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Original Article

Effect of Aromatherapy on Dental Anxiety and Pain in Children Undergoing Local Anesthetic Administrations: A Randomized Clinical Trial

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Abstract

Introduction: In dentistry, local anesthetic (LA) administration in children is often associated with behavioral problems. Hence, the present study evaluated the efficacy of aromatherapy in reducing the dental anxiety and pain during LA procedure.

Methods: This clinical trial was conducted upon 150 children in the age range of 8-12 years. Subjects were randomly divided into five groups; Group 1: Lavender essential oil using nebulizer; Group 2: Lavender essential oil using inhaler; Group 3: Orange essential oil using nebulizer; Group 4: Orange essential oil using inhaler; Group 5: Control (without aromatherapy). For all the children, baseline anxiety was recorded followed by aromatherapy (except for children in the control group). Following the standard protocol, LA was administered. The procedural pain was assessed using Faces, Legs, Activity, Cry and Consolability scale (FLACC) and Faces Pain Scale-Revised (FPS-R). Finally, anxiety was again recorded. Data were analyzed using SPSS version 17.0.

Results: A significant difference in ANOVA test was observed among anxiety scores after LA in aromatherapy groups 1, 3, and 4 compared to control. When the FLACC scores were analyzed using Kruskal-Wallis, there were significantly lower values in aromatherapy groups compared to the control group. The pain scores, as reported in FPS-R, were also lower in aroma groups 1, 3, and 4.

Conclusion: Aromatherapy with lavender or sweet orange, using either nebulizer or inhaler, decreased the dental anxiety of children, whereas, only sweet orange could reduce the pain as self-reported by children.

Introduction

Dental anxiety is prevalent in 5% to 20% of children in various countries, which can increase the pain sensation.[1] To combat this, many non-pharmacological interventions for the prevention of anxiety and pain during pediatric dental care have been suggested in literature.[2] In recent times, the use of complementary and alternative medicines is in an increasing front.[3] Aromatherapy is one such intervention which uses essential or volatile oils extracted from flowers, barks, stem, leaves, roots, fruits and other parts of the plant.[4,5] The use of distilled plant materials dates back to medieval Persia, but the term aromatherapy was first coined by Rene Maurice Gattefosse, in early periods of 20th century,[6,7] claiming the use of this medicine to treat virtually any ailment throughout the human organ system.[7] Currently, aromatherapy is popular throughout the world, as the essential oils for the medicinal use are recognized as safe.[8] Inhalation, massage or simple application on skin surface and baths are the major methods used; among which inhalation (also called olfactory aromatherapy) forms the most basic.[4,9] These oils can be inhaled through a humidifier or by soaking gauze.[7,10] The low cost and minimal side effects are the factors that allure the health care providers to opt this therapy.[6,11]

The effect of aromatherapy, on adults, in the treatment of medical conditions has been extensively reported.[12-14] Studies on the effect of this therapy as a palliative medicine on pain, anxiety, emotional distress, quality of life or sleep in patients with cancer observed inconsistent findings; few studies documenting an improvement,[15] while others reporting no effect.[16,17] The positive effect of aromatherapy on pain, anxiety and depression has also been stated in postpartum woman.[18] Additionally, positive anxiolytic effect of essential oils in healthy adults subjected to anxiogenic challenge is also reported.[19] Contrarily, a study on anxiety and pain in children as well as adolescents undergoing stem cell transplantation[20] and another that assessed the postoperative comfort of children in peri-anesthesia setting[21] found no significant

effect of aromatherapy.

In dentistry, studies done on adults attending dental clinic noted a positive effect of aromatherapy on anxiety, mood, alertness and calmness[22-27]; but contrarily no significant effect on anxiety, mood and perceived level of pain are also documented.[28,29] A systematic review done to know the efficacy of aromatherapy on dental anxiety, reported beneficial effects of this therapy compared to negative control and recommended further randomized trials.[30] On the other hand, in studies done on children undergoing dental restorative procedures, anxiolytic effect of lavender as well as orange aroma oils as observed in reduction of salivary cortisol and pulse rate has been reported.[1,31,32] A significant reduction in anxiety and pain experienced by children during dental extraction, with lavender essential oil, has also been reported in another study.[33] Thus, the literature on aromatherapy in children undergoing dental treatment is meagre. Lack of evidence on comparative efficacy of lavender and orange essential oils in children experiencing the anesthetic injections as well as the influence of mode of inhalation forms the major lacuna in this field. Hence, the present study was planned to determine the effect of two essential oils (lavender and sweet orange), using two modes of inhalation (nebulizers and inhalers), on the dental anxiety and pain in children undergoing local anesthetic (LA) administrations.

