Prevalence of hypothyroidism in adults: An epidemiological study in eight cities of India

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ABSTRACT

Background: Hypothyroidism is believed to be a common health issue in India, as it is worldwide. However, there is a paucity of data on the prevalence of hypothyroidism in adult population of India. Materials and Methods: A cross-sectional, multi-centre, epidemiological study was conducted in eight major cities (Bangalore, Chennai, Delhi, Goa, Mumbai, Hyderabad, Ahmedabad and Kolkata) of India to study the prevalence of hypothyroidism among adult population. Thyroid abnormalities were diagnosed on the basis of laboratory results (serum FT3, FT4 and Thyroid Stimulating Hormone [TSH]). Patients with history of hypothyroidism and receiving levothyroxine therapy or those with serum free T4 <0.89 ng/dl and TSH >5.50 μU/ml, were categorized as hypothyroid. The prevalence of self reported and undetected hypothyroidism, and anti-thyroid peroxidase (anti-TPO) antibody positivity was assessed. Results: A total of 5376 adult male or non-pregnant female participants ≥18 years of age were enrolled, of which 5360 (mean age: 46 ± 14.68 years; 53.70% females) were evaluated. The overall prevalence of hypothyroidism was 10.95% (n = 587, 95% Cl, 10.11-11.78) of which 7.48% (n = 401) patients self reported the condition, whereas 3.47% (n = 186) were previously undetected. Inland cities showed a higher prevalence of hypothyroidism as compared to coastal cities. A significantly higher (P < 0.05) proportion of females vs. males (15.86% vs 5.02%) and older vs. younger (13.11% vs 7.53%), adults were diagnosed with hypothyroidism. Additionally, 8.02% (n = 430) patients were diagnosed to have subclinical hypothyroidism (normal serum free T4 and TSH >5.50 μIU/mI). Anti – TPO antibodies suggesting autoimmunity were detected in 21.85% (n = 1171) patients. Conclusion: The prevalence of hypothyroidism was high, affecting approximately one in 10 adults in the study population. Female gender and older age were found to have significant association with hypothyroidism. Subclinical hypothyroidism and anti-TPO antibody positivity were the other common observations.

Key words: Anti-TPO positive, epidemiology, free T3, free T4, hypothyroidism, India, prevalence, subclinical hypothyroidism, undetected hypothyroidism

INTRODUCTION

Hypothyroidism is characterized by a broad clinical spectrum ranging from an overt state of myxedema, end-organ

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effects and multisystem failure to an asymptomatic or subclinical condition with normal levels of thyroxine and triiodothyronine and mildly elevated levels of serum thyrotropin.^[1-4] The prevalence of hypothyroidism in the developed world is about 4-5%.^[5,6] The prevalence of subclinical hypothyroidism in the developed world is about 4-15%.^[5,7]

In a developing and densely populated country like India, communicable diseases are priority health concerns due to their large contribution to the national disease burden.^[8] In India, hypothyroidism was usually categorized under

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the cluster of iodine deficient disorders (IDDs), which were represented in terms of total goiter rates and urinary iodine concentrations, typically assessed in school-aged children.^[9-11] Ever since India adopted the universal salt iodization program in 1983,^[12] there has been a decline in goiter prevalence in several parts of the country, which were previously endemic.^[13-15] In 2004, a WHO assessment of global iodine status classified India as having 'optimal' iodine nutrition,^[16,17] with a majority of households (83.2% urban and 66.1% rural) now consuming adequate iodized salt^[18,19] India is supposedly undergoing a transition from iodine deficiency to sufficiency state. A recent review of studies conducted in the post-iodization phase gives some indication of the corresponding change in the thyroid status of the Indian population.^[20] However, most of these studies are limited to certain geographical areas or cities, and undertaken in children with modest sample sizes.^[21-24] There have been no nationwide studies on the prevalence of hypothyroidism from India, either in the pre- or post-iodization periods. A large, cross-sectional, comprehensive study was required to provide a true picture of the evolving profile of thyroid disorders across the whole country, especially as the country is in the post-iodization era. The aim of the present study was to estimate the prevalence of hypothyroidism among the adult population in India.

