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Letter to the Editor-in-Chief

Outcomes associated with a change in clinical practice to alleviate emotional harm related to venous thromboembolism

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To the Editor:

Venous thromboembolism (VTE) is a potentially life-threatening condition that affects approximately 900,000 people annually [1]. VTE includes deep vein thrombosis (DVT) and pulmonary embolism (PE). In addition to physical morbidity, VTE has also been shown to be associated with significant emotional harm including anxiety, depression, and fear of bleeding or recurrent VTE [2,3]. We have previously demonstrated increased fear of bleeding and recurrent VTE as measured by the Hospital Anxiety and Depression Scale (HADS) and other validated assessment measures in a national cohort of recent VTE sufferers [2]. Whether clinicians can alleviate emotional harms associated with VTE through changes in patient intake, education, and monitoring practices is currently unknown. Therefore, the purpose of this study was to evaluate the impact of a simple change in clinical practice on emotional harm in patients being treated for VTE.

1. Methods

We performed a pre-post practice change study targeting patients recently initiating anticoagulation therapy for VTE. The practice change was implemented on April 1, 2017. Study participants were administered a survey designed to assess emotional harm attributable to their recent VTE event. The survey has been described in detail elsewhere [2]. The primary outcome for this study was patient-reported emotional harm including HADS scores of 11 or higher in either the anxiety or depression subscales or experiencing worry about bleeding or another VTE either “most” or “all of the time”. Our patient cohort included patients ≥ 18 years old who were at least 30 days out from their most recent episode of DVT or PE. All patients were managed via telephone by anticoagulation providers at the University of Utah Health (UUH) Thrombosis Service. The first cohort of patients were surveyed before the practice change was implemented (May 2016 to January 2017), and the second cohort was surveyed after (May 2017 to June 2018). The study was approved by the University of Utah Institutional Review Board prior to commencing study activities.

The change in practice consisted of the development and presentation of patient educational material specifically acknowledging emotional harm as potentially associated with VTE and encouraging patients to speak to their anticoagulation provider if they were experiencing any anxiety, depression, worry, or other emotional symptoms. In addition, UUH anticoagulation providers were encouraged to use the following scripting during conversations with patients in the first 30 days post VTE: “What concerns have you had about bleeding?” “What concerns have you had about having another blood clot?” “How has your recent clot affected you emotionally?” Anticoagulation providers were trained to address any concerns, validate worry, and offer further emotional support services available at UUH as needed.

The online survey was sent via email pre- and post-change to eligible patients. Patients were invited to participate in the survey during normal clinical interactions, messaging through the electronic medical record, phone calls, and emails. Once patients entered the survey they were screened for inclusion/exclusion criteria and eligible patients then completed the survey in one sitting. The survey took approximately 30 min to complete and patients received an industry standard honorarium to compensate them for their time completing the survey.

Descriptive and inferential statistics including the chi-squared test of association, Fisher's exact test, or Student's *t*-test were used to compare baseline characteristics and outcomes between groups where appropriate. Post-hoc subgroup analyses comparing outcomes of patients according to anticoagulation therapy type (warfarin or direct oral anticoagulants [DOACs]) were also performed. A p-value < 0.05 was considered statistically significant.

2. Results and discussion

There were 61 patients who completed the survey in the pre-change group and 51 in the post-change group. Baseline characteristics in the

Abbreviations: VTE, venous thromboembolism; DVT, deep venous thrombosis; PE, pulmonary embolism; HADS, Hospital Anxiety and Depression Scale; UUHealth, University of Utah Health; DOAC, direct oral anticoagulant

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Table 1
Demographics and self-reported outcomes of patients with VTE pre- and post-change in practice.

