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A Study of Effect of Intranasal Dexmedetomidine on Minimum Alveolar Concentration of Sevoflurane for I-Gel Insertion and Emergence Delirium in Children

[1]Poonam Gurlewad, Senior Resident, Department of Anaesthesia, SRTR Medical College & Hospital, Ambajogai

[2]Anila Malde, Professor & Head, Department of Anaesthesia, LTTMC & Sion Hospital, Mumbai

Corresponding Author: Poonam Gurlewad, Senior Resident, Department of Anaesthesia, SRTR Medical College & Hospital, Ambajogai.

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Abstract

Introduction: Most pediatric patients have anxiety during the preoperative period, which may be due to separation from parents, fear of injections, operation theatre, or unfamiliar faces. This leads to stress, tachycardia, agitation or excessive crying, which make the management of such patients difficult during induction of anaesthesia. Emergence delirium (ED) is a post-surgical phenomenon associated with an increase in morbidity, mortality and resource utilization. Dexmedetomidine (Dex) deepens the level of anaesthesia and facilitates smooth inhalation induction. But there is dearth of literature in children about the use of Dex reducing anesthetic requirement. However, the dose related effects of Dex premedication on the minimum alveolar concentration of sevoflurane for laryngeal mask airway insertion (MAC_{LMA}) remain undetermined in children.

Material & Methods: It was a prospective observational study of 80children; aged 6 months -8 years, with ASA I and II; scheduled for elective infraumbilical surgeries of duration 45 minutes to one hour under general anesthesia with supraglottic devices.

Results: Behavior of patient while entering operation theatre was significantly better in Dex group (1=0%, 2=55%, 3=45%) compared to control group. (1=97.5%, 2=2.5%, 3=0%) (P=0.001). Quality of mask acceptance was significantly better in Dex group (1=0%, 2=0%, 3=50%, 4=42.5%, 5=7.5%) compared to control group (1=87.5%, 2= 10%, 3=2.5%, 4=0%, 5=0%) (P=0.001). Dex group required shorter time for loss of eyelash reflex as compared to control group, centralization of pupil, jaw relaxation and i-gel insertion. Emergence agitation by WATCHA scale and pain assessment by FLACC scale was significantly less in Dex group as compared to control. Parental satisfaction was

significantly better as compared to control group. **Conclusion:** Intranasal Dex 1 μg/kg reduces MAC requirement for i-gel insertion and postoperative emergence delirium. In addition, it also provides better sedation level, better behavior of child while entering operation theatre, better acceptance of mask while inducing the child, perioperative hemodynamic stability, analgesia and parental satisfaction.

Keywords: Dexmedetomidine, Intranasal, Emergence delirium, I gel, Premedication, MAC, Pediatric

Introduction

Most pediatric patients have anxiety during the preoperative period, which may be due to separation from parents, fear of injections, operation theatre, or unfamiliar faces.[1] This leads to stress, tachycardia, agitation or excessive crying, which make the management of such patients difficult during induction of anesthesia. Preoperative anxiety is therefore an important concern for pediatric anesthesiologists.[2] Reducing preoperative anxiety is desired to improve the preoperative experience for patients and parents. Patient's anxiety level influences their immediate postoperative outcomes as well as long-term outcomes after discharge.[3]

The ideal premedicant in children should be readily acceptable and have a rapid and reliable onset of action with minimal side effects. Earlier, drugs such as meperidine and promethazine were commonly used, but now-a-days the commonly used drugs are dexmedetomidine (Dex), ketamine and midazolam.[4] Dex, a highly selective alpha 2-agonist, faster acting than clonidine, with analgesic, sedative actions and devoid of respiratory depressive action, became available in 1999 and has been used as premedication. Dex is used as premedication by oral, intranasal and intravenous routes. [5]

Sevoflurane is widely employed for pediatric anesthesia because of its beneficial pharmacological characteristics. However, the excitatory phenomenon is one of the main disadvantages during the inhalation induction and emergence, particularly in preschool children. Inhalation induction with high alveolar sevoflurane concentration may also be associated with an epileptiform electroencephalogram. There are many studies available which proved that Dex reduces anesthetic requirement for tracheal intubation and supraglottic device insertion in adults. But there is dearth of literature in children about the use of Dex as reducing anesthetic requirement. It also deepens the level of anesthesia and facilitates smooth inhalation induction. However, the dose related effects of Dex premedication on the minimum alveolar concentration of sevoflurane for laryngeal mask airway insertion (MAC_{LMA}) remain undetermined in children.[6] Supraglottic device like i-gel, has been established as a useful device for pediatric anaesthesia, which allows patients spontaneous respiration during general anaesthesia with sevoflurane for minor surgery. However, airway complications (e.g., laryngospasm and cough), sometimes life-threatening, are commonly encountered during Supraglottic airway device placement in children, but it can be smoothly inserted by deepening anaesthesia by using Dex for premedication.[7] This study was an attempt to determine the effect of intranasal Dex 1 μg/kg on minimum alveolar concentration (MAC) requirement for I-gel, a supraglottic device insertion. We have assessed the effect of intranasal Dex 1μg/kg on emergence delirium.

