PRACTICAL SUMMARIES IN

ACUTE CARE

A Focused Topical Review of the Literature for the Acute Care Practitioner

Ketamine Sedation in Children and Adults

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Introduction

Procedural sedation is an essential skill for the practice of emergency medicine. Many different agents are available to be used in a wide variety of clinical situations. The acute care practitioner must be aware of the risks, benefits, and adjunctive medications required/ desired for a given clinical scenario.

Ketamine is an agent that has emerged and become widely accepted as a safe and effective agent for procedural sedation, but several questions still remain. Is the use of a benzodiazepine necessary with ketamine? Is midazolam effective for preventing the emergence phenomenon reported with the use of ketamine? Which antisialagogue should be used with ketamine?

The author explores the key issues associated with the use of ketamine in the acute care setting for procedural sedation.

Myth: Benzodiazepine use with ketamine decreases incidence of emergence reaction

Source: Wathen JE, Roback MG, Mackenzie T, et al. Does midazolam alter the clinical effects of intravenous ketamine sedation in children? A double-blind, randomized, controlled, emergency department trial. *Ann Emerg Med* 2000;36:579-588.

The investigators in this study[1] endeavored to determine the frequency and severity of emergence phenomena in ketamine-sedated children with and without adjunctive midazolam. It was a double-blind randomized, controlled trial (RCT) of ASA (American Society of Anesthesiologists physical status) I or II patients ages 4 months to 16 years who received sedation in a pediatric emergency department (ED) with ketamine (1 mg/kg IV) and glycopyrrolate (5 mcg/kg IV). Patients were randomized to two groups: the first group (K + M) received ketamine plus glycopyrrolate with midazolam (0.1 mg/kg IV) (n = 137); the second group (K) received ketamine plus glycopyrrolate alone (n = 129). A blinded assessment of the videotaped sedation was performed using the Observational Scale of Behavioral Distress (OSBD-R).

No significant differences between the two groups were observed in terms of efficacy, time of sedation, or emergence phenomena. Emergence phenomena (nightmares, hallucinations, and severe

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agitation) occurred in 6% of the K + M group and 7% of the K group (Δ 1% [95% CI, 5% to 7%]).

However, the number of oxygen desaturation events was significantly more frequent in the K + M group, occurring in 7% of the K + M group, compared with 2% of the K group (Δ 6% [95% CI, 11% to 1%]). Fewer vomiting episodes were observed with K + M; episodes occurred in 10% of this group, compared with 19% in the K group (Δ 10.0 [95% CI, 1% to 18%]). In a post-hoc subgroup analysis, midazolam caused more agitation in children age 10 or older; agitation occurred in 36% of the K + M subgroup, compared with 6% of the K group (Δ 30 [95% CI, 11% to 49%]).

Commentary

Contrary to popular opinion, the addition of midazolam to ketamine in this well-done pediatric RCT did not change the rate of emergence phenomena. Indeed, given the caveat that a post-hoc subgroup analysis is statistically undesirable, the authors paradoxically observed increased emergence phenomena in the subgroup of older children who received supplemental midazolam. They further observed that the addition of midazolam to ketamine increased the rate of hypoxic events but decreased the rate of vomiting.

Recovery agitation in ketamine-sedated children with or without midazolam

Source: Sherwin TS, Green SM, Khan A, et al. Does adjunctive midazolam reduce recovery agitation after ketamine sedation for pediatric procedures? A randomized, double-blind, placebo-controlled trial. *Ann Emerg Med* 2000;35:229-238.

This study[2] also focused on determining the frequency and severity of emergence phenomena in ketamine-sedated children with or without adjunctive midazolam. Sherwin and colleagues used a recovery agitation visual analogue scale (VAS) to compare ketamine 1.5 mg/kg with atropine 0.01 mg/kg IV given alone or supplemented with midazolam 0.05 mg/kg (to a maximum of 2 mg). Patients were randomized to two groups: the first (K + M) received ketamine plus atropine with midazolam (n = 53); the second (K) received ketamine plus atropine alone (n = 51). The VAS ranged from 0-100 mm and was devised by the authors.

No significant differences between the groups were observed in terms of sedation adequacy (perfect scores for both groups), recovery time (61 minutes vs. 64 minutes [K + M compared to K, p = 0.61]), airway complications (4% vs. 2% [p = 1.0]), emesis (2% vs. 12% [CI 0-20%, p = 0.06]), or agitation as measured by VAS (4 mm vs. 5 mm [p = 0.7]).

Commentary

The addition of midazolam to ketamine in this second well-done pediatric randomized, controlled trial (RCT) did not change the rate of emergence phenomena.

Are potent sedative agents safe and effective to use in emergency medicine?

