

Commonwealth of Massachusetts Board of Registration in Medicine

Quality and Patient Safety Division

Advisory Venous Thromboembolism Risk Assessment and Prevention

December 2013

Background

The Quality and Patient Safety Division (QPSD) has received a number of Safety and Quality Review (SQR) reports of patient complications associated with venous thromboembolism (VTE). This advisory is issued to share some of the lessons learned by the reporting health care facilities, and to support health care facilities in the review and development of their protocols for assessing patients for VTE risk and initiating appropriate patient-specific VTE prophylaxis. While some references are provided, this advisory does not include a comprehensive review of the literature; nor is it intended to provide specific recommendations for evidence-based practice. Publication of this Advisory does not constitute an endorsement by the Board of any studies or practices described in the Advisory and none should be inferred.

Overview

Symptomatic deep venous thrombosis (DVT) and pulmonary embolus (PE) occur annually in over 500,000 people in the United States.¹ Without VTE prophylaxis, DVT can occur in 10-20% of medical patients, in 15-40% of general surgery patients and in as many as 60% of patients having major orthopedic surgery.² A 300-bed hospital that lacks a systematic approach to VTE prevention may have 150 cases of hospital-acquired VTE per year with 50-75 of the cases potentially preventable.³ Both medical and surgical patients can be at high risk for VTE and together present a broad and complex set of issues. This advisory will focus on post-operative patients, primarily orthopedic, as they represent a more discrete and high risk population. The general principles discussed, however, may be applied to all hospitalized patients.

Pharmacological methods for VTE prevention/prophylaxis are numerous and increasing, and include both oral and injectable medications. The only mechanical prophylaxis option consists of an

¹ Centers for Disease Control and Prevention. Venous Thromboembolism in Adult Hospitalizations—United States, 2007–2009. MMWR 2012; 22:401-404.

² Michota, FA. Bridging the Gap Between Evidence and Practice in Venous Thromboembolism Prophylaxis: The Quality Improvement Process. J Gen Intern Med 2007; 22(12):1762-70.

³ Maynard, G et al. Preventing Hospital-Acquired Venous Thromboembolism: A Guide for Effective Quality Improvement. AHRQ Publication No. 08-0075, August 2008.

intermittent pneumatic compression device with a monitor to ensure it is worn at least 18 hours a day. As one or more of these methods may be chosen by a surgeon for use for differing lengths of time, VTE prophylaxis regimens can be as idiosyncratic and variable as patient risk factors and surgeon preferences. The goal is achieving the appropriate balance between VTE prevention and minimizing post-operative bleeding.

The identification of medical and surgical VTE risk factors, safe and effective implementation of prophylactic measures, and comprehensive discharge planning are important facets of a hospital-based VTE reduction program. 4,5 However, incongruous data, guidelines and opinions as to the choice of prophylaxis method, the risks of VTE versus bleeding complications, and the duration of treatment make it difficult to develop consistent and coordinated hospital-based approaches to VTE prevention. Studies have shown that management of VTE prevention is often suboptimal with many patients failing to receive appropriate dosing and monitoring of anticoagulant therapy. 6 Key elements for a successful VTE prevention program include institutional support, a multi-disciplinary team, accurate data, specific and achievable goals, and a solid QI framework.⁷

Cases and Lessons Learned

The SQR reports reviewed for this Advisory involved patients in the age range of 40 to 65 years, who developed VTE following orthopedic surgical procedures on the knee, (i.e., meniscus and ACL repair, total knee replacement). The cases illustrated the following:

- the need for careful evaluation of patient comorbidities and risk factors (for example, history of VTE, post-menopausal hormone replacement⁸);
- the difficulty in establishing clear system wide protocols, due to the wide range of options available for VTE prophylaxis, and lack of clarity as to the best option;^{9,10}
- the importance of engaging the patient in discussion of the risks, so as to assure compliance with the treatment plan post-discharge (for example, early ambulation); and

⁴ Michota, op. cit.

⁵ Merli, G. Improving Venous Thromboembolism Performance: A Comprehensive Guide for Physicians and Hospitals. Hosp Practice 2010; 38(3):7-16.

⁶ Dobesh, PP et al. Role of the Pharmacist in Achieving Performance Measures to Improve the Prevention and Treatment of Venous Thromboembolism. Pharmacotherapy 2013;33(6):650–664).

