Letters to the Editor

Evaluations of Activated Clotting Time Technologies Require Understanding Activating Clotting Time System Differences

To the Editor,

The article, “Comparison of Point-of-Care Activated Clotting Time Systems Used in a Single Pediatric Institution” by Ojito et al. (JECT. 2012;44:15–20), presented an interesting in vitro comparison of four different systems for measuring the activated clotting time (ACT) test. The results of this evaluation confirmed earlier studies in demonstrating that no two ACT test systems report the same results on a given blood sample, the clear message being that there is no standardization in ACT testing (1–5).

In their discussion, the authors appropriately call attention to the potential clinical consequences of using multiple systems for the measurement of ACTs within a single institution when the results of these different ACT systems may not be directly comparable. However, they neglect to point out the more critical need, to select the appropriate ACT for each clinical application. The selection of the appropriate ACT was not performed in this study.

The level of heparin evaluated (calculated by the authors to be 1.7 U/mL) is a low to moderate level, most frequently observed in diagnostic catheterization and the cardiac intensive care unit. Despite this low level of heparin, three of the four systems studied (Medtronic HMS, Medtronic ACT Plus®, and Abbott i-STAT®) were evaluated using cartridges intended to be used for moderate to high heparin level monitoring (Medtronic HRACT and i-STAT kaolin ACT). Only the Hemochron® Signature ELITE™ was evaluated using a test specifically designed for this heparin level, the Hemochron Jr. ACT-LR cuvette. The higher coefficient of variation seen in this system can easily be attributed to the higher sensitivity to minor fluctuations in anticoagulation that this test is designed to detect (6).

The stated goals of this study were “to determine the [ACT systems’] accuracy, reproducibility, ease of use, and cost.” Accuracy can only be evaluated when there is a “true” value to which all systems can be compared, ease of use was omitted from the results and discussion of the article, and cost was listed only in a table in the appendix. Reproducibility was the only parameter evaluated and all four systems revealed performance (coefficient of variation <10%) well within the general expectations for ACT test precision (3,6). The observed differences in reproducibility (coefficient of variation range 3.3–7.1%) would have no effect on clinical decisions to increase or decrease heparin dosing, even for extremely low-range heparin anticoagulation such as patients on continuous heparin infusion for thromboembolic therapy.

The authors draw conclusions on the efficacy of each system evaluated across all clinical applications based on the coefficient of variation measured from samples withdrawn from a blood circuit titrated with 1.7 U/mL of unfractionated heparin. It would be beneficial to all involved in ACT testing if such a study were repeated in two different manners. In the first, the Hemochron ACT-LR cuvette would be compared with the Medtronics LRACT cartridge at heparin levels similar to those in the current evaluation. The second evaluation would encompass more varied clinical applications and use heparin levels more commonly associated with interventional cardiology and cardiac surgery (i.e., 2–5 U/mL). Such a study would require the use of the Hemochron ACT+ cuvette, rather than the ACT-LR, compared with the same three systems evaluated in the current study.

This publication serves a very important function of raising the reader’s awareness of the differences between ACT test systems. It is disappointing that the study was not performed using ACTs that share intended use populations and that the authors saw fit to draw wide-ranging conclusions based on a single precision evaluation.

Marcia L. Zucker, PhD
President
ZIVD, LLC
10 Tulsa Ave.
Metuchen, NJ 08840

Marcia L. Zucker, PhD
President
ZIVD, LLC
10 Tulsa Ave.
Metuchen, NJ 08840
REFERENCES