

EAPD Guidelines on Sedation in Paediatric Dentistry

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It should be emphasized that these guidelines are only dealing with conscious sedation, which implies that the patient has

- Minimally depressed consciousness
- Ability to maintain open airway
- Protective reflexes maintained
- Response to physical and verbal stimulation

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Introduction

Development of the present guidelines on sedation in paediatric dentistry was initiated during a workshop held 11th of April 2003 at the University of Aarhus, Denmark.

During the development of the guidelines it became clear, that very few RCTs have been performed in the area of sedation of children for dental care. Thus, the present guidelines had to be based on lower levels of evidence, such as guidelines developed by other professional organisations, as well as clinical experience. One of the obvious recommendations therefore is, that there is a need for well-controlled clinical studies on sedation of children for dental care.

Sedation in Paediatric Dentistry

Need for guidelines on sedation

Current understanding of paediatric oral health includes absence of dental fear and anxiety as well as healthy oral structures with the aim of forming the basis for good oral health throughout life. This implies two main dimensions in paediatric oral care: (1) to keep the oral environment healthy, and (2) to keep the patient capable of, and willing to utilize the dental service.

In recognition of the expanding need for both the elective and emergency use of sedative agents and the importance of delivering painless treatment to children, guideline for the use of sedative agents among children are important.

Paediatric dentists should be aware that sedation represents a continuum. Thus, a patient may move easily from a light level of sedation to a deeper level, which may result in the loss of the patient's protective reflexes. The distinction between conscious sedation and deep sedation is made for the purpose of describing the level of monitoring needed, as well as the responsibility of the dentist.

Legislation

The rules and regulations governing dental practice differ between European countries. Important differences as to the rights of the dentist to utilize various methods of sedation also exist. Some member countries of EAPD have already developed guidelines on sedation of children for dental care (*e.g.* United Kingdom (1) and Norway (2)), as has single institutions/departments dealing with dental care for children. Therefore the present guidelines have to be implemented in the context of each country's national regulations on conscious sedation.

Restraint

The use of restraint in dentistry (including such restraining devices as the papoose board) is practiced to at varying extent in European countries, but in some countries, as the Nordic, forbidden to use by law. A mouth prop may be used to help a child support the lower jaw and thus assist it in holding the mouth open. It may not be used to forcefully get a child to hold the mouth open, which may also make it more difficult to assess the level of sedation.

Sedation and pain control

The treatment and alleviation of pain is a basic human right that exists regardless of age and demands treatment for this reason alone. Therefore all children should expect painless, high quality dental care. Sedation is required for some child patients in order for the dentists to be able to deliver high quality, pain-free dental care. When sedation is used there is an additional, separate need for pain control in form of local anaesthesia, and behaviour management (3).

Objectives for sedation in paediatric dentistry

Objectives for sedation in paediatric dental care consider both the needs of the child and the dentist:

- The child
 - Reduce fear and perception of pain during the treatment
 - Facilitate coping with the treatment

- Prevent development of dental fear and anxiety
- The dentist
 - Facilitate accomplishment of dental procedures
 - Reduce stress and unpleasant emotions
 - Prevent “burn-out” syndrome

Definitions

These guidelines include a number of terms which are defined below (see also (4)).

Paediatric patients: All patients below the age of 18 years, as defined by the UN Convention on the Rights of the Child (5).

Must or shall: Indicates an imperative need or duty that is essential, indispensable, or mandatory.

May or could: Indicates freedom or liberty to follow a suggested or reasonable alternative.

ASA Physical Status Classification: Guidelines for classifying the physical status according to the American Society of Anaesthesiologists (6) (Appendix I).

Preoperative anxiolysis: By the use of low doses of anxiolytics minimize anxiety prior to dental treatment or facilitate sleep the night before dental appointment in patients with dental anxiety.

Conscious Sedation¹: A medically controlled state of depressed consciousness that allows protective reflexes to be maintained, retains the patient’s ability to maintain a patent airway independently and continuously, and permits appropriate response by the patient to physical stimulation or verbal command, e.g., “open your mouth”.

