**Δ non-HDL-C, mmol/L** 0.22 0.09 0.00 0.09 0.22 (-0.02; 0.46) 0.07

**Δ HDL-C, mmol/L** 0.27 0.04 0.04 0.04 0.11 (-0.06; 0.25) 0.38

**Δ LDL-C*, mmol/L** 0.26 0.08 0.08 0.08 0.12 (-0.05; 0.39) 0.42

Rigshospitalet, COPECARE & DANBIO, Glostrup, Denmark

Disclosure of Interests: None declared

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**EFFECTS OF ADALIMUMAB ADDED TO TREAT-TO-TARGET STRATEGY WITH METHOTREXATE AND INTRA-ARTICULAR TRIAMCINOLONE ON LIPIDS IN EARLY- AND TREATMENT NAIVE RHEUMATOID PATIENTS: SECONDARY ANALYSES FROM THE MULTICENTER DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED OPERA TRIAL**

D. Masic1, K. Stengaard-Pedersen2, B. B. Logstrup3, K. Horslev-Petersen4, M. L. Heltedal5, P. Junker6, M. Østergaard7, C. Ammitzbøll8, S. Möller9, R. Christensen1, T. Ellingsen1. 1SDU, Research Unit of Rheumatology, Odense, Denmark; 2Aarhus University, Dep. of Rheumatology, Aarhus, Denmark; 3Aarhus University, Dep. of Cardiology, Aarhus, Denmark; 4SDU, King Christian 10th Hospital for Rheumatic Diseases, Sønderborg, Denmark; 5Righospitalet, COPECARE & DANBIO, Glostrup, Denmark; 6SDU, OPEN, Odense, Denmark

Background: Systemic inflammation in rheumatoid arthritis (RA) is associated with reduced serum lipid levels (LL) and treatment with disease modifying anti-rheumatic drugs has been associated with increased serum LL [1]. It is unclear whether the changes in serum LL reported in association with adalimumab (ADA) treatment are due to suppressed inflammation or the ADA treatment per se.

Objectives: The primary objective was to compare the effect of ADA + methotrexate (MTX) to placebo (PBO) + MTX on changes in low density lipoprotein cholesterol (LDL-C) from baseline to month 12 in patients with early- and treatment naive RA. Secondary objectives were to compare the treatment groups on changes in total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglycerides, very low density lipoprotein cholesterol (VLDL-C) and non-HDL-C (=TC – HDL-C).

Methods: We present secondary analyses from the OPERA trial, which was an investigator-initiated, multicenter double-blind, placebo-controlled, treat-to-target trial of 180 early and treatment naive RA patients, who were randomized (1:1) to oral MTX 20 mg once a week in combination with either PBO or ADA 40 mg SC EOW [2]. Any swollen joint was injected with triamcinolone hexacetonide. Lipid profiles of each patient were assessed at baseline and 12 months. All randomized patients with available LDL-C at baseline were included in Intention To Treat (ITT) analysis. Sensitivity analyses were performed on the Per Protocol (PP) and the ITT population with baseline observations carried forward (BOCF). All analyses were based on repeated measurements using mixed linear models.

Results: In total, 174 patients (97% of the original OPERA trial population) were included in ITT analysis (ADA n=86; PBO n=88) and 156 patients (ADA n=78; PBO n=78) continued the study with LDL-C measurements at both baseline and 12 months (PP). At baseline mean LDL-C was 2.9 mmol/L (SD 0.9) with 63 (36.2%) patients having an LDL-C above 3.0 mmol/L. There was no significant difference in LDL-C change between ADA+MTX and PBO+MTX groups after 12 months. A nearly statistically significant between-group difference in TC change was found. Other changes in LL were comparable across the two groups. Results in ITT, PP and ITT with BOCF populations were similar.

Conclusion: In early RA patients treated to target with methotrexate and intra-articular triamcinolone, 12 months with the addition of adalimumab did not affect lipid levels.

References: