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Degree of Agreement between Vitros ECi Instruments in Serological Tests by Bland-Altman Analysis

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Abstract

Objectives: Serological tests for HIV, HBsAg and HCV are commonly done as a part of Pre-operative patient work-up. Variation in test results is common when it performed on 2 instruments. This study aimed at estimating the degree of agreement between the values obtained by 2 different instruments for HIV, HBsAg and HCV tests.

Materials & methods: 2 automated instruments with enhanced chemiluminescence technology were chosen for the study. Both instruments are equal in their model and manufactured by the same company. 1 patient sample was chosen randomly and the 3 serological tests were run simultaneously on both the instruments. The values obtained were recorded in excel sheet and analyzed using Bland Altman method.

Results & conclusion: A total of 524 set of values each were obtained for HIV, HBsAg & HCV tests during a period of 22 months. The values were analysed using Bland Altman plot. It was found that more than 90% of the values were within the limits of agreement.

Keywords: Bland Altman plot, Degree of agreement, Serological test, Vitros ECi

Introduction

Pre-operative screening of patients for Human Immunodeficiency Virus (HIV), Hepatitis B (HBV) and Hepatitis C (HCV) are commonly performed tests in the laboratory attached to a tertiary care hospital. Most of the hospital laboratories have automated systems for performing these tests for rapid results. Accredited laboratories also have a stand-by automated system because of statutory requirements. Variation in the results is a common finding encountered in serological tests when the same test parameter is run on 2 different instruments.

Some variations may have direct impact on patient management and the laboratories try to reduce this variation to the minimum. Accuracy in the results obtained by 2 different instruments for the same test parameter is one of the quality indicator. Measurement of this accuracy or the degree of agreement between instruments is a statutory requirement by the accreditation bodies like NABL, ISO. Validation of a clinical measurement method is a compelling and lengthy process, which necessitates acceptable Limits of Acceptance between two techniques. When the comparing methods yield continuous variables (e.g. leucocyte count, antibody titer, body temperature), the Bland-Altman analysis is an appropriate way to perform this comparison and presents quantified measures to decide whether the new method is acceptable or not.[1] It is a graphical representation of the differences between the values (on the Y axis) and the mean of the two readings (X-axis). This study aims to estimate the degree of agreement between two Vitros ECi instruments for the HIV, HBsAg and HCV results.

Materials & methods

Study was performed in Microbiology lab, of 800 bed tertiary care hospital which conducts approximately 4000 serological tests per month. The hospital has a policy of testing all patients undergoing surgery for anti-HIV antibodies, Hepatitis B surface antigen (HBsAg) and anti-Hepatitis C antibodies pre-operatively. These tests are performed on automated instruments – Vitros ECi, Model 360 manufactured by Ortho Clinical Diagnostics, which work on the principle of enhanced chemiluminescence technology. The quality control for these tests were run every day and were within acceptable limits. As a quality assurance policy 1 random sample in a day was tested for HIV antibodies, HBsAg and HCV antibodies on 2 different, but same model instruments viz Vitros ECi 360. The values obtained were recorded in excel spread sheet and analysed. The duration of collection of data was from January 2018 to October 2019.

Results

A total of 524 set of values were collected for HIV, HBsAg and HCV each. These values were plotted using Bland Altman plot and the following figures shows the degree of agreement between the instrument values.

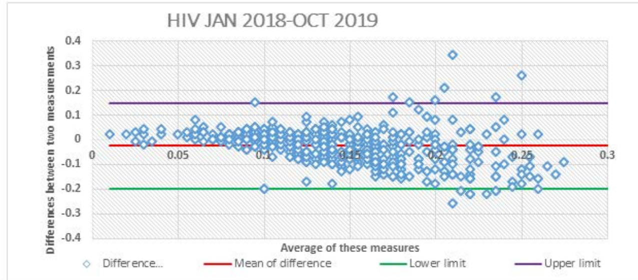

Figure 1: Bland Altman Plot for Anti-HIV antibody values

Shows the degree of agreement of values obtained for Anti-HIV antibodies between the 2 Vitros ECi instruments. More than 90% of the values are between the limits of agreement.

