Week 12, seletalisib treatment led to a reduction in the size and cellular organisation of mononuclear inflammatory cell foci vs PBO (Table 2). TEAEs were reported by 13/13 (100.0%) seletalisib and 13/14 (92.9%) PBO patients; most frequently reported: diarrhoea (5/13 [38.5%] vs 0/14 [0%]) and headache (3/13 [23.1%] vs 2/14 [14.3%]). Serious TEAEs were reported by 3/13 (23.1%) vs 1/14 (7.1%), and discontinuations due to TEAEs by 5/13 (38.5%) vs 1/14 (7.1%) seletalisib and PBO patients, respectively.

Table 2. Change from baseline at Week 12 in characteristics of mononuclear inflammatory cell foci from paired minor salivary gland biopsies

	Seletalisib n=7 Mean (SD)	PBO n=11 Mean (SD)
Average focus area, mm^2	–0.02 (0.02)	0.01 (0.06)
Focus score, number foci present/4 mm^2 biopsy tissue	–0.43 (0.99)	0.20 (2.73)
Percentage infiltration	–1.3 (1.4)	2.5 (8.0)
Percentage of germinal centres	–13.5 (14.3)[a]	–0.9 (15.8)[b]
Percentage of T/B cell segregation	–17.6 (8.6)[c]	–12.7 (32.3)[d]
Percentage of foci with follicular dendritic cells	–23.2 (17.1)[e]	15.1 (40.7)

SD, standard deviation

[a] n=3; [b] n=7; [c] n=4; [d] n=9; [e] n=6

Conclusion: Although this Phase II PSS study was terminated early due to slow recruitment, seletalisib demonstrated a trend to clinical improvement in patients with PSS and acceptable safety and tolerability. Histological analyses demonstrated encouraging effects of seletalisib on the organisation and extent of salivary gland lymphocytic infiltration in patients with PSS.

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AB0459

IMMUNOGLOBULINS COMBINED WITH STANDARD THERAPIES FOR THE PREVENTION OF RELAPSES IN REFRACTORY OBSTETRICAL ANTIPHOSPHOLIPID SYNDROME: A SERIES OF 103 CASES

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Background: Optimal standard therapy in obstetrical antiphospholipid syndrome (APS) (aspirin and LMWH) is effective in 72- 80% of pregnancies (1). Intravenous immunoglobulins (IVIG) are not more efficient than standard therapy (2, 3) and seems to be reserved to high risk pregnant APS patients (4) and/or refractory cases (5).
Objectives: The main aim of this study was to analyse the outcome of pregnancies in APS patients with recurrent obstetrical event despite conventional treatment, who received IVIG.
Methods: We have performed a retrospective multicentre open-labelled study (2010-2018).
Results: 103 patients (107 pregnancies) with obstetrical APS from 8 international centres were included. In all cases, the previous standard treatment was inefficient. Obstetrical APS was present in 73%, while 27% had obstetrical and thrombotic APS. Median age was 28 years. Triple antiphospholipid antibody (tAPL) positivity was found in 51% of patients and lupus anticoagulant (LA) in 60%. IV IG use was associated with favourable outcome in 101/107 pregnancies (94%). In multivariate analysis, previous history of prematurity and Ig use were associated with live-birth pregnancy (odds-ratio 0.12 95%CI 0.03-0.37, p 0.005). The dosages of IV IG were variable: 0.4g/kilo day-2g/kilo day but without differences on outcomes between patients (p 0.8). There were no differences in outcomes of pregnancies between patients with tAPLand/or LA positivity and patients with other antibodies profiles (p 0.8).
Conclusion: IVIG could be effective in cases of refractory obstetrical APS but prospective studies are necessary.

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AB0460 USE OF PLATELET RICH PLASMA (PRP) IN TREATMENT OF DRY EYE SYNDROME IN THE PATIENTS WITH SJÖGREN SYNDROME: PRELIMINARY RESULTS

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Background: Xeroftalmia and xerostomia are the hinge symptoms of Sjögren Syndrome and often they negatively influence patients' quality of life. The eyewashes use based on Platelet Rich Plasma (PRP) has been applicate in the treatment of the xeroftalmia, both primitive and secondary.
Objectives: To evaluate the effect of subconjunctival injections and PRP based eyewashes on the ocular dryness (subjective and objective) in patients suffering of primary Sjögren syndrome (pSS).
Methods: Six pSS patients (6 females, age at the beginning 48.2±9.7 years) have been recruited in the study. All patients were reaching the criteria for pSS diagnosis; for each patient clinical and immunological data have been recorded. Patients with Schirmer Test value, in at least an eye, inferior to 10 mm after 5 minutes, and suffering from severe dryness calculated by OSDI score (between 33 and 100, severe condition of dry eye) in spite of therapies with tear substitutes were selected. The OSDI (Ocular Surface Index) is a questionnaire for the evaluation of the subjective ocular dryness. Selected patients have been addressed to treatment with PRP. The PRP is constituted by human plasma enriched with plaques by means of the utilisation of a special kit, therefore each patient has been subjected to a blood drawing, from which PRP has been extracted. Of this, a part has been injected in subconjunctival seat; from remained one, an eyewash has been extracted that the patients have assumed 6 times in the day up to exhaustion (about 5 days) during which another topic therapy was not used. The patients have been valued to the basal time and after ten days of the procedure; besides follow-up visits each three months are scheduled. To each evaluation Schirmer Test data and OSDI have been checked.
Results: Each patient had severe xeroftalmy, evaluated by Schirmer Test (right Eye: 3.33±2.66; left eye: 6.83±6.5) and index OSDI (59.71±20.72). All the patients had Schirmer Test values, in at least an eye, lesser than 10 mm after 5 minutes. The analized cohort had homogeneous clinical characteristics (presence of xerostomy and absence of inflammatory indexes, hypergammaglobulinemia, arthritis and linfoadenomegaly). After one week (T1), OSDI values were significantly more reduced compared to the basal time (38.89±15.12; p=0.028). The Schirmer Test values were not significative different to the follow-up visit compared to the basal one. No patients presented pre- and post-procedural complications, neither related infectious events. At 3 months follow up after first treatment (T2) no statistically significant difference in OD/OS Schirmer test values and OSDI score compared to the basal time were observed.
Conclusion: The use of PRP in dry eye syndrome in patients with Sjögren syndrome seems to be effective in alleviating symptoms and improving patients' life quality. Is need further follow-up to confirm data, to value effect also on the objective tests and to evaluate necessity of repeating treatment.

