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Original Research Article

Maternal and fetal outcomes in pregnant patients with lupus nephritis

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ABSTRACT

Background: Pregnancy in a woman with lupus nephritis (LN) carries a high risk of maternal and fetal morbidity and mortality. This study aims to analyze the effect of LN on maternal and fetal outcomes and lupus activity.
Methods: In a single-center, cross-sectional observational study at national hospital Kandy, 32 pregnancies in 23 women with biopsy-proven LN between 2007 and 2019 were analyzed retrospectively.
Results: Mean age at pregnancy was 28.4 years (SD=4.8, range 19–38 years). In six women, LN developed during pregnancy, 17 patients were already diagnosed with LN when they became pregnant. A renal biopsy performed 4.6 (SD=3.8) years before pregnancy, showed diffuse LN in 18 (78.3%) and focal LN in 5 (21.7%) cases. At conception, most patients were in complete (43.8%) or partial (21.9%) remission. Therapeutic abortion was performed in 8 pregnancies (indications: renal flares in 5, pre-eclampsia in 3) at a mean period of amenorrhea (POA) of 16.8 weeks (range 8-28 weeks). Spontaneous fetal loss occurred in one pregnancy. Among 23 live births, there were four pre-term deliveries (<36 weeks gestation) and 19 term deliveries. In term deliveries mean birth weight was 2.62 kg (SD=0.5) and in pre-term babies, it was 1.85 kg. Sixteen caesarian sections were performed in term deliveries, three as emergencies. All the pre-term babies were delivered by emergency caesarian sections. There was no statistically significant relationship ($p>0.05$) between LN histological type, initial clinical presentation and treated hypertension with fetal outcome. No case of neonatal lupus or congenital heart block was noted. During pregnancy, there were five (15.6%) renal flares and two acute kidney injury cases; all were reversible. Eight patients (25%) developed PIH
Conclusions: Pregnancy induced hypertension is a more commonly encountered complication in pregnancies with lupus nephritis. The fetal outcome is unfavorable in pregnancies with renal flares.

Keywords: Lupus nephritis, Pregnancy, Maternal outcomes, Fetal outcomes, Sri Lanka

INTRODUCTION

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease associated with multi-system inflammation resulting from abnormal immunological functions.[1] The disease is diagnosed in approximately 20 to 150 persons per 100,000 in the United State of America. According to the results of previous studies conducted worldwide, ninety percent of the SLE patients are women and the condition is more severe among patients of black African or of Asian descent.[2] Complications of SLE are diverse and associated with many organ systems of the human body. The common complications include; musculoskeletal, cutaneous, renal, neuropsychiatric, pulmonary, cardiac, hematological, and gastrointestinal complications.[1,2]

About 50% of SLE patients develop lupus nephritis (LN) and it is associated with significant morbidity and mortality.[2,3] It commonly affects women in their

reproductive age. Even though the pregnancy in these patients is usually possible and women report fertile, SLE affects the outcome of pregnancy. A study conducted in Taiwan has shown a significant relationship between adverse pregnancy outcomes and pregnant women with SLE.[4] At the same time, a meta-analysis done in Ireland has reported premature births and maternal hypertension in SLE patients.[5] As a summary, previous researchers have identified that lupus pregnancies are associated with outcomes such as intrauterine growth restriction, prematurity, and occasionally neonatal lupus.[6] Several risk factors have been identified for poor prognosis. Hypertension, antiphospholipid syndrome (APS), lupus activity, the grade of proteinuria, a previous adverse pregnancy outcome, hyperprolactinemia, and renal involvement are some of those.[7-10]

However, a study conducted at the University of Western Ontario in Canada has concluded that careful planning of pregnancy coupled with multidisciplinary monitoring and treatment leads to better outcomes.[11] The level of the prognosis depends on the health care systems and the treatment modalities of a particular country. To provide quality care to these SLE patients, it is very important to study them and identify complications.

Even though several studies have been conducted worldwide, up to date, to the best of our knowledge there are no published research data in Sri Lanka on this area. Through this study, we intended to study the effects of LN on maternal and fetal complications. Furthermore, risk factors related to poor outcomes and lupus activity were studied through an interviewer-administered structured questionnaire. Undoubtedly, the results of this study will be beneficial for the entire nephrology team to provide quality care to patients with lupus nephritis.

METHODS

This was a retrospective cross-sectional, observational study in which we collected data on 32 pregnancies in 23 patients with biopsy-proven lupus nephritis attending the nephrology clinic, National hospital Kandy, Sri Lanka. They conceived from January 2007 to June 2019. All patients fulfilled criteria for the diagnosis of systemic lupus erythematosus, at least 4 of the 11 criteria of the American College of Rheumatology (ACR) and at least 4 criteria, with at least one clinical criterion and one immunologic criterion of systemic lupus international collaborating clinic (SLICC) diagnostic criteria. Clinical remission was diagnosed according to systemic lupus erythematosus disease activity index (SLEDAI).

Demographic and clinical profile data collected included age, family history of SLE, smoking history, alcohol usage, past medical history, gravidity, parity, age at SLE diagnosis, clinical features at first presentation, key organ manifestations, pre-and post-natal immunosuppressive history, and laboratory data. Investigations obtained were full blood count, renal function tests, antinuclear antibodies, anti-double-stranded DNA (dsDNA) antibodies, serum albumin, urine analysis, and renal biopsy.

Maternal outcomes were noted as pregnancy-induced hypertension (PIH) (defined as new-onset hypertension after 20 weeks of gestation), pre-eclampsia (defined as new-onset hypertension with proteinuria and edema after 20 weeks of gestation) and eclampsia (pre-eclampsia with convulsions), SLE disease flare (defined as worsening of clinical and/or serological parameters or new-onset clinical manifestations requiring escalating or adding immunosuppressive treatment), pre-term delivery (birth at a gestational age of <36 weeks), term delivery (birth at a gestational age of >36 weeks), spontaneous abortion (a miscarriage in which the fetus is born <20 weeks of gestation), and therapeutic abortion (abortion induced when the continuation of pregnancy cause mental and physical harm to the mother), acute kidney injury and requirement of renal replacement therapy (RRT). PIH, pre-eclampsia, and eclampsia were diagnosed by the referred obstetrician. Fetal outcomes included birth weight (normal or low birth weight (<2.5 kg)), stillbirth (baby born dead), neonatal death (neonate dies within 28 days after delivery), neonatal lupus, and congenital heart disease.

Each pregnancy was considered as a separate observation. All statistical data were analyzed using appropriate tests. Pearson's Chi-square test is used to assess the association of different study parameters. Continuous variables were analyzed using mean±standard deviation. A p-value of <0.05 was considered statistically significant and a p value <0.01 was considered very significant. Statistical package for the social sciences (SPSS) 23 (trial version) software was used for data analysis.

RESULTS

Demographic profile of the patients

We analyzed 32 pregnancies in 23 patients with LN. Only one patient had a family history of SLE, in her younger sister. None of the patients smoked or consumed alcohol. Three patients had hypertension and two patients had diabetes mellitus by the time they were diagnosed as LN. The mean age at SLE diagnosis was 25.4 years (SD=5.2). The mean age at pregnancy was 28.4 years (SD=4.8, range 19–38 years). In six women, LN was diagnosed during pregnancy, 17 patients were already diagnosed with LN when they became pregnant (3 pregnancies in 1 patient, 2 pregnancies in 7, and single pregnancy in 9 patients). Fifteen (46.9%) were primigravida, and 17 (53.1%) were multigravida. At conception most patients were in complete; 14 (43.8%) pregnancies or partial remission; 7 (21.9%) pregnancies. In 11 (34.4%) pregnancies the disease was active.

Common initial clinical presentations were body swelling/edema (73.9%) and frothy urine (69.6%), followed by joint pain/myalgia (65.2%), alopecia (65.2%),

body rash (60.9%), oral ulcer (47.8%), fever (39.1%), exertional dyspnea (39.1%) hematuria (8.7%) and seizure episodes (8.7%) (Table 1).

Anemia (hemoglobin <12 g/dl) was a noteworthy finding in 19 (82.6%) patients with the mean hemoglobin value of 9.5 g/dl (SD=2). Thrombocytopenia (<150 × 109/l) was seen among 4 (17.4%) patients. Six (26%) patients had high serum creatinine (>130 umol/l).

Table 1: Clinical manifestations of initial presentation.

Clinical manifestation	Number of patients (%)
Body swelling	17 (73.9)
Frothy urine	16 (69.6)
Joint pain	15 (65.2)
Alopecia	15 (65.2)
Body rash	14 (60.9)
Oral ulcers	11 (47.8)
Fever	9 (39.1)
Exertional dyspnea	9 (39.1)
Hematuria	2 (8.7)
Seizure	2 (8.7)

ANA reports were available in 17 patients and were positive in 13 and negative in 4 patients. Of 8 patients with Ds DNA tested, 7 patients tested positive and 1 patient tested negative. Renal biopsy was performed 4.6 (SD=3.8) years before pregnancy. Diffuse LN (class IV) was the commonest histological pattern accounting for 18 (78.3%) cases. This was followed by focal LN (class III) present in 5 (21.7%).

