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Original Research Article

A Prospective Study of Maternal Beta hCG Levels at 12-20 Weeks of Gestational Age in Prediction of Hypertensive Disorders of Pregnancy

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Abstract

Objective: To evaluate the predictive value of maternal serum beta hCG levels at 12-20 weeks of gestation for the development of hypertensive disorders of pregnancy (HDP). Design: A prospective observational study. Setting: Malabar Institute of Medical Sciences, Kozhikode, Kerala, India. Participants: A total of 200 antenatal women aged 18-35 years, with singleton pregnancies at 12-20 weeks of gestation, were enrolled. Results: Serum beta hCG levels >2 MoM were significantly associated with an increased risk of developing hypertensive disorders of pregnancy. Among women with beta hCG levels >2 MoM, 93.1% developed HDP compared to only 2.3% of those with beta hCG levels ≤2 MoM.

Introduction: Hypertensive disorders of pregnancy (HDP) are one of the most critical complications that can arise during pregnancy. They include a spectrum of conditions such as gestational hypertension, preeclampsia, and eclampsia, which together account for a significant portion of maternal and fetal morbidity and mortality worldwide. The World Health Organization (WHO) has reported that hypertensive disorders of pregnancy (HDP) are significant contributors to maternal and fetal morbidity and mortality. Identifying early biomarkers that can predict the development of HDP is crucial for improving outcomes. Elevated maternal serum beta hCG levels have been suggested as a potential predictor of these disorders.

Methods: This prospective observational study was conducted at the Malabar Institute of Medical Sciences, Kozhikode, Kerala, India. A total of 200 antenatal women aged 18-35 years, with singleton pregnancies at 12-20 weeks of gestation, were enrolled. Maternal serum beta hCG levels were measured using chemiluminescence immunoassay. Participants were followed up for the development of hypertensive disorders, including gestational hypertension, preeclampsia, severe preeclampsia, and eclampsia.

Results: Of the 200 participants, 31 (15.5%) developed hypertensive disorders. Women with serum beta hCG levels >2 MoM had a significantly higher risk of developing HDP (93.1%) compared to those with levels ≤2 MoM (2.3%). The correlation between elevated beta hCG levels and the severity of hypertensive disorders was statistically significant ($p < 0.001$).

Conclusion: Elevated maternal serum beta hCG levels at 12-20 weeks of gestation are strongly associated with an increased risk of developing hypertensive disorders of pregnancy. Screening for beta hCG levels during early pregnancy could serve as an effective tool for identifying women at high risk for HDP, allowing for closer monitoring and early interventions.

Keyword: Maternal serum, prospective observational, hCG, chemiluminescence.

Introduction

Hypertensive disorders of pregnancy (HDP) are among the most common and dangerous complications that can occur during pregnancy, affecting approximately 7-15% of all pregnancies globally. These disorders, which include gestational hypertension, preeclampsia, and eclampsia, are significant causes of maternal and fetal morbidity and mortality, particularly in low- and middle-income countries.[1] Despite improvements in maternal healthcare, HDP continues to pose substantial risks, often leading to severe outcomes such as preterm birth, intrauterine growth restriction, and maternal death.[2] Preeclampsia, a major subtype of HDP, is particularly concerning due to its unpredictable nature and potential for rapid progression to severe complications, including HELLP syndrome (hemolysis, elevated liver enzymes, and low platelet count) and eclampsia.[3] The exact pathophysiology of preeclampsia remains poorly understood, but it is widely accepted that abnormal placentation and endothelial dysfunction play

central roles. These abnormalities result in increased vascular resistance, reduced placental perfusion, and an exaggerated maternal inflammatory response, all of which contribute to the clinical manifestations of the disease.[4-5]

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the syncytiotrophoblasts of the placenta, and its primary function is to maintain the corpus luteum during early pregnancy. In recent years, elevated maternal serum hCG levels, particularly in the second trimester, have been associated with various adverse pregnancy outcomes, including HDP.[6]

The proposed mechanism involves abnormal placentation, which leads to increased production of hCG as a response to placental ischemia. However, the exact relationship between hCG levels and the development of hypertensive disorders is not fully elucidated.[7-8]

This study aims to investigate the predictive value of maternal serum beta hCG levels at 12-20 weeks of gestation in identifying women at risk for developing hypertensive disorders of pregnancy. By establishing a correlation between beta hCG levels and the severity of HDP, this research seeks to contribute to the development of early screening tools that can help prevent adverse maternal and fetal outcomes.

