

Original Research Article

RISK STRATIFICATION AND EVALUATION OF CLINICAL AND BIOCHEMICAL PROFILES IN TYPE 2 DIABETES MELLITUS PATIENTS AT A TERTIARY CARE CENTER

Mahesh Jayadharan¹, Hibu Geev Joseph¹, Joel Thomas¹, Balakrishnan Valliyot²

¹Junior Resident, Department of General Medicine, Govt Medical College, Kannur, Kerala, India ²Professor, Department of General Medicine, Govt Medical College, Kannur, Kerala, India

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Corresponding Author:

Dr. Mahesh Jayadharan Junior Resident, Department of General Medicine Govt Medical College Kannur, India. Email: maheshj485@gmail.com

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ABSTRACT

Background: In the last two decades, the number of patients with type 2 diabetes mellitus is showing an unpredicted increase in the world, with the maximum increase noted among the Indian population. This study was done to study the clinical and biochemical parameters of diabetics attending the hospital and stratify them according to their risk factors. The objective is to assess profile of Type 2 Diabetes Mellitus patients attending in a diabetic clinic at a tertiary care centre and stratify their risk factors.

Materials and Methods: A hospital based descriptive study was conducted among 350 diabetic patients of age between 30 to 65 attending Government Medical College, Kannur during the period between June 2019 to June 2020. All the patients after informed consent, were given a well structuredproforma. Patients were subjected for general examination, fundus examination and peripheral neuropathy examination and regular investigation like FBS, PPBS, HbA1c, Renal Profile, Urine routine and ECG was done. Patient were divided into three levels according to The Danish Risk Stratification Score. Statistical analyses were performed by using a statistical software package SPSS, version 20.0.

Results: Among 350 diabetic patients who visited in Government Medical College Kannur, 87.4% of patient had other comorbidities other than diabetes, out of which obesity was the leading comorbidity.63.7 % patient had diabetes related complications, out if which 54.9% had diabetic nephropathy. Danish Risk Stratification score was an easy to do classification for diabetes patients and it a positive correlation was seen between the level and duration of diabetes. **Conclusion:** Strict diabetic control is an important factor for control of diabetic related complications. Danish Risk Stratification Score is an easy method to classify the diabetic patients at risk of complication and to manage them accordingly.

Keywords: Gestational Diabetes, Metformin, Insulin, Glycaemic Control, Neonatal Outcomes.

INTRODUCTION

Non Communicable diseases (NCDs) encompasses a vast variety of diseases like cardiovascular diseases, diabetes, systemic hypertension, chronic respiratory diseases, cancer etc. India's burden of NCDs is escalating. NCDs are usually seem among middle aged individuals, but their onset occurs in India a decade earlier (\geq 45 years of age).^[1,2] Diabetes

mellitus is one of leading causes of mortality and morbidity worldwide. As per estimations in the year 2000, there will be an increase in diabetic patients from 171 million to 366 million in 2030, with maximum absolute rise in India from 31.7 million to 79.4 million by 2030.^[3] In latest diabetic atlas 2015, by International Diabetic Federation, it has been mentioned that worldwide diabetes prevalence is around 415 million at 2015 and will rise to 642 million by 2040. In India the prevalence for year 2015 was 69.2 million, which was more than what was expected and is estimated to reach 123.5 million by 2040.^[4] This change in trend shows the rapid upsurge in the number of diabetic patients in worldwide, especially in India. The first nationwide study on the prevalence of Type 2 diabetes mellitus (T2DM) reported 2.1% and 1.5% prevalence in the urban and rural populations of India, respectively. The recent NCD risk factor surveillance (from five states), estimated self-reported diabetes in urban areas (7.3%), peri-urban/slum (3.2%), and rural areas (3.1%).^[5] These datas show that there is an alarming rise not only the urban population but also among the rural population.

Type 2 Diabetes mellitus is a multifactorial disease and development of T2D is the result of interaction between environmental factors and a strong hereditary component. Genetic factors may have to be modified by environmental factors for diabetes mellitus to become overt. An individual with a susceptible gene may become diabetic if environmental factors modify the expression of these genes.^[6] These genetic predisposition has increased the number of young people getting affected by Type 2 Diabetes mellitus. Early onset of disease will lead to early development of complication, thus increasing morbidity and mortality of diabetes mellitus. These concerns show the need of early screening and case detection and intervention among the population. There are very few studies which have focused these issues in our population.

MATERIALS AND METHODS

A hospital based observational descriptive study was conducted among diabetes patients attending Medicine outpatient and inpatient department and diabetic clinic in a tertiary care centre of Government Medical College Kannur, Pariyaram, Kerala, India. The study was conducted over a period of one year from June 2019 to June 2020.

Sample size estimation-

Based on Prevalence

n = 4 p x q

d2 Where,

p= prevalence of disease q= 1-prevalence of disease d= absolute precision = 5% Confidence level = 95% p = $32.8\%^{[7]}$ so, n = $4 \times 32.8 \times 67.2$ 25

 $= 352.67 (\approx 350)$

Sample size was taken as 350.

