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Supplying Pharmacist Home Visit and Anticoagulation Professional Consultation During Transition of Care for Patients With Venous Thromboembolism

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Objective: The aim of the study was to assess the feasibility, satisfaction, and effectiveness of a care transition intervention with pharmacist home visit and subsequent anticoagulation expert consultation for patients with new episode of venous thromboembolism within a not-for-profit health care network.

Methods: We randomized patients to the intervention or control. During the home visit, a clinical pharmacist assessed medication management proficiency, asked open-ended questions to discuss knowledge gaps, and distributed illustrated medication instructions. Subsequent consultation with anticoagulation expert further filled knowledge gaps. At 30 days, we assessed satisfaction with the intervention and also measured the quality of care transition, knowledge of anticoagulation and venous thromboembolism, and anticoagulant beliefs (level of agreement that anticoagulant is beneficial, is worrisome, and is confusing/difficult to take).

Results: The mean ± SD time required to conduct home visits was 52.4 ± 20.5 minutes and most patients agreed that the intervention was helpful. In general, patients reported a high-quality care transition including having been advised of safety issues related to medications. Despite that, the mean percentage of knowledge items answered correctly among patients was low (51.5 versus 50.7 for intervention and controls, respectively). We did not find any significant difference between intervention and control patients for care transition quality, knowledge, or anticoagulant beliefs.

Conclusions: We executed a multicomponent intervention that was feasible and rated highly. Nevertheless, the intervention did not improve care transition quality, knowledge, or beliefs. Future research should examine whether alternate strategies potentially including some but not all components of our intervention would be more impactful.

Key Words: venous thromboembolism, anticoagulation, care transitions, clinical pharmacology, medication safety, patient education

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The National Action Plan for Adverse Drug Event Prevention identified anticoagulants as the drug class most associated with patient safety incidents in the U.S.[1] This is particularly concerning for patients with venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE). Unlike patients with atrial fibrillation or other cardiac indications for anticoagulation who routinely receive follow-up with a cardiologist, patients with VTE may not receive any follow-up with a physician specialist. Moreover, although anticoagulation clinics are available in some health systems, they primarily serve patients prescribed warfarin and not direct oral anticoagulants (DOACs).[2]

The lack of timely, specialized guidance for many patients with new episodes of VTE can contribute to adverse clinical endpoints. Several studies have documented that the rate of recurrent VTE and major bleeding are highest in the first month after diagnosis.[3–5] This period includes the time of care transition, defined as "movement of patients between health care practitioners, settings, and home as their condition and care needs change."[6] Researchers have begun to measure the quality of care transitions.[7] High-quality care transitions include thorough transmission of information to patients, organization of appointments, and empowerment of the patient to care for himself or herself. Although there is limited research establishing the linkage between improving the quality of care transition and lowering the rate of recurrent VTE and bleeding events, there are related examples where improving patient knowledge and adherence has led to fewer of these adverse events.[8–13]

Direct assessment of patient medication management, such as a pharmacist home visit shortly after discharge, is one potential strategy for improving the quality of care transition, patient knowledge, and adherence. Previous studies[14,15] demonstrated a benefit to pharmacist home visits in terms of identifying drug-related problems and improving adherence. However, these home visit studies occurred outside of the U.S. and were not focused specifically on patients with new episodes of VTE. Given the complexities of U.S. healthcare, retesting the value of a home pharmacist visit in patients shortly after diagnosis of VTE in the U.S. would be an important contribution to scientific knowledge.

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Use of illustrated medication instructions is another strategy for improving the quality of care transition, patient knowledge, and adherence. Medication instructions are not understandable or engaging to the average patient.[16] Moreover, whereas issuance of medication instructions is standard with discharge from the hospital, patients who are diagnosed and started on treatment without a visit to either a hospital or an emergency department may not receive any written instructions at all.[17] Well-written patient instructions with illustrations can overcome the problems associated with typical medication instructions.[18]

A third strategy to improving the quality of care transition, patient knowledge, and adherence is adding a second point of consultation a week after the home visit. Several published care transition interventions included telephone calls early after discharge (i.e., 1–5 days after discharge) without any subsequent contact or education offered to patients.[19–24] A second point of contact, such as a telephone consultation with an expert, a week or more after a home visit, may reinforce topics discussed in the initial consultation.

