

# Anticoagulation Management Outcomes in Veterans: Office vs Telephone Visits

Katherine Kelly, PharmD, BCOP; Jessica Bradley, PharmD; Kidest-Mimi A. Demesse, PharmD; Lisa U. Nguyen, PharmD, CGP; Kevin C. Kelly, PharmD, BCPS; and April Y. Allen, PharmD, CACP

Patients on anticoagulation therapy who transitioned to telephone visits from office visits showed no change in therapeutic outcomes.

Oral anticoagulation with warfarin is used for the treatment and prevention of a variety of thrombotic disorders, including deep venous thrombosis (DVT), pulmonary embolism (PE), stroke prevention in atrial fibrillation (AF) and atrial flutter, and other hypercoagulable conditions. Although a mainstay in the treatment for these conditions, warfarin requires close monitoring due to its narrow therapeutic range, extensive drug and dietary interactions, and dosage variability among patients.<sup>1</sup> Patients outside the therapeutic range are at risk of having a thrombotic or bleeding event that could lead to hospitalization or fatality.<sup>1</sup> To reduce the risk of these events, patients on warfarin are managed by dose adjustment based on the international normalized ratio (INR). Research has shown that patients on warfarin in pharmacist-managed specialty anticoagulation clinics have more consistent moni-

toring and lower rates of adverse events (AEs) compared with traditional physician or nurse clinics.<sup>2-6</sup> Management through these clinics can be achieved through office visits or telephone visits.

There are advantages and disadvantages to each model of anticoagulation management for patients. Telephone clinics provide time and cost savings, increased access to care, and convenience. However, disadvantages include missed phone calls or inability to contact the patient, difficulty for the patient to hear the provider's instructions over the phone, and patient unavailability when a critical INR is of concern. Office visits are beneficial in that providers can provide both written and verbal instruction to patients, perform visual or physical patient assessments, and provide timely care if needed. Disadvantages of office visits may include long wait times and inconvenience for patients who live far away.

Telephone anticoagulation clinics have been evaluated for their efficacy and cost-effectiveness in several studies.<sup>5,7,8</sup> However, few studies are available that compare patient outcomes between office visits and telephone visits. Two

prior studies comparing groups of anticoagulation patients managed by telephone or by office visit concluded that there is no difference in outcomes between the 2 management models.<sup>9,10</sup> However, a retrospective study by Stoudenmire and colleagues examined extreme INR values ( $\leq 1.5$  or  $\geq 4.5$ ) in each management model and found that telephone clinic patients have a significant increase in extreme INR values but no difference in AEs between the 2 management models.<sup>11</sup>

The VA North Texas Health Care System (VANTHCS) includes a major medical center, 3 outlying medical facilities, and 5 community-based outpatient clinics (CBOCs). A centralized pharmacist-managed anticoagulation clinic is used to manage more than 2,500 VANTHCS anticoagulation patients. To meet the National Patient Safety Goal measures and provide consistent management across the system, all anticoagulation patients from CBOCs and medical facilities are enrolled in the clinic.<sup>12</sup> To facilitate access to care, many patients transitioned from office visits to telephone visits. It was essential to evaluate the transition of patients from office to telephone visits to

**Dr. Katherine Kelly** is a clinical pharmacy specialist in hematology/oncology, **Dr. Bradley** is an anticoagulation pharmacist, **Dr. Demesse** and **Dr. Nguyen** are ambulatory care pharmacists, **Dr. Kevin Kelly** is a pharmacoeconomics pharmacist, and **Dr. Allen** is an anticoagulation program manager, all at VA North Texas Health Care System in Dallas.

**Table 1. Baseline Characteristics (n = 111)**

Characteristics	Study Population, n (%)
Male	107 (96)
Mean age	66 y
Mean time on warfarin prior to investigation period	788 d
Goal INR (2 to 3 range)	109 (98)
Primary indication for warfarin	
Atrial fibrillation/atrial flutter	70 (63)
Deep venous thrombosis/pulmonary embolism	18 (16)
Other indication	23 (21)
Documented hearing impairment	12 (11)
Procedure during investigational period	48 (43)
Hospitalization during investigational period	43 (39)

Abbreviation: INR, international normalized ratio.

ensure continued stability and continuity of care across both models. The objective of this study was to determine whether a difference in anticoagulation outcomes exists when patients are transitioned from office to telephone visits.

