

A Comparative Study on Effectiveness of Parental Presence versus Sedative Premedication for Reducing Anxiety in Children Undergoing General Anesthesia

Abstract

Background: Preoperative anxiety is an important, yet often unattended problem in children. Minimizing anxiety and distress at the time of anesthetic induction may reduce adverse psychological and physiological outcomes. Sedative premedication and parental presence during anesthesia induction are among the most commonly employed strategies for reducing child anxiety. **Aims and Objective:** The study aimed to compare the effectiveness of a pharmacological intervention (premedication with midazolam) versus behavioral intervention (parental presence) in reducing preoperative anxiety in children undergoing general anesthesia. **Methodology:** Sixty patients of age group of 4–12 years, of ASA Grade 1 and 2 and either sex posted for elective surgery under general anesthesia were divided into two groups of 30 each Group M (midazolam group) and Group P (parental presence). Group M received intravenous midazolam 0.03–0.05 mg/kg preoperatively and anxiety was measured in preoperative room, during separation from parents and during introduction of anesthesia mask, whereas in Group P, parents accompanied the child inside the operation theater and anxiety was measured at preoperative room and during introduction of mask. Parental anxiety was measured in both groups at preoperative room and waiting room. Modified Yale Preoperative Anxiety Scale (mYPAS) and State Trait Anxiety Inventory (STAI) tool was used to measure anxiety in children and parents, respectively. **Results:** The mean mYPAS score while the introduction of anesthesia mask in Group M was 31.30 ± 12.04 and in Group P was 63.19 ± 25.31 , and the difference was found to be statistically significant ($P = 0.001$). In preoperative room, there was no significant difference in anxiety in the two study groups. The mean STAI score in Group P was 45.63 ± 1.45 and in Group M was 41.10 ± 1.69 , and the difference was found to be statistically significant ($P = 0.001$). In preoperative room, parental anxiety was found to be comparable among the two groups. The mean duration of induction of anesthesia in Group M was 5.53 ± 1.01 min, and in Group P, it was 8.77 ± 2.03 min. The difference was found to be statistically significant ($P = 0.001$). **Conclusion:** Both interventions were effective in reducing anxiety in children, but midazolam was more effective compared to parental presence. Parents in Group M were less anxious in the waiting room than Group P. Children in Group M were more compliant during the induction of anesthesia, hence a lesser duration of induction than Group P.

Keywords: Children, midazolam, premedication, preoperative anxiety

Introduction

Anesthesia and surgery are common sources of anxiety and stressful experiences in children.^[1]

Young children may express anxiety through verbalizing their fears or behaviorally in the form of crying, agitation, nonplayful shouting, withdrawal, and clinging to parents.^[2] Ignoring preoperative anxiety results in poor perioperative outcome such as high postoperative pain, delay in hospital discharge, higher incidence of sleep

disturbances, and emergence delirium.^[3,4] Additionally, parents are also anxious during the preoperative period.^[3] It is strongly related to child's perioperative anxiety and postoperative pain. Kain and Mayes reported that up to 60% of all young children undergoing anesthesia and surgery report significant anxiety.^[1-3] A major role is played by anesthesiologists in recognizing and dealing with preoperative anxiety in children. A variety of measures can be used to assess the anxiety in children and their parents such as the Modified Yale Preoperative Anxiety Scale (mYPAS), Yale Preoperative Anxiety Scale (YPAS),^[5,6] Clinical Anxiety

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Rating Scale, Global Mood Scale, Visual Analog Scale, serum cortisol estimation,^[7-9] and State-Trait Anxiety Inventory (STAI).^[7] The methods to reduce anxiety can be pharmacological or nonpharmacological (behavioral).^[10] Pharmacological interventions include premedication with midazolam (oral or intravenous route), ketamine, or dexmedetomidine.^[11] Nonpharmacological interventions include psychological interventions such as distraction, hypnosis, environmental interventions, equipment modifications, and social interventions.^[12] Sedative premedication can have several undesirable effects, including postoperative behavioral changes, restlessness, cognitive impairment, paradoxical reactions, and respiratory depression.^[13] Hence, nonpharmacological methods are sought to improve the perioperative safety and comfort of children. The various nonpharmacological methods have been studied in isolation; however, their relative efficacy in comparison to pharmacological agents remains to be proven.^[10,13] Literature on the comparison of sedative premedication given by intravenous route with a nonpharmacological method remains scarce. The purpose of this study was to compare the effectiveness of a pharmacological intervention (midazolam), and a behavioral intervention (parental presence) for reducing the anxiety in children undergoing surgery under general anesthesia. Parental anxiety and duration of induction of anesthesia in both the groups were also measured.

