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# Universal SARS-CoV-2 polymerase chain reaction screening and assisted reproductive technology in a coronavirus disease 2019 pandemic epicenter: screening and cycle outcomes from a New York City fertility center

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**Objective:** To evaluate the prevalence of coronavirus disease 2019 (COVID-19) and efficacy of a universal screening program in patients undergoing controlled ovarian stimulation (COS).

**Design:** Single-center retrospective cohort study.

**Setting:** Academic fertility center in an epicenter of the COVID-19 pandemic.

**Patient(s):** All patients undergoing COS from June 17, 2019, to February 28, 2021.

**Intervention(s):** Universal COVID-19 screening starting June 17, 2020, with SARS-CoV-2 polymerase chain reaction testing within 5 days of oocyte retrieval, patient-reported symptom screening, and temperature monitoring.

**Main Outcomes Measure(s):** The primary outcome was the number of positive COVID-19 cases in patients undergoing COS cycles. The secondary outcomes were cycle outcomes compared with before COVID-19 COS cycles, adverse outcomes in COVID-canceled cycles, and center-specific COVID-19 detection rates compared with New York City cases.

**Result(s):** From June 17, 2020, to February 28, 2021, 1,696 COS cycles were initiated with only seven positive COVID-19 cases for an overall positivity rate of 0.4%. When compared with before COVID cycles from June 17, 2019, to February 28, 2020, the volume of COS cycles were higher, while the overall cycle cancellation rate was lower during COVID-19. Cycle outcomes including oocyte yield and blast utilization rates were unchanged from pre-COVID cycles. Cases of COVID-19, while very low, occurred more frequently during surges in New York City rates.

**Conclusion(s):** Assisted reproductive technology can be performed during the COVID-19 pandemic utilizing frequent universal screening and safe practices with low SARS-CoV-2 positivity, low cycle cancellation rates, and positive patient outcomes. (Fertil Steril® 2021;116:980-87. ©2021 by American Society for Reproductive Medicine.)

**El resumen está disponible en Español al final del artículo.**

**Key Words:** COVID-19, controlled ovarian stimulation, universal screening



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The first diagnosed COVID-19 case in the United States was reported on January 19, 2020, although serologic reports suggest that it was present earlier (1). New York City (NYC) confirmed its first patient on February 29, 2020, initiating a rapidly expanding epicenter of COVID-19 cases (2). In response, health systems were forced to restructure healthcare delivery in all areas of medicine. Outpatient clinics limited in-person visits and expanded the use of telemedicine (3), while hospitals mobilized resources for advanced critical care. By March 17, 2020, a cumulative total of 923 COVID-19 cases were reported in NYC (4). This coincided with the recommendations from the American College of Surgeons and American Society for Reproductive Medicine for the suspension of new, nonurgent treatments in preparation for the expected increase in COVID-19 cases (5–7). On March 23, 2020, New York Governor Andrew Cuomo issued an executive order for statewide suspension of all elective surgeries and procedures (8). As fertility care is time sensitive, secondary to age-related decline, the delays in treatment provoked by the pandemic heightened the inherent stress and anxiety that already exist in the setting of infertility treatment with several patients rating infertility as their top stressor above COVID-19, employment, and finances during the early pandemic (9). Interestingly, a study by Romanski et al. (10) found no difference in live birth rates from assisted reproductive technology (ART) with a 3-month delay in treatment, possibly alleviating some of these concerns. However, at the onset of the pandemic, it was unclear how long fertility treatments may need to be delayed.

Given this uncertainty, it quickly became clear that clinical practices must evolve to incorporate patient and staff safety protocols to enable timely return to fertility services. Women undergoing ovarian stimulation for in vitro fertilization (IVF) or oocyte cryopreservation require frequent in-person encounters for ultrasound and laboratory monitoring, culminating in a surgical oocyte retrieval (11). Several safety practices and screening time points could be considered: pre-cycle and intracycle COVID screening, contact tracing, pre-visit symptom checks or preprocedure SARS-CoV-2 polymerase chain reaction (PCR) testing. However, while broad recommendations from reproductive societies were suggested, no direct guidelines have been established (12). While there are limited studies evaluating these various screening options in the infertility population, a small study in the early months of the NYC COVID-19 pandemic demonstrated a low incidence of COVID-19 rates and safe resumption of fertility treatments through symptom screening and SARS-CoV-2 PCR testing before starting controlled ovarian stimulation (COS) (13). As more time has elapsed and NYC has experienced a second surge in cases, more data are available to better understand and evaluate ART practices during COVID in terms of cycle cancellation and fertility office COVID-19 prevalence rates to provide patients with actual outcomes, counseling on risks, and expectations about ART treatment during a pandemic.

By June 17, 2020, our center fully operationalized a COVID-19 safety program including universal SARS-CoV-2 PCR screening of all patients undergoing COS. With a large patient population and over 9 months of screening practices,

our objective for this study was to evaluate the prevalence of COVID-19 and efficacy of a COVID-19 universal screening program in patients undergoing COS.

## MATERIALS AND METHODS

### Design

This is a retrospective cohort study of all patients seeking ART at a single academic fertility center in New York City. Institutional Review Board (IRB) approval was obtained by the institution [institution removed for blinded review] (IRB #i13-00389).

### Subjects

All cycles of COS from June 17, 2019, until February 28, 2021, were eligible for inclusion. Cycles were included if stimulation was initiated, regardless of whether an oocyte retrieval was performed. All cycles of patients aged <18 years were excluded.

### COVID-19 Outpatient Safety Program

Our center implemented a three-tier safety program on resuming patient services in the ongoing COVID-19 pandemic: universal patient SARS-CoV-2 screening including mandatory preprocedure PCR testing; revised office protocols to maximize social distancing; and required employee safety protocols. On June 14, 2020, New York State issued mandated guidelines that all office-based surgery practices must perform COVID-19 testing on patients within 5 days of the procedure (14). Effective as of June 17, 2020, as part of Tier 1, every patient at our center underwent screening with SARS-CoV-2 real-time PCR nasopharyngeal swab testing before oocyte retrieval. Patients were instructed to schedule a PCR test on cycle day 9 or 10 of stimulation and then delayed testing if necessary to meet the required window within 5 days of their oocyte retrieval. Patients testing positive for COVID-19 at any time during ovarian stimulation were canceled and prohibited from returning to the office until no longer symptomatic and contagious according to institutional infectious disease guidelines. Patients with a prior positive SARS-CoV-2 PCR test did not require repeat testing if the positive test was <90 days and the patient remained asymptomatic.

As part of Tier 2, all persons entering our facility were screened for COVID-19 symptoms and exposures, and temperatures were taken on presentation. Patients with a temperature above 37.5 degrees Celsius were isolated and evaluated by a physician. Patients with a positive COVID-19 screen or known exposure were required to have SARS-CoV-2 PCR testing with negative result before entry. All patients were offered testing at any time during their cycle and required to acknowledge cancellation if COVID-19 positive before cycle start via consent form.

Moreover, alterations were made to standard monitoring protocols to enable a high volume of patients to safely undergo laboratory and ultrasound visits. Monitoring visits were limited to cycling patients only and were scheduled in 20-minute time blocks, with a cap on the number of patients

per block. Phlebotomy stations and waiting room seats were redistributed for adequate social distancing. When possible, partners were encouraged to collect semen specimen at home as part of COS cycles.

Finally, for Tier 3, all employees were required to perform automated daily symptom checks and temperature screening before entry into our facility. In addition, all staff was required to wear appropriate protective equipment including a surgical mask and face shield for all patient encounters. Contact tracing was performed in the office when a patient or employee tested positive. Employees were offered PCR testing for any concern of exposure and were prohibited from coming to work if they developed any symptoms until a negative PCR test was demonstrated.

