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Intravenous sedation for dental treatment in patients with intellectual disability-efficacy of nasal airway, pharyngeal suction tube and oxygen tube placement.

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Abstract

Background/Purpose: We performed a comparison of the quality and safety of dental treatment under intravenous sedation in patients with moderate or severe intellectual disability using the conventional method (intravenous sedation: IVS group) and a method using a nasal airway, suction tube and oxygen tube placed into the pharynx (intravenous sedation with airway and suction tube: IVSAS group).
Materials and Methods: The medical records of 43 patients (72 cases) with moderate or severe intellectual disability who underwent dental treatment under intravenous sedation were retrospectively evaluated for patient characteristics, sedation time, amount of medication and quality of sedation. The level of sedation was assessed using the Ramsay Sedation Scale (RSS).
Results: Median patient age was 18 years (6 to 46 years). Comparison of the IVSAS and IVS groups indicated no significant differences in patient background. The median RSS score during treatment was 5 in the IVSAS group and 4 in the IVS group, suggesting no difference. In terms of the quality of sedation, cough reflex was observed in 40 cases, (22/50 cases in the IVSAS group, 18/22 cases in the IVS group), and 30 patients moved spontaneously (14/50, 16/22, respectively); the incidence of such events was lower in the IVSAS than IVS group.
Conclusions: In patients with moderate or severe intellectual disability, intravenous sedation (deep sedation) together with use of a nasal airway, suction tube and oxygen tube placed in the pharynx was considered to improve the quality and safety of sedation during dental treatment.

Keywords: Intravenous sedation, Special needs, Dental treatment, Nasopharyngeal airway, Suction tube.

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Introduction

Psychosedation is recognized as a form of medicinally-induced behavioral adjustment in the dental treatment of patients with intellectual disability (ID), the aim of which is to achieve adequate control of motor function. Conscious sedation using nitrous oxide may be feasible in patients with mild forms of ID [1], although general anesthesia is often chosen in moderate and severe cases; however, intravenous sedation is also an option for dental clinics lacking the equipment needed to perform general anesthesia [2-7]. Intravenous sedation under these circumstances often necessitates deep sedation, which in turn poses challenges in preventing airway obstruction, pharyngeal reflexes and water aspiration [8].

Among the various studies on the complications of intravenous sedation during dental treatment in patients with developmental disorders, Boynes et al. reported that 23.8% of patients experienced complications during anesthesia management (90.6% for intravenous sedation and 7.4% for general anesthesia), the most frequent of which were airway obstruction (11.4%) and nausea/vomiting (9.4%) [2]. Airway obstruction was particularly common among patients with ID and cerebral palsy, and it was treated with nasopharyngeal airway placement (56.5%) or jaw thrust (43.5%); however, none of the patients required tracheal intubation [2]. In a study by Yoshikawa et al. involving the use of deep sedation with midazolam and/or propofol, decreased arterial oxygen saturation (SpO_2<90%) occurred in 17.8% of patients, specifically those with Down syndrome, ID or cerebral palsy

[3]. Analysis of these findings also showed that male patients with Down syndrome and co-administration of midazolam and propofol were significant risk factors for decreased oxygen saturation [3]. Meanwhile, Isik et al. reported complications in mentally and physically handicapped patients under deep sedation, such as nausea and vomiting (7.1%), postoperative delirium (2.5%) and decreased arterial oxygen saturation (SpO_2<90%) (2.2%) [7].

As these studies show, hypoxia and nausea/vomiting are typical complications during intravenous sedation in patients with developmental disorders, and are generally treated by nasopharyngeal airway placement, jaw thrust, and pharyngeal aspiration tube placement [2,7,8]. To the best of our knowledge, however, no studies have compared the quality and safety of intravenous sedation with and without these procedures.

In the present study, we compared conventional intravenous sedation with a method involving sedation together with the placement of a nasopharyngeal airway, suction tube and oxygen administration tube in the pharynx, and retrospectively investigated the quality and safety of each method in patients with moderate or severe ID.

Materials and Methods

Study patients

This retrospective study was conducted at the Shiga Dental Association Oral Health Center, which does not have an investigational review board or ethics committee. Hence, approval was obtained from the Review Board and Ethics Committee of the Japanese Society for Disability and Oral Health, of which the Center is a member (clinical research no: 140003). The protocol of this study was conducted in accordance with the Declaration of Helsinki. The study retrospectively investigated the medical records of 43 patients (31 males and 12 females) with moderate or severe ID who underwent a total of 72 dental procedures under intravenous sedation at the Shiga Dental Association Oral Health Center between September 2012 and October 2014.

