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A comparison between the effect of lignocaine and articaine in nitrous oxide sedated paediatric dental patients: A prospective study

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Abstract
Background*: Nitrous oxide-oxygen (N_2O-O_2) sedation prior to local anaesthesia for dental treatment is highly accepted behaviour modification technique for anxious paediatric patients. This study aimed to compare the effects of 2% lignocaine and 4% articaine in patients under N_2O-O_2 sedation.*
Materials and Methods*: Total 36 patients requiring mandibular molar extractions were selected. They were divided into two groups: Group A - 2% lignocaine with adrenaline 1:80,000 and Group B - 4% articaine with adrenaline 1:100,000. Ellis scoring system was used to grade their behavioural characteristics under sedation. Childrens' disruptive behaviour was assessed using Face, Legs, Activity, Cry, Consolability (FLACC) scale. Peripheral arterial oxygen saturation (SpO_2), Pulse Rate (PR) and Respiratory Rate (RR) were recorded at three stages: 3 min before injection (Stage 1), during injection (Stage 2), and 5 min after injection during extraction (Stage 3). Independent sample t-test, chi square test and paired sample t-test were used.*
Results*: FLACC scores were statistically insignificant between the groups but higher value of FLACC for lignocaine group was clinically obtained. Statistically insignificant changes were seen in SpO_2 and RR mean values in both the groups ($P > 0.05$). There was statistically significant difference in stage 2 and stage 3 PR readings ($P < 0.05$) between the groups while it was statistically insignificant in stage 1.*
Conclusion*: Lower values of FLACC and stable haemodynamic parameters during extraction makes articaine a likely choice as anaesthetic in paediatric patients.*
Key words*: Local Anaesthetic; Nitrous Oxide; Paediatric Dentistry.*

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I. Introduction

Behaviour management is a cornerstone of the paediatric dental specialty. If non pharmacological behavior management techniques alone prove unproductive, pharmacological sedative agents should be considered as an effective option. "The standard sedative technique'' in pediatric dentistry at present is nitrous oxide oxygen inhalation sedation. Use of pharmacological behavior management techniques such as nitrous oxide conscious sedation coupled with local anaesthesia when required forms the foundation of the delivery of pain-free dentistry to children[1]. Mixtures of nitrous oxide in oxygen are known as "relative analgesia"[2]. Nitrous oxide has not only sedative properties but also anxiolytic and analgesic properties and therefore can help to reduce anxiety and pain associated with dental treatment.

Among the local anaesthetics, lignocaine is considered the gold standard and is the typical benchmark for comparisons among local anaesthetics. Articaine is an effective local anaesthetic for dental procedures and control of postoperative pain[3,4]. The clinical advantages of articaine include the duration of its anaesthetic action and its superior diffusion through bony tissue. Malamed et al., after comparing the drug with 2% lignocaine and epinephrine 1:100,000, reported articaine to be a safe local anaesthetic that can be used in both adults and children, with an anaesthetic latency and duration that makes it adequate for clinical use and comparable to the rest of local anaesthetics[5].

