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A COMPARATIVE STUDY AMONG INTRANASAL DEXMEDETOMIDINE, ORAL MIDAZOLAMAND ORAL CLONIDINE AS PREMEDICATION IN PAEDIATRIC CASES. A RANDOMISED DOUBLE BLIND STUDY.

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ABSTRACT

INTRODUCTION:

It is generally accepted that apprehension and anxiety should be controlled before children are transported to the operating room for anaesthetic induction. Anxiety during the perioperative period has been described as a subiective feeling of apprehension, fear, and nervousness[1].

The ideal preanesthetic medication should provide a quick onset, have short-lived effects while enabling easy separation of the child from the caregivers.

The drugs used for premedication in paediatric cases are Intranasal Dexmedetomidine, oral Midazolam and oral Clonidine.

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MATERIALS AND METHODS:

After approval from hospital ethical & proforma committee, this study conducted on 96 patients in department of anaesthesiology, S.N. Medical, Agra .This study included children aged 2 - 12 years, undergoing surgery under general anaesthesia.

Study was double blind, randomized and placebo controlled. The mode of induction was decided by attending anaesthetist according to standard protocol of department. All study drugs were prepared by a chemist, who was not involved in further steps of study after handing over drug to nursing staff. While handling over the premedication drugs, chemist was not allowed to tell anything about the type/group of drug to nursing staff.

Premedication drug were given by nursing staff, who were not involved in any further step i.e. observation or administration of anaesthesia. The observer also noted down patient, serial number in every case.

Group D- Children received 1 mcg/kg intranasal dexmedetomidine 45 minutes before surgery and oral placebo at 30 and 60 minutes before surgery, in form of saline.

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Group C- Children received oral clonidine 4 mcg/kg 60 minutes before _surgery and received intranasal placebo at 45 minutes before surgery and oral placebo 30 minutes before surgery.

Group M- Children received oral midazolam 0.5 mg/kg 30 minutes before surgery and received oral placebo 60 minutes before surgery and received intranasal placebo 45 minutes before surgery.

To facilitate blinding, the volume of intranasal and oral medication was kept same in all the groups. Intranasal -0.5 ml, oral-5 ml.

STATISTICAL ANALYSIS

Sample size calculation from power analysis revealed that 32 patients per group would be required to provide 80% power at 0.05 level of significance to detect a 35% difference in the proportion of children, who attained satisfactory sedation with oral midazolam, oral clonidine and intranasal dexmedetomidine.

Differences in the age, weight, duration of surgery and duration surgery among the When a significant result was obtained, the Turkey test was applied for post hoc pairwise comparisions.Kruskal-wallis t-test was applied to test variation in heart rate & blood pressure Sedation, behaviour and wakeup behaviour scores were analysed by Kruskal-Wallis test .When a

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significant result was obtained, the for post Mann-Whitney U-test was applied for post hoc pairwise applied was comparision. Categorical data were analysed by chi-sqare test. three groups were compared by one-way analysis of variance (ANOVA).

RESULTS

This prospective, double-blind, randomized, controlled trial compared intranasal dexmedetomidine, oral midazolam, oral clonidine as premedication in healthy children of 2-12 yrs. age. According to sample size calculation 32 patients per group were taken. In our study, oral & nasal routes were used because advantages of these routes over intravenous & intramuscular routes are non-invasiveness, which is very important in pediatric cases.

In our study, some degree of sedation was provided by all 3 drugs midazolam, clonidine & dexmedetomidine. However, dexmedetomidine provided sedation in 75% & 53.1% children at the time of separation from parents & at induction respectively. While, midazolam provided satisfactory sedation in 21.9% & 18.8% children respectively. Clonidine provided satisfactory sedation in 59.4% & 40.6 children respectively on statistical comparison, dexmedetomidine proved to be the best among 3 drugs followed by clonidine &

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midazolam In contrast to our findings, many studies have shown good sedation in patients receiving midazolam.

CONCLUSION

Sedation at the time of separation from parents & at induction was most satisfactory in children receiving dexmedetomidine followed by clonidine and least with midazolam.

Regarding age group comparison, dexmedetomidine was best as premedicant for children aged 2-5 yrs (preschool children).

Attenuation in emergence agitation after surgery was best with dexmedetomidine, followed by clonidine.

Keywords: Intranasal Dexmedetomidine, emergence agitation, alpha adrenoceptor agoinst.

INTRODUCTION

The art of premedication has evolved over the time so that in modern anesthetic practice the goal is to allay anxiety, thereby making the experience of anesthesia and surgery more pleasant and less traumatic.

