



the  
**changing face**  
of anticoagulant therapy

Improving the Management of Patients at  
Risk for Venous Thromboembolism

ASHP Advantage E-Newsletter

Winter 2010

## Practice Pearls in the Changing Face of Anticoagulant Therapy

A midday symposium about the use of anticoagulation to prevent venous thromboembolism (VTE) was held at and broadcast live from the 44th ASHP Midyear Clinical Meeting and Exhibition in Las Vegas, Nevada, on December 8, 2009. Attendees at the symposium and participants in the live broadcast submitted questions that were later addressed by the faculty in a live webinar conducted on January 21, 2010. During the webinar, the faculty shared practice “pearls” based on their extensive experience, and many of these practice pearls are described in this newsletter. Additional information and an update on emerging anticoagulants will be provided in another newsletter to be released this spring.

### Question: What specific performance feedback measures pertaining to VTE prophylaxis should be collected and shared with individual health care practitioners?

The Society of Hospital Medicine (SHM), an organization of hospitalists (physicians specializing in the delivery of comprehensive medical care to hospitalized patients) whose mission is to promote quality improvement (QI), is a good source of information on the assessment of performance and quality. Venous thromboembolism is the focus of one of several QI resource rooms on the SHM Web site ([www.hospitalmedicine.org](http://www.hospitalmedicine.org)) that provide the information and tools needed to lead QI projects. These materials were developed through interprofessional (i.e., multidisciplinary) efforts involving pharmacists, other health care professionals, and informatics experts.

Quality metrics (i.e., measures) should be devised to provide feedback regarding institution-wide performance first and practitioner-specific feedback second. The metrics chosen to evaluate performance in preventing VTE should be derived from available data and yield information that is meaningful to the person or group whose performance is assessed. An interprofessional group of key people at the institution should be convened

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to serve as a QI team in identifying appropriate metrics and coordinating other efforts to optimize VTE prophylaxis in the institution.

The core performance measures pertaining to VTE prophylaxis required by The Joint Commission (e.g., documentation of VTE prophylaxis within 24 hours of admission to the hospital or intensive care unit) should be shared with key audiences in the institution.<sup>1</sup> Data related to specific anticoagulants used for VTE prophylaxis might be highlighted in internal reports. Table 1 shows a sample approach to adapting The Joint Commission core measures for use in auditing VTE process and outcome measures to improve quality.

**Table 1. Possible Approach to Auditing VTE Process and Outcome Measures for Quality Improvement<sup>a</sup>**

*Process Measures*

- Randomly select 5 cases per week (current admissions on selected wards) to audit (1 case per day, 20 cases per month)
- Determine the % of these patients who had orders for appropriate VTE prophylaxis written within 24 hours of admission
- Determine the % of these patients who received appropriate VTE prophylaxis within 24 hours of admission

*Process Measures*

- Identify the number of DVT/PE admissions to the hospital and ED
- Select a subset (e.g., 20-50) of these cases to audit each month
- Determine the % of these cases that are temporally related to a prior stay at your hospital (e.g., within 30 days)
- Determine the % of these cases in which appropriate VTE prophylaxis was used during the prior hospital stay

DVT = deep vein thrombosis; ED = emergency department; PE = pulmonary embolism; VTE = venous thromboembolism

<sup>a</sup>Based on Society of Hospital Medicine metrics and Joint Commission core measures

**Question: What considerations enter into decisions about the duration of VTE prophylaxis?**

Several factors need to be considered in determining the duration of VTE prophylaxis for a patient, including the presence of unmodifiable risk factors for VTE, chronic conditions that increase the risk for VTE, and risk factors for harm from VTE prophylaxis (Table 2). The costs of prolonged hospitalization for and treatment of VTE or adverse effects from VTE prophylaxis also are considerations.

Clinical trial data supporting the use of prolonged VTE prophylaxis are limited. The efficacy and safety of prolonged pharmacologic prophylaxis are not well studied in surgical patients, with the exception of patients undergoing total hip or knee replacement or hip fracture repair surgery. Table 3 lists the suggested duration of prophylaxis for these and various other conditions based on available evidence.

Prolonged prophylaxis has been used successfully in clinical trials of emerging anticoagulants in

patients undergoing total hip replacement. Dabigatran, an oral direct thrombin (factor IIa) inhibitor, was used for 28-35 days, and rivaroxaban, an oral direct factor Xa inhibitor, was used for 35 days.<sup>6,7</sup>

**Table 2. Factors to Consider in Determining the Optimal Duration of VTE Prophylaxis**

- Presence of unmodifiable risk factors for VTE
  - Advanced age
  - History of thrombosis
- Presence of chronic conditions that increase the risk for VTE
  - Cancer and other hypercoagulable states
  - Obesity
  - Immobility/paralysis
- Presence of risk factors for harm from VTE prophylaxis
  - Bleeding
  - HIT

