# Scientific Article

# Effects of Deep Sedation on Behaviors and Side Effects in Children Undergoing Different Dental Procedures

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Abstract: Purpose: The purpose of this study was to determine behavioral characteristics and side effects in children undergoing restorative dental treatment with or without dental extractions under deep sedation. Methods: This study comprised 68 healthy 4- to 7-year-old children; 34 each were assigned to extraction and restorative groups. Children's behaviors were assessed using the following scales: (1) modified Frankl scale (preoperative period); (2) modified Houpt behavior rating scale (venipuncture period); and (3) modified Wilton behavior scale (recovery period). All complications observed during and after sedation were also recorded. Results: The occurrence of agitation was higher in the extraction group; however, this difference was statistically significant only at 15 minutes after completion of sedation. In both groups, the most common side effects observed were: involuntary movement (during sedation); sleepiness; agitation and dizziness (during the early recovery period); irritability; crying; and sleepiness (following hospital discharge). Conclusions: Agitation may be observed during procedures involving extractions. Few side effects were observed during and after the sedation procedure in both groups. (Pediatr Dent 2011;33:158-64) Received September 16, 2009 | Last Revision March 11, 2010 | Accepted May 17, 2010

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Sedation has been used in dentistry for several decades. The sedation of children is different from the sedation of adults. While moderate sedation is often sufficient for performing dental treatment in adults, deeper sedation levels may be required occasionally for children younger than 7-years-old.<sup>1</sup> Children are often sedated to control their behavior and ensure the safe and quality completion of a procedure. Moderate sedation may not always be sufficient in managing behavior, and deep sedation or general anesthesia may be required.<sup>2</sup>

Deep sedation is defined by the American Society of Anesthesiologists as a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.<sup>3</sup>

Restorative treatment with or without dental extractions is a widely used therapeutic procedure in young children. The purpose of this study was to determine behavioral characteristics, side effects, physiological changes, and recovery times in children undergoing restorative dental treatment with or without dental extractions under deep sedation.

#### Methods

Subjects were selected, as a convenience sample among 4to 7-year-olds who applied to the Department of Dentistry, Faculty of Dentistry, Ankara University, Ankara, Turkey, for routine dental treatment between 2006 and 2007. Children who needed invasive dental treatment, but whose behavior could not be managed and whose parents consented to treatment under deep sedation, were included in the study. All children were seen initially using basic behavior management techniques, such as: tell-show-do; positive reinforcement; controlled expectations; distraction; modeling; and suggestion by the same pediatric dentist before sedation was considered. Children with medical illnesses or moderateto-severe mental retardation were excluded from the study.

In total, 68 healthy children (ASA I) were included in the study. Of these, 34 who required 1 or more extractions in addition to restorative treatment were assigned to an extraction group (Group E), and 34 children who required restorative treatment without extraction were assigned to a restorative group (Group R). Dental treatment of both groups consisted of restorative treatments, such as: compomer, amalgam, or glass ionomer restorations; stainless steel crowns; pulp capping; pulpotomies; fissure sealants; and topical fluoride application. Five to 8 teeth of each patient were restorated and types of procedures performed were similar between the two groups with the exception of the extractions. During dental treatment a plastic mouth prop was used to keep the children's mouth open. All cavity preparations were performed using water coolant. Due to loss of airway

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reflexes, sponges were used to protect the airway from aspiration of water, blood etc. In addition, because of continued salivary flow, the oropharyngeal region was aspirated frequently. Therefore, a rubber dam was not used so that the oropharynx could be cleaned easily, and the teeth were isolated with cotton pellets during dental treatment. In Group E, only decayed teeth that were nonrestorable were extracted. Written informed consent was obtained from parents of all participants, and ethics committee review and approval by Ethics Committee of Faculty of Dentistry (Ankara University, Turkey) was completed.

