The VILOCITY Trial: Validating Incubators in the Lab, Optimizing Culture and Investigating BlasTulation Yield, a Randomized Control Trial (RCT)

P4

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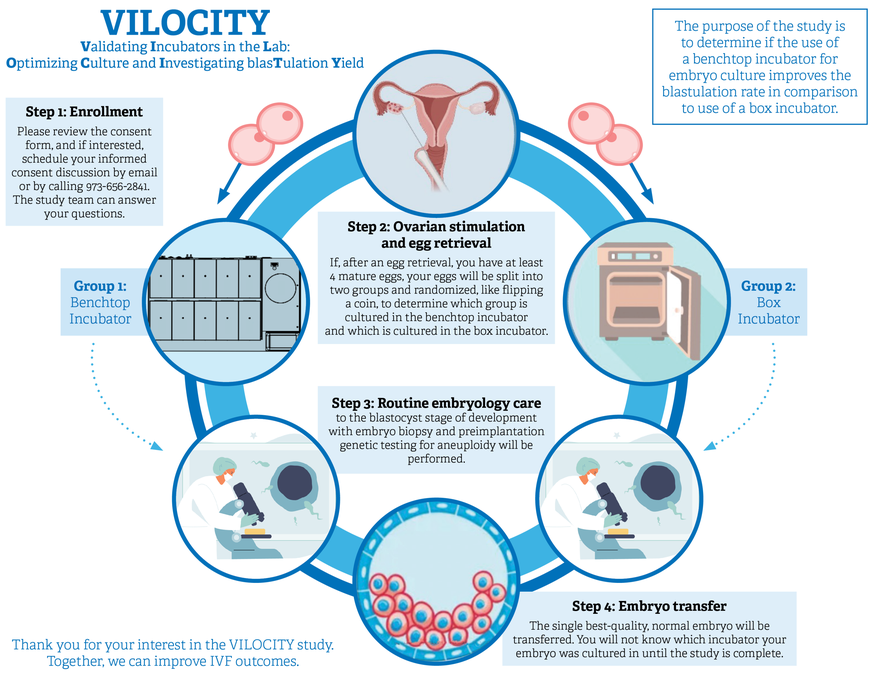
INTRODUCTION

- Embryo culture incubators are critical to IVF labs (1), with both box (BOX) and benchtop (BEN) systems commonly used.
- While BEN may offer advantages in space and efficiency, prior comparisons are limited by small samples, outdated technology, and inconsistent culture conditions (2-8).
- Therefore, results are mixed, and no clear consensus exists on whether benchtop incubators improve embryo development or outcomes due to inability of prior studies to synchronize for culture conditions.

OBJECTIVE

This study sought to determine if the use of a benchtop incubator improves IVF outcomes compared to a box incubator.

METHODS



- Split cohort double-blind RCT including patients undergoing a first IVF cycle with PGT-A followed by single FET
- Each patient's M2s were split and randomized to culture in either the BEN or BOX. Systems were synchronized for O2, CO2, temperature and pH.

Inclusion criteria:
- <42 years old
- Normal ovarian reserve testing (AMH ≥ 1.2 ng/mL, AFC ≥ 8, FSH ≤ 12 IU/L)
- BMI<35 kg/m^2
- ≥ 4 metaphase II (M2s) at retrieval were randomized

Exclusion criteria:
- PGT-M or PGT-S
- OD/GC
- >1 failed ET
- Surgical Sperm
- Prior cycle with no blastocysts
- Surgical sperm
- Endometrial insufficiency

- **Primary outcome:** blastulation rate per M2
- **Secondary outcomes**: fertilization rate, embryo morphology, day of blastulation and ploidy rates in addition to pregnancy outcomes

- **Statistical analyses:** Intention-to-treat analyses were performed. Categorical variables were compared using Chi-square test or Fisher's Exact test and continuous variables were compared using *t*-test. Wilcoxon signed-rank test was used to compare outcomes between the split cohorts.
- Ongoing pregnancy rate (OPR) and pregnancy loss rates were examined by bivariate and univariate analysis and also multivariate regression controlling for age, BMI and embryo quality.
- A futility analysis was performed at 65% completion.

RESULTS

2,152 M2s were randomized from 145 enrolled patients.

