2003 to 8.7% in 2006. International normalized ratio values were either in range or lower than the target range for all patients. Protocols are being put into place to examine patient susceptibility to warfarin in the future and other potential reasons for this increase.

Discussion: Further study is needed to determine if other institutions are seeing similar outcomes after VTE prophylaxis. Although preventing VTEs is an important quality concern, mandating prophylaxis for all patients could have unintended adverse outcomes. These guidelines might need to be reevaluated for hip and knee arthroplasty patients.

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PAPER #23

LOW-MORBIDITY LOW-COST DEEP VEIN THROMBOSIS PROPHYLAXIS IN LOW-RISK PATIENTS UNDERGOING TOTAL KNEE ARTHROPLASTY

John J. Callaghan, MD*, Lucian C. Warth, BS, Jamal Hoballah, MD, Steve Liu, MD, Chris Wells

Introduction: Optimal deep venous thrombosis (DVT) prophylaxis after total knee arthroplasty is controversial. Our objective of the study was to address the question: "What is the efficacy of a DVT and pulmonary embolism prophylaxis protocol after total knee arthroplasty (TKA) in which low-risk patients had only aspirin and mechanical devices for prophylaxis, unless a predischarge Doppler study was positive for DVT?"

Methods: Four hundred twenty-seven consecutive primary TKAs were performed on 329 patients. Based on preoperative assessment, patients were assigned to 1 of 2 postoperative prophylactic protocols (high vs low risk). Deep vein thrombosis prophylaxis for low-risk patients (73.1% of TKAs) consisted of early ambulation (postoperative day 1), TEDs and foot pumps, aspirin (325mg PO BID), and routine predischarge bilateral Duplex studies. Deep vein thrombosis prophylaxis for high-risk patients (26.9% of TKAs), (including patients with history of DVT, venous stasis, long-term warfarin use, or bilateral procedures), included warfarin instead of aspirin and no routine Duplex scans.

Results: Before discharge, routine duplex scans performed 2 to 9 days postoperatively on low-risk patients were positive for distal DVT in 2 (0.8%) and proximal DVT in 4 (1.6%) of knees. In addition, 3 symptomatic DVTs (1%) developed at 22, 44, and 51 days postoperatively after duplex scans had initially revealed negative findings before discharge. At 90-day follow-up, a total of 2 low-risk patients (0.8%) and 3 high-risk patients (3.9%) had been readmitted for DVT or related complications. No low-risk patient initially found positive for DVT on routine predischarge duplex was readmitted for DVT, but all were treated with warfarin for 6 weeks. At 90-day follow-up, overall mortality was 0.6% (2/329) with both patients in the high-risk group, and both were cardiac related deaths. There were no deaths in the low-risk protocol group.

Discussion: A multimodal approach to DVT prophylaxis using aspirin as the primary mode of chemoprophylaxis is successful in preventing DVT-related morbidity and mortality in low-risk total knee arthroplasty patients. There were no DVT-related deaths and no deaths in general at 90 days of follow-up, coupled with a low rate of readmission for thromboembolic events and no readmissions or reoperations for bleeding in this group. The low-morbidity low-cost prophylaxis should be considered an appropriate protocol for low-risk patients undergoing TKA.

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PAPER #24

THE ORAL DIRECT THROMBIN INHIBITOR, DABIGATRAN ETEXILATE, IS EFFECTIVE AND SAFE FOR PREVENTION OF MAJOR VENOUS THROMBOEMBOLISM AFTER MAJOR ORTHOPEDIC SURGERY

Michael H. Huo, MD*, Joseph Caprini, MD*, Stefan Hantel, MD*, Janet Schnee, MD*

Introduction: Major venous thromboembolism (VTE) and VTE-related death, the composite of proximal deep venous thrombosis, symptomatic pulmonary embolism, and VTE-related death, are well-recognized important clinical end points in VTE prevention studies. A prespecified pooled analysis of major VTE and VTE-related death after major orthopedic surgery, was performed across the more than 8000-patient phase III primary VTE prevention program of dabigatran etexilate (REMODEL, RE-MOBILIZE and RE-NOVATE Studies).

