POEMs

Patient-Oriented Evidence That Matters

High-Dose Recombinant Influenza Vaccine: NNT = 3,000 to Prevent One More Infection, No Impact on Hospitalization

Clinical Question

Is a high-dose recombinant influenza vaccine (FluBlok) more effective than a standard-dose vaccine in adults 50 to 64 years of age?

Bottom Line

Although there is a very small absolute reduction in the risk of influenza with high-dose recombinant vaccines, they have no impact on hospitalization. The recombinant vaccines may be less likely to have a mismatch due to antigenic drift from year to year, but this has not been proven because the match for both vaccines was relatively poor during the study years. (Level of Evidence = 1b–)

Synopsis

The study was a cluster randomized study (unmasked) set in the U.S. Kaiser Health System that compared a high-dose recombinant vaccine with standard-dose inactivated influenza vaccines. During the 2018/2019 and 2019/2020 influenza seasons (the 2020/2021 season was excluded), participating Kaiser sites were matched by size and randomly assigned to block A (high-dose vaccine in even-numbered weeks) or block B (high-dose vaccine in odd-numbered weeks). Ultimately, 632,962 patients received the high-dose recombinant vaccine and 997,366 received the standard-dose vaccine. Overall, 44% of the patients were men, 49% were non-White, and 74% had received the influenza vaccine the previous year. The authors used propensity score matching to adjust for differences between groups. They also used respiratory syncytial virus infection as a negative control because it was not expected to differ between groups. They report that the high-dose recombinant vaccine was 15% more effective (95% CI, 6.0% to 24.5%) in patients 50 to 64 years of age, but the actual number of cases of influenza confirmed by polymerase chain reaction testing was 2.0 cases per 1,000 people in the high-dose group and 2.34 cases per 1,000 people in the usual-dose group, or about one fewer case of influenza per 3,000 people. There was no difference in the important outcomes of hospitalization for influenza (0.34 vs. 0.39 per 1,000 persons; $P = .19$) or hospitalization for community-acquired pneumonia (0.38 vs. 0.46 per 1,000 people; $P = .13$). According to GoodRx, the retail price of FluBlok is $90 compared with approximately $30 for standard-dose inactivated vaccines.

Study design: Randomized controlled trial (nonblinded)

Funding source: Industry

Allocation: Unconcealed

Setting: Outpatient (any)

Reference: *Hsiao A, Yee A, Fireman B, et al. Recombinant or standard-dose influenza vaccine in adults under 65 years of age.* N Engl J Med. *2023;389(24):2245-2255.*

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Positive, Rather Than Negative, Messaging of Weight Loss Might Motivate Patients to Try to Lose Weight

Clinical Question

Is a framework that highlights the benefits of weight loss better than one that highlights the risks of excessive weight when suggesting weight loss to patients?

Bottom Line

Presenting weight loss as an opportunity is a better approach than scolding patients for their weight. Framing weight loss in terms of its positive effects, rather than listing the risks of excessive weight, increased weight loss and participation in a weight-loss program. (Level of Evidence = 2b)

Synopsis

The study evaluated conversations between clinicians and participants in a study of brief interventions to motivate patients to lose weight. The 246 recorded conversations were coded by three authors to determine the valence of the initial information from clinicians by categorizing it as good news, bad news, or information that was provided neutrally. When the clinician began the discussion by offering weight loss as an opportunity or by asserting the benefits of weight

loss, especially in an enthusiastic manner, participants were more likely to agree to attend a weight-loss program, actually attend the program, and lose more weight (an average of 3.62 kg [7.98 lb]) than when the solicitation was delivered in neutral terms or by listing the harms of excessive weight.

Study design: Cohort (prospective)

Funding source: Government

Setting: Outpatient (primary care)

Reference: *Albury C, Webb H, Stokoe E, et al. Relationship between clinician language and the success of behavioral weight loss interventions: a mixed-methods cohort study.* Ann Intern Med. *2023;176(11):1437-1447.*

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Wait-and-Watch Is an Option for Patients With Symptomatic but Uncomplicated Gallstones

Clinical Question

Is it safe to watch patients with symptomatic gallstone disease without complications?

Bottom Line

Uncomplicated gallstones can be managed over time with analgesia and monitoring, although approximately 25% of patients will undergo cholecystectomy over the following 18 months. Yet, there appears to be no need to rush to surgery without evidence of common bile duct blockage or acute pancreatitis. (Level of Evidence = 1b–)

Synopsis

The British researchers enrolled 434 adults with uncomplicated, symptomatic gallstone disease referred to secondary care. Using concealed allocation, the patients received conservative management or laparoscopic cholecystectomy. Patients were excluded if they had evidence or history of common bile duct gallstones, acute pancreatitis, obstructive jaundice, or infection. A total of 67% of the participants were assigned to surgery over the next 18 months, and 25% of the participants who were assigned to conservative management had surgery. In the intention-to-treat analysis, patients were evaluated in their original group (despite crossover to the other group), and the analysis showed that pain scores over 18 months were similar in both groups. Quality of life, measured by quality-adjusted life years, was similar in both groups. In the United Kingdom, initial assignment to the conservative approach saved £1,033 ($1,334) over time after accounting for the use of health sources over 18 months.

Study design: Randomized controlled trial (nonblinded)

Funding source: Government

Allocation: Concealed

Setting: Inpatient (ward only)

Reference: *Ahmed I, Hudson J, Innes K, et al.; C-GALL Study Group. Effectiveness of conservative management versus laparoscopic cholecystectomy in the prevention of recurrent symptoms and complications in adults with uncomplicated symptomatic gallstone disease (C-GALL trial): pragmatic, multicentre randomised controlled trial.* BMJ. *2023;383:e075383.*

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Brexpiprazole Improves Agitation Scores in Adults With Alzheimer Disease and Agitated Behaviors

Clinical Question

Does brexpiprazole (Rexulti) decrease agitation in adults with Alzheimer disease and agitated behaviors?

Bottom Line

In the study of patients with Alzheimer disease and agitated behaviors, brexpiprazole modestly reduced agitation scores and was well tolerated. (Level of Evidence = 1b)

Synopsis

Researchers randomly assigned adults with Alzheimer disease and agitated behaviors to receive brexpiprazole (n = 226; 2 or 3 mg daily) or placebo (n = 116) for 12 weeks. The researchers evaluated the patients' scores on various validated measures of agitation and global assessments every 2 weeks. Approximately 87% of the patients (mean age was 74 years; 56.5% were female) completed the study. At the end of the study, the brexpiprazole-treated patients had a greater reduction in agitation scores than the placebo-treated patients (effect size was 0.35, which corresponds to a small to medium effect size) and a similar change in global assessment scores (effect size was 0.31, which also corresponds to a small to medium effect size). Medication discontinuation due to adverse effects was similar in the two groups (4.3% of the participants treated with placebo vs. 5.3% of those treated with brexpiprazole).

Study design: Randomized controlled trial (double-blinded)

Funding source: Industry

Allocation: Concealed

Setting: Outpatient (specialty)

Reference: *Lee D, Slomkowski M, Hefting N, et al. Brexpiprazole for the treatment of agitation in Alzheimer dementia: a randomized clinical trial.* JAMA Neurol. *2023;80(12):1307-1316.*

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Editor's Note: Dr. Ebell is deputy editor for evidence-based medicine for *AFP* and cofounder and editor-in-chief of Essential Evidence Plus, published by Wiley-Blackwell. Dr. Shaughnessy is an assistant medical editor for *AFP*. ■