- 1079 M2s cultured in the BEN, resulting in 555 blastocysts
- 1073 M2s cultured in the BOX resulting in 543 blastocysts
- Demographic variables were equivalent between groups: the mean oocyte age was 35 (p=0.95), mean BMI was 26 (p=0.91) and mean number of M2s retrieved was 7.4 (p=0.92) in both groups
- There were no significant differences in the embryology outcomes (**Figure 1**).
- There were also no differences in day of blastulation (p=0.46), expansion (p=0.16), inner cell mass grade (p=0.33), trophectoderm grade (p=0.97), or euploid rate (67% BOX and 65% BEN, p=0.60).
- There were no significant differences in pregnancy outcomes among completed ETs (**Figure 2**).
- The futility analysis resulted in a conditional power of 0.56%, indicating the probability of reaching a statistically significant difference was <1%, so the study was discontinued.

FIGURE 1. Comparable embryology outcomes between the Box and Benchtop Incubators

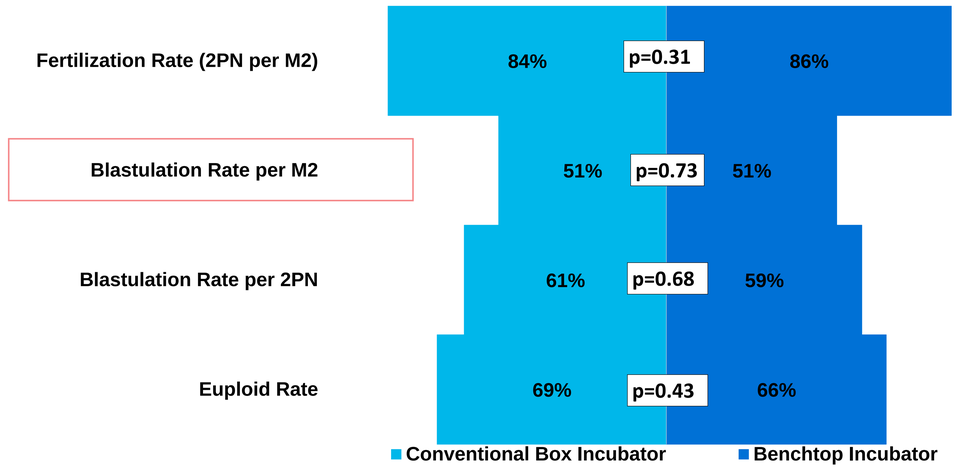
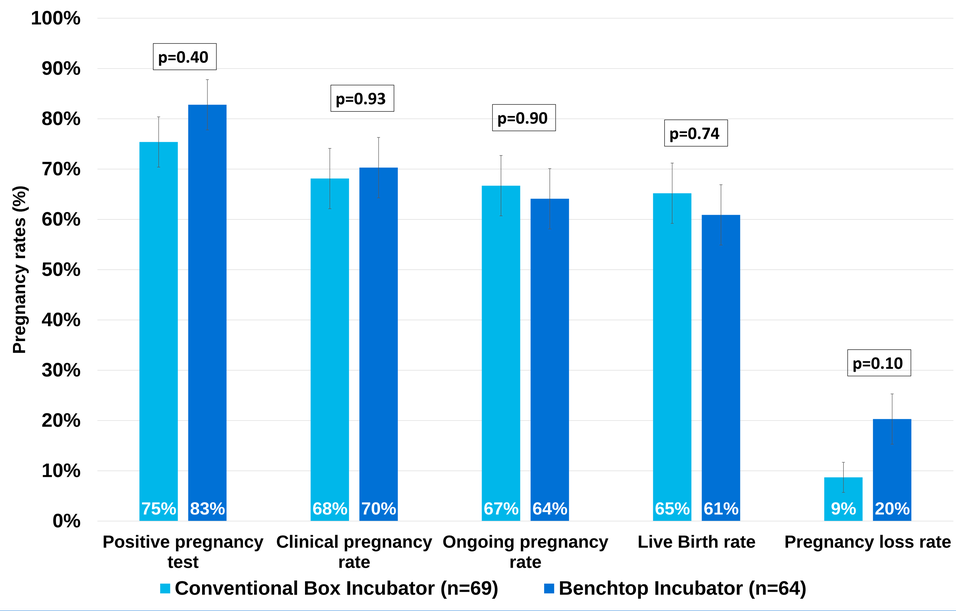


FIGURE 2. Comparable pregnancy outcomes between embryos transferred after culture in the Box versus Benchtop Incubators



CONCLUSIONS

This study demonstrated no significant differences in blastulation rate or pregnancy outcomes between the box and benchtop indicating that both incubators provide equally effective environments for embryo development.

REFERENCES