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# Description and Validation of a Noninvasive Placebo Acupuncture Procedure

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## ABSTRACT

**Objective:** To evaluate a simulated acupuncture technique for use in randomized controlled trials assessing the efficacy of acupuncture for low-back pain.

**Setting:** The clinic of an accredited acupuncture college in Seattle, Washington.

**Subjects:** Acupuncture-naïve enrollees of Group Health Cooperative who had visited their primary care provider with a complaint of back pain that persisted for at least 3 months.

**Experimental design:** In the first experiment, subjects received six insertions of real needles and six pokes with a toothpick in a guidetube in a two-period crossover design. In the second experiment, subjects were randomly assigned to receive either a complete treatment with real acupuncture needles or a simulated treatment using a toothpick in a guidetube.

**Outcomes:** In the first experiment, we compared subjects' perceptions about which implement was used for each "insertion" while in the second, we compared the perceptions (e.g., acupuncturist's warmth and caring, the reasonableness of acupuncture as a treatment) and pain relief of those who received an acupuncture treatment using needles to those receiving simulated acupuncture.

**Results:** In the first experiment, the toothpick insertions were perceived as slightly more like real needling than the real needling (mean ratings of 2.8 and 2.1, respectively; $p = 0.08$). In the second experiment, 52% percent of those receiving the simulated needling versus 65% of those receiving real acupuncture believed they were "definitely" or "probably" receiving real acupuncture ($p = 0.33$). Perceptions of acupuncture, as measured by a credibility questionnaire, were similar in the two groups. Those receiving real acupuncture were more likely to report immediate pain relief, and this was the factor most predictive of the subject's belief about which treatment they had received ($p = 0.02$).

**Conclusions:** The simulated acupuncture procedure evaluated in this study represents a reasonable control treatment for acupuncture-naïve individuals in randomized controlled trials assessing the efficacy of acupuncture for low-back pain.

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## INTRODUCTION

Clinical studies of acupuncture have used a variety of comparison groups including no treatment, standard medical care, and "placebo" treatment that may be invasive or noninvasive (Ernst and White, 1997; Hammerschlag, 1998). Because it is practically impossible to devise a physiologically inert treatment that is indistinguishable from real acupuncture, there is no perfect control group in studies of efficacy (Vincent and Lewith, 1995). A noninvasive control that simulates needling sufficiently to maintain patient blinding would minimize concerns that the comparison treatment actually had a therapeutic physiologic effect.

A few studies have used ostensibly inert placebo controls: acupuncture needles were rubbed against the skin (Borglum Jensen et al., 1979) or glued to it (Vincent and Richardson, 1986); the skin was pricked with a fingernail to simulate acupuncture (Junnila, 1982), and the skin was touched superficially with the blunt end of the needle (Hesse et al., 1994). Unfortunately, these studies did not examine the extent to which people in the control group believed they were receiving real acupuncture. In a study of dental pain, Lao et al. (1995, 1999) simulated acupuncture in a control group with the use of a needle guidetube. By using acupuncture-naïve patients who received only one treatment while their eyes were covered, they were able to show that patients were unable to determine whether or not they received acupuncture. For a study of headaches, White et al. (1996, 2000) modified Lao's technique by inserting a blunted cocktail stick inside the guidetube.

Another physiologically inert comparison used in many acupuncture studies is a disconnected transcutaneous electrical nerve stimulation unit (mock TENS) (Thorsteinsson et al., 1978; Vincent and Lewith, 1985). Even though several studies have found that acupuncture and mock TENS are similarly credible (Petrie and Hazelman, 1985; Wood and Lewith, 1998), the placebo power of mock TENS has been shown to be dependent on how it is presented to the patient (Kaptchuk, 2000; Langley, 1984).

Two research groups have recently developed noninsertive blunt-tipped acupuncture needles with shafts that telescope into the needle handle when tapped (Park et al., 1999; Streitberger and Kleinhenz, 1998). To study subjects, these needles appear indistinguishable from standard needles. One of these needles has been used successfully in a study evaluating acupuncture for shoulder pain (Kleinhenz et al., 1999).

