Original Article

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The Effect of Intravenous Deep Sedation on Behaviour of Non Cooperative Children in the Dental Office- An Interventional Study

Dentistry Section

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ABSTRACT

Introduction: Recently, there has been an increasing need for sedation techniques to reduce anxiety in children undergoing painful diagnostic and therapeutic procedures. Therefore, multiple tactics (oral sedation, Intravenous (IV) sedation) were devised to help practitioners manage such cases.

Aim: To determine the efficiency and effects of propofol on the behaviour of anxious children during dental treatment.

Materials and Methods: This interventional study was conducted at Damascus University, Damascus, Syria, from August 2018 to September 2020. Total 23 children aged 3 to 6 years who were physically healthy (American Society of Anesthesiologists I (ASA I) and uncooperative (negative or definitely negative according to Frankel's behaviour scale) were included to determine the effects of intravenous propofol on their behaviour during treatment. Behaviour during treatment was evaluated using the Ohio State University Behavioural Rating Scale (OSUBRS). Also, the sedation level was evaluated using the University of Michigan Sedation Scale (UMSS). Mann-Whitney test was used to compare the levels of behaviour and degrees of sedation between males and females. The significance level was set at p-value <0.05.

Results: Behaviour according to OSUBRS and degree of sedation according to UMSS during treatment were favourable, and treatment was completed for all participants. The Mann-Whitney test showed no statistically significant difference between males and females regarding the level of behaviour (p-value=0.605) or the degree of sedation (p-value=0.376). A strong positive relationship between treatment time and awakening time was found using the Pearson's correlation coefficient (0.813, p-value<0.01).

Conclusion: In the presence of an anaesthesiologist, intravenous propofol deep sedation was considered effective in managing anxious and uncooperative children during dental treatment.

Keywords: Anxiety, Ketamine, Ohio state university behavioural rating scale, Propofol

INTRODUCTION

Dental anxiety is considered one of the most frequently encountered issues in dentistry due to the excessive anxiety experienced by a good percentage of children, which creates a real challenge for practitioners. Children tend to avoid not only dental treatment but also examination. Dental problems will exacerbate and require more complex and difficult procedures because of this avoidant behaviour towards dental treatment, leading to an increase in anxiety levels in children [1].

The past few decades witnessed a noticeable increase in diagnostic procedures and minimal surgeries in paediatric patients outside of the traditional operating room, also in the awareness and interest in sedation and pain reduction, resulting in an increased need for sedation methods in dental clinics, emergency departments, and radiography facilities [2,3]. Sedation differs between children and adults. In children, the goal is mainly to modify behaviour and additionally to eliminate anxiety. The chronological age and the degree of cognitive and emotional development are keys to the child's ability to control their behaviour and cooperate with the dental practitioner [4].

Several simple procedures are carried out using distraction techniques, topical or local anaesthesia, and minimal sedation if needed. As for lengthier procedures in children under six years of age, which require the child to be still, or in children with cognitive problems, deeper sedation levels are often needed to control their behaviour [5,6]. Deep sedation is important in dental care because it aids in helping patients to complete treatment with a minimal amount of psychological and physiological stress. The use of deep sedation in paediatric dentistry has continued for several years [7]. The superiority of deep sedation over general anaesthesia is confirmed by its benefits that include: Quick awakening period, minimal patient preparation requires less monitoring equipment and less skill to be applied [7]. Several drugs were used as sedative agents in the dental treatment of paediatric patients like chloral hydrate [8], meperidine [9], hydroxyzine [10], promethazine [11], ketamine [12], propofol [13], and midazolam [14] and each has its own advantages and disadvantages.

Propofol is considered one of the most important drugs used in intravenous sedation. It is a phenolic derivative (2,6-Di-isopropylphenol) and was clinically introduced in 1985 by Pecaro BC and Houting T [15]. Propofol sedation is an effective treatment modality for the management of dentally anxious adolescents as a safe alternative to general anaesthesia [16]. It is used for intravenous sedation in multiple medical fields including Ophthalmology [17], Gynaecology [18], Gastroenterology [19], Neurosurgery [20], Intensive Medical Care, Paediatric Surgery [21], and Dentistry [22].

