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Parental presence, clowns or sedative premedication to treat preoperative anxiety in children: what could be the most promising option?

Running title: Treat preoperative anxiety in children

Laura Vagnoli°, MSc, Simona Caprilli°, PhD; Andrea Messeri*, MD

° Psychologist, *Anesthesist

Laura Vagnoli lauravagnoli@virgilio.it (Corresponding author)

Simona Caprilli s.caprilli@meyer.it

Andrea Messeri a.messeri@meyer.it

Pain Service, A. Meyer Children’s Hospital – Florence, Italy.

Viale Pieraccini, 24 - 50139 – Firenze

Tel. 0039 555 662 456

Fax 0039 555 662 400
ABSTRACT

Background and Objectives: A significant number of children undergo surgery experience high levels of anxiety in the presurgical period. The aim of this study is to investigate which intervention is more effective in reducing preoperative anxiety.

Methods/Materials: The sample was composed of 75 subjects (ages 5-12 years) who had to undergo minor day-surgery. Children were randomly assigned to: the Clowns group (N = 25), accompanied to the preoperative room by the clowns and by a parent; Premedication group (N=25) premedicated with oral Midazolam and accompanied to the preoperative room by one parent; or the Control group (N = 25) only accompanied by one parent. Anxiety in the preoperative period was measured by using the Modified Yale Preoperative Anxiety Scale (m-YPAS). Parental anxiety was measured by using the State-Trait Anxiety Inventory (STAI Y-1/Y-2).

Results: The Clown group was significantly less anxious during the induction of anesthesia compared with Premedication group and Control group. There were not any significant differences between Control group and Premedication group.

There was an increased level of anxiety in the induction room in comparison to the waiting room: this difference was statistically significant for Control group and Premedication group, whereas it was not significant in Clown group.

Conclusions: PPIA+clown intervention is more effective in reducing anxiety in children during the preoperative period than PPIA alone or PPIA+oral Midazolam.

KEY WORDS
Preoperative anxiety, induction anesthesia, children, clowns, Premedication, PPIA.

ABBREVIATIONS: OR, operating room; m-YPAS, Modified Yale Preoperative Anxiety Scale; STAI, State-Trait Anxiety Inventory; PPIA, parental presence during induction of anesthesia, CG, Clown Group; PG, Premedication group; CG, Control group.
A) INTRODUCTION

Several studies have indicated that numerous children exhibit significant manifestations of anxiety in the presurgical period. The induction of anesthesia appears to be the most stressful procedure for a child during the preoperative period. Preoperative anxiety and fear have been associated with long-term negative postsurgery behaviours.\(^1\)\(^2\).

At present, there are several types of pharmacological and non-pharmacological intervention to reduce the incidence of this phenomenon in children.\(^3\) In order to treat preoperative anxiety some anaesthesiologists routinely opt for sedative premedication and parental presence during induction of anesthesia (PPIA), simultaneously or interchangeably.\(^4\) Recent studies found that presence of clown together with PPIA was an effective intervention for managing child anxiety during preoperative period.\(^5\)\(^6\) However the findings of the research presented in relevant literature were controversial and there was not an agreed view about the best technique to reduce anxiety in pediatric surgery. Therefore, the purpose of this randomized study was to investigate which intervention was more effective for reducing preoperative anxiety in children undergoing minor surgery: a pharmacological intervention with sedative premedication (Midazolam), or a non-pharmacological technique such as the presence of Clowns + PPIA, or only PPIA.

B) MATERIALS AND METHODS

B1) Patients

The population of this randomized prospective study consisted of children who were classified as physical status I-II according to the American Society of Anaesthesiologist standards, and who were scheduled to undergo general anesthesia for minor surgery at Anna Meyer Children’s Hospital in Florence (Italy), and of their parents. We considered only Italian children as being eligible so as to avoid any misinterpretation of the evaluation instruments used.

The sample examined was composed of 75 randomly assigned consecutive children aged 5 to 12, residents in Florence or in the close surroundings of the city. Children with a history of chronic
illness, premature birth, developmental delay or previous anaesthetic experience were excluded from this study. The subjects had to be chosen from a population of children who were supposed to undergo minor day surgery and were assigned to one of three groups by using computer-generated list random assignment.

The study protocol was approved by the hospital ethics committee and informed consent was obtained from the parents before inclusion of their children in the study.

Primary end point was the anxiety of the child in the preoperative period. The goal of the study was to determine whether the presence of clowns was more effective in reducing preoperative anxiety in the child than sedative premedication (with Midazolam), or only PPIA. As a secondary end point we aimed to identify the difference in the levels of parents’ anxiety in the three groups.

**B2) Study Groups**

Eligible patients were randomly assigned following simple randomization procedures (computerized random numbers) to one of the three study groups:

1. **Clown group (CG):** children were accompanied in the preoperative room by two clowns and a parent. They interacted with clowns before entering the OR (operating room) and stayed with them and their parent throughout the anesthesia-induction process.

2. **Premedication group (PG):** children were premedicated with 0.5 mg/kg oral Midazolam at least 45 minutes before the surgical procedure began, and a parent was present throughout the anesthesia-induction process.

3. **Control group (CG):** children were accompanied in the OR by one parent, without any clowns, other distractions or premedications, during induction of anesthesia. PPIA is considered control group because is routinely used in our hospital.

In each group, the children were observed during the preoperative process in two different rooms: the waiting room and the induction room. They personally chose the parent who stayed with them. Anesthesia was induced in all patients by pediatric anaesthesiologists by means of a scented mask using a standardized oxygen (O₂)/nitrous oxide(N₂O)/sevoflurane technique.
In the CG, two clowns stayed with the child during the whole process: they arrived approx. 30 minutes before the child was taken to the OR, and stayed with him/her for approx. 15 minutes. The clowns, taking into account the children’s age and experience, used various methods to entertain them (eg, magic tricks, gags, music, games, puppets, word games, soap bubbles, etc). The clowns are professional performing artists with specialties ranging from music to magic who have been carefully selected and trained to apply their skills to a hospital’s special needs. When the nurse took the child to the OR, the clowns accompanied the child and the parent and stayed with them during the anesthesia-induction process.

