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Evaluation of the effect of aromatherapy with *Rosa damascena* Mill. on postoperative pain intensity in hospitalized children in selected hospitals affiliated to Isfahan University of Medical Sciences in 2013: A randomized clinical trial

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Abstract

Background:

Pain is the common complication after a surgery. The aim of this study was to evaluate the effect of aromatherapy with *Rosa damascena* Mill. on the postoperative pain in children.

Materials and Methods:

In a double-blind, placebo-controlled clinical trial, we selected 64 children of 3–6 years of age through convenient sampling and divided them randomly into two groups. Patients in group A were given inhalation aromatherapy with *R. damascena* Mill., and in group B, the patients were given almond oil as a placebo. Inhalation aromatherapy was used at the first time of subjects' arrival to the ward and then at 3, 6, 9, and 12 h afterward. Common palliative treatments to relieve pain were used in both groups. Thirty minutes after aromatherapy, the postoperative pain in children was evaluated with the Toddler Preschooler Postoperative Pain Scale (TPPPS). Data were statistically analyzed using Chi-square test, one-way analysis of variance (ANOVA), and repeated measures ANOVA.

Results:

There was no significant difference in pain scores at the first time of subjects' arrival to the ward (before receiving any aromatherapy or palliative care) between the two groups. After each time of aromatherapy and at the end of treatment, the pain score was significantly reduced in the aromatherapy group with *R. damascena* Mill. compared to the placebo group.

Conclusions:

According to our results, aromatherapy with *R. damascena* Mill. can be used in postoperative pain in children, together with other common treatments without any significant side effects.

Keywords: Aromatherapy, children, operation, pain intensity, *Rosa damascena* Mill

Introduction

Nowadays, despite numerous advancements in pediatric care, many needed interventions to treat the diseases remain traumatic, painful, and disturbing.[1] Millions of people undergo surgery each year. They report that their pain after surgery is not managed.[2] Pain is not often thoroughly treated and the clients often suffer from pain after a disease or due to lack of pain management.[3] The pain caused due to any reason and not managed may lead to long-term physiologic, mental, social, and behavioral consequences. Pain is among the important nursing diagnoses in pediatric nursing for the children undergoing surgery and the health care team should prioritize pain management.[4] Therefore, the level of patients' pain should be measured and sedatives prescribed to relieve patients' pain.[2] Narcotics are among the medications that are routinely used in treatment of postoperative pain and can result in general side effects and signs, and are associated with tolerance and cessation-related syndrome in patients. Non-meditational methods are also used as a complementary intervention and not a replacement for meditational methods. There are methods in complementary medicine that can be used by nurses to help the patients.[4] One of the treatments with a notable growth in recent years, compared to other complementary medicine methods, is aromatherapy.[5] Research shows that aromatherapy can reduce anxiety, depression, pain, fatigue, nausea, and vomiting and can heal dermatologic lesions of diseases, although these effects have not been precisely proved.[6] For instance, inhalation aromatherapy with Bergamot in children and adolescents undergoing stem cell transplantation showed that although aromatherapy alone cannot reduce anxiety, nausea, and pain in children, it can be effective, if added to standard supportive treatments.[7] In another study, conducted in England on HIV-positive children on the effect of Lavender and Chamomile on sleep, comfort, and sedation of physical pain, the results showed that all children had a positive response to this combination, had better sleep, and their need to pain relief medications such as acetaminophen or morphine was reduced, although their pain was not thoroughly relieved.[8] Fowler Nancy states in a literature review study that the essence of sweat oranges reduced stress and relaxed the 5–14 year old children who were severely sick and underwent invasive procedures during hospitalization in Harvard University in USA.[9] In another study conducted on the effect of aromatherapy on head and face surgery postoperative distress in 6–36 month old children in three groups receiving M massage with carrier oil, M massage with tangerine oil, and postoperative standard care, the results showed no effect of the interventions.[10] The controversial studies in this context show that the effect of aromatherapy on children's pain needs further studies. With regard to the special condition in children and prohibition of usage of many types of aroma for them, the researcher, through a vast research, selected *Rosa damascena* Mill. as a harmless aroma for the children, which is consistent with Iranian patients' culture and beliefs and is also available at a reasonable price in the market. *R. damascena* Mill. is a refreshing cardiotropic, neurotropic traditional herb, which relieves earache, sore eyes, rectum and uterus pain, and is antipyretic, anti-infective, and anti- inflammatory and edema with wound healing effect.[11,12,13,14,15,16,17,18]

