Effective Health Care

Prevention of Venous Thromboembolism in Orthopedic Surgery Nomination Summary Document

Results of Topic Selection Process & Next Steps

- Prevention of venous thromboembolism in orthopedic surgery will go forward for refinement as a comparative effectiveness or effectiveness review. The scope of this topic, including populations, interventions, comparators, and outcomes, will be further developed in the refinement phase.

- When key questions have been drafted, they will be posted on the AHRQ Web site and open for public comment. To sign up for notification when this and other Effective Health Care (EHC) Program topics are posted for public comment, please go to http://effectivehealthcare.ahrq.gov/getinvolved.cfm?involvetype=subscribe.

Topic Description

Nominator: Health care professional association

Nomination Summary: This nomination concerns the prevention of venous thromboembolism (VTE) in orthopedic surgery. The nominator is interested in the effectiveness of thromboprophylaxis in patients undergoing major orthopedic surgery (total hip and knee replacement, hip fracture surgery), the effectiveness and comparative effectiveness of agents for thromboprophylaxis in these patients (including pharmacological and mechanical interventions), and the impact of pre-discharge ultrasound. The nominator questions the baseline risks for these patients and what factors may affect rates of VTE or bleeding outcomes. The nominator also questions whether VTE can be estimated by measuring deep vein thrombosis as a surrogate outcome. Finally, the nominator questions the effectiveness and comparative effectiveness of thromboprophylactic agents for patients with other orthopedic conditions (e.g., distal to knee injuries, injuries requiring knee arthroscopy, and elective spine surgery).

Key Questions from Nominator:

1. In patients undergoing major orthopedic surgery (total hip and knee replacement, hip fracture surgery), what is the relative impact of thromboprophylaxis (any agent, any external mechanical intervention) compared to no thromboprophylaxis on VTE (i.e., asymptomatic DVT [surrogate for symptomatic VTE]; symptomatic DVT; non-fatal pulmonary embolism; fatal pulmonary embolism); bleeding (operative site vs. non-operative site); discomfort; re-admission; re-operation; and total mortality?
2. In patients undergoing major orthopedic surgery (total hip and knee replacement, hip fracture surgery), what is the relative impact of aspirin compared to injectable antithrombotic agents (low molecular weight heparins (LMWH) vs. unfractionated heparin vs. fondaparinux) compared to oral vitamin K antagonists (VKAs) compared

to external mechanical interventions on VTE (i.e., asymptomatic DVT [surrogate for symptomatic VTE]; symptomatic DVT; non-fatal pulmonary embolism; fatal pulmonary embolism); bleeding (operative site vs. non-operative site); discomfort; re-admission; re-operation; and total mortality?

3. In patients undergoing major orthopedic surgery (total hip and knee replacement, hip fracture surgery) who have known contraindications to antithrombotic agents, what is the relative impact of prophylactic vena cava filter placement compared to any external mechanical intervention on VTE (i.e., asymptomatic DVT [surrogate for symptomatic VTE]; symptomatic DVT; non-fatal pulmonary embolism; fatal pulmonary embolism); bleeding (operative site vs. non-operative site); discomfort; re-admission; re-operation; placement risks and long-term risks associated with vena cava filters; and total mortality?
4. In patients undergoing major orthopedic surgery (total hip and knee replacement, hip fracture surgery), what is the relative impact of pre-discharge ultrasound DVT screening (plus DVT treatment, if positive) compared to no pre-discharge DVT screening on VTE (i.e., asymptomatic DVT [surrogate for symptomatic VTE]; symptomatic DVT; non-fatal pulmonary embolism; fatal pulmonary embolism); bleeding (operative site vs. non-operative site); discomfort; re-admission; re-operation; and total mortality?

Elaboration on population for PICO questions 1-4:

- What is the overall baseline risk of VTE outcomes in patients undergoing hip surgery, hip fracture surgery, and knee replacement surgery? Does this risk vary over time?
- What is the overall baseline risk of bleeding outcomes in patients undergoing hip surgery, hip fracture surgery, and knee replacement surgery? Does this risk vary over time?
- What patient characteristics, if any, can differentiate patients according to risk of VTE outcomes in patients undergoing hip surgery, hip fracture surgery, and knee replacement surgery? Do these factors vary across the three surgeries?
- What patient characteristics, if any, can differentiate patients according to risk of bleeding outcomes in patients undergoing hip surgery, hip fracture surgery, and knee replacement surgery? Do these factors vary across the three surgeries?

Elaboration on interventions for PICO questions 1-4:

- What are the desirable and undesirable effect estimates when comparing within different class agents (e.g., injectable antithrombotic agents: low molecular weight heparins (LMWH) vs. unfractionated heparin vs. fondaparinux)?
- What are the desirable and undesirable effect estimates of combination antithrombotic treatment vs. single modality/agent (e.g., mechanical intervention plus ASA)?
- What are the desirable and undesirable effects of different timings of starting thromboprophylaxis (e.g., 10 hours or 2 hours before surgery or at different time points post op)?
- What are the desirable and undesirable effects of prolonging thromboprophylaxis (any method) for 30 days or longer compared to no thromboprophylaxis after 7 days?

Elaboration on outcomes for PICO questions 1-4:

- In the absence of patient important outcomes, can the relative risk for such outcomes (e.g., less symptomatic VTE) reliably be estimated by measuring surrogate outcomes, such as proximal or distal deep vein thrombosis (DVT) as detected by venography or ultrasound diagnosis?

5. In patients with other orthopedic conditions (e.g., distal to knee injuries; conditions requiring knee arthroscopy; elective spine surgery), what is the relative impact of thromboprophylaxis (any agent, any mechanical intervention) compared to no thromboprophylaxis intervention on VTE (i.e., asymptomatic DVT [surrogate for symptomatic VTE]; symptomatic DVT; non-fatal pulmonary embolism; fatal pulmonary embolism); bleeding (operative site vs. non-operative site); discomfort; re-admission; re-operation; and total mortality?

6. In patients with other orthopedic conditions (e.g., distal to knee injuries; conditions requiring knee arthroscopy; elective spine surgery), what is the relative impact of injectable antithrombotic agents (LMWH vs. unfractionated heparin vs. fondaparinux) compared to mechanical interventions on VTE (i.e., asymptomatic DVT [surrogate for symptomatic VTE]; symptomatic DVT; non-fatal pulmonary embolism; fatal pulmonary embolism); bleeding (operative site vs. non-operative site); discomfort; re-admission; reoperation; and total mortality?

Considerations

- The topic meets all EHC Program selection criteria. (For more information, see http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/.)

- In 2008, the acting Surgeon General issued a Call to Action to reduce the number of cases of deep vein thrombosis (DVT) and pulmonary embolism (PE) in the US. The Call to Action urges a coordinated, multifaceted plan to reduce the number of cases of DVT and PE nationwide, with an emphasis on increased awareness of DVT and PE; evidence-based practices; and additional research on the causes, prevention, and treatment of VTE.

- Patients undergoing major orthopedic surgery (total knee replacement, total hip replacement, or hip fracture surgery) are at particularly high risk for VTE.