CI[1.69- 21.77]). The same finding was observed between high concentrations of HDL-C and the prevalence of VF adjusted in the same variables ($p=0.006$, OR: 197.01, 95% CI [4.64-8363.51]).

Conclusion: Although there was no relation between lipid plasma levels and BMD in our population. There was a significant association between high concentrations of TC, HDL-C and the prevalence of VF.

Disclosure of Interests: None declared

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FRI0069

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

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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 naïve 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 naïve RA patients, who were randomized (1:1) to oral MTX 20mg once a week in combination with either PBO or ADA 40mg 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) completed 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

Table. Change in primary and secondary outcomes in the ITT analysis

	Adalimumab (n=86)		Placebo (n=88)		Difference between means	(95% CI)	P value
	Mean	SE	Mean	SE			
Δ LDL-C*, mmol/L	0.26	0.08	0.07	0.08	0.18	(-0.05; 0.42)	0.12
Δ TC, mmol/L	0.49	0.10	0.22	0.10	0.27	(-0.002; 0.54)	0.052
Δ HDL-C, mmol/L	0.27	0.04	0.23	0.04	0.05	(-0.06; 0.15)	0.38
Δ TG, mmol/L	-0.07	0.07	-0.18	0.07	0.11	(-0.08; 0.29)	0.25
Δ VLDL-C, mmol/L	-0.03	0.03	-0.07	0.03	0.03	(-0.05; 0.12)	0.43
Δ non-HDL-C, mmol/L	0.22	0.09	0.00	0.09	0.22	(-0.02; 0.46)	0.07
Δ LDL-C, Sensitivity Analyses							
Per Protocol	0.27	0.08	0.08	0.08	0.19	(-0.04; 0.42)	0.11
BOCF	0.26	0.08	0.08	0.08	0.18	(-0.03; 0.40)	0.10

Δ = 12 months - baseline. *Primary outcome. ITT: Intention To Treat. BOCF: Baseline Observation Carried Forward. LDL-C: low-density lipoprotein cholesterol. TC: total cholesterol. HDL-C: high-density lipoprotein cholesterol. TG: triglycerides. VLDL-C: very-low-density lipoprotein cholesterol. non-HDL-C = TC – HDL-C.

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:

[1] England BR *et al.*, *Bmj* 2018;**361**:k1036

[2] Hørslev-Petersen K *et al.*, *Ann Rheum Dis* 2014;**73**:654–61

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FRI0070

PREGNANCY AND OFFSPRING OUTCOME IN RA FEMALE PATIENTS- A BOW BETWEEN CENTURIES

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Background: Clinical and preclinical rheumatoid arthritis (RA) may negatively impact several pregnancy and offspring outcome parameters [1,2].

Objectives: Assessing pregnancy and offspring outcome in RA patients and controls.

Methods: RA pregnant patients (G1) were prospectively recruited. Demographic data, disease activity scores, immunology and obstetric/offspring outcome parameters were recorded. The same parameters were retrospectively collected (interview) in RA patients who delivered children before RA onset (G2) and in healthy subjects (C). Ethical committee approval for the study was obtained and all participants signed informed consents.

Results: Table 1 presents demographic and disease related data. Table 2 shows the outcome parameters in the 3 groups. G1 delivered babies between the years 2008-2019. CsDMARDs were stopped by the majority of patients in the 1st trimester of pregnancy; 2 patients continued low dose corticosteroids throughout pregnancy (Fig 1). G2 and C delivered the babies between the years 1963 and 2000.

Table 1.

Parameter	G1	G2	C
Subjects ^Δ	22	27	36
Disease duration (y±SD)	5.92±6.14	-	-
Disease activity*			
T1-R/LDA/HDA ^Δ	9/15/5	-	-
T2- R/LDA/HDA ^Δ	15/6/8		
T3- R/LDA/HDA ^Δ	18/6/5		
RF + (%)	86.36	92.59	-
ACPA + (%)	36.36	62.96	-
Contraception ^Δ	0	3	5
Fertility treatment ^Δ	1	1	1

^Δ- number, y- years, SD- standard deviation, R-remission, LDA-low disease activity, HDA-high disease activity, * DAS 28 3 variables, T-trimester

Overall, RA pregnant patients were older at conception, had a lower number of pregnancies/deliveries and a higher rate of spontaneous abortions and 'C' sections compared to G2 and C. Time to pregnancy (TTP) was increased in G1 when compared to G2 and C. Both G1 and G2 newborns were smaller for their gestational age versus C, the majority of them still being in the normal range. All these aforementioned parameters showed statistical significance. Number of premature deliveries and pregnancy/offspring pathology events showed a low frequency and no difference was identified between groups when comparing them.