Materials and Methods

This was a randomized clinical trial with parallel design and allocation ratio of 1:1:1:1:1.

Participants were selected, at the department from July 2018 to July 2019, based on the following eligibility criteria; age range of 8-12 years, complete physical and mental health, a score of >6 on Modified Child Dental Anxiety Scale - Faces version [$MCDAS_{(f)}$-simplified], requirement of LA administration (in maxilla/mandible) for pulp therapies/extraction of primary teeth and who gave their assent and whose parents a written informed consent.

Children with previous LA administration, presence of dental or medical emergency and systemic disorders were excluded.

The recruited children were randomized using block randomization and assigned to one of the following five groups.

- Group 1: Aromatherapy with lavender essential oil using nebulizer
- Group 2: Aromatherapy with lavender essential oil using inhaler
- Group 3: Aromatherapy with orange essential oil using nebulizer
- Group 4: Aromatherapy with orange essential oil using inhaler
- Group 5: Control (without aromatherapy) (Figure 1).

The allocation concealment of the participants was done using opaque sealed envelope.

Two essential oils (Figure 2), lavender [Elansa lavender essential oil, Sweet floral (Kapco International limited, Himachal Pradesh, India; Country of origin, India)] and sweet orange [Elansa sweet orange essential oil, (Kapco International limited, Himachal Pradesh, India; Country of origin, Brazil)], using nebulizer/inhalers (Figure 3) were employed in the present study.

Aromatherapy with inhalers was carried out in an open clinical setting. Two drops of lavender oil was dispensed into a cotton wick of the inhaler, whereas for those in sweet orange group 3 drops was dropped into the wick. The children were asked to inhale the aroma from the inhalers for 2 minutes followed by an induction period of 15 minutes.

Aromatherapy with nebulizers was carried out in a closed air-conditioned room. For those in lavender oil group, 80

