Acupuncture as an Adjunct for Sedation During Lithotripsy

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ABSTRACT

Objective: To determine whether a combination of auricular and body acupuncture is effective as an adjunct for the preprocedural anxiety and pain management in patients undergoing lithotripsy procedures.

Design: Randomized controlled study.

Setting and Location: Lithotripsy suite located at the Yale New Haven Hospital, New Haven CT.

Subjects: Adult patients who were scheduled to receive elective lithotripsy procedures.

Interventions: Acupuncture group: Preprocedural auricular acupuncture intervention combined with intraprocedural electroacupuncture stimulation (n = 29); Sham control group: Preprocedural sham auricular acupuncture intervention combined with intraprocedural sham electroacupuncture stimulation (n = 27).

Outcomes measurement: Preprocedural anxiety, intraprocedural alfentanil consumption, visual analogue scale for pain.

Results: Patients in the acupuncture group were less anxious preprocedure than those in the Sham Control Group (29–34) versus 40 (35–45) (p = 0.029). Similarly, patients in the Acupuncture Group used a lesser amount of alfentanil than those in the sham control group (p = 0.040). The adjustable alfentanil consumption as expressed by median rate of alfentanil consumption of 1 (0.6–1.6) μg kg⁻¹minute⁻¹ in the acupuncture group was lower than that of 1.5 (0.9–2.3) μg kg⁻¹minute⁻¹ in the sham control group. Patients in the Acupuncture group also reported lower pain scores on admission to the recovery room (p = 0.014).

Conclusions: A combination of auricular and body acupuncture can be used as an adjunct treatment to decrease preprocedural anxiety and intraprocedural analgesia in patients undergoing lithotripsy.

INTRODUCTION

Shock-wave lithotripsy (SWL) is a technique that uses shockwaves to fragment small renal and upper ureteral calculi.1,2 Although SWL is a noninvasive technique, it can lead to significant discomfort during and after the procedure. In fact, the majority of patients who undergo SWL require sedatives or analgesics such as intravenous opioids.3–5 Because avoidance or minimization of opioids is generally desirable, other treatment modalities that can provide the analgesic effect are currently being explored.

Acupuncture and related techniques have been used as a treatment for many medical conditions. Indeed, acupuncture is reported to be effective in the management of periopera-

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tive conditions such as preoperative anxiety, postoperative nausea and vomiting, and postoperative pain. A literature search revealed two reports that describe the use of acupuncture as an analgesic modality during SWL. The first report is a case series of 3 individuals who received acupuncture during SWL, and the second report is a non-randomized, uncontrolled, cohort study that examined the analgesic effect of acupuncture during SWL.

Previous studies conducted by our laboratory have demonstrated that auricular acupuncture at the valium, master cerebral, and relaxation points can reduce preoperative anxiety of adults undergoing ambulatory surgery. Also, a Chinese acupuncture textbook and several other recent studies report that body acupuncture stimulation applied to the Liver 3 and Large Intestinal 4 acupuncture points can decrease back and visceral pain. Based on these previous studies, we hypothesized that the application of retained auricular acupuncture would reduce preprocedural anxiety and, when combined with electroacupuncture stimulation, will decrease the intraprocedural alfentanil consumption during SWL.

MATERIALS AND METHODS

A double-blinded, sham-controlled, randomized study was conducted in a group of patients who were scheduled to receive elective lithotripsy (compact Donier 4 lithotriptor) for either renal or upper ureteral calculi at Yale-New Haven Hospital. The institutional ethics committee approved the study protocol, and all patients provided informed written consent prior to participating in the study. The American Society of Anesthesiologists’ Physical Status I-III English-speaking patients, ages 18–65 years who had no previous experience of acupuncture were enrolled in this study. Exclusion criteria for participation included a history of psychiatric problems, previous experience in acupuncture treatment, and analgesic use within 1 week before the procedure.

Potential patients were identified from the schedule several days in advance from the operating room scheduling system. An investigator called eligible patients the night before surgery and provided study information; explained the participation required, and obtained a verbal informed consent over the telephone. On the day of procedure, scheduled patients arrived at the Yale-New Haven Hospital and underwent routine admitting procedures. When the routine admission procedures were completed, a research assistant obtained a written informed consent as instructed by the institutional review board. Next, patients completed a demographic questionnaire and the baseline State-Trait Anxiety Inventory (STAI).

While in the holding area, the acupuncturist performed the appropriate auricular acupuncture intervention, ipsilateral to the patient’s dominant hand, without the presence of the research assistant. Patients in the acupuncture group received auricular acupuncture at the Relaxation, Master Cerebral, and Valium points of the Ear and patients in the sham group received auricular acupuncture at the Wrist, Shoulder, and Extraauricular sham points of the Ear (Fig. 1A). All auricular acupuncture interventions (both acupuncture and sham groups) were achieved using sterile, single-use, sticker press needles (retainable needles), which are 0.25 mm × 2 mm (Seirin Pyonex®, SaiShui, Japan). The press needle has a circular base (2 mm² in diameter) that is directly attached to self-adhesive tape and once positioned, it remains in place. Both ears were then covered with a surgical hat to conceal the needle locations and thus blind the observers. Thirty (30) minutes after the initiation of auricular acupuncture, all patients (both Acupuncture and Sham Groups) completed a second self-assessment of state anxiety (STAI).

FIG. 1. A. Auricular acupuncture points for “True acupuncture” and “Sham control” groups. B. Acupuncture points for “four gates.”
Patients were next brought to the lithotripsy suite and after patients were situated on the lithotripsy table, electrocardiogram, noninvasive arterial blood pressure, arterial oxygen saturation, and end-tidal carbon dioxide tension monitors were placed. The anesthesiologist connected the patient to an alfentanil patient-controlled analgesia (PCA) pump (3 μg kg⁻¹ bolus of alfentanil with a 5-minute lockout interval). Patients were told to use the PCA pump whenever they experienced pain and were asked to indicate any pain during the procedure if the self-administered alfentanil was not adequate. The anesthesiologist was instructed to give supplemental alfentanil boluses (3 μg kg⁻¹) only if the patient complained of pain while the PCA pump was in a lockout period. Next, the anesthesiologist administered an intravenous dose of 20 μg kg⁻¹ of midazolam, 10 μg kg⁻¹ of alfentanil, and 10 mg of metoclopramide over 5 minutes to all study patients. Then, the acupuncturist was called to the lithotripsy suite and placed the body acupuncture needles according to group assignment.

Patients in the acupuncture group received body acupuncture at bilateral Liver 3 and Large Intestine 4 points. Liver 3 is located on the dorsum of the foot in the depression distal to the junctions of the first and second metatarsals, and Large Intestine 4 is located on the radial side of the middle of the second metacarpal (Fig. 1B). Body acupuncture interventions were performed using 0.3 × 50 mm needles (Addiqui,® Ito Co., Ltd., Shanghai, China). After the body acupuncture insertion process, these needles were attached to a Patheon® Electro Stimulator 4-C (Venice, CA) (Fig. 2). This electrical stimulator has four isolate microcurrent output channels, which deliver symmetrical biphasic waveform, with spike-shaped waves on the top and bottom. The positive and negative aspects of the waveform are equal in voltage amplitude, and the net DC bias of the waveform is zero. The pulse width is 4 milliseconds. The acupuncturist adjusted the frequency to 2 Hz and 25 V.

Patients in the sham group received body acupuncture using 0.3 × 50-mm needles (Addiqui) at the Bilateral Liver 3 and Large Intestine 4 points. Although the location of the body acupuncture needles was identical in both study groups, the depth of needle insertion varied significantly. That is, the acupuncture group received the traditional Chinese needle insertion, whereas the sham group received only a superficial insertion (1–2 mm). After the insertion process, the needles were attached to the same Patheon Electro Stimulator 4-C, but no electrical stimulation was delivered. All patients were told that they might or might not experience vibration when the electrodes were applied and during the adjustment of output. It is important to note that the stimulator was encased in a sealed box to conceal output settings in order to ensure blindness of the research assistant, anesthesiologist, nursing staff, and urologist during the procedure. This sealed box containing the stimulator was then placed at the foot of the bed so the patient was not able to see the box while lying in the supine position needed for SWL. All patients then received a standardized shockwave protocol treatment (2500 shocks for renal calculi and 3000 shocks for ureteral calculi) to a maximum level of 6. At the conclusion of the lithotripsy, the acupuncturist was called to the lithotripsy suite to remove the auricular and body acupuncture needles. Patients were then transported to the Recovery Room.

