Pain relief by applying transcutaneous electrical nerve stimulation (TENS) on acupuncture points during the first stage of labor: A randomized double-blind placebo-controlled trial

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Abstract

Transcutaneous electrical nerve stimulation (TENS) is one of the non-pharmacological means of pain relief for labor and delivery. We aimed to investigate the efficacy and safety of TENS on specific acupuncture points for reducing pain in the first stage of labor. In this double-blind, placebo-controlled trial, we randomly assigned healthy full-term parturients in active phase of first-stage labor to either TENS on four acupuncture points (Hegu [Li 4] and Sanyinjiao [Sp 6]) (n = 52) or the TENS placebo (n = 53). Visual analogue scale (VAS) was used to assess pain before and 30 and 60 min after treatment. The primary outcome was the rate of VAS score decrease \( \geq 3 \) in each group. A questionnaire was given at 24 h post-partum to evaluate the satisfaction of pain relieving method and the willingness to have the same treatment again. Mode of delivery and neonatal effect were measured as secondary outcome. One hundred women were eligible for analysis. TENS group experienced VAS score reduction \( \geq 3 \) significantly more common than the TENS placebo group (31/50 [62%] vs 7/50 [14%], \( P < 0.001 \)). Willingness of using the same analgesic method for a future childbirth was also significantly different (TENS: 48/50 [96%] vs TENS placebo: 33/50 [66%], \( P < 0.001 \)). Operative delivery was increased in the TENS group (12/50 [24%] vs 4/50 [8%], \( P = 0.05 \)), but the neonatal outcomes were not different. The application of TENS on specific acupuncture points could be a non-invasive adjunct for pain relief in the first stage of labor.

Keywords: Pain; Acupuncture points; Transcutaneous electrical stimulus; Randomized control trial

1. Introduction

Pain relief in labor is a very important task in medicine as it may concern thousands of reproductive women. Transcutaneous electrical nerve stimulation (TENS) is available for analgesia in labor in UK and some European countries, but used only in fewer than 6% deliveries (Steer, 1993; Carroll et al., 1997). Most of the studies were small or non-randomized trials (Grim and Morey, 1985; van der Ploeg et al., 1996; van der Spank et al., 2000). In a systematic review of eight randomized controlled trials of 712...
women, women received real TENS (n = 352) and TENS placebo (n = 360), overall effect for pain relief using TENS in labor was weak (Carroll et al., 1997).

Likewise, many studies give encouraging results regarding the use of acupuncture in obstetrics, but significant improvement in labor pain derived from controlled clinical trials is limited (Ramnero et al., 2002; Skilnand et al., 2002; Nesheim et al., 2003; Lee and Ernst, 2004). Combining implications of acupuncture and TENS to treat low-back pain have been studied (Fox and Melzack, 1976; Lehmann et al., 1986). Lehmann et al. (1986) reported that the electroacupuncture group consistently demonstrated greater improvement than TENS on the outcome measures of pain. Fox and Melzack (1976) indicated that placing TENS over acupuncture points had similar good results. Application of TENS at the acupuncture points during the first stage of labor has, however, not yet been reported.

We did a double-blind randomized controlled trial to compare the efficacy of pain relief and the acceptability of TENS vs TENS placebo on acupuncture points during the first stage of labor.

2. Methods

2.1. Participants

Parturients under the service of the four obstetricians (A.S. Chao, T.H. Wang, H.H. Peng, and S.D. Chang) from Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital who participated this Institutional Review Board approved study were invited to join this trial. The inclusion criteria were: (1) an initial wish to deliver without epidural analgesia; (2) signed informed consent; (3) planned vaginal childbirth without obstetrical or non-obstetrical complications; (4) fetal vertex presentation; (5) term pregnancy (>37 weeks of gestation); (6) at active phase of the first stage of labor with cervical dilatation ≤5 cm; (7) age between 20 and 40 years; (8) no experience of pain relief by systemic or epidural anesthesia in a previous delivery; (9) no experience in acupuncture or TENS for other reasons; and (10) no previous poor obstetrical outcome (either maternal or fetal).

Exclusion criteria were: (1) maternal cutaneous lesions on the application sites such as wound scars, urticaria or insect bites; (2) candidates for vaginal birth after cesarean section; and (3) pacemaker users.

