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EFFECTS OF INTRANASAL MIDAZOLAM AS PREMEDICATION IN PAEDIATRIC ANAESTHESIA – A CLINICAL STUDY

Anaesthesiology

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ABSTRACT

Introduction: Surgery and Anaesthesia techniques induce considerable emotional stress upon children. Temper tantrums are also well known. Preoperative anxiety in unpremedicated children is two-fold. Hence all the paediatric patients need to be premedicated to decrease preoperative anxiety. **Aims And Objectives:** To evaluate the efficacy of intranasal midazolam in children as premedication. **Materials And Methods:** This study was conducted in 60 patients, after approval of institute ethics committee, of ASA grade I and II of both sexes in the age group of 3 to 6 years who were scheduled for various elective surgeries were randomly allocated into 2 groups of 30 each. **Results:** From the present study, it is observed that the intranasal Midazolam 0.2 mg/kg produces a significant level of sedation at 5 min after administration. Children in the midazolam group could be easily separated from the parents compared to the children in the saline group. In Midazolam group showed a satisfactory response to venipuncture. In Midazolam group, children had satisfactory response to mask placement. **Conclusion:** On the basis of the present study, it is concluded that administration of preservative-free intranasal midazolam in the dose of 0.2 mg/kg as premedication in paediatric patients produces satisfactory sedation

KEYWORDS

Intranasal midazolam, sedation, venipuncture, mask placement

INTRODUCTION

Surgery and Anaesthesia techniques induce considerable emotional stress upon children.[1] The consequences of this emotional stress remain in the child's psyche long after the hospital experience has passed.[2,3] Although it is difficult to determine which component of a child's hospitalisation experience results in psychological problems, age, parental anxiety level, previous hospital experiences and type of surgery are factors that influence a child's anxiety level and mental well being.[2]

Preoperative anxiety activates sympathetic, parasympathetic and endocrine system leads to an increase in blood pressure, heart rate, and cardiac excitability. Children of age two to five years are especially vulnerable to this problem since their understanding is limited.[4]

Preoperative anxiety in children can lead to postoperative maladaptive behaviours in the form of eating problems, bad dreams, enuresis, increased fear of doctors & hospitals. Temper tantrums is also well known. Preoperative anxiety in unpremedicated children is two-fold.[5,6] Hence all the paediatric patients need to be premedicated to decrease preoperative anxiety.

The preoperative interventions directed towards reduction of anxiety are divided into psychological/non-pharmacological and pharmacological methods. Although the non-pharmacological approaches in the form of a friendly visit by the anesthesiologist to establish rapport with the child, briefing about the procedure whenever feasible, helps to minimise the child's anxiety. Pharmacological agents are often helpful to provide smooth induction and sedation. Even parental presence 2 inside the operation theatre may not be fully effective. Sedative premedication is more effective in this regard.[7]

AIMS AND OBJECTIVES

AIM

To evaluate the efficacy of intranasal midazolam in children as premedication.

OBJECTIVES

This study was designed to evaluate the following effects after premedication with intranasal midazolam.

1. Degree of Sedation.
2. Ease of separation from parents.
3. Response to venepuncture
4. Response to induction/mask placement

MATERIALS AND METHODS

This study was conducted in 60 patients, after approval of institute ethics committee, of ASA grade I and II of both sexes in the age group of 3 to 6 years who were scheduled for various elective surgeries were randomly allocated into 2 groups of 30 each.

Group M: Children received 0.2 milligram/kg of intranasal midazolam preservative-free injectable preparation, and the concentration of the drug was 5 milligram/ml.

Group S: Children received 0.04 millilitre/kg of Normal Saline

With the children sitting on the parents' lap, the Saline (or) midazolam drug administered drop by drop with the help of a 2ml syringe by the anesthesiologist to avoid wastage through the anterior and posterior nostril. Parenteral preparation was used & the concentration was 5mg/ml.

At 5 mins after administration of the midazolam drug/saline, the degree of sedation, HR, RR, SpO2, NIBP were noted (Table no.1) At 10 min, children were separated from the parents & shifted to the Operation theatre. Reaction to parental separation was assessed (Table no.2). IV Canulation attempted & reaction to venepuncture recorded (Table no.3)

After 15 minutes of premedication, general anaesthesia was induced using N2O, oxygen, sevoflurane & response to mask placement assessed & recorded (Table no.4).

Postoperative recovery score was assessed at 10, 20, 30 min on a ten-point scale using the following parameters-colour, airway, respiration, level of consciousness and movement of all the four limbs. (Table no.5)

Inclusion Criteria

- Patients undergoing elective surgeries
- Aged between 3- 6 years
- ASA I and ASA II

Exclusion Criteria

- Patients with rhinopharyngitis.
- Patients with nasal pathology.

