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Complement Ther Med. 2011 Aug;19(4):187-93. doi: 10.1016/j.ctim.2011.06.004. Epub 2011 Jul 16.

A multicenter, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of a far infrared-emitting sericite belt in patients with primary dysmenorrhea.

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Abstract

OBJECTIVE: To determine the efficacy and safety of a sericite which emits far infrared rays in the management of primary dysmenorrhea.

DESIGN: A multicenter randomized double-blind placebo-controlled trial.

SETTING: One hundred four patients with primary dysmenorrhea were randomized to wear a sericite or placebo belt during sleep for 3 menstrual cycles, and followed for 2 menstrual cycles. Hot packs were used to heat the ceramics and ensure slight pain relief in both groups.

MAIN OUTCOME MEASURES: The main outcome measures were the severity of dysmenorrhea assessed by a 10-point visual analog scale (VAS) and the number of patients who took analgesics at each menstrual cycle. Safety was evaluated by physical examination and self-reporting of adverse events.

RESULTS: The baseline VAS scores were 7.27 ± 0.19 in the experimental group and 7.38 ± 0.19 in the control group. The severity of dysmenorrhea gradually decreased during the treatment period in both groups, with major improvements observed in the third treatment cycle (4.96 ± 0.30 in the experimental group and 5.69 ± 0.30 in the control group, $p=0.087$). During the follow-up period, the decreased VAS score was maintained in the experimental group, whereas the VAS score gradually returned to baseline in the control group, which resulted in significant difference between the groups (5.08 ± 0.31 vs. 6.47 ± 0.31 at cycle 5, difference -1.39 [95% CI, -2.25 to -0.53], $p=0.0017$). The number of patients who took analgesics decreased in both groups, but the differences were not statistically significant. No serious adverse events related to wearing the sericite belt occurred.

CONCLUSIONS: Our data suggest that a far infrared-emitting sericite belt with a hot pack might be used as an effective and safe non-pharmacologic treatment option for women with primary dysmenorrhea, with a prolonged effect after treatment.

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