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Pediatric Anesthesia

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

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3 **Parental presence, clowns or sedative premedication to treat preoperative anxiety in children:**
4
5 **what could be the most promising option?**
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10 **Running title:** Treat preoperative anxiety in children
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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 children³. In order to treat preoperative anxiety some anaesthesiologists routinely opt for sedative premedication and parental presence during induction of anesthesia (PPIA), simultaneously or interchangeably⁴. 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

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2
3 illness, premature birth, developmental delay or previous anaesthetic experience were excluded
4
5 from this study. The subjects had to be chosen from a population of children who were supposed to
6
7 undergo minor day surgery and were assigned to one of three groups by using computer-generated
8
9 list random assignment.
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11

12 The study protocol was approved by the hospital ethics committee and informed consent was
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14 obtained from the parents before inclusion of their children in the study.
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16

17 Primary end point was the anxiety of the child in the preoperative period. The goal of the study was
18
19 to determine whether the presence of clowns was more effective in reducing preoperative anxiety in
20
21 the child than sedative premedication (with Midazolam), or only PPIA. As a secondary end point
22
23 we aimed to identify the difference in the levels of parents' anxiety in the three groups.
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27 **B2) Study Groups**

28 Eligible patients were randomly assigned following simple randomization procedures
29
30 (computerized random numbers) to one of the three study groups:
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34 (1) Clown group (CG): children were accompanied in the preoperative room by two clowns and a
35
36 parent. They interacted with clowns before entering the OR (operating room) and stayed with them
37
38 and their parent throughout the anesthesia-induction process.
39
40

41 (2) Premedication group (PG): children were premedicated with 0.5 mg/kg oral Midazolam at least
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43 45 minutes before the surgical procedure began, and a parent was present throughout the anesthesia-
44
45 induction process.
46
47

48 (3) Control group (CG): children were accompanied in the OR by one parent, without any clowns,
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50 other distractions or premedications, during induction of anesthesia. PPIA is considered control
51
52 group because is routinely used in our hospital.
53
54

55 In each group, the children were observed during the preoperative process in two different rooms:
56
57 the waiting room and the induction room. They personally chose the parent who stayed with them.
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59 Anesthesia was induced in all patients by pediatric anaesthesiologists by means of a scented mask
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using a standardized oxygen (O₂)/nitrous oxide(N₂O)/sevoflurane technique.

1
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3 In the CG, two clowns stayed with the child during the whole process: they arrived approx. 30
4 minutes before the child was taken to the OR, and stayed with him/her for approx. 15 minutes. The
5 clowns, taking into account the children's age and experience, used various methods to entertain
6 them (eg, magic tricks, gags, music, games, puppets, word games, soap bubbles, etc). The clowns
7 are professional performing artists with specialties ranging from music to magic who have been
8 carefully selected and trained to apply their skills to a hospital's special needs. When the nurse took
9 the child to the OR, the clowns accompanied the child and the parent and stayed with them during
10 the anesthesia-induction process.
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15 In the PG oral Midazolam was administered by a nurse approx. 45 minutes before the surgical
16 procedure. Then, the same nurse accompanied the child with a parent in the OR.
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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 anesthesia⁷. For our study the coding method was translated from English into Italian⁵.

State-Trait Anxiety Inventory

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2
3 The State-Trait Anxiety Inventory (STAI) self-report anxiety behavioural instrument consists of
4 two separate 20-item subscales that measure trait (baseline) and state (situational) anxiety in adults.
5
6 The STAI trait subscale measures relatively stable individual differences in anxiety proneness (i.e.,
7 differences in the tendency to experience anxiety), and the STAI state subscale measures transitory
8 anxiety state (i.e., subjective feelings of apprehension, tension and worry that vary in intensity and
9 fluctuate depending on the situation).

10
11 Parents responded on a 4-point scale. Total scores for state and trait sections separately range from
12 20 to 80, with higher scores denoting higher levels of anxiety. Test-retest correlations for the STAI
13 are high (range: 0.73-0.86), and the studies have demonstrated good validity. In this study we used
14 form Y (Y-1/Y-2) developed by Spielberger⁸, as well as with the table to calculate the score
15 according to the Italian standard version⁹.

26 27 28 **B4) Data Analysis**

29
30 All the instruments were administered by two psychologists who had significant background in
31 behavioural research. The two independent observers evaluated the child's anxiety (m-YPAS) in the
32 waiting room and in the induction room. Parental anxiety was assessed on the same day as surgery
33 with STAI (Y-1/Y-2) immediately after separation between parent and child, and during the
34 operation. We measured trait and state anxiety in that moment in order to avoid organizational
35 problems in keeping contacts with the families, trait anxiety being supposed to be a stable measure
36 anyway.

37
38 Descriptive statistics provide an overview of the relationships between child and parent variables, as
39 well as anxiety levels in child and parent. Data are presented as mean±SD.