All type 2 diabetes mellitus patients in the age group of 30 to 65 years attending in the outpatient, inpatient and diabetic clinic of Government Medical College Kannur will be selected for the study. Diagnosis of Type 2 diabetes mellitus is by the American Diabetic Association Criteria FPG>/=126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h.

2-HPG >/= 200mg/dL (11.1mmol/L) during OGTT. The test shouldbe performed as described by the WHO, using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water. OR

A1C >/= 6.5% (48 mmol/mol). The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay. OR

In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose >/= 200 mg/dL (11.1 mmol/L).

Inclusion Criteria

- Age 30 Years to 65 Years
- Known case of Diabetes Mellitus

Exclusion Criteria

- Known case of other endocrine diseases like thyroid dysfunction, Cushing syndrome etc.
- Chronic tobacco usage
- Previously diagnosed of complications of diabetes mellitus
- Pregnant Women

Study Procedure

Informed consent was taken from all participants in this study. A well structured and validated proforma was used for collecting the data. Proforma, was completed from the data provided by the patient or the bystander in case the patient is unable to provide the necessary information. Socio- demographic details were recorded. Details regarding type 2 diabetes mellitus- duration of diabetes, family history, daily activity were recorded. All patients were subjected to general examination, fundus examination and peripheral neuropathy examination. Relevant investigations including FBS, PPBS, HbA1c, Renal profile, Urine PCR and ECG were done. All the datas were entered in the proforma.

The subjects were stratified in to three levels according to The Danish Risk Stratification Model,^[8] according to their HbA1c level, Blood pressure and their microvascular and macrovascular complications.

Statistical Analysis: The data was entered in Excel spread sheet. Categorical and quantitative variables were expressed as frequency (percentage) and mean \pm SD respectively. Chi-square test was used to association of score with selected variables. For all statistical interpretations, p<0.05 was considered the threshold for statistical significance. Statistical analyses were performed by using a statistical software package SPSS, version 20.0.

RESULTS

The study included population between ages of 30 and 65. 8.28% was from age 31 to 40, 33.4% was between 41 to 50, 34.2% was between 51 to 60, 15.7% was between 61 to 65. The mean age of sample

is 52.73 and Standard deviation is 8.34. Total sample taken was 350 which included 190 males (54.3 %) and 160 females (45.7%). With a male to female ratio

of 1.18:1. 53.7 % of total sample belonged to rural population and 46.3% belonged to urban population.

| Table 1: Percentage distribution of the sample according to age and Sex. | | | | |
|--------------------------------------------------------------------------|------------------|---------|--|--|
| Age | Frequency | Percent | | |
| 31 - 40 | 29 | 8.28 | | |
| 41 - 50 | 117 | 33.4 | | |
| 51 - 60 | 120 | 34.2 | | |
| 61 - 65 | 55 | 15.71 | | |
| Mean \pm SD | 52.73 ± 8.34 | | | |

| Table 2: Percentage distribution of the sample according to waist. | | | | | |
|--------------------------------------------------------------------|-----------|---------|--|--|--|
| Waist circumference (cm) (57) | Frequency | Percent | | | |
| Low risk (<80cm female, < 94 cm male) | 85 | 24.3 | | | |
| Increased risk(80cm to 87.9 cm female, 94 to 101.9cm male) | 219 | 62.6 | | | |
| High risk(>88 cm female , >102 cm male) | 46 | 13.1 | | | |

29.7 % patient had normal BMI (18.5 to 24.9), 58.6% of sample were overweight (BMI 25 to 29.9) and 11.7% of patients were obese (BMI more than 30). 24.3% of patients had a waist circumference less than 94 cm for males and 80cm for females. 62.6% of

patients had a waist circumference in between 94 to 101.9cm for males and 80 to 87.9cm for females. 13.1% of patients had waist circumference more than 120cm for males and more than 88cm for females.

| Table 3: Complications of Diabetes | | | | |
|------------------------------------|-----------|---------|--|--|
| Co morbidity | Frequency | Percent | | |
| Cardiac H/o | 143 | 40.9 | | |
| Retinopathy | 172 | 49.1 | | |
| Neuropathy | 106 | 30.3 | | |
| Nephropathy | 192 | 54.9 | | |

Out of the total sample, 40.9 % of patients had history of cardiovascular disease, 49.1% had diabetic retinopathy, 30.3% had diabetic neuropathy and 54.9% had diabetic nephropathy. Out of 49.1% who had diabetic nephropathy, 24.9% had simple retinopathy, 17.4% had non progressing diabetic retinopathy and 6.9% had proliferative retinopathy. Out of 30.3% of the patients who had diabetic nephropathy, 4.9% had diabetic ulcer. 54.9% of the total sample had diabetic nephropathy, of which 37.7% had microalbuminuria and 17.1% had macroalbuminuria.