In the PG oral Midazolam was administered by a nurse approx. 45 minutes before the surgical procedure. Then, the same nurse accompanied the child with a parent in the OR.

The managing anaesthesiologist, the parents and the other observers were kept blinded to the purpose of the study and the groups involved, but it was impossible to be blind entirely to assignment for the children in the CG. In addition, parents of the PG were informed that their children had been given a drug.

B3) Evaluation Instruments

**Modified Yale Preoperative Anxiety Scale**

The Modified Yale Preoperative Anxiety Scale (m-YPAS) was used to evaluate the behaviour of the child in the waiting room and in the induction room. The m-YPAS is an observational behavioural checklist developed by Kain et al.\(^7\) to measure the state anxiety of young children. It contains 27 items divided into 5 categories: activity, emotional expressivity, state of arousal, vocalization, use of parents. Each category receives a score on a scale of 4 (6 for vocalization) according to the behaviour of the patient. The m-YPAS score ranges from 23 to 100, with higher scores indicating greater anxiety. This scale has good-to-excellent interrater and intraobserver reliability and validity for measuring children’s anxiety in the preoperative holding area and during induction of anesthesia\(^7\). For our study the coding method was translated from English into Italian\(^5\).

**State-Trait Anxiety Inventory**
The State-Trait Anxiety Inventory (STAI) self-report anxiety behavioural instrument consists of two separate 20-item subscales that measure trait (baseline) and state (situational) anxiety in adults. The STAI trait subscale measures relatively stable individual differences in anxiety proneness (i.e., differences in the tendency to experience anxiety), and the STAI state subscale measures transitory anxiety state (i.e., subjective feelings of apprehension, tension and worry that vary in intensity and fluctuate depending on the situation).

Parents responded on a 4-point scale. Total scores for state and trait sections separately range from 20 to 80, with higher scores denoting higher levels of anxiety. Test-retest correlations for the STAI are high (range: 0.73-0.86), and the studies have demonstrated good validity. In this study we used form Y (Y-1/Y-2) developed by Spielberger, as well as with the table to calculate the score according to the Italian standard version.

**B4) Data Analysis**

All the instruments were administered by two psychologists who had significant background in behavioural research. The two independent observers evaluated the child’s anxiety (m-YPAS) in the waiting room and in the induction room. Parental anxiety was assessed on the same day as surgery with STAI (Y-1/Y-2) immediately after separation between parent and child, and during the operation. We measured trait and state anxiety in that moment in order to avoid organizational problems in keeping contacts with the families, trait anxiety being supposed to be a stable measure anyway.

Descriptive statistics provide an overview of the relationships between child and parent variables, as well as anxiety levels in child and parent. Data are presented as mean±SD.

The agreement between the two observers codifying the data of m-YPAS was verified through Cohen’s $k$ calculation. Differences between groups were examined using one-way analysis of variance and all pairwise multiple comparisons were performed using the Scheffé test: we compared the scores of anxiety level obtained by the three groups with m-YPAS in the surgery process and the scores of the level of state (STAI Y-1) and trait anxiety (STAI Y-2) of parents. The
anxiety level of children within the same group, in the waiting room and in the induction room were compared by using a repeated-measures analysis of variance (within-subjects factors) for each group, and also using the Scheffé post hoc test. The Pearson’s correlation coefficient (r) was used to evaluate the demographic characteristics and the relations between the child’s anxiety level, the child’s age and the parents’ anxiety. The correlation was also calculated within the groups, correlating the scores of waiting room and induction room.

The sample size was based on some investigations involving clown, sedative premedication (with Midazolam), PPIA and children. These studies show significant reduction in the level of anxiety of the children. A sample size of 75 subjects was calculated to be sufficient to detect a difference in anxiety level considering the number of patients hospitalized routinely in day surgery in our hospital.

Data were analysed by using SPSS version 11.5 for Windows (SPSS Inc, Chicago, IL, USA). P was accepted as significant at < .05.

C) RESULTS

The 75 participants were recruited from April to December 2009. The demographic and clinical characteristics of the three groups of children and parents are presented in Table 1 and 2 and they are similar across groups, with no significant differences in age or in gender distribution. However, the ratio of mother to father is different: there are more mothers than fathers who accompany their child during preoperative process.

The two observers who codified the data are agree: the results of Cohen’s k for every category m-YPAS and for both the preoperative rooms are broadly significant with values between .73 and .91. In each group, the anxiety of children increased during the induction of anesthesia \( F_{(2,72)} = 12.994\); \( p = .001 \). Using post-hoc Scheffé test, we found that the level of anxiety was significantly lower in the CG compared to PG \( (p = .038) \) and to CG, whose level of anxiety was significantly higher \( (p = .000) \). There were not any significant differences between CG and PG. Furthermore there were no
significant differences in the observed anxiety level (m-YPAS) among the three groups in the waiting room \[F(2,72) = 2.515; p = .005\] (Tab. 3).

Using a repeated-measures ANOVA, we analysed changes in the level of anxiety in the two locations. We found that in each group there was an increased level of anxiety in the induction room in comparison to the waiting room: this difference was statistically significant for CG \[F(1,24) = 30.300; p = .001\] and PG \[F(1,24) = 6.425; p = .005\], whereas it was not significant in the CG (Tab. 3). The post-hoc Scheffé about the results of repeated-measures ANOVA in the two rooms demonstrated that the increased level of anxiety in children of CG is significantly higher compared to CG \(p = .000\), while there was no difference with PG \(p = .279\). In contrast, the anxiety of children in the CG was significantly lower compared with both the other groups: CG \(p = .000\); PG \(p = .015\) (Fig. 1). The Pearson’s correlations were statistically significant between: state anxiety of parent and age of child \(r = -.24; p < .05\); anxiety of child in waiting room and age of child \(r = .27; p < .05\); level of anxiety in waiting room and level of anxiety in induction room \(r = .35; p < .01\).

