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Nosocomial Covid-19 Infection in Women Undergoing Elective Cesarean Sections: A prospective cohort study

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**Short Title:** Postoperative Covid-19 Nosocomial Infection Cesarean Section

Nosocomial Covid-19 Infection in Women Undergoing Elective Cesarean Sections: A prospective cohort study

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**Condensation:** Our prospective study of 111 patients undergoing elective cesarean section showed that no patients developed a Covid-19 infection 6-9 days after hospitalization.

**AJOG at a Glance:**

- There have currently been no studies demonstrating the nosocomial Covid-19 infection rate for patients undergoing elective surgeries.
- We found that if strict peri-operative protocols are maintained there is a 0% infection rate for patients undergoing elective cesarean section to develop Covid-19.
- This study is the first to demonstrate that elective cesarean sections can be performed safely amid the current Covid-19 pandemic.

**Keywords:** Cesarean Section, Covid-19, Nosocomial Infection

Statement of Authorship

Contribution of Authorship: AN: Conception, Planning, Data Analysis, Writing and Editing; MN: Conception, Planning, Writing and Editing; AM: Conception, Planning, Writing and Editing; GLG: Conception, Planning, Writing and Editing; SM: Planning, Data Collection; EM: Conception, Planning, Writing and Editing

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Details of patient's consent: All patient's informed consent was obtained prior to participating in our study.

Details of ethics approval: Northwell Institutional Review Board Approval was obtained on 5/14/2020. IRB # 20-0404.

## **Abstract**

**Background:** The Covid-19 pandemic placed Obstetricians in the difficult position of continuing to perform elective cesarean sections without knowledge of the risk of nosocomial spread of the Covid-19 virus.

**Objectives:** To determine the nosocomial infection rate in women undergoing elective cesarean section at two academic institutions.

**Design:** This non-randomized prospective cohort trial evaluated patients undergoing elective cesarean section during the reopening phase of the Covid-19 pandemic in New York State at two large volume Labor and Delivery Units. Eligible patients with negative pre-operative Covid-19 reverse transcriptase-polymerase chain reaction test and IgG antibody test were re-tested 6-9 days after discharge. The primary objective was the Covid-19 test conversion rate defined as a positive PCR test after discharge with a negative pre-operative test. This was used as a proxy for the nosocomial infection rate.

**Results:** 136 patients were screened for participation. Two patients tested positive for Covid-19 on preoperative testing and 25 declined to participate. 111 patients consented to participate and

96 underwent both preoperative and postoperative testing. No patients with a negative PCR test pre-operatively had a positive PCR test for the Covid-19 virus postoperatively.

Conclusions: With a strict and methodical perioperative and postpartum protocol, we can limit nosocomial Covid-19 infections in women undergoing elective cesarean section.

Keywords: Covid-19, Cesarean Section, Nosocomial Infection

**Introduction:** In response to the Covid-19 outbreak, the U.S Surgeon General, Center for Disease Control (CDC), and surgical societies recommended suspending non-urgent surgical procedures in March of 2020<sup>1-4</sup>. A similar approach was followed worldwide, with an estimated 28 million cases cancelled or postponed<sup>4</sup>. Based on recommendations from the American College of Surgeons<sup>5</sup>, elective surgeries resumed nationwide during the Summer of 2020. During this unprecedented time the incidence of nosocomial infections among those undergoing elective procedures remains unknown. Furthermore, due to their time-sensitive nature, elective cesarean sections were never halted during the Covid-19 pandemic.

The decision to resume and continue elective surgical cases during the pandemic was done at the local level. Hospitals were expected to interpret their counties incidence and capacity for both patients positive and negative for Covid-19 infection and extrapolate their ability to maintain elective operations. As demonstrated by Wu et al., there is not always a clear answer for hospital systems and a hypothetical question of whether to halt or continue elective procedures was met with three differing, but equally plausible responses<sup>6</sup>. Multiple reviews have shown that elective surgeries performed on patients with known Covid-19 infection had significantly worse

perioperative morbidity and mortality<sup>7-8</sup>. Retrospective chart reviews from the height of the pandemic in March and April 2020 suggested that closed units were able to maintain a low rate of nosocomial Covid-19 infection, between 0-2%<sup>9-10</sup>. These trials were done in hospitals that were overwhelmed by the initial Covid-19 surge and isolated patients that tested negative from those that tested positive. Furthermore, the Covid-19 pandemic has had significantly impacted pregnant women worldwide<sup>11-13</sup>. Due to these effects our institution began routinely testing all patients undergoing elective surgeries, including cesarean sections for Covid-19. To our knowledge there has not been a prospective trial thus far to demonstrate the nosocomial Covid-19 infection rate in elective surgeries.