- Patients with H/O allergy to the study drug.
- Patients on sedative medication.
- Patients on treatment with theophylline, H2 receptor antagonists.
- Patients with H/O prematurity or chronic illness.
- Patients with H/O developmental delay.
- Patients with the cardiorespiratory disorder.
- Patients with Hepatic and Renal disease
- Patients with ASA Grade III & above.

Statistical Analysis

The results of continuous variables are given as mean ± SD and proportion as a percentage. The difference between the two groups (Group M & Group S) was assessed by student's – t-test and chi-square test.

RESULTS

The demographic parameters of the children in this study age, gender, weight & ASA physical status were comparable.

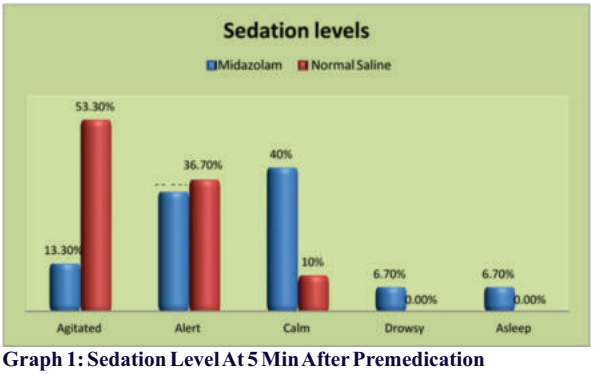
Table 1 and Graph 1 shows that in group M the sedation level at 5 min was better than group S. Majority of the children 26 (86.7%) in group M were adequately sedated (i.e. alert, calm, drowsy, asleep) when compared to group S, in which majority of the children 16 (53.3 %) remain agitated.

P value observed was 0.0101 ($p<0.05$); found to be statistically highly significant as shown in TABLE-1.

Table 1: Sedation Level At 5 Min After Premedication

Sedation	Group M		Group S	
	No. of Patient	%	No. of Patient	%
Agitated	4	13.3	16	53.3
Alert	10	33.3	11	36.7
Calm	12	40	3	10
Drowsy	2	6.7	0	0
Asleep	2	6.7	0	0
Total	30	100	30	100

Chi square value	Degree of freedom	P value
10.8	4	0.0101



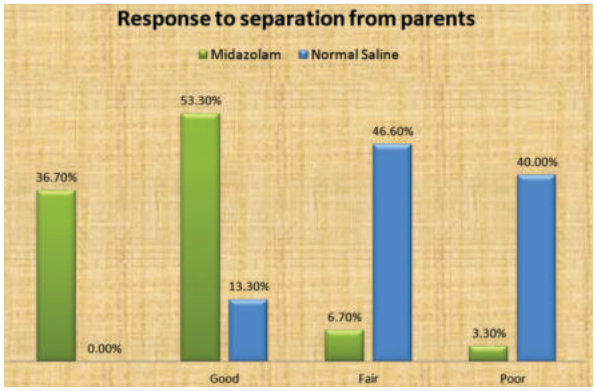
Graph 1: Sedation Level At 5 Min After Premedication

Table: 2 and Graph 2 shows Separation from parents was much easier in group M when compared to group S. In Midazolam group, at the end of 10 min, it was found that 27 (90%) Children were separated easily from Parents (grading being excellent & good) whereas in Normal Saline group, 26 (86.6%) children separation was not satisfactory (grading being fair& poor) needed further convincing and persuation. P value obtained was <0.00001, statistically very highly significant

Table 2: Response to separation from parents at 10 min after premedication

Seperation	Group M		Group S	
	No. of Patient	%	No. of Patient	%
Excellent	11	36.7	0	0
Good	16	53.3	4	13.3
Fair	2	6.7	14	46.6
Poor	1	3.3	12	40
Total	30	100	30	100

Chi square value	Degree of freedom	P value
35.3	3	<0.00001



Graph 2: Response to separation from parents at 10 min after premedication

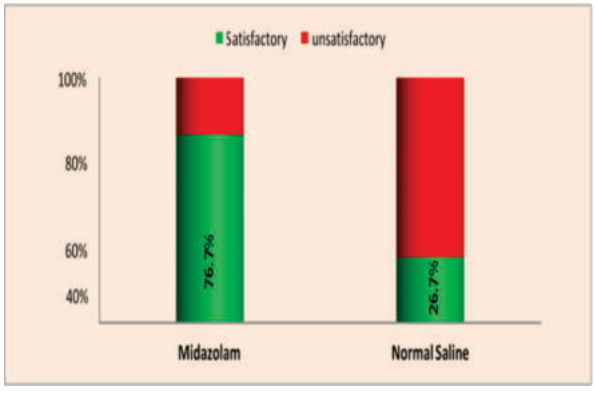
Table:3 and Graph 3 shows that In Midazolam group, 23 (76.7%) children responded satisfactorily to Venepuncture when compared to Normal Saline group, where only 8 (26.7 %) children responded satisfactorily. In Midazolam group, only 7 (23.3%) showed unsatisfactory response to venipuncture whereas in Normal Saline, 22 (73.7%) children response was unsatisfactory.

