ORIGINAL ARTICLE

Pattern of Thyroid Dysfunction in Type II Diabetes Mellitus Patients in a Tertiary Care Center: A Cross-Sectional Study

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ABSTRACT

Background: Early identification and intervention of thyroid dysfunction which occurs in association with type-II diabetes mellitus may significantly reduce the risk of adverse cerebrovascular and cardiovascular events in such patients. Hence, this study analyzed the pattern of thyroid dysfunction in T2DM (Type 2 Diabetes mellitus) patients. **Methods:** The present cross-sectional study was done on 250 T2DM patients, who visited the department of General Medicine in a tertiary care teaching center. Medical history was recorded and venous blood samples were collected for investigations (HbA1C (Hemoglobin A1C), FBS (Fasting blood sugar), PPBS (Postprandial blood sugar), TSH (Thyroid stimulating hormone), T4 (Tetraiodothyronine), anti-TPO (Thyroid peroxidase), and fasting lipid profile). Thyroid dysfunction in patients with T2DM was considered as the primary outcome variable. P value <0.05 was considered statistically significant. Data were analyzed using coGuide software, V.1.03. **Results:** Females (55.6%) outnumbered males (44.4%) in this study. The prevalence of thyroid dysfunction in our study was 23.6% (95%CI 0.184 to 0.293). Subclinical hypothyroidism was found in 67.79% (95%CI 0.543 to 0.793) participants, overt hypothyroidism in 27.11% (95%CI 0.163 to 0.402), and hyperthyroidism in 5.10% (95%CI 0.010 to 0.141). Females (84.6%) had significantly higher prevalence of anti-TPO positivity compared to males (15.4%)(p=0.013). **Conclusions:** Findings of this study showed that T2DM patients have higher prevalence of thyroid dysfunction with predominance of subclinical hypothyroidism. Hence, this study emphasizes the importance of annual investigation of TSH levels in all the patients with T2DM.

KEY WORDS: Autoimmune Diseases, Hyperthyroidism, Hypothyroidism, ThyroidStimulating Hormone, Type II Diabetes Mellitus.

Introduction

Diabetes mellitus (DM) refers to a group of common metabolic disorders that share the phenotype of hyperglycemia, caused either by an absolute or relative deficiency of insulin. The International Diabetes Federation estimated that 387 million people worldwide had DM, in 2014.[1] India stands at the second position after China worldwide, with 69 million people affected by diabetes(almost every tenth adult).Although type II diabetes (T2D) is grossly under diagnosed, it was found that T2D accounts for > 90% of the diabetes burden across the globe.

Thyroid dysfunction (TD) consists of a spectrum of disorders affecting the thyroid gland, clinically presenting either as hypothyroidism or hyperthyroidism, causing a difference in the circulating levels of thyroid-stimulating hormone (TSH). It may present as thyroid enlargement (diffuse or nodular), hypothyroidism, hyperthyroidism, thyrotoxicosis, or may be asymptomatic (the subclinical state).[2] In 1979, the first report on the association between TD and DM was published. The prevalence of TD in diabetes varies from 2.2%-46.5%.[3]

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In a study conducted by Perros et al., the overall prevalence of TD in diabetic patients was reported to be 13.4%, with the highest and lowest prevalence rates in type 1 diabetic females (31.4%) and type 2 diabetic males (6.9%), respectively.Although most TD is higher in T1D patients, studies have demonstrated that TD is higher in T2DM compared to the general population, with a prevalence range of 5.4%-31.4%.[4,5] Several studies reported hypothyroidism (either subclinical or overt) as the most frequent type of TD in T2DM, with a prevalence range of 16%-65.83%.[6,7]

In hypothyroid patients, the rate of insulin degradation will be reduced, which in turn, may lower exogenous insulin requirement and is often accompanied by abnormalities in the metabolism of plasma lipid, which include elevation in the concentration of triglyceride, cholesterol and low-density lipoprotein (LDL). Dyslipidemia coexisting with T2DM gets exacerbated by subclinical hypothyroidism (SCH) and further increases the risk of cardiovascular diseases. Hence, it is necessary to diagnose TD in T2DM patients as early as possible for the provision of effective treatment since undiagnosed TD in diabetic people can adversely affect metabolism in such patients, thereby causing an elevation in the risk of diabetic complications.[8] There is a lack of sufficient literature in the present study area to address these problems or assess the magnitude of the problem. In light of the aforementioned issues, the present study aimed to assess the prevalence of thyroid dysfunction among type II diabetic patients.

Objective: To describe the prevalence and pattern of thyroid dysfunction in patients with type 2 Diabetes Mellitus.

Methods

Study Population and Study Site

Diabetic patients who attended the Department of General Medicine M S Ramaiah Hospital, Bangalore, during the study period.