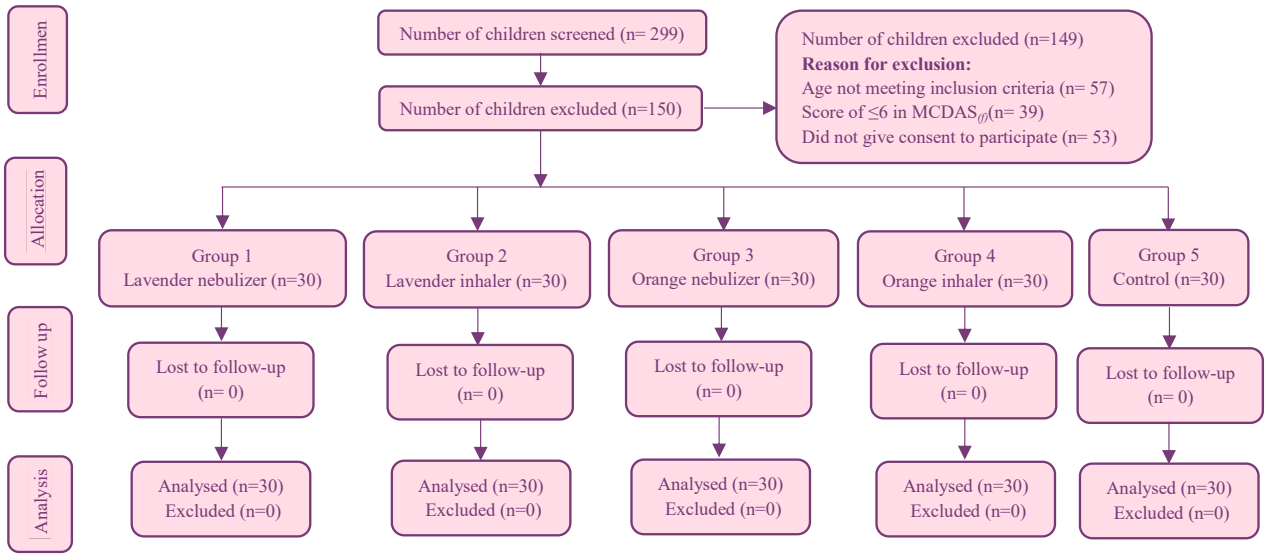

Figure 1. Flowchart of the study

Figure 2. Essential oils used in the study

Figure 3. Nebulizer and inhaler employed in the study

mL of distilled water, as a medium, was dispensed into the water tank of the nebulizer, followed by six drops of essential oil. For those in orange oil group, for 80 mL of distilled water, eight drops of essential oil was added. All the children were subjected to aromatherapy for about 2 minutes followed by 15 minutes of induction period. This was followed by the routine LA administration by a single trained investigator (RK).

In the pre-operative period, 20 minutes before starting the treatment (as for children in aromatherapy groups, 2 minutes of inhalation and 15 minutes of induction period was employed), $MCDAS_{(f)}$, (scores ranging from 6 to 30; last two question pertaining to sedation and general anesthesia were omitted) a self-report measure of anxiety[34] was recorded for all the children, irrespective of the treatment groups. For those who were randomized to experimental groups, the essential oils lavender or orange were employed using either nebulizer or inhaler, based on the group to which the child was assigned. During LA administration, the pain was assessed using FLACC scale (scores ranging from 0 to 10).[35] After LA administration FPS-R (scores ranging from 0 to 10) was recorded as a self-report measure of pain[36] and anxiety was again recorded using $MCDAS_{(f)}$ for all the children. All the variations in the pulse rate, from 15 minutes before starting the treatment to 10 minutes after LA administration were recorded using pulse oximeter (BPL Medical Technologies, India), and the mean of the values at the starting time, before, during and after LA administration were calculated. The scores obtained in all the five groups were tabulated, compared and analyzed statistically.

$MCDAS_{(f)}$ and FPS were considered as primary outcome measures for anxiety and pain respectively, whereas pulse rate and FLACC scores were secondary outcome measures. All the outcome measures were recorded by a single trained examiner (NK).

Based on the pilot study findings with 25 participants (5 for each group; not included in the main study), taking alpha error of 0.05 and 0.9 power, considering $MCDAS_{(f)}$ as the primary outcome measure a sample size of 26 (in each group) was determined. When the difference in FPS values was considered, the sample size was 28 (in each group). Hence, a sample of 150 (30 in each group) was intended. It took a period of one year to recruit this sample.

Restricted randomization i.e., block randomization was employed in the study with single block size of 10. The table of random numbers was used to generate the random allocation sequence. To prevent the selection bias, centralized assignment was used as an allocation concealment mechanism. It was an open trial.

The statistical analysis was carried out using SPSS17.0 version for Windows (SPSS Inc., Chicago, Ill., USA). The normality of the data was assessed using Shapiro-Wilk test and the level of significance was set at 0.05 level. The inter-rater reliability of FPS and FLACC was done using Cohen's kappa. The intergroup comparison of $MCDAS_{(f)}$ scores and Pulse rate among the five groups was assessed using one-way ANOVA and post hoc Bonferroni tests. The intergroup comparison of FPS-R and FLACC was assessed by Kruskal-Wallis and Mann-Whitney tests. The intragroup comparison of $MCDAS_{(f)}$ scores and pulse rate in all the five groups was done using paired *t* test.

Results

A total of 150 children (84 boys and 66 girls) were recruited into the study. The detail regarding recruitment of participants is shown in Figure 1. The mean (Standard deviation; SD) age of the participants was 9.56(1.54) (range: 8-12). The mean (SD) baseline $MCDAS_{(f)}$ score

was16.63 (4.48) (range: 7-27), whereas after intervention it was 14.45 (4.72) (range: 6-30). The mean (SD) baseline pulse rate of all the recruited children was 94.1 (15.65) (range: 62.25-152), whereas after intervention it was 97.64 (15.95) (range: 22.85-153.71). The inter-rater reliability, as calculated using Cohen's kappa, for FPS was 0.99; whereas for FLACC it was 0.98 (Done for the pilot study participants).

