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Pinellas Medical Journal

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PCMA MISSION STATEMENT

The Pinellas County Medical Association's overall mission is to inform, serve and advocate, mainly through the following programs and services: physician referral and employment, insurance and education, medical-legal and practice management seminars, legal consultation and a successful and active Tallahassee Legislative Visitation Program.

Our purposes are to further the precepts of providing high quality medical care for patients and to promote and monitor the ethical and competent practice of medicine.
In addition, the Association provides consumer advocacy through:

a) referral service,

b) physician participation in community events, services and programs, and

c) dissemination of general information about physicians and health services available.

—Board of Governors

Cramps in Seniors

Owen Linder MD, FACP
Pinellas County Medical Society Board of Governors

Muscle cramps are common in persons taking statins. Some physicians have thought cramps related to the statins but find little supportive evidence in the texts or teachings.

On the hunch that muscle cramps, muscles aches and muscle tenderness are caused by statins, the symptoms were put together with rhabdomyolysis. We do know statins can cause rhabdomyolysis.

This was supported by the observation that persons with the cardinal biochemical sign of rhabdomyolysis, elevated cpk, also had visible fasciculation's, quivering, or gross tremors.

They also complained of cramps. I saw about five patients on statins with rhabdomyolysis over the years of statin enthusiasm before I read up on the biochemistry of statins.

As all physicians who prescribe part of the 20 billion dollars-a-year worth of statins know, statins are biochemically hydroxymethyl coenzyme A reductase inhibitors. This inhibition prevents the sequence of cellular reactions leading to farnesyl pyrophosphate at the step of production of HMGCoA to mevalonate. The mevalonate goes through reactions leading to farnesyl pyrophosphate. It in turn is needed to become cholesterol. This pathway also produces Coenzyme Q ten one step dissimilar from cholesterol production.

So reducing cholesterol, though highly desirable in one respect, reduces a little recognized but essential second product. Harkening back to medical school biochemistry, we may recall the movement of electrons from ADP to ATP and NADP to NADPH requires an enzyme. This obligate enzyme is Coenzyme Q ten. The phosphorylation energy of mitochondria requires all of these substances.

A great many researchers have been trying to connect the inhibition of the production of Coenzyme Q ten with evidence of muscle problems. Not until December of 2009 was I aware from reading the prior studies that Coenzyme Q ten could be measured in humans or in anything else. Gradually over the last two years, I began measuring Coenzyme Q ten in my patients who admitted to cramps to see what their levels were.

Eventually I developed a cohort of patients who had cramps and aches after being on statins for several years. I found their Coenzyme Q ten levels averaged 0.8 microgram per ml. I understood from Dr. Kopecky of Mayo Clinic cardiology department, that it takes three months to restore a depleted body store of Coenzyme Q ten. Using that guide, I chose to ask my patients to take the Coenzyme Q ten for a prolonged period of time. Eventually I ended up measuring a second assay on average nine months after the first assay.

I did not measure the assay often because measuring it takes the patient out of his comfort zone. Unlike ordinary phlebotomy and centrifugation which we perform in the office, this assay is impractical for my office. Coenzyme Q ten assays have to be drawn into a darkened tube and then frozen before being shipped to a reference laboratory. Even after ordering a total of over 200 assays, I am not able to justify equipping my office for this work. Both Labcorp and Quest have protocols in their phlebotomy station manuals.

The average result was that I titrated the dose up to an average of 260 mg a day by the time nine months had passed. In almost every patient out of 62 I assayed twice the muscle cramps had either ceased or were greatly ameliorated. The average Coenzyme Q ten assay trebled on average by nine months. The average second assay was 2.5 microgram per ml.

The Tampa Bay Times published an interview with a research person at the Byrd Alzheimer's department last week (in November 2011), complaining it was not apparently possible to get a large pharmaceutical company to fund research into the possible prevention of Alzheimer in rats using caffeine. A similar economic puzzle exists with Coenzyme Q ten. It is a normal constituent of the body. It was discovered in the 1950's. It is not patented any more than thyroid hormone is patented. The FDA defines it as a food supplement, not a drug. It has held a hearing on this subject in the last decade. Research has been going on, but plodding and working against null result studies in healthy people. In other words, simple and pure studies for short periods of time didn't find an effect.

