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To assess the Compliance and Sedation Score of Intranasal Midazolam and dexmedetomedine Premedication among Children

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Abstract

Background: The pre anesthetic medication forms an integral part of anesthetic management. Some form of premedication is almost universally given before induction of anesthesia. In ancient days both wine and opium were given to lessen the fear of surgery. *Objective*: To assess the Compliance and Sedation Score of Intranasal Midazolam and dexmedetomedine Premedication among Children between 1 to 5 years of age. *Methodology*: A longitudinal study was conducted from June 2012 to December 2012 at Department of Anesthesiology of Shri M.P. Shah Medical College, Jamnagar, Gujarat. A total of 30 Cases were selected based on age sex matched with each group for the purpose of the study randomly as per the computer generated random Numbers. Group 1 received intranasal midazolam spray and Group 2 was given intranasal dexmedetomedine. *Results*: The sedation score was found to be statistically significant at 30 and 45 min post induction. Postoperative recovery score at 30 min was found to statistically highly significant with suggested that postoperative recovery score was better in group 1 as compared to group 2. *Conclusion*: Intranasal dexmedetomidine spray better sedative condition, response to IV cannulation, separation and induction as compared to intranasal midazolam in majority of patients. This study concludes that intranasal dexmedetomedine is better than intranasal midazolam as premedication in pediatric patients.

Keywords: Intranasal; Pre Anesthesia; Sedation; Compliance.

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Introduction

The preanaesthetic medication forms an integral part of anaesthetic management. Some form of premedication is almost universally given before induction of anaesthesia. In ancient days both wine and opium were given to lessen the fear of surgery.

In an Allien and apparently hospital place where unfamiliar human faces are covered by mask and cap, the child who is about to undergo new and frightening experience of anaesthesia may suffer severe mental distress. It is at such time that the calming and hypnotic effects of premedicants are particularly valuable [1].

To prevent these changes, many methods have been advocated in children to prevent undesirable psychic trauma and personality changes. In 17% of post-operative follow up cases there were personality changes, bed wetting and night mares and this has been attributed to the unpleasant induction and crying at the time of induction of anaesthesia [2].

As per Robert M. Bruzustowic [3], an ideal premedicant in children should have good patient acceptance, predictable results and free from any serious side effects.

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He also studied the decreased incidence of crying upon arrival in operating room as well as decrease the pre and post induction secretion are favorable for smooth induction of anaesthesia especially in pediatric patients. The conditions were significantly improved with premedication [3].

As the children dislike injection, our forcible administration from this route will lead to struggling and psychological impact [4,5,6]. For this reason, other route of premedication such as oral, rectal, intranasal and sublingual were found to be effective. Intranasal premedication certainly creates a quitter atmosphere when groups of children are involved for surgery and for a better psychological balance of the children. Intranasal route of administration has advantage over the other routes [7,8,9].

There are combinations of drugs used for premedication like narcotics, barbiturates, anticholinergic, phenothiazines, benzodiazepines, phencyclidine (ketamine) and newer drugs like alpha 2 agonists.

In our present study we used Intranasal Midazolam and Compared with Intranasal Dexmedetomidine as premedication among the children.

Objective

To assess the Compliance and Sedation Score of Intranasal Midazolam and dexmedetomedine Premedication among Children between 1 to 5 years of age.

Materials and Methods

A longitudinal study was conducted from June 2012 to December 2012 at Department of Anesthesiology of Shri M.P. Shah Medical College, Jamnagar, Gujarat. The children aged between 1 to 5 years who were posted for the surgery were included in the study. A total of 30 Cases were selected based on age sex matched with each group for the purpose of the study randomly as per the computer generated random Numbers. Group 1 received intranasal midazolam spray 0.5mg/kg body weight and Group 2 was given intranasal dexmedetomedine instillation 1mcg/kg body weight.

