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Pregnancy Outcomes in Systemic Lupus Erythematosus: A Prospective Cohort of Two Hundred and Twelve Pregnancies: Hydroxychloroquine Adherence, Flare Patterns, and Maternal-Foetal Outcomes

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Abstract*-- Pregnancy in systemic lupus erythematosus (SLE) carries elevated maternal and foetal risks including disease flare, pre-eclampsia, preterm birth, small-for-gestational-age delivery, and foetal loss. Hydroxychloroquine (HCQ) is the single intervention with the strongest evidence for improving SLE pregnancy outcomes, with current international guidelines recommending continuation throughout pregnancy. We undertook a prospective cohort study of 212 SLE pregnancies reaching 12 weeks gestation at a tertiary obstetric medicine service. HCQ adherence stratification identified high adherence in 112 (52.8%), moderate in 58 (27.4%), and low or discontinued in 42 (19.8%). Flare-free pregnancy survival differed substantially: approximately 70% of high-adherence patients remained flare-free through 40 weeks compared with 32% of low-adherence patients. Adverse pregnancy outcomes (preterm birth, SGA, pre-eclampsia, NICU admission) all showed strong gradients across HCQ adherence strata. Strongest predictors of adverse pregnancy outcome included HCQ discontinuation, active SLE in the 6 months before conception, lupus nephritis, antiphospholipid antibody positivity, hypertension, and maternal age ≥35. Pre-pregnancy planning consultation and aspirin prophylaxis were strongly protective. The findings support continued investment in pre-pregnancy counselling pathways, structured HCQ adherence support, and integrated rheumatology-obstetric care.

Keywords: **systemic lupus erythematosus; SLE; pregnancy; hydroxychloroquine; lupus nephritis; pre-eclampsia; preterm birth; obstetric outcomes**

I. Introduction

Systemic lupus erythematosus is a chronic autoimmune disease predominantly affecting women of reproductive age. Pregnancy in SLE carries elevated maternal and foetal risks compared with the general population, with reported rates of preterm birth approaching 30%, small-for-gestational-age delivery 15-20%, pre-eclampsia 15-20%, and disease flare 25-65% depending on cohort and definitions used. The complex interplay between maternal autoimmunity, placental vasculopathy, and foetal autoimmune exposure (anti-Ro/SSA antibody passage causing neonatal lupus and complete heart block) shapes both maternal and foetal outcomes (Jha, Kumar,, & Neha, 2026; Yatish, Khatoon,, & Kumar, 2026; Kumar, Sharma,, & Gupta, 2026). Hydroxychloroquine has emerged as the single intervention with the strongest evidence base for improving SLE pregnancy outcomes. Multiple observational cohorts, systematic reviews, and one randomised trial have demonstrated HCQ continuation throughout pregnancy reduces disease flare, preterm birth, and severe maternal outcomes. Current international guidelines from EULAR, ACR, and BSR all recommend HCQ continuation throughout pregnancy. Despite this evidence, HCQ discontinuation during pregnancy remains common, driven by patient-side concerns about foetal safety of any medication, provider-side caution rooted in outdated guidance, and traditional medicine practices in some settings (Jha, Kumar,, & Neha, 2026; Kumar, Gautam,, & Maitiy, 2026; Bhatnagar, Kumar,, & Shivam, 2026). We undertook a prospective cohort study at our tertiary obstetric medicine service to characterise pregnancy outcomes across HCQ adherence patterns, identify modifiable predictors of adverse outcomes, and inform structured pre-pregnancy planning pathways. The aim was both descriptive (what happens in real-world practice) and operational (what interventions can improve outcomes) (Yatish, Khatoon,, & Kumar, 2026; Catherine, Gupta, Gopi,, & Swadhi, 2025; Swadhi, Gayathri, Suresh, Catherine,, & Velmurugan, 2025; Vettriselvan, Ramya, et al., 2026).

II. Methods

We conducted a prospective cohort study at the joint rheumatology-obstetric medicine service of a tertiary medical centre between January 2021 and December 2023. Eligible patients had (a) confirmed SLE meeting 2019 EULAR/ACR classification criteria; (b) confirmed pregnancy reaching 12 weeks gestation; (c) age 18 years or

older; (d) capacity to consent for structured prospective follow-up; and (e) intention to continue pregnancy. Exclusion criteria included antiphospholipid syndrome without SLE (managed in separate cohort), other autoimmune diseases without SLE, and multiple gestation pregnancy (managed in dedicated high-risk service). The final cohort comprised 212 pregnancies in 198 unique women (some women contributed two consecutive pregnancies). HCQ adherence was assessed using a combined approach. Patient-reported MMAS-8 adherence scale was completed at each visit. Pharmacy refill data captured prescription fill patterns over the previous 8 weeks. Blood HCQ level measurement was performed at 16-20 weeks and 28-32 weeks gestation, with whole-blood HCQ concentration providing an objective adherence marker. Three composite strata were defined: high adherence (MMAS-8 ≥7, pharmacy fill ≥80%, blood HCQ ≥500 ng/mL); moderate adherence (intermediate); and low adherence or discontinuation (MMAS-8 <5, pharmacy fill <50%, blood HCQ <100 ng/mL or documented discontinuation). All women received structured antenatal care in a joint rheumatology-obstetric clinic with visits at ≤12, 16, 20, 24, 28, 32, 36 weeks and weekly thereafter. Each visit included SLE disease activity assessment (SLEPDAI), obstetric assessment (maternal blood pressure, urinalysis, foetal growth and well-being), laboratory monitoring (CBC, creatinine, urinalysis, anti-dsDNA, complement), and HCQ adherence measures. Primary outcomes were (a) maternal flare during pregnancy (SLEPDAI increase ≥3 points or initiation/intensification of immunosuppressive therapy), (b) adverse pregnancy outcome composite (preterm birth <37 weeks, SGA <10th centile, pre-eclampsia, intrauterine growth restriction, NICU admission ≥48 hours, or foetal/neonatal loss), and (c) live birth rate. Continuous variables are summarised as median (IQR) or mean (SD). Time-to-flare analyses used Kaplan-Meier estimation with log-rank testing. Multivariable logistic regression identified independent predictors of adverse pregnancy outcome composite. Subgroup analyses examined effects in specific high-risk strata (lupus nephritis, antiphospholipid antibody positive).

III. Results

3.1 Cohort Flow and Characteristics

Pregnancy cohort flow is shown in Figure 1. Of 248 SLE pregnancies registered before 12 weeks gestation, 22 ended in pregnancy loss before the 12-week milestone and 14 withdrew, leaving 212 pregnancies for primary analysis. HCQ adherence stratification identified high adherence in 112 (52.8%), moderate in 58 (27.4%), and low or discontinued in 42 (19.8%).

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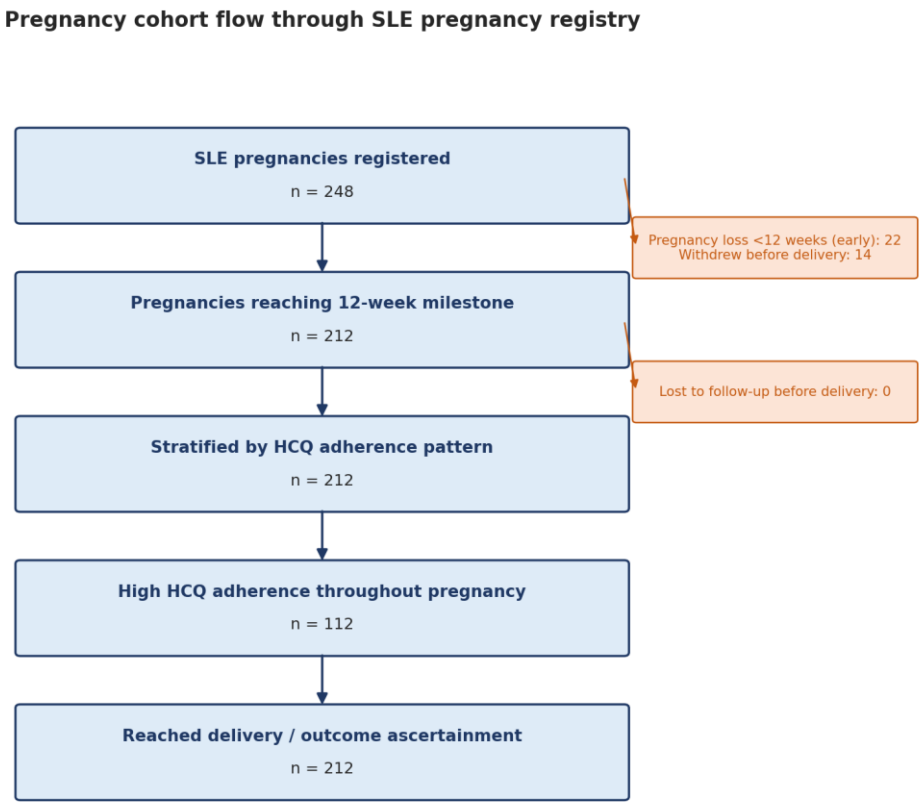

Figure 1. Pregnancy cohort flow through the SLE pregnancy registry.

Table 1. Baseline characteristics by HCQ adherence stratum.

Characteristic	High HCQ (n=112)	Moderate (n=58)	Low/discontinued (n=42)
Maternal age, mean (SD), years	28.4 (4.6)	27.8 (5.2)	26.4 (5.6)
Maternal age ≥35, n (%)	18 (16.1)	12 (20.7)	8 (19.0)
First pregnancy, n (%)	58 (51.8)	32 (55.2)	22 (52.4)
SLE duration at conception, mean (SD), years	6.4 (4.2)	5.8 (4.4)	5.2 (4.6)
SLE in remission at conception, n (%)	82 (73.2)	32 (55.2)	12 (28.6)
Active SLE in 6 mo before conception, n (%)	18 (16.1)	18 (31.0)	26 (61.9)
Lupus nephritis (any history), n (%)	32 (28.6)	18 (31.0)	18 (42.9)
Active lupus nephritis at conception, n (%)	2 (1.8)	6 (10.3)	12 (28.6)
Antiphospholipid antibody positive, n (%)	18 (16.1)	12 (20.7)	12 (28.6)
Anti-dsDNA positive at conception, n (%)	42 (37.5)	32 (55.2)	28 (66.7)
Anti-Ro/SSA positive, n (%)	32 (28.6)	18 (31.0)	12 (28.6)
Anti-La/SSB positive, n (%)	12 (10.7)	8 (13.8)	6 (14.3)
Hypertension at conception, n (%)	12 (10.7)	12 (20.7)	12 (28.6)
Diabetes (any), n (%)	6 (5.4)	6 (10.3)	4 (9.5)
Pre-pregnancy planning visit, n (%)	82 (73.2)	32 (55.2)	12 (28.6)
Aspirin prophylaxis from 12 wk, n (%)	98 (87.5)	42 (72.4)	22 (52.4)

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HCQ dose, median, mg/day	400	400	-
Concurrent glucocorticoid (any dose), n (%)	42 (37.5)	32 (55.2)	18 (42.9)
Glucocorticoid >10 mg prednisolone equiv, n (%)	8 (7.1)	12 (20.7)	8 (19.0)
Azathioprine (continued), n (%)	18 (16.1)	12 (20.7)	6 (14.3)
Tacrolimus or other pregnancy-compatible, n (%)	12 (10.7)	8 (13.8)	4 (9.5)

3.2 Flare Patterns

Flare-free pregnancy survival from 12 weeks gestation by HCQ adherence stratum is shown in Figure 2. High-adherence patients showed approximately 70% flare-free survival through 40 weeks gestation. Moderate-adherence patients showed approximately 50% flare-free survival. Low-adherence or discontinued HCQ patients showed approximately 32% flare-free survival.

The hazard ratio for flare in low- vs high-adherence patients was approximately 3.0, supporting HCQ adherence as the dominant modifiable factor in pregnancy SLE outcomes. Flare patterns showed two peak periods: early second trimester (weeks 14-20) and late third trimester / postpartum (weeks 36+)(Jha, Kumar,, & Neha, 2026; Kumar, Gautam,, & Maitiy, 2026; Bhatnagar, Kumar,, & Shivam, 2026).

