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Procedural sedation and analgesia for gastrointestinal endoscopy in infants and children: how, with what, and by whom?

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Abstract

Endoscopic procedures involving the gastrointestinal tract have been successfully developed in paediatric practice over the last two decades, improving both diagnosis and treatment in many children's gastrointestinal diseases. In this group of patients, experience and co-operation between paediatricians/endoscopists and paediatric anaesthesiologists should help to guarantee the quality and safety of a procedure and should additionally help to minimise the risk of adverse events which are greater the smaller the child is. This principle is more and more important especially since the announcement of the Helsinki Declaration on Patient Safety in Anaesthesiology in 2010, emphasising the role of anaesthesiology in promoting safe perioperative care. The Helsinki Declaration has been endorsed by all European anaesthesiology institutions as well as the World Health Organisation's 'Safe Surgery Saves Lives' initiative including the 'Surgical Safety Checklist'. Although most of these procedures could be performed by paediatricians under procedural sedation and analgesia, children with congenital defects and serious coexisting diseases (ASA ≥ III) as well as the usage of anaesthetics (e.g. propofol) must be managed by paediatric anaesthesiologists. We have reviewed the specific principles employed during qualification and performance of procedural sedation and analgesia for gastrointestinal endoscopy in paediatrics. We have also tried to answer the questions as to how, with what, and by whom, procedural sedation for gastrointestinal endoscopy in children should be performed.

Key words: gastrointestinal endoscopy, children, sedation

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The number of gastrointestinal endoscopies (GE) performed in childhood has increased over the last two decades, improving both diagnosis and treatment of children's gastrointestinal diseases. Many of these procedures can be performed under procedural sedation and analgesia (PSA), but they must be tailored to the demands of the paediatric population [1, 2]. Enhanced co-operation between endoscopists and anaesthesiologists could improve the level

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of safety and minimise the risk of adverse events and this principle has become increasingly important since the announcement of the Helsinki Declaration on Patient Safety in Anaesthesiology in 2010 [3]. This declaration emphasises the role of anaesthesiology in promoting safe perioperative care and was endorsed by all European anaesthesiology institutions in supporting the World Health Organisation's (WHO) 'Safe Surgery Saves Lives' initiative. Considering the potential risks of performing endoscopies under PSA, the question is whether some groups of patients can be managed using minimal or moderate sedation, and, if not, then what is appropriate: deeper sedation or anaesthesia? The next consideration is who might undertake such sedation if suitable guidance and protocols are put in place, i.e. paediatricians rather than anaesthesiologists. Considerations that would affect such protocols would involve the age and size of patients as well as their background medical status.

Children often present a constellation of potential problems that differ greatly from those of adults. Achieving deeper levels of sedation than intended may, in turn, lead to more frequent adverse events and increased mortality [4]. Data published in 2000 suggested that the frequency of anaesthesia-related cardiac arrests in children was 0.014% [5]. Mortality in this group was high (24%) and some of the surviving children (15–30%) were left with irreversible neurological disabilities, decreasing the quality of life for both child and parents [6]. In fact, the most recent data emphasises that the ratio of ventilatory problems is predominant in paediatrics compared to cardiovascular adverse events. In the group of smaller children, the ratio of ventilatory adverse events is 17.8% and and 1 in 200 children undergoing sedation/anaesthesia requires airway and ventilatory support [7]. For this reason, the person providing the sedation must have the skills to rescue the patient even though this technique seems to be safe when used by non-anaesthesiologists [8]. Cote et al. [9] showed that safety during PSA is determined by the circumstances and professional skills of the person performing the procedure, rather than by particular medications, except in cases of overdosing or drug interactions and when three or more drugs were used.

This review describes specific considerations concerning the skills necessary for the safe performance of paediatric gastrointestinal endoscopy under PSA, and examining the key question about which personnel should perform PSA for this procedure in children.

