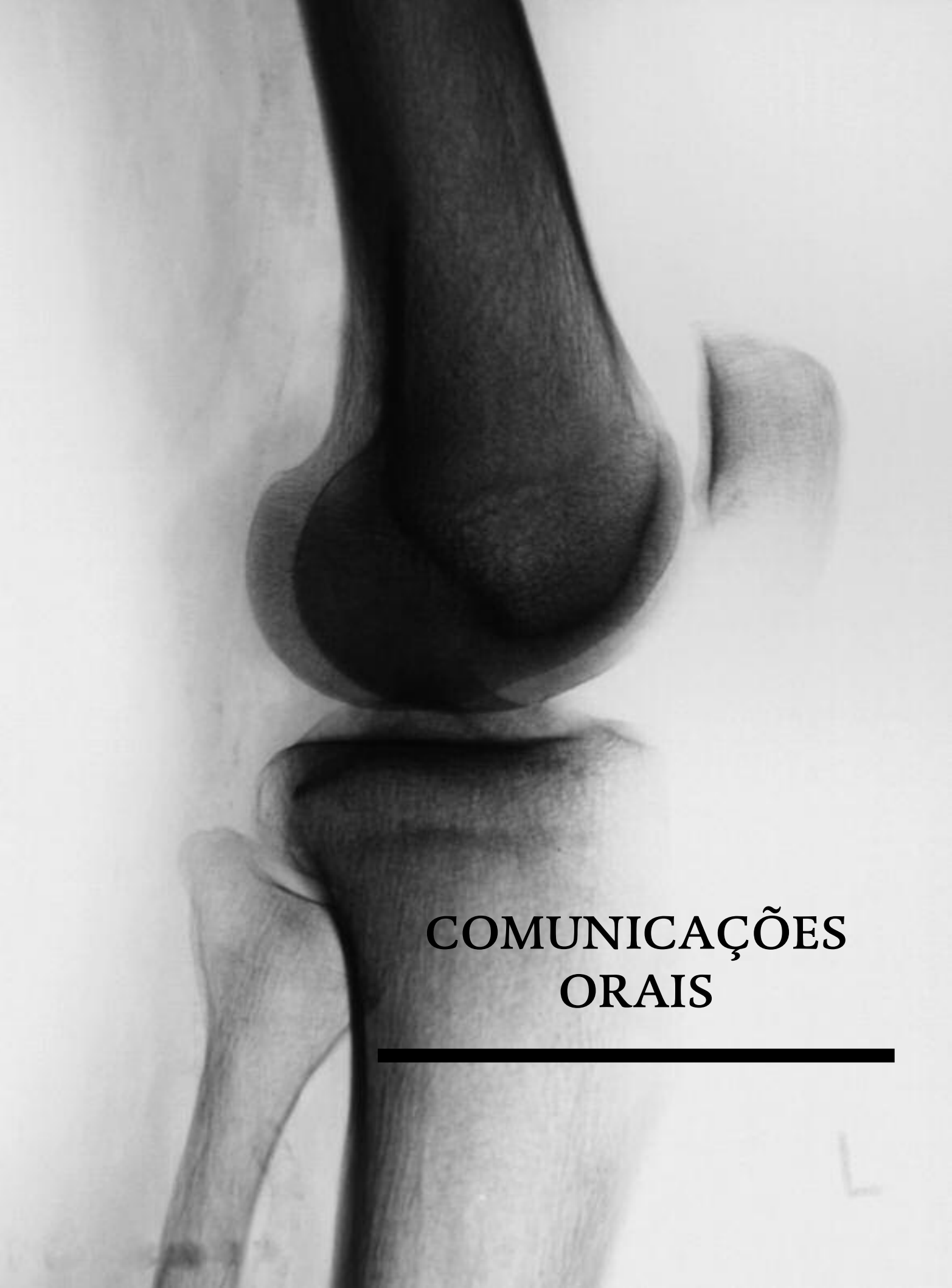

# COMUNICAÇÕES ORAIS

# Comunicações orais

ACTA REUMATOL PORT. 2017:42:27-45 (SUP)

## SESSÃO I

### C015 – THE ROLE OF INDIVIDUAL AND COUNTRY-LEVEL SOCIO-ECONOMIC FACTORS IN WORK PARTICIPATION IN PATIENTS WITH SPONDYLOARTHRITIS ACROSS 22 COUNTRIES WORLDWIDE: RESULTS FROM THE COMOSPA STUDY

Santiago Rodrigues-Manica[1, 2], Alexandre Sepriano[1, 3], Sofia Ramiro[3], Fernando Pimentel-Santos[1, 2], Putrik P[4], Nikiphorou E[5], Moltó A[6, 7], Dougados M[6, 7], Désirée van der Heijde[3], Robert Landewé[8], Van den Bosch F[9], Boonen A[4]

1. CEDOC, Nova Medical School, Lisboa, Portugal
2. Rheumatology Department, Hospital Egas Moniz (CHLO), Lisboa, Portugal
3. Rheumatology, Leiden University Medical Center, Leiden, Netherlands
4. Department Internal Medicine, Division of Rheumatology, Maastricht University Medical Center, Maastricht, Netherlands
5. KCL, London, United Kingdom
6. Rheumatology B Department, Paris Descartes University, Cochin Hospital, AP-HP, Paris, France
7. INSERM (U1153), Clinical Epidemiology and Biostatistics, PRES Sorbonne Paris-Cité, Paris, France
8. ARC, Amsterdam & Atrium MC Heerlen, Amsterdam, Netherlands
9. Department of Rheumatology, Ghent University Hospital, Ghent, Belgium

**Background:** Spondyloarthritis (SpA) carries substantial financial costs, including direct costs (use of medical services and treatments) and indirect costs (loss of work productivity). While disease related factors have been repeatedly shown to be associated with work outcomes, information on the role of educational attainment and the economic wealth of the patients' country of residence is scarce.

**Objectives:** To explore the role of individual and country level socio-economic (SE) factors on employment, absenteeism and presenteeism across 22 countries.

**Methods:** Patients with a clinical diagnosis of SpA, fulfilling the ASAS SpA criteria and in working age (≤65 years old) from COMOSPA were included. Outcomes explored were employment-status, absenteeism and presenteeism according to the Work Productivity and Activity Impairment Specific Health Problem (WPAI--SHP) questionnaire. Absenteeism and presenteeism were assessed in employed patients. Multilevel logistic (for work status) and linear (for absenteeism and presenteeism) regression models with random intercept for country were constructed. Independent contribution of individual (education) and country level socioeconomic factors (country healthcare expenditures and gross domestic product (GDP) (all low vs medium/high tertiles) were assessed in models adjusted for clinical factors.

**Results:** In total 3,114 patients from 22 countries were included [mean (SD) age 40.9 (11.8) years; 66% males; and 63% employed].

Of these, 89% had axial SpA and 11% a peripheral SpA. Unadjusted employment rates ranged from 28% (Colombia) to 83% (Canada). After adjustment for relevant socio-demographic and clinical variables, differences between countries in work status persisted (Figure).

High healthcare expenditures were associated with higher employment (OR=2.42; 95%CI=1.53;3.81) and lower presenteeism (β=-4.53;CI=-8.90;-0.17). Similarly, higher GDP was associated with higher employ-

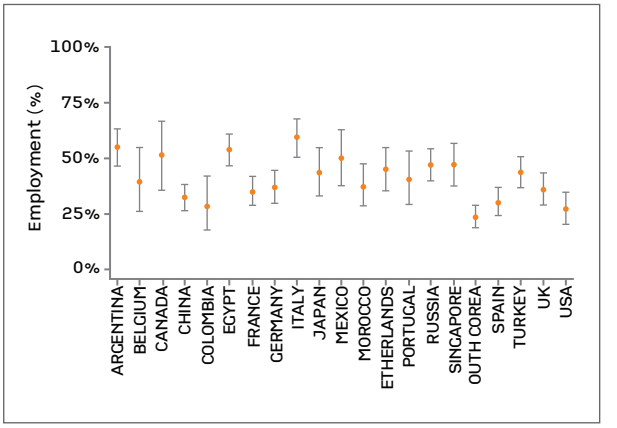


**FIGURE.** Adjusted estimates of employment rate (and 95%CI) by country derived from final multivariable, two-level model of work status, adjusted for health expenditure per capita (in USD), socio-demographic and clinical

**TABLE. IMPACT OF INDIVIDUAL AND COUNTRY SE FACTORS ON WORK OUTCOMES, IN TWO-LEVEL MODELS ADJUSTED FOR SOCIO-DEMOGRAPHIC AND CLINICAL VARIABLES**

| | Outcome | | |
|---|---|---|---|
| Independent predictors | Work status (employed vs not) (N=2,897) OR (95% CI) | Absenteeism (0-100%) (N=1,619) β (95% CI) | Presenteeism (0-100%) (N=1,497) β (95% CI) |
| Country health expenditure per capita (US dollars) | 2.42 (1.53;3.81) | -3.42 (-13.07;6.23) | -4.53 (-8.90;-0.17) |
| Age (years) | 0.98 (0.97;0.99) | -0.04 (-0.17;0.09)** | -0.20 (-0.31;-0.10) |
| Gender (ref: Female) | 2.26 (1.88;2.72) | -4.38 (-7.28;-1.49) | -4.30 (-6.59;-2.01) |
| Education (ref: Primary school or less) | | | |
| Secondary | 2.35 (1.77;3.11) | -5.42 (-10.45;-0.40) | -3.09 (-7.03;0.85) |
| University | 3.90 (2.91;5.24) | -7.25 (-12.33;-2.27) | -7.48 (-11.44;-3.51) |
| Marital status (ref: single) | | | |
| married/living together | 2.28 (1.83;2.85) | | |
| divorced | 2.37 (1.54;3.67) | | |
| widower | 2.00 (0.84;4.73) | ¥ | £ |
| RDCI (0-9) | 0.83 (0.84;0.91) | ¥ | 2.43 (1.21;3.66) |
| ASDAS-CRP | ¥ | 3.83 (2.17;5.50) | 7.43 (6.12;8.74) |
| BASFI (0-10) | 0.98 (0.98;0.98) | 0.13 (0.05;0.20) | 0.45 (0.39;0.51) |

RDCI=Rheumatic Disease Comorbidity Index; ASDAS-CRP= Ankylosing Spondylitis Disease Activity Score C-Reactive Protein; BASFI=Bath Ankylosing Spondylitis Functional Index;
¥ Not selected during multivariable regression analysis (p ≥0.05).
£ Not selected during univariable analysis (p>0.20)

ment (OR=1.70; 95%CI=1.02;2.83), and in the same direction with presenteeism but without reaching statistical significance (β=-3.42;CI=-13.07;6.23). No significant association between any country SE indicators and absenteeism was found. At individual level, higher education was positively associated with employment-status, presenteeism and absenteeism.

