

evidenced by Spearman correlation coefficients of  $\geq .50$  were hypothesized between IPAQ-LF total or its subscales and the armband to conform convergent construct validity ( $p < .05$ ).

**Results:** IPAQ-LF total PA (Median (IQR): 16.71 (5.91–45.15) MET.hrs/day) was associated with Physical Activity Level ( $r=.434$ ,  $p < .01$ ), moderate to (very)vigorous PA ( $\text{MET} \geq 3$ ,  $r=.439$ ,  $p < .01$ ), moderate PA ( $\text{MET} \geq 3-6$ ,  $r=.432$ ,  $p < .01$ ) and inactive time ( $\text{MET} \leq 1.8$ ,  $r=-.382$ ,  $p < .05$ ) obtained with the armband. Similar, IPAQ-LF moderate PA (Median (IQR): 10.39 (2.41–23.71) MET.hrs/day) was related with PAL ( $r=.492$ ,  $p < .01$ ), moderate to (very)vigorous PA ( $r=.456$ ,  $p < .01$ ), moderate PA ( $r=.444$ ,  $p < .01$ ) and inactive time ( $r=-.491$ ,  $p < .05$ ). Also, IPAQ sitting (Median (IQR): 14.91 (10.89–20.80) hrs/day) was correlated to PAL ( $r=-.461$ ,  $p < .01$ ), moderate to (very)vigorous PA ( $r=-.391$ ,  $p < .05$ ), moderate PA ( $r=-.386$ ,  $p < .05$ ) and inactive time ( $r=-.496$ ,  $p < .01$ ). No relevant nor significant correlations were found for the other IPAQ-LF subscales. Taken together, no hypothesis could be confirmed.

**Conclusions:** Even at a group level, the convergent construct validity of IPAQ-LF in axSpA was not confirmed. Self-reported PA outcomes may provide important contextual information on PA, but perform poor at quantifying PA levels in axSpA. Future research on a feasible self-reported PA measurement tool for these patients is required.

**Disclosure of Interest:** None declared

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## HPR epidemiology and public health (including prevention)

### FRI0751-HPR SAFETY PROFILE OF TOFACITINIB IN PATIENTS WITH RHEUMATOID ARTHRITIS - A REAL WORLD EXPERIENCE WITH GOOD RESULTS

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**Background:** Tofacitinib is an oral Janus Kinase for the treatment for rheumatoid arthritis (RA). The efficacy and safety of tofacitinib in monotherapy or in combination with other DMARDs has been demonstrated in clinical trials. However previous studies had report hematological changes and infections associated to the use of this medication (1, 2); in the European Union (EU) Tofacitinib is an investigational medicine and has not been approved for use because concernings regarding its safety.

**Objectives:** We aim to describe the safety profile of Tofacitinib in patients with RA in a real-life setting in Bogotá, Colombia.

**Methods:** During 2015- 2016 we followed patients from a RA specialized center in Colombia receiving Tofacitinib. Patients were treated with therapeutic goals T2T and a multidisciplinary approach. Adverse events were classified according the Common Terminology Criteria for Adverse Events (CTCAE) of the World Health Organization. Descriptive epidemiology for continuous variables, measure of central tendency and dispersion for qualitative and categorical variables through percentages and averages were calculated.

**Results:** We included 56 patients receiving tofacitinib, 80% were woman, 20% men. Mean age was 60±11 years. The mean time with RA was 17 months ± 12. 70% of patients had comorbidities; the most frequent comorbidity was hypertension 30%, followed by osteoporosis 25%, 7.5% Sjogren's syndrome, 7.5% diabetes mellitus among others. 70% of patients received some Anti-TNF drugs before using Tofacitinib; average time receiving tofacitinib was 33±32 weeks, mean DAS28 was 3.7±1.6. Regarding safety profile 10 of 56 patients presented any adverse event. 5 were mild, 4 moderate and 1 severe (1.7%). Diarrhea 1, Infections 1, Abdominal discomfort 3, Mouth papules 1, Rash 1, Sinusitis 1, Headache 1, Folliculitis 1 and Pancreatitis 1.

**Conclusions:** Tofacitinib is a safe and effective medication for patients with AR; regarding safety the proportion of patients with any AE is lower compared to previous studies, but the type of events were similar to clinical trials (1); none of

our patients presented hematological changes; none of our patients presented Herpes Zoster infection.

