

Evaluation of the effectiveness of an aromatherapy treatment with lavender essential oil to reduce post-operative nausea and vomiting: study protocol of a randomised controlled trial

Valutazione dell'efficacia di un trattamento di aromaterapia con olio essenziale di lavanda per ridurre la nausea e il vomito post-operatorio: protocollo di studio di un trial randomizzato controllato

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Key words: post-operative nausea and vomiting; comfort; aromatherapy; lavender; essential oil.

ABSTRACT

Background: The most common post-operative symptoms are nausea and vomiting. Aromatherapy has been shown to reduce post-operative nausea and vomiting and thus could be used as a complementary therapy to antiemetic drugs; however, no studies have considered the exclusive use of Lavender in these patients. The study's aim is to assess aromatherapy in reducing nausea and vomiting in post-operative patients.

Materials and Methods: A 2-arm randomised controlled interventional study was carried out in the Neurosurgery, General Surgery, Vascular Surgery, and Gynaecology facilities of the SS Antonio e Biagio e Cesare Arrigo Hospital of Alessandria. Study inclusion criteria: patients over the age of 18, who sign an informed consent form, have had an anaesthesiologic examination, have had general anaesthesia, and are clinically stable with a nausea score of NRS>0. Multiple instruments will be used, including a numerical rating scale, a Likert rating scale, and a Likert rating scale to assess Vomiting and the degree of satisfaction.

Conclusions: The use of complementary non-pharmacological methods such as aromatherapy may help patients feel more comfortable in the post-operative period.

Background: La nausea e il vomito post-operatorio rappresentano i sintomi più frequenti che si verificano dopo un intervento chirurgico. L'aromaterapia ha un effetto positivo nel ridurre nausea e vomito post-operatorio e quindi potrebbe essere considerata come una terapia complementare ai farmaci antiemetici, tuttavia non esistono studi che abbiano trattato l'impiego esclusivo della lavanda in questi pazienti. Scopo dello studio è quello di valutare l'efficacia dell'aromaterapia nel ridurre la nausea dei pazienti nel periodo post-operatorio.

Materiali e Metodi: Studio interventistico randomizzato e controllato a 2 braccia condotto presso le SC Neurochirurgia, SC Chirurgia Generale, SC Chirurgia Vascolare, SS Ginecologia dell'Azienda Ospedaliera SS Antonio e Biagio e Cesare Arrigo. Saranno inclusi i pazienti con età >18 anni, che sottoscrivono il consenso informato, che abbiano eseguito la visita anestesiológica, sottoposti ad anestesia generale, pazienti clinicamente stabili, con punteggio di nausea rilevato con NRS>0. Verranno utilizzati diversi strumenti: Numerical Rating Scale, scala di valutazione Likert, per la valutazione del vomito e scala di valutazione Likert per il grado di soddisfazione.

Conclusioni: L'utilizzo di metodi complementari non farmacologici come l'aromaterapia può contribuire ad aumentare il comfort dei pazienti nel periodo post-operatorio.

BACKGROUND

Post-operative Nausea and Vomiting (PONV) are the most common symptoms that occur within the first 24 hours of surgery.¹ In relation to surgical, anaesthesiologic, and patient-specific risk factors, the global incidence of PONV ranges from 30% to 80%.^{2,3}

The type and length of surgery, the anaesthetic technique used (regional anaesthesia or general anaesthesia), and the use of volatile anaesthetics (nitrous oxide, N₂O, or opioid analgesics) are all risk factors for surgical and anaesthetic procedures.⁴ Female sex, young age, anxiety, a prior history of PONV, a history of motion sickness, and non-smoker status are all patient-related risk factors.^{2,5}

Several risk stratification tools for PONV have been proposed with the aim of targeting specific preventive strategies; depending on the level of risk detected, prophylaxis is administered, either with a specific drug or a combination therapy of antiemetic drugs with distinct action mechanisms.⁶

