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Parental Auricular Acupuncture as an Adjunct for Parental Presence during Induction of Anesthesia

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Background: **The purpose of this study was to determine whether parental auricular acupuncture reduces parental preoperative anxiety and thus allows children to benefit from parental presence during induction of anesthesia.**

Methods: **Mothers of children who were scheduled to undergo surgery were randomly assigned to an acupuncture intervention group (auricular press needles at relaxation, tranquilizer point, and master cerebral point) or a sham acupuncture control group (auricular press needles at the shoulder, wrist, and extraneous auricular point). The intervention was performed at least 30 min before the child's induction of anesthesia. All mothers were present during induction of anesthesia. The behavioral and physiologic anxiety of mothers and children were rated during the perioperative process.**

Results: **Multivariable analysis examining maternal anxiety as a function of group found a group-by-time interaction ($F_{1,65} = 4.1$, $P = 0.04$). That is, after induction, maternal anxiety in the acupuncture group was significantly lower (42.9 ± 10 *vs.* 49.5 ± 11; $P = 0.014$). A multivariate model ($F_{1,65} = 4.8$, $P = 0.031$) also showed that children whose mothers received the acupuncture intervention were significantly less anxious on entrance to the operating room (34.9 ± 20 *vs.* 47.4 ± 26; $P = 0.03$) and during introduction of the anesthesia mask (38.6 ± 25 *vs.* 55.6 ± 31; $P = 0.016$). There were no significant differences in maternal blood pressure and heart rate between the two groups.**

Conclusions: **Auricular acupuncture significantly decreased maternal anxiety during the preoperative period. Children of mothers who underwent acupuncture intervention benefitted from the reduction of maternal anxiety during the induction of anesthesia.**

PREOPERATIVE anxiety is a common clinical phenomenon in children undergoing surgery.[1,2] Interventions such as sedative premedication, parental presence during induction of anesthesia, and preoperative preparation programs have been used to treat this anxiety.[3–7]

Recent data indicate that over the past 7 yr, there has been a significant increase in the use of parental presence during the induction of anesthesia.[8–11] Interestingly, recent randomized controlled trials have concluded that parental presence during induction of anesthesia does not decrease the anxiety of the child or the parent.[8,12] Both Kain *et al.*[13,14] and Bevan *et al.*[15] have suggested, however, that the anxiety of the parents who are present during the induction process is related to the child's anxiety and thus is of importance. Reducing parental anxiety during the induction of anesthesia process, however, is not an easy task because premedicating the parents is not feasible and behavioral interventions may be expensive and time consuming.

Recently, we found that auricular acupuncture can reduce state anxiety among healthy volunteers, adult patients undergoing ambulatory surgery, and patients undergoing prehospital emergency transport.[16–18] We found that this technique is easy to apply, its anxiolytic onset is relatively rapid, and there are no side effects other than the initial minor pinch at the time of needle insertion.[19] We therefore designed this randomized controlled trial to determine whether auricular acupuncture reduces parental preoperative anxiety, thus allowing children to benefit from parental presence during induction of anesthesia.

Materials and Methods

Study Design and Interventions

The study population of this randomized, double-blind, sham-controlled trial consisted of mothers and their children. Children were aged 2–7 yr, had an American Society of Anesthesiologist physical status I or II, and underwent general anesthesia and outpatient surgical procedures at Yale–New Haven Children's Hospital (New Haven, Connecticut). Children who had a history of chronic illness, prematurity or developmental delay, or central nervous system dysfunction and mothers who had a history of psychological illness (*e.g.*, anxiety, depression) were not invited to participate in this study. A history of previous surgery did not exclude patients from participation in this study. All participants provided informed consent for this study, and Yale University's Institutional Review Board approved the study protocol.

Mothers of children undergoing surgery were randomly assigned to the following two groups. The randomization process was based on a random number table that was generated by a computer. The randomization code was broken by the acupuncturist after patient recruitment and just before the intervention was administered. It is important to note that the mother, the child, the surgeon, the anesthesiologist who performed the induction, and the research assistant who assessed the outcomes were all blinded to group assignment.

