



Parental active participation during induction of general anesthesia to decrease children anxiety and pain

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ABSTRACT

Surgical experiences are always stressful for both children and parents. Preoperative anxiety in children is very common. The aim of this study was to evaluate the effect of parent active participation in anesthesia induction on the preoperative anxiety levels of 120 children who were scheduled for elective orthopedic surgery at EL Hadara Orthopedic University Hospital. Children were randomly assigned to two groups. The experimental group intervention included parent active sharing in anesthesia induction, whereas the other group of parent attended anesthesia induction. The primary outcome was anxiety during induction of anesthesia (modified Yale Preoperative Anxiety Scale). Secondary outcomes were self-reported and observed pain, emergence delirium, need for rescue analgesia and parental anxiety. When compared with the other group, the results showed that children and parents in active participation group experienced significantly decreased anxiety levels ($P < .001$). Parent active participation reduces children's preoperative anxiety and improves their compliance with induction of anesthesia.

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KEYWORDS

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1. Introduction

Surgery and anesthesia develop a series of perceived or real threats to the child [1]. Child is aware enough to appreciate the hospital environment stress and family separation, and separation of parents can also result in psychological drawbacks for a child [2]. Around 50–70% of children suffer from anxiety on the day of surgery [3]. Preoperative anxiety is accompanied by troublesome anesthesia induction with possibility of emergence delirium [4], exaggerated pain and low-quality recovery [5]. Anxious children exposed to surgery are also at great risk of posttraumatic stress symptoms [6]. These adverse outcomes mandate the important need for successful interventions to overcome preoperative anxiety.

Based on both physiological and behavioral responses, Kain et al. [3] have demonstrated that induction of anesthesia seems to be the most stressful event the child experiences during the entire preoperative period. Both pharmacological interventions (e.g., sedative premedication of the child prior to parent separation) and behavioral interventions (e.g., parental presence during anesthesia induction) have been examined in many clinical trials to treat children preoperative anxiety [7]. The increasing popularity of outpatient surgery has led to a great percentage of pediatric surgical operations that are managed on a day case basis. Using sedative premedication to the

child before parent separation in this context is not always the ideal solution as it is not easy to achieve optimal dosing and timing [8]. On the other hand, presence of parents during induction of anesthesia is also controversial. Early studies suggested low child anxiety and increased cooperation [9]. More updated reports suggest that presence of parents may not be beneficial enough to avoid premedication use or to lessen parent's separation-induced child anxiety [10]. The inability of children to get benefits from preoperative preparation and to accept new social contacts [9] may explain that presence of parents during induction of anesthesia may not be enough to provide support and comfort to their children while exposing to any new experience and or stress. Active participation of parents in induction of anesthesia has not been evaluated before. Given that, we hypothesize from this prospective study that active participation of parents in induction of anesthesia could result in reducing child fear and anxiety and better outcome.

2. Methods

The study was approved by the research ethics committee of faculty of medicine, Alexandria University, and was registered in Pan African Clinical Trial Registry (PACTR202103591612264). Informed parental consent was obtained preoperatively. The minimal

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sample size was calculated based on a previous study aimed to determine whether this approach has advantages over treating children with sedatives alone. [11] Kain et al. [11] concluded that parental presence during induction of anesthesia in addition to 0.5 mg/kg oral midazolam has no additive effects in terms of reducing a child's anxiety. Parents who accompanied their children to the operating room, however, were less anxious and more satisfied. Based on their results, adopting a power of 90% to detect a standardized effect size in modified Yale scale (primary outcome) of 0.4343 and level of significance 95% ($\alpha = 0.05$), the minimum required sample size was found to be 113 pediatric patients per group (number of groups = 2) (total sample size = 226 pediatric patients). Any withdrawal for any reason was compensated by replacement to control for attrition (withdrawal) bias. The sample size was calculated using GPower version 3.1.9.2.

One hundred and twenty children scheduled for elective day case orthopedic surgeries were selected with the following inclusion criteria: age: 3–8 years old, American Society of Anesthesiologists (ASA) grades I–II and accompanied by a parent with whom they usually lived. Exclusion criteria were mental retardation, reported developmental delay or significant behavioral disturbances, epilepsy, visual impairment, history of previous surgery and or hospitalization, chronic illness, (ASA) physical status at least III and need for preoperative anxiolytic medication. The study was conducted at EL Hadara University Hospital, Alexandria, during the period from 1 June 2020 to 31 May 2021. Eligible children and their parents were assigned to one of two study groups according to a random-number table: a “treatment” group, in which the parent was participating in induction of anesthesia, and a “control” group, in which the parent was invited to stay with his child during induction of anesthesia. The decision was taken to consider only mother from parents to accompany the child during anesthesia induction in both groups.

3. Outcomes measures and study protocol

The primary end point was evaluation of levels of anxiety of children before and during induction of anesthesia, while postoperative observed pain, emergence delirium and need to rescue analgesia in children were secondary endpoints.

4. Instruments of assessment (measured parameters)

The modified Yale Preoperative Anxiety Scale (mYPAS) [12]. The mYPAS is taken as the cornerstone in observational instruments to evaluate children preoperative anxiety. The mYPAS is used to evaluate the mental

anxiety of children aged 2–12 years during the perioperative period. It was completed by a nurse blinded to the study at three time points: baseline upon hospital admission, before induction of anesthesia in holding area and during induction of anesthesia. The mYPAS consists of 27 items divided into five categories: activity, emotional expressivity, state of arousal, vocalization and use of parents. We calculated mYPAS as Kain et al. [12] proposed: the total score can range from 23.3 to 100, and any score more than 30 is classified as anxiety, with higher scores indicating higher anxiety levels.