Pain was assessed using a visual analogue scale (VAS) on admission to the recovery room and every 15 minutes throughout the entire recovery period. The VAS rating system consists of a 100-mm line that represents the two extremes at either end of a continuum (i.e., no pain [score of 0] and extremely painful [score of 10]). A bolus of 25 μg of intravenous fentanyl was administered by a recovery room nurse if the patient achieved a score of 3 or higher on the VAS pain scale. The total dose of fentanyl was administered, and episodes of nausea and vomiting and postoperative anti-emetic requirements were documented. Routine electrocardiogram, noninvasive blood pressure, and arterial oxygen saturation were monitored throughout the recovery period. To assess the sensory and affective dimension of pain prior to patients’ discharge from the Recovery Room, we used the short-form McGill questionnaire (SF-MPQ), which comprised a total of 15 words (11 words from sensory category and 4 words from affective category) that allowed us to obtain more information from the patient than just the intensity of pain.

Finally, upon discharge from the hospital, all patients were asked to grade their satisfaction with intraprocedural SWL analgesia using the VAS satisfaction and whether they believed that they received the true acupuncture treatment. This rating system consists of a 100-mm line that represents the two extremes at either end of a continuum (i.e., not satisfied [score of 0] and extremely satisfied [score of 10]).

Statistics

Sample size was based on data obtained from our previous study of adult patients undergoing lithotripsy using

![FIG. 2. The Patheon® Electro Stimulator (Venice, CA).](image-url)
alfentanil sedation. In that study, the alfentanil requirement of the control group was a mean (standard deviation) 119 ± 16 µg min⁻¹. Twenty-seven (27) patients are therefore required in each group to achieve a 20% effect, with an alpha of 0.05 and a power of 85%. Normally distributed data are presented as mean (95% CI) and non-normally distributed data are presented as median (25%–75%). Continuous variables were analyzed using an independent-sample two-sided Student’s t test; categorical variables were analyzed using chi-square tests. The Mann-Whitney test was used for continuous nonparametric data (alfentanil dose, VAS pain scores upon arrival in the recovery room and SF-MPQ pain scores on discharge from the hospital). Adjusted-alfentanil rate was calculated by dividing the total dose of alfentanil by patients’ weight (kg) and duration of the procedure (min). Two-way repeated-measures analysis of variance (ANOVA) was used to explore the STAI anxiety data before and after the intervention. Data were analyzed using SPSS version 10 (SPSS Inc., Chicago, IL). A probability value of less than 0.05 was considered significant.

RESULTS

One hundred and thirty-four (134) patients were identified from the operating room schedule. After a chart review,
we found that 48 patients were not eligible because of consumption of psychiatric medication or chronic analgesics, a physical status of ASA 4, or the inability to contact the patient before the procedure date. Of the remaining 86 patients, 28 patients declined participation because of one of the following reasons: preference for general anesthesia, deficiency in English language, fear of acupuncture needles, prior experience in acupuncture treatment, and no interest in being a study subject. Thus, a total of 58 patients provided informed consent for participation in the study and none of them had preprocedural hydronephrosis. Two patients, however, did not complete the study because of logistical issues relating to the availability of study drugs (i.e., our pharmacy had a shortage of alfentanil that was needed for this study).