Source: Mace SE, Barata IA, Cravero JP, et al. Clinical policy: evidence-based approach to pharmacologic agents used in pediatric sedation and analgesia in the emergency department. *Ann Emerg Med* 2004;44:342-377.

Using an evidence-based approach, these authors[3] evaluated six sedative agents (etomidate, fentanyl/midazolam, ketamine, methohexital, pentobarbital, and propofol) that are commonly used for emergency pediatric procedural sedation and analgesia (PSA). The

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authors graded studies of the agents by the strength of evidence (classes I, II, or III) and made recommendations (A, B, or C) for patient management. Within the studies, each agent was evaluated for both safety and efficacy when used in the emergency department (ED) setting. The authors concluded that the six agents were safe and effective for emergency pediatric sedation. Ketamine was rated the highest (level A) for efficacy and safety.

Commentary

This analysis confirms the findings of the first two citations and concludes that procedural sedation is an appropriate skill for use by emergency physicians. Historically, most of these agents have at some time been restricted from use in ED procedural sedation.[4-6] Acceptance of this practice has been marked by territorial struggles that have greatly improved as the specialty of emergency medicine matures. Specialized sedation skills are an essential part of emergency medicine training and practice.[3,7-9]

Which antisialagogue should be used with ketamine: Atropine or glycopyrrolate?

Source: Sengupta A, Gupta PK, Pandy K. Investigation of glycopyrrolate as a premedicant drug. *Br J Anaesth* 1980;52:513-516.

These authors[10] compared glycopyrrolate, atropine, and scopolamine for efficacy as an antisialagogue (salivation-diminishing) sedative adjunct by performing a double-blinded randomized trial of 90 healthy subjects who received anesthesia for minor gynecological procedures.[10] Patients were randomized to three groups: the first received atropine, the second scopolamine, and the third glycopyrrolate. Sequential vital signs were recorded and patients were observed for specific symptoms.

Patient demographics were similar in all groups. The increase in mean arterial blood pressure, pulse, respiratory rate, and temperature were greater with atropine than with the other two drugs. At baseline, mean pulse ranged from 83 to 86. An hour after administration of each agent, the pulse increased by 22 in the atropine group, 3 in the scopolamine group, and 9 in the glycopyrrolate group. Differences in pulse and other vital signs were clinically insignificant at other periods. Nausea and vomiting was greatest in the atropine group, sedation greatest in the scopolamine group, and blurred vision greatest in the atropine group. The glycopyrrolate group had the fewest side effects and the least effect on vital signs. All three agents had equivalent antisialagogue effects as measured by suctioning frequency.

Commentary

This study was an efficacy study. It demonstrated side effect superiority (e.g., fewest side effects) for glycopyrrolate over atropine or scopolamine. The quaternary structure of glycopyrrolate restricts it from crossing the blood-brain and placental barriers, unlike the tertiary amines atropine or scopolamine. This also explains another advantage of glycopyrrolate, its lack of central nervous system (CNS) effects. This is contrasted with scopolamine, which has pronounced sedative effects, and atropine, which can cause a "central anticholinergic syndrome" with the occurrence of delirium especially in the elderly.[11,12] Several textbooks also document glycopyrrolate's superior antisialagogue effects when compared to atropine.[11,12]

This study reminds emergency physicians that salivation-reducing alternatives to atropine are readily available as sedative adjuncts, particularly when side effects such as tachycardia, vomiting, or sedation are not desired. The need for salivation reduction in emergency procedural sedation itself is unclear and may depend on the patient and the clinical situation.

The use of such muscarinic anticholinergic drugs (glycopyrrolate, atropine, or scopolamine) does prevent harmful vagal reflexes as well as decrease vagal secretions; thus, they are often used in pediatric patients, and especially in infants. The use of such agents as an anesthetic premedication has decreased in recent years, with the modern inhaled anesthetics replacing ether, although "routine preoperative use of these drugs as antisialagogues continues in some pediatric and otorhinolaryngologic cases or when fiberoptic intubation is planned."[11]

Another rationale for their use is that hypersalivation or any stimulation of the upper airway may predispose the patient to laryngospasm. However, since laryngospasm is, fortunately, a rare occurrence, the association of hypersalivation and laryngospasm is difficult to assess.

Thus, while some emergency physicians may choose increased salivation over the side effects that may result from injection of an additional agent during a sedative procedure, there are indications for a muscarinic anticholinergic agent. Many physicians use them in specific patients and situations, especially in the pediatric popu-

lation, prior to upper airway procedures, and perhaps, to prevent laryngospasm.[11,12]

Glycopyrrolate vs. atropine for anesthesia

Source: Oduro KA. Glycopyrrolate methobromide 2 comparison with atropine sulphate in anesthesia. *Can Anaesth Soc J* 1975;22:466-473.

