Section: General Medicine

Original Research Article

# A CROSS-SECTIONAL STUDY TO ASSESS THE RELATION OF C-REACTIVE PROTEIN LEVELS WITH THE HBA1C AMONG TYPE 2 DIABETES AT A TERTIARY CARE HOSPITAL, GUNTUR

*Vardhini Kamineni[1], P Sudha Rani[2], Pavana Roy Patibandla[3], S Aruna Devi[4]*

[1]*Phase III Part I MBBS Student, GMC, Guntur, India.*
[2]*Assistant Professor, Department of Biochemistry, GMC, Guntur, India.*
[3]*Assistant Professor, Department of Physiology, GMC, Guntur, India.*
[4]*Assistant Professor, Department of Community Medicine, GMC, Guntur, India.*

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**Corresponding Author:**
**Dr. S Aruna Devi,**
Assistant Professor, Department of Community Medicine, GMC, Guntur, India.
Email: draruna0304@gmail.com

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ABSTRACT

**Background:** Long term uncontrolled diabetes is a major cause of damage in various organs and life-threatening complications such as cardiovascular disease, neuropathy, nephropathy, retinopathy, peripheral vascular disease, stroke, pulmonary embolism and renal failure. People with type 2 diabetes have an increased risk of cardiovascular disease, and serum levels of CRP are strong predictors of this risk, especially among women which lead to macrovascular and microvascular injuries. Hence understanding the role of CRP in inflammation process among diabetics with poor glycemic control is relevant to early identification and prevention of complications of diabetic people and enhance the quality of life in all aspects.

**Materials and Methods:** In this cross sectional study, 210 diabetic participants attending General Medicine OPD were recruited and after taking medical history, laboratory investigations like HbA1C and CRP were performed**.**

**Results:** In this study of 210 patients, there were 14 patients (6.67%) suffering with cerebrovascular disease (CVA), 59 patients (28.10%) had cardiovascular diseases (CVD), and 45 patients (21.43%) are related to renal diseases. There were 45 patients (21.43%) who had other complications, and 47 patients were not related to any complications referred as none.

**Conclusion:** Given the T-test value of 7.20466E-10 (which indicates a highly statistically significant result) and a correlation coefficient (r) of 0.42486 (indicating a moderate positive relationship), that there is a statistically significant moderate positive correlation between $HbA_1C$ and CRP levels among diabetics ($p < 0.05$).

**Keywords:** Type 2 Diabetes, Microvascular and Macrovascular complications, HbA1c, CRP.

## INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder and a major public health problem. According to International Diabetes Federation (IDF) 10th edition, an estimated 537 million adults were living with diabetes worldwide, between the ages of 20 to 79 (10.5% of all adults in this age range). By 2030, 643 million people will have diabetes globally, increasing to 783 million by 2045.[1] Long term uncontrolled diabetes is a major cause of damage in various organs and life-threatening complications such as cardiovascular disease, neuropathy, nephropathy, retinopathy, peripheral vascular disease, stroke, pulmonary embolism and renal failure.[2] Pre-diabetes and diabetes are significant risk factors for cardiovascular diseases.

Unfortunately, the mortality rate for cardiovascular disease in diabetic patients is alarmingly high at 70%, and the risk of such mortality is 24 times greater in diabetics compared to non- diabetics.[3]

The prevalence of diabetes was found to be 2.1% in the urban areas and 1.5% in the rural areas. More than two decades later, the National Urban Diabetes Study sampled individuals from six major metropolitan cities of India and reported prevalences ranging from 9.3% in Mumbai to 16.6% in Hyderabad.[2] A systematic and meta-analysis report review indicated that prevalence of inadequate glycemic control in patients with type 2 diabetes is high and ranged between 45.2% to 93%.[4]

