Methods: The study represents analysis of capillaroscopic images of 32 patients with RP – primary and secondary in the context of SSc or other rheumatic diseases i.e., undifferentiated connective tissue disease (UCTD) and systemic lupus erythematosus (SLE). All the patients had signed an informed consent for participation in a study of their capillaroscopic, laboratory and clinical associations. The study represents retrospective analysis of the capillaroscopic images obtained from 8 fingers (II-V bilaterally) using USB capillaroscope (Dinolite) at magnification 200x. Capillary diameters were measured (arterial, venous and apical loop) as well as the number of capillaries per millimeter. The capillaroscopic images were categorized into the following groups i.e., I. Absence of microangiopathy: i) normal pattern, ii) nonspecific changes (dilated capillaries with arterial diameter > 0.015mm, venous > 0.020mm; haemorrhages and/or other nonspecific changes), II. Presence of microangiopathy i.e., “scleroderma”/“scleroderma-like” pattern. Presence of giant capillaries with capillary diameter >0.050mm was considered as a sufficient criterion for classifying the image as “scleroderma”/“scleroderma-like” pattern. For “scleroderma” type images in SSc patients staging of Cutolo et al (2000) was used i.e., “early”, “active”, “late” phase (1).

Results: Images suitable for analysis with good visibility that permits analysis of the major capillaroscopic parameters were available in all patients. Among 32 included patients, 9 patients were with SSc, 12 cases with primary RP, and 10 patients with secondary RP in other CTD (7 patients with UCTD and 3 patients with SLE). „Scleroderma” pattern was detected in 6 patients with SSc and in all these cases the capillaroscopic images were classifiable into one of the three distinct phases i.e., “early”, “active” and “late” phase. Presence of microvascular changes (“scleroderma-like” pattern) was detected also in 5 among the 10 patients with other CTD i.e., UCTD and SLE. In primary RP patients capillaroscopy revealed either normal pattern or nonspecific findings but without features of microangiopathy.

Conclusion: Good capillaroscopic images, which could be analyzed and interpreted, are usually obtained using USB capillaroscope. This permits evaluation of the major capillaroscopic parameters. The available software although less sophisticated vs those of videocapillaroscopes, gives the opportunity for measurement of capillary diameters, mean capillary density, etc. The images received from USB capillaroscope are easily classified into “scleroderma”, “scleroderma-like”, non-specific changes and normal pattern. The most important conclusion from capillaroscopy is about presence or absence of microangiopathy. This was easily detected via USB capillaroscope that could be suggested as an ideal alternative for videocapillaroscopes in every day rheumatology practice especially at low budget cases. Measurements of capillary diameters and capillary density provide quantitative data that make these devices also appropriate for scientific research.

REFERENCES:

- [1] Cutolo M, Sulli A, Pizzorni C AS. Nailfold videocapillaroscopy assessment of microvascular damage in systemic sclerosis. *J Rheumatol.* 2000;27(1):155–60.

Disclosure of Interests: None declared.

DOI: 10.1136/annrheumdis-2021-eular.4159

AB0461 “SCLERODERMA-LIKE” PATTERN AS A PRESENTING FEATURE OF CONNECTIVE TISSUE DISEASES

S. Lambova¹. ¹Medical University - Plovdiv, Department of Propaedeutics of Internal Diseases, Plovdiv, Bulgaria

Background: The role of capillaroscopy for early diagnosis of systemic sclerosis (SSc) is well-known and pathological capillaroscopic pattern is a component of the new set of criteria for SSc (EULAR/ACR 2013). While it is also known that similar microvascular changes i.e., “scleroderma-like” could be observed in other rheumatic diseases i.e., undifferentiated connective tissue disease (UCTD), overlap syndromes, systemic lupus erythematosus (SLE), etc., the data about the time of their appearance in other rheumatic diseases different from SSc are scarce.

Objectives: The aim of the study was to evaluate the prevalence of capillaroscopic features of microangiopathy in Raynaud's phenomenon (RP) patients at the time of their first referral to rheumatology setting.

Methods: 22 in- and outpatients were included in the study that were referred for consultation in our rheumatology unit in the last 6 months. Inclusion criteria were presence of RP at their first consultation or still unclear diagnosis. Presence of known rheumatic disease diagnosed at previous consultation with rheumatologist as well as signs of definite diagnosis SSc were exclusion criteria. All the patients underwent capillaroscopic examination with USB capillaroscope Dinolite (magnification 200x). Routine laboratory tests were ordered i.e., complete blood count, ESR, CRP, biochemistry as well as immunological tests. ANA test was performed in all patients while antibodies against extractable nuclear antigens, antiphospholipid antibodies or other tests were ordered depending on the clinical presentation and overall context. The patients signed an informed consent for participation of the study.

