Original Article

Impact of Point-of-Care Implementation in Pharmacist-Run Anticoagulation Clinics Within a Community-Owned Health System: A Two-Year Retrospective Analysis

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Abstract

Background: Point-of-care (POC) testing devices allow laboratory monitoring to be performed in various settings and accessed immediately.

Objective: To evaluate the outcomes of monitoring anticoagulation patients in pharmacist-managed, multicenter clinics utilizing i-STAT POC machines.

Methods: This study was a retrospective, multicenter chart review of 150 patients before and after implementation of the POC intervention for anticoagulation monitoring. Data collected included international normalized ratio (INR) results, indication for warfarin, minor and major bleeds, thromboembolic events, emergency room (ER) visits, and hospitalizations before and after i-STAT POC implementation.

Results: The time in therapeutic INR range (TTR) was significantly higher after i-STAT POC implementation than before implementation ($60.4\% \pm 21.2\%$ and $52.5\% \pm 21.5\%$, respectively; $P = .0001$). There were no reports of major bleeding during the study period. Twenty-three minor bleeds were reported after i-STAT POC implementation compared to 19 events before implementation ($P < .0001$). One thromboembolic event was reported after i-STAT POC implementation. There was a significant difference in the number of hospitalizations before i-STAT POC implementation as opposed to after implementation (2 and 0, respectively; $P < .0001$). There was also a significant increase in ER visits after i-STAT POC implementation ($P < .0001$).

Conclusion: The results of the study indicate improvement in TTR in pharmacist-managed anticoagulation clinics by 7.8%. Although the use of the i-STAT POC machine detected an increase in minor bleeds, thromboembolic events, and ER visits, there was a decrease in hospitalization. The outcomes of this multicenter study indicate that implementation on this scale provides improvement in regard to safety and cost.

Key Words—pharmacist anticoagulation clinic, point of care, warfarin

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The American College of Chest Physicians evidence-based clinical practice guidelines (8th ed.) recommend that optimal management of vitamin K antagonist (VKA) therapy be provided by an anticoagulation management service.¹ This service should be provided in a systematic and coordinated fashion incorporating patient education, international normalized ratio (INR) testing, and adequate follow-up and communication on results and dosing decisions. A pharmacist-managed clinic is one model that has been shown to be effective in the management of patients on VKA therapy.¹⁻³

Point-of-care (POC) testing devices have streamlined and revolutionized the patient care process. These portable devices allow for laboratory monitoring to be performed in various settings, and health care professionals can access real-time results within minutes rather than hours. The impact on outcomes of anticoagulation patients who are closely monitored by a clinical pharmacist using the i-STAT (Abbott, Abbott Park, IL) POC machine has been previously reported. The study found that the use of the i-STAT POC machine increased the percentage of time within therapeutic INR range (TTR), and a trend toward improved safety, adherence, and cost was observed.⁴

The previous study assessed patients at a single community health program (CHP), whereas this study assessed a larger patient population at multiple CHPs. The purpose of this study was to determine the impact of i-STAT POC implementation on outcomes of anticoagulation patients.

METHODS

Setting

The Harris Health System is a community-owned health care system that operates 3 hospitals and 14 CHPs throughout Harris County in Houston, Texas. The retrospective data collection was conducted at 7 CHPs that provide outpatient health care services to almost 400 patients daily. Each CHP has a residency-trained clinical pharmacist specialist who manages patients who are taking warfarin via the i-STAT POC machine.

POC Analysis

At each health center, patient INR levels had been acquired through venipuncture in the health system's laboratories. INR results were unable to be analyzed onsite; therefore, blood samples were transported to the health system's nearby hospitals for analysis. The turnaround time was

approximately 3 to 6 hours. Consequently, patients were asked to schedule 2 separate appointments.

In October 2008, each CHP received an i-STAT POC machine; the clinical pharmacists utilized it to determine the prothrombin/international normalized ratio (PT/INR) of their patients during each visit. The test is a whole blood analysis of prothrombin time that is determined by the time required for complete activation of the extrinsic pathway of the coagulation cascade when activated with a thromboplastin. The i-STAT POC machine uses an electrochemical sensor to detect this conversion, and it only takes minutes to complete the analysis.⁵ The reportable range of INR by i-STAT is 0.9 to 8.0; however, our health system's anticoagulation clinic policy required verification of any INR greater than 6.0 with venipuncture. Prior to implementation, the i-STAT POC machines successfully passed several correlation studies performed by our hospital anticoagulation clinic and our laboratory department. All i-STAT POC machine users in our institution were properly trained and perform daily calibrations, monthly control tests, and quarterly user evaluations.

