|| ISSN(online): 2589-8698 || ISSN(print): 2589-868X ||
International Journal of Medical and Biomedical Studies
Available Online at www.ijmbs.info
PubMed (National Library of Medicine ID: 101738825)
Index Copernicus Value 2018: 75.71
Original Research Article
Volume 4, Issue 2; February: 2020; Page No. 143-145

TO FIND OUT AN APPROPRIATE CUT-OFF VALUE OF HUMAN β-HCG LEVELS IN CERVICOVAGINAL SECRETIONS FOR PREDICTION OF PRETERM DELIVERY

Dr. B S Meena[1], Dr. Alka Jilowa[2], Dr. Purva[3], Dr. Anusha[4], Dr. Samta[5], Dr. Neelam[6]
[1] Senior Professor and Head, [2-6] Resident Doctor
Department of Obstetrics & Gynaecology, SMS Medical College & Attached Group of Hospitals, Jaipur, Rajasthan

Article Info: Received 24 January 2020; Accepted 11 February 2020
DOI: https://doi.org/10.32553/ijmbs.v4i2.945
Corresponding author: Dr. Alka Jilowa
Conflict of interest: No conflict of interest.

Abstract
Background: Preterm birth is the leading cause of neonatal morbidity and mortality worldwide and account for 75% of neonatal deaths and 50% of long term morbidity, including respiratory disease and neurodevelopment impairment.
Methods: Hospital based descriptive type of Observational study conducted at Department of Obstetrics and Gynaecology. SMS Medical College and Hospital, Jaipur (Raj.)
Results: ROC curve analysis was performed to determine the optimal cut-off values of significant variables (β-hcg harmone) detected between the two groups. A 19.05 mIU/ml (Positive if greater Than or Equal To) area under the curve (AUC = 0.906) optimal cut- off value of β-hcg harmone, with a sensitivity of 86% and a specificity of 97.1%, was determined with SE 0.036. This level is good to use as a diagnostic test.
Methods: β-HCG test is good and β-hcg has high sensitivity and specificity so can be used as a diagnostic test for preterm labor.
Keywords: β-HCG, Sensitivity, Specificity, Diagnostic.

Introduction

Preterm birth is the leading cause of neonatal morbidity and mortality worldwide and account for 75% of neonatal deaths and 50% of long term morbidity, including respiratory disease and neurodevelopment impairment.[1]

Two-thirds of PTBs are spontaneous, and one-third comprises induced PTB for medical reasons, mainly preeclampsia and/or fetal growth restriction. Preterm delivery is responsible for 75-80% of neonatal deaths. Most neonatal deaths of healthy infants occur when they are born before 34 gestational weeks.The estimate of 13 million preterm infants born each year worldwide is most probably an underestimation, as most countries have an incomplete birth registration. The risk of neonatal morbidity and mortality is inversely related to gestational age at delivery.[2-3]

It may be related to the elevation of β-hCG levels in the cervicovaginal secretions before active labor[4]

The aim of the current study is to assess the predictiblity of β-subunit of human chorionic gonadotropin (β-hCG) in cervicovaginal secretions, as a biochemical predictor of preterm labor.

The cut off value of βhCG in the gestational age of 24-<37 weeks with a high confidence can distinguish preterm delivery from term delivery and can be a suitable method for predicting preterm delivery and could be used as a predictor test which is easy and free of any medical consequences[4]

Material and Methods

Type of Study: Hospital based descriptive type of Observational study.

Study Design: Prospective study.

Place of Study: Department of Obstetrics and Gynaecology. SMS Medical College and Hospital, Jaipur (Raj.)

Duration of Study: From April 2018 to November 2019 (after taking the approval from Institutional Review Board and Ethical committee).

Study population: Study population will be any pregnant woman coming to study location during study period between gestational age 24 weeks to < 37 weeks with pain abdomen.

INCLUSION CRITERIA:

- Gestational age: 24-<37 weeks with pain abdomen.
- Informed Consent.

EXCLUSION CRITERIA:

- Gestational age <24 and >37 weeks

- Polyhydromnios
- Multiple pregnancy
- Abruption placenta
- Placenta previa
- Cervical cerclage
- Hypertensive disorders
- Presence of gross blood in the vagina
- Sing and symptom of intra amniotic infections
- Fetal congenital anomalies
- Non cooperative woman
- Patient in severe illness or physically unable to give consent

METHODOLOGY

This prospective study would be conducted in the Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur from April 2018 till completion of the study.

Sample population obtained after applying inclusion and exclusion criteria on pregnant women attending ANC and cervicovaginal β-hcg level will be done on sample population and they will be followed upto their delivery.

