

## Comparing the diagnostic power of qualitative and quantitative measurements of $\beta$ -hCG in cervicovaginal washing-fluid for the diagnosis of PROM

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### Abstract

**Introduction:** Premature rupture of membranes (PROM) is defined as rupture of membranes before the onset of labor at any time during the gestational period, which occurs in 2-25% of pregnancies. Based on complications related to PROM, such as preterm labor and increased perinatal mortalities, the importance of correct and on-time diagnosis of PROM and high false positive and negative results of diagnostic tests, this research was conducted to compare the diagnostic power of qualitative and quantitative measurements of  $\beta$ -hCG in cervicovaginal washing-fluid for the diagnosis of PROM in pregnant women attending Vali-e-Asr Hospital in Zanzan, Iran during 2006.

**Materials & Methods:** This case-control research process design was done on cervicovaginal samples collected from 86 singleton pregnancies between 14-41 weeks of gestational age. Data were collected through a questionnaire, which included demographic data, pregnancy histories and a checklist for entering the result of speculum examination, fern and nitrazine tests, ELISA and qualitative strip tests for  $\beta$ -hCG. Subjects with a chief complaint of amniotic fluid leakage, who had been matched for gestational age, were divided into two 43-member groups: 1- Confirmed PROM by speculum examination, with positives result of amniotic fluid pooling, nitrazine paper test and fern test and 2- The control group undergoing speculum examination with negative results of amniotic fluid pooling, nitrazine paper test and fern test. Cervico-vaginal fluids were collected from the posterior vaginal fornix by 5ml of sterile saline irrigation and aspiration technique. Subsequently,  $\beta$ -hCG was checked by quantitative ELISA and one-step qualitative pregnancy test.

**Results:** The mean  $\beta$ -hCG levels were  $250.60 \pm 118.6 \text{ mIU/ml}$  and  $6.2 \pm 10.6 \text{ mIU/ml}$  in PROM and the control groups respectively. Calculations of receiving operating characteristic curve showed that the cut-off point for ELISA was  $22.32 \text{ mIU/ml}$  and its sensitivity, specificity, positive and negative predictive values and accuracy were 95.3%, 97.7%, 97.6%, 95.5% and 96%, respectively. The one-step qualitative pregnancy test was positive in 42 PROM subjects, (97.7%), and in 5 of the control group, therefore, its sensitivity, specificity, positive and negative predictive values and accuracy were 97.7%, 88.4%, 89.4%, 97.5% and 93%, respectively. It seems that a very good agreement exists between the results of the two methods based on a Kappa coefficient value of 0.86.

**Conclusion:** It seems that qualitative and quantitative measurements of cervicovaginal washing-fluid  $\beta$ -hCG are accurate, fast and simple for the diagnosis of PROM, especially in suspicious cases.

**Key Words:** Premature rupture of membranes,  $\beta$ -hCG, Cervicovaginal discharge, Amniotic fluid, Preterm labor.

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