



Research Article

A multicenter interventional study aimed to assess the effectiveness of Lavanda aroma in reducing anxiety and pain in patients undergoing PROstatic BIOPsy (LA-BIOPRO): Study protocol

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Abstract

Background: A prostatic biopsy is a diagnostic test used in cases of suspected prostate cancer. The patient expresses significant levels of anxiety from the very first outpatient visits; anxiety and pain management is essential for a successful outcome of the procedure. Lavender oil is one of the essential oils that is commonly used in aromatherapy to reduce anxiety and pain, its low toxicity and side effects have made it the preferred treatment in complementary medicine.

Aim: To assess the effectiveness of lavender scent in decreasing the levels of anxiety and pain in patients undergoing a prostatic biopsy.

Methods: An interventional non-pharmacological, randomized, two-arm, multi-center, nonprofit study. The SS Antonio e Biagio e Cesare Arrigo Hospital and the City of Alessandria Clinic, Monza Polyclinic of Alessandria, will enroll consecutively all adult patients undergoing outpatient prostatic biopsy from April 1, 2022, to October 1, 2022. The Numerical Rating Scale and Hamilton Anxiety Rating Scale will be used for assessments.

Conclusion: Lavender oil aromatherapy could have a clinically significant effect on reducing pain and anxiety during prostatic biopsy procedures; its simple use, safety, and low cost provide a therapeutic option to be considered, complementary to other medical interventions in certain clinical settings.



Background

A prostatic biopsy is a diagnostic test used in cases of suspected prostate cancer. During the ultrasound-guided biopsy, a specific needle guided by an ultrasound probe is used to take the biopsy sample [1].

The patient expresses significant levels of anxiety from the very first outpatient visits; anxiety and pain management is essential for a successful outcome of the procedure. Due to the need for repeated biopsies and the vast number of specimens required, 'effective pain management is essential; to date, it is unclear in this regard which anesthesia approach is best [2].

It is possible to manage anxiety either pharmacologically or non-pharmacologically. Pharmacological therapy is associated with side effects such as dizziness, fatigue, and discomfort; most patients need longer monitoring periods before discharge. Therefore, nowadays non-pharmacological methods of anxiety management such as aromatherapy are preferred [3].

Lavender oil is one of the essential oils that is commonly used in aromatherapy to reduce anxiety and pain, its low toxicity and side effects have made it the preferred treatment in complementary medicine [4]. There are many ways to use the lavender plant, such as orally, topically, or inhaled. Lavender essential oil is 100 times more effective than the plant itself and is used in medicine as a sedative, narcotic, anti-inflammatory, and antidepressant [5]. The active compounds in lavender are Linalool and Linalool Acetate, which act as sedatives and narcotics by stimulating the parasympathetic system [5].

There has been no study of the effects of lavender oil in urology: This study aims to assess whether lavender scent can reduce anxiety and pain levels in prostate biopsy patients.

The study

Aim: The aims of the study are: I) To assess the efficacy of lavender oil in an inhaled form in reducing anxiety and pain levels in patients undergoing prostatic biopsy; II) To assess the physiological response to the aromatherapy; III) To evaluate the degree of patient-perceived satisfaction following the lavender oil treatment.

Design: An interventional non-pharmacological, randomized, two-arm, multi-center, no-profit study.

Participation sample: The SS Antonio e Biagio e Cesare Arrigo Hospital and the City of Alessandria Clinic, Monza Polyclinic of Alessandria will enroll consecutively all adult patients undergoing outpatient prostatic biopsy from April 1, 2022, to October 1, 2022.

Patients who are aged >18, who sign informed consent, with normal vital parameters, and who have undergone anesthesiologic consultation will be included. Patients prone to severe bleeding, with acute infection and fever, severe anorectal disease, hypertensive seizures, unstable blood glucose status, patients who have taken analgesics or sedatives in the two days prior to the exam, patients with communication and cognitive

difficulties, and patients who are allergic to lavender will be excluded.

Data collection: The study consists of two arms: an experimental and a control arm.

