Parental Presence during Induction of Anesthesia
A Randomized Controlled Trial

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Background: To determine whether parental presence during induction of anesthesia is an effective preoperative behavioral intervention, a randomized controlled trial with children undergoing outpatient surgery was conducted.

Methods: Eighty-four children were randomly assigned to a parent-present or parent-absent group. Using multiple behavioral and physiologic measures of anxiety, the effect of the intervention on the children and their parents was assessed. Predictors for the response to the intervention were examined using multivariate linear regression analysis.

Results: When the intervention group (parent-present) was compared to the control group (parent-absent), overall there were no significant differences in any of the behavioral or physiologic measures of anxiety tested during induction of anesthesia. Using the child's serum cortisol concentration as the outcome, parental presence, the child's age and baseline temperament, and trait anxiety of the parent, were identified as predictors of the child's anxiety during induction. Analysis of variance demonstrated that three groups showed diminished cortisol concentrations with parental presence: children older than 4 yr (P = 0.001), children whose parent had a low trait anxiety (P = 0.02), and children who had a low baseline level of activity as assessed by temperament (P = 0.05).

Conclusions: Children who were older than 4 yr or those with a parent with a low trait anxiety or who had a low baseline level of activity/temperament benefited from parental presence during induction. (Key words: Anesthesia, pediatric; general; induction; parental presence.)

PARENTAL PRESENCE DURING INDUCTION OF GENERAL ANESTHESIA

Data regarding parental presence tools are elicit:

- E.A.S.I (Emotional Availability Scale Instrument)
- Yale Preoperative Anxiety Scale
- Post Hospital Behavior Questionnaire (PHBQ)
- Clinical Anxiety Assessment Scale
- State Trait Anxiety Inventory

A total of sixty-five completed forms were completed for trained observer by children undergoing surgery and the CARSA tool.

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Materials and Methods

In this randomized controlled trial, the study population consisted of 84 children aged 1–6 yr who were randomly assigned to parent-absent (control) or parent-present (intervention) groups. All subjects (ASA physical status 1 or 2) underwent surgery and general anesthesia at Yale-New Haven Hospital. The variables, any history of illness or injury, chronic illness, and other factors that might influence the outcome were controlled. Subjects were premedicated with oral diazepam of day (morning) and their parents in normal hospital clothing. Premedication was given to the subject and all accompanying family members and the Institution's informed consent was obtained.

Behavioral and Physiologic Measures

Data regarding parental presence tools are elicit:

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ical status 1 or 2) underwent elective outpatient surgery and general anesthesia at the Children’s Hospital at Yale-New Haven. To avoid potential confounding variables, any history of previous surgery, hospitalization, chronic illness, or developmental delay excluded subjects from participation in this study. All inductions were performed in an induction room at the same time of day (morning) with the parents dressed in their own clothing. Premedication was not administered to any subject and all inductions were performed by a single attending anesthesiologist. The study was approved by the Institutional Review Board and written informed consent was obtained from the parents.

Behavioral and Physiologic Assessments

Data regarding the following behavioral assessment tools are elucidated in the Appendix.

- E.A.S-I (Emotionality, Activity, Sociability, Impulsivity) Instrument of child temperament
- Yale Preoperative Anxiety Scale (YPAS)
- Post Hospitalization Behavior Questionnaire (PHBQ)
- Clinical Anxiety Rating Scale (CARS)
- State Trait Anxiety Inventory (STAI)
- Anxiety Visual Analog Scale (VAS)

A total of six behavioral tools were used, the parents completed four tools, the STAI, EASI, VAS, and PHBQ; trained observers completed three tools, the VAS, YPAS, and the CARS. A developmentalist, a psychologist, and an anesthesiologist served as observers and administered the various observational assessments. Interoobserver agreement among these three observers were measured in a previous investigation; for a sample of 58 preschool children the agreement ranged from 0.66 to 0.98 for the YPAS, VAS, and the CARS.

Corollary analysis was done as follows: after obtaining the subjects’ blood each sample was transferred immediately into a precooled tube containing heparin. After gentle mixing, the blood was centrifuged at 4,000 RPM for 2 min and the plasma stored at −70°C. Plasma cortisol concentration was determined in duplicate using radioimmunoassay kits from Diagnostic System Laboratories (Webster, TX). Samples were determined in a single large batch, duplicates agreed within 15%, and quality assessment samples were well within the manufacturer’s defined range.

