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SPECIAL ARTICLE

Clown Doctors as a Treatment for Preoperative Anxiety in Children: A Randomized, Prospective Study

Laura Vagnoli, PhD; Simona Caprilli, PhD; Arianna Robiglio, BA; and Andrea Messeri, MD

ABSTRACT. *Background.* **The induction of anesthesia is one of the most stressful moments for a child who must undergo surgery: it is estimated that 60% of children suffer anxiety in the preoperative period. Preoperative anxiety is characterized by subjective feelings of tension, apprehension, nervousness, and worry. These reactions reflect the child's fear of separation from parents and home environment, as well as of loss of control, unfamiliar routines, surgical instruments, and hospital procedures. High levels of anxiety have been identified as predictors of postoperative troubles that can persist for 6 months after the procedure. Both behavioral and pharmacologic interventions are available to treat preoperative anxiety in children.**

Objective. **The aim of this study was to investigate the effects of the presence of clowns on a child's preoperative anxiety during the induction of anesthesia and on the parent who accompanies him/her until he/she is asleep.**

Methods. **The sample was composed of 40 subjects (5–12 years of age) who had to undergo minor day surgery and were assigned randomly to the clown group (*N* = 20), in which the children were accompanied in the preoperative room by the clowns and a parent, or the control group (*N* = 20), in which the children were accompanied by only 1 of his/her parents. The anxiety of the children in the preoperative period was measured through the Modified Yale Preoperative Anxiety Scale instrument (observational behavioral checklist to measure the state anxiety of young children), and the anxiety of the parents was measured with the State-Trait Anxiety Inventory (Y-1/Y-2) instrument (self-report anxiety behavioral instrument that measures trait/baseline and state/situational anxiety in adults). In addition, a questionnaire for health professionals was developed to obtain their opinion about the presence of clowns during the induction of anesthesia, and a self-evaluation form was developed to be filled out by the clowns themselves about their interactions with the child.**

Results. **The clown group was significantly less anxious during the induction of anesthesia compared with the control group. In the control group there was an increased level of anxiety in the induction room in comparison to in the waiting room; in the clown group anxiety was not significantly different in the 2 locations. The questionnaire for health professionals indicated that the clowns were a benefit to the child, but the majority of the staff was opposed to continuing the program because of perceived interference with the procedures of the operating room. The correlation between the scores of the form to self-evaluate the effectiveness of the clowns and of the Modified Yale Preoperative Anxiety Scale is significant for both the waiting room and induction room.**

Conclusions. **This study shows that the presence of clowns during the induction of anesthesia, together with the child's parents, was an effective intervention for managing children's and parents' anxiety during the preoperative period. We would encourage the promotion of this form of distraction therapy in the treatment of children requiring surgery, but the resistance of medical personnel make it very difficult to insert this program in the activity of the operating room.** ***Pediatrics*** **2005; 116:e563–e567. URL: www.pediatrics.org/cgi/doi/10.1542/peds.2005-0466;** ***analgesia, anesthesiology, anxiety, parenting stress, psychological impact.***

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ABBREVIATIONS. OR, operating room; m-YPAS, Modified Yale Preoperative Anxiety Scale; STAI, State-Trait Anxiety Inventory.

Multiple studies, beginning in the 1970s, have shown that humor has many positive effects on physical and mental health and well-being. Previous investigations have reported that humor has beneficial effects on the immune system,[1,2] stress related to potentially fatal illnesses,[3] pain tolerance,[4] and mental functions (vigilance, memory, and anxiety).[5]

Induction of anesthesia can be a frightening event for children, and it is estimated that 60% of children suffer anxiety in the presurgical period.[6] Therefore, we designed this randomized study to investigate if the presence of clowns is able to reduce preoperative anxiety in children who must undergo minor surgery.

METHODS

Patients

Children who underwent general anesthesia for minor surgery were considered eligible for the study. The sample examined was composed of 40 randomly assigned consecutive children who were 5 to 12 years old, American Society of Anesthesiology risk level I-II, residents of Florence, Italy, and the immediate surroundings, and underwent minor day surgery at Anna Meyer Children's Hospital in Florence.

