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Efficacy of the device combining high-frequency transcutaneous electrical nerve stimulation and thermotherapy for relieving primary dysmenorrhea: a randomized, single-blind, placebo-controlled trial☆

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ABSTRACT

Objective: To investigate the efficacy and safety of the combined therapy with high-frequency transcutaneous electrical nerve stimulation (hf-TENS) and thermotherapy in relieving primary dysmenorrheal pain.

Study design: In this randomized, single-blind, placebo-controlled study, 115 women with moderate or severe primary dysmenorrhea were assigned to the study or control group at a ratio of 1:1. Subjects in the study group used an integrated hf-TENS/thermotherapy device, whereas control subjects used a sham device. A visual analog scale was used to measure pain intensity. Variables related to pain relief, including reduction rate of dysmenorrheal score, were compared between the groups.

Results: The dysmenorrheal score was significantly reduced in the study group compared to the control group following the use of the devices. The duration of pain relief was significantly increased in the study group compared to the control group. There were no differences between the groups in the brief pain inventory scores, numbers of ibuprofen tablets taken orally, and World Health Organization quality of life-BREF scores. No adverse events were observed related to the use of the study device.

Conclusions: The combination of hf-TENS and thermotherapy was effective in relieving acute pain in women with moderate or severe primary dysmenorrhea.

Introduction

Primary dysmenorrhea develops without pelvic pathology. The pain of primary dysmenorrhea usually lasts 8–72 h during the menstrual cycle [1] and is commonly managed with nonsteroidal anti-inflammatory drugs (NSAIDs) and oral contraceptive pills [1,2]. However, these pain treatments are associated with various adverse effects such as nausea, intermenstrual bleeding, and breast tenderness [1,3]. Moreover, the evidence supporting their effectiveness in controlling pain is not enough [2,3]. Therefore, there has been the need for non-pharmacologic management of dysmenorrhea [2,3].

High-frequency transcutaneous electrical nerve stimulation (hf-TENS, conventional TENS) commonly delivers low-intensity electrical impulses at a frequency of 50–120 Hz [4]. Several randomized trials and a meta-analysis have reported that hf-TENS significantly reduced the intensity of primary dysmenorrheal pain compared to placebo TENS [4–7]. Furthermore, two randomized studies have demonstrated that low-intensity topical heat therapy delivered via a abdominal patch or a heat wrap significantly reduced the intensity of primary dysmenorrheal pain [8,9]. It is not certain how TENS or thermotherapy relieve pain. However, analgesic effect of these may be explained by the gate control theory of pain in which stimuli from TENS or thermotherapy are delivered to the A-beta nerve fiber. Then, the signals from the A-beta fibers are transmitted to the spinal cord where they temporarily block the transportation of pain sensations

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to the brain [10–12]. Therefore, both treatments may be effective for primary dysmenorrhea [13,14].

In this study, we used a pain-relieving device that integrates hf-TENS and thermotherapy. A treatment combining TENS and neuromuscular electrical stimulation was reported to be more effective in reducing chronic back pain than each method alone [15]. Similarly, both TENS and thermotherapy may provide analgesia through altering pain sensation following peripheral stimulation. Therefore, we hypothesized that a similar effect could be achieved by applying this combinatory approach to dysmenorrhea.

The effectiveness of non-pharmacologic therapies such as TENS, topical heat therapy, and acupuncture for relieving dysmenorrhea have been demonstrated through randomized studies although they have been limited to small-scale trials (3–9). However, the effectiveness of combination therapies have not been evaluated. Therefore, this study aimed to test the efficacy and safety of the combined therapy comprising hf-TENS and thermotherapy in relieving dysmenorrheal pain.

Methods

Our prospective, randomized, single-blind, placebo-controlled study included women who enrolled for clinical trial in two University Hospitals from May 24, 2012 to November 23, 2012. This study was approved by the Institutional Review Board of Seoul National University Bundang Hospital (no. E-1112/069-001) on July 23, 2012 and Chungbuk National University (no. 2009-03-019) on March 26, 2009.

Inclusion criteria were as follows: premenopausal women who were over 20 years old, had moderate or severe lower abdominal dysmenorrhea [visual analog scale (VAS) score $\geq$ 5/10] that required analgesics to control pain for a minimum of 6 months, and provided voluntary consent to the present clinical trial. Exclusion criteria were as follows: pregnant women; women with history of surgery in the lower abdomen; women who had been diagnosed with cancer in the last 5 years or had suspected cancer; those who could not use TENS, for example, because of a permanent pacemaker or skin disease; and those with contraindications for ibuprofen, such as peptic ulcer.