Deep Sedation²: A medically controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused. It may be accompanied by a partial or complete loss of protective reflexes, and includes the inability to maintain a patent airway independently and respond purposefully to physical stimulation or verbal command.

General Anaesthesia: A medically controlled state of unconsciousness accompanied by a loss of protective reflexes, including the inability to maintain a patent airway independently and respond purposefully to physical stimulation or verbal command.

It should be emphasised that these guidelines are only dealing with conscious sedation. This implies that the dentist should be able to act as his/her own sedationist without the presence of an anaesthesiologist, provided that these guidelines are followed.

Patient selection and assessment

Patient assessment must include a full medical and dental history as well as a social history.

Each patient must be classified according to the ASA Physical Status Classification System (6). Patients who are ASA Class I or Class II may be considered candidates for conscious sedation as outpatients. Patients in ASA Class III and Class IV represents special problems and require individual consideration and shall be treated in a hospital environment, involving the assistance of medical doctors when appropriate.

Indications and contraindications

When identifying children in need of conscious sedation it is useful to make a combined judgement of the following two groups of factors.

¹ The Department of Health in the U.K. has in 2002 defined conscious sedation as: “A technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drug and technique used to provide conscious sedation for dental treatment should carry a margin wide enough to render loss of consciousness unlikely (7).”

² In several countries this is analogue to general anaesthesia, as protective reflexes are suppressed or lost.

- Children with low coping ability
 - Behaviour management problems
 - Dental fear and anxiety, odontophobia
 - Mental retardation
 - General disorders, psychiatric conditions
- Treatment need
 - Emergency treatment
 - Moderate to large and complicated treatment needs

Sedation of children below the age of 1 year is said to be contraindicated, and hardly ever relevant in the dental setting.

Pregnancy represents a relative contraindication to extensive elective dental care, particularly during the first trimester. Conscious sedation during pregnancy requires careful assessment of risks versus the benefits.

Patient monitoring

Continuous clinical observation

Paediatric dental patients under conscious sedation must be monitored continuously clinically, as this is the most important element in patient monitoring. Clinical monitoring include

- Response by the patient to
 - Physical stimulation
 - Verbal command
- Observing breathing
- Movements of the thorax
- Passage of the air stream
- Respiratory frequency
- Observing skin colour

Pulsoximetry

The use of pulse oximetry has been widely discussed. In the case of conscious sedation, oxygen desaturation (*i.e.* below 95%) is probably rare.

Pulsoximetry is not deemed required for conscious sedation with nitrous oxide/oxygen sedation, but is preferable in benzodiazepin sedation. It is however vital that the staff are adequately trained in the use of clinical monitoring, and if used the management of electronic monitoring. When pulse oximetry is used, more than 3 out of 4 of the alarms may be false positives due to movement artefacts, sensor displacement or other reasons. Young children especially may react with increased anxiety to the placement of the pulsoximeter. More research is needed in order to determine the feasibility and utility of pulsoximetry.

Patient information

Written and oral information and consent

Pre- and postoperative instructions in writing must be given in advance of the procedure to the child and the parent or guardian.

Informed consent shall follow the legislation of the country.

An adult who is well known to the child should always escort them to and from treatment. In the context of school dental clinics and the use of nitrous oxide/oxygen sedation schoolchildren can after parents consent get treatment without the presence of an adult escort, provided the parents have consented.

Fasting

Fasting rules vary slightly between the European countries, Prior to conscious sedation it is recommended, that the child shall be fasted according to the following rules:

- No clear liquids 2-3 hours before sedation
- No solid foods or non-clear liquids 4 hours before sedation.

Clear liquids are non-fruity juice, water, tea, and coffee. All milk products (non-clear liquids) are considered as solid foods. Children under school age shall drink sugar containing clear liquid up to 2 hours before treatment in order to avoid low blood sugar.

For the emergency patient, where proper fasting has not been assured, the increased risk of sedation must be weighted against the benefits of the treatment, and the lightest effective sedation should be used. If possible, such patients may benefit from delaying the procedure.

