

**A COMPREHENSIVE PROGRAM TO MANAGE
ANTICOAGULATION THERAPY IN UNDER-SERVED
URBAN COMMUNITIES: ESTABLISHING A PROTHROMBIN
TIME MONITORING SYSTEM AND PROTOCOL**

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A COMPREHENSIVE PROGRAM TO MANAGE ANTICOAGULATION THERAPY IN UNDER-SERVED URBAN COMMUNITIES: ESTABLISHING A PROTHROMBIN TIME MONITORING SYSTEM AND PROTOCOL

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ABSTRACT

The Improving Anticoagulation in Detroit (IAD) Task Force was created to improve access to, and management of, anticoagulation therapy in under-served communities of Detroit. To achieve this end, the IAD is committed to developing a comprehensive anticoagulation management program which incorporates out-patient comprehensive care in an anticoagulation clinic (ACC) setting, professional home visitation (i.e., visiting nurse services, VNS) and appropriate patient self testing (PST). As a first step towards achieving a diverse management program, a pilot study was conducted to evaluate and validate the use of a point-of-care (POC) Prothrombin Time (PT) device.

Methods: The aim of this pilot study was to evaluate the correlation of the ProTime® Monitor (International Technidyne Corporation) to the central Detroit Medical Center (DMC) clinical laboratory. This analyzer uses capillary (fingerstick) blood to perform a PT test, with simultaneous integral controls. The integral controls identify reagent or sample collection error, thereby providing protection against reporting of a false result. ProTime results were collected by professional staff from adult warfarin-treated patients (N=50) and healthy volunteers (N=10). The ProTime generated INR was compared to that obtained using a spun citrated blood specimen tested in the laboratory using an ACL3000 analyzer (Instrumentation laboratory) and Thromboplastin-C Plus (Dade).

Results: In the test population (N= 50 warfarin patients and N=10 healthy volunteers) the ProTime and laboratory result were highly correlated ($r = 0.997$) over an INR range of 1.0 to 10.0. The ProTime result showed a slight bias (mean difference = 0.44 INR) from the lab result. Further studies are required to understand the cause of the bias, which could be attributable to either assay.

Conclusion: The highly reproducible ProTime result provides the opportunity for reliable clinical management of the warfarin patient using the POC system. This preliminary data provides validation of the system as a POC monitor, in lieu of traditional laboratory monitoring. The next phase of the IAD task force is the integration of this monitoring system with the comprehensive anticoagulation program including ACC, VNS and PST applications.

RATIONALE

The Improving Anticoagulation in Detroit (IAD) Task Force was created to improve access to, and management of, anticoagulation therapy in under-served communities of Detroit. To achieve this end, the IAD is committed to developing a comprehensive anticoagulation management program which incorporates outpatient comprehensive care in an anticoagulation clinic setting, professional home visitation (visiting nurse services), and appropriate patient self testing. In order to achieve this goal as well as to improve the flow through our anticoagulation clinic, the IAD Task Force sought to institute point-of-care (POC) prothrombin time (PT) testing. POC provides almost immediate PT/INR results, thereby shortening the time required to assess patient status and alter therapy, as appropriate.

OBJECTIVE

- Compare the ProTime monitor (International Technidyne Corporation) to current laboratory method for PT/INR determination used at the DMC laboratory.
- Design the comprehensive program including POC testing in the clinic and the patient's home.

MATERIAL AND METHODS

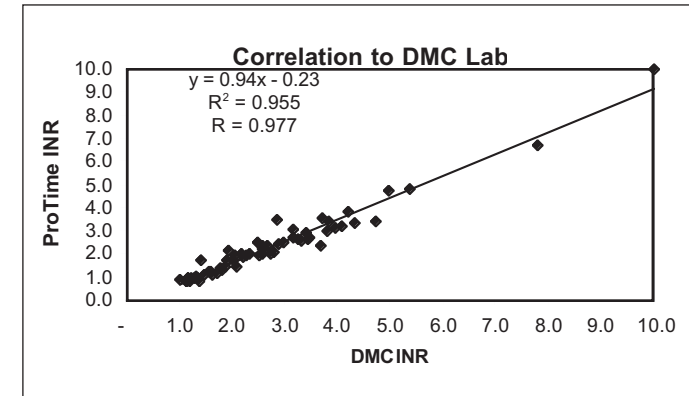
The study was conducted with 50 warfarin-treated patients from our Anticoagulation Clinic at DMC and 10 volunteers not receiving warfarin. The ProTime monitor uses capillary blood to perform a PT test, with simultaneous integral controls identifying sample collection error or reagent error protecting from false results reporting. A trained pharmacist collected all capillary blood samples. The ProTime generated INR, using an ISI of 1.0, was compared to that obtained using a spun citrated (3.2%) blood specimen tested in laboratory using an ACL3000 analyzer (Instrumentation laboratory) and Thromboplastin-C Plus (Dade) with an ISI of 1.99.

