



# Measuring Dabigatran in an Anticoagulation Clinic Population with the Dilute Russell Viper Venom Confirm Assay



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## Introduction and Objectives

- The STA-CLOT DRVV Confirm (DRVVC, Diagnostica Stago, Parsippany, NJ) is a clot-based dilute Russell Viper venom assay employed to confirm lupus anticoagulant (LA)
- We compared the DRVVC to the clot-based Biophen Hemoclot Thrombin Inhibitor Assay (HTI, Aniara, Westchester, OH) for its ability to measure dabigatran in samples from anticoagulation clinic patients
- Protocol sponsored by the United States Air Force Office of the Surgeon General and monitored by the local IRB under protocol #FWH20120123H

## Materials and Methods

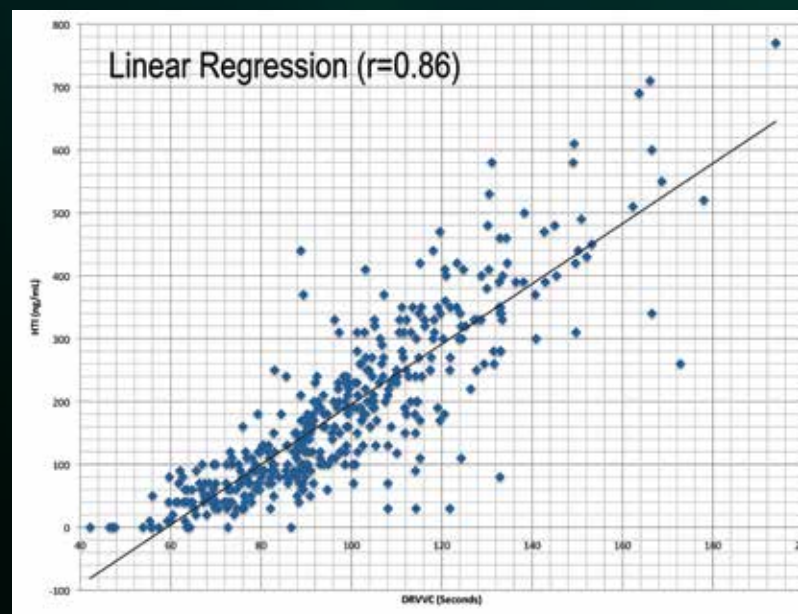
- We obtained Informed consent for all subjects. All subjects were >18 years and had a creatinine clearance >30 mL/min.
- All subjects had been taking 150 mg dabigatran BID for at least one month prior to enrollment except one who took 75 mg BID due to having one kidney. None were excluded for parallel medications or other health issues.
- We originally enrolled 64 males, average age 77, and 38 females, average age 76. Average CHAD2VASc score was 3.2; average BMI 29.8.
- Seventy-two subjects completed the 6 month collection period.
- A 3 mL 3.2% sodium citrate whole blood specimen was collected from each patient monthly for 6 months on a date  $\pm$  5 days of the start date for each subject for that month. Specimens were centrifuged immediately to prepare platelet poor plasma, aliquotted, and stored at  $-70^{\circ}\text{C}$  until ready for testing.
- Aliquots were thawed rapidly and mixed immediately prior to testing.
- Aliquots were assayed for DRVVC and HTI employing the STAR-Evolution automated coagulation analyzer (Stago).
- We analyzed 418 data points after attrition.
- We did not correlate specimen collection time with the medication dosing time.
- We collected specimens from 44 subjects who were not taking dabigatran to establish reference intervals (RIs).

## Results

Mean and RI: Non-dabigatran Subjects		
	DRVVC	HTI
Mean	39.1 s	0.0 ng/mL
RI; $\pm$ 2SD	35.9–42.4 s	NA

Mean and Range: Dabigatran Subjects	
DRVVC	HTI
97.6 s	184.1 ng/mL
42.2–193.9 s	0.0–770 ng/mL

## Results



## Conclusions

- DRVVC failed linearity at levels compared to HTI values below 30 and above 550 ng/mL
- The DRVVC is a FDA cleared assay used for detecting the presence of LAs.
- Our study shows that it could be employed to measure dabigatran within the range of 30-550 ng/mL

## References

- Exner T; Ellwood; Rubie J; A Barancewicz. Testing for new oral anticoagulants with LA- Resistant Russells viper venom reagents. An in vitro study. Thromb Haemost 2013;109:762-765.
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- J Stangier et al: Measurement of the pharmacodynamic effect of dabigatran etexilate: Thrombin Clotting time", Poster PP-TH-134; ISTH 2009.

