

A Multicenter Controlled Trial Of Anticoagulation Patient Self-Management In Germany Using The Protime System

El Rouby, S.¹ for the German ProTime Study Group: Völler, H², Hartwig, I³, Kadar, J⁴, Dovifat, C², Taborski, U⁵, Wegscheider, K⁶, Zucker, ML¹, LaDuca, FM¹, Ansell, J⁷. ¹ITC, Edison, NJ, USA ²Klinik Am See, Rüdersdorf, Germany ³MtBASA, Berlin, Germany ⁴Schlunzszentrum Köln - West, Köln, Germany ⁵Gesellschaft für Humanplasma, Bad Nauheim, Germany ⁶Institute for Statistics and Econometry, University of Hamburg, Hamburg, Germany ⁷Boston University Medical Center, Boston, USA

BACKGROUND

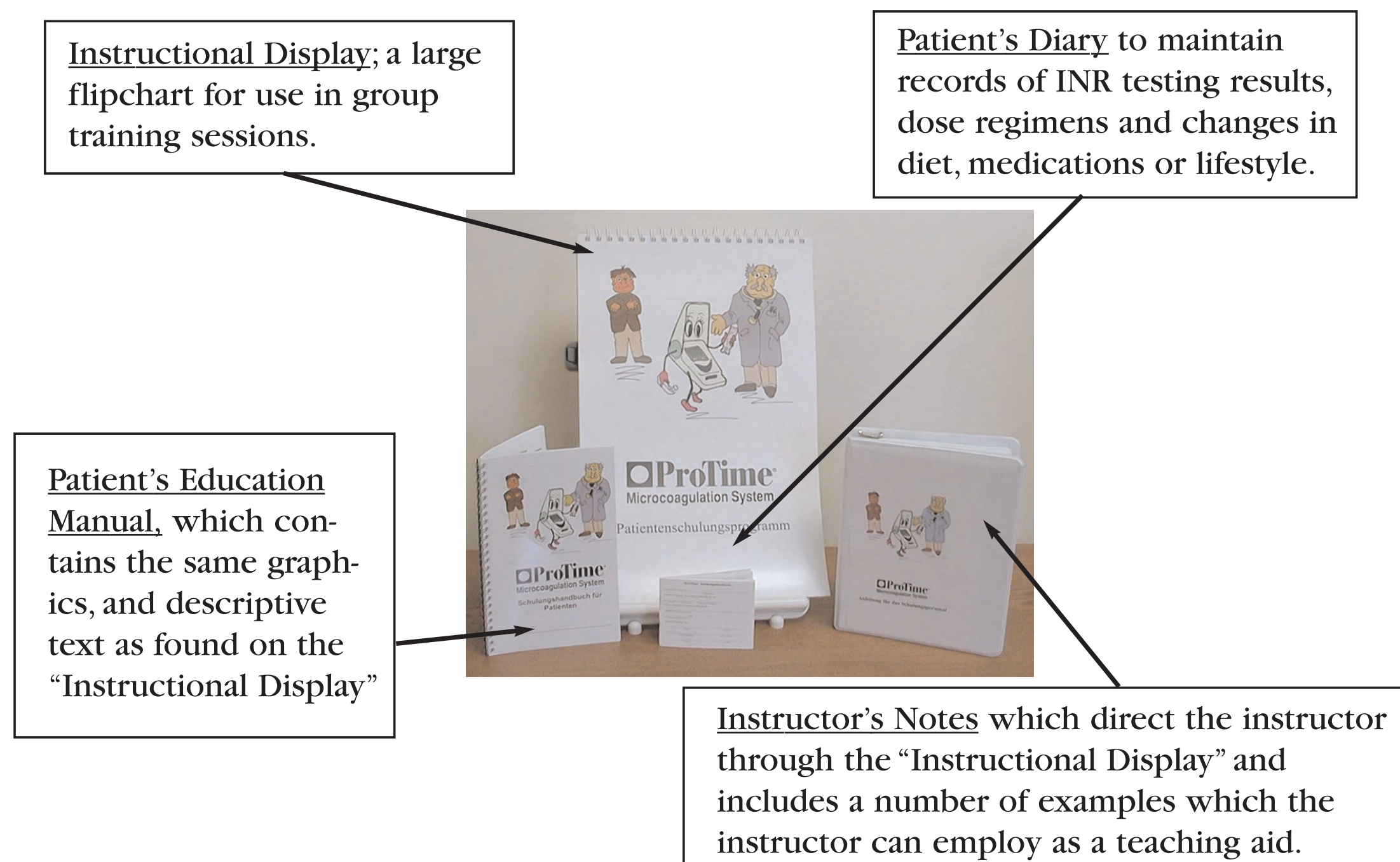
- The objective of long-term oral anticoagulant therapy is to maintain the INR in a narrow therapeutic window to:
 - Prevent the formation of thrombus
 - Prevent major bleeding
- Maintenance of the INR within this range is challenging since the INR is affected by many factors in addition to dosage including:
 - Dietary level of Vitamin K
 - Travel
 - Illness
 - Concomitant medications.
- Germany was the first medical community to embrace PST.
 - Since 1986, more than 70,000 German patients requiring anti-coagulation drugs have been monitored and managed using PST and patient self-management (PSM).
 - The key to the success of the program is a well-developed patient training program, which gives the patient specific guidelines and instruction.

