

## Editorial

# Round and round we go: sedation – what is it, who does it, and have we made things safer for children?

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In this issue of Pediatric Anesthesia several papers and commentaries authored by anesthesiologists and nonanesthesiologists describe different perspectives regarding sedation/analgesia for children in the UK and the USA. I will provide historical perspectives from the USA and then examine these reports to see how they compare with current USA practice.

I had the good fortune of being the co-author of the first Sedation Guideline (pediatric or adult) supported by any organization. This initial attempt at providing guidance for a systematic and safe approach to procedural sedation was a result of a number of sedation accidents in children undergoing dental procedures. We worked closely with our pediatric dental colleagues and developed joint guidelines (1,2). Unfortunately we adopted terminology that had been approved by the National Institutes of Health, i.e., the phrase ‘conscious sedation’ (3). This resulted in much confusion particularly since the intended ‘appropriate (purposeful) response to physical stimulus or verbal command’ was often miss-interpreted to mean any movement at all in response to any stimulus including painful stimuli! As time passed the American Academy of Pediatrics (AAP) recognized that sedation was provided by many specialists besides dental practitioners so the original guideline was revised in 1992 (4). A special emphasis was placed on a ‘systems’ approach modeled after our specialty (anesthesiology). Points of interest included: (i) informed consent (parents needed to know that sedative/analgesics can cause harm); (ii) a pre-sedation history was required (how would the child’s underlying medical conditions affect the safety of sedation?); (iii) a focused airway examination (was

there an airway abnormality or large tonsils that might affect airway patency or complicate airway management?); (iv) proper fasting prior to elective procedures and the need to balance the risk of sedation in children who required urgent or emergent procedures was described; (v) appropriate monitoring especially continuous pulse oximetry during the procedure and into the recovery period was required for the first time; (vi) appropriate monitoring by an independent observer whose only responsibility was to ‘watch the patient’ was required during deep sedation; (vii) appropriate staffing and monitoring were required during recovery; and (viii) the children had to be returned to their pre-sedation level of consciousness prior to discharge.

With this 1992 revision, the dental community separated from the AAP and published their own specialty specific guideline which deviated significantly from that of the AAP (5–7). In 2002, the AAP published an addendum so that the AAP, the American Society of Anesthesiologists (ASA) and the Joint Commission of Accreditation of Healthcare Organizations all used the same terminology. The phrase ‘conscious sedation’ was changed to ‘sedation/analgesia’ and then changed again to ‘moderate sedation’ (8,9). Children sedated in all venues including private offices were considered to fall under these guidelines. In particular, the updated guideline states that children aged <6 years usually require a state of ‘pharmacologic coma,’ i.e., ‘deep sedation’ to successfully complete most procedures without major psychologic trauma to both provider or child. A clear emphasis was made that sedative medications were only to be administered under the safety net of medical supervision (no home

prescriptions), that age and size appropriate equipment must be available, and that sedation should only be administered by 'individuals skilled in airway management and cardiopulmonary resuscitation.' The concept of patient rescue was introduced.

At the request of the executive committee of the AAP, a task force was formed with the American Academy of Pediatric Dentistry (AAPD) so that the two organizations could once again come together as we were in 1985 and a joint AAP–AAPD Sedation Guideline was developed and published in 2006 (10). This most recent iteration re-stated the basic principles defined in the previous documents but went into more detail in several areas: (i) a statement that 'sedation of pediatric patients has serious associated risks, such as hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment' was inserted and that 'reflex withdrawal' alone to a painful stimulus is not considered to be 'moderate sedation' but such a response is rather consistent with 'deep sedation'; (ii) it was acknowledged that the data regarding dietary precautions in emergency situations are inadequate and that further research is required; (iii) potential interactions between herbal medications and sedative/analgesics were described and providers were encouraged to address this in their presedation interview; (iv) an acronym (SOAPME) was introduced to underscore proper preparation (**S**uction, **O**xygen source, proper functioning **A**irway equipment, appropriate **P**harmaceuticals, **M**onitors, and special **E**quipment); (v) tables for calculation of local anesthetics were added; (vi) the use of capnography was encouraged for the first time in nonoperating room venues; (vii) quality assurance techniques are emphasized; (viii) the desirability of patient simulation was encouraged; and (ix) a clarification regarding nitrous oxide and its interaction with other sedating medications was added.

