

EVALUATION OF URINARY ESTRIOL BY LATEX AGGLUTINATION INHIBITION REACTION

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Summary: The urinary estriol values of a morning sample determined by a new semiquantitative method was correlated with the total 24 hour estriol excretion determined by colorimetric method on patients with normal and pathologic pregnancy. The correlation coefficient, calculated on 240 assays operated on urine samples obtained from 70 normal pregnant women, is highly significant statistically ($P < 0.001$). The profiles of the serial assays, obtained by these two procedures on patients with pathologic pregnancy, show a very strong analogy. The Authors believe that such a method, just for its simple and rapid realization, may be applied alternatively to RIA assay or colorimetric method for the cases which are believed to be in need of rapid evaluation of estriol and/or when another method is unfeasible.

Estriol assay is still one of the most used parameters in pregnancy monitoring during 3th trimester of gestation.

Recent availability of a new, rapid and easy semiquantitative method for estriol evaluation on a single urine sample, offers new prospects to obstetrical practice, removing disadvantages due to 24 hour urine collection.

We wished to value correlation between this new, simple and rapid method and 24 hour urinary estriol measurement in pregnancy monitoring.

MATERIAL AND METHODS

Study was performed on 70 normal pregnant women and 8 with pathologic pregnancy. This last group included 6 patients with placental insufficiency, one with polyhydramnios and fetoplacental hydrops, and one with diabetes mellitus White's class C.

Correlation between the two procedures was performed, as to normal pregnancies on the bases of 240 tests, performed from 26th week of gestation to term, whereas pathologic pregnancies were studied as single clinical cases.

24 hour urine samples were used for estriol assay colorimetric method, while urine specimen immediately following was collected separately

and used for estriol assay semi-quantitative method. 24 hour urinary estriol was assayed by Rourke, Marshall and Shelley's colorimetric method (1). Semiquantitative method is that proposed by Miyakawa et Coll. (2), based on agglutination inhibition reaction of latex particles sensitized with E₃-16-G (LAIR, latex agglutination inhibition reaction). Test is performed diluting urine samples: 1 : 50, 1 : 100, 1 : 200 with buffer. The results may be valued after two minutes. Agglutination inhibition in various wells indicates an estriol concentration of 5, 10, 20 µg/ml respectively.

Data were analysed by calculating correlation coefficients.

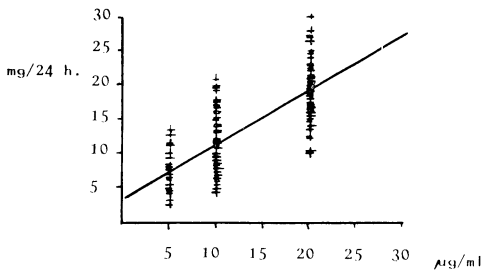
RESULTS

Results obtained displayed a good linear correlation between values following from colorimetric method and those from semiquantitative method. Figure 1 illustrates the correlation between the two examined methods. Statistical test was performed by calculating coefficient of correlation on 240 assays operated on urine samples obtained from 70 normal pregnant women. The correlation coefficient r is 0.77, statistically significant for $P < 0.001$.

The linear regression equation is

$$y = 3.213 + 0.812X$$

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$r = 0,77$; $W = 3,213 + 0,812 X$;
 $P < 0,001$; $N = 240$.

Fig. 1. — Correlation between urinary estriol values by lair and colorimetric method.

Fig. 2 and 3 report estriol values assayed in the patients with pathological pregnancy. The profiles of urinary estriol values determined by LAIR method showed a pathologic trend in 3 of the 6 cases with feto-placental insufficiency (n. 1-4-6), while, among the others, resulted at lower limit of normal in one case (no. 2), and perfectly normal in the other two cases

(3-5). Regarding the profiles of values determined by colorimetric method, we noticed a pathologic trend in 4 cases (no. 1-4-5-6), at lower limit of normal range in one case (no. 2), and perfectly normal for the other (no. 3). Among these patients with placental failure, pregnancy development was favourable in 5 cases with birth of alive and viable neonates. Labor accomplishment occurred through vaginal via in two and by cesarian section in 3 cases. In the remaining one an intrauterine fetal death occurred during 31st week of gestation. For the patient with polyhydramnios and fetoplacental hydrops (no. 7) and the other (no. 8) with diabetes mellitus White's class C, estriol values from the two techniques resulted into normal ranges, even if LAIR values were lower if compared to those obtained by colorimetric method. Evolution of these pregnancies was unfavourable: in the first case intrauterine fetal death occurred during 30th, in the second during 32nd gestation week.

