Session 16: DVT Debate in Joint Arthroplasty

Learning Objectives
Upon completion of this activity, participants should be able to:

1. Understand the similarities and differences between the various guidelines that have been developed for deep vein thrombosis prophylaxis after total hip arthroplasty.

2. Define advantages and disadvantages of different prophylaxis agents used for prophylaxis after total hip and knee arthroplasty.

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Chest Surgeon Guidelines

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Introduction: In 2004, updated American College of Chest Physicians (ACCP) guidelines were published.¹ These recommendations became the de facto “gold standard” for third parties, such as hospitals, insurance companies, and attorneys.

Materials and Methods: Strengths and weaknesses as well as methodology will be evaluated. Concerns with application of Chest guidelines will be discussed. Warfarin (INR 2-3), low-molecular-weight heparin (LMWH), and fondaparinux met Grade 1A criteria for recommendation for total hip replacements (THR) and total knee replacements (TKR). Additionally, intermittent pneumatic compression received a Grade 1B recommendation for TKR.

Results: The strength of the Chest guidelines is that evidence-based medicine was truly applied to the process. There were very strict criteria for studies to be referenced. These studies were critically evaluated by experts in the field. Recommendations were appropriately stratified as to Grade 1 (strong recommendation with benefits outweighing risk, burden, and cost) and Grade 2 (less certainty) with “A” rated recommendations having randomized controlled trials (RCTs) with consistent unbiased results, “B” having RCTs with inconsistent results or methodology weaknesses, and “C” recommendations from observational studies.
Orthopaedic surgeons have reported complications with implementation of these guidelines. Burnett et al\textsuperscript{2} reported significant surgical site complications when administering LMWH for 10 days (4.7% readmission, 3.4% irrigation and debridement rate, and 5.1% prolonged hospitalization). Parvizi et al\textsuperscript{3} have shown that those patients with wound hematoma or persistent wound drainage are at increased risk of postoperative deep joint infection.

Discussion: Orthopaedic surgeons are acutely concerned about postoperative wound complications and infections. Given similar efficacies in prevention of pulmonary emboli, orthopaedists may prefer less “risky” methods of prophylaxis than those recommended by the ACCP. Additionally, these ACCP guidelines may be more expensive to patients.

Summary: Orthopaedic surgeons must carefully weigh the risks and benefits of proposed DVT prophylaxis.

References


AAOS Guidelines

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A work group of the American Academy of Orthopaedic Surgeons, with the assistance of the Center for Clinical Evidence Synthesis at Tufts–New England Medical Center, has proposed a guideline for the prevention of symptomatic (and fatal) pulmonary embolism in patients undergoing total hip and knee arthroplasty. This guideline includes recommendations from both a consensus process and an analysis of 42 publications since 1996. The end points included symptomatic and fatal pulmonary embolism rates, total death rates, and major bleeding complications. The guideline recommends the preoperative evaluation of all patients for “standard” and “high” risks of both pulmonary embolism and major bleeding complications. The use of regional anesthesia, mechanical prophylaxis, rapid mobilization, and patient education were consensus recommendations.
The choice of a specific medication post-operatively should be based on an individual risk-benefit analysis of pulmonary embolism and major bleeding complications.

**General Recommendations**

**Consensus Process**

- Assess all patients preoperatively for standard vs high risk for pulmonary embolism (III B)
- Assess all patients preoperatively for standard vs high risk for bleeding complications (III C)
- Consider patients who have contraindications for anticoagulation for vena cava filter (V C)
- Consider intraoperative and/or immediate postoperative mechanical compression (III B)
- Consider regional anesthesia for the procedure (in consultation with anesthesiologist) (IV C)
- Consider continued use of mechanical prophylaxis postoperatively (IV C)
- Rapid patient mobilization (V C)
- Routine screening for thromboembolism is not recommended (III B)
- Patient education on symptoms of thromboembolism after discharge (V B)
Recommendation – Medication
Literature Review – Analysis Process

• Standard risk pulmonary embolism and major bleeding
  (in alphabetical order)
  aspirin
  LMWH
  penta-saccharide
  warfarin (INR ≤ 2)
  (III B)
  (C dosing, timing)

