



## Research article

# Evaluation of lavender and rose aromatherapies on the success of inferior alveolar nerve block in symptomatic irreversible pulpitis: A randomized clinical trial

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## ABSTRACT

**Trial design:** This is a prospective, block-randomized, blinded, multiple arm and parallel-group superiority clinical trial.

**Methods:** Seventy-eight patients satisfying the recruitment standards, were randomly allocated into three groups as follows: Group I (n = 26) – Inferior alveolar nerve block (IANB) devoid of aromatherapy (AT); Group II (n = 26) - IANB with lavender AT and Group III - IANB with rose AT (n = 26) with the help of the ultrasonic aroma diffuser (with respective oils)for 20 min/2 h in operatories 1,2 and 3 respectively. For AT, 3–4 drops of lavender and rose-conditioned oils were added from a 100 ml solution containing 100 mg of these medicinal plants. The pre-operative (PRO) and access opening (AO) pain as well as the anxiety of patients were recorded using the Visual Analog Scale (VAS) and Modified Dental Anxiety Scale (MDAS) respectively. Data thus obtained was entered into the Excel sheet and subjected to statistical tests (analysis of variance and paired *t*-test). The *p*-value less than 0.05 was considered statistically significant.

**Results:** Group I showed non-significant disparity between PRO and AO for both VAS as well as MDAS (*p* = 0.62, *p* = 0.71). However, group II (*p* = 0.04, *p* = 0.02) and group III (*p* = 0.03, *p* =

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0.01) revealed significant differences between PO - AO VAS and MDAS. MDAS and VAS inter-group comparison revealed a significant difference among groups I and II ( $p = 0.03$ ,  $p = 0.04$ ), and groups I and III ( $p = 0.02$ ,  $p = 0.03$ ). However non-significant disparity was observed among groups II and III ( $p = 0.85$ ,  $0.34$ ). Moreover, there was a statistically significant reduction in anxiety levels in females compared to males after rose AT ( $p = 0.02$ ). Nevertheless, groups I and II did not show any gender predilection for anxiety as well as pain.