**References:**

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- [2] He Y, Wong AY, Chan EW, Lau WC, Man KK, Chui CS, et al. Efficacy and safety of tofacitinib in the treatment of rheumatoid arthritis: a systematic review and meta-analysis. *BMC musculoskeletal disorders*. 2013;14:298.

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### FRI0752-HPR COMPUTER PODOMETRIC MEASURING SYSTEM IN ASSESSMENT OF FLAT FEET AND LOWER LIMBS DEFORMITIES IN PATIENTS WITH SYSTEMIC SCLEROSIS

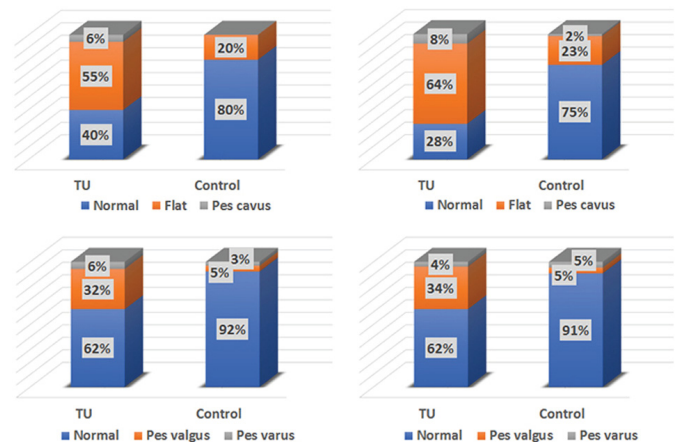
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**Background:** Systemic sclerosis (SSc) is a connective tissue disease characterized by an excessive collagen production, fibrotic changes in the skin, internal organs, and vascular involvement. Patients with SSc may have pathological changes in their joints, especially in feet that enclosed: flat feet, valgus or varus foot, hallux valgus, tendinopathy, foot ulcers, joint space narrowing, joint subluxation and degenerative changes [1, 2].

**Objectives:** The aim of the study was to assess occurrence and the severity of lesions and deformities of spine and joints of lower limbs, especially of feet, in patients with SSc, in comparison to the healthy volunteers.

**Methods:** All subject have anamnesis, anthropometric tests, and feet assessment with the computer podometric measuring system.

**Results:** The study enclosed 53 patients with SSc (69.8% female) in mean age 55±12 and 65 healthy volunteers (53.8% female) in mean age 45±15. Disease duration median was 3 years (IQR =6). In comparison to healthy volunteers, patients with SSc have more frequent flat feet and pes valgus ( $p < 0.001$ ) – Figure 1. No significant differences ( $p=0.96$ ) were observed in round back (8% both groups) and round-concave back (28% vs. 30%) occurrence. Patients with SSc have diminished spine mobility (15.06±5.52 vs. 26.09±6.52 [cm];  $p < 0.001$ ), to small knee-joint and ankle flexion/extension regardless of body side, more often hallux valgus and longitudinal flat foot. No differences were observed in transverse flat foot and heel varus/valgus occurrence.



**Abstract FRI0752-HPR** – Table 1. Results of ANOVA with repeated measurements in SSc and control group with comparison between feet

Group	TU		Control		ANOVA		
	Right	Left	Right	Left	P <sub>group</sub>	P <sub>foot</sub>	P <sub>group*foot</sub>
Knee-joint flexion (°)	108.7±11.9	107.4±12.6	136.2±6.8	136.2±6.7	<0.001	0.61	0.63
Knee-joint extension (°)	0.13±3.86	-0.68±4.22	-1.29±1.63	-1.28±1.74	<0.05	0.34	0.32
Ankle flexion (°)	8.7±4.8	9±5.4	18.9±2.2	18.8±2.2	<0.001	0.82	0.73
Ankle extension (°)	32.8±10.9	31.6±10	45±4.3	44.9±4.5	<0.001	0.53	0.58
Computer podometric measuring system							
Hallux valgus angle α (°)	10.5±7.2	12.0±8.8	7.7±5.6	7.8±6.4	<0.01	0.22	0.26
Hallux varus angle β (°)	15.9±5.1	15.6±5.9	15.3±4.1	16.1±4.4	0.98	0.39	0.09
Heel angle γ (°)	14.3±1.6	14.4±1.8	14.3±1.4	14.7±1.4	0.59	0.06	0.15
Godunov- Sztriter Index (KY)	0.45±0.12	0.46±0.16	0.42±0.06	0.43±0.08	<0.05	0.46	0.68
Chippaux-Smirak Index (CSI)	0.38±0.09	0.40±0.11	0.29±0.09	0.30±0.09	<0.001	<0.01	0.06
WGWP	24.9±4.3	24.4±6.4	28.4±2.7	28.1±3.9	<0.001	0.48	0.82
Wejsiflog Index	2.56±0.1	2.57±0.1	2.58±0.08	2.58±0.09	0.35	0.80	0.48

WGWP - The index of depth of the longitudinal arch of the foot.

