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A PILOT RANDOMIZED CONTROL TRIAL TO ASSESS THE IMPACT OF LAVENDER ON ANXIETY AND COMFORT AFTER CESAREAN BIRTH AND THE BARRIERS ENCOUNTERED

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Abstract

Objective: This study aimed to assess the effect of lavender aromatherapy on anxiety and comfort after cesarean birth.

Study Design: Randomized control trial.

Methods: Forty-eight patients who had a cesarean birth were asked to complete the six-item State and Trait Anxiety (STAI-6) score to assess their level of anxiety pre- and postapplication of either lavender aromatherapy or placebo during their inpatient postpartum stay. Their comfort and pain levels pre- and postadministration were assessed, and differences between groups were analyzed. Results: There was no difference in STAI-6 scores between the aromatherapy and placebo

groups ($p = .56$). Women who received the lavender aromatab[®] had significantly ($p = .037$) higher self-reported levels of comfort ($M 2.6 SD .82$) when compared with those who received placebo ($M 2.0 SD 1.0$).

Clinical Implications: Many women use aromatherapy at home to promote comfort and relaxation. Women feel lavender aromatherapy improves their comfort in the hospital setting after cesarean birth. Clinicians should consider ways to safely use aromatherapy as one option to promote postoperative cesarean birth care.

Key words: Anxiety; Aromatherapy; Cesarean section; Lavandula; Pain.

The National Association for Holistic Aromatherapy (2021) defines aromatherapy as a practice that uses “natural plant extracts, such as essential oils, hydrosols, and carrier oils, in a variety of ways to heal the body, mind and spirit” (para 1). Lavender (*Lavandula angustifolia*) has a floral herbal scent and has been used medicinally for centuries for aromatherapy (Conrad, 2019). Medicinal lavender has been used in many clinical scenarios and has been suggested for use as an antidepressive, anxiolytic, sedative, and for its calming and pain-reducing properties (Conrad). Lavender is a popular aroma, and its use is safe, however, other essential oils may be preferable in patients experiencing seasonal allergies or with asthma (Conrad).

The ability of lavender to decrease pain and anxiety could be especially useful in maternity care. Perioperative opioid prescribing is associated with persistent opioid use after surgery; thus, it is important for nurses and other health care providers to consider nonpharmacologic strategies that could improve pain relief and comfort and decrease anxiety, which in turn could result in a decrease in postoperative opioids requirements (Centers for Disease Control and Prevention, 2020).

Use of lavender aromatherapy to decrease pain and anxiety has been explored in many settings. In maternity care, recent studies have shown that lavender aromatherapy may be effective in pain management and in relieving maternal anxiety in women in labor (Abbasjahromi et al., 2020; Tabatabaeichehr & Mortazavi, 2020). Kianpour et al. (2016) found that among women who inhaled three drops of lavender essential oil every 8 hours for 4 weeks postpartum, mean stress, anxiety, and depression scores at 2 weeks ($P = .012$, $P < .0001$, and $P = .003$), 1 month ($P < .0001$), and 3 months after birth ($P < .0001$) were significantly lower than those who received placebo. Hadi and Hanid (2011) analyzed the impact of lavender aromatherapy on pain scores after cesarean birth at 3, 8, and 16 hours postoperatively. They reported women who used lavender aromatherapy had a more significant reduction ($p < .001$) in postoperative pain than controls at each time. Although there are data to support the impact of lavender on pain and anxiety, further study is needed, as methods and types of lavender use as an intervention vary significantly between studies (Kang et al., 2019). Thus, the primary aim of this study was to assess the effectiveness of a hospital-grade lavender oil (*Lavandula angustifolia*) aromatherapy tab (Elequil aromatab®s) in reducing pain and anxiety and to assess its impact on maternal comfort after cesarean birth.

Methods

This was a pilot randomized control trial conducted with women who gave birth via cesarean at a large tertiary referral center in south central Pennsylvania where approximately 3,000 births occur annually. The study was reviewed and approved by the Institutional Review Board (IRB) at the study site. To be enrolled in the study, participants had to have given birth via cesarean to a live newborn within the past 6 hours and be transferred

for postpartum care to the hospital's maternity unit. Women were excluded if they had an allergy or sensitivity to lavender or any other plant oils or did not speak English.

