STUDY OF ANTHROPOMETRY, VITAMIN D LEVELS AND MAGNESIUM IN NEWLY DIAGNOSED TYPE 2 DIABETES MELLITUS PATIENTS

Original Research Article

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Abstract

Background: The extra-skeletal effects of Vitamin D have attracted considerable interest in the recent years. Deficiency of Vitamin D is emerging as one of the important nutritional risk factors for development of insulin resistance and Type 2 Diabetes Mellitus. Besides being a frequently encountered electrolyte disorder in diabetic patients, hypomagnesaemia has been implicated as a contributory factor in various long term complications of diabetes mellitus. Hypomagnesaemia through its association with insulin resistance and carbohydrate intolerance has been associated with worsening diabetes. **Materials and Methods:** We conducted this hospital based cross-sectional comparative study on newly diagnosed Type 2 Diabetes Mellitus patients over a period of 1 year from July 2022 to June 2023 in a tertiary care hospital in the State of Bihar in India. The study commenced after obtaining proper Institutional Ethics Committee approval in type 2 Diabetes Mellitus patients between 30-60 years age, of either sex or who were to be started on treatment for Type 2 Diabetes Mellitus. **Result:** A total of 220 patients were screened of which 110 patients were enrolled for the study. Thus the prevalence of new onset Type 2 Diabetes Mellitus among the Study Group in the age range of 30-60 years was 28.17%. The study population included 220 individuals. Out of 220, 110 new onset Type 2 Diabetes Mellitus patients (Cases) and 110 non Type 2 Diabetes Mellitus individuals (Controls)]. The mean age of the cases (new onset Type 2 Diabetes Mellitus) was 51.23 years (+6.04 SD) and the mean age of the controls (individuals without Type 2 Diabetes Mellitus) was 50.74 years (+5.04 SD). **Conclusion:** The study thus recommends routine screening of Vitamin D and Magnesium levels in newly diagnosed Type 2 Diabetes Mellitus patients.

INTRODUCTION

Type 2 Diabetes Mellitus is a metabolic disorder characterized by hyperglycaemia which arises due to inability of the body to use insulin properly. Its prevalence is increasing not only in developed nations but also in the developing world. The diabetic population is expected to exceed double by 2030 from 171 million to a remarkable 366 million worldwide with ninety percent being Type 2 Diabetes Mellitus.[1,2] If untreated, Type 2 Diabetes Mellitus can increase the burden of chronic micro vascular and macro vascular conditions like retinopathy, nephropathy, neuropathy and cardiovascular disease (CVD).[3]

India contributes to a major part of the global burden of Type 2 Diabetes Mellitus. India being home to 69.1 million diabetics, ranked second highest after China in terms of the population with Type 2 Diabetes Mellitus in 2015.[4,5] In India, the prevalence of Diabetes Mellitus ranges between 5–17%, with higher prevalence rates in the southern parts of the country and in urban areas.[6-8] Progressive cultural and social changes like ageing populations, increasing urbanization, dietary changes, reduced physical activity and unhealthy behaviour contribute to the increasing trends of Diabetes Mellitus. As per recent epidemiological data the rising trend in the incidence of Diabetes Mellitus transcends the affluent class affecting urban India's middle class and working poor equally. Indians are genetically more predisposed to diabetes and have a greater degree of insulin resistance.[9,10]

The magnitude of the Type 2 Diabetes Mellitus epidemic with the burden it poses on the individuals and the society at large, stresses on the importance of finding ways to prevent and ameliorate the

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deleterious effects of this disease.[11,12] Type 2 Diabetes Mellitus has a multi-factorial pathogenesis with complex interplay between the potential causes. In addition to genetics which predisposes individuals to developing Type 2 Diabetes Mellitus, other factors like physical inactivity, poor nutrition practices and obesity, insulin resistance, deranged fatty acid metabolism, mitochondrial dysfunction and endoplasmic reticulum stress potentiate Type 2 Diabetes Mellitus through complex interactions many of which are unclear and are merely postulated. Moreover increasing evidence suggests that deficiency of Vitamin D and Magnesium may also contribute to the pathogenesis of Type 2 Diabetes Mellitus.[13,14]