## Variables

As aforementioned, the objective of this study was to evaluate both the prevalence of COVID-19 and efficacy of a universal COVID-19 screening program in patients undergoing COS. Safety was defined as low SARS-CoV-2 PCR positivity, low COVID-related cycle cancellation rates, and low adverse outcomes in COVID-positive patients. Safety was determined by comparing cycle outcomes with pre-COVID cycles and analyzing medical and ovarian stimulation-related adverse outcomes in COVID-19-positive patients. Efficacy was defined as the ability to detect cases with our safety program and was evaluated by comparing center rates to New York City rates over the same weekly periods.

The primary outcome of this study was the number and rate of SARS-CoV-2 PCR tests in patient undergoing COS. The secondary outcomes included the following: cycle characteristics, cancellations, and outcomes compared with before COVID cycles; adverse outcomes in COVID-19-positive patients; and center-specific COVID-19 detection rates compared with New York City cases. Patient data was collected from electronic medical records and included demographics, cycle characteristics and outcomes, and COVID-19 testing. New York City COVID-19 case statistics were obtained from publicly available daily case data on [nyc.gov](https://www.nyc.gov), with cases reported as of March 5, 2021.

## Analysis

Statistical analysis was performed in SPSS (v25.0) and included the Mann-Whitney U test, Fisher's exact test, and the Pearson chi-square test, as appropriate. *P* values of <0.05 were considered statistically significant.

## RESULTS

Since the initiation of comprehensive universal SARS-CoV-2 PCR preretrieval screening at our institution on June 17, 2020, until February 28, 2021, 1,696 COS cycles were initiated. Three cycles were excluded from analysis because of patient age of <18 years old. The median patient age was 37 (range, 21–48) years. Most of the patients in this study identified as Caucasian with low representation from Hispanic and Black patient populations. Overall, the patients were healthy with a median body mass index of 23 kg/m<sup>2</sup>, although 25% of

patients were overweight and 13% were obese with a body mass index up to 56 kg/m<sup>2</sup> (Table 1).

Cycles were compared with COS cycles performed a year prior (June 17, 2019, to February 28, 2020) (Table 2). More cycles were started, and fewer cycles were canceled from June 17, 2020, onward, despite the COVID-19 pandemic (*P* < .02). Cycles were primarily IVF, with similar proportions of embryo banking and oocyte cryopreservation for elective and medical indications between time periods (*P* = .19). Cycles were mainly antagonist protocols, with similar total gonadotropin dosage administered in each cohort. Starting follicle-stimulating hormone and estradiol levels varied between years because of a change in the platform used to perform the analysis but were overall as expected. More significantly, cycle outcomes including the number of oocytes and embryos cryopreserved, mature oocytes, and blast utilization rates were similar. As our center primarily employs a freeze-all approach to IVF, the number of fresh embryo transfers was overall low but similar between years.

For the primary study outcome, seven positive COVID-19 PCR tests were identified of the 1,693 COS cycles initiated for a positivity rate of 0.4%. Six patients tested positive before oocyte retrieval and, thus, had their cycle canceled. In general, cycle cancellations were primarily for low response to stimulation in both time periods, with COVID-19 having a slight additional impact (Table 2). The seventh patient tested positive the day after the retrieval. This patient was an asymptomatic healthcare worker, underwent elective testing before travel, and tested negative 4 days before oocyte retrieval. Table 3 details each positive patient's reason for COVID-19 testing if before mandated preretrieval screening, the cycle day and ovarian stimulation level when canceled, and any adverse hyperstimulation or medical outcomes. Two patients were asymptomatic and tested positive on their required preretrieval PCR screen. Four patients requested earlier tests for symptoms or known exposure. One patient (patient 1)

**TABLE 1**

**Patient demographics, controlled ovarian stimulation cycles from June 17, 2020, to February 28, 2021.**

### Patient demographics

Age, years	
Median	37 years
Range	21 to 48 years
Ethnicity (self-reported), number	
Asian	287 (17%)
Black	88 (5%)
Caucasian	1121 (66%)
Hispanic	45 (3%)
Other/multiple	113 (7%)
Unknown	39 (2%)
Body mass index, number	
Underweight (<18.5 kg/m <sup>2</sup> )	70 (4%)
Normal (18.6–24.9 kg/m <sup>2</sup> )	955 (57%)
Overweight (25–29.9 kg/m <sup>2</sup> )	418 (25%)
Obese, class 1 (30–34.9 kg/m <sup>2</sup> )	141 (8%)
Obese, class 2 (35–39.9 kg/m <sup>2</sup> )	53 (3%)
Obese, class 3 (>40 kg/m <sup>2</sup> )	26 (2%)
Unknown	30 (2%)

Shaw. COVID-19 screening in IVF. *Fertil Steril* 2021.