Methodology

This comparative study was conducted at a tertiary care teaching institute in Central India. The study was preapproved by the institutional ethics committee (IEC) for the final permission (letter No.EC/MGM/February-20/55).

Sixty patients of age groups of 4–12 years, of ASA Grade 1 and 2, and either sex posted for elective surgery under general anesthesia from March to September 2020 were divided into two groups of thirty each.

For children younger than 7 years of age, a valid, written, informed consent was obtained from the parents/legal guardians; for minors aged 7–12, a child assent form was obtained in addition to parental consent. The eligible patients were randomly assigned to one of two study groups using random numbers table as shown in Figure 1.

In the parental presence group (Group “P”), a parent accompanied the child to operating room and stayed through the induction of anesthesia, whereas in the midazolam group (Group “M”), the child was premedicated with 0.05 mg/kg intravenous midazolam and was separated after 5 min of administration of the drug.

Before the day of surgery, parents were counseled about the nature of the study, process of induction of anesthesia, and its complications. Voluntary candidates were recruited under Group “P” and Group “M” randomly using random numbers table as shown in consort diagram.

Candidates allotted to Group “P” were counseled about the operation theater environment, maintenance of sterility, and attire inside the operation theater. After recruitment, the demographic data including birth order, number of siblings, and parental education were obtained.

If the child’s condition changed or the parent’s presence was found to be distracting or disruptive to the induction of anesthesia, the anesthesiologists or medical staff had the right to send the parent out of the operating room, and the child was excluded from the study. On the day of surgery, in preoperative holding area, anxiety of the child was measured using the modified Yale Preoperative Anxiety Scale (with permission) in both the groups, and anxiety of parents was measured using the STAI tool (with permission) in both groups. Modified Yale Preoperative Anxiety Scale (mYPAS)^[5] and STAI^[14] are commonly used tools available in the public domain.

In the Parental Presence Group (Group P), parents were again given detailed instructions and counseled properly about what to expect and how to behave inside operation theater and how to interact with their child during the induction. They were asked to converse, do physical contact, and maintain eye contact with their children. mYPAS was measured at two points: preoperative room and introduction of anesthesia mask.

After attaching the monitors, induction was carried out using injection propofol 2 mg/kg and an injection atracurium 0.5 mg/kg. As soon as the patient was induced, parents in the parental presence group were sent to the waiting area and were asked to rate their own anxiety (STAI).

In Group M, children received the sedation (intravenous midazolam 0.5 mg/kg) during separation from parents (the child was separated 5 min after the administration of midazolam).

mYPAS was measured at three points: preoperative room, separation from parents, and introduction of anesthesia mask. The duration of induction of anesthesia was measured in both the groups. Moreover, parental anxiety was measured in both the groups at the waiting room using STAI Tool.

Sample size (*n*) was calculated to be 60 with a minimum sample size required in each group being 30 for statistical inference.

Modified Cochran’s formula was used for sample size estimation. After calculation of the sample sizes, an additional 10% was added to compensate for dropouts, and the final numbers were 30 subjects for each group. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 23 (SPSS Inc., Chicago, IL, USA). Analysis of continuous data was performed using Student’s *t*-test (unpaired) and categorical data using the Chi-square test. *P* < 0.05 was considered statistically significant.

Results

Both the groups were comparable with regard to demographic characteristics (age distribution and sex), baseline measurements of child temperament, and parental trait anxiety [Table 1].

There was no significant difference seen in the child temperament in both the groups in preoperative room [Table 1]. During the separation from parents in midazolam group, the mean mYPAS while separating from the parents in Group M was 34.51 ± 13.44 .

The mean mYPAS score while the introduction of anesthesia mask in Group M was 31.30 ± 12.04 and in Group P was 63.19 ± 25.31 . The difference was found to be statistically significant ($P = 0.001$), showing a significantly lower mean mYPAS score in Group M in comparison to Group P [Table 2].

Midazolam was more effective than parental presence in reducing the anxiety of the patient while introducing the anesthesia mask.

The mean STAI score in preoperative room was 46.80 ± 1.24 and 46.87 ± 1.38 in Group M and Group P, respectively [Graph 1]. The difference was found to be statistically insignificant ($P = 0.845$).

The mean STAI score in the waiting room was 45.63 ± 1.45 in Group P and 41.10 ± 1.69 in Group M [Graph 2]. The difference was found to be statistically significant ($P = 0.001$), showing a significantly lower STAI Score in Group M in comparison to Group P.

