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**The Infant and Effects of Parental Presence in the Operating Room  
During Induction of Anesthesia**

**A Thesis Submitted to the  
Yale University School of Medicine  
In Partial Fulfillment of the Requirements for the  
Degree of Doctor of Medicine**

**By:**

**Deborah Kaplan**

**2007**

## INFANTS AND PARENTAL PRESENCE DURING INDUCTION OF ANESTHESIA

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Previous studies have investigated the physiological and behavioral effects of parental presence in the operating room during the induction of anesthesia (PPIA) both on the child and the parent. Since the characterization of anxiety in infants presents a unique challenge due to their inability to communicate verbally, these studies have typically focused on children greater than two years old. In the present study we addressed this understudied population directly by using highly reliable and validated behavioral instruments as well as analyzing sleep patterns and signs of distress in the infants. The hypothesis tested was the same as in the older child populations: parents and infants of parents who are present in the OR during the induction of anesthesia will demonstrate less behavioral and physiological anxiety than those parents and infants who do not experience PPIA.

According to randomized controlled study design, the subjects were randomly assigned into either (1) the PPIA group (parents present in the OR until the infant is asleep) or (2) the Control group (parents not present in the OR).

To date we have enrolled 10 patients to this study (n=10). Patient recruitment is ongoing. Because of the small sample size, data are unstable and thus a detailed discussion is beyond the scope of this abstract.

Parental presence is a highly significant issue for parents of children undergoing induction of anesthesia. This topic is particularly important within the context of family centered care. Further data are needed to finalize our conclusions.

**Acknowledgements**

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## **Introduction**

### **PERIOPERATIVE ANXIETY**

As many as three million children undergo anesthesia and surgery annually in the United States <sup>1</sup>. Based on previous data, it is estimated that the prevalence of preoperative anxiety in children ranges from 40 to 60 % <sup>2, 3</sup>. Preoperative anxiety is operationally defined as feelings of apprehension, nervousness, worry, tension, and vigilance associated with increased autonomic nervous system activity <sup>2-4</sup>. Children in the surgical environment are threatened not only by the upcoming surgery, but also by anticipated separation from their parents, pain, loss of control, uncertainty about “going to sleep”, and by masked strangers working in a highly technical, non-child-focused environment.

Following admission to the surgery center, children and parents typically wait in the preoperative holding area for about an hour. A minority of children may receive a preoperative sedative approximately 30 minutes prior to surgery. When it is time for the surgery, children are taken into the operating rooms by anesthesia personnel, with or without their parents. If parents don't accompany the child into the operating room, separation then occurs upon entry to the operating rooms. This separation is often quite traumatic for the child. Next, once in the operating room, monitors are applied to the child, a mask is held over the child's face, and volatile anesthetics (with unpleasant smell) are administered through the mask. When anesthesia personnel judge that the child is “asleep”, parents are then escorted back to the waiting area. At times, fearful children try to leave the operating room and are consequently forcefully held down by the operating room staff and/or the parents (if present), while screaming and crying <sup>5</sup>.

These behaviors, though extreme, unfortunately occur in 20% of all children and are called “brutane induction” in the anesthesia community <sup>5</sup>.

Anxiety in young children undergoing anesthesia and surgery may be expressed in many forms. Some children verbalize their fears, while for others, anxiety is expressed only behaviorally. Many children look scared, become agitated, hyperventilate, tremble, stop talking or playing, and may start to cry. Others may unexpectedly wet or soil themselves, have increased motor tone, and may actively attempt to escape from the medical personnel <sup>6, 2-4</sup>. These reactions are direct manifestations of the child's fear of separation from parents and home environment, as well as loss of control in the setting of unfamiliar routines, and hospital procedures. Previous studies have indicated, based on both behavioral and physiological responses, that induction of anesthesia appears to be the most stressful procedure the child experiences during the preoperative process <sup>2-4, 7</sup>. Appropriate treatment of this clinical phenomenon is important as preoperative anxiety leads to both psychological and physiological adverse outcomes, including prolonged induction of anesthesia, separation anxiety, and sleep and eating disturbances <sup>3, 8</sup>.

In addition to the behavioral manifestations detailed above, previous studies have documented that significant fear and anxiety prior to surgery are associated with physiological changes in neuroendocrine levels, such as increased serum cortisol, epinephrine, growth hormone, IL-6, and increased Natural Killer cell activity <sup>9-12</sup>. Evidence of other physiological manifestations of anxiety such as heart rate and blood pressure changes <sup>13, 14</sup>, increased postoperative pain, increased postoperative analgesic requirements, prolonged recovery and prolonged hospital stay have also been

documented<sup>15-18</sup>. Several studies of adults undergoing surgery have reported that low levels of preoperative anxiety are associated with a good postoperative behavioral recovery, while moderate and high levels of preoperative anxiety are associated with a poor postoperative behavioral recovery<sup>11, 15, 19-22</sup>. Reviews of this research conclude that psychologically prepared adult patients have an improved postoperative recovery<sup>16, 23-30</sup>. The fact that low preoperative anxiety predicts favorable postoperative outcomes underlies many interventions in which the aim is to reduce preoperative anxiety across all patient populations and ages.

Several studies report that at 2 weeks after surgery, 40 to 55% of all children undergoing elective surgery exhibit new-onset maladaptive behavioral changes, such as nightmares, separation anxiety, eating problems, and increased fear of doctors<sup>3, 5, 31-37</sup>. Kain et al. has also demonstrated that 19% of children continue to demonstrate such maladaptive behavior changes at 6 months postoperatively, and in 6% of all children these maladaptive behaviors persist at one year<sup>3</sup>. In fact, some children develop long lasting psychological effects, adversely affecting their responses to subsequent medical care. Children's anxiety while in the preoperative holding area, as well as during induction of anesthesia, predicts these postoperative behavioral problems<sup>3</sup>. In another investigation, it was found that increased preoperative anxiety also leads to a higher likelihood of emergence delirium in the recovery room (extreme agitation, crying and thrashing), which in turn leads to delayed discharge from the recovery room and the need for additional medications and medical care<sup>38</sup>.

In addition, high levels of anxiety prior to surgery adversely affect postoperative sleep. Recently, our laboratory examined the effect of preoperative anxiety on



postoperative sleep in a large cohort of 169 children ages two to ten years old <sup>39</sup>. We found that that heightened preoperative anxiety in children undergoing surgery leads to postoperative sleep disturbances as assessed by both actigraphy (the use of a motion detector device to measure sleep versus awake states which will be discussed in detail later) and the post-hospitalization behavior questionnaire (PHBQ) <sup>39</sup>.

Interestingly, parental anxiety during the preoperative process is also an important variable as previous research has demonstrated that it is significantly related ( $r=0.5$ ) to child's anxiety <sup>3</sup>. Furthermore, increased parental anxiety has been identified as a risk factor for the development of postoperative behavioral changes in children <sup>3</sup>. This phenomenon is now increasingly recognized in the literature, as evidenced by development of interventions <sup>7-10</sup> directed toward treatment of parental preoperative anxiety.

## INTERVENTIONS

Both behavioral interventions (e.g., parental presence during induction of anesthesia) and pharmacological interventions are available to treat preoperative anxiety in children <sup>40</sup>. Recent surveys have indicated that while some anesthesiologists strongly advocate the use of sedatives in children undergoing surgery <sup>41</sup>, others favor the use of parental presence during induction of anesthesia <sup>41</sup>. Generally, there are three approaches for bringing a child into the operating room (OR): no intervention vs. sedative premedication vs. parental presence during induction of anesthesia (PPIA). Currently, sedative premedication and PPIA are not the 'standard of care' for children less than two

years old at our institution. In many community hospitals less than 20% of all children are premedicated or have their parents present during induction of anesthesia <sup>41</sup>.