It is generally accepted that apprehension and anxiety should be controlled before children are transported to the operating room for anesthetic

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induction. Anxiety during the perioperative period has been described as a subiective feeling of apprehension, fear, and nervousness[1].

Premedication is frequently administered, prior to anesthesia induction to provide anxiolysis, proper sedation, facilitate separation from parents and lessen the adverse psychological effects of hospital experiences.

In children, the issues of premedication are made more difficult as intravenous access is frequently difficult and the children often resist or did not allow placement of an IV canula or administration of intramuscular medication or putting of facemask before surgery.

The ideal preanesthetic medication should provide a quick onset, have short-lived effects while enabling easy separation of the child from the caregivers.

The selection of premedicating drug before general anesthesia affects not only degree of sedation, anxiolysis and smoothening of induction, but also postoperative pain and recovery.

Besides this, the act of premedication adds in easy separation from parents at the time of taking the child to operating room and analgesia.

Many drugs have traditionally been used as preoperative medication to eliminate or to suppress the stress reaction to anaesthesia and surgery and to

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control the fear and anxiety experienced by many patients. They simultaneously potentiate the effects of general anaesthetic agents, reduce their dose requirements and attenuate sympathoadrenal responses to noxious stimuli encountered during anaesthesia and surgery, thus providing improved hemodynamic, metabolic, and hormonal stability.

Clonidine alpha adrenoceptor against is the drug premedicant. New agent from the same class being introduced in the clinical practice is dexmedetomidine.

Midazolam as premedication is best given by an oral route in children as they often exhibit an exaggerated psychological response to a needle prick. Midazolam, with its rapid onset and relatively short duration of action, has proven to be a useful premedication to decrease preoperative anxiety and facilitate separation from parents and improving compliance at induction of anaesthesia .Although amnesia is a good advantage of midazolam, but restlessness and negative postoperative behavioural changes are drawbacks in calling it as ideal premedication.

Alpha-2 adrenergic agonists such as clonidine can produce sedation and analgesia without compromising respiratory function.

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Dexmedetomidine, a drug of non-barbiturate class is a new potent and highly selective alpha 2 agonist with sedative, analgesic and anxiolytic intranasal effects. Keeping these factors in mind, we therefore planned to evaluate & compare the effects of oral midazolam, oral clonidine, and dexmedetomidine as premedication in children undergoing various surgical procedures under general anaesthesia. The study was conducted in the department of anaesthesiology and critical care, S.N. Medical College, Agra.

AIMS AND OBJECTIVES

The aim of this prospective study was to compare intranasal dexmedetomidine, oral clonidine and oral midazolam as premedicating

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agent on children undergoing surgeries under general anaesthesia in terms of the following:

- Preoperative degree of sedation and change in behaviour.
- Separation anxiety.
- Effect on Emergence agitation after surgery.
- Adverse effects.

(Department of anaesthesiology, queen mary hospital, hong kong[6] concluded that patients receiving intranasal dexmedetomidine for unilateral third molar surgery with local anaesthesia were more sedated perioperatively with better postoperative pain relief. No delay in psychomotor recovery was seen. Dexmedetomidine is an alpha 2-adrenoreceptor agonist, which induces sedation and analgesia. This study

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aimed to determine whether intranasal dexmedetomidine offered perioperative sedation and better postoperative analgesia. Patients having unilateral third molar surgery under local anaesthesia were recruited and allocated to receive either intranasal dexmedetomidine 1 ug kg (group d) or same volume of saline (group p) 45 min before surgery.

Perioperative sedation, postoperative pain relief and analgesic consumption, vital signs, adverse events, postoperative recovery, and satisfaction in sedation and analgesia were assessed.

MATERIAL & METHOD

After approval from hospital ethical & proforma committee, this study conducted on 96 patients in department of anesthesiology, S.N. Medical, Agra This study included children aged 2 - 12 years, undergoing surgery under general anesthesia.

Patient Selection

96 patients of ASA physical status grade I & II of either sex, between 2-12 years age, who underwent routine surgeries were randomly selected for the study.

Patient Evaluation

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All patients were subjected to a thorough pre-anesthetic checkup in the PAC clinics and then the evening before surgery as per the protocol followed in our hospital. The patients were randomly divided into 3 groups of 32 each on the basis of drug given for premedication. Written informed consent was obtained.

Exclusion criteria's were:

1. Mental Retardation
2. Psychological/emotional/cognitive abnormalities
3. Cardiac arrhythmias/significant cardiac abnormalities
4. Recent history of respiratory infection
5. Any neurological condition that may limit patient's ability to communicate or understand (according to age)
6. Patient allergies of hypersensitive to study drugs.

