



Original Research Article

A STUDY ON PREVALENCE OF HYPOTHYROIDISM (CLINICAL/SUBCLINICAL) IN TYPE 2 DIABETES MELLITUS PATIENTS AND CORRELATION OF HbA1C AND TSH LEVELS

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ABSTRACT

Background: Diabetes mellitus (DM) and thyroid disorders are among the most common endocrine disorders. Studies have reported significant association of thyroid dysfunction with Type 2 Diabetes Mellitus (T2DM). The presence of hypothyroidism, particularly subclinical hypothyroidism (SCH), in T2DM patients can negatively affect glycaemic control, increasing complications such as cardiovascular diseases. The present study was designed to find the prevalence of hypothyroidism in T2DM patients and to evaluate the correlation between HbA1C and Thyroid-Stimulating Hormone (TSH) levels.

Materials and Methods: The study was a cross sectional study done in a tertiary care center in Kerala, India. A purposive sampling technique was used to recruit 155 T2DM patients aged 18 years and above. Data collected were patient demographics, body mass index, duration of diabetes, presence of hypertension and thyroid function tests (TSH, FT3, FT4). Also measured were indices of sugar like fasting blood sugar (FBS), postprandial blood sugar (PPBS) and HbA1C levels. Objectives to estimate the prevalence of Hypothyroidism (Clinical/Subclinical) In type 2 Diabetes Mellitus patients attending OP/IP of a tertiary center in Kerala. To determine the correlation between HbA1C levels and TSH levels in the above-mentioned population.

Results: The population's average age was 57.2 ± 8.05 years with a male predominance (56.8%). SCH was present in 14.2% of the participants, overt hypothyroidism in 9.7%, and euthyroidism in 76.1%. There was a significant correlation between TSH and HbA1C levels ($r = 0.662$, $p < 0.001$) which suggests that poorer glycaemic control is associated with higher TSH levels. The level of FT4 was positively correlated with the level of HbA1C ($r = -0.495$, $p < 0.001$), which indicated that lower FT4 levels were associated with higher insulin resistance.

Conclusion: The current study demonstrates a high prevalence of thyroid dysfunction among patients with T2DM, with SCH being the most common type. The strong association of TSH levels with poor glycaemic control emphasises the need for routine screening of thyroid function in diabetic individuals to prevent complications. Early recognition and treatment of thyroid disorders may improve metabolic outcomes in T2DM patients.

Keywords: Diabetes Mellitus, Hypothyroidism, Subclinical Hypothyroidism, HbA1C, Thyroid-Stimulating Hormone, Glycemic Control.

INTRODUCTION

Diabetes mellitus (DM) refers to a group of metabolic diseases characterised by hyperglycemia resulting from defects in insulin secretion, insulin action or both.^[1] Since 1980, the number of people with diabetes has almost doubled worldwide, from 4.7% to 8.5% of the adult population.^[2] WHO stated that in the year 2000, India had about 31.7 million people with DM and this is projected to increase to 71.4 million by 2030. According to the National Health and Nutrition Examination Survey (NHANES) III, about 14 percent of adults have diabetes or impaired fasting glucose levels.^[3] Moreover, data from the Centers for Disease Control and Prevention suggest that DM is often underdiagnosed with an estimated 35% of adults >20 years old and 50% of adults >65 years old having prediabetes based on fasting glucose or HbA1c levels.^[4] The prevalence of thyroid disease is high in the general population and increases with age. Hypothyroidism is far more common than hyperthyroidism, and is often due to autoimmune conditions like Hashimoto's thyroiditis or primary atrophic hypothyroidism. The average incidence of autoimmune hypothyroidism is reported to be approximately 4 per 1,000 women and 1 per 1,000 men. Research finds that thyroid problems are more prevalent in people with diabetes than in the general population.^[5] The association is also related to autoimmune mechanisms but thyroid function is intrinsically related to the insulin resistance. Several factors have been identified that contribute to both elevated TSH levels and insulin resistance.^[6] The prevalence of thyroid disorders in patients with type 2 DM is reported to be as high as 31% with the commonest disorder being subclinical hypothyroidism, followed by subclinical hyperthyroidism, overt hypothyroidism and overt hyperthyroidism.^[7] Hypothyroidism in DM can slow down the rate of insulin degradation, and therefore reduce the need for exogenous insulin. Hypothyroidism is also associated with higher levels of triglycerides (TG), low-density lipoprotein (LDL) and total cholesterol (TC) which increase the risk of cardiovascular disease.⁵ Subclinical hypothyroidism (SCH) is defined as an elevated TSH with normal serum free thyroxine concentrations, whereas subclinical hyperthyroidism is defined as normal free thyroxine and triiodothyronine levels with suppressed TSH.^[8,9] SCH has been linked to increased TC, TG, LDL, coronary artery disease, left ventricular diastolic dysfunction, left ventricular systolic dysfunction during exercise, increased peripheral vascular resistance and mental health problems such as depression.^[10] Thyroid hormones participate in glucose metabolism via various mechanisms. Hyperthyroidism has been associated with hyperglycemia,^[11] for a long time, mainly because of a decreased insulin half-life due to increased degradation and increased secretion of

