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RESEARCH ARTICLE

EFFECTS OF SYSTEMIC LUPUS ERYTHEMATOSUS IN PREGNANCY WOMEN: A REVIEW OF CLINICAL FEATURES AND OUTCOMES OF 122 PREGNANCIES

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ABSTRACT

Background: The pregnancy outcome in Chinese women with systemic lupus erythematosus (SLE) has been controversial. Research looking at predictive factors in this population is sparse in China. **Objective:** The aim of this study was to determine the frequencies of abnormal pregnancy outcomes in a Chinese cohort and to identify clinical factors predicting adverse fetal and maternal outcomes in Chinese women with SLE. **Patients and Methods:** We retrospectively reviewed the medical records of 122 pregnant women with SLE diagnosed patients from 2011 to 2017, regarding the association of the clinical features including lupus nephritis, pre-eclampsia and the adverse outcomes in Qilu Hospital of Shandong University. Univariate and multivariate analyses were used to evaluate the predictors of maternal and fetal outcomes. **Results:** The Mean age of pregnant women with SLE was29.15±3.99years and mean average SLE duration was 5.03±4.64 years. Of 122 pregnant women, 83.6% women had live births and the preterm live birth was 32.0%. Average mean of baby weight was 2254.79±1114.51 grams. The most common maternal complication was premature rupture of membranes 18.0%, followed by pre-eclampsia or eclampsia 17.2%. **Conclusion:** Age group, SLE duration, hemoglobin, erythrocyte sedimentation rate (ESR), anticardiolipin antibodies (aCL) were independent predictor of fetal loss for pregnant women with SLE. Further studies were needed to investigate the predictor factors of Chinese pregnant women with SLE.

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INTRODUCTION

Systemic lupus erythematosus (SLE) isa serious multisystem autoimmune connective tissue disorder which primarily affects women predominantly in their childbearing age.SLE is characterized by various laboratory abnormalities, hemoglobin levels during pregnancy. Pregnant women with SLE have increased risk of adverse outcomes including disease flare, spontaneous abortion, intrauterine growth restriction (IUGR), preeclampsia/eclampsia (PE), preterm birth and maternal death compared with healthy women, as have been well documented in several studies across the world (Buyon *et al*. 2015; Ku *et al*. 2016; Ling *et al*. 2018; Maksimova and Sidorova 1991; Moroni and Ponticelli 2016; Park *et al*. 2014). Therefore, pregnancies in SLE patients are considered as high-risk condition. Maternal health and fetal development should be monitored frequently during pregnancy.

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Although, there have been improvement in treatment and survival outcomes of SLE for the past decades, SLE remains an important contributor to maternal and fetal morbidity and mortality, especially in low- and middle-income countries (LMICs) like China(de Jesus *et al*. 2015; Wu *et al*. 2018). In China, the pregnancy outcomes in women with SLE has been investigated but remains controversial, especially with regard to the clinical factors predicting adverse fetal and maternal outcomes during gestation. Some previous epidemiological studies report optimistic pregnancy outcomes with less maternal complications and less adverse fetal outcomes (Tian *et al*. 2015; Wang *et al*. 2006; Ye *et al*. 2012), while others report a significant number of SLE flare during pregnancy with adverse pregnancy outcomes(Ku *et al*. 2016; Ling *et al*. 2018; Zhan *et al*. 2017; Zhan *et al*. 2016). Several reasons have been proposed to explain this disparity in outcomes, but the differences in the composition of patient cohorts and the use of non-standardized definitions of lupus flare make comparison between studies difficult. Moreover, many complications common to pregnancy may be mistakenly attributed to SLE (Maksimova and Sidorova 1991; Wang *et al*. 2006).

Meanwhile, published data have identified several risk factors for poor pregnancy outcomes, including hypertension, anti-phospholipids syndrome, and SLE renal involvement (Buyon *et al*. 2015; Park *et al*. 2014; Tian *et al*. 2015; Ye *et al*. 2012; Zhan *et al*. 2017; Zhan *et al*. 2016). We therefore conducted a retrospective study based on a large number of patients during the last 10 years, from our single center which aims to examine the association of maternal and fetal complications and SLE, but also to identify the clinical and laboratory predictor's factors for adverse fetal and maternal outcomes of pregnancy women with SLE.