Study was double blind, randomized and placebo controlled. The mode of induction was decided by attending anaesthetist according to standard protocol of department. All study drugs were prepared by a chemist, who was not involved in further steps of study after handing over drug to nursing staff. While handling over the premedication drugs, chemist was not allowed to tell anything about the type/group of drug to nursing staff.

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Premedication drug were given by nursing staff, who were not involved in any further step i.e. observation or administration of anaesthesia. The observer also noted down patient, serial number in every case.

After submitting all recordings of all cases, case wise matching of group of drug and its observation were done by asking the name & serial no. from chemist & observer. Thus, study was double blinded.

Group D- Children received 1 mcg/kg intranasal dexmedetomidine 45 minutes before surgery and oral placebo at 30 and 60 minutes before surgery, in form of saline.

Group C- Children received oral clonidine 4 mcg/kg 60 minutes before _surgery and received intranasal placebo at 45 minutes before surgery and oral placebo 30 minutes before surgery.

Group M- Children received oral midazolam 0.5 mg/kg 30 minutes before surgery and received oral placebo 60 minutes before surgery and received intranasal placebo 45 minutes before surgery.

To facilitate blinding, the volume of intranasal and oral medication was kept same in all the groups. Intranasal -0.5 ml, oral-5 ml.

Intravenous canulation was the first step in all patients. Induction was either by inhalation / intravenous route and was decided was attending

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anaesthesist.67 children were induced by i.v. drugs and 29 were induced by inhalational method.

Maintenance of anaesthesia was done by oxygen, nitrous oxide, halothane/ isoflurane/ sevoflurane, muscle relaxant and opioid as per requirement.

EVALUATION SCORES

SEDATION STATUS

Sedation status was categorized as being satisfactory: If condition of child relates to 1 of the following 4 points:

- Does not correspond to mild prodding or shaking.
- Responds only mild prodding or shaking.

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- Responds after name is called loudly or repeatedly
- Lethargic response to name spoken in normal tone

Sedation status was categorized as being unsatisfactory : If condition of child related to 1 of the following 2 points:

- Appear asleep but respond readily to name spoken in normal tone.
- Appear alert and awake, response readily to name spoken in normal tone.

BEHAVIOUR STATUS

Behaviour status was categorized as being satisfactory: If condition of child relates to 1 of the following 2 points:

- Calm and cooperative
- Anxious but reassurable

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EMERGENCE AGITATION SCALE

1. Obtunded with no response to simulation
2. A sleep but responsive to movement or stimulation
3. Awake and calm, non-irritating to touch
4. Crying
5. Thrashing behaviour that requires restraint

TABLE – 1

VARIATION IN HEART RATE DURING PREMEDICATION PERIOD

(Mean ± standard deviation)

Group	**Baseline**	**After 15 minutes**	**After 30 minutes**	**After 45 minutes**	**After 60 minutes**

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M	92 ± 12	89 ± 19	90 ± 11	88 ± 10	87 ± 14
C	93 ± 12	96 ± 10	94 ± 8	90 ± 9	90 ± 11
D	92 ± 11	92 ± 13	92 ± 9	73 ± 7	70 ± 8

- There was no statistically significant difference in heart rate in group M and C (p-value >0.05)
- There was no statistically significant difference in heart rate in group D upto 30 minutes (p-value>0.05).
- But a significant reduction in heart rate was noticed after 45 & 60 minutes in group D (p-value<0.001).

TABLE – 2

VARIATION IN SYSTOLIC BLOOD DURING PREMEDCATION PERIOD

(Mean ± standard deviation)

Group	**Baseline**	**After 15 minutes**	**After 30 minutes**	**After 45 minutes**	**After 60 minutes**

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M	103 ± 10	101 ± 13	101 ± 12	97 ± 10	95 ± 10
C	100 ± 10	100 ± 9	98 ± 15	99 ± 12	95 ± 12
D	103 ± 8	95 ± 12	91 ± 12	88 ± 8	87 ± 10

In group M, reduction in systolic blood pressure was seen in period from premedication to induction, but it was statistically insignificant (p=0.003). In group C, reduction in systolic blood pressure was seen in period from premedication to induction, but it was statistically insignificant (p>0.05). In group D, reduction in systolic blood pressure was seen in period from premedication to induction. Specially after 45,60 minutes, it was significantly reduced (p<0.001).

