Deep Sedation for Pediatric Dental Procedures: Is this a Safe and Effective Option?

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Objective: *Sedation may be needed for safe, effective completion of pediatric dental procedures. Procedural sedation is performed in a children's hospital based dental office. The three sedation approaches: a propofol-only (P-O) approach (2-3mg/kg titrated to the needed level of sedation), an approach that includes either IV ketamine (K+P) (0.25 or 0.5mg/kg) or IV fentanyl (F+P) (0.5- 1mcg/kg) prior to propofol administration. We sought to determine safety and efficacy of various propofol based sedation protocols.* ***Study Design:*** *Retrospective review of 222 patients receiving a propofol-only (P-O), ketamine+propofol (K+P) or fentanyl+propofol (F+P) approach.* ***Results:*** *There were 44 patients in P-O group, 154 in K+P group and 24 in F+P group with mean age (4.8±3.4y) and mean weight (19.7±6.7kg). All the patients completed procedures successfully. Mild hypoxemia occurred in 24% of cases and resolved with nasal cannula. Mean total dose of propofol was similar in all groups (P-O 8.2mg/kg, K+P 9.5mg/kg, F+P 9.6mg/kg, p=0.15). Although procedure and recovery times were similar in all groups, discharge times in K+P group were significantly shorter than P-O group and F+P group respectively (K+P 9.35±8.93.min, P-O 13.57±10.42min, F+P 10.42±4.40 p= 0.002).* ***Conclusion:*** *Sedation can be accomplished safely and effectively in a children's hospital based dental office using propofol-based sedation.*

Key words:Pediatric dental sedation ,Propofol, Financial Implications.

INTRODUCTION

Fear, anxiety and pain may be anticipated and experienced with dental procedures, where delicate, but invasive, procedures using sophisticated instruments need to be conducted. In order to complete these procedures, patients need to remain calm and still, this may be particularly difficult for a subset of children who require invasive or extensive dental interventions and have high levels of anxiety, underlying behavior disorders or mental disabilities.

Various patient management strategies have been employed during complex dental procedures that include behavioral techniques, oral sedatives, inhaled nitrous oxide (N_2O), and general anesthesia.[1,2] Although widely used, minimal or moderate sedation (for example using oral sedatives and N_2O) is unpredictable especially in young children.[3] General anesthesia is more successful, but is invasive and higher-risk. For a number of non- and semi-invasive procedures in children, deep sedation provided by non-anesthesiologist specialists has shown to be safe, effective and cost effective.[2]

In 2011 our intensivist-led sedation team began to provide procedural deep sedation for the hospital-based dental office. To date, there are no other reports analyzing the use of deep sedation for pediatric dental procedures performed in this setting. We hypothesized that deep sedation for dental procedures in selected pediatric patients is safe and effective.

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MATERIALS AND METHOD

Retrospective chart review in which the following data was collected: patient demographics, adverse events, physiologic variables, drug dosages, the time required to sedate the patient, time needed to complete the dental procedure and recovery time. After approval by the Institutional Review Board, we conducted a retrospective analysis of all patients who received deep sedation for dental procedures between February, 2011 and July, 2014.

Institutional sedation policies, based on guidelines developed by the Joint Commission on Accreditation of Health Care Organization and the American Academy of Pediatrics, were closely followed. All patients were screened to make sure that they were appropriate sedation candidates (ASA I and II). [4] The screening process includes chart review, past medical, surgical and anesthetic histories. Parents are contacted directly by telephone to resolve any unclear medical issues. Vital signs including pulse oximetry, heart rate, non-invasive blood pressure monitoring, and nasal capnography were continuously monitored and documented every five minutes throughout sedation.

