



EVALUATION OF HUMAN CHORIONIC GONADOTROPIN IN VAGINAL WASHINGS FOR THE EARLY DIAGNOSIS OF PREMATURE RUPTURE OF FOETAL MEMBRANES: A CLINICAL STUDY

Gynaecology

Dr. Komal Yadav* Post Graduation 3rd Year Dept. Of Obstetrics And Gynaecology National Institute Of Medical Sciences And Research (NIMS), Jaipur. *Corresponding Author

Dr. Sadhna Mathur Head Of Department Dept. Of Obstetrics And Gynaecology NIMS, Jaipur

Dr. Surabhi Tomar Professor Dept. Of Obstetrics And Gynaecology NIMS, Jaipur.

Dr. Faizah Yousuf Post Graduation 3rd Year Dept. Of Obstetrics And Gynaecology NIMS, Jaipur

ABSTRACT

Aim: This study is aimed to evaluate and validate the qualitative human chorionic gonadotropin β subunit (β -hCG) test of the vaginal fluid washings of pregnant women with premature rupture of fetal membranes (PROM). **Materials & Methodology:** A total of 60 pregnant women between 26- and 36-weeks' gestation had participated in this study. The patients with leaking from the vagina were designated Group A, the patients with no leaking from the vagina were Group B. After administering 5 cc of normal saline to posterior fornix by sterile injector, a total of 5 cc washing fluid was collected. human chorionic gonadotropin were examined on the same day on collected fluid and both groups were compared statistically. **Result:** In the current study 53.4% patients in group 1 and 60.0% patients from control group were between 19-25 years of age group. Majority of patients were unbooked in both groups. 46.6% patients in PROM group and 56.6% patients in control group presents before 34 weeks of gestation. There is no statistical significance between two groups in terms of demographic data. Beta -HCG values in vaginal fluid of Group 1 was significantly higher than values in Group 2 with cut off value of Beta -HCG as 50mIU/dL. 83.4% patients from Group 1 (PROM Group) shows Beta -HCG value more than 50mIU/dL.

KEYWORDS

INTRODUCTION:

Preterm premature rupture of membranes (PPROM) refers to rupture of the amniotic membranes before 37 weeks of pregnancy¹.

PROM is divided into two categories including term PROM (PROM after 37 weeks of gestation) and preterm PROM (PPROM) before 37 weeks of gestation².

The most common complication of PROM is infection. Although term births with prolonged PROM are at risk of infection, the main threat involves preterm cases. Infection risk increases concomitantly with a prolonged latent period³.

PPROM is largely a clinical diagnosis based on history of watery discharge from vagina which should not be ignored and confirmed on sterile per speculum examination.

Diagnosis of ROM is simple in the cases of obvious rupture, but when the rupture is scant, it is difficult or even impossible⁴.

The traditional method for the diagnosis of PPROM relies on clinician ability to document three clinical signs on sterile per speculum examination: visual pooling of clear fluid from vagina, an alkaline pH of the cervicovaginal discharge detected by nitrazine test or microscopic ferning of the cervicovaginal discharge on drying⁵.

Its prevalence ranges from 8 to 19.53% of term pregnancies and 2–25% of all pregnancies and is responsible for preterm birth which is one of the most important cause of perinatal mortality and morbidity throughout the world⁶.

Beta-human chorionic gonadotropin (β -hCG) is produced by trophoblastic tissue, which is present in varying degrees in serum, urine, and amniotic fluid during pregnancy. It is present in AF as well as maternal blood and urine, at concentrations ranging from approximately 2000-70,000 mIU/mL. Unfortunately, there is no information available about β -hCG levels in vaginal fluid. Because β -hCG is secreted by cervical glands, a certain level should be present in vaginal fluid. Therefore, we measured and compared β -hCG levels in the vaginal fluid of normal pregnant women, pregnant women with PROM and pregnant women with suspected PROM. In this study, our aim was to determine the diagnostic value of β -hCG level in vaginal washing fluid for PROM⁶.

β -hCG is a glycoprotein, biosynthesized by the syncytiotrophoblast, and is present in varying concentration in maternal serum, urine, and

amniotic fluid during pregnancy. It is also secreted by the cervical glands and is present at a certain level in vaginal fluid. It is found in high concentration until 20 weeks of gestation, but after 20 weeks, it remains at a very low stable level in second and third trimester of pregnancy. The mean level of β -hCG in the vaginal fluid in a pregnancy with intact membranes varies throughout the pregnancy from 37.9 mIU/mL in the first trimester to 9.5 mIU/mL in the second trimester, and from 6.3 to 7.71 mIU/mL in the third trimester. On the other hand, the β -hCG levels in pregnancies with PROM in the literature ranges from 330.88 to 468.06 mIU/mL. The present study has been done to determine whether β -hCG in vaginal fluid can be used as a biochemical marker for PPROM in suspected cases; its correlation with onset of labour; its role in modifying the management and finally its role in maternal and neonatal outcome.⁷

Materials and Methodology

The following clinical study was conducted in the Department of Obstetrics and Gynaecology, NIMS Hospital Jaipur Rajasthan.

The study was performed in accordance to the written consent of the all the participants.

Study Design

Observational cross-sectional study

Study Duration

October 2019 to March 2020 (6 months)

Sample Size

60 healthy pregnant women.

Inclusion Criteria

1. Gestation age should be > 28 weeks and <37 weeks (confirmed by USG and LMP)
2. Participant should be physically and mentally healthy and sound.
3. Participant should be willing to take part.