Methods: Each of the double-blind, randomized studies compared 220 and 150 mg of dabigatran etexilate, once daily after a half-dose on the day of surgery, to enoxaparin. Enoxaparin was given 40 mg once daily in the 2 mainly European studies and 30 mg twice daily in the mainly North American study. Treatment duration was 6 to 15 days post knee arthroplasty and 28 to 35 days post hip arthroplasty. Definitive diagnostic testing was required for all suspected symptomatic VTE events. Bilateral venography was performed at the end of the treatment period.

Results: Major VTE and VTE-related death occurred in 3.3% of the enoxaparin group (69/2096) vs 3.0% (62/2033) of the dabigatran etexilate 220 mg group (risk difference, −0.2%; 95% CI, −1.3% to 0.9%) and 3.8%, (78/2071) of the 150-mg group (0.5%; 95% CI, −0.6% to 1.6%). Major bleeding events were infrequent, and occurred at comparable rates across all treatment groups: enoxaparin 1.4% (39/2716), dabigatran 220 mg 1.4% (38 of 2682), and dabigatran 150 mg 1.1% (29 of 2737).

Conclusions: Dabigatran etexilate was efficacious and comparable with enoxaparin in the prevention of major VTE and VTE related mortality after knee and after hip arthroplasty.

The Food and Drug Administration has not cleared the following pharmaceutical (Dabigatran, Boehringer-Ingelheim) for the use described in this presentation.

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PAPER #25

PAIN RELIEF AND FUNCTIONAL IMPROVEMENT AFTER TOTAL KNEE ARTHROPLASTY

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Introduction: Total knee arthroplasty (TKA) is one of the most reliable and beneficial elective operative procedures because of the pain relief and improvement in physical function it provides patients with severe arthritis. Although pain relief is consistently achieved in the overwhelming majority of patients after TKA, the amount of improvement in physical function varies after TKA. Our previous publications show that patients with a low emotional health (SF12 mental composite score [MCS]) have an increased risk of less improvement in physical function after TKA. A clearer understanding of the determinants of suboptimal functional gain is critical to patient and surgical decision making.

Methods: A total of 2645 primary, unilateral TKA patients were enrolled in a prospective institutional review board–approved protocol after informed consent between 2000 and 2005. Patient demographics, clinical scores (Knee Society [KS], SF-12) radiographic evaluation and clinical evaluation were recorded preoperatively, 6 months, and 12 months postoperatove. Associations between 12-month functional improvement (SF-12/PCS), patient demographics (race, sex, age), and patient clinical attributes (including body mass index [BMI], emotional health [SF-12/MCS], preoperative diagnosis, quadriceps strength, preoperative pain, and preoperative PCS) were analyzed using multivariate regression models, including mixture models for bimodal distributions.

Results: Significant pain relief (SF-12 and KS pain score) was reported in more than 95% of patients after TKA. The mean KS pain score improved from 37 to 80 ($P < .001$), and pain improvement was normally distributed. The overall mean functional gain (PCS) after TKA was 15 points. However, unlike pain relief, the distribution of functional gain was bimodal. The 63% of patients with highest functional gain reported mean PCS improvement of 21 (SD, 7), as compared with the second group (37% patients) with a mean gain of 4.1 (SD, 7). Higher odds of less functional gain were associated with each 5-year increase in patient age, BMI above 40, lower preoperative MCS, non-OA diagnosis, and poor/fair quadriceps strength. Patients with BMI above 40 and poor quadriceps strength had more than 2:1 odds of poorer functional gains after TKA.

Conclusion: Although TKA surgery consistently relieves pain due to knee arthritis, one third of patients reported limited functional gains at 12 months after surgery. It is critical to understand the *modifiable* patient attributes associated with limited improvement in post-TKA function to meet patient expectations and to design innovative strategies to improve functional outcomes in these patients.

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