CRP is a sensitive marker of systemic inflammation which has direct inflammatory effects at endothelial level when increased leads to augmented risk of thrombotic events.[6] CRP is most reliable marker of cardiovascular inflammation found to be associated with development of diabetes during early years of follow up in elderly people,[7] and thus CRP contribute to insulin resistance and atherosclerosis, triggered by inflammation.[3] Less is known about, whether CRP in people with diabetes is related to level of glycemic control, which is measured by the HbA1C levels in blood samples,[5] from patients. People with type 2 diabetes have an increased risk of cardiovascular disease, and serum levels of CRP are strong predictors of this risk, especially among women which lead to macrovascular and microvascular injuries.[8] CRP shows short-term fluctuations, and single determination of CRP can predict future clinical disease.[7] CRP is also an independent predictor of myocardial infarction and stroke.[9]

Despite these observations, there is limited data evaluating the relationship between CRP and glycemic control in the development of type 2 diabetes mellitus.[10] Hence understanding the role of CRP in inflammation process among diabetics with poor glycemic control is relevant to early identification and prevention of complications of diabetic people and enhance the quality of life in all aspects.

**Aims and Objectives**

- To estimate the prevalence of glycemic control of diabetes mellitus.
- To assess the relation between HbA1C and CRP.
- To understand the elevated CRP in relation with diabetic complications.

## MATERIALS AND METHODS

1. **STUDY DESIGN:** A prospective, observational cross-sectional study.
2. **STUDY PARTICIPANTS:** The patients of type 2 diabetes mellitus, attending the outpatient Department of General Medicine in a tertiary care hospital, Guntur, Andhra Pradesh.
3. **TYPE OF STUDY:** Cross sectional study
4. **STUDY SETTING:** The study was conducted in a tertiary care hospital, Guntur, Andhra Pradesh.
5. **STUDY PERIOD:** 2 months (September-October 2024)
6. **SAMPLING METHOD:** Simple random sampling, 210 diabetic patients who are attending General Medicine OP of Government General Hospital within the study period of 2 months.
7. **SAMPLE SIZE:** $n=\frac{Z^2 \times P \times Q}{d^2}$

Z=1.96, d=7% allowable error of p

P=79% (from study by Dipti Gautam et.al.,) [3]

Q=100-79 Q=21

$n=\frac{1.96 \times 1.96 \times 79 \times 21}{5.53 \times 5.53}$

$=\frac{6373.2}{30.58}$

n=208 (rounded off to 210)

8. **STUDY SCHEME:**

1. Ethical clearance from institutional ethical clearance committee.
2. Study participants will include in the study after taking informed consent.
3. Data collect by using a structured case study form and from laboratory.
4. Data entry.
5. Data analysis.
6. Summary and conclusion of study.

9. **ETHICAL CONSIDERATIONS:** Approval from the institutional Ethics Committee was taken prior to the start of study. Permission was obtained from the heads of the department and hospital. Informed consent was taken from the patients before conducting the study after briefly explaining the purpose of the study.
10. **CONFIDENTIALITY:** Privacy and strict confidentiality was maintained while collecting data from the people during study. Patients were not probed with questions and sufficient time was given for the subject to respond.
11. **SELECTION CRITERIA:**

**Inclusion Criteria**

- Patients clinically diagnosed and confirmed with type 2 diabetes having HbA1C level >6.5%, by a general physician at tertiary care hospital aged 18 years or older.
- Patients who were willing to participate and give consent.

**Exclusion Criteria**

- Gestational diabetic patients and lactational mothers.
- Patients who used anti-inflammatory drugs or cholesterol-lowering drugs with in the previous 30 days.
- People who are physically and mentally disabled.
- Patients who did not give consent.

12. **PROCEDURE:**

i. Recruitment and consent.
ii. Sample collection.
iii. Laboratory Analysis of HbA1C and CRP.
iv. Instruments used in laboratory:

- Afinion™ 2 Analyzer for HbA1C.
- Rx Daytona+ Analyzer for CRP.

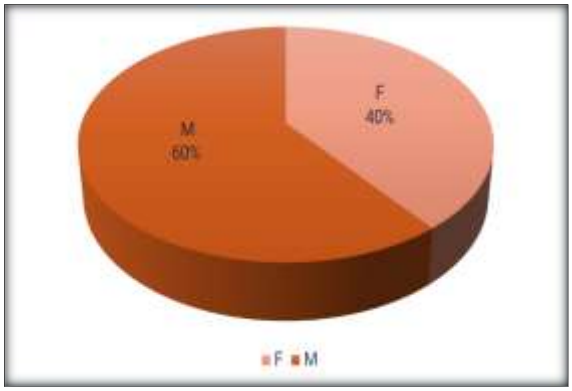
v. Quality control.

