Original Research Paper Anaesthesiology

Comparative study of Preoperative Sedation and Face Masks Acceptance of Intranasal Dexmedetomidine versus Intranasal Midazolam of age group 2-7 years

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ABSTRACT

Background : Face mask acceptance is very important in childrens. Due to anxiety and fear there is increase in heart rate, blood pressure and behavioral changes. The purpose of this study is to compare sedation and face mask acceptance in age goup 2-7 years between dexmedotomidine and midazolam group. **Methods:** This study was conducted as a randomized clinical trial among 60 childrens undergone elective surgery. The patients were randomly allocated into two groups. 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 10% of children in Dexmedetomidine group and 30% of the children in Midazolam group were sleepy and drowsy, eyes open, 36.7% of children in Dexmedetomidine group and 10% in Midazolam group had their eyes closed but verbally arousable, 33.3% of dexmedetomidine and 40% of the Midazolam group had their eyes closed but arousable with light physical stimulation and 20% in both the groups had eyes closed but not arousable with physical stimulation. **Conclusion:** Dexmedetomidine and midazolam had shown the same effectiveness in Parental separation. pre induction mask acceptance. Dexmedetomidine and midazolam had shown the same effectiveness in pre induction mask acceptance.

KEYWORDS : Dexmedetomidine , Intranasal, Midazolam , premedication

INTRODUCTION

Anesthesia and surgery represent an enormous time of stress for the child. The reasons for the stress can include separation from the parents, strange surroundings, painful procedures, frightening procedures and survival.[1] Hence, premedication plays an important role for pediatric patients who are posted for surgery. Pediatric patients are more uncooperative during securing IV line, IV/IM drug administration, separation from parents and induction of anesthesia.[2,3]

The literature available has shown that about 50 -75% of the children shows signs of significant preoperative fear and anxiety.[4] It has also been reported that there are correlations between the heart rate, blood pressure and behavioral ratings of anxiety.[5] 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.[6,7]

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.[8,9]

The drugs which are commonly used for sedation and anxiolysis are midazolam, keatmine, clonidine and dexmedetomidine. Route of administration of these drugs is mainly parenteral, which make it more invasive and painful.[10,11,12]

The ideal premedication in children should be readily acceptable and should have a rapid and reliable onset with minimal side effects. The drugs which have been tried as premedication is ketamine, it is an easily administered parenteral anesthetic that produces profound analgesia in subanaesthetic doses and lacks the cardio-respiratory depression seen with most other general anesthetics, but it produces excessive salivation and hallucination.[13]

Midazolam is a water soluble benzodiazepine and most commonly used sedative premedicant in children. The advantages of midazolam include rapid onset, effective sedation, aneterograde amnesia, anxiolysis and reduction in post operative vomiting. However, the undesirable effect such as restlessness, hiccups and paradoxical hyperactive reaction, that accompany the use of midazolam render this drug a less than ideal sedative.[14]

Dexmedetomidine is a highly selective alpha – 2 agonist with both analgesic and sedative effects. It produces a type of sedation recognized as cooperative or arousable which is different from the clouding of consciousness sedation included by drugs acting on the GABA system. These characteristics make it potentially useful for anesthesia premedication in children.[15]

The difficulty in securing IV line, excessive cry and apprehension, intranasal (Dexmedetomidine and Midazolam) help us to get rid of apprehension, several unwanted pricks to secure IV line, excessive crying and achieve the goal, i.e. pediatric patients free from anxiety, inapprehensive about separation from parents and uncooperative during induction of anesthesia.

AIM AND OBJECTIVE

- To compare and evaluate the efficacy on the preoperative sedation i.e, the ease of separation from parents
- To compare and evaluate the efficacy on the face masks acceptance i.e., sedation at induction of anesthesia

MATERIAL 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 general surgery and pediatric surgery in Rajendra Institute of Medical sciences, Ranchi, Jharkhand, were included as study sample in this study. They were randomly allocated to two groups Group D and Group M, using closed envelope method and each comprising of 30 children. 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.

- 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.

Premedication were given to children in the preoperative holding area in the presence of parents. Intranasal drug was given into both nostrils using a 1 ml insulin syringe with the child in the recumbent position. To avoid from trickling to phyranx 3-4 drops were given in each nostril and then repeated the remaining dose after 2 minutes.

Baseline parameters like heart rate (HR), noninvasive blood pressure (NIBP) and SpO2 recorded in both groups at 10 minutes interval.

Pre anesthetic assessment:

All patients were visited and evaluated for fitness for the intended procedure and anesthesia on the day prior to the surgery. During this visit, the procedure of the study planned was explained to the parents. An attempt was made to alleviate the anxiety of the patients. Patients were nil per oral by guidelines. General clinical examination of the patients was performed including a general physical and systemic examination.

A thorough laboratory examination was performed on all the subjects of the study including complete blood picture, HIV and HBsAg, Routine urine examination and chest x – ray if required. No oral liquids up to 3 hours before the procedure and avoidance of milk/ solids for 6 prior to the procedure.

Premedication

Midazolam 0.2 mg/kg body weight intranasal 40-45 minutes prior to induction in group **M**

Dexmedetomidine 1 microgram/kg body weight intranasal 40-45 min prior to induction in group **D**

- Inj. Glycopyrrolate 10 microgram/kg body weight IV, was given 5-10 minutes prior to inductions.
- Inj. Ondansetron 0.1 mg/kg body weight IV, was given 5-10 minutes prior to inductions.
- Inj. Fentanyl 2 microgram/kg body weight IV, was given 5-10 minutes prior to inductions.

