**International Journal of Medical and Health Research**
**www.medicalsciencejournal.com**
**ISSN: 2454-9142**
**Received: 13-03-2022, Accepted: 27-03-2022, Published: 14-04-2022**
**Volume 8, Issue 4, 2022, Page No. 5-7**

# Assessment of association and correlation between pulse pressure and framingham risk score in type 2 diabetes patients at a Tertiary Care Center in Kishanganj, Bihar- a cross sectional study

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## Abstract

**Purpose of the Study:** Pulse pressure (PP) calculated as the difference between systolic blood pressure and diastolic blood pressure has been considered as a preferable predictor of coronary heart disease (CHD) risk than systolic blood pressure (SBP) or diastolic blood pressure (DBP) in older adults. The Framingham Risk Score is a gender-specific algorithm used to estimate the 10-year cardiovascular risk of an individual. Individuals with type 2 diabetes are at greatly increased risk for cardiovascular disease. Although PP is important in predicting mortality among individuals with impaired glucose tolerance, hardly few researches have focused on the predictive value of PP in persons with diabetes mellitus.

**Methods:** An Observational Cross sectional study conducted over a period of 1.5 years at Outpatient department of a tertiary care center located in East Bihar. Type 2 Diabetes Patients were distributed into three groups based on the HbA1C level. (Controlled HbA1c= ≤ 7, Moderately Controlled with HbA1C 7-8, Uncontrolled with HbA1c level ≥8). Sample size of 894 having 298 samples in each group were distributed post sample size calculation using inferential data from a similar study at 95% confidence limit with power of the study at 80% Informed Consent were taken before the Study from each Sample. Ethical Clearance was obtained prior to the study. Pulse pressure and Framingham risk score were calculated and co-related for each group. Data was analysed using SPSS (Statistical Package for the Social Sciences) version 16. All the quantitative parameters such as SBP, DBP, Fasting Blood Sugar (FBS), pulse pressure, Triglycerides, HbA1c and Framingham Risk score were expressed as mean with Standard deviations for all three groups and subjects.

**Results:** Statistically significant association was found using ANOVA and Post-hoc analysis between three different groups and the Pulse pressure (p=0.001, F= 7.7). Although no association was established for Diastolic BP, other parameters SBP, Triglyceride, FBS and FRS showed statistically significant difference amongst the group. Upon Correlation Analysis a positive correlation was obtained between Pulse Pressure and Framingham Risk score in Group II (r =0.136, p =0.019) and Group III (r =0.47, p =< 0.001) of the study.

**Conclusions:** Pulse pressure can be used as an important marker to predict risk for coronary heart disease in type 2 diabetics with uncontrolled HbA1c levels.

**Keywords:** systolic blood pressure, type 2 diabetes, pulse pressure, framingham study, fasting blood sugar

## Introduction

Diabetes has been considered as a well-known global health challenges of this century. Massive increase in the number of cases having type 1 and type 2 diabetes has been a cause of a concern leading to severe economic drain to the patients and to the society at large. Comparing the types, Type 2 diabetes is the most common and prevalent underwrites pointedly to the snowballing trend. According to the International Diabetes Federation, globally there are 415 million people with diabetes in 2015 and is foretold to increase to 642 million by 2040 [1].

Although Individuals with type 2 diabetes are swelling in every single nation, however more than 80% animate to the low and middle –income countries such as India, Bangladesh, Bhutan, Pakistan, Sri Lanka, Philippines and Indonesia. Amongst the top 10 nations in the world, India stances second with 69.2 million individuals with diabetes and additional 36.5 million with prediabetes which has been considered as the high-risk form for diabetes and cardio-vascular disease [1] this growing incidence has been primarily ascribed to the lifestyle changes.

A recently stated Indian Council of Medical Research – India Diabetes (ICMR-INDIAB) study steered in four diverse zones of rural and urban India exhibited prevalence of diabetes and prediabetes being on a higher side

compared to previous studies. This documents an inter-state variations in prevalence, ranging from 4.3% in Bihar, 10.4% in Tamil Nadu and 13.6% in Chandigarh [2].

Long – term diabetes roots an increased risk of complications and disability thereby distressing the heart, eyes kidneys and nerves. Cardiovascular ailments in particular is one of the foremost causes of demises amid individuals with diabetes [3].

The Framingham risk score (FRS) is a shortened and the most common tool for the assessment of risk level of Coronary Artery Diseases (CAD) over 10 years. The FRS contemplates six coronary risk factors, including age, gender, total cholesterol (TC), high density lipoprotein cholesterol (HDL), smoking habits, and systolic blood pressure. FRS is the most pertinent method for forecasting the individual's chance of having cardiovascular disease (CVD) in longer run. Because this risk score gives an indication of the likely paybacks of prevention, it can be valuable for both the patients and clinicians to decide on how to look forward to lifestyle alterations and preventive medical treatment [4].

