POEMs

Patient-Oriented Evidence That Matters

Fecal Occult Blood Testing Is Inaccurate as Part of Diagnostic Workup

Clinical Question

Is fecal occult blood testing (FOBT) reliable as part of evaluating patients with clinical indications?

Bottom Line

In this well-conducted systematic review, FOBT, although useful in screening for colorectal cancer, is not highly accurate in evaluating patients with clinical indications. (Level of Evidence = 2a)

Synopsis

The authors searched Medline and Embase for full publications of any research design, except case reports, that evaluated the use of FOBT, either via guaiac test or fecal immunochemical test (FIT), in the evaluation of adults with clinical indications such as diarrhea, iron deficiency anemia, and so forth. The studies also had to include a reference standard, such as endoscopy. Two authors independently assessed the eligibility of studies for selection, as well as the risk of bias of each included trial. The senior author settled any disagreements. The authors included 22 studies that each enrolled between 26 and 1,132 patients. Twelve of the studies evaluated patients with iron deficiency anemia without overt signs of bleeding, eight included patients with ulcerative colitis, and two included patients with diarrhea. Only two of the studies were at low risk of bias. Nine studies evaluated guaiac tests and 13 evaluated FITs. Compared with upper or lower endoscopy, FOBT was 58% sensitive (95% CI, 53% to 63%) and 84% specific (95% CI, 75% to 89%) for diagnosing any gastrointestinal abnormality in patients with iron deficiency anemia, with no meaningful difference between guaiac testing or FIT. FOBT was 83% sensitive (95% CI, 72% to 90%) and 79% specific (95% CI, 68% to 86%) for diagnosing colorectal cancer in patients with iron deficiency anemia. In the studies of patients with ulcerative colitis, FOBT (all of the studies used FIT) was 72% sensitive (95% CI, 57% to 84%) and 80% specific (95% CI, 67% to 89%) for active disease. For patients with diarrhea, the sensitivities of FOBT (both studies used guaiac testing) were widely divergent (38% and 87%) as were the specificities (58% and 85%).

Study design: Meta-analysis (other)

Funding source: Self-funded or unfunded

Setting: Various (meta-analysis)

Reference: *Lee MW, Pourmorady JS, Laine L. Use of fecal occult blood testing as a diagnostic tool for clinical indications: a systematic review and meta-analysis.* Am J Gastroenterol. *2020;115(5):662-670.*

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Easy Rule Identifies Patients with Low-Risk Penicillin Allergies

Clinical Question

Which adult patients with a history of penicillin allergy will have positive allergy testing?

Bottom Line

A label of penicillin allergy clears the shelves of many effective treatments for various infections. A simple rule outlined in the synopsis effectively identifies (without allergy testing) low-risk penicillin allergies in patients with a history of a penicillin allergy event. (Level of Evidence = 1a)

Synopsis

The PEN-FAST rule was developed using a group of 622 patients with a history of reacting to penicillin who were referred for allergy testing, and

then validated on a second group of 945 patients who were referred for allergy testing at three other sites. Allergy testing consisted of skin prick, intradermal, or patch testing, with a positive test confirmed by oral challenge. In the validation group, 27.4% reported a history of angioedema and/or anaphylaxis. Following testing in this group, the prevalence of reacting to any allergy test was 9.9%, but only 21 participants reacted to the oral challenge (2.2%). For patients who report a PENicillin allergy, here is the FAST rule:

F (five years or less since the reaction): 2 points

A (anaphylaxis or angioedema) or S (severe cutaneous reaction): 2 points

T (treatment required for reaction): 1 point

Patients with a score of 0 had a likelihood of a positive test result of less than 1%; a score of 1 or 2 yielded a positive test result in 5%. Among the three cohorts, sensitivity ranged from 70.4% (prevalence 27%) to 87.5% (prevalence 14.4%).

Study design: Decision rule (validation)

Setting: Outpatient (any)

Reference: *Trubiano JA, Vogrin S, Chua KYL, et al. Development and validation of a penicillin allergy clinical decision rule.* JAMA Intern Med. *2020;180(5):1-9.*

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Vaginal Bleeding Decreases over Time with a Levonorgestrel Intrauterine System

Clinical Question

What changes in vaginal bleeding can women expect after the placement of a levonorgestrel-releasing intrauterine system (52 mg; Mirena or Liletta)?

