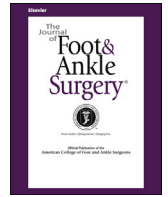




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Routine Use of Low-Molecular-Weight Heparin For Deep Venous Thrombosis Prophylaxis After Foot and Ankle Surgery: A Cost-Effectiveness Analysis



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ABSTRACT

The purpose of the present study was to determine whether certain foot/ankle surgeries would benefit from the routine use of low-molecular-weight heparin (LMWH) as postoperative deep venous thrombosis prophylaxis. We conducted a formal cost-effectiveness analysis using a decision analytic tree to explore the healthcare costs and health outcomes associated with a scenario of no prophylaxis and a scenario of routine LMWH prophylaxis for 4 weeks. The 2 scenarios were compared for 5 procedures: (1) Achilles tendon repair (ATR), (2) total ankle arthroplasty (TAA), (3) hallux valgus surgery (HVS), (4) hindfoot arthrodesis (HA), and (5) ankle fracture surgery (AFS). The outcomes assessed included short- and long-term costs, quality-adjusted life-years (QALYs), and incremental cost per QALY gained. The costs were evaluated from the healthcare system perspective and are expressed in U.S. dollars at a 2015 price base. In the short term, routine prophylaxis was always associated with greater costs compared with no prophylaxis. For ATR, TAA, HA, and AFS, prophylaxis was associated with slightly better health outcomes; however, the gain in QALYs was minimal compared with the cost of prophylaxis (incremental cost-effectiveness ratio well above \$50,000/QALY threshold). For HVS, prophylaxis was associated with both worse health outcomes and greater costs. In the long term, routine prophylaxis was always associated with worse health outcomes and either cost more (HA, AFS, HVS) or saved very little (ATR, TAA). We concluded that policies encouraging the routine use of LMWH after foot/ankle surgery are unlikely to be cost-effective. Decisions to perform prophylaxis should be on a case-by-case basis and should emphasize individual patient risk factors.

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Venous thromboembolic disease (VTED), which includes deep venous thrombosis (DVT), affects 300,000 to 600,000 people and is the proximate cause of >60,000 deaths annually in the United States (1). Surgery is a recognized risk factor for VTED (2–7); however, the incidence after foot and ankle surgery has been considerably lower than that reported for other areas of the body (8–12). Low-molecular-weight heparin (LMWH), for example, is routinely prescribed after hip and knee replacement surgery (13); however, its use varies widely among providers after foot and ankle surgery (14,15). Recommendations from several prominent foot and ankle societies have recently suggested that routine chemical prophylaxis is not warranted when

Risk factors for venous thromboembolism disease during management of foot and ankle conditions

| Patient Specific | Treatment Specific | Surgery/Injury Specific |
|--|--|--|
| Primary | | |
| Personal history of VTED Hypercoagulability Active/recent (<6 mo) cancer | Immobilization >4 wk | |
| Secondary | | |
| Advanced age (>60)* Obesity (BMI >30) Family history of VTED OCP or HRT use [†] Varicose veins Diabetes mellitus or >1 comorbidity Severe foot/ankle injury | Non-weightbearing Hospitalization Bed rest | Achilles tendon rupture [‡] Ankle fracture [‡] Total ankle replacement Hindfoot arthrodesis General anesthesia |

Abbreviations: BMI, body mass index; HRT, hormone replacement therapy; OCP, oral contraceptive pill; VTED, venous thromboembolism disease (includes deep venous thrombosis or pulmonary embolism).

Fig. 1. Risk factors for deep venous thrombosis after foot and ankle surgery can be divided into 1 of 3 categories generally—patient specific, treatment specific, and surgery specific. Although none of the surgery-specific factors in the far right column identified in the recent American College of Foot and Ankle Surgeons clinical consensus statement reached the level of a primary risk factor, the present study tested this assumption using direct costs and utilities as outcomes. Reprinted, with permission, from Fleischer et al (16).

carrying for foot/ankle disorders that require immobilization. They instead recommended that patients be risk stratified by their provider and have a VTED prevention plan (which could include the use of LMWH) tailored to their individual risk level (13,16,17). Because it is well known that the rate of VTED varies greatly after foot/ankle surgery (e.g., the rate of distal, asymptomatic DVT varies anywhere from 2% with hallux valgus surgery (18) to as much as 36% after Achilles tendon surgery (19)), we postulated that, similar to hip and knee replacement surgery, the decision to provide chemical prophylaxis, from a strictly cost-effectiveness perspective, might be entirely explained by the type of foot/ankle surgery, regardless of patient-specific factors (e.g., medications, comorbidities, personal history; Fig. 1).

