

24.06±8.9kg, $p=0.005$) and RLF 13.44±7.43 vs 24.26±7.65kg, $p=0.0003$). Patients with VFs lose their balance faster during one-leg-standing test with open eyes (5.0 [1.0; 10.0] vs 7.5 [5.0; 10.5] sec in control group, $p=0.03$) and with closed eyes (2.0 [0; 3.0] vs 3.5 [3.0; 5.0] sec, $p=0.04$). Fukuda-Unterberger test showed greater side displacement in study group — 40° [25; 45] vs controls 30° [10; 45], ($p=0.02$). According to stabilometry study group was characterized vs control group by lower balance coefficient with open eyes (77.2±7.6 vs 85.7±9.4%, $p=0.002$) and with closed eyes (67.1±9.8 vs 73.4±9.9%, $p=0.03$), greater sagittal displacement (6.8 [2.1; 37.7] vs 4.8 [1.8; 10.7] mm, $p=0.025$) and deviation in the sagittal plane (1.2 [-1.07; 1.5] vs -1.2 [-1.5; 1.2] mm, $p=0.01$), and also less pressure center velocity (9.51±4.4 vs 7.1±2.7 mm/sec, $p=0.009$).

Conclusion: Osteoporotic VFs are associated with reduction of trunk muscles strength and negatively affect static and dynamic balance function that should be taken into account when developing rehabilitation programs for these patients.

Disclosure of Interests: None declared.

DOI: 10.1136/annrheumdis-2021-eular.4260

POS0017 **IMC-1, A FIXED DOSE COMBINATION OF FAMCICLOVIR AND CELECOXIB, IMPROVES COMMON SYMPTOMS ASSOCIATED WITH FIBROMYALGIA IN ADDITION TO PAIN: POST HOC ANALYSIS OF A PHASE 2A TRIAL**

W. Pridgen¹, C. Duffy², J.E. Gendreau³, R. M. Gendreau⁴. ¹Tuscaloosa Surgical Associates, P.C., LLC, Tuscaloosa, United States of America; ²University of Alabama, Department of Biological Sciences, Tuscaloosa, United States of America; ³Gendreau Consulting, LLC, Poway, United States of America; ⁴Virios Therapeutics, Alpharetta, United States of America

Background: Fibromyalgia is a chronic disease characterized by widespread pain and severe fatigue that may be triggered by reactivation of latent herpes simplex virus type 1 (HSV-1). In a Phase 2a proof of concept trial, IMC-1 (a fixed dose combination of famciclovir and celecoxib) demonstrated greater tolerability and statistically significant reduction in pain compared with placebo, as measured by change from baseline to week 16 in 24-hour recall pain intensity on an 11-point Numerical Rating Scale (NRS) and 7-day recall pain intensity on the 11-point pain item on the Revised Fibromyalgia Impact Questionnaire (FIQ-R).

Objectives: In this post hoc analysis, we evaluated the effects of IMC-1 compared with placebo on other fibromyalgia symptoms, including lack of energy, stiffness, problems with sleep, problems with memory, depression, and anxiety.

Methods: In the double-blind, multi-center, placebo-controlled trial, male or female patients 18–70 years of age who met diagnostic criteria for fibromyalgia and had at baseline a 24-hour recall average pain intensity score between 4 and 9 on the NRS were randomized 1:1 to 16 weeks of treatment with IMC-1 or placebo. Mean changes from baseline to week 16 in FIQ-R symptom scores were analyzed using a Mixed-Effect Model Repeated Measure (MMRM) model with treatment as the main effect, and investigative site and baseline FIQ-R symptom scores as covariates.