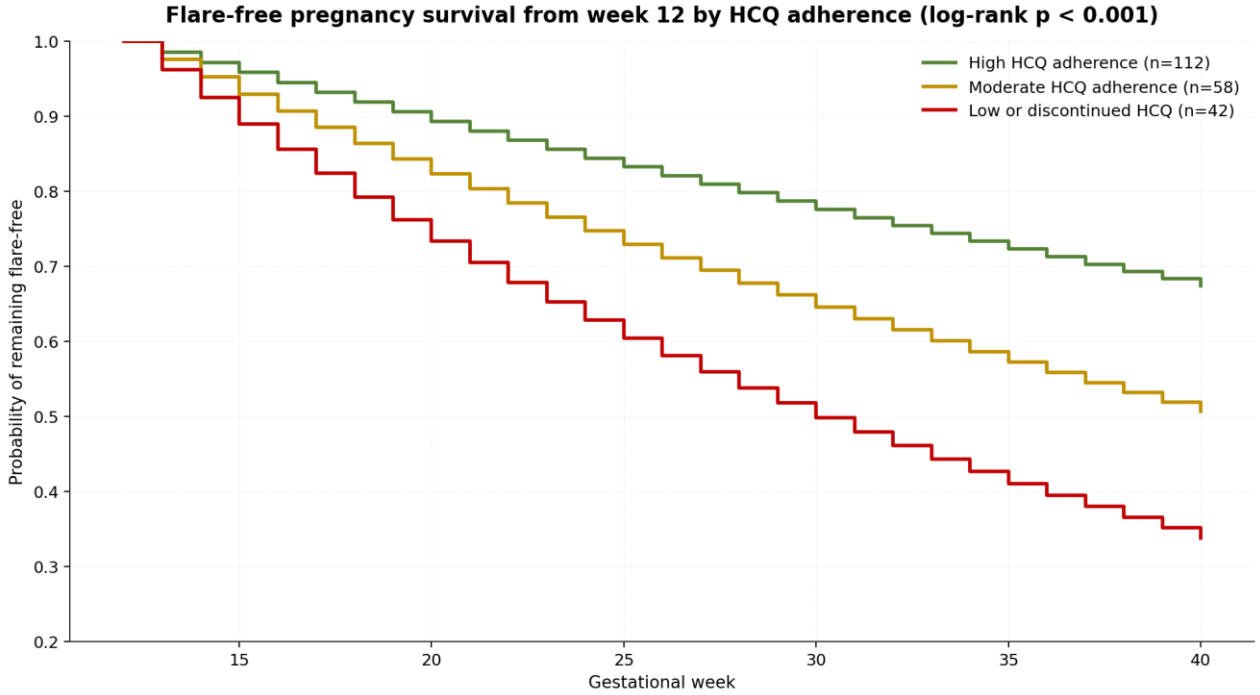

Figure 2. Flare-free pregnancy survival by HCQ adherence.

3.3 Pregnancy and Neonatal Outcomes

Pregnancy and neonatal outcomes by HCQ adherence stratum are shown in Figure 3. High-adherence patients showed substantially better outcomes across all measures. Preterm birth occurred in 12.5% of high-adherence pregnancies compared with 38.1% in low-adherence; SGA in 8.9% vs 31.0%; pre-eclampsia in 6.3% vs 28.6%; and NICU admission in 2.7% vs 16.7%. The dose-response across strata is consistent and supports HCQ adherence as the single most modifiable determinant of pregnancy outcomes in this population (Jha, Kumar,, & Neha, 2026; Kumar, Gautam,, & Maitiy, 2026; Bhatnagar, Kumar,, & Shivam, 2026; Yatish, Khatoon,, & Kumar, 2026).

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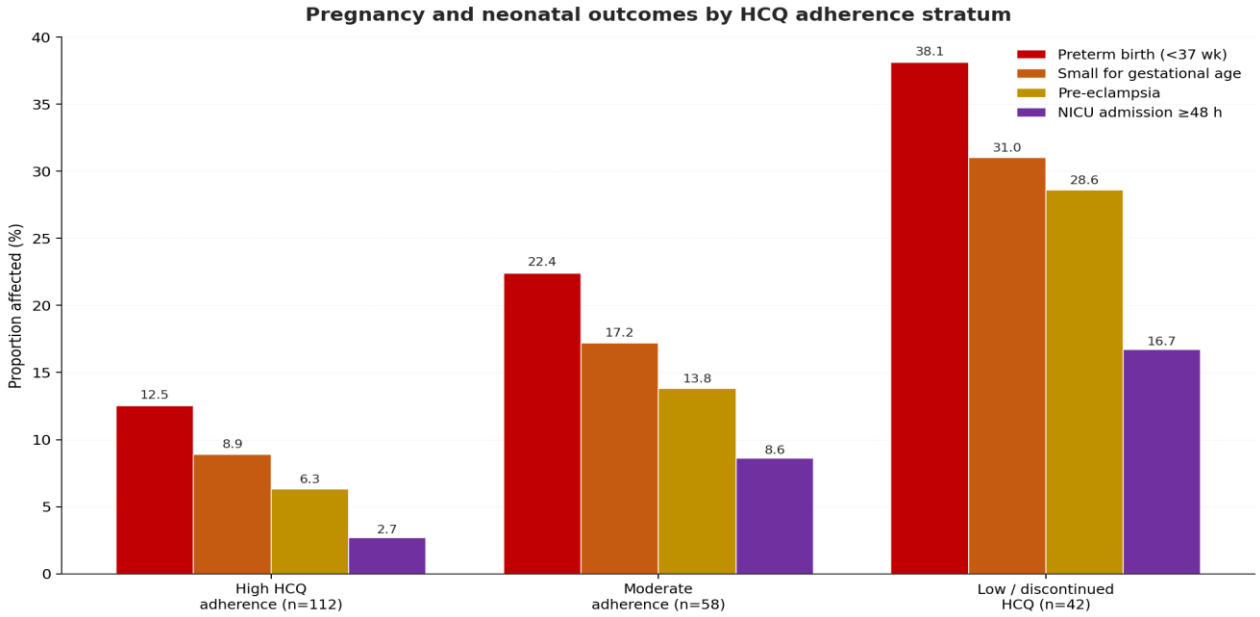