Study variables were patient characteristics (age, sex, height, weight), sedation time, treatment time, required wait time (i.e., the amount of time after completion of treatment until patients were allowed to return home), premedication and amount of medication used during treatment (midazolam, propofol, pentazocine, flumazenil), changes in vital signs (blood pressure, heart rate and arterial oxygen saturation (SpO_2)) and bispectral index (BIS), quality of sedation during treatment (the number of episodes of cough reflex stimulation, as evidenced by choking, spontaneous body movement, and the number of times airway maintenance strategies, such as jaw thrust, were required to treat airway obstruction). The body movements evaluated in this study were spontaneous movements that were large enough to interrupt dental treatment. Vital signs and sedation level were recorded at least every 5 minutes. Episodes of coughing and spontaneous body movement have a tendency to continue for a few minutes once they begin, so repeated occurrences within a span of 5 minutes were counted as a single episode. Frequency of airway management using the jaw thrust technique was assessed each time vital signs were recorded, with 1 or more jaw thrusts within a span of 5 minutes being counted as a single intervention.

Levels of sedation were assessed after premedication and during treatment using the Ramsay sedation scale (RSS). After premedication, level of sedation was assessed immediately prior to establishing venous access. During treatment, the level of sedation was assessed as the most frequently observed level of sedation.

Sedation methods

Sedation management was performed and anesthesia charts were recorded by an anesthesiologist (YM). Intravenous sedation was used in patients who met the following criteria:

1. Extremely uncooperative patients who could not follow the directions of medical providers at all.

2. Patients who could temporarily follow the directions of medical providers, but were uncooperative for a certain period of time during dental treatment.

The anesthesiologist examined the patients 1 to 2 weeks before the scheduled intravenous sedation. Patients were instructed to fast for 4 hours before the sedation and their compliance with the instructions was confirmed on the treatment day. Premedication with intramuscular injection was administered in patients who were extremely uncooperative and in whom an IV line could not be established, while the others received oral premedication. Depending on the patient's level of cooperation, premedication consisted of 0.3-0.4 mg/kg oral or 0.15-0.2 mg/kg intramuscular midazolam. After 30 minutes, venous access was obtained using a 22 or 24 G indwelling needle. At the same time, monitoring of blood pressure, pulse rate, electrocardiogram (ECG), arterial oxygen saturation (SpO_2) and BIS was initiated. From the start of the study (in September 2012) until March 2013, intravenous sedation (IVS) was performed using the conventional method, in which administration of propofol (4 mg/kg/h) was followed by administration of oxygen (2-3 L/min) using a nasal cannula (Nasal Cannula®; Nakamura Medical Industry Co., Ltd., Japan). Patients treated using this technique was assigned to the IVS group (22 cases). From April 2013 until the end of the study (in October 2014), propofol (4 mg/kg/h or 2.0 μg/mL) was administered using a target controlled infusion (TCI) and, once adequate sedation was achieved, an uncuffed nasotracheal tube (Ivory PVC, Nasal, Soft Seal® Uncuffed Tracheal Tube [Smiths Medical; ID 5.0-6.0 mm]) was inserted as a nasopharyngeal airway through one nostril into the epipharynx, while a suction tube (Suction Catheter®; Top Corp., Japan; 10-12 Fr) and oxygen administration tube (2-3 L/min oxygen) were inserted via the opposite nostril into the epipharynx, and a gauze pack was inserted into the oropharyngeal fauces. During treatment, if the gauze pack became wet due to irrigation, it

was replaced with fresh gauze, as needed. Patients treated using this technique were assigned to the "intravenous sedation with airway and suction tube" (IVSAS) group (50 cases). After completion of sedation, patients who did not suffer from convulsions/epilepsy received 0.3-0.5 mg intravenous flumazenil. When spontaneous body movement was not adequately prevented under intravenous sedation using midazolam and propofol, pentazocine (3-5 mg/dose) was additionally used as needed. In both groups, patients were positioned with their heads tilted slightly back by lowering the headrest and inserting a shoulder pillow.

The dental treatments performed under the above sedation protocols included periodontal, endodontic, restorative, prosthodontic and surgical (tooth extraction) treatments; when the treatment was accompanied by pain, local anesthesia was appropriately used so as not to affect the level of sedation.

Statistical analysis

Statistical analyses were performed using SPSS ver. 16.0 software (SPSS Japan). Data are expressed as median values (quartiles) and analyzed using the Mann-Whitney U test with a 5% significance level.

