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Comparative Assessment of Analytical Performance of Conventional Chemistry Analyzer and Modular Cobas 6000 System Using Routine Chemistry Parameters

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Abstract: In last three decades, as requirement increases with availability of newer technology, automated equipments took over manual and semi-automatic analysis of patients samples. This trend was observed most profoundly at tertiary care hospitals, where faster turnaround time is a patient care necessity. These automation, nonetheless, also provided better reproducibility, precision and accuracy of results; in addition to 24/7 availability of major lab testing panels. In this regard, the present study described the comparative equipment performance evaluation of conventional chemistry analyzer, Hirachi 912 with modular Cobas 6000 (c 501). Blood samples from patients of either gender, n = 70 (Males = 58, female = 42) were collected during Dec 2011 to Dec 2012 for test panel of Urea, Creatinine, ALT, uric acid, sugar and cholesterol. Standard methodologies and principles were used to analyze all parameters on both instruments. Data were compared using regression analysis and statistical significance of $P< 0.05$. Comparative analysis showed excellent data correlations among all six parameters on both instruments with R^2 regression ranging from 0.8435 to 0.998, depicting the precision and reliability of methods, standardization and system equivalency. Correlation results showed regression R^2 for urea as R^2 0.9678, Creatinine R^2 0.8435, ALT R^2 0.9955, uric acid R^2 0.993; sugar R^2 0.9988 and cholesterol R^2 0.9952. In conclusion, regression analysis exhibited near-equivalent data representation ranging from 84.3% to 99.8% of both instruments, thus depicting that both are standardized and properly calibrated to be used simultaneously and inter-changeable for routine chemistry analysis of referred parameters.

Key words: Chemistry Analyzers · TAT · Automation · Cobas 6000 · Hitachi · Analytical Performance

INTRODUCTION

All our the world, clinical laboratories, either in independent capacity or being associated with a hospital, required to have the tests performed according to standardized protocols with appropriate turnaround time 'TAT" [1-4]. During last three decades, gradually, automated equipments took over manual testing, especially in tertiary care hospitals, where faster TAT is a necessity [2,5]. Furthermore, it also allowed better reproducibility, precision and accuracy of results; in addition to 24/7 availability of major lab testing panels [6-8].

Traditionally, shifting a manual test to automation (Or semi automation, where applicable) requires the analytical evaluation of analyzer, methods, calibration and test profile before introduction of the equipment into the clinical lab system [3, 4, 9, 10]. Moreover, even if

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automated system is already available within the lab, addition or replacement with advanced version or as a backup, respectively also requires that its multi-channels, variability, test profiles, international standards, in addition to reproducibility, accuracy and precision be also assessed before placing it into routine use [4,5,6,11].

In this regard, the present study describes the comparative equipment performance evaluation of conventional chemistry analyzer, Hirachi 912 with modular Cobas 6000 (c 501) Serum Work Area (SWA) on panels of Urea, Creatinine, uric acid, cholesterol, alanine aminotransferase (ALT) and sugar.

MATERIALS AND METHODS

Blood samples from patients of either gender, n = 70 (Males = 58, female = 42) were collected for the present study during Dec 2011 to Dec 2012. This observational and comparative study group includes patients with 1st time requests, those with known conditions, patients with known co-morbids but under treatment and also those where clinical condition persisting since many years. Blood was collected following standard procedures, plasma separated and stored at -20°C until use. Comparative performance assessment of instruments, the conventional automated Hitachi chemistry analyzer 912 and modular system Cobas 6000 (c501), was done through analysis of six parameters, urea, creatinine, sugar, ALT, uric acid and cholesterol. Urea was analyzed by UV-urease assay [12], whereas Creatinine by Jeff's rate-blanked and compensated method [13]. Glucose, ALT, uric and cholesterol were assessed by Gluco-quant-hexokinase, Schimdt [14] IFCC with pyridoxal phosphate activation [15], uric acid plus-uricase [16] and cholesterol-oxidase-para-amino phenazone [17-18] methods, respectively. Manufacturers' instructions were used for standardization, calibration, controls, dilutions and additions of reagents and resulting analytical determinants, complexes and end-products. The normal ranges of parameters are, urea = 16.6-48.5 mg/dl; Creatinine = 0.50-1.20 mg/dl; sugar Fasting = 74-106 mg/dl; ALT = 10-50 U/L; uric acid = M = 3.4-7.0 mg/dl, F = 2.4-5.7 mg/dl; cholesterol = less than 200 mg/dl. All steps were performed automatically through modular/Hitachi programs provided with the instruments (Roche, Basil). Data analysis, comparative studies and regression correlation of respective conventional Hitachi 912 and modular Cobas 6000 systems were performed with duplicates for precision and accuracy and through SPSS (ver 10, USA) for statistical analysis.

