

Comparative Evaluation between Cognitive Behavioural Therapy and Nitrous oxide-oxygen inhalation sedation in the Management of Anxious Pediatric Patients during Dental Extraction.

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I. Introduction

Dental anxiety denotes a state of apprehension that something dreadful is going to happen during the dental treatment and it is coupled with sense of losing control. Dental anxiety and fear is a frequently encountered problem in dental offices that result in avoidance of dental care.¹ It has been cited as the fifth most common cause of anxiety by Agrus et-al.² Studies have revealed that one in four children (22%) seen by pediatric dentists may present a marked behavior management problem.³ The presence of disruptive behavior whether the result of anxiety, temperament or simple non-compliance is of particular concern for a pediatric dentist. First, children with high dental fear are more likely to delay or avoid dental visits.^{4, 5} Second such children may prove difficult to treat, require more time and present with behavior problems which result in stressful and unpleasant experience for both the patient and the dentist.⁶ Finally, these anxious children because of their avoidant behavior often have worse oral health.^{7, 8} Owing to such widespread significant impact, it is of utmost importance to identify such children at the earliest or else they can be a considerable source of stress for the dentist.⁹ The dentist should aim at alleviating the anxiety and fear in such a way that these children are positively motivated on a long term basis for future dental visits. Broadly dental anxiety can be managed by psychotherapeutic and pharmacological interventions depending on the level of anxiety, patient characteristics and clinical situations. Psychotherapeutic interventions include behavioral or cognitively oriented therapies¹⁰ while as pharmacologically these patients can be managed using either conscious sedation or general anesthesia.¹¹⁻¹³

The aim of behavioural modification techniques is to change the unacceptable behavior through modeling, hypnosis, positive self-talk, breathing relaxation, positive reinforcement, "tell show do" and audio-visual distraction. Cognitive strategies aim to alter and restructure the negative cognitions to enhance the control over negative thoughts. Cognitive behavioral therapy (CBT) is a combination of both behavioral and cognitive therapy.⁹ Although these methods are helpful, but are not always fully effective especially for highly un-cooperative children. For them pharmacological means of sedation such as the use of nitrous oxide/oxygen (N₂O/O₂) are indispensable to avoid distress and cancellation of subsequent dental visits.¹⁴

Pharmacological techniques such as inhalation sedation and general anesthesia involve the administration of a drug or a combination of drugs that act centrally to help in the management of anxious patients.¹⁵ Inhalation sedation with N₂O/O₂ tends to be the first choice for child patients who are able to communicate and has been used with good results in children who fear the dentist.¹⁶ It is described as a standard technique for pediatric dentistry and a successful procedure in 90% of adequately selected patients.¹⁷

Despite the numerous studies on cognitive behavioral therapy and N₂O/O₂ conscious sedation, there is dearth in literature about the comparison between them in eliminating the un-cooperative behaviours and dental anxiety in children. Therefore, the aim of this study was to assess and compare the effect of N₂O/O₂ conscious

sedation and CBT on anxiety levels during extraction of primary teeth under local anesthesia in children aged 6-12 years.

II. Materials And Methods:

This study was approved by the Research Development and Sustenance Committee: Bapuji Dental College and Hospital, Davangere Karnataka India (Ref. No BDC/Exam/283/2016-17). Before recruiting subjects, a full verbal and written explanation was given to the child and the parent. It was deemed essential that the child was happy to take part in the study and only then was parental consent for both inclusion and treatment in the study obtained.

Sample size: The size of the sample necessary to detect a statistically significant difference was determined with a power calculation based on the results from previous studies¹⁸ using formula given by Chow et-al.¹⁹ To achieve an 80% power to detect a statistical difference of 5% between the two groups a sample size of 40 was required.

Subjects: Male and female patients aged 6-12 years were selected from the out-patient department of the Pedodontic and Preventive dentistry of the college who reported for the routine dental checkup. The inclusion criteria were the absence of mental retardation, ASA physical status I and II, no history of current episodes of medications or drug therapy, Frankel behavior rating of 2 or 3 and presence of at least one primary molar needing extraction under local anesthesia. The exclusion criteria included undrained pneumothorax, recent middle ear surgery or upper respiratory infection and a difficult airway.

Study design: This study was designed as a prospective, randomized controlled clinical trial with parallel group design. The children were randomly divided into two groups-CBT group and N₂O/O₂ group. The principle investigator performed the randomization before beginning the study. Each participant received an opaque envelope containing a number to assign him/ her to one of the two groups. After selection, the base line anxiety was recorded using Venham's anxiety rating scale²⁰ by an independent observer. The next appointment was scheduled five days after screening the child to perform the extraction. It was decided that the same treatment (extraction) be carried in all the children to ensure standardization. All extractions were scheduled in the morning and performed by one pediatric dentist.