Results: 12 of the examined patients were diagnosed with primary RP and their capillaroscopic examination revealed absence of microangiopathy i.e., normal pattern or non-specific changes (mainly dilated capillaries). In 7 patients the final diagnosis was UCTD and 4 of them exhibited microvascular pathology i.e. “scleroderma-like” pattern, while in 3 cases the capillaroscopic findings were non-specific. Among other patients 1 case was diagnosed with prescleroderma with “early” phase “scleroderma” pattern (according to definition of Cutolo et al., 2000 (1)), 1 case was with onset of SLE (“scleroderma-like” pattern, active phase) and in one case the microvascular pathology that included single giant capillary loop no other signs of connective tissue disease were found and the final conclusion was “suspected secondary” RP with necessity for a regular follow-up.

Conclusion: In conclusion, definite features of microvascular pathology, known as “scleroderma-like” capillaroscopic pattern, could be observed as an initial pathological feature in CTD different from SSc such as UCTD and SLE and the overall diagnosis should be made in the overall context. Capillaroscopy inherits high significance in patients with UCTD, in whom clinical presentation could be obscure in the beginning and identification of microvascular capillaroscopic pathology is among the crucial signs to support the diagnosis. Future studies are necessary to delineate the role of microvascular pathology for prediction of future evolution of UCTD.

REFERENCES:

- [1] Cutolo M, Sulli A, Pizzorni C AS. Nailfold videocapillaroscopy assessment of microvascular damage in systemic sclerosis. *J Rheumatol.* 2000;27(1):155–60.

Disclosure of Interests: None declared.

DOI: 10.1136/annrheumdis-2021-eular.4172

Spondyloarthritis – treatment

AB0462 BMI IS ASSOCIATED WITH BOTH DISEASE ACTIVITY AND TNF- α INHIBITOR SERUM TROUGH LEVELS IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS ON LONG-TERM TREATMENT WITH TNF- α INHIBITORS

L. De Wolff¹, S. Arends¹, E. Brouwer¹, H. Bootsma¹, A. Spoorenberg¹.

¹University Medical Centre Groningen and University of Groningen, Rheumatology and Clinical Immunology, Groningen, Netherlands

Background: TNF- α inhibitors (TNFi) are widely used in axial spondyloarthritis (axSpA) patients with active disease. Approximately half of patients stop TNFi treatment, often due to loss of treatment efficacy.¹ TNFi serum trough levels have been associated with initial therapeutic response in axSpA patients.² Additionally, a relation was found between serum trough TNFi levels and BMI.³

Objectives: To explore in axSpA patients on long-term TNFi therapy associations between randomly measured TNFi serum trough levels, disease activity and BMI.

Methods: Patients from the UMCG on adalimumab or etanercept and a regular visit in the Groningen Leeuwarden Axial Spondyloarthritis (GLAS) cohort were approached for a random TNFi serum trough level measurement. Based on reference values of Sanku³, serum trough levels were stratified in therapeutic and below therapeutic levels. The Ankylosing Spondylitis Disease Activity Score (ASDAS) from a regular outpatient GLAS visit was used for analyses, if assessed <2 months of the serum trough level measurement. Active disease according to ASDAS was defined as ≥ 2.1 . Correlations and univariable logistic regression were performed. Multivariable logistic regression was performed to correct the relation between therapeutic drug levels and ASDAS for potential confounders.

Results: 94 axSpA patients on adalimumab or etanercept were approached for a random TNFi serum trough level measurement, of which 55 (59%) had a measurement taken. See Table 1 for patient characteristics. No significant correlations were found for adalimumab or etanercept serum trough levels (as continuous variable) with ASDAS (adalimumab: $r=-0.16$, $p=0.39$; etanercept: $r=-0.29$, $p=0.20$). According to Sanku definitions of therapeutic TNFi levels, 26 patients (47%) had therapeutic serum trough levels: 19/34 (56%) for adalimumab and 7/21 (33%) for etanercept. Univariable logistic regression showed no significant associations between therapeutic levels (yes/no) and ASDAS. In multivariable analyses, BMI was identified as the only confounder for the relationship between therapeutic drug levels and ASDAS. Median BMI was higher, although not statistically significant, in patients with below-therapeutic serum trough levels compared to therapeutic levels (27.1, IQR 24.6-31.7 vs. 24.3, IQR 22.7-31.4, $p=0.08$). Furthermore, BMI had a significant, negative correlation with adalimumab and etanercept serum levels (adalimumab: $r=-0.48$, $p=0.01$, etanercept: $r=-0.46$, $p=0.04$) (Figure 1). Patients with active disease according to ASDAS had higher BMI than patients with inactive disease (median 29.7 vs. 24.5, $p=0.01$).

