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SOCIAL AND BIOLOGICAL FACTOR OF TYPE 2 DIABETES MELLITUS

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ABSTRACT: Diabetes mellitus is reaching potentially epidemic proportions in India. The level of morbidity and mortality due to diabetes and its potential complications are enormous and pose significant healthcare burdens on both families and society. In this study 400 blood serum samples were collected from various laboratories and diabetic centre in and around Tirupur, Tamil Nadu, India. Blood glucose level was estimated like Fasting Blood Glucose (FBG), Post Prandial Blood Glucose (PPBG), HbA1c and lipid content. Totally 215 (53.7%) samples were positive for diabetic. This study revealed that type 2 diabetic patients followed up in the diabetic center in Tirupur District, showed a high rate of chronic complications which often occurred in a mid age between 41 to 60 years and also hypertension and high cholesterol was not a major influence for diabetic complications. Numerous socio demographic and biological factors were significantly associated with the high rate of complications. Social and clinical factors significantly associated with high rate of complications were age between 41 to 60 years (74.87 %), male gender (61.86 %), the absence of family history of diabetes (72.09 %), and low glycated hemoglobin (HbA1c) level (79.99%).

INTRODUCTION: Diabetes mellitus (DM) is one of the most common non - communicable diseases in the world. Type 2 diabetes mellitus (DM) is a chronic metabolic disorder in which prevalence has been increasing steadily all over the world. The incidence of the disease in general population by the year 2010 was 210 million, and it is presumed to be increased to 300 million by the year 2025 [1].

India, the second most populous country of the world, has been severely affected by the global diabetes epidemic. As per the International Diabetes Federation (2015) [2, 3], approximately 50% of all people with diabetes live in just three countries like China (98.4 million), India (65.1 million) and the USA (24.4 million).

Type 2 diabetes mellitus is a growing affection with an epidemic trend that became a public health concern problem worldwide, particularly in developing countries where the estimated progression is higher than in developed countries. In India, the steady migration of people from rural to urban areas, the economic boom, and corresponding change in life-style are all affecting

the level of diabetes. Yet despite the increase in diabetes there remains a paucity of studies investigating the precise status of the disease because of the geographical, socio-economic, and ethnic nature of such a large and diverse country. Given the disease is now highly visible across all sections of society within India, there is now the demand for urgent research and intervention at regional and national levels to try to mitigate the potentially catastrophic increase in diabetes that is predicted for the upcoming years.

Type 2 DM is characterized by insulin insensitivity as a result of insulin resistance, declining insulin production, and eventual pancreatic beta-cell failure [4, 5]. This leads to a decrease in glucose transport into the liver, muscle cells, and fat cells. There is an increase in the breakdown of fat with hyperglycemia. The involvement of impaired alpha-cell function has recently been recognized in the pathophysiology of type 2 DM [6]. Type 2 DM results from interaction between genetic, environmental and behavioral risk factors [7]. The present study is to determine the rate of complications in the type 2 diabetic patients in Tirupur District, Tamil Nadu, India and to identify the factors associated to these complications.

MATERIALS AND METHODS: Totally 400 blood samples (3 to 5 ml) were drawn from each patient and control subject by vein puncture through plastic disposable syringes. The blood samples were collected in clean dried Non VAC disposable tubes. The serum was separated after centrifugation, it was transferred to clean, previously acid rinsed, washed and oven dried tubes with plastic caps. The serum should be stored at 4°C for further works. Biochemical assays on the serum was performed with a multichannel MISPA automated autoanalyzer (MISPA, Agappe Laboratories Ltd., India). Following Parameters were determined in this study like Fasting Blood Glucose (FBG), Post Prandial Blood Glucose (PPBG), HbA1c (Glycated Hemoglobin) and Total Cholesterol (TC).

The Fasting and Post Prandial blood glucose concentration was determined by using enzymatic glucose oxidase, peroxidase (GOD-POD) method [8]. Glucose oxidase catalyzes the oxidation of glucose to gluconic acid. The generation of hydrogen

peroxide is indirectly measured by oxidation of *o*-dianisidine in the presence of peroxidase. The direct enzymatic HbA1c assay was measured by fructosyl valine oxidase (FVO) method [9]. Lysed blood samples were subjected to proteolytic digestion. Glycated valines are released and serves as a substrate for fructosyl valine oxidase. The produced hydrogen peroxide is measured using a horseradish peroxidase-catalyzed reaction with achromogen. Total cholesterol was determined by an enzymatic method. The cholesterol esters are hydrolyzed to free cholesterol by cholesterol esterase. The free cholesterol is then oxidized by cholesterol oxidase to cholesten-3-one with the simultaneous production of hydrogen peroxide. The hydrogen peroxide produced couples with 4-aminoantipyrine and phenol, in the presence of peroxidase, to yield a chromogen with maximum absorbance at 505 nm [10].

