the main therapy of SLE, has a long half-life. Thus, undetectable blood HCQ concentrations can be used to identify patients who do not take their treatment

Objectives: To identify the determinants of poor therapeutic adhesion in patients with SLE.

Methods: Case-control, retrospective, monocentric study. The cases were enrolled in our centre from 02/11/2011 to 13/01/2015 according to the following criteria: SLE defined according to ACR classification criteria and blood concentration of HCQ <100 ng/ml after a minimum of 2 months on therapy. For each case, the matched control was a lupus patient, enlisted from our centre the same week, with an HCQ dose greater than or equal to 800 ng/ml. Case and control characteristics were compared using standard tests and a uni-multivariate logistic regression.

Results: One hundred and fifty patients were included, 75 cases (68 women) and 75 controls (72 women), with an average age of 35.7 years (±11.3 years) vs 35.6 years (±10.6 years). Most patients had inactive lupus (3 patients had SLEDAI ≥4), 27% of them had benefited from therapeutic education sessions. The average dosage of HCQ was 1110 ng/ml within the control group. In our univariate analysis, nonadherent patients lived significantly further away from the centre than adherent patients (median distance [interquartile range]: 22^{11-52} vs 14 km [5.9–35], respectively, p=0.03) and were more likely to be unemployed, (23 vs 8%, respectively, p=0.006). Nonadherent patients had less often benefited from the patient's therapeutic education program (18 vs 35%, respectively, p=0.018), were taking less treatment (3 vs 4, respectively, p=0.008), had a significantly lower level of education (61% compared to 89% of patients with at least a bachelor's degree, p<0.001). In our multivariate analysis, a level of education below the A levels was the strongest factor explaining poor therapeutic adherence, OR (IC 95): 4.09 (1.5–10.8).

Conclusions: The main drivers of therapeutic adherence during SLE are socio-economic factors. The least educated and most disadvantaged patients are most likely to display poor therapeutic adherence. Targeted preventive actions and enhanced therapeutic education should be provided to them.

Disclosure of Interest: None declared

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FRI0338 HYDROXYCHLOROQUINE MAY HELP TO IMPROVE THE IN VITRO FERTILIZATION-EMBRYO TRANSFER OUTCOMES IN ANA AND DS-DNA POSITIVE PATIENTS

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Background: Assisted reproductive technology has helped a large quantity of couples having trouble in natural pregnancy. Failure of *in vitro* fertilization-embryo transfer (IVF-ET) may be attributed to ANA and ds-DNA. ANA+/anti-dsDNA was related to low-quality embryos, low clinical pregnancy, and early miscarriage rate.[1] Hydroxychloroquine (HCQ) is recommended preconceptionally and throughout pregnancy for patients with SLE, and was proved to benefit the patients with Antiphospholipid syndrome. For those women with positive ANA and ds-DNA, but haven't any symptoms related to lupus or any other autoimmune diseases, the treatment for improving reproductive outcomes was controversial. In the present study, we retrospectively reviewed 156 patients with positive ANA and ds-DNA who underwent IVF-ET, compared the efficacy among different therapeutic strategies and observed side effects of the medication.

Objectives: To assess the efficacy, safety and tolerability of HCQ as preconceptionally and throughout pregnancy therapy in the treatment of IVF-ET patients with positive ANA and ds-DNA.

Methods: We retrospectively reviewed 156 patients in the treatment of IVF-ET with positive ANA and ds-DNA but without any symptoms in south China from January 2010 to December 2016 who received prednisone or prednisone +HCQ as preconceptionally and throughout pregnancy therapy. Prednisone was administrated at a dose of 7.5 mg/day. HCQ was administrated at a dose of 0.2 twice a day. Details of the IVF-ET outcomes and side effects were collected.

Results: Of the 156 patients, no significance of demographic variables and reproductive related parameters such as duration of infertility, basal sex hormone, total Gn dose, E2 level on the day of HCG initiation, and number of retrieved oocytes was found among prednisone group (65 cases) and prednisone +HCQ group (91 cases). Fertilisation rate, implantation rate and clinical pregnancy rate were significantly higher in prednisone +HCQ group than in prednisone group, 75.8% vs 60.0%, p=0.017, 29.7% vs 15.4%, p=0.032, and 62.6% vs 47.7%, p=0.028, respectively. Abortion rate was lower in prednisone +HCQ group, 7.0% vs 12.9%, but not significantly. Clinical pregnancy rate was not associated the titers of ANA or ds-DNA. Low C3 was correlated with failure of implantation. None of the cases on prednisone or prednisone plus HCQ had side effects affecting the treatment course.