The six-facial visual facial anxiety scale (VFAS) [13] includes six facial expressions scored from 0 to 5; a higher score denotes a higher level of anxiety. The following instructions were given to the mother: “There are six pictures of faces on this paper. The smiling face equals no anxiety and the crying face equals the highest anxiety. Could you please choose the face that describes your anxiety level?” Mothers indicated their own anxiety levels on VFAS that were completed at two time points: baseline upon hospital admission and directly after induction of anesthesia.

Postoperative pain was reported in the recovery room by two informants; the six-faces revised Faces Pain Scale (FPSr): range 0–10 [14], where children with the help of their mothers reported their postoperative pain intensity.

Face, legs, activity, cry and consolability (FLACC) scale: range 0–10 [15], where a nurse blinded to the study assessed pain intensity of children.

Pediatric anesthesia emergence delirium (PAED) scale: range 0–20 [16], where emergence delirium was assessed in the recovery with the same recovery nurse blinded to the study.

5. Study protocol

Children and mothers were recruited 10–14 days before surgery with anesthetic evaluation and a preoperative preparation program. The program consisted of providing illustrated information and orientation tour to the operating and recovery rooms for the children and parents. Full explanation of the proposed technique of anesthesia, the mother will share in, either by attending the induction period or through active participation of induction; they were trained how to be familiar with inhalation mask induction, breathing circuits and how to apply the face mask and to ask their children to inhale through the face mask. In this period, the anesthetist tried to establish an intimate relationship with the child and made him familiar with the anesthesia attachments. During the preoperative consultation, pediatric orthopedic surgeon instructed the parents

about routine surgical preoperative preparation. Following recruitment, demographical data were obtained.

On the morning of surgery and after informed consent was obtained, anxiety of the child was measured in the surgical ward by a blind assessor using mYPAS. The mother was then invited to be with her child during anesthesia induction. None of the children received preoperative anxiolytic, premedication. In anesthesia holding area, the blind assessor measured child anxiety again using mYPAS. Mother rated her on anxiety using VFAS. Children and their parents next were assigned randomly to one of two groups: a "treatment" group, in which the parent was participating in induction of anesthesia, and a "control" group, in which the parent was invited to stay with his child during induction of anesthesia.

At the proper time of surgery, mothers and children were brought together into the anesthesia induction room. In both groups, the mother was advised to sit on a comfort special chair previously prepared for this task. The mother put her child within her lap with face to face and then she applied the SpO₂ probe on the child's hand. The child was cuddled by his mother for few seconds, and she was instructed to nicely whisper to him. No intravenous cannulation was done at this stage.

The induction of anesthesia was then started through inhalation of sevoflurane in a mixture of oxygen and air. In the treatment group, the mother used scented anesthesia mask by herself alone without any help from the attending pediatric anesthetist who was observing the process to ensure safety induction of anesthesia. She started to encourage her child to take multiple deep breaths through the mask until beginning of loss of consciousness. As soon as the child lost consciousness, the anesthetist continued the task from the mother thereafter. In the control group, while the child was cuddled by his mother, the pediatric anesthetist started to administer the anesthetic through scented mask, while mother encourage her child to inhale through the mask until the child lost consciousness. Following loss of consciousness, the anesthetist continued the anesthesia task without mother. An intravenous (i.v.) cannula was inserted, and endotracheal intubation was performed. After the end of surgery, patients were awakened and transferred to the Post Anesthesia Care Unit (PACU). One of the family members was allowed with the child in the PACU.

The child's anxiety during induction was assessed by blind assessor using mYPAS. As soon as general anesthesia was induced, mothers were escorted to the waiting area and asked again to rate their own anxiety using VFAS. During intraoperative period, i.v. fentanyl was given according to the discretion of the

anesthesiologist. At the end of the surgery, initial doses of i.v. diclofenac 1 mg kg and Paracetamol 20 mg kg⁻¹ were given, and i.v. morphine 0.1 mg kg⁻¹ was also given if needed. After extubation, children were brought to the recovery area. After the end of surgery, children were awakened and transferred to the recovery room. Rescue analgesia, extra morphine, could be given by the recovery nurse according to perceived clinical need. Mother was allowed with the child in the recovery room.

In the recovery room, following awakening from anesthesia, incidence of adverse effects and analgesic requirements were recorded. Children reported their pain intensity with the FPSr. A blinded same observer nurse assessed pain intensity with the FLACC scale. Emergence delirium was measured with the PAED scale by a blinded same observer nurse.

All the observations were taken by the same observer to reduce bias and variability during the study.

6. Statistical methodology

- Data were collected and entered into the computer using SPSS (Statistical Package for Social Science) program for statistical analysis (ver 21) [17].

- Kolmogorov–Smirnov test of normality [18].

- Data were described using minimum, maximum, mean, standard deviation and 95% CI of the mean [19] for the normally distributed data.

- Data were described using minimum, maximum, median and inter-quartile range (IQR) for not normally distributed data (scale variables).

- Categorical variables were described using frequency and percentage.

- Comparisons were carried out between two studied independent normally distributed variables using independent sample t test [20].

- Comparisons were carried out between two studied independent not normally distributed subgroups using Mann–Whitney U test. [21].

- Z-test for independent proportions is used to compare two independent proportions [22]. Percentage change was calculated as follows:

percentage change (%) = measurement (after) – measurement (before) × 100/ measurement (before)

- Bar charts were used accordingly.

-An alpha level was set to 5% with a significance level of 95%, and a beta error was accepted up to 20% with a power of study of 80% (beta error was used during sample size calculation phase).

7. Results

Age of the treatment group ranged from 3.00 to 8.00 years with a mean of 5.58 ± 1.53 years, while in the control group it ranged from 3.00 to 8.00 years

with a mean of 5.65 ± 1.56 years. There was no statistical significance between the two groups as regard age ($p = 0.739$). In the treatment group: 48.33% were males and 51.67% were females, while in the control group: 47.50% were males and 52.50% were females. There was no statistical significance between the two groups ($p = 0.897$). Regarding ASA for treatment group: 84.17% were ASA I and 15.83% were ASA II, while in the control group: 80.00% were ASA I and 20.00% were ASA II. There was no statistical significance between the two groups as regard ASA ($p = 0.400$).