Pharmacologic interventions include the use of midazolam, a benzodiazepine with potent sedative, amnesic and anxiolytic properties, as a preanesthetic medication in the pediatric population. The routine use of preoperative sedatives such as midazolam, however, results in increased pharmacy costs, additional nursing and medical staff and an increased need for appropriately monitored beds in the preoperative holding area <sup>42</sup>. Also, administration of midazolam to children undergoing short surgical procedures may result in increased lengths of stay in the post-anesthesia care unit (PACU) with related increases in hospital and third party payer costs <sup>43, 44</sup>. Emergence delirium responses to midazolam have also been reported <sup>45</sup>; these complications further increase costs. Furthermore, in order to be effective, midazolam *must* be given 20-30 minutes prior to surgery. If administered less than 20 minutes before surgery, the sedative will not yet be effective, and if administered over 40 minutes before surgery, its effect will be diminished *and* the likelihood of preoperative paradoxical agitation will increase dramatically. Considering these timing issues, it is quite difficult for the anesthesiologist to accurately estimate the optimal time midazolam should to be given to a particular child. In fact, anesthesiologists do not (and cannot) accurately estimate case start times in at least two-thirds of all cases. Thus one can see why administration of midazolam is not widely used to treat preoperative anxiety.

Parental presence during induction of anesthesia is currently one behavioral method used to treat preoperative anxiety in young children. While recent randomized controlled trials do not support the routine use of this intervention,<sup>46-48</sup> the overwhelming

majority of parents strongly favor this practice<sup>41, 49-50</sup>. Indeed, previous studies have confirmed that close to 90% of parents questioned indicate that they would like to be present during their child's induction of anesthesia<sup>51</sup>. Parental presence during induction of anesthesia has been associated with increased parental satisfaction regarding not only the separation process from the child, but extending also to increased satisfaction with the overall functioning of the hospital<sup>52</sup>. Nonetheless, a majority of parents report being upset while present during the induction process<sup>53, 54</sup>. Isolated reports of disturbances in the operating room and parental syncopal episodes have been documented in the medical literature<sup>55, 56</sup>. An editorial by Lerman<sup>57</sup> also raised the possibility of cardiac rhythm abnormalities and myocardial ischemia among parents while they are present in operating rooms<sup>58</sup> although a follow up study that measured ECG and blood pressure found no significant parental morbidity associated with presence in the operating rooms<sup>54</sup>.

The benefits of parental presence include forestalling the need for premedication like midazolam, reduced costs, improved operating room efficiency and avoidance of the screaming and struggling that happens in many children upon separation from the parents at the operating room doors. In fact, many clinicians feel that since including the parent in this stressful procedure is part of family-centered-care, parental presence as such should be incorporated into the "patient's bill of rights". Other potential benefits, such as decreasing children's anxiety, increasing the child's cooperation during induction, and improving postoperative outcomes, remain unproven. Concerns about the regular use of PPIA include possible adverse reactions (psychological, physiological and behavior) of the parent. However, one report that described four years of experience with 3,086 children in a free-standing ambulatory surgery center

noted that *no* parent needed to be escorted from the operating room because of undue anxiety, and only two parents developed syncope, with prompt recovery<sup>57</sup>.

Considering the increased operational costs and the major logistical hurdles involving administration of oral midazolam, it is no surprise that many hospitals *actively discourage* the use of preoperative sedatives for children undergoing surgery. In fact, a recent large-scale survey our laboratory conducted found that currently only about 20-30% of anesthesiologists in the US administer midazolam to young children undergoing surgery<sup>59</sup>. Multiple anesthesiologists, nurses, surgeons, child-life specialists and advocate groups suggest that parental presence during induction of anesthesia (PPIA) should be used as an alternative to midazolam. Other non-pharmacological alternatives such as music therapy and extensive hospital-based preoperative preparation programs have been suggested as well, but data indicate that they do not reliably decrease children's anxiety during induction of anesthesia<sup>60</sup>.

## INFANT ANXIETY

Every year there are at least 15,000 surgical cases performed on infants between zero and two years old at Yale New Haven Children's Hospital, alone. These small patients bring with them a host of large challenges and difficulties for the medical personnel caring for them in the OR. One such challenge to overcome is the ability to secure and stabilize the patient's airway. While the small size of the infant's anatomy presents an obvious physical problem, even the most adept anesthesiologist is faced with the knowledge that laryngospasm often complicates the induction of anesthesia in this population.

One study from the UK found that in a cohort of 64 infants less than one year of age (ASA 1 or 2) undergoing elective surgery almost 47% experienced airway complications<sup>61</sup>. Originally designed to compare the effectiveness of isoflurane and halothane for induction of anesthesia in infants, this study meticulously recorded all abnormal respiratory events, no matter how minor, including the incidence of cough, breath holding, laryngospasm, and hiccups. This data underscores the magnitude of the difficulty in securing a stable airway in the infant population. Although laryngospasm is quite frequent as described above, parents are not likely to understand if it occurs to their child and are likely to experience increased anxiety and fear during such an event. Additionally, this is an important consideration in offering parents of infants the opportunity to be in the OR during the induction of anesthesia, as the presence another individual, especially a parent, may increase the level of anxiety the anesthesiologist experiences.

While there is a significant body of literature devoted to describing the impact of parental presence in children older than two years and their parents, the literature addressing the impact on children younger than two years is limited. One randomized controlled study by Palermo et al. looked at a cohort of 73 infants (aged 1-12 months) specifically to determine if parental presence had any treatment effect on the parent's level of anxiety and satisfaction with care<sup>62</sup>. Although they did not find any significant treatment effects, the study was the first to assess the infant population. Interestingly, the primary endpoint of this study was parental anxiety and parental attitudes toward the health care delivered while infant anxiety was a secondary endpoint. The only measure used to assess infant anxiety and behavior was a modified version of the child distress

rating scale developed by Hannallah and Rosales with scores of 1 (no distress), 2 (crying softly), 3 (full-lunged cry), and 4 (body flailing)<sup>63</sup>. One score was assigned to each infant by the anesthesiologist just after the induction of anesthesia. This clearly illustrates one of the difficulties intrinsic in the study of infants; they have not yet achieved the developmental milestones that allow for analysis of complex interpersonal interactions and verbal communication.

However, like older children, infants can express stress reactions with both physiological and behavioral manifestations. While physiologic changes are generally detectable at any age, behavioral characteristics may become easier to assess as children grow. Several validated study instruments are available to determine baseline temperament in older children, to follow their anxiety levels on the day of surgery and then to follow-up any post-operative changes in behavior. By asking questions about habits, likes, dislikes, and coping mechanisms (answered either directly by the child or by the parent for the child) a baseline temperament score can be assigned<sup>64</sup>, and there is a validated observational measure of preoperative anxiety in children two to ten years old (YPAS)<sup>65</sup>. Similarly, validated measures have been developed to assess temperament of infants, their level of distress, and changes in behavior<sup>66-68</sup>. These measures use characteristics of the baby's eating and sleeping habits, as well as their cry and facial expressions in lieu of the more purposeful behaviors used to assess older children. Ultimately, the studies about perioperative anxiety explore the interactions between at least two of the following three factors: 1) baseline temperament of the patient (and/or parents), 2) stress reaction (physiologic and/or behavioral) and 3) a measurable outcome

(short-term and/or long-term). With the availability of specific infant measures for all three factors, there is no need to exclude the infant population from these studies.

## INFANT MEASURES

Temperament, defined by Rothbart and Derryberry (1981) as an individual's inborn responsiveness and ability to self-regulate given a particular situation<sup>69</sup>, has been widely studied in the literature throughout all stages of child development<sup>66-77</sup>. Goldsmith and Campos (1990) offer a more vivid description of temperament in the following passage:

Presented with a novel toy, some infants flash a quick smile and grasp the toy immediately. Other infants are initially sober, and they approach the toy reluctantly or not at all. When behavioral patterns like these are coherent and stable, they are often attributed to the infant's *temperament*<sup>72</sup>.

