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 a non-invasive 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 for negative clinical outcomes including inadequate dose and inappropriate outcome measures.

Fixed-site high-frequency TENS (FS-TENS) is an emerging form of TENS in which the stimulator is designed for a predetermined location rather than for co-localization with the pain location. A single target site enables design of small wearable devices that may be used while active and sleeping, thereby facilitating adequate dosing. The objective of the present study was to evaluate the effectiveness of regular (i.e., daily or near daily) FS-TENS use in a large, real-world CLBP population.

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 NRS. Device users were included if they provided demographic data and pain characteristics indicative of CLBP (i.e., daily/weekly pain, pain duration >3 months, low back pain and ≥1 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 ≥50% utilization were allocated to treatment (adequate dose) and those with <50% 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.

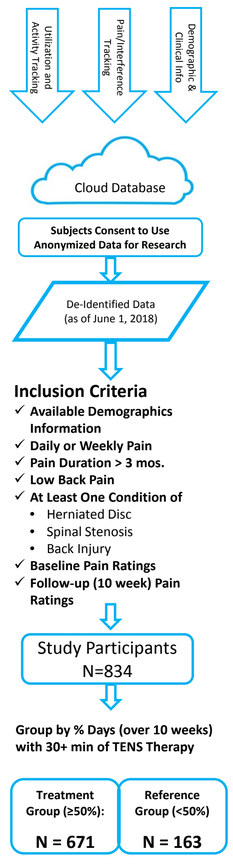

Table 1. Demographic and Pain Characteristics

	Treatment (N=671)	Reference (N=163)
Demographics		
Female: (%)	55.4%	50.3%
Age: (yrs)*	57.8 ± 12.9	55.6 ± 13.9
BMI: (kg/m²)*	30.5 ± 6.8	31.9 ± 7.9
Self-Reported Painful Health Conditions		
Musculoskeletal		
Arthritis	72.1%	66.9%
Fibromyalgia	27.3%	20.2%
Spinal		
Herniated Disc	51.0%	49.7%
Spinal Stenosis	47.5%	44.8%
Neuropathic		
Diabetes*	12.7%	22.1%
Restless Leg Syndrome	22.5%	23.3%
Complex Regional Pain	17.4%	15.3%
Previous Injury		
Back	69.4%	74.2%
Neck*	32.6%	44.2%
Arm/Hand	28.8%	35.6%
Leg/Foot	30.7%	30.7%
Head Aches/Migraines	27.0%	32.5%
Baseline Pain Ratings		
Pain Intensity	6.4 ± 2.0	6.5 ± 2.0
Interference w/Sleep	5.4 ± 3.0	5.8 ± 2.7
Interference w/Activity	6.8 ± 2.4	6.9 ± 2.1
Interference w/Mood	6.5 ± 2.6	6.5 ± 2.5
Composite Pain	6.3 ± 2.1	6.5 ± 1.9

Mean and standard deviation are shown. * indicate group mean is different (p<0.05).

Table 2. Change in Pain Rating over 10 Week Study Period

	Treatment Group	Reference Group	Group Diff. p-value
Direct Comparison			
Pain Intensity	-0.60 ± 2.39	+0.13 ± 2.63	0.001
Interference w/Sleep	-0.48 ± 2.90	-0.04 ± 3.13	0.091
Interference w/Activity	-1.24 ± 2.77	-0.29 ± 2.65	<0.001
Interference w/Mood	-1.25 ± 2.84	-0.41 ± 2.70	<0.001
Composite Pain	-0.89 ± 2.30	-0.15 ± 2.29	<0.001
Propensity Score Matching Comparison			
Composite Pain	-0.89 ± 2.30	-0.01 ± 2.30	<0.001

Treatment Effect Estimation by Propensity Score Matching Method. Propensity Score matching (PS) methods reduce confounding bias in observational studies. The PS model was comprised of demographics, potential confounders and risk factors; the latter two variables were determined by univariate statistical testing. The final model included age, gender, BMI, baseline composite pain, hand/wrist pain, foot pain, diabetes, prior hand/arm injury and prior leg/foot injury. Arm pain was a risk factor but was excluded because it prevented effective matching. The PS was estimated by logistic regression. The matched reference group was created by 1-1 nearest neighbor matching (caliper 0.1) with replacement. Balance between the treatment and reference groups was assessed by the standardized percentage bias (SPB). Differences between groups were tested by the Wilcoxon rank-sum and Pearson chi-square tests.

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 group 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=0.043). 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 ± 2.3 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, use 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 uncorrected 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.

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