

Prevalence, clinical and biochemical profile of subclinical hypothyroidism in normal population in Mumbai

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ABSTRACT

Background: Subclinical Hypothyroidism (ScHt) affects 3–15% of the adult population. It's clinical and biochemical profile is not well defined, especially in Indian scenario. Our study aimed at screening normal population to define normative ranges of thyroid hormones and Serum thyroid stimulating hormone (S.TSH) and prevalence of ScHt and thyroid autoimmunity. **Materials and Methods:** Two-hundred thirty-seven normal subjects without family history of thyroid disease were evaluated for symptoms and laboratory tests for thyroid dysfunction and autoimmunity. **Results:** The thyroid function tests were as follows: **Euthyroid Group:** Mean values were: T3: 1.79 ± 0.42 ng/mL, T4: 10.23 ± 2.25 μ g/dL, FT3: 1.88 ± 0.19 pg/mL, FT4: 1.12 ± 0.21 ng/dL, S.TSH: 2.22 ± 1.06 μ lu/mL. 10.2% of euthyroid subjects had antimicrosomal antibodies (AMA) +ve (mean titer 1:918) and 23.6% were anti-thyroid peroxidase autoantibody (anti-TPO) +ve (mean titer 15.06 Au/mL). The euthyroid outlier range for S.TSH was 0.3–4.6 μ lu/mL. The values were comparable in both the sexes. Those with S.TSH ≥ 5 μ lu/mL were defined to have ScHt. **ScHt Group:** Prevalence of ScHt was 11.3% (M:F ratio 1:3.7). 74% belonged to 35–54 years age group and prevalence increased with age (post-menopausal females: prevalence 20%). S.TSH was 9.8 ± 7.22 μ lu/mL, mean S.AMA was 1:5079 (40.7% positivity) and mean S.anti-TPO was 260 Au/mL (47.6% positivity). Majority were agoitrous (74%), and stage I goiter was seen in 26% of this population. Symptom score of 5–8 was seen in 55% ScHt subjects versus 35% normal subjects. **Conclusion:** Mean S.TSH in our population was 2.22 μ lu/mL (euthyroid outliers: 0.3–4.6 μ lu/mL); hence, S.TSH above 4.6 μ lu/mL should be considered as abnormal. The prevalence of thyroid autoimmunity increases after age of 35 years. ScHt presents mainly in agoitrous form and with positive antibodies, suggesting autoimmunity as the cause.

Key words: Autoimmunity, normative ranges, prevalence, subclinical hypothyroidism

INTRODUCTION

Subclinical hypothyroidism (ScHt) is defined as high S.TSH concentration with normal serum Free Thyroxine (FT₄) and Free Triiodothyronine (FT₃) concentrations, associated with few or no signs and symptoms of hypothyroidism.^[1] Subclinical hypothyroidism is the most prevalent thyroid disorder affecting 3–15%^[2] of the adult population. Its

incidence increases with advanced age,^[3-5] female gender,^[4,6] and greater dietary iodine intake.^[7-10]

Various studies have shown that ScHt is associated with hyperlipidemia,^[3,5,10-14] neuromuscular^[15-17] and neuropsychiatric symptoms,^[15-17] myocardial dysfunction^[18-21] and decrease in quality of life with progression to overt hypothyroidism.^[5,10,12]

Due to apparently asymptomatic nature of the illness, the "American Thyroid Association"(ATA) has recommended routine population screening of both sexes at age 35 years and then every 5 years thereafter for early detection and treatment of ScHt. There is paucity of Indian data on prevalence, clinical profile, biochemical profile and therapy of this condition. There are no Indian guidelines for screening of high-risk population for ScHt. This study attempts to determine the normal thyroid hormone

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ranges in Indian population and to find an answer to issues regarding the prevalence and biochemical and clinical features of ScHt, which can help in early diagnosis.

AIMS AND OBJECTIVES

1. To define the normal ranges for thyroid hormones and S.TSH.
2. To study the prevalence of ScHt in paramedical population of a public hospital in Mumbai.
3. To study association of S.TSH with goiter and thyroid autoimmunity in this population.

