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Comparative Assessment of Anxiety during Inferior Alveolar Nerve Block under Nitrous Oxide + Oxygen and 6Oxygen Inhalation Sedationin Children Aged 6–12Years: A Randomized Clinical Trial

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Introduction

Today, dental treatment is easily accessible to most part of the population, yet the fear of pain and rejection in stressful situations makes it difficult to provide quality dental care.1 Dental fear and dental anxiety are often considered two sides of the same coin. Dental anxiety has clearly been shown to be associated with avoidance of regular dental care.2,3 Anxious children require approximately 20% more chair time than less anxious children,4 leading to management difficulties affecting the efficiency of treatment by more frequent interruptions, which may cause the treatment time to prolong.5 Children often show a negative response to the use of injection for LA. Inadequate LA has been reported in approximately 12% of all pediatric dental patients, increasing the need for supplemental analgesia and alteration of the anxiety response.6 To overcome the obstacles related to dental fear and anxiety, no pharmacological behavior management techniques are frequently utilized and are sufficient to gain a child's confidence and permit the dentist to perform the procedures. However, it is difficult to attain the same in very fearful or anxious children, thus warranting the need for pharmacological behavior management techniques,

such as conscious sedation, which has proved to be a valuable tool by practitioners.7 Averley et al.,8 stated that conscious sedation is a safer alternative to general anesthesia wherever possible. According to the Council of European Dentists,9 "the standard sedative technique" in pediatric dentistry at present is N2O–O2 inhalation sedation. Unique advantages of nitrous oxide inhalation sedation (NOIS) include rapid onset of action, maintaining the effect of sedation as long as administered, producing analgesia with minimal impairment of any reflexes, and fast postoperative recovery within 5 minutes.10 The administration of N2O–O2 prior to and during LA for dental treatment was a highly accepted and often practiced behavior modification technique for anxious pediatric patients.11,12 Owing to the benefits, NOIS was used in the present study with the purpose to focus on the effectiveness and success of N2O– O2 inhalation sedation alone on anxious children while using the IANB.

Methodology

A randomized controlled, double-blinded study was conducted in the Department of Paedodontics and Preventive Dentistry in 60 3–12-year-old children visiting the department selected as per the selection criteria. The study had received Institutional Ethical Committee approval (SVIEC/ON/Dent/BNPG15/D15024). Informed and written consent was obtained from the participants and their parents participating in the study.

Inclusion Criteria

• Normal healthy subjects in accordance with the American Society of Anesthesiologists (ASA) physical status classification13 category 1.

• Children falling under Frankl's behavior rating scale14 2–3.

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• Those requiring IANB for dental procedures not exceeding 1 hour duration.

• First exposure to NOIS and LA.

Exclusion Criteria

• Parents who were unwilling to give written consent.

• Children with a history of chronic obstructive pulmonary diseases, upper respiratory tract infections, anatomic abnormalities in the airway, presence of tonsillar hypertrophy, or those at increased risk for airway obstruction.

• Any known allergy or hypersensitive reaction to the LA agent being used during the procedure.

Selected children were randomly divided into two groups of 30 each (by chit pick method). Group I (intervention group) received N2O– O2 and group II (control group) received 100% O2.

Blinding was done as follows:

• The subject: The subject handed over the chit to the administrator prior to the procedure. The administrator kept a note of the same separately.

• The observer: The observer was seated in such a way that the digital screen of the flowmeter of the N2O unit was not in the sight of evaluation.

Details of Examination

The parents of the selected subjects were given a detailed description about the study through the information sheet.

Written and informed consent and assent were obtained fromthe parents and subjects. The parents were instructed to allow only light meals and clear liquids 2 hours prior to the scheduled procedure.

Baseline Recordings

On the day of the procedure, the subject was seated on the chair; the baseline values of the physiological parameters, namely pulse rate, blood pressure, O2 saturation, and respiration rate, along with the demographic details, such as name, age, gender, and behaviour rating were recorded by the observer.

The probe of the pulse oximeter was placed on the left index finger. The cuff to measure the blood pressure was secured on the right arm. The respiratory rate was measured by observation. A nasal

hood of the appropriate size was selected by trial and error method.