Results: A total of 143 patients were enrolled and randomized to treatment with IMC-1 ($n=69$) or placebo ($n=74$). Baseline demographic and clinical characteristics were comparable between treatment groups; the majority of patients were Caucasian (95.8%) and female (93.7%) with a mean age of ~49 years. Compared with placebo, treatment with IMC-1 resulted in statistically significant improvements in the FIQ-R symptom scores of stiffness (least squares mean change from baseline -0.96 vs. -1.92, $P=0.03$), sleep quality (-0.76 vs. -1.76, $P=0.039$), depression (-0.44 vs. -1.33, $P=0.016$), and anxiety (-0.30 vs. -1.69, $P<0.001$), but not in energy level (-0.67 vs. -1.29, $P=0.115$) or memory problems (-0.71 vs. -1.24, $P=0.165$).

Conclusion: In addition to alleviation of chronic pain, treatment with IMC-1 appears to be effective in improving many of the other symptoms often associated with fibromyalgia. Further clinical trials are warranted.

REFERENCES:

[1] Pridgen WL, Duffy C, Gendreau JF, Gendreau RM. A famciclovir + celecoxib combination treatment is safe and efficacious in the treatment of fibromyalgia. *J Pain Res*. 2017;10:451-460.

Disclosure of Interests: William Pridgen Consultant of: Virios Therapeutics, Carol Duffy Consultant of: Virios Therapeutics, Grant/research support from: The University of Alabama, Department of Biological Sciences has received financial research support from Innovative Med Concepts (now Virios Therapeutics) in the form of two Sponsored Research Agreements., Judy F. Gendreau Consultant of: Tonix, Dare Bioscience, Virios Therapeutics, R. Michael Gendreau Consultant of: Tonix, Teva, Swing Therapeutics, Dare Bioscience, Employee of: Virios Therapeutics.

DOI: 10.1136/annrheumdis-2021-eular.1424

POS0018 **INVESTIGATING VIRTUAL IMMERSIVE EXPERIENCES IN THE MANAGEMENT OF CHRONIC PAIN – THE VIPA STUDY (PRELIMINARY RESULTS)**

J. Tsigarides¹, V. Grove¹, D. Sethi¹, J. Chipping¹, S. Miles¹, N. Shenker², S. Sami¹, A. Macgregor¹. ¹University of East Anglia, Norwich Medical School, Norwich, United Kingdom; ²Addenbrookes University Hospital, Rheumatology, Cambridge, United Kingdom

Background: Chronic pain is debilitating and prevalent. Current non-pharmacological management of pain conditions such as Fibromyalgia Syndrome (FMS) are labour intensive to implement and poorly available, especially during the pandemic. There is an urgent need to develop widely adoptable, innovative treatment options for pain cohorts.

Virtual reality (VR) provides an innovative therapeutic tool, immersing users within a three-dimensional, interactive virtual environment with use of a head-mounted display (HMD). Beneficial effects of VR have been demonstrated in acute pain¹, with limited studies in chronic pain. Given the variation of available VR technologies, it is vital to investigate the impact of different VR characteristics on acceptability in specific chronic pain cohorts.

Objectives: This feasibility study aims to establish the acceptability of four different VR technologies in patients with FMS whilst undertaking a single interactive VR experience.

Methods: Patients with FMS were recruited through outpatient clinics at the Norfolk and Norwich University Hospital. Baseline questionnaires were used including the McGill pain questionnaire (MPQ-SF), pain visual analogue scale (VAS) and Revised Fibromyalgia Impact Questionnaire (FIQR). Subjective experience questionnaires collected acceptability data with 7-point Likert scale rating questions (strongly disagree to strongly agree). The simulation sickness questionnaire (SSQ) gained side-effect data (total severity score: 0-235). Categorical data were described using frequencies; and continuous data using mean and standard deviation. Likert-scale data were dichotomised (rating ≤ 3 : disagree, rating ≥ 5 : agree).

Four VR systems representing the spectrum of commercially available technologies were used (seen in Figure 1). These possess different characteristics including screen resolution, processor speed, weight, strap and controller type. The VR experience used with each headset was co-developed alongside industry partners (Orbital Global). Participants are immersed within a naturalistic environment, situated on a wooden boat travelling slowly along a calm river surrounded by trees and hills. The interactive element involves the user shooting targets that appear using handheld controllers.