The goal of our study was to determine the Covid-19 test conversion rate in patients undergoing elective cesarean sections. The test conversion rate was used as a proxy for our institutional nosocomial infection rate in surgical patients as it would not be possible to prove that any infections were acquired during the hospital stay.

### **Methods:**

The primary objective of this study was to determine the nosocomial infection rate for women undergoing scheduled cesarean section at a New York academic institution during the Covid-19 pandemic. The study was undertaken from June 26th 2020 and September 4<sup>th</sup> 2020. Patients were assessed for the trial by the research team and operated on by their primary Obstetrician. All patients were required to have a negative PCR for Covid-19 prior to enrollment into the study. If patients agreed to participate, they were then screened with a pre-operative survey to assess for symptoms or exposure to Covid-19 in the 14 days prior to their scheduled cesarean section and

serum Covid-19 IgG antibody test. All enrolled patients underwent their scheduled cesarean section and postoperative care in a private room in a Covid-free postpartum ward.

Patients of any ethnic background undergoing scheduled cesarean section were eligible for the trial if they were age 18 or more, had no prior exposure to Covid-19, symptoms of Covid-19, or positive Covid-19 PCR or serum antibody test. Participants were excluded if they were admitted to the hospital prior to their scheduled cesarean section, were deemed a person under investigation for Covid-19, were taking antiviral medications, had documented immunodeficiency, or had a severe or uncontrolled concurrent medical disease. Once enrolled, patients underwent their scheduled cesarean section and postoperative course and discharge. They then returned for a second Covid-19 PCR test and postoperative survey 6-9 days after discharge. Indications for scheduled cesarean section included repeat cesarean section, primary elective cesarean section, and primary cesarean section for fetal malpresentation.

The primary endpoint of this trial was a positive Covid-19 PCR 6-9 days after discharge from the hospital. This was used as a proxy for the nosocomial Covid-19 infection rate for those undergoing elective surgery during the Covid-19 pandemic. We screened 287 women undergoing same-day admission for an elective cesarean section at two Northwell Health academic institutions during the trial period. This trial was investigator-initiated with no external funding or sponsors. Study data were collected and managed using REDCap electronic data capture tools hosted at Northwell Health. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data

manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources<sup>14, 15</sup>. Confidence intervals were calculated using the Wilson score interval. All statistics were performed using SPSS (IBM Corp. Released 2020. IBM SPSS Statistics for Macintosh, Version 27.0. Armonk, NY: IBM Corp).

### **Results:**

During the trial period a total of 136 patients were approached for participation. Two patients tested positive for Covid-19 on pre-operative testing and 23 patients declined participation. One hundred and eleven women consented to participate in the study. 96 of the 111 women underwent post-discharge Covid-19 PCR evaluation with 15 patients either lost to follow-up or declined the post-discharge PCR evaluation. All 111 patients completed the pre-operative and post-operative survey.

Demographic information are shown in Table 1. The mean age was 34.7 years (range 20.7-49.9). The race and ethnic distribution was as follows: White (52.2%), African-American (12.6%), Asian (18%), Hispanic (0.9%), and Other (16.2%) The majority of patients in our cohort classified themselves as never smokers (94.8%) and only 2 patients reported any pre-pregnancy pulmonary issues (asthma). All patients had regional anesthesia for the procedure with either a spinal block or combined spinal block with epidural catheter placement, and no patients underwent endotracheal intubation. The median hospital stay was 3 days (range 2-5 days). Post-

operatively all patients were admitted to private rooms in a postpartum floor with no Covid-19 positive patients or patients under investigation. The rates of medical comorbidities including obesity, hypertension, diabetes, and asthma were representative of our typical patient population<sup>16,17</sup>.

Results of the pre-operative and post-operative surveys are shown in Figure 1. Pre-operatively no patients reported symptoms or exposure to Covid-19 patients within 14 days of their scheduled cesarean section. Furthermore, no patients gathered in a group of 10 or more people prior to their cesarean section. Post-operatively no patients reported symptoms or exposure to Covid-19 patients, however, four (3.6%) patients reported participating in an event with more than 10 participants. None of the 96 patients tested post-operatively were positive with a 0% test-conversion rate in our patients (95% confidence interval (CI), 0.000-0.039). This rate was used as a proxy for the nosocomial Covid-19 infection rate. Two patients were re-admitted after discharge who tested negative at both their scheduled post-operative PCR appointment and upon readmission to the hospital. There were no readmissions for Covid-19 within 14 days of surgery in our cohort.