• Elevated risk pulmonary embolism; standard risk bleeding
  (in alphabetical order)
  LMWH
  penta-saccharide
  warfarin (INR ≤ 2)
  (III B)
  (C dosing, timing)

• Standard risk pulmonary embolism; elevated risk bleeding
  (in alphabetical order)
  aspirin
  warfarin (INR ≤ 2)
  none
  (III C)

• Elevated risk pulmonary embolism and bleeding
  (in alphabetical order)
  aspirin
  warfarin (INR ≤ 2)
  none
  (III C)
The Centers for Medicare and Medicaid Services (CMS) is in the process of reevaluating how it reimburses hospitals and physicians for medical care. In 2007, Thomas Gustafson, PhD, Director of the Center for Medicare Management, said, “Since its inception, the fee-for-service Medicare program has been largely a passive payer of health care services. Given the size and impact of this program, now and in the future, it is vital that we transform into an active purchaser of high-quality, efficient care both from a health and fiscal policy perspective. We must attend with particular care to how we pay hospitals and physicians given the growth in the volume and intensity of their services.”

Several new terms and phrases have emerged that are important for physicians to understand. These include:

1. “Hospital-acquired conditions,” also known as preventable medical error, potentially avoidable conditions, and health care–associated conditions. Hospital-acquired conditions are complications that occur even within the practice of evidence-based medicine. An example would be a postoperative wound infection.

2. “Never events,” complications that should never occur and are often reportable to state and federal agencies. An example of a never event is an object left in during surgery.

Certain hospital-acquired conditions deemed by the CMS to be “reasonably preventable” and acquired during the inpatient hospital stay will not receive additional payment. Included in these conditions for fiscal year 2009 are deep venous thrombosis and pulmonary embolism after primary total hip and knee replacement, partial hip replacement, total hip resurfacing, and partial hip resurfacing. Based on the Medicare Severity Diagnosis-Related Groups (MS-DRGs) system in place prior to this fiscal year, only pulmonary embolism has payment implications as historically deep venous thrombosis as a complication did not modify the DRG, resulting in higher reimbursement for the hospital.

It is also important for surgeons to know about the Surgical Care Improvement Project (SCIP), a national project aimed at reducing postoperative complications by 25% by 2010. SCIP is one of the Joint Commission’s Core Measures that will be reported publicly. The SCIP measures include venous thromboembolism (VTE) prophylaxis. For elective total knee replacement, any of the following are deemed appropriate: low-molecular-weight heparin (LMWH), adjusted-dose warfarin, fondaparinux, or intermittent pneumatic compression. For total hip replacement, any of the following are
deemed appropriate: LMWH, adjusted-dose warfarin, or fondaparinux. The medical record must document that VTE prophylaxis was ordered and that it was instituted within 24 hours prior to surgery to 24 hours after surgery. If there is a medical contraindication to the recommended prophylaxis, it must be documented in the medical record.

Aspirin is Enough

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Aspirin (ASA) when used within a multimodal approach for venous thromboembolism (VTE) prophylaxis for total joint replacement (TJR) continues to be an excellent choice for many surgeons because:

1. Low-dose ASA is inexpensive, tolerated by almost all patients, and does not require monitoring.1
2. ASA works, is safe, and has a long and excellent track record in the TJR literature.1-3
3. The primary reason for the use of chemoprophylaxis should be for pulmonary embolism (PE) or death, not deep venous thrombosis (DVT). ASA compares favorably when considering these end points.4
4. ASA does not complicate anesthesiologists’ practice patterns or adversely affect neuraxial bleeding complication rates associated with other anticoagulants.5
5. ASA, given preoperatively, is protective for prevention of platelet aggregation in the operating room and in the immediate postoperative time period, which is in contrast to chemoprophylaxis agents that require a designated time delay postoperatively before administration.
6. Low-dose ASA, unlike other anticoagulants, allows for the concomitant use of nonsteroidals (NSAIDs) in the postoperative period as a part of a multi-modal pain management approach.
7. The use of ASA is associated with an extremely low incidence of wound healing problems, hematoma, and the other serious bleeding complications associated with anticoagulants.1,4
8. Postoperatively, patients already taking ASA, are likely to have a better prognosis when untoward postoperative medical complications, such as stroke or myocardial infarction, inevitably occur.6,7

