ESHRE 2020 Virtual (5-8 July 2020)

Questions for the speakers

Session 50: Androgen treatment in fertility management

A prospective study of testosterone gel treatment in poor ovarian reserve in IVF-ICSI cycles - Randhir Singh (India)

Q: You likely stated max stim in both groups (300-450IU) and days antagonist decreased by 1, why did dose of stim with testo decrease by about 600 IU

A: Please see attachment-1, a sample stimulation protocol to explain the FSH dose and antagonist days.

Q: What is your rationale for using testosterone for 21 days prior to stimulation - time-frame and dose?

A:21-days Testosterone gel pre-treatment in a dose of 12.5 mg per day has worked effectively in several previous studies all over the world, with minimum side-effects.

Q: Can you discuss the duration of testosterone supplementation chosen in your protocol?

A: In the study group , once daily application of Transdermal Testosterone Gel was started from sixth day of E-P pretreatment and continued for 21 days.

Q: Did you continue the gel during the Gn ovarian stimulation?

A: No, the gel application was stopped before Gn ovarian stimulation.

Q: Why did you give Estrogen and Prog in pre cycle with testosterone?

A: All the patients included in our study were above 40 years of age, with irregular/shortened cycle length in many of them. The E+P pretreatment ensured that all participants received a full duration of testosterone gel treatment prior to ovarian stimulation.

Q: Why did you not add LH in simulation?

A: Recently Humaidan et al. (2017) published the results of the largest RCT in patients aligned with the Bologna criteria (ESPART trial). In this trial, a total of 939 patients were randomized to either a fixed daily dose of either 300 IU r-hFSH plus 150 IU r-hLH or rhFSH 300 IU alone. The results indicated no significant differences between groups regarding LBR. That is the reason we decided to use only recombinant-FSH in our study.

Q: Do you have information about the FORT test in both groups studied of your study?

A: The FORT test is only used in structured teaching programs, therefore not applicable here.

Q: Since androgens are so important to granulosa cells why not use them during ovarian stimulation?

A: In this small group of patients, we specifically wanted to assess the results of pre-treatment with androgens, prior to gonadotropin stimulation, for a period not exceeding three weeks. The results of longer duration of testosterone gel treatment will probably become clear after the T-Transport Trial is over.

Q: Was serum-testosterone different between the two groups before and after you started the intervention? Moreover, what about the live birth rate?

A: Serum testosterone estimation was not a part of our trial. The endpoint of our study was taken as the Clinical Pregnancy Rate as ours is a dedicated ART unit and it becomes difficult to follow-up patients who come from all over India.

Q: Is there any study comparing with without testo in same pt in two different cycles?

A: We do have such patients but the data has not been analysed. Probably it could be taken up in our future research. Thanks.

Q: Is there a role of measurement of Testosterone or DHEAS before start of treatment?

A: In our study, we did not measure the total testosterone/ DHEAS levels before start of treatment as it did not have an effect on the final outcome of the study. It also increased the cost of the cycle.

Q: Why did you opt for separately administering E+P rather than simple COC Pills?

A: This was done only to have uniformity in cycle regulation.

Q: How did you achieve a sample size of only 52 women? What was the alpha and beta levels which you considered? Kindly give details.

A: We had fixed the study duration and a complete enumeration of patients fulfilling the inclusion criteria was done during this period. In a complete enumeration, alpha and beta errors need not be considered.

Q: You started stimulation with 225 IU Gn instead of the accepted 300 IU for POR. Please explain why considering that the women were proven poor responders

A: Our patients were POSEIDON Group-4 and had AFC <5-7. In our study, we wanted to prove that even a dose of rec-FSH 225 IU is able to recruit all the available antral follicles in poor responders and this may become the norm in the future.

Q: Was your trial registered as per your country's norms with the national body?

A: Yes

Q: You had presented on the same topic few years back at ESHRE. Why didn't you use LBR as a primary outcome this time?

A: It was not possible to use LBR as the primary oucome because we are a dedicated ART unit getting patients from all over India. It is difficult to follow-up the obstetric outcome as patients frequently switch from government to private health services and vice versa.