TABLE – 3

SEDATION STATUS AT PARENTAL SEPARATION, AT INDUCTION, PROPORTION OF CHILDREN WHO HAD CHANGE SEDATION FROM SATISFACTORY TO UNSATISFACTORY AT INDUCTION

	Group- M		**Group- C**		**Group- D**		**P- value**
AT separation	Number	%	Number	%	Number	%	

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from parents							
Satisfactory	7	21.9	19	59.4	24	75	<0.001*
Unsatisfactory	25	78.1	13	40.6	8	25	
At induction							
Satisfactory	6	18.8	13	40.6	17	53.1	0.016***
Unsatisfactory	26	81.3	19	59.4	15	46.9	
Change**							0.828
Number of Changed/total	1/7	14.3	6/19	31.6	7/24	29.2	

*Significantly different between group M & C and also beween M & D at 0.05 level

**Proportion of children whose sedation status changed from satisfactory to unsatisfactory at induction

*** Significantly different between group M and D at 0.05 level

TABLE – 4

SEDATION STATUS AT PARENTAL SEPARATION, AT INDUCTION, PROPORTION OF CHILDREN WHO HAD CHANGE BEHAVIOUR FROM SATISFACTORY TO UNSATISFACTORY AT INDUCTION

	Group- M	**Group- C**	**Group- D**	**P-**

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							value
AT separation from parents	Number	%	Number	%	Number	%	
Satisfactory	6	18.8	7	21.9	24	75	<0.001 *
Unsatisfactory	26	81.3	25	78.1	8	25	
At induction							
Satisfactory	26	81.3	29	90.6	31	96.9	0.148
Unsatisfactory	6	18.8	3	9.4	1	3.1	
Change**							0.012
Number of Changed/total	6/32	18.8	1/30	3.3	0/31	0	

*Significantly different between group M and D at 0.05 level

** proportion of children whose behaviour status changed from satisfactory to unsatisfactory at induction

TABLE – 5

EMERGENCE AGITATION SCORE

Group	**M**	**C**	**D**	**P-**

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							value
Age 2-5	N=15		N=13		N=15		
Baseline	6	[6-6]	6	[6-6]	6	[6-6]	0.393
After Surgery	6	[6-6]	2	[1-5]	1	[1-2]	<0.001
Age 6-9	N=10		N=12		N=13		
Baseline	6	[6-6]	6	[6-6]	6	[6-6]	0.287
After Surgery	5.5	[4.75-6]	2.5	[1.25-5.75]	2	[1-6]	0.122
Age 10-12	N=7		N=7		N=4		
Baseline	6	[6-6]	6	[6-6]	6	[6-6]	1000
After Surgery	6	[1-6]	5	[3-6]	2	[1.25-2]	0.112

.GROUP WISE: Emergence agitation scores of children from group C & D were significantly different from group M.

AGEWISE: Children between 2-5 yr. age showed statistically significant reduction in emergence agitation ($p<0.0001$) in group D.

STATISTICAL ANALYSIS

Sample size calculation from power analysis revealed that 32 patients per group would be required to provide 80% power at 0.05 level of

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significance to detect a 35% difference in the proportion of children, who attained satisfactory sedation with oral midazolam, oral clonidine and intranasal dexmedetomidine. Differences in the age, weight, duration of surgery and duration surgery among the three groups were compared by one-way analysis of variance (ANOVA). Hemodynamic variables including blood pressure and heart rate were also analysed by ANOVA.When a significant result was obtained, the Turkey test was applied for post hoc pairwise comparisions.Kruskal-wallis t-test was applied to test variation in heart rate & blood pressure Sedation, behaviour and wakeup behaviour scores were analysed by Kruskal-Wallis test .When a significant result was obtained, the for post Mann-Whitney U-test was applied for post hoc pairwise applied was comparision. Categorical data were analysed by chi-sqare test. The adjusted P value was applied to the post hoc pairwise comparision for nonparametric and categorical data. The adjusted P value for the 0.05 level of significance was 0.017.

DISCUSSION

This prospective, double-blind, randomized, controlled trial compared intranasal dexmedetomidine, oral midazolam, oral clonidine as

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premedication in healthy children of 2-12 yrs. age. According to sample size calculation 32 patients per group were taken.

It was noticed that attenuation in emergence agitation when premedicated with dexmedetomidine was maximum in age group 2-5 yrs.In fact, this was the only age group (2-5 yrs.), in which statistically significant drop in emergence agitation was seen (table-5)

While giving intranasal premedication, no child complained of pain. Only 4 children resisted a little to intranasal drug, but drug could be given to them without much discomfort. Previous studies have shown that intranasal route is an effective way to administer premedication and sedation to children (Almenrader et al 2007)[2]. In our study, oral & nasal routes were used because advantages of these routes over intravenous & intramuscular routes are non-invasiveness, which is very important in pediatric cases.