40
41 The agreement between the two observers codifying the data of m-YPAS was verified through
42 Cohen's *k* calculation. Differences between groups were examined using one-way analysis of
43 variance and all pairwise multiple comparisons were performed using the Scheffé test: we
44 compared the scores of anxiety level obtained by the three groups with m-YPAS in the surgery
45 process and the scores of the level of state (STAI Y-1) and trait anxiety (STAI Y-2) of parents. The

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3 anxiety level of children within the same group, in the waiting room and in the induction room were
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5 compared by using a repeated-measures analysis of variance (within-subjects factors) for each
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7 group, and also using the Scheffé *post hoc* test. The Pearson's correlation coefficient (r) was used to
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9 evaluate the demographic characteristics and the relations between the child's anxiety level, the
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11 child's age and the parents' anxiety. The correlation was also calculated within the groups,
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13 correlating the scores of waiting room and induction room.
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17 The sample size was based on some investigations involving clown, sedative premedication (with
18
19 Midazolam), PPIA and children^{3,5,6}. These studies show significant reduction in the level of anxiety
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21 of the children^{3,5,6}. A sample size of 75 subjects was calculated to be sufficient to detect a difference
22
23 in anxiety level considering the number of patients hospitalized routinely in day surgery in our
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25 hospital.
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29 Data were analysed by using SPSS version 11.5 for *Windows* (SPSS Inc, Chicago, IL, USA). P was
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31 accepted as significant at $< .05$.
32

33 34 C) RESULTS

35
36 The 75 participants were recruited from April to December 2009. The demographic and clinical
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38 characteristics of the three groups of children and parents are presented in Table 1 and 2 and they
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40 are similar across groups, with no significant differences in age or in gender distribution. However,
41
42 the ratio of mother to father is different: there are more mothers than fathers who accompany their
43
44 child during preoperative process.
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48 The two observers who codified the data are agree: the results of Cohen's k for every category m-
49
50 YPAS and for both the preoperative rooms are broadly significant with values between .73 and .91.
51

52
53 In each group, the anxiety of children increased during the induction of anesthesia [$F_{(2,72)} = 12.994$;
54
55 $p = .001$]. Using *post-hoc* Scheffé test, we found that the level of anxiety was significantly lower in
56
57 the CG compared to PG ($p = .038$) and to CG, whose level of anxiety was significantly higher ($p =$
58
59 $.000$). There were not any significant differences between CG and PG. Furthermore there were no
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2
3 significant differences in the observed anxiety level (m-YPAS) among the three groups in the
4 waiting room [$F_{(2,72)} = 2.515; p = .005$] (Tab. 3).

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8 Using a repeated-measures ANOVA, we analysed changes in the level of anxiety in the two
9 locations. We found that in each group there was an increased level of anxiety in the induction room
10 in comparison to the waiting room: this difference was statistically significant for CG [$F_{(1,24)} =$
11 30,300; $p = .001$] and PG [$F_{(1,24)} = 6,425; p = .005$], whereas it was not significant in the CG (Tab.
12 3). The *post-hoc* Scheffé about the results of repeated-measures ANOVA in the two rooms
13 demonstrated that the increased of level of anxiety in children of CG is significantly higher
14 compared to CG ($p = .000$), while there was no difference with PG ($p = .279$). In contrast, the
15 anxiety of children in the CG was significantly lower compared with both the other groups: CG ($p =$
16 .000); PG ($p = .015$) (Fig. 1). The Pearson's correlations were statistically significant between: state
17 anxiety of parent and age of child ($r = -.24; p < .05$); anxiety of child in waiting room and age of
18 child ($r = .27; p < .05$); level of anxiety in waiting room and level of anxiety in induction room ($r =$
19 .35; $p < .01$).

20
21
22 The anxiety of parents attending the induction of anesthesia. Using one-way analysis of variance,
23 we found no significant differences among the parents of three study groups: only state anxiety was
24 lower in PG (Tab. 3). The correlations between the anxiety level of the child and that of the parents,
25 and between the anxiety of the parents and demographic characteristics were not significant. As for
26 level of anxiety of parents we found a significant correlation between state anxiety (STAI Y-1) and
27 trait anxiety (STAI Y-2) ($r = .23; p < .05$).

28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 **D) DISCUSSION**

52
53 Relieving preoperative anxiety in the child is necessary to reduce maladaptive postsurgery
54 behaviours, as well as negative children's responses to successive medical care. The increase of
55 anxiety in the presurgical period is associated with increased postoperative pain, analgesic
56 consumption, general anxiety, **incidence of emergence delirium, sleeping problems and poor**
57 **postoperative eating improvement behavioural problems**^{10,11}. We found that the CG was

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2
3 significantly less anxious during the induction of anesthesia compared with CG and PG, and there
4
5 were no significant differences between the level of anxiety in the two rooms the waiting room
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7
8 and the level of anxiety in the induction room in children who were accompanied by clowns.