Post-operative Nausea (PON) causes anxiety and discomfort in the patient, whereas Post-operative Vomiting (POV) can result in more serious complications such as dehydration, electrolyte imbalances, airway compromise, surgical wound dehiscence, oesophageal lacerations, and hypotension,^{1,7} resulting in more days of hospitalisation and associated healthcare costs.⁸

Treatment for PONV includes anti-emetic drugs other than those used in prophylaxis, which can cause unwanted side effects such as headache, dizziness, drowsiness, or cardiac rhythm disturbances,⁵ as well as increased healthcare costs.¹

Complementary therapies are becoming more popular as a treatment option.⁹

Integrative medicine, also known as Complementary and Alternative Medicine (CAM), refers to a variety of practises and products that are not considered to be part of conventional medicine.¹⁰

Aromatherapy,¹¹ which involves the therapeutic use of the aroma of essential oils of a plant nature, is the most widely used CAM.¹²

Although there are few studies on the use of aromatherapy in reducing PONV, the current evidence suggests that aromatherapy has a positive effect in reducing post-operative nausea and vomiting and could thus be considered as a complementary therapy to antiemetic drugs.¹ One study demonstrated the benefit of aromatherapy using peppermint, ginger, or a combination of lavender, peppermint, ginger, and spearmint oils in reducing post-operative nausea.² Some studies also report high patient satisfaction with aromatherapy treatment, citing an improvement in comfort.^{2,13}

Lavender essential oil is 100 times more effective than the plant itself, and it has been used medicinally as a sedative, narcotic, anti-inflammatory, antidepressant¹⁴ and antiemetic.¹⁵

Although there is evidence that aromatherapy has positive effects, there have been no studies published to date that have used aromatherapy with the sole use of lavender to treat post-operative nausea and vomiting.^{16,17}

The aim of this study is to assess the efficacy of aromatherapy in reducing nausea in post-operative patients.

Objectives

The study's aim is to assess the effectiveness of inhaling *Lavandula Angustifolia* essential oil in reducing nausea after abdominal, vascular, neurosurgical, and gynaecological surgery under general anaesthesia during the 24-hour post-operative period.

Furthermore, it was intended to assess: a) the number of antiemetic administrations in the experimental arm versus the control arm; and b) patient satisfaction in the experimental group related to the Lavender essential oil aromatherapy intervention at hospital discharge.

MATERIALS AND METHODS

This is a two-arm randomised controlled interventional study that will be conducted in the following wards: SC Neurosurgery, SC General Surgery, SC Vascular Surgery, and SS Gynaecology, of the SS Antonio e Biagio e Cesare Arrigo Public Hospital of Alessandria.

Patients aged >18 years, who sign informed consent, have undergone anaesthesiologic examination, have undergone general anaesthesia, are clinically stable, have a nausea score with Numerical Rating Scale (NRS) >0, and have undergone surgery in the complex and/or simple facilities listed below are eligible for the study and respect inclusion criteria.

- SC of Neurosurgery, undergoing spinal surgery
- SC of General Surgery, undergoing surgery on one of the abdominal cavity organs
- SC of Neurosurgery, undergoing spinal surgery sclerotherapy (to treat varicose veins) vein stripping (removal of a vein segment in the treatment of varicose veins) laser therapy
- SS Gynaecological Surgery undergoing operations on female genital apparatus organs.

Patients with current significant cognitive impairment (Six Item Screener score 4), allergies or sensitivity to lavender essential oils, asthma, Chronic Obstructive Pulmonary Disease (COPD), chronic bronchitis, Obstructive Sleep Apnea (OSA), or changes in their sense of smell will be excluded.

Patients in the experimental group who have nausea, intercepted with the NRS scale, regardless of intensity (all values from 1 to 10 on the scale), will be given a 2x2 gauze or gauze pad moistened with 5 drops of 10% lavender essential oil to smell for 5 minutes, at 7/10 cm from the olfactory apparatus. This procedure can be performed autonomously by the patient or by the nurse in the event of incapacity: in the case of autonomous performance by the patient, the nurse should monitor the procedure during the 5 minutes to ensure that it is performed correctly.

