Medians for maternal serum unconjugated estriol during normal pregnancy in Russian population with competitive ELISA

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Background-aim

Unconjugated estriol (uE3) is the major estrogen formed by the fetoplacental unit during pregnancy. About 90% of the estriol excreted by the mother derives from the fetal precursors at 20 weeks gestation. DHEAS is the major substrate for the placental estrogen production. Estriol then diffuses in the maternal circulation. Only 17% of circulating estriol is free or unbound to sex steroid-binding globulin or other carrier proteins. Circulating estriol is reconjugated with glucuronic acid in the maternal liver and excreted in bile and urine. These metabolic pathways indicate that measurement of free or uncojugated estriol in plasma or serum is the most sensitive marker of fetoplacental estrogen synthesis. Maternal serum uE3 levels have been recommended to monitor fetal status. Determination of the normal range limits plays an important role in this process

Methods

Data derived from 323 serum samples which were obtained from unaffected, singleton white pregnant women (mean age 29 years, Central Russia and Volgo-Viatsky Region). Fresh maternal serum from gestation weeks 4-37 was used. Gestation age was estimated by ultrasound or by the first day of the last menstrual period. Concentrations of uE3 were measured using a quantitative competitive solid phase enzyme immunoassay. An enzymeimmunoassay (DS-EIA- free Estriol) was developed. Estriol-6-BSA was used as antigen for the antiserum production with low cross reactivities to estrone (0.4%) and estriol 16 glucuronide (0.3%). The test requires a simple photometer for the measurement of enzyme label (HRP). The developed DS-EIA- free Estriol needs a short incubation time (50 minutes). The results of testing were examined in retrospective study with software Analyze-it for Microsoft Excel.

Results

Maternal serum uE3 values were ranged according to the gestational week. Medians and multiples of medians (MoM) were calculated for every gestational week. Normal range limits (0.5 MoM-2 MoM) for gestational weeks from 12 to 33 are represented in Table 1. uE3 concentration values were log10 transformed and the weeks were on arithmetic scale. In this study, we wish to find what regression model gives a good fit and produces robust estimates of the regression coefficients. Complete polynomial analysis up to the third degree was carried out. Table 1 compares uE3 medians obtained with the first-degree and the second-degree polynomial equations.

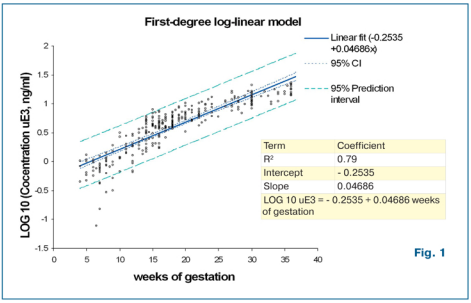

Fig. 1

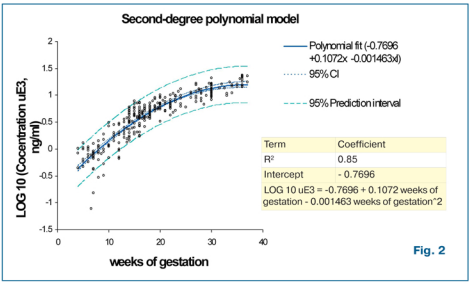

Fig. 2

Table 1

Expected values of maternal serum uE3 and obtained regressed medians for normal pregnancy state in central Russian population by DS-EIA- free Estriol.

Number of gestation weeks	N	uE3, ng/ml				
		Median	Normal range		Regressed median log-linear	Regressed median log-second-degree polynominal
			0.5 MOM	2.0 MOM		
12	12	1.28	0.64	2.56	2.04	2.02
13	11	2.39	1.20	4.79	2.27	2.38
14	21	3.27	1.63	6.53	2.53	2.78
15	22	4.20	2.10	8.40	2.81	3.23
16	28	4.32	2.16	8.64	3.14	3.72
17	17	3.98	1.99	7.96	3.49	4.27
18	24	4.98	2.49	9.95	3.89	4.85
19	11	6.05	3.02	12.1	4.33	5.48
20	16	6.78	3.39	13.6	4.83	6.15
21	7	6.10	3.05	12.2	5.38	6.86
22-23	17	7.30	3.65	14.6	6.32	7.98
24-25	6	7.92	3.96	15.8	7.84	9.52
26-27	11	11.3	5.64	22.6	9.73	11.1
28-29	10	10.9	5.45	21.8	12.1	12.5
30-31	27	12.7	6.34	25.4	15.0	13.8
32-33	6	13.6	6.81	27.2	18.6	14.8
34-35	6	14.6	7.31	29.3	23.1	15.4
36-37	15	18.2	9.11	36.4	28.6	15.6

Conclusions

The normal limits of maternal serum uE3 for Central Russia population with DS-EIA-free Estriol were defined. uE3 levels increase gradually during pregnancy and most rapidly in the third trimester. Second-degree polynomial equation gave a better fit which describes the relationship between gestational weeks and the log10 transformed concentrations of uE3. As the normal ranges for uE3 are very wide, it is recommended to monitor each patient for establishment of individual trend.