

CLINICAL INVESTIGATIONS

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Parental Presence and a Sedative Premedicant for Children Undergoing Surgery

A Hierarchical Study

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Background: Although some anesthesiologists use oral sedatives or parental presence during induction of anesthesia (PPIA) to treat preoperative anxiety in children, others may use these interventions simultaneously (e.g., sedatives and PPIA). The purpose of this investigation was to determine whether this approach has advantages over treating children with sedatives alone.

Methods: The child's and the parental anxiety throughout the perioperative period was the primary endpoint of the study. Parental satisfaction was the secondary endpoint. Subjects (n = 103) were assigned randomly to one of two groups: a sedative group (0.5 mg/kg oral midazolam) or a sedative and PPIA group. Using standardized measures of anxiety and satisfaction, the effects of the interventions on the children and parents were assessed. Statistical analysis (varimax rotation) of the satisfac-

tion questionnaire items resulted in two factors that described satisfaction of the separation process and satisfaction of the overall care provided.

Results: Anxiety in the holding area, at entrance to the operating room, and at introduction of the anesthesia mask did not differ significantly between the two groups ($F[2,192] = 1.26, P = 0.28$). Parental anxiety after separation, however, was significantly lower in the sedative and PPIA group ($F[2,93] = 4.46, P = 0.037$). Parental satisfaction with the overall care provided (-0.28 ± 1.2 vs. $0.43 \pm 0.26, P = 0.046$) and with the separation process (-0.30 ± 1.2 vs. $0.47 \pm 0.20, P = 0.03$) was significantly higher among the sedative and PPIA group compared with the sedative group.

Conclusions: PPIA in addition to 0.5 mg/kg oral midazolam has no additive effects in terms of reducing a child's anxiety. Parents who accompanied their children to the operating room, however, were less anxious and more satisfied. (Key words: Anxiety; induction; pediatric anesthesia; satisfaction.)

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SEDATIVE premedication and parental presence during induction of anesthesia (PPIA) are used routinely to treat anxiety in children undergoing surgery and general anesthesia.¹ Although some anesthesiologists use these two interventions interchangeably, others use premedication and PPIA simultaneously²; that is, PPIA and sedative premedication for the same child. Multiple previous studies have shown that oral midazolam is an effective intervention for the treatment of preoperative anxiety in children.^{3,4} In contrast, a growing body of literature indicates that, overall, PPIA is not an effective intervention to treat the anxiety of children undergoing induction of general anesthesia.⁵⁻⁷ An obvious question that remains, however, is whether PPIA has an additive anxiolytic effect on children if combined with oral midazolam.

Previously, the medical community held the view that the only "real" outcomes are those that have an immediate and direct influence on patient morbidity and mortality rates. This view has changed dramatically during the past decade, and, currently, issues such as patient

satisfaction and quality of life are considered by many to be equally as important as morbidity.⁸⁻¹⁰ This new development is echoed in recent review articles and editorials in the anesthesia literature that suggest that patient satisfaction should serve as an important endpoint and indicator of overall quality of anesthesia care.¹¹⁻¹³

Interventions such as sedative premedication and PPIA have been evaluated previously for endpoints, including anxiety of children and their parents and cooperation of children during induction of anesthesia.^{3,5-7} We suggest that parental satisfaction should be incorporated as a clinically relevant endpoint in the areas of preoperative anxiety and preoperative preparation for surgery. The purpose of this investigation, therefore, was to determine whether a combination of parental presence and sedative premedication is more effective than sedative premedication alone for reducing anxiety in children and their parents and for improving parental satisfaction and compliance of the child.

Materials and Methods

The study population consisted of 103 children aged 2-8 yr, classified as American Society of Anesthesiologists physical status I or II, undergoing general anesthesia and elective, outpatient surgery at Yale-New Haven Hospital. Children with a history of chronic illness, prematurity, or developmental delay were excluded from participation in this study. The study protocol was approved by the institutional human investigation committee, and all parents provided written informed consent.

Interventions

In this randomized, controlled trial, eligible children and their parents were assigned to one of two study groups according to a random-numbers table:

Sedative premedication group

Children in this group were premedicated with oral midazolam syrup (0.5 mg/kg) at least 20 min before the surgical procedure.

