

Aromatherapy with Rosa Damascenes in Apnea, Bradycardia and Spo₂ of Preterm Infants; a Randomized Clinical Trial

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Abstract

Background

Apnea is one of the most common problems in preterm neonates. This study aimed to evaluate the effectiveness of aromatherapy on the reduction of apnea, bradycardia, and Pulse Oximetry (SPO₂) in premature infants.

Materials and Methods

In a clinical trial study, 60 preterm neonates randomly divided in two groups and exposed to aromatherapy with Rosa damascenes distillate or distilled water beside the routine treatment. In experimental group, two drops of 10% Rosa damascenes distillate was dropped on the pad eye in second day of birth at 6 Am. The intervention was repeated in 9 AM, 12 Am, 15 PM and 18 PM hours. A same condition applied for control group and distilled water was dropped on the pad eye. The number of apnea attacks, bradycardia and decrease in SpO₂ compared between two groups using chi-square test, independent t-test and repeated measure test.

Results

The overall apnea attacks, bradycardia, and SPO₂ in tree studied days were lower in intervention group than control group (0.47±0.13 vs. 2.6±0.41, 0.47±0.13 vs. 2.56±0.41 and 0.70±0.17 vs. 2.77±0.21, respectively). In addition, the repeated measurement test showed that the mean number of apnea attacks, decrease in heart pulse rate, and decrease in SpO₂ was statistically lower in intervention group with aromatherapy than controls in first, second, third and sum of three days (P< 0.05).

Conclusion

Aromatherapy with Rosa damascenes distillate can reduce more and speedy the occurrence of apnea attacks, bradycardia and SPO₂ in premature infants, along with other routine treatment.

Key Words: Aromatherapy, Neonatal, NICU, Premature infants, Rosa damascena.

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1- INTRODUCTION

Apnea is defined as the breathing cessation that happened for more than 15 seconds with cyanosis, bradycardia or hypotonic (1, 2). Apnea is one of the most common clinical manifestations in premature deliveries and it is occurred in 80% of neonates lower than 1,000 gr and in 25% of them that are lower 2,500gr (3).

Moreover, Apnea of prematurity (AOP) reversely associated with gestational age and neonate weight in a way that it would be happened in 80% of neonates that born before 30th week of gestational age(2). Central, obstructive and mixed apnea are three types of apnea that occurs in preterm babies due to relatively small airways, large occiput (back of the head) and hypotonic neck muscles comparing to term infants (2, 4).The mixed apnea is the most prevalent type of apnea in in preterm infants. Mixed apnea is observed in more than 50% of all apneas while pure central or obstructive apneas are responsible for about 20% of all apneas(2, 5).

Increased inhibitory reflexes of breathing, decreased hypersonic responses and hypoxic and ventilator depression are the pathophysiological mechanisms leading to AOP(2, 3). Being in warm condition and provocation the back of pharynx due to sudden insert of suction tube are the helpful condition for AOP (1, 3, 6, 7).

More than of 80% of sleep in premature infants spend in Rapid Eye Movement (REM) phase and the respiratory depression occurred in this phase(8). Therefore, the majority of AOPs happens in REM phase. Today's, Caffeine and Theophylline are the medical drugs for AOP. Slow contact on the back of neonates, prone and supine position are also a nonmedical interventions (2, 9, 10). Moreover, aromatherapy is a new nursing care as complementary treatment (11-13) that has calming, sedating and pain-reducing, stimulatory in patients especially

in psychological disorders, labor, and postpartum practices (14-17).

Rosa damascena, is known in Iran as "Gole Mohammadi" and it is used as a complementary therapy due to some pharmacological effects such as antibacterial, antioxidant, Antitussive, hypnotic, and relaxant effect as well as the perfuming effect in aromatherapy method (18, 19) (**Figure.1**). There are some studies that assessed the effect of Aromatherapy with valerian, lavender and Rosa damascene and have found beneficial effects in behavioral disorders such as pain relief, anxiety, stress, sleep quality of patients (11-14, 18, 20, 21).

