

The Effects of Preanesthetic Parental Presence on Preoperative Anxiety of Children and their Parents: A Randomized Clinical Trial Study in Iran

Abstract

Introduction: Parental presence during induction of anesthesia (PPIA) has been a controversial issue, with some studies showing its effects on reducing anxiety. Hence, this study aimed to investigate the effects of PPIA on preoperative anxiety of children as well as their parents. **Materials and Methods:** This clinical trial was conducted among 60 children aged 2–10 years and their parents. Children were randomly assigned to intervention ($n = 30$) and control ($n = 30$) groups. Children in the control group were taken to the operating room (OR) alone, while those in the intervention group were taken to the OR with one of their parents. When the anesthetic mask was placed on the children's face (induction), the children's preoperative anxiety in both groups was assessed using Modified-Yale Preoperative Anxiety Scale (M-YPAS), and after that the parents in the intervention group were escorted to the waiting area. Parents' anxiety in both the groups was measured by the Spielberg State-Trait Anxiety Inventory (STAI) in the waiting area. Data were analyzed using descriptive and inferential (independent t -test and Chi-square test) statistic methods through the Statistical Package for the Social Sciences version 18 software. **Results:** Results showed no significant difference between children's anxiety in the intervention (70.83) and control (70.39) groups in the preanesthetic period. In addition, no significant difference was seen between the intervention (79.23) and control (85.86) groups regarding total parents' anxiety. **Conclusions:** PPIA was not successful in reducing the children's preoperative anxiety as well as parents' anxiety. Future studies in this area are needed to clarify the effects of this intervention in pediatric populations.

Keywords: Anesthesia, anxiety, children, parental presence, preoperative care

Introduction

Induction of anesthesia has been identified as one of the distressing aspects of pediatric surgery.^[1] It has been reported that anxiety levels of children remains high throughout the perioperative period, however, anxiety levels peak when the anesthesia care provider introduces the face mask and begins the induction of anesthesia.^[2] Elevated children's preoperative anxiety is associated with negative behaviors including separation anxiety, nightmares, aggression toward authorities, nocturnal enuresis, and eating disorders, and may increase postoperative analgesic requirements prolonging postoperative recovery process, which may be emotionally traumatic for children and their parents.^[3-5] Hence, minimizing children's as well as their parents' surgical anxiety at the time of anesthetic induction may reduce adverse psychological and physiological outcomes, and is considered to be an important care, especially for advanced practice nurses.^[6]

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Today both pharmacologic and nonpharmacologic interventions are available to reduce children's preoperative anxiety during induction of anesthesia.^[7,8] In pharmacologic methods, large doses of sedatives and premedication are administered preoperatively that are regarded by many as undesirable because they may create unnecessary risks, are time-consuming, and may be associated with delayed emergence from anesthesia.^[9,10] Therefore, currently there is great motivation towards nonpharmacological interventions aimed at reducing anxiety for children and their families, such as animated cartoons, video games, educational programs, hypnosis, clown doctors, as well as parental presence during induction of anesthesia (PPIA).^[7,8]

Among the abovementioned nonpharmacologic methods, PPIA has been the most frequently studied intervention

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in recent years for reducing children's preoperative anxiety.^[11,12] Researches have shown that most parents prefer to be present during induction of anesthesia, believe that their presence make the anesthesiologist's job easier, and consider it helpful to reduce their children's preoperative anxiety.^[13,14] Despite the benefits of PPIA for both children and parents, clinical evidence does not support the routine use of this method during anesthesia induction, and there are differing views among health professionals on whether parents should be present at anesthesia induction.^[13] In addition, results of recent clinical trials, where parents were randomly assigned to be present or absent during anesthetic induction, have not been positive and no differences in children's preoperative anxiety were observed between parental presence or absence groups.^[15,16] A recent Cochrane review of nonpharmacological methods to reduce children's preoperative anxiety showed that PPIA did not reduce children's preoperative anxiety compared with not having a parent present in 5 trials, and in 3 trials, no clear difference was observed in children's preoperative anxiety whether a parent was present or not.^[7] In another review study, PPIA alone was the least effective means of decreasing a child's anxiety during the induction of anesthesia compared to premedication midazolam and behavioral distraction.^[12]

In light of the differing opinions and varied and controversial research findings and because much of the research has been focusing on the effects of PPIA only on children's preoperative anxiety and very few emphasizing its effects on the parents, we decided to assess the effects of PPIA on the preoperative anxiety of both the children and their parents.

