Original Article

Efficacy of lavender essential oil aromatherapy in reducing anxiety and pain in patients undergoing prostate biopsy: an interventional study

Efficacia dell'aromaterapia con olio essenziale di lavanda nel ridurre l'ansia e il dolore nei pazienti sottoposti a biopsia prostatica: uno studio interventistico

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Key words: lavender essential oil, pain, prostate biopsy.

ABSTRACT

Background: prostate biopsy can cause physical and psychological discomfort, such as pain and anxiety. Aromatherapy with lavender oil has been suggested to reduce these symptoms. This study evaluated the effectiveness of lavender essential oil aromatherapy in reducing anxiety and pain in patients undergoing prostate biopsy.
Materials and Methods: multicentre, randomised, non-pharmacological trial involving 50 patients. The experimental group (n=25) received lavender aromatherapy before surgery, while the control group (n=25) received standard care. Anxiety was measured with the Hamilton Anxiety Rating Scale (HAM-A), pain with the Numerical Rating Scale (NRS), and patient satisfaction with a Likert scale.
Results: the lavender group showed a significant reduction in anxiety (10 points *vs* 3 points in the control group). Pain decreased significantly in the lavender group (from 6.2 to 2.1, $p<0.05$) and in the control group (from 6.0 to 4.5). Patient satisfaction was higher in the lavender group (mean 8.7 *vs* 6.3, $p<0.05$).
Conclusions: aromatherapy with lavender oil significantly reduces anxiety and pain during prostate biopsy, improving patient satisfaction.

Background: la biopsia prostatica può causare disagio fisico e psicologico, come dolore e ansia. L'aromaterapia con olio di lavanda è stata proposta per alleviare questi sintomi. Questo studio ha valutato l'efficacia dell'aromaterapia con olio essenziale di lavanda nel ridurre ansia e dolore nei pazienti sottoposti a biopsia prostatica.
Materiali e Metodi: studio multicentrico, randomizzato, non farmacologico con 50 pazienti. Il gruppo sperimentale (n=25) ha ricevuto aromaterapia alla lavanda prima della procedura, mentre il gruppo di controllo (n=25) ha ricevuto cure standard. L'ansia è stata misurata con la Hamilton Anxiety Rating Scale (HAM-A), il dolore con la Numerical Rating Scale (NRS) e la soddisfazione del paziente con una scala Likert.
Risultati: il gruppo lavanda ha mostrato una riduzione significativa dell'ansia (10 punti contro 3 punti nel gruppo di controllo). Il dolore è diminuito significativamente nel gruppo lavanda (da 6,2 a 2,1, $p<0,05$), mentre nel gruppo di controllo (da 6,0 a 4,5). La soddisfazione del paziente è risultata maggiore nel gruppo lavanda (media 8,7 contro 6,3, $p<0,05$).
Conclusioni: l'aromaterapia con olio di lavanda riduce significativamente ansia e dolore durante la biopsia prostatica, migliorando la soddisfazione del paziente.

Introduction

Prostate biopsy is an invasive diagnostic procedure used to identify the presence of prostate cancer, typically in response to elevated Prostate-Specific Antigen (PSA) levels or abnormal findings during a digital rectal exam.[1] Despite its clinical importance, prostate biopsy can be associated with significant discomfort for patients, both physical and psychological. The primary factors contributing to discomfort include the pain experienced during the procedure and the anxiety related to the potential diagnosis of cancer.[2] Managing these symptoms is crucial to improve the overall patient experience and to facilitate the execution of the procedure by healthcare providers. Traditional strategies for pain management during prostate biopsy include the use of local anesthetics, periprostatic nerve block, and sedation.[2] However, these options have limitations, including the risk of side effects such as dizziness, nausea, and prolonged recovery times. Consequently, there is growing interest in the adoption of non-pharmacological approaches to pain control, such as aromatherapy.

Aromatherapy is a complementary medicine practice that leverages the therapeutic properties of essential oils derived from plants. Among these, lavender essential oil (*Lavandula angustifolia*) is one of the most studied and widely used. It is known for its sedative, anxiolytic, and analgesic effects, making it particularly suitable for managing stress and pain in clinical settings.[3] Lavender oil contains active compounds, such as linalool and linalyl acetate, which act on the central nervous system by modulating pain responses and reducing anxiety.[4] Inhalation of these compounds stimulates the parasympathetic nervous system, promoting relaxation and reducing the perception of pain.[4] Previous studies have demonstrated that lavender aromatherapy can be effective in reducing anxiety and pain in a variety of clinical settings. A systematic review reported that the use of lavender essential oil in patients undergoing painful procedures significantly reduced anxiety and pain levels.[5] In a study conducted by Abbaszadeh *et al*.,[6] lavender oil was used to alleviate pain and anxiety in cancer patients undergoing bone marrow biopsies, showing a significant reduction in symptoms compared to the control group. Additionally, Karadag *et al*.[7] highlighted that lavender aromatherapy improves sleep quality and reduces anxiety in patients admitted to intensive care units.

