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BEST ABSTRACTS PRESENTATION

OP 1

Anti-S1 antibodies after vaccination with anti SARS-CoV-2 mRNA vaccines in patients with rheumatoid arthritis differ in magnitude and kinetics from healthy controls: Results from a prospective, observational controlled study

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Background: Vaccination against anti SARS-CoV-2 is recommended in patients with rheumatic diseases, but limited data are available in patients on immunosuppressive therapy. The objective of this study is to analyse magnitude and kinetics of mRNA vaccine induced anti-S1 titers in patients with rheumatoid arthritis (RA) on DMARD therapy and healthy controls (HC).

Methods: 77 RA patients and 21 HC were eligible for vaccination according to federal guidelines and were enrolled in the prospective RECOVER trial (Rheumatoid Covid-19 Vaccine Immune Response) between 10th January and March 15th 2021. Vaccination itself was not part of the study. The anti-SARS-CoV-2 vaccines mRNA-1273 and BNT162b2 were applied according to the manufacturers' recommendations. All patients continued their DMARD therapy. Serum samples were obtained before the first vaccine, 3 weeks after the first, 2 weeks after the second vaccine and after 12 weeks. Quantitative antibody testing was performed using the Roche Elecsys® Anti-SARS-CoV-2 S1 assay that measures antibodies to the S1 protein (range 0.4-2500 U/l) and nucleoprotein to exclude subclinical SARS-CoV-2 infection. A threshold level of anti-S1 that correlates to neutralization has been proposed at 133 U/l. More recently, even lower cut-off levels (>15 U/l) have been suggested.²

Results: At present, 43/77 patients reached the 12 week timepoint after the first vaccine dose. 4/77 patients with antibodies to nucleoprotein at baseline were excluded from the analysis. Median titers of anti-S1 antibodies were significantly lower in RA patients at all time points. 3 weeks after the first vaccine dose, 9/21 HC but only 1/73 RA patients developed anti-S1 titers exceeding 133 U/l ($p = 0.0001$) or 15 U/l (19/21 HC versus 11/73 RA patients). Two weeks after the second vaccine, the proportion of RA patients with anti-S1 titers exceeding 133 u/l was still significantly lower than in HC (75.3% versus 100%, $p = 0.01$).

Of note, RA patients on abatacept ($n = 9$) or JAK inhibitors ($n = 19$) achieved both threshold levels significantly less frequently compared to patients on csDMARDs and/or anti-cytokine directed biologics.

Conclusions: The development of anti-S1 titers after vaccination with mRNA vaccines against SARS-CoV-2 in patients with RA is overall slower and results in lower antibody titers in comparison to healthy controls.

Reference

1Resman Rus K et al. J Clin Virol 2021, 2Rubio-Acero R et al. medRxiv 2021

OP 2

Plasma Mitochondrial DNA as a Biomarker in the Diagnosis and Follow-up of Systemic Lupus Erythematosus

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Objectives: Cell free DNA is involved in the pathogenesis of systemic lupus erythematosus (SLE) but the clinical value of cell-free DNA measurements in SLE is unknown. Our aim was therefore to examine the utility of mitochondrial (mt) DNA and nuclear (n) DNA quantification in SLE.

Methods: EDTA plasma was drawn from 103 consecutive SLE patients, control plasma was drawn from 56 healthy blood donors. mtDNA and nDNA copy numbers were quantified by PCR from cell free plasma. Clinical parameters were recorded prospectively.

Results: Circulating mtDNA copy numbers were increased 8.8-fold in the plasma of SLE patients (median $6.6 \times 107/\text{mL}$) compared to controls (median $7.6 \times 106/\text{mL}$, $P < 0.0001$). Among all 159 individuals, a cut-off set at 1.8×107 mtDNA copies in a receiver operated curve identified SLE patients with 87.4% sensitivity and 94.6% specificity; the AUC was 0.95 ($P < 0.0001$).

mtDNA levels were independent of age or gender, but correlated with SLEDAI on multivariable analysis ($P = 0.004$). Conversely, SLEDAI was associated with prednisone dose ($P < 0.001$), anti-dsDNA-titers ($P = 0.003$) and mtDNA levels ($P = 0.005$), but not nDNA copy numbers. In 33 SLE patients with available follow up, the changes of mtDNA, but not those of nDNA concentrations, robustly correlated with the evolution of the SLEDAI ($r = 0.55$, $P = 0.001$).

Conclusions: Circulating mtDNA unlike nDNA molecules are markedly increased in SLE plasma. Regardless of disease activity, circulating mtDNA levels distinguish SLE patients from non-inflammatory controls with high sensitivity and represent an independent marker of SLE activity.

OP 3

HRCT-based Radiomics for Prediction of Treatment Response in SSc-ILD

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Background: Management of patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) is complicated by high inter-patient variability. To date, no validated predictors of treatment response are available for routine use. High resolution computed tomography (HRCT)-based radiomics have previously been shown to be successful in discriminating (SSc-)ILD phenotypes. Since HRCT is an integral part of the routine work-up in SSc, HRCT-based radiomic features may hold potential as non-invasive biomarkers.

Objectives: To predict treatment response using two-dimensional (2D) HRCT-based radiomics in SSc-ILD patients from a prospectively followed cohort.

Methods: For this study, patient data from the University Hospital Zurich's (ZH) and the Oslo University Hospital's (OL) prospective patient cohorts were analyzed. Inclusion criteria were diagnosis of SSc-ILD in HRCT, a chest HRCT scan within 12 months prior to start of a new treatment, and available clinical data. Response was defined as the absence of all of the following over a period of 12-24 months: decrease in forced vital capacity (FVC) $\geq 5\%$, increase of ILD in HRCT, change in treatment due to non-response, ILD-related death or lung transplantation. Of each HRCT, 6 slices were manually segmented and 2D radiomic features were extracted using the in-house software Z-Rad (Python 2.7). Features were Z-score transformed and pre-filtered for inter- and intra-reader robustness. Features were then selected by significant ($p < 0.1$) association with response in the ZH cohort using a linear regression model. Significant features were then validated in the OL cohort.

Results: A total of 54 and 35 (ZH and OL, respectively) pre-treatment HRCTs were assessed. Response rates for ZH and OL were 50.0% ($n = 27$) and 25.7% ($n = 9$). Univariate linear regression showed significant association of 9 radiomics features with treatment response in the ZH cohort, 3 of which also performed significantly in OL (values representing ZH and OL, respectively):

LH_mbdGLCM_maximalCorrelationCoefficient ($p = 0.002$ and 0.045 , odds ratio (OR) = 0.31 and 0.29 , area under the curve (AUC) = 0.76 and 0.74), LH_mfGLCM_maximalCorrelationCoefficient ($p = 0.043$ and 0.029 , OR = 0.37 and 0.22 , AUC = 0.75 and 0.75) and HL_hist_median ($p = 0.058$ and 0.059 , OR = 1.80 and 2.26 , AUC = 0.64 and 0.71).

Conclusion: Our results indicate that radiomics may be a promising tool for future pre-treatment patient stratification.

CASES

C 1

Genetic double strike: VEXAS and TET2 positive myelodysplastic syndrome in a patient with long-standing refractory autoinflammatory disease. Case report.Lötscher Fabian¹, Seitz Luca¹, Sarbu Adela¹, Maurer Britta¹¹ Department of Rheumatology and Immunology, Inselspital, Bern University Hospital, University of Bern, Switzerland

The VEXAS (Vacuoles, E1 enzyme, X-linked, Autoinflammatory, Somatic) syndrome is a recently discovered adult-onset autoinflammatory syndrome (AIS) characterized by a somatic mutation of the UBA1 gene, leading to a wide range of clinical symptoms and mimicking rheumatic disease.

A 68-years old male patient repeatedly presented with relapsing fever and inflammatory arthritis since 2016. Extensive serologic testing for autoimmune disorders and workup for infectious diseases was unremarkable, further laboratory analyses repetitively showed increased inflammatory markers accompanied by mild hyperferritinaemia with a normal differential blood count. Due to a good initial response to corticosteroids and a possible diagnosis of a seronegative RA, a steroid-sparing therapy with tocilizumab and methotrexate was initiated. After repeated flares in disease activity including novel manifestations such as pulmonary infiltrates with pleurisy, scleritis and neutrophilic dermatosis, adult-onset Still's disease was postulated, and therapy was adapted accordingly: TNF-inhibitors, IL-1 antagonists and JAK-inhibitors were applied in combination with colchicine or cyclosporine, all with unsatisfactory therapeutic effect as further symptoms arose (nodular phlebitis) while others relapsed, resulting in corticosteroid dependence. During the disease course, an increasingly macrocytic anemia and intermittent thrombocytopenia arose, which eventually made regular erythrocyte concentrate transfusions necessary. Three bone marrow aspirations (BMA) were performed over a period of 3 years, but only the latest confirmed a myelodysplastic syndrome (MDS) with multilineage dysplasia and TET2 mutation on cytogenetic analysis. Despite of being aware of MDS related AIS in association with TET2 mutation and the absence of characteristic vacuoles in hematopoietic cells on BMA, we insisted on testing for the VEXAS syndrome. Rather surprisingly, the detection of a somatic mutation in the UBA1 gene confirmed the diagnosis.

This case illustrates that in elderly patients with AIS and concomitant hematological manifestations, an extensive work-up including genetic testing is indicated and justified. In addition, it shows, that VEXAS can be present without the characteristic vacuoles on BMA. Due to the only very recent discovery of the VEXAS syndrome, the description of affected patients is valuable and will increase the knowledge of the range of different clinical phenotypes and treatment options.

C 2

A 81-year-old man with jaw pain and vision lossGuemara Romain¹, Pieren Amara¹, John Gregor², Tapparel Ludovic¹, Brülhart Laure¹¹Réseau hospitalier neuchâtelois, Dpt de Médecine, Service de Rhumatologie;²Réseau hospitalier neuchâtelois, Dpt de Médecine, Service de Médecine interne

We present the case of a 81 years old man known for arterial hypertension, dyslipidemia, bilateral atrophic macular degeneration and with a recent diagnosis of Waldenström's disease.

He initially presents with upper left jaw pain, prompting a consultation with the dentist who first removes a tooth. Because of a gradual visual loss, he consults then an ophthalmologist who suspects a posterior optic neuropathy and refers him to the emergency department.

Except visual loss, he has no further neurological complaint, no jaw claudication or scalp dysesthesia, and no general symptoms such as asthenia or fever. Physical examination finds an apyretic patient. Left jaw is sensitive with no tenderness on temporal artery and no arterial murmur. Cardiac, pulmonary and neurological status is otherwise not relevant.

Cerebral angioCT is unremarkable and the biological assessment finds an isolated mild normochromic normocytic anemia, with an ESR up to 65 mm/h. Giant cell arteritis (GCA) is suspected and IV methylprednisolone treatment is immediately started.

The left temporal artery biopsy, the Doppler ultrasound, the cranial MRI and the retinal angiography are all unremarkable. The abdominal fat biopsy finds no amyloidosis, and immunological markers are negative. Due to the modest negative predictive value of the unilateral biopsy for GCA and in absence of an alternative diagnosis suspected at this point, a first diagnosis of GCA with posterior ischemic optic neuropathy is made and patient is discharged with 1mg per kg of prednisone.

He's admitted once again 20 days later with severe left retro-orbital pain and progressive left visual loss. Clinical examination shows a complete left eyelid ptosis and unilateral blindness with fixed mydriasis and no eye movement. A new MRI shows signs of an ischemic optic neuropathy with lysis of the left ethmoid sinus wall, suspicious for an ischemic optic neuropathy related to lymphoplasmacytic infiltration of Waldenström's disease (Bing-Neel Syndrome). Tyrosine kinase inhibitor (ibrutinib) in combination with dexamethasone is then introduced.

Because of no improvement despite good prognosis, an infectious aetiology is finally suspected, and a left sphenoid sinus biopsy highlights an angio-invasive aspergillosis with rhino-orbital infiltration presenting as an ischemic optic neuropathy.

Oncologic treatment is discontinued and antifungal therapy with Voriconazole is introduced, leading to an optimal clinical and radiological evolution.

C 3

Anti-BAFF Therapy for the treatment of B cell depletion-resistant primary Sjögren's syndrome with secondary cryoglobulinemic vasculitis and membranoproliferative glomerulonephritis: a case reportF. Lopez E¹, Gadola S¹¹Department of Rheumatology, Bethesda Hospital, Basel

Background: Primary Sjögren's syndrome (pSS) is a B-cell driven autoimmune connective tissue disease for which no approved disease modifying drugs exist. We describe the disease course and treatment in a patient with pSS who developed acute severe extraglandular complications due to cryoglobulins.

Case report: A 25y old woman with biopsy-proven pSS (ANA+, anti-SSA+, anti-SSB+, RF+) presented with parotid gland enlargement, hypergammaglobulinemia, increased free light chains and low C3 and C4 complement. The patient didn't suffer from fatigue or severe sicca symptoms, and there were no other signs of systemic inflammatory activity.

In 5/2020, she developed a transient rash on the extremities and trunk resembling urticaria. However, at the next outpatient visit, these symptoms had disappeared, and no or other signs of extraglandular activity were present. In 10/2020, she developed acute renal insufficiency with nephrotic syndrome, as well as severe fatigue. Biopsy showed membranoproliferative GN with cryoprotein deposits. High-dose steroids and rituximab were initiated, with normalization of renal function but persistence of proteinuria after 3 months. Already 4 months after the first rituximab dose, renal function and proteinuria deteriorated again, requiring a 2nd treatment cycle with rituximab. Anti-BAFF mAb was added one month after the 2nd rituximab cycle. Under this treatment, renal function, proteinuria and fatigue markedly improved, while the prednisone dose could be reduced to 15mg/d.

Discussion: Our patient illustrates the unmet need in pSS and a clinical dilemma: Whether and when to start B-cell depletion therapy in patients with clear signs of B cell hyperactivation and subclinical activation of complement. Monotherapy with anti-CD20 antibodies leads to a rapid reactive increase in BAFF (1) and has been related to the selective survival of autoimmune B-cell clones in pSS salivary glands (2).

Combination therapy with rituximab and the anti-BAFF antibody belimumab has been successfully used in severe, difficult-to-treat pSS (3,4,5) and this combination is currently being tested in clinical studies, in pSS patients with clinically manifest extraglandular complications (3,4,5). Conversely, no effective treatment strategies exist to prevent extraglandular complications in high-risk patients such as presented here.

C 4

In vivo urate spherulites in a patient with gout - a case reportPirker Ian¹, Nussberger Madalina¹, von Kempis Johannes¹¹Division of Rheumatology and Immunology, Cantonal Hospital St. Gallen, Switzerland

An 88-year-old patient presented with a painful right first metatarsophalangeal joint, with acute onset of symptoms and persisting for the last 24 hours. He had been hospitalized for cerebral ischemic stroke due to internal carotid artery stenosis for one week and been treated with low dose acetylsalicylic acid and clopidogrel. A carotid artery thrombectomy was performed 24 hours prior to onset of arthralgia. The patient had no fever and his vital parameters (blood pressure, heart rate, oxygen saturation) were normal. He further suffered from chronic decreased kidney function with creatinine levels at 126 mmol/l (normal range: <95 micromol/l). Uric acid levels were elevated at 522 micromol/l (normal range: 150-360 micromol/l).

Ultrasound examination of the right first metatarsophalangeal joint showed an effusion and a double contour sign (figure 1), indicating monosodium urate crystal arthropathy.