**METHODS**

The VANTHCS anticoagulation clinic policy for office visits requires that patients arrive at the Dallas VAMC 2 hours before their appointment for INR lab draw. During the office visit, the anticoagulation pharmacist evaluates the INR and pertinent changes since the previous visit. The patient is provided verbal instructions and a written dosage adjustment card. Telephone clinic protocol is similar to office visits with a few exceptions. Any patient, regardless of INR stability, may be enrolled in the telephone clinic as long as the patient provides consent and

has a working telephone with voice mail. Patients enrolled in the telephone clinic access blood draws at the nearest VA facility and are given a questionnaire that includes pertinent questions asked during an office visit. Anticoagulation pharmacists evaluate the questionnaire and INR then contact the patient within 1 business day to provide the patient with instructions. If a patient fails to answer the telephone, the anticoagulation pharmacist leaves a voicemail message.

**Study Design**

This retrospective study was conducted by chart review using Computerized Patient Record System (CPRS) at VANTHCS on patients who met inclusion criteria between January 1, 2011 and May 31, 2014, and it was approved by the institutional review board and research and development committee. The study included patients aged ≥ 18 years

on warfarin therapy managed by the VANTHCS anticoagulation clinic who were previously managed in office visits for ≥ 180 days before the telephone transition, then in telephone visits for another ≥ 180 days. Only INR values obtained through the VANTHCS anticoagulation clinic were assessed.

Patients were excluded from the study if they were not managed by the VANTHCS anticoagulation clinic or received direct oral anticoagulants (DOACs). The INR values were excluded if they were non-clinic related INR values (ie, results reported that do not reflect management by the anticoagulation clinic), the first INR after hospitalization, or INRs obtained during the first month of initial warfarin treatment for a patient.

For all patients included in the study, demographic information, goal INR range (2 to 3 or 2.5 to 3.5), indication for warfarin therapy, and duration of warfarin therapy (defined as the first prescription filled for warfarin at the VA) were obtained. Individual INR values were obtained for each patient during the period of investigation and type of visit (office or telephone) for each INR drawn was specified. Any major bleeding or thrombotic events (bleed requiring an emergency department [ED] visit, hospitalization, vitamin K administration, blood transfusion, and/or warfarin therapy hold/discontinuation) were documented. Procedures and number of hospitalizations also during the investigation were recorded.

The primary outcomes measures evaluated INRs for time in therapeutic range (TTR) using the Rosendaal method and percentage of INRs within range.<sup>13</sup> The therapeutic range was either 2 to 3 or 2.5 to 3.5 (the “strict range” for INR management). Because many patients

fluctuate around the strict range and it is common to avoid therapy adjustment based on slightly elevated or lower values, a “nonstrict” range (1.8 to 3.2 or 2.3 to 3.7) also was evaluated.<sup>14</sup> The secondary outcomes examined differences between the 2 management models in rates of major AEs, including thrombosis and major bleeding events as defined earlier.

Frequencies, percentages, and other descriptive statistics were used to describe nominal data. A paired *t* test was used to compare TTR of patients transitioned from office to telephone visits. A *P* value of < .05 was used for statistical significance.

**RESULTS**

A total of 111 patients met inclusion criteria (Table 1). Most patients were elderly males with AF or atrial flutter as their primary indication for warfarin therapy. No statistically significant difference was found for percentage INRs in strict range (56.8% in office vs 56.9% in telephone, *P* = .98) or TTR (65.9% in office vs 62.72% in telephone, *P* = .23) for patients who transitioned from office to telephone visits (Table 2). Similar results were found within the nonstrict range.

In examining safety, 5 major AEs occurred. One patient had 2 thrombotic pulmonary embolism events. This patient had a history of nonadherence with warfarin therapy. Three major bleeding events occurred (2 in the telephone group and 1 in the office group). Two bleeding events led to ED visits, and 1 event led to hospitalization. Although 43% of patients had a procedure during the study period, only a portion of patients received bridging with low-molecular-weight heparin (LMWH). None of the 3 reported bleeding events discovered during the study were associated with recent LMWH use. No events were fatal (Table 3).

