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A Prospective Study for Evaluation of β Human Chorionic Gonadotrophin in Cervicovaginal Fluid as a Predictor of Preterm Delivery in Department of Obstetrics and Gynaecology at Sawai Man Singh Medical College Jaipur

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Abstract

Background: 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.

Methods: 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.

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.

Conclusion- This study showed that the rate of β-hCG values in the gestational age of 24 to <37 weeks with a high confidence can distinguish preterm delivery from term delivery and can be use as a predictor test which is easy and free of any medical consequence. Overall test is good and β-hcg has high sensitivity and specificity so can be used as a diagnostic test for preterm labor.

Keywords: ROC curve, Preterm, β-hCG

Introduction

Preterm labour is defined as regular contractions before 37 weeks that are associated with cervical changes. Preterm infants are those delivered before 37 completed weeks. Preterm delivery is the leading cause of perinatal morbidity and mortality throughout the world[1].

The incidence of preterm birth range from 5% to 8% in most developed and developing countries, but it still increasing worldwide[2] attributed to rise in multiple gestations from assisted reproductive techniques, better dating scans and iatrogenic deliveries.

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.[3]

The elevation of β-hCG levels in the cervicovaginal secretions via maternal serum may be due to the inflammatory process that can precede the onset of labor.

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.

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.

Selection Criteria

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

- Appropriate parametric and non parametric statistical tests will be used to analyse linear

and categorical variables respectively depending on data yield.

- 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 And Discussion

Table No. 1.Distribution of the cases according to preterm delivery

	GROUP A (Preterm Delivery)		GROUP B (Term Delivery)		Total	
	No.	%	No.	%	No.	%
Cases	50	41.67	70	58.33	120	100.00

Among of the attended patients with preterm labor, 41.67% cases get preterm delivery and 58.33% had full term delivery.

Table No. 2.Distribution of the cases according to age groups

	Group A		Group B		Total		P Value LS
	No.	%	No.	%	No.	%	
≤20	3	6	5	7.14	8	6.67	
21 to 25	27	54	27	38.57	54	45.00	
26 to 30	20	40	22	31.43	42	35.00	0.009
31 to 35	0	0	14	20.00	14	11.67	
>35	0	0	2	2.86	2	1.67	
Total	50	100	70	100.00	120	100.00	
Mean±SD	24.76	2.82	26.69	4.55	25.88	4.02	

Chi-square = 13.641 with 4 degrees of freedom; P = 0.009

The above table depicts the distribution of cases according to age group wise where we have found that there was significant difference among the groups. For Group A, 54% cases was in the age group of 21 to 25 years whereas the same age group in Group B with 38.57% and so on for other age groups across the groups.

Table No. 3.β-HCG among the groups

β-HCG Value (mIU/ml)				
Group	N	Mean	Std. Deviation	P Value LS
Group A	50	83.14	112.21	<0.001S
Group B	70	14.44	3.51	
Total	120	43.06	79.68	

The above table depicts the distribution of cases according to value of cervicovaginal β-hcg among the groups. There was significant difference observed among the groups. For Group A, the value was 83.14±112.21 which was higher than Group B as 14.44±3.51.

In this study we observed that cervicovaginal β-hcg level was 5.8 times more in group A than group B

This observation was similar to study of Guvenal et al (2001)[5], Garshasbi et al (2004)[6], Adhikari et al (2009)[7], Sak Erdal et al (2010)[8] and Bahasadri et al (2013)[9].

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.

This observation was similar to study of:

1. K Adhikari et al (2009)[7] who found β-hCG sensitivity 83.3%, specificity 85.8% and cut off value 77.8mlIU/ml.
2. Sak Erdal et al (2010)[8] who found β-hCG sensitivity 71.6% and specificity 91.6% and cut off value 75mlU/ml.
3. R. Bagga et al (2010)[10] who found β-hCG sensitivity 95.8% and specificity 73.7% and cut off value 45mlU/ml.

Conclusion

This study showed that the rate of β-hCG values in the gestational age of 24 to <37 weeks with a high confidence can distinguish preterm delivery from term delivery and can be use as a predictor test which is easy and free of any medical consequence. Overall 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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