**Conclusions:** Individual- and country-level SE factors affect work participation in SpA, and this varies significantly across countries. Better socio-economic welfare seems to support SpA patients to stay employed and productive.

## CO188 – PROPORTION OF HIP AND NON-HIP MAJOR FRACTURES: COSTS AND QUALITY OF LIFE

Mary Lucy Marques[1], Andrea Marques[1], Alexandra Daniel[1], Luisa Brites[1], JAP da Silva[1]
1. Rheumatology Department, Centro Hospitalar Universitário de Coimbra, Coimbra, Portugal

**Background:** FRAX® country specific risk estimates are a mainstay of current treatment decisions and public health policies in osteoporosis. Because the registries of major non-hip fractures (NHF) is poor in most countries, this estimate is based on the gender and age-specific ratio of hip fractures (HF) to NHF observed in a prospective population-based study performed in Malmo, Sweden[1]. FRAX® presumes, therefore, that the ratio of incidence and cost of hip/major osteoporotic fractures is similar, in every country, to that observed in Sweden. This major assumption has seldom been questioned.

**Objectives:** This retrospective single-centre observational study aimed to assess the proportion of HF vs. NHF and the impact of wrist and vertebral fractures, in terms of costs and health-related quality of life (HrQoL), 1 year after the fracture in Portugal.

**Methods:** We revised the records of all patients observed in an emergency department through a period of 3 months and included those aged 50+ diagnosed with a fragility (low energy) HF or NHF. A telephone interview was conducted in a randomly selected subsample of patients from each type of fracture 1 year after fracture. A questionnaire with socio-demographic data, resource consumption over 1st year and HrQol (EQ-5D)

**TABLE I. PROPORTION, COSTS AND HRQOL PER TYPE OF FRACTURE IN PORTUGAL AND SWEDEN**

| | Portugal | | | Sweden | | |
|---|---|---|---|---|---|---|
| Type of fracture | Hip | Wrist | Vertebral | Hip | Wrist | Vertebral |
| Number (%) of observed fragility fractures | 129 (51) | 100 (39) | 26 (10) | 278 (44) | 276 (43) | 81 (13) |
| Costs (€) per patient, 1st year (95% CI) | 13,434 (12,290;14,576)* | 2220 (1626;2575) | 5390 (1947;6412) | 14,221 (12,912;15,790) | 2147 (1923;2477) | 12,544 (10,059;16,324) |
| Weighed mean cost (€) | 13,434 | 2867 | | 14,221 | 4558 | |
| Average loss of HrQoL – mean (95% CI) | 0.29 (0.22;0.36)* | 0.11 (0.06;0.15) | 0.38 (0.24;0.52) | 0.23 (0.21;0.26) | 0.10 (0.08;0.12) | 0.30 (0.25;0.36) |

CI, Confidence interval; HrQoL, health-related quality of life; *according to data published elsewhere [2]

was applied to patients or their caregivers. Costs were estimated from a societal perspective, including direct and indirect costs. Information is summarized as arithmetic means with 95% confidence intervals (CIs) or percentages as appropriate.

**Results:** In the study period, 1760 patients were observed by the orthopaedics emergency team. Of these, 435 patients had suffered a fracture (129 fragility HF and 152 NHF). The remaining fractures were not considered low-trauma and were therefore excluded. Humerus fractures were also excluded, to mirror the Swedish study. The randomly selected subsample of patients consisted of 66 NHF (55 with wrist and 11 with clinical vertebral fractures). Patients were mostly females in all types of fractures (58%-82%). The mean age at fracture was higher in HF (81.6±8.59 vs. 69.1± 10.06). Falls were the cause of fracture in 97% of cases. Inpatient care was provided to 100% of HF patients vs. 25.8% of NHF patients. The proportion of fractures, average fracture-related costs for the 1st year, and the mean impact upon HrQoL are shown in Table 1.

**Conclusions:** The proportion HF/NHF observed in Portugal is similar to the Swedish reference values (0.44/0.56). The highest cost were attributed to hip fractures in both countries, followed by vertebral fractures and lastly by wrist fractures. The reduction in HrQoL was higher for vertebral fractures in both countries. The reported costs of vertebral fractures are much higher than in Portugal which may significantly affect the calculation of cost-effectiveness thresholds for intervention.


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## CO179 – INCIDÊNCIA DE FRATURA DA EXTREMIDADE PROXIMAL DO FÉMUR EM MULHERES PÓS-MENOPÁUSICAS E A MORTALIDADE PÓS-EVENTO – ESTUDO DE UMA POPULAÇÃO DO INTERIOR DE PORTUGAL


Sara Paiva[1], Pedro Abreu[1, 2]

1. Faculdade de Ciências da Saúde, Universidade da Beira Interior, Covilhã, Portugal

2. Rheumatology Department, Unidade Local de Saúde de Castelo Branco, Castelo Branco, Portugal


**Introdução:** A osteoporose (OP) atinge 10,2% da população portuguesa, afetando sobretudo mulheres. Caracteriza-se pela diminuição da massa óssea e deterioração da microarquitectura óssea, elevando o risco de fraturas de baixo impacto, as quais ocorrem maioritariamente em mulheres após a menopausa e em idosos de ambos os sexos. A Unidade Local de Saúde de Castelo Branco (ULSCB) localiza-se numa região que, para além de apresentar um índice de envelhecimento significativo, apresenta uma prevalência desta patologia de 10,9%. Assim, com o aumento da esperança de vida e consequente envelhecimento populacional, prevê-se um aumento dessa prevalência e da incidência de fraturas de baixo impacto.

**Objetivo:** Calcular as taxas de incidência de fratura da

extremidade proximal fémur (FEPF) de baixo impacto e de mortalidade pós-evento em mulheres pós-menopáusicas e avaliar a sua associação com parâmetros relativos à doente, ao quadro clínico e aos cuidados prestados antes, durante e após o evento.

**Materiais e métodos:** Estudo observacional, retrospetivo, longitudinal e analítico de mulheres com idade igual ou superior a 65 anos, internadas por FEPF de baixo impacto no Serviço de Ortopedia da ULSCB, entre Janeiro 2014 e Dezembro 2015. A recolha de dados foi feita através da consulta de processos clínicos. Os dados foram analisados através de estatística descritiva e, posteriormente, realizaram-se testes estatísticos de correlação para determinar a associação entre variáveis.

**Resultados:** Calculou-se uma incidência anual de FEPF, em mulheres com idade igual ou superior a 65 anos, de 922,4 por 100.000 habitantes. A idade média foi de 84,50 ± 6,44 anos. A hipertensão arterial foi a comorbilidade mais observada (69,0%). 32,3% das doentes apresentava antecedentes de fratura e 8,8% tinha registo de 2 ou mais episódios prévios. A maioria (63,3%) estava medicada com 5 ou mais fármacos. Apenas em 11,6% das doentes estava registado o diagnóstico prévio de OP, estando somente 7,8% previamente medicadas com tratamento anti-osteoporótico. Posteriormente à FEPF, foi prescrita medicação anti-osteoporótica a 11,3%. Um ano após fratura, a taxa de mortalidade foi de 16,3%. Verificou-se apenas uma correlação muito fraca entre a mortalidade e as variáveis: nº de comorbilidades, tratamento posterior, classificação ASA e tratamento conservador.

**Conclusão:** Os resultados deste trabalho são preocupantes e demonstram a importância da problemática que constituem as FEPF, sobretudo em mulheres pós-menopáusicas, onde as taxas de incidência e mortalidade associadas são significativas. Aliando os restantes parâmetros estudados, verificou-se que, apesar de existir uma resposta pronta às FEPF, existe uma grande lacuna em termos de prevenção, diagnóstico e tratamento da OP, mesmo com a existência de guidelines nacionais e internacionais.

## SESSÃO II

### CO165 – 2016 UPDATE OF THE ASAS-EULAR MANAGEMENT RECOMMENDATIONS FOR AXIAL SPONDYLOARTHRITIS

Fernando Pimentel-Santos[1, 2], Désirée van der Heijde[3], Sofia Ramiro[3], Robert Landewé[4], X Baraliakos[5], Van den Bosch F[6], Alexandre Sepriano[1, 2, 3], A Regel[5], A Ciurea[7], Hanne dagfinrud[8], Dougados M[9, 10], F vanGaalen[3], R Inman[11], P Geher[12], I Horst-Bruinsma[4], Uta Kiltz[5], T Kvien[13], Pedro MAchado[14], H Marzo-Ortega[15,16], A Molto[9, 10], J Reveille[17], V Navarro[18], S Ozgozmen[19], Martin Rudwaleit[20], Joachim Sieper[20], P Sampaio-Barros[21], D Wiek[22], Juergen Braun[5]

1. CEDOC, NOVA Medical School. Faculdade de Ciências Médicas da Universidade NOVA de Lisboa, Lisboa, Portugal
2. Rheumatology Department, Hospital Egas Moniz (CHLO), Lisboa, Portugal
3. Rheumatology, Leiden University Medical Center, Leiden, Netherlands
4. Clinical Immunology & Rheumatology, Academic Medical Center, University of Amsterdam, Amsterdam (official), Netherlands
5. Rheumatology, Rheumazentrum Ruhrgebiet, Herne, Germany
6. Department of Rheumatology,, Ghent University Hospital, Ghent, Belgium
7. Department of Rheumatology, University Hospital Zurich, Zurich, Switzerland
8. Norwegian School of Sport Sciences, Oslo, Norway
9. Department of Rheumatology, Cochin Hospital, Paris, France
10. INSERM (U1153), Clinical Epidemiology and Biostatistics, PRES Sorbonne Paris-Cité, Paris, France
11. University of Toronto, Toronto, Canada
12. Hospitaller Brothers of St John of God Hospital, Budapest, Hungary
13. Department of Rheumatology, Diakonhjemmet Hospital, Oslo, Norway
14. Centre for Rheumatology Research & MRC Centre for Neuromuscular Diseases, University College London, London, United Kingdom
15. Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, United Kingdom
16. NIHR Leeds Musculoskeletal Biomedical Research Unit, Leeds Teaching Hospitals Trust, Leeds, United Kingdom
17. The University of Texas-Health McGovern Medical School, Dallas, United States
18. Department of Rheumatology, University Hospital La Paz, Madrid, Spain
19. Division of Rheumatology, Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Erciyes University, keyseri, Turkey
20. Rheumatology Department, Charité – University Medicine, Berlin, Germany

21. Faculdade de Medicina da Universidade de São Paulo, Sao Paulo, Brazil
22. EULAR PARE Patient Research Partner and Chair of EULAR PARE, Berlin, Germany

**Background:** In 2010 the latest ASAS-EULAR recommendations for ankylosing spondylitis and the ASAS recommendations for the use of TNF-inhibitors (TNFi) have been published. Since then new treatments for axial Spondyloarthritis (axSpA) have become available.
**Aim:** To update and integrate the two sets of recommendations into one set applicable to patients with axSpA.
**Methods:** The EULAR Standardised Operating Procedures have been followed. First, two Systematic Literature Reviews have been performed to update the evidence on all treatment options (pharmacological and non-pharmacological) since 2009. The results have been presented during a one-day meeting of the task force. Thereafter, overarching principles and recommendations were updated by a process of achieving consensus and voting.
**Results:** A total of 5 overarching principles and 13 recommendations have been formulated. The first 3 recommendations deal with personalised medicine including treatment target and monitoring. Recommendation 4 deals with non-pharmacological management. Recommendation 5 describes the central role of NSAIDs as first pharmacological treatment. Recommendations 6 to 8 define the limited place of analgesics, glucocorticoids and conventional synthetic DMARDs. Biological DMARDs (bDMARDs) include TNF- and IL17-inhibitors and are indicated in patients diagnosed with axSpa by a rheumatologist, who have radiographic sacroiliitis and/or inflammation on MRI and/or an elevated CRP-level. Patients should also have high disease activity despite the use of -or intolerance for- at least 2 NSAIDs. High disease activity is defined as an ASDAS ≥2.1 or BASDAI ≥4 and an indication to start a bDMARD by a rheumatologist. The continuation of a bDMARD should be considered if an improvement of ASDAS ≥1.1 or BASDAI ≥2 has been achieved after at least 12 weeks. Current practice is to start with a TNFi. Switching to another TNFi or an IL-17i is recommended in case of failure of TNFi treatment. Tapering -but not stopping- of a bDMARD can be considered in patients with sustained remission. The final two recommendations deal with surgery and fractures.
**Conclusion:** The 2016 ASAS-EULAR recommendations provide up-to-date guidance on management of patients with axSpA.