We conducted a randomized controlled trial to assess the combination of previous strategies, including a pharmacist home visit, illustrated medication instructions, and subsequent telephone consultation with an anticoagulation expert in patients diagnosed with new episodes of VTE. To assess effectiveness, we measured the quality of care transition, patient knowledge, and adherence (through inquiring about patient anticoagulation beliefs). To assess the feasibility of, and satisfaction with our intervention, we tracked the time to implement and patient perception of each intervention component.

METHODS

Population

We identified adults 18 years and older diagnosed with a new episode of VTE and prescribed anticoagulation. To be eligible, we required confirmation of DVT or PE through radiologic exam. In terms of anticoagulation, we included participants prescribed warfarin, DOACs, or an injectable agent (low-molecular weight heparin or fondaparinux). We excluded patients discharged to a rehabilitation or skilled nursing facility, patients who did not speak English, patients who were unable to self-consent, pregnant patients, and prisoners.

Setting

This study was conducted within the UMass Memorial Health Care system, a multihospital health care system in central Massachusetts. The University of Massachusetts Medical School institutional review board reviewed and approved this study.

Procedure

Recruitment and Randomization

For patients approached in the hospital or emergency department, we obtained written consent during our initial meeting. We subsequently randomized these patients after their discharge. In contrast, for patients recruited by telephone, we obtained verbal consent and subsequently performed randomization the same day. We then sought written consent via mail and made up eight telephone calls to remind the patient to return the forms. If the patient did not return the consent forms within 50 days of providing verbal consent, we treated this patient as unenrolled and did not report further data.

Randomization Protocol

We randomized study patients to either intervention or control, stratified by anticoagulation type (warfarin, DOAC, or injectable). Specifically, we adjusted block size for each strata based on previous data about the distribution of anticoagulation type within our facility.

Baseline Interview

After obtaining consent, study staff conducted an interview to collect demographic information, patient activation through the 13-item Patient Activation Measure,[25] and depression through two questions from the Patient Health Questionnaire.[26] Our interview also included measurement of health literacy using two validated single-item instruments.[27,28]

Intervention Protocol

Home Visit Training

To conduct home visits, we required our pharmacists to hold active state registered pharmacist licensure through the Commonwealth of Massachusetts. Our pharmacist team included five school of pharmacy faculty members and three pharmacy residents. To ensure standardization of the home visit, we composed a manual for the conduct of home visits (Appendix A, http://links.lww.com/JPS/A212).[29]

Home Visit Protocol

For patients allocated to the intervention arm, we scheduled a home visit with a clinical pharmacist to occur within 7 days of randomization. Before the visit, we provided the pharmacist the most current documentation available regarding the new VTE episode (e.g., discharge summary, emergency department record, or outpatient clinic note). We also supplied the pharmacist a list of medications, which was entered into an online software that generates illustrated medications instructions, PictureRx (mypicturerx.com), developed through National Institutes of Health funding and later purchased and optimized by Bioscape Digital Inc (Atlanta, GA).[30]

The visit consisted of three parts. Initially, the pharmacist conducted a medication self-management simulation that builds on the "show me" paradigm advocated by experts.[31] This followed a protocol we previously validated.[32]

In the second part of the home visit, the clinical pharmacist asked a series of open-ended questions to assess patient understanding of medications and VTE condition. These included questions about lab work required for patients on warfarin, dietary issues while on an anticoagulant, medication interactions, adverse reactions with anticoagulant, and symptoms to report to the anticoagulation prescriber.

In the final part of the home visit, the pharmacist reviewed and updated the list of medications in PictureRx. Instructions from PictureRx included a picture of the anticoagulant medication, a picture of the indication for the use of each medication, and a pictorial of the time of day when each medication should be taken (see Appendix B for example, http://links.lww.com/JPS/A213).[19] The pharmacist printed a color copy of the illustrations using a portable printer provided to the pharmacist for the study.

To gauge the feasibility of conducting the different parts of the home visit, the pharmacists recorded the start and end times for individual parts of the visit, as well as the total time they spent in the home.

