

## Original Article

# Comparison of Clonidine with Midazolam as premedication agent in Children: A Clinical Study

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### ABSTRACT:

**Background:** Child management is a challenging task in any procedure. Induction of anaesthesia in children is stressful procedure during the peri-operative period. The aim of the present study is to compare the efficacy of midazolam with clonidine as a premedication in children. **Materials & methods:** This study was conducted in department of anaesthesia in 2011. This study comprised of 80 children with ASA grade I and II were selected. Pre - anaesthetic check up was done in all children including physical examination. They were divided into 2 groups of 40 children each. Group I (40) received 4mcg/kg of oral clonidine while group II (40) received 0.5mg/kg as a premedication about 1 hour before induction of anaesthesia. We compared drug acceptance, sedation level, anxiety score, parental separation score and quality of induction in both groups. **Results:** The acceptance for clonidine was better as compared to midazolam. The difference was significant (P<0.01). The onset of sedation was earlier in group I as compared to group II. It was significantly more at 30 minutes and 45 minutes. The level of sedation was better in group I as compared to group II. A satisfactory sedation with a sedation score of  $\geq 2$  was achieved in 100% of the children in both groups. These results were found to be statistically insignificant (P>0.05). There was no significant difference in the onset of anxiolysis and in the satisfactory anxiolysis in both the groups (P>0.05). However, the quality of the pre-operative anxiolysis was significantly better in group I (P<0.05). 4 patients in group I and 8 patients in group II showed score 1. 10 patients in group I and 16 patients in group II showed score 2. 26 patients in group I and 16 patients in group II showed score 3. The quality of parental separation was better in group I as compared to group II. The difference was significant (P<0.05). The quality of induction was better in group I as compared to group II. The difference was significant (P<0.01). **Conclusion:** Author concluded that clonidine is better pre anesthetic agent as compared to midazolam. Better sedation, anxiolytic, parental separation and quality of induction was seen with clonidine. Hence it can be use as an alternative to midazolam.

**Key words:** Clonidine, midazolam, premedication

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## INTRODUCTION

Child management is a challenging task in any procedure. Induction of anaesthesia in children is stressful procedure during the peri-operative period. Children are particularly vulnerable to the global surgical stress response because of the limited energy of the reserves, large brain masses and the obligatory glucose requirements. Post-operative pain, sleeping

disturbances, parent child conflict and separation anxiety in children are factors that effects the child management and surgical procedure. It also activates the human stress response, leading to increased levels of serum cortisol and epinephrine and natural killer cell activity.<sup>1</sup>

A variety of non pharmacological and pharmacological measures have been tried in reducing pre-operative anxiety in children.

Pharmacological agents such as sedatives and non-pharmacological agents such as parental presence, behavioural preparation programs, music, acupuncture, etc are widely used in order to relieve pain and anxiety in children.<sup>2</sup>

Most commonly used pharmacological agent is midazolam which is a benzodiazepine which produces amnestic, hypnotic, anxiolytic and skeletal muscle relaxant effects. It is paediatric premedication. The route of administration is intranasal, sublingual, rectal and the oral routes. It has rapid onset and short half life. Though it is widely used agent in children, various disadvantages are seen with its use. It is associated with a delay in either the discharge of the patients from the hospital or in the recovery time. Few studies have reported maladaptive behavioural changes in few children.<sup>3,4</sup> Another effective agent is clonidine, introduced in 1993. It has significant sedative and analgesic properties. It is another agent used in premedication in children. It has been shown that oral clonidine effectively produces pre-operative sedation and anxiolysis in children, it acts as an analgesic, it decreases the volatile anaesthetic agent requirement and also improves the peri-operative haemodynamic stability. Clonidine can be administered orally (4 mcg/kg) and intranasally (2mcg/kg).<sup>5</sup> The aim of the present study is to compare the efficacy of midazolam with clonidine as a premedication in children.

## MATERIALS & METHODS

This study was conducted in department of anaesthesia in 2011. An informed written consent was taken from the parents of the children. After getting consent, patients particulars such as name, age, sex etc was recorded. This study comprised of 80 children with ASA grade I and II were selected. Pre-anaesthetic check up was done in all children including physical examination. They were divided into 2 groups of 40 children each. Group I (40) received 4mcg/kg of oral clonidine while group II (40) received 0.5mg/kg as a premedication about 1 hour before induction of anaesthesia. Both drugs were given by crushing the tablet in honey.

**DRUG ACCEPTANCE:-** It was noted as 1 = good, 2 = indifferent and 3 = bitter and unpleasant. Children's vital signs such as heart rate, blood pressure, respiratory rate, oxygen saturation and the sedation and anxiety levels were noted at the time of

administration of the premedication and then they were monitored continuously. The readings were recorded at 0, 15, 30, 45 and 60 minutes.

**SEDATION LEVEL:-** It was assessed as 1 = awake, 2 = drowsy, and 3 = asleep. A sedation score of  $\geq 2$  was considered as satisfactory.