Results: 13 patients with FMS were included (mean age 41.8±15.6, 92.3% female). Most had severe disease (mean FIQR 67.8±14.1) with moderate self-reported pain at baseline (mean MPQ 25.5±8.8, VAS 6.0±1.7). Most had no previous VR exposure (69.2%). 100% of participants agreed that they would be open to using VR for future pain management (mean rating 6.5±0.7) and that they would use VR regularly at home (mean rating 6.5±0.7). VR HMD comfort and enjoyment data are presented in Table 1. Mean ratings of comfort were high across the four HMDs (Gear VR: 4.9±1.7, Oculus Go: 4.5±1.8, Oculus Quest 5.3±1.9, Oculus Rift 6.6±0.5). Mean ratings of enjoyment with each HMD were also high (Gear VR: 5.4±1.6, Oculus Go: 5.4±1.8, Oculus Quest: 5.6±1.9, Oculus Rift S: 6.6±0.5). Low levels of side effects were described with mean SSQ total scores ranging from 20.1±16.8 (Oculus Rift S) to 38.0±23.9 (Gear VR).

Conclusion: Preliminary results indicate that FMS patients find VR acceptable, describing high ratings of comfort and enjoyment across the VR HMD spectrum. Side-effect frequency was low, with most settling after HMD removal. All participants were open to future use of VR for home-based pain management.

REFERENCES:

[1] Dascal J, Reid M, Ishak WW, Spiegel B, Recacho J, Rosen B, Danovitch I. Virtual reality and medical inpatients: A systematic review of randomized, controlled trials. *Innov Clin Neurosci* 2017;14(1-2):14-21

Table 1. Subjective experience results across VR HMDs

VR HMD	Mean Likert scale ratings (% agreement: rating ≥ 5)	
	Overall, I found the VR experience using this equipment comfortable	Overall, I enjoyed using this VR headset
Gear VR	4.9±1.7 (62%)	5.4±1.6 (77%)
Oculus Go	4.5±1.8 (54%)	5.4±1.8 (75%)
Oculus Quest	5.3±1.9 (77%)	5.6±1.9 (100%)
Oculus Rift S	6.6±0.5 (100%)	6.6±0.5 (100%)

Figure 1

Spectrum of VR technologies used in this study. From left to right: Oculus Quest, Oculus Go, Gear VR, Oculus Rift S.



Acknowledgements: I would like to acknowledge the contributions of the staff working within the Rheumatology department at the Norfolk and Norwich University Hospital. I would also like to thank and acknowledge our participants for being involved in the study.

Disclosure of Interests: Jordan Tsigarides Grant/research support from: Our digital health industry partners (Orbital Global) provided a small financial contribution to support this study., Vanessa Grove: None declared, Dheeraj Sethi: None declared, Jacqueline Chipping: None declared, Susan Miles: None declared, Nicholas Shenker: None declared, Saber Sami: None declared, Alex MacGregor: None declared.

DOI: 10.1136/annrheumdis-2021-eular.2017

POS0019

PREDICTORS OF SUSTAINED 6 MONTHS REMISSION AND FLARE IN PATIENTS WITH POLYMYALGIA RHEUMATICA

C. Perricone¹, E. Fiumicelli¹, G. Cafaro¹, R. Bursi¹, R. Ilenia¹, E. Bartoloni Bocci¹, R. Gerli¹. ¹Rheumatology, Department of Medicine and Surgery, Perugia, Italy

Background: Polymyalgia rheumatica (PMR) is a typical inflammatory disease of the elderly. The mainstay of treatment is usage of oral glucocorticoids (GC) usually leading to a dramatic response. However, long-term treatment is often required. In some instances, remission cannot be achieved and disease flares can occur. To date, few papers investigated the predictive factors of response to GC therapy suggesting a role for weight, elevated plasma viscosity and C-reactive protein (CRP). Moreover, there are no data on predictor factors of disease flares after 6 months of sustained remission.

