Activated Clotting Time (ACT): The Reproducibility of Three Techniques

Paul V. Sillick, Daniel M. Amiot, and George Pancner
The Cleveland Clinic Foundation
Cleveland, OH

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Abstract

(J. Extra-Corpor. Technol. 19[3] p. 265–267 Fall 1987, 6 ref.) The ACT has routinely been used to monitor anticoagulation during surgical procedures, including open heart surgery. Since there is no laboratory substrate that can serve as a control for the test, it is important to know the reproducibility of the ACT. This study examined the reproducibility of three ACT techniques using the single syringe method.

Before heparinization, a 7cc sample of blood was collected from each of 50 open heart surgery patients. From this sample two Hemochron ACTs (H-ACT), two Sonoclot Coagulation ACTs (SonACT), and two manual ACTs (M-ACT) were simultaneously performed. The mean ± S.D. (seconds) was found to be 105.6 ± 31.8 for the SonACT, 109.7 ± 27.2 for the H-ACT, and 126.8 ± 15.4 for the M-ACT. Five minutes after heparinization the ACTs showed means of 485.5 ± 93.3 for the SonACT, 455.6 ± 101.9 for the H-ACT, and 471.2 ± 84.9 for the M-ACT.

The absolute value of the difference between the paired observations, a function of the reproducibility, was seen to have a mean of 8.8 ± 13.4 for the SonACT, 6.1 ± 7.0 for the H-ACT, and 8.3 ± 7.6 for the M-ACT. Post heparinization, the absolute difference between the paired observations gave means of 90.7 ± 99.7 for the SonACT, 56.7 ± 59.8 for the H-ACT, and 40.4 ± 45.4 for the M-ACT.

Before heparinization, all three techniques gave acceptable results. With heparinization the M-ACT showed the most reproducibility, followed by the H-ACT, while the SonACT provided the least consistent results.

Introduction

Activated Clotting Time (ACT) has long been used to assess anticoagulation during open heart surgery. As a test of the intrinsic and common coagulation pathway, it provides information regarding patient safety before extracorporeal circulation is initiated. Many patient dependent factors such as temperature, levels of heparin and heparin cofactors, and platelet activity, can influence ACT measurement. In addition, there is the inherent error of the ACT method since there is error in every type of laboratory measurement. The lack of a control substrate that can mimic the coagulation of whole blood necessitates the examination of deviation between pairs of observations drawn from a single sample of whole blood under the best of circumstances. This study is a comparison of such deviation among 3 techniques.

Materials and Methods

Fifty adult patients undergoing cardiopulmonary bypass surgery were selected for a study. Patient population is described in Table 1. Any patients with any coagulopathy or prior anticoagulation were excluded from the study. Two sets of ACTs were performed, one at baseline prior to any major surgical trauma or heparin administration, and another set 5 minutes post heparinization.

A 7cc arterial blood sample was drawn into a room-temperature, nonheparinized, 10cc syringe. Exactly 2ccs of this sample were placed into a warmed glass tube containing 12 mg of diatomaceous earth for a manual ACT (M-ACT OR). A timer was started and the tube was inverted 8 times and returned to the 37°C warming block. After 60 seconds and at every 10 sec-

Direct communications to: Paul V. Sillick, Department of Perfusion Services, Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, OH 44106
Table 1

Demographics

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Mean</th>
<th>S.D.</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>50</td>
<td>58.6</td>
<td>9.8</td>
<td>59</td>
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<tr>
<td>Weight (kg)</td>
<td>50</td>
<td>79.2</td>
<td>11.4</td>
<td>80</td>
</tr>
<tr>
<td>BSA</td>
<td>49</td>
<td>1.9</td>
<td>0.16</td>
<td>1.9</td>
</tr>
<tr>
<td>HCT (baseline)</td>
<td>50</td>
<td>38.7</td>
<td>3.4</td>
<td>39</td>
</tr>
<tr>
<td>Temp (baseline)</td>
<td>50</td>
<td>35.9</td>
<td>0.6</td>
<td>36</td>
</tr>
<tr>
<td>Heparin</td>
<td>50</td>
<td>24530</td>
<td>3228</td>
<td>24000</td>
</tr>
<tr>
<td>HCT (post)</td>
<td>47</td>
<td>38.3</td>
<td>3.6</td>
<td>38</td>
</tr>
<tr>
<td>Temp (post)</td>
<td>49</td>
<td>35.7</td>
<td>0.6</td>
<td>36</td>
</tr>
</tbody>
</table>