Anaesthesia will be induced with :

- Pre oxygenation done for 3-5 minutes with 100% oxygen.
- Inj. Thiopentone 5 mg/kg body weight IV
- Inj. Atracurium 0.5 mg/kg body weight IV given and IPPV done for 3-4 minutes with bag and mask.
- Appropriate size ETT placed and position secured.

Anesthesia was maintained with :

- N2O:O2 40-60%
- Sevoflurane 1-1.5%
- Incremental dose of atracurium
- Reversal was done by inj. Neostigmine 50-70 microgram/kg plus Inj. Glycopyrrolate 10 microgram/kg IV.

MONITORING

- Continuous monitoring of heart rate, blood pressure, ECG
- Respiratory rate, tidal volume, $ETCO_2$.

Assessment

Sedation score at time of premedication to the time of separation was assessed using a 5 point score system (Wilson score)[16]

A.	Completely awake and oriented	1
B.	Sleepy and drowsy, eyes open	2
C.	Eye closed but verbally arousable	3
D.	Eye closed by arousable with light physical stimulation	4
E.	Eye closed but not arousable with physical stimulation	5

At every 10 minutes of interval sedation of patient was assessed and sedation at the time of separation from parents was taken as final wilsons score.

Sedation score at time of induction was assessed using three point score[17]

A.	Calm, cooperative or asleep	1
B.	Moderate fear of mask, co – operative reassurance	2
C.	Combative,crying	3

A mask induction score of 3 was consider unsatisfactory while a score of 1or 2 was regarded as successful response to premedication.

Statistical analysis

P < 0.001 was considered as highly significant

OBSERVATIONS & RESULTS

Table1. Distribution of patients according to behavior at parental separation

Behaviour at parental separation	Group	
	Group D N=30 (%)	Group M N=30 (%)
A. Completely awake & oriented	0	0
B. Sleepy and drowsy, eyes open	3 (10.0)	9 (30.0)
C. Eyes closed but verbally arousable	11 (36.7)	3 (10.0)
A. Eyes closed but arousable with light physical stimulation	10 (33.3)	12 (40.0)
E. Eye closed bout not arousable with physical stimulation	6 (20.0)	6 (20.0)
Total	30 (100)	30 (100)

P value= 0.051, **NS:-** Not significant

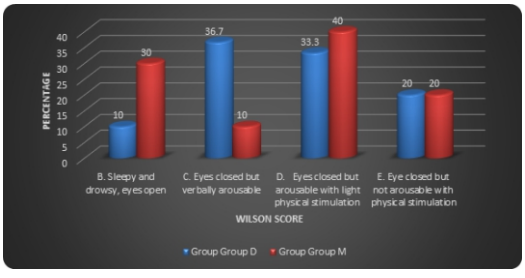

Figure 1. Distribution of patients according to behavior at parental separation

Table and figure no 1 shows that about 10% of children in Dexmedetomidine group and 30% of the children in Midazolam group were sleepy and drowsy, eyes open, 36.7% of children in Dexmedetomidine group and 10% in Midazolam group had their eyes closed but verbally arousable, 33.3% of dexmedetomidine and 40% of the Midazolam group had their eyes closed but arousable with light physical stimulation and 20% in both the groups had eyes closed but not arousable with physical stimulation. This difference in behavior at parental separation was statistically not significant between both the groups.

Table 2. Distribution of patients according to Pre induction scores

Pre induction sedation scores	Group	
	Group D N=30 (%)	Group M N=30 (%)
A. Calm, cooperative or asleep	6 (20.0)	7 (23.3)
B. moderate fear of mask, cooperative reassurance	13 (43.3)	14 (46.7)
C. Combative, crying	11 (36.7)	9 (30.0)
Total	30 (100)	30 (100)

P value= 0.855, **NS:-** Not significant

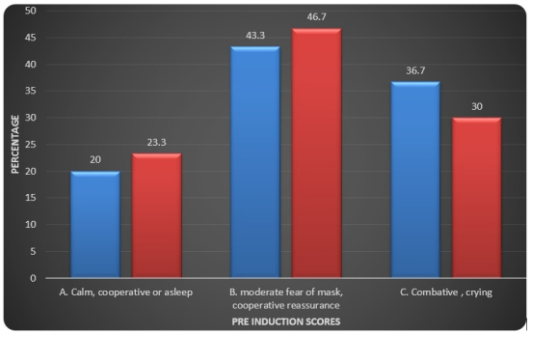

Figure 2. Distribution of patients according to Pre induction scores

The pre induction scores have shown that, about 20.0% of the Dexmedetomidine group children and 23.3% of the Midazolam group children were calm, cooperative or asleep, 43.3% of the Dexmedetomidine group children and 46.7% of the Midazolam children had moderate fear of mask, cooperative reassurance and 36.7% of the children in Dexmedetomidine group and 30% in Midazolam group were combative, crying. There was no statistically significant difference between the Pre induction sedation scores between the two groups.

Conclusion

- Dexmedetomidine and midazolam had shown the same effectiveness in Parental separation. pre induction mask acceptance.
- Dexmedetomidine and midazolam had shown the same effectiveness in pre induction mask acceptance.

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