

Comparative study of oral Ketamine and oral Midazolam as Premedication in paediatric patients

Aasim SA ¹, Zubair SI ²

¹Professor, ²PG Student,
Department of
Anaesthesiology
ChalmedaAnandRao Institute
of Medical Sciences
KARIMNAGAR -505001,
Andhra Pradesh, INDIA.

Correspondence:

Dr. Aasim SA,
MD (Anaesthesiology)
E-mail:
aasim.dr@rediffmail.com

ABSTRACT

Aim: The aim of the study is to compare the efficacy and safety of oral ketamine and oral midazolam as premedication in paediatric patients.

Methods: 60 patients were taken in study. All patients were premedicated with Ketamine 6mg/kg and midazolam 0.5 mg/kg given for each group.

Results: Out of 60 patients studied calm (68%) and apprehensive (32%) in Group A and calm (84%) and apprehensive (16%) in Group B.

Conclusion: The present study concludes that 6mg/kg of oral ketamine is better than 0.5mg/kg of oral midazolam as premedication in children.

KEY WORDS: Premedication, ketamine, midazolam, paediatrics.

INTRODUCTION

Anesthetic premedication is a challenging role in children. The aim of premedication in children are to relieve anxiety, reduce the trauma associated with separation from their parents and facilitate induction of anesthesia without prolonging the recovery period⁽¹⁾. Oral premedication is the most common mode of delivery, probably due to better acceptance and ease of administration⁽²⁾. Ketamine is now a popular induction agent of choice in paediatric anesthesia⁽³⁾. Ketamine has been used in premedication of children using different routes and doses. Ketamine is a very popular among anesthesiologists for short surgical procedures. Many adjuvants to ketamine anesthesia have been investigated in reducing the incidence of these sequelae^{(1),(2)}. Ketamine is an aryl cyclohexilamine that is structurally related to phencyclidine. Ketamine is a water soluble compound with PKa of 7.5 and is available in 1%, 5% and 10% aqueous solutions. Midazolam is water soluble, does not require propylene glycol for solubilising, an active metabolites (1 hydroxy midazolam). We compared the efficacy and safety of oral ketamine and oral midazolam as premedication in paediatric patients. The aim of the study is to compare the efficacy and safety of oral ketamine and oral midazolam as premedication in paediatric patients.

MATERIALS AND METHODS

The study was a prospective observational study conducted

in 60 patients undergoing minor short elective surgical procedures. The study was conducted at CAIMS HOSPITAL, Karimnagar in 2011-2012. The study was done for a period of 12 months and approved from our institute ethics committee.

Inclusion Criteria : age group 1-10 years, American society of anaesthesiologist (ASA) grade I and II, ketamine 6mg/kg, midazolam 0.5mg/kg, sedation score (0-6), anxiety score, heart rate, pulse rate, systolic/diastolic blood pressure.

Exclusion Criteria : Children already on other sedative drugs, patients with upper respiratory tract infection, history of allergy to any of the study drugs, emergency cases.

TREATMENT PROTOCOL

Parents are allowed to stay in the preoperative room, where the study drugs are administered 30 minutes prior to surgery. Group A patients will receive parental formulation of ketamine (50 mg/ml vial) in a dose of 6 mg/kg and group B patients will receive parental formulation of midazolam (1mg/ml vial) in a dose of 0.5 mg/kg, orally after mixing with equal volume of sugar or dextrose crystal. There after the child will be constantly observed to see changes in mood, behavior and appearance.

OUTCOME SCALES

Sedation score

Response to Verbal Commands	Numerical Score
Agitated	6
Responds readily to name spoken in normal tone	5
Lethargic response to name spoken in normal tone	4
Responds only after the name is called loudly or repeatedly.	3
Responds only after mild shaking	2
Does not respond to mild shaking	1
Does not respond to test stimulus	0

RESULTS

The acceptance of premedication was good in group “A” patients. After giving oral ketamine or oral midazolam following variables were compared and assessed. The degree of sedation and anxiolysis, The ease of parents child separation, The behavior of child at induction, Reaction of child at intravenous cannulation, The study of adverse effects if any.

DISCUSSION

The word premedication first appeared in an article by the American editor anaesthetist Frank.H. McMechan in 1920.

ANXIETY SCALE

Generalised Anxiety Disorder (GAD-7) Scale	Not at all sure	Several Days	Over Half the Days	Nearly Emergency
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being restless that its hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

TABLE 1: Demographic Data, duration of Anesthesia and Surgery and time to extubation and to discharge from recovery room.

	Group A	Group B	P
Age (Years)	6.53	6.08	>0.05
Height	17.07	16.04	
Gender : Male	15	14	
Female	15	16	
Duration of Anaesthesia	45 minutes	45 minutes	
Duration of Surgery	35 minutes	35 minutes	
Time to Extubation	38 minutes	38 Minutes	
Time to Discharge	5 days	5 days	

TABLE 2: Sedation Score, Anxiety Score, Mask Co-operation Score

Sedation Score	Group A		Group A		P
	Before	After	Before	After	
1	-	-	-	-	>0.05
2	-	-	-	3	
3	1	20	-	25	
4	12	4	15	2	
5	17	-	15	-	
Anxiety Score					= 0.02
1	-	9	-	1	
2	4	20	1	27	
3	14	1	21	2	
4	12	-	8	-	=0.00
Mask Cooperation Score					
1. Unafraid	13		1		
2. Slight Apprehensive	17		17		
3. Moderate Fear	-		12		

Significant (P< 0.05)

However, the technique of premedication was well established for some 40 or 50 years before. Undergoing surgery can be a traumatic experience for children. These can be overcome by using pharmacological agents as premedication because psychological assurance alone is not sufficient⁽²⁾. While varied premedication have been advocated to allay anxiety and facilitate smooth separation of children from parents. The ideal premedicant remains elusive.

Ketamine, a phencyclidine derivative acts on the NMDA receptor⁽⁸⁾ and causes central dissociation of the cerebral cortex while providing analgesia and amnesia. Midazolam is an imidazole benzodiazepine derivative with an imidazole ring in its structure that accounts for its stability in aqueous solution and rapid metabolism. The ideal premedicant in children should be readily acceptable, have rapid, reliable onset of action with minimal side effects⁽⁵⁾.

Rosenberg et al 1991⁽¹⁶⁾ described a case utilizing the techniques of achieving deep sedation by administration of oral ketamine 6-8 mg/kg combined with oral glycopyrolate in an extremely mentally handicapped female requiring dental treatment. Reinemerr HC et al 1996 studied two ketamine-diazepam regimes 4mg/kg and 8 mg/kg ketamine in conjunction with 0.1mg/kg diazepam and concluded that the 4mg/kg regime resulted in more negative behavior and less sleep and the 8 mg/kg regime resulted in less negative behavior and more sleep.

The study was undertaken on ASA I and II aged between 1 – 10 years undergoing elective surgeries. The patients were randomly allocated into two groups of each Group A = Received oral ketamine (6mg/kg), Group B = Received oral midazolam (0.5mg/kg)⁽⁶⁾. These drugs were mixed with dextrose given to patients 30 minutes prior to the surgery.

CONCLUSION

The Present study concludes that both oral ketamine and oral midazolam are good premedicating agents in children with minimal side effects, while premedication with 6mg/kg of oral ketamine is better than 0.5mg/kg of oral midazolam in achieving better acceptability, sedation and anxiolysis.

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