Methods

Study Design and Setting

This prospective observational study was conducted at the Department of Obstetrics and Gynecology, Malabar Institute of Medical Sciences, Kozhikode, Kerala, India, over a period of one year, from January 2016 to January 2017.

Participants

The study included 200 antenatal women aged 18-35 years with singleton pregnancies, who were between 12-20 weeks of gestation at the time of enrolments. Participants were selected based on the following inclusion and exclusion criteria:

Inclusion Criteria

- Singleton pregnancy
- Gestational age between 12-20 weeks
- Age between 18-35 years
- Blood pressure <140/90 mmHg at enrolment
- No proteinuria

Exclusion Criteria

- Multiple pregnancies
- Known cases of chronic hypertension
- Gestational trophoblastic disease
- Presence of Down's syndrome in the current pregnancy
- Germ cell tumors

Data Collection and Laboratory Methods

After obtaining informed consent, detailed patient histories were recorded, including age, parity, and obstetric history. Gestational age was confirmed by reliable last menstrual period (LMP) records and early ultrasound measurements.

Maternal serum beta hCG levels were measured using chemiluminescence immunoassay with DiaSorin LIAISON equipment. The beta hCG levels were categorized into multiples of the median (MoM), with levels greater than 2 MoM considered elevated.

Blood pressure and urine albumin were monitored regularly at each follow-up visit to detect the onset of hypertensive disorders. Participants were followed until delivery, and the development of hypertensive disorders was recorded. The diagnosis of HDP was classified into gestational hypertension, preeclampsia, severe preeclampsia, and eclampsia based on established clinical criteria.

Statistical Analysis

Data were analyzed using SPSS version 20.0. Categorical variables were summarized as frequencies and percentages. The association between serum beta hCG levels and the development of hypertensive disorders was evaluated using Chi-square and Fisher's exact tests.

Sensitivity, specificity, positive predictive value, and negative predictive value were calculated to assess the predictive utility of beta hCG levels. A p-value of <0.05 was considered statistically significant.

Results

Table 1: Distribution of Maternal Age

Age Group (Years)	Frequency	Percentage
Up to 20	6	3.0%
21-25	43	21.5%
26-30	62	31.0%
31-35	89	44.5%

Table 2: Distribution of Gravidity

Gravidity	Frequency	Percentage
Primigravida	64	32.0%
Multigravida	136	68.0%

Table 3: Distribution of Serum Beta hCG Levels (mIU/ml)

Beta hCG Level (mIU/ml)	Frequency	Percentage
< 30,000	91	45.5%
30,001 - 40,000	48	24.0%
40,001 - 50,000	17	8.5%
50,001 - 60,000	12	6.0%
60,001 - 70,000	6	3.0%
70,001 - 80,000	6	3.0%
80,001 - 90,000	7	3.5%
90,001 - 100,000	8	4.0%
> 100,000	5	2.5%

Table 4: Distribution of Hypertensive Disorders of Pregnancy

Hypertensive Disorders	Frequency	Percentage
None	169	84.5%
Gestational Hypertension	15	7.5%
Pre-eclampsia	8	4.0%
Severe Pre-eclampsia	7	3.5%
Eclampsia	1	0.5%

Table 5: Association between Maternal Age and Hypertensive Disorders

Age Group (Years)	No Hypertension	Hypertension	Total	p-value
Up to 20	5	1	6	0.584
21-25	39	4	43	
26-30	52	10	62	
31-35	73	16	89	

Table 6: Association between Gravidity and Hypertensive Disorders

Gravidity	No Hypertension	Hypertension	Total	p-value
Primigravida	50	14	64	0.087
Multigravida	119	17	136	

