A cross-sectional study on prediction of preterm delivery with phosphorylated insulin like growth factor binding protein-1 test

[1]Dr. Sana Tak, Resident doctor, Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur.

[2]Dr. Pushpa Nagar, Senior professor, Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur.

[3]Dr. Akansha Kumawat, Resident doctor, Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur.

[4]Dr. Aditi Bansal, Associate professor, Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur.

[5]Dr. Bhavini, Resident doctor, Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur.

Corresponding Authors: Dr. Bhavini, Resident doctor, Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur.

How to citation this article: Dr. Sana Tak, Dr. Pushpa Nagar, Dr. Akansha Kumawat, Dr. Aditi Bansal, Dr. Bhavini, "A cross-sectional study on prediction of preterm delivery with phosphorylated insulin like growth factor binding protein-1 test", IJMACR- February - 2023, Volume – 6, Issue - 1, P. No. 647 – 651.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Aim and objective: To predict preterm deliveries in symptomatic patients using a bedside kit for phosphory lated Insulin like Growth Factor Binding Protein-1 in cervical secretion. It will enrich obstetricians in early identification, preparedness and timely obstetricians' interventions to reduce anticipated fetal complications in threatened preterm.

Materials and methods: It was hospital based cross-sectional study including 78 pregnant women between 28 weeks to 37 weeks of gestation with threatened preterm labor. Phosphory lated Insulin Like Growth Factor Binding Protein Test was done and data analysis was done using Student's t – test, Receiver operator characteristic curve and chi square test.

Results: Among 78 women with threatened preterm labor, 53 (67.9%) tested positive for phIGF-BP1 out of which 52(98.1%) delivered preterm and among them 36(67.9%) delivered within 48hours of the test. So the test was extremely sensitive in predicting preterm labor.

Conclusion: phIGFBP-1 test had a great role in the management of women presented with threatened preterm labor. It will allow more focused management of female and avoid un - necessary admissions and treatment, to contain health care costs.

Keywords: Preterm labor, phIGFBP-1.

Introduction

Preterm labor refers to the onset of labor after fetal viability but before 37 completed weeks of gestation. The diagnostic criteria are onset of increasingly frequent

and painful uterine contractions (at least 4 contractions per 20 minutes) with progressive effacement and dilatation of the cervix i.e., 80% cervical effacement and at least 2cm dilatation (or cervical length <1cm).[1]

It is a major challenge in perinatal health care. Preterm birth occurs in 5% to 18% of all deliveries worldwide. It is estimated that 15 million preterm births occur each year with 1.1 million infants dying from preterm birth complications.[1]

Prediction of preterm labor enables taking early action for preterm birth as in- utero transfer to tertiary care centres, reasonable administration of corticosteroids while avoiding un-necessary use, magnesium sulphate treatment for neuro protective effect and antibiotic treatment in case of infection.[2]

Current screening tests for the prediction of preterm labor can be divided into three general categories

(1) Risk factor assessment

(2) Cervical measurement

(3) Bio-chemical markers

One of the early changes that precede preterm birth is cervical shortening, which may be detected even several weeks prior to the onset of active labor. But due to limitations in ultrasound availability and operator expertise, cervical length alone cannot be reliably utilised to predict preterm labor or used as routine screening tool.[3]

Cervico-vaginal fluid, a complex mixture of secretions from vagina, endo cervix, endometrial decidua and amniochorion serves as an important diagnostic tool for preterm labor prediction. Two most commonly used biochemical markers used for prediction of preterm labor are -fetal fibronectin and phosphory lated Insulin like growth factor binding protein -1(ph-IGFBP-1).

Fetal fibronectin is a glyco protein produced by amnio cytes and Cytotropho blasts. It is normally found in cervico-vaginal fluid before 22weeks of gestation but its presence between 24 to 34 weeks of gestation indicates a risk of preterm birth. But this test has several dis advantages or limitations including high cost, limited availability, sexual inter course or vaginal examination interferes with the test and reduces its accuracy

Phosphory lated Insulin like growth factor binding protein -1 (ph-IGFBP-1) was requested as a marker for predicting preterm birth for being positive at significantly higher rates in cervical fluids of patients with preterm birth. An immune chroma to graphic test (one step dipstick test) detects ph-IGFBP-1 in cervix, can be used from 22 weeks onwards with fast results. Test results are not affected by urine, intercourse semen, vaginal medications, lubricants or infections. It has 98% (high) negative predictive value that helps to avoid unnecessary treatment and reduces cost.[4]

Aim and objectives

To predict preterm deliveries in symptomatic patients.

To assess sensitivity, specificity, positive predictive value and negative predictive value of the phosphory lated Insulin like Growth Factor Binding Protein-1 test for prediction of preterm labour in symptomatic patients.

