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Pain relief effects of aromatherapy with rose oil (Rosa damascena Mill.) inhalation in patients with primary dysmenorrhea: A randomized controlled clinical trial

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ABSTRACT

Introduction: Pharmacological agents, such as non-steroidal anti-inflammatory drugs (NSAIDs), and non-pharmacological techniques, including acupuncture and aromatherapy, are commonly used for the management of abdominal pain in patients with primary dysmenorrhea. Essential rose oil obtained from Rosa Mill (RDM) is often used in aromatherapy for the treatment of many diseases. This study was aimed at using visual analog scale (VAS) pain scores and total analgesic consumption to evaluate the effects of adding RDM essential oil inhalation to the standard treatment (NSAID) of primary dysmenorrhea.

Methods: In this prospective randomized controlled clinical trial, 86 patients were randomized into groups R and C. The patients in group C only used standard analgesics (50 mg diclofenac sodium enteric film tablets). In group R, patients used both standard analgesics and RDM inhalation aromatherapy. A 10-point VAS was used to determine the pain values of the patients and was recorded as pre-treatment (VAS-0) and post-treatment (VAS-60). The analgesic consumption by the patients was recorded for 24 h.

Results: In both groups, there was a significant decrease in VAS scores after treatment. The VAS-60 scores in group R were significantly lower than those in group C (2 [1–4] vs. 5 [2–5], respectively; $P = 0.013$). Analgesic consumption in group R was significantly lower than in group C (50 [50–100] mg vs. 100 [50–100] mg, respectively; $p = 0.003$).

Conclusion: Inhalational rose oil aromatherapy is a good self-treatment option for primary dysmenorrhea.

1. Introduction

Dysmenorrhea is one of the most common health disorders in women of reproductive age. Abdominal pain and additional symptoms, such as fatigue, anxiety, and nausea occur frequently during menstrual periods in women who have no anatomic pathology in their pelvic structures; hence, these women are diagnosed with primary dysmenorrhea. Pharmacological treatments, including non-steroidal anti-inflammatory drugs (NSAIDs), and non-pharmacologic methods, such as acupuncture and aromatherapy, are commonly used for the management of abdominal pain in women with primary dysmenorrhea (Dawood, 2006; Song et al., 2018; Sut and Kahyaoglu-Sut, 2017).

Medicinal plants have been used worldwide, to treat various diseases for millennia. Currently, the effectiveness of aromatic plants for the management of different diseases is the subject of intense research activities (Afrasiabian et al., 2019; Rashrash et al., 2017; Shavakhi et al., 2022).

Aromatherapy involves the use of essential oils obtained from plants for the treatment of diseases through massage or inhalation (Ali et al., 2015). Essential rose oil obtained from Rosa damascena Mill (RDM) is commonly used for aromatherapy (Bani et al., 2014). RDM is a well-known plant that is often grown in wide geographic areas in countries, such as Iran, Turkey, and Bulgaria. RDM has been used for the treatment of many diseases in complementary and alternative medicine (CAM), and in the perfume industry (Agaoglu, 2014; Baydar et al., 2016).

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The efficacy of RDM in terms of its antimicrobial, anti-inflammatory, antioxidant, anticancer, protective neuronal, cardiac, gastrointestinal, and hepatic effects has been evaluated in both human and animal studies (Nayebi et al., 2017).

Several studies have been publised on the use or aromatherapy for the treatment of dysmenorrhea (Lee et al., 2016a, 2016b; Sut and Kahyaoglu-Sut, 2017). However, only a small number of these studies was based on randomized controlled trials (RCT) (Pirotta, 2008; Zhu et al., 2007). Currently, the analgesic efficacy of essential rose oil remains an interesting research topic. However, available reports in the literature need to be supported by high quality evidence-based RCTs. This study was therefore aimed at evaluating the analgesic efficacy of rose oil in patients with primary dysmenorrhea.

The study's hypothesis was that in terms of the analgesic efficacy in patients with primary dysmenorrhea, there would be no differences between rose oil aromatherapy added to standard treatment (NSAID) compared with standard treatment (NSAID) alone.

2. Materials and methods

2.1. Trial design

This prospective RCT was planned in accordance with the current guidelines of the Declaration of Helsinki. RDM has a distinct and easily recognizable odor; therefore, blinding was not achieved for patients in this study.

2.2. Participants, inclusion and exclusion criteria

Women who presented with symptoms of dysmenorrhea to the Obstetrics and Gynecology Polyclinic of Kirsehir Education and Research Hospital, and were diagnosed with primary dysmenorrhea between October 1, 2018 and October 1, 2019, were examined in this study.