**Conclusions:** Patients with SSc have a relatively high prevalence of feet pathological deformities and a smaller range of flexion of the joints than the lowest normal range, but mostly normal curvature of the spine.

**References:**

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**FRI0753-HPR PAIN SPREAD AND PAIN INTENSITY IMPROVE OVER TIME IN WOMEN WITH FIBROMYALGIA AND CHRONIC WIDESPREAD PAIN. A 12 YEAR FOLLOW UP STUDY**

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**Background:** In the Western world, the prevalence of chronic widespread pain (CWP) is about 10–15% while Fibromyalgia (FM) affects approximately 1–3% of the population. The ACR 1990 criteria define CWP as pain  $\geq 3$  months on the right and left side of the body, above and below the waist and axial skeletal pain. The 1990 criteria for FM are CWP in combination with pain in  $\geq 11$  of 18 tender points on manual palpation. Previous studies indicate that some patients with FM or CWP improve over time and the key to improvement is an important question in research and clinical practice.

**Objectives:** The primary objective was to investigate the change of pain intensity and pain distribution after 12 years in 166 women with FM or CWP.

The secondary objective was to compare baseline values of health related variables between patients who fulfilled the criteria for FM/CWP at the 12 year follow-up and patients who did not.

**Methods:** In 2004, 166 women with FM or CWP participated in a randomized controlled trial in Sweden aiming to investigate effects of patient education and pool exercise. All 166 were invited to the present study in 2016 and 126 women (75%) participated. Data was collected by a standardized interview, questionnaires of health related aspects and a physical examination. Primary, within-group changes were calculated for pain distribution (Bergman's pain drawing 0–18) and the subscale for pain intensity (0–100 mm) included in the Fibromyalgia Impact Questionnaire (FIQ).

Secondary, the group who fulfilled criteria for FM or CWP at follow-up were compared with the group who did not fulfil the criteria for FM or CWP, in overall health status (FIQ total), symptoms of stress (Stress and Crisis Inventory – SCI-93), walking capacity (6 min walk test), hand grip force (the Grippit) and self-reported physical activity (Leisure time physical activity instrument).

**Results:** Primary: The 126 women with FM or CWP improved in pain distribution: mean values at baseline 12.9 (SD 3.4) vs follow-up 11.4 (SD 4.7),  $p < 0.001$  and pain intensity: mean values at baseline 69 mm (SD 18.5) vs follow-up 59 mm (SD 22),  $p < 0.001$ .

Secondary: 18% (n=23) of the 126 women did not fulfil the 1990 criteria for FM or CWP at follow-up, and they showed significantly better health status, lower symptoms of stress and higher walking capacity in 2004, than the women who still had FM or CWP at follow-up. Baseline mean values FM/CWP (n=123) vs Not FM/CWP (n=23): FIQ total 66 (SD 16) vs 55 (SD 15),  $p = 0.006$ ; SCI-93 80 (SD 23) vs 59 (SD 22),  $p < 0.001$ ; 6 min walk test 502 m (SD 86) vs 542 m (SD 80),  $p = 0.028$ . No significant differences were found between the groups for baseline values of hand grip force and level of physical activity.

**Conclusions:** This study showed that distribution and severity of pain improved during 12 years in women with FM or CWP. The group that improved most (18%), reported better health status, lower stress and had better walking capacity 12 years earlier. This knowledge is important for health care professionals to motivate the patients to apply a variety of strategies, including physical activity, to improve their health and symptoms.

