

Pregnancy and Disease Outcome in Patients with Systemic Lupus Erythematosus (SLE): A Study at Srinagarind Hospital

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Background: Systemic lupus erythematosus (SLE) is a multi-system involvement autoimmune disease that commonly occurs in childbearing age women. During pregnancy and postpartum period, disease activity may be severe or unchanged. Disease flare during pregnancy consistently affects pregnancy outcome.

Objective: To study pregnancy outcomes and predictive factor for disease flare during pregnancy in SLE patients.

Material and Method: Retrospective descriptive study was performed. The study population was pregnant SLE patients who were treated between January 1997 and December 2006 at Department of Obstetrics-Gynecologic and Medicine, Srinagarind Hospital, Khon Kaen University, Thailand.

Result: The medical records of 37 pregnant SLE patients were reviewed. Of these, 33 cases gave delivery at Srinagarind Hospital. Mean age was 27.3 ± 3.26 years, and mean disease duration was 59.67 ± 38.62 months. Mostly SLE was established before pregnancy; about 10% SLE were firstly recognized during pregnancy. During pregnancy, the disease activity was defined active in about two third (25 cases) of the patients. In most cases (60%), disease activity was continued from the pre-pregnancy period. The most common manifestations during pregnancy were lupus nephritis, hemolytic anemia, cutaneous rash, and arthritis respectively. In 40% (10 patients), SLE was severely active but could be controlled with high doses of corticosteroid, two of these required immunosuppressant.

Overall live-birth in SLE patients who delivered at Srinagarind Hospital was 72.7%. Among this group, premature labor and intrauterine growth retardation were more commonly found in the patients who had active SLE than who had disease remission throughout pregnancy period with ratio of 4:1 and 7:1 respectively. Pregnancy lost (27.3%) was due to abortion (6 cases) and dead fetus in utero (DFIU; 2 cases)

Termination of pregnancy was performed in 10 patients. Indications were severe active lupus (6 cases), DFIU (2 cases), and premature rupture of membrane (1 case). Pregnancy outcome was the best in patients who had inactive disease throughout pregnancy (75%) and worse in groups of patients whose disease flared up (54.5%) or emerged (50%) during pregnancy.

Conclusion: Even contraception was routinely advised in treating SLE patients, getting pregnant during active disease was eventually found. Lupus nephritis was the most common manifestation. Overall live-birth was 72.7%. Pregnancy lost was due to abortion and dead fetus in utero. Pregnancy outcome was worse in SLE patients who had disease flares up or emerging during pregnancy.

Keywords: Fetal death, Fetal growth retardation, Infant, Newborn, Diseases, Lupus erythematosus, Systemic, Postpartum period, Pre-eclampsia, Pregnancy, Pregnancy outcome

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Systemic lupus erythematosus (SLE) is a serious autoimmune disease commonly occurring in childbearing age women⁽¹⁻⁴⁾. The disease may cause organ inflammation and permanent structural damage.

Physiologically, defective immune response was demonstrated in pregnant women. Functions of natural killer cells, phagocytes, and cell mediated cytotoxic T-cells are normally depressed⁽⁵⁾. In lupus patients, the disease activity during pregnancy and post-partum may be severe or unchanged⁽⁶⁻¹⁰⁾. In pregnant woman who had severe active diseases and required high dose immunosuppressants, defective immune function may be enhancing. This can increase risk of immunosuppressant side effects, disease complications, and can affect pregnancy outcome. Therefore, family planning should be emphasized in SLE patients particularly in child-bearing age group.

Objective

To study clinical features and pregnancy outcome of pregnant SLE patients who were treated at Srinagarind Hospital, Khon Kaen University, during January 1997 - December 2006.

Material and Method

Retrospective descriptive study was performed in pregnant SLE patients who were treated at the Department of Obstetrics and Department of Medicine, Srinagarind Hospital, between January 1997 and December 2006.

All medical records giving diagnosis of SLE according to American College of Rheumatology (ACR) criteria⁽¹⁷⁾, and pregnancy were searched from department of Medical Record and Registration. The patients were categorized into four groups, patients who had ongoing active SLE while getting pregnant, patients whose disease flared up during pregnancy, patients whose SLE was established during pregnancy, and lastly patients who had inactive diseases throughout pregnancy. Chronological data, disease duration, active organ involved, laboratory data, medications used prior to and during pregnancy, and pregnancy outcome were reviewed.