Fig. 1 shows the flow diagram of this randomized trial. At the first visit, participants were asked for informed consent. Assessment of eligibility, urinary human chorionic gonadotropin test, gynecological examination, transvaginal ultrasound, and randomization were performed.

Gynecological examination and transvaginal ultrasound, which is commonly used in our country, were performed to determine the type of dysmenorrhea. The findings of gynecological examination indicating secondary dysmenorrhea were as follows: uterine hypertrophy, uterine mass, adnexal mass, and chronic pelvic inflammatory disease. The findings of transvaginal ultrasound indicating secondary dysmenorrhea were as follows: uterine myoma (largest diameter >5 cm), adenomyosis (globular uterine enlargement with an obscure endometrial/myometrial border or asymmetrical uterine wall thickening [16]), and endometrioma (unilocular cyst with homogeneous ground glass echogenicity of cyst fluid [17]). The diagnosis of secondary dysmenorrhea could be established based on other findings at the discretion of the investigators. Subjects were diagnosed with primary dysmenorrhea if secondary dysmenorrhea was excluded.

Stratified randomization was performed according to the clinical trial hospital and the type of dysmenorrhea by a statistician who had no direct contacts with the participants. Subjects were randomly assigned to the study and control groups at a 1 to 1 ratio,

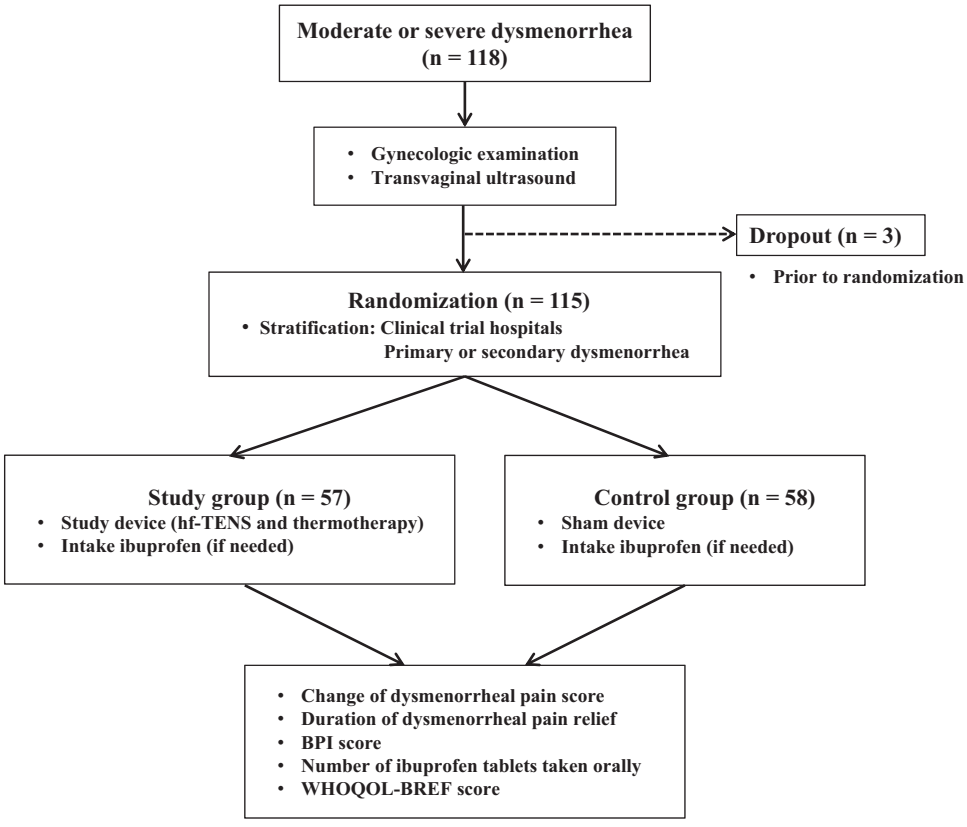

Fig. 1. Flow diagram of this randomized, single-blind, placebo-controlled study. Three subjects were excluded from the analyses before randomization based on the exclusion criteria.