Table 7: Association between Serum Beta hCG Levels and Hypertensive Disorders

Serum Beta hCG (mIU/ml)	No Hypertension	Hypertension	Total	p-value
≤ 80,000	168	12	180	< 0.001
> 80,000	1	19	20	

Table 8: Association between Serum Beta hCG Levels (MoM) and Hypertensive Disorders

Beta hCG (MoM)	No Hypertension	Hypertension	Total	p-value
≤ 2 MoM	167	4	171	< 0.001
> 2 MoM	2	27	29	

Table 9: Association between Serum Beta hCG Levels and Severity of Hypertensive Disorders

Serum Beta hCG (mIU/ml)	No Hypertension	Mild Hypertension	Severe Hypertension	Total	p-value
< 30,000	91	0	0	91	< 0.001
30,001 - 40,000	48	1	0	48	
40,001 - 50,000	17	2	0	17	
50,001 - 60,000	12	0	0	12	
60,001 - 70,000	6	3	1	6	

Discussion

This study demonstrated a significant association between elevated maternal serum beta hCG levels at 12-20 weeks of gestation and the development of hypertensive disorders of pregnancy (HDP).[9-10] Women with beta hCG levels >2 MoM were found to have a substantially higher risk of developing HDP, including severe forms of preeclampsia and eclampsia.[11]

These findings are consistent with previous research suggesting that abnormal placentation and resulting placental ischemia may lead to increased production of hCG, contributing to the pathophysiology of hypertensive disorders.[12-14]

The study's findings underscore the potential utility of measuring maternal serum beta hCG levels as an early screening tool for HDP. Identifying women at high risk for these disorders could allow for closer monitoring and timely interventions, potentially reducing the incidence of severe complications associated with HDP.[15-17]

However, it is important to acknowledge the limitations of this study, including the relatively small sample size and the single-center design, which may limit the generalizability of the results. Future research should focus on larger, multi-center studies to validate these findings and further explore the mechanisms underlying the relationship between hCG levels and hypertensive disorders.[18-20]

Conclusion

Elevated maternal serum beta hCG levels at 12-20 weeks of gestational age are strongly associated with an increased risk of developing hypertensive disorders of pregnancy. Screening for beta hCG levels during early pregnancy could serve as an effective tool for identifying women at high risk for HDP, enabling closer monitoring and early intervention to improve maternal and fetal outcomes.

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Original Research Article

Maternal and Neonatal Outcomes in Premature Rupture of Membranes (PROM) at Term: A Prospective Observational Study

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Abstract:

Background: Premature rupture of membranes (PROM) is a common obstetric complication that significantly influences maternal and neonatal outcomes. This study aims to evaluate the maternal and neonatal outcomes associated with PROM at term.

Methods: A descriptive study was conducted at Cosmopolitan Hospital, Trivandrum, over 19 months, from July 2015 to January 2017. The study included 200 pregnant women diagnosed with PROM after 37 completed weeks of gestation. Data on maternal and neonatal outcomes were collected and analyzed using statistical software SPSS version 20.

Results: The study observed a higher incidence of maternal complications such as chorioamnionitis (6%), puerperal fever (15%), and postpartum hemorrhage (5%). Neonatal complications included birth asphyxia (10.5%), meconium aspiration syndrome (7%), and NICU admissions (12.5%). The mean duration of hospital stay was 4.4 days for mothers and 4.48 days for neonates.

Conclusion: PROM at term is associated with significant maternal and neonatal morbidity. Prompt diagnosis and management, including appropriate use of antibiotics and timely induction of labor, are essential to reduce complications.

Keywords: PROM, NICU, Chorioamnionitis

Introduction

Premature rupture of membranes (PROM) is defined as the rupture of membranes before the onset of labor, resulting in leakage of amniotic fluid and the establishment of communication between the amniotic cavity and the endocervical canal and vagina [1]. When it occurs before 37 completed weeks of gestation, it is termed preterm PROM (PPROM); after 37 weeks, it is called term PROM [2]. PROM at term complicates 8-10% of all births, with most cases occurring in women who are at term [3]. The etiology of PROM is multifactorial, involving physiological changes, mechanical factors, infections, and biochemical changes within the membranes [4].