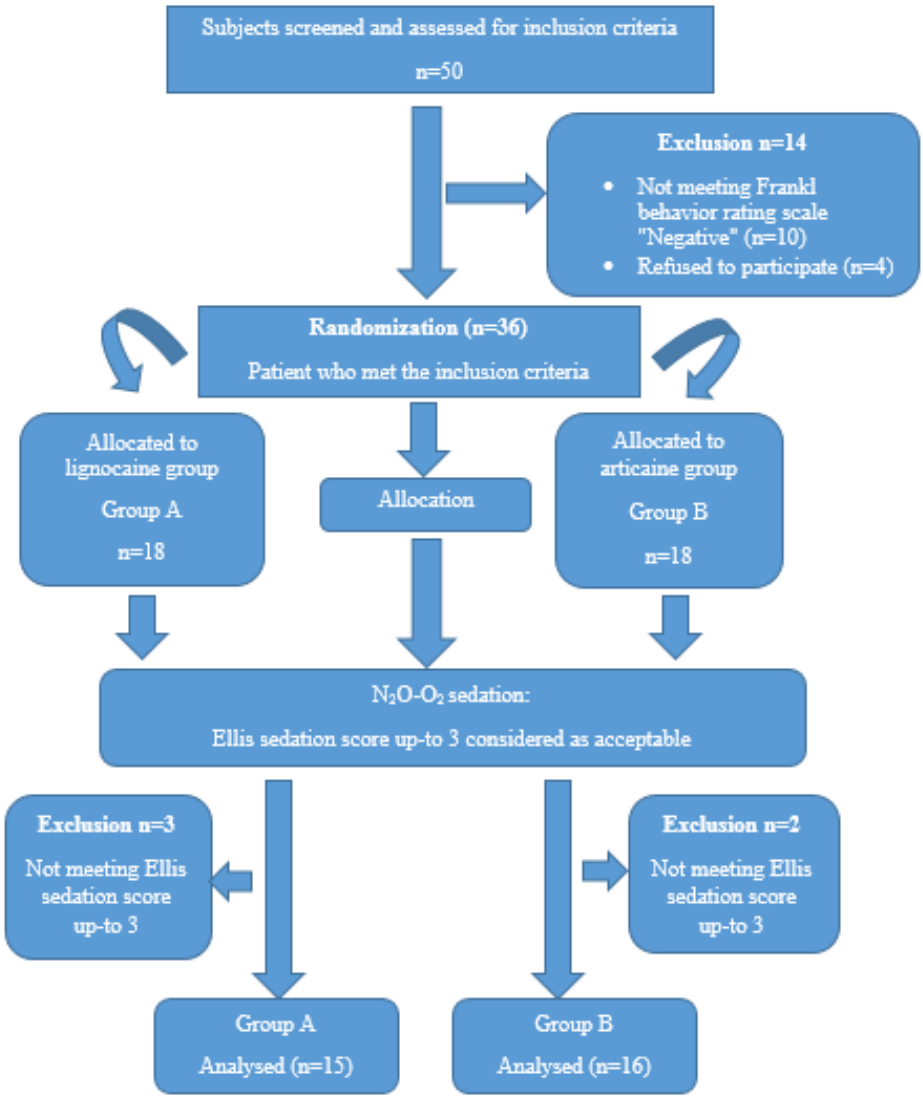
To the best of our knowledge, no study has yet been conducted to assess and compare the effects of lignocaine and articaine in nitrous oxide sedated paediatric patients. So the present study compared the effectiveness of 2% lidocaine and 4% articaine during extraction of mandibular primary molars in N_2O-O_2 sedated patients.

II. Material and Methods

This randomized, triple-blinded, prospective study was carried out at department of paediatric and preventive dentistry of Karnavati school of dentistry. Ethical approval for the study was obtained from the Ethics Committee of Karnavati School of Dentistry with IRB No. KSDEC/16-17/Apr/36. Before recruiting patients, a full verbal explanation of the study was given to the patient and the parent. Informed consent (written and verbal) was obtained from parent/guardian of each patient before the intervention.

The sample size was estimated using GPower software v.3.1.9.2. with power of 90%, margin of error of 5% and significance level of 0.050 using a two-sided two-sample t-test. The required sample size was 30 children (15 in each group). After initial screening, total of 50 healthy children aged between 4-12 years, were assessed for eligibility for participation in the present study. Out of 50 children, 4 refused to participate in the study and 10 didn't meet Frankl scale "Negative" criteria, so total 14 children were excluded from the study. Remaining 36 children were randomly allocated into two groups using the chit-pick box method. Figure no 1 shows a consort diagram of flow of patients.

Figure no 1: A consort diagram showing the flow of patients



Group A (n=18) - 2% lignocaine HCL with adrenaline 1:80,000 (Xicaine, ICPA, Mumbai, Maharashtra, India).

Group B (n=18) - 4% articaine HCL with adrenaline 1:100,000 (Septanest, Septodont, France).

