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A National Study of the Complications of Lupus in Pregnancy

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Abstract

Objective—To determine the risk of rare complications during pregnancy for women with systemic lupus erythematosus (SLE).

Study Design—Using the Nationwide Inpatient Sample from 2000 to 2003, we compared maternal and pregnancy complications for all pregnancy-related admissions for women with and without SLE.

Results—Out of over 16.7 million admissions for childbirth over the 4 years, 13,555 were to women with SLE. Maternal mortality was 20-fold higher among women with SLE. The risks for thrombosis, infection, thrombocytopenia, and transfusion were each 3–7-fold higher for women with SLE. Lupus patients also had a higher risk for cesarean sections (OR 1.7), preterm labor (OR 2.4), and preeclampsia (OR 3.0) than other women. Women with SLE were more likely to have other medical conditions, including diabetes, hypertension, and thrombophilia, that are associated with adverse pregnancy outcomes.

Conclusions—Women with SLE are at increased risk for serious medical and pregnancy complications during pregnancy.

Keywords

pregnancy; systemic lupus erythematosus; maternal mortality; preeclampsia

Introduction

As the treatment of systemic lupus erythematosus (SLE) improves, more women with this disease are able to become pregnant. Pregnancy outcomes have improved dramatically over

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This data was presented as an abstract at the Annual Scientific Conference of the American College of Rheumatology, November 10–14 2006, in Washington, DC. The abstract was selected for a press conference at this meeting and was published on Reuters and, therefore, included in newspapers world-wide.

Condensation

In a national database, pregnant women with lupus were at increased risk for death, thrombosis, infection, preterm birth, preeclampsia, and cesarean section.

the last 40 years, with the pregnancy loss rate falling from 43% in the 1960's to 17% by 2000. (1) The risks for maternal complications from SLE pregnancies, however, are not well documented. As each previously reported cohort has ranged from 25 to 265 pregnancies, reliable data for rare complications has not been available. Though lupus is no longer a contraindication to pregnancy, the extent of risk to a woman has been difficult to assess.

In this study, we have reviewed the Nationwide Inpatient Sample (NIS), a large database that includes detailed information on 20% of all hospitalizations throughout the United States. Using this database, we sought risk estimates for more rare, but potentially devastating, maternal complications, including thrombosis, infection, and maternal death.

Methods

The research protocol used in this study was reviewed and approved by the Duke University Medical Center Institutional Review Board. The Nationwide Inpatient Sample (NIS), from the Healthcare Cost and Utilization Project (HCUP) of the Agency for Healthcare Research and Quality (AHRQ) was queried for all pregnancy-related discharge codes for the years 2000–2003. The NIS contains data from approximately 1000 hospitals and is the largest all-payer inpatient care database in the U.S. It is a 20% stratified sample from a sampling frame that comprises 90% of all U.S. hospital discharges. Included in the sample are general hospitals and academic medical centers. (2–5) The hospitals are divided into strata based on ownership, bed size, teaching status, urban versus rural location and region. Sampling probabilities are proportional to the number of hospitals in each stratum.

The NIS has been used to analyze pregnancy outcomes by several investigators to identified risks for myocardial infarction, stroke, and thrombosis, as well as cesarean section rates. (4–8)

Information included in the NIS is what can be derived from a typical discharge abstract, with safeguards to protect the privacy of individual patients, physicians, and hospitals. These data include diagnoses and procedures; admission and discharge status; demographic information such as gender, age, race and median income for ZIP code; and hospital characteristics. Although the data are limited, the NIS is the most reliable source of data on hospital admissions and discharges. Reliability is supported by agreement between the NIS, a telephone survey and the National Health Interview Survey (a national, door-to-door survey). Invalid or inconsistent diagnostic codes are flagged. (2,3,5)

The pregnancy-related discharge records included in the sample from 2000–2003 were identified using the International Classification of Diseases Ninth Revision (ICD-9) and were classified as to whether they were an admission during pregnancy or postpartum. A pregnancy admission was defined as any discharge record with a pregnancy-related code (ICD-9 codes 630–648) or delivery code (ICD-9 codes 74 for cesarean delivery and 72, 73, 75, v27, or 650–659 for vaginal delivery). A postpartum admission was defined as any discharge record that included a postpartum diagnosis (ICD-9 codes 670–677) and did not also include a delivery code.

