

Intelligent Medicine Shorts: Pradaxa risks, calcium scoring for heart disease and new benefits from pomegranate



From time to time, this newsletter will feature short summaries of noteworthy news stories of the day with my comments appended, hopefully offering you a unique perspective on health news.

Another Drug Bites the Dust . . .

According to a recent report, an investigation by the *British Medical Journal* concludes that the manufacturer of Pradaxa, a blood thinner used for patients with atrial fibrillation, withheld critical data from government regulators during the approval process.

Initially billed as a safer alternative to the old-fashioned blood thinner Coumadin, Pradaxa has caused numerous incidents of severe bleeding.

Since its introduction, the number of Pradaxa lawsuits has climbed into the thousands, and its manufacturer, Boehringer Ingelheim, has even set aside a war chest of \$650 million to settle 4,000 U.S. lawsuits over Pradaxa injuries.

COMMENT: Patients with atrial fibrillation are at higher risk

of blood clots, which can cause strokes, and, until recently, only the drug Coumadin was available as a blood thinner. Pradaxa and drugs of its ilk were designed to circumvent problems with Coumadin—specifically, the need to curtail dietary intake of vitamin K, as well as requirements for frequent blood tests to gauge its effectiveness.

But apparently, in its haste to gain approval, Pradaxa's manufacturers deep-sixed data that suggested that, like Coumadin, Pradaxa levels should be monitored. While tests for blood levels of Pradaxa are available in Europe, inexplicably the test has not yet been approved for use in the U.S.

Additionally, it turns out that vitamin K's liability of turning off Coumadin proves to be an advantage. Hemorrhages in patients taking Coumadin can quickly be reversed with an injection of vitamin K. No such antidote exists for Pradaxa.

When Pradaxa and a similar drug, Xarelto, were previewed a few years back, even I was optimistic that they would prove an advance over Coumadin. I should have reserved my skepticism. When I collared a cardiologist at a cocktail party soon after Pradaxa's rollout, he told me confidentially that his malpractice insurance carrier was issuing bulletins that advised cardiologists to be wary of prescribing Pradaxa. The bloom was off the rose.

As I have often said on *Intelligent Medicine*, when a new drug is introduced, unless your life literally depends on it, don't be the first kid on the block to try it. Instead, I suggest that you wait two to three years to see if the highly touted "new and improved" drug crashes and burns once thousands of people start taking it.

The trail of now-disfavored or banned blockbuster drugs (such as Vioxx, Avandia, Fen-Phen, Meridia and Zelnorm to name but a few) keeps on growing thanks to overzealous BigPharma marketing and complicit FDA regulators.

I wish that natural blood thinners such as fish oil, garlic, nattokinase and vitamin E were enough to prevent strokes in patients with atrial fibrillation, but relying on these is a bit like playing Russian Roulette. Until such time as safer, reliable alternatives to Coumadin are developed, I'll counsel my patients, readers and listeners to continue with Coumadin—"Better the *devil you know* than the devil you don't."

Calcium Score is a Useful Way of Screening Patients for Heart Disease Risk

I recently interviewed cardiologist Matthew Budoff about a new study that showed that Kyolic Aged Garlic Extract slowed the progression of calcium plaque in men with pre-existing coronary artery disease.

Dr. Budoff is Professor of Medicine at the David Geffen School of Medicine and Director of Cardiac CT at the Division of Cardiology at the Harbor-UCLA Medical Center in Torrance, California.

Dr. Budoff recently published a study proving the effectiveness of calcium scoring via non-invasive radiological testing to determine whether a previously healthy adult is at risk of heart disease.

A calcium score of zero predicted negligible risk. A score of 1-99 boosted risk by 50 percent; those with scores of 100-399 were 80 percent more likely to die of heart disease; and those with scores of 400 or more were three times more likely to succumb to coronary mortality.

COMMENT: Around 15 years ago, I began using the EBT (Electron Beam Tomography) heart scan as a means of discerning which of my patients with high cholesterol but no heart disease really needed aggressive cholesterol-lowering therapy. At the time, many doctors questioned the test, deeming it useless. Now, with new studies like this substantiating its accuracy, I feel

vindicated in offering this test to my patients over the years.

Typically, a patient will come to me for a second opinion because their doctor has prescribed statins merely on the basis of a high cholesterol score. I am not inalterably opposed to use of statins, or alternatively red yeast rice, but if there's no need for patients to be on statins, why expose them to the unnecessary risks?

Even if patients don't experience side effects of statins, new studies suggest they sometimes deter takers from rigorous programs of diet and exercise. Seeing a "good" cholesterol—artificially lowered with a drug—may offer an overweight, sedentary patient a false sense of security.

With the EBT heart scan (or, alternatively, the CT heart scan), I can discover whether a patient's constellation of risk factors is consequential. Mere blood testing alone is only partially predictive, but the arterial wall is where "the rubber meets the road" when it comes to actual risk of heart attack.

Patients often are surprised that their high cholesterol scores are not associated with coronary plaque; alternatively, I have sometimes galvanized preventive efforts by patients when they *do* turn out to have calcium buildups. "A picture is worth a thousand words" and I sometimes give patients a copy of scans highlighting their coronary artery deposits to affix to their refrigerator doors for motivation.

In typical "penny-wise, pound-foolish" fashion, many insurers still refuse to reimburse for calcium scans, but they're generally pretty economical and well worth the nominal price. Hopefully, with results of research like this, the picture will change.

Pomegranate Drug Promises to Stem Alzheimer's, Parkinson's

Science Daily reports that work is underway to purify a derivative of pomegranate to slow the progression of neurodegenerative disease. The natural precursor to the prospective drug is called *punicalagin*, a polyphenol compound.

COMMENT: Around five years ago, I decided to reformulate one of my Premium Formulations supplements, PhytoGuard. It already contained many of my favorite phytonutrients: lycopene, quercetin, EGCG from green tea, broccoli sprout extract, resveratrol and curcumin. I elected to add pomegranate to enhance PhytoGuard's portfolio of beneficial compounds.

In view of the above study, and others documenting pomegranate's benefits on heart, circulatory system, prostate and even bone, my decision appears strongly validated. The makers of POM Wonderful, a pomegranate drink, have underwritten millions of dollars of pomegranate research. POM was recently locked in an epic battle over freedom of speech with the Federal Trade Commission, who wants to muzzle truthful claims about pomegranate's healthful properties.

A note of caution: While plant compounds have often proven beneficial in disease prevention, efforts at tweaking natural polyphenols into patentable drugs often have not improved over Mother Nature. A case in point is resveratrol. Hundreds of millions of dollars invested by GlaxoSmithKline in an effort to transform resveratrol into a lucrative pharmaceutical have so far produced only disappointing results. Consumption of natural compounds has so far trumped efforts to develop souped-up counterfeits.