

Original Research

ART outcomes during the COVID-19 pandemic

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Abstract

Background: To evaluate whether the ongoing coronavirus disease 2019 (COVID-19) pandemic has had an impact on assisted reproductive technology (ART) outcomes and assess the possible role of geographic differences in the pandemic's trajectory on these outcomes.

Methods: Multi-center retrospective cohort study involving patients who underwent oocyte cryopreservation, *in vitro* fertilization (IVF), embryo cryopreservation, or frozen euploid embryo transfer in 2019 and 2020 at two academic fertility centers located in regionally distinct areas of the US with high coronavirus infection rates. Patients were screened for infectious symptoms, exposure to sick contacts, and fevers, and tested with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) polymerase chain reaction testing within 5 days of oocyte retrieval. The primary outcomes were the number of oocytes retrieved, embryos fertilized, blastocyst or euploid embryos produced in oocyte retrieval and IVF cycles, and rates of embryo implantation, biochemical pregnancy or no pregnancy following frozen embryo transfer (FET). **Results:** We found no consistent significant differences in the number of oocytes retrieved, embryos fertilized, blastocysts or euploid embryos produced at either institution over the study period. Furthermore, we did not detect any differences in FET outcomes, including rates of embryo implantation, biochemical pregnancy, or no pregnancy, at either institution during the study time period. **Conclusions:** There were no significant differences in ART outcomes in patients who received fertility treatment during the pandemic at our centers. Patients and providers can be reassured that with proper testing, sanitizing, and distancing measures, treatments can continue safely during the pandemic without compromising outcomes.

Keywords: oocyte cryopreservation; IVF; embryo transfer; COVID-19; assisted reproduction

1. Introduction

There has been much uncertainty surrounding the potential impact of the coronavirus disease 2019 (COVID-19) virus on human fertility and reproduction. As a result, during the initial stages of the pandemic precautions were taken to limit severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) exposure to patients undergoing fertility treatments. Significant among these was the American Society for Reproductive Medicine (ASRM) moratorium on assisted reproductive technology (ART) therapies and interventions which was initially placed on March 17, 2020, reaffirmed on April 27th, and finally conditionally lifted on May 11, 2020, with guidelines on how to safely resume clinical practice during the pandemic.

These initial concerns were based on the available research at the time. Preliminary reports that angiotensin converting enzyme 2 (ACE2), transmembrane protease serine 2 (TMPRSS), and basigin (BSG), the receptors and modulators employed by COVID-19 to enter and infect cells, are present in male and female urogenital tracts, suggested that reproductive organs may be susceptible to infection [1,2]. Reports of male reproductive hormone dysregula-

tion, as well as decreased sperm quality parameters in patients infected with COVID-19 further suggested a direct viral effect on fertility [3–5]. Additional areas of concern included whether the virus resides in reproductive fluids, potential sexual spread, susceptibility of embryology laboratory workers to infection [6], and potential negative consequences on pregnancy and offspring [7].

There were also other, more indirect, potential effects of the pandemic on fertility. Lockdowns, along with ART treatment suspension, disrupted people's daily lives, careers and family building plans. Fertility patients were negatively affected with multiple reports documenting increased rates of anxiety and depression because of the lockdown and delays in treatment [8,9]. Social isolation also impacted exercise and dietary habits, with a concomitant increase in BMI during the pandemic and decreased adherence to a Mediterranean diet due to the lockdown [10]. In addition, disruption of any routine increases the possibility for errors, especially in systems of exceptional complexity and delicacy. With the pandemic, clinical practices relied more heavily on telemedicine to communicate with patients, and embryology laboratories altered their protocols to adopt precautionary measures to prevent viral spread [11]. Addition-



ally, pandemic related staff shortages have forced medical practices to adapt to new working conditions and resources. Whether these changes have an effect on outcome is unknown.

