

# Demographic, Clinical and Biochemical Characteristics of Drug Naive Type 2 Diabetes Patients of Bangladesh

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## Abstract

**Background:** Although the frequencies of getting drug naive type 2 diabetes patients among all the diabetic patients are very low, nowadays it claims more attention in the treatment procedures of drug naive diabetic patients. But in Bangladesh, we have very few research-oriented data regarding the demographic, clinical and biochemical characteristics of drug naive type 2 diabetes patients. The aim of this study was to determine the demographic clinical and biochemical characteristics of drug naive type 2 diabetes patients of Bangladesh. **Methods:** This was an open label observational real-life study which was conducted in the chambers of the investigators in several places of Bangladesh as outdoor setting during the period from August 2020 to December 2020. In total, 250 patients with drug naive type 2 diabetes mellitus were enrolled as the study population. Proper written consents were taken from all the participants before starting data collection. A pre-designed questionnaire was used in patient data collection. All data were processed, analyzed and disseminated by MS Office and SPSS version as per need. **Result:** Two hun-



dred and fifty (250) participants were selected as study population. The male-female ratio of the participants was 1.4:1. The highest number of participants was from 51 - 60 years' age group (31.20%). The highest number of participants (41%) was with overweight (BMI: 25 - 30 kg/m<sup>2</sup>). Majority (65%) of the patients of this study suffered from diabetes for ≤5 years. The mean (±SD) SBP of the participants was 137.25 ± 17.50 mmHg and the mean (±SD) DBP of the participants was 85.16 ± 13.39 mmHg. We found the mean (±SD) fasting blood sugar (mg/dl), post prandial blood sugar (mg/dl), total cholesterol (mg/dl), triglycerides (mg/dl), HDL-Cholesterol (mg/dl), LDL-cholesterol (mg/dl), VLDL-cholesterol (mg/dl), uric acid (mg/dl), creatinine (mg/dl), urea (mg/dl), total bilirubin (mg/dl), direct bilirubin (mg/dl), SGOT (IU/L) and SGPT (IU/L) were 251.51 ± 112.08, 349.72 ± 128.68, 219.59 ± 68.25, 196.44 ± 94.34, 35.14 ± 11.85, 145.72 ± 64.33, 40.88 ± 18.12, 3.45 ± 1.51, 0.86 ± 0.37, 29.16 ± 9.81, 0.87 ± 0.4, 0.48 ± 0.4, 37.15 ± 10.9 and 35.83 ± 23.04 respectively. **Conclusion:** Obesity and hypertension demand more attention of diabetologists in diagnosis and treatment of patients or suspected patients of diabetes. Patients aged ≥ 50 years are most vulnerable and suspicious for diabetes. Besides age consequence habits of tobacco smoking, family history, smoking and HTN, alcohol intake and presence of nitrites in the urine may be considered as the most potential comorbidities for diabetic patients. Diagnosis of demographic, clinical and biochemical characteristics of drug naive type 2 diabetes patients may play a vital role in proper treatment.

## Keywords

Demographic, Biochemical, Clinical Characteristics, Drug Naive Type 2 Diabetes, Bangladesh

## 1. Introduction

Diabetes may be a growing drawback worldwide, significantly in developing countries wherever rates have skyrocketed. In keeping with the International diabetes disorder Federation (IDF), of the 382 million individuals with diabetes disorder (a range expected to be nearly double by 2035), a staggering eightieth board developing countries, that area unit least equipped to trot out this rising crisis. The region presumably to expertise the most force of the epidemic is South East Asia, wherever diabetes disorder is predicted to extend by seventy-one inside successive twenty-five years [1]. Bangladesh is among the highest 10 countries globally in terms of diabetes disorder burden with increasing prevalence of diabetes disorder in each urban and rural areas [2] [3]. In South Asia, the majority of diabetes disorder cases are the unit kind of type two diabetes disorder (T2D). The South Asian population presents with variety of various risk factors for T2D because of a mixture of many genetic and environmental factors [4]. A recent survey showed that diabetes disorder has become epidemic among the adult Bangladeshi population and also the prevalence of this disorder and pre-diabetes was 100% and twenty third severally [5]. The prevalence of that

