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Evaluating the efficacy of lavender aromatherapy on peripheral venous cannulation pain and anxiety: A prospective, randomized study

Tugba Karaman*, Serkan Karaman, Serkan Dogru, Hakan Tapar, Aynur Sahin, Mustafa Suren, Semih Arici, Ziya Kaya

Department of Anesthesiology and Reanimation, School of Medicine, Gaziosmanpasa University, 60100, Tokat, Turkey

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ABSTRACT

Objective: This study was designed to evaluate the effectiveness of lavender aromatherapy on pain, anxiety, and level of satisfaction associated with the peripheral venous cannulation (PVC) in patients undergoing surgery.
Method: One hundred and six patients undergoing surgery were randomized to receive aromatherapy with lavender essential oil (the lavender group) or a placebo (the control group) during PVC. The patients' pain, anxiety, and satisfaction scores were measured.
Results: There was no statistically significantly difference between the groups in terms of demographic data. After cannulation, the pain and anxiety scores (anxiety 2) of the patients in the lavender group were significantly lower than the control group (for $p = 0.01$ for pain scores; $p < 0.001$ for anxiety 2 scores). In addition, patient satisfaction was significantly higher in the lavender group than in the control group ($p = 0.003$).
Conclusion: Lavender aromatherapy had beneficial effects on PVC pain, anxiety, and satisfaction level of patients undergoing surgery.

1. Introduction

Peripheral intravenous cannulation is a mandatory phase in patients undergoing general or regional anesthesia during surgery. Although it is one of the most common invasive procedures performed by an anesthesiologist, it is often disregarded that it can lead to severe pain, anxiety, and discomfort [1,2]. However, these unfavorable feelings may cause needle phobia, which could result in the avoidance of receiving medical care [3].

Pain is described as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. The nature of pain is not obvious; it is known that pain consists of physical and psychological factors [4]. Moreover, pain and emotion have been shown to have common linguistic and neurologic pathways [5,6]. Thus, not surprisingly, several studies have presented information on the linear relationship between anxiety and acute pain [7–9].

In alternative medicine, aromatherapy is a way to use essential oils, and it is becoming increasingly popular. Research has confirmed the anxiolytic effect of aromatherapy with lavender [10,11]. However, its analgesic effect is unknown. Some studies that have evaluated pain that arises from surgery failed to identify the positive analgesic effects of lavender [12,13]. A literature search revealed that only one study [14] has evaluated the effect of aromatherapy with lavender oil on pain and anxiety during needle insertion in healthy volunteers. Nevertheless, there is no data about the effect of aromatherapy with lavender oil on pain in patients under high stress conditions, such as surgery. Thus, this study was designed to test the hypothesis that aromatherapy with lavender oil can decrease pain and anxiety and increase the satisfaction scores of patients undergoing surgery during the placement of a peripheral venous access catheter.

* Corresponding author. Department of Anesthesiology and Reanimation, School of Medicine, Gaziosmanpasa University, Ali Şevki EREK Campus, School of Medicine, 60100, Tokat, Turkey.
E-mail address: drtugbaguler@hotmail.com (T. Karaman).

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2. Materials and method

2.1. Patients and study design

This prospective, randomized, single-blind, parallel-group, placebo-controlled study was performed during peripheral venous cannulation in patients that underwent surgery from November 2015 to March 2016. Study approval was obtained from the Gaziosmanpasa University Clinical Research Ethics Board (15-KAEK-132, 25/08/2015). After registering at www.clinicaltrials.gov (NCT02592044), and after obtaining written informed patient consent, patients with American Society of Anesthesiologist (ASA) physical status I and II, between the ages of 18 and 65, were scheduled for elective surgery at the Gaziosmanpasa University School of Medicine Hospital. Patients with a history of anxiety disorders, preoperative pain, asthma, chronic obstructive pulmonary disease, a poor sense of smell, and allergies to lavender essential oil and anxiolytic or analgesic drugs, or who were pregnant or breastfeeding, were excluded from the study. A researcher that was not involved in the study evaluated the eligibility criteria and selected the patients that participated in the study. The patients were randomized into two groups: a lavender group and a control group, on a 1:1 ratio using a computer-generated random table. The group allocation information was concealed in a sealed opaque envelope and opened by the preoperative care room (PCR) nurse on the day of the procedure. The patient and the outcome assessor were unaware of the group allocation. However, because of lavender's odor, it was impossible to blind the patients from knowing that they were being treated with the essential oil.