With these concerns in mind, we sought to clarify whether clinical ART outcomes during the COVID-19 pandemic were different from outcomes prior to the pandemic. As patients undergoing treatment are routinely screened for COVID-19, and retrievals only done in those who test negative, we restricted our analysis to COVID negative patients. Our primary objective was to determine whether there were any differences in oocyte recovery rates, fertilization rates, euploid embryo formation rates, as well as embryo implantation rates during the pandemic.

In order to account for geographical differences among rates of COVID infection, hospitalization, and COVID related death, we analyzed the ART outcomes at two major academic medical centers, located in two large and diverse metropolitan cities. These centers were in very different geographical regions in the US (Northeast and Southwest) with considerably different COVID-19 infection, hospitalization, and death rate trajectories at different times during the pandemic. We compared our objectives using data from both New York University Fertility Center, as well as the Family Fertility Center of Baylor College of Medicine.

2. Material and methods

A retrospective cohort study was conducted with patients who underwent ART at New York University Fertility Center (NYUFC) in New York City, New York, and the Texas Children's Hospital Family Fertility Center (FFC) of Baylor College of Medicine in Houston, Texas.

Patients who underwent cryopreservation, *in vitro* fertilization, or embryo cryopreservation cycles with or without preimplantation genetic testing for aneuploidy (PGT-A) from January 2019 through December 2019, prior to the onset of the COVID-19 pandemic, were separated by institution and month of treatment, and compared to patients who received treatment in the corresponding month from January 2020 through December 2020. All patients for retrievals in 2020 were tested for COVID-19 within 3 days of retrieval day. Patients testing positive were cancelled and did not undergo oocyte retrieval and only patients with negative results advanced to oocyte retrieval. In patients with multiple cycles, only the first treatment cycle was included. Demographics, AMH, numbers of oocytes retrieved, oocytes matured, oocytes fertilized, blastocysts formed, and euploid embryos were compared using Student's *t*-test (alpha level 0.05).

Patients who underwent frozen embryo transfer (FET) of a single euploid embryo at NYUFC and FFC over January 2019 through September 2019 were similarly separated by institution and month of treatment and compared to patients from the corresponding month in 2020. Euploidy

was confirmed by PGT-A. Only the first cycle was used for any given patient. Patients were not tested for COVID prior to embryo transfer but were screened for symptoms, fever, and exposure to COVID-19. Criteria for intrauterine gestation (IUG) were met with the presence of a gestational sac on transvaginal ultrasound (TVUS), whereas a biochemical pregnancy (BCM) was defined as a serum beta human chorionic gonadotropin (B-HCG) level greater than or equal to 5.3 mIU/mL without evidence of an intrauterine gestational sac on TVUS. Absence of either a gestational sac or B-HCG elevation was classified as "no pregnancy" (NP). Demographics were compared using Student's *t*-test and transfer outcomes were compared with contingency Chi Square (alpha level 0.05).

3. Results

We analyzed a total of 4133 treatment cycles. 3511 cycles were performed at NYUFC (1797 from 2019 and 1714 from 2020), and 622 cycles were performed at FFC (348 in 2019 and 274 in 2020). The number of first-time ART cycles performed during the study period at each institution is displayed in Fig. 1.

There were 2467 NYUFC retrieval cycles—1239 from 2019 and 1228 from 2020—as well as 422 FFC retrieval cycles—238 from 2019 and 184 from 2020. Mean patient age, AMH levels, number of oocytes retrieved, number of oocytes fertilized, number of blastocysts formed and number of euploid embryos, are listed in Table 1 for NYUFC and Table 2 for FFC. We did not detect any consistent or meaningful differences in any of those outcomes between the two years at either institution.

At NYUFC, while the number of cycles were remarkably decreased over March and April of 2020 as compared to the prior year, the overall number of cycles between the two years was very similar. There was a decrease in the average patient age in March of 2020, but that difference was not detected in any subsequent months. There were additionally isolated differences in some outcomes, such as an increase in the number of oocytes retrieved in March 2020, and an increase in the number of blastocysts formed in April 2020, but these did not appear in any of the other months. Importantly, there were no differences in the number of euploid embryos throughout any of the months between the two years. The complete NYUFC retrieval results are listed in Table 1.