Patients diagnosed with primary dysmenorrhea, who had no pathology in their pelvic anatomy, with symptoms of painful menstrual periods, and aged 18–24 years were included in the investigation. Patients with abnormal menstrual bleeding, allergies to rose oil and analgesic drugs, or asthma-like respiratory diseases were excluded.

Patients who constantly used analgesics for other reasons, those treated for any upper respiratory tract disease that might cause edema in the nasal mucosa and interfere with the sense of smell, and those who had anosmia as diagnosed by an otorhinolaryngologist were also excluded from the study. In addition, prospective volunteers for the study were given a sample of rose oil in the polyclinic and asked if they could identify the smell. Those who could not answer correctly were excluded from the study.

Volunteers who failed to deliver their data at any time were not included in the final statistical evaluation. Those who used analgesics persistently for any other reason or were treated for upper respiratory tract infections during their menstrual period within the study period were excluded.

2.3. Sample size and randomization

Based on the study by Uysal et al. (2016) the sample size was determined using the G*Power 3.1.9.7 statistical program (Universitat Kiel, Germany) (Faul et al., 2007), as 43 participants in each group, making a total of 86 participants ($\alpha = 0.05$, power $(1\text{-}\beta) = 0.8$).

The random number generation program of Microsoft® Excel software, ver. Microsoft 365 (Microsoft, USA) was used to determine the groups of patients, and 86 randomization cards were used to randomize the participants into the rose group (group R) and the control group (group C). Randomization was done by an independent statistician. The patients identified their groups using the closed-envelope method.

2.4. The essential oil

The rose oil used in this research was obtained by distillation from fresh petals of RDM grown at the Faculty of Agriculture of, Kırsehir Ahi Evran University Kırsehir, Turkey. The essential rose oils were extracted from rose fresh petals by Clevenger hydrodistillation system. The rose oil was stored at 4 °C until analyzed. Gas chromatography/mass spectrometry (GC/MS) was used to determine the rose oil composition. A chemical analysis of rose oil obtained by the Faculty of Agriculture had been performed previously in a different project—the rose oil that remained after that project was used in this study (Kiymaz et al., 2022). No additional budget was required. A mixture of rose oil was prepared at Kırsehir Ahi Evran University Central Biochemistry Laboratory.

Analysis of the RDM essential oil used in this study showed that citronellol (26.14%), nonadecane (21.32%), heneicosane (10.33%), geraniol (5.08%), methyl eugenol (1.46%), ethanol (0.48%), and linalool (0.12%), were the main constituents of the RDM oil.

2.5. Outcome measures

The age (years), body mass index (BMI), age at menarche (years), duration of menstruation (days) of the patients were recorded.

A 10-point visual analog scale (VAS) (0 = no pain, 10 = severe pain) was used to determine the level of pain perceived by the patients during the study. After the examinations at the Obstetrics and Gynecology Polyclinic, blinded volunteers were trained by the researcher (SSD) on how to evaluate pain scores, how to perform the inhalation and how to collect the analgesic consumption data for 24 h.

2.6. Intervention

Patients were provided with forms to register their pain scores during their menstrual period.

All patients registered VAS-0 values when they first experienced abdominal pain during their next menstrual period.

If not contraindicated, diclofenac sodium 50 mg enteric film tablets were recommended as the primary treatment for all patients in groups C and R, with a VAS score of 4 or above. The patients were instructed to take the medication a maximum of three times daily (maximum dose of 150 mg) with sufficient water.

The patients in group C only used standard analgesics (diclofenac sodium 50 mg enteric film tablets).

In group R, patients used standard analgesics (diclofenac sodium 50 mg enteric film tablets) as the primary treatment. The patients emptied 10 mL of the pre-prepared RDM mixture (100 mL of 2% rose oil mixture in 20 mL of ethyl alcohol, 78 mL of distilled water and 2 mL of rose oil) in the bottle onto a piece of paper handkerchief. Despite the primary treatment, inhalation was applied to patients with VAS scores of 4 and above at the 30th minute, only after their first pain. They covered their faces with the paper and inhaled oil on the paper for 15 min

In both groups, the pain score 60 min after the VAS-0 measurement was recorded as VAS-60.

2.7. Ethical considerations

Ethical approval was obtained from the Krsehir Ahi Evran University Clinical Investigations Ethics Committee (decision number: 22/05/2018 2018–10/95). Permission for the research was obtained from the Complementary Medical Department of the Republic of Turkey Ministry of Health (77979112/502.10). The study was registered with IRCT (IRCT20180324039145N2).