PSA DEFINITION

Procedural sedation and analgesia (PSA) is defined as a state that allows patients to tolerate unpleasant and painful procedures [10]. Depths of sedation can be seen as a continuum but it is useful to differentiate PSA into Minimal Sedation (MS), Moderate Sedation (MDS), Deep Sedation (DS) and then General Anaesthesia (GA). During MS, cognitive function is suppressed along with reduced anxiety and fear, essentially anxiolysis. The child is able to respond to verbal stimulation and to breathe efficiently and spontaneously. Cardiovascular function is unaffected. MS is commonly employed in older children for painless diagnostic procedures. MDS is usually performed in both younger and older children for uncomfortable (or potentially moderately painful) and prolonged procedures. Although the patient retains the ability to respond to stimuli, depression of consciousness is directly drug-induced and can change from 'moderate' to 'deep' without any particular increase in symptoms, but depending on the child's sensitivity to the drug or due to dispensing error. DS is characterised by significant drug-induced brain depression during which the patient can be aroused only by repeated or painful stimuli and where the maintenance of respiratory function may be compromised. For this reason, MDS and DS require the presence of a trained person who is at least competent to provide paediatric advanced life support (ALS), airway management and cardiopulmonary resuscitation (CPR). During PSA, both spontaneous breathing and protection of the airway can be lost, particularly amongst infants and smaller children (< 1 yr), necessitating manual or mechanical support of the airway and ventilation [11]. The rate of other respiratory complications during PSA does not seem to depend on whether an anaesthesiologist performs the sedation or not, but rather on factors such as higher ASA classifications of the patients as well as the use of multiple sedation modalities [12].

PRE-PROCEDURAL MANAGEMENT

Routine paediatric assessment before PSA should predict and seek to eliminate more obvious risks, namely: smaller child (under 12 months), and the presence of co-existing morbidity (congenital or acquired). A higher ratio seems to be correlated with greater ASA grade assessment (ASA ≥ III), although 33% of children with reported cardiac arrest were previously categorised as ASA I or II [13]. The most important strategies could be directed to the assessment of potential ventilatory problems during PSA, typical for childhood, and initiated when pre-procedural assessment is done. This management should identify potential airway problems (congenital defects: Pierre-Robin syndrome etc., systemic diseases: Down's syndrome etc.) especially where complications worsen in the supine position for both infants and children [12]. Secondly, recognition of potential difficulties arising from supported ventilation is important for those patients with uncorrected heart or lung diseases (left-to-right shunts, bronchopulmonary dysplasia etc.). Thirdly, the Mallampati classification, commonly used in adult anaesthetic practice, can also be usefully applied in paediatric patients and per-

formed as a modified technique when the sitting position is replaced by a position that is more comfortable for children, such as the supine position with the neck slightly extended [14]. The examiner can use a tongue depressor in younger and non-co-operative children. Finally, assessment of the risk factors such as laryngeal spasm is extremely important in young babies (under three months of age) and children and would include recent upper respiratory tract infections, asthma, those exposed to tobacco inhalation and those with coexisting gastro-oesophageal reflux [11, 15]. Even though laryngospasm is infrequent (0.4%), it can be a life-threatening complication and recommendations specific to paediatric practice indicate an interval between severe upper respiratory tract infection and any medical procedure of at least 15 days, particularly when cough, fever, purulent sputum and elevated C-reactive protein or X-ray pulmonary abnormalities are confirmed [16]. During oesophageal endoscopic procedures, multiple suctioning secretions can also lead to stimulation of the throat, thereby enhancing laryngospasm. Barbi et al.[17] reported that almost 5% of children undergoing sedation/analgesia were in urgent need of anaesthesiologist intervention: 50% of them for facilitating the insertion of the endoscope and 41% for the treatment of laryngospasm. In more complicated cases, it is the anaesthesiologist who is the most appropriate person to manage serious laryngeal spasm.

