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A HOSPITAL BASED STUDY ON EFFICACY OF DEXMEDETOMIDINE AND NALBUPHINE SEDATIVE EFFECTS IN PEDIATRIC DENTAL PATIENTS

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ABSTRACT

Background and objective: Severe anxiety and extreme fear experienced by younger children regarding dental procedures have made dentists reluctant to render medical care to them. Many dentists prefer to refer young patients to centers capable of offering general anesthesia or conscious sedation. Objective: this study is aimed to compare efficacy of Dexmedetomidine and nalbuphine sedative effects in pediatric dental patients

Materials and Methods: Cross sectional study was conducted in Department of Dentistry, Integral institute of medical sciences and research, Lucknow. Forty eight generally healthy children between 4-8 years of age for whom basic behavior modification techniques were not successful in providing dental treatment were considered for the study. Each parent or guardian was requested to fill a written informed consent form at the initial appointment. All the analysis was carried out on SPSS 16.0 in version.

Result: Mean value of onset of sedation for atomizer was 13.2±3.7minutes and nasal drop was 11.5±2.3 minutes so atomizer has rapid onset of action. Efficacy parameter for the intranasal dexmedetomidine was found to be the improved for procedural sedation. Intranasal administration with atomizer and nasal drop has no significant difference.

Conclusion: Combination of dexmedetomidine and nalbuphine provided a safe and useful sedative alternative for dental treatment in a pediatric patient. Further studies are needed to establish the optimal doses of dexmedetomidine and nalbuphine when used in combination

KEYWORDS : Sedative , Dexmedetomidine, Nalbuphine

Introduction:

Relentless anxiety and intense fear experienced by younger children regarding dental procedures have made dentists reluctant to render medical care to them.[1] Many dentists prefer to refer young patients to centers capable of offering general anesthesia (GA) or conscious sedation (CS).[2] Parents often have little information about the procedures for GA and CS, and parental orientation to either of them is likely dependent on the practicing physician. CS has been expected to provide a safe method for enabling dental treatments in children. [3,4] For this reason, a CS procedure should create a comfortable work environment and time period for dentists. [4] In addition, a medical center using GA or CS must meet all the requirements associated with emergency life support. [5] Recently, as parental demands have increased the number of centers capable of administering CS or GA has increased, leading to an increased need for related data and for personnel with specialized training in the CS technique. There are some studies related to the CS technique as applied to dentistry in the literature. [3,4,6,7] There is a long list of drugs that are used for procedural sedation by various routes the years but none of them have been proved ideal. Dexmedetomidine is approved by the Food and Drug Administration (FDA) in 1999 to be used in humans for short term sedation in intensive care unit. Initially, it has emerged as a native to premedication in pediatric anesthesia. Dexmedetomidine is one of the advanced drug has gainedpopularity among the list of drugs used for procedural sedation but been sparingly used in our country.[8] Nalbuphine is considered as a drug with a relatively low risk of inducing respiratory failure with specific mechanism of action providing potent analgesic effects, Thus,the drug is reported to be safe and effective alternative for premedication in children. Hence, this study is aimed to compare efficacy of Dexmedetomidine and nalbuphine sedative effects in pediatric dental patients

Materials and Methods:

Present study was conducted in Department of Dentistry, Integral institute of medical sciences and research, Lucknow. Forty eight generally healthy children (ASA type I) between 4-8 years of age for whom basic behavior modification techniques were not successful in providing dental treatment were considered for the study. After obtaining institutional ethical clearance. A thorough medical history followed by dental history was taken. Each parent/guardian was requested to fill a written informed consent form at the initial appointment. Risks and benefits of the sedation followed by the pre-sedation instructions were explained to the parent/guardian at the initial examination appointment. Fearful and anxious children who are uncooperative towards dental treatment and difficult to be managed by non-pharmacological means of behavior management. Children satisfying American Society of Anaesthesiologists (ASA I) physical status criteria were included. Patients were randomly divided into two groups (On the basis of drug) and each group was subdivided (on the basis of mode to be used drug administration i.e., Nasal drop and Atomized