2.2. Procedure

No medication was administered to the patients before the procedure. In the PCR, the patients were monitored using electrocardiography and pulse-oximetry, and their blood pressure was recorded. The PCR nurse placed either two drops of 1% lavender essential oil (Lavandula angustifolia oil, Talya Herbal Products, Antalya, Turkey) or pure water on a 5 × 5 cm impermeable gauze pad and asked the patients to inhale for 5 min, while in a seated position. After 5 min, the patients were asked to turn their head to the left and an 18G venous cannula (Med Devices, London, United Kingdom) was inserted into a peripheral vein on the back of the right hand. The patients also continued to inhale either the lavender essential oil or the pure water during cannulation. If cannulation was not achieved at the first attempt, the patient was excluded from the study.

2.3. Outcomes and assessment

The primary outcome of this study was to determine the patients' pain scores during the peripheral venous cannula insertion process. Pain was evaluated by the researcher, who was blind to the patient allocation group, using the 10 cm visual analog scale (VAS), 2 min after cannulation in the PCR. The secondary outcomes of the study were to determine the patients' anxiety and satisfaction levels. The same researcher measured and recorded each patient's anxiety level (anxiety 2) using the 10 cm VAS, 2 min after cannulation; patient satisfaction was measured using the 5-point Likert scale (0: worst to 4: best) 15 min after cannulation. The demographic data, age, sex, body mass index (BMI), ASA physical status, and anxiety scores (anxiety 1) of the patients at admittance to the PCR were also noted.

2.4. Sample size

In our previous study [15], the mean and standard deviation (SD) pain scores of patients during peripheral venous cannulation were found to be 3.16 ± 2.21. We then hypothesized that aromatherapy with lavender essential oil could reduce the VAS scores by 40%. Assuming a two-sided type 1 error 0.05 ($\alpha = 0.05$) and a power of 0.80 ($\beta = 0.02$), we calculated that a minimum of 48 patients per group would be required. We increased the sample size by 10%—106 patients (53 patients per group) to account for the possibility of study drop outs.

2.5. Statistical analysis

All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) software version 20.0 (SPSS Inc., Chicago, IL, USA). Descriptive data were presented as mean (±SD) for the continuous variables, median (range) for the ordinal variables, or as a number (frequencies) for the categorical variables. The one-sample Kolmogorov-Smirnov test was used to detect the normality of distribution. The normally-distributed continuous variables were evaluated using independent samples t-tests. The continuous variables that were not normally distributed were compared using Mann-Whitney U tests. The categorical variables were analyzed using Pearson's chi-square or Fischer's exact tests. Analysis of the correlation among the variables was conducted using Spearman's correlation coefficients. The Wilcoxon's test was used to evaluate the pretreatment and post-treatment data; p values < 0.05 were considered to be statistically significant.

3. Results

One hundred and fifty patients that were scheduled for elective surgery were assessed for eligibility to participate in the study, and 44 of them were excluded because they did not meet the inclusion criteria, or they declined to participate. A total 106 patients were enrolled in the study; 53 patients were randomized into the lavender group and 53 patients were randomized into the control group. After being enrolled in the study, two patients in the lavender group and three patients in the control group were excluded because of protocol violations. The details for the study are shown in the consort flow diagram (Fig. 1).

The two groups were comparable in terms of the patients' demographic characteristics (age, sex, BMI)(Table 1).

The patients' mean (range) pain score was 1.94 (1–4) in the lavender group and 2.48 (1–5) in the control group. The patients' pain scores in the lavender group were significantly lower during the venipuncture process in comparison to the control group ($p = 0.01$; Fig. 2).

The anxiety scores of the patients were similar in both groups at admittance to the PCR ($p = 0.80$, Table 2). However, after aromatherapy with lavender essential oil, the anxiety scores in the lavender group were significantly lower than the control group (pure water placebo; $p < 0.001$, Table 2, Fig. 3). The pain scores showed a moderate correlation with the anxiety 2 scores when all patients evaluated (Spearman's rho, $r = 0.258$, $p = 0.009$). However, no correlation was found between the pain scores and the change (Δ anxiety) in the anxiety scores (anxiety 1 − anxiety 2) ($p = 0.233$).

The mean (range) satisfaction level of the patients was 2.29 (1–4) in the lavender group and 1.82 (0–3) in the control group, and a significant difference was observed between the groups ($p = 0.003$, Table 2). The best degree of satisfaction (VAS: 4) was found in only one patient in the lavender group, and only one patient in the control group was found to have the worst degree of satisfaction (VAS: 0). A moderate negative correlation was found