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Greater Benefit with Rivaroxaban Than Aspirin for Extended Treatment of VTE

Clinical Question

What is the safest and most effective therapy for the extended treatment of venous thromboembolism (VTE)?

Bottom Line

Compared with aspirin, the use of rivaroxaban (Xarelto) to extend anticoagulation beyond the initial six to 12 months to treat provoked or unprovoked VTE reduces the risk of recurrent symptomatic VTE without increasing the risk of bleeding. You would need to treat approximately 30 to 33 patients with full- or low-dose rivaroxaban to prevent one additional clot. (Level of Evidence = 1b)

Synopsis

These authors recruited 3,396 adult patients with symptomatic proximal deep venous thrombosis or pulmonary embolism who had received six to 12 months of anticoagulation with a vitamin K antagonist or a direct oral anticoagulant. Those who already required extended anticoagulation therapy were excluded. Patients were then randomized, using concealed allocation, to receive 20 mg of rivaroxaban, 10 mg of rivaroxaban, or 100 mg of aspirin once daily with a placebo version of the treatment they were not receiving. The three groups had similar baseline characteristics. Approximately 60% of the index VTEs were provoked and 40% were unprovoked. The median duration of study treatment was also similar across the three groups at almost 12 months.

After excluding patients who did not take any study medications, 3,365 patients were included in the intention-to-treat analysis. The primary outcome—a composite of symptomatic, recurrent, fatal, or nonfatal VTE—was decreased in both rivaroxaban groups compared with the aspirin group (20-mg rivaroxaban vs. aspirin: 1.5% vs. 4.4%; hazard ratio [HR] = 0.34; 95% confidence interval [CI], 0.20 to 0.59; 10-mg rivaroxaban vs. aspirin: 1.2% vs. 4.4%; HR = 0.26; 95% CI, 0.14 to 0.47). Rates of major bleeding and clinically relevant nonmajor bleeding were similar in all three groups (major bleeding: 0.5% with 20-mg rivaroxaban vs. 0.4% with 10-mg rivaroxaban vs. 0.3% with aspirin; nonmajor bleeding: 2.7% with 20 mg vs. 2.0% with 10 mg vs. 1.8% with aspirin). This study was not powered to determine whether the lower dose of rivaroxaban is noninferior to the higher dose.

Study design: Randomized controlled trial (double-blinded)

Funding source: Industry

Allocation: Concealed

Setting: Outpatient (any)

Reference: Weitz JJ, Lensing AW, Prins MH, et al.; EINSTEIN CHOICE Investigators. Rivaroxaban or aspirin for extended treatment of venous thromboembolism. *N Engl J Med*. 2017;376(13):1211-1222.

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High False-Positive Rate with Lung Cancer Screening

Clinical Question

What can patients expect when they undergo computed tomography (CT) to screen for lung cancer?

Bottom Line

If you are thinking about adding lung cancer screening to your delivery of preventive care, be sure to prepare patients. They are likely to receive a positive result, most of the positive results will not be lung cancer, and one in four patients will require additional tracking (i.e., follow-up scans). In this study, more than one-half (59.7%) of the current or former smokers screened for lung cancer using low-dose CT had a positive result of some sort. However, 97.5% of them were falsely positive,

and one-half of the patients who screened positive were identified as needing to undergo additional monitoring. (Level of Evidence = 1a)

Synopsis

This study was conducted in eight academic medical centers among 93,033 primary care patients. From this group (96.3% of whom were men), the researchers identified 4,246 current or former (quit date less than 15 years ago) cigarette smokers who had smoked a minimum of 30 pack-years, and invited them to be screened for lung cancer using low-dose CT. Of these, 2,106 patients had the screening CT. Overall, 1,257 screened patients (59.7%) had a positive finding, including 1,184 patients (56.2%) who had one or more nodules that needed to be followed. A total of 73 patients (3.5% of all patients screened) had findings suspicious for possible lung cancer, and 31 patients (1.5%) had that diagnosis confirmed within the following year. This means that for appropriately screened patients undergoing CT, more than one-half will have a positive finding and 94% of these patients will need additional follow-up. One patient in 17 will be told he or she may have lung cancer, but only one in 42 patients with a positive result will actually have lung cancer. Overall, 97.5% of patients with a positive CT scan will not have lung cancer.

Study design: Cohort (prospective)

Funding source: Government

Setting: Outpatient (primary care)

Reference: *Kinsinger LS, Anderson C, Kim J, et al. Implementation of lung cancer screening in the Veterans Health Administration. JAMA Intern Med. 2017;177(3):399-406.*

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Niacin Does Not Decrease Mortality in Patients with Coronary Artery Disease or Low HDL

Clinical Question

Is niacin effective to reduce cardiovascular events and mortality in patients with or at risk of coronary artery disease?

Bottom Line

We are now flush with data about the effects of niacin in patients with elevated cholesterol levels. Despite its

ability to raise high-density lipoprotein (HDL) serum cholesterol levels, it does not add additional mortality or morbidity benefit to statin treatment. Patients with diabetes mellitus may also experience worse blood glucose control, as well as other niacin-related adverse effects. (Level of Evidence = 1a)

Synopsis

Niacin (nicotinic acid, vitamin B₃) has been used to increase HDL levels since the 1970s, based on studies that showed a mortality benefit. However, these initial studies were conducted before the era of optimized statin therapy. The researchers conducting this meta-analysis searched for all randomized studies that compared niacin with placebo, either alone or in combination with statin treatment or other treatments that lower low-density lipoprotein cholesterol levels. The authors searched four databases, including Cochrane Central, and identified 13 studies that enrolled a total of 35,206 patients. The number of studies is misleading; a single study, published in 2013, provides 73% of the patients included in the analysis. The systematic review was conducted according to PRISMA standards.

Several studies published since 2000 have looked at the effect of niacin added to a statin. Although niacin can increase HDL levels by an average of 21.4%, it does not affect all-cause mortality rates. It also does not lower the risk of cardiovascular mortality, nonfatal myocardial infarction, stroke, or the need for revascularization. There was no significant heterogeneity among trials. Even studies that specifically enrolled patients with low HDL levels did not find benefit. In patients with pre-existing diabetes, treatment with niacin worsens blood glucose control (odds ratio = 1.44; 95% confidence interval, 1.31 to 1.59). Flushing and gastrointestinal and musculoskeletal adverse effects were also significantly more likely with niacin.

Study design: Systematic review

Funding source: Self-funded or unfunded

Setting: Various (meta-analysis)

Reference: *Garg A, Sharma A, Krishnamoorthy P, et al. Role of niacin in current clinical practice: a systematic review. Am J Med. 2017;130(2):173-187.*

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