MATERIALS AND METHODS

Study design and enrollment criteria

This was a cross-sectional, multi-centered epidemiology study conducted at eight sites in India namely Bangalore, Chennai, Delhi, Goa, Ahmedabad, Hyderabad, Kolkata and Mumbai. These cities were selected to ensure participation of a diverse study population with respect to geographic origin, occupation, socioeconomic status and food habits. Primary outcome measure of the study was the prevalence of hypothyroidism assessed by measurement of thyroid hormones. Secondary outcome measures were the prevalence of: i) self-reported and undetected hypothyroidism, ii) sub-clinical hypothyroidism (SCH) and iii) anti-thyroid peroxidase (TPO) antibody positivity in the study population. All male or female natives (residing in that area for at least 5 years) aged ≥ 18 years, were invited to participate in a general health checkup camp, and those willing to sign a written informed consent and provide blood sample for laboratory investigations were included in the study. Participants were excluded if they were pregnant, or had any acute or chronic systemic illnesses as judged by investigator; or if they were receiving drugs (like lithium or steroids) that could interfere with thyroid function tests. The study was approved by a Central Ethics Committee (CEC) and carried out in accordance

with the approved protocol, principles of Declaration of Helsinki and Good Clinical Practices. It was registered with the Clinical Trials Registry India (registration no: CTRI/2011/11/002180). All participants were required to provide written informed consent before study entry.

Subjects

Enrolment of 5277 participants was planned to form a target population that constituted 0.01% of the total population of the eight cities. Sample size for each city was calculated by performing stratification according to the 2001 national census data. Participants were selected through a single visit they made to any one of the 94 general health camps organized across the eight cities. For creating awareness of each general health camp, 5000-6000 invitation leaflets were distributed door to door covering approximately five kilometers area around the camp venue, banners were exhibited at appropriate areas and 8-10 general health camp posters were displayed in the vicinity of the camps. The general health camps were led by physicians certified in internal medicine.

Study procedure

Before enrolment, participants underwent medical history assessment, a general physical examination (including anthropometry and thyroid gland examination) and laboratory investigations. A central certified laboratory performed the hematological and biochemical investigations. Assays for thyroid hormone (FT3, FT4 and TSH) were performed by the chemiluminescence method using Advia Centaur automated immunoassay analyzer (Siemens Diagnostics Tarrytown, NY, USA). Anti-TPO antibodies were measured by the enzyme-linked immunosorbent assay (ELISA) using Immulite 2000 (Siemens Diagnostics Llanberis, Gwynedd, UK). Analytical sensitivity of the kit used to measure TSH, FT3, FT4 and anti-TPO antibodies was $0.010 \,\mu IU/mL$, $0.1 \,ng/mL$, $0.3 \,\mu g/dL$ and $5.0 \,IU/mL$, respectively.

Based on previous thyroid history and current thyroid function test results, participants were classified using following definitions: *Hypothyroid*: Serum-free thyroxine (FT4) <0.89 ng/dL and thyroid stimulation hormone (TSH) >5.50 μ U/mL, *Hyperthyroid*: Serum FT4 >1.76 ng/dL and TSH <0.35 μ IU/mL, *Subclinical hypothyroidism*: Normal serum FT4 and TSH >5.50 μ IU/mL. *Subclinical hyperthyroidism*: Normal serum FT4 and TSH <0.35 μ IU/ml, *Self-reported hypothyroidism*: Subjects with history of hypothyroidism: Subjects without history of hypothyroidism and detected to have hypothyroidism through thyroid function tests. *Anti-TPO antibody positive*: Presence of anti-TPO antibodies above 35 IU/ml.