disorder was nearly double in urban compared to rural areas (15.2% and 8.3%, respectively); diabetes patients were older, had considerably a lot of cardiovascular disease and fat compared to those while not [5]. In Bangladesh, as in different countries, T2D is related to high body mass index (BMI), central fat, which may be a risk issue for each vessel diseases (CVD) and diabetes [6] [7]. The CVD risk which will be attributed to diabetes is even a lot of distinguished among South Asians than in different populations [8]. Above all, cardiovascular disease and diabetes worsen each other and together will dramatically increase the speed of complications [9]. Previous studies have shown that diabetes will increase the prevalence of dyslipidemia by a minimum of 2-fold conjointly resulting in CVD [10]. Secondary complications of diabetes begin early and progress chop-chop among South Asians which will be reduced considerably through early detection and adequate management [11]. Metformin is the pharmacologic treatment for type 2 diabetes [12]. Glucophage acts in the main by reducing viscus aldohexose production via inhibition of gluconeogenesis [12] [13] and conjointly will increase aldohexose uptake in peripheral tissue [13]. Glucophage is related to a coffee risk of hypoglycaemia and is weight neutral or will cause weight loss [12]. However, as type 2 diabetes disorder progresses, Glucophage monotherapy typically fails to keep up glycemic management [14]. SGLT2 inhibitors act by reducing urinary organ aldohexose biological process, thereby increasing urinary aldohexose excretion and reducing symptom [15]. Empagliflozin may be a potent and selective SGLT2 mattet [16]. Most of the aldohexose by the urinary organ is reabsorbed by the Na aldohexose cotransporter two (SGLT2) [17]. Once used as associate add-on to Glucophage in patients with type 2 diabetes, empagliflozin (10 mg and 25 mg) significantly reduced HbA1c, fast plasma aldohexose (FPG), and weight and was well tolerated, with a coffee risk of hypoglycaemia [18]. This study is undertaken to see the demographic and clinical characteristics of Drug Naive type 2 diabetes Patients of Bangladesh comparison the efficacy and safety of combos of Empagliflozin and Glucophage immediate unharness (IR), Vildagliptin and Glucophage with Glucophage IR monotherapy in patients with type 2 diabetes disorder.

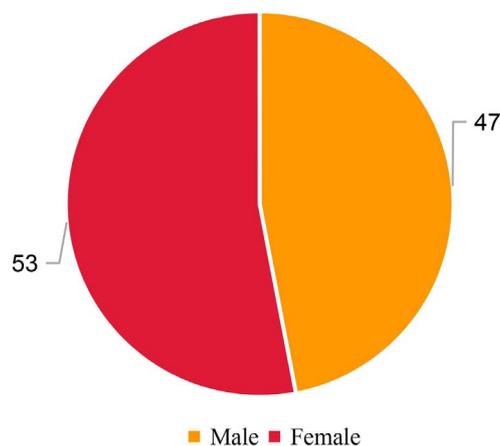
## 2. Methodology & Materials

This was an open label observational real-life study which was conducted in the chambers of the investigators in several places of Bangladesh as outdoor setting during the period from August 2020 to December 2020. In total 250 patients with drug naive type 2 diabetes mellitus were enrolled as the study population. According to the Standard of Care of American Diabetes Association 2021 study defined drug naive type 2 diabetes mellitus [19]. Proper written consents were taken from all the participants before starting data collection. A pre-designed questionnaire was used in patent data collection. According to the exclusion criteria of this study patients with type 1 DM, history of urinary tract infection more than 3 times in last 12 months, patient with history of recent (in last 3 months) genital mycotic infection and pregnant & women of child bearing po-

