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Community-Based Correlation Study of Early Indicators of Complications amongst Asymptomatic Type-2 Diabetes Patients

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Abstract: This cross-sectional, community-based study was conducted in the area of the Urban Health Training Centre of a municipal medical college, located about 30 kms from Mumbai (India). The participants were 57 females (mean age: 63.91±8.91 years) and and 47 males (mean age: 62.13±10.16 years) with type-2 diabetes mellitus for five or more years preceding the study period but who did not have symptoms related to complications of diabetes mellitus, who gave written informed consent. The participants were interviewed using a semi-structured questionnaire. Their records of follow-up pattern were correlated with the occurrence of manifestations suggestive of early onset of common and morbid complications. Nine participants revealed maternal history of diabetes mellitus while four had a paternal history. 35 females and 38 males had no other diabetic in their families, while four patients revealed that three or more of their family members were affected. 55 (52.88%) were asymptomatic. Among the symptomatic, the complaints were weakness (18.27%), spells of fainting or giddiness (11.54%), loss of body weight (7.69%), polyuria and polydipsia (7.69%). The gender difference in the mean body mass index was statistically significant (Z=2.348; p=0.019) while that for mean systolic (Z=0.942; p=0.3472), diastolic blood pressure (Z=0.596; p=0.549), mean fasting (Z=0.399; p=0.689) and post-prandial blood sugar levels (Z=1.364; p=0.174) was not significant. As per available medical records and responses given by participants to the questionnaire, regular follow-ups were inadequate and a significant proportion was not on specific anti-diabetic medications.

Keywords: Asymptomatic, Complications, Diabetes Mellitus, Early indicators.

INTRODUCTION

About 80% of the globally estimated 366 million diabetics live in low and middle income countries and about 50% are undiagnosed. [1] The Indian Council of Medical Research India Diabetes (ICMR-INDIAB) Study estimated that 62.4 million Indians were diabetics and the weighted prevalence of the disease was 13.6%, 10.4% and 8.4% in Chandigarh, Tamil Nadu and Maharashtra, respectively [2,3].

The “Asian Indian Phenotype” (that renders Indians more prone to developing diabetes) denotes distinctive clinical and biochemical abnormalities in Indians, such as, higher waist circumference despite lower body mass index (BMI), lower adiponectin, increased insulin resistance, and higher levels of highly sensitive C-reactive protein levels [4].

Though female predisposition has been reported from north India, [5] male preponderance has been reported from south India has reported higher prevalence in males. [6] Observance of religious fasts with inadequate physical activity impedes control of diabetes among females [7]. The habit of walking barefoot, especially among the rural people increases the risk of diabetic foot ulcers [8].

Persistent dysglycemia often marks the beginning of onset of chronic complications of diabetes. Complications associated with diabetes, such as cardiovascular disease, cerebrovascular disease, nephropathy, neuropathy, and retinopathy can be delayed or prevented with suitable treatment of raised levels of blood glucose, blood pressure, and lipids [9,10]. A study from rural Goa reported that the prevalence of complications among diabetics were neuropathy (60%), coronary heart disease (32.2%), cataract (20%), and retinopathy (15.4%), peripheral vascular disease (11.5%) and stroke (6.9%) [11]. However, other Indian studies [12,13] have reported relatively lower rates of diabetic retinopathy.

Frequently, diabetes is detected while investigating cases presenting with neurological deficits, visual disturbances, or premature coronary, peripheral or cerebrovascular disease. Many early indicators of complications of diabetes that develop over time may go unnoticed if the patient does not regularly follow up or get screened for them. Since diabetes is a "silent" and insidious disease in its early stages, patients (irrespective of educational status) tend to be irregular in taking their prescribed treatment till the morbid complications manifest. These complications are mostly irreversible and sometimes, untreatable. Moreover, complications of diabetes mellitus are known to occur even among patients on regular anti-diabetic treatment [14].

This community-based study was conducted to determine the early indicators of complications amongst asymptomatic type-2 diabetes patients.

