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ANALYZING SERUM PROGESTERONE LEVEL IN INDIAN WOMEN DURING THREE TRIMESTERS OF NORMAL PREGNANCY AT REFERENCE INTERVALS

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ABSTRACT

Background: For both the mother and the fetus, the hormonal milieu throughout pregnancy becomes a critical predictor. A certain hormone concentration evaluated at each trimester can be a good predictor of feto-maternal outcomes.

Aim: The purpose of this study was to evaluate the reference range for a trimester-specific progesterone assay in healthy pregnant Indian women.

Methodology: The study comprised 138 pregnant women in good health who were in all three trimesters of their pregnancy. The included subjects' serum progesterone levels were measured using an enzyme-linked immunosorbent assay (ELISA).

Results: The study's female participants' progesterone range and interval were evaluated for each trimester of pregnancy. The results showed that the upper limit for progesterone in the first trimester was 93.07 ng/ml, the upper limit for the second trimester was 247.65 ng/ml, and the upper limit for the third trimester was 908.85 ng/ml. For the first, second, and third trimesters, the corresponding confidence intervals were 73.11-119.04, 181.90-333.90, and 745.04-1084.22. In the first, second, and third trimesters of pregnancy, the lower limit for progesterone was 5.47, 6.55, and 95.54 ng/ml. For the study individuals, the corresponding confidence intervals for the lower limit were 4.45-6.93, 5.20-8.59, and 80.22-117.47 for the first, second, and third trimesters of pregnancy, respectively.

Conclusion: The current investigation reveals that there is a significant discrepancy between the progesterone values observed in healthy Indian females and the defined reference range. The current study's findings indicate that serum progesterone levels gradually rise during pregnancy.

Keywords: pregnancy trimester, reference values, progesterone range, and Indian females

INTRODUCTION

Numerous hormones and the feedback systems that regulate them balance out the endocrine functions of the human reproductive system. Progesterone, estradiol, FSH (follicle-stimulating hormone), and LH (luteinizing hormone) all have an impact on the cyclic deviation observed in the menstrual cycle. These hormones are regulated by the

hypothalamic-pituitary-gonadal axis (HPA). The complex regulation of placental hormones is maintained throughout pregnancy. Throughout the entire pregnancy, there are frequent changes to the hormonal environment. Therefore, it is essential to accurately estimate the length of pregnancy in order to anticipate the feto-maternal consequences.1. The development of chronic diseases in both the mother and the fetus during pregnancy is largely controlled by endocrinologic alterations. Determining the particular hormones present in a certain trimester of pregnancy could be a valid biomarker for accurately predicting the feto-maternal outcomes.

The literature data indicates that because Indian pregnant women have distinct reproductive profiles from those of Western women, the reference of progesterone regarded normal in Western women may not apply to them. While measuring these hormonal concentrations in late pregnancy can predict the risk for ovarian or breast cancers, measuring hormones in early pregnancy, during the organogenesis phase of the fetus, may reliably predict the neuro-developmental abnormalities observed in the fetus. In the absence of a luteal shift, the corpus luteum generates progesterone, aids in maintaining pregnancy, and controls the first 11 weeks of gestation. Therefore, the hormone concentration during the luteal phase may determine the likelihood of conception and the success of a pregnancy.2.

A steroid hormone called progesterone is generated by the ovary's granulosa cells. It enhances endometrial decidualization and encourages blastocyst implantation in the uterus. Progesterone also reduces the immunological response, which results in contraction of the smooth muscle in the uterus and graft rejection. Pregnancy outcomes in the first trimester are solely determined by the level of progesterone at the time of natural conception. Therefore, after a natural conception without the need for outside progesterone support, pregnancy viability is an essential component that needs to be evaluated, along with its correlation to blood progesterone levels.3

When predicting outcomes for the mother and fetus throughout pregnancy, the hormonal milieu is a trustworthy indicator. It is required to comprehend the elements essential to this evaluation.

