IL-6, IL-10, IFN- γ and TNF- α in ROC curve may be more predictive for finding bacterial infection in SLE and may prompt clinicians more promptly and accurately to help them make correct medication.

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SAT0206

MINOR SALIVARY GLAND BIOPSY AND SEROLOGICAL PROFILE IN PRIMARY SJÖGREN'S SYNDROME: A SINGLE TERTIARY REFERRAL CENTER EXPERIENCE

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Background: Minor salivary gland biopsy (MSGB) portrays an important role as part of the diagnostic criteria of primary Sjögren's syndrome (pSS) in the ACR/EULAR 2016 classification. Autoantibodies anti-Ro/SSA and anti-La/SSB embody part of these criteria. Patients with negative serology have been classified as pSS using MSGB outcomes in up to 40% of cases.

Objectives: Compare MSGB and serological characteristics between pSS positive biopsy versus pSS negative biopsy and sicca groups.

Methods: 174 subjects with sicca symptoms and MSGB biopsy were studied. Patients who fulfilled the ACR/EULAR 2016 criteria were classified as pSS. Serological profile: Rheumatoid factor (RF) (IgA, IgG and IgM), Anti La/SSB and Anti-Ro/SSA, available in 148 and 161 patients respectively, as well as histopathological characteristics of MSGB were recollected (Table 2).

Comparison between subgroups according to biopsy status was performed. Differences between serology and MSGB were reported using Chi square, a $p < 0.05$ was considered statistically significant

Results: 95 (54.59%) pSS patients with positive biopsy, 47 (27.02%) pSS with a negative biopsy and 32 (18.39%) sicca patients were included.

A positive serology profile (RF, Anti-Ro/SSA, Anti-La/SSB) was found more frequently in the pSS positive biopsy cohort when compared to the pSS negative biopsy and sicca groups (Table 1).

Table 1. Comparison between serological and histopathological characteristics in pSS and sicca groups.

Groups	Positive biopsy n=95	Negative biopsy n=47	Sicca n=32	p^1	p^2
Age (years) mean, (SD)	54.59 (11.69)	50.17 (12.35)	49.18 (12.74)	0.42 (0.43-0.45)	0.78
Female, n (%)	92 (96.8)	46 (97.87)	32 (100)	0.779	0.58
Serological profile					
Rheumatoid factor					
IgA (%)	26 (27.4)	12 (25.5)	4 (12.5)	0.35 (0.47-0.49)	0.23
IgM (%)	47 (49.5)	25 (53.19)	7 (21.9)	0.34 (0.41-0.43)	0.015
IgG (%)	13 (13.7)	7 (14.8)	1 (3.1)	0.35 (0.45-0.47)	0.25
Positivity Anti-Ro/SSA, n (%)	47 (52.8)	12 (30)	2 (6.3)	0.015 (0.013-0.018)	<0.05
Positivity Anti-La/SSB, n (%)	17 (19.77)	3 (9.09)	0(0)	0.003 (0.002-0.004)	0.019

¹ p of the comparison between pSS positive biopsy group vs pSS negative biopsy group

² p of the comparison of the 3 groups

Anti-Ro/SSA: available in pSS biopsy positive group n=89, pSS negative biopsy group n=40
Anti-La/SSB: available in pSS biopsy positive group n=86, pSS negative biopsy group n=33

Table 2. Histopathologic characteristics and comparison in pSS and sicca groups.

Characteristics	Positive biopsy n=95	Negative biopsy n=47	Sicca n=32	p^1	p^2
Lobules, n (SD)	12.45 (7.24)	15.2 (9.95)	11.84 (9.84)	0.19 (0.13-0.15)	0.43
Foci, n (SD)	3.23 (3.16)	0(0)	0(0)	<0.05	<0.05
Atrophy, n (%)	27 (28.4)	9 (9.5)	7 (21.9)	0.007	0.57
Adipose infiltration, n (%)	22 (23.2)	12 (12.6)	6 (18.8)	0.12	NA
Ductal dilatation, n (%)	22 (23.2)	8 (8.4)	6 (18.8)	0.05	0.73

¹ p of the comparison between pSS positive biopsy group vs pSS negative biopsy group

² p of the comparison of the 3 groups

Histopathological characteristics of MSGB are described in Table 2. Sicca group had more alterations when compared to pSS negative biopsy group.

Conclusion: Histopathological alterations in MSGB (atrophy, adipose infiltration and ductal dilatation) can act as confounding data at biopsy interpretation since they were found in close prevalence in the pSS positive biopsy group and sicca group and should be carefully taken into account at diagnosis. A positive serologic profile was associated with more histopathological alterations in the positive biopsy group.