The ICD-9 code used for Systemic Lupus Erythematosus was 710.0. Women were identified as having a hypercoagulable condition using codes 286.5, 289.9, 795.79, 273.8, 286.9, 289.91. There is no designated ICD-9 code for antiphospholipid syndrome (APS), but we believe that women with this syndrome will be included in this hypercoagulable group. For other comorbidities and complications, both the ICD-9 code for a particular condition in pregnancy and the general ICD-9 code for that condition were utilized. If the pregnancy-related code was not specific, it was not utilized.

Data were analyzed based on the NIS sampling design, a multi-staged sampling frame consisting of three stages. The three stages are strata (geographic region, urban versus rural location, teaching status, type of ownership and bed size), hospitals within the strata, and individual discharges weighted by population counts and controlled for missing data. STATA 9.0 (Stata Corp LP, College Station, TX) with its SVY (survey data) commands utilizing these three stages were used for all analyses, both descriptive and inferential. Two-way chi square analyses were performed, accounting for the complex survey design of the NIS. The two-way weighted chi square analyses yielded cell frequencies and their proportions. Logistic regression analyses were used to compute odds ratios with 95% confidence intervals for medical conditions and obstetric complications. Logistic regression models adjusted for age for co-morbidities, pregnancy complications and medical computations yield new adjusted odds ratios with 95% confidence intervals.

Results

There were over 16.7 million deliveries between 2000 and 2003, 13,555 of which were to women with a diagnosis of systemic lupus erythematosus (SLE). These pregnancies resulted in 18.3 million pregnancy-related hospitalizations, 17,263 of which were to women with a diagnosis of SLE.

The demographic make-up of the SLE pregnancies was different from the non-SLE pregnant population. (Table I) Women with SLE were, on average, older than women without SLE. A larger proportion of SLE pregnancies were to African-American women, consistent with the demographic distribution of this disease. According to this database, 0.08% of Caucasian deliveries, 0.12% of African-American deliveries, and 0.06% of Hispanic deliveries were to women with SLE.

The modifiable life-style risk factors for poor pregnancy outcome were not statistically different for women with SLE. (Table I) A similar proportion of women with SLE were reported to be obese, smoked tobacco, or abused alcohol or drugs during pregnancy, compared to the non-SLE population. These risk factors were rare, with only 3% of women smoking during pregnancy.

Women with SLE have more co-morbid conditions that place their pregnancies at higher risk than other women. (See Table II) Diabetes mellitus and hypertension diagnosed prior to pregnancy were both more common among women with SLE, however when adjusted for maternal age, the OR for pre-gestational diabetes was no longer statistically significant for SLE and non-SLE populations (OR 1.1, CI 0.9–1.3). Pulmonary hypertension and renal failure, both signs of advanced connective tissue disease and relative contraindications to pregnancy, were rare, but more common among women with SLE. After adjusting for the older maternal age among women with SLE, the OR of pulmonary hypertension (OR 2.6, CI 1.7–3.6) and renal failure (OR 3.7 CI 2.8–4.6) remained elevated, though not as high as when unadjusted. Thrombophilia, diagnosed in this study by using a broad spectrum of ICD-9 codes that included women with antiphospholipid syndrome and other hypercoagulable states, more frequently complicated SLE pregnancies. Thrombophilia remained elevated (OR 20.9, CI 13.5–32.4) when adjusted for the older age of women with SLE.

Pregnancy Complications

Women with SLE had a 2 to 4-fold increased rate of pregnancy complications than the non-SLE population. (See Table III) Over one-third of women with SLE had a cesarean section and one-fifth were admitted with preterm labor. Preeclampsia was diagnosed in 22.5% of women with SLE. When adjusted for the increased maternal age of the women with SLE,

the risks for preeclampsia, preterm labor, and IUGR remained unchanged. Intrauterine or fetal growth restriction occurred in 5.6% of SLE pregnancies, but the database did not contain the birth weight, so we cannot comment on the frequency of small for gestational age infants.

Medical Complications

Women with SLE also had more medical complications during pregnancy than healthy women. (See Table IV) The risk of maternal death (325/100,000 live births) was over 20-fold higher than the non-SLE population. The actual rate of death was 0.32% among all SLE pregnancies, which averages to about 11 maternal deaths per year in the United States. When adjusted for 11 maternal age, the risk of maternal death remained markedly elevated for women with SLE (OR 17.8, CI 7.2–44).

