

Anxiolytic premedication in paediatric patients before surgery: An observational study

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Abstract

Background and objectives: Anxiolytics are part of premedications administered to the paediatric populations in preoperative period. The aim of this study was to evaluate the efficacy of these pharmacotherapy by assessing level of anxiety relief through one of the standard parameters (modified Yale Preoperative Scale - mYPAS). **Methods:** A prospective cross sectional observational study was conducted in children between 9 months to 12 years of age from the period of Feb'2021 – April'2021 in our institute and 62 Children were enrolled in the study. Anxiety was assessed using modified Yale Preoperative Scale (mYPAS) after giving premedications. Parent child separation time and complications if any were noted. **Results:** Data was entered and analysed using SPSS software version 26.0 software. Results were presented in numbers/mean and expressed in terms of percentage. The mean anxiety scores after premedication decreased upto 11.30 +/- 4.37 min when parent child separation was possible. Only 13 out of 62 patients had low anxiety scores after 10 min and in midazolam group only 6.66% achieved low anxiety scores. Additional anxiolysis was required in 8 patients out of them 7 were in Midazolam only group. **Interpretation:** To conclude, more than one drug used as anxiolytic lead to lower anxiety scores in comparison to single drug.

Key words: anxiolysis, observational, pediatrics, surgery.

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INTRODUCTION

In paediatric population, anxiety related to surgical procedures is quite distressing for patients, parents and even health care workers. Children are distressed even while on separation from parents in preoperative room. To tackle with the distress in children, various forms of anxiolytic and other premedications are administered in preoperative room. This helps to indirectly mitigate the hemodynamic consequences of stress and thereby ensue perioperative smooth conduct of anaesthesia. There has been various studies to assess anxiolysis after anxiolytic

premedications.^{1,2} The premedication are administered according to the patient profile, surgical need, duration of surgery and even anaesthetist's preference. Every different premedication lead to anxiolysis in a different manner, henceforth affect time of separation from parent before anaesthesia differently. Taking into consideration of these aspects, this study aims to observe the efficacy of various premedication's on anxiolysis of children before surgery. And also note down the time at which the child is separated from parent after giving premedication.

MATERIALS AND METHODS

After approval from Institutes ethical committee, this prospective observational study was conducted for the period of three months starting from February 2021. All the paediatric patients of ASA class less than 4 risk from age 9 months to 10 years scheduled for elective surgeries were evaluated for inclusion criteria and if the patient was eligible for this study, patient's guardian was informed about the study and were enrolled in the study if he/she gave written consent. Assent from the child of 7-10 years of age was also considered. We aimed to include posted for any major or minor surgical procedure. Considering

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inclusion criterias, follow up loss and willing to participate in the study, 62 patients were enrolled in this study. We excluded patients who refused to give consent, or with hearing/visual impairment or developmental disability/neurological diseases. Protocol for giving premedication for anaesthesia in elective surgery in paediatric patients is as follows in our institute: Preanaesthetic check-up before surgery, on the day of surgery, premedication is given before surgery in preoperative room, intravenous line is secured and intravenous fluid is started before or after premedication as per anaesthesia administrator's choice. We did not interfere with management of consultant anaesthesiologist allotted to conduct the anaesthesia. All confidentiality of patients in terms of their identity as was maintained. Patients were given identification number and name was not mentioned anywhere in the study. Age, sex, weight, birth history, NBM (nil by mouth) status, clinical diagnosis, surgery planned, anaesthesia planned, ASA (american society of anaesthesiologists) class, history in

brief including comorbidities were noted. Drug/s, dosage and mode of administration of premedication was noted. Vitals, general and systemic examination findings was noted. Temperature, pulse rate, respiratory rate, systolic BP, SPO₂, Modified Yale Preoperative Anxiety scale(mYPAS) score⁵ of child were noted at arrival to preanaesthetic room, then every 2 min interval upto 10 min and afterwards every 10 min upto 60 minutes. Time at which child is separated from parent after premedication was noted. Complications if any and additional premedication if required will be noted. Parent child separation time was considered when premedication is administered in preanaesthetic room till they are shifted to operation theatre for surgery without parent/guardian. mYPAS score is an observation score of anxiety assessment.^[5] It contains 22 items in five categories including activity, emotional expressivity, state of arousal, vocalization and use of parents. High anxiety was considered as a score of 30 or more on mYPAS.^{1,5}

