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ORIGINAL ARTICLE

Prevalence and Impact of Hypothyroidism on Glycaemic Control in Indian Patients with Type 2 Diabetes Mellitus: A Cross-Sectional Study

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Abstract

Objectives. This study aimed to determine the prevalence of hypothyroidism in Indian patients with T2DM and explore its impact on glycemic control and comorbidities.

Methodology. This cross-sectional study involved 218 patients with T2DM attending a tertiary care centre. Patient demographics, comorbidities, and blood samples were collected to measure glycosylated haemoglobin (HbA1c) and thyroid-stimulating hormone (TSH) levels. Patients were classified as euthyroid, hyperthyroid, or hypothyroid based on TSH levels. A sub-analysis compared demographic and biochemical parameters between euthyroid and hypothyroid groups.

Results. The study included 218 patients with T2DM with a mean age of 57.6 ± 11.1 years, and a female predominance (54.1%). The prevalence of hypothyroidism was 58.7%, higher among females. No significant differences in comorbidities or HbA1c levels were observed between euthyroid and hypothyroid patients. Among patients with HbA1c ≥6.4%, women showed a higher prevalence of hypothyroidism.

Conclusion. The high prevalence of hypothyroidism among patients with T2DM, particularly in females, underscores the need for routine thyroid function screening in this population. Despite the lack of significant differences in comorbidities or glycaemic control between euthyroid and hypothyroid patients seen in this study, the potential impact of thyroid dysfunction on diabetes management warrants further investigation.

Key words: type 2 diabetes mellitus, hypothyroidism, thyroid dysfunction, glycaemic control, comorbidities

INTRODUCTION

The burden of type 2 diabetes mellitus (T2DM) in India is escalating, with projections estimating 134 million cases by 2045, highlighting a significant public health challenge.[1] Contributing factors include demographic shifts such as urbanization and an aging population, alongside lifestyle changes characterized by increased prevalence of obesity, physical inactivity, and poor dietary habits.[2] Current prevalence rates indicate a concerning trend, with diabetes distress affecting approximately 33% of patients with T2DM, which complicates management and adherence to treatment.[1] Additionally, the rise in gestational diabetes mellitus (GDM) from 0.53% to 0.80% between 2015-2021 suggests a growing risk for future onset of T2DM in mothers and their offspring.[3]

The relationship between type 2 diabetes mellitus and thyroid dysfunction, particularly hypothyroidism, is well-documented, with hypothyroidism being the most prevalent thyroid disorder among patients with diabetes. Studies indicate that individuals with T2DM exhibit a higher prevalence of thyroid disorders compared to the general population, with subclinical hypothyroidism being notably common, affecting approximately 12-15% of patients with diabetes.[4,5] Metabolic disturbances inherent in diabetes, along with poor glycemic control, have been linked to an increased risk of thyroid dysfunction.[4,5] Specifically, elevated thyroid-stimulating hormone (TSH) levels correlate with poor metabolic control, suggesting that thyroid dysfunction may exacerbate diabetic complications.[6] Furthermore, the interplay between insulin and thyroid hormones indicates that metabolic syndrome may predispose individuals to thyroid disorders, highlighting the importance of screening for thyroid dysfunction in patients with T2DM to optimize management and improve outcomes.[6,7]

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Identifying hypothyroidism in patients with diabetes is crucial due to the significant impact on glycemic control and cardiovascular risk. Hypothyroidism, found in 6-20% of patients with type 2 diabetes mellitus, exacerbates metabolic complications, including increased rates of retinopathy (13.8%), nephropathy (19.04%), and neuropathy (25%) in individuals with hypothyroidism compared to their non-hypothyroid counterparts.[5] The prevalence of hypothyroidism in patients with T2DM varies globally, with studies indicating rates of 14% in Indian populations.[8] However, discrepancies exist, as some studies report lower prevalence rates, highlighting the need for region-specific research to understand local variations better.[9] Furthermore, hypothyroidism is associated with metabolic syndrome and increased cardiovascular risks, thus necessitating routine screening for thyroid dysfunction in patients with diabetes to facilitate early intervention.[8-10]

Studying the prevalence of hypothyroidism in Indian patients with T2DM is essential due to the significant impact on diabetes management and outcomes. Despite global evidence of a strong link between T2DM and hypothyroidism, large-scale studies in India are lacking, and existing data show inconsistent findings. Identifying hypothyroidism in patients with diabetes could lead to tailored treatment strategies and better management of comorbidities. This study aims to determine the prevalence of hypothyroidism in Indian patients with diabetes and the relationship of hypothyroidism with diabetes-related complications, co-morbidities and health outcomes.

