

This edition of the Nutrition Research Update highlights two very important advances in the study of cardiovascular disease (CVD). Dr. Kevin Maki and Alyssa Eakley discuss alternative biomarkers for the assessment of CVD risk. While low density lipoprotein cholesterol (LDL-C) has long been known to reflect future CVD risk, new research suggests there are additional measures that should be considered in addition to LDL-C. Also in this issue, clinical lipid specialist Lynn Cofer-Chase reviews the revolutionary new class of lipid-lowering agents, PCSK9 inhibitors. This therapy has generated a great deal of excitement in the field of cardiology as an effective alternative to statin drugs with minimal side effects.

We are committed to featuring new and exciting research findings in the Nutrition Research Update on topics relevant to optimal health and disease prevention, and hope the information presented here will continue to facilitate further research and discussion in health and nutrition. If you have any questions or comments regarding the present content, or suggestions for future feature articles, please feel free to contact us at info@eggnutrition.org.

Regards,



Tia M. Rains, PhD
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SPECIAL FEATURE

Beyond LDL Cholesterol: Alternative Measures of Atherogenic Lipoprotein Burden and Cardiovascular Disease Risk

In recent decades, much emphasis has been placed on the low density lipoprotein cholesterol (LDL-C) level as the key lipid-related predictor of cardiovascular disease (CVD) risk. However, coronary events can occur even in individuals with LDL-C levels that are considered to be low or "normal".^{1,2} It is becoming increasingly clear that alternative measures, in addition to LDL-C, are valuable in the assessment of CVD risk...[read full article](#).

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Will new drugs (PCSK9 inhibitors) reduce CV risks?

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SPECIAL FEATURE

Beyond LDL Cholesterol: Alternative Measures of Atherogenic Lipoprotein Burden and Cardiovascular Disease Risk

By:

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In recent decades, much emphasis has been placed on the low density lipoprotein cholesterol (LDL-C) level as the key lipid-related predictor of cardiovascular disease (CVD) risk. However, coronary events can occur even in individuals with LDL-C levels that are considered to be low or "normal". (1, 2) It is becoming increasingly clear that alternative measures, in addition to LDL-C, are valuable in the assessment of CVD risk. [The National Lipid Association](#) (NLA) recently released recommendations for the management of dyslipidemia (3) that include non-high density lipoprotein cholesterol (non-HDL-C; comprising LDL-C and triglyceride-rich lipoprotein cholesterol [TRL-C]) as a primary target of therapy, citing evidence from epidemiological studies demonstrating that non-HDL-C is a stronger predictor of atherosclerotic cardiovascular disease morbidity and mortality than LDL-C. (4) Moreover, it has been observed that when values are "discordant" (i.e., LDL-C is low or normal while non-HDL-C is elevated, and vice versa) during treatment with statin drugs, risk more closely follows non-HDL-C than LDL-C.5 (5).

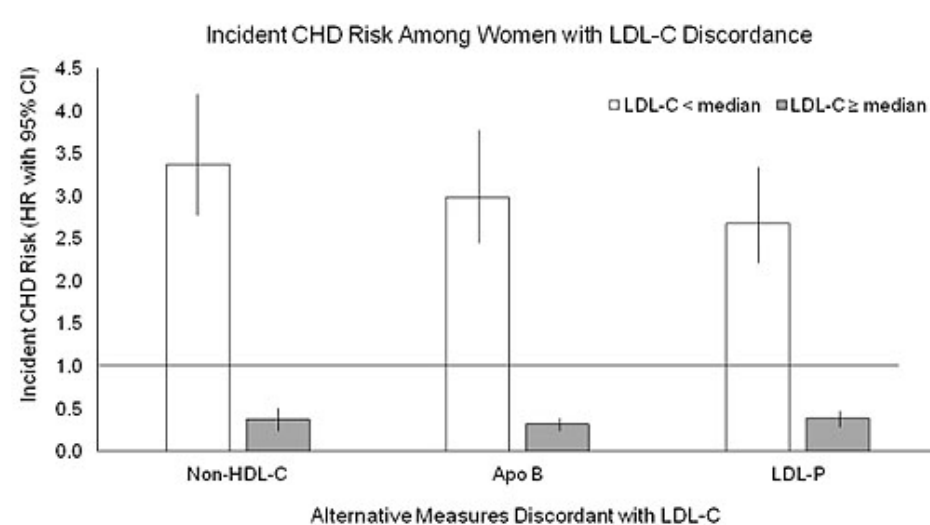
Additional measures also recognized to predict risk include apolipoprotein B (apo B) and LDL particle concentration (LDL-P). Because there is one molecule of apo B in each LDL and triglyceride-rich lipoprotein particle, the apo B concentration provides a direct indication of the number of circulating lipoprotein particles with atherogenic potential, while the non-HDL-C level reflects the amount of cholesterol carried by all potentially atherogenic lipoprotein particles. An elevated LDL-P value in the presence of a normal level of LDL-C often indicates a predominance of small, dense LDL particles, which may have increased atherogenic potential. (6)

Recently, Mora and colleagues investigated the issue of discordance in a large cohort. (7) In this study of 27,533 healthy women ≥ 45 years, LDL-C discordance (defined by median cutpoints) was observed in 11.6%, 18.9%, and 24.3% for non-HDL-C, apo B, and LDL-P. Among women with LDL-C below the median value (121 mg/dL), coronary risk was underestimated in those with above-median values for non-HDL-C (HR: 3.37; 95% CI: 2.69-4.23), apo B (HR: 2.98; 95% CI: 2.41-3.68), and LDL-P (HR: 2.68; 95% CI: 2.18-3.30) compared to women with LDL-C concordance (i.e., those with below-median values for LDL-C and the alternate measure of non-HDL-C, apo B, or LDL-P; see Figure). Conversely, when LDL-C values were equal to or above the median, risk was consistently overestimated with discordant (below median) non-HDL-C, apo B, or LDL-P (see Figure).

