

Patients' Experience with Home INR Monitoring

Lucy A. Sankey, BS, Sian M. Carr-Lopez, PharmD, Peter M. Campanella, PharmD and Elizabeth A. Caplener, PharmD

A study was performed to determine patient satisfaction with the ProTime[®] home monitoring device for international normalized ratio (INR) and to compare an anticoagulation clinic with home monitoring from a patient satisfaction and a time-in-motion perspective. Patients who were on chronic warfarin therapy and managed in the anticoagulation clinic at David Grant Medical Center, Travis AFB, for a minimum of six months were randomly selected and invited to participate. Subjects signed an informed consent document, were trained to use the ProTime[®] home monitoring device and were provided with the monitor and supplies for the six-month study period. Subjects received assessment, education, and warfarin dose adjustments by a pharmacist via telephone appointments for the duration of the study. Patient satisfaction and time-in-motion surveys were administered at baseline and at three and six month time points. Thirty-seven patients completed the six-month study. Seventy-six percent of patients reported increased satisfaction with home-based monitoring compared to the anticoagulation clinic. No patients reported being less satisfied. The mean time spent by the patient for each appointment decreased from 147 minutes (anticoagulation clinic) to 15 minutes (home monitoring with telephone consultation by pharmacist). The use of the Protime[®] home monitoring device improved patient satisfaction and required less time per appointment for the patient. *J Air Force Pharm.* 2003; 10(01):19-21.

INTRODUCTION

Lifetime warfarin therapy is recommended for patients with atrial fibrillation, mechanical heart valves, recurrent deep vein thrombosis or pulmonary emboli, and congestive heart failure with low ejection fraction.¹ To insure optimal clinical outcomes, patients must have international normalized ratio (INR) tests performed regularly.

In 1997, the Food and Drug Administration approved ProTime[®], by International Technidyne Corporation, a portable instrument for home INR testing. This device offers an alternative to laboratory monitoring of warfarin therapy. A cuvette, which contains various reagents for the INR test, is placed in the home monitoring device. A few drops of blood from the patient are placed in a fingerstick device and attached to the cuvette. Once started, the instrument draws in the amount of blood necessary to run the test. Results are displayed on the device screen within minutes of starting the test.²

The anticoagulation clinic at David Grant Medical Center is staffed by pharmacists and manages approximately 400 appointments per month. Although originally responsible for serving active-duty and retired personnel within a 20 mile radius, patients now come from greater distances due to recent base closures.³ Home INR monitoring with telephone care follow-up could provide an appealing alternative to clinic-based monitoring for patients who travel long distances to the clinic.

The purpose of this paper is to describe one institution's experience with home monitoring of warfarin therapy, specifically patient satisfaction and a time-in-motion comparison of the anticoagulation clinic with home monitoring.

METHODS

A protocol to evaluate patient satisfaction with the ProTime[®] home monitoring device and to compare our anticoagulation clinic with home monitoring from a time-in-motion perspective was approved by the Institutional Review Board. Patients 18 years or older prescribed chronic warfarin therapy and followed in the anticoagulation clinic for at least six months were eligible. Subjects were randomly selected and invited to participate.

About the Authors: Lucy A. Sankey, Capt, USAF, BSC is a Pharmacy Resident at David Grant USAF Medical Center, Travis AFB, CA. Dr. Sian Carr-Lopez is Professor, University of the Pacific School of Pharmacy and Health Sciences and Regional Clerkship Coordinator, Department of Pharmacy, David Grant USAF Medical Center, Travis AFB, CA. Dr. Peter M. Campanella is Chief of Pharmaceutical Research, Clinical Investigations Facility, David Grant USAF Medical Center, Travis AFB, CA, and Adjunct Clinical Professor, University of the Pacific School of Pharmacy and Health Sciences. Dr. Elizabeth A. Caplener is Ambulatory Care Clinical Pharmacist, Department of Pharmacy, David Grant USAF Medical Center, Travis AFB, CA, and Adjunct Clinical Professor, University of the Pacific School of Pharmacy and Health Sciences. For questions on this article, please contact Dr. Carr-Lopez at David Grant USAF Medical Center, 101 Bodin Circle Travis AFB, CA 94535-1800 or (707) 423-7132, DSN: 799-7132.

