Journal of Pediatric Sciences

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Journal of Pediatric Sciences 2015;7:e243
http://dx.doi.org/10.17334/jps.99464

How to cite this article:

Patel RV, Gohil JR, Parekh AN, Gosai MM, Chadhari B. Epidemiological, clinical, and prognostic aspects of preterm birth over 10 years in Ouagadougou, Burkina Faso. Journal of Pediatric Sciences. 2015;7:e243. http://dx.doi.org/10.17334/jps.99464

ORIGINAL ARTICLE

To study the efficacy and safety of injectable ketamine in pediatric ward procedure in age group of 6 month to 12 year in tertiary care hospital

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Abstract:

Background: The literature concerning the efficacy and safety of ketamine for conscious sedation during procedures in pediatric ward was reviewed. Aims: To see the efficacy and safety of injectable ketamine in pediatric ward procedure in age group of 6 month to 12 year in tertiary care hospital and parental satisfaction. Settings and Design: prospective unicentric, interventional, pilot study. Patients admitted in pediatric ward in tertiary care medical college hospital. Methods and Material: Ketamine 1mg/kg intravenously given in fifteen-twenty second to patients goes into different ward procedure except in exclusion criteria. If adequate effect not produced within five minutes, same dose is repeated. Time required for dissociation, duration of effect, pre & post procedural heart rate, respiratory rate, blood pressure and oxygen saturation and other significant side effects were recorded after five & thirty minutes. Vitals and behaviour monitoring was done for twenty four hours after procedure. Statistical analysis used: basic biostatistics used. Results: During study period twenty three patients were studied. Three patients were excluded from data analysis in study as per exclusion criteria. Twenty patients were analyzed. Peak effect seen within one to five minute after injection. Heart rate, respiratory rate, systolic and diastolic blood pressure rise in all patients and return to base line after thirty minute. Side effect including vomiting seen in one patient and increase salivation in five patients but no active management required. Repeat dose required in three patients. Conclusions: we found that ketamine in dose of 1mg/kg is alone effective and safe drug and is suitable for use in children requiring conscious sedation for variety of painful and anxiety producing procedures with good parental satisfaction. Side effects encountered were minimal and no intensive management required in any patient due to side effects.

Keywords: *conscious sedation, ketamine, and pediatric ward, painful invasive procedur*

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Introduction

The literature concerning the efficacy and safety of ketamine for conscious sedation during procedures in pediatric emergency departments was reviewed. Data were obtained from the Guidelines for Monitoring and Management of Pediatric Patients during and after Sedation for Diagnostic and Therapeutic Procedures developed by the American Academy of Pediatrics Committee on Drugs, and from a MEDLINE search (January 1966-July 2004). Articles relevant to pediatric age group 6month to 12 year were selected. Clinical end points were efficacy and adverse effects associated with ketamine. Conscious

sedation is a controlled state of depressed consciousness that preserves protective reflexes, allows maintenance of a patent airway independently and continuously, and permits the patient to respond appropriately to physical stimulation and verbal command [1]. Conscious sedation has traditionally been used in inpatient settings, such as the operating room, where skilled anesthesia personnel are available to titrate drugs and maintain airway patency [2]. An increasing need to accomplish procedures outside the operating room has led to the use of conscious sedation in outpatient settings, such as emergency departments. Many procedures in the pediatric emergency department are well tolerated with a local anesthetic and an acceptable level of sedation and analgesia achievable with conscious sedation.

Most agents for conscious sedation have traditionally been used by anesthesiologists in the controlled environment of an operating room. Thus, the use of these agents in a less controlled environment, such as the emergency department, requires practitioners to be cognizant about possible adverse effects [3] and apply the skills necessary to manage these effects as needed [4]. Guidelines for monitoring and managing pediatric patients during and after conscious sedation were developed by the American Academy of Pediatrics Committee on Drugs 1 to ensure the safe and effective management of conscious sedation in the outpatient setting. The goals of pediatric sedation are to protect the patient's safety and welfare, minimize physical discomfort or pain, provide analgesia to minimize negative physiologic responses and maximize the potential for amnesia, control behaviour, and return the patient to a state in which safe discharge from the emergency department is possible.

The ideal sedative agent can be described as having a relatively fast and consistent onset; short duration; uniform efficacy; an effective combination of analgesia, sedation, and amnesia; ease of administration without unnecessary pain or anxiety; and minimal contraindications, adverse effects, and cost. It is important to identify an agent or combination of agents that maximizes these properties [5]. Classes of drugs used for conscious sedation are the benzodiazepines (e.g. midazolam, lorazepam), opioids (e.g., morphine, fentanyl), and sedative-hypnotics (e.g., chloral hydrate, ketamine) [6].

