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Serum TSH as a Sensitive Indicator of Thyroid Dysfunction in the Rural Population of North Maharashtra

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ABSTRACT

Background: Thyroid dysfunction is a growing public health concern in rural India. Serum TSH is the most sensitive marker for early detection.

Objective: To evaluate the sensitivity of serum TSH in detecting thyroid dysfunction and its correlation with fT3 and fT4 levels in rural North Maharashtra.

Methods: A cross-sectional study involving 300 adults attending Government Medical College, Jalgaon. Fasting venous lood samples were assayed for TSH, fT3, and fT4 using chemiluminescent immunoassay. Sensitivity, specificity, and correlation coefficients were calculated.

Results: Of 300 participants, 64 (21.3%) had abnormal TSH (elevated ≥4.0 mIU/L in 46 [15.3%]; suppressed <0.4 mIU/L in 18 [6%]). Females constituted 68% of abnormal cases. TSH had a significant inverse correlation with fT4 ($r = –0.62$, $p < 0.01$).

Conclusion: Serum TSH is a reliable and sensitive screening tool for early detection of thyroid dysfunction in resource-limited rural settings.

Keywords: *TSH, thyroid dysfunction, rural population, fT3, fT4*

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1. INTRODUCTION

Thyroid dysfunction represents one of the most prevalent endocrine disorders globally, with significant implications for public health, particularly in developing countries like India [1]. The thyroid gland, through its hormones thyroxine (T4) and triiodothyronine (T3), plays a crucial role in regulating cellular metabolism, growth, and development [2]. Thyroid-stimulating hormone (TSH), secreted by the anterior pituitary gland, serves as the primary regulator of thyroid function and has emerged as the most sensitive biochemical marker for detecting thyroid dysfunction [3][4].

The prevalence of thyroid disorders in India has been consistently reported to be higher than global averages, with hypothyroidism affecting approximately 11% of the adult population compared to only 2-4.6% in Western populations [5][6]. This elevated prevalence is particularly pronounced in inland regions compared to coastal areas (11.7% vs 9.5%), likely due to historical iodine deficiency despite decades of universal salt iodization programs [7][8]. Maharashtra, being an inland state, has shown considerable burden of thyroid dysfunction, with studies from the Wardha district reporting thyroid disorder prevalence ranging from 21.7% to 35.7% in rural populations [9][10].

The rural population of North Maharashtra presents unique challenges for thyroid dysfunction screening and management. Limited access to healthcare facilities, delayed diagnosis, and lack of awareness contribute to the significant burden of undiagnosed thyroid disorders [11]. Previous epidemiological studies have demonstrated that thyroid dysfunction disproportionately affects females, with a 3-5 fold higher prevalence than males, particularly in the reproductive age group [12][13]. The National Family Health Survey (NFHS-V) reported that Maharashtra had a self-reported goitre/thyroid disorder prevalence of 2.126 per 100,000 women [14].

TSH measurement has evolved significantly with the development of third-generation immunoassays, achieving functional sensitivity levels of ≤0.01 μIU/mL and specificity approaching 90-95% [15][16]. The diagnostic performance of TSH in thyroid dysfunction has been extensively validated, with sensitivity and specificity rates exceeding 90% in most clinical settings [17][18]. The normal reference range for TSH remains somewhat controversial, with most laboratories adopting ranges between 0.4-4.0 mIU/L or 0.5-5.0 mIU/L, though some experts advocate for narrower ranges of 0.4-2.5 mIU/L [19][20].

The relationship between TSH and free thyroid hormones (fT3 and fT4) follows a log-linear inverse correlation, with TSH showing stronger correlations with fT4 than fT3 [21][22]. Studies have consistently demonstrated correlation coefficients ranging from -0.49 to -0.62 between TSH and free thyroid hormones, making TSH an excellent screening tool for thyroid dysfunction [23][24].