Materials & Methods: In this prospective, observational study of two years, in a tertiary care

teaching institution; 80 children of 6 months to 8 years, ASA grade I or II undergoing infraumbilical surgeries under general anaesthesia with supraglottic airway device insertion were observed. Those patients who did not receive premedication were labelled as 'control' group and those patients who received premedication with intranasal Dex 1µg/kg 45 minutes before surgery were labelled as 'Dex' group. Preoperatively baseline parameters were noted in both the groups. Hemodynamics, respiratory rate, sedation by Ramsay sedation score (RSS) were noted in Dex group. Both the groups received standard general anaesthesia protocol. Behavior of patient while entering operation theatre, quality of mask acceptance, time to loss of eyelash reflex, centralization of pupil, jaw relaxation, i-gel insertion were noted in both the groups. Dial concentration of sevoflurane, fraction inspired and expired concentration of sevoflurane and MACage were noted at various time points. Excitement score was also noted. Postoperatively WATCHA scale, pain assessment by FLACC scale, shivering, nausea/vomiting and parental satisfaction were compared. If data was not normally distributed median and interquartile range were calculated and analyzed by using Mann Whitney u test. $P<0.05$ was considered as significant.

Results

Table 1: Behaviour of patient while entering operation theatre:

			Group		Total
			Control (n=40)	Dex (n=40)	
Behaviour of patient while entering operation theatre (1-3)	1	n (%)	39 (97.5%)	0 (0.0%)	39 (48.8%)
	2	n (%)	1 (2.5%)	22 (55.0%)	23 (28.8%)
	3	n (%)	0 (0.0%)	18 (45.0%)	18 (22.5%)
	Total	n (%)	40 (100.0%)	40 (100.0%)	80(100.0%)

Behavior of patient while entering operation theatre: 1=Poor (anxious and combative), 2=Good (anxious and easily reassured), 3= Excellent (sleeping and calm)

Table 1: Behavior of patient while entering operation theatre was significantly better in Dex group (1=0%, 2=55%, 3=45%) compared to control group (1=97.5%, 2=2.5%, 3=0%) (P=0.001). Patients premedicated with Dex were calm and sedated while unpremedicated patients were crying, agitated, anxious.

Table 2: Association of Quality of Mask Acceptance:

			Group		Total
			Control (n=40)	Dex (n=40)	
Quality of Mask Acceptance (1-5)	1	n (%)	35 (87.5%)	0 (0.0%)	35 (43.8%)
	2	n (%)	4 (10.0%)	0 (0.0%)	4 (5.0%)
	3	n (%)	1 (2.5%)	20 (50.0%)	21 (26.3%)
	4	n (%)	0 (0.0%)	17 (42.5%)	17 (21.3%)
	5	n (%)	0 (0.0%)	3 (7.5%)	3 (3.8%)

	Total	n (%)	40 (100%)	40 (100%)	80 (100%)

Five-point scale for mask acceptance: 1=Combative and crying, 2= Moderate fear of mask not easily calmed, 3=Cooperative with reassurance, 4= Calm, cooperative 5=Asleep, steal induction

Table 2: Quality of mask acceptance was significantly better in Dex group (1=0%, 2=0%, 3=50%, 4=42.5%, 5=7.5%) compared to control group (1=87.5%, 2= 10%, 3=2.5%, 4=0%, 5=0%) (P=0.001). On the other hand, unpremedicated patients were agitated and quality of mask acceptance was poor. They didn't allow easy mask holding.

Table 3: Excitement Score:

	Control (n=40)		Dexmedetomidine (n=40)		Mann-Whitney U	p value
	Median	IQR	Median	IQR		
ES (1-4)	2	1	1	1	12.5	0.000

1= None, 2= Mild, 3= Moderate, more movement but no significant interference with induction 4= Severe, excessive movements interfering with induction and requiring restraint

Table 3 Indicates excitement score was less in Dex group as compared to control group.