In the preanaesthetic room, vital parameters, dosing time and acceptance of premedicant were noted The response to drug administration was classified as cooperative if child accepted the premedication willingly, didn't cry and uncooperative if child cried .

Sedation level was assesed by the sedation Score.

Statistical analysis was done using 't' test for quantitative data and chi square (χ^2) test for qualitative data and results considered insignificant if P value > 0.05, significant if p<0.05, highly significant if p<0.0001.

Level of Sedation	Sedation Score
Agitated, clinging to the parent or crying.	1
Alert but anxious, not clinging to parent, may whimper but not cry.	2
Calm, sitting or lying comfortably with eyes open.	3
Drowsy, eyes closed but respond to verbal or tactile stimulation.	4
Asleep, not responding to minor stimulations.	5

Results

The two groups were analyzed for 30 subjects in each group.

In group 1, 73.33% patients were cooperative to the acceptance of intranasal route of midazolam and 26.67% were uncooperative to the acceptance of intranasal route of midazolam. In group 2, 70% patients were cooperative to the acceptance of intranasal route of dexmedetomidine and 30% patients were uncooperative (Table 1).

Table 1: Distribution of patients according to Acceptance of study drug

Acceptance	Group 1	Group 2
Co-operative	22(73.33%)	21(71%))
Un co-operative	8(26.67%)	9(30%)
Total	30	30

The Sedation Score was found to be not Significant between the groups at 5 and 15 Minutes post Premidication among the study groups, whereas the sedation score was found to highly statistical Significant post administration of pre anesthetic medications at 30 and 45 minutes between the groups (Table 2).

Table 2: Showing the sedation score at various interval Sedation score at 5, 15, 30 and 45 min

Sedation Score		1	2	3	4	5	X^2 test	P value	Sig
Sedation score at 5min.	Group 1	25	5	0	0	0	0.000	1.000	NS
	Group 2	24	6	0	0	0			
Sedation score at 15 min.	Group 1	0	29	1	0	0	2.00	0.36	NS
	Group 2	1	29	0	0	0			
Sedation score at 30 min	Group 1	0	16	14	0	0	16.088	<0.0001	HS
	Group 2	0	1	29	0	0			
Sedation score at 45 min	Group 1	0	3	27	0	0	16.088	<0.0001	HS
	Group 2	0	0	1	16	13			

Table 3: Showing response score to compliance of Premedication Procedure

Score		1	2	3	X^2 test	P value	Sig
Response score to iv cannulation (45 min. after premedication)	Group 1	12	13	5	13.88	0.001	S
	Group 2	2	11	17			
Separation and induction score	Group 1	9	15	6	10.18	0.381	NS
	Group 2	19	11	0			
Postoperative recovery score at 30 min	Group 1	1	19	10	29.98	<0.0001	HS
	Group 2	20	10	0			
Postoperative recovery score at 45 min	Group 1	0	16	14	30.13	<0.0001	HS
	Group 2	18	11	1			

Table 4: Showing side effects in two groups

Side effects	Group 1	Group 2
Nasal secretions	16	6
Nasal redness	6	2
Lacrimation	8	6
Increased salivation	0	0
Upper airway obstruction	0	0

After applying χ^2 test for the response score to IV cannulation, χ^2 value was 13.88 with DF 2 having P value 0.001 which showed significant result and suggested that patients in group 2 were more cooperative than group M during intravenous cannulation.

The Separation and Induction score was found to be not significant on applying chi square test was not significant and Suggested that separation score was same between both the groups.

Postoperative recovery score at 30 min was found to statistically highly significant with suggested that postoperative recovery score was better in group 1 as compared to group 2.

Postoperative recovery score at 45 min was found to statistically highly significant with suggested that postoperative recovery score was better in group 1 as compared to group 2.

In group 1, 16 patients had nasal secretion, 2 had nasal redness, 8 had lacrimation and none had increased salivation or upper airway obstruction. In group 2, 6 patients had nasal secretion, 2 had nasal redness, 7 had lacrimation and none had increased salivation or upper airway obstruction.

