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Clowns for the prevention of preoperative anxiety in children: a randomized controlled trial

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Summary

Objective: To determine if specially trained professional clowns allayed preoperative anxiety and resulted in a smooth anesthetic induction compared to the use of midazolam or no intervention.
Methods: This was a randomized, controlled, and blinded study conducted with children 3–8 years of age undergoing general anesthesia and elective outpatient surgery. Patients were assigned to one of three groups: Group 1 did not receive midazolam or clown presence; group 2 received 0.5 $mg \cdot kg^{-1}$ oral midazolam 30 min before surgery up to a maximum of 15 mg; and group 3 had two specially trained clowns present upon arrival to the preoperative holding area and throughout operating room (OR) entrance and mask application for inhalation induction of anesthesia. The children were videotaped for later grading.
Results: The clown group had a statistically significant lower modified-Yale Preoperative Anxiety Scale score in the preoperative holding area compared to the control and midazolam group. The clowns' effect on anxiety reduction continued when the children entered the OR but was equal at this point to the midazolam group. Upon application of the anesthesia mask no significant differences were detected between the groups.
Conclusions: This study found that the use of preoperative medically trained clowns for children undergoing surgery can significantly alleviate preoperative anxiety. However, clowns do not have any effect once the anesthesia mask is introduced.

Keywords: clowns; perioperative anxiety; pediatric surgery

Introduction

The perioperative environment, often anxiety-provoking for adults, may be quite frightening for children. Anxiety during induction of anesthesia is correlated with increased distress in the postoperative period (1–4). Many preoperative systems allow parental, pharmacologic, and anticipatory interventions to facilitate a relaxed perioperative environment for children.

Unfortunately, scheduling conflicts, side effects, and limited resources conspire to limit their usefulness. For example, only 10% of respondents in a

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recent survey used parental presence during induction of anesthesia for a majority of their patients (5). This may be due to the belief by some that parental anxiety may in fact increase children's anxiety (6). According to the same survey, only 50% of children undergoing surgery receive sedating premedication (5). Distraction techniques, such as the use of toys or video games, may also decrease perioperative anxiety (7,8), however their effectiveness during induction of anesthesia is not well characterized (9,10). The efficacy of toys and video games is somewhat dependent upon the child reaching certain developmental milestones. Anesthesiologists continue to search for an easy and comprehensive method for anxiety reduction in the pediatric surgical population. We propose that specially trained professional clowns may allay preoperative anxiety and result in a smooth anesthetic induction.

Material and methods

This randomized, controlled study was conducted with children undergoing general anesthesia and elective outpatient surgery. Consecutive patients aged 3–8 years of age, ASA physical status I–II, scheduled to undergo general anesthesia and elective outpatient surgery were considered for enrollment. Children were excluded from participation if they had a history of previous anesthesia or chronic illness, prematurity, developmental delay, or significant hearing or visual impairments. The Institutional Review Board approved the study protocol, and informed consent was obtained from the parents of each child.

Children's parents were present in the preoperative holding area, during entrance to the operating room (OR), and during mask application. Children and parents remained in private areas within the ambulatory surgery unit before transfer to the OR. Parents were given descriptions of what to expect when they entered the OR and were dressed in appropriate OR attire while in the ambulatory surgery unit.

The primary end-point of this study was the anxiety manifested by children during the induction of anesthesia. During enrollment, the potential clown involvement was explained to parents; of course, if the parents were concerned about potential fear of clowns (coulrophobia), the parents were free to decline participation. Patients were assigned to one of three groups by using computer-generated random assignment: Group 1 (N = 22) children did not receive midazolam or clown presence; group 2 (N = 22) children received 0.5 $mg \cdot kg^{-1}$ oral midazolam 30 min before surgery up to a maximum of 15 mg; and group 3 (N = 21) children had two specially trained clowns present upon arrival to the preoperative holding area and throughout OR entrance and mask application for inhalation induction of anesthesia.

The clown intervention and distraction techniques were semi-structured; they began in the holding area and lasted for approximately 20–30 min. All variation in session length was due to OR timing constraints. The clowns used various methods for entertaining the child according to the child's age (e.g. magic tricks, gags, music, games, puppets, word games, bubbles) The clowns then accompanied each child into the OR and stayed until the anesthetic induction was complete. The clowns were women of middle age who had received specific training involving pediatric distraction techniques with at least 5 years experience. Two clowns were sufficient to provide distraction for the study's entirety.

Each child was videotaped at three different locations: the preoperative holding area, entrance to the OR, and during application of the anesthesia mask. Videos were edited into three separate 2-min clips, coded, and then randomly presented to the evaluators. Every effort was made to keep the clowns out of the video, however clowns were visible in less than 10% of the video clip collection. Likewise, the film clips were not edited to remove frames demonstrating instability in children receiving preoperative midazolam.

Evaluators were trained by using videotapes of children undergoing the induction of anesthesia to reliably measure children's anxiety using the modified Yale Preoperative Anxiety Scale (m-YPAS). The evaluators were blinded to both the study's design and hypothesis. All children in the study were videotaped in the holding area until the induction of anesthesia. These blinded evaluators then used the videotapes to rate children's anxiety for this study. The same evaluator ranked the child's anxiety at the various time points.