This report provides the results of a multi-center trial to evaluate a Patient Training Program developed for use with the ProTime System for INR testing.

METHODS

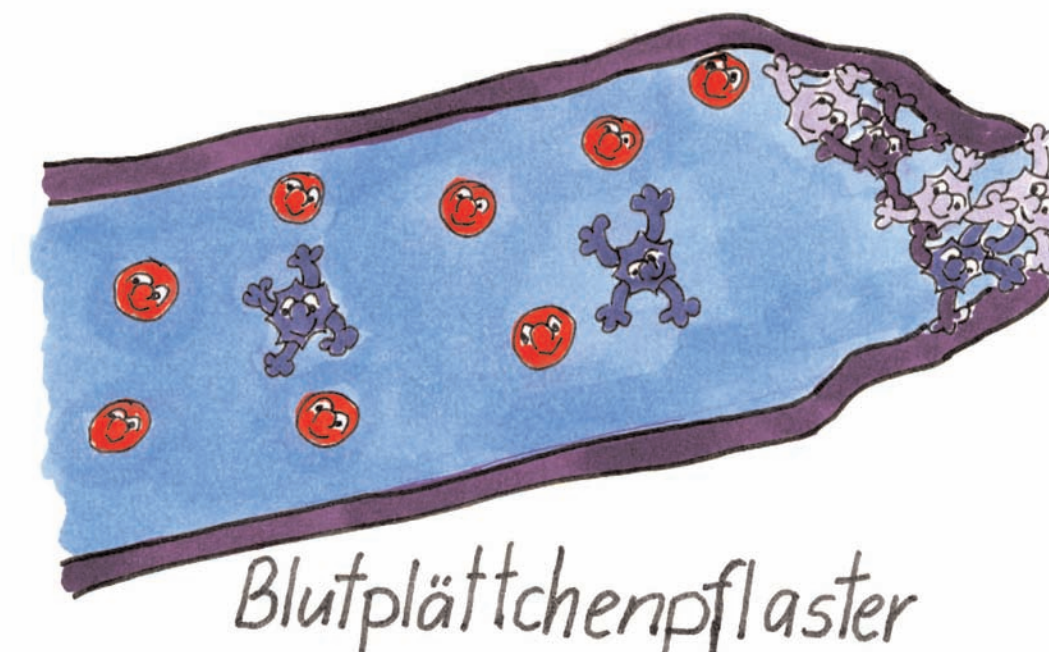
- Determine the efficacy of a new Patient Training Program designed for PSM at three training centers throughout Germany.
- Qualitative Assessment of the patient's ability to learn about anti-coagulation management and how to use the ProTime system.
 - Endpoint: Increase in, and retention of, knowledge using a self-assessment test.
- Evaluation of the ProTime System for self-testing of INR.
 - Endpoint: Time In therapeutic Range (TIR), measured by using the method of Rosendaal et al.
 - Endpoint: Patient satisfaction.