The patients included in the study were informed about the study, and each signed an informed consent form.

2.8. Statistical analysis

The following hypothesis was tested: In terms of analgesic efficacy in primary dysmenorrhea, there are no differences between the rose oil aromatherapy added to the standard treatment (NSAID) compared with standard treatment (NSAID) only.

The primary endpoint was VAS pain scores before and after administration during the menstrual period for each patient. The primary subendpoint was the analgesic consumption of the patients for 24 h. The secondary endpoint was the appearance of an allergic reaction after rose-oil aromatherapy. These patients were included in the study. Adverse effects were recorded in both groups.

Statistical Package for the Social Sciences (SPSS) version 21.0 (IBM SPSS Inc., Chicago, IL, USA) was used for data analysis. Descriptive statistical variables are presented as frequency (n), percentage (%), mean, standard deviation (SD), median (25th - 75th percentile), and [minimum–maximum]. The normality of the data distribution was evaluated using the Kolmogorov-Smirnov and Shapiro-Wilk tests. The Wilcoxon signed-rank test was used to compare pre-and post-treatment measurements because the data were not distributed normally, and the Mann-Whitney U test was used for between-group comparisons. Statistical significance was set at $P < 0.05$.

3. Results

3.1. Patients enrollment

During the study period, 212 patients with primary dysmenorrhea were examined. Each gropu consisted of 43 patients, making a total of 86 patients. During the study, 5 patients in group R and 4 patients in group C did not submit their data. These patients were excluded from follow-up and statistical evaluation. Finally, 77 patients were statistically evaluated. The CONSORT flowchart for this randomized study is shown in Fig. 1.

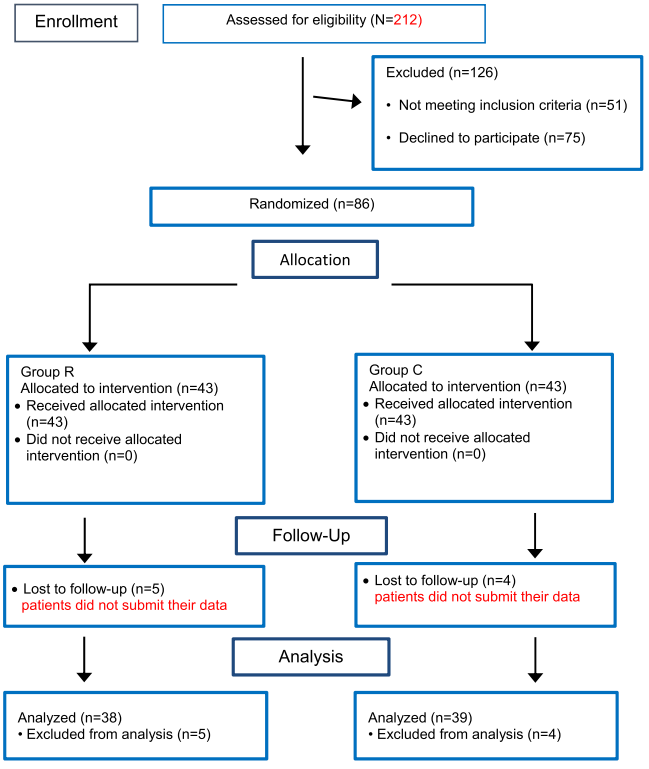

Fig. 1. CONSORT Flow Diagram. Group R: Group Rose, Group C: Group Control.

3.2. Baseline clinical characteristics

The mean of age of patients was 21.51 ± 1.63 years and the mean BMI was 22.37 ± 3.36 kg/m^2.

There were no statistical differences between the groups in terms of age at menarche (years), menstruation period (days), and duration of menstruation (days). Patient characteristics are presented in Table 1.

3.3. Clinical response

In both groups, there was a significant decrease in VAS scores after treatment (Fig. 2). VAS-60 scores were significantly lower in group R than in group C (2 [1–4] vs. 5 [2–5], respectively; P = 0.013). A comparison of the VAS scores between the groups is presented in Table 2.

Analgesic consumption in group R was significantly lower than in group C (50 mg [50–100] vs. 100 mg [50–100], respectively; p = 0.003). A comparison of the consumption of analgesic between the groups is presented in Table 3.

As adverse effects, in the form of symptoms of gastrointestinal irritation, occurred in four patients in each group (a total of 8 patients) after anti-inflammatory drug treatment.

4. Discussion

In this study, RDM was administered by inhalation to reduce the doses of NSAID used for the treatment of primary dysmenorrhea owing to the adverse effects of these drugs. It was found that when the RDM essential oil was inhaled along with standard treatment (NSAID), VAS pain scores and total analgesic consumption were lower than those in the standard treatment group (NSAID only).

