Laboratory Science Discussion Group. Circulation [Internet]. 2004 Dec 21 [cited 2020 Oct 20];110(25).

- [2] Munoz. Lipoprotein ratios: Physiological significance and clinical usefulness in cardiovascular prevention. VHRM. 2009 Sep;757.
- [3] Walldius G, Jungner I, Holme I, Aastveit AH, Kolar W, Steiner E. High apolipoprotein B, low apolipoprotein A-I, and improvement in the prediction of fatal myocardial infarction (AMORIS study): a prospective study. The Lancet. 2001 Dec;358(9298):2026–33.

Disclosure of Interests: None declared.

DOI: 10.1136/annrheumdis-2021-eular.3938

AB0519

PHYSICAL ACTIVITY AND OBESITY IN PATIENTS WITH ANKYLOSING SPONDYLITIS

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Background: Ankylosing Spondylitis (AS) is associated with an increased cardiovascular risk. Obesity and limited activity in patients with AS may contribute to this cardiovascular risk.

Objectives: We aimed to evaluate physical Activity and obesity in patients with AS.

Methods: We conducted a cross-sectional observational study of 40 patients with AS, over a period of 3 months. We evaluated the level of physical activity using the IPAQ (International Physical Activity Questionnaire). We also measured body mass index (BMI), body fat percentage, waist circumference, hip circumference and their ratio in all patients.

Results: The mean age of our population was 44±10 years. A male predominance was noted with a sex ratio =1.1. The mean ASDAS-CRP and BASDAI levels were 2.1±0.95 and 2.25±1.33. The mean of IPAQ was 3900 MET minutes per week, with a median of 3069 and extremes of 339 and 11000. 45.5% of patients had moderate physical activity and 20% had low activity. The mean BMI was 26.5 ± 4.7 kg/m². Twenty percent of patients were obese. The mean body fat percentage was 25% with a median of 23.7% and extremes of 8-46%. Forty-five percent of the patients had a high fat mass. The mean waist circumference was 95±13 cm, hip circumference 104±9.5 cm. The mean waist to hip ratio was 0.9±0.07. Thirty-seven percent of patients had a high waist to hip ratio. BMI and body fat percentage were negatively correlated with HDL level; (r=-0.365, p=0.024) and (r=-0.393, p=0.015) respectively.

Conclusion: The majority of our patients have moderate or low levels of physical activity. The increase in BMI and fat mass appear to be associated with disturbance of the lipid balance, with low HDL values.

Disclosure of Interests: None declared.

DOI: 10.1136/annrheumdis-2021-eular.4023

AB0520

PUBIC SYMPHYSIS INVOLVEMENT IN NON-RADIOGRAPHIC SPONDYLARTHROSIS

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Background: Structural change within pubic symphysis (PS) occurs in 20–25% of patients with spondylarthrosis (SpA). It occurs in all developmental stages, even in the early stages of the disease. Changes in the symphysis can sometimes precede spine and sacroiliac involvement. Radiological findings in PS were poorly described in the SpA, especially on its non-radiographic form (nr-axSpA).

Objectives: We aimed in this study to evaluate pubic symphyseal features in patients with a confirmed diagnosis of nr-axSpA and to assess the correlation of these changes with clinical and imaging features of nr-axSpA in these patients. We also focused on the relationship between parity and radiographic changes in pubic symphysis (PS).

Methods: We retrospectively reviewed the data of 40 patients diagnosed with nr-axSpA according to the ASAS criteria. Radiological-morphological changes of PS were assessed in pelvic radiography by two distinct rheumatologists. Grading symphyseal involvement was made as follow: scores ranged from 0-4 per reading: grade 0 = normal; grade 1 = subtle irregularity and/or subchondral sclerosis, grade 2 = clear erosions, 3 = marked sclerosis, grade 4 = ankylosis.

For all patients, we calculated the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and the BASRI (Bath Ankylosing Spondylitis Radiology Index).

For all patients, we recorded the sacroiliac changes showed by the previous pelvic radiography and/or the pelvic scanner and/or by magnetic resonance imaging (MRI).

Results: We enrolled forty patients with a sex-ratio H/F=1/3. Mean age of patients at diagnosis was 39.9 ± 10.8 [17-59]. Forty percent of patients had peripheral enthesitis, and 45% had peripheral arthritis. BASDAI mean score was 4.63 ± 0.9 [0-8.6]. HLA B-27 was present in 32.3% of cases. We noted radiographic changes in PS in 37.5% (15 patients): grade 1 (n=1), grade 2 (n=10), grade 3 (n=3) and grade 4 (n=1). There was not a significant difference between the sex group (p=0.85). A comparison of 2 groups (women with 3 children or more and women with less than 3 children) concluded that childbirth did not modify PS changes (p=0.9). Also, PS changes did not differ with age (p=0.5). There was no correlation between the BASRI value with the presence of PS changes nor with its grades (p=0.5 and p=0.89, respectively). Also, disease activity did not influence the PS involvement (p=0.4). Radiological findings in PS was not correlated with the sacroiliac features found on MRI or pelvic CT scan (p=0.59 and p=0.1).

