Could conscious sedation with midazolam for dental procedures be an alternative to general anesthesia?

E Silay, C Candirli¹, F Taskesen¹, I Coskuner, KT Ceyhanlı², H Yildiz

Department of Anaesthesiology and Reanimation, Faculty of Medicine, Kahramanmaras Sutcu Imam University, Kahramanmaras, Turkey ¹Department of Oral and Maxillofacial Surgery, ²Department of Endodontics, Faculty of Dentistry, Karadeniz Technical University, Trabzon

Abstract

Aim: The aim of our study was to evaluate the likelihood that conscious sedation (CS) with intravenous midazolam could become an alternative modality to general anesthesia (GA) for dental procedures.

Materials and Methods: In our study, 58 and 47 American Society of Anesthesiologists (ASA)-1 pediatric patients, aged 2–12 (mean 6) years, underwent dental procedures and minor oral surgical procedures under GA and CS with intravenous midazolam, respectively. The two groups were evaluated in terms of vital signs, duration of the treatment procedure, patient behavior, and the treatment comfort experienced by the physicians.

Results: The oxygen saturation level was significantly lower (GA: 99.0 ± 0.30, CS: 98.4 ± 1.02; \( P < 0.001 \)) and the duration of the treatment procedure was significantly shorter (\( P < 0.001 \)) in the sedation group compared with the GA group. The physicians encountered various difficulties during implementation of the treatment strategy in cases where they used CS. Minor oral surgical procedures and tooth extraction processes requiring no saline irrigation, however, could be performed successfully under CS.

Conclusions: In cases requiring multiple dental management issues, the sedation method was not found to be a useful alternative to GA.

Key words: Conscious sedation, general anesthesia, pediatric dentistry

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Introduction

Severe anxiety and extreme 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] Although distinct views regarding sedation methods in dental treatments exist, the most appropriate CS method and the feasibility of sedation methods in dentistry have yet to be determined.

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Recent studies have focused on the sedative effect and mode of application of midazolam. This agent, a benzodiazepine derivative, has received attention because of its convenience in administration and low risk for complications. In this study, we compared procedural parameters and physician comfort levels during dental treatments performed in pediatric patients under CS with intravenous (IV) midazolam versus GA.

**Materials and Methods**

To determine the number of samples for the study, we evaluated similar studies in the literature. In our study, 58 and 47 American Society of Anesthesiologists (ASA)-1 pediatric patients, aged between 2 and 12 (mean age 6) years, underwent dental procedures and minor oral surgical procedures under GA and CS with IV midazolam, respectively. Fifty of the cases were males and 55 were females. The pre-diagnosis and related treatment plans were established at Dentalpark Oral and Dental Health Center. Informed consent was obtained from the parents of all patients prior to the procedure. Ethical approval for this study was obtained from the local ethical committee.

The techniques to be used for pain management were disclosed to and discussed with parents and caretakers. The patients and the parents were free to choose any of the anesthesia techniques for their dental treatment after they received comprehensive information about both techniques.

Prior to treatment, all cases had consulted with the relevant medical departments with regard to the anesthetic procedure to be performed, and all were evaluated in accordance with ASA guidelines.

Patients were instructed to fast for about 8 h prior to anesthesia procedure. We put drops of 0.5 mg/kg of dexametomidine to the nasal cavity of the non-cooperative patients to calm them prior to anesthesia, if needed. Adrenaline (0.5 mg/ml), atropine (0.5 mg/ml), and cardiopulmonary resuscitation devices were present for the management of possible complications of anesthesia.

After assessment by an anesthesiology specialist physician in advance, all patients underwent dental procedures performed by two dentists or minor oral surgeries performed by a single maxillofacial surgeon. Dental fillings and root canal treatments constituted the majority of the dental treatments; the surgical procedures more commonly involved tooth extractions, phrenilectomies, and impacted tooth extractions. Midazolam was administered via the intravenous route in the cases assigned to the CS group, and oral intubation was performed in all cases undergoing GA.

The following issues were assessed and recorded by an observing dentist not participating in the treatment:

1. initial and repeated doses of anesthetic and sedative agents administered;
2. vital signs of the patients (oxygen saturation, pulse rate);
3. treatment procedures performed;
4. duration of the procedures;
5. patients’ behavior patterns while under CS; and
6. procedural comfort experienced by the physicians. The behavioral patterns of the patients were evaluated using the Houpt sedation rating scale [Table 1].