The intergroup comparison of $MCDAS_{(f)}$ score – 'baseline' and 'after procedure' values are represented in Table 1. There was no significant difference in the $MCDAS_{(f)}$ baseline scores among the five groups, whereas a significant difference ($P = 0.001$) was noted in the 'after procedure' values. In the post hoc, a significant difference was observed in groups 1 to 5 ($P = 0.005$), 3 to 5 ($P = 0.006$) and 4 to 5 ($P = 0.02$). Thus, lavender nebulizer, sweet orange nebulizer and sweet orange inhaler groups had a significant impact in decreasing the anxiety scores after the procedure compared to control.

The intergroup comparison of pulse rate are represented in Table 2 and 3. There was no significant difference among the five groups in pulse rate values – 'baseline'

Table 1. Intergroup comparison of $MCDAS_{(f)}$ scores among the five groups (Each group n = 30)

Parameter	Group 1	Group 2	Group 3	Group 4	Group 5	*P* value[a]
	Mean (SD) (range)					
$MCDAS_{(f)}$ baseline	16.77 (3.95) (7-23)	17.47 (4.52) (9-27)	16.73 (4.52) (7-25)	15.40 (4.73) (7-24)	16.77 (4.70) (8-26)	0.5
$MCDAS_{(f)}$ after procedure	12.87 (3.73) (6-20)	15.60 (4.29) (8-26)	13.10 (4.21) (6-20)	13.53 (4.67) (6-23)	17.13 (5.32) (8-30)	0.001***
Intergroup comparisons - *P* value[b]						
Metric data	$MCDAS_{(f)}$ Baseline	Group 1 vs group 2	1	$MCDAS_{(f)}$ After procedure	Group 1 vs group 2	0.19
		Group 1 vs group 3	1		Group 1 vs group 3	1
		Group 1 vs group 4	1		Group 1 vs group 4	1
		Group 1 vs group 5	1		Group 1 vs group 5	0.003**
		Group 2 vs group 3	1		Group 2 vs group 3	0.32
		Group 2 vs group 4	0.77		Group 2 vs group 4	0.76
		Group 2 vs group 5	1		Group 2 vs group 5	1
		Group 3 vs group 4	1		Group 3 vs group 4	1
		Group 3 vs group 5	1		Group 3 vs group 5	0.006**
		Group 4 vs group 5	1		Group 4 vs group 5	0.02*

$MCDAS_{(f)}$: Modified child dental anxiety scale - Faces version; [a] Using one-way ANOVA test; [b] Using post hoc Bonferroni test; Statistically significant at level $^{*}P \leq 0.05$, $^{**}P \leq 0.01$ and $^{***}P \leq 0.001$.

Table 2. Intergroup comparison of pulse rate among the five groups (Each group n = 30)

Parameter	Group 1	Group 2	Group 3	Group 4	Group 5	*P* value[a]
	Mean (SD) (range)					
Pulse rate-Baseline	94.29 (18.35) (62.25-128.50)	92.80 (14.92) (63.20-122.16)	96.49 (12.01) (68.50-115.60)	92.49 (12.57) (75.0-116.12)	94.40 (19.64) (65.50-152.0)	0.88
Pulse rate-Before procedure	97.39 (18.04) (70-148.25)	93.92 (16.90) (64.37-135.90)	98.80 (11.18) (69.70-119.66)	92.96 (12.03) (69.20-111.80)	98.05 (19.03) (65.0-150.0)	0.51
Intergroup comparisons (post hoc) - *P* value[b]						
Metric data	Pulse rate-baseline	Group 1 vs group 2	1	Pulse rate- before procedure	Group 1 vs group 2	1
		Group 1 vs group 3	1		Group 1 vs group 3	1
		Group 1 vs group 4	1		Group 1 vs group 4	1
		Group 1 vs group 5	1		Group 1 vs group 5	1
		Group 2 vs group 3	1		Group 2 vs group 3	1
		Group 2 vs group 4	1		Group 2 vs group 4	1
		Group 2 vs group 5	1		Group 2 vs group 5	1
		Group 3 vs group 4	1		Group 3 vs group 4	1
		Group 3 vs group 5	1		Group 3 vs group 5	1
		Group 4 vs group 5	1		Group 4 vs group 5	1

[a] Using one-way ANOVA test; [b] Using post hoc Bonferroni test.

and 'before procedure', whereas significant difference was observed in the values recorded 'during' ($P=0.01$) and 'after procedure' ($P=0.008$). The pulse rate was less in aroma groups compared to control. In the post hoc, a significant difference was observed in the groups 2 to 5 ($P=0.05$) and 4 to 5 ($P=0.03$) during the procedure. Thus, lavender/sweet orange inhalers had a significant effect on pulse. On the other hand, in those recorded after the procedure, significant difference was observed in groups 1 to 5 ($P=0.03$) and 2 to 5 ($P=0.02$). This signifies the long lasting effect of lavender on the pulse.