Table 1: Characteristics of study subjects and their parents

Baseline characteristics	Group M	Group P	P
Age (years)			
4–8	21	24	0.371
9–12	9	6	
Sex			
Female/male	8/22	12/18	0.273
Child temperament (mYPAS) at preoperative room	60.80±21.82	53.28±20.65	0.110
Parents temperament (STAI) at preoperative room	46.80±1.24	46.87±1.38	0.845

Data in mean±SD. mYPAS: Modified Yale Preoperative Anxiety Scale; STAI: State-trait anxiety inventory; SD: Standard deviation

Table 2: Modified Yale Preoperative Anxiety Scale score while the introduction of anesthesia mask

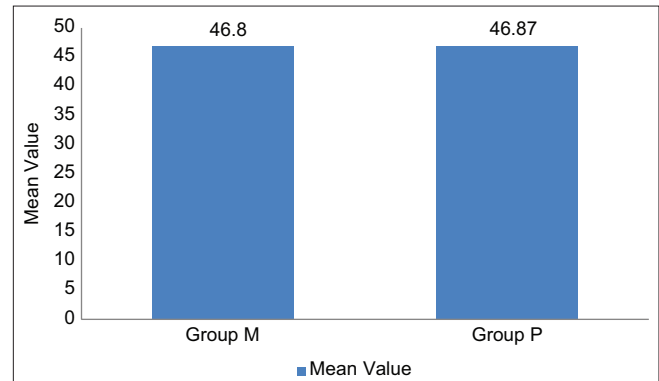
Group	n	mYPAS score, mean±SD	t	P
Group M	30	31.30±12.04	-6.232, df=58	0.001*
Group P	30	63.19±25.31		

Unpaired t-test applied. * $P < 0.05$, significant. mYPAS: Modified Yale Preoperative Anxiety Scale; SD: Standard deviation

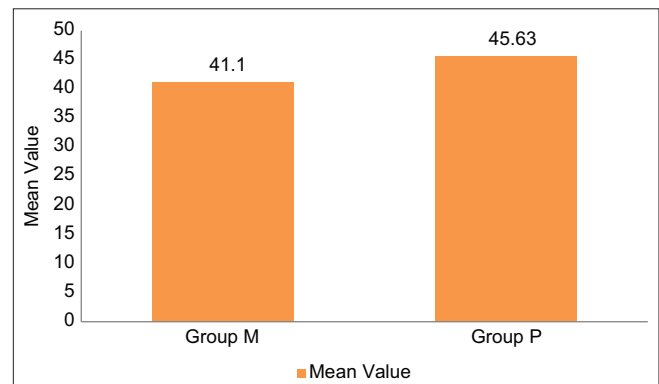
The mean duration of induction of anesthesia in Group M was 5.53 ± 1.01 min, and in Group P, it was 8.77 ± 2.03 min [Graph 3]. The difference was found to be statistically significant ($P = 0.001$), showing a significantly longer duration of induction of anesthesia in patients of Group P in comparison to Group M patients.

Discussion

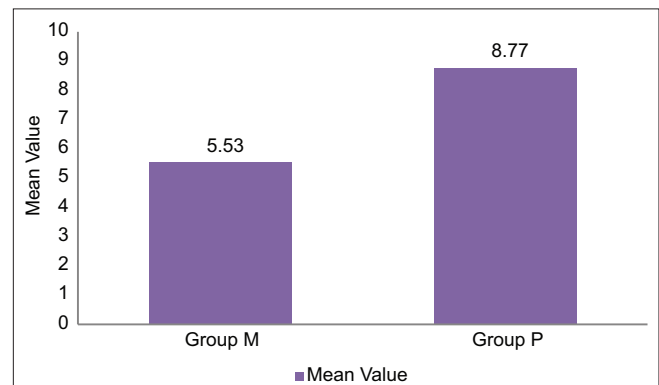
The present study was aimed at comparing the efficacy of a pharmacological and a nonpharmacological method for reducing anxiety in children aged 4–12 years



Graph 1: Bar diagram comparing the mean state-trait anxiety inventory score at the preoperative room



Graph 2: Bar diagram comparing the mean state-trait anxiety inventory score at the waiting



Graph 3: Bar diagram comparing the duration of induction of anesthesia (Min)

