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Aromatherapy for Procedural Anxiety in Pain Management and Interventional Spine Procedures: A Randomized Trial

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ABSTRACT

Objective:

The aim of this study was to evaluate a non-sedating agent, lavender aromatherapy, to reduce anxiety prior to interventional spinal procedures.

Design:

In this prospective, single-blind study performed at a tertiary care center for an academic institution, 144 patients undergoing spinal procedures (epidural steroid injection, medial branch block, or radiofrequency ablation) were randomized into two groups of 72 patients. The experimental group was exposed to a tablet formulation of lavender aromatherapy while the control group was exposed to tablets devoid of any scent. The exposure duration for each group was 5 minutes. The primary outcome measurement was patients' anxiety state prior to the spinal procedure using the six-item State Trait Anxiety Inventory (STAI-6). Secondary outcomes quantified the rate of vasovagal events and aborted procedures due to patient intolerance.

Results*:*

Compared with the control group, the post-treatment anxiety score of those exposed to lavender aromatherapy revealed a statistically significant difference as measured by the six-item State Trait Anxiety Inventory (STAI-6) 12.15 ± 2.67 and 10.67 ± 2.81 ($p<0.05$). Within group, the experimental group's anxiety level decreased from 12.26 ± 2.75 to 10.67 ± 2.81 ($p<0.05$). There were two vasovagal episodes and one aborted procedure in the control group, while there was

one vasovagal episode and no aborted procedures in the aromatherapy group.

Conclusions:

Lavender-based aromatherapy is effective in reducing pre-procedural anxiety prior to interventional spine procedures for pain management.

Key Words: aromatherapy; anxiety; pain management; spine

What is Known: Aromatherapy has been shown to be effective in reducing peri-procedural anxiety in gastrointestinal, cardiac, and orthopedic surgeries, to name a few.

What is New: To the best of our knowledge, there are no studies in the literature to date describing the effects of aromatherapy in reducing pre-procedural anxiety prior to interventional spinal procedures for pain management. Lavender aromatherapy is a non-sedating alternative effective in reducing pre-procedural anxiety in interventional pain management.

INTRODUCTION

During invasive diagnostic and therapeutic procedures, patient anxiety may present as a major barrier for a provider to effectively perform or complete the intervention. Patient anxiety can be particularly challenging in pain management and interventional spine procedures as patient movement can compromise physician performance and result in increased rates of muscle tension, procedure time, vasovagal syncope, and, ultimately, aborted procedures.[1-3] Emotions such as anxiety, fright and panic - which can be experienced prior to any interventional procedure – are all possible psychiatric causes of syncope.[4]

While many providers rely on sedation to reduce anxiety during therapeutic spinal injections, severe complications may be missed if the patient is overly sedated.[5] It is critically important for a patient to be able to communicate changes in pain or altered neurological sensations, and for the physician to be able to test neurologic function. Guidelines from national organizations recommend avoiding deep sedation given the increased risk of complications.[6] The American Society of Regional Anesthesia and Pain Medicine (ASRA) advises that general anesthesia or use of heavy sedation should not be used, as it eliminates the ability of the patient and/or physician to be aware of adverse neurologic sensations that may occur as a result of the interventional neuraxial procedures.[7] Furthermore, there are undesirable side effects of these medications including drowsiness, confusion, dizziness and weakness.[8] With significant risks associated with sedation, the use of non-sedating alternatives to mitigate periprocedural anxiety is appealing. One such option is lavender aromatherapy.

Lavandula angustifolia (lavender) is an essential oil widely used in aromatherapy and has been studied as an anxiolytic with a minimal adverse effect profile.[9] Multiple studies have demonstrated a positive effect for the use of aromatherapy with lavender in the preoperative period.[9-12] Kritsidima et al. utilized lavender aromatherapy for dental anxiety and found it to be effective for reducing current state anxiety, but ineffective for future anxiety-provoking thoughts.[10] Furthermore, Hosseini et al. found significant reduction in anxiety and blood cortisol levels in candidates for open heart surgery when comparing lavender aromatherapy to a control.[12] Given the positive results of the previous studies in other fields, using lavender aromatherapy appears to be safe and has not been studied for use in fluoroscopically-guided neuraxial procedures. The purpose of this study is to evaluate one non-sedating alternative, lavender aromatherapy, to reduce pre-procedural anxiety in individuals undergoing interventional spinal procedures.

