POEMs

Patient-Oriented Evidence That Matters

Guideline, with No Evidence, Suggests Annual Screening for Urinary Incontinence in Women

Clinical Question

Should women be screened for symptoms of urinary incontinence?

Bottom Line

The goal of screening is to identify a disorder before it becomes symptomatic if early treatment has the potential for greater benefit than waiting until symptoms are reported. Despite the failure to meet this definition, this guideline suggests annual screening of women for urinary incontinence and the effect, if any, on their lives. This guideline development group has too much investment in the recommendations to be credible, especially given the lack of evidence. (Level of Evidence = 5)

Synopsis

This guideline comes from the Women's Preventive Services Initiative, a collaboration between the U.S. government and the American College of Obstetricians and Gynecologists, with input from several other professional societies whose members care for women. Seeming to step on the sensible shoes of the U.S. Preventive Services Task Force, the stated goal of this group is to assure that women receive a comprehensive set of preventive services that are paid for by the government (https://www.womenspreventivehealth.org/about/). This is already an inherent conflict of interest, so let us dig a little deeper. The authors performed a systematic review, finding no studies that evaluated the effectiveness of screening on improving symptoms, quality of life, or function. The strength of the evidence that supports the accuracy of screening methods is low. There is no research into the adverse effects of screening. The strength of the evidence that supports treatments for incontinence is low to moderate, and there is no evidence that suggests early detection results in better outcomes. Yet, the group has decided that clinicians should use a validated assessment instrument annually for all women to determine whether they have incontinence and whether it affects their health, function, or quality of life.

Study design: Practice guideline

Funding source: Government

Setting: Outpatient (any)

Reference: *O'Reilly N, Nelson HD, Conry JM, et al.; Women's Preventive Services Initiative. Screening for urinary incontinence in women: a recommendation from the Women's Preventive Services Initiative.* Ann Intern Med. *2018;169(5):320-328.*

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Aspirin's Benefits and Harms Are Less Clear for Primary Prevention in Moderate-Risk Patients

Clinical Question

Is low-dose aspirin effective for the primary prevention of cardiovascular disease in moderate-risk patients?

Bottom Line

In this study, after five years of treatment, patients at a moderate risk of heart disease who took low-dose aspirin did not show a decrease in

coronary events and all-cause mortality and had slightly more gastrointestinal bleeding. If you are confused by all the aspirin-related folderol of late, join the club. Using aspirin for primary prevention of cardiovascular disease is not a one-size-fits-all proposition. We need to risk-stratify patients according to benefits and harms and engage in shared decision-making with each patient. (Level of Evidence = 1b)

Synopsis

Low-dose aspirin for secondary prevention and in the face of acute coronary events is pretty much a slam dunk. Despite years of research, several meta-analyses, and numerous guidelines, its use for primary prevention still seems to be controversial. The researchers point out that most of the recommendations are largely for patients whose 10-year risk of a coronary event exceeds 20% and the role of aspirin in patients of intermediate risk is less clear. They conducted a double-blind randomized trial of aspirin, 100 mg daily (n = 6,270), or placebo (n = 6,276) in patients at a moderate risk of coronary artery disease. The study participants were men at least 55 years of age or women at least 60 years of age with a 10% to 20% 10-year risk based on age, sex, smoking status, blood pressure, lipid concentrations, and family history. They excluded patients with diabetes mellitus and those at high risk for bleeding complications. Using intention-to-treat analysis, after five years the rate of events (a composite of myocardial infarction, stroke, cardiovascular death, unstable angina, or transient ischemic attack) was similar between the treatment groups (4.3% vs. 4.5%, respectively). The overall death rate was the same (2.6%) in each group. The aspirin-treated patients had more bleeding events (1% vs. 0.5%), although few had moderate or severe gastrointestinal bleeding. The graphs in the paper demonstrate nearly a linear relationship in outcomes over time, so the projected 10-year outcomes indicate that 9% of the placebo-treated patients would have had a coronary event. Recall another study that suggested aspirin's effect was potentially influenced by weight and sex (*Lancet*. 2018;392[10145]:387-399).

Study design: Randomized controlled trial (double-blinded)

Funding source: Industry

Allocation: Concealed

Setting: Outpatient (any)

Reference: *Gaziano JM, Brotons C, Coppolecchia R, et al.; ARRIVE Executive Committee. Use of aspirin to reduce risk of initial vascular events in patients at moderate risk of cardiovascular disease (ARRIVE): a randomised, double-blind, placebo-controlled trial.* Lancet. *2018;392(10152):1036-1046.*

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No Reduction in Delirium with the Use of Haloperidol or Ziprasidone in Critically Ill Patients

Clinical Question

Does the use of antipsychotics decrease the duration of delirium in critically ill patients with respiratory failure or shock?

