

Family-centered Preparation for Surgery Improves Perioperative Outcomes in Children

A Randomized Controlled Trial

Zeev N. Kain, M.D., M.B.A.,* Alison A. Caldwell-Andrews, Ph.D.,† Linda C. Mayes, M.D.,‡ Megan E. Weinberg, M.A.,§ Shu-Ming Wang, M.D.,|| Jill E. MacLaren, Ph.D.,# Ronald L. Blount, Ph.D.**

Background: Children and parents experience significant anxiety and distress during the preoperative period. Currently available interventions are having limited efficacy. Based on an integration of the literature in both the anesthesia and psychological milieus, the authors developed a behaviorally oriented perioperative preparation program for children undergoing surgery that targets the family as a whole.

Methods: Children and their parents (n = 408) were randomly assigned to one of four groups: (1) control: received standard of care; (2) parental presence: received standard parental presence during induction of anesthesia; (3) ADVANCE: received family-centered behavioral preparation; and (4) oral midazolam. The authors assessed the effect of group assignment on preoperative anxiety levels and postoperative outcomes such as analgesic consumption and emergence delirium.

Results: Parents and children in the ADVANCE group exhibited significantly lower anxiety in the holding area as compared with all three other groups (34.4 ± 16 vs. 39.7 ± 15 ; $P = 0.007$) and were less anxious during induction of anesthesia as compared with the control and parental presence groups (44.9 ± 22 vs. 51.6 ± 25 and 53.6 ± 25 , respectively; $P = 0.006$). Anxiety and compliance during induction of anesthesia was similar for children in both the ADVANCE and midazolam groups (44.9 ± 22 vs. 42.9 ± 24 ; $P = 0.904$). Children in the ADVANCE group exhibited a lower incidence of emergence delirium after surgery ($P = 0.038$), required significantly less analgesia in the recovery room ($P = 0.016$), and were discharged from the recovery room earlier ($P = 0.04$) as compared with children in the three other groups.

Conclusion: The family-centered preoperative ADVANCE

preparation program is effective in the reduction of preoperative anxiety and improvement in postoperative outcomes.

A RECENT survey reported increases in the number of children in the United States who receive various treatments to reduce their anxiety before surgery.¹ Because of a lack of availability and limited effectiveness of many of these treatments, however, millions of children in the United States continue to have considerable anxiety and distress before undergoing surgery.²⁻⁷ This is of particular importance because preoperative anxiety in children is associated with adverse postoperative outcomes, such as increased incidence of emergence delirium,⁸ increased pain,^{9,10} and increase in the incidence of maladaptive postoperative behaviors.^{11,12} In addition, it is important to note that many parents report clinically significant increases in their own anxiety before their child's surgery, and that such increases in parental anxiety are associated with concomitant increases in the child's anxiety.^{13,14}

Currently available interventions to treat preoperative anxiety in children fall into three broad categories: (1) administration of sedatives before surgery, (2) allowing the parents to be present during induction of anesthesia, and (3) providing hospital-based preparation programs before surgery. Administration of benzodiazepines such as midazolam reliably reduces children's anxiety before surgery but may be associated with increased operational hospital costs, potential operating room delays, and slower discharge from the recovery room in patients undergoing ultrashort surgical procedures.¹⁵⁻¹⁷ Merely allowing parents to be present during induction of anesthesia has been shown by multiple randomized controlled trials not to reliably reduce a child's anxiety.^{13,18,19} Currently, the majority of preoperative preparation programs in children are unstructured, outdated, and unsupported by reliable, valid outcome data. Further, recent findings indicate that any effects of such programs are limited to the preoperative holding area and not carried to the induction of anesthesia process or the recovery room.²⁰ This is of high importance because induction of anesthesia provokes the most intense stress response during the perioperative period.³⁻⁶

Given the upsurge of interest in family-centered care in the past decade, in combination with investigations that show a strong association between parental and child anxiety^{13,14,21} and a relation between parental anxiety

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* Vice-Chair and Professor of Anesthesiology and Pediatrics and Child Psychiatry, Center for the Advancement of Perioperative Health and the Departments of Anesthesiology, Pediatrics, and Child Psychiatry, † Associate Research Scientist, § Research Assistant, || Associate Professor of Anesthesiology, Center for the Advancement of Perioperative Health and the Department of Anesthesiology, # Post-Doctoral Associate, Departments of Anesthesiology and Child Psychiatry, Center for the Advancement of Perioperative Health, ‡ Arnold Gesell Professor of Child Psychiatry, Pediatrics and Psychology, Departments of Pediatrics and Child Psychiatry, Yale University School of Medicine, New Haven, Connecticut. ** Associate Professor of Psychology, The University of Georgia Department of Psychology, Athens, Georgia.