Study Protocol

All subjects were recruited 1 week before surgery while the children were undergoing a behavioral preoperative preparation program. The program consists of providing information to the child and parent, an orientation tour of the operating room and postanesthesia care unit and modeling using dolls by child-life specialists as related to the specific surgery planned for the child. This is done on an individual basis and was modified based on the age of the child. After recruitment, demographic data including birth order, number of siblings, parental education, temperament of the child (EASI), behavior of the child in previous medical encounters (VAS), and trait anxiety of the parent (STAI) were obtained (fig. 1). Also, baseline heart rate and blood pressure were measured in all parents of subjects.

Day of Surgery, Preoperative Holding Area. The anxiety of both the child and parent were rated by an independent “blinded observer” using the VAS. Parents also were asked to rate their subjective levels of anxiety using a self-report VAS. Next, subjects were randomly assigned to a parent-absent group (control) or a parent-present group (intervention). The randomization was done using a computer-generated random numbers table.

Day of Surgery, Induction Room. Anesthesia was induced using oxygen/nitrous oxide and halothane administered via a scented mask. All inductions were videotaped to facilitate later independent assessments of the observational scales. Child’s anxiety (YPAS, CARS) and cooperation (VAS), during induction were assessed using the videotapes by three independent observers (e.g., each observer rated the videotapes using one behavioral measure only). The rating was done at two points: (1) on entrance to the induction room, and (2) during introduction of the anesthesia mask to the child. As soon as anesthesia was induced, the parents were accompanied to the waiting area and asked to rate their situational anxiety (STAI) level and an investigator measured their blood pressure and heart rate. Similarly, the attending anesthesiologist’s blood pressure and heart rate were recorded. Immediately after the insertion of an intravenous cannula, a 2-ml sample of blood was withdrawn from each subject for serum cortisol analysis. Adverse effects, such as laryngospasm were noted and duration of induction was recorded (for the purpose of this study, the duration of induction was defined as the time from entering the room until loss of con-
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acquired in our patient population developed parental anxiety. After eliminating all confounders and variables from the model, with three significant predictor variables, we performed a regression analysis with Tukey's post hoc test for multiple comparisons. The significance level for the analysis of variance test has a correction for multiple comparisons.

Results

Demographics

Eighty-four subjects were included in the study. There were no significant differences between the control group and the intervention group regarding gender, age, or anxiety score. A detailed analysis revealed no significant differences in anxiety categories between the two groups and the intervention groups.

Table 1. Demographic Characteristics

Statistical Analysis

The sample size was based on a preliminary investigation and was calculated based on the study's significance level. The data were analyzed using inferential statistics, including t tests (for an overall perspective on the likelihood of intervention and control). Mann-Whitney U tests (i.e., for the case of skewed data), stepwise multiple regression (to determine which of the predictors is the most significant predictor based on our data), and analysis of variance with Tukey's post hoc test for multiple comparisons (to localize the effect when interactions were identified in the stepwise regression model).

To better understand whether certain children benefit from parental presence, we developed a stepwise multiple regression model to test for interaction effects between parental presence and several possible predictors of anxiety. The predictors that were considered included variables suggested in the literature and some

sciences occurred). After the induction, the anesthesiologist was asked to rate his own situational anxiety (STAI) level and to complete a questionnaire rating the helpfulness of the parents.

Day of Surgery, Recovery Room. Incidence of adverse effects, time to discharge, sedative requirements, time to first voiding and amount of fluid intake was recorded. Parents also were asked to rate their helpfulness to the child during induction and their satisfaction with nursing, anesthesia, and surgical staff. The rating was done using a VAS scale that ranged from "not satisfied" (score of 0) to "extremely satisfied" (score of 100).