Materials and Methods

Design

This study was a randomized clinical trial and was registered on the Iranian Registry of Clinical Trials (IRCT) with registration number IRCT2013100612830N2.

Participants

Participants in this study included 60 children, aged 2–10 years, who underwent minor-medium elective surgical procedures with an indication of general anesthesia at Busheher educational hospitals along with their parents from January 9th to April 16th 2014. Inclusion criteria were having a parent present during the admission and hospitalization and American Society of Anesthesiologists (ASA) physical status I and II. Children with previous surgeries and history of central nervous system diseases, psychiatric diseases, and neurological or cognitive impairments or diseases were excluded from the study.

The sample size was computed based on a previous study^[17] using clinical trial formula and analysis of variance estimates. Given a medium effect size (i.e., $f = 0.25$), a

power of 80%, and an alpha statistic of 0.05, approximately 30 samples were calculated in each group.

Outcome measures

For collecting demographic and clinical data, a researcher-made questionnaire was used including sex, age, birth order, parental education, kind of surgery, and parent who accompanied the children to the operating room (OR).

Modified-Yale Preoperative Anxiety Scale (M-YPAS) was used to measure children's preoperative anxiety. This observational behavioral scale was developed by Kain *et al.* to measure the anxiety state of young children. It contains 27 items divided into 5 categories including activity, emotional expressivity, state of arousal, vocalization, and use of parents. Each category receives a score on a scale of 4 (6 for vocalization) according to the behavior of children. The M-YPAS score ranges from 23–100, with higher scores indicating greater anxiety.^[18] This scale has good reliability and validity for measuring children's preoperative anxiety in the preoperative holding area and during the induction of anesthesia.^[15,16]

For assessing parents' anxiety, Spielberg State-Trait Anxiety Inventory (STAI) was used. This self-report anxiety instrument contains two separate subscales that measure trait (baseline) and state (situational) anxiety. State anxiety has been defined as an emotional status characterized by feelings of apprehension and tension with changes in the level of activity of the autonomous nervous system, which can alter overtime. Trait anxiety is related to the stable aspects of the individual's personality, which tend to generate anxiety. For the purpose of this study, both subscales were taken into consideration. This inventory consists of 40 items based on the Likert model. Each response is scored between 1–4 points (1 meaning "not at all" and 4 meaning "very much"). Total scores for state and trait questions separately range 20–80. This implies that the higher the score the higher is the anxiety. The reliability and validity of this scale was verified in previous studies.^[19]

Procedure

Once a child met the study inclusion criteria, the researcher contacted the parents by telephone and asked about their interest in having their child participate in the study. If the parents were willing, the researcher arranged to meet the parent(s) and child on the day of the surgery. Approximately 60 min before the children's surgery, the researcher met both the child and the parent(s) to obtain parental written informed consent for the child's participation in the study and to obtain the child's verbal assent. After that, demographic data about the children and parents were obtained and they were randomly assigned based on surgical types (ear, nose, and throat [ENT] surgeries and nonENT surgeries) and age group (2–5 and 6–10 years) to parent present group ($n = 30$) and parent absent group ($n = 30$).