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Address correspondence to Dr. Kain: Department of Anesthesiology, Yale University School of Medicine, 333 Cedar Street, New Haven, Connecticut 06510. zeev.kain@yale.edu. Individual article reprints may be purchased through the Journal Web site, www.anesthesiology.org.

and parental feelings of inadequate preparation,²² we opted to develop a behavioral preparation program for the family as a whole rather than exclusively for the child. Therefore, we constructed a behavioral preoperative preparation program that integrated psychological principles of shaping, exposure, and modeling with coaching and distraction interventions from the literature.²³⁻³²

In conclusion, the purpose of this randomized controlled trial was to examine our hypothesis that this family-centered, behaviorally based preparation program would reduce anxiety during induction of anesthesia and improve children's recovery in the postanesthesia care unit as assessed by analgesic requirements, emergence delirium, and discharge time.

Materials and Methods

The population of this randomized controlled trial consisted of parents and children (aged 2-10 yr old) who were in good health (American Society of Anesthesiology physical status I or II) and who were undergoing general anesthesia and elective, outpatient surgery between November 2000 and October 2004 at Yale-New Haven Children's Hospital. To avoid confounding variables, children with a history of chronic illness, prematurity (fewer than 36 weeks' gestation), or diagnosed developmental delay were not recruited for this study. Parents and their children were recruited 2-7 days before the child's surgery while undergoing a hospital-based surgery preoperative program. This 20-min program, which has existed at our institution since 1993, provides information to children and parents through an orientation tour of the operating rooms and *via* interviews by a nurse, an anesthesiologist, and a child-life specialist. Yale University's institutional review board (New Haven, Connecticut) approved the experimental protocol, and all parents provided written, informed consent for this study; children supplied written assent if age appropriate.

Experimental Conditions

Based on a computer-generated random number table, participants were randomized into four experimental conditions. This randomization sequence was concealed before interventions were assigned, and all participants were randomized in strict order as assigned by the random number table. The allocation sequence was generated at the beginning of the study by the first author; research assistants enrolled participants and assigned them to groups according to the random number table. Although participants could not be blinded to group assignment, raters were as blind to group assignment as possible; assignment could not be absolutely blinded as far as whether parents were present, but beyond these

two groupings (children with or without parents), there was no other obvious information about group assignment that could be ascertained *via* videotape by the raters.

- *Control group*: Participants received the standard of care at our hospital. That is, these participants did not receive premedication or have parental presence during induction of anesthesia.
- *Parental presence group*: Participants received the standard of care, plus parents were allowed to be present during induction of anesthesia. Because this is a standard practice in the United States, these parents did not undergo any specific preparation for their presence in the operating rooms and were instructed to be present during the induction and to avoid contact with any sterile areas (as is common practice).
- *ADVANCE behavioral preparation group*: Participants received standard-of-care treatment plus our newly developed, multicomponent behavioral preparation program, ADVANCE (Anxiety-reduction, Distraction, Video modeling and education, Adding parents, No excessive reassurance, Coaching, and Exposure/shaping; see appendix 1 for a description).
- *Midazolam group*: Participants received the standard of care plus oral midazolam. That is, at 30 min before separation to the operating room, participants in this group received 0.5 mg/kg oral midazolam.

Outcomes, Instruments, and Procedures

Our primary outcome was children's perioperative anxiety, and our secondary outcomes included the parents' anxiety, incidence of emergence delirium, analgesic requirements, and discharge time from the postanesthesia care unit. A psychologist supervised all assessment and administration of the various observational tools.

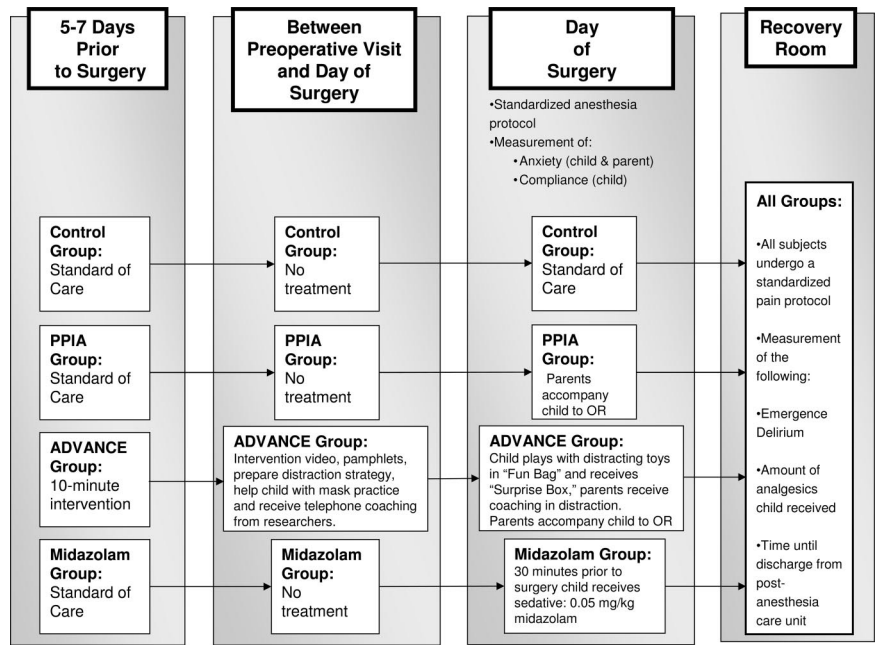
Primary Outcome Instruments.