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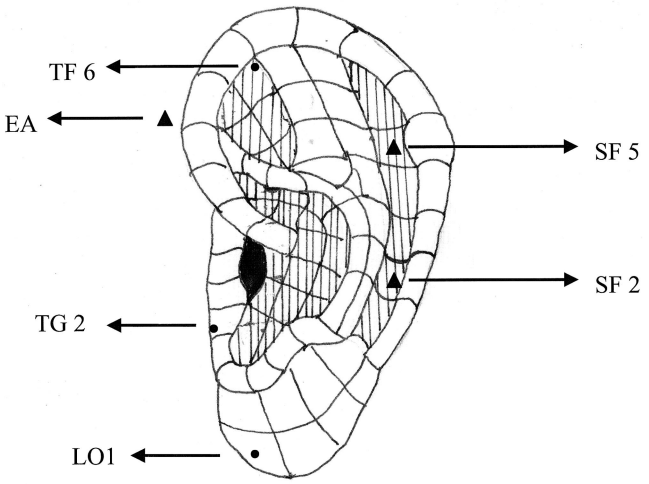

Fig. 1. Location of acupuncture press needles in the ear for both the intervention and sham control groups. ● = Intervention group (L01 = lobe zone 1, master cerebral point; TF 6 = triangular fossa zone 6, hypertension; TG 2 = tragus zone 2 [tranquilizer point]). ▲ = Control group (*EA* = extraneous point; SF 2 = scaphoid fossa zone 2, wrist; SF 5 = scaphoid fossa zone 5, shoulder).

1. Acupuncture group: Mothers in this group received three occlusive auricular press needles at the external ear ipsilateral to the dominant hand. The three auricular points were the relaxation point, the tranquilizer point, and master cerebral point; all three of these ear points have been documented previously by our laboratory[17] to reduce state anxiety (fig. 1).
2. Sham control group: Mothers in this group received three auricular press needles at the external ear ipsilateral to the dominant hand. The three sham ear points selected were the hand point, the wrist point, and the extraneous point. None of these ear points is known to reduce anxiety (fig. 1).

The first author (S.-M. W.), who is a certified acupuncturist, administered the assigned intervention to all the mothers who participated in the study. The research assistants who evaluated all outcomes were blinded to group assignment. The research assistants informed all mothers that they might or might not experience a pinching sensation associated with insertion of the needles. They informed mothers that this sensation is not related to group assignment. To avoid the possibility of bias, the acupuncturist had minimal communication with parents. This communication was standardized (*e.g.*, a greeting, an introduction, and a very brief explanation of the procedure) and was the same for all mothers who were part of this study. It is important to note that the acupuncturist was not involved in any aspect of assessment or data collection in this study.

Behavior and Physiologic Assessment Instruments

State-Trait Anxiety Inventory. The State-Trait Anxiety Inventory, a self-report anxiety inventory, consists of two separate subscales that measure baseline and situational anxiety. Total scores range from 20 to 80, with higher scores indicating higher levels of anxiety. The State-Trait Anxiety Inventory shows excellent reliability and validity and is widely used.[20]

Blood Pressure and Heart Rate. Both heart rate and blood pressure have been extensively used as variables in studies designed to alter anxiety levels and are frequently cited as physiologic indicators of stress in the medical literature.[21–23]

Modified Yale Preoperative Anxiety Scale. Our laboratory has developed the Modified Yale Preoperative Anxiety Scale, an observational state anxiety instrument, to assess the anxiety of young children undergoing anesthesia. This instrument consists of five categories (Activity, Emotional Expressivity, State of Arousal, Vocalization, and Use of Parent) with 27 items. The scale has good to excellent reliability and validity for measuring children's anxiety in the preoperative holding area and during induction of anesthesia.[24]

Induction Compliance Checklist. The Induction Compliance Checklist observation instrument was previously developed by our laboratory to describe the compliance of a child undergoing induction of anesthesia. This instrument has a high interclass *r* both within (0.998) and between observers (0.978).[25]

Study Protocol

Recruitment of Subjects. As is standard at our hospital, all parents were instructed to arrive to the operating rooms 1 h before the scheduled surgery time. After completion of the preanesthetic assessment, eligible mothers were then invited to participate in the study.

