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Steven E. Reznick, M.D. FACP

7280 W. Palmetto Park Rd., Suite 205 N, Boca Raton, FL 33433

561-368-0191 or email DrR@BocaConciergeDoc.com

New Medicine on the Horizon for Influenza Treatment

The *New England Journal of Medicine* published three studies showing favorable results for the new Roche anti-influenza antiviral drug Baloxavir marboxil. This medication works differently than Tamiflu (oseltamivir) by preventing viral reproduction or replication in a complicated process known as “cap snatching.”

The first study done in Japan looked at how the medication issued at different dosages compared to a placebo drug when patients presented with early influenza infection. They found the higher the dosage used, the more effective the drug was in reducing symptoms with the higher dose being slightly better by a few hours than the lower dosage. All dosages were statistically superior to the placebo product.

The second study compared the new drug to Tamiflu in time until symptom reduction but, more importantly, reduction and prevention of viral shedding. Viral shedding is a mechanism whereby others exposed to the virus can be infected. Both the Tamiflu and the Baloxavir showed similar efficacy in time until symptoms were diminished with both far superior to a placebo product. The Baloxavir was far superior in reducing the volume of virus shed to one day. The Baloxavir only needed to be administered one time to achieve this reduction in viral load and symptoms. Tamiflu is taken twice a day for five days. This means that patients with the flu administered one dose of Baloxavir are less likely to spread the flu to others around them. Both Tamiflu and Baloxavir had a similar and minimal adverse effect or side effect profiles.

Baloxavir has not yet been approved by the FDA for administration in the USA and is currently being set up to be tested on individuals who are high risk for developing influenza. The addition of a single dosage medication that works by a different mechanism than Tamiflu will be a valuable addition to the treatment of influenza.

Flu Shot Protection Diminishes Over Time

It is flu shot season and the Public Health Departments are promoting vaccination beginning September 1, 2018. The large chain pharmacies which have been given the green light to lead the nation’s vaccination programs ahead of physician offices started pushing flu shots weeks ago. What better than to come into your pharmacy for a flu shot and receive a free ten dollar gift coupon?

I was taught years ago that over time, especially in senior citizens, the immunity begins to diminish after 90 days. Since flu makes a late appearance in south Florida and peaks in early February, my concern was that when the flu peaked your immunity was diminishing. That theory has been confirmed by a study published yesterday in *Clinical Infectious Disease Journal*. They looked at about 45,000 patient records from the Kaiser Permanente Northern California Health System between 2010 and 2017 who tested positive for influenza. They found there were more cases of influenza in patients vaccinated 42 – 69 days after the shot than in patients vaccinated 14 to 41 days prior. This was most noticeable in patients who had Influenza A.

Since it takes 10 to 14 days to develop immunity after the shot it is probably best to wait until just before influenza arrives in your area to be vaccinated. Public Health officials are concerned that this doesn’t give them enough time to vaccinate everyone who needs it. I try to encourage my family and patients to get their flu shots between

Halloween and Thanksgiving unless the flu arrives earlier or they are travelling to an area of the world that flu arrives earlier. It's nice to have the evidence to back that suggestion up.

Influenza Vaccination Begins on October 15th

Our annual supply of influenza vaccine has arrived. We will begin vaccination on October 15th. Please call my practice to schedule your vaccination. Don't delay. Many are anticipating a rougher than usual flu season.

The Valsartan Recall – Part II

I have previously written about my concerns about the FDA's ability to inspect local and foreign plants which produce our medications entirely because of funding cut backs preventing hiring and training inspectors. To my surprise, the European and Asian recall of Valsartan produced by Solco and Major Pharmaceuticals was joined two weeks later by an FDA voluntary recall of Valsartan produced by Teva Pharmaceuticals. Valsartan, also commercially named Diovan, is a popular blood pressure and heart failure drug.

Media announcements were made, but who is responsible for informing patients prescribed Valsartan that it may be part of a recalled product? Is it the job of the pharmacy that distributed it and was paid for it? Is it the job of the insurance company benefits manager who placed the medication on its formulary and approves the prescription? Is it the responsibility of the doctor's office that wrote the script?

I responded by asking my office manager to contact our computer electronic health vendor to prepare a list from our computerized software of patients taking Valsartan / Diovan. My electronic health record system comes from a firm named Greenway using a product called Prime Suite. One of the major reasons we chose this product was because our large hospital system, buying up practices, was installing this program in their physician offices as preparation for integrating it with the soon to come hospital electronic health record software. This product is distributed locally by a long time family-owned vendor who sells, trains on software, bills, trouble shoots and upgrades the products for a monthly and per project fee. To meet U.S. government requirements, the software needed a second system for electronic medicine prescribing which is produced by SureScripts. We actually have a subcontracted pharmaceutical software program within our electronic medical record software. To me this seemed like an easy task preparing a report from a computer.

One week later no report was complete. My office manager had called our vendor but their trainers were busy elsewhere and no one else there had a clue. I contacted SureScripts directly through their website and obtained a case number but no help so far. When I make a reasonable request to individuals I pay handsomely to perform such services and no one responds I tend to sound more like a football offensive line coach than a life coach discussing positive motivation techniques. This resulted in a short spreadsheet arriving on my desk the next day. Half the listings involved former or dead patients. Additionally, there was no contact information on the sheets so I had to access that data myself. When I accessed our patient contact information I found that it was often old, incorrect or incomplete. When I mentioned that they used the search word "Valsartan", instead of "Diovan", my staff was embarrassed. A new request was made. Two days later I had a complete list.

