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Patient Engagement in Management of Warfarin: A Quality Improvement Study

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ABSTRACT

Self-monitoring of long-term oral anticoagulant therapy has been possible since 2002. Warfarin self-dosing, although an accepted practice by the American College of Chest Physicians, is seldom offered to patients. This quality improvement study involved implementing and evaluating patient engagement in self-management of warfarin (international normalized ratio self-testing and warfarin self-dosing). This practice was found to be as safe and effective as provider management and resulted in tighter control of variance of international normalized ratio. This intervention should be offered to eligible patients because it promotes engagement in behaviors that reduce the impact of their disease and decreases the burden of care on the provider.

Keywords: disease management, health promotion, patient engagement, self-management, warfarin

BACKGROUND

Approval of international normalized ratio (INR) home testing machines by Medicare in 2002 for mechanical valve patients, and in 2008 for other chronic conditions, has made self-monitoring of oral anticoagulant therapy possible. Warfarin is still the most commonly used oral anticoagulant that requires frequent INR testing.[1] Self-management of anticoagulant therapy, which includes both INR self-testing and warfarin self-dosing, is recommended by the American College of Chest Physicians, based on consistent, good quality evidence from several trials.[2-4]

Unfortunately, self-management of warfarin has been slow to be adopted into practice in the United States.[3,4] The purpose of this quality improvement (QI) study was to implement self-management of warfarin in a large cardiology practice and evaluate the quality, safety, and efficacy compared with provider dosing. A secondary aim was to increase patient engagement in self-care.

METHODS

Design

This investigation was a QI study where data on outcome measures were collected 13 weeks before and after implementation of self-management of warfarin. This time frame was based on previous studies that showed differences in outcomes within 8 weeks.[4]

Setting and Sample

The setting was a large cardiology practice in the Yale New Haven Health System. Because the researchers were accessing patient information, institutional review board approval was obtained. Patients who were $\geq$ 18 years of age, English speaking and reading, used INR self-testing for $\geq$ 3 months, compliant with weekly or biweekly INR self-testing, and never used self-management were invited to participate.

Data Collection

Participants attended a 2-hour education class where they learned how to adjust their warfarin dose based on INR value. A nurse practitioner reviewed the effects of diet, other medications, and any illness/injury or surgery. Participants continued INR self-testing weekly or biweekly and began self-adjusting their warfarin dose.

Participants continued to report their INR levels to the cardiology office to maintain safety. There was a 2-week learning period before data collection began and participants were contacted by the researchers to check warfarin dosing for accuracy.

Outcome measures included: percentage of time the INR remained in the therapeutic range (TTR) for their diagnosis and comorbidities; mean variance of the INR from the patient's prescribed therapeutic range; frequency of testing (weekly or biweekly); variance categories (mean variance $\leq$ 0.4, no variance,

mean variance > 0.4); if the variance was higher than or lower than their designated range; and adverse events (minor or major bleeding or thromboembolic events).

Minor bleeding was defined as any bleeding due to the INR being high but not requiring the patient to access emergency care or hospital. Major bleeding was any bleeding due to the INR being high and requiring emergency care or hospitalization or vitamin K, fresh frozen plasma, or blood transfusion.[5] Thromboembolic events were defined as any new incidence of clotting related to the INR being low.

Statistical Analyses

Applied statistical software (PASW, version 18.0; SPSS, Inc.) was used to analyze the data using the *t*-test, Pearson's correlation, and Wilcoxon's rank sum test.

RESULTS

A total of 151 patients were using warfarin and INR self-testing. Of these, 135 (89%) patients met criteria and 50 (37%) agreed to participate in self-management, completed the education class, and practiced self-management for 13 weeks. There were no statistically significant differences in baseline characteristics for participants versus nonparticipants (Table 1). The increase in mean age among the nonparticipants was due to a 99-year-old patient; however, the variability in age was similar in both groups.

Before self-management, the mean TTR was 71.92 (20.30), and during self-management it TTR was 72.86 (22.30). There were 2 outliers for TTR before self-management, whereas during self-management there were no outliers. There was no significant change in TTR before self-management and during self-management [$t(49) = -.33$, $P = .74$, 95% confidence interval (CI) -6.68 to 4.79].

Before self-management, there was 1 outlier for mean variance, with no explainable cause. During self-management that participant was no longer an outlier; however, there were 3 other outliers with extreme variances in their INR levels because their warfarin had been discontinued for upcoming procedures or surgery. These 3 participants had extreme variance during self-management, but were not identified as having extreme variances before self-management; therefore, the analysis was executed without these participants. A paired *t* test compared the mean variance for the remaining 47 participants. The results of this analysis show a significant decrease in the mean variance during self-management [$t(46) = 2.31$, $P = .03$, d = .34, 95% CI 0.01-0.21].

Table 1. Baseline Characteristics of Participants and Nonparticipants

	Participants [*f* (%)]	Nonparticipants [*f* (%)]
Gender male	30 (60)	46 (54)
Race white	50 (100%)	85 (100%)
Monitor		
Coaguchek PST	18 (36)	34 (40)
INRRatio2 PT/INR	32 (64)	51 (60)
Diagnosis for warfarin		
Atrial fibrillation	12 (44)	48 (57)
St. Jude valve	12 (24)	19 (22)
Other	16 (32%)	18 (21)
	Mean(SD)	Mean(SD)
Age	69.8 (10.01) Range 45-88	74.8 (10.88) Range 48-99
CHA_2DS_2VASc score	3.3 (1.36)	3.8 (1.31)
HAS-BLED score	2.26 (0.94)	2.01 (0.82)

INR = international normalized ratio; PT = prothrombin time.

Variance was also defined in terms of 3 categories, based on the clinical risk of using warfarin. An INR that varies by ≤ 0.4 is not associated with an increased risk of adverse events; however, an INR variance of > 0.4 increases the risk of adverse events.[6] When the INR did vary outside of the designated range there was a shift toward a smaller variance during self-management compared with before self-management: the variance rate of ≤ 0.4 increased by 24%; the variance rate of > 0.4 decreased by 30%; and no change in variance rate increased by 6%.

Data in Table 2 demonstrate that, during self-management when the participant's INR varied outside their designated range, it tended toward the high range. Clinically, it is better to err on the side of blood being too thin (high range) than too thick and prone to clots (low range).[7] Although there was an observable shift in the INR variance category after