Following clinical and radiographic examinations, all treatment was planned and executed by an experienced pediatric dentist, and all behavioral assessments were performed by another pediatric dentist. Children fasted for at least 4 hours prior to sedation, and EMLA cream was applied to possible venipuncture sites by parents. Before the procedure, children were allowed to play in a playroom for 15 to 20 minutes. During this preoperative observation period, their behaviors were observed and recorded using a modified Frankl behavior rating scale (Table 1).<sup>4</sup> Patients and their parents were then taken to the dental unit, where an anesthesiologist provided the children with a simplified, easily understand-able explanation of the intravenous catheterization procedure.

Table 1.	able 1. MODIFIED FRANKL SCALE					
Rating	Behavior					
1	Definitely negative	Refusing to play game, crying forcefully or fearfully, or any other overt evidence of extreme negativism				
2	Negative	Reluctance to playing, uncooperative behavior, and some evidence of negative attitude that is not pronounced				
3	Positive	Acceptance of playing, willingness to comply with the dentist, cooperative behavior				
4	Definitely positive	Good rapport with the dentist, interested in the environment, laughing and enjoying the situation				

Table 2.	MODIFIED HOUPT SCALE
Houpt behavior s	scale
1	No movement
2	Controllable movement
3	Continuous movement
4	Violent movement
Houpt crying sca	le
1	No crying
2	Intermittent mild crying
3	Continuous persistent crying
4	Hysterical crying

The children's behaviors during venipuncture were evaluated using the modified Houpt behavior rating scale (Table 2).<sup>5</sup> All preoperative and postoperative phases and the intravenous catheterization procedure were videotaped to verify the reliability of the behavior scales. The pediatric dentist who performed all behavioral assessments randomly selected videotapes of 10 patients and assessed each twice to standardize the behavioral assessments.

The first rating assessed was taken as the actual rating. Intraexaminer reliability regarding the modified Frankl scale, modified Houpt scale, and modified Wilton behavior scale was evaluated via Kappa statistics. Kappa values were: 0.91 for the modified Frankl scale; 0.87 for the modified Houpt scale; and 0.79 for the modified Wilton behavior scale. According to Fleiss, values between 1 and 0.75 represent excellent agreement.<sup>6</sup>

Pulse oxymetry and ECG monitoring were applied to all children, and baseline vital signs were recorded before drug administration. After obtaining intravenous access, all patients were sedated with midazolam (Dormicum, Roche, Fontenay, France; 0.1 mg/kg<sup>-1</sup>) and propofol (Propofol, Abbott, Chicago, USA; 1 mg/kg<sup>-1</sup>) by the anaesthesiologist. Parents were allowed to stay with their children during venipuncture. Once unconscious, children were positioned in a dental chair, provided with supplemental oxygen (4 L/minute<sup>-1</sup>) via a nasal cannula, and allowed to breathe spontaneously. Then, children were administered fentanyl citrate (Fentanyl, Janssen Pharmaceutica N.V., Belgium) intravenously (1 µg/kg<sup>-1</sup>). All children were monitored by the anesthesiologist during the entire procedure. Children exhibiting signs of insufficient sedation (ie, involuntary movement, coughing, irregular breathing, laryngospasm, and tachycardia) during the procedure were administered supplemental propofol (0.5 mg/ kg<sup>-1</sup>) or fentanyl (0.5-1 µg/kg<sup>-1</sup>), as required. Oxygen desaturation was defined as mild (85-90%) and severe (<85%); bradycardia and tachycardia were defined as a heart rate 30% below or above baseline, respectively. All complications observed during sedation were recorded by the same anesthesiologist, who was available at all times to interrupt the procedure and check the airway, if necessary.

Following restorative treatment, all Group E children received additional doses of fentanyl (0.5 mg/kg<sup>-1</sup>) and propofol (0.5 mg/kg<sup>-1</sup>) prior to extraction to prevent postoperative pain following extraction. Infiltration anesthesia (4% articaine hydrochloride with 1:100,000 epinephrine, 4 mg/kg<sup>-1</sup>) was also administered to control hemorrhage, and extractions were performed.

