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Comparative Efficacy of Three Different Doses of Intranasal Dexmedetomidine for Premedication in Children

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Abstract:
Background*: Premedication plays a vital role in permitting for a smooth separation of the child from the parent before surgery. Incomplete premedication can cause a child to experience challenging anaesthetic induction with adverse behavioural consequences. Dexmedetomidine is a selective alpha-2 receptor agonist that has sedative and analgesic effects. Due to poor oral bioavailability, intranasal route is preferred for children for premedication.*
Objective: *This study was done to know the role of three different doses of intranasal dexmedetomidine as a premedication in children scheduled for various surgeries.*
Materials and Methods*: This study was done at tertiary care teaching hospital in the Department of Anaesthesiology at NRI Institute of Medical Sciences, Chinakakani, Andhra Pradesh., India from October 2022 to December 2022. 60 children were included as per the eligibility criteria.They were divided into groups A, B and C based on the dose of intranasal dexmedetomidine given. Age, gender, type of surgery, sedation and behaviour scores were compared between three groups of children*
Results*: There is no significant difference in the mean age, gender between three groups. The most common surgery underwent by children was adenotonsillectomy, followed by tonsillectomy. There was significant difference in the mean sedation score and behaviour score between three groups of children. Sedation score was highest in group C and behaviour score was least in group C children.*
Conclusion:*1.5 mcg/kg body weight dose of intranasal dexmedetomidine produced more sedation and less behaviour changes in children before surgery. Hence it can be used ideally as a premedication.*
Key Words: *Dexmedetomidine, Efficacy, Children, Premedication, Intranasal route*

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I. Introduction

Premedication plays a vital role in permitting for a smooth separation of the child from the parent before surgery. Incomplete premedication can cause a child to experiencechallenging anaesthetic induction with adverse behavioural consequences.Pre-surgical anxiety is a major concern to paediatricanaesthesiologists. Around 60% of children suffer from preoperative anxiety.[1] Children can become more uncooperative duringvenepuncture, or mask application before surgery. Pre-induction techniques were aimed at decreasing. They include: giving sedative, presence of a parent during induction of anaesthesia. Parental presence has a questionable roleon various upcoming non-pharmacological options exist ns, butanaesthesiologistsstill preferproviding effective pharmacological interventions. Therefore, in spite ofadvances in non-pharmacologic interventions, healthcare workers and practitioners still depend on sedative premedications.[2]Though, benzodiazepines likemidazolam is acommonest oral premedication given to children, which isreported to be safe and effective for separation from parents and induction of anaesthesia.[3-5] Studies on role of premedication using alpha agonists like dexmedetomidine were less with inconclusive results.[6-8]Hence the current study was undertaken. Recently intranasal premedication using dexmedetomidine has been studied as an alternative option to oral premedication with varying results.[9]Dexmedetomidine is a selective alpha-2 receptor agonist that has sedative and analgesic effects. Due to poor oral bioavailability, intranasal route is preferred for children for premedication.

Objective: To compare sedation score at separation, behaviour scores using there different intranasal doses of dexmedetomidine.

II. Material And Methods

This Interventional randomized study was done at a tertiary care centre in IndiafromOctober 2022 to December 2022

Study Design: Interventional randomized study

The study is interventional, as therapy was given to all children in the form of intranasal dexmedetomidine, as a part of the study.

Study Location: This study was done at a tertiary care teaching hospital in the Department of Anaesthesia at NRIInstitute of Medical Sciences, Andhra Pradesh, India.

Study Duration: October 2022 to December 2022

Sample size: 60children

Sampling procedure: Simple random sampling

Sample size calculation: As per the previous study done by Yuen et al.[10] 75% of children who received dexmedetomidine had satisfactory sedation scores during separation from parents.Considering this prevalence, with 90% confidence level and 10% error, minimum sample size was calculated 52 in the study. We included 60 children, considering incomplete data for some children.

Subjects & selection method: The study population was drawn from patients who were admitted into the General medicine ward, with clinical features suspicious of stroke. The study is randomized, as children were divided into three different groups by computer-generated randomization software. Children were divided into 3 different groups.

Group A: 20 children who received0.5 mcg/kg body weight ofintranasal dexmedetomidine

Group B: 20 children who received 1 mcg/kg body weight of intranasal dexmedetomidine

Group C: 20 children who received 1.5 mcg/kg body weight of intranasal dexmedetomidine

Inclusion criteria:

1. Children aged 2 to 12 years, scheduled for various surgeries
2. Either sex
3. Children of ASA physical status I and II
4. Children of parents who provided informed consent.