In this report, we describe a nonneedle simulated acupuncture procedure, a toothpick in a needle guidetube, developed for a study of acupuncture and chronic low-back pain. The credibility of this procedure as a placebo control was tested in two experiments using acupuncture-naïve participants. In the first experiment, in which participants received both real needle insertions and simulated insertions, we compared subjects' perceptions about which implement was used for each "insertion." In a separate experiment, we compared the perceptions of subjects who received an acupuncture treatment using needles to those of subjects receiving simulated acupuncture.

## METHODS: EXPERIMENT 1

### *Simulated acupuncture needling technique*

A procedure was developed to simulate a complete acupuncture treatment, including "insertion," "needle stimulation," and "needle withdrawal." Subjects were asked to lie face down on a treatment table. Before the treatment, the acupuncturist wiped the skin around each acupoint with alcohol. To simulate needle insertion, the acupuncturist held the skin taut around each acupuncture point and placed a standard acupuncture needle guidetube that contained a toothpick against the skin. The acupuncturist then tapped the toothpick gently, twisted it slightly so that it felt to the subject like an acupuncture needle grabbing the skin, and quickly withdrew both the toothpick and guidetube while keeping his or her fingers against the skin for a few additional seconds to imitate the process of inserting the needle to the proper depth. The subject remained on the table for approximately 20 minutes to simulate the period that acupuncture needles were typically left *in situ*. Because acupuncturists commonly stimulate the acupuncture needles approximately

midway through the period of needle retention, the acupuncturist touched each acupuncture point with the tip of a toothpick (without a guidetube) and then rotated the toothpick clockwise and then counterclockwise less than 30°. The subject remained on the table for another 10 minutes. Finally, to simulate withdrawal of the needle, the acupuncturist stretched the skin around each acupoint tightly, pressed a cotton ball firmly on the stretched skin, then touched the skin with a toothpick (without a guidetube) momentarily, and finally pulled the toothpick away quickly using the same hand movements as in regular needle withdrawal. Slight variations occurred among acupuncturists in performing this procedure paralleling the normal variations in needle insertion among acupuncturists. In the first experiment, only needle insertion was simulated, whereas in the second experiment, a complete treatment was simulated.

*Study design*

Acupuncture-naïve subjects each received six insertions of real acupuncture needles and then six simulated needle (toothpick) "insertions" (or the reverse) in a two-period crossover design. Either acupuncture needles (Seirin 1-inch, 36-gauge; Weymouth, MA) were inserted and then quickly removed or the simulated insertion procedure was quickly performed. The participants, who were lying face down on a massage table with their heads in face cradles and their arms at their sides on the tables, were unable to observe which implement was being used for each of the 12 toothpick pokes or needle insertions. The six toothpick pokes (or needle insertions) in each period of the crossover study were performed at six distinct acupoint locations (three on the low back, ashi, UB23, Du3, or Du4; one on the side of the hand, SI3; one on the back of the knee, UB40; and one on the side of the foot, Ki3) (Deadman and Al-Khafaji, 1998). Five of these acupoint locations were the same for both periods, except that opposite sides of the body (left or right) were stimulated during the first and second periods; the remaining location was a pair of points on the spine (Du 3 or Du4). The order in which acupoints were stimulated was randomly determined in both periods of the crossover (using a pair of orthogonally partitioned Latin squares). Acupoints were selected to include those anatomic locations most commonly stimulated during acupuncture treatments for chronic low-back pain (i.e., lower back, hands, leg, foot). (Sherman et al., 2001).

Two experienced, licensed acupuncturists who practiced Traditional Chinese Medicine (TCM) acupuncture performed the insertions and simulated insertions in the clinic of an accredited acupuncture college (Northwest Institute of Acupuncture and Oriental Medicine, Seattle, WA). After each insertion or simulated insertion, participants were asked which treatment they thought they received using a 5-point scale: 1 = definitely real needle; 2 = probably real needle; 3 = uncertain; 4 = probably imitation needle; or 5 = definitely imitation needle.

*Subjects*

The study protocol was approved by the Group Health Cooperative institutional review board and all patients gave written informed consent prior to treatment. The study was conducted using subjects from Group Health Cooperative, a group model health maintenance organization (HMO) in Washington State. Thirteen people who had visited their primary care providers for back pain between 6 and 7 months previously and who had indicated interest in a previous acupuncture study—but were not included—completed this study. This included two subjects who had acupuncture more than 10 years in the past and one whose treatment deviated from the current protocol.

