

EBOLA VACCINE SHOWS PROMISE

A vaccine against the Ebola virus has shown promise in a phase 1 clinical trial. A group of researchers in Canada reported no safety concerns and signs of immunogenicity after a single dose of an “alive attenuated recombinant vesicular stomatitis virus (rVSV) vaccine expressing Zaire Ebolavirus glycoprotein.”¹

The vaccine was evaluated in 40 healthy adults 18 to 65 years old. Participants were separated into four groups, receiving one of three vaccine doses or placebo. Following

a 180-day safety monitoring period, the vaccine was well-tolerated and safe, the authors said. Minor adverse events and viremia were minimal, mild to moderate, and subsided quickly. Moreover, participants who received vaccinations demonstrated high titers of serum immunoglobulin G when measured at 180 days after immunization.¹

1. ElSherif MS, Brown C, MacKinnon-Cameron D, et al. Assessing the safety and immunogenicity of recombinant vesicular stomatitis virus Ebola vaccine in healthy adults: a randomized clinical trial. *CMAJ*. 2017;189(24):E819-E827.

Self-Management Education for Type 2 Diabetes Patients Reduced Mortality Risk

Education in self-management for type 2 diabetes can reduce the risk of all-cause mortality, a meta-analysis of 42 randomized clinical trials found.¹ With the benefit of education in self-management, individuals with type 2 diabetes had an absolute reduction in all-cause mortality of four fewer deaths per 1,000 person-years, according to the analysis.

The meta-analysis included only randomized controlled trials comparing diabetes self-management education with standard care. The 42 studies identified included a total of 13,017 participants followed for an average of 1.5 years. There were 187 deaths from all causes in the patients receiving traditional care (3.1%), compared with 159 (2.3%) in patients receiving self-management education. Additionally, the mortality risk was significantly reduced for patients receiving self-management education regardless of the way in which they received the education.

1. He X, Li J, Wang B, et al. Diabetes self-management education reduces risk of all-cause mortality in type 2 diabetes patients: a systematic review and meta-analysis. *Endocrine*. 2017;55(3):712-731.

Heart Attack Risk Increased With NSAIDs

The risk of myocardial infarction (MI) is notably increased following the prescription of oral NSAIDs for 1 week or more, according to an analysis published in the *British Medical Journal*.¹ The level of risk was related to the strength and duration of the dose and was highest during the first month of treatment, the analysis found. Risk of MI with the selective COX-2 inhibitor celecoxib was comparable with that for traditional nonselective NSAIDs and lower than that for rofecoxib.

The analysis included 446,763 individuals, including 61,460 who had MIs, and was sourced from studies of Canadian and European health care databases. The authors analyzed the correlation between individual NSAID drugs and the

occurrence of acute MI. The probability of increased risk of MI was 92% for celecoxib, 97% for ibuprofen, and 99% for diclofenac, naproxen, and rofecoxib.

1. Bally M, Dendukuri N, Rich B, et al. Risk of acute myocardial infarction with NSAIDs in real world use: bayesian meta-analysis of individual patient data. *BMJ*. 2017;357:j1909.

Respiratory Infection Linked to Increased Heart Attack Risk

Respiratory infection can trigger MI. This is the conclusion of a retrospective study that sought to confirm the association between respiratory infection and increased short-term risk of MI.¹

Earlier studies have reported the correlation between respiratory infection and risk of MI, but none had included angiography, allowing the possibility of nonischemic causes for high levels of troponin and abnormalities in a patient's electrocardiogram, the study's authors noted. They explored the causal relationship as confirmed by angiography.

The researchers interviewed 578 patients with MI confirmed by angiography, and asked about recent exposure to respiratory infection symptoms and the frequency of such symptoms. They found that the relative risk (RR) for MI occurring within 1 to 7 days after respiratory symptoms was 17.0, declining in later time periods. The RR was lower in individuals taking cardiac medications regularly.

1. Ruane L, Buckley T, Hoo SYS, et al. Triggering of acute myocardial infarction by respiratory infection. *Intern Med J*. 2017;47(5):522-529.

Number of Pregnant Women With Hepatitis C Climbing

Hepatitis C virus (HCV) infection is increasing among pregnant women, according to a report published by the Centers for Disease Control and Prevention.¹ In the 5 years from 2009 to 2014, HCV infection at the time of delivery increased by 89%, from 1.8 to 3.4 per 1,000 live births in states that report maternal HCV status on birth certificates.

The highest HCV infection rate in 2014, 22.6 per 1,000 live births, was seen in West Virginia. The rate in Tennessee was 10.1 per 1,000. A rural geographic location and the presence of additional risk factors such as coexisting hepatitis B or smoking during pregnancy further increased the prevalence of HCV infection.

