Letter to the Editor
Diagnostic Hematology
Ann Lab Med 2014;34:64-65
http://dx.doi.org/10.3343/alm.2014.34.1.64
ISSN 2234-3806 eISSN 2234-3814
ANNALS OF LABORATORY MEDICINE

Comments on Point of Care D-Dimer Testing in the Emergency Department: A Bioequivalence Study

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Dear Editor

We read with interest the article "Point of Care D-Dimer Testing in the Emergency Department: A Bioequivalence Study" by Perveen et al. published in Ann Lab Med 2013;33:34-38 [1]. In this article, the authors compared the performance of the D-dimer assays on the AQT90 FLEX analyzer (Radiometer Medical Aps, Åkandevej, Denmark) and the VIDAS analyzer (bioMérieux SA, RCS Lyon, France). The study had 2 objectives:

1. To determine any significant difference between the 2 assays in the time from sample draw until result.
2. To quantify the agreement between the results obtained by the 2 assays when performed on samples from the same sample draw.

A pilot study determined that a minimum sample size of 100 patients was required for the first objective. The main study included 104 patients and revealed a significant difference between the 2 assays in the time from sample draw until result. For the second objective, determining the agreement between the results obtained by the 2 assays, the pilot study did not determine a minimum sample size; however, the data from the 104 patients were used in this regard. Additionally, imaging results were available for 40 patients in the study sample. Among these, 7 patients had positive imaging and 33 patients had negative imaging results. Only these 40 imaging results were used to calculate the sensitivity and the specificity for the 2 assays. Therefore, we agree with the authors when they state that the sample size was not large enough to compare the clinical performance of both assays with respect to venous thromboembolism.

Discordant results between the 2 assays were found in 8 patients. In all of these 8 cases, a positive result was found with the VIDAS assay and a negative result with the AQT90 FLEX assay. All of these 8 patients had negative imaging results. The authors have presented the results for these 8 patients in a table.

Then, the authors measured the ratios between the AQT90 FLEX and VIDAS results. The range is presented as 0.34-2.13. However, this must be a typographical error since the results for sample 7 in Table 2, using the 2 analyzers, is 318 ng/mL and 1,300 ng/mL. Thus, we assume the true range to be 0.24-2.13. This means that there is a 9-fold difference between the highest and the lowest ratio. The authors concluded that the average ratio is 0.85.

The authors claim that the average ratio of 0.85 is the reason behind the 8 discrepant results and that this difference between the assays raises the question of whether it is acceptable to use the AQT90 FLEX assay in the emergency department. We disagree with that statement since the imaging results yielded negative findings in the 8 cases.

There is no consensus on the standardization of D-dimer assays. Goodacre et al. [2] found in their meta-analysis, which in-

Received: April 9, 2013
Accepted: September 2, 2013

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cluded 97 study reports on 198 D-dimer assays in 99 different patient groups, a substantial heterogeneity, particularly with regard to specificity. Even though linear regression analysis may show a good correlation between the 2 D-dimer assays, the correlations are often not good across the measuring range [3]. The variation, which can be seen especially near the cutoff, is clearly shown by Sukhu et al. [4]. Although 12% of their samples showed discordant values, the 2 assays (Stalia and VIDAS) did not differ significantly in clinical performance.

A useful comparison of the D-dimer assay performance is the one made against a gold standard or "truth." For D-Dimer assays, that gold standard is imaging. Since the imaging results, were in agreement with the AQT90 FLEX D-Dimer results in the discrepant cases (VIDAS vs. AQT90 FLEX), we believe that the data from Perveen et al. support the findings by Sidelmann et al. [5] who compared the AQT90 FLEX assay to several other assays including the VIDAS. Sidelmann et al. [5] concluded that the AQT90 FLEX D-dimer assay demonstrated excellent performance and that it was comparable to routine D-dimer assays.

Authors' Disclosures of Potential Conflicts of Interest

The authors are both employees at Radiometer Medical Aps.

REFERENCES

1. Perveen S, Unwin D, Shetty AL. Point of care D-dimer testing in the emergency department: a bioequivalence study. Ann Lab Med 2013;33:34-8.
2. Goodacre S, Sampson FC, Sutton AJ, Mason S, Morris F. Variation in the diagnostic performance of D-dimer for suspected deep vein thrombosis. QJM 2005;98:513-27.
3. Coen Herak D, Milos M, Zadro R. Evaluation of the Innovance D-DIMER analytical performance. Clin Chem Lab Med 2009;47:945-51.
4. Sukhu K, Beavis J, Baker PM, Keeling DM. Comparison of an immunoturbidometric method (S Talia D-DI) with an established enzyme linked fluorescent assay (VIDAS) D-dimer for the exclusion of venous thromboembolism. Int J Lab Hematol 2008;30:200-4.
5. Sidelmann JJ, Gram J, Larsen A, Overgaard K, Jespersen J. Analytical and clinical validation of a new point-of-care testing system for determination of D-Dimer in human blood. Thromb Res 2010;126:524-30.