Table 3.	MODIFIED WILTON BEHAVIOR SCALE				
Rating	Behavior				
1	Agitated				
2	Alert, restless				
3	Calm, eyes spontaneously open				
4	Drowsy, responds to minor stimulation				
5	Asleep, able to rouse, but does not respond to minor stimulation				

Sedation was stopped upon completion of treatment, and patients were taken to a recovery room with their parents. Time to eye opening and responsiveness to verbal commands were recorded in minutes. Recovery characteristics were assessed at 5-minute intervals using a modified Wilton behavior scale (Table 3).<sup>7</sup> All side effects observed during the hospital stay were recorded. Time to discharge was defined as the time from the end of the procedure until the child fulfilled the discharge criteria, which included being fully awake and able to cough or breathe deeply, move all limbs voluntarily and maintain an oxygen saturation level greater than 93% on room air.<sup>8</sup> The anesthesiologist determined the discharge time of all patients.

Parents were instructed to contact the hospital if they observed any adverse event that could be related to the procedure (eg, nausea, vomiting, or difficulty breathing) within 24 hours after discharge from the hospital. Parents were contacted by phone 48 hours after the procedure to answer a questionnaire related to complications observed at home by the same pediatric dentist who made all behavior assessments.

Statistical analysis of data was performed using SPSS 9.0 (SPSS Inc, Chicago, Ill). To compare demographic data, time to eye opening, time to responsiveness to verbal commands, drug doses, and duration of hospital stay between groups, t tests were used (Table 4). The chi-square test was used to

Table 4. DEMOGRAPHIC DATA, TIME TO EYE OPENING, TIME TO RESPONSIVENESS TO VERBAL COMMANDS, DRUG DOSES, AND DURATION OF HOSPITAL STAY OF EXTRACTION AND RESTORATIVE GROUPS					
	Group E (N=34)	Group R (N=34)	P-value		
Age (year) ±(SD)	5.0±0.9	5.0±0.8	.70		
4	12	11			
5	10	12			
6	10	11			
7	2	0			
Weight (kg) ±(SD)	17.5±2.9	17.5±3.4	.90		
Gender (males/females)	16/18	19/15	.60		
Duration of procedure (min) ±(SD)	58.5±13.5	58.2±12.9	.90		
Time to eye opening (min) ±(SD)	9.6±3.4	7.8±3.0	.02		
Time to answering verbal command (min) ±(SD)	11.3±3.6	9.0±3.0	.005*		
Time to discharge (min) ±(SD)	31.3±2.2	30.7±2.7	.18		
Total dose of midazolam (mg) ±(SD)	2.1±0.3	2.2±0.8	.70		
Total dose of fentanyl (µg) ±(SD)	41.9±11.8	39.7±12.4	.45		
Total dose of propofol (mg) ±(SD)	143.6±30.8	138.6±36.9	.54		

### Table 5. DISTRIBUTION OF PATIENTS ACCORDING TO MODIFIED FRANKL SCALE AND

	Group E patients N (%)	Group R patients N (%)
Modified Frankl scale		
Cooperative (3-4)	22 (65)	25 (74)
Uncooperative (1-2)	12 (35)	9 (26)
Modified Houpt scale		
Houpt behavior scale		
Acceptable (1-2)	21 (62)	23 (68)
Not acceptable (3-4)	13 (38)	11 (32)
Houpt crying scale		
Acceptable (1-2)	21 (62)	23 (68)
Continuous and hysterical crying (3-4)	13 (38)	11 (32)

compare incidences of adverse events during and after sedation between groups. A *P*-value of less than .05 was considered statistically significant.

#### Results

Demographic data, time to eye opening, time to responsiveness to verbal commands, drug doses, and duration of hospital stay are given in Table 4. Time to eye opening and time to responsiveness to verbal commands were statistically longer (P=.02 and P=.005, respectively) in Group E vs Group R. There was no difference in the duration of hospital stay between the 2 groups (P>.05).

