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PREMATURE RUPTURE OF MEMBRANES;

DIAGNOSTIC ACCURACY OF β-hCG TEST IN VAGINAL WASHINGS TAKING AMNIOTIC FLUID POOLING AS GOLD STANDARD OF DIAGNOSING PRON

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ABSTRACT… Background: Pre-labour rupture of the membranes is one of the most common clinical presentations in an obstetric setting. Early diagnosis is a major challenge faced by every obstetrician and key to effective management and prevention of complications. As a result of PROM, amniotic fluid that provides protection to the developing fetus is lost, exposing it to the outside environment. β-hCG is a hormone secreted by syncytiotrophoblasts found in amniotic fluid that can be studied for the evaluation of PROM. **Objectives:** To find the Diagnostic Accuracy of β human chorionic gonadotrophin test in vaginal washings taking amniotic fluid pooling as gold standard of diagnosing PROM. **Study Design:** Cross-sectional study. **Setting:** Unit II, Department of Obstetrics & Gynecology, Lahore General Hospital, Lahore. **Period:** Three months from January 2017 to March 2017. **Material and methods:** Females of age 18-40 years with gestational age ≥36weeks (calculated by LMP) complaining of PV leaking were included in the study. Samples for β-hCG measurements were taken after informed consent. A β-hCG kit (Acu-check) was used for detection of β-hCG in vaginal fluid washings of pregnant women. **Results:** Diagnostic accuracy of β-hCG test was 91.66%. Sensitivity and specificity of β-hCG test was 86.66% and 96.66%. Positive predictive and negative predictive value was 96.29% and 87.87% respectively. **Conclusion:** Results of this study showed that for diagnosis of patients having PROM, beta human chorionic gonadotrophin (β-hCG) is a reliable, easy and quick test.

Key words: β-hCG, Vaginal Washings, PROM, Amniotic Fluid, Premature Ruptures of Membranes.

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INTRODUCTION

Prelabour Rupture of Membranes (PROM) or Premature Rupture of Membranes is a condition in pregnancy which occurs when there is rupture of the membranes before the onset of labor. At term, programmed cell death and activation of catabolic enzymes such as collagenase and mechanical forces, result in ruptured membranes, but when membranes rupture before 37 weeks of gestation, it is called preterm prelabour rupture of membranes.[1]

PROM occurs in approximately 1-3% of pregnancies and is accompanied by maternal and fetal risks. Large numbers of exogenous risks factors have been associated with PROM including genital tract infection, cervical incompetence and nutritional deficiencies like that of ascorbic acid and copper. Patients with PROM come with PV leaking, discharge, bleeding and pelvic pressure but without contractions. It causes serious threats to the mother such as chorioamnionitis, preterm labor, placental abruption, and postpartum endometritis while risks for fetus include fetal and neonatal infection, cord compression and cord prolapsed, respiratory distress syndrome (as a result of prematurity) and brain damage.

Accurate and timely diagnosis of PROM is very important to avoid these complications because an inaccurate diagnosis will lead to interventions like hospital admission, antibiotics and even plan for induction. Patient history and examination can diagnose over 90% cases of PROM especially when large amount of liquor is leaking; however on many incidents, there may be scanty or intermittent leakage and membranes are ruptured without evident presence of amniotic fluid.

Previously used tests such as nitrazine test, fern test, or staining of fetal cells are associated with high false negative and false positive results. Detection of amniotic fluid biomarkers present at a very low level in cervicovaginal secretions in pregnant women with otherwise intact membranes have been studied for diagnosis of PROM. Dipstick tests on fluid or discharge are helpful in assessment of rupture of membranes such as Actim Prom or Amnisure.[2]

The rationale of our study is to find the Diagnostic Accuracy of β-human chorionic gonadotrophin test in vaginal washings taking amniotic fluid pooling as Gold standard for diagnosing pre-labor rupture of membranes.

Traditionally, the vaginal sampling is collected and measurements of β-hCG using radio-immunoassay are done in laboratories but this is a time consuming method. Through this study, we want to develop a true, rapid, easy and reliable test by using a commercial β-hCG kit for testing of pregnancy as it does not require laboratory involvement, provides immediate results and has a reasonable cost for better fate and better management of these patients.

MATERIAL AND METHODS

It was a cross sectional study conducted at Lahore General Hospital, Lahore. The study period was three months from January 2017 to March 2017. Study included two groups: one group PPROM having history of leaking from vagina with confirmed diagnosis of membranes rupture and the other was a control group with normal pregnant women without any complaints; 60 patients in each group. A Cusco's speculum (sterile) was used to visualize the cervix. Patients having contaminations of amniotic fluid leaking with blood were not included in this study. 3ml of liquor was obtained directly from posterior fornix of patients in PROM group whereas in Control group, posterior fornix of vagina was irrigated by 3ml saline and aspirated. 3 drops were applied on β-hCG kit. Threshold sensitivity of test is 20mIU/ml, which is higher than the mean HCG level present in discharge from vagina at 3rd trimester of pregnancy. A positive and negative result depends upon the concentration of β-hCG. It may be observed in 40 seconds but for the negative result a complete time for reaction which is five minutes is necessary and kit doesn't read results after passing thirty minutes. One color band indicates negative test on control region and excluded amniotic fluid. A positive test is indicated by distinct color bands on the test and the control, amniotic fluid and regions. An invalid test is indicated by no visible band. It may also be indicated that if there is one color band in this condition test was repeated.

In this study we had calculated sensitivity, specificity, positive predictive, negative predictive values and accuracy.

