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Effect of Transcutaneous Electrical Nerve Stimulation for Pain Relief on Patients Undergoing Hemorrhoidectomy: Prospective, Randomized, Controlled Trial

[Original Contributions]

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Abstract^

PURPOSE: Posthemorrhoidectomy pain control remains a challenging problem. Transcutaneous electrical nerve stimulation is known to be effective in the treatment of many diseases. Our aim was to investigate the effect of transcutaneous electrical nerve stimulation on pain relief in patients undergoing hemorrhoidectomy.

METHODS: Sixty patients with symptomatic hemorrhoids were randomly allocated into two groups, the acupoint group (n = 30) and the nonpoint control group (n = 30). Transcutaneous electrical nerve stimulation was applied to those patients who received hemorrhoidectomy, and patient-controlled analgesia was achieved by injection of morphine through ambulatory infusion pumps. The dependent measures in this study were pain score from 0 (no pain) to 10 (agonizing pain), analgesic doses administrated through patient-controlled analgesia, and postoperative complications.

RESULTS: The subjective pain scores evaluated 8, 12, 16, and 24 hours after hemorrhoidectomy in the control group and the acupoint group were 5.9 ± 0.5 and 4.1 ± 0.5, 5.7 ± 0.5 and 3.5 ± 0.4, 4.1 ± 0.4 and 2.3 ± 0.3, and 3.2 ± 0.4 and 1.9 ± 0.2, respectively (two-way analysis of variance; $P < 0.05$). There was a significant difference between treatment groups in morphine use, with 11.6 ± 2.2 mg in the control group and 6.2 ± 1.3 mg in the acupoint group ($P < 0.05$). The acupoint group tended to have less postoperative acute urinary retention (Fisher's exact probability test; $P = 0.145$) and less need for analgesics than the control group ($P = 0.112$, Fisher's exact test).

CONCLUSION: Transcutaneous electrical nerve stimulation is effective for pain relief in patients receiving hemorrhoidectomy. Its efficacy and safety could assist outpatient pain management after hemorrhoidectomy.

Hemorrhoid is a common disease worldwide and causes symptoms in 4.4 percent of the population.[1] Among several modalities studied for the treatment of hemorrhoids, surgical resection seems effective in eradicating the symptoms about which patients complain.[2] However, agonizing postoperative pain and thus the need of hospitalization for pain relief remains the major drawback for a patient undergoing hemorrhoidectomy.[3] Several interventions, for example, transdermal delivery of fentanyl, intraoperative use of Toradol® (Syntex Laboratories, Palo Alto, CA), and use of a subcutaneous morphine pump, have been used to relieve postoperative pain after hemorrhoidectomy [3-6] Nevertheless, the results are unsatisfactory.

Several large-scaled, randomized, controlled trials and meta-analysis of the clinical trials have demonstrated the effectiveness of acupuncture in relieving pain, in improving the breathing difficulties of chronic pulmonary diseases, in reducing symptoms of nausea in pregnancy, and in improving the functional outcome in cerebral infarction.[7-10] Thanks to the rapid advance in studies on the endogenous opioid system, acupuncture analgesia (AA) or electroacupuncture analgesia (EA) are now known to result from the mobilization of specific neuropeptides by peripheral stimulation of identified frequencies.[11]

Transcutaneous electrical nerve stimulation (TENS) is peripheral stimulation *via* electrodes applied to the skin used as a medical procedure for health care and pain control.[12] Several lines of evidence suggest a similar effect in TENS and electroacupuncture.[11] Moreover, TENS has been shown to relax the lower esophageal sphincter in patients with achalasia and to relax the sphincter of Oddi in patients with biliary dyskinesia.[13, 14] Because present management methods for posthemorrhoidectomy pain remain unsatisfactory, the effect of TENS for

pain relief on patients undergoing hemorrhoidectomy is worth investigation.

PATIENTS AND METHODS^

Sixty consecutive patients with symptomatic hemorrhoids, Grade II to IV, were eligible for surgical resection of the hemorrhoids. Patients with chronic liver insufficiency (serum bilirubin >2.0 mg/dl), massive ascites, chronic renal insufficiency (serum creatinine >1.5 mg/dl), pregnancy, involvement of colorectal cancer, history of bleeding, long-term analgesic intake, cardiac arrhythmia, and pacemaker implantation were excluded from the study. Under regulations of the Veterans General Hospital, Taipei and in accordance with the standards of the committee on human experimentation, patients giving informed consent were prospectively assigned to two groups as described below. Surgical procedures, including one to three wedge resection(s) of the hemorrhoids, were standardized and performed by a single surgical team. Perioperative prescriptions for hemorrhoidectomy included preoperative sedation (diazepam, 10 mg intramuscularly), intraoperative perineal anesthesia with 30 ml of a mixture of 0.25 percent Marcaine™ (bupivacaine, Winthrop Pharmaceuticals, New York, NY), with units of epinephrine at 1:200,000 and two ampules of Wydase™ (hyaluronidase; Wyerst-Ayerth Laboratories, Philadelphia, PA). Management of perioperative dehydration (no intravenous fluid supplement) was prescribed to avoid acute urinary retention induced by volumes. After the operation, patient-controlled analgesia (PCA) was administered by an ambulatory infusion pump (model 5800, Pharmacia Deltec, Inc., St. Paul, MN) administering morphine intravenously. A bolus dose of 2 mg of morphine sulfate was given, followed by patient-controlled bolus doses of 0.5 mg every six hours. The PCA ambulatory infusion pump was programmed to administer bolus doses with a lockout feature to prevent overdosing. For ethical reason, in addition to PCA a suboptimal dose of additional analgesics (meperidine, 20 mg intramuscularly) was given whenever the postoperative pain became intolerable and the patient called the nurse for further management. This dose was not enough for adequate pain relief, so that it was feasible to evaluate the usefulness of postoperative TENS.

