P-198 6:30 AM Tuesday, October 19, 2021

USE OF INVOCELL INTRAVAGINAL EMBRYO CUL-
TURE SYSTEM FOR FIVE DAYS OF INCUBATION: A PROSPECTIVE STUDY OF SAFETY AND TOLERABILITY. Karen R. Hammond, DNP, CRNP,
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OBJECTIVE: The purpose of this single-center study was to prospectively evaluate the INVOcell culture device with its retention device in planned day-5 embryo transfer cycles, as to its retention, comfort, and possible vaginal mucosal irritation. INVOcell is presently approved in the US for up to 3 days.

MATERIALS AND METHODS: The study was prospectively approved by WCG IRB (#1295533). Women scheduled for oocyte retrieval planning blastocyst transfer at a single center (N1/431) were invited to participate in the study; all gave written informed consent. Two failed screening; 29 were enrolled in the study aged 26-41 (median 36) years with body mass in- dex of 20.1-39.5 (median 30.5) kg/m^2. A vaginal speculum exam was done at the completion of each retrieval, and after INVOcell removal at 5 days; before examination of INVOcell contents, all women completed the study questionnaire. The primary endpoint of the study was device retention, deter- mined by patient report. Secondary endpoints of patient comfort and vaginal tissue reaction to the INVOcell system were assessed after its removal by patiient questionnaire and speculum exam.

RESULTS: The INVOcell system was retained by 100% of participants. One woman felt that the system was dislodged; she was able to readjust the system to maintain it in position. A conservative analytic approach thus gives a 96% rate of successful retention. All women completed the questionnaire, which assessed overall subject comfort and satisfaction with wearing the INVOcell system. Only two subjects reported any discomfort, and that was at a tolerable level not requiring medical intervention. The overall Likert rating for discomfort of 0.17 (pain scale of 0-10 with 0 being no pain/discomfort and 10 being severe pain/discomfort) demonstrates the favorable comfort level for the INVOcell and retention device during 5- day incubation. Whereas bleeding was noted immediately after oocyte retrieval in the majority of women and considered to be a normal sequela of this procedure, at Day-5 vaginal speculum exam no lesions, ulcerations, erythema, or bleeding were noted.

CONCLUSIONS: In conclusion, our study demonstrates that the INVO- cell system can be safely used for a 5-day embryo incubation without causing vaginal irritation or mucosal injury. Our results also verify that the system is well tolerated.

IMPACT STATEMENT: With blastocyst transfer being the modal goal of ART cycles, the INVOcell intravaginal culture system is shown to be a viable alternative to standard laboratory embryo culture that practitioners may wish to use to save patient cost. Our study supports its off-label use for 5-day incubation.