A computer-generated list of random numbers was used by an individual outside the study to generate the allocation, which was concealed by the use of security envelopes. The children in the parent absent group (control group) were taken to the OR alone, while those in the parent present group (intervention group) were taken to the OR with one of their parent. The decision as to which parent would accompany the child was left to them. In this study, parents were not prepared beforehand for accompanying the child into the OR. It was then explained to them that their presence in the OR may be beneficial for their child, and explained how to accompany them in the OR. It is noticeable that no participant received premedication. After routine monitoring, all children's noninvasive blood pressures, oxygen saturation values, and heart rates were recorded in both the groups. Anesthesia was induced using 60% nitrous oxide in oxygen and Sevoflurane 6–8% via a mask and Vecuronium 0.1 mg/kg was administered to facilitate orotracheal intubation. When the anesthetic mask was placed on the children's face (induction), the children's anxiety was assessed using the M-YPAS by researcher. As soon as anesthesia was induced, parents in the intervention group were escorted to the waiting area and were asked to fill the STAI in the presence of the researcher.

Statistical analysis

Quantitative variables were shown as mean and standard deviation, and qualitative variables were represented as number of frequency and their percentage. To examine differences in qualitative and quantitative variables among the two groups, we used Chi-square and independent sample *t*-test, respectively. Statistical analysis of data was done using the Statistical Package for the Social Sciences software version 18 (SPSS, Inc. Chicago, IL, USA). *P* < 0.05 was considered to be significant.

Ethical considerations

The trial was approved by a research ethics board at Bushehr University of Medical Sciences (Bushehr, Iran), and written informed consents were obtained from all participants.

Results

Follow up

Of the 136 participants who were eligible to participate, 22 did not meet the inclusion criteria, 42 declined to participate, and 12 could not participate for other reasons (e.g., the OR was running ahead of schedule). Of the remaining 60 participants, 30 were randomly assigned to the control group and 30 were randomly assigned to the intervention group. Of the 60 parents who participated, all adhered to the study protocol. Hence, data from all 60 children and their parents were included in the analyses [Figure 1].

Primary outcome

Most children in both the intervention and control groups were females. Mean and SD of children's age in the intervention and control groups were 5.11 ± 2.30 and 5.81 ± 2.32 years, respectively. Children in the control and intervention groups were similar with respect to their ages and baseline characteristics, and Chi-square test showed no significant difference in this regard [Table 1]. There was also an even distribution of children across the four randomization groups (i.e., ages 2–5: ENT surgery; ages 6–10: ENT surgery; ages 2–5: nonENT surgery; and ages 6–10: nonENT surgery), indicating that the sample was equally distributed across age groups and surgical types. Among the ENT groups, procedures consisted mainly of tonsillectomy (*n* = 16), adenoidectomy (*n* = 9), and myringotomy (*n* = 5). Among the nonENT groups, the most common procedures were hernia repairs (*n* = 9), circumcisions (*n* = 11) and orchidopexy (*n* = 10).

Table 1: Demographic and clinical characteristics of children in intervention and control groups

| Variables | Intervention group, <i>n</i> (%) | Control group, <i>n</i> (%) | <i>P</i> |
|-----------------------------|----------------------------------|-----------------------------|----------|
| Age of children (years) | | | |
| 2-5 | 26 (86.7) | 21 (70.0) | 0.201 |
| 6-10 | 4 (13.3) | 9 (30.0) | |
| Gender of children | | | |
| Male | 8 (26.7) | 11 (36.7) | 0.612 |
| Female | 22 (73.7) | 19 (63.3) | |
| Birth order of children | | | |
| First child | 20 (66.7) | 16 (53.3) | 0.313 |
| Second child | 6 (20.0) | 6 (20.0) | |
| Third child | 3 (10.0) | 5 (16.7) | |
| Forth child | 0 | 3 (10.0) | |
| Fifth child | 1 (3.3) | 0 | |
| Kind of surgery | | | |
| ENT | | | |
| Tonsillectomy | 9 (30.0) | 7 (23.2) | 0.501 |
| Adenoidectomy | 4 (13.3) | 5 (16.7) | |
| Myringotomy | 3 (10.0) | 2 (56.7) | |
| Non-ENT | | | |
| Hernia repairs | 4 (13.3) | 5 (16.7) | |
| Circumcisions | 5 (16.7) | 6 (20.0) | |
| Orchidopexy | 5 (16.7) | 5 (16.7) | |
| Parents | | | |
| Mother | 19 (63.3) | 6 (20.0) | 0.201 |
| Father | 11 (36.7) | 24 (80.0) | |
| Parents' education | | | |
| Illiterate | 1 (3.3) | 2 (6.6) | 0.932 |
| Primary graduate | 6 (20.0) | 4 (13.3) | |
| Secondary graduate | 8 (26.7) | 10 (33.3) | |
| High school graduate | 10 (30.3) | 10 (33.3) | |
| University student/graduate | 5 (16.7) | 4 (13.3) | |