METHODOLOGY

Study design and population

This cross-sectional study was conducted among patients with T2DM who attended a primary care centre in India. Participants were included if they had a confirmed diagnosis of T2DM and were aged 18 years or older, irrespective of their pregnancy status. Patients with type 1 diabetes, those on thyroid hormone therapy, and those with a history of thyroid surgery or radiotherapy were excluded from the study. Individuals meeting the inclusion criteria were continuously recruited from June 2021 to April 2024. Only individuals with complete data were included in the study. The study was conducted in accordance with the Declaration of Helsinki. All the patients were oriented about the study, informed oral consent was obtained, and institutional approval for using the data for the current study was received.

Sample size estimation

Considering the prevalence of thyroid disorders in 60% of individuals with T2DM at 95% CI and with a finite sample size of 200, we estimated a margin of error in the range of 7%. The sample size was then estimated to be 189. To account for a 10% drop out rate, 208 was considered for the enrolment.

Data collection

Data on patient demographics, including age and gender, were collected. Information on comorbidities such as hypertension, dyslipidaemia, coronary artery disease, chronic kidney disease, and other conditions was also recorded. Potential confounders such as the duration of diabetes and a family history of thyroid disorders were also noted. Blood samples were collected after an overnight fast to measure glycosylated haemoglobin (HbA1c) and thyroid-stimulating hormone (TSH) levels. HbA1c levels were used to assess glycaemic control, and TSH levels were measured to evaluate thyroid function.

Classification and grouping

The primary outcome of the current study was to determine the prevalence of hypothyroidism in Indian patients with T2DM. The secondary outcome was to determine factors associated with the incidence of hypothyroidism in T2DM. Patients were classified into euthyroid, hyperthyroid, and hypothyroid groups based on TSH levels. Hypothyroidism was defined as TSH level >4.5 mU/L, while hyperthyroidism was defined as TSH level <0.4 mU/L. Euthyroid status was defined as TSH level within the normal reference range (0.4-4.5 mU/L).

Sub-analysis

A sub-analysis was conducted to compare demographic and biochemical parameters between euthyroid and hypothyroid patients. Gender distribution, age, family history, co-morbidities, and HbA1c levels were analyzed. Further comparisons were made between euthyroid and hypothyroid patients with HbA1c ≥6.4%.

Statistical analysis

Data were presented as mean ± standard deviation (SD) for continuous variables and as frequencies and percentages for categorical variables. Distributions of variables were assessed. The chi-square test was used to compare categorical variables, and the independent t-test was used for continuous variables. Analyses were performed using available-case data for each variable. A p-value <0.05 was considered statistically significant.

RESULTS

The current study included 218 patients with T2DM (Table 1), with a mean age of 57.6 ± 11.1 years and M:F ratio of 0.85:1. HbA1c data were available for 208 of 218 patients. For subgroup analyses, hyperthyroid patients (n = 5) were excluded. Among the remaining patients, HbA1c values were available for 203 individuals. Majority had a diabetes duration of 1-5 years. Comorbidities were present in 145 (66.5%) patients, of which hypertension was the most common, found in 84/145 (57.9%) patients, followed by dyslipidaemia in 36/145 (24.8%) patients and coronary

artery disease in 28/145 (19.3%) patients. The average HbA1c level was 7.8 ± 1.5%, with 87.5% of patients having HbA1c >6.4%, indicating a high proportion of patients with poor glycaemic control.

A family history of thyroid disorders was observed in 89 (40.8%) patients. The prevalence of hypothyroidism among our cohort was 58.7%. Following this, a sub-analysis was conducted to compare the demographic and biochemical parameters between euthyroid and hypothyroid patients (Table 2). The prevalence of hypothyroidism was higher among females compared to males with T2DM. No significant differences were observed in the comorbidity profile or HbA1c levels between euthyroid and hypothyroid patients (Table 2; Supplement Table 1).

Among patients with HbA1c ≥6.4%, females demonstrated a higher prevalence of hypothyroidism. Additionally, five out of six patients with a history of coronary artery bypass surgery were hypothyroid.