The retrieval results were similar at FFC. There were no cycles performed during April 2020 at FFC, only one primary cycle in May 2020, and overall, fewer cycles performed over 2020 when compared to 2019. There were sporadic, and contradictory, significant differences in the number of euploid embryos and fertilized oocytes between the two years. In August and September of 2019 more euploid embryos were formed, as compared to 2020, but the reverse was true when comparing November, with greater numbers of euploid embryos in 2020 as compared to 2019. Similarly,

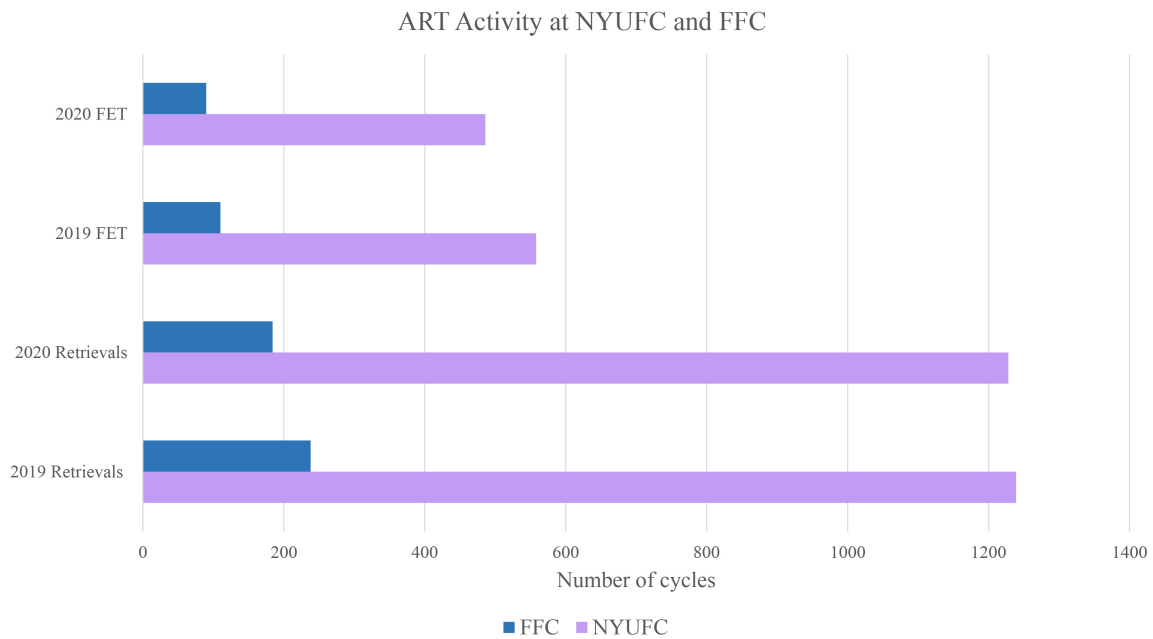


Fig. 1. ART Activity at NYUFC and FFC. The number of retrieval and FET cycles performed at NYUFC and FFC in 2019 and 2020 during the study period.

Table 1. Retrieval Results at NYUFC.

