Real-World Effectiveness of Fixed-Site High-Frequency Transcutaneous Electrical Nerve Stimulation in Chronic Low Back Pain

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Purpose

Chronic low back pain (CLBP) is a common health problem associated with substantial disability and economic burden. Recent studies estimated the prevalence of CLBP in U.S. adults at 10-13%. Patients with CLBP are frequently managed with pharmacological therapy, including prescription opioids. However, lack of efficacy, adverse events, and addiction risk lead many to discontinue treatment. There is a need for non-pharmacological options.

Transcutaneous electrical nerve stimulation (TENS) is an effective treatment for chronic pain that has no significant side effects. Conventional TENS is delivered through surface electrodes to generate a strong, nonpainful sensation. Although TENS has been used in CLBP for several decades, its efficacy remains controversial due to conflicting conclusions from systematic reviews. Several factors have been identified as potential confounding outcomes including inadequate dose and inappropriate outcome measures.

Fixed-site high-frequency TENS (FS-TENS) is an emerging form of TENS in CLBP. The device is placed on the upper calf and provides semi-continuous stimulation (60-minutes every other hour) of sensory nerves in the S2-L4 dermatomes. The device and companion smartphone app collect utilization data, demographics, pain characteristics and pain ratings (provided at user’s discretion) that are stored in a cloud database. The pain ratings include intensity and interference with activity, sleep and mood on an 11-point Numeric Rating Scale (NRS) (0-10). The NRS is included if they provided demographic data and pain characteristics indicative of CLBP (i.e., daily/weekly pain, pain duration > 5 months, low back pain and 2 self-reported condition among herniated disc, spinal stenosis and previous back injury), baseline and 10-week pain ratings.

Methods

Study Design and Inclusion Criteria. This retrospective, observational study evaluated users of a FS-TENS device (Quell®, NeuroMetrix, Waltham, MA) to treat CLBP over a 10-week period. The device is placed on the upper-calf and provides semi-continuous stimulation (60-minutes every other hour) of sensory nerves in the S2-L4 dermatomes. The device and companion smartphone app collect utilization data, demographics, pain characteristics and pain ratings (provided at user’s discretion) that are stored in a cloud database. The pain ratings include intensity and interference with activity, sleep and mood on an 11-point Numeric Rating Scale (NRS) (0-10). The NRS is included if they provided demographic data and pain characteristics indicative of CLBP (i.e., daily/weekly pain, pain duration > 5 months, low back pain and 2 self-reported condition among herniated disc, spinal stenosis and previous back injury), baseline and 10-week pain ratings.

Group Allocation and Primary Outcome. Study participants were allocated to the treatment or reference group based on their device utilization (%days with ≥ 30 minutes of FS-TENS use). Participants with ≥25% utilization were allocated to treatment (adequate dose) and those with ≤25% utilization were allocated to reference (low dose). The primary study outcome was the baseline to 10-week change in composite pain, defined as the average of pain intensity and the three pain interference values.

RESULTS

A total of 834 device users met the inclusion criteria and were assigned to the treatment (671, 80%) or reference (163, 20%) group. Table 1 gives summary demographics and pain characteristics for the treatment and reference study subjects. The two groups had similar demographic and pain characteristics at baseline except that the treatment group was older (p=0.035) and had lower BMI (p=0.045). In addition, the treatment group was more likely to have hip pain (p=0.037) and less likely to have diabetes (p=0.002) or a prior neck injury (p=0.006). No difference in the baseline pain ratings.

A match was found for each participant in the treatment group. Of the 163 participants in the reference group, 143 (88%) served as matches for the treatment group. 71% of the reference participants matched 5 or fewer treatment participants.

Table 2 shows the pain ratings change comparisons between two groups. The baseline to 10-week follow-up change in composite pain was -0.89 ± 2.30 for the treatment group and –0.01 ± 2.30 for the matched reference group. The standardized mean difference between the groups was 0.38 (95%CI 0.27, 0.49).

Conclusions

This study demonstrated that 10-weeks of regular FS-TENS use improved pain outcomes in a real-world sample of CLBP when compared to a reference group with low utilization. Study strengths included evaluation of a large real-world sample of a concurrent reference group, allocation of participants to treatment or reference based on objective data, and reduction of bias by PS matching. Study limitations were the possibility of uncorrelated bias due to unmeasured confounders and a potential impact of the outcome on group allocation.

This study suggests that regular FS-TENS use is effective in improving pain outcomes in CLBP.