Acceptability and utility of the CONSORT algorithm for calculating recombinant human follicle-stimulating hormone starting doses for ovarian stimulation in assisted reproductive technology: an observational study

JL Pouly, F Olivennes, N Massin, M Celle, N Caizergues, F Contard, on behalf of the French CONSORT study group

Unité de FM, CNRS Eduing, Clermont Ferrand, France; Clinique de la Martre, Paris, France; Unité d’Assistance Médicale à la Procréation, Université Paris 13, Centre Hospitalier Intercommunal, Creteil, France; SOLADIS, Lyon, France; Med’Serena S.A.S., Lyon, France

25th Annual Meeting of the European Society of Human Reproduction and Embryology (EESREH); 7-10 July 2013, London, UK

Introduction

- Follitropin-α (FSH) products are used during controlled ovarian stimulation (COS) to promote follicular development and key aspects of assisted reproductive technology (ART). Indirect responses to COS use after pregnancy and so the choice of FSH starting dose is an important clinical decision.
- The CONSORT calculator is a recombinant FSH starting dose for individualized (re)CALCukanter (n=40) in a dosing algorithm that uses (n=40) patient characteristics, (n=40) ovulatory characteristics, (n=40) and (n=40) FSH concentrations. (n=40)
- The CONSORT calculator was designed to provide an optimal starting dose of recombinant FSH (r-hFSH) in anovulatory women aged 35–45 years undergoing COS in a long gonadotropin-releasing hormone (GnRH) agonist protocol for ART.
- This study assessed the acceptability and utility of the CONSORT calculator by physicians for selecting starting doses of r-hFSH for COS in assisted reproductive clinical practice.

Methods

Study design

- This was a prospective, multicentre, non-interventional, observational study using data from patients treated at private and public ART centres in France.
- Physicians participated on a voluntary basis.
- Recruitment was limited to five patients (three per physician).
- Exploratory analyses were the acceptability and utility of the CONSORT calculator.

Patients

- Women aged 18 to 35 years undergoing their first ART cycle, with a (complementary) protocol and FSH criteria being used, were included in the study.
- Other inclusion criteria: BMI ≤35 kg/m², early follicular phase (cycle Days 2–4), serum FSH level ≤5 IU/L, within 3 months prior to study inclusion, no ovulatory cycle abnormalities, and presence of both ovaries.
- Evaluation criteria were: polycystic ovary syndrome, endometriosis. Grade II or III contraception in fertile patients, ovulation-inducing and/or gonadotropin treatments used for ART and contraception in proportion.
- Patients were also excluded if they had received dopamine cromate or gonadotropin within 30 days prior to down-regulation or required stimulation treatment with luteinizing hormone, human menopausal gonadotropin, urinary FSH, dopamine cromate, or methotrexate drugs.
- The study selection criteria meant that this patient population had a good prognosis for COS.

Treatment

- Prior to accessing the CONSORT calculator, physicians recorded their planned starting dose of FSH for each patient.
- The CONSORT calculator was then used to compute an r-hFSH starting dose using the following five baseline factors: BMI, serum FSH level (cycle Days 2–4), within 3 months prior to protocol and AFC (follicles <11 mm at cycle Days 2–4).

Data analysis

Acceptability of the CONSORT calculator

- Physicians were asked to rate the calculator: unhelpfulness and ease of use (easy/very easy).
- Acceptability was defined as the proportion of physicians for whom the CONSORT calculator was acceptable (i.e., not exceedingly burdensome and easy-to-use) to 80% of the patients, or the patient was expressed as a percentage.
- The primary objective was to test whether significantly more than 75% of patients were included.
- Acceptability was used to calculate the physician sample size (i.e., to determine the minimum number of physicians required to participate in the study).

Utility of the CONSORT calculator

- The utility of the CONSORT calculator was assessed per patient, according to the physician’s response when asked if they had followed the CONSORT calculator.

Results

- In total, 197 patients undergoing their first cycle of COS for ART at a private or public ART unit were included between February 2010 and April 2011 were included.
- Mean±SD age of the included patients (N=197) was 34.0±1.9 years.
- As of 165 patients initiated a COS cycle with r-hFSH: 12 patients did not have a COS cycle started.
- Seven patients were withdrawn before down-regulation; and COS cycles were not indicated for these patients due to spontaneous menstruation during down-regulation.

Complementary analyses

COS characteristics

- Of the 168 patients who had a COS cycle started, 91 (54.2%) were prescribed an r-hFSH starting dose that supported IVF; and/or significantly influenced IVF the CONSORT-calculated dose.
- The COS characteristics for the three groups of physicians’ behaviour regarding the CONSORT calculator are shown in Table 3.

Conclusions

- To our knowledge, this is the first study assessing the acceptability and utility of a dosing algorithm for ART physicians in clinical practice for assessing the starting dose of FSH.
- The use of algorithms can lead to greater individualization of treatment, and this study suggests that algorithms show potential for use in routine clinical practice.

References


Acknowledgements

The authors would like to thank all the O Turkish Society for Obstetrics and Gynaecology, 8.6.1999. Published. Fertil Steril. 1999. English version.

Study support

Fertil Support to the preparation of this presentation was provided by Merck Serono. All authors confirmed the final approval of the paper.

Disclosures

Page 451 of 450

Table 4. Treatment outcomes for patients who had a COS cycle started (Complementary analyses population, N=181).

Table 3. COS characteristics for the three groups of physicians’ behaviour regarding the CONSORT calculator, are shown in Table 5.

Figure 1. Acceptability of the CONSORT calculator by physicians and according to behavior group.

Figure 4. Acceptability of the CONSORT calculator by physicians and according to behavior group.

Figure 5. Acceptability of the CONSORT calculator by physicians and according to behavior group.

Figure 6. Acceptability of the CONSORT calculator by physicians and according to behavior group.