Conclusion: In this cross-sectional, observational study of axSpA patients on long-term TNFi treatment, BMI was significantly correlated with adalimumab and etanercept serum trough levels. Furthermore, BMI was significantly higher

in patients with active disease. Therefore, overweight /obese patients on TNFi treatment and active disease, might benefit from an increase in TNFi dose.

REFERENCES:

[1] Arends et al, Clin Exp Rheumatol 2017;35:61-68
[2] Kneepkens et al, Ann Rheum Dis 2015;74:396-401
[3] Rosas et al, Clin Exp Rheum 2017;35:145-148
[4] Sanquin Amsterdam. Diagnostic tests. Available via: www.sanquin.org/nl/producten-en-diensten/diagnostiek/diagnostische-testen/index

Table 1. Characteristics of 55 axSpA patients with random adalimumab or etanercept serum trough level measurements

	Adalimumab (n=34)	Etanercept (n=21)
Age (years)	45 ± 13	46 ± 12
Gender (male)	14 (41)	12 (57)
BMI (kg/m ²)	26.6 (24.5-32.7)	24.3 (21.9-29.5)*
Symptom duration (years)	21 ± 14	20 ± 8
HLA-B27 positive	26 (79)	16 (84)
ASDAS	2.3 (1.7-3.1)	1.6 (1.3-2.0)**
Treatment duration current TNFi (months)	27 (7-57)	58 (12-76)
Serum trough level (µg/ml)	5.2 (3.7-8.0)	1.6 (1.1-2.4)

Values are mean ± SD, median (IQR) or n (%)*Significant difference (p<0.05) and **(<0.01) compared to patients on adalimumab

Figure 1. Scatterplot of BMI and serum trough level of adalimumab (A) and of etanercept (B)

Disclosure of Interests: Liseth de Wolff: None declared., Suzanne Arends Grant/research support from: Pfizer, Elisabeth Brouwer Grant/research support from: Pfizer, Hendrika Bootsma: None declared., Anneke Spoorenberg Consultant of: Abbvie, Pfizer, MSD, Novartis and UCB, Grant/research support from: Abbvie, Pfizer and Novartis.
DOI: 10.1136/annrheumdis-2021-eular.521

AB0463 IMPROVEMENTS IN PATIENT-REPORTED OUTCOMES IN ANKYLOSING SPONDYLITIS PATIENTS TREATED WITH GOLIMUMAB: SUB-ANALYSIS OF ASIAN PATIENTS ENROLLED IN PHASE-3 CLINICAL TRIALS

W.C. Tsai¹, C. Bao², D. Furtner³, K. H. Lo⁴, Y. Zhou⁴, E. C. Hsia^{4,5}. ¹Kaohsiung Medical University, Department of Internal Medicine, Kaohsiung, Taiwan, Republic of China; ²Renji Hospital, Department of Rheumatology, School of Medicine, Shanghai Jiao Tong University, Shanghai, China; ³Janssen, a Division of Johnson & Johnson Pte Ltd., Singapore, Singapore; ⁴Janssen Research & Development, LLC, Spring House, United States of America; ⁵University of Pennsylvania Medical Center, Rheumatology, Philadelphia, United States of America

Background: Clinical efficacy and safety of golimumab (GLM) for patients with ankylosing spondylitis (AS) who have not received prior biologic therapy were studied in two phase-3 clinical trials (NCT00265083 - GO RAISE and NCT01248793). In both studies, a greater proportion of patients treated with GLM 50mg every 4 weeks achieved improvement in clinical signs and symptoms measured by ASAS20 and in patient-reported outcomes, such as Health Related Quality of Life (HRQoL) and sleep disturbance when compared with placebo (PBO) at Weeks 14 and 24.

Objectives: To assess the effect of GLM on HRQoL, back pain, and sleep disturbances in phase-3 studies in Asian patients with AS.

Methods: Post-hoc sub-analysis to examine HRQoL, measured with the Short Form 36 (SF-36) Physical and Mental Component Summary (PCS and MCS), total back pain (VAS) and sleep disturbance, assessed with the Jenkins Sleep Evaluation Questionnaire (JSEQ) in active AS patients enrolled from Asian countries (China, including Taiwan region and South Korea). Improvement from baseline to Week 24 was expressed as mean and standard deviation (SD) for

SF-36 PCS and MCS and total back pain. Reduction of sleep disturbance was expressed as the proportion of patients with improvement from baseline ≥2 points in the JSEQ, defined as baseline value minus post-baseline value with lower scores indicating the better sleep evaluation.

Results: At Week 24, active AS patients treated with GLM 50mg had greater mean improvements in SF-36 and total back pain than PBO. The pooled results were comparable with patients enrolled from other regions (Table 1). A higher proportion of Asian patients who received GLM had reduced sleep disturbance (JSEQ ≥2) after 24 weeks than PBO (59.7% [83/139] vs 38.5% [47/122]; Δ21.2) and the results were similar with AS patients on GLM (67.4% [64/95] vs 45.6% [26/57]; Δ21.8) pooled from other regions.

