Incidence of first trimester pregnancy loss in the infertile population during the first wave of the coronavirus disease 2019 pandemic in New York City

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Objective: To describe the incidence of first trimester clinical pregnancy loss in the infertile population during the first wave of the COVID-19 pandemic in New York City.
Design: Web-based cross-sectional survey.
Setting: New York City-based academic reproductive medicine practice.
Patient(s): A total of 305 infertile patients with a confirmed intrauterine pregnancy in their first trimester between December 1, 2019, and April 1, 2020, were matched by age and treatment type to pregnant patients from the year prior.
Intervention(s): None.
Main Outcome Measure(s): First trimester clinical pregnancy loss rate.
Result(s): In total, the first trimester pregnancy loss rate was lower in the COVID-19 era cohort compared with that in the pre-COVID-19 era cohort (11.9% vs. 20.1%). There was no difference between cohorts in the pregnancy loss rate of women conceiving via fresh embryo transfer (19.6% vs. 24.4%) or via frozen embryo transfer with preimplantation genetic testing (5.4% vs. 9.5%,). In women conceiving via frozen embryo transfer without preimplantation genetic testing, the pregnancy loss rate was statistically lower in the COVID-19 group (12.5% vs. 24.5%). There was no difference in the pregnancy loss rate by treatment type when stratifying by COVID-19 testing or symptom status. Of the 40 (13.1%) patients with a pregnancy loss, there was no difference in self-reported COVID-19 symptoms or symptom type compared with results in those who did not experience a pregnancy loss.
Conclusion: Despite patients expressing significant worry about COVID-19 and pregnancy, our data provides reassuring information that the first trimester pregnancy loss rate is not elevated for women conceiving via assisted reproductive technology during the global COVID-19 pandemic. (Fertil Steril Rep® 2021;2:209–14. ©2021 by American Society for Reproductive Medicine.)
Key Words: COVID-19, pandemic, miscarriage, assisted reproduction, first trimester pregnancy loss

Discuss: You can discuss this article with its authors and other readers at https://www.fertstertdialog.com/posts/xfre-d-21-00006

Coronavirus disease 2019 (COVID-19) is a global pandemic caused by the novel coronavirus SARS-CoV-2. The virus was first detected in early December 2019 in China and has rapidly spread throughout countries around the globe. On March 1, 2020, the first case of COVID-19 disease was reported in New York City, and as of November 2020, over 12×10^6 cases have been recorded in the United States (1). While the pandemic continued to grow, women with infertility continued to seek and access assisted reproductive technology (ART) to conceive, albeit with enhanced precautions and counseling (2). A primary concern of women and clinicians alike is how COVID-19 may impact pregnancy and, specifically, whether the potential risks warrant delaying pregnancy until the pandemic has subsided.

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Data from the Centers for Disease Control have suggested that pregnant women with symptomatic COVID-19 are at a significantly higher risk of intensive care unit admission, intubation, extracorporeal membrane oxygenation, and death compared with their nonpregnant counterparts (3). The reasons for this are likely multifactorial, including physiologic changes related to pregnancy, a shift away from cell-mediated immunity, and an elevated risk for thromboembolic events (4). However, the impact of COVID-19 on early pregnancy, specifically the risk of pregnancy loss, is not well described (5, 6).

Given the ongoing COVID-19 pandemic, information about early pregnancy risk for women conceiving through ART is essential, as additional delays in access to treatment may be expected. The objective of our study is to report the incidence of first trimester pregnancy loss in a cohort of infertile women conceiving via ART during the COVID-19 pandemic and compare this rate with that of a prepandemic historical cohort. Furthermore, we will characterize their experience with COVID-19 symptoms and testing during the first trimester as well as their perceptions of how COVID-19 may impact their reproductive health.