	Pre-change n = 67	Post-change n = 51	*p*-Value
Age, mean (SD)	52 (17)	53 (14)	0.14
Male, N (%)	26 (39)	24 (47)	0.37
Comorbid conditions, N (%)			
Anxiety	15 (22)	12 (24)	0.88
Previous DVT	48 (72)	31 (61)	0.21
Depression	18 (27)	13 (25)	0.87
Diabetes	8 (12)	6 (12)	0.98
Heart disease	9 (13)	7 (14)	0.96
Hypertension	24 (36)	9 (18)	0.03
High cholesterol	13 (19)	5 (10)	0.20
Previous PE	38 (57)	30 (59)	0.82
Last VTE 1–3 months ago, N (%)	9 (13)	15 (29)	0.03
Anticoagulant type, N (%)			
Warfarin only	36 (54)	12 (24)	0.001
DOAC only	13 (19)	23 (45)	0.003
Switched between warfarin and DOACs)	1 (1)	4 (8)	0.16
Switched between DOACs	6 (9)	11 (22)	0.05
Emotional harms, N (%)			
Worry about bleeding	9 (20)	5 (18)	1.00
Worry about clotting	21 (31)	20 (39)	0.37
HADS depression score 11 +	9 (13)	5 (10)	0.58
HADS anxiety score 11 +	11 (16)	8 (16)	0.92
Satisfied with home VTE care, N (%)	44 (66)	39 (76)	0.20
Satisfied with VTE education conversation, N (%)	53 (79)	46 (90)	0.08

VTE—venous thromboembolism, SD—standard deviation, DVT—deep vein thrombosis, PE—pulmonary embolism, DOAC—direct oral anticoagulant.

two groups were similar, except hypertension was more common in the pre-change group (36% vs 18%, $p = 0.03$), and more recent VTE was more common the post-change group (13% vs. 29%, $p = 0.03$) (Table 1). More patients in the pre-change group were prescribed warfarin (54% vs 24% $p = 0.001$) and more patients in the post-change group were prescribed DOACs (19% vs 45%, $p = 0.003$). More patients switched between different DOAC types in the post-change group (9% vs 22% $p = 0.05$).

Self-reported emotional harm outcomes were largely unchanged following the change in practice (Table 1). There was a nominal improvement in the proportion of patients expressing satisfaction with VTE education conversations in the post-change group, although statistical significance was not met (79% vs 90% $p = 0.08$).

Sub-analysis stratified by anticoagulant type demonstrated that for patients receiving warfarin there were no significant differences in any of the emotional harm outcomes or patient satisfaction scores before or after the practice change. More patients in the post-change group expressed worry about having another clot but statistical significance was not met ($p = 0.058$). However post-change group patients receiving DOAC therapy reported significantly increased satisfaction with hospital care ($p = 0.016$) and home care ($p = 0.026$). Patients prescribed DOACs showed trends toward increased satisfaction with care provided by the UUH Thrombosis Service and improved HADS depression subscale scores following the change (Fig. 1).

Our study demonstrated that a simple practice change had a non-significant effect on alleviating emotional harm overall. We did observe increased care satisfaction and nominal improvement in the HADS depression subscale scores among the post-change group compared to the pre-change group for patients receiving DOACs, although further evaluation is warranted to determine how much of this is directly attributable to the practice change. It is possible that the practice change was too subtle to have a major impact on patient's emotional well-being following their VTE diagnosis. Also, we relied on busy UUH anticoagulation providers to apply the change selectively to newly diagnosed patients with VTE and concede that it may not have been administered to all eligible patients (i.e. coverage error).

Our study is limited by the small sample size and the potential for coverage error. Recruitment for the survey proved challenging and many eligible patients declined to participate. Differences in the proportion of patients prescribed DOACs pre- and post-change could have confounded our results which is why we performed subgroup analyses stratified by anticoagulant type. Strengths of this study included the use of validated outcomes measures in the survey, specifically HADS depression and anxiety scores.

3. Conclusion

A simple change in clinical practice was not associated with less emotional harm following VTE. Multi-modal interventions such as focused education on bleeding and recurrent VTE risk or providing more emotional support tools to every VTE patient including referral to patient support groups and counseling may be required. Further studies are needed to determine if a more intensive structured intervention or targeting higher risk patients will reduce the risk of emotional harm during VTE treatment.