TABLE 2

## Cycle outcomes compared before and during coronavirus disease 2019.

Cycle characteristics and outcomes	Before COVID-19 (6/17/19 to 2/28/20)	During COVID-19 (6/17/20 to 2/28/21)	P value
COS cycles initiated (n)	1,352	1,693	.02
Retrieval performed	1,241 (92%)	1,591 (94%)	
Cycle canceled	111 (8%)	102 (6%)	
Reason for cancelation			.01
Low response	98 (88%)	74 (73%)	
Premature ovulation	8 (7%)	14 (14%)	
Positive COVID-19 PCR		6 (6%)	
Other	5 (5%)	8 (8%)	
Cycle type			.19
In vitro fertilization	858 (63%)	1,142 (67%)	
Elective oocyte cryopreservation	347 (26%)	383 (23%)	
Elective embryo banking	62 (5%)	70 (4%)	
Medical oocyte cryopreservation	29 (2%)	42 (2%)	
Medical embryo banking	23 (2%)	27 (2%)	
Oocyte donation	33 (2%)	29 (2%)	
<b>Cycle characteristics</b>			
Total gonadotropins, median	3,925 IU	3,900 IU	.49
Day 2 FSH, <sup>c</sup> median	6.1 mIU/mL	7.4 mIU/mL	< .01
Day 2 estradiol, <sup>c</sup> median	56 pg/mL	41 pg/mL	< .01
Estradiol on trigger day, <sup>c</sup> median	2,421 pg/mL	2,626 pg/mL	.01
<b>Cycle outcomes</b>			
Total oocytes, median	14	13	.30
Vitrified metaphase II oocytes, <sup>a</sup> median	11	12	.35
Two-pronuclear zygotes, <sup>b</sup> median	7.0	7.0	.58
Vitrified blastocysts, <sup>b</sup> median	3.0	4.0	.63
Blast utilization rate, <sup>b</sup> median	57%	58%	.74
Cycles with fresh embryo transfers <sup>b</sup>	5.1%	4.2%	.33

Note: COS = controlled ovarian stimulation, COVID-19 = coronavirus disease 2019, FSH = follicle-stimulating hormone, PCR = polymerase chain reaction.

<sup>a</sup> Oocyte cryopreservation cycles only.

<sup>b</sup> In vitro fertilization or embryo banking cycles only.

<sup>c</sup> Different laboratory platforms used to evaluate these samples before and during COVID-19.

Shaw. COVID-19 screening in IVF. *Fertil Steril* 2021.

required hospitalization for shortness of breath and received supplemental oxygen but was not intubated and had no known long-term sequelae. No other patient required emergency evaluation or hospitalization. All patients were afebrile with a recorded T max of 37.8 degrees Celsius, including the patient who required hospital admission. Three patients had follicles measuring 14 mm or greater at the time of COVID-19 diagnosis and were triggered with Lupron; none experienced symptoms of ovarian hyperstimulation syndrome.

To further evaluate the efficacy of our universal screening protocol, we compared the incidence of our COVID-19 cases to the incidence of cases in New York City by week (Fig. 1). The weekly positive rate at our center remained low, with a peak of two positive cases in November corresponding to the start of the second surge of cases in NYC and a NYC positive rate of 3%. Positive cases in patients with COS occurred more frequently, although at a rate of one per week, in January and February 2021, when NYC positive rates were

