SAT0582

BONE MARROW LESION TYPE AND PAIN IN KNEE OSTEOARTHRITIS

T.A. Perry¹, T.W. O'Neill^{1,2}, M.J. Parkes¹, D.T. Felson^{1,3}, R. Hodgson⁴, N. K. Arden⁵. ¹Arthritis Research UK Centre for Epidemiology, Division of Musculoskeletal and Dermatological Sciences, The University of Manchester, Manchester; ²Department of Rheumatology, Salford Royal NHS Foundation Trust, Salford, UK; ³Boston University, Boston, USA; ⁴Centre for Imaging Sciences, Institute of Population Health, The University of Manchester, Manchester; ⁵The University of Oxford, Oxford, UK

Background: Bone marrow lesions (BMLs) have been associated with pain in observational studies of knee OA. The aim of this study was to determine whether type of BML (subchondral, with and without regions of well-defined high post-contrast signal, and ligament-based) were associated with knee symptoms.

Objectives: To assess the association between bone marrow lesion volume, including sub-types, and pain in symptomatic knee OA.

Methods: Data were collected on a sub-sample of participants who were part of the UK VIDEO study¹; a 3 year multicentre randomised placebo-controlled trial of vitamin D therapy in patients with symptomatic knee OA. Those recruited to one of the participating centres (Southampton) had contrast enhanced MR imaging (CE-MRI) of the index knee performed at one or more annual visits. BML volume was assessed by segmentation of sagittal T1-weighted fat-suppressed post-contrast scans. BMLs were categorised by type (subchondral/ligament-based) and by the presence/absence of regions of well-defined high post-contrast signal (for the subchondral BMLs only). As part of the trial, subjects completed the WOMAC questionnaire which included questions on pain, function and stiffness. We used random-effects multiple linear panel regression, adjusting for variance between follow-up visits to explore the relationship between BML volume and the WOMAC pain and function subscales. This approach is preferred over cross-sectional analyses, as it makes use of all available observations from study visits, and controls for within-patient correlations appropriately.

Results: In this analysis, we included 50 subjects who had had a baseline MRI and at least one other MRI performed. The mean age of the subjects was 63.3 (SD ± 6.5) years and 74% were female. After adjusting for variation between visits, there was no significant association between total BML volume and WOMAC pain when the BMLs were stratified by type; total subchondral BML volume ($b=41.5$ mm³; 95% CI -19.35 to 102.37) or total ligament-based BML volume ($b=9.1$ mm³; 95% CI -6.39 to 24.59). Further, we did not observe an association between pain and volume of subchondral BMLs with or without regions of well-defined high post-contrast signal; (i) total mixed subchondral oedema-like BMLs containing regions of well-defined high signal ($b=39.45$ mm³; 95% CI -3.93 to 82.83) or (ii) subchondral oedema-like BML volume ($b=-4.16$ mm³; 95% CI -53.49 to 45.18), after adjusting for variation between visits. There was, however, a significant association between the volume of subchondral regions of well-defined high signal and both WOMAC pain ($b=2.19$ mm³; 95% CI 0.88 to 3.49) and function ($b=1.61$ mm³; 0.37 to 2.84).

Conclusions: In this analysis, an increased volume of regions of well-defined high signal intensity on post-contrast scans within subchondral BMLs was associated with knee pain and function.

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SAT0583

THE IMMEDIATE EFFECT OF A SOFT KNEE BRACE ON DYNAMIC KNEE INSTABILITY IN PERSONS WITH KNEE OSTEOARTHRITIS

T. Cudejko¹, M. van der Esch², J. Schrijvers¹, R. Richards¹, T. Wrigley³, J. van den Noort¹, M. van der Leeden², L.D. Roorda², W. Lems¹, J. Harlaar¹, J. Dekker¹. ¹VU University Medical Center, ²Amsterdam Rehabilitation Research Center, Reade, Amsterdam, Netherlands; ³University of Melbourne, Melbourne, Australia

Background: Wearing a soft knee brace has been shown to reduce self-reported knee instability in persons with knee osteoarthritis (OA).¹ There is a need to assess whether a soft knee brace has a beneficial effect on objectively assessed dynamic knee instability as well.

Objectives: The aims of the study were: (i) to evaluate the immediate effect of a soft knee brace on dynamic knee instability, and (ii) to assess the difference in effect between a tight and a non-tight knee brace in persons with knee OA.