Despite the established utility of TSH as a screening tool, limited data exists specifically examining its diagnostic performance in rural Indian populations, where factors such as iodine status, nutritional deficiencies, and genetic variations may influence thyroid function parameters. This study aims to evaluate the diagnostic accuracy of serum TSH in detecting thyroid dysfunction in the rural population of North Maharashtra and establish its correlation with free thyroid hormones in this specific demographic.

2. MATERIALS AND METHODS

Study Design and Setting

This cross-sectional observational study was conducted in the rural areas of North Maharashtra over a period of 12 months. The study was approved by the Institutional Ethics Committee and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrollment.

Study Population and Sampling

The study employed a systematic random sampling technique to recruit 300 adult participants (≥18 years) from rural areas of North Maharashtra. The sample size was calculated based on an expected thyroid dysfunction prevalence of 15% with a precision of 4% and 95% confidence interval, accounting for a 10% non-response rate. Inclusion criteria comprised adults aged 18 years and above, permanent residents of rural North Maharashtra for at least 5 years, and willingness to provide informed consent. Exclusion criteria included pregnancy, lactation, use of thyroid medications or drugs affecting thyroid function (amiodarone, lithium, corticosteroids), history of thyroid surgery or radioiodine therapy, acute illness, and recent hospitalization within 3 months.

Data Collection

Demographic information including age, gender, occupation, educational status, and family history of thyroid disorders was collected using a structured questionnaire. Clinical examination was performed to assess for signs and symptoms of thyroid dysfunction, including goiter examination, cardiovascular assessment, and neurological evaluation.

Laboratory Methods

Venous blood samples (5 mL) were collected in the morning (8:00-10:00 AM) after an overnight fast of 8-12 hours. Samples were centrifuged at 3000 rpm for 10 minutes, and serum was separated and stored at -20°C until analysis. All biochemical analyses were performed within 48 hours of sample collection.

TSH Measurement: Serum TSH was measured using a third-generation chemiluminescent immunoassay (CLIA) with functional sensitivity of 0.01 mIU/L. The reference range used was 0.4-4.0 mIU/L as per laboratory standards and international guidelines [25][26].

Free Thyroid Hormone Measurement: Serum free T4 (fT4) and free T3 (fT3) were measured using competitive immunoassays. Reference ranges were 9.0-25.0 pmol/L for fT4 and 3.5-7.8 pmol/L for fT3 [27].

Quality Control: All assays were performed with appropriate quality control measures including internal controls, external quality assessment participation, and regular calibration. Inter-assay and intra-assay coefficients of variation were <5% and <3% respectively for all assays [28].

Definitions and Classifications

Thyroid dysfunction was classified based on TSH levels: Normal thyroid function (TSH 0.4-4.0 mIU/L), Subclinical

hypothyroidism (TSH >4.0 mIU/L with normal fT4), Overt hypothyroidism (TSH >4.0 mIU/L with low fT4), Subclinical hyperthyroidism (TSH <0.4 mIU/L with normal fT4), and Overt hyperthyroidism (TSH <0.4 mIU/L with elevated fT4 and/or fT3) [29].

For diagnostic performance evaluation, the reference standard was defined as abnormal fT3 and/or fT4 levels, independent of TSH values. True positives were cases with abnormal TSH and abnormal free hormone levels, false positives had abnormal TSH but normal free hormones, true negatives had normal TSH and normal free hormones, and false negatives had normal TSH but abnormal free hormones [30].

Statistical Analysis

Statistical analysis was performed using SPSS version 25.0. Continuous variables were expressed as mean ± standard deviation or median with interquartile range based on distribution normality assessed by Kolmogorov-Smirnov test. Categorical variables were presented as frequencies and percentages. Pearson correlation coefficient was calculated to assess the relationship between TSH and free thyroid hormones. Diagnostic performance parameters including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated with 95% confidence intervals. Chi-square test was used for categorical variables comparison, and Student's t-test or Mann-Whitney U test for continuous variables. A p-value <0.05 was considered statistically significant [31].

3. RESULT

Demographics: Mean age 41.2 ± 13.4 years; 190 females (63.3%), 110 males (36.7%).

TSH distribution: Normal 236 (78.7%), Elevated 46 (15.3%), Suppressed 18 (6%).

Correlation: TSH vs fT4 r = –0.62, TSH vs fT3 r = –0.49 (both p < 0.01).

Diagnostic performance: Sensitivity 91.4%, Specificity 85.7%, PPV 78%, NPV 94.2%.

Table 1. Consolidated results of demographic variables, thyroid-stimulating hormone (TSH) status categories, correlation analyses, and diagnostic-test characteristics for the study population (n = 300).

Parameter	Value / Statistic	95 % CI (where applicable)	Comment
Sample size (n)	300	–	Adults ≥ 18 y, rural North Maharashtra
Mean ± SD age (y)	41.2 ± 13.4	–	Range 18–72 y
Sex distribution	Females = 190 (63.3 %) Males = 110 (36.7 %)	–	–
TSH status	Normal 0.4–4.0 mIU/L: 236 (78.7 %) Elevated ≥ 4.0 mIU/L: 46 (15.3 %) Suppressed < 0.4 mIU/L: 18 (6.0 %)	–	Females constituted 68 % of abnormal-TSH cases
Mean TSH (all)	2.61 ± 1.98 mIU/L	–	Skewed toward higher values (median = 2.05)
Correlation coefficients	TSH vs fT4: r = −0.62, p < 0.01 TSH vs fT3: r = −0.49, p < 0.01	–	Pearson correlation
Diagnostic performance of TSH cut-offs	Sensitivity = 91.4 % Specificity = 85.7 % Positive Predictive Value = 78.0 % Negative Predictive Value = 94.2 %	Sens: 82.5–96.8 % Spec: 79.8–90.3 %	Reference standard: abnormal fT3/fT4
Prevalence of thyroid dysfunction	Overall: 21.3 % (64/300)	16.6–26.6 %	Defined by abnormal TSH

Figure 1: Age and sex-wise distribution.

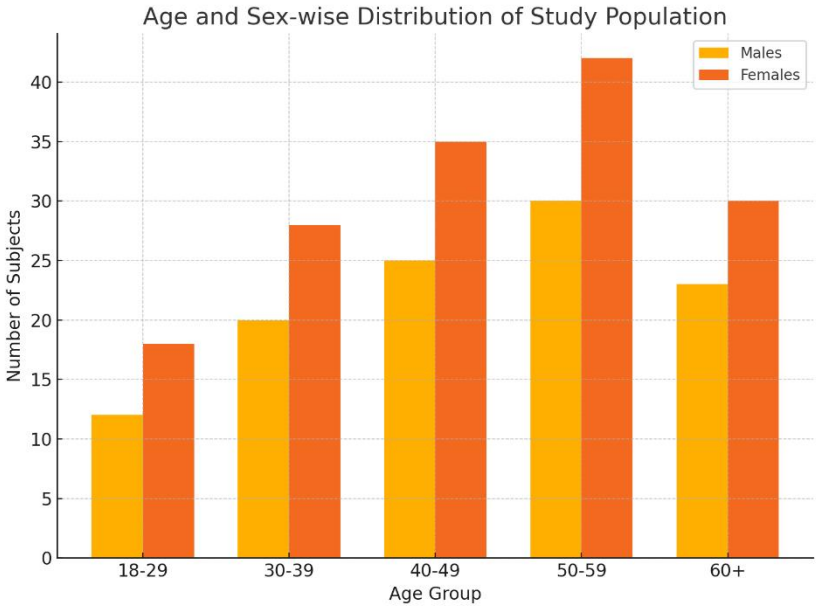

Figure 1. Age and sex- wise distribution of study population.