Sedative premedication and parental presence group

Children in this group were premedicated with oral midazolam syrup (0.5 mg/kg) at least 20 min before the surgical procedure and a parent was present throughout the anesthesia induction process.

Instruments

Detailed psychometric data regarding the following behavioral instruments were reported previously by our

study group.^{6,14} A psychologist functioned as the assessor and administered the various observational tools.

Temperament, Anxiety, and Compliance.

- State-Trait Anxiety Inventory (STAI):^{15,16} This self-report anxiety instrument contains two separate 20-item subscales that measure trait (baseline) and state (situational) anxiety.
- Modified Yale Preoperative Anxiety Scale (mYPAS):^{17,18} This observational measure of anxiety contains 27 items in five categories (activity, emotional expressivity, state of arousal, vocalization, and use of parents) indicating preoperative anxiety in children.
- Induction Compliance Checklist (ICC):⁶ This observational scale measures the compliance of a child during induction of anesthesia.

Satisfaction Questionnaire. A satisfaction questionnaire was developed using a rational empiric approach¹⁹ that involved three steps: (1) conceptual grouping of items with input from anesthesiologists, nurses, child-life specialists, psychologists, and surgeons; (2) factor analysis; and (3) examination of internal consistency.

The initial version of the questionnaire consisted of 28 items regarding parental satisfaction. Satisfaction was assessed using a series of statements that the respondents were asked to answer using a 5-cm visual analogue scale that was marked on one end as "strongly agree" and on the other end as "strongly disagree." The initial version of the questionnaire was pretested by 25 parents whose children underwent general anesthesia and surgery. A total of seven questions were deleted because the parents indicated that they were unclear or because more than 90% of parents responded to the statements with a score of more than 4.5 cm or with a score of less than 0.5 cm. The final list of questions is presented in the Appendix.

Next, factor analysis with varimax rotation (SPSS version 8.0; SPSS, Chicago, IL) were performed for the 21 items of the questionnaire. This procedure is used to identify underlying factors that explain the correlations among a set of items in a questionnaire. Its purpose is to summarize a large number of questionnaire items ($n = 21$) with a smaller and meaningful number of concepts (factors). This procedure is particularly useful if one compares two study groups because it prevents multiple comparisons (*i.e.*, 21 Student *t* tests). Two principal components accounted for 73% of the questionnaire variance, with 51% of the variance accounted for by factor I and 22% of the variance accounted for by factor

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II. The individual items loading the highest on factor I described the overall parental satisfaction from the function of the children's hospital, the pediatric surgery center, the nurses, the surgeons, and the anesthesiologists. The individual items loading the highest on factor II described parental satisfaction with their children's separation process. The internal consistency (Cronbach coefficient α) of the questionnaire was assessed as well. We found that the Cronbach α for the two factors was high: 0.93 for factor I (overall care) and 0.94 for factor II (satisfaction). That is, the questionnaire items within each factor were closely related to each other and evaluated the same concept.

Study Protocol

Subjects were recruited 2–7 days before surgery while undergoing a behavioral preoperative preparation program or the night before surgery if they did not participate in the preparation program. The program was voluntary and consisted of providing information to the children and parents through an orientation tour of the operating room (OR) and the postanesthesia care unit (PACU) and modeling using dolls by child-life specialists. The modeling is tailored to the specific surgery planned for the child and is modified based on the age of the child. After recruitment, demographic and behavioral data were obtained.

On the day of surgery in the preoperative holding area, the child's anxiety was assessed using the mYPAS and parental anxiety was assessed using the State-Trait Anxiety Inventory. Children and their parents next were assigned randomly to one of two groups, and the intervention was applied. At separation to the OR, the child's anxiety was again assessed (mYPAS). In the parental presence group, the child's separation anxiety was the reaction of the child to separation from the parent who did not enter the OR. Anxiety of parents in the sedative premedication groups was assessed by the State Trait Anxiety Inventory after separation to the OR occurred.

Anesthesia was induced using oxygen-nitrous oxide and sevoflurane administered *via* a scented mask. The child's anxiety during induction was assessed (mYPAS) at entrance to the OR and at introduction of the anesthesia mask. Compliance of the child during anesthetic induction also was rated (Induction Compliance Checklist). As soon as general anesthesia was induced, parents in the parental presence group were escorted to the waiting area and asked to rate their own anxiety (State-Trait Anxiety Inventory).