Results

Median age, height and weight of the patients were 18 years (range of 6-46 years), 160 cm (quartile 154.8-166.5 cm) and 55 kg (37-70 kg), respectively. Concurrent conditions besides ID included pervasive developmental disorder (autism) (n=21), epilepsy (n=16), cerebral palsy (n=5), Down syndrome (with atrial septal defect and urethral stenosis) (n=1), hearing impairment (n=1) and Cornelia de Lange Syndrome (n=1). None of the patients had significant systemic comorbidities and none had sufficient tolerability for dental treatments. Six patients received sedation thrice, and 13 patients received sedation twice. Four patients received both types of sedation. The patients' Mallampati class, to assess the ease of endotracheal intubation, was not estimated because most of the patients were uncooperative. However, none of the patients had obvious micrognathia or episodes of airway obstruction in daily life.

Table 1. *Comparison of patients' background.*

	IVSAS (n=50)	IVS (n=22)	P value	U value
Age (yo)	20.0 (16.0-33.3)	18.0 (14.0-29.5)	0.164	436.5
Gender (male/female)	36/14	15/7	0.744	529.0
Height (cm)	162.8 (155.0-170.0)	162.0 (155.0-172.0)	0.926	199.0
Weight (Kg)	59.5 (43.8-71.0)	50.0 (39.3-62.3)	0.165	436.5
Sedation time (min)	105.0 (80.0-120.0)	102.5 (60.0-121.3)	0.540	500.0
Treatment time (min)	80.0 (55.0-95.0)	85.0 (45.0-110.0)	0.860	511.5
Required wait time (min)	37.5 (26.3-58.8)	40.0 (32.5-52.5)	0.443	104.5

IVSAS: Intravenous Sedation with Airway and Suction Tube; IVS: Intravenous Sedation

Comparison of the IVSAS and IVS groups did not reveal any differences in patient characteristics, sedation time, treatment time or required wait time (Table 1). In terms of premedication, there were no intergroup differences in the dose of midazolam administered intramuscularly and orally, and the RSS level following premedication. The median dose of propofol tended to be higher in the IVSAS group (median: 5.00 mg/kg/h in IVSAS group *vs.* 4.46 mg/kg/h in IVS group), but not significantly so, and BIS values also did not differ (median 67.5-43.0 *vs.* 68.5-41.5 in IVSAS *vs.* IVS groups, respectively). An additional bolus of 20-60 mg propofol was also administered in 45 out of 50 IVSAS group cases, to control body movement during nasopharyngeal airway insertion, with 4 of these cases having a ≤ 20 second apnea episode that resolved with assisted ventilation using a bag valve mask. Median RSS score during treatment indicated a tendency to a deeper level of sedation in the IVSAS group than in the IVS group, at 5 *vs.* 4, but not significantly so (Table 2).

Table 2. *Comparison of intravenous sedation.*

	IVSAS (n=50)	IVS (n=22)	P value	U value
Route of premedication (im/po)	43/7	17/5	0.315	469.0
Midazolam im (mg)	12.5 (9.0-15.0)	10.0 (7.5-15.0)	1.000	14.0
Midazolam po (mg)	20.0 (7.0-25.0)	17.5 (15.0-20.0)	0.149	285.5
RSS after premedication	5 (4-5)	4 (3-5)	0.063	392.0

Total volume of propofol (mg)		460 (300-600)	350 (162.5-495.0)	0.067	352.0
Mean volume of propofol (mg/kg/h)		5.00 (4.39-6.40)	4.46 (4.01-4.90)	0.106	135.0
Pentazocine (used/ not used)		29/21	20/2	0.006	369.0
Dose of pentazocine (mg)		4.0 (0.0-9.0)	7.50 (5.63-10.50)	0.043	388.0
Frumazenil (used/ not used)		16/34	3/19	0.113	451
RSS during sedation		5 (4-6)	4 (3-5.5)	0.073	388.0
Cough reflex (positive/negative)		22/28	18/4	0.003	342.0
Times of cough reflex (times)		0 (0-1)	2 (1-4)	<0.001	217
Body movement (positive/negative)		14/36	16/6	<0.001	304.0
Times of body movement (times)		0 (0-1)	2 (0-4)	<0.001	273.0
Jaw thrust (used/not used)		12-38	8/14	0.284	482.0
Times of jaw thrust (times)		0 (0-0.25)	0 (0-4)	0.131	453
BIS	maximum	67.5 (56.5-76.3)	68.5 (62.8-77.4)	0.568	409.0
	minimum	43.0 (35.0-52.5)	41.5 (34.3-45.3)	0.448	396
SBP (mmHg)	maximum	125.0 (119.8-135.0)	120 (105-130.0)	0.077	385.0
	minimum	95.5 (88-100)	92 (87-98)	0.309	445
DBP (mmHg)	maximum	68.5 (60-76.3)	70 (60.5-78.5)	0.767	502
	minimum	45.0 (40.0-54.3)	43 (39-50.5)	0.528	475.0
Pulse rate (bpm)	maximum	95.5 (88-105)	98.5 (84.8-115.5)	0.405	482.0
	minimum	75.5 (66.8-85)	77.5 (62.8-88.3)	0.956	546
SpO_2 (%)	maximum	100 (100-100)	100 (100-100)	0.500	497.0
	minimum	98 (96-99)	97 (95.5-98.3)	0.613	489