I called most of the patients myself. I asked them to contact their pharmacy and ask if their supply came from a recalled batch. For the very elderly and cognitively impaired I called the pharmacy myself. I was surprised when the drugs were on the recall list and the chain pharmacists felt no responsibility to notify the customer. I put a note in each and every chart and substituted product if there was no accessible untainted product.

It is clear that no one really cares. My computer software manufacturer and vendor are just not comprehensive. The insurers and benefit managers are not interested.

Fortunately, the risk of illness from this tainted product is small. I shudder to think what would occur if the risk was greater.

Low Carbohydrate Diets Linked to Higher All-Cause Mortality

At Reznick family gatherings, my brother, who has no formal training in nutrition or health, always joked that it is important to consume the “three essential food groups - alcohol, fat and sugar.” His comment has always resulted in some strange glares from other guests and family members.

However, the European Society of Cardiology Congress 2018 released which may offer some support of his humor. Researchers analyzed data from the National Health and Nutrition Examination Survey including almost 25,000 men and women followed for 6.5 years. They compared participants who got 66% of their calories from carbohydrates with others getting 57%, 49% and 39%. Surprisingly the participants with the lowest carbohydrate intake had a 32% increase in total mortality and a 35% increase in cancer mortality. There was also a 51% and 50% increase in mortality from heart disease and stroke. The differences were most noticeable in non-obese adults over the age of 55 years. Dietary guidelines for the United States call for a carbohydrate intake of between 45% - 65 % of total calories consumed.

This was an observational study which by design cannot prove cause and effect. Experts in nutrition and cardiovascular disease were quick to point out that limiting “carbs” for a short period of time to lose some weight probably is not deleterious. It once again emphasizes the need for moderation in our diet.

Several days later *The Lancet* published an article showing that individuals who consumed at least one or two servings of dairy per day have a lower risk of cardiovascular disease and mortality than those who do not. The PURE Study (Prospective Urban Rural Epidemiology Cohort Study) looked at almost 137,000 individuals between 2003 and 2018 who completed food questionnaires. The questionnaires included cheeses and whole milk. I guess cheese in moderation in addition to milk in your coffee or teas are not so bad for you. Once again moderation in choices seems to be the best option.

Coffee and the Healthy Heart

Two German biologists are stating there is sufficient data to claim that four cups of caffeinated coffee is the optimal daily dosage to maintain a healthy heart. Their findings were published in *Plos Biology* and summarized in Inverse Magazine. The scientists cite past warnings by public health officials of the danger of caffeine when given to people with heart conditions. Quite the contrary. They believe that up to four cups of coffee per day are actually therapeutic for the heart.

In their research they noted caffeine helps a protein called “p27” enter the energy producing mitochondria of heart cells making them function more efficiently. They experimented with rats comparing the mitochondrial function of old rats and young rats. When they injected the older rats with the caffeine equivalent of four cups of coffee, their aging mitochondria performed at the level of young rats’ mitochondria. They then experimentally caused the older rats to have a heart attack or myocardial infarction. Half of these heart damaged rats were injected with the equivalent of four cups of coffee and their heart cells repaired themselves at a far more rapid rate than those not exposed to that dose of coffee and caffeine.

The researchers conclude that four cups of coffee is probably the optimal daily dosage of coffee for a healthy heart. They caution that certain patients, especially those with malignant tumors, should probably avoid that much coffee because it may promote growth of blood vessels to the tumors. They additionally caution against using caffeine pills or energy drinks because their research was done with coffee.

Keep in mind, this biologic evidence was obtained in rats not human beings. Fortunately, I have not seen rats breaking into my local Dunkin Donuts and Starbucks craving a lifesaving nutrient.

Coffee has been associated with preventing cognitive dysfunction, preventing diabetes and now keeping your heart healthy. If you enjoy coffee, drinking it in moderation makes sense to me.

More Good News for Coffee Drinkers

When I first started practicing, fresh out of my internal medicine residency and board certification, we were taught that consuming more than five cups of coffee per day increased your chances of developing pancreatic cancer. Thankfully, that theory has been proven to be false.

Recently, I reviewed a publication in a peer reviewed journal which showed that if you infused the equivalent of four cups of coffee into the energy producing heart cell mitochondria of older rodents, those mitochondria behaved like the mitochondria found in very young healthy rats. The authors of that article made the great leap of faith by suggesting that four cups of caffeinated coffee per day was heart healthy.

The *Journal of the American Medical Association Internal Medicine* published a study which said if you drank eight cups of coffee per day your mortality from all causes diminished inversely. Their study included individuals who were found to be fast and slow metabolizers of caffeine. It made no distinction between coffee types.

The research study investigated 498,134 adults who participated in the UK Biobank study. The mean age of the group was 57 years with 54% women and 78% coffee drinkers. The study participants filled out questionnaires detailing how much coffee they drank and what kind. During a 10 year follow-up there were 14,225 deaths with 58% due to cancer and 20% due to cardiovascular disease. As coffee consumption increased, the risk of death from all causes decreased. While instant coffee and decaffeinated coffee showed this trend, ground coffee showed the strongest trend of lowering the mortality risk.

This is an observational study which does not prove cause and effect. However, it is comforting to know that having an extra cup or two seems to be protective rather than harmful. At some point a blinded study will need to be done to prove their point. If the caffeine doesn't keep you up or make you too jittery, and the coffee itself dehydrate you or give you frequent stools, then drink away if you enjoy it.

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