MATERIALS AND METHODS

Study design

A cross-sectional observational study was conducted in the Endocrinology Department of a Municipal Charitable hospital in Mumbai. Two-hundred thirty-seven subjects from paramedical personnel registry were selected for the same. The study was conducted after being approved by the Institutional Ethics Committee.

Sample size calculation

Sample size was based on the formula “sample size = $n/1 - n/\text{population}$ ” as per which 196 subjects were required to be screened to achieve a level of confidence of 99.99%. Volunteers were selected by stratified random multistage sampling using random number table. Every 7th “healthy person” from the registry was invited to participate into the study. Sample was stratified based on gender (207 females and 30 males) as ScHt is reported to be more prevalent in females.^[4]

Volunteer selection

Subjects ≥ 18 years of age of both sexes and those who consented to participate and take screening tests in the protocol were included in the study. Subjects with known current or past thyroid disorders, pregnant females and subjects with any known illnesses or on chronic medications were excluded from the study.

Statistical considerations

Statistical analysis of the data was performed by SPSS statistical software (version 10.1). Chi-square test was used to test the significance of association in cases of qualitative data, unpaired ‘t’ test was used to test the significance of association in case of quantitative data between two separate groups, while paired ‘t’ test was used to test the significance of association in case of paired quantitative data amongst individual groups. Pearson’s correlation coefficient (r) was used to assess the correlation of S.TSH with quantitative data and Spearman’s correlation coefficient (ρ) was used

to assess the correlation of S.TSH with qualitative data. P values > 0.05 were not significant and values ≤ 0.05 were significant.

Methods

The volunteers were evaluated by a detailed history and clinical examination for evaluation of thyroid disease based on proforma designed for the same. Symptom questionnaire, which involved questions regarding various clinical features of thyroid dysfunction, was used such that 1 point was awarded to every symptom present and then all points were added to obtain the symptom score. Goiter staging was done based on the PAHO staging into 4 grades (0–III).

Assay methodology

Laboratory tests for thyroid function tests (serum levels of T_3 , T_4 , FT_3 , FT_4 , and S.TSH) and serum thyroid autoantibody titers (antimicrosomal antibodies [S.AMA], and anti-thyroid peroxidase autoantibody [S.anti-TPO]) were evaluated in these subjects.

Total T_3 and T_4 were determined by standard double antibody radioimmunoassay technique, supplied by BRIT Mumbai. Sensitivities of these tests were 0.24 ng/mL and 0.5 ng/mL, respectively. Free T_3 (FT_3) and Free T_4 (FT_4) were determined by direct one-step radioimmunoassay using gamma coat free T_3 I¹²⁵ and free T_4 I¹²⁵ RIA kit supplied by Diasorin, USA. Sensitivities of these tests were 0.05 pg/mL and 0.07 ng/dL, respectively. S.TSH was determined by 2-site immunoradiometric assay (IRMA) using kit supplied by BRIT Mumbai. Its sensitivity was 0.025 μ lu/mL. S.AMA was tested using Serodia-AMC reagent. Positive reaction at any dilution ($\geq 1:400$) was taken as a reactive test. S.anti-TPO antibodies were determined by two staged IRMA assay using AB-TPOK-3 kit supplied by Diasorin, USA. S.anti-TPO was positive when values were > 15 AU/mL. Sensitivity of this reaction was < 1 AU/mL.

Observations

Figure 1, Table 1 and Figure 2, Table 2 and Figure 3.