Inclusion Criteria

- Patients with type II DM, who were either under treatment or newly diagnosed
- The age range of >35 years

Exclusion criteria

- Patients with infections and trauma
- Pregnant women
- Patients with pre-existing liver disease
- Patients on medication that alter thyroid functioning

Study design

A cross-sectional study.

Sample size

The literature survey indicated that the prevalence of thyroid dysfunction is around 29.7% in patients with type II diabetes mellitus[9]; therefore, this prevalence was selected for estimating the sample size for the present study. With a majority of 29.7%, a relative precision of 6%, and a confidence interval of 95%, the sample size was estimated to be 223 patients. Nonetheless, considering 12% lost to follow-up, another 27 patients were added, and the overall sample was considered 250. The sample size was determined using the formula, which was followed in the study of Daniel WW et al.[10]

Sampling method

Using the universal sampling method, a total of 250 consecutive patients who fulfilled the inclusion and exclusion criteria were included in this study.

Study duration

From November 2011 to September 2013 (22 months).

Ethical consideration and consent

The study was approved by the Institutional Review Board and the Ethics Committee of M S Ramaiah Medical College, Bangalore.

Data collection tools and clinical examination

A single examiner from general medicine department collected the demographic details, duration of diabetes, treatment details and comorbidities from both medical records and patients. HbA1c >46 mmol/mol (6.4)[11] or fasting casual blood glucose (CBG) at least 126 mg/dL (7·0 mmol/L) was diagnosed as diabetes[12]. Hypertension was diagnosed as systolic BP $\geq$ 140 mmHg and diastolic BP $\geq$ 90 mmHg.[13]

Laboratory investigation

Venous blood samples of participants were collected, HbA1c, fasting blood glucose (FBG), and lipid measurements were performed on the same day. The remaining serum was collected in plain F bottles, allowed to clot, and separated by centrifugation within 3 hours of collection. The sera were

frozen at -20ºC and then subjected to TSH, free tri-iodothyronine (FT3), and free thyroxine (FT4) analyses using an automated immunoassay platform. Antithyroid peroxidase (anti-TPO) antibodies were measured by enzyme-linked immunosorbent assay. A blood sample for Post Prandial Blood Sugar (PPBS) was also collected.

Based on the definitions of ATA guidelines, the patients were classified as subclinical hypothyroidism and hyperthyroidism, overt hypothyroidism and hyperthyroidism.[14,15] The SCH was defined as TSH-4.5 mU/L to 10 mU/L with normal FT4, overt hypothyroidism as TSH>10 mU/L with low FT4, hyperthyroidism as <0.45 mU/L TSH with raised FT4, and subclinical hyperthyroidism as <0.45 mU/L TSH with normal FT4. Dyslipidemia was regarded as LDL>100 mg/dL or on statin therapy.

Statistical analysis

Thyroid dysfunction in patients with type II diabetes mellitus was considered the primary outcome variable. Demographic variables, comorbidities, and treatment were regarded as other study-relevant variables. The descriptive analysis was carried out by mean and standard deviation for quantitative, frequency, and categorical variables. The mean values were compared between study groups using an independent sample t-test (two groups) for normally distributed quantitative parameters. The categorical outcomes were compared between study groups using the chi-square test. A p-value less than 0.05 was considered statistically significant. Data were analyzed in coGuide software (version 1.0).[16]

Results

A total of 250 participants were included in the final analysis. The mean age of the study group was 54.02±8.7 years, and the majority of them (44.8%) were aged between 45.1-55 years. Out of 250 patients, 139 (55.6%) cases were female, and 111 (44.4%) subjects were male. Regarding the duration of diabetes, most patients were inflicted with this disease for 0-5 years. The prevalence of thyroid dysfunction in this study was 23.6% (95% CI 0.184 to 0.293), out of whom 67.79% (95% CI 0.543 to 0.793), 27.11% (95% CI 163 to 0.402), and 5.1% (95% CI 0.010 to 0.141) had subclinical hypothyroidism, overt hypothyroidism, and overt hyperthyroidism, respectively; nonetheless, none of them had subclinical hyperthyroidism. The majority of participants (66.4%) were only on oral antihyperglycemic agents (OHAs) (Table 1).

