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Conclusions: The levonorgestrel 52 mg IUS is highly effective over eight years of use and has an excellent extended safety profile.

Impact Statement: This report details the longest efficacy and safety data for continuous use of a levonorgestrel 52 mg IUS for contraception.

Support: The study was funded by Medicines360.

O-189 11:15 AM Wednesday, October 20, 2021

Educating by Experience – Do Fellow Performed Embryo Transfers Affect Live Birth Rates?1 Sarah H. Bjorkman, MD, 1 Kurt R. Bjorkman, MD, 2 Eyu Hakan Duran, MD, 3 Amy E. Sparks, PhD 4 1University of Iowa, Division of Reproductive Endocrinology & Infertility, Iowa City, IA; 2University of Iowa, Division of Pediatric Cardiology, Iowa City, IA; 3University of Iowa, Iowa City, IA; 4University of Iowa Center for Advanced Reproductive Care, Iowa City, IA.

Objective: To evaluate the outcomes of embryo transfer (ET) performed by fellow versus attending physicians.

Materials and Methods: Prospective observational cohort study of all day 5 ET from 01/01/2016 – 06/30/2020. Cohorts were defined as exposure to fellow or attending physician ET. If fellow unable to complete ET due to difficulty, attending completed procedure. Patient and transfer variables were assessed for significant differences between groups: patient age, race, BMI, previous pregnancy (Gs) & previous delivery (Ps), cycle number, antral follicle count (AFC), number of embryos transferred, preimplantation genetic testing (PGT), oocyte source, fresh versus frozen transfer. ET was then analyzed for pregnancy and live birth, and adjusted odds ratios (OR) calculated controlling for all variables above.

Results: A total of 3,027 day 5 ET were included; 1,322 completed by eight fellows and 1,705 completed by nine attending physicians. Patient and transfer variables are summarized in Table 1. The pregnancy rate in the fellow group was 60.3% (797/1,322) versus 60.1% (1,024/1,705) in the attending group; live birth rates were 50.2% (664/1,322) and 51.1% (871/1,705) respectively. The adjusted ORs for pregnancy and live birth after an embryo transfer performed by a fellow compared to attending physicians were 1.08 (95% CI 0.95 - 1.22) and 1.10 (95% CI 0.97 - 1.25).

Conclusions: No significant difference exists between rates of clinical pregnancy or live birth rate when comparing ET completed by fellows versus attending physicians.

Impact Statement: Recent literature reported 40% of fellows graduated having performed fewer than 10 ET and 21% without ever performing this procedure. Given no significant difference in outcome, however, patients and attending physicians should be reassured that with appropriate training and supervision, fellows can safely perform this essential skill without compromising patient care or outcomes.

Table 1. Patient and Transfer Characteristics of ET Performed by Fellow and Attending Physicians

| Characteristic     | Fellows (n = 1,322) | Attendants (n = 1,705) | p-value* |
|--------------------|---------------------|------------------------|----------|
| Age (years)        | 33.8 ±4.5           | 34.3 ±4.7              | <0.001   |
| Race               |                     |                        |          |
| White              | 91.1% (1,204)       | 88.2% (1,504)          | 0.011    |
| Black              | 1.2% (16)           | 2.8% (48)              | 0.002    |
| Hispanic           | 1.6% (21)           | 1.8% (31)              | 0.628    |
| Asian              | 4.0% (53)           | 4.5% (76)              | 0.542    |
| Other/Unknown      | 2.0% (26)           | 1.5% (26)              | 0.354    |
| BMI                | 28.4 ±7.0           | 28.2 ±6.9              | 0.385    |
| Gs                 | 1.45 ±1.5           | 1.44 ±1.5              | 0.832    |
| Ps                 | 0.64 ±0.8           | 0.64 ±0.8              | 0.847    |
| Cycle Number       | 2.57 ±1.7           | 2.79 ±1.9              | <0.001   |
| AFC                | 23.4 ±13.7          | 24.0 ±12.9             | 0.415    |
| Embryos            | 1.16 ±0.4           | 1.19 ±0.4              | 0.049    |
| PGT                | 10.4% (138)         | 10.4% (177)            | 0.974    |
| Non-Donor          | 92.4% (1,221)       | 90.4% (1,541)          | 0.063    |
| Fresh              | 42.2% (558)         | 35.4% (604)            | <0.001   |
| Live Birth         | 50.2% (664)         | 51.1% (871)            | 0.628    |

Results are presented as % (n) or mean ± standard deviation
*Statistically significant difference for p < 0.05

Support: None

References:
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O-190 11:30 AM Wednesday, October 20, 2021

Exposure of Ovaries to COVID-19 Vaccination does not impair fertility.

Randi S. Morris, MD, Alexis J. Morris, Undergraduate, IVF1, Naperville IL.

Objective: Misinformation regarding Covid vaccination has contributed to vaccine hesitancy. Initially, there were claims that immune cross reactivity between the SARS-CoV-2 spike protein and syncytin-1 would prevent embryo implantation. We previously demonstrated no difference in implantation and sustained implantation rates between previously vaccinated or infected women compared to other women.

More recently, misinterpretation of vaccine biodistribution data has led to a second claim that mRNA containing lipid nanoparticles are concentrated in the ovaries and spike protein produced there would also cause infertility.

The purpose of this study is to determine whether prior in vivo ovarian exposure to lipid nanoparticle-mRNA vaccination against SARS-CoV2 spike protein reduces subsequent fertility in women.

Materials and Methods: This is an ongoing observational study of women undergoing frozen embryo transfer with a single expanded blastocyst. This is an interim report (n=128) encompassing transfers between Jan 1 and Jul 02. All patients had serum analyzed prior to starting stimulation for egg retrieval to quantitatively determine the level of Anti-SARS-CoV2 Spike IgG. Reactive (antibody positive) patients were questioned to determine a history of vaccination or infection. Patients were divided into three groups based on their status. Women who were vaccinated (n = 26); women who had previous infection with SARS-CoV-2 (n=11) and women without a history of either vaccination or infection (n=91). Only patients receiving the mRNA vaccines from BioNTech / Pfizer (BNT162b2) and Moderna (mRNA-1273) were analyzed. Outcome measure for the three groups were initial implantation rate (serum hCG level > 5 mIU/mL obtained 8 days after embryo transfer followed by a rising level two to three days later), sustained implantation rate (transvaginal ultrasound documented positive FHTs at two time points at least one week apart) and miscarriage rate (the difference between initial and sustained implantation rates). Baseline characteristics were analyzed using ANOVA. Chi square analysis was used to compare pregnancy rates.

Results:

| Characteristic | Non-reactive Vaccination Infection P Value |
|---------------|------------------------------------------|
| Total transfers | 91% (n=79) 26% (n=22) 84.6% (n=22) 90.9% (n=10) 0.19 |
| Implantation rate | 63.7% (n=58) 61.5% (n=16) 54.6% (n=6) 0.10 |
| Sustained implantation rate | 23.1% 23.1% 36.3% 0.15 |

Conclusions: Embryos produced from oocytes exposed in vivo to lipid nanoparticles containing mRNA for the SARS CoV2 spike protein are not less likely to produce pregnancy or more likely to miscarry.

Impact Statement: This data refutes the rumors that Covid-19 vaccinations are “toxic” to the ovaries & adds to the growing body of evidence that vaccinations do not cause infertility.

Support: None

Reference: