



TO COMPARE THE EFFICACY OF PREMEDICATION WITH ORAL KETAMINE AND ORAL MIDAZOLAM IN CHILDREN UNDERGOING ELECTIVE SURGICAL PROCEDURES

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ABSTRACT

Fears of operation, injections, physicians and peculiar operation theatre environment where the children are separated from their parents prior to anaesthesia invariably produce traumatic experiences in the tender mind of the young children. An atraumatic premedication can minimize these problems when a calm separation from parents and a smooth induction of anaesthesia is achieved. In paediatric patients midazolam and ketamine are commonly used as premedicants. 60 patients in the age group of 2-10 years belonging to ASA I undergoing elective surgeries was randomly allocated to two groups of 30 each. Group A received (4mg/kg) oral ketamine & Group B received oral midazolam (0.5mg/kg) 45 minutes before induction of anaesthesia. The children were separated from their parents 30 minutes after the oral premedication and were taken inside operation theatre. An intravenous cannula of 22G was placed. Anxiety level at the time of separation from parents, Response to IV cannulation, time of onset of sedation, face mask acceptance, sedation score & time of recovery from anaesthesia was noted. Children were assessed for development of side effects postoperatively. It was observed that both drugs were well tolerated in both the groups. Sedation and anxiolysis was found to be better in ketamine group. There was no statistically significant difference in recovery time in both groups. There were minimal adverse effects in both groups. This study concludes that oral premedication with (4mg/kg) ketamine is better than (0.5mg/kg) midazolam.

Key words: Paediatric anaesthesia, Oral premedication, Ketamine, Midazolam.

INTRODUCTION

Induction of anesthesia in paediatric age group is a challenging job. Fears of operation, injections, physicians and peculiar operation theatre environment where the children are separated from their parents prior to anaesthesia invariably produces traumatic experiences in the tender mind of the young children [1]. Fear of alien environment, separation anxiety and fear for injections and needles can result in an agitated and crying patient which can add to the difficulty in inducing anesthesia. It becomes a skill full speciality as fear of operation theatre and injection can produce traumatic experience in tender minds of young children. 70% of children before anesthesia show lot of stress and anxiety [2]. Preoperative anxiety can have

negative physiological and psychological effects on child [3].

An atraumatic premedication can minimize these problems when a calm separation from parents and a smooth induction of anaesthesia is achieved. Different kind of medical products have been used for premedication like benzodiazepines, ketamine, opioids etc [4]. Key features of ideal premedication are ease of administration, quick onset and smooth recovery and minimal side effects [5]. Oral route for premedication is preferable as it can be easily administered and accepted by children without much hesitation. Easy acceptance, rapid onset, short duration of action and lack of significant side effects are desirable

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qualities in a good pre-medication [6]. Midazolam and ketamine are commonly used by oral, nasal and rectal routes. Oral and rectal application of midazolam and ketamine are widely used in this age group [7]. The aim of the present study is to compare the efficacy of ketamine and Midazolam as oral premedication in children.

MATERIAL & METHODS

The present study was conducted in 60 children in the age group of 2-10 years (ASA grade1) undergoing elective surgeries after obtaining permission from their parents and hospital ethical committee.

INCLUSION CRITERIA

Children in the age group of (2-10yrs) undergoing elective surgeries under general anaesthesia.

EXCLUSION CRITERIA

- ASA II or more
- Known allergy to trial drugs
- Parents refusal
- Children with URTI, metabolic disorders and systemic illness.

All children were randomly allocated to two groups of 30 each. A randomized controlled study of children were assigned to two groups of 30 each. KETAMINE GP-Group (A) oral Ketamine [4mg/kg). MIDAZOLAM GP-Group (B) oral Midazolam (0.5mg/kg)

Drugs of premedication was given 45 minutes before surgery. All children were assessed continuously for PR, RR, B.P. and SP02 at 0, 10, 20, 30, 40 min and scoring was done at the end of 40 min.

The child was observed preoperatively for 30 minutes, intra-operatively and postoperatively. Baseline pulse rate, oxygen saturation was noted preoperatively and after premedication.

All monitors attached in operation theatre. Inj.glycopyrrolate 0.04mg/kg, inj.ondensetron 0.1mg/kg and inj.fentanyl 2µg/kg was given.

General anesthesia was induced with sevoflurane 6% and 100% oxygen, trachea was intubated by appropriate size endotracheal tube after intravenous (IV) Atracurium 0.7mg/kg. Reversal and extubation was uneventfull in all patients. Sedation score was estimated by

single observer according to sedation scale.

Parameters observed were

- Time of onset of sedation, Level of sedation and score of sedation.
- Emotional reaction: crying, apprehension and calm.
- Separation reaction: crying, apprehension and good.
- Acceptance reaction to face mask.
- Reaction to intravenous cannulation.
- Side-effects and recovery time.