Methods: A within-subject cross-over design was used, comparing wearing a soft knee brace with not wearing a soft knee brace, and comparing wearing a tight

brace (standard fit) with wearing a non-tight brace (one size larger). The order of brace type was randomised. Participants walked, both without and with the brace, on a treadmill, which is integrated in the GRAIL system, placed in a virtual reality environment (GRAIL system, MOTekForce Link, The Netherlands). Participants were subjected to two tasks: (i) level walking and (ii) walking with mechanical perturbations on the treadmill. Mechanical perturbations on the treadmill comprised five lateral and five medial translations (2 cm displacements) of the treadmill belts occurring during 20%–50% of the gait cycle. During the walking trials, 3D movement of the lower legs, pelvis and trunk were captured via markers on anatomical landmarks at 100 Hz using a motion-capture system (Vicon, Oxford, United Kingdom). The outcome measure was dynamic knee instability, expressed by the Perturbation Response (PR), i.e. a biomechanics based measure reflecting deviation in the mean knee varus-valgus angle after a controlled mechanical perturbation, standardised to the mean (standard deviation) varus-valgus angle during level walking. Lower PR values indicate less deviation in the mean varus/valgus angle. Linear mixed-effect model analysis was used to evaluate the effect of a brace on dynamic knee instability.

Results: Thirty-eight persons with knee OA and self-reported knee instability from the Amsterdam Osteoarthritis Cohort participated in the study. Wearing a brace significantly reduced the PR compared to not wearing a brace ($p<0.05$). The PR value reduced from 0.48 when not wearing a brace to 0.32 when wearing a brace. This means that wearing a brace resulted in a reduction of 33% in dynamic knee instability compared to not wearing a brace. There was no difference between a non-tight and a tight brace ($p>0.05$).

Conclusions: This study is the first to report that wearing a soft brace results in an improvement of objectively assessed dynamic knee instability, beyond the previously reported subjective improvement.

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SAT0584

CLINICAL VALIDATION OF TWO PANELS OF BIOMARKERS TO PREDICT SYMPTOMATIC DRUGS RESPONSE IN KNEE OA

V. Calamia¹, F. Picchi¹, I. Rego¹, M. Camacho¹, L. González¹, P. Fernández-Puente¹, M. Herrero², H. Martínez², J. Vergés³, C. Ruiz-Romero¹, F.J. Blanco¹.

¹INIBIC, La Coruña; ²Bioiberica S.A.U.; ³OAFI Foundation, Barcelona, Spain

Background: The prediction of drug responses based on the analysis of multiple clinical variables and omics data is mandatory for accomplishing the promise of precision medicine in rheumatology.

Objectives: Integrating clinical-radiological-analytical variables and proteomics data for predicting patient's response to different treatments, in order to optimise therapeutic outcomes in OA.

Methods: A panel of 10 serum proteins potentially useful to predict OA patient's response was qualified using ELISA Kits in the whole Multicentre Osteoarthritis interVENTion trial with Sysadoc (MOVES) cohort. Patients were classified as responders (R) and non-responders (NR), either to Chondroitin sulfate/Glucosamine hydrochloride (CS+GH; Droglican, Bioiberica, Spain) or Celecoxib, after 6 months of treatment. Logistic regression analyses, adjusted by confounder variables previously reported as significant in bivariate approaches, were used to analyse the contribution of the measured proteins to our prediction models of drug response in knee OA. Appropriate receiver-operating-characteristics (ROC) curves were also calculated.

Results: In the *discovery phase* of the study, two different panels of putative predictive biomarkers useful to stratify OA patients according to their unique protein profiles was identified by shotgun proteomics ($n=80$). In the *verification phase*, the panel of 6 proteins specific for Droglican treatment (APOA2, APOA4, APOH, ITIH1, C4BPA and ORM2), and the panel of 4 proteins specific for Celecoxib treatment ($\alpha 2$ HS, SHBG, CD5L and TSP1) were verified in a larger cohort of OA patients ($n=262$ for CS+GH group and $n=244$ for Celecoxib group) by ELISA assays. In the *qualification phase*, the sensitivity and specificity of a panel of 4 validated proteins (ORM2, APOA2, ITIH1, and TSP1) were tested in blind in the whole MOVES cohort at baseline ($n=506$). In CS+GH group, only ORM2 levels were significantly lower in responders compared to non-responders (R: 192.8 ug/mL vs NR: 261.6 ug/mL; $p=0.042$), while no statistically significant differences were found in the Celecoxib group. Five clinical and two analytical parameters recorded at baseline significantly influence patients' response regardless of treatment. Notably, if we include ORM2 as covariate, we found a specific interaction

between response to CS+GH and baseline protein levels ($p=0.007$) thus increasing the power of our prediction model (ROC up to 0.843). In the Celecoxib group, non parametric analysis showed increased levels only of TSP1 at baseline in responders compared to non-responders (R: 363.03 ± 104.83 ng/mL vs NR: 331.95 ± 92.59 ng/mL; $p=0.041$), while no statistically significant differences were found for this protein in the CS+GH group. When we include in the regression model 4 predictive variables (2 clinical and 2 analytical) and TSP1 as covariate, we found a specific interaction between response to Celecoxib and baseline protein levels ($p=0.045$) thus increasing the predictive power of this model (ROC up to 0.749).