The anxiety of parents attending the induction of anesthesia. Using one-way analysis of variance, we found no significant differences among the parents of three study groups: only state anxiety was lower in PG (Tab. 3). The correlations between the anxiety level of the child and that of the parents, and between the anxiety of the parents and demographic characteristics were not significant. As for level of anxiety of parents we found a significant correlation between state anxiety (STAI Y-1) and trait anxiety (STAI Y-2) \(r = .23; p < .05\).

**D) DISCUSSION**

Relieving preoperative anxiety in the child is necessary to reduce maladaptive postsurgery behaviours, as well as negative children’s responses to successive medical care. The increase of anxiety in the presurgical period is associated with increased postoperative pain, analgesic consumption, general anxiety, **incidence of emergence delirium, sleeping problems and poor postoperative eating improvement** **behavioural problems**. We found that the CG was
significantly less anxious during the induction of anesthesia compared with CG and PG, and there were no significant differences between the level of anxiety in the two rooms the waiting room and the level of anxiety in the induction room in children who were accompanied by clowns.

Recent study\textsuperscript{6} found that the use of preoperative medically trained clowns for children undergoing surgery can significantly alleviate preoperative anxiety compared to the CG and PG, but however, clowns do not have any effect once the anesthesia mask is introduced. Therefore our research demonstrates that the clowns could be the most promising option to treat preoperative anxiety in children.

\textit{Several researchers have shown the efficacy of a series of approaches to prevent and manage anxiety and fear in the presurgical period, both with pharmacological\textsuperscript{2} interventions (e.g. sedative premedication\textsuperscript{2}) and with non-pharmacological interventions\textsuperscript{3} (e.g. preoperative visits in the O.R., PPIA, psychological preparation of the child and parents, with audio/video devices, leaflets, painting books\textsuperscript{12}, acupuncture, toys\textsuperscript{13,14}, flavoured anesthesia mask, fun transportation system - i.e. wagons\textsuperscript{15}, music\textsuperscript{16}, clown\textsuperscript{5,6}).}

\textit{Several researchers have shown the efficacy of a series of approaches to manage anxiety in the presurgical period, both with pharmacological\textsuperscript{2} and with non-pharmacological interventions\textsuperscript{3,5,6,12,13,14,15,16}.}

Among drugs used in the preoperative period, Midazolam is the most commonly administered: \textit{this drug is effective in reducing anxiety prior and during the induction of anesthesia}. It has proved more effective than only parental presence\textsuperscript{17} in reducing anxiety and it is a drug which onsets rapidly and with short half-life, although it is not without disadvantages (\textit{e.g. delay in emergence, recovery and discharge, amnesia, increase in postrecovery anxiety})\textsuperscript{16,18}. Many patients frequently show extreme distress and lack of compliance during induction of anesthesia despite premedication\textsuperscript{18}: \textit{the administration of oral premedication to children is often met with apprehension, reluctance, or refusal}\textsuperscript{18}. The clown can facilitate the induction process, leave a pleasant memory and represent an alternative to Midazolam, which often leaves the child amnesic
of the induction itself. Without the memory of this event, subsequent inductions may indeed appear novel, distressing and frightening\textsuperscript{21,19}. It is even likely to leave them with a pleasant memory\textsuperscript{19,20, 20,21}.

The presence of parents during the induction is controversial in relevant literature: numerous studies underline the benefits of this intervention\textsuperscript{3}, highlighting that it helps reducing the use of premedication and increasing child cooperation\textsuperscript{15}, whereas others studies point out the possibility that it may increase parental anxiety and child behavioural problems. As a matter of fact, PPIA is routinely used in some hospitals while actively discouraged in others.

As for non-pharmacological intervention, following the results of previous study on the efficacy of clowns during the induction of anesthesia\textsuperscript{3,5,6}, we hypothesize that the presence of clowns stimulates the children’s imagination and creativity, allowing them to participate actively in the induction experience while being in a playful state, to reduce muscle tension and to improve respiration.

It is likely that children establish an alliance with clowns and are thus given the opportunity to take control over their playful experience in an environment where their power is generally limited\textsuperscript{22}.

In recent times there has been an increase in the presence of clowns in pediatric hospitals: clowns in health care settings use games and laughter to provide ill children with another way to express their emotions and to provide control and social interaction during hospitalisation and treatment\textsuperscript{22,23,24}. This is possible if the activity is carried out by professional artists having gone through careful and rigorous training programmes, both about clowning and psychology of children in hospitals. Beside, in order to be successful, the clown programme should not interfere with the work of doctors and nurses.

In recent times there has been an increase in the presence of clowns in pediatric hospitals: the successful of this activity is possible if it is carried out by professional artists having gone through careful and rigorous training programmes\textsuperscript{22,23,24}.
In our study we found that the CG maintained the same level of anxiety during all the preoperative period without differences between the two locations. We can assume that the mask and the induction of anesthesia are less frightening for the children belonging to this group compared with the others. These results are consistent with previous studies that demonstrated the effectiveness of clowns in pediatric settings and with other research that showed the influence of the environment on anxiety, especially in the induction room. In this study, indeed, anxiety increased during the induction of anesthesia in every group.

Furthermore we found that, both in CG and in PG, the level of anxiety was significantly higher in the induction room than in the waiting room. The level of anxiety of CG was significantly higher compared with CG, but there were no differences from PG. This finding is in line with some studies of relevant literature that show that PPIA in addition to premedication has no additive effects in terms of reducing the child’s anxiety.

These results are consistent also with those of other studies which compare the use of Midazolam to alternative interventions for managing preoperative anxiety in children: as hand-held video games, indeed children who received PPIA + hand-held video games showed less anxiety when the anesthesia mask was used compared to PPIA group and Midazolam Group and music. The results of one of these studies show that music therapy may be helpful on separation and entrance to the OR (depending on the therapist), but it doesn’t appear to relieve anxiety during the induction of anesthesia: the Midazolam group was significantly less anxious during anaesthetic induction in comparison to both the music group and the control group.

