



Research Article

Association Between High-Sensitivity C-Reactive Protein and Gestational Diabetes Mellitus: A Case-Control Study

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Abstract: Background: Gestational diabetes mellitus (GDM) is associated with metabolic and inflammatory alterations during pregnancy. High-sensitivity C-reactive protein (hs-CRP), a marker of low-grade systemic inflammation, may be elevated in women with GDM. This study aimed to assess the association between serum hs-CRP levels and gestational diabetes mellitus among pregnant women.

Methods: A hospital-based case-control study was conducted in the Department of Obstetrics and Gynaecology, Rajah Muthiah Medical College and Hospital, Chidambaram, over one year from May 2021 to May 2022. A total of 64 pregnant women at 24–28 weeks of gestation were included, comprising 32 women with GDM and 32 controls with normal glucose tolerance. Sociodemographic, obstetric, anthropometric, and glycemic characteristics were recorded. Serum hs-CRP was estimated using a Sandwich Enzyme-linked immunosorbent assay. Data were analyzed using SPSS version 26. Independent-samples t-test and chi-square test were applied, with $p < .05$ considered statistically significant. **Results:** Women with GDM had significantly higher mean weight (67.88 ± 12.11 vs. 61.25 ± 12.72 kg, $p = .037$), body mass index (29.25 ± 4.88 vs. 25.88 ± 5.11 kg/m², $p = .009$), and glucose challenge test values (125.01 ± 25.61 vs. 92.48 ± 16.63 mg/dL, $p = .001$). Mean hs-CRP levels were also significantly higher in the GDM group than in controls (0.23 ± 0.11 vs. 0.11 ± 0.05 pg/mL, $p = .009$).

Conclusion: Pregnant women with GDM had significantly elevated hs-CRP levels compared with women with normal glucose tolerance, indicating an association between systemic inflammation and GDM. Larger prospective studies are warranted to determine the independent clinical utility of hs-CRP.

Keywords: Gestational Diabetes Mellitus, High-Sensitivity C-Reactive Protein, Inflammation, Pregnancy, Insulin Resistance

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INTRODUCTION

Gestational diabetes mellitus (GDM) is one of the most important metabolic disorder encountered during pregnancy and represents a major component of hyperglycemia in pregnancy [1]. It is characterized by glucose intolerance that is first recognized during pregnancy and may occur in women without previously diagnosed diabetes mellitus. Hyperglycemia during pregnancy is associated with considerable maternal and fetal morbidity and therefore remains an important public health and obstetric concern [2]. The increasing prevalence of GDM worldwide has further emphasized the need for timely identification of affected women and improved understanding of the biological mechanisms contributing to its development [3].

The burden of GDM varies considerably across geographical regions and populations. The prevalence is particularly high in regions with increasing rates of obesity, sedentary lifestyles, and metabolic disorders [4]. South and Southeast Asian populations are considered to have a substantial burden of gestational hyperglycemia, with Indian studies reporting considerable variation in prevalence across different settings [5]. Differences in maternal age, body mass index, ethnicity, lifestyle, socioeconomic characteristics, and diagnostic criteria may contribute to the observed variation. Given its increasing frequency and its implications for both maternal and offspring health, GDM has become an important area of clinical and epidemiological research [6].

Pregnancy is accompanied by several physiological and metabolic adaptations that are necessary to support fetal growth and development [7]. Progressive insulin resistance develops during pregnancy as a result of hormonal and metabolic changes, particularly during the second and third trimesters. In most women, pancreatic beta cells compensate for this increased insulin resistance by enhancing insulin secretion [8]. However, when this compensatory response is inadequate, maternal glucose concentrations increase and GDM may develop [9]. Several maternal factors,

including excess body weight, obesity, genetic susceptibility and metabolic abnormalities may influence this process and increase the likelihood of developing gestational hyperglycemia [10].

In addition to metabolic alterations, pregnancy is characterized by changes in oxidative and inflammatory pathways [11]. Oxidative stress plays a physiological role in implantation, placental development, fetal growth, and parturition; however, excessive oxidative stress may contribute to abnormal metabolic responses [12]. In women with GDM, an imbalance between the production of reactive oxygen species and antioxidant defense mechanisms may result in increased oxidative stress. This process may promote inflammatory responses and contribute to the development and progression of insulin resistance, thereby providing a possible biological link between inflammation and GDM [13].

