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Complications - Other

The Effectiveness of a Risk Stratification Protocol for Thromboembolism Prophylaxis After Hip and Knee Arthroplasty

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ABSTRACT

Background: This study's purpose was to present our institution's experience with the use of a risk stratification protocol for venous thromboembolism (VTE) prophylaxis in joint arthroplasty in which "routine" risk patients receive a mobile compression device in conjunction with aspirin and "high"-risk patients receive warfarin for thromboprophylaxis.

Methods: This was a prospective study of patients undergoing primary or revision knee or hip arthroplasty. Exclusion criteria were patients with a current deep vein thrombosis, history of pulmonary embolism, chronic warfarin therapy, planned multiple surgeries, and prolonged postoperative immobilization. Patients were stratified as either routine or high risk. Routine risk patients received mobile compression devices for 10 days and aspirin twice daily for 6 weeks, whereas high-risk patients received warfarin for 4 weeks and compression stockings for 6 weeks.

Results: A total of 3143 total joint arthroplasties were enrolled (2222, 70.7% "routine"; 921, 29.3% "high risk"). The rate of symptomatic VTE within 6 weeks postoperatively was 0.7% (95% CI 0.3%-1.0%) in the standard vs 0.5% (95% CI 0.01%-1.0%) in the high-risk cohort ($P = .67$), and within 6 months postoperatively was 0.6% (95% CI 0.3%-1.0%) in the standard vs 1.1% (95% CI 0.4%-1.8%) in the high-risk cohort ($P = .23$). The rate of major bleeding events was significantly lower in the routine (0.4%; 95% CI 0.1%-0.6%) vs high-risk (2.0%; 95% CI 1.0%-3.0%; $P < .001$) cohort.

Conclusions: This study demonstrates that use of a risk stratification protocol allowed the avoidance of more aggressive anticoagulation in 70% of patients while achieving a low overall incidence of symptomatic VTE.

Venous thromboembolic events (VTEs), including deep vein thrombosis (DVT) and pulmonary embolism (PE), remain a significant cause of concern for both surgeons and patients after total hip arthroplasty (THA) and total knee arthroplasty (TKA) [1]. The reported rates of symptomatic VTE after THA and TKA range from 0.83%-15% [2-5] and 2%-10% [5], respectively. Thus, some form of VTE prophylaxis should be routinely administered after total joint arthroplasty. Recommendations from the American Academy of Orthopaedic Surgeons (AAOS) have focused on the overall safety profile of VTE prophylaxis regimens, raising concerns of postoperative bleeding, wound complications, readmission, and potential infection with the use of more potent thromboprophylactic medications [6-9]. In addition, recent guidelines from the American College of Chest Physicians (ACCP) have changed to more closely reflect AAOS recommendations [10].

Thus, orthopedic surgeons now have more flexibility regarding their choice of VTE prophylaxis regimen, yet it remains unclear which is optimal. In 2011, the AAOS clinical practice guideline noted that "the workgroup cannot recommend for or against a specific prophylactic regimen in these patients because current evidence is unclear about which strategy (or strategies) is or are optimal or suboptimal" [11,12]. In the most recent edition of ACCP guidelines, a grade-1 recommendation was made if there was certainty that the benefits of a particular

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VTE prophylaxis regimen did or did not outweigh the risk of burdens of that regimen, and a grade-2 recommendation was given if there was lower quality evidence. In addition, recommendations were graded as A, B, or C based on the quality of the randomized trials (A or B), or C, if there were only observational studies available for review. Versus the use of no antithrombotic prophylaxis, warfarin, aspirin, low-molecular-weight heparin, and oral factor Xa inhibitors were all given a 1B recommendation, whereas the use of intermittent pneumatic compression devices (MCDs) was given a 1C recommendation [10]. However, patients at low risk of VTE may receive excessive anticoagulation and unnecessarily risk further perioperative morbidity after total joint arthroplasty [8,9]. Although "risk stratification" for VTE events and/or bleeding has been recommended by the AAOS, this is difficult because of limited evidence elucidating specific risk factors that elevate VTE risk [13]. Thus, the search for the optimal balance between safety and efficacy with thromboprophylactic regimens remains elusive.

With an evolving health care landscape, emphasis on complications and readmissions, and shorter inpatient hospitalizations, it is imperative that a VTE prophylaxis regimen is simple, effective, easy to monitor, and has high patient compliance. With this in mind, MCDs have been used with greater frequency after total joint arthroplasty, with multiple reports demonstrating their effectiveness in VTE prevention with or without the addition of aspirin for chemical prophylaxis [14-19]. At our institution, a risk stratification protocol has been implemented in patients undergoing joint arthroplasty in which those deemed "routine" risk for VTE receive a MCD in conjunction with aspirin, whereas patients deemed "high" risk receive warfarin for thromboprophylaxis. The purpose of this prospective study was to present our experience with the use of this risk stratification protocol and VTE prophylaxis regimen. We hypothesized that after risk stratification, the use of MCDs with aspirin would be noninferior to warfarin in the prevention of VTE after joint arthroplasty.