The necessity for laboratory assessment prior to gastrointestinal endoscopic procedures in children depends on the precise individual circumstances. The need for such tests would depend on the invasiveness of endoscopy on the one hand and the child's health status on the other. Relatively healthy children (ASA I or II) can be sedated without any laboratory investigations. With children categorised as ASA ≥ III, or when the endoscopist anticipates any bleeding or complication, it would be necessary to check a minimum of blood type, blood count, electrolytes and coagulation parameters. In children with severe chronic diseases, it would be advisable that during pre-procedural assessment an up-to-date opinion of the appropriate specialty is sought [18]. Uncompensated abnormalities revealed by such re-assessment and/or laboratory tests would be contraindications to elective endoscopy under PSA in children.

IMMUNISATIONS

Recommendations for sedation/anaesthesia strategy in relation to routine vaccination in childhood are not yet settled. In 2009, the Expert Panel of the Infectious Diseases Society of America (IDSA) published updated guidelines for immunisation programmes but did not provide any guidelines with respect to when sedation/anaesthesia and an invasive procedure could be safely performed [19]. It may be possible to suggest different time intervals between PSA and vaccinations, according to the probability of adverse events following immunisation (AEFI), depending on the type of vaccine given. Procedures for children just inoculated should be postponed for 2–3 days for non-live vaccines and 2–3 weeks for live, attenuated vaccines, to avoid misinterpretation between AEFI and post-procedural complications [20]. The presence of or contact with patients with contagious diseases should be dealt with by postponement of the procedure for 2–3 weeks. Children recovering from post-viral infection without any symptomatic signs are probably fit for this procedure.

FASTING RECOMMENDATIONS

A period of fasting before PSA and endoscopy would be important both for the quality of the endoscopic procedure and for the patient's safety during sedation. The risk of aspiration increases dramatically when conscious sedation becomes deeper in an unplanned manner, and is exacerbated by gastro-oesophageal reflux, ileus or obstructive intestinal disease. It is widely acknowledged that safety improves when a patient fasts before an endoscopic procedure under sedation; however fasting for too long is not beneficial [21]. Summarising the recommendations of the European Society of Anaesthesiology (ESA), The American Academy of Paediatrics (AAP) and the American Society of Anesthesiologists (ASA), children should be encouraged to drink clear fluids up to two hours before the procedure. Infants can be given breast milk up to four hours before and other types of milk up to six hours before a procedure. Solid food should be prohibited for six hours for every infant or child [22].

PREMEDICATION

The primary goal of PSA is patient comfort. For younger (< 5 yrs) and non-co-operative children, endoscopic procedures may be difficult to understand and accept, especially when they must be repeated frequently. In this group of patients, effective premedication could promote anxiolysis and co-operation, and importantly in gastroenterological practice, a decrease in autonomic reflexes. Some recommend that the oral administration of midazolam is suggested, 30 minutes before, in age-dependent doses: higher for children between 1–6 years — 0.25–0.30 mg kg^{-1}, lower for older children — 0.25–0.50 mg kg^{-1}. Infants (if they need one) require a dose of 0.5 mg kg^{-1}. Oral administration may compromise gastroscopy due to the prolonged presence of drug residues in the stomach, and then the rectal route could be considered among some infants and small children. Alternative routes and drugs may be used instead. The use of alpha-2 agonists, dexmedetomidine and clonidine, has become more widespread. The clinical effect of these drugs is anxiolysis accompanied by pain reduction, and yet the

patient is easily aroused, which is a unique feature. Most importantly, these drugs are relatively free of respiratory and circulatory depression side effects. The effects on the digestive system include decreased salivation and secretion, and decreased bowel motility, but these effects have been observed during prolonged sedation in the ICU rather than after a single dose [23]. The oral dosing for dexmedetomidine and clonidine is 2.5 mcg kg^{-1} and 4.5–5.0 mcg kg^{-1}, respectively [24]. These drugs can be effectively given to children nasally, in the dose of 1 mcg kg^{-1} [25]. This route is quick, painless and relatively non-invasive, and acceptable to children. Limitations on the use of this method may arise due to inaccessibility to pharmaceutical preparation or staff preference [26].

