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Thyroid Dysfunction in Patients with Metabolic Syndrome with special reference to Diabetes Mellitus

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Introduction

Diabetes Mellitus (DM) is a significant global contributor to health complications and mortality across various populations. Thyroid disorders are prevalent within the general population, ranking as the second most common endocrine condition. It is not unusual for individuals to experience both thyroid dysfunction and diabetes simultaneously. Emerging research highlights a complex interplay between thyroid hormones (TH), mechanisms regulating appetite and energy expenditure, and the modulation of insulin sensitivity and secretion. There is growing evidence that insulin sensitivity and medications targeting it can influence thyroid growth and function. A clearer understanding of the relationship between DM and thyroid hormones is essential to enhance the management and treatment of diabetes.

Aims and Objectives

1. To analyze the prevalence of thyroid dysfunction in the metabolic systems of patients with Type 2 Diabetes Mellitus.
2. To examine the characteristics and patterns of thyroid dysfunction in these individuals.

Materials and Methods

This cross-sectional observational study was conducted over 18 months and included 230 participants from the outpatient clinics and wards of the Medicine Department at TD Medical College, Alappuzha, who met the diagnostic criteria for Type 2 Diabetes Mellitus. A comprehensive evaluation, including detailed history and clinical examination, was performed. Thyroid function tests were carried out, and the data collected were recorded using a structured proforma. The information was entered into Microsoft Excel and analyzed using SPSS software. Statistical significance was determined at a p-value of <0.05, and the results were analyzed using chi-square tests for correlation.

Aim and Objectives of the Study

Primary Objective

To assess the prevalence of thyroid dysfunction in individuals with Type 2 Diabetes Mellitus.

Secondary Objective

To evaluate the characteristics and patterns of thyroid dysfunction in these patients.

Methodology

Study-Design

A hospital-based, cross-sectional observational study.

Study-Duration

18 months, from January 2018 to June 2019, following the approval of ethical clearance.

Study-Setting

The study will involve patients diagnosed with Type 2 Diabetes Mellitus who attend the outpatient department or are admitted to the wards of the General Medicine Department at TDMC, Alappuzha.

Sample Size

- Based on a recent study conducted in India, the prevalence of thyroid dysfunction among individuals with Type 2 Diabetes Mellitus was reported to be 25%.
- The sample size was calculated using the formula: $n = 4pq/d^2$
    - p = 25 (prevalence rate in percentage)
    - q = 100 - p = 75 (complement of prevalence)
    - d = 20% of p = 5 (acceptable margin of error)
- Substituting the values into the formula: $n = (4 \times 25 \times 75) / (5 \times 5) = 300 / 25 = 240$
- Thus, the required sample size for the study is calculated to be 240 participants.

Sampling-Method

A consecutive sampling technique was employed.

Study-Population

The study included 240 patients who visited the Medicine Outpatient Department or were admitted to the General Medicine Department at TDMC, Alappuzha, during the study period, and met the inclusion and exclusion criteria.

Inclusion Criteria

- Individuals aged 18 years and above diagnosed with Type 2 Diabetes Mellitus, including newly diagnosed cases, attending the Medicine OPD or admitted to the General Medicine wards at TDMC.
- Patients with diabetes, irrespective of their glycemic control.
- Patients with diabetes, regardless of their treatment method (oral hypoglycemic agents or insulin).

Exclusion Criteria

- Individuals with Type 1 Diabetes Mellitus.
- Patients with a history of thyroid disease.
- Individuals diagnosed with chronic kidney disease or diabetic nephropathy.
- Patients with acute medical conditions such as sepsis, acute myocardial infarction, severe heart failure, or recent admission to the intensive care unit.
- Individuals with hepatic dysfunction.
- Patients with psychiatric disorders.
- Pregnant individuals.
- Patients taking medications known to affect thyroid function, including amiodarone, propranolol, corticosteroids, and oral contraceptives.