**Table 2. TTR Outcomes**

Outcomes	Range	Office	Telephone	P Value
Average INRs within range, %	Strict	56.8	56.9	.975
	Nonstrict	72.8	74.5	.908
Average TTR, %	Strict	65.9	62.7	.230
	Nonstrict	79.5	77.7	.402
TTR combined office & telephone, %	Strict	64.4		NR
	Nonstrict	79.2		

Abbreviations: INR, international normalized ratio; NR, not reported; TTR, time in therapeutic range, calculated by Rosendaal method.

**Table 3. Major Adverse Events**

Events	Bleed Type	Result	Visit Type
Bleeding events	1 Hematuria	Emergency department visit	Telephone
	1 Hematoma	Emergency department visit	Office
	1 Rectal/gum bleed	Hospitalization, hold of warfarin	Telephone
Thrombotic events	2 pulmonary embolism events (same patient)	2 hospitalizations	1 office & 1 telephone

**DISCUSSION**

This study demonstrates that patients transitioned from office to telephone visits for warfarin management will have no significant change in their TTR. Additionally, patients had similar rates of major AEs before and after transition, although there were few events overall.

Previous research comparing anticoagulation outcomes in telephone vs office visits also has described outcomes to be similar between these 2 management models. Wittkowsky and colleagues examined 2 university-affiliated clinics to evaluate warfarin outcomes and AEs in patients in each management model (office vs tele-

phone) and found no difference in outcomes between the 2 management models.<sup>9</sup>

Staresinic and colleagues designed a prospective study of 192 patients to evaluate TTR and AEs of the 2 management models at the William S. Middleton Memorial Veterans Hospital in Madison, Wisconsin.<sup>10</sup> This study found no difference between the 2 groups in percentage of time maintained within INR range or AEs and concluded that the telephone model was effective for anticoagulant management.

A retrospective study by Stoudenmire and colleagues evaluated office vs telephone management effects on extreme INR values

( $\leq 1.5$  or  $\geq 4.5$ ), TTR, and AEs.<sup>11</sup> This study found overall TTR and AEs to be similar between groups, but the telephone clinic had a 2-fold increase in extreme INR values compared with the office clinic.<sup>11</sup>

The current study differs from the previously discussed studies in that it evaluated outcomes for the same patients before and after the transition to telephone. This study did not exclude specific patients from telephone clinic. In the Wittkowsky study, patients were enrolled in the telephone clinic based on criteria such as patient disability or living long distances from the clinic.<sup>9</sup> Additionally, in the current study, patients transitioned to telephone visits did not have scheduled office visits for anticoagulation management. In contrast, patients in the Staresinic study had routine anticoagulation office visits every 3 months, thus it was not a true telephone-only clinic.<sup>10</sup>

This study's findings support prior studies' findings that telephone clinics are acceptable for anticoagulation management. Furthermore, safety does not seem to be affected when transitioning patients, although there were few AEs to review. Providers can use telephone clinics to potentially decrease cost and facilitate access to care for patients.

### Limitations

Patients were required to be in office and telephone for a sequential 6 months, and this may have produced selection biases toward patients who adhered to appointments and who were on long-term warfarin therapy. Many patients that were excluded from the study transitioned back and forth between the 2 management models. Due to the retrospective nature of this study, the authors were unable to control for all

confounding variables. Patients also were not randomly assigned to be transitioned from office to telephone. Although a strength of this study was the limited telephone clinic selection criteria, there may be a few individual situations in which the pharmacist's clinical judgment influenced the transition to the telephone clinic, creating selection bias.

There may be time bias present as clinical guidelines, providers, and clinic population size differed over the study period and might have influenced management. The population of VA patients was mainly elderly males; therefore, the study results may not be applicable to other populations. Last, the results of the study are reflective of the VANTHCS clinic structure and may not be applicable to other clinic designs.

### CONCLUSION

Veterans in a pharmacist-managed anticoagulation clinic experienced the same outcomes in terms of TTR and major AEs when transitioned from the traditional face-to-face office visits to telephone visits. The study supports the safety and efficacy of transitioning patients from a pharmacist-managed anticoagulation office clinic to telephone clinic. ●

### Author disclosures

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