⁷ Worel, JN. Venous Thromboembolism. What is preventing achievement of performance measures and consensus guidelines? J Cardiovasc Nursing 2009; 24(6S):S14-19.

⁸ Sidney, S et al. Recent Combined Hormonal Contraceptives (CHCs) and the Risk of Thromboembolism and Other Cardiovascular Events in New Users. Contraception 2013; 87:93-100.

⁹ Stewart, DW et al. Aspirin for the Prophylaxis of Venous Thromboembolic Events in Orthopedic Surgery Patients: A Comparison of the AAOS and ACCP Guidelines with Review of the Evidence. Ann Pharmacother 2013; 47:63-74.

¹⁰ Maletis, GB et al. Incidence of Symptomatic Venous Thromboembolism after Elective Knee Arthroscopy. J Bone Joint Surg Am 2012; 94:714-20

• the necessity for periodic assessment of the literature to assure that hospital-wide and departmental VTE prevention guidelines are up to date.

Areas for Health Care Facility Systems Review

The areas described below provide topics and references, as support for internal discussion and review of health care facility VTE prevention protocols.

Screening for patient VTE and bleeding risk factors

- Surgical and patient risk factors. It is critical that consistent screening for surgical procedure and patient risk factors for VTE and bleeding is carried out in the pre-operative period. The screening data may then be used to tailor VTE prophylaxis for optimal patient safety and can help guide discharge planning and medication reconciliation. Surgical procedure factors (e.g. length of surgery, presence of trauma, orthopedic surgery) have a significant impact on VTE risk regardless of patient characteristics. Patients may have risk factors for VTE (e.g. advanced age, sepsis, history of VTE), bleeding (e.g. known bleeding disorder, severe liver or kidney impairment) or both.
- Screening tools. There are a number of effective screening tools for patient VTE and bleeding
 risk factors. The Caprini VTE Risk Assessment method is frequently used for surgical patients.¹¹
 Implementing a consistent VTE and bleeding screening protocol for surgical patients is
 recommended.
 - The Institute for Clinical Systems Improvement developed a VTE prophylaxis guide¹² with a full checklist of standard VTE and bleeding risk factors, including the Caprini model, and is available at https://www.icsi.org/asset/ht2bhd/VTEProphy-Interactive1112.pdf
 - An online VTE incidence calculator for hospitals is available from Institute for Healthcare Improvement/Society of Hospital Medicine at http://www.ihi.org/knowledge/Pages/Tools/HospitalAcquiredVTEIncidenceCalculator.as
 px
 - An online bleeding risk calculator from the University of Massachusetts Medical School Center for Outcomes Research is available at http://www.outcomes-umassmed.org/IMPROVE/risk score/bleeding/index.html

¹¹ Caprini, J. Thrombosis Risk Assessment as a Guide to Quality Patient Care. Dis Mon 2005; 51:70-78.

¹² Jobin, S et al. Venous thromboembolism prophylaxis. Institute for Clinical Systems Improvement (ICSI); 2012; 1-51. Accessed on 8/21/13 at https://www.icsi.org/ asset/ht2bhd/VTEProphy-Interactive1112.pdf.

VTE prevention guidelines differences and impacts on hospital prevention programs

There are several issues that may impede or complicate the implementation and success of hospital VTE prevention programs:

- There are several major guidelines (see additional references) on VTE prevention that have changed significantly over time. The differing recommendations between guidelines give providers wide latitude in VTE prevention options, allowing for individual variation and preferences, but also complicating efforts at standardization and consistency in hospital VTE prevention programs. Table 1 highlights examples of these differences.
- National Hospital Inpatient Quality (NHIQ) VTE measures, derived initially from the 8th edition of the ACCP guidelines released in 2008, require pharmacologic VTE prophylaxis for most hospitalized patients unless the provider gave a reason for no prophylaxis or alternative choices. The ACCP guidelines are intended for patients at increased risk for VTE, and the broad application of the recommendations to most hospitalized and surgical patients raised concerns for the unnecessary disruption of existing effective hospital VTE prevention programs and the increased risk of bleeding and post-operative infections for low-moderate VTE risk patients. ^{13,14}

Table 1: Guideline differences regarding VTE measures for Total Hip/Knee Arthroplasty (THA/TKA)