biologically inactive insulin precursors.^[12-13] Altered glucose metabolism is also seen in hypothyroidism with reduced hepatic glucose output resulting in reduced insulin needs in subjects with diabetes.^[14]

The association between diabetes and thyroid disease has been well studied.^[15-17] Considering the spectrum of different types of thyroid disorders and their complications in diabetic patients, the present study is conducted to explore the prevalence of subclinical and hypothyroid disorders in people with DM.

Aim and Objectives

The main objective of the present study was to study the prevalence of hypothyroidism (clinical and subclinical) in patients with type 2 diabetes mellitus and to evaluate the correlation between the levels of HbA1C and TSH. The specific objectives of the study are to estimate the prevalence of clinical or subclinical hypothyroidism in type 2 diabetes mellitus patients attending the outpatient or inpatient departments of a tertiary center in Kerala and to establish the correlation between HbA1C levels and TSH levels in this specific population. The research hypothesis also states that the prevalence of hypothyroidism in type 2 diabetes mellitus patients will be between 22-25% and there is no correlation between HbA1C and TSH levels.

MATERIALS AND METHODS

The present study is cross-sectional study and the duration is 18 months (June 2023 to December 2024). The study was conducted at Pushpagiri Institute of Medical Sciences and Research Center, Thiruvalla among diabetic patients (both outpatients and inpatients) attending the center. Study participants Patients aged 18 years or older with type 2 diabetes mellitus who gave written informed consent to participate in the study. Patients who are pregnant, critically ill, on steroids chronically, have autoimmune disorders, type 1 diabetes mellitus, secondary diabetes or any other cause of thyrotoxicosis will be excluded from the study. Other exclusion criteria are history of thyroid surgery, sepsis, history of thyroid malignancy in the last 5 years, non-compliance to provide informed consent and current use of lithium, calcium, vitamin D supplements and other drugs that can cause thyroid dysfunction.

Method of Collection of Data

All in and out patients >18 years with Type 2 DM attending the Medicine OPD/IPD of Pushpagiri Institute of Medical sciences And Research center, Thiruvalla were included in the study. (PIMSRC/E1/388A/44/2023) clearance from the Institutional Ethical Committee was obtained before the beginning of the study. Purposive Sampling technique was used to include study participants in the study.

Patients diagnosed with diabetes mellitus were included in the study until the sample size was

reached. Prior to data collection, informed consent was obtained from all participants. Socio-demographic variables and history of diabetes mellitus were collected by interview method using pre-tested semi structured questionnaire. Fasting and post prandial blood sugars, HbA1C levels, Serum T3, T4, TSH was done for all the study participants.

Statistical Analysis

The data was collected and compiled in the MS excel. The data has been presented using descriptive statistics. Data analysis was conducted using SPSS (Version 26.0). The level of significance was set at 5% ($\alpha = 0.05$). Qualitative variables are presented as frequency and percentages Quantitative variables are presented as Mean and Standard Deviation.

RESULTS

The study enrolled 155 subjects with a mean age of 57.20 ± 8.05 years. Most of the participants were in the age group of 51 - 60 years (43.2%) followed by 61 - 70 years age group (34.8%). The 41-50 years category had a smaller percentage of participants (18.7%) and very few participants were younger

than 40 years or older than 70 years. Males predominated in the study (88, 56.8%) compared to females (67, 43.2%). This suggests a slight male preponderance of type 2 diabetes mellitus (T2DM) in this population. Out of 155 participants, 88 (56.8%) had hypertension and 67 (43.2%) did not have hypertension. Twenty participants (12.9%) reported a family history of thyroid disorders, while 135 (87.1%) had no such history. The mean BMI of the study population was 27.99 ± 3.61 , suggesting that most of the participants were in the overweight to obese range. A large share of the study population (54.2%) was classified as overweight by BMI and 18.7% were in the obesity category. The mean duration of diabetes in the study population was 6.41 ± 2.46 years. Almost half of the participants (47.1%) had diabetes for <5 years and 39.35% had diabetes for 6-10 years. A lesser percentage (12.26%) had diabetes for 11-15 years and very few had diabetes for >15 years. All the participants ($n = 155$) were on oral hypoglycemic agents (OHAs), and 23 participants (14.8%) required additional insulin therapy.

