POEMs

PATIENT ORIENTED EVIDENCE THAT MATTERS

Practice Recommendations from Key Studies

Taper proton pump inhibitor to once daily for GERD

Iadomi JM, McIntyre L, Bernard L, Frederick AM. Step-down from multiple- to single-dose proton pump inhibitors (PPIs): a prospective study of patients with heartburn or acid regurgitation completely relieved with PPIs. Am J Gastroenterol 2003; 98:1940–1944.

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PRACTICE RECOMMENDATIONS

For patients with gastroesophageal reflux disease (GERD) who take proton pump inhibitors (PPIs) more than once daily, an attempt to reduce dosing to once daily will be successful in over 80%, with little change in quality of life.

Given the expense of these medications, clinicians should undertake a trial of once-daily dosing for patients on higher doses, after their initial symptoms are controlled for at least 8 weeks. Though dose reduction is harder to achieve when patients have been taking a PPI long-term, 84% of such patients who could not tolerate an initial dose reduction were able to do so on a subsequent attempt.

BACKGROUND

PPIs provide very effective, but expensive, therapy for GERD. Many people start on more than once-daily dosing. The researchers report the results of a systematic attempt to reduce more frequent PPI dosing to just once daily.

POPULATION STUDIED

This study took place in the Veterans Administration Healthcare Center in Ann Arbor, Michigan, which includes several outpatient centers in the region. The researchers enrolled 117 subjects receiving more than 1 daily dose of a PPI—defined as more than 30 mg lansoprazole (Prevacid) or more than 20 mg omeprazole (Prilosec) daily—for the treatment of heartburn or acid regurgitation.

Patients were eligible for the study if their symptoms had resolved for at least 8 weeks on a stable dose of medication. Exclusion criteria included weight loss, evidence of gastrointestinal bleeding, dysphagia, extraesophageal disease secondary to acid reflux (such as pulmonary and laryngeal disease), and non-GERD esophageal or gastric pathology (such as peptic ulcer, varices, esophageal malignancy, acid hypersecretory states, or motility disorders).

The average age of those in the study was 64.8 years; 95% were male, 31% were smokers, and 35% were drinkers. The initial PPI was lansoprazole for 88% of subjects and omeprazole for the remaining 12%.

STUDY DESIGN AND VALIDITY

This study is a prospective cohort study. Identified patients were prescribed once-daily dosing of 30

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What is a POEM?

Each month, the POEMs (Patient-Oriented Evidence that Matters) editorial team reviews 105 research journals in many specialties, and selects and evaluates studies that investigate important primary care problems, measure meaningful outcomes, and have the potential to change the way medicine is practiced. Each POEM offers a Practice Recommendation and summarizes the study's objective, patient population, study design and validity, and results. The collected POEMs are available online at www.jfponline.com.

mg lansoprazole or 20 mg omeprazole, half an hour before breakfast, as well as given instructions for lifestyle modification. Subjects were evaluated after 2 weeks, and those without recurrence of heartburn or GERD were followed at 3-month intervals for 6 months. (Those with recurrence were returned to their former regimen.)

Three-fourths of the subjects had undergone endoscopy or pH monitoring in establishing diagnosis. Since this was a VA study, it included low numbers of women and younger patients, and the results may not apply to these groups.

In addition, we are uncertain whether greater than single-dose therapy was initially required in subjects since the rationale for more frequent treatment was not recorded. The study did not consider alternative, possibly more cost-effective, clinical practices, such as the substitution of H_2 blockers for PPIs. (*Level of evidence:* **2b**)

OUTCOMES MEASURED

The primary outcome variable was the proportion of subjects without recurrence of heartburn or acid regurgitation after 6 months. Secondary outcomes included changes in health-related quality of life, pharmacy expenditures, and predictors of successful step-down. Quality of life was evaluated using 2 instruments: the 12-item Short Form Health Survey for generic quality of life, and a validated disease-specific measure not otherwise described.

RESULTS

Of the 117 patients participating in the study, 93 (79.5%) remained successfully stepped down after 6 months. All but 1 of the 24 failures occurred within 3 months of the dose change. Of subjects who had been on single-dose therapy prior to needing to step up to greater than single-dose treatment, 77.1% successfully stepped down. Of subjects who had never been on single-dose therapy, 82.1% successfully stepped down. Of 19 subjects who had previously attempted step-down unsuccessfully, 16 (84%) succeeded in establishing a single-dose regimen during the study, indicating that previous failure does not contraindicate a new attempt.

