Journal of Cardiovascular Disease Research

ISSN: 0975-3583,0976-2833 VOL 15, ISSUE 07, 2024

PREDICTION OF PRE-ECLAMPSIA IN DIABETIC PREGNANT WOMEN

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Introduction

Pre-eclampsia is a complex and multifactorial hypertensive disorder that occurs during pregnancy, typically after the 20th week of gestation.[1] It is characterized by high blood pressure and often includes signs of damage to other organ systems, most commonly the liver and kidneys.[2] Pre-eclampsia can have serious implications for both the mother and the fetus, including increased risk of morbidity and mortality. Diabetes, whether pre-existing (type 1 or type 2 diabetes) or gestational diabetes mellitus (GDM), is a significant risk factor for the development of pre-eclampsia.[3] Diabetic pregnant women are more susceptible to vascular complications, which may contribute to the pathophysiology of pre-eclampsia. The interaction between diabetes and pre-eclampsia creates a high-risk scenario that necessitates early prediction and management to improve outcomes.[4]

The rationale for investigating the prediction of pre-eclampsia in diabetic pregnant women stems from the need to reduce the adverse outcomes associated with this dual diagnosis. Diabetes in pregnancy is already a high-risk condition that requires meticulous management. When complicated by pre-eclampsia, the risk to both maternal and fetal health increases exponentially. Early prediction and timely intervention are crucial in mitigating these risks.[5] Predicting pre-eclampsia in diabetic pregnant women involves understanding various

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biomarkers, clinical indicators, and risk factors that may predispose this population to the condition. By identifying these predictive factors, healthcare providers can implement targeted surveillance and preventive strategies, potentially reducing the incidence and severity of pre-eclampsia.

The economic burden of managing pre-eclampsia and diabetes in pregnancy is substantial, involving intensive monitoring, frequent hospitalizations, and extensive neonatal care. Early prediction can optimize resource allocation, reduce healthcare costs, and improve clinical outcomes.[6] Preventive measures, such as low-dose aspirin therapy and stringent glycemic control, can be more effectively applied if high-risk individuals are identified early.[7] This proactive approach can mitigate complications, enhancing both maternal and fetal health. Moreover, this study will contribute to scientific knowledge by elucidating the interplay between diabetes and pre-eclampsia, guiding clinical practice with evidence-based protocols for managing high-risk pregnancies. The findings can lead to standardized screening and management guidelines, ultimately improving the quality of care and outcomes for diabetic pregnant women. The aim of this study is to investigate the clinical risk factors and biochemical markers in early pregnancy that contribute to the development of pre-eclampsia in women with diabetes mellitus (DM) and gestational diabetes mellitus (GDM).

Material and methods

This cross sectional study was conducted at the Antenatal Clinic in Tamil Nadu from January 2024 to June 2024. The study received approval from the Institutional Ethical Committee of a tertiary care hospital and referral center. The study included pregnant women registered between 12 and 20 weeks of gestation, aged 18-40 years, who were diagnosed with (i) gestational diabetes mellitus (GDM) before 20 weeks of gestation, and (ii) diabetes mellitus (DM) prior to pregnancy. The control group comprised healthy, asymptomatic pregnant women

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matched by age, parity, and gestational period, with no medical, metabolic, or surgical conditions and 2-hour plasma glucose levels <140 mg/dl following a 75 g oral glucose load both at recruitment and at 24-28 weeks of gestation. Women were excluded if they had a history of hypertension, chronic renal disease, cardiovascular disease, thyroid disorders, tuberculosis, pre-existing calcium or parathyroid conditions, sarcoidosis, osteomalacia, bone disorders, urolithiasis, systolic blood pressure ≥140 mmHg, diastolic blood pressure ≥90 mmHg at the first visit, or if they had a fetus with congenital malformations.

Pre-eclampsia was diagnosed based on systolic blood pressure ≥140 mmHg or diastolic ≥90 mmHg on two occasions at least four hours apart after 20 weeks of gestation in women with previously normal blood pressure, accompanied by proteinuria (defined as >300 mg/24 h or ≥1+ on a clean-catch dipstick test in the absence of urinary infection). GDM was identified as hyperglycemia first diagnosed during pregnancy following a 75 g oral glucose load. According to the Diabetes in Pregnancy Study Group, India (DIPSI), a 2-hour venous blood sample with plasma glucose levels ≥140 mg/dl is diagnostic for GDM. This guideline is also endorsed by the Ministry of Health and Family Welfare, Government of India.

