

12-6-2021

## Optimal Management During Systemic Lupus Erythematosus Cesarean Section: An Educational Module

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### Recommended Citation

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Optimal Management During Systemic Lupus Erythematosus

Cesarean Section: An Educational Module

A DNP Project Presented to the Faculty of the  
Nicole Wertheim College of Nursing and Health Sciences

Florida International University

In partial fulfillment of the requirements  
For the Degree of Doctor of Nursing Practice

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## TABLE OF CONTENTS

ABSTRACT .....	5
INTRODUCTION .....	6
Description of the Problem .....	6
Background .....	8
Systematic Review Rationale.....	11
PICO Question .....	12
METHODOLOGY .....	12
Information Sources and Search Strategy .....	12
Study Selection and Screening Method .....	17
Collection, Analysis, and Data Items.....	18
RESULTS.....	19
Study Selection .....	19
Study Characteristics .....	23
Definitions and Findings Outcomes .....	25
Risk of Bias .....	27
DISCUSSION .....	28
Summary of Evidence .....	27
Limitations of the Systematic Review .....	32
Recommendations for Future Research .....	33
CONCLUSION OF LITERATURE REVIEW.....	33
QUALITY IMPROVEMENT IMPLEMENTATION PLAN .....	34
Setting.....	34
Recruitment and Project Participants.....	35
Intervention & Procedures.....	35
Protection of Human Subjects.....	36

Data	
Collection.....	36
Measurement and Analysis.....	36
RESULTS OF QUALITY IMPROVEMENT.....	37
Pre-test and Post-test Sample.....	37
Pre-test Knowledge.....	38
Post-Test Knowledge.....	39
Perspective of Use in Practice.....	40
DISCUSSION OF QUALITY IMPROVEMENT .....	41
Limitations.....	41
Future Implications for Advanced Nursing Practice.....	42
CONCLUSION.....	42
REFERENCES .....	43
Appendix A: PRISMA Flow Diagram.....	49
Appendix B: Matrix Table.....	50
Appendix C: IRB Exemption Letter.....	53
Appendix D: QI Project Consent Form.....	54
Appendix E: QI Project Survey .....	57
Appendix F: Educational Module .....	61

## ABSTRACT

**Background:** Systemic lupus erythematosus (SLE) is a lifelong multisystem autoimmune disorder characterized by the presence of autoantibodies that are directed against nuclear antigens. The disease is the most common type of lupus that has a heterogeneous presentation, and an affinity for the female gender with a peak onset in normative childbearing years. It becomes important for anesthesia providers to understand the potential complications that they may encounter during the obstetric management of this population, during cesarean sections. Recommendations that address the disease's heterogeneous presentation and effect on the parturient organ systems provides a template for anesthesia providers during the perioperative management of the obstetric SLE patient.

**Objectives:** This quality improvement (QI) project aims to improve healthcare provider knowledge regarding the clinical implications of SLE, during the obstetric management for a cesarean section, to reduce morbidity and mortality for mother and newborn.

**Setting: Setting:** A 716-bed acute care hospital in Broward County, Florida, which has a large obstetric population requiring anesthetic services. Anesthesia providers at this facility will be educated on the maternal- foetal dyad that can present during the management of the SLE mother during cesarian section.

**Methods:** A pretest survey will be administered to assess anesthesia providers' knowledge, attitudes, and behaviors regarding the management of the SLE parturient during cesarian section. An educational module will then be provided. Finally, a posttest survey containing the same questions as the pretest will be administered to participants.

**Results:** Following the educational intervention, there was an increase in knowledge scores and stronger attitudes and beliefs regarding the role of anesthesia providers in the management of the SLE parturient during a cesarean section. Furthermore, most participants reported that they were highly likely to implement this into their clinical practice.

**Conclusions:** The empirical evidence shows that parturients with SLE present with a higher incidence of systemic complications that increases the risk of poorer outcome for both the mother and baby. Anesthesia providers must have a thorough understanding of the clinical implications of SLE, during the obstetric management for a cesarean section, as this will reduce morbidity and mortality for mother and newborn. An educational module can enhance anesthesia provider knowledge and increase the likelihood of improved outcomes for mother and neonate, during the anesthetic management of a SLE parturient during a cesarean section.

**Keywords:** Systemic Lupus Erythematosus, SLE, Lupus, Pregnancy, Cesarean Delivery, Cesarean Section, Anesthesia, Obstetric Anesthesia

## **INTRODUCTION**

### **Description of the Problem**

Systemic lupus erythematosus (SLE) is a multisystem autoimmune disorder characterized by the presence of autoantibodies that are directed against nuclear antigens. The disease has a heterogeneous presentation, dominating in the female gender with a peak onset being between ages 15 and 40; during normative childbearing years.<sup>1,2,3</sup> Parturients with SLE face innumerable challenges throughout pregnancy, as the disorder compromises the potential for the best maternal and fetal–neonatal outcome. Women presenting with the condition are at risk for systemic issues from lupus flares; these include deteriorating renal impairment, inception or worsening hypertension, pre-eclampsia, and venous thromboembolism.<sup>1,2,3</sup> The presence of SLE in parturients leads to complications that may result in adverse fetal and parturient outcome, making it necessary for providers to have an optimized perioperative anesthetic plan in place.

It is estimated that a little over 200,000 Americans experience SLE.<sup>4</sup> In recent studies, an actual account of the extent of the illness reviewed available data from several state registries to track the illness, that was created over a decade ago, by the U.S Centers for disease Control and Prevention (CDC).<sup>4</sup> The study concluded that for every 100,000 people, 72.8 have SLE.<sup>4</sup> The research additionally identified that women were nine times more likely to have SLE with it disproportionately affecting women of Black, American Indian/Alaskan Native and Hispanic descent.<sup>4</sup> The condition comes statistically close to being considered a rare disease, as defined by the U.S Rare Diseases Act of 2002, which identifies conditions that affect 200,000 or fewer Americans.<sup>4</sup> Researchers previously relied on the estimates of patients with SLE, which were largely over estimated and unverified. Researchers have determined that acknowledging that SLE’s statistical closeness to being considered a rare illness decreases the number of study participants needed for testing, new treatments, and clinical trials for the disease.

Women with lupus were once advised by providers that pregnancy should be avoided due to the potential risks to mother and baby. Novelty research has led to knowledge about the nature of the disease and new approaches to treat and manage the condition. Additionally, research has shown that understanding the specific factors that increase the risk during SLE pregnancies can lead to successful outcome for the parturient and the baby. A provider's understanding of important factors that have been shown to increase the risk of complications for the parturient and baby include severe organ damage related to prior disease, active or uncontrolled SLE and the time of delivery and the presence of autoantibodies. Even with improvements in the management of the SLE parturient, women with lupus are more likely to experience pregnancy related complications, when compared to women without the disease. Complications experienced by the SLE parturient, at the time of delivery, may include premature delivery, low- birth weight babies and unmanageable lupus flare ups that may cause organ damage to the parturient. Pregnant women with lupus also have a much higher risk of experiencing complications such as preeclampsia, and eclampsia, when compared to the general parturient population.

Parturients with SLE require anesthesia that is tailored to their individual need, and successful anesthetic management requires optimized practice guidelines for patients who present for elective or emergent cesarean sections. This research synthesizes various study designs published in the last 20 years, with a focus on recommendations based on current scientific management for the parturient. The compilation of current research serves to review the systematic effects of lupus and present best practices that will optimize the perioperative anesthetic management of this population, during cesarean section.

## Background

Systemic lupus erythematosus (SLE) is a multisystem autoimmune disease that primarily affects women during their reproductive years.<sup>1,2,3</sup> To date, there are no general treatments for SLE because of the heterogeneity of the disorder characterized by periods of remission and exacerbation. The expected onset usually occurs during the second to fourth decades of life which places women at increased risks for exacerbation during pregnancy.<sup>2,3,4</sup> The management of SLE during pregnancy is challenging for providers, and the unfortunate outcome for parturients with this condition include pre-eclampsia, eclampsia, preterm delivery, spontaneous abortions, intrauterine growth retardation, and intrauterine foetal death.<sup>1,2,3</sup> Parturients presenting with SLE are faced with the added task of having their babies via cesarean section, emergently or electively, as the complications faced by these parturients lessens the probability of natural or vaginal births.<sup>2,4</sup>

Historically, the occurrence of preterm birth and cesarean deliveries occur more frequently in patients with SLE when compared to the general population.<sup>1,2,3,4,5</sup> Comparatively, parturients with cutaneous lupus erythematosus (CLE) and rheumatoid arthritis (RA) are less likely to present with lower rates of disease exacerbation when compared to parturients with SLE.<sup>5,12</sup> Additionally, parturients with SLE are reported to have a higher rate of medically indicated deliveries, when compared to CLE and RA mothers, at the time of labor.<sup>12</sup> Much of the implications in the pathogenesis of SLE are genetic, as the rate of lupus is 24%-60% in monozygotic twins and 2%-5% among dizygotic twins.<sup>10</sup>

In the United States, the occurrence of cesarean deliveries has dramatically increased over the past 30 years.<sup>6</sup> Retrospective studies show that parturients with SLE experience more pregnancy complications.<sup>2</sup> While it has been documented that preterm deliveries and cesarean sections occur more frequently in parturients with SLE, studies are limited as to whether these preterm deliveries are spontaneous or medically indicated.<sup>5</sup> The anesthetic management during cesarean section of a parturient with SLE can be successful; if appropriate measures are



implemented. Moreover, inappropriate anesthetic care can cause mismanagement of SLE parturients, which leads to poor outcomes such as fetal loss, preterm birth.<sup>1</sup>

The successful perioperative management of the SLE parturient, during a cesarean section relies heavily on an anesthetic plan that is tailored for the individualized needs of the patient.<sup>4,5,7</sup> Anesthetic choice technique and patient management relies on the discretion of the provider and their decision that should consider the severity of the disease, drug interactions with immunosuppressants, and unexpected difficult airway, coagulopathy, and systemic organ function for the parturient. SLE systems overlap with the physiological changes of pregnancy and as a result, may present as nonspecific.<sup>1-4</sup>

Cardiovascular involvement in the SLE parturient can include pericarditis, myocarditis, atherosclerosis, and myocardial ischemia. Noninfectious vegetation, known as Libman- Sachs is one of the ways in which valvular anomalies may present in this pertinent.<sup>6,7</sup> Additional cardiac variance may include rhythm and conduction anomalies and atrioventricular blocks.

Complications involving hypertension can affect up to 20% of parturients with SLE which may be brought on by pregnancy and can increase the risk of preeclampsia.<sup>7</sup> Approximately one in every 5 lupus pregnancies experience preeclampsia, which may unfortunately require immediate treatment and often the cesarean delivery of the baby.<sup>7,8</sup>

Airway and pulmonary involvement can range from the unexpected difficult airway with subglottic stenosis and laryngeal edema to the presence of pleuritis, pleural effusion, alveolar hemorrhage, and interstitial disease.<sup>8</sup> Pulmonary hypertension, pulmonary parenchymal and vascular inflammation can present secondary to SLE, in the parturient with SLE. The parturient can present with arthritis, due to the prolonged use glucocorticoids for immunosuppression that can lead to osteoporosis; contributing to the increased incidence of reported atlantoaxial subluxation.<sup>6,7</sup>

Proteinuria, hematuria and abnormal urinary segments can be seen in a urine analysis for the pregnant patient with lupus and irrespective of their pre-pregnancy renal status, the parturients

with SLE are at a higher risk of developing pregnancy induced hypertension (PIH).<sup>8,10</sup> This risk increases even more in SLE parturients requiring greater than 30mg of prednisolone for daily disease management.<sup>10</sup> Lupus nephritis is the primary presentation of renal complications in the parturient presenting with SLE. Approximately 37-39% of parturients with lupus manifest peripheral nervous system complications; with symptoms that range from headaches, seizures, cardiovascular disease, psychosis, acute confusion to demyelinating disease states.<sup>8,9</sup>

Anemia in the SLE combined with the dilutional anemia of pregnancy worsens the hematologic state of the parturient. Hematologic conditions commonly seen in parturients with SLE include anemia, thrombocytopenia and leukopenia; with anemia of chronic disease is present in half of the patient population.<sup>8,10</sup> Other causes of anemia in the SLE parturient include: autoimmune hemolytic anemia, iron deficiency anemia, anemia of chronic renal failure, and cyclophosphamide myelotoxicity.<sup>8,10</sup> The diverse array of autoantibody production, immune complex deposition, and tissue organ damage are a few other defining characteristics of SLE.<sup>10,28</sup> Studies conducted show that the coagulation cascade and complement system had an interaction effect on SLE disease severity, this effect was pronounced among patients with excess inflammation.<sup>10,28</sup>

Conditions that may occur secondary to SLE include antiphospholipid syndrome which is clinically characterized by the recurrence of miscarriages and the presence of lupus antibodies that can prolong the partial thromboplastin time.<sup>6,7,10,28</sup> The SLE Parturient with a pregnancy complicated by antiphospholipid syndrome necessitates the use of heparin and aspirin to prevent thrombosis.<sup>6,7,10</sup>

The preferred method of anesthesia, for the SLE parturient presenting for a cesarean section is regional anesthesia. As with all cesarean sections, the anesthesia provider should anticipate and prepare for a difficult airway, which may range from mild inflammation to laryngeal edema, epiglottitis, vocal cord paralysis to an acute airway obstruction.<sup>6</sup> An anesthesia provider must have available: smaller sized tube, and laryngeal mask airway in preparation for a

potential laryngeal or subglottic involvement. Unfortunately, the pathophysiology of laryngeal inflammation of SLE is not entirely understood, however, it is believed that tissue deposition of immune complexes with activation of complements is probably the cause.<sup>6,7</sup> Other airway complications include left palsy, in the SLE parturient which is due to the compression of the recurrent laryngeal nerve by the pulmonary artery.<sup>6</sup> Parturient with lupus who require a cesarean section may also have additional extracellular fluid resulting in additional engorgement, significantly increasing the risk of airway trauma during instrumentation or failed intubation.<sup>6</sup>

The primary goal for the successful perioperative management of parturient with SLE during a cesarean section, is to provide care that prevents serious adverse sequelae. The multisystem disorder requires a thorough preanesthetic evaluation and an individualized plan based on the parturients system involvement, current medications regimen and laboratory findings. Additionally, providers must have a thorough understanding of the disorder and its effects on a parturient during a cesarean obstetric anesthetic management.

### **Systematic Review Rationale**

The American College of Rheumatology (ACR) has provided standardized guidelines for the diagnosis and management of SLE, with the original recommendations, published in 1982 updated in 1997.<sup>9</sup> Additionally, there are international clinical practice guidelines (CPG) for the treatment of SLE, however, there are limited practice guidelines for obstetric anesthetic management during cesarean section. In this paper, the reader will find a presentation of the clinical features exhibited by SLE parturients and recommended guidelines for the anesthetic management of a patient with SLE during a cesarean section.

Systemic Lupus Erythematosus has several disease manifestations that may be exhibited in the parturient during cesarean delivery. Some of the more common indicators include arthritis, hematological disorders, neuropsychiatric disorders, nephritis, pleuritis, pericarditis, and photosensitivity. Patients with SLE can present with myocardial injury that is attributed to accelerated atherosclerosis, myocardial inflammation, and disease that are microvascular in

nature (14). In this population, the use of troponin I (cTnI) and troponin T (cTnT) are the cardiac biomarkers of choice for patients presenting with chest pain.<sup>14,15</sup> In a double-blinded study performed between 2007 and 2010, 473 patients were analyzed, and highly sensitive assay cTnT measured in serum was the first identified biomarker independently associated with incident CVE in SLE patients.<sup>14</sup> Myocardial involvement, in the presence of SLE requires clinical attention in parturients, as this can lead to cardiac arrhythmias, heart failure, and cardiogenic shock.<sup>14,15</sup>

Pericarditis is a common cardiac manifestation and is recognized by the ACR as a diagnostic criterion for SLE. Incidence of pericarditis widely ranges in the literature, from 11-54%, with one-third of these patients develop symptomatic pericardial involvement (14, 15,16). The usual occurrence of pericarditis is at the onset of the disease and during flare-ups, when the patient faces physiological stressors, such as pregnancy.<sup>14, 15</sup> Standard management would include Nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroids; more extensive management of a cardiac tamponade would include pericardiocentesis or a pericardial window. Myocarditis is another characteristic of SLE and is seen in up to 10% of patients experiencing this disease.<sup>14</sup> SLE myocarditis can progress to arrhythmias, heart failure, dilated cardiomyopathy, ventricular dysfunction, and dilated cardiomyopathy, although other factors may be responsible such as hypertension, accelerated atherosclerosis with ischemia, valvular disease, renal failure, and treatment toxicity from cyclophosphamide or hydroxychloroquine.<sup>14,15</sup>

### **PICO Question**

The PICO format was utilized to frame the clinical question, which guided the search criteria. From the research presented on SLE, the following PICO question was formulated: *For parturients with systemic lupus erythematosus (SLE), does current practice, when compared to non- SLE parturients, reduce perioperative anesthetic complications during cesarean section?*

### **METHODOLOGY**

#### **Information Sources and Search Strategy**

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist was used as the focused guide used to locate systematic reviews and meta-analyses for randomized studies.<sup>12</sup> A thorough search was conducted on several electronic databases, including Cumulative Index to Nursing and Allied Health Literature (CINAHL), MedLine (ProQuest) and Excerpta Medica Database (EMBASE). The search results were restricted to articles that were published in English from the year 2000 to 2020 to establish any gaps within the literature. The initial search criterion was inclusive of articles published between 2010 to 2020; this, however, limited the availability of studies inclusive of parturients with SLE. Table 1. Provides a detailed list of the exact terms, subject terms, headings, and filters applied in each database search. The identified problem and PICO question guided the literature search. The comprehensive literature search helped retrieve 9 articles that were synthesized into two themes. The themes included pregnancies complicated by SLE and parturient need for cesarean section Figure 1, is a PRISMA flow diagram used to provide a visual representation of this systematic review and the screening processes used in this systematic review.<sup>16</sup>

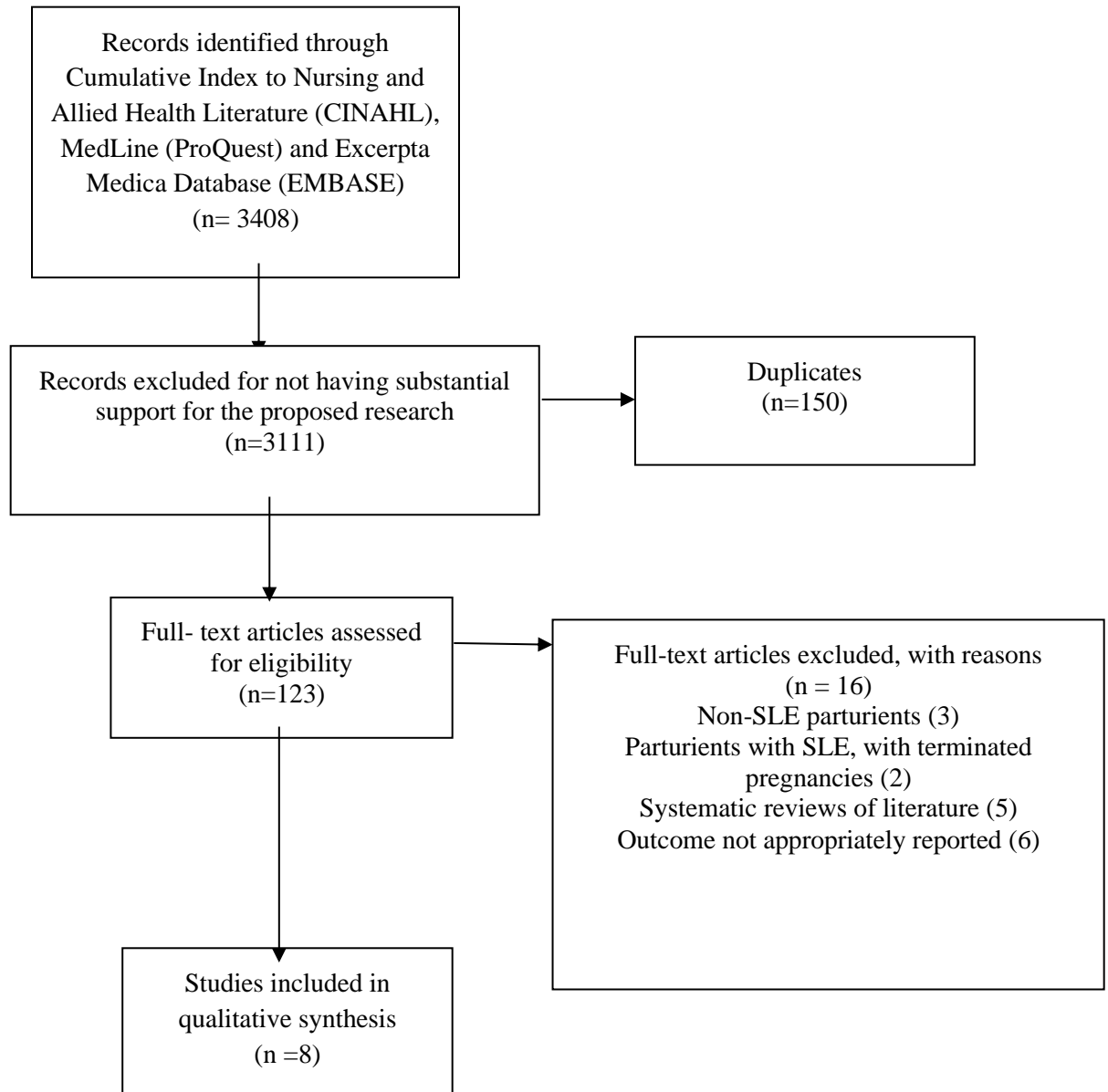
**Table 1. Database Search Table**

<b>Concepts/ Topics</b>	<b>Systemic Lupus Erythematosus or SLE or Lupus</b>	<b>Pregnancy, Pregnant or Parturient</b>	<b>Anesthesia or Obstetrics</b>	<b>Cesarean Section or Delivery or Labor</b>	<b>Filters Applied</b>
<b>CINAHL</b>	(MH "Systemic Lupus Erythematosus") OR (MH "SLE") OR (MH "Lupus")	(MH "Pregnant") OR (MH "Pregnancy") OR Parturient*  OR pregnan*	(MH "Anesthesia ") OR (MH "Anesthesia, Obstetrical") OR anesthes* OR	(MH "Cesarean Section") OR (MH "Cesarean Delivery") OR C	• Peer reviewed filter applied and <b>78</b> <b>results</b> found

			anaesthes*	Section*	
			OR	OR	
			Obstetric*		
			OR regional	labor*	
<b>MEDLINE</b> <b>(Proquest)</b>	MESH.EXACT (" Systemic Lupus Erythematosus" ) OR MESH.EXACT ("Lupus") OR MESH.exact(" Management--- SLE") OR MESH.EXACT ("SLE") OR systemic lupus OR Lupus  OR "Lupus*"	MESH.exact(" Pregnant") OR MESH.exact ("Parturient") OR MESH.exact(" Pregancy") OR pregnan* OR parturient*	MESH.exact ("Anesthesia ") OR MESH.exact ("Obstretric, Anestheia - - adverse effects") OR MESH.exact ("Anesthia* ") OR anaesthes* OR regional	MESH.E XACT("C esarean Section") OR MESH.E XACT("L abor") OR Cesarean* OR cesarean deliver* OR c section	998 results Applied peer reviewed, female filter, English Filter, 2000-2020, Human Filter, and Journal Article type to get <b>122</b> <b>results</b>

<b>EMBASE</b>	' Systemic Lupus Erythematosus OR 'Lupus" OR 'SLE OR Systemic Lupus OR System* Lupus OR "SLE*" OR "Lupus*"	'pregnant'/exp OR 'Pregnancy' /exp OR 'Parturient'/ex p OR pregnant parturient	'anesthesia/ exp OR 'Obstetrics '/exp OR 'obstetric anesthesia'/e xp OR OB OR regional anesthes* OR anaesthes*	'obstetric delivery'/e xp OR 'gynecolo gic surgery'/e xp OR Obstetric* OR parturient * OR labor OR gynecolog ic* OR pregnant	112 results Found Filters applied: Female, Article publicatio n type, drugs ondansetro n, and dates 2000- 2020. 31 results then found • EMBASE ONLY (removed Medline duplicates) and came out to <b>17</b> <b>results</b>
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**Figure 1.** PRISMA Flow Diagram





## Study Selection and Screening Method with Inclusion/Exclusion Criteria

The investigators screened titles and abstracts specific to the preliminary PICO question. The investigator reviewed the data collection and analysis to make the appraisal more reliable and to prevent bias. Selected articles were organized using “EndNote Library” into a “relevant” and “irrelevant” folder. A total of 123 articles were placed in the “irrelevant” folder and 8 articles into the “relevant” folder.

The investigators completed a full- text assessment on all 8 relevant articles based on the following inclusion criteria: articles published in the English language, articles published between 2000 to present, double-blinded RCTs, Systemic Lupus Erythematosus or SLE or Lupus, Pregnancy or Obstetrics, Cesarean Delivery or Cesarean Section and Anesthesia. Results that did not include the previously mentioned search terms were excluded from this systemic review. Table 2 outlines the exclusion criteria and inclusion criteria used for this systematic review. The studies that did not include the parturient population or address patient management during cesarean sections were also scrutinized, some were selected and used for this systematic review due to the lack of research specific the SLE parturient. Additionally, limitations in the availability of double- blinded RCTs, resulted in the expansion of the inclusion criteria to also include retrospective cohort studies, population based- national studies and case studies.

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**Table 2.** Inclusion and Exclusion Criteria

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<b>Inclusion</b>	<b>Exclusion</b>
Population: <ul style="list-style-type: none"><li>• Female</li><li>• Women</li><li>• Obstetric (OB)</li></ul>	Population: <ul style="list-style-type: none"><li>• Male</li><li>• Non-OB</li><li>• Children (&lt;18 years old)</li></ul>
Type of procedure: <ul style="list-style-type: none"><li>• Anesthesia for cesarean delivery</li><li>• Management during cesarean delivery</li></ul>	Type of procedure: <ul style="list-style-type: none"><li>• Anything other the management of parturients for cesarean delivery (e.g., laparoscopy, cardiac or cystoscopy procedure for SLE population)</li></ul>
Intervention:	

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<ul style="list-style-type: none"> <li>• Studies that include various considerations for the management of parturients with SLE during cesarean sections</li> </ul>	<p>Intervention:</p> <ul style="list-style-type: none"> <li>• Obstetric management of patients who do not have SLE</li> <li>• Patients with SLE who are not undergoing cesarean sections</li> <li>• Parturient complications for patients who do not have SLE</li> </ul>
<p>Primary outcomes:</p> <ul style="list-style-type: none"> <li>• Selective maternal outcomes- included cesarean section, pre-eclampsia, hypertension, postpartum hemorrhage, perioperative or post-operative blood transfusion, thromboembolic disease, post-operative maternal fever</li> <li>• Selective fetal outcomes- included spontaneous abortions, premature births, stillbirths, fetal death, low birth weight, one-minute Apgar scores less than 7</li> <li>• Anesthetic implications for SLE parturient during cesarean obstetric management- regional anesthesia</li> </ul>	<p>Primary Outcomes:</p> <ul style="list-style-type: none"> <li>• Anything unrelated to cesarean obstetric management of an SLE parturient</li> <li>•</li> </ul>
<p>Type of study:</p> <ul style="list-style-type: none"> <li>• English language</li> <li>• Randomized controlled trials</li> <li>• Publication date 2007-Present</li> <li>• Retrospective Analysis</li> <li>• Cohort Studies</li> <li>• National Studies</li> </ul>	<p>Type of study:</p> <ul style="list-style-type: none"> <li>• Non-English</li> <li>• Publication date pre-2000</li> <li>• Duplicates of the same study</li> <li>• Systematic reviews</li> <li>• Questionnaire</li> <li>• Dissertations/theses</li> </ul>

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### Collection, Analysis and Data Items

Using an appraisal checklist, studies were evaluated and selected for this systematic review.<sup>17</sup> A Critical Appraisal Skills Programme's Checklists (CASP) provided the structural framework which allowed the investigator to appraise the cohort studies and case control studies that we selected.<sup>17</sup> The rating scheme for research evidence, outlined by the CASP checklist uses 11 questions to help in understanding randomized controlled trials. Items taken into consideration by the CASP assesses the validity of the trial, the soundness of the study method, assessment of the results questions the value of the experiment to the persons in the investigator's selected target population.<sup>17</sup>

A nationwide population-based study was also used in this systemic review. The 11 question CASP Checklist for Case Control Study addressed three broad issues which assessed the actual results, questioned the validity of the results and the importance of the finding to the

investigator's population. The use of the CASP Case Control Study Checklist and the CASP Cohort Study Checklist were also used to evaluate the literature presented in the case studies and retrospective studies that were also included in the systematic review.<sup>17</sup>

Upon the completion of each evaluation, a level of quality was assigned to each study, based on the critical appraisals performed by the investigator on each CASP checklists used for literature evaluation. Table 3 presents the strengths and weakness of each study as well as the information obtained and evaluated from each study. The content provided in the table includes: the study design and method, study sample or setting, major variables studies and defined, measurement and data analysis, study findings, results, and study conclusion. The evaluation table also cites the author and year of publication.

## **RESULTS**

### **Study Selection**

Three thousand four hundred and eight articles were obtained after performing an electronic search of Cumulative Index to Nursing and Allied Health Literature (CINAHL), MedLine (ProQuest) and Excerpta Medica Database (EMBASE). Following careful review of titles, abstracts, 3,111 articles were eliminated for not having substantial support for the proposed research. An additional 150 duplicates were removed and a total of 123 full-text articles were assessed for suitability. Further elimination, based on the strict inclusion and exclusion criteria included articles that did not include parturients with SLE (3), studies that included parturients with SLE who terminated the pregnancy (2), systematic reviews of literature (5) and outcomes that were not appropriately reported (6). Unfortunately, search results did not identify RCTs that included the anesthetic management of the SLE parturient during a cesarean section that met this systematic review. Two Case- Control Studies addressed the use of regional anesthesia during the management of the SLE parturient. Ultimately, the study selection resulted in 6 retrospective cohort studies, 1 population based- national study and 2 case-controlled studies that were included in this systematic qualitative review that answered the PICO question: "For parturients

with systemic lupus erythematosus (SLE), does current practice, when compared to non- SLE parturients, reduce perioperative anesthetic complications during cesarean section?” According to the John’s Hopkin’s appraisal scale, cohort studies allow investigators to draw conclusions regarding the link between risk factors and disease.<sup>19</sup> The goal of this review is to use these studies to enhance the anesthesia provider’s understanding of the potential complications associated with the care of the SLE parturient, during a cesarean section. Table 3 provides a summary of all studies included in the systematic review.

**Table 3.** Studies Included in the Appraisal

<b>Author (Year) &amp; Type of Study</b>	<b>Study Method, Participants, Interventions, &amp; Setting</b>	<b>Findings</b>
Abdwani et al. (2018)  Retrospective Cohort Study	Maternal and neonatal outcomes of pregnancies in SLE patients.  Pregnancies in health controls were used as the comparison.  The study was conducted in a tertiary hospital in Oman  147 pregnancies  56 (38%) parturients with SLE were involved in the study.  91(61.9%) parturients without SLE	Abortions (42.8% vs. 15.3%; p < 0.001), Gestational diabetes (28.3% vs. 10.2%; p = 0.004). Polyhydramnios (7.1% vs. 0.0%; p = 0.020), Previous preterm pregnancies (8.9% vs. 1.0%; p = 0.030), Intrauterine growth retardation (21.4% vs. 0.0%; p < 0.001).
Eudy et al. (2018)  Retrospective Cohort Study	Parturients with SLE and RA prospectively followed until child-birth to assess type of birth and gestational age of infant at time of birth.	S LE pregnancies had modestly higher rates of preterm birth (24% SLE vs 14% RA), pre-eclampsia (15% SLE vs 7% RA) cesarean delivery (48% SLE vs 30% RA) Majority of preterm births among women with SLE were indicated

	<p>The study was conducted in a tertiary hospital in the United States</p> <p>126 total pregnancies</p> <p>82 parturients with SLE were involved in the study.</p> <p>44 parturients with RA</p>	<p>(70%), commonly for pre-eclampsia or the health of the infant or mother.</p>
Clowse et al. (2005)	<p>Assess all pregnancies in a cohort of lupus patients who were observed prospectively from 1987 to 2002.</p> <p>Study was conducted in the United States.</p> <p>267 pregnancies in 203 parturients with SLE were evaluated in this study.</p>	<p>229 (85.8%) resulted in a live birth. High-activity lupus occurred in 57 pregnancies (21%). Fewer pregnancies among women with high activity lupus ended with live births (77% versus 88% of those with low-activity lupus; P= 0.063). Full-term delivery was achieved in 15 pregnancies (26%) among women with high-activity lupus. 127 pregnancies (61%) achieving full-term in those with no or mild lupus activity (P &lt; 0.001). High-activity lupus in the first and second trimesters led to a 3-fold increase in pregnancy loss (miscarriages and perinatal mortality).</p>
Retrospective Cohort Study		
Lui et al. (2012)	<p>Frequency of abnormal pregnancy outcomes, Identifiable laboratory findings and clinical factors that could predict adverse maternal and fetal outcomes among women diagnosed with SLE</p> <p>The study was conducted in China.</p> <p>111 Parturients</p> <p>105 parturients with SLE were involved in the study.</p>	<p>There were 23, 2, and 5 elective, spontaneous, and still births, respectively.</p> <p>Live births were reported in 81 of the pregnancies out of which 17% were in the patients with SLE.</p> <p>Preeclampsia/eclampsia (OR ¼ 14.83, 95% CI: 3.83–57.41) and thrombocytopenia (OR ¼ 4.43, 95% CI: 1.12–17.60) were predictors of fetal loss; preeclampsia/eclampsia (OR ¼ 8.04, 95% CI: 2.00–32.34). Preterm birth; preeclampsia/eclampsia (OR ¼ 8.92, 95% CI: 2.25–35.44) were significantly associated with active SLE (OR ¼ 19.90, 95% CI: 2.38–166.27). Thrombocytopenia (OR ¼ 4.03, 95% CI: 1.24–17.25) were significant predictors of maternal SLE flare-up.</p>
Retrospective Cohort Study		

Mehta, et al. (2019)	Assess nationwide trends and disparities in maternal and fetal complications among pregnant women with SLE	Outcomes improved during those 18 years.
Retrospective Cohort Study	Adult pregnant women with and without SLE who had hospitalizations recorded in the National Inpatient Sample (NIS) database between 1998- 2015  Study occurred in United States.  93 820 parturients with SLE were involved in the study  78 045 054 parturients without SLE	In-hospital maternal deaths (per 100 000 admissions) declined among patients with as well as those without SLE (442 vs. 13 for 1998 to 2000 and <50 vs. 10 for 2013 to 2015),  Decrease was greater in women with SLE (difference in trends, $P < 0.002$ ).  The percentage of patients with SLE in all pregnancy-related, as well as delivery-related, admissions increased significantly.
Vyas et al. (2014)	Management of an antinuclear antibody positive parturient who spinal anesthesia was administered during caesarian section	It was identified that the patient had a normal bleeding, clotting, and activated partial thromboplastin time. The baby cried immediately after delivery, had a normal APGAR score, and no signs of neonatal lupus were identified.
Case- Control Study	No data analysis conducted  A report of the guidelines adhered during the spinal anesthesia	
Nili et al. (2013)	Determine maternal and neonatal outcomes in pregnancies complicated by systemic lupus erythematosus (SLE).	SLE increased the risks of Caesarean section (OR 1.8; 95% CI 1.1 to 2.8, $P = 0.005$ ), postpartum hemorrhage (OR 2.4; 95% CI 1.3 to 4.3, $P = 0.003$ ), need for blood transfusion (OR 6.9; 95% CI 2.7 to 17, $P = 0.001$ ), postpartum fever (OR 3.2; 95% CI 1.7 to 6.1, $P = 0.032$ ), small for gestational age babies (OR 1.7; 95% CI 1.005 to 2.9, $P = 0.047$ ), and gestational age $\leq 37$ weeks (OR 2.1; 95% CI 1.3 to 3.4, $P = 0.001$ ).
Retrospective Cohort Study	Study occurred in Canada.  97 parturients with SLE  211255 parturients without SLE  The study was conducted at an intensive care unit and department of anesthesiology of a healthcare facility.	Neonatal death was not shown to be more common in women with SLE (RR 3.05; CI 0.43 to 21.44, $P = 0.28$ ).

Kiran et al. (2016)	Anesthetic management of a parturient with who underwent elective lower segment cesarean section	patient's recovery from general anesthesia was not associated with any complications. The patient's vitals were stable and no damage to the organ systems such as the neurological, musculoskeletal, cardiac, renal, hematological, and respiratory systems were identified.
Case- Control Study	No measurement of data reported	

### Study Characteristics

The selected peer-reviewed literature used in this review had a combined total of over 20 million parturients, of which 107,983 parturients were diagnosed with SLE. All studies referenced were published between 2000 to 2020, in the English language. The patient demographic characteristics and intervention features were not significantly different across all 8 studies. All participants were female parturients who were potential candidate for cesarean section. The participants included individuals diagnosed with and without SLE.

