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Current challenges in paediatric sedation

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Current treatment options and challenges – Dr. K. Becke

Background

An increasing number of diagnostic and treatment procedures are performed outside the operating room. Without sedation even minor procedures such as vaccination can be painful, stressful and lead to severe trauma. Sedation ensures optimal conditions for performing safe and high-quality interventions.

Children are at increased risk from the combination of analgesia and sedation, especially from respiratory complications. The recently published APRICOT study found a higher incidence of severe critical events associated with anaesthesia than previously believed (Habre et al. 2017).

Sedation and analgesia for short interventions are increasingly carried out by non-anaesthesiologists. The Paediatric Research Consortium's analysis of 50,000 sedations/anaesthetic procedures showed that only 10% were performed by paediatric anaesthesiologists (Cravero et al. 2009).

Sedation goals

The goals of paediatric sedation are to:

- Guard the patient's safety and welfare
- Minimise physical discomfort and pain for the patient
- Control anxiety, minimise psychological trauma, and maximise the potential for amnesia
- Modify behaviour and/or movement so as to allow the safe completion of the procedure (particularly important in radiology)
- Return the patient to a state in which discharge from medical/dental supervision is safe (Coté et al. 2016)

The Safetots.org initiative summarised good perioperative practice as the '10 Ns':

1. No fear
2. Normovolemia
3. Normotension
4. Normocardia
5. Normoxemia
6. Normocarbia
7. Normonatremia
8. Normoglycemia
9. Normothermia
10. No pain

Interdisciplinary framework

Hospitals should take a systematic approach to sedation by defining sedation, qualifications of the team, pre-sedation evaluation and regimes for different interventions.

Procedural sedation

The new pragmatic approach is to distinguish between two types of sedation:

- Minimal sedation or anxiolysis without compromise of cardiorespiratory or neurologic function, is appropriate for minor procedures such as inserting an IV line and making dressings.
  - Drugs for minimal sedation or anxiolysis include
    - Midazolam
    - Single dose opioid (e.g. IN)
    - Nitrous oxide (< 50%)
    - Dexmedetomidine
- Deep sedation is equivalent to general anaesthesia, and is appropriate for radiology procedures.
  - Drugs for deep sedation include propofol, ketamine, remifentanil, dexmedetomidine or combinations

Sedation team

Nurses, dentists and paediatricians are competent to administer minimal sedation or anxiolysis, where only SpO_2 monitoring is required.

Teams performing deep sedation must have the requisite knowledge and competencies in order to avoid respiratory adverse events. Team members will be anaesthesiologists, intensivists or emergency doctors, who have basic and advanced paediatric life support training, and can insert intravenous lines, and have bag mask ventilation skills and airway management skills to secure the airway.

Pre-sedation evaluation

Preoperative evaluation and preparation for sedation is the same as for general anaesthesia. Patients and parents need to be informed about what is going to be performed. The anaesthesiologist needs to make careful preoperative evaluation of the patient, particularly their medical history,

including difficult airway situations and comorbidities.

Fasting prior to sedation is important, with recommended fasting times as follows:

- Solids, 6 hours
- Breast milk/formula (children < 1 year), 4 hours
- As for general anaesthesia, all children should receive clear fluids for up to 2 hours before sedation

Monitoring

The minimal standards for deep sedation are ECG, BP, SpO_2 and capnography. There may also be specific prerequisites depending on the environment, e.g. telemetrics in the MRI suite.

Regimes for different interventions

Standardised interdisciplinary sedation regimes should be devised and implemented in each department, e.g. radiology, oncology, endoscopy. Measures of quality assessment and improvement should be performed continuously.

Documentation and follow-up

Sedation should be documented as for general anaesthesia. After deep sedation the patients should go to the recovery room and be monitored. There needs to be defined discharge criteria, information for patients and families on behaviour at home, and what to do in case of complications and a contact telephone number.