Materials and Methods

This was a prospective, institutional review board–approved study of patients undergoing primary or revision TKA, unicompartmental knee arthroplasty, primary or revision THA, and surface replacement arthroplasty at a single academic medical center. Six, fellowship-trained, orthopedic surgeons enrolled patients in this study. All patients provided informed consent before their inclusion. Inclusion criteria were patients aged older than 18 years undergoing an elective, unilateral joint arthroplasty procedure. Patients were excluded if they had a positive lower extremity DVT detected on preoperative ultrasound or were being treated for a recent DVT (surgery would be delayed), a history of PE (these patients would receive low-molecular-weight heparin and warfarin postoperatively), were on chronic warfarin therapy, or were scheduled for multiple surgeries (within 3 months) in close proximity. A preoperative ultrasound was performed in all patients with a personal history of DVT. If an acute DVT was present, surgery was delayed for medical management of the DVT and the patient was excluded. This included all patients presenting with a thrombosis involving the femoral or popliteal veins or veins of the calf distal to the knee that appeared acute in nature based on Doppler ultrasound examination demonstrating abnormal vein distention and a hypoechoic or complex echo pattern [20,21]. Any patient determined to be at high risk for wound complications based on their health history (ie, poor nutritional status) were excluded at the discretion of the treating surgeon. Patients with a history of wound healing complications, patients on immunosuppressive medications for inflammatory arthritides or a solid organ transplant, or on renal dialysis were also excluded because of their potential increase of wound healing complications and to limit potential confounding variables in our analysis.

All enrolled patients were stratified to either a "routine" or "high"-risk VTE thromboprophylaxis regimen. Currently, there is no validated approach to stratify patients undergoing total joint arthroplasty based on their risk of VTE [22]. Thus, patients were stratified as "high" risk if they met any of the following criteria based on the clinical protocol at our institution (Table 1). For this study, heart disease was considered present in patients with a history of coronary artery bypass graft, cardiac stent, mechanical valve replacement, or myocardial infarction; lung disease in patients with a history of chronic obstructive pulmonary disease, restrictive lung disease, or chronic bronchitis requiring medical management; and diabetes in patients requiring medical management for type I or type II diabetes. The use of multiple medical comorbidities as an inclusion criteria in the high-risk cohort was based on National Institute for Health and Care Excellence guidelines [23] that recognize this as a potential risk factor of VTE in patients admitted for surgery. A family history of VTE was considered present if a parent or sibling had a VTE event not occurring after a specific traumatic event or surgical procedure. A patient was considered to have limited weight bearing if they were not full weight bearing on their operative extremity starting postoperative day 1. If none of these criteria were met, the patient was stratified to the "routine" risk regimen. After 2 years of patient enrollment (April 2010 to May 2012), a midterm analysis was performed to determine the effectiveness of our risk stratification protocol and to assess if inclusion criteria for the high-risk cohort could be narrowed. Low rates of VTE were seen in both the "routine" and "high"-risk cohorts with a significant increase in major bleeding, wound problems, and incisional drainage in the "high"-risk cohort. Given our encouraging preliminary results and the known difficulty in warfarin dosing and/or monitoring, age $\geq$70 years, multiple medical comorbidities, and body mass index $\geq$40 kg/m^2 were removed as inclusion criteria for the high-risk cohort for the period of study from May 2012 to October 2014. Expansion of our criteria was also influenced by concomitant reports demonstrating the effectiveness of MCDs in VTE prevention after excluding patients with a history of venous thromboembolism, coagulation disorder, active cancer, or major surgery in the past 3 months [18,24,25].

All patients in both the routine and high-risk cohorts received MCDs (Active Care+ SFT; Medical Compression Systems, Or Akiva, Israel) [17,24,26] applied to the contralateral lower extremity before the operative procedure and to the operative extremity postoperatively in the operating room. The protocol for anticoagulation therapy in the routine risk cohort consisted of use of MCDs for a goal of 23 hours a day for 10 days, along with enteric-coated aspirin (325 mg twice daily) started the evening of surgery for 6 weeks postoperatively. This dose of aspirin was already used as part of our institution's protocol and thus was not changed for the purpose of this study. During the introduction of MCDs, compliance was recorded via patient-reported responses and from

Table 1
Criteria to Determine "High"-Risk Patients.

Age $\geq$70 y
History of deep vein thrombosis with negative preoperative ultrasound examination
Active cancer
Hypercoagulable states (protein C, protein S, factor V Leiden, and so forth)
Multiple medical comorbidities (2 of the following 3 conditions: heart disease, lung disease, diabetes)
Morbid obesity (BMI $\geq$40 kg/m^2)
Family history of deep vein thrombosis or pulmonary embolism
Immobility (ie, limited weight bearing)–surgeon's discretion

BMI, body mass index.