The propofol-only (P-O) sedation protocol consisted of an intravenous (IV) bolus of propofol 1 mg/kg over 15 -30 seconds. Repeat boluses were used as needed to achieve and maintain the desired level of sedation until the procedure was over. In the ketamine+propofol (K+P) group, sedation was started with a single low dose of ketamine bolus (0.5/kg mg < 20 kg; 0.25/kg mg > 20kg) followed with IV propofol titrated as above. For the fentanyl+propofol (F+P) group, a fentanyl bolus of 0.5- 1 µg/kg (maximum 50µg) was given followed by propofol.

There was no maximum dose of propofol as long as the patient's respiratory and hemodynamic status remained stable. Supplemental oxygen was administered via nasal cannula if saturation dropped to less than 90% for more than 30 seconds. Procedure time started with the beginning of administration of bolus of the first drug and ended with the completion of procedure. Recovery time was defined as the time from the end of the procedure to actual time the patient was back to his base line status.

Data are presented as means ± and standard deviations, unless mentioned otherwise. Propofol-induced vital sign changes from baseline for the entire study cohort were compared using Student's t-test and Mann–Whitney rank-sum test, depending on the distribution of the data. Patients were divided into three subgroups depending on additional medications received. A propofol-only (P-O) or ketamine+propofol (K+P) or fentanyl+propofol (F+P) approach to sedation for dental procedures. These three sedation groups were compared with respect to age, weight, blood pressure, heart rate, procedure time, and discharge time using Analysis of Variance methods. If the omnibus p-value was significant, pairwise comparisons were performed to see which pairs were significantly different statistically, using the Bonferroni correction. Incidence of desaturation and hypotension were analyzed with Fisher's Exact test. Data were analyzed using dedicated statistical software SAS v9.3 (SAS Institute, Cary, NC). A p-value< 0.05 was considered statistically significant.

Table-1:Patients Demographics P-O vs. F+P Group vs. K+P

	Ketamine+Propofol (n=154)	Propofol only (n=44)	Fentanyl + Propofol (n=24)	P-value
Age (years)	5.04 (2.35)	4.44 (1.34)	5.00 (2.53)	0.2807
Weight (kg)	20.63 (8.60)	18.80 (5.26)	19.74 (6.51)	0.3811
Male	79 (51.3)	20 (45.5)	13 (54.2	0.7348

RESULTS

All 222 patients were successfully sedated using a propofol-containing regimen. The most common indication was dental caries. There were 44 patients treated with P-O group, 154 with K+P group and 24 with F+P group. Mean age (P-O 4.44±1.34y; K+P 5.00±2.35y; F+P 5.00±2.53y) and weight (P-O 18.80±5.26kg; K+P 20.63±8.60kg; F+P 19.74±6.51kg) were similar in all groups (P=NS). (Table-1) Mean total dose of propofol was similar in all groups (P-O 8.2mg/kg, K+P 9.5mg/kg, F+P 9.6mg/kg; p=0.06). (Fig-1) Although procedure and recovery times for all sedation groups were not statistically different , discharge time in K+P group was significantly shorter than P-O group and F+P group, respectively (K+P 9.35±8.93min, P-O 13.57±10.42min, F+P 10.42±4.42min; omnibus p=0.002, with K+P being significantly different from P-O). No apneic events were observed but mild hypoxemia (SaO2 < 90%) occurred in 24% of patients, all of which resolved with supplemental oxygen.

Hypotension was defined as a decreased in systolic blood pressure > 20% from the baseline values.[5] The incidence of hypotension between the groups was not statistically significant (P= 0.65). Although a drop of blood pressure was commonly observed, medical intervention was not needed.

In the population of 222 patients, no children had heart rates below the age-specific normal awake range during sedation based on the published norm of L H Mathers et al., nor did the lowest recorded heart rate fall >20% below the given baseline average range. [5, 6] Bradycardia (HR<60/min) as defined according to Pediatric Advance Life Support (PALS) guidelines, was also not observed in any child. (P=0.83) Table 2 gives general heart rate and blood pressure associations with sedation groups.