TABLE 3

## Description of controlled ovarian stimulation COVID-19 polymerase chain reaction positive cases.

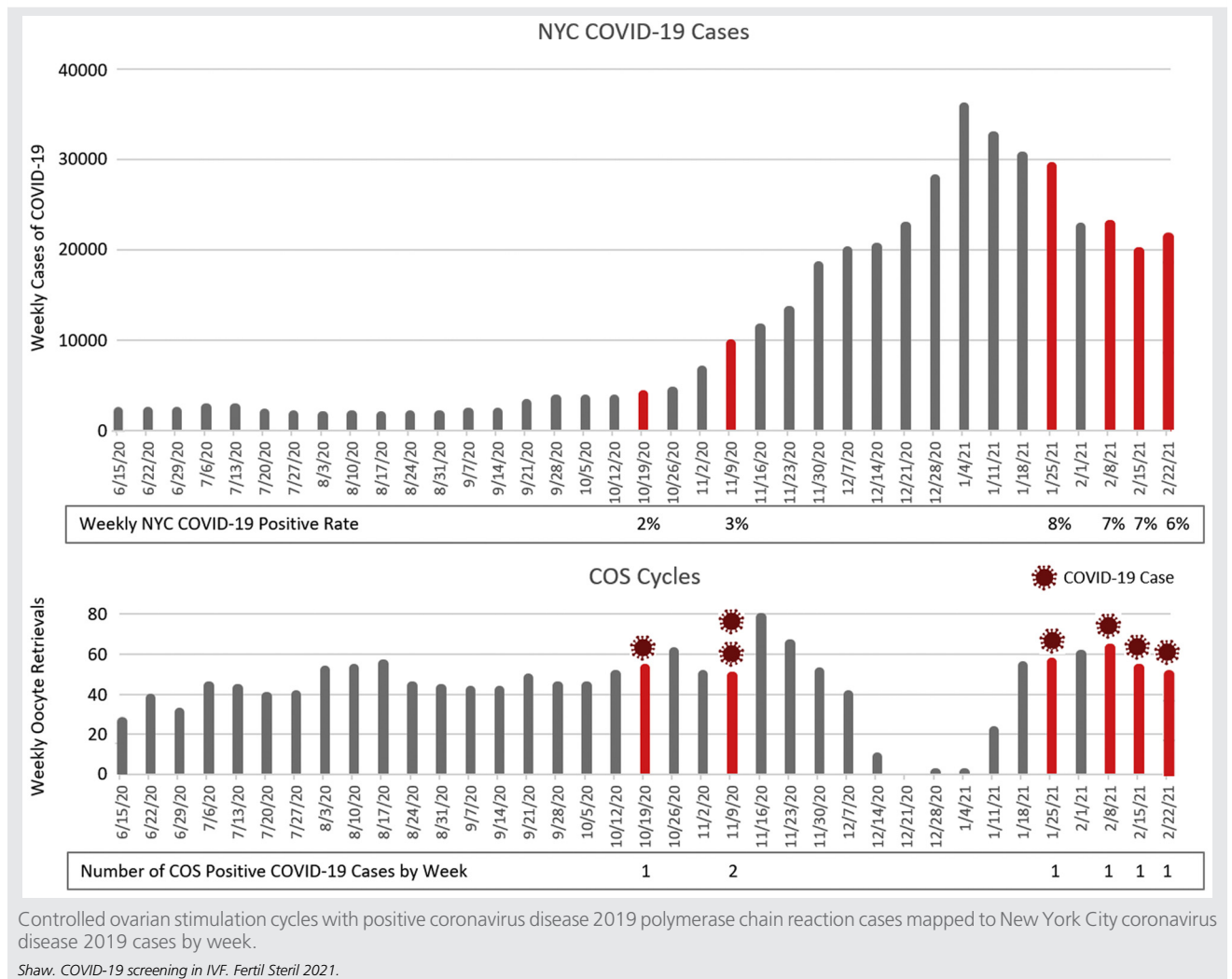
Patient	Reason for COVID-19 test	Cycle day canceled	Lead follicle	Last E2	Trigger required	OHSS symptoms	Severe COVID-19
Patient 1	Congestion; Tmax 37.8 degrees Celsius	5	<10 mm	242 pg/mL	No	No	Yes
Patient 2	Cough; fatigue; Tmax 37.8 degrees Celsius	6	<10 mm	23 pg/mL	No	No	No
Patient 3	Known exposure (asymptomatic)	6	12 mm	119 pg/mL	No	No	No
Patient 4	Headache; congestion; Tmax 37.3 degrees Celsius	9	14 mm	1523 pg/mL	Lupron	No	No
Patient 5	Preretrieval (asymptomatic)	14	18.5 mm	1144 pg/mL	Lupron	No	No
Patient 6	Preretrieval (asymptomatic)	14	21 mm	1172 pg/mL	Lupron	No	No
Patient 7	Personal request after retrieval (asymptomatic)					No	No