**ANXIETY SCORE:-** It was evaluated by a 4-point scale: 1 = crying, very anxious, 2 = anxious, not crying, 3 = calm, but not cooperative and 4 = calm, cooperative or asleep. The anxiolysis score of  $\geq 3$  was considered as satisfactory.

**PARENTAL SEPERATION SCORE:-** The separation of the children from their parents was evaluated on a three point scale: 1 = Poor: Anxious or combative, 2 = Good: Anxious but easily assured and 3 = Excellent : Calm/Sleeping.

**QUALITY OF THE INDUCTION:-** It was evaluated on a 5-point scale: 1 = combative, crying, 2 = moderate fear of the mask, not easily calmed, 3 = cooperative with reassurance, 4 = calm, cooperative and 5 = asleep, steal induction.

All the children received intravenous atropine 0.02 mg/kg body weight. Anaesthesia was induced by giving propofol 2 mg/kg body weight intravenously, plus 60% nitrous oxide and 40% oxygen with incremental halothane administration from the start of 0.5% induction upto 3%, depending on the requirement. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

## RESULTS

Table I shows data of patients. The age range in group I was  $6.02 \pm 1.26$  years and in group II  $5.6 \pm 1.26$  years. Weight was  $20.0 \pm 4.21$  kg in group I and  $19.2 \pm 3.14$  Kg in group II. The time for surgery in group I was  $40.2 \pm 6.24$  minutes in group I and  $41.6 \pm 4.12$  minutes in group II. The difference among both groups was non significant (P-0.2).

The drug acceptance score was compared in both the groups. The acceptance for clonidine was better as compared to midazolam. The difference was significant (P-0.01) (Table II).

The onset of sedation was earlier in group I as compared to group II. It was significantly more at 30 minutes and 45 minutes. The level of sedation was better in group I as compared to group II (Table II).

A satisfactory sedation with a sedation score of  $\geq 2$  was achieved in 100% of the children in both groups. These results were found to be statistically insignificant ( $P>0.05$ ) (Table III). Table IV shows anxiety scores in both groups. There was no significant difference in the onset of anxiolysis and in the satisfactory anxiolysis in both the groups ( $P>0.05$ ). However, the quality of the pre-operative anxiolysis was significantly better in group I ( $P<0.05$ ). Graph I shows parental separation score in

both the groups. 4 patients in group I and 8 patients in group II showed score 1. 10 patients in group I and 16 patients in group II showed score 2. 26 patients in group I and 16 patients in group II showed score 3. The quality of parental separation was better in group I as compared to group II. The difference was significant ( $P<0.05$ ). Graph II shows that the quality of induction was better in group I as compared to group II. The difference was significant ( $P<0.01$ ).

**Table I:** Patient Particulars

	<b>Group I</b>	<b>Group II</b>
AGE	6.02±1.26	5.6±1.26
GENDER	<b>20/20</b>	<b>20/20</b>
WEIGHT	20.0±4.21	19.2±3.14
ASA I/II	70/30	75/25
TIME FOR SURGERY (MINS)	40.2±6.24	41.6±4.12

**Table II:** Drug acceptance score in both groups

<b>Score</b>	<b>Group I</b>	<b>Group II</b>
<b>1</b>	22	18
<b>2</b>	12	10
<b>3</b>	6	12

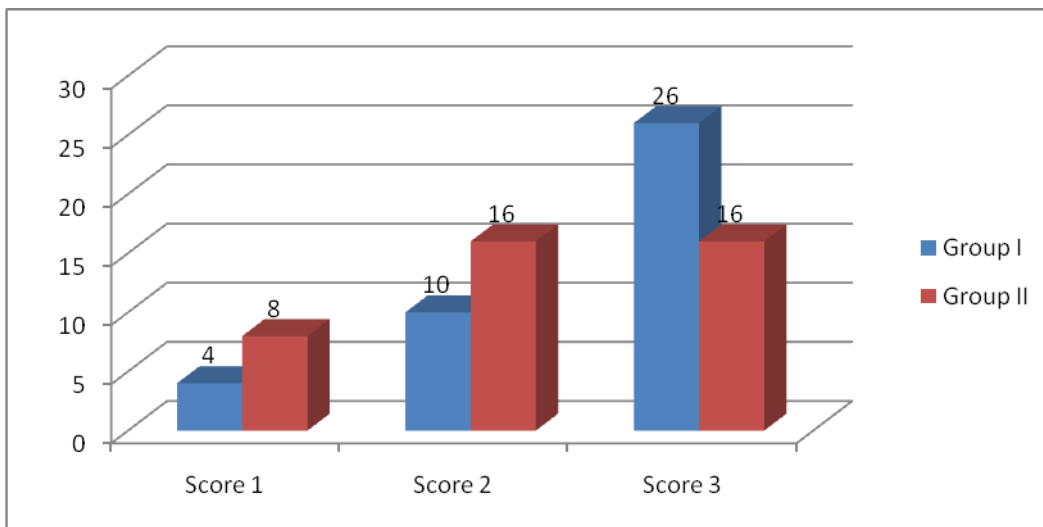
**Table III:** Sedation scores in both groups