C-reactive protein (CRP) is an acute-phase protein belonging to the pentraxin family and is primarily synthesized by the liver in response to pro-inflammatory cytokines. High-sensitivity C-reactive protein (hs-CRP) assays enable the detection of relatively low concentrations of circulating CRP and are therefore useful for assessing low-grade systemic inflammation [14]. Chronic low-grade inflammation has been associated with insulin resistance and disturbances in glucose metabolism. Consequently, elevated hs-CRP concentrations during pregnancy may reflect an enhanced inflammatory state associated with the metabolic abnormalities observed in GDM. Assessment of hs-CRP may therefore contribute to a better understanding of the inflammatory mechanisms associated with gestational hyperglycemia [15].

Although an inflammation is increasingly recognized as an important component of the pathophysiology of GDM, the relationship between circulating hs-CRP concentration and GDM requires further evaluation across different populations and clinical settings. Examining hs-CRP levels among pregnant women with and without GDM may provide additional evidence regarding the association between systemic inflammation and gestational glucose intolerance. Furthermore, data from individual institutional settings may contribute to the existing evidence regarding inflammatory alterations in GDM. Therefore, the present study was conducted to assess and compare serum high-sensitivity C-reactive protein levels among pregnant women with gestational diabetes mellitus and pregnant women with normal glucose tolerance.

Aims and Objectives

Aim: To assess the association between serum high-sensitivity C-reactive protein levels and gestational diabetes mellitus among pregnant women.

Objectives

- To compare the sociodemographic, obstetric, anthropometric, and glycemic characteristics of pregnant women with gestational diabetes mellitus and pregnant women with normal glucose tolerance
- To compare serum high-sensitivity C-reactive protein levels between pregnant women with gestational diabetes mellitus and those with normal glucose tolerance

MATERIALS AND METHODS

Study Design and Setting

A hospital-based case-control study was conducted in a tertiary care hospital in Cuddalore. The study was undertaken to compare serum high-sensitivity C-reactive protein (hs-CRP) levels between pregnant women with gestational diabetes mellitus (GDM) and pregnant women with normal glucose tolerance.

Study Population

The study population comprised pregnant women attending the Obstetrics and Gynaecology outpatient department or admitted to the obstetric wards of Rajah Muthiah Medical College and Hospital during the study period. Pregnant women diagnosed with GDM constituted the case group, while pregnant women with normal glucose tolerance constituted the control group. A total of 64 pregnant women were included, comprising 32 cases and 32 controls.

Study Duration

The study was conducted over a period of one year, from May 2021 to May 2022.

Inclusion and Exclusion Criteria

Pregnant women aged more than 20 years who were between 24 and 28 weeks of gestation and who provided informed consent were included in the study. Women with pre-existing type 1 diabetes mellitus, Pregnancy-induced hypertension, or overt diabetes mellitus were excluded from the study.

Sample Size and Sampling Technique

The sample size was estimated based on the findings of Yu *et al.* [7], who reported significantly higher hs-CRP levels among women with gestational diabetes mellitus compared with women with normal glucose tolerance during the second trimester.

The sample size for comparing two independent groups were calculated using the formula: $n = 2(Z_{\alpha/2} + Z_{\beta})^2 \sigma^2 / d^2$, where n represented the required sample size in each group, $Z_{\alpha/2} = 1.96$ for a 95% confidence level, $Z_{\beta} = 0.84$ for 80% power, σ represented the pooled standard deviation, and d represented the expected difference between the two group means. Based on the effect observed in the previous study and allowing for an adequate power to detect a clinically meaningful difference, the minimum sample size was estimated at approximately 32 participants in each group. Thus, a total of 64 participants, comprising 32 women with GDM and 32 controls, were included in the present study.

A total of 64 pregnant women were included in the study, with 32 pregnant women diagnosed with GDM included as cases and 32 pregnant women with normal glucose tolerance included as controls. For each identified case, a pregnant woman without comorbidity who subsequently attended the outpatient department and fulfilled the eligibility criteria was selected as a control. The source manuscript did not provide a formal sample-size calculation or the statistical assumptions used to determine the sample size.

Study Procedure

After obtaining informed consent, baseline information was recorded for all participants. Demographic and obstetric characteristics, including age, parity, and gestational age, were documented. Anthropometric measurements, including height and weight, were obtained using standard procedures, and body mass index was calculated. Blood pressure was measured using a sphygmomanometer.