According to the Frankl and modified Houpt scales, there was no significant difference between the behavior of the 2 groups during the presedation or venipuncture periods (P>.05; Table 5). Immediately after administering sedative drugs, oxygen desaturation on room air was observed in 24 Group E patients (71%) and 22 Group R patients (65%). In all cases, however, desaturation was mild and quickly returned to a satisfactory level (≥95%) following neck repositioning (head-tilt, chin-lift) and application of nasal oxygen. Mild desaturation during treatment also was observed for a short period (<20 seconds) in 6 Group E patients (18%) and 7 Group R patients (21%). This desaturation was caused by an additional opioid dose in 2 patients, laryngospasm in 1 patient and tonsillar hypertrophy in 1 patient. In the other 9 patients, the cause of desaturation was sponges and water from the dental turbine. These hypoxic occurrences were rapidly normalized by neck repositioning, removal of sponges, or oropharyngeal aspiration.

Side effects observed during sedation and the early recovery periods are shown in Table 6. Involuntary movement was the most common side effect observed during sedation in both groups. Although the occurrence of involuntary movement was higher in Group R (N=29; 85%) than in Group E (N=24; 71%), the difference was not statistically significant (P=.14). The most common side effects observed during the early recovery period were dizziness, sleepiness, and agitation. Dizziness was seen in all Group E patients (100%) and in 29 Group R patients (85%). The difference in occurrence of dizziness between the groups was statistically significant (P=.02). The rate of sleepiness was higher in Group E (N=24; 71%) than in Group R (N=21; 62%) and was not statistically significant (p= 0.44). Severe agitation was also seen in 3 Group E patients (9%) and 5 Group R patients (15%) and was not statistically significant (P>.23).

Wilton behavior scale (WBS) scores for the early recovery period are shown in Table 7. At 5 minutes postsedation, 18 Group E patients (52%) and 5 Group R patients (14%) were

Table 6. SIDE EFFECTS OBSERVED DURING SEDATION AND EARLY RECOVERY PERIOD					
	Group E patients N (%)	Group R patients N (%)			
During sedation					
Laryngospasm	0 (0)	1 (3)			
Coughing	10 (29)	8 (24)			
Apnea	0 (0)	0 (0)			
Excessive secretion	2 (6)	0 (0)			
Desaturation	6 (18)	7 (21)			
Involuntary movement	24 (71)	29 (85)			
Tachycardia	0 (0)	3 (9)			
Bradycardia	0 (0)	0 (0)			
Early recovery period					
Coughing	3 (9)	2 (6)			
Nausea	0 (0)	0 (0)			
Vomiting	0 (0)	0 (0)			
Agitation	3 (9)	5 (15)			
Sleepiness	24 (71)	21 (62)			
Dizziness	34 (100)	29 <sup>•</sup> (85)			
Incontinence	1 (3)	2 (6)			

\**P*=.02.

asleep (WBS=5). At 10 minutes, 5 Group E patients (14%) were asleep, but no Group R patients. Prior to 15 minutes, there were no differences between groups in the number of patients with WBS scores of 1 (agitated and alert) or 2 (restless). After 15 minutes, the incidences of WBS scores of 1 and 2 were significantly higher in Group E than in Group R.

Side effects after discharge were reported by parents in a questionnaire administered 48 hours after the procedure (see Table 8). The most frequently observed side effects were irritability, crying, and sleepiness during the 48 hours after the procedure. Irritability was observed in 18 Group E patients (53%) and 14 Group R patients (41%). Of these, 13 Group E patients (72%) and 11 Group R patients (79%) were also rated as uncooperative, according to the Frankl scale, before the sedation procedure. Crying was observed in 12 Group E patients (35%) and 7 Group R patients (21%). Neither of the differences between groups, however, was statistically significant. Only 1 Group E patient and 0 Group R patients had nightmares.

#### Discussion

Deep sedation is an alternative method of sedation for painful procedures in children. While the goals of pediatric sedation may vary according to the procedure performed, they generally target relief of anxiety and pain as well as control of excessive movement. There is no universal protocol for the sedation of children undergoing restorative treatment. Ideally, the sedation technique should be tailored to the needs of the patient and the procedure being performed.<sup>9</sup> Studies on deeply sedated pediatric patients and recovery characteristics in dentistry, however, are limited. This study investigated be-havioral characteristics, side effects, and recovery times in deeply sedated pediatric patients undergoing restorative dental treatment with or without dental extractions.