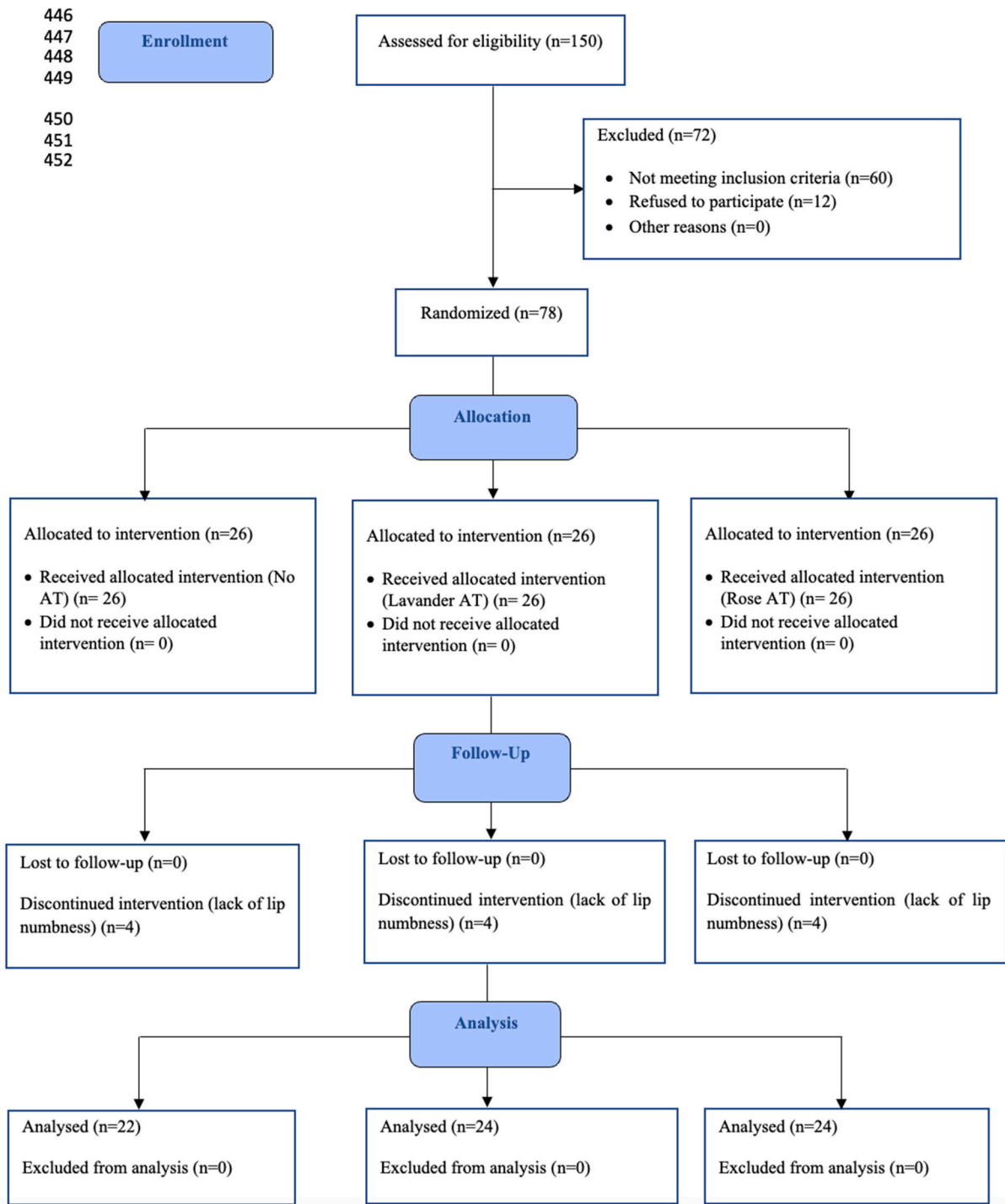


Fig. 1. CONSORT flow diagram.

**Conclusion:** Alleviation of dental anxiety as well as reduction in pain during AO of teeth with SIP can be achieved using Lavender and rose AT. In female patients, rose AT can be preferred over lavender AT.

## 1. Introduction

The endodontic management of teeth with symptomatic irreversible pulpitis (SIP) is a treatment challenge. Various reasons have been cited in the literature for the limited success of local anaesthesia in teeth with symptomatic irreversible pulpitis (SIP). In SIP cases, inflamed and/or infected tissues have decreased pH, which results in less availability of anaesthetic in the base form that can penetrate nerve membranes to produce anaesthesia. Moreover, upregulation of anaesthetic-resistant sodium channels in nerve membranes, prevent the effective anaesthesia [1]. TTX-resistant class of sodium channels are also responsible for local anaesthetic failures as these channels which are expressed on nociceptors, are relatively resistant to lidocaine and their activity is increased with PGE 2 [2,3]. Central sensitization may also contribute to local anaesthetic failures [4]. In endodontics, the infiltration anaesthesia technique is used for the maxillary molars, while block anaesthesia is needed for the mandibular teeth. Mandibular molars show a higher chance of local anaesthesia failure compared to maxillary posteriors [5]. Inferior alveolar nerve block (IANB) is given to secure anaesthesia for the root canal treatment of the mandibular molar with SIP. However previous studies showed that the success rate of IANB was only 19%–56 % in such teeth [6]. Moreover, patients with tooth pain are often worried, which also affect the pain as it lowers the pain threshold. Apprehensive patients with reduced pain threshold results in local anaesthetics failure. Physiologically, entorhinal cortex of the hippocampus formation responds differentially to noxious stimuli in case of anxiety [7–9]. Review of literature shows that dental anxiety (DA) influences success of IANB [1,10]. The prevalence of DA is on higher side when patient is waiting for dental treatment in clinics [11]. Hence, endodontic treatment of mandibular molars with SIP is often demanding [12,13].