The standing of arterial blood pressure (BP) as a determinant of cardiovascular risk, and the benefits of treatment have been well established in a large number of randomized controlled trials. Lately, the pre-eminence of diastolic blood pressure (DBP) in forecasting coronary heart disease (CHD) risk has been confronted and emphasis on systolic (SBP) and pulse (PP) pressure, especially in older individuals has been given. Indeed, the latest data from Framingham Heart Study demonstrate that PP is the sturdiest predictor of CHD risk in the individuals over 50 years of age [5].

Pulse pressure is related micro- and macrovascular complications of type 2 diabetes [6]. Although PP is important in predicting mortality among individuals with impaired glucose tolerance, the data remains scarce investigating the predictive value of PP in persons with diabetes mellitus especially in Indian scenario. The current Cross Sectional study aims to strengthen the hypothesis that pulse pressure would be a better predictor of cardiovascular events in type 2 diabetes as the condition affects the older subjects and has been associated with premature arterial stiffening.

## Methodology

**Study Design and Study Setting:** A Cross Sectional Observational study was conducted over a period of One and a Half Years from January 2020 to July 2021 at the Out Patient Department (General Medicine) of Kishanganj Medical College a Tertiary Care Centre located in East Bihar.

Ethical Clearance was obtained by the ethical committee, Kishanganj Medical College and Hospital.

All the participants included in the study were explained about the procedure and informed Consent were obtained prior to Data Collection and clinical examination.

### Participants and Sample Size Calculation

A pilot study with 20 samples meeting the Exclusion and Inclusion Criteria was undertaken prior to the study to calculate the sample Size as well as to calibrate the Researcher. Based on the Pilot study and inferential data from a similar study[7] using OpenEpi, Version 3, at 95% confidence limit with power of the study at 80% with the mean Risk stratification of 2.6, 4.5 and 7.7 of the three groups[7] a Sample Size of 894 was Obtained.

Type 2 Diabetes Patients were distributed into three groups based on the HbA1C level. (Controlled HbA1c= $\leq$ 7, Moderately Controlled with HbA1C 7-8, Uncontrolled with HbA1c level $\geq$8) [8]. Having 298 samples in each group.

### Inclusion Criteria

Diabetic patients having no previous history of cardiovascular diseases were included in the study.

### Exclusion Criteria

Pathological cause of increase in pulse pressure that could interfere with study leading to Bias were excluded such as Thyrotoxicosis, increased intracranial hypertension, anaemia, beriberi, or established cardiovascular disease or other ailments interfering with pulse pressure measurement. Patient with Age lesser than 50 years were excluded from the study.

### Measuring Parameters

Pulse pressure was measured manually using a sphygmomanometer. Blood pressure recordings were done according to the norms prescribe by ACC 2017 Guidelines as published in JACC.[8]

Waist and hip circumference were calculated using a measuring tape. Fasting blood sugar, Cholesterol and triglycerides were analysed by NABH accredited laboratory part of Kishanganj Medical College and hospital. Framingham Risk Score was calculated using Framingham Cardiovascular Risk Calculator (Sergio Grzon Hernandez), an application software available on Google Play Store.

Quantitative parameters such as SBP, DBP, FBS, HbA1C, pulse pressure, Triglycerides and Framingham Risk score were obtained for Statistical Analysis.

### Statistical Analysis

Analysis of the data collected was done using SPSS (Statistical Package for the Social Sciences) version 16 and the results were compared. All the quantitative parameters such as SBP, DBP, FBS, HbA1C, pulse pressure,

Triglycerides and Framingham Risk score were expressed as mean with Standard deviations for all three groups and subjects. The difference in mean values amongst the three groups in control subjects (Group I T2DM Controlled), (Group II T2DM Moderately Controlled) and, (Group III T2DM Uncontrolled) were tested for statistical significance by employing analysis of variance. Further Bonferroni test and significance was employed for post hoc statistical significance. Further to evaluate the relationship of pulse pressure with SBP, DBP, FBS and FRS Pearson correlation coefficient was computed along with the significance levels.

**Results**

Clinical parameters such as Fasting Blood Sugar (FBS), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Pulse Pressure (PP), HbA1C, Triglycerides (TG) and Risk Stratification (FRS) for the various groups namely Group 1 (Controlled blood sugar subjects) Group 2 (Moderately controlled subjects) and Group 3 (Uncontrolled blood sugars) were examined and tested for statistical Analysis using ANOVA. (TABLE 1).

