A Question of Personal Health

The true effect of statin drugs on your body By Sally Jackson RN, CLNC, CPT, PT.ADV, July 2009

In the past thirty years we have evolved into a fast paced, highly technical and "modern society". We move at an ever increasing pace, eat "on the go" meals, fuel ourselves with caffeine and sugar, communicate with cell phones and computers. We drive at lightning speeds to high stress jobs, where we eat poorly if at all, sit for hours at a time and use tobacco products. When it comes to addressing our poor health or even health maintenance, we "take a pill". In today's society an increased emphasis is placed on health maintenance or disease prevention. But our present medical system is only designed to address illness once it occurs. Your doctor will give you that yearly health physical, and write a prescription or two to treat those lab values that are not quite at an acceptable range. This is the closest you will get to "health maintenance"; the rest is left up to you.

How do we learn our personal health care? Most of us start with what our parents teach us as we grow up. We diligently follow their lead, which is what they learned from her parents, until we learn that crossing our eyes and making those 'funny faces' will not cause permanent damage. In school we learn what STD's are and how to practice personal hygiene. The rest of our education consists of bits and pieces of information along the way. As an adult we depend on our physicians to "maintain our health", but the era of the true "family physician", who would encourage and coach us in lifestyle changes for maintenance of good health, is long past. And we are left with a pat on the back and a prescription in hand as we walk out of his door. For a majority of our population this means that we fill the prescription and continue our lives as usual, until illness strikes and the good doctor steps into our lives to "treat the illness", unfortunately this happens more often than it should.

There are a large variety of teaching materials available to us that can give guidance in our daily health, but what about that prescription you have in your hand? There is that 'ticker tape style' form of information that comes with the drug that's supposed to warn you about all the possible problems that might occur, and what symptoms you should observe for, which a majority of the population never reads.

Of the thousands of drugs on the market in this country, there are a few that should have more than just a warning label. "Forewarned is forearmed", and the goal here is to arm you with more knowledge about some of the most popular, as well as dangerous, prescription medications in use in this country today. Remember, your doctor only writes the prescription, he doesn't swallow the pills, you are the one who must decide whether or not to take the medication in question, and that little 'ticker tape' of information is no where clear enough.

This brings us to the drug in question, which actually is a family of drugs called statins (Chlesterol lowering drugs). The five top competitors in this group consists of; Lipitor (Atrovastatin) the leader in this competition, Zocor (simvastatin), Mevacor (Lovastatin), Prevachol (Pravastatin), and Crestor (rosuvastatin). It has been estimated that sixteen million American people take a daily dose of Lipitor, one of the most popular drugs in this country today. It is widely advertised as safe and effective by its producer and marketer, Pfizer; the world's largest pharmaceutical company, deriving a major portion of its income from this drug.

Statin drugs are prescribed at a staggeringly high rate, doled out like candy to children, by 2 cardiologists as well as every other medical specialty, including gynecology. The production and sales of statin drugs in this country has become a competitive, uncontrolled frenzy, with pharmaceutical promotions and unsupported claims. Such rivalry has put the fast food industry sales of 'on-the-go meals' to shame.

The American Heart Association lists the six risk factors for heart attack as follows; high blood pressure, use of tobacco (smoking), diabetes, gender (male), family history of heart disease, and high blood cholesterol. One third of this nation's population has an elevated serum cholesterol level, according to IMS health (a pharmaceutical market research group). Thirty years ago if you were a male, possessed at least two of these risk factors and had a cholesterol level of 250 or greater, then your doctor would place you on a diet and exercise program. A statin drug would only be added, if that diet program was ineffective over six months. Twenty years ago that number dropped to 240 with only one risk factor. With the publication of the 2001 federal cholesterol guidelines, the number was again reduced to 200 and somewhere along the line the trusted diet and exercise recommendation was dropped, while the population of females was added to the list. In the past year it has been suggested that this 'treatment number' be reduced again to 180 and that everyone, even those people who are otherwise healthy should be, according to the pharmaceutical industry, treated with statins. The federal government and the insurance industry have so far given the pharmaceutical industry their blessing. To date there are no true measurements to determine where to draw the line when it comes to cholesterol. The present data being used to measure the 'normal' cholesterol was determined by the FDA in 2001, following a review of clinical trial results and recommendations, which were funded for and supplied to them by the pharmaceutical companies, who were seeking the approval of their form of statin drug for commercial sales.

Since heart disease is the number one cause of death in this country today, it would only make sense, that we aim our health efforts at preventing its occurrence. Today's physicians do not have the time to study and research all of the new drugs flooding the market. As a result they have learned to depend on the drug companies to do that research and provide guidance when it comes to use, dosage and effects of their drugs.