MATERIALS AND METHODS

This cross-sectional, community-based study was conducted in the area of the Urban Health Training Centre (UHTC) of a municipal medical college, located about 30 kms from Mumbai city in Western India. After obtaining permission from the Institutional Ethics Committee and the institutional authorities, the purpose of the study was explained to prospective participants. The participants included patients of either sex, diagnosed to have type-2 diabetes mellitus for five or more years preceding the study period but who did not have symptoms related to complications of diabetes mellitus and who gave written informed consent.

Patients of type-2 diabetes mellitus who were symptomatic for complications of the disease, those with raised blood urea or serum creatinine, those currently suffering from urinary tract infection, or having trophic ulcers on lower extremities or were diagnosed to have the disease for less than five years preceding the study period and those who did not give written informed consent were excluded.

Patients who satisfied the inclusion criteria and gave written informed consent (n=104) were interviewed using a semi-structured questionnaire. Their follow-up pattern was correlated with the occurrence of manifestations suggestive of early onset of common and morbid complications.

Height of participants was measured in metres with a measuring tape hoisted on a vertical wall, with the participant standing in erect position without shoes or headgear with head in Frankfort plane, feet together, heels, buttocks and upper part of the back touching the hoisted measuring tape [15]. Body weight was measured, before lunch, in kilograms using a pre-calibrated digital weighing scale (OMRON Healthcare India Pvt. Ltd., Gurgaon, Haryana), with the participant standing evenly on both feet without footwear, wearing normal indoor clothing [15]. Body Mass Index (BMI) was calculated by dividing the weight (in kilograms) by the square of the height (in metres). A BMI of 25 or more was taken as the cut-off point for defining "overweight" in both males and females [16].

To preclude instrument and observer-related variations, the systolic and diastolic blood pressures (BP) were measured by a single observer on the left brachial artery in supine position using the same pre-calibrated mercury sphygmomanometer (Diamond BPMR-120; Industrial Electronic and Allied Products, Pune-Satara Road, Pune, Maharashtra) for all participants. Systolic and diastolic BP were categorized as – normal, high normal, and mild, moderate and severe hypertension [17].

Neurological examination for fine touch and temperature was performed in the "glove and stocking" areas of the extremities. Fine touch was tested by a 5.07 gauge-10 g monofilament nylon (Atlas Biomechanics, Scottsdale, Arizona, USA) and thermal sensation by hot and cold water bulbs. Fine touch and thermal sensation were recorded as "normal" or "impaired" [18].

Blood sugar levels (fasting and post-prandial) were estimated using One Touch Select Simple handheld glucometer (Johnson & Johnson Private Limited, Jogeshwari-East, Mumbai) and urine protein excretion was determined using URI Sign Dipstick, (Savi Rapid Diagnostics Company, Sarkhej-Bavla Highway, Morriaya, Ahmedabad, Gujarat) which was provided with colour reference chart on the container for interpretation of result and recorded on the proforma.

History of follow ups done by the patient from diagnosis till date was recorded with details about symptoms, investigations done and change of treatment done, if any.

The data were statistically analyzed using EpiInfo Version 7.0 (public domain software package from the Centers for Disease Control and Prevention, Atlanta, GA, USA). Categorical data were presented as percentages and continuous data as Mean and Standard Deviation (SD). The 95% Confidence interval (CI) was estimated and stated as: [Mean-(1.96)*Standard Error)] - [Mean+(1.96)*Standard Error)]. Karl Pearson's Chi-square test with Mantel-Haenszel correction, where required, was used. The standard error of difference between two means was calculated. Statistical significance was determined at $p<0.05$.

RESULTS AND DISCUSSION

Demographic Profile

104 persons (females: n=57, 54.81%; males: n=47, 45.19%) participated in the study. The mean age of females was 63.91±8.91 (95% CI: 61.60-66.22) years, while that for males was 62.13±10.16 (95% CI:

59.23-65.03) years. The gender difference in the mean ages was not statistically significant (Z=0.94; p=0.3472). The demographic profile is depicted in Table-1. Age-wise, the maximum, median and first quartile for age was higher for females, while the minimum age was lower for females. There was no age-wise gender difference in the third quartile. (Fig-1)

Family History

Nine (26.32%) participants (females n=8, 21.05% and male n=1, 2.63%) had maternal history of diabetes mellitus while four (10.53%) participants (female n=1, 2.63% and males n=3, 7.89%) had a paternal history of diabetes mellitus. 35 (61.40%) females and 38 (80.85%) males revealed that no other family member was currently suffering from diabetes. However, 03 (05.26%) females and one male (02.13%) mentioned that three or more of their family members were affected.

