REFERENCE RANGE OF SERUM TSH AND ITS COMPARISON WITH VALUES FROM OTHER LABORATORIES

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ARTICLE INFO
Article history
Received 23/08/2015
Available online
31/08/2015

Keywords
Thyroid Disease,
Reference Range,
TSH,
Chemiluminescence.

ABSTRACT
Thyroid diseases are common worldwide. In India too, there is a significant burden of thyroid diseases. According to a projection from various studies on thyroid disease, it has been estimated that about 42 million people in India suffer from thyroid diseases. In the present paper, we address the current use of TSH as the dominant parameter in thyroid function testing, to ascertain its normal reference range, explain some major limitations of this approach, and attempt to suggest areas of possible improvement. The study was conducted in the super speciality hospital, Department of Biochemistry, GMC, Jammu. Total number of subjects was 50 (25 males, 25 females) aged 30-70 years. 2ml of venous blood was collected from antecubital vein under aseptic conditions from each individual. Whole blood specimen were analysed for TSH by chemiluminescence. The normal range of TSH was found to be 0.35 μu/L - 4.95 μu/L, for males and females alike. The corresponding values reported by standard laboratories like Dr. Lal Path Labs: 0.35 μu/L - 5.50 μu/L and SRL Labs: 0.35 μu/L to 5.25 μu/L, were comparable (p>0.05). The TSH value has to change by at least 30% to discriminate between a natural variation and a real progression. Additional influences such as gender, age, or time of sampling are less pronounced. A better understanding of thyroid hormone homeostasis including the role of TSH in the context may therefore aid in improving the diagnostic reliability of TSH measurement from both a methodological and clinical perspective.

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Please cite this article in press as Ashima Badyal et al. Reference Range of Serum TSH And Its Comparison With Values From Other Laboratories. Indo American Journal of Pharmaceutical Research.2015:5(08).

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INTRODUCTION

Thyroid diseases are different from other diseases in terms of their ease of diagnosis, accessibility of medical treatment, and the relative visibility that even a small swelling of the thyroid offers to the treating physician. Early diagnosis and treatment remains the cornerstone of management. Thyroid diseases are, arguably, among the commonest endocrine disorders worldwide, India being no exception.[1] TSH is a pituitary hormone, not a thyroid hormone, so TSH is an implied measurement of thyroid status. It has become the single best screening test for hyperthyroidism and hypothyroidism.[2] There are too many instances where TSH levels fall below the reference range (which implies hyperthyroidism, when the patient’s variation is actually hypothyroid or normal but certainly not hyperthyroid).[3]

TSH displays a seasonal variation in healthy people, with TSH levels lowest in the spring. In fact, TSH has a circadian rhythm, with a peak around mid night and low in the afternoon, and fluctuations are normal.[4] The issue of an appropriate TSH assay technology has promoted thyrotropin (TSH) measurements from participation in a multi-analyte assessment of thyroid function to a statistically defined screening parameter in its own right.[5] While this approach has been successful in many ways, it has some grave limitations. This includes the basic question of what constitutes an agreed reference range and the fact that the population-based reference range, by far, exceeds the variation of the intra-individual set point. Both problems result in a potential misdiagnosis of normal and pathological thyroid function in a substantial proportion of patients.[6]

Based on the methodological advances in TSH determination, the parameter has progressively evolved from its early adoption as an adjunct to the measurement of thyroid hormones to an exclusive parameter in its own right and consequently now dominates thyroid function testing. Modern diagnostic strategies have accordingly become heavily reliant on TSH measurement.[7] They have attributed various roles to TSH measurement as a screening tool, a therapeutic target in thyroid hormone treatment, and a prognostic marker.[8] With current disease classification based on TSH, this has introduced the subclinical states of hyperthyroidism or hypothyroidism that are defined by an abnormal TSH value in the presence of FT4 and FT3 values that still lay within their respective reference limits.

While this approach has been successful in many ways, it has also shifted the focus of TSH from its reactive and interactive role with thyroid hormones to an exclusive statistical parameter whose value is assumed to define the functional state of the subject. The present paper attempts to address some of the consequences of this paradigm shift and to assess some future perspectives for clinical decision-making.[9] Most problems of TSH measurement have been successfully resolved from the point of view of assay development and the analytical goals have been well defined, important issues that relate to the clinical application of the method still remain unsettled. The assay performance does not resolve the problem that the immunological activity of TSH determined by the methods may not equate fully with its bioactivity.[10]

MATERIALS AND METHODS

The study was conducted in the super speciality hospital, Department of Biochemistry, GMC, Jammu. Total number of subjects was 50 (25 males, 25 females) aged 30-70 years. 2ml of venous blood was collected from antecubital vein under aseptic conditions from each individual with his/her consent, duly following the guidelines and norms of the hospital. Whole blood specimen was analyzed via automated chemiluminescent microparticle immunoassay (cmiatechnology, ARCHIECT TSH assay). [11]

RESULT AND DISCUSSION

The normal levels of TSH were found to be 0.35 mu/L - 4.95 mu/L, for males and females alike. The corresponding values reported by standard laboratories like Dr. Lal Path Labs: 0.35 mu/L - 5.50 mu/L and SRL Labs: 0.35 mu/L - 5.25 mu/L (both obtained from the respective lab-in-charge via personal communication) were comparable (p>0.05). As far as TSH cut-off levels are concerned, there has been a broad debate on the issue, particularly the setting of the upper reference limit, in which some authors argue for a wider reference range of approximately 0.3 to 4 mu/L and others advocate a narrower interval with an upper limit of 2 mu/L.[12] The current state of affairs has recently been reviewed by Laurberg et al.[13] It has been pointed out that normal ranges and reference ranges are not necessarily to be considered as equivalent.[14] Importantly, TSH values are not normally distributed in a population, rather displaying a pattern of logarithmic normalization and a skewed distribution. The latter findings have been questioned by arguing that if subjects with subtle thyroid disorders are included in the reference population; this may have distorted the observed normal distribution.[15] However, even when disease-free reference collectives were used, the disagreements still remain.[16] The issue arises from the apparent distortion observed at the upper region of the TSH spectrum that has been frequently described, but not convincingly explained.[17] If one were to attribute the discrepancy to diseases such as unrecognized thyroid autoimmunity, a case could be made to adjust the spread of the normal distribution and consequently lower the upper reference limit. This is, however, not agreed nor is the reference interval.[18] Andersen and colleagues also found the thyroid hormone concentrations in normal subjects to vary much less in an individual than in the population.[19]

CONCLUSION

The distinction between a normal and pathological value cannot rely on the population-defined reference, but has to account for the individual patient’s normal set point within the individual laboratory’s reference range. The high ratio of inter-individual to intra-individual variability conflicts with any efforts to define a universally applicable clear cut-off and considerably limits the usefulness of the population-based reference values for clinical decision-making. The TSH value has, therefore, to change by at least 30% to discriminate between a natural variation and a real progression. Additional influences such as gender, age, or time of sampling are less pronounced. A better understanding of thyroid hormone homeostasis including the role of TSH in the context may therefore aid in improving the diagnostic reliability of TSH measurement from both a methodological and clinical perspective.
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