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Human β-hCG In Cervicovaginal Secretions As A Predictor Of Preterm Delivery

Dr. Alakananda[1], Dr Naba Kumar Hazarika[2]
[1]*Professor (O&G) Gauhati Medical College*
[2] *Professor & HOD Dept. of Microbiology,Dr Madhulika Misra*

Abstract: *This prospective study was carried out over a period of one year in Gauhati Medical College with the aim to find out association of β-hCG level in cervico-vaginal secretion with preterm labour (PTL) and preterm delivery (PTD)and to find out a cut –off value for prediction of pre- term delivery. 225 cases were enrolled between 24-36 weeks of gestation including 150 cases as control (group ll) having no pre-term labour pain and 75 cases in the study group having preterm labour pain of which 50 had preterm delivery (group la) and 25 term delivery(group lb).* ***β-hCG*** *in cervico-vaginal secretion were estimated and found to be higher in study group Ia with mean value of 25.5mIU/ml as compared to study group Ib with mean value of 7.41mIU/ml and control group with mean value of 2.86±7.07mIU/ml. P value is significant (p<0.001). Cut-off value >14mIU/ml was obtained using receiver-operator curve with sensitivity 85.3% and specificity 84.7%.*
Conclusion *: Level of β-hCG >14mIU/ml in cervico-vaginal secretion can be used as a predictor of PTD in patients presenting with PTL.*
Keywords: *Beta human Chorionic Gonadotrophin, cervicovaginal secretions, preterm delivery.*

I. Introduction

Preterm birth is defined as delivery before 37 completed weeks. Preterm delivery is the leading cause of perinatal morbidity and mortality throughout the world .Prediction is important for adoption of preventive measures and providing optimal care to the newborn. Some of the biochemical markers proposed as predictor of preterm delivery are

1. Salivary estriol
2. MSAFP
3. Fetal fibronectin
4. Alkaline phosphatase
5. Prolactin
6. Insulin like growth factor 1 and 2
7. Cervicovaginal β-hCG

Presence of β- hCG in maternal serum and amniotic fluid are the result of diffusion throughout pregnancy. Source of elevated β- hCG in cervicovaginal secretions are maternal serum or amniotic fluid. Escape of β- hCG may be due to the inflammatory process that can precede the onset of preterm labour.

Aims and Objectives

1. To find out an association of human β- hCG levels in cervicovaginal secretions in preterm labour and preterm delivery.
2. To find out an appropriate cut-off value of human β- hCG levels in cervicovaginal secretions for prediction of preterm delivery in patients presenting with preterm labour.
3. To find out an association between human β- hCG levels in cervicovaginal secretions and outcome of pregnancy.

Materials and Method

This prospective, cohort study was conducted in the Department of Obstetrics & Gynaecology in collaboration with Deptt. of Microbiology, Gauhati Medical College and Hospital from 1st June 2012 till 31st May 2013.

225 cases were enrolled having 24 - 36 weeks of pregnancy attending antenatal OPD and those admitted as emergency. They were divided into three groups . Study group la with 50 cases who had pre-term labour pain and delivered prematurely, study group lb with 25 cases who had pre-term labour pain but delivered at term, group ll as control with 150 cases having no pre-term labour pain and delivered at term .

Inclusion criteria:

Singleton pregnancy accurately dated by early second trimester ultrasonographic examination
Cervical dilatation <3cm
Intact amniotic membranes.
Absence of any maternal and fetal complications at admission and during pregnancy.

Exclusion criteria:

Fetal congenital anomalies
Placenta praevia
Vaginal bleeding
Hypertensive disorders
Fetal growth retardation
Fetal distress
Multiple gestation

Patient's particulars, detailed history and clinical examination findings were noted in a structured proforma. Tocolytic given to all cases of study groups la and lb and routine investigations of pregnancy done for all.

Cervicovaginal □-hCG level: Samples of cervicovaginal secretion were obtained before digital examination and prior to administration of tocolytic therapy. A cotton tipped swab was placed first into the endocervical canal and then into the posterior fornix for 30 seconds to obtain samples of cervicovaginal secretions. The swab was then placed in a tube containing 1 ml of saline solution and the tube was shaken for 1 minute. Samples were centrifuged for 5 minutes at the rate of 1500 rpm. Supernatant was refrigerated at temperature of -20°C for upto 30 days. Quantitative estimation of β-hCG was done by Accu-Bind (ELISA Microwells) Kit manufactured by monobind Inc lake foresit CA-92630, USA.Qualitative estimation of β-hCG was done by commercially available sensitive test cassettes.

II. Results

Out of 225 patients, 150 patients of the control group came without labour pain and had full term delivery. 75 patients in the study group came with preterm labour and out of them 50 had preterm delivery and 25 had term delivery. Maximum number of subjects were in age group 21-25yrs and distribution of cases according to age,parity and BMI were similar in all the 3groups.Pre-term delivery was more in cases of low socio-economic status compared to middle and upper class with p value 0.02.