	Year	N	Age	AMH	#Oocytes	#Fertilized	#Blasts	#Euploid
January	2019	169	36.9 ^a	2.8	15.2	6.7	3.4	2.1
	2020	150	35.9 ^a	2.9	16.7	6.5	3.5	2.4
February	2019	133	36.3	2.7	16.1	7.3	3.8	2.7
	2020	127	36.7	2.8	18.0	7.7	3.8	2.5
March	2019	124	36.7 ^b	2.3 ^c	13.8 ^d	5.5	3.0	2.2
	2020	59	35.1 ^b	3.4 ^c	15.5 ^d	5.3	3.0	3.0
April	2019	113	36.4	2.8	16.8	6.2	2.9 ^e	2.2
	2020	25	36.0	2.7	17.7	9.0	5.4 ^e	3.6
May	2019	96	36.4	2.9	17.7	7.3	4.0	2.9
	2020	101	35.7	2.9	16.6	7.0	4.0	2.2
June	2019	115	36.3	2.6	16.4	5.9	3.3	2.5
	2020	108	36.1	2.8	16.1	6.1	3.0	2.3
July	2019	101	36.3	3.4	17.0	6.2	3.0	2.4
	2020	120	36.7	2.7	17.3	7.3	4.0	2.4
August	2019	31	36.6	3.7	19.0	5.0	2.7	2.6
	2020	134	35.6	3.1	17.8	7.5	4.2	2.8
September	2019	113	36.4	3.5	17.6	7.9	4.2	2.9
	2020	110	36.0	3.3	17.5	7.9	4.1	2.5
October	2019	105	35.4	3.2	17.4	7.0	3.7	2.7
	2020	133	36.3	3.2	15.8	5.9	3.6	2.7
November	2019	134	36.8	3.4	17.7	8.1	4.0	2.7
	2020	157	36.3	3.1	17.5	6.2	3.2	2.4
December	2019	5	35.2	5.9	19.2	-	-	-
	2020	4	31.5	4.3	30	7	1.3	1

^a $p = 0.030$, ^b $p = 0.015$, ^c $p = 0.037$, ^d $p = 0.017$, ^e $p = 0.019$.

Table 2. Retrieval Results at FFC.

	Year	N	Age	AMH	#Oocytes	#Fertilized	#Blasts	#Euploid
January	2019	22	37	4.6	16.9	9.5	4.8	1.9
	2020	21	37	3.1	13.3	7.0	3.2	2.2
February	2019	19	35	2.8	13.0	8.1	3.5	2.1
	2020	30	34	4.1	20.1	11.0	6.6	3.7
March	2019	26	34	4.1	23.2	10.8	5.6	4.4
	2020	11	35	2.4	18.6	8.0	2.6	2.5
April	2019	16	35	3.0	19.4	11.4	6.0	2.9
	2020	-	-	-	-	-	-	-
May	2019	32	35	3.4	12.8	7.5	3.7	2.5
	2020	1	-	-	-	-	-	-
June	2019	18	34	4.6	16.7	9.9 ^a	5.2	1.9
	2020	30	35	3.5	14.0	6.5 ^a	3.2	2.1
July	2019	13	36	3.7	14.8	8.2	4.2	1.3
	2020	11	33	4.4	17.9	10.2	4.8	2.6
August	2019	26	34	4.7	20.1	10.6	4.9	3.5 ^d
	2020	16	36	3.3	14.8	6.8	3.3	1.6 ^d
September	2019	10	35	4.2	24.5	17.3	10.3	5.8 ^e
	2020	14	36	4.2	20.3	10.0	5.0	1.9 ^e
October	2019	26	34	3.7	14.8	7.1 ^b	3.6	1.8
	2020	25	35	4.3	19.0	10.7 ^b	5.3	2.4
November	2019	24	36	3.1	13.0	6.4	3.2 ^c	1.4 ^f
	2020	20	35	3.9	16.7	9.8	4.9 ^c	3.0 ^f
December	2019	6	34	1.7	15.3	4.8	3.0	2.0
	2020	6	33	2.2	12.3	4.8	3.0	2.0

^a $p = 0.037$, ^b $p = 0.039$, ^c $p = 0.047$, ^d $p = 0.28$, ^e $p = 0.0069$, ^f $p = 0.031$.

contradictory results were found in the number of fertilized oocytes, with greater numbers of fertilized oocytes in June 2019 and October 2020, as compared to their respective comparative months. Presumably these differences were due to a smaller sample size. The complete FFC retrieval results can be found on Table 2.

We compared FET outcomes from January through September in 2019 and 2020. There were 1044 FETs with PGT-A at NYUFC over that time—558 in 2019 and 486 in 2020. 168 transfers in 2019 and 160 transfers in 2020 did not have PGT-A and were therefore not included. At FFC, there were 200 PGT-A FET's—110 in 2019 and 90 in 2020. 25 transfers in 2019 and 20 transfers in 2020 did not have PGT-A and were thus not included.

