FRI0047

STRATEGIES REGARDING GOAL SETTING AND SELF-MANAGEMENT IN DIFFICULT-TO-TREAT RHEUMATOID ARTHRITIS: PRELIMINARY RESULTS OF A SYSTEMATIC LITERATURE REVIEW INFORMING THE 2020 EULAR RECOMMENDATIONS FOR THE MANAGEMENT OF DIFFICULT-TO-TREAT RHEUMATOID ARTHRITIS

N. M. T. Roodenrijs[1], A. Hamar[2], M. Kedves[3], G. Nagy[4], J. M. Van Laar[1], D. Van der Heijde[5], P. Welsing[1]. [1]*University Medical Center Utrecht, Department of Rheumatology & Clinical Immunology, Utrecht, Netherlands*; [2]*University of Debrecen, Department of Rheumatology, Debrecen, Hungary*; [3]*Bács-Kiskun County Hospital, Department of Rheumatology, Kecskemét, Hungary*; [4]*Semmelweis University, Department of Genetics, Cell and Immunobiology & Department of Rheumatology, 3rd Department of Internal Medicine, Budapest, Hungary*; [5]*Leiden University Medical Center, Department of Rheumatology, Leiden, Netherlands*

Background: Rheumatoid arthritis (RA) patients treated according to European League Against Rheumatism (EULAR) recommendations failing ≥2 biological or targeted synthetic disease-modifying antirheumatic drugs with a different mode of action who still have complaints which may be suggestive of active disease and for whom management is perceived as problematic by patient and/or rheumatologist have been defined as suffering from 'difficult-to-treat RA'. A mismatch in goal setting between patient and health care professional, and suboptimal self-management may contribute to this disease state, while specific management recommendations regarding these factors are currently lacking.[1]

Objectives: To systematically summarise evidence in the literature on the identification and optimisation of a mismatch in goal setting and suboptimal self-management in difficult-to-treat RA patients, informing the 2020 EULAR recommendations for the management of difficult-to-treat RA.

Methods: A systematic literature review (SLR) was performed: PubMed, Embase and Cochrane databases were searched up to December 2018. Relevant papers were selected and appraised. Effect sizes were extracted or calculated.

Results: Three studies were selected on the identification and four on the optimisation of a mismatch in goal setting (Figure 1). No accurate measures were found to identify a mismatch in goal setting, but patients expressed a desire to take their quality of life goals more explicitly into account. Education was found to improve goal setting (4 of 4 studies, effect size not calculable).

Five studies were selected on the identification and 31 on the optimisation of suboptimal self-management (Figure 1). Although formal evaluations in high quality studies were lacking, the Arthritis Self-Efficacy Score was found to be the most reliable tool to identify suboptimal self-management. Patients were found to desire more education on nutrition, the disease and the diagnostic process to be able to improve self-management. Self-management programs, educational and psychological interventions were found to improve self-management (Table 1).

Table 1: Effect sizes of studies on the optimisation of self-management

Outcome	Type of intervention	Benefit of intervention compared to control[1] in *n* of *n* selected studies	Studies with effect size (*n*)	Effect size per study[2]
Self-efficacy	Self-management programs	12/13	6	0.18–0.39; 0.23–0.67; 0.37; 0.43–0.53; 0.49;[3] 7.52–8.25
	Education	6/6	3	0.05–0.17; 0.22–0.59; 1.23
	Psychological	2/2	2	0.20–0.35; 0.45
Anxiety	Psychological	1/2	1	0.17[3]
Depressive symptoms	Psychological	1/2	1	0.15–0.33[3]
RA knowledge	Education	3/3	2	0.34–0.47; 0.84

n: number of studies; RA: rheumatoid arthritis.

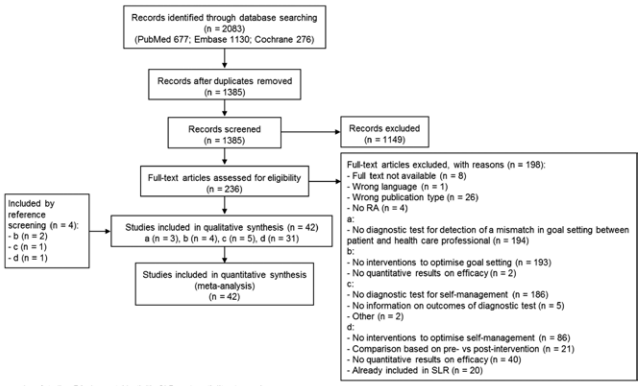
1. Mostly usual care or wait list; 2. If different outcome measures were used the range in effect sizes over these measures is reported; 3. Pooled effect size, reported in systematic literature review.