RESULTS

N	120
Mean	27.17
SD	4.55
Minimum	18
Maximum	40

Table-I. Age Distribution of women (years)

Mean age of women was 27.17±4.55 years. Minimum and maximum age was 18 and 40 years respectively.

N	120
Mean	36.16
SD	3.30
Minimum	28
Maximum	42

Table-II. Distribution of gestational age (weeks)

Mean gestational age of women was 36.16±3.30 weeks. Minimum and maximum gestational age was 28 and 42.

	Prom +ve n=60	Prom –ve n=60
Positive	52	2
Negative	8	58

Table-III. Diagnostic accuracy of qualitative β-hCG test (cut off value=20mIU/ml)

Sensitivity=86.66%
Specificity=96.66%
PPV=96.29%
NPV=87.87%

Diagnostic Accuracy=91.66%

Diagnostic accuracy of test was 91.66% when taking beta HCG concentration at 20mIU/ml.

DISCUSSION

For diagnosis of PROM different markers have been studied but there are still limitations for diagnosis with a standard test. Correct assessment of PROM is very important because wrong assessment can lead to undesired complications e.g. preterm birth, chorioamnionitis; whereas over diagnosis can lead to inessential interventions like hospital admissions.[3]

Clinically, it is possible to diagnose 90% of the cases of PROM based on detailed history and examination documenting the presence of a nitrazine positive vaginal pool of fluid. However, there are certain limitations to this test, generating the possibility of false positive results e.g. in case of alteration of vaginal PH by semen or blood contamination or bacterial vaginosis, or if alkaline antiseptics are present. Similar cases of false positive results of ferning test can be avoided by taking sample from posterior fornix of vagina or sidewall of vagina to reduce\avoid cervical mucus.[4]

In our study sensitivity and specificity of β-hCG was determined while keeping the results of Amniotic fluid pooling paper test as gold standard. Results showed that sensitivity and specificity of β-hCG as 86.66% and 96.66%. Overall diagnostic accuracy of β-hCG was 91.6% taking HCG concentration at 20mIIU/ml.

Farideh Movahed in his study reported the Sensitivity, specificity, positive predictive value and negative predictive for β-hCG test as 83%, 91%, 90% and 84% respectively. Results of this study are consistent with our results regarding sensitivity and positive predictive value. However specificity and negative predictive value of this study is not consistent.[5]

N Kariman from Iran compared three rapid HCG dipsticks and ELISA in determination of PROM. As per results of that study sensitivity, specificity, PPV, NPV and diagnostic accuracy of ACON kit was 90%, 92%, 92.1%,90% and 91% respectively.[6] Results of this study is consistent with results reported by Kariman.

In one study sensitivity, specificity, positive, negative predictive values and diagnostic accuracy for β-hCG in detecting premature rupture of membranes was reported as 100%, 100%, 85.6% and 91% respectively.[7]

Orhan Temel in his study showed sensitivity, specificity, PPV and NPV were calculated as 71.2%, 100%, 100%, and 65.1%, respectively at 100 mIU/mL of HCG concentrations.[8]

Mohamed Abd El-Razik determine the diagnostic value of qualitative testing of (β-hCG) in the cervico-vaginal fluid for the diagnosis of PPROM. The test reported sensitivity, specificity, PPV and NPV for β-hCG as 90%, 98%, 97.8%, and 90.7% respectively and accuracy was 94%. [9]

Omneya M. Osman reported sensitivity, specificity, PPV, NPV and accuracy as 83%, 100%, 100%, 85.6%, and 91% respectively.[10]

ChunFang Tian his findings showed that the receiver operating characteristic (ROC) for PROM and PROM + C groups (β-hCG ≥23,900.50 IU/l) had a sensitivity of 77.5% and a specificity of 78.6%.[11]

Our diagnosis of PROM and PPROM is relied on vaginal discharge. Sometimes contamination of sample gives false positive results; however, on the other hand, false negative rate is high due to inadequate sample in premature rupture of membranes.

Human chorionic gonadotrophin is a glycoprotein hormone and is mainly biosynthesized by placental syncytiotrophoblast as early as 8th day.[12,13]

HCG can be used as a tumor marker because β-hCG is secreted by choriocarcinomas, teratomas and islet cell tumors. More recently the beta subunit of HCG has been evaluated as marker for PPROM and possible predictor of

preterm delivery.[14]

Apart from presence of β-hCG in maternal blood, urine and amniotic fluid, it is noteworthy that a small amount of it secreted by the cervical glands; therefore, it is present at a certain level in vaginal fluid. Several studies have also documented stable and low β-hCG levels in the washings of vagina of pregnant women with intact membrane and no complaints. On the contrary, they documented approximately nine-fold increased levels of β-hCG in the pregnant women with PROM. Therefore, measurements of β-hCG in the vaginal washing fluid may be considered as diagnosis of correct PROM.[15]

β-hCG measurement is easy and quick which can be done on bedside while other measurements are not always easy to do in most of centers at all times.

CONCLUSION

Results of this study showed that for diagnosis of patients having PROM, beta human chorionic gonadotrophin (β-hCG) is a reliable, easy and quick test. It can be used where there is absence of macroscopic contamination. No additional instrumentation require where a β-hCG kit is available.

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He who refuses to obey cannot command.

– Kenyen Proverb –

AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
1	Azmeena Azam	Write up, Proof reading, Literature search.	
2	Hafiz Maoz Husnain	Conceptualization of study design, Data analysis and interpretation.	
3	Iqra Marryum	Data collection	