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An Observational Study to Evaluate Prolactin Levels in Cervicovaginal Secretions in Women with Preterm Labour and Normal Pregnancy in The Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur

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Abstract

Background: Preterm labour is defined as the onset of labour occurring after the fetus reaches the period of viability (28 weeks) but before 37 completed weeks of gestation. The presence of prolactin in Cervicovaginal secretions may reflect decidual membrane separation or subclinical membrane injury, which suggests its potential role as a predictive marker for preterm labor.

Methods: Study conducted in 100 primi gravida women with single ton pregnancy distributed in Group A & B (50 in each group). Prolactin levels in the Cervicovaginal secretions were measured using the Electrochemiluminescence Immunoassay (ELISA) technique is to evaluate the role of prolactin levels in Cervicovaginal secretions as a potential biomarker for predicting preterm labor.

Results: Manage was similar in both groups (~24 years), Cervicovaginal prolactin levels between Group A and Group B, the mean prolactin level in Group A was markedly higher at 6.9 ± 2.28 ng/ml, compared to 1.52±0.78 ng/ml in Group B. In Group A, 54% of pregnant women experienced preterm births, while 46% delivered at term. In preterm deliveries (Group A), the mean Prolactin level was 11. 55 ± 7.86 ng/mL compared to 3.36 ± 2.60 in the term group. This difference was statistically significant, with a p-value of 0.01, in

dicatinga meaning ful association between levated levels of Cervicovaginal prolactin and the incidence of preterm delivery.

Conclusion: Elevated prolactin levels in Cervicovaginal secretions may reflect early physiological changes associated with the onset of preterm labor.

Identifying women at increased risk enables timely clinical interventions such as enhanced monitoring, administration of to colytics, or preparations for neonatal support, that can improve both maternal and neonatal outcomes.

Keywords: Preterm, Cervicovaginal secretion, Prolactin, ELISA

Introduction

The American College of Obstetricians and Gynecologists (ACOG) define preterm labour as the onset of regular, painful uterine contractions associated with progressive cervical effacement and dilatation occurring before 37 completed weeks (i.e., before 259 days) of gestation, calculated from the first day of the last menstrual period and after the attainment of fetal viability. The prevalence of preterm labour varies globally, with the highest rates reported in Africa (31%) and Asia (54%). In India, the incidence is approximately 14.5%. In nearly 50% of cases, the exact cause of preterm labour remains unknown.[1,3]

One of the key mechanisms involves premature activation of the fetal hypothalamic-pituitary- adrenal (HPA) axis in response to stress. This leads to the secretion of corticotropin- releasing hormone (CRH), adrenocorticotropic hormone (ACTH), cortisol, and placental CRH. Preterm labour has multifactorial causes. Maternal factors include genital tract infections, chorioamnionitis, a history of recurrent abortions, and congenital uterine abnormalities. Pregnancy-related factors include multiple gestations, placenta previa, and polyhydramnios. Fetal contributors include intrauterine growth restriction (IUGR), fetal distress, intrauterine death, congenital malformations, and unexplained idiopathic causes.[2,3]

Prolactin is a single-chain polypeptide hormone synthesized by the anterior pituitary under the regulation of the hypothalamus. During pregnancy, it is secreted by both maternal and fetal pituitary glands, and also produced locally by the chorionic Cytotrophoblast, Syncytiotrophoblast, decidua, and amnion. Its concentration peaks in amniotic fluid during the second trimester and remains elevated throughout gestation. The presence of prolactin in cervicovaginal secretions may reflect decidual membrane separation or subclinical membrane injury, which suggests its potential role as a predictive marker for preterm labor.[1,2,4-5]

The purpose of this study is to evaluate the role of prolactin levels in cervicovaginal secretions as a potential biomarker for predicting preterm labor. By comparing prolactin concentrations between women presenting with preterm labor and those with normal pregnancies, the study aims to determine whether elevated or altered prolactin levels in Cervicovaginal secretions are significantly associated with the risk of spontaneous preterm delivery. Establishing such an association may contribute to the early identification of at-risk pregnancies and enable timely interventions to reduce maternal and neonatal complications associated with preterm birth.

