Clinical Trials

CT-01 ASSOCIATION BETWEEN HYDROXYCHLOROQUINE NON-ADHERENCE AND DISEASE ACTIVITY IN A PREDOMINANTLY HISPANIC SYSTEMIC LUPUS ERYTHEMATOSUS COHORT

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Background Hydroxychloroquine (HCQ) is a key component of therapy for Systemic Lupus Erythematosus (SLE). Medication non-adherence is reported in 40%–80% of lupus patients and results in increased morbidity, mortality, and health care utilization. HCQ levels are a sensitive and reliable method to assess medication adherence. Our study evaluated the feasibility of HCQ level measurement in a routine clinical setting and its association with disease activity in a predominantly Hispanic population.

Univariable and multivariable regression models were constructed to evaluate the association between HCQ level and disease activity measured by SLEDAI-2K.

Results One-hundred and eight patients were enrolled (table 1); the mean age was 38 years, 91% were female, and 62% were Hispanic. The average SLEDAI-2K was 4.3 (0–20). Forty-one percent of patients had HCQ levels <500 ng/ml consistent with non-adherence, of whom 19% had undetectable levels. A higher SLEDAI-2K score was associated with low HCQ levels ($p < 0.001$). This association remained significant after adjusting for age, sex, race/ethnicity, education, primary language, glomerular filtration rate, depression, smoking, major organ involvement, steroid use, and immunosuppression ($p < 0.004$).

Conclusions HCQ levels <500 ng/ml were associated with higher disease activity and accounted for 32% of the SLEDAI variability. HCQ levels are a simple and reliable method to evaluate medication adherence in SLE. Levels <500 ng/ml should be discussed with patients and the reasons for non-adherence should be further explored and addressed.

Acknowledgements We acknowledge the patients who participated in this study.

Abstract CT-01 Table 1 Patient characteristics by adherence status

	HCQ level<500 (n=44)	HCQ level≥500 (n=64)	p value
Socio-Demographics			
Age, years	38 (19–64)	38 (20–66)	0.867
Female	40 (91)	58 (91)	1.0
Race/Ethnicity			
White	4 (9)	11 (17)	0.254
Hispanic	30 (68)	37 (58)	0.214
African American	9 (21)	12 (19)	0.985
Other	1 (2)	4 (6)	0.350
Primary Language, n (%)	(n=40)	(n=60)	
Spanish	13 (32)	15 (25)	0.174
Literacy score, mean (range)	3.1 (0–6), n=28	2.9 (0–6), n=40	0.623
Household income <\$15,000,	21 (70), n=30	29 (58), n=50	0.551
Education	n=34	n=53	
Did not complete high school	6 (18)	10 (19)	0.210
SLE and Additional Characteristics			
Disease Duration, years	9 (1–35)	9 (1–29)	0.985
Organ Involvement, n (%)	28 (64)	31 (48)	0.147
Lupus Nephritis	20 (45)	19 (30)	0.127
CNS	1 (2)	9 (14)	0.041
SLEDAI-2K	5.7 (0–20)	3.2 (0–15)	<0.001
SLICC SDI	0.97 (0–4)	0.76 (0–5)	0.400
Use of steroids in past month, n (%)	24 (55)	30 (47)	0.507
Current use of immunosuppressant agent, n (%)	30 (68)	38 (59)	0.498
Smoker, n (%)	4 (9)	6 (9)	0.990
eGFR, mean (range)	58 (30–60)	54.5 (4–60)	0.116
Weight, mean kg (range)	73.5 (34.6–121)	70.9 (30–115)	0.432
Diagnosis of Depression	16 (36)	14 (22)	0.055

Methods SLE patients from the Columbia University Lupus cohort, treated with HCQ for ≥6 months and reporting medication-adherence were included. HCQ levels were measured by whole blood high performance liquid chromatography. Non-adherence was defined as HCQ level <500 ng/ml.

CT-02 KIDNEY BIOPSY FINDINGS OF LUPUS NEPHRITIS PATIENTS IN REMISSION AND RENAL FLARE AFTER WITHDRAWAL OF MAINTENANCE THERAPY: A PROSPECTIVE OBSERVATIONAL COHORT STUDY

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Background One of the most difficult management issues in lupus nephritis (LN) is duration of maintenance immunosuppression after patients are in clinical remission. Most patients receive immunosuppression for years, based mainly on expert opinion. Prospective data are unavailable. Complicating this issue are data that patients in clinical remission can still have histologically active LN, however the implications of this are unknown. The Lupus Flares and Histological Renal Activity at the end of Treatment (LuFla) study was designed to examine whether residual histologic activity predisposes to LN flares in class III and IV LN.

Methods Patients in complete clinical remission for at least 12 months who had received at least 36 months of immunosuppression were eligible. Patients consented to a second kidney biopsy and were then tapered off maintenance immunosuppression. The patients were followed prospectively for LN flares over 24 months.

Results LuFla enrolled 44 patients and 36 completed the study. LN flares occurred in 11 patients (30.5%) and 10 (90.9%) of these had residual histologic activity on biopsy 2 (figure 1). All patients with an NIH activity index (AI) >2 flared (figure 1). Endocapillary proliferation, a component of the AI and duration of SLE at biopsy 2 were independent predictors of flare. A predictive equation based on these variables discriminated between flare and no-flare with a sensitivity of 100%, specificity of 92%, and a misclassification rate of 5.6%.

Conclusions These data suggest a repeat kidney biopsy is useful in managing maintenance immunosuppression in LN, and