Child Anxiety. Child anxiety was assessed using the modified Yale Preoperative Anxiety Scale (mYPAS), an observational state anxiety measure for young children containing 27 items in five categories (activity, emotional expressivity, state of arousal, vocalization, and use of parents). The mYPAS has good to excellent reliability and validity for measuring children's anxiety in the preoperative holding area and during induction of anesthesia.^{33,34} Researchers who administered the mYPAS for this study were trained to reliability levels of at least 0.80 (κ statistics).

Secondary Outcome Instruments.

Parental Anxiety. Parental anxiety was assessed using the State-Trait Anxiety Inventory. This self-report anxiety instrument contains two separate 20-item subscales that measure trait (baseline) and state (situational) anxiety.^{35,36} The State-Trait Anxiety Inventory is widely used, and is a valid and reliable instrument.³⁷

Fig. 1. Study flow diagram. PPIA = parental presence during induction of anesthesia.



Emergence Behavior. Trained observers assessed emergence behavior upon each participant's arrival to the recovery room after surgery. Children's emergence behavior was rated based on a three-point scale developed and validated by Keegan *et al.*,³⁸ with 1 indicating no symptoms of emergence delirium and 3 indicating moderate to severe symptoms of emergence delirium including crying, thrashing, and need for restraint.

Analgesic Requirements. Pain management in the post anesthesia care unit was standardized and was managed by a protocol detailed later in this section [see Study Protocol, Postanesthesia Care Unit (Recovery Room)]. To calculate analgesic requirements, all analgesics administered in the postanesthesia care unit were converted to codeine units.

Discharge Time. This variable was measured by our research assistant and was defined as the time between arrival to the postanesthesia care unit and discharge home. All medical personnel in the recovery room were blinded to group assignment and the preoperative interventions.

Other Measures.

Parent's Baseline Coping Style. The parent's baseline coping style was assessed using the Miller Behavioral Style Scale. This standardized self-report instrument assesses coping style in adults through four scenarios of stressful situations and identifies information-seeking, information-avoiding, and distraction coping styles. This measure has good reliability and validity.^{39,40}

Study Protocol

Figure 1 diagrams the flow of patients throughout the study.

Preoperative Visit (Hospital-based Preparation Program). After recruitment to the study, observers measured the children's anxiety (mYPAS). Participants were then randomized to one of the four groups using a computer-generated random number table. During the preoperative visit, participants in the ADVANCE group received instruction and preparation materials. Participants in other groups received the standard of care.

Days 1 and 2 Immediately before the Day of Surgery. Children and parents in the ADVANCE group received telephone coaching calls from the researcher.

Day of Surgery: Preoperative Holding Area. On the day of surgery, upon arrival to the hospital, parents in all groups completed a questionnaire packet (State-Trait Anxiety Inventory, Miller Behavioral Style Scale), and children were videotaped to facilitate blinded ratings of their state anxiety using the mYPAS. Children in the control group and parental presence group received the standard of care during this time. Children in the midazolam group received 0.5 mg/kg midazolam at 30 min before entrance to the operating room. Children in the ADVANCE group received coaching and distraction interventions as detailed in appendix 1.

Day of Surgery: Induction of Anesthesia. Parents in both the parental presence group and the ADVANCE group accompanied their child to the operating room for induction of anesthesia. Parents in the control and midazolam groups separated from their child outside the operating room doors, as is usual practice at this hospital. Children were videotaped throughout the induction process so that state anxiety (mYPAS) could be rated by naive raters upon entrance to the operating room and upon introduction of the anesthesia mask. Attending anesthesiologists then followed a standardized protocol,

and anesthesia was induced using oxygen-nitrous oxide and sevoflurane administered *via* a scented mask. Insertion of the intravenous cannula occurred after induction of anesthesia. Maintenance of anesthesia was conducted based on a standardized protocol (appendix 2). Parents in the parental presence and ADVANCE groups were asked to leave the operating room when the child had loss of lid reflex; directly after leaving the operating room, parents completed a final assessment of their anxiety (State-Trait Anxiety Inventory).

Postanesthesia Care Unit (Recovery Room). Nursing staff assessed children's pain every 15 min or more frequently if a child reported pain or was crying. A faces scale was used, and patients were given 1 $\mu\text{g}/\text{kg}$ fentanyl if the Bieri faces scale score was above 3. Children's pain was reassessed 10 min after administration of fentanyl to assure comfort of the child. Initial postoperative delirium (as assessed by the emergence delirium scale), analgesic requirements, and time to discharge were recorded. Medical personnel in the recovery room were blind to group assignment. The standard of care at our institution calls for all parents to be with their children throughout their recovery room stay. Accordingly, all parents in this study were present in the recovery room with their children.

