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Never Events and Related Quality Measures Following Total Hip and Total Knee Replacement

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educational objectives

As a result of reading this article, physicians should be able to:

1. Discuss the burden of venous thromboembolism (VTE) in patients undergoing total joint replacement surgery and explain the role of thromboprophylaxis in reducing VTE events.
2. Enumerate obstacles to VTE prevention in the post-surgical setting and propose responses to these challenges.
3. Describe the "never events" decision that relates to VTE events occurring in hospital and discuss how it may reduce the incidence of these events.
4. Define current and emerging options for thromboprophylaxis.

It has been more than a decade since incidence data from a large, population-based study revealed that an estimated $\geq 350,000$ persons in the United States developed venous thromboembolism (VTE) each year.^{1,2} Recent modeling suggests that the total number of incident or recurrent, fatal and nonfatal VTE events that occur in the United States each year is

$>600,000$.³ At least 100,000 deaths each year are thought to be related to VTE, which includes both deep vein thrombosis (DVT) and pulmonary embolism (PE).²

The risk of VTE is particularly high among patients undergoing major orthopedic surgery, including total hip replacement (THR) and total knee replacement (TKR), with an incidence of venographic

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DVT of 40% to 60% in the absence of prophylaxis.⁴ In fact, in the absence of thromboprophylaxis, PE remains the leading cause of death following total joint replacement.^{5,6} Given the high risk of VTE associated with major orthopedic surgery, routine thromboprophylaxis is the standard of care for all such patients.⁴ Numerous up-to-date clinical practice guidelines for the prevention of VTE are available from both specialty medical societies and professional associations.⁷

Nevertheless, despite effective prophylaxis and established guidelines for clinicians, VTE continues to occur in the postsurgical setting. The therapy failure rate for low-molecular-weight heparin (LMWH) at the approved dose following THR is 10% to 11%.⁸ Data from large retrospective studies indicate that the actual use of thromboprophylactic therapy lags behind best evidence-based practice.⁹⁻¹¹ As a result, numerous health care safety agencies have identified VTE as a largely preventable condition and outlined performance measures/consensus standards for prophylaxis against VTE following major orthopedic surgery.

This article provides a brief review of the epidemiology and prevention of VTE in the context of the growing consensus around the need for improvements in VTE prophylaxis in the postsurgical setting.

VTE EPIDEMIOLOGY AND CLINICAL IMPACT

As noted, patients undergoing total joint replacement are at a highly elevated risk for developing VTE. In addition, the risk of VTE increases with age, with rates of DVT and PE ~5 to 6 times higher among patients 70 years and older compared with patients aged 20 to 69 years.¹²

A VTE event significantly impacts patient morbidity and mortality. The overall 1-year survival rate following VTE has been reported to be 64% (85% for DVT, and 48% for PE±DVT).¹³ Further, many of those who survive have complications that have a serious and negative impact

on the quality of their lives.² Major complications of VTE include chronic venous insufficiency (ie, post-thrombotic syndrome, as well as dependent leg swelling and pain, and stasis dermatitis), venous ulcer, and chronic thromboembolic pulmonary hypertension.¹⁴ Approximately 30% of patients experiencing a VTE event will develop a recurrence within 10 years.¹⁵ The risk of recurrence is greatest within the first 6 to 12 months following the initial event.¹⁴

OBSTACLES TO OPTIMAL VTE PREVENTION

Selecting appropriate thromboprophylaxis following orthopedic surgery requires balancing efficacy and safety. A primary concern among surgeons is the risk of bleeding, which can result in additional complications, including hematoma formation or wound infection, which can lead to the need for reoperation. This concern leads some surgeons to use subtherapeutic prophylactic regimens and ineffective prevention strategies. Any bleeding is potentially serious, but the risk of bleeding in postsurgical patients receiving thromboprophylaxis can be overestimated.¹⁶

Clinicians may be unaware of existing guidelines, or they may be uncertain about the appropriate timing, duration, and selection of the most effective agent for prophylaxis. For example, the continuing trend to reduced length of hospital stay for THR and TKR patients means that VTE typically occurs post-discharge.¹⁶ Thus, surgeons are less likely to see VTE during the immediate postoperative period, a fact that likely contributes to a perception among some surgeons that the burden of the disease is overstated and leads to inadequate provision of appropriate thromboprophylaxis.¹⁷

