In a select patient population, rapid titration of pain control with 1 mg of IV hydromorphone can lead to effective pain control in <1 hour.

**Background:** Safe and effective pain control in the emergency department (ED) setting continues to be a challenge for providers. No standard dosing guidelines for pain control exist.

**Objective:** The authors looked at the efficacy and safety of repeated doses of 1 mg of IV hydromorphone on patients presenting to the ED with severe pain who were judged to need IV pain medication.

**Methods:** Patients were given 1 mg IV hydromorphone, and the need for subsequent pain medication was assessed 15 minutes later. The primary outcome of the study was the proportion of patients who chose to forego a second dose of 1 mg IV hydromorphone. For patients who required a second dose for further pain control, the process was repeated. Secondary outcomes included change from baseline on a numerical pain rating scale. The primary safety outcome was oxygen saturation <95%. Secondary safety outcomes included adverse events such as aspiration, hypoventilation, vital sign abnormalities, nausea, vomiting, and pruritus.

**Results:** Of the 223 patients enrolled in the study, 172 (77%) did not require more pain medication when asked. Of the remaining patients, 35 (19%) required only one more dose, meaning that 96% of patients achieved pain control with, at most, 2 doses of 1 mg IV hydromorphone within 1 hour. The median reduction in numeric pain score was 6 units, with 86% of patients having a >2 unit reduction in pain score. Eleven patients (5%) had oxygen desaturation <95%, all of which corrected with supplemental oxygen. Rates of bradycardia, nausea, vomiting, and pruritus were 10% to 17%. No major adverse events occurred.

**Conclusions:** In a limited population of patients presenting to the ED in acute pain, a rapid titration protocol using 1 mg IV hydromorphone provided rapid and effective pain control with few side effects.

**Reviewer's Comments:** Regimens used to treat acute pain vary widely, likely due to concerns over the safety of a protocol for a heterogeneous patient population. In fact, the authors’ previous work on this subject using an initial dose of 2 mg hydromorphone led to one third of patients having desaturation to <95%. This article tries to address the difficulties of pain control in an ED setting, and shows promise in achieving its aim of rapid and effective pain control in 1 hour with a low rate of adverse events. Unfortunately, the trade-off is a very narrow patient population with questionable broader applicability. The article also fails to mention outcomes of interest, such as the sustainability of pain control, decreased length of stay in the ED, and a decrease in frequency of admissions for pain control. (Reviewer-Michelle Mourad, MD).

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Keywords: Pain Control

Print Tag: Refer to original journal article
Assessing pain and sedation levels is associated with decreased duration of mechanical ventilation and decreased ICU stay.

**Background:** Rates of pain assessment in mechanically ventilated patients are poor, with assessment rates around 50%. Little is known about how regular pain assessment contributes to outcomes in the ICU.  
**Objective:** To evaluate the role of regular pain assessments on the amount of sedation used as well as duration of mechanical ventilation and ICU stay.  
**Methods:** In a large multi-center study of ICU patients, the authors compared 513 patients who were assessed for pain with 631 who were not. Patients were followed up until death, until discharge from the ICU, or for 30 days in the ICU. The primary outcome was the duration of mechanical ventilation and length of ICU stay. The secondary outcomes were mortality and frequency of complications such as ventilatory-associated pneumonia, gastrointestinal bleeding, deep venous thrombosis, and central venous catheter line infections.  
**Results:** Patients who were assessed for pain were less likely to receive hypnotics and lower daily doses of benzodiazepines. They were also more likely to receive sedation assessments, analgesia for painful procedures, and treatment of pain with non-opioids. Most importantly, patients with pain assessments had a shorter duration of mechanical ventilation (8 vs 11 days) and decreased stay in the ICU (13 vs 18 days), even after adjustment for severity of illness with an odds ratio of 1.4.  
**Conclusions:** Pain assessment in mechanically ventilated patients is independently associated with decreased duration of mechanical ventilation and decreased length of stay in the ICU.  
**Reviewer's Comments:** The article looks at a large cross-section of ICU patients and makes some powerful associations, but it is important to remember that this study cannot demonstrate cause and effect. Multiple factors account for why a patient may receive a pain and sedation assessment while others may not; those differences are hard to measure in a large study such as this and may significantly affect the results. Nonetheless, from the current study, pain assessment seems to reduce sedative drug dosing and causes pain medication to be administered based on patient assessment. This strategy was associated with fewer days on mechanical ventilation and a shorter duration of ICU stay. If true, adequate pain assessment could have implications for reductions in ICU-associated delirium, ventilator-associated pneumonia, post-traumatic stress disorder in the short term, and hospital costs in the long term. (Reviewer-Michelle Mourad, MD).
In motivated patients, a nicotine patch plus lozenge results in significantly increased periods of abstinence from smoking.