Sex: Male 43 (86%)  
Female 7 (14%)  
Procedure:  
CABG 47 (94%)  
Valve 2 (4%)  
CABG & Valve 1 (2%)  

Second interval thereafter, the tube was inverted and checked for clot, with time recorded at the appearance of the first distinguishable clot.

The remaining blood was taken to the lab and another manual ACT was performed (M-ACT LAB). From the same sample, 1cc of blood was given to each of two Hemochron 400° devices using prewarmed PCA 210 tubes containing 12 mg of diatomaceous earth. The test was run according to manufacturer's guidelines.

From the same sample, 0.4 ml were given to each of two warmed, shaken, SONOCLOT® Coagulation Analyzer cuvettes containing Koalin activator, and the test was run according to manufacturer’s guidelines. A second set of ACTs were performed five minutes after a loading dose of heparin (300 units/Kg) had been administered.

Results

Figures 1, 2, and 3 represent ACT observations. All of the pairs of ACTs were performed on a single sample of blood, so that patient dependent variables would be estimated. Agreement between the pairs of ACTs is expressed as distance to the line with a slope of 1.

Table 2 summarizes the functions upon the observed ACTs as a group. That the mean of the paired difference is near zero in all techniques indicated similar accuracy with each device and operator. In Figure 4, reproducibility is expressed as the ratio of the mean absolute value (to eliminate sign differences) of the difference in paired observations to the mean ACT.

b Hemochron, International Technidyne, Edison, NJ 08820  
c Johns-Manville activator as supplied by International Technidyne, Edison, NJ 08820  
d Sienco, Inc., Morrison, CO 80465  
e Lot #338432 LyphoMed, Inc., Rosemont, IL 60018
Table 2

<table>
<thead>
<tr>
<th>ACT Measurements</th>
<th>5 mins Post Heparin (sees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (sees)</td>
<td>N</td>
</tr>
<tr>
<td>Manual ACT OR</td>
<td>48</td>
</tr>
<tr>
<td>LAB</td>
<td>49</td>
</tr>
<tr>
<td>OR-LAB</td>
<td>48</td>
</tr>
<tr>
<td>OR-LAB/2</td>
<td>48</td>
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</tbody>
</table>

In the operating room. For one, the ACT entails relatively few manipulations, so that the test can begin within seconds after the sample is drawn. Also, the ACT relates well to the activation of whole blood in contact with the foreign surfaces used in cardiopulmonary bypass devices. Nevertheless, in the clinical laboratory, the ACT is poorly accepted, since there is no substrate available that can serve as a control for the contact activation of whole blood.

This study demonstrates that even with the most carefully designed and executed technique, the ACT has considerable error; a single ACT observation is not an absolute measure of the coagulation system. Perhaps a more accurate viewpoint is that each ACT observation can probably be reproduced. If, for example, the ACT was 470 seconds by the manual technique, the probability of paired agreement within 40.4 seconds would be 50%. The probability of agreement in this range of at least 85.8 seconds (one standard deviation) would be 83%.

In the baseline range, all three techniques were quite reproducible, since the rate and strength of fibrin formation produces a sharp endpoint in the intact coagulation system. In the heparinized range, the manual ACT showed superior reproducibility.

References


Questions from the Audience

Question: Steve Murphy, Southern California: Have you used or tried the HemoTec ACT block yet?
Response: We have. We're evaluating it. But I really can't comment on that.

Question: Frank Hurley, Chicago, IL: Did you monitor the temperature during these studies?
Response: We monitored temperatures by the bladder temperature. We attempted to keep all temperatures as close to normal as possible. There was always some temperature drift of the patient and I display that. It will be in the paper. It was 35.9 seconds for the baseline ACT and 35.4 for the heparinized ACT.