The NRS scale will be used to assess nausea 10 minutes after the end of inhalation; if symptoms persist at any intensity, the patient will be treated according to standard care.

Aromatherapy will be stopped if there is emesis during the procedure or within the next 10 minutes, and the referring physician will be called/informed, proceeding with standard care.

Aromatherapy may only be used for the first episode of nausea that occurs within 24 hours of surgery; if nausea occurs again during this time period, it will be treated according to standard care.

Patients in the control group will follow standard procedure, which includes administering antiemetics if indicated in therapy or reporting to the doctor with a subsequent treatment decision.

Tools

The study employed a range of tools. The NRS is a one-dimensional quantitative 11-point pain rating scale that has also been validated to detect nausea, and its score is an adequate measure of nausea intensity.¹⁸ The scale requires the operator to ask the patient to select a number from 0 to 10 that best describes the intensity of their

nausea at that precise moment. The survey will be administered to both groups on an hourly basis for the first 24 hours following surgery, or at the patient's request at any time.

Vomiting is assessed using a Likert Scale of 0 to 4, with 0 representing no vomiting and 4 representing severe vomiting. The number of occurrences indicates the severity (0 = no episode, 1 = 1-2 episodes, 2 = 3-4 episodes, 3 = 5 or more episodes). The nurse will record every vomiting episode in the first 24 hours after surgery, and at the end of the 24 hours, they will fill out a final Likert scale for all enrolled patients.

Statistical analysis

Data from enrolled patients will be aggregated and described in terms of demographic, clinical, therapeutic, satisfaction, and self-perceived efficacy characteristics. For normally distributed variables, mean and standard deviation will be calculated, while median and interquartile range will be calculated for variables that are not normally distributed. The levels of nausea and vomiting in the two groups will be compared using either the student's t-test or the Mann-Whitney test, depending on the distribution of the variable under consideration. The chi-square test will be used to compare the proportions of each group's use of antiemetic drugs and *Lavandula Angustifolia*. With an effect size of 0.5 and a power of 0.80, a total sample size of 128 patients was estimated: 64 in the experimental group and 64 in the control group.

Data collection

The study's data will be collected using rating scales that indicate the demographic, clinical, and therapeutic variables of the participants, as well as the scores taken for nausea and vomiting in the post-operative period and a survey on satisfaction and self-perceived effectiveness of the complementary medicine intervention with lavender essential oil. Following that, the data will be entered into the computerised online platform 'Electronic Data Capture' (REDCap), which is currently in use at the promoting centre and will be tailored to study specifics.

DISCUSSION

The aim of this study is to assess the efficacy of aromatherapy using lavender oil in reducing nausea and vomiting in post-operative patients.

PONV is a common side effect in anaesthesiology practise: this condition has a negative impact on the patient by delaying his recovery and prolonging his hospitalisation, both of which have a significant impact on his daily activities.¹⁹ There are numerous medications available to treat PONV, but they may have undesirable sedative effects or put the patient at risk of cardiac arrhythmias. Aromatherapy is a non-pharmacological alternative, complementary nursing intervention that can be used alone or in conjunction with other forms of therapy to treat PONV.

Lavender oil is a herbal extract that is commonly used in a variety of clinical situations, including anxiety, pain, and inflammation.^{20,21} According to research, it has anticholinergic, antihistamine, and anti-inflammatory properties,²² which are similar to those of commonly used antiemetic drugs. As a result, it is assumed that lavender oil can help alleviate post-operative nausea and vomiting. However, no studies have been conducted to assess the effects of lavender essential oil on nausea. One study on the effects of lavender

oil on dysmenorrhoea symptoms discovered that symptoms, including nausea, were statistically significantly lower in the lavender aromatherapy group than in the placebo group.²³ Furthermore, in the aromatherapy studies, there was an increase in patient satisfaction²⁴ with improved comfort and a decrease in anxiety.

CONCLUSIONS

Patients undergoing surgical procedures are at risk of experiencing nausea and vomiting. Considering the complications of drug therapy, the use of complementary non-pharmacological methods such as aromatherapy can help to increase patients' comfort in the post-operative period.

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