In the PACU, initial postoperative excitement (as assessed by the excitement scale),²⁰ incidence of adverse effects, analgesic requirements, time to "postoperative recovery" (as assessed by the Steward postoperative recovery scale),²¹ and time to discharge from the PACU were recorded.

Finally, parents were given the satisfaction questionnaire just before leaving the PACU and were asked to complete the questionnaire 2 weeks after surgery. At 2 weeks after surgery, a research assistant telephoned the parents and reminded them to complete the questionnaire and mail it back to the research facility.

Statistical Analysis

The primary endpoint of this study was the anxiety of the child during induction of anesthesia. Data from a previous investigation involving PPIA was used *a priori* to calculate sample size.¹⁴ Given a mYPAS level of 42 ± 17 in the PPIA group¹⁴ and based on a two-sided α level of 0.05, a 25% effect size, and power of 0.90, a total of 94 subjects were needed to complete this study. Subjects were matched between the two groups with a yoked design based on surgical histories; that is, the first child undergoing surgery who had not undergone surgery before was randomized (using a randomization table generated from a random-numbers table) to one of the two groups. The second child undergoing surgery with no surgical history was allocated automatically to the other group. This ensured almost equal distribution of surgical experience in the two groups.

Descriptive statistics provide an overview of the relations between the child and parent variables and the anxiety level in the child and parent. Chi-square analysis and the Student *t* test were used to assess differences in baseline characteristics. Two-way analysis of variance with repeated measures was used to analyze the changes in anxiety level of children along the various time points: in the holding area (T_1), at entrance to the OR (T_2), and at introduction of the anesthesia mask (T_3). Anxiety of the parents was evaluated along two time points: in the holding area (T_1) and at separation (T_2), using two-way analysis of variance with repeated measures. Analysis to localize a group-by-time interaction was performed using analysis of covariance, with baseline parental anxiety as a covariate. Normally distributed data are presented as the mean \pm SD and skewed data as the median and interquartile range (25–75%). Comparisons were considered to be significant if $P < 0.05$.

Table 1. Baseline Characteristics of Study Population

Characteristic	Premedication	Premedication + PPIA	P
Child's age (yr)*	3.6 ± 1.6	3.3 ± 1.7	0.27
Child's gender (male/female)†	69.6/30.4	59.6/40.4	0.30
Parental trait anxiety*‡	37.6 ± 6.2	36.8 ± 6.4	0.53
Preadmission Visit (yes/no)†§	33.3/66.7	44.2/55.8	0.28
Previous surgery (yes/no)†	65.2/34.8	61.5/38.5	0.71

* Mean ± SD.

† Percent.

‡ State-Trait Anxiety Inventory, trait subscale.

§ Preadmission visit = anesthesia interview, nursing interview, child-life preparation.

PPIA = parental presence during induction of anesthesia.

Results

A total of 103 children and their parents were enrolled in the final phase of this study. Five children, however, were excluded because of major protocol violations, such as refusing to swallow the sedative premedication. Three families refused to participate after notification that they had been randomized to undergo the operation. Baseline characteristics are presented in table 1. The two groups were similar with regard to the children's age and gender; surgical procedures; participation in the preparation program; children's history of surgery; and parental social status, trait anxiety, and coping style. For example, for both groups, the distribution of procedures was the same: 41.3% of the premedication group *versus* 42.3% of the PPIA group underwent otolaryngological procedures, 13.0% of the premedication group *versus* 9.7% of the PPIA group underwent urogen-

ital procedures, 10.9% of the premedication group *versus* 15.4% of the PPIA group underwent minor general surgical procedures, and 34.8% of the premedication group *versus* 32.6% of the PPIA group underwent other procedures.

Primary Outcome: Children's and Parents' Anxiety

The children's observed anxiety increased significantly from the holding area (T_1) to entrance to the OR (T_2) and to introduction of the anesthesia mask (T_3) ($F[2,192] = 19.1$; $P = 0.0001$; fig. 1). The observed anxiety of children, however, was not different between the two study groups ($F[1,96] = 0.95$; $P = 0.49$), and there was no group-by-time interaction ($F[2,192] = 1.26$; $P = 0.28$).