METHODS

This prospective, randomized, single-blind, placebo-controlled study was designed to test the hypothesis that lavender scented aromatherapy administered prior to fluoroscopically-guided spine interventions would reduce pre-procedural anxiety more than placebo. Participants were recruited from an academic tertiary care center between January 29, 2020 to March 10, 2020. The types of interventional spinal procedures were compared between groups. In addition, data was collected to assess whether using aromatherapy led to a reduction in vasovagal episodes and aborted procedures. After obtaining written informed patient consent, patients between the ages of 18 and 85, who were scheduled for either an epidural steroid injection (ESI), medial branch block (MBB) or radiofrequency ablation (RFA), were asked if they would participate in this

study. As part of the consent process, the patients were informed of the possibilities of either being exposed to aromatherapy or no scent at all. This aspect of the study made it impossible to adequately blind patients and resulted in the single-blind design. Patients with a history of anxiety disorders, currently on anxiolytic therapy, a poor sense of smell or allergy/aversion to aromatherapy were excluded from the study.

The study was conducted in accordance with the Institutional Review Board (IRB) committee under protocol #1610017667 and is registered on clinictrials.gov under identifier NCT04156009. This study conforms to all CONSORT guidelines and reports the required information accordingly (see Supplemental Checklist, Supplemental Digital Content 1, http://links.lww.com/PHM/B201). The study was funded by the Department of Rehabilitation Medicine at Weill Cornell Medical Center.

Randomization

Once the patients met inclusion/exclusion criteria, and agreed to participate in the study, they were randomized into two groups, a lavender group and a control group, on a 1:1 ratio using a computer-generated random table. All patients completed the baseline questionnaire on check-in to the clinic which was approximately 20 minutes prior to the injection. The allocation information was concealed in a sealed opaque envelope and opened once they arrived in the preoperative area. The patient and the procedure nurse were unaware of the group allocation. The only participant of the study aware of the identity of the scents was the one who was assigned to placing the scent allocation information inside each sealed envelope.

Aromatherapy

For the treatment group (aromatherapy), patients were exposed to a formulation of lavender aromatherapy using Elequil Aromatabs® (#372) from Beekley Medical® (Bristol, CT) for five minutes. This tab was covered using masking tape in order to ensure blinding from the patient and physician. The control group was also given a tab, covered in masking tape that did not contain any aroma or scent. Following exposure for 5 minutes, the tabs were removed, and the patients again completed the same outcome measure questionnaire in the pre-procedure holding area while waiting for treatment. Answering the questions was entirely self-paced. After completion of the questionnaire, each patient was escorted from the pre-procedure waiting area to the procedure suite. The treating physician (JRS) then consented the patient for the injection and proceeded with the planned intervention.

Outcomes and assessment

The primary outcome of this study was to determine the patients' anxiety state prior to a fluoroscopically-guided spine intervention. Participants were asked to complete a brief questionnaire and a demographic information sheet. The demographic information sheet gathered information regarding participants' age, gender, and planned procedure. State anxiety was measured by the six-item State Trait Anxiety Inventory (STAI-6) on a four-point Likert scale.[13,14] In addition, the patient's current pain score on a numeric rating scale from 0-10 was assessed with 0 describing no pain and 10 meaning the most severe pain.

Score Interpretation

Range of scores for the STAI-6 is (4-24), the higher score indicating greater anxiety.] Category

values and normative data are as follows: 4-7, low stress level; 8-10, moderately low stress level; 11-14, average stress level; 15-19, moderately high stress level; 20-24, high stress level.[15]

Secondary outcomes quantified the rate of vasovagal events and aborted procedures due to patient intolerance.