Previous studies have assessed several plausible pharmacological and non-pharmacological methods to improve the anaesthetic success of IANBs [14–16]. Use of anti-inflammatory medications in pharmacological method may result in adverse effects such as gastrointestinal ulcers, allergic reactions [17]. However, there are several advantages of non-pharmacological methods like Aromatherapy (AT), such as safety, lack of adverse effects compared to pharmacological methods [18]. Aromatherapy (AT) is one of the safe non-pharmacological methods that alleviate pain by direct or indirect pathways. It involves use of aromatic oil that is absorbed through the skin to induce relaxation and thereby reduce anxiety. AT is free of adverse effects as compared to traditionally used pharmacological methods [19–21]. Lavender oil is obtained from the flowers of *Lavandula angustifolia* and Rose oil is obtained mainly from *Rosa damascena* also known as Damask rose. *Lavandula angustifolia* is a flowering plant in the family Lamiaceae, native to the Mediterranean (Spain, France, Italy, Croatia). Damask rose is found in Bulgaria, India, France, Tunisia, Morocco, and other Middle Eastern nations. Lavender and rose are the most frequently used essential oils for anxiety and pain management in the medical disciplines like during lumbar epidural steroid injections, caesarean section, insertion of Intra uterine device and open-heart surgery patients [22–25]. In dentistry, lavender and rose have shown promising effects [26,27–29]. Among lavender and rose, lavender has been successfully used to increase the effectiveness of IANB in irreversible pulpitis. Study conducted by Jadhav *et al.* concluded that success rate of lavender aromatherapy in effectiveness of IANB to be 100 % as compared to control group (55 %) [27]. However, no research has been dedicated to comparing the effect of rose AT with lavender AT in the anaesthetic success of IANB. Hence the study was planned to compare the effects of lavender as well as rose aromatherapies on pain, anxiety and to evaluate the success of IANB during endodontic management of teeth with SIP.

### 1.1. Material and methodology

This prospective, block-randomized, blinded, multiple arm and parallel-group superiority clinical trial was planned after obtaining ethical clearance (IEC/Faculty/026/2023) (Fig. 1). The trial was registered under the Clinical Trial Registry of India (CTRI/2023/09/057615). All the procedures were followed conforming to the Helsinki Declaration of the World Medical Association. The sample size was calculated (<https://drsm.in/>) assuming the study's power to be 80 % ( $1-\beta$ ) and the level of significance to be 5 % ( $\alpha$ ). Based on the calculations, the minimum sample size was obtained to be 70. Assuming about 10 % dropouts, a minimum 26 patients were recruited in each group. Hence a total of 78 ( $n = 26$  in each group) patients were recruited in the study. Visual analogue scale (VAS) is divided into 4 categories as 0–4 mm (no pain), 5–44 mm (mild pain), 45–74 mm (moderate pain) and 75–100 mm (severe pain) [30]. For the ease of evaluation, these score values were dichotomized as success (for no to mild pain) and failure (for moderate to severe pain). Hence the success of the IANB was evaluated as  $\leq 44$  on the VAS during access opening (AO). The patient's anxiety level was evaluated on the Modified Dental Anxiety Scale (MDAS) corresponding to five different dental situations. *Consolidated Standards of Reporting Trials (COSORT)* guidelines were followed in this clinical trial. Two endodontists ( $> 8$  years of academic and clinical expertise) carried out all the clinical steps of the study by randomly dividing participants from each group using a coin toss method.

The adult participants ( $n = 150$ ) referring to the Department of conservative dentistry and endodontics in the institute with SIP in lower molars were included in the study. They were explained about the study protocol along with the use of pain and anxiety scales. The participants fulfilling the inclusion criteria ( $n = 78$ ) were requested to give written informed consent. The eligibility criteria used for the inclusion of participants in study was as follows. The healthy participants with SIP in the mandibular molar (lingering pulp cold sensibility tests response and preoperative pain  $\geq 50$  mm on the VAS), no peri-apical changes in IOPA x-ray, and vital pulp were included in the trial. The participants with satisfactory olfaction, with no allergy to lignocaine, no history of consumption of analgesics

12 h prior, and healthy periodontium were included. The participants with the lack of lip numbness after IANB administration from group I ( $n = 4$ ), group II ( $n = 2$ ), and group III ( $n = 2$ ) were excluded from the study.