RESULTS

Comparative performance assessment of six parameters, urea, Creatinine, glucose, ALT, uric acid and cholesterol was carried out on two instruments, the conventional chemistry analyzer Hitachi 912 and modular cobas 6000 (c 501). Standardized methodology and protocols were used on both systems as per kit inserts or/and manufacturer's manual and procedural instructions. Fifty eight males and fifty two female samples were included in the study. Most of the results showed within normal ranges data or few with slightly above the normal reference values. Severely chronic patients were excluded from the study during initial screening. The mean values of urea on 912 was 48.12 ± 4.30 mg/dl and on c501 was 47.95 ± 5.10 mg/dl; for Creatinine, 1.16 ± 0.89 mg/dl and 1.09 ± 0.76 mg/dl; for ALT, 48.18 ± 10.60 IU/L and 47.80 ± 9.62 IU/L; for uric acid, 6.10 ± 0.90 mg/dl and 6.02 ± 0.82 mg/dl; for sugar 172.10 ± 15.20 mg/dl and 172.31 ± 14.60 mg/dl and for cholesterol, 201.41 ± 26.40 mg/dl and 200.30 ± 24.50 mg/dl, respectively. Comparative analysis showed excellent data correlations among all six parameters on both instruments with R^2 regression ranging from 0.8435 to 0.998, depicting the precision and reliability of methods, standardization and system equivalency. Correlation results showed regression and y intercept for urea as y = 1.0829 x -0.6813, R^2 0.9678 (Fig. 1), Creatinine y = 0.971 x -0.0433, R^2 0.8435 (Fig. 2), ALT y = 0.996 x -0.2008, R^2 0.9955 (Fig 3), uric acid y = 1.002 x 0.0766, R^2 0.993 (Fig. 4); sugar y = 1.01 x -1.5274, R^2 0.9988 (Fig. 5) and cholesterol y = 0.962 x + 5.429, R^2 0.9952 (Fig. 6).

DISCUSSION

Both instruments, Hitachi 912 and Cobas 6000 (c501) component are random access systems for clinical chemistry analytes, including urea, Creatinine, electrolytes, liver and cardiac function tests, serum proteins, enzymes, with available options of analysis through spectrophotmetry, turbidometry, UV/kinetics, chromogen end product and indirect potentiometry in many samples such as plasms, serum, urine, cerebrospinal, synovial and pleural fluids. Analytical evaluation of analyzers can be done through determination of within rum and between-run imprecision, inaccuracy evaluations and comparison of methods, where applicable [1].

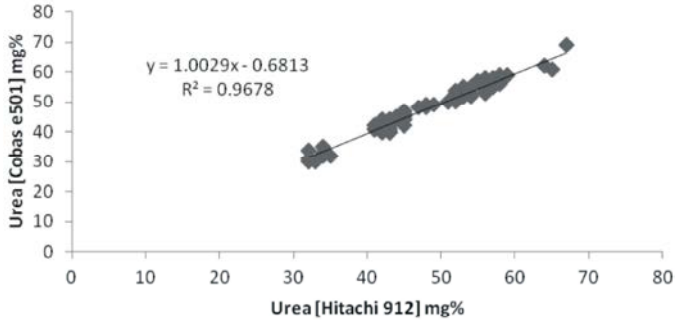

Fig. 1: Comparative performance evaluaion of Urea analyte on Hitachi 912 and Cobas e501