Inclusion criteria:

- Children within the age group of 4-12 years.
- A preoperative anxiety score of "negative" according to Frankl Behaviour Rating Scale.
- Mandibular primary molars requiring local anaesthesia injection for extraction.
- Children with no previous dental experience.
- Children falling under ASA I category (normal, healthy patient).
- No evidence of soft tissue infection/inflammation near site of injection.
- Not taking any medications that potentially interfere with pain assessment within 24 hours before the treatment.
- No neurological disorders with sensory disturbances or communication difficulties.

Exclusion criteria:

- Children/parents not willing to participate.
- Children with any emergency treatment needs such as acute or sub-acute dental abscess, cellulitis and space infections.
- Children with any systemic problems, physical and mental disabilities and with clinical condition contraindicating the use of N_2O-O_2 sedation.
- Children with known allergy to local anaesthetics.

Procedure methodology:

Fasting instructions before the sedation procedure were given. A preoperative radiograph was taken before extraction. Baseline vitals: Peripheral arterial oxygen saturation (SpO_2), Pulse Rate (PR), and Respiratory Rate (RR) were checked and recorded. A compact, portable machine (Unicorn DenMart Ltd., Mumbai, Maharashtra, India) permitting continuous flow of Nitrous oxide (N_2O) and Oxygen (O_2) was used. The standard titration technique for the N_2O-O_2 sedation was used under the observation of general anesthesiologist. The appropriate flow rate was established while the child was breathing 100% oxygen (5-6 L/min) for 1-2 min. The percentage of N_2O was started initially at 10%. Then, it was titrated in approximately 10% increment rise every 60 seconds up to 20-30%. The Ellis scoring system was used to grade the behavioral characteristics of patients under sedation[6]. Children who sustained Ellis score up-to 3 were considered eligible while those who showed score of 4 and score 5 were excluded from the study as shown in figure no 1.

Then children were assigned to receive inferior alveolar nerve block (IANB) with either 2% Lignocaine HCL with adrenaline 1:80,000 (Group A) or 4% Articaine HCL with adrenaline 1:100,000 (Group B). All the procedures were performed by the principal operator who was unaware of the anesthetic solution used. Depending upon the drug dosage formula (Clark's rule) the dosage of the local anesthetics was calculated for children. Up to 1.8 ml of lignocaine (maximum dose: 7mg/kg body weight) and 1.7 ml of articaine (maximum dose: 5mg/kg body weight) was administered. Mucosal tissues at the injection site were dried with a gauze, and topical anesthetic (Xylonor spray, Septodont, France) was applied and left in place for 1 min. Local anesthetic solution was injected slowly at an average rate of 1 ml/min. Symptomatic testing of soft tissue anesthesia was undertaken 5 min after the completion of anesthetic administration, and extraction procedure was carried out.

Childrens' disruptive behavior was assessed using Face, Legs, Activity, Cry, Consolability (FLACC) scale[7] by playing back the video record of each patient which was performed by the second co-investigator after receiving training of the FLACC scale. The investigator was at the distance of 2 meter from the patient. The level of response for each observation was given a numerical value from "0" to "2", with "0" being the most comfortable with no pain and "2" being the most painful. Each of FLACC's 5 categories-(F)face, (L)legs, (A)activity, (C)cry, and (C)consolability was scored from "0" to "2", which results in a total score between "0" and "10". FLACC scores during extraction procedure were recorded.

SpO_2 and PR were recorded via pulse-oximeter (Olex, Vats Medical Healthcare Pvt. Ltd., India) by the co-investigator who was blinded to the type of local anesthetic used. The RR was assessed by the same co-investigator by counting the number of breaths for one minute by counting how many times the chest rises and were recorded in the patient's assessment sheet. Three sets of readings: 3 min before injection (Stage 1), during injection (Stage 2), and 5 min after injection during extraction (Stage 3) were recorded.