There were decreased numbers of FETs performed over March and May of 2020 and no transfers performed during the month of April 2020 at NYUFC. There were notably fewer transfers completed over the nine-month period in our study, as compared to the corresponding period in 2019. There were no significant differences in mean patient age between the two years. Importantly, there were no differences seen in the number of clinical or biochemical pregnancies over the study period ($X^2 = 14.6$, DF 16, $p > 0.05$). Post-hoc analysis comparing outcomes in the

combined months of March, April and May, as well as the combined nine-month period, between the two years similarly did not reveal any significant differences in outcomes ($X^2 = 0.04$ DF 2 and $X^2 = 1.68$ DF 1 respectively, $p > 0.05$). Complete FET results for NYUFC are displayed in Table 3 and Fig. 2.

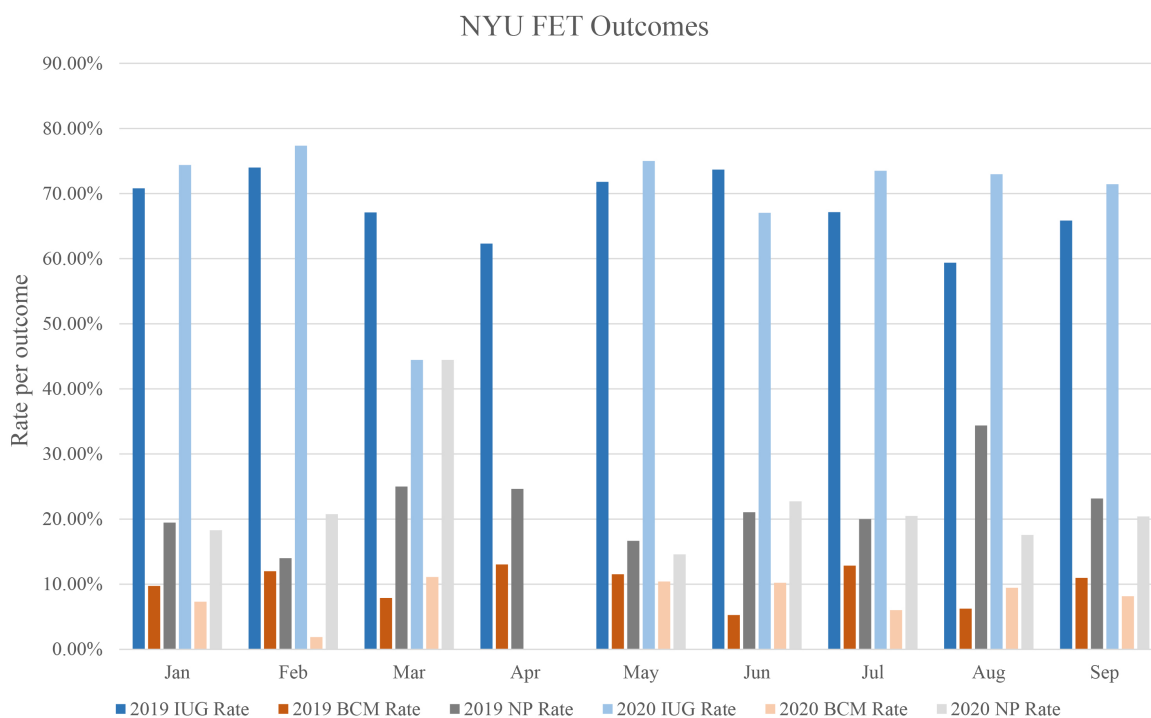
FET results were similar for FFC over this time period. There were no transfers over April and May 2020, and fewer transfers over the entire nine-month period in 2020 as compared to 2019. Mean patient age was significantly lower for June 2019 as compared to June 2020 (33.5 vs. 36.9, $p = 0.04$). There were no differences noted in outcomes following FET's between individual months over this nine-month period, over the combined months of June, July and August, or over the combined nine-month period ($X^2 = 10.81$, 0.45 and 0.65 respectively, DF 16, 2, 1 respectively, $p > 0.05$). Complete FET results at FFC for this time period are reported in Table 4 and Fig. 3.