Blood samples were collected under strict aseptic precautions in appropriate sodium fluoride, Heparin, Ethylenediaminetetraacetic acid (EDTA) vacutainers. EDTA samples were used for hematological investigations. Serum was separated by centrifugation at 3000 rpm for 15 minutes, and baseline biochemical investigations were performed on the same day using a semi-automated analyzer (ERBA CHEM-7). Heparinized blood was centrifuged at 3000 rpm for 15 minutes, and the separated plasma was stored at -80°C until analysis of the study parameters. A postprandial blood sample was also collected for plasma glucose estimation.

Serum hs-CRP was estimated using commercially available kits manufactured by Elabscience. The assay was based on the sandwich enzyme-linked immunosorbent assay (ELISA) principle. Samples or standards were added to micro-ELISA plate wells coated with antibodies specific to the analyte, followed by addition of the corresponding detection antibody and avidin-horseradish peroxidase conjugate. After incubation and washing to remove unbound components, substrate solution was added and the reaction was terminated using stop solution. The concentration of hs-CRP was determined from the optical density obtained during the assay.

Operational Definitions

- **Gestational Diabetes Mellitus:** Pregnant women who had been diagnosed with gestational diabetes mellitus during the study period were considered cases. The manuscript indicated that GDM was diagnosed according to American Diabetes Association criteria, however, the specific glucose thresholds and testing protocol used were not described in the source document
- **Control:** Pregnant women with normal glucose tolerance and without the specified comorbidities who fulfilled the eligibility criteria were considered controls
- **High-Sensitivity C-Reactive Protein:** hs-CRP referred to the circulating C-reactive protein concentration measured using a high-sensitivity sandwich ELISA assay. The mean hs-CRP concentration was subsequently compared between the GDM and control groups

Statistical Analysis

The collected data were entered into Microsoft Excel and a master chart was prepared. The data were subsequently imported into IBM SPSS Statistics version 26 for statistical analysis. Quantitative variables were summarized using mean and standard deviation, while qualitative variables were expressed as frequencies and percentages. The independent-samples t-test was used to compare mean values of continuous variables between the GDM and control groups, while the chi-square test was used to assess differences in categorical variables between the groups. A p value of less than .05 was considered statistically significant.

Ethical Consideration

Ethical clearance for the study was obtained from the Institutional Ethics Committee of Rajah Muthiah Medical College and Hospital before commencement of the study. Written informed consent was obtained from all participants prior to enrolment and collection of clinical and laboratory data.

RESULTS

Among the 64 study participants, 32 women with gestational diabetes mellitus (GDM) and 32 controls with normal glucose tolerance were included. In the GDM group, 40.6% of participants were aged 21–25 years and another 40.6%

Table 1: Comparison of Sociodemographic and Obstetric Characteristics between Women with Gestational Diabetes Mellitus and Controls (N = 64)

Characteristic	Category	GDM (n = 32), n (%)	Control (n = 32), n (%)	χ^2	p value
Age group (years)	≤20	2 (6.3)	3 (9.4)	0.652	0.884
	21–25	13 (40.6)	11 (34.4)		
	26–30	13 (40.6)	15 (46.9)		
	>30	4 (12.5)	3 (9.4)		
Parity	Primigravida	16 (50.0)	20 (62.5)	2.540	0.468
	G2P1L1	12 (37.5)	9 (28.1)		
	G3P2L2	4 (12.5)	2 (6.3)		
	G4P3L3	0 (0.0)	1 (3.1)		

No statistically significant differences were observed between the groups with respect to age distribution or parity

Table 2: Comparison of Anthropometric and Glycemic Characteristics between Women with Gestational Diabetes Mellitus and Controls

Variable	GDM (n = 32), Mean±SD	Control (n = 32), Mean±SD	t value	p value
Weight (kg)	67.88±12.11	61.25±12.72	2.13	0.037*
Height (cm)	152.38±7.32	153.69±5.47	0.81	0.420
Body mass index (kg/m ²)	29.25±4.88	25.88±5.11	2.69	0.009*
GCT (mg/dL)	125.01±25.61	92.48±16.63	13.01	0.001*

*-Statistically significant

Independent-samples t-test was used

Table 3: Comparison of High-Sensitivity C - Reactive Protein Levels between Women with Gestational Diabetes Mellitus and Controls

Variable	GDM (n = 32), Mean±SD	Control (n = 32), Mean±SD	t value	p value
hs-CRP (pg/mL)	0.23±0.11	0.11±0.05	5.61	0.009*

*-Statistically significant

hs-CRP = high-sensitivity C-reactive protein.Independent-samples t-test was used

were aged 26–30 years, while 12.5% were older than 30 years and 6.3% were aged 20 years or younger. In the control group, the largest proportion of participants belonged to the 26–30-year age group (46.9%), followed by 21–25 years (34.4%). With respect to parity, 50.0% of women in the GDM group and 62.5% of controls were primigravida, while 37.5% and 28.1%, respectively, were G2P1L1. There were no statistically significant differences between the GDM and control groups with respect to age distribution ($\chi^2 = 0.652$, $p = .884$) or parity ($\chi^2 = 2.540$, $p = .468$) (Table 1).

