

A STUDY TO COMPARE T3, T4 AND TSH ANALYSIS USING POCT INSTRUMENT AND FULLY AUTOMATED CHEMILUMINESCENCE ANALYSER

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Abstract

Background: There is an increase in prevalence and incidence of thyroid disorders therefore the screening for thyroid diseases has been included in the screening programs and population based studies. The diagnosis and monitoring of thyroid diseases are based on the measurement of TSH (thyroid stimulating hormone), T3 (triiodotyrosine) and T4 (tetraiodotyrosine). So, the aim of this study is to compare the serum concentrations of T3, T4 and TSH measured by Point of care testing (POCT) and fully automated chemiluminescence immune assay (CLIA) analyser. **Materials and Methods:** Around fifty venous blood samples were randomly selected from our routine thyroid profile (T3, T4 and TSH) testing requests. The samples were processed on both POCT and CLIA analyser. **Result:** There is no statistically significant difference in the mean and standard deviation for the T3, T4 and TSH test performed by POCT and CLIA analyser. **Conclusion:** Our study concludes that the POCT reduces analysis time as compared to the CLIA so are helpful especially in emergency conditions and for the screening purposes.

INTRODUCTION

The disturbance in the functioning of the thyroid gland results in the hypo and hyperthyroidism. The hypo and hyperthyroidism are one of the most common endocrine disorders. The diagnosis and monitoring of thyroid diseases are based on the measurement of TSH, T3 and T4. TSH is currently considered as a reference test and the best marker of thyroid dysfunction and forms a basic for classification of thyroid diseases.^[1] Iodine deficiency disorders in children causes poor school performance and mental development disorders. In addition, iodine deficiency in females is associated with spontaneous miscarriage, stillbirth, and perinatal mortality.^[2] As Iodine is essential for brain development during fetal life and neonatal period. If its deficiency occurs during this phase it causes endemic cretinism which is characterized by severe mental retardation, neurological symptoms and hypothyroidism.^[3] Iodine deficiency also has a negative impact on the quality of life and economic status.^[2] Iodine prophylaxis programs implemented by the World Health Organization have decreased the prevalence of iodine deficiency disorders but have caused major changes in the pattern of thyroid disorders by an

increased prevalence of autoimmune thyroid diseases like atrophic thyroiditis, Hashimoto's thyroiditis, Graves' hyperthyroidism, non-autoimmune hyperthyroidism, and autonomous thyroid nodules.^[1,4,5] Due to the increase in prevalence and incidence of thyroid disorders, this has been included in screening programs and population-based studies.^[3]

In the laboratory many equipments are used to measure the hormones in which we run daily maintenance, calibrators, quality controls and the test samples. So the tests require more turnaround time and skilled technicians. The instruments are big and require more space. The Point of care test (POCT) devices are usually used at OPD or clinic setup as they are having the short turnaround time for the test, requires less space, cost of the equipment is less and requires less skilled personal.^{6,7} In the present study, we aimed to compare serum concentrations of T3, T4 and TSH measured by POCT and fully automated chemiluminescence analyser.

Objectives

- To analyse the T3, T4 and TSH in point-of-care testing analyzer.
- To analyse the T3, T4 and TSH in fully automated chemiluminescence analyser.

- To compare the T3, T4 and TSH values of POCT and fully automated chemiluminescence analyser

MATERIALS AND METHODS

This is a cross sectional study conducted in the central diagnostic laboratory of a tertiary care hospital. The study was conducted after obtaining institutional ethical committee approval. The written informed consent was also taken from the subjects. Around 50 venous blood samples were randomly selected from our routine thyroid profile (T3, T4 and TSH) testing requests. Blood samples were centrifuged at 2500rpm for 10 minutes. The sera from the samples were divided into two aliquots that were processed on the chemiluminescent enzyme immunoassay instrument, and POCT instrument using the fluorescence sandwich immunoassay technique. The samples were processed on each analyzer according to the manufacturer's instructions and data was collected and studied. Venous samples of all ages group irrespective of disease status were included in this study. The hemolysed samples, samples collected in inappropriate tubes, low volume samples were excluded from the study.

RESULTS

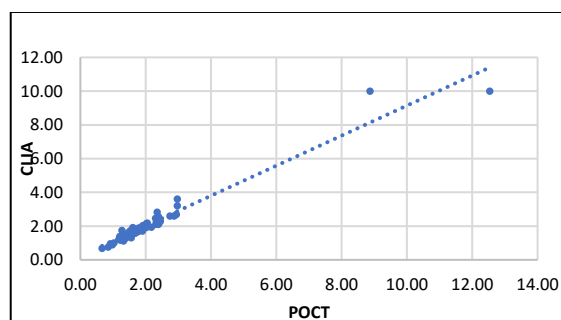
Analysis was done using SPSS version 23.0. Descriptive statistical analytes such as mean, standard deviation and co efficient of variance was done.