One report suggested that ketamine for conscious sedation prevents excessive pain and discomfort for the child, avoids hospital admissions, and offers economy of time and resources for paediatricians, and ward staff [7]. Ketamine relative cardiovascular stability and limited effects on the respiratory system make it a suitable alternative to other agents that can cause more deleterious effects.

Ketamine is hydrochloride. Chemical name is (RS)-2-(2-Chlorophenyl)-2-(methylamine) - cyclohexan-1-one.Ketamine was invented by Dr. Craig Newlands. It was then developed by Parke-Davis in 1962. Ketamine is classified as an NMDA receptor antagonist, and also bound to upload and mule receptor. Ketamine is metabolized by hepatic N-methylation to norketamine, which has approximately one third the activity of the parent compound. Further metabolism results in hydroxylation; norketamine then undergoes urinary excretion. The concentration of norketamine is higher in children than adults, suggesting faster metabolism and perhaps higher dosage requirements in children. Ketamine belongs to a class of drugs called “dissociative anesthetics”. Dissociative sedation is defined as "a trancelike cataleptic state characterized by profound analgesia and amnesia, with retention of protective airway reflexes, spontaneous respirations, and cardiopulmonary stability."

In pediatric hospital practice, many procedure need to be done in the ward for diagnostic and therapeutic purpose. They are both painful and frightening to a child. Traditional anesthesia cannot be practiced for procedure like, lumber puncture, bone marrow or fluid aspiration and other minor procedures in the wards. What are required are safe, effective and short acting drugs to reduce the anxiety, pain and to produce amnesia and parental satisfaction. Ketamine fulfils all the criteria and use alone and combination with other drugs.

Material and Methods

Study design

It is a prospective unicentric, interventional, pilot study conducted in patient age group 6 month to 12 year admitted in pediatric ward in tertiary care hospital, who’s are undergone different painful invasive ward procedure except venepuncture were selected in study from Jan 2010 to Jun 2010.

Aim & objectives

To study the efficacy and safety of injectable ketamine in painful invasive pediatric ward procedure except venepuncture in age group of 6 month to 12 year in tertiary care hospital

Inclusion criteria

Children from 6 month to 12 year selected for different painful invasive ward procedures like lumber puncture, bone marrow, pleural tapping, liver biopsy, abscess drain except venepuncture.

Exclusion criteria

Raised intracranial tension, hypertension, heart failure, head injuries, coma states, psychosis, previous allergy to ketamine, patient on thyroxin and penobarbitone

After explaining about procedure, side effects and benefits of ketamine informed written consent of parents are taken. Pre-procedure child kept nil per oral for 3 hrs. Whenever urgent intervention required, ketamine was given without starvation. Research personnel consisted of a practitioner responsible for treatment of the patient and administration of drugs for sedation, and nurses responsible for constant monitoring of vital signs and assisting with any supportive or resuscitation measures. Before procedure vital of child were recorded in form of heart rate, respiratory rate, blood pressure and oxygen saturation with facilities for intubation, assisted ventilation and oxygen kept on standby. Ketamine is available in 50mg/ml strength. It is diluted with normal saline to 5mg/ml. Ketamine 1mg/kg given intravenously slowly over 15-20 sec. if adequate effect not produced within 5 minutes, same dose is repeated. Time required for dissociation, duration of effect, post procedural heart rate, respiratory rate, blood pressure and oxygen saturation and other significant side effects were recorded after 5 & 30 minutes. Vitals and behaviour monitoring was done for 24 hours after procedure. After 24 hours , child having consisted of satisfactory and stable cardiovascular function and airway patency, easily arousable with protective reflexes intact, child able to talk and to sit up unaided, pre-sedation level of responsiveness or a level as close to that as possible for an impaired child, and adequate state of hydration then child excluded from study.

Measurements/data collection

For all patients receiving sedation in pediatric ward, procedural sedation sheet, which become part of the medical record, are automatically generated. Nurses and physicians caring for the patients complete these sheets. Data pertaining to procedure type, drugs and doses used, vital signs, adverse events were extracted from the procedural sedation sheet and recorded in a separate data collection sheets made for this study. Further chart review done to confirm the data. Descriptive Statistical analysis was performed using the statistical package for the social sciences software.