Two Weeks and Six Months after the Operation. The parent completed the PHBQ and returned it by mail. At 2 weeks after surgery, completed questionnaires were received from 78 subjects (92.8%) after three mailings. At 6 months, the response rate was 73.8% (62 of 82) after three mailings. To assess the "nonresponse bias," a sample of 33.3% (2 of 6) of parents who did not respond at 2 weeks and 22.7% (5 of 22) of parents who did not respond at 6 months were contacted by telephone and a PHBQ interview was conducted to ensure the validity of the results. The nonresponse PHBQ interview for 2 weeks and 6 months indicated that the nonresponders did not differ significantly from the responders either in the prevalence of behavioral changes or in the types of behavioral changes. Also, demographics of nonresponders was similar to that of the responders.
acquired in our practice to affect the response of the child to parental presence during induction of anesthesia. After eliminating the statistically insignificant variables from the stepwise regression, we were left with three significant interactions. To localize the effects, we performed three two-factor analyses of variance with Tukey’s procedure, using the child’s anxiety (cortisol concentration) as the outcome, and parental presence as one factor. Owing to multiplicity of comparisons, significance was accepted at the 0.016 level for the analyses of variance. The post hoc Tukey’s test has a correction built in to the algorithm to account for multiple comparisons.

Results

Demographics and Univariate Analysis

Eighty-four subjects were entered into this study. There were no significant differences between the control (parent-absent) and intervention (parent-present) groups regarding demographics such as age or baseline temperament of the child or parent (table 1). When the control group was compared to the intervention group there were no significant differences in any of the behavioral or physiologic measures tested in the holding area and during induction of anesthesia (table 2). A detailed analysis for each one of the five YPA anxiety categories failed to demonstrate any difference between the two groups. The cooperation of the control group and the intervention group as measured by a VAS also was similar (85 [67–91] vs. 89 [73–92], P = NS). All behavioral and physiologic anxiety ratings for the parents and the anesthesiologist in the preoperative holding area and during induction were likewise similar between the two groups (table 3). The length of induction did not differ between the two groups (2.6 ± 1.2 min vs. 2.8 ± 0.9, p = NS). No anesthetic complications such as laryngospasm occurred during any of the inductions and no parent demonstrated disruptive behavior or refused to leave the induction suite. In the recovery room, incidence of nausea and vomiting (23% vs. 22%, P = NS), analgesic use (21% vs. 23%, P = NS), and time to discharge (62 ± 14 min vs. 67 ± 11, P = NS) was similar for the two groups. Finally, the PBHQ score 2 weeks after surgery (83 ± 4 control vs. 83 ± 7 intervention, P = NS), and 6 months after surgery (82 ± 4 control vs. 83 ± 10 intervention, P = NS) also was similar between the two groups.

Predicting the Response to Parental Presence

To better understand whether certain children benefit from parental presence during induction, we developed a stepwise regression model to test for interaction effects between parental presence and several possible predictors of anxiety. The predictors that were considered included variables suggested in the literature and acquired in our clinical practice to affect the response of the child to parental presence during induction of anesthesia. Such variables include age and temperament of child, anxiety of the child at previous medical encounters and in the preoperative holding area, baseline and situational anxiety level of the parent in the pre-

Table 1. Demographic and Baseline Characteristics

<table>
<thead>
<tr>
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<th>Control (n = 41)</th>
<th>Intervention (n = 43)</th>
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<td>Parent’s age (yr†)†</td>
<td>30 ± 5</td>
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<td>Gender (M:F) (%)</td>
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<td>Anxiety score of previous medical encounters (VAS)*</td>
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<td>14 (8–29)</td>
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<tr>
<td>EASI†</td>
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<tr>
<td>Emotionality</td>
<td>11 ± 4</td>
<td>12 ± 4</td>
<td>NS</td>
</tr>
<tr>
<td>Activity</td>
<td>16 ± 4</td>
<td>16 ± 4</td>
<td>NS</td>
</tr>
<tr>
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<td>18 ± 3</td>
<td>18 ± 3</td>
<td>NS</td>
</tr>
<tr>
<td>Impulsivity</td>
<td>16 ± 4</td>
<td>15 ± 4</td>
<td>NS</td>
</tr>
<tr>
<td>STAI-Parent†</td>
<td>9 ± 2</td>
<td>8 ± 2</td>
<td>NS</td>
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VAS = visual analog scale, range 1–100; EASI = child’s temperament instrument; STAI = state trait anxiety inventory; NS = not significant.
* Mean ± SD.
† Mean ± SD.

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operative holding area and during induction, and situational anxiety level of the anesthesiologist. Also, demographics such as socioeconomic status of the parent, birth order, number of siblings, enrollment in daycare, and experience of the parents with previous anesthetics were considered.