The mechanisms of action of propofol on the central nervous system include its effect on the level of receptors for neurotransmitters especially gamma-aminobutyric acid A receptor [23]. Intravenous propofol is characterised by a rapid onset of action similar to that of barbiturates as well as similarly quick recovery time, this rapid onset of action is ensured by propofol's high lipophilicity, and rapid redistribution from central to the peripheral compartment causes quick offset of anaesthetic action [24]. Its disadvantages include the likelihood of a burning sensation during intravenous administration and the cost of the drug and an infusion pump [25].

Thus, this study was aimed to determine the efficiency of propofol and its effects on the behaviour of anxious children during dental treatment.

MATERIALS AND METHODS

This interventional clinical single-arm trial was conducted from August 2018 to September 2020 at the teaching hospital of the Department of Paediatric Dentistry at Damascus University, Damascus, Syria. Ethical and licensing approvals were obtained from the Ethics Committee of Damascus University (No. 1363, date: 12/03/2018).

The study was carried out on 23 healthy children American Society of Anesthesiologists I (ASA I) of both sexes.

Inclusion criteria: Children aged between three and six years (ASA grade I) who required dental treatment (pulpotomy) in atleast two carious primary molars under deep intravenous sedation due to their uncooperative behaviour (negative or definitely negative according to Frankel's behaviour scale) were included [26]. The children had no previous dental treatment experience were included.

Exclusion criteria: Children who were allergic to medications used in the study and those suffering from respiratory tract infections or systemic diseases were excluded.

Sample size calculation: The sample size was calculated by using G*Power 3.1.9.4 computer program, a minimum sample of 19 was set to ensure that an adequate sample size was collected to show 95% power, an effect size of 0.8 and 5% level of significance.

The dentist initially tried using basic behaviour management techniques such as tell-show-do; distraction and modeling before approving sedation procedure [27]. There was no use of restraints in our study. A written consent was obtained from the parents and caretakers after explaining the procedures. The paediatric dentist clinically evaluated every child and the parents with the help of the dentist filled medical questionnaires. All children were instructed to fast for six hours (from solid foods and non human milk), 4 hours (from human milk), and 2 hours (from water and clear liquids) before the procedure [4].

Age, sex, weight, duration of treatment, recovery time, and the following vital signs (blood pressure, pulse rate, respiration rate, oxygen saturation levels) were noted before the procedure and were monitored every five minutes until the end of treatment. All children were premedicated intramuscularly (in an operation theatre), by an experienced anaesthetist using midazolam (0.1 mg/kg) and ketamine (0.3 mg/kg) [28], after the onset effects of sedation started appearing, an intravenous route was established, and atropine (0.01 mg/kg) [29] was administered. Intravenous sedation was maintained with intermittent administration (bolus injection) of propofol (10-20 mg) [30] based on the anaesthesiologist's estimation so that the child can be kept in a deep sedative state.

The child's behaviour was registered using the Ohio State University Behavioural Rating Scale (OSUBRS) [Table/Fig-1] [31], and University of Michigan Sedation Scale (UMSS) was used to register the sedation levels throughout the procedure [Table/Fig-2] [32]. In the end of treatment, any complications were recorded, and the children were discharged after full recovery and when all vital signs were in the norm. Parents were contacted approximately 24 hours later, to confirm the absence of any complications.

STATISTICAL ANALYSIS

After data collection, statistical analysis software Statistical Package for the Social Sciences (SPSS, version 22.0, IBM, USA) was used.

Score	Behaviour
1	Quiet
2	Crying, no movement
3	With movement without crying
4	Struggling

[Table/Fig-1]: Ohio State University Behavioural Rating Scale (OSUBRS) [30].

Value	Patient state
0	Awake and alert
1	Minimally sedated: tired/sleepy, appropriate response to verbal conversation, and/or sound
2	Moderately sedated: somnolent/sleeping, easily aroused with light tactile stimulation or a simple verbal command
3	Deeply sedated: deep sleep, aroused only with significant physical stimulation
4	Unarousable

[Table/Fig-2]: The University of Michigan Sedation Scale (UMSS) [31].