The data were collected from June to December 2003.

The sample consisted of Italian children to avoid any misinterpretation of the evaluation instruments used. Children with a history of chronic illness or premature birth were excluded from this study. Children who received any premedication were excluded to avoid the influence of the medication on their behavior. Also, children with previous anesthetic experience were excluded. Subjects were chosen from a population of children who under-

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TABLE 1. Questionnaire for the Medical Staff

1. What do you think about the presence of the clowns in the preoperative room during the induction? Place a cross next to the one that you prefer.
   1. Very favorable
   2. Favorable
   3. Indifferent
   4. Contrary
   5. Very contrary
2. In your opinion, this activity is useful for the
   Child
      Yes
      No
      I don't know
   Parents
      Yes
      No
      I don't know
   Staff
      Yes
      No
      I don't know
3. Do you feel the clowns are a disturbance in the OR?
   Yes
   No
   Sometimes
4. Are you favorable to continue the activity of the clowns in the OR?
   Yes
   No

went minor day surgery, so we drew lots among children who were present each morning in the surgery ward.

Anesthesia was administered by pediatric anesthesiologists. The study protocol was approved by the hospital ethics committee, and consent was obtained from parents before inclusion of their child in the study.

The goals of the study were to determine (1) the influence of a clown on the preoperative anxiety of the child and on the anxiety the parent present during the induction of anesthesia, (2) the reaction of the medical staff about having a clown present in the operating room (OR), and (3) the perception of the clowns about their interaction with the children.

Study Groups

Patients were assigned to 1 of 2 study groups: (1) a clown group, in which children interacted with clowns before entering the OR and stayed with them and their parent throughout the anesthesia-induction process or (2) a control group, which was composed of children accompanied only by a parent, with no other distractions.

In both groups the child chose the parent who waited with him or her in the waiting room and induction room during the induction of anesthesia. The age of the child was recorded so that the child's anxiety could be assessed with regard to this variable.[6,7,8] Anesthesia was induced through a scented mask using a standardized oxygen/nitrous oxide/sevoflurane technique.

In the clown group, a pair of clowns spent time with the child in the preoperative room. The clowns arrived ~30 minutes before the child went to the OR and stayed with him or her for ~15 minutes.

The clowns used various methods for entertaining the child according to the child's age (eg, magic tricks, gags, music, games, puppets, word games, soap bubbles, etc). When the nurse took the child to the OR, the clowns accompanied the child and the parent to the induction room and stayed during the anesthesia-induction process.

Evaluation Instruments

Modified Yale Preoperative Anxiety Scale

The Modified Yale Preoperative Anxiety Scale (m-YPAS) was used to evaluate the behavior of the child in the waiting room and the induction room. It is an observational behavioral checklist developed by Kain et al[9] to measure the state anxiety of young children. It contains 22 items in 5 categories: activity, emotional expressivity, state of arousal, vocalization, and use of parents. Each category receives a score on a scale of 4 (6 for vocalization) according to the behavior of the patient. This scale has good-to-excellent reliability and validity for measuring children's anxiety in the preoperative holding area and during induction of anesthesia.[9] For our study the coding method was translated from English to Italian.

State-Trait Anxiety Inventory

The State-Trait Anxiety Inventory (STAI) self-report anxiety behavioral instrument consists of 2 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 (ie, differences in the tendency to experience anxiety), and the STAI state subscale measures transitory anxiety state (ie, subjective feelings of apprehension, tension, and worry that vary in intensity and fluctuate based on the situation).

Parents respond 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,[10] with the table to calculate the score according to the Italian standard version.[11]

Questionnaire for Health Professionals

This questionnaire (Table 1) was developed to obtain the health professionals' opinion of the presence of clowns during the induction of anesthesia and to determine if they are useful in reducing anxiety.

