An Analysis of an Orthopedic Venous Thromboembolism Prophylaxis Protocol at Beth Israel Deaconess Medical Center

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INTRODUCTION

VTE is highly prevalent in postoperative orthopedic patients, the adverse outcomes are severe, and thromboprophylaxis has been shown to be effective.[3] For these reasons VTE prophylaxis has been considered the standard of care in major orthopaedic surgery for over 15 years.[6,7]

The American College of Chest Physicians (ACCP) published its most recent guidelines regarding VTE prophylaxis in 2004.[4] Recommended methods of prophylaxis for total hip arthroplasty (THA), total knee arthroplasty (TKA), and hip fracture surgery (HFS) are low molecular weight heparin (LMWH), fondaparinux, and vitamin K antagonists. Additionally, low-dose unfractionated heparin (LDUH) is recommended for HFS. It is recommend that aspirin not be used as the sole method of prophylaxis after any of the above procedures.

In September 2004 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Quality Forum (NQF) began a collaboration to form national standards for the prevention and treatment of VTE. In November 2004 the anticoagulation guidelines from CHEST were reviewed by the Beth Israel Deaconess Medical Center (BIDMC) anticoagulation committee. This committee included departmental representatives from medicine, surgery, nursing, pharmacy and healthcare quality. In December 2004 the anticoagulation clinic was reported to be unable to meet the needs of the expanding population of total joint recipients receiving warfarin for thromboprophylaxis. The anticoagulation committee devised a protocol for VTE prophylaxis at BIDMC following major orthopedic surgery that was intended to comply with national guidelines while reducing the demand on the warfarin clinic. On April 14, 2005 the protocol was presented at a staff meeting of the BIDMC orthopedics department.

This study measured the rate of compliance with the VTE prophylaxis protocol at BIDMC based upon ACCP guidelines and was designed to identify factors affecting physician response to the protocol. A secondary aim was to examine the effect of the protocol on VTE incidence and bleeding complications. A dual methodological approach utilized medical chart review to conduct a historical cohort study combined with a survey of orthopedic surgeons practicing at BIDMC.

MATERIALS AND METHODS

The BIDMC VTE protocol was similar for THA, TKA, & HFS, recommending enoxaparin 30mg sc q12h, beginning 12h postoperatively unless an epidural was present. If creatinine clearance was estimated to be < 30ml/min, the recommended enoxaparin dosage was 30mg sc q24h. Finally, if the patient's weight was > 150kg, the recommended enoxaparin dosage was 40mg BID.

Chart review was employed to conduct a historical cohort study comparing prescribed prophylaxis at discharge by type, dosage, and duration before vs after the institution of the VTE prophylaxis protocol at BIDMC. Also recorded were VTE incidence, bleeding complications and patient comorbidities. Being a nonrandomized retrospective study, patients were assigned groups based upon surgery date (pre-protocol vs post-protocol).

The use of VTE prophylaxis regimens and rates of other complications were compared before vs after protocol implementation with Fisher's exact test. P values and odds ratios were calculated with corresponding 95% confidence intervals. When the p values showed significance, the absolute risk reduction was calculated.

Multivariate analysis examined the potential impact of patient factors on physician prescribing practices before and after protocol implementation. The analysis included 13 factors for the total joint group and 14 factors for the hip fracture group that had been hypothesized to affect decision-making. The factors analyzed were; discharge service, sex, age, insurance, preadmission warfarin, previous VTE, history of GI bleed, history of renal insufficiency, ICU days, cross-matched transfusion, wound hematoma, GI bleed during admission, race, and for the hip fracture group alone, additional fractures.

A physician survey was created to identify physician factors associated with protocol compliance and to gather suggestions regarding future protocol implementation. The questionnaire was created based on a literature review that identified physician-related factors previously found to affect guideline compliance (lack of awareness, lack of familiarity, lack of agreement, lack of self-efficacy, lack of outcome expectancy, inertia of previous practice, external barriers, and guideline related barriers). The surveys were confidential yet not anonymous, allowing for the results to be correlated to the chart review data.

Participants were all adult inpatients having undergone elective TKA, elective THA, or HFS at BIDMC between 12/26/2003 and 8/11/2006. They were identified through a search of hospital records by procedure and diagnostic codes. Those who underwent surgery before protocol implementation (April 14th, 2005) were assigned to the control group. Those who underwent surgery after protocol implementation were assigned to the intervention group.

