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Original Research Article

Calming contest - a battle between nitrous oxide and oral sedation - who wins in paediatric minds

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ABSTRACT

Background: The aim of the study was to compare the pre and post use of oral melatonin as oral sedative drug with nitrous oxide-oxygen sedation in young uncooperative children.
Methods: Twenty children aged 5 to 10 years were chosen to participate in the study and were equally divided into two groups: group 1 oral melatonin and group 2 nitrous oxide sedation. Parameters evaluated included Ramsay sedation scale, Houpt behaviour rating scale and Chota Bheem scale for anxiety, heart rate and oxygen saturation. The student t-test was used to compare the groups, and proportions were analysed using the Chi-square test.
Results: The treatment carried out was successful in 80% and 73% of the children in the melatonin and nitrous oxide groups respectively with no statistically significant differences between the two groups.
Conclusion: The study found that children aged 5 to 10 years can be sedated well with either of the sedative regimens. However, administering nitrous oxide oxygen sedation requires clinically higher patient compliance.

Keywords: Anxiolysis, Oral melatonin, Nitrous oxide-oxygen inhalation, Sedative effects

INTRODUCTION

Fear and anxiety remain as the substantial barriers that prevent many people from seeking good dental treatment, even in the face of tremendous advancements in painless dentistry.[1] This can include extreme phobias about anything associated with dental care or anxiety even on seeing a small needle. The smell and taste of dental materials, the sight of needles and burs, the sound of hand pieces and drills, or the feel of the instruments in their mouths can all make these people anxious when they visit the dentist office. Not getting dental care can have a negative impact on the patient's general health and quality of life. The patient's overall health may suffer as a result of skipping dental appointment, which lowers their quality of life.[1] It is estimated that between 50 and 70 percent of people experience anxiety prior to visiting a dentist, and 15 to 20 percent of people avoid going because they are afraid.[2] Since dental fear is usually persistent and difficult to overcome, whether it is brought on by personal experience or anxiety triggered by what they have heard from others, these frightening experiences have long-term implications.[2]

Children are frequently helped to relax during dental procedures by a variety of pharmacological behaviour management techniques, including oral sedation, nasal and IV sedation, nitrous oxide sedation and general anaesthesia.[3] Every approach has its own pros and cons, the child's age, medical history, and the procedure's intricacy all influence the sedation option selected for each patient.[3]

Planning dental treatment for children requires consideration of their distinct physical, emotional and psychological needs as they are not just miniature adults.[4] Giving an oral anxiolytic medication has been thought to be the best strategy for reducing anxiety and fear.[5] This

method is called as oral sedation which is used to expedite dental procedures and lessen patient's dental anxiety.[5] In dentistry, benzodiazepine-class medications, including triazolam, midazolam, lorazepam, and diazepam, have been the most often prescribed oral anxiolytics for patients.[6] However, all of these medications can result in respiratory depression, cognitive dysfunction, unpleasant responses, memory loss and psychological dependence.[7]

Therefore, there's a novel medicine that might be utilized for premedicating anxious children with less side effects and unpleasant responses.[8] According to a number of studies, melatonin is as effective in reducing anxiety as benzodiazepines without having the majority of their negative effects.[8]

Conscious sedation is described as "medically regulated state of reduced consciousness that permits the patient to maintain their defense reflexes; maintains their ability to maintain a patent airway continuously and independently; and permits an appropriate response by the patient to verbal command or physical stimulation.[4] It was underscored in year 1992, that patients could seamlessly shift between different levels of sedation, thereby necessitating heightened vigilance and meticulous monitoring.[13] There should be enough safety margin in this approach to avoid unintentional unconsciousness.[14] In order to have safe sedation of paediatric child, a detailed pre-sedation assessment is necessary, which includes details about large tonsils or anatomical abnormalities in the airway, following fasting guidelines for elective procedures, knowing the pharmacodynamics and pharmacokinetics of the sedatives used, having venous access and airway equipment of the right size, having a recovery area that is well-equipped, and having clear discharge criteria.[4]

The current body of literature presents a significant dearth in the comparative analysis of oral melatonin and nitrous oxide sedation in paediatric dentistry. This research endeavour seeks to address this void by meticulously examining the pre- and post-administration effects of oral melatonin as a sedative agent, in comparison with nitrous oxide sedation. The primary objective is to formulate a safe and efficacious sedation protocol, thereby ensuring the successful and satisfactory dental treatment of uncooperative children.