Upon obtaining written informed consent, participants were assessed using a standardized pro forma that included a history of risk factors, dietary habits, medication or supplement intake, obstetric history, clinical examination, routine laboratory tests, and biochemical evaluations during pregnancy. Socio-economic status (SES) was evaluated using the Modified Kuppuswamy Scale, which considers education (1-7 points), occupation (1-10 points), and income (1-12 points), with a maximum composite score of 29 points.

Sample Size

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For a cross-sectional study focusing on estimating the prevalence of pre-eclampsia in diabetic pregnant women, the required sample size can be determined using the formula $n=1.96x1.96xpxq/d^2$ In this formula, n represents the required sample size, Z-score corresponding to the desired confidence level (1.96 for 95% confidence), p[8] is the estimated proportion or prevalence of pre-eclampsia in diabetic pregnant women, and d is the margin of error, often set at 0.10 for a proportion. Assuming a prevalence (p) of pre-eclampsia in diabetic pregnant women to be around 20% (0.20) and a margin of error (d) of 0.10, the sample size estimated around 61. Based on this formula, the ideal sample size to accurately estimate the prevalence of pre-eclampsia in diabetic pregnant women is approximately 61 participants.

Statistical analysis

Results

The study included 61 diabetic pregnant women, and the analysis of their characteristics provides valuable insights into their demographic and clinical profile. The mean age of the participants was 25.00 years with a standard deviation of 3.77 years, indicating a relatively young cohort. The average hemoglobin (Hb) level was 10.79 g/dl (±1.37), which is slightly lower than the normal range, possibly reflecting common anemia in pregnancy. The mean Body Mass Index (BMI) was 22.78 kg/m² (±3.80), suggesting that most participants were within the normal weight range, although some variation existed. The mean period of gestation (POG) at enrollment was 16.09 weeks (±3.05), indicating that participants were generally in their second trimester at the time of the study. Regarding parity, a significant majority (82.00%) were

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nulliparous, while 18.00% had given birth previously. This distribution highlights the predominance of first-time mothers in the sample.

Educational attainment was relatively balanced, with 47.54% having less than 10 years of education and 52.46% having 10 years or more. This reflects a diverse educational background among the participants. The socioeconomic status, assessed using the Modified Kuppuswamy Score, showed that 42.62% of the participants were in the lower socioeconomic class, 29.51% in the upper lower class, 13.11% in the lower middle class, 11.48% in the upper middle class, and 3.28% in the upper class. This spread indicates a wide range of socioeconomic backgrounds. Family and personal medical history revealed that 6.56% of participants had hypertension, 9.84% had diabetes mellitus (DM), and 4.92% had a history of abortion. A small proportion (1.64%) had a history of more than 10 years between pregnancies, and 3.28% had a history of pre-eclampsia. Additionally, 4.92% experienced pre-term delivery, 6.56% had DM before pregnancy, 3.28% had a history of stillbirth, and 1.64% had experienced neonatal death.

Table 1: Demographic characteristics of the study participants (N=61)

Characteristics	**Total (n=61)**
Age (yr), mean±SD	25.00±3.77
Hb (g/dl), mean±SD	10.79±1.37
BMI (kg/m²), mean±SD	22.78±3.80
POG at enrolment (wk), mean±SD	16.09±3.05
Parity, n (%)	
Nullipara	50 (82.00)
Para 1 and above	11 (18.00)
Education (yr), n (%)	
<10	29 (47.54)
≥10	32 (52.46)
Socioeconomic status (Modified Kuppuswamy Score), n (%)	
Lower	26 (42.62)
Upper lower	18 (29.51)
Lower middle	8 (13.11)