Materials and methods

The study was conducted in the Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur. Women with singleton pregnancy 28 to 37 weeks of gestation with intact fetal membranes, who presented with threatened preterm labour were included in the study after taking written informed consent. Pregnant women with Preterm premature rupture of membranes (PPROM), advanced preterm labour, those women who

require iatrogenic preterm induction of labor were excluded.

The study sample was 78 cases and they were subjected to detailed history if any were noted. Abdominal examination was done for presentation of fetus and frequency of uterine contractions. Amniotic fluid leak was confirmed on per speculum examination and the test for detection of phosphorylated Insulin like Growth Factor Binding Protein-1 was done. The test was positive if two blue lines appeared and negative if only one blue line was seen.

Statistical analysis

The data collected was entered in MS excel sheet. Continuous variables were summarized as mean and were analyzed by using unpaired t test. Nominal / cate gorical variables were summarized as proportions and were analyzed by using chi-square / Fischer exact test. P value <0.05 was taken as significant. Diag nostic accuracy was assessed using following terms: Sensitivity, Specificity, PPV and NPV. Medcalc 16.4 version software was used for all statistical calculations.
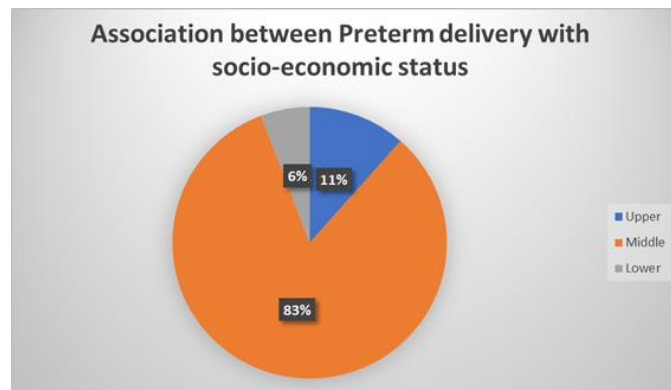
Results

Table 1: Socio-demographic factors

Variable	Preterm delivery		p-value
	Yes	No	
Age			< 0.143
18-25years	33(63.5%)	12(46.2%)	
26-30years	17(32.7%)	10(38.5%)	
>30years	2(8.8%)	4(15.4%)	
Socio-economic status			<0.223
Upper	6(11.5%)	2(7.7%)	
Middle	43(82.7%)	19(73.1%)	
Lower	3(5.8%)	5(19.2%)	
Residence			<0.150
Urban	29(55.8%)	10(38.5%)	
Rural	23(44.2%)	16(61.5%)	
BMI			<0.709
<18.5kg/m2	12(63.2%)	7(36.8%)	
18.5-22.9kg/m2	40(67.8%)	19(32.2%)	

Graph 1:

Graph 2:
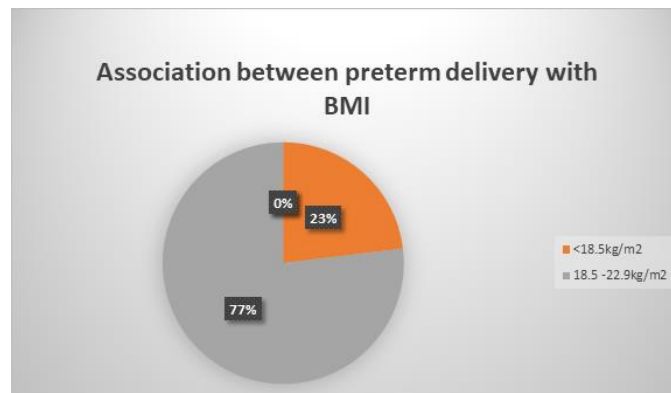
Table 2: Risk factors for preterm delivery

Risk factor	Preterm delivery	
	Yes	No
History of vaginosis (31)	24(77.4%)	7(22.6%)
History of threatened abortion (33)	24(72.7%)	9(27.3%)

p-value (history of vaginosis)- <0.0102

p-value (history of threatened abortion)-<0.331

Table 3: Complication in last delivery

Complication in last delivery	Preterm delivery	
	Yes	No
Preterm delivery (58)	35(60.34%)	23(39.66%)
Vaginal infection (12)	9(75%)	3(25%)
UTI (5)	5 (100%)	0(0.00%)

p-value-<0.200

Table 4: Association between preterm birth and ph-IGFBP-1 test

Preterm delivery	PhIGFBP-1 test	
	Positive	Negative
Yes (52)	52 (100%)	0(0.00%)
No (26)	1(3.85%)	25(96.15%)