9
10 Recent study⁶ found that the use of preoperative medically trained clowns for children undergoing
11
12 surgery can significantly alleviate preoperative anxiety compared to the CG and PG, but however,
13
14 clowns do not have any effect once the anesthesia mask is introduced. Therefore our research
15
16 demonstrates that the clowns could be the most promising option to treat preoperative anxiety in
17
18 children.
19

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22 Several researchers have shown the efficacy of a series of approaches to prevent and manage
23
24 anxiety and fear in the presurgical period, both with pharmacological² interventions (e.g.
25
26 sedative premedication²) and with non-pharmacological interventions³ (e.g. preoperative
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28 visits in the O.R., PPIA, psychological preparation of the child and parents, with audio/video
29
30 devices, leaflets, painting books¹², acupuncture, toys^{13,14}, flavoured anesthesia mask, fun
31
32 transportation system - i.e. wagons¹⁵-, music¹⁶, clown^{5,6}).
33

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35
36 Several researchers have shown the efficacy of a series of approaches to manage anxiety in the
37
38 presurgical period, both with pharmacological² and with non-pharmacological
39
40 interventions^{3,5,6,12,13,14,15,16}.
41

42
43 Among drugs used in the preoperative period, Midazolam is the most commonly administered: this
44
45 drug is effective in reducing anxiety prior and during the induction of anesthesia. It has proved
46
47 more effective than only parental presence¹⁷ in reducing anxiety and it is a drug which onsets
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49 rapidly and with short half-life, although it is not without disadvantages (e.g. delay in emergence,
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51 recovery and discharge, amnesia, increase in postrecovery anxiety)^{16,18}. Many patients
52
53 frequently show extreme distress and lack of compliance during induction of anesthesia despite
54
55 premedication¹⁸: the administration of oral premedication to children is often met with
56
57 apprehension, reluctance, or refusal¹⁸. The clown can facilitate the induction process, leave a
58
59 pleasant memory and represent an alternative to Midazolam, which often leaves the child amnesic
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1
2
3 of the induction itself. Without the memory of this event, subsequent inductions may indeed appear
4
5 novel, distressing and frightening^{21,19}. It is even likely to leave them with a pleasant
6
7 memory^{19,20, 20,21}.

8
9
10 The presence of parents during the induction is controversial in relevant literature: numerous studies
11
12 underline the benefits of this intervention³, highlighting that it helps reducing the use of
13
14 premedication and increasing child cooperation¹⁵, whereas others studies point out the possibility
15
16 that it may increase parental anxiety and child behavioural problems. As a matter of fact, PPIA is
17
18 routinely used in some hospitals while actively discouraged in others.

19
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21 As for non-pharmacological intervention, following the results of previous study on the
22
23 efficacy of clowns during the induction of anesthesia^{3,5,6}, we hypothesize that the presence of
24
25 clowns stimulates the children's imagination and creativity, allowing them to participate
26
27 actively in the induction experience while being in a playful state, to reduce muscle tension
28
29 and to improve respiration.

30
31
32 It is likely that children establish an alliance with clowns and are thus given the opportunity
33
34 to take control over their playful experience in an environment where their power is generally
35
36 limited²².

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38
39 In recent times there has been an increase in the presence of clowns in pediatric hospitals:
40
41 clowns in health care settings use games and laughter to provide ill children with another way
42
43 to express their emotions and to provide control and social interaction during hospitalisation
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45 and treatment^{22,23,24}. This is possible if the activity is carried out by professional artists having
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47 gone through careful and rigorous training programmes, both about clowning and psychology
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49 of children in hospitals. Beside, in order to be successful, the clown programme should not
50
51 interfere with the work of doctors and nurses.

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54 In recent times there has been an increase in the presence of clowns in pediatric hospitals: the
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56 successful of this activity is possible if it is carried out by professional artists having gone
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58 through careful and rigorous training programmes^{22,23,24}.

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3 In our study we found that the CG maintained the same level of anxiety during all the preoperative
4 period without differences between the two rooms locations. We can assume that the mask and
5 the induction of anesthesia are less frightening for the children belonging to this group
6 compared with the others. These results are consistent with previous studies that demonstrated the
7 effectiveness of clowns in pediatric settings⁵ and with other research that showed the influence of
8 the environment on anxiety, especially in the induction room²⁵. In this study, indeed, anxiety
9 increased during the induction of anesthesia in every group.

10
11 Furthermore we found that, both in CG and in PG, the level of anxiety was significantly higher in
12 the induction room than in the waiting room. The level of anxiety of CG was significantly higher
13 compared with CG, but there were no differences from PG. This finding is in line with some studies
14 of relevant literature²⁶ that show that PPIA in addition to premedication has no additive effects in
15 terms of reducing the child's anxiety.

