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Effectiveness, In Real Life, of Preconception Counselling to Predict the Pregnancy Complications of Systemic Lupus Erythematosus

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Abstract

Background: During pregnancy, SLE-patients have an increased risk of complications: development of new-onset or reactivation of lupus nephritis, development of pre-eclampsia and/or damage to the fetus. To reduce this risk and start a "safe" pregnancy, preconception counselling is proposed that assesses the disease activity score and the coexistence of an immunological quiescent state for at least 6 months.

Materials and Methods: Two groups of 10 women each were studied: Group A had a pregnancy without complications and Group B with complications. The 2 groups were comparable for age, disease duration, disease activity free interval and disease activity score at conception.

Results: The two groups, while reporting differences in complications during gestation and/or fatal outcome, did not show differences in the various characteristics studied at the time of conception.

Conclusions: Based on the current knowledge, in real life during a preconception evaluation it is not possible to guarantee to the future pregnant SLE-women the absence of maternal and/or fatal complications.

Keywords: Pregnancy; Disease Activity; Lupus Nephritis

Abbreviations: SLE: Systemic Lupus Erythematosus; EULAR: European League Against Rheumathism; ACR: American College of Rheumatology; UP: Uncomplicated Pregnancies; HCQ: Hydroxychloroquine.

Background and Aims

Pregnancy in women with Systemic Lupus Erythematosus (SLE) is associated with an increased risk of maternal [1] and fatal [2] complications, compared to women who are not previously affected by this disease. Thus, a multidisciplinary counselling with close obstetric, rheumatologic, nephrologic and neonatal monitoring is recommended to optimize both maternal and foetal outcomes.

To reduce this risk, the current proposed selection criteria are:

- SLE should be quiescent for at least six months prior to the patients attempting pregnancy [3]: the low disease activity is verified through the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI)

score, which was validated as a clinical index for the measurement of disease activity in SLE [4]. In fact, it has been shown that a SLEDAI score greater than or equal to 4 within 6 months of conception, in patients with SLE, predicts adverse outcomes in mothers and / or fetuses [5].

- Non-suspension of hydroxychloroquine (HCQ) in patients who follow the therapeutic plan before the pregnancy [6].
- Administration of low dose aspirin starting from the 12th week of pregnancy [7].

It is also believed that complications are more frequent in primigravidae [8] and in patients with a previous medical history of lupus nephritis [5]. All these criteria are in accordance with the guidelines of the European League against Rheumathism (EULAR) [9] and the American College of Rheumatology (ACR) [10]. In "real life", however, these criteria may prove to be insufficient to predict the mother and fetus outcomes during pregnancy. We present below the data relating to a single-centre retrospective observational study, which assessed the trends among pregnancies of women with SLE.

Materials and Methods

20 pregnant patients were enrolled.

Inclusion Criteria

- SLEDAI pre-conception score less than 4 for at least 6 months;
- Review of patient's treatment plans to verify that those who took hydroxychloroquine before pregnancy continue to swallow it even during pregnancy.
- All patients took low dose aspirin starting from week 12 of pregnancy.

The patients were divided into 2 groups: Group A, made up of 10 patients who carried on 10 uncomplicated pregnancies (UP) and Group B, made up of 10 patients carried on 10 pregnancies which, conversely, became complicated (CP). The characteristics of these 2 groups of women are described in Table 1 and Table 2, respectively.

Patient	Type of Labor	Birth Time (weeks + days)	Infant Sex (female or male)	Birth Weight (grams)	Complications
1	Scheduled Cesarean (THA)	39 w	F	3170	none
2	Unplanned Cesarean (CTG modifications and no cervical dilatation)	40 w + 3 d	F	2930	none
3	Scheduled Cesarean	39 w	F	3240	none
4	Unplanned Cesarean (CTG modifications)	39 w	F	3320	none
5	Vaginal birth	39 w + 1 d	F	3594	none
6	Vaginal birth	39 w + 6 d	F	3532	none
7	Vaginal birth	40 w + 3 d	F	3160	none
8	Vaginal birth (PROM)	39 w + 3 d	F	3440	none
9	Labor induction and vaginal birth	38 w + 1 d	F	2805	none
10	Unplanned Cesarean (fetal macrosomia)	37 w + 6 d	F	3560	none

Table1: Uncomplicated pregnancies.