Interventions to reduce dental fear and anxiety:

In the cognitive behavioural therapy group (Group I), the children were left in the play room for five minutes where they had the opportunity to play with painting board, colour pencils, play dough and some other toys and dolls and meanwhile the dentist tried to establish a rapport with him/her. After this a film of a happy cooperative child undergoing dental treatment was shown to the child to draw his /her attention towards the happiness of the child being treated and answer the child's questions about the dental procedure shown in the film. The parents accompanied their child when the child was playing in the playroom. After this the child was taken to the extraction room to carry out the extraction. The topical anesthetic gel (benzocaine 20%) was applied to the dried mucosa for two minutes and then lidocaine 2% (1: 80,000) was administered. The pulse rate was monitored using pulse oximeter. Once anesthesia was achieved the teeth were extracted.

In group II N₂O/O₂ was delivered via nasal mask using Quantiflex MDM system. All the children were instructed not to eat for two hours before the extraction. At the start of the treatment 100% oxygen was delivered for 2 minutes and then nitrous oxide was titrated in 5-10% increments to the maximum desired level for each child and once the desired level was achieved it was maintained throughout the procedure. An experienced operator trained in sedation technique was responsible for administering the N₂O/O₂. A maximum concentration of 30% nitrous oxide and 70% oxygen was chosen to avoid the risk of over sedation. The extraction was carried in the same manner as in group I. The blood pressure, pulse rate, arterial oxygen saturation and level of response were monitored throughout the treatment. At the completion of treatment the children were transferred to recovery room where monitoring and supervision continued for 20 minutes after the commencement of conscious sedation. The criteria for discharge were that the vital signs were within the normal range, able to walk unaided and full verbal communication. The post-surgical and sedative instructions were given and the child was finally discharged from the clinic.

Anxiety measuring parameters

The anxiety level was assessed by using both physiological and psychological parameters.

Physiological parameter: Heart rate was recorded using fingertip pulse oximeter (Phoebus P121) at the start of treatment, three minutes after giving local anesthesia and at the completion of extraction.

Psychological parameter: The psychological assessment was done by recording anxiety at the completion of extraction using Venham's anxiety rating scale.²⁰ The recordings of Venham's anxiety rating

scale and pulse oximeter were noted by an independent observer who assessed the child throughout the dental extraction.

Collected data was entered in excel and analyzed using R software version 3.23. Continuous data was presented as mean and standard deviation. Categorical variables were presented as count and percent. Independent t-test was used to compare means of two groups and $P < 0.05$ was considered as statistically significant.

III. Results

Of the 40 children enrolled in the study there were 11 boys and 9 girls in group I and 9 boys and 11 girls in group II. There was no significant difference regarding gender between the two groups ($p=0.945$) table 1.

Table 1: Distribution of patients according to gender

Sex	Group				Total	
	CBT (I)		N ₂ O/O ₂ (II)			
	Count	%	Count	%	Count	%
F	9	45.0	11	55.0	20	50.0
M	11	55.0	9	45.0	20	50.0
Total	20	100.0	20	100.0	40	100.0

$P=0.945$

The mean age of patients in group I was 9.00 ± 1.88 and in group II it was 9.2 ± 1.84 which is statistically non-significant ($p=0.736$) table 2.

Table 2: Mean values of age, anxiety and pulse rate in the two groups

	Group						p value
	CBT (I)			N ₂ O/O ₂ (II)			
	N	Mean	S D	N	Mean	S D	
Anxiety baseline	20	1.9	0.72	20	1.9	0.67	0.821
Post treatment anxiety	20	1.3	0.66	20	0.7	0.57	0.004
Pulse rate Initial	20	93.0	7.15	20	93.2	4.95	0.919
Pulse rate-3Minute	20	104.2	7.36	20	89.8	5.94	0.000
Pulse rate end	20	102.3	8.42	20	90.2	5.32	0.000
Age	20	9.0	1.88	20	9.2	1.84	0.736

There was statistically no significant difference in the initial pulse rate ($P=0.919$) between the two groups. However statistically high significant difference was seen in the pulse rate recorded three minutes after administering local anesthesia ($P=0.000$) and at the end of extraction ($P=0.000$) table 2.