Since the characterization of temperament relies on observation of stable patterns of behavior, it seems reasonable that parent (or caregiver) report instruments are the least intrusive and time consuming method for accessing this information; the alternative is specific situational testing in the laboratory. While potential sources of error in these measurements exist, such as the parent's ability to accurately remember the exact nature, timing and frequency of behaviors, or the parent's wish to report their child with socially desirable behaviors, the Revised Infant Behavior Questionnaire (IBQ-R) has proven to be valid and reliable<sup>78</sup>. The IBQ-R decreases the likelihood of error due to parent memory by asking parents only about recent behaviors that occurred in the past one to two weeks. Additionally, the behaviors referred to in the IBQ-R are presented in the context of a

particular setting, such as eating, sleeping, or bathing and dressing. By limiting the scope of the behaviors to only a specific setting rather than to the infant's general daily routine, parents may be less hesitant to ascribe certain undesirable behaviors to their infants. In these ways, the IBQ-R has been found to reliably measure individual differences in infant reactivity and emotional regulation as compared to laboratory studies and other physiological measures<sup>78</sup>.

The challenge of studying infant populations is to find the least invasive and intrusive measures possible. Since infants are unable to verbally communicate their distress, several authors have investigated the use of facial expressions and/or the cry of the infant to assess acute situational stress in the infant<sup>79-84</sup>. Infant cry can be recorded and analyzed using carefully trained technicians and specialized software to look at three main parameters, time (including time from stimulus to start of cry and length of cry episode,) frequency (including aspects of harmonics, melody, jitter and vibrato), and cry intensity. The basis for these analyses is that a sufficiently distressed infant, (an infant in pain for example,) will have a physiological change that would affect the neurological integrity of the vocal apparatus creating a cry that is distinct and unique to that emotion<sup>82</sup>. Much of the cry analysis literature, however is limited to conclusions about the pain response and is not able to distinguish cry characteristics of the general stress response<sup>79,80</sup>. Because of the need for adequate training, expertise, and software in order to accurately apply cry analysis to the measurement of distress in the infant, we will not record infant cries in this study.

Fortunately, the literature about the use of facial expressions as a way of measuring the stress response of the infant uses a broadened definition of distress to



include unfamiliar experiences and uncomfortable rather than painful stimuli <sup>81-84</sup>. Distress was found to be associated with brow bulge, eye squeeze, naso-labial furrow, open lips, mouth stretched (both vertical and horizontal), taut tongue with pursed lips, and chin quiver <sup>82</sup>. Interestingly, these authors also found tongue protrusion to be associated with response to non-painful, but distressing stimuli and could be important to score when looking at infant anxiety.

One significant problem for older children undergoing anesthesia and outpatient surgery is the development of new-onset sleep disturbances postoperatively. A previous study found that 54% of all pediatric outpatient surgical patients exhibit problems including general anxiety, nighttime crying, enuresis, separation anxiety, and temper tantrums with as many as 20.1% showing increased nightmares and incidents of waking up crying <sup>39</sup>. Although some of the more specific sleeping problems identified in this study may not be readily detectable in an infant, (for example enuresis and nightmares), babies are known to have naturally regular sleep-wake cycles. Measuring disturbances in the infant's sleeping patterns may be used to indicate distress.

While the gold standard for measuring sleep-wake cycles in humans remains the polysomnography, this is a very expensive, and time-consuming test that requires the patient to stay in the hospital overnight and to be connected to several electronic measurement devices. Fortunately, recent advances in technology have offered an alternative method that simply uses body movement as a way to distinguish between sleep-wake states, with the assumption that people will not move during the time that they are sleeping and any sign of motion is therefore synonymous with a waking state <sup>85</sup>. This method, known as actigraphy uses a small motion detector device (an actigraph) that

is attached to the subject's body (usually the wrist of adults and the left ankle of infants) to measure the amount of acceleration that occurs during one minute segments as long as the individual is wearing the device<sup>85-87</sup>. This data can then be downloaded and analyzed with the use of special software to identify the percentage of time spent actually sleeping<sup>88, 89</sup>. Additionally, data can be analyzed for values including sleep latency and number of nighttime wakings, both factors that contribute to quality of sleep. When compared to polysomnography, the accuracy of the prediction of sleep-wake states has been found to be about 77-92%, thus validating this method for use in measuring sleep in infants<sup>85</sup>. Actigraphy is therefore a reliable and non-invasive method to perform home-monitoring of sleeping patterns of both parents and infants. Furthermore, actigraphy has been used in children for many years without any adverse effects, with a large amount of literature regarding the safe use in children and infants<sup>85-88, 90</sup>.

## PURPOSE

The purpose of this randomized controlled trial was to examine the impact of parental presence during induction of anesthesia on selected aspects of the physiological and behavioral stress response in both infants and their parents. In fact, this study was designed to test the hypothesis that an infant whose parent is present during induction of anesthesia, and the parent themselves, demonstrates less behavioral and physiological anxiety than those who do not experience parental presence in the OR.

Specifically, this study aimed to do the following: 1) To determine the behavioral response of parents and infants before, during and after a surgical procedure as defined by changes in sleep patterns, eating patterns, infant crying and facial expressions, and

other validated subjective behavioral measures. 2) To determine the physiological response of parents and infants before a surgical procedure as defined by changes in heart rate, blood pressure, blood oxygen saturation, skin galvanic conductance, and cortisol levels. 3) To determine if parents who are present in the OR during induction of anesthesia experience less of a physiological stress response than those who are not present in the OR. 4) To determine if infants who are accompanied by their parent into the OR show less of a behavioral stress response to induction of anesthesia than those infants who are not accompanied by a parent into the OR.

The primary endpoint for this study was the stress response of parents during the perioperative period as determined by changes in heart rate (HR), blood pressure, skin conductance level (SCL), and standardized self-report measures of anxiety. Infant anxiety and distress as based ultimately on disturbances in the sleep-wake cycles as determined by actigraphy recordings three days prior to surgery and three days after surgery will also be considered as a secondary endpoint.

## **Methods**

### **STUDY DESIGN**

This study was designed as a randomized controlled trial and the protocol was approved by the Human Investigation Committee, which serves as the Internal Review Board for research involving human subjects at Yale University School of Medicine. Subjects were randomized into either: (1) the PPIA group (parents who will be present in the OR during the induction of anesthesia) or (2) the Control group (parents who will not be in the OR). The entire study protocol is illustrated by the flow chart in Figure 1 (see page 23).

### **MEASURES**

Each measure was selected based on evidence from the literature cited, and based on the model outlined in specific aims.

#### **Baseline Characteristics:**

*Demographic/Background Information Questionnaire.* This questionnaire was designed to gather demographic information about the family, including age of the child, age of parents, marital status, educational level of the parents, prematurity, number and type of previous surgeries and/or hospitalizations, history of chronic illnesses, and behavior of the child during previous medical visits.

*Sleep History.* A short five question survey designed to ask parents about their own recent sleeping patterns and habits.

#### **Temperament**

*Revised Infant Behavior Questionnaire (IBQ-R)*<sup>78</sup>. The IBQ-R is a parent-report measure widely used to assess the baseline temperament of the infant. Parents are asked

to use a 7-point Likert scale to rate the frequency of specific behaviors observed over the previous week (or 2 weeks for some items). Items assess the following domains: activity level, distress to limitations, approach, fear, duration of orienting, smiling/laughter, vocal reactivity, sadness, perceptual sensitivity, high and low intensity pleasure, cuddliness, soothability, and falling reactivity/rate of recovery from stress. The IBQ-R has good reliability and validity.

*The NEO Personality Inventory, Revised (NEO-PI-R)*<sup>91</sup>. The NEO-PI-R is a 240-item adult measure of personality style and temperament consisting of five domains that are each divided into six subscales, or "facets." We will only administer the 48 items in the N scale to parents in this study. The N scale represents "Neuroticism", which is an indicator of high levels of general worry and anxiety. Items are answered using a five-point Likert scale that ranges from 0 (strongly disagree) to 4 (strongly agree). The reliability and validity of the NEO PI-R have been well-supported.

**Coping Style:**

*Miller Behavioral Style Scale or "Monitor Blunter Style Scale" (MBSS)*. The MBSS assesses parental coping style through four scenarios of stressful situations<sup>92</sup>. This standardized tool was developed for patients undergoing medical procedures and identifies monitoring-type (information seeking and/or information avoiding behaviors) and blunting-type (distracting and nondistracting behaviors) coping styles. A list of eight possible reactions to the situation is presented and the subject is asked to check each behavior in which they would engage in that situation. Four of the reactions are of a monitoring or information seeking variety, and four are of a blunting or information avoiding variety. This measure has excellent reliability and validity.