After statistical analysis of results, it was noticed that at the time of transferring patients to the OT, the HR was significantly less in the dexmedetomidine group compared to the midazolam group (p=0.036) and the SBP was significantly less in the dexmedetomidine group compared to the midazolam group (p=0.032). However, there were no episodes of bradycardia, hypotension, or hypertension in both groups.

Discussion

Premedication is even important in case of children. They are aware of separation from their parents and of the strange hospital environment. Also they are not able to fully understand the

necessity for their surgery, nor are they amenable to reasoned explanation [1,10].

Fear of painful and unpleasant procedures, separation from parents and an unwillingness to breathe through an anesthesia face mask may produce stormy anaesthetic induction in un-premedicated patients [2,3]. Because of this pre-anaesthetic sedation should be an integral part of pediatric anaesthetic practice.

Premedication in children can pave the way to achieve a smooth anaesthetic induction and post-operative course [2]. It is also an important adjunct to help alleviate the stress and fear of surgery as well as to ease the child parent separation and promote a smooth induction of anaesthesia [11]. Most anaesthetists although preferring the 2-4 year age group to be asleep before reaching the theatre, but desire for older children to be arousable and rational, as well as sleepy and quiet.

A well sedated, co-operative and sleepy child with dry upper respiratory tract is very ideal for induction and maintenance of any type of general anaesthesia [12].

This study was designed to evaluate the safety, acceptability, efficacy and applicability of intranasal midazolam and dexmedetomedine as a premedication in pediatric surgical patients.

The Results are comparable to the other study findings of Lane RD, SChunk JE [13], who also concluded that atomized intranasal midazolam is effective in providing anxiolysis to children undergoing minor procedures in the pediatric emergency department. Frank TC et al. [14] also concluded that that low dose intranasal midazolam is an effective and patient friendly solution to overcome anxiety and is superior to that of the orally administered form.

Yearly D M et al. [15] also concluded that intranasal midazolam was a safe and effective sedative for laceration repair under local anesthesia in preschool aged children and they recommended a dose of 0.3 to 0.5 mg/kg with treatment failure less likely after 0.4 to 0.5 mg/kg compared with less than 0.3 mg/kg, this finding did not correlate with our study as requirement of dose for sedation for laceration repair under local anesthesia may be higher than that required for preanaesthetic sedation for paediatric patients.

The cooperation and acceptance of the intranasal route of Preanasthetic medication in our study was comparable to the study findings of Gustaf Ljungman, Anders Kreuger, et al. [16] and Gudmundsdottir H, Masson M, et al. [17].

The Sedation score differences were very striking and significant. This denotes the efficacy of sedating the children and providing anxiolysis for stressful period by intranasal dexmedetomidine is better choice than intranasal midazolam spray.

The study findings in our research were comparable with the study findings of Ghali AM et al. [18], Antilla M et al. [19] and Yuen et al. [20] Even in the study done by Mark D Talon et al. concludes that intranasal dexmedetomedine is useful drug for sedation and is superior to the intranasal midazolam at inducing sleep preoperatively.

The Separation and induction score in our study was comparable to the study findings of Ghali a M et al. [18] and Fishbein, Mark, Lugo et al. [21].

The post-operative recovery among the groups in our study findings were similar to the study findings of Ghali a M et al. [18].

Conclusion

The results analyzed showed that route of drug administration as nasal spray was somewhat irritable to some patients in both groups, but sedation and anxiolysis were better in group 2 as compared to group 1 both during separation from parents and intravenous cannulation. Induction and recovery was also smooth in group 2 than group 1. Intranasal dexmedetomidine spray better sedative condition, response to IV cannulation, separation and induction as compared to intranasal midazolam in majority of patients. This study concludes that intranasal dexmedetomedine is better than intranasal midazolam as premedication in pediatric patients.

Conflicts of Interest: NIL

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