



## **CARES TRIAL (CELIAC DISEASE AND REPRODUCTIVE EFFECTS): A GLUTEN-FREE DIET DOES NOT IMPACT IVF OUTCOMES.**

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**OBJECTIVE:** Celiac disease is a systemic autoimmune disease that occurs in genetically susceptible patients and is provoked by the ingestion of gluten. One reported extra-intestinal manifestation of celiac disease is infertility or subfertility, although the anticipated improvement gained from a gluten-free diet has not yet been established. This analysis sought to determine if patients who report to be gluten-free demonstrate improvement in IVF outcomes.

**DESIGN:** Prospective cohort study

**MATERIALS AND METHODS:** Women ages 18-45 years participating in IVF at a single infertility center from January 2016 to March 2017 were recruited for participation. Only patients with a sole diagnosis of male factor infertility or utilizing oocyte donation or gestational carrier were excluded. Patients were invited to complete a 10 question "yes or no" survey to assess their medical history, prior testing, dietary habits, and pertinent symptoms. Patients were divided into 2 groups: (1) those who reported being gluten-free and (2) those who admitted to gluten ingestion. IVF outcomes were recorded prospectively and compared. Statistical analysis included both parametric and nonparametric tests for both categorical and continuous data when appropriate where an alpha error of 0.05 was considered significant.

**RESULTS:** 987 of 1000 enrolled patients completed the questionnaire (98.7%). 84 patients reported being gluten free (8.5%). Patient characteristics including age (35.4 v. 34.8 years,  $p=0.348$ ) and antimullerian hormone level (2.2 v. 2.6 ng/mL,  $p=0.437$ ) were not different between groups. 708 patients (71.2%) patients reported at least one symptom associated with celiac disease. Fertilization rates (82.4% v. 83.6%,  $p=0.576$ ) and blastulation rates (45.8% v. 48.6%,  $p=0.367$ ) were equivalent between those who were gluten-free and those who reported gluten ingestion. 714 of these patients have undergone a blastocyst transfer since participation. PGS utilization (72.7% v. 66.9%,  $p=0.378$ ), clinical implantation rate (80.0% v. 75.0%,  $p=0.422$ ), and sustained implantation rate (75.0% v. 66.0%,  $p=0.194$ ) were not different between groups. Rates of biochemical loss ( $p=0.428$ ) and clinical loss ( $p=0.211$ ) were also equivalent.

**CONCLUSIONS:** This is the first large prospective cohort study investigating IVF outcomes in patients who report being gluten-free. In this analysis, when patients implemented a gluten-free diet, there was no therapeutic advantage. Therefore, this intervention should not be applied to solely impact IVF outcomes.