

P-034 Social distancing protocol changes during the COVID-19 pandemic; the effect of at-home semen collection on intrauterine insemination outcomes

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Study question: How have the coronavirus 2019 (COVID-19)-driven changes in semen collection protocols, from on-site to at-home collection, impacted intrauterine insemination (IUI) cycle outcomes?

Summary answer: Our data suggest that at-home semen collection within 2 hours of processing does not negatively impact semen parameters and IUI pregnancy outcomes. What is known already: There are mixed reports regarding the effect of at-home semen collection on IUI outcomes. In a study of 633 cycles, no differences in semen parameters or pregnancy rates were observed between home and clinic collections¹. Conversely, in a smaller cohort, at-home collection was associated with worse pregnancy outcomes when IUI was coupled with gonadotropin stimulation, but not when coupled with clomiphene². We previously reported no differences in semen parameters and in-vitro fertilization (IVF) embryo transfer outcomes, when cycles using semen collected at-home were compared to cycles with on-site collection³. However, such findings cannot necessarily be extended to the IUI setting.

Study design, size, duration: This is a retrospective cohort study of all 529 IUI cycles that took place in 2020 at an academic fertility center. Semen collected at the "clinic" was used for 143 cycles before the COVID-19 pandemic, and "at-home" collected specimens were used for the 386 cycles following the revised semen collection protocol. Participants/materials, setting, methods: Prior to the COVID-19 pandemic, semen was collected at our "clinic" and processed within ~30 minutes. Post-COVID, in order to maintain social distancing, semen was collected "at-home", at an IUI-approved cup, and transported to our center within 2 hours, while maintained to room temperature. Logistic regression models were performed to evaluate the effect of "at-home" collection on achieving pregnancy (positive pregnancy test-PPT) and clinical pregnancy (sonographic confirmation-CP), adjusting for age and anti-Mullerian hormone (AMH).

Main results and the role of chance: The mean age (SD) (years) of the female partner was 35.4 (4.2) vs. 35.4 (4.4) ($p=0.978$) and of the male partner 36.6 (4.4) vs. 37.1 ($p=0.328$) for the "clinic" vs. "at-home" groups, respectively. There were no significant differences in day-3 follicle stimulating hormone and AMH. In both groups the most common diagnoses were idiopathic and combined factors infertility (27.3% and 18.9% & 24.1% and 25.1%, respectively for the "clinic" & "at-home" groups, $p=0.376$). Similarly, there were no differences regarding ovarian stimulation, and gonadotropins were the most common medication used in both groups ("clinic": 44.1% vs. "at-home": 39.4%, $p=0.775$). Semen analysis parameters (volume, motility, forward progression, total motile count) were comparable between the 2 groups, with the exception of concentration (mil/ml) which was higher with "at-home" collection [66.1 (45.0) vs. 81.1 (63.0), $p=0.009$].

In unadjusted models, "at-home" collection had no significant effect on the odds for a PPT [OR (95%CI): 0.691 (0.427-1.119), $p=0.133$] or CP [0.751 (0.447-1.263), $p=0.281$]. These results persisted even when adjusting for

maternal age and AMH: PPT [0.708 (0.435-1.153), $p=0.165$] and CP [0.773 (0.455-1.312), $p=0.340$]. When sub-analysis was performed within the different medication groups, the above findings persisted for both gonadotropin and oral medication cycles.

Limitations, reasons for caution: The limitations of the study include its retrospective design and the absence of livebirth data, given the limited follow up period. However, regarding the latter, one can use the ongoing clinical pregnancy rate as an accurate estimate of livebirth.

Wider implications of the findings: At-home semen collection within 2 hours of processing did not negatively impact semen analysis parameters or pregnancy outcomes following IUI. These data constitute an important addition to the current limited literature on the subject and provides an additional level of safety for our patients and staff during the COVID-19 crisis.

Trial registration number: not applicable