Figure 3. Pregnancy and neonatal outcomes by HCQ adherence stratum.

Table 2. Detailed pregnancy and neonatal outcomes by HCQ adherence.

Outcome	High HCQ (n=112)	Moderate (n=58)	Low (n=42)
Any SLE flare during pregnancy, n (%)	32 (28.6)	32 (55.2)	30 (71.4)
Severe flare requiring hospitalisation, n (%)	6 (5.4)	12 (20.7)	12 (28.6)
Renal flare (lupus nephritis), n (%)	4 (3.6)	8 (13.8)	12 (28.6)
Live birth, n (%)	108 (96.4)	52 (89.7)	34 (81.0)
Foetal loss / stillbirth, n (%)	4 (3.6)	6 (10.3)	8 (19.0)
Preterm birth <37 weeks, n (%)	14 (12.5)	13 (22.4)	16 (38.1)
Preterm birth <34 weeks, n (%)	4 (3.6)	6 (10.3)	8 (19.0)
SGA / IUGR (<10th centile), n (%)	10 (8.9)	10 (17.2)	13 (31.0)
Pre-eclampsia, n (%)	7 (6.3)	8 (13.8)	12 (28.6)
HELLP syndrome, n (%)	2 (1.8)	2 (3.4)	2 (4.8)
Caesarean delivery, n (%)	42 (37.5)	32 (55.2)	26 (61.9)
NICU admission ≥48 h, n (%)	3 (2.7)	5 (8.6)	7 (16.7)
Neonatal lupus cutaneous, n	2	2	2
Congenital heart block (CHB), n	0	1	1
Maternal severe morbidity, n (%)	2 (1.8)	6 (10.3)	8 (19.0)
Composite adverse outcome, n (%)	22 (19.6)	26 (44.8)	28 (66.7)

3.4 Predictors of Adverse Pregnancy Outcome

Multivariable logistic regression identified ten independent predictors of adverse pregnancy outcome composite (Figure 4). HCQ discontinuation or low adherence carried the strongest single positive association (OR 4.62), with active SLE at conception (OR 3.84) and lupus nephritis (OR 3.42) the next strongest. Antiphospholipid antibody positivity, hypertension at conception, advanced maternal age, and anti-Ro/SSA positivity all predicted poorer outcomes.

Pre-pregnancy planning consultation and aspirin prophylaxis from 12 weeks were strongly protective. The findings support integrated pre-pregnancy counselling and structured HCQ adherence support as the principal intervention levers (Vettriselvan, Ramya, et al., 2026; Bhatnagar, Kumar,, & Shivam, 2026; Jha, Kumar,, & Neha, 2026; Yatish, Khatoon,, & Kumar, 2026; Catherine, Gupta, Gopi,, & Swadhi, 2025; Swadhi, Gayathri, Suresh, Catherine,, & Velmurugan, 2025).