Statistical analysis

Statistical analysis was performed using SAS[®] for Windows (Version 9.2, SAS Institute). The analysis was performed on the set of all eligible subjects enrolled in the study according to the study protocol. The prevalence of hypothyroidism and other thyroid disorders was summarized as counts and percentages. A Chi-square test was used to assess the trends in the prevalence of hypothyroidism, among different age groups and gender categories. Multiple Logistic Regression was used to describe factors associated with hypothyroidism, using 'whether the subject has hypothyroidism or not' as the dependent variable and 'Age' and 'Gender' as the independent variables. Similar analyses were performed for SCH and anti-TPO antibody positivity.

Table 1: Demographic characteristics and thyroid

related history of the study population	
Total subjects	5360
Gender, <i>n</i> (%)	
Female	2932 (54.70)
Male	2428 (45.30)
Age (years)	
Mean±SD	45.85±14.68
Min-Max (years)	18-100
Age-group, n (%)	
18-35 years	1447 (27.00)
36-45 years	1244 (23.21)
46-54 years	1068 (19.93)
55 and above	1601 (29.87)
Common concurrent conditions, n (%)	
Diabetes mellitus	866 (16.16)
Hypertension	1095 (20.43)
History of thyroid disease, n (%)	
Hypothyroid	427 (7.97)
Hyperthyroid	17 (0.34)
Goitre	116 (2.25)*
Thyroid malignancy	6 (0.11)
Subacute viral thyroiditis	2 (0.04)
History of thyroid surgery, <i>n</i> (%)	13 (0.24)
Current or past thyroid medications, n (%)	
Levothyroxine	379 (7.07)
Thyroid supplements	15 (0.27)
Carbimazole	13 (0.24)
Methimazole	1 (0.02)

*For history of goiter, 4 observations were missing

RESULTS

Five thousand three hundred and seventy six (5376) participants were enrolled across eight urban cities in India, from March 2011 to July 2011. Sixteen participants were withdrawn due to ineligibility (n = 11) or lack of laboratory data (n = 5). Out of the 5360 analyzable subjects, 2932 (54.70%) were females [Table 1]. The mean age of the study subjects was 45.85 with a range of 18 to 100 years. Hypertension (n = 1095; 20.4%) and diabetes mellitus (n = 866; 16.2%) were the most common concomitant diseases observed in the study population. Five hundred and ninety eight (11.15%) participants gave history of thyroid dysfunction including thyroid surgery. Thyroid medications were in current or previous use in approximately 8% (n = 408) of the population. A majority (88.27%; n = 4731) of the study population (n = 5360) was reportedly consuming iodized salt.

Hypothyroidism

The prevalence of hypothyroidism in the overall study population was 10.95% (n = 587, 95% CI, 10.11-11.78) of which 3.47% (n = 186) were previously undetected and 7.48% (n = 401) were self-reported cases. Positive history of hypothyroidism was given by 427 subjects, however only 401 of them were on thyroxine therapy. Out of these 401 self reported cases accurate dosing details of thyroxine therapy were available with 379 patients. Among these 379 patients 272 (71.77%) had a TSH <5.5 μ IU/mL) on a mean dose of 1.19 mcg/kg, while the remaining (n = 107, 28.23%) had a TSH >5.5 μ IU/mL on a mean dose of 1.10 mcg/kg.

Among all cities, Kolkata recorded the highest prevalence of hypothyroidism (21.67%), while others showed comparable rates ranging from 8.88% (Hyderabad) to 11.07% (Delhi) [Table 2]. Cities located in the in-land regions of India (Delhi, Ahmedabad, Kolkata, Bangalore

