




(<https://www.sri-online.org/meetings-calendar/2020/>)

Session 13 - Reproductive Endocrinology and Infertility I

O-084 - A Multi-Center, Prospective, Blinded, Non-Selection Study Evaluating the Predictive Value (PV) of an Aneuploid Preimplantation Genetic Testing for Aneuploidy (PGT-A) Diagnosis and Impact of Biopsy

 March 13, 2020, 11:15 AM - 11:30 AM

 East Meeting Room 2

Keywords

IVF,ART,PGT-A,,

Authors

Ashley W. Tiegs^{†,1,2} Xin Tao,³ Yiping Zhan,³ Chaim Jalas,³ Christine Whitehead,¹ Emre Seli,^{1,4} George Patounakis,⁵ Jacqueline Gutmann,⁶ Arthur Castelbaum,⁷ Richard T. Scott*.^{1,2} ¹RMA New Jersey, Basking Ridge, NJ, United States; ²Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, PA, United States; ³Foundation for Embryonic Competence, Basking Ridge, NJ, United States; ⁴Yale School of Medicine, New Haven, CT, United States; ⁵RMA Florida, Lake Mary, FL, United States; ⁶RMA Philadelphia, Philadelphia, PA, United States; ⁷RMA Philadelphia, Philadelphia, NJ, United States.

Abstract

Introduction: Two concerns regarding PGT-A are: 1) embryos labeled aneuploid may be reproductively competent and thus may be wrongfully discarded, and 2) trophoctoderm (TE) biopsy may have an adverse effect on embryo reproductive potential. This study addresses these concerns by 1) directly measuring the predictive value (PV) of an aneuploid PGT-A diagnosis, and 2) comparing sustained implantation rates (SIR) of the study group to a control group, in which biopsy/PGT-A were not utilized.

Methods: 1) We first conducted a prospective, blinded, multi-center, non-selection study, in which all participants (n=440) underwent ICSI and blastocyst culture. Blastocysts underwent trophoctoderm (TE) biopsy followed by vitrification. In the next cycle, patients underwent single embryo transfer (SET) of the best embryo selected solely on morphology. PGT-A analysis (targeted amplification, NGS-based) was performed only after the clinical outcome was known. Clinical outcomes were compared to PGT-A results to calculate the PV of the "aneuploid" diagnosis. 2) To determine the impact of biopsy, the SIR of the patients in the non-selection study (n=440) was compared to that of a control group (n=972) undergoing cryo-SET not using PGT-A. As neither had access to PGT-A results, the groups differed only in that embryos in the study group had undergone TE biopsy.

Results: 1) In the non-selection study, PGT-A analysis of the TE samples diagnosed 95 embryos (out of 440 transferred) as "aneuploid". The SIR of embryos diagnosed as aneuploid was 0% (0/95) (binomial proportion 95% CI 0-2.4%); therefore the PV of an aneuploid result for failure to deliver was 100%. The PV for a euploid result to predict SIR was 64.9% ($p < 0.001$). 2) When compared to the control group (n=972) who underwent cryo-SET without biopsy or PGT-A, the mean SIR of all patients in the non-selection study group (including all euploid and aneuploid transfers) was not different (49.2% vs. 52.2%, $p = NS$), demonstrating no detectable detrimental effect of TE biopsy.

Conclusion: The PGT-A assay evaluated does not result in the discard of embryos with significant reproductive potential. Additionally, the TE biopsy has no detectable adverse impact on sustained implantation. Overall, these data support the safety and benefit of utilization of this PGT-A assay.