IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Galvanic stimulation describes unidirectional electrical current between two electrodes placed on the skin. It has been proposed as a treatment for various conditions, including inflammation, pain, and nausea.

Background

Galvanic stimulation is proposed to work by facilitating ion movement under the skin, promoting circulation near the negative electrode, while reducing circulation near the positive electrode. It is theorized that these changes in circulation promote wound healing, reduce edema and inflammation, and decrease pain. Finally, galvanic stimulation is also proposed to work on the vestibular nerve to help with balance and nausea.

MEDICAL POLICY CRITERIA

Galvanic stimulation devices are considered **investigational** for the treatment of all indications, including but not limited to pain.
SCIENTIFIC EVIDENCE

The principal outcomes associated with treatment of pain due to any cause may include: relief of pain, improved functional level, and return to work. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCTs) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from an electrical stimulation device provides a significant advantage over the placebo.

Treatment with an electrical stimulation device must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with an electrical stimulation device should be compared with other forms of conservative therapy such as splinting, rest, non-steroidal anti-inflammatory medications, physical therapy, or steroid injection.

Literature Appraisal

There is no published evidence on the use of galvanic stimulation for edema reduction or wound healing.

Systematic Reviews

In 2013 Cochrane updated their 2009 Cochrane review of electrotherapy for neck pain included a review of galvanic stimulation.[1] The original review found that the published literature on galvanic stimulation appeared promising; however, it concluded that the evidence was of very low quality and that more studies were needed to reliably establish effectiveness. In the updated review, authors concluded very low quality evidence showed that modulated galvanic stimulation was no more effective than placebo.[2]

Randomized Controlled Trials

Current evidence from randomized controlled trials (RCTs) not included in the Cochrane reviews above regarding the benefits of galvanic stimulation is limited to three small studies.

In 2016, Volkening et al. evaluated the effects of bipolar galvanic vestibular stimulation (GVS) on spatial neglect, extinction and verticality perception in 24 stroke patients.[3] The GVS group received treatments of 1.5mA for 20 minutes with cathodes on the left and right mastoid, while the sham group received treatments of only 30 seconds with cathodes on the left mastoid. There was a total of 10-12 treatments, one daily five days per week, for both groups, and all patients additionally received a standard therapy of smooth pursuit eye movement training. The outcomes were Neglect test, visuo-tactile search task, subjective visual and tactile vertical, and these were assessed at baseline, immediately after treatment, and at two and four week follow-up visits. Neither group showed significant improvements in neglect symptoms.

In 2013, Krewer et al. conducted a randomized observer-blinded cross-over trial to evaluate the after-effects of GVS, machine-supported gait training with the Lokomat, and physiotherapy with visual feedback components (PT-vf) on pusher behavior in 25 stroke patients (15 pushers, 10 non-pushers). The scale for conservative pushing (SCP) and Burke lateropulsion scale (BLS) were used to evaluate patient pushing behavior, both before and after a single session of each intervention. The authors reported no significant effect was observed on either scale with GVS.[4]
Cevette et al. evaluated the effect of GVS on simulator sickness (SS) during flight simulations in 21 normal subjects.\[5\] In a baseline simulation, GVS dose response predictions were formulated for each subject based on perceptions of roll, pitch and yaw simulations. These data were then used to create a stimulation algorithm in order to synchronize visual and GVS-induced vestibular sensation. Subjects were then randomly exposed to the designed stimulation or nothing during flight simulation. Patients were then given a SS checklist after each session to evaluate sickness. Authors reported the overall SS score for gastrointestinal, central, and peripheral categories were 17%, 22.4%, and 20% for the control group and 6.3%, 20%, and 8% for the treatment group, respectively. Although there is reported improvement in SS with GVS treatment, neither patients nor researchers were blinded to stimulation, allowing for treatment bias. In addition, self-reporting bias was not properly controlled for as SS was evaluated only by a self-administered patient questionnaire.

Clinical Practice Guidelines

There are no evidence-based clinical practice guidelines that recommend the use of galvanic stimulation devices.

Summary

There is not enough research to show if or how well galvanic stimulation works for pain, nausea, or any other condition. No clinical guidelines based on research recommend the use of galvanic stimulation devices. Therefore, galvanic stimulation devices are considered investigational for all indications.

REFERENCES


CROSS REFERENCES

Electrical Stimulation Devices Index, Durable Medical Equipment, Policy No. 83
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