With each version of the guideline, we intentionally avoided discussion of specific sedative/analgesic medications and doses because we wanted to present general concepts of safe practice and not provide cook-book sedation recipes. In addition, we did not want to dictate to subspecialists how to sedate their particular patient population.

With this background we can now examine differences and similarities between sedation in the

USA and sedation in the UK. The Scottish Intercollegiate Guidelines Network (SIGN) (11) has taken a slightly different approach than the AAP–AAPD document (10). The governing principles of safe sedation and the definitions of the levels of sedation in SIGN are identical to those of the AAP–AAPD document. However in SIGN, the 'grades of recommendation' are evidence based and much more detail is provided regarding sedation administered by nurses, sedation for painful vs nonpainful procedures, and specific issues regarding many subspecialties. Thus, the end result and the take home message is the same: proper preparation, proper evaluation, appropriate skills to rescue the patient, and proper recovery lead to safe and successful sedation of children.

Now let me examine and comment upon the papers in this issue of Pediatric Anesthesia. The first paper by Isabelle Holroyd is a review of UK guidelines for inhalation sedation with nitrous oxide in dentistry. I would start off by stating that the phrase 'conscious sedation' is an oxymoron for children and that this contradictory phrase must be expunged from our language (12). However, the concept of interaction with the patient is an important concept and consistent with 'minimal or moderate sedation' as defined by the AAP–AAPD document. A very nice description is given of how nitrous oxide analgesia is delivered in the dental suite (the mask just covers the nose so entrainment of room air is possible), the need for appropriate scavenging, and she appropriately emphasizes that the nitrous oxide is administered without other sedating/analgesic medications. She does not describe any monitoring requirements. The difference I see in this document and that of the AAP–AAPD, is that in the AAP–AAPD guideline when nitrous oxide is limited to 50% or less this is considered to be 'minimal sedation' but when higher concentrations are used or when combined with other medications, then the guidelines for moderate or deep sedation including appropriate monitoring must be applied (13–16).

In the next paper, Sury and Smith (17) describe their experience with sedation from the viewpoint of anesthesiologists in a busy specialist children's hospital. The authors appropriately point out the difficulty of sedating a child for a nonpainful procedure and the dilemma of testing their arous-

ability to assess depth of sedation. I agree that this completely defeats the purpose of the sedation (like a nurse waking up a patient to give to have him/her take a sleeping pill) and this certainly is not recommended by the AAP–AAPD guideline. It is for that reason that even q5-minute vital signs are not required for ‘moderate sedation’ since in these lightly sedated children, even taking their blood pressure might arouse them; therefore ‘intermittent’ vital signs are recommended without specifying the interval. However, they still must be monitored with continuous pulse oximetry. Sury and Smith describe weight-specific techniques (triclofos or triclofos and alimemazine) that have been successfully used for sedation and appropriately describe it as ‘deep sedation’; the nuance here is that the person providing the sedation and monitoring must have the skills to rescue the patient. Despite the wide experience and the safe use of these techniques one must never lose sight of the fact that any child can have sensitivity to the drug or that a dispensing error may occur, and that some children may become very deeply sedated even to a state of general anesthesia. This has been clearly demonstrated by Malviya *et al.* and others (18–21). Therefore, even though these techniques can be safely used by nonanesthesiologists, proper monitoring, recovery, and emergency backup must be in place. What concerns me more is the new phrase ‘minimal anesthesia’ introduced in this paper; I am not certain that this is different from being ‘a little pregnant.’ Propofol is a wonderful and very versatile intravenous anesthetic but let us not lose sight of the fact that it is an anesthetic. This is not a tool to be placed in the hands of the untrained nor is its use in the hands of the untrained to be encouraged. The pediatric literature cited by Sury and Smith (22,23) are insufficiently powered to say anything about safety and a reduction of desaturation events from 16% to 3% when oxygen was administered is simply covering up hypoventilation. It should be noted that one study was carried out by pediatric anesthesiologists and the other had an anesthesiologist ‘available on the ward’ for emergencies. I know of few places that have the luxury of having an anesthesiologist waiting in the background to rescue children from elective sedation provided by nonanesthesiologists. It should also be noted that those authors double published their series (22,24) and that one patient had ‘prolonged