At the end of the extraction, N_2O inhalation was discontinued and 100% O_2 inhalation was administered to the patient for 3 to 5 minutes. On completion of treatment, each child was transferred to the recovery room. The child was required to remain in the recovery area for 20–90 min, and then discharged after assessing the following[8]:

• Vital signs within normal limits.
• Response to verbal stimulation.

• Absence of any signs and symptoms of compromised respiration.
• State of wakefulness without any adverse conditions.
• Able to walk unaided.

Data were analyzed using SPSS software version 20.0 (SPSS Inc., Chicago, USA). For the analysis of results the significance level was kept at 0.05. Independent sample t-test was used to assess age, gender, weight, number of extracted teeth and vital sign values difference between the two groups. Chi square test was used to compare the FLACC scale scores and Ellis sedation score between the two groups and paired sample t-test was used to compare Peripheral arterial oxygen saturation (%), Pulse Rate (beats/min), and Respiratory Rate (bpm) values at different stages in both the groups.

III. Results

Baseline demographic and clinical characteristics are explained in Table no 1. There were no significant differences between the groups in patient demographics, number of teeth extracted and baseline vital signs ($p>0.05$).

Table no 1: Distribution of samples between two groups according to baseline demographics and vital sign values

Demographic and clinical details	Group A Lignocaine (N=15)	Group B Articaine (N=16)	Intergroup p-value
Age (years)	7.67	7.38	0.598
Gender			
Male	8	9	
Female	7	7	
Weight (kg)	23.13	20.56	0.158
Number of extracted teeth			
1 extraction	11 (73.3%)	12 (75.0%)	0.916
2 extraction	4 (26.7%)	4 (25%)	1.00
Vital signs			
Peripheral arterial oxygen saturation (%)	98.27	98.44	0.444
Pulse Rate (beats/min)	93.20	91.63	0.324
Respiratory Rate (bpm)	17.07	16.75	0.665

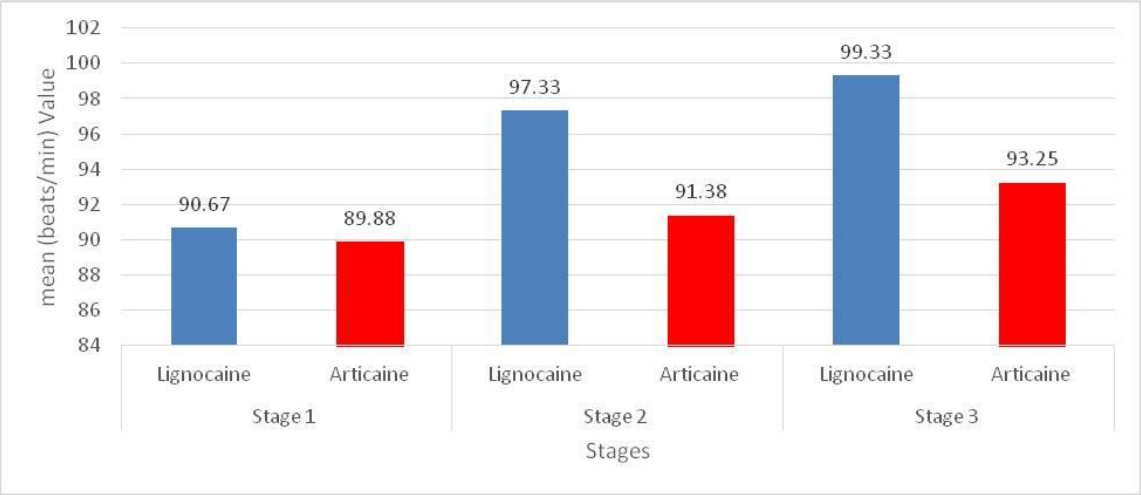
While comparing the two groups according to FLACC parameter, the values were not found to be statistically significant ($p=0.179$) as shown in Table no 2.