IVSAS: Intravenous Sedation with Airway and Suction Tube; IVS: Intravenous Sedation; im: Intramuscular Injection; po: Per Oral Intake; RSS: Ramsay Sedation Scale; BIS: Bispectral Index; SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure; SpO_2: Arterial Oxygen Saturation

There were no differences in blood pressure, pulse rate, ECG or SpO_2. Complications during treatment included cough reflex stimulation due to choking in 40 cases (22/50 IVSAS *vs.* 18/22 IVS cases; P=0.003), spontaneous body movements in 30 cases (14/50 IVSAS *vs.* 16/22 IVS cases; P<0.001) and airway obstruction in 20 cases (12/50 IVSAS *vs.* 8/22 IVS cases; P=0.284). In four of the cough reflex cases in the IVSAS group, the suction tube could not sufficiently aspirate the secretions in the pharynx because the patients had excessive postnasal discharge due to pollinosis, which produced viscous secretions that accumulated in the pharynx. Intergroup comparison showed that cough reflex stimulation (median: 0 *vs.* 2 episodes in IVSAS *vs.* IVS groups) and spontaneous body movements (median: 0 *vs.* 2 episodes in IVSAS *vs.* IVS groups) were more common in the IVS group. Pentazocine was administered more frequently in the IVS group (20/22 cases) than in the IVSAS group (29/50 cases); the dose was also higher in the IVS group (median: 4 mg *vs.* 7.5 mg, in IVSAS *vs.* IVS groups). There was no difference between the groups in the frequency of jaw thrust interventions due to airway obstruction (median: 0 *vs.* 0) (Table 2).

None of the complications that occurred after sedation were severe. Mild complications included 1 case of mild epistaxis due to nasopharyngeal airway insertion and 1 case of post-sedation delirium in the IVSAS group and 3 cases of shivering in the IVS group. However, all of these cases resolved during postoperative observation and the patients could return home uneventfully. There were no cases of vomiting.

Discussion

During intravenous sedation for dental treatment, the surgical field is also part of the airway, and fluid is prone to accumulate in the mouth due to irrigation during the use of dental instruments, such as air turbines, among others; hence, keeping the patient conscious and maintaining upper respiratory tract reflexes are essential. During conscious sedation, patients maintain their own airway and can respond to physical stimuli and verbal instructions. Senel et al. reported that conscious sedation equivalent to a RSS score of 2 has a low incidence of complications of 1.4% [4].

In patients with serious intellectual disability who display extremely uncooperative behavior during dental treatment,

sedation can be used as a way to control this behavior. In these circumstances, since patients often display denial behavior as long as they are conscious, deep sedation is a method of rendering the patient less prone to being uncooperative for a certain period of time. If the patient loses consciousness during deep sedation, the body's protective reflexes and ability to maintain upper airway patency may also be lost. Patients under deep sedation can still breathe spontaneously, but require assistance to maintain airway patency, and can move in response to strong stimuli but can still tolerate oral procedures. Hence, at the very least, they require perioperative management based on general anesthesia [2].

The intravenous sedation method in the present study involves the use of deep sedation with a BIS of <60 in patients with a disability. When sedated, the incidences of coughing and body movements (44% and 28%) in the IVSAS group were lower than in the IVS group (81.8% and 72.7%). Deep sedation often involves tilting the patient's head back to secure the airway. The amount of fluid that the patient can swallow, therefore, decreases, and water and saliva accumulate in the patient's pharynx during dental treatment, resulting in a tendency towards choking and coughing and body movements when this fluid passes the glottis [9,10]. The incidence of choking on fluids was still high in the IVSAS group because the suction tube placed in the pharyngeal region could not remove all of this fluid, but it was lower than in the IVS group in which no suction tube was placed. Thus, the IVSAS technique was deemed to enable sedation that was safer and of superior quality.

