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Serum High-Sensitivity C-Reactive Protein Levels in Women with Polycystic Ovary Syndrome: A Case-Control Study

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ABSTRACT

Introduction: Polycystic Ovary Syndrome is a prevalent endocrine disorder marked by reproductive and metabolic disturbances, often accompanied by chronic low-grade inflammation. High-sensitivity C-reactive protein (hs-CRP) has gained attention as a potential marker reflecting this inflammatory burden and its metabolic consequences. This study aimed to assess the diagnostic value of hs-CRP and its association with clinical features in women with PCOS.

Method: A case-control study was done over one year at a tertiary care center, including 42 women diagnosed with PCOS based on Rotterdam criteria and 83 age-matched healthy controls. Demographic, anthropometric, clinical, and biochemical parameters were recorded. hs-CRP levels were estimated using standardized laboratory methods. Statistical analysis included independent t-tests, chi-square tests, and ROC curve analysis, with $p < 0.05$ considered significant.

Result: PCOS patients had significantly higher hs-CRP levels (3.9 ± 3.6 mg/L) than controls (1.0 ± 1.1 mg/L; $p < 0.001$). ROC analysis showed good diagnostic performance (AUC 0.827). A cutoff of 1.17 mg/L showed 85.7% sensitivity and 68.7% specificity. Dysmenorrhea showed a significant association with higher hs-CRP categories, while other symptoms showed non-significant trends toward elevated levels.

Conclusion: hs-CRP is a valuable marker for identifying inflammatory and metabolic risk in PCOS and may support early risk stratification.

Keywords: PCOS, hs-CRP, inflammation, metabolic risk, diagnostic marker, Rotterdam criteria

INTRODUCTION

Polycystic Ovary Syndrome is a common and heterogeneous endocrine disorder affecting women of reproductive age and is a leading cause of anovulatory infertility worldwide.[1]

C-reactive protein (CRP), an acute-phase reactant synthesized by the liver in response to pro-inflammatory cytokines like interleukin-6, can be accurately measured at low concentrations using high-sensitivity assays (hs-CRP), enabling detection of subclinical inflammation. [2]

The interplay between insulin resistance and adipose tissue dysfunction plays a pivotal role in the inflammatory milieu of PCOS.[3] Insulin resistance promotes hyperandrogenism and enhances secretion of inflammatory cytokines, including tumor necrosis factor-α and interleukin-6, particularly from visceral adipose tissue.[4] This inflammatory cascade stimulates hepatic synthesis of hs-CRP, linking metabolic dysfunction to systemic inflammation.[5] While multiple inflammatory markers and composite indices have been evaluated in PCOS, many are limited by assay variability, short half-life, and lack of standardization. In contrast, hs-CRP is a stable, reproducible, cost-effective biomarker with well-established clinical utility in cardiometabolic risk assessment, making it more suitable for routine clinical application.

Although elevated hs-CRP levels in PCOS have been reported previously, evidence regarding its diagnostic performance and its ability to differentiate metabolically high-risk PCOS phenotypes remains inconsistent, particularly across different populations. Furthermore, few studies have systematically examined hs-CRP in relation to anthropometric, biochemical, and metabolic parameters within a single cohort.[6–8] The present study addresses this gap by evaluating the diagnostic role of hs-CRP using receiver operating characteristic analysis and exploring its association with key clinical and metabolic variables in women with PCOS. This approach aims to clarify the clinical relevance of hs-CRP as a practical biomarker for early identification of inflammation-associated metabolic risk in PCOS.

MATERIALS AND METHODS

The present study was done as a case-control study in tertiary care center, Bareilly, over a duration of one year after getting ethics committee permission (IEC/IRB No: 55,2024 dated 12/01/2024). Women attending the outpatient department were screened based on their presenting complaints and clinical features. Women who reported menstrual irregularities, exhibited signs of clinical hyperandrogenism like hirsutism or acne, or had been previously diagnosed with polycystic ovarian syndrome according to the Rotterdam criteria were considered for enrolment, provided they were not undergoing any form of treatment at the time of recruitment. A Consecutive sampling technique was adopted for participant selection. The study population was divided into two groups: women diagnosed with PCOS constituted the case group, and age, waist circumference and BMI-matched non-PCOS women without menstrual abnormalities or hyperandrogenic features served as controls in a 1:2 ratio.

The sample size for the study was calculated using OpenEpi software based on previously reported mean and standard deviation values of high-sensitivity C-reactive protein (hs-CRP) among PCOS patients and healthy controls. A mean hs-CRP level of 3.86 ± 6.19 mg/L in the PCOS group and 1 ± 1.08 in the control group was considered for computation. [9] Using standard statistical parameters, including a 95% confidence interval and 80% power, the required sample size was calculated as 42 cases and 83 controls. Women aged 15 to 45 years who met the Rotterdam diagnostic criteria [10] for PCOS and provided written informed consent were included in the study. women with diabetes mellitus, prolactin or thyroid disorders, and those with any acute illness, as such conditions could independently influence inflammatory marker levels and not willing to participate were excluded.