Obtaining samples and method of β-hCG measurement:

For two groups, before digital examination, cervicovaginal secretions will be taken by applying speculum. At the first step, 1 cc normal saline will be poured into the posterior fornix of vagina and then after 30 seconds, 1cc of the present secretion will be taken by a syringe and pour into a dry test tube for transportation to the laboratory.

All samples will be taken before administrating tocolytic medications. Levels of β-hCG will be measured by applying the method of chemiluminescence immunoassay that will be done at Pandit Deen Dayal Upadhyay Hospital Laboratory under SMS Hospital, Jaipur.

STATISTICAL ANALYSIS

- ROC curve will be made to find out optimum cut off value to predict maximum preterm delivery cases.
- P value <0.05 will be taken as significant. Medcalc 16.4 version software will be used for all statistical calculations.

OBSERVATIONS

ROC curve is to identify and compare cut-off point of βhCG hormone in two groups

Diagnostic performance of β-hcg harmone for the differential diagnosis of preterm delivery the optimal cut-off points of the ROC analysis curves. ROC plot of β-hcg harmone in reference to preterm delivery

Receiver operating characteristic ROC for β-hcg harmone showing

(1-specificity) on the X axis and sensitivity on Y axis excersing different cut off value to land at the choice the most apposite cut off point and which provide the greatest sum of sensitivity and specificity.

Table illustrate sensitivity, specificity, 1- specificity (False positivity rate) of β-hcg harmone at diverse level appropriate for preterm delivery. As the level of β-hcg harmone increases, sensitivity lessens and specificity enhances.

The optimum cut off value was obtained by points of test values that grants the highest Youden Index that is (SN+SP)-1.

ROC curve analysis was performed to determine the optimal cut-off values of significant variables (β-hcg harmone) detected between the two groups. A 19.05 mIU/ml (Positive if greater Than or Equal To) area under the curve (AUC = 0.906) optimal cut- off value of β-hcg harmone, with a sensitivity of 86% and a specificity of 97.1%, was determined with SE 0.036. This level is good to use as a diagnostic test.

Area under the curve

Test Result Variable(s): β-HCG

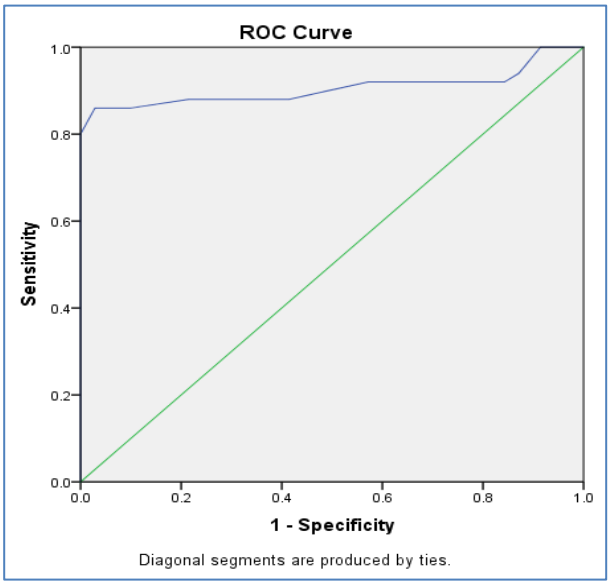
Area	Std. Error	Asymptotic Sig.	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.906	.036	.000	.835	.976

The test result variable(s): β-HCG has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

Positive if Greater Than or Equal To	Sensitivity	1 - Specificity	Specificity	Yodon index
19.50	.860	.029	0.971	0.831



Discussion

In our study ROC curve analysis was performed to determine the optimal cut-off values of significant variables (β-hcg harmone) detected between the two groups. A 19.05 mIU/ml (Positive if greater Than or Equal To) area under the curve (AUC = 0.906) optimal cut- off value of β-hcg harmone, with a sensitivity of 86% and a specificity of 97.1%, was determined with SE 0.036. This level is good to use as a diagnostic test.

This observation was similar to study of :

1. K Adhikari et al (2009)[5] who found β-hCG sensitivity 83.3%, specificity 85.8% and cut off value 77.8mlIU/ml.

2. Sak Erdal et al (2010)[6] who found β-hCG sensitivity 71.6% and specificity 91.6% and cut off value 75mlU/ml.

3. R. Bagga et al (2010)[7] who found β-hCG sensitivity 95.8% and specificity 73.7% and cut off value 45mlU/ml.

Conclusion:

β-hcg test is good and β-hcg has high sensitivity and specificity so can be used as a diagnostic test for preterm labor.

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