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"COMPARISON OF FENTANYL VERSUS DEXMEDETOMIDINE INTRANASALLY AS PREMEDICATION IN PAEDIATRIC PATIENTS UNDERGOING GENERAL ANAESTHESIA: A RANDOMISED INTERVENTIONAL STUDY"

Anaesthesiology

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ABSTRACT

Background: Premedication is often used in children to alleviate perioperative anxiety, ease parental separation and smooth induction. Perioperative anxiety and psychological trauma associated with surgery has adverse clinical outcomes like emergence delirium, negative behavioural changes and increased analgesic and anaesthesia requirement. In this study we compared efficacy of intranasal fentanyl and dexmedetomidine as premedicants in pediatric patients.
Methods: 60 patients of age 2-6 years were enrolled in the study, out of which 30 in group A received intranasal 1.5µg/kg fentanyl and group B received 1µg/kg dexmedetomidine 30 minutes prior to induction.
Results: Patients who received fentanyl had earlier onset of anxiolysis and sedation, but dexmedetomidine provide better anxiolysis and deeper sedation. Dexmedetomidine provides significantly ($p<0.05$) better child-parent separation and mask acceptance during induction and better and quiet emergence with prolonged postoperative sedation was observed.
Conclusion: Fentanyl has early onset of anxiolysis and sedation, but short duration of action and respiratory depressant effect makes it less preferable than dexmedetomidine which provides better anxiolysis, induction and emergence from anaesthesia.

KEYWORDS

Fentanyl, dexmedetomidine, pediatric, intranasal premedication.

INTRODUCTION

Premedication refers to the administration of medications to relieve anxiety before surgery. It also includes any medication given in the preoperative period and therefore includes prophylactic analgesia and antiemetic agents, as well as drugs used to promote gastric emptying or counteract acid secretions[1].

Premedication is useful to control anxiety, postoperative pain, nausea, vomiting and to reduce the risk of aspiration during induction of anesthesia. Most premedicants do not prolong recovery when given in appropriate doses for appropriate indications[2]. Premedication may be administered orally, IM, IV, rectally, sublingually, or nasally. Each one has its drawbacks. Oral or sublingual premedication does not hurt but may have slow onset or can be spit out; drug taste and child cooperation are the main determinants of success. IM medications hurt & may result in a sterile abscess. IV medications may be painful during injection or at the start of infusions. Rectal medications make the child feel uncomfortable, cause defecation and occasionally burn. Nasal medication can be irritating, although absorption is rapid[1].

The ideal volume per nostril is 0.2-0.3 ml; in practice, the maximum volume for single administration into one nostril (in adults and pediatrics) is 0.5 ml and 0.1 ml in neonates. Larger volumes should be divided (i.e. half dose in each nostril), Splitting the dose doubles the available mucosa surface area and increases absorption.

Using a concentrated form of the medication reduces the volume to be administered. If the volume per nostril exceeds 0.5 ml, the dose should be administered in two separate applications 5 – 10 minutes apart, spacing between doses allow the former dose to absorb[3].

Dexmedetomidine is highly selective α_2 adrenergic agonist. α_2 receptors are present primarily in pre synaptic neurons where it modulate the release of neurotransmitter. Its sedative effect is because of decreasing activity of noradrenergic neurons in locus ceruleus in the brainstem, and increasing activity of inhibitory GABA neurons in ventrolateral preoptic nucleus. Fentanyl, a synthetic opioid is important in anesthetic practice being extremely potent analgesic, short time to peak analgesic effect (~5min), rapid termination of effect after single bolus dose reflect its rapid redistribution.

MATERIALS AND METHODS

STUDY UNIVERSE: Cases undergoing ophthalmic surgery under general anesthesia.

STUDY LOCATION: Department of Anaesthesia, Ophthalmology OT, Sawai Man Singh Medical College and Attached group of hospitals, Jaipur.

STUDY DESIGN: A prospective, randomized, double blind, interventional study.

STUDY DURATION: February 2019 to march 2020.
SAMPLE SIZE: Sample size was calculated 30 patients in each group at 95% confidence interval with α error 0.5 and 80% study power to verify the expected difference of (10.40±8.5) in early onset of anxiolysis in both groups.

SAMPLING TECHNIQUE: 60 eligible cases will be allocated into two study groups using sealed envelope double blind method.

STUDY POPULATION: (n=60) Pediatric patients of 2-6 years of age.

