

Original Research Article

COMPARISON OF ORAL PREMEDICATION IN CHILDREN (1-16 YEARS) USING MIDAZOLAM VERSUS CLONIDINE: A PROSPECTIVE DOUBLE-BLIND STUDY

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ABSTRACT

Background: Premedication in pediatric anesthesia is a challenge for Anesthesiologist. Anxious children have higher incidence of negative postoperative behaviors for up to two weeks after surgery. Hence, right premedication is the eternal search for anesthesia fraternity. The aim and objective is to compare oral midazolam (0.5mg/kg) with oral clonidine (4 micro-grams/kg) as a pre medication in children.

Materials and Methods: This study was carried out on 30 children who were admitted to Yenepoya Medical College & Hospital for surgical intervention under general anaesthesia during the period from 01-10-2009 to 30-11-2011.

Results: In the midazolam group the mask acceptance was good in 86.7% of the subjects. In the Clonidine group 100% of the subjects had good acceptance. In the midazolam group parental separation were good only in 56% of the subjects where as it was 93.3% in the Clonidine group which is statistically highly significant. In the midazolam group the sedation score after 30 mins and 90 mins, 80% of the subjects were awake. In the Clonidine group it was found that 66.7% are drowsy at 30 mins and 70% are drowsy at 90 mins. The difference between the groups was statistically highly significant.

Conclusion: Present study showed that premedication oral clonidine appeared to superior than oral midazolam. Oral clonidine produces significantly better sedation than oral midazolam.

Keywords: Consumer Protection Act, CPA 2019, medical negligence, informed consent, litigation, healthcare law, patient rights, defensive medicine, India.

INTRODUCTION

Anesthesiologists is bestowed with the challenge to minimize psychological upset and scaring for children in the operating theatre and to conduct a smooth induction of anesthesia.^[1] Premedications often finds as important armament for anesthetist. Premedication are the drugs administered before induction of anesthesia which act as a antisialogogue, sedative agents, analgesics and antacid.

Apprehension and fear of operation, physicians, needles, theater sight, and parental separation can cause traumatizing experiences in young children resulting in postoperative maladaptive behavioral changes leading to terrible experiences in young children.

To the parents important thing is their child safety. Usually parents are not aware of any events taking place inside an operating room. Evaluation of the physician takes place in holding room based on the separation experience with their child. Researches has documented that the child's resultant fear and distress on the day of the surgery extends beyond the immediate postoperative period. Anxious children have higher incidence of negative postoperative behaviors for up to two weeks after surgery.

Furthermore recent investigation concluded that "stormy induction" are associated with a significantly increased occurrence of postoperative maladaptive behavioral changes.^[2] Therapy for Pre-anaesthetic anxiety comprises two parts Psychological preparation and treatment with anxiolytic drugs.

The psychological approach to deal with anxiety is to allow one parent accompany the children into the operation theatre. Some studies suggest reduced anxiety and increased cooperation if parents were present during induction.^[3] However all recent controlled investigations indicate that routine parental presence is not beneficial.^[4] Thus in addition to psychological preparation, sedation before surgery is an effective and widely used method for decreasing anxiety in young children.

The goals of premedication in children are:

- Facilitate a smooth and anxiety-free separation from the parents and induction of anesthesia.
- Administration of analgesics if the patient is in pain or if strategy of pre-emptive analgesia is planned.
- Provide perioperative amnesia.
- Supplement and reduce the requirement of drugs
- Antisialagogue effect: Although various combination of drugs and routes of administration have been used in children for preanaesthetic sedation, oral route remains the least threatening and most accepted methods of drug administration. It is painless easy and reliable.^[5] In this study an attempt is made to compare midazolam, a gold standard premedication in pediatric patients, with an alpha 2 agonist clonidine as a premedication in children which has desirable sedative properties which are yet to be fully explored. For effective premedication the drug has to be administered 2hrs before induction of anaesthesia.

Aims and Objectives

Aim: To compare oral midazolam (0.5mg/kg) with oral clonidine (4 micrograms/kg) as a pre medication in children

Objectives

- To assess the pre operative sedation
- To assess face mask acceptance during induction
- To assess the emergence agitation during recovery
- To compare the vital parameters

MATERIALS AND METHODS

Source of Data: This study was carried out in children who were admitted to Yenepoya Medical College & Hospital for surgical intervention under general anaesthesia during the period from 01-10-2009 to 30-11-2011.

Sample Size: 30 subjects in each group

Inclusion Criteria

- Patients of age between 1 to 16 years
- ASA type I & II Both
- Children undergoing elective Surgery lasting less than two hours

Exclusion Criteria

- Patients with ASA type III & IV
- Developmental or congenital anomaly.

Methodology: Sixty pediatric patients belonging to ASA II and I between the age group 1-16 yrs scheduled for elective surgery in YMC hospital were the study group. An informed consent was taken from the parents of the children.

