

## **POSITION STATEMENT**

### **The Use of Venous Thromboembolic Disease Prophylaxis in Foot and Ankle Surgery**

#### **Position Statement**

There is currently insufficient data for the American Orthopaedic Foot & Ankle Society (AOFAS) to recommend for or against routine venous thromboembolic disease (VTED) prophylaxis for patients undergoing foot and ankle surgery. Further research in this field is both necessary and encouraged.

The AOFAS is an international medical society of more than 2,400 orthopaedic surgeons and allied health practitioners who specialize in the diagnosis and treatment of injuries, diseases, and other conditions of the foot and ankle. Through education, research, and advocacy, AOFAS mobilizes our members and the healthcare community to improve patient care.

#### **Background**

VTED, encompassing both deep venous thrombosis (DVT) and pulmonary embolism (PE), is a potentially fatal complication of orthopedic surgery. In hip replacement surgery, for instance, the historical incidence of VTED in patients not receiving prophylaxis is as high as 69%.<sup>6,17</sup> The incidence decreases dramatically with various prophylactic measures.<sup>8</sup> Prophylaxis, however, especially by chemical means, is not without risk, including the risk of major bleeding.

Clearly defining and studying VTED in patients undergoing foot and ankle surgery is difficult. First, VTED occurs in patients undergoing foot and ankle procedures with less frequency than in patients undergoing knee and hip arthroplasty. Also, in the surgical treatment of foot and ankle conditions, the procedures performed range widely including isolated toe surgery, arthroplasty, and major trauma surgery. This variability is compounded by the diversity of post-operative protocols, including the use of different levels of immobilization and weight bearing restrictions. Finally, analysis of VTED after foot and ankle surgery is complicated by the fact that the thrombotic endpoint varies in the literature (e.g. clinical<sup>16</sup> versus phlebographic<sup>14</sup> detection and proximal versus distal location).

The existing literature regarding VTED after foot and ankle surgery is conflicting. In a group of patients who underwent Achilles tendon repair, the overall incidence of phlebographically confirmed DVT was 36% in patients not receiving prophylactic anticoagulation, 6% of which were proximal. These rates were not significantly different from those in the patients who did receive prophylactic anticoagulation with dalteparin.<sup>13</sup> A retrospective study of 945 patients with Achilles ruptures treated non-operatively found an incidence of clinically identified DVT of 1.05% and PE of 0.32% without any prophylaxis.<sup>9</sup>

Historical data from a randomized controlled study of plaster immobilization following fracture has reported an incidence of symptomatic DVT of 4.3% without prophylaxis and a 0% incidence with prophylaxis.<sup>12</sup> Meanwhile, a much larger study that examined clinically symptomatic disease reported a rate of VTED under 1% in over 45,000 patients undergoing ankle fracture surgery.<sup>10</sup> Similarly, a study evaluating non-operative treatment of fractures distal to the knee with immobilization and no thromboprophylaxis found only 4 objectively confirmed VTEDs in a population of 1179 subjects.<sup>21</sup> In a more diverse population of 2600 patients undergoing elective foot and ankle surgery over a 7 year time frame, the incidence of symptomatic VTED was between 0.42% and 1.43% with no difference between those treated with aspirin and those who received no prophylaxis.<sup>7</sup>

Guidelines from several different organizations are available to aid in directing clinical decision making, but these, too, are incomplete and contradictory. The United Kingdom's National Institute of Clinical Excellence (NICE) recommends anticoagulation following foot and ankle surgery when there will be prolonged immobilization, when surgical time is greater than 90 minutes or when risks of VTE outweighs the risk of bleeding.<sup>18</sup> The American CHEST guidelines do not recommend use of prophylaxis in isolated lower leg injuries requiring leg immobilization.<sup>3</sup> Neither of these guidelines clearly define best practice for elective foot and ankle surgery cases or the types of surgeries for which prophylaxis should be considered. Both recommendations agree on the importance of risk assessment specific to each patient when making a decision on the use of prophylaxis.

The decision to implement anti-thrombotic prophylaxis, as well as the measures used to do so, should be based upon a patient specific risk/benefit analysis. This must take into consideration the patient's risk for VTED and the potential risks of the proposed prophylactic measures.

There are several known risk factors for VTED. A personal history of thromboembolic disease and a hypercoagulable state have been identified as strong risk factors. Additional risk factors that have been cited include, but may not be limited to, history of recent malignancy, family history of VTED, obesity, oral contraceptive use, multi-trauma, age > 60 years, venous stasis/varicose veins, and prolonged immobilization.<sup>2,15</sup> The amount of increased risk attributed to any individual risk factor has not been definitively defined and their correlation with any specific foot and ankle procedure has not been robustly investigated.<sup>15</sup> Obesity, for instance, has not been shown to be an independent thrombotic risk in all cases.<sup>5</sup> Graded risk assessments have been used in other specialties but have not been validated in foot ankle surgery.<sup>2</sup>

### **Risks and Benefits of VTED Prophylaxis**

Mechanical prophylaxis such as elastic compression stockings and sequential compression calf pumps or foot pumps on the contralateral extremity can be utilized intra-operatively and continued post operatively through the duration of the hospital stay.<sup>1,22</sup> While the true efficacy of this modality in foot and ankle surgery is unknown, complications are negligible and compression pumps may be considered in both the outpatient and

inpatient setting. Whether there is a threshold duration of the surgical procedure for which these are beneficial is unknown, as is the optimal duration of their use post-operatively.