STUDY GROUPS: Patients will be randomly allocated into 2 groups. (30 patients in each group)

GROUP A (n=30): patients will receive fentanyl 1.5µg/kg intranasally 0.5ml in each nostril.

GROUP B (n=30): patients will receive dexmedetomidine 1µg/kg intranasally 0.5ml in each nostril.

PROCEDURE

On arrival in the operation theatre, fasting status, written informed consent and PAC was checked. Routine non invasive monitors attached and baseline parameters i.e. heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP), and SpO_2 were recorded.

Demographic data including age, weight, sedation scale before premedication were recorded. The calculated dose of the study drug was administered, 0.5ml in each nostrils 30 min before induction of anesthesia. The study drug was administered prefilled in a 1ml syringe. Dilution of drug was done according to body weight of the patient so that volume of drug would not exceed 0.5ml/nostril. For next 30 minutes patient was asked to maintain supine position with slight head low. HR, BP, RR, oxygen saturation, sedation and anxiety levels were noted at the time of administration of premedication then monitored continuously. Readings were recorded every 5 min until the time patient attain ramsay sedation score of 4 or 5. We were alert, vigilant and ready with IV cannula, if need to be taken preoperatively in case of any complication.

Before induction data was collected for onset of anxiolysis and

sedation, degree of sedation recorded with a six points sedation score. Response to venepuncture was noted when peripheral IV cannulation was done. Injection glycopyrrolate 5µg/kg body weight was given intravenously. We gave 100% oxygen via facemask and the mask acceptance by the child was noted. Pre-oxygenation for 3 min with 100% oxygen was done. 4% inhaled concentration of isoflurane was given with the Jackson-Rees circuit for induction. Inj. atracurium 0.5mg/kg was used to facilitate endotracheal intubation. Maintenance of anesthesia was done with (50:50) O_2:N_2O with isoflurane 1%-2% and Inj. atracurium 0.1mg/kg intravenously. If required rectal acetaminophen suppository was administered for postoperative analgesia.

In the end, isoflurane and N_2O were discontinued. Neuromuscular blockade was reversed with Inj. Glycopyrrolate 0.01mg/kg and Inj. Neostigmine 0.06mg/kg body weight intravenously. The child was extubated after suctioning of oral cavity and return of protective reflexes and after adequate neuromuscular recovery and regular respiratory rate were achieved. Patient was shifted to PACU and continuous monitoring of vitals and sedation was done for 2 hrs postoperatively at an interval of 15 min.

RESULTS

60 ASA grade I and II patients of either sex aged 2-6 years, having weight 9-16 kg scheduled for various ophthalmic surgeries under general anaesthesia were selected for this study. There was no significant difference between both the groups with respect to age and sex distribution.

There is no significant difference in baseline heart rate and heart rate 30 minutes after giving the premedication drug between the two groups. But a significant fall ($p<0.05$) observed in group B after induction, 1min and 5 min after intubation when compared to group A. After 10 min upto postoperative period fall in heart rate was statistically insignificant ($p>0.05$).

No significant fall observed in O_2 saturation in any of the group throughout the study. A statistically significant ($p<0.05$) fall in respiratory rate observed in group A when compared to group B after giving premedication, after induction till postoperative period.

Table 1: Anxiolysis Score

	Group A		Group B	
	No.	%	No.	%
Score 1	6	20.00	2	6.67
Score 2	6	20.00	2	6.67
Score 3	6	20.00	2	6.67
Score 4	12	40.00	24	80.00
Total	30	100.00	30	100.00
P value	0.024 (S)			

The mean onset of anxiolysis in group A, was 12.6 ± 1.75 min.
The mean onset of anxiolysis in group B was 23.03 ± 1.77 min.
The difference of onset of anxiolysis and anxiolysis score was statistically significant ($p<0.05$) between group A and B.

Table 2: Ramsay Sedation Score

	Group A		Group B	
	No.	%	No.	%
Score 1	2	6.67	2	7.00
Score 2	17	56.67	4	13.00
Score 3	6	20.00	3	10.00
Score 4	3	10.00	8	27.00
Score 5	2	6.67	9	30.00
Score 6	0	0	4	13.00
Total	30	100.00	30	100.00
P value	0.001 (S)			

The mean onset of sedation in group A, was 20.97 ± 1.61 min.
The mean onset of sedation in group B, was 29.30 ± 2.18 min.
The difference of onset of sedation and ramsay sedation score was statistically significant ($p<0.05$) between group A and B.