**Disclosure of Interest:** None declared

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**FRI0754-HPR IMPACT OF CORTICOSTEROID UTILIZATION ON BIOLOGIC DISEASE-MODIFYING ANTIRHEUMATIC DRUG INITIATION AMONG PATIENTS WITH RHEUMATOID ARTHRITIS**

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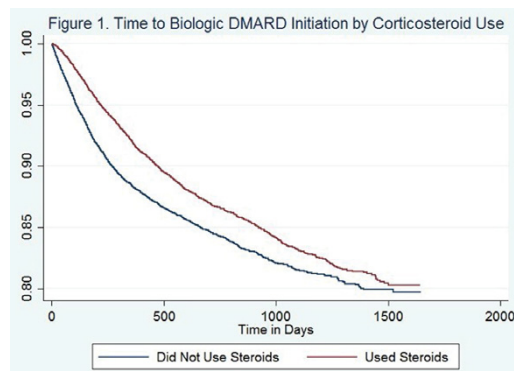
**Background:** Treatment guidelines recommend low dose corticosteroids (steroids) as an effective short-term (<3 months) therapy among rheumatoid arthritis (RA) patients to “bridge” patients until benefits of disease modifying anti-rheumatic drugs (DMARDs) are observed and in flare management.<sup>1</sup> Physician quality reporting system (PQRS) measures in the US require a documented

management plan for patients on steroids >10 mg/day and this may be a prompt to advance RA therapy. Understanding steroid treatment patterns and associated burden prior to biologic DMARD initiation can inform clinical and policy decision-makers on the appropriate use of these two drug classes in RA management.

**Objectives:** To examine effects of steroid treatment patterns on initiation of biologic DMARDs and adverse effects of steroid utilization before biologic DMARD initiation among patients with RA.

**Methods:** A retrospective analysis was conducted of adult RA patients (18 and older) in the US MarketScan Database (2011–2015). The earliest date a patient was diagnosed with RA was the index date. The following patterns of oral and injectable steroid utilization were analyzed: whether steroids were used; duration of steroid use (short/long duration defined as < or  $\geq 3$  months); and steroid dosage (low as <2.5 mg/day, medium as 2.5–<7.5 and high as  $\geq 7.5$  mg/day). Kaplan-Meier survival analysis was used to compare time to initiation of first biologic DMARD across groups of steroid utilization. The effects of steroid use on initiation of biologic DMARDs were examined using Cox proportional hazards models. Likelihood and number of adverse events were examined using logistic and negative binomial regression models. Independent variables in all models included patient demographics and health characteristics.

**Results:** A total of 25,537 patients were included (40.82% used steroids). Based on Kaplan-Meier survival analysis, steroid users (Figure 1), those with longer duration, and in lower dosage categories had delayed time to initiation of a biologic DMARD than their counterparts (nonusers, those with shorter duration and higher dosages, respectively) ( $P < 0.001$ ). According to Cox proportional hazards model, lower hazard of biologic DMARD initiation was associated with steroid use (HR)=0.89, 95% Confidence Interval [CI]=0.83–0.96, compared to nonusers), longer steroid duration (HR)=0.73, 95% CI=0.60–0.89 compared to short duration) and lower dosages (HR)=1.10, 95% CI=0.99–1.23 for medium dose and HR=1.93, 95% CI=1.59–2.34 for high dose compared to low dose). Higher likelihood of adverse events was associated with steroid use (Odds Ratio [OR]=1.13, 95% CI=1.06–1.20), and longer duration (OR)=1.75, 95% CI=1.47–2.09) than their counterparts. Likelihood of adverse events did not significantly differ across dosages. Similar effects of steroid utilization were found on the number of adverse events.



**Conclusions:** The findings indicate that RA patients who use steroids, those with longer duration and lower dosages have delayed initiation of biologic DMARDs than their counterparts. RA patients who use steroids and those with longer duration have higher likelihood/number of adverse events prior to initiating biologic DMARDs.

**References:**

- [1] Singh JA, et al. doi: 10.1002/acr.22783.

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**FRI0755-HPR POTENTIAL BENEFITS OF BIOLOGICS ON CARDIOVASCULAR DISEASES AND ORTHOPEDIC SURGERIES IN PATIENTS WITH RHEUMATOID ARTHRITIS: A NATIONWIDE POPULATION-BASED COHORT STUDY IN TAIWAN**

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**Background:** Rheumatoid arthritis (RA) is a chronic, systemic inflammatory disorder, precipitating chronic inflammation of the joints, and also affects organs throughout the body, and even results in joint deterioration/disability. RA-related inflammation that is responsible for synovial lesions may be implicated in