MATERIALS AND METHODS

This Retrospective study of SLE diagnosed patients among pregnant women, was approved byQilu Hospital of Shandong University Institutional Review Board (IRB).

Study Population and Data Collection: The data reported in this study were obtained from a reference hospital (Qilu Hospital) that performs at least 2,000 high risk deliveries each year and has an assistance protocol specifically designed for the care of pregnant women with SLE. Medical records of 122 patients from2011 to 2017 in Qilu Hospital were succinctly reviewed and classified accordingly to the inclusion and exclusion criteria. Subjects were considered eligible if they met the following criteria: (1)They met the 1997-Revised American College of Rheumatology (ACR) criteria for SLE(Hochberg 1997) and were followed up according to a specific protocol for the care of pregnant women with SLE(Knight and Nelson-Piercy 2017; Lateef and Petri 2013). (2) They have complete clinical and follow-up data including medical history (past obstetric history, duration of SLE, activity of the disease at conception, and SLE disease activity index (SLEDAI)(American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Response 2004; Romero-Diaz *et al*. 2011). However, pregnant women with previous history of co-morbidities diseases including personal or family histories of pre-eclampsia, multifocal gestation (twins and above), or certain medical conditions such as pulmonary hypertension, diabetes, advanced renal insufficiency, stroke, cardiac involvement, severe interstitial lung disease, andother viral forms were excluded from the study.We also excluded subjects with higher risk of hypertension (smoking habits) or other worrisome medical conditions including liver conditions, thyroid dysfunction or other autoimmune disorder (rheumatoid arthritis and systemic sclerosis). A total of 122 pregnancies with SLE diagnosed patients were included in this study for further analysis.

Population characteristics and Health outcomes: The baseline characteristics of the population were recorded to identify potential confounding factors. These factors included maternal age at delivery, gestational time of delivery, baby weight, clinical manifestations, laboratory findings, mode of delivery and pregnancy outcome. The primary outcome was pregnancy-specific adverse maternal or fetal outcome. Maternal outcomes included pre-eclampsia/eclampsia, lupus nephritis or encephalopathy, premature rupture of membranes (PROM) and Pregnancy-induced hypertension (PIH). Fetal outcomes included preterm birth (early onset of delivery, immaturity or birth before 37 weeks gestation), spontaneous abortion (unspecified abortion or intrauterine death), induced abortion, and ectopic pregnancy. The following definitions were used in this study.

Statistical analysis: Quantitative variables were reported as mean and standard deviation (SD).Absolute and relative frequencies wereused for categorical variables. The impact of clinical and laboratory characteristics on the outcomes was tested by univariate analysis using chi-square test. Statistical significance was seatP-value < 0.05. Logistic regression was used to assess the predictive value of each variable on binary outcomes taking into account the interaction or confounding effect of the other covariates. Odds ratio (OR) and 95% confidence intervals (95% CIs) were reported. All statistical analyses were performed with SPSS software, version 23 (SPSS Inc., Chicago, IL), using two-sided testing with a significance level at p-value of 0.05.

RESULTS

This study included 122 pregnant women with SLE who were monitored between 2011 and 2017 in Qilu Hospital. The baseline characteristics of the population are shown in the Table 1. Average maternal age of these 122 women was 29.15±3.99yearsand mean SLE duration was5.03±4.63 years. Of all deliveries, 66.4% (81) were by cesarean section and 51.6% (63) of pregnant women had at least 37gestational weeks of delivery. In addition, the mean average of baby weight was 2254.79±1114.51grams and there was significant difference between baby weight (≥ 2500 *vs*. <2500 grams) for pregnant women with SLE (P=0.010). While, pregnant women with SLE duration (<6 years) had mean baby weight of 2309.81±1088.82 grams and 2153.72±1166.47 grams was mean average of baby weight for pregnant women with SLE history (≥6 years). There were significant differences in pregnant women with SLE history (<6 years) between the baby weight (≥2500 *vs*.<2500 grams) (P=0.021) but no statistically significant between the baby weight (≥2500 *vs*. <2500 grams) (P=0.308) for pregnant women (≥6 years).

