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Performance Evaluation of Thyroid Hormones and Thyroid Stimulating Hormone (TSH) Assays by Conventional and Modular Electro-Chemi Luminescence (ECL) Systems

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Abstract: In last two decades, considerable research work have been reported regarding comparative performance assessment of equipments, technology, assays, procedures and proficiency. The data provided opportunity to enhance the capabilities of a diagnostic lab to respond to patient's needs with quality assured immunoassay reports, facilitated through appreciable precisions and accuracy. In this pretext, the present study describes the comparative analysis of thyroid hormones, T3, T4, FT3, FT4 and pituitary hormone, TSH on conventional Elecsys 2010 and Cobas 6000-c601 (Roche, Basil) analyzers utilizing electro-chemi-luminescence technology (ECL). Blood samples were collected from known patients of thyroid disorders. All six parameters showed excellent proportional linearity in analytical performance on both instruments; with regression correlation ranging from R^2 0.9722 in T4 to R^2 0.9279 in FT4, depicting markedly significant correlations. The y-intercept and R^2 of T3, T4, FT3, FT4 and TSH were; T3 = y 0.9938 x +0.0321 R^2 0.9446; T4 = y 0.9248 x +0.6632 R^2 0.9722; FT3 = y 1.0289 x -0.1591 R^2 0.9581; FT4 = y 0.9676 x +0.0425 R^2 0.9279; TSH = y 1.0316 x -0.0278 R^2 0.9664, respectively. It is concluded that considerable significant precision and accuracy was manifested by both instruments depicted through R2 values of 0.9722 to 0.9279, suggesting that both are reliable, accurate and compatible (interchangeable) for analytical purposes at a tertiary care hospital.

Key words: Elecsys 2010 · Cobas 6000 C601 · Electro Chemi-Luminescence (ECL)

INTRODUCTION

Hormonal assays are now a mandatory requirement to evaluate, diagnose and treatment of patients suffering from endocrine disorders. Starting from early days of cumbersome manual assays when antibody-antigen reactions, addition of chromogens and reactants took place step by step, through pipettes and waiting times were hours, until the results were available, to present day of fully automated instruments where one gets a result, mostly within an hour. Even with today's technology advancements and extremely proficient turnaround time (TAT), competiveness regarding further enhancements of analytical methods, that can measure hormones upto nano-grams level, is still going on. In this context, MEIA, MIA, RIA and the new electro Chemi-luminescence technology is making inroads in diagnostic labs for improved patients care. In last two decades, comparative performance assessment of equipments, technology, assays, procedures and proficiency have provided us with opportunity to enhance our capability of providing patients with quality assured immunoassay reports with

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appreciable precisions and accuracy [1-9]. The present study described the comparative performance evaluation of thyroid stimulating hormone (TSH) and thyroid hormones on conventional immunoassay analyzer with a modular system.

MATERIALS AND METHODS

Patients and Sample: For the present study, blood samples were collected (Males = 25, Females = 25) from 50 patients. The individuals include those with past and recent history of thyroid disorders, either on medication since past one year or initiated treatments within past 3 weeks. Those patients or individuals with non-compliance of medications or whose medication regiments altered quite often due to resistance were excluded from the study. The age range was 21-82 years for males and 19-76 years for females. Serum samples were separated and stored at -20°C until analyze.

Equipments and Technology Assay: For comparative analysis, T3, T4, FT3, FT4 and TSH of all patients were assayed on conventional Elecsys 2010 and Cobas 6000 c601 (Roche, Basil) analyzers utilizing electro-chemi-luminescence technology (ECL). Analyzers were calibrated according to manufacturer's advice using both normal and pathological controls. The normal ranges for adults for thyroid and pituitary hormones are T3 = 0.8-2.00 ng/ml; T4 = 5.1-14.1 □g/dl; FT3 = 2.5-5.6 pg/dl; FT4 = 1.1-1.7 ng/dl; TSH = 0.27-0.42 □l U/ml. Samples were ran in duplicate on each analyzer necessarily to avoid systemic bias.

Statistical Analysis: Comparative analyzers performance evaluation was carried out by using regression correlation analysis [R^2]. Results were considered as significant when $P < 0.05$ and expressed as mean ±SD.