HIT = heparin-induced thrombocytopenia; VTE = venous thromboembolism

**Table 3. Suggested Duration of VTE Prophylaxis<sup>2-5,a</sup>**

- General surgery: 4-10 days, with up to 28 days for major procedures
- Acute spinal cord injury: 2-3 months
- Trauma: until discharge or while mobility is impaired
- History of VTE:  $\geq 3$  months
- Gynecologic surgery: up to 28 days
- Total hip or knee replacement or hip fracture surgery: 4-6 weeks

VTE = venous thromboembolism

\*Based on limited clinical trial evidence

## **Question: Is any information available about the use of the emerging anticoagulants for VTE prophylaxis in patients receiving epidural or spinal anesthesia or analgesia?**

The presence of an epidural or spinal catheter for administration of anesthesia or analgesia may be a consideration in the use of anticoagulant therapy for VTE prophylaxis because of concerns about bleeding and spinal hematoma formation, a rare but potentially devastating complication.<sup>2</sup> Initiation of anticoagulant therapy often is delayed until after catheter removal to avoid this problem. Spinal hematoma formation also is a concern during the insertion of epidural or spinal catheters in patients receiving anticoagulants.

Limited information is available about the manner in which patients receiving epidural or spinal anesthesia or analgesia were handled in clinical trials of the emerging anticoagulant agents. The best information can be found in European monographs for these agents. The use of dabigatran (known as Pradaxa in Europe where the drug is already approved) is not recommended in patients undergoing anesthesia with postoperative indwelling epidural catheters.<sup>8</sup> The first dabigatran dose should not be given until at least 2 hours after the

catheter is removed.

Epidural catheters should not be removed within 18 hours after the last dose of rivaroxaban (known as Xarelto in Europe where the drug is already approved).<sup>9</sup> Rivaroxaban should not be given within 6 hours after catheter removal. If traumatic spinal or epidural puncture occurs, the administration of rivaroxaban should be delayed for 24 hours.

Desirudin is an injectable direct thrombin inhibitor that may become available soon in the United States. The pharmacokinetic profile of the drug should be considered when using epidural or spinal anesthesia to reduce the risk of bleeding.<sup>10</sup> Placement of the catheter prior to initiating desirudin and removal of the catheter when the anticoagulant effect of desirudin is low should be considered. The half-life of desirudin (approximately 2 hours) is shorter than that for the other emerging agents (5-9 hours for rivaroxaban, and 12-17 hours for dabigatran), which facilitates safe catheter insertion and removal.<sup>10,11</sup>

Information about the use of emerging anticoagulants in patients with epidural or spinal catheters should be incorporated into institutional policies, procedures, and protocols for use of the drug.

**Question: If a patient undergoes knee or hip replacement surgery and develops deep vein thrombosis (DVT) despite receiving VTE prophylaxis, will it be considered a “never event” that is not reimbursable under Centers for Medicare & Medicaid Services (CMS) rules? Is there a time limit after which VTE is not considered a never event? Is VTE considered a never event only if it develops during the hospital stay? If VTE develops after hospital discharge, how does Medicare take into account the role of patient nonadherence to prescribed prophylaxis?**

The DVT observed in such a patient would be considered a never event by CMS if it developed while the patient was in the hospital or within 30 days after hospital discharge, even if patient nonadherence contributed to the problem. The agency withholds payment for the treatment of VTE following knee or hip replacement surgery that develops in this time frame. The CMS rules for reimbursement of never events are controversial because they may have unintended consequences (Table 4).<sup>12-14</sup> Financial incentives to avoid venous thromboembolism can reduce patient safety if excessive anticoagulation is used and bleeding occurs.

**Table 4. Potential Unintended Consequences of CMS Rules for Reimbursement of VTE as a Never Event After Knee or Hip Replacement Surgery<sup>12</sup>**

- Hospitals may deny care to patients at the highest risk for VTE
- Surgeons may decide not to perform hip and knee replacement surgeries
- Clinicians may not pursue the diagnosis of VTE when it is suspected
- Excessively aggressive prophylaxis methods may be used without regard for the risks involved

CMS = Centers for Medicare & Medicaid Services; VTE = venous thromboembolism

## Coming in March 2010

If you missed the midday symposium about the use of anticoagulation to prevent VTE at the 2009 ASHP Midyear Clinical Meeting and Exhibition and want to learn more about this topic, a web-based activity based on the symposium will be available in March. Two hours (0.2 CEUs) of continuing pharmacy education credit will be offered. Podcast interviews with the faculty, which were conducted after the live program in Las Vegas, are also available. These activities are available on the activity website ([www.ashpadvantage.com/vte](http://www.ashpadvantage.com/vte)).

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## We Value Your Feedback

If you attended the live symposium in Las Vegas, please complete the post-activity outcomes survey, if you have not done so already. The survey is short, but it is important because it enables us to document changes in practice as a result of the live educational activity. To access the survey click on the button below.

[Take Survey](#)

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