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Effect of Two Techniques of Parental Interaction on Children's Anxiety at Induction of General Anaesthesia-A Randomized Trial

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Objective: Several non-pharmacological techniques, such as parental presence and behavioral preparation, are used to decrease children's anxiety at anaesthesia induction. We compared the mean anxiety score in children at the time of anaesthesia induction with two different physical techniques of parental interaction and a control group with no parent present. The secondary objective was to determine the face mask acceptance during induction.

Methods: This study recruited 123 ASA I & II children, aged 1 to 8 years, undergoing day care surgery, who were randomly allocated to three groups. Children either went to the operating room (OR) alone (Gp C), or one parent sat next to the child at induction (Gp PS), or the child sat in parent's lap (Gp PH). The anxiety score on the modified Yale Preoperative Anxiety Scale (mYPAS) was recorded in the preinduction area of OR and at the induction of anaesthesia before the face mask application. A cut-off value of less than 30 indicated low anxiety. The face mask acceptance was also rated.

Results: All patients had the mYPAS scores higher than 30 in the preinduction area with no significant difference between groups. Prior to induction, the Gp C score was significantly high as compared to Gp PS ($p=0.016$) and Gp PH ($p=0.001$), but it was not different between the Gp PS and PH ($p=1.00$). The face mask acceptance was easy in 4.9 % patients in Gp C, 26.8% in Gp PS, and 56% in Gp PH.

Conclusion: Parental presence during induction did not prevent children's anxiety, but it reduced it, irrespective of the physical technique used. The face mask acceptance was better in Gp PH.

Keywords: Anaesthesia, pediatric, anxiety, prevention and control, parents

Introduction

Induction of anaesthesia is a stressful experience for a child undergoing surgery (1). This may prolong induction and cause emotional trauma for both the child and his or her parents and the operating room (OR) staff (2). Parental presence during induction of anaesthesia is one of several methods used in treatment of preoperative anxiety in pediatric surgery (3). The technique is not a standard of care as it has both advantages and disadvantages (4). The presence of parents provides emotional support to the child, but on the other hand, anxious parents may increase the child's anxiety (5).

The effect of parental presence may also vary in different cultures (6). In our country, allowing parents at the time of induction is dependent on the anaesthetist's preference, and it therefore varies.

The objective of this study was to compare the mean anxiety score in children at the time of induction of anaesthesia with two different physical techniques of parental presence and interaction with a control group with no parental presence. The primary outcome variable was the anxiety score as measured by the modified Yale Preoperative Anxiety Scale (mYPAS). The secondary outcome was the effect of technique on the face mask acceptance in children and to observing the influence of the child age on anxiety.

Methods

This randomized controlled study was conducted in the operating rooms of the Aga Khan University Hospital (AKUH), Karachi, Pakistan in 2014, after getting an approval from the ethical review committee of AKUH. Written consent was

obtained from parents. This manuscript adheres to the CONSORT guidelines.

The sample size was calculated based on a previous study by Kain et al. (7). Forty-one patients per group were needed to detect a difference of 12.3 in the mean anxiety score (using the modified Yale Preoperative Anxiety Scale (mYPAS scale)) between groups with 80% power, using the analysis of variance (ANOVA) and assuming an (two-sided) alpha of 0.05. An expected mean anxiety score was 61.8 (SD 21.8) in children with their parents absent, and an expected mean anxiety score of other two interventions was 49.5 (SD17.5).

Our inclusion criterion was ASA (American Society of Anesthesiology) I and II children between 1 and 8 years of age undergoing elective surgery (e.g., inguinal hernia repair) as day care cases. Patients with a history of previous surgery or hospitalization, developmental delay or mental retardation, and language barrier were excluded. Parents were briefed in the holding area about child's possible reaction to induction of anesthesia. No premedication was administered.

The children were observed in the waiting area of the OR in the presence of their parents, and the mYPAS forms were filled. The mYPAS questionnaire consisted of 22 items in five categories of behavior (8) (see Appendix). A total score was calculated. Study subjects were then randomized in one of the three groups by using the opaque sealed envelope technique. The random allocation sequence was generated by a statistician not associated with the study. The groups were the following:

Control group (Gp C): The child went to the OR alone with a staff member, and parents stayed in the preinduction area. The child sat on the operating table for induction of anaesthesia.