It is showed that olfactory stimulation with fragrances and acquaintance aromas such as mother milk and amniotic odour could decrease AOP with mild bradycardia (7, 17) and neonatal crying in pain(22).

However, based on our search, the effect of Rosa damascene aromatherapy on apnea occurrence in preterm neonates has not been investigated yet in patients that hospitalized in Neonatal Intensive Care Unit (NICU). Therefore, since the Rosa damascena is acceptable by parents and due to accessibility, low cost and low complication of this flower, we aimed to assess the Rosa damascene aromatherapy effect on decreasing apnea attacks, bradycardia and SpO₂ in preterm neonates.



Fig.1: Rosa damascena (Gole Mohammadi)

2- MATERIALS AND METHODS

A double blind randomized clinical trial was conducted in NICU of Beheshti hospital of Isfahan, Iran on premature neonates at summer of 2015. All premature neonates with inclusion criteria could recruit in the study. Inclusion criteria was including: gestational age between 29-33 weeks, neonatal weight between 900-1500 grams, being in incubator, having hemoglobin over 10 gr/dl, without heart disease or any infection, no need to ventilator or breathing with Continues Positive Airway Pressure (CPAP) as well as parent consent and neonatal specialist. The neonates excluded from the study if their parents withdrawal the informed consent. Moreover, death or discharge before completing the study intervention course, affecting to skin or respiratory reactions were the exclusion criteria. Sampling conducted based on convenience method and after taken informed consent from eligible subjects, the random assignments was used to divide the 60 eligible patients to intervention group and control group equally. The intervention group exposed to aromatherapy with Rosa damascena distillate (manufactured by Barijesans Co.) and distilled water was used for control group (manufactured in DaruPakhsh Co.).

The routine non-drug treatment was used in two study groups beside study interventions. In experiment group, two drops (0.1 cc) of 10% Rosa damascena distillate was dropped with dropper and by a trained nurse on the pad eye in second day of birth at 6 Am, which was located at a distance of 30 cm of head. Each patient has exposed to pad eye for 12 hours that contains the Rosa damascena distillate or distilled water. Therefore, in any three hours for three days, two drops of the Rosa damascene distillate or distilled water added to the eye pad in intervention and control group, respectively. Therefore, the intervention was repeated in 9 AM, 12

AM, 15 PM and 18 PM hours. A same condition applied for control group and aromatherapy with distilled water was conducted. Measurements of outcomes in two groups conducted at 14 AM of each day. The study protocol registered in IRCT by IRCT Cod: IRCT2015121925601N4. Measurements were conducted after approving the ethical committee of Isfahan University of Medical Sciences, Isfahan-Iran. Informed consent was taken from all study subjects after describing the objectives of the study and full agreements of neonate's parents. Data gathered by direct observation by trained nurse in research team and by the ICU monitoring system that recorded the respiratory and heart rate of the patients.

First, the ICU monitoring system calibrated and all data measured by one ICU monitoring system for increasing the validity of data. At the baseline measurements, all demographic data including neonate gender and weight, gestational age and delivery type were gathered and the baseline analysis showed the goodness of random allocation. The neonate weight was measured by Rasa model scale (made in Iran). The research team tried to prevent in all under study neonates from each practice can cause apnea attack including harsh interventions to neonate, sudden suction, sever contact provocation and creation vociferous beside statement a true neck position as non-drug treatments. Routine treatments such as mild massage of back and having true position and drug treatments were used if the apnea attack occurred in the study subjects for two groups.

Finally, Chi-square test, independent t-test, and repeated measure test in Generalized Linear Models (GLM) were used respectively to compare the frequency, mean number and trend of apnea attacks, bradycardia, and decrease in SpO₂ compared between two groups. All statistical tests conducted in SPSS V.18

software and p lower than 0.05 considered as significant.

3- RESULTS

The Mean of gestational age and birth weight in studied subjects was 31.4 ± 1.4 weeks and 1321 ± 178 gr, respectively. The gestational age varied between 29-33 weeks and the neonatal weight was between 900-1500 gr. The t-test results showed that there was no significant difference between two groups regarding to the mean of gestational age and neonatal weight. Moreover, based on Chi-square test there was no difference in two study groups based on gender distribution and delivery type (**Table.1**).