RESULTS

A total of 62 children were enrolled in the study in the period of three months. The demographic characteristics such as age, gender, weight and height and ASA class are demonstrated in Table 1. Patients went through various surgeries including orthopaedic procedures like tenotomy, hip spica, fractures, spine surgery, implant removal; surgical procedures like congenital hernia, gastrotomy, excision of swelling, circumcision; ophthalmologic repairs of cornea; ENT procedure like BERA, meatotomy, sinus excision, tongue tie release, mastoidectomy, adenoidectomy; urological procedures like urethral dilatation. Various medications like Midazolam (40mcg/kg) with or without pentazocine (0.5 mg/kg)/ phenargan (0.5 mg/kg) /tramadol (1mg/kg) or butorphanol (50 mcg/kg) or dexmedetomidine (1 mcg/kg) were used as premedication as per institutes protocol.^[11] In one patient, only pentazocine was used whereas phenargan with pentazocine was used in 3 patients [figure 1] The data collected was entered into a database Microsoft excel sheet and results were expressed as mean +/-standard deviation. Statistical analysis was performed using SPSS® version 26.0. Qualitative variables were expressed as median and minimum- maximum values. Categorical variables expressed as frequencies and percentages. 45 out of 62 patients were given only midazolam. All the 62 patients had high baseline anxiety (57 +/- 12.32 SD mYPAS) and average mYPAS score gradually decreased (34.38 +/- 6.44 SD) upto 10 mins after giving premedication [figure 2]. 13(21%) out of 62 patients had low anxiety after average 11.30 minutes. [table 2] Amongst them only 6.66% of midazolam only group (that comprised of majority of patients) had low anxiety. On the other hand, 49 (79%) patients didn't reach the criteria of less than 30 mYPAS [table 3] But 4 patients who were given two or more drugs, achieved near 30 scores while majority from others were in midazolam only group.

Table 1: Patient characteristics and baseline variables

Children (n=62)	
Age(years)	5.84 +/- 3.2
Mean+/-SD	
Gender(NO OF PT (%))	
Male	41(66%)
Female	21(34%)
Weight (kg)	17.86
ASA physical status	
I	1(2%)
II	48(77%)
III	13(21%)

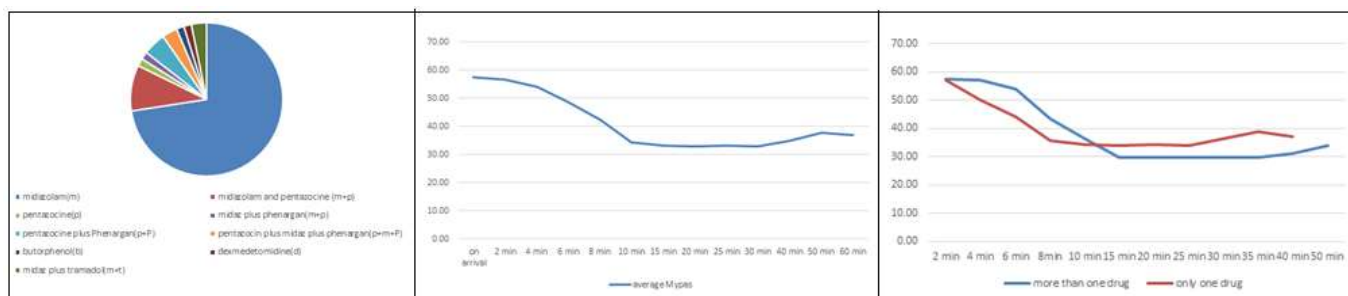


Figure 1

Figure 2

Figure 3

Figure 1: Number of patients; Figure 2: Average mYPAS upto 60 min after different premedications; Figure 3: Average mYPAS after premedication comparing one versus more than one drug administered