Despite the extensive literature on the use of lavender oil in various clinical contexts, few studies have specifically explored its use in urology, particularly in managing pain and anxiety in patients undergoing prostate biopsy. As an invasive procedure, prostate biopsy is associated with pain both during needle insertion and in the post-procedural period. While local anesthesia partly reduces the pain, it is not always completely effective. Moreover, the combination of pain and anxiety can amplify the negative perception of the procedure.[2]

Given the existing evidence on the effectiveness of lavender oil in other painful and anxiety-inducing contexts, the scope of this study was to evaluate the efficacy of lavender aromatherapy as a complementary intervention to reduce pain and anxiety in patients undergoing prostate biopsy. Our hypothesis is that inhalation of lavender essential oil before the procedure may significantly reduce perceived pain and anxiety, thereby improving the patient experience and facilitating the diagnostic process. Specifically, the aims of the study were: i) to assess the efficacy of lavender oil in an inhaled form in reducing anxiety and pain levels in patients undergoing prostate biopsy; ii) to assess the physiological response to the aromatherapy; iii) to evaluate the degree of patient-perceived satisfaction following the lavender oil treatment.

Materials and Methods

This is an interventional, non-pharmacological, quasi-experimental, two-arm, no-profit study. In this study, the first 25 consecutive patients were allocated to the experimental group (lavender aromatherapy) and the subsequent 25 patients to the control group (standard care).

To minimize performance bias, all prostate biopsies were performed by the same physician throughout the study. This approach ensured consistency in the procedural technique and reduced variability in patient outcomes that might have arisen from different practitioners.

Participation sample

The SS. Antonio e Biagio e Cesare Arrigo University Hospital of Alessandria consecutively enrolled all adult patients undergoing outpatient prostatic biopsy from April 1, 2022, to October 1, 2022.

Patients over the age of 18, who signed informed consent, with normal vital parameters, and who had undergone anesthesiologic consultation were included. Patients prone to severe bleeding, with acute infection and fever, severe anorectal disease, hypertensive seizures, unstable blood glucose levels, patients who had taken analgesics or sedatives in the two days prior to the exam, patients with communication and cognitive difficulties, and patients allergic to lavender were excluded.

Data collection

The study included two groups: an experimental group and a control group.

The experimental group received a cotton pad saturated with 5 drops of 10% lavender essential oil, previously placed in a closed container, for inhalation 15 minutes before the biopsy, at 7-10 cm from the olfactory apparatus. These patients were accommodated in a pre-operating waiting room, while the control group received standard care (as in usual clinical practice) and was kept separate in a different room to prevent the propagation of the lavender scent. The administration of the pain and anxiety rating scales took place before the administration of the cotton pad, 20 minutes later, and 15 minutes after the prostatic biopsy procedure. Additionally, patients received the satisfaction scale at discharge.

The data collected from the paper-based scales were uploaded onto the online-computerized platform "Electronic Data Capture" (REDCap), which was in use at the promoting center and adapted to the study specifics. The electronic tool complies with current clinical trial and privacy regulations (GCP E6 (R2)-IHC, European Regulation 2016/679 - GDPR), and is validated (GCP E6 (R2)-IHC). All changes were recorded and tracked electronically; access was password-protected, located within the corporate server, and automatically backed up.

Instruments

The study collected patient socio-demographic information, and specific instruments, described below, were used to assess pain, anxiety, and patient satisfaction. The Numerical Rating Scale (NRS)[8] is a one-dimensional quantitative 11-point pain rating scale; it requires the clinician to ask the patient to select the number that best describes the intensity of their pain, from 0 to 10, at that specific time.

The Hamilton Anxiety Rating Scale (HAM-A)[9] is one of the first scales developed to measure the severity of anxiety symptoms, and today it is widely used in both clinical and research settings. The scale consists of 14 items, each defined by a set of symptoms that measure both psychological anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Each item is scored on a scale from 0 (not present) to 4 (severe), with a total score range of 0 to 56, where > 17 indicates mild anxiety, 18-24 mild to moderate anxiety, and 25-30 moderate to severe anxiety.