RESULTS

Compliance

The protocol successfully increased the use of enoxaparin relative to warfarin following major orthopedic surgery, and did so while maintaining compliance with national guidelines. The results show an excellent level of compliance by type and duration of prophylaxis while compliance by recommended dosage was relatively poor. Individual surgeons were shown to be aware and familiar with the protocol, however, compliance was associated with increased duration of practice, lack of agreement with guidelines, and external barriers (preadmission warfarin).

Multivariate Analysis

Multivariate analysis identified multiple independent predictors of warfarin use vs enoxaparin. These independent predictors changed with protocol implementation. Prior to protocol implementation renal insufficiency, preadmission warfarin use, and increasing age were predictors of warfarin use in the hip fracture group while cross-matched transfusion, previous VTE, and increasing age were predictors in the total joint group. Following protocol implementation in the hip fracture group age ceased to be a predictor while ICU stay, GI bleed and non-Caucasian status became predictors. In the total joint group ICU stay and discharge by orthopedic service were predictors of warfarin use. Insurance status did not predict prophylaxis choice in any group.

VTE Outcomes & Complications of Prophylaxis

There was no change in the incidence of VTE following protocol implementation. PE incidence was significantly increased among total joint patients treated with aspirin than with warfarin or enoxaparin. There was a trend toward increased PE incidence among hip fracture patients treated with warfarin vs enoxaparin. Significantly fewer transfusions were found among patients prescribed enoxaparin vs warfarin in the total joint group. There was a trend toward fewer GI bleeds among hip fracture patients treated with enoxaparin vs warfarin.

DISCUSSION

Guideline compliance requires correct type, dosage, and duration of prophylaxis. This study found that these measures of compliance were satisfied at a high rate except correct dosage of prophylaxis. Therefore, the most likely way to improve compliance at BIDMC is by increasing use of the recommended dosage. Survey results included suggestions regarding increasing use of the computer-based provider order entry (POE) system for protocol implementation, such as creation of an automatic POE prompt for VTE prophylaxis.

As described above, lack of knowledge was not found to be a factor affecting compliance with the protocol while surgeon agreement with the protocol, duration of practice, and external barriers did affect compliance. Applying this knowledge, protocol compliance would most likely be improved by interventions that increase agreement with future protocols and that specifically affect the attitudes of more experienced surgeons on staff at BIDMC. These interventions include such actions as encouraging staff participation in protocol formation.

The independent predictors of noncompliance identified by multivariate analysis were different for the total joint and hip fracture groups. Notably, preadmission warfarin use and renal insufficiency were predictors in the hip fracture group and not the total joint group (most likely due to the increased age and number of comorbidities in hip fracture patients). Survey results related surgeons' concerns of increased bleeding with enoxaparin, possibly explaining transfusion requirement as a predictor of warfarin use in the total joint group.

There was also a difference in the predictors before and after protocol implementation in each group. In the hip fracture group, no GI bleeds occurred prior to the protocol, so the change in this predictor appears incidental. However, the loss of age as a predictor and the addition of ICU stay and non-Caucasian status as predictors indicate a change in decision-making related to protocol implementation. In the total joint group the additional predictors of ICU stay and orthopedic discharge after protocol implementation also demonstrated a change in decision-making following protocol implementation, possibly related to concerns of increased bleeding with enoxaparin and the orthopedic service being more confident in deviating from its own protocol when necessary.

A higher rate of PE among patients treated with aspirin has been shown in previous studies. Confirmation in this study provides further evidence to support those findings. It remains uncertain if the lower rate of transfusion among patients treated with enoxaparin was due to a confounding effect such as a surgeon bias toward using warfarin in patients more likely to have a bleeding event. It was independently true in the pre & post protocol groups, and therefore less likely to be simply due to a change in transfusion delivery mechanisms or policy.

CONCLUSIONS

1. Protocol successfully increased use of enoxaparin relative to warfarin while maintaining compliance with ACCP guidelines
2. Aspirin was associated with increased PE incidence vs other prophylaxis in total joint group
3. Lower transfusion rate with enoxaparin vs warfarin in total joint group
4. Fewer GI bleeds with enoxaparin vs warfarin in the hip fracture group deserves further study
5. Multivariate analysis identified a number of patient-related independent predictors of prophylaxis type, notably race was a predictor of warfarin use

FUTURE DIRECTIONS

This study was designed to aid in future protocol implementation in orthopedic surgery for the benefit of patients through improved healthcare quality. Conclusions made from this research can be used to guide future decision-making at BIDMC as well as to assist researchers in designing future studies of this nature. Recommendations for future protocol implementation include emphasizing dosage in future protocols and integration of protocols into the POE system. Statistical analysis is ongoing, including additional multifactorial analysis aimed at further elucidating the role of race in prophylaxis choice. Final results will be submitted for publication this spring.

References

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