**Patient demographics.** The obstetric patients in the studies were identified as women, from various ethnic backgrounds, with an age range of 18-50.<sup>6,7,8,20, 23,24</sup> In one study, it was highlighted that some women in the cohort had several pregnancies during the study period, that ranged from 1988 to 2008, because of the statistical significance of observed differences, the data was assessed using a generalized estimating equations approach.<sup>21</sup> The overall range of SLE patient evaluation spanned from 1987- 2015.<sup>6,7,8,20, 23,24</sup> The gestational weeks for the participants ranged from 37-42 weeks in 3 of the studies.<sup>6,7,24</sup> In study performed by Mehta et al. it was noted that mothers with SLE were older than the non-SLE parturient.<sup>25</sup> All the studies were explicit in stating their inclusion and exclusion criteria.<sup>6,7,8,20, 23,24</sup>

**Hospital Demographics.** Most of the studies took place at hospitals in the United States (U.S.). One of the U.S. based cohorts was the Hopkins Lupus Cohort which only included pregnancies that occurred during the woman's care in the Lupus Clinic are included in

this analysis.<sup>6</sup> The retrospective cohort study conducted by Nili et al., took place in Canada; the team obtained data from the Nova Scotia Atlee Perinatal database.<sup>20</sup> The National Inpatient Sample (NIS) was the database used for the study conducted by Mehta et al; It provided healthcare records from more than 1000 participating hospitals.<sup>24</sup> Another was conducted at the Sultan Qaboos University Hospital, a rheumatology referral center in Oman.<sup>8</sup> The only Chinese retrospective study used the data collected from January 1990 to December 2008 in Peking Union Medical College Hospital in Beijing.<sup>1</sup>

**Methodology.** Studies that acknowledged original data collection for the studies included physicians, specializing in pediatrics and rheumatology.<sup>6,7,8,20, 23,24</sup> Additionally, one study also included a pharmacist.<sup>21</sup> Due to the retrospective focus of majority of the studies used for this systematic review, data used were primarily obtained from registries. In one study, pregnant women with SLE and RA were prospectively followed by a single rheumatologist in the Duke Autoimmunity in Pregnancy (DAP) Registry from 2008 to 2016.<sup>7</sup> Trained personnel, using standardized forms collected the data for the Nova Scotia Atlee Perinatal database, in Canada.<sup>20</sup> Ninety- Five percent of the U.S. population is represented in the NIS, the system used to retrieve data for the retrospective study performed by Mehta et al.<sup>24</sup>

Variations were noted in the data collection practices in all the studies used in the systematic review. In the 2005 study by Clowse et al., the study design was to assess all pregnancies, with SLE, who were observed prospectively from 1987 to 2002.<sup>6</sup> The parturients lupus activity was estimated with the use of a visual analog scale (high-activity lupus defined as a score of  $\geq 2$ ).<sup>6</sup> The physician's estimates for lupus activity (PEA) were based on the patient medical history, examination findings and laboratory findings, with a scale range of 0 to 3.<sup>6</sup> The disease activity in each trimester was compared and the investigators assessed the impact of high-activity lupus during pregnancy on gestational age, live birth rate, and small for gestational age babies.<sup>6</sup> Potential comorbidities, including demographics of the women as well as maternal history of lupus, renal lupus, and antiphospholipid antibody syndrome, were analyzed through



multivariate analysis.<sup>6</sup> Post-pregnancy outcomes were later reassessed via clinic visits, telephone, or mail.<sup>6</sup> Data obtained regarding gestational age fetal survival.<sup>6</sup>

The frequency of abnormal pregnancy outcomes, identifiable laboratory findings, and clinical factors that could predict adverse maternal and fetal outcomes among women diagnosed with SLE, was the focus of the retrospective study performed by Liu et al., in 2010.<sup>1</sup> The data of 111 women, 105 of whom were SLE parturients, between January 1990 and December 2008 were reviewed.<sup>1</sup> The SLEDAI for the parturient was confirmed by senior rheumatologists.<sup>1</sup> The laboratory assessments included: antinuclear antibodies, anti-double-stranded DNA antibodies, lupus anticoagulant (LAC), anticardiolipin antibodies, and immunoreactive C3.<sup>1</sup> Additionally, C4, serum creatinine, and 24-hour proteinuria were recorded before conception and were repeated at first, second, and third trimester during pregnancy and within 2 months postpartum or whenever a SLE flare-up were suspected.<sup>1</sup>

### **Definitions and Findings of Outcomes**

Studies done by Abdwani et al. and Liu et al., define SLE using the 1997 American College of Rheumatism classification.<sup>1,6</sup> Additionally, both studies used the SLE Disease Activity Index (SLEDAI) to define and assess the activity levels of the parturients disease.<sup>1,6</sup> Abdwani et al. conducted a retrospective cohort study to determine the maternal and neonatal outcomes of pregnancies in SLE patients. A sample of 147 pregnant women was involved in the study.<sup>8</sup> Out of the 147 women, 56 (38%) had SLE, while 91(61.9%) were healthy. The healthy women were included in the control group.<sup>8</sup> The Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) was used to assess the patients' disease activity.<sup>8</sup> Pregnant women diagnosed with SLE were treated with hydroxychloroquine, prednisolone, and azathioprine.<sup>8</sup> Analyzing the data helped the researchers identify that pregnant women with SLE had higher abortions (42.8% vs. 15.3%), gestational diabetes (28.3% vs. 10.2%), polyhydramnios (7.1% vs. 0.0%), previous preterm pregnancies (8.9% vs. 1.0%), and Intrauterine growth retardation (21.4% vs. 0.0%) when compared to women with normal health.<sup>8</sup> Additionally, pregnant women diagnosed with SLE

were more likely to experience neonatal births that are preterm (28.5% vs. 1.0%;  $p < 0.001$ ), contain low birth weight ( $< 2\,500$  g) (32.1% vs. 1.0%;  $p < 0.001$ ), and stillbirth (7.1% vs. 0.0%;  $p = 0.010$ ) than healthy women.<sup>8</sup> Based on the findings, SLE results in higher maternal and neonatal complications. Thus, there is a need for pregnancies among women with SLE to be accurately planned, monitored, and managed using the best practices provided by a multidisciplinary team to decrease the occurrence of maternal and neonatal complications.<sup>22</sup>

Clowse et al. assessed the perils associated with increased lupus activity and the potential complications in obstetric outcome.<sup>6</sup> In the study, the researchers use a national wide representative sample to observe 277 pregnancies.<sup>6</sup> An analysis of the collected data helped the researchers to identify that maternal mortality was 20-fold higher in women diagnosed with SLE than those without the condition.<sup>6</sup> Clowse et al. identified that the peril of thrombosis, transfusion, infection, and thrombocytopenia were three to seven-fold higher among women with SLE.<sup>6</sup> Additionally, patients diagnosed with SLE had a higher peril for cesarean section (Odds Ratio [OR]: 1.7), preterm labor (OR: 2.4), and pre-eclampsia (OR 3.0) compared to women without SLE. Women with SLE were at a higher peril of thrombophilia, hypertension, and diabetes, which are medical conditions that result in adverse pregnancy outcomes.<sup>6</sup> Clowse et al. concluded that women with SLE are at increased peril for pregnancy and medical complications.<sup>6</sup>

Unlike Clowse et al., Kiran et al. focused on general anesthesia.<sup>6, 23</sup> The researchers indicated that SLE's clinical symptoms among parturients vary with the severity of damage impacted to organ systems such as renal, cardiac, musculoskeletal, respiratory, and neurological systems. The researchers' purpose was to assess the implications for practicing anesthesiologists who provide care to parturients diagnosed with SLE, specifically those who need elective lower segment cesarean section. In this case, the patient was admitted to the facility with hematuria and vaginal bleeding. The patient was treated with 7 U of packed red cells and platelet-rich concentrates.<sup>23</sup>

As an autoimmune disease, SLE is associated with complications such as increased fetal loss, incidences of pre-eclampsia, and neonatal lupus.<sup>21</sup> The use of therapeutic interventions, such as anticoagulants, steroids, and immunosuppressive, could risk anesthesia and surgery.<sup>21</sup> Vyas et al. study reported the perioperative activities and anesthetic management of a parturient with SLE. The parturient had a bad obstetric history and underwent an elective caesarian section.<sup>21</sup> The patient had regular blood sugar, complete blood count, and urine examination.<sup>21</sup> Electrocardiography, liver, and renal function tests were conducted, which helped eliminate systemic involvement. Low molecular weight heparin was administered to the patient twice a day to improve fetal outcomes. The patient's bleeding, clotting, and activated partial thromboplastin time were monitored. Low molecular weight heparin was withheld 24 hours before the surgery.<sup>21</sup> The patient's perioperative bleeding, clotting, and activated partial thromboplastin time were normal.<sup>21</sup> The patient was administered 2 milliliters (ml) of 0.5% Bupivacaine in a lateral position.<sup>21</sup> A 25G Quincke needle was used to achieve blockage at the T6 dermatome level.<sup>21</sup> Upon delivery, the baby cried after being born and had normal APGAR scores.<sup>21</sup> No signs of neonatal lupus were identified. Vyas et al. concluded that administering 2 ml of 0.5% Bupivacaine during spinal anesthesia, together with comprehensive monitoring, decreases the occurrence of adverse outcomes.<sup>21</sup>

### **Risk of Bias**

One of the challenges of retrospective studies are the risks of bias and The Critical Appraisal Skills Programme's Checklists (CASP) provided the structural framework which allowed the investigators to appraise the cohort studies and case control studies for bias.<sup>17</sup>

The retrospective nature of the study conducted by Liu et al. restricted researchers from assessing how the adverse outcomes can be mitigated.<sup>1</sup> Additionally, the large cohort used by Nili et al, has the potential to create a systematic error that maybe caused an over or under estimation of an association.<sup>20</sup>

Selection bias can occur in case-controlled studies if controls are more or less likely to be exposed. The study by Vyas et al. provided no data analysis and is limited in nature given that the report was of one patient.<sup>3</sup> Bias can be avoided by carefully defining selection (inclusion) criteria. Additionally, Have an adequately sized sample, as well as clear, homogenous definitions of disease and exposure. Retrospective studies are self-limiting, however, if researchers select precise and accurate measures of exposure and outcome in addition to sharing all data collected, the risk of bias can be mitigated. The use of retrospective studies play a significant role in health research, particularly when evidence from randomized controlled experiments is not available or feasible.

## **DISCUSSION**

### **Assessment of the Quality of the Included Studies**

The investigators used RCTs in the systematic review to prevent selection bias leading to improved quality of included studies.<sup>33</sup> The selected studies involved equal distribution in a selected population. The selected studies are suitable to establish the relations between an intervention and outcome. The use of RCTs in the systematic review helps to promote the generalizability of the study findings to different settings and populations. The selected studies involve comprehensive abstracts containing information about all sections of studies, including background, aim, discussion, results, and conclusion. The information presented in the article helps in determining the strength of the study. An abstract help determine that the study is consistent and contains generalizable results, suitable sample size, appropriate research design, adequate control, and definitive conclusions. Among the selected studies, only a study by Vyas et al. (2014) and Kiran et al. (2016) lacked a comprehensive abstract. Other studies, including that of Abdwani et al. (2018), Clowse et al. (2005), Lui et al. (2012), Eudy et al. (2018), Nili et al. (2013), and Liu et al. (2012), contained abstracts that have clearly presented information relating to background, objective, method, study design, results, and conclusion.

### **Justification for the exclusion of studies**

The systematic review involved nine articles containing RCTs. The studies were synthesized into two themes, including pregnancies complicated by SLE and parturient need for cesarean section. Systematic Reviews and Meta-Analyses (PRISMA) checklist was used to locate meta-analyses and systematic reviews for randomized studies.<sup>12</sup> The electronic databases used in the search process included MedLine (ProQuest), Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Excerpta Medica Database (EMBASE). The search results were restricted to articles that were published in English from the year 2000 to 2020 to establish any gaps within the literature. The search process involving CINAHL, Excerpta Medica Database (EMBASE), and ProQuest yielded 3408 results. The investigators excluded 3111 articles for not having substantial support for the proposed research. There were 150 articles excluded because they were duplicates. The investigators assessed 123 full-text articles for eligibility. There were eight relevant full-text articles that were selected by the investigators based on inclusion criteria. The criteria were articles: Published between 2000 to present, written in the English language, double-blinded RCTs, Systemic Lupus Erythematosus or SLE or Lupus, Cesarean Delivery or Cesarean Section and Anesthesia, or Pregnancy or Obstetrics.

