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Original Research Article

Assessing Serum Progesterone with Reference Interval During Three Trimesters of Normal Pregnancy in Indian Females

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Abstract

Background: During pregnancy, the hormonal environment becomes a vital predictor for both fetus and mother. To predict feto-maternal outcomes, a specific concentration of hormones measured during each trimester can serve as a reliable predictor. The literature data suggest the reference of progesterone considered normal in females of West may be inapplicable in Indian pregnant females as they have different reproductive profiles.

Aim: The present study was conducted to assess the reference range of progesterone assay particular to a trimester in healthy pregnant females of India.

Methodology: In 138 healthy pregnant females from all three trimesters of pregnancy were included in the study. Progesterone levels were assessed from the serum of included subjects using ELISA (Enzyme-linked Immunosorbent Assay).

Results: The results of the present study have shown a gradual increase in levels of serum progesterone during pregnancy.

Conclusion: The present study concludes that a marked difference is seen between the established reference range of progesterone to the values seen in healthy Indian females.

Keywords: Indian females, Progesterone range, Reference values, Pregnancy Trimester.

Introduction

Endocrine functions of the human reproductive system are widely balanced by various hormones and by feedback mechanisms that control them. Cyclic deviation seen in the menstrual cycle is affected by progesterone, estradiol, FSH (Follicle-stimulating hormone), LH (luteinizing hormone), which in turn, are controlled by HPA (hypothalamic-pituitary-gonadal axis). Placental hormones are regulated intricately and are maintained during pregnancy. The hormonal environment is regularly changed during the whole pregnancy. Hence, to predict the feto-maternal outcomes, an accurate assessment of pregnancy duration is vital.[1] Chronic disease development in fetus and mother during pregnancy is widely governed by endocrinologic changes seen. Estimating the specific hormones seen during a specific pregnancy trimester may be a reliable biomarker that can predict the feto-maternal outcomes appropriately. Estimation of hormones during early pregnancy, during the organogenesis phase of the fetus, may reliably predict the neuro-developmental anomalies seen in the fetus by assessing the concentration of hormones, whereas, assessment of these hormonal concentrations during late pregnancy can predict the risk for ovarian or breast malignancies. Corpus luteum produces progesterone and helps in pregnancy sustainment and regulates the initial pregnancy stage till 11 weeks of gestation unless luteal shift takes place. Hence, during the luteal phase, the concentration of hormones may assess the conception chances and viable pregnancy outcomes.[2]

Progesterone is a steroid hormone that is produced by granulosa cells of the ovary and promotes blastocyst implantation in the uterine cavity and increases endometrial decidualization. Progesterone

also decreases immune response causing graft rejection and uterine smooth muscle contraction. Pregnancy outcomes during the first trimester are exclusively governed by the progesterone concentration during the natural conception. Hence, pregnancy viability is a vital aspect to be assessed following natural conception with no external progesterone support and assessment of its relationship with serum progesterone values.[3]

During pregnancy, the hormonal milieu is a reliable predictive factor for assessing outcomes related to both fetus and mother. Understanding the factors vital to this assessment is necessary. A reference range of hormones may help to assess if any deviation is seen. The majority of the data concerning these changes in literature has assessed the females from the West region and might not apply to Indian females as various pregnancy variations are seen in Indian females compared to the females of the West.[4] The present study was conducted to assess the reference range of progesterone assay particular to a trimester in healthy pregnant females of India. Also, any deviation from females of the West region was assessed.