At enrollment we recorded a complete obstetrical and non-obstetrical history including parity, maternal age, gestational age, height and weight. The assignment of participants to TENS or TENS placebo group was done randomly by permuted blocks with stratification for parity. A block of four was used to ensure that the TENS assignment was balanced after every four participants in each stratum. Neither the medical personnel nor the participants knew which group was assigned. Active phase was confirmed and diameters of cervical dilatation were determined by the obstetrical personnel.

2.2. Apparatus and treatment

A portable battery-powered TENS unit has two pairs of electrode-pads placed on the skin (HANS model, LH202H, Singapore). The current output was individually titrated, with intensity at a range between 10 and 18 milliampere (mA), according to the body weight of the individual. The heavier the body weight of the parturient, the stronger the intensity is required to provide an effective electrical stimulation, which elicits a tingling sensation. A frequency of 100 Hz with a burst frequency of 2 Hz (dense-dispersed waveform), pulse duration (0.25 ms) was used for 30 min. The two pairs of disposable rubber electrode-pads measuring 30 × 30 mm were placed at bilateral Li 4 (Hegu) points (midpoint between first and second carpal bones, first web space dorsal side) (Fig. 1A) and Sp 6

![Fig. 1. (A) Location of Li 4 (Hegu) point. (B) Sp 6 (Sanyinjiao) point.](image-url)
(Sanyinjiao) points (5 cm above medial malleolus in lower leg) (Fig. 1B). The TENS placebo group received a very low electrical stimulation with less than 5 mA only and no burst frequency (DeLisa and Gans, 1998).

Two research nurses were trained by a qualified acupuncture doctor as study personnel to operate the TENS on the four acupuncture points. A session of TENS or TENS placebo for 30 min was applied when the parturient needed pain relief during the first stage of labor, and such treatment was stopped at the point of complete cervical dilatation. Repeated applications of TENS or TENS placebo were arranged upon request. Patients could change to epidural analgesia at her own will, if she was not satisfied with the pain relief provided by TENS/TENS placebo.

2.3. Assessment

Visual analogue scale (VAS) was the main assessment of pain relief efficacy by having a scale with a range from 1 to 10, where 1 represented no pain and 10 the most painful. Participants were asked by study personnel to estimate how painful during the last contractions before the application of TENS, 30 and 60 min after TENS application, respectively. VAS was recorded at each application (first, second application, and so forth) as described until the end of first stage. Within 24 h after delivery, the women were asked to fill in a questionnaire regarding the willingness to have the same treatment again. The person who assessed the VAS was blinded to the group to which the participants belonged.

Augmentation of labor was administered to achieve three uterine contractions in 10 min in the first stage according to the protocol of induction of labor. Continuous electronic fetal heart rate monitoring and tocodynamometry were used for fetal surveillance. Details of the progression of cervical dilatation and the length of first stage after the application of TENS were recorded. Meperidine intravenously in doses of 25–50 mg every 2–4 h could be administered during the first stage of labor. The amount and frequency was to be recorded if used. Shifting to epidural anesthesia was considered as off study. Adverse events such as discomfort of movement restriction, skin allergy, or electrical accident were recorded if any. Decision of performing operative delivery was made only according to maternal and fetal indications. Neonatal assessments were Apgar score at 1 and 5 min after birth. Birth weight was recorded immediately after delivery.

2.4. End points

The primary outcome was the rate of VAS score decrease $\geq 3$ in each group. The secondary outcomes were the mode of delivery (operative or spontaneous), the use of epidural analgesia, time from starting study analgesia to the end of the first stage, total length of the first stage, the effect on neonates and willingness to have the same treatment again.

2.5. Statistical analysis

The statistical analysis was made according to intention to treat (ITT), which is a strict analysis according to randomization group regardless of subsequent protocol violation. A pain reduction of VAS score $\geq 3$ was defined as a response (significant pain relief). It was assumed that the response rate for TENS placebo group will not be greater than 15% (Hrobjartsson and Gotzsche, 2001). Therefore the sample size with 50 subjects in each arm based on two sample proportion test using continuity correction with $\alpha = 0.05$, and $\beta = 0.2$ will detect at least a 27% absolute statistical difference in the response rates, i.e., 42% of TENS group vs 15% of the TENS placebo group. This will give us an even more power if the true TENS response rate is greater than 42% (Piantadosi, 1997).