Univariate analysis showed that only the duration of prior PPI use predicted failure. For every additional year of PPI use, subjects were 34% more likely to not tolerate step-down dosing. Overall quality of life did not significantly change at 6-month follow up. GERD drug costs in this cohort were reduced by 53%, resulting in a $521 annual savings per reduction attempt.

Sertraline effective for children and adolescents with major depression

Wagner KD, Ambrosini P, Rynn M, et al. Efficacy of sertraline in the treatment of children and adolescents with major depressive disorder. Two randomized controlled trials. JAMA 2003; 290:1033–1041.

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PRACTICE RECOMMENDATIONS

Sertraline (Zoloft) is effective and generally well tolerated for the short-term treatment of major depressive disorder in both children and adolescents.

Although the studies were not powered to detect a difference in efficacy and safety between age groups, decreased efficacy and increased side effects were seen in children ages 6 to 11 years. Because treatment with sertraline was only studied for 10 weeks, the efficacy and safety of long-term treatment remain unknown.

BACKGROUND

Few treatment options are available for children and adolescents with major depressive disorder due to a lack of efficacy data, particularly with tricyclic antidepressants. Although limited evidence supports the use of selective serotonin reuptake inhibitors (SSRIs), increased adverse

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effects have been reported with paroxetine (Paxil) and venlafaxine (Effexor). Fluoxetine (Prozac) is the only SSRI approved by the US Food and Drug Administration for the treatment of major depressive disorder in children and adolescents.

POPULATION STUDIED

These 2 studies included 376 children and adolescents aged 6 to 17 years who were diagnosed with major depressive disorder as determined by the *Diagnostic and Statistical Manual of Mental Disorders* (4th ed) criteria.

STUDY DESIGN AND VALIDITY

Both studies were multicenter, randomized, double-blind, placebo-controlled trials evaluating the effects of sertraline (n=189) compared with placebo (n=187) in children and adolescents with major depressive disorder. Subjects were randomly assigned to receive a flexible dose of sertraline (50–200 mg) or matching placebo for 10 weeks.

Subjects were required to have a diagnosis of major depressive disorder of at least moderate severity lasting 6 weeks. During a 2-week pretreatment screening period, the diagnosis of major depressive disorder was confirmed with the Kiddie Schedule for Affective Disorders and Schizophrenia for School Age Children–Present and Lifetime Version (K-SADS-PL). The Children's Depression Rating Scale-Revised (CDRS-R) and Clinical Global Impression of Severity of Illness (CGI-S) scales were used to determine clinical history and symptom severity. The CDRS-R and CGI-S were also performed at the end of weeks 1, 2, 3, 4, 6, 8, and 10.

Subjects were prohibited from taking psychotropic medications and receiving cognitive behavioral therapy while enrolled in the study. Other forms of psychotherapy were permitted as long as specific issues of depression were not addressed and subjects were receiving this form of therapy prior to enrollment into the study.

Allocation assignment was concealed and results were analyzed by intention-to-treat. There were no significant baseline differences in CDRS-R or CGI-S scores between the 2 study groups. The short duration of this study may limit applicability to clinical practice. Although a subset of patients continued into a 24-week open-label extension study, efficacy and safety results were not reported. (*Level of evidence:* **1b**)

OUTCOMES MEASURED

The primary efficacy outcome measure was the CDRS-S scale, with input provided by subjects, parents, and clinicians blinded to group assignment. Secondary efficacy outcomes included a proportion of CDRS-S responders, defined as patients having at least a 40% decrease in the total adjusted CDRS-S score. In addition, scores on the CGI-I and proportion of CGI-I responders, defined as patients with a CGI-I score of 2 or lower, were also used as secondary efficacy measures. Other scales were used to assess anxiety symptoms, social functioning, and quality of life.

RESULTS

A total of 69% of subjects in the sertraline group and 59% in the placebo group responded to treatment using the CDRS-R evaluation (P=.05; number needed to treat [NNT]=10). In addition, 63% of subjects in the sertraline group and 53% of subjects in the placebo group responded to treatment using the CGI-I evaluation (P=.05; NNT=10). There were no statistically significant differences between groups in any of the patient-rated secondary outcomes.

