BASELINE CHARACTERISTICS IN PATIENTS OF CARDIOMETABOLIC DISORDERS WITH VITAMIN D DEFICIENCY IN AHMEDABAD POPULATION

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ABSTRACT

Background*: Cardiometabolic disorders and vitamin D deficiency are pandemic worldwide which includes India. The incidence of cardiometabolic disorders is growing with high alert worldwide. The previous reported studies had identified the pathological association between vitamin D deficiency and cardiometabolic disorders. Therefore, the aim of the study was to assess the baseline characteristics for patients of cardiometabolic disorders with vitamin D deficiency. These data is gathered from our own study; the effect of vitamin D supplements in cardiometabolic disorders with vitamin D deficiency.* **Methods:** *This study is an open labeled, randomized, parallel, single centric and prospective design conducted at Tej Hospital, Ahmedabad, Gujarat. This study is an ongoing prospective study, however in this research article we have analyzed only baseline parameters which includes gender, age, relevant medical history, body mass index (BMI), systolic blood pressure (SBP), diastolic blood pressure (DBP), Waist circumference (WC), fasting blood glucose (FBG), Glycated haemoglobin (HbA1c), post prandial blood glucose (PPBG), total cholesterol (TC), triglycerides (TG), high density lipoprotein cholesterol (HDL), low density lipoprotein cholesterol (LDL), very low density lipoprotein cholesterol (VLDL), and 25(OH)D.* **Results***: A total of 124 patients were recruited after screening 183 patients of cardiometabolic disorders with vitamin D deficiency. All the characteristics of cardiometabolic disorders such as hypertension, lipid abnormalities and insulin resistance were observed in more than 50% patients.* **Conclusion:** *We have analyzed our data and it suggests that vitamin D deficiency may be one of the potent risk factor for cardiometabolic disorders. There was higher prevalence of cardiometabolic disorders in males than females.*

Keyword: - Cardiometabolic disorders *,Vitamin D, Clinical Study, Ahmedabad, Baseline*

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1. INTRODUCTION

Cardiometabolic disorders are a group of metabolic disorders which are characterized by insulin resistance and impaired glucose tolerance, atherogenic dyslipidemia, hypertension and intra-abdominal adiposity [1]. Cardiometabolic disorders comprising of cardiovascular diseases, type-2 diabetes mellitus and metabolic syndrome are major causes of morbidity and mortality worldwide [2,3,4]. About 25% of the world's adults are suffering from cardiometabolic disorders [1]. Cardiovascular diseases are the foremost cause of mortality in diabetes [5]. Observational studies suggested that there is association of vitamin D deficiency in the pathogenesis of cardiometabolic disorders [6]. Interventional studies also reported some positive response of vitamin D

supplementation on cardiometabolic disorders [7,8,9,10]. Many degree of vitamin D deficiency was found on approximately 75 to 85% in Indian population [11]. Most of adult population and older population are at major risk for vitamin D deficiency [2]. The latest guideline of Institute of Medicine recommended that vitamin D level less than 12 ng/ml should be considered as vitamin D deficient [12].Vitamin D is a fat soluble secosteroid which is responsible for intestinal absorption of calcium and phosphorus [13]. Pleiotropic effects of vitamin D are on extensive research worldwide. Studies discovered that vitamin D supplementation may help to overcome the risk of cardiometabolic disorders [2]. Kelishadi et al [14] and Von Hurst et al [15] reported favorable effects of vitamin D supplementation on cardiometabolic disorders whereas Pittas el al [16] and Salekzamani et al [7] reported no beneficial effects of vitamin D supplementation on cardiometabolic disorders. These controversial results might be due to incorrect duration, dosage, route of administration, patient's characteristics, inadequate outcome measures [6]. Moreover, Norris et al [17] reported that there is difference in vitamin D effect according to race/ethnicity. Therefore, we have designated the gujarati ethnic group of Ahmedabad region of Gujarat, India where an abundant sunlight is present, still people are vitamin D deficient [13] as well as having cardiometabolic disorders [18].