Method of Data Collection

- Participants were enrolled based on the inclusion and exclusion criteria.
- After obtaining informed and written consent, a structured proforma was provided to collect detailed medical history and physical examination data.
- Basic laboratory investigations, including CBC, ESR, RBS, RFT, LFT, serum electrolytes, and chest X-ray, were documented in the proforma. Thyroid function tests, including serum FT3, FT4, and TSH, as well as serum cholesterol levels, were conducted.
- Thyroid function test results were analyzed and categorized into five groups: normal,

overt hypothyroidism, subclinical hypothyroidism, overt hyperthyroidism, and subclinical hyperthyroidism.
- Correlations were evaluated between the prevalence of thyroid dysfunction and factors such as gender, age, hypercholesterolemia, hypertension, family history of diabetes, and body mass index.

Case Definition of Type II Diabetes Mellitus
Patients were diagnosed according to the American Diabetes Association (ADA) criteria:
- Symptoms of diabetes along with a random blood glucose level of 10.0 mmol/L (180 mg/dL) or higher, or
- Fasting plasma glucose of 6.5 mmol/L (117 mg/dL) or higher, or
- Two-hour plasma glucose of 10.0 mmol/L (180 mg/dL) or higher during an oral glucose tolerance test (OGTT).

- **Systemic Hypertension (As per JNC VII Guidelines)**
  Subjects were considered hypertensive if they were on antihypertensive medications or had a systolic blood pressure of ≥135 mmHg and/or diastolic blood pressure of ≥85 mmHg.

Hypercholesterolemia
Based on the American Heart Association's 2018 Cholesterol Management Guidelines, a total cholesterol level of ≥180 mg/dL was considered abnormal.

Overweight and Obesity
The Body Mass Index (BMI) classification for the Asian population, as per WHO criteria, was used to categorize participants based on their weight status.

BMI Group	BMI (kg/m²)
Underweight	<18.5
Normal weight	18.5-23.0
Overweight	23.1-29.9
Obesity	≥30.0

Thyroid-Profile
Reference Values:
- FT3: 1.5-4.0 pg/ml
- TSH: 0.4-5.5 mIU/L
- FT4: 0.8-1.9 ng/dL
- **Overt hypothyroidism**: TSH >6.0 mIU/L with FT4 <0.8 ng/dL
- **Subclinical hypothyroidism**: TSH >5.0 mIU/L with normal FT3 and FT4 levels
- **Overt hyperthyroidism**: TSH <0.3 mIU/L with FT4 >1.9 ng/dL
- **Subclinical hyperthyroidism**: TSH <0.3 mIU/L with normal FT3 and FT4 levels

Data-Analysis
The collected data will be entered into Microsoft Excel and analyzed using SPSS Software version 16. Descriptive statistics, including percentages and proportions, will be used for analysis. To assess the correlation between abnormal thyroid profiles and factors such as gender, age, hypercholesterolemia, hypertension, family history of diabetes, and body mass index, the chi-square test will be applied. A p-value of <0.05 will be considered statistically significant.
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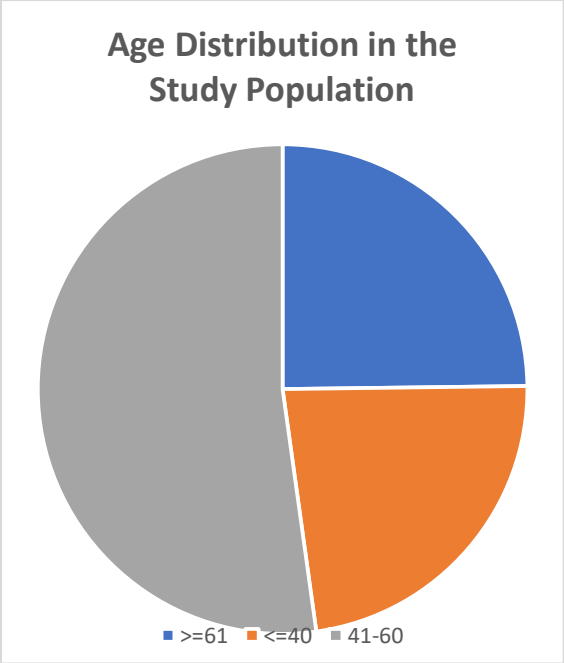
Analysis and Results
Table 1: Age Distribution in the Study Population

Age Group	Frequency	Percent
≤40	53	23.0
41-60	120	52.2
≥61	57	24.8
Total	230	100

Chart 1: Age Distribution in the Study-Population



A total of 230 patients were enrolled in the study. The majority, 52.2%, were between the ages of 41 and 60 years. 23.0% of patients were aged 40 years or younger, while 24.8% were over the age of 60.