13. **DATA COLLECTION:** Detailed clinical history including socio- demographic details like age, gender etc, medical history like type and duration of diabetes and laboratory investigations HbA1C, CRP etc, and treatment history was collected from the patients suffering from diabetes.
14. **DATA ANALYSIS:** The data so collected was entered into the MS Excel Spreadsheet and it was analyzed using SPSS version 28(Statistical Package for Social Sciences). Results were represented in the form of tables and figures. Statistical tests were done to know the significance of the results wherever applicable.

## RESULTS

The total number of patients in the study was 210, with a mean age of 49.13 ± 11.32 years. Patients are segregated based on age into 5 groups where there were 21 females (25.30%)and 28 males (22.05%) in the first group with age <40 years,21 females (25.30%) and 34 males (26.67%) in the second group with age 40-49,29 females (34.94%) and 45 males (35.43%) in the third group with age 50-59,8 females (9.64%) and 16 males (12.60%) in the fourth group with age 60-69 and 4 females (4.82%) and 4 males (3.15%) in the fifth group with age ≥70.

In total, there were 83 females (39.52%), and 127 males (60.48%) involved in the study which showed higher prevalence in males than that of females. But there was no significance between different age groups in this study (p>0.05). [Table 1]




**Pie chart 1: Distribution of patients according to gender.**

According to American Diabetes Association (ADA), level of HbA1C <5.7% is normal, 5.7% to 6.4% is a pre-diabetic condition and >6.5% is considered as diabetes.[9] In our study, 8 subjects were normal ,58 were pre-diabetic and 144 were diabetic. [Pie Chart 1]

In this study of 210 patients, distribution of HbA1C across different age groups was shown. Among patients with age <40, 6(2.80%) are categorised as normal, 19 (9.04%) as pre- diabetic, and 24 (11.42%) as diabetic. In the 40-49 age group, no patients were classified as normal, while 15 (7.14%) were pre-diabetic, and 40 (19.04%) were diabetic. For those aged 50-59, 2 patients (0.95%) were normal, 15 (9.04%) were pre-diabetic, and 57 (27.14%) were diabetic. The 60-69 age group had no individuals classified as normal, while 7 (3.33%) were pre-diabetic and 17 (8.09%) were diabetic. Finally, for individuals ≥70, none were normal, 2 (0.95%) were pre-diabetic, and 6 (2.85%) were diabetic. The data demonstrates a clear trend of increasing prevalence of diabetes with age, peaking in the 50-59 age group. [Table 2]

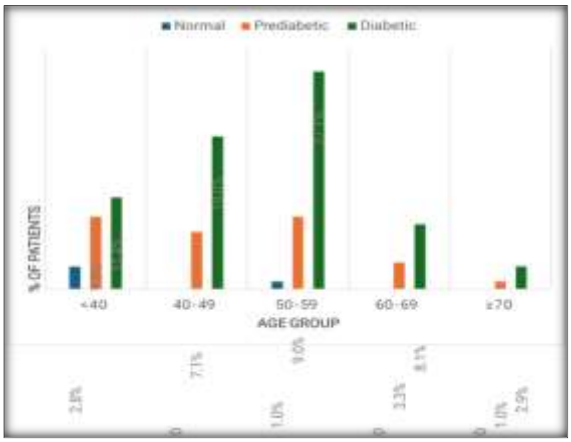



**Chart 1: Segregation of patients based on HbA1C levels according to age group.**

According to National Institute Health (NIH), level of CRP <3mg/L is normal, 3 to 10mg/L is considered as moderate elevation and >10mg/L is considered as marked elevation. In our study 34 patients (16.19%) had normal levels of serum CRP, 87 (41.42%) patients had moderately elevated CRP, 89 patients (42.38%) showed marked elevation. [Chart 1]