Table 1: Summary of baseline parameters in the study population (n=250)

	Parameters	Summary
	Mean Age	54.02±8.7
Age group (in years)	35-45	37 (14.8%)
	45.1-55	112 (44.8%)
	55.1-65	76 (30.4%)
	65-75	22 (8.8%)
	>75	3 (1.2%)
Gender	Male	111 (44.4%)
	Female	139 (55.6%)
Duration of diabetes	0-5 years	140 (56.0%)
	5.01 to 10 years	83 (33.2%)
	10.01 to 15 years	22 (8.8%)
	>15 years	5 (2.0%)
Thyroid function	Euthyroid	191 (76.4%) (95% CI 0.711 to 0.816)
	Thyroid dysfunction	59 (23.6%) (95% CI 0.184 to 0.293)
	Subclinical hypothyroidism	40 (67.79%) (95% CI 0.543 to 0.793)
	Subclinical hyperthyroidism	0 (0%)
	Overt hypothyroidism	16 (27.11%) (95% CI 163 to 0.402)
	Overt hyperthyroidism	3 (5.10%) (95% CI 0.010 to 0.141)
Comorbidities	Hypertension	118 (47.2%)
	Dyslipidaemia	96 (38.4%)
	Dyslipidaemia & hypertension	75 (30%)
Treatment	Insulin	15 (6.0%)
	Oral antihyperglycemic agents	166 (66.4%)
	Insulin+oral antihyperglycemic agents	69 (27.6%)

The mean age of diabetics with TD was higher compared to the euthyroid subjects; however, the difference was not significant (P>0.05). The parameters like BMI, duration of diabetes, age of patient, dyslipidemia, HbA1C, hypertension, FBS, PPBS, and treatment and thyroid function did not show any statistically significant difference (P>0.05; Table 2).

The mean scores of BMI and HbA1C were higher in overt hypothyroid patients, as compared to

those in other groups (8.96±1.42 and 25.09±2.10), respectively (Table 3).

Table 2: Association between various parameters and thyroid function (n=250)

Parameter	Euthyroid	Thyroid dysfunction	P-value
Age (in years)	53.96±8.754	54.22±8.660	0.841*
Gender			
Male (n=139)	96 (86.5%)	15 (13.5%)	
Female (n=111)	95 (68.3%)	44 (31.7%)	<0.001†
HbA**1C**	8.56±1.58	8.85±1.40	0.207*
Duration of diabetes			
0 to 5 years (n=140)	112 (80%)	28 (20%)	0.254†
5.01 to 10 years (n=83)	58(69.9%)	25(30.1%)	
10.01 to 15 years (n=22)	18(81.8%)	4(18.2%)	
>15 years (n=5)	3(60%)	2(40%)	
Hypertension			
Yes (N=118)	92 (78%)	26 (22%)	0.581†
No (N=132)	99 (75%)	33 (25%)	
Dyslipidaemia			
Yes (n=96)	68 (70.8%)	28 (20.2%)	0.102†
No (n=154)	123 (79.9%)	31 (20.1%)	
Fasting Blood Sugar	132.34±31.27	134.20±27.24	0.681*
Post-Prandial Blood Sugar	190.93±43.61	198.36±49.20	0.268*
Body mass index	24.63±2.51	25.12±2.19	0.178*
Dyslipidaemia and hypertension			
Yes (n=75)	56 (74.67%)	19 (25.33%)	0.673†
No (n=175)	135 (77.14%)	40 (22.86%)	
Treatment			
Insulin (n=15)	10 (66.67%)	5 (33.33%)	0.657†
Oral antihyperglycemic agents (n=166)	128 (77.11%)	38 (22.89%)	
Insulin+oral antihyperglycemic agents (n=69)	53 (76.81%)	16 (23.19%)	

* Independent sample t-test, †Chi-square test

Table 3: Comparison of mean hemoglobin A1c and body mass index for each thyroid group

Thyroid function	N	Mean HbA1C ± SD (in %)	Mean body mass index
Euthyroid	191	8.56±1.58	24.75±2.51
SCH	40	8.80±1.34	24.76±2.30
Overt hypothyroid	16	8.96±1.42	25.09±2.10
Hyperthyroid	3	8.80±1.54	22.62±0.55

There was a statistically significant gender wise difference in antithyroid peroxidase (anti-TPO) (P=0.013) (Table 1).

Discussion

The mean age of participants was reported as 54.02±8.7 years, and the majority of them (55.6%) were female. The prevalence of thyroid dysfunction in this study was obtained at 23.6% (95% CI 0.184 to 0.293), out of whom 67.79% (95% CI 0.543 to 0.793), 5.1% (95% CI 0.010 to 0.141), and 27.11% (95% CI 163 to 0.402) had subclinical hypothyroidism, overt hypothyroidism, and overt hyperthyroidism, respectively. The mean difference of HbA1c and BMI across thyroid dysfunction was not statistically significant, whereas there was a statistically significant gender wise difference in anti-TPO.

