

Intravenous procedural sedation: an alternative in the treatment of patients with intellectual disability

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Abstract

Conscious sedation has become established as an important alternative to general anesthesia (GA) in dental treatment of patients with intellectual disability (ID). **Aim:** to investigate dental patients undergoing sedation using a mean dose of 0.6 mg/kg intravenous midazolam and the adverse events of sedation in patients with ID. **Methods:** This study analyzed the records of 163 dental patients with ID aged between 2 and 76 years who had undergone conscious intravenous sedation (CIV) using a mean dose of 0.61 mg/kg of midazolam at Araçatuba Dental School, São Paulo State University, Brazil. The efficacy and complications induced by CIV were evaluated in each subject. **Results:** CIV was effective for dental treatment in 80% of the cases. A total of 626 dental procedures were performed. The mean treatment time was 33.9 minutes. There was statistically significant difference ($p < 0.05$) between absence and presence of adverse reactions. Adverse reactions were observed in 21.47% of the cases. **Conclusions:** The results of this study showed that CIV is a useful method for dental treatment of patients with ID and these patients can need higher doses of sedative to reach an adequate level of sedation.

Keywords: dental anesthesia, dental care, intellectual disability, sedation.

Introduction

It has been acknowledged that the population with disabilities has higher rates of poor oral hygiene, gingivitis, and periodontitis than the general population. Moderate or severe gingivitis has been found almost ordinarily, with degree and extent increasing with age and severity of mental retardation¹⁻². Moreover, special needs patients tend to have more decayed and missing teeth compared to non-disabled patients³. An extended series of reports on the use of dental services by children and adults with disabilities focuses on limited physical access to buildings, limited practitioner willingness to provide care, and associated insurance and financial difficulties resulting in longer periods between dental visits and a tendency to have had extractions at the last visit⁴⁻⁵.

Sedation is a useful method for relieving dental fear and anxiety in patients, and it is often essential for people with ID undergoing dental treatment⁶. Benzodiazepines are currently the pharmacological group of choice due to their greater effectiveness provided by their efficacy and safety margin. In addition, muscular relaxant effect of these drugs helps calming the patient down. In this group, midazolam has been efficient in controlling the anxiety and maintaining blood pressure and oxygen saturation within normal levels⁷⁻¹².

The pharmacological characteristics that made midazolam a drug of choice for clinical sedation are: quick action, short half life and suitable sedation duration.

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Its anxiolytic, hypnotic and amnesiac effects compose the main objectives to be reached with its utilization. Moreover, the diversity of administration routes (oral, rectal, intramuscular, endovenous and intranasal) offers alternatives that better suits a great number of patients^{7-8,12-13}.

Conscious intravenous sedation (CIV) is frequently provided for dental patients as an alternative to GA in the Center of Dental Care to Special Needs Patients of Araçatuba Dental School, São Paulo State University (CAOE/FOA/UNESP), Brazil. However, the decision about the required dose for an adequate level of sedation is difficult because the effect of sedation cannot be adequately assessed in patients with severe ID. It has been reported that a high dose of sedative is required for patients with ID to obtain an adequate level of sedation^{9,14}, but an appropriate sedative dose has not been satisfactorily established for dental patients with ID. Thus, the authors investigated dental patients undergoing sedation using a medium dose of 0.6 mg/kg intravenous midazolam and the adverse events of sedation in patients with intellectual disability (ID).

Material and methods

One hundred and sixty three mentally handicapped patients were treated under CIV at the CAOE/FOA/UNESP, Brazil between January and July 2003 (Figure 1).

This treatment was chosen because each patient had previously exhibited combative behavior sufficiently negative to dental treatment using routine behavior management techniques or presented muscular spasticity (cerebral palsy patients). The Research Ethics Committee of Araçatuba Dental School, São Paulo State University, Brazil, approved the study (Protocol #FOA 876/2003).

The age of the patients undergoing CIV ranged from 2 to 76 years. Only patients with ASA I or ASA II physical status were eligible for the study. CIV was induced with a bolus intravenous administration of midazolam ranging 0.3 to 1.2 mg/kg for a mean dose of 0.61 mg/kg and all patients were immobilized with bands to control involuntary movements that might occur during the dental procedure. The dental treatment started 2 min after midazolam administration. Once the patients were sufficiently sedated, local anesthesia with 2% lidocaine with 1/100,000 adrenaline was delivered before the clinical procedures. The maximum

dose of local anesthetic was limited strictly to 4.4 mg/kg for all patients. Resuscitation equipment was available if required and a medical team followed each treatment session.