Patient	Type of Labor	Birth Time (weeks + days)	Infant Sex (female or male)	Birth Weight (grams)	Complications
1	Vaginal birth	37 w + 6 d	M	2980	Lupus nephritis flare
2	Emergency Cesarean section (pre- eclampsia and HELLP syndrome)	33 w	F	IUGR	Lupus nephritis flare
3	Unplanned Cesarean	40 w	M	> 3000	Lupus nephritis flare + pre-eclampsia

4	Emergency Cesarean section (pre- eclampsia)	34 w	F	2151	HELLP syndrome
5	Labor induction and vaginal birth	38 w + 1 d	M	2710	HELLP syndrome
6	Emergency Cesarean section (pre- eclampsia and HELLP syndrome)	29 w + 5 d	F	958	Lupus nephritis flare
7	Unplanned Cesarean	36 w + 6 d	M	2355	New-onset lupus nephritis
8	Scheduled Cesarean	39 w	F	3050	New-onset lupus nephritis
9	Labor induction and vaginal birth	37 w + 2 d	F	3115	New-onset lupus nephritis
10	Vaginal birth	39 w	F	> 3000	Lupus nephritis flare

Table 2: Complicated pregnancies.

Statistical Analysis

Continuous variables were compared using the Mann-Whitney test depending on their distribution. Statistical significance was evaluated by the two-tailed t-test ($p < 0.05$). The $\chi 2$ test for independence was used to compare, between the two groups of patients (A and B), the proportion of patients who had already developed lupus nephritis before pregnancy.

Results

The patients of the two groups studied did not differ in age, disease duration, duration of disease remission and SLEDAI score at the time of conception (Table 3). The condition of primigravida was more frequent in group A (n=9) than in group B (n=7). The number of patients who had already developed a lupus nephritis prior to pregnancy were similar in the two groups (5 in Group A and 5 in Group B, $\chi 2$ test for independence = 0, p=1). Nonetheless, Group B experienced the following complications affecting the mother and/or fetus: 4 flares of lupus nephritis, 3 new-onsets of lupus nephritis, 3 new-onsets of severe pre-eclampsia, 1 fetus affected by intrauterine growth restriction and 1 small for gestational age new-born.

	Age (years old)			Disease Duration (years)			Duration Of Disease REMISSION (Months)			Sledai Score At Conception		
	N	M ± SE	P-value	N	M ± SE	P-value	N	M ± SE	P-value	N	M ± SE	P-value
Uncomplicated pregnancies	10	35,90 ± 0,88	0,053	10	14,10 ± 2,17	0,85	10	6,50 ± 1,28	0,53	10	1,30 ± 0,52	0,390
Complicated pregnancies	10	33,70 ± 1,70		10	12,60 ± 2,56		10	7,10 ± 0,59		10	1,80 ± 0,42	

Table 3: The patients of the two groups' disease duration, duration of disease remission and SLEDAI score at the time of conception.

Conclusions

In the current state of knowledge, in real life, even by including the best preventive care services and the most accurate preconception screening, it is not possible to predict the development of adverse pregnancy outcomes in women with systemic lupus erythematosus. Based on the data derived from the clinical experience of our group and due to the fact that clinical-biohumoral exams do not allow to estimate who develop a complicated or uncomplicated pregnancy, we believe that during the pre-conceptional counseling SLE-patients should be correctly informed about the risks of pregnancy, in order to decide if they want to become mothers.

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