In this study we reported the demographic features and baseline characteristics of the patients from cardiometabolic disorders who had participated in the trial.

2. METHODOLOGY
We had already reported our protocol for the study [19]. This study got prior approval from Riddhi Medical Nursing Home Institutional Ethics Committee, Ahmedabad, Gujarat, India before recruiting the patients and was carried out accordance to Indian Council of Medical Research (ICMR) guidelines. Written informed consent form was obtained from participants. At the screening time demographic data (age, gender, race, ethnicity), relevant medical history were taken from all patients.

This is a prospective, open-labeled, randomized, parallel and single centric trial. This study is conducted at Tej Hospital, Ahmedabad, Gujarat. This study is ongoing prospective study, however in this research article we have analysed only baseline parameters. On the basis of inclusion and exclusion criteria, patients of cardiometabolic disorders with vitamin D deficiency were enrolled.

Inclusion Criteria

Patients (Males or females) aged 18 to 75 years were screened for both cardiometabolic disorders and vitamin D deficiency (<12ng/ml).According to American Heart Association, out of the following criteria, minimum 3 criteria should be fulfilled for considering cardiometabolic disorders [20] which are as follows:Fasting blood triglycerides ≥ 150 mg/dl;HDL < 40 mg/dl in males and <50 mg/dl in females; Systolic blood pressure (SBP) ≥130 and/or diastolic blood pressure (DBP) ≥85 mm Hg; Fasting Blood Glucose ≥ 100 mg/dl ;Waist circumference (WC) >102cm in males or >88 cm in females. These criteria must be fulfilled for participation in the study.

Exclusion Criteria
Participants younger than 18 years of age; Pregnant women; Participants with known history of type 1 diabetes; Patients with known history of Primary hyperparathyroid disease or any other conditions that might interfere with calcium or vitamin D homeostasis including participants on dialysis; Patients with known history of nephrolithiasis, hypercalciurea, malignancy, sarcoidoisis, Paget's disease, malabsorption symptoms.

Total sample size was calculated as 124 subjects [19] in the study. The baseline data variables which include heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), Body mass Index (BMI), Waist circumference (WC), fasting blood glucose (FBG), Glycated haemoglobin (HbA1c), post prandial blood glucose (PPBG), total cholesterol (TC), triglycerides (TG), high density lipoprotein cholesterol (HDL), low density lipoprotein cholesterol (LDL), very low density lipoprotein cholesterol (VLDL) and 25(OH)D level was measured.

3. RESULTS AND DISCUSSION
We had already reported the calculation of sample size [19]. Demographic data's were described by using descriptive statistics. Baseline characteristics of all variables of cardiometabolic parameters were represented as mean ± standard deviation. Categorical variables were compared by using Chi square test with p<0.05 was considered as statistically significant. Figure 1-5 represents the graph of the baseline characteristics for the patients of cardiometabolic disorders with vitamin D deficiency. In the current study, subjects were enrolled only of Gujarati

ethnicity from Ahmedabad origin. A total of 124 patients were recruited having cardiometabolic disorders with vitamin D deficiency after screening 183 patients. As per guideline, vitamin D level <12 ng/ml which is considered as vitamin D deficiency were seen in all patients of the study. Maximum numbers of patients (38) in this study were seen under age range (46-55) years as shown in Table 1.Baseline demographic characteristics for the patients were represented in Table 2. The average age of overall participants was 56.08±11.31 years. Out of 124 patients, the number of males was 78 (62.9%) and number of females was 46 (37%). In this study, the prevalence of cardiometabolic disorders were found more in males than females [p<0.05]. In obesity criteria, as per BMI index, most of patients (68%) were categorized under overweight category [21]. In abdominal obesity, a total of 42.3% of males had been found with higher WC (>102cm) while 76% of females had been found with higher WC (>88cm) [p<0.05]. Most of patients (55%) were found with stage 1 hypertension [22] .Majority of patients were observed with borderline high triglycerides (67%), LDL level above optimal border (40%) , high VLDL level (86%) and intermediate HDL levels (56%) [23]. Lower levels of HDL were observed more in females (82.6%) than males (48.7 %) [p<0.05]. Most of patients were identified with high FBG (82%), PPBG (56%), HbA1c (98%) level [24]. Clinical Characteristics of the patients were summarized in Table 3. Out of 5 criteria minimum 3 criteria must be required for diagnosis of cardiometabolic disorders, however in our study maximum number of patients (49) fulfilled 4 criteria for cardiometabolic disorders as shown in Table 4.