Material and Methodology

The Prospective Observational study was carried out in the Department of Obstetrics and Gynaecology, SMS Medical College and Attached Hospital, Jaipur. After obtaining ethical clearance from the Institutional

Review Board and Ethics Committee, the study was commenced from October 2023 onwards, over a period of one year or until the desired sample size was reached. The sample size was calculated based on findings from a previous study, which reported a minimum detectable mean difference of 2.1 ng/mL with a standard deviation of 2 ng/mL, using 80% power and a 5% alpha error. The required sample size was 30 participants in each group. After adjusting for a potential 10% attrition, the final sample size was 33 participants per group, making a total of 100 women 50 in each group.

Participants were included in the study if they met the following criteria:

- Women aged 20–35 years, who were primigravida with singleton pregnancies.
- Women presenting with preterm labor or those having a normal pregnancy.
- Women with intact amniotic membranes.
- History of preterm birth in previous pregnancy, if applicable.
- Willingness and ability to provide written informed consent.
- Women not participating in any other ongoing clinical study.

Participants were excluded if they had:

- Placenta previa or any episode of vaginal bleeding.
- Recent vaginal infection.
- Fetal abnormalities including congenital anomalies, fetal growth restriction, fetal distress, or multiple gestations.
- Hypertensive disorders of pregnancy.
- Conditions known to cause hyperprolactinemia, such as prolactinomas, hypothyroidism, chronic kidney disease (CKD) stage 4 or 5, or severe renal insufficiency.

All participants underwent a detailed medical history, clinical examination, and routine obstetric evaluation.

The participants were grouped as follows:

Study Group (Group A): Women who presented with signs and symptoms of preterm labor. These women were followed until delivery to determine the gestational outcome.

Comparison Group (Group B): Women with normal pregnancies and no symptoms of preterm labor during antenatal visits. These women were also followed till delivery.

A single cervicovaginal sample was collected from each participant at the time of enrollment.

The sampling procedure involved placing a cotton-tipped swab into the endocervical canal and posterior fornix of the vagina, each for 30 seconds, to collect cervicovaginal secretions. The swab was then immersed in a tube containing 1 mL of saline solution, which was shaken for one minute before the swab was discarded.

Prolactin levels in the cervicovaginal secretions were measured using the Electrochemiluminescence Immunoassay (ELISA) technique. The value of prolactin was recorded in a pre-designed data collection sheet.

All participants also underwent transabdominal sonography (TAS) to assess gestational age, amniotic fluid index (AFI), and fetal viability.

Statistical Analysis

The collected data were compiled and analyzed using standard statistical methods. Continuous variables were expressed as mean ± standard deviation (SD) and analyzed using the unpaired t-test. Categorical variables were expressed as percentages, and analyzed using the

Chi-square test. A p-value < 0.05 was considered statistically significant.

Results & Observations

The mean maternal age was nearly identical between groups (24.14 ±2.30 years in Group A and 24.18 ±3.17 years in Group B) and Body Mass Index (BMI) exhibited a slight variation between the groups, with Group A having a mean BMI of 23.11 ± 2.51 kg/m² and Group B showing a higher average of 25.56 ± 3.22 kg/m².

Table 1: Gestational Age Distribution in Group A and Group B

Gestational Age (weeks)	Group A No. of pregnant women (%)	Group B No. of pregnant women (%)
28–29 + 6 weeks	2 (4%)	0 (0%)
30–31 + 6 weeks	5 (10%)	0 (0%)
32–33 + 6 weeks	13 (26%)	0 (0%)
34–36 + 6 weeks	30 (60%)	0 (0%)
Subtotal (Preterm < 37 weeks)	50 (100%)	—
37–38 + 6 weeks (Early term)	—	30 (60%)
≥ 39 weeks (Full/Post-term)	—	20 (40%)
Subtotal (Term ≥ 37 weeks)	—	50 (100%)
Mean ± SD (weeks)	33.6 ± 1.12	39.24 ± 1.13

As shown in Table 1 in Group A (preterm), the mean gestational age was 33.6 ± 1.12 weeks. A total of 2 (4%) patients were in the 28–29 weeks gestation, 5 (10%) in 30–31 weeks 6 days, 13 (26%) in 32–33 weeks 6 days, 18 (36%) in 34–35 weeks 6 days, and 12 (24%) in 36–37 weeks 6 days. The majority of patients (36%) were in the 34–35 weeks 6 days gestation. In Group B (term), the mean gestational age was 39.24 ± 1.13 weeks, with 30 (60%) patients in the 38–39 weeks 6 days gestational age and 20 (40%) patients in the more than 40 weeks gestational age.