4. Discussion

Much has changed with the onset of the COVID-19 pandemic, including the uncertainty regarding the reproductive implications of the virus. We evaluated treatment outcomes at two large, geographically diverse academic

Table 3. FET Outcomes at NYUFC.

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Total
2019 Total Cycles (N)	113	50	76	69	78	57	70	32	82	558
2020 Total Cycles (N)	82	53	9	0	48	88	83	74	49	486
2019 IUG Rate (%)	70.8	74.0	67.1	62.3	71.8	73.7	67.1	59.4	65.9	69.2
2020 IUG Rate (%)	74.4	77.4	44.4	-	75.0	67.1	73.5	73.0	71.4	72.2
2019 Biochem Rate (%)	9.7	12.0	7.9	13.0	11.5	5.3	12.9	6.3	11.0	9.9
2020 Biochem Rate (%)	7.3	1.9	11.1	-	10.4	10.2	6.0	9.5	8.2	7.8

**Fig. 2. NYU FET Outcomes.** The primary FET outcomes (IUG, BCM and NP) at NYUFC are displayed in bars for both 2019 and 2020 during the study period.**Table 4. FET Outcomes at FFC.**

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Total
2019 Total Cycles (N)	14	15	5	14	11	11	18	14	8	110
2020 Total Cycles (N)	18	12	4	0	0	13	15	13	15	90
2019 IUG Rate (%)	28.6	46.7	80.0	78.6	54.6	54.6	66.7	64.3	87.5	40.0
2020 IUG Rate (%)	55.6	58.3	75.0	-	-	53.9	60.0	53.9	66.7	33.3
2019 Biochem Rate (%)	14.3	26.7	0.0	0.0	0.0	18.2	11.1	14.3	12.5	6.7
2020 Biochem Rate (%)	16.7	25.0	0.0	-	-	23.1	13.3	7.7	13.3	6.7

ART centers prior and during the COVID-19 pandemic. Both states were severely affected by COVID-19, with high infection and hospitalization rates, but were affected at different times throughout the course of the pandemic [12] (Fig. 4). New York experienced its first wave of COVID-19 earlier on in the course of the pandemic, over the months of March, April and May, while Texas had its first major outbreak later on over July, August, and September.

Despite these differences in the pandemic's trajectory, we found no differences in ART outcomes while undergoing treatment during the pandemic at either study site. Our retrieval data shows that there were no differences in retrieval outcomes for cycles performed during the pandemic in COVID negative patients. While we don't have data yet on what the likelihood embryos from these cycles will reach pregnancy is, as the majority were freeze cycles, we do show that all retrieval outcomes remained unaffected by

