

Propofol for procedural sedation in children in the emergency department.

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Reviewer(s): Joseph P. Cravero, MD, Dartmouth-Hitchcock Medical Center

Abstract Synopsis: The authors wished to determine the safety and efficacy of propofol sedation for painful procedures in the emergency department (ED). To accomplish this, a consecutive case series of propofol sedations for painful procedures in the ED of a tertiary care pediatric hospital from July 2000 to July 2002 was performed. A sedation protocol was followed. Propofol was administered in a bolus of 1 mg/kg, followed by additional doses of 0.5 mg/kg. Narcotics were administered 1 minute before propofol administration. Adverse events were documented, as were the sedation duration, recovery time from sedation, and total time in the ED. Results revealed three hundred ninety-three discrete sedation events with propofol were analyzed. Procedures consisted of the following: fracture reductions (94%), reduction of joint dislocations (4%), spica cast placement (2%), and ocular examination after an ocular burn (0.3%). The median propofol dose was 2.7 mg/kg. Ninety-two percent of patients had a transient (≤ 2 minutes) decrease in systolic blood pressure without clinical signs of poor perfusion. Nineteen (5%) patients had hypoxia, 11 (3%) patients required airway repositioning or jaw-thrust maneuvers, and 3 (0.8%) patients required bag-valve-mask ventilation. No patient required endotracheal intubation. Propofol sedation is efficacious and can be used safely in the ED setting under the guidance of a protocol. Transient cardiopulmonary depression occurs, which requires vigilant monitoring by highly skilled practitioners. They conclude that propofol is well suited for short, painful procedures in the ED setting.

Propofol sedation by emergency physicians for elective pediatric outpatient procedures.

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Abstract Synopsis: The authors describe the efficacy of propofol sedation administered by pediatric emergency physicians to facilitate painful outpatient procedures. Methodology used included a protocol for patients receiving propofol sedation in an emergency department-affiliated short-stay unit, a prospective, consecutive case series was performed from January to September 2000. Patients were prescheduled, underwent a medical evaluation, and met fasting requirements. A sedation team was present throughout the procedure. All patients received supplemental oxygen. Sedation depth and vital signs were monitored while propofol was manually titrated to the desired level of sedation. Results showed that there were 291 separate sedation events in 87 patients. No patient had more than 1 sedation event per day. Median patient age was 6 years; 57% were male patients and 72% were oncology patients. Many children required more than 1 procedure per encounter. Most commonly performed procedures included lumbar puncture (43%), intrathecal chemotherapy administration (31%), bone marrow aspiration (19%), and bone biopsy (3%). Median total propofol dose was 3.5 mg/kg. Median systolic and diastolic blood pressures were lowered 22 mm Hg (range 0 to 65 mm Hg) and 21 mm Hg (range 0 to 62 mm Hg), respectively. Partial airway obstruction requiring brief jaw-thrust maneuver was

noted for 4% of patient sedations, whereas transient apnea requiring bag-valve-mask ventilation occurred in 1% of patient sedations. All procedures were successfully completed. Median procedure duration was 13 minutes, median sedation duration was 22 minutes, and median total time in the short stay unit was 40 minutes. The authors conclude that propofol sedation administered by emergency physicians safely facilitated short painful procedures in children under conditions studied, with rapid recovery.

Commentary:

These studies are important to review for many reasons. First, in fairness, it should be recognized that they come from the same institution with many of the same authors on both papers. This is a critical point since (as the authors point out) their conclusions about safety are directed at the context and conditions under which the studies were performed. In this case, it is a major children's hospital and teaching institution. Clearly the rescue and back-up systems that are present 24 hours a day are different in this situation than they might be in a community hospital emergency department. As always we need to note that even at several hundred patients, the numbers are very small to make sweeping generalizations about the safety of this practice.

The studies are very important in that there are very few studies that systematically review the use of propofol in the emergency department involving children. As the use of propofol is rapidly becoming very wide-spread in emergency departments across the country, reports such as these are sorely needed in order to better understand the nature of propofol use and categorize the benefits and risks. It will be reassuring when we have reports of its use in tens of thousands of patients having a wider variety of procedures and in varying venues.

In describing their experience with protocol driven propofol delivery, the authors should be complemented for including their careful patient selection process. Even in the non-elective cases, patients were all ASA I or II and had been fasted for at least 3 hours. None had significant airway abnormalities. When considering the outcomes from these studies this screening process should be taken into account.