Sample size

Previous research has found the effect size (ES) of lavender aromatherapy on anxiety to be around 0.5.[9,16,17] A power analysis determined that 64 subjects were needed per group to determine treatment differences (power = .80, alpha = .05, ES = .5). The investigators planned to enroll 150 subjects over a course of 3 months, with anticipation that around 20 subjects may not be eligible for the study based on their responses to the screening, the medical history questionnaire, or their inability to complete the second STAI-6 due to personal preference or time constraints.

Statistical analysis

All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) software version 20.0 (SPSS Inc., Chicago, IL, USA).

Primary Outcome: STAI-6

The unpaired *t*-test was used to compare the baseline mean STAI-6 value between patients in the control group versus those in the lavender group. A paired t-test was used to compare the mean STAI-6 value within group before and after exposure to either lavender aromatherapy or control.

All *P* values are 2-sided with statistical significance evaluated at the .05 α level. *P* values were not corrected for multiple comparisons because of the exploratory (ie, hypothesis-generating) nature of the study and the small sample size available in each of the cohorts. Ninety-five percent confidence intervals were calculated to assess the precision of the obtained estimates.

The types of interventional spine procedures planned were compared between groups using a chi-square test.

RESULTS

There was a total of 72 patients in the control group and 72 patients in the aromatherapy group. The mean age in the control group was statistically similar to the aromatherapy group (59.7 ± 16.4 years and 56.0 ± 17.9 years, p=.19). In addition, there was no statistical difference among pain scores between the control and aromatherapy groups (5.8 ± 2.3 and 5.3 ± 2.3, p=.19). Baseline anxiety scores as measured by STAI-6 revealed that both groups displayed an average level of anxiety (11-14) prior to the procedure and that there were no statistically significant differences between the control and aromatherapy groups (11.48 ± 2.97 and 12.26 ± 2.75, p=.10). The demographic characteristics of the sample are shown in Table 1.

The interventional spine procedure planned was not different between groups. The majority of the procedures were lumbar epidural steroid injections, followed by lumbar medial branch blocks and radiofrequency ablation (Table 1). There was no statistically significant difference between the control and aromatherapy groups (p=.69).

Comparison of post-treatment anxiety score between the control group and those exposed to lavender aromatherapy revealed a statistically significant difference between groups (12.15 ± 2.67 and 10.67 ± 2.81, $p < .05$) (Table 2).

In terms of within group, the control group's anxiety level went from 11.48 ± 2.97 to 12.15 ± 2.67, while the group that was exposed to lavender aromatherapy went from 12.26 ± 2.75 to 10.67 ± 2.81. This difference was not statistically significant in the control group but was statistically significant within the lavender group, $p<.05$ (Table 2).

There were two vasovagal events and one aborted procedure in the control group, while those exposed to lavender aromatherapy had one vasovagal event and zero aborted procedures during this study trial (Table 3).

DISCUSSION

This study investigated the role of aromatherapy, composed of 100% pure lavandula angustifolia (lavender) essential oil, on pre-procedural anxiety in the setting of pain management and interventional spine procedures. The findings demonstrated a significant difference in pre-procedural anxiety levels between treatment and control groups using a validated and reliable anxiety scale (STAI-6).[11] The formulation of lavender aromatherapy using Elequil Aromatabs® from Beekley Medical® (Bristol, CT) was chosen in order to provide a consistent treatment and to restrict diffusion of the scent through the pre-procedure suite. This limited exposure to the

desired patient. Five minutes of aromatherapy exposure was selected in order to simulate a practical period of exposure in a real-world clinic setting.

To the author's knowledge, this is the first study investigating the role of aromatherapy for anxiety in the setting of pain management and interventional spine procedures. The results of this study confirm the findings in other fields such as dentistry, abdominal and cardiac surgery, among other fields.[9-12,18] However, there is heterogeneity amongst these studies in the variety of formulations of lavender aromatherapy, types of applications, anxiety outcome measures, dilution, and duration of exposure that makes direct comparison difficult. Of note, one study in the setting of endoscopic gastrointestinal procedures did not demonstrate a significant difference between groups.[19] These findings may be the result of a shorter duration of aromatherapy treatment or the use of a more dilute 10% solution of lavender oil aromatherapy.