Maternal and fetal outcomes

Therapeutic abortion was performed in 8 pregnancies. Indications for therapeutic abortions were renal flares in 5 pregnancies and pre-eclampsia in 3 pregnancies, at a mean period of amenorrhea (POA) of 16.8 weeks (range 8-28 weeks). Partial remission of LN was associated with pre-eclampsia (p=0.03). There was one spontaneous fetal loss in a patient who was diagnosed with LN during pregnancy. She developed pre-eclampsia.

Among 23 live births, there were four pre-term deliveries due to PIH and 19 term deliveries. Mean gestational age at delivery was 35.6 weeks (SD=3.4). In term deliveries mean birth weight of the babies was 2.62 kg (SD=0.5) and in pre-term babies, it was 1.85 kg.

There were nine low birth weight babies. Lower section caesarean sections (LSCS) were performed in 16 term deliveries, three as an emergency. All the pre-term babies were delivered by emergency caesarean sections. There was no statistically significant relationship (p>0.05) between LN histological type, initial clinical presentation, and fetal outcome. No case of neonatal lupus or congenital heart block was noted. During pregnancy, there were five (15.6%) renal flares and two acute kidney injury cases; all were reversible. Eight patients (25%) developed PIH.

All patients were on oral prednisolone and hydroxychloroquine during pre and postnatal period. Pre and post-natal prednisolone dose was less than 10mg/day in patients who had complete and partial remission (21 patients) at conception. Among active LN patients, six patients received intravenous methylprednisolone (500 mg/day for 2 or 3 days), while in others oral prednisolone dose was increased to 1 mg/kg/day and gradually tailed off. Fixed-dose hydroxychloroquine 200 mg/day was continued pre and postnatally. There were 13 patients with 21 pregnancies on azathioprine 50-100 mg/day which continued pre and postnatally.

Five patients received intravenous cyclophosphamide (750 mg/1.73 m^2) 6 doses (first two doses 2 weeks apart and 4 doses monthly) following therapeutic abortion as the remission induction treatment. Four patients were on mycophenolate mofetil when conceiving, and those were changed to azathioprine.

Table 2: Maternal and fetal outcomes.

Pregnancy out come	Value
Mean gestational age at live birth delivery (weeks)	35.6±3.4
Live births	23
Term delivery	19
Pre-term delivery	4
Mean gestation age at abortion (weeks)	16.8±3.2
Therapeutic abortion	8
Spontaneous abortion	1
Method of term delivery	
Normal vaginal delivery	3
LSCS	16
Method of pre-term delivery	
LSCS	4
PIH	8
Pre-eclampsia	4
Eclampsia	0
Renal flare	5
Acute kidney injury	2
Birth weight	
Low birth weight	9
Normal birth weight	14
Average birth weight (kg)	
Term baby	2.62±0.5
Pre-term baby	1.85±0.1
Neonatal lupus	0
Congenital heart block	0

DISCUSSION

In our study, we retrospectively analyzed thirty-two pregnancies in twenty-three patients with biopsy-proven LN. There was only one spontaneous abortion (3.1%). When comparing to the other studies; Ahmed et al had

10% and Eman et al had 15%, which shows much higher incidence than ours.[12,13] In the study, Morani et al have demonstrated an 8.4% percentage of spontaneous abortion, which is also higher than our study (Table 3).[14] However, eight therapeutic abortions were performed in our study due to LN renal flares in five and pre-eclampsia in three patients. This might be a contributor to have fewer incidences of spontaneous abortions. If considering both spontaneous and therapeutic abortions, the percentage is 28.1%, which is at the upper level of previously reported abortion incidence; ranging 4%-28%.[12-15] Another important remark was all pregnancies that developed pre-eclampsia (n=4) ended up with either spontaneous or therapeutic abortions, and partial remission of LN was associated with pre-eclampsia (p=0.03).

The preterm delivery rate in our cohort was 17.4% (n=4), all due to the development of PIH. All pre-term babies were delivered by LSCS. The incidence is much high compared to that of other studies showed; 5% in Ahmed et al and 13% in Eman et al. However, Morani et al and Day et al demonstrated much higher rates of pre-term deliveries in their cohorts, 28.2% and 31% respectively (Table 3).[16] The main precipitants for preterm delivery in other studies were pre-eclampsia and deterioration of renal functions.[12,16,17]

Table 3: Comparison of maternal and fetal outcomes.