β-hCG mean value in the study group was higher than in the control group, 19.47±18.46 mlU/ml and 2.86±7.07mIU/ml respectively with p value <0.001 (Fig 1) . β-hCG mean value in the study group Ia who had pre-term delivery was significantly higher than in study group lb who delivered at term and values were 25.5±18.65 mIU/ml and 7.41±10.67 mIU/ml respectively with p value <0.001 (Fig 2). To find out an optimal cut-off value for β-hCG the receiver-operator curve was used .Suggested predictive value was estimated at >14mIU/ml with sensitivity 85.3%, specificity 84.7%.

III. Discussion

There was no statistically significant difference in the mean age between study and control group. Low socioeconomic status predisposes to preterm delivery.This observation is similar to that reported by Eltahir M Elshibly[1]. As parity increases there is increased chance of preterm delivery and similar was the observation reported by Kiran Shaikh et al[2]. No association was found between body mass index and preterm delivery. Goldenberg et al(2008)[3] found that women having BMI<19kg/m^2 were associated with 16.6% chance of preterm delivery.

There was significantly rise in the level of cervico-vaginal β-hCG in the study group as compared to the control group. Comparing group Ia and Ib there was significant difference with Ia having higher level than Ib. Similar was the observation by Guvenal et.al.[4] who included 50 patients and Sak et.al (2010)[5] in his study on 55 patients. Garshashbi et.al(2004)[6] in his study including 540 patients having PTL found 3.2 fold increase of cervico-vaginal β-hCG in PTB than in term delivery. Esim et. al (2003)[7] in his study including 141 patients observed significantly higher level of β-hCG in PTD group compared to PTL group. Adhikari et.al (2009)[8] and Bagga et.al (2010)[9] included cervical length and β-hCG and reported higher level of cervico-vaginal β-hCG in PTL compared to term delivery. Bahasadri et.al. (2013)[10] in a cross-sectional study including 123 women reported that vaginal fluid β-hCG may be used as a suitable, fast and reliable test for detecting rupture of membrane.

IV. Conclusion

β-hCG values were higher in patients who came with preterm labour pain and had preterm delivery as compared to patient with preterm labour pain and had term delivery and normal pregnancy with no preterm labour pain.Cut-off value of β -hCG ≥ 14mIU/ml in cervicovaginal secretions can be used as a predictor for preterm delivery in patients presenting with preterm labour.

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Author	No of cases	Cut-off mIU/ml	Sensitivity	Specificity	P value
Guvenal et al 2001	60	27.1	87.5%	65.4%	0.031
Esim et al 2003	141	65	68%	95%	<0.001
Garshashbi et al 2004	540	77.8	87.5%	97%	
Adhikari et al 2009		>14	83.3%	85.5%	
Bagga et al 2010	100	>45	95.8%	73.7%	
Sak et al 2010	55	75	76%	91.6%	<0.001
Bahasadri et al 2013	123	79.5	95%	84%	<0.001
Present study	225	>14			<0.001

Table showing results of various authors

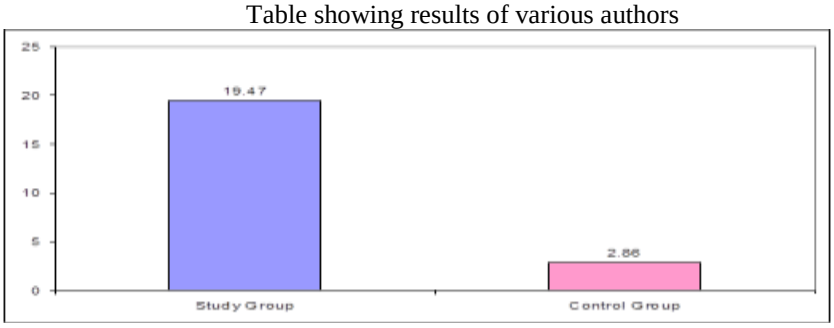

Fig. 1 There is significant rise in mean value of β-hCG in study group

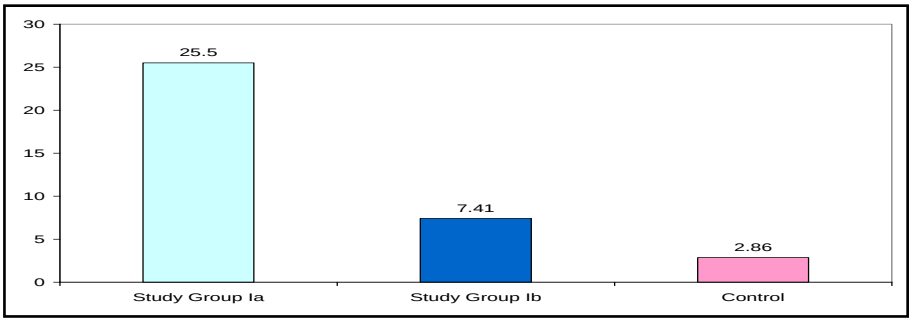

Fig. 2. There is significant rise in mean value of β-hCG in study group 1a as compared to study group 1b and control group