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# comparision of dexmedetomidine with midazolam for intra nasal premedication in children

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**ABSTRACT**

*Backgroundand Aim: Intranasal route is widely accepted to administer premedication in children as it is noninvasive, painless and relatively easy to administer drug through it. We had conducted a prospective randomized study to evaluate the effect of intranasal dexmedetomidine as a premedication in children and compared it with midazolam, Primarily with regards to hemodynamic changes,Spo2, Sedation, Anxiolysis, mask acceptance and secondarily for recovery profile, parental satisfaction and occurrence of any adverse effects.*

*Methods: A total of 60 children posted for surgery under anaesthesia were selected. Group D received intranasal dexmedetomidine 1 µ/kg 90 minutes before and Group M received intranasal midazolam 0.3 mg/kg 30minutes before being transferred to operationtheatre.Haemodynamic parameters,Spo2,anxiety score and sedation score were noted. Inside the operation room, acceptance of facemask during induction of anesthesia was assessed. Two hours after surgery, recovery profile was assessed. After 24 hours, parental satisfaction with regards to premedication given to their child was assessed.*

*Results: Both the groups were comparable with regards to demographic parameters.*

*At peak effect of premedication, group D had significantly less pulse rate compared to group M(100.73±15.87 vs 114±16.53)*

*more number of children in groupD had better sedation score(83.33% vs56.66%) and satisfactory Mask acceptance(90%vs66.66%). Both the groups had good and comparable anxiolytic effect. Significantly more number of children in group D achieved satisfactory Recovery profile than group M(86%vs63%). Most of the parents in both the groups were satisfied with their child's premedication (89.99%vs86.66%). None of the patient had clinically significant bradycardia, hypotension or desaturation.*

*Conclusion: Intra nasal dexmedetomidine (1µ/kg) is a better choice for premedication in children than intranasal midazolam (0.3mg/kg).*

**KEYWORDS : Dexmedetomidine, Intra nasal, Premedication, children.**

## INTRODUCTION

Whenever a surgery is planned for a child, the challenge to the attending anaesthesiologist is not only to win the heart of a child but also has to console the parents who are anxious about the surgery and safety of the child. The anaesthesiologist has to meet the surgeon's requirement also. Thus, it is evident that adequate preoperative anxiolysis and sedation without harmful effects on respiratory and hemodynamic parameters is important while giving anesthesia to a child.

Numerous premedications have been used since long time to meet these requirements. An ideal premedication to a child should be easy to administer, preferably non invasive, not causing impairment of respiratory or hemodynamic parameters and acceptable by both children and parents. Oral, rectal, intramuscular and intravenous routes are being used since long time but, each of these routes has its own advantages and disadvantages.

Nasal administration of premedication is suggested to have a rapid and reliable onset of action. This is a non invasive mode, avoids painful injection and relatively easier to administer.

Dexmedetomidine, the d-enantiomer of medetomidine which provides sedation, anxiolysis, hypnosis, analgesia and sympatholysis. It is a more selective alpha 2 agonist with 1600 greater selectivity for alpha 2 receptors compared to alpha 1 receptors. It is introduced into clinical practice in 1999 for short term sedation in mechanically ventilated ICU patients.[1]Its sedative and analgesic properties and absence of respiratory depressant effect render it a potentially useful drug as a premedication.

In the present study, we evaluated intranasal dexmedetomidine as a premedication in children and compared it with intranasal midazolam.

## METHOS

After obtaining institutional ethical committee approval, this prospective randomized study was conducted on 60 children of age group 2 to 8 years, of either sex, ASA physical status 1 or 2,undergoing elective surgical procedures under anaesthesia.Exclusion criteria included ASA Class 3 and above, a negative consent from parents, sinus bradycardia and allergy to study drug.

After obtaining informed consent from parents, children were divided randomly into two groups using computer generated random numbers. Children of group D received intra nasal dexmedetomidine 1µ/kg 90 minutes before being transferred to operating room and that of Group M received intra nasal midazolam 0.3 mg/kg 60 minutes before being transferred to operating room. Doses and times of administration were based on published data [2, 3, 4, 5]. Group assignments were sealed in sequentially numbered opaque envelopes, which are opened by an anaesthesiologist, who prepared a drug and not involved in data collection.

When children arrived in pre operative room, they were weighed and allowed to lay down comfortably either in parent's lap or on the bed. Baseline hemodynamic parameters, RR, anxiety score and sedation score were noted. After attaching pulse oximeter, study drug was administered intranasally with subjects in supine position. Oxygen saturation and heart rate were monitored continuously, while SBP and RR were recorded every 15 minutes throughout the study period.

sedation scores were also noted for baseline values . .Thereafter,they were kept in the preoperative holding area in a quite environment. Pulse rate and $spo_2$ were monitored continuously.

In the pre operative area, child's anxiety level and degree of sedation were noted every 5 minutes interval, while Pulse rate, blood pressure and $spo_2$ were recorded at 15 minutes interval till it was transferred to operation theater.

Anxiety level was assessed with a 4 point anxiety score(1=very anxious and crying,2= anxious and crying,3=calm but not cooperative,4=calm,co operative or aleep).

