

A Randomized, Controlled Trial of IV Versus IM Ketamine for Sedation of Pediatric Patients Receiving Emergency Department Orthopedic Procedures

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Study objective: We compare adverse events, efficacy, and length of sedation of intravenous (IV) versus intramuscular (IM) ketamine procedural sedation and analgesia for orthopedic procedures in the emergency department (ED).

Methods: Pediatric patients receiving ketamine for orthopedic procedures were enrolled in a prospective, randomized, controlled trial in a children's hospital ED. All patients were initially randomized to receive ketamine either 1 mg/kg IV or 4 mg/kg IM. Demographics, adverse events, sedation efficacy, and length of sedation were recorded.

Results: Two hundred twenty-five patients were randomized (116 IV, 109 IM). Two hundred eight patients, aged 14 months to 15 years, completed the study, 109 IV and 99 IM. Respiratory adverse events were similar between groups (IV 8.3% versus IM 4.0%; odds ratio [OR] 0.47; 95% confidence interval [CI] 0.14 to 1.6). Vomiting in the ED was more common in the IM group (26.3% versus 11.9%; OR 2.60; 95% CI 1.2 to 5.9). Using the Faces Pain Scale, patients in the IM group reported significantly less pain from the procedure. Video observers reported significantly lower distress in the IM group during the painful procedure (Observation Score of Behavioral Distress scores 0.35 IM versus 0.74 IV; mean difference 0.38; 95% CI 0.04 to 0.72). Length of sedation was significantly longer in the IM group (median 129 versus 80 minutes). Satisfaction of sedation was high in parents and physicians, with no difference in reported satisfaction between groups. This study was terminated early because of nursing resistance based on the longer recovery times observed in patients receiving ketamine IM.

Conclusion: In this study of pediatric sedation for orthopedic procedures, we found that ketamine 4 mg/kg IM was more effective than 1 mg/kg IV but demonstrated significantly longer recovery times and more vomiting. [Ann Emerg Med. 2006;48:605-612.]

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INTRODUCTION

Background

Ketamine has been administered extensively through the intravenous (IV)¹⁻⁴ and intramuscular (IM)⁵⁻⁸ routes for pediatric procedural sedation and analgesia in the emergency department (ED) setting. Despite the existence of several studies that support the relative safety of ED pediatric ketamine procedural sedation and analgesia,¹⁻¹⁴ some controversy about its use still exists,¹⁵⁻¹⁷ and the need for IV access during sedation to ensure patient safety and ease of rescue, if needed, continues to be discussed.¹⁸

Importance

To our knowledge, no prospective comparisons of IV versus IM ketamine for pediatric procedural sedation and analgesia in the emergency setting have been reported. By performing a prospective, randomized, controlled trial comparing IV to IM ketamine we hope to broaden the available information about the effects of ketamine administered IV and IM, which may help clinicians make decisions about how ketamine may be best used for pediatric procedural sedation and analgesia in their ED setting.

Goals of This Investigation

The goal of this study was to compare the incidence of adverse events, efficacy, and length of sedation between

Editor's Capsule Summary*What is already known on this topic*

The safety and efficacy of pediatric ketamine sedation by both the intravenous (IV) and intramuscular (IM) routes have been widely reported but not yet subjected to prospective controlled comparison.

What question this study addressed

How do adverse events, efficacy, and length of sedation differ between the IV and IM routes for ketamine-assisted emergency department orthopedic procedures in children?

What this study adds to our knowledge

This randomized controlled trial of 208 children with orthopedic injuries found that 4 mg/kg IM was more effective than 1 mg/kg IV; however, this may reflect the doses chosen for the study rather than the route. Children receiving ketamine IM required almost 50 minutes longer to recover and experienced approximately twice the rate of recovery vomiting.

How this might change clinical practice

This study confirms shorter recoveries with IV ketamine compared to IM and suggests less vomiting as well.

ketamine procedural sedation and analgesia administered IV versus IM for pediatric orthopedic reduction in the ED.

MATERIALS AND METHODS**Study Design**

This is a randomized, controlled trial of ketamine administered IV versus IM for pediatric procedural sedation and analgesia. Written, informed consent was obtained from all patients' parents or guardians, as well as assent from all patients 7 years of age or older, before enrollment in the study. The study was approved by the Colorado Multiple Institutional Review Board.