**Emotion modulation:**

*Visual Analog Scale (VAS)*. Widely used as both a self-report and observational measure, this scale consists of a 100-mm line with extreme descriptors at either end. The research participant (the parent in this case) is asked to make a single vertical mark along the line to indicate where they feel they are on the continuum defined by the designated descriptors. The VAS has excellent reliability and validity.

*State-Trait Anxiety Inventory*. This is a widely used self-report anxiety assessment instrument for adults. To date, over 1,000 studies using the STAI have been published in peer reviewed literature<sup>93</sup>. Standard scores for children and adults are available. The questionnaire contains two separate, 20-item, 4-point self-report rating scales for measuring trait and state anxiety. Total scores for situational (state) and general (trait) anxiety range from 20 to 80 each; higher scores denote higher levels of anxiety. Test-retest correlations for the STAI are high, range 0.73 to 0.86. Validity of the adult instrument was examined in two studies in which the STAI was given under high- and low-stress conditions to large samples of students<sup>93</sup>.

*CASA-P*<sup>94</sup>. The CASA-P is a reliable and valid instrument used to measure specific components of surgery-related state anxiety. By evaluating cognitive, autonomic and somatic stress reactions the CASA-P serves as a highly sensitive indicator of state anxiety changes during the perioperative period.

**Physiological Measures**

*Biolog* ® (UFI; Morro Bay, CA) is an ambulatory physiological data recorder (Holter). This data recorder continuously records electrocardiogram and skin conductance level (SCL). SCL is a measure of skin conductance resulting from sweat

gland activity, which is modulated by the level of emotional stress experienced at that moment<sup>95</sup>. SCL recording was done using two Ag-AgCl electrodes filled with BioGel electropotential medium and connected to the volar surface of the second and third fingers of the non-dominant hand. All recorded electrocardiogram and SCL data are stored on a PCMCIA memory card. When recording is complete, the card is removed from the Biolog®, inserted into a card reader and connected to the host PC through a serial port. The Downloading and Plotting Software (DPS) operating on a PC host computer (win31/9x) is used to download and plot the data, after which it can be viewed, printed, or converted into channel specific ASCII data files.

*Salivary Cortisol.* Salivary samples were obtained by having the parent soak a sterile cotton swab in their mouths. Samples were obtained in the holding area on the day of surgery, after separating from their child, and on entering the recovery room. Samples can be analyzed by radioimmunoassay in the laboratory.

### **Infant Distress**

*Neonatal Facial Coding System (NFCS)*<sup>84</sup>. This coding system is used to assess the level of distress in the infant as recorded during videotaped inductions of anesthesia. The facial actions that comprise the scale include: brow bulge, eye squeeze, nasolabial furrow, open lips, mouth stretch (horizontal and vertical), lip purse, tongue tautening, and chin quiver. An action receives a score if it occurs. The NFCS coding system has been found to be valid and reliable<sup>19</sup>.

### **Sleep Monitoring:**

*Actigraphy.* The actigraph device is a miniaturized motion detection system (MotionLogger Actigraph, Ambulatory Monitoring, Inc., Ardsley, NY) that collects

motion activity numerically, making it available for analysis. The size of a digital wrist watch, the unit can be placed on the wrist or ankle via a Velcro band. The system is able to collect motion data for up to 9 days and runs off a lithium cell battery. The device counts all movements (accelerations  $> 0.01$  g) and stores cumulative counts in memory each minute. Although actigraphy does not assess REM sleep and slow wave sleep, as do laboratory based assessments, it allows subjects to remain in their natural and home environments while reliably quantifying movement patterns during sleep. All children and one of their parents wore actigraphs for six days (three days prior to their child's surgery and three days after their child's surgery) so as to monitor the impact of surgery on their sleep. Infants all wore the actigraphs on their left leg, as is standard for infants who are undergoing actigraphy.

*Sleep/Actigraph Diary.* The sleep record simply is a place for parents to record what time they went to bed and what time they awoke each morning while wearing the actigraph. The Actigraph Diary provides a place for parents to record the times they remove the actigraph from their child's ankle for bathing or swimming.



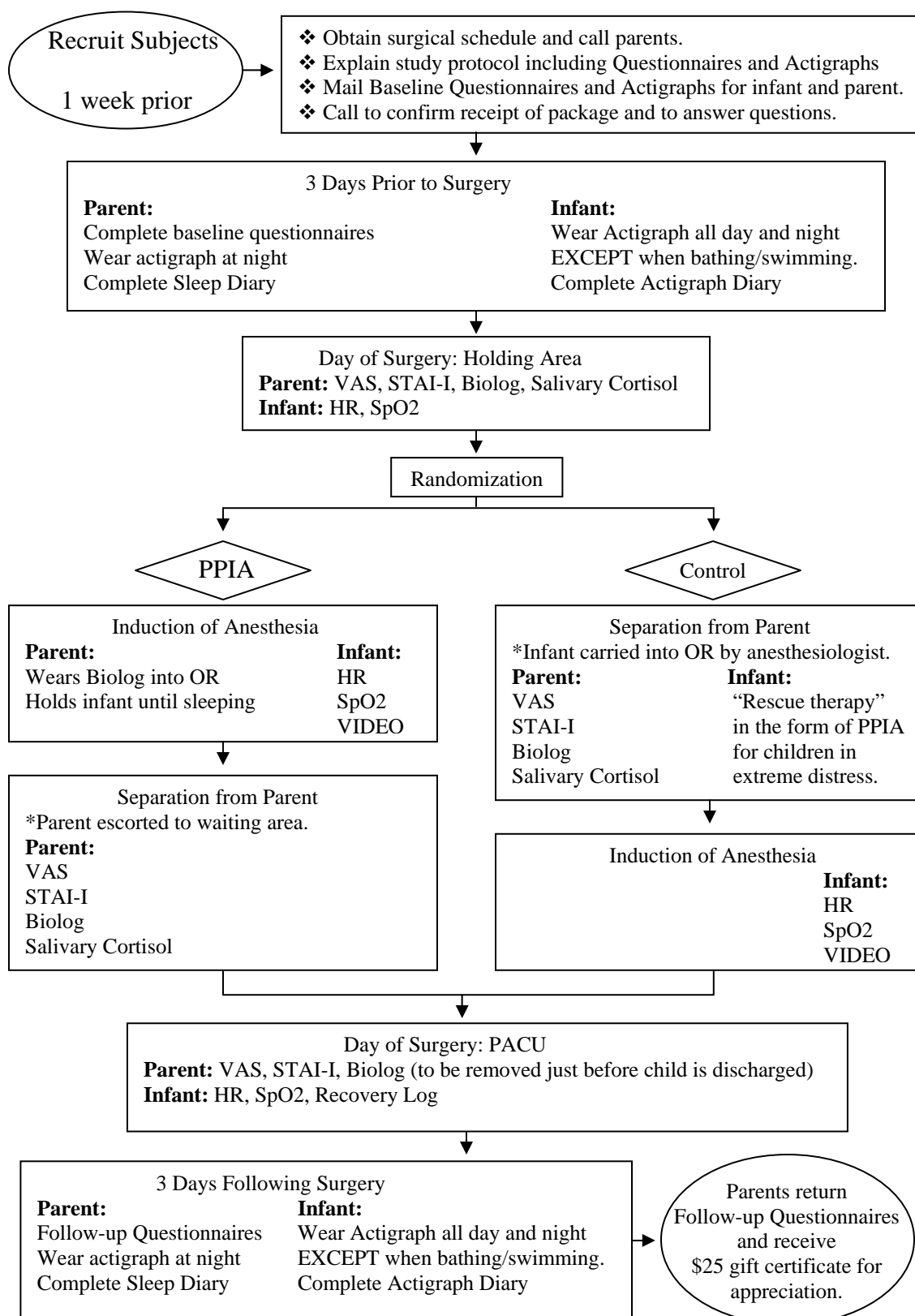


Figure 1: Flow chart summarizing entire study protocol. Chart specifically illustrates two arms of study (PPIA and no PPIA/Control) and the timing of all study interventions and measures.

