Activated Clotting Time (ACT): Comparison of the Hemochron Signature Elite and the Abbott i-STAT

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BACKGROUND

ACT is commonly used for heparin anticoagulation monitoring during procedures including cardiopulmonary bypass surgery, coronary angioplasty, and interventional radiology. To prevent thrombosis, moderate to high levels of heparin anticoagulation are required. The Hemochron Signature Elite (HSE, Accriva Diagnostics, formerly ITC, San Diego, CA) was implemented at TJUH as a replacement for the older model Hemochron Response (Accriva/ITC Model HRS.110, San Diego, CA). Operating room (OR) perfusionists reported irreproducible high results using HSE that could not be explained clinically. In consideration of use of i-STAT analyzers (Abbott Point of Care, Princeton, NJ) as an alternative to HSE, we performed a comparison of ACT results as analyzed by HSE and i-STAT (Abbott Point of Care, Princeton, NJ) analyzers.

METHODS

A comparison of inter-device reproducibility of results for each method was performed using the same samples for both the HSE and i-STAT (22 OR patient specimens, sampled across all analyzers within a 10 sec interval), measured in duplicate across two separate analyzers for each method. Measuring ranges were: HSE-68-1005 sec; i-STAT-50-1000 sec. Linearities for HSE (Kaolin ACT+ cartridges) and i-STAT (ACT-K cartridges) analyzers were assessed by heparin dilution curves. Precision for each method was measured by repeat testing of controls. In the duplicates experiment, 10 additional specimens were excluded because HSE results exceeded the HSE measuring range.

RESULTS

Precision for i-STAT controls (n=40) were 3.6% CV and 3.5% CV (91-169 sec and 406-754 sec, respectively) across devices. These were comparable to precision for HSE controls (n=78), which were 5.5% CV and 2.2% CV (110-196 sec and 284-504 sec, respectively) (***Table 1).*** A heparin curve demonstrated acceptable linearity for the i-STAT ACT therapeutic range (units heparin/mL = x, heparin response (sec) = y, $R^2 = 0.9613$, $y = 99.607x + 174.61$, range = 107-748 sec) and also for the HSE ACT therapeutic range. A comparison of inter-analyzer reproducibility between HSE and i-STAT showed significant differences, however. Among 22 specimens, the average % difference from the mean for HSE results across two analyzers (4.6%; median ACT = 477 sec, range 91-757 sec) was significantly different ($p < 0.002$) from that for i-STAT results (1.8%; median ACT = 374 sec, range = 106-951 sec) (***Table 2)***. Correlation of average results was $r^2 = 0.5881$, $0.946x + 35.5$.

CONCLUSIONS

- Both i-STAT (ACT-K cartridge) and Hemochron Signature Elite (Kaolin ACT+ cartridge) analyzers showed acceptable linearity,
  - There was reasonable correlation between ACT results from each.
- However, we found that the iSTAT ACT-K cartridge performed with better precision and cross-device reproducibility than the Hemochron Signature Elite (Kaolin ACT+ cartridges) for patient samples.
- The i-STAT was subsequently chosen for measurement of ACT in the OR.

Table 1: Precision Data	**Accriva Hemochron Signature Elite with ACT+ Cuvettes**	**Abbott i-Stat 1 with ACT K Cuvettes**
First QC Level Acceptable Range	110-196	91-169
CV	5.5%	3.6%
Second QC Level Acceptable Range	284-504	406-754
CV	2.2%	3.5%

Table 2: Reproducibility Data	**Accriva Hemochron Signature Elite with ACT+ Cuvettes**	**Abbott i-Stat 1 with ACT K Cuvettes**
Median ACT (sec)	477	374
ACT Range (sec)	91-757	106-951
Average % difference from mean	4.6%	1.8%

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