Pentazocine was administered in 20/22 cases in the IVS group to control body movements, compared to just 29 of 50 cases in the IVSAS group. Fentanyl may be administered in addition to midazolam and propofol when inducing deep sedation [4,7] but, given the complexity of storage and handling of narcotic drugs at dental clinics, pentazocine is typically used in Japan. Pentazocine was administered more often and in higher doses in the IVS group, leading to an increased risk of depressed respiration and a decline in sedation quality. As such, the IVSAS method described in the present study is more suitable than conventional intravenous sedation methods for improving the safety and quality of deep sedation.

Previous studies have reported that the incidence of airway obstruction and decreased SpO_2 during deep sedation in patients with intellectual and physical disabilities undergoing dental treatment is 7.1 to 17.8% [2,3,7]. In the present study, the jaw thrust maneuver was used to treat airway obstruction in 36.4% of cases in the IVS group versus 24.0% of cases in the IVSAS group; this incidence, thus, tended to be high in the IVS group. Besides, a deeper level of sedation could be maintained in the IVSAS group (RSS score 5) and, despite the placement of a nasopharyngeal airway, there was no intergroup difference in the high incidence of airway obstruction. The authors conclude that, in future, it would be safer to manage patients at a slightly lighter level of sedation, equivalent to that in the IVS group.

Propofol administration was adjusted manually in all cases in the IVS group, but only in 8 cases in the IVSAS group, with the TCI method used in the remaining 42 cases. Using the above-mentioned techniques to sedate ID patients during dental treatment, Sakaguchi et al. reported that the TCI method enabled a reduction in both the dose of propofol and time to recovery [11]. In the present study, however, there was no intergroup difference in either propofol dosage or the time patients were required to wait before returning home. Moreover, the previous study did not use BIS as an indicator, and used manual control of propofol administration; hence, the dosage may have been high [11]. On the other hand, the present study did not reveal any intergroup differences in propofol dosage because the use of BIS as a monitor of sedation level enabled its proper administration.

BIS during treatment was maintained at $\leq$ 60 in both the IVSAS and IVS groups, which is within the range achieved under general anesthesia. Opinions are divided on whether or not BIS under general anesthesia is affected by the extent of intellectual disability, with Ponnudurai et al. arguing that BIS is not affected [12] and Dahaba asserting that it is affected by the level of ID and is, therefore, not a useful indicator of sedation in these patients [13]. However, although it is unclear whether the absolute BIS values in the present study accurately reflected the clinical effects, the authors do recognize the importance of monitoring relative changes in BIS during sedation.

When performing the IVSAS technique, the ability to ensure good airway management is essential; hence, it is crucial to examine the patient prior to surgery to assess the condition of the airway (i.e., presence of micrognathia, obesity, ability to lay in the supine position, snoring, and sleep apnea). In a study by Chaushu et al. patients with Pierre Robin syndrome required emergency tracheal intubation during sedation [8]. The authors of the present study therefore decided that general anesthesia should be selected for patients expected to have airway issues, and referred these patients to an appropriate facility. When performing airway management under sedation, it is important to position the patient with the head tilted back slightly and to place a nasopharyngeal airway, to prevent fluid from entering the trachea by placing a suction tube in the pharynx and a gauze pack in the oropharyngeal fauces, and to maintain oxygenation by inserting an oxygen tube. Appropriate suctioning of excess fluid in the oral cavity is also essential.

Above all, the IVSAS method suggested lower incidences of coughing and body movements when deep sedation was performed; further, fewer patients required pentazocine. Thus, the IVSAS method described in the present study is more suitable than conventional intravenous sedation methods for improving the safety and quality of deep sedation among ID patients.

A limitation of the present study is that it was a retrospective chart study and hence, recording of the patients' condition was not unified. In future, a prospective randomized control trial including a major population should be performed.

In conclusion, we compared the conventional method of intravenous sedation with a method involving intravenous sedation together with placement of a nasopharyngeal airway, suction tube and oxygen administration tube in the pharynx, and investigated the quality and safety of each method in patients with moderate or severe ID. For intravenous sedation (deep sedation) of patients with intellectual disability, placement of a nasopharyngeal airway suction tube and oxygen administration tube in the pharynx is a superior sedation technique in terms of both quality and safety.

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