## PROTOCOL

According to the protocol approved by the IRB, potential subjects were identified based on age and outpatient status by monitoring the updated surgery schedule available to the surgeons and anesthesiologists for OR planning and treatment purposes. Initial contact was made by telephone using a pre-written script at least one week prior to surgery. All parents were offered the opportunity to come in for a pre-admission visit and a face to face discussion with the researcher prior to consenting to any research procedures. Parents who declined this offer, but still wanted to participate, were asked to give verbal consent over the telephone and to provide the investigator with their name and address so that the packet of baseline questionnaires, written informed consent and HIPPA Research Authorization forms could then be mailed to them. Along with the baseline questionnaires, two actigraph watches were sent to the home to be worn for three days prior to the scheduled surgery by the consenting parent and the infant. It was explained that the same parent who signed the informed consent form was the same parent who was responsible for all further study activities (questionnaires, physiological data, and parental presence if randomized to this group).

Baseline questionnaires included demographic data, temperament of the infant (IBQ-R), and trait anxiety of the parent (VAS, STAI, MBSS, Neo, and CASA-P) and took approximately 15-20 minutes to complete. In addition to receiving the two actigraphs (one for the infant and one for the parent), parents also received a Sleep/Actigraph Diary to log the time spent wearing the actigraphs. Parents and infants were asked to wear an actigraph to collect sleep data for three days prior to the scheduled

surgery and for three days following the surgery. Actigraphs were then be returned by pre-arranged and pre-paid express mail.

On day of surgery, in the holding area- When the family arrived in the holding area on the day of surgery, the parent who wore the actigraph was fitted with a blood pressure cuff and Biolog ambulatory monitor. Initial physiological measures, including heart rate, blood pressure, and salivary cortisol were taken. From that point on heart rate was continuously monitored by the Biolog device and blood pressure readings were taken two more times, once after separation of the infant from the parent and once when the parent was reunited with the child in the recovery room following the surgical procedure. Salivary cortisol was only collected again after separation and not in the recovery room. Parents were asked to rate their subjective levels of anxiety using the VAS, STAI and CASA-P at three separate times: in the holding area, after separation, and in the recovery room. Each set of these questionnaires took about 5-10 minutes to complete.

A blinded researcher randomized the subjects to 2 groups:

- a) Parental presence during induction of anesthesia
- b) Control (parents not present in the OR during induction of anesthesia)

On the day of surgery, separation to the OR- Parents in the control group were be asked to rate their anxiety (VAS, STAI and CASA-P) immediately after their child was carried to the OR by the anesthesiologist, a second blood pressure reading was taken, and a cortisol sample was obtained. For children in the control group, rescue therapy in the form of parental presence was available for children who might exhibit extreme anxiety and distress upon separation (though this was not necessary for any subjects in this

study). The determination about the need for ‘rescue therapy’ was made solely by the attending anesthesiologist managing the case.

On day of surgery, in the operating room- Induction of anesthesia was accomplished in the usual manner, no change in the medical management occurred. The child’s initial heart rate, blood pressure, and blood oxygen saturation was recorded during the induction as is routine. Infants were videotaped during induction of anesthesia (approximately 2 minutes for the entire length of videotaping). Videotapes were to be coded later using the NFCS and erased immediately after coding is completed. As soon as the child was asleep, parents in the PPIA group were escorted back to the waiting area and were asked to rate their anxiety level (VAS, STAI and CASA-P), a second blood pressure reading was taken, and a cortisol sample was obtained.

On day of surgery, in the recovery room – Medications administered, incidence of adverse effects, time to discharge and amount of fluid intake was recorded for the child by nursing staff. After parents were reunited with their child in the recovery room, they were asked to rate their anxiety level (VAS, STAI and CASA-P), and a third blood pressure reading was taken. Parental heart rate monitoring via the Biolog device was discontinued at this time, as well.

Postoperative recovery – Parents and infants wore the actigraphs for three days following the surgery and completed the Sleep/Actigraph Diary on each of those three days.

Four days after the surgery - Parents were asked to complete follow-up questionnaires (VAS, STAI, CASA-P, and IBQ-R). They were asked to return the questionnaires, the actigraphs, and the Sleep/Actigraph Diary via the mail in a pre-paid padded envelope.

Upon completion of the study and receipt of the follow-up questionnaires and actigraphs, parents received a \$25 gift certificate and a soft wrist-toy for their child.

## Results

Although fourteen infant-parent pairs were recruited to participate in this study, the final results yielded only ten complete data sets for analysis. One infant had the date of surgery rescheduled due to illness and was lost to follow-up. The parents of two infants did not complete the follow-up questionnaires, and were also excluded from the analysis. The fourth subject was excluded from the analysis because it was not recorded whether this infant was a member of the control group or the parental presence group. Thus, the total number of subjects included in the data analysis was ten, three of which were members of the control group and seven were members of the PPIA group. The characteristics of the subjects included in this study are summarized in Table 1.

Due to randomization of the ten subjects recruited into the study thus far, the number of subjects in each of the study arms (PPIA and Control) was not balanced. Only three subjects were randomly assigned to the Control group, while seven were assigned to the PPIA group. Additionally, the Control group was more homogeneous than the PPIA group. Specifically, all three infants in the Control group were male, while two of the seven infants in the PPIA group were female. One of the infants in the PPIA group had been previously hospitalized in the NICU due to premature birth at 35 weeks gestation. Two infants in the Control group had previous surgeries, (one circumcision and one hydrocelectomy/inguinal hernia repair). All three infants in the Control group were scheduled for urological surgeries during the study protocol, while the PPIA group contained infants undergoing urological and ENT surgeries, one ophthalmological procedure (lacrimal duct probing), and one general surgery (dermoid cyst removal). All parental informants in the study were mothers, except one father in the PPIA group.

**Table 1.** Demographic data for the 10 subjects included in the data analysis.

		<b>Group I (Control) (n=3)</b>	<b>Group II (PPIA) (n=7)</b>
<b>Infants:</b>			
Age (weeks)	Mean $\pm$ SD	49 $\pm$ 3	39 $\pm$ 11
	Median	50	40
Gender (%)	Male	100	29
	Female	0	71
Previous Hospitalizations*		0	1
Previous Surgery†		2	0
Surgeries	Urological	3	2
	ENT	0	3
	Ophthalmological	0	1
	General‡	0	1
<b>Parents:</b>			
Mother as Informant (%)		100	85
Maternal Age (years)	Mean $\pm$ SD	31 $\pm$ 1	29 $\pm$ 5
	Range	31 - 33	20 – 36
Paternal Age (years)	Mean $\pm$ SD	32 $\pm$ 2	32 $\pm$ 5
	Range	31 - 35	24 – 41
Parental Anxiety§			
STAI – Baseline		42.7 $\pm$ 7.8	38.5 $\pm$ 8.9
STAI – Trait		41.7 $\pm$ 7.0	42.7 $\pm$ 7.8

\* NICU due to prematurity

† 1 circumcision and 1 hydrocelectomy/hernia repair

‡ dermoid cyst removal

§ State-Trait Anxiety Inventory **scores reported only for parental informant.**

Scores range from 20–80 with higher scores representing higher levels of anxiety.

Parental anxiety was assessed via the State-Trait Anxiety Inventory (STAI) at four times during the study protocol. Initially, parents reported their general level of anxiety using the STAI-Trait questionnaire. The STAI-State measured situational anxiety as the parent was experiencing at four different times: at baseline, in the holding area before their infant's surgery, just after separation from their infant at or in the OR, and finally when just after they were reunited with their infant in the recovery room. Figure 2 shows the changes in anxiety level for the control group and the PPIA group.

