INTRAVAGINAL EMBRYO CULTURE: MORE THAN JUST A NOVELTY?

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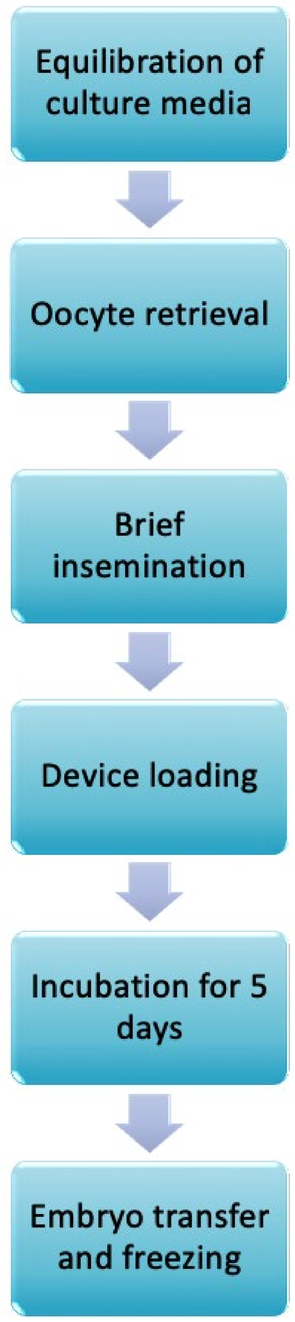
Introduction

Intravaginal culture (IVC) devices offer a novel assisted reproductive technology (ART) treatment option at a significantly reduced cost from traditional in-vitro fertilization (IVF) cycles, offering patients a unique treatment option between intrauterine insemination (IUI) and full IVF cycles. This retrospective study aimed to assess the efficacy of the INVOcell intravaginal culture device with fresh day 5 blastocyst transfers compared with IUI cycles in our center.

Methods

Patients were initially informed that IVC had unknown success rates in our clinic prior to starting their cycle. These cycles were offered at a discounted cost. Patient inclusion criteria included: normal semen analysis, normal uterine cavity, anti-mullerian hormone value of 1 - 6 ng/mL, follicular stimulating hormone value of <10 mIU/mL, estradiol level <60 pg/mL. Exclusion criteria included previous IVF cycle failures, plastic allergies, and history of toxic shock.

Patients underwent a stimulation with either a letrozole/FSH or microdose flare protocols. Following oocyte retrieval, cumulus oocyte complexes were trimmed and inseminated for 5 minutes before being placed in an IVC device (INVO Bioscience) loaded with equilibrated continuous culture media and overlaid with mineral oil (Irvine Scientific). The device was inserted into the patient's vagina for incubation and carried for 5 days before returning for embryo development evaluation and transfer. Good quality, supernumerary embryos were vitrified for future use. Ovulation induction stimulations utilized the oral agents Femara or Clomid. IUI's were performed with gradient prepared semen per standard protocols. Data for both procedures was collected for a single calendar year in 2017.



Results and Discussion

A total of 36 patients, between ages 27 and 42, opted to have IVC cycles performed. The device was well tolerated, with no adverse events requiring its premature removal. The per-start positive biochemical pregnancy rate was 50% and the ultrasound confirmed pregnancy rate was 39%. The per-transfer pregnancy rates were 64% and 50% respectively with a total of 28 transfers performed (a 22% non-transfer rate). The pregnancy rates for IUI performed in the same calendar year were 11% and 9% respectively for patients in the same age range with a total of 828 cycles performed.

	<35	35-37	38-40	41-42	All Cycles
Number of Starts	21	3	8	4	36
Number of Transfers	17	2	5	4	28
Mean Oocytes Ret (Range)	10 (3-24)	8 (6-10)	7 (1-13)	7 (6-7)	9 (1-24)
Mean # Blastocysts (Range)	2 (0-8)	1 (0-2)	1 (0-2)	3 (2-4)	2 (0-8)
Average # of Embryos Transferred	1.2	1.0	1.2	2.3	1.3
Cycles Without Fertilization	14%	0%	13%	0%	11%
No Blastocysts for Transfer	19%	33%	38%	0%	22%
+ Biochemical Preg / Start	52%	67%	38%	50%	50%
+ Ultrasound Preg / Start	33%	67%	38%	50%	39%
+ Biochemical Preg / Transfer	65%	100%	60%	50%	64%
+ Ultrasound Preg / Transfer	41%	100%	60%	46%	50%
Number of IUIs	501	191	112	24	828
+ Biochemical Preg	15%	14%	13%	4%	11%
+ Ultrasound Preg	13%	10%	10%	4%	9%

Advantages over IUI

- Higher success rates: 39% vs 9% ($p<0.01$) ultrasound confirmed pregnancy per stimulation start
- Diagnostic value: stimulation response, oocyte quality, embryo development can all be observed
- Reciprocal embryo transfer for female same sex couples
- An additional treatment option for patients who feel IVF is unnatural

Conclusion and Future Directions

Intravaginal culture with day 5 blastocyst transfer offers a significant increase in pregnancy rates compared with intrauterine insemination. This novel treatment gives patients an option between a simple IUI and a full IVF cycle. More in depth analysis of cycles in addition to a larger number of patients will help elucidate the patient population that is most suited to benefit from IVC cycles.

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Note from INVO Bioscience: INVO incubation period is country specific and is indicated for 3-5 days. In the US, the INVOcell Culture Device and Retention Device is not indicated for incubation periods exceeding 72 hours. FDA has not approved or cleared the product as safe and effective for use for incubation periods exceeding 72 hours (off-label).