VTE events after total knee replacement (TKR) and total hip replacement (THR) have been reduced over the past decade, for a variety of reasons. These include early mobilization, more efficient and less traumatic surgical procedures, and use of pneumatic compression devices, better pain management allowing early mobilization, use of regional anesthesia, and the now-routine use of a variety of chemoprophylaxis agents in a multi-modal approach toward VTE. ASA has been used as chemoprophylaxis method
following TJR for decades. Many surgeons continue to believe that, after patient risk assessment for VTE, ASA remains the safest option for the majority of their TJR patients.\textsuperscript{1} For the thoughtful surgeon, choosing a chemoprophylaxis method is a classic risk versus benefit analysis of reduction in the incidence of DVT offset by an increased incidence of bleeding events.\textsuperscript{4} These bleeding concerns are often considered to be minor by pulmonologists and other medical specialists recommending chemoprophylaxis protocols for TJR.\textsuperscript{8-10} This disparity of perspective has caused considerable controversy due to organized efforts to “standardize” practice patterns and adopt treatment guidelines.

Many currently proposed anticoagulant agents are associated with significant bleeding risks for surgical and anesthesia procedures.\textsuperscript{4,11} Furthermore, VTE data obtained in prospective-randomized drug trials have occurred only in healthy patients with no prior DVT or VTE events. VTE data should be collected in all patient groups, not just healthy patients, as most clinicians also provide care for sick patients and the consequences of bleeding events in sick and elderly patients are almost certainly increased in severity and incidence. One must also ask whether the lack of any well-controlled clinical trials—including and assessing aspirin prophylaxis for TJR—is perhaps due to a lack of economic incentive for drug companies who sponsor trials of many new chemoprophylaxis agents.

To date, investigators have focused only on DVT in healthy patients without prior DVT as the marker of a successful chemoprophylaxis regimen. DVT is most likely not an accurate marker for risk for embolic disease after TJR as no association has been demonstrated between the presence of a DVT and subsequent symptomatic or fatal PE after TJR.\textsuperscript{4} If DVT were an accurate marker, the incidence of PE should decline proportionately with DVT reduction; a correlation never demonstrated. The use of DVT as a surrogate marker for the patient at risk for PE must be carefully reevaluated. Rather, primary questions to ask include whether aspirin is as effective as judged by the prevalence of fatal PE, nonfatal PE, and symptomatic DVT in the first 6 weeks after TJR. Most large clinical trials that demonstrate a DVT reduction are not designed to determine clinical outcomes and the impact of DVT or adverse events related to the use of anticoagulation in patients after TJR.\textsuperscript{1} No analysis has been made regarding the final result in patients who have substantial bleeding, minor bleeding, wound healing problems, medical complications, or thrombotic events. A significant concern with regard to the reporting of bleeding complications, and their outcomes, is whether or not past studies have even categorized these events into minor or major bleeding events correctly.\textsuperscript{4} Rather, the concepts of all-cause mortality\textsuperscript{12} and clinical functional outcomes\textsuperscript{1,13} associated with a chosen chemoprophylaxis method seem to be rational end points to consider in future investigations.

In conclusion, ASA in combination with contemporary practice protocols for TJR may be all that is required for a safe and effective VTE chemoprophylaxis regimen for the majority of patients undergoing TJR.\textsuperscript{1,2,4,14-25}
References


**Low-Molecular-Weight Heparin: The Latest Facts**

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*Background:* Without prophylaxis, venous thromboembolic events (VTEs) may occur in 40% to 85% of patients who undergo hip and knee replacement. Of greater concern is the risk of symptomatic and fatal pulmonary embolus. Without prophylaxis, the overall rates of pulmonary emboli and fatal pulmonary emboli have been reported to be between 1% to 28% and 0.1 to 2.0% respectively. Prophylaxis with a variety of chemical and mechanical agents has been shown to reduce the occurrence of all VTEs, and consequently it has become the standard for patients undergoing major orthopaedic surgery. A survey of members of the American Association of Hip and Knee Surgeons showed 100% use some form of prophylaxis. However, controversy still surrounds the
most suitable modalities. Tradeoffs in efficacy, incidence of bleeding events, patient convenience, and cost issues exist with all modalities. Low-molecular-weight heparin is one option.