The exclusion of studies is justified because language is an important factor in the use and dissemination of study findings.<sup>34</sup> It was essential for the investigator to use a language that is applicable to the target recipients of the study findings. The exclusion of articles to eradicate duplicates was essential to facilitate accuracy in data collection, analysis, and production of correct results. The exclusion helped to remove duplication of data to improve the validity and reliability of study findings. The action of the investigators to exclude articles that did not contain full text is justified to ensure that the selected sources have information relating to background, objective, methodology, data analysis, results, and conclusion. The elimination of articles based on the duration of publication is essential to ensure that the systematic review involves most of the latest studies. Additionally, the use of double blinded RCTs helped in improving internal validity.<sup>35</sup>

## Alternative Explanation for Observed Result

In a systematic review, data were collected from the selected studies. The investigators analyzed collected data to generate results. In this part of the paper, a discussion of the results is presented. Abdwani et al. (2018) conducted a study aimed to determine the maternal and neonatal outcomes of pregnancies in SLE patients compared to pregnancies in healthy controls. The researchers found out that pregnancies among patients with SLE were connected to abortions (42.8% vs. 15.3%;  $p < 0.001$ ), intrauterine growth retardation (21.4% vs. 0.0%;  $p < 0.001$ ), gestational diabetes (28.3% vs. 10.2%;  $p = 0.004$ ), previous preterm pregnancies (8.9% vs. 1.0%;  $p = 0.030$ ), and polyhydramnios (7.1% vs. 0.0%;  $p = 0.020$ ).<sup>8</sup> Findings of the a study by Abdwani et al. (2018) relate to the results of a study by Eudy et al. (2018).<sup>8,13</sup> The focus of Eudy et al. (2018) was to determine reasons for medically, and cesarean indicated deliveries in a registry of pregnant women with SLE compared to RA. The findings of the study indicated that SLE pregnancies had discreetly higher rates of cesarean delivery (48% SLE vs. 30% RA), preterm birth (24% SLE vs. 14% RA), and preeclampsia (15% SLE vs. 7% RA). The majority of preterm births among women with SLE were indicated (70%), frequently for the health of the infant, mother, or preeclampsia.<sup>8</sup>

Clowse et al. (2005) found out that high-activity lupus occurred in 57 pregnancies (21%). There were fewer pregnancies among women with high activity lupus ended with live births (77% versus 88% of those with low-activity lupus;  $P = 0.063$ ). High-activity lupus in the first and second trimesters caused a 3-fold increase in pregnancy loss. There were full-term deliveries in 15 pregnancies (26%) among women with high-activity lupus compared to 127 pregnancies (61%) among those with no or mild lupus activity ( $P < 0.001$ ). The results indicate that high-activity lupus is associated with negative obstetric Outcomes. The results relate to the findings of Dietz (2019) that women with SLE compared with those without the condition have a higher rate of miscarriage (18.7% vs. 16.8%), preterm birth (9.2% vs. 6.2%), and stillbirth (0.7% vs. 0.4%).<sup>31</sup>

A study by Lui et al. (2012) showed similar results to those in Clowse et al. (2005) and Dietz (2019). Lui et al. (2012) found out that there were 23 elective, two spontaneous, and five stillbirths among women with SLE. There were only 17% live births in 81 of the pregnancies among patients with SLE. The findings of the study reveal that there is a high rate of stillbirths among women with SLE. Nili et al. (2013) also discovered that SLE is associated with increased negative obstetric outcomes. SLE increased the risks of Caesarean section (OR 1.8; 95% CI 1.1 to 2.8, P = 0.005), need for blood transfusion (OR 6.9; 95% CI 2.7 to 17, P = 0.001), postpartum hemorrhage (OR 2.4; 95% CI 1.3 to 4.3, P = 0.003), postpartum fever (OR 3.2; 95% CI 1.7 to 6.1, P = 0.032), gestational age  $\leq$  37 weeks (OR 2.1; 95% CI 1.3 to 3.4, P = 0.001), and small for gestational age babies (OR 1.7; 95% CI 1.005 to 2.9, P = 0.047). The findings support the outcomes of a study by Pastore et al. (2019) that found out that woman with systemic lupus erythematosus (SLE) is associated with preterm premature rupture of membranes (16.6%), preterm labor (12.7%), and preeclampsia or eclampsia (15.6%).

Kiran et al. (2016) found that anesthetic management for cesarean section among patients SLE facilitated recovery and prevented complications. The patient's vitals were stable with no damage to the organ systems such as the hematological, neurological, cardiac, musculoskeletal, renal, and respiratory systems were identified.<sup>23</sup> The findings support the results of a study by Vyas et al. (2014), who found out that successful management of an antinuclear antibody among women with SLE was associated with positive obstetric outcomes. The patient had normal clotting, bleeding, and activated partial thromboplastin time. The baby cried immediately after delivery; no signs of neonatal lupus were identified and had a normal APGAR score.<sup>3</sup>

### **Gaps in Research**

There is a gap in research relating to the studies included in the systematic review. The studies have not explored the approach of dealing with pregnancies among mothers with SLE.<sup>37, 38, 39, 40</sup> It is essential for investigators to investigate suitable interventions for preventing adverse

effects associated with SLE. Additionally, it is necessary to investigate suitable interventions for improving obstetrical outcomes among mothers with SLE.

### **Limitations of the Systematic Review**

The first limitation of the study relates to the inclusion of articles that are only written in English that can result in language bias. The bias might negatively affect the conclusion of the systematic review. Language bias can also exclude people from using the finding of the study.

The second limitation in this systematic review is dissimilarities among the eight included RCTs. The investigators in the included RCTs have a different definition of SLE. For instance, Nili et al. (2013) define SLE as a chronic multisystem inflammatory autoimmune condition characterized by autoantibody production with a wide range of manifestations and multiple body systems.<sup>20</sup> Abdwani et al. (2018) define SLE as a chronic autoimmune condition that affects women mainly of childbearing age. The dissimilarity may have a negative effect on the reliability of the study findings. Additionally, there is a high heterogeneity among the selected studies with different investigators' different definitions of dependent variables. Among dependent variables contained in the selected studies are obstetrical outcomes, maternal and fetal outcomes, and pregnancy outcomes.<sup>20, 24, 29</sup>

The third limitation of the systematic review is differences in the time intervals for data collection among the selected studies. Liu et al. (2012) collected data involving SLE patients from January 1990 to December 2008. Clowse et al. (2005) collected data of patients from 1987 to 2002. Nili et al. (2013) used data collected between January 1, 1988, and December 31, 2008. Mehta et al. (2019) retrieved data collected from 1998 through 2015. Abdwani et al. (2018) used data of neonates born to mothers with SLE from 2007 to 2013. Heterogeneity among included studies may negatively affect the reliability of this systematic review. Another limitation is that most of the studies included in the systematic review involved small sample sizes. For instance, Liu et al. (2012) involved 105 SLE patients, Clowse et al. (2005) involved 267 pregnancies, while



Nili et al. (2013) focused on 97 pregnancies among women with SLE.<sup>1, 20, 29</sup> The use of a small sample size reduces reliability and validity of study findings.<sup>41</sup>

### **Recommendations for Future Research**

To reduce and prevent adverse outcomes for babies are related to prematurity among mothers with SLE, it is essential to develop a suitable intervention involving a multidisciplinary approach. A multidisciplinary method is suitable to facilitate diagnosis and successful management of SLE among pregnant women to deal with complications during childbirth. Further research should focus on including homogenous studies making measurement outcomes comparable to other published studies, thus reducing heterogeneity. The investigators should use many RCTs containing larger sample sizes and involving multi-centers to facilitate the generalizability of findings. Future RCTs should include interventions suitable in reducing or eliminate adverse fetal outcomes, including preterm birth, fetal loss, and children with congenital heart block. The further study should focus on RCTs dealing with intervention dealing with high-risk pregnancies in women with SLE. Additionally, the selected studies in the further research should involve the implementation of educational interventions targeting women with SLE to ensure that their pregnancies are accurately planned, managed, and monitored to prevent adverse effects.

### **CONCLUSION OF LITERATURE REVIEW**

The selected studies have definitive conclusions that facilitate generalizability.<sup>35</sup> Based on conclusions of the studies, lupus in pregnancy is associated with adverse fetal outcome including preterm birth, fetal loss, and reduced live births.<sup>1, 6</sup> The conclusions from the selected studies helps to generalize that mothers with SLE have a high risk of medically indicated delivery, cesarean section, blood transfusion, and postpartum hemorrhage.<sup>20</sup> The investigators can generalize the findings based on the conclusion that mothers with SLE have a higher chance of delivering smaller babies, premature babies, and children with congenital heart block.<sup>7, 20</sup> The conclusions of the selected studies are essential in generalizing the findings indicating that it is

essential to closely monitor and treat pregnancies in lupus patients to improve outcomes.<sup>1</sup>

Pregnancy among women with SLE should be accurately monitored, planned, and managed using a multidisciplinary treatment schedule.<sup>8</sup>

Overall, with the advancements in healthcare, providers now have a better understanding of the maternal- foetal dyad that can present during the management of the lupus mother during cesarian section. The literatures reviewed highlighted that in the presence of highly active lupus; there may be an increase in premature birth and a decrease in live births. Additionally, pregnancies in lupus patients must be closely observed and treated during all trimesters to improve pregnancy outcomes. Providers are more likely to encounter an increase in pregnant lupus patients and must understand the multisystem nature of the disease, the potential for severe organ involvement, and the drugs that are used in treatment. The outcome of pregnancies can be successful in most women with SLE, however there can be increase in SLE activity, even in patients with the disease who are well controlled. Having a well-formalized anesthesia care plan, for parturients presenting for cesarean sections can help to limit negative outcome and optimize care.

## **QUALITY IMPROVEMENT IMPLEMENTATION PLAN**

### **Setting**

The setting for this project took place in Fort Lauderdale, Florida. In 2019 and 2020, the estimated population Broward county was 1,952,778 and 1,944,375 respectively.<sup>42</sup> The Broward community hospital used for this project is a 716 -bed facility which has a team of 3,100 medical professionals and approximately 800 physicians.<sup>43</sup> Anesthesia services are provided by Anesco Broward North Anesthesia Group, LLC (Anesco); they provide anesthesia services for five hospitals in the district.

### **Recruitment**

The target population was recruited after obtaining approval from the investigators at Florida International University (FIU) and Anesco. The International Review Board (IRB)

deemed the project *exempt* through the Exempt Review process. The population of interest was certified registered nurse anesthetists (CRNAs) and anesthesiologists. Anesco identified the participants and provided an email contact list, which was utilized to connect with the participants virtually.

### **Project Participants**

Anesco staff CRNAs and anesthesiologists were eligible to participate in the educational intervention. Student Registered Nurse Anesthetists (SRNAs) and anesthesia medical residents were excluded from participation in the project. Anesco staff that met inclusion criteria were emailed and provided the voluntary pre-test survey, the educational voice-over PowerPoint, and the post-test survey to complete (See Appendix E and F). A total of 28 participants were contacted, and six participants completed the pre-test and post-test.

### **Intervention**

An evidence-based education module addresses the anesthetic management of the SLE parturient during cesarean section. The presentation identifies that anesthesia providers must have a thorough understanding of the clinical implications of SLE, during the obstetric management for a cesarean section, as this will reduce morbidity and mortality for mother and newborn. The intervention was staged, with the pretest survey provided first to analyze the current knowledge of the SLE parturient and their anesthetic management during cesarean section. Upon pre-test completion, participants were provided with an evidence-based voiceover PowerPoint presentation. The education module provided staff with defining presentation and complications associated with SLE; it identified the importance of an individualized anesthetic care plan for presenting parturient, identified the multisystemic presentation of the high risk parturient, and discussed the results of seven studies used in the literature review that was used to guide this project. Lastly, subjects completed a post-test survey to determine learning outcomes, the efficacy of the intervention, and overall interest in having an anesthetic management plan for the SLE parturient during cesarean section.

## **Procedure**

Participants on the email list provided by Anesco were sent an informational email inviting them to participate in the project. Within the content of the email, there was an anonymous link provided, which gave subjects access to the pre-test questionnaire through the Qualtrics survey platform. After completing the survey, participants were able to access the 15-minute voiceover PowerPoint presentation via email. Upon completing the educational intervention, the Qualtrics survey platform was accessed by an anonymous link that directed users to the post-test survey. Participant privacy was never jeopardized as no personal identifiable information was required to partake in this project.