We can hypothesize that the clowns have a greater effect than music during induction because they involve the child actively, with mental and motor participation, performing gags and improvisations which are not standardised but created for every individual child in line with his/her characteristics and personality.

Previous studies had shown that children over seven years had a higher level of anxiety in the waiting room than younger children and that the parents’ anxiety was a predictor of the child’s
anxiety during the preoperative period. In agreement with these findings, we can affirm that anxiety in children seems to increase with age. Moreover, since in our study a correlation between child anxiety in the waiting room and age of the child, as well as a correlation between parent anxiety during surgery and child age exist, we found that the younger children are, the more anxious parents tend to get.

In addition, we noticed that a correlation can be also found between the child’s level of anxiety in the two rooms: waiting room and in the induction room; children who were more anxious during the wait were also more anxious during the induction, unlike children who were more relaxed during the wait, who also showed less anxiety during the induction.

We didn’t find any correlations between level of anxiety and gender of the child. According to the literature, gender does not influence preoperative anxiety, nor development of postoperative behavioural problems.

In according to the literature we didn’t find any correlations between level of anxiety and gender of the child.

Finally, in our study the secondary end point was the level of anxiety of parents present during the induction of anesthesia. There were not significant differences between each group. Only the scores obtained with the STAI by the parents of PG showed lower levels of anxiety. We can assume that parents who knew that their son or daughter had taken a specific drug to reduce preoperative anxiety were more reassured than parents who simply accompanied their children in the OR, or only with the support of some kind of distraction. Probably drugs give more security and guarantee: a qualitative study with interviews could help to identify the reasons of lower anxiety.

We didn’t find any correlations between the level of anxiety of parents and the level of anxiety of children: on the contrary, many studies identify the anxiety of the parent as a predictor of the child’s anxiety.
As for parents’ anxiety, we found a significant correlation between state anxiety (STAI Y-1) and trait anxiety (STAI Y-2): these data show that characteristics of personality influenced the level of anxiety during stressful moments.

Study limitations include small sample size, lack of data on time of induction, and to know if there were any differences in adverse behavioural responses in the week post-discharge for each group.

In conclusion in our study we determined that PPIA + clown intervention is better to reduce anxiety in children during the preoperative period than PPIA alone or PPIA + oral Midazolam.

Considering the importance of non-pharmacological intervention in this context, it would be very interesting to study the application of different distraction techniques in order to assess which one is the most effective in different age group and cultures, in children with chronic illness and with behavioural problems.

Thus, in future studies it would be interesting to compare clown intervention alone with PPIA alone and with Midazolam alone, so as to determine if the presence of clowns, or parental presence, or Premedication, actually lessens the children’s anxiety. In addition we might study the difference between populations of different cultures and traditions which may provide different results.

Knowing that the psychological impact of anesthesia and surgery on children covers many areas, the presence of professional clown doctors for managing the child's anxiety during the preoperative phase, should be encouraged in pediatrics hospitals, with correct information being provided to both child and parents.

E) ACKNOWLEDGEMENTS

We thank the Anna Meyer Foundation, which supporting “Clown in Corsia” project; the clowns of Soccorso Clown ONLUS who work in A. Meyer Children’s Hospital, Florence, Italy.
F) REFERENCES


**CONSORT 2010 checklist of information to include when reporting a randomised trial**

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<td><strong>Ancillary analyses</strong></td>
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<td>Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory</td>
</tr>
<tr>
<td><strong>Harms</strong></td>
<td>19</td>
<td>All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)</td>
</tr>
<tr>
<td><strong>Discussion</strong></td>
<td>20</td>
<td>Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses</td>
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<td></td>
<td>21</td>
<td>Generalisability (external validity, applicability) of the trial findings</td>
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<td>22</td>
<td>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</td>
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<tr>
<td><strong>Other information</strong></td>
<td>23</td>
<td>Registration number and name of trial registry</td>
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<tr>
<td></td>
<td>24</td>
<td>Where the full trial protocol can be accessed, if available</td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>Sources of funding and other support (such as supply of drugs), role of funders</td>
</tr>
</tbody>
</table>

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org)
CONSORT 2010 Flow Diagram

**Enrollment**

Assessed for eligibility (n=75)

- Excluded (n=0)
  - Not meeting inclusion criteria (n=)
  - Declined to participate (n=)
  - Other reasons (n=)

Randomized (n=75)

**Allocation**

Allocated to intervention (n=25)
- Received allocated intervention (n=25)
- Did not receive allocated intervention (give reasons) (n=)

Allocated to intervention (n=25)
- Received allocated intervention (n=25)
- Did not receive allocated intervention (give reasons) (n=)

**Follow-up**

Lost to follow-up (give reasons) (n=0)
Discontinued intervention (give reasons) (n=)

**Analysis**

Analysed (n=25)
- Excluded from analysis (give reasons) (n=)

Analysed (n=25)
- Excluded from analysis (give reasons) (n=)

Analysed (n=25)
- Excluded from analysis (give reasons) (n=)
Parental presence, clowns or sedative premedication to treat preoperative anxiety in children: what could be the most promising option?

**Running title:** Treat preoperative anxiety in children

Laura Vagnoli°, MSc, Simona Caprilli°, PhD; Andrea Messeri*, MD

° Psychologist, *Anesthesist

Laura Vagnoli [lauravagnoli@virgilio.it](mailto:lauravagnoli@virgilio.it) (Corresponding author)

Simona Caprilli [s.caprilli@meyer.it](mailto:s.caprilli@meyer.it)

Andrea Messeri [a.messeri@meyer.it](mailto:a.messeri@meyer.it)

Pain Service, A. Meyer Children’s Hospital – Florence, Italy.

Viale Pieraccini, 24 - 50139 – Firenze

Tel. 0039 555 662 456

Fax 0039 555 662 400
ABSTRACT

Background and Objectives: A significant number of children undergo surgery experience high levels of anxiety in the presurgical period. The aim of this study is to investigate which intervention is more effective in reducing preoperative anxiety.