Discharge

Before discharge, children should be alert and oriented (or have returned to an age-appropriate base line). A responsible adult must be present to observe the child for complications after discharge, and to control that the child sits with the head in an upright position to facilitate breathing. In the situation of an outpatient child and if the responsible adult is driving a car to the home another adult must be present if the child is young. The adult must be given written and oral instructions on

- Appropriate diet
- Medications
- Management of possible postoperative bleeding
- Level of activity.

Documentation and records

It is recommended that the documentation include

- Medical history including prescribed medication
- Previous dental history
- Previous conscious sedations and general anaesthesia
- Indication for the use of conscious sedation
- Pre-sedation assessment
- Written instructions provided pre- and post-operatively
- Presence of an accompanying responsible adult
- Arrangements for suitable post-operative transportation and supervision
- Compliance with pre-treatment instructions
- The course of the treatment
 - Monitoring
 - Dose, and route of administration of sedative drugs
 - Dental treatment performed
 - Sedation evaluation (sedation scale)
 - Accept of sedation and treatment (behavioural scale)
 - Complications
- Post-sedation assessment and time of discharge home

Appendix II is a sedation scale, that can be used to monitor the effect of the sedation (8).

Safety for the staff

Inhalation sedation requires special scavenging equipment to ensure safety for the personal in the operating room (9-13).

Education and Training

Training of paediatric dentists in sedation should include theoretical training as well as practical training. EAPD Guidelines for postgraduate training in paediatric dentistry should be followed in developing appropriate training programmes in sedation (14).

Theoretical training should cover all the subjects referred to in the present document. Practical training should include knowledge of the drugs and equipment used for conscious sedation, and must be completed before the clinical training. Knowledge of management of complications due to conscious sedation is essential. Training and experience should be regularly updated and maintained.

Documented, contemporaneous supervised hands-on experience must be acquired for each conscious sedation technique used. The minimum number of documented supervised cases completed should be no less than those specified by appropriate authorities.

Dental auxiliary personnel assisting during conscious sedation sessions shall also have appropriate but shorter training.

All clinical staff requires theory and practical training in basic life support. Basic life support must conform to contemporary guidelines issued by national authorities and dental associations.

Training can be through informal courses where clinical training is included or in theoretical courses with clinical demonstrations in combinations with clinics where conscious sedation is regularly performed for hands-on supervision.

Those arranging such training have a duty to ensure that the quality of training and trainers is appropriate and that all theoretical and practical training is documented.

Drugs

Drugs used for paediatric dental sedation includes inhalation agents where the gas is delivered through a specially designed machine and the patient inhales the gas through a nasal hood (mainly nitrous oxide), benzodiazepines and other agents with sedative properties.

Nitrous oxide

Nitrous oxide is a gas with anxiolytic and sedative effects combined with varying degree of analgesia and muscular relaxation. Recent research suggest that both GABA_A and NMDA-receptors are affected by nitrous oxide (15;16). Nitrous oxide when administered to patients for inhalation must be given in a mixture with oxygen (30% or more) to safeguard the patient's oxygen supply. Nitrous oxide is non-irritant to the respiratory tract, has a low tissue solubility, and a minimum alveolar concentration (MAC) value of more than one atmosphere. Therefore nitrous oxide has a rapid onset, a fast recovery (both within minutes) and is a poor anaesthetic.

Benzodiazepines (BZD)

Benzodiazepines (BZD) are a group of drugs, which has the following effects: anxiolysis, sedation/hypnosis, skeletal muscular relaxation, anterograde amnesia, respiratory depression and an anticonvulsive effect (17).

BZD exert their effect via specific receptors in the CNS associated with the GABA-receptor. When the inhibitory neurotransmitter GABA binds to its receptors, a suppressing effect is initiated on nerve cells activated by other neurotransmitter substances. The GABA-mediated inhibition works more efficiently in the presence of BZD. BZD as a group have a wide margin of safety between therapeutic and toxic doses. BZD has a high lipid solubility and therefore a rapid action on the CNS. Different BZD have minor, but clinically important differences in absorption, peak plasma concentration, redistribution and elimination. BZD have been widely used in dentistry. BZD have no analgesic effect.