The intergroup comparisons of FPS-R and FLACC scores are represented in Table 4. There was a significant difference in both the FPS-R and FLACC scores recorded among the five groups. When the FPS-R values were observed, there was no significant difference in groups 1 to 3, 1 to 4 and 3 to 4. There was no difference between groups 2 and 5, with both groups reporting higher values (median = 2) than groups 1, 3 and 4 (median = 0). When the FLACC scores were observed, there was a significant difference in the groups 1 to 5 ($P<0.001$), 2 to 5 ($P=0.001$), 3 to 5 ($P=0.002$), 4 to 5 ($P=0.001$), with group 5 showing higher values.

The intragroup comparisons of the parameters

Table 3. Intergroup comparison of pulse rate among the five groups (Each group n = 30)

Parameter	Group 1	Group 2	Group 3	Group 4	Group 5	*P* value[a]
			Mean (SD) (range)			
Pulse rate – during procedure	95.26 (18.73) (60.32-151.50)	92.73 (15.38) (58.0-117.66)	100.14 (12.94) (78.07-126.80)	91.80 (14.81) (70.0-142.53)	104.780 (19.16) (75.0-161.16)	0.01*
Pulse rate – after procedure	93.66 (19.42) (22.85-141.83)	92.84 (12.89) (70.20-116.25)	100.03 (13.88) (71.0-133.0)	95.89 (12.73) (71.60-121.60)	105.78 (17.09) (70.60-153.71)	0.008**
Intergroup comparisons (Post hoc) - *P* value[b]						
Metric data	Pulse rate - during procedure	Group 1 vs group 2	1	Pulse rate - after procedure	Group 1 vs group 2	1
		Group 1 vs group 3	1		Group 1 vs group 3	1
		Group 1 vs group 4	1		Group 1 vs group 4	1
		Group 1 vs group 5	0.26		Group 1 vs group 5	0.03*
		Group 2 vs group 3	0.82		Group 2 vs group 3	0.74
		Group 2 vs group 4	1		Group 2 vs group 4	1
		Group 2 vs group 5	0.05*		Group 2 vs group 5	0.02*
		Group 3 vs group 4	0.51		Group 3 vs group 4	1
		Group 3 vs group 5	1		Group 3 vs group 5	1
		Group 4 vs group 5	0.03*		Group 4 vs group 5	0.14

[a] Using oneway ANOVA test; [b] Using post hoc Bonferroni test; Statistically significant at level * $P\leq0.05$, ** $P\leq0.01$.

Table 4. Intergroup comparison of FPS-R and FLACC scores among the five groups (Each group n = 30)

Parameters	Group 1	Group 2	Group 3	Group 4	Group 5	*P* value[a]
			Median, mode (range)			
FPS-R	0, 0 (0-6)	2, 2 (0-10)	0, 0 (0-6)	0, 0 (0-6)	2, 0 (0-10)	< 0.001***
FLACC	1, 1 (0-4)	1, 1 (0-6)	1.5, 1 (0-4)	1.5, 1 (0-5)	3, 3 (1-8)	0.001***
Intergroup comparisons - *P* value[b]						
Categorical data	FPS-R	Group 1 vs group 2	0.01**	FLACC	Group 1 vs group 2	0.9
		Group 1 vs group 3	0.55		Group 1 vs group 3	0.62
		Group 1 vs group 4	0.62		Group 1 vs group 4	0.89
		Group 1 vs group 5	0.002**		Group 1 vs group 5	<0.001***
		Group 2 vs group 3	0.001***		Group 2 vs group 3	0.76
		Group 2 vs group 4	0.003**		Group 2 vs group 4	0.99
		Group 2 vs group 5	0.21		Group 2 vs group 5	0.001***
		Group 3 vs group 4	0.99		Group 3 vs group 4	0.73
		Group 3 vs group 5	<0.001***		Group 3 vs group 5	0.002**
		Group 4 vs group 5	0.001***		Group 4 vs group 5	0.001***

FPS-R: Faces pain scale-revised; FLACC: Faces, Legs, Activity, Cry and Consolability scale.