Table 1: Glycemic Indices

GLYCEMIC INDICES	Mean	Standard Deviation
FBS (mg%)	143.70	55.43
PPBS (mg%)	225.52	80.28
HbA1c (%)	7.85	2.328

The average fasting blood sugar (FBS) was 143.70 ± 55.43 mg/dL and the average postprandial blood sugar (PPBS) was 225.52 ± 80.28 mg/dL. The mean

HbA1c was $7.85 \pm 2.33\%$, suggesting that a large proportion of the participants had suboptimal glycaemic control. [Table 1]

Table 2: Thyroid Function Tests

TFT	Mean	Standard Deviation
FT3 (pg/ml)	2.77	0.70
FT4 (ng/dl)	1.13	0.32
TSH (μ IU/ml)	6.98	13.36

The mean free T3 (FT3) was 2.77 ± 0.70 pg/mL, free T4 (FT4) was 1.13 ± 0.32 ng/dL, and TSH was 6.98 ± 13.36 μ IU/mL. In some people, high TSH

means hypothyroidism or subclinical hypothyroidism, which is more common in people with diabetes. [Table 2]

Table 3: Thyroid Profile

THYROID PROFILE	Frequency	Percentage
Euthyroid	118	76.1
Subclinical hypothyroidism	22	14.2
Hypothyroidism	15	9.7

The euthyroid status was found in 76.1% of the participants, subclinical hypothyroidism in 14.2% and overt hypothyroidism in 9.7%. Thus,

approximately one in four diabetic patients had any type of thyroid dysfunction, the most common being subclinical hypothyroidism. [Table 3]

Table 4: Association of thyroid profile with HBA1C

THYROID PROFILE	HBA1C		P VALUE
	Mean	Std. Deviation	
Euthyroid	6.780	1.18	<0.001
Subclinical hypothyroidism	10.08	0.65	
Hypothyroidism	12.95	1.35	

The study showed significant correlation of thyroid dysfunction with HbA1c levels. The mean HbA1c was lowest in euthyroid, i.e. $6.78 \pm 1.18\%$ and was significantly higher in subclinical hypothyroidism ($10.08 \pm 0.65\%$) and overt hypothyroidism ($12.95 \pm 1.35\%$). The p value was <0.001 showing a

statistically significant correlation. This shows that the thyroid dysfunction has a negative effect on glycaemic control and therefore thyroid function should be monitored in diabetic patients with poor glycaemic control. [Table 4]

Table 5: Correlation of Thyroid Hormones with HBA1C

HbA1c (%)	Pearson Correlation	P VALUE
FT3 (pg/ml)	-0.106	0.190
FT4 (ng/dl)	-0.495	<0.001
TSH (μ IU/ml)	0.662	<0.001

FT3 showed weak negative correlation with HbA1c ($r = -0.106$, $p = 0.190$) suggesting no significant association. A moderate negative correlation was observed between FT4 and HbA1c ($r = -0.495$, $p < 0.001$), with lower FT4 levels being associated with higher HbA1c levels. TSH positively correlated with HbA1c ($r = 0.662$, $p < 0.001$), indicating that higher TSH levels were associated with poorer glycaemic control. [Table 5]

DISCUSSION

Hypothyroidism happens when the thyroid gland's activity slows down, producing less hormone. It can present as overt hypothyroidism with myxedema and end organ findings leading to multiorgan failure or subclinical hypothyroidism with normal thyroxine (T4) and triiodothyronine (T3) levels and mild elevation of serum thyrotropin (TSH). Studies show that hypothyroidism affects about 4%–5% of the population in developed countries whereas in India the prevalence is higher affecting about 1 in 10 adults.^[18-21]

