Comparing the diagnostic power of qualitative and quantitative measurements of β-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 β-hCG in cervicovaginal washing-fluid for the diagnosis of PROM in pregnant women attending Vali-e-Asr Hospital in Zanjan, 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 β-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. Cervicovaginal fluids were collected from the posterior vaginal fornix by 5ml of sterile saline irrigation and aspiration technique. Subsequently, β-hCG was checked by quantitative ELISA and one-step qualitative pregnancy test.

Results: The mean β-hCG levels were 250.60±118.6 mIU/ml and 6.2±10.6 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 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 β-hCG are accurate, fast and simple for the diagnosis of PROM, especially in suspicious cases.

Key Words: Premature rupture of membranes, β-hCG, Cervicovaginal discharge, Amniotic fluid, Preterm labor.

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