P value was 0.000107 ($P<0.05$) which was found to be very highly significant.

Table 3: Response to Venepuncture

Response to Venepuncture	Group M		Group S	
	No. of Patient	%	No. of Patient	%
satisfactory	23	76.7	8	26.7
unsatisfactory	7	23.3	22	73.3
Total	30	100	30	100

Chi square value	Degree of freedom	P value
15.00	1	0.000107



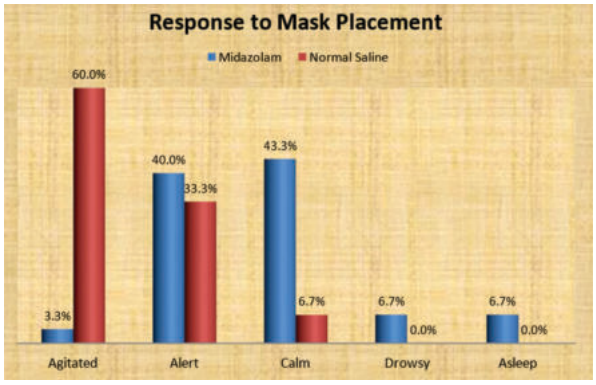
Graph 3: Response to Venepuncture

Response to mask placement: There was a favourable response to mask placement in 29 (96.7 %) of the children (grading being alert, calm, drowsy, asleep) & one (3.3 %) among 30 was agitated in Midazolam group as shown in Table 4 and Graph 4. But, in Normal Saline group, only 12 (40%) of them showed a favourable response & the remaining 18 (60%) children were agitated. P value was found to be <0.00001, which was found to be very highly significant.

Table 4: Response to Mask Placement

Response to Mask placement	Group M		Group S	
	No. of Patient	%	No. of Patient	%
Agitated	1	3.3	18	60
Alert	12	40	10	33.3
Calm	13	43.3	2	6.6
Drowsy	2	6.7	0	0
Asleep	2	6.7	0	0
Total	30	100	30	100

Chi square value	Degree of freedom	P value
22.25	4	<0.00001



Graph 4: Response to Mask Placement

However, there was no significant difference in the heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate between the two groups at any time interval.

DISCUSSION

The outcome of any anaesthetic is determined by how well prepared the anesthesiologist is to handle that particular patient. Children admitted to hospital are displaced from their comfort zone of home, family and siblings. Even a short stay can be traumatic enough to induce a lifelong aversion to hospitals. Children who have had previous surgeries, long hospital or ICU stays may suffer lasting psychological effects. It is one of the tasks of the anesthesiologist to ensure the psychologic and physiologic well being of the patients.[8]

Sedation: Manjushree Roy et al. [9] compared 2 doses of intranasal midazolam with that of Normal saline and concluded that the majority of the children in Midazolam group had a significant level of sedation at 5 mins with 0.2 mg/kg and delayed onset of sedation at 10 min with 0.3mg/kg.

Wilton et al.[10] administered 2 doses of Midazolam 0.2milligram/kg and 0.3milligram/kg and compared with placebo, and he concluded that the significant level of sedation occurred in the lower dose of Midazolam group from 5 min after administration. And in the high dose of 0.3 milligram/kg from 10 min. 60 % of the children were found agitated in the Normal saline as compared to only 3% in the Midazolam group

Ease Of Parenteral Separation

Children in the midazolam group could be easily separated from the parents compared to the children in the saline group. Similar results were obtained by Karl et at. [11] Administered Midazolam (0.2mg/kg) in 2 different routes (sublingual and intranasal) in 93 patient aged 0.5 to 10 years. Children in the intranasal group showed decreased anxiety in response to the stress of separation, compared to the sublingual group (p=0.01) at 11 min.

Ease Of Induction

Davis et al. compared 2 doses of intranasal Midazolam (0.2 & 0.3 mg/kg) with saline as placebo in 88 patients and concluded that the patients receiving midazolam had better induction scores than the patients who received NS.

CONCLUSIONS

On the basis of the present study, it is concluded that administration of preservative-free intranasal midazolam in the dose of 0.2 mg/kg as premedication in paediatric patients produces satisfactory sedation.

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