Table 1: The Ohio State Behavioral Rating Scale as described by Lochary and co-workers was employed for the patient's acceptance of drug administration.[9]

Score	Temperament
1	Crying and struggling(CS)
2	Struggling(S)
3	Crying (C)
4	Quiet(Q)

Tables 2a: The ease with which treatment could be completed and the level of sedation were measured using separate 5-point scales.[10]

Sedation rating scale		
Score	**Sedation level**	**Response**
1	No Sedation	Typical response/cooperation for this patient
2	Minimal	Anxiolysis
3	Moderate	Purposeful response to verbal command
4	Deep	Purposeful Response after repeated verbal command or painful stimulation
5	General Anesthesia	Not Arousable

Tables 2b: The ease with which treatment could be completed and the level of sedation were measured using separate 5-point scales.[10]

Ease of treatment completion rating scale		
Score	**Classification**	**Behavioral sign**
5	Excellent	Quiet and cooperative, treatment completed without difficulty
4	Good	Mild objections or whimpering but treatment not interrupted. Treatment completed without difficulty
3	Fair	Crying with minimal disruption to treatment. Treatment completed with minimal difficulty
2	Poor	Struggling that interfered with operative procedures. Treatment completed with difficulty

1	Prohibitive	Active resistance and crying, treatment cannot be rendered

After the completion of the treatment, the patient wastransferred to a quiet room for recovery. Once fullyrecovered, the time required for complete recoverywas recorded. The patient was discharged after fulfilling the American Academy of Pediatric Dentistrydischarge criteria.[11]

Statistical Analysis:

The results are presented in frequencies, percentages and mean±SD. Chi- square test was used to compare the categorical variables between the groups. Unpaired t-test was used to compare continuous variables between the groups. The p value <0.05 was considered significant. All the analysis was carried out on SPSS 16.0 in version (Chiacgo, Inc., USA).

Result:

Subjects were randomly divided in 2 groups of 24 each. Groups 1 and 2 were further subdivided into subgroups group la (Atomizer), group lb (Nasal drop), group 2a (Atomizer) and group 2b (Nasal drop) on the basis of mode of administration of drugs

Table 3: Comparison of Rating Scales between Atomizer and Nasal Drop in Group 1

Rating Scales	Group 1(24)		Group 2(24)	
	Subgroup 1a(n=12)	Subgroup 1b(n=12)	Subgroup 2a(n=12)	Subgroup 2b (n=12)
Ease completion of Treatment				
Good	2(16.6)	2(16.6)	3(25.0)	4(33.4)
Fair	7(58.4)	6(50.0)	5(41.6)	7(58.4)
Poor	3(25.0)	4(33.4)	4(33.4)	1(8.2)
Acceptance of drug				
Crying and struggling	3(25.0)	3(25.0)	1(8.2)	3(25.0)
Struggling	4(33.3)	2(16.6)	4(33.4)	3(25.0)
Crying	3(25.0)	4(33.4)	4(33.4)	4(33.4)
Quite	2(16.7)	3(25.0)	3(25.0)	2(16.6)
Adequate depth of sedation				
No Sedation	1(8.3)	1(8.3)	0(0.0)	0(0.0)
Minimal	4(33.4)	5(41.6)	5(41.7)	5(41.7)
Moderate	6(50.0)	4(33.4)	5(41.7)	5(41.7)
Deep	1(8.3)	2(16.7)	2(16.6)	2(16.6)

Table 3 shows that the comparison of rating scales between the groups 1a and 1b. In which , 25.0 % of subjects in group 2a and 33.4% in group 2b showed good ease of treatment. 41.6% in group 2a and 58.4% in group 2b, subjects were fair. Depth of sedation, 0% 2a and in group 2b showed no sedation. 16.6% of subjects in group 1a and 16.6% in group 1b showed good ease of treatment 58.4% in group 1a and 50.0% in group 1b, subjects were fair. (table 3)

Table 4: Comparison of time parameters between Atomizer and Nasal Drop in Group 1