Between the groups analysis suggested statistical significance Difference amongst the groups for the parameters FBS, SBP, PP, HbA1c, TG and FRS (p value $\leq 0.05$). Aforementioned parameters showed a trend of increasing mean value with lowest being Group 1 and highest for Group 3.

Bonferroni Post Hoc Analysis revealed statistical significant difference in Mean Pulse Pressure between Group 1 and Group 3 as well as Group 2 and Group 3 with mean Difference of -2.37819,

-2.47819 and p value of 0.02 and 0.01 respectively. Whereas within the group Analysis of FRS showed statistical significant difference among all the groups (p value less than 0.05) with a marked mean difference of -4.238 between Group 1 and Group 3. (TABLE 2)

The Pearson's correlation between Pulse pressure value and Framingham Risk Score was found to be positive amongst Group 2 and Group 3 with p value of 0.019 and 0.00 respectively.

To out the strength of association between HbA1c and FRS amongst uncontrolled Diabetics, the Pearson's correlation test suggested a strong positive correlation with a p value of 0.00. (TABLE 4)

A mild corelation was found between Group 3 Pulse Pressure and HbA1C with a p value of 0.00. (TABLE 5)

**Table 1**

| Parametres | Groups | N | Mean | Std. Deviation | F | ANOVA pValue |
|---|---|---|---|---|---|---|
| FBS | GROUP 1 | 298 | 91.745 | 4.61982 | 237.7 | .000 |
| | GROUP 2 | 298 | 124.75 | 4.61982 | | |
| | GROUP 3 | 298 | 173.75 | 4.61982 | | |
| | Total | 894 | 130.08 | 34.02139 | | |
| SBP | GROUP 1 | 298 | 129.98 | 6.15433 | 4.597 | .010 |
| | GROUP 2 | 298 | 130.01 | 6.24991 | | |
| | GROUP 3 | 298 | 131.41 | 7.29805 | | |
| | Total | 894 | 130.47 | 6.61432 | | |
| DBP | GROUP 1 | 298 | 83.0134 | 4.76577 | .230 | .794 |
| | GROUP 2 | 298 | 83.0134 | 4.76577 | | |
| | GROUP 3 | 298 | 82.7896 | 4.40631 | | |
| | Total | 894 | 82.9388 | 4.64503 | | |
| PP | GROUP 1 | 298 | 46.9953 | 7.89982 | 7.757 | .000 |
| | GROUP 2 | 298 | 46.9953 | 7.89982 | | |
| | GROUP 3 | 298 | 49.4735 | 9.61517 | | |
| | Total | 894 | 47.7880 | 8.57426 | | |
| TG | GROUP 1 | 298 | 86.6208 | 45.51035 | 163.508 | .000 |
| | GROUP 2 | 298 | 139.80 | 22.94724 | | |
| | GROUP 3 | 298 | 143.23 | 53.94847 | | |
| | Total | 894 | 123.22 | 50.04320 | | |
| HBA1C | GROUP 1 | 298 | 7.4574 | 1.72272 | 6.589 | .001 |
| | GROUP 2 | 298 | 7.2746 | 1.48489 | | |
| | GROUP 3 | 298 | 6.6185 | 4.60781 | | |
| | Total | 894 | 7.1168 | 2.98525 | | |
| FRS | GROUP 1 | 298 | 3.6453 | 1.56633 | 316.456 | .000 |
| | GROUP 2 | 297 | 4.7832 | 1.47982 | | |
| | GROUP 3 | 291 | 7.8842 | 2.97451 | | |
| | Total | 886 | 5.4190 | 2.76555 | | |

**Table 2**

| Bonferroni Post Hoc | | | | | |
|---|---|---|---|---|---|
| Dependent Variable | (I) G1G2G3 | (J) G1G2G3 | Mean Difference (I-J) | Std. Error | Sig. |
| FBS | Group 1 | Group 2 | -33.00000* | .37847 | .000 |

| | | | | | |
|---|---|---|---|---|---|
| | | Group 3 | -82.00000* | .37847 | .000 |
| | Group 2 | Group 3 | -49.00000* | .37847 | .000 |
| SBP | Group 1 | Group 2 | -.03322 | .53970 | 1.000 |
| | | Group 3 | -1.43356* | .53970 | .024 |
| | Group 2 | Group 3 | -1.40034* | .53970 | .029 |
| DBP | Group 1 | Group 2 | .00000 | .38086 | 1.000 |
| | | Group 3 | .22383 | .38086 | 1.000 |
| | Group 2 | Group 3 | .22383 | .38086 | 1.000 |
| PP | Group 1 | Group 2 | .01000 | .68717 | .930 |
| | | Group 3 | -2.37819* | .69717 | .002 |
| | Group 2 | Group 3 | -2.47819* | .69717 | .001 |
| TG | Group 1 | Group 2 | -53.17987* | 3.51036 | .000 |
| | | Group 3 | -56.60973* | 3.51036 | .000 |
| | Group 2 | Group 3 | -3.42987 | 3.51036 | .986 |
| HBA1C | Group 1 | Group 2 | .18282 | .24304 | 1.000 |
| | | Group 3 | .83893* | .24304 | .002 |
| | Group 2 | Group 3 | .65611* | .24304 | .021 |
| FRS | Group 1 | Group 2 | -1.13793* | .17326 | .000 |
| | | Group 3 | -4.23889* | .17415 | .000 |
| | Group 2 | Group 3 | -3.10096* | .17429 | .000 |
| *. The mean difference is significant at the 0.05 level. | | | | | |