Study Design

This was a retrospective, multicenter study. Patients included in the study were at least 18 years of age, had a physician-documented indication for anticoagulation, and had been taking warfarin for at least 1 year before i-STAT POC implementation. Patients must have attended at least 80% of their clinical pharmacist visits and have had at least 4 INR readings in a 6-month period. All patients were referred to the clinical pharmacist by their primary care physician. Patients were excluded if they were younger than 18 years of age and had been taking warfarin for less than 1 year before i-STAT POC implementation. Patients with lupus anticoagulant were excluded, as the i-STAT POC machine is not accurate for those patients. Pregnant women were also excluded from this study as warfarin has a Pregnancy Category X designation. Data collected from a qualifying patient's electronic medical record included gender, INR goal, race, age, indication, number of clinic visits, minor and major bleeds, thromboembolic events, emergency room (ER) visits, and hospitalizations before and after i-STAT POC implementation from October 2007 to December 2009. INR TTR was calculated using the fraction or percent of INRs in range. This method takes into account the number of visits that had INR results in range and

divides this number by the total number of visits.⁶ The primary outcome of this study was INR TTR. Secondary outcomes included major and minor bleeds, thromboembolic events, ER visits, hospitalizations, and cost. Major bleeding was defined as a decrease in hemoglobin of 2 g/dL or more, a transfusion of 2 or more units of packed red blood cells or whole blood, bleeding into a critical site (intracranial, intraspinal, intraocular, pericardial, intramuscular, retroperitoneal, intra-articular), and death due to hemorrhage. Minor bleeding was defined as bleeding not meeting the criteria for major bleeding such as hematemesis, hematochezia, hematuria, hemoptysis, subconjunctival hemorrhage, and abrasion/contusion. Thromboembolic events included deep vein thrombosis (DVT), pulmonary embolism (PE), and stroke.

A cost analysis was conducted before and after i-STAT POC implementation. Prior to i-STAT POC implementation, patients were sent to the laboratory for venipuncture PT/INR analysis. Once the PT/INR results were received by the pharmacist, follow-up was conducted in person and via telephone. Costs prior to i-STAT POC implementation included the cost of the office visits, lab draw, hospitalizations, and ER visits. Cost after i-STAT POC implementation included costs of the i-STAT POC device, i-STAT POC cartridges, i-STAT POC downloader/charger, i-STAT simulator, estimated training and testing costs, office visits, hospitalizations, and ER visits.

Statistical Analysis

Literature review indicated that a 10% increase in the INR TTR was an acceptable outcome in a pre-post study. Therefore, based on a 2-sided paired *t* test, with a power of 80% and alpha of 0.05, 142 patients per group would be required to detect a 10% increase in INR TTR from 50% to 55%.

The primary outcome of INR TTR was analyzed using the paired Student *t* test. Secondary outcomes were analyzed using McNemar's chi-square test as appropriate for paired data. Linear regression was utilized to determine whether there were any associations between TTR and covariants of interest. All tests were 2-tailed, and *P* values less than .05 were considered statistically significant.

RESULTS

Data Analysis

One hundred fifty patients met the study inclusion criteria. Of these patients, the majority were female, and the mean age was 60.6 years. One hundred

twenty-four (83%) patients had a target INR goal range of 2.0 to 3.0 (Table 1). The TTR was higher after i-STAT POC implementation in comparison to before implementation (60.4% ± 21.2% and 52.5% ± 21.5%, respectively; *P* = .0001) (Table 2). The number of clinic visits for anticoagulation monitoring also increased after i-STAT POC implementation from an average of 13.41 to 14.95 visits (*P* = .01) (Table 3).

There was no occurrence of major bleeding during the study period. Twenty-three minor bleeds were reported after i-STAT POC implementation compared to 19 events before (*P* < .0001). No thromboembolic events were reported 1 year prior to i-STAT POC implementation. However, after i-STAT POC implementation, one patient had a DVT, which occurred perioperatively while the patient was not receiving anticoagulation therapy.

