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Economic impact of ovarian stimulation with corifollitropin alfa versus conventional daily gonadotropins in oocyte donors: a randomized study

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KEY MESSAGE

According to the economic analysis, corifollitropin alfa increased the overall cost of the treatment as well as the cost per retrieved and effective oocyte. Cost savings can be achieved using less costly gonadotrophins. The cost of corifollitropin alfa compared with recombinant FSH and highly purified human menopausal gonadotrophin should be considered when making treatment decisions.

A B S T R A C T

Assisted reproductive technologies are well-established treatments for many types of subfertility representing substantial economic and healthcare implications for patients, healthcare providers and society as a whole. In order to optimize outcomes according to the type of gonadotrophins within an oocyte donor programme, we performed an economic evaluation based on data collected in a multicentre, prospective, randomized study within three private clinics belonging to the IVI Group. Results showed no relevant between-group differences in the clinical variables. According to the economic analysis, ovarian stimulation with corifollitropin alfa increased the overall cost of the treatment as well as the cost per retrieved and effective oocyte, although the differences were not statistically significant. In conclusion, cost savings can be achieved using cheaper gonadotrophins during ovarian stimulation. The cost of corifollitropin alfa compared with recombinant FSH and highly purified human menopausal gonadotrophin should be considered when making treatment decisions.

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Introduction

Since its introduction in the early 1980s, oocyte donation has played an increasingly important role in assisted reproduction treatments. The increased success and availability of these infertility treatments has resulted in broader use of this strategy (Kalfoglou, 2001).

The IVF process itself is increasingly recognized as contributing to the physical, psychological and emotional burden of infertile patients. Ovarian stimulation is the phase of the IVF cycle that requires patients to most actively participate, because it involves daily injections that may continue for several weeks. However, stimulation therapy has been revolutionized in the last two decades. Several advances have been made in the use of gonadotrophins, from initial attempts to extract them from animals to the production of recombinant gonadotrophins, which have improved the efficacy and ease of administration of ovarian stimulation protocols (Azziz, 2006). Furthermore, novel drug delivery systems will ultimately lead to simpler and more convenient dosing regimens and superior safety, rendering greater patient satisfaction.

Corifollitropin alfa is a long-term recombinant FSH molecule that provides sustained stimulation. Pharmacological and pharmacodynamic properties of this molecule may facilitate the design of simpler stimulation protocols and the need for fewer resources when tracking the patient, and is considered a good alternative for ovarian stimulation. Its safety profile, combined with gonadotrophin-releasing hormone (GnRH) antagonists, may increase treatment convenience, by reducing the number of injections needed for effective and safe follicular maturation (Requena et al., 2013).

On the other hand, assisted reproductive technologies are well-established treatments for many types of subfertility, representing substantial economic and healthcare implications for patients, healthcare providers and society as a whole. While the majority of costs associated with IVF, such as human resources, are fixed, the choice of gonadotrophins is one area where clinicians can make cost-effective decisions that directly influence healthcare budgets (Wechowski et al., 2007). The desire to optimize outcomes underpins the need to compare three types of gonadotrophins within an oocyte donor programme: corifollitropin alfa, follitropin beta and menotropins.

Materials and methods

We performed an economic evaluation based on data collected in a multicentre, prospective, randomized study conducted within three private clinics belonging to the IVI Group. All procedures and protocols were approved by the Institutional Review Board (1403-MAD-013-AR; October 2014); the study is registered on clinicaltrials.gov (NCT02213627).

Study population

Oocyte donors (n = 208) undergoing their first stimulation cycle were allocated to stimulation with recombinant FSH, highly purified human menopausal gonadotrophin (HP-HMG) or corifollitropin alfa.

Oocyte donors were healthy women aged between 18 and 35 years, with regular menstrual cycles, no hereditary or chromosomal diseases, with normal karyotype and negative for sexually transmitted diseases (Garrido et al., 2002). Inclusion in the oocyte donor pool also required that the donor had at least six antral follicles per ovary at the beginning of the cycle. Donors who had polycystic ovary syndrome based on Rotterdam criteria (Azziz, 2006) or multifollicular ovaries were excluded. A commercially available corifollitropin alfa preparation (Elonva® 100 µg) was used; therefore, donors were also required to weigh less than 60 kg to fulfil the indication criteria for the application of this drug (de Greef et al., 2010). In order to avoid any bias imposed by this limitation, all participants in the study weighed less than 60 kg.

Consenting donors were randomly allocated to an ovarian stimulation group. Randomization was performed with an online randomization programme (AleatorMetod; Ramos Álvarez©), during the control visit at the start of menses and before beginning ovarian stimulation. An oral contraceptive pill (Ovoplex® 150/30; Wyeth Farma, Madrid, Spain) was taken for a maximum of 21 days, starting on day 1 or 2 of menses of the previous cycle. After a wash-out period of 5 days after the last pill, donors started with their assigned stimulation protocol. Donors were allocated to receive 100 µg of corifollitropin alfa (Elonva® 100 µg; MSD, Spain), which could be followed by daily administration of recombinant FSH beginning on day 8 if instructed by the researcher; daily doses of 150 IU recombinant FSH (Puregon® 900 IU; MSD, Spain) or 225 IU HP-HMG (Menopur® 1200 IU; Ferring, Spain). The rationale of using a higher HMG starting dose is based on previous studies (Andersen et al., 2006; Devroey et al., 2012) comparing recombinant FSH against HP-HMG. Daily doses of 0.25 mg GnRH antagonist (Orgalutran®; MSD, Spain) were started on day 6 of stimulation in all groups. Finally, a single dose of 0.1 mg GnRH agonist (Decapeptyl®; Ipsen Pharma, Spain) was administered to trigger final oocyte maturation. Transvaginal oocyte retrieval was performed 36 h later.

Economic evaluation

Economic assessments were performed as a cost-effectiveness analysis from the clinical perspective, focusing on direct medical costs during treatment.

Data on resource use were collected from the individual donors. For each woman, the interventions and medications received during the ovarian stimulation protocol were registered until the oocyte pick-up. The unit cost of each gonadotrophin was considered together with the cost of nursing, infrastructure, patient care time and consumables. Medical expenses, except the cost of the drugs, were only charged to treatment with conventional gonadotrophins during the first 5 days of stimulation, because donors included in the long-acting recombinant FSH group did not have to go to the clinic to receive the medication during this period. To calculate the costs, stimulations that were cancelled were also considered.

Statistical analysis

Data from clinical outcomes are presented as descriptive statistics. The cost of treatment with corifollitropin alfa was used as the reference for economic differences, and compared with the costs of treatment with recombinant FSH and HP-HMG, respectively. Clinical results were analysed using Student's t-test for comparison of means and chi-squared test for proportions. A P-value <0.05 was considered statistically significant. Statistical analyses were performed using the Statistical Package for the Social Sciences 19.0 (IBM Corporation, NY, USA).

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