Anticoagulation Expert Consultation

Subsequent to the home visit, the anticoagulation expert, a nurse practitioner working in the UMass Memorial Health Care Anticoagulation Clinic, contacted the patient via telephone. This occurred from 8 to 30 days from study randomization. During the

TABLE 1. Comparison of Key Characteristics Recorded at Beginning of Intervention for Patients From Three Provider Groups

Characteristic	Intervention Patients Frequency (% of 77 Total)	Control Patients Frequency (% of 85 Total)	*P*
Age, y			
75+	16 (20.8)	14 (16.5)	0.46
65–74	21 (27.3)	22 (25.9)	
55–64	13 (16.9)	23 (27.1)	
<55	27 (35.1)	26 (30.6)	
Sex			
Female	32 (41.6)	38 (44.7)	0.69
Male	45 (58.4)	47 (55.3)	
Racial background			
White	68 (88.3)	64 (75.2)	0.18
Black	4 (5.2)	7 (8.2)	
Asian/Pacific Islander/Native American/Alaskan/More than one race	2 (2.6)	6 (7.1)	
Don't know/prefer not to answer/missing	3 (3.9)	8 (9.4)	
Ethnicity			
Hispanic	2 (2.6)	9 (10.6)	0.09
Non-Hispanic	73 (94.8)	72 (84.7)	
Don't know/prefer not to answer/missing	2 (2.6)	4 (1.2)	
Income level			
≤100% poverty level	8 (10.4)	5 (5.9)	0.30
100%–400% poverty level	19 (24.7)	15 (17.7)	
>400% poverty level	23 (29.9)	24 (28.2)	
Don't know/prefer not to answer/missing	27 (35.1)	41 (48.2)	
Education			
High school or below	21 (27.3)	18 (21.2)	0.54
Above high school	54 (70.1)	63 (74.1)	
Missing	2 (2.6)	4 (4.7)	
Health literacy – confidence filling out medical forms			
Inadequate (somewhat/a little bit/not at all)	21 (27.3)	17 (20.0)	0.46
Adequate (extremely/quite a bit)	54 (70.1)	64 (75.3)	
Missing (don't know/prefer not to answer)	2 (2.6)	4 (4.7)	
Health literacy – hard time understanding when people speak quickly?			
Strongly agree or agree	36 (48.0)	36 (43.9)	0.83
Disagree or strongly disagree	39 (52.0)	46 (56.1)	
Missing	3 (2.6)	2 (4.7)	
Patient activation – PAM-13 score			
1 – Disengaged and overwhelmed	4 (5.2)	8 (9.4)	0.44
2 – Becoming aware, but still struggling	11 (14.5)	18 (21.2)	
3 – Taking action	31 (40.8)	28 (32.9)	
4 – Maintaining behaviors and pushing further	30 (39.5)	31 (36.5)	
Charlson Comorbidity Index			
0	35 (21.6)	29 (17.9)	0.03
1	21 (13.0)	17 (10.5)	
2	8 (4.9)	23 (14.2)	
3+	13 (8.0)	16 (9.9)	
VTE type			
DVT alone	40 (52.0)	33 (38.8)	0.25
PE	24 (31.2)	34 (40.0)	
Both	13 (16.9)	18 (21.2)	

(Continued next page)

TABLE 1. *(Continued)*

Characteristic	Intervention Patients Frequency (% of 77 Total)	Control Patients Frequency (% of 85 Total)	*P*
VTE etiology			
Provoked VTE	28 (36.4)	35 (41.2)	0.92
Cancer associated	9 (11.7)	10 (11.8)	
Unprovoked VTE	31 (40.3)	30 (35.3)	
Unclear/unable to determine/missing	9 (11.7)	10 (11.8)	
VTE history			
Yes	27 (35.1)	24 (28.2)	
No	49 (63.6)	58 (68.2)	0.40
Unclear/unable to determine/missing	1 (1.3)	3 (3.5)	
Anticoagulant prescribed			
Warfarin	37 (48.1)	39 (45.9)	0.92
Novel oral anticoagulant	29 (37.7)	32 (37.7)	
Enoxaparin	11 (14.3)	14 (16.5)	
Care transition type			
Hospital to home	48 (62.3)	59 (69.4)	0.49
Emergency department to home	15 (19.5)	16 (18.8)	
Ambulatory to home	14 (18.2)	10 (11.8)	

PAM-13, Patient Activation Measure-13; VTE, venous thromboembolism.

consultation, patients were asked the same series of open-ended questions posed during the home visit. The nurse practitioner reviewed the patient's medication list, updated the list in PictureRx, and mailed a color copy of the updated instructions to the patient.