Clown Effectiveness Self-Evaluation Form

This form was filled out by the clowns themselves about their interaction with the child in 3 periods: on the ward, in the preoperative waiting room, and during the induction of anesthesia. It contains 4 items indicating participation of the clowns: looked interested, participated, reacted positively, and smiled. The score is on a scale of 5 (Table 2).

Data Analysis

The m-YPAS was completed during the preoperative period by 2 psychologist observers who were present during the whole process. The parent present during the induction of anesthesia completed the STAI (Y-1/Y-2) during the child's operation. We decided to measure the trait and state anxiety on the day of the surgery to avoid organization problems in keeping contact with the families, although the trait anxiety is supposed to be a stable measure.

At the end of the induction process, nurses ($n = 9$), anesthetists ($n = 8$), and surgeons ($n = 9$) filled out the questionnaire concerning the value of the presence of clowns in the OR, and the clowns ($n = 12$) filled out the self-effectiveness form to evaluate their own activity.

TABLE 2. Assessment Report on the Efficacy of the Interaction of the Clowns

	For Nothing	A Little	Enough	A Lot	Very Much
The child					
Looked interested	1	2	3	4	5
Participated	1	2	3	4	5
Reacted positively	1	2	3	4	5
Smiled	1	2	3	4	5

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Data were analyzed with the use of SPSS 11.0 for Windows (SPSS Inc, Chicago, IL). $P < .05$ was considered significant.

The analysis of the statistics was done through a verification of agreement between 2 observers codifying the data of m-YPAS with Cohen's κ calculation. Descriptive statistics provide an overview of the relationships between child and parent variables and the children's and parents' anxiety levels. Data are presented as mean ± SD.

One-way analysis of variance was used to compare the scores on the anxiety level obtained by the 2 groups with m-YPAS in the waiting room and the induction room to determine if there is a significant difference between the average of the 2 groups. The same statistical analysis was done for the scores of the level of state (STAI Y-1) and trait anxiety (STAI Y-2) obtained by the parents present during the induction of anesthesia.

To establish a significant difference between the anxiety level of children within the same group in the 2 different surgery rooms, a repeated-measures analysis of variance (within-subjects factors) was used for both groups.

The questionnaires and the forms for self-evaluation of the effectiveness of the clowns were analyzed with descriptive statistics. To appraise the reliability as inside coherence (interitem consistency) of the form to self-evaluate the effectiveness of clowns or the degree of correlation among the items of the scale, Chronbach's α coefficient was used.

The association between the demographic characteristics was examined by using Pearson's correlation coefficient (r). The variables correlated for both groups with the anxiety level of the child were (1) age of the child and (2) anxiety of the parents. The correlation was also calculated within the groups, correlating the scores of the waiting room and induction room.

RESULTS

The agreement between the 2 observers who codified the data (Cohen's κ for every category m-YPAS and for both the preoperative rooms) gave broadly significant results, with values between .86 and .98.

The demographic and clinical characteristic of the 2 groups of children and parents are presented in Tables 3 and 4. There were no significant differences between the 2 groups in these data; only the ratio of mothers to fathers is significantly different; there were more mothers than fathers that stayed with the children during the induction of anesthesia.

The primary end point was the anxiety of the child assessed by the m-YPAS. Analysis of the data indicates that the anxiety of the child was significantly less in the clown group [$F(1,38) = 14\,896$; $P = .001$] compared with the control group during the induction of anesthesia. There was no effect of presence of the clown on parental anxiety or on anxiety of the child in the waiting room (Table 5).

In the control group there was an increased level of anxiety in the induction room in comparison to the waiting room [$F(1,19) = 21\,253$; $P = .001$], unlike in the clown group, for which anxiety was not significantly different in the 2 locations (Table 5).

The correlation between the scores obtained with m-YPAS within the group in the waiting and induction rooms was not significant in the control group, but it was in the clown group ($r = 0.93$; $P < .001$). The highest m-YPAS score during each time period observed, in the waiting room and in the induction room, for each group is shown in Table 5.