Setting

This study was conducted at a university-affiliated, urban children's hospital, which is a regional pediatric referral center and Level I trauma center. The annual census is 47,000 visits.

Selection of Participants

Patients 4 months to 18 years of age, presenting with an orthopedic injury, American Society of Anesthesiologists grade I or II¹⁹ (either a normally healthy patient or a patient with a mild systemic disease), and receiving procedural sedation and analgesia for orthopedic reduction were eligible. Excluded patients had contraindications for receiving ketamine such as hypertension, glaucoma or acute globe injury, increased

intracranial pressure or central nervous system mass lesion, major psychiatric disorder, porphyria, or previous adverse reaction to ketamine, or the parent, guardian, or patient declined to provide informed consent.

Interventions

Random allocation sequence was determined from a computer-generated, random-number table. The table was kept in a notebook, located on a designated shelf in the ED, separate from patient care areas. Patients provided written informed consent to attending, fellow, or resident physicians; nurses; or research assistants. After patients provided consent, a nurse accessed the randomization table and placed the patient's name in the next open slot on the table, thus assigning patients to IV or IM groups. In this manner, patients were randomized to receive an initial dose of ketamine (1 mg/kg IV, maximum dose 100 mg, or 4 mg/kg IM, maximum dose 200 mg) and glycopyrrolate 5 μ g/kg (maximum dose 250 μ g). For patients randomized to ketamine IV, glycopyrrolate was administered IV just before ketamine. For patients randomized to ketamine IM, glycopyrrolate was administered IM in the same syringe as the ketamine. Subsequent doses of ketamine were administered at the discretion of the attending physician. Per ED protocol at our institution, ketamine is administered by ED attending physicians IV during 1 to 2 minutes.

All encounters were videotaped from the time of informed consent to time ready for discharge. To blind the bedside nurse, who documented adverse events and efficacy of sedation, to route of administration, a second nurse placed the IV or taped a sham IV to the patients' arms after they were randomized to route. The drugs were administered by the attending physician either IV or IM, depending on the route to which they were randomized. The bedside nurse then returned to the room to monitor and document the sedation. Early in the study, however, it became evident that efforts to blind the bedside nurse were unsuccessful. At this time, attempts to blind the bedside nurse were discontinued.

All patients were monitored by following published sedation guidelines,²⁰⁻²³ including measurements of vital signs and pulse oximetry at baseline, during the procedure (recorded every 5 minutes), and postprocedure. All patients received continuous pulse oximetry and cardiorespiratory monitoring for the duration of sedation. Airway management equipment was available at the bedside of all patients.

Length of the procedure was defined as the time reduction attempts began until a splint or cast was placed. Procedures were considered successful if patients did not require further reduction in the operating room.

Discharge criteria were as follows: (1) airway patent with adequate oxygenation; (2) awake or easily aroused; minimal tactile or vocal stimulation may be necessary; (3) swallowing reflex present, demonstrating ability to swallow clear liquids while protecting the airway; and (4) pre-sedation level of responsiveness should be achieved. Readiness for discharge was