Table-1: Demographic Profile

Parameter		Males (n=47)	Females (n=57)
Age	≤45 years	02 (03.51)	04 (08.51)
	46-60 years	16 (28.07)	15 (31.91)
	>61 years	39 (68.42)	28 (59.57)
Education	Illiterate	30 (52.63)	06 (12.77)
	Primary	06 (10.53)	05 (10.64)
	Secondary	20 (35.09)	25 (53.19)
	College+	01 (01.75)	11 (23.40)
Occupation	Skilled	05 (08.77)	12 (25.53)
	Semi-Skilled	01 (01.75)	03 (06.38)
	Unskilled	02 (03.51)	06 (12.77)
	Unemployed	21 (36.84)	14 (29.79)
	Other	28 (49.12)	12 (25.53)

Other = Homemaker, Retired; Figures in parentheses indicate percentages

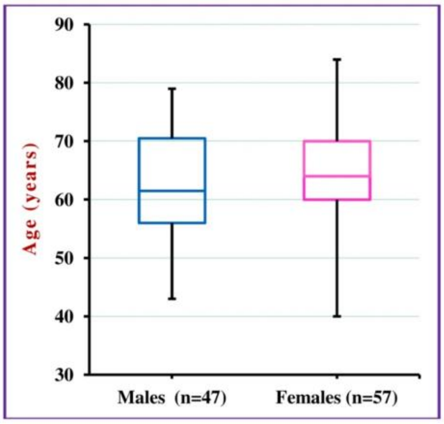

Fig-1: Age distribution of participants

Table-2: Symptoms

Parameters		Males (n= 47)	Females (n=57)	Chi square #	p value	Odds Ratio
Symptoms at interview	Spectacle change	13	10	1.503	0.216	0.556
	Tingling numbness	32	42	0.394	0.531	1.132
	Slow wound healing	17	15	1.174	0.279	1.587
	Burning micturition	22	26	0.015	0.903	0.953
Reason for check-up	Admission	3	2	0.461	0.497	0.533
	Dental extraction	2	2	0.038	0.845	0.818
	Fitness	0	2	1.665	0.197	---
	Surgery	9	14	0.438	0.508	0.727
	Routine check-up	12	9	1.517	0.208	0.547
	Onset of symptoms	21	28	0.204	0.652	1.195

Karl Pearson's Chi-square test with Mantel-Haenszel correction, where required

Symptoms

At the time of detection, 55 (52.88%) were asymptomatic. Of the 19 (18.27%) participants who complained of weakness, 8 (7.69%) were females and 11 (10.58%) were males. Out of 12 (11.54%) who reported spells of fainting or giddiness, 9 (8.65%) were females and 3 (2.88%) were males. Loss of body weight was stated by 8 (7.69%), of which 6 (5.77%) were females and 2 (1.92%) were males. 7 (7.69%) of the participants (females n=2, 1.92% and males n=5, 4.81%) complained of polyuria and polydipsia. The details of symptoms at the time of interview are outlined in Table-2.

Body Mass Index

The mean BMI for females was 26.16±3.52 (95% CI: 25.25-27.07) kg/m^2 while that for males was 24.43±3.91 (95% CI: 23.31-25.55) kg/m^2. The gender difference in the mean BMI was statistically significant (Z=2.348; p=0.019). 36 (63.15%) females and 16 (34.04%) males had a BMI higher than 25 and hence labelled "overweight". (Table 3) Among males, the maximum BMI was higher, while the third quartile, median, first quartile and the minimum BMI was lower as compared to that of females. (Fig-2) The BMI has been reported to be an independent and significant predictor of glucose tolerance in the Bedford Study [19]. A Chinese study [20] revealed that active lifestyle interventions for over 6 years can avert or defer diabetes for up to 14 years.