We performed an ultrasound-guided arthrocentesis of the right first metatarsophalangeal joint. Evaluation of synovial fluid with polarizing light microscopy revealed multiple spherulites, consisting of an aggregation of strongly negative birefringent crystals (the black arrow indicates the axis of the compensator) and identified as monosodium urate spherulites (figure 2, magnification x 400). The joint was injected with glucocorticosteroids (10 mg triamcinolone acetonide) and the start of urate lowering therapy was recommended. Fiechtner et al. described in vivo urate spherulites in gouty synovia and further studies demonstrated spherulite growth patterns of urate crystals in vitro.^{1, 2} While polarization microscopy of synovial fluids in patients with gout shows monosodium urate in needle shape in the vast majority of cases, crystallization can also lead to in vivo urate spherulites which are considered as equally specific for the diagnosis of gout.

References

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2. Ahmed S, Hasan MM, Mahmood ZA. Growth patterns of monosodium urate monohydrate (gouty and urinary) crystals in gel: An in vitro study. *Pak J Pharm Sci*. Nov 2017;30(6):2101-2108.

C 5**A dangerous cause of pseudo-radiculopathy: thoracic aortic dissection presenting as radicular back pain with distal weakness of the right leg**E. Passia¹, A-C Debrach¹, T. Hügler¹¹Department of Rheumatology, CHUV Lausanne, Switzerland

A 37 year-old man presented to the emergency department with an acute episode of back pain that started when he stood up from a chair. The pain was associated with paralysis of the right leg below the knee. Initially, the patient felt a sharp episode of chest pain immediately followed by abdominal pain, which disappeared within minutes and localized to the lower back and to the right calf.

Radiculopathy was suspected and Magnetic Resonance Imaging of the lumbar spine was performed, which revealed a significant paramedian discal hernia of L5-S1 in contact with the S1 root. Admission to the rheumatology ward was therefore requested.

On clinical examination, there was no pain on percussion of the lumbar spine. Straight leg raise test was negative. Dorsiflexion and plantar flexion of the right ankle and extension of hallux were impossible (M0). There was complete sensory loss to fine touch below the knee, and Achilles reflex on the right side was abolished.

The right leg was pale and cold; dorsalis pedis as well as posterior tibial pulses were absent, suggesting acute lower extremity ischemia. Doppler ultrasound of the right leg was performed showing very altered blood flow in the arteries of the lower right leg, with absent blood flow in the posterior tibial and dorsalis pedis arteries, confirming the diagnosis. A CT scan of the chest, abdomen and pelvis was therefore realized, revealing aortic dissection Stanford A with a false channel extending to the common right iliac artery.

This highlights the importance of performing a thorough clinical examination and extending the differential diagnosis in case of discrepancy with radiological findings.

C 6**Chasing two zebras in the same patient: A case of recurrent febrile neutrophilic dermatosis masked by Whipple's disease**Muraru S¹, Inauen C², Meier-Schiesser B³, Nemeth J⁴, Jelcic I², Distler O¹¹Department of Rheumatology, University Hospital Zürich, Switzerland; ²Department of Neurology, University Hospital Zürich, Switzerland; ³Department of Dermatology, University Hospital Zürich, Switzerland; ⁴Department of Infectious Diseases, University Hospital Zürich, Switzerland

Febrile neutrophilic dermatosis (Sweet's syndrome) is a rare entity with an unclear multifactorial pathogenesis involving a dysregulation of cytokines and accumulation of neutrophils in the affected tissue.

A 76-year old man with a history of recurrent cutaneous nodules associated with febrile episodes for around 3 years and a treatment-refractory seronegative oligoarthritis was diagnosed with Whipple disease, based on positive Tropheryma whipplei PCR in the synovial fluid of two different joints, as well as in stool-, sputum samples, duodenal biopsies and cerebrospinal fluid (CSF). He completed the antibiotic treatment according to the guidelines, needing an additional second-line course because of a relapsing monoarthritis of the elbow. Several months after concluding the treatment and having no more signs of active Whipple disease, he presented with acute episodes of unilateral periorbital cellulitis, accompanied by fever up to 40°C and a highly inflammatory syndrome (CRP up to 300 mg/l, peripheral leukocytosis with neutrophilia). There was an inflammatory CSF syndrome with moderate, sterile neutrophil pleocytosis (78 cells/ μ l) and severe blood brain barrier disruption. The histology samples of the orbital tissue, as well as the initial biopsies of the cutaneous lesions 3 years ago, showed a neutrophil predominance, without evidence of infection in the cultures or PCR.

We performed an extensive screening of other differential diagnoses, including vasculitis, malignancy, as well as Tropheryma whipplei PCR in the previously affected sites, all turning out negative, with the exception of the knee, where the patient was asymptomatic, having a well-functioning knee-prosthesis.

After interdisciplinary discussions, we concluded that the most likely diagnosis was a Sweet Syndrome with periorbital and neurologic involvement and that the presence of Tropheryma whipplei in the knee represented a chronic colonization of the prosthesis. We initiated an intravenous pulse steroid therapy with excellent response of both the clinical symptoms and inflammatory parameters, which unfortunately could not be maintained after tapering the oral Prednisone dosage, so that an additional steroid-sparing therapy with Secukinumab is planned.

By presenting this case, we would like to outline the diagnostic and therapeutic challenges when facing two very rare conditions with similar manifestations, each bearing the risk of being disguised as the other one.

C 7**Alternating foot drop**Schlöpfer-Pessina A¹, Debrach A-C¹, Bill O², Dan D¹, Dumusc A¹¹Service of Rheumatology, Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland; ²Service of Neurology, Département des neurosciences cliniques, Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland

We report the case of a 55-year-old woman, hospitalized in March 2021 because of a one-month history of foot extension paresis and paresthesia of the dorsal face of the right foot.

She has been treated for a suspected psoriatic arthritis with adalimumab, certolizumab, stopped in 2016, then methotrexate and apremilast until 2019, without treatment ever since. She had presented 2 similar episodes in 2018 on the left, then on the right foot, respectively, which had resolved spontaneously. The ENMG had showed at that time an axonal polyneuropathy (PNP) of the lower limbs. The patient reported fatigue, arthralgia of MCPs and PIPs, with morning stiffness transit disorders, dizziness, dry skin, dry mouth and dry eyes.

The clinical examination revealed livedo reticularis of the lower limbs, psoriasis of the scalp, decreased strength of the right extensor hallucis muscle (M4), and hypoesthesia in the right superficial peroneal nerve territory, and no synovitis.

Laboratory tests showed an ESR of 26 mm/h, ANA titer of 1:320 and positive anti-SSA. Anti-dsDNA and ACPA were initially positive, then negative 5 weeks later. There was no complement consumption, no monoclonal gammopathy, nor cryoglobulins. Urine analysis showed no proteinuria or hematuria.

Usual causes of PNP were ruled out, especially hypovitaminosis and infectious diseases (Lyme, syphilis, viral hepatitis, HIV, HTLV-1/2).

The Schirmer test was normal. The minor salivary glands biopsy showed no significant lymphocytic infiltrate (no focus).

The ENMG showed now a predominantly sensory and axonal multiple mononeuropathy. We plan a nerve biopsy, suspecting an immune-mediated origin.

Due to the presence of anti-SSA, we mainly suspect a Sjögren's syndrome in our patient, disease which is associated with peripheral neurological involvement in 10% of cases. A concomitant RA or a concomitant primary or anti-TNF-induced SLE are also possible, due to the transient positivity of anti-CCP and anti-dsDNA. A polyarteritis nodosa is less likely. An alternative diagnosis is an anti-FGFR3 associated neuropathy, often related to autoimmune diseases (the results for anti-FGFR3 are pending). A para-neoplastic origin seems unlikely, as symptoms are present for 3 years.

Based on the nerve biopsy, a treatment with azathioprine or rituximab will be considered.

In conclusion, our case underlines the importance of questioning an initial diagnosis and pursuing the investigations in the face of an atypical presentation.

C 8

Extrapyramidal symptoms (ES) under leflunomideHuber F¹, Miller A¹, Tschopp M², Scherrer E³¹Medizinische Poliklinik, Departement Medizin, Kantonsspital Winterthur, Switzerland; ²Rheumatologie, Privatklinik Belair, Schaffhausen, Switzerland; ³Neurologie, Departement Medizin, Kantonsspital Winterthur, Switzerland

A 50-year-old farmer presented with pains and muscle weakness, especially in the thigh, shoulder and arm muscles. Under the assumption of a Polymyalgia Rheumatica he received prednisolone since January 2019. Due to insufficient response to therapy (even with high-dose prednisolone), further rheumatological investigations were carried out (extensive autoantibody diagnostics, protein electrophoresis, HBV, HCV, HIV screening, chest X-ray, abdominal sonography and MR angiography of the aorta), but the etiology remained unclear. Because of disabling symptoms and necessary steroid reduction, the therapy was changed to methotrexate in August 2019 and, in the case of insufficient effectiveness, to leflunomide from October 2019. At the first consultation in our general internal medicine consultation 5 weeks after starting with leflunomide, the patient presented new myoclonic to choreiform movement disorders of the arms. Furthermore, there was a Parkinson's syndrome with rigor, increased muscle tone and initiation disorder with small-step gait pattern. In the MR examination of the skull a (sub)acute ischemia, especially of the basal ganglia, could be excluded. There were no signs of an infectious/autoimmune etiology in the CSF puncture, the EEG was inconspicuous. In addition, Wilson's disease, hyperthyroidism, HIV and syphilis infection were excluded. Due to the association between the occurrence of the ES and the start of leflunomide, a drug-toxic side effect was proposed and leflunomide stopped. Due to half-life of 4 weeks - since the active metabolite of leflunomide is subject to the enterohepatic circulation - colestyramine was used. Within one week the ES subsided. The muscle pain increased significantly in intensity. Discussion: ES after taking leflunomide have been reported 8 times worldwide since its launch in 1998. The average duration of leflunomide use was 6-12 months, with only female patients aged 50-59 years being affected. In addition, 75% of patients were co-medicated with methotrexate. Apart from age, our patient did not correspond to any of these observations. Nevertheless, due to the temporal correlation as well as the prompt improvement after discontinuation, we assume a drug-toxic side effect on leflunomide. An explanation for the short interval between the start of therapy and the onset of symptoms could be explained by the known MAO-inhibition of leflunomide with consecutive serotonergic syndrome.

C 9

Inflammatory back pain + HLA-B27 positive = axial spondyloarthritis?Lindinger L¹, Muckenhuber A², Popp F¹, Schäfer H³, Scheidler J⁴, Welcker M¹, Wörter K⁵, Moog Ph¹¹1 MVZ für Rheumatologie Dr. M. Welcker, Planegg, Deutschland; ²2 Technische Universität München, Institut für Allgemeine Pathologie und Pathologische Anatomie, Deutschland; ³3 Technische Universität München, Nephrologie, Deutschland; ⁴4 Radiologisches Zentrum München, München, Deutschland; ⁵5 Technische Universität München, Institut für diagnostische und interventionelle Radiologie, Deutschland

History: A 32-year-old male patient presented with back pain that had been increasing for one year and a weight loss of 14 kg in the last 3 months. The pain was mainly in the thoracic spine improving during the day and with exercise. In addition, there was a tendency to night sweats. Laboratory tests showed increased inflammation values and a good response of the pain to a probatory glucocorticoid trial over 3 days by the treating orthopedist. The general practitioner ordered a normal CT scan of the abdomen and a gastroscopy and colonoscopy, all without conclusive findings. Leading symptoms at disease manifestation: Inflammatory back pain, weight loss of 14 kg in 3 months, and night sweats.

Diagnostics: MRI of the thoracic spine did not reveal any characteristic findings of axial spondylarthritis, but there was an elongated cuff of soft tissue approximately 5 mm thick absorbing contrast material pre- and paravertebrally and along the anterior longitudinal ligament. On PET-CT, this soft tissue formation showed markedly increased metabolic activity in a course from Th 3 to L 1. Beyond that, no evidence of a malignancy-

suspected organ lesion or evidence of inflammatory changes. Laboratory findings: CrP 46.6 mg/dl; BKS 84, HLA-B-27 and anti-CCP antibodies positive, IgG4 215 mg/dl, ANCAs and ANAs negative. CT-guided biopsy of the lesion yielded histologic evidence of a moderately cell dense spindle cell proliferate without higher grade nuclear atypia in collagen fiber-rich, fibrosing impacted stromal component. 25% of IgG-positive plasma cells expressed IgG4. There was no evidence of lymphoma or sarcoma in the additional staining. Thus, the clinical picture, MRI findings, slightly elevated serum IgG4, and predominantly IgG4-positive plasma cells in the histology of the lesion most likely indicated an IgG4-associated disease.

Therapy: Due to the good response to prednisolone, steroid monotherapy was initially continued in decreasing doses.

Further course: We plan an imaging follow-up after 3 months with an MRI of the spine and consider therapy with methotrexate and / or rituximab depending on the course.

C 10

Marfan syndrome: how much ligamentous stability does an ankle prosthesis need?Zimmermann J¹, Knupp M²¹Fuss- und Sprunggelenkschirurgie, Orthopädie Sonnenhof Bern, Switzerland; ²Mein Fusszentrum AG Basel, Switzerland

Background: Marfan's syndrome is a congenital connective tissue disease with a prevalence of < 1 : 5000. In the majority of cases, an autosomal dominant inherited mutation in the FBN1 gene can be detected on chromosome 15. The gene codes for the glycoprotein fibrillin-1, which is part of the microfibrils. In addition to cardiovascular and ophthalmological aspects, joint hypermobility due to ligamentous laxity is an important manifestation of the disease [from Kodolitsch 2016]. Severe instabilities in the upper ankle joint are considered a contraindication for prosthetic implantation, as no guided prostheses are available. The following case report describes the successful implantation of an ankle joint prosthesis in a patient with Marfan's syndrome.

Method: A 62-year-old patient presented with rapidly progressive pain symptoms in the left ankle and a very limited walking distance. A synopsis of the preoperative clinical-radiological findings showed an instability related to osteoarthritis in the left ankle. After weighing the advantages and disadvantages with regard to a prosthetic fitting, a left ankle prosthesis was implanted with sufficient residual ligamentous ankle stability. This was followed by immobilization in a lower leg cast or using a stability shoe (Künzli Schuh®) for 10 weeks. A total of 2 years postoperatively, the patient was found to be pain-free with improved joint mobility, adequate walking distance and a fully integrated and correctly positioned prosthesis.

Discussion: The sometimes pronounced ligamentous laxity in Marfan patients can lead to significant joint instabilities and secondary, as in the case described, osteoarthritis. In terms of stability and integrity, the ankle joint is heavily dependent on the ligamentous conditions and the joint geometry. The presence of a severe joint hypermobility syndrome, such as Marfan's syndrome, is therefore cited in the literature as a contraindication for joint replacement in addition to sensorimotor dysfunctions [Hintermann 2003]. The success of the implantation of an ankle joint prosthesis depends not only on the exact surgical technique and a stable, balanced capsular ligament apparatus, but also on the postoperative follow-up care. This should take place, taking into account the various clinical manifestations, as a collaboration of a multidisciplinary team and make a contribution with regard to the quality of life and self-perception of the patients [von Kodolitsch 2016].

C 11

Symptomatic altered platelet functions during apremilast treatment for psoriatic arthritis: a case reportTsilimidos G¹, Blum S¹, Aliotta A¹, Dumusc A², Alberio L¹¹Service and Central Laboratory of Hematology, Lausanne University Hospital (CHUV) and UNIL, Lausanne, Switzerland.; ²Department of Rheumatology, Lausanne University Hospital (CHUV), Lausanne, Switzerland.