Conclusion: Asian patients with AS treated with GLM demonstrated improved HRQoL, total back pain, and reduced sleep disturbance. The pooled results were comparable with other regions.

Table 1. Mean Improvement from Baseline in HRQoL and total back pain at Week 24: Randomized Patients in AS Studies Pooled for Asia and all other regions

	Pooled AS in APAC				Pooled AS in All Other Regions			
Parameter	Placebo		GLM 50 mg		Placebo		GLM 50 mg	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
SF-36 PCS	122	2.51 (6.372)	139	7.10 (8.434)	58	1.91 (8.268)	99	10.12 (11.096)
SF-36 MCS	122	0.22 (9.609)	139	3.32 (9.280)	58	1.20 (9.705)	99	1.98 (8.032)
Total Back Pain	120	1.86 (2.469)	135	2.73 (2.607)	58	0.79 (2.688)	99	3.39 (3.210)

APAC, Asia-Pacific; AS, ankylosing spondylitis; GLM, golimumab; HRQoL, Health Related Quality of Life; MCS, mental component summary; PCS, physical component summary; SD, standard deviation; SF-36, Short Form 36

Disclosure of Interests: Wen-Chan Tsai Consultant of: Pfizer, AbbVie, Roche, and Eli Lilly, Chunde Bao: None declared., Daniel Furtner Shareholder of: Johnson & Johnson, Employee of: Johnson & Johnson Pte. Ltd., Singapore, Kim Hung Lo Shareholder of: Johnson & Johnson, Employee of: Janssen Research & Development, LLC, Yiyi Zhou Shareholder of: Johnson & Johnson, Employee of: Janssen Research & Development, LLC, Elizabeth C Hsia Shareholder of: Johnson & Johnson, Employee of: Janssen Research & Development, LLC.
DOI: 10.1136/annrheumdis-2021-eular.951

AB0464 DRUG SURVIVAL OF TNFI AND SECUKINUMAB IN AXIAL SPONDYLARTHRTIS: A REAL-WORLD MULTICENTRIC COHORT OF 370 PATIENTS

T. Delepine¹, P. Philippe¹, E. Cailliau², E. Houvenagel³, X. Deprez⁴, R. M. Flipo¹, J. G. Letarouilly¹. ¹Lille University Hospital, Department of Rheumatology, Lille, France; ²Lille University Hospital, Biostatistics, Lille, France; ³Saint-Philibert Hospital, Rheumatology, Lomme, France; ⁴Valenciennes Hospital, Department of Rheumatology, Valenciennes, France

Background: IL17 inhibitors (IL17i) are an alternative for patients with axial spondyloarthritis (axSpA) who did not respond to TNF inhibitors (TNFi). Secukinumab (SEC) is the first human monoclonal antibody that binds to the protein interleukin-17A.

Objectives: The objectives of this study were to describe the characteristics of axSpA patients treated with IL17i and TNFi and to assess the persistence with IL17i and TNFi in a real world cohort.

Methods: A retrospective multicenter observational study was conducted. axSpA patients (pts) according to ASAS criteria initiating a IL17i or TNFi between June 2016 and December 2019 were included. Demographic features, current and previous use of biologic Disease-modifying antirheumatic drugs (bDMARDs) were collected. Date and reasons of discontinuation – i.e., lack of efficacy, safety issue, sustained remission or others – were collected. Kaplan-Meier analysis were performed.

Results: 370 pts were included. Among the 202 patients who received TNFi, 90 (44.6%) were female, mean age was 43.2 +/- 13.2 years, mean body mass index was 26.1 kg/m² +/- 5.4, 49 pts (46.7%) were smokers. The most common SpA phenotype was axial radiographic (n = 89, 54.9%) and 114 (68.3%) pts were HLA B27 positive, mean BASDAI was 5.75 +/- 14.6, median disease duration was 8.6 years [3.0-10.5]. Among the 168 patients who received SEC, 78 (46.4%) were female, mean age was 47.7 +/- 11.8 years, mean body mass index was 27.2 kg/m² +/- 5.8, 45 pts (44.1%) were smokers. The most common SpA phenotype was axial radiographic (n = 106, 76.3%) and 114 (78.1%) pts were HLA B27 positive, mean BASDAI was 62.8 +/- 14.8, median disease duration was 9 years [5.0-19.0]. TNFi was the first line bDMARD in 116/202 pts (57.4%) and SEC was the first line bDMARD in 15/168 pts (8.9%). SEC was prescribed at 150mg every month in 121/168 (73.3%) pts. The median persistence with TNFi and SEC were 18.0 months [11.0-27.0] and 12.0 months [6.0-22.0],