Does seropositivity influence differentially drug discontinuation of biologic antirheumatic agents with non-anti-TNF mode of action?

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Background: Rheumatoid factor (RF) and anti-citrullinated protein antibodies (ACPA) are used as diagnostic tools, but may also be used as prognostic factors or as predictors of response to therapy, as these biomarkers have been associated with better clinical responses to some bDMARDs.

Objectives: To examine whether seropositivity has a similar impact on drug discontinuation of different bDMARDs with a non-anti-TNF mode of action (non-aTNF bDMARDs).

Methods: This is a pooled analysis of 10 observational European RA registries (FEDRA, COPAS, GR, PT, RO, ES, SE, NL). Inclusion criteria were a diagnosis of RA, initiation of treatment with abatacept (ABA), rituximab (RTX) or tocilizumab (TCZ) and available information on RF and/or ACPA status. The exposure of interest was seropositivity, which was defined as positive if RF or ACPA was positive, and negative if both were negative. The primary endpoint was overall drug discontinuation, defined as the period between treatment initiation and treatment discontinuation. Drug discontinuation was analyzed using a Cox proportional hazards model, including drug, seropositivity, their interaction, adjusting for age, gender, disease duration, baseline DAS28, comoncomitant synthetic DMARD (sDMARDs), number of previous sDMARDs and bDMARDs, and stratifying by country and calendar year.

Results: We could analyze data from 12040 patients. In crude analyses, seropositivity was associated with a lower drug discontinuation with all 3 bDMARD (p-value interaction 0.22), with a hazard ratio for seropositive vs. seronegative (HR) 0.89 (95% CI: 0.82–0.97). In adjusted analyses, seropositivity remained associated with a lower drug discontinuation, but the effect differed by drug (p interaction 0.01): ABA: HR for seropositive vs. seronegative: 0.76 (95%CI: 0.66–0.88), RTX: 0.88, (95%CI: 0.70–1.10), and TCZ: 1.08, (95% CI: 0.89–1.31). Two-by-two drug to drug comparisons showed that the effect of seropositivity differed between ABA and TCZ (p = 0.004), but not between ABA and RTX (p = 0.29), or between TCZ and RTX (p = 0.16).

Conclusions: Data from this pooled European registry analysis suggests that seropositivity is associated with lower drug discontinuation of non-aTNF bDMARDs. This effect differed between drugs and was significant for ABA, but not for TCZ or RTX. The impact of seropositivity on other measures of effectiveness will be presented.

TNF blockers inhibit spinal radiographic progression in ankylosing spondylitis by reducing disease activity: results from the Swiss Clinical Quality Management (SCQM) cohort

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Objectives: To analyze the impact of tumour necrosis factor inhibitors (TNFi) on spinal radiographic progression in ankylosing spondylitis (AS).

Methods: AS patients in the Swiss Clinical Quality Management Cohort with up to 10 years of follow-up and radiographic assessments every 2 years were included. Radiographs were scored by two readers according to the modified Stoke Ankylosing Spondylitis Spine Score (mSASSS) with known chronology. The relationship between TNFi use before a 2-year radiographic interval and progression within the interval was investigated using binomial generalized estimating equation models with adjustment for potential confounding. Ankylosing Spondylitis Disease Activity Score (ASDAS) was regarded as a mediator of the effect of TNFi on progression and added to the model in a sensitivity analysis.

Results: A total of 432 AS patients contributed to data for 616 radiographic intervals (mean (SD) intervals per patient 1.4 (0.7), range 1–5). Mean (SD) mSASSS increase in 2 years was 0.9 (2.6) units. Radiographic progression was defined as an increase in ≥2 mSASSS units in 2 years. Prior use of TNFi reduced the odds of progression by 48% (odds ratio (OR) 0.52, 95% confidence interval (CI) 0.30–0.91) in the multivariable analysis. Adding ASDAS to the model decreased the estimated effect of TNFi: OR 0.63, 95% CI 0.36–1.11. In this model, an increase in ASDAS by one unit would increase the odds for progression by 1.4 (p = 0.02).

Conclusion: TNFi reduce spinal radiographic progression in patients with AS and this effect seems mediated through the inhibiting effect of TNFi on disease activity.

Biomarkers formed through extracellular matrix turnover predict progression of fibrosis in systemic sclerosis

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Background: Systemic sclerosis (SSc) is a complex autoimmune disease with extensive fibrosis of the skin and internal organs. Impairment in the formation and degradation of collagens results in fibrosis. Quantifying the tissue turnover in a highly fibrotic disease such as SSc is very important for the prediction of disease progression and therapeutic efficacy.

Objectives: To evaluate the potential of selected ECM–derived serological biomarkers for prediction of clinical outcomes and disease progression in SSc.

Methods: Healthy controls (HC; n = 29), stable SSc (n = 149), and progressive SSc patients (n = 23, progression defined either as 10% decrease in FVC% predicted or increase in mRSS ≥2 mSASSS in one year clinical follow up), meeting the 2013 ACR/EULAR classification criteria were analyzed. Data and sera collection were done according to EUSTAR standards. Measurement of ECM-degradation (C3M, VICM, C4M2, BGM) and ECM-formation biomarkers (P1NP, P4NP7S, Pro-C3, Pro-C5, Pro-C6) in sera using ELISA-based assays was performed by Nordic Bioscience. Statistical analysis was done by Man-Whitney U, Kruskal-Wallis, Spearman tests and by multivariate regression analysis. Biomarkers’ sensitivity and specificity was examined by ROC analysis.