The extra-skeletal effects of Vitamin D have attracted considerable interest in the recent years. Deficiency of Vitamin D is emerging as one of the important nutritional risk factors for development of insulin resistance and Type 2 Diabetes Mellitus. Its association has also been implicated in poor glycemic control and progression of complications among patients of Type 2 Diabetes Mellitus. In India, despite adequate exposure to sunlight throughout the year, deficiency of Vitamin D among Indians is a well-documented fact. The relationship of Vitamin D and Type 2 Diabetes Mellitus gains paramount importance with the surge in both Type 2 Diabetes Mellitus and hypo-vitaminosis D among Indians. Vitamin D directly stimulates insulin secretion from beta cells of pancreas, increases intracellular calcium levels, which attenuates insulin synthesis, improves insulin sensitivity in peripheral muscle and fats cells and plays important roles in glucose metabolism. Growing evidences suggest an association between vitamin D deficiency and an increased risk of developing Type 2 diabetes.[15-17]

Diabetic patients often develop electrolyte disorders with diverse pathophysiology which may increase the morbidity and mortality associated with Type 2 Diabetes Mellitus. These electrolyte disturbances though are more common in decompensated diabetics, in elderly diabetics and diabetic patients with renal impairment but may also be observed in new onset diabetes mellitus subjects. Besides being a frequently encountered electrolyte disorder in diabetic patients, hypomagnesaemia has been implicated as a contributory factor in various long-term complications of diabetes mellitus. Hypomagnesaemia through its association with insulin resistance and carbohydrate intolerance has been associated with worsening diabetes. This insight can pave way for pathophysiology-directed therapy, thus contributing to the avoidance of the several ominous effects associated with hypomagnesaemia and its treatment.[18]

Objective
To study the prevalence of Vitamin D deficiency in newly diagnosed Type 2 Diabetes Mellitus patients and its relation with insulin resistance and insulin secretion defect.

To study the prevalence of Magnesium (Mg) deficiency in newly diagnosed Type 2 Diabetes Mellitus patients and its relation with insulin resistance and insulin secretion defect.

MATERIALSANDMETHODS

We conducted this hospital based cross-sectional comparative study on newly diagnosed Type 2 Diabetes Mellitus patients over a period of 1 year from July 2022 to June 2023 in a tertiary care hospital in the State of Bihar in India. The study commenced after obtaining proper Institutional Ethics Committee approval in Diabetes Mellitus patients between 30-60 years age, of either sex or who were to be started on treatment for Type 2 Diabetes Mellitus. Patients with Type 1 Diabetes Mellitus or other forms of Diabetes; Patients with known history of Type 2 Diabetes Mellitus; Patients with known history of Hypertension; Patients with complications of Type 2 Diabetes Mellitus like Retinopathy, Neuropathy and Nephropathy; Geriatric patients> 60 years who may have associated hypo-vitaminosis D and electrolyte disorders which are age related; Patients with known Vitamin D deficiency; Patients with known electrolyte disorders; Patients who refused to participate in the study were excluded from the study.

Sample Size and Study Group
The required sample size was calculated as 110 cases and 110 controls rounding to the next nearest number, using the formula suggested for case-control studies, and hypothesizing that almost 30% of the study population were diabetics.

A total of 220 patients were screened from the outpatient unit of the Department of Medicine based on inclusion and exclusion criteria. Out of this, 110 patients were enrolled for the study after each one of them went through the Patient Information Sheet and consented by signing the Informed Consent Form in the local language. All the 220 enrolled study participants underwent estimation of Vitamin D levels, Serum Mg, Fasting Blood Sugar, Post Prandial Blood Sugar, Fasting Insulin levels and Glycosylated haemoglobin (HbA1C). The investigations were conducted in the Department of Biochemistry, NMC, Patna, Bihar.

Criteria of the different parameters in the study
Patients were considered having Type 2 Diabetes Mellitus based on the American Diabetes Association (ADA) guidelines if the patient fulfilled any one of the following criteria (on two occasions in two consecutive days).

- A fasting blood sugar ≥ 126 mg/dl (7.0 mmol/l). The definition of "Fasting" was the first test in the morning before breakfast with no calorie intake except water for at least 8 hours
- HbA1C ≥ 6.5%
- 2 hour blood sugar ≥ 200 mg/dl (11.1 mmol/l) after an oral intake of 75 gms glucose dissolved in water.
- For the purpose of this study, 25-hydroxy vitamin D below 30 ng/ml was considered low [19].

