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ARTICLE *in* ANESTHESIA & ANALGESIA · OCTOBER 2005

Impact Factor: 3.42 · DOI: 10.1213/01.ANE.0000175212.17642.45 · Source: PubMed

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Acupressure and Preoperative Parental Anxiety: A Pilot Study

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In this randomized sham-controlled study we examined the anxiolytic and sedative effects of acupressure on parents in the preoperative holding area before their children's surgery. Sixty-one parents received acupressure either at the Yintang point (midpoint between the two eyebrows) or at a sham point. Anxiety (as measured by the Stait-Trait Anxiety Inventory), arterial blood pressure, and heart rate were assessed before and after the intervention and a Bispectral Index monitor was used to continuously monitor hypnotic sedation levels. Repeated-measures analysis of variance showed that parents in the acupressure group reported significantly less anxiety at 20 min postintervention as compared with parents in the sham group (37 ± 10 versus 45 ± 13, $P = 0.03$). Bispectral Index values, heart rate, and arterial blood pressure, however, did not differ between the two study groups (P = not significant). We conclude that acupressure at the Yintang point may be used as a treatment for parental preoperative anxiety. Future studies are needed to quantify the magnitude and duration of the anxiolytic effect.

(Anesth Analg 2005;101:666–9)

It is well established that parents of children undergoing surgery experience significant anxiety and fear during the preoperative period (1,2). Unfortunately, management of parental preoperative anxiety is challenging because pharmacological interventions are not feasible; thus, nonpharmacological interventions have been suggested (3–6).

We previously reported that auricular acupuncture decreases preoperative anxiety in mothers whose children underwent surgery (7). Although the diameter of the needles used for auricular acupuncture is quite small, this intervention is still associated with some discomfort. As a result, health care providers and parents may have reservations regarding the use of this technique for the treatment for parental preoperative anxiety.

Recently, Fassoulaki et al. (8) reported that acupressure at the Yintang point (midpoint between the eyebrows) results in sedation and decreases anxiety in healthy volunteers in laboratory settings. Because acupressure is noninvasive, we wanted to explore whether this modality would remain effective in clinical settings. We therefore hypothesized that acupressure at the Yintang point would decrease anxiety in parents of children who present for surgery.

Methods

Participants in this randomized, blinded, sham-controlled trial were 61 parents of children who were scheduled to undergo elective surgery. Parents were ASA physical status I–II with no known history of psychiatric illness and no previous experience with acupuncture as reported on direct inquiry. Only one parent (mother or father) per child participated in the study. The Human Investigation Committee at Yale University approved the study, and written, informed consent was obtained from all participants.

Parents were randomized to an acupressure group or a sham group based on a computer-generated randomization table. Parents in both groups were treated with an acupressure bead (Helio, San Jose, CA) manufactured with an occlusive tape covering that creates standardized pressure; no further pressure or manipulation was applied after the bead was secured. Patients in the acupressure group received the bead at the Yintang point, the mid-point between the two

Supported, in part, by the National Institutes of Health grants NCCAM, R21AT001613–01 to SMW and NICHD, R01HD37007–02 to ZNK.

Accepted for publication March 28, 2005.

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DOI: 10.1213/01.ANE.0000175212.17642.45

0003-2999/05

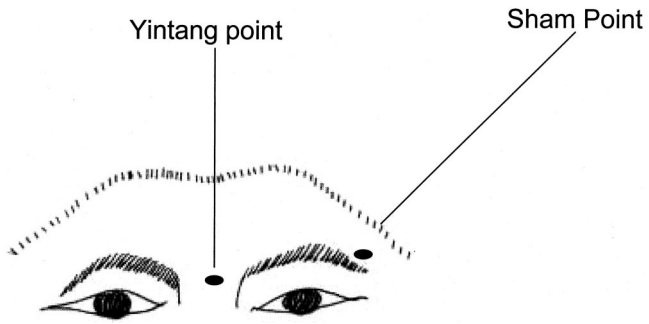

Figure 1. Location of Yintang and sham points.

eyebrows (Fig. 1). Parents in the sham group received the bead at a sham point located above the lateral border of the left eyebrow (same dermatomal distribution as the Yintang point).

The primary outcome of the study was parental anxiety as assessed by the State Trait Anxiety Inventory (STAI), a reliable and valid measure widely used to measure preoperative anxiety (9–12). Anxiety was also assessed at two time points using physiological markers such as heart rate and arterial blood pressure. We also measured changes in sedation as a function of the intervention using the Aspect A-2000® system (Aspect Medical Systems, Inc., Natick, MA) to examine changes in the Bispectral Index (BIS) (13). Although the BIS value is not well validated for the assessment of mild sedation (14,15), we used this instrument, as we wanted to replicate the laboratory-based volunteer study by Fassoulaki et al. (8).

On recruitment, participants completed a demographic questionnaire and both the trait and state portions of the STAI. A research assistant blinded as to group assignment and without acupuncture experience applied the BIS Quatro probe to each participant; a period of 5 min was allowed for each parent to obtain a wake steady-state BIS value. At this time, baseline heart rate and arterial blood pressure were also measured.

