Pulsed Radiofrequecy Electromagnetic Field Therapy for Menstrual Pain, a Double Blind, Randomized and Placebo Controlled Study

Principle Investigators: Dr. Barry Eppley, Dr Sheena Kong

Background

Primary Dysmenorrhea, commonly referred to as menstrual cramping, is a medical condition characterized by pain from contractions in the lower abdomen occurring at the onset of menstruation in the absence of an identifiable pelvic disease. Sharp pains in the lower abdomen begin at the start of menstruation and may continue for up to 5 days. The pain can range from mild to severe and can interfere with many normal activities. While the majority of women who have menstrual periods experience some discomfort, an estimated 10% or more are temporarily disabled by the high level of pain they experience. A miniaturized, lightweight and battery pulsed shortwave radiofrequency electromagnetic field (PEMF) device – Allay has been developed as a wearable pain therapy. The device operates at the 27.12MHz radio frequency, 1000Hz pulse rate with a pulse width of 100μseconds. The electromagnetic field is delivered by a 12 cm loop wire antenna.

Methods

A total of ninety-one (91) women were enrolled with moderately to severe dysmenorrhea. Subjects self-reported perceived levels of pain for each day of their menstrual cycle prior to participation in the clinical trial were collected. Subjects were then randomly assigned a number coded PEMF device, either active or placebo. The energy from the functioning device can't be felt by the recipient so subjects were unable to determine device allocation through use. The patients ranged in age from 18-34 years, with an average age of 26.2. Forty-eight (48) patients were assigned active devices while the remaining forty-three (43) received placebo devices. Subjects were asked to wear the PEMF device over the lower abdomen, from the onset of their symptoms, for 24 hrs per day for 5 days, and record their daily VAS pain scores on an 11 point scale (0 -10 scale). Subjects were not restricted in use of pain medications.

Results

On average, pain was decreased significantly on a daily basis, with the study group reporting a 31% decrease in pain compared to the placebo group on day 1, 39% day 2, 42% day 3, 48% day 4 and 63% day 5. Average VAS scores for the 5 days of the study were, day 1 control v study group 8.3 v 5.7, day 2: 7.9 v 4.8, day 3: 7.4 v 4.3, day 4: 6.5 v 3.4 and day 5 5.7 v 2.1. The result indicate that over time 5 days the percentage of decrease in pain increases, suggesting that there is a strong correlation between duration of use of the PEMF device and amount of pain reduction. Overall 77% study group subjects reported a decrease in pain compared to 14% in the control group. No significant adverse events were reported.

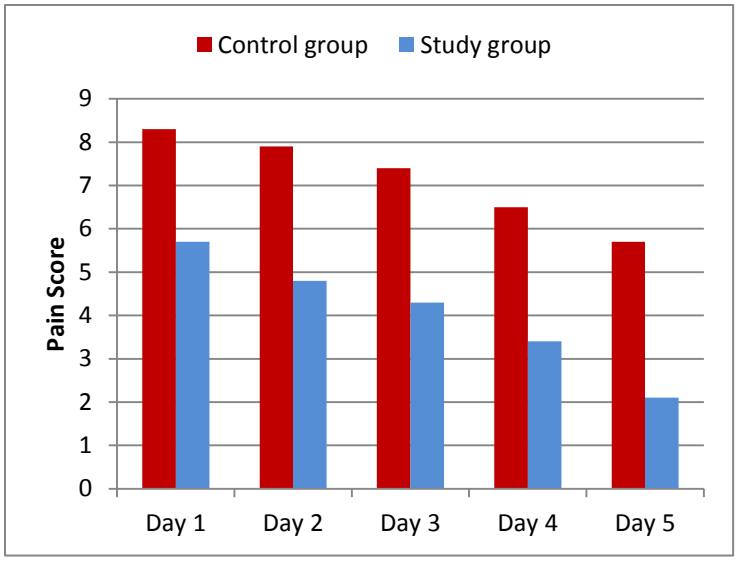

Figure 1. The mean pain level in the study group were significantly lower than on each day compared to the control group using the placebo device. Overall over the 5 days of the study period those in the study group experienced 43% less pain than those in the control group.

Conclusion

The clinical study demonstrated that the PEMF menstrual pain therapy is an effective and safe non-drug method for use in the treatment of primary dysmenorrhea. The results suggest that PEMF in this form can be used as a drug-free treatment method for women suffering from moderate dysmenorrhea. In more severe cases of dysmenorrhea, it can be a possible adjuvant treatment allowing for a reduction in the amount of oral pain medications used.