All nurses and researchers who collected outcome measures for analgesic requirements, emergence delirium, and postoperative behavior were blinded to group assignment. We videotaped children in the holding area and during induction of anesthesia so that naive observers could perform blind ratings for children's anxiety. That is, although it is obvious that parents are present in some groups, the difference between the parental presence group and the ADVANCE group is not obvious to a naive observer. We should note, however, that researchers' ratings for anxiety of the videotaped children could not be blinded completely when comparing children without parental presence to children with parental presence.

Statistical and Analytical Approaches

Specific hypotheses and statistical tests for primary outcomes were as follows: A significant time \times group interaction on children's anxiety would be identified in a two-way repeated-measures analysis of variance. The interaction would be explored using *post hoc* tests to determine (1) whether the anxiety of children in the ADVANCE group differed from anxiety of children in the other three groups in the holding area and (2) whether the anxiety of children in the ADVANCE group differed from the anxiety of children in the control and parental presence groups during induction of anesthesia, and did not differ from anxiety of children in the midazolam group. It is important to note that anxiety of the children in this study was assessed using the mYPAS, which is a continuous

scale. Kurtosis and skewness of the mYPAS was assessed at the various time points at which it was used in this study and indicated that data of mYPAS was normally distributed; therefore, a repeated-measures analysis of variance was appropriate for this instrument.

Secondary outcomes were examined through chi-square analysis (emergence delirium) and one-way analyses of variance (parental anxiety, analgesic consumption, and time until discharge). Naive observers who were trained to acceptable levels of interrater reliability on the mYPAS-evaluated children's state anxiety used videotapes to rate children's anxiety in the holding area and during induction of anesthesia. These naive observers were blind to group assignment (as much as possible given that some children had parents present and some did not) and blind to study procedures and hypotheses.

Sample Size. The sample size for this study was based on children's anxiety ratings during induction of anesthesia as assessed by the mYPAS. Sample size was computed *a priori* using data from our previous investigations involving children's preoperative anxiety during induction of anesthesia.^{14,41} That is, given the average mYPAS level for children in the parental presence group, and based on a two-sided α level of 0.05 and power of 0.90, a total of 94 subjects per group was needed to complete this study.

Results

We enrolled a total of 408 subjects (aged 2–12 yr) in this randomized, controlled trial. No attrition occurred between recruitment and the day of surgery. A number of patients, however, could not receive the designated interventions because of issues related to the operating room schedule (*e.g.*, cases delayed, cases moved between various operating rooms; $n = 21$; fig. 2). Using intention-to-treat analysis, we nonetheless included data that were available from these patients. We found that the four study groups were similar with regard to characteristics such as age, sex, ethnicity, parent's rating of child's behavior during previous medical visits, baseline anxiety, parental trait anxiety, parental coping style, and parent's education (table 1). The age range of children in this study had good variability (27% were aged either 2 or 3 yr, 20% were aged 4 yr, 12% were aged 5 yr, and 15% were aged 8 yr or older).

Primary Outcome

Children's Anxiety. Using two-way repeated-measures analysis of variance analysis, we found an overall group \times time interaction, indicating that the differences between mYPAS anxiety scores in each group were dependent on time of assessment ($F_{6,744} = 2.73$; $P =$