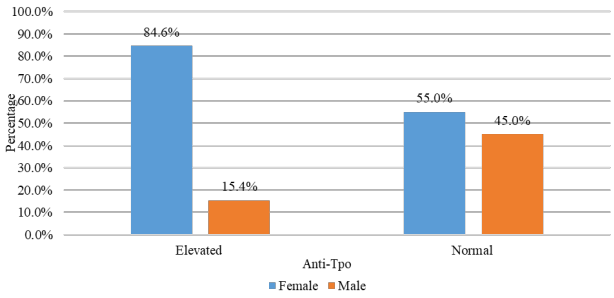

Chart 1: Cluster bar chart of comparison of anti-TPO between gender (N=59)

Based on the findings of the present research, the prevalence of thyroid dysfunction in diabetic patients was 23.4%, which is similar to the results of the studies by Khassawneh A H et al., Kumar et al., and Demitrost L et al. who reported the prevalence rates of 26.7%, 24%, and 31.2%, respectively.[7,17,18]

This increased prevalence of TDs in this study stresses the importance of screening of TDs in this target population. Among other thyroid dysfunction in diabetic patients, subclinical hypothyroidism (67.79%) was most common, followed by overt hypothyroidism (27.11%) and overt hyperthyroidism (5.1%). Similar findings were reported by other authors, with subclinical hypothyroidism being the most prevalent TD in T2DM patients.[18–20] A review and meta-analysis revealed a 1.93-fold increase in the risk of subclinical hypothyroidism inT2DM patients, as compared to that in non-diabetics. They also reported that diabetes complications were more prevalent in patients with both T2DM and subclinical hypothyroidism than those with T2DM and normal thyroid function.[4]

In agreement with the results of a study by Kamrul Hassan AB et al., the mean HbA1c was similar in both the groups in the present research.[21] On the contrary, another study reported a higher frequency of thyroid dysfunction in patients with uncontrolled diabetes.[6] A study conducted in India revealed that baseline HbA1c levels were significantly higher in hypothyroid patients, as compared to those in control individuals despite similar glucose levels.[22] In line with the findings of the study by Diez JJ et al.,[23] the mean FBS and PPBS scores were more in patients with TD, compared to euthyroid patients; however, the difference was not statistically significant. Participants with thyroid dysfunction had BMI similar to that of euthyroid ones in the current study. At the same time, a higher frequency of TD was reported in overweight or obese T2DM patients in multiple studies.[2,6,21]

In the present study, many patients were found to have elevated levels of antithyroid antibody (AITD) anti-TPO, which was higher in females (84.62%) and was statistically significant. Similar findings were observed in other studies.[24,25] A multi-center study conducted in India reported that 21.85% of Indian adults had AITD[26], suggesting that TD in T2DM patients have an autoimmune mechanism.

In the present study, 20.2% of T2DM patients with TD had dyslipidemia. An Indian study detected a significant association between hypothyroidism and dyslipidemia, while another study did not find any difference between euthyroid and hypothyroid in type II diabetics.[20,27] In the current research, 22% of hypertensives had thyroid dysfunction, which was not statistically significant. Kim BY et al. pointed out that even though the TD patients had higher mean SBP and DBP it was not significant.[28]

In this study, there was no significant association between TD and the duration of diabetes. Similar findings were reported by other researchers.[23,29] On the contrary, Al-Geffari M et al. suggested that patients with diabetes for more than 10 years are at risk of developing hypothyroidism.[30] As illustrated in many other studies, a female predominance was noticed for T2DM patients with TD in the current study, although it was not statistically significant.[29,30]

The present study observed a higher prevalence of thyroid dysfunction with predominance of subclinical hypothyroidism. Hence, this study emphasizes the importance of annual investigation of TSH levels in all the patients with T2DM.

The present study is not without limitations. The reference for sample size calculation was from a study in Nigeria, affecting the generalisability of the study results to Indian population. Among the different limitations of the present study, one is selection bias; since the subjects of this study were attending a tertiary referral hospital and were already under medical care in this study. Moreover, the confounders were not adjusted since the iodine present in diet and family history of TDs were not considered. Furthermore, the results cannot be generalized since this was a local hospital-based study in one canter.

Conclusion

High frequency of TD was observed in T2DM patients and subclinical hypothyroidism was the most common form noticed in these subjects. Females had a significantly higher thyroid autoimmunity and TD, as compared to males. The presence of high levels of antithyroid antibody suggests presence of autoimmunity in T2DM pathogenesis. Therefore, further research is required to promote early screening of TD and autoantibodies in T2DM patients; moreover, timely interventions need to be performed to prevent the associated complications.

Declarations

Ethical and informed consent: Ethical approval was obtained from the institutional review board of the centre concerned. Informed written consent was obtained before the study started and confidentiality was maintained throughout.

Conflict of interests: The authors declare no conflicts of interest.

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