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AB0461 BELATACEPT IN SLE KIDNEY TRANSPLANT PATIENTS

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Background: Lupus nephritis (LN) results in the need for renal replacement therapy (RRT) in 10-30% of LN pts; of these 30% receive a kidney transplant (KT). Belatacept (bela) is a second-generation selective T-cell co-stimulator blocker (inhibits CTLA-4) used as an alternative to calcineurin inhibitors (CNI) for maintenance regimens after KT. The pathogenic relevance of CTLA-4 inhibition and the favorable cardiovascular profile of bela make it an attractive therapeutic option in SLE. Additionally, bela IV ensures therapeutic adherence.
Objectives: The current study was initiated to evaluate the effect of bela on graft function and extrarenal SLE.
Methods: This retrospective single-center study evaluates the outcomes of LN KT recipients treated with bela from 2006–2018 at the Columbia University Lupus and Renal Transplant Cohorts. The bela regimen was 5mg/kg every 2 weeks x 5 doses, then monthly. CNI weaning among the bela group was not standardized. Immunosuppressive regimen, kidney allograft function, and SLE activity were examined.

Figure 1: Creatinine trend before and after bela

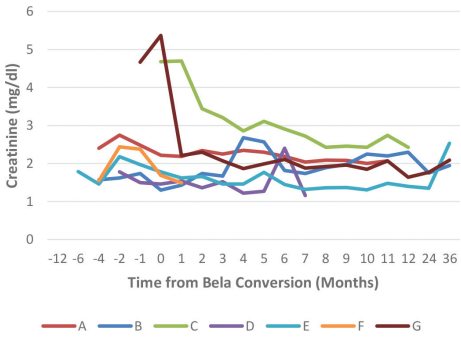

Figure 2: SLEDAI-2KG before and after bela

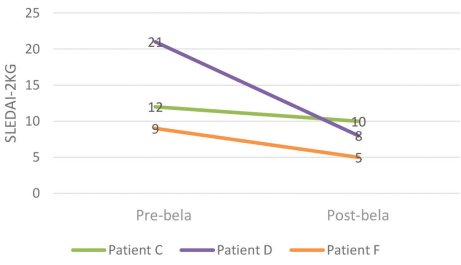

Table 1: Characteristics of patients on bela.

ID	Age at SLE dx	Race	LN class	Time to KT (yrs)	Type KT	Induction	Reason for conversion	Immunosuppressive regimen before conversion
A	16	Black	IV, VI	13	DDKT	ATG	Non-adherence	TAC, MMF
B	30	Asian		2	LRKT	ATG	Mod IFTA & Arteriosclerosis	TAC, MPA, PRED
C	18	White	IV, V	23	DDKT	ATG	Cortical necrosis	CYC, MMF, PRED
D	19	Black	V	9	LUKT	ATG	CNI side effects	TAC, MPA, PRED
E	22	Asian		5	LRKT	ATG	CNI side effects	TAC, MMF, PRED
F	18	Black	V	17	DDKT	Alemtuzumab	CNI side effects	TAC, MMF, PRED
G	25	White (Hispanic)	III, IV	23	DDKT	Basiliximab	TMA (biopsy)	TAC, MPA, PRED

Results: 48 pts with LN had undergone KT between 2006–2018 with follow-up time of 72.2 ± 74.6 months. Bela was started in 7 pts on CNI regimens (TAC N=6, cyclosporine N=1) at 15.5 ± 17.1 months after KT. All pts were female, age at SLE diagnosis 21.1 ± 4.9 yrs; 5 had undergone RRT prior to KT (4 hemodialysis, 1 peritoneal dialysis) for 38.7 ± 37.8 months. The interval between SLE diagnosis and KT was 13.1 ± 8.3 yrs. At the time of bela initiation, all pts were also treated with prednisone (7.1 ± 2.7 mg/day), 6 with mycophenolate (1123 ± 625 mg/day), and 1 azathioprine (25mg/day). CNIs were continued in 5/7 patients at 6 months after bela. 2 pts were on hydroxychloroquine, 2 took it only prior to KT. In 5 patients, creatinine stabilized 6 months after bela, 1 returned to HD due to CNI-toxicity and pyelonephritis and 1 is relisted for KT due to ACR and cortical necrosis (Fig. 1). No allograft failure due to recurrent