Type of surgery: pelvic osteotomy (25.83%) and for control group (29.71%) with no statistical significance between the groups ($p = 0.56192$ NS). Psoas tenotomies: in the treatment group (25.00%) and for control group (22.50%) who had Psoas tenotomies. With no statistical significance between the groups ($p = 0.64552$ NS). Femoral derotation osteotomy: in the treatment group (30.83%) and for control group (30.83%) who had Femoral derotation osteotomy. Achilles lengthening: in the treatment group 22/120 (18.33%) and for control group 21/120 (17.50%) who had Achilles lengthening with no statistical significance between the groups ($p = 0.86502$ NS).

In the present study, the duration of surgery in the treatment group ranged from 130.00 to 200.00 minutes with a mean of 160.33 ± 14.14 minutes, and a 95% CI for the mean of 157.77–162.88 minutes, while in the control group it ranged from 130.00 to 195.00 minutes with a mean of 159.83 ± 14.08 minutes with 95% CI for the mean of 157.28–162.37 minutes. There was no statistically significant difference between both groups as regard duration of surgery ($p = 0.784$). 15.83% had previous hospitalization in the treatment group, while in the control group: 27/120 (22.50%) were with previous hospitalization. There was no statistical significance between the two groups ($p = 0.190$) (Table 1).

As regard mYPAS (baseline), in the treatment group, it ranged from 23 to 30 with a mean of 26.83 ± 1.88 , and a 95% CI for the mean of 26.49–27.17. While in the control group, it ranged from 23 to 30 with a mean of

26.78 ± 2.04 with 95% CI for the mean of 26.41–27.15. There was no statistical significance between the two groups ($p = 0.843$ NS) (Table 2, Figure 1).

Before induction: In the treatment group, it ranged from 30 to 42 with a mean of 36.30 ± 3.27 and a 95% CI for the mean of 35.71–36.89. While in the control group, it ranged from 31 to 43 with a mean of 36.61 ± 3.50 with 95% CI for the mean of 35.98–37.24. There was no statistical significance between the two groups ($p = 0.481$ NS) (Table 2, Figure 1).

During induction: In the treatment group, it ranged from 30 to 50 with a mean of 42.07 ± 4.93 , and a 95% CI for the mean of 41.18–42.96. While in the control group, it ranged from 39 to 58 with a mean of 48.87 ± 5.36 with 95% CI for the mean of 48.90–50.84. There was a statistical significance between the two groups ($p = 0.000^*$) (Table 2, Figure 1).

FLAAC: In the present study, FLAAC in the treatment group ranged from 0.00 to 1.00 with a mean of 0.21 ± 0.41 and a 95% CI for the mean of 0.13–0.28. As the variable was not normally distributed, the non-parametric statistical approach was adopted so median (IQR) 0.00 (0.00–0.00). The FLAAC of control group ranged from 0.00 to 1.00 with a mean of 0.23 ± 0.42 with 95% CI for the mean of 0.15–0.30. There was no statistical significance between the two groups as regard FLAAC considering scale variable ($p = 0.754$) (Table 3, Figure 2).

FPSr: In the present study, FPSr in the treatment group ranged from 0.00 to 4.00 with a mean of 1.18 ± 0.83 and a 95% CI for the mean of 1.03–1.32. As the variable was not normally distributed non-parametric statistical approach was adopted so median (IQR) 1.00 years (1.00–2.00). The FPSr of control group ranged from 0.00 to 4.00 with a mean of 1.22 ± 0.90 with 95% CI for the mean of 1.05–1.38 (1.00–2.00). There was no statistical significance between the two groups as regard FPSr considering scale variable ($p = 0.739$ NS) (Table 4, Figure 3).

PAED: In the present study, PAED in the treatment group ranged from 4.00 to 11.00 with a mean of 6.23 ± 1.38 and a 95% CI for the mean of 5.98–6.48.

Table 1. Demographic data of the patients.

Variable	Mean (range) or count (%)		P value
	Treatment	Control	
Age (years)	5.58 ± 1.53 [3–8]	5.65 ± 1.56 [3–8]	$p = 0.739$ NS
Sex			
Male	58 (48.3)	57 (47.5)	$p = 0.897$ NS
Female	62 (51.7%)	7 (52.5)	
Duration of surgery (minutes)	160.33 ± 14.14 (130–200)	159.83 ± 14.08 (130–195)	$p = 0.784$ NS
Previous Hospitalization			
Yes	19 (15.8)	27 (22.5)	$p = 0.190$ NS
No	101 (84.2)	93 (77.5)	
ASA			
I	101 (84.2)	96 (80)	$p = 0.400$ NS
II	19 (15.8)	24 [20]	
Type of surgery			
Pelvic osteotomy	31 (25.8%)	35 (29.2%)	$p = 0.56192$ NS
Psoas tenotomies	30 (25%)	27 (22.5%)	$p = 0.64552$ NS
Femoral derotation osteotomy	37 (30.8%)	37 (30.8%)	NA
Achilles lengthening	22 (18.3%)	21 (17.5)	$p = 0.86502$ NS

NS: Statistically not significant ($p \geq 0.05$)

Table 2. Modified Yale Anxiety Scale.