Parents sitting next to child (Gp PS): One parent (either father or mother) accompanied the child into the OR, where he or she sat on a chair near the operating table. The child sat on the operating table, and anaesthesia induction was performed in the sitting child without the parent holding the child.

Parent holding the child (Gp PH): Parents (either mother or father) accompanied the child to the OR, and the parent sat on a chair. The child sat on their lap. Child's head was rested on the mother's/father's arm or shoulder, and the parent wrapped their arm around the child holding the child closely.

The enrollment of patients was based on the inclusion and exclusion criteria and was done by one of the investigators who was not involved in the observations. Observations were done by the second investigator.

Due to the nature of the study, blinding was not possible. The mYPAS scoring was repeated in the OR before the face mask

application. Additional information collected was child's demographic data and which parent (mother or father) accompanied the child to the OR. After scoring mYPAS, the child's ability to accept a face mask during induction of anaesthesia was recorded as easily accepting, resisting, or not accepting. All children underwent the inhalational induction with oxygen and sevoflurane using the Ayres T piece with Jackson Rees modification. An age-appropriate mask size was used. The induction technique was standardized. The data collection ended once the child was anaesthetized. A cut-off value of more than 30 on the mYPAS was taken as an indicator that the child was anxious.

Statistical analysis

Statistical tests were performed using the Statistical Package for the Social Sciences (SPSS Inc.; Chicago II, USA version 19.0 for Windows). The primary outcome variable was the anxiety score. Quantitative data, that is, age, weight, and anxiety score were presented as the mean and standard deviation, while qualitative data, that is, gender and ASA were presented as the frequency and percentage. After checking the normality of anxiety score, the Kruskal-Wallis test and one-way ANOVA were used to compare the mean anxiety score among groups. For multiple comparisons, the Bonferroni test was applied. The effect of age was controlled by stratification techniques. $P \leq 0.05$ was considered as the level of significance. Chi-square test was used to compare the proportion difference among groups.

Results

One hundred and twenty-three patients aged 1 to 8 years were enrolled in the study. The average age of the patients was 3.14 (SD 2.12) years. There were 95 (77.2%) male and 28 (22.8%) female children. Forty-one patients were assigned and analyzed in each group. All patients who were enrolled completed the study, and there were no dropouts. Demographic data and the ASA status of the children are presented in Table 1. There was no significant baseline difference between the groups.

Sixty-three percent of the children in Gp C and 71 % of the children in both Gp PS and Gp PH had a mYPAS anxiety score above 30 in the preinduction area, and the score was not significantly different between groups. Ninety-seven percent of children in Gp C and 95% children in both Gp PS and Gp PH had anxiety scores above 30 inside the OR. A significant difference was observed in the mean anxiety score among different groups ($p=0.001$) before the face mask application (Figure 1). The score was high in Gp C as compared to both Gp PS (50.3 ± 13.9 vs. 43.5 ± 10.4 ; $\text{diff}=6.8 \pm 2.4$ $p=0.016$) and Gp PH (50.3 ± 13.9 vs. 41.1 ± 7.6 ; $\text{diff}=9.2 \pm 2.4$ $p=0.001$).

The comparison of the face mask acceptance among groups is shown in Table 2. Only 5% of children in Gp C in contrast to 27% of children in Gp PS and 56% in Gp PH easily

Table 1. Comparison of demographics and ASA status among groups

Variables	Gp C n=41	Gp PS n=41	Gp PH n=41	p
Age (Years)	2 (3)	3 (3)	2 (3)	0.37
Weight (kg)	14 (6)	14 (8)	12 (12)	0.54
Gender; n (%)				
Male	24 (82.9%)	28 (68.3%)	33 (80.5%)	
Female	7 (17.1%)	13 (31.7%)	8 (19.5%)	0.23
ASA status; n (%)				
I	27 (65.9%)	33 (80.5%)	35 (85.4%)	
II	14 (34.1%)	8 (19.5%)	6 (14.6%)	0.09

Data are presented as median [IQR] and n (%). The Kruskal-Wallis test was used to compare the median among groups, and Chi-squared test used to compare the proportion difference among groups.