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- Patients with serum Mg concentrations of ≤1.5 mg/dl were considered to have frank hypomagnesaemia. While Mg concentrations of ≤1.8 mg/dL were considered as preclinical hypomagnesaemia.[20]
- Insulin levels are proportional to blood glucose levels in normal healthy individuals. However, insulin levels are either high or normal in the initial stages of Type 2 Diabetes Mellitus while insulin levels are low in the secondary stage of Type 2 Diabetes Mellitus.
- Insulin Resistance (IR) and beta-cell function for the purpose of this study was calculated as below using the following simple indices:
- HOMA-IR: Fasting glucose (mmol/L) ×fasting insulin (μU/mL)/22.5.[20]
- HOMA-B: 20 × fasting insulin (μU/ml)/fasting glucose (mmol/L) − 3.5.
- Insulin resistance was considered in patients when HOMA-IR was ≥2.6.

Sample collection and processing

A total of 7 ml of venous blood was withdrawn and divided in the Glucose vial, Clot vial and the EDTA (Ethylenediamine Tetra-Acetic Acid) vial. The EDTA blood sample was used for doing HbA1C

assay. Investigations were carried out using standard techniques. Fasting and Post Prandial Plasma Glucose and Serum Magnesium estimation was performed using Standard Colorimetric techniques. Serum Vitamin D level estimation, and Insulin levels were done by ECLIA (Electrochemiilluminiscence immunoassays) method. HbA1C was done by HPLC (high performance liquid chromatography) method.

RESULTS

A total of 220 patients were screened of which 110 patients were enrolled for the study. Thus the prevalence of new onset Type 2 Diabetes Mellitus among the Study Group in the age range of 30-60 years was 28.17%.

The study population included 220 individuals. Out of 220, 110 new onset Type 2 Diabetes Mellitus patients (Cases) and 110 non-Type 2 Diabetes Mellitus individuals (Controls)].

The mean age of the cases (new onset Type 2 Diabetes Mellitus) was 51.23 years (+6.04 SD) and the mean age of the controls (individuals without Type 2 Diabetes Mellitus) was 50.74 years (+5.04 SD).

Table 1: Distribution of patients according to sex.

Sex	Case	Percentage	Control	Percentage	p value
Male	50	45.45%	53	48.18%	0.212
Female	60	54.54%	57	51.12%	
Total	110	100%	110	100%	

There were 60 (54.54%) females and 50 (45.45%) males in the cases (new onset Type 2 Diabetes Mellitus), whereas 57(51.12%) females and 53 (48.18%) males in controls (without Type 2 Diabetes Mellitus).

Table 2: Baseline and demographic characteristics of the study group.

Parameter	Case (Mean±SD)	Control(Mean±SD)	t value,df	p value
Age (years)	51.23±6.04	50.74±5.04	-0.144,116	0.778
25-Hydroxy VIT D (ng/ml)	27.15±12.15	39.04±20.15	5.440,116	0.000
Mg(mg/dL)	02.00±0.18	2.24±0.15	11.874,116	0.000

Table 3: Distribution of serum 25-Hydroxy Vitamin D level of the study group.

	Case			Control			p value
	Male	Female	Total	Male	Female	Total	
Normal (≥30 ng/ml)	24(63.15%)	14(36.84%)	38(34.54%)	32(61.53%)	20(38.46%)	52(47.27%)	0.000
Low (<30ng/ml)	27(37.50%)	45(62.50%)	72(65.45%)	23(39.65%)	35(60.34%)	58(52.72%)	0.000
Total	50(45.45%)	60(54.54%)	110(100%)	53(48.18%)	57(51.81%)	110(100%)	0.000

Table 4: Distribution of serum magnesium (Mg) level of the study group.

	Case			Control			p value
Parameter	Male	Female	Total	Male	Female	Total	
Normal (≥1.8 mg/dl)	43 (48.31%)	46 (51.68%)	89 (80.90%)	53 (48.18%)	57 (51.18%)	110 (100%)	0.000
Preclinical hypomagnesaemia (1.5 mg/dl)	7 (33.33%)	14 (66.66%)	21 (19.09)	0	0	0	0.000
Frank hypomagnesaemia (≤ 1.5 mg/dl)	0	0	0	0	0	0	0.000
Total	50 (45.45%)	60 (54.54%)	110 (100%)	53 (48.18%)	57 (51.18%)	110 (100%)	0.000

Table 5: Multivariate analysis with HbA1C, HOMA-IR and HOMA-B and Age, Sex, 25-hydroxy vitamin D and Mg level.

Variables	Determinants	p value
HbA1C	Age	0.64
	Sex	0.104

	25-Hydroxy VITD level	0.000
	Mg level	0.000
HOMA-IR	Age	0.788
	Sex	0.245
	25-Hydroxy VITD level	0.000
	Mg level	0.144
HOMA-B	Age	0.334
	Sex	0.578
	25-Hydroxy VITD level	0.001
	Mg level	0.034

DISCUSSION

Demographics

We enrolled 220 participants in our study who were divided into two groups, of CASE (having new onset Type 2 Diabetes Mellitus) and CONTROL (nondiabetic individuals) with each group containing 120 participants. The mean age of the Cases was 51.23 years (+6.04 SD) while that of the Controls was 50.74 years (+5.04 SD).