DISCUSSION

Screening studies to assess thyroid disorder prevalence have provided valuable insights in understanding the epidemiology of all thyroid disorders in the population worldwide. There is a rise in the prevalence of all the thyroid disorders including ScHt in India post iodization era. However, screening studies have been a rarity in India and there is scanty literature on prevalence of these disorders in all regions of India. Our study has shown

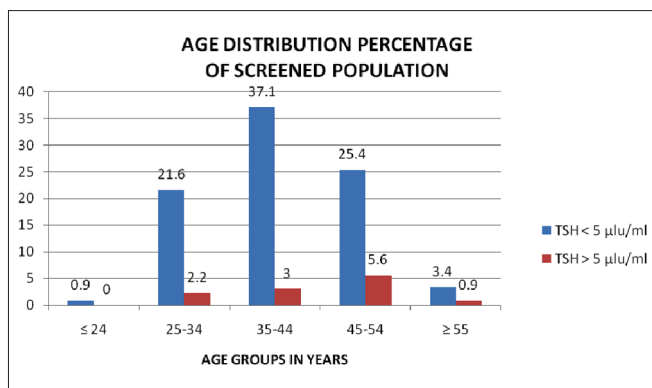


Figure 1: Prevalence of ScHt showed a rising trend after age of 35 years

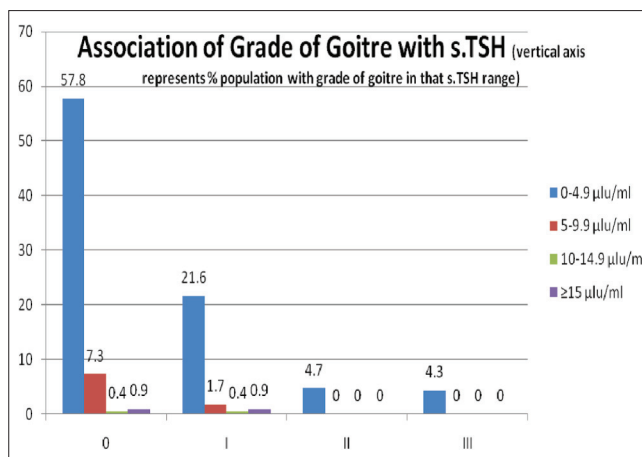


Figure 2: Most of the ScHt patients had no goiter or stage 1 goiter. However, 9% of euthyroid subjects had stage II or III goiter.

Table 1: The thyroid function tests in screened normal population

KIT range	Euthyroid population		ScHt patients	
	Range	Mean ± SD	Range	Mean ± SD
S.T3 (ng/mL)	0.7–2.0 ng/mL	1.79 ± 0.42	1.2–2.3	1.77 ± 0.31
S.T4 (µg/dL)	5.5–13.5 µg/dL	10.23 ± 2.25	6.1–15.3	9.75 ± 0.53
S.FT3 (pg/mL)	1.5–5 pg/mL	1.88 ± 0.19	0.71–2.4	1.71 ± 0.45
S.FT4 (ng/mL)	0.95–2.23 ng/mL	1.12 ± 0.21	0.69–2.0	1.18 ± 0.30
S.TSH (µIU/mL)	0.17–4.05 µIU/mL	2.22 ± 1.06	5–31	9.822 ± 7.26
S.anti TPO (Au/ml)	Positive > 15 Au/mL Negative ≤ 15 Au/mL	1.2–190.6	2.1–1249.9	260 ± 424.06
S.AMA titer	Reactive - positive at dilution ≥ 1:400 Non-reactive - negative reaction at dilution < 1:400	1:100–1:25600	1:100–1:102400	1:5079.68

The euthyroid outlier range for S.TSH was 0.3 to 4.6 µIU/mL. Of the studied population 11.3% subjects had ScHt; 1.6% had overt hypothyroidism; 0.4% had overt hyperthyroidism; while none had subclinical hyperthyroidism. The prevalence of ScHt in postmenopausal women was 19.6%. The male: female ratio was 1:3.7. Age distribution and its association with S.TSH of the screened population was as shown in Figure 1.

Table 2: Serum thyroid stimulating hormone levels and thyroid autoimmunity

S.TSH (µIU/mL)	S.AMA			S.anti-TPO		
	Negative N (%)	Positive N (%)	Total N (%)	Negative N (%)	Positive N (%)	Total N (%)
<5.0	184 (89.7)	21 (10.2)	205 (100)	42 (76.4)	12 (23.6)	55 (100)
> 5.0	16 (59.2)	11 (40.7)	27 (100)	11 (52.4)	10 (47.6)	21 (100)
Total	200 (86.3)	32 (13.7)	232 (100)	53 (70)	23 (30.2)	76 (100)

S.AMA and S.anti-TPO positivity was maximum in age group 35–54 years. Goiter prevalence was independent of thyroid autoimmunity, 11% of AMA positive and 28.8% of anti-TPO positive subjects were agoitrous. We assayed anti-TPO antibodies in 76 subjects. 3.7% anti-TPO negative subjects were AMA positive while 19% subjects with AMA negative were anti-TPO positive.