The efficacy of RDM as an antimicrobial, anti-inflammatory, antioxidant has been extensively investigated. In particular, studies on the pain relief effects of RDM have shown promising results, although it was highlighted that confirmatory studies were needed with standardized products (Nayebi et al., 2017).

The effectiveness of RDM in treating different types of pain, such as renal colic, labor, and postoperative pain, has also been studied by many researchers (Ayan et al., 2013; Kheirkhah et al., 2014; Suriya and Zuriati, 2019). In obstetric clinical studies, RDM has been shown to be effective in treating pain during labor (Kheirkhah et al., 2014). In another RCT, RDM oil reduced the intensity of pregnancy-related low back pain (Shirazi et al., 2017).

Similar to this study, Bani et al. (2014), and Uysal et al. (2016) investigated the pain relief effect of RDM in patients with primary dysmenorrhea. Bani et al. (2014) also compared RDM extract capsules (200 mg) and mefenamic acid capsules (250 mg) for pain relief in patients with primary dysmenorrhea. In this study, the analgesic effects of RDM and mefenamic acid were similar. Moreover, RDM had no adverse effects (Bani et al., 2014). In contrast to the study by Bani et al., in this study RDM was administered as inhalation aromatherapy, similar to the study by Uysal et al. (2016), who compared diclofenac sodium (75 mg/IM) and diclofenac sodium with inhalation aromatherapy (2% rose essential oil) in 100 patients. According to this study, aromatherapy

Table 1
Participants' Baseline characteristics.

	Group R (n = 38)	Group C (n = 39)	*P*
Age (years)	22 [21–23]	22 [19–22]	0.259[a]
BMI (kg/m^2)	21.1 [19.9–22.6]	22.6 [20.1–26.8]	0.311[a]
Age of first menstruation (years)	13 [11–13]	12 [11–13]	0.832[a]
Menstruation period (day)	29 [28–30]	30 [28–30]	0.441[a]
Menstruation duration (days)	6 [5–7]	6 [5–7]	0.482[a]

Group R: Rose; Group C: control; BMI: Body mass index
The data are presented as median [25th - 75th percentile].
[a] Mann-Whitney U Test.

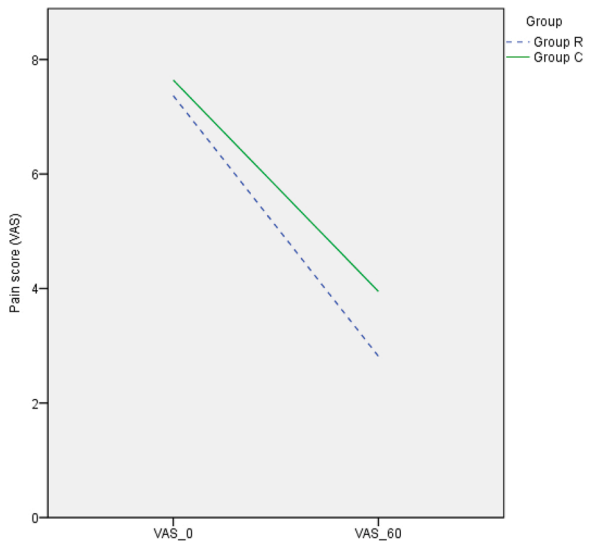

Fig. 2. Changing of groups' pain scores. VAS: Visual Analog Scale VAS-0: pre-treatment score VAS-60: post-treatment score.

Table 2
Comparison of pain scores (VAS) of group R and group C.

	VAS_0	VAS_60	P^a
Group R	8 [7–8] 7.37(1.217) [5–9]	2 [1–4] 2.82(1.738) [1 – 7]	< 0.001
Group C	8 [7–8] 7.64(0.743) [6–9]	5 [2–5] 3.95(1.946) [0 – 6]	< 0.001
P^b	0.537	0.013	

Group R: Rose; Group C: Control.
The data are presented as median [25th - 75th percentile], mean (SD) and [min-max].
[a] Wilcoxon Signed Ranks Test.
[b] Mann-Whitney U.

Table 3
Comparison of Analgesic consumption of group R and group C.