## C025 – SAFETY AND EFFICACY OF CERTOLIZUMAB PEGOL OVER 204 WEEKS IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS, INCLUDING ANKYLOSING SPONDYLITIS AND NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

Ana Lourenço[1], Atulya Deodhar[2], Maxime Dougados[3], Robert Landewé[4], Joachim Sieper[5], Walter P. Maksymowych[6], Martin Rudwaleit[7], Filip Van den Bosch[8], Juergen Braun[9], Philip J. Mease[10], Alan Kivitz[11], Jessica Walsh[12], Owen Davies[13], Bengt Hoepken[14], Luke Peterson[15], Désirée van der Heijde[16]
1. UCB Pharma, Lisboa, Portugal
2. Oregon Health & Science University, Portland, United States
3. Department of Rheumatology, Cochin Hospital, Paris, France
4. Academic Medical Center, University of Amsterdam and Zuyderland Medical Center, Heerlen, Netherlands
5. Rheumatology Department, Charité – University Medicine, Berlin, Germany
6. Department of Medicine, University of Alberta, Edmonton, Canada
7. Department of Internal Medicine and Rheumatology, Klinikum Bielefeld, Bielefeld, Germany
8. Ghent University Hospital, Brussels, Belgium
9. Rheumazentrum Ruhrgebiet, Herne, Germany, 10Swedish Medical Center and University of Washington, Seattle, United States
11. Altoona Center for Clinical Research, Duncansville, United States
12. University of Utah School of Medicine, Salt Lake City, United States
13. UCB Pharma, Slough, United Kingdom
14. UCB Pharma, Monheim, Germany
15. UCB Pharma, Raleigh, United States
16. Rheumatology, Leiden University Medical Center, Leiden, Netherlands

**Background/Purpose:** RAPID-axSpA (NCT01087762) investigated the efficacy and safety of certolizumab pegol (CZP) in patients (pts) with axial spondyloarthritis (axSpA), including ankylosing spondylitis (AS) and non-radiographic (nr)-axSpA. Previously, CZP treatment has been shown to improve the signs and symptoms of axSpA over 96 weeks (wks).1
**Methods:** RAPID-axSpA was double-blind and placebo-controlled to Wk 24, dose-blind to Wk 48 and open-label (OL) to Wk 204. Pts fulfilled ASAS criteria

and had active axSpA with positive sacroiliac joint MRI and/or raised CRP (>7.9 mg/L). Pts randomized to CZP (200 mg Q2W or 400 mg Q4W) continued their assigned dose in the OL period. Efficacy data are presented for pts originally randomized to CZP (combined doses) as observed case (OC) and with imputation: NRI for categorical measures; LOCF for continuous measures. The safety set included all pts treated with ≥1 dose of CZP.

**Results:** 218/325 pts were randomized to CZP from Wk 0, of whom 65% (n=142) completed to Wk 204 (AS: 67% [n=81]; nraxSpA: 63% [n=61]). In the OL

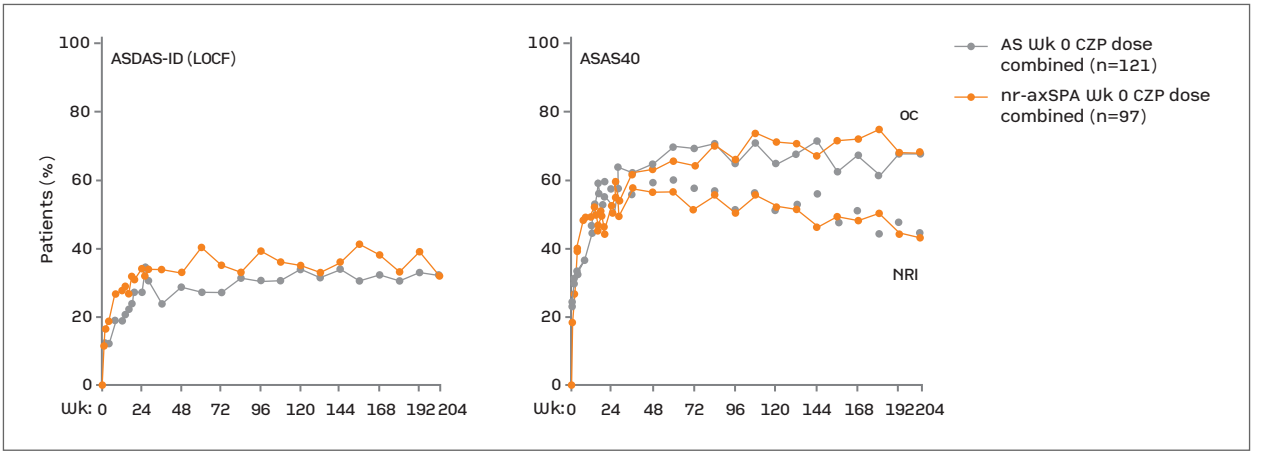


**FIGURE.**

**TABLE.**

| | Wk 0 CZP (dose combined: 200mg Q2W + 400mg Q4W) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | axSpA | | | AS | | | nr-axSpA | | |
| % | Wk24 (NRI) n=218 | Wk204 (NRI) n=218 | Wk204 (OC) n=135 | Wk24 (NRI) n=121 | Wk204 (NRI) n=121 | Wk204 (OC) n=75 | Wk24 (NRI) n=97 | Wk204 (NRI) n=97 | Wk204 (OC) n=60 |
| ASAS20 | 68.3 | 54.1 | 83.7 | 68.6 | 56.2 | 85.3 | 68.0 | 51.5 | 81.7 |
| ASAS40 | 51.8 | 44.0 | 68.1 | 52.9 | 44.6 | 68.0 | 50.5 | 43.3 | 68.3 |
| ASAS PR | 30.3 | 23.4 | 36.5[a] | 28.1 | 21.5 | 32.5[b] | 33.0 | 25.8 | 41.7 |
| Mean [c] | BL n=218 | Wk24 (NRI) n=218 | Wk204 (LOCF) n=218 | BL n=121 | Wk24 (LOCF) n=121 | Wk204 (LOCF) n=121 | BL n=97 | Wk24 (LOCF) n=97 | Wk204 (LOCF) n=97 |
| ASAS PR | 3.8 | 2.1 | 2.0 | 3.9 | 2.1 | 2.0 | 3.8 | 2.0 | 1.9 |
| ASDAS-ID (%) | – | 30.3 | 32.1 | – | 27.3 | 32.2 | – | 34.0 | 32.0 |
| BASDAI | 6.4 | 3.3 | 3.0 | 6.4 | 3.4 | 3.0 | 6.6 | 3.3 | 2.9 |
| BASFI | 5.3 | 3.0 | 2.7 | 5.6 | 3.3 | 3.0 | 5.0 | 2.6 | 2.2 |
| BASMI-linear | 3.8 | 3.2 | 3.1 | 4.2 | 3.6 | 3.6 | 3.2 | 2.6 | 2.5 |
| MASES | 3.5 | 1.6 | 1.2 | 3.0 | 1.1 | 0.9 | 4.0 | 2.3 | 1.6 |
| Back Pain (NRS) | 7.0 | 3.8 | 3.3 | 7.0 | 3.8 | 3.4 | 7.0 | 3.8 | 3.3 |
| Nocturnal Back Pain (NRS) | 6.9 | 3.3 | 3.0 | 6.8 | 3.3 | 3.1 | 7.0 | 3.2 | 2.9 |
| MOS Sleep Scale [d] | 48.1 | 31.3 | 29.9 | 46.4 | 33.0 | 30.1 | 50.2 | 30.4 | 29.6 |

[a] n=137; [b] n=77; [c] Unless otherwise noted; [d] Sleep disturbance. ASAS PR: ASAS Partial Remission; ASDAS-ID: ASDAS Inactive Disease (<1.3); BL: baseline; LOCF: Last observation carried forward; MASES: Maastricht Ankylosing Spondylitis Enthesis Score; MOS: Medical Outcomes Study; NRI: non-responder imputation; NRS: numerical rating scale; OC: observed case

period, 9.2% of pts withdrew due to an adverse event and 1.4% due to lack of efficacy. The proportion of pts achieving ASAS20/40 and partial remission (PR) responses at Wk 24 was maintained to Wk 204 in pts remaining in the study (Figure/Table). All other clinical and patient-reported outcomes also showed maintenance of efficacy to Wk 204, with similar improvements in AS and nr-axSpA pts (Table) and in both CZP dose regimens (data not shown). Spinal mobility (BASMI-linear) and function (BASFI) also improved in both subpopulations, improvements that were maintained until Wk 204. NraxSpA pts had lower scores at Wk 204, but also lower levels of impairment at baseline (BL). 148 pts had BL enthesitis (MASES>0). Increasing proportions of this group who completed to Wk 204 achieved complete enthesitis clearance (MASES=0; OC): 39.6% at Wk 12, 52.5% at Wk 24, and 63.5% at Wk 204. Similarly, of 52 pts with BL heel enthesitis (tenderness at proximal insertion of ≥1 Achilles tendon; OC), 48.0% achieved clearance at Wk 12, 65.3% at Wk 24, and 74.3% at Wk 204. Pts in the safety set (N=315) had a total CZP exposure of 981 patient-years (PY), with a serious adverse event rate per 100 PY of 10.4. Event rate for serious infections was 2.3/100 PY, for malignancies 0.5/100 PY and for serious cardiovascular events 0.4/100 PY. No new safety signals were identified from Wk 96 to Wk 204, and no deaths were reported over 4 years.