Kritsidima et al.[10] studied the use of lavender as aromatherapy to reduce pre-procedure anxiety in 340 dental patients. The study indicates a decrease in perceived anxiety with the use of lavender oil based upon the STAI-6 scale. In a separate study that examined the effects of lavender aromatherapy on 72 patients who were in a pre-operative area for cardiac or abdominal surgery, there was a statistically significant reduction in pre-procedural anxiety with use of lavender aromatherapy.[11] In the study by Braden et al.[9], 150 patients were randomized to 1 of 3 possible groups: control, lavender, or jojoba- the latter was considered a sham group. The patients were mainly pre-operational for gastrointestinal, genitourinary, or orthopedic procedures, and both topical and inhalation of either lavandin or jojoba were implemented. The study found that the level of anxiety at the time of transfer to the operating room was significantly decreased as

compared to the control and sham jojoba arms of the study.

In a study by Hosseini et al.[12], 90 patients in the pre-operative period for open heart surgery were either exposed to lavender essence or to the control, distilled water. Levels of anxiety reduction were significantly decreased in the intervention group. Additionally, cortisol level measurements taken before and after inhalation of both lavender and distilled water were decreased to a statistically significant level. However, the mean difference was higher in the lavender group. Finally, the study by Lehrner et al.[18] further supports the findings of previous studies, demonstrating that patients awaiting dental treatment upon inhaling either lavender or orange scents had a significant reduction in anxiety levels. These prior studies serve to increase the reliability of our findings, as repeated measurements of anxiety levels have consistently been decreased by use of lavender scent.

The precise mechanism of how lavender aromatherapy may decrease anxiety is not fully understood. There are several rationales described in prior publications.[10] Olfactory stimulation may lead to alterations of one's emotional state, which has been demonstrated on neuroimaging.[11] Lavender is thought to have its effect post-synaptically by affecting levels of cAMP, which are linked to sedation and the autonomic nervous system. Another study proposed that components of lavandula may act to enhance the anti-anxiety effects of the GABA neurotransmitter.[20]

Perception of pain and anxiety may be related, and therefore pain levels were also measured in this study. However, no significant differences in pain rating after exposure to lavender were

seen between the aromatherapy and control groups. Perhaps this is due to the formulation and type of aromatherapy, or may be due to a lack of a treatment effect. Studies of aromatherapy in pain management, including a Cochrane Review of aromatherapy in pain management during labor demonstrated consistent findings with our study, where no difference in pain intensity was found between groups.[21] However, only two randomized controlled trials met inclusion criteria for the review and there is overall a paucity of quality research investigating aromatherapy on pain.

According to the mean anxiety scores in our study, both the control and treatment groups demonstrated an average level of stress (11-14) in both the baseline and post-exposure surveys. Important to note, as reflected by the standard deviations, anxiety scores ranged from the low stress level (4-7) to the moderately high stress level (15-19) categories in both groups. While there was no change in the anxiety category according to the mean for pre- and post-exposure groups, the results of our study do show a statistically significant difference in the treatment group in anxiety reduction after exposure to lavender aromatherapy. Interestingly, the control group demonstrated a slight increase in anxiety scores that we hypothesize may be related to the approaching procedure time.

An important distinction deserving of discussion is whether this statistically significant difference found in the treatment group is clinically significant. One method of determining the clinical significance is by using the minimally important difference (MID), described by Jaeschke et al[22] as the smallest difference in score the patient perceives to be beneficial. In a systematic review of over thirty studies aimed at computing an MID for health-related quality of

life instruments, Norman et al[23] concluded the MID to be one half of a standard deviation. Therefore, the minimal level of change consistent with clinical significance, one that a patient perceives as beneficial, is 0.5 standard deviations. In our study the change in anxiety scores for the treatment group is slightly greater than half of the standard deviation, suggesting the reduction in anxiety within the treatment group to be both statistically and clinically significant.