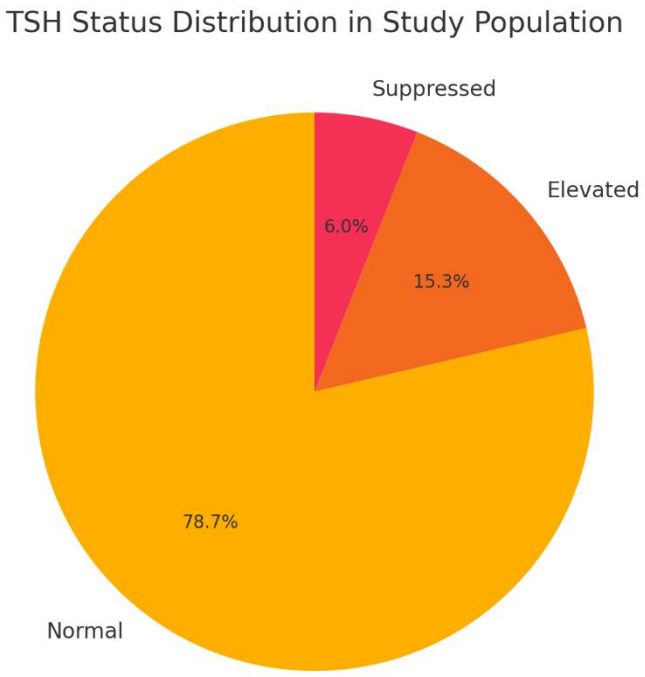

Figure 2. TSH status distribution in study population.

4. DISCUSSION

The present study demonstrates that serum TSH serves as a highly sensitive and specific marker for detecting thyroid dysfunction in the rural population of North Maharashtra, with diagnostic performance characteristics comparable to international standards. Our findings reveal a significant burden of thyroid dysfunction in this population, with important implications for public health screening strategies and clinical practice.

Prevalence and Demographic Patterns

The overall prevalence of thyroid dysfunction in our study population was 21.3% (95% CI: 16.6-26.6%), which is substantially higher than the national average of 10.95% reported in urban Indian populations [32]. This elevated prevalence aligns with previous studies from rural Maharashtra, where Korde et al. reported 13.9% prevalence in the Wardha district [33], and other rural studies showing rates ranging from 16.48% to 35.7% [34][35]. The higher prevalence in our study may be attributed to the rural setting, where factors such as dietary iodine intake variations, genetic predisposition, and environmental influences may contribute to increased thyroid dysfunction risk [36].

The female predominance observed in our study (63.3% of total participants, 68% of abnormal TSH cases) is consistent with global epidemiological data showing 3-10 fold higher prevalence of thyroid disorders in women [37][38]. This gender disparity has been attributed to hormonal influences, particularly estrogen's effects on thyroid hormone metabolism and immune function, making women more susceptible to autoimmune thyroid disorders [39]. The mean age of our study population (41.2 ± 13.4 years) reflects the adult rural demographic, with the age distribution spanning from 18-72 years, providing a comprehensive representation of the adult population at risk.

TSH Distribution and Reference Ranges

The mean TSH level in our population (2.61 ± 1.98 mIU/L) with a median of 2.05 mIU/L indicates a right-skewed distribution, which is consistent with the known non-Gaussian distribution of TSH in populations [40]. This distribution pattern supports current recommendations for using log-transformed TSH values in population studies and highlights the importance of establishing population-specific reference ranges [41].

Our findings show that 78.7% of participants had TSH levels within the conventional reference range (0.4-4.0 mIU/L), while 15.3% had elevated TSH (≥4.0 mIU/L) and 6.0% had suppressed TSH (<0.4 mIU/L). This distribution is comparable to other Indian studies, though the proportion of elevated TSH cases is slightly higher than reported in coastal regions, supporting the hypothesis of geographical variations in thyroid function across India [42][43].

Diagnostic Performance of TSH

The diagnostic performance characteristics of TSH in our study demonstrate excellent clinical utility. The sensitivity of 91.4% (95% CI: 82.5-96.8%) and specificity of 85.7% (95% CI: 79.8-90.3%) are comparable to international standards and validate TSH as the primary screening tool for thyroid dysfunction [44]. These values are consistent with previous reports showing TSH sensitivity ranging from 89-98% and specificity of 85-95% in various populations [45][46].