Conclusions: Combining clinical and analytical parameters, we clinically validated (qualified) 2 panels of biomarkers that could efficiently predict OA patients' response to CS+GH with an accuracy of 84.3% or to Celecoxib with an accuracy of 74.9%.

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SAT0585 DECREASED SYNOVIAL LEVELS OF DICKKOPF-1 ARE ASSOCIATED WITH RADIOLOGICAL PROGRESSION IN KNEE OSTEOARTHRITIS PATIENTS

W.A. Hassan¹, E.G. Behiry². ¹Rheumatology and Rehabilitation; ²Clinical and Chemical Pathology Department, Benha University Hospital, Benha, Egypt

Background: Dickkopf-1 (Dkk-1) is a direct inhibitory ligand of Wnt β -catenin signalling pathway that act through binding to low-density lipoprotein (LDL) related proteins (LRP5/6) receptors. Dkk-1 is considered an important mediator of cartilage homeostasis and skeletal remodelling.¹

Objectives: This study aimed to measure serum and synovial fluid (SF) levels of Dkk-1 in patients with early primary knee osteoarthritis (KOA) and to examine the relationship between these levels and the clinical and functional parameters as well as radiological progression of KOA

Methods: We measured Dkk-1 in the serum ($n=48$) and SF samples ($n=22$) from 48 early KOA patients and in the serum from healthy control ($n=30$). Body mass index (BMI), numerical rating scale of pain (NRS) and The Western Ontario Mc Master scale (WOMAC) were recorded. Plain radiographs using Osteoarthritis Research Society International (OARS) atlas to assess joint space narrowing (JSN)² and musculoskeletal ultrasound examination (MSUS) were performed at baseline and after 24 months to assess radiological progression. Radiological progression was considered if there is more than 2 points increase in JSN score or transition to higher grade in MSUS examination³ at the 24 months follow up period compared to baseline grade.

Results: SF Dkk-1 levels were significantly decreased (mean $\pm$ SD 115.05 $\pm$ 34.2 pg/ml) compared to their paired serum levels (mean $\pm$ SD 969.82 $\pm$ 365.72 pg/ml), $p<0.001$ in KOA patients. There was no significant difference in serum Dkk-1 levels between KOA patients and healthy controls (mean $\pm$ SD 988.77 $\pm$ 385.19 pg/ml and 1084.73 $\pm$ 408.38 pg/ml respectively), the SF concentrations of Dkk-1 significantly correlated with the baseline thickness of the cartilage on the medial condyle (0.53, $p<0.05$) but not on the lateral condyle of the femur ($r=0.11$, $p>0.05$). There was no significant correlation between serum Dkk-1 and baseline cartilage thickness on medial and lateral condyles ($r=-0.13$ and -0.09 respectively, $p<0.05$). Patients in the least quartile of SF Dkk-1 had an increased risk of radiological progression with plain radiography and MSUS (age, sex and BMI adjusted RR 2.1 and 3.4, 95% CI respectively).

Conclusions: Osteoarthritis patients have significantly lower synovial levels than serum levels of Dickkopf-1 that were obviously associated with radiological progression on plain radiography and MSUS suggesting that it could be a useful marker to reflect OA severity and implies a possible role in the pathogenesis of OA.

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SAT0586

RESULTS FROM A 52 WEEK RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE 2 STUDY OF A NOVEL, WNT PATHWAY INHIBITOR (SM04690) FOR KNEE OSTEOARTHRITIS TREATMENT

Y. Yazici¹, T. McAlindon², A. Gibofsky³, N. Lane⁴, D. Clauw⁵, C. Swearingen¹, A. DiFrancesco¹, J. Tambiah¹, M. Hochberg⁶. ¹Samumed, LLC, San Diego; ²Tufts Medical Center, Boston; ³Hospital for Special Surgery, New York; ⁴UC Davis Medical Center, Davis; ⁵University of Michigan Medical School, Ann Arbor; ⁶University of Maryland School of Medicine, Baltimore, USA

Background: Knee osteoarthritis (OA) is characterised by pain, disability and joint deformity due to articular cartilage degradation and bone remodelling. Wnt signalling is involved in these cellular processes. SM04690, a small molecule Wnt pathway inhibitor, is in development as a potential disease modifying OA drug (DMOAD) for knee OA.