Mann-Whitney test was used to study the differences in levels of behaviour and degrees of sedation between males and female patients during treatment. Pearson's correlation coefficient was used to study the relationship between treatment time and recovery time. The significance level was set at p-value <0.05.

RESULTS

The study was conducted on a sample of 23 children with an average age of 4.4±1.1 years. The sample consisted of 13 males and 10 females [Table/Fig-3]. Most of the vital parameters fell within normal ranges for healthy paediatric patients as shown in [Table/Fig-4].

Variable	Value
Sex (Male: Female)	13:10
Age (years) (mean±SD)	4.4±1.1
Weight (kg) (mean±SD)	16.1±5.1
Treatment duration (minutes) (mean±SD)	50.2±12.29
Recovery time (minutes) (mean±SD)	22.3±4.4

[Table/Fig-3]: Demographic details.

Vital signs	Overall (Mean±SD)	Male (Mean±SD)	Female (Mean±SD)
Systolic blood pressure (mmHg)	102.4±3.4	101.9±3.2	103.1±3.6
Diastolic blood pressure(mmHg)	67.0±3.3	65.5±3.3	69.1±2.2
Heart rate (beats/min)	107.04±9.23	113±7.9	103.04±8.9
Oxygen saturation (SpO_2) (%)	97.2±0.6	97.54±0.6	96.9±0.5
Respiratory rate (breaths/min)	21.7±0.7	21.7±0.7	21.7±0.8

[Table/Fig-4]: Vital signs.

Side-effects observed during sedation were desaturation in 13 children (56.5%), coughing in 4 children (17.3%), excessive secretion in 2 children (8.7%), involuntary movement and apnea in none. Side-effects observed postoperatively after 24 hours: nausea in 1 children (4%), agitation 3 (13%), dizziness 18 (78%). The dental procedures were successfully completed in all patients.

Children scores on OSUBRS and UMSS are shown in [Table/Fig-5]. [Table/Fig-6] shows the test results of Mann-Whitney pairwise comparisons between males and females regarding the level of behaviour and the degree of sedation. The average treatment time was (50.2±12.29 min) and the average recovery time was (22.3±4.4 min). Pearson's correlation coefficient between them was 0.813, which is considered a strong correlation (p-value <0.01).

Children score system	Overall n (%)	Males n (%)	Females n (%)
OSUBRS score			
1	18 (78.3)	11 (84.6)	7 (70)
2	3 (13)	1 (7.7)	2 (20)
3	2 (8.7)	1 (7.7)	1 (10)
4	0 (0)	0 (0)	0 (0)
UMSS value			
0	0 (0)	0 (0)	0 (0)
1	0 (0)	0 (0)	0 (0)
2	4 (17.4)	1 (7.7)	3 (30)
3	19 (82.6)	12 (92.3)	7 (70)
4	0 (0)	0 (0)	0 (0)

[Table/Fig-5]: Children scores on the OSUBRS and UMSS.

Score system	Males	Females
OSUBRS score	p-value=0.605	
UMSS value	p-value=0.376	

[Table/Fig-6]: The test results of Mann-Whitney pairwise comparisons between males and females regarding the level of behaviour and the degree of sedation.
significant difference at p-value=0.05

DISCUSSION

In present study, there was no statistically significant difference between males and females regarding the level of behaviour or the degree of sedation. A strong positive relationship between treatment time and awakening time was found. Uncooperative child behaviour is one of the most challenging issues that dental practitioners face, rendering them unable to deliver optimal dental care [33,34]. Behaviour management methods vary widely, ranging from simple to advanced non pharmacological approaches, pharmacological approaches, and general anaesthesia [35].

Propofol is one of the most common medications used for intravenous sedation in paediatric patients due to its known merits such as the rapid onset of action and quick recovery. Therefore, it is widely used to reduce anxiety in children undergoing therapeutic or diagnostic procedures. It is also known that propofol has a strong sedative effect and can be classified as a deep sedative or even as a general anaesthetic agent [23,36,37].