Next, the first author, a trained licensed acupuncturist, applied the adhesive acupressure bead to the appropriate intervention point. To achieve external validity, parents were not separated from their children and all interventions and tests were done in the preoperative holding area with no change in any routine preoperative environments or care. Twenty minutes after the onset of the intervention, the blinded research assistant administered a second state-anxiety assessment (STAI) and measured the parent's heart rate and arterial blood pressure. The acupressure beads and BIS electrodes were then removed and the study was terminated.

Sample size was calculated *a priori* based on findings from our previous study (16). Considering a repeated measures design, a 20% effect of intervention, an α of 0.05 and power of 85%, 27 patients were needed in each study group. Data were analyzed using SPSS version 10.0 (SPSS Inc., Chicago, IL). Two-way analysis of covariance with repeated measures was used to analyze changes in state anxiety (STAI-S), with trait anxiety (STAI-T) as the co-variable. Average BIS values were recorded for each 5 min of continuous BIS data, as downloaded from the BIS monitor. Two-way analysis of variance with repeated measures was used to analyze changes in sedation (BIS value). Comparisons were considered significant if $P < 0.05$; data are reported as mean ± SD.

Table 1. Baseline Data of Parents and Children

	Acupressure group (n = 28)	Sham group (n = 33)
Parental age (yr)	37.7 ± 5.9 (26–51)	37.5 ± 6.9 (26–57)
Parental gender (Male/Female)	17/11	24/9
Child age (yr)	5 ± 2.4 (2–9)	5.8 ± 2.4 (2–9)
Parental education (yr)	15 ± 2.7	15 ± 2.9
Trait anxiety	39 ± 8	37 ± 6

Values are mean ± SD (range) or n.

Results

Sixty-one parents were recruited to this study. No protocol violations occurred. There were no differences in baseline demographic characteristics or trait anxiety data between acupressure and sham groups (Table 1).

We found that state anxiety (STAI-S) between the two study groups differed over time, as evidenced by a significant group × time interaction ($F = 7.59$, $P = 0.008$). At baseline, the state anxiety of parents did not differ between groups (44 ± 11 versus 43 ± 11, $P = 0.65$); at 20 min postintervention, parents in the acupressure group were significantly less anxious (37 ± 10 versus 45 ± 13, $P = 0.03$). We next conducted a two-way repeated-measures analysis of variance to compare the BIS values of the two groups. We found no BIS differences either within groups or between groups (P = not significant). That is, BIS values did not change within the groups from baseline to the follow-up period and there were no BIS differences between the two study groups in any of the time intervals examined (5 min, 10 min, 15 min, 20 min). Finally, there were no significant differences in arterial blood pressure and heart rate between the two groups (P = not significant).

Discussion

Under the clinical conditions of this preliminary study, parents who received acupressure at the Yintang point reported less anxiety as compared to the

sham group. We did not, however, observe any difference in BIS values or heart rate and arterial blood pressure between the two study groups.

In this study, STAI-S scores of parents in acupressure group decreased an average of approximately 8 points. As STAI scores range from 20 to 80, one could raise the question whether an 8-point change in the STAI-S is clinically significant. In 1991, Jacobson and Truax (17) published a seminal methodological article detailing the determination of clinically significant change. This methodology has elucidated the difference between statistically significant change (changes that result in $P < 0.05$) versus clinically significant change (clinically meaningful changes). Indeed, a review of multiple trials that used the STAI indicated that a change of at least 8 points on the STAI is considered clinically significant (18). Thus, we submit that the acupressure treatment provided not only statistically significant differences but also clinically significant changes in average anxiety scores. Although one might think that the change in anxiety scores observed in this study was smaller as compared with the laboratory-based study conducted by Fassoulaki et al. (8), the difference is related to a different outcome measure and study design. In contrast to previous investigations that used a simple visual analog scale to assess anxiety, we used a validated and reliable anxiety assessment instrument that has been used in a number of studies examining preoperative anxiety (9–12). Also, subjects in previous studies were volunteers in a relaxing environment, whereas subjects of the current study were parents who were actively participating in the care of children who were about to undergo surgery and were waiting in a regular preoperative holding area. These changes in the settings, subjects, and outcome assessment instrument and the different acupressure technique are likely reasons for the smaller magnitude of change in anxiety scores in our study.

In this study, we did not observe any difference in BIS values between the two study groups. This finding is in contrast to previous studies (8,19). One should note, however, that previous studies have used an active circular motion that stimulated the muscle; this motion was not standardized. In contrast to previous investigations, we used beads to create standardized acupressure and we did not actively manipulate or cause muscle movement. Overall, we are not surprised by the lack of difference in BIS values. Although there are ample data to suggest that BIS values correlate with depth of anesthesia, it has been reported that BIS values are not sensitive in the mild sedative range (14,15).

We decided *a priori* to include both mothers and fathers, as we have not observed a gender-based response to acupuncture in our previous studies. However, we are aware that traditional acupuncturists believe that gender may play a role in the effect of acupuncture (20). Future studies could include gender as a potential variable of interest. Moreover, we expected patient attrition as a result of protocol violation or voluntary withdrawal; however, as such attrition did not occur, our final number of subjects was somewhat larger than we had planned.

In conclusion, we found that acupressure at the Yintang point results in decreased parental anxiety. A limitation of this preliminary study, however, is the short follow-up period subsequent to the intervention. Future investigations are needed to establish the duration of this anxiolytic effect as well as the impact of this parental intervention on the child's anxiety.

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