Statistical calculations were performed using SPSS version 11.0 (SPSS, Chicago, IL). Statistical methods for analyzing differences between groups and associations between variables were $\chi^2$ tests for proportional variables, $t$ test for continuous variables with normal distribution and Mann–Whitney $U$ test for continuous variables with skewed distribution. Statistical significance was defined as $P < 0.05$ (two-sided).

3. Results

3.1. Subject characteristics and trial profile

Our study included parturients between August 1, 2002 and November 30, 2003. One hundred and five parturients were enrolled in this clinical trial, 52 women were randomly assigned to TENS, and another 53 women to the TENS placebo group. Five parturients had precipitous labor courses and were unable to complete at least one session of TENS or TENS placebo application hence not evaluable for VAS. A total of 100 women were eligible for evaluation. Fig. 2 depicts the trial profile. Table 1 summarizes the basic characteristics of the two groups. There was no significant difference in age, gestational age, parity, weight, diameter of cervical dilatation at enrollment between the two groups. However, the maternal height of the TENS group was significantly shorter ($P = 0.03$) than the TENS placebo group. There was no significant difference between the body mass index of the TENS and TENS placebo groups ($P = 0.22$).

3.2. Pain outcomes

Outcome data are depicted in Table 2. The median pain score was not different between the groups at the
beginning of TENS. After the assigned treatment, the median VAS score in first stage of labor at 30 and 60 min after the TENS showed significant lower in the TENS group than TENS placebo group (30 min, TENS vs TENS placebo: 4.5 [1–10] vs 7 [2–10], \( P < 0.001 \); 60 min: 6 [3–9] vs 7.5 [4–10], \( P < 0.001 \)). The difference of VAS between before and 30 min after application in TENS group was significant (\( P < 0.001 \)) but insignificant in TENS placebo (\( P = 0.35 \)). The rates of VAS score decrease \( \geq 3 \) of the two groups (TENS vs TENS placebo) were significantly different (62% [31/50] vs 14% [7/50], \( P < 0.001 \)). Based on an ITT analysis with those five participants having precipitous labor counted as failure to achieve VAS score decrease \( \geq 3 \), the difference between the two groups remained significant (\( P < 0.001 \)) but insignificant in TENS placebo (\( P = 0.35 \)). The rates of VAS score decrease \( \geq 3 \) were also significantly different in both primiparous and multiparous groups (primiparous, TENS vs TENS placebo: 60% [18/30] vs 11.4% [4/35], \( P < 0.001 \); multiparous, 65% [13/20] vs 20% [3/15], \( P = 0.02 \)).

### 3.3. Labor courses and neonatal outcomes

Application of TENS did not result in significant difference between the TENS and TENS placebo groups in the duration of first and second stages of labor (Table 3). Durations of second stage of labor were not obtainable for the five women underwent cesarean section. Use of operative delivery was increased in the TENS group (24% [12/50] vs 8% [4/50], \( P = 0.05 \)). Among the 11 parturients receiving vacuum delivery, 55.6% (5/9) in the TENS group and 50% (1/2) in the TENS placebo group had their newborn birth weight >3500 g. The cesarean section rate was slightly higher but insignificant (6% vs 4%). Five cesarean sections including three in TENS and two in TENS placebo were performed. Two cases in TENS and one case in TENS placebo had arrest of labor. One case of fetal distress occurred in each group with cord around neck and chorioamnionitis, respectively.

The median Apgar scores at 1 and 5 min of each group were similar. At 1 min post-delivery, there were significant in both primiparous and multiparous groups (primiparous, TENS vs TENS placebo: 5 [3–10] vs 7 [4–10], \( P < 0.001 \); multiparous, TENS vs TENS placebo: 4 [1–7] vs 6 [2–10], \( P < 0.001 \)).

### Table 1

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Treatment group</th>
<th>( P )</th>
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<tbody>
<tr>
<td></td>
<td>TENS (N = 50)</td>
<td>TENS placebo (N = 50)</td>
</tr>
<tr>
<td>Age (years, mean [SD])</td>
<td>27.9 (5.6)</td>
<td>28.8 (4.5)</td>
</tr>
<tr>
<td>Gestational age (weeks, mean [SD])</td>
<td>39.0 (1.2)</td>
<td>38.9 (1.2)</td>
</tr>
<tr>
<td>Primiparous/multiparous</td>
<td>30/20</td>
<td>35/15</td>
</tr>
<tr>
<td>Augmentation of labor</td>
<td>40 (80%)</td>
<td>43 (86%)</td>
</tr>
<tr>
<td>Weight (mean [SD])</td>
<td>67 kg (9)</td>
<td>67 kg (9)</td>
</tr>
<tr>
<td>Body height (mean [SD])</td>
<td>158 cm (5)</td>
<td>161 cm (5)</td>
</tr>
<tr>
<td>Body mass index (mean [SD])</td>
<td>26.7 kg/m(^2) (3.3)</td>
<td>26.0 kg/m(^2) (3.2)</td>
</tr>
<tr>
<td>Diameter of cervical dilatation at enrollment (mean [SD])</td>
<td>2.2 cm (0.9)</td>
<td>1.8 cm (1.3)</td>
</tr>
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</table>