OBSERVATION & RESULTS

Table 2 shows that both groups were comparable with respect to age, weight & sex ratio without any statistically significant difference.

Table 3 shows there was no statistically significant difference with regard to duration of surgery between the two groups.

Table 4 shows that the Mean sedation score was 2.23 +/- 0.61 in Midazolam group while it was 3.6 +/- 0.23 in ketamine group, which was significant statistically. Anxiolysis score as shown in table was 1.61 +/- 0.31 in group B which it was 2.41 +/- 0.44 in A group. Hence it was observed that Ketamine produce significant anxiolysis when compared to midazolam. Parental separation score was 2.11 +/- 0.36 in A group and 1.87 +/- 0.21 in B group which was statistically.

Score of response to venepuncture was 2.03 +/- 0.48 in A group while it was 1.87 +/- 0.21 in B group which shows significant statistically. Total score of all 4 score in Midazolam group was 7.24 +/- 1.41 while it was 10.15 +/- 1.51 in Ketamine group which is highly significant. Intraoperative vitals i.e. PR and SPO2 were compared and no significant difference was noted.

Table 5 shows that mean onset time of sedation was comparatively lesser in ketamine group as compared to midazolam group. 21.25±2.25 minutes in ketamine group to 22.01±3.05 minutes in midazolam group & the difference was statistically significant. Mean Post op recovery time was also lesser in ketamine group(18±9.71 minutes) as compared to midazolam group(20±8.16 minutes). Side effects like secretion, nausea and vomiting were minimal in both the groups. Post-operative analgesia requirement was 52.64% in group A, while it was 72.61% in group B and the difference was statistically significant.

Table 1. Sedation scale

Score	Sedation	Anxiolysis	Parenteral Separation	Venepuncture
1	Alert	Thrashing	Need to restrain	Fight without success
2	Awake	Crying	Separated with cry	Fight with success
3	Drowsy	Apprehensive	Separated with cry	Minor resistance
4	Asleep	Friendly	Happily separated	No reaction

Table 2. Demographic data

Parameter	Group A	Group B	P-Value
Age (yrs) Mean± S.D	6.43±3.86	5.42±4.21	0.08
Sex (M:F)	13:17	16:14	0.21
Weight (Kg) Mean± S.D.	12±5.81	14±2.87	0.41

Table 3. Duration of surgery

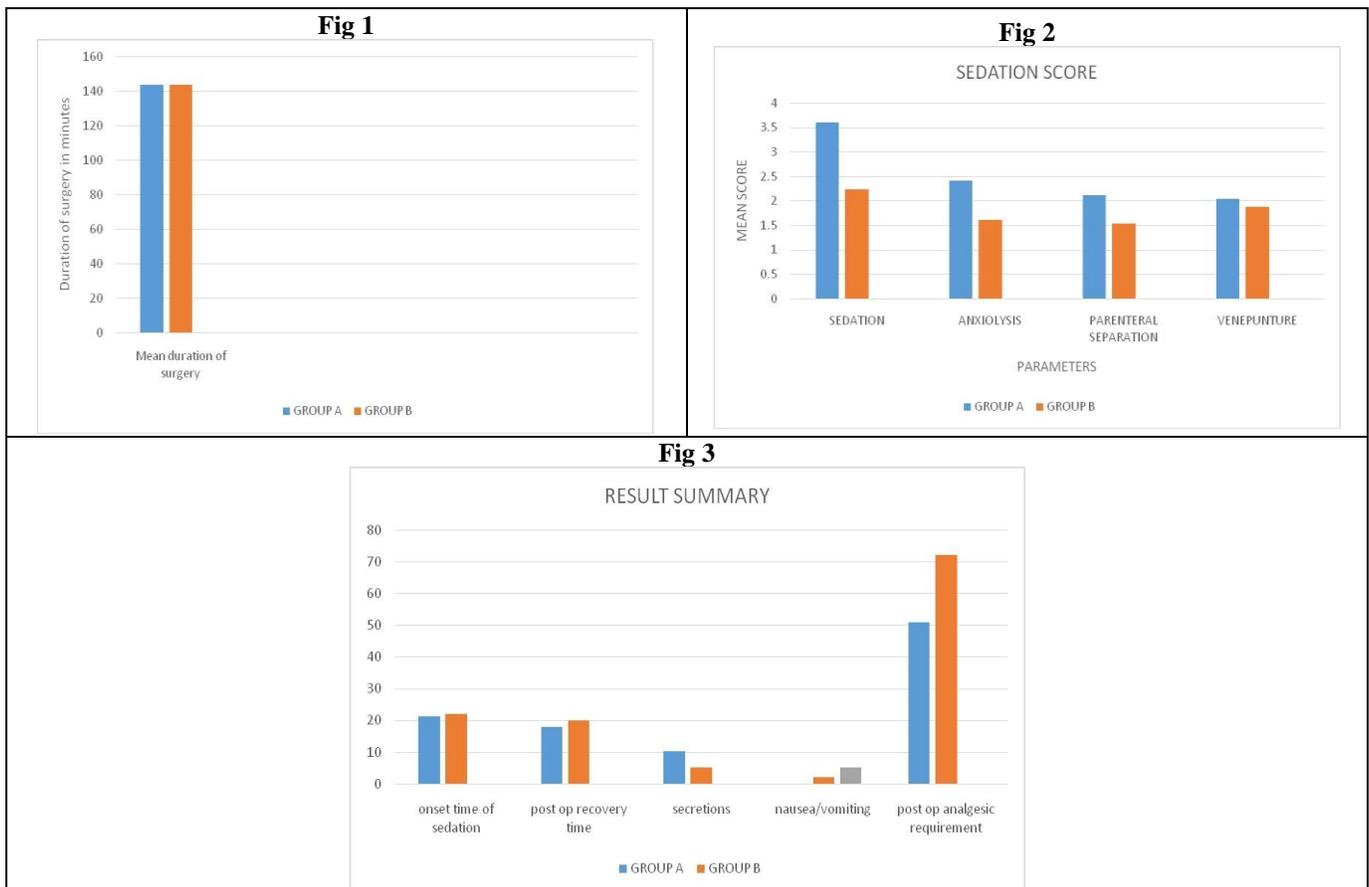
Duration of Surgery	Group A	Group B	P-Value
Time(in minutes) mean ±S.D	144.28±20.32	139.76±23.82	0.73