And regarding the predictive value of a 5-minute Apgar, no statistical differences in Apgar (≥ 7 *vs*. <7) were observed across the subgroup of women with SLE (<6 years, P=0.879) and (≥6 years, P=0.082). Meanwhile, statistical differences were observed for the number of babies transferred to neonatal for women with SLE (<6 years, P=0.002), but no statistically significant for women with SLE (≥6years, P=0.620). However, there were statistically differences in the total number of babies transferred to neonatal (Yes *vs*. No) for overall pregnant women with SLE (P=0.032). Of 122 pregnant women, 17.2 % (21), 14.8% (18) and 18.0% (22) have developed pre-eclampsia or eclampsia, lupus nephritis or encephalopathy and premature rupture of membranes (PROM) respectively. But, no statistically significant differences were observed within maternal outcomes (P=0.411). Moreover, there were 102(83.6%)live births and20(16.4%) pregnant loss. Of 102 live births, only 32.0% babies were preterm live births and no statistically significant differences were observed for the pregnant women with SLE (<6 and ≥6 years) (all P>0.05), as shown in the Table 1.

DISCUSSION

In this retrospective study, we explored relevant clinical factors affecting pregnant women with SLE. The data showed that there were statistically differences across various subgroups for pregnant women with different SLE duration (≥ 6 and < 6 years).

Maternal Outcomes	Definition
Pregnancy-induced hypertension (PIH)	Defined as an increase in blood pressure to ≥140/90mm Hg on at least two occasions, at least 6hours apart observed after the 20th week of pregnancy.
Pre-eclampsia	PIH with proteinuria >0.3g/L/day in the absence of a urinary tract infection or the abrupt onset of hypertension and proteinuria after 20 weeks of gestation. Seizures were required for a diagnosis of eclampsia.
Eclampsia	Generalized convulsions and/or coma in the setting of preeclampsia, and in the absence of other neurological conditions.
Premature rupture of membranes (PROM)	a rupture of the amniotic sac prior to the onset of lab our
Fetal Outcomes	
Live birth	the birth of a living child
Preterm birth	was defined as a live birth occurring before 37 weeks of gestation
Spontaneous abortion	Spontaneous loss of a fetus before 20 weeks gestation
Therapeutic abortion:	Termination of pregnancy for medical indications
Intrauterine fetal death (IUFD)	Intrauterine fetal demise at ≥20 weeks of gestation.
Stillbirths	as no signs of life in a fetus delivered after 24 weeks of gestation
Intrauterine growth restriction (IUGR)	Estimated birth weight less than 10th percentile for gestational age
Neonatal death	Death of a neonate before 28 days following birth
Fetal loss	defined as all pregnancies that did not end with a live birth including spontaneous abortions, therapeutic abortions, stillbirths or intrauterine fetal deaths

Table 1. Baseline characteristic of selected pregnant women with SLE

Variable	Number of years for patients with SLE		Number of years for patients with SLE		Total Patients	
	< 6 years n=79(64.75)	P-value	≥6 years n=43(35.25)	P-value	N=122 (%)	P-value
Age (Mean±SD) years	28.82±3.91	0.598	29.76±4.1	0.777	29.15±3.99	0.766
19-25	15(19.0)		6(14.0)		21(17.2)	
26-30	38(48.1)		22(51.2)		60(49.2)	
31-43	26(32.9)		15(34.9)		41(33.6)	
Delivery Mode		0.897		0.655		0.788
Cesarean Delivery	54(68.4)		27(62.8)		81(66.4)	
Natural Labor	3(3.8)		4(9.3)		7(5.7)	
Other indications	22(27.8)		12(27.9)		34(27.9)	
Gestation (weeks)		0.714		0.360		0.540
<28	8(10.1)		8(18.6)		16(13.1)	
28-36	30(38.0)		13(30.2)		43(35.2)	
>36	41(51.9)		22(51.2)		63(51.6)	
Baby weight (Mean±SD) grams	2309.81±1088.82	0.021	2153.72±1166.47	0.308	2254.79±1114.51	0.010
<2500 g	36(45.6)		17(39.0)		53(43.4)	
≥ 2500 g	43(54.4)		26(60.5)		69(56.6)	
Apgar 1,5 minute		0.879		0.082		0.203
<7	18(22.8)		10(23.3)		28(23.0)	
≥7	61(77.2)		33(76.7)		94(77.0)	
Transferred to Neonatal		0.002		0.620		0.032
No	60(75.9)		33(76.7)		93(76.2)	
Yes	19(24.1)		10(23.3)		29(23.8)	
Maternal outcomes		0.255		0.948		0.411
Pre-eclampsia or eclampsia	13(16.5)		8(18.6)		21(17.2)	
Lupus nephritis	10(12.7)		8(18.6)		18(14.8)	
PROM	15(19.0)		7(16.3)		22(18.0)	
Other indications	41(51.9)		20(46.5)		61(50.0)	
Pregnancy outcomes		0.470		0.066		0.439
Live Birth	68(86.1)		34(79.1)		102(83.6)	
Pregnancy loss	11(13.9)		9(20.9)		20(16.4)	
Term live births	41(51.9)		22(51.2)		63(51.6)	
Preterm live births	27(34.2)		12(27.9)		39(32.0)	