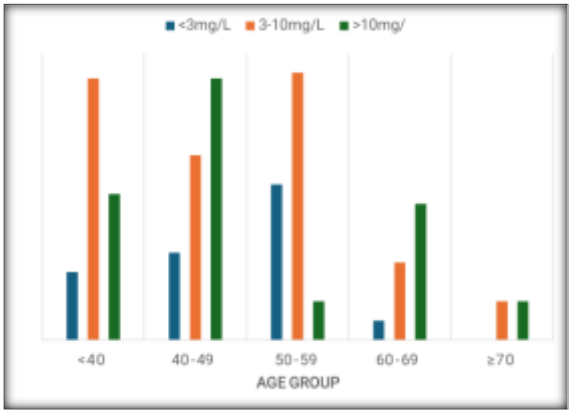



**Chart 2: Segregation of patients based on CRP levels according to age group**

According to World Health Organisation (WHO), defines the Body Mass Index (BMI) into distinct categories. Patients having BMI <18.5 are considered as underweight whereas the BMI that lies in the range of 18.0 -24.9 are considered as normal weight. Patients lying in the range of 25.0-29.9 comes under overweight category and patients having BMI greater

than >30.0 are obese. In the study of 210 patients, there were 12 patients (5.70%) with BMI <18.5, 78 patients (37.14%) with in the BMI range of 18.0-24.9, 90 patients in the BMI range of 25.0-29.9 and 30 patients with BMI > 30.0. [Chart 2]

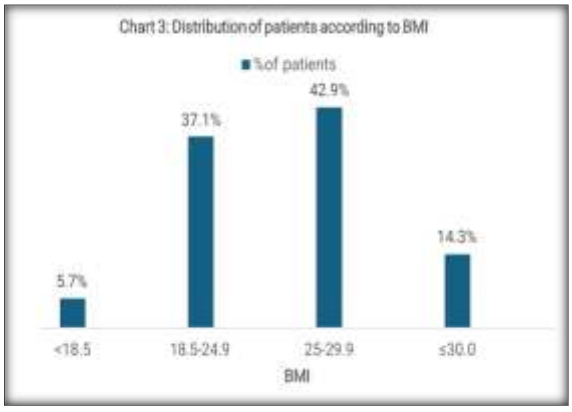



**Chart 3: Distribution patients according to BMI**

In this study of 210 patients,133 patients (63.33%) were related to smoking at present or in past and 77 patients (36.67%) were never smokers. Likewise, 117 patients (55.70%) had a habit of alcohol consumption, and 93 patients (44.29%) were not related to alcohol consumption. [Chart 3]

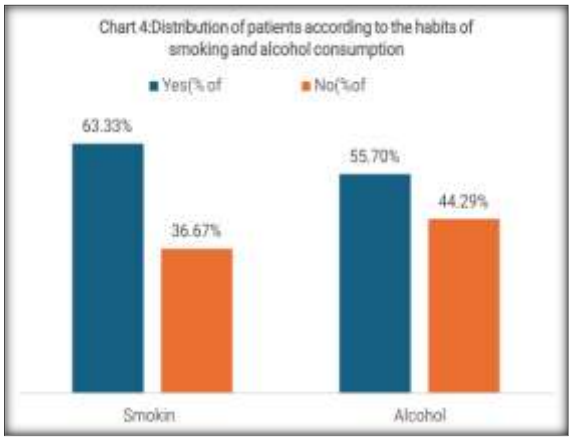
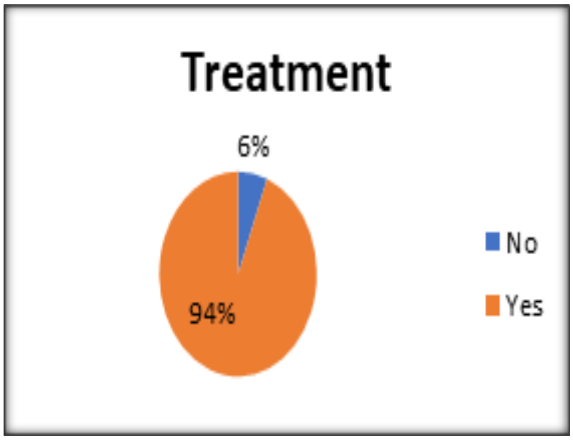



**Chart 4: Distribution of patients according to the habits of smoking and alcohol consumption**

In this study of 210 patients,13 (6.19%) were not taking treatment and the rest of the patients, that is 197 (93.81%) were under treatment.