Conclusion: In SpA criteria, PS changes were not considered. It can be an additional help in making the diagnosis. Interestingly, pubic symphysis may exist without sacroiliitis.

Disclosure of Interests: None declared.

DOI: 10.1136/annrheumdis-2021-eular.4147

Psoriatic arthritis – treatment

AB0521

EARLY REAL-WORLD EXPERIENCE OF TOFACITINIB FOR PSORIATIC ARTHRITIS: DATA FROM A UNITED STATES HEALTHCARE CLAIMS DATABASE

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Background: Tofacitinib is an oral Janus kinase inhibitor for the treatment of psoriatic arthritis (PsA). It was approved in the United States (US) in December 2017 for use in combination with non-biologic disease-modifying antirheumatic drugs (DMARDs).

Objectives: This analysis of real-world data assessed demographic and baseline clinical characteristics, as well as treatment persistence/adherence, in patients (pts) with PsA who had newly initiated tofacitinib treatment.

Methods: This retrospective cohort study included pts aged ≥18 years in the Truven MarketScan™ US Commercial and Medicare Supplemental Claims and Encounters database with ≥1 tofacitinib claim (first = index) between 14 December 2017–30 April 2019, and PsA diagnoses (≥1 inpatient or ≥2 outpatient [30–365 days apart]) on or within 12 months pre-index. Pts were continuously enrolled for 12 months pre-index and 6 months post-index, with no pre-index claims for tofacitinib. Pt demographic and clinical characteristics on the day of index, history of advanced therapy treatment (≥1 claim for biologic DMARDs or apremilast within 12 months pre-index) and tofacitinib treatment regimen (monotherapy or combination therapy [≥1 claim for conventional synthetic DMARDs or apremilast on or within 90 days post-index]) were recorded. Outcomes at 6 months post-index included tofacitinib persistence (<60-day gap without tofacitinib treatment) and adherence (proportion of days covered ≥80% and medication possession ratio [data not shown]). A sensitivity check was performed by analysing a sub-cohort that excluded pts with a diagnosis of rheumatoid arthritis (RA) on or within 12 months pre-index and within 6 months post-index.

Results: Of 17 321 pts receiving tofacitinib, 440 pts met the inclusion criteria for the overall cohort, with 315 pts included in the sub-cohort. In the overall cohort, pts were mostly female, with a mean age of 52.3 years and a mean PsA duration of 738 days (data not shown). Most pts were exposed to ≥1 advanced therapy within 12 months pre-index (mean = 1.1; range = 0–4); most commonly secukinumab (Table 1). Overall, 60.7% of pts received monotherapy and 39.3% of pts received tofacitinib combination therapy post-index; most commonly methotrexate (data not shown). At 6 months post-index, persistence was similar in pts receiving tofacitinib monotherapy vs combination therapy; adherence was slightly lower in pts receiving tofacitinib monotherapy vs combination therapy (Figure 1). Results were similar in the sub-cohort (Table 1, Figure 1).

Table 1. History of advanced therapy on or within 12 months pre-index in pts with PsA

	All pts (N=440)	Pts with no RA ^a (N=315)
Pts exposed to advanced therapy, n (%) ^b		
Any advanced therapy ^c	336 (76.4)	241 (76.5)
Secukinumab	113 (25.7)	91 (28.9)
Adalimumab	93 (21.1)	58 (18.4)
Apremilast	81 (18.4)	59 (18.7)
Etanercept	70 (15.9)	47 (14.9)
Unique advanced therapy prescriptions		
Mean (SD)	1.1 (0.8)	1.1 (0.8)
Median (IQR)	1 (1–2)	1 (1–2)
Range	0–4	0–4
Number of unique advanced therapies, n (%)		
0	104 (23.6)	74 (23.5)
1	214 (48.6)	153 (48.6)
2	100 (22.7)	73 (23.2)
≥3	22 (5.0)	15 (4.8)

^aExcludes pts with a diagnosis of RA on or within 12 months pre-index and within 6 months post-index; ^bPts with ≥1 claim for biologic DMARDs or apremilast within 12 months pre-index;

^cOther advanced therapies reported in <10% of all pts were abatacept, certolizumab, golimumab, infliximab, ixekizumab and ustekinumab (QR, interquartile range; N, number of pts per cohort; n, number of pts per category; SD, standard deviation)

Figure. Tofacitinib treatment a) persistence^a and b) adherence (PDC ≥0.8)^b in pts with PsA at 6 months post-index

^aPts with <60-day gap without tofacitinib treatment; ^bPts achieving ≥80% of days covered; ^cPts with ≥1 claim for a conventional synthetic DMARD or apremilast on or within 90 days post-index; ^dExcludes pts with a diagnosis of RA on or within 12 months pre-index and within 6 months post-index; N, number of pts in each cohort; PDC, proportion of days covered; SD, standard deviation

Figure 1

Conclusion: This analysis of US-based claims data indicated that pts newly initiated tofacitinib treatment an average of 2 years after PsA diagnosis, with the majority (>60%) of pts receiving tofacitinib as monotherapy. High levels of persistence and adherence to tofacitinib were observed 6 months after treatment initiation. Findings were similar when pts with PsA who also had a diagnosis of RA were excluded. Data were limited in that claims data cannot confirm that pts took the medication for which they filed a claim.