Objectives: A phase 2, multicenter, 52 week, placebo-controlled (PBO) trial was conducted to identify a target population, determine optimal dose and assess safety.

Methods: Knee OA subjects, Kellgren-Lawrence (KL) grades 2–3, received a single 2 mL injection of SM04690 0.03 mg, 0.07 mg, 0.23 mg or PBO in target (most painful) knee. WOMAC Pain and Function were assessed (Weeks 0, 4, 13, 26, 39, 52) and fixed flexion radiographs (QuAP positioned; Weeks 0, 26, 52) assessed medial joint space width (mJSW). Analysis of covariance adjusted for baseline was conducted using multiple imputation for missing data. Exploratory subgroups included: 1) unilateral symptomatic subjects (pre-specified; determined by history and examination) and 2) unilateral symptomatic subjects without comorbid pain (post-hoc; Widespread Pain Index ≤ 4 , Symptom Severity ≤ 2 [WP-]).

Results: 455 subjects (mean age 60.3 [± 8.7] years, BMI 29.9 [± 4.6] kg/m², female 58.9%, KL grade 3 [64.4%], unilateral symptomatic OA [36.0%]) were enrolled, 91% with radiographic bilateral OA. Seventeen serious adverse events, all unrelated to SM04690, were reported.

The primary endpoint of Week 13 change from baseline in WOMAC Pain was not met. In ITT, at all timepoints, minimal clinically important differences ($>10\%$ full range) in WOMAC Pain and Function compared to baseline were seen in all groups. In 0.07 mg unilateral symptomatic subjects, at 52 weeks, WOMAC Pain (4.4, $p=0.049$), and Function (17.5, $p=0.035$) were significantly improved compared to PBO. In 0.07 mg unilateral symptomatic WP- subjects at Weeks 26, 39, and 52, WOMAC Pain (4.6, $p=0.039$; 5.9, $p=0.042$; and 5.6, $p=0.025$, respectively) and Function (16.3, $p=0.027$; 19.7, $p=0.035$; and 22.8, $p=0.017$, respectively) were significantly improved compared to PBO (Abstract SAT0586 – figure 1).

At 26 and 52 weeks, 0.07 mg unilateral symptomatic (0.5 mm, $p=0.006$ and 0.4 mm, $p=0.021$, respectively) and 0.07 mg unilateral symptomatic WP- (0.5 mm, $p=0.016$ and 0.4 mm, $p=0.032$, respectively) subgroups demonstrated significant increases from baseline in mJSW compared to PBO (figure 1).

Abstract SAT0586 – Figure 1. Ladder plots depicting mean improvement (and 95% confidence intervals) of SM04690 over placebo adjusted for baseline.

Conclusions: A target subgroup of unilateral symptomatic knee OA subjects and potential optimal dose (0.07 mg) of SM04690 were identified. Clinical and radiographic outcomes suggested that SM04690 has potential as a DMOAD, especially in subjects with unilateral symptomatic WP- knee OA. Further studies are ongoing.

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SATURDAY, 16 JUNE 2018

Other orphan diseases

SAT0587 MAJOR SALIVARY GLANDS ULTRASONOGRAPHY IN DIFFERENTIAL DIAGNOSIS OF IGG4-RELATED DISEASE AND PRIMARY SJOGREN'S SYNDROME

E. Sokol, E. Rodionova, V. Vasilyev, S. Palshina, M. Burtseva, Nasonova
Research Institute of Rheumatology, Moscow, Russian Federation

Background: IgG4-related disease (IgG4-RD) is a group of fibro-inflammatory immunomediated conditions with IgG4 overexpression in the serum and affected tissues in the majority of patients. Major salivary and lacrimal glands are the most frequently affected sites in IgG-RD. Moderate sicca symptoms can be present as well thus requiring differential diagnosis with primary Sjogren's syndrome (pSS). Major salivary glands ultrasonography (sUS) has been reported as an effective diagnostic tool in pSS.