Mora and colleagues nicely demonstrated that although correlations of LDL-C with non-HDL-C, apo B, and LDL-P were high, LDL-C discordance was common, particularly for LDL-P (approximately 24%). Notably, when discordance was present, the LDL-C concentration over- or underestimated risk substantially. Mora's results align well with those of Boekholdt et al. (2012) from their analysis of discordance between LDL-C and non-HDL-C during statin therapy.

A growing body of evidence suggests that LDL-C, the traditional measure of cardiovascular risk, may not be telling the whole story. Among concordant individuals, LDL-C has similar clinical value to non-HDL-C, apo B, and LDL-P. However, when discordance is present, it appears that consideration of alternative atherogenic lipoprotein markers may be helpful. (8) Additional clinical studies are needed to enhance our understanding of these complex relationships, and to establish whether risk can be further lowered by lowering these alternative measures of risk in individuals who have elevated levels of non-HDL-C, apo B, or LDL-P despite low levels of LDL-C. Finally, research is needed to identify predictors of elevations in apo B and LDL-P, which will be helpful to design more effective methods for identification of those with potential residual risk who might benefit from more aggressive intervention with lifestyle and pharmacologic therapies. In the meantime, non-HDL-C elevation may be easily identified from the standard lipid profile as the difference between total and HDL-C concentrations. The NLA recommendations identified goal levels of non-HDL-C for primary and secondary prevention of CVD of <130 and <100 mg/dL, respectively. (3)

Figure. Hazard ratios (HR) and 95% confidence intervals (95% CI) for an incident coronary heart disease (CHD) events among women discordant for low-density lipoprotein cholesterol (LDL-C) and alternate measures of atherogenic lipoprotein burden – non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (apo B) and low-density lipoprotein particle concentration (LDL-P) based on median splits. Median values were 121 mg/dL for LDL-C, 154 mg/dL for non-HDL-C, 100 mg/dL for apo B, and 1216 nmol/L for LDL-P.



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Will new drugs (PCSK9 inhibitors) reduce CV risks?

By:

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Clinical Lipid Specialist, National Clinical Educator

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Several new drugs that significantly reduce low density lipoprotein cholesterol (LDL-C) levels have recently been recommended by experts for approval by the Federal Drug Administration (FDA). Many have been extremely optimistic about the approval of alirocumab (suggested trade name Praluent) and evolocumab (suggested trade name Repatha) in recent months. Note the suffix "mab," which stands for monoclonal antibodies. This class of medications is currently being used in the treatment of non-cardiovascular conditions by gastroenterologists, oncologists, and rheumatologists, and is known particularly for being able to very specifically target their effect with little off-target effects. Both of these PCSK9 inhibitors are "fully human" monoclonal antibodies, which bodes well for them.

Pro-protein convertase subtilisin-like Kexin type 9 (PCSK9) inhibitors specifically target PCSK9, the enzyme that attaches to low-density lipoprotein (LDL) receptors and leads to their degradation, stopping them from their return to the surface of the cell to remove more LDL from the blood. Although PCSK9 inhibitors have to be given via subcutaneous injection once every 2 to 4 weeks, they have been shown to lower LDL-C in the 60% range, even on top of statin therapies and/or other LDL lowering agents. (1, 2) Patients with familial hypercholesterolemia, for example, can reduce LDL-C levels from around 300 mg/dL to 100 mg/dL when these drugs are added.

Some forecast that the PCSK9 inhibitors will be as revolutionary to cardiovascular risk reduction therapy as the statins were when first introduced in the late 1980s. Excitement was tremendous when data from ODYESSY Long-Term (n=2341) and OSLER (n=4465) results showed reductions of LDL- from an average of 120 mg/dL to 48 mg/dL or baseline LDL-C levels >70mg/dL to 48 mg/dL in these trials, respectively. (1, 2) Additionally, data from both trials suggested significant reductions in clinical events (e.g., death, heart attack, fatal or non-fatal strokes, revascularization, etc.). (1, 2) Though neither of these trials was powered to look at hard clinical outcomes, one showed event reduction in a post-hoc analysis and the other in an unblinded extension study. There are several very large trials currently underway that are specifically designed to look at hard cardiovascular outcomes with this new class of drugs, but they are not expected to be completed until 2017.

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² Sabatine, MS et al. OSLER investigators. Efficacy and safety of evolocumab in reducing lipids and cardiovascular events. *N Eng J Med* 2015; 372:1500-1509.

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