Apremilast is an oral selective phosphodiesterase 4 inhibitor used for treatment of psoriasis and psoriatic arthritis. Common adverse events are diarrhea, headache, upper respiratory tract infection, nasopharyngitis, and nausea. Here, we report a case of voluminous cutaneous hematomas after introduction of apremilast in a 43-year-old woman suffering from psoriatic arthritis. Since coagulation tests and platelet count were normal, we decided to explore platelet functions by flow cytometry analysis. This investigation was performed under treatment and subsequently 6 months after apremilast discontinuation. We observed some mild anomalies (platelet hypo-activation under thrombin or collagen analogue) that persisted after apremilast discontinuation, being compatible

with a mild subclinical preexisting platelet dysfunction. However, while we measured a low level of procoagulant platelets generated during apremilast treatment [22% (normal range 25%-55%)], this was normalized off medication (45%). This specific subpopulation of platelets is an essential component to form a stable and efficient hemostatic clot. Moreover, a decreased generation of procoagulant platelets is known to be associated with clinically relevant bleeding episodes and severity. Therefore, the observed normalization of procoagulant platelets together with the clinical disappearance of hematomas off treatment and their reappearance upon re-challenging suggested a possible etiologic correlation between apremilast treatment and impaired platelet procoagulant activity. Taken together, we postulate that in our patient, a preexisting, clinically not manifest mild platelet dysfunction has been revealed by the additional impairment of the procoagulant function during apremilast treatment. This highlights a potential unnoticed adverse event of apremilast, particularly in subjects with a mild, subclinical platelet dysfunction. Further studies are required in order to evaluate a possible direct or indirect effect and potential mechanisms of apremilast on platelet functions.

POSTERS

P 1

Bromodomain Protein-regulated Stress Response in Rheumatoid Arthritis Synovial FibroblastsSeifritz Tanja¹, Züllig Thomas¹, Moser Larissa¹, Distler Oliver¹, Ospelt Caroline¹, Klein Kerstin^{2,3}¹Center of Experimental Rheumatology, Department of Rheumatology, University Hospital Zurich, University of Zurich, Switzerland; ²Department of BioMedical Research, University of Bern, Bern, Switzerland; ³Department of Rheumatology and Immunology, University Hospital Bern, Bern, Switzerland**Background:** Hypoxia and subsequent oxidative stress are early events in the RA joint and activate synovial fibroblasts (SF). Small molecule inhibitors, targeting the bromodomain and extra-terminal (BET) protein family, have anti-inflammatory properties in RA. Here we analyzed their role in regulating stress response pathways in RA SF.**Methods:** SF were obtained from RA patients undergoing joint replacement surgery. We mimicked hypoxic conditions by treatment of SF with dimethylxylglycine (DMOG; 0.5 mM, 24 h) and oxidative stress with 4-hydroxynonenal (4-HNE; 5 µM, 48h) and TNF (10 ng/ml, 48h). Experiments were performed in absence and presence of I-BET151 (1 µM). The expression of hypoxic and oxidative stress response genes was measured by Real-time PCR (n = 7-10). Autophagy (LC3B-II), stabilization of HIF1α and GLUT1 protein expression were assessed by Western blotting.**Results:** Treatment of SF with DMOG stabilized HIF1α protein. I-BET treatment suppressed the DMOG-induced expression of the hypoxic response genes VEGFA, PDK1, GLUT1 and HK2. Hypoxic conditions induced the GLUT1 protein expression by 101.8-fold (± 108.2-fold), which was suppressed by 62.2% (± 32.1%) in presence of I-BET (p<0.05). TNF treatment induced the expression of all measured stress response genes. Oxidative stress further induced the TNF-induced expression of VEGFA, PDK1, GLUT1, HK2 and CAT. In contrast to results obtained under hypoxic conditions, I-BET treatment further increased the expression of hypoxia response genes under oxidative stress conditions. We have detected similarities and differences regarding the BET-mediated regulation of oxidative stress response genes under different stress conditions. I-BET increased basal HMOX1 and CAT expression in all conditions, and suppressed GPX1 expression under hypoxia and oxidative stress. In contrast, BET inhibition decreased the expression of SOD2 only during oxidative stress but not under hypoxia. I-BET further increased the expression of HMOX1 during oxidative stress, but suppressed the expression of HMOX1 during hypoxia. I-BET induced the accumulation of LC3B-II protein by 2.7 (± 1.4)-fold, which was further increased to 4.5 (± 2.9)-fold in presence of DMOG (p<0.05). Oxidative stress conditions did not further induce the I-BET-induced expression of LC3B-II.**Conclusions:** BET protein inhibition affects stress-response target genes in a stimulus-dependent manner. Furthermore, we have identified BET proteins as regulators of autophagy.

P 2

Comparative Treatment Effectiveness In Rheumatoid Arthritis With And Without Concomitant Sjögren's Syndrome – Results From The Swiss Clinical Quality Management CohortChrist L¹, Kissling S², Müller R³, Finckh A⁴, Fisher BA^{5,6}, Maurer B¹, Möller B¹, Kollert F¹¹Department of Rheumatology and Immunology, University Hospital (Inselspital) and University of Bern, Bern, Switzerland; ²Statistics and Data Management Group, Swiss Clinical Quality Management Foundation, Zurich, Switzerland;³Clinic of Rheumatology, Medical University Hospital Aarau, Aarau, Aargau, Switzerland; ⁴Division of Rheumatology, University Hospitals of Geneva, Geneva, Switzerland; ⁵Institute of Inflammation and Ageing, College of Medical and Dental Sciences, University of Birmingham, UK; ⁶National Institute for Health Research (NIHR) Birmingham Biomedical Research Centre and Department of Rheumatology, University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK**Background/Purpose:** The variety of treatment options in RA contrasts with a lack of personalized medicine. The presence of concomitant SjS

might be associated with differences in RA pathobiology. We hypothesize that the clinical phenotype and treatment response differs in RA/SjS compared to RA alone with an inferior response to TNF-inhibitors (TNFi) over other target specific therapies.

Methods: In this retrospective observational cohort study data from the Swiss Clinical Quality Management in Rheumatic Diseases (SCQM) registry were obtained (01.01.2000-01.01.2021). All treatment courses (TC) from patients aged 18 and older with RA as diagnosed by the treating rheumatologist and definite SjS status undergoing TNFi, other modes of action (OMA) bDMARD (Abatacept, IL6-inhibitors, Rituximab) or JAK-inhibitors (JAKi) were assessed. Two group-comparison between RA/SjS and RA/non-SjS were performed. P-values are from Fisher test for nominal and Kruskal test for continuous variables. We estimated crude hazard ratios (HR) from univariate Cox models with the outcome of stop or start of a new bDMARD.**Results:** A total of 9601 TCs were analyzed (5373 TNFi, 3201 OMA, 1027 JAKi). RA/SjS were more likely to be female, non-smoker, to have longer RA disease duration, a higher DAS28 and HAQ-score. Additionally, RA/SjS patients were more likely to receive OMA or concomitant steroid treatment and had a higher number of prior biologic treatments.

Median retention time for RA/SjS versus RA/non-SjS was: TNFi 489 versus 714d; OMA 619 versus 768d; JAKi 693 versus 801d. There was evidence that RA/SjS have a higher hazard for stopping TNFi treatment than RA/non-SjS (crude HR 1.35, 95% CI 1.05 to 1.74, p = 0.02). No evidence was found for a difference in OMA (crude HR 1.13, 95% CI 0.92 to 1.39, p = 0.23) or JAKi (crude HR 1.12, 95% CI 0.76 to 1.67, p = 0.57).

Conclusion: The unadjusted Cox model suggests that patients with RA and associated SjS have an inferior response to TNFi than RA patients without SjS.

P 3

Disease activity and pregnancy outcome in a Juvenile Idiopathic Arthritis: a single center cohortMazza Viktoria^{1,2}, Zbinden Astrid¹, Förger Frauke¹¹Dpt. of Rheumatology and Immunology, Inselspital, University of Bern, Switzerland; ²Department of Obstetrics and Gynecology and Obstetrics, Spital Grabs, Switzerland**Background:** Juvenile idiopathic arthritis (JIA) is the most common chronic inflammatory rheumatic disease in paediatrics. Women with JIA want to live a normal life including family planning. However, the interaction of pregnancy and JIA bears potential risks.**Objectives.** The aim of our study was to analyse the disease course during pregnancy and postpartum as well as pregnancy outcome among women with JIA followed at the department of rheumatology, Inselspital Bern.**Methods:** 24 pregnancies in 21 women with JIA (1 systemic, 11 polyarticular, 6 oligoarticular, 3 enthesitis) were analysed. All data were retrieved from hospital records and the electronic data capture system of the clinic. Patients were usually followed once at each trimester and 6-8 weeks postpartum. We used the DAS 28-CRP score, C-reactive protein as well as any change of medication to assess disease activity. The pregnancy outcome was compared to the general population in Switzerland.**Results:** We studied 21 women with JIA, who delivered 24 children. During pregnancy, the majority of JIA patients (55 %) had stable inactive disease; 18 % experienced an improvement of their disease from the 1st to the 3rd trimester. A worsening of symptoms was most often seen after delivery (61% of JIA patients) and was less frequent during pregnancy (14% of JIA patients). With regard to pregnancy outcome in JIA, preterm births occurred in 12.5% of the pregnancies, which was higher than the percentage in the general CH-population (6.7%). Similarly, low birth weight (<2500g) was reported more often in neonates of mothers with JIA (8.3%) as compared to the general CH-population (6.1%). Patients with JIA most often had a vaginal delivery (54.2%). A caesarean section was performed in 37.5% of the patients, which is higher than the rate in the general CH-population (32%).

Conclusion: The majority of patients with JIA experience inactive or improved disease during pregnancy (73%) and a postpartum worsening of symptoms after delivery (61%). Compared to the general population, the rate of adverse pregnancy outcome and delivery by C-section is elevated in mothers with JIA. Further investigations are needed to understand the impact of disease activity and medication on these excess risks.

P 4

Heterogeneity in adverse event assessment between countries participating in an international collaboration of registries of rheumatoid arthritis patients using Janus kinase inhibitors (the JAK-pot study)

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Background: Registries provide a unique opportunity to understand the safety of newer therapies, but pharmacovigilance studies require large number of patients to evaluate rare drug-related adverse events (AEs). Because JAK-inhibitors (JAKi) have only recently been approved for the treatment of rheumatoid arthritis, it makes sense to combine data from several registries to obtain a sufficiently large sample size to promote earlier detection of AEs.

Objectives: The purpose of this analysis was to evaluate how AEs are assessed in the various registries in preparation for a collaborative pharmacovigilance analysis, and present preliminary results.

Methods: The “JAK-pot” collaboration includes 19 RA registries. The principal investigators were sent a structured questionnaire on AE assessment and 18 (94%) provided complete responses on the AE assessment procedures of their registries. We present descriptive statistics of the AE assessment procedures.

Results: The 19 registries represent 7186 patients initiating a JAKi, who are on average 57 years old, with a mean disease duration 11 years, seropositive (83%), female (82%) and with moderate disease activity at treatment initiation.

Of the participating registries, 16 (89%) assess incident AEs, using a pre-specified extraction form (n = 3), free text (n = 5), a combination of both (n = 6) and/or the use of linkage to external electronic records (n = 3). AEs are coded using a predefined coding system by 11 registries (MedDRA (n = 8), other (n = 3)), but nearly all are recording the severity of the AE (n = 15, 94%), AE related-death (n = 15, 94%), or AE-related hospitalisation (n = 15, 94%). AEs of special interest, such as serious infections (n = 15, 94%), thromboembolic events (n = 15, 94%), or shingles (n = 9, 56%), are recorded by most registries. Incident AEs are linked by the treating physician to specific therapies in 11 registries (69%), while the other 5 extrapolate potential causal associations based on therapy start and stop dates. A pre-specified adjudication process for AEs is made only by 5 registries (31%).

Conclusion: Substantial heterogeneity exists among registries regarding AE assessment within the JAK-pot collaboration. These differences must be taken into account when analysing the safety of JAKi across different countries in collaborative studies. For comparative analyses,

stratified analyses by country are required to account for differential AE assessment and varying degrees of potential under-reporting.

P 5

A Histogram-based Densitometry Index to Support the Identification and the Assessment of Severity of Interstitial Lung Disease in Systemic Sclerosis: Applicability in Conventional and Low-dose Computed Tomography.

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Background: Histogram-based densitometry analysis is an automated quantitative evaluation of systemic sclerosis-related interstitial lung disease (SSc-ILD). Mean lung attenuation, skewness, and kurtosis are the main extractable variables, recently merged into a Computerized Integrated Index (CII). We aimed at testing the CII in low-dose 9-slices (reduced) CT, in comparison to high-resolution computed tomography (conventional CT), in discriminating for the presence and severity of SSc-ILD.

Methods: We analyzed conventional and reduced CTs of SSc patients from the Rheumatology Department, University Hospital of Zurich. The Goh et al staging (limited vs extensive ILD) was applied by an experienced radiologist. Conventional and reduced CTs were analyzed using the software Horos to obtain the CII, named conventional and reduced CII respectively. We tested association with a GEE linear regression model. The predictive power of CII was tested with ROC curve analysis.

Results: We enrolled 468 SSc patients: 427 had undergone at least one conventional CT (total 719 CTs), 345 at least one reduced CT (total 814 reduced CTs). Both CT and reduced CT images were available at the same visits for 243 patients (total 294 conventional + reduced CTs). The three groups were comparable for prevalence of ILD and extensive ILD (48%vs45%vs48% and 25%vs21%vs20%, respectively).

Both conventional and reduced CII significantly differentiated ILD vs non-ILD (conventional CII -0.46.15 vs 0.670.09, p<0.001 vs reduced CII -0.500.17 vs 0.480.11, p<0.001). Similarly, they separated limited vs extensive ILD (conventional CII -0.120.14 vs -1.480.21, p<0.001 vs reduced CII -0.250.13 vs -1.710.20, p<0.001, respectively).

Both CII similarly discriminated for ILD presence [conventional CII AUC 0.72 (95% CI 0.66-0.77) vs reduced CII AUC 0.68 (95% CI 0.62-0.74); p = 0.28] and for extensive vs limited ILD [conventional CII AUC 0.77 (95% CI 0.68-0.87) vs reduced CII 0.78 (95% CI 0.70-0.87), p = 0.86].

A cutoff for conventional CII<-0.96 (85% sensitivity, 62% specificity) or a reduced CII<-1.85 (85% sensitivity, 54% specificity) was chosen for an optimal sensitivity to detect extensive ILD.

Conclusion: We validated the ability of the conventional CII to detect the presence of ILD and identified cut-offs for both conventional and reduced CII to discriminate between extensive versus limited ILD. Further validation of the proposed cut-offs is ongoing to further support its use in clinical practice and research.

P 6

Association Of The Soluble Terminal Complement Complex C5b-9 (sC5b-9) With Urinary Signs Of Kidney Disease In a Swiss SLE Cohort

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Background/Objective: The role of the soluble terminal complement complex, sC5b-9, in active SLE has yet to be elucidated. The objective of the study was to correlate clinical activity with sC5b-9 and laboratory parameters of standard care. In completion of the preliminary analyses based on 2 consecutive patients' visits¹, we here present the analysis of all 4 visits during the 2-year time period of the study of 127 patients.

Methods: Study population and design: Patients from the Swiss SLE Cohort Study (SSCS, from St. Gallen centre, fulfilling the ACR criteria at inclusion), entered into a prospective observational cross-sectional study. Determined at 2-4 clinical visits, (≥ 6 months apart), compared with 48 healthy controls:

- clinical disease activity (SELENA-SLEDAI, PGA), PROs (FACIT, SF-36) and SLICC-Damage
- sC5b-9 by ELISA
- standard of care routine laboratory parameters

Statistics: Independent associations of continuous variables, studied by analysis of covariance (ANCOVA) models, followed by Spearman rank correlation analyses.

Results: Disease activity was generally low (SELENA-SLEDAI total 1.7 ± 2.6 (mean \pm SD)). SLEDAI > 4 (8.1 ± 3.3 (mean \pm SD) in 8.5% patients, age 48 [38-54] years (73% female), disease duration 5.3 [3.8-8.8] (median [IQR]) years. Clinical manifestations: hematologic 59%, musculo-skeletal 56%, skin 41%, photosensitivity 41%, oral ulcers 37%, renal 15%.