Adverse effects resulting in study discontinuation were reported in 17 (9%) patients in the sertraline group and 5 (3%) in the placebo group (number needed to harm=17). Children in the sertraline group represented the majority of subjects that discontinued the study early due to adverse effects. The increase in adverse effects among children may be a dose-limiting effect; lower doses may be warranted to assure tolerability, safety, and efficacy. The most common adverse events reported were insomnia, diarrhea, vomiting, anorexia, and agitation.

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Screening and intervention for excessive drinking produce small results

Beich A, Thorsen T, Rollnick S. Screening in brief intervention trials targeting excessive drinkers in general practice: systematic review and meta-analysis. BMJ 2003; 327:536–540.

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PRACTICE RECOMMENDATIONS

It is reasonable to consider screening for excessive alcohol consumption if time and circumstances permit, realizing the ultimate benefit will be extremely small.

Overall, if a practitioner screens 1000 patients, carries out further assessment in 90 (9%) who screen positive, and gives feedback, information, and advice to the 25 (2.5%) who qualify for brief intervention, 2 or 3 patients can be expected to have reduced their alcohol consumption to below recommended maximum levels after 12 months. This results in a number needed to screen with outcome measured at 1 year (NNS_1) of 500. To put this in perspective, the NNS_5 (to prevent 1 death in 5 years) for dyslipidemia is 418; for hypertension, 274–1307; for hemoccult testing, 1374; for mammography in those aged 50–59 years, 2451.

BACKGROUND

The World Health Organization has recommended screening for excessive alcohol consumption. However, the effectiveness of screening, as a precursor to brief intervention, has not been systematically evaluated. This meta-analysis aims to measure the effectiveness of screening followed by a brief intervention in a primary care setting as a significant factor in the reduction of alcohol consumption.

If a physician screens 1000 patients, 2 or 3 excessive drinkers can be expected to reduce their drinking

POPULATION STUDIED

The 8 US, UK, and Australian studies conducted in a primary care setting were combined to include a screened group of 134,693 adults aged 17 to 84 years. Of these, 12,345 screened positive for excessive alcohol consumption (variously defined as consuming from >11 to >29 drinks per week); 3317 were randomized to receive a brief intervention.

To be included, a study must have focused on excessive drinking, had a recruitment that involved screening, performed brief interventions, used a randomized controlled design, and reported at least 1 discrete outcome measure reflective of a significant change in alcohol consumption. Trials were excluded if the authors did not report the number screened or report an event outcome.

STUDY DESIGN AND VALIDITY

This meta-analysis of 8 randomized controlled trials was designed to evaluate the effect a 2-step process—screening for excessive alcohol consumption followed by a brief intervention—had on decreasing alcohol consumption in a clinically meaningful manner. The authors used robust methodology outlined by the Cochrane collaboration to locate and select relevant studies; they performed a solid and clearly outlined internal and external validity assessment on each trial before inclusion.

Only English-language studies were included, and all trials used a general health or lifestyle questionnaire provided as a screening tool to patients when they came to visit their doctor. The interventions ranged from a 10-minute consultation to as many as 5 consultations lasting 5 to 20 minutes.

This study was very well done. Its strengths included strong methodology in assessing trials for inclusion, use of randomized controlled

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9% of patients screened positive for excessive drinking; 2.5% qualified for a brief intervention

trials, large number of patients screened, use of an intention-to-treat model to calculate event rates, homogeneity of trials included, and good follow-up for all studies. Weaknesses were relatively minor and included different definitions of excessive drinking among some trials, some variation in the lengths of intervention, and limiting trials to those written in English. (*Level of evidence:* **1a**)

OUTCOMES MEASURED

The primary outcome was number needed to screen (NNS); that is, the number of people identified as excessive drinkers who would need to receive the intervention for 1 person to benefit. Secondary outcomes were the proportion of patients positive for excessive drinking on screening, the proportion given brief interventions, and the effect of screening.