*Statistical analyses*

Mean scores of participant's ratings of the likelihood they had received real needling were calculated for the simulated insertions and the real insertions (Table 1). A Wilcoxon signed rank test was performed to determine whether there were significant differences in the participants' ratings of simulated needling and real needling. Analyses were conducted including and excluding the two acupuncture subjects who had had acupuncture more than 10 years ago and the person who was not treated according to protocol.

Table 1. Perceptions of Participants Who Received Both Real Needle Insertions and Simulated Insertions About the Type of Insertion They Received[a]

| Participant[b] | Mean rating scores[b] | | | p- value[c] (based on all 10 participants) |
|---|---|---|---|---|
| | Real needles (R) | Imitation needles (I) | Difference (I–R) | |
| 1 | 3.00 | 3.00 | 0.00 | |
| 2 | 2.33 | 3.83 | 1.50 | |
| 3 | 3.17 | 1.33 | −1.83 | |
| 4 | 2.33 | 1.50 | −0.83 | |
| 5 | 3.00 | 1.00 | −2.00 | |
| 6 | 3.17 | 1.67 | −1.50 | |
| 7 | 1.50 | 1.00 | −0.50 | |
| 8 | 2.83 | 3.17 | 0.33 | |
| 9 | 3.00 | 2.17 | −0.83 | |
| 10 | 3.67 | 2.50 | −1.17 | |
| Mean | 2.80 | 2.12 | −0.68 | 0.08 |

[a]Five-point rating scale: 1 = definitely real needle; 2 = probably real needle; 3 = uncertain; 4 = probably imitation needle; 5 = definitely imitation needle. Participants received, in random order, either 6 real needle insertions followed by 6 simulated insertions or the reverse.

[b]Three participants were excluded from this analysis: Two had received acupuncture previously (12 years or 15 years ago) and one received one simulated insertion when a needle insertion was required by the protocol.

[c]$p$ value computed from a Wilcoxon signed-rank test.

## RESULTS

The 10 acupuncture-naïve individuals who received the correct protocol included five men and five women between 28 and 61 years of age (mean, 42 years). On average, the toothpick "insertions" were perceived as slightly more realistic than the real needling (mean ratings of 2.1 and 2.8, respectively; $p = 0.08$; Table 1). An analysis including the two subjects who received acupuncture 12 or 15 years ago and the subject whose treatment deviated from the protocol showed similar results. Moreover, no effect of practitioner, period, or treatment order on ratings were seen in a logistic regression of the individual scores; thus the balance that was intended by the Latin squares was confirmed.

## METHODS: EXPERIMENT 2

### *Study design*

The original plan was to randomly assign 60 subjects to receive a standardized acupuncture treatment using real acupuncture needles ($n = 30$) or to a "treatment" using the toothpick–guidetube simulation at the same acupoints ($n = 30$). In this experiment, an entire acupuncture treatment was simulated using the technique described earlier.

The real treatment included insertions of eight needles into three distinct acupoints on the low back (ashi, Du3, UB23 bilateral), one on the back of the knee (UB40 bilateral), and one on side of the foot (Ki3 bilateral) (Deadman and Al-Khafaji, 1998). Acupuncturists used only Seirin 1-inch, 36-gauge needles. Treatments were provided in the clinic of an acupuncture college by six experienced licensed acupuncturists, five who normally practiced TCM acupuncture and one who normally practiced Japanese acupuncture. The treatment lasted 20 minutes with stimulation of the acupuncture point after 10 minutes, and again, just before needle withdrawal.

During telephone recruitment, information was solicited about participants' knowledge of acupuncture, their experience with it, and their expectations of effectiveness using questions previously developed by Lao et al. (1999). Lao's post-treatment questionnaire included a modified version of the Borkovic and Nau treat-

ment credibility scale adapted by Vincent (1990) for use in acupuncture studies. During the treatment, a research assistant remained in the room with the participants. Immediately after the treatment session, participants were asked to complete a 13-item "post-treatment psychologic impact questionnaire" questionnaire developed by expanding and revising the post-treatment instrument used by Lao et al. (1999). Information was collected about the treatment the subject believed they had received and a variety of perceptions including the sensations of needle insertion and needle withdrawal, the caring of the acupuncturist, expectations that acupuncture could relieve pain, and willingness to recommend acupuncture to others with back pain. The questions on the baseline and post-treatment questionnaires were designed to solicit information using scales that contained between three and seven possible responses.