PSA

Midazolam has been used for many years for PSA in infants and children, and it is safe in the hands of non-anaesthesiologists [27, 28]. Midazolam is a short acting imidazobenzodiazepine allowing it to readily cross the blood-brain barrier and quickly achieve the desired clinical effect. In children, the $T_{1/2}$ is rather short (2.5–4 hours), especially since its metabolite, hydroxymidazolam, has minimal clinical activity. The clinical activity in obese patients may be prolonged up to eight hours. According to published data, i.v. administration is often preferred for gastrointestinal endoscopies [29, 30]. It should be emphasized that children exhibit PK/PD differences and the best level of sedation is found by careful intravenous drug titration, to avoid uncontrolled over-sedation [29].

Diazepam is a poor drug in this context because of its $T_{1/2}$ (0.8–2.25 days), and this is even longer in neonates, infants and obese patients (up to 3.2–3.9 days). Additionally, its metabolites are active, disqualifying this drug from day-case procedural practice in paediatrics. Lorazepam is also less useful during PSA in view of its slow onset of action (15–20 min) and long duration (6–8 hours).

Publications from the last two decades have increasingly presented data concerning the use of hypnotic, anaesthetic induction agents, such as propofol, ketamine or etomidate by non-anaesthesiologists for sedation during endoscopy [31]. Guidelines published in the European Journal of Anaesthesiology in December 2010 gave rise to significant discussion about propofol sedation by non-anaesthesiologists, among both proponents and opponents of this idea [32]. The proposed recommendations gave rise to controversy, even among adult anaesthesiologists [33]. These discussions suggested differing ranges of competence and expertise and generated debate between paediatric anaesthesiologists and paediatric endoscopists experienced in such procedures [34, 35].

Propofol has gained the most attention as an ideal intravenous sedative-hypnotic agent due to its favourable PK/PD, and it is extremely useful in day-case anaesthetic practice. Propofol is a short-acting hypnotic characterised by both rapid onset of action and short recovery time. Effective sedation can usually be achieved by a single dose, for older children (0.5–1.5 mg kg^{-1}) and for children younger than 8 years (1.5–3.0 mg kg^{-1}), as well as with continuous infusion with a fast recovery time (but this is affected by context-sensitive half times if the infusion is prolonged). The disadvantage of propofol is its narrow therapeutic range and this principle is reflected in the US Food and Drug Administration (FDA) decision to deny the petition of the American College of Gastroenterology to change the registration for this drug. The practice of non-anaesthesiologist administration is uncommon in children's hospitals and in contrast to the literature involving adult patients, but the paediatric literature on non-anaesthesiologist-delivered propofol sedation for GE is limited [36, 37]. Many authors agree that propofol administration does, in fact, qualify as deep sedation and anaesthesia care, and requires adherence to the rules applicable to anaesthesia and necessitating a higher level of competence in rescue techniques [38–40]. Published reports have evaluated the incidence of complications during paediatric propofol sedation as follows: desaturation 9.3%, apnoea 1.9%, assisted ventilation 1.4%, hypotension 15.4%, unplanned intubation 0.02%, post-procedure emesis 0.14%, laryngospasm 0.1%, and bradycardia 0.1% [41–43]. Critical incident analysis of adverse events seen during propofol sedation demonstrates that 80% of events present initially as respiratory compromise and negative outcomes occur because of drug administration practices, a lack of clinical knowledge, poor monitoring standards and as a result of failure to rescue the patient, not simply because of the type of the drug itself [44]. In a randomised trial, desaturation incidents were even higher (10.7–18%), especially when fentanyl was used as an adjunct medication [45]. The authors emphasise the role of capnography to detect respiratory depression before it is observed clinically and to reduce desaturation, apnoea and assisted ventilation [46]. A further complication is hypotension with a frequency rate of 15.4% and a range of 6.7% to 35.5%, potentiated by bradycardia. Many authors have described incidents of unplanned intubations (0.02%) after propofol administration, mostly by non-anaesthesiologists and when performed on babies and younger children with significant comorbidities and previous limited physiological reserves [43, 47].