RESULTS

Nine percent of patients (range, 3.3%–18%) screened positive. Further assessment of drinking history identified 2.5% (range, 0.9%–5.4%) who qualified for a brief intervention. Of these patients, about 10% decreased their drinking as a result of the intervention (absolute risk reduction [ARR]=10%; 95% confidence interval [CI], 7.1%–13.9%). The pooled screening effect was 2.6 (95% CI, 1.7–3.4) patients who achieved sensible drinking out of the 1000 screened.

Azithromycin ineffective for secondary coronary heart disease prevention

O'Connor CM, Dunne MW, Pfeffer MA, et al. Azithromycin for the secondary prevention of coronary heart disease events. The WIZARD study: A randomized controlled trial. JAMA 2003; 290:1459–1466.

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PRACTICE RECOMMENDATIONS

For now, a 3-month regimen of azithromycin should not be used to prevent recurrent coronary heart disease (CHD) events in patients with a previous myocardial infarction and evidence of exposure to *Chlamydia pneumoniae*. This does not exclude the possibility that other antibiotic regimens may produce a significant benefit in reducing morbidity and mortality from CHD.

BACKGROUND

Several studies have found an association between infection with *C pneumoniae* and atherogenesis. Unfortunately, results from smaller studies as to whether antibiotics are helpful in preventing CHD events have been mixed. The objective of the Weekly Intervention with Zithromax for Atherosclerosis and Related Disorders (WIZARD) study was to determine if 3 months of treatment with azithromycin had an effect on recurrent CHD events in a large population of stable patients who have been exposed to *C pneumoniae*.

POPULATION STUDIED

The investigators studied 7747 adult outpatients with a history of myocardial infarction more than 6 weeks before screening (documented by electrocardiogram or elevation of creatinine kinase) and an immunoglobulin G titer to *C pneumoniae* of 1:16 or greater. Patients were excluded if they had undergone coronary artery bypass graft surgery or percutaneous coronary intervention in the

preceding 6 months, required chronic antibiotic therapy, or had received antibiotics in the previous 3 months. Patients were enrolled from the United States, Canada, United Kingdom, Germany, France, Spain, Austria, India, and Argentina.

STUDY DESIGN AND VALIDITY

In this double-blind study, participants were randomly assigned to receive either azithromycin 600 mg or placebo daily for 3 days, then weekly for the next 11 weeks. Randomization was performed by blinded medication blocks, which contained an equal number of each treatment assignment. Sealed envelopes containing the treatment assignment were also provided to each site, to be opened only in case of emergency. Study participants were seen in clinic for blood samples (red blood cell indices, creatinine, and liver function) or contacted by phone at 6-week to 4-month intervals. Investigators who were blinded to treatment assignment assessed outcomes based on predefined criteria for primary and secondary endpoints.

Overall, this was a well-done large study that was designed to have a 90% power to detect a treatment effect of 18.5%. Based on the method of randomization, allocation was concealed. The investigators used a modified intention-to-treat analysis (they included all enrolled patients who received at least 1 dose of study drug). More than 90% of patients completed the 12 weeks of study treatment, and 99.5% were available at the median follow-up of 14 months. (*Level of evidence:* **1b–**)

OUTCOMES MEASURED

The investigators defined a primary event as the first occurrence of death by any cause, recurrent myocardial infarction, coronary revascularization procedure (coronary artery bypass graft surgery or percutaneous coronary intervention), or hospitalization for angina. Secondary outcomes included a noncoronary atherosclerotic event (stroke, transient ischemic attack, or intervention for peripheral vascular disease, whichever occurred first), cardiovascular death, and hospitalization for congestive heart failure.

RESULTS

Treatment with azithromycin was associated with no significant reduction in the risk of developing any of the primary endpoints studied, including all cause death, myocardial infarction, coronary revascularization procedure or hospitalization for angina (relative risk=7%; 95% confidence interval, –5% to 17%; P=.23). Secondary outcomes were also unaffected by treatment with azithromycin.

Adverse events related to the study drug were reported by 13.2% of those randomized to azithromycin compared with 4.6% randomized to placebo. The most common adverse effects were diarrhea (8.1% vs 1.4%) and abdominal pain (2.2% vs 0.8%).

Influenza vaccine does not prevent acute otitis media in young children

Hoberman A, Greenberg DP, Paradise JL, et al. Effectiveness of inactivated influenza vaccine in preventing acute otitis media in young children. A randomized controlled trial. JAMA 2003; 290:1608–1616.