Materials and Methods

The present prospective clinical study was conducted to assess the reference range of progesterone assay particular to a trimester in healthy pregnant females of India. Also, any deviation from females of the West region was assessed. The study was conducted at Department of Obstetrics and Gynaecology, Rajendra Institute of Medical sciences, (RIMS), Ranchi, Jharkhand. After explaining the detailed study design, informed consent was taken from all the subjects in both written and verbal form. The present study included healthy pregnant Indian females with no associated complications and no pre-existing systemic disease and the subjects who were willing to participate in the study. The exclusion criteria for the study were subjects having comorbidities associated with pregnancy, subjects who underwent infertility treatment, and subjects who were not willing to participate in the study. The subjects were finally included in the study based on the inclusion and exclusion criteria. After final inclusion, detailed history was recorded for all the subjects followed by physical examination. Detailed demographics were recorded for all the subjects along with recording the medical disorder history, history of medication, family history, hypertension history, history of previous pregnancy, parity, and age. Under aseptic and sterile conditions, 4ml intravenous blood was collected from the antecubital vein which was then placed in test tubes followed by centrifugation at 2500rpm for 5 minutes which separated the serum from the blood cells. The blood was then analyzed and stored at -40°C. Collection of serum from pregnant females was collected in the first trimester, second trimester, and third trimester for progesterone assessment using ELISA (Enzyme-linked Immunosorbent Assay). The collected data were subjected to the statistical evaluation using SPSS software version 21 (Chicago, IL, USA) and one-way ANOVA and t-test for results formulation. The data were expressed in percentage and number, and mean and standard deviation. The level of significance was kept at $p<0.05$.

Results

The present prospective clinical study was conducted to assess the reference range of progesterone assay particular to a trimester in healthy pregnant females of India.

Also, any deviation from females of the West region was assessed. In 138 healthy pregnant females from all three trimesters of pregnancy were included in the study. Progesterone levels were assessed from the serum of included subjects using ELISA (Enzyme-linked Immunosorbent Assay). The present study was hospital-based included, 138 pregnant Indian females. There were 28.98% (n=40) subjects from 1st trimester, 39.85% (n=55) subjects from 2nd trimester, and 31.15% (n=43) subjects from 3rd trimester of the pregnancy. The collected data were subjected to the statistical evaluation using SPSS software version 21 (Chicago, IL, USA) and one-way ANOVA and t-test for results formulation. The data were expressed in percentage and number, and mean and standard deviation. The level of significance was kept at $p<0.05$. On assessing the progesterone range and interval in different trimesters of pregnancy in the study females, it was seen that in females during the first trimester of pregnancy, the upper limit for progesterone was 93.07, in 2nd trimester the upper limit was 247.65, and for the third trimester, the upper limit was 908.85 ng/ml. The respective confidence interval for the 1st, 2nd, and 3rd trimester was 73.11-119.04, 181.90-333.90, and 745.04-1084.22. The lower limit for progesterone in the first, second, and third trimesters of pregnancy was 5.47, 6.55, and 95.54 ng/ml. The respective confidence interval for the lower limit in the first, second, and third trimester of pregnancy was 4.45-6.93, 5.20-8.59, and 80.22-117.47 respectively in the study subjects (Table 1).

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

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

Discussion

A vital role is played by hormones in defining the human inception's optimum conditions. In the first 9 weeks of pregnancy, progesterone, estrone, and maternal estradiol are primarily stored in the maternal ovary, adrenal cortex, and corpus luteum in humans. Gradually and slowly, from the second trimester, steroid hormones synthesis takes place in placental trophoblasts with increasing concentration. In the present study, the age range of study subjects was from 18 years to 37 years where 25 females were primigravida and 113 females were multigravida in the present study.

In the first trimester of pregnancy, the mean serum progesterone concentration was seen as 30.86ng/ml which increased in the second and third trimester to 75.61ng/ml and 379.20ng/ml respectively. This was in agreement with the studies of progesterone change seen in healthy pregnant females as established in the previous literature data.[5]

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In one study conducted by Whitaker-Azmitia PM et al[8] in 2014 concerning progesterone concentration, the highest concentration of progesterone was seen in females of less than 30 years and who were nulliparous, whereas, in nulliparous females of age more than 30 years, had the progesterone concentration higher than young parous or nulliparous females irrespective of any age. Another study by Lukanova A et al[9] in 2012 conducted on progesterone hormone concentration showed reduced progesterone levels in pregnant females at 16 and 27 weeks of gestation. However, owing to the stricture of pre-natal diagnostic techniques, no comparison was made in the present study. Also, the inclusion of both multigravida and primigravida was a limitation in the present study. The data and range of progesterone seen in the present study were higher than the previously reported values of progesterone in the literature in females of the West region.

Conclusion

Within its limitations, the present study concludes that a marked difference is seen between the established reference range 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.

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