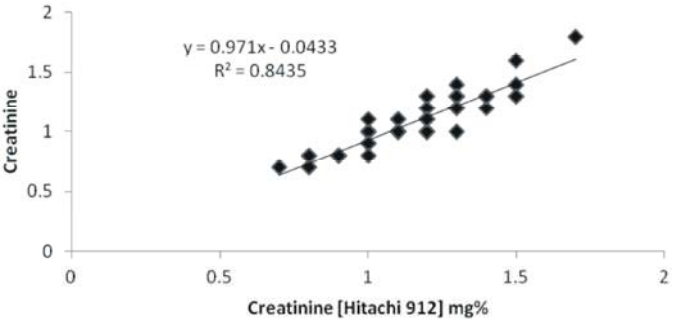

Fig. 2: Comparative performance evaluaion of Creatinine analyte on Hitachi 912 and Cobas e501

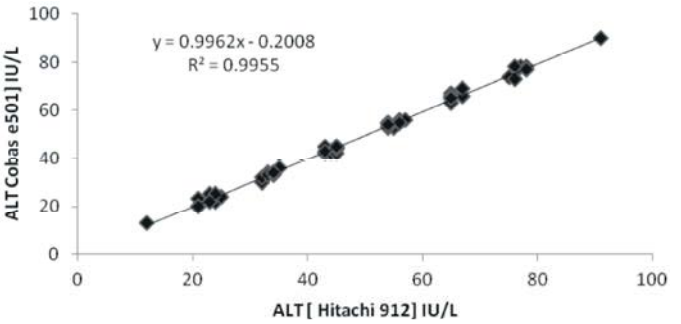

Fig. 3: Comparative performance evaluaion of ALT analyte on Hitachi 912 and Cobas e501

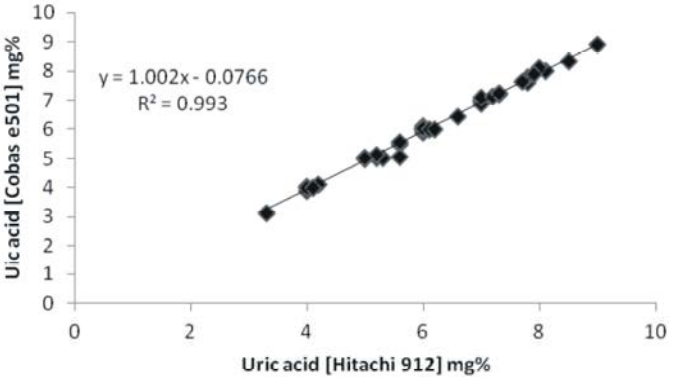

Fig. 4: Comparative performance evaluaion of Uric acid analyte on Hitachi 912 and Cobas e501

Our presented study evaluated comparable data of all six parameters viz, urea, Creatinine, uric acid, ALT, glucose and cholesterol on both Hitachi 912 and modular cobas 6000 (c501). Results showed correlated precision and standardized methodology by conventional and modular systems, which is exhibited through regression

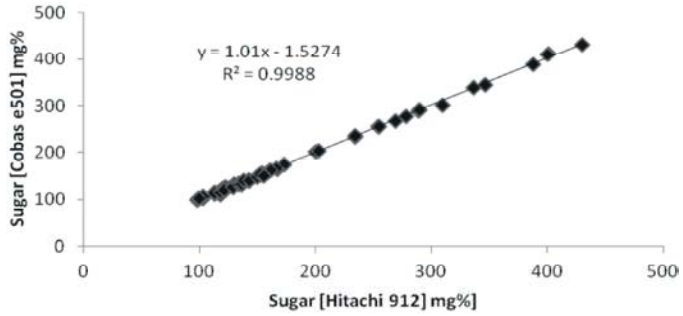

Fig. 5: Comparative performance evaluaion of Sugar analyte on Hitachi 912 and Cobas e501