Definitions

Disease duration was determined by time period between disease onset to date of contraception.

Active disease was determined by active organ involved according to ACR criteria⁽¹⁷⁾.

Medical treatment prior to pregnancy was determined by medication used within 1 month prior to pregnancy.

Medication used during pregnancy was determined by the highest dose of immunosuppressant used during pregnancy.

Pregnancy outcome was determined as the following; abortion- pregnancy loss before 28 weeks of gestation, dead fetus in utero (DFIU) - fetal death after 28 weeks of gestation, preterm - fetal delivery before 36 weeks of gestation, intrauterine growth retardation (IUGR) - birth weight less than 10th percentile of normal birth weight, termination of pregnancy-either therapeutic abortion or induction of labor.

Clinical data was analyzed by using simple method of analysis, presented as percents and mean \pm SD.

Results

Thirty-seven pregnant SLE patients were included in the present study. Thirty-three cases (89.2%) SLE were established prior to pregnancy, and in the remainder, the disease emerged at the time of pregnancy.

Overall mean age was 27.3 ± 3.26 years (20-34 years) and mean disease duration was 59.67 ± 38.62 months (1-156 months).

Clinical characteristic of the four groups is summarized in Table 1. The number of patients who had active disease before pregnancy, disease flare up during pregnancy and inactive disease throughout pregnancy was equally distributed; 10, 11 and 12 patients respectively.

Among patients whose SLE was established prior to pregnancy, antenatal care (ANC) was started at the first trimester in 23 of 33 cases (69%), the rest came at second trimester (9 cases), or third trimester (1 case). During ANC, the tests of lupus anticoagulant and/or anti-cardiolipin antibody were performed in 12 cases (36.4%). The results were all negative. Anti-Ro antibody was tested in five cases (15.2%) and was found positive in two cases, one developed skin flare during pregnancy. None of the studied patients had renal impairment (serum creatinine > 1.4 mg/dl) before pregnancy. Four patients (12.1%) had anemia, while hypoalbuminemia (serum albumin < 3.0 g/dl), thrombocytopenia, and leucopenia (WBC $< 4,000$ cell/mm³) were noted in one each.

Among 15 cases whose disease flared up or emerged during pregnancy, it could occur in any period of pregnancy, 46.7% during 1st trimester, 33.3% during 2nd trimester, and 20% during 3rd trimester.

Table 1. Clinical characteristics of pregnant SLE: comparison among 4 groups of patients

Data	SLE and pregnancy (n = 37)			
	Active disease before pregnancy (n = 100)	Disease flared during pregnancy (n = 11)	Disease emerged during pregnancy (n = 4)	Inactive disease throughout pregnancy period (n = 12)
Mean age \pm SD (yr)	25.66 \pm 3.71 (20-32)	28.42 \pm 3.42 (22-34)	27.3 \pm 3.11 (22-30)	27.25 \pm 2.26 (23-30)
Mean disease duration \pm SD (month)	41.80 \pm 28.69 (1-84)	70.19 \pm 48.53 (8-156)	-	64.92 \pm 33.06 (18-120)
Active organ involvement				
Major organ	8	8	3	-
Renal alone	5	4	-	-
Hemolytic anemia alone	1	3	-	-
Other				
Renal with hemolytic anemia	-	-	1	-
Renal with skin	1	1	1	-
Hemolytic anemia with skin	-	-	1	-
Thrombocytopenia with skin	1	-	-	-
Minor organ	2	3	1	-
Skin alone	1	1	1	-
Arthritis alone	-	2	-	-
Arthritis with skin	1	-	-	-
Hypertension	2	1	1	-
Low complement level during pregnancy	3 (6)	7 (8)	3 (4)	0 (3)
Medical treatment 1 month before pregnancy				
Steroid	8	7	-	6
High dose (> 30 mg/d)	2	-	-	-
Moderate dose (15-30 mg/d)	2	-	-	-
Low dose (< 15 mg/d)	4	7	-	6
Antimalarial	1	4	-	2
Immunosuppressive agent	1 ^a	1 ^b	-	-
Medical treatment during pregnancy				
Steroid used	9	11	3	6
High dose (> 30 mg/d)	2	5 ^c	3 ^d	-
Moderate dose (15-30 mg/d)	3	3	-	-
Low dose (< 15 mg/d)	4	3	-	6
Antimalarial	3	2	1	-
Immunosuppressive agent	-	1 ^e	1 ^f	-