Results: The expression of C4M2, Pro-C3, BGM and C3M was significantly increased in SSc patients compared to HC (p <0.0001, AUC = 0.93; p <0.001, AUC = 0.74; p = 0.003, AUC = 0.67; p <0.001; AUC = 0.94, respectively). Furthermore, Pro-C3, VICM and Pro-C6 levels were significantly higher in SSc progressors versus stable SSc patients at follow up (p <0.0001, p <0.001, p <0.0001, AUC = 0.86; p = 0.003, AUC = 0.75; p = 0.0005, AUC = 0.81, respectively). The ECM-degradation markers C4M2, BGM, C3M were significantly lower in SSc progressors versus stable SSc patients at follow up (p <0.0001, p <0.001, p <0.0001, respectively). Consistently, the formation marker Pro-C6 was significantly increased (p = 0.001, AUC = 0.71) indicating a profound imbalance of ECM turnover in SSc progressors. The largest difference between progressive and stable SSc patients was seen for the ratio between the formation and degradation biomarkers Pro-C3/C3M (p <0.0001 AUC = 0.86).

Conclusions: This data suggest that ECM-derived biomarkers have prognostic value in the clinical monitoring of progressive patients at one year follow up. The ratio of Pro-C3/C3M is as a new potential predictive index for differentiation of stable vs. progressive patients.
Two refractory recurrent scleroderma cases treated with tocilizumab

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Scleroderma is a rare autoimmune disease causing high morbidity and mortality with scarcity of disease-modifying treatment. Inflammation usually happens in the early stage and flare is rarely seen in scleroderma. The recently published faSScinate phase 2 trial showed tocilizumab, an IL-6R inhibitor, had potential beneficial effect on the skin and lung fibrosis of dcSSc. We report here two dcSSc cases treated with tocilizumab. A 42-year-old female patient diagnosed as dcSSc with active polyarthritis, digital ulcers, lung fibrosis, and elevated ESR/CRP came to our clinic in May 2012. Initial treatment of steroid and MTX failed to improve the symptoms. Tocilizumab started in November 2012. Arthralgia alleviated quickly. Steroid and DMARDs were withdrawn 6 months later. Both skin and lung fibrosis improved in January 2014. Then tocilizumab was discontinued according to patient’s wish. However, the recurrence of arthritis, deterioration of skin and lung fibrosis with elevated ESR/CRP were found in January 2015. Monthly tocilizumab infusion was restarted, ESR/CRP normalised, the lung function stabilised and no other internal organ got involved until February 2017. The other 41-year-old female patient was diagnosed as dcSSc overlapping with RA in January 2013. Symptoms included progressive skin thickening, severe digital ulcers, polyarthritis, and lung fibrosis. Skin fibrosis was getting worse and inflammatory markers kept rising in spite of MTX initial treatment. Low-dose prednisone and tocilizumab combined therapy started in November 2013. Inflammation was suppressed and skin/lung fibrosis stabilised during the following 1-year period. Then the patient decided to terminate tocilizumab treatment. Unfortunately, she suffered from new-onset congestive heart failure, acute coronary syndrome with elevation of CRP and died in July 2015. The subsequent pathological-anatomical report confirmed pronounced myocardial fibrosis and renal thrombotic microangiopathy attributed to scleroderma. Both patients positively responded to tocilizumab on skin/lung fibrosis and inflammatory markers. They suffered from inflammation flare and deterioration of disease activity after discontinuation of tocilizumab. The one who restarted tocilizumab regained disease remission, while the other died from multiorgan failure. An on-going phase 3 trial will provide further data to evaluate the efficacy and safety of tocilizumab, which might be the first efficient molecular-targeted treatment for scleroderma.

Outcomes in systemic lupus erythematosus (SLE) patients treated with belimumab in clinical practice settings: results from the observe study in switzerland von Kempis J1, Dütsch S2, Reuschling N1, Villigen PSI, Switzerland; 1Division of Rheumatology & Immunology, Medical University of South Carolina, Charleston, SC, United States

Background: Interstitial lung disease (ILD) is a life-threatening complication in systemic sclerosis (SSc). Substantial research progress has identified genomic and molecular subtypes in SSc-ILD and brought targeted therapies within reach. However, personalized medicine approaches are still lacking since clinical tools for individualized patient stratification are not yet available.

Objectives: To assess the possibility of imaging molecular targets as a biomarker for stage-dependent assessment of ILD in the model of bleomycin (BLM)-induced lung fibrosis.

Methods: Integrin αvβ3 and folate receptor (FR-β) expression was analyzed in lungs from patients with idiopathic pulmonary fibrosis (IPF), SSc-ILD, and healthy controls as well as from BLM-treated mice and saline treated controls using immunohistochemistry (n = 4–10).

Results: In lung sections of SSc-ILD and IPF patients expression of integrin αvβ3 was significantly increased compared to healthy controls (p < 0.05). In contrast, FR-β expression was only upregulated in SSc-ILD (p < 0.07), but not in IPF patients. Similarly, in lungs of BLM-treated mice, but not of controls, FR-β expression was increased time-dependently with highest expression at day 7, the peak of inflammation in BLM-induced lung fibrosis (p < 0.01). In contrast, expression of integrin αvβ3 was most upregulated at days 7 and 14 in BLM-treated mice, and thus in the inflammatory and fibrotic stages (p < 0.01). 18F-FDG-PET and HRCT detected changes of metabolic activity and ILD morphology in BLM-treated mice. However, compared with these routinely employed yet specific imaging techniques, molecular targeted imaging of integrin αvβ3 or FR-β specifically detected ILD time-dependently and in correspondence with the expression changes at the tissue level. The specific lung uptakes of 177Lu-RGD and 18F-Azafol and the unspecific uptake of 18F-FDG over time was shown by biodistribution studies and ex vivo lung scans.

