MEDICAL UPDATES

EGYPHAR

Issue No.: 17 April 2014

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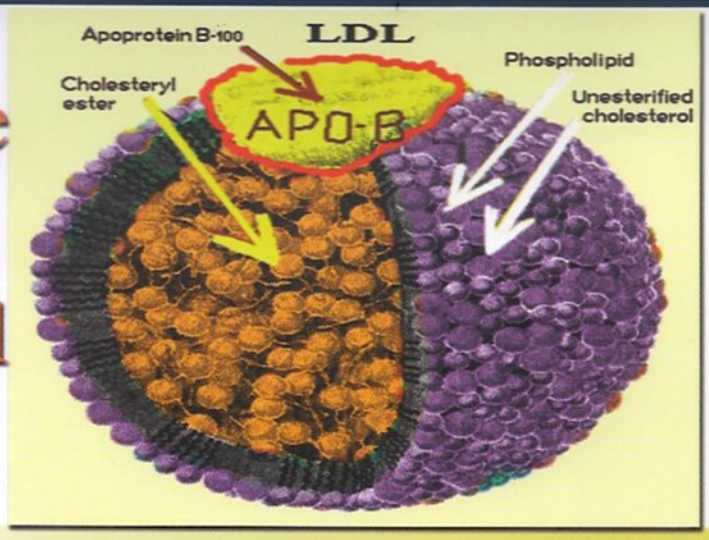

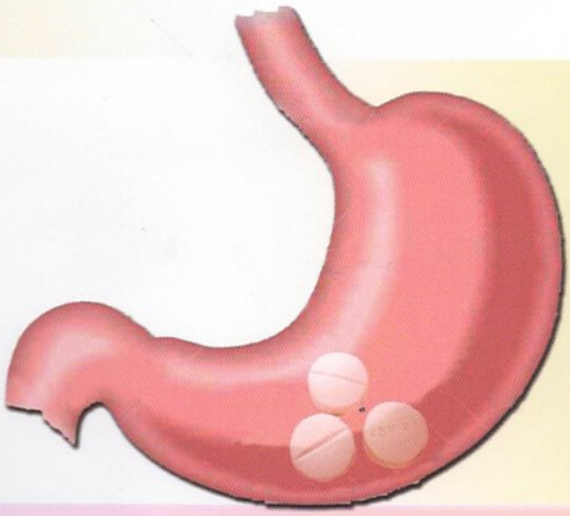

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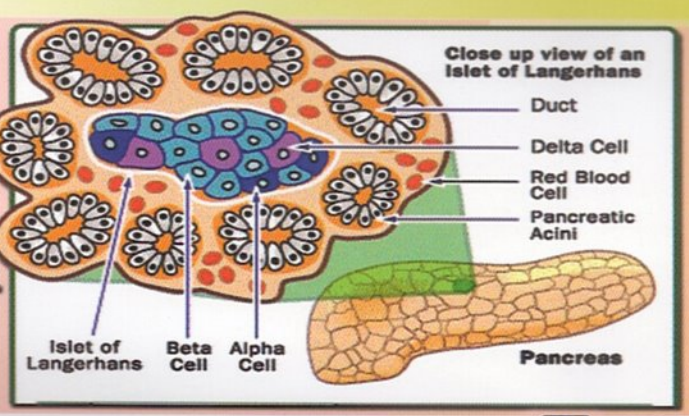


