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PARENTAL SEPARATION AND FACIAL MASK ACCEPTANCE IMPROVE WITH SUPPLEMENTARY LOW-DOSE ORAL KETAMINE

Sai Kishore M[1], Yugandhar E[2*]

[1]Assistant Professor of Anaesthesia, Sri Lakshmi Narayana Institute of Medical Sciences, (Affiliated to Bharath University, Chennai), Pondicherry, India.
[2]Associate Professor of ENT, Sri Lakshmi Narayana Institute of Medical Sciences, (Affiliated to Bharath University, Chennai), Pondicherry, India

ABSTRACT
Both parents and children experience stress during anaesthesia. Children can benefit from anxiolytics, but there may be side effects. There is no one method that clearly outperforms the others in calming the child and keeping him/her cooperative. In this study, ketamine was added to midazolam-based oral premedication in order to determine whether ketamine was efficacious and safe in improving separation and acceptance of face masks between children and their parents. Elective surgeries were scheduled for 40 preschool children. Group C consisted of patients receiving oral midazolam at 0.5 mg/kg, whereas group S included patients receiving midazolam at the same dose plus ketamine at 2 mg/kg. Using scores for parent satisfaction and child reaction to parent separation, we rated parent separation and child reaction. The child's undertaking of the face mask was describe as being satisfactory following the investiture of anaesthesia using Sevoflurane in 100% oxygen. A bigger difference was seen between children in group (S) versus children in group (C). There were no cases of deep sedation in either group. Moreover, the sedation score in group (S) was better, along with more satisfactory parent satisfaction. Children with an established midazolam-based premedication regimen were shown to benefit from oral ketamine in addition to midazolam to improve separation with parents and acceptance of a pleasant face mask.

Key words: Ketamine, Parents, Children, Midazolam.

INTRODUCTION

Children and parents are under a lot of stress at the time of their anaesthesia induction, one of the challenges that paediatric anaesthetists face. As 50% of these children become worried in the perioperative time, a variety of methods have been used, including studies for the child and family. Separation from parents and pain are the two main concerns for children. Children who undergo routine outpatient surgery are more likely to present with behavioural disturbances at two weeks following their surgery, such as anxiety, night-time crying, enuresis and sleep or eating disorders. Nonpharmacological, behavioural approaches have been shown to reduce the incidence of these delayed sequelae. There are a variety of techniques available for coping with stress, including music, stories, and flavored face masks. The choice of premedication is less important than the psychological preparation of the child and family before surgery [1]. Sadly, these techniques alone cannot manage a small percentage of uncooperative or fearful children [2]. Anxiety between parents and kids may be transferred, so any method that reduces parents' anxiety may reduce children's anxiety as well [3].

Some form of pharmacological sedation or anaesthesia can be used to treat patients who do not respond to behavioural management strategies. It is the responsibility of the anaesthesiologist to minimize the potential adverse psychological and physiological effects of anaesthesia on children.

Corresponding Author: **Yugandhar E** Email: drjournal2021@gmail.com

A child should receive premedication by oral route since they may exhibit a psychological reaction to a needle, and oral administration is easier than nasal or rectal administration [4]. Preoperative anxiety can be reduced and separation from parents can be facilitated more easily with midazolam, which has a rapid onset and relatively short duration of action [5]. The use of oral ketamine in children may provide sedation and anxiolysis better than oral Midazolam 0.5mg/kg as far as side effects are concerned [6,7]. However, high doses of ketamine may cause nausea or vomiting in some children [8]. In order to overcome its side effects if given in high doses, a relatively low dose of ketamine was chosen in the present study.

A low oral dose of ketamine was added to midazolam premedication in order to investigate the effects of ketamine on pleasant separations between children and their parents during elective surgeries. Parents' satisfaction and acceptance of face masks are secondary aims.

Patients and Method

As part of the study, 40 healthy preschool children scheduled for elective pediatric surgeries under general anesthesia were enrolled after obtaining approval from the Hospital Ethics Committee and written informed consent from their parents. Surgery includes; ENT surgery, circumcision, hernia repair, and dental rehabilitation (Table 1). The sample size calculation was based on the findings. who calculated 80% power to detect a clinically meaningful, medium effect size in child anxiety with 30 participants per group. As a primary outcome, anxiety levels of the child were used to calculate sample size, and anxiety levels of the one-parent group were used for comparison purposes [10]. Based on our calculations, the power of analysis will be approximately 90% with 40 patients per group. Due to frequent cancellations and postponements, we increased the number of enrolled pediatric patients to 100.