Preoperative Period. After recruitment and informed consent, mothers completed demographic questionnaires and baseline state and trait anxiety assessments (State-Trait Anxiety Inventory). A research assistant blinded to the group assignment assessed the mother's baseline blood pressure and heart rate as well as the child's baseline anxiety (Modified Yale Preoperative Anxiety Scale). The acupuncturist then administered the randomly assigned intervention as described above. Thirty minutes after the intervention, mothers completed a second assessment of state anxiety (State-Trait Anxiety Inventory). At this same time point, the blinded research assistant again assessed the child's anxiety (Modified Yale Preoperative Anxiety Scale). As per our preoperative holding routine, the mother and the child stayed in the holding area until the time for surgery. No sedative premedication was given to any children participating in this study. At the time of surgery, all mothers accompanied their children to the operating room.

Induction of Anesthesia. When the mother and her child entered to the operating room and the child was properly situated, the anesthesia induction began with an oxygen–nitrous oxide–sevoflurane technique *via* a

Table 1. Baseline Characteristics of Mothers and Children

	Intervention Group (n = 34)	Control Group (n = 33)	*P* Value
Mothers			
Age, yr	34 ± 6	34 ± 6	0.84
Education, yr	14.8 ± 4	14.9 ± 5	0.69
Baseline heart rate, beats/min	74.7 ± 11	75.5 ± 10.7	0.77
Baseline systolic blood pressure, mmHg	109.5 ± 12	107 ± 20	0.66
Baseline diastolic blood pressure, mmHg	73.1 ± 10	76.8 ± 12	0.15
Trait Anxiety (STAI)	38.7 ± 8	37.7 ± 8	0.39
State Anxiety (STAI)	45.1 ± 12	47.4 ± 10	0.64
Coffee drinker, yes/no, %	82/18	82/18	0.99
Relaxation with alcohol intake, yes/no, %*	50/50	38/62	0.42
Belief in acupuncture, yes/no/not sure, %	76/17/7	74/22/4	0.80
Belief in alternative medicine, yes/no/not sure, %	87/10/3	73/27/0	0.16
Children			
Age, yr	4.3 ± 2	3.6 ± 2	0.13
Sex, M/F, %	53/47	54/46	0.54
Baseline anxiety (mYPAS)	31.5 ± 13	33.1 ± 14	0.63
History of previous surgery, yes/no, %	44/56	42/58	0.61
Attendance at preparation program, yes/no, %	29/71	21/79	0.44

Data are presented as mean ± SD.

* Assessed whether subject experienced relaxation with alcohol intake; such relaxation is thought to be related to endogenous endorphin release and susceptibility to acupuncture.

mYPAS = Modified Yale Preoperative Anxiety Scale; STAI = Spielberger State-Trait Anxiety Inventory.

scented anesthesia mask. The research assistant assessed the child's anxiety when he or she entered the operating room and when the induction mask was introduced. Mothers stayed in the operating room until the child was under anesthesia, and then the research assistant escorted the mother to the waiting room. On arrival in the waiting room, the mother's blood pressure and heart rate were measured, and the state anxiety of the mothers was once more assessed (State-Trait Anxiety Inventory).

After completion of this final assessment, mothers were told that the study was concluded and were offered the option of keeping the auricular needles in place or having them removed. Auricular needles are easily removed without the aid of an acupuncturist. Mothers who decided to retain the press needles were instructed to remove the needles within 24 h after the surgery. The mothers' decisions to remove or keep the needles in place were recorded.

Statistics

Sample size was calculated *a priori* based on our previous study.[17] Given a repeated-measures design, a 20% intervention effect, and an α of 0.05, 30 patients were needed in each group to yield power of 0.85. Normally distributed data are presented as mean ± SD. Continuous variables were examined using *t* tests, and categorical variables were examined using chi-square tests. Anxiety levels (mothers and children), heart rate, and blood pressure data were compared using two-way repeated-measures analyses of variance. *P* values of less than 0.05 were considered statistically significant. Data were analyzed using SPSS version 10 (SPSS Inc., Chicago, IL).