**Conclusion:** The RAPID-axSpA trial is the first study to report on the efficacy of an anti-TNF across the broad axSpA population, including both AS and nr-axSpA pts. Long-term data from this study show that pts from both subgroups treated with CZP were able to maintain improvements in disease activity, measured both clinically and by patient-reported outcomes, with no new safety signals, over 4 years of treatment.

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## CO36 – THE GO-DACT PROTOCOL: A RANDOMIZED CONTROLLED TRIAL TO COMPARE THE EFFICACY OF GOLIMUMAB IN COMBINATION WITH METHOTREXATE (MTX) VERSUS MTX MONOTHERAPY, IN IMPROVING DACTYLITIS AND ENTHESITIS, IN MTX NAÏVE PSORIATIC ARTHRITIS PATIENTS

Elsa Vieira-Sousa[1, 2], Helena Canhão[3], JE Fonseca[1, 2]

1. Rheumatology Research Unit, Instituto de Medicina Molecular, Lisboa, Portugal
2. Rheumatology Department, Hospital de Santa Maria (CHLN), Lisbon Medical and Academic Centre, Lisboa, Portugal
3. CEDOC, NOVA Medical School, Nova University, Lisboa, Portugal,

On behalf of the GO-DACT research team

**Background:** Dactylitis is a hallmark manifestation of psoriatic arthritis (PsA) and a key feature for PsA diagnosis. Active dactylitis is associated with a higher risk of erosions and can severely impact function. The therapeutic strategies for dactylitis are however largely empirical, with a profound absence of knowledge regarding efficacy, as primary endpoint, and impact on disease progression. The use of biologic disease modifying anti-rheumatic drugs (DMARDs) in patients with dactylitis, refractory to non-steroidal anti-inflammatory drugs (NSAIDs) or local corticosteroids, is recommended by EULAR guidelines, over the use of conventional DMARDs, based in the scarcity of evidence and properly designed studies in this field.

**Methods:** GO-DACT is an investigator initiated ongoing multicentric trial, involving 13 national Rheumatology departments. Patients older than 18 years, with the diagnosis of PsA and active dactylitis (tenderness score≥1), refractory to NSAIDs, for 3 months, were included. Patients were randomized on a 1:1 ratio, to either MTX in combination with golimumab or placebo, for a period of 24 weeks. The primary aim of this trial is to determine differences of efficacy between the two treatment arms, in improving dactylitis (and enthesitis), as assessed by the dactylitis severity score (DSS) at 24 weeks. Key secondary outcomes include: Leeds dactylitis index (LDI), Leeds enthesitis index (LEI), joint counts, psoriasis area and severity index (PASI) and nail psoriasis severity index (NAPSI), health assessment questionnaire (HAQ), Dermatology life quality index (DLQI) and composite indexes for disease activity. The effect of treatment arms, on different tissue compartments, will be analysed by contrast-enhanced magnetic resonance imaging (MRI), with high resolution images for dactylitis, at baseline and 24 weeks.

**Results/Conclusions:** The results from GO-DACT are expected to have implications in clinical practice, bringing robust and valid data for the definition of dactylitis treatment stratification and algorithm. GO-DACT will also contribute to understand dactylitis pathogenesis through the assessment of treatment efficacy, namely in distinct tissue compartments as defined

by MRI. https://www.clinicaltrials.gov (NCT02065713)
**Acknowledgments:** This investigator initiated trial was supported by a research grant from Merck Sharp and Dome.

## SESSÃO III

### CO139 – PERFORMANCE OF SLEDAI-2K TO DETECT A CLINICALLY MEANINGFUL CHANGE IN SLE DISEASE ACTIVITY: A 36-MONTH PROSPECTIVE COHORT STUDY OF 334 PATIENTS

Diogo Jesus[1], Marília Rodrigues[1], Ana Matos[2], Carla Henriques[2,3], JAP da Silva[1,4], Ines L[1,4,5]
1. Rheumatology Department, Centro Hospitalar Universitário de Coimbra, Coimbra, Portugal
2. Escola Superior de Tecnologia e Gestão, Instituto Politécnico de Viseu, Viseu, Portugal
3. Departamento de Matemática, Universidade de Coimbra, Coimbra, Portugal
4. Faculdade de Medicina, Universidade de Coimbra, Coimbra, Portugal
5. Faculdade de Ciências da Saúde, Universidade da Beira Interior, Covilhã, Portugal

**Background:** The Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) is the core determinant of response in the SLE Responder Index (SRI), a primary efficacy outcome in SLE clinical trials. However, SLEDAI is unable to discriminate partial improvement/worsening, as it scores each item categorically. Furthermore, potentially severe lupus manifestations, such as hemolytic anemia are not scored in SLEDAI.
**Objective:** To evaluate the performance of SLEDAI-2K to detect a clinically meaningful change in SLE disease activity.
**Methods:** Prospective cohort study of SLE patients followed at a tertiary care lupus clinic from January 2014 to December 2016. Consecutive patients fulfilling the ACR'97 and/or the SLICC'12 classification criteria were included. At each outpatient visit, disease activity from the last 30 days was scored in the Physician Global Assessment (PGA) (0-3 cm scale) and in SLEDAI-2K. The association between PGA and SLEDAI-2K at each visit was tested with Spearman's Correlation. A clinically meaningful change in SLE disease activity was defined as difference in PGA ≥0.3 cm at follow-up compared to the baseline visit. Performance of change in SLEDAI-2K was tested in two models: against worsening and improvement in PGA ≥0.3 cm from baseline using Receiver Operating Characteristic (ROC) curve analysis. Sensitivity, specificity, positive and negative predictive values (PPV, NPV) of SLEDAI-2K to change in PGA was calculated. Statistical significance was set at 0.05.
**Results:** We included 334 patients (87.1% female, mean age at baseline - 44.8±14.5 years). At baseline, median PGA and SLEDAI-2K score was 0.2 points (range 0-2.5) and 2 points (range 0-19), respectively.

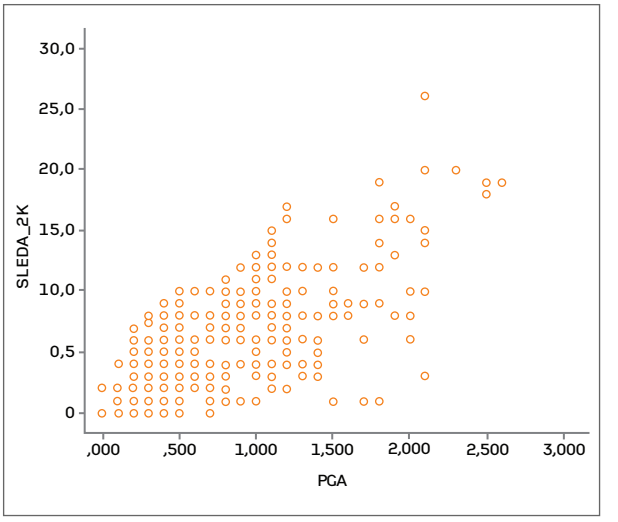


**FIGURE.** Scatter diagram showing linear positive correlation between PGA and SLEDAI-2K scores (Spearman's rho=?0.82, p<0.0001)

**TABLE. PERFORMANCE OF SLEDAI-2K TO DETECT A CLINICALLY MEANINGFUL CHANGE IN PGA, USING CUT-OFFS OF DECREASE AND INCREASE (FOR A CLINICAL IMPROVEMENT AND WORSENING, RESPECTIVELY) IN SLEDAI-2K t1 AND t4 POINTS.**

| | Δ SLEDAI-2K≥1 | | | | Δ SLEDAI-2K≥4 | | | |
|---|---|---|---|---|---|---|---|---|
| | Sens. | Spec. | PPV | NPV | Sens. | Spec. | PPV | NPV |
| Improvement PGA≥0.3 | 0.7 | 0.571 | 0.397 | 0.825 | 0.288 | 0.929 | 0.622 | 0.763 |
| Worsening PGA≥0.3 | 0.725 | 0.903 | 0.627 | 0.936 | 0.353 | 0.996 | 0.947 | 0.873 |

Sens: Sensitivity; Spec: Specificity; PPV: Positive predictive value; NPV: Non predictive value.

Eighty-three patients (24.8%) had a PGA ≥0.4 points at baseline. During follow-up of 36 months, 2129 visits were performed. PGA and SLEDAI-2K scores presented a high correlation (rho=0.82, p<0.0001) (Fig. 1). Reductions in SLEDAI-2K presented in ROC analysis an area under curve (AUC) of 0.697 [95% CI (0.628-0.766), p<0.0001] for an improvement in PGA≥0.3. For a worsening of PGA≥0.3 points, increase in SLEDAI-2K presented an AUC of 0.877 [95% CI (0.822-0.932), p<0.0001]. Estimated sensitivities, specificities, PPV and NPV are presented in Table 1.

**Conclusions:** SLEDAI-2K presents a limited performance in detecting a clinically meaningful change in SLE disease activity, failing to identify more than a quarter of cases with clinically meaningful improvement or worsening. There is a need to optimize SLE disease activity measures.

## CO106 – INFLUENCE OF PATIENT GLOBAL ASSESSMENT ON THE DISEASE ACTIVITY ASSESSMENT IN PATIENTS WITH RHEUMATOID ARTHRITIS: A METEOR CROSS-SECTIONAL STUDY

Ricardo J. O. Ferreira[1, 2], Mwidimi Ndosi[3], Cátia Duarte[1, 4], Pedro David Carvalho[1], Arvind Chopra[5], David Vega[6, 7], Karen Salomon-Escoto[8], Désirée van der Heijde[9], Pedro MAchado[10], JAP da Silva[1, 4]

1. Rheumatology Department, Centro Hospitalar e Universitário de Coimbra, Coimbra, Portugal
2. Health Sciences Research Unit: Nursing (UICiSA:E), Coimbra, Portugal
3. HAS – Nursing and Midwifery, University of the West of England, Bristol, United Kingdom
4. Faculdade de Medicina, Universidade de Coimbra, Coimbra, Portugal
5. Center for Rheumatic Diseases, New Delhi, India
6. Hospital Universitario "Dr. José Eleuterio González", Mexico City, Mexico
7. Universidad Autónoma de Nuevo León, Mexico City, Mexico
8. Rheumatology, UMass Memorial Medical Center, Boston, United States
9. Rheumatology, Leiden University Medical Center, Leiden, Netherlands
10. Centre for Rheumatology Research & MRC Centre for Neuromuscular Diseases, University College London, London, United Kingdom

**Background:** Disease activity indices (DAI) are used to guide immunosuppressive therapy in rheumatoid arthritis (RA). The inclusion of patient global assessment (PGA) in these indices has been questioned as it conveys mainly disease impact rather than disease activity.