Table no 2: Comparison of FLACC values between lignocaine and articaine groups

Scale description	Group A (Lignocaine) N (%)	Group B (Articaine) N (%)	p-value
Score 0 (relaxed/comfortable)	9 (60)	13 (81.3)	
Score 1-3 (mild discomfort)	5 (33.3)	3 (18.8)	
Score 4-6 (moderate pain)	1 (6.7)	0	
Score 7-10 (severe discomfort/pain)	0	0	0.179

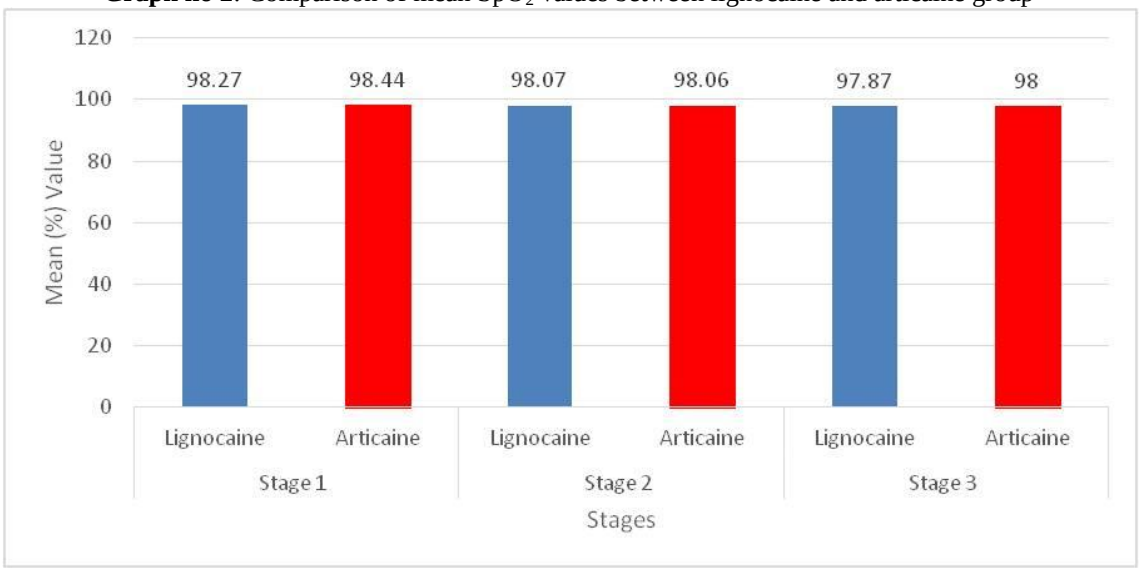
Graph no1 shows the comparison of mean pulse rate values between lignocaine and articaine groups. The mean of Pulse Rate (beats/min) increased from Stage 1 (90.67 +/- 5.22) to Stage 2 (97.33 +/- 7.51) and to Stage 3 (99.33 +/- 9.09) in the lignocaine group which was statistically significant ($p<0.05$). In the articaine group also the mean of PR increased from Stage 1 (89.88 +/- 5.63) to Stage 2 (91.38 +/- 5.64) and to Stage 3 (93.25 +/- 6.23) which was statistically significant only from stage 2 to stage 3 ($p=0.011$) while it was statistically non-significant from stage 1 to stage 2 ($p=0.111$). Comparing PR readings between the two groups, there was statistically significant difference in stage 2 and stage 3 PR readings ($p<0.05$) while it was statistically non-significant in stage 1 ($p=0.688$).

Graph no 1: Comparison of mean pulse rate values between lignocaine and articaine groups