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SAT0207

ANTI-SSA/RO POSITIVITY AND CONGENITAL HEART BLOCK: OBSTETRIC AND FETAL OUTCOME IN A COHORT OF ANTI-SSA/RO POSITIVE PREGNANT WOMEN WITH AND WITHOUT AUTO-IMMUNE DISEASES FROM THREE ITALIAN TERTIARY REFERRAL CENTERS

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Background: neonatal lupus syndrome (NLS) is an acquired disease caused by the transplacental passage of anti-SSA antibodies. Congenital heart block (CHB) represents the most serious manifestation of NLS. The rate of CHB in Anti-SSA positive pregnant women ranges from 1 to 5% in different studies

Objectives: to retrospectively assess the prevalence of CHB in a cohort of anti-SSA positive pregnant women followed in 3 Italian tertiary centers

Methods: pregnancies of anti-SSA positive women attending the pregnancy clinic of ASST Pini CTO/Policlinico Mangiagalli, Rheumatology Division of Spedali Civili, Brescia and Rheumatology Division of Ospedale S Matteo, Pavia from 2009 to 2019 were included. Patients underwent monthly clinical examination. Fetal heart rate was assessed weekly by Doppler ultrasound from 14th to 26th gestational week. On week 14 and 26, a fetal echocardiography was performed. A EKG was performed at birth

Results: 351 prospectively followed pregnancies in 292 anti-SSA/Ro positive women were included. Table 1 reports diagnosis. None of the prospectively followed pregnancies were complicated by complete CHB. Seven additional patients were referred

Table 1. patients diagnosis

	n	%
Sjogren's Syndrome	58*	20
Systemic lupus erythematosus	76	26
UCTD	74	25
Asymptomatic Ro carriers	56	19
Other	28	10
	292	100

Table 2. maternal and fetal outcome

	healthy controls N=3158	Anti-SSA/Ro pts N=244	P value
Previous CHB n (%)		2 (0.8)	
Anti-SSB pos n (%)		46 (18.8)	
aPL pos n (%)		49 (20)	
Pregnancy			
Live births	3158	241	
Preeclampsia, n (%)	43 (1.1)	2 (0.8)	ns
Delivery			
Delivery <37 wks, n (%) / < 34 wks n (%)	401 (12.6) / 201 (6)	35 (15.6) / 14 (6)	ns / ns
Cesarean Section, n (%)	897 (29.3)	115 (47.5)	<0.001

to our clinics after diagnosis of CHB and were subsequently found to be anti-SSA positive, reporting no symptoms of diseases. Considering the 7 additional pregnancies, the incidence of CHB was 1.9%. We observed 3 neonates (0.8%) with cutaneous NLS and 1 case of transient increase of liver enzymes. In another neonate, a 1st degree A-V block was found after birth. A complete analysis of maternal and fetal outcome was possible in 244 cases (Table 2) and compared with 3158 unselected healthy controls. Among these 244 cases, 65% were taking hydroxychloroquine

Conclusion: none of the patients prospectively followed in our centers before and during pregnancy developed complete CHB. If the 7 cases of anti-SSA positivity diagnosed after CHB detection were included in the analysis, the incidence of CHB was comparable to previous reports. Our data suggest that a strict follow up and proper treatment of anti-SSA positive patients with or without an autoimmune disease before and during pregnancy can reduce the risk of NLS. Further studies are warranted to confirm a possible protective role of anti-rheumatic treatments, including HCQ

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SAT0208

INCIDENCES OF ADVERSE EFFECTS AND DISEASE FLARE DUE TO PNEUMOCYSTIS PNEUMONIA PROPHYLAXIS WITH TRIMETHOPRIM/SULFAMETHOXAZOLE IN SYSTEMIC LUPUS ERYTHEMATOSUS PATIENTS

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Background: Methods of preventing pneumocystis pneumonia (PCP) in systemic lupus erythematosus (SLE) are controversial. Previous studies have verified the efficacy and safety of trimethoprim/sulfamethoxazole (TMP-SMX) in patients with rheumatic diseases¹. However, as for SLE, some clinicians advise against prescribing TMP-SMX because sulfa allergy is reportedly more common in SLE than in other rheumatic diseases^{2,3}. Anecdotally, sulfonamides may also worsen SLE itself, but few data are available on lupus flares related to sulfonamides³.

Objectives: This study aimed to assess the incidences of adverse effects and disease flare due to PCP prophylaxis with TMP-SMX in SLE patients.