^a Cyclophosphamide was stopped after pregnancy was detected

^b Cyclophosphamide was stopped after pregnancy was detected and disease flared after stopping for 31 week

^c Two cases received methylprednisolone 1 gm

^d One case received methylprednisolone 1 gm

^e Azathioprine for AIHA

^f Cyclophosphamide intravenous infusion for nephritis case

Among patients who had active disease during pregnancy (25 patients), 76% (19 patients) had major organ flare up. The most common clinical flare up was lupus nephritis (13 patients), followed by active hemolytic anemia (6 patients).

Duration of disease remission before pregnancy was recorded in 16 out of 23 cases. In the group who had inactive disease throughout pregnancy (n = 9), 77.8% (7 patients) had disease remission over 6 months before pregnancy. Two patients who had

remission duration less than 6 months experienced only minor organ involvement. In the group who had flared up disease during pregnancy (n = 7), 57.1% (4 cases) had remission duration less than 6 months, the rest had remission duration between over 6 months. In this group, active organ involved during pregnancy were almost similar to organ involved before pregnancy (4 had lupus nephritis, 2 had arthritis). Only one case had a different organ involved during pregnancy; lupus nephritis instead of arthritis. There was no significant laboratory data predicting of SLE flare during pregnancy in both groups.

Active lupus nephritis during pregnancy was found in 13 cases; about half (6 patients) ongoing lupus nephritis was noted prior pregnancy. Two were severe active lupus nephritis with hypertension that required high dose corticosteroid steroid treatment. One of the two cyclophosphamide therapy was also given. The rest were mild (2 cases) or moderately severe (2 cases) lupus nephritis. Lupus nephritis flared up during pregnancy was found in five cases. Two had severe lupus nephritis with hypertension and required high dose methylprednisolone treatment. The rest were controlled with moderate dose corticosteroid. Lupus nephritis emerging during pregnancy was severe (2 cases). Both required high dose corticosteroid treatment, and cyclophosphamide was indicated in one case. All active lupus nephritis patients had been controlled and had stable disease during the postpartum period. Cyclophosphamide therapy was continued at post partum period in one case.

Active AIHA was found in six patients. One developed active AIHA prior to pregnancy and ongoing moderate dose corticosteroid. The rest flared up or emerged during pregnancy indicating high dose corticosteroid treatment.

Serum complement was evaluated in 21 patients (56.75%). Low serum complement was more common in patients who had disease flare or emerged during pregnancy, in 87.5% and 75% respectively. Meanwhile only half had been noted in patients who had active disease prior to pregnancy and none was found in patients who had inactive disease throughout pregnancy.

Overall, 78.4% (29 cases) received corticosteroid treatment during pregnancy, 44.8% (13 cases) required only low dose corticosteroid for both maintenance therapy and minor disease activities, 34.5% (10 cases) required high dose corticosteroid treatment; and three of them received methylprednisolone.

Among 10 patients who had active disease prior to pregnancy, 40% (4 cases) had been receiving moderate to high dose corticosteroid. Disease activity of the rest (6 cases) had been controlled with low dose corticosteroid and antimalarial drugs. Cessation of antimalarial drugs was found in both groups, active and inactive SLE during pregnancy, in an equal number (2 cases in each group).

Details of pregnancy outcome are summarized in Table 2. Term pregnancy was found in 57.5% (19 cases) and about 42% among these had low birth weight. 15.2% (5 cases) had preterm delivery. Pregnancy lost was found in 27.3% due to abortion and dead fetus in utero (DFIU).