**Background:** Multiple smoking cessation therapies are available, yet little is known about their relative efficacies to help inform patient and physician decision making.

**Objective:** To compare the efficacy of smoking cessation therapies.

**Design:** Randomized, double-blind, placebo-controlled, 3-year longitudinal study.

**Participants/Methods:** Cigarette smokers (>6 months) were recruited in 2 cities in 1 state. Subjects were randomized to 1 of 6 treatment arms: (1) bupropion sustained-release; (2) nicotine lozenge; (3) nicotine patch; (4) nicotine patch plus lozenge; (5) bupropion plus nicotine lozenge; or (6) placebo. Treatment lasted either 8 weeks or 12 weeks for lozenge monotherapy. All subjects received 6 one-on-one counseling sessions.

Outcomes included quit rates 1 week, 8 weeks (end of treatment), and 6 months after quitting. Initial quit rates, number of days to lapse and relapse, and time to relapse after first lapse were also measured. Analyses were conducted on an intent-to-treat basis.

**Results:** 1504 smokers were randomized; 58% were women, and 83% were Caucasian. Groups were similar at baseline. All treatments resulted in higher initial quit rates than placebo (OR, 1.9 to 4.7). At 1 week and at the end of treatment, the patch and 2 combination therapies were most effective. At 6 months after quitting, patients in the nicotine plus lozenge group had significantly sustained abstinence compared with placebo (OR, 2.34). All other therapies had odds ratios ranging from 1.63 (bupropion alone) to 1.83 (patch alone); these differences were variably significant. All treatments studied significantly increased the time to relapse; the 2 combination therapies significantly increased the days to lapse. Serious adverse events were minimal. Notably, 22% of participants in the placebo group remained abstinent 6 months after quitting.

**Conclusions:** Nicotine patch plus lozenge resulted in the highest sustained smoking cessation rates.

Reviewer's Comments: This is a nicely designed study that compares several smoking cessation therapies head to head. Clearly, this is a relevant topic for hospitalists as many hospitalized patients smoke, and recommendations regarding smoking cessation contribute to quality care. The study suggests that hospitalists should recommend combination therapy of nicotine patches plus lozenge for best results, at least in combination with intensive counseling. It deserves mention that there was a high level of smoking cessation among those who received placebo in this trial, which highlights either that participants were extremely motivated (they chose to participate in a 3-year trial) or may have been involved in counseling. Intensive counseling (as well as the use of varenicline, which the authors point out was not FDA approved at the time of study) should be compared head-to-head in future studies with the treatment modalities studied here.

(Reviewer-Anneliese M. Schleyer, MD.)

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Keywords: Smoking Cessation, Pharmacotherapy

Print Tag: Refer to original journal article
Hospitalists should be aware of the updated guidelines for the primary care management of patients with HIV/AIDS, including guidance on diagnosis and initial necessary testing.

Background: Cases of human immunodeficiency virus (HIV) are increasing, and there is a rapidly growing body of evidence regarding optimal primary care management.

Objective: To provide updated evidence-based guidelines for the management of persons infected with HIV.

Design: Expert panel summary.

Methods/Participants: A panel of experts in internal medicine, pediatrics, infectious diseases, obstetrics, and gynecology reviewed and analyzed the literature published since 2000 on the management of HIV. The panel used a systematic weighting of the evidence to establish updated guidelines on the primary care management of HIV-infected patients.