Surgeons should be aware that VTE, rather than bleeding-related complications, is the most common reason for readmission following THR/TKR surgery,¹⁸ with the consequent costs entailed in a second hospital stay. Current guidelines

recommend that thromboprophylaxis following THR be continued for at least 10 and up to 35 days and suggest that extended-duration prophylaxis is also beneficial following TKR.⁴ Recent studies have clearly demonstrated that longer duration of VTE prophylaxis following THR is significantly more effective than shorter duration in preventing VTE.¹⁹

PROPHYLAXIS AGAINST VTE: QUALITY MEASURES AND THE NEVER EVENTS DECISION

Venous thromboembolism following major orthopedic surgery is associated with substantial morbidity, mortality, and economic burden, and is largely preventable. Substantial data indicate that thromboprophylactic interventions following surgery can effectively reduce DVT, PE, and fatal PE, decreasing adverse clinical outcomes, as well as costs.^{4,20}

In 2001, the Agency for Healthcare Research and Quality (AHRQ) identified the appropriate use of prophylaxis to prevent VTE in patients at risk as the top priority for improving the safety of hospitalized patients.²¹ As a result, numerous health care quality organizations have developed consensus standards and performance measures to evaluate health care organizations and to help providers improve their practices, with the goal of decreasing the incidence of VTE. Most prominent among these organizations are the National Quality Forum (NQF), the Joint Commission, the Office of the Surgeon General of the United States, and the Centers for Medicare and Medicaid Services (CMS). These organizations agree that VTE imposes a substantial burden on both patients and the health care system as a whole. The NQF and the Joint Commission together initiated the National Voluntary Consensus Standards for Prevention and Care of Venous Thromboembolism, the purpose of which is to develop standardized performance measures for preventing and treating VTE.

In May 2008, NQF published 6 performance measures for VTE that are designed



to guide health care provider organizations and provide a means to evaluate their progress in decreasing the risk of hospital-acquired VTE. Similarly, the Joint Commission, in recognition of the complexity of anticoagulation therapy, has developed the National Patient Safety Goal 03.05.01 (formerly Requirement 3E), which aims at promoting improvements in patient safety by reducing the 'likelihood of patient harm associated with the use of anticoagulation therapy.'²² The Joint Commission also issued a Sentinel Event Alert in September 2008 to highlight factors that contribute to anticoagulant medication errors.²³

In September 2008, the Office of the Surgeon General issued a call to action to prevent DVT and PE.² The call to action emphasized the need for a coordinated plan to reduce the incidence of DVT/PE by increasing awareness of these conditions among both patients and providers. It also highlighted the gap between evidence-based, effective thromboprophylaxis, and the use of those interventions in high-risk patients.²

Beginning in financial year 2008, CMS identified 8 preventable conditions for which it would no longer make additional payments. These 'serious reportable events' or 'never events' are identifiable and preventable medical errors that result in serious clinical consequences for patients, as well as unnecessary costs to Medicare and Medicaid. For financial year 2009, DVT and/or PE following THR or TKR were added to the list of hospital-acquired conditions that would no longer be reimbursable under Medicare.²⁴ This policy has important implications for reimbursement from commercial health plans, which are likely to follow suit.

Centers for Medicare and Medicaid Services is advancing other quality improvement initiatives to address the issue of VTE. The Surgical Care Improvement Project (SCIP) is a partnership of health care organizations dedicated to improving the safety of surgical care by reducing postoperative complications. With a goal

of reducing the incidence of surgical complications by 25% by the year 2010, SCIP has 2 VTE process outcome measures. The first looks at postsurgical orders for VTE prophylaxis, and the second deals with administration of appropriate prophylaxis within 24 hours prior to and 24 hours after surgery.²⁵ In addition, as part of the Physician Quality Reporting Initiative, CMS pays incentives to physicians who successfully document orders/protocols for appropriate VTE prophylaxis.²⁶