Table 2: Sex Distribution in the Study Population

Sex	Frequency	Percent
Female	110	47.8
Male	120	52.2
Total	230	100

Diagram: Sex Distribution in the Study Population

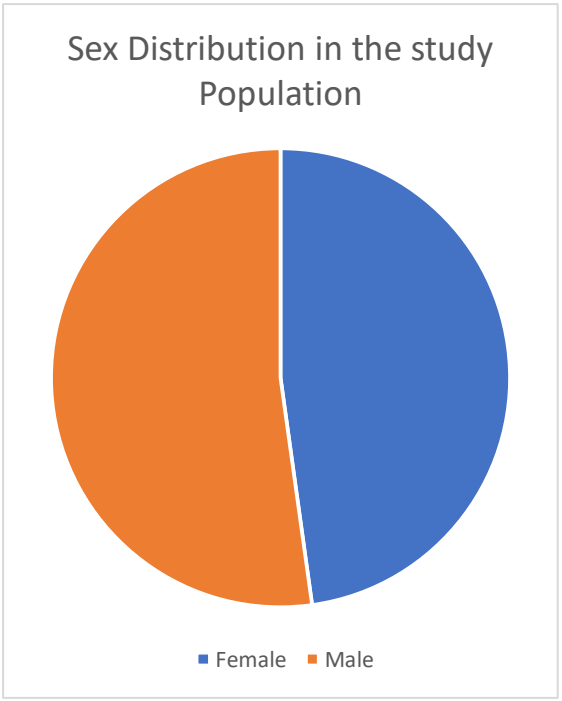


Table 3: BMI Distribution in the Study Population

BMI Range	Frequency	Percent
<18.5	2	0.9
18.5-23.0	58	25.2
23.1-29.9	160	69.6
≥30	10	4.3
Total	230	100