About 70% (23 patients) of the patients had normal delivery. In 10 patients termination of pregnancy was indicated due to severe active SLE (6 cases), DFIU (3 cases), and premature rupture of membrane (1 case). Among the patients who had terminated pregnancy from active SLE, two cases were lupus nephritis, two cases were AIHA, and one case was cutaneous vasculitis.

Pregnancy outcome in the patients who had active lupus nephritis was analyzed. Among severe active lupus nephritis during pregnancy, termination of pregnancy was indicated in two cases (1 premature labor and another required therapeutic abortion), two had preterm delivery, and one developed IUGR. Among moderately severe lupus nephritis, two had IUGR, one had DFIU, and one underwent criminal abortion. Among lupus nephritis patients who had remission duration more than 6 months before pregnancy, 71.4% (5 patients) had term pregnancy with live-birth.

Among six patients who had active AIHA during pregnancy, two had preterm delivery, two had abortion, and another one who received azathioprine had IUGR with underdeveloped ear pinna. The remaining patient was delivered at a local hospital.

In high dose corticosteroid treating group (n = 9) 11% (1 case) had term pregnancy with normal delivery, 33.3% (3 cases) had abortion, and the rest had IUGR and/or premature labor. In low dose steroid treating group (n = 11), 72.7% (8 cases) had term pregnancy, 9% (1 case) had preterm delivery, and 18% (2 cases) had abortion (1 was criminal abortion). None in both groups had DFIU.

At the post partum period, disease activity had been controlled in all patients who had active disease during pregnancy. No maternal death was found. SLE flared up at the post partum period in two patients who had inactive disease throughout

Table 2. Pregnancy outcomes of pregnant SLE: comparison among 4 groups of patients

Data	SLE and pregnancy (n = 37)			
	Active disease before pregnancy (n = 10)**	Disease flared during pregnancy (n = 11)***	Disease emerged during pregnancy (n = 4)	Inactive disease throughout pregnancy period (n = 12)
Delivery condition				
Normal delivery*	6	5	3	9
Termination	1	5	1	3
Indication of termination				
Severe disease activity	1	4	1	-
Dead fetus in utero	-	1	-	2
PROM	-	-	-	1
Trimester of termination				
1 st trimester	-	2	-	-
2 nd trimester	1	1	-	2
3 rd trimester	-	2	1	1
Pregnancy outcome				
Live-birth	7	6	2	9
Preterm	2	-	2	1
Term	5	6	-	8
Normal	1	3	-	7
IUGR	4	3	-	1
Death	-	4	2	3
Abortion	-	3	2	1
Spontaneous	-	1	2	-
Criminal	-	1	-	1
Therapeutic	-	1	-	-
DFIU	-	1	-	2

* Included vaginal delivery and cesarean section

** Three cases delivered at another hospital

*** One case delivered at another hospital

pregnancy. Both had lupus nephritis and had been controlled with moderate dose corticosteroid.

Neonatal thrombocytopenia was noted in a maternal lupus patient who had thrombocytopenia and required intravenous immunoglobulin therapy at day 2. One fetal anomaly had been noted (undeveloped left ear pinna) in a maternal lupus patient requiring azathioprine therapy for intractable active AIHA. Neither had neonatal heart block nor neonatal rash. Neonatal jaundice developed in seven cases. Two cases were hemolytic jaundice, two were minor blood incompatibility, one was breast milk jaundice, one was preterm jaundice, and one case unknown cause.

Discussion

Pregnancy outcome in SLE has been reported by many centers. Twenty percent of cases were pre-

term related with hypertensive medication use, corticosteroid use, severe flared disease during pregnancy, nephrotic range proteinuria, and anti-cardiolipin antibody⁽¹¹⁻¹⁶⁾. In the present series, preterm pregnancy and IUGR were more common in the patients who had active diseases during pregnancy compared to the disease remission group, 4:1 and 7:1 respectively. In addition, severe active disease was the most common indication for termination of pregnancy.