While not readily apparent from the abstracts, both of these studies (not just Bassett) involved the use of adjunctive opiates for any procedure that was deemed "painful". This is a critical point since movement during painful procedures such as lumbar punctures can be unacceptable if not accompanied by adjunctive opiates - unless the dose of propofol is extremely large. The opiate administered in the Guenther study was fentanyl (1-2mcg/kg) one minute prior to the administration of propofol while in the Bassett study it was morphine for pain in the emergency department (dose determined by the emergency medicine physician) with 1-2mcg/kg of fentanyl given prior to the administration of propofol. Interestingly the investigators did not give opiates to children who were on chronic opiate therapy when it might be argued that those patients would need the adjunctive opiates more than any other population.

One real drawback of these two studies is the lack of any type of objective pain or sedation scale used during the procedures. The authors state that "non-purposeful movement that did not interfere with the procedure and verbalizations including moaning or minimal crying were tolerated without additional medication administration". This type of methodology leaves the reader uncertain of the exact effectiveness of the sedation that was provided. With a strong helper, what type of movement exactly interferes with the procedure?

It is always hard to know how to consider the complications mentioned in studies such as these. Mild hypoxemia that is readily reversed by manipulation of the jaw or chin may not

represent a major problem at all. On the other hand, the 1% incidence of apnea requiring bag-mask ventilation remains a strong reminder that only those absolutely comfortable with the management of pediatric airways should undertake this practice. The incidence of less common (but not unheard of) advanced airway interventions such as endotracheal intubation cannot be determined because of the size of the cohorts involved. Finally, we are always interested in the inclusion of hypotensive data in studies of propofol sedation. In the setting of brief sedation with a bolus of propofol in an otherwise well child, what decrease in blood pressure is unexpected and in need of intervention (or mention)? We would argue that a mild decrease in blood pressure is indeed normal after a bolus of propofol and while it should be tracked, probably only very significant decreases should be reported as findings that need to be noted.

These papers were accompanied by a review article entitled *Propofol in the Emergency Medicine: Pushing the Sedation Frontier*. Authors are Seven Green MD and Baruch Krauss MD. *Annals of Emergency Medicine* 2003 Vol 42 (6) 792-7. This is an extensive article that reviews the previous reported literature on propofol, the key points of the two papers mentioned above, and the various questions that have been raised about propofol use in the emergency department. We will not attempt to summarize all of this article except to say that the authors conclude that based on the information provided by the two articles mentioned above (together with sparse reported literature before this) propofol is an accepted standard of care in the emergency department. They argue that some anesthesiologists will maintain that studies the size of those existing for general anesthesia, literally hundreds of thousands of cases are necessary to validate the profile of newer procedural sedation and analgesia agents. Most established therapies are based on hundreds rather than thousands of patients, and ED practice patterns and standard of care must of necessity be based on smaller samples.”

Additional Commentary:

Well...where do we begin? We would like to note that it is not just anesthesiologists that require large numbers of patients to establish the safe use of new protocols or therapeutic regimens. However, perhaps their insistence on good evidence to guide practice is the reason anesthesiologists have the best record for safety and quality improvement in the field of medicine – as noted in the last two Institute of Medicine reports on the subject. Anesthesiologists are also the only practitioners that have a six sigma rating for quality and safety standards. It would be foolish to apologize for, or retreat from these standards. In addition, not that the above quote was referring to this newsletter, we would like to be clear that the comments we make are *not* in reference to “standard of care” but rather to conclusions like “regimen X is safe and effective”. Safety has to be considered in context. In this case we stand by the statement that three hundred encounters at one institution cannot begin to prove safety in a field where critical incidents should only occur on the order of one in tens of thousands.

We would also like to point out that Dr. Green and Dr. Krauss may be correct that some standards are based on “hundreds” of case experiences, and that makes sense concerning care of relatively rare entities or infrequent therapeutic strategies. Our contact with emergency medicine physicians and data from the Pediatric Sedation Research Consortium would indicate that, in fact, thousands of children are receiving propofol in emergency departments across the country every day. We would encourage more reports on its usage. We believe the gold standard, “anesthesia level” evidence of safety really would not be that hard to come by.