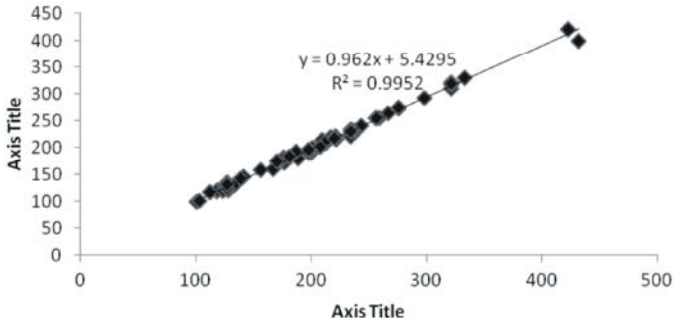

Fig. 6: Comparative performance evaluaion of Cholesterol analyte on Hitachi 912 and Cobas e501

analysis data of 0.8435 to 0.9988. The mean values of all analytes also exhibited comparative near-equivalent results on both equipments.

Recent and past studies regarding performance evaluation, technology comparison and instrument validation show appreciable data [1,3, 5, 7,8]. These includes work-flow performance of special chemistry tests such as CEA, PSA, AFP, folate, B12 T4, TSH, FT4 on Architect ci800 [3], analytical evaluation of routine chemistry parameters such as glucose, Creatinine, uric acid, cholesterol, triglyceride, calcium ALT etc on Olympus AU 2700-plus [4],calibration verification for Olympus and Hitachi analyzers using single chemical analyte (Albumin) through currently approaches of CAP [6] and assessment of consolidation of procedure performance for Cobas 6000 compared with Beckman Coulter AU640 using 30 analytes comprising all ranges of metabolic enzymes, trace elements and proteins [7]. Even inter-laboratory evaluation of equipments such as Cobas integra 400 [5], evaluation of multiple critical care analyzers with NOVA stats and Dimensions RxL systems [8], comparison of biochemistry analyzers Olympus AU2700 and AU 640 according to accreditation of status vs ISO 15189 [11] and policy making regarding new approaches to automation through modular system, were studies in labs of tertiary care hospitals, research institutes and clinical laboratories over past one decade.

Our comparative performance evaluation analysis also exhibited similar pattern of precision, accuracy and workflow coordination between both conventional and modular systems. Additionally, all methods, principles and protocols found to be at equivalency and standardized levels to each other as evident by correlation of 84% to 99.8%. Furthermore, analytical steps and reagent specifications that were available on conventional system were also found compatible on modular system as well. One of the previous study comprehensively covering special chemistry analytes such as hormones/tumor markers and vitamins showed acceptable coefficients of variation, < 6%-11%, for most of the tests when analyses were compared on Architect AU ci800 versus Centaur (Bayer), Liaison (DiaSorin), Behring BN II, Olympus AU640 and Cobas integra 800 [3]. Alternatively, calibration assessment and verification is also one of the protocols to evaluate equipments' comparative performance. A study carried out with albumin as a component, to verify calibration status of two analyzers, Hitachi and Olympus through CAP protocols [6]. The conclusion drawn from that multi-centered study reiterates the confirmation that 64.5% of the participating labs passed the evaluation for both instruments. More recently within equipment precision was examined in 14 laboratories in Australia, Europe and USA regarding Cobas 8000 modular system with a wide spectrum of

routine and immuno chemistry parameters [1]. The resultant data, that were obtained over a period of two years emphasize that the system and its analytical configurations will improve the service-providing abilities of laboratories and thus enhance customer-care.

In conclusion, the present study described the comparative analytical performance of two instruments, one being the conventional Hitachi chemistry analyzer 912 and other being the modular version Cobas 6000, using six routine chemistry parameters. Regression analysis exhibited near-equivalent data ranging from 84.3% to 99.8%, thus ensuring that standardization and proper calibration of both instruments is upto the mark for routine chemistry analysis of referred parameters.

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