The primary aim of study was to compare degree of sedation, behaviour and degree of attenuation in emergence agitation among three groups. Because sedation is not only the act of reducing anxiety,stress ,pain& sympathetic activity but also makes mask acceptance easier & smoothens the induction.

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In our study, some degree of sedation was provided by all 3 drugs midazolam, clonidine & dexmedetomidine. However, dexmedetomidine provided sedation in 75% & 53.1% children at the time of separation from parents & at induction respectively. While, midazolam provided satisfactory sedation in 21.9% & 18.8% children respectively. Clonidine provided satisfactory sedation in 59.4% & 40.6 children respectively on statistical comparison, dexmedetomidine proved to be the best among 3 drugs followed by clonidine & midazolam In contrast to our findings, many studies have shown good sedation in patients receiving midazolam.

High vascularity of subepithelial surface of nasal cavity and bypassing of first pass metabolism by nasal route provide the better bioabilability.

There was a tendency for more children who had received dexmedetomidine to awaken during transfer from preoperative area to operation theatre (29.2% comparison to 14.3% in midazolam group),but this was insignificant statistically(p=0.828)(table 3)

As far as behavioural changes are concerned, a good proportion of children showed satisfactory behaviour at induction with all 3 premedicants in study (81.3%, 90.6%, 96.9% in group M,C,D respectively) (table 4)

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In our study, attenuation in emergence agitation was seen best with dexmedetomidine followed by clonidine, but midazolam proved to be ineffective in this regard Interestingly, age group effect was seen also here, children of a particular age group only (2-5 yrs.) showed statistically significant attenuation in emergence agitation($p < 0.001$) (table-5)

Mizrak et al[4] (2009) found that dexmedetomidine 0.5 mg/kg i.v. reduces agitation significantly, when compared with placebo($p<0.05$). In study of Kamal et al (2008), 30 children were taken in both groups M & D (midazolam & dexmedetomidine) undergoing strabismus surgery. Finding of kamal et al were similar to that of our study. Postoperative agitation was present in 23% children in comparision to 45% in midazolam group ($p<0.05$) .This agitation reducing property of dexmedetomidine also proved in a study by Suf et al (2011) in which a 24 week gestation neonate on ventilator in i.c.u was successfully treated for refractory agitation.

The secondary aim of study was to assess adverse effect of study drugs i.e. hemodynamic and respiratory effects of these premedicants. There was no significant change in heart rate in premedication period in M &

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C group. P- value <0.001 was got in only D group, that too only after 45& 60 minutes after giving premedication. **Table 1**

According to dr Alisher et al, dexmedetomidine evokes a biphasic response to blood pressure, an early transient phase of hypertension [mediated by alpha-2b ar receptors] followed by hypotension, as evident in our study & also many studies. Hypotension was mediated by alpha-2a-ar receptors.

Oral clonidine in our study caused only 4% & 5% drop in heart rate & systolic blood pressure respectively 1 hr after premedication. This drop was insignificant statistically. But in a study by chandrashekhar et al on patients undergoing lap. Cholecystectomy found a significant($p<0.001$) reduction in heart rate(16.6%),S.B.P.(22.43%), M.A.P.(14.8%) after using oral clonidine tab. 150 mcg in adult patients.

Similar to our study Kain et al [2] found that separation anxiety usually begins after 9 month of age, with children 1-5yr of age having the highest risk for developing extreme anxiety. But finding of kain et al statistically significant in contrast to our finding. This may be due to absence of children of 1-2 yrs age in our study, who should be most prone to develop separation anxiety.

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SUMMARY AND CONCLUSION

The present study was done in department of Anaesthesiology & Critical Care, S.N. Medical College, Agra. The study was conducted after approval from Hospital ethical & Performa committee. A total of 96 paediatric patients of either sex belonging to ASA status I -II were enrolled for the study. Patients chosen were those who undergone surgeries under general anaesthesia. All surgeries finished within 1.5 hr duration.

The patients were randomly allocated in 3 groups on basis of premedication given. After noticing the acceptability of route of drug, children were observed every 15 min. till shifting of child in operating room to assess sedation & behaviour status. Heart rate, blood pressure (systolic &diastolic), sp02 were also recorded every 15 minutes preoperatively, every 30 min. intraoperative and in recovery room.

Children were discharged from PACU, when vitals were within 20% of baseline.

CONCLUSIONS:

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1. Sedation at the time of separation from parents & at induction was most satisfactory in children receiving dexmedetomidine followed by clonidine and least with midazolam.
2. Regarding age group comparison, dexmedetomidine was best as premedicant for children aged 2-5 yrs (preschool children).
3. Attenuation in emergence agitation after surgery was best with dexmedetomidine, followed by clonidine.

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