In studies conducted on *R. damascena* Mill., its suppressing effect on sympathetic system and the reduction of blood adrenaline level have been revealed.[19] It was also observed to induce sleep in rats.[20] The doubt in the efficiency of complementary medicine has slowed down its application in the society and even among the medical society due to lack of evidence-based adequate research conducted among children. This has resulted in prohibition of these interventions in nursing care too. Therefore, the researcher decided to study the effect of aromatherapy on children's post-surgery pain intensity.

We hope these results can act as an efficient step toward recognition of complementary medicine in pediatric nursing society to suggest appropriate strategies based on the findings of this study.

Materials and Methods

This is a clinical trial (IRCT 2014030516850N1). The obtained results were collected from two groups and in five stages, during which the effect of independent variable of type of aromatherapy on the pain intensity (dependent variable) was investigated. Baseline variables were children's sex, age, and the diagnosis. The confounding factors such as the type of surgery, history of hospitalization or surgery were controlled by random allocation in the two groups and through statistical tests. Out of control variables (limitations) included existing unpleasant smells in the ward, use of air fresheners by the accompanying persons, and open windows during aromatherapy. The subjects were selected through convenient sampling in such a way that all children hospitalized in the pediatric surgery ward of Imam Hossein and Al-Zahra hospitals and

who met the inclusion criteria were selected. Inclusion criteria were: Children of age 3–6 years of both sexes, hospitalized for surgery, not having several surgical incisions, not being tr ansferred to ICU after surgery, having a caretaker, no history of respiratory diseases like asthma, sinus disorders, and rennet allergy, narcotics, tranquilizers, or benzodiazepines not used for the child by the family during 1 week prior to intervention, no respiratory allergy to any essence, perfume, or aroma in the children or in their mothers, no history of dermatologic allergy and dermatitis in the children and their mothers, no chronic pain in the children, and not applying any complementary method of medicine (aromatherapy, etc.) for the child 1 week prior to intervention. Exclusion criteria were: Lack of the child's and his/her family's interest to continue with the researcher at any stage of the study, child's discharge or death before the end of intervention, signs of dermatologic and respiratory allergy during the study, incidence of infection in the subject's surgical incision site during the study, and the subject's critical condition during the disease or the study, which stopped the intervention. Then, the subjects were assigned to aromatherapy with *R. damascena* Mill. group or sweet almond aroma group through random allocation until the complement of the subject's number. Sample size was calculated by the sample size formula:

$$N = \frac{(Z_1 + Z_2)^2 (2S^2)}{d^2}$$

Considering Z_1 (confidence interval) =95% and Z_2 = 80% and S =0.7, the sample size was calculated as 32 in each group (a total of 64 subjects). Immediately after subjects' arrival to the ward from the operating room, pain intensity assessment checklist was ticked for them for the first time to measure the pain intensity. Then, the aromatherapy intervention was started with one to two drops of *R. damascena* Mill. extract in the study group and standardized sweet almond oil (due to having no proved respiratory effect and its frequent application in other studies as a placebo) in the other group. The essences were put on an eye pad and at the time of subjects' arrival to the ward, were laid by the child's head at a distance of 30 cm (after the first pain intensity measurement, and then 3, 6, 9, and 12 h after surgery). Both groups also received routine postoperative care of the related surgery (taking sedation, antipyretics, and intake of fluids, electrolytes, and antibiotics and other interventions).

To investigate pain, 30 min after each aromatherapy, the pain intensity assessment checklist was ticked through 5-min observation of the child by the researcher. Pain checklist was also completed. Data collection tools were a questionnaire and a checklist.

The questionnaire contained six demographic questions including sex, age, diagnosis, type of surgery, and the history of hospitalization or surgery. The checklist for measurement the pain is Toddler Preschooler Postoperative Pain Scale (TPPPS) that was designed by Sali *et al*. in 1992 to measure pain among the toddlers and children by Massachusetts Medical University surgical department, and its validity and reliability have been already established (Cronbach's alpha = 0.88). This checklist includes seven items. Three items are for verbal expression of pain, three for facial expression of pain, and one for body expression of pain, with the scores being on a scale of 0–7.