Table 2: Prevalence of thyroid disorders in eight urban cities of India											
City	n	Hypothyroidism n (%)	Self reported, hypothyroidism n (%)	Undetected hypothyroidism n (%)	Subclinical hypothyroidism n (%)	Hyperthyroidism n (%)	Subclinical hyperthyroidism n (%)	Anti-TPO positivity n (%)			
Ahmedabad	377	40 (10.61)	31 (8.22)	9 (2.39)	27 (7.16)	3 (0.8)	2 (0.53)	50 (13.26)			
Bangalore	867	80 (9.23)	47 (5.42)	33 (3.81)	63 (7.27)	7 (0.81)	9 (1.04)	151 (17.42)			
Chennai	430	42 (9.77)	33 (7.67)	9 (2.09)	23 (5.35)	2 (0.47)	7 (1.63)	111 (25.81)			
Delhi	1,436	159 (11.07)	102 (7.10)	57 (3.97)	138 (9.61)	5 (0.35)	15 (1.04)	316 (22.01)			
Goa	142	10 (7.04)	4 (2.82)	6 (4.23)	6 (4.23)	1 (0.7)	5 (3.52)	26 (18.31)			
Hyderabad	383	34 (8.88)	15 (3.92)	19 (4.96)	28 (7.31)	2 (0.52)	5 (1.31)	91 (23.76)			
Kolkata	466	101 (21.67)	84 (18.03)	17 (3.65)	55 (11.8)	5 (1.07)	2 (0.43)	106 (22.75)			
Mumbai	1,259	121 (9.61)	85 (6.75)	36 (2.86)	90 (7.15)	11 (0.87)	23 (1.83)	320 (25.42)			
$Total \rightarrow$	5360	587 (10.95)	401 (7.48)	186 (3.47)	430 (8.02)	36 (0.67)	68 (1.27)	1,171 (21.85)			

TPO: Thyroid peroxidase

and Hyderabad) reported a significantly higher prevalence of hypothyroidism (11.73%) than those (Mumbai, Chennai and Goa) in the coastal areas (9.45%), P = 0.01. Logistic Regression Analysis demonstrated a statistically significant (P < 0.05) interaction of patient age and gender with the prevalence of hypothyroidism. As compared to young adults (aged 18-35 years), older adults had greater chances of being diagnosed of hypothyroidism (36-45 years: OR = 1.49, 95% CI: 1.14-1.94, P = 0.0036; 46-54 years: OR = 1.53, 95% CI: 1.16-2.01, P = 0.0024; 55 years and above: OR = 1.560, 95% CI: 1.21–2.02, P = 0.0006). The prevalence of hypothyroidism was the highest in the age-group of 46 to 54 years (13.11%) and the lowest in that of 18 to 35 years (7.53%).

A larger proportion of females than males (15.86% vs. 5.02%; P < 0.0001) were found to be affected by hypothyroidism. Females were also more likely to be detected with hypothyroidism than males (OR = 3.36, 95% CI: 2.720-4.140; P < 0.0001).

Subclinical hypothyroidism

Subclinical hypothyroidism (SCH) was observed in 430 (8.02%, 95% CI: 7.29-8.74) participants. Frequency of SCH was highest (8.93%) in the age group of above 55 years and lowest in the age group of 18-35 years (6.91%), though no statistically significant association was found with age (P = 0.1534). A significantly higher number of females (8.73%) than males (7.17%, P = 0.0358) were detected to have SCH.

Anti-TPO antibodies

A total of 1171 (21.85%, 95% CI, 20.74-22.95) subjects tested positive for anti-TPO antibody. The anti-TPO positivity was consistently high, with five cities recording a prevalence of more than 20%. Lowest prevalence of anti-TPO antibodies was seen in Ahmedabad (13.26%) while highest prevalence was seen in Chennai (25.81%).

There was no significant association (P = 0.1796) between age and the presence of anti-TPO antibodies. Females showed a greater prevalence (26.04%) than males (16.81%), P < 0.05. Females in the age group of 46-54 had the highest prevalence (27.86%) of anti-TPO antibodies.

Hyperthyroidism

A total of 36 (0.67%, 95% CI, 0.45-0.89) participants including 21 females (0.72%) were diagnosed with hyperthyroidism. There was no association (P > 0.05) between hyperthyroidism and age or gender. Subclinical hyperthyroidism was seen in 68 (1.27%, 95% CI, 0.96-1.56) patients.