<b>Time (Mins)</b>	<b>Group I</b>			<b>Group II</b>			<b>P value</b>
	1	2	3	1	2	3	
<b>0</b>	40	0	0	40	0	0	-
<b>15</b>	36	4	0	34	6	0	0.2
<b>30</b>	24	10	6	12	18	4	0.04
<b>45</b>	6	4	12	4	2	4	0.01
<b>60</b>	0	2	4	0	4	4	0.1

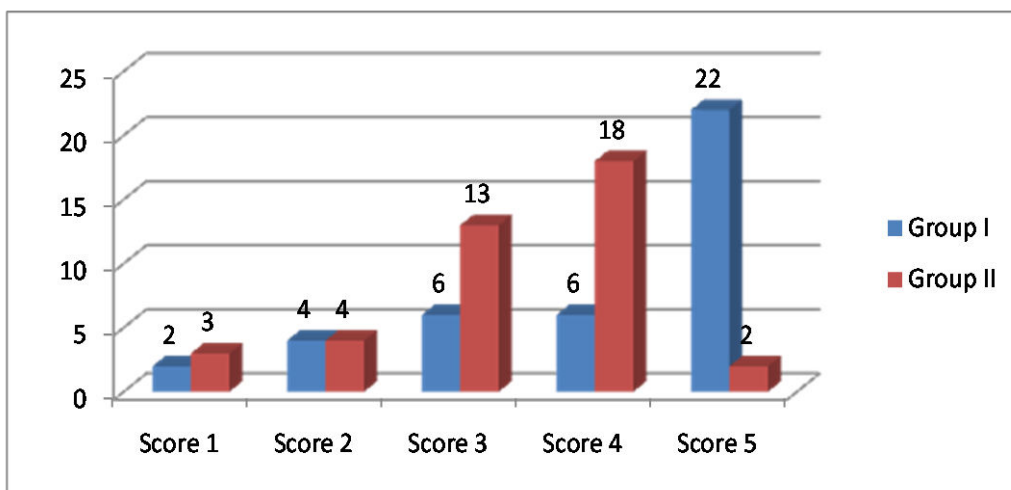
**Table IV:** Anxiety scores in both groups

<b>Time (Mins)</b>	<b>Group I</b>				<b>Group II</b>				<b>P value</b>
	1	2	3	4	1	2	3	4	
<b>0</b>	32	8	0	0	34	6	0	0	-
<b>15</b>	1	4	34	1	0	2	34	4	1
<b>30</b>	24	10	6	0	12	18	4	6	0.02
<b>45</b>	0	2	4	8	0	0	8	0	0.01
<b>60</b>	0	1	2	4	0	0	2	2	0.1

**Graph I Parental separation score in both groups**



**Graph II: Quality of induction in both groups**



**DISCUSSION**

The management of children in any surgical procedure is a challenging task. The main problem is the age of the children. The anxiety level is quite high in children as compared to adults. Hence the main purpose of any procedure is achieved by reducing anxiety and pain in children before starting any process. The aim of the present study is to compare the efficacy of midazolam with clonidine as a premedication in children.

This study was conducted in department of anaesthesia in 2011. This study comprised of 80 children with ASA grade I and II were selected. Pre - anaesthetic check up was done in all children including physical examination. They were divided

into 2 groups of 40 children each. Group I (40) received 4mcg/kg of oral clonidine while group II (40) received 0.5mg/kg as a premedication about 1 hour before induction of anaesthesia.

In present study, we compared the drug acceptance in both groups. We found group I has better drug acceptance as compared to group II. Similar results were seen in study of Horn EP.<sup>6</sup> The onset of sedation was earlier in group I as compared to group II. It was significantly more at 30 minutes and 45 minutes. The level of sedation was better in group I as compared to group II. A satisfactory sedation with a sedation score of  $\geq 2$  was achieved in 100% of the children in both groups. Almenrader et al.<sup>7</sup> conducted a study and they

achieved a significantly better level of sedation with oral clonidine than with oral midazolam, but clonidine needed to be administered at least 45 minutes prior to the induction for an optimum sedation, which could be achieved in 30 minutes with oral midazolam. We compared anxiety scores in both groups and found that it was better in group I as compared to group II. McCann<sup>8</sup> found similar results in his study. We also compared parental separation score in both groups. The quality of parental separation was better in group I as compared to group II. Peterson<sup>9</sup> found similar results in his study. The quality of induction was better in group I as compared to group II. Fazi et al<sup>10</sup> in his study found clonidine as better pre- anaesthetic agent as compared to midazolam.

### CONCLUSION

Author concluded that clonidine is better pre anesthetic agent as compared to midazolam. Better sedation, anxiolytic, parental separation and quality of induction was seen with clonidine. Hence it can be use as an alternative to midazolam.

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