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P88. OVALEAP EFFECTIVENESS IN COMPARISON TO GONAL-F: A POST-HOC ANALYSIS

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Context
Ovaleap® (follitropin alfa), a biosimilar to Gonal-f®, demonstrated non-inferiority in a phase 3 study, with comparable number of oocytes retrieved (primary endpoint). Some secondary endpoints in the study demonstrated variances, not statistically significant, between the products. A post-hoc analysis was conducted to explore these variances as the original study did not.

Objective
To assess the relationship between the observed variances in some of the secondary endpoints of the phase 3 study and the effectiveness of Ovaleap® and Gonal-f®.

Method
Post-hoc analysis of an Ovaleap® phase 3 non-inferiority study, stratified by age (<30 years, 30-34 years, >34 years).

Patients
Infertile women, otherwise healthy, aged 18 to 37 years who were normally gonadotrophic, had 2 confirmed normal ovaries and were undergoing controlled ovarian stimulation with assisted reproductive technology.

Interventions
Ovaleap® or Gonal-f®

Main Outcome Measures
Estradiol level on day of human chorionic gonadotropin (hCG); number of follicles > 14 mm; total dose of recombinant human follicle-stimulating hormone (r-hFSH); duration of FSH treatment; oocyte maturity; embryo quality; number of blastomeres per embryo transferred

Results

[1] Teva Pharmaceuticals, [2] Teva Pharmaceuticals, [3] Teva Pharmaceuticals

The analysis included women receiving Ovaleap® or Gonal-f®: n = 32 and 33 (<30 years), 92 and 72 (30-34 years), and 25 and 35 (> 34 years), respectively. Compared to Gonal-f®, mean estradiol level on hCG day was lower for Ovaleap® in patients <30 years, similar in patients 30-34 years and higher in patients >34 years. Number of follicles >14 mm was slightly higher in Gonal-f® patients <30 and 30-34 years but higher in Ovaleap® patients >34 years. Total r-hFSH dose and days of therapy were lower in Ovaleap® patients <30 and 30-34 years, though lower in Gonal-f® patients >34 years. Oocyte maturity was similar across both treatments. Embryo quality was fairly constant with Ovaleap® independent of age, while Gonal-f® demonstrated slightly higher variability by age. The number of blastomeres per embryo transferred, distribution of the number of blastomeres, and dynamics of embryo growth, was similar in both treatments.

Conclusions

Ovaleap® is an established biosimilar to Gonal-f®. This post-hoc analysis confirms that the variances between the two products observed in the phase 3 study do not indicate different product effectiveness given the lack of consistency across the three age groups and thus are not clinically relevant.