RESULTS AND DISCUSSION: Indians seem to be at higher risk for diabetes. Apart from the conventional risk factors propelled by urbanization, industrialization, globalization and aging, other factors may also contribute. It has been proposed that obesity, regional adiposity, higher percentage body fat, early life influences including foetal programming and genetic factors contribute to increased risk. The variables independently associated with diabetes in adults include age, BMI, WHR, income and family history of diabetes.

TABLE 1: ASSOCIATION WITH SOCIO DEMOGRAPHIC FACTORS

S. no.	Factors	No. of patients	Rate in Percentage (%)
1	Age group		
	< 40 yrs	n=02	0.93
	41 – 50 yrs	n=74	34.41
	51 – 60 yrs	n=87	40.46
	≥61 yrs	n=52	24.18
2	Gender		
	Men	n=133	61.86
	Women	n=82	38.13
3	Family history of diabetes		
	Yes	n=60	27.90
	No	n=155	72.09
4	Diabetes duration		
	<8 yrs	n=130	60.46
	9 – 14 yrs	n=60	27.90
	15 – 18 yrs	n=41	6.51
	19 – 25 yrs	n=11	5.11

Out of 215, 115 samples were higher in average plasma glucose concentration (HbA1c). In healthy people, the HbA1c level is less than 6% of total hemoglobin. Studies have demonstrated that the complications of diabetes can be delayed or prevented if the HbA1c level can be kept below 7%.

Out of 400 samples, totally 215 (53.75 %) samples were positive for diabetic, 133 were men (61.8%) and 82 (38.1%) women. Study of factors associated with clinical and biological factors in diabetic patients shown in **Table 1** and **Table 2**. As **Table 1** showed, diabetic rate was significantly higher in men than in women and type 2 diabetic patients of 50 years or older showed higher diabetic rate.

TABLE 2: ASSOCIATION WITH CLINICAL AND BIOLOGICAL FACTORS

S. no.	Factors	No. of patients	Rate in Percentage (%)
1	Fasting Blood Glucose (FBG)		
	<110	n=73	33.90
	110 – 120	n=37	17.20
	120 – 130	n=27	12.50
	130 – 140	n=19	8.80
	>140	n=59	27.40
2	Post Prandial Blood Glucose (PPBG)		
	160 – 180	n=68	31.60
	180 – 200	n=47	21.80
	200 – 220	n=25	11.60
	220 – 240	n=21	9.70
	240 – 260	n=28	5.10
	260 – 280	n=11	5.10
	280 - >300	n=15	6.90
3	Hypertension		
	Yes	n=61	28.37
	No	n=154	71.62
4	High cholesterol		
	Yes	n=41	19.06
	No	n=174	80.93
5	Glycated hemoglobin (HbA1c) (%)		
	< 6	n=100	46.51
	6 – 7	n=72	33.48
	7 – 8	n=35	16.27
	>8	n=8	3.72

For many people with type 1 and type 2 diabetes, the goal is to keep the HbA1c levels under 7%, since keeping levels below 7 % has been shown to delay the complications of diabetes like diabetic retinopathy, nephropathy, diabetic neuropathy and macro vascular diseases. The glycated hemoglobin (HbA1c) is useful for determining blood sugar control overtime. In July 2009, the International Expert Committee (IEC) recommended the additional diagnostic criteria of an HbA1c result ≥ 6.5 % for Diabetes mellitus. This committee suggested that the use of the term pre-diabetes may be phased out but identified the range of HbA1c levels ≥ 6.0 % and < 6.5 % to identify those at high risk of developing diabetes mellitus (IEC., 2009) [21].

It can be noticed that patients without familial history of diabetes presented significantly higher rate of complications suggesting that those with familial history of diabetes are more prone to better care of their condition than the others. No correlation was recorded in hypertension and high cholesterol for type 2 diabetes mellitus **Table 2** [14, 15]. Mean age of patients of 45 ± 10 years observed

in our study is similar to what had been reported by Belkhadir *et al.*, 1993 [11] and closed to 52 years reported by Toure, 1998 [12] but lower than 62 years reported by Romom *et al.,* 2003 [13] in France, showing that in developing countries, diabetes and its complications appear in a younger age than in developed countries. Factors classically associated with high rate of complications in type 2 diabetes such as patient's age, the duration of the disease, hyperglycemia, the presence of hypertension, cholesterol and high HbA1c level have been evidenced in our study.

The frequency of hypertension in diabetic population is 28.37% in India about 50% of diabetics have hypertension [16, 17]. In the Hong Kong cardiovascular risk factor prevalence study, only 42% of people with diabetes had normal blood pressure and only 56% of people with hypertension had normal glucose tolerance [18]. In the US population, hypertension occurs in approximately 30% of patients with Type 1 diabetes and in 50% to 80% of patients with Type 2 diabetes [19, 20].