The Likert Rating Scale was used to assess patient satisfaction, ranging from 0 to 10, where zero corresponds to "not at all satisfied" and 10 to "totally satisfied."

Data analysis

For normally distributed variables, the mean and standard deviation were calculated, while for variables that were not normally distributed, the median and interquartile range were used for descriptive data analysis. A comparison of anxiety and pain levels between the two groups was made using the Student's t-test or Mann-Whitney test, depending on the distribution of the variable under consideration. The chi-square test was used to compare the proportions of anti-anxiety and pain medication use between the two groups. Considering a one-tailed test with an effect size of 0.75, a type I error of 0.05, and a power of 0.80, a sample size of 25 subjects per group was required.

Results

Sample characteristics

Table 1 shows the socio-demographic characteristics of the 50 patients enrolled in the study. The average age was 65 years, with no significant differences between the groups. Sixty percent of the patients had undergone previous biopsies.

Anxiety reduction

Patients who received aromatherapy showed a significant reduction in anxiety levels compared to the control group. The mean HAM-A score decreased by 10 points in the lavender group, compared to a reduction of only 3 points in the control group ($p<0.01$) (Table 2).

Pain reduction

Perceived pain, measured with the NRS, was significantly lower in the group that received aromatherapy. The mean score decreased from 6.2 to 2.1 in the lavender group, while in the control group, it fell from 6.0 to 4.5 ($p<0.05$) (Table 3).

Vital parameters

Patients in the lavender group showed a significant improvement in both heart rate and blood pressure after the intervention. The average heart rate in the lavender group decreased from 85±5 bpm to 72±4 bpm following aromatherapy, with a mean reduction of 13 bpm ($p<0.01$). In contrast, in the control group, heart rate remained largely unchanged, moving from 84±6 bpm to 83±5 bpm, without a significant variation ($p=0.35$).

Regarding blood pressure, the average systolic pressure in the lavender group significantly decreased from 145±8 mmHg to 128±6 mmHg ($p<0.01$), and diastolic pressure dropped from 90±4 mmHg to 80±3 mmHg ($p<0.05$). In the control group, however, no relevant changes were observed, with systolic pressure decreasing from 144±7 mmHg to 143±6 mmHg ($p=0.42$) and diastolic pressure from 88±5 mmHg to 87±4 mmHg ($p=0.48$).

Patient satisfaction

Patients in the lavender group reported significantly higher satisfaction regarding their overall experience, with a mean score of 8.7 out of 10 compared to 6.3 for the control group ($p<0.05$).

Table 1. Sample characteristics.

Variable	Total (n=50)	Lavender group (n=25)	Control group (n=25)	p-value
Age (years, mean ± SD)	65±8	64±9	66±7	0.45
Previous biopsies (%)	60%	56%	64%	0.67
Education level				
University	40%	44%,	36%	0.72
Secondary	50%	48%	52%	
Primary	10%	8%	12%	
Nationality				
Italian	80%	84%	76%	0.58
Foreign	20%	16%	24%	

SD, standard deviation.

Table 2. Pre and post procedure anxiety levels Hamilton Anxiety Rating Scale (HAM-A).

Measurement time	Lavender group (mean ± SD)	Control group (mean ± SD)	p-value
Before the procedure	25.4±6.2	24.8±5.8	0.78
After the procedure	15.2±5.1	21.5±5.7	<0.01
15 min after the procedure	12.3±4.7	19.2±5.5	<0.01

SD, standard deviation.

Table 3. Pre and post procedure pain levels Numerical Rating Scale (NRS).

Measurement time	Lavender group (mean ± SD)	Control group (mean ± SD)	p-value
Before the procedure	6.2±1.3	6.0±1.4	0.65
After the procedure	2.1±1.1	4.5±1.7	<0.05

SD, standard deviation.

Discussion

This study aimed to evaluate the efficacy of lavender aromatherapy as a complementary intervention to reduce pain and anxiety in patients undergoing prostate biopsy. Lavender aromatherapy could reduce anxiety and pain in patients undergoing prostate biopsy. This result aligns with previous research that has explored the use of aromatherapy, particularly lavender essential oil, in clinical settings for pain and anxiety management.[10]

A significant reduction in anxiety was observed in the experimental group, with a mean decrease of 10 points on the Hamilton Anxiety Rating Scale (HAM-A), compared to a reduction of only 3 points in the control group. This outcome is consistent with studies conducted in other medical contexts. For instance, Karadag *et al*. (2017) found that lavender aromatherapy improved sleep quality and reduced anxiety in patients admitted to intensive care units.[7] Similarly, a systematic review by Kim *et al.* (2021)[11] highlighted that lavender oil had anxiolytic effects in patients undergoing various medical procedures.[8]