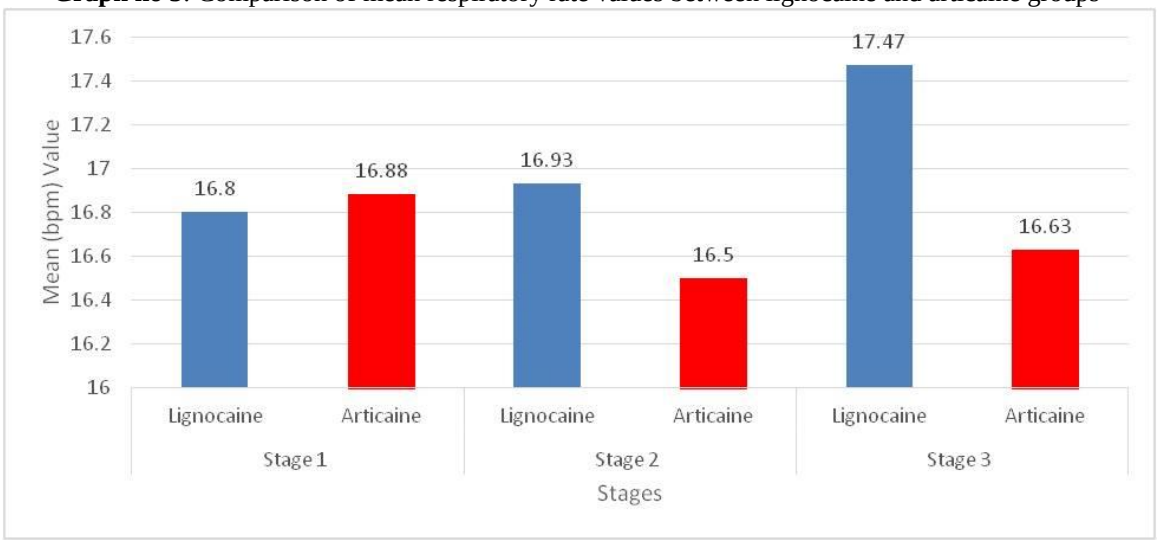
Graph no 2 shows the comparison of mean SpO_2 values between lignocaine and articaine group The mean of SpO_2 (%) in the lignocaine group was (98.27 +/- 0.70) in stage 1, (98.07 +/- 0.46) in Stage 2 and (97.87 +/- 0.35) in Stage 3. In the articaine group, it was (98.44 +/- 0.51) in Stage 1, (98.06 +/- 0.44) in Stage 2 and (98.00 +/- 0.63) in Stage 3. There was no any significant change in SpO_2 readings from stage 1 to stage 2 to stage 3 in both the groups ($p>0.05$). Comparing SpO_2 readings between the two groups, there was no statistically significant difference ($p>0.05$).

Graph no 2: Comparison of mean SpO_2 values between lignocaine and articaine group



Graph no 3 shows the comparison of mean respiratory rate values between lignocaine and articaine groups. There were few differences in the Respiratory Rate (bpm) readings for Stage 1 (16.80 +/- 1.66), Stage 2 (16.93 +/- 1.83), and Stage 3 (17.47 +/- 1.77) in the lignocaine group.There were not many differences in RR readings for Stage 1 (16.88 +/- 1.93), Stage 2 (16.50 +/- 1.71), and Stage 3 (16.63 +/- 2.16) in the articaine group which was statistically non-significant ($p>0.05$). Comparing RR readings between the two groups, there was no statistically significant difference ($p>0.05$).

Graph no 3: Comparison of mean respiratory rate values between lignocaine and articaine groups



IV. DISCUSSION

The value and safety of lignocaine has been proved through clinical use and research to be efficacious, with minimal toxicity and low reports of allergic reactions. Thus, it is the 'gold standard' to which all new local anaesthetics is compared[9]. Due to the perception that it has enhanced anaesthetic efficacy, articaine has been considered a superior reputation by numerous reviews and studies[10]. The outcomes of different studies revealed a general tendency for articaine to outperform the lignocaine in dentistry[11,12]. Yet, there seems to be no clear agreement on which local anesthetic solution is more efficacious in dental treatment for children. The technique of local anesthetic administration is an important consideration in behaviour guidance of paediatric patients.