16
17 These results are consistent also with those of other studies which compare the use of Midazolam to
18 alternative interventions for managing preoperative anxiety in children^{3,13,16}: as hand-held video
19 games^{3,13}, indeed children who received PPIA + hand-held video games showed less anxiety
20 when the anesthesia mask was used compared to PPIA group and Midazolam Group and
21 music¹⁶. the results of one of these studies show that music therapy may be helpful on separation
22 and entrance to the OR (depending on the therapist), but it doesn't appear to relieve anxiety during
23 the induction of anesthesia: the Midazolam group was significantly less anxious during
24 anaesthetic induction in comparison to both the music group and the control group^{3,16}.

25
26 We can hypothesize that the clowns have a greater effect than music during induction because they
27 involve the child actively, with mental and motor participation, performing gags and
28 improvisations which are not standardised but created for every individual child in line with
29 his/her characteristics and personality.

30
31 Previous studies^{2,27} had shown that children over seven years had a higher level of anxiety in the
32 waiting room than younger children and that the parents' anxiety was a predictor of the child's

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3 anxiety during the preoperative period. In agreement with these finding we can affirm that anxiety
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5 in children seems to increase with age. Moreover, since in our study a correlation between child
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7 anxiety in the waiting room and age of the child, as well as a correlation between parent anxiety
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9 during surgery and child age exist, we found that the younger children are, the more anxious parents
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11 tend to get.
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15 In addition, we noticed that a correlation can be also found between the child's level of anxiety in
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17 the two rooms waiting room and in the induction room: children who were more anxious during
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19 the wait were also more anxious during the induction, unlike children who were more relaxed
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21 during the wait, who also showed less anxiety during the induction.
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25 We didn't find any correlations between level of anxiety and gender of the child. According to
26
27 the literature, gender does not influence preoperative anxiety, nor development of
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29 postoperative behavioural problems¹⁷.
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32 In according to the literature we didn't find any correlations between level of anxiety and
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34 gender of the child¹⁷.
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36 Finally, in our study the secondary end point was the level of anxiety of parents present during the
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38 induction of anesthesia. There were not significant differences between each group. Only the scores
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40 obtained with the STAI by the parents of PG showed lower levels of anxiety. We can assume that
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42 parents who knew that their son or daughter had taken a specific drug to reduce preoperative
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44 anxiety were more reassured than parents who simply accompanied their children in the OR, or
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46 only with the support of some kind of distraction. Probably drugs give more security and
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48 guarantee: a qualitative study with interviews could help to identify the reasons of lower
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50 anxiety.
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54
55 We didn't find any correlations between the level of anxiety of parents and the level of anxiety of
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57 children: on the contrary, many studies identify the anxiety of the parent as a predictor of the
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59 child's anxiety^{15,27}.
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3 As for parents' anxiety, we found a significant correlation between state anxiety (STAI Y-1) and
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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.**

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For Peer Review

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

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3-4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	3
Participants	4a	Eligibility criteria for participants	3
	4b	Settings and locations where the data were collected	3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4-5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	4
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
Allocation concealment mechanism	9	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	4-5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4-5

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3	tion			
4	Blinding	11	If done, who was blinded after assignment to interventions (for example,	5
5		a	participants, care providers, those assessing outcomes) and how	
6		11	If relevant, description of the similarity of interventions	-
7		b		
8	Statistical	12	Statistical methods used to compare groups for primary and secondary	6
9	methods	a	outcomes	
10		12	Methods for additional analyses, such as subgroup analyses and adjusted	-
11		b	analyses	
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14	Results			
15	Participant	13	For each group, the numbers of participants who were randomly assigned,	7
16	flow (a	a	received intended treatment, and were analysed for the primary outcome	
17	diagram is	13	For each group, losses and exclusions after randomisation, together with	-
18	strongly	b	reasons	
19	recommend			
20	ed)			
21	Recruitment	14	Dates defining the periods of recruitment and follow-up	7
22		a		
23		14	Why the trial ended or was stopped	-
24		b		
25	Baseline	15	A table showing baseline demographic and clinical characteristics for each	Table 1 -
26	data		group	2
27	Numbers	16	For each group, number of participants (denominator) included in each	7
28	analysed		analysis and whether the analysis was by original assigned groups	
29	Outcomes	17	For each primary and secondary outcome, results for each group, and the	Table 3
30	and	a	estimated effect size and its precision (such as 95% confidence interval)	
31	estimation	17	For binary outcomes, presentation of both absolute and relative effect	-
32		b	sizes is recommended	
33	Ancillary	18	Results of any other analyses performed, including subgroup analyses	7-8
34	analyses		and adjusted analyses, distinguishing pre-specified from exploratory	
35	Harms	19	All important harms or unintended effects in each group (for specific guidance	-
36			see CONSORT for harms)	
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39	Discussion			
40	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if	13
41			relevant, multiplicity of analyses	
42	Generalisab	21	Generalisability (external validity, applicability) of the trial findings	13
43	ility			
44	Interpretatio	22	Interpretation consistent with results, balancing benefits and harms, and	13
45	n		considering other relevant evidence	
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48	Other information			
49	Registration	23	Registration number and name of trial registry	-
50	Protocol	24	Where the full trial protocol can be accessed, if available	-
51	Funding	25	Sources of funding and other support (such as supply of drugs), role of	-
52			funders	

