Abstract FRI0325. Table 1.. * Analysed in MA of Souza 2016

Author/year	Souza 2016	Devauchelle 2014*	Meijer 2010*	Dass 2008*	Carubbi 2013	Pipje 2005	Gottenberg 2013	Mekinian 2012	Seror 2007
Study type (LOE)	SR and MA (1+)	RCT (1+)	RCT (1+)	RCT (1-)	Not randomised (1-)	Not controlled ³	Retrospective ³	Retrospective ³	Retrospective ³
Groups and N	RTX 145/Pbo 131	RTX 63/Pbo 59	RTX 20/Pbo 10	RTX 8/Pbo 9	RTX 19/ DMARDs22	RTX 7	RTX 86	RTX 17	RTX 16
Dryness:									
VAS (oral, ocular, global).	-	-	-	-	+				
Salivary flow	+	-	-	-	+	+			
Schirmer	-	-	-	-	+	-			
Lissamine green			+						
Rose Bengal						+			
TBUT			-			+			
General and systemic manifestations:									
ESSDAI	-	-			+		+	+	
SF-36	-	-	-	-		+			
Fatigue VAS.	-	-		-	+	+			
Global VAS: patient/physician.		-/-			+/+				
Lab (IgG/A/M, beta2-microglobulin, RF, B cells).		+	+	+		+			+
Systemic:			+		+		+	+	

with placebo and a follow-up time of 6 months. The quality of the studies was assessed through the levels of evidence (LOE) of SIGN scale.

Results: The search resulted in a total of 749 articles and only 9 of them were selected (**figure 1**). The best available evidence for each variable studied is summarised in **chart 1** ("+" significant improvement; "-" no significant improvement). The most relevant results obtained in the studies with **LOE 1+**, showed significant differences comparing RTX with placebo ($p < 0.05$) in: 1) Souza 2016: Salivary flow rate at 24 w (weeks) (0.09; 95% CI 0.02 to 0.16). 2) Meijer 2010: Ocular dryness VAS score at 24 (-27.00, 95% CI -46.28 to -7.72), 36 and 48 w. Lissamine green test at 24 w (-2.00, 95% CI -3.52 to -0.48). Absolute number of B cells from 5 to 48 w (-0.23; IC 95% -0.31 to -0.15). Rheumatoid Factor at 12, 24 and 36 w. Tendomyalgia at 12 and 36 w. Vasculitis at 24 w. 3) Devauchelle-Pensec 2014: Immunoglobulin's G (1.2 g/L; 95% CI 0.4 to 2 g/L), A, M and beta2-microglobulin (1.6 g/L; 95% CI 0.5 to 2 g/L) at 24 w. The studies with **LOE 3** also report improvement in a percentage of patients in other systemic manifestations, but without demonstrating statistical significance.

Abstract FRI0325 – Figure 1. Flow chart.

Conclusions: The studies of high methodological quality that evaluate the efficacy of RTX in pSS do not find significant improvement in the primary outcome variables, such as ESSDAI, glandular involvement and other objective parameters of dryness. However, open and retrospective studies find significant improvement in activity parameters, systemic manifestations, glandular involvement and improvement of certain objective tests of dryness.

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FRI0326

IMMUNE CELLULAR PROFILE ASSOCIATED WITH DIFFERENT TREATMENT OUTCOME IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS ON CYCLOPHOSPHAMIDE

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Background: Cyclophosphamide (CFA) is an effective immunosuppressive drug used for treatment of severe manifestations of systemic lupus erythematosus (SLE). The knowledge about modulatory effect of CFA on circulating immune cells and its changes associated with treatment response is limited.

Objectives: To determine the effect of a cumulative dose of CFA on circulating immune cells in SLE patients and to assess its association with treatment outcome.

Methods: Using 6-colour flow cytometry (BD FACSCanto II) we analysed T and B lymphocytes, NK cells, neutrophils, and monocytes in peripheral blood from 11 SLE female patients. SLE patients were investigated before and after cumulative 1000 mg and 3000 mg of CFA dose. Patients subgroups were assessed according to the treatment response (n=5, good responders; n=6, poor responders); SLEDAI (Systemic Lupus Erythematosus Disease Activity Index) was used to assess the disease activity. Healthy age-matched females (n=12) were included in the study. Statistics was done by GraphPad Prism and R statistical software package.

Results: Cumulative dose of 1000 mg of CFA resulted in decreased percentage of B lymphocytes ($p=0.0004$) and CD4 +T lymphocytes ($p=0.02$) and increased the percentage of total and CD8 +T lymphocytes ($p=0.03$; $p=0.0003$ respectively). After 3000 mg CFA, the percentage of B lymphocytes ($p=0.002$), naïve B lymphocytes ($p=0.005$), memory B lymphocytes ($p=0.02$) and CD4+/CD8 +ratio ($p=0.01$) decreased while the percentage of CD8 +T lymphocytes ($p=0.0003$), Tregs ($p=0.01$) and CD69 +NK cells ($p=0.02$) increased. CFA treatment in our patients resulted in reduction of B lymphocyte percentage reaching the values of healthy controls. In good responders, decreased percentage of B lymphocytes ($p=0.04$), CD4 +T lymphocytes ($p=0.04$), CD4+/CD8 +ratio ($p=0.007$) and increased percentage of CD8 +T lymphocytes ($p=0.004$), CD69 +NK cells ($p=0.04$) and non-classical monocytes ($p=0.04$). In poorly responding patients percentage of CD8 +T lymphocytes ($p=0.01$), activation marker HLA-DR on both CD4 +and CD8+T lymphocytes ($p=0.01$; $p=0.02$ respectively), Tregs ($p=0.02$), memory B lymphocytes ($p=0.03$) were increased and percentage of total B lymphocytes was decreased ($p=0.02$). The analysis using advanced data mining methods for identification of treatment outcome related profiles are ongoing

Conclusions: Administration of CFA modulates several cell populations in SLE patients, whereas changes in B and T lymphocytes were associated with different treatment outcome. Whether the immune profile may predict the treatment response deserves further investigation.

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