

MULTICENTER TRIAL OF ACCURATE HOME SELF-TESTING IN ORAL ANTICOAGULANT PATIENTS WITH A NOVEL WHOLE BLOOD SYSTEM

Richard Becker, MD, Worcester, MA; Maureen Andrew, MD, Toronto, Ontario; Jack Ansell, MD, Boston, MA; Daniel Becker, MD, Charlottesville, VA; Douglas Triplett, MD, Muncie, IN; and Alexander Sheperd, MD, Ph.D., San Antonio, TX.

ABSTRACT

The study tested the accuracy of anticoagulant patient self-testing at home compared to the standard plasma assay. Adults (n=82) and children (n=11), from multiple clinics in the US and Canada, were trained to use the ProTime[®] Microcoagulation System (International Technidyne Co., Edison, NJ) with a fingerstick sample. The ProTime[®] instrument performs five concomitant tests: 3 replicate PT and 2 controls, results are reported only when internal controls are sufficient. The study called for fingerstick self-testing at home (HOME) with matched venous samples (VS) obtained in the local hospital within 3 hours of the HOME test, for six weeks. The VS was first tested with the ProTime[®] System and sent to the local laboratory (LAB) where the plasma test was conducted (ISI ranged from 1.2 to 2.1). Aliquots of frozen plasma was shipped to a reference lab (REF) where it was tested (Ortho Recomboplastin (ISI=1.0), Ortho Diagnostics Raritan, NJ). Patient questionnaires graded the ease of instrument use at home, and the preferred method of blood sampling. No difference was detected between repeat ProTime[®] tests. (Student's t Test) and the results were highly correlated (r=.92, n=535). Patients were classified with respect to their prescribed therapeutic range: (1) in range, (2) out of range-high, and (3) out of range-low. LAB and HOME results were compared against the REF by therapeutic range classification. LAB and HOME equally predicted the REF INR correctly (67.9% and 67.2%, respectively). Both test methods under-estimated the REF classification (24.9% and 26.1%) more frequently than over-estimating the REF (7.2% and 6.7%). The correlation of HOME results to LAB by site ranged from r=.81 to r=.93 depending on the PT reagent employed. Fingerstick sampling was the preferred method for 95% of the participants. Overwhelmingly, patients graded the ProTime[®] System easy to use at home (85%). In conclusion, the ProTime[®] Microcoagulation System was easily and correctly used by patients for home PT testing resulting in INR classification similar to standard hospital testing.

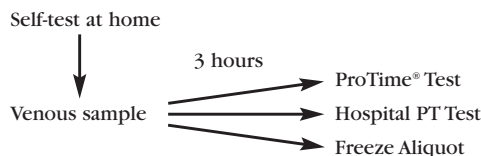
METHODS

SUBJECTS: Volunteers

TRAINING

- Video & Written Instructions
- Demonstration
- Supervised self-test
- Home Practice

STUDY: 6 weekly PT tests



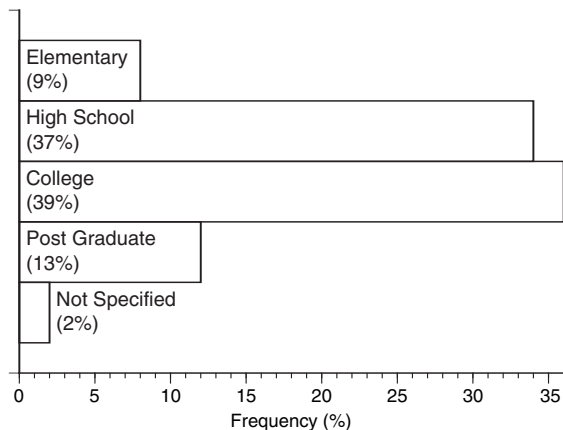
ProTime[®] Microcoagulation System



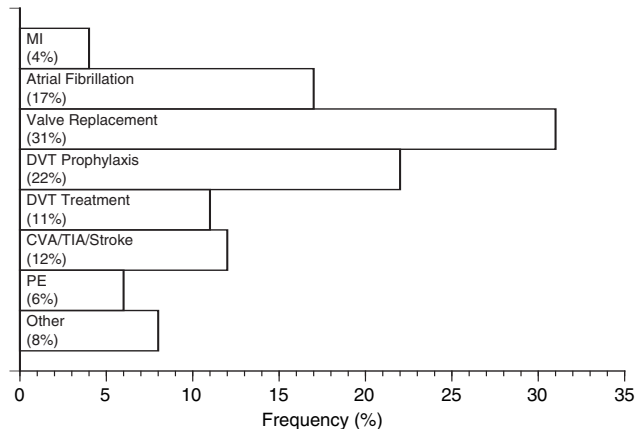
PATIENT DEMOGRAPHICS

	ADULTS	CHILDREN
Number	82	11
Males	50	4
Females	32	7
Mean age	55 yrs	12 yrs
Range	18-81 yrs	7-17 yrs

