POEMs

Patient-Oriented Evidence that Matters

There are four POEMS in this issue. These covers: advice to patients with dyspepsia symptoms; risk prediction methods for cardiovascular events; whether selective serotonin reuptake inhibitor antidepressants increase the risk of gastrointestinal bleeding; and whether telling patients their lung age will help them quit smoking. Editor.

Clinical question

In patients with dyspepsia symptoms, is it more cost-effective to test and treat Helicobacter pylori infection or to treat empirically with acid suppression therapy?

Bottom line

In patients with undifferentiated dyspepsia symptoms (i.e. epigastric pain with or without heartburn but without a specific diagnosis), results are similar with empiric acid suppression (omeprazole 20mg for one month) and testing for and treating Helicobacter pylori infection. The percent of patients who are symptom free at one year is similar between the two groups, and the increased cost of testing is offset by a decrease in subsequent testing and procedures. (LOE = 1b)

Reference

Delaney BC, Qume M, Moayyedi P, et al. Helicobacter pylori test and treat versus proton pump inhibitor in initial management of dyspepsia in primary care: multicentre randomised controlled trial (MRC-CUBE trial). BMJ 2008;336:651-654.

Study Design

Randomised controlled trial (single-blinded)

Funding

Government

Allocation

Concealed

Setting

Outpatient (primary care)

Synopsis

Is it reflux? Peptic ulcer? So-called functional dyspepsia? In primary care there is a move away from a strict diagnosis in patients without alarm symptoms (hematemesis and so forth) to empiric treatment to control symptoms. The UK researchers conducting this study enrolled 699 adults who presented with general symptoms of epigastric pain, heartburn, or both, lasting for at least four weeks but without alarm symptoms. Using concealed allocation, the patients were randomly assigned to one of two intervention groups. The test-and-treat group were tested for the presence of H. pylori using the urea breath test, and the 29% of patients who had a positive result were treated with eradication therapy and one month of acid suppression with a low-dose proton pump inhibitor (omeprazole 20mg daily). Patients who had a negative test result were treated only with the acid suppression. Patients in the empiric treatment group did not undergo testing but received the same dose and duration of acid suppression. Using intention-to-treat analysis, the researchers compared the cost, percent of patients who were symptom free at the end of 12 months, and quality of life, expressing the final results as quality-adjusted life years. Data were available for 76% of patients. There was no difference between the test-and-treat group and the empiric acid suppression group with regard to the number of patients with symptoms at one year, quality of life, or costs. The increased cost of H. pylori testing was offset by decreases in costs incurred by other imaging.

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** Patient-Oriented Evidence that Matters. See editorial (NZFP 2003; 30:150)*

Clinical question

Are risk prediction methods using laboratory testing and methods not using laboratory testing comparable in predicting cardiovascular events?

Bottom line

Cardiovascular prediction models that do not require laboratory testing perform as well as models that use laboratory testing. (LOE = 2b)

Reference

Gaziano TA, Young CR, Fitzmaurice G, Atwood S, Gaziano JM. Laboratory-based versus non-laboratory-based method for assessment of cardiovascular disease risk: the NHANES I Follow-up Study cohort. Lancet 2008;371(9616):923-931.

Study Design

Cohort (prospective)

Funding

Government

Setting

Population-based

Synopsis

Since most of the world's cardiovascular deaths occur in developing countries where laboratory testing is a costly luxury, these researchers sought to determine if cardiovascular prediction models that don't use laboratory testing perform as well as those that do. To do this, they identified nearly 6200 patients with no known heart disease and used Framingham-based prediction models to estimate cardiovascular disease risk. In the Framingham model, cholesterol levels are used along with other factors. These researchers replaced body mass index for cholesterol in the nonlaboratory-based model. The patients had completed a comprehensive set of surveys and tests in the 1970s and their vital status was assessed 20 years later. The research team obtained medical records, pathology reports, electrocardiograms, and so forth to confirm diagnoses. Finally, they evaluated the performance of the models on men and on women. During the 21 years of follow up, 38% of the patients died from cardiovascular disease and there were more than 1500 first-time cardiovascular events. For women, both prediction models were 83% accurate. For men, both models were 78% accurate.