CONCLUSION: Type 2 DM is a metabolic disease that can be prevented through lifestyle modification, diet control, and control of overweight and obesity. Education of the population is still key to the control of this emerging epidemic. Novel drugs are being developed, yet no cure is available in sight for the disease, despite new insight into the pathophysiology of the disease. Management should be tailored to improve the quality of life of individuals with type 2 DM. The high prevalence of long term troubles in type 2 diabetic patients attending the diabetic treatment. It is now well known that the good control of the disease is associated with reduced problem.

As the presence of these problems is also associated with the duration of the disease, the challenge must be precocious diagnosis and tight control of diabetes. In this study, social demographic factors were associated with several aspects which are patient's age and the male gender can be underlined and family history was not influenced. In biological factors, no correlation was recorded in hyper-tension and high cholesterol but HbA1c level have been evidenced in our observation for type 2 diabetes mellitus.

CONFLICT OF INTEREST: Nil

REFERENCES:

1. Rotella D: Novel second - generation approaches for the control of type 2 diabetes. J. Med. Chem. 2004; 47: 4111.
2. International Diabetes Federation. IDF Diabetes Atlas Edition 7th, 2015. Available online: http://www.diabetesatlas.org/resources/2017-atlas.html - Accessed on 15 November 2017
3. World Health Organization. Global Report on Diabetes. 2016. Available online: http://www.who.int/diabetes/global-report/en/ Accessed on 15 November 2017.
4. Kahn SE, Cooper ME and Prato DS: Pathophysiology and treatment of type 2 diabetes: Perspectives on the past, present and future. Lancet 2014; 383: 1068-1083
5. Robertson RP: Antagonist: diabetes and insulin resistance - philosophy, science, and the multiplier hypothesis. J Lab Clin Med 1995; 125(5): 560-564, 565.
6. Fujioka K: Pathophysiology of type 2 diabetes and the role of in certain hormones and beta-cell dysfunction. JAAPA 2007; 3-8.
7. Chen L, Magliano DJ and Zimmet PZ: The worldwide epidemiology of type 2 diabetes mellitus: present and future perspectives. Nature reviews endocrinology 2011. Available at: www.nature.com/uidfinder
8. Huggett AS and Nixon DA: Use of glucose oxidase, peroxidase, and o-dianisidinein determination of blood and urinary glucose. Lancet 1957; 273: 368-70.
9. Liu L, Hood S, Wang Y, Bezverkov R and Dou C: Direct enzymatic assay for % HbA1c in human whole blood samples. Clin Biochem 2008; 41(7-8): 576-583.
10. Allain CC, Poon LS, Chan CS, Richmond W and Fu PC: Enzymatic determination of total serum cholesterol. Clin Chem. 1974; 20: 470-5.
11. Belkhadir J and El Alaoui Z: Approche épidémiologique du diabèteen milieu marocain. Médecine du Maghreb1993 37: 35-37.
12. Toure A: Suivi du diabète de type 2: Epidémiologie, traitement et evolution. These de Médecine, Université duMali 1998.
13. Romon I, Brindel P, Fagot-Campagna A and Bloch J: Analyse de la relation entre l' existence d' unepriseen charge pour affection de longue durée et le suivi des recommandations de bonnespratiquesdansle diabète de type 2. Bulletin Epidémiologique Hebdomadaire 2003; 20: 88-89.
14. World Health Organisation: Use of Glycated Haemoglobin (HbA1c) in the diagnosis of diabetes mellitus. Abbreviated Report of a WHO Consultation 2011.
15. Lozano R: Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the global burden of disease study2010. Lancet 2012; 380; 2095-2128.
16. Singh RB, Beegom R and Rastogi V: Clinical Characteristics and Hypertension among known patients of non insulin dependent diabetes mellitus in North and South Indians. J Diab Assoc India 1995; 36: 45-50.
17. Jain S and Patel JC. Diabetes and hypertension. J Diab Assoc India 1983; 23: 83-6.
18. Cheung BM: The hypertension-diabetes continuum. J Cardiovasc Pharmacol. 2010; 55: 333-9.
19. Landsberg L and Molitch M: Diabetes and hypertension pathogenesis, prevention and treatment. Clin Exp Hypertens 2004; 26: 621-8.
20. Agardh E, Allebeck P, Hallqvist J, Moradi T and Sidorchuk A: Type 2 diabetes incidence and socio-economic position: a systematic review and meta-analysis. Int J Epidemiol 2011; 40: 804-818.
21. International Expert Committee: International Expert Committee report on the role of the A1C Assay in the diagnosis of diabetes. Diabetes Care 1992; 32: 1-8.