Sedation status was assessed with 3 point scale(1=awake,2=drowsy,

3=asleep).

In the operation room, acceptance to face mask was assessed using a 4 point score.

- Combative and crying child.
- Moderate fear of mask, not easily calm.
- Cooperative with assurance.
- Calm, cooperative or asleep.

Score 3 and 4 were considered as satisfactory.

After surgery, patients were taken to the recovery room. Recovery profile was assessed after two hours in a recovery room, using a 3 point scale and then shifted to ward.

**3 point scale**
1-Agitated, crying.
2-Crying but easily consolidated.
3-Calm or asleep.
Satisfaction of parents with the premedication given to their child was assessed after 24 hours using a 3 point scale as

1-Not satisfied
2-Good, Satisfied
3-Excellent, very satisfied.

**Statistical analysis**
The analysis of data was done with the help of Epi Info version 7.0.Data derived from study were compared using't' test. P< 0.05 was considered as statistically significant; whereas, p<0.001 was considered as statistically highly significant and p>0.05 was regarded as statistically not significant. To generate the graphs and tables Microsoft Office 2007 (word and Excel) have been used.

**RESULTS**
There was no statistically significant difference between the groups with regards to demographic data (age, bodyweight, sex) and ASA class of children.

**(Table-1).**
Before premedication, 96.66% patients of group D and 90% of group M had an anxiety score of either 1 or 2.

At the time of peak effect of premedication, most children in both the groups had satisfactory anxiolysis.

In group D ,73.33% of children had anxiety score of 4 and 23.33% had anxiety score of 3 while in group M,53.33% of children had anxiety score of 4 and 36.66% had anxiety score of 3. (Figure- 1)

The basal pulse rate and SBP were comparable in both the groups. At the time of peak effect, the mean pulse rate was significantly less in group D as compared to group M, but SBP was comparable in both the groups.(Figure-2) None of the children from either group had bradycardia or fall in $spo_2$ throughout the study period.

Mask acceptance was significantly better in group D as compared to group M (p=0.02),as 90% of children in group D as compared to 66.6% in group M had satisfactory mask acceptance(score 1 or 2).

In group D 86.66% of children while in group M 36.66% of children had recovery profile of 3.(p=0.018) Most parents, 90% in group D and 86.66% in group M were satisfied with their child's premedication.

**DISCUSSION**
Dexmedetomidine is establishing its place in perioperative setting. Its sedative, anxiolytic, analgesic, respiratory and hemodynamic effects make it a useful adjunct to anesthetic drugs.

The present study was conducted to evaluate the efficacy of intranasal dexmedetomidine as a premedication in children.

We selected children of age group 2 to 8 years as this age group is most susceptible to the anxiety.[2]

Intra nasal route offers some advantages like painless delivery, simple and noninvasive method and higher patient and provider satisfaction. [3]Though the onset is delayed compared to i.v route, it avoids initial hypertensive response and first pass metabolism via liver resulting in high bio-availability of medication.[3]

In our study, many children responded to intranasal instillation of study drug, either by agitation or crying but all children accepted it after persuasion. One study reported 62% acceptance rate of intra nasal midazolam in preschool children. [6]The acceptance rate was quite good in our study, but we didn't measure it.

Yuen et al[2] in a randomized crossover evaluation of healthy adult volunteers, demonstrated that intra nasal 1 and 1.5 μ/kg dexmedetomidine produce sedation in 45-60 minutes and peaks in 90-105 minutes. In addition, they observed only a modest reduction in HR and arterial blood pressure.

A significant change in sedation score was observed in both the groups at the peak effect and it was maintained during induction of anaesthesia. Significantly more number of patients in dexmedetomidine group became either calm or drowsy(sedation score 2 or 3) as compared to midazolam group(83.33% vs 56.66%).several studies show satisfactory sedation with intranasal dexmedetomidine.[4,7,8] 73.33% children in group D and 53.33% in group M achieved satisfactory anxiolysis, which help them in easy parental separation and also in smooth induction(mask acceptation).In group D 90%(27/30) of children and in group M only 66.6%(20/30) of children had satisfactory mask acceptance. Mostafa .G. Mostafa et al[8] compared intranasal midazolam ,ketamine and dexmedetomidine as a premedication in children,found that in group D 93.7% of children as compared to 87.5% in group M achieved satisfactory 'child parent separation score'. Uday S Ambi et al[9] found that all children with intranasal dexmedetomidine accepted parental separation very well. V.M.yuen et al[10]observed significantly better behavior on induction of anaesthesia in children who received intranasal dexmedetomidine than oral midazolam. which were similar to our study.

We have observed that, at the time of discharge to ward, 86.66% patients in group D and only 63.33% children in group M were calm or asleep. C. W. Cheung et al (2011)[7] observed satisfactory post anaesthetic discharge score in all the patients who received intranasal dexmedetomidine. Ashraf. M. Ghali et al. (2010 Jan to March 2011) [11] observed that time to achieve adequate Aldrete score was similar with intra nasal dexmedetomidine and oral midazolam given as a premedication in children.