In Modified Dental Anxiety Scale (MDAS), the participants grade their anxiety by their assessment of different dental situations. It contains a set of 5 questions with 5 possible answers based on the grades of anxiety ranging from not anxious to extremely anxious (score 1 to 5). The final score (ranges between 5 and 25) is obtained by adding each question's score. In VAS, the 100-mm line was divided into four categories - 0–4 mm for no pain, 5–44 mm for mild pain, 45–74 mm for moderate pain, and 75–100 mm for severe pain. If the first two categories (no to mild pain) were seen during AO then AT was considered effective. Here, VAS was dichotomized into two categories to separate the success (no to mild pain = 0–44 mm) of AT from failure (moderate to severe pain = 45–100 mm). Patients were asked to portray a line perpendicular to a VAS line at the point corresponding to their pain. The distance between the patient's mark line and the "0 mm" point was calculated with the help of a vernier calliper. VAS and MDAS are valid and reliable scales for pain and anxiety assessments respectively [31,32]. Olfactory function test was performed in patients before inclusion in the study as the present study was related to aromatherapy which involves inhalation of essential oils. Walker HK *et al.* has given a protocol to test intact olfactory function [33]. According to this protocol, the participant with closed eyes was instructed to seal his/her one nostril and to sniff four different substances (vanilla, lemon, scented soap, and freshly ground coffee). The source of the odour was kept at a distance of less than 30 cm. The same steps were carried out for another nostril. An accurate diagnosis of a substance shows that the olfactory function of a participant is intact (Fig. 1).

The randomization was achieved using a Random Sequence Generator (<http://www.random.org/>). An independent researcher generated random numbers through the randomization algorithm and these numbers were allocated to participants as they completed enrolment. Enrolled and consenting patients were allocated randomly (block randomization) equally into 3 groups (1:1:1) as group I (control – no AT), group II (lavender AT) and group III (rose AT). Here, the masking was achieved using a sealed envelope method. In the sealed envelope method, the randomly generated number was written on paper and it was kept in an opaque sealed envelope by data entry operator. A field assistant opened the sealed envelope and participants were assigned to the respective treatment groups accordingly. Pre-operative (PRO) pain evaluation was completed before treatment initiation. In groups II and III, lavender and rose-conditioned oils (Exotic aromas, Vancom solutions, Gurgaon, Haryana) were added to the ultrasonic aroma diffuser (Iris – ultrasonic aroma diffuser, IRIS Home Fragrance, Mysuru, India. AT was applied for 20 min/2 h during treatment as it gives the best results in short bursts due to the suspension of ionized micro-droplets in the air. For AT, 3–4 drops of lavender and rose-conditioned oils were added from a 100 ml solution containing 100 mg of these medicinal plants. In group I, a similar protocol was followed except aroma oil was substituted by plain water. Three distinct operatories were selected with similar operator interior and same clinical set-ups to ensure the internal validity of the study.

IANB was administered using a 5 cc syringe with a 27-G needle using the Traditional Halsted technique. (Xicaine, ICPA Health Products Ltd., Mumbai, India). Traditional Halsted technique is most commonly used technique for anaesthesia of the inferior alveolar nerve. It is a direct technique in which the inferior alveolar nerve is reached by an intraoral access before it penetrates the mandibular canal. In this technique, needle was inserted and once it hit the bone, aspiration was carried out and the anaesthetic solution (2 % lidocaine with 1:80000 epinephrine) was deposited if it showed negative aspiration. Lidocaine with epinephrine is the most commonly used local anaesthetic drug in dentistry. Epinephrine is added to lidocaine to minimize the hemorrhage, minimize systemic absorption of lidocaine and increase the duration of anaesthesia. All signs and symptoms (eg - lip numbness) of successful administration of IANB were checked after 15 min. The participants showing a lack of these symptoms were excluded from the trial. The tooth isolation was achieved using a rubber dam and conventional access opening (AO) was done. The participant was instructed to rate his/her pain. This pain was evaluated by an independent evaluator who was blinded about the participant's group allocation.