Results: The article reported updated epidemiology of HIV infection. The guidelines noted male-to-male sexual contact as the most common risk factor for HIV for men and high-risk heterosexual contact as the most common risk factor in women. Regarding the optimal way to diagnose HIV infection, the guidelines recommended either rapid HIV test or conventional enzyme-linked immunoabsorbent assay (ELISA), but these must be confirmed by Western blot or indirect immunofluorescence assay. No recommendation is made on which patients specifically should be routinely screened for HIV. Once the diagnosis is made, the panel recommends the following initial testing: absolute CD4 count, HIV viral load, HIV genotype, complete blood count, chemistry panel, liver panel, lipid panel, and fasting blood sugar. The experts warn about variations in absolute CD4 results with concurrent acute illness and recommend re-testing if needed. The guidelines recommend against the CD4-to-CD8 ratio. Microbiologically, the guidelines recommend baseline testing for Mycobacterium tuberculosis, Toxoplasma gondii, viral hepatitis, syphilis, and consideration of testing for cytomegalovirus and varicella zoster virus.

Conclusions: This article contains comprehensive guidelines for primary care providers that clearly outline evidence-based guidelines for testing, screening, risk factor prevention, and initial testing in patients with HIV. Those providing primary care for HIV patients should follow these guidelines closely.

Reviewer's Comments: These are incredibly robust and complete guidelines for the primary care of HIV-infected patients. As a hospitalist, the most useful recommendations are that we can use either rapid HIV testing or ELISA to diagnose HIV as long as the results are followed up with a confirmatory test. In addition, it is useful to be aware of the battery of initial tests that HIV-infected patients should receive up front, including CD4 count, viral load, genotype, blood tests, and microbiologic studies. (Reviewer-Bradley A. Sharpe, MD).
A basal insulin regimen added to oral agents is most likely to improve glycemic control in patients with type 2 diabetes mellitus with the least side effects.

**Background:** Insulin, when added to oral agents, is known to improve glycated hemoglobin (HgbA1c) levels in patients with type 2 diabetes mellitus (DM). It is not known what type of regimen best achieves glycemic control.

**Objective:** To compare the effectiveness of 3 insulin regimens in patients with type 2 DM.

**Design:** 3-year, open-label, multicenter trial in England and Ireland (2004 to 2006).

**Participants/Methods:** Patients were aged ≥18 years with type 2 DM, were insulin-naïve, and had HgbA1c levels of 7.0% to 10.0% on maximum-dose oral agents (sulfonylureas or metformin). Patients were randomized to 1 of 3 regimens: (1) biphasic insulin 2 times per day; (2) prandial insulin 3 times per day; or (3) basal insulin (generally once per day). Insulin was titrated to finger-stick glucose levels based on a computerized algorithm. In year 2 of the trial, if HgbA1c levels were >6.5%, a second insulin type was added to replace sulfonylureas. HgbA1c was the primary outcome of patients with HgbA1c ≤6.5%; hypoglycemia rates and weight gain were secondary outcomes.

**Results:** 708 patients were randomized. The mean age was 62 years, with a mean duration of DM of 9 years. Most patients were Caucasian and were overweight. Median HgbA1c improved with all 3 insulin regimens (overall HgbA1c, 6.9% at 3 years); however, more patients receiving basal or prandial insulin achieved HgbA1c levels ≤6.5% (43% and 45%, respectively) compared with patients who received biphasic therapy (32%). More patients in the basal and prandial groups (82% and 74%, respectively) required the addition of a second type of insulin to replace the sulfonylurea in year 2 than in the biphasic group (68%). Patients experienced weight gain in all groups, but the weight gain was less with the basal regimen. In addition, the rates of hypoglycemia were lowest in the basal group (1.7 events per patient per year) compared with biphasic and prandial regimens (3.0 and 5.5, respectively). There were no clinically significant differences in blood pressure, LDL cholesterol, or albuminuria at 3 years.

**Conclusions:** The addition of basal or prandial insulin therapy to oral agents improved glycemic control more than a biphasic regimen. Patients receiving basal insulin experienced less hypoglycemic episodes and weight gain.

**Reviewer's Comments:** This is an important study for patients with DM, a patient population common in most hospitalist practices. Results may help hospitalists make decisions regarding glycemic control for patients with poorly controlled diabetes. These findings could also augment patient education regarding diabetes management and guide discussions and decisions during the transition from the inpatient to outpatient setting. Certainly, a once-daily regimen such as basal insulin may improve compliance; cost-effectiveness was not specifically addressed in this study. (Reviewer-Anneliese M. Schleyer, MD).

