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New Drug Approved for Cholesterol Elevation

Over the years, the relationship between an elevated cholesterol especially the LDL (low density lipoprotein) fragment of cholesterol and the development of cardiovascular and cerebrovascular disease has strengthened. Treatment of high cholesterol has involved trying to modify your diet, trying to get patients to reduce their weight plus regular exercise, smoking cessation and blood pressure control. When all these efforts are applied there are a sizable portion of the population who still need medication as well to reduce cholesterol. The statin medications have been used for over forty years for this purpose with today's versions including atorvastatin (Lipitor), simvastatin (Zocor), pravastatin (Pravachol), rosuvastatin (Crestor) and pitavastatin (Livalo), leading the way. These medications were wonderfully successful in lowering cholesterol and reducing cardiovascular disease but were associated initially with fears of liver injury (rare and unfounded) and muscle cramps and aches. A large, randomized study recently disproved the muscle issues, but the complaints keep occurring. A patient population of individuals who could not tolerate any of the statin medications evolved and grew and for this group the newer injectable medications Praluent (alirocumab) and Repatha (evolocumab) have been developed. These are injected at home under the skin every two weeks. Their biggest negative issue is the cost with either of these medications costing about \$1350 a month before prescription drug benefits company steps in and helps reduce the cost. After insurance reduces the cost, I still pay \$248 a month for my Praluent.

The Food and Drug Administration approved Leqvio (inclisiran), manufactured by Novartis, in January to lower cholesterol. It is an injectable given twice a year to be used with diet and maximal statin dosage. It is designed for patients with a genetically inherited familial type of hypercholesterolemia plus cardiovascular patients not achieving goal levels on maximal statins.

Leqvio interferes with RNA involved in producing LDL cholesterol. The Orion 9, 10 and 11 studies proved its efficacy in reducing LDL cholesterol and total cholesterol. The drug had few adverse effects which were felt in 3% of the recipients and were mild including soreness at the injection sites, joint pains, diarrhea, bronchitis. The drug will be available in pharmacies by February 2022. The cost has not been published. The manufacturer, Novartis, has sent out email invitations to practicing physicians and pharmacists to participate in an internet based educational session on the new product later this month.

An Extra Tablespoon of Olive Oil Per Day May Keep Death Away

Dr. Marta Guash-Ferre' and team at Harvard T. H. Chan School of Public Health evaluated whether substituting a teaspoon of olive oil daily to replace margarine, butter, mayonnaise and dairy fat led to a drop in the likelihood of death from cardiovascular disease, cancer, dementia and respiratory diseases.

Her team looked at 92,000 participants who were free of cancer and cardiovascular disease in 1990. Every four years, for the next 28 years of follow-up, the researchers assessed each person's diet through a detailed questionnaire. Olive oil consumption was determined from olive oil used on salads, cooking, or used on breads and foods.

Their long-term calculations showed that olive oil consumption increased in the study participants during the test period while consumption of margarine decreased, and other fats stayed the same. Participants with higher olive oil consumption were more likely to be physically active, less likely to smoke, consumed more fruits and vegetables than lower olive oil consumers. When the researchers compared those with little olive oil consumption to those with the highest consumption, the high consumers had a 19% lower risk of death from cardiovascular disease, a 17% lower risk of cancer death, a 29% lower risk of death from dementia and an 18% lower risk of respiratory disease death. The study also concluded that substituting ten grams of olive oil per day (a bit less than one tablespoon) for other fats such as butter, margarine, mayonnaise, and dairy fat their death risk dropped by 8-34% from all causes.

In reviewing the data, it seems their study group represented an extremely well-educated health-conscious group of individuals. Substituting olive oil for other fats is certainly a worthy goal based on these numbers and I will certainly aim to try it.

Cancer Detection Blood Test

For several years I have been following the development of blood tests drawn in a physician's office which can be used to detect malignancies in their early stages. Recently, a publication discussed the proper use of four blood tests that already exist paired with a flow sheet or algorithm to identify those individuals most likely to develop pancreatic cancer. I am in the process of researching that study and learning how to introduce it into our office practice for my patients benefit.

Two weeks ago, a wise, worldly, extremely disciplined, and health-conscious individual asked me if I would draw blood on him and send it to a particular lab for evaluation and detection of early cancers. I had not yet received any literature on this company or test, but it is certainly easy enough to draw blood and send it off. He provided the name of the firm and through the miracle of computers and the internet I found their website and information about the testing. This firm was in the fifth year and version of cancer detection.