RESULTS

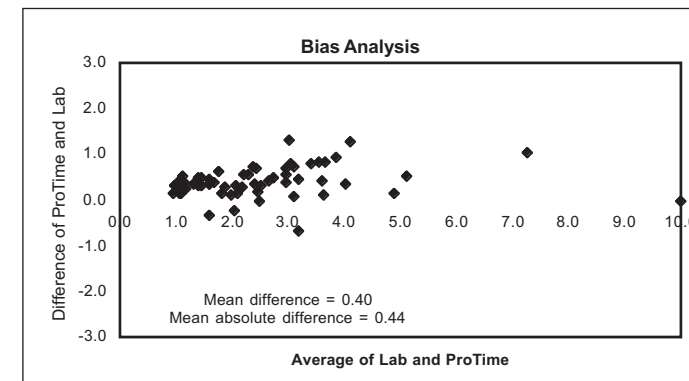
Demographics

TARGET INR	Indication	# Patients
1.8 - 3.0	PE	1
2.0 - 2.5	AFIB	6
	LVD	1
	LVT	1
2.0 - 3.0	PE	1
	AFIB	13
	CVA	1
	DVT	4
	LVC	1
	LVD	3
	MI	1
	STROKE	2
2.0 - 3.5	TIA	1
	AFIB	1
	AVR	2
2.5 - 3.0	DVT	1
	MVR	2
	AFIB	1
2.5 - 3.5	AVR	2
	AVR/DVT	1
	MVR	2
	LVD	1
3.0 - 4.0	LVD	1

Correlation



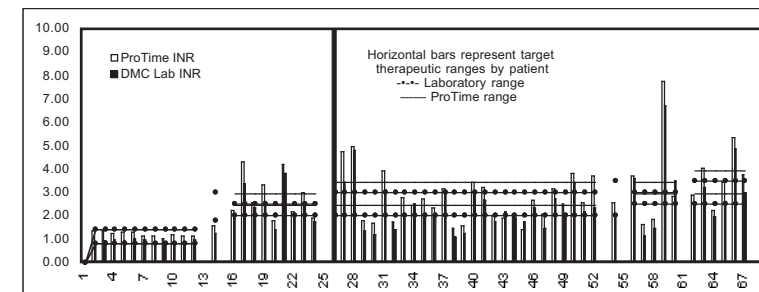
A linear regression was performed in order to find the strength of the relation between the two methodologies. The correlation coefficient value (r) is 0.977, which indicates that two-test systems correlate highly with each other. The data derived from the Mean vs. Difference plot showed the positive bias of 0.44 INR units seen with ProTime monitor compared with the DMC laboratory.



A paired Student's t-test for means confirmed that the ProTime consistently yielded values higher than the DMC laboratory. Both an analysis of variance (ANOVA) and a Student's t-test assuming equal variance showed no significant difference ($p=NS$) which indicate that the positive bias is consistent across all values.

Establishing the Therapeutic Range

Based on the known correlation of the DMC laboratory and the POC test, and the consistency of the bias observed, the patient's target therapeutic range could be adjusted such that both PT tests yield identical clinical objectives and management decisions.



Design of the Comprehensive Anticoagulation Management Program

The IAD task force established a multi-targeted program to improve anticoagulation management. This program, based in an anticoagulation clinic, will employ patient PT testing and anticoagulant dose adjustment in three environments:

- Centralized anticoagulation clinic at the Detroit Medical Center.
- Visitation at patients' homes by professional staff (Visiting Nurse Service).
- Testing by selected and trained patients in their own homes (Patient Self-Testing).

Protbrombin Time Evaluation

- POC PT testing will be employed to optimize the efficacy of the anticoagulation clinic.
- The ProTime correlates well to the DMC laboratory and is an acceptable POC test system for the Comprehensive Anticoagulation Management Program.
- The ProTime may be used in our Management Program:
 - In the Anticoagulation Clinic
 - By Visiting Nurses
 - By Patient self-testers

CONCLUSION

Point of care PT testing proved highly reliable and accurate in a professional clinic environment and is an appropriate management tool for our Comprehensive Anticoagulation Program.