Methods/Materials: The sample was composed of 75 subjects (ages 5-12 years) who had to undergo minor day-surgery. Children were randomly assigned to: the Clowns group (N = 25), accompanied to the preoperative room by the clowns and by a parent; Premedication group (N=25) premedicated with oral Midazolam and accompanied to the preoperative room by one parent; or the Control group (N = 25) only accompanied by one parent. Anxiety in the preoperative period was measured by using the Modified Yale Preoperative Anxiety Scale (m-YPAS). Parental anxiety was measured by using the State-Trait Anxiety Inventory (STAI Y-1/Y-2).

Results: The Clown group was significantly less anxious during the induction of anesthesia compared with Premedication group and Control group. There were not any significant differences between Control group and Premedication group.

There was an increased level of anxiety in the induction room in comparison to the waiting room: this difference was statistically significant for Control group and Premedication group, whereas it was not significant in Clown group.

Conclusions: PPIA+clown intervention is more effective in reducing anxiety in children during the preoperative period than PPIA alone or PPIA+oral Midazolam.

KEY WORDS

Preoperative anxiety, induction anesthesia, children, clowns, Premedication, PPIA.

ABBREVIATIONS: OR, operating room; m-YPAS, Modified Yale Preoperative Anxiety Scale; STAI, State-Trait Anxiety Inventory; PPIA, parental presence during induction of anesthesia, CG, Clown Group; PG, Premedication group; CG, Control group.
A) **INTRODUCTION**

Several studies have indicated that numerous children exhibit significant manifestations of anxiety in the presurgical period. The induction of anesthesia appears to be the most stressful procedure for a child during the preoperative period. Preoperative anxiety and fear have been associated with long-term negative postsurgery behaviours\(^1,2\).

At present, there are several types of pharmacological and non-pharmacological intervention to reduce the incidence of this phenomenon in children\(^3\). In order to treat preoperative anxiety some anaesthesiologists routinely opt for sedative premedication and parental presence during induction of anesthesia (PPIA), simultaneously or interchangeably\(^4\). Recent studies found that presence of clown together with PPIA was an effective intervention for managing child anxiety during preoperative period\(^5,6\). However the findings of the research presented in relevant literature were controversial and there was not an agreed view about the best technique to reduce anxiety in pediatric surgery. Therefore, the purpose of this randomized study was to investigate which intervention was more effective for reducing preoperative anxiety in children undergoing minor surgery: a pharmacological intervention with sedative premedication (Midazolam), or a non-pharmacological technique such as the presence of Clowns + PPIA, or only PPIA.

B) **MATERIALS AND METHODS**

B1) **Patients**

The population of this randomized prospective study consisted of children who were classified as physical status I-II according to the *American Society of Anaesthesiologist* standards, and who were scheduled to undergo general anesthesia for minor surgery at Anna Meyer Children’s Hospital in Florence (Italy), and of their parents. We considered only Italian children as being eligible so as to avoid any misinterpretation of the evaluation instruments used.

The sample examined was composed of 75 randomly assigned consecutive children aged 5 to 12, residents in Florence or in the close surroundings of the city. Children with a history of chronic illness, premature birth, developmental delay or previous anaesthetic experience were excluded.
from this study. The subjects had to be chosen from a population of children who were supposed to undergo minor day surgery and were assigned to one of three groups by using computer-generated list random assignment.

The study protocol was approved by the hospital ethics committee and informed consent was obtained from the parents before inclusion of their children in the study.

Primary end point was the anxiety of the child in the preoperative period. The goal of the study was to determine whether the presence of clowns was more effective in reducing preoperative anxiety in the child than sedative premedication (with Midazolam), or only PPIA. As a secondary end point we aimed to identify the difference in the levels of parents’ anxiety in the three groups.

**B2) Study Groups**

Eligible patients were randomly assigned following simple randomization procedures (computerized random numbers) to one of the three study groups:

1. **Clown group (CG):** children were accompanied in the preoperative room by two clowns and a parent. They interacted with clowns before entering the OR (operating room) and stayed with them and their parent throughout the anesthesia-induction process.

2. **Premedication group (PG):** children were premedicated with 0.5 mg/kg oral Midazolam at least 45 minutes before the surgical procedure began, and a parent was present throughout the anesthesia-induction process.

3. **Control group (CG):** children were accompanied in the OR by one parent, without any clowns, other distractions or premedications, during induction of anesthesia. PPIA is considered control group because is routinely used in our hospital.

In each group, the children were observed during the preoperative process in two different rooms: the waiting room and the induction room. They personally chose the parent who stayed with them. Anesthesia was induced in all patients by pediatric anaesthesiologists by means of a scented mask using a standardized oxygen ($O_2$)/nitrous oxide($N_2O$)/sevoflurane technique.
In the CG, two clowns stayed with the child during the whole process: they arrived approx. 30 minutes before the child was taken to the OR, and stayed with him/her for approx. 15 minutes. The clowns, taking into account the children’s age and experience, used various methods to entertain them (eg, magic tricks, gags, music, games, puppets, word games, soap bubbles, etc). The clowns are professional performing artists with specialties ranging from music to magic who have been carefully selected and trained to apply their skills to a hospital’s special needs. When the nurse took the child to the OR, the clowns accompanied the child and the parent and stayed with them during the anesthesia-induction process.

In the PG oral Midazolam was administered by a nurse approx. 45 minutes before the surgical procedure. Then, the same nurse accompanied the child with a parent in the OR.

The managing anaesthesiologist, the parents and the other observers were kept blinded to the purpose of the study and the groups involved, but it was impossible to be blind entirely to assignment for the children in the CG. In addition, parents of the PG were informed that their children had been given a drug.