Clinical question

Do selective serotonin reuptake inhibitor antidepressants increase the risk of gastrointestinal bleeding?

Bottom line

Upper gastrointestinal (GI) bleeding is associated with the use of selective serotonin reuptake inhibitors (SSRIs); the risk is increased when patients are also taking nonsteroidal anti-inflammatory drugs (NSAIDS). The risk for each individual is still low; but given the number of people taking SSRIs, the impact across a population may be noticeable. (LOE = 3a)

Reference

Loke YK, Trivedi AN, Singh S. Meta-analysis: gastrointestinal bleeding due to interaction between selective serotonin uptake inhibitors and non-steroidal anti-inflammatory drugs. Aliment Pharmacol Ther 2008;27:31-40.

Study Design

Systematic review

Funding

Unknown/not stated

Setting

Various (meta-analysis)

Synopsis

To estimate the risk of upper GI bleeding with SSRIs, these researchers assembled studies of various types, including unpublished data from pharmaceutical companies' Web sites and www.clinicalstudyresults.org, case reports from the Canadian Adverse Events Database and the United States FDA Adverse Event Reporting System, and observational studies indexed in PubMed. They included studies published in any language. They did not explain how the data were reviewed or evaluated. From the observational studies, one cohort study, and three case-control studies, the pooled odds ratio for upper GI

bleeding associated with the use of SSRIs was 2.36 (95% CI, 1.44 – 3.85); the combination of SSRIs and NSAIDs increased the odds ratio to 6.33 and was higher than the odds ratio associated with NSAIDs alone (3.16). Given a baseline upper GI bleeding risk of 23 per 10 000 patients per year in patients 50 years or older, one additional episode of bleeding would occur for every 318 patients treated with an SSRI for one year (number needed to treat = 318). The combination of SSRI and NSAID would produce an additional episode of GI bleeding for every 82 patients over the course of one year. From reports to federal agencies, it seems that bleeding occurs after approximately 25 weeks of SSRI use. These estimates are based on the assumption of baseline risk and are suitable only for helping us understand that there is a risk; the actual magnitude of the risk is speculative.

Clinical question

Can determining patients' lung function and telling them their 'lung age' urge them to quit smoking?

Bottom line

Evaluating lung function in patients who smoke and giving them the results in terms of their 'lung age' – the age of the average nonsmoker with the same FEV1 as the patient – increases rates of sustained cessation in patients in primary care who were not interested in quitting. Most patients (77%) were in the precontemplative stage of change and thus were not highly motivated before finding out their lung function. (LOE = 1b)

Reference

Parkes G, Greenhalgh T, Griffin M, Dent R. Effect on smoking quit rate of telling patients their lung age: the Step2quit randomised controlled trial. BMJ 2008;336:598-600.

Study Design

Randomised controlled trial (single-blinded)

Funding

Foundation

Allocation

Concealed

Setting

Outpatient (primary care)

Synopsis

The UK researchers performing this study recruited by mailed invitation 561 patients older than 35 years who smoked. After obtaining baseline data and performing spirometry, the patients were randomly assigned, using concealed allocation, to one of two groups. Control group patients were asked to return in one year for follow-up lung function testing. The intervention group received an explanation of their 'lung age', the age of the average healthy individual who would perform similar to them on spirometry. For example, a 50-year-old patient with an FEV1 of 65% predicted would have a lung age of 75 years. Patients in both groups were strongly urged to quit smoking but were not given any specific instruction or intervention. Despite an average smoking history of 33 pack-years, most patients had normal spirometry rates at baseline. Quit rates were confirmed at 12 months by measuring expired carbon monoxide and also serum cotinine levels. Quit rates were 6.4% of the control group and 13.6% in the intervention group (P = .005). Fourteen people would need to be given their lung age for one additional person to quite smoking (number needed to treat = 14). Patients with a greater difference in lung age were no more likely to quit smoking. A similar proportion of patients in both groups used smoking cessation aids (8%–11%).