Interaction With Primary Care Provider

If the pharmacist home visit or subsequent consultation identified a significant concern in terms of patient safety, the pharmacist or nurse practitioner corresponded through secure e-mail with the patient's primary care provider. For urgent matters, they called the primary care provider to discuss the matter.

Control Patients

We informed control patients of their treatment allocation but did not provide any education beyond what patients typically received. At discharge from the hospital, a clinical pharmacist typically met with each patient prescribed anticoagulation. We did not provide a protocol or curriculum to conduct these encounters. No medication simulations or illustrated medication instructions were provided during the study. In addition, patients discharged from the emergency department or other outpatient setting did not typically meet with a clinical pharmacist.

Follow-Up Interview

We asked all patients to complete a follow-up telephone interview 30 to 50 days after randomization. During that interview, we collected information that formed the basis of the outcomes we measured (see outcomes section). Patients who completed the follow-up interview received a U.S. $25 gift card.

Outcomes

Feasibility and Satisfaction

We calculated the mean time required for conducting each portion of the home visit and the anticoagulation expert consultation. We also asked patients to report their level of agreement with statements about the helpfulness of each of the individual parts of the intervention using a five-item Likert response format ranging from strongly agree to strongly disagree.

Effectiveness

(1) *Quality of care transition*. We measured quality of the care transition using the Care Transition Measure (CTM) 15 developed and validated previously by Coleman et al.[7] (Appendix C, http://links.lww.com/JPS/A214). After gathering responses from each patient, we calculated a global score on a scale of 0 to 100, following an algorithm published by the developer of the instrument.[33]

(2) *Knowledge.* We also assessed patient knowledge regarding anticoagulation and the interactions, risks, and signs and symptoms to report to the anticoagulation prescriber. Specifically, we administered a modified version of a previously published questionnaire[28] (Appendix D, http://links.lww.com/JPS/A215). We calculated a total score as a percentage of items answered correctly.

(3) *Anticoagulant Beliefs.* Previous studies have demonstrated that a patient's beliefs about a medication predict his or her adherence to it.[34] We therefore administered a previously published questionnaire,[28] which included 14 items assessing a patient's beliefs about the anticoagulant prescribed to him or her (Appendix E, http://links.lww.com/JPS/A216). Four of these items comprised a subsidiary outcome "Anticoagulant is Beneficial." They assessed the extent to which a patient believed that his current and future health depended on his anticoagulant and whether he would become ill without his anticoagulant. Five questions assessed worry about health and adverse effects since starting an anticoagulant. Finally, five questions assessed patient confusion and difficulty with taking an anticoagulant. All items used a response scale ranging from 1 to 5, with corresponding response options ranging from strongly disagree to strongly agree.

Covariates

We adjusted our outcomes for age, sex, race, ethnicity, poverty level, educational attainment, health literacy, patient activation, VTE type, anticoagulant prescribed, etiology of VTE event, Charlson score, and setting of care transition in categories as listed in Table 1.

Analysis

First, we calculated the distribution of the covariates mentioned previously for intervention versus control patients. We then compared outcomes for these patients first in an unadjusted fashion. We then controlled for covariates using multiple linear regressions to account for residual confounding and loss to follow-up of patients after randomization. We also examined the effect of our intervention in key subsets of patients including a subset restricted to patients transitioning from hospital to home and a subset restricted to those patients for whom the VTE event was unprovoked and not related to cancer.

RESULTS

Of the 415 eligible patients, 194 verbally consented to participate in the study and were still eligible at the time of randomization. Because we required written consent, and many patients did not return written consent documents to us, our final fully consented cohort included 163 patients. These 163 patients participated in 30-day interviews from which we derive our outcome results. From these 163 intention-to-treat cohort, 49 patients received both the home visit and consultation from the anticoagulation expert. Together with the 77 patients in the control group, our completers cohort included 126 patients (Fig. 1; Table 1).