*Subjects*

Using automated visit data, we identified and mailed letters to 1049 patients (between 25 and 64 years of age) who visited a Group Health Cooperative primary care provider for low-back pain at least 3 months previously. Of 116 people who expressed interest in the study, 56 individuals were ineligible for a variety of reasons including previous acupuncture, history of major medical conditions, and inability to lie prone on the treatment table. Sixty (60) study subjects were randomized and received a treatment. Eight subjects who had had previous acupuncture were mistakenly randomized (six to a real treatment and two to a simulation) and excluded from the analyses. Written informed consent was obtained from all subjects. The results presented here are from the 52 acupuncture-naïve participants who received a standardized acupuncture treatment with real needles ($n = 23$) or the same protocol using toothpicks in guidetubes ($n = 29$).

*Statistical analyses*

Student's $t$ tests were used to determine differences between group means. Most results are presented dichotomously, with $p$ values from $\chi^2$ or Fisher's exact tests. Wilcoxon rank sum tests using ungrouped data did not yield materially different results and are not presented, except for a comparison between groups of subjects' certainty about which treatment they received. We performed an ordinal logistic regression using subjects' certainty about which treatment they received (as measured on a five point scale from 1 = definitely real acupuncture needles to 5 = definitely not real acupuncture needles) as the dependent variable and including treatment group and all the perceptions of acupuncture in Table 2 as potential predictor variables.

## RESULTS

The baseline characteristics of the groups receiving needle acupuncture and simulated acupuncture were generally similar (Table 3). The biggest difference was that twice as many subjects in the acupuncture group had been previously informed that acupuncture was moderately or very effective ($p = 0.08$). In addition, four patients in the acupuncture group compared to one in the simulated treatment group said they were "moderately or very concerned" about receiving treatment ($p = 0.16$).

The perceptions of participants receiving real needling were similar to those who received the simulated treatment (Table 4). Fifty-two percent (52%) of those receiving the simulated needling versus 65% of those receiving real acupuncture believed they were "definitely" or "probably" receiving real acupuncture ($\chi^2 = 0.96$, $p = 0.33$). None of the participants in the simulated acupuncture group believed they "definitely" received simulated acupuncture and less than one third of those receiving real acupuncture were certain they had received real acupuncture. Subjects receiving the simulated treatment were slightly more likely to believe that they "probably" received the simulation than those receiving real acupuncture (21% versus 9%, Fisher's exact test, $p = 0.28$).

We were concerned that even if participants could not distinguish between the two treatments, they might feel different sensations when real and imitation needles were inserted or removed. In fact, slightly more participants receiving real acupuncture reported feeling the

Table 2. Comparison of Responses of Participants Receiving a Real or Stimulated Acupncture Treatment on Post-Treatment Questionnaire

| Question | Treatment Group: Simulated (n = 29) | Treatment Group: Real (n = 23) | p-value[a] |
|---|---|---|---|
| | % | % | |
| Back pain moderately or much improved?[b] | 4 | 33 | 0.01[c] |
| Acupuncturist's warmth & caring high? | 56 | 57 | 0.94 |
| Probably or definitely seek acupuncture treatment? | 34 | 43 | 0.51 |
| Believe acupuncture probably or definitely relieves pain? | 21 | 39 | 0.14 |
| Probably or definitely would recommend acupuncture? | 28 | 30 | 0.82 |
| Acupuncture probably or definitely a reasonable treatment? | 41 | 43 | 0.89 |
| Acupuncture probably or definitely helpful for back pain? | 31 | 26 | 0.70 |

[a]$\chi^2$ test were performed unless otherwise noted.
[b]Two subjects who received a real treatment and one who received the stimulated treatment did not answer this question.
[c]Fisher's exact test.

needles inserted (83% versus 69% respectively, $p = 0.34$) while the proportion of participants receiving real and simulated acupuncture who reported that it felt as if needles were being removed was similar (43% versus 41%, respectively, $p = 0.88$).

