Comparison Between Black Top CA510 and Flip Top FT CA510 Test Tubes in the Hemochron Blood Coagulation Timing System

Francisco Robles, BS, Anthony J. DelRossi, MD, Jonathan H. Cilley Jr., MD, Sidney J. Fuller, BS, CCP, Robert D. Dunmire, CCP, Roger A. Vertrees, BA, CCP

Cooper Hospital/University Medical Center, Department of Surgery
School of Cardiovascular Perfusion, Camden, NJ

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ABSTRACT

The Hemochron System for in vivo determination of blood coagulation, commonly referred to as ACT, has routinely been used for patients undergoing extracorporeal bypass surgery. A modified version of the Black Top CA510 Hemochron test tube, the Flip Top FT CA510, has become increasingly utilized in the clinical setting. A comparative study determining reliability, reproducibility and relative accuracy between the two Hemochron tubes has been established.

Simultaneous ACT tests were performed on three hospitalized patients, totaling 22 blood samples taken altogether. Each tube was injected with 2ccs of blood per patient. ACT results were obtained and there appeared to be no significant difference between Group A (Black Top CA510) and Group B (Flip Top FT CA510). Additionally, the results in Group B indicated a higher degree of reliability with the newer tubes.

INTRODUCTION

That anti-coagulation is a necessary adjunct to perfusion technology is without argument.[1,2] The activated clotting time (ACT) has been found to be an accurate method of measuring the effect on the coagulation system of heparin.[3] The maintenance of an ACT of 500 seconds or greater [4] has been proved to correlate with an acceptable level of anti-coagulation for perfusion. The necessary level of anti-coagulation,[5,6] however, is still uncertain. The ACT as measured by the Hemochron[a] is the method of Hattersley[7] and is a reliable and safe method of assaying the effect of heparin under varying conditions.[8,9]

The current Hemochron ACT test available fuses diatomaceous earth, or celite as the clot accelerator which results in a 10 fold increase in the clotting times as compared to a Lee White Coagulation Test.[10] The accelerator is contained within a test tube denoted by the name of Black Top (BT) CA510 and consists of a black rubber stoppered test tube through which the blood must be injected. The observation has been made that when introducing blood through the stopper there would be times that a portion of the stopper would be sheared off and introduced into the test blood as a contaminant. Does this form of contamination alter the results of the test? Quite recently, Hemochron introduced as replacement for the BT CA510 the Flip Top (FT) CA510. The purpose of this study was to determine if this tube is a clinically acceptable substitute.

Address correspondence to: Anthony J. DelRossi, M.D., Department of Surgery, Division of Cardiothoracic Surgery, Cooper Hospital/University Medical Center, Three Cooper Plaza, Suite 411 Camden, NJ 08103

MATERIALS AND METHODS

A protocol was designed to test the following two hypotheses derived from the foregoing questions. Initially, H = the presence of the contaminant does effect the ACT; and secondly, H = the FT CA510 is clinically equivalent to the BT CA510. This protocol was designed in three different phases: Phase 1 - Machine Reproducibility; Phase 2 - Clinical Reliability; and Phase 3 - Tube Reproducibility. The BT CA510 is shown in the photo along with its replacement, the FT CA510.

Three adult patients undergoing cardiopulmonary bypass surgery (CPB) for coronary artery bypass grafts (CABG) were randomly selected. On each patient a minimum of six paired samples were drawn and randomly selected into either Machine A or B and the results recorded. A total of 22 paired samples were analyzed and contained pre-heparin, heparinized, or post-protamine blood samples. These results were recorded **(Table 1).** In Phase 2, from 60 ccs of previously heparinized patient blood that was a residual from a clinical case, 13 paired samples were analyzed. Again, each pair was randomly selected to either Machine A or B. The results were recorded **(Table 2).** Statistics were done using the paired sample Student t-Test and the R value for co-efficient of correlation.

RESULTS

Simultaneous samples randomly assigned to either Machine A or B showed no significant differences.

In these three patients and 22 samples, there were no significant differences between the results of the BT tube group or the FT tube group. In fact, the values are as follows: For the first patient, R value was .880, for the second patient .966 and

a. Cardio Medical Products, Inc., Belleville, NJ

TABLE #1

PATIENT #1 - ACT

	BLACK TOP	MACHINE	NUMBER	FLIP TOP
	690	B	A	719
	948	A	B	930
	800	B	A	888
	626	A	B	745
	425	B	A	591
	138	A	B	139
M	604.5			668.7
S.D.	±287.7			±286.8
CORR. COEFF. .9656				

TABLE 2

TABLE #2

MACHINE ACCURACY - ACT

BLACK TOP	MACHINE		FLIP TOP
144	A	B	155
313	A	B	315
329	A	B	385
370	A	B	373
363	A	B	545
438	A	B	411
455	A	B	543
427	A	B	555
554	A	B	657
443	A	B	600
413	A	B	491
404	A	B	512
330	A	B	269

for the third patient, .796. These all show a direct correlation between one sample and another, despite the fact that 7 of the 22 samples in the BT CA510 group, there was particulate contamination from the rubber stopper. The second portion of the protocol, where the reproducibility of the machine was tested, 13 paired values were run, the R value between the two groups was .885. This R value represents a high value of correlation between the two samples indicating that there appears to be no difference in the results garnered by using the BT CA510 tube or FT CA510 tube nor was there any disparity between the results obtained by the two Hemochron 400 Machines A or B.

DISCUSSION

The original two hypothesis were: first, the contaminant would not affect the results of the ACT, and second, there would be no difference in results between the BT CA510 or the FT CA510 groups. Twenty-two paired samples of blood were analyzed for their ACT's. Group A, the BT group vs Group B, the FT group. The purpose of this study was to determine whether there existed any difference in ACTs as measured over the full clinical range in either group. No significant differences were found. In all three patients, a high degree of reliability was observed in this phase. Contamination by the shard from the rubber stopper did not alter the results at all and apparently causes no change in the ACT. Phase 2 revealed no significant difference between Groups A and B and once more confirmed the reliability of both tests when done on the same blood 13 times showing that reproducibility correlates highly.

CONCLUSION

This protocol was designed with two purposes in mind: first to determine if there was any significiant alteration in the values obtained from the BT CA510 test tube when particulate contamination was introduced. This contamination occurred because of the black rubber being sheared off the stopper when blood was being introduced into the tube. The second purpose was to determine if there was any abberation in results between FT CA510 being substituted for the stopper BT CA510 test tube. The first study, in which 22 samples were analyzed from the three patients, the correlation value was quite high showing that either device, the FT CA510 or BT CA510, could be substituted for the other. Phase 2 was a check on the reproducibility of the samples within each group, and revealed a high degree of reliability within the machines in measuring the amount of time it took to clot a sample of blood. Therefore, it is the finding of this study that the particulant contamination did not cause an abberency in the results. It is also a finding that the FT tube is certainly as reliable and is an acceptable replacement for the BT tube. Due to the fact that it is safer for the health care provider to use, it is probably the device of choice.

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