Conclusion: Our data suggest that stage-dependent assessment of ILD with radiotracers that specifically target key markers of lung inflammation and/or fibrosis could be the first step towards precision medicine in SSc-ILD.
to evaluate the impact of the sedentary on the BMD, on the bone microarchitecture (assessed indirectly by the TBS), on the body composition (fat mass, lean mass, VFA), OsteoLaus is a population-based cohort of 1500 randomly selected Caucasian women, aged between 50 and 80 and living in Lausanne. For this study, all the participants replied to the PAQO (Physical Activity Frequency Questionnaire) and to the FRAX® questionnaire, had a BMD, TBS and body composition measurement. Exclusion criteria are: on corticosteroids, antidepressants, antineoplastic drugs or immunosuppressive treatments, Cushing disease, hyperparathyroidism, respiratory or cardiac insufficiency and malabsorption. Sedentary is defined by: ≤10% physical activity in 4+BMR (Basal Metabolic Rate, definition of the ‘Bus santé’ study from Geneva). 1026 women were included in our study. All results were adjusted for alcohol, tobacco, age and BMI. 63.7% of the subjects were considered as sedentary. Between the 2 groups the following results were all statistically significant (p < 0.05): active women are younger (63.30 vs 65.03 yo) have a lower BMI (24.71 vs 25.99 kg/m²), BMD at the femoral neck and at the total hip (0.732 vs 0.723 g/cm², and 0.858 vs 0.848 g/cm² respectively) is higher. They have a better spine TBS (1.366 vs 1.357) and a lower FRAX TBS (10.31 vs 11.15%). There was no significant difference. In conclusion the active postmenopausal women in the OsteoLaus cohort have a better bone health. They have less fat mass and less VFA, in turn associated with reduced cardiovascular risk. We did not see differences in terms of lean mass and ALMI. Prevention, including physical activity, could have a positive influence on chronic diseases: by reducing the BMI and visceral fat mass which are deleterious for cardiovascular health, and by delaying the emergence of osteoporosis.

Evolution of turnover bone markers after denosumab discontinuation: a preliminary study

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Introduction: The subcutaneous administration of denosumab (Dmb) twice yearly reduces bone turnover and increases bone mineral density. Dmb discontinuation is associated with bone turnover rebound and increased risk of vertebral fracture. However this risk of fracture may depend of other osteoporotic substances given. The aim of our study was to evaluate the evolution of this turnover rebound if a bisphosphonate (BP) was prescribed before and/or at the end of the biological effect of Dmb.

Method: We randomly selected a subset of women from our daily practice who have received subcutaneous Dmb treatment (60 mg subcutaneously every 6 months) for osteoporosis for at least one year (2 injections) between 2010 and 2016. We separated them in four groups. A: No BP neither before nor after Dmb, B: No BP before but BP after Dmb, C: BP before but no BP after Dmb, D: BP before and 6 months after the last Dmb injection. We retrospectively analyzed the evolution of bone turnover markers with T-collpeptide (CTX, ng/l) up to 12 months after the last Dmb injection (6 months after the last BP prescription). Appropriate statistics were applied.

Results: The first 38 women were included (mean age 65 +/- 10 yo before the first injection of Dmb). 8 in group A, 13 in group B, 10 in group C and 7 in group D. At the end of Dmb treatment, CTX values were significantly lower than baseline for all groups (p < 0.05) and were respectively: A: 84 (+/-54); B: 336 (+/-266); C: 80 (+/-60) and D: 95(+/-63). 12 months after the last Dmb injection (--6 months after the last BP prescription), the CTX were respectively A: 1075 (+/-321), B: 241 (+/-236), C: 677 (+/-359) and D: 370 (+/-286), with significantly lower CTX in group B compared to group A (p = 0.03) and in group C compared to group A (p = 0.05).

Conclusion: In this preliminary study, the exposition to BP before or after Dmb treatment attenuates significantly the turnover rebound. However, the prescription of BP 6 months after Dmb tends to be better than pre-treatment with BP but without reaching significance. We failed to demonstrate the superiority of pre- and post-treatment use of BP (group D) which is associated with an increase in the size of our preliminary study.

Denosumab for the management of giant cell tumours of bone

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Giant cell tumours of bone (GCTB) are osteolytic tumours, mostly benign though locally aggressive with high recurrence risk. Anti-RANKL antibody (denosumab) show promise for more potent targeted treatment than bisphosphonates. After promising early results, concerns appeared about high recurrence rate at discontinuation of denosumab, mostly due to surgical complications, unknown optimal treatment duration and some reported cases of secondary degeneration. We followed-up two patients with recurrent GCTB of the distal radius treated with denosumab before or after surgery. In both cases, denosumab administration resulted in resolution of clinical symptoms with dramatic regression of radiographic abnormalities. To manage the risk of relapse, we opted for both progressive spacing of denosumab injections and gradual decrease in dosage. We have implemented this process with several support tools, such as clinical parameters and biochemical markers of bone turnover. There are currently no recommendations to guide denosumab treatment duration and discontinuation in cancer patients. The rebound effect of rapid bone loss following denosumab discontinuation, recently described in osteoporosis, confirms the urgent need for clear recommendations on its use for the management of GCTB. Bone remodelling markers appear to reflect denosumab efficacy and be able to predict the onset of the rebound effect at discontinuation. We therefore propose gradual denosumab discontinuation in patients with GCTB, using bone remodelling markers as reference. Permanent cessation in the absence of relapse could be proposed by relay with bisphosphonates. Prospective studies to validate this practice are essential.