This double-blind randomized study included a random sample of children. Patients who have neurological problems, inborn metabolic faults, morbidly obese children, or allergies to any medication used were excluded from the study. Using computer-generated random numbers, patients were randomly assigned to receive midazolam or ketamine-midazolam as an oral premedication (Control group «group C»). The anesthetist explained what will happen during the surgery morning to the child and family during the preoperative visit. A sealed envelope with the child's code number was provided for the child to choose before being blinded to the used drug. As soon as the sealed envelope was chosen, the name, file number, and body weight were recorded. It was blindness that caused the anesthesiologist to see the patient preoperatively and anaesthetize him. Medications were prepared into identical 10ml syringes sequentially numbered by a trained nurse on the morning of the operation (who was not involved in any other part of the study). Our protocol was understood by parents, but they were unaware of the premedication components. The children received apple juice in each syringe labelled with their names. Under the supervision of another nurse, one parent administered premedication. Patients in group C received 0.5mg/kg of midazolam mixed with apple juice to fill a 10ml syringe; patients in group S received the same dose of Dormicum along with 2mg/kg of Ketamine. Pulse oximetry was used to detect hypoxia (due to respiratory depression) in all children. Child behavior scores (acceptance of drugs, parental separation score, mask acceptance score) and sedation scores are shown in Table 2. Premedication action by the attending nurse (Table 1) and sedation level (Table 3) were recorded, and vomiting was recorded; children who vomited were excluded from the study. The hospital's policy prohibits parents' presence in the induction room within 30 minutes after premedication. However, they were allowed in the operating room after premedication, but not in the induction room after premedication.

The separation score was used to rate how the child reacted to the separation of his parents. A face mask was used to induce anesthesia using 6 vol% sevoflurane in 100% oxygen (6L/min). By blowing a balloon, the anesthetist gave the child an experience. As a result of the Cooperation Score at induction, acceptance and tolerance of the face mask was assessed. From the time the mask was inducted, peripheral venous cannulation was allowed to take place within sixty seconds. Cisatracurium 0.15mg/kg was administered, as well as apatropine 0.02mg/kg and fentanyl 1-2g/kg. Within three minutes of starting manual ventilation, an airway device suitable for the type of surgery was intubated with lubricated and suitable-sized airway devices. A ratio of 35:65% of oxygen to air was used to maintain anesthesia using Sevoflurane 1.5–2 vol%. Routine non-invasive monitoring was used to monitor all patients. A 100% oxygen solution (6L/min) was introduced after the anesthetic agents had been discontinued. Atropine and neostigmine reversed residual neuromuscular blockade. Extubating was performed on children. Premedication type was not known to the anesthesia technician or nurse who recorded scores and observations. Parent satisfaction was rated on a 3-point scale before discharge from the hospital based on the satisfaction of the parents with their child's premedication.

RESULTS

Our study included 40 patients [20] of whom were medicated with only midazolam because they were in group C and 20 who were medicated with both midazolam and ketamine because they were in group S. The data presented in table 1 show no evidence of differences between groups in terms of demographics and operations. Premedication mixtures were well accepted in both groups, as evidenced by the Acceptance Score (P=0.54). One patient in group S was excluded from the study due to

vomiting, but no respiratory depression (no hypoxia) was observed. There was a shorter onset of action in group S than in group shown in the table 1. A reliable degree of sedation was observed in both groups without cases of deep sedation or crying. However, group S showed better results than group C, since 82.5% of children were drowsy when they opened their eyes compared to 60% of group C, and 15% compared to 40% were awake and calm. Group S showed better reaction to parent separation than group C. Significant statistical differences (p=0.02) were observed between group S and group C regarding acceptance and tolerance of the face mask. Parental satisfaction is higher in the groups with good evidence for differences between the two groups (P=0.03).

TABLE 1: Demographics and operative data of the patient (mean ± SD).