Table 1. Demographic and clinical profile of the study population

Total population (N)	218
Age	57.6 ± 11.1
Age [Median IQR]	58.0 [50.0, 66.0]
Age distribution (in year)	
18-30 – Young adults	4 (1.8%)
31-50 – Middle-aged adults	51 (23.4%)
51-70 – Older adults	140 (64.2%)
>70 – Elderly	23 (10.6%)
Gender distribution	
Male	100 (45.9%)
Female	118 (54.1%)
Family history of thyroid disorders	89 (40.8%)
Duration of T2DM	6.3 ± 6.8
Duration of T2DM	
<1 year	32 (14.7%)
1-5 years	102 (46.8%)
>5 years	82 (37.6%)
Number of comorbidities	
Zero comorbidities	73 (33.5%)
Single comorbidities	45 (20.6%)
Double comorbidities	81 (37.2%)
Triple comorbidities	19 (8.7%)
Number of individuals with comorbidities	145
Comorbid conditions	
Hypertension	84/145 (57.9%)
Dyslipidaemia	36/145 (24.8%)
Coronary artery disease	28/145 (19.3%)
Chronic kidney disease	23/145 (15.9%)
Anaemia	22/145 (15.2%)
Bronchial asthma	1/145 (0.7%)
Irritable bowel syndrome	1/145 (0.7%)
Osteoarthritis	1/145 (0.7%)
Insulin Resistance	2/145 (1.4%)
Benign Prostatic Hyperplasia in men	64/100 (64%)
Coronary artery bypass graft surgery	8 (3.7%)
N	208
HbA1c (in %)	7.8 ± 1.5
HbA1c [Median IQR]	7.4 [6.7, 8.4]
HbA1c Distribution	
<5.7% – Non-diabetic	4 (1.9%)
5.7% to 6.4% – Prediabetes	22 (10.6%)
>6.4% – Diabetes	182 (87.5%)
N	218
TSH (in mU/L)	4.1 ± 2.5
TSH [Medin IQR]	3.3 [2.4, 5.1]
Euthyroid	85 (39.0%)
Hyperthyroid	5 (2.3%)
Hypothyroid	128 (58.7%)
FT3	3.4 ± 1.0
FT4	1.4 ± 0.5

HbA1c – Haemoglobin A1c; TSH – Thyroid Stimulating Hormone

Table 2. Comparison of demographics and biochemical parameters between euthyroid and hypothyroidism patients with T2DM

	Euthyroid	**Hypothyroid**	***P*-values**
Total population (N)	85	128	
Age	58.3 ± 11.3	57.1 ± 11.1	0.443#
Age [Median IQR]	60.0 [51.5, 66.5]	57.0 [50.0, 65.0]	
Age distribution (in year)			
18-30 – Young adults	1 (1.2%)	3 (2.3%)	0.820*
31-50 – Middle-aged adults	18 (21.2%)	32 (25.0%)	
51-70 – Older adults	57 (67.1%)	79 (61.7%)	
>70 – Elderly	9 (10.6%)	14 (10.9%)	
Gender distribution			
Male	54 (63.5%)	45 (35.2%)	<0.001*
Female	31 (36.5%)	83 (64.8%)	
Family history of thyroid disorders	35 (41.2%)	51 (39.8%)	0.194*
Comorbidities			
No comorbidities	34 (40.0%)	40 (31.3%)	0.190*
Hypertension	28 (32.9%)	53 (41.4%)	0.211*
Benign prostatic hyperplasia	21 (24.7%)	43 (33.6%)	0.164*
Dyslipidemia	10 (11.8%)	25 (19.5%)	0.133*
Coronary artery disease	12 (14.1%)	15 (11.7%)	0.603*
Chronic kidney disease	9 (10.6%)	14 (10.9%)	0.936*
Anaemia	8 (9.4%)	13 (10.2%)	0.857*
Bronchial asthma	0 (0.0%)	0 (0.0%)	-
Irritable bowel syndrome	1 (1.2%)	0 (0.0%)	-
Osteoarthritis	0 (0.0%)	1 (0.8%)	-
Insulin Resistance	0 (0.0%)	2 (1.6%)	-
Coronary artery bypass graft surgery (N = 6)	2 (33.3%)	4 (66.7%)	0.250*
Other comorbid conditions			
Zero comorbidities	34 (40.0%)	38 (29.7%)	0.329*
Single comorbidities	19 (22.4%)	26 (20.3%)	
Double comorbidities	26 (30.6%)	52 (40.6%)	
Triple comorbidities	6 (7.1%)	12 (9.4%)	
N	83	120	
HbA1c (in percentage)	7.8 ± 1.6	7.7 ± 1.5	0.650#
HbA1c [Median IQR]	7.4 [6.8, 8.9]	7.3 [6.7, 8.4]	
N	83	120	
HbA1c (in percentage)			
<5.7% – Non-diabetic	2 (2.4%)	2 (1.7%)	0.846*
5.7% to 6.4% – Prediabetes	8 (9.6%)	14 (11.7%)	
>6.4% – Diabetes	73 (88.0%)	104 (86.7%)	