RESULTS

The results are summarized in Fig. 1-5. A total of 50 samples were obtained from male and female patients (25 each) of age between 19-82 (Males = 21-82, females 19-76) and analyzed for thyroid hormones T3, T4, FT3, FT4 and pituitary hormone TSH for comparative analytical performance of two instruments, the conventional Elecsys 2010 and modular Cobas 600 c601 system. The patients belong to a variable group of individuals with overt disease, history of thyroid disorders and newly diagnosed patients. The mean (X ±SD) values of T3 on Elecsys 2010 and Cobas c601 were, 1.6022 ± 0.12 and 1.6244 ± 0.75 ng/ml respectively; T4 = 8.6124 ± 1.76 and 8.628 ± 2.00 □g/dl; FT3 3.908 ± 0.75 and 3.862 ± 0.80 pg/dl; FT4 = 1.034 ± 0.20 and 1.043 ± 0.30 ng/dl and TSH = 1.734 ± 0.65 and 1.761 ± 0.58 □l U/ml, respectively. All six parameters showed excellent proportional linearity in analytical performance on both instruments; with regression correlation ranging from R^2 0.9722 in T4 to R^2 0.9279 in FT4, depicting markedly significant correlations. The y-intercept and R^2 of T3, T4, FT3, FT4 and TSH were; T3 = y 0.9938 x +0.0321 R^2 0.9446 (Fig. 1); T4 = y 0.9248 x +0.6632 R^2 0.9722 (Fig 2); FT3 = y 1.0289 x -0.1591 R^2 0.9581 (Fig. 3); FT4 = y 0.9676 x +0.0425 R^2 0.9279 (Fig. 4); TSH = y 1.0316 x -0.0278 R^2 0.9664 (Fig. 5), respectively. The comparative analytical data manifested R^2 correlation of 92% to 97% among all parameters when simultaneously analyzed on both instruments, suggesting that both conventional and modular systems were at par regarding ECL technology, quality assurance, analytical steps and resultant outcome.

DISCUSSION

Comparative performance evaluation of analytical instruments is routinely and widely used in diagnostic laboratory settings all around the world to assess the feasibility, compatibility, variability of tests, precisions, accuracy and inter-assay variations of technologies, instrument itself and even the brands [2, 4, 7,10]. The present study described the comparative analytical performance evaluation of two instruments, a conventional immunoassay analyzer Elecsys 2010 and the modular Cobas 6000 c601 series, using thyroid hormones, T3, T4, FT3, FT4 and TSH as parameters. The data generated excellent significant linear correlations with R^2 values ranging from 0.927 to 0.972 depicting correlating proficiency of 92 to 97% between both instruments. A recent study done regarding comparative study of FT3 and FT4 immunoassay in healthy individuals and thyroid patients on three immunological analyzers, UniCel DcI800, Architect i2000 and Elecsys 2010, showed promising correlations of 0.915, 0.740 and 0.770, where as FT3 exhibited R^2 0.615, 0.589 and 0.790 [DxI800 vs Elecsys; DxI800 vs Architect and Elecsys 2010 vs Architect] [2]. Similarly a performance evaluation carried out same year showed concordance of DxI-AxSym, DxI-Immulite and AxSym Access-Immulite 2000, when tested for TSH, FT3, FT4, ranging from 83.1%, 76.2% and 68.5% for low TSH

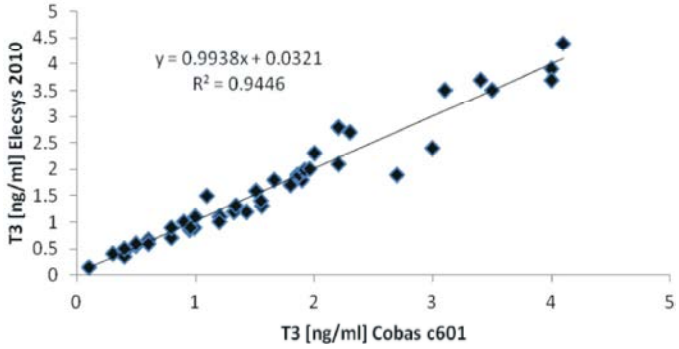

Fig. 1: T3-Elecsys 2010 vs Cobas c601

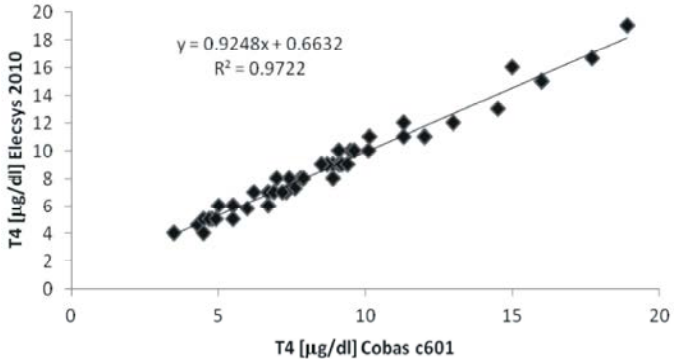

Fig. 2: T4-Elecsys 2010 vs Cobas 6000 (c601)