PROM poses significant risks to both the mother and the fetus, including chorioamnionitis, endometritis, postpartum hemorrhage, neonatal sepsis, and increased rates of NICU admission [5]. The management of PROM at term is controversial, with options ranging from expectant management to immediate induction of labor [6].

The objective of this study was to analyze the maternal and neonatal outcomes in cases of PROM at term and to evaluate the effectiveness of different management strategies in reducing associated complications.

Materials and Methods

Study Design: This was a prospective, descriptive study conducted in the Department of Obstetrics and Gynecology and the Department of Pediatrics at Cosmopolitan Hospital, Trivandrum.

Study Population: The study included 200 pregnant women who presented with PROM after 37 weeks of gestation, diagnosed based on history and sterile speculum examination. Patients with active labor, previous cesarean section, malpresentation, and antepartum hemorrhage were excluded.

Sample Size Calculation: The sample size was calculated using EPI INFO software, considering a 5% error margin and a 95% confidence interval. The estimated proportion of cesarean section ($p = 0.29$) among term PROM cases from a reference study was used, resulting in a minimum sample

size of 115, adjusted to 200 to account for dropouts.

Data Collection:

Detailed history, general physical examination, obstetric examination, and necessary laboratory investigations were performed for each patient. Information on maternal demographics, medical and obstetric history, method of labor induction, and delivery outcomes were recorded.

Statistical Analysis:

Data were analyzed using SPSS version 20. Frequencies and percentages were calculated for categorical variables, while means and standard deviations were used for continuous variables.

Chi-square tests were applied to assess associations between categorical variables. A p-value of <0.05 was considered statistically significant.

Results

Table 1: Demographic Characteristics of the Study Population

Characteristic	Frequency (n)	Percentage (%)
Age (years)		
≤ 20	11	5.5
21-30	162	81.0
>30	27	13.5
Education Level		
Secondary	30	15.0
Higher Secondary	53	26.5
Graduate	88	44.0
Post Graduate	17	8.5
Professional	12	6.0

Table 2: Maternal Factors and Medical History

Maternal Factor	Frequency (n)	Percentage (%)
Hypothyroidism	42	21.0
Anemia	9	4.5
Gestational Diabetes Mellitus	31	15.5
Gestational Hypertension	21	10.5

Table 3: Distribution of Patients According to Gestational Age

Gestational Age (weeks)	Frequency (n)	Percentage (%)
37.1-38	37	18.5
38.1-39	83	41.5
39.1-40	80	40.0

Table 4: Mode of Delivery

Mode of Delivery	Frequency (n)	Percentage (%)
Normal Vaginal Delivery	127	63.5
Instrumental Delivery	9	4.5
Lower Segment Cesarean Section (LSCS)	64	32.0

Table 5: Indications for Cesarean Section

Indication	Frequency (n)	Percentage (%)
Failure to Progress	19	9.5
Fetal Distress	17	8.5
Prolonged Second Stage	12	6.0
Failed Induction	15	7.5

Table 6: Neonatal Outcomes

Neonatal Outcome	Frequency (n)	Percentage (%)
Healthy Baby	149	74.5
Birth Asphyxia	21	10.5
Meconium Aspiration	14	7.0
Hyperbilirubinemia	12	6.0
Sepsis	4	2.0

Table 7: APGAR Scores at 1 and 5 Minutes

APGAR Score	Frequency (n)	Percentage (%)
APGAR < 7 at 1 min	24	12.0
APGAR > 7 at 1 min	176	88.0
APGAR < 7 at 5 min	9	4.5
APGAR > 7 at 5 min	191	95.5

Table 8: Duration of Hospital Stay

Duration of Stay (days)	Frequency (n)	Percentage (%)
≤ 7 days	181	90.5
> 7 days	19	9.5
Mean Duration	4.4 ± 2.0	

