

Assessment of Efficacy of Clonidine with Midazolam as Premedication Agent: A Comparative Study

Randhir Singh¹, Rangit Priyakar Pandey^{2*}

¹Assistant Professor, ^{2*}Associate Professor, Department of Anaesthesia, Rajshree Medical Research Institute & Hospital, Bareilly, Uttar Pradesh, India.

ABSTRACT

Background: The present study was conducted to compare the efficacy of midazolam with clonidine as a premedication in children.

Materials & Methods: This study was conducted in department of anaesthesia, Rajshree Medical Research Institute & Hospital, Bareilly, Uttar Pradesh (India) on 50 children with ASA grade I and II were selected. They were divided into 2 groups of 25 children each. Group I received 4mcg/kg of oral clonidine while group II received 0.5mg/kg as a premedication about 1 hour before induction of anaesthesia. We compared drug acceptance and sedation level in both groups.

Results: In group I, score 1 was seen in 11, 2 in 7 and 3 in 8 children. In group II, score 1 was seen in 14, 2 in 6 and 3 in 5 children. Score 1 was seen in 12, score 2 in 10 and score 3 in 3 children at 15th minutes. At 30th minute, score 1 was seen in 14, score 2 in 9 and score 3 in 2 children. At 60th minute, score 1 was seen in 15 children, score 2 in 10 children. Score 1 was seen in 22, score 2 in 3 at 15th minutes. At 30th minute, score 1 was seen in 20, score 2 in 2 and score 3 in 3 children. At 60th

minute, score 1 was seen in 18 children, score 2 in 3 and score 3 in 4 children. The difference was significant (P<0.01).

Conclusion: Clonidine found to be better pre anesthetic agent as compared to midazolam. Better sedation, and drug acceptance score makes it as an alternative to midazolam.

Key words: Children, Clonidine, Midazolam.

*Correspondence to:

Dr. Rangit Priyakar Pandey,
Associate Professor,
Department of Anaesthesia,
Rajshree Medical Research Institute & Hospital,
Bareilly, Uttar Pradesh, India.

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INTRODUCTION

Administration of anesthesia in children is a tedious task. Child management is a challenging task in any procedure. Induction of anaesthesia in children is stressful procedure during the peri-operative period. 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.¹⁻³ It has been observed that 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.^{4,5}

Studies have revealed that midazolam which is a benzodiazepine which produces amnestic, hypnotic, anxiolytic and skeletal muscle relaxant effects. It is pediatric premedication. The route of administration is intranasal, sublingual, rectal and the oral routes. It has rapid onset and short half-life. Clonidine introduced in 1993 is another effective agent.⁶ 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 hemodynamic stability.⁴ The present study was conducted to compare the efficacy of midazolam with clonidine in children.

MATERIALS & METHODS

This study was conducted in department of Anaesthesia, Rajshree Medical Research Institute & Hospital, Bareilly, Uttar Pradesh, India. It consisted of 50 children with ASA grade I and II. An informed written consent was taken from the parents of the children. The study design was approved by the institutional ethical committee.

Patients particulars such as name, age, sex etc was recorded. Pre-anaesthetic checkup was done in all children including physical examination. All were divided into 2 groups of 25 children each. Group I received 4mcg/kg of oral clonidine and group II received 0.5mg/kg as a premedication about 1 hour before induction of anaesthesia.

Drug acceptance was recorded as good, indifferent, bitter and unpleasant. Sedation level was recorded as 1 = awake, 2 = drowsy, and 3 = asleep. Anxiety score 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. 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