tential who are planning for pregnancy were excluded. Patients have been assessed for ensuring the eligibility criteria by the investigator. Detailed medical history with baseline laboratory levels, clinical evaluations, and medicine information in predefined questioner format (Patient file). Standard prescription with medicine names and dosage recommendation. Patients came in a follow up visit after one week. The investigator gave suggestion to patients regarding disease and medication (If any). Two follow up visits have been done at 3 months interval. The patients have been asked to perform some predefined laboratory test and bring those results in subsequent follow up visit. Subjects would have been given a diary. In between the three months if patient feel any Adverse Events (AE) they recorded it. For any Adverse Events they would ask to inform the respective Investigator directly or over phone. Investigator also suggested the patients over phone or if necessary, can ask the patient for a chamber visit. Patients have been given a reminder by the health staffs 1 day before the schedule visit. In 2nd visit (after 3 months) patients came to the chamber for follow up with the reports of the advised laboratory investigations. The reports recorded along with clinical assessment and diary card assessment in the patient specific questioner. The 3rd visit was conducted after 3 months of the 2nd visit (6 month after the enrolment). The same process has been applied for all patients by respective investigator. Each investigator handled 8 (8 for each arm,  $8 \times 3 = 24$  in total) patients and there will be 14 investigators so total 50 patients' data has been generated. Safety end points included clinical laboratory parameters and adverse events (AEs), with preferred terms coded according to the Medical Dictionary for Drug Regulatory Activities (MedDRA) version 23.0. AEs included all events with an onset after the first dose and up to 7 days after the last dose of trial medication. Confirmed hypoglycemic AEs, defined as AEs with plasma glucose, 70 mg/dL (3.9 mmol/L) and/or requiring assistance, were identified by direct plasma glucose measurements and by home blood glucose monitoring performed by the patient. Other predefined AEs of special interest included events consistent with urinary tract infection (UTI), genital infection, and volume depletion, identified using prospectively defined search categories based on 67, 87, and 8 MedDRA preferred terms, respectively. AEs related to increased urination were assessed based on a post hoc search for the MedDRA preferred terms polakiuria, polyuria, and nocturia. Data analyzed by computer with the help of SPSS (Statistical Package for Social Science). Statistical analyses have been done by using appropriate statistical tool like "chi-square" test, student's "T" test, where applicable. Statistical significance is set at 0.05 level and confidence interval at 95% level. Data has been presented in the form of table and graphs.

### 3. Result

In this study, 250 participants were selected as study population. Among them 53% (n = 133) were male whereas 47% (n = 117) were female (Figure 1). So, male was dominating in number and the male-female ratio was 1.4:1. In this study in analyzing the ages of the participants we observed, the highest number



**Figure 1.** Sex distribution of the participants (n = 250).

of participants were from 51 - 60 years' age group which was 31.20%. Besides this 1.20%, 9.20%, 12.80%, 22.00% and 23.60% were from  $\geq 20$ , 21 - 30, 31 - 40, 41 - 50 and  $>60$  years' age groups respectively. Among all the participants of this study the highest number of participants were with overweight (BMI: 25 - 30 kg/m<sup>2</sup>) which was found in 40.80%. Then 34% were obese (BMI:  $>30$ ) and the rest 25.20% were with normal BMI ( $<25$  kg/m<sup>2</sup>) (**Table 1**). The highest number of patients of this study suffered from diabetes for  $\leq 5$  years which was 65% (n = 162) whereas 35% patients suffered for more than 5 years which was 35% (**Figure 2**). In this study, 38% participants were with hypertension. In analyzing the systolic blood pressure of the participants, we observed, the highest number of participants were with normal SBP which was found among 35.20% participants. Then 26.80%, 24.80% and 13.20% were with pre HTN (120 - 139), HTN, Stage 1 (140 - 159) and HTN, Stage 2 (160) SBP. The mean ( $\pm$ SD) SBP of the participants was  $137.25 \pm 17.50$  mmHg. On the other hand, in analyzing the diastolic blood pressure of the participants, we observed, the highest number of participants were with normal DBP which was found among 36.40% participants. Then 26.80%, 24.80%, 13.20% were with pre HTN (80 - 89), HTN, Stage 1 (90 - 99) and HTN, Stage 2 (100) DBP. The mean ( $\pm$ SD) DBP of the participants was found  $85.16 \pm 13.39$  mmHg (**Table 2**). In analyzing the biochemical status of the participants, we found the mean ( $\pm$ SD) fasting blood sugar (mg/dl), post prandial blood sugar (mg/dl), Total cholesterol (mg/dl), triglycerides (mg/dl), HDL-cholesterol (mg/dl), LDL-cholesterol (mg/dl), VLDL-cholesterol (mg/dl), uric acid (mg/dl), creatinine (mg/dl), urea (mg/dl), Total bilirubin (mg/dl), direct bilirubin (mg/dl), SGOT (IU/L) and SGPT (IU/L) were  $251.51 \pm 112.08$ ,  $349.72 \pm 128.68$ ,  $219.59 \pm 68.25$ ,  $196.44 \pm 94.34$ ,  $35.14 \pm 11.85$ ,  $145.72 \pm 64.33$ ,  $40.88 \pm 18.12$ ,  $3.45 \pm 1.51$ ,  $0.86 \pm 0.37$ ,  $29.16 \pm 9.81$ ,  $0.87 \pm 0.4$ ,  $0.48 \pm 0.4$ ,  $37.15 \pm 10.9$  and  $35.83 \pm 23.04$  respectively (**Table 3**). In analyzing the comorbidities among the participants, we found in 54.80%, 30.80%, 28.80%, 18.80%, 4.40% and 8.80% participants aged  $\geq 50$  years, tobacco smoking, family history, smoking & HTN, habit of alcohol intake and nitrites in the urine were the noticeable comorbidities respectively (**Table 4**).