METHODS

Study design

This study was designed as a randomized, controlled, clinical trial in the Department of Paediatric and Preventive Dentistry, K. D. Dental College, Mathura. The study was conducted over a six-month period, from January to June 2025. The study was performed after achieving the ethical clearance from the Institutional Review Board and Ethical Committee and informed consent from respective parents. 20 patients between the ages of 5 and 10 who reported to the OPD for invasive dental procedures and had an ASA of 1 or 2 and a Frankl behaviour rating score of 2 or 3 were chosen. Both the patient and their parent received a thorough written and verbal description of the study prior to patient selection.

Inclusion criteria

Inclusion criteria included children aged between 5 to 10 years, child who belongs to ASA 1 or 2 and Frankl's behaviour rating score of 2 (negative) or 3 (positive).

Exclusion criteria

Exclusion criteria included children who have a history of allergies or hypersensitivity reactions to the medications used during the treatment, children who have experienced systemic disorders in the past and children who have previously experienced developmental delays.

Randomization and sedation technique

Group nitrous oxide children received nitrous oxide-oxygen inhalation at a concentration below 50%.

Group melatonin children received oral melatonin (according to young's formula).

Before sedation procedure, patients were meticulously instructed to adhere to the established pre-procedural guidelines.[15] On the day of the procedure, a thorough medical evaluation was conducted to ensure if each patient received medical clearance. Baseline measurements were systematically recorded, encompassing the child's weight, blood pressure, heart rate, and oxygen saturation levels. These initial readings served as critical reference points for subsequent monitoring. Throughout the sedation process, the patient's vital signs were rigorously and continuously monitored, ensuring a vigilant and comprehensive oversight of their physiological status.

Group nitrous oxide

Nrudent Nise portable N_2O/O_2 conscious sedation machine was used in the study (Figure 1). Behaviour modification was done using "tell-show-do" method, in which the paediatric patient was first shown how to put the nasal hood over their nose and breathe in cold air and after that sweet-smelling breath. After the patient was at ease, the nasal hood of proper size was chosen and oxygen cylinder was turned on. The child's acceptance for the mask inhalation was next evaluated. The flow rate was adjusted accordingly. After five minutes of 100% oxygen inhalation, 10% nitrous oxide was gradually added at 5-minute intervals, depending on the patient's needs, without raising the concentration to 40%. Depending on the patient's needs, the nitrous oxide was kept between 30% and 50%.[16]

Figure 1 (a and b): Melatonin syrup for oral sedation and nitrous oxide sedation machine for conscious sedation.

The onset of sedation was carefully monitored, with specific indicators such as drooping eyelids and tingling sensations in the extremities. The dental operation was started right away as these symptoms became apparent. Nitrous oxide sedation was meticulously maintained at the established level, with a gradual decrease in concentration as the procedure neared completion. In the final stages, 100% oxygen was administered for a duration of 5 minutes to ensure patient stability, followed by the removal of the nasal mask (Figure 2).[16]

Figure 2 (a and b): Procedure for oral sedation and procedure for conscious sedation.

Group melatonin

Oral melatonin syrup (ALTONIL 3 mg/5 ml, Avenue Remedies Pvt Ltd, Solan, India) was used in the study (Figure 1). The medication dosage was determined using Young's Formula prior to administration.[17] The medicine was taken from the syrup bottle with the help of dropper for precision and placed in disposable cup. Thereafter, the child was asked patiently to consume the oral melatonin syrup. The acceptance for the same was evaluated. In this process, if the child expectorated all or some part of the medication, a reappointment was scheduled to ensure proper administration of drug.[11] The precise time of drug administration was recorded. To facilitate the onset of the drug's action, a mandatory waiting period of at least 45 minutes was kept between administration of the medication and the commencement of the treatment procedure (Figure 2).[10]

The onset of sedation was meticulously evaluated by observing specific indicators such as dazed look, delayed eye movements, lack of muscle coordination, slurred speech, and the most important onset of sleep. Upon confirming the achievement of adequate sedation, the dental procedure was subsequently conducted under local anaesthesia.[16]