Sample Size. G power® was used to determine sample size. A sample size of 200 (100 placebo; 100 lavender) was needed to achieve an $\alpha = 0.05$ and power of 80%. Eligible participants were randomly assigned to either aromatherapy or control. Envelopes were numbered with randomly generated numbers, and the numbers were then associated with either a placebo or lavender tab (Figure 1). Each tab included the same labeling for both the intervention and placebo, the difference in the product was that the placebo had a white pad and no aromatherapy and the lavender aromatab® was purple. The randomly numbered envelopes held the associated study forms and either a placebo or lavender aromatab® as appropriate.

Aromatherapy Intervention. Essential oils vary in quality and thus may not all be suitable for use in clinical settings. When using aromatherapy clinically, it is necessary to use high-quality 100% pure essential oils from a reputable supplier (Buckle, 2015). Beekley Elequil aromatab®s are designed for use in the clinical setting. The tabs are created from 100% pure essential *Lavandula angustifolia* oil with a consistent amount of essential oil on each tab. The self-adhesive tab is placed on the participant's gown at chest level and the plastic that encloses the tab is torn to allow for maximum release of the aromatherapy.

FIGURE 1. ELEQUIL® LAVENDER AROMATAB®



TABLE 1. PARTICIPANT CHARACTERISTICS

	All	A	P	
	N = 48	N = 24	N = 24	p
Age	M 29.6 (SD 4.9)	M 29.7 (SD 5.8)	29.5 (SD 3.8)	.98
	N(%)	N(%)	N(%)	
Married	27(56.3)	11(45.8)	16(66.7)	.24
Insurance type				.5
Medicaid	13(27.1)	7(29.2)	7(29.2)	
Multiparous	42(87.5)	22(52.4)	20(47.6)	.66
Scheduled cesarean	30(62.5)	15(62.5)	15(62.5)	1
Repeat cesarean	28(58.3)	16(66.6)	12(50)	.38
Infant in NICU at time of transfer to maternity	3(6.3)	2(8.7)	1(4.1)	.97
History of anxiety or depression	20(41.7)	13(54.2)	7(29.2)	.14
Patient use of aromatherapy prior	24(51.1)	12(50)	12(50)	1.00

Note. NICU = neonatal intensive care unit.

Population and Study Procedures. Women were identified for potential participation in the study by the postpartum nurse caring for the patient following cesarean birth on the unit charge nurse on transfer from labor and delivery. They notified a nurse on the study team who met the identified patient to ensure they met inclusion criteria, provided education about the study, and obtained informed consent. Then a numbered envelope was retrieved from the study office. The consenting nurse asked the woman to self-assess their comfort using a Likert scale of 1–4, their anxiety, using the State and Trait Anxiety scale (STAI-6), and their pain using the numeric scale (1–10) prior to the intervention. Participants received either a self-adhesive Elequil® lavender scented or a placebo tab to wear at chest level on their hospital gown. The study team member placed a sign that stated *aromatherapy in use* on the door when leaving the room to ensure other staff and visitors were aware aromatherapy was being used. After 1 to 2 hours had passed, the nurse caring for the participant had the participant rescure their pain, comfort level, and complete the postintervention STAI-6 form.

Participants were told they may choose to remove their tab at any time. If the participant chose to remove the aromatherapy tab prior to the nurse returning at 1 to 2 hours to, no follow-up assessments were planned. If participants removed their tab, the protocol was to ask about their reason for removing the tab. Participants in both groups (intervention and placebo) received all other treatments and procedures that were considered standard of care for patients after cesarean birth.

State-Trait Anxiety Inventory. STAI-6 is a commonly used self-reported measure of trait and state anxiety. We used the shortened STAI-6 that includes six Likert scale (1–4) questions: I feel calm, I am tense, I feel upset, I am relaxed, I feel content, and I am worried. Participants were asked to read each statement then circle the most appropriate number (1 [not at all]–4 [very much]) to

indicate how they were feeling right at this moment. The shortened version of the STAI was developed for use in circumstances where the full form is inappropriate and to allow for quicker completion (Spielberger et al., 1983). We felt the short form was most appropriate due to the postoperative administration of the survey. When testing the overall reliability and validity of the short form, Marteau and Bekker (1992) reported correlation coefficients greater than .90 when using the four- or six-item version of the STAI. Subsequently, use of the six-item short form produces scores similar to those obtained when using the full form (Marteau & Bekker, 1992).