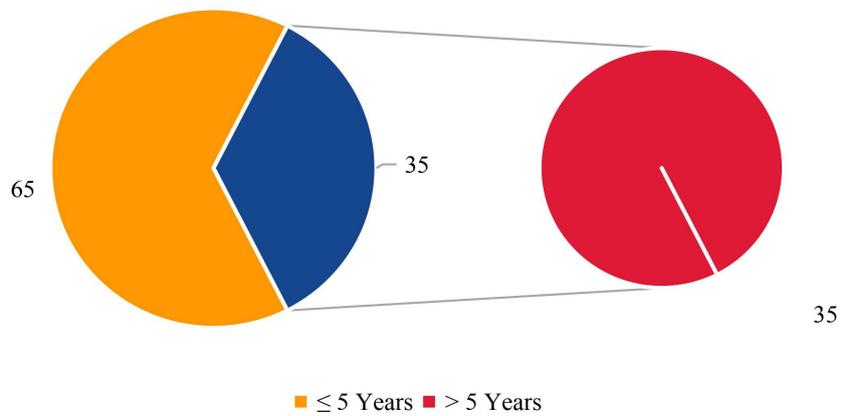
**Table 1.** Age and BMI distribution of participants (n = 250).

Age Distribution	n = 250	%
≥20 years	3	1.20
21 years - 30 years	23	9.20
31 years - 40 years	32	12.80
41 years - 50 years	55	22.00
51 years - 60 years	78	31.20
>60 years	59	23.60
<b>BMI (Kg/m<sup>2</sup>)</b>		
Normal (<25)	63	25.20
Overweight (25 - 30)	102	40.80
Obese (>30)	85	34.00

**Table 2.** Distribution of systolic BP and diastolic BP among participants (n = 250).

Systolic BP (mmHg)	n = 250	%
Normal (<120)	88	35.20
Pre htn (120 - 139)	67	26.80
Htn, stage 1 (140 - 159)	62	24.80
Htn, stage 2 (160)	33	13.20
Mean (±sd)	137.25 ± 17.50	
<b>Diastolic BP (mmHg)</b>		
Normal (<120)	91	36.40
Pre htn (120 - 139)	71	28.40
Htn, stage 1 (140 - 159)	58	23.20
Htn, stage 2 (160)	30	12.00
Mean (±sd)	85.16 ± 13.39	

### Duration of Diabetes



**Figure 2.** Duration of diabetes among the participants (n = 250).

**Table 3.** Biochemical status of the participants (n = 250).

Characteristics	Mean $\pm$ SD
Fasting Blood Sugar (mg/dl)	251.51 $\pm$ 112.08
Post Prandial Bl. Su. (mg/dl)	349.72 $\pm$ 128.68
Total cholesterol (mg/dl)	219.59 $\pm$ 68.25
Triglycerides (mg/dl)	196.44 $\pm$ 94.34
HDL-Cholesterol (mg/dl)	35.14 $\pm$ 11.85
LDL-Cholesterol (mg/dl)	145.72 $\pm$ 64.33
VLDL-Cholesterol (mg/dl)	40.88 $\pm$ 18.12
Uric acid (mg/dl)	3.45 $\pm$ 1.51
Creatinine (mg/dl)	0.86 $\pm$ 0.37
Urea (mg/dl)	29.16 $\pm$ 9.81
Total Bilirubin (mg/dl)	0.87 $\pm$ 0.4
Direct Bilirubin (mg/dl)	0.48 $\pm$ 0.4
SGOT (IU/L)	37.15 $\pm$ 10.9
SGPT (IU/L)	35.83 $\pm$ 23.04