Diagram: BMI Distribution in the Study Population

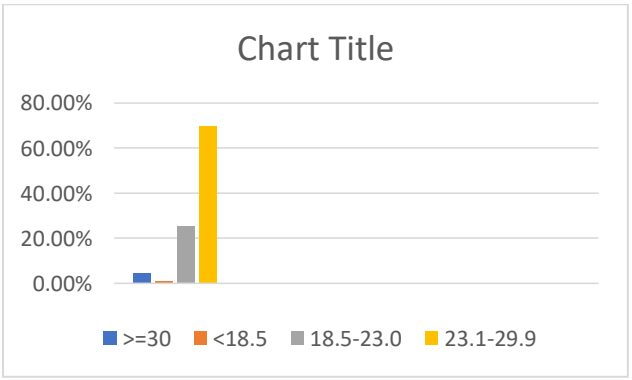


Table 4: Distribution According to Type of Treatment

Treatment Type	Yes	No
OHA	170	60
Insulin	85	145
OHA + Insulin	40	190

Table 5: Distribution According to History of Hypertension

Hypertension	Frequency	Percent
No	115	50.0
Yes	115	50.0
Total	230	100

Diagram: Hypertension Distribution in the Study Population

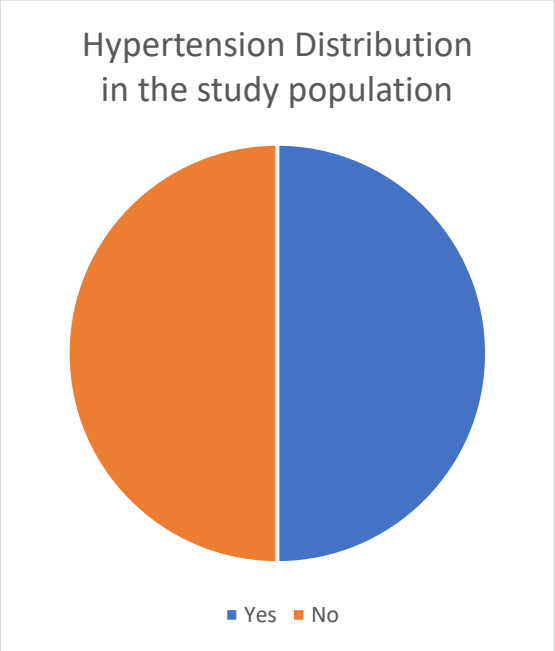


Table 7: Distribution Based on Hypercholesterolemia

Hypercholesterolemia	Frequency	Percent
No	160	69.6
Yes	70	30.4
Total	230	100

Table 8: Thyroid Profile Among the Cases

Thyroid Profile	Frequency	Percent
Normal	190	82.6
Overt Hyperthyroidism	2	0.9
Overt Hypothyroidism	12	5.2
Subclinical Hyperthyroidism	5	2.2
Subclinical Hypothyroidism	21	9.1
Total	230	100

Chart 9: Thyroid Abnormality Among the Cases
Among the study participants, **42 (18.3%)** had thyroid abnormalities, while **188 (81.7%)** had normal thyroid function.

Table 10: Case Distribution According to FT3 Levels

FT3 Level	Frequency	Percent
<1.5 pg/ml	15	6.5
1.5-4.0 pg/ml	210	91.3
>4.0 pg/ml	5	2.2
Total	230	100

Chart 10: Case Distribution According to FT3 Levels
Of the participants, **15 (6.5%)** had low FT3 levels, **210 (91.3%)** had normal FT3 levels, and **5 (2.2%)** had high FT3 levels.

Table 11: Case Distribution According to FT4 Levels

FT4 Level	Frequency	Percent
<0.8 ng/ml	8	3.5
0.8-1.9 ng/ml	205	89.1
>1.9 ng/dl	17	7.4
Total	230	100

Abnormal Thyroid Profile vs Hypercholesterolemia
Among the 42 patients with abnormal thyroid profiles, 19 (45.2%) had normal cholesterol levels, while 23 (54.7%) had hypercholesterolemia. This

difference was not statistically significant when compared to the group with normal thyroid profiles.

Abnormal Thyroid Profile vs Age Group

Among the 42 patients with abnormal thyroid profiles, 10 (23.8%) were aged 61 years or older, 25 (59.5%) were between 41 and 60 years, and 7 (16.7%) were aged 40 years or younger. There was no statistically significant difference when compared to those with a normal thyroid profile.

Age Distribution

In this study of 230 patients with Type 2 diabetes, 51 patients (22.2%) were aged 40 years or younger, 130 patients (56.5%) were between 41-60 years, and 49 patients (21.3%) were 61 years or older. The highest prevalence of the disease was observed in the 41-60 year age group. This finding aligns with the WHO report, which suggests that while the increase in diabetes cases will be most notable among individuals aged 65 and above in developed countries, in India and other developing nations, the most significant rise is expected in the 45-65 year age range. Similar findings were reported by Kapu et al., who noted that the majority of diabetes diagnoses occurred between the ages of 40 and 59, with no notable gender differences.

Sex Distribution

In our study, 51.7% (119) of the participants were male, and 48.3% (111) were female, resulting in a male-to-female ratio of 1.07:1. This is consistent with findings from Jali et al. and Flatau et al., who also observed a higher prevalence of diabetes in men compared to women. However, this contrasts with the study by Michalek et al., who reported a higher prevalence of diabetes among women than men.

Family History of Diabetes Mellitus

In this study, **57% (131)** of the patients reported having a family history of diabetes, while **43%** (99) did not. This is similar to the findings of Tattersal and Fojans, as well as Vishwanathan. Vishwanathan et al. conducted a study among 107 participants and found that 73 individuals had a positive family history of diabetes, with 19 of them later developing the condition.

Abnormal Thyroid Profile vs Sex

Out of the 42 patients with abnormal thyroid profiles, 18 (42.8%) were male and 24 (57.2%) were female. A statistically significant difference was found when compared with the group having normal thyroid function.