The efficacy of sedation and the duration of the dental treatment were investigated. The efficacy of sedation was evaluated by judgment of the patient cooperation to the dental treatment and the determination of the dose to be administered to each patient was accomplished by the cardiologist responsible for the sedation at CAOE/FOA/UNESP, according to the patient's body weight, physiological, nutritional and pathological evaluation. In the present study, the mean effective dosage was 0.61 mg/kg. According to the observations made by the senior researcher, the sedation was considered to be effective when the patient was classified as "Cooperative" (the patient was sedated and remained awake, sleeping or sleepy during the treatment session, but was cooperative). The sedation was considered not-effective when the patient was classified as "Non-cooperative" (the patient was awake and uncooperative, not allowing the procedures to be done, even after sedation). The adverse effects of CIV were also evaluated in each subject. The incidence of pre- and post-CIV complications, including vomiting, respiratory depression and others (tremor, tachycardia), were also evaluated.

Data were analyzed statistically by the chi-square test. Statistical differences were considered significant at $p < 0.05$.

Results

A total of 626 dental procedures, such as amalgam, resin and glass ionomer cement restorations, sealants, extractions, scaling and root planing, root canal therapy, and others (frenectomy, ulectomy and biopsy), were performed (3.8 procedures *per patient* on the average) (Figure 2).

The mean treatment duration was 33.9 min (Table 1). In 56% of the patients, all necessary procedures were completed in a single session.

CIV was effective for dental treatment in 80% of the subjects with ID. There was accentuated resistance in 20% of the patients during the dental procedures, and these patients were subjected to GA in another day. There was no statistically significant association ($p > 0.05$) between midazolam dose (mg/Kg) and patient response (Table 2).

There was statistically significant difference ($p < 0.05$) between the absence and the presence of adverse reactions

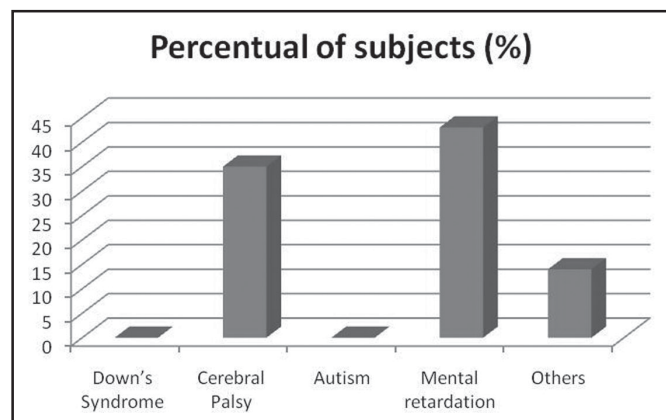


Fig. 1. Classification of patients according to the handicapping condition.

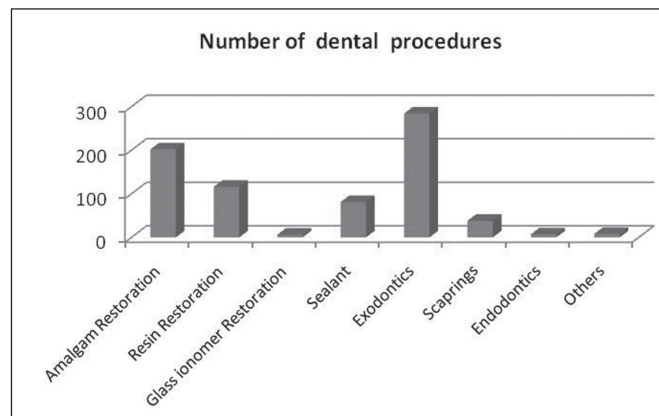


Figure 2. Number of dental procedures performed under sedation.

Table 1 - Number of subjects according to the duration of procedures in minutes.

Duration of procedures (Min)	Number of subjects
00 – 20	45 (27.6%)
21 – 40	73 (44.8%)
41 – 60	40 (24.5%)
61 – 80	4 (2.4%)
81 – 100	1 (0.7%)
Total	163 (100%)

in this study. There were 49 episodes of adverse reactions in 35 patients (only 21.47%), in which 16.5% were related to respiratory depression, 6.7% to vomiting, 4% to flutter and 2.4% to other reactions (Table 3).

In these cases, patients received appropriate medical assistance and medication. There was no difference regarding to the dosage *per* body weight of medication administered to the patients who developed adverse reactions (Table 2).

Discussion

Over the last few years several management modalities have been developed to overcome difficulties encountered during complex dental procedures for treatment of special needs patients. Various methods of sedation and sedatives have been described for dental treatment for patients with ID as preferred alternative to full GA^{6,9-10}.