In the study, according to the duration of onset of diabetes, patients were divided into four categories. In first category, there were 97 patients (46.19%) with ≤5 years of duration of onset. In the second category, there were 75 patients (35.71%) within the range of 5-10 years of duration of onset. In the third category, there were 38 patients (18.09%) within the range of 10-15 years of duration of onset.

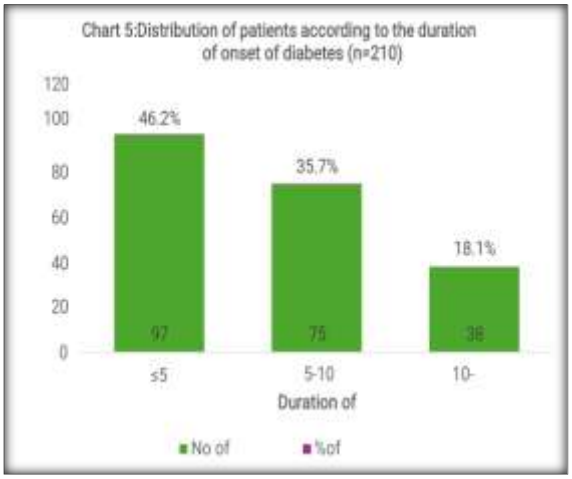



**Chart 5: Distribution of patients according to the duration of onset of diabetes (n=210)**

Some of the major complications of diabetes that were considered in this study were related to cardiovascular disease, cerebrovascular disease and renal diseases. In this study of 210 patients, there were 14 patients (6.67%) suffering with cerebrovascular disease (CVA), 59 patients (28.10%) had cardiovascular diseases (CVD), and 45 patients (21.43%) are related to renal diseases. There were 45 patients (21.43%) who had other complications, and 47 patients were not related to any complications referred as none. [Chart 5]

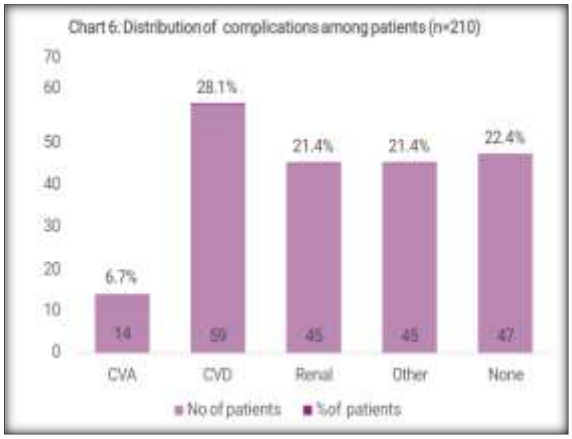



**Chart 6: Distribution of complications among patients (n+210)**

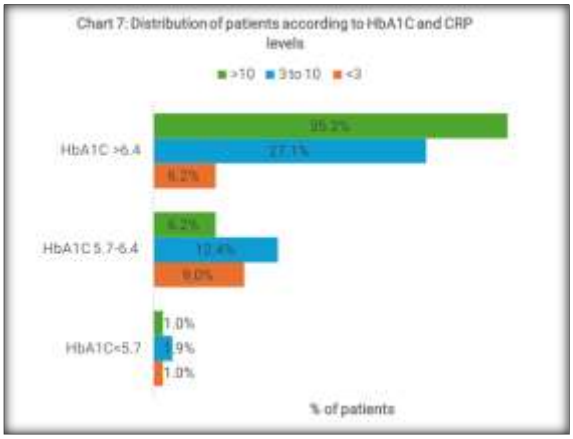



**Chart 7: Distribution of patients according to HbA1c and CRP levels**

Statistical analysis was done using Pearson's correlation test. Given the T-test value of 7.20466E-10 (which indicates a highly statistically significant result) and a correlation coefficient (r) of 0.42486 (indicating a moderate positive relationship), that there is a statistically significant moderate positive correlation between HbA1C and CRP levels among diabetics ($p < 0.05$). [Chart 7]