The risk for sepsis and pneumonia was several-fold higher among women with SLE, though the absolute risk of infection remained low. Postpartum infections occurred slightly more commonly among women with SLE (OR 1.4, $p<0.001$).

Hematologic complications are common among lupus patients, and so not surprisingly among lupus pregnancies. Anemia was diagnosed in over 12% of SLE pregnancies at the time of delivery. Thrombocytopenia, a common manifestation of lupus, was identified 8-times as often as in non-SLE pregnancies. These hematologic abnormalities, perhaps, combined to increase the risk for transfusion 3-fold among women with SLE. Interestingly, the rate of postpartum hemorrhage was only slightly higher than in the remainder of the population (OR 1.2, $p<0.001$).

The risk for venous thromboembolism was 5 to 8-fold higher and the risk of stroke was 6.5-fold higher for women with SLE compared to other women. Even when adjusted for the older age of women with SLE, the risk for thrombosis (DVT, PE, or CVA) remained over 10-fold higher for women with SLE.

Discussion

When compared to other women, SLE patients are at increased risk for maternal death, preeclampsia, preterm labor, thrombosis, infection, and hematologic complications during pregnancy. These elevated risks make clear the need for close monitoring by both maternal-fetal medicine physicians and rheumatologists during pregnancy.

Women with SLE in the NIS cohort had several demographic and medical risk factors for adverse pregnancy outcomes, beyond the diagnosis of SLE. Women with SLE were older and more were African-American compared to the non-SLE population. As would be expected given the natural history of SLE, women with this disease had a higher incidence of co-morbid conditions, including diabetes, hypertension, pulmonary hypertension, and renal failure. (9) Treatment with corticosteroids during pregnancy can increase the risk for diabetes and hypertension. Pulmonary hypertension and renal failure are both life-threatening complications of severe SLE. (10) Many would consider both conditions relative contraindications to pregnancy; the low number of pregnancies is evidence that this message is reaching these women.

Reliable maternal mortality rates for women with SLE have not been previously available. In the Hopkins Lupus Cohort, 3 maternal deaths occurred in 265 pregnancies, leading to a rate of 1100 per 100,000 births. (11) This cohort is from a quaternary care referral center and would be expected to include women at higher risk of death than the general SLE population. In the NIS, we found that the maternal mortality rate of 325 per 100,000 live

births (0.325%) to women with SLE is over 20-fold higher than the mortality rate for the non-SLE population. This statistic is alarming and should heighten the level of vigilance that we use for SLE pregnancies. However, the rate is not surprising given the annual mortality rate for women with SLE. Among studies published since 1995, the annual mortality rate for non-pregnant SLE patients range between 790 and 3208 deaths per 100,000 patient-years (0.79–3.2%). (12–16) Though it is not ideal to compare mortality rates between different types of studies, the maternal mortality rate found in this study is at least several folds lower than expected in the non-pregnant SLE patient.

Non-pregnant women with SLE are at increased risk for venous and arterial thrombosis with an estimated 2% having a thrombotic event during each year of disease. (17–19) Pregnancy also increases the risk of thrombosis by about 3 fold, even in otherwise healthy women. In this study, however, we found that the risk for thrombosis increased even further among women with SLE, by 10-fold when adjusted for maternal age. This led to 1.7% of SLE pregnancies having a thrombotic complication. Given this elevated risk, women with SLE who complain of possible thrombotic symptoms should be evaluated carefully. In addition, further thrombotic risk factors, such as thrombophilia (in particular antiphospholipid antibodies), hypertension, tobacco use, and immobility should be addressed prophylactically in women with SLE during pregnancy.

Women with SLE are at increased risk for infection due to both disease-related immune dysregulation and immunosuppressive therapy. This is reflected in the increased risk for pneumonia and sepsis found in this study. In a prospective cohort of SLE patients, sepsis occurred in 0.24 of every 100 patient years and pulmonary infection 1.4/100 patient years. (20) The frequency of sepsis and pneumonia found in this pregnancy study is similar to that expected in non-pregnant SLE patients.