Descriptive statistics were analyzed; mean and frequency data are reported. As data did not meet the assumptions of normal distribution required for parametric testing, the Mann Whitney U test was used to assess differences in continuous variables in the aromatab® and placebo groups. Chi square (χ^2) was used to assess differences in categorical variables and the continuity correction was reported when appropriate. Statistical significance was set to $p < .05$.

Results

We enrolled 24 in our aromatherapy group and 24 in our placebo group. All participants wore their tab for the entirety of the study.

Participant Characteristics

Participant characteristics are reported in Table 1. There were no significant differences between groups. Most participants were White (89.6%, $n = 43$), non-Hispanic (85.4%, $n = 41$), and married (56.3%, $n = 27$). Participants were more often multiparous (87.5%, $n = 42$) and had scheduled cesareans (62.5%, $n = 30$; Table 1). It is important to note that more participants in the aromatherapy group (54.2%; $n = 13$) than placebo (29.2%; $n = 7$) had a documented history of anxiety or depression.



The ability of lavender to improve comfort and decrease pain and anxiety could be especially useful in maternity care.

Pain

Participants in the aromatherapy group had significantly higher (M 3.3 SD 2.1) pain scores than the placebo group (M 2.06 SD 2) at baseline ($p = .046$). Pain scores stayed relatively stable postintervention. The aromatherapy group mean pain score postintervention was 3.4 (SD 1.7) and the placebo group mean pain score was 2.11 (SD 1.93; $p = .051$). Although the mean pain score of those in the aromatherapy group was significantly higher than controls before the intervention, there was no significant difference after the aromatherapy intervention (Table 2).

STAI-6

Among those who received the lavender aromatab®, the mean preintervention STAI-6 score was 13.1 (SD 2.1) and 13.6 postintervention (SD 1.5). There was no significant difference in postintervention STAI-6 scores between aromatherapy and placebo groups ($p = .56$). (Table 2).

Comfort

We asked participants who received the lavender aromatab® to rate their comfort after aromatherapy on

a scale from 1 to 4. Individuals who received the lavender aromatab® reported significantly ($p = .037$) higher levels of comfort (M 2.6 SD .82) when compared with those who received placebo (M 2.0 SD 1.0). In the aromatherapy group, 66.6% ($n = 16$) participants stated that the tab either moderately or very much improved their comfort. Only 23% ($n = 6$) in the control group reported that the placebo tab either moderately or very much improved their comfort (Table 2).

Patient Use

Of those who received the aromatherapy tab, 91.7% ($n = 22$) reported they enjoyed using the aromatherapy. Fifty percent ($n = 24$) of all participants reported using aromatherapy at home or work. Of those, 12 participants specifically listed lavender as a scent used and two others said any or all scents.

Impact on Nurses

We asked nurses who collected postintervention data to rate the amount of lavender aroma noted in the room on a scale from 1 (no smell) to 5 (a strong smell). Nurses caring for those participants wearing the lavender aromatab® reported almost no smell in the room (M 1.25 SD 1.15).

Clinical Implications

All participants continued wearing the aroma tabs at the time of postintervention follow-up, indicating the intervention was well received. One-half of women in our study reported using aromatherapy at home or work and of those, lavender was reported as a commonly used essential oil. This suggests the popularity of aromatherapy and essential oils outside of the clinical setting.

In our study, although use of lavender did not result in a reduction in STAI-6 scores, it is possible that if participants wore the aromatab® for longer we may have noted that lavender had a more significant impact on patient anxiety. Participants who received the lavender aromatab® reported significantly higher levels of self-reported comfort after the intervention than those who received the placebo, and participants more often reported that the lavender aromatab® moderately or very much improved their comfort. After cesarean birth, women should

TABLE 2. PAIN, STAI, AND COMFORT SCORES BY AROMATHERAPY AND PLACEBO GROUPS

	Total	Aromatherapy	Placebo	
	$N = 48$	$N = 24$	$N = 23$	
	M (SD)	M (SD)	M (SD)	p
Prepain score	2.7 (SD 2.1)	3.33 (SD 2.1)	2.15 (SD 1.95)	.046
Postpain score	2.7 (SD 1.9)	3.4 (SD 1.7)	2.11 (SD 1.93)	.051
Pre-STAI score	13.1 (SD 2.1)	13.1 (2.0)	13 (2.2)	.814
Post-STAI score	13.8 (SD 2.2)	13.6 (1.5)	14 (2.8)	.56
Postcomfort score	2.3 (SD .96)	2.6 (SD .824)	2.0 (SD 1.0)	.037

Note. STAI = State and Trait Anxiety Scores.

