Electrical stimulation or electromagnetic therapy as adjunctive treatments for chronic skin wounds

BlueCross BlueShield Association

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Authors' objectives
The objective of this Assessment is to determine whether electrical stimulation and/or electromagnetic therapy are effective adjunctive treatments for chronic skin wounds.

Authors' conclusions
Based on the available evidence, the Blue Cross and Blue Shield Medical Advisory Panel made the following judgments about whether electrical stimulation or electromagnetic therapy as an adjunctive treatment for chronic skin wounds meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.

1. The technology must have final approval from the appropriate governmental regulatory bodies.

- No electrical stimulation device or electromagnetic therapy device is currently cleared or approved by the U.S. Food and Drug Administration (FDA) for the specific indication of wound healing. A number of devices have been cleared for marketing for other indications. Use of these devices for wound healing is an off-label indication.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

- The evidence is not sufficient to permit conclusions on the efficacy of electrical stimulation or electromagnetic therapy as adjunctive treatments for wound healing. The body of evidence for electrical stimulation and electromagnetic therapy consists of numerous small RCTs (n=10 for electrical stimulation; n=5 for electromagnetic therapy). To conclude that either of these technologies is an effective adjunctive treatment for wound healing, the body of evidence must have certain properties. Well-designed and well-conducted sham placebo-controlled RCTs are needed that consistently show better outcomes for active treatment over placebo, reflected in statistically and clinically significant results. The available evidence does not convincingly demonstrate that electrical stimulation or electromagnetic therapy results in clinically significant improvement in the most important outcome, i.e., the percent of patients that heal completely.

Wound healing treatment trials must show that an intervention has efficacy independent of the many confounding factors and the variable natural history of the disorder. Such trials will ideally have the following features: 1) enroll patients with one type of wound; 2) assess patients on a wide range of baseline characteristics, and demonstrate that potential confounders are equally distributed among groups; 3) use a double-blind design, with a sham placebo control; 4) ensure that optimal standard care is delivered to both treatment and control groups; 4) report on the percent of patients with complete healing, and/or time to complete healing; 5) assess outcomes in an independent, blinded fashion; and 6) follow up patients for at least 3 months to assess complete healing and recurrences.

Electrical Stimulation: Only 5 of 10 electrical stimulation studies report on the key health outcome, complete healing.
The other 5 studies found statistically significant advantages for electrical stimulation in percent reduction in ulcer size, with follow-up periods ranging between 3 weeks and 8 weeks across studies. While greater change in wound size suggests better healing with electrical stimulation, follow-up is generally short, and this outcome is not a substitute for measuring the incidence and timing of complete healing. Only 2 of the 5 studies that reported complete healing found results that significantly favored electrical stimulation. The strongest study included 71 patients, and there was confounding of baseline characteristics favoring the control group. Adjustment for confounders was not employed but the proportion of complete healing at 8 weeks was 58% in the electrical stimulation group and 3% in the placebo group (p<0.0001). The other study (n=64) achieving statistical significance had more significant flaws: confounding of unclear direction, no statistical adjustment, and high overall loss to follow-up (20%). At 12 weeks, 42% in the electrical stimulation group achieved complete healing, compared with 15% in the placebo group (p<0.05).

A study of 80 patients with 192 wounds showed a pattern of higher complete healing with electrical stimulation, but confounding of unclear direction was present and no statistical test results were given. The 2 remaining studies do not provide support for the efficacy of electrical stimulation. In both, confounding appeared to favor electrical stimulation, but neither found a statistically significant result. While some of the results from electrical stimulation trials are favorable, methodologic flaws were common, and statistical significance was achieved in only 2 studies reporting on the primary outcome of complete healing.

Electromagnetic Therapy: For electromagnetic therapy, the evidence follows a similar pattern, with a lesser quantity of evidence. Of the 5 available studies, 3 report on the outcome of complete healing, and only 1 study reports statistically significant differences in favor of the electromagnetic therapy group. One of the 5 studies reports a shorter mean time to healing for the electromagnetic therapy group. Three of the 5 studies report a larger decrease in wound size for the electromagnetic therapy group, and 2 studies report better pain scores for the electromagnetic therapy group.

The results suggest that electrical stimulation and electromagnetic therapy may promote wound healing or some aspect(s) of wound healing, but considerable uncertainty remains as to whether these modalities lead to clinically significant health outcome benefits, given various flaws in how studies were conducted. To demonstrate efficacy for these treatments, larger, well-conducted, randomized, controlled trials are needed. These trials should focus on one type of wound, demonstrate baseline comparability on important confounders, and account fully for dropouts. Statistical analysis should include both multivariate approaches to controlling for confounders and methods to account for loss to follow-up. The outcome of complete healing should be the primary outcome in these studies, and follow-up should be long enough to assess recurrences.

3. The technology must improve the net health outcome; and

4. The technology must be as beneficial as any established alternatives.

- The evidence does not permit conclusions as to whether electrical stimulation or electromagnetic therapy as an adjunctive treatment for chronic skin wounds improves health outcomes or is as beneficial as established alternatives.

5. The improvement must be attainable outside the investigational settings.

- Whether electrical stimulation or electromagnetic therapy as an adjunctive treatment for chronic skin wounds improves the net health outcome has not been established in the investigational settings.

Based on the above, electrical stimulation or electromagnetic therapy as an adjunctive treatment for chronic skin wounds does not meet the TEC criteria.