There were no significant differences between the two study groups regarding demographic variables, baseline anxiety, size of calculi, and the locations of calculi (Table 1). No additional medication was administered to any of the participants during the lithotripsy except the list of study medications. Two-way repeated-measures ANOVA demonstrated a significant Group × Time interaction for anxiety before SWL \([F(1,72) = 6.6, \ p = 0.010]\). That is, patients in the Acupuncture Group reported significantly \((p = 0.029)\) less anxiety at 30 minutes after initiation of auricular acupuncture as compared with patients in the Sham Group (Table 2). During SWL, we found that the median rate of alfentanil consumption of 1.0 (0.6–1.6) \(\mu\)g kg\(^{-1}\)minute\(^{-1}\) in the Acupuncture Group was significantly \((p = 0.040)\) lower than that of 1.5 (0.9–2.3) \(\mu\)g kg\(^{-1}\)minute\(^{-1}\) in the Sham Group.

A VAS pain scale was used to assess the level of the pain in all patients upon admission to the recovery room. We found that the median pain scores of 0.0 (0.0–1.3) in the acupuncture group were significantly \((p = 0.014)\) lower than those of 1.7 (0–3.2) in the sham group when they arrived to the recovery room. Similarly, pain scores at discharge from the hospital as assessed by the SF-MPQ were lower in the Acupuncture Group than those of the Sham Group \((p = 0.047, \text{Table 2})\). Fentanyl requirements in the recovery room, however, did not differ between the two groups \((p = 0.220)\) (Table 2).

Finally, there were no statistical significant differences between the acupuncture group and the sham group in the incidence of nausea and vomiting during the recovery period \((7\% \ vs. 18\%)\), time to oral intake of clear fluids, time to discharge from the recovery room, satisfaction with the analgesia management, or the number of patients who believed that they received the true acupuncture \((p = 0.519)\) (Table 2).

**DISCUSSION**

Under the conditions of this study, we found that patients who received auricular acupuncture were less anxious before undergoing SWL as assessed by STAI-S \([32 (29–34)\) vs. 40 (35–45), \(p = 0.029]\), and that the combination of auricular acupuncture and body electroacupuncture reduced the amount of alfentanil needed during SWL. Patients who received acupuncture also indicated lower levels of pain upon admission to the Recovery Room as assessed by a VAS for pain \([0.0 (0.0–1.3) vs. 1.7 (0–3.2), p = 0.014]\). The results of this randomized, controlled trial are consistent with previous reports suggesting that acupuncture can be used as an adjuvant to pharmacologic analgesia for patients undergoing SWL.\(^{13,14}\)

We submit that the observed reduction of analgesic requirements may be caused by the release of endogenous endorphins via electroacupuncture stimulation\(^{16,25}\) or a decreased perceived pain secondary to reduced anxiety.\(^{26,27}\) A direct causal explanation for this effect, however, is not yet clear and further research is needed in this area. We have previously reported the effectiveness of auricular acupuncture in decreasing preoperative anxiety in adult patients and parents of children undergoing surgery.\(^{6,15}\) This randomized, controlled trial has confirmed these previous findings in the setting of a combined treatment scheme, using two different acupuncture-based modalities for the treatment of both anxiety and pain.

Interestingly, although the amount of alfentanil used during lithotripsy was lower in the acupuncture group, this was not associated with a statistically significant difference in the incidence of nausea and vomiting in the recovery room. However, because the study was not powered to detect a difference in nausea and vomiting, the lack of statistical significance may very well be due to a Type II error. Future studies are needed to clarify this point.

A major limitation of the present study is that we did not include a control group without any acupuncture intervention or another sham Control Group that consisted of electrical stimulation at sham locations. The readers should note, however, that the inclusion of a control group without any acupuncture intervention already unblended the subject and that several recent studies indicated that electroacupuncture-induced analgesia does not show strong acupoint specificity.\(^{19,28,29}\) Lastly, between the two groups, we did not find any difference in the number of patients who believe they did receive the true acupuncture intervention throughout the periprocedural period.

**CONCLUSIONS**

We found that a combination of auricular and body acupuncture can affect intraprocedural alfentanil requirements during lithotripsy. At present, we are not certain whether this reduction of analgesic requirement during lithotripsy is mainly caused by the reduction of anxiety or the additional body electroacupuncture stimulation or a combination of both. Future studies with more complex design are needed to clarify this issue.
REFERENCES


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