Keywords: giant cell tumour of bone, denosumab, RANKL, rebound effect, bone remodelling markers

P 7

Change of Metacarpal Shaft Morphology in Rheumatoid Arthritis, A Longitudinal pQCT Study

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Aim: To quantify the effect RA and therapy on metacarpal bone shaft morphology.

Method: Consecutive pm RA patients fulfilling ACR Criteria and consecutive pm healthy controls (HC) were recruited. pQCT measurements at 3rd metacarpal were performed at baseline and follow-up. Use of BP, glucocorticoids, biologics and disease modifying anti-rheumatic drugs were performed at baseline and follow-up. The following parameters were measured: total CSA, cortical CSA, cortical vBMD, porosity of the compact cortex, CSA of the transitional zone and CSA of the compact zone. Handgrip strength was measured by sphygmomanometer. The Student’s t-test for mean comparison, Wilcoxon rank-sum test for median comparison and local regression (LOESS) to model the progression in the HC and RA group. The linear mixed-effects model predicts outcome progress in the patient subgroups using both fixed (subgroup) and random (individual) effects.

Results: 36 consecutive postmenopausal patients with RA and 40 consecutive postmenopausal healthy controls (matched for age, height, and weight) were included. Mean f-up was 57.7 months (RA patients: mean 54.4 months, range 13–83; HC: mean 60.6 months, range 35–78; p = 0.129). 18 RA patients were on BP , 22 were BP naïve. Compared to HC, RA patients had lower handgrip strength, for which we corrected in a sensitivity analysis. RA status was correlated with faster loss of cortical density, cortical CSA and cortical thickness. RF+/ACPA+ RA patients had higher porosity of cortical cortex, increased...
transitional CSA and lower cortical CSA and BMD compared to RF and ACPA negative RA Patients. BP naïve RA Patients showed differences in cortical porosity, cortical CSA and thickness. **Conclusion:** RA leads to endosteal and periosteal drift at the shaft of the metacarpal bone over time. GC use, disease activity and RF/ACPA are additional factors influencing metacarpal shaft morphology.

**P 8**

Elevating the significance of outcome effects from the statistical to the clinical level by the minimal clinically important difference (MCID)

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**Background:** In measurement of outcome effects, the patient’s subjective perception to feel a change in health defines clinical effectiveness irrespective of statistical significance. The aim was to illustrate and discuss current and proposed new concepts of effect quantification and significance.

**Methods:** Different methods for determining statistically significant and minimal clinically important differences (MCIDs) are reviewed and further developed focusing on their characteristics and (dis)advantages.

**Results:** In controlled studies, every empirical score difference between verum and placebo becomes statistically significant if the sample sizes are sufficiently large. MCIDs by contrast, are defined by patients’ perceptions, which led to “anchoring” of effects by the “transition” item, which patients rate their change of health between baseline and follow-up in an evaluation study. The MCID for improvement by the “mean change method” is the difference of the mean change experienced by the “slightly better” group minus that of the “almost equal” group. The MCID can be expressed as absolute or relative score, as effects size (ES), standardized response mean (SRM) and standardized mean difference (SMD) (bivariate). It can further be adjusted by multivariate regression modeling. In our example of knee osteoarthritis, the MCID for pain relief was 8.74 score points, 17.15% of the baseline score, ES = 0.407, SRM = 0.413, SMD = 0.469. This is consistent to the range of 0.30-0.50 for MCIDs reviewed in literature. After adjusting for potential confounders, the MCID was 7.09 score points or an increase of 2.9% per score point to feel better in literature. After adjusting for potential confounders, the MCID was 7.09 score points or an increase of 2.9% per score point to feel better in literature.

**Conclusion:** Absolute and relative MCIDs are easy to interpret and apply to data of investigatory studies, MCIDs expressed as ES/SRM/ SMD reduce bias, which mainly results from dependency on the baseline score. Multivariate linear and logistic regression modeling further reduces bias by adjustment for possible confounders and increase validity. Anchor-based methods use clinical/subjective perception to define MCIDs and should be clearly differentiated from distribution-based methods that provide statistical effect significance only.


**P 9**

Observed health changes of knee osteoarthritis and risk for total joint replacement up to 5 years after comprehensive rehabilitation

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**Background:** Comprehensive inpatient rehabilitation of knee osteoarthritis induced moderate short-term improvements. The aim was to follow-up those patients to 5 years by 1) quantifying observed effects in pain, function, and psychosocial health and 2) associating risk factors to total knee arthroplasty during the observation period.

**Methods:** Prospective cohort study with assessments at baseline (start of rehabilitation) and 1, 2, 3, 4, 5 years after. Comprehensive rehabilitation lasted 2–3 weeks for inpatients and 6 weeks for outpatients. Changes between baseline and follow-ups were measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Short Form 36 Health Survey (SF-36) and expressed as effect sizes (ES). Multivariate logistic regression included potential sociodemographic and disease-modifying confounders and provided adjusted odds ratios (OR) for the risk of getting total knee arthroplasty.

