Evidence-Based Medicine and the

Treatment of Cholesterol and Triglycerides

By James L. Holly, MD

Your Life Your Health

The Examiner

August 27, 2009

It's time for your annual physical and you're confident. When your doctor told you a year ago that you were at high risk of a heart attack, you began watching your diet and exercising regularly. You did everything your doctor recommended to keep your cholesterol under control, and you're relieved but not surprised when the lab results show that your cholesterol level is lower than it was on your last visit.

So, when your doctor suggests you start taking a cholesterol-lowering statin drug, you're confused. Familiar alarm bells start ringing in your mind. What happened?

She/he explains that new clinical studies found that people at high or moderately high risk of a heart attack benefit from more aggressive treatment. The studies led the National Cholesterol Education Program (ACEP) to update its treatment guidelines to recommend that these people should do all they can to lower their levels of LDL ("bad") cholesterol. If diet and exercise haven't done it, this means initiating cholesterol-lowering drug therapy for many more patients.

But, how did the doctor determine that your risk was high? It was done by the use of multiple formulae which are based on research and clinical studies. These formulae are:

- Framingham Cardiovascular Risk Score
- Global Cardiovascular Risk Score
- Cardiovascular Risk Factors
- Cardiometabolic Risk Score both the ACEP and the World Health Organization versions
- Measured LDL Level
- Fredrickson Classification of Dyslipidemia

The Framingham Cardiovascular Risk Score is a computation based on the following factors:

- Your systolic blood pressure
- Wether your blood pressure is treated or not
- Your age
- Your gender
- Your HDL (good cholesterol)
- Your total Cholesterol
- Whether you smoke or not

- Whether you have diabetes or not
- Whether you have enlargement of the left ventricle of your heart or not

These nine factors are used to calculate a risk score which tells you the probability of having a heart attack in the next ten years. SETMA uses an electronic method to calculate this score on each patient who comes into the clinic. Research has shown that if the Framingham Risk Score is moderate or high, aggressive treatment of bad cholesterol (LDL) to get it below 100 or even 70 is beneficial in avoiding heart disease.

Global Cardiovascular Risk

Now, just as research and what are called "random controlled studies" prove the validity of the Framingham Risk Score, new studies have shown that the age and gender bias of this score can obscure risk for the very young and can overstate the risk of the elderly. Therefore a few years ago, another score, based on the Framingham Study was devised. This score called the Global Cardiovascular Risk Score eliminated age and gender as risk factors. This score is calculated on the basis of:

- Systolic Blood Pressure
- HDL
- Total Cholesterol
- HgbA1C (rather than asking if the patient has diabetes, the results of this test which estimates the average blood sugar over the past three months is used)
- Packs of cigarettes per day (rather than asking if the patient smokes are not, the amount of tobacco used is quantified)

If this score is above 4, then you are at a higher risk of a cardiac event and should have more aggressive treatment of your cholesterol. This is true regardless of your age or gender. This score is useful because it often uncovers high risk in the very young and/or relatively low risk in the elderly.

Other Cardiovascular Risk Factors

Additionally, research has shown that the following risk factors increase your risk of having a cardiovascular event. Those factors are:

- A history of coronary heart disease, angina pectoris, previous MI or coronary bypass surgery.
- A history of non coronary atherosclerosis (hardening of the arteries) such as peripheral vascular disease, cerebrovascular disease, aortic aneurysm, carotid artery disease
- Family History of a first degree family member (parent or sibling) who had premature Cardiovascular Disease which for a male is less than 55 years of age or a female less than 65 years of age.

The presence of these risk factors including the Framingham Risk Score and/or Global Cardiovascular Risk Score indicates to your healthcare provider how aggressive the treatment of your cholesterol should be. (For an in-depth discussion of these risk factors, please see the fourteen-part series entitled "Cardiovascular Risk Factors" which can be found at www.setma.com under Your life Your Health.

LDL and Cardiovascular Risk

In addition, when the Framingham Study was started, LDL cholesterol was not being measured directly and was therefore not a part of the formula. Now we know that regardless of your Risk Factors and/or your Framingham Score, a high LDL is an independent risk factor for heart disease, therefore if your LDL is high, you should receive more aggressive treatment. All of this is based on scientific evidence derived from random controlled studies and thus is called "evidence based medicine." It is not the opinion of your physician or nurse practitioner. It s not based on their experience; it is based on science.