**B3) Evaluation Instruments**

*Modified Yale Preoperative Anxiety Scale*

The Modified Yale Preoperative Anxiety Scale (m-YPAS) was used to evaluate the behaviour of the child in the waiting room and in the induction room. The m-YPAS is an observational behavioural checklist developed by Kain et al.\(^7\) to measure the state anxiety of young children. It contains 27 items divided into 5 categories: activity, emotional expressivity, state of arousal, vocalization, use of parents. Each category receives a score on a scale of 4 (6 for vocalization) according to the behaviour of the patient. The m-YPAS score ranges from 23 to 100, with higher scores indicating greater anxiety. This scale has good-to-excellent interrater and intraobserver reliability and validity for measuring children’s anxiety in the preoperative holding area and during induction of anesthesia\(^7\). For our study the coding method was translated from English into Italian\(^5\).

*State-Trait Anxiety Inventory*
The State-Trait Anxiety Inventory (STAI) self-report anxiety behavioural instrument consists of two separate 20-item subscales that measure trait (baseline) and state (situational) anxiety in adults. The STAI trait subscale measures relatively stable individual differences in anxiety proneness (i.e., differences in the tendency to experience anxiety), and the STAI state subscale measures transitory anxiety state (i.e., subjective feelings of apprehension, tension and worry that vary in intensity and fluctuate depending on the situation).

Parents responded on a 4-point scale. Total scores for state and trait sections separately range from 20 to 80, with higher scores denoting higher levels of anxiety. Test-retest correlations for the STAI are high (range: 0.73-0.86), and the studies have demonstrated good validity. In this study we used form Y (Y-1/Y-2) developed by Spielberger, as well as with the table to calculate the score according to the Italian standard version.

B4) Data Analysis

All the instruments were administered by two psychologists who had significant background in behavioural research. The two independent observers evaluated the child’s anxiety (m-YPAS) in the waiting room and in the induction room. Parental anxiety was assessed on the same day as surgery with STAI (Y-1/Y-2) immediately after separation between parent and child, and during the operation. We measured trait and state anxiety in that moment in order to avoid organizational problems in keeping contacts with the families, trait anxiety being supposed to be a stable measure anyway.

Descriptive statistics provide an overview of the relationships between child and parent variables, as well as anxiety levels in child and parent. Data are presented as mean±SD.

The agreement between the two observers codifying the data of m-YPAS was verified through Cohen’s $k$ calculation. Differences between groups were examined using one-way analysis of variance and all pairwise multiple comparisons were performed using the Scheffé test: we compared the scores of anxiety level obtained by the three groups with m-YPAS in the surgery process and the scores of the level of state (STAI Y-1) and trait anxiety (STAI Y-2) of parents. The
anxiety level of children within the same group, in the waiting room and in the induction room were compared by using a repeated-measures analysis of variance (within-subjects factors) for each group, and also using the Scheffé post hoc test. The Pearson’s correlation coefficient (r) was used to evaluate the demographic characteristics and the relations between the child’s anxiety level, the child’s age and the parents’ anxiety. The correlation was also calculated within the groups, correlating the scores of waiting room and induction room.

The sample size was based on some investigations involving clown, sedative premedication (with Midazolam), PPIA and children. These studies show significant reduction in the level of anxiety of the children. A sample size of 75 subjects was calculated to be sufficient to detect a difference in anxiety level considering the number of patients hospitalized routinely in day surgery in our hospital.

Data were analysed by using SPSS version 11.5 for Windows (SPSS Inc, Chicago, IL, USA). P was accepted as significant at < .05.

C) RESULTS

The 75 participants were recruited from April to December 2009. The demographic and clinical characteristics of the three groups of children and parents are presented in Table 1 and 2 and they are similar across groups, with no significant differences in age or in gender distribution. However, the ratio of mother to father is different: there are more mothers than fathers who accompany their child during preoperative process.

The two observers who codified the data are agree: the results of Cohen’s k for every category m-YPAS and for both the preoperative rooms are broadly significant with values between .73 and .91. In each group, the anxiety of children increased during the induction of anesthesia \( F_{(2,72)} = 12.994; p = .001 \). Using post-hoc Scheffé test, we found that the level of anxiety was significantly lower in the CG compared to PG \( p = .038 \) and to CG, whose level of anxiety was significantly higher \( p = .000 \). There were not any significant differences between CG and PG. Furthermore there were no
significant differences in the observed anxiety level (m-YPAS) among the three groups in the waiting room \[F_{(2,72)} = 2.515; p = .005\] (Tab. 3).

Using a repeated-measures ANOVA, we analysed changes in the level of anxiety in the two locations. We found that in each group there was an increased level of anxiety in the induction room in comparison to the waiting room: this difference was statistically significant for CG \([F_{(1,24)} = 30.300; p = .001\] and PG \([F_{(1,24)} = 6.425; p = .005]\), whereas it was not significant in the CG (Tab. 3). The post-hoc Scheffé about the results of repeated-measures ANOVA in the two rooms demonstrated that the increased level of anxiety in children of CG is significantly higher compared to CG \((p = .000)\), while there was no difference with PG \((p = .279)\). In contrast, the anxiety of children in the CG was significantly lower compared with both the other groups: CG \((p = .000)\); PG \((p = .015)\) (Fig. 1). The Pearson’s correlations were statistically significant between: state anxiety of parent and age of child \((r = -.24; p < .05)\); anxiety of child in waiting room and age of child \((r = .27; p < .05)\); level of anxiety in waiting room and level of anxiety in induction room \((r = .35; p < .01)\).

The anxiety of parents attending the induction of anesthesia. Using one-way analysis of variance, we found no significant differences among the parents of three study groups: only state anxiety was lower in PG (Tab. 3). The correlations between the anxiety level of the child and that of the parents, and between the anxiety of the parents and demographic characteristics were not significant. As for level of anxiety of parents we found a significant correlation between state anxiety (STAI Y-1) and trait anxiety (STAI Y-2) \((r = .23; p < .05)\).

**D) DISCUSSION**

Relieving preoperative anxiety in the child is necessary to reduce maladaptive postsurgery behaviours, as well as negative children’s responses to successive medical care. The increase of anxiety in the presurgical period is associated with increased postoperative pain, analgesic consumption, general anxiety, behavioural problems\(^{10,11}\). We found that the CG was significantly less anxious during the induction of anesthesia compared with CG and PG, and there were no
significant differences between the level of anxiety in the two rooms in children who were accompanied by clowns.