DISCUSSION

In the present study, we assessed the nationwide prevalence of thyroid disorders, particularly hypothyroidism, in adults residing in various urban cities that represent diverse geographical regions of India. Hypothyroidism was found to be a common form of thyroid dysfunction affecting 10.9% of the study population. The prevalence of undetected hypothyroidism was 3.47% i.e., almost one-third of the hypothyroid patients (186 out of 587) were diagnosed for the first time during the course of study-related screening. This suggests that a significant proportion of patient population may go undetected and untreated even as it continues to impair the daily quality of life, work performance and economic productivity of an individual.

On the other hand, among the subjects who self-reported themselves to be hypothyroid, a significant proportion (28%) still had a high TSH value. This calls for a review of current practices in the management of thyroid disorders, including active screening of endocrine function among patients at greater risks and an emphasis on regular monitoring of the thyroid status and dose adjustments to provide effective therapy in those with established diagnosis.

In general, India is now considered to be in the post-iodization phase.^[17] Our results suggest that, nationwide, the prevalence of hypothyroidism in adults is very high in this era. Unfortunately, no prevalence data exist on the occurrence of hypothyroidism among adults in the pre-iodization phase. The slight, but statistically significant increased prevalence of hypothyroidism among the inland vs. coastal cities in our study leads us to speculate whether iodine deficiency may continue to play a role in hypothyroidism in India.

The emergence of Kolkata as the worst affected city was unanticipated, particularly as the city was established to be iodine replete over a decade back.^[25] However, in a comparable geographical area of Gangetic basin in West Bengal, the prevalence of hypothyroidism in 3814 subjects from all age groups was even higher (29%).^[26] The high prevalence figures in Kolkata have ascertained that thyroid disorders in India are not confined to the conventional iodine-deficient sub-Himalayan zone but also extended to the plain fertile lands. A possible etiological role of cyanogenic foods acting as goitrogens to interfere with iodine nutrition has been previously suggested for, but not limited to this area.^[27,28] Increasing exposure to thyroid disruptors including industrial and agricultural contaminants has been identified as a growing health concern throughout India.^[29]

There was a predominance of thyroid dysfunction in women in our study, and is consistent with worldwide reports, especially those in midlife (46-54 years). Given the association between thyroid disorders and cardiovascular risk factors such as hypertension and dyslipidemia,^[30] the prevalence figures noted for women in this study draw attention to the growing health needs of this important segment of the Indian population.

Another significant observation was that approximately one fifth of the study population had anti-TPO positivity, which is an established marker of autoimmune thyroid disease.^[31] There seems to be a steady rise in the prevalence of anti-TPO positive in India. In a study conducted from 2007 to 2010 in Delhi, the percentage of adults testing TPO antibody positive was 13.3%;^[32] the figure was 22.01% in the current study. A similar increase was apparently observed in the southern part of India. Earlier, Kerala saw a 16.7%^[33] prevalence of anti-TPO positivity in adults, and the rate in a neighboring state (represented by Chennai) reported in the current study is 25.81%. Reasons for the increase in anti-TPO positivity remain unclear; the underlying pathogenesis may involve a complex interplay of genetic, environmental and endogenous factors.^[15,34-36]

Our study has important limitations: Firstly, it was done in urban India, and the prevalence of hypothyroidism in rural India remains unknown. Secondly, from the consumption of iodized salt, the study presumed that the target population was iodine sufficient, without testing for reliable markers such as iodine content in salt samples or urinary iodine excretion.^[37] Thus, with regard to the cause of hypothyroidism, there may be etiological factors other than the iodization status.

To summarize the present study is to first provide nationwide data on the prevalence of hypothyroidism in the adult population. The study shows a high prevalence of hypothyroidism and positivity to anti-TPO antibodies. This poses a public health concern and an important challenge to the policy makers and health professionals.

CONCLUSIONS

Hypothyroidism is a commonly prevailing disorder in adult Indian population. Older overweight females seem to be more prone. Autoimmune mechanisms appear to play an etiological role in a significant proportion of patients. Iodine intake ceases to be the sole etiological contender for thyroid disorders in urban areas. Identification of multiple risk factors and plausible underlying mechanisms is warranted.

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