A PROSPECTIVE STUDY ON EFFECT OF PREMEDICATION WITH ORAL MIDAZOLAM ON PREOPERATIVE ANXIETY IN CHILDREN WITH HISTORY OF PREVIOUS SURGERY

Laxminarayana Anpuram[1]

[1]*Associate Professor, Department of Anaesthesiology, Niloufer Hospital / Osmania Medical College, Hyderabad, Telangana.*

ABSTRACT

BACKGROUND

Addressing child anxiety during medical procedures is a growing trend and dental treatment is no exception.

MATERIALS AND METHODS

Randomized, prospective, double-blind study. Seventy-eight American Society of Anesthesiology (ASA) I children were divided into two groups of 39 each. Children of the first group were premedicated with oral Midazolam 0.5 mg/Kg, while children of the control group were premedicated with a placebo. Scores for parental separation, mask acceptance, postoperative emergence delirium, and time spent in the post-anaesthesia care unit were compared statistically.

RESULTS

Anxiety scores after premedication were statistically insignificant in children without a history of previous surgery and in those with a history of previous surgery. Baseline anxiety scores were comparable in the two groups.

CONCLUSION

Anxiety scores after premedication with midazolam were similar in children with history of previous anaesthesia exposure and those experiencing anaesthesia for the first time. Anxiety was compared after premedication in children with a history of previous surgery and those without a history of previous surgery.

KEYWORDS

Premedication, Oral Midazolam, Preoperative Anxiety, Previous Surgery.

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BACKGROUND

Preoperative period is an anxious and stressful time, detachment from parents, unacquainted hospital environment, account to their non-cooperation for induction of anaesthesia and painful procedures. Premedication by producing anxiolysis and sedation, optimize conditions for smoother induction. Since long time, benzodiazepines are established drugs because of convenient route of administration, cardiovascular stability, having less effects on respiration, midazolam being agent of choice for premedication.

Midazolam possesses desirable attribute of premedicant, rapid onset of action, high effectiveness, shorter distribution and elimination half-life, facilitating rapid recovery, high lipid solubility, low toxicity levels. Midazolam possesses properties of benzodiazepines, such as sedation, hypnosis, anticonvulsant action, skeletal muscle relaxation, good anterograde amnesia. Further midazolam given as premedicant may combat emergence delirium which may occur after sevoflurane anaesthesia in children including agitation, restlessness, extreme fright. Increased preoperative anxiety not only causes distress to the child and parents but also delays the induction and recovery from anaesthesia, increases the patient's pain experience and increases the likelihood of emergence delirium and maladaptive behaviour.[1,2] Previous history of surgery has been found to be one of the risk factors for increased preoperative anxiety in some studies.[3,4] However, these findings have not been confirmed by other investigators.[5,6] In present study we have observed that children who have undergone surgery in recent past exhibit increased levels of anxiety when rescheduled for surgery and remain anxious even after premedication.

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Corresponding Author:
Dr. Laxminarayana A,
H. No. 12-1-331/102, Dattatreya Colony,
Asifnagar, Hyderabad,
Telangana.
E-mail: draln@yahoo.com
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MATERIALS AND METHODS

This is a prospective study was conducted between December 2016 and June 2017, in children in the age group of 4-10 years, belonging to American Society of Anesthesiologists' physical status I or II, undergoing elective urogenital, abdominal or orthopaedic surgical procedures under general anaesthesia.

Group I -30 children who were undergoing surgery for the first time and did not have any history of previous surgery.

Group II- 30 children with a history of previous surgery within the last 2 years.

Exclusion Criteria

Children with a decreased level of consciousness, delayed milestones or neurodevelopmental anomalies, those with history of chronic illness, hypersensitivity to benzodiazepines and children who refused mask induction of anaesthesia.

Baseline anxiety of children was measured in the preoperative holding room using the modified Yale Preoperative Anxiety Scale (mYPAS). It is an observational instrument of anxiety assessment and contains 22 items in five categories, namely, activity, emotional expressivity, state of arousal, vocalisation and use of parents. Children were premedicated with 0.5 mg kg^{-1} of oral midazolam syrup about 20–30 min prior to induction of general anaesthesia. Anxiety was reassessed using the same scale 20 min after premedication. High anxiety was defined as a score of 30 or more on mYPAS.

Anxiety was also evaluated at the time of parental separation on a 4-point scale-

1 = crying, very anxious
2 = anxious, not crying
3 = calm, but not cooperative
4 = calm, cooperative or asleep

Children were transferred to the operating room by the anaesthesiologist without the parents. Anaesthesia was induced with sevoflurane (8%) in oxygen using a transparent mask. Mask acceptance during induction of anaesthesia was graded on a 4-point scale.

Parental separation and mask acceptance scores of 1 or 2 were considered unsatisfactory, while scores of 3 or 4 were considered satisfactory effects of premedication. Assessment of anxiety and scoring was done by another trained staff who did not participate in the anaesthetic management and was not aware of group allocation. The rest of the anaesthetic management was at the discretion of the attending anaesthesiologist.

We compare the anxiety after premedication in children without a history of previous surgery and those with a history of previous surgery and anaesthesia, also we have compared the baseline anxiety, and the incidence of satisfactory parental separation and mask acceptance in these children.

Statistical analysis was performed using SPSS® version 15 (Statistical Packages for the Social Sciences). Normally distributed data are presented as mean ± SD and analysed using Student's t-test. A P value of <0.05 was considered to be statistically significant.