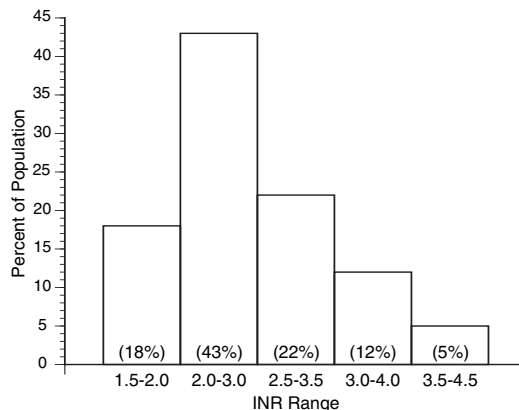
FORMAL EDUCATION OF PATIENT POPULATION



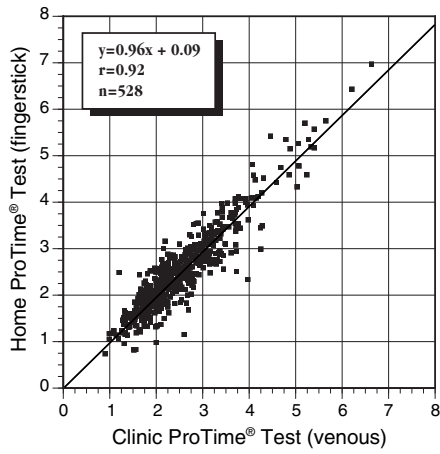
DIAGNOSIS



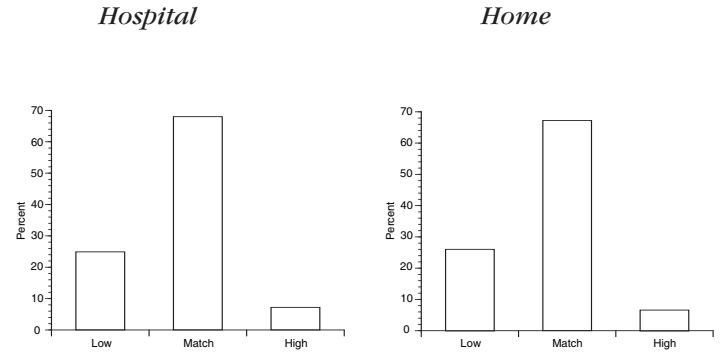
THERAPEUTIC RANGE



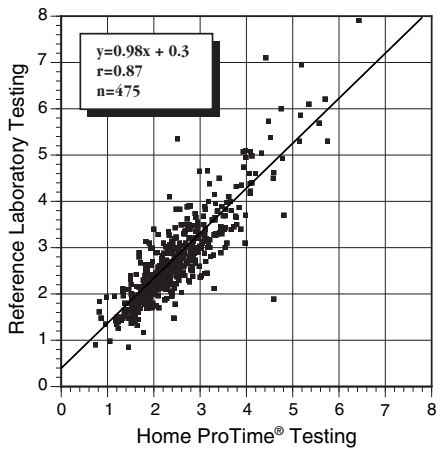
COMPARISON OF PROTIME RESULTS AT HOME AND CLINIC



CLASSIFICATION COMPARED TO REFERENCE LAB WITH RESPECT TO THERAPEUTIC RANGE



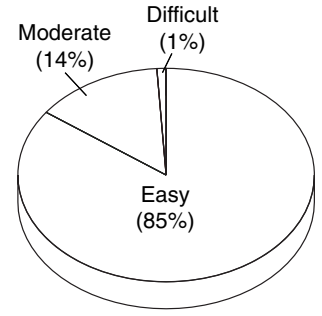
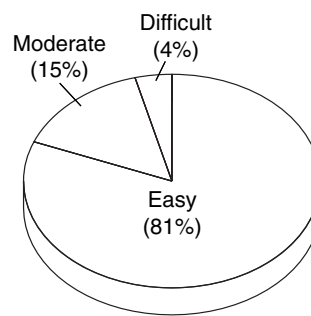
COMPARISON OF HOME PROTIME RESULTS AND REFERENCE LABORATORY RESULTS



PATIENT QUESTIONNAIRE

Use Tenderlett® Plus

Operate ProTime®



SUMMARY

TRAINING AND ACCURACY

- Patients were easily trained to operate the ProTime® Microcoagulation System.
- Home and Clinic results were highly correlated.
- Accurate INR results were obtained by patients at home.

QUESTIONNAIRE

A majority of patients:

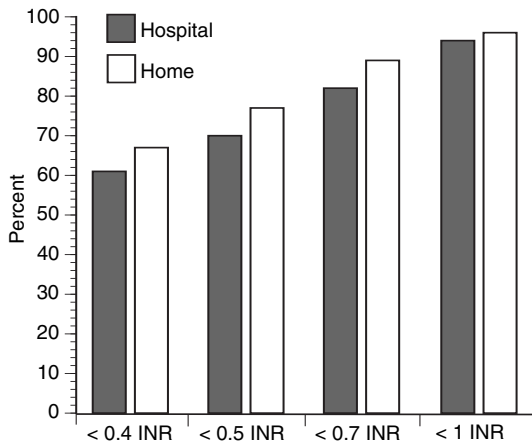
- Preferred the fingersstick over venous sampling.
- Rated the instrument easy to use.
- Rated the ProTime® System easy to use at home.

CONCLUSIONS

The ProTime® Microcoagulation System yields accurate results with patient self-testing at home.

Patients learn quickly and accurately test themselves using the ProTime® Microcoagulation System.

AGREEMENT TO REFERENCE LABORATORY



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