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PRACTICE RECOMMENDATIONS

Administration of influenza vaccine to children aged 6 to 24 months to prevent acute otitis media is not recommended.

BACKGROUND

Influenza vaccines have been shown to prevent acute otitis media in children aged <2 years; reductions of 30% to 44% have been reported. This study was designed to determine the effectiveness of influenza vaccine in reducing the

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Azithromycin should not be used to prevent recurrent CHD even in patients exposed to *C pneumoniae*

occurrence of acute otitis media in children aged 6 to 24 months.

POPULATION STUDIED

The investigators recruited 786 healthy children aged 6 to 24 months from Children's Hospital of Pittsburgh primary care center (52%) and from the community (48%) over 2 consecutive respiratory seasons (December 1–March 31) starting in 1999. The 2 cohorts included 411 children and 375 children, respectively.

Children with any of the following characteristics were not eligible for the study: premature birth, craniofacial abnormality, neurological disorder, history of tympanostomy tube insertion, hypersensitivity to vaccine ingredients, a febrile or severe respiratory illness within the preceding 48 hours. About half of all study participants were male, white, between 6 and 12 months old at enrollment, and covered by private insurance.

Forty percent were the only children in a household, 20% had a history of recurrent acute otitis media, and 27% were in day care. In the vaccine group, 35% were exposed to household cigarette smoke; 40% of the placebo group had this exposure.

STUDY DESIGN AND VALIDITY

Children were randomly assigned to either vaccine or placebo in a 2:1 ratio after stratification by attendance in day care, history of multiple acute otitis media episodes, and a history of pneumococcal conjugate vaccination (second cohort only). Allocation was concealed.

Two doses of inactivated trivalent influenza vaccine (or placebo) were given approximately 4 weeks apart. The first cohort was examined biweekly through the respiratory season, then monthly for a total of 1 year; the second cohort was seen biweekly during the ensuing respiratory season. Interim visits were conducted for any upper respiratory symptoms. Investigators used pneumatic otoscopy, tympanometry, and acoustic reflexometry for examinations. Acute otitis media and middle-ear effusion were diagnosed based on strict criteria.

Additionally, parents were asked at all visits about other healthcare visits to physicians or emergency rooms, and about hospitalizations. Parents were also asked about time lost from work and alternative child-care arrangements due to their child's illness.

All parents, investigators, and research personnel conducting clinical follow-up of the children and nonstudy healthcare providers were blinded throughout the study. Research nurses who administered the vaccine were not blinded. Follow-up was excellent: 373 (91%) and 346 (92%) of the first and second cohorts, respectively, completed the study.

The randomization provided 2 similar groups for comparison. Analysis was by intention-to-treat. The study had 80% power to detect a 33% reduction in the proportion of children who had at least 1 episode of acute otitis media. (*Level of evidence:* **1b**)

OUTCOMES MEASURED

The investigators measured four primary endpoints: 1) proportion of children who developed acute otitis media; 2) monthly occurrence rate of acute otitis media; 3) estimated proportion of time with middle-ear effusion, and 4) use of selected health care and related resources.

RESULTS

For both cohorts, there was no significant difference in the proportion of vaccinated children who experienced at least 1 episode of acute otitis media (49.2% and 55.8% for first and second cohorts, respectively) compared with placebo groups (52.2% and 48.3%) during the respiratory season.

Older children (19–24 months) showed a trend toward vaccine prevention (36.8% vaccine vs. 54.3% placebo; P=.09), but only in the first

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cohort. There were no differences between vaccine and placebo groups in the monthly occurrence of acute otitis media episodes, the estimated proportion of days with middle-ear effusion, and use of selected healthcare and related resources.

Elevated D-dimer level predicts recurrent VTE

Eichinger S, Minar E, Bialonczyk C, et al. D-dimer levels and risk of recurrent venous thromboembolism. JAMA 2003; 290:1071–1074.

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PRACTICE RECOMMENDATION

Patients with venous thromboembolism (VTE) and no obvious underlying cause or major clotting protein abnormalities whose D-dimer levels are <250 ng/mL have a significantly reduced long-term risk of recurrent VTE. Physicians should consider obtaining this test and providing this information to patients.

