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Research Article

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Standardization and Precision comparison of total Vitamin D (25-OH-Vit D) on Cobas E411 and Beckman Access 2

Ishrat Sultana, Shazia Naureen, Junaid Mahmood Alam, Qurat-Ul Ain Jabbar

Department of Biochemistry lab services and Chemical Pathology, Liaquat National Hospital and Medical College, Karachi-74800. Pakistan
Corresponding author: dr_jmalam@hotmail.com

Abstract *Background:* Vitamin D (Vit D) deficiency, as determined by blood concentrations of 25(OH) Vit D forms, creates musculoskeletal disorders. Competitive immunoassay or its sister technique protein-binding assays, performed on fully automated or manual instruments are commonly used 25-OHD-measurement methods. To maintain compatibility and competitiveness, clinical laboratories acquires analytical instruments from more than one vendor/company to maintain level of competitiveness, edge regarding availability of best of the best technology and compatibility of every instrument. *Aim*: Present study describes assessment of compatibility and precision of Vitamin D analyses on two Immunoassay instruments, Beckman Coulter Access 2 and Roche Cobas E411. *Materials and Methods*: Blood samples were collected from 100 individuals/patients for 25 OH-Vit D, 25 each from diseases population (groups I, II and III) and 25 healthy individuals (group IV) and analyzed for 25-OH-Vit D on Cobas e411 using electro-chemiluminescence (ECLi) immunoassay technology (Roche Diagnostics, Basil) and Beckman Coulter Access 2 using chemiluminescence technology (Beckman, USA). Data was compared statistically by using SPSS ver 20.0 (USA), regression correlation analysis and considered significant when $P < 0.05$. *Results*: Regression correlation analysis exhibited excellent compatibility and two instruments standardization with R2 0.988 (Fig 1), R2 0.9903 (Fig 2), R2 0.9877 (Fig 3) and R2 0.996 (Fig 4) manifesting precision of 98.8%, 99.03%, 98.77% and 99.6%, respectively. Regression Y intercepts of all four groups shows calculations as $y = 0.9172x+0.869$, $y = 0.9883x+0.2252$, $y = 1.0057x -0.093$ and $y = 1.01017x -0.421$, respectively. *Conclusion*: Regression R^2 data exhibited linearity upto R2 0.996, translating reproducibility and compatibility ranging from 98.8% to 99.6% by comparative analysis on Beckman Access and Cobas e411 for 25-OH-Vit D. All previous studies of similar objectives at international forum also support our findings and suggested observations.

Keywords 25-OH-Vit D, Total Vitamin D, chemiluminescence, Beckman Access, Cobas Roche

Introduction

Vitamin D (Vit D) is a fat soluble vitamin, by product of sterols and its deficiency, as determined by blood concentrations of 25(OH) Vit D forms, creates musculoskeletal disorders [1,2]. Our population being Vitamin D deficient, demands analysis ad labitum, resulting in voluminous samples, consequence of which laboratories shifting to more and more fully automated immunoassays [3]. Vitamin D is related to secosteroids, exists in two forms—one made by skin when exposed to UVB sun rays (cholecaliferol, vitamin D3) and the other made by plants (ergocalciferol, vitamin D2) [4]. In liver vitamin D undergo hydroxylations to form 25-hydroxyvitamin D [25(OH)

D] and in kidneys into 1,25-dihydroxyvitamin D [1,25(OH)2D]. It is reported that 1,25(OH)2D is the biologically active metabolite, however 25(OH)D characterized best and true nutritional status of Vitamin D reflecting calcium absorption and deficiency status [3,5].