Acknowledgements: Study sponsored by Pfizer Inc. Medical writing support was provided by Gemma Turner, CMC Connect, and funded by Pfizer Inc.

Disclosure of Interests: Philip J Mease Speakers bureau: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly, Genentech, Janssen, Novartis, Pfizer Inc, UCB, Consultant of: AbbVie, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Eli Lilly, Galapagos, Gilead, Janssen, Novartis, Pfizer Inc, Sun, UCB, Grant/research support from: AbbVie, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Eli Lilly, Galapagos, Gilead, Janssen, Novartis, Pfizer Inc, Sun, UCB, Pamela Young Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, David C Gruben Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Lara Fallon Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Rebecca Germino Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Arthur Kavanaugh Grant/research support from: Pfizer Inc.

DOI: 10.1136/annrheumdis-2021-eular.390

AB0522

SAFETY PROFILE OF UPADACITINIB UP TO 3 YEARS IN PATIENTS WITH PSORIATIC ARTHRITIS: AN INTEGRATED ANALYSIS FROM THE PHASE 3 PROGRAM

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Background: The efficacy and safety of upadacitinib (UPA), an oral Janus kinase inhibitor, in patients (pts) with active psoriatic arthritis (PsA) were demonstrated through 24 weeks in the phase 3 SELECT-PsA 1 and SELECT-PsA 2 placebo-controlled clinical trials.^{1,2}

Objectives: To describe the long-term integrated safety profile of UPA relative to adalimumab (ADA) in pts with PsA treated in the SELECT program.

Methods: The SELECT-PsA program enrolled pts with prior inadequate response or intolerance to ≥1 non-biologic DMARD (SELECT-PsA 1) or ≥1 biologic DMARD (SELECT-PsA 2). Both trials include UPA 15 mg and 30 mg, and only SELECT-PsA 1 includes long-term comparison with ADA 40 mg every other week. Treatment-emergent adverse events (TEAEs; AE onset ≥first dose and ≤30 days after last dose for UPA and ≤70 days for ADA) were summarized for the following: pooled UPA 15; pooled UPA 30; and ADA. TEAEs are reported as exposure-adjusted event rates (EAERs; events/100 pts years [E/100 PY]) up to a cut-off date of 20 June 2020.

Results: 2257 pts received ≥1 dose of UPA 15 (N=907; 1247.2 PYs), UPA 30 (N=921; 1257.4 PYs), or ADA (N=429; 549.7 PYs), with median (max) exposures of 69 (155), 69 (154), and 68 (152) weeks, respectively. EAERs of TEAEs and serious AEs were generally similar between UPA 15 and ADA and higher with UPA 30; rates of AEs leading to study drug discontinuation were generally similar across all groups (Table 1). Similarly, rates of serious infection were comparable between UPA 15 and ADA and higher with UPA 30 (Figure 1 next page). The most common serious infection was pneumonia. Rates of herpes zoster were lower with UPA 15 than UPA 30 but higher than ADA. Most herpes zoster events involved a single dermatome; no events involved the central nervous system or other internal organs. Lower rates of opportunistic infections (OI) excluding tuberculosis were observed with UPA 15 vs UPA 30; the most common OI was mucosal candida infection. Malignancies were reported at similar rates across all treatment groups; no events of lymphoma were reported. Age-gender-adjusted standardized incidence ratios for malignancies excluding NMSC indicated no increased risk with UPA compared to the general population. Rates of adjudicated major adverse cardiovascular events and venous thromboembolic events were ≤0.3 E/100 PY for both UPA arms; all pts had ≥1 risk factor. One adjudicated gastrointestinal perforation was reported with UPA 15.

Table 1. Overall Treatment-emergent AEs for Upadacitinib and Adalimumab (E/100 PY [95% CI])

	UPA 15 mg QD N=907 (1247.2 PY)	UPA 30 mg QD N=921 (1257.4 PY)	ADA 40 mg EOW N=429 (549.7 PY)
AEs	263.9 (254.9, 272.9)	321.5 (311.6, 331.5)	286.5 (272.4, 300.7)
Serious AEs	10.3 (8.6, 12.1)	13.2 (11.2, 15.2)	9.6 (7.0, 12.2)
AE leading to discontinuation	6.7 (5.2, 8.1)	7.8 (6.2, 9.3)	7.8 (5.5, 10.2)
Deaths^a	0.2 (-0.1, 0.4)	0.2 (-0.0, 0.5)	0.2 (-0.2, 0.5)

^aDeaths included non-treatment emergent deaths: UPA 15, 1; UPA 30, 1; ADA, adalimumab; AE, adverse event; CI, confidence interval; E, event; EOW, every other week; PY, patient years; QD, once daily; UPA, upadacitinib.