The dependent measures in this study were pain score, analgesic doses administered through the ambulatory infusion pump, frequency of the nurse being called for analgesics, and complications such as acute urinary retention. Postoperative pain was measured with a visual analog scale from 0 (no pain) to 10 (agonizing pain). Patients were asked to rate their pain on this scale 6, 12, 18, and 24 hours after hemorrhoidectomy. The total dosage of morphine used in PCA and the number of nurse calls for analgesics were recorded.

Study Design^

The patients were randomly assigned by selection from a random number table into the acupoint group and the nonpoint control group. In both circumstances the same supportive postoperative treatment, including stool softeners and standard postoperative care, were prescribed. In the acupoint group, two electrodes, according to the guideline of Chinese acupuncture literature,[15] were applied to the skin areas on the dorsal web between the first and the second metacarpal bones (Hegu, Large Intestine meridian, 4th ampoint, negative electrode) and on the radial side 3 cm proximal to the wrist crease (Lieque, Lung meridan, 7th ampoint, positive electrode) of the same hand. In the nonpoint group or control group, two disposable electrodes were applied to the skin areas on the ulnar border of the hypothenar muscle as shown in Figure 1. Transcutaneous electrical nerve stimulation (TENS) from a pocket stimulator (Han Acutens, WQ1002F, Beijing, China)[12] was given two times per day. The stimulation was pulse-waved with frequency alternating beween 2 and 100 Hz, 300 μsec pulse duration and a 30-minute stimulation duration. The intensity was adjusted until rhythmic flexion of thumb and index finger was obtained without producing pain, usually at 20 to 30 mA.

Figure 1. Electrode placement with transcutaneous electrical nerve stimulation (TENS). Two groups were randomized and evaluated. In the acupoint group two electrodes were applied to skin areas on the dorsal web between the first and second metacarpal bones (negative electrode) and on the radial side 3 cm proximal to the wrist crease (positive electrode) of the same hand. In the nonpoint, or control group, two electrodes were applied to skin areas on the ulnar border of the hypothenar muscle.

Statistics^

Data were expressed as means ± standard error of the mean. The homogeneity of the studied group (acupoint group) and control group (nonpoint group) was analyzed with the Wilcoxon rank sum test for continuous variables and Fisher's exact probability test for noncontinuous variables. Severity of postoperative pain was measured in terms of pain score (0-10) at successive time intervals after hemorrhoidectomy. Two-way analysis of variance (ANOVA) was used to test the significance of differences between acupoint and control groups. Two-way ANOVA with repeated measures (Manova) on the time factor was performed by use of the general linear models procedure (SAS® biostatistical package program, SAS Institute, Inc., Cary, NC). Dosages of analgesics used for PCA in the treatment groups were compared with Wilcoxon rank sum test. A two-tailed *P* value <0.05 was defined as statistically significant.

RESULTS^

There were no dropouts or deaths during the period of hospitalization. The study was easily feasible; the availability of patients, their acceptance of the study procedures, and physician cooperation presented no difficulties. Comparison of patient characteristics, including age, gender, grading of hemorrhoids, and operative procedure (Table 1) showed no statistically significant differences between acupoint and control groups ($P > 0.05$).

Table 1. Demographic Characteristics in Patients Treated with Transcutaneous Electrical Nerve Stimulation After Hemorrhoidectomy

The subjective complaint of pain after hemorrhoidectomy was evaluated by patients and scored with pain level from 0 (no pain) to 10 (agonizing pain). The pain level in the control group and the acupoint group evaluated 8, 12, 16, and 24 hours after operation was 5.9 ± 0.5 and 4.1 ± 0.5, 5.7 ± 0.5 and 3.5 ± 0.4, 4.1 ± 0.4 and 2.3 ± 0.3, and 3.2 ± 0.4 and 1.9 ± 0.2, respectively (Fig. 2). The difference between treatment groups was statistically significant (two-way ANOVA, $P < 0.0005$). The analgesic dose needed through PCA after hemorrhoidectomy also showed a significant difference between treatment groups, with 11.6 ± 2.2 mg of morphine needed in the control group and 6.2 ± 1.3 mg of morphine needed in the acupoint group ($P = 0.016$; Fig. 3).