MATERIALS AND METHODS

Study Population

All patients undergoing fresh embryo transfer, frozen embryo transfer (FET), ovulation induction, or natural cycle monitoring at the Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine during the study period were reviewed. Patients in the FET group were further stratified on the basis of whether preimplantation genetic testing (PGT) was performed. Patients were included if they had confirmation of an intrauterine pregnancy (presence of at least one gestational sac) between December 1, 2019, and April 1, 2020. These dates were chosen to include women who were in their first trimester of pregnancy during and in the weeks leading up to the first confirmed case of COVID-19 in New York City on March 1, 2020, as it is believed that SARS-CoV-2 cryptic transmission may have started as early as December 2019 (7). Patients were excluded if they did not complete the electronic survey in its entirety (n = 21), if they were later found to have a cornual ectopic pregnancy (n = 1), or if they underwent an elective termination of pregnancy for fetal anomalies (n = 3).

Survey

A 36-question survey (Supplemental material, available online) was distributed and data were collected using REDCap electronic data capture tools hosted at Weill Cornell Medicine (8, 9). REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies. The survey consisted of multiple-choice questions about COVID-19–related symptoms, testing, and disease course/severity. Additionally, the survey asked respondents about first trimester pregnancy symptoms, pregnancy loss, and any subsequent intervention or management. Finally, respondents were asked about their perceptions of the influence of COVID-19 on their fertility, pregnancy, and health. On completion of the survey, the patient's electronic medical record was queried for additional demographic and cycle-level variables. The first invitation to complete the web-based survey was sent on September 1, 2020, and reminder emails were sent every 10 days for 4 occurrences. Data collection was completed on October 11, 2020. In total, 330 out of 990 invited patients responded to the survey for a response rate of 33.3%.

Definition of Outcomes

The primary outcome was first trimester clinical pregnancy loss rate, defined as spontaneous or missed abortion at $\leq$14 weeks of gestation divided by the number of pregnant women with a confirmed intrauterine pregnancy. Ongoing pregnancy was defined as clinical intrauterine pregnancy with a fetal heartbeat beyond 14 weeks of gestation. Regarding COVID-19 status, respondents were considered "COVID-19 positive or symptomatic" if they reported at least one COVID-19–related symptom (i.e., fever, cough, sore throat, runny nose, diarrhea, shortness of breath, muscle aches, loss of smell or taste) or if they reported a positive SARS-CoV-2 nasopharyngeal swab, nasal swab, saliva/cheek swab, or serum testing result. Respondents were considered "COVID-19 Unknown/Negative and Asymptomatic" if they did not report any of the previous symptoms and were COVID-19 negative or were never tested for COVID-19.

Definition of the Study Groups

Cases (n = 305) were defined as women completing the study questionnaire in its entirety who met the inclusion criteria. Of the cases, women conceiving via fresh embryo transfer, FET with PGT, and FET without PGT (i.e., the "COVID-19 Fresh and Frozen ET Cohort") were then matched with controls. Controls were identified from the electronic medical record using the same calendar months as the study time period but from one year before the COVID-19 pandemic (December 2018 to April 2019) and are referred to as the "Pre-COVID-19 Fresh and Frozen ET Matched Cohort." Cases who conceived via fresh transfer (n = 56) were matched 1:3 by the age groups previously defined by the Society for Assisted Reproductive Technology (ages $<$30, $\geq$30 but $<$35, $\geq$35 but $\leq$37, $\geq$38 but $\leq$40, $\geq$41 but $\leq$42, and $>$42 years old) using Microsoft excel software random number generator. Because of a smaller number of FET controls, cases who conceived via FET (n = 146) were matched 2:1 by PGT status (PGT vs. no PGT) and the following age categories (ages $<$35, $\geq$35 but $\leq$37, $\geq$38 but $\leq$40, and $>$40 years old). Because of an insufficient number of cases to be matched for the $\geq$35 but $\leq$37 and $>$40 groups conceiving via FET without PGT, all of the patients in these two groups were included (n = 56 and n = 24, respectively). Spontaneously conceived pregnancies and those conceived via intrauterine insemination were not matched with controls given the incomplete data capture of pregnancy outcomes in our electronic medical record.