**Table 1: Age distribution in males and females**

| Age Group | No of Females (f=83) | % of females | No of Males (m=127) | % of males |
|---|---|---|---|---|
| < 40 | 21 | 25.30% | 28 | 22.05% |
| 40-49 | 21 | 25.30% | 34 | 26.77% |
| 50-59 | 29 | 34.94% | 45 | 35.43% |
| 60-69 | 8 | 9.64% | 16 | 12.60% |
| ≥70 | 4 | 4.82% | 4 | 3.15% |

**Table 2: Distribution of patients according to HbA1C**

| HbA1C range | No of patients (n=210) | %of patients |
|---|---|---|
| **< 5.7%(Normal)** | **8** | **3.81%** |
| **5.7 - 6.4%(Pre-diabetic)** | **58** | **27.62%** |
| **> 6.4%(Diabetic)** | **144** | **68.57%** |

**Table 3: Distribution of patients according to CRP levels**

| CRP Range | No of patients (n=210) | %of patients |
|---|---|---|
| **<3mg/L** (Normal) | 34 | 16.19% |
| **3 to 10mg/L** (Moderate elevation) | 87 | 41.42% |
| **>10mg/L** (Marked elevation) | 89 | 42.38% |

**Table 4: Mean values of HbA1C and CRP of patients according to habit of smoking**

| Smoking | Mean HbA1C±SD | Mean CRP±SD |
|---|---|---|
| **Yes** | **8.05±1.91** | **15.26±14.92** |
| **No** | **6.98±1.69** | **12.38±1.82** |

**Table 5: Mean values of HbA1C and CRP of patients according to habit of alcohol consumption**

| Alcohol | Mean HbA1C±SD | Mean CRP±SD |
|---|---|---|
| **Yes** | **8.25±1.92** | **16.86±15.21** |
| **No** | **6.90±1.57** | **10.86±13.91** |

**Table 6: Mean HbA1C and mean CRP values according to duration of onset of diabetes**

| Duration of onset (Years) | Mean HbA1C | Mean CRP |
|---|---|---|
| **≤5** | **7.20** | **12.56** |
| **5-10** | **7.79** | **14.73** |
| **10-15.** | **8.23** | **16.14** |

## DISCUSSION

Diabetes mellitus describes a metabolic disorder of multiple etiology, characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both.[11] It is becoming widely accepted that the pathophysiology of DM involves a chronic inflammatory response that may be present even before the disease is diagnosed, and that the vascular strain associated with this response results blood vessel dysfunction and damage. In this sense, diabetes is closely tied to vascular insult, a key component of the triad of thromboembolic risk factors.

Cardiovascular disease is the leading cause of both morbidity and mortality among patients with diabetes. The most common cardiovascular complications experienced by diabetic patients include atherosclerosis, myocardial infarction, and stroke.[12] C- reactive protein (CRP), a marker of systemic inflammation is emerging as independent risk factor for cardiovascular diseases.[13] It is helpful to identify patients at higher risk for vascular complications. This study was conducted to determine the relationship between HbA1C and RP in diabetic patients.

In this study it was observed that most (63.33%) of the patients were aged 40-60 years. The mean age was found (49.13±11.3) years with a range from 18-78 years. In a similar report, Hanan Elimam et al,[14] found the mean age of diabetic patients was (50.83 ± 8.26) years. The majority of the patients are male (60.48%) in the present study which is in concordance with Haamid Bashir et al,[8] Birendra Kumar et al,[15] and Ravish Gupta et al.[16] But it is in discordance to Hanan Elimam et al,[14] and Dipti Gautam et al.[3] The present study suggests that the association between CRP and diabetes risk was stronger in men than in women.