p-value-<0.001

Table 5: Association between phIGF BP-1 test and test delivery interval

Test delivery interval	PhIGFBP-1 test	
	Positive	Negative
<=48hours (36)	36(100%)	0(0.00%)
48hours but within 7days (9)	9(100%)	0(0.00%)
>7 days (33)	8(24.24%)	25(75.76%)

p-value-<0.001

Results and discussion

An accurate diagnosis of preterm labor is clinically difficult. In this study, we evaluated the value of the rapid phIGFBP-1 test in predicting preterm births in patients. In the study, majority of the participants (78) belonged to age group 18-25 years (45) and among this group, around 63.5% (33) had preterm delivery. Naoko Kozuki et al (2013)[5]reported in their study that early and late maternal age is an important risk factor for preterm labor. In this study, participant distribution is equal (50%) among rural and urban areas. Various studies have given variable results on association of preterm delivery with ethnicity but data on distribution in areas are non-conclusive.

In this study, 10.3% (8) women were from upper economic class, 79.5% (62) from middle economic class and 10.3% (8) were from lower socio-economic class. Among them maximum preterm delivery around 82.7% (43) were in middle socio-economic group. This finding was not in accordance with the study done by L. Ochoe (2021)[6]where poor or lower socio-economic status with lower education and income levels had more chances of preterm delivery.

In this study, 75.6% (59) women had BMI between 18.5 -22.9 kg/m2 and among them 67.8% (40) had preterm delivery. The exact mechanisms explaining the link between BMI and preterm delivery are not well known, however one theory suggests that significant preterm delivery risk increasing continuously with rising BMI.

In our study, among participants (78) around 66.7% (52) delivered preterm. Among preterm delivered 77.4% (24) had a history of vaginosis and 72.7% (24) had a history of threatened abortion in the present pregnancy. As per Kurki et al (1992)[7], Bacterial vaginosis had 2- 6 times increased risk for preterm labor.

As per the study by Salah Roshdy (2012)[8], women with threatened abortion had a significantly increased risk of preterm labor. In our present study, those who delivered preterm, 71.4% (35) had a history of previous preterm delivery, 18.4% (9) had a history of vaginal infection in previous delivery and 10.2% (5) had a history of UTI in previous pregnancy. As per the study by Yang (2017), a prior preterm birth increases the risk for a subsequent preterm birth with higher odds.

In our study, out of 78 women, 53 (67.9%) tested positive for phIGFBP-1 test and 25 (32.1%) tested negative result. Those who tested positive 52 (98.1%) delivered preterm and only 1 (1.9%) delivered term. Those who tested negative were not delivered preterm.

As the test has a high negative predictive value, this may enable physicians to prevent overtreatment of patients with preterm labor. Therefore, many unwanted side effects and complications of potentially hazardous tocolytic therapy can be prevented.

In our study those who tested positive 67.9% (36) for phIGFBP-1 (53) were maximally delivered within 48hours and 17% (9) delivered between 48 hours to 7 days and 15% (8) delivered after 7days of the test. Those who tested negative (25) were all delivered after 7 days of the test. So, the test was extremely sensitive in predicting preterm labor.

Limitation of the study

The sample size of study may be small for the result to be significant enough to be applicable to the general population, but it is big enough to be significant for the study population.

Conclusion

In this study, results show that there is a role of cervical phIGFBP-1 test in the management of women presenting with suspected preterm labor, it may replace cervical ultrasonography and fetal fibronectin in the future or at least serve as a useful adjunct to these tests. Thus, it will allow more focused management of women who are more likely to deliver preterm and perhaps avoid unnecessary admissions and treatment, to curtail health care costs.

Informed consent statement

All subjects here were already informed and gave consent.

References

1. Pallavi S. Vishwekar, Anahita R. Chauhan, Naju Turakhia, International Journal Of Reproduction, Contra ception, Obstetrics And Gynecology, Vol 6, No 8 ,2017- Prediction of preterm delivery with a novel bedside test.

2. Koul Lali B et al (2016) Risk assessment and management to prevent preterm birth.

3. WHO-Preterm birth 2016 [updated November 201624/3/2017].

4. Jung E et al (2016) -Prediction of impending preterm delivery based on sonogra phi cervical length and different cytokine levels in cervico vaginal fluid in preterm labor.

5. Naoko Kozuki, Arme CC Lee (2013) - The Association of parity and maternal age with small for gestational age, preterm and neonatal and infant mortality.

6. L. Ochoa-Association of neigh bour hood socio economic trajectories with preterm birth and small-for- gestational - age in the Nether lands: a nationwide population-based study.

7. Kurki, Tapio MD (1992). Bacterial vaginosis in preterm labour.

8. Pregnancy Outcome in Women with Threatened Miscarriage- (2012) a Year Study-Salah Roshdy Ahmed, Mohamed El-Khatem El-Samman.