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Original Research Paper

Pharmacology

A COMPARITIVE STUDY OF INCIDENCE OF POST OPERATIVE COMPLICATIONS AND SIDE EFFECT OF INTRANASAL DEXMEDETOMEDINE VERSUS INTRANASAL MIDAZOLAM AS PREMEDICANT IN CHILDREN

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ABSTRACT

Background: Anesthesia and surgery represent an enormous time of stress for the child. The purpose of this study is to study of incidence of post operative complications and side effect of intranasal dexmedetomedine versus intranasal midazolam as premedication in children.

Methods: This study was conducted as a randomized clinical trial among 60 childrens undergone elective surgery. Group D – children received dexmedetomidine, 1 µg/kg intranasally 40 – 45 min prior to anaesthesia induction. Group M - children received midazolam 0.2 mg/kg intranasally 40 – 45 min prior to anesthesia induction.

Results: All the children in Dexmeditomidine group had no post operative nausea and vomiting. About 10% of children in Midazolam group had nausea/ vomiting and 90% had no nausea/vomiting. None of the children in Dexmeditomidine group had other side effects and 6.7% of the children in Midazolam group had other side effects.

KEYWORDS :

INTRODUCTION

Anesthesia and surgery represent an enormous time of stress for the child. Hence, premedication plays an important role for pediatric patients who are posted for surgery. The literature available has shown that about 50 -75% of the children shows signs of significant preoperative fear and anxiety.[1,2] It has also been reported that there are correlations between the heart rate, blood pressure and behavioral ratings of anxiety.[3,4] In order to alleviate physiological and psychological effects of preoperative anxiety in children, most anesthesiologists use either parental presence or sedative premedication, since separation from parents and induction of anesthesia are considered the most perioperative stress inducing phases. Both approaches are considered appropriate choice of interventions. Anesthesiologists who allow parental presence during induction of anesthesia, use sedative premedication least frequently, and vice versa.[5,6]

Premedication is commonly used to reduce the preoperative anxiety, to facilitate the separation from parents and to promote acceptance of mask induction. Among the different goals that can be achieved with premedication, the primary objective in children is anxiolysis. Premedication that effectively calms the child also minimizes the parental anxiety.[7]

AIM AND OBJECTIVES

- To compare the incidence of post operative complications like shivering vomiting etc.
- To find out any complications and side effect of studying drugs.

MATERIALS AND METHODS

About 60 children belonging American Society of Anesthesiologists (ASA) Grades I and II of both sexes, aged between 2 and 7 years who posted for surgery in Rajendra Institute of Medical sciences, Ranchi, Jharkhand, were included as study sample in this study. An informed consent, written and bilingual consent was obtained from the parents of the children before they were included in to study. Ethical clearance was obtained from the institutional ethical committee. The inclusion and exclusion criteria was as follows,

INCLUSION CRITERIA

- Male or female patients aged 2 – 7 years.
- Children without other co morbidities.
- Children undergoing elective surgeries only.
- American Society of Anesthesiologists (ASA) physical status I & II.
- No Known history of allergy, sensitivity or any other form of reaction to the drugs used.
- Parents willing to sign informed consent.

EXCLUSION CRITERIA

- Parent's refusal.
- Children with chronic pain and central nervous system disorders.
- Nasal deformity, rhinitis, nasal polyps and other nasal diseases.
- Previous reactions to dexmeditomidine or benzodiazepines.
- Patients with ASA grade ≤ 2.
- Patient scheduled to undergo emergency surgery.
- The patients thus selected were randomly divided into two groups Group D and Group M, each comprising of 30 children by using a computer generated random numbers.
- Group D children received dexmedetomidine, 1 µg/kg intranasally 40 – 45 min prior to anaesthesia induction.
- Group M children received midazolam 0.2 mg/kg intranasally 40 – 45 min prior to anesthesia induction.

Statistical analysis

The data thus obtained was collected in a predesigned proforma and entered in to a spread sheet. The data was transferred to Statistical Package for Social Services (vs 20). The data analysis was performed by unpaired Student's t test and Chi Square test. A P value of < 0.05 was considered as statistically significant and P < 0.0001 was considered as highly significant

RESULTS

Table 1. Distribution of the study group according to post operative nausea and vomiting

Post operative Nausea/ Vomiting	Group	
	Group D N (%)	Group M N (%)
No	30 (100)	27 (90.0)
Yes	0	3 (10.0)
Total	30 (100)	30 (100)

χ^2 value= 3.158 df=1 P value= 0.119, NS

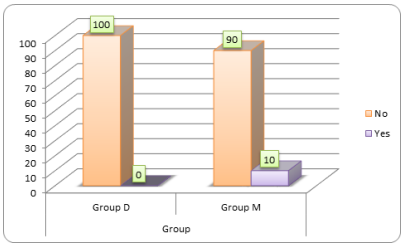

Chart 1. Distribution of the study group according to post operative nausea and vomiting

All the children in Dexmeditomidine group had no post operative nausea and vomiting. About 10% of children in Midazolam group had nausea/ vomiting and 90% had no nausea/vomiting. There was no statistically significant difference in post operative nausea and vomiting between the two groups.

Table 2. Distribution of the study group according to other side effects

Other side effects	Group	
	Group D N (%)	Group M N (%)
No	30 (100)	28 (93.3)
Yes	0	2 (6.7)
Total	30 (100)	30 (100)

χ^2 value= 2.069 df=1 P value= 0.246, NS

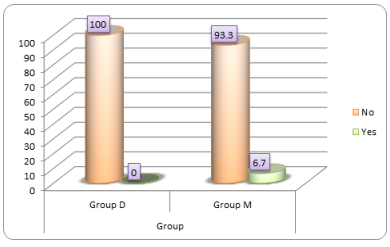

Chart 2. Distribution of the study group according to other side effects

None of the children in Dexmeditomidine group had other side effects and 6.7% of the children in Midazolam group had other side effects. This difference in other side effects was not statistically significant.

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