Table 1. Age range of patients	
Age range	**No. of patients**
18-25	0
26-35	7
36-45	15
46-55	38
56-65	37
66-75	27

Table 2. Baseline demographic characteristics of patients	
Characteristics	
Gender (%)	**n**
Male	78 (62.9%)
Female	46 (37%)
History of Cardiometabolic Diseases	
Dyslipidemia	45 (36.2%)
Hypertension	25 (20.1%)
Diabetes Mellitus 2	68 (54.8%)
Cardiovascular Diseases	16 (12.9%)
	Mean±SD [Range]
Age (years)	56.08±11.31 [28-74]
BMI (kg/m2)	27.89±3.95 [21.1-46.9]

Heart Rate (bpm)	82.43±7.39 [60-110]
Waist Circumference (cm)	93.82±8.87 [78.7-115]
Systolic blood pressure (mmHg)	141.35±13.82 [110-230]
Diastolic blood pressure (mmHg)	84.55±7.29 [70-110]

Table 3. Baseline Clinical Characteristics (Mean±SD) of patients		
Parameters	**Males** **(Mean±SD)**	**Females** **(Mean±SD)**
Total Cholesterol (mg/dl)	192±38.58	191.44±37.61
Triglycerides (mg/dl)	183.7±52.8	169.57±53.39
HDL (mg/dl)	39.54±7.59	43.05±7.72
LDL (mg/dl)	115.93±34.85	114.47±33.3
VLDL (mg/dl)	36.62±10.65	33.91±10.76
FBG (mg/dl)	166.37±54.67	173.5±52.23
PPBG (mg/dl)	228.04±75.03	243.3±74.53
HbA1c (%)	8.34±1.80	8.59±1.76
25(OH)D (ng/ml)	8.20±1.37	8.31±1.99

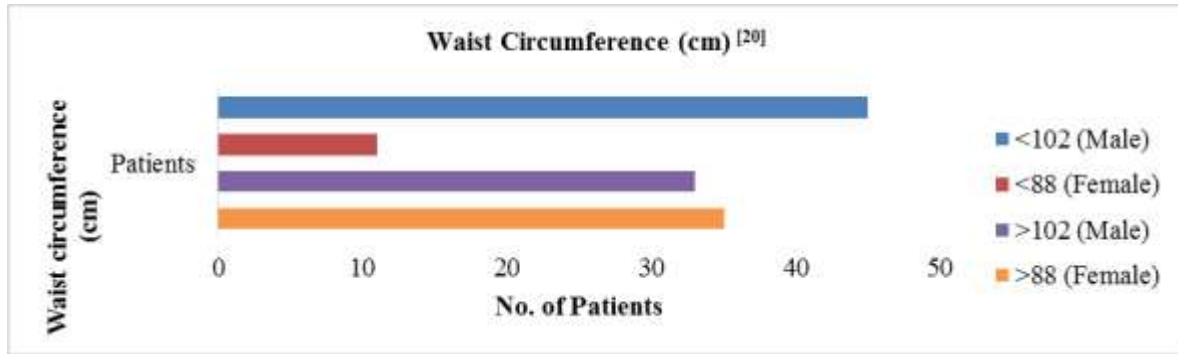| **Table 4. Number of criteria fulfilled for cardiometabolic disorders by patients**	
No. of criteria fulfilled for cardiometabolic disorders	No. of patients
3	40
4	49
5	35