	Group		Test of significance of p value
	Treatment	Control	
Modified Yale Anxiety Scale (baseline (at hospital admission))			
-n	120		t _(df=238) = 0.198
-Min-Max	23–30	120	p = 0.843 NS
-Mean ± S.D.	26.83 ± 1.88	23–30	
-95% CI for mean	26.49–27.17	26.78 ± 2.04	
		26.41–27.15	
Modified Yale Anxiety Scale (before induction)			
-n	120	120	t _(df=238) = 0.706
-Min-Max	30–42	31–43	p = 0.481 NS
-Mean ± S.D.	36.30 ± 3.27	36.61 ± 3.50	
-95% CI for mean	35.71–36.89	35.98–37.24	
Modified Yale Anxiety Scale Percentage change (%) (before induction vs baseline)			
-n	120	120	t _(df=238) = 0.781
-Min-Max	0.00–75.00	3.33–86.96	p = 0.436 NS
-Mean ± S.D.	35.85 ± 14.66	37.41 ± 16.27	
-95% CI for mean	33.20–38.50	34.47–40.35	
Modified Yale Anxiety Scale (during induction)			
-n	120	120	t _(df=238) = 11.731
-Min-Max	30–50	39–58	p = 0.000*
-Mean ± S.D.	42.07 ± 4.93	49.87 ± 5.36	
-95% CI for mean	41.18–42.96	48.90–50.84	
Modified Yale Anxiety Scale Percentage change (%) (during induction vs baseline)			
-n	120	120	t _(df=238) = 10.208
-Min-Max	17.24–95.83	33.33–147.83	p = 0.000*
-Mean ± S.D.	57.40 ± 20.67	87.23 ± 24.44	
-95% CI for mean	53.66–61.13	82.81–91.65	
Modified Yale Anxiety Scale Percentage change (%) (during induction vs before induction)			
-n	120	120	t _(df=238) = 8.591
-Min-Max	-17.07 – 66.67	-4.65 – 87.10	p = 0.000*
-Mean ± S.D.	16.88 ± 17.94	37.32 ± 18.90	
-95% CI for mean	13.64–20.13	33.90–40.74	

n: Number of patients

Min-Max: Minimum–Maximum

CI: Confidence interval

S.D.: Standard deviation

t = independent samples (Student's) t test

df: degree of freedom

NS: Statistically not significant (p ≥ 0.05)

As the variable was not normally distributed non-parametric statistical approach was adopted so median (IQR) 6.00 years (5.00–7.00). The PAED of control group ranged from 3.00 to 11.00 with a mean of 6.29 ± 1.55 with 95% CI for the mean of 6.01–6.57 (5.00–7.00). There was no statistical significance between the two groups as regard PAED considering scale variable (p = 0.626 NS) (Table 5, Figure 4).

VFAS: VFAS (Baseline (at hospital admission)):

In the treatment group, it ranged from 0.00 to 3.00 with a mean of 1.45 ± 1.01 and a 95% CI for the mean of 1.27–1.63. While in the control group, it ranged from 0.00 to 3.00 with a mean of 1.49 ± 0.96 with 95% CI for the

mean of 1.32–1.67. There was no statistical significance between the two groups (p = 0.703 NS) (Table 6, Figure 5).

VFAS (After induction):

In the treatment group, it ranged from 0.00 to 2.00 with a mean of 0.85 ± 0.75 and a 95% CI for the mean of 0.71–0.99. While in the control group, it ranged from 0.00 to 3.00 with a mean of 1.62 ± 0.96 with 95% CI for the mean of 1.44–1.79. The VFAS after induction was statistically significantly higher in the treatment group when compared with controls (p = 0.000 NS) (Table 6, Figure 5).

VFAS (change):

In the treatment group, it ranged from -2.00 to 1.00 with a mean of -0.60 ± 0.75 and a 95% CI for the mean of -0.74 to -0.46. While in the control group, it ranged from -1.00 to 1.00 with a mean of 0.13 ± 0.42 with 95% CI for the mean of 0.05–0.20. The VFAS decrease was statistically significantly higher in the treatment group when compared with controls (p = 0.000 NS) (Table 6, Figure 5).

Side effects

Regarding side effects in the treatment group: 5.00% had side effect, compared to 2.50% in the control group. There was no statistical significance between the groups (p = 0.30772). In the treatment group, 3/6 (2.50%) had vomiting, while for the control group 2/3 (1.67%) had vomiting (p = 0.65272 NS). For both treatment group and control group, there was only one patient (0.83%) who had stridor. Desaturation was found only in treatment group in two patients (1.67%). There was no statistical significance between the two groups (p = 0.1556), (Table 7).

7.1. Need for postoperative rescue analgesia

For the treatment group (n = 120): 19/120 (15.83%) needed postoperative rescue analgesia, while in the control group (n = 120): 21/120 (17.50%) needed postoperative rescue analgesia (Table 7).

8. Discussion

Anxiety is a subjective experience with valuable cultural and social influence. It is well proven that a lot of children express anxiety, fear and suffer from distress with anesthesia induction [23]. Young children express a distress behavior in response to medical interference ranging from verbalization of fear to vocal protests and escape attempts [24]. Some children may manifest distress by crying, whereas others may verbally or physically resist anesthesia doctors attempts to apply the anesthesia mask [24].