The children were allocated into one of two groups. Group I received oral midazolam 2hrs before surgery. The drug used was the injectable 1mg/ml preservative free ampoules. The drug was mixed with paracetamol syrup to mask the bitter taste during administration. Group II received oral clonidine 4 mcg /kg 2hrs before surgery. Oral clonidine was prepared by dissolving crushed tablets of oral clonidine 4mcg/kg 2hrs as per body weight dose in paracetamol syrup. The heart rate, blood pressure, were noted before and after premedication.

Parental separation was assessed holding room. Mask acceptance was noted before induction of anaesthesia.

Emergence agitation was noted after extubation inside the theatre after shifting to the postoperative room.

Vital signs were analysed with unpaired student t test. Sedation, parental separation, mask acceptance, emergence agitation was compared using chi square test. A p value less than 0.05 was considered statistically significant.

Scoring system

Table 1: Sedation scoring:

Score	Status
1	Awake
2	Drowsy
3	Asleep

Table 2: Mask acceptance scoring:

Score	Status
1	Accepted
2	Not accepted

Table 3: Parental separation scoring:

Score	Status
1	Poor
2	Good

Table 4: Emergency agitation scoring:

Score	Status
1	No
2	Yes

RESULTS

Table 5: Age profile

Groups	N	Mean	SD	P value
1.00	30	7.57	2.85	0.75
2.00	30	7.83	3.74	

* Not significant

Table 6: Pulse rate

Group	Time	Pulse Rate (Mean)	SD	F	P value
I	Before 30	95.33	5.09		
	After 30	100.93	9.84		

	After 90	95.86	8.64	4.35	0.016*
II	Before 30	91.43	6.95		
	After 30	92.30	6.182		
	After 90	91.76	6.886	0.128	0.880

*Significant

Table 7: Systolic Blood pressure

Timings	Group	N	Mean	SD	P Value
Before	I	30	98.83	5.68	0.858*
	II	30	99.13	7.19	
30 minutes	I	30	98.80	6.04	0.721*
	II	30	99.40	6.88	
90 minutes	I	30	97.80	4.51	0.759*
	II	30	98.26	6.71	

*Not Significant

Table 8: Sedation score 30 minutes

State	Group I	Group II	Total
Sleep	0 (0%)	2 (6.7%)	2 (3.3%)
Awake	24 (80%)	8 (26.7%)	32 (53.3%)
Drowsy	6 (20%)	20 (66.7%)	26 (43.3%)
Total	30 (100%)	30 (100%)	60 (100%)

Table 9: Sedation score 90 minutes

State	Group I	Group II	Total
Sleep	0 (0%)	1 (3.3%)	1 (1.7%)
Awake	24 (80%)	8 (26.7%)	32 (53.3%)
Drowsy	6 (20%)	21 (70%)	27 (45%)

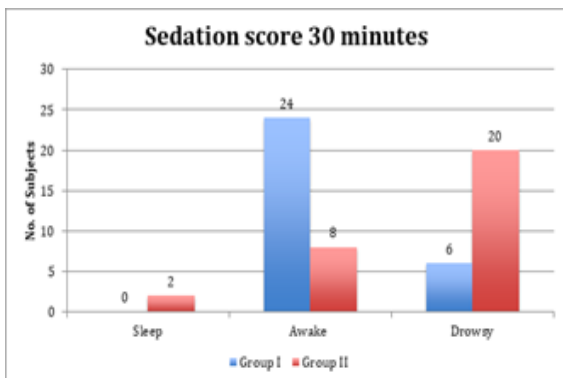


Figure 1

Total 30(100%) 30(100%) 60(100%)

*Significant (p <0.05)

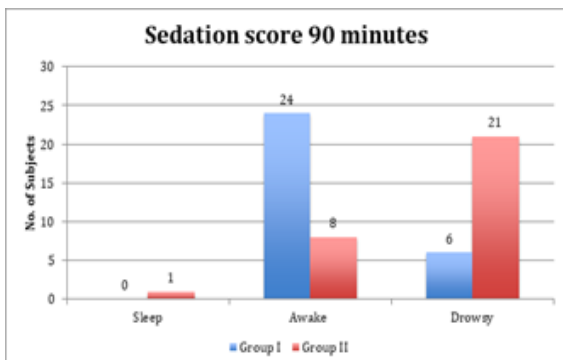


Figure 2

Table 10: Parental separation score

State	Group I	Group II	Total
Good	17 (56.7%)	28 (93.3%)	45 (75%)
Poor	13 (43.3%)	2 (6.7%)	15 (25%)
Total	30 (100%)	30 (100%)	60 (100%)

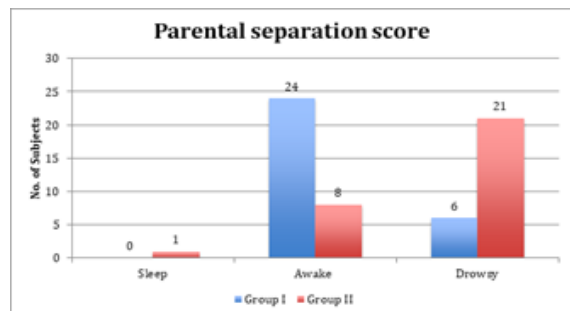


Figure 3

Table 11: Mask acceptance

State	Group I	Group II	Total
Bad	4 (13.3%)	0 (0%)	4 (6.7%)
Good	26 (86.7%)	30 (100%)	56 (93.3%)
Total	30 (100%)	30 (100%)	60 (100%)