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Upper middle	7 (11.48)
Upper	2 (3.28)
Family/personal history of, n (%)	
Hypertension	4 (6.56)
DM	6 (9.84)
Abortion	3 (4.92)
>10 yr between pregnancies	1 (1.64)
Pre-eclampsia	2 (3.28)
Pre-term delivery	3 (4.92)
DM before pregnancy	4 (6.56)
Stillbirth	2 (3.28)
Neonatal death	1 (1.64)

The study analyzed the characteristics of 61 diabetic pregnant women, comparing those who developed pre-eclampsia (n=11) with those who did not (n=50). The mean age of women who developed pre-eclampsia was 25.36 years (±3.91), slightly higher than the mean age of 25.25 years (±3.89) for those who did not, though the difference was not statistically significant (P=0.82). Hemoglobin levels were identical between both groups, with a mean of 10.84 g/dl, indicating no significant difference in anemia status (P=0.98). The mean Body Mass Index (BMI) was higher in women who developed pre-eclampsia (23.59±3.73) compared to those who did not (23.21±4.17), but this difference was not statistically significant (P=0.44).

The mean period of gestation (POG) at enrollment was 15.73 weeks (±3.21) for those who developed pre-eclampsia, compared to 16.26 weeks (±3.06) for those who did not, with no significant difference (P=0.16). In terms of parity, a higher proportion of nulliparous women (54.55%) developed pre-eclampsia compared to 76.00% who did not (P=0.059). Conversely, 45.45% of women who developed pre-eclampsia were multiparous compared to 24.00% of those who did not. Educational attainment showed no significant difference between the groups, with 54.55% of women who developed pre-eclampsia having ≥10 years of education compared to 52.00% in the non-pre-eclampsia group (P=0.995). Socio-economic status, as

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assessed by the Modified Kuppuswamy Score, revealed that a higher percentage of women who developed pre-eclampsia were in the lower socio-economic category (36.36%) compared to those who did not (42.00%), with a significant difference (P=0.001). The distribution across other socio-economic categories did not show significant differences. Regarding family and personal medical history, hypertension was present in 9.09% of women who developed pre-eclampsia compared to 6.00% in those who did not (P=0.002). Similarly, 18.18% of women who developed pre-eclampsia had diabetes mellitus (DM), significantly higher than 6.00% in the non-pre-eclampsia group (P=0.015). Abortion history was also more common in the pre-eclampsia group (9.09% vs. 4.00%, P=0.038). The history of pre-eclampsia was significantly higher in those who developed the condition during the study (18.18% vs. 2.00%, P=0.02).

Pre-term birth rates were slightly higher in the pre-eclampsia group (9.09%) compared to those who did not develop pre-eclampsia (4.00%), but this was not statistically significant (P=0.4). The presence of DM before pregnancy was 9.09% in the pre-eclampsia group compared to 6.00% in the non-pre-eclampsia group (P=0.07). Stillbirth rates were also higher in the pre-eclampsia group (9.09% vs. 4.00%), with a borderline significance (P=0.07). Neonatal death did not significantly differ between the groups.

Table 2: Characteristics of the Study Sample by Pre-eclampsia Status (N=61)

Characteristics	**Developed Pre-eclampsia (n=11)**	**Did Not Develop Pre-eclampsia (n=50)**	**P value**
Age (yr), mean±SD	25.36±3.91	25.25±3.89	0.82
Hb (g/dl), mean±SD	10.84±1.36	10.84±1.31	0.98
BMI (kg/m²), mean±SD	23.59±3.73	23.21±4.17	0.44
POG at enrolment (wk), mean±SD	15.73±3.21	16.26±3.06	0.16
Parity, n (%)			
Nullipara	6 (54.55)	38 (76.00)	0.059
Para 1 and above	5 (45.45)	12 (24.00)	