After extraneous variables were eliminated from the model with child’s serum cortisol concentration as the outcome, interactions were identified between parental presence and each of the following three predictors: child’s age (T = −4.07, P = 0.001, R² = 0.25), baseline anxiety level of the parent (T = 3.04, P = 0.004, R² = 0.18), and baseline temperament (EASI-activity: T = 2.54, P = 0.014, R² = 0.15). The three interactions had a multiple R² of 0.41 (F = 3.7, P = 0.004). Analysis of variance with Tukey’s post hoc procedure was then used to localize the effects in these three cases. Results of these analyses demonstrated that serum cortisol concentration was lower in the presence of their parents for children who had a parent with low trait anxiety (lower 25% of the STAI; 71 ± 8 μg/ml vs. 116 ± 18 μg/ml, adjusted Tukey’s P = 0.02), or children who had a low baseline level of activity (lower 25% of the EASI-activity; 69 ± 7 μg/ml vs. 105 ± 14 μg/ml, adjusted Tukey’s P = 0.05). Similarly, children older than 4 yr age had lower serum cortisol concentration in the presence of their parents during induction (70 ± 5 μg/ml vs. 131 ± 22 μg/ml, adjusted Tukey’s P = 0.001). In contrast, there was a trend in children younger than 4 yr toward having higher serum cortisol concentrations if their parent was present (96 ± 32 μg/ml vs. 77 ± 26 μg/ml, unadjusted P = 0.049, adjusted Tukey’s P = 0.42).

Opinions about Parental Presence
The parents and the anesthesiologist expressed different opinions about how helpful the parents were during the induction. While most parents thought their presence made the anesthesiologist’s job easier (68%), the anesthesiologist believed this to be the case only 31% of the time. Similarly, while most (90%) parents rated themselves as being helpful to their child, the anesthesiologist rated only a minority as being helpful (12%). The overwhelming majority of parents (98%) present during induction indicated that if their child needed surgery again, they would like to be present during the induction. Parent’s satisfaction with the anesthesiologist (80 ± 41 control vs. 88 ± 34 intervention), nursing (87 ± 34 vs. 90 ± 30), and overall preoperative care (91 ± 31 vs. 90 ± 33) did not differ between the intervention and control groups.

Discussion
This study demonstrates that only children who were older than 4 yr, had a parent with a low trait anxiety level or a low baseline level of activity as assessed by temperament ratings benefited from parental presence during induction of anesthesia. In contrast, there was a trend among the anxious during the induction. We also have shown that parental presence during anesthesia, without affecting the outcomes. We found that children who had less anxiety were less anxious when their parent was present during the induction. Children who were more anxious in non-affecting situations were less anxious when their parent was present during the induction. Children who were more anxious in non-affecting situations were more anxious when their parent was present during the induction. Children who were more anxious in non-affecting situations were more anxious when their parent was present during the induction.
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<th>Anesthesiologist</th>
<th>Postinduction</th>
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<tr>
<td>Area</td>
<td>Postinduction</td>
</tr>
<tr>
<td>42 ± 7</td>
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<tr>
<td>41 ± 8</td>
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<td>6 (0-15)</td>
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<td>5 (0-14)</td>
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<td>138 ± 14</td>
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<td>138 ± 16</td>
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<td>90 ± 11</td>
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32 µg/ml vs. 77 ± 46, adjusted Tukey's P

Influence

Anesthesiologist expressed dif- ferent views on whether parental presence was important. The majority of parents thought their child’s job easier (68%), but a few (2%) considered it to be the case only for younger children. Although most (90%) parents felt that parental presence to their child, the majority of parents (98%) agreed that if their child experienced anxiety, they would like to be present during induction. Satisfactory satisfaction with the presence of the anesthesiologist (88 ± 34 inter- va l, 10 ± 30), for the majori ty of parents (98%) also agreed that if their child experienced anxiety, they would like to be present during induction. Satisfaction with the presence of the anesthesiologist (88 ± 34 inter-va l, 10 ± 30), and overall satisfaction (70 ± 33) did not differ significantly between control groups.

Younger children do not necessarily have the cognitive capacity to anticipate potential dangers or frightening situations in the induction, whereas the older child may anticipate pain and the fear of “going to sleep.”