An alternative for mechanical prophylaxis is the utilization of inferior vena cava (IVC) filters. Indications for these devices include patients at high risk for VTED with a specific contraindication to chemical anticoagulation and those who have sustained a pulmonary embolism despite therapeutic anticoagulation. IVC filters are not indicated as first line prevention against thrombosis or embolism and do not prevent the development of a deep vein thrombosis. They are also associated with the risk of significant complications, including vessel injury, hemorrhage, migration, fistula formation, pneumothorax, and thrombosis.<sup>11</sup>

Chemical prophylaxis includes the use of anti-coagulants such as warfarin, unfractionated heparin, and low molecular weight heparins (LMWHs). It also includes aspirin, which is an antiplatelet agent. Aspirin, warfarin, and LMWHs may be continued beyond the hospital or outpatient stay and, therefore, may offer more prolonged protection. The specific indications for the use of these agents in foot and ankle surgery, however, remain undefined. For instance, one investigation failed to demonstrate a statistically significant difference between the incidence of both proximal and distal DVT in patients who underwent Achilles tendon repair and were randomized to receive either dalteparin or placebo.<sup>13</sup> Another investigation, however, demonstrated that in patients requiring prolonged immobilization for treatment of either an Achilles rupture or leg fracture, the use of riviparin resulted in a statistically significant decrease in the rate of distal, but not proximal, DVT confirmed by venography.<sup>14</sup> The extrapolation of either of these studies is limited due to their small numbers.

Several larger, more recent studies have also found mixed results in rates of VTED prevention with the use of chemical prophylaxis. In a study of 1,540 ambulatory patients with ankle fractures requiring open reduction and internal fixation, the incidence of thromboembolic events was 2.99%, with 2.66% involving a deep venous thrombosis and 0.32% involving a nonfatal pulmonary embolism. The clinically detectable thromboembolic event was not influenced by the use of LMWH, warfarin, or no thromboprophylaxis.<sup>19</sup> A British review examined rates of VTED in 2654 patients who underwent 2 or more weeks of immobilization and who were treated with either no prophylaxis (n=1576) or aspirin (n=1078). The overall incidence s of symptomatic VTE's in the two groups was 0.47% and 0.39%, respectively. When assuming all those patients lost to follow up had VTE, in the non-treatment group the rate only rose to 1.46%.<sup>7</sup> A recent randomized, controlled double blinded study of 258 surgically managed isolated fractures below the knee compared dalteparin to placebo and found no statistically significant difference in the rates of VTED's (1.5% vs 2.3%, p=0.68).<sup>20</sup> In fact, the study was cut short as they deemed that there was no additional benefit to treatment. It should be noted that, in all of these studies, patients identified as having increased risk for VTED's were excluded, making it difficult to extrapolate best practices for this population.

Chemical prophylaxis has risks, including both major and minor bleeding events. Major

bleeding events, defined as those that require transfusion, can result in significant morbidity and even be life threatening. These include intra-ocular and intra-cranial bleeds, major bleeds at the surgical site and bleeding in the gastrointestinal tract. Minor bleeds do not require transfusion but can still result in substantial morbidity for the patient. Chemical anti-coagulation may also result in increased wound drainage and peri-incisional hematoma, which can contribute to longer hospital stays and increased risk of surgical site infection. Finally, heparin based chemoprophylaxis carries the specific risk of heparin induced thrombocytopenia (HIT), a potentially fatal side effect characterized by abnormal platelet activation. Patients with HIT may develop DVT, PE, leg ischemia, bleeding, stroke, and myocardial infarction. HIT has been reported to occur more frequently following orthopedic surgery compared to other types of surgery.<sup>4,15</sup>

### **Conclusion**

The exact risk of VTED in patients undergoing foot and ankle surgery remains unclear due to the wide variation in injuries, treatments and rehabilitation protocols. There is currently insufficient data to make broad recommendations for or against the use of routine VTED prophylaxis in patients undergoing foot and ankle surgery.

We can recommend that a comprehensive assessment of risk factors should be performed to aid in the decision making process. If sufficient risk factors are present, VTED prophylaxis through mechanical and/or chemical interventions should be considered and weighed against the potential risks of prophylaxis. Exactly what constitutes sufficient risk, however, remains undetermined, especially in those patients without a strong risk factor.

The AOFAS recognizes that further research in this field is necessary and strongly encourages future investigations into VTED in patients undergoing treatment for foot and ankle conditions.

## **Definitions**

**Venous thromboembolic disease (VTED).** A clinical spectrum of pathologic clotting that encompasses both deep venous thrombosis and pulmonary embolism (see below).

**Deep venous thrombosis (DVT).** The formation of a blood clot, or thrombus, in one of the deep veins of the body.

**Pulmonary embolism.** A pulmonary embolism is a sudden blockage of one or more of the arteries in your lung by a blood clot that has travelled from another body part (e.g. the leg).

**Mechanical prophylaxis.** The use of external, physical devices to prevent the occurrence of VTED. These include elastic compression stockings worn on the legs and also sequential compression pumps that cause the blood to continue flowing through the veins of the leg.

**Chemical prophylaxis.** The use of pharmacologic agents to prevent the occurrence of VTED. These include medications taken by mouth (e.g. aspirin and warfarin) and those administered by an injection (enoxaparin).

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