RESULTS



The training program, with the components illustrated above, employs colorful graphics to help patients learn and retain the concepts of anticoagulation management. The instruction session is divided into two half-day trainings including:

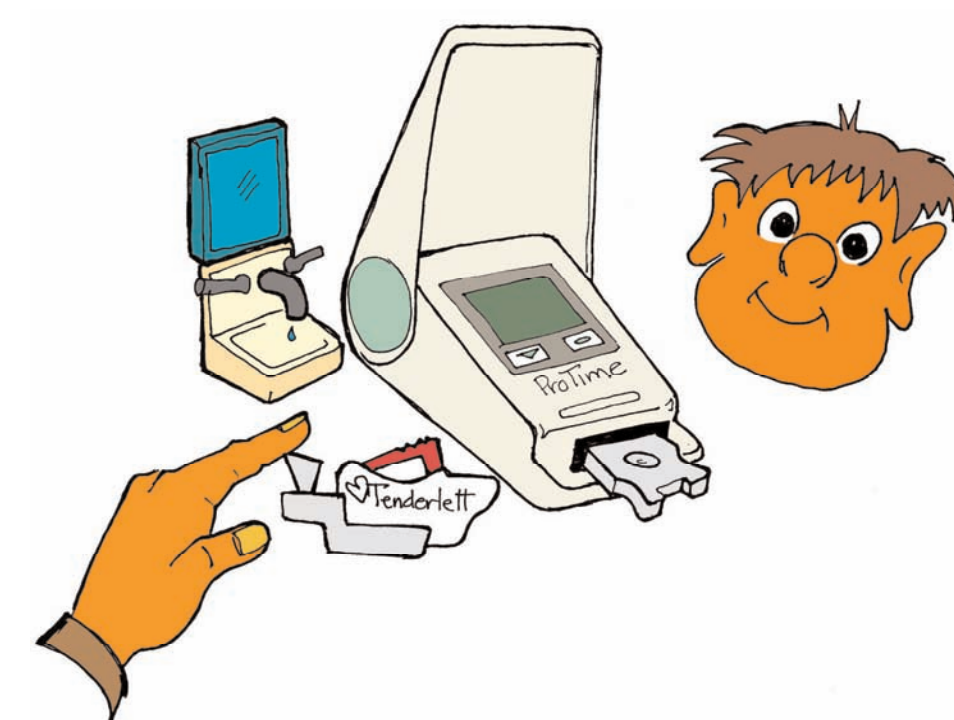
- General information about anticoagulant therapy (OAT); blood coagulation, anticoagulation theory, and indications for treatment.



- Potential interactions with prescription medications, foods and common drugs.