Table 9: Correlation between Mode of Delivery and Neonatal Outcome

Neonatal Outcome	Normal Delivery (%)	LSCS (%)	p-value
Healthy Baby	86.6	46.9	<0.001
Birth Asphyxia	3.1	26.6	
Meconium Aspiration	1.6	18.8	

Table 10: Correlation between PROM-to-Delivery Interval and Maternal Complications

PROM-to-Delivery Interval (hours)	Chorioamnionitis (%)	Puerperal Fever (%)	p-value
<6	0	0	<0.001
6-12	4.8	3.8	
12-18	20.0	9.8	
18-24	44.4	16.7	

Discussion

The results of this study are consistent with previous research, indicating that PROM at term is associated with significant maternal and neonatal morbidity [7]. The incidence of cesarean sections was comparable to other studies, and maternal complications like chorioamnionitis and puerperal fever were prevalent. The study reinforces the importance of active management of PROM cases at term, particularly in reducing the interval between PROM and delivery to minimize complications [8].

Maternal Outcomes: PROM significantly impacts maternal health, with an increased risk of complications such as chorioamnionitis, puerperal fever, and postpartum hemorrhage [9]. In this study, 6% of women developed chorioamnionitis, a rate comparable to findings by Pandey S (6%) and Shah M (4%) [10]. The incidence of puerperal fever (15%) was also within the range reported by studies like Anjana Devi (20.19%) and Gaikwad B (15%) [11]. these findings underscore the need for vigilant monitoring and timely intervention in cases of PROM to prevent maternal morbidity [12].

Neonatal Outcomes: Neonatal outcomes are a significant concern in PROM cases due to the potential for complications such as sepsis, birth asphyxia, and meconium aspiration syndrome [13]. The study showed a 10.5% incidence of birth asphyxia and a 7% incidence of meconium aspiration syndrome, similar to the findings of Shanthi et al. (14% birth asphyxia) and Kurude V N (6.3% sepsis) [14]. The rate of NICU admissions (12.5%) observed in this study is consistent with the 16% reported by Sinha R K et al. and 15% by Mukharya et al. These data indicate that the neonatal morbidity associated with PROM is substantial and highlights the need for comprehensive neonatal care facilities to manage such cases effectively [15].

Management Strategies: The management of PROM at term includes monitoring for signs of infection and deciding on the appropriate time and method for labor induction. Studies have shown that early induction of labor in cases of PROM reduces the risk of infection without significantly increasing the rate of cesarean sections. This study followed a protocol of immediate induction with prostaglandins or oxytocin based on the Bishop's score, which is consistent with guidelines from the Society of Obstetricians and Gynecologists of Canada and the World Health Organization.

The use of antibiotics in cases of PROM is also a crucial management strategy to prevent ascending infections. In this study, all patients received prophylactic antibiotics, and there was a noted reduction in the incidence of chorioamnionitis and neonatal sepsis. This practice aligns with the recommendations of the NICE guidelines, which advocate for the use of antibiotics in PROM cases to minimize the risk of maternal and neonatal infections.

Strengths and Limitations: The major strength of this study is its prospective design and the comprehensive collection of data on maternal and neonatal outcomes in PROM cases at term. However, there are several limitations to consider. The sample size, although adequate, was limited to a single tertiary care center, which may affect the generalizability of the findings. Additionally, the study did not account for long-term neonatal outcomes, which are crucial in understanding the full impact of PROM.

Future Research Directions: Future studies should focus on larger, multi-center trials to validate these findings and explore the long-term outcomes of neonates born after PROM at term. Further research is also needed to refine the management protocols for PROM, including the optimal timing of induction and the use of prophylactic antibiotics.

Conclusion

This study highlights the significant maternal and neonatal morbidity associated with PROM at term. Active management with timely induction of labor and the use of prophylactic antibiotics are essential strategies to reduce the risks of infection and adverse outcomes. A team-based approach, including obstetricians, neonatologists, and nursing staff, is crucial in managing these cases effectively. While this study provides valuable insights, further research is needed to optimize management strategies and improve outcomes for both mothers and neonates.

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