

THE PREVENTIVE CARDIOLOGY AND APHERESIS CLINIC OF THE HEART GROUP OF LG HEALTH: POSITION STATEMENT

The American Heart Association in conjunction with the American College of Cardiology recently issued updated guidelines for cholesterol management. Several aspects of the guidelines run counter to traditional practice:

1. Lower LDL isn't necessarily better
2. Treating to risk-based goal is no longer necessary
3. Clinicians should use an untested risk calculator which will indicate whether treatment is necessary
4. Non-statin drugs have no role in cholesterol management and should not be used

The media has reported on the departure of Dan Radar M.D., a thought leader from the University of Pennsylvania, from the writing group. Upon release of the guidelines, the National Lipid Association released a statement indicating they also departed from the process and could not endorse the new guidelines. Often when practice-changing guidelines are contemplated, a pre-release for public comment occurs prior to the final adoption. This did not happen with these new guidelines.

The writing committee utilized only the highest quality randomized clinical trials in formulating their recommendations. They correctly point out the absence of trials designed to assess whether treating to a risk-based goal is superior to the newly recommended high-intensity or moderate intensity statin regimen. In the November 27, 2013 edition of *JAMA*, Dr Braithwaite speaks to 'evidence-based medicine's 6 dangerous words: there are no data to suggest', offering technically accurate but absurd examples to illustrate the point:

"There is no evidence to suggest that hospitalization compared to not hospitalizing patients with acute shortness of breath reduces mortality."

"There is no evidence to suggest that looking both ways compared to not looking both ways when crossing a street lowers pedestrian fatalities."

The author notes, "beyond its ambiguity, 'there is no evidence to suggest' creates an artificial frame for the subsequent decision."

Apropos the guidelines it is true there is no data to suggest that treating to a risk based goal versus a statin intensity based goal results in better outcomes. However that has been the position of the Adult Treatment Program for years. Also, new born humans, sub-human primates and aboriginal cultures typically

have LDL levels of 50 mg/dl. We are now told the level of LDL no longer matters (although we are told to treat levels > 190 mg/dl). Are we to abandon traditional practice because 'there is no data to suggest'?

Most lipidologists believe one of the main drivers of atherosclerosis is serum concentration of LDL which, by mass gradient transfer, diffuses to the sub endothelial space to initiate and propagate the atherosclerotic process. We also understand this process is not simply 'osmotic' which would create a convenient linear relationship between LDL and disease burden. Clinicians often see those with high LDL and no apparent disease (even angiographically) and those with severe disease and modest LDL levels. We appreciate the Nurse's Health Study which showed improved outcomes with higher LDL and low levels of inflammation (hs-CRP) as opposed to a lower LDL but high levels of inflammation.

There are points on which the lipidology community agrees with the guidelines:

1. LDL > 190 mg/dl needs treatment
 2. Diabetics need treatment
 3. Those with known vascular disease need treatment
- Remaining uncertain:

1. How to best treat hypertriglyceridemia
2. Residual risk patients; we understand our patients treated with statins enjoy a 30% risk reduction, but they remain exposed to 70% of their pre-treatment risk
3. How to best treat those with metabolic syndrome who are at significant risk for vascular disease as a result of discordance between LDL cholesterol and LDL particle number, a more sensitive marker for disease progression
4. Understanding the role of a yet-to-be-validated metric for disease risk estimation
5. How to best treat those with elevated levels of Lp(a)

Guideline writers deal with data. Clinicians deal with the individual patient, few of whom are identical to those studied in clinical trials. Our goal at The Preventive Cardiology and Apheresis Clinic of LG Health is to help the clinician achieve the best possible outcome with their challenging patients. Guidelines are helpful but they are no substitute for experience and clinical competency in lipidology.