A significant association in line with urinary signs of renal manifestations:

- haematuria ($F = 2.501$, $p < 0.0001$) and/or increase in glomerular dysmorphic erythrocytes ($F = 1.593$, $p = 0.039$) and sC5b-9

A significant correlation of proteinuria, albuminuria or pyuria with sC5b-9 could not be detected.

Further correlations between sC5b-9 and:

- dsDNA antibodies (ab) ($r = 0.119$, $p = 0.014$), IgG ($r = 0.181$, $p < 0.0001$), soluble IL-2 receptor ($r = 0.100$, $p = 0.042$), ESR ($r = 0.112$, $p = 0.017$), CRP ($r = 0.223$, $p < 0.0001$), C3a ($r = 0.317$, $p < 0.0001$), C3 ($r = 0.224$, $p < 0.0001$)

IgG ($F = 2.420$, $p = 0.004$) and sIL-2 receptor ($F = 8.756$, $p < 0.0001$) levels were significantly associated with SELENA-SLEDAI in a multivariate model after adjustment for age, gender, CRP, ESR, levels of dsDNA ab, C3 and C4.

Conclusions: Soluble C5b-9 was associated with laboratory parameters in line with urinary signs of renal manifestation. It may contribute to the pathogenesis of renal glomerular manifestation in SLE and serve as a new marker of active renal disease.

Reference

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P 7

Cutaneous involvement in anti-HMGCR positive necrotizing myopathy

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Objective: Anti-3-Hydroxy-3-methylglutaryl-coenzyme A reductase (HMGCR) positive immune-mediated necrotizing myopathy (IMNM) is a rare disease. It is induced by exogenous substances, most often by statins. Little is known about cutaneous manifestations of HMGCR positive IMNM and about HMGCR antibody positivity in other diseases.

Methods: Characteristics of all patients with anti-HMGCR autoantibodies, diagnosed between January 2012 and September 2020 were studied. Data of patients with IMNM were compared to those with positive antibodies but without muscle involvement. Associations of IMNM with other organ involvement were searched for.

Results: Of 32 patients, 23 showed characteristics of IMNM, 9 did not fulfill current classification criteria but most showed signs of connective tissue diseases. Patients with IMNM were older (66 and 35 years, respectively; 0.92 ($0.73 - 0.98$); $p < 0.001$), had more frequent statin exposure (87% and 33%, respectively; 0.84 ($0.61 - 0.94$); $p = 0.005$) and a higher mean peak CK (8717U/l and 329U/l, respectively; 1.0 ($0.85 - 1.0$); $p < 0.001$). 13/23 (56%) of IMNM patients showed cutaneous lesions; none of the patients suffered from cancer; only three IMNM patients showed drug-free complete remission. Incidence of IMNM in the catchment area of our center is at least 2.7/Mio/year.

Conclusion: Cutaneous lesions were found to be more frequent in anti-HMGCR positive IMNM than previously reported. Titer of anti-HMGCR antibodies and CK levels were significantly higher in IMNM than in other autoimmune connective tissue diseases. The data support the hypothesis of an antigen-driven response in IMNM and suggests an activation of autoreactive B-lymphocytes in non-IMNM patients.

P 8

Prediction of digital ulcers in patients with systemic sclerosis based on the use of platelet inhibitors and other parameters - a EUSTAR study on derivation and validation of a clinical prediction model

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Background: Platelets are known to be activated in SSc, therefore, platelet inhibitors might represent a therapeutic option in the management of digital ulcers (DUs).

Aim: The study aimed to develop and validate a prediction model for the occurrence of DUs in patients with SSc based on platelet inhibitors and other parameters.

Methods: We used prospectively collected data from the European Scleroderma Trials and Research group (EUSTAR) registry. Patients fulfilling the 2013 ACR/EULAR SSc classification criteria with complete longitudinal data on the presence of DUs and platelet inhibitors were included in the analysis. Multiple imputation using a random forest algorithm was implemented to handle missing values.

The dataset, containing the information of the last follow-up visit of every patient, was split into a derivation cohort (patients recorded before 2017-01-01 in the EUSTAR registry) and validation cohort (patients recorded after 2017-01-01). To investigate the response for the binary dependent variable of DUs, binary logistic regression was implemented to develop a prediction in the derivation cohort and to validate it using ROC analysis and calibration plots to address discrimination and calibration, respectively.

Results: Of 3,710 patients (14.6% males, 67.8% limited cutaneous SSc, median age 56.97 years, median disease duration 8.94 years), 486 had current DUs at the baseline and 150 were exposed to platelet inhibitors. At the follow-up visit (median follow-up time 1.03 years) 487 had current DUs and 90 remained exposed to platelet inhibitors.

The discrimination ability of the model evaluated by ROC curve analysis showed an AUC = 80.8% (95% CI = [78.7% to 83.0%]) for the derivation cohort (2,827 patients) and AUC = 83.4% (95% CI = [80.0% to 86.8%]) for the validation cohort (883 patients), respectively, corresponding to an acceptable discrimination. The calibration plots revealed an adequate calibration of the model.

Amongst our 24 predictive factors, our model revealed that exposure to platelet inhibitors is associated with a reduced odds ratio of DUs occurrence at the next follow up visit (OR = 0.25, 95%CI [0.07-0.77]).

Conclusion: Our model shows good discrimination and adequate calibration for the difficult task of predicting the occurrence of DUs at a one-year follow up visit. Use of platelet inhibitors was among the factors predicting lower probability of DU occurrence at follow up.

P 9

Belimumab in Autoimmune Liver Diseases with associated Sjögren's Syndrome

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Background: Autoimmune hepatitis (AIH) is an auto-inflammatory disease of the liver with, if untreated, a high mortality rate. About 75% of patients are responsive to synthetic disease modifying drugs (sDMARD). Primary biliary cholangitis (PBC) is an inflammatory disease of small and medium sized bile ducts. Despite standard treatments (ursodeoxycholic acid (UDCA), fibrates and obeticholic acid (OCA)), a significant proportion of patients has progressive disease. Twenty percent of PBC patients have Sjögren's syndrome (SjS). PBC has many features in common with SjS: epidemiology, epithelitis, well-characterized autoantibodies and a poor response to immunosuppressive treatments.

Hypothesis: Based on the increased B cell-activating factor (BAFF) levels in AIH, PBC and SjS patients and the similarities between PBC and SjS, we hypothesized that belimumab is effective in AIH and PBC.

Methods: Retrospective analysis of treatment responses to belimumab in three female patients with AIH and/or PBC with moderate to advanced liver fibrosis and concomitant SjS. Patient 1: 52y, with AIH, PBC and SjS. Indication: active AIH with intolerance to previous treatments (AZA, MMF, rituximab); belimumab since 01/20. Patient 2: 72y, with PBC and SjS. Indication: refractory PBC despite UDCA and fibrates (OCA declined

by health insurance); belimumab since 11/20. Patient 3: 54y, with PBC (with ductopenia), SjS and erosive rheumatoid arthritis (RA). RA responding insufficiently to all commonly used sDMARDs and biologicals. She was on low dose steroids, HCQ and etanercept. Her PBC was active despite UDCA and fibrates (OCA not tolerated). Indication: refractory PBC; belimumab since 11/20. We discontinued etanercept, when belimumab was started.

Results: Patient 1: Remission of AIH under belimumab. Patient 2: Remission of PBC after 6 months of belimumab. Patient 3: Stable cholestasis parameters. Improvement of slightly elevated transaminases and almost normalization of IgM.

Improvement of sicca symptoms in all patients. Two patients had a transient improvement in fatigue. RA in patient 3 remained on a level of moderate disease activity.

Conclusions: These preliminary findings suggest belimumab as a promising treatment option in AIH and PBC, with so far no safety concerns.

Our study shows how the basket of autoimmune diseases can guide us to evaluate new drug candidates in a more efficient way and highlights the strengths of a tight collaboration between hepatology and rheumatology.

P 10

Socio-economic impact of Sjögren's syndrome in Western Switzerland: a cross-sectional study

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Background: Patients with Sjögren's syndrome (SS) have an increased risk of work disability and a reduced health-related quality of life. SS is associated with increased direct and indirect healthcare costs. There are no published data about Switzerland, a country with high resources and easy access to healthcare except dental care.

Objectives: To evaluate the professional and economic impact of SS in patients living in Western Switzerland.

Methods: Cross-sectional survey-based study conducted in December 2020, during the pandemic.

Patients suffering from SS were invited by the regional association of patients with SS to complete a survey.

Results: Most participants were women (95%) with a mean (SD) age of 54.2 (12.3). Participants lived predominantly in canton of Vaud (40%). In terms of level of education, 34% of the participants went to university, 11% went to high school and 42% to elementary school. 55/86 (86%) patients completed the survey. Mean (SD) EULAR SS Patient Reported Index was 6.5 (1.6).

In the working age population (<65, n = 39), 64% of the participants reported to be employed, 88% of whom working part-time. They reported to work 23.3 (10.1) hours per week (mean, SD). 60% reported SS-related work incapacity periods during the past year. 72% of participants had to reduce their working hours and 27% had to change careers due to SS.

In terms of work disability, 27% of the participants depended on disability insurance pension, of whom 38% received a full pension. A minority of participants (11%) reported to receive a minimum subsistence allowance from the local social service.

Participants estimated to pay 2752 CHF (3000) per year (median, IQR) out of their own pocket for health care not covered by health insurances. 95% of the patients had to pay for dental medicine costs. Public health insurance contributed to dental costs for 44% of the patients and private health insurance for 28% of them. 22% of the patients reported to limit dental care for financial reasons.

Conclusion: Two-thirds of the patients with SS remained in active employment, most of them working part-time, with a substantial loss of income. One third of the patients are work disabled and depend on a disability pension. Dental care was not reimbursed in half of the patients by their health insurance, leading to dental care access restriction for 20% of them. Despite a relatively high wage level in Switzerland, SS represents a substantial financial burden for most of the patients.

P 11

Ultrasound-guided core needle biopsy: an effective and safe tool to diagnose Sjögren's syndrome and lymphoma of the major salivary gland

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Background: Histopathology is a cornerstone of diagnostics in Sjögren's syndrome (SjS). The current widely accepted standard, minor salivary gland (lip) biopsy, has several disadvantages including permanent sensory loss of the lips as a well-known complication. Moreover, lymphoma of salivary glands cannot be excluded. Ultrasound (US)-guided core needle biopsy (CNB) is an excellent diagnostic tool with good safety and encouraging results as compared to open biopsy.

Objectives: To retrospectively analyze safety and diagnostic outcome of US-guided CNB in patients with known or suspected SjS.

Methods: Retrospective analysis of a case series of four patients with known or suspected SjS treated at the outpatient clinic of the Department of Rheumatology & Immunology, and the Department of Otorhinolaryngology. All patients underwent US-guided CNB using a 20 g needle (Bard) and a Logiq S8 GE US device with a 6-15 MHz matrix linear transducer. After local anesthesia, a 2mm skin incision was performed at the most suspicious focal sonographic lesion (sampling length 20mm; 2-3 needle passes through the same skin access).

Results: Representative histopathological samples were obtained from all patients. In patient 1 (62y) with known SjS and parotid swelling, mucosa-associated lymphoid tissue (MALT) lymphoma was diagnosed (previous lip biopsy with no proof of malignancy). Also in patient 2 (35y) with known SjS and a 20-years history of parotid swelling, MALT lymphoma was diagnosed. In this patient a lip biopsy was performed in the previous year supporting the diagnosis of SjS, but without proof of malignancy. In patient 3 (64y) with SSc, anti-Ro/SSA positivity and dry eyes and mouth, the biopsy established the diagnosis of SjS. In patient 4 (59y) with SSc, negative anti-Ro/SSA antibodies and dry eyes/mouths, SjS could be excluded. In the corresponding US, all patients showed hypoechoic lesions and inhomogeneous parenchyma of major salivary glands reflecting OMERACT grade II-III SjS US score. No safety signals were observed. Patients with prior lip biopsies perceived US-guided CNB as preferable.

Conclusion: This pilot study suggests that US-guided CNB in SjS is a safe procedure with an excellent diagnostic yield allowing the diagnosis of lymphoma of the salivary glands, which is superior to lip biopsy. Given these encouraging results, we will now increase patient numbers for further validation.

P 12

sVCAM-1 Expression in Patients with Takayasu Arteritis Treated with DMARDs and Tocilizumab in a Prospective Pilot Study

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Background: Takayasu arteritis (TA) is a rare disease that frequently is difficult to diagnose. Biomarkers might be helpful for earlier diagnosis and treatment monitoring. Serum soluble vascular cell adhesion molecule-1 (sVCAM-1) was described as a marker of inflammation in a variety of rheumatic diseases, including vasculitis. Tocilizumab (TCZ) has been shown to be efficacious in TA. However, sVCAM-1 has never been analysed as a biomarker in TA patients treated with TCZ.

Objective: To analyze sVCAM-1 in TA patients treated with TCZ or conventional DMARDs in a prospective clinical trial, and compare these results to age-matched healthy controls (HC). MRI analyses of aortic wall thickening and enhancement might serve as a morphologic correlate of serologic disease activity.

Methods: 29 TA patients were prospectively followed between 2016 and 2019 (27 females, mean \pm SD: 39.2 \pm 13.9 years) at the Department

of Rheumatology of the University Hospital of Bern. Baseline demographics: No treatment (n = 8), TCZ (n = 13), GC (n = 4), GC + methotrexate (MTX) (n = 1), infliximab (IFX) + MTX (n = 1), GC + IFX (n = 1), MTX (n = 1). Three follow-ups were performed after 12, 24, 36 \pm 3 months. sVCAM-1 was analysed in serum using a commercially available ELISA kit (R&D Systems, Germany). Results were compared to 29 sera of matched HC (27 females, 40.8 \pm 15.1 years). Inflammatory aortic changes in MRI were scored (0-3) and cumulated sVCAM-1 concentrations from each MRI scoring group were compared to HC.

Results: At baseline, significantly increased serum concentrations of sVCAM-1 (ng/ml) were observed in TA patients without treatment (n = 8, 537.3 \pm 130.1, p = 0.002) vs HC (336.0 \pm 76.1). A smaller difference was found between patients under treatment and HC (n = 21, 468.2 \pm 105.3 vs 405.1 \pm 82.5, p = 0.04). Follow-up in the TCZ group showed no significant difference vs HC. However, sVCAM-1 levels decreased more rapidly under TCZ than under DMARDs. Changes over time in all treated patients vs HC were as follows: 12 months: 505.8 \pm 126.4 vs 395.6 \pm 60.2, p = 0.04 (n = 8), 24 months: 437.8 \pm 76.2 vs. 396.4 \pm 91.9, p = 0.24 (n = 12), 36 months: 440 \pm 43.3 vs. 323 \pm 50 p = 0.03 (n = 8). Elevated sVCAM-1 concentrations did not correlate with increased MRI score.

Conclusion: The results suggest that sVCAM-1 is a diagnostic biomarker in patients with TA. Follow-up showed a faster decrease in patients with TCZ than DMARDs. sVCAM-1 concentrations did not correlate with disease activity as assessed with MRI.

P 13

Use of 2-Mercaptoethane Sodium Sulfonate (Mesna) Prophylaxis in Cyclophosphamide (CYC)-Treated Patients with ANCA-Associated Vasculitis (AAV): Results of an Electronic Survey

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Purpose: Co-prescribing mesna with CYC for AAV aims to prevent the potential urotoxic effects of CYC. We investigated current clinical practice related to prescribing mesna prophylaxis or not for CYC-treated patients with AAV.

