Safety and effectiveness of cranial electrotherapy in the treatment of tension headache.

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Abstract

One hundred patients were enrolled in a multicenter double-blind study to evaluate the safety and effectiveness of the Pain Suppressor Unit, a cranial electrotherapy stimulator for the symptomatic treatment of tension headaches. Treatment consisted of extremely low level, high frequency current applied transcranially. Pain scores before and after 20 minute treatments of individual headaches as well as patient and physician global evaluations were the primary efficacy variables. Following use of the active unit, patients reported an average reduction in pain intensity of approximately 35%. Placebo patients reported a reduction of approximately 18%. The difference was statistically significant (p = 0.01). The active unit was rated as moderately or highly effective in 40% by physicians, and in 36% by patients. Both physicians and patients scored the placebo unit moderately or highly effective for only 16%. The difference in ordered outcomes was statistically significant (p = 0.004). Approximately 10% of patients in each group reported at least one minor adverse experience. Cranial electrotherapy stimulation is distinct from TENS, and is safe and often effective in ameliorating the pain intensity of tension headaches. It should be considered as an alternative to the chronic usage of analgesics.

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