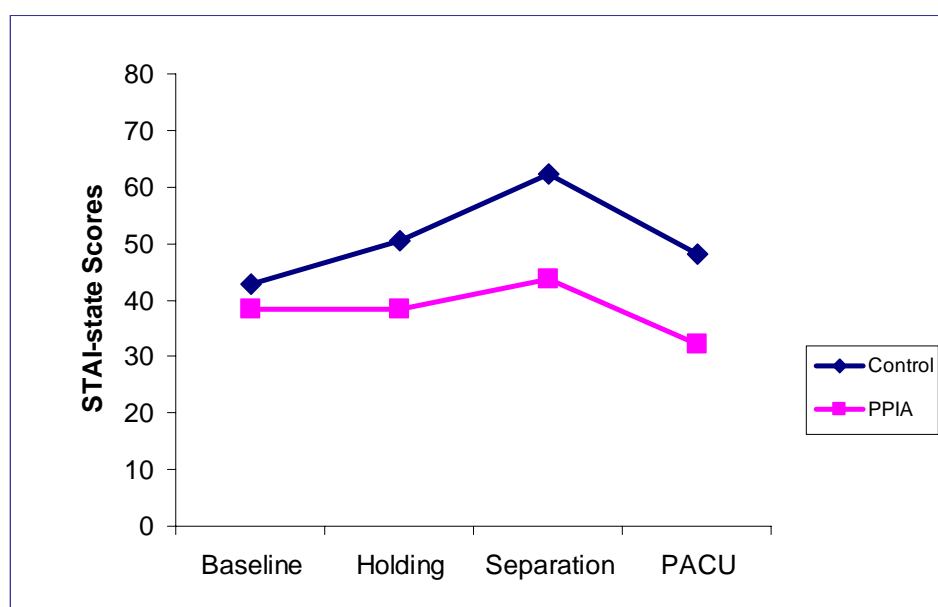


Figure 2: Parental anxiety as measured by the STAI-state at baseline, in the holding area, at separation from their infant, and upon reunion with infant in PACU.

Taking into consideration the small number of parents in the study cohort at this time, the data above may suggest certain trends. All parents began with similar levels of baseline anxiety and anxiety increased for all parents on the day of surgery with the maximum level of anxiety just after separation. However, anxiety was greatest for the control parents that did not carry their infant into the OR. Additionally, the anxiety level



of the three parents in the control group never returned to their baseline level after rejoining their infant after surgery, while the parents in the PPIA group reported levels of anxiety even lower than their original baseline levels.

Parents also completed questions for selected infant temperament domains from the IBQ-R before and after their infant's surgery (Table 2). Before surgery, infants were scored on their baseline activity level, cuddliness, stress recovery rate, perceptual sensitivity, approach, fear and soothability. Infants were rescored in the areas of stress recovery rate, fear and soothability after surgery to assess for any changes in these domains that could be attributed to the intervention of parental presence in the operating room during the induction of anesthesia.

**Table 2.** Infant Temperament Scores for Selected Domains of IBQ-R.

		<b>Group I (Control) (n=3)</b>	<b>Group II (PPIA) (n=7)</b>
<b>Before Surgery:</b>			
Activity Level	(Mean $\pm$ SD)	4.2 $\pm$ 0.1	4.2 $\pm$ 1.5
Cuddliness		5.2 $\pm$ 1.0	6.0 $\pm$ 0.9
Stress Recovery Rate		5.6 $\pm$ 0.4	5.8 $\pm$ 0.6
Perceptual Sensitivity		4.8 $\pm$ 0.4	4.5 $\pm$ 1.1
Approach		6.3 $\pm$ 0.4	6.1 $\pm$ 1.0
Fear		3.0 $\pm$ 1.9	2.7 $\pm$ 1.0
Soothability		4.9 $\pm$ 0.6	5.3 $\pm$ 0.7
<b>After Surgery:</b>			
Stress Recovery Rate		4.8 $\pm$ 0.5	5.7 $\pm$ 0.5
Fear		3.0 $\pm$ 0.9	2.4 $\pm$ 0.8
Soothability		5.2 $\pm$ 0.5	5.4 $\pm$ 0.9

Although there is not enough statistical power at this point in the study to determine the significance of differences in infant temperament scores before and after surgery, (only ten subjects with complete data sets), Figure 3 illustrates the changes measured at this point. As would be expected, the rate of recovery from a stressful stimulus decreased for both groups following surgery. That is it took all infants longer to recover from a stressful event after the surgery than before the surgery. However, there was a greater decrease in the Control group, (although not significant), showing that following surgery the three infants in the Control group required more time to recover from stress than the seven infants in the PPIA group.

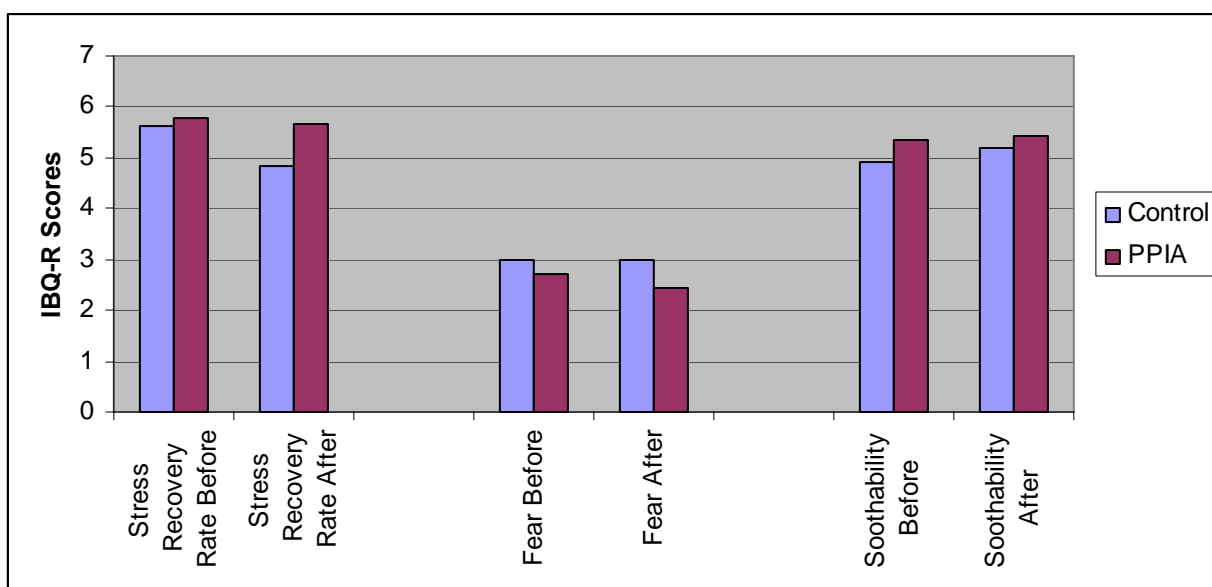
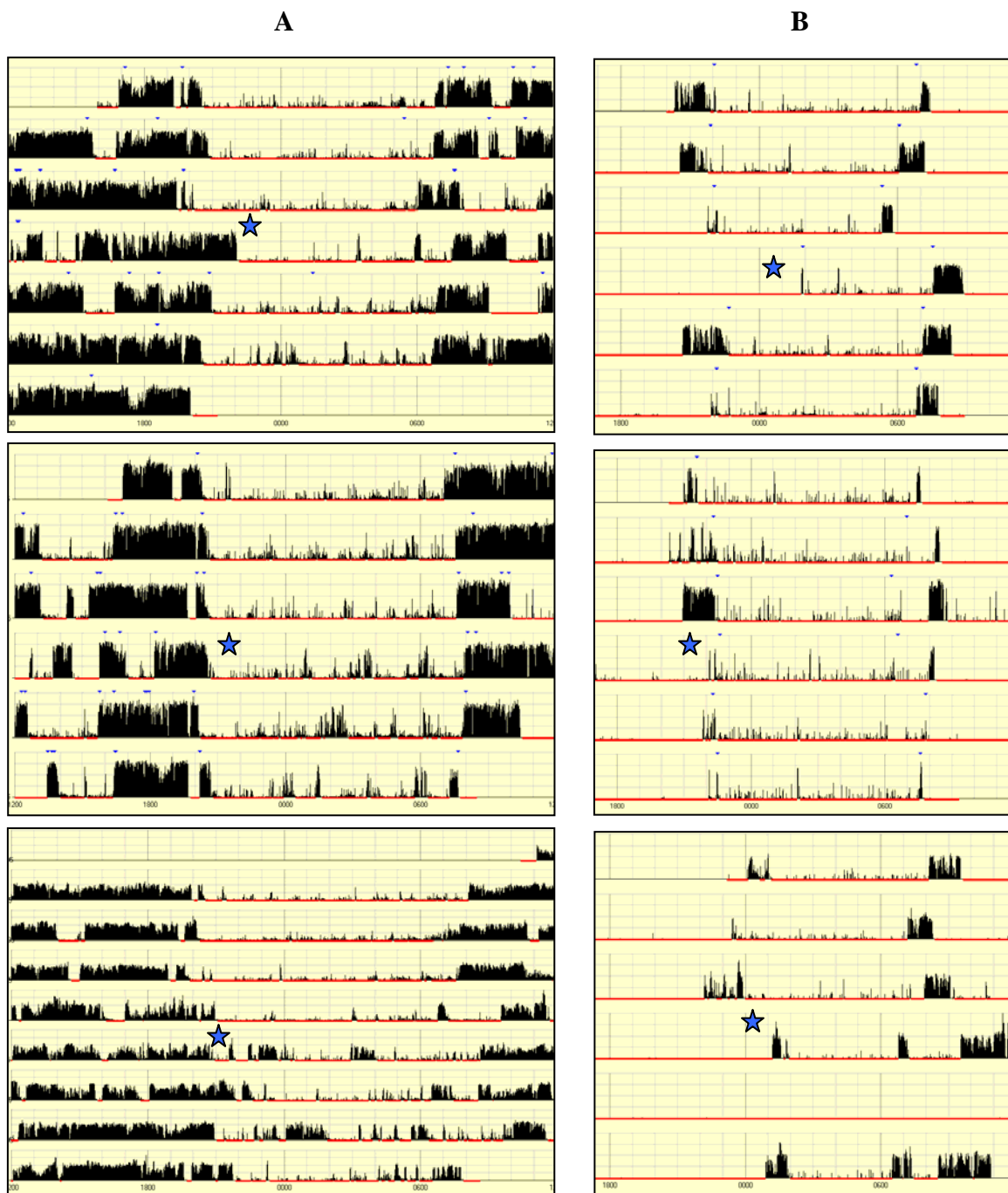