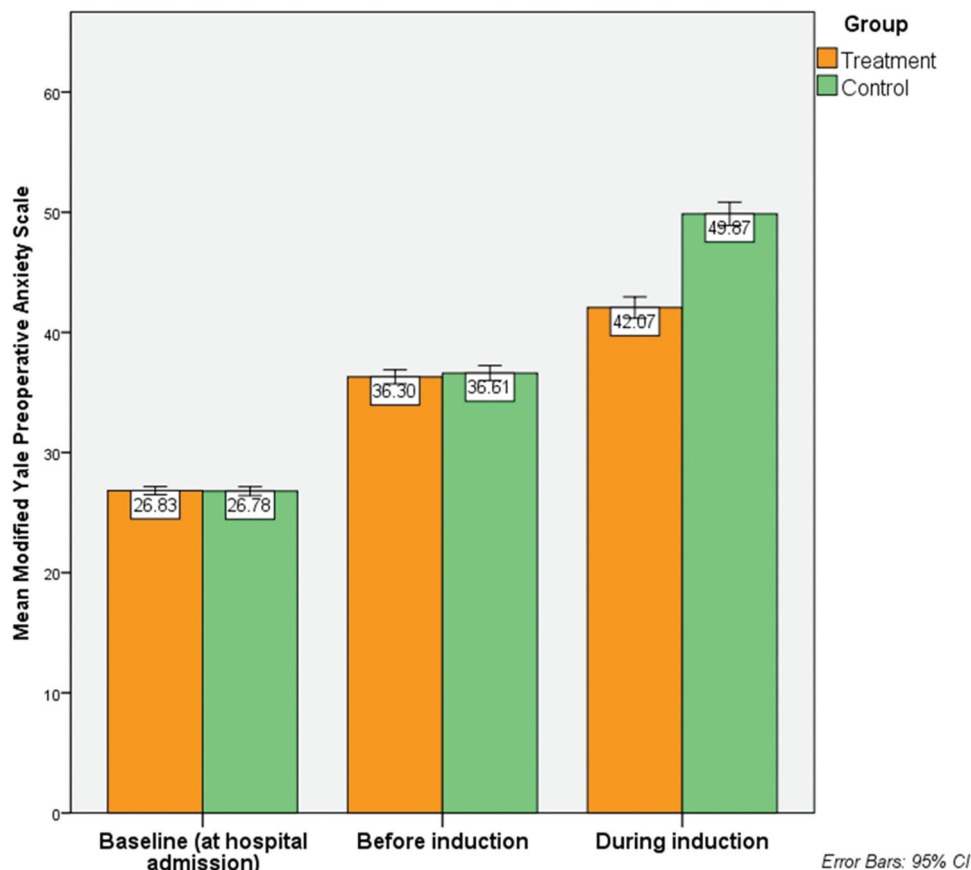


Figure 1. Bar chart of the mean (with 95% CI error bar) of the modified Yale anxiety scale in the studied groups.

Table 3. The Face, Legs, Activity, Cry and Consolability (FLACC) scale.

FLACC	Group	
	Treatment	Control
FLACC	120	120
• n	0.00–1.00	0.00–1.00
• Min-Max	0.21 ± 0.41	0.23 ± 0.42
• Mean ± S.D.	0.13–0.28	0.15–0.30
• 95% CI for mean	0.00 (0.00–0.00)	0.00 (0.00–0.00)
• Median (IQR)	D = 0.487,	D = 0.479,
• KS test of normality	p = 0.000*	p = 0.000*
Test of significance	$Z_{(MW)} = 0.313$	
p value	p = 0.754 NS	

n: Number of patients

Min-Max: Minimum–Maximum

CI: Confidence interval

S.D.: Standard deviation

MW: Mann–Whitney test

KS: Kolmogorov–Smirnov

*: Statistically significant ($p < 0.05$)

NS: Statistically not significant ($p \geq 0.05$)

While some authors reported that parents' presence during anesthesia induction resulted in child calmness, others suggested that a parent existence doesn't influence the mood of child during anesthesia induction [25–27]. The idea of parental participation in anesthesia induction has not been previously evaluated before, so this study was performed to evaluate the importance of active participation of parent during anesthesia induction with mask compared with parental presence only in young children exposed to anesthesia and surgery.

No significant differences were found between both groups in operation characteristics, child demographics, pain, emergence delirium, rescue analgesia or postoperative side effects. However, children's anxiety in the treatment group as demonstrated by mYPAS Scale was significantly lower during anesthesia induction when compared to the other group. Moreover, level of parental anxiety as evaluated by VFAS was significantly lower in the treatment group compared with the other group.

These results revealed that active participation of parent seems to be more practical and concrete support than the comfort effect of only parent attendance. It perhaps allow adequate interaction between mother and children to support child during anesthesia induction. From the other side, it's well known that anxiety of children correlates with that of their parents. Previous trials found how anxiety of parents could affect their children to feel more fear and less cooperation [28,29]. Parents also suffer from anxiety during their children's preoperative period. Clinical trials confirmed a positive correlation between parents' and children's anxiety levels pre- and postoperatively [30,31].

The results of the present study also revealed that presence of parents and their active participation had successfully reduced their anxiety levels and subsequently resulted in a simultaneous reduction in their children's anxiety levels. Hosseinpour and Uemarzadeh [32] discovered that children may forget easily the

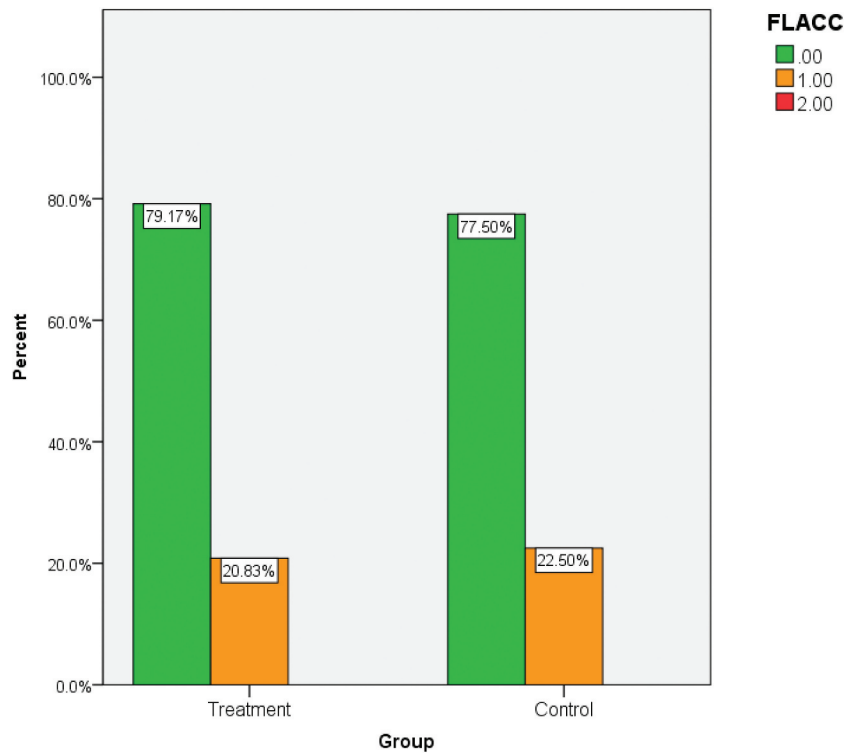


Figure 2. Clustered bar chart of the percentage of FLACC distribution in the studied groups.

