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Immunochemical FOBTs Moderately Sensitive and Highly Specific for Colorectal Cancer

Clinical Question

Are immunochemical fecal occult blood tests (FOBTs) sensitive and specific enough to be used for colorectal cancer screening?

Bottom Line

Immunochemical FOBTs, such as OC-Micro, OC-Sensor, or OC-Light, are moderately sensitive (73% to 89%) and highly specific (92% to 95%) for identifying colorectal cancer. In comparison, Hemoccult Sensa has a lower sensitivity (64% to 80%) and specificity (87% to 90%). Immunochemical FOBTs also have the advantage of requiring only one sample. (Level of Evidence = 1c)

Synopsis

These researchers searched five databases and the reference lists of included studies, finding 19 eligible studies that evaluated the diagnostic accuracy of immunochemical FOBTs. Two authors used the STARD (Standards for Reporting of Diagnostic Accuracy) and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) protocols and independently determined study eligibility, extracted the data, and evaluated study quality. They included cohort studies and randomized studies that used colonoscopy or longitudinal follow-up as the diagnostic standard and only included studies published in English. They excluded studies or results that evaluated only the detection of adenomas.

Limiting analysis to only currently available immunochemical FOBTs found a sensitivity of 82% (95% confidence interval, 73% to 89%) and a specificity of 94% (95% confidence interval, 92% to 95%). These numbers translate into a positive likelihood ratio of 13.10 and a negative likelihood ratio of 0.19. There was no difference in performance among different commercial products, and multiple sampling was no more accurate than a single sample. Heterogeneity among the studies was acceptable when removing products that are not commercially available. There was some evidence of publication bias. There are no head-to-head studies comparing one type of test with another, and no research evaluating the effectiveness of immunochemical FOBT testing on cancer-related mortality or all-cause mortality.

Study design: Meta-analysis (other)

Funding source: Government

Setting: Various (meta-analysis)

Reference: *Lee JK, Liles EG, Bent S, Levin TR, Corley DA. Accuracy of fecal immunochemical tests for colorectal cancer: systematic review and meta-analysis.* Ann Intern Med. *2014;160(3):171-181.*

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Opioids for Chronic Back Pain: Short-Term Effectiveness, Long-Term Uncertain

Clinical Question

Are opioids effective in the treatment of chronic low-back pain?

Bottom Line

Overall, in patients with chronic low-back pain, opioids are moderately more effective than placebo in the short term for pain relief and slightly more effective in the short term for improving function. However, data for long-

term use are virtually nonexistent. The long-term use of opioids for patients with chronic low-back pain is controversial. Physicians are asked to provide comfort to patients, yet the regulatory and safety concerns of long-term use are a sobering counterpoint. (Level of Evidence = 1a–)

Synopsis

This is an update to a Cochrane review published in 2007. The authors systematically searched several databases to identify randomized trials comparing opioids with placebo or other drugs. The studies had to have masked outcome assessments and evaluated at least one of the following: pain, function, global improvement, or the proportion of patients reporting 30% or 50% pain relief. Two authors independently assessed studies for inclusion, reconciling disagreements by discussion. Additionally, three authors independently extracted data from included studies. Finally, they used an explicit approach to assess the quality of each study and to assess the role of publication bias. Eventually, these authors included 15 trials with 5,540 participants. For the most part, the reviewed trials had low to moderate quality, high dropout rates, short duration, and limited interpretability of functional improvement.

Six studies evaluated tramadol (Ultram) alone or in combination with acetaminophen (five compared with placebo, one as an active comparator against a centrally acting nonopioid); two studies compared buprenorphine with placebo; and seven studies assessed strong opioids (morphine, oxymorphone, hydromorphone [Dilaudid], oxycodone [Oxycontin]). Of the seven trials of strong opioids, three were not designed to assess opioid effectiveness. Twelve of the 15 total studies were at low risk of bias. The five studies comparing tramadol with placebo generally had more methodologic bias and showed greater overall pain relief than placebo and greater improvement in functional outcomes than placebo. In the two studies of buprenorphine, the authors found very low-quality evidence that this agent reduces pain more than placebo and that it improves function. The studies of strong opioids found small reductions in pain and small improvements in function.

Study design: Meta-analysis (randomized controlled trials)

Funding source: Self-funded or unfunded

Setting: Various (meta-analysis)

Reference: *Chaparro LE, Furlan AD, Deshpande A, Mailis-Gagnon A, Atlas S, Turk DC. Opioids compared with placebo or other treatments for chronic low back pain: an update of the Cochrane review.* Spine (Phila Pa 1976). *2014;39(7):556-563.*

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2013 ACC/AHA Cholesterol Guideline Greatly Increases Number Eligible for Statin Treatment

▶ **See related Practice Guidelines on page 260, and Editorials on pages 212 and 223.**

Clinical Question

How many more adults will be eligible for statin therapy under the 2013 American College of Cardiology (ACC)/American Heart Association (AHA) guideline than under previous guidelines?