Results

During study period twenty three patients were received. Three patients were excluded from data analysis in study as per exclusion criteria (two raised intracranial tension & one congestive heart failure). Twenty patients were analysis. The age ranged from 6 months to 12 years with 11(55%) male and 9(45%) female. Out of it fifteen in 1-5 years, two in 6-10 yrs and three in 11-12 yrs age group. Total procedures are eleven-lumber puncture, four-bone marrow, 3-pleural tapping, one-liver biopsy and one-abscess drain. Ketamine was given to all patients intravenously in dose of 1mg/kg. Peak effect was seen within 1-5 min after injection. Variation in heart rate (HR) seen (Mean ± SD) is 129.0 ± 21.14 as compared with basal HR (Mean ± SD) is 116.3 ± 22.53 ($p<0.0001$). Variation in respiratory rate (RR) seen (Mean ± SD) is 34.7 ± 10.70 as compared with basal RR (Mean ± SD) is 37.2 ± 11.17 ($p<0.0001$). Variation in systolic blood pressure (SBP) is (Mean ± SD) is 104.0 ± 12.39 as compared with basal SBP Mean ± SD) is 92.2 ± 10.91 ($p<0.0001$). Variation in diastolic blood pressure (DBP) is (Mean ± SD) is 60.5 ± 6.67 as compared with basal DBP (Mean ± SD) is 55.0 ± 05.89 ($p<0.0001$). Blood pressure (BP) returns to baseline at 30 min. But tachycardia, tachypnea and hypertension, which were noted in the vital signs, are expected effects of ketamine sedation and were not recorded as complications shows in Table-1. One patient had vomiting (20%) after 2 hr. five patients had increased salivation (25%) responded to only oral suction and atropine was not required. In three patients (one lumber puncture, two bone marrow aspiration) repeat dose was required because no desirable sedation produced by first dose. No respiratory depression seen in study probably due to lower dose used. Emergence reaction while coming out, hallucination or abnormal behaviour was not seen in study group.

Table I. Vital signs before and after ketamine sedation

Vital signs	before ketamine (Mean ± SD)	5 minute after ketamine (Mean ± SD)	30 minute after ketamine (Mean ± SD)	p
Heart rate	116.3 ± 22.53	129.0 ± 21.14	115.2 ± 22.4	< 0.0001
Respiratory Rate	37.2 ± 11.17	34.7 ± 10.70	36.9 ± 11.2	<0.0001
Systolic BP	92.2 ± 10.91	104.0 ± 12.39	92.1 ± 11.01	<0.0001
Diastolic BP	55.0 ± 05.89	60.5 ± 6.67	54.92 ± 05.90	<0.0001

Discussion

Article written by anesthesiologists suggest that ketamine anesthesia requires presence of skilled anesthetists as any other form of anesthesia. But in our small study we observed that ketamine is safe and effective in the hands of pediatric residents (or anyone trained for resuscitation) in the wards. As recovery is rapid after ketamine anesthesia, it can be given to day-care patients it is as comparable to intravenous ketamine is a consistently effective method of producing a rapid, brief period of profound sedation and analgesia in children in the emergency department. As shown in study by Robert JD, George MI [8].

In our study only few children had minor side effects like vomiting, increased salivation were seen, increased salivation does not required atropine, which is as comparable to study by Steven M Green in Department of Emergency Medicine Riverside General Hospital, which concluded wide margin of safety is afforded without the respiratory and cardiovascular depression when ketamine used for emergency procedures in children [9].

In our study we had given 1mg/kg intravenous Ketamine ,which produced adequate sedation and analgesia for the procedure in single dose in 90% of children without hypoventilation, which is comparable to pilot study Grace Kim MD whose results showed No hypoventilation was observed pediatric patients receiving ketamine 1.5 mg/kg administered IV over 1 minute [10].

In our study only minimal side effect like vomiting and increased salivation is observed. There was no emergence phenomenon observed in comparison with previous study by Lohit K, who showed that ketamine exhibited significant increase in severity and frequency of occurrence of post operative adverse events as a part of emergence phenomenon [11].

Our study show that ketamine can be given by doctor who are aware of dangers of drug and be able to give a positive pressure ventilation which is comparable to study by Mistry who showed that Ketamine should be administered by pediatrician who are adequately trained in its use and in airway management and resuscitation [12].

In study, ketamine used in dose 1 mg/kg, May be repeated if required. No need of premedication with atropine or glycopyrrolate required with ketamine because of no significant complication noted. As adequate sedation, and analgesia, is produced by ketamine alone, no need of other sedation or hypnotic along with ketamine is required.

In conclusion, we found that ketamine in dose of 1mg/kg is alone effective and safe drug and is suitable for use in children requiring conscious sedation for variety of painful and anxiety producing procedures with parental satisfaction. Side effects encountered were minimal and no intensive management required in any patient due to any side effects.

What is already known?

Ketamine along with other sedatives is effective for conscious sedation in painful pediatric ward procedures in dose of 1-2 mg/kg.

What is my study adds?
Ketamine alone is safe and effective for conscious sedation in painful pediatric ward procedures (except venepuncture) in dose of 1mg/kg.

There were few minor side effects for which no active management was required.

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