### Table 2

<table>
<thead>
<tr>
<th>Outcome parameter</th>
<th>Treatment group</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting VAS score (median [range])</td>
<td>8 (1–10)</td>
<td>8 (3–10)</td>
</tr>
<tr>
<td>VAS score after 30 min of treatment (median [range])</td>
<td>4.5 (1–10)</td>
<td>7 (2–10)</td>
</tr>
<tr>
<td>VAS score after 60 min of treatment (median [range])</td>
<td>6 (3–9)</td>
<td>7.5 (4–10)</td>
</tr>
<tr>
<td>Difference of VAS score at 30 min (median [range])</td>
<td>3 [(–3)–(7)]</td>
<td>0 [(–4)–(4)]</td>
</tr>
<tr>
<td>VAS score reduction ( \geq 3 )</td>
<td>31 (62%)</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>Use of epidural</td>
<td>2 (4%)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Willing to use same analgesic method in future childbirth</td>
<td>48 (96%)</td>
<td>33 (66%)</td>
</tr>
</tbody>
</table>

* Only the first applications were counted.
four babies in each group having score <9 (TENS: four with score 8; TENS placebo: one with score 6, two score 7, and one score 8). At 5 min post-delivery, only one baby had score 9 in TENS group; but two had score 9 and one score 8 in the TENS placebo group, all the others had a score of 10.

4. Discussion

Pain relief in labor is a unique problem (Cunningham et al., 2001). The most important factors causing labor pain are dilatation of the cervix and contractions of the uterus. Individual pain perception depends on the intensity and duration of the contractions, the speed with which the cervix dilates, the physical condition of the woman as well as a complexity of emotional factors such as previous experiences, present expectations, and cultural factors (Steer, 1993).

TENS is a battery-powered unit that sends electrical impulses through electrode-pads usually placed on or near the skin at painful points. Analgesia is thought to achieve either by blocking pain impulses to the brain by increasing A-β fibre transmission (gate theory) (Melzack and Wall, 1965) or by stimulating the local release of endorphins (Sjolund et al., 1977; Han, 2004). Melzack and Wall (1965) suggested that the pain was controlled by the closing of the spinal cord “gate” through activities of nerve cells in the cord with modulation by higher centers. Differential release of opioid peptides in central nervous system by TENS has been noted, with a frequency of 2 Hz triggering the release of enkephalins and β-endorphins, and 100-Hz stimulation selectively increasing the release of dynorphin in the spinal cord. A combination of both frequencies allows synergistic interaction among the three endogenous opioid peptides and provides a powerful analgesic effect (Han, 2004).

Traditionally, two pairs of electrodes are placed alongside the spine at the thoracic vertebra 10-lumbar 1 and sacral vertebrae 2-4 for labor pain relief. These segments correspond to the pathways of A fibres into the inhibitory circuits in the laminae of the dorsal horn of spinal cord (Augustinsson et al., 1977). However, randomized controlled trials showed no evidence of analgesic effect using conventional TENS during labor (van der Ploeg et al., 1996; Carroll et al., 1997).

Acupuncture is an ancient system widely used in the treatment of pain for thousands of years in China (Ramnero et al., 2002; Skilnand et al., 2002; Lee and Ernst, 2004). Usually four to six needles are inserted at the adequate acupoints with twirling and then left in place for 15–20 min each application. TENS on acupuncture points for pain relief during labor was designed for this study to work by a combination of the central and peripheral actions to release much more endogenous opioid peptides. Hegu (Li 4) on both hands and Sp 6 (Sanyinjiao) points on both legs were chosen because these were one of the traditional acupuncture points used in relieving labor pain that would not interfere with obstetrical practice. This study was designed to be a double-blind study, therefore we used a TENS placebo above the sensory threshold without a recognizable effect. Hrobjartsson and Gotzsche (2001) found that the effect of placebo on pain corresponds to a reduction in the mean intensity of pain of 6.5 mm on a 100-mm VAS (95% confidence interval, 3.6–9.6).