Type 2 diabetes mellitus (T2DM) and hypertension share common underlying pathophysiologic mechanisms with hypothyroidism. Studies indicate a significant prevalence of TDs in T2DM (12%–23%) and hypertensive individuals (22.5%). Plasma T3 and T4 may be decreased in uncontrolled T2DM affecting thyroid hormone levels. Genetic, biochemical or hormonal factors may be responsible for the association of diabetes and hypothyroidism. Hypothyroidism is frequently observed in type 1 diabetes mellitus (T1DM) due to the shared autoimmune origins. Several studies have reported a higher prevalence of TDs in patients with T2DM and hypothyroidism is the most common thyroid dysfunction.^[22-25]

Hypothyroidism is not only a direct cardiovascular risk factor, but it also worsens other contributing factors, such as hyperlipidaemia and hypertension, increasing cardiovascular morbidity. Mild, subclinical hypothyroidism has been linked to an increased risk of heart failure and stroke in studies, particularly in younger people. Hypothyroidism has also been associated with nonalcoholic fatty liver disease, cancer-related mortality, arthritis and kidney dysfunction, although the causal link is uncertain in these cases.^[26,27] A recent meta-analysis

of 61 studies demonstrated an increased prevalence of subclinical hypothyroidism in subjects with type 2 diabetes mellitus and an increased risk of microvascular complications in the coexistence of the two conditions 28. The present study comprised 155 patients of type 2 diabetes mellitus (T2DM) with a mean age of 57.20 ± 8.05 years. Most of our participants were in the age group of 51–60 years (43.2%) followed by participants of age group 61–70 years (34.8%) which indicates the increased risk of thyroid dysfunction in older adults with diabetes. The mean age in the study by Talwalkar et al,^[25] was similar to our study, which was 50.7 ± 12.18 years. The current sample was slightly male-dominated with 56.8% males and 43.2% females. Talwalkar et al,^[25] found 52.4% males and 47.6% females in their diabetic population similarly. 56.8% of our patients had hypertension. This underlines the frequent co-existence of diabetes with cardiovascular risk factors. Conversely, Talwalkar et al,^[25] reported 33.5% hypertensives and 28.9% of having both diabetes and hypertension in their study. In addition, 12.9% of our participants had a family history of thyroid disease, suggesting a genetic predisposition to thyroid dysfunction in this population. However, Talwalkar et al,^[25] reported that 41.5% of T2DM patients had a family history of T2DM, hypertension or thyroid disease. In the study by Talwalkar et al., the higher proportion might stem from increased clustering of metabolic and endocrine disorders within families and could account for the high rates of overt hypothyroidism. The mean BMI in the present study was 27.99 ± 3.61 kg/m², suggesting that most participants were overweight or obese — a common finding in T2DM due to the association between obesity and insulin resistance, similar to the Talwalkar et al. study where their diabetic participants' BMI was found in the range of 26.3 ± 4.24 kg/m². However, Talwalkar et al. reported a higher percentage of obesity (65.3%) compared to our findings.

In the present study, the mean duration of diabetes was 6.41 ± 2.46 years. Nearly half of the participants (47.1%) in our study had diabetes for less than five years. Similarly Talwalkar et al,^[25] reported a slightly higher mean duration of diabetes 8.3 ± 6.9 years in their study. In terms of treatment, all our patients were on oral hypoglycemic agents (OHAs) and 14.8% of them needed insulin as well,

showing that there is a variation in the degree of glycaemic control.

Glycaemic index in our study showed suboptimal glucose control with mean HbA1c of $7.85 \pm 2.33\%$, FBS of 143.7 mg/dL and PPBS of 225.52 mg/dL. Thyroid function tests revealed a mean TSH level of 6.98 ± 13.36 μ IU/ml, with FT3 and FT4 levels within normal ranges. Nevertheless, Talwalkar et al. reported a mean HbA1c of 8.5% in their T2DM patients.