After treatment, those receiving real and simulated needling had similar perceptions of the acupuncturist's warmth and caring, the likelihood of seeking acupuncture treatment in the future, the likelihood of recommending acupuncture to others, the reasonableness of acupuncture as a treatment, and the helpfulness of acupuncture for the treatment of low back pain (Table 2). However, in spite of these similarities, 33% of subjects in the acupuncture

Table 3. Baseline Characteristics of Participants Receiving a Needle Acupuncture Treatment or Simulated Acupuncture Treatment

| Characteristic | Treatment group: Simulated (n = 29) | Treatment group: Real (n = 23) | p-value[a] |
|---|---|---|---|
| Age (mean) | 43.2 | 44.8 | 0.63[b] |
| Women (%) | 66 | 48 | 0.20 |
| Talked to people who have tried acupuncture (%) | 48 | 52 | 0.78 |
| Talked to people who have used acupuncture for low-back pain (%) | 17 | 22 | 0.73[c] |
| Heard acupuncture is moderately or very effective (%) | 24 | 48 | 0.08 |
| Heard acupuncture is moderately painful (%) | 3 | 4 | 1.0[c] |
| Have moderately or very positive view of acupuncture (%) | 48 | 35 | 0.33 |
| Know acupuncture needles are very thin (%) | 72 | 61 | 0.38 |
| Know acupuncture needles may or may not hurt (%)[d] | 74 | 65 | 0.45 |
| Moderately or very concerned about receiving treatment (%) | 3 | 17 | 0.16[c] |

[a]$\chi^2$ tests are performed, unless otherwise noted.
[b]Student's *t*-test
[c]Fisher's exact test.
[d]Three subjects receiving a real treatment and two receiving the simulated treatment did not answer this question.

TABLE 4. PERCEPTIONS OF PARTICIPANTS ABOUT THE TREATMENT THEY RECEIVED BY TREATMENT GROUP

| *Perception* | *Treatment Group* | | p-*value (based on all responses)* |
|---|---|---|---|
| | *Simulated (n = 29)* | *Real (n = 23)* | |
| Which treatment did you receive? | % | % | |
| Definitely real acupuncture needles | 14 | 30 | |
| Probably real acupuncture needles | 38 | 35 | |
| Not certain | 28 | 26 | |
| Probably not real acupuncture needles | 21 | 9 | |
| Definitely not real acupuncture needles | 0 | 0 | 0.15[a] |
| Did it feel like needles were being inserted? | | | |
| Yes | 69 | 83 | |
| No | 17 | 17 | |
| Not certain | 14 | 0 | 0.34[b] |
| Did it feel like needles were being removed? | | | |
| Yes | 41 | 43 | |
| No | 48 | 43 | |
| Not certain | 10 | 13 | 0.88[c] |

[a]Obtained from Wilcoxon rank-sum test.
[b]Obtained from Fisher's exact test (no and not certain are combined).
[c]Obtained from $\chi^2$ test (no and not certain are combined).

group reported that their back pain was moderately or much improved compared to 4% in the simulated acupuncture group ($p = 0.01$). In a logistic regression designed to determine which perceptions in Table 2 were predictive of belief in receiving a real treatment, only back pain improvement was statistically significant ($p = 0.02$).

## DISCUSSION

The results suggest that the toothpick and guidetube acupuncture simulation technique is an adequate placebo control for evaluating acupuncture as a treatment for chronic low-back pain using acupuncture-naïve participants. Although those receiving a needle treatment were more likely to believe they were definitely getting the real treatment and less likely to think they were probably getting a simulation, the differences were small. It is noteworthy that none of the 29 subjects in the simulated acupuncture group felt certain that they were receiving the placebo treatment and more than two thirds of these subjects reported they felt needles being inserted. These data, coupled with the observation that those acupuncture-naïve participants who experienced both real and simulated insertions found the simulated insertions slightly more convincing, suggest that this technique represents a reasonable acupuncture placebo. In addition, these results are similar to the effectiveness of blinding in previous clinical trials of TENS units and $\beta$-blocker therapy (Byington et al. 1985; Deyo et al. 1990).