Conclusion: In difficult-to-treat RA patients, limited evidence was found on a mismatch in goal setting and suboptimal self-management, especially regarding their identification. Non-pharmacological interventions were found to improve goal setting and self-management.

References:

[1] Smolen JS *et al. Ann Rheum Dis* 2020. Epub ahead of print.

Figure 1. Flow charts of search and selection of studies: (a) The identification of a mismatch in goal setting and (b) optimisation of goal setting, and (c) the identification and (d) optimisation of suboptimal self-management.



n: number of studies; RA: rheumatoid arthritis; SLR: systematic literature review.

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NUMBER NEEDED TO TREAT TO ACHIEVE MINIMUM CLINICALLY SIGNIFICANT DIFFERENCES IN PATIENT-REPORTED OUTCOMES IN PATIENTS TREATED WITH BARICITINIB

V. Strand[1], L. Sun[2], J. Ross Terres[2], C. L. Kannowski[2]. [1]*Stanford University School of Medicine, Division of Immunology/Rheumatology, Portola Valley, United States of America*; [2]*Eli Lilly and Company, Indianapolis, United States of America*

Background: Baricitinib (BARI) provided rapid and sustained improvements in patient-reported outcomes (PROs) in randomized, controlled trials (RCTs) in patients (pts) with active rheumatoid arthritis (RA) and inadequate responses (IR) to methotrexate (MTX) (RA-BEAM; NCT01710358)[1,2] and biologic DMARDs (bDMARD-IR; RA-BEACON; NCT01721044)[3,4].

Objectives: To determine the number needed to treat (NNT) to report improvements ≥minimum clinically important differences (MCIDs) in multiple PROs at Week (Wk) 12 after treatment with BARI 4-mg in RA-BEAM and BARI 2-mg or BARI 4-mg in RA-BEACON. NNTs ≤10 vs placebo (PBO) are considered clinically meaningful.

Methods: Evaluated PROs with respective MCID definitions included Patient Global Assessment of Disease Activity (PtGA, 0-100 mm visual analog scale [VAS], MCID ≥10 mm), pain (0-100 mm VAS, MCID ≥10 mm), physical function (Health Assessment Questionnaire-Disability Index, MCID ≥0.22 points), fatigue (Functional Assessment of Chronic Illness Therapy-Fatigue [FACIT-F], MCID≥4.0), and health-related quality of life (SF-36 physical component summary [PCS: MCID ≥2.5] and domain scores: physical function [PF], role physical [RP], bodily pain [BP], general health [GH], vitality [VT], social functioning [SF], role emotional [RE], mental health [MH], MCID ≥5.0).[5] The percentages of pts reporting improvements ≥MCID were determined at Wk 12. NNTs were calculated as 1/difference in response rates between BARI 2-mg or 4-mg and PBO.

Results: At Wk 12, percentages of pts reporting clinically meaningful improvements were greater and statistically different from PBO ($p<0.01$) with BARI 2-mg and 4-mg across most PROs in both RCTs. Most NNTs were ≤10. (Figure)

Conclusion: Across different populations, MTX-IR and bDMARD-IR pts with active RA reported clinically meaningful improvements in PROs after BARI treatment. The NNTs in these analyses indicate that <10 pts need to be treated with BARI 2- or 4-mg to report a clinically meaningful benefit.

References:

[1] Taylor et al. NEJM, 2017;376: 652-62
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[5] Strand et al. J Rheumatol, 2011; 38: 1720-27