## **Protection of Human Subjects**

IRB approval was obtained before any of the activities involved in this project were initiated. The IRB has deemed this project *exempt* under the Exempt Review process as it fits one of the exempt category descriptions defined by the Federal Regulations for Protection of Human Research Subjects.<sup>34</sup> There is no more than “minimal risk” to human subjects, and the identification of human subjects cannot be readily determined directly or through identifiers associated with the subjects.<sup>44</sup> Additionally, this research project's pre-test and post-test survey responses do not place the subjects at risk for any civil or criminal liability.<sup>44</sup> Participation will not result in damaging consequences that would affect the subjects financially, their employment or education status, or reputation.<sup>44</sup>

## **Analysis**

The primary tools utilized in the study included a preassessment and post-assessment application used to analyze the effects of the educational module. The Qualtrics platform was used to generate both tests and the educational voiceover PowerPoint presentation. Ten questions in the pre-test survey were used to determine baseline knowledge of SLE and the management of parturients during cesarean sections. In contrast, the post-assessment survey included the same

questions to validate the effectiveness of the educational PowerPoint and the application of knowledge. All data is confidential, and no subject identifiers were recorded in the study.

**Measure**

The primary DNP student obtained Anesco associates’ email addresses. The emails were used to communicate the study's purpose, intent and to send the pretest, posttest, and voicer PowerPoint presentation. Each question was measured via Qualtrics statistical analysis to identify base knowledge before and after participation in the study. Through analysis, the impact of the educational module will be assessed based on participation outcomes and patterns identified. All data will be stored in a password-protected computer by the co-investigator.

**IMPLEMENTATION RESULTS**

**Pre/Post-Test Demographics**

The pre-test demographics are represented below in Table 4.

**Table 4.** Pre/Post-Test Participant Demographics

<b>Demographics</b>	<b>N (%)</b>
Total Participants	6 (100%)
<b>Gender</b>	
Male	2 (33.3%)
Female	4 (66.7%)
<b>Age</b>	
25 - 35 yr.	4 (66.7%)
36 - 45 yr.	1 (16.7%)
46 – 55 yr.	1 (16.7%)
55 – 66 yr.	0 (0%)
<b>Ethnicity</b>	
Hispanic	1 (16.7%)
Caucasian	4 (66.7%)
African American	1 (16.7%)
Asian	0 (0%)
Other	0 (0%)
<b>Education</b>	
Masters	4 (66.7%)

Doctorate	2 (33.3%)
<b>Years of Practice</b>	
0 – 2 yr.	2 (33.3%)
2 – 5 yr.	2 (33.3%)
5 – 10 yr.	1 (16.7%)
10 – 20 yr.	1 (16.7%)

A total of six participants completed the study in its entirety. The pre-test demographics representation included female (n=4, 66.7%) to male participants (n=2, 33.3%). Various ethnicities were also represented among the participants, with the majority being Caucasian (n=4, 66.7%), followed by African American (n=1, 16.7%), and Hispanics (n=1, 16.7%). Most participants fell into the 25 to 35 age group (n=4, 66.7%), while the 36 to 45 age group accounted for (n=1, 16.7%). One of the surveyed respondents fell into the 46 to 55 category (n=1, 16.7%) and none in the 55 to 66 age range. Two participants were CRNAs with Doctoral degrees (n=2, 33.3%) and the remaining participants were graduates with a Master’s degree (n=4, 66.7%). Lastly, all individuals were asked how many years they have been practicing as CRNAs: 0 to 2 years (n=2, 33.3%), 2 to 5 years (n=2, 33.3%), 5 to 10 years (n=1, 16.7%), and 10-20 years (n=1, 16.7%).

**Pre-Test Identification of Knowledge of Anesthetic Management of the Systemic Lupus Erythematosus Parturient During Cesarean Section**

The pre-test consisted of 10 questions that assessed current knowledge of anesthetic management of the systemic lupus erythematosus parturient during cesarean section. All the participants were able to define SLE (n=6, 100%). None of the participants correctly identified some of challenges faced by parturients with SLE or the number of Americans who struggle with the disorder (n=0, 0%). All but two participants identified that women of childbearing age were primarily affected by SLE (n=4, 66.7%). All participants identified that a successful anesthetic management plan for the SLE parturient must be individually tailored (n=6, 100%).

The pulmonary involvement in the SLE parturient were all correctly identified by all the participants completing the pre-test (n=6, 100%). When asked to identify what the studies used in the systemic review concluded, only 2 participants successfully identified that SLE parturients had a higher risk of medically directed deliveries and cesarean sections (n=2, 33.3%). One of the final two pre-test questions focused on the prolonged use of glucocorticoids which are used for immunosuppression. Only one respondent identified that its use would increase the risk of atlantoaxial subluxation (n=1, 16.7%). Optimizing flow and maintaining normal sinus rhythm were identified by 4 respondents as the correct cardiovascular management of the parturient with SLE during a cesarean section (n=4, 66.7%). Finally, all participants agreed with the successful use of regional anesthesia in the parturient undergoing cesarean section, with SLE (n=6, 100%).

#### **Post-Test Identification of Knowledge of Anesthetic Management of the Systemic Lupus Erythematosus Parturient During Cesarean Section**

Table 5 highlights the pre-test and post-test differences in responses.

**Table 5.** Difference in Pre- and Post-Test Knowledge

<b>Questions</b>	<b>Pre-test</b>	<b>Post-test</b>	<b>Difference</b>
<b>1. Systemic lupus erythematosus is defined as:</b>	100%	100%	0%
<b>2. Some of the challenges faced by the parturient with Systemic lupus erythematosus include:</b>	0%	66.7%	66.7%
<b>3. Approximately how many Americans struggle with systemic lupus erythematosus?</b>	0%	50%	50%
<b>4. Systemic lupus erythematosus primarily affect:</b>	66.7%	100%	33.3%
<b>5. Successful anesthetic management of the systemic lupus erythematosus parturient, during a cesarean section relies heavily on:</b>	100%	100%	0%
<b>6. Pulmonary involvement in a systemic lupus erythematosus parturient include:</b>	100%	100%	0%
<b>7. The studies used in this systematic review concluded that systemic lupus erythematosus parturients:</b>	33.3%	100%	66.7%
<b>8. What can prolong use of glucocorticoids for immunosuppression lead to in a parturient with Systemic lupus erythematosus:</b>	16.7%	66.7%	33.3%
<b>9. The principal goal of cardiovascular management in the Systemic lupus erythematosus parturient:</b>	66.7%	100%	33.3%
<b>10. Epidural anesthesia for cesarean delivery in the Systemic lupus erythematosus parturient:</b>	100%	100%	0%

After participants viewed the voiceover PowerPoint presentation, most of the categories increased from baseline knowledge. The most significant increase in knowledge improvement were seen in participants being able to identify the challenges faced by parturients with SLE and the ability to identify what the studies used in the systemic review concluded about the management of the SLE parturient; the questions reflected a 66.7% increase. There was an increase of 50% in knowledge pertaining to the identification of number of Americans who struggle with SLE.

After watching the educational presentation, all participants were able to correctly identify the pulmonary involvements in SLE (n=6, 100%). The educational intervention also resulted in a 100% response (n=6, 100%) in the successful use of regional anesthesia, unless contraindicated in the SLE parturient. An understanding of the principal goal of the cardiovascular management in the SLE patient reflected a 33.3% increase in the respondents' knowledge, after the educational intervention. Additionally, the same percentile increase was noted in participants being able to identify the principal goals of the cardiovascular management in the SLE parturient (n=2, 33.3%).

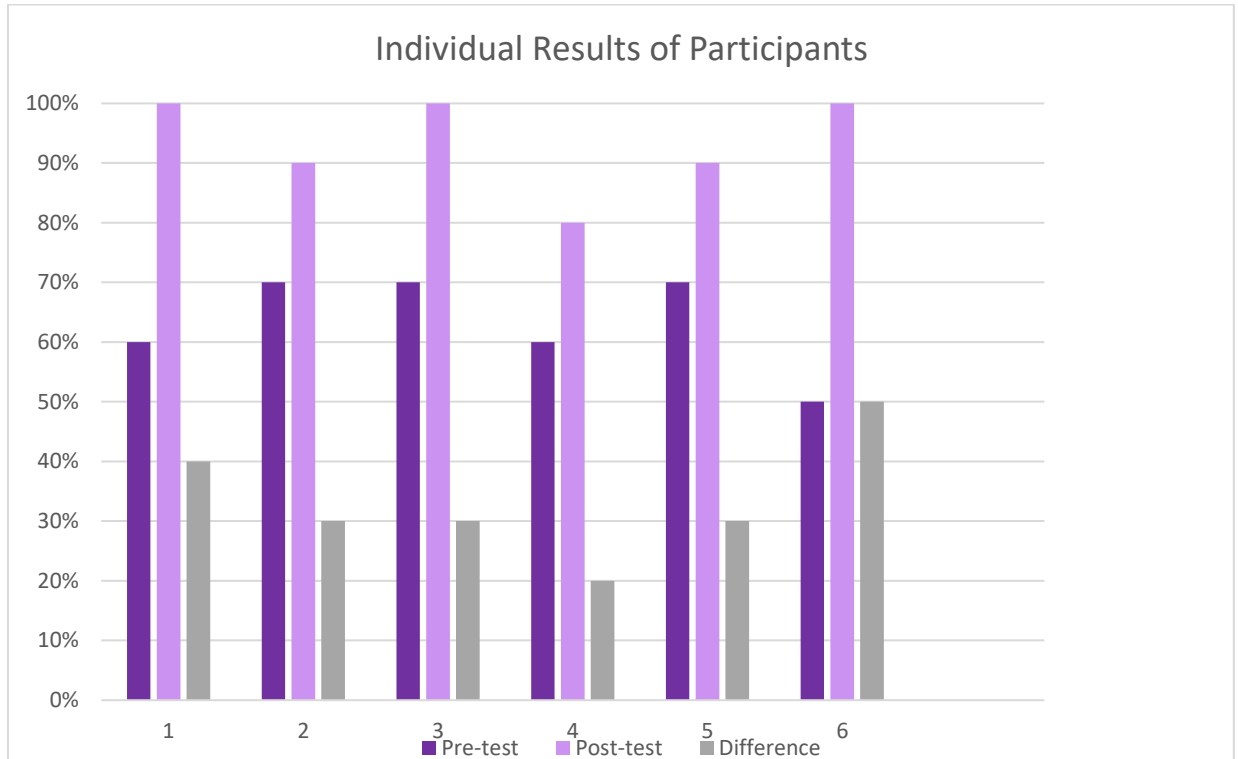
### **Summary of Data**

Overall, most of the pre-test and post- test responses, demonstrated an increase in knowledge base of the participants. Notable knowledge improvements were seen in the participating anesthesia providers' ability to identify some of the challenges faced by the parturient with SLE and identifying the amount of Americans who struggle with the disorder. Additionally, anesthesia providers who participated in the study showed an improvement in their knowledge deficit regarding the systemic studies used in the presentation. The providers who participated were able identify that a higher risk of medically directed deliveries and cesarean section were seen in parturients who presented with SLE. Seven out of 10 post test questions resulted in the correct answer, after viewing the educational presentation.

Graph 1 below shows individual results.



**Graph 1. Individual Results of Participants**



## **IMPLEMENTATION DISCUSSION**

### **Limitations**

Several limitations are identified in this study, including a small sample size and the length of time required for participants to complete the study. Out of the 36 emails sent to anesthesia providers from Anesco North Broward Anesthesia Group, only six participants completed the pre-test and post-test survey. A larger and more diverse sample size would have reflected a more accurate representation of the knowledge of anesthetic management of the SLE parturient during a cesarean section. Additionally, the email recipients were all CRNAs and excluded anesthesiologists. Lastly, participants were given a limited time of 2 weeks to complete the project, and an extended time frame may have increased the response rate.

### **Future Implications for Advanced Practice Nursing**

For many years pregnancy has been contraindicated in patients with SLE, particularly when multisystem involvement was present. Today, pregnancy is no longer considered

impossible in women with lupus. Yet, lupus pregnancies are still considered high-risk. The prognosis has considerably improved for pregnant women but the fetal risk, although progressively reduced, is still higher in pregnancies of patients with SLE than in pregnancies of healthy women. Miscarriage, premature delivery, and preeclampsia, as well as heart problems in the baby are the major complications that can occur. Anesthesia providers' knowledge of SLE and management of parturients during a cesarean section has increased through educational intervention. The principal goal of the management of a parturient with SLE.

Future studies may benefit from understanding anesthesiologists' views and attitudes towards future studies may benefit from the adverse fetal outcome including fetal loss, preterm birth, and SGA increases significantly with SLE flares during pregnancy with preeclampsia/eclampsia, thrombocytopenia, and active SLE serving independent predictors of adverse fetal and maternal outcome. In general, lupus in pregnant population is generally similar to other cohorts. Pregnancies can be successful in most women with SLE. However, an increase in SLE activity can occur in a significant number of patients, even those who are well controlled, as demonstrated by the studies reviewed.