NICE National Institute for Health and Care Excellence

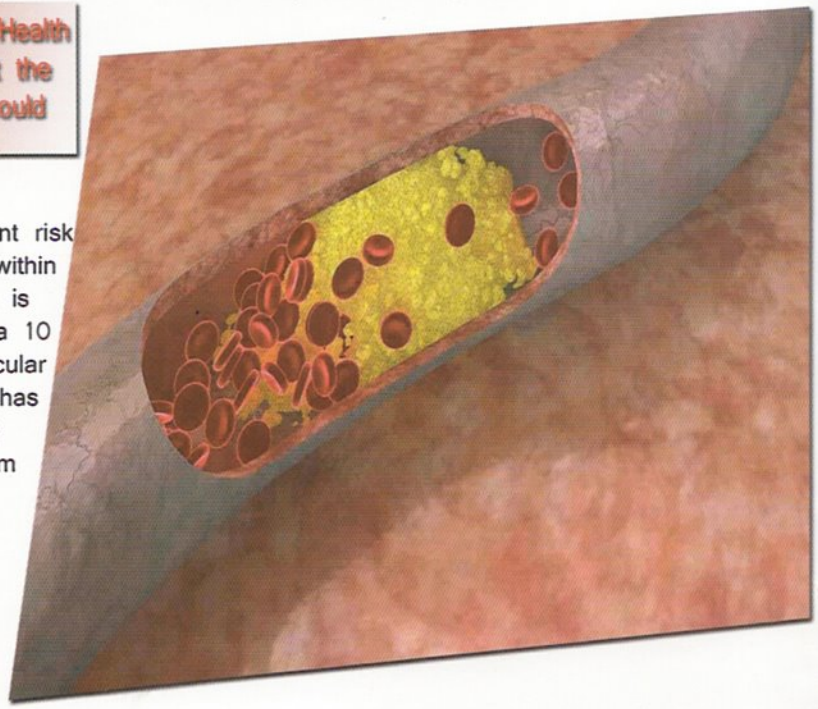
'Millions' more to be prescribed statins to beat high cholesterol

Jane Kirby

Nice cuts threshold for when doctors should consider the drugs in half

Millions more people in the UK could be prescribed cholesterol-lowering statins in a bid to prevent more cases of heart disease, heartattacks and strokes. In draftguidance to the NHS, which is subject to consultation, the National Institute for Health and Care Excellence (Nice) has cut the threshold in half for when doctors should consider prescribing the drugs.

Statins are taken by as many as seven million people in the UK but this could rise dramatically with experts predicting as many as five million more may have them prescribed.



At present, people with a 20 per cent risk of developing cardiovascular disease within 10 years are offered statins, but this is being cut to include all people with a 10 per cent risk of developing cardiovascular disease within 10 years. While Nice has yet to start work on how many extra people this could affect, evidence from Oxford University researchers shows millions more could take the drugs.

A 2012 Oxford University study, published in The Lancet medical journal, showed that even very low-risk patients benefited from statins.

Rory Collins, professor of medicine at Oxford University, worked on the research and said the number of people who could begin taking statins as a result of the new Nice guidance "would be in the the order" of around five million. He added: "The evidence is very strong that the treatment is cost-effective at these lower levels. Doctors are now in a position to offer statins on this basis." He said it was up to individual patients to decide whether they wanted to take statins, based on their risk assessment, but Nice's strategy would "reduce the burden on the health service". He went on: "People say you are medicalising the population by recommending statin use at these lower levels.

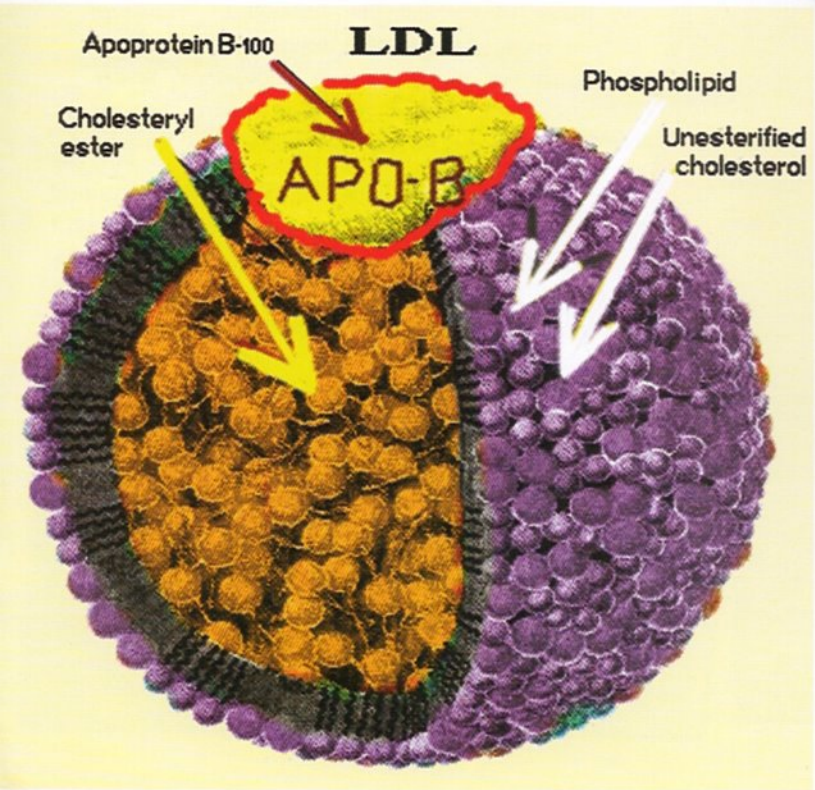
"That's complete nonsense. This remains a choice for the patient, it's not mandatory." He said doctors and patients could work together to understand how much benefit an individual patient would receive from statins. "If they are at high risk then doctors will be saying to patients they will get a big benefit, but at lower levels the benefits will be smaller and the patient has the choice," he said. "Before, if the patient had lower levels of risk - despite it being cost-effective for them to get the treatment - they would not have had that choice.