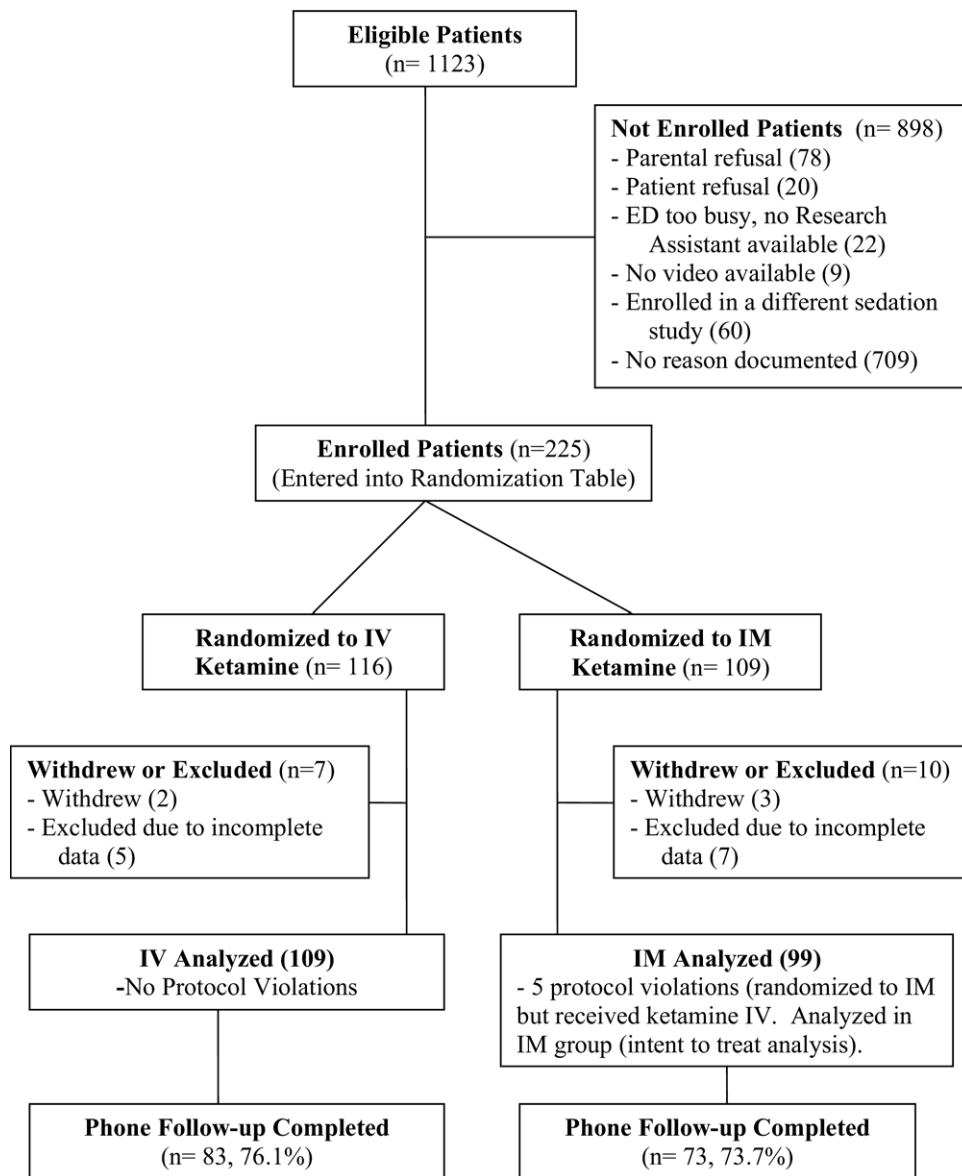


Figure 1. Patient flow diagram.

documented by the bedside nurse with the Vancouver Sedation Recovery Scale.²⁴

Methods of Measurement and Data Collection and Processing

Patients, parents or guardians, physicians, and videotape-trained observers were not blinded to route of ketamine administration. Adverse events and efficacy and length of sedation were observed and recorded by bedside nurses on a standard data collection sheet. Data on adverse events experienced by patients not enrolled and those who withdrew or were excluded were obtained through data collected on all patients who receive procedural sedation and analgesia in our ED as part of a quality assurance initiative.

Data were collected to assess effectiveness of sedation in the following ways. Just before discharge, the self-assessment of pain severity experienced by children was determined with the Faces Pain Scale²⁵ for IV placement or IM injection and pain experienced during the procedure. Pain was rated by patients as 1 (no pain) to 7 (most pain) using the Faces scale and related to the bedside nurse. The Faces scale is validated for patients 5 years of age and older in the pediatric ED and therefore not used in patients younger than 5 years.²⁶

Parents or guardians were queried on completion of sedation about their level of satisfaction, from 1 (least satisfied) to 7 (most satisfied), using a Likert scale. Physicians performing the orthopedic reduction were queried about whether they were satisfied, very satisfied, or unsatisfied with the sedation.

After patient discharge from the ED, 2 trained observers (a pediatric emergency nurse and an ED medical technician/research assistant) reviewed videotapes of the sedation and procedure for patient distress. The nursing observer reviewed all tapes for patient distress and to confirm adverse events. Patient distress was documented using the Observation Score of Behavioral Distress,²⁷ which was scored at 4 intervals: pre-sedation, during IV placement or IM injection, during the painful procedure, and after the patient recovered from sedation (postsedation). Twenty percent of the total number of patients had their videotapes reviewed by both reviewers so that interrater reliability of report of patient distress could be determined.

Patients' parents or guardians were also contacted by telephone beginning 3 days after discharge from the ED to obtain follow-up information about adverse events and satisfaction with sedation, rated from 1-7 with a Likert scale.

