A Retrospective Review of the Abbott i-STAT® INR Result Compared to the Patient's INR by Venipuncture and Processed by the CA-1500 or STAGO Laboratory Analyzer

Paul T. Kocis, PharmD, CACP[1], Junjia Zhu, Ph.D.[2], Thomas W. Stipe, BS, MLT[1], Raymond K. Reichwein, MD[1]

[1]Penn State Milton S. Hershey Medical Center, Hershey, PA, United States / [2]Dept of Public Health Sciences, Penn State Milton S. Hershey Medical Center, Hershey, PA United States

Introduction

A computer program was specifically designed by PSHMC to capture the i-STAT® POC INR test along with the corresponding venipuncture INR for patients aged ≥18 years of age and data captured from 01/01/09 to 04/27/11.

The ACC obtains a capillary specimen for the i-STAT® INR test and the EMER normally obtains a non-citrated venous specimen for the i-STAT® INR test.

Objectives

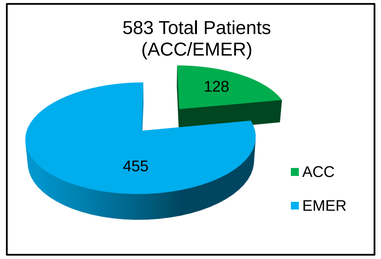
This retrospective study was designed to determine if a difference existed between the Abbott i-STAT® POC (Princeton, NJ) INR test result and a corresponding venipuncture INR test result obtained within ≤ 240 minutes of each other.

A secondary objective was to determine if there were statistically significant INR differences between locations (ACC vs. EMER).

Methods

Of the 583 total patients in this study, 128 (22%) patients were seen in the Anticoagulation Clinic (ACC) and 455 (78%) patients were from Emergency Department (EMER) visits.

ACC = Anticoagulation Clinic
EMER = Emergency Department

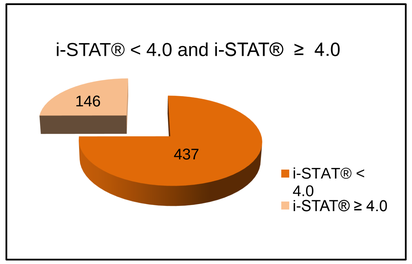


The PSHMC Clinical Laboratory processed the venous INR specimens via the Dade Behring CA-1500 photometric analyzer (Deerfield, IL) for data from 01/01/09 to 05/12/10.

On 05/13/10, PSHMC began processing venous specimens via the Diagnostica STAGO (Parsippany, NJ) mechanical analyzer for data from 05/13/10 to 04/27/11.

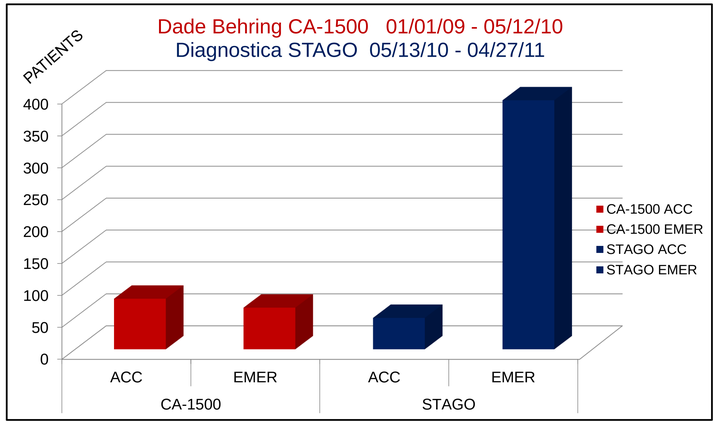
Results

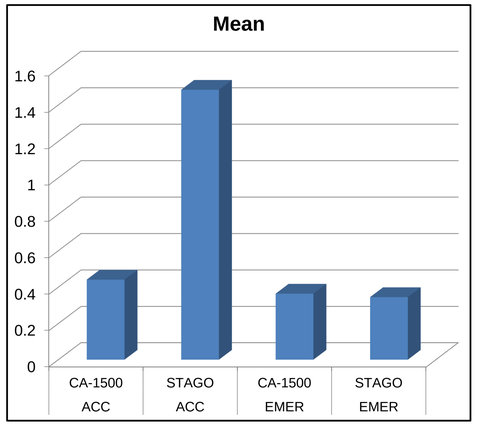
Of the 583 total patients, 437 (75%) patients had an i-STAT® POC INR <4.0 and 146 (25%) patients had an i-STAT® POC INR ≥ 4.0.



The mean intra-patient difference (bias) between the i-STAT® POC INR and the venipuncture INR values are analyzed statistically. The mean (std dev) values of the difference are 0.441(0.789) for 79 ACC patients processed by the CA-1500 analyzer; 1.483 (1.131) for 49 ACC patients processed by the STAGO analyzer; 0.364 (0.811) for 65 EMER patients processed by the CA-1500 analyzer; and 0.345 (0.723) for 390 EMER patients processed by the STAGO analyzer.

Location	Machine	Number	Mean	Std Dev
ACC	CA-1500	79	0.441	0.789
ACC	STAGO	49	1.483	1.131
EMER	CA-1500	65	0.364	0.811
EMER	STAGO	390	0.345	0.723





Results

Of the 128 ACC patients, 79 (62%) patients were processed via the CA-1500 analyzer and 49 (38%) patients via the STAGO analyzer.

Of the 455 EMER patients, 65 (14%) patients were processed via the CA-1500 analyzer and 390 (86%) patients via the STAGO analyzer.

Discussion

Further statistical investigation (by a two-way ANOVA model) shows that the factors of location (ACC vs. EMER) and analyzer (CA-1500 vs. STAGO), as well as the location by analyzer interactions, all significantly contribute (p-value <0.0001) to the variation of the bias between the intra-patient difference of the i-STAT® POC INR and the venipuncture INR values.

Specially, the bias has the largest value for the ACC/STAGO, which is significantly different (p-value <0.0001, Tukey's test) from the other three combinations.

The mean bias values of (ACC/CA-1500, EMER/CA-1500, and EMER/STAGO) are not significantly different from each other. Our statistical analysis shows that in all 4 combinations the i-STAT® POC INR values are significantly higher than the corresponding venipuncture INR values (p-value all <0.0001) using the paired T-test and confirmed by the nonparametric Wilcoxon Signed-Rank test.

Discussion

Conclusions

The mean bias was investigated between the i-STAT® POC INR and the venipuncture INR in the combination of two locations (ACC vs. EMER) and two types of analyzers (CA-1500 vs. STAGO).

It was found that the i-STAT® POC INR values are all significantly higher than the venipuncture INR values (in all combinations) and the measurement taken in ACC by STAGO has the largest bias, which is significantly higher than the biases in all other three combinations.

Urgent Software Recall Notice

In March 2012, an Urgent Recall Notice was received from Abbott Point of Care indicating that internal studies demonstrated that the i-STAT® INR cartridges had the potential to exhibit incorrectly elevated INR results by approximately 20% in the therapeutic range of (1.8 to 3.5).

A software upgrade (CLEW B23) was issued by Abbott and installed by PSHMC on 3/30/12 to correct this issue.