Results

A total of 67 pairs of mothers and children participated in this study. Children underwent the following surgical procedures: PE tube placement (11.9%), tonsillectomy with or without adenoidectomy (25.4%), minor general and urologic procedures (28.4%), minor plastic and endoscopic procedures (29.9%), and strabismus surgery (4.5%). Mothers enrolled in this study were aged 34 ± 6 yr (range, 20–48 yr), and children were aged 4.0 ± 1.7 yr (range, 2–7 yr). Baseline characteristics such as age, years of education, attendance at the voluntary preoperative preparation program, and baseline anxiety level did not differ between the two groups (table 1) or with regard to type of surgery ($P = 0.84$). The time elapsed from the introduction of acupuncture (intervention or sham) to completion of induction of anesthesia ranged from 30 to 80 min (52 ± 17 min). There were no group differences in the time elapsed between these two points ($P = 0.99$).

Maternal anxiety was assessed at three time points: at baseline (T_1), at 30 min after the intervention (T_2), and on completion of the child's anesthesia induction (T_3). Repeated-measures multivariate analysis examining maternal anxiety as a function of group assignment showed a group-by-time interaction ($F_{1,65} = 4.1$, $P = 0.04$) and a group difference ($F_{1,65} = 4.5$, $P = 0.037$). Results showed no statistical differences between the two groups at baseline (T_1; $P = 0.7$) and 30 min after the intervention (T_2; $P = 0.2$), but immediately after induction of anesthesia, mothers in the intervention group were significantly less anxious as compared with moth-

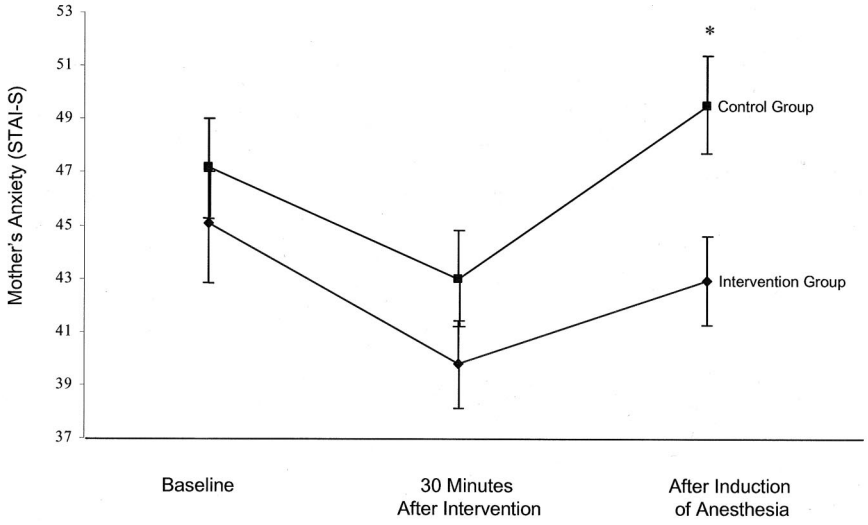

Fig. 2. Anxiety of mothers in the intervention group as compared with the sham control group. STAI-S = State-Trait Anxiety Inventory Scale. * Statistically significant difference between groups; $P = 0.014$.

ers in the sham control group (T_3; 42.9 ± 10 *vs.* 49.5 ± 11, $P = 0.014$; fig. 2).

Children's anxiety was assessed at four time points: at baseline (T_1), at 30 min after the intervention (T_2), on entrance to the operating room (T_3), and on introduction of the anesthesia mask (T_4). A multivariable model examining the child's anxiety as a function of group assignment showed a group-by-time interaction ($F_{1,65} = 4.8$, $P = 0.031$) as well as within-group time changes ($F_{1,65} = 18.1$, $P = 0.0001$). Similar to maternal anxiety, the analysis showed no statistical differences in children's anxiety at baseline (T_1; $P = 0.63$) or at 30 min (T_2; $P = 0.12$). However, children of mothers in the acupuncture group were significantly less anxious as compared with children in the control group both on entrance to the operating room (T_3; 34.9 ± 20 *vs.* 47.4 ± 26, $P = 0.03$) and on introduction of the mask (T_4; 38.6 ± 25 *vs.* 55.6 ± 31, $P = 0.016$; fig. 3).