This RCT[13] compared glycopyrrolate and atropine in healthy adult patients undergoing anesthesia for elective abdominal operations, most commonly for cholecystectomy. Patients were blindly randomized to receive either glycopyrrolate (n = 49) or atropine (n = 49) in addition to general anesthesia, either intramuscularly or intravenously. Serial vital signs were recorded. The amount of salivation was estimated by the anesthesiologist. For controlling neostigmine-induced salivation, glycopyrrolate was superior to atropine ($p < 0.005$). However, for periods outside of neostigmine administration, no difference in salivation was found. Atropine produced more tachycardia than glycopyrrolate when administered intravenously.

Commentary

Although this is an older study, it used sound methodology: blinding, randomization, controls, and specific endpoints. Like the prior study, it observed a greater pulse change with atropine than with glycopyrrolate. Glycopyrrolate also had some advantage in salivation reduction, though this was observed in relation to neostigmine injection alone, not with other anesthetic agents. Like the previous study[10] and textbooks note,[11,12] this study documents glycopyrrolate's superiority as an antisialagogue (with fewer side effects and a greater decrease in salivation) than atropine or scopolamine.

Is prolonged fasting needed prior to procedural sedation in the emergency department?

Source: Treston G. Prolonged pre-procedure fasting time is unnecessary when using titrated intravenous ketamine for pediatric procedural sedation. *Emerg Med Australas* 2004;16:145-150.

The authors[14] report on 257 patients who had procedural sedation in a pediatric ED over a 16-month period. Patients ages 1-12 years were sedated with ketamine (1.25 mg/kg IV). Pre-sedation fasting times were collected prospectively using standard data forms. One-half of the patients (49%) had fasted for more than 3 hours; the remaining patients had not. Vomiting occurred in 14% of patients and occurred more frequently in older patients ($p = 0.001$). All vomiting episodes were short-lived, occurred during recovery, and did not change treatment. No patients developed aspiration, pneumonia, airway obstruction, or required suctioning. Paradoxically, patients who fasted for more than 3 hours had significantly more vomiting episodes than those who did not (16% vs. 7%, $p = 0.08$).

Commentary

Ketamine was safely administered in this moderately sized group of pediatric emergency department patients whose sedation was not restricted by preset fasting periods. In adults and children older than age 3, The American Society of Anesthesiology (ASA) recommends fasting 2-3 hours for clear liquids and 6-8 hours for solids and non-clear liquids, although the literature does not show an increase in adverse events or a change in outcomes in non-fasted pediatric patients undergoing procedural sedation in the ED.[8,9,15-19] There may even be an increase in failed sedations with fasting.[20-22] This series confirms other studies that question the need for pre-procedural fasting periods in children undergoing ED sedation.

Controversy: Ketamine is poorly tolerated in the very young and in older patients

Source: Green SM, Sherwin TS. Incidence and severity of recovery agitation after ketamine sedation in young adults. *Am J Emerg Med* 2005;23:142-144.

The authors[23] evaluated the use of ketamine on a small series of teenagers (n = 26) ranging in age from 16 to 19 years.[23] Adjunctive atropine was given to one-half of the patients. Ketamine was administered intravenously and dosing ranged from 1.0 to 3.8 mg/kg. Sedation was deemed adequate for all patients. Two patients vomited and one developed urticaria, which may have been due to concurrent use of fentanyl. Emergence reactions were rated on a 100 mm visual analog scale based on observed agitation, crying, unpleasant hallucinations, and nightmares (100 mm being the worst). No patients had unpleasant hallucinations or nightmares. One patient had agitation (46 mm rating), and one patient

Table 1. Ketamine: Pearls and Pitfalls

- Ketamine is safe and effective for procedural sedation in the ED
- Use of a benzodiazepine with ketamine does not decrease emergence reactions and only increases the risk of an adverse airway event
- The preferred antisialagogue for use with ketamine is glycopyrrolate, not atropine
- Glycopyrrolate is preferred because it is a better antisialagogue, has fewer side effects, and avoids the possibility of central anticholinergic syndrome that can occur with atropine
- Recent studies suggest that ketamine use is not contraindicated in young infants (< 3 months of age) or in older children and adolescents
- Prolonged preprocedural fasting is not necessary and may actually increase the incidence of complications such as vomiting and/or failed sedations

Table 2. Points for Ketamine Sedation

- Pre-procedural fasting may be unnecessary
- Adjunctive midazolam may worsen the ketamine sedation state
- If an antisialagogue is desired, consider glycopyrrolate

wept (23 mm rating). Both of these occurrences resolved spontaneously without treatment. The authors concluded that their data support the use of ketamine in young adults.

Commentary

Despite a superb safety and efficacy profile, some practitioners are reluctant to use ketamine due to the possible occurrence of emergence reactions.