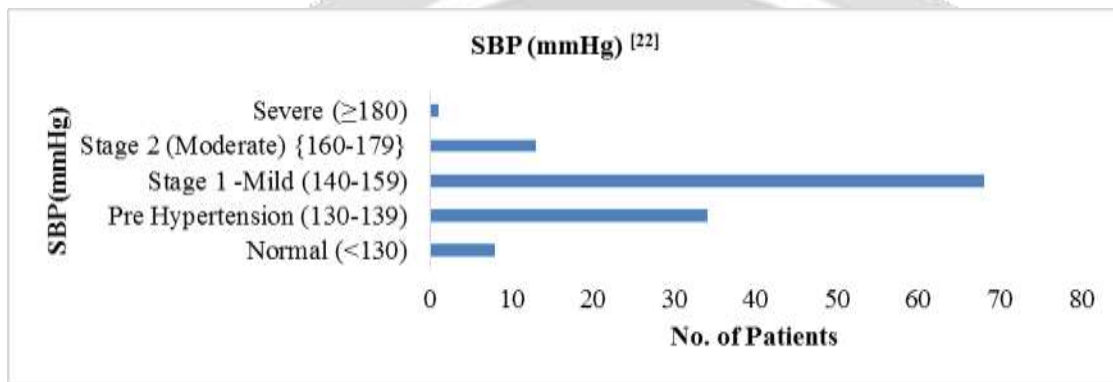**Figure 1.Baseline characteristics of patients for WC (cm)**

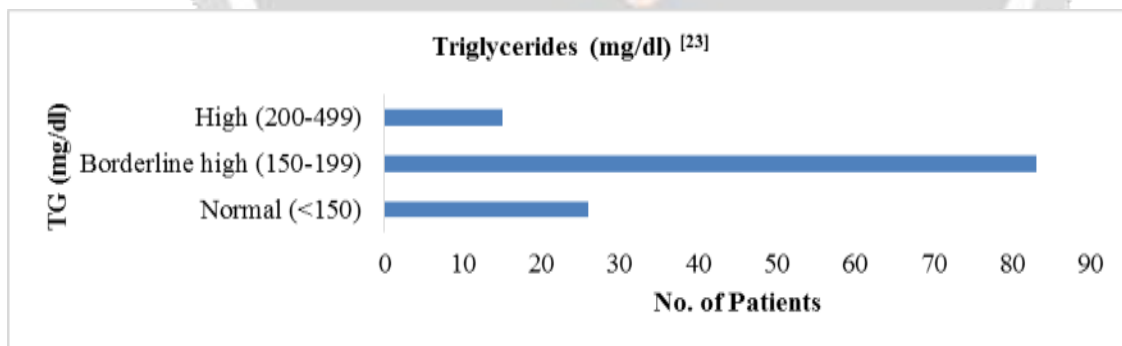**Figure 2.Baseline characteristics of patients for SBP (mm Hg)**