In contrast, my patients are ill in a number of diseased ways. Their average age is 77. Most everyone was placed on statins for a high pre-drug cholesterol over 200 or LDL above the criteria of 160 in noncardiac patients, 100 in cardiac patients or 75 in diabetic cardiac patients.

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Cramps in Seniors cont'd. from page 37

In fact, ten of the 62 did not have statin therapy any time in several years. Their illnesses range widely and include lupus, a diagnosis of post cancer chemotherapy fibromyalgia, chronic blepharospasm, oxygen dependent COPD, diabetes, a diagnosis of myasthenia gravis, malabsorption post colectomy, and ankylosing spondylitis. They had in common cramps which improved after adding Coenzyme Q ten to their established regimen.

After having suggested Coenzyme Q ten to almost all of the 142 patients, I have assayed once or more I have observed a side effect which is not described in the literature. About ten percent of persons taking Coenzyme Q ten are distressed by having firm to hard and less frequent fecal excrement. For persons not forewarned and used to a daily BM, this is off-putting if not panicking.

For this reason, I start anyone with a tendency to constipation on a very small starting dose of 30 to 50 mg a day. I titer up as the tolerance is established or signs are noted. Sometimes needing a stool softener, people have been titered up to the dose needed to abolish or greatly ameliorate cramps. The highest dose so far in a person with painful, tender muscles, large frame and high BMI is 800 mg a day with resolution of symptoms and no side effects for most of a year.

In general, I raise the dose by 100 g a month to leave me time to talk about and respond to all side effects early or to determine a plateau in effectiveness. Start low, go slow.

I am also careful to explain the food supplement is not covered by insurance, but can be purchased by phone or internet very inexpensively. I pay $18 including shipping and handling for 180 200 mg capsules at the Swanson's website. This company and many others run two-for-one sales all the time.

In looking at over four brands, I found that most brands are manufactured by the same company, the Kaneka Corp in Japan. The three people around the country I spoke with indicated that the Jarrow brand was the most trustworthy. But it prices out as the most expensive. Secondly, it comes from the same source as some cheaper brands. Thirdly, I can't observe a difference when patients use one brand or another.

While I believe my observations constitute a pilot study, they also lack the scientific rigor needed to be a formal study. Though this study had the ironic merit of not costing much to anyone, it cut scientific corners like symptom profile scales and identical drugs.

I would like to find a physician who does not use Coenzyme Q ten because he knows it has not been proven for use. Such a group of patients would be a great placebo cohort. If we then start half of matched patients on Coenzyme Q ten, then an acceptable study worthy of an IRB might happen. Anyone game?

Department of Health, Bureau of Vital Statistics

FLORIDA DEPARTMENT OF HEALTH

Physicians' Online Tutorial for Completing Cause of Death on the Florida Death Record

The Department of Health Bureau of Vital Statistics, in cooperation with the Florida Medical Association and the Florida Association of Medical Examiners, has an **online tutorial for physicians**. This complimentary tutorial takes about one hour to complete and can be accessed at: http://floridavitalstatisticsonline.com/

The tutorial is constructed for physicians, providing an overview of the death registration process in Florida and how to go about properly completing the medical information on the death record. It provides sample case histories; an explanation of the physician's, the medical examiner's, and the funeral director's responsibilities in getting death records filed; how mortality data is used and why the death record is so important to families.

EDRS—Electronic Death Registration System

Vital Statistics has moved to electronic filing of Florida Death records. This means the record is filed online, via a secure Internet site, using the Electronic Death Registration System (EDRS). The user has direct access to the state database for entry of death record information. EDRS increases accuracy and timeliness while improving statistics for state and national surveillance systems.

Funeral directors are online users and complete the demographic/personal information on the decedent. The EDRS record is then sent electronically to the physician for certifying the medical information.

The certifying physician can be an **online user** and complete the medical certification electronically, using EDRS; **OR** can be an **offline user** and complete the medical certification via **Fax Attestation**. The fax is system generated and looks much like the medical portion of the paper death record.

Questions? 904-359-6900, ext. 9020 — Quality Assurance • Bureau of Vital Statistics
P.O. Box 210 • Jacksonville, Florida 32231-0042