Bottom Line

For patients with acute respiratory failure or shock who develop delirium in the intensive care unit (ICU), the use of haloperidol or ziprasidone (Geodon) does not reduce the duration of delirium. This trial was powered to detect at least a two-day difference in the duration of delirium, so a smaller difference cannot be excluded. (Level of Evidence = 1b)

Synopsis

This study included critically ill patients with delirium who were using invasive or noninvasive mechanical ventilation, taking vasopressors, or requiring an intra-aortic balloon pump. The patients were randomized to receive intravenous haloperidol, 2.5 mg; ziprasidone, 5 mg; or a placebo, 0.5 mL of normal saline. Patients 70 years or older received one-half of these doses. Doses were administered every 12 hours and were doubled up to the maximum dose if a patient still had delirium, halved to a minimum dose if the patient did not have delirium for two consecutive assessments, and withheld if a patient did not have delirium for four consecutive assessments. Therapy was continued for 14 days or until ICU discharge. Therapy was stopped permanently if a patient developed torsades de pointes, neuroleptic malignant syndrome, or a severe drug reaction. Of the 20,000 patients screened for eligibility over a six-year period, 566 patients agreed to participate and met the criteria for randomization. Patients in the three groups had similar baseline characteristics, and almost 90%

had hypoactive delirium at the time of randomization. Analysis was by intention to treat. Compared with placebo, the use of either haloperidol or ziprasidone did not significantly increase the median number of days alive without delirium or coma (8.5 days with placebo, 7.9 days with haloperidol, 8.7 days with ziprasidone; $P = 0.26$ for overall effect across all three groups). Additionally, there were no differences in 30-day or 90-day survival, ICU discharge or readmission, or hospital discharge. Excessive sedation was the most common safety end point and did not differ among the groups.

Study design: Randomized controlled trial (double-blinded)

Funding source: Government

Allocation: Concealed

Setting: Inpatient (ICU only)

Reference: *Girard TD, Exline MC, Carson SS, et al.; MIND-USA Investigators. Haloperidol and ziprasidone for treatment of delirium in critical illness.* N Engl J Med. *2018;379(26):2506-2516.*

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Statins Ineffective for Primary Prevention of Cardiovascular Disease in Patients 75 Years or Older Without Diabetes Mellitus

Clinical Question

In older persons without a history of cardiovascular disease (CVD), is statin treatment associated with better outcomes?

Bottom Line

In this retrospective study, statin treatment in patients 75 years or older without preexisting CVD did not change the likelihood of developing CVD or reduce any-cause mortality. However, patients 75 to 84 years of age with diabetes mellitus benefitted from treatment. These results support the results from the ALLHAT study. (Level of Evidence = 2b)

Synopsis

This study enrolled 46,864 patients 75 years or older with no CVD from a population database in Spain. The patients were an average age of 76 years (63% were women) and were followed up for an average of 5.6 years. Of these, 6,550 patients began statin treatment in the 18 months before the start of the study. In participants without diabetes there was no difference in the onset of CVD (hazard ratio [HR] = 0.94; 95% CI, 0.86 to 1.04) or the rate of mortality due to any reason (HR = 0.98; CI, 0.91 to 1.05). In patients 85 years or older, there also was no reduction in the likelihood of CVD (HR = 0.93; CI, 0.82 to 1.06) or all-cause mortality (HR = 0.97; CI, 0.90 to 1.05), However, in patients with diabetes who were between 75 and 84 years of age, the likelihood of developing CVD was reduced (HR = 0.76; CI, 0.65 to 0.89). All-cause mortality was decreased over an average of 5.6 years, with one additional person alive for every 16 persons treated with a statin (number needed to treat = 15.63; CI, 9.5 to 49.6). The difference was not significant for any patients 85 years or older.

Study design: Cohort (retrospective)

Funding source: Government

Setting: Population-based

Reference: *Ramos R, Comas-Cufí M, Martí-Lluch R, et al. Statins for primary prevention of cardiovascular events and mortality in old and very old adults with and without type 2 diabetes: retrospective cohort study.* BMJ. *2018;362:k3359.*

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