All these items should be checked during a 5-min observation.[21] This checklist was ticked immediately after arrival to the ward and then at 3, 6, 9, and 12 h after surgery by the main researcher or her co-researcher. Finally, the data were analyzed by descriptive statistics and analytical tests [Chi-square, repeated measures analysis of variance (ANOVA), one-way ANOVA, and analysis of covariance (ANCOVA)] through SPSS 18.

Ethical considerations

This study has confirmations Ethics Committee (No. 3310). Informed consent was obtained from participants.

It should be noted that the details of the study are presented in Table 4 (CONSORT Table).

Results

Chi-square test showed no significant difference in subjects' demographic characteristics including age, sex, diagnosis, type of surgery, history of hospitalization and surgeries between the two groups. These

findings have been presented in Table 1.

In Table 2, the two groups of study and control have been compared with each other in five time points. Intragroup comparison in the group administered aromatherapy with *R. damascena* Mill. revealed that the mean score of pain intensity decreased through time and showed a significant difference ($P < 0.0001$). The intragroup comparison in sweet almond group revealed that the mean score of pain intensity decreased through time and showed a significant difference ($P < 0.001$). Least significant difference (LSD) *post-hoc* test showed no significant difference in *Rosa* and sweet almond groups in the time point of immediately after arrival to the ward ($P = 0.16$), but in each time point of 3, 6, 9, and 12 h after arrival to the ward, the mean score of pain intensity in the *Rosa* group was lower than that in the sweet almond group, and the difference in the mean scores of pain intensity was significant between the two groups ($P < 0.05$).

Discussion

The obtained results showed that pain intensity score was higher in the *Rosa* group at the time of arrival to the ward (before intervention), which seems normal due to disappearance of anesthesia effect and not using any intervention to relieve pain. In this group, pain intensity score showed a significant difference in different time points of 9, 6, 3, and 12 h after the surgery ($P < 0.05$) in such a way that it decreased after intervention with *R. damascena* Mill., and this decrease had a significant association with time ($P < 0.001$). Gharabaghi, in a study on the curing effect of *R. damascena* Mill. on elective cesarean section post surgery pain, obtained consistent results with the present study. The author showed that pain intensity scores in the *Rosa* group in time points of 12, 6, 3, and 24 h post surgery decreased and this decrease in pain intensity had a significant association with time.[22] In their study, oral capsules, containing *Rosa* powder, were used before anesthesia; but in the present study, *R. damascena* Mill. was used through inhalation. In another study, Hajhashemi *et al*. investigated the analgesic and anti-inflammatory effect of *R. damascena* hydro-alcoholic extract in animal models and reported its analgesic response in different phases after intervention in the study group compared to the control group.[23] They used the hydro-alcoholic extract of *Rosa* through intraperitoneal injections on animal models. Their obtained results concerning the use of *Rosa* and the positive analgesic effect were in line with the present study.

In the sweet almond group, the mean score of pain intensity was higher at the time of arrival to the ward (before intervention) due to reasons similar to those of *Rosa* group (no application of any pain relief method before aromatherapy). After aromatherapy with sweet almond oil, the mean scores of pain intensity decreased in different time points after arrival to the ward and undergoing intervention, and this reduction had a significant association with time ($P < 0.001$). The reduction observed in the mean score of pain intensity through time in this group was associated with the sedative and tranquilizing effect of medications such as acetaminophen, phenobarbital, etc., although both groups had routine pain relief interventions. It can possibly be due to the psychological effects of placebo too. The results of the present study showed a minor difference in the mean scores of pain intensity between the two groups at the time of arrival to the ward, which was not significant ($P = 0.16$). This insignificant difference between the two groups at the time of arrival and before intervention reveals the homogeneity of the subjects in both groups, as before administration of any routine intervention or aromatherapy, the groups were relatively identical concerning the pain intensity score.