## **CONCLUSION**

Evidence shows that parturients with SLE present with a higher incidence of systemic complications that increases the risk of poorer outcome for both the mother and baby. Anesthesia providers must have a thorough understanding of the clinical implications of SLE, during the obstetric management for a cesarean section, as this will reduce morbidity and mortality for mother and newborn. Systemic Lupus Erythematosus has several disease manifestations that may be exhibited in the parturient during cesarean delivery. The advancements in healthcare, providers now have a better understanding of the maternal- foetal dyad that can present during the management of the lupus mother during cesarian section. The literatures reviewed highlighted that in the presence of highly active lupus; there may be an increase in premature birth and a decrease in live births. Additionally, pregnancies in lupus patients must be closely observed and

treated during all trimesters to improve pregnancy outcomes. Providers are more likely to encounter an increase in pregnant lupus patients and must understand the multisystem nature of the disease, the potential for severe organ involvement, and the drugs that are used in treatment.

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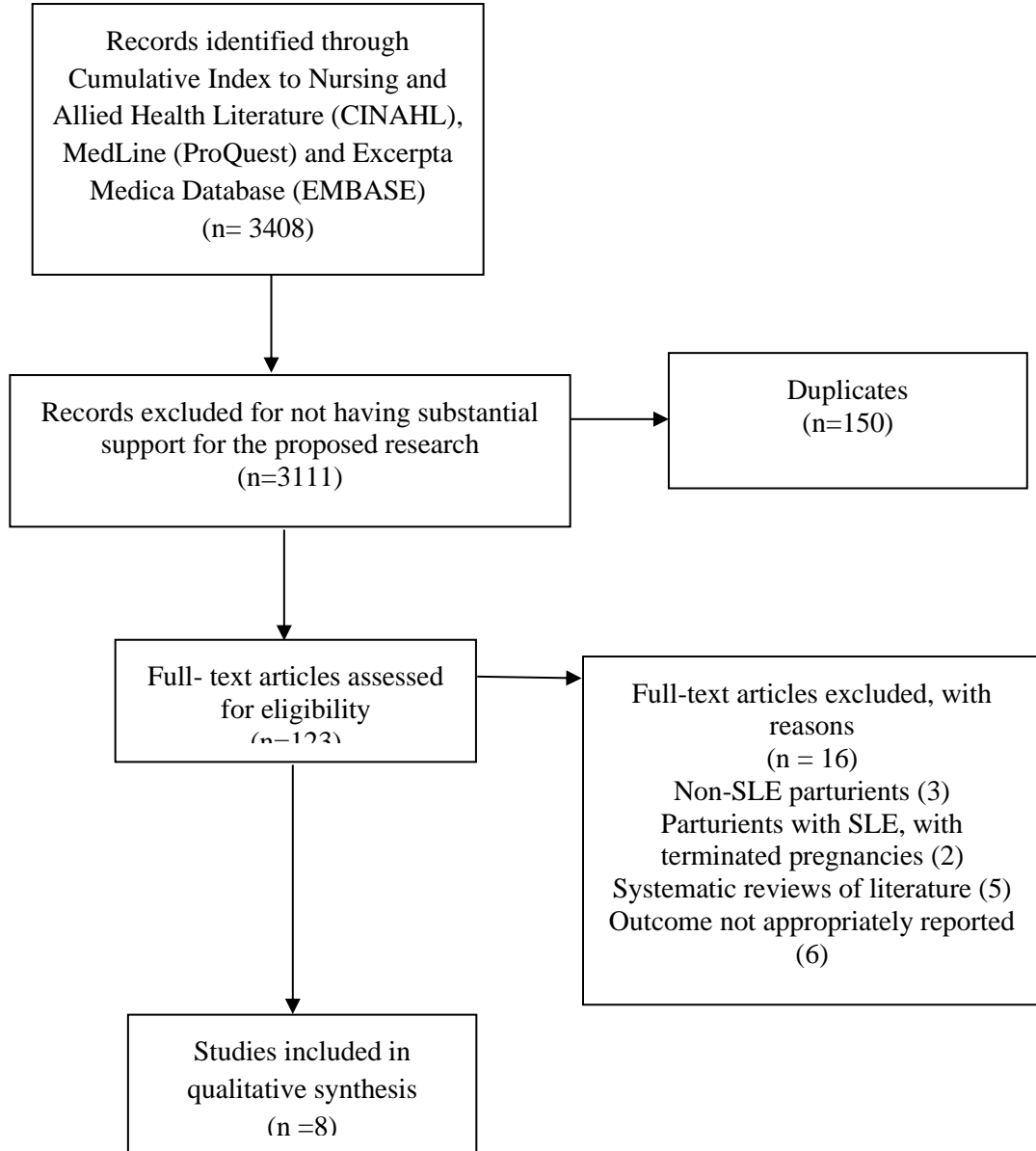


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## Appendix

### Appendix A: PRISMA Flow Diagram

**Figure 1.** PRISMA Flow Diagram



Appendix B: Literature Matrix Table

**Table 3.** Studies Included in the Appraisal

<b>Author (Year) &amp; Type of Study</b>	<b>Study Method, Participants, Interventions, &amp; Setting</b>	<b>Findings</b>
Abdwani et al. (2018)  Retrospective Cohort Study	Maternal and neonatal outcomes of pregnancies in SLE patients.  Pregnancies in health controls were used as the comparison.  The study was conducted in a tertiary hospital in Oman  147 pregnancies  56 (38%) parturients with SLE were involved in the study.  91(61.9%) parturients without SLE	Abortions (42.8% vs. 15.3%; $p < 0.001$ ), Gestational diabetes (28.3% vs. 10.2%; $p = 0.004$ ). Polyhydramnios (7.1% vs. 0.0%; $p = 0.020$ ), Previous preterm pregnancies (8.9% vs. 1.0%; $p = 0.030$ ), Intrauterine growth retardation (21.4% vs. 0.0%; $p < 0.001$ ).
Eudy et al. (2018)  Retrospective Cohort Study	Parturients with SLE and RA prospectively followed until child-birth to assess type of birth and gestational age of infant at time of birth.  The study was conducted in a tertiary hospital in the United States  126 total pregnancies  82 parturients with SLE were involved in the study.  44 parturients with RA	S LE pregnancies had modestly higher rates of preterm birth (24% SLE vs 14% RA), pre-eclampsia (15% SLE vs 7% RA) cesarean delivery (48% SLE vs 30% RA) Majority of preterm births among women with SLE were indicated (70%), commonly for pre-eclampsia or the health of the infant or mother.

Clowse et al. (2005)	Assess all pregnancies in a cohort of lupus patients who were observed prospectively from 1987 to 2002.	229 (85.8%) resulted in a live birth. High-activity lupus occurred in 57 pregnancies (21%). Fewer pregnancies among women with high activity lupus ended with live births (77% versus 88% of those with low-activity lupus; P= 0.063). Full-term delivery was achieved in 15 pregnancies (26%) among women with high-activity lupus. 127 pregnancies (61%) achieving full-term in those with no or mild lupus activity (P < 0.001). High-activity lupus in the first and second trimesters led to a 3-fold increase in pregnancy loss (miscarriages and perinatal mortality).
Retrospective Cohort Study	Study was conducted in the United States.  267 pregnancies in 203 parturients with SLE were evaluated in this study.	
Lui et al. (2012)	Frequency of abnormal pregnancy outcomes, Identifiable laboratory findings and clinical factors that could predict adverse maternal and fetal outcomes among women diagnosed with SLE	There were 23, 2, and 5 elective, spontaneous, and still births, respectively. Live births were reported in 81 of the pregnancies out of which 17% were in the patients with SLE. Preeclampsia/eclampsia (OR ¼ 14.83, 95% CI: 3.83–57.41) and thrombocytopenia (OR ¼ 4.43, 95% CI: 1.12–17.60) were predictors of fetal loss; preeclampsia/eclampsia (OR ¼ 8.04, 95% CI: 2.00–32.34). Preterm birth; preeclampsia/eclampsia (OR ¼ 8.92, 95% CI: 2.25–35.44) were significantly associated with active SLE (OR ¼ 19.90, 95% CI: 2.38–166.27). Thrombocytopenia (OR ¼ 4.03, 95% CI: 1.24–17.25) were significant predictors of maternal SLE flare-up.
Retrospective Cohort Study	The study was conducted in China.  111 Parturients  105 parturients with SLE were involved in the study.	
Mehta, et al. (2019)	Assess nationwide trends and disparities in maternal and fetal complications among pregnant women with SLE	Outcomes improved during those 18 years.  In-hospital maternal deaths (per 100 000 admissions) declined among patients with as well as those without SLE (442 vs. 13 for 1998 to 2000 and <50 vs. 10 for 2013 to 2015),  Decrease was greater in women with SLE (difference in trends, P < 0.002).
Retrospective Cohort Study	Adult pregnant women with and without SLE who had hospitalizations recorded in the National Inpatient Sample (NIS) database between 1998- 2015	

	<p>Study occurred in United States.</p> <p>93 820 parturients with SLE were involved in the study</p> <p>78 045 054 parturients without SLE</p>	<p>The percentage of patients with SLE in all pregnancy-related, as well as delivery-related, admissions increased significantly.</p>
<p>Vyas et al. (2014)</p> <p>Case- Control Study</p>	<p>Management of an antinuclear antibody positive parturient who spinal anesthesia was administered during caesarian section</p> <p>No data analysis conducted</p> <p>A report of the guidelines adhered during the spinal anesthesia</p>	<p>It was identified that the patient had a normal bleeding, clotting, and activated partial thromboplastin time. The baby cried immediately after delivery, had a normal APGAR score, and no signs of neonatal lupus were identified.</p>
<p>Nili et al. (2013)</p> <p>Retrospective Cohort Study</p>	<p>Determine maternal and neonatal outcomes in pregnancies complicated by systemic lupus erythematosus (SLE).</p> <p>Study occurred in Canada.</p> <p>97 parturients with SLE</p> <p>211255 parturients without SLE</p> <p>The study was conducted at an intensive care unit and department of anesthesiology of a healthcare facility.</p>	<p>SLE increased the risks of Caesarean section (OR 1.8; 95% CI 1.1 to 2.8, P = 0.005), postpartum hemorrhage (OR 2.4; 95% CI 1.3 to 4.3, P = 0.003), need for blood transfusion (OR 6.9; 95% CI 2.7 to 17, P = 0.001), postpartum fever (OR 3.2; 95% CI 1.7 to 6.1, P = 0.032), small for gestational age babies (OR 1.7; 95% CI 1.005 to 2.9, P = 0.047), and gestational age <math>\leq</math> 37 weeks (OR 2.1; 95% CI 1.3 to 3.4, P = 0.001). Neonatal death was not shown to be more common in women with SLE (RR 3.05; CI 0.43 to 21.44, P = 0.28).</p>
<p>Kiran et al. (2016)</p> <p>Case- Control Study</p>	<p>Anesthetic management of a parturient with who underwent elective lower segment cesarean section</p> <p>No measurement of data reported</p>	<p>patient's recovery from general anesthesia was not associated with any complications. The patient's vitals were stable and no damage to the organ systems such as the neurological, musculoskeletal, cardiac, renal, hematological, and respiratory systems were identified.</p>

Appendix C: IRB Exception Letter



Office of Research Integrity  
Research Compliance, MARC 414

**MEMORANDUM**

To: Dr. Vicente Gonzalez  
CC: Alicia Bennett  
From: Elizabeth Juhasz, Ph.D., IRB Coordinator *EJ*  
Date: May 21, 2021  
Protocol Title: "Anesthetic Management of the Systemic Lupus Erythematosus Parturient during Cesarean Section: An Educational Module"

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The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the Exempt Review process.

IRB Protocol Exemption #: IRB-21-0180      IRB Exemption Date: 05/21/21  
TOPAZ Reference #: 110157

As a requirement of IRB Exemption you are required to:

- 1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
- 2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
- 3) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

*Special Conditions:* N/A

For further information, you may visit the IRB website at <http://research.fiu.edu/irb>.