Table-3: Current parameters

Current parameters		Males (n=47)	Females (n=57)	Chi square #	p value	Odds Ratio
BMI (kg/m^2)	Normal	31 (65.96)	21 (36.84)	8.735	0.003	0.301
	Above Normal	16 (34.04)	36 (63.16)			
Systolic BP (mm Hg)	Normal (<130)	28 (59.57)	26 (45.61)	2.011	0.156	0.569
	Hypertensive	19 (40.43)	31 (54.38)			
Diastolic BP (mm Hg)	Normal (<80)	13 (27.66)	17 (29.82)	0.059	0.808	1.112
	Hypertensive	34 (72.34)	40 (70.18)			
Fasting BSL (mg/dl)	Normal (<120)	26 (55.32)	31 (54.39)	0.009 *	0.924	0.963
	Above Normal	21 (44.68)	26 (45.61)			
Post-prandial BSL (mg/dl)	Normal (<140)	07 (14.89)	08 (14.04)	0.015 *	0.901	0.933
	Above Normal	40 (85.11)	49 (85.96)			
Urine protein excretion	Yes	16 (34.04)	16 (28.07)	0.431	0.511	0.756
	No	31 (65.96)	41 (71.93)			

BMI = Body mass index; BP = Blood pressure; BSL = Blood sugar level
Figures in parentheses indicate percentages; * statistically significant
Karl Pearson's Chi-square test with Mantel-Haenszel correction, where required

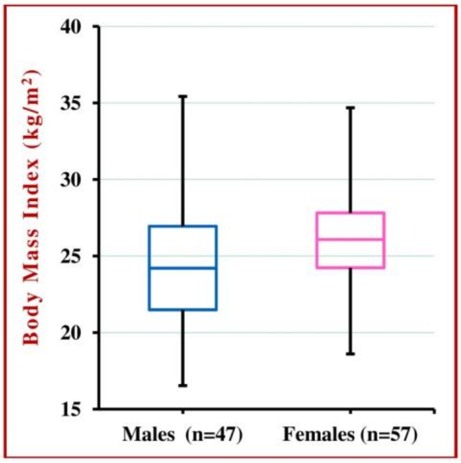

Fig-2: Box-and-Whisker Plot of Body Mass Index

Blood pressure

The mean systolic blood pressure (BP) was 128.56±13.79 (95% CI: 124.98-132.14) mm Hg and 125.74±16.26 (95% CI: 121.09-130.39) mm Hg for females and males, respectively. The mean diastolic BP among females was 80.53±9.71 (95% CI: 78.01-83.05) mm Hg while that for males was 79.45±8.75 (95% CI: 76.95-81.95) mm Hg. The gender difference in the mean systolic (Z=0.942; p=0.3472) and diastolic BP (Z=0.596; p=0.549) were not significant. 45.61% females and 59.57% males had normal systolic BP while only one woman had severe hypertension. (Table-3) The first quartile of systolic BP was identical in both sexes (120 mm Hg) while the maximum was higher in males. However, the third quartile, median and minimum was higher in females. (Fig 3) For diastolic BP, the first quartile and median was lower amongst females while the maximum, third quartile and minimum were higher as compared to that of males (Fig-3).