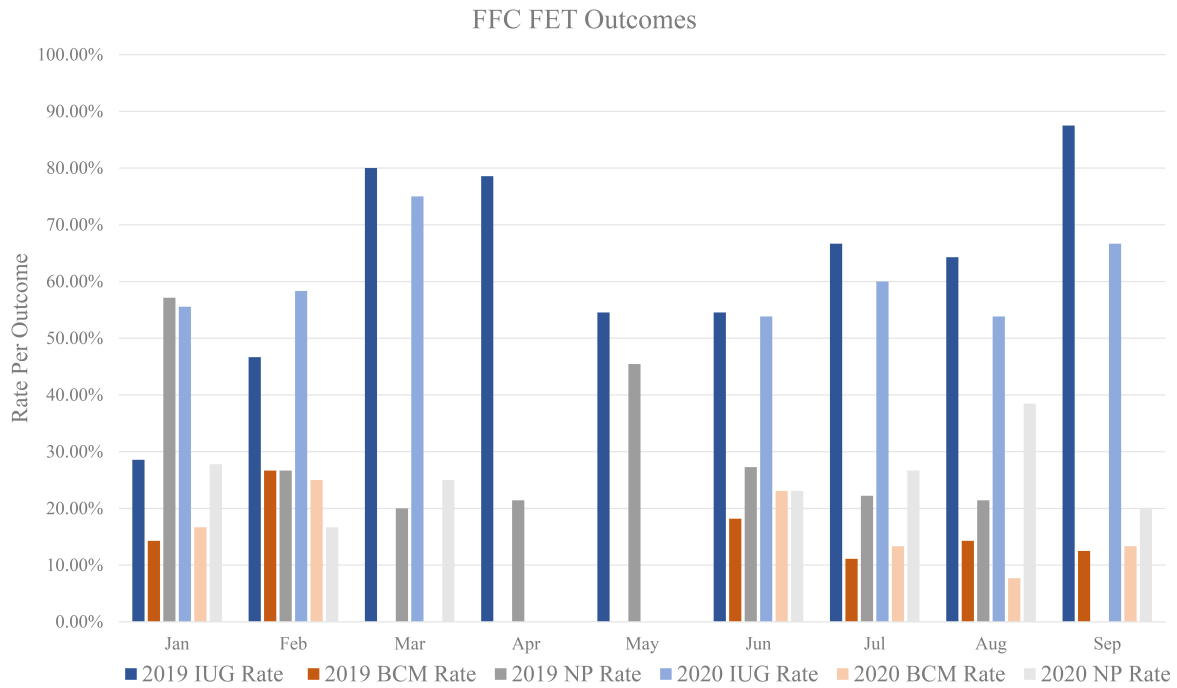


Fig. 3. FFC FET Outcomes. The primary FET outcomes (IUG, BCM and NP) at FFC are displayed in bars for both 2019 and 2020 during the study period.

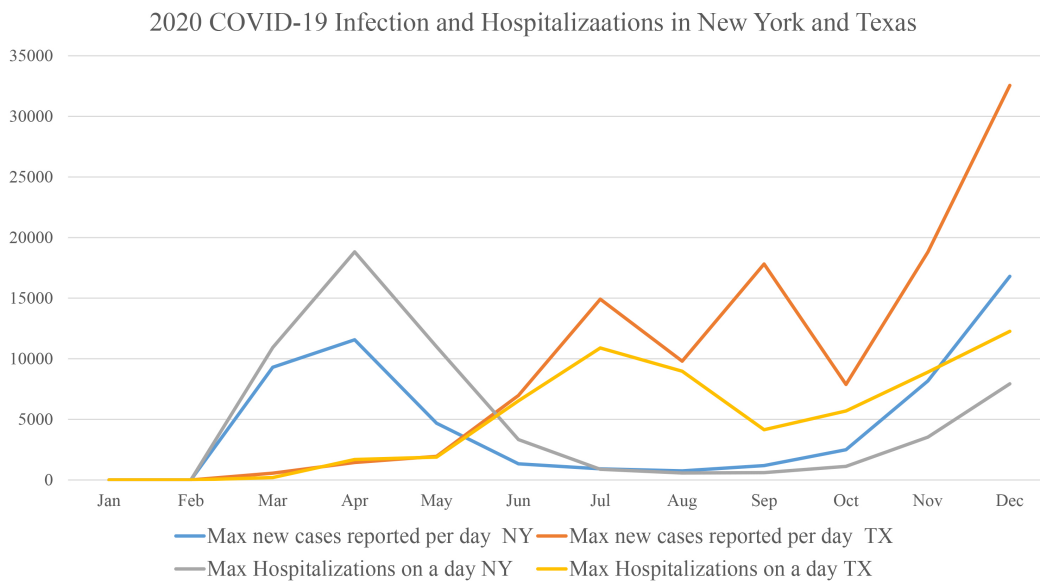


Fig. 4. 2020 COVID-19 infections and hospitalizations. The maximum number of new cases or hospitalized patients of COVID-19 on any given day in each month are represented. Data was retrieved from The COVID Tracking Project.

the pandemic. We also show that outcomes following FET transfers were similarly unaffected by the pandemic. Our study provides information to both providers and patients regarding the safety and success of fertility treatments in the current COVID-19 era and is in agreement with the ASRM COVID-19 Task Force recommendations regarding treatment [13]. It also provides reassurance to couples attempting pregnancy naturally during the pandemic regarding the safety and efficacy of doing so.