The positive predictive value of 78.0% indicates that approximately 4 out of 5 individuals with abnormal TSH levels truly have thyroid dysfunction when compared to free hormone levels. The negative predictive value of 94.2% is particularly noteworthy, suggesting that normal TSH levels effectively rule out thyroid dysfunction in this population, supporting its use as a first-line screening test [47].

Correlation with Free Thyroid Hormones

The strong negative correlation between TSH and fT4 ($r = -0.62$, $p < 0.01$) and moderate correlation with fT3 ($r = -0.49$, $p < 0.01$) confirm the expected inverse log-linear relationship between TSH and thyroid hormones [48]. These correlation coefficients are within the range reported in previous studies and validate the physiological feedback mechanism between pituitary TSH secretion and thyroid hormone production [49][50].

The stronger correlation with fT4 compared to fT3 supports current guidelines recommending TSH and fT4 as the preferred combination for thyroid function assessment, while fT3 measurement is reserved for specific clinical scenarios such as suspected T3-toxicosis or monitoring thyroid hormone replacement therapy [51].

Clinical Implications and Public Health Significance

Our findings have several important clinical and public health implications. The high prevalence of thyroid dysfunction (21.3%) in this rural population underscores the need for systematic screening programs, particularly targeting women of reproductive age. The excellent diagnostic performance of TSH supports its use as a cost-effective first-line screening tool in resource-limited rural settings [52].

The predominance of subclinical thyroid dysfunction, as evidenced by the high number of cases with abnormal TSH but normal free hormone levels, highlights the importance of early detection and monitoring. Subclinical hypothyroidism, in particular, has been associated with cardiovascular risks, dyslipidemia, and neuropsychiatric symptoms, making early identification clinically relevant [53][54].

Comparison with National and International Data

When compared to national data, our findings show higher prevalence than the NFHS-V reported rates for Maharashtra (2.126 per 100,000 women) [55]. This discrepancy likely reflects the difference between self-reported thyroid disorders in population surveys versus biochemical detection in systematic screening studies. International comparisons show that our prevalence rates are higher than Western populations but consistent with other developing regions facing similar iodine

status transitions [56].

Limitations and Strengths

This study has several limitations that warrant consideration. The cross-sectional design limits causal inferences, and the single-center nature may affect generalizability to other rural regions. We did not measure thyroid antibodies (TPOAb, TgAb), which could provide insights into the autoimmune etiology of thyroid dysfunction. Additionally, factors such as dietary iodine intake, nutritional status, and environmental goitrogens were not systematically assessed.

However, the study has notable strengths, including the systematic sampling methodology, adequate sample size with appropriate power calculation, use of validated third-generation TSH assays with established quality control measures, and comprehensive statistical analysis with appropriate confidence intervals. The focus on rural populations addresses an important gap in the literature, as most previous Indian studies have been conducted in urban settings.

Future Research Directions

Future research should focus on longitudinal studies to establish temporal relationships and progression patterns of thyroid dysfunction in rural populations. Investigation of genetic, environmental, and nutritional factors influencing thyroid function in this demographic would provide valuable insights for targeted interventions. Additionally, cost-effectiveness studies of TSH-based screening programs in rural Indian settings would inform policy decisions regarding implementation of systematic screening initiatives.

The development of point-of-care TSH testing technologies could revolutionize thyroid screening in remote rural areas where laboratory infrastructure is limited. Studies evaluating the diagnostic accuracy and clinical utility of such technologies in field conditions would be highly valuable for expanding access to thyroid function testing.

5. CONCLUSION

This study confirms that serum TSH serves as an excellent screening tool for thyroid dysfunction in the rural population of North Maharashtra, with diagnostic performance characteristics supporting its use as the primary first-line test. The high prevalence of thyroid dysfunction (21.3%) in this population, with significant female predominance, underscores the urgent need for systematic screening programs and improved healthcare access in rural areas. The strong correlations between TSH and free thyroid hormones validate the physiological basis for TSH-based screening strategies. These findings support the implementation of TSH-based thyroid screening programs in rural Indian populations, with potential for significant public health impact through early detection and management of thyroid dysfunction.

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