They have learned that developing malignancies send out a signal through the bloodstream using genetic tools to announce their presence. Their genetic methylation testing procedures can detect these early signals. The company went on to say that for many cancers such as breast cancer, lung cancer, prostate cancer, colon cancer and skin cancers there are quality driven early detection screening programs available to patients and physicians. About two thirds of cancer deaths yearly occur in cancers with no early detection programs designed to find them. Their blood test was designed to do just that. The website for the company listed their research findings, the endorsement of several major national cancer centers in the United States and contained an educational video for doctors and patients.

It was clear from the video that if my patient were to receive this test, I would be only a passive phlebotomist drawing her blood and sending it to the lab. I first was asked to establish an account and agree to receive the results and explain them to the patient. Thus, my role was no longer that of a passive good Samaritan. I was expected to be an interpreter of an innovative technology I knew little about.

The cost of the test was listed as \$1250 but my patient assured me, she could get it for less at \$955. The turnaround time from drawing the blood, to receiving results, is supposed to be less than two weeks. I called the Center for Medicare Services (CMS) and Florida Blue Cross Blue Shield and asked if this test would be a covered service. They both said it would not. I next asked this question of them and two Medicare expert consultants I have worked with for decades, "If the test reports a positive signal for an unexpected malignancy, will your insurance pay for the diagnostic testing to confirm or refute the labs indication of cancer being present." They again said, "absolutely not."

This means that if the blood test suggests the patient has pancreatic cancer, they will now need at least a CT scan of the abdomen with contrast for about \$500 and an ERCP procedure including a gastroenterologist, anesthesia, nurse, and a facility fee for about \$5000+. These costs will all be out of pocket and non-reimbursable by insurance. If these diagnostic tests fail to detect a malignancy, does it mean there is not one or, does it mean the test is so sensitive that it picked up the tumor prior to it being large enough to be detected? How often will you need to repeat these tests? No one knows yet.

Under the current program design, the findings of the blood test will become part of your permanent health chart and record. What will that do to future attempts to obtain health or life or disability insurance?

I am in no way trying to be negative about a medical breakthrough of extraordinary importance. I am just saying it's incredibly early, expensive and there are many unanswered questions requiring research prior to being tested.

Shampoos and Allergens

I saw my dermatologist because of an allergic skin condition he called atopic dermatitis or eczema. Dry itching crusty skin is neither fun to live with or fun to look at. He gave me a bunch of hypoallergenic "clean" soaps, creams and shampoos to try.

Ironically, while reading one of my online medical synopsis journals I came upon an article about allergic substances in shampoos. There are apparently traditional shampoos and other shampoos supposedly less allergenic and called "clean." There are no regulations over the right to claim your product is hypoallergenic or "clean."

In a study published in the *Journal of the American Academy of Dermatology*, authored by L. Ghafari and associates, they found that every clean shampoo and 99% of the traditional shampoos contained fragrances. If you are allergic to fragrances, then all of these products can produce irritation or an allergic reaction.

The researchers went to three stores and identified 85 clean shampoos and 124 traditional shampoos . The clean shampoos were less likely to use allergenic chemicals such as methylisothiazolinone than the traditional shampoos. Both types of products used chemicals that are known to be less irritating or allergenic than others, but few were actually "clean".

The moral of the review was that few of the clean shampoos were actually "clean". If you have sensitive allergic skin then your dermatologist or allergist may have to suggest a prescription product or particular over-the-counter product that is truly hypoallergenic to prevent your skin allergic reaction.

Dementia - Telltale Indicators

In the United States, 11% of adults 65 years of age, and 33% over 80 years old, are diagnosed with dementia. My generation of Baby Boomers likes to pretend that today's "80" is like yesterday's 55 years old but it simply is not true.

To combat dementia researchers are looking at numerous causes to try and reduce the number of future patients. An interesting article looked at the resting heart rate of senior citizens. Those who had a resting heart rate over 80 beats per minute were statistically more likely to develop dementia.

At the same time, the same research group was looking at resting heart rate another research group was looking at inflammatory markers that can be detected with a blood draw and be prognostic. They found an association between having a low HDL level and elevated Triglyceride level and an increased risk of developing cognitive impairment. This was especially true in individuals with Type II Diabetes Mellitus.

Researchers are looking for genetic markers that would hint at an increased risk of dementia. Others are trying to develop medications that will stop or interrupt the process and prevent or limit the disease.

In the meantime, we are left with trying to live a healthy lifestyle starting at an early age. Being active, avoiding smoking, avoiding excessive alcohol and keeping our weight and blood pressure under control will still be our best defense. Starting at any age helps but developing healthy living habits as a young adult seems to be the best choice.

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