The efficacy of the sedative agent was evaluated through a comprehensive assessment of the following parameters and outcome measures Houpt behaviour rating scale was measured to measure treatment outcome (Table 1), Ramsay sedation scale to check level of sedation (Table 2), Chota Bheem scale to measure patient acceptance for the treatment (Figure 3), physiological status-heart rate and oxygen saturation were recorded using pulse oximeter before the administration of sedation, during sedation and immediately after sedation procedure.[18-21]

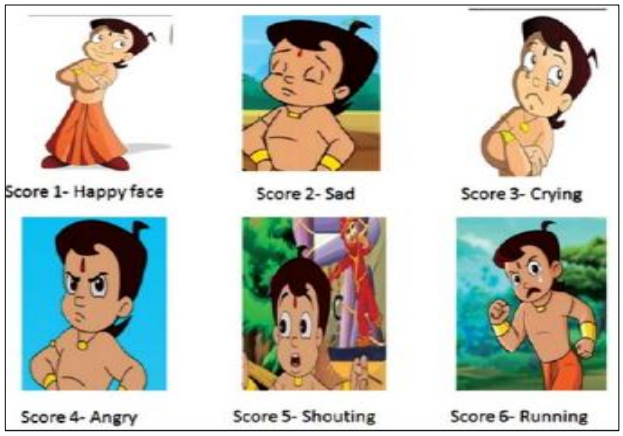

Figure 3: Chota Bheem anxiety scale.

The child's parents were contacted by the operatory's clinician for whole day in order to assess the child's alertness, sleep patterns, and any unfavorable side effects, such as vomiting.[16]

Statistical analysis

Statistical package for the social sciences (SPSS) 21 was used for analysis after the data was entered into an Excel sheet. An independent t test was employed for statistical analysis to compare means on two independent groups if there is a statistically significant difference between them. The threshold for statistical significance was set at $p<0.05$.

In this study while comparing oral melatonin and nitrous oxide sedation, independent t-test was utilized for comparing means of two separate groups and to determine whether the mean values of the sedation effectiveness (e.g., sedation levels, safety profiles, and treatment success rates) differ significantly between the two groups. Also,

the independent t-test yields a p value, which indicates the probability that any observed differences between the groups are due to random chance. A low p value (typically less than 0.05) suggests that the differences are statistically significant.

Table 1: Houpt rating scale.

Score	Description
1	Aborted: no treatment rendered
2	Poor: treatment interrupted, only partial treatment was completed
3	Fair: treatment interrupted but eventually completed
4	Good: difficult but all treatment was completed
5	Very good: some linited crying or movement
6	Excellent: no crying or movement

Table 2: Ramsay sedation scale.

Score	Definition
1	Awake and alert, minimal or no cognitive impairment
2	Awake but tranquil, purposeful responses to verbal commands at conversation level
3	Appears asleep, purposeful responses to verbal commands at conversation level
4	Appears asleep, purposeful responses to verbal commands but at louder than usual conversation level or requiring light glabellar tap
5	Asleep, sluggish purposeful responses only to verbal commands or strong glabellar tap
6	Asleep, sluggish purposeful responses only to painful stimuli
7	Asleep, reflex withdrawal to painful stimuli only (no purposeful response)
8	Unresponsive to external stimuli, including pain

RESULTS

The present clinical study assessed 0.5 ml/kg of oral melatonin compared to nitrous oxide-oxygen inhalation for conscious sedation in 20 children aged between 5 to 10 years. The level of anxiety, patient acceptance, level of sedation and treatment outcome were assessed.

The studied sample consisted of four males (40%) and six females (60%) in the Melatonin group with a mean age of 7.4 years (±1.81). Nitrous oxide group consisted of five males (50%) and 5 females (50%) with an average age of 8.2 years (±1.67) with both the variables not being statistically significant in both the groups. The mean weight of the patients included in the study was 30 kg. The mean dose of melatonin administered was 8.6 ml.

Heart rate and peripheral oxygen saturation data at three different time points were considered. The data for the same is given in Figures 4 and 5 respectively. Throughout the study, all vital signs consistently stayed within clinically acceptable boundaries with both types of sedation techniques.

Mean±SD of heart rate before treatment in group 1 and group 2 was 93.60±5.379 and 96.20±2.658 respectively. Mean±SD of heart rate during treatment in group 1 and group 2 was 99.30±16.760 and 105.60±15.883 respectively. Results were found to be statistically insignificant when comparing heart rate before, during, after treatment in group 1 and group 2. Heart rate was maximum in group 2 in comparison to group 1 as seen in Figure 4.