There are some physicians in this country who prescribe statin drugs only rarely and in extreme circumstances, unfortunately these doctors are themselves, rare. Most doctors tend to 'jump in with both feet', ordering a statin drug, rather than recommending diet and exercise which is safer and has a wide variety of long term positive effects beyond that of simply lowering cholesterol, such as; lower blood pressure, prevention or elimination of diabetes.

When it comes to the negative effects, usually referred to as 'side effects', all statin drugs create the same effects, to varying degrees (brand and dosage dependant). But before we can understand statin drugs and their side effects, a more thorough understanding of their direct effect on the human body, is necessary.

A majority of the tissues that form our vascular and nervous systems, including the brain, are made of cholesterol. In fact, over fifty percent of the dry weight of our brain is cholesterol. Cholesterol is the main constituent of cell membranes throughout the body, making our cells water resistant. It is a key player in the production of hormones that facilitate growth, development, stress response and memory. The circulating cholesterol in the bloodstream plays several other key rolls. It is an integral part of the function of the body's immune system. Blood cholesterol also; transports nutrients, stimulates enzyme production and the repair of tissues. All scar tissue in the body contains high levels of cholesterol. Structures that are found within each cell's membrane (outer coating) are called 'lipid rafts'. They are also made of cholesterol, acting 3 as both protection of cells protoplasm and transporter for multiple nutrients, enabling cell function.

We need to ask; what is truly a normal cholesterol level and when do we cross over into dangerously high or low serum concentrations? Keep in mind that the number we use as a guide, is only a measurement of the free cholesterol circulating in the bloodstream. Dangerously low cholesterol levels are rare, but are now seen frequently in those under 'statin therapy'. Before the advent of 'statin therapy', high cholesterol was treated with diet changes and exercise. This is still the proven and effective therapy, but the changes in lifestyle must be permanent.

We derive cholesterol from plants as well as animals. It is synthesized from acetyl Co-A through the HMG-Co-A -reductase enzyme. It is absorbed and utilized by molecular chain reaction, to form three unique molecular substances; cholesterol, dolichol, and ubiquinone.

Dolichol is a part of the necessary chain in the formation of DNA proteins, resulting in genetic body programming. Without dolichol the DNA sequence chain becomes broken. This may be the reasoning behind why all pharmaceutical companies that produce statin drugs, makes a clear statement; that these drugs should not be taken by pregnant women or those who can become pregnant. But they do not include males who produce the sperm. Genetic body programming is inherent and predetermined in all single cells; this includes the egg and the sperm, and does not occur after pregnancy.

Ubiquinone, which is also known as Coenzyme Q-10, is the key ingredient necessary for all cell respiration, cell membrane integrity, nerve conduction and muscle integrity. Of all the muscles in the body, the heart produces the highest energy demand, by virtue of its oxygen consumption via cell respiration, utilizing the largest portion of available Coenzyme Q-10 in the body.

All statins work the same way within the human body, by blocking the production of HMG-Co-A-reductase enzyme. This is the enzyme needed for that molecular chain reaction which produces cholesterol, dolichol, and ubiquinone. With the introduction of statin drugs, this chain reaction is broken, creating a loss of structural components of the cell's membrane. Once the circulating blood cholesterol is below that level which is needed by each individual human body to maintain its own cell membrane integrity and function (the body's 'normal' level), then a new chain reaction begins, with the slow degradation of the cell membrane, culminating in eventual necrosis and cell death. This is seen on the cellular level, in all tissues. Once the cells die, they liquefy into the tissue bed. Unnoticed, this reaction continues, with slowly expanding microscopic loss of tissue, eventually producing symptoms. In some areas of the body these tissue losses are permanent, even if the blood cholesterol returns to the body's 'normal' level. **This new chain reaction, ending in cell death, can occur anywhere throughout the body, including the heart.**

Keep in mind that the molecular reactions explained here is a part of complex biochemistry. The microscopic substances and their reactions remain unchanged; a broader view has been given to facilitate better understanding.

As a result of aggressive advertising we have 'learned' that the presence of an elevated cholesterol level is a risk factor for heart disease, which can lead to heart attack. But heart disease encompasses a multitude of physiologic problems, of which the presence of cholesterol plays a very minor roll. And to date, there is no research to prove that; the presence of an elevated serum cholesterol (somewhere above 180) is a direct cause of heart attack. Recently, a new campaign for statin use has surfaced, stressing 'the reduction of plaque formation' to 'prevent heart attack' (**plaque; blood platelets - a necessary constituent of normal blood clot formation**). Yet the only studies in this area show no direct correlation between the formation of 4 plaque and elevated serum cholesterol.