Figure 2. Pain score ratings in groups treated with transcutaneous electrical nerve stimulation (TENS). The subjective complaint of pain in patients of the control ([white circle]) and acupoint (•) groups after hemorrhoidectomy is shown at intervals of 8, 12, 16, and 24 hours after operation. Pain level was scored from 0

(no pain) to 10 (agonizing pain).

Figure 3. Intravenous morphine given through a patient-controlled analgesia (PCA) pump in groups treated with transcutaneous electrical nerve stimulation (TENS). Asterisk indicates a statistically significant difference between acupoint and control groups. ([square with upper right to lower left fill]) = control group; ([white square]) = acupoint group.

With regard to the surgical outcomes after hemorrhoidectomy, acute urinary retention was noticed in 7 of 30 patients in the control group and 2 of 30 patients in the acupoint group (Fisher's exact probability test; $P = 0.145$). The frequency of nurse calls for analgesics was 4 of 30 patients in the control group and 0 of 30 patients in the acupoint group (Fisher's exact probability test; $P = 0.112$; Table 2). No complications associated with use of the TENS device, such as contact dermatitis, arrhythmia, or heart attack, were detected. There were no significant differences in hospital stay, with 3.5 ± 0.9 days for the control group and 3.9 ± 1.5 days for the acupoint group.

Table 2. Surgical Outcomes in Patients Treated with Transcutaneous Electrical Nerve Stimulation After Hemorrhoidectomy

DISCUSSION^

We used TENS to treat posthemorrhoidectomy pain in a prospective, randomized, controlled fashion. To our knowledge this is the first controlled study of the use of TENS with patients undergoing hemorrhoidectomy. Most Chinese people trust traditional Chinese medicine (TCM), including acupuncture and medicinal herbs. Therefore, there were no dropouts or deaths during the period of hospitalization nor communication difficulties between patients and physicians.

It was not until recently that the efficacy and safety of acupuncture for treatment of many kinds of diseases were proved. Acupuncture and moxibustion have been recommended by the World Health Organization for the treatment of 43 disorders, including respiratory tract, gastrointestinal, and neuromuscular disorders.[16] Several recent studies, including those making use of meta-analysis, have pointed out that a prospective, randomized, controlled design is critical for studies to reach solid conclusions concerning the efficacy of acupuncture treatment.[7, 8, 17] In this study the sham point (Fig. 1) was chosen because few acupoints have been mentioned in the literature of TCM or had their therapeutic effect tried in TCM. Therefore, this study was intended to provide a needed prospective, randomized, controlled trial. Analgesic effects might be evident in patients who receive nonpoint TENS if compared with patients without TENS (sham TENS) treatment. However, for ethical reasons there was no sham TENS control group in this study, because severe pain occurs without exception after hemorrhoidectomy. Nevertheless, our results showed obvious pain relief by TENS on true acupoints after hemorrhoidectomy compared with TENS on sham points.

Many clinical trials have shown that acupuncture is effective in pain relief.[7, 18] Thanks to rapid advances in the study of the endogenous opioid system, acupuncture analgesia (AA) and electroacupuncture analgesia (EA) are now known to result from mobilization of specific neuropeptides by peripheral stimulation with identified

frequencies.[11] Central neurotransmitters such as [beta]-endorphin, enkephalin, and dynorphin can be released by peripheral electroacupunctural stimulation with frequency of 2, 15, and 100 Hz, respectively.[18-20] TENS is an alternate device similar to acupuncture and electroacupuncture. It provides almost the same therapeutic effect, especially for pain relief, as does the electroacupuncture. Furthermore, differential release of human central peptide from preproenkephalin and preprodynorphin has been reported *via* TENS used with a different frequencies to sustain the pain-relieving effect.[12]

In addition to scientific proof of the efficacy of TENS for treatment of acute, chronic, and labor or delivery pain,[21, 22] several studies have shown that TENS relaxes the lower esophageal sphincter in patients with achalasia and relaxes the sphincter of Oddi in patients with biliary dyskinesia.[13, 14] The increased concentration of central opioids and serum vasoactive intestinal peptide (VIP) level suggests that TENS may stimulate the release of either central or peripheral neurotransmitters.

Although acupuncture is generally safe with the use of needles, fatal complications such as hemopericardium have been reported.[23] However, TENS is a non-invasive device without needle puncture and thus avoids unnecessary complications. In this study no TENS-related complications, such as cardiac arrhythmia, palpitation, or contact dermatitis were noticed. Furthermore, the cost per person for disposable electrodes was less than one United States dollar, and these electrodes could be reused on the same person.

In summary, TENS is a device that is easily applied, and its efficacy and safety could assist in pain relief for outpatients receiving hemorrhoidectomy.

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