DISCUSSION

Conventional non-pharmacologic behavioral management techniques, along with local anesthetics, are frequently used in pediatric dentistry. However, for the group of children with high anxiety or behavior disorders, sedation is needed to facilitate safe completion of the dental procedure. [7] This appears to be the first report of using deep sedation in dentistry.

Although general anesthesia is relatively safe in a hospital setting, it is now recognized that general anesthesia (GA) should be avoided whenever possible due to increased risk of complications. [8] GA is also costly as it requires the use of highly specialized personnel and equipment. An alternative approach is to perform pediatric dental procedures under deep sedation. However, due to

potential and real risks, it is likely that this will only be provided in a hospital-based dental setting where other support resources are available and by the physicians trained and skilled in airway management such as Pediatric Intensivists, Emergency Medicine Physicians or Anesthesiologists.

Propofol is a powerful sedative characterized by rapid onset and short duration of action. [9] Adverse effects include transient hypotension and dose-dependent respiratory depression. [10] Propofol has been shown to allow rapid recovery, making it an ideal agent for minor procedures outside operating suites. [3, 11] For example, in a case series of 104 children undergoing pediatric gastrointestinal endoscopic procedures, propofol was used successfully without serious adverse effects. [12] This agent could also serve an important role in dentistry. [13]

Fentanyl is often co-administered for pain control during procedural sedation. [14] However, this may have an additive respiratory depressant effect with propofol. [15] Similarly, a sub-dissociative dose of ketamine has been used for its analgesic effects as an adjunct to propofol, and has been shown to be effective in procedural sedations for painful procedure with less respiratory and hemodynamic depressant effects. [16, 17]

Administering an adjunct analgesic during propofol procedural sedation is not a routine practice. However, recently, recommendations were made to use propofol following achievement of analgesia with an opioid. [18] Although sedated patients may not clearly recall procedural pain, painful stimuli can sensitize the nervous system of clinically- unresponsive patients and may lead to increased post-operative pain and hyperalgesia. [19] The use of IV analgesics including opioids and ketamine has been encouraged to avoid this phenomenon. [16, 20] Therefore, it is important to differentiate between sedation and analgesic effect and to treat expected intraoperative pain adequately during procedural sedation.

In our study, deep sedation was accomplished in all three groups. Treatment procedures were completed comfortably, which is contrary to findings as described by Kavitha *et al* [21] In this study, propofol was used for moderate sedation for dental procedures. According to their findings, propofol was highly effective in terms

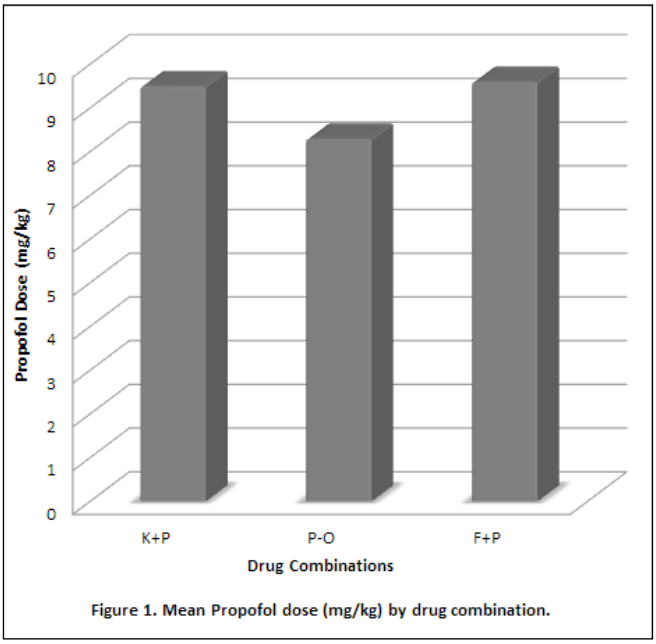

Figure 1. Mean Propofol dose (mg/kg) by drug combination.