A combination of nitrous oxide/oxygen and BZD may be used for conscious sedation, as there is an additive effect of the nitrous oxide to the BZD sedative effect. In these cases more strict fasting rules should be followed.

Among the different benzodiazepines available, midazolam and diazepam are the most suitable for use in paediatric dentistry.

Other agents with sedative properties

The efficacy of fentanyl and pethidine is questionable and the associated risks may outweigh their benefit and some are only recommended in some countries for use in hospital settings and by qualified anaesthetists (1).

The use of propofol and ketamine in paediatric dentistry is still experimental and requires the assistance of or has to be administered by a qualified anaesthesiologist.

Nitrous oxide/oxygen inhalation sedation

Nitrous oxide/oxygen has been shown to be an effective anxiolytic and sedative inhalation agent for conscious sedation during dental treatment and is recommended as the preferred drug (18-27). The gas mixture shall contain a maximum 50 % nitrous oxide. Nitrous oxide/oxygen is reliable in terms of onset and recovery as long as the patient accepts the nasal hood and breathes through the nose. Nitrous oxide has minimal effect on cardiovascular and respiratory function, as well as on the laryngeal reflex. Nitrous oxide is a weak analgesic, most often insufficient to ensure painless dental treatment.

Nitrous oxide/oxygen sedation and local anaesthesia is an alternative to general anaesthesia (28).

Delivery systems

Only dedicated dental nitrous oxide/oxygen delivery systems must be used. The system must contain fail-safe device (*i.e.* if the oxygen pressure falls, the supply of nitrous oxide automatically stops), flow-meter for individual set of gas flow and nitrous oxide concentration, emergency air-valve, non re-breathing, tubes with low breathing resistance, and an effective scavenging device for exhaled and excess gas (18;29-34). The use of rubber dam improves the effect of the sedation and reduces atmospheric pollution (13).

Dental operators should ensure that they comply with national guidelines in respect to nitrous oxide pollution and gas safety.

Indications

Nitrous oxide/oxygen sedation is useful in children 4 years and older.

Further to the general indications for conscious sedation mentioned previously, nitrous oxide/oxygen can be used in patients with a strong gagging reflex, which makes dental treatment impossible, as well as in patients with muscular tone disorders such as cerebral palsy, in order to avoid unintentional movements.

Patients belonging to ASA Class III and Class IV can be treated with the help of nitrous oxide/oxygen sedation provided other indications are present, but treatment of these patients must be restricted to hospital settings, where an anaesthesiologist can be present.

Contraindications

Nitrous oxide/oxygen sedation should not be used in

- Pre-co-operative children
- Patients with upper airway problems as common cold, tonsillitis or nasal blockage
- Patients with sinusitis or recent ENT operations (within 14 days)
- Patients in bleomycin chemotherapy (35)
- Psychotic patients
- Patients with porphyria

Side effects

Observed side effects of nitrous oxide are over sedation, nausea, vomiting, dysphoria, sweating, restlessness, panics, headache, nightmare, tinnitus and urinary incontinence (18;25;36).

Dosage

Sedation is initiated by giving pure oxygen for 2 to 5 minutes. Following that, the nitrous oxide concentration is increased every second minute. The maximum recommended concentration of nitrous oxide is determined by national regulations, and varies between the Europe countries from 50 to 70 %.

At the end of the session the child is given pure oxygen for 5 minutes.

Safety for the staff

Chronic exposure to trace concentrations of nitrous oxide has been reported to constitute an occupational health hazard (9;10). Consequently, the dental staff must follow strict indications for the use of nitrous oxide, only use nitrous oxide delivery systems with an efficient scavenging system, have appropriate technique for disconnection of the delivery system, and have methods for testing the integrity of the breathing system.