Older children may rely on a number of coping strategies including verbal questioning and cognitive mastery (e.g., learning about heart monitors or what surgeons do) to mediate their anxiety, whereas younger children are generally more dependent during times of extreme distress on adults’ comforting interventions. It may also be that for younger children, having their parent present but unable to intervene and protect them is, in and of itself, too novel and stressful and thus, not beneficial.

Bevan et al. reported that children of anxious parents were more anxious when having a parent present during induction of anesthesia than if they were separated. Parental anxiety mediates children’s response to stressful situations such as induction of anesthesia. Parents may act as stress reducers for their children, however, parents who are themselves anxious in a given situation are less available to respond to their child’s needs and his or her signals of increasing distress. Indeed, in these instances, children’s distress may further compound parental anxiety, thus rendering the parent increasingly less able to respond effectively. Parental trait anxiety may therefore be associated with increased child’s anxiety during induction of anesthesia.

Preschool children are old enough to appreciate the unfamiliar environment of the operating room and the separation from their parents. Their ability to cognitively process aspects of psychological preparative preparation and develop effective coping strategies for dealing with their anxiety about the surgery, however, is still limited. Parental presence during induction of anesthesia has been suggested as one of the behavioral solutions for this problem. Although early studies suggested reduced anxiety and increased cooperation if parents were present during induction, more recent investigations indicate that parental presence may not always be beneficial. Furthermore, a recent preliminary report found less anxiety in preschool and school-aged children who were not accompanied by a parent during induction. Some of these contradictory results may be explained by the methodological complexity of this issue. Confounding variables such as a child’s previous hospitalization or surgery, type of anesthesia induction (mask vs. intravenous), location of induction (operating room versus induction room) and the number of anesthesiologists participating in the study must be controlled. Other variables such as baseline anxiety and the interactions between the child, parent, and anesthesiologist should be considered. Evaluating the effectiveness of parental presence as an intervention to reduce anxiety also has been hindered by the absence of a statistically valid structured instrument for assessing anxiety, such as the YAS used in the current study. Studies have been further limited by the absence of physiologic anxiety markers such as serum cortisol concentration.

In addition to validated behavioral measures, physiologic measures such as serum cortisol concentration, heart rate, and blood pressure were incorporated to evaluate the anxiety of the children and their parents. Numerous studies have demonstrated that acute psychological stress, including preoperative anxiety, is associated with increased serum cortisol concentrations. This measure also has been used extensively to study the psychological reactions of pilots to flight stressors such as flying high-performance aircraft and crew workload and landing. Ideally, the cortisol measure should be the change between baseline plasma concentrations and postinduction rather than a single value. Appropriate baseline plasma levels must be ob-

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tained in a relatively low stress atmosphere, such as at the patient’s home several days before surgery. Because of logistical limitations this was not done.

Although a previous study suggested that parental presence may result in prolonged induction of anesthesia, this was not the case in our study.22 We have shown that routine parental presence during induction of anesthesia can exist without affecting the length or safety of induction or the stress level of the anesthesiologist. This suggests that this intervention, if adopted for a select group of patients, can be used effectively in a busy practice setting.

It is important to note several important methodological issues that may limit the applicability of the results of this study to routine clinical practice. First, a single anesthesiologist administered all the anesthetics. Second, all children and their parents underwent a preoperative preparation program (see Methods) and it is possible that this program combined with a caring anesthesiologist minimized preoperative anxiety sufficiently to obviate the benefits of parental involvement. Third, all children in this study were not premedicated. Because all these variables may affect the response of the child to induction of anesthesia, the conclusions from the study should be received with caution. Finally, currently there is no “gold standard” to measure preoperative anxiety and therefore comparisons or correlations used to assess the validity of the behavioral instruments measure congruence between different tests rather than real validity. Although we have made every effort to use validated instruments to measure anxiety during induction of anesthesia, we must realize that this a limitation of the study and its conclusions. Ideally, all evaluators should be masked and unaware to the presence or absence of the parent. Surrogates could not be used because the children would obviously recognize their parents and their behavior would indicate to the evaluator the presence or absence of the parent. In addition, because the parents were an integral part of the induction we were unable to completely isolate the children from their parents while we were videotaping the induction.

