

PCV13) in patients with RA enrolled in the ongoing Phase 2 open-label extension study BALANCE-EXTEND.

Methods: Patients from BALANCE-EXTEND receiving PCV13 vaccination were required to be on UPA 15 mg once daily (QD) or 30 mg QD and background MTX for ≥ 4 weeks prior to, and after, PCV13 vaccination; MTX was not interrupted prior to vaccination. Vaccination antibody titers were collected pre-vaccination (Week 0) and post-vaccination (Weeks 4 and 12). The primary variable was the proportion of patients with satisfactory humoral response to PCV13 (≥ 2 -fold increase in antibody concentration from pre-vaccination [Week 0] in $\geq 6/12$ pneumococcal antigens [1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F]) at 4 weeks post-vaccination.

Results: Of 111 patients (UPA 15 mg, n=87; UPA 30 mg, n=24), 86% were female, most (98%) were white, and mean (standard deviation) age was 58.4 (12.0) years. Prior to vaccination, patients had a median (range) duration of RA of 9.3 (3.4–35.0) years and had been receiving UPA for a median (range) of 3.9 (3.0–4.9) years. All but 3 patients were taking concomitant MTX, and 44.1% were taking a CS (median daily dose, 5.0 mg). All 111 patients received PCV13, none discontinued UPA during the first 4 weeks, and blood samples were available from 83/23 and 79/22 patients in the UPA 15/30 mg groups at Weeks 4 and 12, respectively. At 4 weeks, satisfactory humoral response to PCV13 occurred in 67.5% (95% confidence interval [CI]: 57.4–77.5) and 56.5% (95% CI: 36.3–76.8) of patients receiving UPA 15 and 30 mg, respectively. At 12 weeks, satisfactory humoral response to PCV13 occurred in 64.6% (95% CI: 54.0–75.1) and 54.5% (95% CI: 33.7–75.4) of patients receiving UPA 15 and 30 mg, respectively (Figure 1). There was no clear difference in response between patients receiving and not receiving concomitant CS. Within 30 days post-vaccination, 2 adverse events (AEs) were considered as possibly related to UPA (1 case of diverticulitis, UPA 15 mg; 1 case of anemia, UPA 30 mg) and no serious AEs were reported (Table 1). Two patients experienced pyrexia and 1 subject each experienced vaccination-site pain and headache within 1 day post-vaccination (all in UPA 15 mg group).

Table 1. Safety through 30 days post-PVC13 vaccination in UPA-treated patients

Event, n (%)	UPA 15 mg QD (n=87)	UPA 30 mg QD (n=24)
Any AE	15 (17.2)	3 (12.5)
Serious AE	0	0
AE leading to discontinuation of study drug	0	0
AE with reasonable possibility of being related to UPA ^a	1 (1.1) ^b	1 (4.2) ^c
Death	0	0

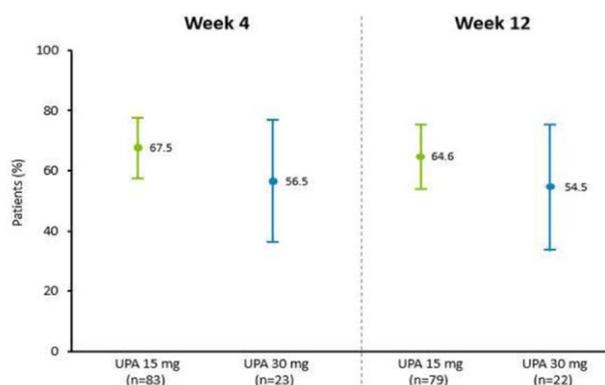
^aAs assessed by the investigator. ^bDiverticulitis. ^cAnemia. AE, adverse event; PVC13, Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM₁₉₇ Protein]; QD, once daily; UPA, upadacitinib.

Conclusion: Satisfactory humoral response to PCV13 at 4 weeks occurred in ~two-thirds of patients with RA receiving long-term treatment with UPA 15 mg QD + background MTX. This is broadly consistent with pneumococcal vaccine humoral responses observed in patients with RA treated with other JAK inhibitors, biologics, or placebo.^{2–4}

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Figure 1. Proportion (%; 95% CI) of UPA-treated patients with satisfactory humoral response^a to PVC13 at Weeks 4 and 12 (full analysis set)^b



^aSatisfactory humoral response was defined as ≥ 2 -fold increase in antibody concentration from the vaccination baseline in ≥ 6 out of 12 pneumococcal antigens (1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). ^bNumber of patients based on availability of blood samples collected at Weeks 4 and 12. CI, confidence interval; PVC13, Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM₁₉₇ Protein]; UPA, upadacitinib.

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POS0509 PREVALENCE OF RHEUMATOID CACHEXIA AND ITS ASSOCIATION WITH SERUM FETUIN-A LEVELS IN CAUCASIAN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Rheumatoid cachexia is an under-recognized pathological condition, which is characterized by a loss of muscle strength and can be presented as a low fat-free mass and normal or high BMI in patients with rheumatoid arthritis determined by dual-energy X-ray absorptiometry (DEXA) [1]. Though fetuin-A is one of a major noncollagen proteins in bone tissue it is of interest to clarify its association with rheumatoid cachexia.