RESULTS

Variable	Group-I	Group-II	p-Value
Age in Years	5.5 + 1.61	5.8+1.92	>0.05
Gender (M:F)	14/16	15/15	>0.05
Weight in kgs	17.5+3.9	18.3+4.0	>0.05
Height in cms	105+10.9	107+11.9	>0.05

Table 1. Demographic Details in Study

Demographic variables are insignificant in both groups.

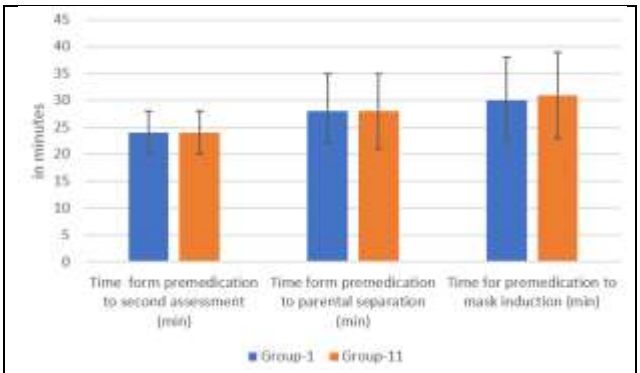

Figure 1. Time Form Premedication to Mask Induction

Time form premedication to second assessment, parenteral and mask induction are insignificant in both groups.

Anxiety Score		Group-I	Group-II	P-Value
mYPAS Score	Baseline	32 (24-40)	44 (33-55)	>0.05
	20 Minutes After Premedication	30 (24-36)	32 (27-37)	>0.05
Incidence of High Anxiety mYPAS Score	Baseline	19(55)	26(76)	>0.05
	20 Minutes After Premedication	18(55)	19(57)	>0.05

Table 2. Anxiety Scores in The Two Groups

The median anxiety scores assessed 20 min after premedication were not significantly different in the two groups. The baseline anxiety scores were also statistically similar in the two groups. The number of children with high anxiety was similar in the two groups before and after premedication with midazolam.

DISCUSSION

The time spent in the operating room holding area prior to surgery is often traumatic to children's psychology,[7] especially for children who already suffer dental fear. In 1999, Kain et al.[8] demonstrated that extreme preoperative anxiety is associated with the occurrence of negative postoperative behavioural changes. The lack of effect on

postoperative ED may appear contradictory to Kain et al's report;[8] however, they demonstrated that reducing preoperative anxiety does reduce the incidence of postoperative behavioural changes, but not postoperative ED. We found that the anxiety scores after midazolam premedication in children with previous history of surgery and anaesthesia are not different from those in children scheduled for surgery for the first time. We also found that the baseline anxiety in these two groups of children was not different. Pulak Priyadarshi Padhi et al[9] studied on effect of premedication with oral midazolam on preoperative anxiety in children with history of previous surgery. Fortier et al. studied children undergoing day-care surgery and found that history of previous surgery or hospitalisation was not a predictor of increased perioperative anxiety. Fortier et al. studied adolescents in another investigation and found similar results. On the other hand, Vetter et al. showed that having undergone previous surgery was a significant predictor of problematic preoperative behaviour.[10] Previous surgery or anaesthesia exposure was shown as a predictor of increased anxiety in children coming for subsequent procedures in few other studies also. The current study is in agreement with Mountain et al.'s[11] report that a dose of 0.5 mg/kg significantly reduces preoperative anxiety and helps in anaesthetic mask acceptance by children. They compared Midazolam to Dexmedetomidine as preoperative anxiolytic medications and reported that the latter has an advantage of reducing postoperative ED. Other studies[12] demonstrated a better anxiolytic outcome with higher doses of Midazolam up to 1.0 mg/kg.

We used mYPAS to assess anxiety as it has been validated for this purpose in children in the perioperative settings.[8] It is an observational instrument which can be easily applied to assess the anxiety in less than 2 min. We included children who had experienced an anaesthetic within the past 2 years, as an exposure earlier than that was unlikely to be remembered and be a cause of anxiety during subsequent procedures. Pulak Priyadarshi Padhi et al[9] also used mYPAS to assess anxiety which in agreement with our study.

Kain et al. found that a score of 30 or more on mYPAS identified high anxiety.[8] The same cut-off score was validated in a previous study conducted by Mathew et al.[2] Using this cut-off value of mYPAS score, we observed that the incidence of high anxiety was similar in children with or without previous history of anaesthetic exposure, before and 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.

We found that the anxiety scores in children operated as day-care or as admitted patients were similar which in coincidence with study of Pulak Priyadarshi Padhi.[9] Davidson et al. observed that hospital admission via the day-stay ward was associated with less anxiety. This may be due to the fact that day-care patients stay in a familiar environment and with people they know right till the time of surgery as opposed to admitted patients who are exposed to an unfamiliar environment and unknown people the night before surgery.

The number of children with satisfactory parental separation and mask acceptance was similar in the two groups in our study. Also, a high percentage of children in both the groups had a satisfactory parental separation and mask acceptance scores, despite high anxiety scores at baseline and after premedication. Premedication with oral midazolam has been seen earlier to be associated with satisfactory mask acceptance in more than 80% of children.

The effect of the child's experience during previous anaesthesia and surgery on preoperative anxiety can be the subject of future studies. The interaction of this factor with other predictors of anxiety can also be evaluated.

CONCLUSION

Anxiety scores after premedication with midazolam were similar in children with history of previous anaesthesia exposure and those experiencing anaesthesia for the first time.

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