**Introduction**

- Chronic pain is associated with significant sleep disturbance, which has been linked to poor health including cardiovascular disease, diabetes, and obesity.²⁻³
- Pharmacological and nonpharmacological options are available to treat chronic pain and associated sleep disturbance.¹
- Nonpharmacological treatments have a low incidence of adverse events and lack of drug interactions, and can be used alone or in conjunction with pharmacological agents.¹
- Fixed-site, high-frequency transcutaneous electrical nerve stimulation (FS-TENS) is a nonpharmacological, noninvasive treatment that relieves pain. It is applied to a single predetermined location and can be used while a person is active and during sleep.¹
- In a large-scale observational study (N=1713), 38.7% of participants using FS-TENS daily for chronic pain reported a reduction in pain intensity with sleep used as the key outcome on an 11-point scale, which is considered clinically meaningful improvement.¹

**Objective**

- Evaluate whether objective sleep metrics are improved by FS- TENS use in individuals with chronic pain and without sleep impairment.

**Methods**

**Study Design, Assessments, and Outcomes**

- This retrospective, observational, real-world study evaluated the effect of FS-TENS device use on sleep outcomes among persons with chronic pain, with and without sleep impairment, over a 10-week period using a follow-up rating (Figure 1).

**Results**

**Demographics and Baseline Characteristics**

- A total of 2780 device users contributed baseline data at 2272 (79%) in the AS group and 703 (24%) in the IS group:
  - A subset of 880 participants (AS: 692/2272 [30.4%]; IS: 1970/703 [27.0%]) had actigraphy sleep data at follow-up, thus, 78% of this subset was in the AS group and 22% in the IS group.
  - The IS group was older, had a higher BMI, had a smaller percentage of people who had a long sleep duration ≥14 hours, had a smaller percentage of women, and had greater pain interference with sleep compared with the AS group (Table 1).

**Statistical Analyses**

- Change in sleep outcomes from baseline to follow-up was assessed by analysis of variance with sleep status (AS or IS) as an independent factor and demographics, pain characteristics, TENS utilization, overnight stimulation, and number of nights of device use during baseline and follow-up as covariates.
- Differences between the AS and IS groups were analyzed using a 2-sample t-test with equal variances.

**Effects of FS-TENS on Objective Sleep Metrics**

- All sleep metrics at baseline and follow-up were significantly different between groups (Table 2).

**Conclusions**

- In this real-world study, people who had sleep impairment related to chronic pain experienced improved sleep (increased TST and sleep efficiency) and a reduction in pain intensity and pain interference with sleep during a period of FS-TENS device use.
- Patients with chronic pain but no sleep impairment at baseline did not show objective sleep improvements, but reported subjective improvement in pain ratings and pain interference with sleep after using the FS-TENS device.

**References**


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**Disclosures**

Shai Gozani and Xuan Kong are employees of Neurotechnology, Inc. Dawn Chesser and Taara Madhavan are employees of GlaxoSmithKline Consumer Healthcare.