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Is intravenous immunoglobulins (IVIg) efficacious in early pregnancy failure? A critical review and meta-analysis for patients who fail in vitro fertilization and embryo transfer (IVF).

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Erratum in:

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PROBLEM: Intravenous Immunoglobulins (IVIg) are widely used off label in the treatment of early reproductive failure. As IVIg is expensive, and may have side-effects, evidence of efficacy is needed. Previous results have suggested that the pre-conception treatment of primary recurrent abortion patients might be effective, but the data set has been too small for adequate statistical power. More recently it has been suggested that IVIg may improve the success rate of in vitro fertilization and embryo transfer (IVF) in patients with prior IVF failures, but clinical trials have given conflicting results that need explanation. Systematic reviews generating inconclusive results have focused on methodological rigor to the exclusion of biological plausibility. **METHODS:** Review of current basic science of design, measurement, and evaluation of clinical trials and basic science mechanisms providing a rationale for treatment. Meta-analysis of published randomized controlled and cohort-controlled trials (updated with two unpublished data sets) evaluating IVIg treatment in IVF failure patients. Live birth rate was used as the most relevant endpoint. The ability of different sources of IVIg to suppress natural killer (NK) cell activity was determined using a standard (51)Cr-release assay in vitro. **RESULTS AND CONCLUSIONS:** Meta-analysis of three published randomized controlled trials (RCTs) of IVIg in IVF failure patients shows a significant increase in the live birth rate per woman ($p = 0.012$; Number Needed to Treat for 1 additional live birth, NNT = 6.0 women). Using live birth rate per embryo transferred, and adding data from two cohort-controlled trials to the meta-analysis further supports this conclusion (overall $p = 0.000015$, NNT = 3.7 women). Relevant variables appear to include properties and scheduling of the IVIg, and selection of patients with abnormal immune test results. Different IVIg preparations vary significantly in their ability to suppress NK activity in vitro. A rationale for use of IVIg is provided by a review of mechanisms of IVIg action and mechanisms underlying failure of chromosomally normal embryos.

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