**Results:** At baseline, n = 205 knee osteoarthritis patients were included: 77.1% females, median age 65.7 years (sd = 10.5y), 81.5% having 3 or more comorbidities. Up to the 5 year follow-up, n = 133 (64.5%) remained with imputable data, 48 (23.4%) received arthroplasty. At 5 years, ES were 0.13 to 0.79 for pain, −0.12 (worsening) to 0.42 (improvement) for function, and −0.25 to 0.21 for psychosocial health. At the last follow-up before surgery, WOMAC pain had worsened by ES= −0.42 (p = 0.001) and WOMAC function by ES = −0.54 (p = 0.002) in the total knee arthroplasty group. Getting total knee arthroplasty was statistically significantly associated with female sex (OR = 3.30), educated at university (OR = 3.54), minus 1 comorbidity less (OR = 1.41), and 10 (of 100 possible) points worsening on the WOMAC factor ascending/descending scale (OR = 1.60).

**Conclusions:** Moderate to small improvements on pain, function, and psychosocial health were observed up to 5 years after comprehensive rehabilitation of knee osteoarthritis. Nevertheless, almost one quarter of the participants with knee OA went to total knee arthroplasty suffering from significant deterioration in pain and function. Highly educated women with low number of comorbidities and high disability to manage stairs were more likely to receive total knee arthroplasty. The WOMAC seems to be sensitive to predict the need for arthroplasty.

**P 10**

Interdisciplinary rehabilitation after whiplash injury: an observational prospective 5 years outcome study

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**Background:** Persistent pain and disability of whiplash injury associated disorders (WAD) cause high burden for the individual and costs for healthcare. The aim of this study was to determine state and change of health and working-capacity five years after a standardized inpatient pain management program of four weeks.

**Methods:** This prospective cohort study quantified health and quality of life by the generic Short Form 36 (SF-36, 100 = best), the neck-specific Northern American Spine Society (NASS) form, and the Coping Strategies Questionnaire (CSQ). SF-36 data were compared to age-, sex-, and comorbidity-specific German population norms. Changes of health were determined using effect sizes (ES) at the 6 month and the 60 month follow-up.

**Results:** The 59 participants had mean age of 40.3 years (sd = 12.9), 83% were women, and 37% had one or more comorbidities. At 5 years, health was worse on all SF-36 scales when compared to the norms, varying from mean 41.5, norm 82.3 on role physical to mean 65.7, norm 71.0 on mental health. At 5 years, SF-36 physical functioning improved by ES = 0.99 to entry and ES = 0.16 to the 6 month follow-up. The corresponding effects were 2.22 and 0.83 on role physical, 1.61 and 0.78 on bodily pain, 0.89 and 0.32 on vitality, 0.61 and 0.30 on mental health; CSQ catastrophizing decreased by ES = 1.03 and 0.82. NASS pain improved by ES = 1.12 from entry to 5 years and by 0.57 from 6 months to 5 years. The corresponding ES for NASS function were 0.78 and 0.26. Median working capacity improved from 0 at entry to 2.1 at 6 months and to 30 hours/week at 5 years.

**Conclusions:** Moderate to large long-term effects were observed. Substantial improvements still occurred between 6 and 60 months after start of the pain program, especially in pain, catastrophizing, and physical role performance. Improvements observed after the inpatient pain program can be maintained and expanded in the long-term at home.

Reference


**P 11**

Corticosteroid injections for greater trochanteric pain syndrome: a randomized double-blind placebo-controlled trial

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**Objectives:** To perform a randomized double-blind placebo controlled trial to investigate the efficacy of local corticosteroid (CS) injection in the management of greater trochanteric pain.

**Methods:** The trial was conducted in the Rheumatology unit of the Geneva University Hospital (HUG). Inclusion criteria were lateral hip...
Short-term and long-term efficacy of sclerotherapy in chronic mechanical tendonopathies with neovascularization

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Background: In athletes and even in amateur sportmen, chronic tendonopathy can be extremely troublesome in the Patellar and Achilles tendons, preventing the pursuit of sport or even professional activity. In some cases a progressive neo-vascularisation can be observed by US Doppler. Several, publication suggested that the symptomatology and healing could be improved by sclerotherapy with 0.5% Aethoxyxsclerol.

Objectives: To evaluate the short- and long-term clinical effectiveness of a sclerotherapy over solution of 0.5% Aethoxyxsclerol.

Method: Design of the study: prospective evaluation of all patients who underwent sclerotherapy on chronic in Lausanne between 2008 and 2017. 12/14 agreed to participate in the study. The prospective data are extracted from the files. For the follow-up we used the date of the files but also contacted the patients for a control visit including an ultrasound. Technique: 1 to 3 injections at 15 days interval (Aethoxyxsclerol 0.5%). Injections into the feeder vessel, away from the enthesis, under US Doppler control.

Results: Basic data: all 12 patients (10 men and 2 women, 15 tendons, median age: 32 years) were sportsmen or athletes with an average of 8.7 hours of sport per week, with a predominance of basketball and soccer. Average duration of symptoms before the first sclerotherapy session: 38 months (37.75). Only 3 patients had sclerosis as the first treatment.