Objectives: To evaluate the factors predictive of sustained 6 months remission and of flare in patients with PMR.

Methods: We evaluated clinical data from 137 PMR patients treated with GC for more than 6 months between September 2002 and June 2020. Patients were evaluated at baseline, re-evaluated at 1 month and after 3 months and then at least every 3 months. We analyzed the differences between patients who achieved remission within 6 months of diagnosis, who maintained it for at least 6 months, and patients who did not. Remission was defined as 1) the absence of clinical symptoms, 2) <7.5 mg / day of prednisone equivalents and 3) negativity of ESR and CRP. Patients treated with methylprednisolone were excluded from the analysis.

Results: Among the 137 patients (baseline F68: M69, mean age \pm SD 74.5 \pm 6.6 years, mean ESR \pm SD 49.9 \pm 27.7 mm/h, mean CRP \pm SD 6.1 \pm 11.4 mg/dl), 57 achieved remission at 6 months (41.6%), and after this period, another 47 went into remission for a total of 104 patients (75.9%). The months required to achieve remission averaged 6.4 \pm 3. No differences were observed between patients who achieved remission and patients who did not regarding age, sex, CRP, starting dose of GC, anti-CCP and rheumatoid factor. The ESR at baseline was higher in patients who did not achieve remission (58.1 \pm 33.4 mm/h) than in patients who achieved it (46 \pm 24.8 mm/h, $p=0.06$). ESR at baseline correlated with the time needed to reach normalization of both ESR and CRP ($p=0.01$, Figure 1). Thirty-six of 104 patients (34.6%) had a disease flare after a mean of 6.1 \pm 2.7 months of remission. The mean GC intake at flare was 2.8 \pm 3 mg/day. Only 15/36 (41.6%) patients were able to withhold GCs after flare, compared with 48/68 (70.5%) patients who achieved remission and did not experience flare. There were no significant differences in any analyzed parameters between patients who experienced flares and those who did not, including ESR and CRP values at baseline (50.3 \pm 26.7 mm/h and 6.8 \pm 12.1 mg/dl, respectively). A higher percentage of patients who did not achieve remission experienced flare than patients who went into remission ($p=0.009$).

Conclusion: Achieving complete remission at 6 months occurs in a consistent percentage of patients with PMR. Despite this, a significant percentage of patients may need prolonged steroid treatment and may experience flare, even after 12 months of follow-up. Remission at 6 months is likely to be a good predictor of remission at 12 months, as already reported in recent studies (1, 2). Elevated ESR at diagnosis appears to be a negative predictor for remission at 6 months. Patients who achieve complete remission are less likely to develop flare. True remission should coincide with the discontinuation of steroid treatment; in

fact, the maintenance of steroid therapy, even at low doses, is predictive of the development of flare.

REFERENCES:

- [1] Hattori K, et al. *Int J Rheum Dis.* 2020
[2] Camellino D, et al. *Nat Rev Rheumatol.* 2020

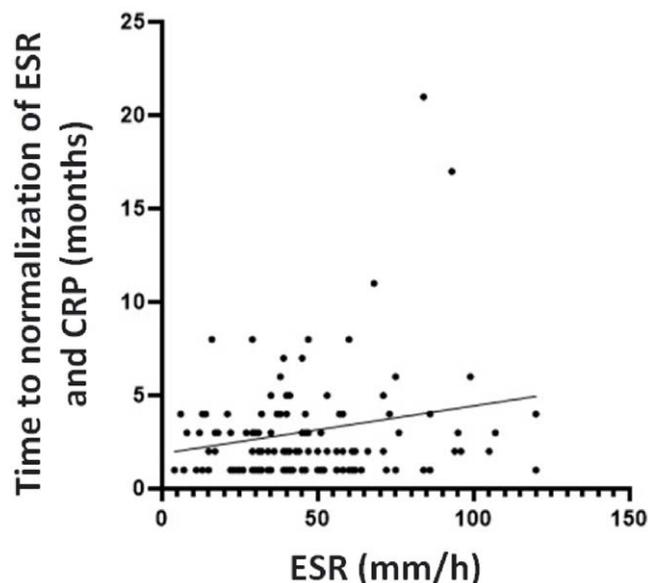


Figure 1.