Methods: We searched MEDLINE for publications with the MeSH term "ANCA-associated vasculitis" over a 10-year period. Email addresses of authors were extracted from the online information. These authors were invited by email to participate in an online SurveyMonkey survey asking about the characteristics of the respondent, their experience with AAV, and their practice in using CYC to treat AAV and in using mesna in CYC-treated patients with AAV and the underlying rationale. We compared 15 response variables to identify factors associated with the use of mesna. Response variables with multiple categories were first analyzed across all categories; if the omnibus test result was significant, additional analyses were used to identify the categories, which were the sources of group separation. Statistical analyses involved Pearson's chi-square test or Fisher's exact test. For multiple-response variables, the Rao-Scott correction was applied.

Results: The 139 participants were from 34 countries and were essentially MDs (98%) who mainly worked in rheumatology (50%), nephrology (25%) or internal medicine/immunology (18%). Mesna was given with CYC systematically, never, or on a case-by-case basis by 68%, 19% and 13% of respondents, respectively. As compared with systematic mesna-prescribers, never/occasional mesna-prescribers reported a longer time since receiving their degree (\geq 15 years: 80% vs 50%, P<0.001), were more frequently based in England/United States (than in France/Germany/Italy) (78% vs 21%, P<0.001), had longer involvement in care of patients with AAV (\geq 15 years: 62% vs 37%, P = 0.006), had less practice in using intermittent pulse therapy as the exclusive/predominant CYC administration scheme (62% vs 89%, P<0.001), and, as a rationale underpinning their mesna practice, had less adherence to local operational procedures (47% vs 73%, P = 0.002) or (inter)national management guidelines for AAV (16% vs 49%, P<0.001).

Conclusion: Practice with regard to prescribing mesna in conjunction with CYC to treat AAV is heterogeneous. Systematic mesna use prevailed over never or occasional use. The decision to prescribe mesna may be based more on circumstantial than structural reasons.

P 14

Aspects of prevention and prevalence of osteoporosis among older patients in Switzerland

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Introduction: Risk of bone fragility and developing osteoporosis is known to increase with age. Results of a Swiss survey published in 2008 revealed osteoporosis was underdiagnosed and undertreated in patients aged 50 years and above presenting with a fragility fracture. In addition, based on demographic projections for 2025, number of incident fractures is expected to rise substantially. Our recent survey therefore provides new insights into osteoporosis prevention and prevalence among older patients in Switzerland.

Material and Methods: Our physician and patient questionnaires covering the prevention, diagnosis and treatment of osteoporosis were distributed to various specialists across Switzerland in the language of the respective region. Questionnaires were collected within a one-week period and analyzed by an independent biometric institute.

Results: Participating physicians (n = 262) were mostly GPs (64.9%), followed by rheumatologists (16.8%), gynecologists (12.2%) and endocrinologists (6.1%). Patients (n = 9065) were predominantly female (70.5%), with overall 28.5% being of an older age (≥ 65 years). Mean age and regional distribution were comparable with the general Swiss population. Dietary habits of older patients were similar to those of patients < 65 years, with majority not being on a diet, the intake of dairy products being principally lower and of green vegetables higher than 7 portions per week. Exercise was somewhat more frequent, smoking less common (11.3% vs. 22.4%) and elevated alcohol intake more prevalent than with patients < 65 years (19% vs. 8.7%). Intake of calcium and/or vitamin D supplements was substantially higher (56.8% vs. 37.5%). Older patients more frequently indicated feeling insecure while walking or afraid of falling (22.2% vs. 6.3%) and concerned about their bone fragility than patients below the age of 65 (18.8% vs. 13.3%). 15% of older patients were on osteoporosis treatment, and 8.7% reported having atraumatic fractures. Awareness of the chronic nature of osteoporosis was still substantially lower than in patients < 65 years (31.9% vs. 41.3%). Moreover, nearly 1/3 of older patients did not view osteoporosis as a chronic disease.

Conclusions: Although some lifestyle-related risk factors are less prominent among older patients, prevalence of osteoporosis and associated fractures remains substantial. Improving dietary habits and raising awareness of osteoporosis will be crucial aspects of future disease management.

P 15

Management of Pregnancy-associated osteoporosis presenting severe vertebral fractures: a case series

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Background: Pregnancy-associated osteoporosis (PAO) is a severe type of premenopausal osteoporosis which may occur in the last trimester of pregnancy or immediate postpartum. Some studies suggested that PAO patients usually need an antiresorptive therapy (a bisphosphonate or denosumab) or osteoanabolic therapy with teriparatide to regain their bone mineral density (BMD).

Aim: To present the clinical features and management of cases of PAO from the Department of Rheumatology, University Hospital Zurich.

Methods: Patients presenting in our osteology clinic between 2011 and 2021 with low-trauma vertebral fractures, which either occurred during pregnancy or in the immediate post-partum period were included in this series. We retrieved data pertaining to fracture localization, bone mineral density, risk factors associated with bone fragility and treatment.

Results: We identified five cases with vertebral fractures. The median age at presentation was 38 years [min 26, max 41]. All patients had at least three thoracic or lumbar fractures. In one, three additional vertebral fractures occurred within two months after the first consultation. The BMD analysis revealed a median lumbar Z-score of -3.1 (min -3.6, max -3.0). Regarding risk factors associated with bone fragility, all patients were found to have vitamin D insufficiency at the time of diagnosis, deemed as osteomalacia in one case. Three patients had a family history of osteoporosis, two were underweight and one underwent glucocorticoid therapy prior to the pregnancy. Additionally, two patients were exposed to fertilization medication.

The treatment recommendations were challenging: two patients received teriparatide (in one eventually consolidated with alendronate), one received a bisphosphonate (intravenous ibandronate), with missing/pending outcome. The remaining two patients increased their BMD with vitamin D and calcium supplementation (lumbar Z-score ranging between -2.8 and -2.2 after two years, increasing to -1.6 and -1.5 after three years).

Conclusion: PAO, although rare, remains a severe disorder, the treatment for which is challenging in the clinical setting. Routine testing of vitamin D levels in blood should be recommended to all pregnant women.

P 16

Effectiveness of an inpatient multidisciplinary treatment program for patients with rheumatologic diseases and musculoskeletal pain – a single center, prospective, observational study

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Background: Rheumatologic patients often present with musculoskeletal pain which may complicate the clinical course of non-inflammatory as well as inflammatory rheumatologic disorders. We here present the results of an inpatient multidisciplinary treatment program on musculoskeletal pain and function for patients with rheumatologic disorders.

Methods: 355 consecutive patients were entered into a program of multimodal treatment courses, either in a so-called multimodal rheumatologic complex treatment program (MRCT) or in a multimodal multidisciplinary pain treatment program (MMPT), from January 2015 until March 2020. Both programs included education, evaluation, assessments and treatment by the following disciplines: ergotherapy, physiotherapy, complementary medicine, pain medicine and rheumatology. MMPT additionally included psychological/psychiatric evaluation and treatment. Pain was assessed via visual analogue scale (VAS) and functional impairment via the "Funktionsfragebogen Hannover (FFbH)" and the "Health Assessment Questionnaire (HAQ)" at admission, at discharge and at 12 weeks of follow up. Paired t-test analysis for all treatment episodes were performed.

Results: Mean age (years, ±SD) of the 295 patients treated in the MMPT program was 51.8 ± 11.1 and of the 60 patients in the MRCT program 56.0 ± 12.5, respectively with 73.5% female and 26.5% male patients. Overall, VAS mean at admission was 6.50 ± 1.29 (SD), HAQ mean 0.49 ± 0.33 (SD) and FFbH mean 77.11 ± 11.64 (SD), respectively. Significant improvements in VAS, HAQ and FFbH were demonstrated at discharge in the MMPT as well in the MRCT group (MMPT vs. MRCT) with

- a mean improvement of VAS of 2.36 (95% CI: 2.23-2.48, P value: <0.001) vs. 2.22 (95% CI: 1.98-2.45, P value: <0.001),
- a mean improvement of HAQ of 0.15 (95% CI: 0.13-0.17, P value: <0.001) vs. 0.18 (95% CI: 0.11-0.24, P value: <0.001) and
- a mean improvement of FFbH of -4.62 (95% CI: -5.53- -3.70, P value: <0.001) vs. -5.99 (95% CI: -8.14- -3.83, P value: <0.001).

Follow up assessment at week 12 was recorded in 50 patients (14.1%) with a significant mean improvement in VAS of 1.68 (95% CI: 1.32–2.0, P value < 0.001).

Conclusion: Significant improvement of pain and function was demonstrated at discharge in the MRCT group and in the MMPT group, as well in patients with inflammatory and non-inflammatory diagnosis. A multimodal multidisciplinary therapeutic approach may provide an effective treatment strategy superior to unimodal standard management.

P 17

Self-reported SARS-CoV2 testing and COVID-19 disease in patients with rheumatoid arthritis, axial spondyloarthritis and psoriatic arthritis in a Swiss observational cohort

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Objectives: Assess and compare the rate of COVID-19 infection and SARS-CoV2 testing in patients with RA, rheumatoid arthritis (RA), psoriatic arthritis (PsA) and axial spondyloarthritis (AxSpA) association with their treatment and, for testing, the number of symptoms in a Swiss cohort of patients.

Methods: Inclusion of patients with RA, AxSpA and PsA from the SCQM using a smartphone app (mySCQM) to record information between March and December 2020. Outcomes of interest were self-reported SARS-CoV2 testing, symptoms compatible with COVID-19 during the previous month and confirmed COVID-19 through PCR nasopharyngeal swab. Outcomes were compared between diseases groups, using logistic regression. We also evaluated the association of baseline treatment (TNF-inhibitors, b/tsDMARDs with other modes of action, no b/tsDMARDs) on the odds of symptoms and testing and the association of the number of symptoms (0-9) on the odds of testing. The analyses of SARS-CoV2 testing and COVID-19 symptoms were additionally adjusted for age, gender, glucocorticoids and csDMARDs. Confirmed cases were not adjusted for treatment and other covariates considering the low number of events.

Results: We included 927 patients with RA, 805 with AxSpA and 453 with PsA. 1010 patients reported COVID-19-like symptoms (mostly fever, runny nose and cough), but only 455 of them (45%) reported being tested. 151 patients were tested without symptoms. In between March and December 2020, 7.6% of RA, 8.5% of AxSpA and 10.5% of PsA patients were tested positive for COVID-19 (p = 0.678). The odds of testing, symptoms and confirmed COVID-19 were similar between diseases and not associated with treatment for testing and. The number of symptoms was associated with the odds of testing (OR 1.43, 95%CI 1.37–1.50 by symptom).

Conclusion: Prevalence of COVID-19 symptoms and confirmed cases was similar between diseases, and for symptoms, was not associated with treatment. Despite strong advice from health authorities, less than 50% of patients with inflammatory rheumatic diseases and COVID-19 symptoms were tested. This proportion was not significantly different between diseases and not influenced by type of treatment. Efforts should be made to improve rates of SARS-CoV2 testing in patients with rheumatic diseases.

P 18

Bimekizumab Safety and Efficacy in Patients with Psoriatic Arthritis: 3-Year Results from a Phase 2b Open-Label Extension Study

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Background: Bimekizumab (BKZ), a monoclonal antibody inhibitor of interleukin (IL)-17A and IL-17F, demonstrated clinical improvements in joint and skin outcomes up to 108 weeks (wks) in patients (pts) with active psoriatic arthritis (PsA).^{1,2} We report 3-year BKZ safety and efficacy from the 48-wk phase 2b dose-ranging study (BE ACTIVE; NCT02969525) and its open-label extension (OLE; NCT03347110).

Methods: BE ACTIVE and OLE study design has been described previously.¹ OLE pts received BKZ 160 mg every 4 wks, irrespective of prior dose. Treatment-emergent adverse events (TEAEs) are reported for the safety set (≥1 dose BKZ in the dose-ranging study). Data are presented from dose-ranging study baseline (BL) to Wk152. Efficacy outcomes (full analysis set): ACR50; minimal or very low disease activity (MDA/VLDA); Psoriasis Area and Severity Index (PASI) 90/100; body surface area affected by psoriasis (BSA) 0%; dactylitis/enthesitis resolution (patients with BL Leeds Dactylitis Index >0, and Maastricht AS Enthesitis Score >0, respectively).

Results: To Wk152, exposure-adjusted incidence rates (EAIR) per 100 patient-years (PY) were 126.4 (all TEAEs), 4.1 (serious TEAEs), 0.7 (serious infections) and 4.6 (Candida infections, all localised, mild/moderate). One event was adjudicated as inflammatory bowel disease (microscopic colitis). Proportions of patients with ACR50 response were sustained through Wk152 (N = 206; 52.9% non-responder imputation [NRI]; 69.4% observed case [OC]). Response rates at Wk152: MDA (51.5% NRI; 67.5% OC), VLDA (30.1% NRI; 39.5% OC), PASI90 (64.2% NRI; 82.2% OC), PASI100 (57.7% NRI; 73.8% OC), BSA 0% (56.2% NRI; 72.6% OC) and resolution of dactylitis (71.2% NRI; 100% OC) and enthesitis (62.6% NRI; 80.7% OC).

Conclusions: The safety profile of BKZ in pts with PsA reflects previous observations^{1,2} for up to 3 years. High threshold disease control was achieved by >50% of BKZ-treated pts up to 3 years, reflected in long-term improvements in joint and skin outcomes.

Reference:

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P 19

Pharmacovigilance Pregnancy Data in a Large Population of Patients with Chronic Inflammatory Disease Exposed to Certolizumab Pegol

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Background: Tumour necrosis factor inhibitors (TNFi) are increasingly used to treat chronic inflammatory diseases (CID) in women of reproductive age, in line with recent guidelines. Still, limited data on TNFi-exposed pregnancy outcomes are available. Certolizumab pegol (CZP), a PEGylated, Fc-free TNFi, has no/minimal placental transfer from mother to infant during the third trimester. We report outcomes from over 1,000 prospectively reported pregnancies in women with CZP exposure from the UCB Pharmacovigilance safety database.

Methods: Details of CZP-exposed pregnancies from the UCB Pharmacovigilance safety database were reviewed from the start of CZP clinical development (July 2001) to 1st November 2020. To avoid potential reporting bias, analysis was limited to prospectively reported cases with known pregnancy outcomes.

Pregnancy outcomes reported: live birth, ectopic pregnancy, abortion (spontaneous, medically indicated and elective) and stillbirth. We also report congenital malformations, preterm delivery and, where information was recorded, low birth weight.

Results: Of 5,681 CZP-exposed pregnancies, 1,392 prospective pregnancies (1,425 fetuses) with maternal CZP exposure and known outcomes were reported (rheumatic diseases: 951; Crohn's disease: 293; psoriasis: 61; other: 52; missing diagnosis: 60; some patients may have had multiple indications for CZP treatment). Of these, 1,021 (73.3%) had

at least first-trimester CZP exposure and 547 (39.3%) were exposed during all trimesters. Mean (SD) maternal age was 31.9 (5.1) years. These pregnancies resulted in 1,259 (88.4%) live births. There were 150 (10.5%) abortions, 11 (0.8%) stillbirths, and 5 (0.4%) ectopic pregnancies. Congenital malformations were present in 35 infants (2.5% of all pregnancies); there was no pattern of specific congenital malformations. 124/1,259 (9.8%) of live births were preterm, and 101/1,259 (8.0%) of infants had low birth weight.

Conclusions: This analysis represents one of the largest cohorts of prospective pregnancies with known outcomes, including over 1,000 with at least first-trimester CZP exposure. Recognising limitations of the methodology, including lack of a control group and potential underreporting of outcomes, no increase in specific congenital malformations or adverse pregnancy outcomes after CZP exposure, compared to the general population, was observed. These findings offer further reassurance for women of childbearing age who are considering CZP treatment.

P 20

Clinical responses to upadacitinib or abatacept in patients with rheumatoid arthritis by type of prior biologic disease-modifying antirheumatic drug: Data from the phase 3 SELECT-CHOICE study

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Background: In the phase 3 double-blind SELECT-CHOICE study of patients (pts) with prior inadequate response (IR) or intolerance to bDMARDs, upadacitinib (UPA) showed superiority to abatacept (ABA) in change from baseline in DAS28(CRP) and in the proportion of pts achieving DAS28(CRP) <2.6 at Week 12.