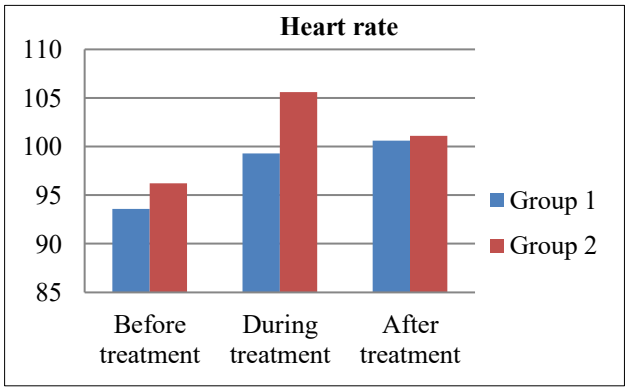

Figure 4: Heart rate.

Mean±SD of oxygen saturation before treatment in group 1 and group 2 was 97.50±2.173 and 97.80±1.398 respectively. Mean±SD of oxygen saturation during treatment in group 1 and group 2 was 98.00±1.826 and 98.30±2.312 respectively. Mean±SD of oxygen saturation after treatment in group 1 and group 2 was 98.20±71.476 and 96.80±2.898 respectively. Results were found to be statistically insignificant when comparing oxygen saturation during, before, after treatment in group 1 and group 2. Oxygen saturation was maximum in group 2 in comparison to group 1 before treatment and during treatment but oxygen saturation was maximum in group 1 after treatment as seen in Figure 5.

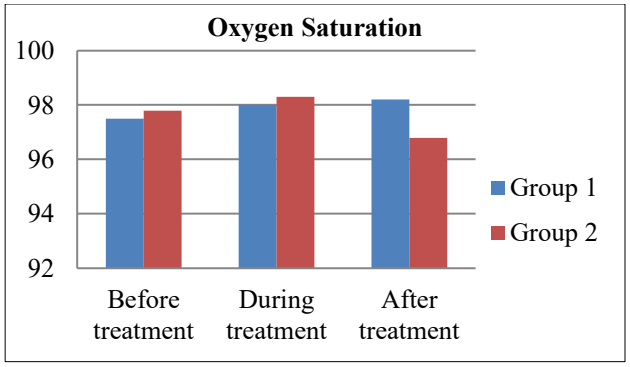

Figure 5: Oxygen saturation.

Mean±SD of sedation level in group 1 and group 2 was 2.50±0.972 and 2.60±1.075 respectively. Results were found to be statistically insignificant when comparing sedation level in group 1 and group 2. Sedation level was slightly maximum in group 2 in comparison to group 1 as seen in Figure 6.

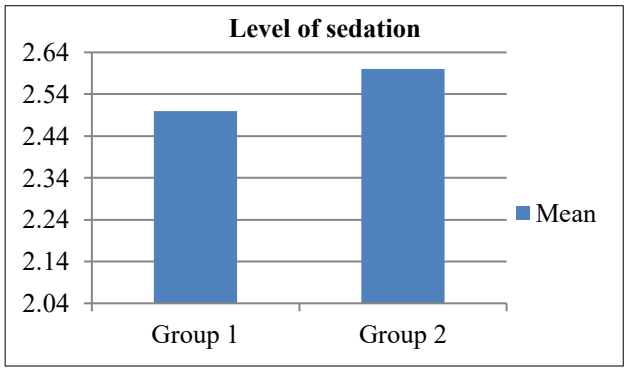

Figure 6: Mean level of sedation using Ramsay sedation scale.

Mean±SD of anxiety and patient acceptance score in group 1 and group 2 was 1.60±0.699 and 1.70±0.823 respectively. Results were found to be statistically insignificant when comparing anxiety score in group 1 and group 2. Anxiety score was maximum means anxiety reduced slightly in group 2 in comparison to group 1 as seen in Figure 7.

Mean±SD of treatment outcome in group 1 and group 2 was 4.00±1.247 and 4.70±0.949 respectively. Results were found to be statistically insignificant when comparing treatment outcome in group 1 and group 2. Treatment outcome was maximum in group 2 in comparison to group 1 as seen in Figure 8.