Professor Colin Baigent, from the Oxford University team, calculated that lowering the threshold to a 10 per cent risk - as Nice now proposes - would lead to around five million more people in the UK taking the drugs. This in turn would save 2,000 lives and prevent 10,000 heart attacks or strokes every year, he said.

Another reason behind Nice's new recommendation is that the price of statins has dropped considerably in recent years to just a few pence per pill. Statins are a group of medicines that help lower rates of low-density lipoprotein (LDL) cholesterol - so called "bad cholesterol" - in the blood. They do this by cutting production of LDL cholesterol inside the liver. High-rates of LDL cholesterol are linked to hardening and narrowing of the arteries, which can cause heart disease, heart attacks and stroke. People can lower their risk naturally by eating a healthy diet, low in saturated fats, and increasing the amount of omega 3 fatty acids in their diet.

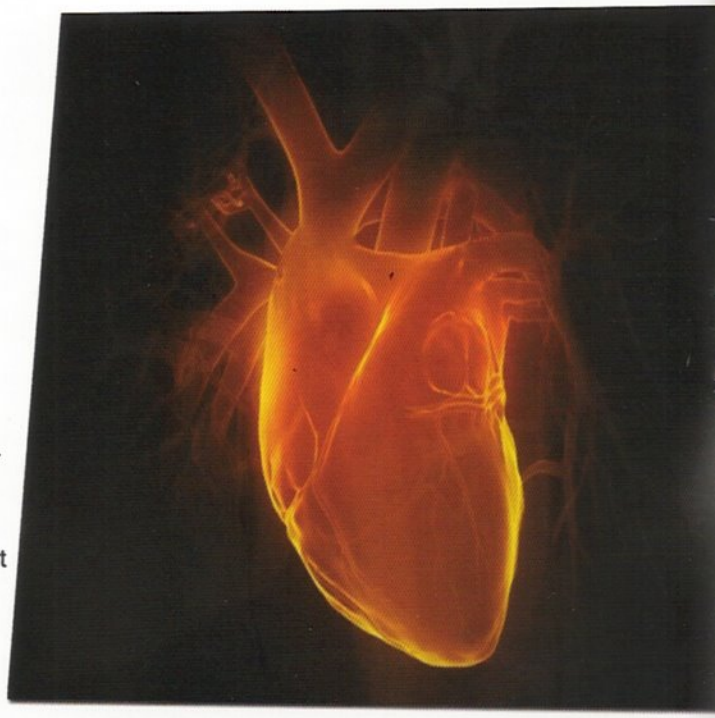
The new Nice guidance says doctors should encourage at-risk patients to stop smoking, cut down on alcohol, take exercise and eat a healthy diet.

Once these factors have been addressed, high intensity statin therapy should be offered to patients.