Variables	**Group CN=20**	**Group SN=20**	**t**	**P**	**95% CI**
Age(years)	2.03 ± 0.7	1.97 ± 0.8	0.65	0.48	(-0.77-0.81)
Weight (Kg)	14.69 ± 1.9	14.7 ± 2.7	0.29	0.49	(-1.7-1.3)
Gender MaleFemale	12(54.4%) 8(45.6%)	14(70%) 6(30%)	0.1	0.44	(0.31-2.06)
Type of surgery Hernia Repair Circumcision ENT Dental	2(8.2%) 4(22%) 10(53%) 4(16.8%)	2(10%) 4(20%) 9(45%) 5(25%)			
PremedicationOnset(min.)	19.72 ± 3.25	16.12 ± 2.5	0.000	-5.55	-4.89- -2.3

Table:2 A comparison of the behaviour of the children and the sedation they experienced after premedication between the two groups

Variables	**Group CI** N=20	**Group S**N=20	**P**	**t**	**(95% CI)**
Drug acceptance Accept Dislike Forced to accept **Refuse**	15(75%) 4(20%) 1(5%) 0	13(65%) 6(32.5%) 1(2.5%) 0	**0.54**	**-0.60**	**-0.32-0.17**
Sedation score 1- (full sleep) 2- Eyes closed (Light sleep) 3 -Eyes opened but looks drowsy 4- Awake 5- Crying	 0 0 12 (60%) 8(40%) 0	 0 1(2.5%) 16 (82.5%) 3(15%) 0	**0.008**	**2.71**	**0.073-0.47**
Reaction to separation Excellent Good Faire Poor	 4(20%) 9(45%) 7(35%) 0	 14(70%) 5(25%) 1(5%) 0	**0.000**	**5.403**	0.5-1.09
Acceptance of mask Cooperative Mildly resistant Resistant to face mask placement	 8(42.5%) 4(20%) 8(37.5%)	 11(55%) 7(35%) 2(10%)	0.02	2.2	0.044-0.755

DISCUSSION

A combination of oral ketamine 2 mg/kg and Midazolam-based premedication 0.5 mg/kg facilitates separation of children from parents and induction of anaesthesia without affecting drug palatability and with a shorter onset of action than Midazolam alone [11,12]. There was no difference in the degree of sedation between the two studies [13]. Compared to 0.5mg/Kg oral midazolam alone, 0.25mg/Kg of midazolam combined with 2.5mg/Kg of ketamine resulted in more awake, calm, and quiet children that could easily be separated from their parents. As a result of the current study, they concluded that both Midazolam and a combination provided similar anxiolysis and separation characteristics, but the combination doses performed better. There was a greater degree of effectiveness in premedication with ketamine 4 mg/Kg combined with midazolam 0.4 mg/kg, or ketamine 3 mg/Kg along with midazolam 0.5 mg/kg alone [14,15]. As we used a smaller dose of ketamine to overcome any adverse effects, we found the same results with different

doses as in our current study. This study, however, did not examine the association between premedication and parent satisfaction. Midazolam sedation offers the benefit of reducing the psychological side effects of ketamine when combined with Ketamine Dormicum. Also, ketamine counteracts the respiratory depression caused by midazolam [16]. According to our research, midazolam (0.75mg/kg) and ketamine (6mg/kg) had no effect on behaviour at separation or induction; the combination of ketamine and midazolam was also ineffective [17]. Induction and separation were both successful with the combination 80% and 70%, respectively. While ketamine and midazolam had similar results, the combination group produced only slightly faster onset times, nystagmus and secretions (vs ketamine) and faster recovery (vs midazolam). There are non-drug alternatives that can be used, but one recent review found that no single method clearly demonstrated an advantage in keeping the child calm and cooperative [18]. It is ideal premedication for children to be readily accepted by them, to have rapid and reliable onset, to provide anxiolysis and sedation, to have minimal side effects and to reduce the risk of premature discharge with rapid elimination. Many of the characteristics of both oral Midazolam and oral Ketamine have been reported in earlier studies, suggesting both may be useful premediates in paediatric anaesthesia [6]. By premediating children prior to surgery, a smoother induction of GA (general anaesthesia) may be achieved with fewer hemodynamic changes and reduced emotional trauma [19,20]. As a result, low dose oral ketamine was administered along with midazolam-based premedication to provide a better preinduction situation and a pleasant child-parent separation with higher satisfaction among parents.

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