Note: COVID-19 = coronavirus disease 2019, E2 = estradiol, OHSS = ovarian hyperstimulation syndrome, Tmax = maximum reported temperature.

Shaw. COVID-19 screening in IVF. *Fertil Steril* 2021.



**FIGURE 1**



5%–8%. It is important to note that the peak of NYC cases during the winter surge occurred during our center’s yearly, prescheduled closure for laboratory maintenance. The distribution of cases in patients with COS at all levels of NYC positive rates suggests that a universal screening program is important even in times of low community rates.

**DISCUSSION**

The COVID-19 pandemic has presented several challenges to patients requiring ART, an essential medical treatment that requires frequent in-person encounters for a safe and effective outcome. This challenge is heightened for patients in urban centers, with higher and denser populations, smaller clinical facilities, and often higher potential exposure with more use of public transportation and apartment dwelling. States, academic societies, governing bodies, and medical institutions have implemented a broad range of COVID-related

screening and testing requirements to reduce transmission and maintain patient safety (15–18). Studies evaluating the effectiveness of these universal screening policies and the COVID-19 infection rates in patients undergoing ART are small or nonexistent. Now, a year into the COVID-19 pandemic and over 8 months with mandatory universal screening, we evaluated the rates of COVID-19 infection in a high volume academic fertility center for all patients undergoing COS. We found that a streamlined universal screening protocol was effective, the COVID-19 positivity rates (and, therefore, cycle cancellation rates) in patients with COS were low, and adverse outcomes in COVID-19-positive fertility patients were infrequent.

Reassuringly, the COVID-19 positivity rate at our center was very low despite a large number of ART cycles. With close to 1,700 cycles, only seven patients tested positive, resulting in a 0.4% overall infection rate, which is significantly below community levels and levels within our hospital system,

including in asymptomatic patients. Our low rates during varying community levels demonstrate the importance of maintaining a universal screening and standardized safety plan at all times. Furthermore, most of the patients who tested positive had an overall benign clinical course with only mild symptoms and no need for emergency evaluation or hospitalization. While cycle cancellation caused disappointment, none of the patients suffered medical complications from cancellation.

The strength of this study is the high number of cycles and SARS-CoV-2 PCR testing available for inclusion representing an active fertility center. Our center's location in NYC, an urban center with dense population, use of public transportation, and smaller clinical facilities, examines COVID-19 rates and screening protocols in a population with arguably higher community exposure risk. We recognize the fortune of access to a reliable PCR tests with a rapid turnaround of <24 h at our intuition. Our center does not require a negative COVID-19 test before cycle start, in which other centers have adopted. Given the low incidence of COVID-19 overall and in asymptomatic patients, this additional test is unlikely to yield significant benefit for a large population.