*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

CONSORT 2010 Flow Diagram

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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=)

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=)

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3 **Parental presence, clowns or sedative premedication to treat preoperative anxiety in children:**
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5 **what could be the most promising option?**
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10 **Running title:** Treat preoperative anxiety in children
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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 children³. In order to treat preoperative anxiety some anaesthesiologists routinely opt for sedative premedication and parental presence during induction of anesthesia (PPIA), simultaneously or interchangeably⁴. 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

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3 from this study. The subjects had to be chosen from a population of children who were supposed to
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5 undergo minor day surgery and were assigned to one of three groups by using computer-generated
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7 list random assignment.
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10 The study protocol was approved by the hospital ethics committee and informed consent was
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12 obtained from the parents before inclusion of their children in the study.
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15 Primary end point was the anxiety of the child in the preoperative period. The goal of the study was
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17 to determine whether the presence of clowns was more effective in reducing preoperative anxiety in
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19 the child than sedative premedication (with Midazolam), or only PPIA. As a secondary end point
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21 we aimed to identify the difference in the levels of parents' anxiety in the three groups.
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24 **B2) Study Groups**

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26 Eligible patients were randomly assigned following simple randomization procedures
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28 (computerized random numbers) to one of the three study groups:
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31 (1) Clown group (CG): children were accompanied in the preoperative room by two clowns and a
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33 parent. They interacted with clowns before entering the OR (operating room) and stayed with them
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35 and their parent throughout the anesthesia-induction process.
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38 (2) Premedication group (PG): children were premedicated with 0.5 mg/kg oral Midazolam at least
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40 45 minutes before the surgical procedure began, and a parent was present throughout the anesthesia-
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42 induction process.
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45 (3) Control group (CG): children were accompanied in the OR by one parent, without any clowns,
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47 other distractions or premedications, during induction of anesthesia. PPIA is considered control
48
49 group because is routinely used in our hospital.
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52 In each group, the children were observed during the preoperative process in two different rooms:
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54 the waiting room and the induction room. They personally chose the parent who stayed with them.
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57 Anesthesia was induced in all patients by pediatric anaesthesiologists by means of a scented mask
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59 using a standardized oxygen (O₂)/nitrous oxide(N₂O)/sevoflurane technique.
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3 In the CG, two clowns stayed with the child during the whole process: they arrived approx. 30
4 minutes before the child was taken to the OR, and stayed with him/her for approx. 15 minutes. The
5 clowns, taking into account the children's age and experience, used various methods to entertain
6 them (eg, magic tricks, gags, music, games, puppets, word games, soap bubbles, etc). The clowns
7 are professional performing artists with specialties ranging from music to magic who have been
8 carefully selected and trained to apply their skills to a hospital's special needs. When the nurse took
9 the child to the OR, the clowns accompanied the child and the parent and stayed with them during
10 the anesthesia-induction process.
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15 In the PG oral Midazolam was administered by a nurse approx. 45 minutes before the surgical
16 procedure. Then, the same nurse accompanied the child with a parent in the OR.
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21 The managing anaesthesiologist, the parents and the other observers were kept blinded to the
22 purpose of the study and the groups involved, but it was impossible to be blind entirely to
23 assignment for the children in the CG. In addition, parents of the PG were informed that their
24 children had been given a drug.
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27 **B3) Evaluation Instruments**

28 *Modified Yale Preoperative Anxiety Scale*

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31 The Modified Yale Preoperative Anxiety Scale (m-YPAS) was used to evaluate the behaviour of
32 the child in the waiting room and in the induction room. The m-YPAS is an observational
33 behavioural checklist developed by Kain et al.⁷ to measure the state anxiety of young children. It
34 contains 27 items divided into 5 categories: activity, emotional expressivity, state of arousal,
35 vocalization, use of parents. Each category receives a score on a scale of 4 (6 for vocalization)
36 according to the behaviour of the patient. The m-YPAS score ranges from 23 to 100, with higher
37 scores indicating greater anxiety. This scale has good-to-excellent interrater and intraobserver
38 reliability and validity for measuring children's anxiety in the preoperative holding area and during
39 induction of anesthesia⁷. For our study the coding method was translated from English into Italian⁵.
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State-Trait Anxiety Inventory

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

10
11 Parents responded on a 4-point scale. Total scores for state and trait sections separately range from
12 20 to 80, with higher scores denoting higher levels of anxiety. Test-retest correlations for the STAI
13 are high (range: 0.73-0.86), and the studies have demonstrated good validity. In this study we used
14 form Y (Y-1/Y-2) developed by Spielberger⁸, as well as with the table to calculate the score
15 according to the Italian standard version⁹.