Table 4. Six-faces revised Faces Pain Scale (FPSr).

FPSr	Group	
	Treatment	Control
FPSr	120	120
• n	0.00–4.00	0.00–4.00
• Min-Max	1.18 ± 0.83	1.22 ± 0.90
• Mean ± S.D.	1.03–1.32	1.05–1.38
• 95% CI for mean	1.00 (1.00–2.00)	1.00 (1.00–2.00)
• Median (IQR)	D = 0.309,	D = 0.309,
• KS test of normality	p = 0.000*	p = 0.000*
Test of significance p value	$Z_{(MW)} = 0.324$ $p = 0.739$ NS	

n: Number of patients

Min-Max: Minimum–Maximum

CI: Confidence interval

S.D.: Standard deviation

MW: Mann–Whitney test

KS: Kolmogorov–Smirnov

*: Statistically significant ($p < 0.05$)

NS: Statistically not significant ($p \geq 0.05$)

upcoming operative interference and subsequently experience less fear and anxiety while playing with something. Smiling and playing with toys could diminish muscular tension and improve immunity [33].

Considering psychological preparation through distraction methodology such as use of animated cartoon, clown doctors, therapeutic play, parental presence, music, puppets and acupuncture as anxiety reduction methodologies are noninvasive, non-pharmacological, safe and pleasant for children [34]. Parent active participation could be considered as distraction technology not been previously examined.

In this trial, the possibility that children react to the face mask that was applied by their mothers could be the real cause to experience less fear and anxiety. The mask that was applied by parent in this way was implemented as a distraction technique to the child, and as it was associated with mother support and participation, it resulted in a significant reduction of anxiety and fear when compared to the other group.

Moreover, during the induction of anesthesia, the degree of cooperation between mother and child is an essential factor that affects the success of anesthesia induction. This degree of cooperation is achieved from parental involvement during the children's preparation. We believe that this active participation not only resulted in low fear and anxiety of the child but also reduced parent anxiety that is linked to child anxiety.

Some randomized controlled studies have evaluated parent participation as a method to reduce parent anxiety. They examined parental involvement during the children's preparation intervention [35] and family-centered surgery preparation as methods to reduce parental anxiety [36] and reported positive influence. In 2007, RCT from Hong Kong evaluated the importance of parental involvement in the form of touring the facility and watching a demonstration of anesthesia induction using doll.

The results revealed lower preoperative anxiety scores among parents in the experimental group compared with control group who received only routine

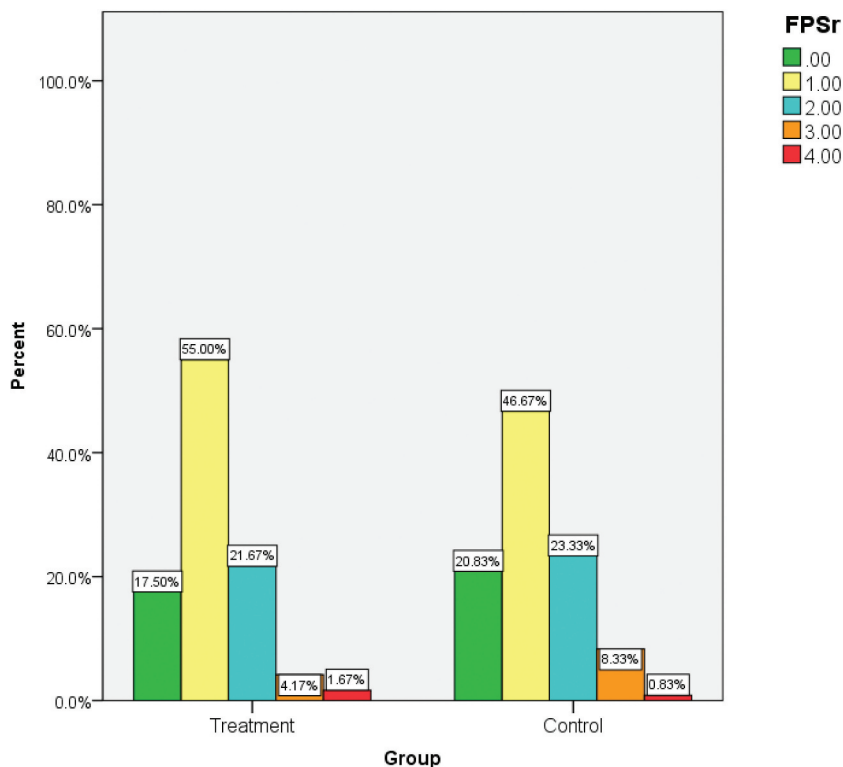


Figure 3. Clustered bar chart of the percentage of FPSr distribution in the studied groups.

Table 5. Pediatric Anesthesia Emergence Delirium (PAED) scale.