Objectives: To describe clinical responses in pts receiving UPA or ABA by number and mechanism of action of prior bDMARDs.

Methods: 612 pts were randomized to once-daily UPA 15 mg or monthly intravenous ABA (<60 kg, 500 mg; 60–100 kg, 750 mg; >100 kg, 1000 mg). All pts continued background therapy with stable conventional synthetic DMARDs. From Week 12, pts who did not achieve ≥20% improvement in both tender and swollen joint counts vs baseline at 2 consecutive visits had background medication(s) adjusted or added. In this post hoc analysis, pts were grouped by the number and/or type of bDMARD received prior to enrollment: 1) lack of efficacy (LoE) to ≥1 tumor necrosis factor (TNF) inhibitor; 2) LoE to ≥1 interleukin-6 (IL-6) inhibitor; 3) intolerance to prior bDMARDs; 4) number of prior bDMARDs (1, 2, or ≥3). Mean change from baseline in DAS28(CRP) and DAS28(CRP) <2.6 and other clinical endpoints were evaluated at Weeks 12/24.

Results: Most pts had LoE to ≥1 TNF inhibitor (536, 87.6%); 96 (15.7%) had LoE to an IL-6 inhibitor; 79 (12.9%) had intolerance to prior bDMARDs; 408 (66.7%), 134 (21.9%), and 64 (10.5%) had received 1, 2, or ≥3 prior bDMARDs, respectively. Mean change from baseline in DAS28(CRP) was generally greater with UPA vs ABA across the different pt subgroups at Weeks 12/24. Across endpoints, regardless of prior bDMARD therapy (except in those who failed ≥3 prior bDMARDs), UPA and ABA demonstrated similar responses at Week 12 compared with those observed for the overall treatment groups, even with more stringent criteria such as ACR70 and Clinical Disease Activity Index (CDAI) ≤2.8. Responses at Week 24 followed a similar trend to those at Week 12 for DAS28(CRP) <2.6 and other endpoints. The safety profile across subgroups was consistent with each respective treatment in the overall study population.

Conclusions: Although sample sizes were small for some subgroups, treatment with UPA led to greater clinical responses vs ABA at Week

12, including in pts with LoE to TNF or IL-6 inhibitors, and those with IR or intolerance to 1, 2, or ≥3 prior bDMARDs.

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Comparison of axial and peripheral manifestations in patients with psoriatic arthritis and ankylosing spondylitis in upadacitinib clinical trials

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Background: Axial, peripheral, and other disease manifestations often overlap between psoriatic arthritis (PsA) and ankylosing spondylitis (AS). Upadacitinib (UPA) is an oral Janus kinase inhibitor under evaluation for the treatment of PsA and AS.

Objectives: To describe and compare baseline characteristics and UPA efficacy across 4 subgroups of patients (pts) from clinical trials: active PsA (with/without axial involvement) and active AS (with/without peripheral involvement).

Methods: Baseline characteristics and efficacy of UPA in reducing axial and peripheral signs and symptoms were assessed via an integrated analysis across the 4 pt subgroups from the SELECT-PsA 1,1 SELECT-PsA 2,2 and SELECT-AXIS3 studies. Analyses of baseline characteristics included pts in the UPA15mg QD, UPA30mg QD, and placebo (PBO) groups; efficacy analyses included pts in the UPA 15 mg QD group only. Axial involvement in PsA (axial PsA) was determined by investigator assessment. Peripheral involvement in AS was defined based on presence of tender or swollen joints (TJC68 >0 or SJC66 >0), or presence of enthesitis at baseline (Maastricht Ankylosing Spondylitis Enthesitis Score >0).

Results: 2102 pts (UPA 15 mg; UPA 30 mg; PBO) were evaluated across the 4 subgroups (PsA [with/without axial involvement]: 626/1289; AS [with/without peripheral involvement]: 135/52). 33% of pts with PsA had axial PsA; 72% of pts with AS had peripheral symptoms. Pts with axial PsA had higher peripheral joint (TJC68 and SJC66) and skin (psoriasis) burden than pts with AS with peripheral involvement (p<0.0001). Pts with AS with peripheral involvement had significantly greater overall pain (pt's assessment of pain; p = 0.0002) and back pain (BASDAI Q2; p<0.0001) scores, and higher total BASDAI (p = 0.0076) and ASDAS (p = 0.0351) scores than pts with axial PsA; physician's global assessment of disease activity, and peripheral pain and tenderness (BASDAI Q3 and Q4) were numerically similar for these 2 subgroups. The efficacy of UPA 15 mg (measured using ASDAS and BASDAI) was generally consistent across the 4 pt subgroups regardless of peripheral or axial involvement.

Conclusions: Pts with PsA with axial involvement and pts with active AS showed some differences in BL characteristics but similar improvements versus placebo with UPA 15 mg QD.

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P 22

Disease Activity and Inflammation Following Withdrawal of Certolizumab Pegol Treatment in Axial Spondyloarthritis Patients Who Did Not Experience Flares during the C-OPTIMISE Study

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Background: C-OPTIMISE investigated certolizumab pegol (CZP) maintenance dose continuation/reduction/withdrawal following achievement of sustained remission in patients (pts) with axial spondyloarthritis (axSpA). Most pts randomised to the full/reduced CZP maintenance dose did not experience disease flares, and a minority of pts who had CZP withdrawn remained flare-free. This post-hoc analysis evaluates disease activity and clinical markers of inflammation in pts without flare.

Methods: C-OPTIMISE (NCT02505542) study design has been described previously.¹ Adult pts with early (<5 years' symptom duration) active axSpA received open-label CZP 200mg every 2 weeks (wks; Q2W) for the first 48 wks; from Wk48 pts who achieved sustained remission (ASDAS<1.3 at Wk32/36 and Wk48) were randomised 1:1 to double-blind CZP 200mg Q2W (full maintenance dose), CZP 200mg every 4 weeks (Q4W; reduced maintenance dose) or placebo (PBO) for a further 48 wks (maintenance period).

Flare was defined as ASDAS_{CRP}≥2.1 at two consecutive visits or ASDAS_{CRP}>3.5 at any visit. We report disease activity (ASDAS, BASDAI) and objective markers of inflammation (CRP, faecal calprotectin) during Wks48–96 in pts who completed Wk96 without flare.

Results: 313 pts entered the maintenance period. 197 (62.9%) completed Wk96 on randomised treatment without experiencing a flare (CZP 200mg Q2W: 89/104 [85.6%]; CZP 200mg Q4W: 84/105 [80.0%]; PBO: 24/104 [23.1%]). During Wks48–96, disease activity (ASDAS, BASDAI) and CRP levels were comparable between the CZP full and reduced maintenance dose group, and lower in both CZP arms than PBO. In Wks60 to Wk96, PBO pts who did not flare had consistently higher mean ASDAS (1.4 at Wk96) versus (vs) CZP-randomised pts (CZP 200mg Q2W: 1.0; CZP 200mg Q4W: 1.1), as well as BASDAI (1.2 vs 0.8 and 0.8) and CRP levels (3.7mg/L vs 2.3 and 2.9). A greater increase in faecal calprotectin levels between Wks48 and 96 was observed in the PBO arm (Δ49.5μg/g) vs both CZP arms (CZP 200mg Q2W: Δ18.2μg/g, CZP 200mg Q4W: Δ11.6μg/g).

Conclusion: Despite not meeting flare threshold, consistently higher disease activity and increases in serologic and inflammatory biomarkers were observed in PBO-randomised pts who did not experience a flare vs those who remained on CZP. These findings confirm that pts with axSpA who achieve sustained remission benefit from continued CZP treatment (full or reduced maintenance dose), over treatment withdrawal.

Reference:

¹ Landewé RBM. *Ann Rheum Dis* 2020;79:920–8

P 23

Effect of Upadacitinib on Reducing Pain in Patients With Active Ankylosing Spondylitis and Inadequate Response to Nonsteroidal Anti-inflammatory Drug

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Background: Pain is a debilitating symptom of AS & negatively impacts patient lives. Upadacitinib (UPA) showed significant efficacy vs placebo (PBO) in the randomized phase 2/3 SELECT-AXIS 1 study. The objective of this analysis was to evaluate the efficacy of UPA on multiple pain assessments through 64 weeks (wks).

Methods: SELECT-AXIS 1 enrolled pts with active AS, who had an inadequate response, intolerance/contraindications to ≥2 NSAIDs, were bDMARD-naïve & met the modified New-York Criteria. Pts were randomized 1:1 to UPA 15mg once daily (QD, n = 93) or PBO (n = 94) for 14 wks (Period 1), followed by open-label UPA 15mg QD during 90-wk extension (Period 2); reported here are data through wk 64. Pain endpoints included the proportion of pts achieving ≥30%/≥50%/≥70% reduction in PGA of pain (0–10 NRS), minimal clinically important difference (MCID)

& much better improvement (MBI) in PGA of pain as well as mean change from BL in PGA of pain, BASDAI questions 2&3, and pt's assessment of total back & nocturnal back pain (0–10 NRS). NRI (binary endpoints) & mixed-effects model for repeated measurements (continuous endpoints) were used for missing data (Period 1); as-observed analysis for Period 2.

Results: A significantly higher proportion of pts with UPA vs PBO achieved reductions in all pain assessments as early as wk 2 that was sustained at all time points in Period 1; (exception ≥70% reduction in PGA of pain significant at wk 4 & sustained thereafter). For ≥30%/≥50%/≥70% reduction & MBI, the response rate increased over time with UPA; the difference for UPA vs PBO increased over time for ≥50% & ≥70% reduction endpoints. For MCID, an increase from BL to wk 2 was observed & plateaued thereafter. The mean change from BL in PGA of pain, BASDAI Q2, total back & nocturnal back pain NRS scores were significantly greater for UPA vs PBO at all time points (Period1). The mean change from BL in BASDAI Q3 was significantly greater for UPA vs PBO starting from wk 8. The effect of UPA on pain reduction was sustained through wk 64. PBO pts who switched to UPA at wk 14 generally reached the same level of pain reduction as those initially randomized to UPA.

Conclusion: In SELECT-AXIS 1 greater proportion of pts treated with UPA achieved rapid, significant & clinically meaningful reductions in pain vs PBO through 14 wks across multiple pain assessments. Reductions in pain were sustained over time & pts switched (PBO to UPA) reached same levels of improvement as continuous UPA.

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Efficacy and Safety of the Adjuvanted Recombinant Zoster Vaccine in Adults with Pre-existing Potential Immune Mediated Diseases: a Pooled Post-hoc Analysis on Two Parallel Randomized Trials

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In 2 pivotal studies, ZOE-50 (NCT01165177) & ZOE-70 (NCT01165229), the adjuvanted recombinant zoster vaccine (RZV) proved to be efficacious against herpes zoster (HZ) in adults ≥50 years of age (Y), with no identified safety concerns, irrespective of the pre-existing medical conditions at enrollment. This post-hoc analysis was performed to evaluate the impact of any pre-existing potential immune mediated diseases (pIMDs) on RZV efficacy (VE) against the first or only episode of HZ & on RZV safety. The ZOE-50 & ZOE-70 studies were phase 3, observer-blind, placebo-controlled, randomized trials conducted in 18 countries. Adults ≥50Y (ZOE-50) and ≥70Y (ZOE-70) received 2 intramuscular doses of RZV or placebo 2 months apart. This post-hoc analysis was performed on the pooled ZOE 50/70 population to evaluate VE overall and by age strata, and safety in participants that had at least 1 pIMD at enrollment. Participants with pre-existing pIMDs were identified by querying the global medical history of the participants included in the total vaccinated cohort (TVC) with a customized MedDRA query for pIMDs. VE was estimated in the modified TVC, which excluded participants who did not receive the second RZV dose or who had a confirmed HZ episode within 1 month after the dose 2. Safety was evaluated in the TVC, which included all participants who received at least 1 RZV dose or placebo. Here, we present serious adverse events (SAEs) & SAEs with fatal outcome reported up to 1 year post-last vaccination.

The pooled TVC included 14,645 RZV and 14,660 placebo recipients. Of TVC, 983 (RZV) and 960 (placebo) participants had pre-existing pIMDs, the majority of these (59.9%, RZV; 60.8%, placebo) were females. VE for participants ≥50Y with at least 1 pIMD at enrollment was 90.5% (95% confidence intervals: 73.5–97.5%) for the modified TVC. High VE against HZ was maintained in all age groups: 50–59Y (92.8%), 60–69Y (100%), 70–79Y (84.4%) and ≥80Y (86.2%). SAEs were reported by 144 (14.6%) RZV and 112 (11.7%) placebo recipients and SAEs with fatal outcome were reported for 12 (1.2%) RZV and 9 (0.9%) placebo recipients with pre-existing pIMDs at enrollment.

This analysis demonstrated that RZV efficacy in adults $\geq 50Y$ is not impacted by the presence of pre-existing pIMDs at enrollment. There were no differences in the proportion of reported SAEs or fatal SAEs between RZV and placebo recipients with pre-existing pIMDs.

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P 25

Efficacy of Upadacitinib in Patients with Psoriatic Arthritis Stratified by Baseline Skin Severity: A Subgroup Analysis of Two Phase III Trials

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Background: In the SELECT-PsA 1 & 2 clinical trials, upadacitinib (UPA) demonstrated efficacy & safety in patients (pts) with active psoriatic arthritis (PsA).^{1,2} PsA is associated with varying degrees of psoriatic symptoms; however, the impact of skin severity on treatment outcomes is not well understood.

Objective: This post-hoc analysis assessed the effects of baseline (BL) skin severity on UPA efficacy.

Methods: SELECT-PsA 1 & SELECT-PsA 2 enrolled pts with PsA and prior inadequate response (IR) or intolerance to ≥ 1 non-biologic disease-modifying antirheumatic drug (DMARD)1 or ≥ 1 biologic DMARD2, respectively. In both trials, pts received once daily UPA15 mg or UPA30 mg or placebo (switched at Wk 24 to either UPA15mg or 30 mg); SELECT-PsA 1 also included the active comparator adalimumab (ADA). Only continuous UPA 15 mg & ADA are presented here. In this analysis, pts were divided into subgroups based on the extent of psoriasis at BL (BSA of $\geq 3\%$ - $<10\%$ or BSA $\geq 10\%$); efficacy endpoints were analyzed at Wk 56. Results for binary endpoints are based on non-responder imputation; continuous endpoints are based on mixed model repeated measures analysis with as-observed data.

Results: In the UPA 15 mg & ADA groups, respectively, 32% (138/429) and 31% (132/429) of pts had a BSA $\geq 3\%$ - $<10\%$ at BL in SELECT-PsA 1; 18% (76/429) in each treatment group had a BSA $\geq 10\%$. In SELECT-PsA 2, 38% (80/211) had a BSA $\geq 3\%$ - $<10\%$ and 24% (50/211) had a BSA $\geq 10\%$ at BL in the UPA15 mg group. Across pt populations (non-biologic DMARD-IR & biologic DMARD-IR), generally consistent results were observed between pts in both skin severity subgroups. In non-biologic DMARD-IR pts, a numerically greater proportion of UPA15mg pts with lower skin involvement compared with higher skin involvement achieved PASI100 & PASI ≤ 1 , two more stringent skin endpoints. The achievement of MDA was generally consistent across skin severity subgroups; when pts were required to achieve the skin component of MDA, results were numerically better in the $\geq 3\%$ - $<10\%$ skin severity group. In non-biologic DMARD-IR pts, results were similar between UPA15 mg & ADA.

Conclusion: UPA is a viable treatment option for pts with active PsA regardless of the extent of psoriasis at BL. Although these results are of interest & hypothesis-generating, they should be interpreted with caution due to low sample size.