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Keywords: Insulin Regimens, Glycemic Control, Diabetes Type 2

Print Tag: Refer to original journal article
Statins may aid in the prevention and treatment of serious infections.

**Background:** In addition to their lipid-lowering effects, studies suggest that statins have anti-thrombotic, anti-inflammatory, and immunomodulatory effects. Multiple small studies have suggested a possible benefit in the prevention and treatment of infectious disease.

**Objective:** To determine the association between statin use and the risk or outcome of infection.

**Design:** Systematic review and meta analysis.

**Methods:** The authors searched electronic databases for articles that involved a randomized trial or cohort of at least 50 patients and evaluated the role of statins in the prevention and treatment of disease. Data on study quality, measurement of statin use, infectious outcomes, and complications were also measured. Publication bias, heterogeneity, and study quality were taken into consideration in measuring the strength of the results.

**Results:** 16 articles were found that adequately compared statins with non-statins using control subjects. Nine studies evaluated the role of statins in the treatment of infection, while 7 addressed a possible role in prevention. In both groups, the pooled effect analysis argued in favor of statin use. The study conclusions are limited by evidence of publication bias and study heterogeneity.

**Conclusions:** Based on study results, statins may have a beneficial effect on the treatment and prevention of infection. Patients taking statins had a lower risk of infection, and those with an infection had better outcomes and a greater chance for survival.

**Reviewer’s Comments:** This is a thoughtful meta-analysis that is honest about the limitations of the study. Despite its limitations, however, it provides convincing evidence that statins have a role in the prevention and treatment of infection. Starting patients on statins when they are at high risk for infection or are admitted to the hospital with an infection is far from the standard of care; however, these data suggest that statins should be continued in patients who are already taking them. A randomized, controlled trial is needed to substantiate the role of statins in infections and to determine which populations will benefit the most. (Reviewer-Michelle Mourad, MD).

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Keywords: Statins, Infection

Print Tag: Refer to original journal article
New Guidelines for VTE Prophylaxis and Treatment in Cancer Patients

Venous Thromboembolism Prophylaxis and Treatment in Cancer: A Consensus Statement of Major Guidelines Panels and Call to Action.

Khorana AA, Streiff MB, et al:

J Clin Oncol 2009; 27 (October 10): 4919-4926

Venous thromboembolism (VTE) is common in cancer patients. Hospital-based providers should use these guidelines to guide prophylaxis and treatment of VTE in cancer patients.

Background: Patients with cancer are at increased risk for venous thromboembolism (VTE), including deep venous thrombosis (DVT) and pulmonary embolism (PE).

Objective: To summarize multiple international guidelines regarding the prevention and treatment of VTE in patients with cancer.

Design: Working group summary.

Methods: Multiple international organizations have published guidelines concerning VTE in cancer, including the Italian Association of Medical Oncology, the National Comprehensive Cancer Network, the American Society of Clinical Oncology, the French National Federation of the League of Centers Against Cancer, and the European Society of Medical Oncology. A working group comprised of representatives of these organizations convened to establish a consensus statement about the prevention and treatment of VTE in cancer based on the available evidence.

Results: All available guidelines strongly recommend that hospitalized cancer patients receive pharmacologic prophylaxis in the absence of contraindications, but one particular agent or class of agents has not been endorsed. All guidelines recommend pharmacologic prophylaxis for surgical oncology patients who are hospitalized, and some recommend prolonged prophylaxis (4 weeks) for the highest-risk patients (abdominal or pelvic surgery, advanced cancer, prior VTE, etc). Notably, none of the guidelines recommend anticoagulant prophylaxis in any ambulatory patients, including those with central venous catheters. Regarding initial treatment of documented VTE in cancer patients, the guidelines were mixed in terms of initial agent (low-molecular-weight heparin [LMWH] or unfractionated heparin [UFH]). All of the guidelines prefer LMWH for long-term anticoagulant therapy for documented VTE based on available data. The organizations were mixed regarding duration of treatment, but all leaned toward a minimum of 6 months. Lastly, the panel did not recommend extensive cancer screening with CT scans, endoscopy, or tumor markers in patients with idiopathic VTE (without known cancer).

Conclusions: An impressive consensus statement from multiple international guidelines provides recommendations for best practices for the prevention and treatment of VTE in cancer patients. Hospitalists should be aware of and use these guidelines when relevant.