Prior cohort studies have demonstrated increased rates of pregnancy complications in women with SLE, but this is the largest to date to describe the risk for cesarean birth, preterm labor, and preeclampsia. The NIS database does not, however, include data on the gestational age at birth or birth weight. Data on early fetal loss that was managed as an outpatient is also not included in the database.

This study confirms prior reports of cesarean section rates, with over one third of pregnancies delivered surgically. Prior reports of SLE pregnancies found similar percentages of cesarean deliveries: 38.2% in a population based study in California in 1993–4, and between 26–38% in tertiary care center cohorts. (21–23)

Though 20.8% of SLE pregnancies in this cohort had a diagnosis of preterm labor at the time of childbirth, this is not an accurate estimate of the rate of preterm birth. Women with premature rupture of membranes, pharmacologically induced labor, or a cesarean section for medical indications may deliver prematurely, but without preterm labor. In a literature review of SLE pregnancy cohorts, one third of all SLE pregnancies were delivered preterm. (1) Risk factors associated with preterm birth in these cohorts include increased SLE activity prior to and during pregnancy, preeclampsia and hypertension, use of prednisone, and low complement. (11,24)

This study confirms that preeclampsia is a significant problem in SLE pregnancies. We included ICD-9 codes for hypertension in pregnancy, mild and severe preeclampsia in this category. Distinguishing between preeclampsia and lupus nephritis (proteinuria, active urine sediment, and hypertension) can be difficult and sometimes impossible. The distinction is important clinically as the treatment for preeclampsia (delivery) and lupus nephritis (immunosuppression) are different. We expect that some patients labeled as having preeclampsia in this study actually had lupus nephritis. Even with this bias, it is still notable

that one fifth of pregnancies are complicated by significant hypertension or preeclampsia. In prior SLE cohorts, 2.7 to 30% of pregnancies were complicated by preeclampsia, a rate up to 5.7-fold higher than expected. (23–25)

The main strength of this study lies in the size of the Nationwide Inpatient Sample (NIS) cohort. The NIS reflects a 20% stratified sample from a sampling frame that comprises 90% of all hospitalizations in the United States and has been demonstrated to be representative of all pregnancies. Prior studies of SLE pregnancies have relied on cohorts of pregnancies collected at single institutions; the largest study included 265 pregnancies. (11) The small size of prior SLE pregnancy cohorts precluded the assessment of rare complications such as maternal death. Prior studies were based in referral centers and administered by rheumatologists with special interest and expertise in SLE pregnancies, and were therefore biased towards the sickest SLE patients. The NIS cohort represents women admitted to all types of hospitals, collecting data on women with all severities of SLE. This makes the NIS lupus cohort more representative of the lupus patients seen by community obstetricians.

Because of the large size of this dataset, we were able to perform a multivariate analysis using maternal age. Unfortunately, data on race is not available for 29% of the pregnancies, as several states did not report this, precluding inclusion of race in the multivariate analysis. After adjusting for age, the OR for pregnancy complications did not change. However, several comorbid illnesses, including pre-gestational diabetes, renal failure, and pulmonary hypertension, appear to be highly dependent on maternal age.

The primary drawback to this study is the inability to confirm the SLE diagnoses included in the NIS. We selected 710.0, the ICD-9 code for systemic lupus erythematosus, because it is the most precise code available for this condition. We suspect that some women with a positive ANA, but not meeting the American College of Rheumatology criteria for SLE, were included in this cohort. However, by virtue of the fact that the diagnosis was included in the discharge paperwork, the SLE generally must have been sufficiently symptomatic to warrant mention.

The Nationwide Inpatient Sample does not include the gestational age at delivery nor data about the infant, such as APGAR scores, birth weight, newborn intensive care unit admission, or congenital abnormalities. The data are de-identified and do not allow for matching of women to infants. Therefore, we are unable to comment on the rate of preterm birth, low birth weight, or other complications in the infant.

Because of the nature of the database, sequential hospital admissions for the same woman cannot be linked together. Undoubtedly, some women had multiple admissions during their pregnancy, and these admissions are counted separately. Similarly, some medical complications that occur during pregnancy (i.e. an infection) may not be recorded at the time of hospitalization for childbirth. We have taken this into account by including all hospital admissions associated with pregnancy when counting the medical complications (events) included in Table IV. The comorbid conditions listed in Table II, which typically continue throughout pregnancy, were only counted at the time of delivery to avoid recounting these persistent conditions.