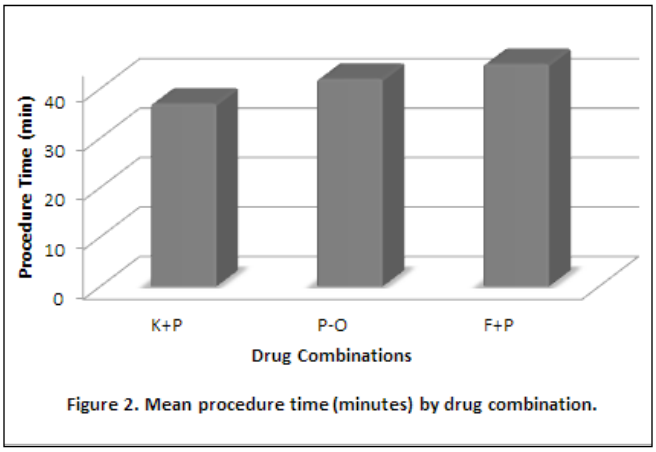

Figure 2. Mean procedure time (minutes) by drug combination.

Table 2: Associations for dental sedations

	Ketamine+Propofol	Propofol only	Propofol+Fentanyl	P-value	P-value
SBP (Pre)	110.95 (13.17)	110.72 (12.73)	115.82 (10.23)	0.2352	0.4805
SBP (Complete)	100.12 (12.42)	99.00 (10.55)	101.83 (11.91)	0.6566	0.8927
SBP (Discharge)	106.30 (14.98)	110.42 (13.62)	116.61 (14.88)	0.0046*	0.0018*
DBP (Pre)	68.41 (13.52)	59.74 (14.60)	67.18 (14.64)	0.0017*	0.0562
DBP (Complete)	55.29 (13.28)	47.57 (10.29)	53.57 (15.04)	0.0027**	0.0210*
DBP (Discharge)	70.25 (14.28)	65.23 (16.01)	75.61 (17.79)	0.0244*	0.0739
HR (Pre)	108.66 (22.38)	112.41 (16.91)	106.58 (14.52)	0.4624	0.3197
HR (Complete)	102.68 (16.20)	101.48 (14.20)	103.83 (14.45)	0.8312	0.9376
HR (Discharge)	106.38 (18.45)	113.25 (18.46)	107.75 (15.80)	0.0897	0.5468
Desaturation	44 (28.6)	7 (15.9)	3 (12.5)	0.0811	

Values are means (standard deviations) for continuous variables and frequency (percent) for categorical variables. P-values are from analyses of variance methods for continuous variables and Chi-Square tests for categorical variables.

*indicates the omnibus p-value and that K+P was significantly different from F+P.

**indicates the omnibus p-value and that K+P was significantly different from P-O.

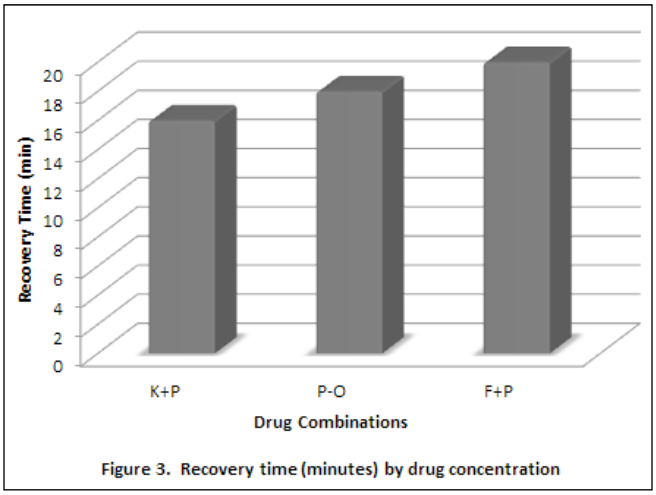

Figure 3. Recovery time (minutes) by drug concentration

of onset of sedation, but continuous movements and crying made the dental procedure very difficult throughout.