In our efforts to become 'heart healthy', the use of statin drugs have contributed to the development of heart failure, diagnosed as 'statin- induced diastolic dysfunction', which is the loss of significant function of the muscle composing the heart wall. Often leading to congestive heart failure, which is a life threatening condition, usually controlled with the use of diuretics and digoxin. Digoxin is a drug that causes slow and forceful contraction of the heart. But this drug may be poorly effective due to the 'statin- induced' pre-existing damage to the muscle wall.

Today it is a common practice for physicians to start patients on statin drugs after a heart attack, regardless of the patient's cholesterol level. It is assumed that; elevated serum cholesterol is present therefore actual testing for base levels before medicating is not usually done.

For those who take statins drugs, the loss of microscopic areas of tissue throughout the body may go completely unnoticed. The recommended lab studies that are used to measure or detect any possible side effects of statin drugs do not become elevated until long after significant symptoms begin.

If you now understand the 'statin induced' chain reaction that leads to cellular necrosis and cell death, then the symptoms that develop as 'side effects' will be more than clear.

In their efforts to make the sales of statin drugs more appealing, the pharmaceutical industry has made broad statements that stress the words "safe' and side effects are noted as 'minor problems'. Along with headaches, nausea, unexplained fevers, and insomnia, which may all be a result of the microscopic tissue necrosis (cell death), we can add;**myopathy, renal failure, liver damage, polyneuropathy, retinal hemorrhages, brain hemorrhages, and infertility**.

The most common complaint seen in all studies is that of **muscle pain or weakness (myopathy),** which is easily dismissed by physicians and treated with anti-inflammatory drugs. One study on statin side effects which is currently being conducted by Dr. Beatrice Golomb a neurobiologist at the University of California at San Diego notes that ninety eight percent of those using the statin drug 'Lipitor', experienced some form of muscle problem. She also noted that those who had a more active lifestyle, experienced more 'muscle pain' than those who live a more sedentary lifestyle. As muscle activity increases, the demand for coenzyme Q-10(cell respiration) also increases. The 'statin- induced' microscopic loss of tissue and coenzyme Q-10, ultimately results in increased 'muscle pain'.

After loss of muscle function occurs, the serum creatinine phosphokinase (recommended blood test) then becomes elevated; this indicates a condition known as**rhabdomyolysis**. This is a skeletal muscle injury, defined as; muscle cell necrosis (death) and release of intracellular contents, resulting in myoglobinuria (blood in urine) and eventual renal failure as well as multiple electrolyte imbalances in the body. This diagnosis requires hospitalization with aggressive treatment and can be life threatening. The tissue damage is permanent and can occur in any muscle of the body, including the heart.

Renal failure is seen as **myoglobinuria** which can be a result of rhabdomyolysis or simply the result of direct microscopic tissue loss within the kidneys, with rupture of the vessels in the renal tubules (kidney filters). Again this necrosis is permanent, leading to permanent loss of kidney function.

Liver damage is only noted with laboratory studies or after the appearance of jaundice (yellow discoloration of eyes and skin). The loss of microscopic areas of tissue in the liver can destroy its intricate functions. The liver is actually the largest gland in the body, and is second only to the brain for its multiple functions. To date there are no studies to verify the fact that this microscopic necrosis in the liver causes permanent damage. The extent of individual damage, as 5 seen beyond that of elevated liver enzymes, in all known studies is also unverified. But we do know that failure of only one or two of the liver's multiple functions can lead a wide variety of diagnosed problems, such as; **diabetes, aggressive infections and renal insufficiency**.

Polyneuropathy, also known as **peripheral neuropathy**, is marked by symptoms described as tingling, numbness and weakness in the hands and feet, occasionally with difficulty walking. The fibrous coating on nerve cells is primarily composed of cholesterol. This coating is necessary for the passage of electrical activity across the cells surface. It has been documented that small nerves can regenerate and repair after damage, but only if the required cholesterol and Coenzyme Q-10 are in sufficient quantities in the circulating bloodstream.

Retinal hemorrhages are defined as the **rupture of blood vessels of the retina of the eye**, with resulting loss of vision (**blindness**). The pharmaceutical industry has no written warnings in

reference to this condition or side effect, stating that the percentage of occurrence is too low to be considered as a risk factor when taking statin drugs.