Symptom score: 55.6% patients with ScHt had a symptom score between 5 and 8 (based upon the symptom questionnaire where each symptom was awarded 1 point). Commonest symptoms were physical fatigue (69%), lethargy (63%), weight gain (62%), dry hair/alopecia (55%), myalgia/ arthralgia (49%), memory loss (48%) and paresthesia (46%) and were significantly higher than the euthyroid population. So, ScHt may not be literally subclinical but may harbor subtle symptoms, which can easily be mistaken for symptoms of menopause.

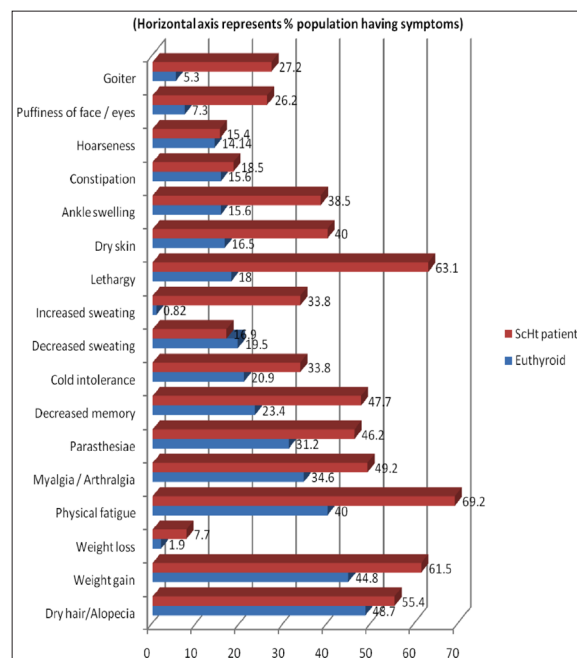


Figure 3: Comparison of symptoms between euthyroid population and ScHt patients revealed following data

that ScHt was the most prevalent thyroid disorder in the study population followed by overt hypothyroidism and hyperthyroidism. This prevalence of ScHt is comparable to the large epidemiologic studies, viz: Framingham, Rotterdam and Colorado studies [Table 3].

The prevalence of ScHt in our population was higher than the Wickham survey, probably because our S.TSH cut off was lower at 5 $\mu\text{IU}/\text{mL}$ and our study population was older. Besides our study population composed of select paramedical staff population while Wickham survey was done on a community basis. The prevalence of ScHt differed in all above studies because the criteria for age and S.TSH cut off ranges were variable. 74% subjects with ScHt belonged to the age group 35–54 years and prevalence showed rising trend with age. This age-wise increase in prevalence is probably due to thyroid autoimmunity, which is known to increase with age as reported in the Wickham survey.^[3] Besides, prevalence was more in females and increased with age, which is similar to that observed by Parle *et al.*^[21] Prevalence was also more in postmenopausal women.

The population S.TSH range correlated with normal kit range, T_3 and T_4 ranges were higher, while FT_3 and FT_4 were lower than normal kit range. This may be due to excess protein binding affinity of thyroid binding globulin in study population.

S.TSH levels inversely correlated with goiter, implying that ScHt may be present without goiter, which was similarly found in the Wickham survey.^[3] This is probably related to the rapid progression of the autoimmune disorder leading to early thyroid gland atrophy, also implying that subclinical autoimmune thyroiditis may manifest initially as goiter but with progression the thyroid gland atrophies, causing ScHt. Thyroid autoantibody positivity was maximum in age group 35–54 years. S.AMA and S.anti-TPO antibodies correlated well with each other and with S.TSH. High S.TSH positively correlated with antibody positive status and was

also associated with a higher symptom score, weight gain, physical fatigue and alopecia being the commonest of symptoms.