Conclusions: Combination of prednisone and HCQ may be more effective than solo treatment of prednisone for patients underwent IVF-ET with positive ANA and ds-DNA who had no clinical symptoms of autoimmune diseases.

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FRI0339 SLEDAI-2K RESPONDER INDEX-50 IS EFFECTIVE IN DEMONSTRATING PARTIAL RESPONSE IN A PHASE 2, RANDOMISED PLACEBO-CONTROLLED STUDY OF USTEKINUMAB IN PATIENTS WITH ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS

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Background: Ustekinumab (UST), a monoclonal antibody that targets shared p40 subunit of cytokines IL-12 and IL-23, is being investigated in pts w/active systemic lupus erythematosus(SLE). While traditional SLE Disease Activity Index 2000(SLEDAI-2K)scoring assesses complete SLE response for individual disease manifestations, SLEDAI-2K Responder Index-50(S2K RI-50)can be used to evaluate SLE responses using partial improvement(≥50%)in each domain.

Objectives: To evaluate SLEDAI-2K vs S2K RI-50 response in a randomised, PBO-controlled trial of UST in pts w/active SLE.

Methods: We conducted a Ph2, PBO-controlled study in adults w/active disease (SLEDAI score ≥6 w/≥1 BILAG A and /or ≥2 BILAG B scores)despite standard-of-care therapy. Pts(n=102)were randomised(3:2) to UST IV~6 mg/kg or PBO at wk0, followed by SC inj of UST 90 mg q8w or PBO beginning at wk8, both added to standard-of-care. We calculated S2K RI-50 response at wk24 using various thresholds to define response including decrease of at least 1,2,3,4,5, or6 points from baseline(BL) in S2K RI-50 score. We also compared proportion of pts w/SLEDAI-2K response vs S2K RI-50 response in pts receiving UST(n=62)vs PBO (n=40)at wk24.

Results: Change from BL SLEDAI-2K and S2K RI-50 scores were strongly correlated(R=0.89,p<0.0001)at wk24. A greater proportion of UST vs PBO pts achieved S2K RI–50 response at wk24, regardless of threshold used to define response (table 1). The greatest differences in S2K RI–50 response rates between UST vs PBO were observed for a 4-point decrease(23.1%,p=0.010),a 5-point decrease(26.8%,p=0.010), and 6-point decrease (25.5%;p=0.016) from BL. S2K RI-50 captured more responders than SLEDAI-2K at wk24, however, the difference in SLEDAI-2K 4-point response in UST vs PBO was △27%(p=0.005) while S2K RI-50 was △23%(p=0.010).

Abstract FRI0339 – Table 1. S2K RI-50 response rates at Wk 24 for various thresholds to define response

Decrease from Baseline	UST (%)[a,b]	PBO (%)[a,b]	Difference between UST and PBO	p-value[c]
1 Point Decrease	96.0	94.2	1.8	0.3664
2 Point Decrease	90.0	84.2	5.8	0.2261
3 Point Decrease	86.9	74.1	12.8	0.0772
4 Point Decrease	86.2	63.1	23.1	0.0101
5 Point Decrease	74.5	47.7	26.8	0.0102
6 Point Decrease	66.3	40.8	25.5	0.0158

Note: S2K RI-50 response is defined differently in each row using different cutoffs. S2K RI-50 uses partial response definition of ≥50% improvement for each individual SLEDAI-2K descriptor.

[a] Values for pts meeting treatment failure criteria are set to missing from point of treatment failure forward.

[b] Response based upon multiple imputations for missing data from Wk16 to Wk24, where Markov chain Monte Carlo method is used to make missing pattern monotone and serial logistic regression is used to impute monotone missing. The imputation model includes treatment group and baseline SLEDAI-2K covariate.

[c] Test for greater treatment effect in UST over PBO (alternative hypothesis) is based upon logistic regression w/treatment group, baseline SLEDAI-2K, baseline medication use for SLE and race as covariates.

Conclusions: S2K RI-50 is an instrument that can capture partial clinically important improvement of ≥50% in SLE disease manifestations. The data suggests