

**FRI0323 APREMILAST THERAPY IN REFRACTORY SKIN LUPUS LESIONS**

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**Background:** Skin lesions of lupus may be refractory to standard therapy. Apremilast is an orally small molecule which inhibits phosphodiesterase-4 (PDE-4) that modulates some inflammatory pathways.

**Objectives:** Our aim was to assess the efficacy of apremilast in lupus rashes refractory to conventional treatment.

**Methods:** Retrospective study on 5 lupus patients treated with apremilast at standard dose of 30 mg twice daily. The outcome was improvement of lupus rashes.

**Results:** We described 5 patients (4 women and 1 male) with a mean age of 44.2 ±8.5 years with extensive skin lesions due to lupus. Three patients had a discoid lupus and 2 patients had systemic lupus erythematosus (SLE) (one with panniculitis and the other with polycyclic ring lupus). The cutaneous lupus was confirmed in all patients by skin biopsy. Prior to apremilast all patients had received conventional treatment: topical corticosteroids (n=5), antimalarials (n=5), topical tacrolimus (n=2), oral corticosteroids (n=2), thalidomide (n=1), belimumab (n=1) and rituximab (n=1). After a mean follow-up of 6.2±2.9 months, all the patients experienced improvement of the skin lesions (in two patients was complete). In one patient it was necessary to reduce the dose of apremilast to 30 mg/day because of digestive symptoms.

**Conclusions:** Apremilast can be useful in the treatment of refractory skin lesions of lupus.

**Disclosure of Interest:** None declared

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**FRI0324 IMMUNOSUPPRESSION FOR PRIMARY SJOGREN'S SYNDROME: A SYSTEMATIC REVIEW AND META-ANALYSIS**

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**Background:** The current focus of treatment in primary Sjogren's Syndrome (pSS) is mainly symptom management. Since pSS is an autoimmune disease with multi-system involvement, there may be a role for systemic immunosuppression and/or biologic therapy. A wide variety of immune response targets have been examined in existing randomised controlled trials including inhibiting purine synthesis, blocking TNF-alpha, and depleting B lymphocytes. There is conflicting evidence as to whether immunomodulation alters disease progression.

**Objectives:** To assess the efficacy and safety of immunosuppressive therapy on pSS from clinical trials.

**Methods:** Five electronic databases (MEDLINE, EMBASE, CENTRAL, CLINICALTRIALS.GOV, WHO ICTRP) were searched to include randomised controlled trials of systemic immunosuppressive therapies in adults with pSS published in English prior to Oct 1, 2017. Efficacy measures included ocular dryness, oral dryness, fatigue, tear production, unstimulated and stimulated salivary flow, quality of life (QOL), ESSPRI, ESSDAI, ESR/CRP; Safety measures included serious adverse events (AEs) and withdrawals due to AEs.

**Results:** The searched yielded 32 trials evaluating 19 different medications. Studies enrolled anywhere between 7 to 133 patients, with the exception of 1 study with 497 patients. Mean age was in the fifth decade, with an average duration of diagnosis up to 9.2 years.

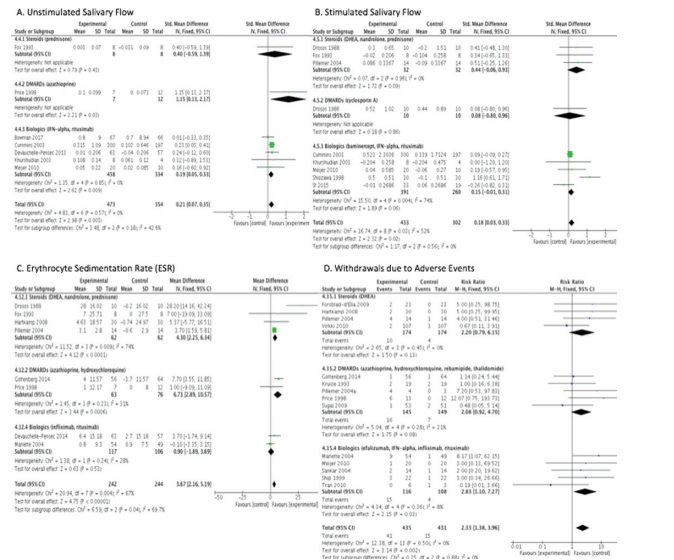
Twenty-two trials examined ocular and oral dryness, of which 2 and 3 revealed statistically significant improvements respectively (table 1). Only 1/14 trials found benefit for fatigue, none for tear production; 3/16 trials and 2/14 trials found increases in unstimulated and stimulated salivary flow respectively. Reductions in ESR were seen in 3/14 trials. Few studies examined QOL, ESSPRI, ESSDAI, and CRP. Trials often noted non-statistically significant trends toward improvement, but no particular drug or drug class consistently showed discrete benefit in subjective or objective efficacy measures possibly due to low statistical power.

**Abstract FRI0324 – Table 1. Efficacy Outcome Measures**

Outcome	# Trials Total	# Trials showing statistical improvement
Ocular dryness	22	1 of 1 Prednisone 1 of 2 Rituximab
Oral dryness	22	1 of 3 Prednisone 1 of 3 Rituximab 1 of 3 DHEA
Fatigue	14	1 of 4 Rituximab
Tear production	19	0
Unstimulated saliva production	16	2 of 3 Rituximab 1 of 3 Interferon alpha

Stimulated saliva production	14	2 of 4 Interferon alpha
Quality of life (mental component)	8	0
Quality of life (physical component)	8	0
ESSPRI	7	1 of 1 Iguratimod
ESSDAI	6	1 of 1 Bamierecept 1 of 1 Iguratimod
ESR	14	1 of 1 Nandrolone 1 of 1 Prednisone
CRP	3	1 of 3 Hydroxychloroquine 1 of 1 Hydroxychloroquine

Meta-analyses of the above outcomes were performed at 6 months (figure 1). With pooled estimates, significant improvements were seen in unstimulated salivary flow (p=0.003), stimulated salivary flow (p=0.02), and ESR (p<0.001). There was a trend towards increased serious AEs in the intervention groups, and a significant increase in withdrawals from AEs (RR 2.33, 95% CI 1.38 to 3.96).



**Abstract FRI0324 – Figure 1. Meta-analyses at 6 months**

**Conclusions:** Reducing immune activity and inflammation potentially improves salivary gland function. Subjective measures may be less helpful as sicca symptoms likely have subtle progression if trials span less than 1 year. Given that most trials were small, beneficial treatment effects could be missed. Standardisation of objective, reliable, clinically meaningful outcome measures that are sensitive to change may allow for positive treatments in the future.

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**FRI0325 RITUXIMAB IN PRIMARY SJÖGREN'S SYNDROME: A SYSTEMATIC REVIEW ON ITS EFFICACY**

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**Background:** Primary Sjögren's syndrome (pSS) is a systemic autoimmune disease that produces a limpho-plasmocitary infiltrate of the exocrine glands. Considering the primary role attributed to B-lymphocytes in pSS pathophysiology, it has been suggested that Rituximab (RTX) may have certain role in controlling the disease.

**Objectives:** To evaluate RTX efficacy in the treatment of xerostomia, xerophthalmia and systemic manifestations (including fatigue) in patients with pSS.

**Methods:** In the framework of the preparation of a recommendations document of the Spanish Society of Rheumatology on the use of biologics in pSS, a systematic search of the literature was carried out (until May 2017). Were included adults older than 18 years who met the 2002 American European Consensus Criteria, treated with RTX, with desired comparison to groups treated with other drugs or