Recent study\textsuperscript{6} found that the use of preoperative medically trained clowns for children undergoing surgery can significantly alleviate preoperative anxiety compared to the CG and PG, but however, clowns do not have any effect once the anesthesia mask is introduced. Therefore our research demonstrates that the clowns could be the most promising option to treat preoperative anxiety in children.

Several researchers have shown the efficacy of a series of approaches to manage anxiety in the presurgical period, both with pharmacological\textsuperscript{2} and with non-pharmacological interventions\textsuperscript{3,5,6,12,13,14,15,16}.

Among drugs used in the preoperative period, Midazolam is the most commonly administered. It has proved more effective than only parental presence\textsuperscript{17} in reducing anxiety and it is a drug which onsets rapidly and with short half-life, although it is not without disadvantages: many patients frequently show extreme distress and lack of compliance during induction of anesthesia despite premedication\textsuperscript{16,18}. The clown can facilitate the induction process, leave a pleasant memory and represent an alternative to Midazolam, which often leaves the child amnesic of the induction itself. Without the memory of this event, subsequent inductions may indeed appear frightening\textsuperscript{19,20,21}.

The presence of parents during the induction is controversial in relevant literature: numerous studies underline the benefits of this intervention\textsuperscript{3}, highlighting that it helps reducing the use of premedication and increasing child cooperation\textsuperscript{15}, whereas others studies point out the possibility that it may increase parental anxiety and child behavioural problems. As a matter of fact, PPIA is routinely used in some hospitals while actively discouraged in others.

In recent times there has been an increase in the presence of clowns in pediatric hospitals: the successful of this activity is possible if it is carried out by professional artists having gone through careful and rigorous training programmes\textsuperscript{22,23,24}. 
In our study we found that the CG maintained the same level of anxiety during all the preoperative period without differences between the two rooms: these results are consistent with previous studies that demonstrated the effectiveness of clowns in pediatric settings\(^5\) and with other research that showed the influence of the environment on anxiety, especially in the induction room\(^25\). In this study, indeed, anxiety increased during the induction of anesthesia in every group.

Furthermore we found that, both in CG and in PG, the level of anxiety was significantly higher in the induction room than in the waiting room. The level of anxiety of CG was significantly higher compared with CG, but there were no differences from PG. This finding is in line with some studies of relevant literature\(^26\) that show that PPIA in addition to premedication has no additive effects in terms of reducing the child’s anxiety.

These results are consistent also with those of other studies which compare the use of Midazolam to alternative interventions for managing preoperative anxiety in children\(^3,13,16\); the results of one of these studies show that music therapy may be helpful on separation and entrance to the OR (depending on the therapist), but it doesn’t appear to relieve anxiety during the induction of anesthesia\(^16\). We can hypothesize that the clowns have a greater effect than music during induction because they involve the child actively performing gags which are not standardised but created for every individual child.

Previous studies\(^2,27\) had shown that children over seven years had a higher level of anxiety in the waiting room than younger children and that the parents’ anxiety was a predictor of the child’s anxiety during the preoperative period. In agreement with these finding we can affirm that anxiety in children seems to increase with age. Moreover, since in our study a correlation between child anxiety in the waiting room and age of the child, as well as a correlation between parent anxiety during surgery and child age exist, we found that the younger children are, the more anxious parents tend to get. In addition, we noticed that a correlation can be also found between the child’s level of anxiety in the two rooms: children who were more anxious during the wait were also more anxious during the induction, unlike children who were more relaxed during the wait, who also showed less
anxiety during the induction. In according to the literature we didn’t find any correlations between level of anxiety and gender of the child\textsuperscript{17}.

Finally, in our study the secondary end point was the level of anxiety of parents present during the induction of anesthesia. There were not significant differences between each group. Only the scores obtained with the STAI by the parents of PG showed lower levels of anxiety. We can assume that parents who knew that their son or daughter had taken a specific drug to reduce preoperative anxiety were more reassured than parents who simply accompanied their children in the OR, or only with the support of some kind of distraction. We didn’t find any correlations between the level of anxiety of parents and the level of anxiety of children: on the contrary, many studies identify the anxiety of the parent as a predictor of the child’s anxiety\textsuperscript{15,27}.

As for parents’ anxiety, we found a significant correlation between state anxiety (STAI Y-1) and trait anxiety (STAI Y-2): these data show that characteristics of personality influenced the level of anxiety during stressful moments.

Study limitations include small sample size, lack of data on time of induction, and to know if there were any differences in adverse behavioural responses in the week post-discharge for each group.

In conclusion in our study we determined that PPIA + clown intervention is better to reduce anxiety in children during the preoperative period than PPIA alone or PPIA + oral Midazolam.

Considering the importance of non-pharmacological intervention in this context, it would be very interesting to study the application of different distraction techniques in order to assess which one is the most effective in different age group and cultures. Thus, in future studies it would be interesting to compare clown intervention alone with PPIA alone and with Midazolam alone, so as to determine if the presence of clowns, or parental presence, or Premedication, actually lessens the children’s anxiety.

Knowing that the psychological impact of anesthesia and surgery on children covers many areas, the presence of professional clown doctors for managing the child's anxiety during the preoperative phase, should be encouraged in pediatrics hospitals.
E) ACKNOWLEDGEMENTS

We thank the Anna Meyer Foundation, which supporting “Clown in Corsia” project; the clowns of Soccorso Clown ONLUS who work in A. Meyer Children’s Hospital, Florence, Italy.
F) REFERENCES