Objectives: To define the prevalence of rheumatoid cachexia in Caucasian patients with rheumatoid arthritis determined by DEXA method and to study the association of serum fetuin-A levels with body composition and rheumatoid cachexia in this group.

Methods: 110 Caucasian patients with rheumatoid arthritis undergone DEXA with «Total Body» program. All patients fulfilled the 2010 ACR/EULAR classification criteria for rheumatoid arthritis. The diagnosis of rheumatoid cachexia was based on Engvall I.L. criteria: fat-free mass index less than 10th percentile with fat mass index above 25th percentile [1]. We used values for these indexes from the study performed in 2008 by Coin A. et al. on Italian population due to a lack of standard values [2]. Fetuin-A in serum was determined by enzyme-linked immunosorbent assay. 72 patients have been taking glucocorticoids for more than 3 months in dose equivalent or higher than 5 mg of prednisolone daily. Statistical analysis was performed using a software package «Statistica 12.0». Parametric data is presented as M \pm St.dev, and nonparametric as Me [Q1-Q3].

Results: Rheumatoid cachexia was diagnosed in 25 patients (22,7%) with mean age of 52,2 \pm 8,14 years. The prevalence of cachexia was the same in groups of patients who took glucocorticoids (n=16, 22,2%) and who didn't (n=9, 23,7%; p = 0,465). Median cumulative dose of oral glucocorticoids in patients with rheumatoid cachexia was higher but fell just short of statistical significance (8,0 [2,9-13,5] g vs 5,4 [0,2-11,6] g; Z=-1,42; p = 0,156). Median serum fetuin-A levels were only slightly significantly lower in patients with rheumatoid cachexia (757,7 [700,5-932,0] μ g/ml vs 769,3 [660,3-843,4] μ g/ml; Z=-1,35; p=0,175). Positive statistically significant correlations were observed between serum fetuin-A levels and bone mass in right (r=0,222, p = 0,027) and left (r=0,263, p = 0,008) lower limbs, trunk (r=0,268, p = 0,007), gynoid region (r=0,293, p = 0,003), both lower limbs (r=0,246, p = 0,014) and whole-body (r=0,235, p = 0,019).

Conclusion: Rheumatoid cachexia was diagnosed in 22,7% of patients with rheumatoid arthritis. No association was observed between glucocorticoids intake and rheumatoid cachexia, despite the expected influence of them on muscle mass. We may suggest that occurrence and pathogenesis of this condition is complex and should be studied more precisely. It is well-known that patients with such condition have a higher risk for metabolic syndrome, arterial hypertension and mortality. We observed positive correlations between serum fetuin-A levels and bone mass in lower limbs, trunk, gynoid region and whole-body. Considering

that fetuin-A is also associated with bone mineral density [3], it may be regarded as a marker of bone remodeling.

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POS0510

EPIDEMIOLOGY OF COCAINE AND HALLUCINOGEN USE DISORDER HOSPITALIZATIONS IN RHEUMATIC DISEASES

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Background: Cocaine use disorder is a frequent cause of drug use disorders in the U.S. Although hallucinogen use disorder is less common, both are potentially preventable public health issues. To our knowledge, epidemiological studies estimating burden of cocaine or hallucinogen use disorders in common Musculoskeletal diseases (MSDs) are lacking.

Objectives: To assess national time-trends in cocaine use and hallucinogen use disorders in people with MSDs

Methods: This study used the U.S. National Inpatient Sample (NIS), a de-identified national all-payer inpatient health care database (<https://www.hcup-us.ahrq.gov/nisoverview.jsp>) from 1998-2014. The NIS is a 20% stratified sample of hospital discharges in the U.S. It is commonly used to derive national estimates of hospitalization and outcomes. Cocaine or hallucinogen use disorder hospitalization was defined in a validated approach as the presence of the following International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic codes: cocaine use disorder, 304.2x, or 305.6x; and hallucinogen use disorder, 304.5x or 305.3x; hospitalizations for drug use in remission, drug counseling, rehabilitation or detoxification were excluded, as in previous studies. MSDs were identified based on the respective ICD-9 codes, a validated approach (5-9), in non-primary position: Gout: 729.xx; rheumatoid arthritis (RA): 714.xx; Fibromyalgia: 729.1; osteoarthritis (OA): 715.xx; or low back pain (LBP): 724.

Results: In 1998-2000, the highest frequency of cocaine use hospitalizations was in people with LBP: LBP (n=5,914), followed by OA (n=4,931), gout (n=2,093), RA (n=2,026), and fibromyalgia (n=1,620). In 2013-2014, the order changed slightly with OA (n=22,185), followed by LBP (n=16,810), gout (n=10,570), RA (n=8,975), and fibromyalgia (n=5,680). Respective rates per 1 million U.S. NIS hospitalizations in 2013-2014 and the relative increase from 1998-2000 to 2013-2014 were: Gout, 10.2 (increase, 4.1-fold); OA, 21.4 (3.5-fold); fibromyalgia, 5.48 (2.5-fold); RA, 8.66 (3.4-fold); and LBP, 16.22 (1.8-fold; figure 1).

