et al.**

<table>
<thead>
<tr>
<th>CER</th>
<th>EER</th>
<th>Relative benefit increase (RBI)</th>
<th>Absolute benefit increase (ABI)</th>
<th>Number needed to treat (NNT)</th>
<th>P-Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>76.5% = 0.765</td>
<td>81.4% = 0.814</td>
<td>(0.814-0.765)/0.765 = 0.064</td>
<td>0.049</td>
<td>1/0.049 = 20.41 = 21 patients</td>
<td>p = 0.68</td>
</tr>
</tbody>
</table>

*Statistically significant p=0.05

Trambert et al. performed a study on 87 female patients undergoing image-guided breast biopsies including stereotactic, ultrasound, and MRI-guided biopsies. Female subjects in the study were randomly assigned to one of three groups, two of which were experimental groups and one of which was the control group. The experimental group received either a lavender/sandalwood (n=30) or orange/peppermint (n=30) aromatherapy tab to adhere to their hospital gown during their breast biopsy. The control group received a placebo tab without an aroma (n=27), which appeared similar in size and shape. Women were not strictly blinded during
this study; however, they were not told their assigned group. Eighty-nine women were originally consented to the study; however, two women did not complete the required paperwork and the study was reallocated appropriately. The aromatherapy tabs remained on patient gowns for the duration of the procedure. Each woman received a “medical-grade, hypoallergenic adhesive” which was placed on the front of her gown and the study was performed in a well-ventilated area. There were no adverse events noted during this study. All 87 women allocated at the beginning of the study were compliant and followed the study to completion.

Trambert et al. compared the STAI state anxiety pre- and post-biopsy results using the Kruskal-Wallis analysis. The Kruskal-Wallis test results demonstrated reduced anxiety among all three aromatherapy groups as proven by calculated p values. All three aromatherapy groups averaged with a p= 0.050 value, which remains statistically significant. Similarly, comparisons between groups were then analyzed using the Mann Whitney U Test and presented as p-values. See Table 4 for the listed p-value for one comparison group. P-values less than 0.05 indicate that the improvement in anxiety symptoms due to aromatherapy was statistically significant. The data in this study were continuous; therefore, the mean change from baseline test statistic was utilized when analyzing the data based on the change in state anxiety. Lavender-sandalwood had a median change value of (-11) while the placebo had a median value of (-4). The mean change from baseline equals 7 for the lavender aroma. A change of 7 is a large value given that this type of study is based on an 80-point anxiety scale as mentioned above in the methods section.

Table 4: Efficacy of Aromatherapy to Reduce Anxiety Associated with Image-Guided Breast Biopsies as Measured by Trambert et al. 2017

<table>
<thead>
<tr>
<th>Comparison Groups</th>
<th>Mean Change From Baseline</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lavender vs. Placebo</td>
<td>7</td>
<td>p= 0.032*</td>
</tr>
</tbody>
</table>

*Statistically significant (p<0.05)
Discussion

As seen in the results, two out of the three studies concluded that aromatherapy is efficacious in treating emotional instability. Franco et al.\textsuperscript{4} and Trambert et al.\textsuperscript{8} both showed statistically significant data as explained by p-values. The Franco et al.\textsuperscript{4} study showed statistically significant data for positive and negative questions in LFO and UO. The Trambert et al.\textsuperscript{8} study showed that patients had reduction in anxiety from the lavender aroma as compared to the placebo. In contrast, Tamaki et al.\textsuperscript{7} concluded that aromatherapy, given the NNT in conjunction with the p-value, would not adequately treat emotional instability better than the comparison during surgical breast procedures.

As the number of breast cancer statistics and elective breast reconstruction surgeries rise today,\textsuperscript{1,2,9} it is beneficial to study ways to treat emotional instability, which is a normal reaction to unknown factors in surgery.\textsuperscript{4,5} Although there are useful medications available, such as benzodiazepines, they are potentially addictive medications with long-term use and have side effects such as sedation or respiratory depression.\textsuperscript{6} Despite the short-term use, individuals may not feel comfortable taking such medications in an acute setting. Along with other safer options, aromatherapy is a nature-based alternative medicine therapy that is relatively inexpensive, easy to obtain, simple to use, and results in few adverse reactions.\textsuperscript{4,7,8} Mild reactions include headache, nausea, or some allergic reactions.\textsuperscript{10}

Although these studies provide a positive advancement in research, it is important to acknowledge limitations to these studies. Specifically, the Tamaki et al.\textsuperscript{7} study was multifactorial addressing multiple functional scales for quality of life, and it remains unclear how much emphasis was placed on emotional functioning in the EORTC QLQ-C30 questionnaire as well as their exact definition of emotional functioning.\textsuperscript{7} Patients were also able to select their aroma in
this study, which incorporates patient bias into the study. Furthermore, only two out of three studies kept their patients blinded to group selection; therefore, it remains unclear how this influenced study outcomes. Lastly, aromatherapy was performed at all different intervals during the perioperative time period as opposed to strictly preoperative, intraoperative, or postoperative.

Conclusions

The results from this systematic review suggest that aromatherapy may be effective in treating emotional instability in women undergoing breast procedures. However, due to the conflicting outcomes of the studies, the objective question remains inconclusive. Although two out of the three studies affirmed that aromatherapy does indeed treat emotional instability, the finite differences among each study, such as the use of various patient questionnaires, the lack of blinding participants in one study, and the use of aromatherapy at different intervals during the perioperative time period, remain too dissimilar in nature to address the objective with a precise conclusion. Due to the inconclusive data, further research is warranted to continue to evaluate the objective of this systematic review. Emotional instability, regardless of the setting, is a subjective feeling that patients interpret differently. Therefore, future studies should measure emotional instability using a matching questionnaire to confirm that each woman is evaluating her emotional instability with similar parameters. In contrast, it may be beneficial to continue studying women undergoing a variety of breast procedures to determine the extent of effectiveness using aromatherapy. Finally, further research could be greatly improved by studying aromatherapy of matching scents to determine the true effect of a particular aroma.
References