The current used is within the safety limits. According to the American Association for Medical Instrumentation (AAMI) recommendation, safety level is below 25 µC per pulse if the electrodes are placed across the heart. This is equivalent to 25 mA at 1.0 milliseconds or 250 mA at 0.1 milliseconds pulse width (Stux, 1998). Other advantages of TENS during labor are non-invasiveness, easy application, and no interference with maternal consciousness or mobility (Grim and Morey, 1985; Kaplan et al., 1997; van der Spank et al., 2000). It could be easily learned and practiced by obstetricians and midwives without specialized training in acupuncture. The hands-on learning time is short. For instance, our two research nurses could perform the study efficiently after a 6-hour training course.
In this trial, TENS group experienced VAS score reduction ≥3 significantly more common than the placebo group (31/50 [62%] vs 7/50 [14%], P < 0.001). Willingness of using the same analgesic method for a future childbirth was also significantly different (TENS: 48/50 [96%] vs placebo: 33/50 [66%], P < 0.001). Operative delivery was increased in the TENS group (12/50 [24%] vs 4/50 [8%], P = 0.05). Use of epidural analgesia in the TENS (n = 2) and TENS placebo (n = 7) group was not significantly different (P = 0.44, Table 2). Although the effect of epidural analgesia has been used as primary endpoint in the study of pain relieving treatment during labor (Ramnero et al., 2002), we did not exclude those women in this study. Instead, use of epidural was placed as one of the secondary outcomes.

There was no difference in the length of first stage after TENS application in the two groups. The application of TENS did not alter the length of first stage. However, increased operative delivery was observed in the TENS group. In the meantime, the babies were heavier in the mothers to whom vacuum deliveries were applied. Presumably, women who gave birth to heavier babies are at risk for vacuum delivery. Heavier birth weights implicated larger babies and may be associated with protracted labor courses that resulted in increased vacuum delivery. In addition, the maternal height of the TENS group was significantly shorter (P = 0.03) than the TENS placebo group. A small woman is likely to have a small pelvis that may be related to increased operative delivery. Nevertheless, stratification of parturients according to the maternal height and estimated fetal body weight was not included in the design of this study. Cesarean section rate was slightly increased in the TENS group. Among the five cases for cesarean section, two sections in the TENS group and one in the TENS placebo group were due to arrest of labor course. Fetal distress was detected one in each group.

Our study has potential limitations. As acupuncture usage is a traditional practice for pain relieving in our culture, the psychological effect of higher acceptance might play a role. This might create a higher satisfactory result than in other ethnic groups. Also, the enrolled women were well informed and prepared for a non-pharmacological means of pain relief. A woman who is free from fear, and who has psychological support from conscientious labor attendants instilling confidence to her, usually requires smaller amounts of analgesia (Cunningham et al., 2001). With these psychological effects and non-invasive characteristics, a high preference of 66% in women with unsatisfactory pain relief in the TENS placebo group would still consider using the same analgesic method for a future childbirth.

The pain management during labor in this study could be the synergistic effect of acupuncture and TENS. TENS as a sole method in reducing pain during labor in eight randomized control trials revealed weak positive effect (Carroll et al., 1997). In reviewing seven databases of randomized control trials involving 496 parturients, evidence of acupuncture in alleviating pain is promising, though invasive (Lee and Ernst, 2004). Meanwhile, experience of TENS and acupuncture in treatment of low-back pain have good results (Fox and Melzack, 1976), but showed a better improvement in electroacupuncture (Lehmann et al., 1986). Hence, with the complement of TENS, acupuncture could be applied in a non-invasive and easy-to-use fashion.

This double-blind randomized placebo-controlled study showed that TENS application on acupuncture points resulted in significantly better pain relief than placebo in the first stage of labor. No obvious adverse effect in maternal and neonatal outcome was noted, though operative delivery was also increased. TENS on the acupuncture point could be an adjunct for pain control in the first stage of labor, for women when epidural analgesia is not available or undesirable to the parturients. Further randomized trials with a larger sample size to compare TENS with more established modality, such as epidural analgesia, are necessary to clarify the role of TENS to acupuncture points on labor pain relief and the relation to increased operative delivery.

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References


