	Fluoroquinolones	Non-Fluoroquinolones	p-value
Age (years)	77.37 ± 9.54	70.13 ± 8.3	0.48
Sex			
Male	6 (75%)	25 (69.4%)	0.75
Female	2 (25%)	11 (30.6%)	
Smoking	5 (62.5%)	1 (2.8%)	0.00
Treatment with CS	4 (50%)	2 (5.6%)	0.01
Treatment with statins	0 (0%)	5 (13.9%)	0.26
Type of rupture			
Spontaneous	7 (87.5%)	8 (25.8%)	0.01
Traumatic	1 (12.5%)	23 (74.2%)	

Conclusion: The Achilles tendon is the most frequent location of tendinopathy associated with FQ, being affected in 95% of cases. The risk factors associated to an increased risk to develop FQ-associated ATR includes age over 60 years, male gender, chronic treatment with CS and organ transplantation, all these being present in our cases. Despite being a relatively frequent adverse event, it is underdiagnosed and the risk of ATR is not usually assessed when indicating FQ treatment. It is important to perform a risk/benefit assessment, specially in patients with associated risk factors, because most ruptures are complete and require surgical treatment, and may be a potential cause of disability.

REFERENCES:

- [1] Bidell M, Lodise T. Fluoroquinolone-Associated Tendinopathy: Does Levofloxacin Pose the Greatest Risk?. *Pharmacotherapy*. 2016;36(6):679-93.
- [2] Godoy-Santos A, Bruschini H, Cury J, Srougi M, De Cesar N, Fonseca L, Maffulli N. Fluoroquinolones and the Risk of Achilles Tendon Disorders: Update on a Neglected Complication. *Urology*. 2018;113:20-25.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.3687

THU0489 REAL-WORD EFFECTIVENESS OF FIXED-SITE HIGH-FREQUENCY TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION IN CHRONIC LOW BACK PAIN

Xuan Kong¹, Dawn Chesher². ¹NeuroMetrix, Inc., Waltham, United States of America; ²GlaxoSmithKline Consumer Healthcare, Weybridge, Surrey, United Kingdom

Background: Fixed-site high-frequency transcutaneous electrical nerve stimulation (FS-TENS) is a form of TENS in which the stimulator is designed for a predetermined location rather than for co-localization with the patient's pain. A small wearable device for localized application while active and sleeping facilitates adequate dosing.

Objectives: To evaluate the effectiveness of regular FS-TENS use in a large, real-world chronic low back pain (CLBP) population.

Methods: This retrospective, observational study evaluated use of FS-TENS (worn on upper calf; providing semi-continuous stimulation of sensory nerves) to treat CLBP across a 10-week period using previously collected therapy utilization, demographic, and clinical (pain characteristics/ratings) data. Data collected by the device and companion smartphone app are stored in a cloud database. Device users were eligible for inclusion if they consented to allow their anonymized data to be used for research, had demographic data and pain characteristics indicative of CLBP (daily/weekly pain for >3 months, low back pain, and self-reported herniated disc, spinal stenosis, and/or previous back injury) and had baseline and 10-week pain ratings. Participants were assigned retrospectively to the treatment group or reference group based on device use (% of days with ≥30 min of FS-TENS use) of ≥50% or <50%, respectively. The primary study outcome was the baseline to 10-week change in composite pain, defined as the average of pain intensity and pain interference with activity, sleep, and mood, measured on an 11-point numeric rating scale. Treatment effect was estimated by comparing outcomes in the treatment group to a matched reference group constructed from the original reference group by propensity score (PS) matching estimated by logistic regression. Differences between groups were tested by Wilcoxon rank-sum test for continuous variables and by Pearson chi-square test for proportions.

