

New USA recommendation for cardiovascular prevention

Ceska R.*

Author:

Richard Ceska, MD, PhD, FACP, FEFIM

President of the Czech Society of Internal Medicine

Chair of the **International Atherosclerosis Society (IAS)** Regional Federation for Europe

In November 2013, immediately before the *American Heart Association (AHA)* Meeting in Dallas, joint recommendations of *AHA* and *American College of Cardiology (ACC)* were presented. The *National Institute of Health (NIH)* also took a crucial part in preparation of the new guidelines. The new recommendations excited the public's interest even before the *AHA* meeting, were controversially and extensively discussed in the press (including newspapers such as the *New York Times*), and became the main topic of the meeting.

New recommendations for cardiovascular prevention are actually a composite of four documents:

- Recommendations for the treatment of obesity and overweight (this is the first time that obesity and overweight are perceived as a disease requiring treatment and are directly incorporated into cardiovascular prevention).
- Recommendations for a healthy lifestyle, including both diet and increasing physical activity. Well-known dietary recommendations are now entrenched primarily to reduce the sodium content in the diet (at 1.5g/day) but I would argue that more attention is paid to physical activity even though 40 minutes of aerobic activity (fast walking – highly rec-

ommended) 3–4 times a week would be sufficient to reduce the cardiovascular risk for the majority of the population.

- Recommendations for the treatment of cholesterol (also including non-high density lipoprotein (HDL) cholesterol) are closely linked to the risk calculator (see below). Perhaps the most revolutionary innovation is a practical retreat omission target of treatment algorithm.

- The last, but probably the most important and indeed the latest recommendation is “recommendations for the calculation of cardiovascular risk”. This recommendation is based on a completely new risk calculator based on the latest results of population studies. In addition to traditional risk factors such as cholesterol, HDL cholesterol, hypertension, diabetes, smoking, age or sex, the riskiness of African-American origin is emphasised. The calculator calculates the risk of a cardiovascular event in the next 10 years. If the risk is 7.5% or higher the patient is “indicated” for treatment.

This criterion of 7.5% was the main source of criticism in the media, which emphasized that more than 30 million Americans may be treated unnecessarily with statins. Even some prominent American physi-

* Corresponding author. Tel: +420 224 962 94. Email: richard.ceska@vfn.cz

cians criticized the risk calculator as overestimating and indicating treatment to more patients than necessary (for example Paul Ridker, who later withdrew his opinion and supported the new recommendations). The authors of guidelines defended their approach in two ways (both of them I find rational).

1. Guidelines in the case of primary prevention and the risk calculated at 7.5% do not represent an imperative to initiate drug therapy with statins. This is the start of a dialogue between a patient and a physician. It also initiates the judgement of the individual at risk especially with regard to family issues (it was repeatedly emphasized at the Meeting as a decisive factor). Is this then the way to more personalised medicine?

2. The authors argue that in a country where a third of the population die from cardiovascular disease (CVD) and 60% will experience a cardiovascular event during their lifetime, is probably not a mistake to treat 30 million people with statins, which have such corroborative data like no other medication.

Secondary prevention, the presence of diabetes mellitus type 2 or 1 and a significant hypercholesterolemia, familial hypercholesterolemia are considered to bear an unquestionable risk.

I followed the Guidelines in printed form, in discussions in professional journals and in newspapers, especially at the *AHA* Meeting. Even the last day of the Meeting Plenary was totally crowded (several thousand participants) which indicates a great interest of doctors who discussed specific cases with guidelines. And it was interesting that even the authors of the guidelines were not dogmatic, they did not insist on a precise recommendation and tried to individualize the procedure. Does this mean that we approach personalised medicine?

New American guidelines on cardiovascular prevention are quite new. We will see how they apply in practice. Even though the American approaches are quite different from the European, we will definitely gain from the new guidelines as well.

For information, see the *European Atherosclerosis Society* (EAS) statement in Appendix 1.

Appendix 1

New guidelines in USA: "2013 ACC/AHA Guidelines on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk". How do they compare with the EAS/ESC Guidelines for the management of dyslipidaemia?

The *AHA* and *ACC* recently released three documents dealing with guidelines for the prevention of CVD: document on lifestyle management, on the as-

essment of cardiovascular risk and on "The treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults". It is welcomed that an updated version on the treatment of cholesterol is now available for the USA. In line with the document released by *EAS* and *ESC* in 2011 for the management of dyslipidaemias the *AHA/ACC* document emphasizes the importance of low density lipoprotein (LDL) cholesterol reduction in cardiovascular prevention, in both the primary and the secondary prevention of CVD. In both the European and in the *AHA/ACC* guidelines the importance of risk stratification is emphasized. In the new US document four groups are identified that could benefit from statin treatment: individuals 1) with clinical atherosclerotic cardiovascular disease (ASCVD), 2) with primary elevations of LDL cholesterol above 4.9 mmol/L (190 mg/dL), 3) with diabetes aged 40-75 with LDL cholesterol 1.8-4.9 mmol/L (70-189 mg/dL) without clinical ASCVD, 4) without clinical ASCVD or diabetes with LDL cholesterol 1.8-4.9 mmol/L and estimated 10-year ASCVD risk $\geq 7.5\%$. In the *EAS/ESC* guidelines risk stratification results in four groups of total cardiovascular risk: very high, high, moderate and low risk. Prevention is adapted according to the total cardiovascular risk estimation. In the European guidelines it is recommended to consider drug treatment of LDL cholesterol in the setting of primary prevention when total cardiovascular risk is high, or very high and/or in those with a moderate risk if LDL cholesterol ≥ 100 mg/dL despite lifestyle changes. In the new *ACC/AHA* guidelines statin treatment is recommended for primary prevention in subjects with a risk of ASCVD event of 7.5%, irrespective of LDL cholesterol level, which would correspond to a 2.5% risk for CVD death in 10 years according to the Systematic COronary Risk Evaluation (SCORE) model. **The impact of the ACC/AHA strategy should be put into the perspective of a much larger number of subjects in the population that would be eligible for lifelong statin treatment from the age of 40 years onwards.** The potential side effects should be considered, if such a large fraction of the population is put on statin treatment.