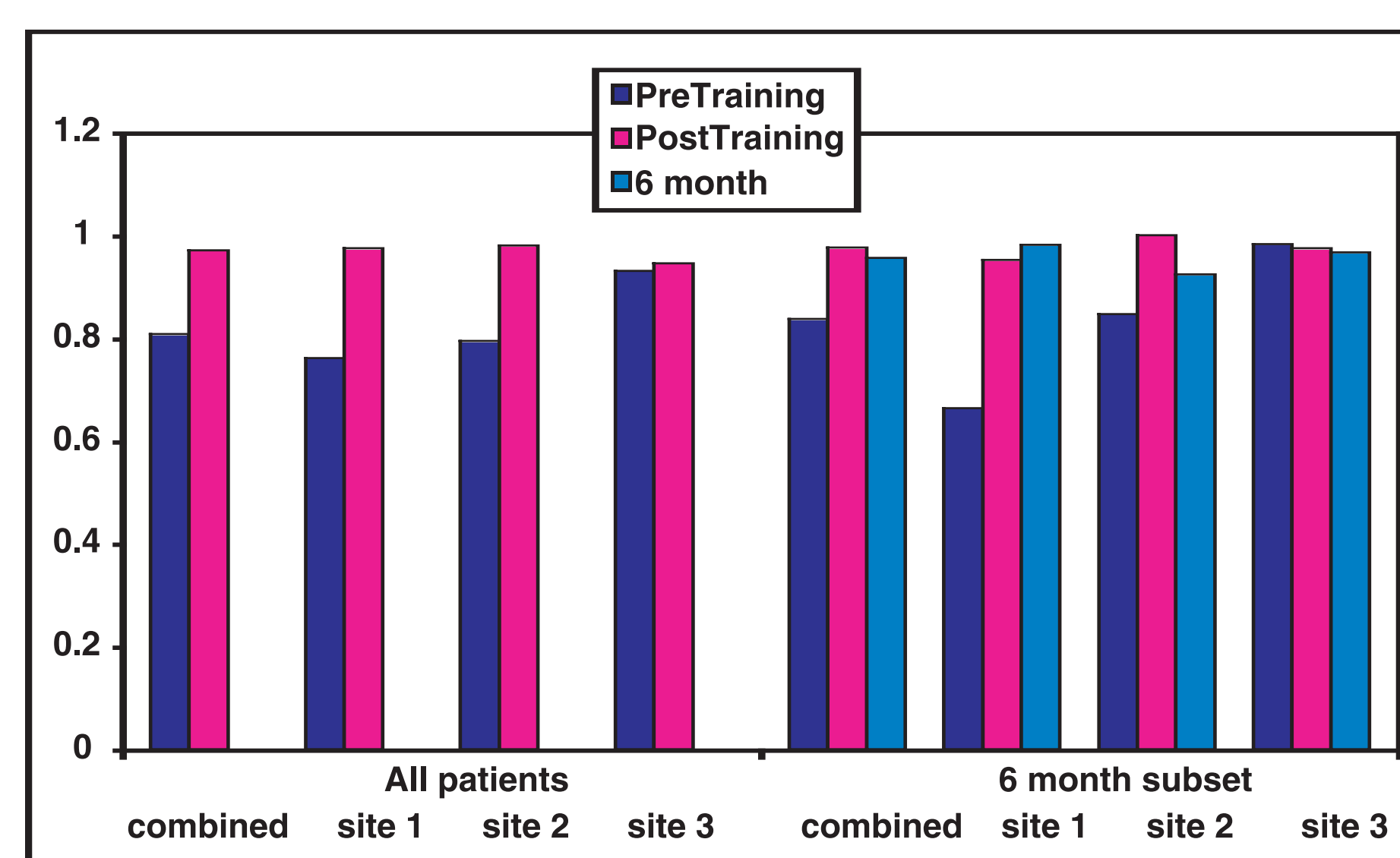
- Explanation of INR testing using product instructions as guide.
- Review of INR testing requirements, desired target INR range, reporting results.



Effectiveness of Training:

Evaluation post-training and after 6 months for knowledge retention.