Clinical follow-up: the mean duration of follow-up was 45.5 months. 6 tendinopathies did not need other means of treatment. In 40% of the cases, the patients announced a favorable clinical improvement with complete or almost complete disappearance of the pain. 33% reported a small improvement, or a transient improvement in symptoms, while 27% did not notice any significant improvement in their pain. 5 patients were able to resume the sport with the same intensity as before; 5 patients only partially recovered and 5 patients had to completely stop the sport which was at the source of their tendonopathy.

Ultrasound follow-up: Neo-vascularisation decreased in 6/13 and disappeared completely in 5/13. The appearance of the tendon was described as normal in only 2 patients.

Conclusion: In case of chronic tendinopathy with neo-vascularization not responding to surgical treatment, sclerotherapy can be tried. In many patients, however, the real impact of the sclerotherapy was difficult to assess since, several other treatments had been added before and after the procedure.
Impact of obesity on the response to tumor necrosis factor inhibitors in axial spondyloarthritis

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Background: Few studies have investigated the impact of obesity on response to tumor necrosis factor inhibitors (TNFi) in patients with axial spondyloarthritis (axSpA). The aim of our study was to investigate the impact of different body mass index (BMI) categories on TNFi response in a large cohort of patients with axSpA.

Methods: Patients with axSpA within the Swiss Clinical Quality Management (SCQM) program were included in the current study if they fulfilled the ASAS criteria for axSpA, started a first TNFi after recruitment and had available BMI data, as well as a baseline and follow-up visit at 1 year (+6 months) (N = 624). Patients were categorized according to BMI: normal (BMI 18.5 to <25), overweight (BMI 25 to 30) and obese (BMI ≥30). We evaluated the proportion of patients achieving the 40% improvement ASAS criteria (ASAS40), as well as Ankylosing Spondylitis Disease Activity Score (ASDAS) improvement and status scores at 1 year. Patients having discontinued the TNFi were considered non-responders. We controlled for age, sex, HLA-B27, axSpA-type, BASDAI, BASMI, elevated C-reactive protein (CRP), current smoking and physical exercise in multiple adjusted logistic regression analyses.

Results: Obese individuals were older, had higher BASDAI levels and a more important impairment of physical function in comparison to patients with normal weight, while ASDAS and CRP levels were comparable between the three BMI groups. An ASAS40 response was achieved by 44%, 34% and 29% of patients with normal weight, overweight and obesity, respectively (overall p = 0.02). Significantly lower odds ratio (OR) for achieving ASAS40 response was found in adjusted analyses in obese patients versus patients with normal BMI (OR 0.30, 95% confidence interval (CI) 0.11–0.77). The respective adjusted ASAS40 OR in overweight versus normal weight patients was 0.66, 95% CI 0.37–1.18. Comparable results were found for the other outcomes assessed.

Conclusions: Obesity is associated with significantly lower response rates to TNFi in patients with axSpA.

Secukinumab sustains individual clinical responses over time in patients with active ankylosing spondylitis (AS): 2-year results from a phase 3 randomized placebo-controlled trial

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Background: The assessment of clinical response to biologics in Ankylosing Spondylitis (AS) is part of treat-to-target recommendations. Here we present patient-level secukinumab (SECU) data to assess the likelihood of achieving an ASAS response and maintaining or improving that response from Week 16 to Week 52 in 104 patients with active AS from the MEASURE 2 trial.1

Methods: This was a post-hoc analysis of AS patients randomized to SECU 150 mg who completed the 16-wk double-blind treatment period, followed by long-term uncontrolled treatment. Shift analyses on ASAS responses between Wks 2 and 16 and Wks 16 and 52/104 were performed for subgroups of SECU-treated patients, based on response at the earlier time point (non-responders for ASAS 20 or ASAS 40 [ASAS NR], ASAS 20 only, or ASAS 40 only) by evaluating these responses.

Results: 65, 61, and 59 AS patients treated with SECU 150 mg had available data to determine ASAS responses for shift analyses from Wks 2 to 16, Wks 16 to 52, and Wks 16 to 104, respectively. Approach. half of the ASAS NR patients at Wk 2 or 16 subsequently developed
Pathologic TS was defined as TS grade 2-3. Characteristics of patients

Methods:
In the present post hoc analysis, the majority of patients on SECU treatment maintained or improved their ASAS responses, consistent with the sustainability of group-level ASAS responses. The vast majority of patients who achieved either an ASAS 20 or ASAS 40 response at Wk 2 or 16 maintained or improved their response by Wks 16, 52, or 104, respectively.

Conclusion: In this post-hoc analysis, the majority of patients on SECU treatment maintained or improved their ASAS responses, consistent with the sustainability of group-level ASAS responses. The vast majority of patients who achieved either an ASAS 20 or ASAS 40 response at Wk 2 or 16 maintained or improved their response by Wks 16, 52, or 104, respectively.

Background:
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Objectives: Ultrasound-guided synovial biopsy is increasingly applied in rheumatology. Usually forceps- or needle-based techniques are used. So far there has been no direct comparison of different devices regarding their suitability in high resolution musculoskeletal ultrasound (hrMSUS)-guided synovial biopsy.

Methods: A core needle biopsy (Quickcore, Cook Medical, Bloomington, IN, USA), an anterograde arthroscopy forceps (Karl Storz GmbH, Tuttlingen, Germany), a retrograde forceps (Retroforce, Karl-Storz GmbH Tuttingen, Germany) and an convexly shaped integrated core needle system (Synovex, Hmp Medical, Kolingen, Germany) were tested for ultrasound-guided synovial biopsy of the suprapatellar recess in cadaver knee joints. Four senior rheumatologists scored each intervention from 0–5 regarding the following characteristics: visualization, handiness, accuracy, synovial tissue yield, invasiveness and overall suitability. Each intervention was recorded as static images and video clips.

