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Original Research Paper

Biochemistry

EVALUATION OF SERUM TSH IN PREMENOPAUSAL AND POST MENOPAUSAL WOMEN IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Objective- To evaluate and compare the level of TSH in premenopausal women (reproductive age group) and post-menopausal women. **Material And Methods-** The study was carried out on 100 premenopausal and 100 post-menopausal women attending Out Patient Departments at RIMS, Ranchi, during the period of January 2018-October 2019. **Study Design: -** Observational Study. **Statistics-** Statistical analysis was done using SPSS software. The data were represented by counts, percentage and mean ± standard deviation. Statistical analysis of TSH was done by t-test to compare these parameters in premenopausal and post-menopausal women. A p-value of <0.05 was considered statistically significant. **Result-** In the present study, we found that the mean serum TSH level in postmenopausal women 2.72 (± 1.06) uIU/ml was comparatively higher than premenopausal women 2.29 (±1.12) uIU/ml and the difference between the two was statistically significant ($p<0.001$). **Conclusion-** Thyroid hormones play an important role in maintaining normal reproductive behaviour by directly effecting on gonadal function and indirectly interacting with sex hormone binding protein. Alteration of thyroid hormone level leads to menstrual irregularities and infertility. The present study clearly demonstrated that there was significant increase in TSH levels in post-menopausal women and was statistically significant. Thus, it proved that postmenopausal women are more prone to subclinical hypothyroidism.

KEYWORDS : TSH, Premenopausal women, post-menopausal women, Hypothyroidism.

INTRODUCTION

Thyroid disorders are amongst the most common endocrine diseases in India. 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 [1]. Thyroid is the largest endocrine gland of the body and is associated with various metabolic functions by secreting thyroid hormones. Normal reproductive behavior and physiology is dependent on having essentially normal levels of thyroid hormones [2].

Thyroid hormones play an important role in normal reproductive function both through direct effects on the ovaries and indirectly by interacting with sex hormone binding proteins. Thyroid dysfunction can lead to menstrual irregularities and infertility [3]. In women, disease of thyroid gland is among the most prevalent disorders worldwide, second only to diabetes [4]. With time, overt hypothyroidism can develop in menopausal age, the symptoms of which can be similar to post-menopausal complaints and are clinically difficult to differentiate. There can also be an absence of clinical symptoms. It is of importance that even mild thyroid failure can have a number of clinical effects such as depression, memory loss, cognitive impairment and variety of neuromuscular complaints. Myocardial function has been found to be subtly impaired. Therefore, routine screening of thyroid function in the climacteric period to determine subclinical thyroid disease is recommended [5]. Elevated TSH in elderly, especially in women can be physiological or pathological.

History of nutritional status, associated illness and follow up with TSH measurement helps to differentiate them. The most common menstrual abnormalities observed by hypothyroid women are changes in character of the uterine bleeding and length of the inter-menstrual interval, prolonged and heavy flow is commonly noted [6,7,8].

The American Thyroid Association (ATA), the Endocrine Society and the American Association of Clinical Endocrinologist (AACE) had recommended aggressive case finding in elderly women.

With this perspective, this study was undertaken to evaluate TSH in premenopausal women (reproductive age group) and post-menopausal women.

AIMS AND OJECTIVES

To evaluate and compare the level of TSH in premenopausal women (reproductive age group) and post-menopausal women.

MATERIAL AND METHODS

The study was carried out on 100 premenopausal and 100 post-menopausal women attending Out Patient Departments of RIMS, Ranchi, during the period of January 2018-October 2019.

Sample Size: A total of 200 subjects were taken.

Inclusion Crieteria

- Premenopausal women of age group 20-30 years (Reproductive age groups)
- Post-menopausal women of age group 50-60 years.

Exclusion Crieteria

- Diabetes Mellitus
- Hypertension
- Endocrinal Disorder
- Patient on Hormone Replacement Therapy or on drug altering serum FT3, FT4 and TSH
- Operated Patient of Hysterectomy
- Premature Menopause
- Pregnancy

Study Tools:

Consent from the subject and an interview based on questionnaires was taken.

Collection of blood samples: - an overnight fasting of at least 12 hours prior to blood collection with caution to avoid haemolysis and contamination.

Processing and biochemical analysis of blood samples and thyroid profile was estimated in the study with the help of fully automated Chemiluminescent Micro-particle Immunoassay (CMIA) Abbott i1000 SR.

COLLECTION OF BLOOD SAMPLES: -

Subjects were instructed to be fasting for at least 12 hours. Following safety measures were taken while collecting blood samples: -

Wearing gloves when handling blood/body fluids.

Changing gloves after handling of each patient or when contaminated.

Washing hands frequently Disposal of items in appropriate containers.