laryngospasm >5 min’ but that the ‘symptoms had almost completely resolved by the time the emergency team arrived.’ This long delay in arrival of the rescue team is not my concept of rescue or safe sedation! Sury and Smith then cite two large adult studies to support their position that propofol could be used by pediatric gastroenterologists. Children are not adults; the endoscope more readily causes airway obstruction because it takes up a far greater part of the hypopharynx in a child than an adult. The child’s oxygen consumption is greater and therefore the time to desaturation is shorter. The problem I see with this type of reasoning is that we have become so good with what we do that we think of hypoventilation, apnea, and even laryngospasm as minor events. This type of reasoning is misleading at best. It takes years of training to become comfortable with managing these complications. Now the authors seem to be advocating that individuals with a residency in gastroenterology become anesthesiologists! It has been clearly demonstrated from the dental experience that one cannot safely sedate a child and perform a procedure at the same time; let us not relearn that lesson the hard way by training nonanesthetists to provide general anesthesia even ‘a little minimal anesthesia’ because what is minimal to us may be maximal for the patient. I was particularly appalled by the fact that Sury and Smith allow their children scheduled for MRIs to have ‘food to be taken 3–4 h before MRI sedation’ when in the previous sentence the authors state that children scheduled for sedation should be ‘fasted according to standard guidelines.’ This alteration in ‘standard practice’ seems like an invitation to disaster and flies in the face of all sedation guidelines. How can we expect nonanesthesiologists to ‘follow the rules’ if we ourselves violate them? The authors finish their review with a call to train sedationists. I could not agree more that if we are going to give this part of our practice away we must do it on our terms so that these individuals are part of the anesthesia department, under our supervision, and responsible to us. If we own it then we can watch it and make certain that bad or sloppy practice does not creep in but if we give it away it is an invitation to disaster.

The next paper in this issue describes the use of ketamine in the emergency room. Ketamine is a very interesting drug because for years anesthesiologists have spent much energy trying to limit its use to the

operating room claiming it was a 'general anesthetic' drug and therefore it 'should only be used by anesthesiologists.' Although I agree in part with this concept as described above under propofol I have a different perspective regarding ketamine. Ketamine has such a wide margin of safety that it is used worldwide by many individuals in battlefield conditions or less medically advantaged countries by individuals with minimal medical training (25). Even when administered in very large doses, respirations are generally preserved (26,27). Ketamine is one of those wonderful medications that when administered in very low doses ( $0.25\text{--}0.5\text{ mg}\cdot\text{kg}^{-1}$ ) will provide sufficient analgesia to accomplish a minor procedure with the simultaneous use of local anesthetic but when given in higher doses induces anesthesia ( $1\text{--}2\text{ mg}\cdot\text{kg}^{-1}$  i.v.) and in still higher doses produces a state of general anesthesia. The child's response is related to dose, titration to effect and skill of the practitioner. It is for these reasons that this drug has gained so much popularity in the emergency department. However, as Dr Morton describes there is a low but nevertheless consistent level of potentially life-threatening complications, such as apnea, laryngospasm, or airway obstruction (28–30). I am delighted to see that the UK emergency medicine physicians would consult with anesthesiologists for ASA III or higher patients requiring sedation/analgesia. I would caution against the conclusion that there has been no association between fasting time and adverse events simply because the literature is inadequately powered to make this statement. The paper describing a 'consensus of experts' who 'considered the maximum period of fasting considered necessary is 3 h' is misleading as these experts are all emergency medicine practitioners (31). I could make a similar statement regarding general anesthesia and a full stomach as I have been fortunate enough as of this writing to not have a clinically important aspiration associated with general anesthesia but I would be simply describing my experience and not the broad experience of the specialty; I know of few people who publish their complications. I suspect that the reason in which the incidence of aspiration is low is because emergency physicians are not manipulating the airway which by itself induces vomiting. The absence of published data is not an affirmation that there is no concern, rather an indication for adequately powered data

collection. The discussion of adjunctive medications is again reflective of underpowered studies. As it is well known that ketamine causes hypersalivation and that secretions on the vocal cords cause laryngospasm, why not advocate the routine use of an anticholinergic? Likewise why not advocate for lower doses of ketamine supplemented with local anesthetic rather than higher doses without local anesthetic? I am delighted that Dr Morton has so clearly defined the complications associated with and the skills required to safely administer ketamine in the emergency department. In particular, I was intrigued with his advocating the use of capnography. The one other area of concern was the brief period of observation time to discharge (25 min) (32). Discharge criteria are not based on the clock but rather on patient responses despite the fact that 'there is no conclusive evidence base for essential discharge criteria following sedation with ketamine.' Again this reflects the under power of the literature and the absence of data.