TABLE 1

Patient demographics by study cohort.

	Survey respondents N = 305	COVID-19 fresh & frozen ET cohort N = 202	Pre-COVID-19 fresh & frozen ET matched cohort N = 518
Age (y), mean (SD)	35.9 (4.3)	36.9 (4.2)	36.3 (4.4)
Gravidity, median (IQR)	1 (0–2)	1 (0–2)	1 (0–2)
Parity, median (IQR)	0 (0–1)	0 (0–1)	0 (0–1)
Prior miscarriage, n (%)			
0	220 (72.1)	137 (67.8)	360 (69.5)
1–2	54 (17.7)	40 (19.8)	105 (20.3)
>2	31 (10.2)	25 (12.4)	53 (10.2)
Ethnicity, n (%)			
White	214 (70.2)	133 (65.8)	305 (58.8)
Asian	37 (12.1)	28 (13.9)	105 (20.3)
Black	6 (2.0)	6 (3.0)	11 (2.1)
Other	48 (15.7)	35 (17.3)	97 (18.7)
Infertility diagnosis, n (%)			
Idiopathic	34 (11.2)	17 (8.4)	42 (8.1)
Diminished ovarian reserve	123 (40.3)	103 (51.0)	269 (51.9)
Anovulation/PCO	33 (10.8)	16 (7.9)	59 (11.4)
Male factor	54 (17.7)	47 (23.3)	156 (30.1)
Endometriosis	18 (5.9)	18 (8.9)	39 (7.5)
Uterine factor	25 (8.2)	21 (10.4)	39 (7.5)
Tubal factor	23 (7.5)	21 (10.4)	84 (16.2)
PGT-M/SR	37 (12.1)	35 (17.3)	89 (17.2)
Previous IUI cycles, median (IQR)	2.5 (1–4)	3 (1–5)	3 (1–4)
Previous IVF cycles, median (IQR)	0 (0–1)	1 (0–2)	1 (0–2)
Treatment type, n (%)			
Fresh embryo transfer[a]	56 (18.4)	56 (27.7)	231 (44.6)
FET with PGT[b]	74 (24.3)	74 (36.6)	148 (28.6)
FET without PGT[b]	72 (23.6)	72 (35.6)	139 (26.8)
Ovulation induction	78 (25.6)	—	—
Spontaneous/natural cycle	25 (8.2)	—	—

Note: COVID-19 = coronavirus disease 2019; ET = embryo transfer; FET = frozen embryo transfer; IQR = interquartile range; IUI = intrauterine insemination; PCO = polycystic ovary; PGT-M/SR = preimplantation genetic testing for monogenic defects/structural chromosomal rearrangements.

[a] Matched 3:1

[b] Matched 2:1

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Statistical Analysis

Descriptive statistics are reported. Given the small number of events encountered, Fisher's exact test was used to compare differences between the groups. Statistical significance was denoted by a *P*-value of $<.05$. Given the small sample size and hypothesis-generating nature of the study, no adjustment for multiplicity of outcomes was performed. Statistical analyses were performed using StataSE 16 (StataCorp LLC, College Station, TX, USA). This study was approved by the Weill Cornell Institutional Review Board (Protocol # 20-04021762).

RESULTS

A total of 305 respondents completed the survey in its entirety. Of the respondents, 202 patients underwent fresh or FET with or without PGT (COVID-19 Fresh and Frozen ET Cohort) and were matched to historical controls (Pre-COVID-19 Fresh and Frozen ET Matched Cohort) as described previously in the Materials and Methods section. Demographic characteristics for both groups are displayed in Table 1.