Bradycardia has been described as a possible adverse effect of propofol when administered alone or in combination with opioids. [22] In our study, the incidence of bradycardia was zero (defined as a decrease in heart rate >20% from baseline). Propofol has also been shown to cause transient decrease in blood pressure when administered as a bolus or prolonged infusion [22]. No patient in this study experienced hypotension (defined as >20% decrease in blood pressure from baseline).

Respiratory events constitute a large proportion (5.5% – 31.7%) of sedation complications in children. [23] We observed similar levels of hypoxemia (24% of patients). This is encouraging if we take into consideration that the procedures were being done in the oral cavity with an inappropriate position of the airway as the dentist has to manipulate the oral cavity to get their tools into appropriate position. Contrary to previous studies, oxygen desaturation was particularly common in K+P group followed by P-O group and P-F groups respectively. The decreased incidence of hypoxia in the P-F group supports our conservative use of fentanyl dose ranging from 0.5 - 1mcg/kg compared to previously reported doses of 1.5 mcg/kg, or it could be a representative of a lower sample size in F+P group(3/24(12.5%) vs. P-O 7/44(16%) vs. K+P 44/154(29%). [24] Mild hypoxemia resolved with nasal cannula and none of the patients required BMV.

Of note, no prophylactic supplemental oxygen was administered unless the oxygen saturation fell below 90%. This likely contributed significantly to the frequency and rapidity of oxygen desaturation. The use of routine supplemental oxygen administration during procedural sedation of selected low-risk patients are debatable. [25] Published trials have not identified a standardized approach to its use. [24,26] It can be asserted that oxygen desaturation in patients breathing room air is an early and rapidly detected sign of respiratory depression, helping the sedating physician to recognize an otherwise subtle event. Additionally, room air desaturation typically responds quickly to administration of oxygen, patient stimulation or interruption of propofol administration.

ETC02 was monitored throughout, yet, the recordings were often unreliable as the oral cavity had to be maintained wide open, thus decreasing the value of continuous capnography as a monitoring tool for this type of procedure. Previous study found that for low- risk patients breathing room air, oxygen desaturation usually precedes changes in capnography during procedural sedation with propofol and is readily reversible. [27] No patient experienced nausea, vomiting, shivering or perspiration with any of the three groups. No emergence phenomenon was observed, which is not surprising given our low dose ketamine. In a previous study using a medium dose of 0.75 mg/kg ketamine co-administered with propofol, 3 of 114 patients experienced emergence reaction and one required treatment. [17]

A variety of drugs have been used for moderate sedation for dental procedures. The efficacy and safety of IV midazolam, ketamine and propofol was assessed in 30 uncooperative children aged 3-6 years requiring oral rehabilitation. Ketamine was most effective without adverse events followed by propofol and midazolam. The latter two drugs were not able to control body movement and crying throughout the procedure. [21] Oral chloral hydrate and I/M Ketamine were compared by Campbell in 15 patients. Satisfactory completion of restorative dentistry longer than 40 minutes was obtained in the group with intramuscular ketamine. [28] In our study, high-dose propofol, (alone or in combination with ketamine or fentanyl) was equally effective for dental procedures. Our total doses of propofol (8.1-9.6 mg/kg) are comparable to other studies after taking into consideration the length of mean procedure time (42 minutes vs. 14 minutes). [29]

Procedure and recovery times were shorter in the K-P group and did reach statistical significance (Fig-2&3). However, it is hard to infer a clinical explanation for this as it does not parallel a similar variation in the propofol dose. Hypoxemia was not associated with any delay in discharge. None of our patients had any short or long-term morbidity from inter-sedation events.

At our institution, average charges incurred to provide treatment under GA are 10 times higher than of those providing same treatment under deep sedation.

CONCLUSION

Sedation can be accomplished safely and effectively in children's hospital based dental office by the physicians trained and skilled in airway management using propofol-based sedation. This also provides a financially valuable alternate option to GA for pediatric dental procedures.

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