Parental anxiety at two time points—holding area (T_1) and separation from children (T_2)—was also evaluated using two-way analysis of variance with repeated measures. A group-by-time interaction was seen ($F[1,95] = 7.78$; $P = 0.006$). Controlling for baseline anxiety, we found that parents who accompanied their children into the OR were significantly less anxious after separation compared with parents who did not accompany their children into the OR (43 ± 11 *vs.* 48 ± 12 ; $F[2,93] = 4.46$; $P = 0.037$).

Secondary Outcomes: Parental Satisfaction and Child's Compliance

Response rate for the satisfaction questionnaire was 68%. A nonresponse bias telephone survey among 13% ($n = 4$) of the nonresponders showed no differences between groups for demographic variables or for responses to the various items of the satisfaction question-

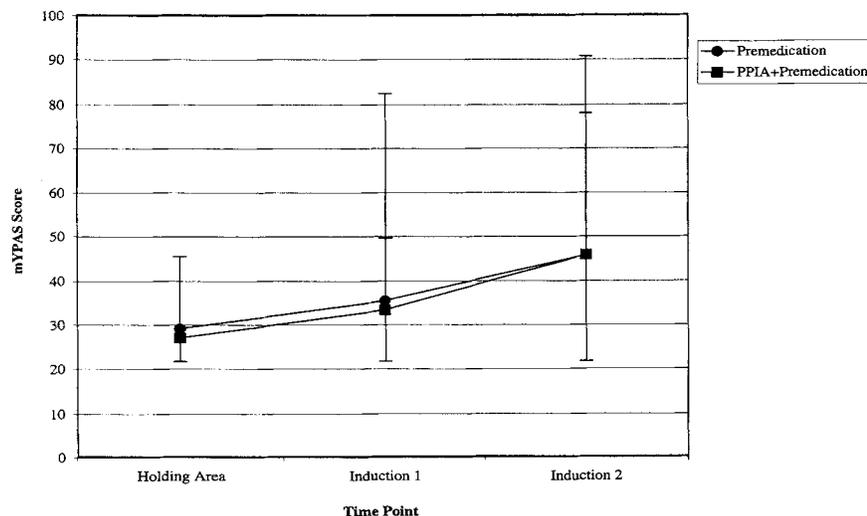


Fig. 1. Anxiety of child across the perioperative period. *P* value not significant. Data presented as the mean ± SD. Induction 1 = entrance to the operating room; induction 2 = introduction of the anesthesia mask to the child; mYPAS = Yale Preoperative Anxiety Scale.

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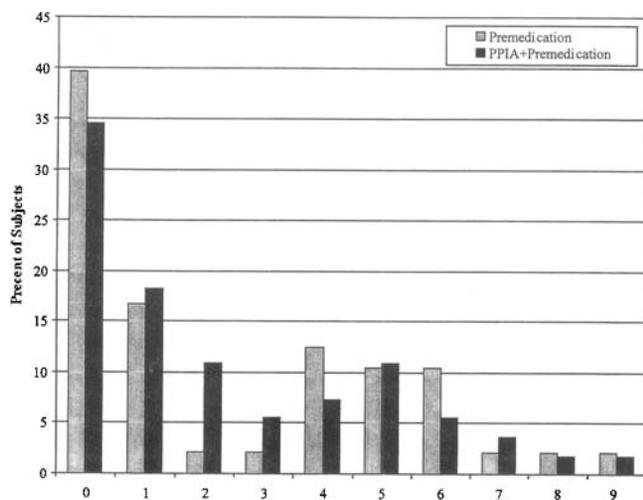


Fig. 2. Child's compliance during induction. *P* value not significant. ICC = Induction Compliance Checklist.

naire. Therefore, the results presented here represent the entire study population. As described previously, factor analysis and varimax rotation of the questionnaire resulted in two factors that describe all the questionnaire items: (1) overall parental satisfaction with the function of the children's hospital, the pediatric surgery center, the anesthesiologists, the nurses, and the surgeons and (2) satisfaction with the quality of the child's separation process. These two factors were compared between the two study groups. We found that satisfaction with the overall care provided in our facility (-0.28 ± 1.2 vs. 0.43 ± 0.26 ; $P = 0.046$) and satisfaction with the separation process (-0.30 ± 1.2 vs. 0.47 ± 0.20 ; $P = 0.03$) were rated higher among the premedication and PPIA group compared with the premedication group.