Vasovagal episodes and aborted procedures were also tracked in this study. There were two vasovagal episodes and one aborted procedure in the control group, while there was one vasovagal episode and no aborted procedures in the aromatherapy group. Though there are fewer events in the aromatherapy group, there were not sufficient numbers of episodes in either group to perform relevant statistical analyses.

Limitations

There were multiple limitations to this study of aromatherapy for neuraxial procedures. Whether the interventional procedure performed during this study was an initial or repeat procedure was not assessed or controlled for between groups. Additionally, the uneven distribution of cervical and lumbar procedures did not allow for analysis of anxiety levels between procedures. This study also only investigated one specific formulation of aromatherapy, a pure lavender essential oil. In terms of blinding, although the identification of the scent was visibly masked, complete blinding of the patient would not be possible as the consent process explained the possibility of individuals being exposed either to aromatherapy or no scent; thereby introducing a possible recall bias when patients answered the STAI-6 questionnaire.

Future Research

The goal of this preliminary study was to evaluate the effect of lavender aromatherapy on pre-procedural anxiety in pain management and interventional spine procedures. Considering the results indicate a significant difference with a short aromatherapy exposure duration of five minutes, continued exposure throughout the procedure or lengthier pre-procedure exposure time may provide additional benefit as seen in the other studies.[9-12,18] Increasing the number of subjects may also assist with investigating whether there is any difference in rates of vasovagal events or aborted procedures, as these events rarely occurred in our sample.

CONCLUSION

Enhancing patients' comfort is often a priority for physicians performing neuraxial procedures in pain management and may help reduce adverse events as well as improve patient compliance and outcomes. The findings of this study indicate that lavender-based aromatherapy is beneficial as a pre-procedure technique to reduce anxiety. Therefore, lavender aromatherapy is a reasonable alternative treatment strategy deserving of additional investigation.

Conflicts of Interest:

All of the authors have no conflicts of interest to report.

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Table 1: Baseline Demographics & Planned Procedure Type (Cervical or Lumbar ESI, MBB, or RFA)

Table 2: State Trait Anxiety Scores

Table 3: Number of Vasovagal and Aborted Procedures by Treatment Group

Table 1: Baseline Demographics & Planned Procedures

	Control	**Aromatherapy**	**P value**	**Confidence Interval**
N	**72**	**72**		
Age (years)	**59.7 ± 16.4**	**56.0 ± 17.9**	**0.19**	**-1.96 to 9.36**
Female Gender	**39**	**29**		
Pain (NRS)	**5.8 ± 2.3**	**5.3 ± 2.3**	**0.19**	**-0.26 to 1.26**
STAI – 6	**11.48 ± 2.97**	**12.26 ± 2.75**	**0.10**	**-1.72 to 0.16**
Planned Procedures			**P= 0.69** χ^2 **= 1.48**	
Lumbar ESI	**52** *50.07* (0.02)	**54** *52.93* (0.02)		
Lumbar MBB/RFA	**10** *9.29* (0.13)	**11** *11.71* (0.14)		
Cervical ESI	**3** *3.19* (0.21)	**2** *2.81* (0.23)		
Cervical MBB/RFA	**7** *7.45* (0.32)	**5** *6.55* (0.37)		

Key:
NRS: numerical rating scale; STAI-6: State-Trait Anxiety Form-6; ESI: epidural steroid injection;
MBB: medial branch block; RFA: radiofrequency ablation;
Expected values are displayed in *italics*
Individual χ^2values are displayed in (parentheses)

Table 2: State Anxiety Scores

	Baseline	After Exposure	P value	Confidence Interval
N	72	72		
Control	11.48 ± 2.97	12.15 ± 2.67	P= 0.16	(-1.6 to 0.26)
Aromatherapy	12.26 ± 2.75	10.67 ± 2.81	< 0.05	(0.67 to 2.50)
P value	P= 0.78	< 0.05		
Confidence Interval	(-0.16 to 1.72)	(0.57 to 2.38)		

Table 3: Vasovagal and Aborted Procedures		
	Control	**Aromatherapy**
N	**72**	**72**
Vasovagal Episodes	**2**	**1**
Aborted Procedures	**1**	**0**