[a] Using Kruskal-Wallis test; [b] Using Mann-Whitney test; Statistically significant at level ** $P\leq0.01$ and *** $P\leq0.001$.

$MCDAS_{(f)}$ and pulse rate are represented in Table 5. In the $MCDAS_{(f)}$ scores, there was a significant difference between 'baseline' and 'after procedure' values in all the aroma groups, with 'after procedure' values being lower than 'baseline'; on the other hand, there was a non-significant increase in the control group. In the pulse rate, there were no significant differences in the aroma groups; only in control a significant increase was observed in different timelines.

Discussion

In pediatric dentistry, LA administration is the common invasive procedure, which triggers dental anxiety and fear in children.[37] Anxious and fearful children experience pain of higher intensity and longer duration.[38] Hence, the main focus of research is to reduce these emotions. To accomplish this, pediatric dentists employ many behavior guidance techniques, either non-pharmacological[2] or pharmacological.[39] The pharmacological anxiolytic drugs, such as benzodiazepines, have been associated with unwanted sedative and withdrawal effects; and the possibility of addiction is another adverse effect.[40,41] Hence, apart from the proposed conventional behavioral guidance techniques for reduction in apprehension and associated pain, many complementary and alternative therapeutic regimens have been advocated and studied as adjunctive therapies.[1,31,39,42] Aromatherapy is one among the proposed, and this has an added clinical advantage of being non-invasive and inexpensive. This therapy uses essential oils which are scented, volatile liquid substances removed from plants using steam or pressure. Thus, it is the controlled use of plant essences for therapeutic purpose which has been successfully reported to alleviate generalized anxiety and pain.[43]

As odours are capable of altering the emotional condition of human beings,[22] this study has been undertaken to test the efficacy of aromatherapy in reducing anxiety and pain associated with LA administration in pediatric dentistry. The essential oils, lavender and sweet orange, have been employed here, as a study done on the preference of essential oils among children have included these oils.[11] Further, the beneficial effect of both these oils on dental anxiety of children undergoing non- invasive treatments as well as adults is well reported.[1,22-27,31] Further, usage of essential oils in waiting room of dental office has been tested for its positive influence on anxiety and improved mood.[22,26,27] Two forms of inhalation, nebulizer and inhaler, were employed in the present study. Nebulizer is an electric or battery powered machine that turn liquid into mist. It works on ultrasonic action and also has humidifier action. It has 100 mL capacity water tank, ultrasonic frequency of 2.4 MHz and automatic off technology. Another method for inhalation aromatherapy considered in the present study was inhalers. These are long lip stick sized with empty cotton wick inside. Dispensing the essential oil onto the wick facilitates even dispersion of oil molecules.

In the current study, there was a definite positive influence of aromatherapy, either in the form nebulizer or inhaler, on the anxiety scores of children. This is in accordance with the previous studies done on the effect of lavender and sweet orange essential oils on dental anxiety.[1,22-27,31] The main difference in this study compared to previous ones is testing the efficacy of inhalers as additional groups. When comparison was made among nebulizers and inhalers, nebulizers had better impact on decreasing the anxiety scores. The beneficial aspect of nebulizer can be due to mild, constant supply of essential oil molecules compared to periodic inhalation of the oil using inhalers. Among the inhaler groups, lavender had less impact compared to sweet orange. This can be due to the difference in the odour; strong pungent nature of lavender, compared to mild, pleasing and acceptable smell of sweet orange. Also, the familiarity of the sweet orange odour might have given better comfort to the children. Another reason reported in literature is that, lavender in high concentration can have a stimulating effect rather than the calming effects noted with moderate quantities,[21] as observed in inhaler group. On the other hand, there was a lack of dose/effect relationship with sweet orange in a study performed on student volunteers to assess the anxiolytic effects.[19] There is no reported study optimizing the posology of aroma for relieving anxiety; the duration of exposure is also not standardized. The therapists recommendation vary from few breaths to few minutes.[19] The unit of dosage cannot be precisely measured as the size of the drop depends on type of oil and dropper used.[44] However, in the current study, two minutes of aromatherapy was given with 2-3 drops dispensed into inhalers and 6-8 drops for nebulizer.