**Objectives:** To determine the influence of PGA on patient disease states and to determine PGA correlations with inflammatory parameters, disease impact, demographic, clinical and contextual factors.

**Methods:** The METEOR international database was used, namely data from patients' first available visit with no missing values on PGA, tender and swollen joint counts (TJC28, SJC28) and C-reactive protein (CRP). Remission rates were compared according to the DAS28CRP3v vs 4v and ACR/EULAR Boolean remission vs near-remission (failing 1 of the 4 criteria) definition. We assessed the correlation of PGA with (predominantly) inflammatory (TJC28, SJC28, CRP) and disease impact (pain and HAQ) factors. We used hierarchical modelling to explain PGA by 4 blocks (B) of independent variables (B1: gender, age, disease duration; B2: biologic DMARD, Gross National Income; B3: pain, HAQ; and B4: TJC28, SJC28, CRP).

**Results:** Among the 18280 patients analysed, 1930 (10.6%) were in DAS28CRP4v remission, and 2197 (12.0%) in DAS28CRP3v remission. According to the Boolean definition, 1207 (6.6%) patients were in remission. PGA was the main obstacle to Boolean remission: 2090 (79.0%) of the 2645 near-remission patients (Table 1). A considerable proportion of patients with low inflammation perceived high PGA (Figure 1).

**TABLE. REMISSION AND NEAR-REMISSION RATES (N=18280)**

| Disease activity | 3v | 4v |
|---|---|---|
| DAS28CRP#, n (%) | | |
| Remission (≤1.9) | 2197 (12.0) | 3855 (21.1) |
| Low (≤2.2) | 12228 (66.9) | 1930 (10.6) |
| Moderate to high (>2.2) | 3485 (19.1) | 12865 (70.3) |
| ACR/EULAR Boolean, n (%) | | |
| Remission | 1207 (6.6) | |
| Near-rem. PGA | 2090 (11.4) | |
| Near-rem. CRP | 214 (1.2) | |
| Near-rem. SJC28 | 165 (0.9) | |
| Near-rem TJC28 | 176 (1.0) | |
| Non-remission | 14428 (78.9) | |

# Fleischmann, R. et al (2015) Ann Rheum Dis. 74(6):1132-7

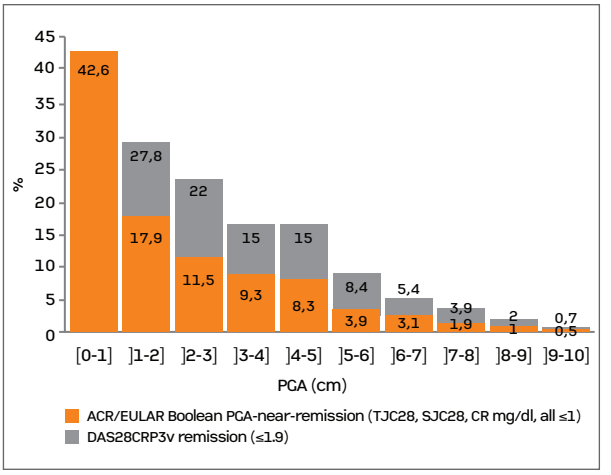


**FIGURE.** PGA distribution in patients in remission by DAS28CRP3v and in PGA-near-remission by Boolean definition

PGA correlated better with Pain (r=.79) and HAQ (r=.55) than with TJC28 (r=.45), SJC28 (r=.36) or CRP (r=.25).

In the entire dataset (n=6388), 60.2% of PGA variance was explained (p<.001) by Pain and HAQ, 1.8% by B1 (age, dender and disease duration) and B2 (Gross National Income and bDMARDS) of covariates and only 1.3% by B4 (TJC28, SJC28, CRP). In near-remission patients (n=831), B4 did not contribute significantly (p>.05) to changes in the model.

**Conclusions:** Two thirds of patients that achieve TJC28, SJC28 and CRP ≤1 still perceive high PGA despite disease "inflammatory" control. The weight of PGA in DAI could put patients at risk of immunosuppressive overtreatment. In these patients, disease impact management, including non-pharmacological treatments delivered by Health Care Professionals, are more likely to be effective.

## CO149 – DRUG SURVIVAL OF THE FIRST BIOLOGIC IN RHEUMATOID ARTHRITIS AND PREDICTORS THEREOF IN REAL WORLD CLINICAL PRACTICE

João Lagoas Gomes[1,2], Alexandre Sepriano[2,3], Sofia Silvério Serra[1], Mónica Eusébio[4], JE Fonseca[5,6], Maria João Saavedra[5], Luís Cunha-Miranda[7], Cândida Silva[7], Miguel Bernardes[8], Diana Rosa-Gonçalves[8], J Costa[9], Walter Castelão[1], Jaime C. Branco[1, 2], Maria José Santos[6, 10]

1. Rheumatology Department, Hospital Egas Moniz (CHLO), Lisboa, Portugal
2. CEDOC, NOVA Medical School. Faculdade de Ciências Médicas da Universidade NOVA de Lisboa., Lisboa, Portugal
3. Rheumatology, Leiden University Medical Center, Leiden, Netherlands
4. Sociedade Portuguesa de Reumatologia, Lisboa, Portugal
5. Rheumatology Department, Hospital de Santa Maria (CHLN), Lisbon Medical and Academic Centre, Lisboa, Portugal
6. Rheumatology Research Unit, Instituto de Medicina Molecular, Lisboa, Portugal
7. Rheumatology Department, Instituto Português de Reumatologia, Lisboa, Portugal
8. Serviço de Reumatologia, Centro Hospitalar de São João, Porto, Portugal
9. Rheumatology Department, Unidade Local de Saúde do Alto Minho, Ponte de Lima, Portugal
10. Rheumatology Department, Hospital Garcia de Orta, Almada, Portugal

**Introduction:** Several clinical trials have clearly demonstrated that biological agents improve signs and symptoms of Rheumatoid Arthritis (RA) in patients that responded inadequately to conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs). 'Real-world' observational data (eg. time to drug discontinuation) yield relevant data easier to translate to clinical practice, but this evaluation was not yet performed in Portuguese RA patients.

**Objective:** To assess drug survival of first line biotechnological treatment in RA using the Rheumatic Diseases Portuguese Register (Reuma.pt) and to identify predictors thereof.

**Methods:** RA patients registered in the Reuma.pt from

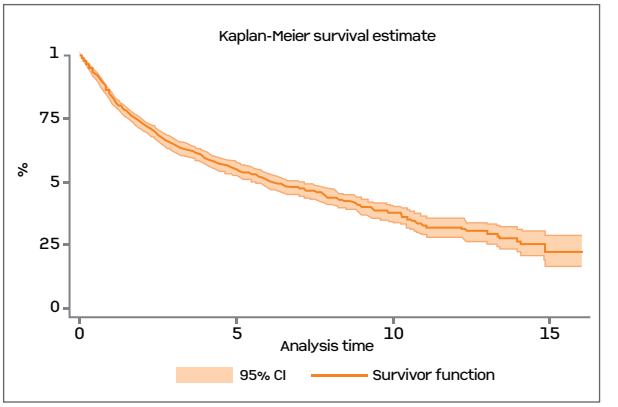


**FIGURE.** Kaplan-Meier survival estimates for first line biologic therapy in Portuguese RA patients

2008 until January 2016 and treated with biotechnological therapies were included in this prospective observational cohort. Discontinuation was defined as a 90-day continuous gap of treatment without a posterior biological treatment or the occurrence of any switch to another biological agent. Baseline sociodemographic and clinical characteristics were registered. The main outcome was time to discontinuation (in years) due to any cause. Drug survival was analyzed using the Kaplan-Meier method. Multivariable Cox-regression models were built to assess the possible effect of baseline factors on drug survival.

**Results:** Of the 1,852 RA patients included in the study, 829 (44.8%) discontinued their first biologic treatment. Lack of treatment efficacy was the leading cause of discontinuation [n=468, (56.5%)], followed by adverse events [n=237, (28.6%)] and other causes [n=80, (9.7%)]. The reason was unknown for 44 patients (5.3%). The median survival time for the first biologic was 6.08 years (IQR: 1.73 – 14.82) and in the multivariable analysis, statistically significant baseline predictors of time to discontinuation were HAQ [aHR=1.44 (1.16-1.78)] and swollen joint count [aHR=0.97 (0.95-0.99)].

**Conclusion:** Inefficacy is the leading cause of drug discontinuation for first line biologic agents in the Portuguese RA population. Baseline HAQ and swollen joint count were found to predict drug discontinuation.

**Disclosures:** This study received an investigator initiated research grant from Pfizer®

## SESSÃO IV

### CO41 - PERSISTENCE WITH FIRST BIOLOGICAL AGENT AND REASONS FOR DISCONTINUATION IN PATIENTS WITH JUVENILE IDIOPATHIC ARTHRITIS: DATA FROM THE PORTUGUESE REGISTER, REUMA.PT

Ana Filipa Mourão[1,2], Mónica Eusébio[3], José Melo-Gomes[4], Filipa Oliveira Ramos [5,6,7], Martins FM[3], Paula Estanqueiro[8], Manuel Salgado[8], Marta Conde[9,10], Sónia Carvalho[11], J Costa[12], Cátia Duarte[13], Iva Brito[14, 15], Carolina Furtado[16], Rodrigues AM[17, 18], Graça Sequeira[19], Raquel Campanilho-Marques[4, 5], Jaime C. Branco[1, 2], Maria José Santos[7, 20], João Eurico Fonseca[5, 7], Helena Canhão[18]

1. Rheumatology Department, Hospital Egas Moniz (CHLO), Lisboa, Portugal
2. CEDOC, Nova Medical School, Lisboa, Portugal
3. Sociedade Portuguesa de Reumatologia, Lisboa, Portugal
4. Rheumatology Department, Instituto Português de Reumatologia, Lisboa, Portugal
5. Pediatric Rheumatology Unit, CHLN, Hospital de Santa Maria, EPE, Lisboa, Portugal
6. Centro Académico de Medicina de Lisboa, Lisboa, Portugal
7. Rheumatology Research Unit, Instituto de Medicina Molecular, Lisboa, Portugal
8. Pediatrics Department, Centro Hospitalar Universitário de Coimbra, Hospital Pediátrico, Coimbra, Portugal
9. Pediatrics, Centro Hospitalar do Porto, Hospital de Santo António, Porto, Portugal
10. Pediatrics, Hospital D. Estefânia, Lisboa, Portugal
11. Pediatrics, Centro Hospitalar de Médio-Ave, Vila Nova de Famalicão, Portugal
12. Rheumatology Department, Hospital Conde de Bertiandos (ULSAM), Ponte de Lima, Portugal
13. Rheumatology Department, Centro Hospitalar Universitário de Coimbra, Coimbra, Portugal
14. Serviço de Reumatologia, Centro Hospitalar de São João, Porto, Portugal
15. Faculdade de Medicina da Universidade do Porto, Porto, Portugal
16. Rheumatology Department, Hospital do Divino Espírito Santo, Ponta Delgada, Portugal
17. SEEBMO, Hospital de Santo Espirito da Ilha Terceira, Angra do Heroísmo, Portugal
18. EpiDoC Unit, CEDOC, NOVA Medical School, NOVA University, Lisboa, Portugal
19. Rheumatology Department, Hospital de Faro, Faro, Portugal
20. Rheumatology Department, Hospital Garcia de Orta, Almada, Portugal

**Background:** Persistence on medication mainly reflects both effectiveness and safety of a drug. Understanding the reasons to stop bDMARD in routine clinical practice can help to better define the efficacy and safety of biologic medications in children with juvenile idiopathic arthritis (JIA).