No statistically significant distinctions were identified between the two groups in any of the evaluated parameters. The treatment carried out was successful in 80% and 73% of the children in the melatonin and nitrous oxide groups respectively with no statistically significant differences between the two groups.

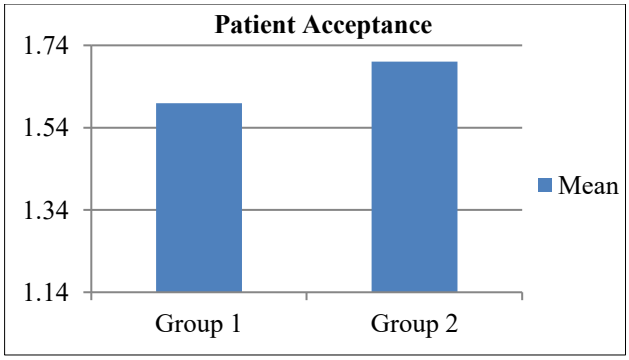

Figure 7: Patient acceptance using Chota Bheem scale.

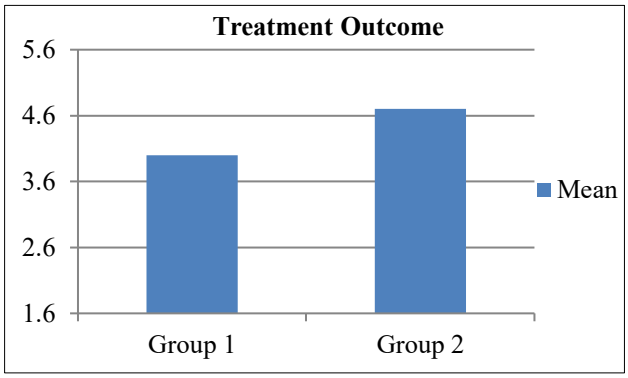

Figure 8: Treatment outcome using Houpt rating scale.

DISCUSSION

Dental fear and anxiety are the response to specific stimuli that patient encounters in a dental clinic during dental procedures. Children, more than adults, tend to exhibit extreme levels of dental anxiety and fear with reduced cooperation in dental settings. It is recognized that anxiety before any dental treatment can affect the postoperative outcomes of the dental treatment. Preoperative anxiety also anticipates for negative behaviour during and after the dental treatment.

To alleviate preoperative anxiety, an array of techniques has been explored so far, encompassing both non-pharmacological and pharmacological approaches. Non-pharmacological techniques encompass distraction techniques, communication skills, positive reinforcement, relaxation techniques and tell-show-do.[3] Nonetheless, certain patients may still necessitate pharmacological interventions for behavior management, as they find it challenging to adhere to the operator's instructions during treatment. Pharmacological techniques comprise of oral sedation, conscious sedation, and general anaesthesia.[3]

To make the ease of treatment time, oral sedation option came into dental science with less side effects and ease of treatment. Oral sedation is a type of mild sedation as it only sedates the child for little time and makes the child

responsive to the commands of operator.[5] It is very safe as there is no risk of major side effects and child going into deep sleep. According to Donaldson et al an orally taken sedative drug is a medication than can decrease patient excitement and agitation providing soothing effect to patient.[5]

Here, we used melatonin as the oral sedative drug as it possesses hypnotic as well as sedative effect when delivered orally.[9] Because it is a naturally occurring hormone in human body, it has the following advantages over other commercially available drugs: it is difficult to overdose, patients find it more acceptable than the uncomfortable ingestion of synthetic pharmaceuticals as compared to benzodiazepines, has a comparatively short half-life, which reduces the likelihood of persistent sedation.[22] In a study conducted by Poggi, it was concluded that melatonin, administered at a dose of 0.5 mg/kg, possesses remarkable anxiolytic and analgesic properties. This dosage appears to confer a therapeutic anxiolytic effect, rendering it a promising option for alleviating anxiety and discomfort in paediatric dental patients during procedures.[23] A study by Samarkandi et al found that oral melatonin at doses of 0.1, 0.25, or 0.5 mg/kg was beneficial in reducing children's anxiety before medical surgical procedures. It also demonstrated a quicker recovery and less excitement after the surgery.[12] In a 2018 study conducted by Archana, it was concluded that oral melatonin was associated with effective preoperative anxiolysis, marked by minimal sedation and a negligible impact on cognitive skills. This favorable profile contributed to a smoother induction of anesthesia. Moreover, there were no postoperative cognitive dysfunctions or adverse effects observed, highlighting oral melatonin as a highly promising agent for preoperative management in pediatric dental patients.[24] Gupta et al also conducted a study to examine the early and later effects of melatonin medicine on sedation, anxiety, and cognitive and psychomotor functioning before and after dental procedures and reported that melatonin is potentially effective in reducing anxiety and performed better as sedative drug.[25]