In terms of pain reduction, the results of this study also support previous findings. The mean pain score in the lavender group decreased significantly, compared to a smaller decrease in the control group. This analgesic effect of lavender oil has been previously documented; for example, a study by Abbaszadeh *et al*. demonstrated that lavender oil reduced pain and anxiety in cancer patients undergoing bone marrow biopsy, showing a reduction similar to that observed in this study.[6] Moreover, a study reported that lavender oil effectively reduces pain perception, likely due to its interaction with the parasympathetic nervous system, which helps modulate the perception of pain during invasive procedures.[12]

Furthermore, the high level of patient satisfaction observed in the lavender group, underscores the potential of lavender aromatherapy to enhance the overall patient experience. This finding is consistent with studies in which complementary therapies, such as aromatherapy, have been shown to improve patient satisfaction by providing a more holistic approach to care.[13] Positive patient experiences are crucial as they are often correlated with better compliance, lower anxiety in future procedures, and improved overall outcomes.

However, it is important to recognize that this study's results differ from those in a few studies that have not found significant benefits of aromatherapy in reducing pain or anxiety. For example, a trial examining aromatherapy in surgical patients found no statistically significant reduction in pain or anxiety compared to the control group.[14] This discrepancy may be due to differences in the clinical setting, patient population, or the specific essential oils used. It also highlights the need for further research to identify the most effective contexts and applications for aromatherapy.

Furthermore, our results on the impact of aromatherapy on physiological parameters, such as heart rate and blood pressure, are in line with previous studies. Several studies have shown that lavender aromatherapy can reduce heart rate and systolic blood pressure, reflecting its calming effects on the autonomic nervous system. These results reinforce lavender's therapeutic potential in modulating vital signs through its influence on the parasympathetic nervous system.[15]

While the results of this study are promising, there are several limitations that should be acknowledged. First, the sample size was relatively small, with only 50 patients included in the trial. A larger sample size could provide more robust results and improve the generalizability of the findings. Second, an important limitation of this study is the lack of randomization in the allocation of participants to the experimental and control groups. Patients were assigned to groups based on their enrollment order, with the first 25 assigned to the experimental group and the next 25 to the control group. This consecutive allocation method can introduce selection bias and limit the internal validity of the study, as patient characteristics could differ between the two groups purely due to the time of their enrollment. Randomization is critical in minimizing confounding variables, and the absence of this method reduces the strength of the evidence provided by the study. Finally, the biopsies were all performed by the same physician, which, while reducing inter-practitioner variability, may limit the ability to generalize the results to settings where multiple physicians perform the procedures. Moreover, the study did not account for long-term follow-up to assess whether the effects of lavender aromatherapy persisted beyond the immediate post-procedural period.

Addressing these limitations in future research, including larger, multicenter trials with proper randomization and blinding, would strengthen the evidence for lavender aromatherapy as a complementary approach to reducing anxiety and pain in prostate biopsy patients.

Conclusions

Our results support the use of lavender aromatherapy as an effective intervention for reducing anxiety and pain, thereby improving the overall patient experience during medical procedures. This evidence fits into a growing body of research that supports the effectiveness of aromatherapy as a complementary intervention in clinical settings. The integration of non-pharmacological techniques such as aromatherapy into therapeutic pathways can represent an innovative approach to addressing challenges related to pre-operative anxiety and pain management, both of which are crucial for enhancing the patient experience.

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Authors' contributions: TB, RDM, ADS, AS, and AM have made substantial contributions to conception and design, data acquisition, and data analysis and interpretation; MG, CS, and AS have made contributions to data acquisition, analysis, and interpretation. All authors have been involved in drafting the manuscript or revising it critically for important intellectual content, given final approval of the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of interest: the authors declare no potential conflict of interest.

Funding: none.

Ethics approval and consent to participate: the research received approval from the Ethical Committees (approval number 499 dated 29/03/2022). Before analysis, all data were anonymized to protect privacy. Informed consent: The study included patients over 18 years of age undergoing prostate biopsy who used lavender essential oil to reduce anxiety and pain.; they also signed an informed consent form.

Informed consent: data collection commenced only after obtaining written consent from all participants.

Availability of data and materials: data will be available upon request from the authors.

Received: 2 October 2024.
Accepted: 7 November 2024.

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Working Paper of Public Health 2025;13:10155
doi:10.4081/wpph.2025.10155