Results: In all devices, enough representative synovial tissue was obtained and the instruments were all visualized by hrMSUS. Core needle biopsy and the integrated needle system were best visualized due to their horizontally shaped closing mechanism. The core needle obtained a high yield of superficial synovial tissue and was the least invasive procedure. Despite handiness and accuracy higher were in the forceps instruments, overall suitability for hrMSUS-guided synovial biopsy was rated highest for the core biopsy needle.

Conclusion: Technically, all of the tested devices can be used for hrMSUS-guided synovial biopsy. Core needle biopsy seems to be most suitable for this intervention due to a low invasiveness, good visualisation and optimal yield of superficial synovial tissue.

Drug retention of tofacitinib versus biologic antirheumatic agents in rheumatoid arthritis: observational data from the Swiss SCQM registry

Background: The oral Janus kinase inhibitor tofacitinib (Tofa) was licensed in Switzerland in 2013 for the treatment of moderate to severe rheumatoid arthritis (RA) patients having failed methotrexate. Besides Tofa, rheumatologists in Switzerland have the choice between 7 alternative bDMARDs licensed with similar indications, including 5 TNF inhibitors (TNFi) and 2 bDMARDs with other modes of action (OMA-bDMARDs).

Objective: To compare the drug retention rate of three alternative treatment options licensed with a similar indications, namely Tofa, TNFi and OMA-bDMARDs, using data from the Swiss registry.

Methods: This is an observational cohort study within the Swiss Clinical Quality Management registry (SCQM). All therapies with Tofa, TNFi, and OMA-bDMARDs initiated in adult RA patients between August 1, 2013 and Dec 1, 2016 were considered. The exposure of interest was treatment with Tofa vs TNFi and vs OMA-bDMARDs (Aabacept or Tocilizumab). The primary outcome was drug retention defined as the time from initiation to discontinuation of treatment. We used Kaplan Meier curves to display drug retention and Cox proportional hazard models stratified by seropositivity to analyze the hazard of drug discontinuation. We also adjusted for potential confounders, including gender, age, disease duration, seropositivity, BMI, smoking status, DAS28-CP and the total number of previous bDMARDs. We applied multiple imputation to account for missing baseline covariate data.

Results: A total of 1996 therapies were initiated during the study period (376 Tofa, 928 TNFi, 692 OMA-bDMARDs). Some differences in disease and treatment characteristics existed between the 3 groups, in particular TNFi tended to be used in patients with fewer previous bDMARDs experience, younger age and shorter disease duration. The crude overall drug retention was similar between the 3 three drug groups (p = 0.24). The adjusted analysis demonstrated a slightly higher hazard of drug discontinuation with TNFi compared to Tofa [HR 1.27 (95% CI: 1.02 – 1.57, p = 0.03)], while no difference was observed for OMA-bDMARDs and Tofa [HR 1.03 (95% CI: 0.83–1.28, p = 0.76)]. Complete case results were consistent with results using multiple imputation of baseline covariates.

Conclusion: The results of this observational study suggest that Tofa is a valuable alternative to treatment options in RA, with Tofa drug retention at least comparable to other available bDMARDs.

Do parity influence joint damage progression in women with rheumatoid arthritis?
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Background: The role of parity on disease activity is controversial, since pregnancy is characterized by a decrease in disease activity,
but the postpartum period by an increase. The long term effect of parity on joint damage progression has only been studied.

Objective: To study the impact of parity on radiographic progression in women with RA.

Methods: This is an observational cohort study of RA patients included in the Swiss Clinical Quality Management in Rheumatoid Arthritis (SCQM-RA). Patients enrolled are followed-up and have x-rays assessments at regular intervals. Information about female hormonal factors, such as pregnancies were retrospectively retrieved using a questionnaire completed by patients or their attending physicians. Analyses were done on all patients with at least two x-rays and full information on reproductive factors. The primary outcome was the rate of radiographic progression (Ratingen erosion score) and the secondary outcome was functional disability progression (HAQ-DI). We compared the rate of progression between parous and nulliparous women using a multilevel regression model for longitudinal data, adjusting for confounders, such as age, disease duration, DAS 28 and treatment. In a subanalysis we explored if the x-ray progression was more severe during the active parous period, operationally defined as the 10 years following the first pregnancy or miscarriage.

Results: A total of 683 women were analysed, of which 395 (58%) were parous, with a median number of pregnancies of 2 (IQR: 2–3), a mean of 5 x-rays per patient and 9 years of follow-up. Baseline patients and disease characteristics were balanced, but parous women were older than nulliparous (median of 48 vs 45 years, p = 0.007). During follow-up, erosion progression did not differ significantly between parous and nulliparous women (p = 0.76). In a subanalysis, the radiographic progression during the active parous period was not different (p = 0.79). The decrease of the HAQ-DI score overtime was not different between parous and nulliparous women (p = 0.04). We did not find differences in radiographic progression or HAQ-DI score between women with a single pregnancy and multiparous women.

Conclusions: In women with RA, the progression of structural damage and of functional disability did not differ between parous and nulliparous women. Although parity is associated with increase in disease activity, our results suggest that parity does not have a negative long term impact on structural damage.

**Septic arthritis of the pubic symphysis**

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Introduction: We present a rare but important differential diagnosis of a cause of pelvic pain. Unawareness of this important diagnosis may result in delayed treatment and dire consequences.