A total of 7 hospitalizations or ER visits were reported over the study period. Of these, 4 visits were anticoagulation related (minor bleeds and an elevated INR) (Table 4). There was a difference in the number of hospitalizations after compared to before i-STAT POC implementation (0 and 2, respectively;

Table 1. Goal international normalized ratio (INR) and indication for anticoagulation

Goal INR range, <i>n</i> (%)	
2.0-3.0	124 (82.67)
2.5-3.5	26 (17.33)
Indication, <i>n</i>	
Antiphospholipid antibody syndrome	1
Atrial fibrillation	83
CHF	11
CVA	10
DVT or PE	33
Factor 5 Leiden	2
Post-MI	2
Protein C or S deficiency	2
Rheumatic valve disease	1
AVR	9
MVR	17
Pulmonic valve replacement	1
≥2 indications for anticoagulation, <i>n</i> (%)	20 (13.33)

Note: AVR = aortic valve replacement; CHF = chronic heart failure; CVA = cerebrovascular accident; DVT = deep vein thrombosis; MI = myocardial infarction; MVR = mitral valve replacement; PE = pulmonary embolism.

Table 2. Results of i-STAT implementation in a multicenter health system

Outcomes	Before i-STAT POC	After i-STAT POC	<i>P</i> ^a
No. of INRs in therapeutic range, <i>n</i>	6.9 ± 3.5	8.6 ± 3.6	<.0001
TTR, %	52.5 ± 21.5	60.4 ± 21.2	.0001
Mean number of clinic visits	13.41	14.95	.01
Minor bleeds	19	23	<.0001
Thromboembolic events	0	1	<.0001
Hospitalizations	2	0	<.0001
Emergency room visit	1	4	<.0001

Note: INR = international normalized ratio; POC = point of care; TTR = time in therapeutic INR range.

^a*P* calculated using the paired Student *t* test and McNemar's chi-square. *P* < .05 is considered statistically significant.

Table 3. Patient characteristics (*N* = 150)

Characteristics	Mean ± SD or <i>n</i> (%)
Age, years	60.6 ± 11.03
Gender	
Male	68 (45.33)
Female	82 (54.67)
Race	
Asian	5 (3.33)
African American	77 (51.33)
Hispanic	45 (30)
White	19 (12.67)
Other	4 (2.67)

P < .0001). Four ER visits were reported after i-STAT POC implementation compared to only 1 reported before implementation (*P* < .0001).

Cost Analysis

In evaluating the differences in visits pre and post i-STAT POC implementation, it was estimated that the follow-up visits took about 25% more time than a scheduled office visit, and thus the total number of visits were multiplied by 1.25. At the time of this study, the clinic fee for a provider visit was \$76. The cost of a venipuncture PT/INR was \$4.00, and an i-STAT PT/INR cartridge cost \$4.89.

A total of 2,012 visits were conducted prior to i-STAT POC implementation. Taking into account the additional time necessary to conduct follow-up visits, it was estimated that the cost prior to i-STAT POC implementation was \$199,188. Post i-STAT implementation, there were 2,243 visits, costing

Table 4. Minor bleeds that occurred after i-STAT implementation (*N* = 24)

Minor bleed	<i>n</i>
Nose bleed	9
Gingival bleed	6
Vaginal bleed/heavy menses	4
Rectal/hemorrhoid bleeding	3
Abrasion	1
Ear bleed	1

about \$181,436. In addition, the costs of adverse events requiring ER visits (\$1,265 each) or hospitalizations (\$6,800 each) decreased by an estimated \$9,805 after implementation of the i-STAT POC machine.^{7,8}

The initial costs of obtaining the i-STAT POC machine and accessories and of training each pharmacist totaled about \$7,230 per pharmacist; roughly \$6,230 accounted for the equipment costs. Excluding initial equipment and training, this study demonstrated about \$27,557 in cost savings as a result of i-STAT POC implementation (Table 5).