To determine whether there is any divergence, a reference range of hormones may be helpful. Since Indian women have different pregnancy variations than those from the West, most of the data regarding these changes in the literature has been evaluated for women from the West and may not apply to Indian women.4

The goal of the current study was to evaluate the reference range for a trimester-specific progesterone assay in healthy pregnant Indian women. Any divergence from the West region's female population was also evaluated.

MATERIALS AND METHODS

In order to determine the reference range of the progesterone assay specific to a trimester in healthy pregnant Indian women, the current prospective clinical investigation was carried out. Any divergence from the West region's female population was also evaluated. The study was carried out with approval from the relevant ethical committee. The female patients who came to the Institute's Department of Obstetrics and Gynaecology made up the study population. All subjects gave their written and verbal informed consent after being fully told about the study's concept.

The patients who volunteered to participate in the study were healthy pregnant Indian women without concomitant conditions or pre-existing systemic disease. Subjects who received infertility treatment, had comorbidities related to pregnancy, or were unwilling to participate in the study were the exclusion criteria for the research. In the end, the study's patients were admitted based on the inclusion and exclusion criteria.

Following final inclusion, each individual had a thorough history taken and a physical examination. Every subject's complete demographic information was documented, in addition to their medical history, medication history, family history, history of hypertension, history of prior pregnancy, parity, and age.

4 ml of intravenous blood was drawn from the antecubital vein under aseptic and sterile circumstances. The blood was then transferred into test tubes and centrifuged for 5 minutes at 2500 rpm to separate the serum from the blood cells. After that, the blood was examined and kept cold (-40°C). First, second, and third trimesters' worth of serum from expectant mothers were collected for progesterone measurement using an enzyme-linked immunosorbent assay (ELISA).

Using SPSS software version 21 (Chicago, IL, USA) for statistical assessment and one-way ANOVA and t-test for result formulation, the gathered data were examined. The data were presented as a mean, standard deviation, percentage, and number. At $p<0.05$, the significance threshold was maintained.

RESULTS

In order to determine the reference range of the progesterone assay specific to a trimester in healthy pregnant Indian women, the current prospective clinical investigation was carried out. Any divergence from the West region's female population was also evaluated. The study comprised 138 healthy pregnant women who were in all three trimesters of

pregnancy. The included subjects' serum progesterone levels were measured using an enzyme-linked immunosorbent assay (ELISA).

138 pregnant Indian women were included in the hospital-based study conducted at this time. There were 39.85% (n=55) from the second trimester, 31.15% (n=43) from the third trimester, and 28.98% (n=40) from the first trimester. Using SPSS software version 21 (Chicago, IL, USA) for statistical assessment and one-way ANOVA and t-test for result formulation, the gathered data were examined. The data were presented as a mean, standard deviation, percentage, and number. At $p<0.05$, the significance threshold was maintained.

After evaluating the study females' progesterone range and interval for each trimester of pregnancy, it was determined that the upper limit for progesterone in the first trimester was 93.07, the upper limit for the second trimester was 247.65, and the upper limit for the third trimester was 908.85 ng/ml. For the first, second, and third trimesters, the corresponding confidence intervals were 73.11-119.04, 181.90-333.90, and 745.04-1084.22.

In the first, second, and third trimesters of pregnancy, the lower limit for progesterone was 5.47, 6.55, and 95.54 ng/ml. Table 1 shows the corresponding confidence intervals for the lower limit in the first, second, and third trimesters of pregnancy in the study subjects: 4.45-6.93, 5.20-8.59, and 80.22-117.47.

DISCUSSION

Hormones are essential in determining the ideal conditions for human genesis. Progesterone, estrone, and maternal estradiol are mostly deposited in the human corpus luteum, adrenal cortex, and maternal ovary during the first nine weeks of pregnancy. Steroid hormones are progressively and slowly synthesized in placental trophoblasts with increasing concentration starting in the second trimester. The age range of the study participants in this investigation was 18 to 37 years old, with 25 females classified as primigravidae and 113 as multigravidae.

The mean serum progesterone concentration was measured at 30.86ng/ml in the first trimester of pregnancy and rose to 75.61ng/ml and 379.20ng/ml in the second and third trimesters, respectively.