Conversely, the approach of conscious sedation involves administering one or more medicines to generate a state of central nervous system depression. This allows for treatment to be administered while verbally communicating with the patient during the sedation period.[26] Conscious sedation using nitrous oxide-oxygen inhalation is currently the inhalation agent in routine use in dental practice. This uses subanesthetic concentrations of nitrous oxide delivered with oxygen from dedicated machinery via a nasal mask. Nitrous oxide is poorly soluble with a high minimum alveolar concentration with rapid onset of action so therefore coupled with a rapid recovery period. The duration of the sedation can be controlled and the patient can quickly return to normal activities.[27] A study conducted by Angela et al found that conscious sedation was a safe and effective way to get cooperation from very young patients.[27] It also had the potential to lower the number of paediatric patients who were transported to hospitals for general anaesthesia.[27] In a 2013 study conducted by Collado et al, resulted that conscious sedation technique utilities intravenous midazolam, with or without premedication and/or inhalation sedation (comprising 50% nitrous oxide and 50% oxygen), were found to be both safe and effective when administered by dentists to patients with intellectual disabilities.[28]

Thus, we have conducted this study to compare oral sedation and conscious sedation, with the objective of evaluating their respective effects on sedation and anxiolysis in uncooperative paediatric patients undergoing dental treatment.

In this study the age group was taken as 5–9 years because patient shows maximum degree of anxiety during their dental visit at this age along with developing cognition and skills. Patients of this age can also communicate effectively with the operator and respond to verbal instructions. Gitto et al done a study and took the age ranging from 5–9 years. Mytily et al also took the age criteria of 2–9 years as the child's cognitive development is still in progress.

An important component that determines a drug's pharmacokinetics and pharmacodynamics is its dosage, which also affects how the drug acts on the liver and brain. There are a few studies on pre-operative melatonin administration in the dose (0.2–0.5 mg/kg orally) in children. Loewy et al has taken 0.5 mg/kg in his study.[30] Kurdi et al has taken oral melatonin in the dose 0.25 mg/kg and 0.5 mg/kg.[11] In this study, we prepared the dose of melatonin for children with the help of Young's formula and in accordance of the previously done studies.

Ilasrinivasan conducted a study in which patients were given 100% oxygen for five minutes. After that, nitrous oxide was added at 10% intervals of five minutes, depending on the patient's needs, but not more than 50%. Consequently, we used the same nitrous oxide sedation concentration in our investigation.[16]

Heart rate and oxygen saturation are reliable physiological indicators, and their fluctuations can provide insight into a patient's emotional and physiological state. Using pulse oximetry for assessing anxiety reduction offers continuous, non-invasive monitoring. A stable heart rate and optimal oxygen saturation might indicate improved relaxation and reduced distress during treatment. Since anxiety often triggers an increased heart rate and a drop in oxygen saturation, these physiological markers serve as valuable indicators for evaluating patient stress levels. In our study, SpO_2 levels were assessed, and the findings showed that the variation between baseline and the 90-minute point was negligible, suggesting that neither medicine significantly affected respiratory or circulatory functions. This is in line with studies by Le Denial et al and Joshi et al, which also discovered that the

administration of oral melatonin had no effect on the respiratory and circulatory systems.[31]

Ramsay sedation scale (RSS) is utilized to assess a patient's state of sedation and consciousness. This scale consists of six levels, from intense agitation to profound coma. Mytily et al and Sethi et al have all used this scale in their study.[32,33] In our study notable distinction in sedation duration was observed between the two groups. The melatonin group exhibited a longer sedation duration compared to the nitrous oxide inhalation group. This phenomenon can be linked to the extended onset time required for orally administered drugs, largely due to their extensive first-pass metabolism. Supporting this observation, studies by Shepherd reported mean procedure durations of 22.6 and 45.2 minutes respectively, when nitrous oxide was utilized.[34]

