A Comparative Evaluation of Efficacy of Clonidine & Midazolam: An Institutional Based study

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ABSTRACT
Background: Child management is a challenging task in any procedure. The present study was conducted to compare midazolam with clonidine.

Materials & Methods: This study was conducted in Department of Anesthesiology, Santosh Medical College & Hospital, Ghaziabad, Uttar Pradesh (India) on 40 children with ASA grade I and II. We compared drug acceptance and quality of induction in both groups.

Results: The age range in group I was 6.14±1.20 years and in group II 5.8±1.24 years. Weight was 21.0±4.4 kg in group I and 19.6±3.04 Kg in group II. The time for surgery in group I was 38.2±6.6 minutes in group I and 40.2±4.9 minutes in group II. The difference was non-significant (P>0.05). The acceptance for clonidine was better as compared to midazolam. The difference was significant (P<0.01). The quality of induction was better in group I as compared to group II. The difference was significant (P<0.01).

Conclusion: Clonidine is better pre-anesthetic agent as compared to midazolam. It can be used as an alternative to midazolam.

Key words: Anesthetic, Clonidine, Midazolam.

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INTRODUCTION
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 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.² Midazolam 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. 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.³ Clonidine was introduced in 1993. It has significant sedative and analgesic properties. It is another agent used in premedication in children.⁴ 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. The present study was conducted to compare midazolam with clonidine.

MATERIALS & METHODS
This study was conducted in Department of Anesthesiology, Santosh Medical College & Hospital, Ghaziabad, Uttar Pradesh (India). This comprised of 40 children with ASA grade I and II were selected. An informed written consent was taken from the parents of the children. Pre-anesthetic checkup was done in all children including physical examination. They were divided into 2 groups of...
20 children each. Group I (20) received 4mcg/kg of oral clonidine while group II (20) received 0.5mg/kg as a premedication about 1 hour before induction of anaesthesia. Drug acceptance 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. Sedation level was assessed as 1 = awake, 2 = drowsy, and 3 = asleep. A sedation score of ≥2 was considered as satisfactory. Quality of the induction 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. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS
Table I shows that the age range in group I was 6.14±1.20 years and in group II 5.8±1.24 years. Weight was 21.0±4.4 kg in group I and 19.6±3.04 Kg in group II. The time for surgery in group I was 38.2±6.6 minutes in group I and 40.2±4.9 minutes in group II. The difference was non- significant (P>0.05).

Graph I shows that the acceptance for clonidine was better as compared to midazolam. The difference was significant (P<0.01). 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: Demographic data of patients

<table>
<thead>
<tr>
<th>Particulars</th>
<th>Group I</th>
<th>Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>6.14±1.20</td>
<td>5.8±1.24</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>21.0±4.4</td>
<td>19.6±3.04</td>
</tr>
<tr>
<td>ASA I/II</td>
<td>70/30</td>
<td>75/25</td>
</tr>
<tr>
<td>Time for surgery (mins)</td>
<td>38.2±6.6</td>
<td>40.2±4.9</td>
</tr>
</tbody>
</table>

Graph I: Drug acceptance score

Graph II: Quality of induction
DISCUSSION
The anxiety level is quite high in children as compared to adults. The management of children in any surgical procedure is a challenging task. The main problem is the age of the children. 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 was to compare midazolam with clonidine as a premedication in children. We found that the age range in group I was 6.14±1.20 years and in group II 5.8±1.24 years. Weight was 21.0±4.4 kg in group I and 19.6±3.04 Kg in group II. The time for surgery in group I was 38.2±6.6 minutes in group I and 40.2±4.9 minutes in group II. 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 Thome et al. Another study by Cao et al., demonstrated that the clonidine premedication provided better levels of anti-anxiety in children than midazolam. Clonidine acts as a sedative and analgesic because of its central alpha-2 adrenergic agonism. A significantly higher parental separation score was noted in the clonidine group. Benner et al. 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. Rohit et al. 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. The quality of induction was better in group I as compared to group II. Fazi et al. in his study found clonidine as better pre-anesthetic agent as compared to midazolam.

Rubina et al. 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 apnea were observed during the peri-operative period in both the clonidine and the midazolam groups.

CONCLUSION
Under the light of above mentioned data, the authors conclude that Clonidine is better pre anesthetic agent as compared to midazolam. It can be used as an alternative to midazolam.

REFERENCES

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Conflict of Interest: None Declared.

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