Midazolam sedation

The effect of midazolam for sedation of children for dental care has been studied in a number of projects, and midazolam is now the standard BZD agent for conscious sedation during dental treatment in children (37-41). After oral administration the peak plasma concentration is reached within 20 minutes, faster via the rectal route in about 10 min. After 45 minutes the sedative effect wears off. The elimination half time is 2 hours, which facilitates a fast recovery.

Indications

See general indications for sedation.

Contraindications

Midazolam must not be given to the following groups of children

- Children under the age of one year
- Children with any form of acute disease
- Children with neuromuscular diseases as myasthenia gravis
- Children with allergy to BZD
- Children with sleep apnoea
- Children with liver dysfunction
- Children with hepatic dysfunction

Side effects

The following side effects should be considered:

- Interactions with other medication
- Paradoxical reaction
- Over sedation
- Hallucinations

Clinical considerations

All drugs in use in the treatment area must be clearly labelled and each drug should be given according to accepted recommendations.

Routes

Oral midazolam can be administered in tablet form (available in some countries) or as a sweetened mixture for delivery either via a drinking cup or drawn into a needleless syringe and deposited in the retromolar area.

Transmucosal administration of midazolam has the advantage of depositing the drug directly into the systemic circulation. Rectal sedation utilises this transmucosal approach. Rectal administration requires syringes and a rectal applicator. In some countries, rectal administration is uncommon due to cultural attitude. Despite this rectal administration of midazolam has a good evidence base.

Rectal administration requires syringes and a rectal applicator. In some countries doctors keep away from rectal administration due to a negative opinion of the public.

Midazolam should administered at the clinic.

Doses

Oral: Children under 25 kilogram of weight shall have 0.3-0.5 mg midazolam per kilogram. Maximum dose 12 mg.

Children over 25 kilogram of weight shall have 12 mg midazolam.

Tablets are given 60 min before dental treatment, and oral mixtures given approximately 20-30 minutes before.

Rectal: Children under 25 kilogram of weight shall have 0.3-0.4 mg midazolam per kilogram bodyweight. Maximum dose 10 mg midazolam.

Children over 25 kilogram of weight shall have 10 mg midazolam.

Rectal solution is administered approximately 10 minutes before treatment starts.

Interactions: Contemporaneous intake of erythromycin, hypnotics, anxiolytics, antidepressants, antipsychotics, antiepileptics, antihistamines, opioids, grapefruit juice, clonidine and alcohol can enhance the effect. Drug interactions shall be followed in national databases.

Diazepam sedation

Diazepam has a long elimination half-life, 24-48 hours, and active metabolites. The clinical action develops within an hour after oral tablet administration. Because of a pronounced distribution, the time of clinical effect is rather short. Inherited metabolic deficiencies occur in some individuals, with a risk of prolonged effect. Diazepam is highly effective in reducing preoperative anxiety, and useful for sleep disturbances prior to treatment.

Routes

Oral administration of tablets can be given either as a single dose 1 hour before treatment, or fractionated, with half the dose taken on the night before, and the remaining half 1 hour prior to treatment. Tablets can be crushed and mixed in sweetened drink in to facilitate administration.

Doses

Children 4-8 years of age: 0.5-0.8 mg diazepam per kilogram. Maximum dose 15 mg. Children over 8 years of age: 0.2-0.5 mg diazepam per kilogram. Maximum dose 15 mg.

Appendix I

Physical-Status Classification of the American Society of Anaesthesiologists (6)

Class	Physical status
I	A normal healthy patient
II	A patient with a mild systemic disease
III	A patient with severe systemic disease that limits activity, but is not incapacitating
IV	A patient with an incapacitating systemic disease that is a constant threat to life
V	A moribund patient not expected to survive 24 hours with or without operation

Appendix II

Sedation scale according to Wilton (8).

Agitated	Clinging to parent and/or crying
Alert	Awake but not clinging to parent, may whimper but not cry
Calm	Sitting or lying comfortable with eyes spontaneous open
Drowsy	Sitting or lying comfortable with eyes spontaneous closing but responds to minor stimulation
Asleep	Eyes closed, rousable but does not respond to minor stimulation

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