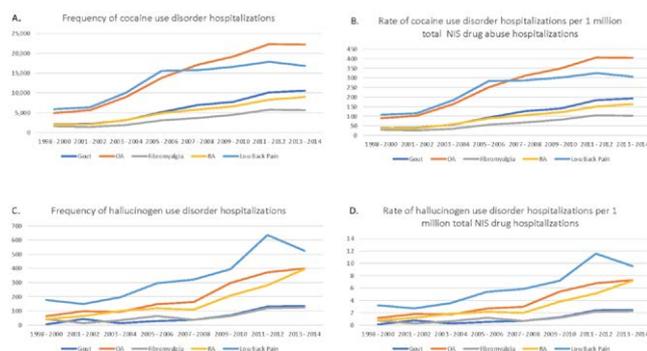


Figure 1. Time-trends in the rates of hospitalization with cocaine use and hallucinogen use disorder (A), non-home discharge (B), and in-hospital mortality (C) per 100,000 NIS hospitalization claims. The x-axis shows rate per 100,000 NIS hospitalization claims and the y-axis shows the study periods

In 1998-2000, hallucinogen use disorder hospitalizations were as follows: LBP (n=176), followed by OA (n=63), RA (n=42), fibromyalgia (n=41) and gout (n<10; cells with frequency of 10 or fewer are reported as <10 per NIS guidance). In 2013-2014, the frequency order was the similar, with the highest numbers for LBP (n=525) followed by OA (n=400), RA (n=395), gout (n=135) and fibromyalgia (n=125). Respective rates per 1 million US NIS hospitalizations in 2013-2014 and the relative increase from 1998-2000 to 2013-2014 were: Gout, 0.13 (increase, 25-fold); OA, 0.39 (5.5-fold); fibromyalgia, 0.12 (2-fold); RA, 0.38 (8.5-fold); and LBP, 0.51 (2-fold; figure 1).

Conclusion: This study confirmed an increasing rate of both, cocaine use and hallucinogen use disorder hospitalizations in people with 5 MSDs over a 17-year period from 1998-2014 in the U.S.

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POS0511

USING HIP STRUCTURAL ANALYSIS MEASUREMENTS TO PREDICT FRACTURE IN RHEUMATOID ARTHRITIS

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Background: Rheumatoid arthritis (RA) is a chronic inflammatory autoimmune disease and increases the risk of developing osteoporosis. Incidence of fracture is higher in this group of patients compared to the general population and can lead to increased morbidity (1). Bone strength of the proximal femur is not only linked to bone mineral density; it also depends on the geometric properties of the bone mass (2). Hip structural analysis (HSA) is a technique used to assess hip bone structure that takes geometric measurements of the femur from dual-energy X-ray absorptiometry (DEXA) images (3).

Objectives: To determine whether HSA measurements help predict fracture in patients with RA.

Methods: Data were collected from June 2004 to August 2017 from RA patients who underwent a DEXA scan at a District General Hospital. This included hip axis length (HAL), cross-sectional area (CSA), cross-sectional moment of inertia (CSMI), distance from centre of femoral head to centre of femoral neck (D1) and to inter-trochanteric line (D2), mean femoral neck diameter (D3), shaft angle (A) neck/shaft angle (Θ) and proximal femur strength index (SI) and distance from centre of mass of femoral neck to superior neck margin (Y). Fracture was predicted by a series of binomial logistic regression models, adjusted for sex, age and bone mineral density (BMD). Odds ratios with 95% confidence intervals and area under the receiver operating characteristic curve (AUC) were calculated.

Results: 2077 patients with RA were identified, 1632 were female and the mean age was 66.7. HAL, D1, D2, D3, A, Θ and Y were not significant predictors of fracture in regression models; odds ratios are included in table 1. CSA, CSMI and SI predicted fracture risk. The AUC for CSA, CSMI and SI regression models were 0.632, 0.609 and 0.625 respectively.

Table 1. Odds ratios of fracture for different HSA parameters in RA patients

HSA Parameter	Odds Ratio (95% Confidence Interval)
HAL	1.01410 (0.99958 - 1.02883)
CSMI	0.99994 (0.99990 - 0.99998)
CSA	0.98523 (0.98065 - 0.98982)
D1	1.01683 (0.98925 - 1.04518)
D2	1.01286 (0.99886 - 1.02705)
D3	1.00664 (0.96958 - 1.04511)
Y	1.04580 (0.98633 - 1.10886)
A	1.00898 (0.98878 - 1.02959)
Θ	1.00276 (0.98672 - 1.01906)
SI	0.56769 (0.43400 - 0.74258)