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Guidelines on Treatment of High Blood Cholesterol

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In 2013, the American College of Cardiology and the American Heart Association jointly has brought out a new set of guidelines on treatment of high blood cholesterol [1]. These guidelines suggest practices that meet the patients' need, but are not a substitute for proper clinical assessment and decision making. The ultimate decision regarding the treatment of the patient rests with the healthcare provider and the patient. All the guidelines are based on the results of multiple randomized clinical trials that are well designed and well executed and done in the past few years which have shown substantial benefit to patients. These data have been used to identify the patients who are most likely to benefit from cholesterol lowering statin therapy. The present guidelines address the treatment of adults ≥ 21 years of age. It is presumed that these recommendations will benefit both primary care physicians and specialists who are involved in the prevention of Atherosclerotic Cardiovascular Disease (ASCVD).

The Expert Panel did not recommend the continued use of specific LDL-C and/or non-HDL targets for treatment as it did not find evidence to favor treatment to target. Further, it also states that nonstatin therapies do not provide acceptable ASCVD risk reduction compared to their potential for adverse effects when used in the routine use of ASCVD. This guideline recommends the use of statins based on an estimated 10-year ASCVD risk in both white and black men and women [2]. Though there is no recommendation for Asians or Indians, the African American can be chosen while calculating the risk for Indians and Asians as per this guideline. The guideline also used the trials to identify the relevant safety considerations in individuals receiving treatment of high blood cholesterol.

This guideline focusses on the ASCVD Risk reduction and has identified four distinct groups of patients who would benefit from reductions in blood cholesterol. These groups are as follows.

1. Individuals with clinical ASCVD.

2. Individuals with primary elevation of LDL-C ≥ 190 mg/ dL

3. Individuals 40 - 75 years of age with diabetes and LDL-C 70 - 189 mg/ dL.

4. Individuals without clinical ASCVD or Diabetes mellitus who are 40 - 75 years of age with LDL-C 70 - 189 mg/dL and an estimated 10-year ASCVD risk of 7.5 % or higher.

These groups have a potential for ASCVD risk reduction benefit clearly exceeding the potential for adverse effects in adults. Clinical ASCVD is the presence of Acute coronary syndromes, a history of myocardial infarction, Stable or Unstable angina, coronary or other arterial revascularizations, stroke, transient ischemic attacks or atherosclerotic peripheral arterial disease. The 10 year ASCVD risk is calculated as per the guidelines on Assessment of Cardiovascular risk of the ACC/AHA. [2]. However, it has to be emphasized that lifestyle modifications like adhering to a heart healthy diet, regular exercise, avoidance of tobacco products and maintenance of a healthy weight is the most important factors in ASCVD risk reductions in addition to drugs in the control of blood cholesterol [3].

Based on the trials, the Expert Panel defined the intensity of statin therapy on the basis of the average expected LDL-C reduction than the absolute values of LDL-C or goals. Consequently, the Panel has recommended the use of "High Intensity", "Moderate Intensity" and "Lower intensity" statin therapy for various groups of patients. The details are as follows.

1. High Intensity Statin Therapy. Here, the daily dose of statin lowers LDL-C by approximately $\geq 50\%$. This is achieved with atorvastatin 40 - 80 mg or Rosuvastatin 20 - 40 mg.

2. Moderate Intensity Statin Therapy. Here, the daily dose lowers LDL-C by approximately 30 - 50%. This is achieved by Atorvastatin 10 - 20 mg, Rosuvastatin 5 - 10 mg, Simvastatin 20 - 40 mg, Pravastatin 40 -80 mg, Lovastatin 40 mg or Pitavastatin 2 - 4 mg.

3. Low Intensity Statin Therapy. Here, the LDL-C lowering is approximately $\leq 30\%$. It may be achieved with Simvastatin 10 mg, Pravastatin 10 - 20 mg, Lovastatin 20 mg or Pitavastatin 1 mg.

In the recommendations regarding the initiation or continuation of statin therapy, two groups of individuals were not included. They are (1) Individuals with NYHA class II-IV heart failure and (2) Individuals undergoing maintenance hemodialysis. This recommendation is in contrast to the ATP III guidelines. This was because of the lack of sufficient information from clinical trials to base recommendations for or against statin treatments. It is also recommended that individuals receiving statins should be counseled on healthy lifestyle habits and also be evaluated for new-onset diabetes according to the current diabetes screening guidelines [4]. Statins are also contraindicated in pregnancy and should not be used in women of childbearing potential unless these women are using effective contraception and are not nursing.

The present guideline is different from the ATP III guideline of 2002 in many aspects. [5]. Whereas the ATP III guideline advised the use of multiple medications to reduce LDL-C below a target level, the present guideline recommends the use of statin alone in patients between the age of 40 and 75 years with a 7.5% or higher 10-year risk of ASCVD. Whereas in the previous ATP III guideline, a baseline LDL-C level of ≥ 130 mg/dL and a 10-year cardiovascular risk of 10 - 20% were candidates for drug therapy, in the present guideline a baseline LDL-C level of 190 mg/dL would require addition of drug therapy (statin). The ATP III guideline suggested the use of statins in patients on hemodialysis whereas the present guideline discourages the routine use of statin in patients undergoing hemodialysis. Liberal use of add-on agents were recommended in ATP III guidelines for lowering LDL-C level whereas the present guideline relegates the use of drugs other than statins to the non-preferred therapy.

Deficiencies in the present guideline

There have been criticisms about the present guidelines and a few deficiencies have been pointed out by critics. It is worth noting these too in the context of the present guidelines. A few of the deficiencies noted are as follows:

1. The present guidelines do not offer guidelines on the management of increased Triglycerides or the management of low HDL-C levels along with an increase of blood cholesterol levels.

2. The use of high intensity statins in the age group > 75 years has not been addressed due to the lack of adequate controlled clinical trials.

3. It has been criticized that the Cardiovascular Risk estimate based on the 2013 publication over estimates the cardiovascular risk in individuals and hence may lead to unnecessary statin therapy in some groups of individuals.

4. The subject of Primary prevention of ASCVD in individuals > 75 years has also not been addressed in this recommendation.

5. Alternate treatment strategies for ASCVD risk reduction in those not tolerant to statins have not been adequately recommended in this guideline.

Only time will tell whether these guidelines will be of benefit to the population at large who are at risk of developing ASCVD and whether the criticisms regarding these guidelines will be adequately addressed in days to come.

References

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