PAED	Group	
	Treatment	Control
PAED	120	120
• n	4.00–11.00	3.00–11.00
• Min-Max	6.23 ± 1.38	6.29 ± 1.55
• Mean ± S.D.	5.98–6.48	6.01–6.57
• 95% CI for mean	6.00 (5.00–7.00)	6.00 (5.00–7.00)
• Median (IQR)	D = 0.226,	D = 0.166,
• KS test of normality	p= 0.000*	p= 0.000*
Test of significance	$Z_{(MW)} = 0.487$	
p value	p= 0.626 NS	

n: Number of patients
 Min-Max: Minimum–Maximum
 CI: Confidence interval
 S.D.: Standard deviation
 MW: Mann–Whitney test
 KS: Kolmogorov–Smirnov
 *: Statistically significant (p < 0.05)

information about preoperative preparation [28]. It’s also well confirmed that nearly all parents and their children prefer to stay with each other during all procedures such as dental procedures, immunization, aspiration of bone marrow and anesthesia induction [37–40].

Several survey studies have confirmed that almost all parents prefer to be existed during anesthesia induction regardless previous operative experience or child age [41,42]. Ryder et al. [43] found that parents presented during induction of anesthesia believed that they were helpful to both their children and anesthesiologists. Kain et al. [44] also found that most of the parents thought that their presence made the job of the anesthesiologists easier, and at the same time, they

rated themselves as being very helpful to their children and anesthesiologists. They would like to attend again if their children need further surgery in the future.

We believe that giving the chance to the attendant mother to participate in anesthesia induction in this trial effectively maintained the intimate link between mother and her child, and at the same time, it preserved the interaction between them. This was effectively helpful to allay the child and mother’s anxiety and reduced the perceived stress and threats [2]. Blount et al. [45] proved that among children exposed to immunization, parents who were previously trained to be successful in distracting their children through reading, conversation and reassuring through eye contact or touch were very successful to decrease the distress of their children. In the same way, the results of previous comprehensive preparation programmed study revealed that children of prepared parents were less anxious, required less analgesics, had low emergence delirium and were discharged earlier than those whose parents were only presented during anesthesia induction but had not been prepared [46].

The preparation was in the form of video modeling, coaching of parents and instruction in coping skills. In the present study, we used this simple, brief, cheap and effective way for parent preparation intervention instead of using this form preparation that requires multi resources that may be expensive or not be available in most medical centers. Bailey et al. [47] found that brief electronically delivered parents’ preparation didn’t successfully reduce children’s anxiety during anesthesia

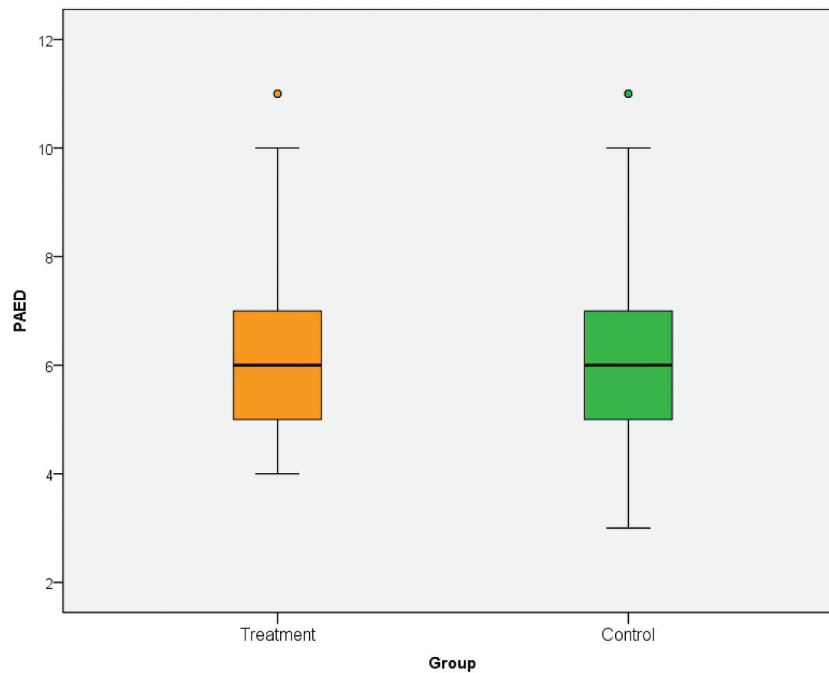


Figure 4. Box and whisker graph of PAED in the studied groups.

Table 6. The six- facial visual facial anxiety scale (VFAS).

	Treatment	Control	Test of significance
VFAS (Baseline (at hospital admission))	0.00–3.00 1.45 ± 1.01 1.27–1.63	0.00–3.00 1.49 ± 0.96 1.32–1.67	$Z_{(MW)} = 0.381$ $p = 0.703$ NS
• Min-Max	1.00 (1.00–2.00)	2.00 (1.00–2.00)	
• Mean ± S.D.			
• 95% CI for mean	D = 0.205,	D = 0.210,	
• Median (IQR)	$p = 0.000^*$	$p = 0.000^*$	
• KS test of normality			
VFAS (After Induction)	0.00–2.00 0.85 ± 0.75 0.71–0.99	0.00–3.00 1.62 ± 0.96 1.44–1.79	$Z_{(MW)} = 6.058$ $p = 0.000^*$
• Min-Max	1.00 (0.00–1.00)	2.00 (1.00–2.00)	
• Mean ± S.D.			
• 95% CI for mean	D = 0.237,	D = 0.214,	
• Median (IQR)	$p = 0.000^*$	$p = 0.000^*$	
• KS test of normality			
VFAS Change	–2.00–1.00 –0.60 ± 0.75 –0.74 –	–1.00–1.00 0.13 ± 0.42 0.05–0.20	$Z_{(MW)} = -8.208$ $p = 0.000^*$
• Min-Max	–0.46	0.00 (0.00–0.00)	
• Mean ± S.D.			
• 95% CI for mean	(–1.00–0.00)	D = 0.458,	
• Median (IQR)	$p = 0.000^*$	$p = 0.000^*$	
• KS test of normality			

n: Number of patients

Min-Max: Minimum–Maximum

CI: Confidence interval

S.D.: Standard deviation

MW: Mann–Whitney test

KS: Kolmogorov–Smirnov

*: Statistically significant ($p < 0.05$)

NS: Statistically not significant ($p \geq 0.05$)

induction. It didn't also lead to less postoperative pain, less emergence delirium or early discharge from recovery room. Depending on only delivered information to parents in their trial without including facilitated skills for both child and parent was the main cause to low

efficacy of parent presence in operating room. Against the result of the present study, a Cochrane review of non-pharmacologic ways to decrease the anxiety of children in the preoperative period found no differences between parents' presence or absence on children's cooperation and anxiety at anesthesia induction [48].