One final concern is the phrase 'dissociative sedation.' Ketamine sedation is no different from any other form of sedation in terms of depth of sedation. Small doses produce 'minimal sedation' higher doses produce 'moderate sedation' and still higher doses produce 'deep sedation/general anesthesia.' Let us not create yet another category of sedation to further muddy the waters. Do we really need minimal sedation, moderate sedation, deep sedation, conscious sedation, sedation analgesia, dissociative sedation, and minimal anesthesia that all describe the same continuum?

Lastly, with respect to the final article on training and credentialing, I will conclude by stating that I disagree with Krauss and Green's statement (33) that 'procedural sedation and analgesia in 2008 is well studied,' we really are quite early in collecting adequately powered series to clarify the safety of various sedation regimens and at the hands of a variety of specialists. Anesthesiologists have been reluctant to allow nonanesthesiologists to use medications that rapidly cause loss of consciousness and cause apnea with good reason but I agree as I stated above that anesthesiologists should take the lead in training and supervising our nonanesthesia colleagues. I suspect that part of the contention between anesthesiologists and nonanesthesiologists described by Krauss is a result of these nonanesthe-

sia trained individuals billing the insurance companies for anesthesia services thus misrepresenting their training, part is the fear that if nonanesthesiologists can provide this service then the insurance companies might decide to reduce anesthesiologist's reimbursement to the level of a nonanesthesiologist, and part is because of the reality that when nonanesthesiologists get into trouble they always rely on our backup and anesthesiologists want to be proactive rather than reactive. The bottom line is that we all want what is best and safest for our children but we have a long road to travel before anesthesiologists will easily allow nonanesthesiologists to practice our specialty without all the years of training we have had.

Obviously, we need to acknowledge the rapidly increasing demand for sedation services and the shortage of pediatric anesthesiologists to fill this need. We also must acknowledge that we are not always immediately available to provide a rescue service nor do we wish to be sedation police. My personal opinion is that anesthesiologists must take the lead here in training, education, and establishing a collegial working relationship with our nonanesthesia colleagues. The common goal should be to train 'sedationists' who are able to recognize potentially difficult patients, help them to maintain airway management skills, assure their thorough understanding of the pharmacology of the medications they use to provide sedation, and encourage them to liberally consult their anesthesia colleagues. We must provide them with appropriate monitoring and adequately staffed recovery facilities with strict discharge criteria. I believe that all sedation services should be under the direct supervision of the Department of Anesthesiology so as to assure that our nonanesthesia trained colleagues can develop and retain the skills needed to safely sedate healthy children while leaving the complex cases to us. The various papers in this issue of Pediatric Anesthesia all seem to be giving a similar message, we just need to figure out how to do this as friends rather than foes. The AAP-AAPD and SIGN guidelines have had a major impact upon who provides sedation, the skills needed to perform sedation and I am certain many children's lives have been affected in a positive way by the encouragement of safe sedation policies and procedures thus making sedation/analgesia available to all children while doing it safely. Now children can sleep safely.

## References

- 1 Committee on Drugs, Section on Anesthesiology, American Academy of Pediatrics. Guidelines for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients. *Pediatrics* 1985; **76**: 317–321.
- 2 American Academy of Pediatric Dentistry. Guidelines for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients. *ASDC J Dent Child* 1986; **53**: 21–22.
- 3 Consensus conference. Anesthesia and sedation in the dental office. *JAMA* 1985; **254**: 1073–1076.
- 4 Committee on Drugs American Academy of Pediatrics. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. *Pediatrics* 1992; **89**: 1110–1115.
- 5 *Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia in Pediatric Dental Patients. Reference Manual 1999–2000*. American Academy of Pediatric Dentistry, 1998: 68–73.
- 6 Coté CJ. Why we need sedation guidelines. *J Pediatr* 2001; **138**: 447–448.
- 7 Coté CJ. Sedation protocols – why so many variations? *Pediatrics* 1994; **94**: 281–283.
- 8 Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: addendum. *Pediatrics* 2002; **110**: 836–838.
- 9 Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology* 2002; **96**: 1004–1017.
- 10 Coté CJ, Wilson S. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: an update. *Pediatrics* 2006; **118**: 2587–2602.
- 11 *Scottish Intercollegiate Guidelines Network (SIGN) – Safe Sedation of Children Undergoing Diagnostic and Therapeutic Procedures*. SIGN, Edinburgh, 2004.
- 12 Coté CJ. "Conscious sedation": time for this oxymoron to go away! *J Pediatr* 2001; **139**: 15–17.
- 13 Litman RS, Kottra JA, Berkowitz RJ *et al*. Breathing patterns and levels of consciousness in children during administration of nitrous oxide after oral midazolam premedication. *J Oral Maxillofac Surg* 1997; **55**: 1372–1377.
- 14 Litman RS, Kottra JA, Berkowitz RJ *et al*. Upper airway obstruction during midazolam/nitrous oxide sedation in children with enlarged tonsils. *Pediatr Dent* 1998; **20**: 318–320.
- 15 Litman RS, Kottra JA, Verga KA *et al*. Chloral hydrate sedation: the additive sedative and respiratory depressant effects of nitrous oxide. *Anesth Analg* 1998; **86**: 724–728.
- 16 Moore PA, Mickey EA, Hargreaves JA *et al*. Sedation in pediatric dentistry: a practical assessment procedure. *J Am Dent Assoc* 1984; **109**: 564–569.
- 17 Sury MRJ, Smith JH. Deep sedation and minimal anaesthesia. *Pediatric Anesthesia* 2007; **18**: 18–24.
- 18 Malviya S, Voepel-Lewis T, Ludomirsky A *et al*. Can we improve the assessment of discharge readiness? A comparative study of observational and objective measures of depth of sedation in children. *Anesthesiology* 2004; **100**: 218–224.
- 19 Dial S, Silver P, Bock K *et al*. Pediatric sedation for procedures titrated to a desired degree of immobility results in unpredictable depth of sedation. *Pediatr Emerg Care* 2001; **17**: 414–420.