We also examined children's compliance during induction of anesthesia. Results showed that children whose mothers were in the intervention group were significantly more compliant with the induction process as compared with children whose mothers were in the sham control group ($P = 0.034$; fig. 4).

Baseline maternal heart rate and systolic and diastolic blood pressures did not differ significantly between the intervention and the sham control group (table 1). Multivariable analysis showed that heart rate (75.2 ± 11 *vs.* 74.5 ± 11 beats/min; $P = 0.81$) and systolic (119 ± 14.8 *vs.* 119 ± 14.6 mmHg; $P = 0.95$) and diastolic blood pressures (76.9 ± 11 *vs.* 77.8 ± 9 mmHg; $P = 0.74$) did not differ significantly between the two groups after induction of anesthesia.

Finally, we analyzed the frequency at which mothers elected to leave the acupuncture press needle in their ear after the completion of the study. We found that a significantly higher number of mothers in the intervention group elected to keep the needles in their ears as compared with the sham group (50% *vs.* 9.1%; $P = 0.0001$).

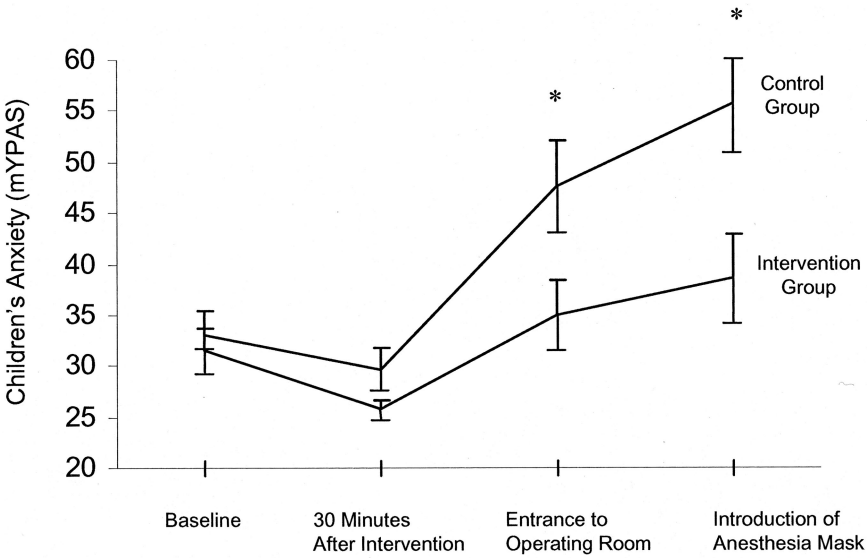

Fig. 3. Anxiety of children whose mothers were in the intervention group as compared with those whose mothers were in the sham control group. mYPAS = Modified Yale Preoperative Anxiety Scale. * Statistically significant differences between groups; $P < 0.03$.

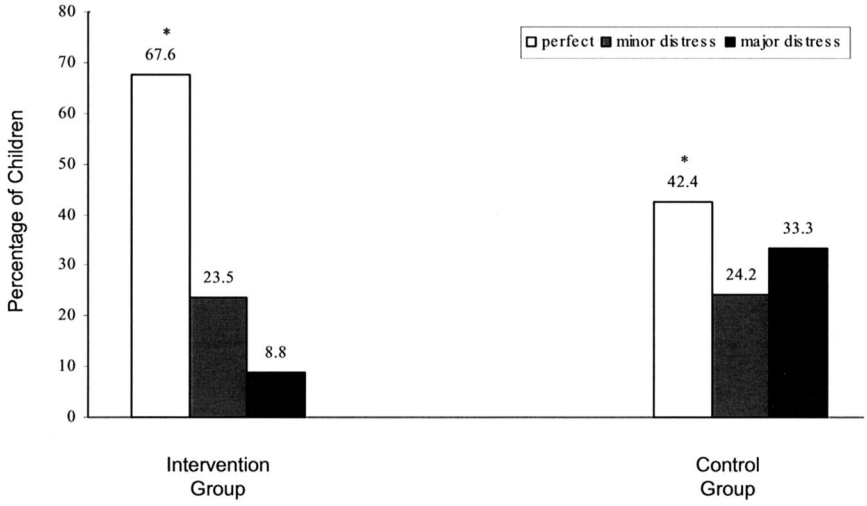

Fig. 4. Compliance during induction of anesthesia of children whose mothers were in the intervention group as compared with compliance of those whose mothers were in the sham control group. * Statistically significant difference between groups on this measure; $P = 0.034$.

