Efficacy and Comvenience of Follitropin β Administered by a Pen Device in Patients Undergoing Controlled Ovarian Hyperstimulation for IVF-ET

Chung-Hoon Kim

Department of Obstetrics and Gynecology, College of Medicine, University of Ulsan, Asan Medical Center, Seoul, Korea

Background and Aims

During the last decade, urinary FSH have been increasingly replaced by recombinant human FSH (rhFSH). RhFSH has been reported to be lower in the risk of immunogenicity as well as infection than that of the urinary products. Recombinant products are highly pure (>99%), and indeed, any antibodies to FSH have not been detected in serum samples from patients who have injected rhFSH. Therefore, The use of this recombinant product has resulted in more efficient and predictable ovulation induction or controlled ovarian hyperstimulation (COH). Additionally, rhFSH has been shown to be suitable for subcutaneous (SC) administration and SC injections allow for easier self-administration by patients. RhFSH was first available as a freeze-dried lyophilized powder, which had to be dissolved in water for injection before administration. Lately, rhFSH has been made available as a premixed ready-to-use solution and this product is more "patient friendly". A subsequent advance in patient-friendly regimens is the development of follitropin β solution, which is in a cartridge form for administration with a pen device. This multiple-use pen device for SC self-administration of rhFSH which is approved under the brand name Puregon® Pen has been available in Europe since 2002.

This study was performed to compare the efficacy and convenience of a pen device for the self-administration of rhFSH (follitropin β) with a conventional syringe delivering rhFSH solution in patients undergoing COH for IVF-ET.

Materials and Methods

A total of 100 patients who were scheduled for IVF-ET, with or without intracytoplasmic sperm injection (ICSI) were enrolled in this prospective study. All subjects were randomized to the pen device group or the conventional syringe group by a computer-generated randomization list using random numbers on a first day of COH. Local tolerance reactions were assessed and filled in a local tolerance book within 5 min, at 1 and 3 h after each injection. On the day of hCG injection, patients were asked to rate the pain and

convenience experienced by means of a visual analogue scale (VAS). Oocyte pickup was scheduled 35~36 hours after hCG administration, and embryos were transferred 3 days after oocyte pickup.

Results

There were no differences in age, body mass index (BMI), infertility duration, endocrine profile and indications for IVF-ET/ICSI between the two groups. The duration of COH with rHFSH was significantly shorter in the pen device group than in the conventional syringe group (8.7±1.1 vs 9.3±1.3 days) ($p<0.05$). Patients included in the pen device group needed significantly less rHFSH with 2091.0±318.8 IU compared with 2248.0±405.0 IU in the conventional syringe group ($p<0.05$). However, no differences between the two groups were found in numbers of oocytes retrieved, mature oocytes, fertilized oocytes and grade I/II embryos, clinical pregnancy rate and miscarriage rate. The prevalence of pain after the daily injection was significantly lower in the pen device group ($p<0.05$). VSA scores were significantly less painful and more convenient for the pen device ($p<0.05$, $p<0.001$, respectively).

Conclusion

The pen device for self-administration of follitropin β is effective, safe, less painful and more convenient for the patients, and can be more beneficial because of the short-term and small dose application of rFSH.