## **Discussion:**

### **Principal Findings**

During the last year, the Covid-19 pandemic has changed the way we live our lives and practice medicine. Many hospital guidelines were developed quickly in response to rapidly accumulating



data. Many hospitals were overwhelmed and faced surge capacity and inadequate personal protective equipment. Our study was performed during the initial reopening phase after all New York City elective surgeries were halted during March and April 2020. In order to protect our expectant mothers, our institutional protocol was to test all patients prior to their cesarean section and to isolate all Covid-19 negative patients during their intra-operative and postpartum hospital course. All patients and providers were required to wear masks during any patient encounters.

### **Clinical Implications:**

We were able to demonstrate a zero percent test conversion rate for Covid-19 in women undergoing elective cesarean sections during the New York City reopening phase for elective surgeries. This served as a proxy for our nosocomial infection rate for elective cesarean sections. At the height of the initial wave in New York City, our hospitals ICU and non-ICU beds were over 100% capacity and by the end of our recruitment period only 1.02% of emergency and inpatient admissions were for an active Covid-19 infection<sup>18</sup>. However, by maintaining a strict perioperative and postpartum protocol, we were able to limit any hospital-acquired Covid-19 infections in this population. As many other studies have shown that isolation and universal mask compliance by staff members can decrease infection significantly<sup>19-21</sup>.

The use of a pre-operative and post-operative questionnaire also improved our ability to ensure that any Covid-19 infections were not acquired prior to cesarean section or after discharge. As anticipated, none of our patients were symptomatic or exposed to a Covid-19 patient prior to or after cesarean section. There were four patients that did gather in a group greater than 10 within the perioperative period. None of these patients became symptomatic or converted during the

study period. The decision to limit groups to 10 were based on the New York State and CDC guidelines to limit personal gatherings to under 10 people at the time.

**Research Implications:**

We did not assess the nosocomial rate of infection in unscheduled labor admissions or scheduled inductions of labor. Such data could be beneficial for the management of labor and delivery units during the pandemic. Due to the timing of the study period, we were unable to assess effect of vaccination on nosocomial spread of the Covid-19 virus on Obstetrical patients.

**Strengths and Limitations:**

Strengths of this study include the prospective design to identify any patients that tested positive for Covid-19 within 10-14 days from their elective cesarean section. To our knowledge, this is the first prospectively designed study looking at this topic. The exclusive recruiting of patients undergoing elective cesarean section was intended to create a homogenous population with a typical hospital course of 2-3 days in a Covid-free ward. Limitations include a significant number of patients lost to follow-up or that dropped out after initially consenting to participate in the study. Those that withdrew cited pain during the initial PCR and fear of leaving their house after hospital discharge. To minimize lost patients due to the latter issue, we employed an outpatient home delivery testing service which significantly decreased patients that withdrew from the study. We also used test conversion as a proxy for our nosocomial infection rate due to our innate inability to prove that any infections acquired postoperatively were definitively acquired in the hospital. However, as there were no test conversions we are able to state that there were also no hospital acquired infections.

**Conclusion:**

To conclude, we have found in our study a 0% (95% CI, 0.000-0.039) nosocomial infection rate in women undergoing elective cesarean section during the initial reopening phase of elective surgeries in New York State. We have demonstrated that if a methodical perioperative and postpartum protocol is enacted, then hospitals can successfully protect patients from acquiring Covid-19 infection during elective surgeries. Furthermore, this data can be used to guide the management of elective surgical procedures during future Covid-19 outbreaks or other respiratory and non-respiratory pandemics worldwide. For the future restoration of elective surgery it is essential that we continue to work to employ strategies to limit nosocomial Covid-19 infections.

Disclosure of Interests None of the authors have any financial, personal, political, intellectual, or religious interests to disclose.