HbA1c – Haemoglobin A1c; TSH – Thyroid Stimulating Hormone, * Chi-square test; # Students t-test

DISCUSSION

The current study highlights the burden of thyroid disorders among Indian patients with T2DM. Majority of patients (~64%) in the study were within 50 to 70 years of age with a slight female predominance (M:F ratio – 0.85: 1.0). This age distribution aligns with the general epidemiology of T2DM, where the risk of thyroid disorders increases with age, particularly among individuals over 50.[8] The slight female predominance is consistent with previous studies, which have also reported higher rates of thyroid dysfunction among females with T2DM (31.4%) due to the autoimmune nature of thyroid disease, which is more common in females.[10]

Hypertension was the most common comorbidity (in 58%), followed by dyslipidaemia (24.8%) and coronary artery disease (19.3%) (Table 1). Hypertension and dyslipidemia are common comorbidities in patients with T2DM and contribute significantly to cardiovascular risk.[11-13] These conditions are interrelated, as both hypertension and dyslipidemia are modifiable risk factors that exacerbate cardiovascular disease (CVD) risk in patients with T2DM.[14]

A family history of thyroid disorders was observed in 89 (40.8%) patients. The prevalence of hypothyroidism in our study population was 58.7%. In India, the reported prevalence of hypothyroidism in the adult population is about 10.8% and increases to about 13% in the older population.[8] Another study reported a 28% prevalence of hypothyroidism among individuals with metabolic syndrome, indicating a higher burden in this subgroup.[14] Due to the practical and logistical constraints associated with recruitment and resource availability, a target population of approximately 200 individuals was deemed to be feasible. Therefore, the sample size estimation was performed within this limit to ensure that the study remains achievable within the given time frame and setting. While this may limit the statistical power to detect smaller effect sizes, it can still yield meaningful preliminary insights for exploratory or pilot studies within specific or limited populations. A study reported that individuals with a family history of thyroid disorders had a nine-fold risk of developing hypothyroidism.[15] This reflects a well-established risk factor for hypothyroidism due to shared genetic predispositions and lifestyle factors.[15]

About 88% of our study participants had poor glycemic control. This finding aligns with prior studies that also report elevated HbA1c levels [HbA1c ≥7% (OR = 4.3, p = 0.025)][9,16] and poor glycemic control (ranged between 45.2% and 93%)[17] in a significant proportion of patients with T2DM, often exacerbated by co-existing conditions such as hypothyroidism. This highlights the potential role of hypothyroidism in complicating glycemic control, as thyroid dysfunction can adversely affect glucose metabolism and insulin sensitivity.[7,18]

In a sub-analysis conducted to compare the demographic variables between euthyroid and hypothyroid patients, the prevalence of hypothyroidism was higher among females compared to males (Table 2). Furthermore, among patients with uncontrolled HbA1c ≥6.4%, females demonstrated a higher prevalence of hypothyroidism (Supp. Table 1). This aligns with existing research that shows a gender disparity in thyroid disorders, with higher rates of hypothyroidism in females.[10]

The observation that no significant differences were observed in the comorbidity profile or HbA1c levels between euthyroid and hypothyroid patients is consistent with previous findings that indicate females with diabetes are at increased risk for thyroid dysfunction, particularly when glycemic control is poor.[10,17] The finding of about 83% (5/6) of patients with a history of CABG surgery afflicted with hypothyroidism is consistent with research linking hypothyroidism to increased cardiovascular risk, including the likelihood of undergoing coronary artery bypass grafting.[19]

Screening for thyroid disorders using a symptom-based approach is cost-effective. However, given that thyroid dysfunction may be asymptomatic, and with thyroid screening becoming more cost-effective in India, it is important for physicians to implement routine thyroid screening among patients with T2DM. The limitations of the current study include a single center study design and lack of long-term follow-up among patients. Future multi-centric large scale longitudinal studies may shed light on the causal relationships between thyroid dysfunction and diabetes outcomes among Indian patients with diabetes.