Results: A total of 834 device users met the inclusion criteria and were assigned to the treatment (671, 80%) or reference (163, 20%) groups. With few exceptions, the two groups had similar demographic and pain characteristics at baseline: the treatment group was older (58±13 vs 56±14, $P=0.035$), had lower body mass index (30.5±6.8 vs 31.9±7.9 kg/m², $P=0.043$), was more likely to have hip pain ($P=0.037$), and less likely to

have diabetes ($P=0.002$) or prior neck injury ($P=0.006$). There was no difference in baseline composite pain (6.3±2.1, treatment; 6.5±1.9, reference; $P=0.364$). Device usage was significantly different between groups (86±15%, treatment; 31±13%, reference; $P<0.001$), as was duration of therapy per week (46±22 hrs/week, treatment; 11±7 hrs/week, reference; $P<0.001$), median stimulation intensity (ratio of stimulation to sensation level expressed in decibels) (5.3 dB, treatment; 6.0 dB, reference; $P=0.045$). Of the 163 participants in the original reference group, 143 (88%) served as matches for the treatment group. 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, with a standardized mean difference between the groups of 0.38 (95% confidence interval, 0.27-0.49; $P<0.001$).

Conclusion: This study demonstrated that 10 weeks of regular FS-TENS use improved pain outcomes in a real-world sample of CLBP patients compared with a reference group with low FS-TENS use. This study suggests that regular FS-TENS use may be effective in improving pain outcomes in CLBP patients.

Disclosure of Interests: : Xuan Kong Employee of: Xuan Kong is an employee of NeuroMetrix, Inc., Dawn Chesher Employee of: Dawn Chesher is an employee of GlaxoSmithKline Consumer Healthcare.

DOI: 10.1136/annrheumdis-2019-eular.6106

THU0490 PREDICTORS OF CHRONIC PAIN RELIEF BY FIXED-SITE HIGH-FREQUENCY TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION

Xuan Kong¹, Dawn Chesher². ¹NeuroMetrix, Inc., Waltham, United States of America; ²GlaxoSmithKline Consumer Healthcare, Weybridge, Surrey, United Kingdom

Background: Fixed-site high-frequency transcutaneous electrical nerve stimulation (FS-TENS) is a form of TENS in which the stimulator is designed for a predetermined location rather than for co-localization with the patient's pain. Previous studies in individuals with chronic pain have demonstrated the efficacy and real-world effectiveness^{1,2} of a small wearable FS-TENS device designed for localized application to a single placement site to ensure comfort while both active and sleeping. Results demonstrated that 50-80% of FS-TENS users with chronic lower extremity or low back pain experience clinically meaningful pain relief,^{1,2} and daily use of the device was associated with greater pain relief relative to intermittent use.²

Objectives: To determine predictors of a positive FS-TENS response.

Methods: This retrospective, observational study evaluated users of a FS-TENS device to treat chronic pain over a 10-week period. The device and companion smartphone app collected dosage data, demographics, pain characteristics, and pain ratings and all data were stored in a cloud database. The primary study outcome was the baseline to week 10 change in composite pain (average of pain intensity and pain interference with sleep, activity, and mood). Device users were included if they provided demographic data, pain characteristics indicative of chronic pain, and baseline and week 10 pain ratings. Participants were defined as a responder or comparator based on their change in composite pain (responder: ≥15% decrease; comparator: ≥15% increase). Stepwise forward probit regression was used to determine independent predictors.

Results: There were 451 responders and 263 comparators. Independent predictors (Table) that were associated with greater response to FS-TENS included age, baseline composite pain, adherence/utilization rate (defined as the percentage of days with at least 30 minutes of stimulation), and stimulation intensity (defined as the ratio of therapeutic stimulation to sensation threshold, expressed in decibels). Negative predictors (associated with lower response) included history of headache/migraine and diabetes. The area under the receiver operating characteristic curve was 0.76 (95% confidence interval, 0.72-0.79).

Conclusion: FS-TENS effectiveness is predicted from baseline pain characteristics and dosage variables, such as frequency/regularity of use and stimulation intensity, with moderate accuracy.

REFERENCE:

- [1] Gozani SN. *J Pain Res*. 2016;9:469-79. 2. Kong X, Gozani SN. *J Pain Res*. 2018;11:703-14.

Abstract THU0490 – Table 1. Independent predictors of responders from probit regression.

Variable	Coefficient
Age (years)	0.01
Baseline composite pain (0-10)	0.27
Headache or migraine	-0.37