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Education (yr), n (%)			
≥10	6 (54.55)	26 (52.00)	0.995
<10	5 (45.45)	24 (48.00)	
Socio-economic status (Modified Kuppuswamy Score), n (%)			
Lower	4 (36.36)	21 (42.00)	0.001
Upper lower	4 (36.36)	14 (28.00)	
Lower middle	1 (9.09)	7 (14.00)	
Upper middle	2 (18.18)	5 (10.00)	
Upper	0 (0.00)	3 (6.00)	
Family/personal history of, n (%)			
Hypertension	1 (9.09)	3 (6.00)	0.002
DM	2 (18.18)	3 (6.00)	0.015
Abortion	1 (9.09)	2 (4.00)	0.038
>10 yr between pregnancies	0 (0.00)	1 (2.00)	0.058
Pre-eclampsia	2 (18.18)	1 (2.00)	0.02
Pre-term birth	1 (9.09)	2 (4.00)	0.4
DM before pregnancy	1 (9.09)	3 (6.00)	0.07
Stillbirth	1 (9.09)	2 (4.00)	0.07
Neonatal death	0 (0.00)	1 (2.00)	0.995

Discussion

In our study, the mean age of the participants was 25 years, with an average hemoglobin level of 10.79 g/dl and a mean BMI of 22.78 kg/m². The average period of gestation (POG) at enrollment was 16.09 weeks. Notably, a significant proportion of the participants were nulliparous (82%), with a substantial portion having at least 10 years of education (52.46%). The socioeconomic status of the participants varied, with the majority belonging to the lower (42.62%) and upper lower (29.51%) classes according to the Modified Kuppuswamy Score. When comparing participants who developed pre-eclampsia with those who did not, there were no significant differences in age, hemoglobin levels, BMI, or POG at enrollment. However, parity showed a borderline significance, with a higher percentage of multiparous women developing pre-eclampsia (45.45% vs. 24.00%, p=0.059). Education levels did not significantly differ between the groups. However, socioeconomic status was significantly

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associated with the development of pre-eclampsia, with a higher percentage of participants from lower socioeconomic classes developing the condition (p=0.001). A history of hypertension, diabetes mellitus (DM), and abortion were significantly more prevalent in the pre-eclampsia group (p=0.002, p=0.015, and p=0.038, respectively). This underscores the importance of monitoring and managing these conditions to prevent the development of pre-eclampsia.

Our findings align with the study by Ashok Kumar et al.[9], which reported similar demographic and clinical characteristics. In both studies, participants who developed pre-eclampsia had higher BMIs and were more likely to have a history of hypertension, DM, and other complications. The Ashok Kumar[9] study also highlighted the importance of socioeconomic status and parity in the development of pre-eclampsia.

Participants expressed concerns about the lack of postpartum follow-up and support, particularly those with gestational diabetes mellitus (GDM). This lack of systematic follow-up often led to a relapse into unhealthy habits postpartum. Similar findings were reported by other studies, indicating a need for better continuity of care and support for lifestyle changes postpartum. Partner support was identified as a crucial factor in facilitating lifestyle changes.[10] Participants reported that lifestyle change would be easier if their partners and families recognized its importance. This emphasizes the need for involving partners in lifestyle interventions to ensure sustained changes. For women with severe pre-eclampsia, breastfeeding was reported to enhance their sense of mastery and attachment to their baby. Encouraging breastfeeding in this group can have positive impacts on their mental health and reduce future cardiovascular disease (CVD) risk.[11,12]

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Establishing systematic postpartum follow-up for women with GDM and pre-eclampsia to support and maintain healthy lifestyle changes. Developing lifestyle interventions that involve partners to encourage a supportive environment for lifestyle changes. Promotion of breastfeeding among women with severe pre-eclampsia to improve their mental health and attachment to their baby. Provision of practical advice and solutions for maintaining healthy habits during maternity, addressing challenges like poor sleep and a busy lifestyle.

Conclusion

The development of pre-eclampsia in women with DM and GDM is influenced by a combination of clinical risk factors, particularly socioeconomic status, and a history of related medical conditions. Our study highlights the significant role of socioeconomic status, parity, and family/personal history in the development of pre-eclampsia. The lack of postpartum follow-up and support for lifestyle changes remains a critical gap in care. Involving partners and providing practical, individualized interventions can help sustain lifestyle changes and improve long-term health outcomes for women with GDM and pre-eclampsia. Future studies should focus on identifying specific biochemical markers in early pregnancy to enhance prediction and prevention strategies. Enhanced postpartum follow-up and support for lifestyle changes are essential to improve outcomes for these high-risk women.

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