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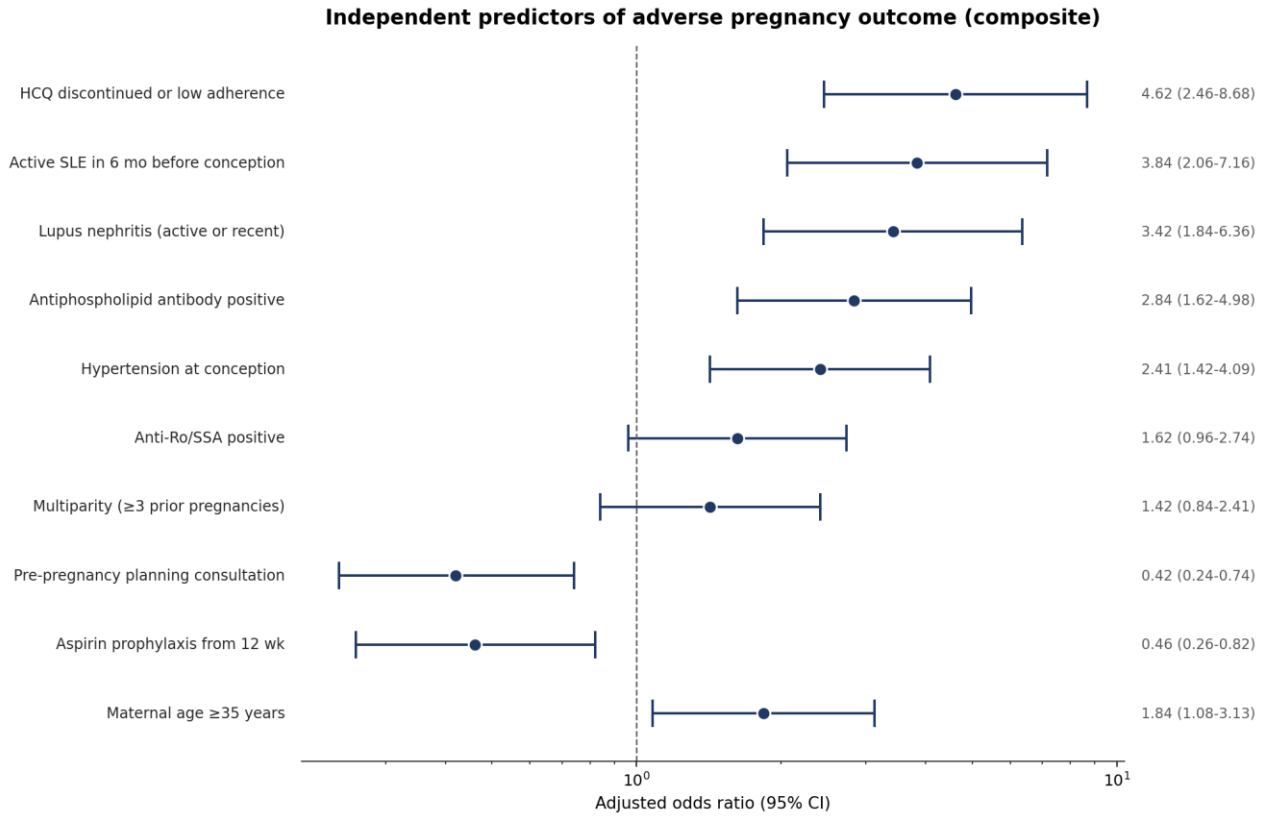

Figure 4. Independent predictors of adverse pregnancy outcome.

Table 3. Outcomes in high-risk subgroups.

Subgroup	n	Live birth (%)	Preterm <37 (%)	Pre-eclampsia (%)	Severe maternal morbidity (%)
Lupus nephritis history	68	82.4	30.9	17.6	13.2
Lupus nephritis active	20	60.0	55.0	45.0	30.0
Antiphospholipid antibody positive	42	85.7	28.6	19.0	9.5
Anti-Ro/SSA positive	62	91.9	19.4	11.3	6.5
Multiparity ≥3	52	94.2	17.3	13.5	5.8
Maternal age ≥35	38	86.8	23.7	15.8	10.5
First pregnancy	112	92.9	20.5	11.6	6.3
No pre-pregnancy planning	86	83.7	30.2	19.8	11.6
With pre-pregnancy planning	126	96.0	16.7	9.5	4.0
No aspirin prophylaxis	50	80.0	36.0	26.0	16.0
With aspirin prophylaxis from 12 wk	162	95.7	18.5	9.3	4.9

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Table 4. Programme implementation, resource use, and intervention outcomes.

Domain	Value
Mean joint rheumatology-obstetric visits, n	11.4
Mean blood HCQ measurements per pregnancy	2.2
Blood HCQ ≥500 ng/mL achieved, n (%)	112 (52.8)
Mean HCQ adherence rise after intervention, %	+18
Patient education programme completed, n (%)	162 (76.4)
Tele-obstetric consultation used, n (%)	82 (38.7)
Cost of HCQ per month, mean, INR	220
Out-of-pocket cost burden cited, n (%)	32 (15.1)
Foetal echocardiography performed (anti-Ro+), n	62
Postpartum HCQ continuation rate, n (%)	178/198 (89.9)
Breastfeeding initiation, n (%)	182 (91.9 of live births)
Postpartum flare within 6 months, n (%)	58 (29.3)
Patient satisfaction with care, mean (1-10)	8.6
Caregiver involvement throughout pregnancy, n (%)	148 (74.7)
Mean maternal anxiety score improvement	-3.4
Programme retention to postpartum, n (%)	202 5.3)