In total, the first trimester clinical pregnancy loss rate was lower in the COVID-19 era cohort compared with that in the Pre-COVID-19 era cohort (11.9% vs. 20.1%, $P = .009$). There was no difference in the first trimester clinical pregnancy loss rate in women conceiving via fresh embryo transfer during the COVID-19 era compared with that in the Pre-COVID-19 era (19.6% vs. 24.4%, $P = .598$) (Table 2). Similarly, there was no difference in the first trimester clinical pregnancy loss rate in women conceiving via FET with PGT during the COVID-19 era compared with that in the Pre-COVID-19 era (5.4% vs. 9.5%, $P = .435$). There was, however, a difference in the first trimester clinical pregnancy loss rate in women conceiving via FET without PGT, with a lower first trimester clinical pregnancy loss rate identified in the COVID-19 era sub-group (12.5% vs. 24.5%, $P = .048$).

When considering all the survey respondents who conceived during the COVID-19 era (n = 305), there was no difference in the first trimester clinical pregnancy loss rate when stratifying by COVID-19 status (COVID-19 positive or symptomatic vs. COVID-19 negative/not tested and asymptomatic) and treatment type. Of the 40 (13.1%) patients who experienced a first trimester pregnancy loss, there was no difference in their self-report of COVID-19 symptoms or

TABLE 2

First trimester clinical pregnancy loss rates by treatment type categorized by COVID-19 era vs. pre-COVID-19 matched cohort.

	COVID-19 fresh & frozen ET cohort N = 202	Pre-COVID-19 fresh & frozen ET matched cohort N = 518	*P*-value
Total, n/N	24/202	104/508	
Clinical pregnancy loss, % (95 CI)	11.9 (7.8–17.2)	20.1 (17.0–24.2)	.009
Fresh embryo transfer, n/N	11/56	56/231	
Clinical pregnancy loss, % (95 CI)	19.6 (10.2–32.4)	24.4 (18.9–30.3)	.598
FET with PGT, n/N	4/74	14/148	
Clinical pregnancy loss, % (95 CI)	5.4 (1.5–13.3)	9.5 (5.3–15.4)	.435
FET without PGT, n/N	9/72	34/139	
Clinical pregnancy loss, % (95 CI)	12.5 (5.9–22.4)	24.5 (17.6–32.5)	.048

Note: 95 CI = 95% confidence interval; COVID-19 = coronavirus disease 2019; ET = embryo transfer; FET = frozen embryo transfer; PGT = preimplantation genetic testing.

Bortoletto. 1st Trimester Pregnancy Loss & COVID-19. Fertil Steril Rep 2021.

symptom type compared with the results of those who did not experience a first trimester clinical pregnancy loss (additional COVID-19–related clinical information is displayed in Table 3). Given concerns about resource utilization during the COVID-19 pandemic, early pregnancy symptoms and contacts with the health care system were additionally evaluated by COVID-19 status (Table 4). Regardless of COVID-19 status, early pregnancy symptoms and their unplanned evaluation were similar between the groups. Approximately one in every three patients required an unscheduled ultrasound for evaluation of early pregnancy bleeding or pain. Although our center was closed for seven weeks for new treatment cycle starts, we remained open throughout to see pregnant patients and emergency visits. Only nausea in early pregnancy was statistically more common in women in the COVID-19 positive or symptomatic group (95.7% vs. 72.7%, $P<.032$).

Finally, respondents were queried about their perceptions of the influence of the COVID-19 pandemic on their fertility, pregnancy, and health (Supplemental Table 1, available online). Nearly half (42.6%) of respondents believed that pregnant women were more susceptible to COVID-19, and 61.0% believed that pregnant women were more likely to have complications if infected. Although over three-fourths (83.6%) of women believed COVID-19 was dangerous to pregnant women, only 50.5% believed that it was dangerous to a developing fetus. Of those women who were still pregnant at the time of survey completion (n = 145), 68.3% were worried about the effect of COVID-19 on their current pregnancy. Lastly, a minority of women believed that delaying pregnancy (13.3%) and infertility treatment (13.7%) was the safest course of action during the COVID-19 pandemic.