Prevalence studies in India

Family studies conducted in Mumbai by Dr Meena Desai *et al.* on first-degree relatives of children with thyroiditis revealed presence of AMA in 43% and thyroid disease in 26%.^[25] Among 71 index cases, overt hypothyroidism was seen in 17% and subclinical hypothyroidism in 32%. Siblings had a 23% incidence of subclinical hypothyroidism and no overt cases were reported.

In an another study done by Marwaha RK, Tandon N, Kochupillai N *et al.* on countrywide screening of goitrous healthy young girls in India, it was seen that in patients with FNAC-proven juvenile autoimmune thyroiditis, subclinical hypothyroidism was seen in 15% cases.^[26]

Various other epidemiological studies in India mentioned in the [Table 4] have shown a prevalence rate varying between 9 and 11.4%, which is similar to that seen in our study.

CONCLUSIONS

Normative data of thyroid functions needs to be established separately for each individual population. Any S.TSH value above 4.6 microIU/mL needs to be considered as abnormal in reference to the diagnosis of ScHt. Screening for ScHt needs to be considered in peri-menopausal females in view of high prevalence of raised S.TSH and thyroid autoimmunity as seen in our study population after the age of 35 years. In our study, ScHt presented mainly in the agoitrous form and was associated with significant comorbidity in form of lethargy, fatigue, and weight gain which is mostly undiagnosed or neglected in peri-menopausal population. Thus, any subject presenting with undiagnosed fatigue and weight gain needs to be screened for presence of ScHt.

Our study provides valuable inputs to help define normative data of thyroid function in Indian population

Table 3: International epidemiological studies

Place of study	Reference	Age (in years)	Sex (%)		Number	Prevalence %			TSH Cut off ($\mu\text{IU}/\text{mL}$)
			M	F		Total	M	F	
Wickham	Tunbridge <i>et al.</i> ^[3]	18+	33	77	2779	8.9	2.8	7.5	> 6
Sweden	Nystrom <i>et al.</i> ^[22] (1981)	44+	0	100	1283	5.1	-	5.1	> 8
Farmingham	Sawin <i>et al.</i> ^[4]	60+	41	59	2139	10.3	5.6	13.5	> 5
Birmingham	Parle <i>et al.</i> ^[24] (1990)	60+	41	59	1210	8.3	2.9	11.6	> 5
U.S.A.	Bauer <i>et al.</i> ^[23] (1998)	65+	0	100	279	6.8	-	6.8	>5.5
Rotterdam	A.E. Hak <i>et al.</i> ^[12] (2000)	55+	0	100	1149	10.8	-	10.8	> 4.0
U.S.A.	Canaris <i>et al.</i> ^[14]	70-79	49	51	2799	3.9	-	11.1	> 5.5
Colorado	Kanaya <i>et al.</i> ^[18] (2002)	18+	44	56	2336	9.5	-	-	> 5.1
Mumbai	Present study (2003)	20-60	13	87	237	11.3	3.3	12.5	> 5

Table 4: Indian epidemiological studies

Place of Study	Reference	Population studied	Number	Prevalence %		
				Total	M	F
Cochin	Unnikrishnan AG <i>et al.</i> ^[27]	adult	971	9	6.2	11.4
Nepal	Rohil <i>et al.</i> ^[28]	adult	1714	26		
Delhi	Sahu <i>et al.</i> ^[29]	pregnant	633		6.4	
Baroda and Dang	Brahmabhatt <i>et al.</i> ^[30]	adult	959		7	
Puducherry	Abraham <i>et al.</i> ^[31]	adult	505			9.5

and epidemiology of subclinical hypothyroidism in India and improving our understanding of the same.

LIMITATIONS

Screening for ScHt should ideally be performed in community population, but due to lack of feasibility we have screened our hospital paramedical staff and extrapolated this data to the community. Small number of male participants in this study precludes any conclusion for screening guidelines in male subjects in this age group.

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