Cardiometabolic Risk Syndrome

Your risk of cardiovascular disease can be further assessed by the ACEP Cardiometabolic Risk Syndrome Score. This is a designation which is based on the following factors:

- Triglycerides
- Wait Size
- Blood Pressure both diastolic and systolic
- Fasting Blood Sugar
- HDL

A World Health Organization version of this formula adds the following elements to the ACEP formula above:

- Insulin Resistance
- BMI
- Waist/Hip Ratio
- 2 Hr GTT test with a blood sugar above 140
- the presence of Diabetes
- Presence of protein in the urine

If you have the Cardiometabolic Risk Syndrome, it is very important for your healthcare provider to encourage you to exercise, lose weight and stop smoking in addition to controlling your blood pressure and your cholesterol. Ask your healthcare provider if you have this syndrome.

Fredrickson Classification of Dyslipidemias

Finally, your risk of cardiovascular disease from elevated bad cholesterol can be assessed by the determination of the classification of your cholesterol abnormality based on the Fredrickson Classification of Dyslipidemias. There are six types. Types IIa, IIb and III carry very high risk of cardiovascular disease. Type IV and V have an increase risk of heart disease but not as high as IIa, IIb, and III. Type I carries no risk of heart disease.

- Type I -- shows an increase in chylomicrons after eating and does not increase your risk of coronary artery disease.
- Type IIa -- shows an increase in bad cholesterol (LDL) but triglycerides are normal. This type significantly increases risk of coronary artery disease.
- Type IIb – LDL (bad Cholesterol is elevated and triglycerides are also elevated. This type also carries a significant elevation of the risk of coronary artery disease.
- Type III --has an increase in a particular type of LDL and in triglycerides and leads to a significant increase risk of heart disease and hardening of the arteries
- Type IV – normal to slightly elevated LDL and triglycerides which is often associated with diabetes type 2 and alcoholism and has a slight increase in heart disease associated with it.
- Type V – shows elevated LDL and triglycerides similar to Type I except Type V has an increased risk of heart disease.

Evidenced Based Lipid Treatment

Aggressive treatment with oral medication to lower your cholesterol based on the above evaluations is not intuitive medicine. It is not based on what a provider thinks or feels or an individual provider's personal experience, it is based on scientific evidence and it is called "evidenced-based medicine." From random control studies, evidence-based medicine teaches us the following about the treatment of cholesterol:

- Statin Therapy is safe -- Muscle symptoms should be monitored, CPK levels measured when clinically indicated and liver enzymes measured periodically.
- Patients with diabetes benefit significantly from statin therapy -- the same benefits were found in diabetes independent of the length of their disease, the control of blood sugar or the presence of hypertension.
- High-risk patients benefit from statin therapy regardless of baseline LDL-C levels -- the results of the HPS study extend cholesterol lowering benefits to patients who previously would not be considered candidates for therapy, notably those with LDL-C levels below current targets.
- Less emphasis should be placed on the actual lipid level and more consideration should be given to the cardiovascular risk profile of the patient.
- The decision to start lipid-lowering therapy should be based on cardiovascular risk and anticipated benefits, rather than on lipid levels alone.
- HPS raises the possibility that the ideal LDL-C level is <70 mg/dL in patients with atherosclerosis or diabetes.
- There is no cardiovascular risk reduction with antioxidant therapy in high-risk individuals
- Lowering cholesterol in individuals with baseline low cholesterol is safe

Conclusion

There is now ample evidence that cholesterol-lowering therapy with statins should be initiated in all high-risk groups, regardless of:

1. Gender
2. Age
3. Presence of diabetes
4. Baseline LDL-C levels.

SETMA and Evidence-based Lipid Treatment

After reading the above, you may wonder, "How can a healthcare provider possibly determine all of this without hours of time spent with a patient?" The answer is what SETMA calls "electronic patient management." SETMA has built the capacity within the NextGen EMR, which we utilize in our clinic, to quickly and easily calculate all seven of the above risk measures. This gives evidence-based guidance to the treatment of lipid abnormalities in our patients. The electronic calculation of all of these risk stratification measures takes less than one minute during a patient encounter. The risk scores are then displayed with evidenced-based recommendation for lowering the LDL, total cholesterol, triglycerides, Cholesterol/HDL ratio, and the Triglycerides/HDL ratio.

Ask your SETMA provider to show you your scores for each of these calculations and to recommend treatment based on those scores. Remember, it is your life and it is your health.