Given the burgeoning numbers of tests being developed to assess thrombophilia risk, the attraction of the D-dimer is that it may represent a global measure of risk of recurrent disease. Physicians should understand, however, that clinical research is still preliminary and look for further evidence of the prognostic performance of D-dimer across populations with different ethnicity and the outcomes of long-term treatment on patients at higher risk of VTE as measured by D-dimer.

BACKGROUND

Management of patients with VTE after completion of anticoagulation remains controversial. This prospective trial evaluates the prognostic value of D-dimer level in predicting VTE recurrence.

POPULATION STUDIED

A total of 610 patients were enrolled—Austrian adults diagnosed with VTE by venography, sonography, ventilation/perfusion (V/Q) scan, or spiral computed tomography and treated for at least 3 months with anticoagulants. Exclusion criteria included more than 1 previous VTE, surgery, trauma or pregnancy within the last 3 months, deficiency of natural anticoagulants or the presence of cancer, lupus anti-coagulant, or long-term antithrombotic therapy.

Of these, 56% were women and 42% were <45 years of age; 38% had previous pulmonary emboli and 31% had factor V Leiden. Thus, these patients were probably similar to those in a typical family practice with a DVT with no obvious underlying cause and no lupus anticoagulant or deficiency of natural coagulant inhibitor. More information about ethnicity and the clinical work-up for underlying causes would be valuable.

STUDY DESIGN AND VALIDITY

Subjects were enrolled at completion of anticoagulation and observed every 3 months during the first year and every 6 months thereafter. Three weeks after discontinuation of oral anticoagulation, antithrombin, proteins C and S, factor V Leiden, factor II G20210A, and D-dimer levels using the enzyme-linked immunosorbent assay (ELISA) method were obtained.

A total of 175 patients were excluded from analysis because of new diagnosis of cancer (11), requirement of antithrombotics for reasons other than VTE (105), pregnancy (17) or loss to follow-up (37). Risk of recurrent VTE was assessed by Kaplan-Meier plots and survival time analysis, after controlling for age, gender, factor V Leiden, factor II G20210A, and high factor VIII levels.

Methodological strengths include the attempt to define a population without obvious underlying causes for VTE, large sample size, prospective design, excellent follow-up, and

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relatively long duration of follow-up. Weaknesses were minor and included lack of information about initial work-up and lack of attention to important confounding variables such as other medications, diet, and activity. (*Level of evidence*: **2b**)

OUTCOMES MEASURED

The major outcome measured was recurrent VTE. Outcomes such as cost, impact of labeling, and clinician/patient satisfaction were not addressed.

RESULTS

The average duration of observation was 38 months; overall frequency of recurrent VTE was 13%. There was a graded increase in risk of recurrence with increasing D-dimer levels. Compared with patients with D-dimer levels ≥250 ng/mL those with levels <250 ng/mL had significantly lower risk of recurrent VTE (relative risk=0.3; 95% confidence interval, 0.1–0.6); controlling for age, sex, factor V Leiden, factor II, G20210, and factor VIII did not change this finding.

After 2 years, patients with D-dimer levels <250 ng/mL had an absolute risk of recurrence of 3.7%, whereas those with levels ≥250 ng/mL had an absolute risk of recurrence of 11.5%. A measure of the clinical significance of the risk may be represented in a number needed to observe (NNO), which is the reciprocal of the absolute risk difference of the risk groups. The NNO was 26, suggesting that clinicians would have to observe 26 high-risk patients for 1 year to see 1 additional VTE compared to low risk patients. Thus, D-dimers have moderate strength as a clinical predictive tool.

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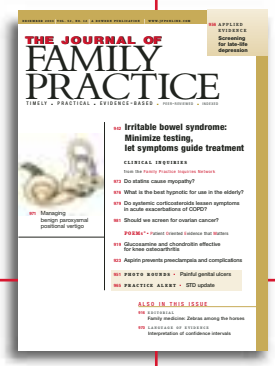

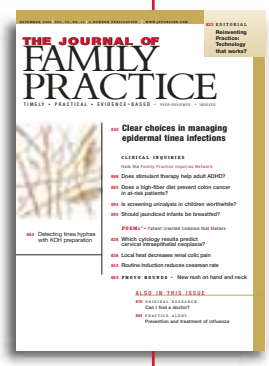

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