Low serum level of vitamin D at time of diagnosis is associated with higher one-year remission rate in patients with newly diagnosed RA, treated aggressively during follow-up: Post-hoc analyses of the CIMESTRA trial

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Background: Vitamin D is often low in Rheumatoid Arthritis (RA), and immunomodulatory properties of vitamin D might be associated with disease-course in RA.

Objectives: To evaluate association between baseline vitamin D metabolites and one-year remission, in newly diagnosed, treatment-naive RA patients, aggressively treated during follow-up.

Methods: The CIMESTRA-cohort comprises 160 newly diagnosed RA patients, treated aiming at remission with methotrexate and intraarticular steroid, further randomized 1:1 to cyclosporine or placebo-cyclosporine. A total of 158 patients had vitamin D metabolites measured at time of diagnosis. Dietary vitamin D supplementation was recommended in early, treatment-naive RA patients, treated aggressively during follow-up.

Results: In univariate analyses, neither D_total nor 1,25(OH)D3 at time of diagnosis predicted remission at year one. In adjusted analysis, D_total < 50 nmol/l at time of diagnosis showed better odds for achieving one-year remission, compared to sufficient D_total. OR 2.56, 95% CI (1.11; 5.90) p = 0.03. 1,25(OH)D was not associated to remission.

Conclusions: Low D_total at time of diagnosis is associated to increased odds for achieving remission at year one, in early treatment-naive RA patients, treated aggressively during follow-up.

References:

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number of color pixels to all the pixels in a selected range of interest (ROI). The study was approved by the proper ethics committee. Statistical analysis: differences between groups were analyzed using U Mann-Whitney test (continuous variables). Correlations between quantitative variables were assessed with the Spearman correlation coefficient. Statistical significance was set at p<0.05.

Results: DAS28: mean 6.0 (SD=0.9); median 6.1 (IQR: 5.5 - 6.6); SDAI: mean 61.1 (SD=38.3); median 51.3 (36.8 - 76.4). No correlation was found between CFI and age, platelet count, CRP, RF, ACPA, DAS28 and SDAI as well as with the disease duration. But there was a strong positive correlation between CFI and PDUS results, rho = 0.71; p < 0.05. As expected, DAS28 and SDAI strongly correlated with inflammatory markers (ESR, CRP). The results showed, that CFI between 2-8 % ia an equivalent of PDUS grade 1, CFI 8-50% of PDUS grade 2 and CFI > 50% of PDUS grade 3.

Conclusion: Although PDUS is a method used to assess synovial inflammation, through the determination of the synovial vasculatization, its results, regardless of the scoring system employed, do not correlate with the systemic inflammation indicators, such as ESR and CRP or with the disease activity – which needs further explanation. i) the approximate equivalence of CFI and of PDUS scoring system is as follows: CFI > 50% - PDUS grade 3, CFI 8-50% - PDUS grade 2, CFI< 8% - PDUS 1, which confirms previously published research.

REFERENCE

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SAT0094

UNITED STATES RHEUMATOLOGY PRACTICE-BASED REAL-WORLD EVIDENCE OF METHOTREXATE UTILIZATION AND RESPONSE TO THERAPY IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH INTRAVENOUS GOLIMUMAB

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Background: AWARE (Comparative and Pragmatic Study of Golimumab IV Versus Infliximab in Rheumatoid Arthritis) is an ongoing Phase 4 comparator study designed to provide a real-world assessment of intravenous golimumab (GLM) and intravenous infliximab (IFX) in patients (pts) with rheumatoid arthritis (RA). The primary objective of AWARE is to assess the incidence of infusion reactions, the concomitant use of methotrexate (MTX) and the incidence of infusion reactions, the concomitant use of methotrexate (MTX) is also reported. The FDA approved label for GLM states that it is indicated for the treatment of patients with moderately to severely active RA in combination with MTX; however prospectively obtained real world evidence based data on the rate of GLM use without MTX has not been reported.

Objectives: Here we compare patient demographics, disease characteristics, response to therapy and discontinuation of GLM treated patients with and without concomitant MTX from an interim analysis (IA) of the AWARE study.

Methods: AWARE is a prospective, noninterventional, observational, multicenter 3-year study conducted in the US. RA pts (1,200 adults) were enrolled at the time of initiating treatment with GLM or IFX. All treatment decisions including MTX utilization are made at the discretion of the treating rheumatologist. Imputations of CDAI data were not performed at this IA. Data shown are mean ± standard deviation.

Results: 678 GLM pts were enrolled; of these 487 (71.8%) were GLM Plus-MTX and 191 (28.2%) were GLM No-MTX. Demographics are shown in the table. Response to therapy was assessed with CDAI5s and shown in the figure below. Overall, 92.6% of GLM Plus-MTX and 91.5% of GLM No-MTX pts had a baseline (BL) categorical CDAI disease activity of moderate or high, and 7.4% of GLM Plus-MTX and 8.5% of GLM No-MTX pts had a BL categorical CDAI disease activity of low or remission. Discontinuation from the study during the period of this IA was similar between the GLM Plus-MTX (173/487; 35.5%) and GLM No-MTX (54/191; 33.5%). 7.9% of GLM No-MTX pts reported infliximab use.


SAT0095

MEDIATION NECESSITY AND CONCERN BELIEFS ARE DISTINCT, INTERACTIVE PREDICTORS OF TREATMENT ADHERENCE IN RHEUMATOID ARTHRITIS

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Background: Medication adherence is instrumental for the successful management of rheumatoid arthritis (RA) to a goal of remission. Awareness of medication necessity and concerns regarding its use influence adherence and respectively foster or undermine the achievement of treatment goals. Objectives: We explored the unique and interactive roles of patient beliefs about the necessity of RA medications and concerns about them in predicting adherence to prescribed treatments.