Table 2: Patients with low anxiety scores(N=13)

Groups with Mypas<30	Number of patients in group	Average mYPAS at 10 min
m+p	1.00	28.33
m+p+p	1.00	28.33
M	3.00 (6.66% of midazolam only group)	28.33
p+p	2.00	28.33
m+p	5.00	27.67
B	1.00	26.67
Total	13.00(21%)	27.95

m(midazolam), p(pentazocine), P(phenargan), t(tramadol), b(butorphenol), d(dexmedetomidine)

Table 3: Patients with high anxiety scores(N=49)

Groups with Mypas >30	Number of patients in group	Average mYPAS at 10 min
m+p+p	1.00	31.67
M	42.00 (93.33% of Midazolam only group)	35.87
D	1.00	41.67
p+p	1.00	31.67
m+t	2.00	32.50
F	1.00	55.00
m+p	1.00	36.67
Total	49.00(79%)	36.09

m(midazolam), p(pentazocine), P(phenargan), t(tramadol), b(butorphenol), d(dexmedetomidine)

Satisfactory separation from parents was possible at an average 11.30 minutes in most of the patients but additional anxiolytic was required in 8 patients out of them 7 were from Midazolam only group.

None of the patients had any premedication related complication in preoperative room.

DISCUSSION

Anxiety amongst children is very common before any surgery that needs to be taken care of as a part of premedications. It has its own negative consequences perioperatively and has been studied for many years since the beginning of anesthesia era. Measures used to reduce anxiety include the use of sedative premedication, parental presence at induction of anaesthesia and various behavioural preparation techniques. Of these measures, the role of sedative premedication is firmly established.⁵ We used Mypas to assess anxiety as has been validated for this purpose in children in the perioperative settings.¹² It is an

observational instrument which can be easily applied to assess the anxiety in less than 2 min. Kain *et al.* found that a score of 30 or more on mYPAS identified high anxiety.¹² The same cut off score was validated in a previous study conducted by Matthew *et al.*⁸ Using this cut-off value of mYPAS score, we observed that the incidence of low anxiety was found more in children with more than two drugs after premedication. Although there was a reduction in the anxiety scores after premedication with midazolam in both the groups, the scores were still more than 30 indicating that premedication was only partially effective in reducing anxiety. In Darlong *et al.* study efficacy of oral

midazolam (0.25 mg/kg), oral ketamine (3 mg/kg), and combination of them were studied on sedation degree, children behaviour type, and separation of children from parents.[8] In combination group, desirable sedation scores after 10 and 20 min were significantly lower than another group. Children separation behaviour type score was not significant among groups.⁸ This finding of Darlong *et al.* study was coordinate with our study. Another study which was performed in 2011 by Banerjee *et al.* sedative effect of oral midazolam, ketamine, and combination of them was evaluated. Again after 20 min of prescription of premedication, sedation degree was superior in combination group¹⁰ as found in our study. In another study which was conducted by Ghai *et al.* there were no significant differences between two groups: Oral midazolam and midazolam plus ketamine.⁹ In this study, Group M received 0.5 mg/kg oral midazolam and Group MK received 0.25 mg/kg oral midazolam with 2.5 mg/kg oral ketamine. Both groups provided equally effective anxiolytics and separation characteristics. However, the combination group provided more children in an awake, calm, and quiet state who could be separated easily from parents.⁹ However, there were a few limitations in our study. Firstly, all the anxiolytics were not studied and secondly other measures of anxiolysis were not included in the study that might affect the result. Hence further analysis is needed to consider scope of other medications and behavioral therapies.

CONCLUSION

To conclude, more than one drug used as premedication before surgery can offer better anxiolysis than a single one.

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