Table 2: Comparison of Prolactin Levels in Group A and Group B

Prolactin (ng/ml)	Group A (n=50)	Group B (n=50)
Mean ± SD	6.9 ± 2.28	1.52 ± 0.78

As shown in Table 2 The comparison of cervicovaginal prolactin levels between Group A and Group B, the mean prolactin level in Group A was markedly higher at 6.9 ±2.28 ng/ml, compared to 1.52 ±0.78 ng/ml in Group B.

Prolactin, a hormone known for its role in reproductive physiology, has been increasingly recognized for its local regulatory functions in the cervicovaginal environment. Its elevated levels in Group A indicative of premature cervical ripening or inflammatory changes that precede the onset of preterm labor. This finding supports the hypothesis that cervicovaginal prolactin could serve as a promising non-invasive biomarker for the early detection or prediction of preterm birth.

Table 3: Prolactin Levels by Gestational Age in Group A and Group B

Prolactin (ng/ml) at Gestational Age	Group A Mean ± SD	Group B Mean ± SD
28–29 + 6 weeks	16.5 ±1.3	0
30–31 + 6 weeks	6.28 ± 2.84	0
32–33 + 6 weeks	5.69 ± 10.16	0
34-36 + 6 Weeks	7.3 ± 3.2	0
37–38 + 6 weeks	0	1.49 ± 0.7
≥ 39 weeks	0	1.55 ± 0.82

As shown in Table 3 Analysis of serum prolactin levels at different gestational ages revealed notable differences between Group A and Group B. The mean prolactin levels in Group A shows that at 28–29 + 6 weeks, the mean prolactin level was 16.5 ± 1.3 ng/ml. At 30–31 + 6 weeks, the mean value was 6.28 ± 2.84 ng/ml, while at 32–33 + 6 weeks it was 5.69 ± 10.16 ng/ml. At 34–36 + 6 weeks, the mean prolactin level was 7.3 ± 3.2 ng/ml. Group B showed that at 37–38 + 6 weeks, the mean prolactin level was 1.49 ± 0.7 ng/ml, and at 39 weeks or more, it was 1.55 ± 0.82 ng/ml.

Table 4: Pregnancy Outcomes in Group A and Group B

Outcome	Group A No. of Pregnant womens (%)	Group B No. of Pregnant womens (%)
Preterm	27(54.00)	0
Term	23(46.00)	50 (100.00)
Total	50	50

As shown in Table 4 In terms of pregnancy outcomes, there was a clear distinction between the two groups. In Group A, 54% of pregnant women experienced preterm births, while 46% delivered at term. In contrast, Group B had no preterm births, with 100% of pregnant women delivering at term. This significant difference suggests that the factors defining each group, potentially linked to maternal health or clinical management, may play a crucial role in determining gestational length and birth timing.

Table 5: Prolactin Levels by Pregnancy Outcome in Group A and Group B

Outcome	Group A Prolactin (ng/mL) Mean ± SD	Group B Prolactin (ng/mL) Mean ± SD	P value
Preterm	11.55 ±7.86	0	-
Term	3.36 ±2.59	1.52 ± 0.78	0.02

As shown in Table 5 Prolactin levels were significantly higher in Group A compared to Group B. In preterm deliveries (Group A), the mean Prolactin level was 11.55 ±7.86 ng/mL, while no preterm cases were observed in Group B. Among term deliveries, Group A had a higher mean Prolactin level (3.36 ±2.59 ng/mL) compared to Group B (1.52 ±0.78 ng/mL), with the difference being statistically significant (p = 0.02).