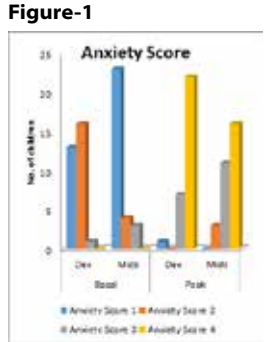
In our study, HR was significantly decreased in group D as compared to group M but fall in SBP was comparable. No child required treatment for them.

**CONCLUSION**
Our study has shown that intranasal dexmedetomidine (1 μ/kg) can be a better choice than intranasal midazolam(0.3 mg/kg) as a premedication in children. It provides better sedation and mask acceptation, comparable anxiolysis and parental satisfaction with hemodynamic stability

| | Group D | Group M | P value |
|---|---|---|---|
| Age (years) | 4.13 ± 2.19 | 3.73 ±1.57 | >0.05 |
| Weight (Kg) | 13.7 ± 4.38 | 12.53±3.13 | >0.05 |

| | | | |
|---|---|---|---|
| Sex (M:F) | 24:6 | 27:3 | >0.05 |

**Figure-1**



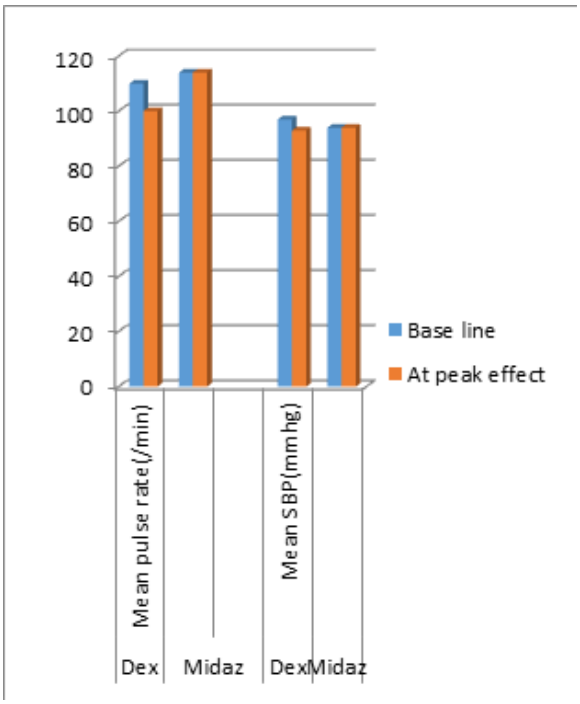



**Figure-2**

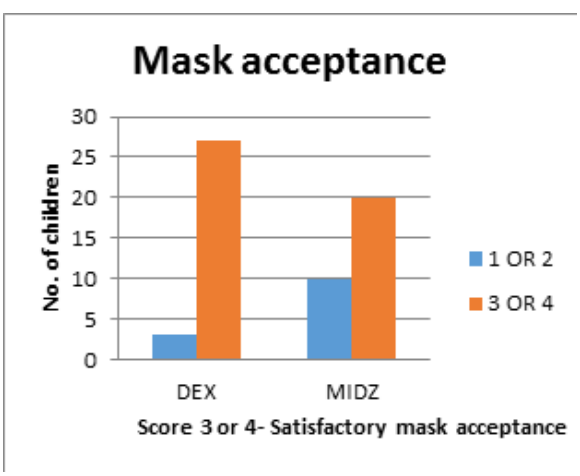



**Figure- 3**

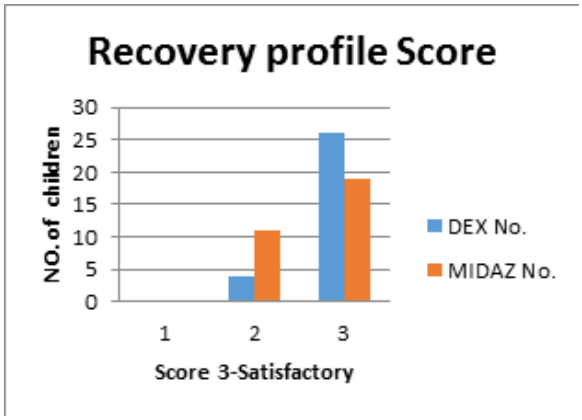



**Figure-4**

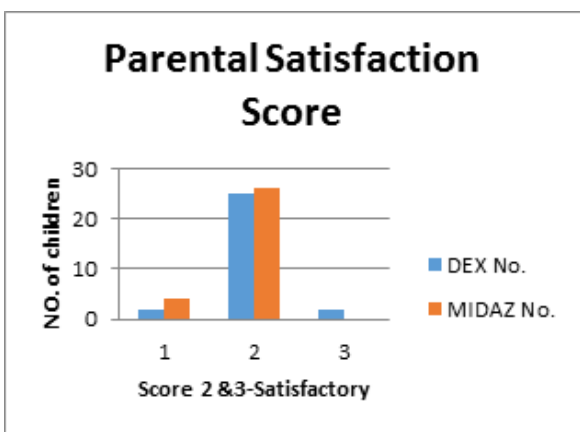



**Figure-5**

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