The mean and SD of T3 test performed by CLIA was 2.15 ± 1.73 and the mean and SD of T3 test performed by POCT was 2.15 ± 1.89 and was not statistically significant. [Table 1]. and the correlation graph (graph 1) $r = 0.949$.

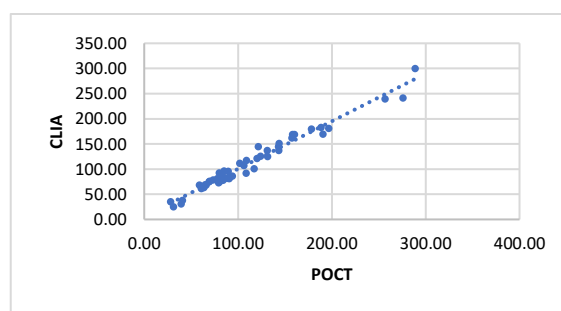
The T4 tests performed by CLIA and POCT was not statistically significant ac the mean and SD for T4 was is 111.43 ± 55.90 by CLIA and 111.62 ± 58.14 by POCT respectively. [Table 2]. and the correlation graph (graph 2) $r = 0.970$.

The mean and SD for TSH test performed by CLIA was 6.59 ± 10.87 and the mean and SD for TSH test

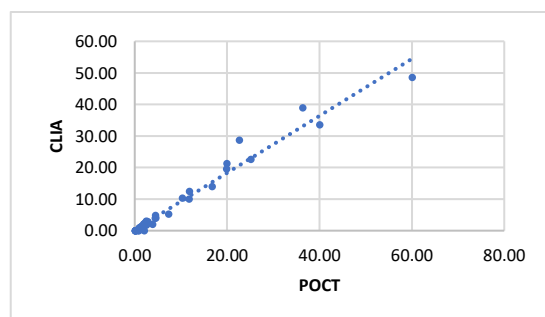
performed by POCT was 7.03 ± 11.84 and was not statistically significant. [Table 3]. and the correlation graph (graph 3) $r = 0.970$.



Graph 1: The correlation graph for T3 test by CLIA and POCT.



Graph 2: The correlation graph for T4 test by CLIA and POCT.



Graph 3: The correlation graph for TSH test by CLIA and POCT.

Table 1: The Mean and SD for T3 test by CLIA and POCT

T3	Mean	SD	CV
CLIA	2.15	1.73	0.80
POCT	2.15	1.89	0.88

Table 2: The Mean and SD for T4 test by CLIA and POCT

T4	Mean	SD	CV
CLIA	111.43	55.90	0.50
POCT	111.62	58.14	0.52

Table 3: Mean and SD for TSH test by CLIA and POCT

TSH	Mean	SD	CV
CLIA	6.59	10.87	1.65
POCT	7.03	11.84	1.69

DISCUSSION

Nowadays thyroid gland disorders are more prevalent in the general population.⁸ The thyroid dysfunction includes diseases ranging from biochemical, asymptomatic subclinical hypothyroidism, asymptomatic subclinical hyperthyroidism, overt symptomatic hypothyroidism and overt symptomatic hyperthyroidism.^[9-11] Measurement of TSH level is the most useful first-line assay for the assessment of thyroid function.^[12] Due to increase in the prevalence of thyroid disorders rapid diagnosis and treatment are required.^[13]

A study done by Kaur J et.al stated that the POCT is cost-effective, most acceptable and also reduces the turnaround time. It can be used for emergency setup and are best suitable for small diagnostic laboratories. They also stated that POCT is an important milestone for the rapid estimation of TSH however assays should be standardized, quality control study should be implicated and repeatability and accuracy should be ensured.^[14]

In accordance with the study done by Cibro DA et.al TSH of the Emerging Point-of-Care Tool assay is a very reliable method for evaluation of TSH of low-physiological, intermediate, and high levels. They also observed that the method is user-friendly, accurate, reproducible, and suitable for use in the clinic.^[13]

A Cohort study also stated that POCT assay is a user-friendly, accurate, reproducible, and suitable for use in the clinic.^[15]

CONCLUSION

Our study concludes that the Point-of-Care Tests (POCT) reduces analysis time as compared to fully automated chemiluminescence hormone analysers, so are helpful especially in emergency conditions and for the screening purpose. Moreover, from a practical point of view Point-of-Care Tests (POCT) are user-friendly, require less space and are suitable for use in the clinics/ OPD/ peripheral set up.

Limitations of the study: The study was performed on a small sample size so further study to be performed on larger sample size.

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