ENT: Ear nose throat

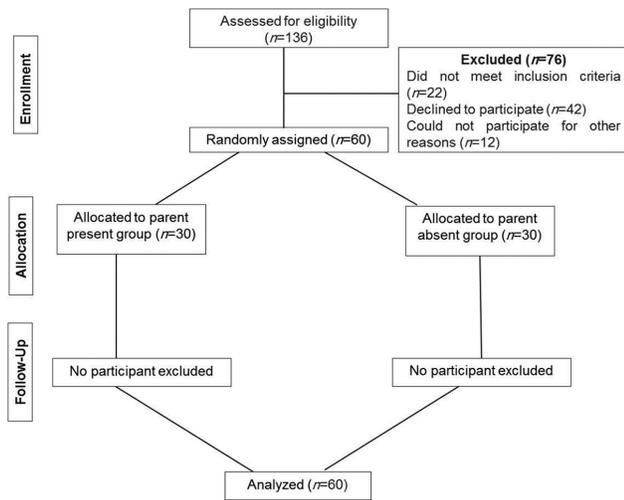


Figure 1: Summary of participant's follow up

Secondary outcome

Regarding children's anxiety subscales, Chi-square test indicated no significant difference between the two groups in activity ($P = 0.601$), vocalization ($P = 0.632$), and emotional expression ($P = 0.612$) subscales, whereas a significant difference was observed between the two groups in state of arousal ($P = 0.033$) and use of parents ($P = 0.031$) subscales [Table 2]. Based on independent t -test, no significant difference was seen between children's preoperative anxiety in the intervention and control groups ($P = 0.621$). Moreover, results showed no significant difference between the intervention and control groups regarding state ($P = 0.056$), trait ($P = 0.826$), and total ($P = 0.208$) parents' anxiety [Table 3].

Discussion

Despite the fact that most parents and children prefer to stay together during procedures such as induction of anesthesia, our results showed that the mean score of parents' and children's anxiety were not significantly different between the two studied groups. To date, a few randomized controlled trials have found PPIA to be an effective anxiety-reducing intervention for children and their parents when compared with the parent absent group. Consistent with our results, in a recent clinical trial study conducted by Bailey *et al.* among 93 children aged 2–10 years, the effectiveness of PPIA in reducing children's preoperative anxiety was not improved by the intervention at the holding stage ($P = 0.15$), the point at which the family left the holding area ($P = 0.39$), the point that they entered the OR ($P = 0.28$), and the point at which the anesthesia mask was introduced ($P = 1.3$).^[15] In a prospective trial done by Kim *et al.* among 117 children aged 2–7 years scheduled for minor elective surgery, parental presence during induction of sevoflurane anesthesia caused no changes in the mYPAS scores from baseline to induction among the studied groups ($P = 0.049$).^[16] In another study performed