There was no significant difference between the average score of the STAI (Y-1/Y-2) obtained by the parents of the 2 groups, even if lower in the parents of the children in the clown group. The correlations between the anxiety level of the children and their age and between the anxiety level of the child and the parents were not significant. Correlation doesn't exist between anxiety of parent and demographic characteristics.

The evaluation of the clown's intervention concerned only the clown group ($N = 20$). For the forms for self-evaluation of the effectiveness of the clowns, the reliability is broadly satisfactory: $\alpha = .90$ for the forms evaluating the interventions performed in the ward; $\alpha = .92$ for those in the waiting room; and $\alpha = .90$ for those in the induction room. We can affirm that the items are homogeneous and extend to measure the same construction. We also obtained descriptive statistics (Table 6) and calculated the correlation between the scores of the form to evaluate the self-effectiveness of the clowns and those of the m-YPAS; the correlation is significant for both the waiting room ($r = 0.83$; $P < .001$) and the induction room ($r = 0.77$; $P < .001$).

The results of the health professionals' questionnaire are shown in Tables 7 and 8. Although acknowledging the benefit of the clowns to the child, a majority of the staff was opposed to continuing the program because of perceived interference with the procedures in the OR.

TABLE 3. Surgical Procedures in the 2 Groups

	Clown Group, n (%) ($N = 20$)	Control Group, n (%) ($N = 20$)
Adenoids	—	6 (30)
Strabismus	3 (15)	3 (15)
Cyst	1 (5)	—
Inguinal hernia	6 (30)	2 (10)
Phimosis	1 (5)	1 (5)
Hydrocoele	3 (15)	1 (5)
Hypospadias	2 (10)	3 (15)
Reflux	1 (5)	1 (5)
Retained testicle	2 (10)	2 (10)
Varicocele	1 (5)	1 (5)

TABLE 4. Demographics of the Study Sample

Variable	Control Group	Clown Group	P
N	20	20	
Age of the child, y, mean ± SD	7.30 ± 2.72	6.85 ± 2.21	.569
Gender, male/female	75/25	70/30	.723
Parent, mother/father	75/25	100/0	.017
Age of the parent, y, mean ± SD	35.7 ± 5.26	36.6 ± 3.89	.543

DISCUSSION

Literature regarding humor in the hospital wards across various age levels shows that not only do patients and medical staff benefit by humor, but hospital personnel interaction with the patients promotes an atmosphere in which laughter and humor are appreciated.[12,13]

In pediatrics, humor is more and more present in the hospital through use of clowns: professional clown doctors began working in hospitals in 1986 under a program called the Big Apple Circus Clown Care Unit, which was started by Michael Christensen

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TABLE 5. Intervention Outcome Variables (Mean ± SD)

Variable	Control Group	Clown Group	*P*
Anxiety of the child in the waiting room (m-YPAS)	35.95 ± 15.64	30.95 ± 11.34	.254
Anxiety of the child in the induction room (m-YPAS)	68.25 ± 28.42	37.50 ± 21.48	.000
State anxiety of the parent (STAI Y-1)	77.85 ± 19.19	73.10 ± 24.96	.504
Trait anxiety of the parent (STAI Y-2)	53.25 ± 24.39	41.45 ± 22.11	.117

TABLE 6. Clown Self-Evaluation (Means ± SD)

Variable	Ward	Waiting Room	Induction Room
N	20	20	20
The child			
Looked interested	3.75 ± 0.851	3.45 ± 0.759	3.5 ± 1.040
Participated	3.90 ± 1.031	3.55 ± 0.999	3.25 ± 1.164
Reacted positively	3.90 ± 0.951	3.70 ± 0.979	3.65 ± 1.089
Smiled	3.80 ± 0.951	3.25 ± 1.070	2.45 ± 1.191
Total	15.15 ± 3.249	13.95 ± 3.456	12.50 ± 4.046