The patient's anxiety and pain scores were entered in a Microsoft Office Excel Sheet (v 2010). SPSS software (Version 21.0. Armonk, NY: IBM Corp) was used for statistical evaluation. Shapiro-Wilk test showed that the data set was normally distributed and hence parametric tests (paired *t*-test and analysis of variance) were applied. Intra-group evaluation (between PRO and AO) of MDAS and VAS was done using paired *t*-test. Inter-group comparison amongst 3 groups was achieved using analysis of variance test. The confidence interval was kept at 95 % and *p* value less than 0.05 was assumed significant.

## 2. Results

Here 40 men and 38 women participated in the study between the period of September 15, 2023 to November 30, 2023. There were no significant harms or unintended effects observed in any of the participants. The participants with the lack of lip numbness after IANB administration from group I ( $n = 4$ ), group II ( $n = 2$ ), and group III ( $n = 2$ ) were excluded from the study. The average ages of the participants were  $26.18 \pm 3.8$  years,  $26.22 \pm 4.4$  years, and  $26.18 \pm 3.8$  years in groups I, II, and III respectively. The age ( $p = 0.97$ ) and gender ( $p = 0.55$ ) did not show any significant difference among all 3 groups. The patient's demographics are depicted in Table 1. The mean PRO MDAS and VAS scores were  $20.38 \pm 4.0$  and  $80.00 \pm 7.8$  in group I,  $19.27 \pm 4.2$  and  $79.27 \pm 7.1$  in group II,  $20.11 \pm$

**Table 1**  
Comparison of Age and Gender (Analysis of Variance test).

Characteristics	Group I	Group II	Group III	<i>p</i> value
Age	$26.18 \pm 3.8$	$26.22 \pm 4.4$	$26.18 \pm 3.8$	0.97
Gender	14 men 12 women	13 men 13 women	13 men 13 women	0.55

4.1 and  $79.99 \pm 7.1$  in group III (Table 2). So, there were no statistically significant differences in PRO MDAS and VAS scores between all groups (Table 3).

There was a statistically significant difference in AO MDAS and VAS scores between groups I-II ( $p = 0.03$  and  $0.04$ ), and I-III ( $p = 0.02$  and  $0.03$ ) (Table 3). However, there was a non-significant difference in AO MDAS and VAS scores between groups II-III ( $p = 0.53$  and  $0.37$ ) (Table 3).

Intragroup comparison of anxiety and pain score reduction revealed significant gender predilection for groups I and II. However, rose AT showed a statistically significant reduction in anxiety score ( $p = 0.02$ ) in females compared to males. (Table 4).

### 3. Discussion

Essential oils used in AT are natural, composite substances taken out from different plant organs [34]. In the medical discipline, lavender and rose AT were commonly used as a non-pharmacological technique for the alleviation of anxiety and pain [35,36]Surya et al. conducted a study with an aim to determine the effectiveness of lavender and rose aromatherapy on pain intensity of postoperative patients after surgery and concluded that both aromatherapies reduced pain intensity successfully [37]. Lavender and rose aromatherapies have been used extensively in medical field, thus its role has been explored in present study. The lavender plant is originated from the Mediterranean region and Rose has its origin in Central Asia and Northern Europe. In dentistry, lavender and rose AT were used for the alleviation of anxiety [38,39]. However, to date, no study compared the pain and anxiety alleviating effect of lavender and rose AT during the endodontic treatment of teeth with SIP. Hence, the current study with an objective to compare the effect of lavender and rose aromatherapies on pain and anxiety during endodontic management of teeth with SIP was conducted.