Centers for Medicare and Medicaid Services is also sponsoring pilot programs that are intended to improve the delivery of health care processes and services. Since the majority of VTEs occur after hospital discharge, the Care Transitions Project is looking at methods to improve the transition of patients from the hospital to the home following surgery.²⁷ The Acute Care Episode Pilot Program, which bundles Medicare Part A and Part B payments by episodes of care, looks at alternative approaches to the delivery of health care services and includes a measure for VTE prophylaxis following THR and TKR.²⁸

CURRENT PHARMACOLOGIC OPTIONS FOR THROMBOPROPHYLAXIS

The ideal prophylactic regimen following major orthopedic surgery has not been identified, but a number of effective agents are currently recommended, including LMWH, warfarin, and fondaparinux.^{4,17}

Aspirin is among the thromboprophylactic options listed by the American Academy of Orthopaedic Surgeons (AAOS) in their guidelines for the prevention of symptomatic pulmonary embolism following THA and TKA. The AAOS recommends aspirin if risk for PE and bleeding (level IIIB) is standard, or if risk for bleeding is elevated, regardless of PE risk (level IIIC). It is not recommended for use in patients at an elevated risk for PE.²⁹ The American Academy of Chest Physicians, however, points out that aspirin is not an anticoagulant and does not recommend its use for thromboprophylaxis against VTE.⁴

Standard unfractionated heparin is not currently recommended for the prevention of VTE following major orthopedic surgery. Aspirin inhibits thromboxane A₂, limiting platelet aggregation and reducing thrombus formation, but it is not as effective as either LMWH or warfarin for preventing DVT.¹⁷ While effective in thromboprophylaxis, LMWHs are injectable, making them less convenient for patients to administer at home. Warfarin requires careful monitoring for individualized dose adjustment, is slow to take effect, and has numerous food and drug interactions. Therefore, the use of warfarin presents challenges to both physicians and patients, even for the short term.³⁰

Data demonstrate a relatively low risk of clinically significant bleeding in association with prophylactic doses of the most commonly used therapies, including LMWH³¹ and vitamin K antagonists.³²

FUTURE OPTIONS FOR THROMBOPROPHYLAXIS

In addition to the recommended prophylactic therapies, a number of new oral anticoagulants are currently undergoing evaluation for the prevention of VTE in major orthopedic surgery. These include the direct Factor Xa inhibitors (rivaroxaban, apixaban, betrixaban, and edoxaban) and the direct thrombin inhibitor dabigatran. It is hoped that by selectively inhibiting specific coagulation factors, these newer agents will have the potential to combine improved efficacy with better safety and ease of administration, thus improving adherence and reducing rates of VTE events. In the ADVANCE-1 study, apixaban failed to demonstrate noninferiority versus the US-approved dose of enoxaparin for VTE prophylaxis following TKR.³³ In ADVANCE-2, however, postoperative apixaban was superior to enoxaparin 40 mg/d in preventing VTE, without increasing bleeding risk.³⁴ While results presented to date have shown dabigatran to be 'noninferior' to enoxaparin following THR,³⁵ dabigatran has not been shown



to be superior to the US-approved dose of enoxaparin following TKR surgery.³⁶ In 4 US studies versus enoxaparin,^{19,37-39} two of which were head-to-head, equal duration of therapy comparisons versus the US-approved dose of enoxaparin for the indication studied,^{37,39} rivaroxaban demonstrated superior efficacy following both THR and TKR surgery, with a similar incidence of bleeding, including major bleeding.

The advent of these new agents may provide not only more convenient and more effective prophylaxis but also may help improve the ease of transition of care as patients move from the hospital to the outpatient setting.

CONCLUSION

Significant progress has been made in prophylaxis against VTE following major orthopedic surgery. However, VTE continues to present a significant health burden for patients and the US health care system. With the AHRQ and CMS taking the lead, several health care organizations have issued guidelines and performance measures to improve patient safety and to increase the use of appropriate thromboprophylaxis in patients at risk of VTE. These measures focus on selection of the most appropriate therapeutic options and administration of those strategies for a sufficient period of time. In addition to those currently available, newer therapies are being evaluated that have the potential to provide safe and effective prevention of VTE, with more convenient administration. These agents, especially those that offer improved efficacy, should help address the deficiencies of current options, as well as help hospitals meet the requirements of new quality standards. 

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