Frankl behaviour rating scale was used to assess the childs' behaviour. In order to eliminate major differences in the level of anxiety and behaviour, children showing negative behaviour according to Frankl behaviour rating scale were included in the study. An important issue in obtaining good anaesthesia in children is the influence of the childrens' behaviour. Thus in this study N_2O-O_2 sedation technique was chosen. All the children who participated in the study had not been exposed to N_2O-O_2 sedation earlier. Nitrous oxide at levels of 20-30% was used which provides adequate sedation, without the risk of over sedation[13]. Ellis scoring system was used to grade the behavioral characteristics of patients under sedation. Only those patients who showed score 1, 2 and 3 were further included in the study.Nitrous oxide is distinguished from other agents in that it does not reduce net ventilation or produce any change in arterial pressure[14]. In this study also there was no much changes in the arterial oxygen saturation, pulse rate and respiratory rate. All patients had oxygen saturation levels of more than 95% throughout their treatment. The Pulse rate reduced from baseline during administration of N_2O-O_2 in both the groups but was well within the normal clinical range. This may be due to the anxiolytic effect of Nitrous oxide. There was no change in the respiratory rate from baseline recording until the end of the observation period. These findings were similar to those in the study by Takkar et al.[1].

Comparison of the FLACC scores showed greater proportion of patients appearing relaxed and comfortable in the articaine group compared to the lignocaine group, but there was no significant difference ($p=0.179$). This result was similar to the results of study by Jaikaria et al.[15], who also showed no statistically significant difference in FLACC pain score while comparing the efficacy of 4% articaine with 2% lignocaine during the extraction of primary molars. These results agree with the results of studies by Arrow et al.[16] and Silva et al.[3] where higher pain scores were observed with lignocaine versus articaine but were not statistically significant. Gregorio et al.[17] reported the intra operative analgesia evoked by articaine may be explained by its ability to readily diffuse through tissues due to the presence of thiophene group in the molecule which increases liposolubility.

There was no change in mean of the respiratory rate from stage 1 to stage 2 to stage 3 in both the groups and were neither clinically significant nor statistically significant. These results are similar to study by Wilson[13] who showed no any change in respiratory rate values during injection of local anesthetics and during extraction procedure in N_2O-O_2 sedation. Several authors have proposed that increased respiratory rate during acute pain reflects the respiratory component of the fight-or-flight response, preparing the organism for a possible attack or injury[18]. But all these studies have been done on non-sedated patients while N_2O-O_2 sedation was used in our study which would have reduced stress and fear which might be the reason for few and ultimately non-significant changes in respiratory rate values in our study.

In the present study the pulse rate increased after the local anaesthetics injection; during the time of extraction of teeth. This was in accordance to Moore et al.[19] and Martinez et al.[20] who reported that increase in pulse rate after injection were likely an expression of endogenous catecholamine because of the injection pain. Simpson et al.[21], Myers et al.[22] and Sanadhya et al.[23] also reported that with the delivery of local anesthetic, the pulse rate increased significantly, showing the association of emotional stress and fear with the enhanced sympathetic activity to be the cause of this increase. There was no significant change noted in the oxygen saturation from stage 1 to stage 2 to stage 3 within both the groups and also between both the groups which was similar to the result by Colombini et al.[24]

Articaine 4% 1:100,000 is reported to be a well-tolerated, safe and effective local analgesia for use in children. Articaine is 1.5 times as potent as lignocaine. So administration uses a smaller volume of solution but a higher concentration of drug. This reduced volume which can be used in infiltration technique may be of value in decreasing the discomfort of analgesia administration, particularly where co-operation in children is inadequate, so that better co-operation level can be achieved. Overall, the evidence suggests that articaine administration leads to few adverse events and is comparable to lignocaine in this respect[25]. While the present study showed trends in FLACC scores and PR that suggest a clinical advantage in patient comfort and pain control with the use of articaine compared to lignocaine.

V. CONCLUSION

This study indicated that articaine is effective as a local anaesthetic and has a similar safety profile to lignocaine in paediatric patients undergoing N_2O-O_2 administration for removal of mandibular molars. Therefore local anaesthesia using articaine is a reasonable alternative in paediatric patients requiring IANB injection for pain control for dental procedures.

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