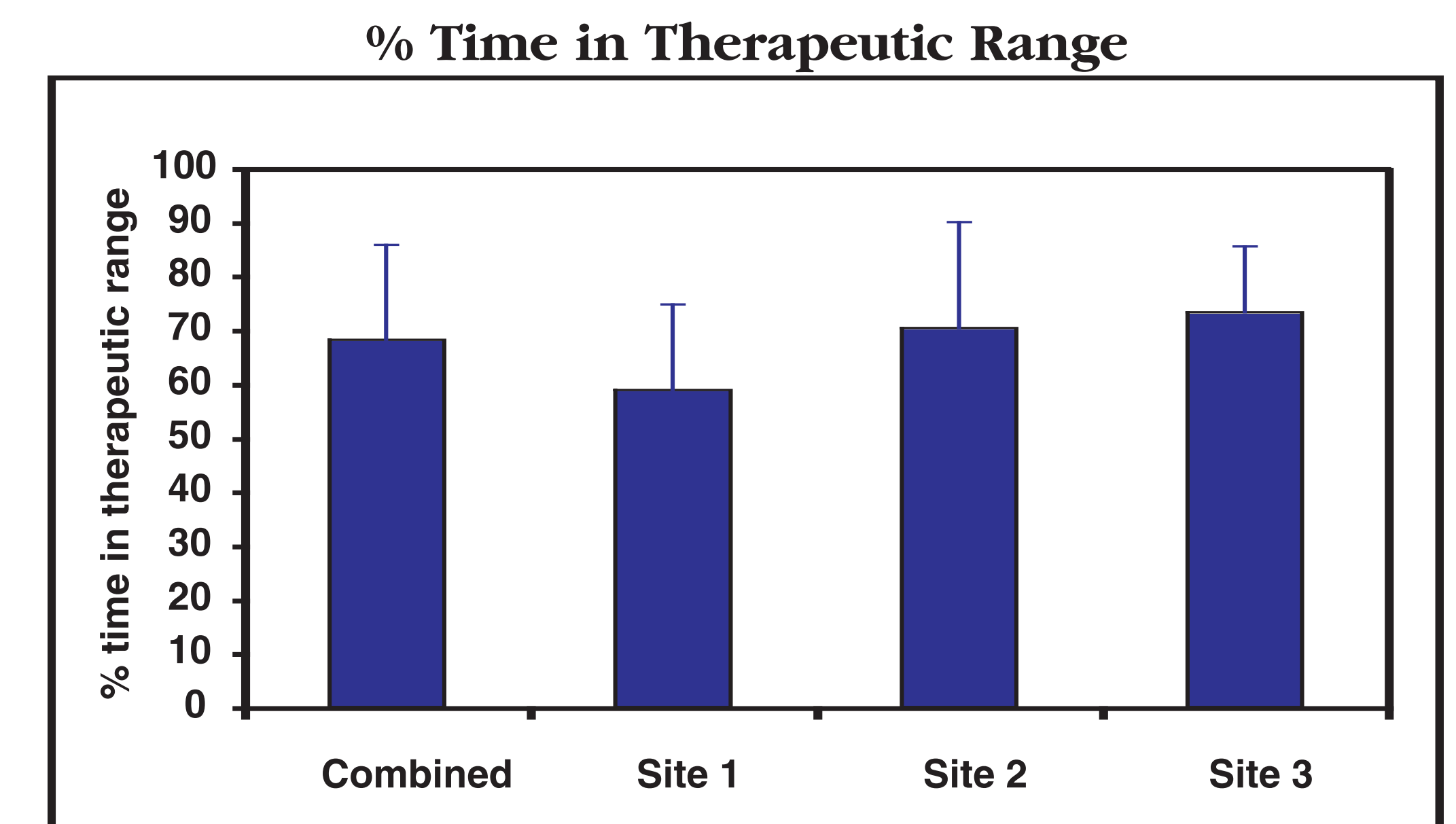
Patient Self-Assessment Performance



- There was a significant increase in patient knowledge ($p < 0.001$) at sites 1 and 2 and when evaluating all sites combined ($N=102$). At site 3 the baseline (pre-training) knowledge was significantly higher than sites 1 or 2, therefore, no post-training increase was observed.
- In the subset of patients completing the 6 month trial to date ($N=28$), there is no significant difference in their knowledge from the post-training assessment to the 6 month assessment.

Time in Therapeutic Range:

Time in therapeutic range was evaluated for patients completing at least 3 months of the trial ($N=40$) shows the maintenance of acceptable % time in range across the study centers.



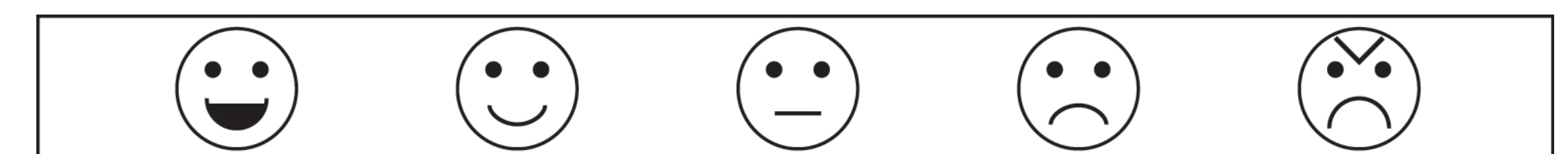
Mean + 1 SD shown for % time in range.