Overall pregnancy outcome was the best in group of inactive disease throughout pregnancy (75%). Notably, minor organ involved prior to pregnancy does not predict pregnancy outcome in lupus patient. Patients who had active lupus activity prior to pregnancy had better pregnancy outcome than a group with disease flare or emerged during pregnancy (70% vs. 54.5% and 50% respectively). This may due to mild

to moderate disease flare at time of pregnancy in the former group compared to moderate to severe disease flare in the others. Severe active lupus prior to pregnancy was naturally excluded in the former group. Since disease flare can play a major role in pregnancy outcome, lupus activity should be carefully monitored during pregnancy to decrease risk of pregnancy lost, premature labor, and IUGR.

The most common disease activity found in the present series was lupus nephritis (45.4%) similar to the report from Branch DW (43%)⁽¹¹⁾. About half was severe active accompanied with hypertension required high dose immunosuppressive drugs. Normal term pregnancy was noted in less than 20% of severe active lupus nephritis, while termination of pregnancy, premature labor, IUGR, and DFIU were more common. Pregnancy outcome was less affected in lupus nephritis patient whose disease was well controlled and long remission duration. In this group, normal term pregnancy was found in 71.4%. Thus, history of lupus nephritis is not a contraindication of pregnancy.

In the group of inactive disease throughout pregnancy, there was a higher number of patients who had remission duration more than 6 months compared to the group of disease flare during pregnancy (77.8% and 42.9% respectively). In addition, most patients who had remission duration less than 1 year developed the same organ flare up as before remission. Thus, short time of disease remission before pregnancy may be a predictor of disease flare during pregnancy and tendency to have the same organ involved as before pregnancy.

Low serum complement level was found in all cases who had disease flare during pregnancy, and none of the patients in inactive group had low serum complement. There was no difference in other laboratory tests observed between these two groups in this small studied population. It would be reasonable to monitor serum level of complement in all SLE patients that plan for pregnancy after disease remission for early detection of disease flare.

The limitation of the present study was the retrospective nature of data collection and analysis. However, preliminary data may provide some value for evaluating pregnant SLE patients in Srinagarind Hospital and could be used for the better family planning in SLE patients in daily practice.

Conclusion

Lupus nephritis was the most common organ involved and fundamentally affected pregnancy out-

come; required termination of pregnancy, high rate of premature labor, IUGR and DFIU. Overall live-birth was 72.7%. Pregnancy outcome was worse in SLE patients who had disease flares up or emerging during pregnancy. Minor organ involvement prior to pregnancy and history of having lupus nephritis were not predictors of pregnancy outcome. SLE patients who had shorter duration of remission and low serum complement tended to have disease flare up during pregnancy.

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ผลกระทบต่อโรคและการตั้งครรภ์ในผู้ป่วยโรคลูปัสที่ตั้งครรภ์: การศึกษาในโรงพยาบาลศรีนครินทร์

ซิงซิง พูเจริญ, รัตนาวดี ณ นคร, หลิงหลิง สาลัง, ศิรภพ สุวรรณโรจน์, อรรชนี มหรรฆานุเคราะห์

ภูมิหลัง: โรคลูปัสเป็นโรคทางออโตอิมมูนที่มีผลต่อระบบต่างๆของร่างกายพร้อมกันได้หลายระบบ พบบ่อยในเพศหญิงวัยเจริญพันธุ์ ระหว่างตั้งครรภ์และหลังคลอดโรคลูปัสอาจมีการกำเริบ หรือ ไม่มีการเปลี่ยนแปลงใด ๆ ก็ได้ กรณีที่มีโรคกำเริบมักจะมีผลกระทบต่อตั้งครรภ์

วัตถุประสงค์: เพื่อศึกษาผลกระทบของโรคลูปัสต่อการตั้งครรภ์ รวมทั้งปัจจัยส่งเสริมที่ทำให้โรคลูปัสกำเริบระหว่างตั้งครรภ์

วัสดุและวิธีการ: เป็นการศึกษาเชิงพรรณนาแบบย้อนหลังในผู้ป่วยลูปัสตั้งครรภ์ที่เข้ารับการรักษาในแผนกสูตินรีเวช และแผนกอายุรกรรม โรงพยาบาลศรีนครินทร์ มหาวิทยาลัยขอนแก่น ประเทศไทยระหว่างเดือนมกราคม พ.ศ. 2540 ถึงเดือนธันวาคม พ.ศ. 2549