Guideline for THA/TKA	LMWH ⁴ preferred	Aspirin recommended	Length of treatment
2008 ACCP ¹	Yes	No	10 days min., consider up to 35 days
2011 AAOS ²	No preference	Yes, with several equal alternatives	Provider-patient discussion
2012 ACCP	Yes	Yes	10-14 days min., consider up to 28-35 days
2010 NICE ³	Yes, one of 5 options	No	10-14 days TKA, 28-35 days THA

¹American College of Chest Physicians, ²American Academy of Orthopaedic Surgeons, ³National Institute for Health and Clinical Excellence (UK), ⁴low molecular weight heparin

¹³ Baker, DW et al. Evidence-Based Performance Measures: Preventing Unintended Consequences of Quality Measurement. Ann Intern Med. 2011; 155:638-640.

¹⁴ Wang, Z et al. Compliance with Surgical Care Improvement Project Measures and hospital-associated infections following hip arthroplasty. J Bone Joint Surg Am 2012; 94:1359-66.

Examples of potential barriers for hospital VTE prevention programs 15,16

- **Provider**: lack of familiarity and/or agreement with guidelines; concern about bleeding; VTE not perceived as a problem; concern about infection from wound hematomas; difficulties with use of oral anticoagulants; prefer to make treatment decisions on a case-by-case difference.
- **Environmental/systems**: lack of adequate time, staff, counseling materials and/or reminder systems; lack of audit tools and feedback; undefined roles and responsibilities; no clear incentives for guideline adherence.
- A 2008 survey of U.S. orthopedic surgeons found that 97% of respondents used VTE prophylaxis but that there were wide variations in prophylaxis practices.¹⁷ While most surgeons recalled VTE episodes more often than clinically important bleeding, 49% were more concerned about bleeding than VTE. This concern may be seen in findings that 23% of surgeons using warfarin preferred a target International Normalized Ratio (INR) of ≤2.0 and only 23% followed the ACCP recommended INR range of 2.0-3.0.

Factors to consider when developing/updating hospital VTE prevention programs

- The lack of a standardized approach can potentially lead to communication difficulties during provider and facility transitions; confusion about medications, dosing and length of therapy; and failure to use hospital and quality improvement resources.
- Components of a hospital VTE prevention program may include: 18,19,20,21,22
 - VTE order sets: VTE and bleeding risk screens, mechanical and pharmacologic options, and dosing parameters.
 - Electronic reminders: EMR alerts for VTE prevention have been shown to have a significant impact on VTE rates.²³

¹⁵ Worel, JN. op. cit.

¹⁶ Merli, op. cit.

¹⁷ Anderson, FA et al. Prevention of Venous Thromboembolism After Hip or Knee Arthroplasty. J of Arthroplasty 2012; 27(5):659-66.

¹⁸ Worel, JN. op. cit.

¹⁹ Maynard, G et al. Designing and implementing effective venous thromboembolism prevention protocols: lessons from collaborative efforts. J Thromb Thrombolysis 2010; 29:159–166.

²⁰ Merli, op. cit.

²¹ Michota, op. cit.

National Collaborating Centre for Acute and Chronic Conditions. Venous thromboembolism: reducing the risk. Reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients admitted to hospital. London (UK): National Institute for Health and Clinical Excellence (NICE); 2010. Accessed on 9/4/13 at http://guidance.nice.org.uk/CG92.

²³ Mitchell, JD et al. A simple reminder system improves venous thromboembolism prophylaxis rates and reduces thrombotic events for hospitalized patients. Journal of Thrombosis and Haemostasis 2012; 10: 236–243.