It is widely accepted that CIV is safer than GA¹¹⁻¹³. However, poorly controlled conscious sedation may result in “deep sedation” or even GA with all its attendant risks¹³. Since the possibility of an exaggerated level of central nervous system depression always exists, the drugs and techniques employed must carry a wide margin of safety, and the physician should be particularly careful to render the loss of reflexes unlikely. This is especially true in some of the disable patients who are chronically medicated, which could alter their response to certain sedative drugs¹². However, it is necessary to emphasize that the highest interaction chances are reported, mainly through the use of oral midazolam, with the following drugs: carbamazepine, phenytoin, rifampicin, roxithromycin, erythromycin, fluconazole and verapamil⁷. It is important that during intravenous sedation vital signs including blood pressure, pulse rate, and arterial blood oxygen saturation are continuously and properly monitored and recorded¹⁵.

Currently, there is divergence among the dose, drugs and administration route used in CIV. The present study describes the use of CIV as an alternative to GA in dental treatment of patients with ID at CAOEF/FOA/UNESP, Brazil. A bolus administration of midazolam was performed, which has been reported to be useful in dental treatment¹⁶⁻¹⁸.

Table 3 - Distribution of side effects in the subjects during dental treatment

Side effects	Number of subjects
Respiratory Depression	27 (55%)
Vomiting	11 (22.4%)
Fluttering	7 (14.2%)
Others	4 (8.4%)
Total	49 (100%)

The subjects in this study had previously exhibited behavior sufficiently negative to dental treatment using routine behavior management techniques. However, the intravenous technique resulted in a sedative effect. Carrying out dental care by this method, the patient’s rejection and evasive behavior patterns were reduced as compared with the controls (previous treatment without intravenous sedation). The rate of behavior evaluated as positive were 80% of cases, although the other 20% that exhibited negative behavior were subjected to GA in another day. It was found that intravenous midazolam is a very effective form of sedation for patients with ID.

The dose used in intravenous sedation in this study for each patient was obtained by analysis of weight, pathology, behavior and physiology. In this analysis a medium dose was 0.61 mg/kg. The doses used were higher than that used in other studies with patients without ID¹⁷⁻¹⁸. In accordance with this result, others studies have also demonstrate that dental patients with ID need higher doses of sedative to obtain an adequate level of sedation^{9,19}.

The reason that dental patients with ID required a higher dose of midazolam than other patients is unclear. Variations among individuals are thought to result from pharmacokinetic and pharmacodynamic factors⁹. In this study, the blood concentration of midazolam was not measured, but it is possible that in subjects with ID it does not increase proportionally to the administered dose¹⁷.

In this way, pharmacokinetic pharmacodynamic factors are thought to be involved in the variations of the required dose of sedative for intravenous sedation. The differences in the required doses of midazolam between subjects with ID and other subjects might derive from differences in sensitivity to the sedative because the success will be dependent on the individual response of each patient⁹.

Adverse events are rare in dental anesthesia, and a definitive evaluation of safety requires a long history of treatment using a given technique. While a trial of this size cannot assess the frequency of possible adverse events, the present results indicate a safe technique. The conscious sedation techniques practiced in the present ensured

Table 2 - Distribution of behavior and side effects of subjects according to the dose of midazolam (mg/kg) during dental treatment.

Dose of midazolam mg/kg	Positive behavior	Negative behavior	Presence of side effects	Absence of adverse reactions
0.1 – 0.60 kg	63	16	12	68
0.61 – 1.20	67	17	23	60
Total	130	33	35	128

cooperation and consciousness throughout the procedure and full control of protective reflexes. This procedure presents minimal risk in contrast to GA¹¹.

The subjects of this study were able to receive the expected dental care, but complications like vomiting, respiratory depression, flutter, tremor and tachycardia could be noted. Despite these reactions, there were not significant differences for the presence of adverse reaction associated to drug dose (mg/kg).

It was defined as a true decrease of oxygen saturation when a pulse oxymeter reading of SpO₂ below 92 percent. It was found 27 episodes of true decrease of oxygen saturation in this study. In accordance with others studies, the respiratory depression was the most predominant adverse reaction occurred during conscious sedation^{15,20-24}. The literature shows that children, elderly, obese, and patients with cerebral palsy, autism or medically compromised who were treated with conscious sedation were more susceptible to respiratory problems^{15,25-26}. Supplemental oxygen has been recommended for all patients undergoing CIV²⁷ and in the present study supplementation was used in some cases, which presented respiratory depression. The reported incidence of nausea and vomiting after sedation and local anesthesia is less than that observed after GA (7% versus 14%). Moreover, the time to discharge was shorter for patients receiving sedation²⁸. This study observed a very low complication rate with the use of oral midazolam in dental treatment for patients with ID.

In conclusion, the results of this study showed that CIV is a useful method for providing dental care to patients with ID and produced fewer adverse reactions in comparison to GA. The dose used indicated that dental patients with ID need higher doses of sedative to obtain adequate levels of sedation. In spite of being considered an important matter, there is insufficient evidence of the health care for subjects with ID, and further studies are necessary for offering better dental care to these patients.

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