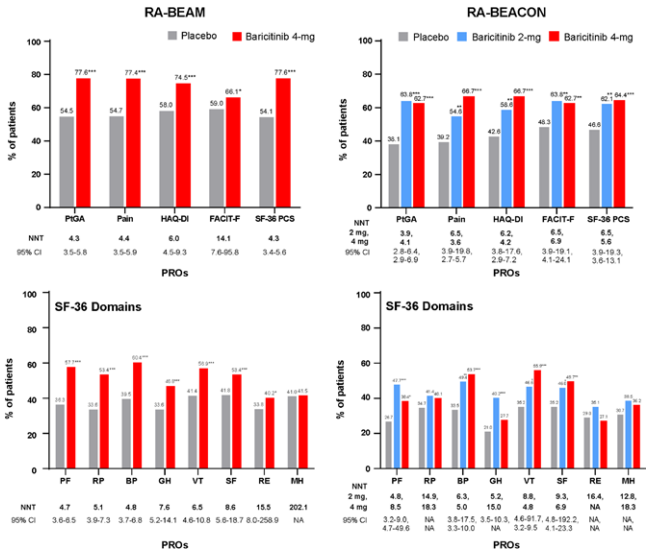

Figure. Percentages of patients reporting improvements ≥MCID with baricitinib vs placebo and associated NNTs for baricitinib in RA-BEAM and RA-BEACON. *p<0.05; **p<0.01; ***p<0.001. Abbreviations: BP, bodily pain; FACIT-F, Functional Assessment of Chronic Illness Therapy-Fatigue; GH, general health; HAQ-DI, Health Assessment Questionnaire-Disability Index; MCID, minimum clinically important difference; MH, mental health; NA, not applicable (ie, difference between treatment and placebo is not statistically significant, confidence interval of NNT is not calculated); NNT, numbers needed to treat; Pain, Patient's assessment of pain; PCS, physical component score; PF, physical function; PtGA, Patient's Global Assessment of Disease Activity; RE, role emotional; RP, role physical; SF-36, Short Form-36; SF, social functioning; VT, vitality

Disclosure of Interests: Vibeke Strand Consultant of: AbbVie, Amgen, Biogen, Celltrion, Consortium of Rheumatology Researchers of North America, Crescendo Bioscience, Eli Lilly, Genentech/Roche, GlaxoSmithKline, Hospira, Janssen, Merck, Novartis, Pfizer, Regeneron Pharmaceuticals, Inc., Sanofi, UCB, Luna Sun Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Jorge Ross Terres Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Carol L. Kannowski Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company

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Rheumatoid arthritis - comorbidity and clinical aspects

FRI0049 RHEUMATOID ARTHRITIS ASSOCIATED INTERSTITIAL LUNG DISEASE: TOBACCO AND OTHER RISK FACTORS

C. Aguilera Cros[1], M. Gomez Vargas[1], R. J. Gil Velez[1], J. A. Rodriguez Portal[2]. [1]*University Hospital Virgen del Rocío, Department of Rheumatology (1), Seville, Spain*; [2]*University Hospital Virgen del Rocío, Department of Pneumology (2), Seville, Spain*

Background: Among the risk factors associated with the development of interstitial lung disease (ILD) in patients with rheumatoid arthritis (RA) are: male sex, old age, erosive RA, rheumatoid nodules, smoking and high levels of rheumatoid factor (RF) and anticitrullinated protein antibody (ACPA). The factors of poor prognosis include: HRCT (High Resolution Computed Tomography) pattern of usual interstitial pneumonia (NIU) with altered baseline functional tests (forced vital capacity FVC <60%, diffusion capacity of the lung for carbon monoxide DLCO<40%).

RA associated UIP (RA-UIP) has an appearance that is identical to idiopathic UIP (idiopathic pulmonary fibrosis [IPF]) on HRCT.

Objectives: To analyze different risk factors and poor prognosis in a cohort of patients with ILD-RA.

To assess the degree of association between tobacco (smokers, ex-smokers and non-smokers) and altered baseline functional respiratory tests (FRT) (FVC <80% and DLCO <40%) with HRCT patterns.

Methods: Descriptive study of 57 patients treated in our Hospital (1/1/2018 until 12/31/2019) with a diagnosis of RA (ACR 2010 criteria) and secondary ILD.

The most recent American Thoracic Society (ATS)/European Respiratory Society (ERS)/Japanese Respiratory Society (JRS)/Latin American Thoracic Society (ALAT) guidelines define three HRCT (High Resolution Computed Tomography) patterns of fibrosing lung disease in the setting of idiopathic pulmonary fibrosis (IPF): definite UIP (traction bronchiectasis and honeycombing), possible UIP and inconsistent with UIP. The distinction between definite UIP and possible UIP in these to the presence or absence of honeycombing. Approved by the Ethics Committee.

Quantitative variables are expressed as mean (SD) and dichotomous variables as percentages (%). The association between tobacco-UIP and FVC-UIP was studied using two Chi-square tests and the DLCO-UIP relationship with an exact Fisher test. Statistical analysis with SPSS version 21.

