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[Title]

Serum testosterone level is not a marker of ovarian reserve nor ART outcome for poor ovarian responders

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[Study question]

Is there a correlation between serum testosterone level and ovarian reserve tests, or assisted reproductive technology (ART) outcomes for poor ovarian responders?

[Summary answer]

No significant correlation was recognized between serum testosterone level and ovarian reserve tests, nor ART outcomes for poor ovarian responders.

[What is known already]

Testosterone, an androgen, has been shown to play an important role in follicular recruitment or development. In a recent meta-analysis, testosterone pretreatment during ART cycle resulted in an increased number of retrieved oocytes. Some researchers suggested an increased chance of live birth with testosterone supplementation, however more supporting data is still required to make such a conclusion. If supplementation of testosterone improves the outcome of ART and contributes to successful implantation, serum testosterone level would have a positive correlation with the number of retrieved oocytes and pregnancy rate in ART cycles.

[Study design, size, and duration]

The present prospective control study is designed to identify correlation between serum testosterone level and ART outcome. Four hundred and forty-one women had blood test in order to record testosterone and anti-mullerian hormone from January 2015 until December 2016. One hundred and fourteen poor responders fulfilled Bologna criteria,

and they had IVF-ETs with ovarian stimulation in the same period.

[Participants, materials, setting, methods]

This study was performed at a private ART clinic located in Japanese urban area. Hormone data was available from all infertile women with various causes after written informed consent. Hormone testing methods were electro-chemiluminescence immunoassay for testosterone, and enzyme-linked immunosorbent assay for AMH gen II. The ART data were collected from medical records on the women who had IVF-ET with conventional or mild ovarian stimulation.

[Main results and the role of chance]

The average age of the participants was 39.2 (SD=4.51, 25-49). The average testosterone was 0.16 ng/mL (SD=0.12, 0-2.25). Testosterone from 151 women (34.2%) showed a below normal limit (0.11 ng/mL), and that of 46 women (10.4%) was below a detection sensitivity limit (<0.03ng/mL). The coefficient of determination were $R^2=0.0036$ (vs. age) and 0.047 (vs. AMH).

The numbers of poor responders with lower testosterone (group A) and those with normal to high testosterone (group B) were 38 and 76, respectively. The profiles of the two groups on age and AMH were identical. The average number of retrieved oocytes in group A was 3.27 ± 2.29 , and 3.21 ± 2.39 in group B. The clinical pregnancy rate (PR) in group A was 36.8%, and 25.0% in group B. The miscarriage rate (MR) in group A was 15.3%, and 26.3% in group B. There were no significant difference in the number of retrieved oocytes ($p=0.45$), PR ($p=0.07$) or MR ($p=0.67$).

[Limitations, reasons for caution]

Small sample size, possible dispersion of the cause of their infertility or the patients' back ground.

[Wider implications of the findings]

One third of infertile women showed decreased serum testosterone level. Testosterone is independent from ovarian reserve markers. ART outcomes such as the number of retrieved oocytes, pregnancy rate and miscarriage rate are identical despite testosterone levels. The findings raise questions regarding the effect of testosterone supplementation on ART treatment.