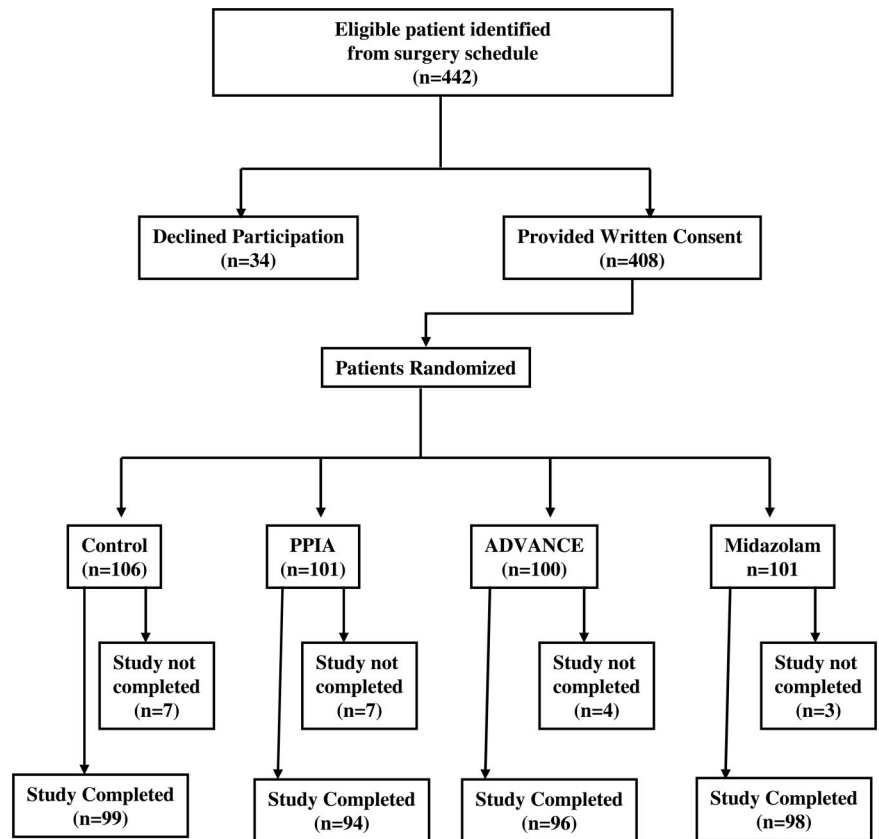


Fig. 2. Randomization of patients. PPIA = parental presence during induction of anesthesia.

0.013; fig. 3). Given this significant effect, we next conducted *post hoc* tests to explore these differences at two time periods: the holding area and during induction of anesthesia.

We had hypothesized that the children in the ADVANCE group would experience lower anxiety upon

arrival to the hospital when compared with the other children in the study. A comparison of mYPAS scores between children in the ADVANCE group and the other children in the study indeed showed that children in the ADVANCE group were significantly less anxious while in the holding area as compared with the other children

Table 1. Baseline Characteristics of Parents and Children

	Study Group			
	Control (n = 99)	Parental Presence (n = 94)	ADVANCE (n = 96)	Midazolam (n = 98)
Children				
Age, yr	5.4 ± 2	5.5 ± 2	5.6 ± 2	5.5 ± 2
Sex, F:M, %	40:60	31:69	38:62	40:60
Ethnicity, % nonwhite	18.5	20.6	25.7	18.2
Previous medical, VAS	82 ± 23	85 ± 17	82 ± 20	80 ± 22
Baseline anxiety, mYPAS	38 ± 16	35 ± 13	37 ± 15	39 ± 16
Parents				
Trait anxiety, STAI	38 ± 6	37 ± 7	36 ± 6	36 ± 6
Coping style, MBSS	5 ± 4	5 ± 4	5 ± 4	4 ± 3
Years of education	15.4 ± 3	15.4 ± 3	15.7 ± 3	15.6 ± 3
Surgical procedure, %				
Otolaryngologic	34	32	31	31
General surgery (minor)	21	24	23	22
Urology (minor)	17	20	16	18
Plastics (minor)	12	12	14	14
Ophthalmologic	5	3	6	6
Miscellaneous	11	9	10	9

Data are mean ± SD.

MBSS = Miller Behavioral Style Scale, measuring parental coping style; mYPAS = modified Yale Preoperative Anxiety Scale as measured at the preoperative visit; Previous medical, VAS = this score represents how well children handled previous medical visits (0–100); STAI = Spielberger State-Trait Anxiety Inventory.

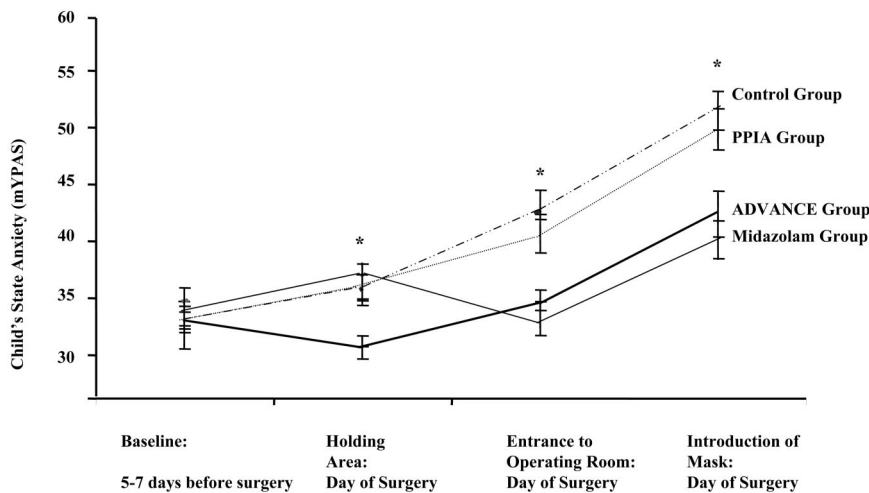


Fig. 3. Changes in anxiety over time by group. * $P < 0.05$ between group analysis. mYPAS = modified Yale Preoperative Anxiety Scale; PPIA = parental presence during induction of anesthesia.