Outcome Measures

The primary outcomes in this study were adverse events, efficacy of sedation, and length of sedation.

Adverse events observed for were respiration and vomiting, as well as those assessed by monitoring physiologic parameters: pulse rate, respiratory rate, and blood pressure. Respiratory adverse events included apnea, laryngospasm, and oxygen desaturations, defined as pulse oximeter reading less than 90% at 5,280 feet above sea level. The use of supportive interventions such as airway positioning, breathing cues, supplemental oxygen, or assisted ventilation was documented.

The nurse videotape observer confirmed adverse events in the following manner: vomiting was confirmed by visual inspection of the tapes, laryngospasm by audio, apnea by seeing the use of bag-valve-mask, and desaturations by seeing the administration of supplemental oxygen.

Patients achieving a score of 18 or higher were determined to be ready for discharge. Length of sedation was defined as time of administration of ketamine until discharge criteria with the Vancouver Sedation Recovery Scale had been met.

Primary Data Analysis

Comparisons of nonnormally distributed continuous data were made using the Mann-Whitney *U* test. Categorical data were analyzed using the χ^2 test. Single odds ratios were calculated. All analyses were performed using SPSS version 13.0 (SPSS, Inc., Chicago, IL).

A sample size calculation was performed a priori to estimate the number of patients required to detect a clinically significant difference in incidence of respiratory adverse events. From a previous study of pediatric ketamine sedation performed at this institution, we estimated that these respiratory adverse events occur in about 5% of patients receiving ketamine IV.¹¹ To detect a difference between 5% and 15% incidence of respiratory adverse events (α of 0.05 and 80% power) in patients receiving IV versus IM ketamine, a total of 282 patients would need to be enrolled.

Table 1. Patient characteristics.

Patient Characteristics	IV (N=109)	IM (N=99)
Age, y		
Median	8.1	7.0
Range	1.2–15.8	1.8–15.5
Sex, male, No. (%)	71 (65.1)	63 (63.6)
Race/ethnicity (%)		
Caucasian	62 (56.9)	63 (63.6)
Hispanic	28 (25.7)	25 (25.3)
Black	18 (16.5)	10 (10.1)
Weight (kg)		
Median	27.2	27.0
Range	11.2–106	12.0–76.0
NPO duration, min		
Median	314	305
Range	85–1030	4–1030
Length of procedure, min		
Median	13.0	13.0
Range	1–90	1–35
Procedure success rate (%)	92.7	96.0
Received multiple doses (%)	27 (24.8)	9 (9.1)
Received opioid premedication (%)	33 (30.3)	24 (24.2)
Total dose (mg)*		
Median	30	108
Range	12–119	55–302

*The 5 patients who were randomized to IM but received ketamine IV (protocol violations) were excluded from this calculation.

Table 2. Characteristics of patients meeting inclusion criteria.

Eligible Patients, N=1,123	Enrolled Patients, N=208 (%)	Not Enrolled, Withdrew, or Excluded Patients, N=915 (%)
Number IV (%)	109 (52.4)	848 (92.7)
Desaturations	13 (6.3)	60 (6.6)
Apnea	2 (0.9)	7 (0.8)
Laryngospasm	1 (0.5)	1 (0.1)
Vomiting	39 (18.8)	59 (6.4)

RESULTS

This study was conducted from July 2000 to October 2004. Patients eligible and enrolled during the study period are shown on the patient flow diagram (Figure 1). Two hundred twenty-five patients were entered onto the randomization table. Demographics of enrolled patients are listed (Table 1). Characteristics of patients who met inclusion criteria during the study period but were not enrolled, who withdrew, or who were excluded (n=915) were compared with those of patients enrolled (Table 2). Respiratory adverse events occurred in both arms of the study, but differences were not statistically significant between groups (Table 3). Two of the 208 (0.9%) patients experienced apnea and desaturations. One of these patients experienced laryngospasm in addition to apnea and desaturations. The patient with apnea and desaturations received a single dose of ketamine 1 mg/kg IV. The second patient, who experienced laryngospasm and apnea, received 2

Table 3. Respiratory adverse events and vomiting.