DISCUSSION

Infertile women who conceived during the COVID-19 pandemic did not have a higher risk of first trimester clinical pregnancy loss when compared with the risk for age- and treatment-matched controls from the year prior. In fact, the first trimester clinical pregnancy loss rate was lower in our patient cohort during the COVID-19 era. Furthermore, no differences in the first trimester clinical pregnancy loss rate were identified when stratifying by COVID-19 status or symptoms. Although our findings are reassuring for patients and providers, there are several potential explanations for our findings that are worth discussion.

Although there was no difference in first trimester pregnancy loss during the COVID-19 era for women undergoing fresh embryo transfer and FET with PGT compared with results for pre-COVID-19 controls, there was a statistically significant decrease in first trimester clinical pregnancy loss during COVID-19 for the FET without PGT group. This large difference (12.5% vs. 24.5%) was a major contributor to the overall first trimester clinical pregnancy loss rate (11.9% vs. 20.1%) in addition being statistically different, although the first trimester clinical pregnancy loss rate was lower in all COVID-19 era treatment groups. When considering the FET without PGT patients only, there were no statistically significant differences in age, body mass index, gravidity, parity, history of pregnancy loss, or biochemical losses between the COVID-19 era cohort and the Pre-COVID-19 comparison group. Only male factor infertility was significantly more common in the control group ($P = .048$). This is likely related to random chance when matching a small cohort of women on age and treatment type alone, as the groups appeared to be well balanced overall (Table 1).

One potential explanation for the lower first trimester pregnancy loss rate during the COVID-19 pandemic is how the COVID-19 pandemic has affected the lives of pregnant women. Reports from Denmark and Ireland early in the pandemic indicated a substantial reduction in preterm birth after nationwide COVID-19 "lockdowns" (10, 11). These early reports have been further corroborated by large national data sets from the Netherlands, which have shown substantial reductions in preterm birth during nationwide COVID-19 mitigation efforts (12). Several potential explanations for this finding have been proposed, including improvements in ambient air quality and reduced contact with pathogens because of social distancing efforts. Additionally, changes in work and commuting patterns may have allowed for optimization of sleep, exercise, and social support, which could have had a positive effect not only on preterm birth but also on early pregnancy loss. Importantly, it is worth highlighting that six out of the seven women with confirmed COVID-19 infections did not experience a first trimester clinical pregnancy loss in our cohort (Table 3).

TABLE 3

COVID-19–related survey responses for women undergoing treatment during the COVID-19 era categorized by first trimester clinical pregnancy loss vs. ongoing pregnancy at 14 weeks.

	First trimester clinical pregnancy loss N = 40 (13.1%)	Ongoing pregnancy N = 265 (86.9%)	*P*-value
Symptoms suggestive of COVID-19	5 (12.5)	22 (8.3)	.373
Known exposure to COVID-19–infected individual	8 (20.0)	30 (11.3)	.127
Exposure was to COVID-19–infected individual whom they live with	1 (12.5)	11 (36.7)	.393
Diagnostic COVID-19 testing	21 (52.5)	160 (60.4)	.389
Positive COVID-19 testing	1 (4.8)	6 (3.8)	.585
Management of COVID-19 symptoms			
Emergency room visit	0 (0)	3 (1.8)	.999
Inpatient admission	0 (0)	0 (0)	—
Intensive care unit admission	0 (0)	0 (0)	—
Ventilatory support	0 (0)	0 (0)	—

Note: Values are number (percentage). COVID-19 = coronavirus disease 2019.

Bortoletto. 1st Trimester Pregnancy Loss & COVID-19. Fertil Steril Rep 2021.