The physiological parameter considered in the present study was the pulse rate, which showed a characteristic observation in the 'during' and 'after the procedure' values. Of the nebulizer and inhaler groups, irrespective of the essential oil used, only inhaler had a beneficial effect. This might be due to quick inhalation of volatile compounds with inhaler compared to nebulizer. There is no reported study where in inhalers were used, and though it is for the first time, this method had shown a positive impact on physiological parameter. Though not similar to the current findings, the sustained placement of lavender oil (3 mL) throughout the night (8 hours) has shown reduction in heart rate.[13]

This is the first study to investigate the effect of inhalation aromatherapy on pain experience of children undergoing LA administration. Pain reduction during invasive procedures has a positive impact on the child and parent satisfaction. In medical field, studies that observed positive effect of essential oils, reported greater impact on acute pain than chronic.[6] Of these studies which are summarized in a review, few have used the inhalational route,[13,18-20] whereas the others considered topical.[8,43] An absolute olfactory mode of stimulation, inhalation, has

Table 5. Intragroup comparison of MCDAS $_{(f)}$ scores and pulse rate values among the five groups

	MCDAS $_{(f)}$	Baseline	After procedure	*P* value[a]	Pulse rate	Baseline	Pulse rate - before procedure	Pulse rate - during procedure	Pulse rate - after procedure
Group 1 (n = 30)		16.77 (3.95) (7-23)	12.87 (3.73) (6-20)	<0.001***		94.29 (18.35) (62.25-128.50)	97.39 (18.04) (70-148.25)	95.26 (18.73) (60.32-151.50)	93.66 (19.42) (22.85-141.83)
Group 2 (n = 30)		17.47 (4.52) (9-27)	15.60 (4.29) (8-26)	0.04*		92.80 (14.92) (63.20-122.16)	93.92 (16.90) (64.37-135.90)	92.73 (15.38) (58.0-117.66)	92.84 (12.89) (70.20-116.25)
Group 3 (n = 30)		16.73 (4.52) (7-25)	13.10 (4.21) (6-20)	<0.001***		96.49 (12.01) (68.50-115.60)	98.80 (11.18) (69.70-119.66)	100.14 (12.94) (78.07-126.80)	100.03 (13.88) (71.0-133.0)
Group 4 (n = 30)		15.40 (4.73) (7-24)	13.53 (4.67) (6-23)	0.01*		92.49 (12.57) (75.0-116.12)	92.96 (12.03) (69.20-111.80)	91.80 (14.81) (70.0-142.53)	95.89 (12.73) (71.60-121.60)
Group 5 (n = 30)		16.77 (4.70) (8-26)	17.13 (5.32) (8-30)	0.60		94.40 (19.64) (65.50-152.0)	98.05 (19.03) (65.0-150.0)	104.780 (19.16) (75.0-161.16)	105.78 (17.09) (70.60-153.71)

Pulse rate									
Group 1	***P* value[a]**	**Group 2**	***P* value[a]**	**Group 3**	***P* value[a]**	**Group 4**	***P* value[a]**	**Group 5**	***P* value[a]**
Baseline to before procedure	0.24	Baseline to before procedure	0.69	Baseline to before procedure	0.25	Baseline to before procedure	0.80	Baseline to Before procedure	0.19
Baseline to during procedure	0.78	Baseline to during procedure	0.98	Baseline to during procedure	0.12	Baseline to during procedure	0.80	Baseline to During procedure	<0.001***
Baseline to after procedure	0.88	Baseline to after procedure	0.98	Baseline to after procedure	0.11	Baseline to after procedure	0.12	Baseline to After procedure	<0.001***
Before procedure to during procedure	0.39	Before procedure to during procedure	0.64	Before procedure to during procedure	0.48	Before procedure to during procedure	0.59	Before procedure to During procedure	0.02*
Before procedure to after procedure	0.35	Before procedure to after procedure	0.72	Before procedure to after procedure	0.56	Before procedure to after procedure	0.17	Before procedure to After procedure	0.02*
During procedure to after procedure	0.54	During procedure to after procedure	0.95	During procedure to after procedure	0.97	During procedure to after procedure	0.08	During procedure to After procedure	0.56

MCDAS $_{(f)}$: Modified child dental anxiety scale- Faces version.