The mean weight of women in the GDM group was significantly higher than that of the control group (67.88±12.11 kg vs. 61.25±12.72 kg), with the difference reaching statistical significance ($t = 2.13$, $p = 0.037$). Similarly, the mean body mass index was significantly higher among women with GDM compared with controls (29.25±4.88 kg/m² vs. 25.88±5.11 kg/m²; $t = 2.69$, $p = 0.009$). The mean height was comparable between the two groups, with values of 152.38±7.32 cm in the GDM group and 153.69±5.47 cm in the control group, and the difference was not statistically significant ($t = 0.81$, $p = 0.420$). The mean glucose challenge test value was also significantly higher among women with GDM than among controls (125.01±25.61 mg/dL vs. 92.48±16.63 mg/dL; $t = 13.01$, $p = 0.001$) (Table 2).

The mean serum high-sensitivity C-reactive protein (hs-CRP) level was 0.23±0.11 pg/mL among women with GDM, compared with 0.11±0.05 pg/mL among women with normal glucose tolerance. The mean hs-CRP level was therefore significantly higher in the GDM group than in the control group, and the observed difference was statistically significant ($t = 5.61$, $p = 0.009$) (Table 3). This finding demonstrated a significant association between higher circulating hs-CRP levels and the presence of gestational diabetes mellitus in the study population.

DISCUSSION

The present case-control study demonstrated important differences in anthropometric and metabolic characteristics between pregnant women with gestational diabetes mellitus (GDM) and women with normal glucose tolerance. Women with GDM had a significantly higher mean weight than controls (67.88±12.11 kg vs. 61.25±12.72 kg, $p = .037$) and a significantly higher mean body mass index (BMI) (29.25±4.88 kg/m² vs. 25.88±5.11 kg/m², $p = .009$). These findings were consistent with previous evidence demonstrating an association between increased maternal adiposity and GDM. Torloni *et al.* reported a progressive increase in the risk of GDM with increasing prepregnancy BMI, while Chu *et al.* similarly demonstrated a substantially greater risk of GDM among overweight and obese women [9, 10]. Kim *et al.* estimated that a considerable proportion of GDM cases could be attributed to maternal overweight and obesity [11]. In the Indian setting, Chudasama *et al.* also observed a higher occurrence of GDM among obese pregnant women [4]. Collectively, these findings support the relationship between increased maternal body weight and impaired glucose regulation during pregnancy.

The significantly greater BMI observed among women with GDM in the present study may be explained by the metabolic effects of excess adipose tissue, including increased insulin resistance and altered inflammatory signaling.

The findings were comparable with those of Torloni *et al.*, whose systematic review demonstrated that the risk of GDM increased across overweight, obese, and severely obese BMI categories [9]. Chu *et al.* likewise reported a dose-dependent increase in GDM risk with increasing maternal BMI [10]. Kim *et al.* highlighted the population-level contribution of overweight and obesity to the occurrence of GDM [11], while Chudasama *et al.* identified obesity among the characteristics associated with a greater occurrence of GDM in pregnant women attending a tertiary-care centre [4]. Thus, the anthropometric findings of the present study are in agreement with a substantial body of evidence indicating that excess maternal adiposity is closely associated with gestational glucose intolerance.

With regard to glycemic status, the mean glucose challenge test value was significantly higher among women with GDM compared with controls (125.01 ± 25.61 mg/dL vs. 92.48 ± 16.63 mg/dL, $p = 0.001$). This finding was expected because the study groups were differentiated according to glucose tolerance status. Nevertheless, it confirms the presence of a clear metabolic difference between the two groups. The findings are compatible with the broader observations of Chudasama *et al.*, who demonstrated a substantial burden of gestational hyperglycemia among pregnant women undergoing glucose testing [4]. The reports by Torloni *et al.*, Chu *et al.* and Kim *et al.* further indicate that metabolic risk associated with increasing maternal adiposity contributes to the development of abnormal glucose tolerance during pregnancy [9–11]. The coexistence of significantly higher BMI and glucose values in the GDM group in the present study further emphasizes the close relationship between maternal adiposity, insulin resistance, and gestational hyperglycemia.