The presence of an anaesthesiologist has been recommended during deep sedation of children because of serious associated risks, such as airway obstruction, hypoxia, hypoventilation, and apnea [4]. In this study, an experienced anaesthesiologist was present throughout the sedation procedure until child had been discharged. Intramuscular ketamine and midazolam were used to induce initial sedation due to the difficulty in gaining intravenous access in anxious children [38]. After establishing an intravenous route, atropine (0.01 mg/kg) was given to reduce secretions and deep sedation was continued intermittently using propofol (10-20 mg). The amount and timing of each propofol dosage were determined based on the anaesthesiologist's estimation. The intermittent boluses were given in anticipation to the response to a stimulus or if signs of inadequate sedation were developing such as low UMSS scale, low OSUBRS scale rating, sounds and movements.

The most common complication observed during sedation was mild desaturation (85-90% SpO_2), immediately after administration of intravenous propofol bolus a. mild desaturation was observed in 13 children (56.5%), and in all of these cases the normal level of oxygen saturation was rapidly restored (>95%) following neck repositioning (head tilt, chin lift) with or without application of nasal oxygen. To our knowledge there were no previous studies done in the field of dentistry to determine the effect of propofol administered in intermittent boluses on the children's behaviour during dental treatment. This study is considered the first of its kind. The administration of propofol in such a method could help avoid one of its drawbacks, which is the need for an expensive infusion pump [25,30,39]. An intermittent bolus technique is the standard method used for deep sedation/general anaesthesia during oral and maxillofacial surgery. Many studies, which compared between intermittent bolus versus continuous infusion technique, found that there were no significant differences in satisfactory sedation and quality of diagnostic procedures with both techniques [30,39].

According to this study, the use of propofol in intermittent boluses led to safe and effective sedation with favourable behaviour. Majority of the children (78.3%) scored 1 on the OSUBRS and (82.6%) of the children were at level 3 on the UMSS and dental treatment was completed. No child experienced any serious complications during treatment that led to the termination of the treatment or required pharmacological or emergency intervention. This confirms the safety of propofol when used to sedate children under the supervision of an anaesthesiologist, and this is consistent with numerous studies that have used propofol in the medical and dental fields [16,40]. The successful treatment of uncooperative children can be attributed to the sedative properties of propofol and its ability to eliminate anxiety with a minimum amount of respiratory complications and its quick recovery time [24].

The use of atropine has helped greatly in reducing the possibility of respiratory complications such as oxygen desaturation due to excessive salivation, which is in agreement with the results of other studies pointing to its ability to limit excessive salivation into the respiratory tract, and also reduces the likelihood of nausea and vomiting [29,41], which are the most encountered complications when inducing sedation using ketamine [42]. The results of this study consistent to a study done by Mittal N et al., where propofol was used to complete endodontic treatment in anxious children and pointed out propofol's superiority in terms of efficacy and safety, where unfavourable effects were at their minimum [43].

This study is in accordance with Chiaretti A et al., which stated that propofol is efficient and safe when used on children by trained personnel, as authors recommended the presence of an anaesthesiologist during such procedures due to the related risks such as respiratory obstruction or hypoxia [44]. In the present study, an anaesthesiologist attended the sedation procedures. The present study indicates a strong relationship between treatment duration and recovery time i.e., the longer the treatment duration the greater the recovery time, thus propofol can be beneficial when used during relatively short dental procedures while noting that there were no previous studies in the dental field that investigated the relationship between treatment duration and recovery time.

Limitation(s)

The present study had a small sample size. Conducting a comparative gender analysis with larger sample size should be considered in future studies. Another limitation of the study was the inability to determine the pure effect of propofol in terms of behaviour and depth of sedation due to the use of premedication with midazolam and ketamine, with the aim of decreasing anxiety.

CONCLUSION(S)

Within the limits of this study, it can be concluded that the use of propofol in intermittent boluses is safe and efficient in the management of anxious and uncooperative children during dental treatment, demonstrating lower recovery time in short treatments. There was no statistically significant difference between males and females regarding the level of behaviour or the degree of sedation.

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