[a] Paired t test; Statistically significant at level*$P \leq 0.05$ and ***$P \leq 0.001$.

been considered in the present study, for which nebulizers and inhalers have been employed. The reason for choosing the inhalation route is the safety issue; no adverse effects have been reported through the inhalation of essential oils considered in the currentstudy.[43] The aromatherapy, either with nebulizer or inhaler, showed a significant effect on the pain scores recorded. These findings were in accordance with other studies projecting aromatherapy as a non-invasive and non-pharmacological alternative intervention.[6,18] Minimum training needed to perform the aromatherapy is an added advantage. The volatile essential oil molecules absorbed through the nasal mucosa are proposed to get transformed into a chemical signal that travels to the olfactory bulb, then amygdala and limbic system, interacting with neuropsychological pathway producing the characteristic effect on the tissues.[45,46] A randomized trial conducted to assess the effectiveness of aromatherapy intervention on the reduction of children's distress in peri-anesthesia setting observed reduction in the distress level for those in essential oil group.[21] This is in accordance with the current study. However, the authors mentioned that the findings cannot be generalized because of the heterogeneity of the sample (children with and without developmental disabilities were included). The use of only observational scale of pain was stated as one of the limitations of their study.[21] The positive aspect of the current study is overcoming these limitations by including homogenous sample and assessing the pain using self-report scale.

When the gender differences were observed, there was a decrease in anxiety scores with aromatherapy in both boys and girls, but statistical difference was observed only in girls. This is in accordance with the previous studies, where females were benefited better by aromatherapy.[46,47] In the pain scores also, it seems girls had the most beneficial effect of aromatherapy.

The results of this study highlight the need to provide additional supportive care for children undergoing invasive dental treatments. The aromatherapy can be used safely along with other medications and need not be down titrated for discontinuation. This can be safely added to behavior guidance techniques to reduce anxiety and pain, as no adverse effects were reported in the current study. Aromatherapy also helps to combat the unpleasant odors that can sometimes provoke anxiety for children in the dental operatory. The major strength of this study is the usage of 100% pure essential oil and the reliability of the findings, as sample size was calculated based on the effect size. Also, both anxiety and pain were considered along with recording of physiological parameter. However, the major limitation of the study is the inclusion of children with different diagnosis and treatment needs. The age group of the study sample is also limited and hence, cannot be generalized to all the children. Additionally, EEG which might prove useful to understand the mechanism of action was not considered. This study is not meant to project aromatherapy as a replacement for conventional approaches, but as an additive. Further studies to investigate the effect of aromatherapy in wider age range and the influence of odorant mixtures can be tried. As the scientific support for this therapy is less, there is a need to perform further randomized controlled clinical trials.

Conclusion

Based on the study findings, within the limitations, it can be concluded that: (*a*) Aromatherapy with lavender or sweet orange using either nebulizer or inhaler decreases the dental anxiety of children; (*b*) Aromatherapy with lavender or sweet orange reduced the pulse rate in children. The effect of essential oils on this parameter was more with inhaler compared to nebulizer; (*c*) Aromatherapy with sweet orange using either nebulizer or inhaler decreased the pain reported by children using FPS-R. On the other hand, lavender using nebulizer decreased the pain whereas inhaler could not; d- In the observational scale of pain (FLACC), aromatherapy decreased the LA pain in children.

Thus, aromatherapy had a positive impact on the dental anxiety and pain of children undergoing LA administration.

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Ethical Issues

Ethical approval was obtained from the Institutional Ethical Committee (Reference No. NDC/IECC/PEDO/12-17/05).

Conflict of Interest

The authors declare no conflict of interest in this study.

Research Highlights

What is the current knowledge?

- Lavender aromatherapy reduced dental anxiety of children during restorative treatment.
- Orange aromatherapy reduced dental anxiety of children during restorative treatment.
- Lavender aromatherapy reduced pain experienced by children during dental extractions.

What is new here?

- Lavender and orange aromatherapy could reduce the dental anxiety and pain experienced by children undergoing local anesthetic administration.
- Usage of essential oils in inhalers was as effective as conventional aromatherapy.

Authors' Contributions

RK: Conceptualization, methodology, formal analysis, supervision; NK, RK: Investigation, data curation, writing-original draft preparation, writing-review and editing, project administration. Both the authors have read and agreed to the published version of the manuscript.

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