The PRO pain and anxiety scores as well as the demographic characteristics of participants (sex and age) were non-significantly different between all three groups (Table 1) (Table 2). Hence, the trial outcome was not affected by these factors. The present study showed a significant reduction in anxiety levels after both lavender and rose AT. These findings agree with the previous study which concluded that lavender oil and rose AT reduced the DA in orthodontic patients [38,40]. S et al. conducted a study to compare the effect on anxiety levels between lavender oil, rose oil, and a placebo and concluded that aromatherapy offers promising effect against dental anxiety among orthodontic patients. Lavender consists of various components. Among those components, the linalool and linalyl acetate components are responsible for anxiolytic effect [41]. These components show interaction with the N-methyl-D-aspartate (NMDA) receptors on which various excitatory neurotransmitters act in the hippocampus which functions in emotionalism and cognition to alleviate anxiety [42]. Administration of NMDA receptor antagonists reduces the anxiety [43]. Moreover, the hydroxyl component of linalool is vital for the functioning of serotonin transporter (SERT). SERT, a primary neurotransmission modulator, plays a central role in the anxiolytic effect and hence antidepressants target it [44]. Inhibiting SERT by linalool component increases the amount serotonin available in the synapse, which in turn leads to downstream cellular and molecular adaptations which results in antidepressant's activity [45]. Thus, lavender shows antidepressant activity by two pathways - modulation of NMDA receptor and SERT hindrance. The relaxing effect of rose oil is due to its components citronellol and geraniol, which excite raphe nuclei present in the brain stem that leads to the release of serotonin which gives a soothing effect [46,47–49]. The above-mentioned pharmacokinetics show that both lavender and rose oil led to an anxiolytic effect and hence our results show a statistically non-significant difference in the anxiolytic properties of lavender and rose AT. This result was in accordance with the previous study conducted by Burnett et al. in 2004, where both scents were employed during anxiety-eliciting tasks in college students. The literature shows that the lavender and rose AT also diminishes anxiety-related tension and fatigue [50]. Our findings are in agreement with the study by Zabirunnisa et al. that exhibited significant anxiety score reduction in the Lavender AT group [51]. So, lavender and rose are an effective means of reducing current anxiety levels and can be perceived as a means of chair-side reduction of patient anxiety in a dental setting. The present study showed that rose AT reduces the MDAS in females to a greater extent as compared to males. This is because the geraniol component of rose oil has an estrogenic activity [52]. Estrogens administration elicits anxiolytic and antidepressant-like effects. Thus, this could be a reason for showing a more anxiolytic effect of rose AT in females as compared to males. This finding is in concurrence with the previous study conducted by Emadikhalaf M et al. in 2023 which concluded that rose AT was better in relieving the job stress of female nurses compared to lavender AT [53]. The present study showed a significant difference in pain scores in Group II and Group III as compared to the control group (Table 3). This analgesic effect of lavender AT is due to its linalool component which reduces the acetylcholine discharge during neural transmission [54]. Acetylcholine is a neurotransmitter at various synapses. When a nerve impulse arrives at the nerve ending, acetylcholine stored in vesicles, is released, and binds to a postsynaptic receptor, causing depolarization. Inhibition of cholinergic receptors or blockage of acetylcholine discharge results in reduction of pain. Phytochemical

**Table 2**

Intragroup comparison (Paired *t*-test) of pre-operative and access opening MDAS and VAS Scores.

Groups		MDAS			VAS		
		Mean	SD	p value	Mean	SD	p value
I	Pre-operative	20.3846	4.01075	0.62	80.0000	7.80769	0.71
	Access opening	14.2273	5.60554		46.6818	14.35398	
II	Pre-operative	19.2743	4.21244	0.04	79.2692	7.13054	0.02
	Access opening	9.5833	2.12473		21.5417	8.25137	
III	Pre-operative	20.1103	4.1321	0.03	79.9932	7.1203	0.01
	Access opening	7.5672	1.8112		21.3117	8.1123	