Case report: A 60-year-old adult female, without a previous history of a pelvic operation, was admitted to hospital because of bilateral inguinal inflammatory pain with progressive difficulty in walking after four weeks. The patient developed fever at 38.2 °C. MRI imaging revealed a retropubic collection, an oedematous infiltration with inflammatory aspect of the adductor, rectus femoris and pectineus muscles. Computed tomography-guided puncture revealed a viscous and highly inflammatory liquid (13’300/1 leucocytes (80% neutrophils). The liquid was put into culture and was positive for a penicillin- and amoxicillin-resistant Staphylococcus aureus. Laboratory findings revealed an inflammatory state with a CRP at 119 mg/l, a normal white cell count at 9 G/l and no left shift. The patient underwent a resection of the pubic symphysis, deep surgical debridement and rinsing as well as insertion of three gentamicine-impregnated sponges.

Bacteriological analysis of surgical specimens revealed a Staphylococcus aureus sensitive to amoxicillin. The patient received intravenous co-amoxicillin 2.2 g t.i.d. for 10 days followed by intravenous fluocloxacin 2 g q.i.d. for one week. This was followed by a six-month period of oral antibiotics (rifampicin 450 mg b.i.d. associated with levofloxacin 500 mg b.i.d.). The patient was provided with regular physiotherapy in order to speed her recovery.

Bacteriological analysis of surgical specimens revealed a Staphylococcus aureus sensitive to amoxicillin. The patient received intravenous flucloxacillin 2 g q.i.d. for one week. This was followed by a six-month period of oral antibiotics (rifampicin 450 mg b.i.d. associated with levofloxacin 500 mg b.i.d.). The patient was provided with regular physiotherapy in order to speed her recovery.

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**Objective:** To report 52 wk results in the PsA subgroup.

**Methods:** The primary endpoint was the proportion of patients achieving ≥90% reduction from BL in PASI score at Wk 16. PASI 75, PASI 100, and IGA mod 2011 responses over time, and changes from BL in the HAQ-DI, WPAI, and DLQI were analysed in the subgroup with concomitant PsA. Analyses used non-responder imputation for efficacy assessments and observed data for PROs.

**Results:** 610 (93.7%) completed 52 wks of study (SECU group, 312 [94.8%]; USTE group, 298 [92.5%]). Concomitant PsA was reported in 69/337 (20.5%) and 54/339 (15.9%) patients in the SECU and USTE groups, respectively. In the subgroup with concomitant PsA, a higher proportion of patients receiving SECU achieved HAQ-DI response (minimum clinically important difference) vs. USTE at Wk 52 (39.4% vs. 23.5%, respectively).

**Conclusions:** The significant efficacy of SECU vs. USTE in clearing psoriasis was sustained through 52 wks. In the subgroup with concomitant PsA, SECU was associated with greater improvements in skin symptoms, physical functioning, quality of life, and work productivity compared with USTE through 52 wks.

**References**

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**Transition into adult care for young people with juvenile idiopathic arthritis: a bi-centre cohort study**

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**Introduction:** Juvenile idiopathic arthritis (JIA) is the most common chronic inflammatory arthritis in children. The International League of Associations for Rheumatology (ILAR) 2001 classification includes 7 subgroups: systemic JIA, polyarticular JIA, oligoarticular JIA, enthesitis related arthritis (ERA), psoriatic arthritis and undifferentiated arthritis. Most paediatric inflammatory arthritides persist into adulthood. A transition from paediatric to adult rheumatology is a necessary step, which should be planned because of the risk of failure in monitoring. Difference in classification criteria in paediatric and adult rheumatology can also cause significant difficulty for rheumatologists.

**Objectives:** The aim of this study was to determine the characteristics of JIA seen during the transition period and to compare paediatric classification criteria to those of adults.

**Methods:** A retrospective bi-centre study was performed. Patients with JIA had a consultation at transition. JIA classification criteria were compared to ACR/EULAR 2010 criteria for rheumatoid arthritis (RA), Yamaguchi criteria for adult Still’s disease and ASAS criteria for spondyloarthritis.

**Results:** 112 patients were included: 17 systemic JIA, 26 polyarticular JIA, 41 ERA and 9 psoriatic arthritis. The median age of transition was 19 years old. 8 cases of uveitis were observed among patients with oligoarticular JIA and 7 with ERA. Radiographic structural damages were assessed and showed 15% of patients with erosions or carpitis, mainly in polyarticular and systemic JIA patients. 29% of patients with ERA displayed sacroiliitis. 42% of patients with systemic JIA fulfilled Yamaguchi criteria and 23% of patients with polyarticular JIA fulfilled ACR/EULAR criteria for RA. 41% of patients with oligoarticular JIA, 73% with ERA and 100% with psoriatic arthritis fulfilled ASAS criteria for spondyloarthritis.

**Conclusions:** Our study confirmed the articular destructive potential of polyarticular and systemic JIA and an ocular risk in oligoarticular JIA. Comparison of JIA criteria to adult rheumatism criteria showed that polyarticular JIA with positive rheumatoid factor fulfilled ACR/EULAR criteria for RA. Oligoarticular JIA and polyarticular JIA without rheumatoid factor did not fulfill any adult rheumatism criteria and seem to be paediatric entities. Finally, most patients with ERA and psoriatic arthritis fulfilled the ASAS criteria for spondyloarthritis.
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