**Table 4.** Comorbidities among participants (n = 250).

Comorbidities	n (%)
Patient aged $\geq$ 50 years	137 (54.80)
Tobacco smoking	77 (30.80)
Family history	72 (28.80)
Smoking and HTN	47 (18.80)
Alcohol intake	11 (4.40)
Nitrites in the urine	22 (8.80)

#### 4. Discussion

The aim of this study was to determine the demographic clinical and biochemical characteristics of drug naive type 2 diabetes patients of Bangladesh. In this current study the male-female ratio of the participants was 1.4:1. The highest number of participants was from 51 - 60 years' age group (31.20%). The highest number of participants (41%) was with overweight (BMI: 25 - 30 kg/m<sup>2</sup>). Majority (65%) of the patients of this study suffered from diabetes for  $\leq$ 5 years. The highest number (35%) of participants were with normal SBP where the mean ( $\pm$ SD) SBP of the participants was 137.25  $\pm$  17.50 mmHg. On the other hand, the highest number (36%) of participants were with normal DBP where the mean ( $\pm$ SD) DBP of the participants was 85.16  $\pm$  13.39 mmHg. In analyzing the comorbidities among the participants, we found in 54.80%, 30.80%, 28.80%, 18.80%, 4.40% and 8.80% participants aged  $\geq$  50 years, tobacco smoking, family history, smoking & HTN, habit of alcohol intake and nitrites in the urine were the noti-

ceable comorbidities respectively. The diabetes epidemic in South Asian countries as well as Bangladesh is related to many risk factors as well as genetic predisposition, unhealthy diet, life-style and different environmental factors [20]. A study among materialistic population in Dhaka found age and case history of diabetes disorder to be considerably related to diabetes disorder [21]. The study reportable that V-day of patients with diabetes disorder were forty years or below that is analogous to our findings (15.3% below forty years) and implies that diabetes disorder starts at a way younger age within the Bangladeshi population compared to, e.g., European countries [22]. This finding regarding the age distribution of our study was supported by various other studies as well, supporting the fact that DM is a disease of middle-aged adults [23]. Hypertension is very important comorbid of type 2 DM. In our study, 38% of type 2 DM patients had concomitant hypertension. Various studies found the prevalence of hypertension in type 2 DM patients in the range of 33% to 54% [23]. Obesity is strongly related with diabetes. Our study population had a very high prevalence of obesity. Approximately 34% of our study population had a high BMI (cut-off BMI > 27 kg/m<sup>2</sup> for obese). A study found elevated BMI in 42% of type 2 DM patients, which was comparable to our study [22]. Another study identified elevated BMI in 21% of type 2 DM patients [24]. Another study determined central obesity in 58% of type 2 DM patients [23]. However, another study found that 72% of type 2 DM patients had high WHR [24]. Various other studies also found similar results [25]. In analyzing the comorbidities among the participants, we found in 54.80%, 30.80%, 28.80%, 18.80%, 4.40% and 8.80% participants aged ≥ 50 years, tobacco smoking, family history, smoking & HTN, habit of alcohol intake and nitrites in the urine were the noticeable comorbidities respectively.

### **Limitations of the Study**

This was an observational study with a small sized sample. So, the findings of this study may not reflect the exact scenario of the whole country.

### **5. Conclusion and Recommendations**

Obesity and hypertension demand more attention of diabetologists in diagnosis and treatment of patients or suspected patients of diabetes. Patients aged ≥ 50 years are most vulnerable and suspicious for diabetes. Besides age consequence habits of tobacco smoking, family history, smoking and HTN, alcohol intake and presence of nitrites in the urine may be considered as most potential comorbidities for diabetic patients. Diagnosis of biochemical characteristics of such patients may play a vital role in proper treatment. For getting more reliable information, we would like to recommend for conducting more studies in several places with larger sized samples.

### **Conflicts of Interest**

The authors declare no conflicts of interest regarding the publication of this paper.

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