Table 2. Comparison among groups of the ability to accept the face mask prior to anaesthesia induction

Variables	Gp C n=41	Gp PS n=41	Gp PH n=41	p
Easily accepting	2 (4.9%)	11 (26.8%)	23 (56.1%)	0.0005*
Resisting	33 (80.5%)	29 (70.7%)	18 (43.9%)	
Not accepting	6 (14.6%)	1 (2.4%)	0 (0%)	

Data are presented as median [IQR] and n (%). Chi-squared test was used to compare the proportion difference among groups.
*p-value significant.
C vs. PS group; p=0.007
C vs. PH group; p=0.005
PS vs. PH group; p=0.20

accepted the face mask. This difference between Gp C and Gp PS, and Gp C and Gp PH was significant (p=0.007 and p=0.005). No difference was observed between Gp PS and Gp PH (p=0.20).

The effect of age was observed after stratification. A detailed comparison among groups regarding the anxiety score showed a statistically significant decrease in the subgroup aged between 5 and 8 years (p=0.001), but not in the group aged between 1 and 4 years of age (p=0.06). In the age group 5 to 8 years, Gp C versus Gp PH showed a higher difference (p=0.001) in comparison to when Gp C was compared with Gp PS (p=0.031). Comparison of the mean anxiety score among groups with respect to age is shown in Figure 2.

Discussion

Preoperative anxiety is a common phenomenon in children. Approximately 40%-60% of children experience anxiety regarding an impending surgical experience (9). This may result in difficult anesthetic induction and a higher incidence of

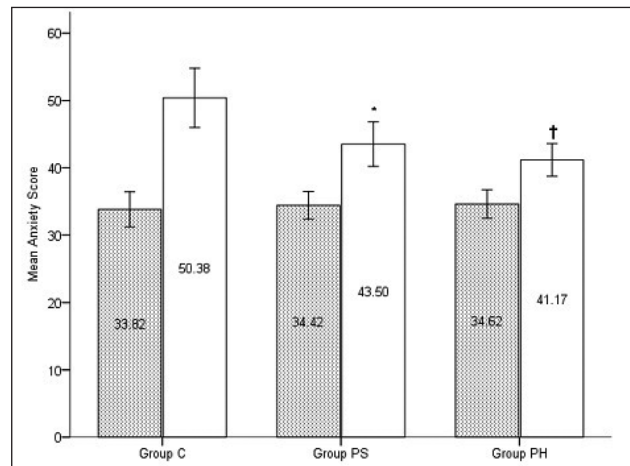


Figure 1. The anxiety score of children in the three groups is shown as dotted bars in the preinduction waiting area and as blank bars in the operating room before the application of face mask. The mean score and SD

†Significant difference between Gp C and Gp PH
*Significant difference between Gp C and Gp PS

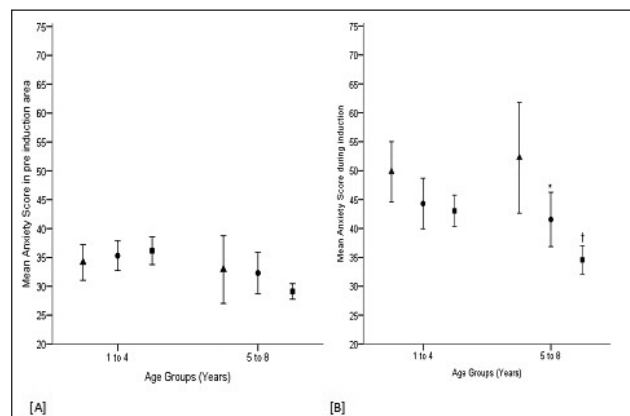


Figure 2. a, b. The effect of age on the anxiety score among groups. Gp C is shown as a triangle, Gp PS as a circle, and Gp PH is shown as a square. The mean score and SD. (a) In the preinduction waiting area. (b) In the OR before the face mask application

For multiple comparisons, the Bonferroni adjusted p-values were used
*p=0.031 Gp C vs. Gp PS
+p=0.001 Gp C vs. Gp PH

postoperative maladaptive behavior (10). Several non-pharmacological methods have been explored to decrease anxiety in these children (11). The efficacy of parental presence during anesthesia induction has been investigated in several studies (12, 13), but the majority of these studies have been done in high-income countries and have shown little effect of parental presence on children's anxiety. Despite this, there has been support for allowing parents to be present during induction of anesthesia because of cost issues of other non-pharmacological strategies such as behavioral preparations (3).