According to (**Table.2**), a significant difference was observed between treatment and control group regarding to the apnea attacks in the first, second and third day after the intervention. Moreover, the overall apnea attacks and decreasing trend in two study groups were statistically significant ($P= 0.001$). **Table.3**, shows the significant difference between two groups in the first, second and third day after the

intervention in bradycardia. The overall bradycardia in three days and trend of decreasing in two groups was statistically significant. **Table.4** shows the decreasing trend in SPO₂ in two studied groups at first up to the three day of the study and the whole of three days ($P= 0.001$). The overall apnea attacks in whole studied days were lower in intervention group than control group (0.47 ± 0.13 vs. 2.6 ± 0.41). Moreover, the overall bradycardia and SPO₂ in whole studied days were lower in intervention group than control group (0.47 ± 0.13 vs. 2.56 ± 0.41 and 0.70 ± 0.17 vs. 2.77 ± 0.21). Furthermore, the repeated measurement test showed that the mean of apnea attacks, decrease in heart pulse rate, and decrease in SpO₂ was statistically lower in intervention group with aromatherapy than controls in first, second, third and sum of three days. The overall trend in apnea attacks, heart pulse rate, and SpO₂ was statistically decreasing based on the trend statistical value in repeated measurement test in both treatment and control groups ($P < 0.05$).

Table 1: Demographic characteristics of the participants in the experimental and control groups

Demographic Characteristics		Experimental group	Control group	P- value
Gender	Female	17(56.7)	18(60)	0.79
	Male	13(43.3)	12(40)	
Birth weight		1345.3(160.3)	1296.7(194.3)	0.294
Gestational age		31.4(1.48)	31.3(1.32)	0.854
Birth type %	cesarean	4(13.3)	10(33.3)	0.067
	vaginal	26(86.7)	20(66.7)	

Table 2: Comparison of the number of apnea attacks in the experimental and control groups from the first up to the three day of the study and the whole three days

Day of study	Experimental group		Control group		P- value†
	Mean	SD	Mean	SD	
First day	0.23	0.09	1.1	0.21	0.001
Second day	0.17	0.07	0.97	0.20	0.001
Three day	0.07	0.05	0.53	0.14	0.003
The whole three days	0.47	0.13	2.60	0.41	0.001
Trend P- value‡	0.002		0.001		

† Based on independent t-test, ‡ Based on the Repeated measurement test in generalized liner model.

Table3: Comparison of the bradycardia in the two groups from the first up to the three day of the study and the whole three days

Day of study	Experimental group		Control group		P- value†
	Mean	SD	Mean	SD	
First day	0.23	0.09	1.1	0.19	0.001
Second day	0.17	0.07	0.97	0.20	0.001
Three day	0.07	0.05	0.53	0.14	0.003
The whole three days	0.47	0.13	2.56	0.41	0.001
Trend P- value‡	0.002		0.001		

† Based on independent t-test, ‡ Based on the Repeated measurement test in generalized liner model.

Table4: Comparison of the decrease of SpO₂ in the two groups from the first up to the three day of the study and the whole three days

Day of study	Experimental group		Control group		P- value†
	Mean	SD	Mean	SD	
First day	0.30	0.09	1.1	0.18	0.001
Second day	0.23	0.08	1.17	0.20	0.001
Three day	0.17	0.07	0.50	0.13	0.030
The whole three days	0.70	0.17	2.77	0.21	0.001
Trend P- value‡	0.001		0.001		

† Based on independent t-test, ‡ Based on the Repeated measurement test in generalized liner model.