The amplified requirements for 25(OH)D analysis in deficient population has led to the beginning of analytical methods based on principles devoid of isotopes and more towards immunoassay categories such as competitive protein binding (CPB) and/or chromatography such as high-performance liquid chromatography (HPLC) with tandem mass spectrometry detection (LC/MS) [6-8]. Competitive immunoassay or its sister technique protein-binding assays, performed on fully automated or manual instruments are commonly used 25-OHD-measurement methods, whereas chromatographic techniques HPLC/UV and tandem mass spectrometry (LC-MS/MS) are considered expensive, time consuming and requires specialized-references and specifically expert staff [9.10]. Generally, allover the world, automated immunoassay (MEIA, ELISA, iECL etc) or protein-binding assays are known simple methods, easy to maintain, allows sharp throughput and compatible immunochemistry analysis on routine analyzers [6,8,10]. To maintain compatibility and competitiveness, clinical laboratories, especially those within tertiary care hospitals, always acquires analytical instruments from more than one vendor/company. Reason are obvious, to maintain level of competitiveness, edge regarding availability of best of the best technology, compatibility of every instruments for opting variable analyses preference and off course better prices.

Present study describes compatibility and precision of Vitamin D analyses on two Immunoassay instruments, Beckman Coulter Access 2 and Roche Cobas E411.

Materials and Methods

Research protocol and Sample selection

Hundred patients (males = 50; females = 50, age range = 26-50 yrs) with either bone diseases, osteoporosis, arthritis, bone pains for groups I, II and III (diseased population) and patients with healthy demeanor for groups IV were selected for Vitamin D (25-OH-D) comparative precision analyses. Study period for this prospective study was from July 1st 2018 to 1st Dec 2018. Samples were selected from normal subjects (non diseases, with no complaints of bone pain and Vit D greater 30 ng/ml; n =25 and patients with bone diseases, osteoporosis, arthritis, bone pains (n = 25 each, with 25-OH Vit D less than 30.00 ng/ml). The patients who are on steroid therapy, underwent surgery, suffering from renal impairment were excluded from the study.

Precision analysis of Total Vitamin D (25-OH Vit D) on Immunoassay analyzers

Previously described protocols were followed for standardization [11,12]. Blood samples were collected from 100 individuals/patients for 25 OH-Vit D, 25 each from diseases population and 25 patients with good healthy status in Clot activator tubes. Plasma was separated and analyzed for 25-OH-Vit D on Cobas e411 using electro-chemiluminescence (ECLi) immunoassay technology (Roche Diagnostics, Basil) and Beckman Coulter Access 2 using chemiluminescence technology (Beckman, USA). Normal and compromised reference range of 25-OH-Vit D are less than 20 ng/ml (Deficiency), 21-29 ng/ml (insufficiency), 30-150 ng/ml (Desirable-normal). The data was compared statistically by using SPSS ver 20.0 (USA), regression correlation analysis and considered significant when $P < 0.05$.

Results

Data is presented in Fig 1 to 4. One hundred patients (males = 50; females = 50, age range = 26-50 yrs) with either severe bone diseases, osteoporosis, arthritis (group I, Fig 1), mild Osteoporosis and bone pains group II (Fig 2), patients of arthritis and osteoporosis under treatments (Group III, Fig 3) and healthy patients with normal clinical status (Group IV, Fig 4) were selected for Vitamin D (25-OH-D) comparative precision analyses.

Fig 1: Precision analysis of Total Vitamin D (25-OH Vit D) on Cobas E411 and Access 2 from patients with significant deficiency

