

## CARES TRIAL (CELIAC DISEASE AND REPRODUCTIVE EFFECTS): CELIAC DISEASE IS NOT MORE COMMON IN PATIENTS UNDERGOING IVF AND OUTCOMES ARE NOT COMPROMISED IN AFFECTED PATIENTS.

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**OBJECTIVE:** Celiac disease is a systemic autoimmune disease that occurs in genetically susceptible patients. One reported extraintestinal manifestation of celiac disease is infertility or subfertility, though the prevalence of disease in the infertile population is unknown. This analysis sought to assess the prevalence of celiac disease in the infertile population undergoing IVF and determine if patients with serologic evidence of disease demonstrate diminished 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 had serum tissue transglutaminase (tTG) and endomysial (EMA) immunoglobulin A testing to screen for celiac disease and were divided into 2 groups: (1) those who displayed serologic evidence of celiac disease and (2) those who did not. 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:** 995 of 1000 enrolled patients completed participation. Only 18 patients screened positive for both tTG and EMA (1.8%). 968 patients underwent vaginal oocyte retrieval. Patient characteristics including age (36.1 v. 36.0 years, p=0.950) and antimullerian hormone level (2.0 v. 2.2 ng/mL, p=0.820) were not different between groups. The number of metaphase II oocytes retrieved, (9.0 v. 8.5 oocytes, p=0.784), fertilization rates (83.4% v. 88.8%, p=0.209) and blastulation rates (48.3% v. 50.4%, p=0.743) were equivalent between those who were seronegative and seropositive. Of the 18 patients who were seropositive, 12 patients have undergone a transfer. All transfers were single embryo, blastocyst transfers resulting in 9 ongoing pregnancies (75.0%) and only 2 losses (16.7%).

**CONCLUSIONS:** This is the first large prospective cohort study investigating the prevalence of celiac disease in infertile patients. In this analysis, the prevalence of seropositive disease is consistent with that of the general population (1.8%) and therefore infertility alone is not an indication for screening. Of note, even when patients are seropositive, IVF outcomes are equivalent.