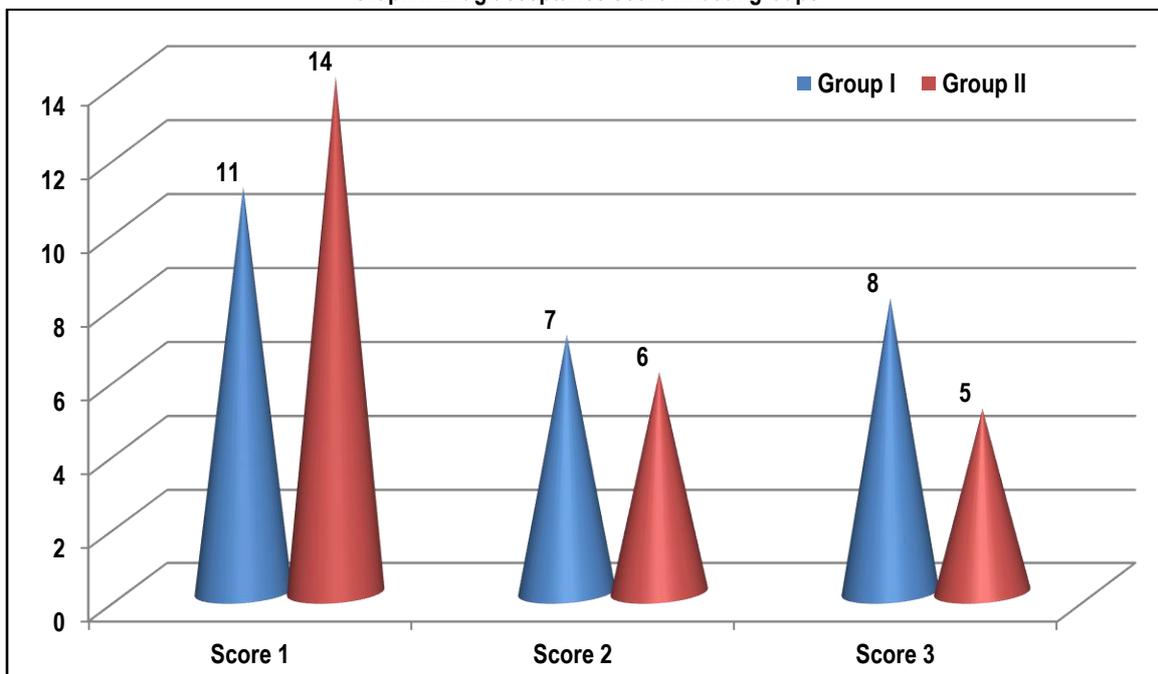
In group I, score 1 was seen in 11, 2 in 7 and 3 in 8 children. In group II, score 1 was seen in 14, 2 in 6 and 3 in 5 children.

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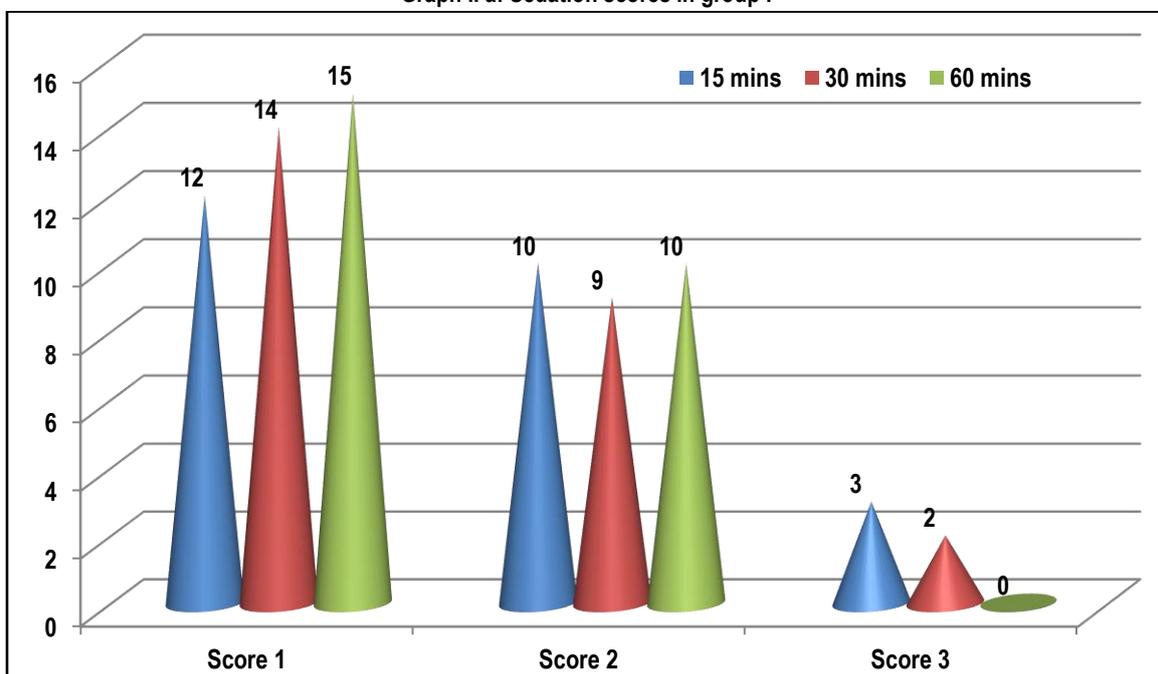
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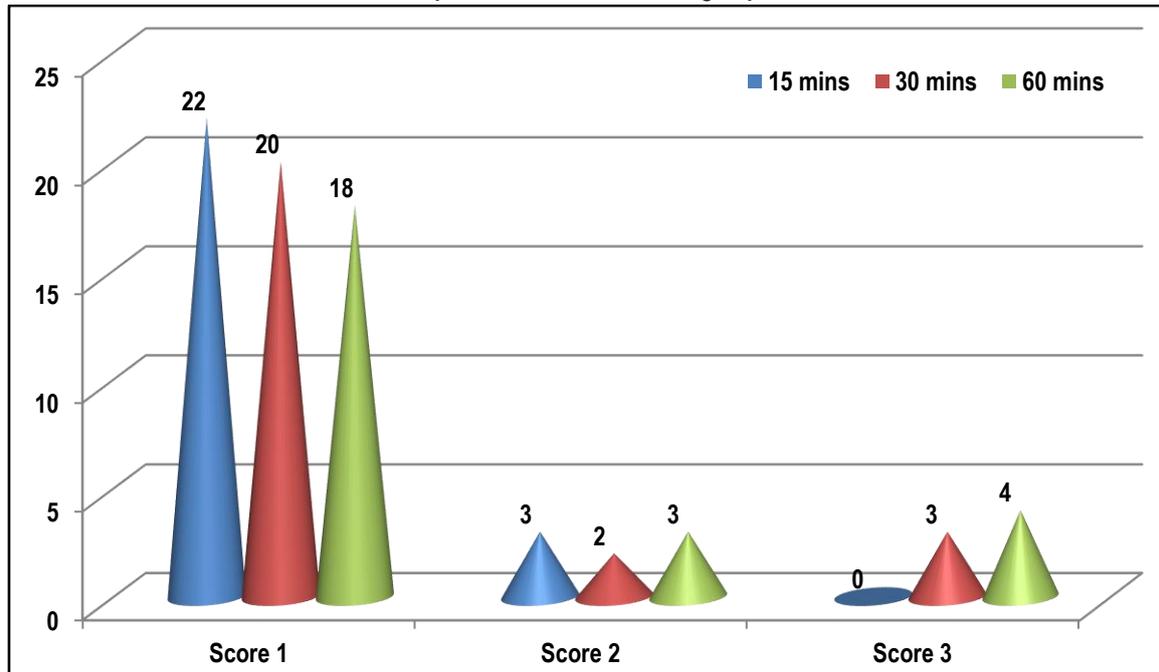
Graph I: Drug acceptance score in both groups