Time parameters	Group 1		Group 2	
	Subgroup 1a(n=12)	Subgroup 1b(n=12)	Subgroup 2a(n=12)	Subgroup 2b (n=12)
Onset of sedation (minutes)	13.2±3.7	11.5±2.3	12.4±2.8	12.0±4.0
Duration of action (minutes)	76.8±21.42	77.6±20.9	65.9±16.5	68.1±32.0
Recovery time (minutes)	116.6±20.88	116.6±21.3	110.4±17.6	99.5±27.5

Table 4 shows that the comparison of time parameters between the groups 1a and 1b. Mean value of onset of sedation for atomizer was 13.2±3.7minutes and nasal drop was 11.5±2.3 minutes so atomizer has rapid onset of action. Mean duration of action was in limitation for nasal drop 77.6±20.9 minutes as compared to atomizer 76.8±21.4 minutes. Recovery from sedation was rapid for nasal drop 116.6±21.3minutes as compared to automizer 116.6±20.88 minutes. Mean value of onset of sedation for atomizer was 12.4±2.8minutes and nasal drop was 12.0±4.0 minutes so atomizer has rapid onset of action. Mean duration of action as in limitation for atomizer 65.9±16.5 minutes as compared to nasal drop 68.1±32.0 minutes. Recovery from sedation was rapid for nasal drop 99.5±27.5 -minutes as compared to atomizer 110.4±17.6 minutes.

Discussion:

A previous paper reported that children were successfully treated with DEX sedation without complications during a dental treatment,[12] We are aware that other drug combinations may be useful and should also be studied in order to expand the range of alternatives for dental procedure sedation in pediatric patients. For example, a combination of ketamine and DEX can provide effective deep sedation during tooth extraction in children.[13] A goal of sedation in pediatric anesthesia is to relieve pre and post-operative anxiety, good parental separation and smooth completion of procedures. Anxiety during perioperative period in children can produce aggressive reactions, increased distress, increased postoperative pain, behavioral changes, and agitation as claimed by Litke et al(2012).[14] In a study by Jamses et al(2014)[15], it was observed that intranasal dexmedetomidine alone did not produce sufficient sedation and analgesia and the combination of dexmedetomidine with a potent opioid offers the potential for increased efficacy of sedation. Therefore, in the present study, combination of dexmedetomidine and an opioid-nalbuphine was used to attain more advantageable and efficacious sedation. Combination also allows lower dose of individual agents resulting in synergistic effect and thus reducing undesired effects.Nalbuphine is a synthetic narcotic agonist-antagonist analgesic as reported by Errick and Heel (1983)[16]. In present study a dose of 2.5 µg/kg of dexmedetomidine was used, which was found to provide effective sedation. Likewise, in a study done by Mohamed Ibrahim (2014)[17]. In the present study onset of sedation for group 1 with atomizer was 13.2±3.7 minutes and with nasal drop 11.5±2.3 minutes. On contrary to present study another study done by Talon (2009)[18] reported that onset of sedation of dexmedetomidine was 15 minutes when administered by a meter-dozed atomizer in a dose of 2µg /kg. In the present study, duration of action of group 1 was 76.8±21.42 minutes and 77.6±20.9 minutes and in group 65.9±16.5minutes and 68.1±32.0 minutes while recovery time of group 1 was 116.6±20.88 minutes and 116.6±21.3 minutes and group 2 was 110.4±17.6 minutes and 99.5 ± 27.5 minutes respectively. This concludes that group 1 and group 2 have comparable sedative efficacy. Similarly, in other study, done by Sury and Cole, (1988)[19] various doses of nalbuphine with midazolam administered intravenous, was compared for outpatient sedation. In the present study there was no significant difference in sedative efficacy of combination and dexmedetomidine alone similar to the finding of another study done by Borges et al (2016)[20].Therefore, we can say that Dexmedetomidine with and without nalbuphine administered by either an atomized device or nasal drop is safe and effective premedication for children.

Conclusion:

Combination of dexmedetomidine and nalbuphine provided a safe and useful sedative alternative for dental treatment in a pediatric patient. Further studies are needed to establish the optimal doses of dexmedetomidine and nalbuphine when used in combination to prevent arousal and sedation during dental treatment in pediatric patients.

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