Table 4: Comparison of time required:

	Control (n=40)		Dexmedetomidine (n=40)		Mann-Whitney U	p value
	Median	IQR	Median	IQR		
Loss of eyelash reflex	143.0	58.3	101.5	11.5	7.500	<0.001
Centralization of pupil	171.0	43.3	116.0	9.5	32.500	<0.001
Jaw relaxation	184.0	44.3	120.5	9.5	1.000	<0.001
At time of i-Gel insertion	190.00	45.750	124.00	9.750	1.000	<0.001

Table 4 (A, B, C, D) Dex group required shorter time for loss of eyelash reflex as compared to control group 101.5 (11.5) vs 143 (58.3), centralization of pupil 116 (9.5) vs 171 (43.3), jaw relaxation 120.5(9.5) vs 184 (44.3) and i-gel insertion 124 (9.750) vs 190 (45.750) seconds. P value at all timings was <0.001. On the other hand, unpremedicated patient required more time for loss of eyelash reflex, centralization of pupil, jaw relaxation, i-gel insertion.

Table 5: Comparison of MACage:

	Control (n=40)		Dexmedetomidine (n=40)		Mann-Whitney U	p value
	Median	IQR	Median	IQR		
Loss of eyelash reflex	3.2	0.9	1.9	0.2	7.500	<0.001
Centralization of pupil	2.7	0.0	1.8	0.3	32.500	<0.001
Jaw relaxation	2.7	0.0	1.8	0.3	1.000	<0.001
At the time of i-gel insertion	2.7	0.0	1.7	0.3	1.000	<0.001

Table 5 (A, B, C, D) Dex vs control group had less median (IQR) FdS, FiS, FeS, MACage at all time points, i.e. loss of eyelash reflex, centralization of pupils, jaw relaxation etc. Dex vs control group had less median (IQR) FdS 3 (1) vs 4 (0), FiS 3 (1) vs 3.9 (0), FeS 2.9 (1) vs 3.8 (0.1), MACage 1.7 (0.3) vs 2.7 (0) for i-gel insertion. P value for all <0.001. Because patients premedicated with Dex allowed easy mask holding, smooth induction.

Table 6: Postoperative Emergence Agitation by WATCHA Scale:

	Control (n=40)				Dexmedetomidine (n=40)				Mann-Whitney U	p value
	Median	IQR	Max	Min	Median	IQR	Max	Min		
WS (0-4)	4	0.00	4	3	2	1	3	1	0.500	0.000

0= Asleep, 1= Calm, 2= Crying, but can be consoled, 3=Crying, but cannot be consoled, 4=Agitated and thrashing around.

Emergence agitation by WATCHA scale was less in Dex group as compared to control [2(1) vs 4(0)] [P= 0.000]. Pain assessment by FLACC scale was significantly less in Dex as compared to control [2(1) vs 7(1)] [P= 0.000]. Post operative nausea/vomiting [2(0.75) vs 2(0.00)] was similar [P=0.356]. Shivering was significantly less in Dex vs control [2(0.75) vs 2(1)] [P=0.000].

Table 7: Comparison between Parental Satisfaction scale:

	Control (n=40)		Dexmedetomidine (n=40)		Mann-Whitney U	p value
	Median	IQR	Median	IQR		
PS (1-4)	3.0	1.0	2.0	1.0	50.000	0.000

Parental Satisfaction Graded As

1. Excellent. 2. Good. 3. Fair. 4. Poor.

Table 7: Shows parental satisfaction was better in Dex group as compared to control group. Parental satisfaction was significantly better as compared to control group [2(1) vs 3(1)] [P=0.000]

Discussion

Management of pediatric patients have anxiety during the preoperative period is difficult during induction of anaesthesia. Patient's anxiety influences their immediate postoperative outcomes as well as long term outcomes after discharge.

Intranasal Dex is an effective sedative for premedication in pediatric patients. Koroglu et al[8], Akin et al[9] and Jin XU [10] et al used Dex as a premedicant and they concluded that it minimizes distress for children in the operating room and facilitates a smooth induction of anesthesia. So, we had included Dex as a premedication drug in our study.

Dex has been extensively studied intranasally in both children and adults. Previous investigations by Yuen et al [11] have shown that intranasal Dex produces significant sedation in healthy adults and in children aged between 1 and 12 years. Intranasal application is a relatively noninvasive and easy route of administration. Dex is well tolerated and does not have pungency unlike midazolam. Hence, we used intranasal route for Dex.