[Table 1] There were 60 (54.54%) females and 50 (45.45%) males in the cases (new onset Type 2 Diabetes Mellitus), whereas 57(51.12%) females and 53 (48.18%) males in controls (without Type 2 Diabetes Mellitus) respectively with P value of 0.212.

[Table 2] The mean age of the cases (new onset Type 2 Diabetes Mellitus) was 51.23 years (+6.04 SD) and the mean age of the controls (individuals without Type 2 Diabetes Mellitus) was 50.74 years (+5.04 SD).

25-hydroxy vitamin D and new onset Type 2 diabetes mellitus

[Table 3] Among the Cases, 25-Hydroxy Vitamin D was normal in 34.54% (38) out of which 36.84% (14) were females while 63.15% (24) were males while among the Controls, 25-Hydroxy Vitamin D was normal in 47.27% (52) out of which 38.46% (20) were females while 61.53% (32) were males. 25-Hydroxy Vitamin D was low in 65.45% (72) of the cases out of which 62.50% (45) were females while 37.50% (27) were males while among the controls 25-Hydroxy Vitamin D was low in 52.75% (58) out of which 60.34% (35) were females while 39.65% (23) were males.

Mean of 25-hydroxy Vitamin D for the Cases is 27.15 ng/ml (+12.15 SD) while the mean among Controls is 39.04 ng/ml (+20.15 SD). This difference is statistically significant with a P value of 0.000.

In a study by Kumar PS, 25-Hydroxy Vitamin D deficiency was observed in 52.5% of the patients. However, in this study 25-Hydroxy Vitamin D levels were not associated with markers of glycemic control or insulin resistance. This study concluded that hypo-vitaminosis D was observed in more than half of the patients with type 2 diabetes suggesting a potential for vitamin D supplementation in type 2 DM patients.[20]

Magnesium and new onset Type 2 diabetes mellitus

Table 4 shows : Among the Cases, Mg level was normal in 80.90% (89) out of which 51.68% (46) were females while 48.31% (43) were males, 19.17% (23) cases had preclinical hypomagnesemia of which 66.66% (14) was a female while 33.33% (07) were males, while there were no cases of frank hypomagnesemia. Among the Controls, Mg level was normal all 100% (110) out of which 51.18% (57) were females while 48.18% (53) were males.

Mean of level of Mg for the Cases is 02.00 mg/dl (+0.18 SD) while that among Controls was 2.24 mg/dl (+0.15 SD). This difference was statistically significant with a P value of 0.000.

Prevalence of new onset Type 2 diabetes mellitus as per the Diabetes Atlas 2019, the prevalence of Diabetes in India is 8.9%. The prevalence of Diabetes Mellitus in India ranges from 5–17%, with higher levels found in the southern parts of the country and in urban areas.[7,8] As per the India State-Level Disease Burden done as a part of the Global Burden of Diseases, Injuries, and Risk Factors Study (GBD) 2016, the crude prevalence of diabetes in adults aged 20 years or older in Bihar in 2016 shows a rate of 20.0-27.9%. 11 In our study we found that the prevalence of new onset Diabetes Mellitus in the age group of 30-60 years was ---28.17%.

CONCLUSION

The study concluded Serum 25-Hydroxy Vitamin D was low in 65.83% of the Cases while it was low in 52.5% of the Controls. 25-Hydroxy Vitamin D is significantly negatively correlated with HbA1C, HOMA-IR and HOMA-B. 25-Hydroxy Vitamin D levels were found to be significantly low in new onset Type 2 Diabetic Mellitus patients and thereby can be considered a determinant for the development and worsening of glycemic status in new onset Type 2 Diabetes Mellitus patients.

The prevalence rate of pre-clinical hypomagnesaemia among the Cases was 19.17% while there were no cases of pre-clinical hypomagnesaemia among the Controls. Serum Magnesium level was significantly negatively correlated with HbA1C, HOMA-IR and HOMA-B and can be considered a significant determinant for the development and worsening of glycemic status in new onset Type 2 Diabetes Mellitus patients.

The study thus recommends routine screening of Vitamin D and Magnesium levels in newly diagnosed Type 2 Diabetes Mellitus patients.

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