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The voluntary, fully informed consent of the subjects used in this research was obtained as required by Air Force Instruction 40-403, Clinical Investigations in Medical Research Guidance and Procedures. All subjects completed the baseline questionnaire and attended a training session. During each training session, a group of five subjects viewed a video produced by International Technidyne Corporation, observed the pharmacist perform the INR test using the ProTime[®] device and then performed the INR test using the device by themselves. Subjects demonstrated proficiency by successfully obtaining an INR result with the device within the first week of the study. If the subject was not able to successfully obtain an INR result at home, the participant was offered an additional, individualized training session.

Forty ProTime[®] machines were available for the study. Each subject was given a home monitoring device and enough supplies to perform one test per week. This insured that subjects would not deplete their supplies even if the pharmacists requested additional testing after a change in warfarin dose. The primary differences between home and clinic based monitoring were that patients obtained the INR results rather than the medical center laboratory, and patients interacted with the pharmacist via the telephone rather than in the clinic. Subjects received assessment, education, warfarin dose adjustments and scheduled follow-up by a pharmacist based on the institution's established clinic protocol.

Questionnaires that assessed patient satisfaction and time per appointment were administered at baseline and at three and six month time points (Table 1). For a clinic appointment, time to travel to the medical center, time for the laboratory to obtain the blood sample, run the INR test and report the results, and time to be evaluated by the pharmacist were assessed. For the home monitoring device, time to set up the machine, run the test and obtain a result and time to be evaluated by the pharmacist via telephone were measured. Factors including distance traveled to and from the medical center, time per appointment and patients' perceived level of involvement with care were analyzed to determine their effects on patient satisfaction using Friedman's Repeated Measures Analysis of Variance.

RESULTS

Forty subjects were enrolled in the study. Eight subjects required re-training by the pharmacist within the first week of the study. During the first month of the study, one subject withdrew because the primary caregiver became ill and was no longer able to perform the home testing and another subject died despite a therapeutic INR. After the three-month time point, one subject transferred to another health care facility. Data from his baseline and three month assessments were included in the results; however, six-month data were not available. Thirty-seven patients completed the six-month study.

Patient Satisfaction

The baseline questionnaire evaluated patient satisfaction with the anticoagulation clinic. Of the 38 subjects, 76% (n=29) were very satisfied, 16% (n=6) were somewhat

satisfied and 8% (n=3) were somewhat dissatisfied. Patient satisfaction was also assessed at the three- and six-month time points to evaluate satisfaction with home monitoring device. The percentage of patients that reported being very satisfied increased to 92% and 95% at the three- and six-month time points. At three and six months, subjects were asked to compare their level of satisfaction between home monitoring and the clinic. Sixty-three percent and 76% reported increased satisfaction with home-based monitoring compared to the anticoagulation clinic at three and six months, respectively. Over 80% of subjects felt more involved in the management of their anticoagulation therapy with the home monitor compared to that experienced with the clinic (Figure 1).

Patient satisfaction was further analyzed to compare the change in satisfaction between subgroups based on distance traveled to the medical center, baseline time per clinic appointment and perceived level of involvement with care. The median distance traveled to and from the medical center was 20 miles. Satisfaction in subjects who traveled greater than 20 miles round trip was compared to patients traveling less than 20 miles. The median time per clinic appointment was 127 minutes. Satisfaction in subjects whose time per appointment was greater than 127 minutes was compared to subjects whose time per appointment was less than 127 minutes. Distance traveled, time per appointment and perceived level of involvement with care were not statistically useful in predicting improvement in subject satisfaction. All subgroups showed a statistically significant increase in their level of satisfaction from baseline to six months ($p < 0.05$).