The mean baseline anxiety in group I was 1.9 ± 0.72 and in group II it was 1.9 ± 0.67 . The difference between these scores was not significant ($P=0.821$). The mean value of post treatment anxiety for the group I was 1.3 ± 0.66 and in group II it was 0.7 ± 0.57 . The difference in post treatment anxiety was found to be significant ($P=0.004$) table 2.

The Venham's anxiety score and pulse rate at different time points between the two groups is illustrated in fig 1 and 2 respectively. The dental anxiety was reduced in both the groups but it was more pronounced in in group II i.e. N₂O/O₂. The heart rate measured by pulse oximeter showed that it was higher, both after giving local anesthesia and at the completion of extraction in cognitive behavioral therapy group than N₂O/O₂ inhalation sedation group.

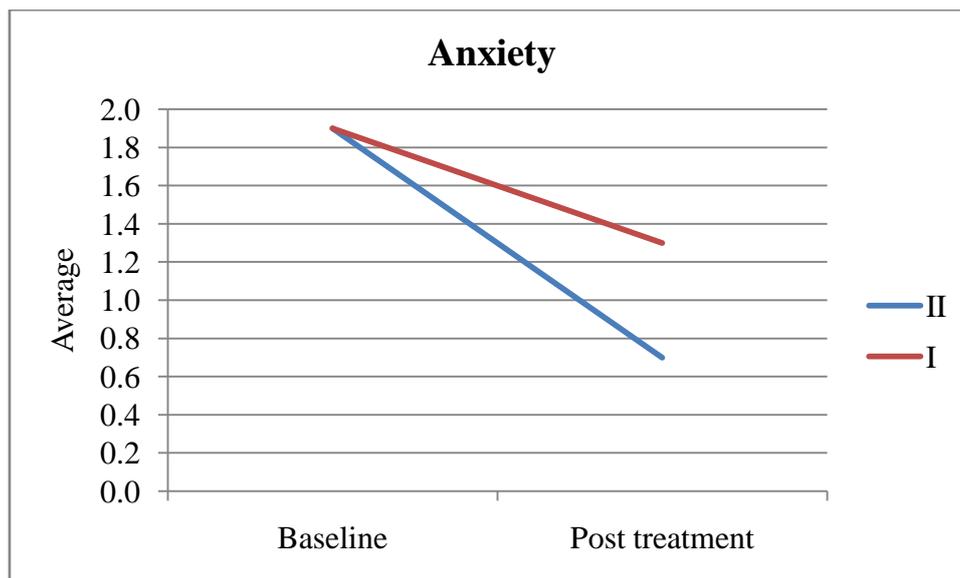


Figure (1): Comparison of Venham’s anxiety rating score between the two groups.

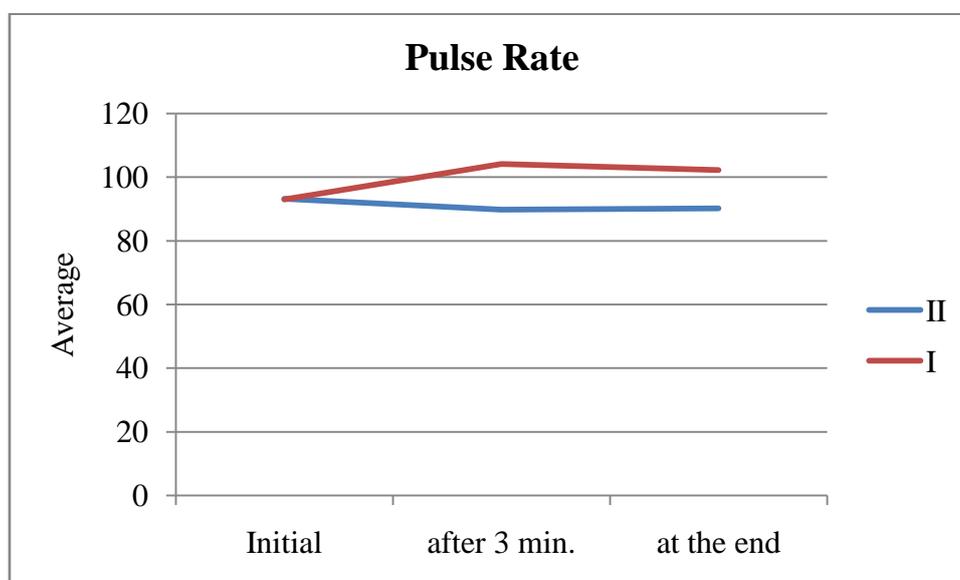


Figure (2): Comparison of pulse rate at different time points between the two groups.