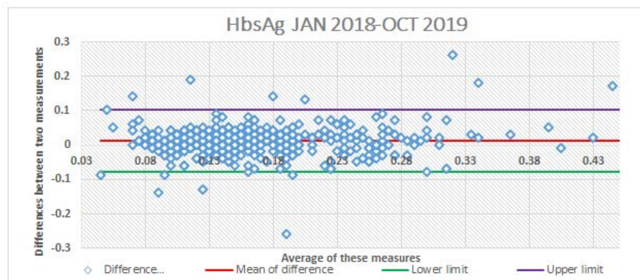

Figure 2: Bland Altman Plot for HBsAg values

Shows the degree of agreement of values obtained for Hepatitis B Surface antigen (HBsAg) between the 2 Vitros ECi instruments. More than 90% of the values are between the limits of agreement.

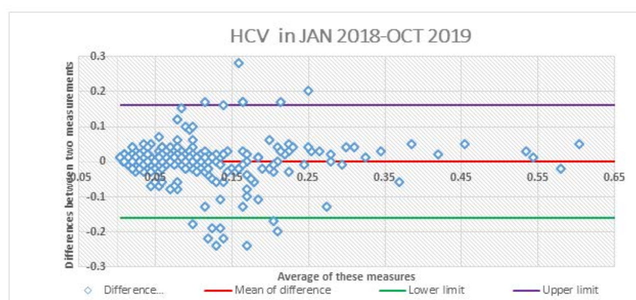

Figure 3: Bland Altman Plot for Anti-HCV antibody values

Shows the degree of agreement of values obtained for Anti-HCV antibodies between the 2 Vitros ECi instruments. More than 90% of the values are between the limits of agreement.

Discussion

Medical laboratories and clinicians often need to assess the agreement between two measurement methods for diagnosis and treatment. Tests performed on two instruments of same model ideally should give same values but practically there is always a variation.

Quantification of variation and its analysis is an important aspect for quality improvements.

For many years, correlation analysis has been used to assess the relationship between one variable and another. Correlation analysis is classified as a part of a larger class of statistical techniques known as regression. Regression analysis uses the principles of correlation, but it does more than just to describe the strength of a relationship between two variables.[2] The main result of correlation analysis is the correlation coefficient (r), which ranges from −1.0 to +1.0. The closer the coefficient is to the ends of this range, the greater the strength of the linear relationship is.[3]. Correlation coefficients can be handled as linear measures for the relationship between variables without providing their agreement. Unfortunately, correlation analysis provides a link between variables which just happen to occur together, without having an association in between. A high correlation does not explicitly imply that there is good agreement between the two methods.[3] Moreover, data which seem to be in a poor agreement can produce quite high correlations.

Bland and Altman quantified the difference between measurements using a graphical method. They draw a scatterplot in which the X-axis represented the average [(K1 + K2)/2], and the Y-axis represented the difference (K1 – K2) of two measurements. After the graph is drawn, the mean bias (mean of the K1 – K2) and its confidence limits (limits of agreement) should be quantified.

Bland-Altman analysis was previously used in many method comparisons in the literature. It may be used to compare two new measurement methods or one measurement method against a reference standard. These measurement variables should be continuous (not categorical) such as hemoglobin level (g/dl), anti-HCV antibody titer or the size of a tumor (cm).[1] Hence this method was used in our study to evaluate a bias and gives useful graphical representation of the agreement between the two tests.

As evident in the figures there was high degree of agreement between two different Vitros ECi instruments of same model for HIV, HBsAg and HCV values. Hence it can be concluded that Bland Altman analysis can be used for comparison of values obtained in serological tests as per the requirement of accreditation bodies. However the B&A plot method only defines the intervals of agreements, it does not say whether those limits are acceptable or not. Acceptable limits must be defined *a priori*, based on clinical necessity, biological considerations or other goals

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