Evaluating the compliance of the children during the anesthesia induction process, we found that the percentage of inductions in which compliance of the child was poor (*i.e.*, Induction Compliance Checklist score > 6) was similar between the two groups (15% vs. 11%; P not significant; fig. 2). Therefore, parental presence did not improve child's compliance during induction of anesthesia.

Adverse Effects

Finally, postoperative excitement scores did not differ between the two groups (sedative 2 [range, 1-3] versus PPIA and sedative 2 [range, 1-2]; $P = 0.28$); no anesthetic complications (*e.g.*, laryngospasm) occurred during the inductions; and no parent demonstrated disrupt-

tive behavior or refused to leave the OR. In the PACU, incidence of nausea or vomiting and time to a score of 7 on the Steward Postoperative Recovery scale was similar for the sedative premedication and PPIA and sedative premedication groups ($P =$ not significant).

Discussion

In this study, PPIA did not reduce or attenuate a child's anxiety beyond that seen with midazolam premedication alone. Furthermore, PPIA did not improve a child's compliance during the induction process. Parents who accompanied their children into the OR, however, were less anxious after separation and more satisfied with the separation process and with the overall function of the OR and the hospital.

Often, PPIA is suggested as an alternative to sedative premedication. Although there is general agreement about the desirability of parents visiting during their children's hospital admissions, immunizations, dental procedures, and bone marrow aspirations,²² their presence during procedures such as induction of anesthesia is controversial.²³ To date, the experimental evidence does not support the routine use of PPIA.^{6,7,14,24} Parents, however, seem to have a very different opinion regarding this subject. Several survey studies have indicated that most parents prefer to be present during induction of anesthesia, regardless of the child's age or previous surgical experience.^{25,26} Ryder *et al.* found that, if parents were present during the induction, an overwhelming number believe they were of some help to their child and the anesthesiologist.²⁶ Kain *et al.* questioned anesthesiologists and parents regarding how helpful the parents were during the induction process.¹⁴ The investigators found that, although most parents thought their presence made the anesthesiologist's job easier (68%), anesthesiologists believed that most parents either had no effect (38%) or made the job more difficult (21%).¹⁴ Moreover, although most parents (90%) rated themselves as being helpful to their child, anesthesiologists rated only a minority of parents as being helpful (12%). Not surprisingly, the majority of parents (98%) indicated that, if their children needed surgery again, they would like to be present during the induction.¹⁴

Two previous randomized, controlled trials reported no differences in parental anxiety levels between parents who were present during induction and parents who did not accompany their children into the OR.^{6,14} Interestingly, parents in the current investigation re-

ported lower anxiety levels if they accompanied their children into the OR. However, in previous studies parents accompanied their unpremedicated children into the OR, but in this investigation they accompanied their premedicated children into the OR. Therefore, it can be hypothesized that in previous investigations the children's increased anxiety during induction led to increased parental anxiety, and decreased anxiety of the children in the current investigation led to lower parental anxiety after induction. Although the differences in parental anxiety between the two groups were statistically significant, they were of limited magnitude; that is, there was only a 10% difference between the two groups. Therefore, the clinical relevance of this finding may be limited.

Our finding that increased parental satisfaction occurred if parents were allowed to be present during induction of anesthesia should come as no surprise, considering the previous reports regarding parental views and wishes. Interestingly, parental satisfaction improved, not only with regard to the separation process, but also, more importantly, with regard to the entire functioning of the pediatric surgery center. An important question that arises, however, is whether increased parental satisfaction is an important endpoint to measure. One may view parental satisfaction as a "surrogate" outcome that can be easily measured but that has no real clinical importance. Previously, the medical community held the view that the only real outcomes are those that are related to morbidity and mortality rates. This view is now changing, and, currently, patient satisfaction is considered by many to be an important endpoint.¹¹⁻¹³ In a recently published editorial, Klock and Roizen²⁷ expressed their hope to "wake up" the specialty of anesthesia to the potential value of patient satisfaction as a means to assess and improve modern anesthesia practice. We believe that these views should be incorporated into experimental research.