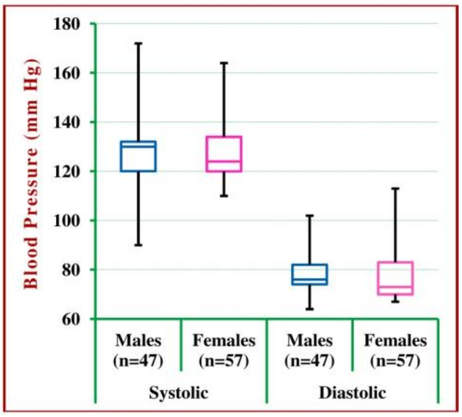

Fig-3: Systolic and diastolic blood pressure

Blood sugar levels

The mean fasting blood sugar level (BSL) was 152.46±59.4 (95% CI: 137.04-167.88) mg per deciliter and 157.57±69.19 (95% CI: 137.80-177.34) mg per deciliter for females and males, respectively. The mean post-prandial BSL among females was 211.49±81.94 (95% CI: 190.22-232.76) mg per deciliter while that for males was 237.68±108.6 (95% CI: 206.65-268.71) mg per deciliter. The gender difference between the mean fasting (Z=0.399; p=0.689) and post-prandial BSL (Z=1.364; p=0.174) was not significant. The minimum and first quartile of fasting BSL was lower for males as compared to that of their female counterparts. Though the minimum and first quartile of post-prandial BSL was identical for the two sexes, the median, third quartile and maximum post-prandial BSL was higher for males (Fig-4).

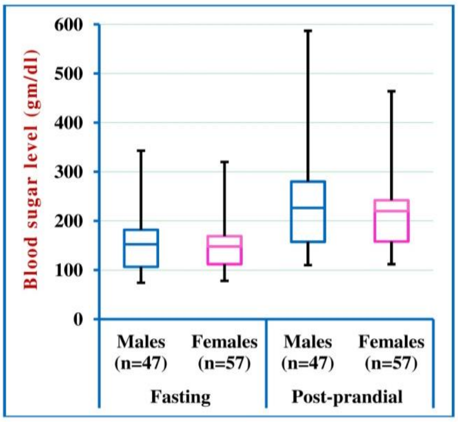

Fig-4: Fasting and post-prandial blood sugar levels

Current Treatment

5 (8.77%) females and 6 (12.76%) males were not receiving any specific treatment for type-2 diabetes mellitus. 22 (38.6%) females and 18 (38.3%) males were on single oral anti-diabetic drug, while 22 (38.6%) females and 14 (29.79) males were taking two oral anti-diabetic drugs. 3 (5.26%) females and 6 (12.77%) males were on three anti-diabetic drugs. 5 (8.77%) females and 3 (6.38%) males were on intermittent or regular insulin. The findings of another study [21] suggest treatment with diet regulation, in combination with tolbutamide, may thwart or delay progression from

impaired glucose tolerance to overt diabetes. During 10 years of post-trial follow-up in the United Kingdom, a continued reduction in risks for myocardial infarction was observed [22].

Pattern of follow-ups

65 (62.5%) of the participants had one follow up after diagnosis while 48 (46.15%) of the participants had gone for a second follow up. The follow up frequency after that steadily decreased with 25 (24.03%) of the participants having visited a physician for a 3rd follow up and only 8 (7.69%) participants had more than 3 follow ups. Cumulatively, 148 follow-up visits were undertaken by the participants while blood glucose levels were done for 126 (85.13%) of the visits, the BP was recorded during 2 (0.013%) visits. Participants had uncontrolled blood sugar at 80 (54.05%) of visits and despite that treatment was not changed in 58 (39.19%) visits. Spearman's Rank Order coefficient showed a high correlation between Systolic BP (0.98), Diastolic BP (1) taken during study and follow ups. Type-2 diabetes mellitus is known to be a silent disease manifesting with morbid complications later and more so complicating almost all co-morbidities. Regular follow ups paired with proper investigations during each follow up and a concomitant change in treatment can effectively prevent those impending complications. A high correlation between BP taken during study and increased number of follow ups can be attributed to the fact that as per available medical records, BP was not taken during routine follow ups and hence has not been treated and remained high despite a history of regular follow ups by the participant Parameters, such as, polydipsia, polyphagia, polyuria, fasting blood glucose, 2-hour postprandial blood glucose and age have been used in a proposed fuzzy hierarchical model for early detection of diabetes mellitus [23].

CONCLUSION

As per available medical records and responses given by participants, regular follow-up visits to qualified physicians were inadequate amongst patients with type-2 diabetes and a significant proportion of diabetics were not on specific medications. Blood pressure, an early indicator of cardiovascular co-morbidities, was not recorded in a substantial proportion of patients during follow-up visits. Community-based and post-diagnosis patient-specific educational interventions would be required to prevent silent progression of these co-morbidities leading to life-threatening complications.

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