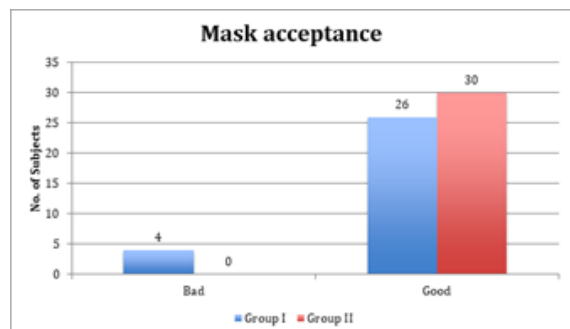


Figure 4

DISCUSSION

The quest for an ideal premedication in pediatric patient is still on. The need for adequate sedation and anxiolysis is widely accepted. Midazolam for a long

time has been considered gold standard for premedication in children.^[6] Clonidine possesses other preoperative benefits and lacks the major side effects of midazolam.^[7]

In this study the midazolam group and the Clonidine group, the age and gender were comparable and their p value is more than 0.05 and is not statistically significant.

In the midazolam group the sedation score after 30 mins and 90 mins, 80% of the subjects were awake. In the Clonidine group it was found that 66.7% are drowsy at 30 mins and 70% are drowsy at 90 mins. The difference between the groups was statistically highly significant.

In the midazolam group parental separation were good only in 56% of the subjects where as it was 93.3% in the Clonidine group which is statistically highly significant.

In the midazolam group the mask acceptance was good in 86.7% of the subjects. In the Clonidine group 100% of the subjects had good acceptance. Statistically the difference between the two groups are significant.

The emergence agitation between two groups were comparable and the study failed to demonstrate any group better than other in this parameter. Vitals were also recorded preoperative, pulse rate and blood pressure and it was found that both, the midazolam group and the Clonidine group did not show any bradycardia or hypotension.

Mikawa et al conducted a study involving oral diazepam 0.4mg/kg and Clonidine 4 microgram/kg and 2 microgram/kg orally. Results showed that Clonidine produced significant sedation and the effect was dose related. Clonidine 0.4mcg/kg provided better separation and acceptance of mask than the other two regimen.^[8]

In a study Almerander et al compared the clinical effects of oral midazolam and oral Clonidine as a premedication. They studied the onset of sedation quality of mask induction and emergence agitation. They concluded that oral Clonidine appear superior to oral midazolam in sedation and mask induction. Those children who had oral Clonidine had less emergence agitation and higher degree of parental satisfaction.^[9]

Malde et al studied the effect of premedication with oral Clonidine 2 mcg/kg and 4 mcg/kg versus diazepam 0.2mg/kg in children in the age group of 2-12 years. Patients receiving 4mcg/kg and 2mcg/kg Clonidine had better sedative effects. Among two Clonidine groups the group receiving 4 mcg/kg gave better sedative effect. Without any significant intergroup difference both Clonidine group gave better parental separation and mask acceptance scores compared to diazepam.^[10]

All the three studies mentioned above had similar outcomes to our result ie better sedation parental separation and mask acceptance in the Clonidine group compared to the midazolam group. But emergence agitation was comparable between the

two groups and the results were satisfactorily not significant.

Table 12: Emergent agitation

State	Group I	Group II	Total
No	30 (100%)	30 (100%)	60 (100%)
Total	30 (100%)	30 (100%)	60 (100%)

A study done roshni sreedharan et al using oral midazolam 0.5mg/kg 30 mins before induction of anaesthesia and oral atropine 20 mcg/kg 60 min before induction of anaesthesia compared with oral Clonidine 4mcg/kg along with oral atropine 20 mcg/kg 60min prior to induction of anaesthesia along with a placebo reported that oral midazolam providing better sedation peaceful parental separation and better mask tolerance. Here the superiority of midazolam compared to Clonidine can be explained by the short duration between the administration of drug and induction of anaesthesia 60 mins compared to our study which was 120 mins and the other studies mentioned above was 90 minutes. The result showed no significant bradycardia or hypotension in the either group which is comparable to the study conducted by Roshni Sreedharan et al and Fazi et al.^[11]

CONCLUSION

The result showed that premedication oral clonidine appeared to superior than oral midazolam. Oral clonidine produces significantly better sedation than oral midazolam. Hence clonidine shown to have useful sedative properties that ease in separation of children from parents. Quality of mask acceptance clonidine group had better acceptance. Both clonidine and midazolam group did not cause significant changes such as bradycardia or hypotension prior to induction of anaesthesia. The study failed in demonstrating oral clonidine better than oral midazolam in reducing the incidence of emergence agitation. To conclude oral clonidine with good sedation, parental separation and quality of mask acceptance can be considered as an alternative to midazolam for premedication in paediatric patients.^[1-11]

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