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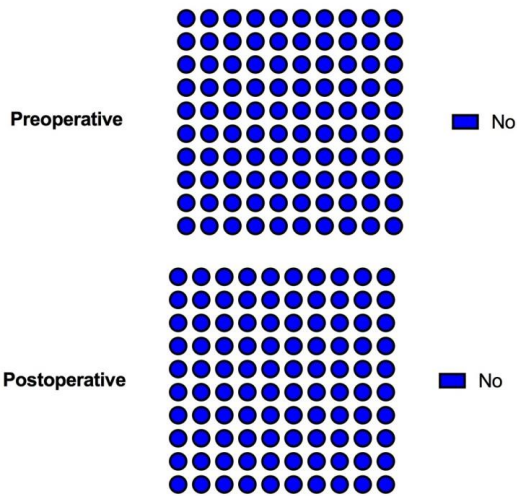
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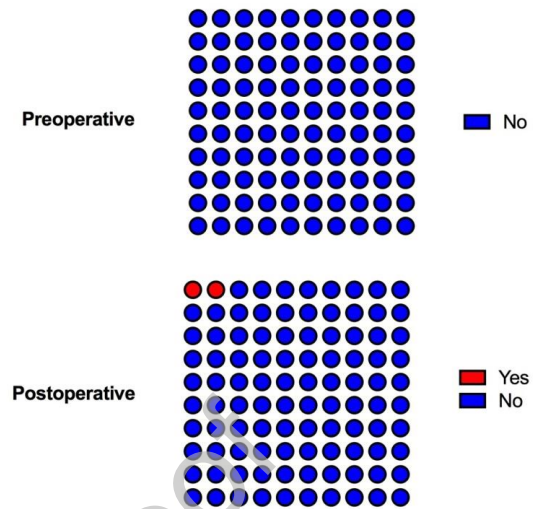
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Figure 1. Results of the Covid-19 Questionnaire in the preoperative and postoperative period.

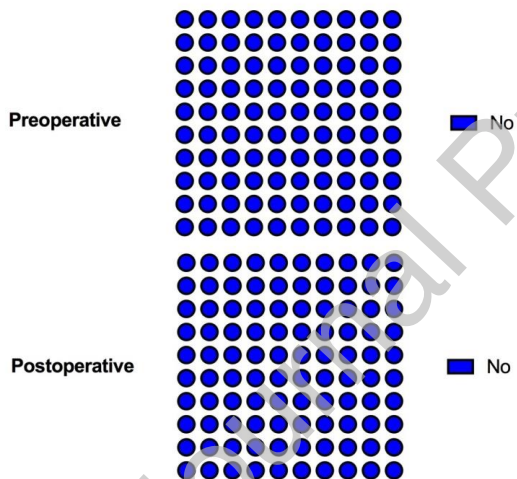
Q1. Recent contact with a Covid-19 patient?



Q2. Recently attending a gathering of 10 or more?



Q3. Recent symptoms of Covid-19



Q4. Recent contact with anyone with symptoms of Covid-19?

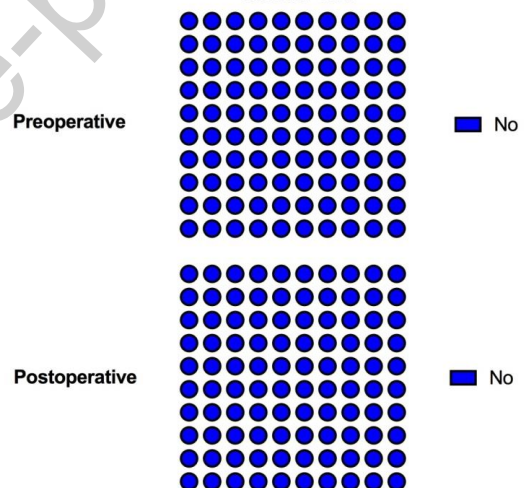


Figure 1. Results of the Covid-19 Questionnaire in the preoperative and postoperative period.

Characteristic	Value (%)
Age (y)	34.7 (20.7-49.9)
Ethnicity	
White	58 (52.2)
African-American	14 (12.6)
Asian	20 (18.0)
Hispanic	1 (0.9)
Other	18 (16.2)
Body Mass Index (range)	33.9 (22.4-58.2)
Hypertension	9 (9.4)
Asthma	2 (1.8)
Diabetes	7 (7.3)
Hypothyroidism	7 (7.3)
Hospitalization (days)	3 (2-5)
14-day Readmissions	2 (1.8)
Positive Covid-19 PCR pre-operatively	0 (0.0)
Positive Covid-19 Serology pre-operatively	0 (0.0)
Positive Covid-19 PCR post-operatively	0 (0.0)

Table 1. Patient demographic information.