TABLE 7. Results of the Questionnaire for Health Professionals

1. Level of appreciation for the presence of clowns during the anesthesia induction, %	
Very favorable	8
Favorable	36
Indifferent	28
Contrary	16
Very contrary	12
2. This activity is useful for	
Child, *n*	
Yes	78
No	6
I don't know	6
Parents, *n*	20
Yes	40
No	40
I don't know	18
Staff, *n*	52
Yes	30
No	
I don't know	
3. Clowns are a disturbance in the OR, %	
Yes	20
No	16
Sometimes	64
4. I am favorable with the activity continuing in the OR, %	
Yes	28
No	72

in New York City. Clown doctor programs now operate in many countries all over the world.[14,15]

Various factors influence preoperative anxiety in the child: anticipation of pain, fear of separation from parents, loss of control, unfamiliar routines, hospital procedures, and surgical instruments.[16] Another important factor is given by the anxiety of the parents; several studies show that parental anxiety is directly correlated with their children's preoperative anxiety.[17–19] Several strategies have been proposed to reduce preoperative anxiety. Some strategies for managing preoperative anxiety are pharmacologic (eg, sedative premedication)[20,21]; nonpharmacologic (eg, preoperative visit to the OR)[6]; the presence of 1 of the 2 parents during the induction of anesthesia[19]; psychological preparation of the child[22,23]; and the use of music as a distraction.[24,25]

There have not been previous studies that evaluated the efficacy of clowns with respect to preoperative anxiety of children and their parents during the induction of anesthesia. In this study we found that the presence of clowns during the induction of anesthesia was an effective intervention for managing a child's anxiety during the preoperative period.

TABLE 8. Motivations of the Medical Staff Who Considered Clowns to Be a Disturbance in the OR

They delay the time of induction, *n*	8
They interfere in the relationship between the medical staff and the child, *n*	8
They make the OR more crowed , *n*	7

In our study, the experimental group was significantly less anxious compared with the control group during the induction of anesthesia. In the control group there was an increased level of anxiety in the anesthesia-induction room in comparison to the waiting room.

The children who interacted with the clowns maintained the same degree of anxiety in the induction room that was shown in the waiting room. Our data are in agreement with previous works that showed the influence of the environment on anxiety, which results in greater anxiety in the induction room than in the waiting room.[16]

In contrast with previous studies,[7,26,27] a correlation was not found between the level of anxiety of the child and either the child's age or the level of anxiety of parents in either the clown group or control group. Previous studies identified parental anxiety as a predictor of preoperative anxiety; excessive parental anxiety may contribute to increased anxiety in children, which has implications not only at the time of the operation but also after the surgery and hospitalization.[16,27] Our data did not show this relationship. The scores obtained with the STAI also pointed out slightly lower levels of anxiety in the parents in the clown group but weren't significant in the analysis of the variance. These data are different from that shown in the literature, perhaps because of the small size of our sample.

Our questionnaires show that the majority of the staff recognized the effectiveness of this technique in children, but only a small number of them were in favor of continuing the activity, because it was believed to interfere with the routine of the preoperative room. On the other hand, some health professionals who didn't consider the presence of the clowns troublesome found them to be useful for the reduction of anxiety in the children, their parents, and the medical staff, as well as for the distraction they presented during the medical procedures.

Physicians and nurses considered clowns to be a disturbance to the OR routine because they think that the clowns delay the procedures and interfere in the

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relationship between the medical personnel and the child.

In this study we didn't measure the difference between the time of induction with and without clowns, so we do not have any information at this time to determine whether the perceived delay is in fact a significant delay in terms of OR function. If the perceived delay is not a significant delay, is it possible that some physicians see the clowns as impinging on their authority in the OR? Additional study will be necessary to answer this question. Since the waiting time, especially in day surgery, is considered to be a predictor of elevated levels of anxiety,[6,8] it would be interesting to expand on this aspect.

CONCLUSIONS

We found that the presence of clowns during the induction of anesthesia, together with one of the child's parents, was an effective intervention for managing child and parent anxiety during the preoperative period. We would encourage the promotion of this form of distraction therapy for children requiring surgery. The resistance of medical personnel to this kind of therapy could be dealt with better by providing information regarding the benefit of the therapy to the children and by investigating whether the presence of clowns during anesthesia induction slows the process in a significant manner.

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