(table 2). To ensure that this difference was not merely an artifact of increased parental involvement due to the ADVANCE intervention (as inclusion of the mYPAS “use of parents” domain might reflect), we next recalculated mYPAS scores in the holding area without the “use of parents” domain. Results of the same analysis using these scores were similar ($P = 0.012$), indicating that differences in children’s anxiety in the holding area were not merely due to increased use of parents as measured by the mYPAS.

We next compared anxiety scores during induction of anesthesia. Results showed significant group differences ($F = 4.2$, $P = 0.006$). *Post hoc* tests to localize these differences showed that the state anxiety of children in the ADVANCE group was significantly lower than state anxiety of children in the parental presence and control groups and similar to the state anxiety of children in the midazolam group (table 2).

Secondary Outcomes: Parental Anxiety and Children’s Postoperative Variables

Parent’s Anxiety. Parents of children in the ADVANCE group were significantly less anxious in the pre-

operative holding area as compared with parents of children in the other groups (39.6 ± 9 vs. 42.5 ± 11 ; $P = 0.019$). These parents remained less anxious than other parents after induction of anesthesia (43.3 ± 10 vs. 46.2 ± 12 ; $P = 0.046$).

Emergence Delirium. Group membership predicted the incidence of severe emergence delirium symptoms such as thrashing, inconsolable crying, and frequent need for restraint. That is, children in the ADVANCE group were least likely to exhibit severe emergence delirium symptoms when compared with children in the control, midazolam, and parental presence groups (10% vs. 24% vs. 21% vs. 16%; $P = 0.038$; table 3).

Analgesic Consumption. We next examined analgesic consumption differences between the four study groups. It is notable that all procedures were minor, outpatient, elective procedures; the specific type of procedure was randomly distributed throughout the groups. We found that children in the ADVANCE group received only half as much fentanyl as children in the parental presence group and approximately one third as much fentanyl as children in the control and midazolam groups ($P = 0.016$; table 2).

Table 2. Perioperative Outcomes

	Study Group				P Value	Effect Size (95% CI)
	Control (n = 99)	Parental Presence (n = 94)	ADVANCE (n = 96)	Midazolam (n = 98)		
Children’s Anxiety (mYPAS)						
Holding area	36 ± 16	35 ± 16	31 ± 12*	37 ± 17	0.001	0.54 (0.78–0.30)
Introduction of mask at induction	52 ± 26	50 ± 26	43 ± 23†	40 ± 24	0.018	0.33 (0.58–0.08)
Postanesthesia care unit						
Fentanyl consumption, $\mu\text{g}/\text{kg}$	1.37 ± 2	0.81 ± 1	0.41 ± 1‡	1.23 ± 2	0.016	0.54 (0.75–0.24)
Time until discharge, min	120 ± 48	122 ± 44	108 ± 46§	129 ± 44	0.040	0.34 (0.60–0.09)

* ADVANCE group anxiety scores were significantly lower than those in all other groups, $P < 0.01$. † ADVANCE group anxiety scores were significantly lower than those in the control and parental presence groups, $P < 0.05$. ‡ ADVANCE group anxiety scores were significantly lower than those in the control and midazolam groups, $P < 0.01$. § ADVANCE group anxiety scores were significantly lower than those in the midazolam group, $P < 0.01$; P values for parental presence and control groups = 0.07. || Cohen’s d effect sizes were calculated for the intervention group vs. other groups combined.

CI = confidence interval; mYPAS = modified Yale Preoperative Anxiety Scale.

Table 3. Emergence Delirium, %

	Emergence Status*		
	1	2	3†
Control group	35.4	40.4	24.2
Parental presence group	57.1	27.4	15.5
ADVANCE group	50.0	39.6	10.4
Midazolam group	42.5	36.8	20.7

* $P = 0.038$. † Denotes marked emergence symptoms = patient is thrashing and crying and may need restraint as he or she emerges from anesthesia after surgery.

Time until Discharge from the Recovery Room.

Children in the ADVANCE group were also discharged significantly earlier than children in the other groups ($P = 0.04$; table 2). Children in the ADVANCE group were discharged an average of 20 min earlier than children in the midazolam group, 10 min earlier than children in the control group, and 13 min earlier than children in the parental presence group.

Discussion

This study demonstrated that a family-centered preoperative behavioral intervention not only reduced children's anxiety before surgery, but also reduced the incidence of postoperative delirium, shortened discharge time after surgery, and reduced analgesic consumption after surgery. That a preoperative intervention can influence postoperative outcomes presents interesting possibilities for developing novel strategies to influence postoperative outcomes.