The experimental arm group will receive a cotton wad saturated with 5 drops of 10% lavender essential oil, previously placed in a closed container, for inhalation, 15 minutes before the biopsy, at a distance of 7/10 cm from the 'olfactory apparatus. The accommodation of these patients will be in a pre-operating waiting room, whilst the control group will receive 'standard care (as is the usual clinical assistance procedure) and will remain separated in a different room to prevent the 'propagation of the lavender scent in the control arm. The administration of the Pain and anxiety rating scales will take place before the wad administration, after 20 minutes and after 15 minutes from the prostatic biopsy procedure; whereas patients will receive the patient satisfaction scale at discharge.

Patients undergoing prostate biopsy do not receive any anesthesia or sedation: however, they may require analgesics both during the procedure and at the end. Should any kind of analgesic or sedative medication be given to the patient, the patient would drop out of the study to isolate the effect of Lavender Oil from the pharmacological effect.

The data collected from the paper-based scales will be uploaded onto the online-computerized platform "Electronic Data Capture" (REDCap), which is currently 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 are recorded and tracked electronically, access is password-protected, located within the corporate server, and backed up automatically.

Instruments: The study will collect patient socio-demographic information and specific instruments, described hereunder, which will assess patient pain, anxiety, and satisfaction. The Numerical Rating Scale (NRS) [6] is a one-dimensional quantitative 11-point pain rating scale; the scale 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) is one of the first rating scales developed to measure the severity of anxiety symptoms, and today it is even more widely used in both clinical and research settings. The scale consists of 14 items, each defined by a set of symptoms, which are both measures of psychological anxiety (mental agitation and psychological distress) as well as somatic anxiety (anxiety-related physical complaints). Each item is scored on a scale from 0 (not present) to 4 (severe), with a total score range of 0 - 56, where > 17 indicates mild, 18 - 24 mild to moderate, and 25 - 30 moderate to severe.



The Likert Rating Scale with a rating from 0 to 10 for satisfaction rating where zero corresponds to "not at all satisfied" and 10 to "totally satisfied".

Data analysis

For variables that are normally distributed we will calculate the mean and standard deviation, whilst for variables that are not normally distributed we will calculate the median and interquartile range as a descriptive data analysis. We will make a comparison of anxiety and pain levels between the two groups by using the Student's t - test or Mann-Whitney test according to the variable distribution under consideration. We will use the chi-square test in order to compare the proportions of anti-anxiety and pain medication use, in the two groups. Considering a one-tailed test with an effect size of 0.75, a first-type error of 0.05 and a power of 0.80 requires 25 subjects per group.

Ethical considerations

The Institutional Board of the Intercompany Ethics Committee of the Public Hospital SS Antonio e Biagio e C. Arrigo, Alessandria, has granted ethical approval (Resolution n.499).

Discussion

This study aims to assess the efficacy of lavender oil in an inhaled form, reducing anxiety and pain levels in patients undergoing prostatic biopsy. Several studies have demonstrated the positive effect of lavender oil on anxiety caused by labor during childbirth (Mirzaei, et al. 2015, Tafazoli, et al. 2011), in surgery (Braden, et al. 2009), dentistry (Lehrner, et al. 2005, Zabirunnisa, et al. 2014), breast surgery (Beyliklioğlu and Arslan 2019) and sternotomy (Khalil, et al. 2019). To our knowledge, the effects of lavender oil in urology have never been studied.

Sometimes pain causes patients to move during the procedure, which can increase complications and occasionally the necessity to discontinue the surgical procedure (Kotamarti, et al. 2022). Due to the need for repeated biopsies and the large number of specimens required, effective pain management is essential; in such regard, it is unclear to date what is the best anesthesia method [2].

The use of aromatherapy could be valuable patient support in addition to the social contribution, considered in a recent study [7] as a dimension that can promote health in patients with prostate cancer.

Conclusion

Lavender oil aromatherapy could have a clinically significant effect on reducing pain and anxiety during prostatic biopsy procedures; its simple use, safety, and low cost provide a therapeutic option to be considered, complementary to other medical interventions in certain clinical settings.

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