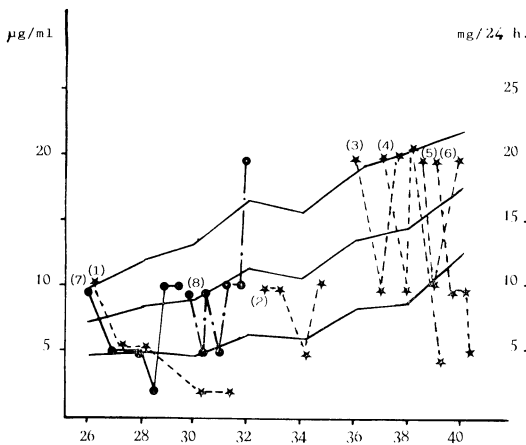


Fig. 2. — Profiles of urinary estriol levels in 8 patients with pathologic pregnancy, assayed by lair method.

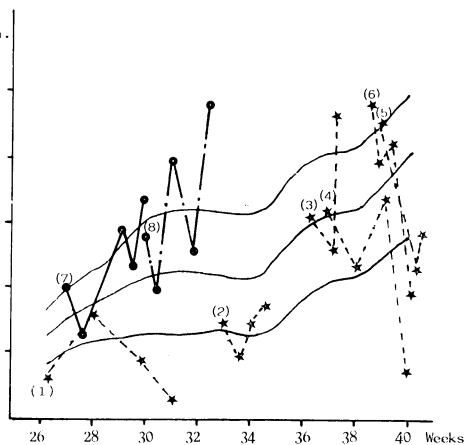


Fig. 3. — Profiles of urinary estriol levels in 8 patients with pathologic pregnancy, assayed by colorimetric method.

Delimited area illustrates mean ± 1 SD of 240 assays performed on 70 pregnant normal women.

- *-----* patient with placental insufficiency
- patient with polyhydramnios and feto-placental hydrops.
- patient with diabetes mellitus White's Class C

DISCUSSION

Results obtained demonstrate that semiquantitative estriol assay (LAIR) on morning urine samples presents a good linear correlation highly significant for $P < 0.001$, with colorimetric method on 24 hour urine specimen in pregnancies in normal evolution. Other Authors (^{2,3}), on the other hand, referred to having obtained a good correlation between values provided by this method and those by plasma estriol RIA. As for pathological pregnancies, a very strong analogy resulted between profiles of the serial assays, obtained by these two procedures. In fact we noticed that in patients with placental insufficiency, deportment of profile of the serial assays obtained by LAIR method is nearly similar to that by colorimetric method on 24 hour urine in a good 5 of 6 cases. In only one case (no. 5) estriol values by LAIR method result into normal ranges, differently from those by colorimetric method resulting below normal. In the other two complicated pregnancies profile deportment was similar, confirming correlation existent between values by two procedures. But no one method allows us to expect the two pregnancies unfavourable outcome.

Even though cases of complicated pregnancies are in too small a number to permit a definitive judgment, these prelimi-

nary data lead us to believe that latex agglutination inhibition method (LAIR) has reliability comparable to that of colorimetric method for some obstetrical pathologies.

In consideration of the good correlation between estriol values measured on morning single specimen and those on 24 hour urine collection, availability of a rapid, reproducible and simple, even if semiquantitative, method is certainly useful in obstetrical practice.

Therefore we believe that such a method, just for its simple realization and its rapid results, may be applied alternatively to RIA assay or colorimetric method for the risk pregnancies which are believed to be in need of rapid evaluation, and/or in those areas displaced from Centers provided of specialized laboratories and skilful technicians.

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