New Cholesterol Guidelines: Boom or Bust?

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Since 1985, the Adult Treatment Panel (ATP) along with National Cholesterol Education Program (NCEP) has been revising and issuing guidelines for the optimal management of hypercholesterolemia. These guidelines help clinicians to provide uniform and evidence based management to cardiovascular patients and raise awareness in the general population to reduce the risks of cardiovascular pathologies. ATP-I, the first ATP guideline was issued in 1988 with the goal of primary prevention of coronary heart disease (CHD) in people with high low density lipoprotein cholesterol (LDL-C) (>160 mg/dL) or with borderline-high LDL-C (130-159 mg/dL) having greater than two risk factors [1]. In 1993, the second ATP-II guidelines were published supporting ATP-I with an additional element specifying the thorough management of LDL-C in patients with established CHD (secondary prevention) and brought a new goal of lowering LDL-C<100 mg/dL in patients with CHD [2,3].

The third ATP guidelines, ATP-III were released in 2001 and updated in 2004. The core of these guidelines was based on ATP-I and ATP-II with updates in the risk prediction model. According to ATP-III, LDL-C<100 mg/dl was the optimum cholesterol level. Framingham risk score (10-year CHD risk) was introduced to measure the treatment intensity and life-habit modification program known as "therapeutic lifestyle changes" was initiated (TLC). In 2004, ATP-III was updated based on five clinical trials involving statin. These trials provided insights and answers to questions that were not previously addressed in the older statin trials. According to the 2004 update, high risk patients with CHD should have a goal of LDL-C <70 mg/dL [1, 4].

On November 12, 2013, American College of Cardiology and American Heart Association released new guidelines to reduce the risk of atherosclerotic cardiovascular disease (ASCVD) in adults by treating elevated blood cholesterol. There were major changes in the new guidelines, which were based on the evidence from pivotal randomized clinical trials (RCT's) and systematic reviews of RCT's. The specific treatment targets for non-high-density and LDL-C and low-intensity statin therapy were discarded in favor of high-intensity and moderate-intensity statin treatment. For ASCVD (stroke, peripheral arterial disease and coronary heart disease), non-statin treatments were no longer preferred due to the lack of clinical trial data. Four groups have been targeted for the statin treatment; 1) people with established ASCVD, 2) those with age group 40 to 75 years with diabetes, 3) people with LDL-C levels of 190 mg/dl or higher, and 4) people with age group 40 to 75 without diabetes and LDL-C levels of 70-189 mg/dL with a 10 year ASCVD risk of 7.5% or higher as calculated by the new risk calculator [5]. Moreover, guidelines did not comment on the treatment of high triglyceride levels due to lack of evidence supporting a clinical benefit of lowering triglycerides. In contrast to the previous guidelines, new guidelines do not specify LDL-C or non-HDL-C levels but have focused on the intensity of statin treatment. Moreover, these guidelines have placed much higher emphasis on the treatment of diabetic patients than previous guidelines [5, 6]. The new guidelines are being subjected to critique by several experts, including the use of the new risk calculator. It has been said that the new risk calculator is not evidence based and several recently published analysis have shown that the calculator has a great potential to over-predict the need for statin treatment. Another criticism is that the findings from the strictly defined patient population enrolled in randomized controlled trials may not be generalizable to many of the "real world" patients. Furthermore, due to complete reliance on the clinical trial data, certain important aspect, such as pathophysiology of the disease process has been ignored in the guidelines. The clinical recommendations for patients younger or older than 40-75 years are lacking. Additionally, these guidelines have not focused on the LDL-C goals which have played an important role in the treatment decisions and in helping patients make dietary and lifestyle changes [5, 6]. The supporters contend that the new guidelines have been designed to inform clinical judgment and not replace it; therefore clinicians need to make appropriate judgment in patients for whom RCT evidence is inadequate [6].

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