

Has NICE got its statins appraisal right?



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On 20 June 2005, the National Institute for Health and Clinical Excellence (NICE) published its first appraisal consultation document (ACD; NICE, 2005), *Statins for the Prevention of Coronary Events*. In summary, NICE is recommending that access to the statin class of treatments be expanded in the UK. It also concludes that statins are both valuable and cost-effective and should be used for the primary and secondary prevention of cardiovascular events in the UK population.

Although I welcome increased access to statins, a number of concerns have been raised about the document's content, particularly with regard to its recommendations on the treatment of patients with type 2 diabetes.

The ACD's preliminary recommendation that statins should be used in adults with clinical evidence of coronary heart disease (CHD) rather than cardiovascular disease (CVD) has raised significant concern. This concern is due to the existence of substantial clinical evidence to support the benefit of statin treatment in patients with existing CVD and not just CHD (Sever et al, 2003), and in people with diabetes (Colhoun et al, 2004) who have been exposed to CV risk factors for a long time prior to diagnosis.

Although the ACD states that people with type 2 diabetes have a higher absolute risk of CHD than people without diabetes, NICE does not accept that the relative effect of statin therapy in lowering cholesterol is greater in people with diabetes. Perhaps most surprising, though, is the recommendation that the decision to initiate statin therapy should be assessed using an appropriate CHD risk calculator, as this actually conflicts with both current guidelines and clinical evidence in this area, which focus on addressing CV risk.

Guidelines

Current guidelines issued by the British Hypertension Society (BHS; Williams et al, 2004) and the forthcoming guidelines from the Joint British Societies regard the risk of a

CV event in patients with type 2 diabetes as equivalent to that in somebody who has established CHD. Indeed, the risk calculators contained in the above guidelines (Williams et al, 2004; BHS, 2005) do not even include diabetes, as this condition is considered alongside several others, such as existing CHD and other major atherosclerotic diseases, to already place the individual at a high risk of a CV event. And we may, in fact, be underestimating the risk in people with diabetes, especially in certain sub-groups, such as South Asian people.

Clinical evidence

As well as guidelines, current evidence also suggests that the risk of death from a CV event in people with type 2 diabetes is as high as that of patients with diabetes who have had a previous myocardial infarction (Haffner et al, 1998). This elevated CV risk may exist prior to clinical diagnosis of type 2 diabetes (Hu et al, 2002). Such data provide a compelling argument for aggressive management of CV risk factors, such as hypercholesterolaemia, in people either with diabetes or at risk of diabetes. Ideally, we should be treating people with diabetes the way we would in secondary prevention.

Most recently, the Collaborative Atorvastatin Diabetes Study (CARDS) showed that treatment with atorvastatin 10 mg reduced CV events by 37% and cut the incidence of stroke by 48% in people with diabetes, no history of vascular disease and relatively low cholesterol levels (Colhoun et al, 2004).

The future

The ACD serves as the first draft of NICE recommendations for this technology appraisal. The final recommendations will be included in the *Final Appraisal Determination* document, which will be issued after the third meeting of the Appraisal Committee. This document is not expected to be published until November 2005. ■