Table 6: Comparison of Cervicovaginal prolactin levels among Preterm and Term in Group A

	Preterm (n=27)	Term (n=23)
Mean ± SD	11.54 ± 8	3.36± 2.6
Std. Error	1.54	0.55
Minimum	1.1	0.9
Maximum	30.4	9.7
P value	0.01	

As shown in Table 6 In Group A, a comparison was made between pregnant women who delivered preterm (n=27) and those who delivered at term (n=23) based on a specific clinical parameter. The mean value of Cervicovaginal prolactin for the preterm group was significantly higher at 11.54 ±8.00, compared to 3.36 ±2.60 in the term group. This difference was statistically significant, with a p-value of 0.01, indicating a meaningful association between elevated levels of Cervicovaginal prolactin and the incidence of preterm delivery.

Table 7: ROC Analysis

Parameter	Value
Cut-off Value	>7 ng/mL
True Positives (TP)	21
True Negatives (TN)	18
False Positives (FP)	5
False Negatives (FN)	6
Sensitivity	77.78% (95% CI: 57.74%–91.38%)
Specificity	78.26% (95% CI: 56.30%–92.54%)
AUC	0.843 (95% CI: 0.729–0.957)

As shown in Table 7 Among the 50 pregnant women in Group A, using a cut- off value of >7 ng/mL for cervicovaginal prolactin, 27 were categorized as preterm and 23 as term. This distribution indicates a significant association between elevated cervicovaginal prolactin levels and preterm birth, with more than half of the pregnant women surpassing the threshold. At this cut-off, the test identified 21 true positives (TP) and 18 true negatives (TN), while there were 5 false positives (FP) and 6 false negatives (FN). The Area Under the Curve (AUC) was 0.843 (95% CI: 0.729–0.957), reflecting good diagnostic accuracy of cervicovaginal prolactin in predicting preterm labor (Fig. 1). The sensitivity was 77.78% (95% CI: 57.74%–91.38%) and the specificity was 78.26% (95% CI: 56.30%–92.54%), demonstrating the test's ability to accurately classify most cases.

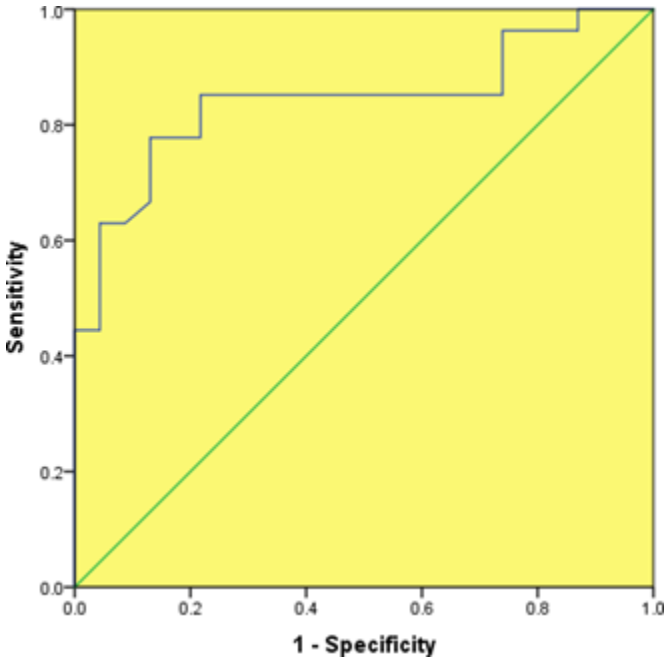

Fig. 1: ROC curve for prolactin for the prediction of preterm delivery

Discussion

A Prospective Observational study was carried out in 100 pregnant women (50 women in each group) to determine whether elevated or altered prolactin levels in Cervicovaginal secretions are significantly associated with the risk of spontaneous preterm delivery. The mean maternal age was nearly identical between groups (24.14 ±2.30 years in Group A and 24.18 ±3.17 years in Group B) and Body Mass Index (BMI) exhibited a slight variation between the groups, with Group A having a mean BMI of 23.11 ± 2.51 kg/m² and Group B showing a higher average of 25.56 ± 3.22 kg/m². Garshasbi et al.[6] 2004, and Gurbuz et al.[7] 2004, where the mean maternal ages were 25.19 ±4.1 years, 24.7 ±6.3 years, and 25.8 ±4.7 years, respectively.