The nasal hood was secured in place and checked for its fit and any leakage. The procedure began with the administration of 100% O2 for 5 minutes. O2 was administered to about 5–6 L/minute in every subject to determine the minute, volume, and flow rate of gases. The reservoir bag was monitored carefully, so as to ensure uniform breathing.

Group I

Slow induction technique for the administration of N2O– O2 was preferred for the study. After determining the flow rate, the N2O concentration was increased in increments of 5–10% every 3 minutes until the desired level of sedation was obtained. The participants were administered N2O at a concentration between 25 and 50%. IANB was administered at this point by the operator using the

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standard protocol. After ensuring profound anesthesia, the N2O flow was tapered by reducing 5–10% N2O every 3 minutes, and 100% O2 was given for 3–5 minutes to prevent diffusion hypoxia and to allow complete recovery from sedation. The physiological parameters of the subject were monitored at all times.

Group II

Nearly 100% O2 was administered at an appropriate flow rate as per the subject's tidal volume. The IANB was administrated after 10 minutes of administration of O2.

Assessment of the Subject

Every subject was monitored preoperatively, intraoperatively (during and after LA administration), and postoperatively for the vitals, behavioral scale, and level of sedation.

The observer scored the participant's response based on the FLACC pain scale at all times (preoperative, intraoperative, and postoperative). The response just before the administration of LA was scored based on RSS to assess the sedation level.

Discharge of the Subject

The subject was discharged after ensuring that all the physiological parameters were well within normal limits and that the subject did not experience any major side effects like nausea, vomiting, or headache.

Statistical Analysis

Chi-square analysis was used to find the significance of study parameters on a categorical scale. Student *t*-tests (two-tailed, paired, and unpaired) were used to find the significance of study parameters on a continuous scale between two groups. Analysis of variance(ANOVA) was used to find the significance of study parameters between the groups (intergroup analysis). Further *post hoc* analysis was carried out if the values of the ANOVA test were significant. The statistical software IBM SPSS statistics 20.0 (IBM Corporation, Armonk, NY, USA) was used for the analyses of the data, and Microsoft Word and Excel were used to generate graphs, tables, etc..

Results

Of the 60 participants, 34 (56.7%) were male and 26 (43.3%) were female, with a mean age of 8.57 and 7.50, respectively. A total of 31 subjects (51.7%) displayed Frankl Behavior rating of 2, while 29

(48.3%) displayed a rating of 3. Group I had 16 (53.3%) participants with a rating of 2 and 14 (46.7%) with a rating of 3. Group II had an equal number of participants with ratings 2 and 3.

All the participants in both groups displayed pulse rates within normal physiological limits preoperatively, intraoperatively, and postoperatively (Table 1). Group I showed reducing levels of pulse rate from baseline to intraoperatively to postoperatively but was not statistically significant; it had clinical significance as compared to group II. All the participants in both groups displayed O2 saturation within normal physiological limits. About two of the 30 participants from group I showed O2 saturation levels below 90% during the administration of LA; however, it regained the normal value soon after the procedure.

All the participants in both groups displayed systolic and diastolic blood pressure readings and respiratory rates within normal physiological limits at all times. A significant difference in group I at

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different time intervals in the FLACC scale score was observed, as shown in Figure 1. A significant difference can be observed in group II at different time intervals (Fig. 2).

The intergroup comparison of the preoperative FLACC scores of both groups showed no significant difference statistically. The initial discomfort experienced by the participants could be due to the placement of the nasal hood (Fig. 3).

The intergroup comparison of the intraoperative—during LA administration, FLACC scores of both groups showed no significant difference statistically (Fig. 4). The intergroup comparison of the intraoperative—after LA FLACC scores, which displayed a statistically significant difference (*p*-value 0.002). Around 25 out of 30 (83.3%) participants from group I felt relaxed after LA, as compared to 11 out of 30 (36.7%) participants in group II. The intergroup comparison of the postoperative FLACC scores displayed a statistically significant difference ($p = 0.0049$). A total of 29 out of 30 (96.70%) participants from group I felt relaxed after LA as compared to 23 out of 30 (76.70%) participants in group II (Figs 5 and 6).