Respiratory Adverse Event, Respiratory Intervention, Vomiting	IV (N=109)	IM (N=99)	Odds Ratio (95% CI)
Respiratory adverse events			
Desaturations	9 (8.3%)	4 (4.0%)	0.47 (0.14–1.6)
Apnea	2 (1.8%)	0 (0%)	
Laryngospasm	1 (0.9%)	0	
Respiratory interventions			
Oxygen	9 (8.3%)	6 (6.1%)	
Breathing cues	3 (2.8%)	0	0.52 (0.17–1.6)
Airway maneuvers	4 (3.7%)	1 (1.0%)	
Bag-valve-mask ventilation	2 (1.8%)	0	
Intubation	0	0	
Patients receiving an intervention	12 (11%)	6 (6.1%)	
Vomiting			
ED	13 (11.9%)	26 (26.3%)	2.6 (1.2–5.9)
Home (not in ED)*	7 (8.4%)	9 (9.1%)	1.5 (0.49–4.9)
Total vomiting (ED plus home only)	20 (18.3%)	35 (35.4%)	2.4 (1.2–4.8)

*Telephone follow-up was obtained in 83 of 109 (76.1%) IV group patients and 73 of 99 (73.7%) IM group patients.

doses of ketamine IV. The first dose was 1 mg/kg IV and the second 0.5 mg/kg IV, for a total of 1.5 mg/kg IV. Both patients were treated with oxygen, airway positioning, and bag-valve-mask ventilations. No IV therapies were administered. No patients experienced clinically apparent pulmonary aspiration.

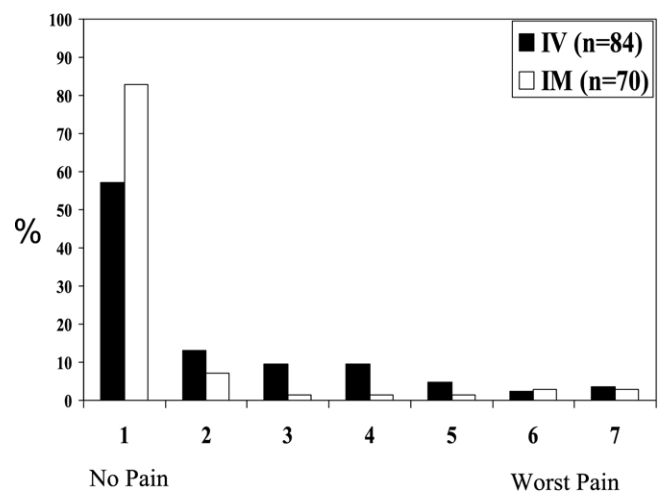
Patients who received ketamine IM were more likely to vomit in the ED than those who received ketamine IV (Table 3).

Telephone follow-up was obtained in 160 of 208 (75.0%) patients (Figure 1). No parent or guardian reported a patient to have experienced breathing problems at home. Vomiting at home is listed in Table 3.

No patients experienced any of the following adverse events: bradycardia, hypertension, seizure, or anaphylaxis.

Videotapes of patient sedation and procedures were obtained in 190 (91.3%) of the 208 patients enrolled. The tapes were reviewed by the nurse videotape observer to confirm the incidence of adverse events. All episodes of respiratory distress and vomiting occurring in videotaped patients and documented at sedation were confirmed. In addition, 2 episodes of vomiting, not recorded by the bedside nurses, were detected on the videotapes and were included in the results found in Table 3. No additional respiratory adverse events were observed on videotape review.

One hundred sixty-three of the 208 (78.4%) patients were able to reliably rate pain using the Faces scale (age 5 years or greater). Of those 163 patients, 154 (94.5%) were successfully interviewed about pain of the procedure (84 of 88 [95.5%] IV and 70 of 75 [93.3%] IM). Median pain of the procedure scores

**Figure 2.** Self-reported pain of procedure (Faces Scale).

was 1 (no pain), with a range of 1 to 7 in both groups. Patients in the IM group reported significantly less procedure-related pain (Mann-Whitney U P = .03, Figure 2).