Of interest is that we found no difference in the anxiety levels of children who were given midazolam and children who received the behaviorally based ADVANCE program. Although this is an important finding, one can question the need for such a complex preparation program when alternatives such as midazolam are readily available. Indeed, although midazolam is an effective treatment for preoperative anxiety and postoperative maladaptive behavioral changes, it does have a number of limitations. First, because the onset of action of midazolam is approximately 20–30 min, timing of administration in busy operating settings may be a challenge. Second, administration of oral midazolam will no doubt cause discharge delays in patients undergoing ultrashort procedures such as pressure-equalizing tube placement. Also, an overwhelming majority of parents both in Great Britain and in the United States prefer to be part of the perioperative process and to be present during induction of anesthesia.¹ Indeed, recently we reported that parents of children who underwent repeated surgery preferred parental presence regardless of any previous

intervention.⁴² That is, even if the child previously received midazolam and had not been anxious during induction of anesthesia, parents still strongly preferred to be present during induction of anesthesia at a subsequent surgery instead of having their child receive midazolam.⁴² Further, this preparation program provides families with a new skill set that is applicable to subsequent medical procedures; indeed, the skills taught in this program have also been effective in managing anxiety in invasive medical procedures. Finally, the results of this study indicate that the ADVANCE intervention is superior to the use of midazolam on clinically relevant postoperative outcomes including emergence delirium, analgesic consumption, and time until discharge.

The issue of cost efficiency of any newly developed intervention is of particular importance in today's medical-economic climate. Indeed, although we have demonstrated that ADVANCE is an effective intervention, one should also note that this is an expensive intervention that maybe adapted only in major children's hospitals. Future follow-up studies should address the issue of a cost-benefit analysis.

Several important conceptual and methodologic issues and limitations should be noted. First, because the ADVANCE program consists of a number of components, it is unclear which of the components are essential; therefore, dismantling studies are needed. Second, the issue of generalizability can be raised because the intervention is complex. It is notable that parental presence and premedication are generally used at the discretion of the anesthesiologist and are rarely provided indiscriminately. Therefore, because the conditions of a randomized controlled trial (*i.e.*, assigned treatments rather than treatment based on clinical judgment) differ from clinical practice, these results may not apply equally well to all children. That is, this study assigned treatments to patients regardless of their personal characteristics, whereas treatments such as parental presence during induction of anesthesia (the parental presence group in this study) might be more effective when matched specifically to individual patients. The generalizability of this study may also be affected by the requirement that all families who participate attend the hospital preparation program, effectively eliminating from participation families who declined to participate or who were unable to attend. In addition, it is unknown whether benefits of the program extend beyond the immediate postoperative period. Future studies are needed to evaluate whether the effects of the ADVANCE program continue during postoperative recovery at home or extend to positively impact future surgeries. Finally, in this study, all parents were included in the postoperative care of their child in the recovery room, and it is possible that parents who participated in the ADVANCE program were able to extrapolate behavioral principles they learned about their

child's preoperative care and apply them to the child's postoperative care. Therefore, it is unclear to what extent decreases in preoperative anxiety are linked to improved postoperative outcomes, as compared with the extent to which parents' postoperative behaviors and the child's sense of competence affected postoperative outcomes.

In 2001, the Institute of Medicine published a report titled "Crossing the Quality Chasm: A New Health System for the 21st Century."⁴³ This report called for a transformational change in health care and described the need to establish new partnerships with patients and families. Family-centered care offers a framework to ensure implementation of these transformational recommendations. Indeed, the family plays an important role in the experience of a young child undergoing surgery. A significant proportion of parents experience anxiety and distress before their child's surgery. We have previously found a very high correlation between parental anxiety and child anxiety and concluded that future interventions must target parents in addition to children.^{44,45} Furthermore, parental anxiety is a relevant concern in its own right. We believe that it is the combination of successful contemporary behavioral techniques and family involvement that resulted in this highly effective intervention.

In conclusion, this report describes the development of a family-centered preoperative preparation program. We evaluated the effectiveness of the program in a large randomized, controlled trial and found that it is similar in effect for anxiety reduction as midazolam. Furthermore, we found that when compared with participants in the other conditions, the incidence of emergence delirium is lower among children who were part of the program; in addition, these children required fewer analgesics and were discharged faster from the recovery room. Future research should evaluate the cost-benefit of this program as it is associated with increased operational hospital costs.

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Appendix 1: Advance Family-centered Behavioral Preparation Details

The ADVANCE program contains multiple components that are represented in the acronym as follows:

- Anxiety reduction (the aim of the program)
- Distraction on the day of surgery
- Video modeling and education before the day of surgery
- Adding parents to the child's surgical experience and promoting family-centered care
- No excessive reassurance—a suggestion made to parents and based on the literature
- Coaching of parents by researchers to help them succeed
- Exposure/shaping of the child *via* induction mask practice

Preoperative Preparation Visit

At the preoperative preparation program, parents were given a preparation package that consisted of a videotape, three pamphlets, and a mask practice kit. Parents were instructed to watch the videotape at least twice before the day of surgery.