The diagnostic confirmation of PCOS was based strictly on the Rotterdam criteria, which require the presence of at least two of the following three features: oligomenorrhea or amenorrhea; clinical or biochemical hyperandrogenism; and ultrasonographic evidence of polycystic ovarian morphology, defined as the presence of 12 or more follicles each measuring 2-9 mm in diameter or an ovarian volume exceeding 10 cc. After confirmation of eligibility, each participant underwent venous blood sampling. Peripheral blood samples were collected using sterile red-top (plain) vacutainers under aseptic precautions. The collected blood samples were processed in the institutional laboratory, where hs-CRP levels were estimated using validated and standardized procedures. The latex agglutination test and serial fold dilution techniques, used ensuring precision and reliability in the measurement of hs-CRP concentrations.

All hs-CRP measurements were recorded for both PCOS and non-PCOS groups. Additional demographic and clinical data were documented simultaneously to evaluate the association between hs-CRP levels and the severity of PCOS features. SPSS V.25 used and independent sample t-test, were applied to compare hs-CRP levels between the PCOS and control groups. A p-value of less than 0.05 was taken as statistically significant.

RESULTS

Table 1: Demographic and anthropometric profile of study participants

Variable	PCOS (n=42)	Control (n=83)	Total (n=125)	p-value
Age Group				
<20 years	7 (16.7%)	12 (14.5%)	19 (15.2%)	
21-30 years	11 (26.2%)	28 (33.7%)	39 (31.2%)	**0.809**
31-40 years	16 (38.1%)	31 (37.3%)	47 (37.6%)	
41-50 years	8 (19.0%)	12 (14.5%)	20 (16.0%)	
Mean Age (years)	30.8 ± 9.3	30.5 ± 8.6	30.6 ± 8.8	**0.862**
BMI (kg/m^2)	27.2 ± 6.7	21.9 ± 3.8	23.7 ± 5.6	**<0.001**
BMI Category				
Normal weight	15 (35.7%)	60 (72.3%)	75 (60.0%)	
Overweight	0 (0.0%)	7 (8.4%)	7 (5.6%)	**<0.001**
Obesity I	14 (33.3%)	4 (4.8%)	18 (14.4%)	
Obesity II	12 (28.6%)	5 (6.0%)	17 (13.6%)	
Underweight	1 (2.4%)	7 (8.4%)	8 (6.4%)	
Waist Circumference (cm)	90.8 ± 20.5	76.4 ± 12.2	81.3 ± 16.8	**<0.001**
WHR	0.91 ± 0.27	0.82 ± 0.09	0.85 ± 0.18	**0.006**

Table 1 shows the demographic and anthropometric characteristics of the study participants, including 42 women with PCOS and 83 healthy controls. The age distribution was comparable between the two groups (p = 0.809) or in mean age (30.8 ± 9.3 years in PCOS vs. 30.5 ± 8.6 years in controls; p = 0.862). The mean BMI was substantially higher among PCOS participants (27.2 ± 6.7 kg/m^2) compared to controls (21.9 ± 3.8 kg/m^2), showing a highly significant difference (p < 0.001). BMI categories also varied significantly between groups (p < 0.001). Waist circumference and waist-hip ratio (WHR) were also significantly elevated in women with PCOS (p < 0.001 and p = 0.006, respectively).

Table 2: Blood pressure and lipid profile characteristics

Parameter	PCOS (n=42)	Control (n=83)	Total (n=125)	p-value
Systolic BP (mmHg)	114.1 ± 14.6	118.5 ± 11.8	117.0 ± 12.9	0.077
Diastolic BP (mmHg)	91.3 ± 7.2	79.5 ± 7.8	83.4 ± 9.4	**<0.001**
HDL (mg/dL)	61.1 ± 21.0	62.3 ± 11.1	61.9 ± 15.1	0.693
LDL (mg/dL)	107.6 ± 31.8	95.9 ± 30.0	99.9 ± 31.0	**0.046**
Triglycerides (mg/dL)	185.1 ± 86.5	68.6 ± 25.5	107.7 ± 77.2	**<0.001**

Table 2 shows the blood pressure and lipid profile of the participants. Although systolic blood pressure did not differ significantly between groups (p = 0.077), diastolic pressure was markedly higher in PCOS patients (91.3 ± 7.2 mmHg) compared to controls (79.5 ± 7.8 mmHg), with a highly significant p-value (<0.001). Lipid parameters also showed metabolic disturbances in the PCOS group. While HDL levels were similar (p = 0.693),

the mean LDL level was significantly higher among PCOS participants (p = 0.046). PCOS group show three times higher triglyceride levels compared to control (p < 0.001).