Thyroid dysfunction was frequent in our study. 76.1% of patients were euthyroid, 14.2% were subclinical hypothyroid and 9.7% were overt hypothyroid. In comparison, Talwalkar et al. showed a higher overall prevalence of hypothyroidism at 29% in their larger sample of 1,501 patients, with 24.8% being T2DM patients. Interestingly, subclinical hypothyroidism (53.8%) was found to be more prevalent than overt hypothyroidism (41.8%) among the diabetics as per the study by Talwalkar et al. which is higher as compared to our study findings. Likewise, several studies 29-31 have been conducted to study the association of diabetes with thyroid dysfunction and the prevalence of hypothyroidism in diabetic patients has been reported between 4.8% and 31.4%. There is evidence that glycaemic control has a marked effect on serum T3 levels, basal TSH levels, and the TSH response to thyrotropin-releasing hormone.^[30] The high prevalence of hypothyroidism in our study might be attributed to longer duration of diabetes and hypertension, older age and more obese patients. In addition, persistent iodine deficiency in the Indian population and environmental factors including higher pesticide use, exposure to industrial pollutants with goitrogenic effects and contaminated drinking water may have further contributed to the increasing incidence of hypothyroidism over the last decade.^[31]

The prevalence of subclinical hypothyroidism in patients with type 2 diabetes mellitus (T2DM) is 1.93 times higher in a systematic review and meta-analysis of cross-sectional studies.^[28] However, the direction of the association is unclear and there is evidence of a possible bidirectional relationship. One of the proposed mechanisms is that the variation of the serum levels of TSH and FT4 is associated with the variation of HbA1C, which may promote increased insulin resistance and T2DM.^[32,33] For instance, T2DM may inhibit TSH levels, affecting conversion of T4 to T3 in peripheral tissues and leading to subclinical hypothyroidism. In contrast, other studies have shown that subclinical hypothyroidism characterised by increased TSH level affects adipocyte function. TSH binds to TSH receptors on adipocytes, causing disruption of adipocyte homeostasis and reduction of the secretion of insulin-sensitizing molecules such as adiponectin, ultimately resulting in insulin resistance.^[34,35]

In comparison, in the study of Fakhroo et al. 36, with 922 participants, 285 participants had T2DM and subclinical hypothyroidism (SCH) prevalence was 4.6% in the T2DM group. But our study found a higher prevalence of SCH. In their study, the logistic regression analysis adjusted for confounding factors showed that odds of T2DM were significantly higher in participants with SCH (OR=2.82, $p=0.026$) although this difference did not reach statistical significance ($p=0.18$).

Similarly, there was a strong association between thyroid status and glycaemic control. In our study, the mean HbA1c was $6.78 \pm 1.18\%$ in patients with normal thyroid function and significantly higher ($10.08 \pm 0.65\%$) in patients with subclinical hypothyroidism. The highest HbA1c level was found in patients with overt hypothyroidism ($12.95 \pm 1.35\%$). In the present study, these differences were statistically significant ($p < 0.001$) suggesting that worsening of thyroid function is associated with poor glycaemic control. Further confirmation of the association between thyroid dysfunction and glycaemic control was obtained from the correlation analysis in the present study. There was a positive correlation between TSH levels and HbA1c ($r = 0.662$, $p < 0.001$), which means that the higher the TSH levels, the worse the glycaemic control. Conversely, FT4 levels were negatively correlated with HbA1c ($r = -0.495$, $p < 0.001$), indicating that lower FT4 levels were associated with higher HbA1c values. There was no statistically significant correlation between FT3 and HbA1c ($r = -0.106$, $p = 0.190$).

In comparison to our study, Fakhroo et al. 36 did not find significant differences in thyroid hormone levels between T2DM and non-T2DM groups for TSH and FT3, but found slightly higher levels of FT4 in their diabetic group ($p=0.004$).

Limitations

Limitations of our study include the relatively small sample size, which may limit generalisability of the findings to larger and more diverse populations. Furthermore, the cross-sectional design of the study does not permit the establishment of causal relationships between thyroid dysfunction and glycaemic control in T2DM patients. Other variables like medication compliance, dietary habits and other comorbid conditions impact on thyroid and diabetic parameters were not analysed in depth. A longitudinal follow-up and a more in-depth assessment of lifestyle and treatment factors would provide a better understanding of the bidirectional relationship between thyroid dysfunction and T2DM.

CONCLUSION

Our study found a significant association between glycaemic control and thyroid dysfunction among patients with type 2 diabetes mellitus (T2DM). Thyroid dysfunction was prevalent in the 155

participants with 14.2% having subclinical hypothyroidism and 9.7% being diagnosed with overt hypothyroidism. There was a strong association between worse thyroid function and higher HbA1c levels, reflecting worse glucose control, as shown by the positive correlation between TSH and HbA1c and the negative correlation between FT4 and HbA1c. The findings underline the need for regular screening of thyroid in T2DM patients to diagnose and manage thyroid dysfunction in a timely manner, which may improve overall glycaemic control and reduce diabetes-related complications.

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