Ramsay Sedation Score (RSS) was 2.80 for group I and 1.80 for group II. This difference was statistically highly significant ($p < 0.001$). The mean of RSS scores in group I and group II did not show with this notion in mind, children with positive and potentially positive behaviour were included in the study. Moreover, as per the AAPD guidelines (2013),20 NOIS is indicated in fearful, anxious, and cooperative children.

The administration of LA by injections is an important consideration for pain control in a pediatric patient. IANB is the most common and painful technique for providing LA of the mandibular posterior teeth. Also, according to the AAPD guideline,22 one of the disadvantages of NOIS is the interference of the nasal hood with the injection to the anterior maxillary region. Owing to the above mentioned factors, the administration of IANB was preferred over the other methods, such as to standardize the study protocol. The participants who had no previous history or exposure to IANB and NOIS were included in the present study to avoid bias.

Nitrous oxide–oxygen (N2O–O2) inhalation sedation can be induced by two different techniques,10 namely, slow induction or titration and rapid induction. Slow induction or titration is a method of administering a drug in incremental amounts until a desired end point is reached, and this method was used to deliver N2O to the participants in this study. Samir et al.23 reported that rapid induction of a preadjusted mix of 30% N2O and 70% O2 has the same efficacy as slow induction in achieving optimal sedation in lesser time.

However, the titration technique is regarded as the current standard of care when administering N2O–O2 for sedation.10 This technique is considered the safest method with less adverse reactions as the level of sedation of the patient can be monitored at every increment.19 The slow induction method was used for the present study. American Society of Anesthesiologist's (ASA)24 and American Academy of Pediatrics (AAP)22 stated that a concentration of N2O below 50% may be accepted as a dose for minimal sedation.

According to AAP, there is risk of increased chance of moderate or deep sedation by N2O concentration >50%.15, 22 Chapman et al.25 stated that the analgesic effect of 30% N2O is as effective as 10–15 mg of morphine. Therefore, a concentration of 25–50% of N2O was maintained for the present study. The mean value of peak % N2O delivered in this study was 33.50 ± 6.71%.

Matsumura et al.26 stated that dental treatments are accompanied by patients' hemodynamic changes (for instance, an increase in blood pressure and pulse rate). Samir and Fere15 stated that during NOIS, consciousness, respiration, and saturation are the three most crucial physiological factors that require regular monitoring. Takkar et al.7 reported a reduction in the pulse rate from baseline during the

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administration of NOIS, which, however, was well within the normal physiological range. Young et al.27 reported pulse oximeter response times of 17–150 seconds in detecting a sudden 10% decrease in O2 saturation. In the present study, group I showed slight reduction in the pulse rate and blood pressure values, the effects of which were evident clinically, suggesting the anxiolytic effect of NOIS. In group I, the mean value of pulse rate decreased clinically from baseline (mean 93.43), intraoperatively (mean 92.27), and postoperatively (mean 89.60). In group B, the findings remained more or less constant at baseline (mean 94.17), intraoperatively (mean 91.60), and postoperatively (94.43). The observations in group I were clinically significant but not statistically ($p = 0.256$, $p > 0.05$). In this study, the O2 saturation levels remained well within the normal limits throughout the procedure, that is, at baseline, intraoperatively, and postoperatively. Similar incidences were reported by Samir and Fere15 and Kaviani and Birang,28 where the O2 saturation returned back to normal levels immediately without any intervention determining it as an error in pulse oximeter reading.

The most commonly observed effects of NOIS are fixed or bright eyes, reduced blinking, happy and smiling face, trans-like expression, relaxed hands and legs, aware of surroundings, response to verbal command, tingling, and heaviness in extremities as observed by Bonafé-Monzó et al.1 and Samir and Fere15 In the present study, the following effects were reported in participants from group I. However, the participants in group II were only calm and relaxed owing to the placebo effect of the gas.

Perkovic et al.29 stated the level of dental anxiety is associated with increased intensity of expected pain. The pain perception of children can be a measure of their anxiety. Gronbaek et al.30 used the visual analog scale score to assess the subject's overall discomfort experienced from the pain tests in their placebo-controlled, double-blinded, crossover trial using N2O–O2 as the sedative agent.