	Group R	Group C	*P*
Analgesic consumption (mg)	50 [50–100] 63.16 (22.313) [50–100]	100 [50–100] 80.77 (27.182) [50–150]	0.003[a]

Group R: Rose; Group C: Control.
The data are presented as median [25th to 75th percentile], mean (SD) and [min- max].
[a] Mann-Whitney U.

with RDM oil added to the standard treatment methods may be helpful for the treatment of primary dysmenorrhea. Uysal et al. (2016) administered inhalation aromatherapy with RDM oil in the emergency department to patients with severe menstrual pain. Patients with primary dysmenorrhea with severe pain often try to treat themselves using several different pharmacological and non-pharmacological methods before presenting to the emergency department. Unlike Uysal et al. (2016), in this study, patients with primary dysmenorrhea with severe pain, who presented to gynecology and obstetrics polyclinics, were taught how to self-administer RDM aromatherapy by inhalation in addition to standard pharmacologic treatment. Considering that most patients with painful primary dysmenorrhea do not visit the emergency department, it is clear that self-RDM inhalation therapy can be an effective method for a wider patient population.

RDM oil aromatherapy is frequently used for massage therapy. The pain-relief effect of rose damascene in patients with primary dysmenorrhea has been investigated in many studies. For instance, a study by Sadeghi Aval Shahr et al. (2015), entitled "The effect of self-aromatherapy massage of the abdomen on the primary dysmenorrhoea," revealed that massage therapy with Rose damascene oil aromatherapy reduced the pain of primary dysmenorrhea more than massage therapy alone (Sadeghi Aval Shahr et al., 2015).

In our study, the inhalation administration of RDM was based on data reported by Lotsch et al. (2016). This knowledge is the primary focus and helps explain the mechanism of action of inhaled aromatherapy. Lotsch et al. (2016) showed that nociception and olfaction share various characteristics at several levels. According to these studies, ion channels and G-protein receptors have a mutual effect on connecting and processing pain and the sense of smell. The same shared areas in the brain process both the sensation of pain and olfactory information (Lotsch et al., 2016). Based on this information, many essential oils have been administered by inhalation aromatherapy to investigate their pain relieving effects in patients with dysmenorrhea (Pirotta, 2008; Raisi Dehkordi et al., 2014).

Studies on inhaled RDM in the current literature frequently focus on anxiety and psychomotor function in humans (Kazmi, 2015). Inhaled RDM affects the human body and decreases the level of anxiety. According to the study of Haze et al., inhalation of the RDM fragrance, unlike essential oils, such as pepper oil and estragon oil, decreased sympathetic activity by 40% and adrenaline concentrations by 30% (Haze et al., 2002). To evaluate the effect of inhaled RDM in the treatment of primary dysmenorrhea, knowledge of both pain relief and anxiety reduction should be evaluated together.

4.1. Limitations

In this study, the time at which the patients felt pain during the day, the time taken to obtain the anti-inflammatory drug, and the first time of analgesic use could not be standardized. Individual compliance and tolerance are variable for inhalational treatments. In addition, the results may vary owing to patients' failure to administer inhalational therapy properly.

Although traditional methods have been used to manage pain for centuries, patients who do not have sufficient knowledge of this subject, and especially young patients, may approach these treatments with prejudice. In this study, anti-inflammatory drugs were administered to all patients as a standard to avoid the effects of prejudice on the effectiveness of aromatherapy treatment.

Anti-inflammatory drugs have several adverse effects. To ensure patient safety, the amount of analgesic used in the study was kept at a minimum. In addition, owing to the protocol of the study, the additive or synergistic efficacy of RDM could not be distinguished.

The main constituents of RDM oil vary according to the climate of the area in which the plants are grown (Baydar et al., 2016; Kovatcheva et al., 2011). The essential oils obtained from single-type RDM leaves grown at the Faculty of Agriculture, Kırşehir Ahi Evran University in the region of Kırsehir, Turkey, were used in this study. The analgesic and anti-inflammatory effects of RDM could vary according to the main constituents of RDM oil. This limitation also existed in this study. Furthermore, similar to all aromatherapy studies, no main constituent standardization was performed.

5. Conclusion

Rose oil aromatherapy by inhalation can be a good option for self-treatment of primary dysmenorrhea. To avoid excessive analgesic consumption and the adverse effects of NSAID, they can be used either alone or as an additional method.

Clinical trial registration number

IRCT20180324039145N2.

Informed consent

Informed consent was obtained from all the participants included in the study.

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CRediT authorship contribution statement

Selda Songur Dağlı: Conceptualization, Methodology, Data curation, Writing – original draft preparation, Writing – review & editing. **Recai Dağlı:** Conceptualization, Methodology, Data curation, Writing – original draft, Writing – review & editing.

Declarations of interest

None.

Data Availability

The data were de-identified from the participants' data. (Microsoft Excel file (. xlsx)). The data generated in this study are available via email from the corresponding authors.

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