Cost-effectiveness analyses (CEAs) are useful tools for determining which of ≥ 2 competing strategies would be the best allocation of resources. In a CEA, health effects can be measured in natural units of outcome (e.g., the number of deaths) or the value individuals place on their health (e.g., quality-adjusted life-years [QALYs]). QALYs estimate a patient's health-related quality of life and their length of life in a less than perfect state of health. QALYs are useful for determining the cost-effectiveness of competing strategies because they act as a common measure of health benefits and account for such things as mortality and morbidity. Specifically, cost per QALY estimates allow for a comparison between different healthcare interventions that compete for the same pool of resources (20,21). To the best of our knowledge, no study has focused on the costs and health effects of VTED prophylaxis with LMWH after foot and ankle surgery. In the present study, we conducted a CEA to assess whether routine prophylaxis with LMWH after foot and ankle surgery would be a good use of resources, irrespective of patient factors.

Materials and Methods

Overview

A decision tree model using a cohort approach was built in TreeAge Pro Healthcare 2014 (TreeAge Software, Inc., Williamstown, MA). The model was used to conduct a CEA that compared the costs and outcomes of implementing LMWH as a form of chemical DVT prophylaxis versus the strategy of implementing no prophylaxis after foot and ankle surgery. The 2 strategies, prophylaxis with LMWH versus no prophylaxis, were

compared in 5 different surgical scenarios: Achilles tendon repair (ATR), total ankle arthroplasty (TAA), hallux valgus surgery (HVS), hindfoot arthrodesis (HA), and ankle fracture surgery (AFS).

For each surgical scenario, the 2 strategies were compared in terms of 2 outcomes: incremental healthcare costs and incremental QALYs. The 2 outcomes were combined in the form of incremental cost-effectiveness ratios (ICERs). We calculated the short- and long-term results; short-term results were the 1-year outcomes and long-term results were the lifetime outcomes. Costs were evaluated from the healthcare system perspective and are expressed in 2015 U.S. dollars. For the long-term analysis, future costs and QALYs were discounted at a 3% annual rate in accordance with recommendations provided by the U.S. Public Health Service and consistent with other CEAs.

Decision Tree Model

Structure

The decision tree model is presented in Fig. 2. Patients receiving no prophylaxis had several health effects possible, including no event, asymptomatic DVT, symptomatic DVT, or pulmonary embolism (PE). In the case of an asymptomatic DVT, our model allowed for 2 likely outcomes: resolution or mild postthrombotic syndrome (PTS). In the case of symptomatic DVT, 5 potential outcomes were included: resolution, PTS, major hemorrhage, recurrent DVT, or subsequent PE. A patient with PTS could have developed either the mild or severe form of PTS after symptomatic DVT. A patient with major hemorrhage either died or the condition resolved. After recurrent DVT, the condition either resolved or the patient experienced a major hemorrhage due to treatment. After a subsequent PE, the possible outcomes were death, chronic pulmonary hypertension (HTN), major hemorrhage due to treatment, or resolution with treatment. In the prophylactic strategy, in addition to the conditions occurring with no prophylaxis, patients were also at risk of major hemorrhage and symptomatic heparin-induced thrombocytopenia (HIT) due to prophylaxis with LMWH. Patients undergoing any of those 2 conditions either had resolution with treatment or died.

Surgical Scenarios and Events

We selected several surgeries known to be associated with an increased VTED risk (i.e., ATS, AFS, HA, TAA) (16,17,22) and also a common foot surgery (HVS) to model. We considered only outcomes and events that had received frequent enough attention in the published data to be able to calculate summary probabilities. Although less commonly reported, we also considered the costs and health effects associated with PTS. PTS can develop after DVT, and those affected can present for treatment of leg pain and swelling (23). PTS can affect 20% to 50% of patients diagnosed with DVT, and the clinical manifestations can occur within 2 years of the inciting event (24). For those living with PTS, especially the severe form of disease, it can lead to a diminished quality of life (25). The severe form of PTS typically includes venous leg ulcers, which

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