



P91. OOCYTE FERTILIZATION RATE, EMBRYO TRANSFER, AND USER SATISFACTION WITH FOLLITROPIN ALFA IN REAL-WORLD ASSISTED REPRODUCTIVE TECHNOLOGY CLINICAL PRACTICE: A MULTICENTER, PROSPECTIVE, OPEN, NON-INTERVENTIONAL STUDY

Wiegratz I (DE) [1], Schneidereit R (DE) [2], Sydow P (DE) [3], Pribbernow K (DE) [4], Keck C (DE) [5]

Context – Ovaleap[®] (follitropin alfa), a recombinant human follicle-stimulating hormone, has shown therapeutic equivalence in efficacy and safety to Gonal-f[®] for controlled ovarian stimulation (COS) in a randomized controlled clinical trial in infertile women using assisted reproductive technology (ART). Both treatments were similar in median number of embryos obtained and transferred. High user satisfaction with the Ovaleap[®] pen was demonstrated in this study.

Objective – To examine fertilization rate, embryo transfer, and user satisfaction with Ovaleap[®].

Methods – Multicenter, prospective, non-interventional study. Recruitment was planned for 1 year. Interim analysis examined women who received Ovaleap[®] dose and had Visit 3.

Patient(s) – Women 18-40 years old (n=155) at specialized reproductive medicine centers in Germany, undergoing first routine ART using in vitro fertilization (IVF)/intracytoplasmic sperm injection (ICSI) following COS with Ovaleap[®].

Intervention(s) - Analysis of real world data of COS cycles using Ovaleap[®] in GnRH antagonist protocol.

Main Outcome Measure(s) –Fertilization rate using IVF/ ICSI; number of transferred embryos; user satisfaction with the Ovaleap[®] pen.

Result(s) – Mean duration of COS with Ovaleap[®] was 9.8+1.7 days (median=10.0), and mean total Ovaleap[®] dose was 1752.7±539.0 IU (median=1650.0). The mean number of metaphase-II oocytes was 8.6±6.1 (median=8.0). Mean percentage fertilization rate of fertilized oocytes in the 2- pro nucleus-stage using IVF/ ICSI (n=142; 10 women excluded with metaphase-II oocytes=0, 3 woman with missing data) was 69.8%±30.0% (median=70.7%). By ART procedure, mean percentage fertilization rate using IVF (n=39) was 60.0%±25.6% (median=60.0%) and using ICSI (n=103) was 73.5%±30.9% (median=75.0%). Mean number of transferred embryos was 1.8+0.4 (median=2.0). Clinical pregnancy

[1] VivaNeo Kinderwunschpraxis Frankfurt, [2] TEVA GmbH, [3] VivaNeo Praxisklinik Sydow, [4] Kinderwunschzentrum Magdeburg, [5] amedes Holding GmbH

was documented in 52 women (33.5%). User satisfaction and convenience with the Ovaleap® pen was high with 96.1% (149/155) of women reporting they were satisfied/very satisfied.

Conclusions – The effectiveness of COS and higher user satisfaction with the Ovaleap® pen appear to extend to real-world ART clinical practice, including IVF and ICSI treatment using GnRH antagonist protocol.