26 27 28 **B4) Data Analysis**

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

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

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39 The agreement between the two observers codifying the data of m-YPAS was verified through
40 Cohen's *k* calculation. Differences between groups were examined using one-way analysis of
41 variance and all pairwise multiple comparisons were performed using the Scheffé test: we
42 compared the scores of anxiety level obtained by the three groups with m-YPAS in the surgery
43 process and the scores of the level of state (STAI Y-1) and trait anxiety (STAI Y-2) of parents. The

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3 anxiety level of children within the same group, in the waiting room and in the induction room were
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5 compared by using a repeated-measures analysis of variance (within-subjects factors) for each
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7 group, and also using the Scheffé *post hoc* test. The Pearson's correlation coefficient (r) was used to
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9 evaluate the demographic characteristics and the relations between the child's anxiety level, the
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11 child's age and the parents' anxiety. The correlation was also calculated within the groups,
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13 correlating the scores of waiting room and induction room.
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17 The sample size was based on some investigations involving clown, sedative premedication (with
18
19 Midazolam), PPIA and children^{3,5,6}. These studies show significant reduction in the level of anxiety
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21 of the children^{3,5,6}. A sample size of 75 subjects was calculated to be sufficient to detect a difference
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23 in anxiety level considering the number of patients hospitalized routinely in day surgery in our
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25 hospital.
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29 Data were analysed by using SPSS version 11.5 for *Windows* (SPSS Inc, Chicago, IL, USA). P was
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31 accepted as significant at $< .05$.
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34 **C) RESULTS**

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36 The 75 participants were recruited from April to December 2009. The demographic and clinical
37
38 characteristics of the three groups of children and parents are presented in Table 1 and 2 and they
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40 are similar across groups, with no significant differences in age or in gender distribution. However,
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42 the ratio of mother to father is different: there are more mothers than fathers who accompany their
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44 child during preoperative process.
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48 The two observers who codified the data are agree: the results of Cohen's k for every category m-
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50 YPAS and for both the preoperative rooms are broadly significant with values between .73 and .91.
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53 In each group, the anxiety of children increased during the induction of anesthesia [$F_{(2,72)} = 12.994$;
54
55 $p = .001$]. Using *post-hoc* Scheffé test, we found that the level of anxiety was significantly lower in
56
57 the CG compared to PG ($p = .038$) and to CG, whose level of anxiety was significantly higher ($p =$
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59 $.000$). There were not any significant differences between CG and PG. Furthermore there were no
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3 significant differences in the observed anxiety level (m-YPAS) among the three groups in the
4 waiting room [$F_{(2,72)} = 2.515; p = .005$] (Tab. 3).

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8 Using a repeated-measures ANOVA, we analysed changes in the level of anxiety in the two
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10 locations. We found that in each group there was an increased level of anxiety in the induction room
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12 in comparison to the waiting room: this difference was statistically significant for CG [$F_{(1,24)} =$
13 30,300; $p = .001$] and PG [$F_{(1,24)} = 6,425; p = .005$], whereas it was not significant in the CG (Tab.
14
15 3). The *post-hoc* Scheffé about the results of repeated-measures ANOVA in the two rooms
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17 demonstrated that the increased of level of anxiety in children of CG is significantly higher
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19 compared to CG ($p = .000$), while there was no difference with PG ($p = .279$). In contrast, the
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21 anxiety of children in the CG was significantly lower compared with both the other groups: CG ($p =$
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23 .000); PG ($p = .015$) (Fig. 1). The Pearson's correlations were statistically significant between: state
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25 anxiety of parent and age of child ($r = -.24; p < .05$); anxiety of child in waiting room and age of
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27 child ($r = .27; p < .05$); level of anxiety in waiting room and level of anxiety in induction room ($r =$
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29 .35; $p < .01$).