This was consistent with research on progesterone changes in healthy expectant mothers, as shown by the findings from earlier literature.5.

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In the first, second, and third trimesters of pregnancy, the lower limit for progesterone was 5.47, 6.55, and 95.54 ng/ml. For the study individuals, the corresponding confidence intervals for the lower limit were 4.45-6.93, 5.20-8.59, and 80.22-117.47 for the first, second, and third trimesters of pregnancy, respectively. This was in line with studies conducted in 2001 by Vicdan K et al. and in 2012 by Hanita O et al., which indicated that the mean progesterone concentration throughout the first trimester was similar to the current study at 25.2 ng/ml.

In a 2014 study on progesterone concentration, Whitaker-Azmitia PM et al8 found that nulliparous females under 30 years old had the highest progesterone concentration, while older nulliparous females of all ages had higher progesterone concentrations than younger parous or nulliparous females of any age. Progesterone levels in pregnant women at 16 and 27 weeks of gestation were shown to be lower in another study on progesterone hormone concentration, carried out by Lukanova A et al9 in 2012. However, no comparison was established in this investigation due to the stringency of prenatal diagnostic methods. Another drawback of the current study was the inclusion of primigravida and multigravida.

Progesterone levels in females from the West region were found to be greater in the current study's data and range than in earlier published studies.

CONCLUSION

Within its limitations, the present study concludes that a marked difference is seen between the established reference ranges of progesterone to the values seen in healthy Indian females. However, the present study had a few limitations including a small sample size, short monitoring time, and geographical area biases. Hence, more longitudinal studies with a larger sample size and longer monitoring period will help reach a definitive conclusion.

REFERENCES

1. Marshall JC. Hormonal regulation of the menstrual cycle and mechanisms of ovulation. In: DeGroot LJ, Jameson JL, editors. Endocrinology. Philadelphia, PA: WB Saunders, 2001:2073–85.
2. Beral V, Bull D, Doll R, Peto R, Reeves G. Breast cancer and abortion: collaborative reanalysis of data from 53 epidemiological studies, including83 000 women with breast cancer from 16 countries. Lancet. 2004;363:1007–16.

3. Wuu J, Hellerstein S, Lipworth L, Wide L, Xu B, Yu GP, et al. Correlates of pregnancy oestrogen, progesterone and sex hormone-binding globulin in the USA and China. Eur J Cancer Prev. 2002;11:283–93.
4. Zainab Ali Abdulla Al Jufairi. The value of Serum ProgesteroneMeasurement in Early Pregnancy. Bahrain Medical Bulletin, Volume22, Number 1, March 2000.
5. Elson J, Salim R, Tailor A, Banerjee S, Zosmer N, JurkovicD. Prediction of early pregnancy viability in the absence of an ultrasonically detectable embryo. Ultrasound Obstet Gynecol 2003;21:57–61.
6. Vicdan K, ZekiIsik A. Luteal phase hormonal profile in prediction of pregnancy outcome after assisted reproduction. Eur J Obste Gynecol Reprod Biol 2001;96:98–101.
7. Hanita O, Hanisah AH. Potential use of single measurement of serum progesterone in detecting early pregnancy failure. Malaysian J Pathol 2012;34:41–6.
8. Whitaker-Azmitia PM, Lobel M, Moyer A. Low maternal progesterone may contribute to both obstetrical complications and autism. Medical hypotheses. 2014;82:313–8.
9. Lukanova A, Surcel HM, Lundin E, Kaasila M, Lakso HA, Schock H, et al.Circulatingestrogens and progesterone during primiparous pregnancies and risk of maternal breast cancer. Int J Cancer. 2012;130:910–20.

TABLES

S. No	Trimester	Upper Limit (ng/ml)	CI	Lower Limit (ng/ml)	CI
1.	**First (n=40)**	93.07	73.11-119.04	5.47	4.45-6.93
2.	**Second (n=55)**	247.65	181.90-333.90	6.55	5.20-8.59
3.	**Third (n=43)**	908.85	745.04-1084.22	95.54	80.22-117.47

Table 1: Reference interval of progesterone at different pregnancy trimesters in study subjects