Exclusion criteria:

1. Children with history of allergies
2. Parental refusal
3. Children on long-term therapy with theophylline, phenobarbitone, carbamazepine, and griseofulvin(as they cause drug interactions with dexmedetomidine).
4. Children with nasal deformity
5. Children with acute or chronic nasal trauma

Methodology:

Premedication was given 60 min before induction of anaesthesia, in holding area in front of parents.Intranasal dexmedetomidine was prepared using 100 μg/ml of parenteral preparation. Normal saline was added to make it a final volume of 0.5 ml. Intranasal drug was administered as dripsin both nostrils in the volume of 0.2 ml in each nostril by 1ml syringe with the child in recumbent position.

Sedation status and behaviour scores were assessed using a 6-point Ramsay sedation scale and 4-point behaviour score.

The following table (Table 1)shows Ramsay sedation score:[11]

Ramsay score	Level of sedation
1	Anxious, agitated, restless
2	Oriented, tranquil
3	Responds to commands
4	Brisk response to light glabellar tap
5	Sluggish response to light glabellar tap
6 (deep sedation)	No response

The following table (table 2) shows the behaviour score:

Calm and cooperative	1
Anxious but re-assurable	2
Anxious but not re-assurable	3
Crying and resisting	4

During induction of anaesthesia and during separation from parents, sedation and behaviour scores were measured.

After including children as per the inclusion and exclusion criteria, data collection was done. A detailed history was taken from the patient's relatives. Thorough physical examination, vital signs and systemic examination were done. The data was subjected to statistical analysis and then a conclusion was drawn.

Parameters assessed:

- Age
- Gender
- Type of surgery
- Sedation score at inductionand during separation from parents
- Behavioral score at induction and during separation from parents
- Side effects

Ethical considerations: Permission was obtained from the Institutional ethical committee attached to the NRI Institute of Medical Sciencesbefore conducting the study. Every parent was explained the whole process and advantages of the study. After parent accepts, an informed consent form is given in the local language or the patient's understandable language and the parent was asked to sign it or put a thumb impression. Informed consent was taken from the child also apart from parent, if child can understand and sign.

Statistical analysis

Data was analyzed using Epi info software version 7.2.5.Results were expressed as percentages and mean with standard deviation.ANOVA was used to compare numerical parameters between three groups. Chi square test was used to compare categorical variables. P value below 0.05 is considered significant.

III. Results

The current study included 60 children scheduled for various surgeries.

Age: There is no significant difference in the mean age of children between three groups, as per ANOVA analysis.

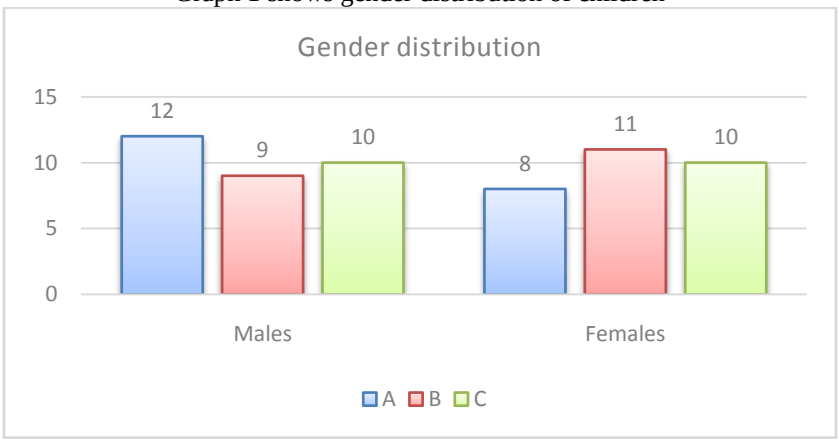
Table no 1: Mean age of children

Group	Mean age	P value
A	6.3±1.1	
B	5.95±2.3	
C	6.4±2.1 years	0.737

Gender:

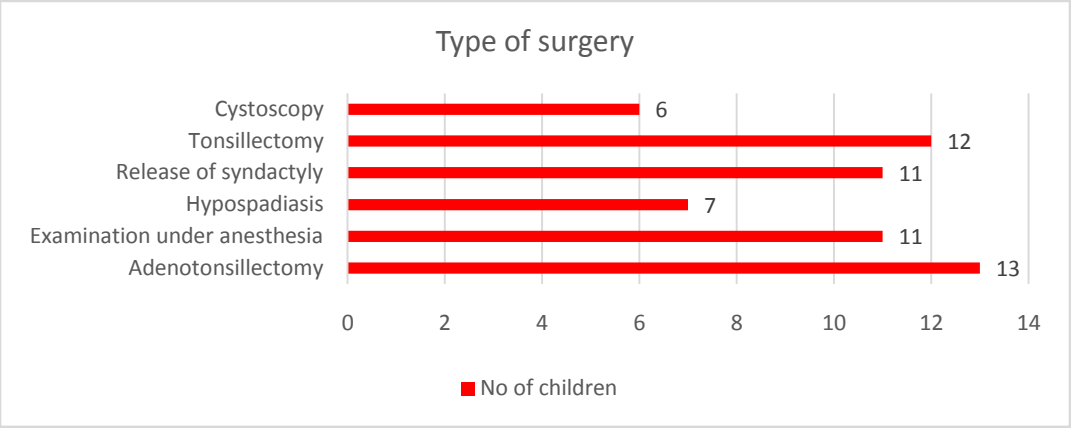
Most of the patients were males. There is no significant difference in gender between three groups(p=0.81).