Disclosure of Interests: Carlo Perricone Speakers bureau: BMS, Lilly, Celgene, UCB, Abbvie, Pfizer, Sanofi, Accord, Novartis, Elena Fiumicelli: None declared, Giacomo Cafaro: None declared, Roberto Bursi: None declared, Ricucci Ilenia: None declared, Elena Bartoloni Bocci: None declared, Roberto Gerli: None declared.

DOI: 10.1136/annrheumdis-2021-eular.3593

POS0020

EFFICACY AND SAFETY OF SECUKINUMAB IN PATIENTS WITH ROTATOR CUFF TENDINOPATHY: A 24-WEEK, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE II PROOF-OF-CONCEPT TRIAL

N. L. Millar¹, I. Mcinnes¹, L. Mindeholm², A. Seroutou³, J. Praestgaard⁴, U. Schramm⁵, R. Levitch⁵, E. Weber⁶, D. Laurent⁷, J. Rosen⁸, G. Schett⁹, R. Roubenoff¹⁰, M. Schieker². ¹Institute of Infection, Immunity & Inflammation, University of Glasgow, Glasgow, United Kingdom; ²Novartis Institutes for BioMedical Research, TM MSD Bone, Joint and Tendon, Basel, Switzerland; ³Novartis Institutes for BioMedical Research, Biostatistics, Basel, Switzerland; ⁴Novartis Institutes for BioMedical Research, Data Science, Cambridge, United States of America; ⁵Novartis Institutes for BioMedical Research, Cardio-renal-metabolic, Basel, Switzerland; ⁶Novartis Institutes for BioMedical Research, MSD LAB WEBER, Basel, Switzerland; ⁷Novartis Institutes for BioMedical Research, BMD Clinical & Transplant Imaging, Basel, Switzerland; ⁸New York Presbyterian Queens, Department of Orthopaedics & Rehabilitation, New York, United States of America; ⁹University of Erlangen-Nuremberg, Department of Internal Medicine 3, Erlangen, Germany; ¹⁰Novartis Institutes for BioMedical Research, Translational Medicine, Basel, Switzerland

Background: Rotator cuff tendinopathy (RC TP) is a multifactorial condition and one of the most common causes of musculoskeletal burden. Current standard of care (SoC) is limited to pain relief with NSAIDs and physiotherapy. Recent evidence indicates that IL-17A-expressing tendon-resident immune cells are present in human overuse tendinopathy, and IL-17A levels are increased in early human tendinopathic tissue samples [1, 2]. Secukinumab (SEC) is a fully human, monoclonal antibody that binds to and neutralises IL-17A.

Objectives: To evaluate the efficacy and safety of SEC in patients with active overuse RC TP refractory to oral NSAIDs/acetaminophen, physiotherapy or corticosteroid injections.

Methods: 96 patients with symptomatic RC TP with no or <50% rupture were randomly assigned to receive seven subcutaneous injections of SEC 300 mg or placebo (PBO) at baseline and Weeks 1, 2 and 3, followed by every 4 weeks starting at Week 4. The primary endpoint was change from baseline in the Western Ontario Rotator Cuff (WORC) index score at Week 14 for SEC vs PBO (two-sided $p<0.1$). Secondary endpoints included, visual analogue scale (VAS) pain score, Disability of Arm, Shoulder and Hand Questionnaire (QuickDASH) score,