Although our findings are reassuring, survey respondents did express significant concern about how COVID-19 impacts their reproductive health (Supplemental Table 1). Most (83.6%) of the respondents believed that COVID-19 is dangerous to pregnant women; however, only 13.3% believed that delaying pregnancy is the safest course of action. Our group has recently reported on how delays in IVF treatment affect live birth rates for women with diminished ovarian reserve (13). We found that delays up to 180 days did not affect live birth rates when compared with that of women who initiate IVF treatment within 90 days of presentation. Regardless of when women choose to conceive, the findings of our current study provide further reassurance that pregnancies conceived via ART are not at higher risk of first trimester clinical pregnancy loss during a period of the COVID-19 pandemic with a high transmission rate in our geographic region. However, replication of our findings on a larger scale is certainly warranted before broad generalization of our results can be made to other populations.

There are several limitations to our study. First, women were queried on their COVID-19–related symptoms over 6 months after the start of the pandemic, potentially introducing a recall bias. Second, we cannot account for how respondents who answered the survey may differ from those who chose not to answer with regards to their COVID-19 exposure, testing, and symptoms. Lastly, because we only matched patients who conceived via fresh embryo transfer or FET to historical controls, we urge caution with extrapolation of our findings to the greater reproductive-age population conceiving spontaneously during the COVID-19 pandemic, as our absolute number of COVID-19 cases and pregnancy losses were small.

In addition, our study has several strengths. First, New York City was the North American epicenter of the COVID-19

TABLE 4

Early pregnancy symptoms and management stratified by COVID-19 status.

	COVID-19 positive or symptomatic N = 19 (6.2%)	COVID-19 negative/not tested and asymptomatic N = 286 (93.8%)	*P*-value
Early pregnancy symptoms			
Vaginal bleeding	2 (10.5)	65 (22.7)	.266
Pelvic pain or cramping	4 (21.1)	66 (23.1)	.999
Nausea	18 (95.7)	208 (72.7)	.032
Emesis	5 (26.3)	73 (25.5)	.999
None	1 (5.3)	49 (17.1)	.332
If vaginal bleeding or pelvic pain/cramping			
Unscheduled physician visit	2 (11.1)	42 (17.7)	.746
Unscheduled ultrasound	2 (33.3)	41 (38.7)	.999
First trimester clinical pregnancy loss	2 (10.5)	38 (13.3)	.999
Management of pregnancy loss			
Expectant management	2 (100)	25 (65.8)	.555
Medical management	0 (0)	4 (10.5)	—
Dilation and curettage	0 (0)	9 (23.7)	—

Note: Values are number (percentage). COVID-19 = coronavirus disease 2019.

Bortoletto. 1st Trimester Pregnancy Loss & COVID-19. Fertil Steril Rep 2021.

pandemic, allowing us to study how patients experiencing the most severe burden of community spread fared in their first trimester of pregnancy. Additionally, we were able to match fresh transfer cycles 3:1 and FET cycles 2:1 to a historical cohort conceiving at the same center during the same 5-month time period one year before the pandemic. This allows us to minimize the potential for changes in patient population and clinical-level variables that may influence the first trimester clinical pregnancy loss rate, such as ovarian stimulation and FET luteal support protocols. In addition, our study is strengthened by the discrete COVID-19–related data collected, including symptoms, exposures, testing, and management.

CONCLUSION

In summary, our study determined that the first trimester clinical pregnancy loss rate was lower for women conceiving via fresh or FET during the COVID-19 pandemic compared with that of age- and treatment-matched controls from the year prior. There were no differences in COVID-19–related symptoms or testing for patients who experienced first trimester clinical pregnancy loss compared with results for those who did not. Additionally, there were no differences in early pregnancy symptoms or unscheduled physician visits for patients by COVID-19 status. Finally, despite patients expressing significant worry about COVID-19 and pregnancy, our data provides reassuring information that the first trimester clinical pregnancy loss rate is not elevated for women conceiving via ART during the global COVID-19 pandemic.

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