Houpt behavior rating scale was also used to measure treatment outcome. It was utilized in the current study due to its reliability, ease of data interpretation, and the frequent success observed in previous research efforts.[35] The values for the same were scored from 0 to 6 on the basis of treatment done to the patient after any of the two types of sedation. Studies done by Ilasrinivasan and Mozaffar et al used Houpt behavior rating scale to assess the treatment outcome on pediatric dental patient.[16,36] This study highlights efficacy of both sedation modalities demonstrating favorable treatment outcomes. Notably, melatonin facilitated smoother execution of less invasive procedures such as restorations and banding for space maintainers, ensuring patient cooperation with minimal intervention. Conversely, nitrous oxide proved advantageous in enabling more invasive treatments like extractions and pulpectomies, supporting the management of complex cases. These findings underscore the tailored applicability of sedation approaches based on procedural demands, reinforcing melatonin's role in promoting gentle, patient-friendly care while nitrous oxide ensures efficiency in more involved interventions.

The Chota Bheem scale was utilized to assess patient dental anxiety and treatment acceptance. This scale is a picture-based test designed specifically for children, known for its simplicity and ease of understanding. The effectiveness of the Chota Bheem scale has been demonstrated in previous studies. For instance, Rahaman et al utilized this scale to measure dental anxiety and patient acceptance, finding it to be a reliable and effective tool.[37] This study highlights a notable contrast in anxiety scores between the two sedation groups, with higher anxiety observed in the nitrous oxide group compared to the oral melatonin group. This difference appears to be influenced by the nasal hood used in nitrous oxide administration, which restricts breathing and may contribute to patient discomfort. In contrast, oral melatonin provides a more unobtrusive sedation experience, promoting relaxation without the need for external apparatus.

In this study, each subject's postoperative quality of recovery, including adverse effects, was recorded over the phone 24 hours following both the melatonin and nitrous oxide trials. Nitrous oxide sedation is generally considered a safe but it is not without potential adverse effects. Common issues include nausea and vomiting, particularly in patients who have eaten before sedation, as well as dizziness and disorientation during recovery. Some individuals may experience post-procedure headaches, especially if oxygen administration is insufficient after discontinuing nitrous oxide. The nasal hood, essential for delivery, can cause respiratory discomfort or a feeling of restriction, potentially increasing anxiety in sensitive patients. Emotional responses can vary, with some experiencing mood swings, euphoria, or even heightened nervousness. Children administered oral melatonin felt nausea and hyperactivity.

Thus, the conclusions drawn from this study indicate that the Ramsay sedation scale, Houpt behavior scale, and Chhota Bheem anxiety scale were effectively employed to observe the differences between pre- and post-treatment outcomes for both oral and conscious sedation methods. The results demonstrated that melatonin exhibited a similar effect to nitrous oxide in reducing postoperative anxiety, without inducing any significant changes in cognitive or psychomotor functions.

Limitations

The study faced limitations as the study examined two distinct drug administration routes, it was limited by its small sample size and the blinding problem. Future studies with larger sample sizes are required to verify the efficacy of these medications in producing anxiolysis in children undergoing dental procedures. Due to individual differences in metabolism, anxiety levels, and general health, children may react differently to sedatives. Because of this heterogeneity, it may be difficult to forecast each patient's precise sedative effect and duration.

CONCLUSION

Upon comprehensive evaluation of all study parameters, several important findings emerged. Nitrous oxide sedation consistently demonstrated superior sedative efficacy and more favourable treatment outcomes compared to melatonin. However, melatonin was associated with greater patient acceptance and a faster quality of recovery, highlighting its appeal as a patient friendly option. Clinically, nitrous oxide requires higher levels of patient compliance during administration, whereas melatonin offers a simpler and more easily accepted approach.

These observations suggest that both agents—nitrous oxide and melatonin—hold value as sedative and anxiolytic options in paediatric dentistry. Their relative advantages emphasize that the choice of agent should not be based solely on pharmacological effect, but rather on a

thoughtful balance between patient comfort, operator experience, and clinical context. In practice, "smart sedation" is about achieving this equilibrium: nitrous oxide provides stronger sedation and treatment efficiency, while melatonin enhances acceptance and recovery. Both agents can therefore be considered effective, with the ultimate decision guided by clinician confidence and patient preference

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