Table 3: hs-CRP levels and diagnostic accuracy

Variable	PCOS (n=42)	Control (n=83)	Total (n=125)	p-value
hs-CRP (mg/L) Mean ± SD	3.9 ± 3.6	1.0 ± 1.1	2.0 ± 2.6	**<0.001**
hs-CRP Categories				**<0.001**
<1 mg/L	5 (11.9%)	51 (61.4%)	56 (44.8%)	
1-3 mg/L	19 (45.2%)	26 (31.3%)	45 (36.0%)	
≥3 mg/L	18 (42.9%)	6 (7.2%)	24 (19.2%)	
AUC (mg/L) (95% CI upper-lower)	827 (0.712 - 0.905)			**<0.001**
Cutoff 1.170 mg/L	Sensitivity 85.7%	Specificity 68.7%	Accuracy 74.4%	Youden Index 0.544

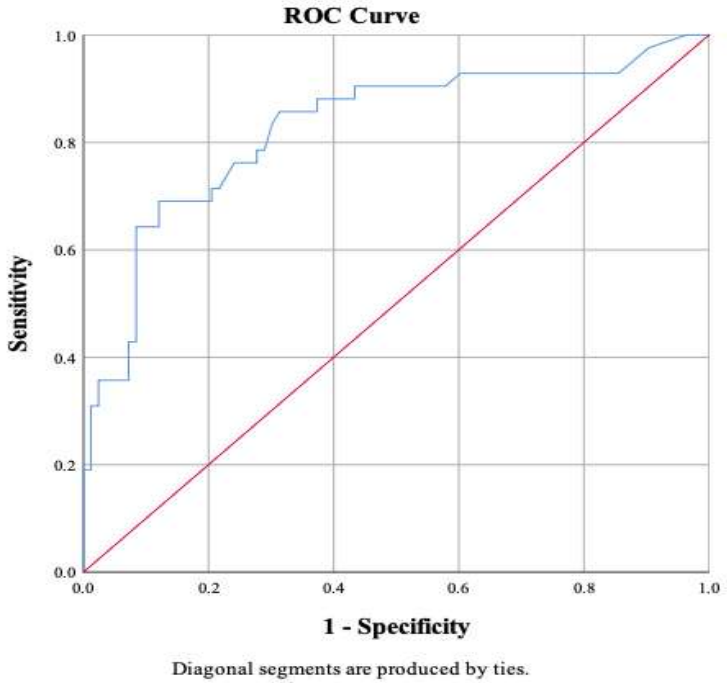

Figure 1: ROC for hs-CRP (mg/L) for prediction of PCOS

Table 3 shows hs-CRP levels and their diagnostic performance for predicting PCOS. The mean hs-CRP level was significantly elevated in women with PCOS (3.9 ± 3.6 mg/L) compared to controls (1.0 ± 1.1 mg/L), with p-value (<0.001). Categorization of hs-CRP levels also showed pronounced differences (p < 0.001), with 42.9% of PCOS patients having hs-CRP ≥3 mg/L, compared to only 7.2% of controls. The ROC analysis showed good diagnostic accuracy, with an AUC of 0.827 ± 0.042 (p < 0.001). An hs-CRP cutoff value of 1.170 mg/L yielded a sensitivity of 85.7%, specificity of 68.7%, overall diagnostic accuracy of 74.4%.

Table 4 shows the association between clinical features of PCOS and hs-CRP categories. Although menstrual irregularity, prolonged bleeding, hirsutism, acne, and hair thinning did not show statistically significant associations with hs-CRP categories (p > 0.05), dysmenorrhea showed a significant association (p = 0.041).

Table 5 further analyzes clinical features in relation to mean hs-CRP levels. Across all symptoms, women presenting with each clinical feature had higher mean hs-CRP levels as compared to those without the feature, although the differences did not reach statistical significance (p > 0.05). The highest mean hs-CRP level was observed among

participants reporting hair thinning (5.2 ± 5.3 mg/L), followed by those with prolonged bleeding and dysmenorrhea.

Table 4. Association Between Clinical Features and hs-CRP Levels

Clinical Feature (present)	<1 mg/L n (%)	1-3 mg/L n (%)	≥3 mg/L n (%)	p-value
Menstrual Irregularity	1 (20.0%)	5 (26.3%)	8 (44.4%)	0.402
Prolonged Bleeding	2 (40.0%)	3 (15.8%)	9 (50.0%)	0.083
Dysmenorrhea	3 (60.0%)	5 (26.3%)	12 (66.7%)	**0.041**
Hirsutism	2 (40.0%)	3 (15.8%)	6 (33.3%)	0.362
Acne	2 (40.0%)	3 (15.8%)	6 (33.3%)	0.362
Hair Thinning	1 (20.0%)	2 (10.5%)	3 (16.7%)	0.804