Feasibility and Satisfaction Results

The mean ± SD time from consent to home visit was 5.4 ± 2.1 days. The mean ± SD time required to conduct home visits was 52.3 ± 20.5 minutes. Patients rated all parts of the intervention highly with mean scores of nearly 4 or higher than 4 of 5, consistent with agreement that the intervention was helpful (Table 2).

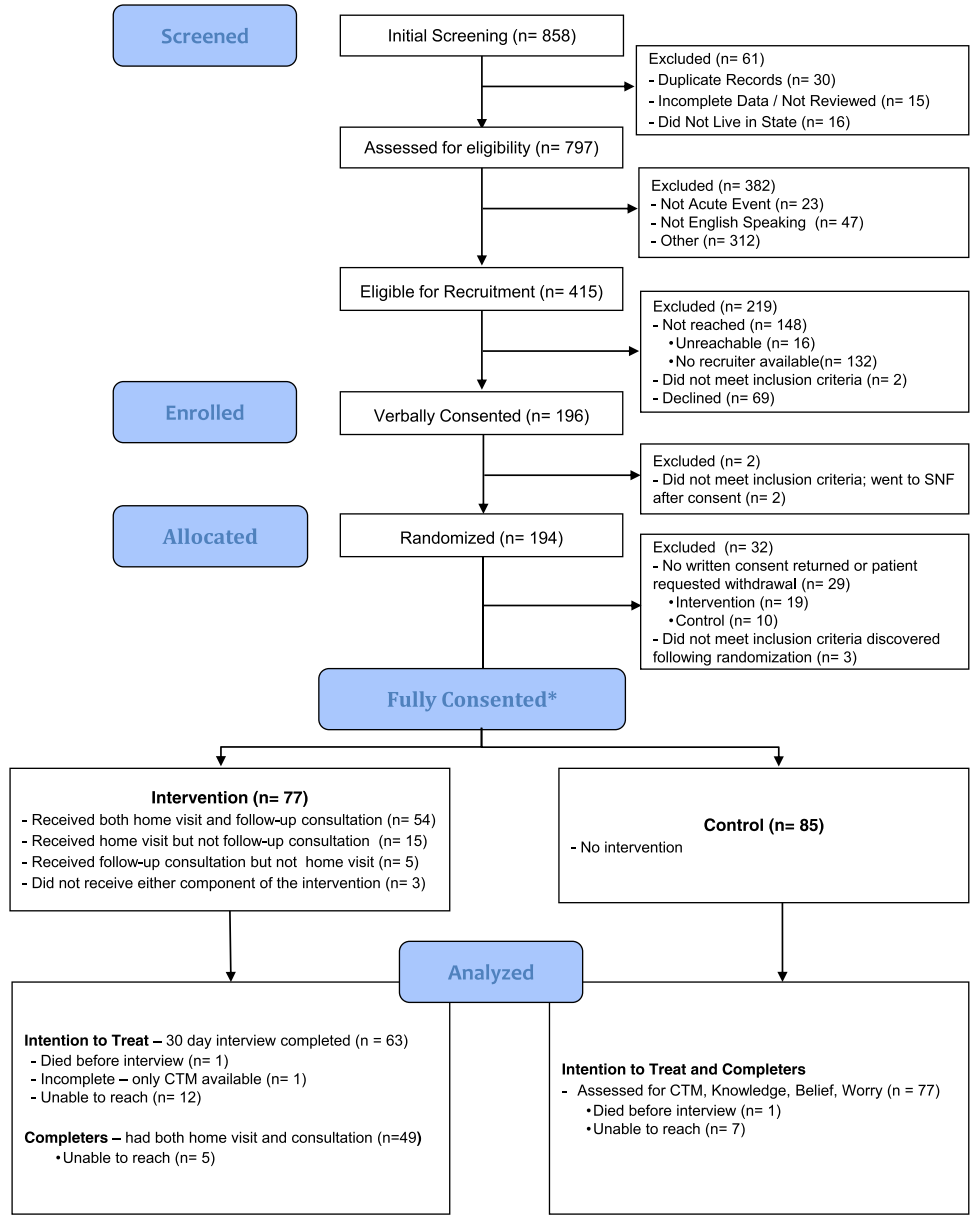

FIGURE 1. Study flow. *Fully Consented represent those individuals consented in person and providing written consent from the outset and those consented by telephone and having returned written consent within 50 days of randomization.