The results of studies on the efficacy of parental presence may be different in different cultures and may not be applicable

universally. This may be due to different style of upbringing in different cultural environments. In our search, we did not come across literature on this topic from South Asia where parents are generally believed to be more highly strung and anxious compared to their Western counterparts and hence may affect their child's anxiety differently. In addition, most low- and middle-income countries do not have formal programs for parental or child's psychological preparation due to cost issues. Majority of hospitals do not have separate induction rooms. Hence, parental presence at induction may have a different effect on children.

At our institution, parental presence at the time of induction is not a standard practice and varies depending on consultant anesthetist's preference. Our study demonstrated that approximately 63% to 70% of the children had the mYPAS scores above the cut-off value of 30 in the preinduction area. Parental presence at induction decreased children's anxiety as compared to no parental presence, irrespective of whether the parent had close physical contact with the child or not. To the best of our knowledge, the effect of different degree of physical contact between the parent and the children has not been published before.

We chose the modified mYPAS as the outcome measurement tool because the scale was easy to use and could be applied in less than 1 minute. It is valid, reliable, and applicable both in the preoperative area as well as during induction (8, 13). The mYPAS is regarded as the current "criterion standard" for assessing child anxiety during induction of anesthesia, and it is considered more sensitive than global measures (14). We were unable to compare our results to older studies as the tools that were used for the measurement of anxiety were different (15, 16). Both Schulman et al. (15) and Hannallah et al. (16) used self-created tools for the measurement of anxiety. We can compare our study to later studies that have used the mYPAS scale for the measurement of anxiety in children and have limited our discussion related to these studies. In 1996, Kain et al. conducted a study on the effectiveness of parenteral presence at the time of induction in North American children. They used six different behavioral and physiological tools, including mYPAS, for measuring children's anxiety at induction with and without parents and found no difference (7).

A Cochrane Database Systematic review on non-pharmacological interventions for assisting induction of anesthesia in children was published in 2009 and updated in 2015 (3, 17). They included 28 trials with 17 interventions. Five of the included trials observed the effect of parental presence. The pooled effect in 557 children did not reduce the children's anxiety. However only two of the studies out of five had used the mYPAS scale for outcome (18, 19). The authors of the systematic review concluded that although overall no benefit was observed, further work is required for confirming or refuting usefulness in addition to using reliable methods

for reporting outcome. The first of the two trials that had used mYPAS observed the North American children between 2 and 10 years of age (18). Ninety-four children had parents present, and 99 children had no parent present at anaesthetic induction, and the authors found no difference. In the second trial, Wright et al. (19) from Canada conducted an RCT in 61 children between 3 to 6 years of age undergoing day care surgery. Using the mYPAS scale, they observed the observer-rated anxiety at five time points and noted a difference between groups at the time of separation from parents with lesser anxiety in the parental presence group. They also argued that the results of the previous studies may have been affected by including older children where parental presence may not affect the child's anxiety. A recent study from a middle-income country, Iran, looked at the mean mYPAS scores at the time of induction between the two groups of parental presence or absence and found lower mean scores for the parental presence group (35.5+16.6 vs. 59.8+22.4, $p<0.001$) (20).

These conflicting results may be due to several reasons as many factors can affect children's anxiety at the time of anaesthetic induction, and it may be difficult to standardize all. Cultural factors can also be responsible for this variation, and this merits further studies in different cultures.

The face mask acceptance at the time of induction has also been identified as an independent marker of measuring the child's anxiety (16). Our study indicated a significantly better acceptance when the children were held in close physical proximity to the parents. Most previous studies have not explored the physical interaction between the parent and the child at the time of induction.

Investigators who have observed the effect of age on anaesthetic induction have also produced conflicting results. Bevan et al. in a study in children undergoing day care surgery indicated that younger children were more anxious at induction than older children (5). Kain et al. (7) demonstrated that children older than 4 years of age benefited more with parental presence compared to those younger than 4. In contrast, a large survey conducted by Holm-Knudsen et al. (21) demonstrated that age was not associated with distress at induction. Our results did not show an influence of age in the preinduction area, but a significant effect of age was apparent at the time of induction where children aged 5 to 8 years who showed significantly decreased anxiety with parental presence, whereas no effect was seen in children aged 1 to 4 years. This decrease in anxiety was more obvious when the parent was in close physical contact with the child.

