Validation of the i-STAT Handheld Activated Clotting Time for Use With Bivalirudin

Jeffrey M. Schussler, MD, Stuart R. Lander, MD, Laurie A. Wissinger, MT, Azam Anwar, MD, Michael S. Donsky, MD, Kenneth B. Johnson, MD, Ravi C. Vallabhan, MD, and Jason B. Wischmeyer, MD

Bivalirudin is being used more frequently as an anticoagulant in the cardiac catheterization laboratory. Newer devices, used to measure activated clotting time (ACT), have not been thoroughly tested for use with bivalirudin. One such device, the i-STAT ACT, measures the generation of activated thrombin to determine the level of anticoagulation. Our study demonstrated a high level of agreement between the i-STAT ACT and the Hemochron ACT in patients anticoagulated with bivalirudin. In addition, the i-STAT was shown to have an extremely high degree of reproducibility. ©2004 by Excerpta Medica, Inc. All rights reserved. 0002-9149/04/$

We have previously reported on the use of the i-STAT handheld activated clotting time (ACT) device (i-STAT Corp., Princeton, New Jersey) with traditional anticoagulation regimens during and after percutaneous coronary intervention (PCI). In that report, there was not enough information to fully evaluate the use of the i-STAT in patients anticoagulated with bivalirudin. In this study, 123 patients who received bivalirudin as their sole anticoagulation for PCI had simultaneous i-STAT and Hemochron (ITC, Edison, New Jersey) ACTs performed and the results compared. This study provides the first direct comparison between the i-STAT and Hemochron devices in patients who received bivalirudin.

Over a period of 3 months, patients who received bivalirudin in the cardiac catheterization laboratory had simultaneous ACTs drawn and run on 2 separate i-STAT machines and a Hemochron machine. ACTs were drawn and run immediately after PCI was performed, or at 15 minutes (whichever came first). After PCI was completed and the patient was transported to the recovery area, additional simultaneous ACTs were performed as part of the routine sheath-pull protocol. Agreement between i-STAT and Hemochron was assessed using the intraclass correlation coefficient (ICC). The ICC, from a comparison of both i-STAT machines, was also used to describe i-STAT reproducibility. Estimates of the ICC and exact confidence intervals were derived by a 1-way random effects model.²³

The ICC and corresponding 95% confidence interval for the i-STAT to Hemochron and i-STAT to i-STAT comparisons in the 123 patients are shown in Table 1. Applying the criteria for acceptable values of ICC as suggested by Landis and Koch,³ these results indicate “near perfect” (ICC ≥0.80) i-STAT to Hemochron agreement. Moreover, the lower bound for each i-STAT to Hemochron ICC is near or >0.75, further demonstrating the equivalence of these tests.⁵ The i-STAT to i-STAT comparison (an evaluation of reproducibility) yielded an even higher ICC.

Agreement between both i-STATs and Hemochron as well as i-STAT reproducibility was evaluated graphically. Figures 1 and 2 show scatter plots for the i-STAT measurements compared with the Hemochron, along with the y = x line as a reference to perfect agreement. In Figures 1 and 2, the points are tightly clustered around the y = x line, indicating good agreement. Figure 3 displays the same plot for both i-STAT measurements and, like the ICC analysis, shows very high agreement (i.e., reproducibility).

Bivalirudin, a direct thrombin inhibitor, is an anticoagulant that has recently increased in popularity for use in PCI. Recent studies have demonstrated a similar efficacy of bivalirudin in PCI compared with heparin and glycoprotein IIb/IIIa antagonists and superiority compared with heparin alone.⁶ Bivalirudin has demonstrated very good clinical efficacy, excellent reliability in reaching therapeutic levels of anticoagulation, and reduction in time-to-sheath removal.⁷

Several studies to date have demonstrated the utility of the i-STAT in point-of-care testing in both hospital and outpatient settings.⁸–¹¹ The i-STAT ACT has been shown to have a high degree of correlation with traditional measurements of anticoagulation in the setting of heparin or with heparin in conjunction with glycoprotein IIb/IIIa antagonists.¹,² We assumed that because the i-STAT ACT measures activated thrombin and bivalirudin is a direct thrombin inhibitor, it would be ideal for measuring anticoagulation with bivalirudin. This has, however, never previously been tested.

Acknowledgment: We would like to thank our research nurses: Cathy Headley, ADN, Rhonda Jones, BSN, and Maureen Schreibfeder, MS, for their help and support. Special thanks to all the staff in the...
cardiac catheterization laboratory and the recovery area at the Baylor University Medical Center/Jack and Jane Hamilton Heart and Vascular Hospital for their help with this project. We would also like to thank David Nicewander, MS, for his invaluable help with the statistical analysis.


