or hydroxychloroquine (HCQ) and daily 5 mg prednisone). A SACQ period was defined as at least 1-year period with persistent serologic activity without clinical manifestations. Flares were defined by SLEDAI-2K Flare Index (3). Damage was assessed by SLICC damage index (SDI). Data were compared by the unpaired student's t test or chi-squared test as appropriate. Predictors of flares after GC withdrawal were analyzed by Cox regression.

Results: Out of 246 SLE patients registered in the Naples Lupus Clinic database, 132 eligible patients were identified. Among them, we selected 57 (43%) patients in whom a GC withdrawal was attempted. 75 (57%) patients were in the prednisone maintenance group.

There were no significant differences between the two treatment groups (table 1). The proportion of patients experiencing a flare was not significantly lower in the maintenance group than in the withdrawal group (15/75 vs 16/57; $p=0.28$). Moreover, the proportion of patients who had an increase in the SDI at the end of follow up was similar between the two groups (14/75 vs 8/57; $p=0.48$). However, among the withdrawal group, the rate of flares was significantly higher in SACQ patients (10/22 vs 6/35; $p=0.02$), while the majority of serologically inactive patients (82%) successfully stopped GCs without subsequent flares. At Cox regression analysis (Table 2), duration of HCQ therapy and >4 year remission at withdrawal were protective factors, while a SACQ disease and history of lupus nephritis (LN) increased the risk of disease flare.

Table 1. Baseline characteristics of 132 patients at study entry

Characteristics	Withdrawal group (n=57)	Maintenance group (n=75)	p-value
Female, no. (%)	54 (94)	70 (93)	0.73
Age, years	26.7±10.1	28.5±11.7	0.37
Disease duration, years	8.5±2.9	9.1±12.9	0.73
History of lupus nephritis, no. (%)	13(22)	22(29)	
SDI score	0.40±0.7	0.57±0.8	0.26
Immunosuppressive drugs, no. (%)	31 (54)	33(44)	0.16
HCQ, no. (%)	52 (91)	66 (88)	0.06
Low C3, no. (%)	28 (49)	41(54)	0.52
Increased dsDNA Ab, no. (%)	11 (19)	19 (25)	0.41

Table 2. Factors predicting lupus flares during follow-up at Cox regression analysis

Variables	HR	95% CI	p value
SACQ	2.99	1.08 – 8.25	0.03
Age	0.97	0.93 – 1.02	0.29
Disease duration	0.99	0.94 – 1.04	0.84
History of LN	3.38	1.22–9.33	0.01
SDI score	1.13	0.63 – 2.01	0.66
Immunosuppressive drugs	2.39	0.86 – 6.62	0.09
HCQ, ever	2.92	0.43 – 35.2	0.95
Duration of HCQ	0.84	0.72 – 0.98	0.03
5years remission	0.12	0.04 – 0.39	0.0003

Conclusion: GC withdrawal is an achievable target in SLE and may be attempted in patients in complete remission. In SACQ patients, maintenance of 5mg prednisone is superior to its withdrawal in order to prevent flares. Long-term HCQ therapy and prolonged remission can significantly reduce the risk of disease relapse after GC withdrawal.

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IMMUNOSUPPRESSANT WITHDRAWAL AFTER REMISSION ACHIEVEMENT IN LUPUS NEPHRITIS: EFFECT ON FLARE OCCURRENCE

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Background: Whether and when immunosuppressive therapy may be safely withdrawn in patients with lupus nephritis (LN) is still poorly defined. Indeed, there is no clear agreement about the optimal duration of maintenance treatment.

Objectives: We aimed at assessing the rate and predictors of flare after IS withdrawal in patients with LN in remission.

Methods: Patients with systemic lupus erythematosus (SLE) (ACR criteria) and biopsy-proven LN diagnosed between 1990 and 2019, ever treated with IS and currently in follow-up were considered. IS discontinuation was defined as the complete withdrawal of any immunosuppressive drug in patients in remission. Remission was defined as normal serum creatinine, proteinuria <0.5g/24h, inactive urine sediment, and no extra-renal SLE activity (clinical SLE Disease Activity Index [c-SLEDAI]-2K=0) on a stable immunosuppressive and/or antimalarial therapy and/or on prednisone ≤5mg/day. Flares were defined according to SLEDAI Flare Index; renal flare was defined as an increase of proteinuria >0.5g/24h requiring an increase in corticosteroid therapy or the reintroduction of IS. Predictors of a subsequent flare were analyzed by multivariate logistic regression analysis.

Results: Out of 456 SLE patients regularly followed-up, 206 (45.1%) had LN and were considered in our study. Eighty-three patients (40.3%) discontinued IS after remission achievement (Table 1). After stopping therapy, patients were followed for a mean±SD of 99±77 months (range 12–378). Nineteen patients (22.8%) developed a flare after IS discontinuation, after a mean±SD follow-up of 78±68 months (range 7–312), and were re-treated; among them, 6 patients (7.2%) experienced a renal and 13 (15.6%) an extra-renal flare. Compared to patients who flared, patients in persistent IS-free remission had longer remission before IS withdrawal (51.2±31.5 vs. 29.3±16.5 months, $p<0.001$), and continued antimalarials after IS discontinuation ($p=0.005$). No differences in flare occurrence according to the type of IS discontinued were found. At multivariate analysis, therapy with antimalarials was the strongest protective factor against disease flare (OR 0.06, 95% CI 0.11–0.41, $p=0.004$) (Table 2). At last follow-up, mean±SD SLEDAI-2K was 3.1±2.8 and 1.5±1.6 in patients who experienced or not a flare after IS discontinuation, respectively ($p=0.058$). Indeed, 10/19 patients (52.5%) who developed a flare re-achieved remission.

Table 1. Characteristics of 83 patients with LN in remission who discontinued immunosuppressive therapy, overall and according to flare occurrence

	Total patients (83)	Patients with flare (19)	Patients without flare (64)	P value
Female, N(%)	72 (88.7)	16 (84.2)	56 (87.5)	ns
Age at 2019, years	43±11	39±11.5	45±10.4	0.049
SLE duration at 2019, years	18±9	16.7±9.0	18.6±8.6	ns
SLE duration at IS discontinuation, years	9.7±7.6	7.1±6.1	10.5±7.8	ns
Time to achieve remission, months	27±37	22.1±35.6	28.5±37.6	ns
Remission duration at IS discontinuation, months	46±30	29 ±16.5	51±31.5	<0.001
IS therapy duration, years	6.7±4.3	5.2±3.8	7.1±4.2	0.061
Anti dsDNA, N(%)	65 (78.3)	18 (95)	47 (73)	0.059
HCQ after IS discontinuation, N(%)	67 (80.7)	12 (63.1)	55 (85.9)	0.005

IS, immunosuppressant; HCQ, hydroxychloroquine

Table 2. Multivariate logistic regression: predictors of flare occurrence

Dependent variable: flare occurrence	OR	95% CI	p value
Number of ISs, ever	3.264	1.030–10.342	0.044
HCQ therapy after IS discontinuation	0.096	0.014–0.652	0.017
Remission duration at IS discontinuation	0.954	0.912–0.997	0.037
Cyclophosphamide, ever	0.065	0.008–0.548	0.012

IS, immunosuppressant; HCQ, hydroxychloroquine

Conclusion: Based on our experience, withdrawal of IS is feasible in selected patients with LN, i.e. patients who achieved stable remission and received maintenance therapy with antimalarials. Patients who experience new flares can re-achieve remission with an appropriate treatment.

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