Table 5: Association of Clinical Features with Mean hs-CRP Levels in PCOS Patients

Clinical Feature	Present (Mean ± SD)	Absent (Mean ± SD)	p-value
Menstrual irregularity	4.7 ± 3.6	3.4 ± 3.6	0.264
Prolonged bleeding	5.0 ± 4.1	3.3 ± 3.3	0.164
Dysmenorrhea	4.9 ± 3.9	2.9 ± 3.1	0.068
Hirsutism	4.7 ± 3.6	3.6 ± 3.6	0.356
Acne	4.7 ± 4.0	3.5 ± 3.5	0.348
Hair thinning / hair loss	5.2 ± 5.3	3.6 ± 3.3	0.342

DISCUSSION

The present study showed that most women with PCOS belonged to the reproductive age group. The mean age of women in the PCOS had no significant difference (p = 0.862). Similarly, Bhatti M et al.[11] reported that 72.7% of PCOS women were younger than 30 years, with a mean age of 30.1 ± 5.78 years. Similarly, studies by Bokka SLA et al. [12] and Adıyeke SK et al. [13] also reported that PCOS predominantly affects younger reproductive-age women and that age alone does not distinguish PCOS patients from controls. We found significantly higher BMI and waist circumference among PCOS women compared with controls. Similarly, Bokka SLA et al.[12], Fakhoury H et al. [14], and Adıyeke SK et al. [13], found significantly greater central adiposity among PCOS women. Also, Mohapatra I et al. [15], showed nearly three-fourths of PCOS women were overweight or obese, and Essah PA et al. [16], reported a 30-75% prevalence of obesity in PCOS populations.

PCOS women in this study show significantly higher diastolic blood pressure compared with controls, although systolic pressure did not differ significantly. These results are similar to Mellembakken JR et al. [17], who documented higher diastolic BP and greater prevalence of hypertension in PCOS. Berbrier DE et al. [18] also showed enhanced systolic reactivity to stress in PCOS, despite similar baseline pressures.

Our study showed significantly higher triglycerides and LDL levels, along with slightly lower HDL levels in PCOS women. These findings are similar to the results from Bhumika P et al. [19] and a meta-analysis by Wild RA et al., which reported an adverse lipid profile among PCOS women independent of BMI. [20]

In this study, 42.9% of PCOS women had hs-CRP ≥ 3 mg/L compared with 7.2% of controls (p <0.001). Similarly, Lejman-Larysz K et al. [9], show hs-CRP cutoff of 1.44 mg/L with high sensitivity and specificity for predicting metabolic syndrome. Our findings at a cutoff of 1.170 mg/L similarly showed good diagnostic performance, showing that hs-CRP is a reliable marker of inflammation and metabolic risk in PCOS. Also, Kalyan S et al. [21] and D R et al. [22] shows that composite inflammatory markers, like the CRP/albumin ratio, provide even stronger diagnostic accuracy. Begum A et al. [23] also supported hs-CRP thresholds above 1.17 mg/L as clinically meaningful in identifying PCOS-related metabolic alterations.

Women with menstrual irregularity showed higher hs-CRP levels compared to those with regular cycles, though not statistically significant (p = 0.264), consistent with trends reported by Begum A et al. [23] and Ramanand S et al. [24]. Participants with prolonged

bleeding also had higher hs-CRP, similar to findings by Lejman-Larysz K et al. [9] and Ramanand S et al. [24].

The study has some limitations like small sample size may affect the robustness and generalizability of the findings. The single-center design further restricts external validity, and the lack of multivariable adjustment limits the ability to control for potential confounders. In addition, potential assay-related variability may have influenced hs-CRP measurements. Future studies should include larger, multicentric cohorts with longitudinal follow-up and apply multivariable analytical models to better elucidate causal relationships. Comparative evaluation of hs-CRP with other inflammatory biomarkers or composite indices may also help refine its role in risk stratification of women with PCOS.

Conclusion

The study shows that women with PCOS have higher hs-CRP levels, showing the presence of low-grade inflammation and an associated adverse metabolic profile, including higher body mass index, central obesity, diastolic blood pressure, low-density lipoprotein cholesterol, and triglycerides. hs-CRP should be regarded as a marker of inflammation and metabolic risk rather than a diagnostic test for PCOS, and its findings are limited to the studied population. Future studies with larger, multicentric, and longitudinal designs are needed to confirm these results and to further clarify the role of hs-CRP in metabolic risk assessment in PCOS.

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Availability of Data: The data supporting this study's findings are available upon reasonable request to corresponding author.

Declaration of Non-use of Generative AI: The authors affirm that no generative artificial intelligence tools were utilized in the design, analysis, interpretation of data, or preparation of this manuscript. All content is the result of the authors' original work.

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