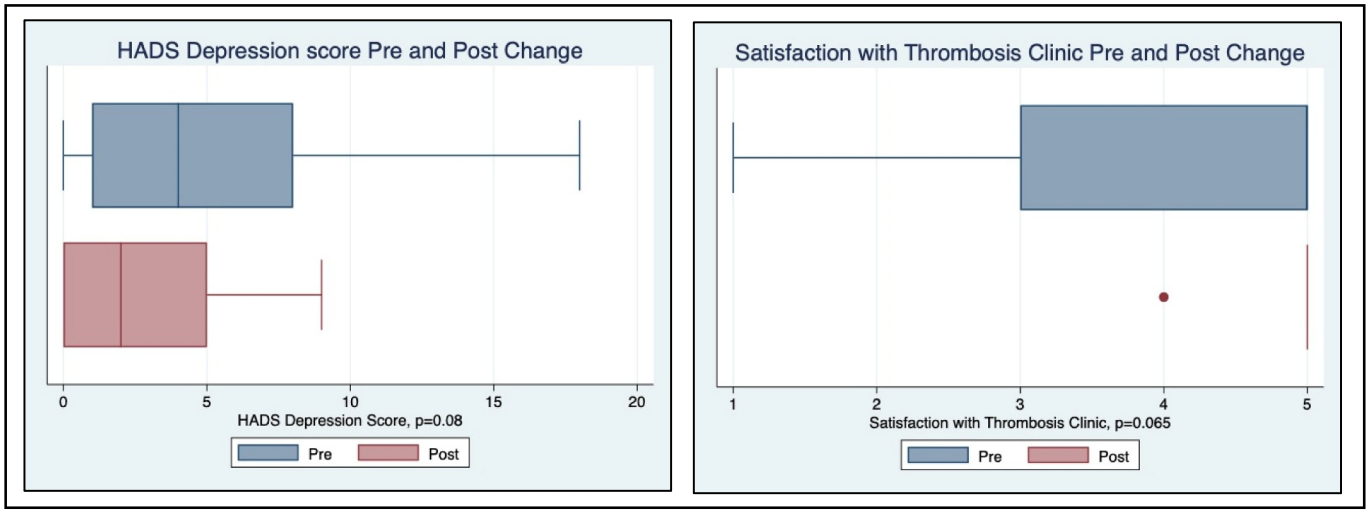

Fig. 1. HADS depression subscale score and satisfaction with thrombosis clinic on DOACs pre- and post-change in practice.
HADS—Hospital Anxiety and Depression Score, DOACs—direct oral anticoagulants.

Declaration of Competing Interests

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Disclosures

Dr. Feehan has consulted to Pfizer previously; other authors: none declared.

References

[1] L. Tamariz, T. Harkins, V. Nair, A systematic review of validated methods for identifying venous thromboembolism using administrative and claims data, Pharmacoepidemiol. Drug Saf. 21 (Suppl. 1) (2012) 154–162.

[2] M. Feehan, M. Walsh, H. Van Duker, J. Godin, M.A. Munger, R. Fleming, S.A. Johnson, M.A. Morrison, M.M. DeAngelis, D.M. Witt, Prevalence and correlates of bleeding and emotional harms in a national US sample of patients with venous thromboembolism: A cross-sectional structural equation model, Thromb. Res. 172 (2018) 181–187.

[3] A.A. Kaptein, I.M. van Korlaar, L.D. Cameron, C.Y. Vossen, F.J. van der Meer, F.R. Rosendaal, Using the common-sense model to predict risk perception and disease-related worry in individuals at increased risk for venous thrombosis, Health Psychol. 26 (6) (2007) 807–812.

Aubrey E. Jones[a,b], Michael Feehan[c], Ryan Fleming[b], Stacy A. Johnson[b,d], Daniel M. Witt[a,b,*]

[a] *University of Utah College of Pharmacy, Department of Pharmacotherapy, Salt Lake City, UT, USA*

[b] *University of Utah Health, Thrombosis Service, Salt Lake City, UT, USA*

[c] *Kantar, LLC, San Francisco, CA, USA*

[d] *University of Utah School of Medicine, Department of Internal Medicine, Salt Lake City, UT, USA*

E-mail address: dan.witt@pharm.utah.edu (D.M. Witt).

[*] Corresponding author at: Department of Pharmacotherapy, College of Pharmacy, University of Utah, 30 South 2000 East, Salt Lake City, UT 84112, USA.