In-hospital paediatric sedation - areas for improvement - Prof. C Hohne

Adverse events in paediatric sedation have a prevalence of around 4.8%. To minimise the potential for adverse events, there are a number of areas where improvements are possible, including fasting times, patient monitoring and new drugs.

Fasting times

Fasting times are as for general anaesthesia. Liquids may be taken up to 2 hours before the procedure, or for up to 4 hours before in infants under 12 months. Food can be taken by children over 12 months until 6 hours before sedation. Gastric content volume is highly variable and independent of fasting time (Schmitz et al. 2011). Beach and colleagues (2016) found that nil by mouth for liquid or solids is not an independent predictor for aspiration—rather age, ASA status, comorbidities or the procedure itself were predictors. If we have a planned procedure, and it is not known if the child has fasted or not, it may not be necessary to postpone due to risk of aspiration. Current specified fasting times are safe, but are often exceeded, leaving children hungry and thirsty (Engelhardt et al. 2011). An observational study by Dennhardt and colleagues found that optimised fasting times decreased ketone body concentration and stabilised mean arterial pressure (Dennhardt et al. 2016).

Monitoring

With mild sedation, oxygen, heart rate and ventilation are monitored, and the anaesthesiologist can still communicate with the child. For deeper sedation, monitoring is as for general anaesthesia, including blood pressure, oxygen saturation and capnography. All vital signs should be recorded and documented, and age-appropriate equipment used (Coté et al. 2016).

Drugs

Drugs for sedation need to be short acting, safe, with predictable effects and keeping the airway patent. Propofol is commonly used for moderate and deep sedation, and is safe when administered by paediatric anaesthesiologists. It has a short recovery time, and if there are haemodynamic and respiratory events, these are easily treated. Careful use is advised in case of aortic or mitral stenosis/pulmonary hypertension due to the vasodilation effect (Tobias 2015). Ketamine or dexmedetomidine alone or in combination may be used either intravenously or intranasally. Dexmedetomidine could be a good alternative for patients with difficult airways. However, with the exception of propofol, most drugs are used off-label, and new drugs are needed.

A novel oral solution for paediatric sedation- Dr. Michael Brackhahn

Midazolam is used routinely for premedication in paediatric anaesthesia, but in many countries it is used off-label. Oral midazolam is used for anaesthetic premedication and for diagnostic and therapeutic procedures, e.g. sutures, IV placement, CT or MRI scans.

Oral midazolam solution is a well-known benzodiazepine with sedative, hypnotic, anxiolytic, amnesic, skeletal muscle relaxant and anticonvulsant properties, and it is an excellent alternative to drugs that require invasive administration routes. Currently available oral midazolam solutions have a bitter taste, which are poorly accepted by children.

ADV6209 is an innovative 0.2% oral midazolam formulation initially developed in 2008 through collaboration between anaesthetists and pharmacists at CHU d'Amiens-Picardie in Northern France. The objectives were to develop a more acceptable oral midazolam formulation, for use in pre-medication before general anaesthesia and moderate sedation, before and during therapeutic and diagnostic procedures. ADV6209 does not have the bitter taste of currently available preparations and so is better accepted by children. The solution has no preservative, lactose or colorants, and is currently undergoing regulatory submission in the EU.

As part of its development, ADV6029 was investigated in a phase II study involving 37 paediatric patients, who received premedication before general anaesthesia at Amiens University Hospital (Guittet et al. 2016). The sedative effect was measured after the patients received a single dose administration of ADV6209 at a mean midazolam dose of 0.27 mg/kg. The findings of the phase II study were compared to previous literature reports. In the trial satisfactory sedation was achieved in 78.4% of the patients, 30 minutes after administration of ADV6209. There was no significant difference between the overall responder rate obtained with ADV6209 and the literature findings observed with other oral midazolam formulations.

ADV6209 was well accepted by children of various ages. ADV6209 was a safe and efficacious sedative at the dose investigated. The recommended dose of ADV6029 is 0.25 mg/kg, with a maximum dose of 20mg. ■

References

For full references, please email editorial@icumanagement.org or visit https://iii.hm/de4