	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.

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

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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.

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

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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.

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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

Diabetes	-0.33
Weather sensitivity	-0.22
Adherence (%) ^a	0.01
Stimulation intensity (dB) ^b	0.02
Constant	-2.36

^aAdherence, percentage of days with at least 30 minutes of stimulation.

^bStimulation intensity, ratio of therapeutic stimulation to sensation threshold expressed in decibels (20log[therapy/sensation]).

All coefficients $P < 0.05$.

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THU0491 RELIABILITY AND VALIDITY OF THE İSTANBUL LOW BACK PAIN DISABILITY INDEX IN LUMBAR RADICULOPATHY

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Background: The Istanbul Low Back Pain Disability Index (ILBPDI) was developed to assess the disability in patients with mechanical low back pain with 18 daily activities questions (1).

Objectives: The aim of this study is to investigate the validity and reliability of the Istanbul Low Back Pain Disability Index in lumbar radiculopathy.

Methods: Patients who were diagnosed with radiculopathy due to lumbar spinal stenosis and/or disc herniation by physical examination and imaging methods were included in the study. Data about age, sex, body mass index (BMI), disease duration (month) were noted. Short Form 36 (SF-36) was used to assess the quality of life. Disability due to low back pain was assessed with Oswestry Low Back Disability Questionnaire. The severity of low back pain and extremity pain due to radiculopathy were assessed on the Visual Analogue Scale (VAS).

The reliability of ILBPDI was determined by internal consistency (Cronbach's alpha coefficient). The construct validity (convergent and divergent validities) was evaluated. The correlations of the ILBPDI with SF-36, Oswestry Low Back Disability Questionnaire, and the VAS scores of the low back pain and radiculopathy were assessed for convergent validity. The relations of the ILBPDI with age, BMI, and disease duration were assessed for divergent validity. The construct validity of the ILBPDI scale was determined by Spearman's correlation coefficient. The descriptive analysis was done for demographic data. $P < 0.05$ accepted as significant. SPSS 20.0 (Statistical package for social sciences for Windows 20.0) program was used for the statistical analysis.

Results: The mean age of 82 patients (44 female, 38 male) with lumbar radiculopathy was 45.45 (SD: 11.96) years. The median (min-max) duration of disease was 5 (1-120) months. The mean BMI of patients was 29.09 (SD: 5.04). The mean score of ILBPDI was 30.73 (SD: 17.04) and the mean score of Oswestry Low Back Disability Questionnaire was 52.73 (SD: 16.98).

The Cronbach's alpha coefficient of the ILBPDI for internal consistency was 0.764. The ILBPDI score had moderate and significant positive correlations with Oswestry Low Back Disability Questionnaire (ρ : 0.610, $p < 0.005$). Statistically significant but low correlation was detected between ILBPDI and the VAS score of radiculopathy (ρ : 0.285, p : 0.010), but there was no correlation with the VAS score of low back pain ($p > 0.05$). As for the correlations between the ILBPDI total score and SF-36 subgroups, significant negative correlations were detected with physical functioning (ρ : -0.672, $p < 0.005$), physical role limitation (ρ : -0.230, p : 0.038), bodily pain (ρ : -0.546, $p < 0.005$), general health (ρ : -0.262, p : 0.017), and social function (ρ : -0.337, $p < 0.005$) subgroups of the SF-36. There were no significant correlations between ILBPDI and age, disease duration, and BMI ($p > 0.05$).

Conclusion: The Istanbul Low Back Pain Disability Index is a valid and reliable instrument in patients with lumbar radiculopathy. This is a preliminary study. The study will continue for the factor analysis.

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THU0492 EFFICACY OF US-GUIDED HYALURONIC ACID INJECTIONS IN ACHILLES AND PATELLAR MID-PORTION TENDINOPATHIES: A PROSPECTIVE MULTICENTRIC CLINICAL TRIAL

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Background: Achilles and patellar tendinopathies are common clinical conditions that determine chronic pain and functional impairment. Conservative treatment can be effective, but it is time-consuming and it requires intensive patient compliance.

Hyaluronic acid (HA) is a key component of the extracellular matrix, and its anti-inflammatory, lubricant and analgesic properties are well established in osteoarthritis. Growing pre-clinical evidence point toward a possible role of HA in the management tendon pathology, while clinical evidences are still lacking.

Objectives: The primary objective was to assess the efficacy of a new formulation of HA (20 mg/2 ml; 500-730 kDa), obtained from biofermentation, in function improvement on VISA-A and VISA-P scores at 90 days of follow-up in patients with Achilles or patellar tendinopathy.

Secondary objectives were to evaluate improvement in pain (NRS-11), US parameters (tendon composition and neovascularization), and quality of life (EQ-5D). Safety of this new HA formulation was also evaluated.

Methods: This was a prospective, open-label, multicenter clinical trial. Thirty-five patients (25 in AT group; 9 patients in PT group), who satisfied strict inclusion and exclusion criteria, were recruited over a 4-month period. Each patient received 1 injection weekly for 3 weeks under US-guidance at the painful site of tendinopathy, and was evaluated at 14, 45 and 90 days after the procedure. Subjects were instructed to record on a diary any intake of the permitted rescue medication for pain relief (i.e. paracetamol up to 3 g per day) throughout the study period and to interrupt treatment at least 24 hours prior to each visit.

Results: Significant improvement on VISA-A (23.22±23.17; 95% CI: 13.20; 33.24; $p < 0.0001$) occurred, and improvement on VISA-P was also revealed (19.25±11.61; 95% CI: 9.54; 28.96; $p = 0.0022$). NRS-11 score significantly decreased in the AT group (4.52±3.25; 95% CI: -5.93; -3.12; $p < 0.0001$) and in the PT group (-4.75±3.20; 95% CI: -7.42; -2.08; $p = 0.0040$).

Significant improvement of US parameters in the AT group was evidenced (McNemar's test; $p = 0.0016$ and $p = 0.0114$, respectively), while in the PT group the presence of these clinical symptoms showed only a tendency to decrease ($p = 0.3173$ for both). EQ-5D-5L total score tended to increase in both the AT and PT groups (mean change vs. baseline at day 90 equal to 15.96±18.95 (range: -50; 45) and 15.50±32.42 (range: -40; 71), respectively).

Conclusion: Three US-guided HA injections may improve pain and function in patients with Achilles and patellar tendinopathy for up to 90 days of follow-up. Amelioration in tendon structure, neovascularization and clinical parameters may also be achieved. The hyaluronic acid injection was also safe and well tolerated.

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