Subramaniam et al.31 used the Houpt's behavior rating scale to assess the behavior (sleep, body movement, and crying) of the child during a dental procedure when treated under 40% N2O, 60% O2, and triclofos sodium (70 mg/kg body weight). The FLACC pain/behavioral scale was used in this study as it is an effective tool to assess the anxiolytic effect of the gases in both groups. The FLACC scores showed that though children in group I had mild discomfort (53%) during LA administration, it was reduced significantly after LA administration (10%), and postoperatively (0%) ($p < 0.001$).

Whereas in group B, the number of children who experienced mild discomfort (46.7%) during LA administration increased afterLA administration (53.3%) and postoperatively (16.7%), which was statistically significant ($p < 0.001$). Intergroup comparisons showed statistically significant results after LA administration (p-value 0.002) and postoperatively (p-value 0.049). Similar findings were reported by Takkar et al.7

Ramsay Sedation Score (RSS)32 was used in this study. The mean RSS in group I was 2.80 and that of group II was 1.80. This indicated clinically and statistically significant ($p < 0.001$) level of sedation was achieved in group I, that is, with NOIS. In group I, five out of 30 children displayed RSS below 2, whereas in group II, 13 of 30 children had RSS below 2, which indicated that 43.3% participants remained "anxious and agitated" during the procedure. According to Ramsay et al.,32 a score below 2 indicated unsatisfactory sedation. None of the participants from either group showed a score of five or more, indicating no incidence of oversedation in any of the participants.

The mean RSS in both groups did not show any significant difference in terms of gender-wise comparison. Whereas, the intergroup gender-wise comparison of the mean RSS did reveal significant results ($p < 0.001$). The results confirmed the sedative effect of NOIS to be effective than O2 inhalation, irrespective of gender.

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Samir and Fere15 used the Richmond Agitation-Sedation Scale to assess the sedation levels in their study. Takkar et al.7 used the Observer's Assessment of Alertness/Sedation Scale for the same purpose and obtained reliable results.

The main complications related to pediatric conscious sedation are hypoxia, nausea, vomiting, and inadvertent general anesthesia (oversedation). According to Langa,33 the most undesirable side

effect of N2O–O2 administration was nausea and vomiting, but the incidence of these conditions was <1%. Sams et al.34 in a retrospective review of case notes, reported that 48% of children had O2 desaturation while sedated for dental treatment. Castera et al.35 demonstrated a higher incidence of headache in patients treated with 50% N2O. Notini-Gudmarsson et al.36 gave no reports of headache in 38 patients treated with 50% N2O. In the present study, one subject from group I reported of headache. No other adverse effects were reported in this study. Diffusion hypoxia theoretically occurs on termination of N20 administration. In the present study, no reported incidences of diffusion hypoxia were observed as all participants were administered 100% O2 for 3–5 minutes to prevent the same and to allow complete recovery from sedation.

Conclusion

The anxious or fearful child can be positively modified with the help of NOIS as it has an anxiolytic and sedative effect on children, even at low concentrations. The overall results of the study displayed improved behavior and decreased anxiety among the children, though mild discomfort was experienced during the administration of IANB but it soon improved after the procedure. This is an important finding and evidence supporting the use of NOIS for children requiring LA.

Limitations and Recommendations

• The study was performed on a smaller sample, the age group wise comparison for the effect of NOIS could not be performed due to the smaller sample size, the standardization of the concentration of N2O–O2 was not done, keeping in mind the biologic variabilty of each participant, the NOIS was administered only for the administration of LA and not the entire procedure.37

• NOIS was used alone in the present study. The effect of combination techniques using NOIS with other oral sedative agents may be evaluated.

• Owing to the safety and efficacy of NOIS, the use of NOIS in pediatric dental practice should be encouraged on a regular basis.

Based on the design and observations of this study, the following can be postulated:

• Nitrous oxide–oxygen (N2O–O2) inhalation does significantly modify the behavior of anxious children as compared to O2 inhalation alone, thus producing safe and effective minimal sedation in children.

• Physiologic parameters are not significantly influenced by N2O–O2 inhalation.

• No adverse reactions were reported with the use of N2O– O2 inhalation at a concentration of 25–50%.

• There was no difference in the effect of NOIS among the gender.

Within the limitations of the study, it can be concluded that NOIS proved to be a safe and effective sedative agent when compared to O2 alone in decreasing anxiety among children during the administration of LA.

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