Discussion

Two previous studies in Canada and the United States suggested that parental anxiety during induction of anesthesia impacts the child's anxiety.[13,15] Other studies have provided support for this hypothesis by establishing the close correlation between the perioperative anxiety of parents and that of children.[13,26,27] We decided to examine this hypothesis using a randomized control study design. The results of this current study confirm the results of these previous studies. We found that, under the conditions of this study, auricular acupuncture reduces maternal preoperative anxiety. Furthermore, maternal presence during induction of anesthesia combined with maternal auricular acupuncture resulted in significantly reduced child anxiety and significantly increased child compliance with the induction process. These findings were not only established by valid behavioral assessments but were also indicated by the increased desire among mothers in the intervention group to continue with the auricular acupuncture intervention even after completion of the study.

Similar to our previous study[16] as well as others in the existing literature,[28,29] there is a lack of correlation between psychological and physiologic responses. The dichotomy between psychological and physiologic responses to anxiety may be explained by the trait-related individual responsiveness of the sympathetic system[30] and the method of obtaining the physiologic data (single measurement per point *vs.* continuous monitoring over the study period).

Auricular acupuncture and auricular acupressure have been found to decrease situational anxiety in a number of contexts.[16–18] To date, however, the precise mechanism by which acupuncture results in anxiolysis remains undetermined. We can speculate, however, that the mechanisms involved in auricular acupuncture may be similar to those of body acupuncture, during which acupuncture modifies incoming stress signals by regulating the release of neurotransmitters such as endorphins, serotonin, norepinephrine, and γ-aminobutyric acid.[31–34]

Our previous findings indicated that auricular acupuncture effectively reduced state anxiety in healthy volunteers and preoperative anxiety in adults undergoing ambulatory procedures within 30 min after the acupuncture intervention.[17] Interestingly, although the current study showed decreased maternal anxiety at 30 min, this decrease did not reach statistical significance. This finding may be a result of maternal anxiety regarding the child's surgery *versus* self-anxiety regarding one's own surgery. That is, it may be that mothers are more anxious regarding their child's surgery as compared with the anxiety that an adult patient feels when he or she is about to undergo surgery, and this anxiety may therefore take more time to dissipate. Our laboratory described a related finding involving parental desire for perioperative information.[35] In a series of two studies, we demonstrated that parents desire significantly more perioperative information regarding their child's surgery as compared with the amount of information desired by adult patients undergoing surgery.[35,36]

Auricular acupuncture/acupressure has several important advantages as compared with pharmacologic and behavioral interventions directed at the treatment of preoperative anxiety, namely that it has minimal equipment requirements, minimal operational costs, ease of application, a relatively rapid onset, and almost no side effects. Therefore, we believe this technique could easily be incorporated into the routine treatment of preoperative anxiety. It should be noted that a major problem in the area of acupuncture for children is that many children are unwilling to accept needle acupuncture. However, because these results show that applying anxiolytic acupuncture to parents of children undergoing surgery can reduce the child's preoperative anxiety, it seems that acupuncture treatment of the

parent may therefore offer a unique opportunity to reduce children's anxiety.

Finally, a methodologic issue elated to this manuscript must be addressed: the potential impact of a maternal placebo effect. That is, although mothers participating in this study were blinded to group assignment, they could have been influenced by nonverbal clues given by the acupuncturist, who was not blinded to group assignment. Although we have adhered to a written protocol and tried to eliminate such as occurrence, this scenario is still plausible. We do not think, however, that such a placebo effect occurred.

In conclusion, we found that maternal auricular acupuncture in combination with maternal presence during induction of anesthesia reduced children's anxiety and increased children's compliance with the induction process. This finding has important management implications for children undergoing anesthesia and surgery.

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