The mean gestational age of Group A (preterm), were 33.6 ± 1.12 weeks with majority of patients (36%) were in the 34–35 weeks 6 days gestation. In Group B (term), the mean gestational age was 39.24 ± 1.13 weeks, with 30 (60%) patients in the 38–39 weeks 6 days gestational

age. Gurbuz et al.[7] 2004 also observed a higher incidence of preterm births clustering around 34–36 weeks in at-risk group. Radwan AM et al.[8]2019 further confirmed the significant difference in mean gestational age between preterm and term groups in their cohort.

Our study shows the cervicovaginal prolactin levels between Group A and Group B, the mean prolactin level in Group A was markedly higher at 6.9 ±2.28 ng/ml, compared to 1.52 ±0.78 ng/ml in Group B. These results are consistent with O Brien et al.[9] 2000 found prolactin to be significantly more prevalent in women with preterm labor compared to asymptomatic controls (50% vs. 5%; $p < 0.0001$). Guvenal et al.[10] 2001 reported significantly higher prolactin levels in the preterm group compared to the term delivery group (2.2 ± 17 mIU/mL vs. 0.83 ± 0.66 mIU/mL; $p = 0.026$).

Our study shows that Group A, 54% of pregnant women experienced preterm births, while 46% delivered at term. In contrast, Group B had no preterm births, with 100% of pregnant women delivering at term. Prolactin levels were significantly higher in Group A compared to Group B. In preterm deliveries (Group A), the mean Prolactin level was 11.55 ±7.86 ng/mL, while no preterm cases were observed in Group B. Among term deliveries, Group A had a higher mean Prolactin level (3.36 ±2.59 ng/mL) compared to Group B (1.52 ±0.78 ng/mL), with the difference being statistically significant ($p = 0.02$), indicating a meaningful association between elevated levels of Cervicovaginal prolactin and the incidence of preterm delivery. Ragam et al.[11] 2023 reported that 70% of women progressed to preterm delivery, while 30% delivered at term. Similar findings were observed in a study by Gurbuz et al.[7] where 78.4% of participants experienced preterm birth. Likewise, Radwan AM et al.[8] found that 50% of the women in their study progressed to preterm delivery. Ragam et al.[11] 2023 et al. involving 40 pregnant women, the researchers compared cervicovaginal prolactin levels between those who delivered at term and those who experienced preterm delivery. The mean prolactin level in women who delivered at term was 4.95 ±2.49 ng/mL, whereas it was significantly higher in those with preterm deliveries, measuring 10.88±3.52ng/mL. This difference was statistically highly significant ($p < 0.001$). Mehrotra Seema et al.[12] (2020) shows that among the 50 women who experienced preterm delivery, the mean prolactin level was 11.81 ±9.3 ng/mL. In contrast, women who delivered at term ($n = 25$) had a lower mean prolactin level of 4.61±6.2 ng/mL. The lowest prolactin levels were observed in women with normal pregnancies who had no complications ($n = 150$), with a mean of 2.15 ±5.1 ng/mL indicating a potential association between elevated cervicovaginal prolactin levels and preterm delivery.

The mean value of Cervicovaginal prolactin for the preterm group was significantly higher at 11.54 ±8.00, compared to 3.36 ±2.60 in the term group. This difference was statistically significant, with a p-value of 0.01, indicating a meaningful association between elevated levels of Cervicovaginal prolactin and the incidence of preterm delivery.