An advisory committee consisting of psychologists, developmentalists, early child educators, child-life specialists, and an anesthesiologist developed this video over a 2-yr period. This committee reviewed a large number of interviews with parents of children undergoing surgery as well as approximately 20 videotapes of children undergoing induction of anesthesia with and without their parents present. A script was then written and revised based on the recommendations of the committee, and a videotape was developed based on the script. The 23-min videotape was staffed by professional adult and child actors and also included interviews with parents whose children underwent surgery. The videotape was developed with funds provided by a grant from Donaghue Foundation for Medical Research (Hartford, Connecticut).

Parents were also instructed briefly in how to best help their child prepare for surgery, and how to best communicate with their child (literature-based recommendations) on the day of surgery.

Parents were also given three pamphlets to read that were written specifically for this project: (1) *Helping Your Child in the Operating Room*, (2) *How to Distract Your Child before and during Induction of Anesthesia*, and (3) *Induction Mask Practice*.

- Pamphlet 1 helped parents understand what to expect on the day of surgery and listed some recommendations on how to manage their own and their child's anxiety.
- Pamphlet 2 gave specific instructions for distracting children on the day of surgery.

- Pamphlet 3 gave specific instructions about how to use the psychological principles of shaping to teach the children to perform the behaviors that would be expected of them in the operating room (*e.g.*, getting onto the table) and about exposure to potentially frightening elements of the operating room (*e.g.*, the induction mask, hairnet) while still in the safety of their home to help children become comfortable with the induction process.

Parents were given a mask practice kit, which contained a sample induction mask, a hairnet, and a facemask for use in the shaping practice.

Two Days before Surgery

A researcher telephoned parents on each of the 2 days preceding surgery to check parents' adherence to the intervention protocol and answer questions. On the second telephone call, researchers recorded the parents' specific plans on how to distract their child the next day.

Day of Surgery: Holding Area

Upon arrival to the Pediatric Surgery Center holding area, children were given a bag of distracting toys to play with while waiting in the holding area. This bag of toys consisted of puzzles, brainteasers, pop-up books, art supplies, a pinwheel, and other distracting small toys. This toy bag was designed to be age appropriate for the range of children in the study and was used in addition to the regular toys that were already in each of the holding rooms. Finally, children were shown a brightly wrapped box and told that this was a "surprise box" that they could open when they were breathing through the induction mask. The box was then left in the holding room for the child to wonder about.

Day of Surgery: Induction of Anesthesia

During the induction of anesthesia process, researchers monitored the parents and prompted them to use planned distraction strategies if needed. The surprise box was carried into the operating room and given to the child to open after introduction of the anesthesia mask. The surprise box contained a Game Boy[®] for use with older children, and a colorful kaleidoscope for younger children. These toys were loaned to children to use during the induction period.

Time Commitment and Expertise Required from Staff

The total amount of direct staff-patient time taken to administer this program was 30 min or less. Researchers spent approximately 10 min explaining the program and providing the program materials at the preadmission visit. Telephone calls to the parents (2 calls) totaled approximately 10 min. Providing parents any reminders about the program required 5 min or less on the day of surgery. Expertise required from staff to run this program involved no special training or education other than ability to establish rapport with parents and children, training in all aspects of the preparation program, and a basic understanding of the principles of shaping and exposure.

Appendix 2: Anesthesia Protocol Details

The anesthetic chart of each participant included an attached study protocol; a research assistant ensured adherence to these protocols by the

anesthesia attending and resident staff. All anesthetic inductions were performed as follows: scent mask with nitrous oxide (N₂O)-oxygen (O₂) × 1 min (measured by a research assistant), then addition of sevoflurane titrated slowly over a 1- to 2-min period. Attending anesthesiologists had the option to use 0.1 mg/kg vecuronium to facilitate intubation and reverse with neostigmine and glycopyrrolate (except pressure-equalizing tubes). Pain for all below procedures (except pressure-equalizing tubes) was managed in the recovery room with 0.5–1 µg/kg fentanyl as needed (score of 3 or above on Objective Pain Scale). Postoperative nausea and vomiting were managed in the recovery room using 0.1 mg/kg metoclopramide (all subjects received 0.1 mg/kg ondansetron during the surgical procedure).

Placement of pressure-equalizing tubes: Preoperatively: 20 mg/kg acetaminophen, orally. When surgeon finished with first ear, turn off N₂O and continue with study drug and O₂ until the end of the case. Postoperative: acetaminophen.

Adenoidectomy: Maintenance: N₂O-O₂ + study drug, 1 µg/kg fentanyl. Home: acetaminophen or acetaminophen and codeine.

Strabismus: Maintenance: N₂O/O₂ + study drug, 3 µg/kg fentanyl. Recovery room: 0.2 mg/kg dexamethasone. Home: acetaminophen.

Herniorrhaphy/endoscopy/hydrocele/orchiopexy: Maintenance: N₂O-O₂ + study drug, 2 µg/kg fentanyl. Home: acetaminophen.

Circumcision: Maintenance: N₂O-O₂ + study drug, 2 µg/kg fentanyl. Home: acetaminophen and codeine.