DISCUSSION

The findings of this study indicate that the implementation of the i-STAT POC machine improved the TTR by 7.8%. This improvement may be attributed to the immediate INR results as well as the immediate opportunity to make warfarin dosage adjustments. The TTR observed after implementation of the i-STAT POC machine was 60.4%, which supports findings of several observational studies conducted in

comparable anticoagulation clinic settings in which TTR ranged from 40% to 60%.⁹⁻¹¹

A statistically significant increase in the number of INRs in range is also noted in our study after the implementation of the i-STAT POC machine, which may be attributed to the increased number of clinic visits. A decrease in the number of clinic visits was anticipated as a result of the improvement in TTR; however, the mean number of clinic visits increased roughly from 13 to 15 after implementation of the i-STAT POC machine. The frequent clinic visits and thus frequent INR monitoring could explain the increased number of INRs in range.

A reduction in hospitalizations was observed after i-STAT POC implementation. However, an unexpected increase in minor bleeds, thromboembolic events, and ER visits was also noted in this study. In a global meta-analysis, a reduction of major thromboembolism and all-cause mortality was observed after i-STAT POC INR testing was initiated in anticoagulation clinics.¹² In our study, it was noted that the thromboembolic event resulted from a lack of anticoagulation therapy during the time of occurrence. The unanticipated increase in minor bleeds and ER visits observed in our study may be attributed to frequent reporting as a result of increased clinic visits as well as increased patient knowledge and awareness of side effects and complications associated with warfarin use, leading them to report more events and follow-up through the ER.

Similar to the previous study conducted by Challen et al, our study demonstrated increased TTR and cost savings after i-STAT POC implementation. In addition, our study showed a reduction in hospitalizations after implementation compared to the previous study.

The findings of this study are promising; however there were several limitations. One approach to calculating TTR is Rosendaal's linear interpolation method; however, in this study we used the traditional method due to the large data set and lack of software to assist in this calculation. The traditional method TTR is determined by the frequency of INRs within target goal range divided by the total time of observation. For events occurring outside of our health care system, we relied on patient reports of bleeding or thromboembolic events, ER visits, and/or hospitalization. Moreover, the reporting of these events to the provider may not have been documented appropriately in the patient's medical records. Another limitation to the study was lack of medication adherence data. Noncompliance to therapy may have impacted TTR or safety outcomes. In addition, subtherapeutic INRs due to interruptions in anticoagulation therapy for procedures were included in our data, which may have reduced TTR. Finally, the indirect cost of transportation of venipuncture PT/INR specimens to one of our hospital laboratories for analysis is unknown and cartridge waste was not captured. Therefore, the economic impact of i-STAT

Table 5. Cost analysis before and after i-STAT implementation

Before i-STAT			Cost, \$	After i-STAT			Cost, \$
Total no. of visits	(2,012 x 1.25)=2,515	x \$76	191,140	2,243	x \$76		170,468
Lab draw	2,012	x \$4	8,048			N/A	
Cartridges	N/A			2,243	x \$4.89		10,968.27
i-STAT machine				\$4,500	x 7		31,500
Downloader/charger				\$1,120.85	x 7		7,845.95
Electronic simulator				\$609	x 7		4,263
Estimated training & testing				\$1,000	x 7		7,000
Hospitalizations	2	x \$6,800	13,600	0			
ER visits	1	x \$1,265	1,265	4	x \$1,265		5,060
Total =			214,053	Total =			237,105.22
				Cost savings ^a			27,557

Note: ER = emergency room.

^aCost savings excluding equipment or training costs.

POC implementation may differ from the number that we report for this study.

Conclusion

The study results have demonstrated improved TTR after implementation of the i-STAT POC machine in 7 pharmacist-managed anticoagulation clinics within a community-owned health system. Furthermore, the use of the i-STAT POC machine demonstrated improved cost savings and reduced hospitalizations. These results were similar to those reported in the previous single-center study evaluating the impact of i-STAT POC utilization on outcomes. Although our study and the previous study showed improved TTR after i-STAT implementation, there was no reduction in the frequency of patient visits. In terms of safety, the previous single-center study reported a decrease in patient-reported adverse events such as minor bleeds after i-STAT POC implementation, but there was no difference in the number of ER visits or hospitalizations. Our multicenter study showed an unexpected increase in patient-reported minor bleeds and one thromboembolic event, which may have been attributed to the increased clinic visits. However, our results showed a significant reduction in hospitalizations after i-STAT POC implementation, which indicates that the use of the i-STAT POC machine can enhance patient safety and result in cost savings.

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