**Objectives:** To investigate persistence on treatment and the reasons for discontinuation of the first biological in patients with JIA.

**Methods:** Portuguese patients with JIA registered in Reuma.pt who started a bDMARD were analyzed. Persistence was defined as the length of time between treatment initiation and discontinuation of the first

bDMARD. The mean time until discontinuation was calculated using Cox regression survival estimates and the reasons for discontinuation of the first bDMARD were registered.

**Results:** Of the 1724 JIA patients registered in Reuma.pt, 319 received biological therapy, 62% (198) female. The mean age at disease onset was 7.7±4.8 years the mean time between the beginning of JIA and the first bDMARD was 8.2±9.4 years. The mean disease duration was 13.7±10.7 years and the mean age at the beginning of biological therapy was 15.8 ± 9.4 years. The distribution of JIA categories was: 19.1% polyarticular RF-negative, 17.2% enthesitis-related arthritis, 16.6% polyarticular RF positive (Poly RF +), 16% extended oligoarticular, 13.5% persistent oligoarticular (OligoP), 12% systemic JIA and 0.9% had undifferentiated arthritis. Considering the whole group, 53.2% have had extra–articular manifestations since the beginning of the disease. The mean time till treatment discontinuation of the first bDMARD (due to any cause) adjusted for gender, biological therapy, JIA subtype, age at the beginning of biological therapy, and disease duration until initiating first bDMARD was 44.8 ± 38.3 months (median: 34.7 months). Considering the categories of JIA, patients with Poli RF + had a longer stay in first biologic treatment (mean: 64.6 ± 48.6; median 50.4 months) while OligoP patients had a shorter duration of biological treatment (mean: 30.9 ± 29.8; median: 18.7 months). The biologic agent with longer persistence was Etanercept (mean: 49.9 ± 40.9; median: 41.4 months). The major reasons for drug discontinuation were inefficacy (49.6%), remission (14.2%), adverse events (10.6%), patient decision (1.6%) and pregnancy planning (1.4%). In 22.7% the reason was not specified.

**Conclusions:** Our study shows that persistence with the first biological treatment in the overall population of JIA was almost four years, being longer in Poly RF+ patients. Almost half of the patients stopped their first biological agent due to lack of response, reinforcing the need for the existence of several treatment options fully studied in JIA.

## CO177 – EFFICACY AND SAFETY OF TUMOUR NECROSIS FACTOR ANTAGONISTS IN A LARGE COHORT OF JUVENILE DERMATOMYOSITIS PATIENTS

Raquel Campanilho-Marques[1,2,3,4], Claire Deakin[2], Stefania Simou[2], Lucy R. Wedderburn[2, 5], Clarissa A. Pilkington[1]

1. Rheumatology, Great Ormond Street Hospital for Children NHS Foundation Trust, London, United Kingdom
2. Infection, Inflammation and Rheumatology Section, UCL, Institute of Child Health, London, United Kingdom
3. Rheumatology Department, Hospital de Santa Maria (CHLN), Lisbon Medical and Academic Centre, Lisboa, Portugal
4. Rheumatology Department, Instituto Português de Reumatologia, Lisboa, Portugal
5. Arthritis Research UK Centre for Adolescent Rheumatology, UCL, UCLH and GOSH, London, United Kingdom

**Background:** Some patients with juvenile dermatomyositis (JDM) have a disease course which is refractory to multiple drug treatments. There is evidence that prolonged disease activity is associated with increased mortality and morbidity. High levels of TNF have been reported in JDM patients with a long disease course, suggesting it may play a significant role in refractory disease. There are no published clinical trials of this therapy but some are in progress. The aim of this study was to evaluate the efficacy and safety of anti-TNF treatment in UK JDM Cohort and Biomarker Study patients. Methods: Data were analysed from children who were recruited to the UK JDM Cohort and Biomarker Study, met Bohan-Peter criteria and were on anti-TNF treatment at the time of analysis, and had had at least 3 months of therapy. Childhood Myositis Assessment Scale (CMAS), Manual Muscle Testing (MMT8), muscle enzymes and physicians global assessment (PGA) were recorded. Skin disease was assessed using modified skin Disease activity score (DAS).

**Results:** 67 patients with JDM actively treated with anti-TNF agents were analyzed. 41 patients were female (61%). The median [IQR] age at disease onset was 5.2 [3.4-9.5] years and the median age at beginning of anti-TNF was 10.1 [6.5-14] years. The median disease duration at beginning of anti-TNF was 3.2 [1.8-5.3] years and the median duration on anti-TNF was of 2.55 [1.5-3.9] years. Muscle involvement significantly improved, with median [IQR] CMAS and MMT8 values at initiation of anti-TNF therapy of 45.50 [39.75-52.25] and 74 [59.5-79.5] respectively, and at current evaluation (or date of anti-TNF treatment completion) of 53 [50-53] and 79 [74.5¬80] ($p<0.0001$ and $p=0.0097$; Mann Whitney test), respectively. For skin involvement the initial modified DAS was 4 [2-5] and final 1 [0-3] ($p<0.0001$; Mann Whitney test). Assess-

ing global disease activity the initial PGA was 2.9 [1.3-4.3] and final 0.5 [0-1.45] ($p<0.0001$; Mann Whitney test). Sixteen patients switched their anti-TNF treatment. Ten of the switches were due to therapy failure, 4 due to adverse events and 2 for patient preference in subcutaneous administration. Of 31 adverse events (AE) registered (13.3 AE per 100 patient-years), 12 were considered severe (5.3 severe AE per 100 patient--years). One patient died due to small bowel perforation (not felt to be related to the use of TNF antagonists). The remaining adverse reactions were not severe and 79% (n=15) of them were due to infections causes. In 5 of the mild to moderate adverse reactions the drug had to be discontinued and switched to another TNF antagonist, while in the remaining patients temporarily withholding the drug proved sufficient. No malignancies or tuberculosis were reported.

**Conclusions:** This study is one of the largest to explore the efficacy and safety of TNF antagonist treatment in a large independent cohort of JDM patients. Both muscle and skin involvement appeared to improve after anti-TNF treatment.

## C073 – REUMA.PT/VASCULITIS – TWO YEARS EXISTENCE OF THE PORTUGUESE VASCULITIS REGISTRY

Nikita Khmelinskii[1,2], Cristina Ponte[1,2], Daniela Peixoto[3], Marília Rodrigues[4], Lídia Teixeira[5], Sandra Sousa[5], Joana Aleixo[6], Teresa Pedrosa[7], Sofia Silvério Serra[7], Walter Castelão[7], Ana Cordeiro[5], Inês Cordeiro[1, 2], Sílvia Fernandes[1, 2], Carla Macieira[1,2], Pedro Madureira[6], Armando Malcata[4], Karine Luz[1, 2], Vítor Teixeira[1, 2], Romana Vieira[6], Mónica Eusébio[8], Martins FM[8], Graça Sequeira[9], Jaime C Branco[7], Lúcia Costa[6], José Canas da Silva[5], JAP da Silva[4], Carmo Afonso[3], JE Fonseca[1, 2], Helena Canhão[8], Raashid A Luqmani[10], Maria José Santos[5, 8]

1. Rheumatology Department, Hospital Santa Maria, CHLN, Lisbon Academic Medical Center, Lisboa, Portugal
2. Rheumatology Research Unit, Instituto de Medicina Molecular, Faculdade de Medicina da Universidade de Lisboa, Lisboa, Portugal
3. Rheumatology Department, Unidade Local de Saúde do Alto Minho, Ponte de Lima, Portugal
4. Rheumatology Department, Centro Hospitalar e Universitário de Coimbra, Coimbra, Portugal
5. Rheumatology Department, Hospital Garcia de Orta, Almada, Portugal
6. Rheumatology Department, Centro Hospitalar de São João, Porto, Portugal
7. Rheumatology Department, Hospital Egas Moniz, CHLO, Lisboa, Portugal
8. Sociedade Portuguesa de Reumatologia, Lisboa, Portugal
9. Rheumatology Department, Hospital de Faro, CHA, Faro, Portugal
10. Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, United Kingdom

**Background:** The vasculitides are a group of relatively uncommon diseases with different manifestations and outcomes. New therapeutic options have led to the need for long-term registries. The Rheumatic Diseases Portuguese Register, Reuma.pt, is an electronic clinical record, created in 2008, which currently includes specific protocols for 11 diseases and >16000 patients registered from 79 national and international rheumatology centres. Since October 2014, a dedicated protocol to vasculitis has been created as part of the European Vasculitis Society initiative for having compatible European registries.

**Objectives:** To describe the structure of Reuma.pt/Vasculitis and characterize the patients registered over the last two years.

**Methods:** We developed a dedicated web-based software, based on Reuma.pt, to enable prospective collection and central storage of anonymised data from patients with vasculitis. All Portuguese rheumatology centres were invited to participate. Data regarding demographics, diagnosis, classification criteria, imaging and laboratory tests, outcome measures of prognosis, damage, disease activity and quality of life, and treatment were collected. We performed a cross-sectional descriptive analysis of all patients registered up to February 2017.