This is the largest study to date of SLE pregnancies and provides a nationwide assessment of pregnancy complications. This study demonstrates that the majority of women with SLE can have a successful pregnancy. However, as has previously been reported, pregnancy can be risky for women with SLE, resulting in more cesarean births, preeclampsia, infections, thromboses, and maternal deaths than pregnancy in other women. We also found that medical complications, including thrombosis, infection, and hematologic abnormalities are more common for patients with SLE. When compared to risks endured by non-pregnant

SLE patients, however, the risks during pregnancy are not elevated. This comparison demonstrates that, though pregnancy can pose a risk to a woman with SLE, this risk may not be higher than any other year of this woman's life.

Prior cohort studies have identified risk factors, such as increased lupus activity prior to and during pregnancy, lupus nephritis, and hypertension, that place a woman with SLE and her pregnancy at particularly high risk. Further large-scale cohorts are required to stratify the risk for rare events based on these factors in order to provide more individualized counseling to SLE patients contemplating pregnancy.

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Table I

Demographics and modifiable risk factors

Demographic and Risk Factors	SLE pregnancies	Non-SLE pregnancies	P-value
Mean Age	30.0	27.5	<0.001
Age at delivery ≥ 35	21.2%	4.2%	<0.001
Ethnicity			
Caucasian	55%	53%	0.05
African-American	20%	14%	<0.001
Hispanic	17%	23%	<0.001
Other	8%	10%	<0.001
Obesity	1.2%	1%	0.39
Tobacco Use	2.9%	2.9%	0.97
Alcohol & Substance Abuse	0.8%	1%	0.30

Table II

Co-morbid illnesses in women with SLE

Co-morbid illness	Percentage of SLE deliveries with the condition	Percentage of non-SLE deliveries with the condition	Odds Ratio	95% CI	p-value
Pre-gestational diabetes	5.6%	4.2%	1.7	1.2–2.2	<0.001
Hypertension	3.9%	0.7%	5.5	4.5–6.8	<0.001
Pulmonary hypertension	0.2%	0.01%	10.9	3.9–30.0	<0.001
Renal Failure	0.2%	0.002%	36.9	25.0–52.3	<0.001
Thrombophilia	4.0%	0.04%	34.7	27.7–43.4	<0.001

Table III

Pregnancy complications in SLE pregnancies

Pregnancy Complication	Percentage of SLE deliveries with the complication	Percentage of non-SLE deliveries with the complication	Odds Ratio	95% CI	p-value
Cesarean section	36.6%	25.0%	1.7	1.6–1.9	<0.001
Preterm labor [/]	20.8%	8.1%	2.4	2.1–2.6	<0.001
Intrauterine (fetal) growth restriction	5.6%	1.5%	2.6	2.2–3.1	<0.001
Preeclampsia	22.5%	7.6%	3.0	2.7–3.3	<0.001
Eclampsia	0.5%	0.09%	4.4	2.7–7.2	<0.001

[/] Preterm labor indicates women admitted for preterm labor, but is not an accurate proxy for preterm birth.

Table IV

Medical complications in SLE pregnancies

Medical Complication	Percentage of SLE pregnancies with the complication	Percentage of non-SLE pregnancies with the complication	Odds Ratio	95% CI	p-value
Thrombotic Complications					
Stroke	0.32%	0.03%	6.5	2.8 to 10.3	<0.001
Pulmonary Embolus	0.4%	0.04%	5.5	2.8 to 10.8	<0.001
DVT	1.0%	0.01%	7.9	5.0 to 12.6	<0.001
Infectious Complications					
Sepsis	0.5%	0.1%	3.5	2.0 to 6.0	<0.001
Pneumonia	1.7%	0.2%	4.3	3.1 to 5.9	<0.001
Henatologic Complications					
Transfusion	2.7%	0.5%	3.6	2.8 to 4.2	<0.001
Postpartum hemorrhage	4.5%	3.3%	1.2	1.0 to 1.5	0.01
Antepartum bleeding	2.0%	0.4%	1.8	1.3 to 2.4	<0.001
Anemia at delivery	12.6%	6.8%	1.9	1.7 to 2.2	<0.001
Thrombocytopenia	4.3%	0.4%	8.3	6.8 to 10.1	<0.001