In our study, parental presence was not associated with a decreased incidence of later behavioral problems. This is hardly surprising because of the short hospital exposure of our subjects. Previous investigators studied the potential value of parental presence on the emergence of negative behavioral responses and concluded that this intervention did not affect later behavioral outcomes.1,3,25,24

In conclusion, this investigation demonstrates that parental presence during induction of anesthesia is beneficial only to some children, and the individual child, parent, and anesthesiologist should be considered whenever the question of parental presence arises.

Appendix

Emotionality, Activity, Sociability, Impulsivity (EASI). Instrument of child temperament. Temperament refers to an individual patterns of behaviors and responses to daily events and is closely akin to “personality.” This instrument includes 20 items in four behavioral categories: emotionality, activity, sociability, and impulsivity.26 The rating scale ranges from 0 to 5 for each category with higher scores indicating higher baseline emotionality, activity, sociability, or impulsivity. The instrument has good validity (r = 0.77) when compared against other measures of temperament for preschool children.25,26 Test-retest reliability of the EASI was 0.85 when mothers were rating their preschool children on adjacent months.25,26

Yale Preoperative Anxiety Scale (YPAS). This observational measure of preoperative anxiety was developed and validated in an investigation involving 58 preschool children. The YPAS consists of 27 items in five categories of behavior indicating anxiety in young children (Activity, Emotional expressivity, State of arousal, Vocalization, and Use of parents). Using Kappa statistics, all YPAS categories have been demonstrated to have good to excellent interobserver and intraobserver reliability (0.73–0.91), and when validated against other global behavioral measures of anxiety, the YPAS had good validity (r = 0.64).6 The “adjusted YPAS total score” ranges from 0 to 100 with higher scores indicating greater anxiety.

Post Hospitalization Behavior Questionnaire (PHBQ). This questionnaire for parents is designed to evaluate behavioral responses and “developmental regression” in children after hospitalization or surgery. Developmental regression refers to loss of previously gained developmental milestones (e.g., loses bladder control, loses previously gained language abilities—talks “baby talk”). The PHBQ consists of 27 items frequently cited in the literature as common behavioral responses of children after surgery or hospitalization. For each item, parents rated the extent to which each behavior changed frequency as compared to before surgery. A summary score was calculated equivalent to the total of all negative behavioral responses. This instrument shows good agreement with psychiatric interviews with parents of preschool children (r = 0.47), and was used in several investigations to document behavioral changes as a function of preoperative interventions.27,28

Clinical Anxiety Rating Scale (CAR). This scale was administered by the observers at the point of entry into the operating room. The child’s anxiety is rated on a 6-point scale, ranging from “relaxed/smiling” (score = 0) to “out of contact with reality—general loud crying” (score = 5). On a sample of 26 preschool children, interrater reliability of the CAR was reported to exceed 0.80,9 and when compared to other measures of anxiety the CAR had good validity (r = 0.85).9

State-Trait Anxiety Inventory (STAI). This is a widely used self-report instrument that estimates situational and baseline anxiety

References


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in adults on the basis of responses to 40 statements. Parents were asked to respond on a 4-point scale, total scores for situational and baseline questions separately range from 20 to 80 with higher scores denoting higher levels of anxiety. Test-retest correlations for the STAI were high (range 0.73–0.86). The reliability data are based on three groups of college students. The students retested after 1 h were exposed to the following experimental conditions: a brief period of relaxation training, a difficult intelligence quotient test, and a film depicting several accidents that resulted in serious injury. Validity was examined in two studies in which the STAI was given under high- and low-stress conditions to large samples of students. The r value ranged from 0.85 to 0.94, suggesting very good construct (whether or not a scale accurately measures the construct its intended to measure).22

Visual Analog Scale (VAS). This scale is widely used as both a self-report and observational measure of anxiety.23,24 The VAS rating system consists of a 100-mm line that represents two behavioral extremes at either end of the continuum, i.e., “not anxious” (score of 0) and “extremely anxious” (score of 100). The degree of anxiety felt or observed is indicated by putting a cross over the line at the point that represents current anxiety level. For the purpose of this study, the VAS was used as an observational measure to rate the children and as a self-report measure for the parents. Test-retest reliability of the VAS range from 0.61 to 0.73 when measured on adjacent days.25,26 Also, when used to measure anxiety, the VAS has good validity against a self-rating depression scale (r = 0.64–0.67).27

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References