TABLE 2. Timing of Study Components and Satisfaction

Intervention Component	Mean ± SD Time, min*	Mean ± SD Satisfaction (Likert Scale)
Home visit (n = 65)		
Simulation	23.8 ± 14.6	
Open-ended	21.3 ± 13.0	
Picture Rx	14.4 ± 11.0	3.9 ± 0.9†
Total	52.4 ± 20.5	4.6 ± 0.7‡
Anticoagulation expert consultation (n = 57)		
Open-ended	7.8 ± 2.9	
Picture Rx	2.8 ± 2.7	3.9 ± 0.9†
Total	10.4 ± 4.0	4.2 ± 0.7§

*Of the 65 completing home visits, we had total time recorded for all patients; similarly for the 57 patients having expert consultation, we had total time for all of these patients; later in the study, we began collecting information about timing for the individual components and thus the number of patients for whom we had home visit timing of simulation, open-ended questions, PictureRx, expert consultation open-ended question, and repeat PictureRx was 64, 35, 45, 56, and 56, respectively.

†This reports "do you agree illustrated medication guide was helpful" on scale of 1–5 with 1 being strongly disagree and 5 being strongly agree; only 26 patients reported this information. This applies to the PictureRx[29] intervention from both home and clinic visits.

‡This reports "do you agree home visit was helpful" on scale of 1–5 with 1 being strongly disagree and 5 being strongly agree; of the 64 completing home visits, only 53 patients reported this information.

§This reports "do you agree clinic visit was helpful" on scale of 1–5 with 1 being strongly disagree and 5 being strongly agree; only 49 patients reported this information.

Fully Consented Cohort Descriptive Information

Among patients from the fully consented cohort, we found that there was balance between intervention and control patients with respect to most variables listed in Table 1. The age of our cohort divided relatively evenly between the following age groups: younger than 55, 55 to 64, 65 to 74, and 75 years or older. We had slightly more men in our study. Most patients were white. More than 70% of our sample had more than a high school education. Most patients scored high in patient activation. The intervention group had more patients in a lower Charlson Comorbidity Index category compared with controls ($P = 0.03$).

Intention-to-Treat Cohort Results

In terms of outcomes, in general, we did not find a significant difference between intervention and control patients. Most patients rated the quality of their care transition highly. More specifically, intervention patient mean ± SD score was 74.5 ± 12.6 versus 73.5 ± 19.6 for controls (Wilcoxon Kruskal Wallis P value of 0.77). In both the intervention and control groups, more than 80% of patients agreed or strongly agreed that since receiving their VTE diagnosis, they clearly understood the purpose of taking each of their medications, including how much medicine to take and when.

The mean ± SD percentage of knowledge items answered correctly among patients was low in both groups: 51.5 ± 11.2 versus 50.7 ± 13.2 for intervention and controls, respectively (Wilcoxon Kruskal Wallis P value of 0.48). This was true even for patients with graduate or higher-level education. Specific items that both groups had a low level of knowledge included knowing that consuming beer or hard liquor could be a problem when taking anticoagulant medication. Less than 50% of patients answered these items correctly. Less than 60% of patients understood that taking an anticoagulant could cause their stomach to bleed (Table 3 for full details).

We did not find any difference between groups in the anticoagulant belief items apart from the item "taking my anticoagulation as prescribed is easy" (Table 4).

Our multivariate analyses and subset analyses did not reveal any significant differences in outcomes compared with the main results reported previously.