EJ



### ADULT CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Improving Provider Knowledge on the Anesthetic Management of the Parturient with Systemic Lupus Erythematosus During a Cesarean Section: A Quality Improvement Project

#### SUMMARY INFORMATION

Things you should know about this study:

- **Purpose:** The purpose of the study is to improve provider knowledge on the anesthetic management of the parturient with systemic lupus erythematosus (SLE) during a cesarean section
- **Procedures:** If you choose to participate, you will be asked to complete a pre-test. After the completion of the pre-test, participants will then attend the classroom style educational session, which is expected to last approximately 20-30 minutes. Four weeks after completing the educational session, participants will be asked to complete the post-test.
- **Duration:** This will take about 1 hour and 10 minutes.
- **Risks:** Participants are not expected to experience any risks, harms, or discomforts though participation in this project.
- **Benefits:** The main benefit to participants include improved knowledge of the pregnancy variances of patients with SLE and the anesthetic management for this population during a cesarean section.
- **Alternatives:** There are no known alternatives available to you other than not taking part in this study.
- **Participation:** Taking part in this research project is voluntary.

Please carefully read the entire document before agreeing to participate.

#### PURPOSE OF THE STUDY

The primary objective of this project is to improve the anesthetic healthcare provider knowledge of the pregnancy complications associated with Systemic Lupus Erythematosus (SLE). The scholarly aim of this study to provide anesthesia providers with an understanding of the multisystemic complications that can arise with the SLE parturient and the effects that they can have on perioperative management during a cesarean section. Upon the completion, participants should have a sound understanding of the disorder and be able to develop an individualized anesthetic care plan that is intended for successful perioperative management of the SLE parturient.

#### NUMBER OF STUDY PARTICIPANTS

If you decide to be in this study, you will be one of 20 people in this research study.

## **DURATION OF THE STUDY**

Participation is expected to span a total of approximately 2 months. The pre-test and post- test assessment are expected to take approximately 15-20 minutes each to complete. The educational session is expected to last approximately 20-30 minutes.

## **PROCEDURES**

If you agree to be in the study, we will ask you to do the following things:

1. Complete a 10-question pre-test.
2. Review a 20–30-minute educational presentation on the management of the parturient with systemic lupus erythematosus during a cesarean section
3. Complete a 10-question post-test.

## **RISKS AND/OR DISCOMFORTS**

The study has the following possible risks to you: Participants are not expected to experience any risks, harms, or discomforts though participation in this project.

## **BENEFITS**

The study has the following possible benefits to you: This study will benefit society by guiding anesthesia health care providers in the successful perioperative management of the SLE parturient during a cesarean delivery.

## **ALTERNATIVES**

There are no known alternatives available to you other than not taking part in this study. Any significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

## **CONFIDENTIALITY**

The records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report, we might publish, we will not include any information that will make it possible to identify you. Research records will be stored securely, and only the researcher team will have access to the records. However, your records may be inspected by authorized University or other agents who will also keep the information confidential.

## **USE OF YOUR INFORMATION**

No identifiable private information is to be collected. Demographic data, including gender, age, ethnicity, and title will be obtained as part of the survey.

## **COMPENSATION & COSTS**

There are no costs to you for participating in this study.

## **RIGHT TO DECLINE OR WITHDRAW**

Your participation in this study is voluntary. You are free to participate in the study or withdraw your consent at any time during the study. You will not lose any benefits if you decide not to



participate or if you quit the study early. The investigator reserves the right to remove you without your consent at such time that he/she feels it is in the best interest.

**RESEARCHER CONTACT INFORMATION**

If you have any questions about the purpose, procedures, or any other issues relating to this research study you may contact Alicia M. Bennett a, (954) 842-9778 or abenn046@fiu.edu.

**IRB CONTACT INFORMATION**

If you would like to talk with someone about your rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

**PARTICIPANT AGREEMENT**

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. I understand that I will be given a copy of this form for my records.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

## Appendix E: Pretest/ Post Test Survey Questions

### INTRODUCTION

The primary objective of this project is to improve the anesthetic healthcare provider knowledge of the pregnancy complications associated with Systemic Lupus Erythematosus (SLE). The scholarly aim is to provide anesthesia providers with an understanding of the multisystemic complications that can arise with the SLE parturient and the effects that they can have on perioperative management during a cesarean section.

Please answer the question below to the best of your ability. The questions are presented in a multiple-choice format and are meant to measure knowledge and perceptions on the anesthetic management of the parturient with SLE, during a cesarean section.

### PERSONAL INFORMATION

1. Gender: Male Female Other\_\_\_\_\_
2. Age: \_\_\_\_\_
3. Ethnicity: Hispanic Caucasian African American/ Black Asian  
Other\_\_\_\_\_
4. Position/Title: \_\_\_\_\_
5. Level of Education: Associates Bachelors Masters  
Other \_\_\_\_\_
6. How many years have you been an anesthesia provide?  
Over 10 5-10 years 2-5 years 1-2 year

## QUESTIONNAIRE

1. Systemic lupus erythematosus is defined as:
  - a. An autoimmune disorder that only targets the respiratory system
  - b. A multisystem autoimmune disorder
  - c. A disorder that only targets the pulmonary and cardiovascular system
  - d. A disorder that does not affect any organ system
2. Some of the challenges faced by the parturient with Systemic lupus erythematosus include:
  - a. Lupus flares
  - b. Venous thromboembolism
  - c. Pre-eclampsia
  - d. All of the above
3. Approximately how many Americans struggle with systemic lupus erythematosus?
  - a. 50,000
  - b. 10,000
  - c. 1 million
  - d. 200,000
4. Systemic lupus erythematosus primarily affect:
  - a. Women older than 75 years
  - b. Women of childbearing age
  - c. Children less than 5 years of age
  - d. Men younger than 25 years
5. Successful anesthetic management of the systemic lupus erythematosus parturient, during a cesarean section relies heavily on:

- a. The gestational age of the baby
  - b. the use of the same anesthetic plan, regardless of patient presentation
  - c. An anesthetic plan that is individually tailored
  - d. The length of the procedure
6. Pulmonary involvement in a systemic lupus erythematosus parturient include:
- a. Pulmonary hypertension
  - b. Pleural effusion
  - c. Alveolar hemorrhage
  - d. All of the above
7. The studies used in this systematic review concluded that systemic lupus erythematosus parturients:
- a. Have higher risk for intraoperative and post-operative blood transfusions
  - b. Have infants with increased morbidity and mortality
  - c. Have a higher risk of medically directed deliveries and cesarean section
  - d. All of the above
8. What can prolong use of glucocorticoids for immunosuppression lead to in a parturient with Systemic lupus erythematosus:
- a. headaches
  - b. osteoporosis
  - c. increased risk of atlantoaxial subluxation
  - d. B & C
9. The principal goal of cardiovascular management in the Systemic lupus erythematosus parturient:
- a. Is to keep blood pressure low, for optimal management.
  - b. Is to optimize flow, and maintain a normal sinus rhythm.
  - c. Allows for high pulmonary vascular resistance (PVR).

d. Ensures that systemic vascular resistance is significantly reduced.

10. Epidural anesthesia for cesarean delivery in the Systemic lupus erythematosus parturient:

a. Can results in sympathetic blockade

b. Has no effect in the parturient

c. Is never a safe option for the parturient

d. Is always a safe option during a cesarean delivery

Appendix F: DNP Project Educational Module PowerPoint Presentation

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## Anesthetic Management of the Systemic Lupus Erythematosus Parturient During Cesarean Section: An Educational Module

Alex Benzeval, BSN  
Florida International University  
Nursing Practice College of Nursing and Health Sciences

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### Learning Goals

After Education you will:

1. Have a better understanding of the high-risk maternal-fetal dyad in Systemic Lupus Erythematosus.
2. Identify the most common clinical presentation of Systemic Lupus Erythematosus parturient.
3. Have an improved understanding of the complications associated with a Systemic Lupus Erythematosus pregnancy.
4. Understand the importance of having a patient-specific anesthetic management plan during cesarean section.

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### Background of Problem

- Systemic lupus erythematosus (SLE) is a lifelong multisystem autoimmune disorder characterized by the presence of autoantibodies directed against a diverse set of self-antigens.
- Due to an increasing childbearing age, the cesarean birth rate for women with SLE is on the rise. This is due to the fact that women with SLE are at a higher risk of complications during the obstetric management of the pregnancy, leading to maternal and fetal morbidity.
- Parturient with SLE are at a higher risk of complications during the obstetric management of the pregnancy for both the mother and fetus.
- Individualized patient care through understanding of the clinical implications of SLE during the obstetric management of a cesarean section, will reduce morbidity, mortality, and readmission.

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### Complications of Systemic Lupus Erythematosus

Maternal SLE	Maternal SLE Complications	Fetal/Infant SLE
Hypertensive Systemic Failure	Pre-eclampsia/Eclampsia	Stillbirth
Thrombocytopenia	Fetal Loss	Maternal Death
Uncontrolled Hypertension	Premature Delivery	Abnormal
Renal Failure	Low Birth Weight Infant	Disability
Pulmonary Hypertension	Deep Vein Thrombosis	Stillbirth
	Pulmonary Embolism	Fetal or Infant Death

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### Systemic Lupus Erythematosus: Other Considerations

- LOSS OF PREGNANCY
- REDUCED FERTILITY DUE TO THE PRESENCE OF ANTI-SL ANTIBODIES
- PRESENCE OF NEUROLOGIC COMPLICATIONS

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### Importance of the Anesthetic Care Plan

- Systemic lupus erythematosus (SLE) is a lifelong multisystem autoimmune disorder characterized by the presence of autoantibodies directed against a diverse set of self-antigens.
- Due to an increasing childbearing age, the cesarean birth rate for women with SLE is on the rise. This is due to the fact that women with SLE are at a higher risk of complications during the obstetric management of the pregnancy, leading to maternal and fetal morbidity.
- Parturient with SLE are at a higher risk of complications during the obstetric management of the pregnancy for both the mother and fetus.
- Individualized patient care through understanding of the clinical implications of SLE during the obstetric management of a cesarean section, will reduce morbidity, mortality, and readmission.

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### Cesarean Delivery for the High Risk Parturient

- Preoperative Planning with Systemic Lupus Erythematosus complications
- Renal Monitoring & Management
- Subcutaneous Clotting Time\*
- Presence of Neuroendocrine Abnormalities (EKG\*) and Lung Abnormalities
- History of Anesthetic Plans
- Antiphospholipid Antibody Syndrome
- Maternal Age associated Complications

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### Anesthetic Cesarean Management: An Overview for Systemic Lupus Erythematosus Parturient Care



- Monitoring during Anesthesia
  - May also need to include blood pressure monitoring for patient with hypertension, chronic treatment, or condition that may flare.
- Fluid Management: Indications with careful prevention
  - Fluids to decrease intracranial pressure should be given with caution (avoiding H<sub>2</sub>O)
- Two orders of compatible blood necessary, prior to cesarean section
- Platelet antiaggregants, cardiovascular drugs, respiratory and coverage
- Administration of reversal of blood thinning agents (e.g. protamine for epidural and spinal anesthesia)
- Close monitoring for both bleeding and thrombotic complications

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### Anesthetic Cesarean Management: Parturient Airway



- Mucosal Ulceration
- Otitis Media/Arthritis
- Laryngeal Pathology
- Temporomandibular Joint Dysfunction
- Epiglottitis
- Vocal Cord Paralysis
- Acute Airway obstruction
- Compression of the recurrent laryngeal nerve
- Restrictive Lung Disease

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### Antiphospholipid Syndrome

- Antiphospholipid syndrome occurs secondary to SLE
- Clinical Characteristics
- Concurrent Antithrombotic Therapy
  - Assess the risk of thromboembolism
  - Assess the risk of operative bleeding

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10

### Role of the Anesthetic Provider

- Extensive Preoperative Assessment
- Detailed History and Physical Examination
- Careful Anesthetic Planning Tailored to the Parturient
- Prudent Intraoperative Monitoring of all Affected Organ Systems
  - Renal, Pulmonary and Cardiovascular Function
- Drug Metabolism in presence of hepatic and renal impairment
- Regional Anesthesia
- Follow-Up During Early Postoperative Period

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### Practice Change

- Increasing frequency of pregnancy in the SLE population
- Increase the effectiveness and efficiency of anesthetic care of the SLE parturient.
- Integrated Team approach

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12

**Summary**

- Pregnancy, in the setting of SLE, remains high-risk, increasing the probability of a caesarean section
- Close monitoring and a prudently individualized anesthetic care plan is essential
- Active disease at conception, is associated with adverse maternal and fetal outcomes
- Specific monitoring and treatment protocols are required in high-risk situations such as presence of anti-fetal antibodies (aPL and anti-Ro)
- Disease flares, pre-eclampsia, fetal loss, prematurity, intra-uterine growth restriction and neurodevelopmental syndromes (including CNS) remain the main causes
- Safe anesthetic care and efficient systemic management goals and should be appropriately used in the presence of the disease for the patient presenting to a caesarean section

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13

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14