While the propofol debate continues between anaesthesiologists and non-anaesthesiologists, a new drug, dexmedetomidine, could become a new alternative agent capable of providing procedural sedation [48]. Dexmedetomidine

may offer advantages in sedation for a population that may include patients with difficult airways due to the lower incidence of respiratory depression. Its safety is improved by high protein binding that is independent of the displacement by other drugs, e.g. fentanyl, as well as metabolism by cytochrome P450, independent of other drug interaction. Additionally, the effects of dexmedetomidine can be antagonised by the antagonist atipamezole. Other antagonists are already available for both benzodiazepines and opioid analgesics, but not to intravenous hypnotic agents. Nevertheless, dexmedetomidine should be carefully used in patients with pre-existent bradycardia, hypovolaemia, and hypotension because of the possibility of arrhythmias. Dexmedetomidine is registered for minimal (MS) or moderate sedation (MDS) and could be used singly or in addition to another drug, perhaps in older children undergoing less painful endoscopic procedures or when 'standard' drugs may be problematic: e.g. children with underlying neurological disorders (who often develop agitation or adverse haemodynamic and respiratory effects with opioids or benzodiazepines); with allergy, end-stage kidney and/or liver failure. With regard to the use of dexmedetomidine for GE in children, Tobias demonstrated that dexmedetomidine was not effective as the sole agent for sedation of an 11-year-old boy for gastroduodenoscopy [49]. Hammer reported that there is no concomitant influence of dexmedetomidine on adequate propofol anaesthesia during GE in young children [50]. In turn, Raman found that a continuous infusion of dexmedetomidine following a bolus of ketamine achieved effective sedation during GDE in an 8-year-old boy with Duchenne muscular dystrophy [51]. Based on reports, the recommended adult dosage range of 0.2 to 0.7 mcg kg^{-1} may also be used in children, with a loading dose of 1 mcg kg^{-1} given over 10 minutes, but in many paediatric centres reduced doses are preferred with a bolus of 0.5 mcg kg^{-1}, or even omitting the loading dose to avoid cardiovascular instability. Dexmedetomidine, being a less potent sedative drug, often requires the addition of other hypnotics or anaesthetic agents in achieving satisfactory sedative effects, while reducing the doses of the concomitant agents. The findings mentioned above suggest safety among children though dexmedetomidine has not still been registered for this patient population. Further prospective controlled trials are needed to define the efficacy of dexmedetomidine for GE under PSA in paediatrics.

Sevoflurane, halogenated ether, as a volatile anaesthetic agent, remains popular both for induction and maintenance of anaesthesia and sedation in children. It has low blood/gas and oil/gas solubility. This produces a more rapid response to changes in inhaled concentration, and quick induction and recovery during anaesthesia, but without analgesia. Sevoflurane decreases arterial pressure by reducing systemic vascular resistance with little effect on cardiac output until higher doses are used, and it lowers the heart rate and therefore can reduce myocardial oxygen consumption. This agent reduces also tidal volume, respiratory rate and smooth muscle tone of the bronchi, but it is not an irritant to the upper respiratory tract. Most of this gas is eliminated via the lungs, with 5% of the absorbed dose being metabolised by the liver. The use of sevoflurane in paediatric patients, which would enable rapid recovery, is complicated by the frequent occurrence of emergence agitation, particularly with high concentration over 6 vol% with spontaneous breathing and over 5 vol% when ventilated mechanically [52]. Sevoflurane remains the only drug of choice for inhalation anaesthesia in children.

