Analytical performances of a new immunoturbidimetric D-dimer assay

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INTRODUCTION

The routine D-dimer quantification to exclude venous thromboembolism has led to the development of many assays, the usefulness of which depends on their reliability and performance.

AIM

To evaluate the analytical performances of the Yumizen G DDi 2 assay (HORIBA Medical) performed with the Yumizen G800 analyzer and to compare it with other available D-Dimer assays: Vidas D-dimer Exclusion II for VIDAS® 3 (BioMérieux), STA®-Liatest® D-Di Plus for STA-R Max® (Diagnostica Stago), Innovance® D-dimer for Sysmex® CS-2100i (Siemens Healthineers) HemosIL® D-dimer HS500 for ACL TOP 700 (Werfen).

METHOD

Within-run and between-run imprecision were evaluated using low- and high quality control plasma samples. The limit of detection, limit of quantification and linearity were determined according to the Clinical and Laboratory Standards Institute guidelines[1]. Interference due to hemolysis, icterus, lipemia, rheumatoid factor (RF) or heterophilic antibodies (HAMA) was evaluated by spiking plasma samples with hemolysate, bilirubin, Intralipid®, RF, or HAMA[2]. The measurements obtained with the different D-dimer assays were compared with the Bland-Altman plot method.

RESULTS

The coefficients of variation values of within- and between-run were in accordance with the specifications by Ricos and colleagues: <3% for D-dimer values >1000 ng/mL fibrinogen-equivalent units (FEU) and <6% for D-dimer values close to the threshold of 500 ng/mL FEU. The assay linearity was very good for a broad range of concentrations, up to 32700 ng/mL FEU. Hemolysis and icterus did not have any effect up to 10 g/L hemoglobin and 300 mg/L bilirubin. Lipemia seemed to generate an underestimation of D-dimer concentration when Intralipid® concentration was > 5 g/L (Figure 1). RF and HAMA did not have any effect. The Bland-Altman analysis showed strong agreements between the Yumizen G DDi 2 assay and other assays performed with 66 fresh plasma samples with a wide range of D-dimer concentrations. Discordant values were found in D-dimer values > 2000 ng/mL FEU, without clinical impact.

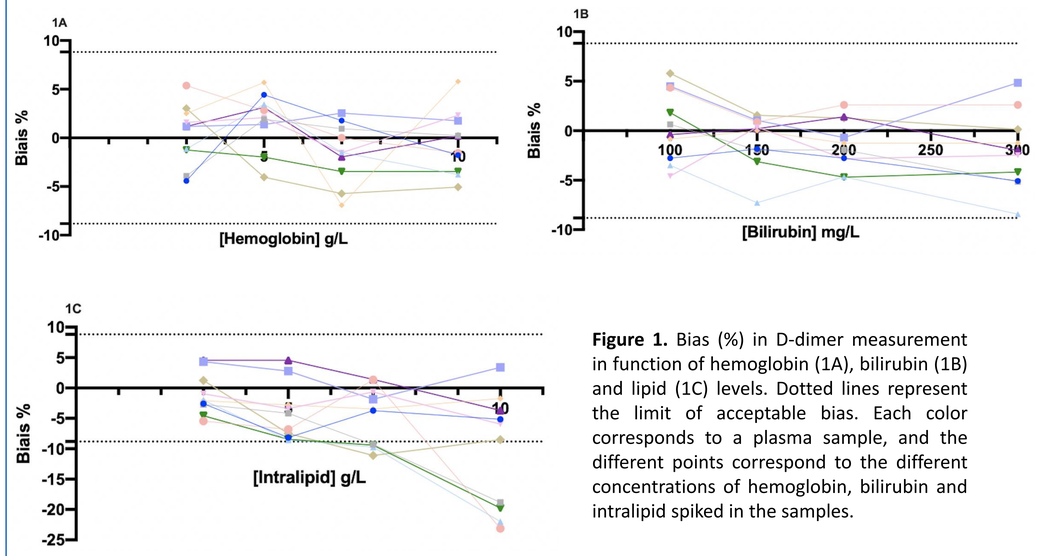

Figure 1. Bias (%) in D-dimer measurement in function of hemoglobin (1A), bilirubin (1B) and lipid (1C) levels. Dotted lines represent the limit of acceptable bias. Each color corresponds to a plasma sample, and the different points correspond to the different concentrations of hemoglobin, bilirubin and intralipid spiked in the samples.

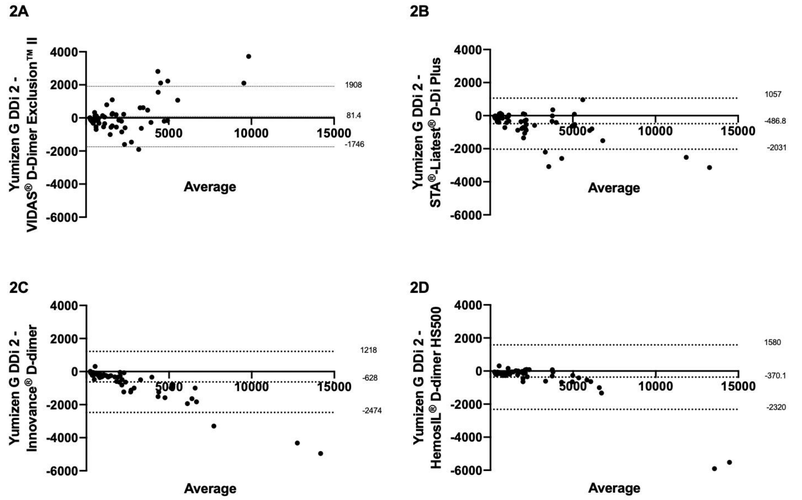

Figure 2. Bland Altman plots of the D-dimer values obtained with the Yumizen G DDi 2 assay and the Yumizen G800 analyzer and other available assays. The X axis represents the mean of the measurements and the Y axis represents the difference between the measurements obtained with the two systems. Continuous and dotted lines represent the bias and the lower and upper limits of agreement with the 95% confidence intervals, respectively.

CONCLUSIONS

Its analytical performances and main technical features indicate that the new Yumizen G DDi 2 is suitable for the rapid quantification of D-dimers in clinical laboratories.

REFERENCES

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