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

47 48 49 50 **D) DISCUSSION**

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53 Relieving preoperative anxiety in the child is necessary to reduce maladaptive postsurgery
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55 behaviours, as well as negative children's responses to successive medical care. The increase of
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57 anxiety in the presurgical period is associated with increased postoperative pain, analgesic
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59 consumption, general anxiety, behavioural problems^{10,11}. We found that the CG was significantly
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less anxious during the induction of anesthesia compared with CG and PG, and there were no

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3 significant differences between the level of anxiety in the two rooms in children who were
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5 accompanied by clowns.
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8 Recent study⁶ found that the use of preoperative medically trained clowns for children undergoing
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10 surgery can significantly alleviate preoperative anxiety compared to the CG and PG, but however,
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12 clowns do not have any effect once the anesthesia mask is introduced. Therefore our research
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14 demonstrates that the clowns could be the most promising option to treat preoperative anxiety in
15
16 children.
17

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19 Several researchers have shown the efficacy of a series of approaches to manage anxiety in the
20
21 presurgical period, both with pharmacological² and with non-pharmacological
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23 interventions^{3,5,6,12,13,14,15,16}.
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27 Among drugs used in the preoperative period, Midazolam is the most commonly administered. It
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29 has proved more effective than only parental presence¹⁷ in reducing anxiety and it is a drug which
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31 onsets rapidly and with short half-life, although it is not without disadvantages: many patients
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33 frequently show extreme distress and lack of compliance during induction of anesthesia despite
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35 premedication^{16,18}. The clown can facilitate the induction process, leave a pleasant memory and
36
37 represent an alternative to Midazolam, which often leaves the child amnesic of the induction itself.
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39 Without the memory of this event, subsequent inductions may indeed appear frightening^{19,20,21}.
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43 The presence of parents during the induction is controversial in relevant literature: numerous studies
44
45 underline the benefits of this intervention³, highlighting that it helps reducing the use of
46
47 premedication and increasing child cooperation¹⁵, whereas others studies point out the possibility
48
49 that it may increase parental anxiety and child behavioural problems. As a matter of fact, PPIA is
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51 routinely used in some hospitals while actively discouraged in others.
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55 In recent times there has been an increase in the presence of clowns in pediatric hospitals: the
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57 successful of this activity is possible if it is carried out by professional artists having gone through
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59 careful and rigorous training programmes^{22,23,24}.
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3 In our study we found that the CG maintained the same level of anxiety during all the preoperative
4 period without differences between the two rooms: these results are consistent with previous studies
5 that demonstrated the effectiveness of clowns in pediatric settings⁵ and with other research that
6 showed the influence of the environment on anxiety, especially in the induction room²⁵. In this
7 study, indeed, anxiety increased during the induction of anesthesia in every group.

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10 Furthermore we found that, both in CG and in PG, the level of anxiety was significantly higher in
11 the induction room than in the waiting room. The level of anxiety of CG was significantly higher
12 compared with CG, but there were no differences from PG. This finding is in line with some studies
13 of relevant literature²⁶ that show that PPIA in addition to premedication has no additive effects in
14 terms of reducing the child's anxiety.

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17 These results are consistent also with those of other studies which compare the use of Midazolam to
18 alternative interventions for managing preoperative anxiety in children^{3,13,16}: the results of one of
19 these studies show that music therapy may be helpful on separation and entrance to the OR
20 (depending on the therapist), but it doesn't appear to relieve anxiety during the induction of
21 anesthesia¹⁶. We can hypothesize that the clowns have a greater effect than music during induction
22 because they involve the child actively performing gags which are not standardised but created for
23 every individual child.

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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

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3 anxiety during the induction. In according to the literature we didn't find any correlations between
4
5 level of anxiety and gender of the child¹⁷.
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8 Finally, in our study the secondary end point was the level of anxiety of parents present during the
9
10 induction of anesthesia. There were not significant differences between each group. Only the scores
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12 obtained with the STAI by the parents of PG showed lower levels of anxiety. We can assume that
13
14 parents who knew that their son or daughter had taken a specific drug to reduce preoperative
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16 anxiety were more reassured than parents who simply accompanied their children in the OR, or
17
18 only with the support of some kind of distraction. We didn't find any correlations between the level
19
20 of anxiety of parents and the level of anxiety of children: on the contrary, many studies identify the
21
22 anxiety of the parent as a predictor of the child's anxiety^{15,27}.
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27 As for parents' anxiety, we found a significant correlation between state anxiety (STAI Y-1) and
28
29 trait anxiety (STAI Y-2): these data show that characteristics of personality influenced the level of
30
31 anxiety during stressful moments.
32
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34 Study limitations include small sample size, lack of data on time of induction, and to know if there
35
36 were any differences in adverse behavioural responses in the week post-discharge for each group.
37
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39 In conclusion in our study we determined that PPIA + clown intervention is better to reduce anxiety
40
41 in children during the preoperative period than PPIA alone or PPIA + oral Midazolam.
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44 Considering the importance of non-pharmacological intervention in this context, it would be very
45
46 interesting to study the application of different distraction techniques in order to assess which one is
47
48 the most effective in different age group and cultures. Thus, in future studies it would be interesting
49
50 to compare clown intervention alone with PPIA alone and with Midazolam alone, so as to
51
52 determine if the presence of clowns, or parental presence, or Premedication, actually lessens the
53
54 children's anxiety.
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57 Knowing that the psychological impact of anesthesia and surgery on children covers many areas,
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59 the presence of professional clown doctors for managing the child's anxiety during the preoperative
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phase, should be encouraged in pediatrics hospitals.