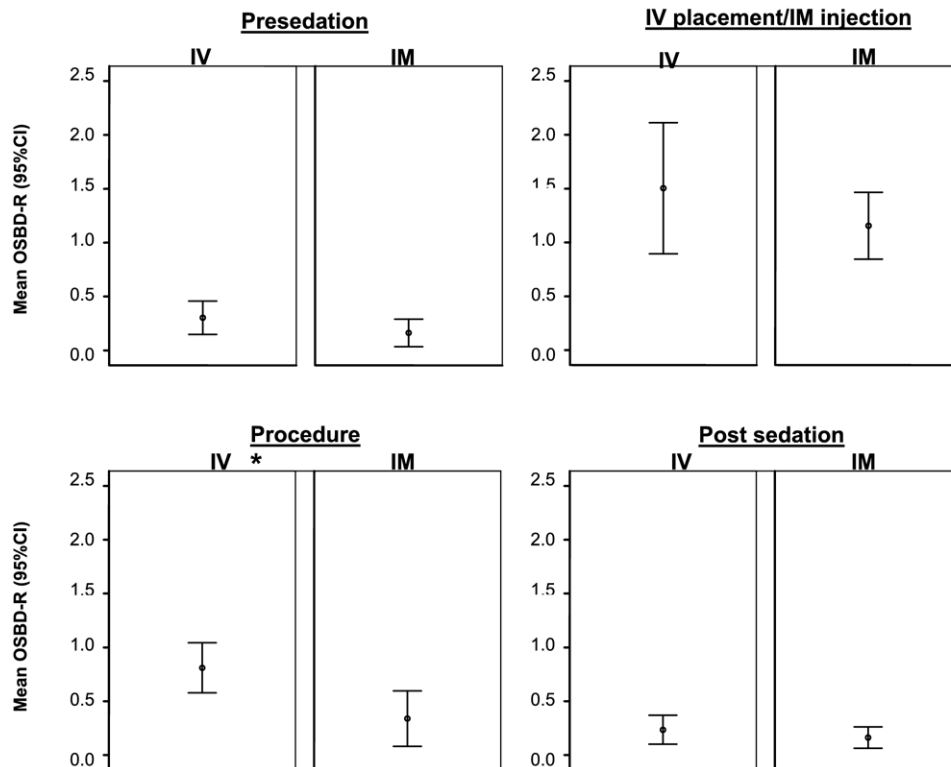
Parental or guardian satisfaction of sedation, before ED discharge, was documented in 102 of 109 (93.6%) IV group patients and 89 of 99 (89.9%) IM group patients. The satisfaction of the physician performing the procedure was documented in 100 of 109 (91.7%) IV group patients and 93 of 99 (93.9%) IM group patients. Median satisfaction of sedation scores was 7 in both the IV and IM groups for parents or guardians (range 1 to 7 for both; P = .153, Mann Whitney U test). Physicians were satisfied or highly satisfied with sedation in 93 of 100 (93%) IV group patients and 91 of 93 (97.8%) IM group patients. At telephone follow-up, parents or guardians were as satisfied with sedation IM as with IV (median satisfaction scores were 7 for IV and IM, range 2 to 7 IV and 1 to 7 IM; P = .294, Mann Whitney U test).

Distress during the painful procedure was lower in IM group patients (lower observed Observation Score of Behavioral Distress scores) compared with the IV group (0.34 versus 0.81; mean difference 0.47; 95% confidence interval [CI] 0.13 to 0.82). No significant difference in distress was observed between groups at the other intervals (Figure 3).

Interrater reliability between 2 observers recording Observation Score of Behavioral Distress scores was calculated. There were 195 paired observations. Absolute agreement on score was 163 of 195 (83.6%). Intraclass correlation coefficient was 0.955 (95% CI 0.940 to 0.966).

Length of sedation was significantly longer in the IM group versus the IV (median 129 versus 80 minutes; range IV 27 to 210 minutes, IM 55 to 365 minutes; P < .001, Mann Whitney U test).

The study was terminated prematurely at nursing request, given that perceived differences in the duration of recovery and rates of emesis between groups markedly hindered enrollment.



*Student's t-test. 0.81 IV vs. 0.34 IM, mean difference 0.47, 95% C.I. (0.13, 0.82)

Figure 3. Mean distress scores (Observation Score of Behavioral Distress). IV n=97; IM n=93.

LIMITATIONS

Essentially no blinding occurred in this study. Subjects were not blinded to route of administration, which may have led to biased reporting of pain. Bedside nurses and videotape observers were also not blinded to route of administration, which could have resulted in biased recording of adverse events and documentation of distress scores. However, through review of the videotapes, adverse events were confirmed for most cases, and interrater agreement of distress scores was high.

Significant differences were seen in vomiting, as well as efficacy and length of sedation. The design of this study does not allow us to determine whether these differences might reflect the doses chosen, rather than the routes of administration.