In this study of 210 patients,127 patients were male, and 83 patients were female with the mean values of (7.67± 1.75) and (7.65±2.12). The mean CRP values in males and females were (14.03±15.28) and (14.31±14.42). There was no significance between male and female patients ($p>0.05$). In this study of 210 patients, HbA1C and CRP were correlated with age. Patients having <40 years were 49 with mean HbA1C and CRP of 7.29 and 11.55 respectively. Patients between 40-50 years were 8 with mean HbA1C and CRP of 7.81 and 13.99 respectively. Patients between 50-59 years were 55 with mean HbA1C and CRP of 7.67 and 14.18 respectively. Patients between 60-69 years were 74 with mean HbA1C and CRP of 7.96 and 16.73. Patients having ≥70 years were 24 with mean HbA1C and CRP of 7.83 and 24.47. There was no significance between different age groups in this study ($p>0.05$) which is supported by the study performed by Birendra Kumar et al,[15] and Ravish Gupta et al.[16]

In the present study, for each level of HbA1C, the mean CRP was as follows: (<6, 7.77); (6- 8, 12.84); (8-10, 17.7); (>10 ;24.47). Overall, 83.79% of patients had elevated CRP which shows a relation between HbA1C and CRP. King and others showed in unadjusted analyzes that higher HbA1C is significantly associated with higher CRP levels.[14,15] In the present study (n=210), a positive correlation is found between serum CRP and HbA1C which support studies of Gautam D et al,[3] King et al,[14] and other studies.[15,16] This can be explained by the fact that HbA1C reflects the biological activities of hyperglycaemia and advanced glycation end products, all of which can trigger inflammation.[3]

In this study of 210 patients, patients with BMI <18.5 was 12 with mean CRP 8.55, BMI between 18.5-24.9 were 78 with mean CRP 5.96, BMI between 25-29.9 were 90 with mean CRP 14.9 and BMI >30 was 30 patients with mean CRP 37.4. There is no significance between BMI and CRP in this study, which supports other studies.[15,16] Eytan Cohen et al,[17] showed inflammatory markers are significantly higher in subjects with abnormal BMI compared to normal BMI, a prominent elevation is seen with CRP when compared to other inflammatory markers. The findings regarding BMI in this study, contrary to others, suggest CRP was not significantly associated with BMI, and inflammation as a potential mechanism in type 2 diabetes mellitus may be independent of obesity.

In the present study, CRP was higher in smokers (15.26±14.92) compared non-smokers (12.38±14.82), with smokers having HbA1C of (8.05±1.91) which is higher relative to non- smokers with (6.98±1.69) which supports the study of Hmood et al.[18] Also, CRP was higher in patients who consume alcohol (16.86±15.21) compared to non-alcoholic patients (10.86±13.91), with alcoholic patients having HbA1C of (8.25±1.92) which is higher than non-alcoholic patients (6.90±1.57).

The recent research evidence supports a link between hyperglycaemia and inflammation, which reveals that CRP can be used as an additional marker of better glycemic control. From this study, we cannot conclude, whether poor glycemic control leads to inflammation or whether inflammation leads to elevated glucose levels. This should be investigated in the further studies to acquire clarity. However, both direction of causality would have important implications. If poor glycemic control leads to inflammation, then better glycemic control should lower inflammation and therefore lower the risk of cardiovascular complications.[19]

Which can be achieved by monitoring blood sugar levels with HbA1C along with early detection of elevated CRP levels in type 2 diabetic patients. This could be essential for the prevention of major complications and consequences of diabetes mellitus.

The limitations for this study were as follows. The CRP measure used is a different and older technique than highly sensitive CRP assay developed more recently. Several previous studies have reported that

exercise affects HbA1C levels which were not considered in this research. As CRP is an inflammatory marker, alteration in its value can occur in several other inflammatory conditions. Hence, prospective studies should account for all these confounding factors.

## CONCLUSION

Given the T-test value of 7.20466E-10 (which indicates a highly statistically significant result) and a correlation coefficient (r) of 0.42486 (indicating a moderate positive relationship), that there is a statistically significant moderate positive correlation between HbA1C and CRP levels among diabetics ($p < 0.05$). Hence, understanding the role of inflammation in the development of diabetes may be relevant to future classification and treatment of diabetes by intervening early in the course of disease.

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**Conflict of Interest:** None

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