**Table 3**

| **PP** | **Group 1** | | **Group 2** | | **Group 3** | |
|---|---|---|---|---|---|---|
| | r | p | r | p | r | p |
| FRS | .058 | 0.315 | 0.136 | 0.019 | 0.470 | .000 |

**Table 4**

| | | **All Groups FRS** |
|---|---|---|
| Group 3 HBA1C | Pearson Correlation | 1.00 |
| | Sig. (2-tailed) | .000 |

**Table 5**

| | | G3HBA1C |
|---|---|---|
| G3PP | Pearson Correlation | .470** |
| | Sig. (2-tailed) | .000 |

**Discussion**

Importance of Arterial Blood Pressure has been well established as a vital determinant of cardiovascular risk. Though lately it has been a topic of considerable debate to ascertain a precise BP component that best forecasts cardiovascular risk [10]. As per the literature the latest data from the Framingham Heart Study advocates that PP, a replacement measure of arterial stiffness, is a better predictor of CHD risk than either SBP or DBP, when individuals of more than 50 years of age are concerned [5]. whereas the opposite seems to apply in younger foci group of patients. Some of the epidemiologic and intervention studies do strengthen the aforementioned Hypothesis [11, 12, 13].

As type 2 diabetes mellitus is allied with significantly increased risk of cardiovascular disease predictive value of the different BP components among diabetic individuals is of importance where arterial stiffness, a key factor in determining PP, self-sufficiently predicts mortality among diabetic subjects [14]. There has been hardly a few studies that have investigated the predictive value of PP in diabetic subjects [15, 16]. An Epidemological study done in Southern part of India by Krishnamurthy V *et al* in the Year 2019 depicts a result in line with the current study [7].

Although there are multiple calculators which can help to compute cardiovascular risk, use of Framingham risk score for 10 years risk assessment has been used globally accepted because of the the ease of calculation with the results obtained easily in percentage. Though the newer modified version of the risk score includes dyslipidaemia age range, hypertension treatment, smoking, and total cholesterol, Type 2 diabetes has been still not considered in spite being a potent CHD Risk Equivalent [7].

The current study depicts an association between Diabetes and Pulse Pressure which is in line with the studies done previously [7,15,16] The study did show an association between Group 1 and Group 3 as well as Group 2 and 3, however no statistical difference was found between Group 1 and Group 2. The one potential limitation of the current study is the nonstandardized method of BP measurement which can lead to minor deflections in the values obtained. A positive correlation between FRS and PP in Group 2 and Group 3 achieved provides a strong

evidence in line with the Hypothesis of the study in diabetes patient. Although FRS is a good predictor of risk of CHD the limitation of its use stands as it was formulated based on a Cohort study performed in American population. There is a need for a modification or more number of researches to strengthen its reliability in Indian scenario. A positive strength of association between HbA1c and FRS amongst uncontrolled Diabetics in our study definitely reinforces the similar analysis documented in the past. To add to the aforementioned point a mild corelation was found between Group 3 Pulse Pressure and HbA1C gives an insight to importance of Pulse Pressure measurement in Diabetics to assess the risk of CHD. Since pulse pressure is a surrogate measure of arterial stiffness, such data indicate that arterial stiffness is a key determinant of cardiovascular risk in older subjects. Indeed, data from the FIELD Study, assessing the impact of insulin therapy in type 2 diabetes, relating to central BP and arterial stiffness may address this important issue[16]. With this current study epidemiological evidence it can be in summary, PP can be a good predictor of CHD risk in older subjects with type 2 diabetes mellitus.

**Conclusion**

Pulse pressure is a useful predictor of future cardiovascular events, however an attempt to find an association and strengthen the hypothesis of PP, CHD and Diabetics, Framingham risk score and PP association was analysed in the current study which depicts a significant association This study highlights the importance of pulse pressure measurement in clinical practice which can be considered as a simple yet an significant measurement tool to assess CHD risk in Diabetics.

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