Time-in-Motion

The amount of time for an anticoagulation appointment was measured. For a clinic appointment, time to travel to the medical center, time for the laboratory to obtain the blood sample, run the INR test and report the results, and time to be evaluated by the pharmacist were assessed. The average time for a clinic appointment was 143 minutes (range 65 to 287 minutes). For the home monitoring device, time to set up the machine, run the test and obtain a result and time to be evaluated by the pharmacist via telephone were measured. The average time per appointment using the home monitoring device was 23 minutes (range 8 to 45 minutes) and 15 minutes (range of 8 to 30 minutes) at the three- and six-month time points, respectively. The initial time spent by the investigator to train the subjects with the Protime[®] monitoring device was not included in the time analysis.

DISCUSSION

This study compared patient satisfaction and patient time per appointment between an anticoagulation clinic and a home monitoring device. Although the majority of patients were satisfied with the anticoagulation clinic, there was an increase in satisfaction with the home monitoring device. Seventy-six percent were very satisfied with the anticoagulation clinic while 92% and 95% were very satisfied at the three- and six-month time points with the home monitoring device. It was anticipated that patients who traveled longer distances to the medical center or who

had experienced lengthy clinic appointments would be more likely to report increased satisfied with home monitoring. However, a majority of patients (76%) reported increased satisfaction with home monitoring compared to the clinic, regardless of distance traveled or average clinic appointment time. The home monitoring device likely offered a convenient option for evaluating therapy.

As with any study protocol, some patients declined the invitation to participate. Patients who were willing to perform home monitoring and complete the questionnaires participated in the study. The marked improvement in satisfaction seen in this population may not be representative of a population who are not receptive to home monitoring. Prior to this study, a formalized training process for this device did not exist. Eight subjects (20%) required additional training with the device during the first week of the study. Based on this experience, a training protocol was developed by the manufacturer and has been implemented nationwide.

Patients on chronic warfarin therapy require frequent measurements of INR to safely manage therapy. In this study, patient satisfaction increased and time per appointment markedly decreased. Home monitoring devices for INR provide an acceptable alternative to clinic-based measurements.

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Table 1. Patient Satisfaction Questionnaire

| Question | Response | Baseline N (%) | Three Months N (%) | Six Months N (%) |
|--|--------------------------|-------------------|-----------------------|---------------------|
| How satisfied are you with the overall care you have received in the past three months? | Very Satisfied | 29 (76%) | 35 (92%) | 35 (95%) |
| | Somewhat Satisfied | 6 (16%) | 2 (5%) | 1 (3%) |
| | Somewhat Dissatisfied | 3 (8%) | 1 (3%) | 1 (3%) |
| | <i>Very Dissatisfied</i> | 0 | 0 | 0 |
| Compared to before entering the study, rate your satisfaction with your overall care in the past 3 months. | More Satisfied | N/A | 24 (63%) | 28 (76%) |
| | <i>Equally Satisfied</i> | N/A | 13 (34%) | 9 (24%) |
| | <i>Less Satisfied</i> | N/A | 1 (3%) | 0 |
| Rate your agreement with the statement "I am actively involved in the management of my Coumadin [®] therapy." | Strongly Agree | 24 (63%) | 32 (84%) | 26 (70%) |
| | Agree | 14 (37%) | 6 (16%) | 11 (30%) |
| | Disagree | 0 | 0 | 0 |
| | Strongly Disagree | 0 | 0 | 0 |
| Compared to before entering the study, rate your level of involvement in managing your therapy using the ProTime [®] home monitor | More involved | N/A | 31 (82%) | 30 (81%) |
| | Equally involved | N/A | 7 (18%) | 7 (19%) |
| | Less involved | N/A | 0 | 0 |



8 Olsen Avenue • Edison, NJ 08820 USA
tel: 732.548.5700 • fax: 732.248.1928

ITC Europe • Strada Rivoltana • 20090 Rodano (MI) ITALY
tel: +39.02.9532.0196 • fax: +39.02.9532.0276
www.itcmed.com

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