Bottom Line

Bleeding decreased over time for most women after the insertion of a levonorgestrel-releasing intrauterine system. Bleeding or spotting requiring the use of sanitary products occurred for a mean of 36 of the first 90 days after insertion and then decreased markedly for most women (to means of 19, 14, and 12 days in the three succeeding 90-day periods, respectively). Days of frank bleeding were fewer on average, with means of 13, eight, six, and five days in each of the four 90-day periods after insertion. (Level of Evidence = 2a)

Synopsis

This systematic review and meta-analysis was conducted for the stated purpose of providing information to help clinicians counsel patients about what to expect regarding vaginal bleeding after the placement of a levonorgestrel-releasing intrauterine system. The authors identified seven studies, four randomized controlled trials, two cohort studies, and one reanalysis of randomized controlled trial data, that met the inclusion criteria with a total of 5,098 participants from 10 countries. Included studies reported outcomes of interest for women with a history of normal menstrual periods for at least 90 days after the placement of the levonorgestrel-releasing intrauterine system according to bleeding diaries. Bleeding outcomes were the number of bleeding and/or spotting days based on World Health Organization definitions. The authors excluded studies if the study population was women with heavy or prolonged menstrual periods, who were actively breastfeeding, who used long-acting contraception methods within six months before placement, or who had anatomic pathologies (such as fibroids or cancer). The authors extracted mean or median days of bleeding only, spotting only, and bleeding and/or spotting in 90-day intervals for the year after placement. They found that bleeding decreased markedly after the first 90-day interval. For bleeding and/or spotting, the results over succeeding periods were 35.6 days (95% CI, 32.2 to 39.1), 19.1 days (95% CI, 16.1 to 21.5), 14.2 days (95% CI, 11.7 to 16.8), and 11.7 days (95% CI, 9.7 to 13.7). The results for bleeding-only days were 13.3 days (95% CI, 10.8 to 15.7), 7.8 days (95% CI, 6.5 to 9.1), 6.2 days (95% CI, 4.9 to 7.5), and 5.0 days (95% CI, 3.9 to 6.1), respectively, for the four 90-day periods. The authors conducted several sensitivity analyses to account for heterogeneity between studies, which did not materially change the findings.

Study design: Meta-analysis (other)

Funding source: Government

Setting: Outpatient (specialty)

Reference: *Maldonado LY, Sergison JE, Gao X, et al. Menstrual bleeding and spotting with the levonorgestrel intrauterine system (52 mg) during the first-year after insertion: a systematic review and meta-analysis.* Am J Obstet Gynecol. *2020;222(5):451-468.e9.*

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Some Drugs Slightly Improve Cognition in People with Dementia; Effects on Behavioral or Psychological Symptoms Remain Unclear

Clinical Question

Can drug treatments improve outcomes in people with dementia?

Bottom Line

Some treatments can improve cognition on research scales, but daily function will not be affected in a noticeable way. Managing behavioral or psychological issues with medication is not supported by current evidence. (Level of Evidence = 1a)

Synopsis

The authors searched four databases, including the Cochrane Library, a clinical trials database, and bibliographies of other systematic reviews, to identify all English-language studies of drug treatments for cognition, function, or behavioral and psychological symptoms associated with Alzheimer-type dementia. Two authors screened possible articles for inclusion. One author performed data extraction, which was verified by a second author. The authors assessed risk of bias and only analyzed results from studies with low or medium risk, removing 97 of the 163 unique studies they identified. The researchers found a small improvement in cognition (standardized mean difference = 0.30) with a low strength of evidence for cholinesterase inhibitors, although there was no effect on overall function or global clinical impression. The most frequently studied cholinesterase inhibitor was donepezil (Aricept). In patients with moderate to severe disease, adding memantine (Namenda) to a cholinesterase inhibitor improved cognition and overall clinical impression, but not function compared with placebo. No treatments had sufficient evidence of their benefit on behavioral or psychological symptoms. Withdrawal from treatment because of adverse effects was higher with cholinesterase inhibitors galantamine (Razadyne) and rivastigmine (Exelon) compared with placebo. There was not significant heterogeneity among the studies. The likelihood of publication bias was not reported.

Study design: Meta-analysis (randomized controlled trials)

Funding source: Government

Setting: Various (meta-analysis)

Reference: *Fink HA, Linskens EJ, MacDonald R, et al. Benefits and harms of prescription drugs and supplements for treatment of clinical Alzheimer-type dementia.* Ann Intern Med. *2020;172(10):656-668.*

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