**Table 3**  
Intergroup comparison (Analysis of Variance test) of Pre-Operative and Access Opening MDAS and VAS Scores.

	Group	MDAS	VAS
		p value	
Pre-operative	I and II	0.74	0.68
	II and III	0.53	0.37
	I and III	0.66	0.57
Access opening	I and II	0.03	0.04
	II and III	0.85	0.34
	I and III	0.02	0.03

**Table 4**  
Intragroup comparison (Student *t*-test) of MDAS and VAS Scores for gender predilection.

		MDAS	VAS
		p value	
I	Male	0.47	0.38
	Female		
II	Male	0.55	0.47
	Female		
III	Male	0.02	0.05
	Female		

components (sytrinol and 2-phenyl ethyl alcohol) of rose oil stimulate the olfactory sensory system. It excites the parasympathetic nervous system as well as reduces the sympathetic activity. This leads to the release of various neurotransmitters (enkephalin and endorphin), cortisol and noradrenalin that reduce the pain after rose AT [55]. Endorphins and enkephalins are powerful peptide or polypeptide analgesics. Moreover, Noradrenaline which is also released by rose aromatherapy inhibits acute pain through  $\alpha_2$ -adrenergic receptors by pre-synaptic (inhibit neurotransmitters release) and post-synaptic (hyperpolarize cell membranes) mechanisms [56]. In a previous study, Manaf et al. stated that lavender and rose AT were evenly successful in reducing childbirth pain [57]. Jadhav et al. in their clinical trial stated that lavender AT improves the success rate of IANB during the endodontic treatment of teeth with SIP [27]. This is the novel clinical trial as it compared the anxiolytic and analgesic effects of lavender and rose AT during the root canal treatment of teeth with irreversible pulpitis. The optimum anaesthesia during the endodontic management of lower molars with SIP is treatment challenge [58,59]. So, the current trial substantiates the use of lavender and rose AT as economical, efficient means for pain as well as anxiety alleviation measures during the endodontic treatment. This reduction in pain as well as anxiety during endodontic treatment improves the patient compliance, satisfaction, and overall treatment success. Numerous scales have been used to assess DA. Here, MDAS was selected due to its properties like validity, accuracy, and multilingual translatability [60]. The pain can be assessed with either unidimensional or multidimensional pain scales. In the current study, a unidimensional pain scale viz VAS was chosen due to its ease of application, validity, reliability, minimum administrative burden and consistency. The previous studies showed the reliability and sensitivity of VAS [61]. Few limitations are associated with the study like inter-patient variability and recruitment of patients from the limited geographical area. So, a multi-centric trail with a wide population coverage can be an area for future research.

#### 4. Conclusion

In conclusion, lavender and rose AT can be used as adjuncts to increase the success rate of IANB in teeth with SIP. Although both scents can be used to relieve anxiety, rose AT should be preferred for female patients. This can be an effective non-pharmacological method to achieve deeper local anaesthesia in teeth pulpal inflammation.

#### Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of the Institute, [ethical clearance (IEC/Faculty/026/2023)]. The trial was registered under the Clinical Trial Registry of India (CTRI/2023/09/057615)]. The study protocol was developed, and all subjects gave their written informed consent for inclusion before they participated in the study.

#### Consent for publications

Not Applicable.

## Availability of data and materials

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

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## CRediT authorship contribution statement

**Priya Mittal:** Formal analysis, Data curation, Conceptualization. **Ganesh R. Jadhav:** Funding acquisition, Formal analysis, Conceptualization. **Mohammed Abdul Kader M:** Resources, Project administration, Methodology, Conceptualization. **Anjali Rajesh Gaikwad:** Supervision, Software, Resources, Project administration, Methodology. **Siddharth Shinde:** Software, Resources, Project administration. **Marco Di Blasio:** Writing – original draft, Visualization, Validation. **Vincenzo Ronsivalle:** Supervision, Software, Resources. **Marco Cicciù:** Writing – review & editing, Writing – original draft, Visualization. **Giuseppe Minervini:** Writing – review & editing, Writing – original draft, Visualization.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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