Although our randomization table was placed in a notebook that was located in a designated area, separate from patient care areas, absolute concealment of its contents cannot be assured. Because we enrolled a convenience sample of patients, it is possible that patients were not enrolled, because of the nurse's knowledge of randomization group.

We found no significant differences in the incidence of respiratory adverse events between IV and IM ketamine; however, the number of patients studied here is not large

enough to make a definitive statement about safety of one route compared with the other.

DISCUSSION

To our knowledge, our study represents the first prospective comparison of ketamine administered IV versus IM for pediatric procedural sedation and analgesia in the ED. We found no significant differences in rates of respiratory adverse events between the 2 groups. However, the study is underpowered to definitely comment on differences in respiratory adverse events. Respiratory adverse events reported here were consistent with those reported in previous studies of ketamine procedural sedation and analgesia.^{9,11-13}

Vomiting was common in our patients receiving ketamine IV or IM, during recovery from sedation and at home. Higher rates of vomiting were observed in the IM group. The effect of dose on incidence of vomiting remains unknown. These data support the importance of informing all patients who have received ketamine procedural sedation and analgesia, regardless of dose and route of administration, that they may vomit during recovery from sedation and after discharge from the ED, whether or not they vomited in the ED.

Lower self-reported pain and lower observed levels of distress during the painful procedure observed in the IM group support better efficacy of sedation for these patients in this study. As mentioned in the Limitations section, the dose of ketamine may be important but was not studied here. Patients in the IV group were more likely to have received additional doses of ketamine, which suggests that the initial dose of ketamine IM was more effective in providing adequate sedation and analgesia. There was no difference in satisfaction of sedation IV versus IM in parents or guardians or physicians, which supports the efficacy of ketamine sedation IV and IM.

The length of sedation was found to be significantly longer in the IM group compared with the IV group. This fact will have to be taken into consideration when clinicians are making decisions about which route of administration to use for ketamine procedural sedation and analgesia.

In summary, we found that pediatric patients administered ketamine 4 mg/kg IM had lower self-reported pain and lower observed distress scores during the painful procedure than those receiving ketamine 1 mg/kg IV. However, patients receiving ketamine IM were also more likely to vomit in the ED, as well as at home, and experienced a longer length of sedation than those who received ketamine IV. We found no difference in respiratory adverse events or parental or guardian and physician satisfaction of sedation between groups.

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Author contributions: MGR, JEW, and TM conceived the study. MGR and JEW oversaw data collection. MGR, JEW, and LB managed the data, including quality control. TM provided statistical advice on study design. TM and LB analyzed the data. MGR drafted the manuscript, and all authors contributed substantially to its revision. MGR takes responsibility for the paper as a whole.

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CORRECTION

In the March 2006 issue, in the article by Hipp and Sinert ("Clinical Assessment of Low Back Pain"; pages 283-285), there were errors in the table. The correct table is shown below. The authors regret these errors.

Table. Operating characteristics of medical history and physical examination findings for nontraumatic causes of lower back pain.

Etiologies of Back Pain	Historical and Physical Exam Findings	Sensitivity/Specificity, %	LR+ /LR-
Cancer	Age >50 y	77/71	2.7/0.3
	Previous hx of cancer	31/98	15.5/0.7
	Unexplained weight loss	15/94	2.5/0.9
	Failure to improve with a month of therapy	31/90	3.1/0.8
	No relief with bedrest	>90/46	1.7/0.2
	Pain duration >1 mo	50/81	2.6/0.6
Compression fracture	Age >50 y, cancer hx, weight loss, or therapy failure	100/60	2.5/0.0
	Age >50 y	84/61	2.2/0.3
Herniated disc	Age >70 y	22/96	5.5/0.8
	Trauma	30/85	2.0/0.8
	Corticosteroid use	6/99	12.0/0.9
Spinal stenosis	Sciatica	95/88	7.9/0.06
	Pseudoclaudication	60/NA	na
Ankylosing spondylitis	Age >50 y	90/70	3.0/0.1
	4 of 5 positive responses	23/82	1.3/0.9
	Age of onset ≤40 y	100/7	1.1/0.0
	Pain not relieved by supine	80/49	1.6/0.4
	Morning back stiffness	64/59	1.6/0.6
	Pain duration ≥3 mo	71/54	1.5/0.5

Hx, History; IVDA, intravenous drug abuse history; LR, likelihood ratio; na, not applicable; UTI, urinary tract infection.