No statistically significant ($p>0.05$) difference was seen in intravenous cannulation acceptance score between group A and B.
Statistically significant ($p<0.05$) difference was observed in child-parent separation score, quality of induction and mask acceptance score between group A and B. where patients who received dexmedetomidine were found to be more calm and cooperative. Also Statistically significant difference ($p<0.05$) was observed between the two groups regarding post operative sedation and emergence score attributed to longer duration of action of dexmedetomidine between the two.

DISCUSSION

In our study, the group A patients who receive fentanyl had earlier mean onset of anxiolysis (12.60 ± 1.75 min.) and sedation (20.97 ± 1.61 min.) as compared to group B who receive dexmedetomidine which was statistically significant ($p<0.001$). The mean onset of anxiolysis and sedation in group B was 23.03 ± 1.77 min. and 29.30 ± 2.18 min. respectively. Results of our study corresponds with the results produced by **Chatrath[4] et al.** in 2018, in their study they concluded mean onset of anxiolysis (13.6 ± 7.0 min) and sedation (21.20 ± 5.25 min) of 1.5µg/kg intranasal fentanyl significantly earlier than 1µg/kg intranasal dexmedetomidine. In group D it was 23.20 ± 8.52 min. and 32.0 ± 5.77 min respectively.

Also **in our study**, the difference in anxiolysis score ($p=0.024$) and ramsay sedation score ($p=0.001$) was statistically significant between the two groups. Though dexmedetomidine provides better anxiolysis and sedation, fentanyl has early onset of action. Similarly results obtained in the study conducted by **Deepika Dhingra[5] et al.** in November 2020, they found intranasal dexmedetomidine to be safe and effective procedural sedative for post-operative follow up examination of pediatric glaucoma patients. In his study **Chen C[6] et al.** in 2019, used higher dose dexmedetomidine as a sole sedative for ocular examination in pediatric patients and get high quality sedation and success rate without any side effects. **Olgun G[7] et al.** used intranasal dexmedetomidine as a solo sedative for MRI of infants and got results in favour of the drug being effective and without any adverse effects.

Group B patients receiving dexmedetomidine found to be significantly ($p<0.05$) better than fentanyl in parental separation and quality of induction and mask acceptance, in our study. But no significant difference present for intravenous cannulation score between the two. Similarly, **Lin Y[8] et al.** during his study in 2016 observed that intranasal dexmedetomidine 1 or 2 µg/kg improved mask acceptance for sevoflurane induction. Although **Chatrath[4] et al.** in 2018 reported that reaction to IV cannulation score was best observed in fentanyl group.

Regarding hemodynamics, in our study we found statistically significant intra operative fall in HR in group B compared to group A, but clinically stable. No deviation from baseline seen in oxygen saturation of patients of either group. Statistically significant ($p<0.05$) difference observed in respiratory rate of patients, owing to the respiratory depressant effect of fentanyl. **Mason[9] et al.** (2006) were the first who studied the sedative effect of dexmedetomidine on pediatric patients for radiological imaging study. They reported that dexmedetomidine produce clinically acceptable reduction of heart rate in pediatric age group. Also **Feld[10] et al.** (2006) compared dexmedetomidine with fentanyl in bariatric surgery, they reported that dexmedetomidine decrease sympathovagal balance and heart rate intra operatively more than fentanyl. Similarly **Ali[11] et al.** (2010) had compared dexmedetomidine with fentanyl in pediatric patients undergoing extra corporeal shock wave lithotripsy and reported same results for hemodynamic stability.

In our study 73.33% patients of group B have excellent emergence from general anesthesia as compared to group A, which is statistically significant ($p<0.05$). Also dexmedetomidine being longer acting and keeping children deeply sedated provide significantly better level of post operative sedation as compared to fentanyl. Likewise **Lin Y[8] et al.** in 2016 found that intranasal dexmedetomidine not only improve mask acceptance and reduce preoperative anxiety but also effectively reduce incidence of emergence agitation in children undergoing cataract surgery with sevoflurane anaesthesia.

CONCLUSION

Intranasal fentanyl 1.5µg/kg provides better premedication because of its early onset of anxiolysis and sedation as well as short duration of action, though it needs strict vigilance being a potent respiratory depressant. However dexmedetomidine is always preferable because it gives better anxiolysis, deeper level of sedation, easy parental

separation and induction, along with this it provides better hemodynamic stability. Owing to longer duration of action of dexmedetomidine, patients are calm and easily arousable from sleep post operatively.

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