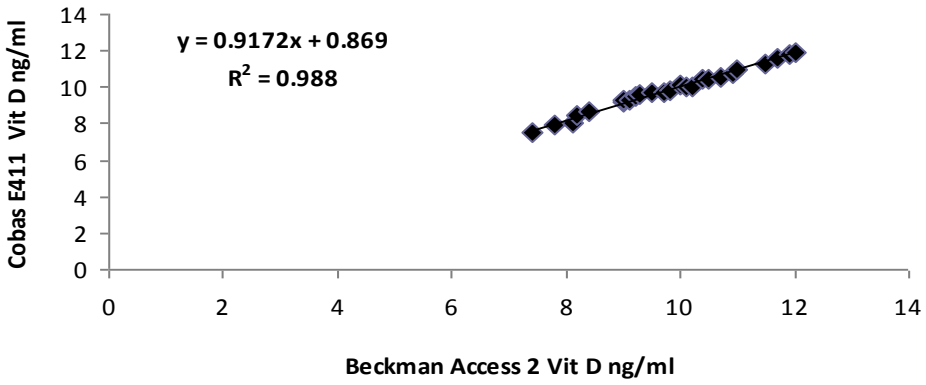


Fig 2: Precision analysis of Total Vitamin D (25-OH-Vit D) on Cobas E411 and Access 2 from patients with mild deficiency

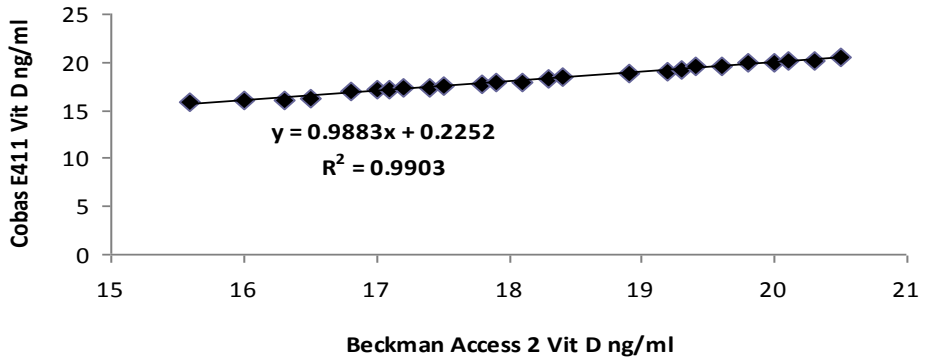
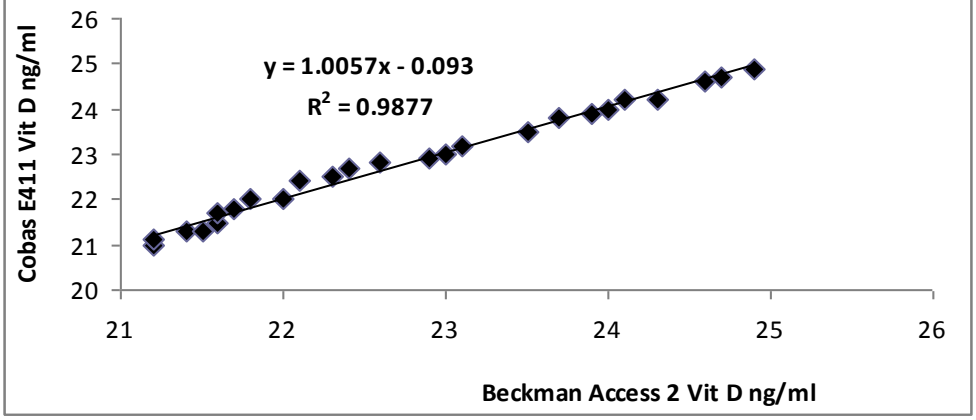
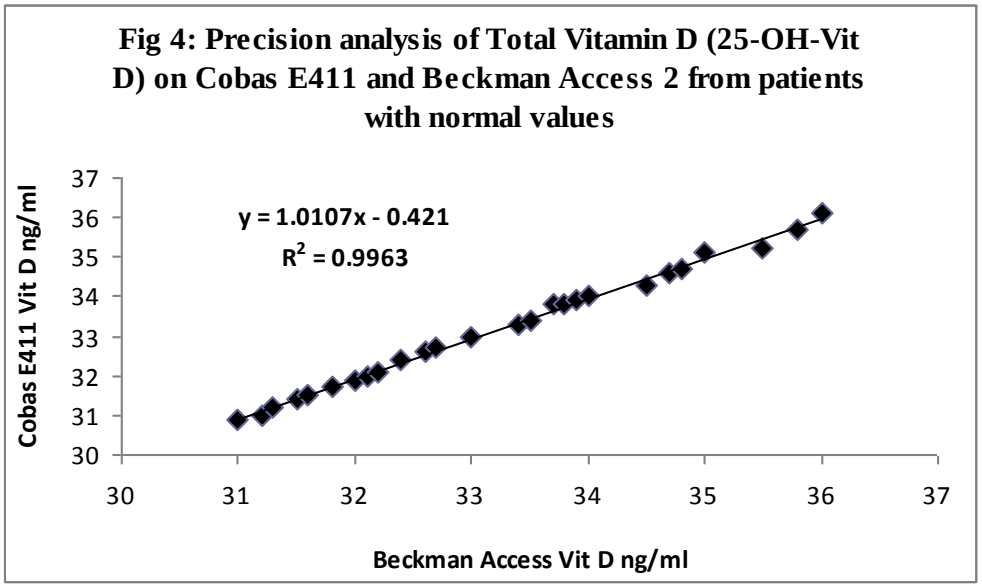