# CONSORT 2010 checklist of information to include when reporting a randomised trial*

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item No</th>
<th>Checklist item</th>
<th>Reported on page No</th>
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<tr>
<td><strong>Title and abstract</strong></td>
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<tr>
<td></td>
<td>1a</td>
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<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)</td>
<td>2</td>
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<tr>
<td><strong>Introduction</strong></td>
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<tr>
<td>Background and objectives</td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
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<td>Specific objectives or hypotheses</td>
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<tr>
<td><strong>Methods</strong></td>
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<tr>
<td>Trial design</td>
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<td>Description of trial design (such as parallel, factorial) including allocation ratio</td>
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<td>Important changes to methods after trial commencement (such as eligibility criteria), with reasons</td>
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<tr>
<td>Participants</td>
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<td>Eligibility criteria for participants</td>
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<td>Settings and locations where the data were collected</td>
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<tr>
<td>Interventions</td>
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<td>The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</td>
<td>4-5</td>
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<tr>
<td>Outcomes</td>
<td>6a</td>
<td>Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed</td>
<td>4</td>
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<tr>
<td></td>
<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
<td>7</td>
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<tr>
<td>Sample size</td>
<td>7a</td>
<td>How sample size was determined</td>
<td>7</td>
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<td></td>
<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
<td>7</td>
</tr>
<tr>
<td><strong>Randomisation:</strong></td>
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<td>SeQUENCE generation</td>
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<td>Method used to generate the random allocation sequence</td>
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<td>8b</td>
<td>Type of randomisation; details of any restriction (such as blocking and block size)</td>
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<tr>
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<td>Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned</td>
<td>4-5</td>
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<tr>
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<td>10</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
<td>4-5</td>
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</tbody>
</table>
For Peer Review

1. If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
2. If relevant, description of the similarity of interventions

Blinding

3. Statistical methods used to compare groups for primary and secondary outcomes
4. Methods for additional analyses, such as subgroup analyses and adjusted analyses

Statistical methods

Results

5. For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
6. For each group, losses and exclusions after randomisation, together with reasons

Participant flow (a diagram is strongly recommended)

7. Dates defining the periods of recruitment and follow-up
8. Why the trial ended or was stopped

Recruitment

9. A table showing baseline demographic and clinical characteristics for each group
10. For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

Baseline data

11. For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
12. For binary outcomes, presentation of both absolute and relative effect sizes is recommended

Outcomes and estimation

13. Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory

Ancillary analyses

14. All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)

Harms

Discussion

15. Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
16. Generalisability (external validity, applicability) of the trial findings
17. Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

Limitations

Other information

18. Registration number and name of trial registry
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Registration

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Analysed (n=25)
- Excluded from analysis (give reasons) (n=)

Analysed (n=25)
- Excluded from analysis (give reasons) (n=)
TABLE 1. Surgical Procedures in the 3 Groups

<table>
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<th>Procedure</th>
<th>Clown Group</th>
<th>Premedication Group</th>
<th>Control Group</th>
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<td>Strabismus</td>
<td>4 (16)</td>
<td>3 (12)</td>
<td>4 (16)</td>
</tr>
<tr>
<td>Cyst</td>
<td>-</td>
<td>3 (12)</td>
<td>3 (12)</td>
</tr>
<tr>
<td>Inguinal hernia</td>
<td>3 (12)</td>
<td>4 (16)</td>
<td>7 (28)</td>
</tr>
<tr>
<td>Phimosis</td>
<td>-</td>
<td>2 (8)</td>
<td>-</td>
</tr>
<tr>
<td>Hydrocoele</td>
<td>2 (8)</td>
<td>3 (12)</td>
<td>4 (16)</td>
</tr>
<tr>
<td>Hypospadias</td>
<td>3 (12)</td>
<td>2 (8)</td>
<td>-</td>
</tr>
<tr>
<td>Reflux</td>
<td>3 (12)</td>
<td>-</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Retained testicle</td>
<td>2 (8)</td>
<td>5 (20)</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Varicocele</td>
<td>2 (8)</td>
<td>-</td>
<td>3 (12)</td>
</tr>
</tbody>
</table>

TABLE 2. Demographics of the Study Participants and their Parents

<table>
<thead>
<tr>
<th>Variable</th>
<th>Clown Group</th>
<th>Premedication Group</th>
<th>Control Group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child’s sex (male/female) (%)</td>
<td>72/28</td>
<td>72/28</td>
<td>64/36</td>
<td>.785</td>
</tr>
<tr>
<td>Age of the child, y, mean±SD (range)</td>
<td>7.04±2.23 (5-12)</td>
<td>8.04±2.11 (5-12)</td>
<td>7.36±2.61 (5-12)</td>
<td>.306</td>
</tr>
<tr>
<td>Parents’ sex (male/female) (%)</td>
<td>4/96</td>
<td>16/84</td>
<td>24/76</td>
<td>.136</td>
</tr>
<tr>
<td>Age of the parent, y, mean±SD (range)</td>
<td>37.04±3.95 (29-44)</td>
<td>37.64±4.44 (29-45)</td>
<td>36.44±5.47 (26-48)</td>
<td>.663</td>
</tr>
</tbody>
</table>

TABLE 3. Intervention Outcome Variables, Mean ± SD (range)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Clown Group</th>
<th>Premedication Group</th>
<th>Control Group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety of the child in the waiting room (m-YPAS)</td>
<td>29.48±10.47 (23-62)</td>
<td>37.40±13.13 (23-63)</td>
<td>34.96±14.39 (23-68)</td>
<td>.088</td>
</tr>
<tr>
<td>Anxiety of the child in the induction room (m-YPAS)</td>
<td>33.16±18.82 (23-100)</td>
<td>49.72±22.86 (23-96)</td>
<td>65.40±24.97 (32-100)</td>
<td>.000</td>
</tr>
<tr>
<td>State anxiety of the parent (STAI Y-1)</td>
<td>58.52±12.73 (41-85)</td>
<td>37.40±13.13 (41-77)</td>
<td>58.32±9.32 (41-72)</td>
<td>.615</td>
</tr>
<tr>
<td>Trait anxiety of the parent (STAI Y-2)</td>
<td>45.48±7.92 (31-69)</td>
<td>49.72±22.86 (29-64)</td>
<td>50.32±10.41 (40-87)</td>
<td>.187</td>
</tr>
</tbody>
</table>

Fig. 1. Distribution of anxiety scores (m-YPAS) of three groups of children during induction of anaesthesia