Methods: SLE patients seen at our hospital between September 2010 and April 2018 who received TMP-SMX as a PCP prophylaxis were enrolled. The clinical manifestations, treatment course, adverse drug reactions, and occurrence of lupus flares were retrospectively assessed from the medical records. The Naranjo adverse drug reaction probability scale⁴ was used to determine whether the reactions were induced by SMX-TMP. According to the British Isles Lupus Assessment Group (BILAG) 2004 index, a severe flare of lupus was defined as a development of a new grade A manifestation, and a moderate flare as a development of grade B manifestation following grade C, D or E. Two board-certificated rheumatologists reviewed the medical records in a blinded fashion to determine the reason for the flare, with disagreement resolved by consensus.

Results: In total, 188 SLE patients were enrolled; of these, 117 (62.2%) had no adverse events and were able to continue taking SMX-TMP as needed. Seventy-one patients (37.8%) stopped SMX-TMP due to suspected adverse drug reactions, including fever, rash, liver function disorder, and cytopenia. The Naranjo scale indicated "definite" in 4, "probable" in 39, and "possible" in 28. Eighteen-patients restarted the SMX-TMP and 9 patients could continue the prophylaxis without adverse effects. Five patients were hospitalized to treat the adverse events: 3 with drug rash (concomitant use of hydroxychloroquine in 2), 1 with hypersensitivity (concomitant use of azathioprine) and 1 with hyponatremia, respectively.

Lupus flares occurred in 10 patients (5.3%) within one month after the start of the SMX-TMP prophylaxis. Macrophage activation syndrome (MAS) or neuropsychiatric SLE occurred in 9 of them. Of 188 cases, 2 patients (1.1%) developed a new onset of MAS during the stable clinical course as the flare, which was considered due to SMX-TMP. Confounding factors, including high disease activity and the reduction of glucocorticoids, were identified in other 8 flares.

Conclusion: PCP prophylaxis with SMX-TMP was tolerable in most SLE patients. However, a small number of SLE patients developed severe adverse effects or disease flares due to the SMX-TMP.

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SAT0209

PREVALENCE AND RELATED FACTORS OF SLEEP DISTURBANCE IN PATIENTS WITH PRIMARY SJÖGREN'S SYNDROME

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Background: The incidence of primary Sjögren's syndrome(pSS) is increasing gradually, and it was ranking second among connective tissue diseases(CTDs) in China. Studies recently have shown that many patients with various CTDs have sleep disturbances, which seriously degraded the patient's quality of life. As well known, Sleep is an important physiological process to maintain human metabolism, tissue repair, and homeostasis. At present, there are relatively several studies on sleep quality in patients with Rheumatoid arthritis(RA) and Systemic lupus erythematosus(SLE), but less reports on pSS in China have been published. Therefore, it is important to explore the quality of sleep and its influencing factors in such patients.

Objectives: The purpose of this study is to evaluate the quality of sleep and related factors in China Mainland patients with primary Sjögren's syndrome(pSS), and to provide reference and theoretical basis for constructing targeted sleep interventions and improve their quality of life.

Methods: A all of 103 pSS patients and 40 matched healthy controls were enrolled in a comparative study of sleep quality using the Pittsburgh Sleep Quality Index(PSQI), and demographic, clinical, and laboratory data were collected from them. The patients completed questionnaires on the European League Against Rheumatism (EULAR) SS Patient Reported Index(ESSPRI), EULAR SS Disease Activity Index (ESSDAI), Xerostomia inventory(XI) with the help of researchers. Pain and fatigue were evaluated with a 100-mm visual analogue scale(VAS). Generalized Anxiety Disorder(GAD-7) and Patient Health Questionnaire(PHQ-9) were used to assess anxiety and depression separately, and whether they have autonomic symptoms (such as sweating, palpitations) will be asked.

Results: The PSQI score and the frequency of poor sleep quality(PSQI>7) were higher in the pSS patients (11.60±5.03, 71.8%) than the healthy controls (5.98±3.85, 25%). Poor sleepers had a significantly higher GAD-7, PHQ-9, XI, ESSPRI, pain and fatigue VAS, and longer disease duration than good sleepers. Additionally, poor sleepers show more frequent autonomic symptoms. Sleep quality of patients with pSS was positively correlated with GAD-7, PHQ-9, XI, ESSPRI, pain and fatigue VAS scores, but no correlation with disease activity. Meanwhile, depression is an independent factor of sleep quality.

Conclusion: Our study showed that the sleep disturbance seen in patients with pSS may contribute to the depression associated with this disease. Future research should investigate that whether antidepressant treatment improve sleep and directly improve quality of life.

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