- Discharge planning: medication reconciliation, pharmacist involvement, improved interfacility communication and scheduling of follow up appointments and testing (if needed).
- VTE prevention multi-disciplinary teams, and multi-disciplinary education strategies for maximum impact.
- o Institutional support is critical for successful implementation.
- Audit and feedback: regular auditing of VTE and bleeding risk assessments and use of appropriate VTE prevention measures, with feedback to providers. An iterative process of audit and feedback can refine or improve a VTE prevention strategy and help providers improve their prophylaxis practice.
- The use of reliable benchmarks to facilitate patient risk assessment and inform data collection.²⁴
- Anticoagulation drug interactions can lead to increased risk of bleeding and other complications.²⁵ Medication reconciliation upon admission, post-operatively and at discharge can reduce adverse drug events.
- Pharmacist led or assisted VTE prevention program²⁶ and/or inpatient pharmacist-directed anticoagulation service²⁷ can reduce the risk of adverse drug events, particularly with warfarin, and improve the effectiveness of a VTE prevention program. Hospitals that do not have access to an anticoagulation service can involve pharmacists and hematologists in the development and implementation of a VTE prevention program. The August 2010 Quality and Patient Safety Division newsletter highlights the successful team approach to anticoagulation therapy at Baystate Franklin Medical Center.²⁸
- Medical inpatients may be at equal or higher risk for VTE and often do not receive appropriate VTE prophylaxis.^{29,30} Many of the measures noted previously can be applied to medical inpatients as well as surgical patients.

²⁴ Januel, JM et al. Symptomatic In-Hospital Deep Vein Thrombosis and Pulmonary Embolism Following Hip and Knee Arthroplasty Among Patients Receiving Recommended Prophylaxis: A Systematic Review. JAMA 2012; 307(3):294-303.

²⁵ Piazza, G et al. Anticoagulation-associated adverse drug events. Am J of Med 2011; 124:1136-42.

²⁶ Dobesh, op. cit.

²⁷ Schillig, J et al. Clinical and Safety Impact of an Inpatient Pharmacist-Directed Anticoagulation Service. J of Hosp Med 2011; 6:322-328.

²⁸ Campbell, G. Baystate Franklin Medical Center: A Team Approach to Anticoagulation Therapy. First Do No Harm, Newsletter of the Quality and Patient Safety Division 2010:4. Accessed 9/2/13 at http://www.mass.gov/eohhs/provider/licensing/occupational/physicans/quality-patient-safety/newsletters.html

²⁹ Bahl, V et al. A Validation Study of a Retrospective Venous Thromboembolism Risk Scoring Method. Ann Surg 2009; 251(2):344-50.

³⁰ Cohen, AT et al. Venous Thromboembolism Risk and Prophylaxis in the Acute Hospital Care Setting (ENDORSE study): a Multinational Cross-sectional Study. The Lancet 2008; 371(9610):387-94.

Conclusion

Venous thromboembolism is a serious risk for surgical and medical inpatients. VTE prevention guidelines differences, resource limitations, and the wide variety of provider approaches and biases present significant challenges. Multidisciplinary teams can be used to review screening protocols and VTE prophylaxis strategies in the development of hospital VTE prevention programs. Pharmacist-led or pharmacist-assisted programs and the use of anticoagulation services should be considered. An iterative development and implementation process can identify potential problems and address provider concerns, allowing for a more successful and effective VTE prevention program.

VTE Prevention Guidelines and Other Resource Materials

ACCP 2008 guidelines: http://journal.publications.chestnet.org/issue.aspx?issueid=22073

ACCP 2012 guidelines: http://www.chestnet.org/Guidelines-and-Resources/Guidelines-and-Consensus-Statements/Antithrombotic-Guidelines-9th-Ed

AAOS 2011 guidelines: http://www.aaos.org/research/guidelines/VTE/VTE guideline.asp

NICE 2010: National Institute for Health and Clinical Excellence (UK) http://guidance.nice.org.uk/CG92

ICSI: Institute for Clinical Systems Improvement

https://www.icsi.org/guidelines more/catalog guidelines and more/catalog guidelines/catalog cardi ovascular guidelines/vte prophy/

NHIQ/The Joint Commission measures:

http://www.jointcommission.org/performance measurement.aspx

Massachusetts Coalition for the Prevention of Medical Errors: Reducing Medication Errors – Anticoagulation Medication Safety http://macoalition.org/Initiatives/inititatives_anticoagulation.shtml

Premier Safety website: https://www.premierinc.com/quality-safety/tools-services/safety/topics/Venous-Thromboembolism/venous-thromboembolism-resources.jsp

AHRQ: Agency for Healthcare Research and Quality, Preventing Hospital-Acquired Venous Thromboembolism http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/vtguide/index.html

Institute for Quality Improvement: Patient Safety Toolkit: Ambulatory Surgery and VTE http://www.aaahc.org/en/institute/Free-Downloads-Patient-Safety-Toolkits-and-Whitepapers/