Review of ketamine complications in infants sedated for bronchoscopy

Source: Berkenbosch JW, Graff GR, Stark JM. Safety and efficacy of ketamine sedation for infant flexible fiberoptic bronchoscopy. *Chest* 2004;125:1132-1137.

This chart review[24] investigated ketamine complications in infants sedated for bronchoscopy. Infants younger than age 1 year received ketamine (1 mg/kg IV), midazolam (0.05-0.10 mg/kg IV), an antisialagogue (atropine or glycopyrrolate), and topical oral lidocaine jelly. One-half of the patients also received fentanyl. The authors collected data on 59 procedures performed in 55 patients. Mean age was 6 months, with a range from 8 days to 11 months. Most patients underwent bronchoscopy with lavage (44). The remainder underwent bronchoscopy alone (3) or could not be bronchoscoped at all due to anatomic obstructions (11) or inadequate sedation (1). Complications occurred in 14 patients (24%) and included hypoxia in 9 patients and apnea in three patients. All complications readily resolved upon withdrawal of the bronchoscope. Some patients required administration of supplemental oxygen and a short period of bag-valve mask ventilation. Because most complications occurred after the bronchoscope passed below the vocal cords, the authors concluded that complications were related to the procedures performed, as well as the patients' anatomic airway characteristics, and not the sedation itself.

Commentary

Some experts have recommended against the use of ketamine in infants younger than 3 months of age. This retrospective case series demonstrated a series of ketamine sedations in young infants, many of whom fell below this age restriction. Despite the number of complications reported, the authors point out that such complications were likely due to patient illnesses or the procedures themselves and were not specifically due to ketamine. Until further data are available, ketamine should not be routinely used in infants younger than 3 months of age.

Summary

Procedural sedation and pain management are essential skills for the practice of emergency medicine. Ketamine is a unique sedative; it is a disassociative agent with well-documented safety, superior efficacy, and broad applicability for emergency patients.

This review has briefly presented evidence pertaining to a few questions regarding ketamine use in emergency sedation. *(See Table 1.)*

Ketamine use may not require procedural fasting. Indeed, fasting increased vomiting in one study of

ketamine-sedated children. Adjunctive midazolam does not appear to decrease emergence reactions. In fact, some evidence suggests midazolam makes ketamine sedation worse. Finally, if an antisialagogue is desired, glycopyrrolate appears superior in both effectiveness and side effect profile to atropine or scopolamine. *(See Table 2.)*

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CME QUESTIONS

51. Which of the following is *incorrect* regarding the use of midazolam with ketamine for pediatric patients undergoing procedural sedation in the ED?
A. May increase the incidence of oxygen desaturation events
B. May increase the incidence of vomiting
C. May actually increase the incidence of emergence reactions in children age 10
D. Does not improve sedation efficacy
E. Does not significantly change sedation recovery time

52. In pediatric patients undergoing procedural sedation in the ED, which of the following is *incorrect* regarding prolonged preprocedural fasting?
A. Prolonged preprocedural fasting increases the incidence of side effects (e.g., vomiting)
B. Prolonged preprocedural fasting may increase the incidence of failed sedations
C. Prolonged preprocedural fasting decreases the incidence of vomiting
D. In adults and children older than age 3, the ASA recommends fasting 2-3 hours for clear liquids.
E. In adults and children older than age 3, the ASA recommends fasting 6-8 hours for non-clear liquids and solids

53. Which of the following is *incorrect* regarding the muscarinic anticholinergic drugs?
A. Atropine results in a greater increase in heart rate than glycopyrrolate.
B. Scopolamine causes more sedation than atropine or glycopyrrolate.
C. A central anticholinergic syndrome causing delirium can occur with atropine.
D. Atropine results in a lesser heart rate increase than glycopyrrolate.
E. Glycopyrrolate has a greater antisialagogue (salivation-decreasing) effect than atropine or scopolamine.

54. Which of the following is correct regarding the use of ketamine?
A. It has never been used in young adults (ages 16-19 years) undergoing procedural sedation in the ED.
B. It has never been used in young infants younger than age 3 months undergoing procedural sedation.
C. Complications of procedural sedation may be related to the procedure itself.
D. Complications of procedural sedation are never associated with the patient's underlying airway anatomy or pre-existing disease or clinical status.
E. In infants undergoing flexible fiberoptic bronchoscopy, complications did not readily resolve when the bronchoscope was withdrawn.

55. Although a very large study involving thousands of patients specifically undergoing procedural sedation in the ED does not exist, using an evidence-based approach, which of the following drugs have been deemed safe and effective for procedural sedation in the ED?
A. Ketamine
B. Etomidate
C. Propofol
D. Fentanyl/midazolam
E. All of the above

Answers:
51. B
52. C
53. D
54. C
55. E

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