Table 2: Comparison of children's preoperative anxiety (Modified-Yale Preoperative Anxiety Scale) in intervention and control groups

| M-YPAS category | Intervention group, n (%) | | | | | | | Control group, n (%) | | | | | | | P |
|------------------------|---------------------------|----------|-----------|-----------|-----------|----------|----------|----------------------|-----------|-----------|----------|-----------|----------|----------|-------|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | |
| Activity | 1 (3.3) | 8 (26.7) | 2 (6.7) | 0 | 19 (63.3) | - | - | 1 (3.3) | 12 (40.0) | 1 (3.3) | 1 (3.3) | 15 (50.0) | - | - | 0.601 |
| Emotional expressivity | 0 | 2 (6.7) | 14 (46.7) | 5 (16.7) | 9 (30.0) | - | - | 0 | 3 (10.0) | 9 (31.0) | 7 (24.1) | 11 (37.9) | - | - | 0.632 |
| State of arousal | 0 | 1 (3.3) | 8 (26.7) | 15 (50.0) | 6 (20.0) | - | - | 0 | 0 | 11 (36.7) | 3 (10.0) | 16 (53.3) | - | - | 0.033 |
| Vocalization | 0 | 6 (20.0) | 1 (3.3) | 4 (13.3) | 9 (30.0) | 5 (16.7) | 5 (16.7) | 0 | 8 (26.7) | 0 | 2 (6.7) | 6 (20.0) | 6 (20.0) | 8 (26.7) | 0.612 |
| Use of parents | 0 | 8 (26.7) | 1 (3.3) | 16 (53.3) | 5 (16.7) | - | - | 0 | 2 (6.7) | 9 (30.0) | 9 (30.0) | 10 (33.3) | - | - | 0.031 |

M-YPAS: Modified-Yale Preoperative Anxiety Scale

Table 3: Comparison of children's and parents' anxiety in intervention and control groups

| Variables | Mean (SD) | | P |
|--------------------|--------------------|---------------|-------|
| | Intervention group | Control group | |
| Children's anxiety | 67.83 (16.78) | 70.39 (20.93) | 0.621 |
| Parent's anxiety | | | |
| State | 40.80 (10.84) | 80.46 (12.91) | 0.056 |
| Trait | 38.43 (10.87) | 39.06 (11.30) | 0.826 |
| Total | 79.23 (19.65) | 85.86 (20.67) | 0.208 |

SD: Standard deviation

by Wright *et al.* among 61 children aged 3–6 years, no significant difference was observed between parental presence and absence groups in children's anxiety during induction of anesthesia, whereas at the time-point when children was typically separated from parents, preoperative children's anxiety was found to be significantly higher in the parental absence group than in the parental presence group.^[20] Regarding parent's anxiety during induction of anesthesia, investigations are scant. In agreement with our results, Akinci *et al.* reported that maternal presence during induction had no effects in reducing the mother's anxiety.^[21] In another study conducted by Kain *et al.* among 80 parents and their children undergoing elective outpatient surgery, there were no significant differences in parents' self-reported anxiety, as measured by the STAI, between parental presence group and control group.^[22]

The findings of this study must be considered in light of several limitations. First, all instructions that nursing staff, residents, and anesthesiologists gave to the parents during parents' preparation and before parents being led into the OR with their child may have impacted the results. To reduce this type of limitation, future studies should quantify the amount of time health care providers spend preparing families and/or measuring their understanding of the preparatory information they receive. Second, all parents in this study were given the option to be present for their child's anesthesia induction regardless of the level of their own or their child's anxiety. Moreover, when parents entered the OR, they were often explained to sit on a chair besides their child and were told they were allowed to hold their child's hand. These explanations may have directed the behaviors of the parents and may have impacted child's anxiety during anesthetic induction. Based on previous research, anxious parents do not benefit anxious children and they actually increase anxiety in calm children during anesthesia induction.^[23,24] In a study, Kain *et al.* reported that presence of a calm parent benefits an anxious child during induction of anesthesia and the presence of an overly anxious parent has no benefit.^[23] Similarly, Messeri *et al.* have recently indicated that anxious parents increase the stress of anesthetic induction in children, even those who have been premeditated.^[24] It is suggested that parents were allowed to use their own coping strategies during the preoperative period.

Conclusion

PPIA had no effects in terms of reducing the parents' or children's anxiety. Hence, future studies in this area are needed to clarify the effects of this intervention in pediatric populations.

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Conflicts of interest

There are no conflicts of interest.

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