4- DISCUSSION

The current study results showed that the aromatherapy effect with *Rosa damascena* distillate is effective on the apnea attacks, heart pulse rate, and SpO₂ in premature neonates beside the routine treatment in comparing to control group that only received the routine treatment with distilled water. Based on the results the mean number of the apnea attacks, heart pulse rate, and SpO₂ was statistically lower than in aromatherapy group in all three-study days in premature neonates that hospitalized in NICU. Marlier et al. study(7) showed that aromatherapy with Vanilla in premature neonates that have gestational age 24-28 weeks was effective on the apnea occurrence at the second days after intervention in compare to the first and third days. Moreover, the SpO₂ was increased in neonates that exposed to aromatherapy with Vanilla. Nevertheless in our study, the decreasing trend in outcome measures including the apnea attacks, heart pulse rate, and SpO₂ was continues. Moreover, the Edraki et al.

study(6) showed that aromatherapy with Vanilla is protective for apnea occurrence and bradycardia in premature neonates. Our study showed same results with a higher power in detecting the aromatherapy with *Rosa damascenes* distillate due to higher sample size. Another clinical trial study by Chen et al. found that Valerian aromatherapy has an increasing effect on sleep duration as well as decreasing effect on insomnia among patients who are hospitalized in ICU(23).

The pharmaceutical effects of aromatherapy with *Rosa damascenes* including antibacterial, antioxidant, antitussive, hypnotic, and relaxant effect is determined in several studies(11, 12, 18, 19, 21). It is demonstrated that aromas has an increasing effect on patients' calmness through its effect on limbic system and the hypnotic, sedative, and anticonvulsive effects of *Rosa damascene* on the central nervous system are effective in alleviates anxiety and promotes relaxation(18, 19, 24). The extract of *Rosa damascena* is stimulation of axons and dendrites in

nervous system(25) and it is containing Christin and Kaempferol that are effective in decreasing pain(26). Moreover, the hydro-alcoholic extract of Rosa damascenahas dilation effect on respiratory airways(26, 27). However, the Rosa damascena is effective on anxiety and sleep quality is correlated with sleep quality in patients especially in premature infants that are hospitalized due to apnea or other complications(19, 21, 24).

The researchers think that these effect are due to fragrance perception of babies from olfactory stimulants in a way that the babies can the baby can detect its mother's breast pad or clothing from other mothers (17). According to our results, there was a significant difference in aromatherapy and control groups in apnea attacks, heart pulse rate, and SpO₂ in all studies days including first, second and third days after intervention. In other words, the mean number of apnea attacks, heart pulse rate, and SpO₂ was lower than in intervention group in comparing to control group while the decreasing trend of attacks were observed in two groups. However, the control group received the routine treatment and the decreasing trend of outcomes was due to the medical interventions.

Nevertheless, the more rapid decreasing trend in intervention group was due to aromatherapy with Rosa damascenes distillate. Furthermore, the recovery in intervention group was in our expectation, but recovery and decreasing the apnea attacks in control group is attributing to routine treatment. However, the current study could demonstrate the effect of aromatherapy with Rosa damascena distillate for premature neonates, but due to ethical consideration, the routine treatments would be conducted in intervention group after the occurrence of apnea attacks and neck position revised if needs.

4-1. Limitations of the study

Low sample size in our study and difficulty in intensive care for preterm neonates were the limitations.

5. CONCLUSION

Aromatherapy with Rosa damascena distillate can reduce more rapidly the occurrence of apnea attacks, bradycardia and SPO₂ in premature infants, along with other common treatment. Therefore, our results showed that using aromatherapy with Rosa damascenes could be used as effective intervention for premature neonates who suffering from premature apnea along or with other medical interventions.

6- SOURCE OF SUPPORT

Isfahan University of Medical Sciences, Iran.

7- CONFLICT OF INTEREST: None.

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9- CONTRIBUTION OF AUTHORS

S A; Contributions to the conception or design of the work and Final approval of the article.

M M; Contributions to the conception or design of the work; analysis, and interpretation of data and Final approval of article.

Z B; Contributions the acquisition and analysis of data for the work and Drafting the article.

M S Z; Contributions to the conception or design of the work; interpretation of data for the work; and Final approval of the article.

Z GH; Contributions to the conception or design of the interpretation of data for the work; and Final approval of the article.

A M; Contributions to the conception or design of the work analysis, or interpretation of data for the work; and final approval of the article.

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