IV. Discussion

It is not unusual for first experience of dental treatment to involve extractions, a potentially traumatic experience. The delivery of dental care to such children can be very challenging. Many pediatric patients can be managed with behavioral management and local anesthesia alone. However use of conscious sedation in the form of N₂O/O₂ inhalation sedation has proved to be very successful for the majority of pediatric dental patients.¹⁶ For children of all ages the impression of distress left by the first dental visit as well as the experience linked with each successive dental procedure build memories that affect conduct on upcoming appointments. So creating positive memories towards the dental treatment in pediatric patients is an important aspect to curtail poor emotional consequences and decrease the perception of pain.¹⁴ The present study investigated the outcome of two different methods for the treatment of dental anxiety i.e. CBT and N₂O/O₂ inhalation sedation.

The rate of prevalence of dental anxiety in most of the populations is seen more in children and tends to decrease as age advances.²¹ The homogeneity in this regard is very important to avoid any bias and facilitate the comparison. There was no significant difference in age between the study groups in the present study. Further the age group chosen was the children between 6-12 years. This age range was chosen because younger children are more anxious and mostly require general anesthesia.²² Weinstein-al²³ noted that children less than 6 years of age do not respond to inhalation sedation and Hallonston et al²⁴ also found a lower acceptance level with younger patients.

It has been revealed that females are more anxious and hence may influence the treatment outcome. Foley J in his study has revealed that male patients less than 10 years of age were found to cope better with inhalation sedation than female patients of the same age.²⁵ The current study showed no significant difference in gender between the study groups.

The presence of dental anxiety and un-cooperative behavior in the first dental visit can affect the validity of the results and should not be overlooked.²⁶ In this study there was no significant difference between the two groups in terms of initial level of anxiety and pulse rate and the difference observed during the treatment sessions could be attributed to pharmacological or CBT used in children. All children were selected with no past dental history as negative experience of the previous dental visit may lead to dental anxiety and fear. Howard and Freeman pointed to the importance of first dental experience where more aversive procedures resulted in less positive behavior in the subsequent dental visits.²⁷

Regarding evaluation of scales to measure the dental anxiety and fear, it has been shown that none of the scale is better than the other nor can act as a gold standard. Venham's anxiety rating scale used in our study is an effective and reliable means of assessing the dental anxiety in children.^{28, 29} The physiological changes were measured by using pulse oximeter which is considered to be an excellent means of monitoring pulse rate. Pulse rate has been used as an outcome measure in numerous medical, paramedical and dental studies of fear and anxiety.^{30, 31}

The results of the present study showed that the children were significantly less anxious during of N₂O/O₂ inhalation sedation than the children undergoing CBT before extraction. This may be because the response to CBT is not immediate and multiple sessions are usually required to alter and restructure the content of negative cognitions and enhance the control over negative thoughts.³²

The use of titrated amounts of N₂O/O₂ inhalation sedation as a behavioral management technique is recognized as safe and effective commonly employed by dentists.^{33,34} In a study by Arch et-al,³⁵ N₂O/O₂ sedation showed a significant reduction in anxiety level in 9-15 years old children during dental extraction. Primosch et-al³⁶ also reported that 40%N₂O/60% O₂ inhalation was significantly more effective in improving the behaviour of children in comparison to 100 oxygen inhalation. A study conducted by Burneit et-al³⁷ reported 96% success rate when N₂O/O₂ was used for pediatric surgical procedures. They also reported that 84% of the patients who received local anesthesia via injection did not recall the shot.

N₂O/O₂ inhalation sedation was supplemented with local anesthesia when dental extraction was performed to achieve satisfactory pain control. The use of local anesthesia is supported by Trieger et-al who concluded that supplementation with local anesthesia is frequently necessary to obtain sufficient pain control.³⁸ A maximum concentration of N₂O 30% was chosen as studies have shown that 20-30% N₂O provides a suitable level of sedation for dental treatment in pediatric patients.^{39,40}

The N₂O/O₂ inhalation sedation is not meant to replace the trust building communication that is inherent to good patient clinician relationship, the present study recommends N₂O/O₂ inhalation sedation to manage the mild to moderately anxious children after trust is established to enhance the positive patient attitude towards the dental experience.

V. Conclusion

The present study found a significant difference between N₂O/O₂ inhalation sedation and CBT and thus concludes that managing pediatric patients with inhalation sedation is an effective method for comfortable handling of these patients in dental clinics.

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