Results: 21 men and 36 women were included, with a mean age of 69 ± 10 years (mean ± SD), history of smoking (smokers 14%, non-smokers 43%, ex-smokers 42%). 83% were positive RF and 70% positive ACPA. Regarding the HRCT findings: 29 (50%) had a inconsistent with UIP pattern and 28 (49%) had an UIP pattern (45% defined, 3% possible). Of the UIP patients, 14 (50%) had a smoking relationship (35% ex-smokers, 25% smokers) and 15 were male (53%). Of the sample analyzed, 8% (5 patients) have died, all ex-smoking men, the UIP pattern being the most frequent found (4 UIP, 1 inconsistent with UIP).

No statistical association was observed between patients with exposure to tobacco and the UIP pattern (p = 0.438), nor among patients with baseline FVC <80% and UIP (p = 0.432) and also among patients with baseline DLCO <40% and UIP pattern (p = 0.459).

Conclusion: Our results, in general, do not match what is published in the literature. Male sex, smoking exposure and fibrosing pattern (UIP) represent a worse prognosis for patients with ILD-RA. However, more studies are required to determine more precisely how these risk factors affect the disease.

Disclosure of Interests: None declared

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FRI0050 EFFICACY OF ATORVASTATIN VERSUS COLCHICINE IN DECREASING BIOMARKERS OF MYOCARDIAL DAMAGE IN PATIENTS WITH SEVERE RHEUMATOID ARTHRITIS

J. A. Alvarado[1], J. M. Lopez[2], A. C. Bardan[1], C. Abud-Mendoza[3]. [1]*Hospital Central Dr. Ignacio Morones Prieto, Internal Medicine, San Luis Potosí, Mexico*; [2]*Hospital Central Dr. Ignacio Morones Prieto, Cardiology, San Luis Potosí, Mexico*; [3]*Hospital Central Dr. Ignacio Morones Prieto, Rheumatology, San Luis Potosí, Mexico*

Background: Patients with rheumatoid arthritis (RA) have been associated to higher morbidity and mortality due to cardiovascular events. The impact of atorvastatin and colchicine in reducing these complications has been evaluated without comparative studies of these drugs in RA patients. We assess whether atorvastatin is superior to colchicine in cardiovascular risk markers (high-sensitivity troponin I (hs-cTnI), echocardiographic abnormalities and inflammatory cytokine) in patients with RA

Objectives: The primary objective was to compare the initial and final levels of hs-cTnI with both treatments. Secondary objectives: Describe initial echocardiographic abnormalities, compare changes in these alterations with treatment, evaluate factors associated with a higher level of hs-cTnI and echocardiographic abnormalities, compare changes in serum levels of inflammatory cytokines (TNF, IL 8, IL 1β, IL 6, IL 10, IL 12p70) and values of lipid profile

Methods: Prospective randomized pilot study, blinded for cardiologist and rheumatologist, with patients with RA and severe disease activity (DAS 28> 5.1), without known heart disease, kidney disease or previous use of atorvastatin and / or colchicine. Patients were assigned according to randomization in two groups: atorvastatin 40 mg/day or colchicine with an initial dose of 0.75 mg/day titled according to tolerance up to a maximum dose of 1.5 mg/day, both were received for four weeks. NCT04056039

Results: Recruitment of September 2018 to August 2019, 60 participants had undergone randomization (30 in each group) with a median age 48. The duration of follow-up from randomization was 28 days in each group. Participants were followed by weekly telephone contact to assess of adherence treatment. A detected value of hs-cTnI was found in all patients, initial value in the atorvastatin group: Median 1ng /L, IQR 1-2 and final: Median 1ng /L, IQR 1-3 vs initial value in the colchicine group: 1ng /L, IQR 1-2 and final: 1ng /L, IQR1-2 p = 0.67. Echocardiographic abnormalities in 46 patients (76.66%); 63.33% diastolic dysfunction, 15% tricuspid regurgitation and 11.66% left ventricular hypertrophy.

There were changes in initial and final diastolic dysfunction in the atorvastatin group from 19 to 9 vs colchicine 19 to 12 p = 0.05, 95% CI 0.49-0.82. Correlation of initial hs-cTnI with age p <0.001 and rheumatoid factor p = 0.02; correlation of diastolic dysfunction and age p <0.001. There was a greater decrease in the