TABLE 3. ADDRESSING BARRIERS TO CLINICAL RESEARCH FOR NURSE SCIENTISTS

Barrier	Advice to Address Some of the Barriers to Research
Lack of dedicated personnel to provide research support and coordination	Seek funding prior to beginning your study: Funding could allow you to hire research team members or cover a portion of your salary so you could dedicate time to the study outside of other work duties. Funding sources could include the Association of Women's Health, Obstetric, and Neonatal Nurses, Sigma Theta Tau nurse research grants, or local hospital auxiliary grants.
Unique clinical setting characteristics	Consider ways to streamline data collection protocols: In labor and delivery and postpartum settings, there are variety of competing responsibilities for new mothers (breastfeeding, visitation with family, caring for the newborn); when designing your study make sure data collection is as streamlined as possible to encourage participation.
Limited research training of nursing staff	Create a core team of research engaged nurses: Many nurses do not have research ethics training that could limit their participation as study team members. Proactively, have interested nurses completed the ethics training. Provide this group with additional training on research protocols as well as nuances of the consent process.
Limited time to dedicate to your study	Collaborate: As a nurse scientist in the hospital setting, research collaborations with local universities may yield relationship with academic nurse scientists who can help support your study.
Lack of understanding of research regulations	Reach out: Contact your hospital Institutional Review Board Chair or Director of Human Research Protections prior to starting a research project to learn more about the steps needed to protect human subjects and to ensure you understand research regulations appropriate to your study design.

have the opportunity to access a variety of nonpharmacologic strategies that promote comfort and reduce anxiety. Lavender aromatherapy may be a useful addition to a comprehensive comfort bundle offered to mothers postcesarean (Burgess et al., 2019).

Employee Health and Safety

The study site currently has a fragrance-free policy. That means patients, visitors, and workers are asked to refrain from wearing perfumes, colognes, aftershave lotions, or other similar products as they believe these can aggravate some health problems including asthma, allergies, and other respiratory conditions of those exposed. To obtain approval from the IRB for this study, additional approvals were required from employee health. Employee health was supportive of our study but had concerns related to the risk to employees, visitors, or other patients who may have respiratory or allergic reactions to the lavender aroma. Essential oils are very safe; however, the concerns outlined by employee health were the primary reasons why we choose to explore the use of Elequil® lavender aromatabs® for this study, rather than essential oil drops or diffusers which disperse essential oils more widely and which require additional training by nurses in their administration. In our study, nurses caring for participants who received the Elequil® lavender aromatab® reported very little aroma in the patient's room. To further address the concern around staff safety, we placed a sign on the door that said "Aromatherapy in Use" to warn anyone who entered the room of a study participant that they may notice an aroma. Use of the Elequil® lavender aromatabs® may be a method to use aromatherapy in the clinical setting while still protecting nurses, employees, and visitors who dislike aromas, or suffer from allergies or other respiratory ailments which could be exacerbated

by smells. Conducting a pilot study, targeting one clinical department to assess for the impact of aromatherapy on a measurable outcome such as anxiety or pain, is foundational to achieving administrative and provider support for the clinical use of aromatherapy with patients and to developing hospital policies that support its use (Buckle, 2015).

Depending on the marketing claims made about its intended use, aromatherapy may be considered a drug and thus regulated by The Food and Drug Administration (FDA) (FDA, 2020). Subsequently, before advancing too far with your study plans discuss your protocol with your IRB and FDA to ensure you have met all regulatory requirements. If aromatherapy is classified as a drug, there are more stringent regulatory requirements which must be met.