Figure 3.Baseline characteristics of patients for TG (mg/ dl)
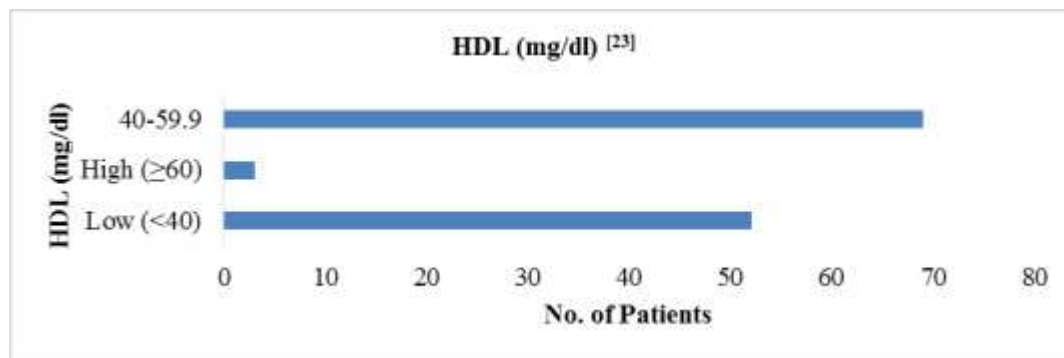
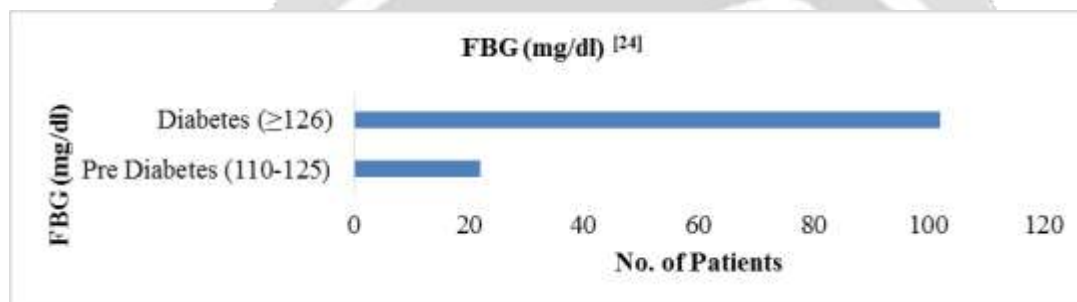**Figure 4.Baseline characteristics of patients for HDL (mg/dl)**

Figure 5.Baseline characteristics of patients for FBG (mg/dl)

Cardiometabolic disorders and vitamin D deficiency are highly prevalent in Gujarat. Literature reviews revealed that vitamin D supplementation may improve cardiometabolic disorders. The possible mechanisms by which vitamin D may protect from cardiometabolic disorders, includes inhibition of renin angiotensin-aldosterone system, improving endothelial function, augmentation of insulin secretion and sensitivity, inhibition of inflammatory cytokines [6]. It was the first study, which showed the baseline characteristics in patients of cardiometabolic disorders with vitamin D deficiency in Gujarati ethnicity of Ahmedabad region, India. Previous study reported debatable results of gender specific difference of cardiometabolic disorders [25]. Current study shows the prevalence of male gender category which is supported by another article which showed that males had higher prevalence of cardiometabolic disorders [26].Cardiometabolic disorders with vitamin D deficiency is highly prevalent in the middle age group (45-65) years, which is similarly observed in another study [27]. The lipid and glucose abnormalities were found in the patients of cardiometabolic disorders with vitamin D deficiency. Our baseline study also showed that abdominal obesity and low HDL were prevalent in female than male. Similar observations were also reported in another study which showed the prevalence of female in abdominal obesity and low HDL level [25]. These baseline data indicated that vitamin D deficiency may be highly prevalent in patients of cardiometabolic disorders in Ahmedabad region of Gujarat and it might play an important role as one of the risk factor for cardiometabolic disorders. This region of people is susceptible for developing diabetes and cardiovascular diseases. It might be due to change in lifestyle, affluence in urbanization, dietary habits of oil and carbohydrates rich food [28]. These data also indicated that presence of vitamin D deficiency, overweight or obesity, lipid abnormalities and high blood glucose level in Gujarati ethnicity in Ahmedabad region population which may be highly prone to develop cardiometabolic disorders.

4. CONCLUSIONS
In conclusion, vitamin D deficiency may be one of the potent risk factor for cardiometabolic disorders. It is highly prevalent in male than female, however, abdominal obesity and low HDL were observed more in female category than male category. All the characteristics of cardiometabolic disorders such as hypertension, lipid abnormalities

and insulin resistance were observed in more than 50% patients. The baseline data shown in the study seems to be encouraging enough to assess the effect of vitamin D supplementation in patients of cardiometabolic disorders in the ongoing trial.

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