Intranasal Dex has been used in doses ranging from 0.5µg/kg to 1.5µg/kg. In a comparative study Yuen et al [11] showed that 75% of the children in group receiving Dex 1µg/kg had satisfactory sedation compared to 59.4% in 0.5µg/kg group. Although patients premedicated with 0.5µg/kg Dex were initially effectively sedated, these children were aroused more easily with external stimulus. Yuen et al, Singla et al[12], Patel et al[13] and Ahmed et al [14] also showed that Dex is effective and safe intranasally in 1µg/kg dose. Hence, we decided to use 1µg/kg dose intranasally.

Onset of action of intranasal Dex is 45 minutes in both adult and pediatric population. Yuen et al [11] in a study to find optimal timing for the administration of intranasal Dex for premedication in children found that median onset time of sedation was 25 minutes. Ninety one percent of subjects had achieved satisfactory sedation 45

minutes after intranasal Dex. Similarly, Talon et al [15] showed intranasal Dex to be effective when given 45 minutes before surgery. Hence, we have used intranasal Dex 45 minutes before surgery.

The time for onset of sedation in our study was 25-30 min. We didn't find the studies that evaluated time to achieve peak sedation in children. In our study the time to achieve peak sedation was 40-45 mins.

Following premedication sedation was evaluated by Ramsay sedation score. Sedation has been evaluated by different scales by different authors. Yuen et al [11] used 6 point Modified Observer's Assessment of Alertness/sedation scale; Ahmed et al[14] used the university of Michigan sedation scale and Sakurai et al [16] used Ramsay sedation scale. We used Ramsay sedation scale because it is standard, easy to use, validated, and convenient and can be used in age group 1-12 years.

We evaluated time of onset of sedation and time to achieve peak sedation. We defined time of onset of sedation as increase in sedation level by 1 from baseline, and peak sedation as Ramsay score 4. As the baseline level of anxiety and sedation keeps varying among patients, it is important to note down change from baseline for that patient as onset time and hence we considered increase in Ramsay sedation score by 1 plus as onset of sedation. Peak sedation has been defined as satisfactory sedation by different authors and their definition differed because they have used different scales to assess sedation. In general, satisfactory sedation was defined as child being calm, cooperative and drowsy. In Ramsay scale score 4= child asleep but has brisk response to light glabellar tap or loud auditory stimuli which we defined as peak sedation. In our study, majority of children were very well sedated. All achieved peak sedation score 4.

We monitored heart rate, blood pressures, respiratory rate and peripheral oxygen saturation (SpO2) preoperatively to assess effects of drugs on hemodynamics, and to monitor any adverse effects. Schmidt et al [17] observed alpha 2 agonists produced low scores of perioperative mean arterial blood pressure and heart rate. Singla et al [12], Ibacache et al[18] and shukrey et al[19] observed intranasal Dex (1 μg/kg) premedication resulted in statistically significant but clinically unimportant lower heart rate and blood pressure following administration. In our study, after premedication there was -10.94 ± 7.91% decrease in heart rate and -7.04 ± 5.93% decrease in systolic blood pressure. Respiratory rate and oxygen saturation in percentage were well maintained throughout the procedure.

We also evaluated behavior of the child while entering operation theatre by 3-point scale and quality of mask acceptance by 5-point scale. Even though child is sedated, he/she can become awake and anxious while taking into operation theatre and during mask holding. Hence it is important to evaluate these two factors. Behavior of child while entering operation theatre was assessed by different scales by different authors. Yuen et al[11] used 4-point scale, we used 3-point scale - Poor (anxious and combative), Good (anxious and easily reassured) and Excellent (sleeping and calm) to evaluate behavior of child while entering operation theatre, which is simple and easy to use. Ghali et al[20] observed that at the time of transferring patients to the theatre, children premedicated with intranasal Dex achieved significantly better (higher) sedation. Ibacache et al[18] used Modified Aldrete Score to assess behavior of patient while entering operation theatre. In our study, we observed that while entering operation theatre behavior of patient premedicated with intranasal Dex was significantly better

than the control group. Parental separation was assessed by different authors. Singla et al[12] Patel et al[13], Peng et al. [21] They observed ease of child parent separation with the use of intranasal Dex.