Pregnant women with SLE (<6 years) were most likely to show significant differences in the following subgroups-baby weight, baby transferred to neonatal care. In our study, the live birth rate among women with SLE was slightly higher (83.6%) and the preterm births rate was 32.0%, which is similar to that found in other studies ranging from 17-54%(Chakra arty *et al*. 2005; Zhan *et al*. 2017). The rate of miscarriages of 16.4% in our study was similar to that found in other studies,which have reported rates ranging from 8–24% inSLE patients (Cortes-Hernandez *et al*. 2002; Georgiou *et al*. 2000; Le Huong *et al*. 1997; Molad *et al*. 2005; Teh *et al*. 2009; Wong *et al*. 1991). Analogous to previous studies(Buyon *et al*. 2015; Choi *et al*. 2012; Hendawy *et al*. 2011; Ling *et al*. 2018; Moroni and Ponticelli 2016; Park *et al*. 2014; Zhan *et al*. 2017). The association of aCL antibodies and fetal loss has been well documented. The literature indicates that presence of these antibodies is associated with higher increased in pregnant loss compared with fetal loss in aCL-negative SLE patients(Clark *et al*. 2012; Cortes-Hernandez *et al*. 2002; Silveira *et al*. 1992). Our findings are similar to these reports, and by multivariate analysis we found aCL to be a strong

predictor of fetal loss. Moreover, our findings suggest that pregnant women with active SLE remain at a high risk of fetal loss as compared with their peers with inactive SLE, which is in agreement with previous studies(Buyon *et al*. 2015; Chakravarty *et al*. 2005; Georgiou *et al*. 2000; Knight and Nelson-Piercy 2017; Ku *et al*. 2016; Molad *et al*. 2005; Moroni and Ponticelli 2016). These findings were in accordance with previous studies (Billett 1994; Buyon *et al*. 2015; Chakravarty *et al*. 2005; Choi *et al*. 2012; Clark *et al*. 2012; Cortes-Hernandez *et al*. 2002; de Jesus *et al*. 2015; Hendawy *et al*. 2011; Knight and Nelson-Piercy 2017; Ling *et al*. 2018; McCrae *et al*. 2001; Molad *et al*. 2005; Petri and Allbritton 1993; Teh *et al*. 2009; Tian *et al*. 2015; Wong *et al*. 1991). Meanwhile, some previous studies (Clowse 2007; Ku *et al*. 2016; Ling *et al*. 2018) including the Hopkins Lupus Pregnancy Cohort did not find that the complement levels, hemoglobin levels and erythrocyte rate (ESR), as independent predictor of pregnancy loss, but the combination of low complement and high activity lupus was statistically linked with an increased risk of pregnancy loss(Clowse 2007). Furthermore, our study found that there were statistically significant differences in pair wise interactions between age group and SLE duration.These findings are in line with previous studies (Billett 1994; Buyon *et al*. 2015; Chakravarty *et al*. 2005; Clowse 2007; Cortes-Hernandez *et al*. 2002; Georgiou *et al*. 2000; Ku *et al*. 2016; McCrae *et al*. 2001).

Conclusion

The present study assessed the frequencies of adverse risk factors in pregnant women with SLE and identified the clinical factors predicting adverse fetal loss in Chinese women with SLE. However, it has some limitations, this is a retrospective-study conducted in a single institution, with limited sample size. Pregnancy in women with SLE is considered of high risk, and that risk is even higher in unplanned pregnancies with high disease activity and when the disease is diagnosed during pregnancy.

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