Figure 3: IBQ-R scores for infant temperament for selected domains before and after surgery. Due to limited statistical power, no differences between values are significant.

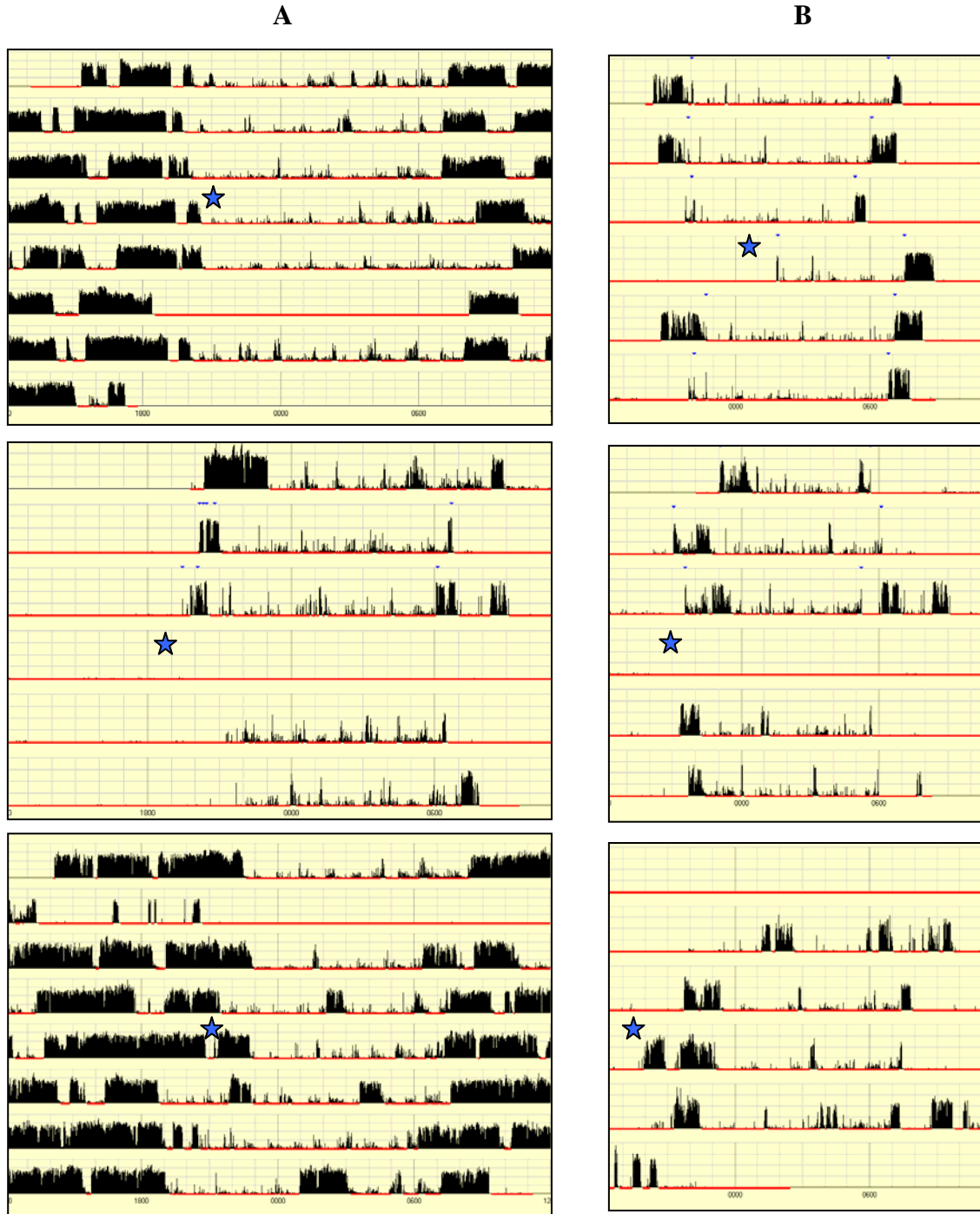
The graph in Figure 3 also shows that parents of the infants in the control group reported their infants' level of fear to be about the same before and after the surgery, while the parents of the infants in the PPIA group reported their infants to have less fear after the surgery. Infant soothability was reported to be slightly increased in both the

intervention and the control group. Recognizing that none of the differences described above have any statistical significance due to lack of power, the changes above are simply suggestive of trends that should be investigated further with a larger sample size.

In addition to the subjective questionnaires completed by the parents, actigraphy added objective behavioral data in the form of measured sleep-wake patterns before and after the infant's surgery. Both the infant and the participating parent were asked to record their sleeping patterns by wearing the motion detecting actigraph watch for three days prior to and three days following the scheduled surgery. Infants were asked to wear the actigraph continuously throughout the day and night except for bathing, swimming, etc, so as to capture day-time napping routines as part of their daily sleep-wake cycles. Recognizing that the majority of adult sleep occurs during the night, the parents were asked to wear the actigraph as they went to bed and then to remove it in the morning when they woke up. Figures 4 and 5 show samples of the raw motion data collected for one infant and their parent. Notice that each vertical black line represents the activity of the individual measured by the computerized accelerometer in the actigraph for that one minute of recording. As previously described by Avi Sadeh (1996), any time period where the amplitude of activity was greater than half the maximum activity level for that individual was considered to be in an awake state <sup>86</sup>.