The principal finding of the present study was the significantly elevated serum high-sensitivity C-reactive protein (hs-CRP) level among women with GDM compared with women with normal glucose tolerance. The mean hs-CRP concentration was 0.23 ± 0.11 pg/mL in the GDM group and 0.11 ± 0.05 pg/mL in the control group ($p = 0.009$). This finding was in agreement with Yu *et al.*, who reported significantly increased hs-CRP concentrations during the second trimester among women with GDM [7]. Yousuf also demonstrated an association between elevated CRP during early pregnancy and subsequent development of GDM [12]. Alamolhoda *et al.* reported that increasing CRP concentrations during early pregnancy were associated with a higher risk of developing GDM [15]. Khamis *et al.* similarly evaluated hs-CRP in the context of early biomarkers of GDM and reported findings supporting an association between inflammatory biomarkers and gestational dysglycemia [14]. These observations collectively support the presence of an enhanced inflammatory state among women with GDM.

The higher hs-CRP concentrations identified in the present study are biologically plausible because chronic low-grade inflammation has been implicated in the development of insulin resistance. Yu *et al.* demonstrated that hs-CRP concentrations were increased among women with GDM and suggested a possible relationship between inflammatory activation and GDM pathogenesis [7]. Yousuf observed that women with elevated CRP early in pregnancy had a greater likelihood of subsequently developing GDM [12], while Alamolhoda *et al.* similarly identified increasing early-pregnancy CRP as a risk factor for GDM [15]. Evidence from Naser *et al.*, however, was not entirely consistent, as their prospective investigation found that first-trimester hs-CRP was not significantly correlated with subsequent development of GDM in their population [13]. This variation across studies may reflect differences in gestational age at biomarker measurement, characteristics of the study populations, diagnostic criteria, maternal adiposity, and assay methods. The current findings therefore strengthen the evidence for an association between inflammation and GDM while also demonstrating the need to interpret hs-CRP within the context of other metabolic risk factors.

Overall, the present study demonstrated that GDM was associated with significantly higher maternal body weight, BMI, glucose intolerance and serum hs-CRP concentrations. The finding of elevated hs-CRP was broadly consistent with the observations of Yu *et al.*, Yousuf, Khamis *et al.*, and Alamolhoda *et al.* [7, 12, 14, 15], although the contrasting findings reported by Naser *et al.* indicate that the relationship may not be uniform across populations [13]. Similarly, the higher maternal weight and BMI observed among the GDM group were supported by the findings of Chudasama *et al.*, Torloni *et al.*, Chu *et al.*, and Kim *et al.* [4,9–11]. Taken together, these findings suggest that GDM is accompanied by both metabolic and inflammatory alterations. However, because hs-CRP was assessed in women after classification according to GDM status in the present case-control study, the findings establish an association rather than a predictive relationship. Prospective studies in which hs-CRP is measured before the onset or diagnosis of GDM, with appropriate adjustment for BMI and other potential confounding factors, are required to determine its usefulness as an independent early biomarker of GDM.

Limitations

The study was conducted at a single centre with a relatively small sample size, which may limit the generalizability of the findings. In addition, the case-control design could establish only an association between hs-CRP, GDM and could not determine a temporal or predictive relationship; residual confounding, particularly from differences in BMI, may also have influenced hs-CRP levels.

CONCLUSION

The present study demonstrated that pregnant women with gestational diabetes mellitus had significantly higher mean weight, body mass index, glucose challenge test values, and serum high-sensitivity C-reactive protein levels compared with women with normal glucose tolerance. The significantly higher hs-CRP concentration among women with GDM suggests that systemic inflammation may be associated with the metabolic alterations occurring in gestational diabetes mellitus. However, the findings should be interpreted as evidence of association rather than prediction.

Further prospective, multicentre studies with larger sample sizes are recommended to evaluate hs-CRP levels before the onset or diagnosis of gestational diabetes mellitus and to determine its potential role as an early biomarker. Future studies should also adjust for important confounding factors such as maternal BMI, age, parity, and other metabolic risk factors and may incorporate multivariable and receiver operating characteristic analyses to assess the independent diagnostic or predictive utility of hs-CRP.

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