The m-YPAS (11), an observational instrument, quantifies children's anxiety in the preoperative area and during the induction of anesthesia. The instrument distributes 27 items into five categories that suggest preoperative anxiety in children: activity, emotional expressivity, state of arousal, vocalization, and use of parents. The m-YPAS has good-to-excellent reliability and validity (12). The State-Trait Anxiety Inventory (STAI), a self-reportable anxiety inventory, contains two separate 20-item subscales that measure trait (baseline) and state (situational) anxiety. It has been used in more than 1000 studies published in peer-reviewed literature (13). After recruitment and informed consent, demographic data were collected and the STAI test was administered to each child's parents. Parental anxiety was also assessed after the separation process using the STAI test.

Anesthesia was induced with oxygen and nitrous oxide, and incremental doses of sevoflurane administered via a scented mask. Videotaping of all children continued throughout the induction of anesthesia to facilitate anxiety (m-YPAS) ratings while maintaining the blinding of the evaluators. The parents were escorted out of the OR following mask induction.

Trained evaluators who were blinded to the study's design, purpose, and group assignments rated the videotapes. Although the clowns were occasionally visible in the videotapes, we believe that the effect on the evaluators who were blinded to the purpose of the study was negligible. A series of multivariate analyses of variance (MANOVA) were carried out for each m-YPAS scale and a total score. For each MANOVA, the three scores (waiting room, OR entry, and application of the anesthesia mask) were treated as a within-subject repeated measure and treatment (control, drug, clown) as a between-subject variable. Data are reported as mean ± standard deviation. Significance was accepted at $P \leq 0.05$. Data were analyzed with SPSS 14.0 (SPSS Inc., Chicago, IL, USA).

Results

The average age was 4.5 years (range 3–8 years). The three groups were similar with regard to age, sex, type of surgery, and parental anxiety state and trait. The clown group had a statistically significant lower m-YPAS score in the preoperative holding area compared to the control group. The clowns' effect on anxiety reduction continued when the children entered the OR, but equal at this point to the midazolam group. Upon application of the anesthesia mask no significant differences were detected between the groups (Table 1). In all groups there was a trend towards elevation of anxiety levels from preoperative holding area to OR entry and to application of the anesthesia face mask. However, at application of the mask, the clown group had the largest increase in m-YPAS score, which surpassed other groups' m-YPAS scores (Figure 1).

Table 1
m-YPAS between groups in different time points

Time	*Group*	*m-YPAS (mean ± SD)*
Preoperative holding area	Control	38.4 ± 12.7
	Midazolam	35.7 ± 11.8
	Clowns	28.3 ± 4.6[a]
Entrance to OR	Control	50.0 ± 17.4
	Midazolam	42.0 ± 10.6
	Clowns	37.3 ± 12.3[b]
Application of mask	Control	54.4 ± 21.6
	Midazolam	49.9 ± 16.0
	Clowns	62.7 ± 14.6

OR, operating room; SD, standard deviation.
[a]$P = 0.01$ when compared to control group (ANOVA).
[b]$P = 0.005$ when compared to control group (ANOVA).

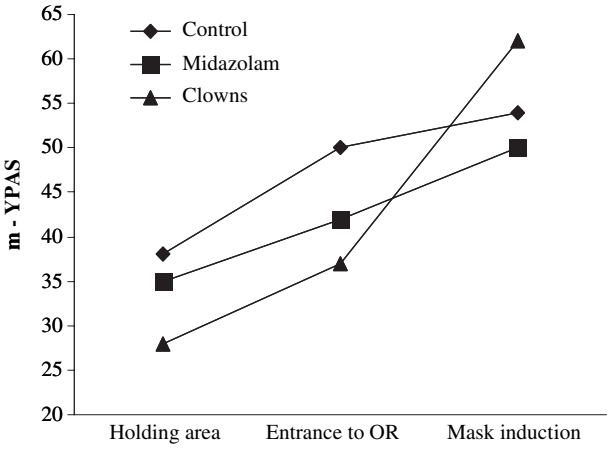

Figure 1
Changes in children's perioperative anxiety (modified Yale Preoperative Anxiety Scale; m-YPAS) for the different groups. Data are reported as mean m-YPAS at different locations.

Discussion

Literature regarding humor in the hospital wards across various age levels shows that not only do patients and medical staff benefit from humor, but interactions involving humor between hospital personnel and patients promote an atmosphere in which laughter and humor self-perpetuate. Other investigations report that humor has beneficial effects on stress related terminal illnesses (14), pain tolerance (15), and mental functions such as memory and anxiety (16). In pediatrics, humor is increasingly 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. Started by Michael Christensen in New York City, clown doctor programs now operate in many countries all over the world (17,18).

Fear of clowns could theoretically have a negative effect on this method of anxiety alleviation. However, we did not encounter the problem in any of our patients. This study shows that the presence of trained clowns significantly reduces the preoperative anxiety in children while waiting for anesthesia and surgery. This positive effect continues when the children are escorted to the operating room. Trained clowns clinically and statistically outperform oral midazolam towards this end. Unfortunately, once the anesthetic mask is applied to their face, the level of anxiety in the children accompanied by clowns peaks and is greater than the anxiety found in children receiving either oral midazolam or no intervention. There is only one previous study involving clowns for anxiolysis in children (19), which found that clown are beneficial in reducing anxiety in children during induction of anesthesia. In that study however, the medical team took part in the interventions as clowns, and the interventions were not blinded.

In conclusion, this study found that the use of preoperative medically trained clowns for children undergoing surgery can significantly alleviate preoperative anxiety. However, the effect that was less evident on entrance to the OR and on introduction of the anesthesia mask. These data seem to indicate that such an intervention should be either limited to the preoperative period, or that further training is required before this modality can be used in the OR.

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Conflict of interest

The authors have no conflicts of interest.

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