**Figure 4.** Raw actigraph data for infants (column A) and participating parents (column B) in the control group. Visual inspection of column A shows that infants in the control group had more nighttime waking after surgery, as evidenced by a greater percentage of one minute epochs more than half the maximum activity level. Parental data did not show any obvious change in the pattern of sleep-wake cycles following their child's surgery. Note that the raw data for the third parent (bottom of column B) was missing for one night prior to surgery (infant actigraph recorded 4 days), and the second night after surgery, as the parent forgot to wear the actigraph. ★ Denotes first night after surgery.



**Figure 5:** Raw actigraph data for infants (column A) and participating parents (column B) in the PPIA group. For unknown reasons, the quality of the activity recordings in the infant group was inconsistent, with unexplained patches of missing data. No general assumptions can be made just upon visual inspection. Parental data from the PPIA group also did not show any obvious change in the pattern of sleep-wake cycles following their child's surgery. ★ Denotes first night after surgery.

## STATISTICAL ANALYSIS

Once the collection of data is complete, it will be analyzed using SPSS 14.0 (SPSS Inc, Chicago). All data will be examined for distribution characteristics. If data will be found to be distributed normally, it will be presented as mean and standard deviation and analyzed using parametric tests. If data will be found to be skewed, it will be presented as median and range and analyzed using non-parametric statistics. Initial exploratory analysis will examine the data for outliers, which will be defined as data that is more than two standard deviations from the mean. These outliers will be excluded from analysis. Intention to treat will be used. That is, all data will be analyzed as original group intention as well as actual group assignment.

Initial analysis will include descriptive statistics with student's t test and chi square test (if data are normally distributed) or Mann Whitney U test and chi square (if data are skewed). Correlations between parental anxiety and infant anxiety, as well as infant anxiety and infant sleep disturbances will be examined as well. Group differences will also be examined using multivariate analysis of variance. Subgroup analyses will examine the impact of the age of the child and child temperament on parental anxiety during induction of anesthesia using multivariate analysis of variance and linear regression.  $P < 0.05$  will be considered to be significant.

## Discussion

This study was aimed to examine the effects of parental presence during the induction of anesthesia of their infants. As we have indicated in the introduction, this is an important issue that has many implications. Since we have recruited to date only 14 patients, statistical analysis is not possible. That is, the data with this limited number of patients are unstable and thus a type II error is likely. Therefore, we would be falsely rejecting the hypothesis that PPIA with infants has an impact. Differently stated, we are prone to false-negatives. As such, we will not discuss the results to date.

It is well established that most parents and children prefer to stay together during procedures such as bone marrow aspiration, lumbar punctures, intravenous insertion, and dental procedures<sup>96-99 100</sup>. A recent survey assessing parents' desire to be present when invasive procedures are performed on their children in an emergency department found that 97.5% of parents preferred to be present for their child's venipuncture, 94.0% for laceration repair, 86.5% for lumbar puncture, and 80.9% for endotracheal intubation. In a major resuscitation scenario, 80.7% wished to be present if their child were conscious during the resuscitation<sup>101</sup>. Although there is general agreement about the desirability of parents visiting during their child's hospitalization, their presence during invasive medical procedures, such as induction of anesthesia, is still very controversial<sup>102</sup>. Potential benefits from parental presence include minimizing the need for premedication and avoiding the screaming and struggling that may result on separation from the parents. Other benefits, such as decreasing the child's anxiety during induction and potentially decreasing the long term behavioral effects of surgery, remain controversial. Common objections to parental presence include concern about disruption of the operating room

routine, operative sterility, crowded operating rooms, and the possibility of an adverse reaction by the parent. In addition, parental anxiety in the operating room may result in increased child anxiety, prolonged induction, and additional stress on the anesthesiologist, especially in the event of an anesthetic complication.

In a series of surveys conducted among pediatric anesthesiologists, general anesthesiologists and pediatric surgeons, a significant variability in the practice and attitudes between respondents from the US and Great Britain was found<sup>103-106</sup>. In 1994, a questionnaire was sent to 1353 pediatric anesthesiologists in Great Britain and the United States<sup>104</sup>. Respondents from Great Britain supported parental presence more strongly than did the United States respondents, allowing parental presence in more than 75% of their cases. The reasons for this practice difference between countries may include a stronger demand for parental presence and less concern about legal implications in Great Britain. In 1985 Adrian While, a consultant ophthalmologic surgeon reported in the *British Medical Journal* the profound dismay that he and his wife felt when their request to be present at the induction of anaesthesia in their 3-year old daughter was firmly denied<sup>107</sup>. The publication of Dr. While's article initiated a debate in the anaesthesia community regarding parental presence and resulted in an increased demand for parental presence in Great Britain<sup>108, 109</sup>. It is not surprising therefore that during the last two decades most of the literature regarding parental presence during induction of anaesthesia is from Great Britain.

Concerns about legal ramifications are much more common among American respondents than British respondents. Recently, a lawsuit was reported in which a mother was invited by a nurse to accompany her son into a treatment room in an Illinois



emergency department <sup>55</sup>. According to the court, the mother fainted in the treatment room and suffered an injury to the head as a result of the fall. In its verdict the Illinois Supreme Court stated that a hospital which allows a non-patient to accompany a patient during treatment does not have a duty to protect the non-patient from fainting. However, if medical personnel invite the non-patient to participate in the treatment then the hospital has a legal obligation toward the non-patient. The practice of parental presence in the United States is no doubt affected by lawsuits like these.

In 1995, Kain et al. sent a questionnaire to over 5000 randomly selected anesthesiologists in the US <sup>105, 106</sup>. Results indicated that less than 20% of anesthesiologists used PPIA routinely for their patients. In 2003, Kain et al. repeated the national survey and examined whether any changes had occurred in the frequency of PPIA in the US. To maintain the scientific validity in terms of comparison, Kain et al. again sent the survey to over 5000 anesthesiologists, and used the same randomization process and the same questions as in 1995. Analysis of these data shows that about 50% of the anesthesiologists in the US currently use PPIA to varying degrees in their routine practice <sup>41</sup>. That is, the frequency of the practice of PPIA significantly increased from 1995 to 2002 ( $\chi^2=26.3$ ,  $p=0.0001$ ), and the number of anesthesiologists who *do not* use PPIA dropped significantly (from about 80% to about 40%).

The rising frequency of the practice of PPIA can be attributed to a number of factors. As a result of the current and widespread initiative advocating for more family-centered care in the US, more parents want to be involved and present in all aspects of the health care of their children: at home, in the emergency department, in the intensive care units and during induction of anesthesia. Other factors include the publication of the *2001*

*Institute of Medicine* report that calls for greater family involvement, and influence from various advocate groups that support PPIA.

As indicated earlier, the experimental evidence to date do not support the routine use of parental presence <sup>42</sup>. When interpreting the results of these studies, however, several factors have to be considered. First, the design of a randomized controlled study (RCT), while considered a ‘gold standard’ in research, may *not* reflect the practice of *all* anesthesiologists. That is, while a RCT is applicable to centers who offer parental presence for *all* parents, it may not be applicable to centers who consider each request for parental presence based on personality characteristics of each child and parent. Such centers may have different results with parental presence than were demonstrated in experimental studies. Second, allowing a parent into an OR without significant preparation may be counterproductive. Some parent behaviors, such as criticism, excessive reassurance, and commands given to older children, are associated with greater distress <sup>110-112</sup>. Research interests in this area should shift towards an emphasis on what parents actually do during induction of anesthesia, rather than simply on their presence. Blount, et al. has reported that among children undergoing immunizations, parents who were taught to be active in distracting the child through conversation and reading or in reassuring them through touch and eye contact were able to reduce the child’s distress <sup>110-112</sup>. It may be that effective methods of training can be developed for parental presence during induction of anesthesia.

In conclusion, we suggest that research interests in this area should shift towards an emphasis on *what parents actually do* during induction of anesthesia, rather than simply on their presence. Moreover, this research shift should also evaluate the

behaviors of the participating health care providers, since these individuals also have considerable potential to impact children's anxiety through their behavior. Thus, allowing a parent into an OR without significant preparation may be counterproductive. Some parent behaviors, such as criticism, excessive reassurance, and commands, are associated with greater distress. Research interests in this area should shift towards an emphasis on what parents actually do during induction of anesthesia, rather than simply on their presence.

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