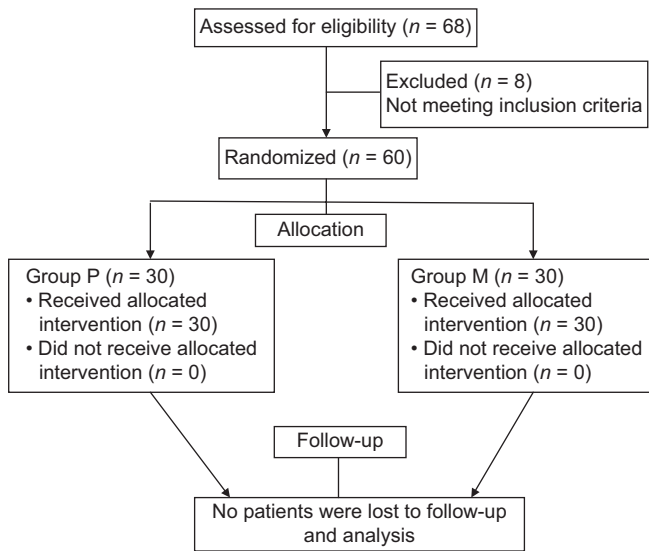


Figure 1: Consort diagram

undergoing general anesthesia. Midazolam is a short-acting benzodiazepine that has anxiolytic, amnesic, hypnotic, and anticonvulsant properties. For anxiolysis, it can be administered through intravenous, oral, intranasal, or per rectal route. Patients included in our study received intravenous midazolam as it as a rapid and predictable onset. Certain drawbacks associated with the administration of midazolam include delayed recovery, sedation, and maladaptive behavior postsurgery.^[11] Nonpharmacological methods such as parental presence during the induction of anesthesia offer an alternate method of allaying anxiety in children without causing these adverse effects.

In the present study, both the groups were comparable in terms of demographic parameters including age and sex distribution.

In Group P (Parental Presence group), anxiety was measured using mYPAS scale at two points – preoperative room and introduction of anesthesia mask. In Group M (midazolam group), anxiety was measured using mYPAS scale at three points – preoperative room, separation from parents, and introduction of anesthesia mask.

In our study, while the introduction of anesthesia mask, the mean mYPAS score in Group M was considerably less than Group P (approximately 31 vs. 63, respectively). This implies that midazolam was more effective in reducing preoperative anxiety in children than in parental presence group. This is accordance with the earlier studies conducted.^[7,15,16] At preoperative room, the difference was found to be statistically insignificant, showing a comparable mean mYPAS between the two groups.

In general, most children and their parents would prefer staying together while undergoing medical procedures.^[17-19] Midazolam proved to be highly efficacious in alleviating separation anxiety at a potentially stressful time point for

children. Moreover, the use of midazolam in preoperative room has shown to reduce the incidence of unwanted postoperative psychological effects.^[4]

Blount *et al.*^[20] reported that, when parents are taught to be active in diverting attention through conversation or in reassuring by eye contact and touch, it resulted in reduction in children’s anxiety. However, new developing body of literature suggests that parental presence during the induction of anesthesia may not be an effective method to treat child’s anxiety.^[7,15,16] These findings were confirmed in our study.

Both interventions led to reduction in anxiety in children. However, intravenous midazolam was more effective in reducing the anxiety of the patient while introducing the anesthesia mask.

Parental anxiety is an important determinant factor of preoperative anxiety in children. Children who have anxious parents have higher odds of being anxious in the operating room than the children who did not have an anxious parent.^[1] Parental anxiety was measured using STAI tool in both the groups at two points, one at preoperative room and other at the waiting room.

In our study, the parental anxiety seemed to be similar in both the groups in the preoperative room. However, in the waiting room, the difference in mean STAI score was found to be statistically significant showing a significantly lower STAI Score in Group M in comparison to Group P at the waiting room. It means among the two groups, parents in the midazolam group were the less anxious after separation than parents in the parental presence group. Vessey *et al.*^[21] reported that the most disappointing factors for parents were watching the child getting agitated before induction, then going limp during induction and eventually getting separated after induction. Therefore, parental presence is not always an effective intervention, in part because of increased parental anxiety. This is supported by previous studies done by Kain *et al.* and Ryder and Spargo.^[7,19]

Induction of anesthesia is prolonged due to preoperative anxiety.^[1,22]

The mean duration of the induction of anesthesia in Group M was considerably less than Group P (5.53 min vs. 8.77 min). This can be attributed to the fact that children in Group M were more compliant during the induction of general anesthesia. There was less incidence of disruptive behavior and better acceptance of face mask during the induction in the midazolam group. This translated to lesser duration of induction of anesthesia than prenatal presence group.

There were a few limitations of the present study. The study was conducted at a single center. The tools used in the study such as mYPAS and STAI Tool, though standard, but are also subjective and tedious during routine OT hours. Moreover, there was no control group in our study.

For more conclusive results, multicentric studies with a control group and a larger sample size need to be conducted.

Conclusion

Intravenous midazolam was more effective in reducing preoperative anxiety in children aged 4–12 years. Parents were more anxious in the waiting room when they accompanied the child to operation theater compared to midazolam group. The duration of induction was comparatively higher in the parental presence group than in the midazolam group because premedicated children were more compliant during the induction of anesthesia.

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Conflicts of interest

There are no conflicts of interest.

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