Real-World Outcomes from High-Dose Transcutaneous Electrical Nerve Stimulation in Individuals With Chronic Knee Pain

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PURPOSE

Background

- One-quarter of adults suffer from frequent knee pain, which limits function, decreases mobility and impacts quality of life.
- Chronic knee pain is usually managed pharmacologically. These medications may cause adverse events and can create addiction risk.
- Transcutaneous electrical nerve stimulation (TENS) is a non-invasive, safe, pain relief option for chronic pain.
- Recent meta-analyses on TENS in chronic knee pain are inconclusive. A likely contributor to the variability is under-dosing.

Wearable TENS

Wearable TENS devices (Figure 1) have been developed for extended use that does not interfere with daytime activity and sleep. These devices provide high-dose TENS, defined as regular (≥ 3-4 days week) stimulation for several hours per day of use.

Figure 1

Study Objective

Assess intention-to-treat outcomes following up to 10-weeks of high-dose TENS use in individuals with chronic knee pain.

METHODS

Design

- Retrospective, observational study of a real-world TENS database.
- Wearable TENS (Quell®, NeuroMetrix, Woburn, MA), see Figure 1.
- TENS device automatically collects usage data and companion smartphone app collect demographics, pain characteristics and pain ratings. All data stored in cloud database.
- Pain ratings (BPI-SF) provided at the user's discretion. Include average pain and interference with activity, sleep and mood items on an 11-point numerical rating scale (NRS).

METHODS (continued)

Inclusion Criteria

Eligible users were those that provided demographic, clinical and pain data prior to initiating therapy. A subset meeting the following criteria were included: a) pain duration greater than 3 months, b) pain frequency at least several times a week, c) baseline pain intensity at least 4 on an 11-point NRS, d) self-reported knee pain and e) stimulation on at least half of the 70-days following the start of TENS.

Outcome Measures

BPI-SF severity and interference were were assessed at baseline and as close to 70-days following the start of TENS as available, using an intention-to-treat analysis. If there was no follow-up rating, then the value was imputed by baseline observation carried forward.

The study outcomes were the baseline to follow-up change in pain severity and interference with function (defined as average of the BPI-SF sleep, activity and mood items).

Statistical Analyses

The changes in pain intensity and functional impairment were defined as the baseline subtracted from the follow-up. The mean group change was calculated across all participants and compared to the null hypothesis of no change with the one-sample t-test.

RESULTS

A total of 1136 device users met the inclusion criteria. See Table 1 for baseline characteristics.

Study participants used wearable TENS on 58 (SD 11) of the 70-day assessment period at an average of 7.0 (SD 2.6) hours per day.

The average follow-up period was 50 (SD 29) days. A follow-up rating was imputed for 88 (8%) participants who only had a baseline rating. The follow-up pain rating was less than 30 days for 220 (19%) participants.

Table 1. Baseline demographic and pain characteristics. Mean (Std) or % indicated.

Age (years)	58.1 (13.3)
Female	61.1%
BMI (kg/m2)	31.5 (7.5)
No. pain sites	5.7 (2.6)
No. pain conditions	4.4 (2.5)*
Pain duration ≥4 years	76.8%
Baseline pain intensity (0-10 NRS)	6.8 (1.6)
Baseline pain interference (0-10 NRS)	
Sleep	5.9 (2.8)
Activity	7.3 (2.2)
Mood	6.5 (2.5)

*Most common: arthritis (73%, 62% osteoarthritis), prior leg injury (45%), prior back injury (46%)

The mean group change from baseline to follow-up was -1.0 (SD 2.3) for pain intensity and -1.4 (SD 2.5) for functional impairment, both $p<0.001$.

CONCLUSIONS

- **Study strengths:** (1) large, real-world sample which supports generalizability of the findings, (2) the use of an intention-to-treat analysis to reduce bias from participants who stopped therapy early, and (3) objective compliance monitoring to improve study fidelity.
- **Study limitations:** (1) lack of a control group against which to compare the change in pain measures and (2) pain measures that were not specific to knee pain.

Key findings:

- Consistent with earlier epidemiological studies of knee pain, the participants in this study were older adults, more likely to be female, tended to be overweight or obese, and had moderate to severe pain and substantial functional impairment.
- Knee pain is not an isolated symptom, as most participants reported additional pain in other body locations.
- In an intention-to-treat population with chronic knee pain, high-dose TENS was associated with clinically meaningful group changes (i.e., 1-point or greater) in pain intensity and functional impairment.

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