Limitations

The study findings are limited by relatively small sample size and absence of long-term follow-up due to feasibility constraints and resource availability. Additionally, potential confounding factors such as medication use, duration of diabetes, and lifestyle parameters were not extensively explored. This is a single center study, which may limit the generalizability of the results to broader populations across different regions of India.

CONCLUSION

This study highlights the significant prevalence of hypothyroidism among patients with T2DM in India, particularly among females, consistent with global trends of higher thyroid dysfunction rates in females. Although no significant differences were observed in glycemic control or comorbidity profiles between euthyroid and hypothyroid patients, the high prevalence of hypothyroidism, especially in those with uncontrolled hyperglycemia, underscores the need for routine thyroid screening in patients with T2DM. This approach could facilitate early intervention, optimizing diabetes management and potentially reducing the risk of diabetes-related complications. The findings also

emphasize the importance of gender-specific strategies in managing T2DM and associated comorbidities.

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Statement of Authorship
All authors fulfilled ICMJE authorship criteria.

CRediT Author Statement
JR: Conceptualization, Methodology, Formal analysis, Data curation, Writing – original draft preparation, Writing – review and editing; **AR:** Methodology, Formal analysis, Data curation, Writing – original draft preparation, Writing – review and editing.

Data Availability Statement
Datasets generated and analyzed are included in the published article.

Author Disclosure
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SUPPLEMENT

Supplement Table 1. Comparison between euthyroid and hypothyroid patients with uncontrolled diabetes (HbA1c >6.49%)

	Euthyroid	Hypothyroid	*P*-value
Total Population (N)	73	104	
Age	59.0 ± 11.4	57.4 ± 10.4	0.3343
Age [Median IQR]	62.0 [52.0, 68.0]	57.0 [50.3, 65.8]	
Age Distribution (years)			
18-30 – Young Adults	0 (0.0%)	0 (0.0%)	-
31-50 – Middle-Aged Adults	14 (19.2%)	26 (25.0%)	0.3953
51-70 – Older Adults	50 (68.5%)	67 (64.4%)	0.5352
>70 – Elderly	9 (12.3%)	11 (10.6%)	0.6965
Gender Distribution			
Male	46 (63.0%)	41 (39.4%)	0.0262
Female	27 (37.0%)	63 (60.6%)	
Family History	32 (43.8%)	46 (44.2%)	0.9760
Comorbidities			
No Comorbidities	29 (39.7%)	31 (29.8%)	0.1706
Hypertension	26 (35.6%)	42 (40.4%)	0.5221
Benign Prostatic Hyperplasia	21 (28.8%)	36 (34.6%)	0.4122
Dyslipidemia	9 (12.3%)	20 (19.2%)	0.2224
Coronary Artery Disease	11 (15.1%)	14 (13.5%)	0.7641
Chronic Kidney Disease	4 (5.5%)	11 (10.6%)	0.2301
Anaemia	7 (9.6%)	11 (10.6%)	0.8336
Bronchial Asthma	0 (0.0%)	0 (0.0%)	-
Irritable Bowel Syndrome	1 (1.4%)	0 (0.0%)	-
Osteoarthritis	0 (0.0%)	0 (0.0%)	-
Insulin Resistance	0 (0.0%)	0 (0.0%)	-
CABG Surgery (N = 6)	1 (16.7%)	5 (83.3%)	0.0021
Other Comorbid Condition			
Zero Comorbidities	29 (39.7%)	32 (30.8%)	0.2187
Single Comorbidities	14 (19.2%)	20 (19.2%)	0.9920
Two Comorbidities	25 (34.2%)	43 (41.3%)	0.3370
Three Comorbidities	5 (6.8%)	9 (8.7%)	0.6599

CABG – Coronary artery bypass graft