Before adopting satisfaction as an endpoint of clinical trials, however, an appropriate measurement tool must be developed. Although single items may be quicker and less expensive to administer and analyze, the data set is richer and more reliable if several different items are used to gain information about a particular topic. The construction of the satisfaction questionnaire used for this manuscript followed a rigorous protocol. The questionnaire first underwent a formal phase of item generation, with input from all disciplines involved with the care of children undergoing anesthesia and surgery

(*i.e.*, good face validity). Once generated, the items were formulated into an initial questionnaire that was tested in a sample of parents of children who underwent anesthesia and surgery. After detailed factor analysis, two factors that explained 73% of the variance were identified. We also assessed this questionnaire for internal consistency within each of the two factors identified. Thus, the satisfaction questionnaire used in this study is a reliable instrument to measure parental satisfaction.

Several design issues related to this study should be noted. First, the anxiety of children in the sedative group was very low. In such a condition, an additional anxiolytic effect of parental presence may be very difficult to detect. A different result may have been found if a lower dose of midazolam or a less satisfactory premedicant drug had been used. It can be suggested, therefore, that the conclusion of this report is "study specific." We should emphasize, however, that midazolam is the most commonly used premedicant among children undergoing surgery in the United States,² and the dose of midazolam chosen for this study reflects common clinical practice. Thus, we believe this study has adequate "external validity." Second, in the current investigation, we used a group of seven anesthesiologists, some children had undergone previous surgery, and not all children underwent a preoperative preparation program. Although the study may be criticized as not being "controlled" enough, this was decided *a priori* to increase the external validity of the study results. Third, all behavioral and satisfaction instruments used in this study have good to excellent psychometric properties. Finally, as in all investigations involving PPIA, assessors were not blind for obvious reasons. It may be suggested that the use of surrogates in the non-PPIA group can lead to the blindness of the assessor. It is our opinion that surrogates could not have been used, however, because the child's behavior toward the surrogates would indicate to the assessor the presence or absence of the parent.

In conclusion, we found that PPIA, in addition to 0.5 mg/kg oral midazolam, has no additive effect in terms of reducing a child's anxiety. Parents who accompanied their children into the OR, however, were less anxious and more satisfied with the separation process and the overall functioning of the pediatric surgery center. Therefore, allowing PPIA in this population increases overall parental satisfaction of the anesthesia care.

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Appendix 1. Satisfaction Questionnaire

Please respond to each of the statements below by marking the line anywhere between "Strongly Disagree" and "Strongly Agree." Each statement concerns some aspect of your child's hospital experience, so we ask that you give an answer to each statement.

For example:

I am confident that my child is getting a good education

Strongly Disagree Strongly Agree

|-----X-----|

Strongly Disagree Strongly Agree

I would come back to the Children's Hospital if my child needed surgery again.

|-----|

My child went to sleep in the worst way possible.

|-----|

The anesthesiologist provided excellent care for my child.

|-----|

I would recommend this experience to others if their children needed surgery.

|-----|

My child went into the operating room in the best way possible.

|-----|

The nurses provided excellent care for my child.

|-----|

The surgeon provided excellent care for my child.

|-----|

The doctors and nurses who took care of my child were responsive to our needs.

|-----|

My child went into the operating room with an ease that exceeded my expectations.

|-----|

The overall medical care of my child at the Children's Hospital was excellent.

|-----|

I would rank this experience at the Children's Hospital as superior to other places (only answer if applicable).

|-----|

The doctors and nurses who took care of my child did not communicate well with us or our child.

|-----|

Overall, I am very satisfied with the way my child went into the operating room.

|-----|

I am totally satisfied with the explanations given for how my child would go to sleep and wake up.

|-----|

My child was satisfied with the way he/she went to sleep.

|-----|

The doctors and nurses made every effort to reduce my child's anxiety.

|-----|

I would not change anything about the way my child went to sleep or the way my child went into the operating room.

|-----|

I would choose to have my child go into the operating room in the same way should another surgery ever be needed.

|-----|

The doctors and nurses made every effort to reduce my anxiety.

|-----|

The doctors and nurses handled the process of taking my child into the operating room extremely well.

|-----|

The doctors and nurses who took care of my child demonstrated caring for us and our child.

|-----|