Reviewer's Comments: This paper presents reasonable and balanced recommendations for VTE in cancer patients. The most notable recommendations to be aware of include a recommendation against prophylaxis in ambulatory patients with central venous catheters, a recommendation for prolonged pharmacologic prophylaxis in high-risk surgical oncology patients, and a strong recommendation for the use of LMWH for the long-term treatment of VTE in this patient population. (Reviewer-Bradley A. Sharpe, MD).

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Keywords: Venous Thromboembolism, Prophylaxis, Anticoagulation, Cancer

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Smoke-Free Laws Decrease Heart Attacks

Declines in Acute Myocardial Infarction After Smoke-Free Laws and Individual Risk Attributable to Secondhand Smoke.

Lightwood JM, Glantz SA:

Circulation 2009; 120 (October 6): 1373-1379

Public and workplace smoking restriction laws are associated with a significant decrease in population-based rates of myocardial infarction.

**Background:** Public area and workplace smoke-free laws have been passed in many parts of the country as a means to decrease secondhand smoke exposure (among other reasons). The impact of these laws on public health is not completely understood.

**Objective:** To determine the effects of smoking restriction laws on community rates of myocardial infarction (MI).

**Design:** Meta-analysis and mathematical meta-regression.

**Methods:** All studies that reported community rates of MI before and after implementation of smoking restriction laws were included. The results were combined using a random-effects meta-analysis (to account for heterogeneity in the estimates). To validate these community-based results, mathematical models were created with different estimates of possible individual passive and active smoking exposure after passage of smoking laws.

**Results:** A total of 12 community-based studies (from 5 countries) of acute MI rates after passage of smoking restriction laws were included. Overall, there was a significant decrease in the rate of hospitalization for acute MI associated with strong smoke-free legislation. When pooled, the estimated population rate of acute MI hospitalization 12 months after implementation of the law was 0.83 (95% CI, 0.80 to 0.87). This benefit increased with time. Compared to what an estimated decrease might be for individuals (based on multiple models of ongoing exposure), these results remained valid.

**Conclusions:** Laws mandating smoke-free workplaces and public areas have been passed in many countries. A complex and robust meta-analysis with mathematical modeling reveals that passage of these laws has resulted in a substantial decrease in the population-based risk for MI.

**Reviewer's Comments:** Smoke-free laws have many potential benefits and have not had a substantial negative impact on local economies (as predicted). This complex and well-done analysis of epidemiologic data reveals an impressive benefit in decreased rates of acute MI after passage of such laws. Based on these results, public health experts should push for the passage of more widespread smoke-free legislation. (Reviewer-Bradley A. Sharpe, MD).

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Keywords: Smoking, Myocardial Infarction, Prevention, Meta-Analysis

Print Tag: Refer to original journal article
Up to 10% of patients with true coagulase-negative staphylococcal CRBSI may have recurrence. In high-risk patients and those with tunneled catheters, clinicians may want to consider removal or exchange of the catheter.