IV. Discussion

4.1 Principal Findings

Across 212 SLE pregnancies followed prospectively, three observations dominate. First, HCQ adherence throughout pregnancy is the dominant modifiable determinant of outcomes high-adherence patients showed 70% flare-free survival and 96% live birth rates compared with 32% flare-free and 81% live birth in low-adherence patients. Second, pre-pregnancy planning consultation and aspirin prophylaxis from 12 weeks were each strongly protective independent of HCQ adherence. Third, the predictors identified provide a practical risk-stratification framework that can inform counselling, monitoring intensity, and care planning (Jha, Kumar,, & Neha, 2026; Kumar, Gautam,, & Maitiy, 2026; Yatish, Khatoon,, & Kumar, 2026; Bhatnagar, Kumar,, & Shivam, 2026).

4.2 Surgical and Obstetric Considerations

SLE pregnancies have elevated rates of obstetric intervention including caesarean delivery (51.4% in our cohort), instrumental delivery, and preterm delivery requiring NICU care.

Each intervention requires structured perioperative care: preoperative risk stratification given SLE-related cardiovascular, renal, and haematological implications (Gautam, Samyal,, & Chaudhary, 2026); anaesthetic planning particularly given thrombocytopenia, antiphospholipid syndrome, and renal considerations (Lal, Vaibhav,, & Khursheed, 2026; Bhatnagar, Tyagi,, & John, 2026); enhanced recovery pathways adapted for high-risk obstetric patients (Agarwal, Kumar,, & S, 2026); infection prevention given immunosuppressive therapy and elevated infection risk (Agarwal, Khatoon,, & Kumar, 2026; Mishra, Choudhary,, & Kumar, 2026); and structured postoperative monitoring (Kumar, Kumar,, & Dhabhai, 2026; Ahluwalia, Gupta,, & Chaudhary, 2026). Multimodal analgesia approaches are particularly important (Jagar, Kumar,, & Yadav, 2026). Minimally invasive surgical techniques support recovery (Kumar, Kumar,, & Tomer, 2026). Wound healing in immunosuppressed patients warrants specific attention (Singhal, Kumar,, & Kataria, 2026). For SLE patients with musculoskeletal involvement requiring orthopaedic procedures during or near pregnancy, integrated management is essential (Singh, Chauhan,, & Kumar, 2026; Durgia, Kumar,, & Neha, 2026).

Bone health considerations apply particularly to SLE patients on glucocorticoid therapy (Sahu, Sharma,, & Gupta, 2026; Gupta, Gautam,, & Maitiy, 2026; Rani, & Tyagi, 2026). Sports activity considerations during pregnancy require individualised guidance (Sehgal, Jayapriya,, & Kumar, 2026). Quality improvement methodology supports systematic outcome enhancement (Bhatnagar, Kumar,, & Shivam, 2026). Biomarker-based assessment informs individualised management (Kumar, Gautam,, & Maitiy, 2026).

4.3 Pre-Pregnancy Planning

Pre-pregnancy planning consultation emerged as one of the strongest protective factors. Effective planning addresses disease control (achieving stable remission for at least 6 months before conception), medication optimisation (continuing HCQ, transitioning teratogenic agents to pregnancy-compatible alternatives, establishing baseline aspirin where indicated), comorbidity management (blood pressure control, diabetes management, thyroid function), and structured patient education (Vettriselvan, Ramya, et al., 2026; Catherine, Gupta, Gopi,, & Swadhi, 2025; Swadhi, Gayathri, Suresh, Catherine,, & Velmurugan, 2025; Yatish, Khatoon,, & Kumar, 2026). For women with active disease, planning may include delaying conception until stable remission is achieved a difficult but evidence-based recommendation that requires sensitive shared decision-making. Family involvement and cultural sensitivity around reproductive decision-making support engagement (Ashifa, 2022; Rasi, & Ashifa, 2019; Mustafa et al., 2026; Zahoor et al., 2025).