In the *ACC/AHA* guidelines the use of a new risk estimation model is recommended for estimating the total CVD risk (Pool cohorts' equations) has been developed. From the available documents it cannot be evaluated how this would work in relation to the European SCORE model. When using such models it is essential that the population from which the model is derived should be as similar as possible to the population that is seen by the clinicians. **For the**

Table 1. Examples of similarities and differences in drug therapy between the EAS/ESC and AHA/ACC guidelines

	Secondary prevention	Statin intolerance in secondary prevention	Primary prevention LDL>4.9 mmol/L	Primary prevention in diabetes	Primary prevention High risk
EAS/ ESC	Target LDL cholesterol<1.8 mmol/L OR at least 50% reduction. If target cannot be reached with statin, drug combination may be considered	Reduce statin dose, consider combination therapy	Target LDL cholesterol<2.5 mmol/L. If target cannot be reached maximal reduction of LDL cholesterol, using appropriate drug combinations in tolerated doses	<u>Diabetes with other risk factors or organ damage:</u> Target LDL cholesterol<1.8 mmol/L or at least 50% reduction. <u>Uncomplicated diabetes:</u> Target LDL 2.5 mmol/L	<u>SCORE</u> ≥5% risk of fatal CVD; Target 2.5 mmol/L
AHA/ACC	High-intensity statin. If 50% reduction is not reached drug combination may be considered.	Moderate or low dose statin, consider combination therapy.	High-intensity statin therapy, at least 50% reduction of LDL cholesterol, if not 50% reduction consider additional therapy	<u>Diabetes with high risk:</u> High-intensity statin therapy. <u>Diabetes with low risk:</u> Moderate intense statin	<u>Total risk for CVD event >7.5%:</u> Moderate to high intensity statin therapy. <u>Risk 5–7.5% risk of CVD event:</u> moderate intense statin therapy

European population we therefore prefer to continue using the SCORE charts or national charts calibrated on SCORE.

The approach to the treatment of the risk groups is in the ACC/AHA guidelines only identified as two options: high intensity or moderate intensity statin treatment (the final choice of strategy is often left to the doctor's clinical judgment). No treatment goals in mmol/L of LDL cholesterol are suggested, although the option of having treatment goals is accepted. It can certainly be argued that treatment goals are arbitrary and often based on extrapolations from available data, but also on an evaluation of a larger pool of knowledge and science in the field. Treatment goals are widely used in different clinical settings, such as for the treatment of hypertension or type 2 diabetes. Targets are in daily practice most important in working with patient to doctor communications and optimizing compliance. **Furthermore risk reduction in general should be individualized for each patient, and this can be more appropriate if targets are defined. The simplistic approach of limiting the current knowledge on cardiovascular prevention only to criteria used in randomized controlled trials may limit the exploitation of the potential that is available for CVD prevention when a wider scientific basis is taken into account.**

In monitoring statin therapy the ACC/AHA guidelines suggest that an expected 50% reduction of LDL cholesterol on intense statin treatment should be used as an adherence control; in high risk patients this may also be a reason to increase dose or consider additional therapy. This is left to the doctors' clinical judgment. **Also in the EAS/ESC guidelines a 50% reduction from baseline level target is suggested as**

an optional target in those at very high total risk if the LDL cholesterol target of <1.8 mmol/L (70 mg/dL) cannot be reached.

When comparing these guidelines it should be considered that the EAS/ESC guidelines had a broader approach on dyslipidaemia in general, while the ACC/AHA guidelines have is focused on statin treatment in cardiovascular prevention. Therefore, in the EAS/ESC guidelines, special groups such as familial hypercholesterolemia, stroke patients, combined hyperlipidaemia and diabetes are discussed more in detail. The EAS/ESC guidelines also include a more in depth discussion and options on other drug treatments than statins.

The European guidelines have worked well in Europe, they have been widely accepted and adopted, and based on the discussion above we recommend the EAS/ESC guidelines as best fitted for Europe. There are differences in approaches to cholesterol lowering between the guidelines, which however should not obscure the common ground in emphasizing the importance of LDL cholesterol lowering in cardiovascular prevention and a very similar view on which high risk groups that should be the target for drug treatment. Examples of similarities and differences in drug therapy between the two guidelines are given in table 1.

References

- Goff DC Jr, Lloyd-Jones DM, Bennett G, et al. 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013 Nov 12. [Epub ahead of print].