Disposal of needles immediately upon removal from the patients.

Cleaning up any blood spills with freshly made 10% bleach disinfectant.

The blood sample was collected in a plain dried vial and allowed to clot for serum TSH estimation. Needles of 20 or 22 G size were used for blood samples. Precaution was taken to prevent needles from breaking, bending. Needles were put in disposable unit immediately after their use.70% isopropyl alcohol was used in cotton swab to wipe and sterilise the skin.

The serum was analyzed on the same day using fully automated Chemiluminescent Micro-particle Immunoassay (CMIA) Abbott i1000 SR.

Estimation Of TSH:

The ARCHITECT TSH assay is a Chemiluminescent Micro-particle Immunoassay (CMIA) for the quantitative determination of human thyroid stimulating hormone (TSH) in human serum and plasma.

Test Principle:

The ARCHITECT TSH assay is a two-step immunoassay to determine the presence of human thyroid stimulating hormone (TSH)in human serum and plasma using Chemiluminescent Micro-particle Immunoassay (CMIA) technology with flexible assay protocols, referred to as Chemiflex.

In first step, sample and anti- TSH antibody coated paramagnetic micro particles and TSH assay diluent are combined. TSH present in the sample binds to the anti-TSH antibody coated micro particles. After washing, anti- SH acridinium labeled conjugate is added in the second step. Pre-trigger and Trigger Solutions are then added to the reaction mixture; the resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of TSH in the sample and the RLUs detected by the ARCHITECT i optical system.

REAGENT REQUIRED: -

1. Micro particle: Anti-β TSH (mouse, monoclonal) coated micro particles in TRIS buffer with protein stabilisers. Preservatives: antimicrobial agents.
2. Conjugate: 1 Bottle (5.9 ml) Anti-α TSH (mouse, monoclonal) acridiniumolabeled Conjugate in MES buffer with protein (bovine) stabilisers. Minimum concentration: 60 ng/ml. Preservatives: antimicrobial agents.
3. Assay Diluent: 1 Bottle (8.0 ml) TSH assay diluent in TRIS buffer. Preservatives: antimicrobials agent.
4. ARCHITECT i Pre-Trigger Solution: Pre-Trigger solution containing 1.32% (w/v) hydrogen peroxide.
5. ARCHITECT i Trigger Solution: Trigger solution containing 0.35N sodium hydroxide.

Sample collection, reagent preparation and assay protocol were same as that for Ft3.

Expected Value:

A normal range of 0.35 μIU/ml to 4.94 μIU/ml (99% confidence interval) was obtained by testing serum specimens from 549 individuals determined as normal by AxSYM Ultra-sensitive hTSH II and AxSYM Free T4 assays.

Conversion Formula: - (Concentration in μIU/ml) x (1) = mIU/L

REFERENCE RANGE: -

(From Tietz Textbook of Clinical Chemistry and Molecular Diagnostic)

TSH-

21- 54 YEARS- 0.4- 4.2 μIU/ml

55- 87 YEARS- 0.5-8.9 μIU/ml

REFERENCE RANGE USED IN OUR LABORATORY TSH - 0.35-4.94 μIU/ml.

This reference range was used in the present study.

STATISTICS

Statistical analysis was done using SPSS software. The data were represented by counts, percentage and mean ± standard deviation. Statistical analysis of TSH was done by t-test to compare these parameters in premenopausal and post-menopausal women. A p-value of <0.05 was considered statistically significant.

OBSERVATIONS AND RESULTS

The present study comprises of 100 cases of premenopausal and 100 cases of post-menopausal women attending Out Patient Departments of the RIMS, Ranchi, during the period of January 2018-October 2019.

Table 1: Age Distribution Of Premenopausal And Post-menopausal Patients (total-200)

Age in years	No. of Patients	Percentage
Premenopausal		
≤20 Years	8	4.00%
21-25 Years	47	23.5%
26-30 Years	45	22.5%
>30 Years	0	0%
Postmenopausal		
≤50 Years	21	10.5%
51-55 Years	27	13.5%
56-60 Years	52	26%
>60 Years	0	0%
Total	200	100%

The youngest patient was 20 years and oldest patient was 60 years of age. The maximum number of patients 47 (23.5%) were in the age group of 21-25 years in premenopausal group and 52 patients (26%) in 56-60 years of age group. The mean (±SD) age in pre and post-menopausal group was 25.02 (3.20) years and 55.62 (3.90) years respectively.

Table 2: Distribution Of Subjects According To Serum TSH Level

Serum TSH (μIU/ml)	Premenopausal	Post-menopausal
S. TSH (0.35- 4.94 μIU/ml)	100	100
S. TSH (>4.94 μIU/ml)	0	0
S. TSH (<0.35 μIU/ml)	0	0

All premenopausal and postmenopausal patients had serum

TSH in the range of 0.35- 4.94 μIU/ml.