1. Patrick SW, Bauer AM, Warren MD, Jones TF, Wester C. Hepatitis C Virus Infection Among Women Giving Birth - Tennessee and United States, 2009-2014. *MMWR Morb Mortal Wkly Rep.* 2017;66(18):470-473.

Drug Safety Concerns Arose Despite FDA Approval

Among 222 drugs approved by the US Food and Drug Administration between 2001 and 2010, 32% were subsequently affected by a “postmarket safety event,” according to a recent analysis.¹

Safety events, as defined in this analysis, included withdrawals from the market (in three cases), the addition of a black-box warning to the product’s labeling (in 61 cases), and the issuance of an FDA safety communication (in 59 cases).

Of the 222 therapeutics approved by the FDA, 183 were classified as pharmaceuticals and 39 as biologics. During a follow-up period lasting through February of this year, there were 123 instances of safety events that warranted action, the study authors found. Higher risks of a safety action were associated with accelerated or near-deadline regulatory approvals. Biologics and psychiatric therapeutics were also at higher risk for a safety event.

1. Downing NS, Shah ND, Aminawung JA, et al. Postmarket safety events among novel therapeutics approved by the US Food and Drug Administration between 2001 and 2010. *JAMA.* 2017;317(18):1854-1863.

One-Fifth of US Cancer Diagnoses Defined as Rare Cancers

Approximately 20% of US cancer patients are diagnosed with rare cancers, according to a recent analysis.¹ The analysis also found that more than two-thirds of cancers in children and adolescents are rare, compared with less than 20% of cancers diagnosed in patients 65 years of age and older.

The study authors defined rare cancers as those with an incidence of fewer than six per 100,000 individuals per year in the United States. They analyzed incidence rates, stage at diagnosis, and survival data for more than 100 such cancers.

Additionally, the study provided information on certain subsets of patients. They found that rare cancers disproportionately affect Hispanics and Asian/Pacific Islanders (at 24% and 22%, respectively) in comparison to non-Hispanic blacks and whites (20% and 19%, respectively).¹

Among solid tumors, almost 60% of rare cancers are diagnosed at regional or distant stages, compared with 45% for common cancers. This helps to explain why 5-year survival is poorer

for patients with rare cancers than those with more common cancers, the authors said. Five-year relative survival is higher for pediatric patients (82%) than for adults aged 65 to 79 years (46%).

1. DeSantis CE, Kramer JL, Jemal A. The burden of rare cancers in the United States. *CA Cancer J Clin.* 2017;67(4):261-272.

Dietary Habits Associated With Risk of Peripheral Artery Disease

There is an inverse association between consumption of fruits and vegetables and prevalent peripheral artery disease (PAD), a recent study found.¹ The study authors also found that the level of fruit and vegetable consumption among participants was low.

The analysis was based on questionnaire responses and ankle brachial index screenings of more than 3.5 million self-referred participants at more than 20,000 health care sites in the United States.

Participants who reported daily intake of three or more servings of fruits and vegetables had 18% lower odds of PAD than those who reported less than monthly consumption.

Less than 30% of respondents reported consuming at least three servings of fruit and vegetables daily. Mean age of the participants was 64 years, and 64% were female.

1. Heffron SP, Rockman CB, Adelman MA, et al. Greater frequency of fruit and vegetable consumption is associated with lower prevalence of peripheral artery disease. *Arterioscler Thromb Vasc Biol.* 2017;37(6):1234-1240.

Coffee Reduced Risk of Hepatocellular Carcinoma

There is a correlation between consumption of coffee (caffeinated and, to a lesser extent, decaffeinated) and reduced risk of hepatocellular carcinoma (HCC), even in the presence of preexisting liver disease, according to a meta-analysis.¹ Because of a lack of randomized trials and of a standardized definition of coffee, however, the authors of the meta-analysis rated the quality of evidence under the GRADE criteria as “very low.”

Consuming an extra 2 cups of coffee a day was associated with a 35% reduction in risk of HCC. The association was not significantly altered by the stage of liver disease or patient status regarding smoking, high alcohol consumption, presence of diabetes, high body mass index, or hepatitis B and C viruses.¹ ■

1. Kennedy OJ, Roderick P, Buchanan R, Fallowfield JA, Hayes PC, Parkes J. Coffee, including caffeinated and decaffeinated coffee, and the risk of hepatocellular carcinoma: a systematic review and dose-response meta-analysis. *BMJ Open.* 2017;7(5):e013739.

Section Editor David S. Boyer, MD

- clinical professor of ophthalmology at the University of Southern California Keck School of Medicine, department of ophthalmology, in Los Angeles, Calif.
- member of the *Retina Today* editorial advisory board
- +1-310-854-6201; vitdoc@aol.com