All providers of deep sedation should be able to rescue patients from the effects of general anesthesia, as mandated by the Joint Commission on Accreditation of Healthcare Organizations. The presence of an anesthesiologist has been recommended during deep sedation of children because of serious

Recovery		Group	E pati	ents (N	)		Group	R pati	ents (N)	1
period			WBS					WBS		
	1	2	3	4	5	1	2	3	4	: 5
Postop 5 <sup>th</sup> min	0	1	0	15	18	0	0	1	24	5
Postop 10 <sup>th</sup> min	1	2	7	21	5	0	5	12	17	0
Postop 15 <sup>th</sup> min	6	10	14	4	0	4	5	25	0	0
Postop 20 <sup>th</sup> min	9	8	17	0	0	5	6	23	0	0
Postop 25 <sup>th</sup> min	8	8	18	0	0	5	8	21	0	0
Postop 30 <sup>th</sup> min	9	6	19	0	0	6	5	23	0	0

Table 8. SIDE EFFECTS OBSERVED FOR 48 HOURS AT HOME AFTER THE PROCEDURE					
Side effect	Group E N (%)	Group R N (%)			
Agitation	17 (50)	12 (35)			
Irritation	18 (53)	14 (41)			
Crying	12 (35)	7 (21)			
Sleepiness	10(29)	12 (35)'			
Nightmare	1(3)	0 (0)			
Nausea	2(6)	1(3)			
Vomiting	0 (0)	0 (0)			
Dizziness	2(6)	4(12)			
Incontinence	0 (0)	0 (0)			

associated risks, such as airway obstruction, hypoxia, hypoventilation, and apnea.<sup>2</sup> In this study, an experienced anesthesiologist was present throughout the sedation procedure.

Previous studies have demonstrated that the use of drug combinations can widen the spectrum of action and decrease the side effects of anesthesia, mainly by reducing the doses of individual drugs required.<sup>2,10,11</sup> Pharmacokinetic research has found a synergistic effect between propofol and fentanyl and propofol and midazolam.<sup>12</sup> Therefore, in the present study, the induction dose was lowered to 1 mg/kg<sup>-1</sup> propofol, used in combination with fentanyl and midazolam.<sup>9,13</sup>

In the present study, short-term desaturation (<20 seconds) was observed in Groups E (18%) and R (21%). Vardi et al.14 and Godambe et al.15 reported higher rates of desaturation (23% and 31%, respectively) in their studies, whereas a study by Vespasiano et al.<sup>16</sup> reported a lower desaturation rate (5%) among children deeply sedated with propofol. In the present study, the lower doses of a combination of 3 drugs may have played a role in lowering the desaturation rate. Airway restriction related to events associated with the dental procedure, however-such as abnormal head and tongue positions; foreign objects like cotton rolls and hand instruments; and the presence of blood, increased secretions, and exogenous water-may have played a role in increasing the desaturation rate. Other airway/respiratory events, such as bronchospasm, apnea, regurgitation, and aspiration, occurred infrequently in our study, in line with Vespasiano et al.<sup>16</sup> Laryngospasm was seen in 1 patient due to aspiration of saliva; this event was eliminated with aspiration of oropharynx.

In the present study, time to eye opening and time to responsiveness to verbal commands were significantly longer in Group E (9.6 and 11.3 minutes, respectively) than Group R (7.8 and 9.0 minutes, respectively). These findings are to be expected, considering that Group E children received additional doses of fentanyl (0.5 mg/kg<sup>-1</sup>) and propofol (0.5 mg/kg<sup>-1</sup>) just prior to extraction in order to achieve a deeper level of sedation. For both groups, time to eye opening was shorter than the time reported for a previous study (12.8 minutes), in which only propofol was used for sedation.<sup>17</sup>

In the present study, the number of children with a WBS score of 3 ("calm, eyes open spontaneously") was higher in Group R than in Group E for all times recorded; however, the difference between groups was only statistically significant at 15 minutes after sedation. This result may be attributed to the longer dormancy of Group E children during the first 15 minutes caused by the additional doses of fentanyl and propofol.