A ROC curve for prolactin for the prediction of preterm delivery was plotted and the Area Under the Curve (AUC) was 0.843 (95% CI: 0.729–0.957), reflecting good diagnostic accuracy of cervicovaginal prolactin in predicting preterm labor (Fig. 1). The sensitivity was 77.78% (95% CI: 57.74%–91.38%) and the specificity was 78.26% (95% CI: 56.30%–92.54%), demonstrating the test's ability to accurately classify most cases. Comparatively, O'Brien et al.[9] 2000 conducted a study

on 40 pregnant women using a lower prolactin threshold of 2 ng/mL, reporting a sensitivity of 88% and specificity of 79%, with a positive predictive value (PPV) of 80% and a negative predictive value (NPV) of 65%. In another study involving 60 pregnant women, Guvenal et al.[10] 2004 established a cut-off at 1.8 ng/mL, demonstrating a sensitivity of 50% and a notably high specificity of 96%, with a PPV of 67% and an NPV of 93%. Other studies, such as those by Buyukbayrak et al.[13]2004 and Kariman et al.[14]

Conclusion

Elevated prolactin levels in cervicovaginal secretions may reflect early physiological changes associated with the onset of preterm labor. Identifying women at increased risk enables timely clinical interventions such as enhanced monitoring, administration of tocolytics, or preparations for neonatal support, that can improve both maternal and neonatal outcomes. Overall, its integration into clinical practice holds potential to advance the early detection and proactive management of pregnancies prone to preterm delivery.

References

1. Lawn JE, Wilczynska-Ketende K, Cousens SN. Estimating the causes of 4 million neonatal deaths in the year 2000. Int J Epidemiol 2006;35(3):706–718.
2. Beck S, Wojdyla D, Say L, et al. The worldwide incidence of preterm birth. A systematic review of maternal mortality and mobidity. WHO Bull 2010;88(1):31– 38.
3. Florio P, Linton EA, Torricellie M, et al. Prediction of preterm delivery based on maternal plasma Urocortin. J Clin Endocrinol Metab 2007;92(12):4734–4737.
4. Malak TM, Sizmer F, Bell SC, et al. Fetal fibronectin in cervicovaginal secretions as a prediction of preterm birth. BJOG 1996;10(7):648–653.
5. Paternoster DM, Muresan D, Vitul A, et al. Cervical phIGFBP-1 in the evaluation of the risk of preterm delivery. Acta Obstet Gynecol Scand 2007;86(2):151–155.
6. Garshasbi A, Ghazanfari T, Faghihzadeh S. Beta-human chorionic gonadotropin in cervicovaginal secretions and preterm delivery. Int J Gynaecol Obstet. 2004;86(3):358-64.
7. Gurbuz A, Karateke A, Ozturkmen M, Kabaca C. Human chorionic gonadotropin assay in cervical secretions for accurate diagnosis of preterm labor. Int J Gynaecol Obstet. 2004;85(2):132-8
8. Radwan AM, Fayez MA. Beta HCG in cervico-vaginal secretion as a predictor of preterm labor. Int J Gynaecol Obstet Res. 2019;1(4):23-9.
9. O' Brien JM, Peeler G, Pitts DW, et al. Cervicovaginal prolactin: a marker for spontaneous preterm delivery. Am obstet Gynecol 1994;171(4):1107–1111.
10. Guvenal T, Kantas E, Erselcan T, Culhaoglu Y, Cetin A. Beta-human chorionic gonadotropin and prolactin assays in cervicovaginal secretions as a predictor of preterm delivery. Int J Gynaecol Obstet. 2001 Dec;75(3):229-34.
11. Ragam A et al. An analysis of cervicovaginal β-HCG and prolactin levels as a predictive biomarker of preterm birth in symptomatic women. International Journal of Clinical Obstetrics and Gynaecology 2023; 7(3): 460-467.
12. Mehrotra S et al. Study of Prolactin in Cervicovaginal Secretion in Women with Preterm Labor and Normal Pregnancy. Journal of South Asian Federation of Obstetrics and

Gynaecology.2020;12(1).

13. Buyukbayrak EE, Turan C, Unal O, Dansuk R, Cengizoğlu B. Diagnostic power of the vaginal washing-fluid prolactin assay as an alternative method for the diagnosis of premature rupture of membranes. J Matern Fetal Neonatal Med. 2004 Feb;15(2):120-5.
14. Kariman N, Hedayati M, Alavi Majd Sh. The diagnostic power of cervico-vaginal fluid prolactin in the diagnosis of premature rupture of membranes. Iran Red Crescent Med J. 2012 Sep;14(9):541-8. Epub 2012 Sep 30.