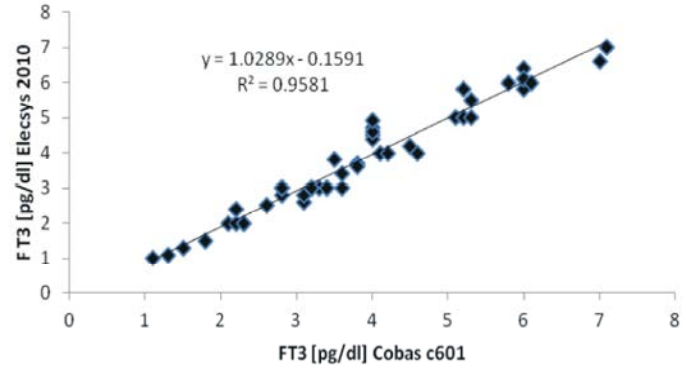

Fig. 3: FT3-Elecsys vs Cobas c601

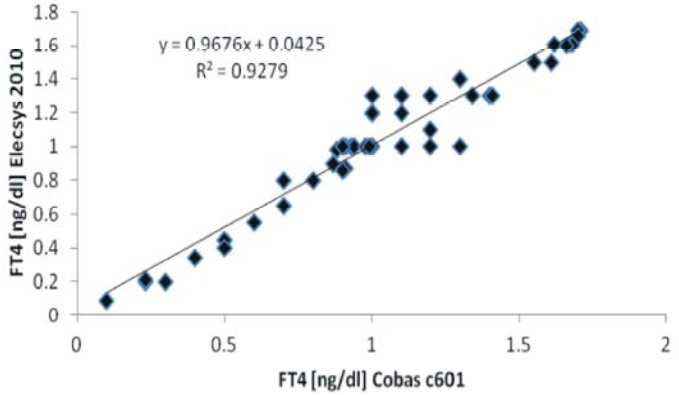

Fig. 4: FT4 Elecsys vs Cobas c601

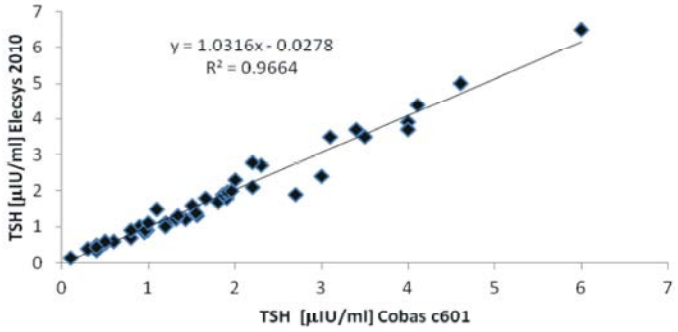

Fig. 5: TSH-Elecsys 2010 vs Cobas c601

and 78%, 86% and 78% for elevated TSH respectively [4]. Several such performance evaluation studies have been carried out during last two decades covering the period of 1995-2013 [1,2, 6, 7,11,12]. This is important to note that performance evaluation of techniques and precisions can also be assessed using only one parameters such as reported earlier with Elecsys 2010 vs ADVIA centaur with excellent R^2 of 0.987 [8]. However multi-parametric assessment remains the rule of thumb if the lab in question is operating in a tertiary care hospital or catering thyroid disease patients [6]. Similarly variable technique comparison is also quite common amongst diagnostic lab such as variability checks RIA vs ECL or IRMA vs MEIA, depicting considerable proportionality of R^2 0.77 to 0.97 among the parameters tested and compared on Elecsys 2010, DPC and RIA [Spectra-Orion Diagnostics] [6].

In conclusion, the present study described the comparative performance evaluation of two instruments, a conventional ECL immunoassay Elecsys 2010 and the modular Cobas 6000 c601 using five parameters of T3, T4, FT3, FT4 and TSH. The data represented considerably significant precision and accuracy among both instruments depicted by R2 values of 0.9722 to 0.9279, suggesting that both are reliable, accurate and compatible for analytical purposes at a tertiary care hospital.

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