Table 4. Sedation score

Score	Group A	Group B	P-Value
Sedation	3.6±0.23	2.23±0.61	0.087
Anxiolysis	2.41±0.44	1.61±0.31	0.612
Parental separation	2.11±0.36	1.53±0.38	0.577
Venepuncture	2.03±0.48	1.87±0.21	0.531
Total score	10.15±1.51	7.24±1.41	0.765

Table 5. Result Summary

Parameter	Group A	Group B	P-Valve
Onset time of sedation (in minutes)	21.25±2.25	22.01±3.05	0.052
Post op recovery time	18±9.71	20±8.16	0.061
Secretions	6.15%	5.12%	0.01
Nausea/ Vomiting	0.1%	2.03%	0.021
Post op analgesic requirement	52.64%	72.61%	0.073



DISCUSSION

Problems of traumatizing experiences in young children as a result of forceful separation from parents prior to anaesthesia with stormy induction with painful injection can be overcome by orally acceptable premedication in addition to psychological preparation of children. With 4 mg/kg of ketamine onset time of sedation was 21.25 ± 2.25 min. Gutstein *et al* had also shown similar results in their study [8].

Lin Y C *et al* showed that 6 mg/Kg of ketamine made better sedation and anxiolysis than 0.5 mg/kg of Midazolam [9].

Feld *et al* and Alderson and Larman observed that 0.5 mg/kg of midazolam could not produce sleep in children even after 30min [10]. No data on IV cannulation are available in these two studies.

Kothari *et al* and Jones *et al* recommended that the optimum dose of midazolam for satisfactory sedation, better separation reaction and co-operation during IV cannulation was 0.75mg/kg and not 0.5 mg/kg [11]. Oral premedication with 6mg/kg of ketamine is associated with minimum side effects and post-operative recovery is smooth. With 0.5 mg/kg of midazolam though post operative recovery is quicker, it is associated with irritability in children. It can be concluded that premedication with ketamine at the dose of 4mg/kg orally provides better sedation and anxiolysis in children with minimal side effects than oral midazolam.

Oral premedication with 4mg/kg of ketamine is associated with minimum side effects and post-operative

recovery is smooth. With 0.5 mg/kg of midazolam though post operative recovery is quicker, it is associated with irritability in children. Attitude, facemask acceptance and Intravenous cannulation were excellent in Ketamine group as compared to midazolam Group. These observations were also noted [12].

Separation reaction was good in Ketamine group as compared to midazolam group. These observations were similar to results observed [13]. Intra operative oxygen saturation, pulse rate and respiratory rate had no significant difference in Group A and Group (B) as per study [8].

Post operatively side-effects were minimal as observed in study done by none of the patients had any emergence reaction in our study done [14].

CONCLUSION

From the above study and various studies conducted in past, It can be concluded that premedication with ketamine at the dose of 4 mg/kg orally provides better sedation and anxiolysis in children with minimal side effects than oral premedication with midazolam at the dose of 0.5 mg/kg

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CONFLICT OF INTEREST:

The authors declare that they have no conflict of interest.

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