Completers Cohort Results

Compared with controls, the subset of completers had a higher percentage of white participants (95.9% versus 77.9%). There was also a trend toward more patients in this cohort having DVT alone (57.1% versus 42.9%) and making a transition from ambulatory care setting to home (22.5% versus 13.0%) (See Appendix F for full comparison, http://links.lww.com/JPS/A217)

Compared with the 77 controls, the 49 patients completing the intervention in full did not report significantly better quality of

TABLE 3. Comparison of Intervention Versus Control Patients for Quality of Care Transition and Knowledge in the Intention-to-Treat Cohort

	Intervention	Control	*P*
Quality of Care Transition – CTM-15[7] (0–100 scale with higher number indicating higher quality)	74.5 ± 12.6	73.5 ± 19.6	0.77*
Knowledge (% correct on 22 item anticoagulant questionnaire[27])	51.5 ± 11.2	50.7 ± 13.2	0.48*

*Based on Wilcoxon Kruskal-Wallis P value.

TABLE 4. Frequency of Agreement With Anticoagulant Belief Statements in Control and Intervention Patients

	Control (n = 77)					Intervention (n = 62)					
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	*P**
Taking my anticoagulant exactly as prescribed is easy	0	7 (9.1)	0	31 (40.3)	39 (50.7)	0	0	0	33 (53.2)	29 (46.8)	0.02*
Taking my anticoagulant exactly as prescribed is confusing	33 (42.9)	40 (52.0)	1 (1.3)	2 (2.6)	1 (1.3)	24 (38.7)	33 (53.2)	0	3 (4.8)	2 (3.2)	0.83
Taking my anticoagulant exactly as prescribed is inconvenient	26 (33.8)	32 (41.6)	7 (9.1)	10 (13.0)	2 (2.6)	16 (25.8)	36 (58.1)	4 (6.5)	5 (8.1)	1 (1.6)	0.44
I worry more about my health since I started taking my anticoagulant	5 (6.5)	19 (24.7)	3 (3.9)	30 (39.0)	20 (26.0)	2 (3.2)	24 (38.7)	6 (9.7)	20 (32.3)	10 (16.1)	0.16
I worry a bit about the side effects of taking my anticoagulant	8 (10.4)	19 (24.7)	6 (7.8)	35 (45.5)	9 (11.7)	5 (8.1)	21 (33.9)	6 (9.7)	24 (38.7)	6 (9.7)	0.76
Having to take an anticoagulant worries me	7 (9.1)	19 (24.7)	11 (14.3)	30 (39.0)	10 (13.0)	6 (9.7)	26 (41.9)	9 (14.5)	17 (27.4)	4 (6.5)	0.20
I sometimes worry about the long-term effects of my anticoagulant	9 (11.7)	20 (26.0)	8 (10.4)	36 (46.8)	4 (5.2)	5 (8.1)	26 (41.9)	11 (17.7)	18 (29.0)	2 (3.2)	0.11
My health at present depends on my anticoagulant	1 (1.3)	13 (16.9)	8 (10.4)	39 (50.7)	16 (20.8)	2 (3.2)	3 (4.8)	3 (4.8)	35 (56.5)	19 (30.7)	0.08
My life would be impossible without my anticoagulant	2 (2.6)	25 (32.9)	23 (30.3)	18 (23.7)	8 (10.5)	1 (1.6)	20 (32.3)	18 (29.0)	16 (25.8)	7 (11.3)	0.99
Without my anticoagulant I would be very ill	3 (3.9)	21 (27.3)	12 (15.6)	33 (42.9)	8 (10.4)	1 (1.6)	10 (16.1)	11 (17.7)	33 (53.2)	7 (11.3)	0.49
My health in the future will depend on my anticoagulant	1 (1.3)	14 (18.2)	10 (13.0)	44 (57.1)	8 (10.4)	0	7 (11.5)	12 (19.7)	34 (55.7)	8 (13.1)	0.56

*P value based on χ^2, unless statistical program warned us about small cell count in which case we used Fisher's exact test.

care transition, higher knowledge, or higher adherence based on response to believe questions.

DISCUSSION

We studied the impact of a multicomponent intervention that included a pharmacist home visit with illustrated medication instructions and subsequent consultation with an anticoagulation expert. The mean time required in the home was feasible (i.e., similar to initial visits with other clinicians) and patients rated these visits and the illustrated medication instructions highly. Nevertheless, we did not find a benefit in terms of overall quality of care transition, knowledge, or anticoagulant beliefs.