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For Peer Review

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

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3-4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	3
Participants	4a	Eligibility criteria for participants	3
	4b	Settings and locations where the data were collected	3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4-5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	4
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
Allocation concealment mechanism	9	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	4-5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4-5

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3	tion			
4	Blinding	11	If done, who was blinded after assignment to interventions (for example,	5
5		a	participants, care providers, those assessing outcomes) and how	
6		11	If relevant, description of the similarity of interventions	-
7		b		
8	Statistical	12	Statistical methods used to compare groups for primary and secondary	6
9	methods	a	outcomes	
10		12	Methods for additional analyses, such as subgroup analyses and adjusted	-
11		b	analyses	
12				
13				
14	Results			
15	Participant	13	For each group, the numbers of participants who were randomly assigned,	7
16	flow (a	a	received intended treatment, and were analysed for the primary outcome	
17	diagram is	13	For each group, losses and exclusions after randomisation, together with	-
18	strongly	b	reasons	
19	recommend			
20	ed)			
21	Recruitment	14	Dates defining the periods of recruitment and follow-up	7
22		a		
23		14	Why the trial ended or was stopped	-
24		b		
25	Baseline	15	A table showing baseline demographic and clinical characteristics for each	Table 1 -
26	data		group	2
27	Numbers	16	For each group, number of participants (denominator) included in each	7
28	analysed		analysis and whether the analysis was by original assigned groups	
29	Outcomes	17	For each primary and secondary outcome, results for each group, and the	Table 3
30	and	a	estimated effect size and its precision (such as 95% confidence interval)	
31	estimation	17	For binary outcomes, presentation of both absolute and relative effect	-
32		b	sizes is recommended	
33	Ancillary	18	Results of any other analyses performed, including subgroup analyses	7-8
34	analyses		and adjusted analyses, distinguishing pre-specified from exploratory	
35	Harms	19	All important harms or unintended effects in each group (for specific guidance	-
36			see CONSORT for harms)	
37				
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39	Discussion			
40	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if	13
41			relevant, multiplicity of analyses	
42	Generalisab	21	Generalisability (external validity, applicability) of the trial findings	13
43	ility			
44	Interpretatio	22	Interpretation consistent with results, balancing benefits and harms, and	13
45	n		considering other relevant evidence	
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47				
48	Other information			
49	Registration	23	Registration number and name of trial registry	-
50	Protocol	24	Where the full trial protocol can be accessed, if available	-
51	Funding	25	Sources of funding and other support (such as supply of drugs), role of	-
52			funders	

*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

CONSORT 2010 Flow Diagram

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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=)

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=)

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60**TABLE 1.** Surgical Procedures in the 3 Groups

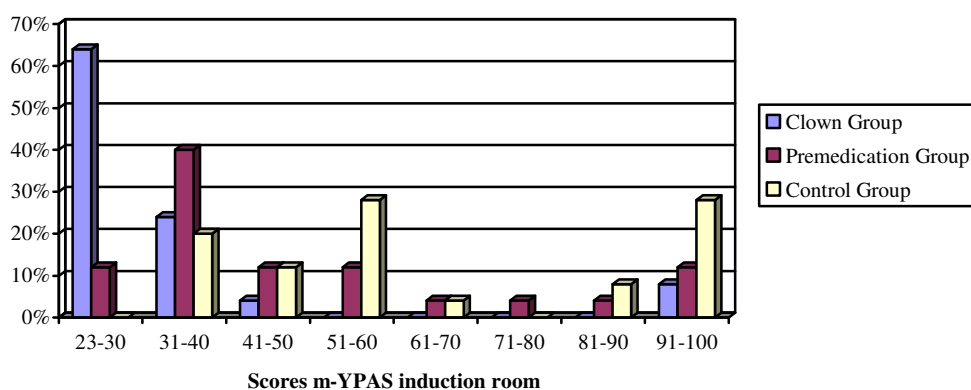
	Clown Group <i>n</i> (%) (<i>N</i> = 25)	Premedication Group <i>n</i> (%) (<i>N</i> = 25)	Control Group <i>n</i> (%) (<i>N</i> = 25)
Adenoids	6 (24)	3 (12)	-
Strabismus	4 (16)	3 (12)	4 (16)
Cyst	-	3 (12)	3 (12)
Inguinal hernia	3 (12)	4 (16)	7 (28)
Phimosis	-	2 (8)	-
Hydrocoele	2 (8)	3 (12)	4 (16)
Hypospadias	3 (12)	2 (8)	-
Reflux	3 (12)	-	2 (8)
Retained testicle	2 (8)	5 (20)	2 (8)
Varicocele	2 (8)	-	3 (12)

TABLE 2. Demographics of the Study Participants and their Parents

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

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

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

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