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CLINICAL ARTICLE

Randomized controlled trial of the ef ficacy and safety of self-adhesive low-level light therapy in women with primary dysmenorrhea

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a r t i c l e i n f o

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Objective: To evaluate the ef ficacy and safety oflow-level light therapy in women with primary dysmenorrhea. Method: A multicenter prospective, randomized, double-blind, placebo-controlled clinical trial including patients 18–35 years of age with primary dysmenorrhea was undertaken at two university hospitals in South Korea between October 2011 and September 2012. Patients were randomized using a computer-generated sequence to receive low-level light therapy using the Color DNA-WSF device or to receive placebo treatment with a dummy device. The severity of menstrual pa in, assessed using a visual analog scale, w as the primary outcome and was evaluated at baseline and during every menstrual c ycle for 3 months following treatmen t. Patients who received more than one application of treatment (with a Color DNA-WSF or placebo device) were included in analyses. Patients and investigators were masked to t he treatment assignments. Results: Overall, 44 patients were assigned to each group. At the final study visit, the reduction in scores using a visual analog scale was signi ficantly greater in patients who received low-level light therapy (n = 41; 4.34 ± 2.22) than among those in the control group (n = 38; 1.79 ± 1.73; P b 0.001 when adjusted for age) No serious adverse events occurred. Conclusion: Low-level light therapy could be an effective, safe treatment modality for women with primary dysmenorrhea.
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1. Introduction

Primary dysmenorrhea is a common complaint among female adolescents, and is characterized by both menstrual pain and idiopathic pelvic pain. It affects up to 25% of all menstruating women, with an estimated prevalence of 20% –90% that reaches its peak during adolescence [1]. Approximately 15% offemale adolescents report experiencing primary dysmenorrhea so severe that it prevents them from taking part in normal social activities for several days during each menstrual cycle [2].

The cessation of progesterone secretion in the uterus before menstruation induces strong in flammatory responses due to the contraction of the uterus and blood vessels, resulting in subsequent uterine ischemia and pain. This is the primary cause of the pain experienced by patients with primary dysmenorrhea.

Non-steroidal anti-in flammatory drugs are the most commonly used medications to relieve menstrual pain. These include ibuprofen, naproxen sodium, and mefenamic acid, which have well-documented efficacy against pain due to primary dysmenorrhea [3]. Other medications, including oral contraceptives, have also been reported to be effective in treating menstrual pain; their ef ficacy originates from a decreased release of prostaglandins during menstruation [4]. However, for patients who are not willing to take non-steroidal anti-in flammatory drugs or hormone therapy owing to fear of adverse effects, nonpharmacological analgesic treatments are recommended; these include transcutaneous electrical nerve stimulation, acupuncture, far-infrared rays, topical heat, and low-level laser therapy [5–8]. However, among these treatment methods, there is little evidence to suggest which should be the preferred treatment modality.

In response to the need for nonpharmacological treatments, we developed a novel treatment modality for patients with primary dysmenorrhea, called the Color DNA-Women Stress Free (Color DNA-WSF, Color Seven Co., Seoul, South Korea); the device consists of microprocessor-controlled light-emitting diodes that are used to direct low-level light therapy to two acupuncture points, conception vessel (CV) 4 (Guanyuan)

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