Comparison with other studies in the literature is limited by differences in the population examined and the outcomes assessed. In a systematic review, Mekonnen et al.[23] studied the impact of medication reconciliation performed by a pharmacist. They found that medication reconciliation led to large reductions in utilization of hospital and ED after initial admission to the hospital for a variety of conditions. By contrast, we focused on a single condition and on outcomes related to the quality of care transition, knowledge, and anticoagulant beliefs. We have not identified another study that measured the same outcomes in patients newly diagnosed with VTE. A previous study conducted by members of our authorship team (KM, JG, PB, JW) from which we borrowed the knowledge instrument did demonstrate that anticoagulation knowledge increased after a video intervention.[28] In that study, the authors included patients with all indications for warfarin, independent of the timing of medication initiation. The timing of assessment of knowledge also differed between studies. They assessed knowledge contemporaneously with distribution of the video (i.e., a questionnaire accompanied video in a common mailer). By contrast, we assessed knowledge at least 23 days after the home visit and typically 2 weeks after consultation with an anticoagulation expert. Thus, it is possible that our intervention also had a temporary increase in knowledge but that increase lessened over time. Our second contact with patients conducted by an anticoagulation expert was conducted over the telephone and lasted only 10 minutes on average. More sustained increases in knowledge may require a more intensive second contact or multiple shorter telephone encounters.

There were several limitations to this study. As mentioned previously, we did not power our study to detect a change in medication errors or the clinical endpoints of recurrent VTE or hemorrhage. We hypothesized that a poor-quality care transition, knowledge gaps, and absence of belief could contribute to the development of medication errors and subsequent adverse clinical endpoints. Further research in a larger sample would better assess the value of a pharmacist home visit and the other components of our intervention on the development of errors, recurrent VTE, and hemorrhage.

The nature of our recruitment strategy, which relied heavily on verbal consent followed by subsequent return of signed written consent, led to significant loss of patients after randomization. Short hospitalizations, significant distances separating multiple facilities from which we recruited, and a growing trend to care for VTE patients in the ambulatory setting compelled us to adapt our approach. Nevertheless, even with improved retention, we doubt that our intervention would have demonstrated higher-quality care transition, improved knowledge, or created stronger beliefs in anticoagulant medication, given the similarities in socioeconomic status, level of patient activation, or health literacy across the intervention and control patients of the completers cohort.

We also acknowledge that we may not have found an effect in the outcomes we measured because our population consisted of mostly white patients with high educational attainment and high patient activation scores. Despite the relatively "advantaged" population we enrolled, the mean scores of the knowledge assessment were low, arguing for continued efforts to develop interventions to improve knowledge.

The instrument we used to measure the quality of care transition, CTM-15, covered medication specific themes but also more general ones such as confidence in managing one's own health. The home pharmacist visit and subsequent anticoagulation expert consultation touched on other themes because they related to VTE. The relatively long lag between discharge and administration of the CTM-15 (up to 50 days after randomization) could also have contributed to the lack of effect, given the difficulty for patients to recall information provided to them during the home visit, which occurred within 1 week of randomization. We attempted to mitigate this by providing the anticoagulation expert consultation in the weeks after the home visit, but this seems not to have improved patient ratings.

Another limitation is that our intervention had limited engagement with caregivers and primary care providers. Because we had not previously tested or validated our simulation exercise to assess and remediate medication self-management with patient-caregiver dyads, we decided to assess and remediate proficiency with the patient alone. We allowed caregivers to be present, but we acknowledge that an intervention that more directly engaged caregivers may have had more significant impact. Similarly, we limited our engagement with primary care providers to correspondence sent at the time of discharge informing the provider about our study. We also did not collect information about whether or not patients were receiving support from dedicated anticoagulation clinics. Because of loss to follow-up, there may have been residual confounding from this variable although our treatment groups were balanced on most covariates. Finally, eight different pharmacists conducted home visits, and although we provided a standardized protocol for these visits, we did not have the sample size available to analyze how variation by pharmacist impacted our results.

CONCLUSIONS

We executed a multicomponent intervention in patients with new episodes of VTE. The intervention was feasible in terms of time, and patients rated the components of the intervention highly. Nevertheless, we did not detect a significant impact of the intervention on the quality of care transition, patient knowledge, or beliefs related to anticoagulants. We welcome additional research to identify interventions effective at improving these outcomes.

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