Exclusion Criteria

1. Confirmed cases of active leaking
2. Gestation period <28 weeks and >37 weeks (confirmed by USG and LMP)
3. Cases with polyhydramnios
4. Cases in active labour
5. Congenital anomalies
6. Anti-partum haemorrhage
7. Participants with debilitating conditions like diabetes,

- hypertension and carcinoma.
8. Mentally not sound

Methodology

The detailed history of all the 60 subjects were taken including chief complaint of patient, menstrual cycle history, menstrual history, obstetrics history, history of present condition, history of chronic illness, general examination, per abdominal examination and per speculum examination was done.

The sample size of 60 subjects was equally divided into 2 groups (consisting of 30 subjects each): Group A (n=30, cases with clinically diagnosed with PROM) and Group B (n=30, pregnant women without loss of amniotic fluid).

Procedure

The patient was made to lie in a lithotomy position in good illumination. Sterile speculum was used for per vaginal examination.

In group A (clinically diagnosed with PROM) Direct aspiration of vaginal fluid done in 5 cc syringe. And in group B (women without loss of amniotic fluid) sample was taken after 5 minutes after injecting 5 cc of normal saline.

Sample collection was done in plain vial and were transported in pathology laboratory for detection of beta hCG by using by Chemiluminescent microparticle assay (CMIA) with 2500 r.p.m, and β -hCG titre was determined Total duration of the test was 15–20 min.

Results:

Table 1.

	Group A (PROM group) (n=30)	Group B (control group)(n=30)
Age (years)		
19-25 year	16 (53.4%)	18(60.0%)
>25 year	14(46.6%)	12((40.0%)
Gestation week		
28- 33week +6 days	14(46.6%)	17(56.6%)
34- 36 week+6 days	16(53.4%)	13(43.4%)
Booking status		
Booked	13(43.4%)	10(33.4%)
Unbooked	17(56.6%)	20(66.6%)
Parity		
Gravida 1	11(36.6%)	16(53.3%)
Gravida 2 or more	19(63.4%)	14(46.7%)

In the current study 53.4% patients in group 1 and 60.0% patients from control group were between 19-25 years of age group. Majority of patients were unbooked in both groups. 46.6% patients in PROM group and 56.6% patients in control group presents before 34 weeks of gestation.

There is no statistical significance between two groups in terms of demographic data.

Table 2.

Beta hCG value	Group A (PROM group)	Group B (control group)
≤ 50 IU	05(16.7%)	28(93.4%)
>50 IU	25(83.4%)	02(16.7%)

Beta -HCG values in vaginal fluid of Group 1 was significantly higher than values in Group 2 with cut off value of Beta -HCG as 50mIU/dL. 83.4% patients from Group 1 (PROM Group) shows Beta -HCG value more than 50Miu/dL.

DISCUSSION

PPROM is related with maternal and foetal morbidity and ultimately leads to preterm labour. Premature rupture of membrane (PROM) is shown in 5-15% of all term births and in 20-40% of all preterm births. Beta-human chorionic gonadotropin (β -HCG) is produced by trophoblastic tissue, which is present in varying degrees in serum, urine, and amniotic fluid during pregnancy. It is present in AF as well as maternal blood and urine, at concentrations ranging from approximately 2000-70,000 mIU/mL⁸

Patient often came to the hospital with complaint of discharge of leaking per vaginum who have no leaking or discharge during the examination is the group difficult to diagnosed with PPRM. There

are various method used for detection of PPRM are: Alpha fetoprotein, insulin like growth factor binding protein 1 (IGFBP 1) ferning test, nitrazine test and beta HCG⁹⁻¹¹. But among all beta HCG is cost effective, simple and easy to use. Beta-HCG is a substance produced by trophoblastic tissue, exists at various concentrations in maternal blood, urine, cervicovaginal secretion and amniotic fluid, and easy to detect The HCG measurement is not modified by the same factors as the ferning and nitrazine tests. In fact, the speculum exam is of no help when it is performed after a long latency period, while a high HCG concentration can be measured in the vaginal fluid 24 hours after the PPRM.¹³

Presence of this substances in vaginal secretions at low concentrations and the increase of vaginal concentration after amniotic drainage at PPRM mean that it would be useful to use beta HCG substances in the diagnosis of PPRM.¹³

In our study, beta HCG values in vaginal washing fluid of Group 1 cases were statistically and significantly higher than the values of Group 2 (Table 2). This is accordance with cooper et al¹², when cut-off value of beta-HCG in vaginal washing fluid for PROM diagnosis was designated as 50 mIU/dL, sensitivity, specificity, and negative and positive predictive values were found as 96%, 79%, 95% and 84%, respectively. In our study, when designating cut-off value of beta-HCG in vaginal bleeding fluid as 50 m IU/dL, sensitivity, specificity, positive and negative predictive values were 85.33%, 93.33%, 92.75% and 86.41%, respectively.

Tigli A et al¹³ conducted a study on roles of beta HCG in vaginal washing fluid in PROM and concluded designating cut-off value of beta-HCG in vaginal bleeding fluid as 50 m IU/dL, sensitivity, specificity, positive and negative predictive values were 85.33%, 93.33%, 92.75% and 86.41%, respectively.

Tigga et al¹⁴ studied the duration from PROM to onset of labour and concluded that β -HCG is a better predictor of onset of labour in confirmed cases of PROM.

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