Abnormal Thyroid Profile vs BMI

Of the 42 patients with abnormal thyroid profiles, 23 (54.7%) were overweight or obese. This finding did not show statistical significance when compared to the normal thyroid profile group.

Abnormal Thyroid Profile vs Family History of Diabetes Mellitus

Among the 42 patients with abnormal thyroid profiles, 23 (54.7%) had a family history of diabetes. This was not statistically significant when compared to the group with normal thyroid profiles.

Abnormal Thyroid Profile vs Hypertension

Among the 42 patients with abnormal thyroid profiles, 24 (57.1%) had hypertension. This was not statistically significant when compared to the group with normal thyroid profiles.

Abnormal Thyroid Profile

In this study, 15.6% (36 patients) of the 230 individuals with Type 2 diabetes had an abnormal thyroid profile. This is similar to findings by Abdel-Rahman et al., who reported that 13.2% of 908 Type 2 diabetic patients had thyroid disease, including 7.4% newly diagnosed and 5.8% with known thyroid dysfunction. In their study, the prevalence of thyroid disease in the non-diabetic control group was 5.4%. Similarly, Chubb et al.

found that 9.2% of 420 Type 2 diabetic patients had subclinical hypothyroidism. Smithson observed a 12.4% prevalence of thyroid disease in the diabetic population, with the control group showing 5.9%. Akbar et al. reported 14.5% prevalence in their study of 100 Type 2 diabetics, compared to 6.7% in the control group. On the other hand, Zdrojewicz et al. found no difference in thyroid function between Type 2 diabetics and non-diabetics, which contrasts with the results of the present study.

Distribution of Thyroid Abnormalities

Among the patients with abnormal thyroid profiles in this study, 10.5% (24) had subclinical hypothyroidism, and 1.9% (4) had subclinical hyperthyroidism. This aligns with the findings of Abdel-Rahman et al., who observed 11.8% prevalence of hypothyroidism (both overt and subclinical) and 1.3% prevalence of hyperthyroidism (both overt and subclinical) in 908 Type 2 diabetic patients. In a study by Smithson et al., out of 233 diabetic patients, 8 had hypothyroidism (overt and subclinical) and 3 had hyperthyroidism (overt and subclinical). Celani et al. found that 28.7% of 290 Type 2 diabetic patients had abnormal TSH concentrations, with 47.9% having subclinical hypothyroidism, 23.4% subclinical hyperthyroidism, 21.6% overt hypothyroidism, and 5.6% overt hyperthyroidism.

Hypertension

In this study, 52.3% (120 out of 230) of the participants had hypertension. This finding is consistent with Tanow's observation that 76% of IDDM patients and 48% of NIDDM patients had hypertension. Fuller et al. noted that the highest prevalence of WHO-defined hypertension was observed in NIDDM patients over the age of 53, with 45% of males and 50% of females affected, which also supports the findings in this study.

Hypercholesterolemia

In this study, 34.1% (78 out of 230) patients had elevated total cholesterol levels, indicating a high incidence of dyslipidemia among diabetic patients. Southwell et al. found that 42% of diabetics had hypercholesterolemia, which aligns with the findings of the current study.

Conclusion

This study aimed to estimate the prevalence of thyroid dysfunction in Type 2 diabetic patients and explore its correlation with various risk factors. A total of 230 Type 2 diabetic patients were included in the study, and both clinical assessments and laboratory investigations were conducted.

The primary finding was that 15.6% (36 patients) of the Type 2 diabetic individuals had an abnormal thyroid profile. Among these, the most common thyroid abnormality was subclinical hypothyroidism (67%), followed by overt hypothyroidism (22%) and subclinical hyperthyroidism (11%).

The study showed a significant correlation between gender and thyroid abnormalities, with 55.6% of patients with abnormal thyroid profiles being female, compared to 44.4% males. However, no significant correlation was found between thyroid dysfunction and factors such as age, type of treatment, hypertension, family history of diabetes, hypercholesterolemia, and BMI.

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