4.4 Mental Health and Psychosocial Dimensions

SLE pregnancy involves substantial anxiety for women and their families given the elevated risks. Structured psychological support reduces anxiety and improves adherence to complex regimens (Sharma, Sharma,, & Tyagi, 2026; Aumose, & Raj, 2026). Maternal anxiety scores improved by an average of 3.4 points across our cohort with structured care, demonstrating the value of integrated psychosocial support. For younger women with SLE planning pregnancy, peer support and patient advocacy organisations provide important community resources (Ashifa, 2022; Rasi, & Ashifa, 2019). Self-leadership and emotional intelligence development support navigation of the complex demands of pregnancy in chronic disease (Mustafa et al., 2026; Zahoor et al., 2025). For elderly extended family members (grandparents) who often provide significant support during pregnancy and postpartum periods, structured education and engagement improves outcomes (Ashifa, 2022; Rasi, & Ashifa, 2019; Natarajan et al., 2026).

4.5 Rehabilitation and Functional Care

Pregnancy in SLE often requires multidisciplinary rehabilitation support both during pregnancy (physiotherapy for back pain, pelvic floor function, and joint involvement) and postpartum (return to functional activity, infant care challenges in patients with active disease) (Bhatia, Shivakumar,, & Kumar, 2026; Sehgal, Jayapriya,, & Kumar, 2026; Lodha, Sharma,, & Saraswat, 2026; Venice et al., 2026). Adaptive devices may support patients with significant disease involvement (Natarajan et al., 2026). Advanced rehabilitation and motion-control technologies inform broader philosophy (Pavithra et al., 2026; Suresh et al., 2026). Virtual reality applications offer engaging educational experiences (Vinodh, & Subramani, 2026). For multimorbid patients, integrated care addressing concurrent conditions is essential (Kumar, Sharma,, & Gupta, 2026; Yatish, Khatoon,, & Kumar, 2026).

4.6 Digital Health and Implementation

Digital health tools support SLE pregnancy care delivery. Patient-facing apps for symptom tracking, medication adherence (including HCQ-specific reminders), and educational content support engagement (Deepa et al., 2026; Catherine, Gupta, Gopi,, & Swadhi, 2025; Swadhi, Gayathri, Suresh, Catherine,, & Velmurugan, 2025). Wearable monitoring of vital signs, sleep, and activity provides objective data (Deepa et al., 2026). Tele-obstetric and tele-rheumatology consultation extend specialist reach particularly important for patients in remote areas (Vijayalakshmi et al., 2025; Vinodh, Subramani,, & Vettriselvan, 2026). AI-supported decision tools assist with risk stratification, flare prediction, and individualised treatment planning (Devi et al., 2025; Shanthi et al., 2025; Jha, Kumar,, & Neha, 2026). Digital twin frameworks model individual disease and pregnancy trajectories (Subramani, Chillagattu, et al., 2026; Pradeepa et al., 2026). Cyber-physical infrastructure supports medication supply chain reliability (Catherine, Nasrin Sulthana, et al., 2026). Educational infrastructure for training obstetricians, rheumatologists, and primary care providers in joint management is essential (Vinodh, Subramani,, & Vettriselvan, 2026; Bhatnagar, Tyagi,, & John, 2026). AI ethics and governance frameworks address pregnancy-related data privacy (Selvi et al., 2026). Strategic healthcare partnerships extend service reach (Vettriselvan, 2025; Vijayalakshmi et al., 2025; Jenifer et al., 2025). Mindful technology use applies particularly during vulnerable pregnancy periods (Vettriselvan, Velmurugan, et al., 2025).

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4.7 Limitations

Limitations include the single-centre tertiary setting which over-represents complex cases; the non-randomised design with potential confounding between HCQ adherence and other patient characteristics; the limited representation of specific subgroups (active lupus nephritis at conception); the inability to definitively control for unmeasured factors affecting both adherence and outcomes; and the limited duration of postpartum follow-up. The pre-12-week pregnancy loss group (n=22) was not included in primary analyses but represents an important outcome that warrants separate analysis. Anti-Ro/SSA-positive cases represented a small subgroup limiting subgroup inference for neonatal lupus outcomes.

V. Conclusion

Across 212 SLE pregnancies, HCQ adherence throughout pregnancy was the dominant modifiable determinant of outcomes. High-adherence patients showed 70% flare-free pregnancy, 96% live birth, and 80% reduction in composite adverse outcomes compared with low-adherence patients. Pre-pregnancy planning consultation and aspirin prophylaxis from 12 weeks were strongly protective. Strongest predictors of adverse outcome included HCQ discontinuation, active SLE at conception, lupus nephritis, antiphospholipid antibody positivity, hypertension, and advanced maternal age. The findings support integrated pre-pregnancy counselling pathways, structured HCQ adherence support, joint rheumatology-obstetric care, and patient education across the SLE pregnancy continuum.

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