However, extensive practitioner training in performing the procedure, to ensure that the treatment feels as realistic as possible, may be critical to the successful use of this technique as a placebo control in clinical trials. Furthermore, the inclusion of other features of a needle treatment, such as the sounds of unwrapping needles and placing needles into special disposal containers at the end of treatment, are likely to enhance the credibility of the simulation.

This noninsertive control is especially useful for studies in which the needles are placed in locations that the subjects cannot see, such as the acupoints used in many back pain and neck pain treatments. Because the sensation of needling varies among acupoints, it would be important to test the technique using the proposed point prescription before using it in a

specific study. If this simulated needling procedure were used in studies where needles are placed in locations visible to the subjects, a screen or a blindfold would be necessary to prevent them from viewing these locations during the treatment.

Few studies have evaluated a noninsertive acupuncture control (Lao et al. 1995, 1999; Streitberger and Kleinhenz, 1998; White et al., 1996, 2000). The success of a simulated needling technique may well depend on the context in which it is presented as well as on as the characteristics of the participants. For example, Streitberger and Kleinhenz (1998) informed healthy, pain-free subjects that two different needles were being evaluated. The subjects had a real needle inserted in their hands for 2 minutes and were then poked with a placebo needle in the same location (or the reverse). Subjects who were unaware that one of the needles had a blunt tip were asked whether they felt each of the needles being inserted and how painful it was. Subjects claimed to feel the needle being inserted in 90% of the real punctures and 78% of the placebo pokes. By contrast, Lao et al. (1999) studied participants who had received a real or a simulated acupuncture treatment using an empty needle guidetube for the relief of acute pain after a molar extraction. During the treatment, participants wore eye covers and were later asked whether they thought they had received a real or placebo treatment. Although initially patients could not accurately guess which treatment they received, by the time they left the clinic several hours later, patients receiving real treatment were more likely to believe that is what they received. Because more people in the real acupuncture group obtained substantial pain relief, such findings are consistent with the idea that in the context of clinical studies, symptom relief plays a role in an individual's belief about what treatment they actually received.

Because practitioners who deliver placebo procedures cannot be masked to the treatment they are giving, they may inadvertently communicate this information to patients. In addition, if the simulated treatment does not match the expectations of the participant about acupuncture, then it could have diminished credibility. Therefore, it is advisable to measure treatment credibility directly in both treatment groups in order to ascertain whether differences in credibility could have influenced the study's outcome. This can be done directly by asking patients to guess what treatment they think they received or indirectly by asking participants' questions similar to those used in this study (e.g., perceptions of whether or not they felt needles inserted, whether or not they received the real or imitation treatment, likelihood of trying acupuncture in the future, the acupuncturist's warmth and caring). In some studies, where patients are being told that they may receive one of two different treatments, credibility can only be assessed indirectly.

The credibility of a treatment may also depend on prior knowledge of acupuncture, and, over time, with the results of treatment, as was demonstrated by Lao et al. (1999). If, for example, acupuncture needling relieves back pain, we would expect that those receiving real needling would be more likely to think they were receiving a real treatment independent of whether they "felt needles being inserted." In our study, we found that those receiving real acupuncture were more likely to report immediate pain relief, and that this was the factor most predictive of the subjects' belief about which treatment they had received. Thus, it is not surprising that participants who received a real needle treatment were slightly more likely to think they got a real treatment than those who received the simulation, even though both groups had many similar perceptions of their treatment as measured by responses to the post-treatment questionnaire. Because acupuncture-experienced individuals have prior expectations based on experience of how their body feels when punctured, it is inappropriate to include them in studies using a noninsertive needle control.

Finally the issue must be raised of whether a noninsertive simulated needle treatment is truly inert. Most authors define acupuncture as the insertion of thin needles into specific points on the body, but there are actually a variety of techniques and styles of stimulation within the traditional practice of acupuncture (Dale, 1997). In fact, noninsertive needling is actually practiced as part of some styles of acupuncture (Birch and Felt, 1999). Therefore, it is probably most accurate to describe this procedure as a

minimal sham treatment (Park et al., 1999). A better understanding of the physiologic basis of acupuncture, especially of the effects of more gentle stimulation, will be required to determine if a noninvasive placebo can be considered a truly inert control.

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