**Results:** A total of 532 patients, with 1206 visits, from 12 centres were registered in Reuma.pt/Vasculitis. The mean age was 53±20 years at last visit; 69% were females. The diagnoses followed the 2012 Chapel Hill Consensus nomenclature (Table). The most common diagnoses were Behçet's disease (BD) (40%) and giant cell arteritis (GCA) (20%). Patients with BD met the International Study Group 1990 criteria, the International Criteria for BD 2006 and 2013 in 86%, 90% and 91% of cases, respectively. Data on HLA typing was available in 34% patients, of whom 49% were HLA--B51 positive. Patients with GCA met the 1990 American College of Rheumatology criteria in 98% of cases. Data on vascular ultrasound was available in 73% of pa-

**TABLE. DIAGNOSIS, DEMOGRAPHICS AND ORGAN INVOLVEMENT OF THE VASCULITIS PATIENTS REGISTERED IN REUMA.PT/VASCULITIS**

| | | Total | TAK | GCA | PAN | MPA | GPA | EGPA | CV | IgAV | BD | CS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Demographics | Number of patients | 532 | 22 | 106 | 24 | 13 | 34 | 22 | 15 | 12 | 215 | 12 |
| | (% of total) | (100) | (4.1) | (19.9) | (4.5) | (2.4) | (6.4) | (4.1) | (2.8) | (2.2) | (40.4) | (2.2) |
| | Female/male ratio | 2.2 | 10 | 1.7 | 1 | 2.3 | 1.1 | 2.7 | 4 | 0.5 | 3.1 | 1.4 |
| | Mean age at diagnosis | 46.5 | 35.2 | 73.8 | 39.6 | 60.7 | 49.2 | 51.2 | 56.6 | 29.0 | 33.5 | 28.4 |
| | in years (SD) | (20.7) | (14.3) | (7.8) | (20.2) | (15.5) | (12.2) | (14.6) | (13.2) | (20.8) | (12.4) | (9.0) |
| Organ involvement in % (n) | General symptoms | 36 | 75 | 55 | 64 | 71 | 67 | 64 | 63 | 25 | 12 | 44 |
| | | (324) | (12) | (75) | (11) | (7) | (18) | (14) | (8) | (8) | (127) | (9) |
| | Musculoskeletal | 51 | 36 | 53 | 73 | 71 | 70 | 57 | 78 | 63 | 45 | 44 |
| | | (329) | (11) | (79) | (11) | (7) | (20) | (14) | (9) | (8) | (128) | (9) |
| | Skin | 57 | 9 | 3 | 73 | 17 | 39 | 69 | 71 | 88 | 80 | 33 |
| | | (375) | (11) | (71) | (11) | (6) | (18) | (13) | (7) | (8) | (184) | (9) |
| | Eyes | 41 | 9 | 45 | 20 | 17 | 33 | 14 | 13 | 0 | 53 | 100 |
| | | (336) | (11) | (73) | (10) | (6) | (18) | (14) | (8) | (8) | (146) | (9) |
| | ENT | 25 | 0 | 47 | 10 | 33 | 79 | 71 | 0 | 0 | 2 | 100 |
| | | (319) | (10) | (74) | (10) | (6) | (19) | (14) | (8) | (8) | (126) | (9) |
| | Chest/pulmonary | 13 | 10 | 0 | 30 | 43 | 50 | 100 | 0 | 0 | 5 | 11 |
| | | (316) | (10) | (70) | (10) | (7) | (18) | (16) | (8) | (8) | (126) | (9) |
| | Cardiovascular | 44 | 92 | 88 | 50 | 33 | 11 | 31 | 0 | 0 | 28 | 0 |
| | | (352) | (12) | (96) | (10) | (6) | (18) | (13) | (8) | (8) | (138) | (9) |
| | Gastrointestinal | 60 | 18 | 4 | 30 | 17 | 17 | 15 | 14 | 75 | 99 | 30 |
| | | (400) | (11) | (72) | (10) | (6) | (18) | (13) | (8) | (8) | (210) | (10) |
| | Genitourinary | 57 | 33 | 6 | 42 | 71 | 68 | 29 | 0 | 75 | 85 | 11 |
| | | (394) | (12) | (71) | (12) | (7) | (19) | (14) | (8) | (8) | (200) | (9) |
| | Neurologic | 50 | 40 | 92 | 67 | 50 | 39 | 81 | 38 | 0 | 28 | 33 |
| | | (349) | (10) | (95) | (12) | (6) | (18) | (16) | (8) | (8) | (132) | (9) |

The patients with single-organ vasculitis, vasculitis associated with systemic disease, vasculitis associated with probable etiology, not-classifiable vasculitis or missing diagnosis are excluded.
BD – Behçet's disease; CS – Cogan syndrome; CV – cryoglobulinemic vasculitis; EGPA – eosinophilic granulomatosis with polyangiitis; ENT – ear nose and throat; GCA – giant cell arteritis; GPA – granulomatosis with polyangiitis; IgAV – immunoglobulin A vasculitis; MPA – microscopic polyangiitis; PAN – polyarteritis nodosa; SD – standard deviation; TAK – Takayasu arteritis

tients; 73% compatible with the diagnosis. Anti-neutrophil cytoplasmic antibody (ANCA) testing was available in 71% ANCA-associated vasculitis (AAV) and 42% polyarteritis nodosa (PAN) patients. The patients with microscopic polyangiitis, granulomatosis with polyangiitis and eosinophilic granulomatosis with polyangiitis were myeloperoxidase-ANCA positive in 60%, 14% and 40% of cases, and proteinase 3-ANCA positive in 20%, 73% and 20% of cases. No patient with PAN had ANCA positivity. Assessment of the Birmingham Vasculitis Activity Score (BVAS) and Vasculitis Damage Index (VDI) was available for all vasculitides and the Five Factor Score calculation of survival rate was available for AAV and PAN. The mean BVAS at first visit was 11±7 for AAV and 11±9 for PAN; the mean VDI at last visit was 2±2 for AAV and 2±2 for PAN. Health related quality of life assessments (SF-36, EQD5, FACIT and HADS) were also collected. Treatment registry with the disease assessment variables shown in graphics was available for all patients; only 6% were under biologic treatment.

**Conclusions:** Reuma.pt/Vasculitis is a registry adapted for routine care, allowing an efficient data repository at a national level with the potential to link with other international databases. It facilitates research, trials recruitment, service planning and benchmarking.

## SESSÃO V

### C063 – ROLE OF ULTRASOUND IN THE ASSESSMENT OF THE CARPAL TUNNEL SYNDROME: SHOULD WE GO MORE DISTAL?

Sandra Falcao[1,2], Alexandre Sepriano[1,3], Sofia Ramiro[1, 3], Carolina Furtado[4], Teresa Novoa[4], Paula Moniz[5], Guilherme Figueiredo[4]

1. CEDOC, NOVA Medical School. Faculdade de Ciências Médicas da Universidade NOVA de Lisboa., Lisboa, Portugal
2. Rheumatology Department, Hospital Egas Moniz (CHLO), Lisboa, Portugal
3. Rheumatology, Leiden University Medical Center, Leiden, Netherlands
4. Rheumatology Department, Hospital do Divino Espírito Santo, Ponta Delgada, Portugal
5. Plastic Surgery, Hospital do Divino Espírito Santo, Ponta Delgada, Portugal

**Background:** Ultrasound (US) measurement of the median nerve cross section area (CSA) has been used to diagnose Carpal Tunnel Syndrome (CTS). The difference between the site of lowest CSA (entrapment area) and the largest CSA (greatest nerve swelling) with a cut-off of 5 mm2 has been described as a high specific (>90%) US sign for CTS diagnosis. However, the 'best' anatomical locations to measure the median nerve remain controversial.

**Objectives:** i) to compare the median nerve CSA at different anatomical landmarks including a newly proposed ultra-distal (UD) site; ii) to compare the proportion of patients 'captured' by the cut-off of 5 mm2 by the 'conventional landmarks' to the proposed UD landmark; and iii) to assess the association between symptoms' duration and the CSA at the different landmarks.

**Methods:** In this cross-sectional study, consecutive patients with clinically suspected CTS referred to a rheumatology department were included from November 2014 to June 2015. Patients with diabetes mellitus, neurological diseases, secondary causes of CTS, wrist surgery or local corticosteroid injection were excluded. Median nerve CSA of both hands was measured (by a rheumatologist expert in US), in square millimetres (mm2), at three different levels: 1) proximal (P-CSA): scaphoid-pisiform line; 2) distal (D-CSA): hook of the hamate line; 3) ultra-distal (UD-CSA): beyond carpal tunnel outlet. The Wilcoxon's test was used to compare the CSA at the different landmarks. Multilevel linear generalized estimating equations (GEE) were used to test the association between symptoms' duration and CSA taking into account the correlation between measurements within the same hand, as well as both sides from the same patient.

**Results:** In total, 96 patients (187 wrists) were included [87 women; mean (SD) symptoms' duration: 5.0 (4.8) years]. In both hands, the median UD-CSA was significantly larger as compared to the P-CSA [right: Δ (IQR) =2.5 (8.0) mm2; p=0.002; left: Δ (IQR)=2.0 (6.0) mm2; p=0.002)], indicating larger 'ultra-distal' edema as compared to the 'conventional' proximal site. Thus, not surprisingly, the likelihood of detecting CTS according to a 'US-definition' based on a 5mm2 cut-off was 2-times higher when using the ultra-distal landmark as compared to the conventional proximal landmark [table; Δ UD-D: 60.8% vs ΔP-D: 43%; OR (95% CI): 2.17 (1.06; 4.71)). Finally, a statistically significant positive association between symptoms' duration and the UD-CSA, adjusted for gender and age [aβ (95%CI) =0.43 (0.12; 0.73); p=0.006] was found. The same association was also seen for the P-CSA [aβ (95%CI) =0.32 (0.13; 0.52); p=0.001], but not for the D-CSA [aβ (95%CI) =0.05 (-0.08; 0.17);

**TABLE I. PROPORTION OF PATIENTS WITH A DIFFERENCE OF THE P-D CSA AND UD-D CSA > 5MM²**

| Δ UD-D* \ Δ P-D* | Δ CSA > 5 mm² | Δ CSA ≤ 5 mm² | Total |
|---|---|---|---|
| Right hand | | | |
| Δ CSA > 5 mm² | 22 | 26 | 48 |
| Δ CSA ≤ 5 mm² | 12 | 19 | 31 |
| Total | 34 | 45 | 79 |
| Left hand | | | |
| Δ CSA > 5 mm² | 20 | 17 | 37 |
| Δ CSA ≤ 5 mm² | 7 | 35 | 42 |
| Total | 27 | 52 | 79 |

* ΔUD-D = difference between the ultra-distal CSA and distal CSA; Δ P-D= difference between the proximal CSA and distal CSA.

p=0.464].

**Conclusion:** In this proof-of-concept study, we have, for the first time, described 'ultra-distal' median nerve swelling among patients with clinically suspected CTS. In addition, edema at this site was significantly larger compared to the 'conventional' proximal landmark, thus increasing the likelihood to detect CTS. Prospective studies are warranted to evaluate the applicability, diagnostic and prognostic values, of this new proposed--site for median nerve assessment.

## C089 – ULTRASOUND ASSESSMENT OF SKIN THICKNESS IN SYSTEMIC SCLEROSIS PATIENTS: CORRELATION WITH CLINICAL FEATURES

Joana Sousa-Neves[1], Marcos Cerqueira[1], Daniela Santos-Faria[1], Joana Leite Silva[1], Ana Raposo[2], Carmo Afonso[1], Filipa Teixeira[1]

1. Rheumatology Department, Hospital Conde de Bertiandos (ULSAM), Ponte de Lima, Portugal

2. Rheumatology, Centro Hospitalar Trás-os-Montes e Alto Douro, Vila Real, Portugal

**Background:** Although modified Rodnan skin score (mRSS) is the most widely used measure for assessment of skin involvement in Systemic Sclerosis (SSc), ultrasound (US) of skin thickness seems to be a promising complementary tool. (1)

**Objectives:** To compare skin thickness measured by US of a defined anatomical point between SSc patients and age and sex matched controls. To compare, among patients, US measurements of skin thickness with local and total mRSS and other specific clinical variables.