Inadequate ventilation and airway obstruction and difficult intubation are everyday hazards in paediatric anaesthesia practice. The vast majority of respiratory complications during PSA can be managed with simple supporting techniques such as supplemental oxygen, opening the airway and bag-mask-ventilation. The most important factor in airway positioning among infants and small children is to place the head in a midline sniffing position, while the neck is extended and the chin is lifted. This manoeuvre very often needs a towel roll placed under the shoulders of the child because of the larger size of the younger child's head. In some children, proper positioning is sufficient to ensure proper ventilation, which can be only supported by adequate oxygen therapy. In other children, attached mask ventilation can be used to provide assisted ventilation, and then the proper size of the mask is the factor that determines its success. Bag-valve-mask ventilation is a fundamental skill of paediatric airway management, and any person responsible for providing PSA should receive a high priority in training. Occasionally endotracheal intubation can be required for prolonged procedures, and when the inhaled technique of PSA is planned. In addition to standard endotracheal intubation, many new devices and techniques are available in paediatric practice such as laryngeal airway mask (LMA), and cuffed oropharyngeal airway tube. There is no single device that is the best, and the choice depends on the patients' or doctors' opportunities and preferences.

CONCLUSIONS

PSA plays an important role in paediatric practice. There are still differing opinions about clinical roles in this area, not helped by confounding variables that influence the likelihood of adverse events such an adjunct opiates, propofol dosing strategies and supplemental oxygen. For these reasons, the exact delineation between what could or should be done by paediatric anaesthesiologists or paediatric specialties is still not agreed. The main issue is the proper definition of PSA and the development of a good classifi-

cation scheme for patients who could be provided for by a non-anaesthesiologist versus those who should not, as well as to understand and refine the elements of sedation systems that lead to best practice. The available data, such as it is, would suggest that there is a set of situations where the presence of an anaesthesiologist would be advisable: not simply where the need for anaesthesia could be anticipated due to a combination of patient and/or parent preferences. Characteristics of either the patient or the procedure should indicate where the tipping points exist. Procedural factors: anticipated discomfort or pain and where the procedure is prolonged, i.e. more than 10–20 minutes. Patient factors: These would include a list of situations leading to higher anticipated difficulty and/or risk: infants, airway compromise, cardio-respiratory conditions, pre-existing aversion/anxiety, hepatic and/or renal insufficiencies. The three main elements: patient/parent preferences, procedural characteristics and the patient's characteristics need to be drawn together to formulate a plan for the best interest of the individual child and where these interests override those of the service. Other factors may come into play such as prevailing national regulatory institutions that may supersede the development of local teams of paediatric gastroenterologists and anaesthesiologists should engage in active dialogue to devise workable protocols suitable to their local and national context.

The next issue concerns the drugs used for procedural sedation. Sedatives such a midazolam have a wide margin of safety, but are typically weak and do not always guarantee success. Anaesthetic drugs, in contrast, generally have more favourable pharmacokinetics, guaranteed potency and a short duration of action, and are more likely to lead to a successful procedure. However, they have a smaller therapeutic window and so, in untrained hands, may lead to significant complications. Techniques using subanaesthetic doses of anaesthetic drugs (e.g. propofol) have been called deep sedation and are safe when used in the context of a programme with oversight such as that described above from anaesthesiology, critical care physicians and specifically trained nurses [53]*. This statement has been also affirmed by the American Society of Anaesthesiologists (ASA) and changes to the guidelines from 2010 reiterated that in order to provide deep sedation safely, certain provisos should exist: there needs to be focused education and training with assessment of competencies that might lead to some form of licencing [53–55]. In a study comparing propofol administration by anaesthesiologists to that by paediatricians, conclusions regarding this question are precluded since the anaesthesiologists generally performed anaesthesia while the endoscopists performed sedation [56]. In paediatric practice, establishing consensual collaborative relationships between anaesthesiologists and non-anaesthesiologists and the establishment of accepted guidelines and training requirements, as well as tailoring to each individual patient, is the only one way to meet common goals — safe PSA for successful gastrointestinal endoscopy practice.

*In Poland as well as in many European countries propofol may be given only by medical doctors, nurses are not allowed to administer propofol and any other anaesthetics.

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