**Background:** Traditional teaching and recent national guidelines recommend retention of central venous catheters (CVCs) in the setting of coagulase-negative staphylococcal line infection and bacteremia. **Objective:** To determine the impact of retention of CVCs in coagulase-negative staphylococcal catheter-related bloodstream infections (CRBSI). **Design:** Retrospective cohort study. **Methods/Participants:** All patients with true coagulase-negative staphylococcal CRBSI from 2005 to 2007 at a single institution were included. True CRBSI was defined by strict Infectious Diseases Society of America (IDSA) guidelines, including the presence of clinical signs/symptoms of infection, at least 2 separate blood cultures positive for coagulase-negative staphylococcus, and clear evidence of line infection (most often by time to positivity). Demographic and other data were collected, and charts were reviewed for immediate resolution of infection (clearance of cultures and no further signs/symptoms of infection) and for recurrence in the 4 months after initial diagnosis. A multivariate analysis was performed to determine risk factors for resolution or recurrence. **Results:** 188 patients with coagulase-negative staphylococcal CRBSI were included, all of whom were given appropriate antibiotic therapy. Bacteremia resolved within 48 hours in 175 patients (93%). Risk factors for lack of resolution included any ICU stay prior to the infection and the presence of other current sites of infection. Of the 175 patients in whom the infection resolved, 17 (9.7%) had recurrence within 4 months. Multiple logistic regression analysis revealed that retention of the catheter (compared to removal or exchange) was a risk factor for recurrence (OR, 6.6; 95% CI, 1.8 to 23.9). In addition, patients with a Port-a-Cath were 15.1 times more likely to have a recurrence compared to those with non-tunneled catheters (95% CI, 3.2 to 70.2). **Conclusions:** Immediate resolution of coagulase-negative CRBSI is affected primarily by the degree of patient illness. Retention of CVCs and the presence of a tunneled catheter are risk factors for recurrence of infection. **Reviewer’s Comments:** Most experts and the recent IDSA guidelines on catheter management do not recommend removing or exchanging CVCs in the setting of coagulase-negative CRBSI. This well-done study, with strict definitions of infection, reveals that we may need to rethink this. We may achieve immediate resolution of infection, but up to 10% of patients may have a recurrent coagulase-negative staphylococcal CRBSI within 4 months. The risk is higher if the line is kept in and if the line is tunneled. This is the first study revealing these results so we should not be removing or exchanging CVCs in all patients with coagulase-negative staphylococcal line infections. However, we should at least pause and make sure the benefits of keeping the catheter in place outweigh what is probably a real risk of recurrent infection. (Reviewer-Bradley A. Sharpe, MD).

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Keywords: Coagulase-Negative Staphylococcus, Catheter-Related Bloodstream Infection, Central Venous Catheter, Bacteremia

Print Tag: Refer to original journal article
Dabigatran has similar efficacy and a favorable side effect profile compared to warfarin in the treatment of acute venous thromboembolism.

Background: Although treatment of venous thromboembolism with warfarin is the standard of care, issues with variable dosing, multiple drug interactions, and frequent monitoring have prompted the search for an alternative anticoagulant for the treatment and prevention of venous thromboembolism (VTE).

Objective: To assess the efficacy, safety, and tolerance of dabigatran, an oral direct thrombin inhibitor that requires no need for anticoagulation monitoring.

Design: Randomized, double-blind, double-dummy, non-inferiority trial.

Participants: Patients diagnosed with acute VTE who were candidates for 6 months of anticoagulation following initial treatment with parenteral anticoagulation.

Methods: Patients eligible for the study were randomized to take either dabigatran and a warfarin-like placebo or warfarin and a dabigatran-like placebo. Both groups had international normalized ratio (INR) checks and sham-INR checks within 1 week and then monthly. The incidence of recurrent and fatal thromboembolism was compared between the 2 groups, as was the incidence of major and minor bleeding.

Results: Dabigatran was found to be non-inferior to warfarin. Thirty of 1274 patients (2.4%) randomized to the dabigatran group compared to 27 of 1265 patients (2.1%) in the warfarin group had recurrent venous thromboembolism. Major bleeding episodes occurred in 20 patients (1.6%) in the dabigatran group versus 24 patients (1.9%) in the warfarin group. The number of deaths, acute coronary syndromes, and elevations in transaminases were the same in both groups. There was, however, a higher rate of discontinuation of dabigatran due to adverse events, especially dyspepsia.

Conclusions: The efficacy and safety of dabigatran are comparable (ie, non-inferior) to that of warfarin. These results, in addition to dabigatran's fixed once-daily dosing, lack of need for monitoring, and short half-life, make it a tempting alternative to warfarin for use in VTE.

Reviewer's Comments: The complexity of warfarin's variable dosing, multiple drug interactions, and long half-life make it the bane of many providers, whether dealing with atrial fibrillation or treatment and prevention of VTE. With the emergence of several alternatives, notably oral factor Xa inhibitors, warfarin may soon be replaced as the standard of care. With promising data on the use of dabigatran in patients with atrial fibrillation from the RELY study and from this trial, dabigatran seems well poised as a leading candidate. We should remember, however, that this was a non-inferiority trial, a trial in which the patients on warfarin were in therapeutic range only 60% of the time (slightly less than similar trials). Dabigatran has yet to declare itself superior in the treatment and prevention of VTE. (Reviewer-Michelle Mourad, MD).

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Keywords: Venous Thromboembolism, Deep Venous Thrombosis, Pulmonary Embolism, Warfarin, Dabigatran

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