Bottom Line

The new guideline from the ACC/AHA increases the number of adults between 40 and 75 years of age who are eligible to take statins by 12.8 million. The largest increases were among adults who would take statins for primary prevention and for adults between 60 and 75 years of age. The authors estimate that the switch could prevent 475,000 future cardiovascular events in this population. (Level of Evidence = 2c)

Synopsis

The 2004 guidelines from the Third Adult Treatment Panel (ATP III) of the National Cholesterol Education Program recommended statin therapy on the basis of the presence of specific risk factors, such as diabetes mellitus or cardiovascular disease (CVD), and on specified treatment targets according to risk level. The 2013 ACC/AHA guideline suggests statins for all adults at risk of CVD, regardless of low-density lipoprotein cholesterol (LDL-C) levels. The research team used National Health and Nutrition Examination Survey (NHANES) data from 2005 to 2010 to determine the proportion of adults who would be eligible to take statins under each guideline and then extrapolated those results to the U.S. population at large. They also compared the risk profiles of patients eligible for statins under each approach and the two different calculators used to estimate risk with each guideline. For the analysis, they used fasting blood samples of a subset of 3,773 adults between 40 and 75 years of age.

Of the study sample, 1,583 patients (42.0%) would receive a statin under the ATP III guidelines, whereas 2,135 (56.6%) would receive a statin under the 2013 ACC/AHA guideline, for an increase of 599 newly eligible adults (15.9%; higher than the net difference because some participants eligible under the ATP III guidelines would not be eligible under the new guideline). When these results were extrapolated to 115 million U.S. adults between 40 and 75 years of age, 43.2 million patients (37.5%) would be prescribed statins under the ATP III guidelines and 56.0 million patients (48.6%) were

eligible under the new ACC/AHA guideline, representing an increase of 12.8 million adults. Of the newly eligible U.S. adults, 61.7% are men, the median age is 63.4 years, and the median LDL-C level is 105.2 mg per dL (2.72 mmol per L). The greatest difference in cholesterol recommendations is among adults 60 to 75 years of age (47.8% eligible under ATP III vs. 77.3% under ACC/AHA). This study may be limited by the accuracy and representativeness of the NHANES data, including self-reporting of statin use and lack of data on peripheral vascular disease or transient ischemic attacks, which may underestimate rates of CVD in the sample.

Study design: Cross-sectional

Funding source: Foundation

Setting: Population-based

Reference: *Pencina MJ, Navar-Boggan AM, D'Agostino RB Sr., et al. Application of new cholesterol guidelines to a population-based sample.* N Engl J Med. *2014;370(15):1422-1431.*

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Anastrozole Decreases Rate of Breast Cancer in High-Risk Postmenopasusal Women

Clinical Question

Does anastrozole (Arimidex) decrease the rate of breast cancer in high-risk postmenopausal women?

Bottom Line

Postmenopausal women at high risk of developing breast cancer who take anastrozole for five years have a lower rate of developing invasive breast cancer during that time frame. (Level of Evidence = 1b)

Synopsis

These authors report outcomes from the second International Breast Cancer Intervention Study (IBIS-II), in which postmenopausal women in 18 countries who were at high risk of breast cancer were randomly assigned to receive anastrozole (1 mg daily for five years; n = 1,920) or placebo (n = 1,944). The authors used a complex series of definitions to identify high-risk women: 40 to 44 years of age with an estimated fourfold increased risk compared with the general population; 45 to 60 years of age with double the estimated risk; and 60 to 70 years of age with 1.5-fold increased risk. The authors also used the Tyrer-Cuzick model and included any additional women with an estimated 10-year risk greater than 5%. They excluded women who were premenopausal, had a previous breast cancer diagnosis, or had previously received chemoprophylaxis.

The researchers and support staff were masked to treatment allocation. The researchers evaluated the women at baseline, six months, 12 months, and then annually for five years. The researchers used intention-to-treat to analyze the rate of incident breast cancers. By the end of the study, 2% of women receiving anastrozole had invasive breast cancer compared with 3% of women who received placebo (number needed to treat = 62 for five years; 95% confidence interval, 38 to 155). Approximately one-third of the women in the anastrozole group and one-fourth in the placebo group stopped taking their medication, mainly because of side effects. There was no difference in the overall death rate (1%) in each group.

Study design: Randomized controlled trial (double-blinded)

Funding source: Industry plus government

Allocation: Uncertain

Setting: Population-based

Reference: *Cuzick J, Sestak I, Forbes JF, et al.; IBIS-II investigators. Anastrozole for prevention of breast cancer in high-risk postmenopausal women (IBIS-II): an international, double-blind, randomised placebo-controlled trial [published correction appears in* Lancet. *2014;383(9922):1040].* Lancet. *2014;383 (9922):1041-1048.*

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