Study	Spontaneous abortions (%)	Pre-term delivery (%)	Low birth weight (%)	Neonatal lupus (n)	Congenital heart lesions (n)
Present study	3.1	17.4	39.1	0	0
Ahmed et al	10	5	26	0	0
Eman et al	15	13	22	1	0
Morani et al	8.4	28.2	-	-	-
Day et al	13	31	34	-	-

Among twenty-three live births, nine (39.1%) reported low birth weight with a mean birth weight of 2.62 kg (±0.5) in term babies and 1.85 kg (±0.1) in pre-term babies. Several studies showed fewer incidences of low birth weight babies than our study; Ahmed et al 26%, Eman et al 22%, and Day et al 34%. However, there is still uncertainty about the exact reason for having higher rates of low birth weight babies in our cohort.

There was no statistically significant relationship (p>0.05) between LN histological type, initial clinical presentation, and fetal outcome. There were no reported cases of neonatal lupus or congenital heart block.

Eight pregnancies developed pregnancy-induced hypertension, four developed pre-eclampsia, and no one developed eclampsia. According to the literature, pre-eclampsia is more frequent in patients with SLE than in the general population. The risk escalates if the patient has pre-existing high blood pressure, chronic renal failure, and active LN and antiphospholipid syndrome.[18] Gladman et al have observed that PIH incidence is different between pregnancies with renal disease and without renal disease; the rate is much higher in pregnant women with renal disease. But the frequency of having pre-eclampsia is much similar in both groups with and without the renal disease.[19]

Five pregnancies (15.6%) complicated with renal flare ended up with therapeutic abortions. Even though some studies demonstrate there is no increment of flare rate during pregnancy, some have noted a significant increment of lupus flares during pregnancy.[20-22] Petri et al in their cohort, have prospectively studied forty pregnancies in thirty-seven SLE patients. They have noted twenty-four (60%) flares during the pregnancy, which is much higher compared to our study. However, flares occurred commonly as constitutional clinical features, renal flares and, skin and joint involvement. And also with their observations, they have concluded that lupus flare during pregnancy is common compared to non-pregnant SLE and even in the same patient after delivery. Another study revealed lupus flares were more frequent in patients with renal disease.[19]

Lupus clinical activity status during pregnancy is a risk factor for developing maternal as well as fetal complications, and it is of the greatest challenges will a Nephrologist face on management point of view as they need to weigh both maternal and fetal wellbeing. Sometimes they need to make difficult decisions like therapeutic abortions to save the mother's life and to prevent developing further adverse complications. It is imperative to manage the patient with the best treatment option to control LN and maintain disease remission during pregnancy and after delivery. In our study, the majority was either complete (43.8%) or partial remission (21.9%). There were eleven (34.4%) patients who had active disease. Patients with complete and partial remission continued prednisolone (dose <10 mg/day), hydroxychloroquine (200 mg/day) and azathioprine (50-100 mg/day) during pregnancy and postpartum. Among patients with active lupus, only five patients required intravenous cyclophosphamide therapy for their remission induction following therapeutic abortion. No one was given teratogenic drugs during pregnancy which possibly resulted in zero fetal malformations.

Main objectives in managing a pregnant woman with LN are to achieve disease remission and remission maintenance, adequate prophylactic treatments against

anti-phospholipid-related thrombotic complications, manage hypertension and pre-eclampsia, and also counsel and prepare the patient for a planned pregnancy. Hydroxychloroquine therapy is safe and efficient in reducing flares, fetal distress, and intrauterine growth retardation. It can be continued during breastfeeding as well.[18,23,24] As prophylactic treatment for anti-phospholipid related thrombotic complications, aspirin (low/moderate dose) and low molecular weight heparin (low or therapeutic dose) can be used. Teratogenic drugs like mycophenolate mofetil, cyclophosphamide, and methotrexate need to be avoided during pregnancy. It is safe to administer azathioprine, low dose cyclosporine, and low dose prednisolone.[25] Anti-hypertensive drugs like angiotensin-converting enzyme inhibitors and angiotensin receptor blockers should not be prescribed.[25,26]

In summary, our study demonstrates that patients can have successful pregnancies even with pre-existing lupus nephritis, as one patient achieved three successful pregnancies and seven patients achieved two successful pregnancies each following the diagnosis of LN. However, it should be a planned pregnancy to have a healthier child and a better maternal outcome. Pregnancy needs to be managed by a multi-disciplinary team including a nephrologist, rheumatologist, obstetrician, and neonatologist.

CONCLUSION

Although pregnancy is not contraindicated in lupus nephritis patients, it is associated with multiple maternal and fetal complications such as spontaneous and therapeutic abortions, pre-term delivery, low birth weight babies, pregnancy-induced hypertension, pre-eclampsia, disease flares, deterioration of renal functions, neonatal lupus and congenital cardiac problems. Therefore, pregnancies in lupus nephritis women need proper counseling, timely planning, adequate preparation, careful monitoring and follow-up and delivery needs to be managed in a facilitated unit. Complete remission before conception results in favorable maternal and fetal outcomes.

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