Barriers to Enrolling our Desired Sample

We encountered a number of barriers when conducting our randomized control trial on our maternity unit that affected our ability to reach our desired sample size. Unlike our cardiology, oncology, and emergency departments, our department does not have a designated research nurse to direct study procedures. Our study team consisted of six research and ethics trained nurses who were able to enroll patients, however, they were not on the unit 24/7, which dramatically affected our ability to achieve our sample size. When on the unit, our study team members had patient care duties, which was a barrier to their ability to enroll patients in accordance with the timing outlined in our protocol. As our protocol required patients be enrolled within 6 hours after birth, our study team needed to be both made aware of patients who met study criteria (postoperative) by either the charge nurse or other nurses and have a gap in their own duties so that they could consent patients to par-

CLINICAL IMPLICATIONS

- Many women use aromatherapy at home; therefore, nurses should work to decrease barriers to its implementation in health care settings.
- The ability of lavender to improve comfort and decrease pain and anxiety could be especially useful in maternity care.
- Use of lavender aromatherapy improved comfort, and thus may be a simple, low-risk, and cost-effective addition to nonpharmacologic bundles used on postpartum units to improve comfort among women who recently gave birth via cesarean.
- Prior to implementing a randomized control trial, it is important for nurse researchers to consider how they will address barriers to enrollment that may affect the success of their study.
- Nurse scientists must find ways to build research infrastructure in a variety of birth settings to support research on issues around pregnancy and birth.

ticipate. Thus, capturing patients soon enough after arrival to the postpartum unit became another barrier to enrollment.

Beyond barriers associated with our study team's ability to enroll participants 24/7, most of our study team who were working to actively enroll subjects were new to clinical research, so as primary investigators we had to ensure our study team was trained on how to properly consent subjects and the importance of strict adherence to research protocols, particularly related to timing of enrollment and completion of follow-up surveys.

Although our study was a small single-center trial, barriers we encountered were like those reported by other researchers. Duley et al. (2008) and Djuriscic et al. (2017) outlined barriers to the conduct of randomized clinical trials that included: inadequate funding, overly complex regulatory requirements; excessive monitoring; overly restrictive interpretation of privacy laws and lack of transparency; inadequate infrastructures to support research development and management; and inadequate understanding of clinical research methodology. As our research was not conducted in a large academic medical center, these barriers were further amplified. Most births nationwide occur outside of academic medical centers. If nurse scientists are to develop clinical trials to answer research questions critical to driving improvement in the specialty of maternal child health, we must find ways to obtain funding and promote collaboration to build research infrastructure within a variety of birth settings to support research on issues around pregnancy and birth (Table 3).

Limitations

Our results must be interpreted with caution as we did not meet our enrollment goals. Results of studies on the

impact of aromatherapy on anxiety and pain vary (Karr et al., 2019), most likely due to variation in the intervention in each study including length of aromatherapy use, timing of reassessment of anxiety or pain scores, and the method and amount of essential oil administered. We encountered challenges in the timing of administration of aromatherapy. We choose to administer aromatherapy soon after transfer to the maternity unit as at that time most patients' pain most often continued to be well controlled from the Duramorph (Morphine Sulfate) administered and participants are less likely to be influenced by other factors that could affect anxiety and comfort such as visitation, feeding challenges, need to ambulate. We acknowledge that participants who like aromatherapy may have been more likely to enroll in this study, which could have biased our results. The small sample may have minimized our ability to observe a positive influence on pain scores, as the p value was .051. Nearly twice as many participants in the aromatherapy group ($n = 13$) when compared with the control group ($n = 7$) had a documented history of anxiety or depression that could have further confounded our results.

Conclusion

Use of aromatherapy is only expected to grow (Grand View Research, 2020), thus clinicians in health care settings should consider how they can embed holistic interventions such as aromatherapy into care to improve comfort and possibly reduce anxiety and pain. Maternity nurses can take the lead in suggesting and evaluating innovative options for nonpharmacologic pain relief and comfort measures for women after cesarean birth. ♦

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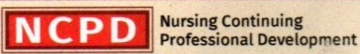
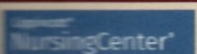
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INSTRUCTIONS

A Pilot Randomized Control Trial to Assess the Impact of Lavender on Anxiety and Comfort After Cesarean Birth and the Barriers Encountered

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