Patient Satisfaction

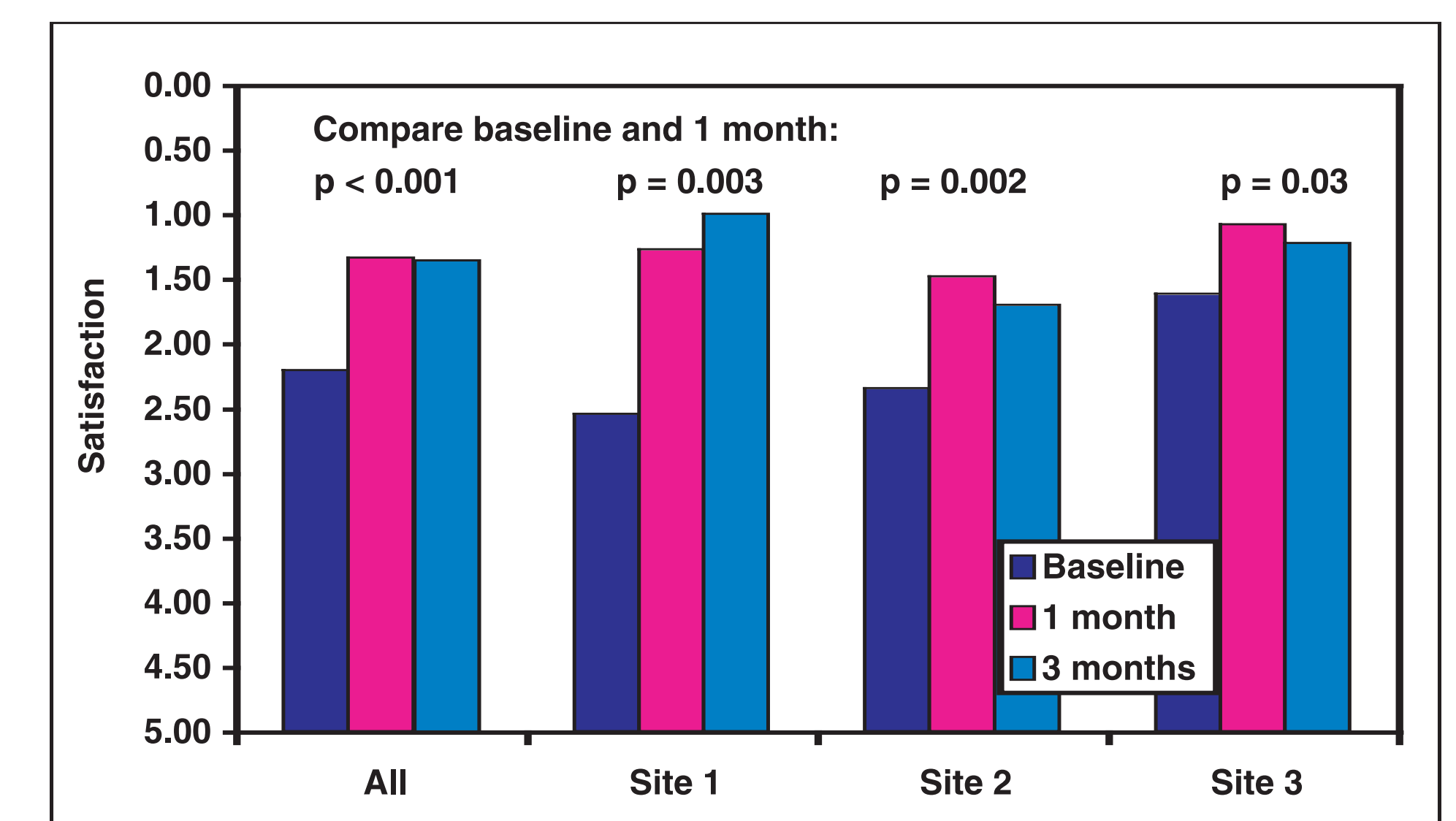
Patient satisfaction was assessed using a 10 question survey where responses were indicated on a five point scale:

Agree Completely

Disagree Completely



Patient satisfaction improved from baseline to one and 3 months for all questions as illustrated below for the statement "I am actively involved in the management of my warfarin therapy".



DISCUSSION

- Use of unique pictures and graphics as well as a large number of examples of real-life situations aided the patients' understanding of the logistics of INR management.
- Patients gained and retained knowledge as a consequence of the training program.
- Trained patients maintained their INRs in the therapeutic range.
- Patients and training center personnel responded favorably to the ProTime Training Program.

CONCLUSION

- The use of point of care system specific training materials can assist in the implementation of a patient self management program.
- This new program has been used successfully in a German population of diverse educational and economic backgrounds.