Agitation can result from any number of sources, including pain, physiological compromise, and anxiety.<sup>18,19</sup> The stress of intravenous induction and/or a rapid return to consciousness in a strange environment may also account for a large portion of behavioral disturbances during recovery.<sup>18,20</sup> Postoperative agitation has been reported to occur in 12% to 18% of all children undergoing anesthesia.<sup>20-22</sup> In a study comparing sevoflurane with propofol, Picard et al.<sup>8</sup> found agitation rates of 9% for patients administered propofol and 46% for those administered sevoflurane. In another study, the postoperative agitation rate was 9% among patients receiving sevoflurane.<sup>23</sup> In a study of dental extraction and restoration performed under general anesthesia, Ersin et al.<sup>24</sup> found postoperative agitation rates of 36% among patients administered halothane and 76% among patients administered sevoflurane.

In our study, the postsedation occurrence of agitation was 18% in Group E and 21% in Group R; however, only 9% of Group E children and 15% of Group R children had complex symptoms consistent with severe agitation.<sup>25</sup> The number of children rated as "agitated and alert" (WBS=1) was higher in Group E than Group R at all recorded times; however, this difference was only statistically significant at 15 minute. It is more likely that the difference in WBS scores between groups is related to the local anesthesia administered to Group E children rather than to pain, since local anesthesia can cause sensations such as parathesia of the mouth, tongue, and cheeks that children have difficulty understanding. In comparison to our study, a previous study in which local anesthesia was not administered reported a higher postoperative agitation rate (74%), which the authors claimed to be associated with postoperative pain following dental treatment.<sup>26</sup> In the present study, to inhibit agitation due to pain, Group E children were administered local anesthesia before extraction.

One of the most significant differences between Groups E and R during the early recovery period was the higher incidence of dizziness found in Group E. This finding is likely due to the additional doses of propofol and opioid administered to Group E children close to the end of sedation and is not surprising, considering the longer period of dizziness and sleepiness associated with the higher drug doses, as also reported by Needleman et al.<sup>26</sup>

One of this study's major findings was that children who exhibited restlessness and behavioral disorders following sedation had also exhibited negative behavior before sedation, according to Frankl scale rates and postoperative irritability rates 48 hours after sedation. This was true for 72% and 79% of the patients with postsedation restlessness in Groups E and R, respectively. These findings agree with those of earlier studies that identified children at risk of developing postanesthesia agitation who are more emotional and impulsive and less social and adaptable to environmental changes.<sup>18,20,27-29</sup> Previous studies have demonstrated an association between preoperative anxiety and postdischarge behaviour.28,30 Kain et al.28 also found that 67% of children exhibited new negative behavior on the day after surgery, 45% at 2 days after surgery, and 23% at 2 weeks after surgery. In the present study, according to parental perceptions, children in Groups E and R experienced high rates of postsedation agitation (Group E=50%; Group R=35%). None of the patients remembered anything about the procedure; however, the Group E child who had exhibited the most negative behavior prior to sedation had a postoperative nightmare.

Some studies have reported that administering opioids can increase the likelihood of postoperative nausea and vomiting.<sup>26,31,32</sup> These postoperative side effects, however, could also be caused by swallowing blood and oral intake of food or fluids pre- and/or postoperatively. In our study, nausea occurred in only 2 Group E patients and 1 Group R patient. These rates are similar to those reported by Vinckier et al.,<sup>33</sup> but lower than those reported in other similar studies.<sup>24,26,34-37</sup> Despite the use of fentanyl, the low rates of nausea observed in the present study may be related to hemorrhage control following extraction and the fasting of children before and after sedation.

#### Conclusions

- 1. A higher rate of behavioral change was observed among children who had extractions performed in addition to restorative treatment when compared to children who underwent restorative treatment only; however, this difference was not statistically significant.
- 2. There was no significant difference between the two groups in relation to side effects.

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