However, in this review, the included studies didn't evaluate prepared parents to be present in the operating room. Eijler et al. [49] also found that distraction therapy for children in day case surgery through provision of virtual reality exposure had no valuable effect on pain and anxiety. In our trial, relatively small proportion of our patients in both groups experienced substantial levels of pain and needed less rescue analgesia. These results are because of adequate pain management. These results are in line with low incidence of emergence delirium in both groups. As it is well known that it is difficult to differentiate between pain from emergence delirium, we included valid scale that may also reflect pain [50]. FLACC scale includes consolability items [15]. It is concluded that low incidence of emergence delirium in both groups could be related to the efficacy of the observer. The well-trained observer in our trial was adequately able to differentiate between agitation due to delirium from other causes such as pain or anxiety [51].

This study had some limitations; we didn't evaluate the influence of sex differences on anxiety levels. We tried to use randomization and control to decrease these influences on anxiety scores. Other limitations were the compliance and knowledge of the parents sharing in the tasks that were not previously evaluated before the operation. It has been confirmed that different social and cultural levels influence preoperative

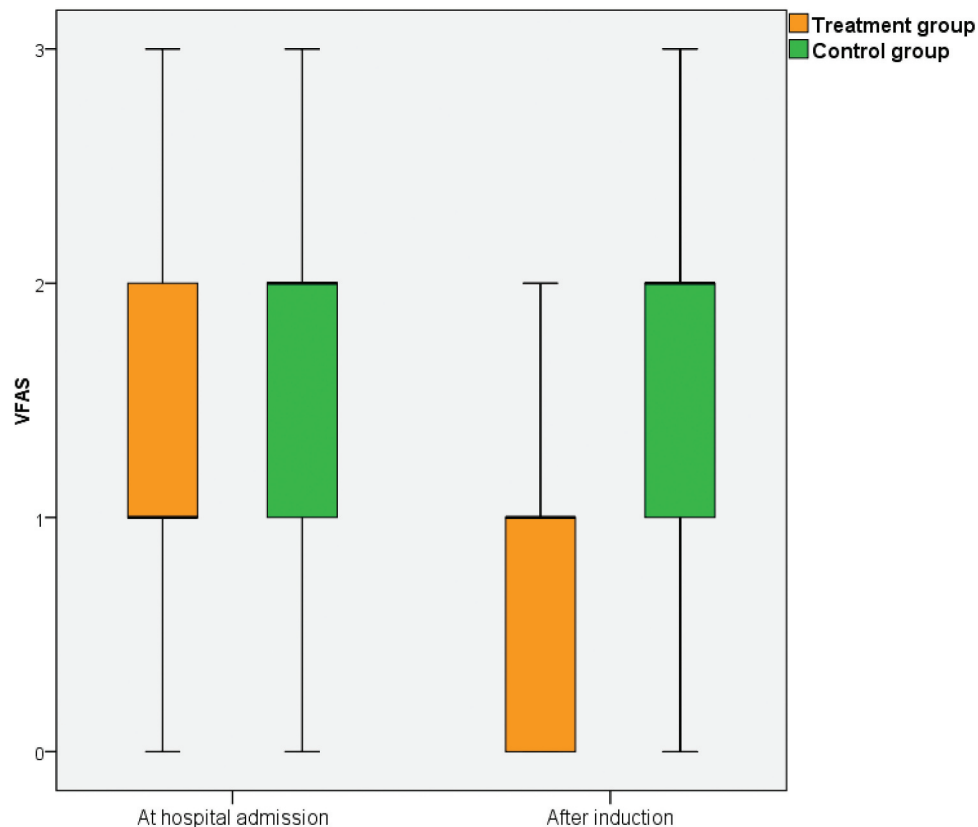


Figure 5. Box and whisker graph of VFAS at hospital admission and after induction in the studied groups.

Table 7. Need for postoperative rescue analgesia and side effects.

Variable	Mean (range) or count (%)	
	Treatment	Control
Need for postoperative rescue analgesia	19 (15.8)	21 (17.5)
Side effects		
Any side effect	6 [5]	3 (2.5)
Vomiting	3 (2.5)	2 (1.7)
Stridor	1 (0.8)	1 (0.8)
Desaturation	2 (1.7)	0 (0)

anxiety of children [52]. However, our institution is university hospital that deals with nearly same culture and social class. Also, all parents shared in our trial were mothers, so we are unable to make generalization of the results if the parents shared were fathers.

Future trials are needed to evaluate the role of fathers in preoperative anxiety outcomes. We didn't include other reference groups without any intervention for reducing preoperative anxiety. Another limitation where all observations were made by a single observer at single interval, multiple assessments at different time intervals for the same score would have given a more valuable insight about the effect of active parents' participation.

9. Conclusion

The results of this study showed that parents' active participation in anesthesia induction was effective in decreasing anxiety levels of children and their mothers. This intervention also may support parents take an active role in helping their young children cope with their anxiety and improve the preoperative care of children who experience surgery. This intervention method is worthy, simple and convenient and can be applied easily in the operation room. It also allows children to remain in a relaxed atmosphere, and some intervention methods could be also valuable; however, they may be time consuming, expensive or not appropriate for the facility conditions of the institute.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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