Table 3: Mean ± SD & P Value Of TSH Levels.

S.TSH (μIU/ml)	Mean ± SD		P value
	Premenopausal	Postmenopausal	
	2.29 ± 1.12	2.72 ± 1.06	0.001

There was statistically significant change in TSH level in premenopausal and postmenopausal patients.

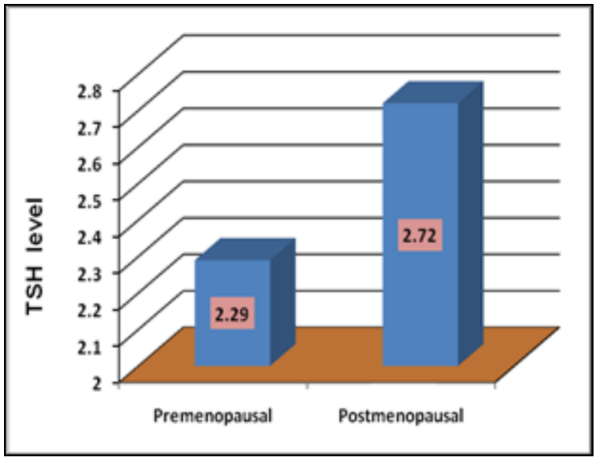

Figure 1: Mean TSH Levels In Premenopausal And Postmenopausal Women.

Table 4: Correlation Between Age And TSH Levels In Pre And Post-menopausal Age Groups

Correlation	r value	p value
Premenopausal age and TSH	-0.023	0.817
Postmenopausal age and TSH	0.025	0.802

DISCUSSION

This prospective observational study was conducted at RIMS, Ranchi during the period of January 2018-October 2019.100 cases of premenopausal and 100 cases of post-menopausal women attending Out Patient Departments were evaluated for serum TSH.

AGE

In the present study, the youngest patient was 20 years and oldest patient was 60 years of age. The maximum number of patients 47 (23.5%) were in the age group of 21-25 years in premenopausal group and 52 patients (26%) in 56-60 years of age group. The mean (±SD) age in pre and post-menopausal group was 25.02 (3.20) years and 55.62 (3.90) years respectively which co-related with other studies by Tasnim et al (2011) [9], with mean age of 26 years in premenopausal group and 54 years in post-menopausal group, chandrashekhar (2018) [10] study with mean age of 34.91 years in premenopausal group and 62.63 years in post-menopausal group.

TSH

In the present study, we encountered that the mean serum TSH level in postmenopausal women 2.72 (± 1.06) uIU/ml was comparatively higher than premenopausal women 2.29 (±1.12) uIU/ml and the difference between the two was statistically significant ($p<0.001$).

Multiple causes were proposed for increase in TSH in elderly, like anti-thyroid antibodies, nutritional iodine supply, and hidden thyroid autonomy. Also, problems regarding sleep disturbances and altered sleep patterns with increasing age may lead to increase in TSH level. [11] Ageing is associated with changes in pituitary-thyroid axis.

Legier V. Rojas et al (2008) [12] found higher TSH level in postmenopausal women (2.80 mIU/L) compared to premenopausal (2.52 mIU/L). They found average TSH values increased with age, although the changes between groups were not significant. They suggest evaluation of TSH levels within groups and within locations to establish appropriate baseline levels. Elizabeth N Pearce et al (2007) [13] study in USA point towards increased TSH levels in post-menopausal women.

Hollowell J.G.et al (2002) [14] found higher TSH levels in women in the older age group in the National Health And Nutrition Examination Survey –NHANES conducted in United States on large population. Analysis of the NHANES III (2007) showed that age-related shifts in TSH distribution were not significantly changed when individuals with antithyroid antibodies were excluded.

Some of the studies showed lower serum TSH in postmenopausal and older women than premenopausal women. Studies by Mariotti et al. (1993) [15] done in Italy, found significantly higher TSH levels in younger women and claim that due to an age-related decrease in TSH secretion by the pituitary. Hershman JM et al. (1993) [16] found the mean TSH in older women, (1.21), was slightly but significantly lower than that in middle-aged women, (1.52).

CONCLUSION

Hence to conclude from this can be said that the prevalence of thyroid disorders, particularly subclinical hypothyroidism, is more in postmenopausal women than premenopausal women.

TSH can be influenced by nutritional status, associated with co-morbidities, co-factors such as body surface area and others. A regular follow-up of the activities of TSH could help in the clinical diagnosis and better management of the patients.

So, screening test for thyroid disorders may be routinely pursued in older women on a regular basis.

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