**Statistical analysis**

SPSS software (ver. 11.5 for Windows) was used for all analyses. Continuous variables were tested for near-normal distribution using the Shapiro–Wilk test. As the data showed a non-normal distribution, non-parametric tests were performed. The interquartile median was calculated for continuous variables. The significance of differences between groups was assessed using the Mann–Whitney U test. Values of $P < 0.05$ were deemed to indicate statistical significance.

**Results**

No complications were encountered in the patients under GA or CS. Based on the assessment criteria, an average of 1.5 mg of midazolam was administered to the patients receiving CS. A repeat dose of midazolam was administered in 32 cases because of the duration of the treatment procedure. The average oxygen saturation level was significantly lower (GA: 99.0 ± 0.30, CS: 98.4 ± 1.02; $P < 0.001$) and the duration of treatment was significantly shorter (GA: 60 ± 15, CS: 30 ± 10; $P < 0.001$) in the CS group compared with the GA group. The physicians were observed to be able to practice more comfortably for longer periods of time in cases using GA.

No significant difference in pulse rate was observed between the groups (GA: 110 ± 18, CS: 115 ± 10, $P = 0.344$) [Table 2].

Restorative treatments, root canal treatments, tooth extractions, and phrenilectomies were performed in both the GA and CS groups. The distributions of treatment protocols performed under GA and CS are shown in Table 3.

Although a sufficient level of CS was achieved, on the basis of the Houpt sedation rating scale, difficulties were noted by the physicians during the treatment of the cases under CS. Limited movements and limited crying were observed in most patients. Although treatments were interrupted in a few patients, all procedures were completed [Table 4]. Occasional head and arm movements by the patients adversely affected the comfort of the physicians during the procedures. Moreover, difficulty in swallowing or total loss of the swallowing reflex was experienced in some patients, prompting the physicians to act in a more anxious and hasty
manner. Cases under CS were noted to be more agitated on recovery, whereas patients under GA experienced a more tranquil phase during recovery.

Discussion

After evaluating previously published studies to determine our study samples, 58 children for GA and 47 children for CS were included in our study. There was a difference in the distribution of the patients in the GA and CS groups and it was due to the choices of the parents who were instructed about both techniques and were free to choose any of the techniques. A sizable number of the pediatric patients in this study were treated for infections and pain accompanying tooth decay; orthodontic tooth extractions and minor oral surgical procedures were performed in the remaining cases. The ratio of cases in the present study was similar to that previously reported for dental management under anesthesia.\(^{[9]}\)

Expectations regarding CS vary dramatically among different patient groups. Adult patients may expect abolition of the fear of injection or the fear of an operation until the time when local anesthesia is achieved at the operation site. After these fears are relieved using CS, the treatment can be continued under local anesthesia without the need for further CS. However, in young children, it is usually necessary to totally abolish fear and anxiety during the entire procedure. Thus, while the comfort of an adult patient can be achieved by the administration of a single initial dose of sedative, this may not be true in pediatric patients, who generally require the administration of CS for longer durations.

In this study, all the dental procedures were completed in a single session in the children under GA, consistent with what parents would generally expect. The primary dental problem can be treated in a single session in children under GA, obviating the need for further restorative dental procedures and surgical operations. However, because of the shorter duration of procedure time permitted under CS, treatment of only the tooth causing pain was accomplished in most cases where CS was used. Unwillingness of the anesthesiologist to administer additional doses owing to the possible risk for respiratory depression in cases necessitating prolonged sedation had an impact on the procedural comfort of the physicians. The administration of repeated doses in an attempt to prolong procedure duration is likely to create a risk for loss of swallowing reflexes or even the emergence of asphyxia.\(^{[10]}\) In contrast, minor oral surgical procedures such as tooth extractions and phrenilectomies could be performed under CS.

