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Reduction of high order multiples without affecting pregnancy. Anthony R. Anderson, Margaret L. Weikert, Jack L. Crain. Institute for Assisted Reproduction, Charlotte, NC; Reproductive Endocrine Assoc of Charlotte, Charlotte, NC.

Objective: The aim of this study is to show high order multiples can be reduced via elective reduction in embryos transferred without affecting overall pregnancy outcomes.

Design: Retrospective analysis of IVF data.

Materials and Methods: Over a two year period a total of 367 non-donor oocyte completed embryo transfers ≥38 years of age were included in the study. The first 328 embryo transfers, the number of embryos transferred were based on age. The second 159 embryo transfers the number of embryos transferred to patients ≥38 years of age was restricted to only 2 embryos unless there was a previous failure. High order multiples was defined as visualization of ≥3 saccs via ultrasound. Ongoing pregnancy was defined as pregnancy sac with cardiac activity and implantation was defined as the number of fetal hearts per embryo transferred. Chi-square analysis was used to determine statistical significance.

Results: Ongoing pregnancy rate was not significantly reduced when the number of embryos transferred was reduced. The first 328 embryo transfers, 178 (54%) ongoing pregnancies were achieved compared to 119/239 (50%) in the second year. Difference in implantation rates were insignificantly different, 178 (54%) ongoing pregnancies were achieved compared to 119/239 (50%) after adjustments for the known prognostic factors listed in the following section.

Conclusions: Our results suggest that IVF outcome may be affected by seasonal changes with a peak in pregnancy and implantation rates during the summer. During this season the higher PR (44%) was observed during the months of June. Since most of our patients underwent down regulation by GnRH agonists we believe that these observations are related to variability in endometrial receptivity modulated by yet unknown input and pathways such as the dark-light cycle. This down regulation of the ovarian-hypothesis axis may, however, interfere with maintenance of early pregnancy and lead to a uniform delivery rate throughout all seasons. Comparable studies especially from the Southern Hemisphere may shed more light on our observations.

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Quality of life (QOL) differentiation analysis in patients undergoing controlled ovarian stimulation (COS) with two different preparations of recombinant human follicle-stimulating hormone (r-hFSH). Salim Daya, Matts Wikland, Kaylen M. Silverberg, Selina Blatz, Gerard Duru, Ariel Beresniak. McMaster Univ, Hamilton, ON, Canada; Carlanderska Hos, Gothenburg, Sweden; Caron List, Austin, TX; Reproductive Endocrine Medicine & Infertility Assoc, Woodbury, MN; National Ctr of Scientific Research, Villeurbanne, France; Serono Intl SA, Geneva, Switzerland.

Objective: The effects of treatment on QOL are important to patients and may have an effect on compliance. Differences in drug effects on the QOL of patients undergoing assisted reproductive techniques have been little studied because of the inherent difficulties of organizing clinical trials with sufficient power to detect small differences between treatment regimens. The objective of this study was to perform a QOL analysis using the Short Form-36 (SF-36) QOL questionnaire combined with mathematical modeling to determine whether differences in QOL exist between patients undergoing COS with follitropin alfa (Follon-F, Serono) and follitropin beta (Follistim/Puregon liquid, Organon). Follitropin alfa has been shown to have superior local tolerability over follitropin beta, but there are no published data on differences in overall QOL.

Design: Prospective, randomized trial with QOL analysis using the Short Form-36 (SF-36) combined with mathematical modeling.

Materials and Methods: The SF-36 questionnaire was administered to patients who received COS with follitropin alfa (n = 22) or follitropin beta (n = 21) in a randomized controlled clinical study. SF-36 scores before and after COS were obtained for each patient. Results for the eight ‘dimensions’ of the SF-36 (physical functioning, physical limitations, pain, general health, vitality, social functioning, emotional limitations and mental health) were projected in one dimension using multifactorial analysis to produce a composite QOL score. Statistical tests were performed to determine the percentage of relevant information captured by the multifactorial analysis and hence the quality of the composite score. A computer simulation technique (bootstrap analysis) was used to generate additional random samples of the same size as the original sample. The Kolmogorov-Smirnov test was used to compare the distributions of the composite scores for the follitropin alfa and beta groups.

Results: The test performed to validate the composite QOL score gave a value of 0.55 (55% of relevant information captured), compared with an expected score of 0.125 for a random projection of eight dimensions into one, confirming the high quality of the multifactorial analysis. The distribution of composite scores for the two groups was significantly different after 30 simulations (p = 0.004), suggesting a difference in the effects of the two treatments on QOL. A graphical plot of the results of 5000 simulations showed that the follitropin beta group had a greater reduction in QOL as a result of COS compared with the follitropin alfa group.

Conclusions: In many therapeutic areas outside reproductive health, QOL analysis has been used successfully to differentiate similar therapeutic agents amongst small patient populations. The application of QOL analysis in COS provides an important clinical decision making tool to understand the impact of gonadotropin stimulation on patients. Mathematical modeling, using standard and robust techniques, confirms a statistically significant difference in QOL effects of the two r-hFSH preparations in favor of follitropin alfa. Infertility treatment providers need to be conscious of the effects that fertility medications have on patient QOL and consider altering their stimulation regimens in order to minimize any adverse effects while simultaneously maximizing patient compliance.

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AUC (Area Under The Curve) for E2 ( Estradiol) levels do not reflect E2 levels on the day of hCG administration among individual patients undergoing COH (Controlled Ovarian Hyperstimulation) for IVF-ET (In-Vitro Fertilization and Embryo Transfer). Mohamed F. M. Mitwally, Hemlata S. Bhakoo, Kent Crickard, Michael W. Sullivan, Ronald E. Batt, John Yeh. Univ at Buffalo, State Univ of New York (SUNY), Buffalo, NY.

Objective: There is a controversy regarding the effect of supraphysiologic estradiol (E2) levels attained during controlled ovarian hyperstimulation (COH) in patients undergoing assisted reproductive technology (ART) cycles on the outcome of treatment. Some investigators suggested unfavorable outcome associated with high responders who attained significantly determined after adjustments for the known prognostic factors listed in the following section.

Results: The pregnancy rates (PR) were 29.9% in the Autumn (September-November), 30.6% in the Winter (December-February), 31.7% in the Spring (March-May), and 37.8% (P=0.008) in the Summer (June-August).

Most of our patients underwent down regulation by GnRH agonists we believe that these observations are related to variability in endometrial receptivity modulated by yet unknown input and pathways such as the dark-light cycle. This down regulation of the ovarian-hypothesis axis may, however, interfere with maintenance of early pregnancy and lead to a uniform delivery rate throughout all seasons. Comparable studies especially from the Southern Hemisphere may shed more light on our observations.