- 20 Coté CJ, Notterman DA, Karl HW *et al.* Adverse sedation events in pediatrics: a critical incident analysis of contributory factors. *Pediatrics* 2000; **105**: 805–814.
- 21 Coté CJ, Karl HW, Notterman DA *et al.* Adverse sedation events in pediatrics: analysis of medications used for sedation. *Pediatrics* 2000; **106**: 633–644.
- 22 Barbi E, Petaros P, Badina L *et al.* Deep sedation with propofol for upper gastrointestinal endoscopy in children, administered by specially trained pediatricians: a prospective case series with emphasis on side effects. *Endoscopy* 2006; **38**: 368–375.
- 23 Perera C, Strandvik GF, Malik M *et al.* Propofol anesthesia is an effective and safe strategy for pediatric endoscopy. *Paediatr Anaesth* 2006; **16**: 220–221.
- 24 Barbi E, Gerarduzzi T, Marchetti F *et al.* Deep sedation with propofol by nonanesthesiologists: a prospective pediatric experience. *Arch Pediatr Adolesc Med* 2003; **157**: 1097–1103.
- 25 Green SM, Clem KJ, Rothrock SG. Ketamine safety profile in the developing world. *Acad Emerg Med* 1996; **3**: 598–604.
- 26 Green SM, Clark R, Hostetler MA *et al.* Inadvertent ketamine overdose in children: clinical manifestations and outcome. *Ann Emerg Med* 1999; **34**: 492–497.
- 27 Kim G, Green SM, Denmark TK *et al.* Ventilatory response during dissociative sedation in children – a pilot study. *Acad Emerg Med* 2003; **10**: 140–145.
- 28 Green SM, Kuppermann N, Rothrock SG *et al.* Predictors of adverse events with intramuscular ketamine sedation in children. *Ann Emerg Med* 2000; **35**: 35–42.
- 29 Green SM, Rothrock SG, Lynch EL *et al.* Intramuscular ketamine for pediatric sedation in the emergency department: safety profile in 1,022 cases. *Ann Emerg Med* 1998; **31**: 688–697.
- 30 Green SM, Rothrock SG, Harris T *et al.* Intravenous ketamine for pediatric sedation in the emergency department: safety profile with 156 cases. *Acad Emerg Med* 1998; **5**: 971–976.
- 31 Green SM, Roback MG, Miner JR *et al.* Fasting and emergency department procedural sedation and analgesia: a consensus-based clinical practice advisory. *Ann Emerg Med* 2007; **49**: 454–461.
- 32 Newman DH, Azer MM, Pitetti RD *et al.* When is a patient safe for discharge after procedural sedation? The timing of adverse effect events in 1367 pediatric procedural sedations. *Ann Emerg Med* 2003; **42**: 627–635.
- 33 Krauss B, Green SM. Training and credentialing in procedural sedation and analgesia in children: lessons from the United States model. *Pediatr Anesth* 2008; **18**: 30–35.

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