

Special Article

**New American guidelines for cholesterol treatment: what changes?
Introduction-Considerations for calculating cardiovascular risk****Ioannis Kyriazis, M.D, Ph.D , FNSCOPE,**

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Correspondence: Saridi Maria, Sina 33 str. Korinthos, Greece, email:sarmar32@windowlive.com**Abstract****Introduction:** The changes proposed by the new American guidelines for the management of high cholesterol is very important and if implemented will have many implications.**Aim:** The aim of the present study is to draw the attention to all health care professionals for the latest American guidelines for cholesterol treatment.**Methods:** Extensive literature search in the electronic database "Pubmed", and the website of the American College of Cardiologists and the new guidelines about the above subject. The articles that were reviewed was of the last two years.**Results:** The concern of many scientific and national medical societies casts doubt on the massive application. Caution is needed in primary prevention (overestimation of CV risk leading to massive unproven helpful administration of statins), in without exception administration of statins to all people with diabetes and to the exclusion of virtually all other therapeutic strategies with also degradation of any dietary intervention. The positive side of this guidance is to ascertain the need for 'aggressive' statin administration strong in people with cardiovascular disease and regardless of whether the starting values.**Conclusions:** The changes proposed by the new American guidelines for the management of high cholesterol is very important and if implemented will have many implications.**Key Words:** cholesterol treatment, statins, cardiovascular disease, cardiovascular risk**Introduction**

The atherosclerotic cardiovascular disease is the most important public health problem, both in Europe and worldwide. It is, also, a particular financial problem for all health systems. The attempt of achieving a common strategy to treat high cholesterol levels includes the incorporation of new scientific data and the classification of it into practical guidelines for clinicians, something that represents the work of several scientific committees around the world (Reiner, 2013).

Any change in guidelines could have significant effects in the treatment of the disease, especially if it has significant differences compared with the past (De Backer et al, 2013)..

On the other hand, numerous guidelines that are flooding the international literature often create confusion and are useless in clinical practice. The American Heart Association and the American College of Cardiologists (AHA / ACC) recently (2013) updated the guidelines for both the assessment of cardiovascular risk and for the treatment of dyslipidemia (Stone et al 2014).

These guidelines propose significant changes that could lead to a complete change of therapeutic strategies. These new guidelines are based, among others, in a different calculation of cardiovascular risk compared to the recent practice (Goff et al 2013).

The new approach to the assessment of cardiovascular risk (CVR) (new equations) emphasizes on the total atherosclerotic

cardiovascular disease (ASCVD) and includes coronary disease and stroke as well. It includes all the episodes and not only the fatal.

There are also different estimated limits (with different equations) for both blacks and whites and other subgroups (eg Hispanic). Finally, the new approach includes different equations for calculating the risk for women. With the new estimation of the CVR, doctors can further assess the entire life risk and not only the risk of a 10 year period.

The new equations for calculating the risk do not nevertheless seem to lead to significantly better predictive ability compared with older models (such as with the equations based on the data of Framingham Study). The new equations proposed with the new guidelines for treatment of high cholesterol levels, incorporate exactly the same risk factors with before, and seem to lead to inaccurate assessment of the cardiovascular risk, especially in certain population groups, such as young people with a highly increased risk factor for cardiovascular disease (Nordestgaard et al 2013).

In general, there seems to be an overestimation of the risk to these equations when applied to real, modern populations although the magnitude of the overestimation remains unclear. The estimated total risk for CVD is considered when deciding the treatment of cholesterol in the new guidelines, too. As a result, the overestimation of the risk could result in abuse of statin treatment.

Basic principles of the treatment of high cholesterol levels

The new American guidelines, define four high-risk groups that benefit from statin treatment. These groups are:

1. Patients with pre-existing atherosclerotic cardiovascular disease
2. Individuals with LDL-C levels ≥ 190 mg / dl,
3. Patients 40-75 years old with diabetes, LDL-C levels between 70 - 189 mg / dl, without cardiovascular disease (primary prevention), and finally,
4. Those aged 40-75 without cardiovascular disease (primary prevention), LDL-C levels between 70-189 mg / dl and calculated risk with

the new equations greater than 7.5% for the next 10 years (this group is the most controversial in the accuracy of the calculation of the CVR).

The new guidelines do not define a specific therapeutic target, considering that this is arbitrary and not based on sufficient scientific evidence. On the other side, statin treatment is based only on the individual characteristics of each patient (high or medium intensity).

Considerations-Review for the changes proposed

If the new guidelines are accepted, indeed, the treatment of high cholesterol levels compared to the one based on the 2011 guidelines of the European Society of Cardiology and the European Society of Atherosclerosis (Reiner et al 2011), results in the following significant changes:

1. The therapeutic approach is practically focused ONLY on statins, especially on powerful statins, in relatively high doses for most patients (Ridker & Cook 2013).
2. There is no need for defining particular therapeutic target for LDL-C. On the other side, a strategy of medium or high intensity treatment is proposed, in order to reduce cholesterol levels 30-50% or $> 50\%$ respectively. Such a strategy will create confusion to many doctors and will reduce the likelihood of patient's compliance, because it would prevent him from having important self motivation.
3. The absence of a therapeutic target in patients in very high cardiovascular risk, discourages clinicians from the assessment of residual cardiovascular risk and individualized approach to assessing the need for additional treatment (eg fibrates, omega-3 fatty acids, ezetimibe, colesvelam, etc.)
4. The reduction of the threshold for primary prevention intervention, could lead to the need of massively statin prescription which may be useful in younger patients, but meaningless and harmful to elderly patients. The estimated cardiovascular risk in the vast majority of men > 65 years is $> 7.5\%$, something that leads to the need for mass administration of statins in the elderly. There is no sufficient evidence of such a strategy.

5. The equation for calculating cardiovascular risk questions the accuracy of the calculation and the reliability, especially in a number of different populations. This should be re-evaluated before being used en masse.

6. The increasing elimination of the value of non-pharmacological means to reduce cholesterol levels leads to a general difficulty of compliance with lifestyle changes, that are very important for the reduction of cardiovascular risk.

7. The new guidelines recommend statin therapy for all people with diabetes over the age of 40 years. Not every patient with diabetes is at high cardiovascular risk (compared to those with established cardiovascular disease), so a most patient-centered and individualized approach to therapy should be established. The American Diabetes Association suggests statin therapy in people with diabetes without a history of cardiovascular disease when the LDL-C remains > 100 mg% despite lifestyle changes, or at the presence of at least one risk factor (hypertension, smoking, microalbuminuria, family history of cardiovascular disease).

8. Finally, the new American guidelines, do not provide recommendations for additional methods of determining cardiovascular risk (such as the scores of calcium in the coronary arteries) that could lead to more individualized therapeutic interventions.

Conclusion

The changes proposed by the new American guidelines for the management of high cholesterol is very important and if implemented will have many implications. The concern of many scientific and national medical societies casts doubt on the massive application. Caution is needed in primary prevention (overestimation of CV risk leading to massive unproven helpful administration of statins), in without exception administration of statins to all people with diabetes and to the exclusion of virtually all other therapeutic strategies with also degradation of any dietary intervention. The positive side of this guidance is to ascertain the need for 'aggressive' statin administration strong in people with cardiovascular disease and regardless of whether the starting values.

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