

Comparing the diagnostic power of qualitative and quantitative measurements of β -hCG in cervicovaginal washing-fluid for the diagnosis of PROM

Kariman N. (M.Sc.)¹, Jafari E. (M.Sc.)², Amiri Moghadam H.R. (Ph.D.)³, Alavi Majd H. (Ph.D.)⁴, Mortazavi M. (M.D.)⁵

1- Department of Midwifery, Faculty of Nursing & Midwifery, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

2- Department of Midwifery, Faculty of Nursing & Midwifery, Zanzan University of Medical Sciences, Zanzan, Iran.

3- Department of Basic Sciences, Faculty of Medicine, Zanzan University of Medical Sciences, Zanzan, Iran.

4- Department of Biostatistics, School of Paramedical Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

5- Shahid Beheshti University of Medical Sciences, Tehran, Iran.

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 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 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. Cervico-vaginal 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 $250.60 \pm 118.6 \text{ mIU/ml}$ 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 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.

Corresponding Author: Nour-Al-Sadat Kariman, Department of Midwifery, Shahid Beheshti Faculty of Nursing & Midwifery, Next to Mofid Pediatric Hospital, Dr. Ali Shariati Avenue, Tehran, Iran.

E-mail: n_kariman@sbmu.ac.ir