LSD *post-hoc* test showed a significant difference in the pain intensity scores in the two groups in time points of 3, 6, 9, and 12 h after arrival to the ward ($P < 0.05$), but the difference in mean pain intensity in different time points after intervention can be due to the different aromatherapy applied in the two groups. As presented in Table 3, LSD *post-hoc* test (in pair comparison of the time points in the two groups) showed a significant difference in just some of the time points ($P < 0.05$). It was such that in aromatherapy with sweet almond, the difference was not significant just for 3 h after arrival, but in *Rosa* group, sedative consumption and the interference of aroma with sedative effects may have influenced the steady trend of pain relief.

Our obtained results are in line with previous studies conducted by Kim *et al*. with the goal of investigating the self-aromatherapy massage of the abdomen for the reduction of menstrual pain in nurses. They used the essence oil of a mixture of aromas of rose absolute (*Rosa centifolia*) and rose Otto (*R. damascena*), clary

sage (*Salvia sclera*), rose geranium (*Pelargonium*), and ginger (*Zingiber officinale*) in a base of almond and jojoba oil for abdominal massage. Almond oil alone was used in the second group, and the subjects in the control group took acetaminophen for their pain relief. Their results showed the effect of massage with the above-mentioned mixed aromas on pain relief of menstrual pain 24 h after intervention, compared to the control group. Post-massage pain had a lower intensity compared to pre-massage pain.[24] In the aforementioned study, although a mixture containing *R. damascena* was used, the effect of each ingredient was not determined. In addition, massage therapy was used instead of inhalation method. In their study, only 24 h after aromatherapy and massage therapy, pain was measured. But both studies are in line with each other concerning the effect of aromatherapy in pain relief. Winter *et al*. (2005) investigated the effect of *Rosa canina* powder on relieving the signs of osteoarthritis and in the reduction of consumed medications. They gave a daily dose of 5 g of *R. canina* to 57 subjects in the study group for three sequential months and placebo under the same conditions to 37 control subjects. All participants were investigated concerning pain, rigidity, disability, and intensity of the disease immediately after entering the study, 3 weeks after and 3 months after starting the treatment. The authors reported a notable reduction in patients' pain 3 weeks after treatment with *Rosa* in the study group compared to control. In addition, the amount of sedative consumption was significantly reduced due to intervention.[25] In their study, although a similar sort of *Rosa* was used for pain relief, the type and method of application, length of use, and length and method of patients' evaluation were different from the present study. In the study of Willich *et al*. (2011) on the effect of *R. canina* on the signs of rheumatoid arthritis (RA), a daily dose of 5 g of *Rosa* was given to the subjects in the study group and the control group received a similar dosage of placebo. Then, the patients were investigated in an out-patient clinic for a period of 6 months. Evaluation of some parameters in RA patients, including Disease Activity Score (DAS-28) and The Health Assessment Questionnaire Disability Index (HAQ-DI), universal physicians scale, and physical scale, showed that the study group receiving *Rosa* recovered while the control group had either gone worse or remained in the same condition. In addition, based on some criteria such as pain intensity, the amount of medication, and patients' mental scale showed no significant difference after this period of time in the two groups. Adding *Rosa* powder to routine treatments of these patients was found to be beneficial to the patients.[26] They also indicated the positive effect of *Rosa* in pain relief after treatment, similar to the present study, but had used a different method of intervention and powder of *Rosa*. The length of intervention with *Rosa* powder and time length and method of patients' evaluation were different from the present study.

Conclusion

The findings showed the effect of *R. damascena* Mill. on postoperative pain in the children hospitalized in pediatric surgery wards, compared to the placebo group. Although pain intensity decreased in both groups through time, this reduction was more in the study group, compared to control. It should be noted that despite conducting a vast search for reports on *Rosa* aromatherapy in children, especially with regard to postoperative acute pain, no other studies were found. Therefore, in some cases, animal studies were discussed in this article. As each study is an introduction for another, this study can open the way for further studies based on its findings. It is suggested to conduct a comparative study on the effects of *Rosa* and rose geranium on the reduction of post-surgery sedative consumption, the preoperative anxiety in children, length of hospitalization among the children undergoing a surgery, the level of parents' anxiety and stress before and after their children's surgery, and pain intensity in children hospitalized in other pediatric wards, and also a comparative study on the effect of *Rosa* and rose geranium with other protocols of children's postoperative pain management.