Graph 1 shows gender distribution of children



Type of surgery:
The most common surgery was adenotonsillectomy, followed by tonsillectomy and cystoscopy.

Graph 2 shows type of surgery underwent by children



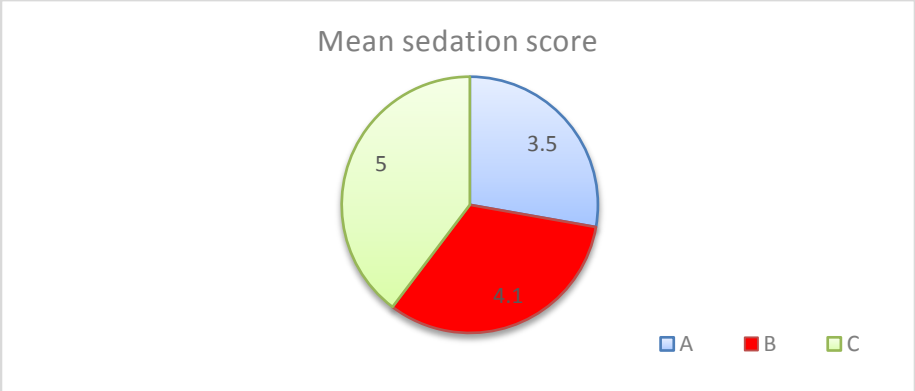
Sedation score at induction:
There is significant difference in the mean sedation score in 3 groups of children, as per ANOVA analysis. It was highest in group C children (1.5 mcg/kg body weight).

Table 2 shows mean sedation score in three groups of children

Groups	Mean sedation score	P value
A	3.1±0.9	
B	3.6±1.1	
C	4.2±1.3	0.011

Sedation score at separation:
There is significant difference in the mean sedation score during separation from parents in 3 groups of children, as per ANOVA analysis(p=0.001). It was highest in group C children (1.5 mcg/kg body weight).

Graph 3 shows sedation score at separation



Behavior score:
There is a significant difference in the mean behavior score during separation from parents and during induction in 3 groups of children. It was least in group C children

Table 3 shows the behaviour score during induction and separation

Groups	Mean behaviour score	P value
A	3.2±0.8	0.01

B	2.5±0.65	
C	1.2±0.09	

IV. Discussion

In the current study, 60children were included. There is no significant difference in the mean age and gender between three groups. Hence the comparison is justifiable.

The most common surgery underwent by study children was adenotonsillectomy. Group C children had significantly more sedation and they were more likely to be calm and cooperative significantly in our study.

Singh et al[12] did a similar study and compared three intranasal doses of dexmedetomidine on 60 children aged 1 to 6 years undergoing various surgeries. There is no significant difference in the mean age and gender between two groups, similar to our study. The sedation score was significantly more in 1.5mcg/kg dexmedetomidine group children, similar to our study.

Yuen *et al*.[13] found that 1 mcg/kg dose of intranasal dexmedetomidine produced good sedation scores during 30min to 60 min after administration.

VM Y *et al*.[10] assessed the efficacy of intranasal dexmedetomidine in doses of 1 mcg and 1.5 mcg/kg among adults and compared them with a placebo. Authors found that the nasal route is safe and easy to use and sedation occurred in 45 min.

Faritus et al. informed that oral dexmedetomidine as a better premedication for children undergoing cardiac surgeries.[14]

Pavithra et al[15] found that 2mcg/kg as a better dose in terms of sedation &behaviour along with intraoperative hemodynamic stabilitycompared to 1 mcg/kg dose of dexmedetomidine.

Akin *et al*. in his study, compared the effects of intranasally midazolam with dexmedetomidine as premedication in children undergoing adenotonsillectomy. Authors reported that both drugs were equally effective in reducing anxiety in children during separation, but mask induction was found to be superior in midazolam group.[16]

Kumar L et al found that 1 μg/kg dexmedetomidine caused better sedation scores and behavioural scores during separation and induction compared to midazolam.[17]

Hemodynamic parameters were not assessed in our study. This is one of the main limitations.

More studies on preoperative anxiety which include psychosocial factors that affectanxiety can be done.Studies with a larger sample size and population sub-group analysis as per the age should be done to obtain better conclusion.

V. Conclusion

1.5 mcg/kg body weight dose of intranasal dexmedetomidine produced more sedation, making the child calmer and more cooperative before surgery. Hence it can be used ideally as a premedication. The study is self-sponsored. There were no conflicts of interest.

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