Brain hemorrhages present with a variety of symptoms, including amnesia, progressive memory loss, insomnia, depression and emotional instability. Such symptoms may ultimately result in an **Alzheimer's disease** or **stroke diagnosis**. All of these symptoms result in decreased cognitive activity (mental function or memory) to varying degrees. Dr. Golomb has noted; that a decrease in cognitive activity occurred in fifteen percent of all the patients taking statin drugs in her study. The pharmaceutical industry denies any connection to the use of statin drugs and memory loss or cognitive impairment. Although many questions have been raised, several published clinical trials which did not examine cognitive response directly, did provide data showing a total figure which did combine all cognitive changes, as one half of one percent of recorded side effects. These clinical trials were small and may not represent the present total population of statin drug users. But this was enough information for the pharmaceutical industry to again state; that this percentage is too low to be considered as a risk factor for taking statin drugs.

Infertility; is seen as **decreased sperm motility** (independent, spontaneous movement) and can only be found on direct examination, which is not one of the recommended tests for managing statin use. Doctors will only run this examination when a couple is seeking assistance with infertility.

This brings up the question; who should take statin drugs?

Children and young adults don't need cholesterol management. Their bodies are able to balance themselves with the assistance of a proper diet and good physical activity.

Adults between the age of 20 and 50 are of child bearing age and should not use statin drugs; this includes men as well as women. It has been found that low tissue levels of Coenzyme Q-10 are associated with decline in energy levels and metabolism with resulting cell structure and **DNA damage**. Every study done so far has found no decrease in risk factors for heart attack in women when using statin drugs, no matter what their age.

The population with an age of over 50 years should not take statin drugs, since this group already has an increased risk of hypocholesterolemia (sever low cholesterol). This is due to age related decreased energy metabolism and the subsequent decreased production of cholesterol as well as Coenzyme Q-10. Which means, their 'normal' cholesterol level is progressively decreasing from what levels they may have had in younger years. And may still be above the pharmaceutical industries and FDA's recommended 'normal'. The risk to this group is much higher and unfortunately many of the symptoms and diseases of the elderly are never associated with the use of statin drugs. When assessing the risk, we must consider the statements made by 6 researchers in the Honolulu Heart Program clinical trial of 2001. Their data accords with previous findings; that show an increased mortality in people over the age of fifty, with 'low serum cholesterol'. Long term persistence of low serum cholesterol concentrations actually increases the risk of death. These clinical trial results support the findings; that those with low cholesterol have a poor outlook when compared with those over 50, who have higher concentrations of serum cholesterol. The data suggests that individuals with a low serum cholesterol (below 200), maintained over a 20 year period, will have the worst outlook for all causes of mortality.

So who is left?

Statin drugs were originally designed to be used only as augmentation to non-pharmacologic interventions that fail, and only on a short term basis of 8 to 12 weeks. When statins are used without the necessary lifestyle changes and the drug is discontinued, then the 'normal body' cholesterol will return to its original level. Which has prompted physicians to then continue the drug and even increase the dose? Today we see long term use of statin drugs as the standard, which is encouraged by the pharmaceutical industry.

When considering the use of statin drugs and other causes of mortality, we must also include **cancer**. Clinical trials have not addressed this disease. Cancer cells grow slowly and are difficult to detect, requiring over six years of study with a cost that would be prohibitive for clinical trials. The CARE study (clinical trials) of the year 2000 did address cancer. Their findings noted an increase in breast cancer of fifteen hundred percent, in those women taking statin drugs. Without the defenses provided by our**immune system** we can develop cancer and other aggressive infectious diseases. The pharmaceutical industry does recognize and makes note of the fact that; statin drug use lowers the immune system. Using this logic, they have recommended that statin drugs be used for the treatment of inflammatory arthritis and transplant patients, a population with an already depleted immune system.

The subject here is the use of statin drugs and their effect on this country. Over the last thirty years heart disease has been the leading cause of death in the United States, although the percentage rate of those deaths has dropped, the overall percentage rate of all causes of death, have equally dropped. During that same time period, new diseases and increasing death rates have occurred, such as; diabetes, and Alzheimer's disease. Ten years ago Alzheimer's disease was not listed as one of the top ten causes of death in this country. In 2006 Alzheimer's disease took the position of number six on that list, and has been steadily rising since. There has also been an impressive rise in diseases affecting our pediatric population including; children with cancer, birth defects and neurological disorders such as autism.

There is no way to tell if the use of statin drugs over the past thirty years, by such an overwhelming number of our population, has created more problems than it has solved. Have future generations been damaged? Have we inadvertently increased disease and death in our older (over 50) population? By clinical studies, it has been shown that the use of statin drugs has not significantly enhanced the 'prevention of heart disease'.

So we are left with the prescription in hand and the ultimate question; Does the benefit of using statin drugs outweigh the risks? Or do the risks, now outweigh the benefits?

Footnote: Since this article was written, research science has discovered a direct link between the development of Congestive Heart Failure and the use of statin drugs. **Watch for future articles on alternative treatments for elevated cholesterol.** 7

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