Similarly, quality of mask acceptance/ease of induction has been evaluated by different authors using different scales. Singla et al[12] used 4-point scale (1= Combative, crying, 2= moderate fear of mask not easily calmed, 3= Cooperative with reassurance, 4= Calm, cooperative). They observed that a greater number of children premedicated with intranasal Dex achieved better mask acceptance. We used 5-point scale (1= combative and crying, 2=moderate fear of mask not easily calmed, 3= cooperative with reassurance, 4= calm, cooperative, 5= asleep, steal induction) which we found to be convenient, simple and sensitive. In our study, we observed better mask acceptance score in Dex group.

Many authors (Kim et al[22], Savla et al[23], Yao et al[24] studied the effect of Dex on MAC of sevoflurane for successful LMA insertion. Di M et al [25] also concluded that Dex decreased the required MAC_{EX} values of sevoflurane to achieve smooth extubating. Savla et al [23], determined MAC_{LMA} by using Dixon's and Massey's Up and down Method. They concluded that Dex reduces MAC of sevoflurane for LMA insertion.

In our study we clinically assessed the adequate depth of anesthesia for i-gel insertion by considering the parameters like loss of eyelash reflex, centralization of pupil, jaw relaxation. We observed that MAC for supraglottic device insertion was lower in Dex group (median 1.7) than control group (median 2.7) ($p < 0.001$). If more than one attempt was needed for successful i-gel insertion, the case was excluded from further analysis.

Intra operatively we monitored hemodynamics and respiratory parameters in both the groups. In Dex group, after premedication there was -10.94 ± 7.19 % reductions in heart rate. After i-gel insertion maximum reduction in heart rate was nearly 16% and heart rate was 96.05 ± 9.27. That means baseline heart rate can be higher because of anxiety which was settled down after premedication (101.30 ± 6.18) and then it remained steady. Whereas in control group heart rate was 124.25 ± 9.38 at the time of i-gel insertion, which means there was nearly 7% increase in heart rate. Since these were healthy children, this much increase in heart rate in control group doesn't really matter. Similarly, in Dex group, there was -7.04 ± 5.93 % decrease in systolic blood pressure following premedication. Maximum decrease in systolic blood pressure noted in Dex group was nearly 7%. This is also clinically not significant. None of the patient showed significant bradycardia or hypotension requiring treatment.

Postoperatively we observed emergence delirium. Many authors used different scales to assess ED. Ahmed et al[14], Hamawy et al[26], and Yao et al[24] used Pediatric Anesthesia Emergence Delirium (PAED) scale. Shukrey et al[19] used WATCHA scale. They concluded that intranasal Dex reduces incidence of postoperative ED. We used WATCHA scale for assessing ED. We calculated the highest emergence delirium score in initial two hours of post-operative period and further analyzed. We observed that intranasal Dex seem to decrease the incidence of postoperative ED. ($p<0.001$)

As Dex has analgesic action, we monitored pain post operatively. Ibacache et al[18] used Children's and Infant's Post-operative Pain Scale (CHIPPS) and they observed that children premedicated with Dex had better CHIPPS score (<3). Shukrey et al[19] used Objective Pain Scale (OPS). Hamid et al [27] used FLACC scale. They observed that FLACC pain scale scores were significantly lower in

Dex group ($p<0.05$). In our study we also used FLACC for post operative pain assessment which considers all parameters and is already validated. We calculated highest pain score in initial two hours of post-operative period and analyzed. In our study, FLACC score were lower in children premedicated with Dex ($p<0.001$).

As Dex has property of reducing nausea, vomiting, shivering and improves parental satisfaction; we monitored post operative nausea, vomiting, shivering and parental satisfaction and in both groups. Hamway et al [26]and Amr et al [28] Peng et al [21] observed that incidence of nausea and vomiting was lower in Dex group. In our study, we used four-point scale to assess post operative nausea and vomiting. We calculated highest nausea/vomiting score in initial two hours of post-operative period. We did not observe significant reduction in nausea/vomiting score in Dex group. Very few studies have been done about anti-shivering property of Dex. Tobias et al [29] observed that Dex may be an effective agent to control shivering post operatively. In our study, we calculated the highest shivering score in initial two hours of post-operative period and analyzed. We observed that children premedicated with Dex had lower scores of postoperative shivering. It can be because of ant shivering property of Dex. Yao et al [24] and Peng et al[21] concluded that intranasal Dex improves parental satisfaction. In our study also parental satisfaction score was better in Dex group as compared to control group.

Conclusion

Intranasal Dexmedetomidine 1 μg/kg reduces MAC requirement for i-gel insertion and postoperative emergence delirium. In addition, it also provides better sedation level, better behavior of child while entering operation theatre, better acceptance of mask while inducing the child, perioperative hemodynamic stability, analgesia and parental satisfaction.

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