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Footnotes

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Conflict of Interest: None declared.

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Figures and Tables

Table 1

GroupsCharacteristics	Aromatherapy *n*=32		Placebo (control) *n*=32		*P* value	Analysis tests
	Mean (*n*)	SD (%)	Mean (*n*)	SD (%)		
Age (years)	4.4	1.3	4.3	1.1	0.67	One-way ANOVA
Sex						
Female	10	31.2	8	25	0.85	Chi-square test
Male	22	68.8	24	75		
Diagnosis						
Congenital abnormality	13	40.6	13	40.6	0.88	Chi-square test
Acquisitive disease	19	59.4	19	59.4		
Type of surgery						
Thorax	1	3.1	3	9.4	0.17	Chi-square test
Abdominal	15	46.9	12	37.5		
Urogenital	12	37.5	12	37.5		
Facial	4	12.5	1	3.1		
Others	0	0	4	12.4		
History of hospitalization						
Yes	20	62.5	20	62.5	0.504	Chi-square test
No	12	37.5	12	37.5		
History of surgery						
Yes	5	15.6	7	21.9	0.592	Chi-square test
No	27	78.1	25	84.4		

ANOVA: Analysis of variance, SD: Standard deviation

Demographic characteristics of the subjects in the aromatherapy and control groups

Table 2

Time groups	First time after arrival toward		3 h afterward		6 h afterward		9 h afterward		12 h afterward		Repeated measures ANOVA
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	*P* value
Aromatherapy	3.8	0.5	1.03	0.3	1.03	0.2	0.9	0.2	0.4	0.08	<0.001
Placebo (control)	3.1	0.4	2.6	0.3	2.03	0.25	1.6	0.2	1.1	0.2	<0.001
One way ANOVA											
P value	0.16		<0.001		0.007		0.01		0.001		

ANOVA: Analysis of variance, SD: Standard deviation

Mean of pain intensity in different time points in the aromatherapy and control groups

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Table 3

Groups times	Aromatherapy	Placebo (control)
First time with 3 h afterward	<0.001	0.18
First time with 6 h afterward	<0.001	<0.001
First time with 9 h afterward	<0.001	<0.001
First time with 12 h afterward	<0.001	<0.001
3 h with 6 h afterward	1.0	<0.001
3 h with 9 h afterward	0.69	<0.001
3 h with 12 h afterward	0.3	<0.001
6 h with 9 h afterward	0.43	0.03
3 h with 12 h afterward	0.01	0.001
9 h with 12 h afterward	0.002	0.005

Multiple comparison of each two times in each group

Table 4

Item no	Checklist item	Reported on page no
Title and abstract		
1a	Identification as a randomised trial in the title	1 and 2
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1 and 2
Introduction		
Background and objectives		
2a	Scientific background and explanation of rationale	3 and 4
2b	Specific objectives or hypotheses	4
Methods		
Trial design		
3a	Description of trial design (such as parallel, factorial) including allocation ratio	4 and 5
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants		
4a	Eligibility criteria for participants	5
4b	Settings and locations where the data were collected	5 and 6
Interventions		
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5 and 6
Outcomes		
6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size		
7a	How sample size was determined	5
7b	When applicable, explanation of any interim analyses and stopping guidelines	5
Randomisation		
Sequence generation		
8a	Method used to generate the random allocation sequence	5
8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism		
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation		
10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding		
11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	5
11b	If relevant, description of the similarity of interventions	5
Statistical methods		
12a	Statistical methods used to compare groups for primary and secondary outcomes	6
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
Results		
Participant flow (a diagram is strongly recommended)		
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	5
13b	For each group, losses and exclusions after randomisation, together with reasons	5
Recruitment		
14a	Dates defining the periods of recruitment and follow-up	6
14b	Why the trial ended or was stopped	5 and 6
Baseline data		
15	A table showing baseline demographic and clinical characteristics for each group	13
Numbers analysed		
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	5
Outcomes and estimation		
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	7 and 13 and 14
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	7

CONSORT 2010 checklist of information to include when reporting a randomized trial