Our results are consistent with research that confirmed the absence of viral products or contamination in embryology lab specimens from COVID negative patients [14]. Additionally, a small case reports suggest that the virus is not present in oocytes of COVID positive patients [15], or in semen of COVID recovered patients [16,17], but additional research is necessary.

Enhanced social distancing precautions were in place at both study site locations and included requiring patients

to wear masks while onsite, promoting patient distancing in the waiting room, requiring patients be scheduled appointments for routine monitoring and ultrasounds, utilizing telemedicine appointments when possible, screening for symptoms and exposure prior to visits, and requiring COVID testing by PCR antigen within three days of retrieval. Patients who tested positive did not undergo retrieval and the cycle costs (aside from medications) were credited towards the next cycle. FET cycles did not undergo COVID testing prior to transfer. Rooms and ultrasound devices were disinfected per pre-existing policies. In addition, staff were required to wear masks and shields, and work offsite if possible. Enhanced laboratory cryopreservation techniques as put forth by ASRM and ESHRE, such as sperm washing, sperm swim up, density gradient centrifugation and closed/sealed vitrification techniques, also help minimize viral contamination during storage and are an important component of minimizing viral spread [18].

Data from NYUFC recently demonstrated the efficacy of these measures in screening and safely caring for patients. Of the 1696 cycles initiated over approximately one year, only 7 tested positive for COVID, for an overall infection rate of 0.4% [19]. Similarly, at FFC there was only one positive COVID-19 patient over the study period.

A strength of our study was the assessment of ART outcomes at varied times during the pandemic and in two distinct geographical locations and clinics. We found that in both of these regions, with their unique COVID-19 disease trajectories, and in both of these unique fertility centers, ART outcomes remained unaffected throughout the 2020 year regardless of the level of severity of the pandemic (Fig. 4).

Limitations of our study include its retrospective nature, as well as having included only retrieval patients who tested negative for COVID-19. While this is the population in which there is the most practical clinical relevance, as patients who test positive for infection are not routinely started on fertility treatment, it would be very valuable to know whether there are any differences in clinical outcomes in such patients as that would help further elucidate any potential direct effects infection with COVID-19 may have on fertility. Our study does, however, provide information on the general population likelihood for treatment success during the ongoing COVID-19 pandemic and any potential indirect effects the pandemic may have had on fertility outcomes, including patient's attitudes on COVID and their fertility goals, their self-selection for treatment, as well as their lack of recent COVID-19 infection and exclusion from treatment.

Another population that deserves additional investigation, and that our study was not designed to adequately assess, are those who recently recovered from COVID-19 infection. It is likely that within our COVID-19 negative population, there was a proportion of patients who were actually recovered from either symptomatic or asymptomatic COVID-

19, and it would be important to determine whether there were any lingering effects on their reproductive outcomes. One additional area of further research is to evaluate pregnancy outcomes following FET's of embryos formed during the pandemic. While we show that retrieval and FET outcomes are each independently unchanged during the pandemic, we do not yet have data on FET's of embryos produced during the pandemic.

5. Conclusions

We demonstrate reassuring ART outcomes despite the presence of the COVID pandemic. These results are valuable to facilitate treatment related decisions particularly as it relates to reproductive timing.

Author contributions

IC, LM, WG, JG and FL designed the research study. IC and MC performed the research. IC and DM analyzed the data. IC wrote the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

All procedures and analysis performed were with informed consent and in accordance with the ethical standards of the Institutional Review Boards at NYU Langone Health (IRB #H13-00389) and Baylor College of Medicine (IRB #H-39094), and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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Conflict of interest

The authors declare no conflict of interest.

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