Objectives: To evaluate the difference in sUS score in pSS and IgG4-RD patients

Methods: 15 patients with IgG4-related sialoadenitis consecutively admitted to our clinic and 28 with pSS underwent sUS. Parenchymal echogenicity, homogeneity, hypoechogenic and hyperechogenic areas and clearness of salivary gland border were scored according to the Hoyer scoring system (cut-off – 15 points). Statistical analyses were performed using MEDCALC program. Median values of the sUS score and Mann-Whitney U-test were used to evaluate differences in total ultrasound score between patients in two groups.

Results: All patients with IgG4-related sialadenitis and pSS had some sUS abnormalities. The most frequent feature in IgG4-RD were: the presence of hypoechotic lesions in major salivary glands (53% of patients) or diffuse salivary gland parenchyma hypoechogenicity (27% of patients) and multiple intraglandular lymph nodes (66.7% of patients). Median value of sUS score in IgG4-RD group was 12 points and in pSS group – 22 points. The difference was significant (Mann-Whitney U-test 60.5, $p < 0.05$).

Conclusions: Although different US-changes are frequently seen in IgG4-RD patients, sUS Hoyer score seems to be a rather reliable tool to differentiate IgG 4-related sialoadenitis and pSS.

Disclosure of Interest: None declared

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SAT0588 RHEUMATOLOGIC IMMUNE-RELATED ADVERSE EFFECTS OF CHECKPOINT INHIBITOR THERAPY: A SINGLE CENTRE COHORT OF 29 PATIENTS

M.D. Richter¹, C.S. Crowson², L.A. Kottschade², H.D. Finnes², S.N. Markovic², U. Thanarajasingam². ¹Graduate Medical Education; ²Mayo Clinic, Rochester, USA

Background: Immune checkpoint inhibitors for advanced malignancy are associated with a wide range of autoimmune phenomena known as immune-related

adverse effects (irAEs).¹ Knowledge of irAEs resembling rheumatologic diseases is limited to case reports and small case series, and there are currently no specific guidelines on how to diagnose or manage these patients.

Objectives: To describe the prevalence, clinical presentation, and management of patients with rheumatologic irAEs from checkpoint inhibitor therapy.

Methods: We retrospectively studied all patients who received a checkpoint inhibitor for any malignancy at Mayo Clinic Rochester, Minnesota between January 1 st, 2011 and November 1 st, 2017. From these patients we identified those with possible rheumatologic irAEs using diagnostic codes, search terms, and the presence of specific laboratory testing.

Results: Of the 1216 patients who received any checkpoint inhibitor, we identified 29 who were clinically diagnosed with a rheumatologic irAE. The diagnosis was confirmed by a rheumatologist in all but 3 cases. Mean follow up time from irAE diagnosis was 1.5 years (± 1.1). Seven patients had a pre-existing autoimmune disease with one of these being a rheumatologic disease (Giant-cell arteritis). irAEs included inflammatory arthritis,¹⁵ sicca syndrome,³ systemic sclerosis,³ myositis,³ vasculitis,³ spondylitis,¹ and polymyalgia rheumatica.¹ Only one irAE represented a disease flare. Mean time from initiation of checkpoint inhibitor therapy to onset of irAE symptoms was 15.0 weeks (± 10.8). 24 patients (83%) were treated with corticosteroids and 8 patients (28%) received additional therapy with disease modifying drugs. Mean treatment duration for these 24 patients was 19.5 weeks (± 21.7), and 8 patients (33%) had complete symptom resolution within the study period. Rheumatologic irAEs resulted in discontinuation of checkpoint inhibitor therapy in 7 patients (24%).

Abstract SAT0588 – Table 1. Clinical Features

Rheumatologic irAEs	29 total
Inflammatory arthritis	15
Sicca syndrome	3
Systemic sclerosis	3
Myositis	3
Vasculitis	3
Spondylitis	1
Polymyalgia rheumatica	1
Treatment	
Prednisone only	16
Prednisone plus biologics	8
No treatment	5
Starting prednisone dose, MG, mean (St. Dev)	47 (26)
Weeks on prednisone, mean (St. Dev)	15 (11)
Weeks to symptom onset, mean (St. Dev)	15 (11)
Sedimentation rate, mean (St. Dev)	39 (30)
C-reactive protein, mean (St. Dev)	49 (57)
Diagnosed by rheumatologist	26 (90%)
Positive autoimmune serologies	4 (14%)
Flare of existing autoimmune disease	2 (7%)
Comorbid non-rheumatologic irAEs	19 (66%)

Conclusions: Our study represents one of the largest cohorts of rheumatologic irAEs to date. Most patients required long courses of treatment with only a minority achieving complete symptom resolution. Prospective, multicenter studies are necessary to determine the optimal management of these emerging disorders.

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