Our study has several limitations. First, our patient demographics may not apply to all groups, including those at higher risk on the basis of medical comorbidities, socioeconomic status, and race as we had low representation from Hispanic and Black patient populations. Second, COVID-19 positivity was determined per cycle, with a small number of patients cycling multiple times; we do not anticipate that this impacted the positivity rate but does represent a lower number of patients in the study. Third, the study included a single clinic, and the study time period was short with our prescheduled center closure for maintenance overlapping with a surge in cases. While community rates in NYC overall are reported here, we do not report specific neighborhood rates where our patients reside. Furthermore, a portion of our patients were essential workers, but this data was not reliably available to assess the impact of occupation on positivity rates while undergoing COS. While it has been shown that essential workers are at increased risk of testing positive for COVID-19, further study of these patients in the infertility population may help stratify patients at higher risk of infection and/or ART cancellation (19). Additionally, employee rates were not able to be assessed in this study but would be another facet of safety measure that could be analyzed. Reassuringly, contact tracing within employees after notification of a positive patient resulted in no positive COVID-19 diagnoses. Finally, this study does not address long-term outcomes, risks of COVID-19 in pregnancy, or pregnancy outcomes from these or other cycles at our center in this time period.

The efficacy of a universal screening protocol as demonstrated here has several implications. The low positivity rate and cycle cancellation rates may help inform patients deciding to undergo ART in a pandemic and quantify the risks associated with COVID-19. We suggest this screening protocol as a platform for other fertility and high volume outpatient centers to adopt as the pandemic continues. Continued monitoring and evaluation of this protocol as the pandemic evolves will

enable adaptation to maintain patient and employee safety during continued delivery of essential fertility care.

As the COVID-19 pandemic and strategies to combat it with vaccines and improved treatments continue to reduce community rates and disease severity, we are hopeful that societal restrictions and access to routine care will improve. However, the risk of new strains with virus mutations and new surges remain. We have demonstrated that universal screening protocols and safety measures can allow ART cycles to continue during a pandemic, with a low risk of cycle cancellation, low impact on cycle outcomes, and low risk of patient infection.



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**Preselección universal con reacción en cadena de polimerasa del SARS-CoV-2 y técnicas de reproducción asistida en un epicentro de la pandemia por enfermedad debido a coronavirus 2019: resultados de la preselección y ciclos en un centro de fertilidad de la ciudad de Nueva York.**

**Objetivo:** Evaluar la prevalencia de enfermedad por coronavirus 2019 (COVID-19) y la eficacia de un programa de preselección universal de pacientes sometidos a estimulación ovárica controlada (EOC).

**Diseño:** Estudio retrospectivo de cohortes en un único centro.

**Entorno:** Centro académico de fertilidad en un epicentro de la pandemia por COVID-19.

**Paciente(s):** Todos los pacientes sometidos a EOC desde el 17 de junio del 2019 al 28 de febrero del 2021.

**Intervención(es):** Pruebas de preselección universal para COVID-19 desde el 17 de junio del 2020 utilizando reacción en cadena de polimerasa para SARS-CoV-2 dentro de 5 días a la recuperación de ovocitos, preselección de síntomas reportados por la paciente, y monitorización de temperatura.

**Medida(s) de Resultado(s) principal(es):** El objetivo principal fue el número de casos COVID-19 positivos en pacientes sometidos a ciclos de EOC. Los secundarios fueron el resultado de los ciclos comparado con aquellos previos al COVID-19, resultados adversos en ciclos cancelados por COVID, y tasas de detección de COVID-19 específicas del centro comparadas con los casos de la ciudad de Nueva York.

**Resultado(s):** Desde el 17 de junio del 2020 al 28 de febrero del 2021, 1696 ciclos de EOC se iniciaron con solo siete casos positivos de COVID-19 con una tasa global de positividad de 0.4%. Cuando se comparó con los ciclos previos desde el 17 de junio del 2019 al 28 de febrero del 2020 el volumen de ciclos fue más alto, mientras la tasa de cancelación fue más baja durante el COVID-19. Los resultados de los ciclos incluyendo la tasa de recuperación de ovocitos y la de utilización de blastocitos permanecieron invariables comparadas con los ciclos pre-COVID. Los casos de COVID-19, aunque pocos, ocurrieron más frecuentemente durante los picos de las tasas de la ciudad de Nueva York.

**Conclusión:** Las técnicas de reproducción asistida pueden realizarse durante la pandemia de COVID-19 utilizando de forma frecuente la preselección universal y las prácticas de seguridad, con una baja positividad por SARS-CoV-2, bajas tasas de cancelación, y resultados positivos para las pacientes.