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Efficacy of Upadacitinib in Patients with Psoriatic Arthritis Stratified by Number of Prior Biologic Disease-modifying Antirheumatic Drugs

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Background/Purpose: Upadacitinib (UPA) has shown efficacy & safety in patients (pts) with active PsA in the Phase 3 SELECT-PsA 1 & -PsA 2 clinical trials. Historically efficacy has been lower with 2nd- & 3rd-line therapy compared with 1st-line TNFi therapy in PsA; however, clinical trial data that describe therapy efficacy in pts who have had an inadequate response (IR) to multiple bDMARDs are limited. This analysis assessed the effects of prior bDMARD failure on UPA efficacy in the SELECT-PsA 2 trial

Methods: SELECT-PsA 2 enrolled pts with prior IR or intolerance to ≥ 1 bDMARD (N = 642). Pts were randomized to placebo (PBO), UPA15mg QD, or UPA30mg QD. Stable background treatment of ≤ 2 non-bDMARDs was permitted; Only the pts who had IR to ≥ 1 bDMARD were included in this analysis; pts were subgrouped based on the number of bDMARDs failed prior to enrollment (1, 2, or ≥ 3). This analysis includes assessment of proportion of pts achieving ACR20/50/70, & change in HAQ-DI, FACIT-Fatigue & SF-36 Physical Component Summary at Wk12; static Investigator Global Assessment of Psoriasis of 0 or 1 and at least a 2-point improvement from baseline, PASI75, & change in Self-Assessment of Psoriasis Symptoms at Wk16; and proportion of pts achieving minimal disease activity (MDA) at Wk24. NRI was used for binary endpoints. Mixed-effects model for repeated measures was used for continuous endpoints. Point estimates & 95% CIs of the PBO subtracted treatment effect were calculated.

Results: 641 pts were randomized; 92% were bDMARD-IR: 391 (61%) of pts failed 1 bDMARD, 116 (18%) failed 2 bDMARDs, and 83 (13%) failed ≥ 3 bDMARDs. In the overall study population, UPA15 and UPA30 demonstrated superiority vs PBO for all endpoints evaluated. In this post hoc analysis, the PBO subtracted treatment effect demonstrates generally consistent efficacy as compared to the overall study population for UPA15 and UPA30 across efficacy endpoints in the subgroups of pts with IR to 1, 2, or ≥ 3 prior bDMARDs. Due to limited sample sizes for pts with IR to >1 bDMARD & the pt subsets analyzed for psoriasis-related endpoints, results should be interpreted with caution.

Conclusion: UPA demonstrated consistent efficacy in treating clinical manifestations of PsA including musculoskeletal symptoms, psoriasis, physical function, fatigue, and quality of life in pts with IR to 1 or multiple prior bDMARDs. Additionally, MDA was generally consistently achieved with UPA regardless of number of prior bDMARDs tried.

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Predictors of Response in Patients with Non-Radiographic Axial Spondyloarthritis Receiving Certolizumab Pegol in the C-axSpAnd Study

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Background: Identification of predictive clinical factors of long-term treatment response in non-radiographic axial spondyloarthritis (nr-axSpA) may contribute to improved management of patients (pts). We investigate whether any demographic or baseline characteristics of nr-axSpA patients from the C-axSpAnd study are predictive of achieving clinical response after 1 years' certolizumab pegol (CZP) treatment.

Methods: C-axSpAnd (NCT02552212) is a phase 3, interventional multi-center study including a completed 52-week (Wk) double-blind, placebo (PBO)-controlled period. Multivariate stepwise logistic regression was used to identify predictors of response. Primary efficacy variable: ASDAS-major improvement (ASDAS-MI) at Wk52; secondary efficacy variable: ASAS40 at Wk52 in pts randomised to CZP 200mg every 2 weeks (Q2W). Predictive factors used in the model included demographic and baseline characteristics and clinical outcomes at Wk12. A p value ≤ 0.05 was required for forward selection; $p = 0.1$ for backward elimination. Non-responder imputation was used to account for missing data or values collected after switching to open-label treatment. A sensitivity analysis was conducted to account for pts who had changes in non-biologic background medication during the 52-wk PBO-controlled period.

Results: 159 pts were randomised to CZP 200mg Q2W, 158 to PBO. Predictive factors identified for Wk52 ASDAS-MI in CZP-treated pts included positivity for both sacroiliitis on MRI and human leukocyte antigen (HLA)-B27 (Odds ratio [OR]: 5.78; 95% Wald confidence limit: 1.59–20.98), higher BASDAI at baseline (OR: 1.91; 1.30–2.80), and larger Wk12 ASDAS improvement (OR: 0.14; 0.07–0.29). For ASAS40 response, MRI+/HLA-B27+ was also identified as a predictor of Wk52 response (OR: 4.75; 1.58–14.28), along with a lower baseline BASMI (OR: 0.71; 0.50–0.999) and larger Wk12 improvements in PtGADA (OR: 0.74; 0.61–0.90) and ASQoL (OR: 0.02; 0.002–0.21). Sensitivity analysis identified the same predictors for ASDAS-MI and ASAS40, except for change from baseline in PtGADA as a predictor of ASAS40. Sensitivity analysis also identified Wk12 ASAS40 achievement as a predictor of Wk52 ASAS40. In PBO pts no meaningful predictors of response at Wk52 were identified.

Conclusion: Presence of sacroiliitis on MRI and HLA-B27 positivity were identified as consistent predictors of Wk52 response (ASDAS-MI and ASAS40) in nr-axSpA pts treated with CZP.

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Predictors of response: Baseline characteristics and early treatment responses associated with achievement of remission and low disease activity among upadacitinib-treated patients with rheumatoid arthritis

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Background: Upadacitinib (UPA) 15 mg once daily (QD) has demonstrated efficacy in phase 3 studies of patients (pts) with RA. Early prediction of response to treatment with UPA could optimize therapy.

Objectives: To identify baseline (BL) characteristics or Week (Wk) 12 disease activity measures that may predict achievement of remission (REM) or low disease activity (LDA) at 6 months in pts with RA receiving UPA15 mg.

Methods: This ad hoc analysis included pts who were randomized to UPA15 mg QD as monotherapy in MTX-naïve pts or in combination with csDMARDs, in pts with inadequate response (IR) to MTX or ≥ 1 TNFi. The association of BL characteristics & Wk12 disease activity parameters with the achievement of CDAI REM (≤ 2.8) or LDA (≤ 10) at Wk24 or 26 was assessed by concordance statistics or area under the receiver operator characteristic curve. C-index values & 95% CIs were calculated by fitting a univariate logistic regression model for demographic & BL characteristics, Wk12 disease activity measures, & change from BL at Wk12 in disease activity measures. A multivariate logistic regression

with stepwise model selection was also performed. Proportion of pts achieving Wk24/26 CDAI REM/LDA was stratified by $\geq 50\%$ improvement from BL in SJC66/TJC68.

Results: 1377 pts were included in the analysis. Across the 4 studies, CDAI REM and LDA were achieved in 11.0–28.4% and 50.0–58.6% of pts, respectively. BL demographics & disease characteristics were weakly predictive (C-index < 0.70) of Wk 24/26 CDAI REM (C-index 0.49–0.69) or LDA (C-index 0.47–0.65). Changes from BL in disease activity measures at Wk12 were weakly or moderately predictive of Wk24/26 CDAI REM or LDA. CDAI value at Wk12 was strongly predictive (C-index > 0.80) of Wk 24/26 CDAI REM or LDA. Disease Activity Score in 28 joints using CRP & pain at Wk12 were strongly predictive of Wk24/26 CDAI REM (except in SELECT-CHOICE). Physician's global assessment at Wk12 was the only common predictor in multivariate regression models for CDAI REM/LDA at Wk24/26 across the studies. Greater proportion of pts achieving $\geq 50\%$ improvement in SJC66/TJC68 at Wk12 achieved CDAI REM (16.5–37.8%vs0–9.4%) or LDA (66.0–72.8%vs20.9–35.7%) at Wk24/26 than those who did not.

Conclusion: BL characteristics did not strongly predict response to UPA, but composite disease activity scores at Wk12 predicted Wk24/26 REM/LDA with UPA across different pts populations. $\geq 50\%$ improvement in SJC/TJC at wk12 was associated with Wk24/26 REM/LDA.

P 29

Real-World Effectiveness of Baricitinib in the Swiss Rheumatoid Arthritis Register (SCQM-RA)

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Objectives: To analyze the effectiveness of BARI (a targeted synthetic DMARD [tsDMARD]) versus biological DMARDs (bDMARDs), as assessed by drug maintenance over time and by response rates at 12 months.

Methods: This is a nested study of rheumatoid arthritis (RA) patients within the prospective Swiss Clinical Quality Management (SCQM) observational cohort. All treatment courses (TC) with BARI or bDMARDs initiated between 2017-09-01 and 2020-06-01, with at least 1 follow-up visit, were included. TC with BARI were compared to TC with alternative bDMARDs (non-BARI), including all b/tsDMARDs except rituximab. The non-BARI group was then subdivided into TNF inhibitors (TNFi) and other mode of action bDMARDs (OMA), excluding tsDMARDs. A secondary analysis focusing specifically on b/tsDMARD naïve patients was conducted. Baseline characteristics were compared using ANOVA or chi2 tests. An adjusted Cox-model survival analysis assessed drug maintenance. 12-month response rates were estimated using an attrition-corrected, confounder-adjusted approach. CDAI score ≤ 10 defined low disease activity state (LDA), and CDAI score ≤ 2.8 defined remission.

Results: Overall, 1218 eligible TC were initiated during the study period (273 in BARI, 154 other tsDMARD, 473 in TNFi and 318 in OMA). Drug maintenance was significantly shorter for TNFi compared to BARI, even after adjustment for potential confounders (Hazard ratio (HR) for drug discontinuation 1.85 (95% CI [1.40–2.43]); $p < 0.001$). Drug maintenance was also numerically shorter for the OMA group compared to BARI, but the difference was not significant (HR 1.18 (95% CI [0.87–1.60]); $p = 0.28$). These differences were larger when analysing only bDMARD-naïve patients. All TC taken together, the rates of LDA and remission did not differ significantly between the 3 groups at 12 months. LDA ranged from 63% to 67% (BARI vs OMA $p = 0.87$; BARI vs TNFi $p = 0.81$) and remission from 19% to 23% (BARI vs OMA $p = 0.30$; BARI vs TNFi $p = 0.77$).

Conclusions: BARI demonstrated a significantly higher overall drug maintenance than TNFi, and a similar drug maintenance to OMA, both in a bDMARD-naïve population and in the overall population. The adjusted 12-month response rates did not differ between BARI, TNFi and OMA groups. These results suggest that prescription of BARI after conventional synthetic DMARD (csDMARD) has at least similar outcomes as alternative bDMARDs.

P 30

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 & safety of upadacitinib (UPA) in patients (pts) with active psoriatic arthritis (PsA) were demonstrated through 24 weeks in the phase 3 SELECT-PsA 1 & -PsA 2 placebo-controlled clinical trials.

Objective: 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 bDMARD (SELECT-PsA 2). Both trials include UPA 15mg & 30mg, only SELECT-PsA 1 includes long-term comparison with ADA 40mg EOW. Treatment-emergent adverse events (TEAEs) were summarized for: pooled UPA15; pooled UPA30; & ADA. TEAEs are reported as exposure-adjusted event rates (EAERs; events/100 pts years [E/100 PY]) up to a cut-off date of 06/2020.

Results: 2257 pts received ≥ 1 dose of UPA15 (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 & serious AEs were generally similar between UPA15 & ADA & higher with UPA30; rates of AEs leading to study drug discontinuation were similar across all groups. Similarly, rates of serious infection were comparable between UPA15 & ADA & higher with UPA30. The most common serious infection was pneumonia. Rates of herpes zoster were lower with UPA15 than UPA30 but higher than ADA. Lower rates of opportunistic infections (OI) excluding tuberculosis were observed with UPA15 vs UPA30; the most common OI was mucosal candida infection. Malignancies were reported at similar rates across all treatment groups. Rates of adjudicated MACE & VTEs were ≤ 0.3 E/100 PY for both UPA arms; all pts had ≥ 1 risk factor. One adjudicated GI perforation was reported with UPA15.

Hepatic disorders were mostly transient, non-serious transaminase increases. CPK elevations were reported more frequently with UPA30 vs UPA15; most were asymptomatic; no rhabdomyolysis reported. Study drug discontinuation due to lab-related TEAEs was uncommon.

Conclusion: Safety profiles of UPA15 & ADA were generally similar; the rates of most AEs were higher with UPA30 vs ADA. Through the cut-off date, the safety profile of UPA15 & UPA30 in PsA pts demonstrated consistent results compared to what has been observed with UPA in rheumatoid arthritis.

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P 31

Upadacitinib as Monotherapy and in Combination with non-biologic DMARDs for the Treatment of Psoriatic Arthritis: Subgroup Analysis from Two Phase 3 Trials

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Background: Approximately 40% of PsA patients (pts) on advanced therapy are on monotherapy. Upadacitinib (UPA) has shown efficacy & safety in pts with active PsA in the Phase 3 SELECT-PsA 1 & -PsA 2 trials. This analysis assessed the efficacy & safety in the subgroups of pts who were treated with UPA monotherapy or in combination with non-bDMARDs.

Methods: The SELECT-PsA program enrolled pts with prior inadequate response (IR) or intolerance to ≥ 1 non-bDMARD (N = 1705) & prior IR or intolerance to ≥ 1 bDMARD (N = 642). Data from both trials was integrated for pts receiving PBO, UPA 15mg QD & UPA 30mg QD; This analysis includes comparison of UPA monotherapy & combination therapy for the endpoints: ACR20/50/70 responses & change from BL in pain & HAQ-DI (Wk12); Static Investigator Global Assessment of Psoriasis of 0 or 1 and at least a 2-point improvement from BL & PASI75/90/100 responses (wk16); proportion of pts achieving resolution of enthesitis, dactylitis, & minimal disease activity (wk24). Binary outcomes were analyzed using the Cochran-Mantel-Haenszel-method & continuous outcomes were analyzed using mixed-effects model for repeated measures in the subgroups of UPA monotherapy & combination therapy. Point estimates & 95% CIs of the PBO subtracted treatment effect were calculated. Treatment-emergent adverse events (TEAEs) were analyzed & summarized through wk24.

Results: Of the 1916 pts included in the analysis, 574 (30%) received monotherapy & 1342 (70%) received combination therapy; 84% in the combination therapy group received MTX +/- another non-bDMARD. Both UPA monotherapy & combination therapy led to improvements in efficacy outcomes vs PBO. Across endpoints, for each UPA dose, generally consistent point estimates of the PBO subtracted treatment effect & associated overlapping CIs were observed between pts on UPA monotherapy & those on combination therapy. Generally, the frequency of AEs were comparable with UPA when administered as monotherapy & combination therapy. The frequency of AEs of serious infections & hepatic disorder were lower with monotherapy while the frequency of AEs leading to discontinuation of study drug were lower with combination therapy.

Conclusion: In the SELECT PsA Phase 3 trials, efficacy & safety of UPA was generally consistent when administered as monotherapy or when given in combination with non-bDMARDs. Results from this analysis support the use of UPA with or without concomitant non-bDMARDs.

P 32

Achievement of Low Disease Activity According to BASDAI with Ixekizumab in Patients with Axial Spondyloarthritis: 16-Week Results from the COAST Trials

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Background: The efficacy of ixekizumab (IXE), a selective interleukin-17A antagonist, was assessed in patients (pts) with axial spondyloarthritis (axSpA) in three Phase 3, randomized, double-blind, placebo (PBO)-controlled trials, COAST-V, COAST-W, and COAST-X. The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) is frequently used by clinicians to measure disease activity and response to treatment in pts with axSpA, and when considering starting biologic DMARD therapy. We present BASDAI and quality of life (QoL) outcomes at 16weeks from the COAST trials.