**Methods:** Forty-eight SSc patients and 45 age and sex matched controls were evaluated in a cross-sectional study at our Rheumatology Unit. SSc patients had a mean age of 56.98 ± 12.73 years and mean disease duration of 9.77 ± 6.12 years; 42 patients had limited cutaneous disease. Regarding US assessment, skin thickness was arbitrarily defined as thickness of epidermis, dermis and subcutaneous tissue, in millimetres, measured at the 2nd finger of both hands of each subject on the dorsal aspect of the proximal phalange. Examination was performed with a 15 MHz linear probe of a General Electric LOGIQ S8 US. For comparison between groups, mean skin thickness (mST) of combined right and left side was used. Patients' local and total mRSS were also assessed. Hand mobility in SSc (HAMIS) was calculated to evaluate functional disability and SSc Severity Scale (SScSS) to estimate activity and damage. Additional data was also collected from patients' clinical charts. Statistical analysis included Mann-Whitney U-test, Kruskal-Wallis and Spearman correlation coefficient test. Statistical significance was defined as P value < 0.05.

**Results:** SSc patients showed higher mST (3.17 mm [2.56 to 3.58]) (median [interquartile range]) compared with controls (1.89 mm [1.55 to 2.08]) (p<0.001). Among SSc group, skin thickness measured by US of both 2nd fingers of each patient strongly correlated with local mRSS assessed by palpation (Spearman's rho=0.698, p<0.001 and rho=0.645, p<0.001 for right and left sides, respectively). US mST was also correlated with total mRSS (rho=0.568, p<0.001), HAMIS (rho=0.520, p<0.001) and SScSS (rho=0.524, p<0.001). A higher mST was found in patients clinically classified with oedematous phase (p<0.001) and in diffuse cutaneous subtype (p=0.039). A mild asso-

ciation was observed for patients with digital ulcers (p=0.05). Age, gender, disease duration and the presence of calcinosis were not associated with US mST (p>0.05).

**Conclusions:** US measurements of skin thickness of 2nd fingers were significantly higher in SSc patients compared with age and sex matched controls. US mST strongly correlated with local and total mRSS and was significantly higher in the presence of oedema, digital ulcers and in patients with diffuse subset. US mST also reflected functional disability and damage.

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## CO163 – UNDIFFERENTIATED CONNECTIVE TISSUE DISEASES – HOW DO THEY DIFFERENTIATE OVER 10 YEARS?

Nathalie Madeira[1], Dina Medeiros[1], Alexandra Cardoso[2], Cândida Silva[1], Cláudia Miguel[1], Filipe Barcelos[1], Helena Madeira[1], Helena Santos[1], José Vaz Patto[1], Luís Cunha-Miranda[1], Manuela Micaelo[1], Manuela Parente[1], Maria Jesus Mediavilla[1], Margarida Silva[1], Miguel Sousa[1], Paulo Clemente-Coelho[1], Sara Cortes[1], Vera Las[1], Augusto Faustino[1]

1. Rheumatology Department, Instituto Português de Reumatologia, Lisboa, Portugal

2. Nutrition Department, Instituto Português de Reumatologia, Lisboa, Portugal

**Background:** Patients who present features of connective tissue diseases (CTD) but do not fulfill classification criteria (CC) for a defined CTD are diagnosed as having an undifferentiated connective tissue disease (UCTD).

**Objectives:** To assess the prevalence and evolution of clinical manifestations and laboratorial findings of patients with a diagnosis of UCTD over 10 years and to determine the rate of those who fulfill CC for a specific disease during follow-up.

**Methods:** We had access to the data collected in 2006 from a cohort of 101 patients with diagnosis of UCTD followed in our Rheumatology Center for at least one year. Mosca et al criteria for UCTD were used: presence of clinical manifestations suggestive of CTD and the presence of antinuclear antibodies (ANA) not fulfilling the classification criteria for CTD. We decided to elaborate a retrospective study based on these data from 2006 (T1) and to complete them until the last evaluation (T2, that took place until 2016) collecting the following parameters from clinical records: demographic, clinical, laboratorial and therapeutics. The CC for the specific diseases used to evaluate the patients until T2 were the ones existing at T1. Statistic data (SPSS v17.0) included Wilcoxon and McNemar tests for related samples, p<0.05.

**Results:** The clinical records of 60 patients were available, 58 (96.7%) of which were female, with a mean age at T1 of 51.9±12.5 years and a mean duration of follow-up of 10.6±5.7 years at T2. The prevalence evolution of the clinical and laboratorial manifestations is reported on table 1. In what concerns treatment, we reported that at T1, all patients were taking non-steroidal anti-inflammatory drugs (NSAID's), glucocorticoid (GC) or DMARDs, or a combination, but at T2 five patients were not taking any of these drugs. The maximum number of DMARDs per patient was 2 in T1 (3 patients) and 3 in T2 (1 patient). Of these 60 patients, 18 (30%) fulfill CC for a specific disease at T2: 7 (38.9%) for systemic lupus erythematosus (SLE), 4 for rheumatoid arthritis, 4 for Sjögren syndrome (one of which secondary to SLE) and 4 for seronegative spondyloarthritis.

**Conclusion:** The prevalence of most of the clinical and laboratorial characteristics increased over time but only few of these differences were significant. The absence of reports of vasculits and the persistence of low prevalence of lung disturbances, myositis and dysphagia over time allow us to admit that most of our cohort remained with a mild disease, without serious organic complications. The fact that some patients were not even under NSAID's, GC or IMT at T2 supports this argument. After a mean follow-up of 10.6 years, the diagnosis of UCTD persisted in 70% of patients, which is concordant with the literature that reports that most patients with UCTD will have the same diagnosis even after several years of follow-up. However, since additional disease manifestations may develop and a non-negligible part could evolve into a defined CTD, these patients should be followed up closely. Other than a classification exercise, the identification of a specific CTD has therapeutic and prognosis impacts, as early diagnosis is one of the best tools for preventing late organ damage. Studies differ about the specific disease for which patients with UCTD more frequently differentiate. In our cohort, as in some of these studies, we found that CC patients most often fulfill were those for SLE. Those differences between studies may be explained by the CC used for each disease.

**TABLE. CLINICAL MANIFESTATIONS, LABORATORIAL FINDINGS AND THERAPEUTICS OF THE STUDIED COHORT AT T1 AND T2**

| | T1 | T2 | p-value |
|---|---|---|---|
| Articular symptoms – N (%) | 59 (98.3) | 60 (100.0) | NS |
| Arthralgia – N (%) | 34 (56.7) | 26 (43.3) | 0.021 |
| Arthritis – N (%) | 25 (41.7) | 34 (56.7) | 0.004 |
| Changes in blood count – N (%) | 19 (31.7) | 26 (43.3) | 0.016 |
| Leukopenia – N (%) | 12 (20.0) | 15 (25.0) | NS |
| Anemia – N (%) | 7 (11.7) | 13 (21.7) | 0.031 |
| Thrombocytopenia – N (%) | 3 (5.0) | 3 (5.0) | NS |
| Sicca symptoms – N (%) | 26 (43.3) | 35 (58.3) | 0.004 |
| Alopecia – N (%) | 7 (11.7) | 10 (16.7) | NS |
| Skin lesions – N (%) | 18 (30.0) | 21 (35.0) | NS |
| Malar rash – N (%) | 5 (8.3) | 8 (13.3) | NS |
| Rash discoid – N (%) | 0 (0.0) | 0 (0.0) | – |
| Sclerodactyly – N (%) | 0 (0.0) | 2 (3.3) | NS |
| Telangiectasias – N (%) | 1 (1.7) | 1 (1.7) | NS |
| Photosensitivity – N (%) | 15 (25.0) | 19 (31.7) | NS |
| Raynaud's phenomenon – N (%) | 16 (26.7) | 21 (35.0) | 0.063 |
| Oral ulcers – N (%) | 15 (25.0) | 20 (33.3) | 0.063 |
| Arterial hypertension – N (%) | 14 (23.3) | 27 (45.0) | <0.0001 |
| Dysphagia – N (%) | 2 (3.3) | 3 (5.0) | NS |
| Fever – N (%) | 2 (3.3) | 3 (5.0) | NS |
| Vasculitis – N (%) | 0 (0.0) | 0 (0.0) | – |
| Lung disturbances (pulmonary hypertension, interstitial fibrosis or pleurisy) – N (%) | 1 (1.7) 1 | (1.7) | NS |
| Myositis – N (%) | 1 (1.7) | 1 (1.7) | NS |
| Serological changes – N (%) | 60 (100.0) | 60 (100.0) | – |
| ANA – N (%) | 60 (100.0) | 60 (100.0) | – |
| Anti-DNAds – N (%) | 2 (3.3) | 4 (6.7) | NS |
| Anti-SSA – N (%) | 8 (13.3) | 9 (15.0) | NS |
| Anti-SSB – N (%) | 3 (5.0) | 5 (8.3) | NS |
| Anti-Scl-70 – N (%) | 1 (1.7) | 1 (1.7) | NS |
| Anti-centromere – N (%) | 2 (3.3) | 2 (3.3) | NS |
| Anti-Jo-1/Anti-Sm/Anti-RNP – N (%) | 0 (0.0) | 0 (0.0) | – |
| Antiphospholipid antibodies/Anti-cardiolipin/Lupus anticoagulant – N (%) | 0 (0.0) | 0 (0.0) | – |
| Anti-cryoglobulin – N (%) | 1 (1.7) | 6 (10.0) | 0.063 |
| Decreased C3 – N (%) | 2 (3.3) | 2 (3.3) | NS |
| Decreased C4 – N (%) | 0 (0.0) | 0 (0.0) | – |
| Decreased CH50 – N (%) | 2 (3.3) | 4 (6.7) | NS |
| Therapeutics | | | |
| Non-steroidal anti-inflammatory drugs (NSAID's) – N (%) | 52 (86.7) | 46 (76.7) | NS |
| Glucocorticoid (GC) – N (%) | 39 (65.0) | 29 (48.3) | 0.041 |
| Dose of glucocorticoids – mean±SD | 3.8±3.5 | 2.67±3.6 | NS |
| Hydroxychloroquine (HCQ) – N (%) | 37 (61.7) | 21 (35.0) | <0.0001 |
| Azathioprine (AZA) – N (%) | 0 (0.0) | 1 (1.7) | NS |
| Methotrexate (MTX) – N (%) | 11 (18.3) | 12 (20.0) | NS |
| Sulfassalazine (SSZ) – N (%) | 1 (1.7) | 5 (8.3) | NS |
| Isolated NSAID's – N (%) | 11 (18.3) | 17 (28.3) | NS |
| Isolated GC – N (%) | 2 (3.3) | 2 (3.3) | NS |