| Table 4: Percentage distribution of the sample according to score | | | | |
|-------------------------------------------------------------------|-----------|---------|--|--|
| Score | Frequency | Percent | | |
| 1 | 100 | 28.6 | | |
| 2 | 138 | 39.4 | | |
| 3 | 112 | 32.0 | | |
| | | | | |

Out of the total sample 28.6% had score one of Danish risk stratification score, 39.4% had score two and 32 % had a score of three.

| Table 5: Association of Score with duration of diabetes | | | | | | | | | |
|---------------------------------------------------------|--------|-----------|---------|-----------|---------|-----------|---------|--------|--------|
| 1 | | 2 | | 3 | | □2 | Р | | |
| | | Frequency | Percent | Frequency | Percent | Frequency | Percent | | |
| Duration of | <=5 | 97 | 45.8 | 86 | 40.6 | 29 | 13.7 | 116.07 | p<0.01 |
| diabetes | 6 - 10 | 3 | 3.2 | 39 | 41.9 | 51 | 54.8 | | |
| | >10 | 0 | 0.0 | 13 | 28.9 | 32 | 71.1 | | |

Out of 350 subjects, 12.9% had duration of diabetes more than 10 years. Out of which 71.1 % was stratified into level 3 of The Danish risk stratification score. The p value was <0.01 which shows a significant relation between duration of diabetes and development of uncontrolled diabetes and diabetes related complications, which was reflected as higher level of Danish risk stratification score.

DISCUSSION

The study was conducted in Government Medical College Kannur over a period of 1 year from June 2019 to June 2020. This study was conducted among the diabetic patients attending hospital. In this study there was a male predominance in diabetes with a male: female ratio of 1.18. According to results, highest prevalence of diagnosed cases of type 2 DM is found in the age group of 51-60 (n=120) constituting 34.2% of the study population. The mean age of study population was 52.73 with a standard

deviation of 8.34 and included patients with age group extending from 30 to 65. Similar Indian study done by Evaru S, had mean age of 49.2 with maximum number of people belonging to age group of 40 to 50.^[9] 60.6 % of patients had duration of diabetes less than 5 years and 26.6% had duration between 6 and 10 years and 12.9% had duration more than 10 years, the mean duration of 5.5 years and standard deviation of 4.4. In a study conducted by Ramesh et al, maximum number of patients had duration of diabetes between 5 to 10 years.^[10]

In our study 63.7% of individuals had complications of diabetes. 40.9% had cardio vascular disease, 54.9% had diabetic nephropathy with 37.7% had microalbumiuria and 17.1% had macrolbumiuria, 30.3% had diabetic neuropathy and 49.1% had diabetic retinopathy. A study conducted by Nagarajan Natarajan et al recorded 95.6% its population having diabetes related complication.^[11] A study conducted by Maniarsu K et al had 59% of population having diabetic neuropathy and 41.1% having diabetic nephropathy, which had more number of patients with diabetic neuropathy.^[7] A study conducted by Khadraoui E had diabetic retinopathy in 47.5% of its study population which is similar to ours.^[12]

The population was stratified into three levels according to the Danish risk stratification score. 28.6% of population belonged to level 1, 39.9% belonged to level 2 and 32% belonged to level 3. A study done by Munch L, Arreskov AB, Sperling M et al. among Danish specialised outpatient clinic, 16% of patient belonged to level 1, 55 % belonged to level 2 and 29% belonged to level 3.^[13]

It is evident from the results that level of Danish risk stratification score had a positive correlation with the duration of diabetes with a p value less than 0.01. 70% of patients who had duration of more than 10 years belonged to level 3 of Danish risk stratification score. This shows a positive correlation between duration of diabetes and poor glycaemic control as years pass by and with duration of diabetes and the occurance of various complications due to diabetes. Similar results were shown in a thirty-year observational study conducted by The Diabetic Control and Complication Trial,^[14] where there was increased rates of poor glycaemic control and increased incidence of diabetes related complications among the subjects.

Our study included only 350 patients. As compared with the prevalence of diabetes sample size is less. Out study was conducted in a Tertiary care centre, so patients presented here had uncontrolled diabetes and diabetic related complications and could not represent a true picture of population.

CONCLUSION

The study showed a mean age of study population to be 52.73 and the mean duration of diabetes was 5.5 years, this shows an early age of occurrence of T2DM among the population and the need for early screening and diagnosis of diabetes. 87.4% of the study population had comorbidities other than diabetes, out of which obesity was the leading comorbidity. This shows how T2DM is not just hyperglycaemia but a syndrome with multiple comorbidities affecting the individual. 63.7% of study population had diabetes related complications, of which 54.9% had diabetic nephropathy.

The Danish Risk Stratification score was an easy to do, OP basis scoring system according to which the diabetic population could be stratified. Our study showed maximum number of patients in level 2 and level 3. There was a positive correlation between the duration of diabetes and poor glycaemic control and incidence of diabetic related complications. The scoring system proved to very effective in classifying the patients and thereby helping in target allocation of medical care according to individual need of patient with the existing medical resources.

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