Fig 3: Precision analysis of Total Vitamin D (25-OH-Vit D) on Cobas E411 and Beckman Access 2 from patients with insuffiency





Regression correlation analysis exhibited excellent compatibility and two instruments standardization with R2 0.988 (Fig 1), R2 0.9903 (Fig 2), R2 0.9877 (Fig 3) and R2 0.996 (Fig 4) manifesting precision of 98.8%, 99.03%, 98.77% and 99.6%, respectively. Regression Y intercepts of all four groups shows calculations as y = 0.9172x+0.869, y = 0.9883x+0.2252, y = 1.0057x -0.093 and y = 1.01017x -0.421, respectively.

Discussion

In our presented standardization and precision analyses study of 25-OH Vit D, excellent compatibility was noted among both Roche Cobas E411 and Beckman coulter Access 2 immunoassay analyzers, works on iECL and ECL technologies, respectively. Regression data exhibited linearity upto R2 0.996, translating reproducibility and compatibility ranging from 98.8% to 99.6%. Previous studies regarding similar comparative data exhibited regression upto 0.716 to 0.863 when Vitamin D was analyzed on Roche's Cobas E411 and Abbott's Architect [13]. Similarly, when 25-OH Vitamin D was analyzed on six major immunoassay analyzers, Beckman Coulter's Access2 and UniCel DxI 800, Abbott Diagnostics's ARCHITECT i2000SR, Siemens's ADVIA Centaur XP, DiaSorin's Liaison XL and Roche's Cobas MODULAR E170, its assays produced variable results as compared to LC/MS/MS, suggesting presence of Vitamin D2 interferes with recovery of 25 OH Vit D (also known as total vitamin D) [14]. Moreover, VIDAS® method for analyses of 25-OH Vitamin D assay exhibited exceptionally good correlation to the LC-MS/MS results with R2 of 0.93, confirming reproducibility and standardized activities of both methods [15]. A recent past study also advocated similar performance for four different immunoassay analyzers by Siemens, DiaSorin, Abbott and Roche [9], where variable outcomes were noted, but acceptable as per performance and variance. A very recent report regarding comparative analysis of 25-OH-Vit D on Beckman Access and Abbott Architect noted recovery of 84.1% to 91% with regression linearity of 0.841 to 0.91 [16]. Our study showed marked correlation, compatibility, linearity amongst both analyzers (of different make and model), advocating shifting of tests on either of the instruments, whenever need arise, without worrying about quality assurance.

Conclusion

Standardized and precision related outcome was noted by our study of 25-OH Vit D on two different analyzers, Roche Cobas E411 and Beckman coulter Access 2 immunoassays. Regression R2 data exhibited linearity upto R2 0.996, translating reproducibility and compatibility ranging from 98.8% to 99.6%. All previous studies of similar objectives at international forum also support our findings and suggested observations.

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