Wearable Transcutaneous Electrical Nerve Stimulation is Associated with Improved Objective Sleep Measures in Poor Sleepers with Chronic Keen Pain

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PURPOSE

Background

- Most people with chronic pain complain of disturbed sleep and daytime lethargy. Polysomnography studies show chronic pain patients have
  - Shorter sleep duration
  - Lower sleep efficiency
  - Greater number of periodic leg movements
- Chronic knee pain is one of the most common forms of chronic pain.
  - Osteoarthritic knee pain may be worse at night leading to sleep abnormalities
- Transcutaneous electrical nerve stimulation (TENS) is a non-invasive, low-risk treatment for chronic pain.

Wearable TENS

TENS device designed for a predetermined location (see Figure 1).

Wearable TENS Benefits

- Design optimized for safe use during sleep
- Integration of physiological sensors for
  - Activity and sleep tracking
  - Dynamic control of TENS therapy based on sleep patterns

Figure 1

Study Objective

Evaluate relationship between wearable TENS use and objective sleep measures in individuals with chronic knee pain in a real-world setting.

METHODS

Study Design

- This retrospective, observational study evaluated the effect of a wearable TENS device on users with chronic knee pain over a 10-week period.
- Wearable TENS (Quell®, NeuroMetrix, Waltham, MA), placed just below the knee, provided semi-continuous stimulation (60 minutes every other hour).
- TENS device and companion smartphone app collected
  - Demographics, pain characteristics, pain ratings (from app)
  - Treatment adherence data (from device), and
  - Objective activity and sleep data (from device based on data from an embedded accelerometer).
- Primary study outcome was baseline to week 10 change in objective sleep measures.

METHODS (continued)

Objective Sleep Measurements

Actigraphy-based sleep analysis algorithm reported the following

- TIB: time in bed in minutes; TST: total sleep time within TIB
- SE: sleep efficiency in %, defined as 100*TST/TIB
- PLMI: number of periodic leg movements per hour of sleep
- Initial assessment: median of all nights during week 1-2
- Final assessment: median of all nights during week 9-10

Study Population

Wearable TENS device users were included if they provided:

- Demographic information (age, gender, height, and weight)
- A valid baseline pain rating occurred on the first day of device use or within the prior 6 days (latest one used).
- Self reported knee pain
- Pain duration > 3 months and pain frequency ≥ several times a week
- Device use duration: ≥10 weeks
- Device use at night: ≥ 3 nights during weeks 1-2 and weeks 9-10,
- Consent to use of anonymous data stored in the cloud for research

Study participants were allocated to two groups based on initial TST

- LS (low sleep duration) group: TST < 360 minutes
- AS (adequate sleep duration) group: TST ≥ 360 minutes

Statistical Analyses

Differences between groups or between the initial and final assessments were evaluated by the two-sample t-test for means or by the two-sample Wilcoxon rank-sum test for medians.

Table 1. Initial Assessment of Sleep Measures

	LS (n=53, 28%)	AS (n=136, 72%)	p-value
TST (minutes)	319 ± 33	442 ± 53	<0.001
TIB (minutes)	372 ± 45	492 ± 62	<0.001
SE (%)	86.3 ± 6.8	89.9 ± 5.6	<0.001
PLMI	8.6 ± 9.2	8.0 ± 8.7	0.680
No of Nights	8.6 ± 7.6	10.2 ± 3.2	0.002
Pain Interference w/Sleep	6.0 ± 3.3	5.7 ± 2.8	0.619

RESULTS

A total of 189 wearable TENS participants met the inclusion criteria. The LS and AS groups had similar demographic and pain characteristics. Table 1 summarizes objective sleep measurements at initial assessment period, together with subjective ratings of pain interference with sleep for LS and AS groups.

Treatment variables were similar in the two groups. Utilization (% of days using device) was 92±10 (LS) compared to 91±14 (AS), p=0.595; weekly therapy (hrs/week) was 59±19 vs 57±21, p=786; median stimulation intensity (ratio of stimulation to sensation level in decibels) was 5.3 (IQR: 3.0–7.6) vs 5.5 (IQR: 3.3–9.3), p=0.304. Overnight utilization (% of nights using device) was lower in the LS group: 50±20 vs 69±23, p=0.001.

Figure 2 shows changes in objective sleep measurements from the initial to final assessment. All changes in LS groups are statistically significant ($p<0.05$). Only SE change in the AS group was significant (p=0.025).
Among participants with follow-up pain ratings, the median decrease in pain interference with sleep was 40% (LS) compared to 25% (AS), p=0.070.

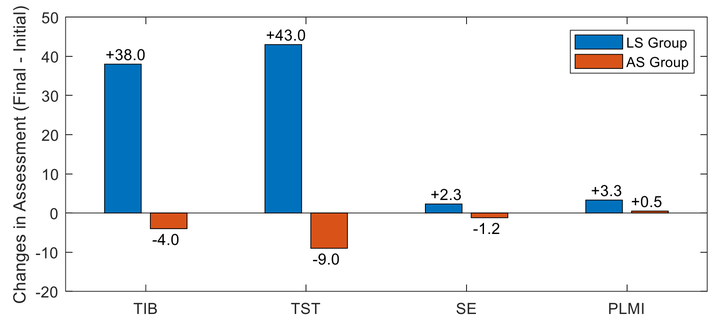

Figure 2. Changes of Objective Sleep Measurements

CONCLUSIONS

- About 30% of participants with chronic knee pain were classified as having low sleep duration (total sleep time < 6 hours during initial assessment period). Low sleep group had similar demographic and pain characteristics compared to participants in adequate sleep group.
- Wearable TENS use was associated with improved objective sleep measures for low sleep group participants.
- Participants with initial adequate sleep maintained their sleep metrics.

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