



Article 13*

The Non-Medicated Life: Assessing Medication Risk and Benefit

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This is the thirteenth in a series on optimal diet and lifestyle to help prevent disease and responsibly avoid an over reliance on medications. This complementary approach is based in the medical evidence of the most successful research trials and the best science available. Any planned change in diet, exercise or treatment should be discussed with and approved by your personal physician before implementation. Consultation with a registered dietitian is strongly advised.

Medicines are a mainstay of American life and the healthcare system not only because they are perceived to work by the individual taking them, but also because their benefit may be shown by the objective assessment of scientific study. Clinical research trials have shown that some of the medicines of Western science may reduce the risk of heart attacks, strokes, and cardiovascular death.

In the first twelve installments of The Non-Medicated Life, informed diet and lifestyle has been shown to accomplish naturally for the majority of individuals, many, if not most of the benefits of medications. The decision, however, to use or not to use any given medication should not be based primarily on subjective preference, but rather should be based on what we objectively need. It may be our preference never to take medication and to reduce our risk naturally. While this is possible for many and perhaps most, it is unfortunately not possible for all. Determining if a medication is truly necessary requires a careful assessment of the risk and benefit of that medication for a given individual.

Unfortunately, all medications are double-edged swords carrying risk and benefit. As has been shown most recently with the group of prescription anti-inflammatory medicines called cox-2 inhibitors, even drugs developed to be safer than over the counter alternatives may

cause death. Perhaps more disconcerting, the most common and seemingly innocuous over the counter medications have caused deaths. Thus, all medications including prescription and over the counter – as well as supplements – must be subjected to a risk-to-benefit analysis.

While physicians routinely perform such risk-to-benefit analysis before prescribing any medication, individuals familiar with the information given below may be more able to understand such an analysis, discuss their own unique potential risk and benefit with their physician and thus be reassured in taking their prescribed medication. Risk-to-benefit analysis must be individualized and put into perspective the appropriate concerns raised many times in an alarmist fashion in mass media. Such an objective analysis for the use of any medication begins with an assessment of the actual risk for a disease or condition which has been shown in clinical studies to benefit from the use of that medication.

For cardiovascular disease the risk-to-benefit assessment begins with symptoms and history. Exertional chest discomfort, pain or shortness of breath may be the first suggestion of cardiovascular disease and would require an evaluation by a physician. However, even individuals without symptoms may be at risk. A personal history of a prior heart attack places

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an individual at high risk for a recurrent heart attack. Even in the absence of a personal history, a family history of cardiovascular disease such as a heart attack, bypass or stent occurring prematurely in a father or brother before the age of 55 or a mother or a sister before the age of 65 places one at increased risk. A history of smoking or prolonged exposure to secondary smoke may also significantly increase risk. Additionally, elevated blood pressure, elevated total cholesterol, elevated LDL or “bad” cholesterol and/or depressed HDL or “good” cholesterol may also increase risk.

Because it is sometimes difficult to gauge the relative contributions of such risk factors to overall risk, a quantitative, global cardiovascular risk determination as recommended by the National Cholesterol Education Program (NCEP) is currently used by most physicians. Called the Framingham risk equation, it may help determine our percent risk of a heart attack or stroke over 10 years. The risk assessment is based on the risk observed in the population of Framingham, Mass. over years as part of the Framingham Heart Study.

Using the risk equation for any given individual allows us to find a group of individuals in the Framingham Heart Study having the same exact risk characteristics such as blood pressure, total cholesterol, HDL or “good” cholesterol, smoking status, age and sex. The observed average percent risk over 10 years for such a risk matched population allows a prediction of the cardiovascular risk for the individual being assessed. A one to nine percent Framingham 10-year risk is considered low. A 10 to 19 percent Framingham risk is considered moderate risk. Over 20 percent is considered high risk or what is called a coronary disease risk equivalent because such individuals are at the same high risk for a heart attack as someone who has already had a heart attack.

Once one’s global cardiovascular risk is known, the decision to use or not use a medication becomes more objective because one may then compare this risk to the actual complication

and/or side effect risk of taking the medication. For example, aspirin is a common, over the counter medication which many individuals use for heart disease prevention even in the absence of established heart disease. Aspirin may reduce the cardiovascular relative risk about 25 percent. Aspirin, however, is not without non-cardiovascular risk such as the risk for bleeding in the gut or brain; although such complication risk is small there are large numbers of people who take aspirin. As a result, a significant number die each year taking recommended doses of the drug. Yet if one’s 10-year Framingham risk is between 10 and 19 percent and with the approval of one’s physician who may assess other possible contraindications, it may make sense to take aspirin. For such individuals, the use of aspirin may be reasonable because one’s risk of dying from a heart attack exceeds one’s risk of dying from a gastrointestinal bleed or a hemorrhagic bleed into the brain caused by aspirin. If one’s 10-year Framingham risk is less than 10 percent, there is no objective rationale to take aspirin.

Indeed, it is the ability to quantitate cardiovascular risk with the Framingham risk equation which also helps determine when the risk/benefit may favor the use of prescription agents such as the statin drugs. Such drugs reduce cholesterol by up to 50 percent and may reduce the cardiovascular relative risk by as much as 30 to 40 percent. If the 10-year Framingham risk for an individual is between 1 and 9 percent, the LDL or “bad” cholesterol should not exceed 160 milligrams per deciliter (mg/dl). Additionally, if the 10-year risk is between 10 and 20 percent, the LDL or “bad” cholesterol should not exceed 130 mg/dl. Finally, if the 10 year risk is 20 percent or greater or the person has a history for atherosclerosis (heart attack, bypass, stent or stroke), the LDL should not exceed 100 mg/dl, and in the most recent NCEP recommendation should not exceed 70 mg/dl with those having a history of atherosclerosis that also have diabetes or smoke. If these targets are exceeded especially at the higher levels of risk, strong drugs including

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statins reduce risk significantly and to the patient's great benefit. For those at the highest levels of risk, the benefits of the drugs far outweigh any potential risk from muscle problems or liver problems. In fact, statin drugs as a class give more benefit and far less risk than over the counter baby aspirin.

For those at the lower levels of risk, however, the case for drug treatment is much less convincing. Complications and side effects don't change, but in the low cardiovascular risk individual, the risk of the complication and side effects may outweigh the actual risk of disease. Medications should not be given solely because individuals do not wish to reduce their intake of saturated fat in the form of hamburgers, hot dogs, bacon and cheesecake.

Medications including over the counter preparations should not be the first choice where a non-medicated approach would work equally well or better. Thus, when considering medication or a non-medicated approach a rational application of risk/benefit analysis done with one's physician is all important. Such an analysis may allow one to rationally and appropriately avoid the proverbial bottle of pills to address some of our most important cardiovascular health problems.

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