Graph II a: Sedation scores in group I



Graph II b: Sedation scores in group II



DISCUSSION

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. The main problem is the age of the children. The anxiety level is quite high in children as compared to adults.⁵ The present study was conducted to compare the efficacy of midazolam with clonidine as a premedication in children.

In present study, we compared the drug acceptance in both groups. We found group I has better drug acceptance as compared to group II. In group I, score 1 was seen in 11, 2 in 7 and 3 in 8 children. In group II, score 1 was seen in 14, 2 in 6 and 3 in 5 children.

Mahajan et al¹⁰ conducted a study in which children were randomly divided into two groups and they were given either clonidine 4 mcg/kg (Group I, n=30) or midazolam 0.5 mg/kg (Group II, n=30) orally, which were dissolved in honey and water solution, 60 minutes prior to the mask induction. The drug acceptance, pre-operative sedation and anxiolysis, parental separation, quality of induction and mask acceptance, the effect on the hemodynamic and the adverse effects were evaluated. They found that oral clonidine tasted significantly better than oral midazolam. The onset of the sedation was significantly faster after the premedication with midazolam (30.5 ± 10.8 minutes) than with clonidine (38.5 ± 12.26 minutes). A satisfactory sedation could be achieved with both the drugs, but the quality of the sedation was significantly better after the premedication with clonidine. The difference in the onset of the anxiolysis was found to be statistically insignificant. A satisfactory anxiolysis was achieved with both, but the quality of the anxiolysis was better with clonidine. The quality of the mask induction was equally satisfactory in both the groups. A steal-induction was performed on 56.7% of the patients of the clonidine group, but on none in the midazolam group. No adverse effects like bradycardia,

hypotension, hypoxaemia or apnoea were observed during the peri-operative period in both the clonidine and the midazolam groups.

We compared sedation score in both groups. Score 1 was seen in 12, score 2 in 10 and score 3 in 3 children at 15th minutes. At 30th minute, score 1 was seen in 14, score 2 in 9 and score 3 in 2 children. At 60th minute, score 1 was seen in 15 children, score 2 in 10 children. Score 1 was seen in 22, score 2 in 3 at 15th minutes. At 30th minute, score 1 was seen in 20, score 2 in 2 and score 3 in 3 children. At 60th minute, score 1 was seen in 18 children, score 2 in 3 and score 3 in 4 children. The level of sedation was better in group I as compared to group II. A satisfactory sedation with a sedation score of ≥ 2 was achieved in 100% of the children in both groups. This is in agreement with Ajay et al.¹⁰ Almenrader et al.¹¹ 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.

CONCLUSION

Clonidine found to be better pre anesthetic agent as compared to midazolam. Better sedation, and drug acceptance score makes it as an alternative to midazolam.

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