ผลการศึกษา: พบเวชระเบียนของผู้ป่วยลูปัสตั้งครรภ์ทั้งหมด 37 ราย แต่ที่คลอดบุตรที่โรงพยาบาลศรีนครินทร์มีจำนวน 33 ราย อายุเฉลี่ยของผู้ป่วย 27.3 ± 3.26 ปี ระยะเวลาเฉลี่ยของการเป็นโรคลูปัสนาน 59.67 ± 38.62 เดือน ผู้ป่วยส่วนใหญ่ได้รับการวินิจฉัยว่าเป็นโรคลูปัสก่อนตั้งครรภ์ ร้อยละ 10 ได้รับการวินิจฉัยครั้งแรกว่าเป็นโรคลูปัสขณะตั้งครรภ์ ประมาณสองในสามของผู้ป่วย (25 ราย) ตรวจพบการอักเสบจากโรคลูปัสขณะตั้งครรภ์ ส่วนใหญ่ (ร้อยละ 60) การดำเนินโรคต่อเนื่องมาตั้งแต่ก่อนการตั้งครรภ์ขณะที่โรคยังไม่สงบ ภาวะที่พบบ่อยที่สุดคือไตอักเสบจากลูปัส รองลงมาได้แก่ภาวะเม็ดเลือดแดงแตกจากโรคออโตอิมมูน ผื่นหรือรอยโรคที่ผิวหนัง และข้ออักเสบ ผู้ป่วย 10 รายมีโรคกำเริบรุนแรงแต่สามารถควบคุมอาการได้โดยใช้ยาสเตียรอยด์ขนาดสูง และ 2 รายต้องได้รับการรักษาด้วยยากดภูมิคุ้มกัน

ในผู้ป่วยที่คลอดบุตรที่โรงพยาบาลศรีนครินทร์ พบคลอดมีชีวิตรอดร้อยละ 72.5 อัตราการคลอดก่อนกำหนด และ/หรือตรวจพบทารกในครรภ์มีการเจริญเติบโตช้าพบได้บ่อยในกลุ่มที่มีการกำเริบของโรคขณะตั้งครรภ์มากกว่า กลุ่มที่โรคสงบตลอดการตั้งครรภ์คิดเป็นสัดส่วน 4:1 และ 7:1 ตามลำดับ ร้อยละ 27.3 ตั้งครรภ์ไม่สำเร็จเนื่องจากแท้งบุตร (6 ราย) และทารกเสียชีวิตในครรภ์ (2 ราย)

ผู้ป่วย 10 รายต้องยุติการตั้งครรภ์ โดยข้อบ่งชี้ได้แก่ โรคกำเริบรุนแรง (6 ราย) ทารกเสียชีวิตในครรภ์ (2 ราย) และถุงน้ำแตกก่อนกำหนด (1 ราย) ผลการตั้งครรภ์จะดีที่สุดในกลุ่มผู้ป่วยลูปัสที่โรคสงบตลอดการตั้งครรภ์ แต่ไม่ค่อยดีนักในกลุ่มผู้ป่วยที่มีโรคกำเริบระหว่างตั้งครรภ์และกลุ่มที่ได้รับการวินิจฉัยโรคลูปัสครั้งแรกขณะตั้งครรภ์ (คลอดมีชีวิตรอดร้อยละ 75, 54.5 และ 50 ตามลำดับ)

สรุป: แม้ว่าผู้ป่วยลูปัสที่อยู่ในวัยเจริญพันธุ์จะได้รับคำแนะนำให้คุมกำเนิดระหว่างการรักษา แต่ยังมีผู้ป่วยจำนวนไม่น้อยที่ตั้งครรภ์ขณะที่โรคยังไม่สงบ ไตอักเสบเป็นภาวะที่พบบ่อยที่สุด ร้อยละ 72.7 คลอดทารกมีชีวิตรอดที่เหลือเป็นการแท้งบุตรหรือทารกเสียชีวิตในครรภ์ซึ่งพบได้บ่อยกว่าในกลุ่มที่มีโรคกำเริบหรือได้รับการวินิจฉัยว่าเป็นโรคลูปัสครั้งแรกขณะตั้งครรภ์