**Low-Molecular-Weight Heparin (LMWH):** The LMWHs have gained in popularity for DVT prophylaxis. They have gained in popularity not only because of their well documented bioavailability but also the failure to require routine monitoring of clotting indices. The efficacy of LMWHs is well documented. After TKA, the total DVT rate using the pooled data from 6 randomized studies was 48% versus 33%, with proximal rates of 10.4% versus 7.1%; however, there was a higher bleeding rate with LMWH versus warfarin, with major bleeding complications occurring in 4.5% versus 2.7% ($P = .02$). Also, cost for the medication remains relatively high.

**Conclusions:** Prophylaxis after hip and knee replacement has become the standard of care with a variety of modalities. The optimal protocol depends on numerous factors; however, it appears that in general a trade-off exists between prevention of VTE and the risk of bleeding. Therefore, each surgeon must consider the risks and benefits.

**Clinical Relevance:** Due to the high rate of VTE following hip and knee arthroplasty, DVT prophylaxis has become the standard of care. LMWH remains an option.

References

**Warfarin: What is Our Goal?**

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**Background:** Venous thromboembolism remains the most common cause of hospital readmission and death after total joint arthroplasty. We sought to define the role of routine screening for deep venous thrombosis (DVT) and the efficacy of extended low-intensity (INR 2.0) warfarin prophylaxis to prevent thromboembolism after total hip and knee arthroplasty.
Methods: The study was conducted at 3 university teaching hospitals from 1984 through 2003; 3293 patients undergoing total hip (N = 1972) or knee (N = 1321) arthroplasty were consented and enrolled. Screening contrast venography performed before discharge was the basis for ongoing anticoagulation therapy. For the duration of the study, patients with negative venography received no outpatient anticoagulation. From 1984 through 1992, patients not completing venography were discharged without further anticoagulation; from 1993 through 2003, patients without venography received low-intensity warfarin (international normalized ratio, 2.0) for 6 weeks after operation. Patients with documented venous thromboembolism (VTE) received standard therapy. All deaths and readmission for DVT, pulmonary embolism (PE), and bleeding were audited 6 months postoperatively.

Results: Extended warfarin prophylaxis reduced overall readmission for VTE (2 of 844 [0.2%] versus 38 of 2449 patients [1.6%]; \( P = .0015 \)) and eliminated PE (0 of 844 versus 17 of 2449 patients [0.7%]; \( P = .01 \)) after total hip and knee arthroplasty. Four patients (3 hip arthroplasty, 1 knee arthroplasty) suffered fatal PE; all had negative venography and received no outpatient warfarin after discharge. Readmission occurred in 1.8% (24 of 1357 patients) who had negative venography and received no further anticoagulation after discharge, compared with 0.2% (2 of 844 patients; \( P = .0007 \)) who completed a 6-week course of warfarin. Three bleeding events (3 among 3293 patients [0.1%]) resulted in 1 death and 2 reoperations.

Conclusions: Extended low-intensity (INR 2.0) warfarin prophylaxis reduces readmission for all thromboembolic events \( (P = .0015) \) and PE \( (P = .01) \) after total hip and knee arthroplasty, with a low rate (0.1%) of clinically meaningful bleeding events.

Clinical Relevance: Low-intensity warfarin represents a therapeutic compromise that effectively prevents thromboembolic events while accepting a residual DVT rate in return for less bleeding than more intensive anticoagulants.

References

Case Presentations and Discussion Panel
C. Lowry Barnes, MD; Paul F. Lachiewicz, MD; William J. Maloney, MD; Arlen D. Hanssen, MD; Henry D. Clarke, MD; Vincent D. Pellegrini, Jr, MD