In previous studies, the gender of the children has not been shown to influence preoperative anxiety (9, 14). We did stratify our data according to gender but did not explore it further due to the inequality in numbers between male and female patients (male gender 34 in Gp C, 28 in Gp PS, 33

in Gp PH vs female gender 7 in Gp C, 13 in Gp PS, and 8 in Gp PH).

This study has certain limitations. First, this was an observational study, and it was not possible to blind the rater to parental presence. Second, the gender of the parent may also affect the child's anxiety (13, 14). We allowed either the mother or the father to accompany the child without restricting gender. Third, parental anxiety can affect the child's anxiety (3). Fourth, the parental anxiety was not measured, and although the effect of physical interaction between the parent and the child was observed, the emotional interaction that may also influence the child's behavior was not observed. The effect of gender of parents on preoperative anxiety and influence of parental anxiety on children's behavior could be a topic of further research.

Conclusion

Children 1 to 8 years of age scheduled for day care surgery exhibited lower anxiety during anaesthesia induction in the OR when accompanied by one of the parents compared to children who were not accompanied by parents, irrespective of the physical technique or parental proximity.

The face mask acceptance during induction of anaesthesia was significantly better in Gp PS where the child sat in parent's lap.

Our analysis of the effect of age indicated that the physical technique of parent holding the child decreased the anxiety of child at the time of anaesthesia induction in children between 5 and 8 years of age, but not in younger children.



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Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Aga Khan University Hospital.

Informed Consent: Written informed consent was obtained from the parents of the patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – F.A.K.; Design – A.H., F.A.K.; Supervision – F.A.K.; Materials – A.H.; Data Collection and/or Processing – A.H.; Analysis and/or Interpretation – A.H., F.A.K.; Literature Search – A.H.; Writing Manuscript – A.H., F.A.K.; Critical Review – F.A.K.

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APPENDIX

Modified Yale Preoperative Anxiety Scale

Activities

1. The child looks around, is curious, plays with toys, reads (or other behavior appropriate for the age group); moves around the preanesthetic/treatment room to get toys or seeks family members; might move toward the equipment in the surgery room.
2. The child does not explore or play, may look down, plays with own hands or sucks its thumb (blanket); may sit close to family members while it is playing or may show a manic quality while playing.
3. The child moves without concentration from the toy to family members, movements are not connected to the activity; movements or play are frantic/agitated; twisting, moving on the table; may push the mask or grab family members.
4. Tries to escape, pushes with feet and arms, may move its entire body; in the waiting room, runs around without purpose, does not look at the toys, does not want to be apart from family members, clings on desperately.

Vocalization

1. Reads (vocalization not adequate for the activity), ask questions, makes comments, stutters, laughs, answers questions promptly, but is usually quiet; child is too young to speak in social situations or too absorbed in the play to answer.
2. Answers to adults but whispers, "baby talk", only shakes its head
3. Quiet, no sound, or does not answer to adults
4. Weeping, moaning, grunting, silent cry
5. Child is crying or might yell no.
6. Crying high pitched and sustained cry

Expressing emotions

1. Happy, smiling, or concentrated on the play
2. Neutral, no discernible face expression
3. From worried (sad) to frightened, sad, worried, or teary eyed
4. Distressed, crying, uncontrolled, eyes might be wide opened

State of arousal

1. Alert, looks around occasionally, notices, or follows anesthesiologist's action (might be relaxed)
2. Withdrawn, calm, and silent, might suck its thumb, or its face might be like an adult's face
3. Attentive, looks around quickly, might be startled by noises, eyes wide opened, body is tense
4. Whines in panic, might cry or shun others and turn body around

Interaction with family members

1. Concentrated while playing, is sitting down inactive or shows behavior appropriate to age and does not need family members, might interact with family members if they initiate the interaction
2. Seeks interaction with family members (gets close to them and talk to family members that were silent until then), seeks and accepts support, might lean against family members
3. Looks silently to family members, apparently observes their actions, does not seek contact or consolation but accepts it if it is offered, clings on to family members
4. Keeps family members at a distance or might leave the area when parents are present, might push family members away or cling desperately to them, not letting them go away