Methods: COAST-V (NCT02696785) and COAST-W (NCT02696798) assessed pts with radiographic axSpA, and COAST-X (NCT02757352) assessed pts with non-radiographic axSpA. All pts fulfilled Assessment of Spondyloarthritis International Society (ASAS) classification criteria for

axSpA. Pts were either biologic-naïve (COAST-V, COAST-X) or TNF α inhibitor-experienced (COAST-W) and were randomized to IXE (80 or 160mg at week 0 then 80mg every 2 or 4weeks [Q2W, Q4W]) or PBO or adalimumab (ADA, 40mg Q2W; COAST-V only). Treatment response at week16 was assessed by the proportion of patients achieving BASDAI<4, 50% reduction from baseline in BASDAI (BASDAI50), and a clinically meaningful change from baseline in BASDAI of at least 2units (Δ BASDAI \geq 2). Categorical variables were analyzed by logistic regression with non-responder imputation (NRI) for missing data. QoL was assessed by change from baseline in Short Form (SF)-36 Physical Component Summary (PCS) scores according to BASDAI<4 response status at week 16; missing data were imputed using modified baseline observation carried forward (mBOCF).

Results: In total, 341 pts from COAST-V, 316 from COAST-W, and 303 from COAST-X were included in this analysis. At week16, a greater proportion of pts treated with IXE achieved BASDAI<4, BASDAI50, and Δ BASDAI \geq 2 compared to PBO across all three trials, and the difference was statistically significant for the majority of endpoints. Furthermore, pts achieving BASDAI<4 showed greater improvements in SF-36 PCS scores.

Conclusion: In the COAST trials, IXE delivered clinically meaningful improvements in pts with axSpA after 16weeks of treatment. Low disease activity (BASDAI<4) was achieved with IXE regardless of axSpA type (radiographic or non-radiographic) or prior use of TNF α inhibitors. Achieving BASDAI<4 was associated with greater improvements in physical QoL.

HPR

HPR 1

Do we assess systematically enough? Evaluating assessments in the context of a low back pain programmeMeier Zürcher Christine¹, Baschung Pfister Pierrette^{1,2}¹Physiotherapie Ergotherapie Universitätsspital Zürich (PEU); ²Forschungszentrum Physiotherapie Ergotherapie, Direktion Forschung und Lehre, Universitätsspital Zürich

Introduction: In the treatment of patients with low back pain, assessments (AS) are essential to evaluate outcomes and to adapt the rehabilitation procedure to the patients' needs. We launched a programme (BPR) for patients with nonspecific low back pain (LBP) at the University Hospital Zürich. We performed AS before (T1) and after the BPR (T2). Our aim was to (a) evaluate the systematic use of AS and to determine the difference of AS outcomes between T1 and T2, and (b) to compare the AS of our BPR with recommendations from the literature.

Methods: We retrospectively determined the number and the date of AS during two years. To find out the difference of AS outcomes before and after treatment, we used the Oswestry Disability Index (ODI) for physical function (PF), the Keele STarT Back screening Tool (KSBT), a strength tests (Tergumed) and a cardiovascular fitness test (IPN). To identify recommended AS tools and to compare them with tools of our BPR, we performed a "rapid review" (PubMed, PEDro, COSMIN).

Results: 55 patients completed the BPR (mean [SD] 43 [11] years). At T1, 65% of all participants had answered the KSBT questionnaire and 75% the ODI; 69% had performed at least one of the strength tests, and 33% the IPN test. At T2 only 7.3-45% of AS were conducted. Eight patients completed the ODI for a second time and had improved with 10.5 (mean) points (95%CI 4.2-16.8, $p = 0.006$). Their strength had significantly enhanced from 1.5 to 3 N per kg bodyweight (median). The number varied from 7 to 20 participants per test. Our literature review yielded 14 guidelines.

The most often cited AS tools were Numeric Rating Scale (NRS) for pain, ODI or Roland and Morris Disability Index for PF and KSBT. The literature recommended measuring strength and fitness, beside other constructs.

Discussion: Since the proportion of missing AS is high, it was not possible to draw conclusions about the efficacy of the BPR. Few patients with two AS showed improved outcomes at T2. According to the literature, ODI and KSBT are good options for assessing LBP. Additionally, NRS for pain should be used. Psychometric properties of the Tergumed and IPN are questionable. Therefore, validity and reliability are important criteria for selecting a test in the context of evaluation. Implications: A high number of missed assessments is a challenge for evaluation, and therefore, it is indispensable to ensure systematic and timely assessments. The selection of AS tools should be literature-based

HPR 3

Systemische Sklerose – Big PictureAlbin S^{1,2}, Strahm (Furler) L¹¹Universitätsklinik für Rheumatologie und Immunologie, Insel Gruppe AG, Bern, Switzerland; ²Departement Gesundheit, Berner Fachhochschule, Bern, Switzerland

Ausgangslage: Die Systemische Sklerose ist ein heterogenes, komplexes und chronisches Krankheitsbild. Der Verlauf und die damit verbundenen Symptome können sehr unterschiedlich ausgeprägt sein. Entsprechend ist eine multimodale und individuell abgestimmte Therapie erforderlich. Neben der medikamentösen Behandlung werden nichtmedikamentöse und präventive Massnahmen getroffen, wobei eine ausgebaute Symptombekämpfung von zentraler Bedeutung ist. Betroffene wünschen und brauchen eine umfassende Aufklärung und Beratung durch Fachpersonen. Hierzu ist ein informiertes und spezialisiertes Betreuungsteam unerlässlich. Die Fluktuationen im Behandlungsteam stellen eine Herausforderung an die Kontinuität dieses spezialisierten Wissens dar. Deshalb haben zwei Fachhochschulstudierende im Rahmen eines Praxisprojektes eine Übersicht zum Krankheitsbild Systemische Sklerose, Symptomen und Massnahmen als Poster erstellt.

Methode: Es wurde eine Literaturrecherche durchgeführt. Die Darstellung der Ergebnisse mit den Schwerpunkten Krankheitsbild, Symptome und pflegerische Massnahmen erfolgte grafisch auf einem Poster.

Ergebnisse: Das erstellte Poster wurde auf der Station ausgehängt. Zudem wurde das Krankheitsbild im Rahmen einer internen Weiterbildungssequenz dem Pflorgeteam präsentiert.

Schlussfolgerungen: Das Poster mit einem Überblick zum Krankheitsbild der Systemischen Sklerose ist allen Pflegefachpersonen zugänglich und dient zur Wissensvermittlung im Team und der Kontinuität des Fachwissens. Die interne Weiterbildung zur Thematik mit Präsentation des Posters wurde von den Teilnehmerinnen geschätzt. Ihr Fachwissen wurde aufgefrischt und erweitert. Diese Rückmeldungen und der Wissenszuwachs decken sich mit den Erkenntnissen von Stadler-Altman. Sie hält fest, dass mit der Wissensvermittlung per Poster ein positiver Lerneffekt erzielt wird, sowohl zur Wissensaneignung als auch zur Steigerung der Kompetenz des Präsentierens (2020).

Die Aufarbeitung des Krankheitsbilds Systemische Sklerose als Poster und die interne Weiterbildung werden von vielen Seiten als Erfolg gewertet. Ausblickend stellt sich daher die Frage, ob eine derartige Bearbeitung weiterer rheumatischer Krankheitsbilder sinnvoll ist. Ob das Poster, ergänzend zu Informationsbroschüren und Beratungsangeboten, auch für betroffene Patientinnen und Patienten einen wesentlichen Mehrwert bieten könnte und ihnen zugänglich gemacht werden soll, gilt es noch zu evaluieren.

HPR 4

Feasibility of a blended therapy approach in the treatment of patients with inflammatory myopathies

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Background: Inflammatory myopathies (IMs) are a group of rare conditions characterized by proximal and often symmetrical muscle weakness and reduced muscle endurance. The recommended medical treatment is based on corticosteroids in combination with immunosuppressants. This anti-inflammatory therapy serves to inhibit and prevent inflammation but does not influence impaired muscle strength. Exercise, particularly progressive resistance training, plays therefore an important role in IMs management.

Blended therapy, a combination of face-to-face treatment and telerehabilitation, may be a powerful therapy option in improving exercise program adherence in these patients.

Methods: The feasibility of a 12-week interactive tablet-based home exercise program combined with face-to-face therapy sessions – a ‘blended therapy’ approach – was evaluated using a quasi-experimental one-group pre-post comparison design. Primary outcomes were recruitment, attrition and adherence rates, plus measures of acceptance (Technology Acceptance Model Questionnaire (TAM)) and satisfaction (satisfaction questionnaire). Secondary outcomes comprised potential effects of the intervention on muscle strength and function, activity limitation, disability and health-related quality of life.

Results: Thirteen of the included 14 participants completed the study without any related adverse events. Mean adherence to exercise program was 84% (range: 25–100%) and participants indicated high acceptance of the intervention with mean TAM scores between 6.1 and 6.5 points. Overall satisfaction with the therapy sessions, the home program, and the technology was good. Approximately half the participants wished for longer training periods and more training sessions per week. There were inconsistent effects on muscle strength, muscle function, activity limitation, disability, and health-related quality of life.

Conclusion: Blended therapy combining the use of an interactive tablet-based resistance training program with face-to-face therapy sessions is feasible and safe and participants’ acceptance with this approach was high. Furthermore, results were obtained that might be useful in selecting appropriate assessments and sample sizes in future trials.

HPR 5

Patient and healthcare professional eHealth literacy and needs for systemic sclerosis support – a mixed methods study

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Introduction: Internet-based information and communication technologies (ICT) have become increasingly important for improving health. To inform development of an enhanced electronic health (eHealth) model of care for systemic sclerosis (SSc), we aimed to assess eHealth literacy of patients and health professionals as well as needs on web-based support.

Methods: We employed an explanatory sequential mixed methods design. First, we conducted a quantitative cross-sectional survey in patients (n = 101) and professionals (n = 47). Next, we conducted three qualitative focus groups with patients, family members and professionals (n = 17, Swiss/international) to explain survey findings in depth.

Results: Quantitative findings indicate patients and professionals are well-versed with ICT. In total, 89.1% of patients used ICT at least weekly for private communication (but not health purposes). Patients reported relatively high comprehension of eHealth information (mean = 6.7, 95% CI 6.2–7.3, 10-point scale), yet were less confident evaluating information reliability (mean = 5.8, 95% CI 5.1–6.4) and finding eHealth apps (mean = 4.8, 95% CI 4.2–5.4). Patients and professionals reported little experience with web-based self-management support.

Focus groups revealed “considering non-ICT-accessible groups” and “fitting patients’ and professionals’ technology” as crucial for acceptability. In relation to understanding/appraising eHealth, participants highlighted that general SSc-information is not tailored to individuals’ disease course. Recommendations included “providing timely, understandable, and safe information” and “empowering end-users in ICT and health decision-making skills” to avoid harmful experiences and ensure eHealth sustainability. Professionals expressed concerns about lack of resources while patients were concerned about data security and person-centredness. eHealth drivers included “addressing perceptions of end-users” and “putting people at the centre of technology”.

Conclusions: Interoperability of patient/provider technology and design that is responsive to end-user needs appears to be critical for developing eHealth interventions. Patients and professionals need systematic education and training to promote uptake. Key elements include guiding patients to safe, reliable information in a timely manner and using eHealth to optimize patient-provider communication. To ensure equity, design must consider individuals who have limited eHealth literacy and/or lack access to ICT.

HPR 6

A Comparison of Low Back Pain Patient Characteristics stratified by Diagnostic Imaging at the Kantonsspital Winterthur's Medical Unit

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Introduction: Patients with low back pain (LBP) admitted to the general medical unit (MU) at the Kantonsspital Winterthur (KSW) are treated according to the clinical pathway for LBP. The clinical pathway aims to facilitate transdisciplinary LBP management. At present, however, it is not known how often and in which patients diagnostic imaging (DI) is prescribed.

Objectives: The primary objective is to determine the frequency of patients with LBP receiving DI who are hospitalized at MU at KSW. The secondary objective is to explore differences in patient data collected through the clinical pathway between patients receiving DI and those not receiving DI.

Method: Patients with LBP admitted to MU were given a set of questionnaires assessing psychological profile, pain, disability and prognostic risk. Medical diagnoses were collected through the KSW's electronic medical records. Differences between patients without and with DI were analyzed using T-test, U-test or Chi-squared.

Results: Of the 159 patients 57.9% received DI whereas 42.1% did not. Significant differences between patients without and with DI were found for age (60.8 vs. 68.6; $p = 0.006$), comorbidities (1.54 vs 2.09; $p = 0.015$), specific LBP (10.4% and 23.9% $p = 0.030$), distress (12.57 vs 9.29; $p = 0.039$), anxiety (3.37 vs 2.13; $p = 0.022$), pain episode duration ($p = 0.026$) and length of stay (6.07 vs 9.12; $p < 0.001$). No significant differences were found for sex (61.2% vs 51.1%; $p = 0.206$), depression (2.62 vs 1.82; $p = 0.103$), somatization (10.72 vs 9.72; $p = 0.220$), kinesiophobia (35.64 vs 35.26; $p = 0.826$), psychological comorbidity (25.4% vs 21.7%; $p = 0.592$), disability (13.27 vs 12.49; $p = 0.496$), pain intensity (7.96 vs 7.5; $p = 0.163$), prognostic risk ($p = 0.833$).

Conclusion: Fewer patients receive DI at KSW in comparison with other acute care hospitals. Patients who received DI were older, showed more comorbidities, distress & anxiety than patients without DI.

HPR 7

Prognostic validity of the SELF instrument (Self Evaluation of Functional Capacity) regarding non-return to work in patients with musculoskeletal pain syndromes

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Background: Musculoskeletal pain syndromes (MSDs) are among the main causes of long-term work disability and early retirement. Return to work is often an important participation-level goal in rehabilitation. Patient-centered care should consider risk factors for predicting return to work to tailor interventions accordingly. The SELF (formerly modified Spinal Function Sort) is a patient-reported outcome to assess physical function. It contains 20 drawings of physical activities rated on a 5-point Likert scale, ranging from "capable" (4 points) to "limited" (3, 2, or 1 point) to "not capable" (0 points), resulting in a total of 0-80 points. Previous research supports the test-retest reliability and construct validity of the SELF. The objective of this study was to evaluate the discriminative accuracy and overall performance of the SELF in predicting no return to work (NRTW) and to determine cutoff points for a three-level risk stratification.

Method: Multicenter prospective cohort study. Patients with MSDs with the allocation goal "return to work" were included at 4 rehabilitation clinics. Subjects (SJs) answered the SELF at the beginning of rehab. Ninety days after rehab, the SJs' work status was assessed. Those who did not work or worked <45 days, <50% workload in 90 days were classified as NRTW. Discrimination accuracy was determined using area under the curve (AUC) of the receiver operating characteristic curve (ROC), overall performance using logistic regression Nagelkerke R² and effect size Cohan's f². For risk stratification, the ROC were analyzed. A sensitivity (SE) of ≥ 0.9 at best possible specificity (SP) was defined for moderate risk and a SP of ≥ 0.9 at best possible SE for high risk of NRTW.

Results: Complete data were obtained from 193 SJs. 42% did not return to work. AUC (95%CI) = .848 (.789-.895); Nagelkerke R² = .42, Cohan's f² = .72. The cutoff value for moderate risk NRTW was ≤ 58 (SE = .91/SP = .66). For high risk, the cutoff point was ≤ 42 points (SE = .43/SP = .9).

Conclusion: The SELF indicates a good discriminatory accuracy and a strong effect size, showing a good prognostic validity regarding NRTW. The cutoff values allow estimation of NRTW risk and support stratified planning of work capacity interventions.

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