Milnes et al. reported the feasibility of implementing dental treatments in a single session using IV midazolam CS compared with other CS techniques.\(^{[11]}\) Unlike Milnes et al., we conclude here that it did not seem feasible to undertake dental procedures likely to require longer times by administering only a single dose of CS agent. Caputo et al. also reported that the administration of additional doses of sedative in an attempt to prolong the duration of CS is likely to result in complications such as asphyxia and hypoventilation.\(^{[10]}\) Moreover, dose escalation in dental treatment procedures performed under CS via the intravenous route in an office setting, not in a hospital, may lead to severe outcomes and even mortality.\(^{[12,13]}\)

Many sedatives and anesthetic agents are known to depress respiratory drive. Hypoxemia is an important factor, especially in those under less-than-meticulous monitoring, and may give rise to severe complications leading to death, as mentioned above.\(^{[10]}\) Midazolam at high doses is capable of exerting a depressive effect on the respiratory system.\(^{[10,12,13]}\)
The anesthesiologist in our study avoided the administration of additional doses of midazolam. Thus, the dental treatments performed under CS were limited to the affected teeth about which the patients complained and other treatments were skipped due to lack of time. In the cases where GA was used, the physicians had sufficient time to treat the affected teeth as well as restored other diseased teeth. In this study, the durations were significantly longer in patients under GA compared with CS.

Hypoxemia was not a complication in patients under GA or CS. Although oxygen saturation levels in patients under GA were significantly higher than those in patients under CS, the mean saturation level in the CS group was not at a critical level and was not likely to have an impact on vital signs. In a study analyzing the oxygen saturation levels in 1750 patients undergoing intravenous sedation for dental procedures, Viljoen et al. found that midazolam and fentanyl at tolerable doses were not detrimental risk factors for oxygen saturation of the blood.[4]

Another important point is the quality of the restorations made. In the present study, the physicians were inclined to act in a hasty manner when treating the children under CS. Despite the achievement of a certain level of CS, the children tended to occasionally move their heads, arms, and legs, and were sometimes reluctant to open their mouths, which adversely affected the operational comfort of the physicians. On the other hand, the physicians did not experience anxiety associated with the time duration of the procedure during the treatment of children under GA, and they managed to comfortably conduct the procedure. A randomized double-blind study examining which dental interventions are feasible under GA and which are feasible under intravenous sedation has yet to be published.[14]

According to the findings of the present study, implementation of GA is recommended for procedures that are likely to take longer times and would thus require repeated doses for sedation if CS were to be used. However, procedures such as tooth extraction and minor oral surgeries can readily be performed under CS. In the same regard, Rodger et al. reported in their retrospective study that anesthesia-related complications occurred in only 1.57% of 3320 patients undergoing oral surgical procedures under sedation via the intravenous route.[14]

GA can only be implemented in the hospital settings[2,9,10] whereas CS can also be performed in an oral and dental health clinic, provided there is close monitoring by an anesthesiologist.[10] This may prompt a physician at a private dental clinic to favor CS.[11] A survey by Ashley and co-workers reported a predilection of dentists for CS procedures, although performing procedures under CS in a private dental clinic has been the subject of debate.[11] Woolley and co-workers discussed the training requirements associated with sedation techniques that are supposed to be met by dentists in the United Kingdom, and most of the participants agreed that sedation techniques other than induction by nitrous oxide inhalation should be implemented in a hospital setting.[9] Additionally, the UK guidelines for pediatric dentistry recommended practicing sedation techniques with an anesthesiologist in a hospital setting.[2,9] Even with supervision by an anesthesiologist, using sedation techniques in private clinical settings can be associated with many risk factors that may lead to death.

GA may result in severe airway-related complications such as obstruction and bronchospasm and involves a general risk of death associated with anesthesia. However, the number of deaths attributed to GA in dental patients is far less than the total GA deaths reported in the literature, not least because dental patients are generally in class 1 or 2 of the ASA Physical Status Classification and typical dental interventions are noninvasive in nature.[15] In the present study, no complications were observed related to GA or CS.

There are several tests for scoring behavioral attitudes and sedation levels.[7,16,17] We used the Houpt sedation rating scale. It is a safe and easy-to-apply test which has been used with a great success in many studies.[8,16,19]

The findings in our study suggest the impossibility of IV sedation with midazolam being an alternative to GA in dental procedures. However, short-term minor surgical or restorative interventions such as tooth extractions that do not require the use of saline irrigation have been reported to be readily performed under IV sedation with midazolam. The present study fails to provide insight with regard to long-term success rates of dental procedures under GA versus CS. Moreover, long-term postoperative effects of the two techniques were not examined in this study. Further prospective studies with larger numbers of cases are needed.

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