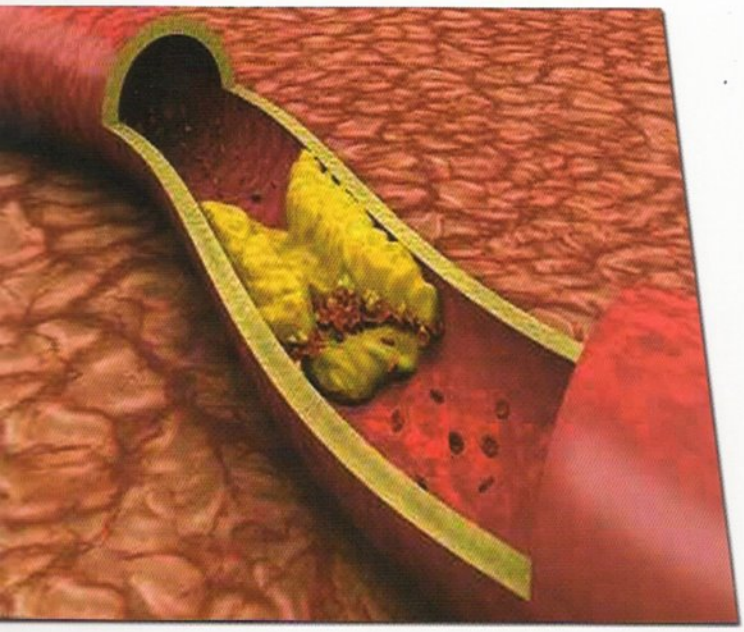


Accord to Nice, as many as seven million people in the UK are on statins, at an estimated annual ncost of £450 million. Professor Mark Baker, director of the centre for clinical practice at Nice, said: "People should be encouraged to address any lifestyle factors such as smoking, drinking too much or eating unhealthily. We also recommend that statins are now offered to many more people - the effectiveness of these medicines is nowwell proven and their cost has fallen."

Prof Baker said as well as taking statins, people with raised cholesterol levels and high blood pressure should reduce the amount of foods containing saturated fat they eat, such as meat, cheese and milk. He said they should exercise more, stop smoking and control their blood glucose levels by reducing their intake of sugar and by losing weight.



According to the NHS, minor side effects of statins include an upset stomach, headache or insomnia. More serious side effects are rare but include kidney failure. Professor Peter Weissberg, medical director at the British Heart Foundation, said: "Reducing your cholesterol level, whether that's through medication or lifestyle changes, will reduce your risk of cardiovascular disease.



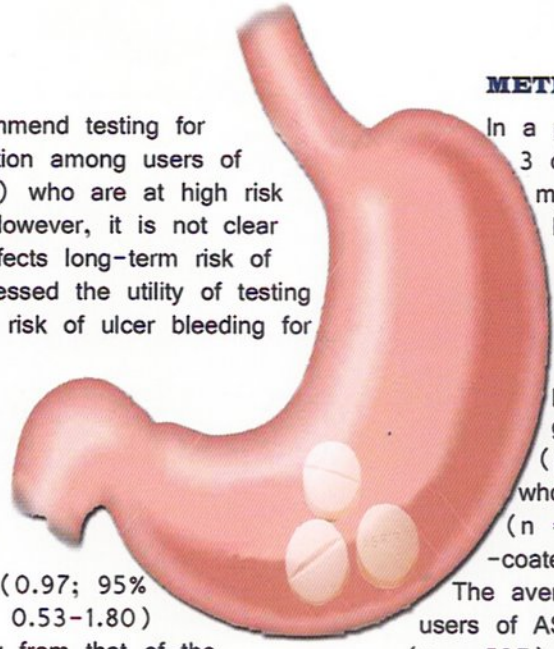
"The current guidance weighed the benefits of taking a statin against what was then the considerable cost to the health service. This pragmatic decision made sure that those of highest risk benefited. "However, as most people who have a heart attack or stroke have average cholesterol levels and since statins are now much cheaper it makes sense to reconsider the threshold."

A 2012 study from the British Heart Foundation found that 36 per cent of people were failing to take their statins. Some 28 per cent said they stopped because their symptoms had vanished while 23% said they had suffered side-effects. Cardiovascular disease is the leading cause of death in England and Wales. In 2010, one in three people died from it. The NHS estimates that statins save 7,000 lives a year in the UK.

Effects of Helicobacter pylori infection on long-term risk of peptic ulcer bleeding in low-dose aspirin users.

· Institute of Digestive Disease, Chinese University of Hong Kong.

Chan FK1, Ching JY, Suen BY, Tse YK, Wu JC,



BACKGROUND & AIMS:

Current guidelines recommend testing for Helicobacter pylori infection among users of low-dose aspirin (ASA) who are at high risk for developing ulcers. However, it is not clear whether this strategy affects long-term risk of ulcer bleeding. We assessed the utility of testing ASA users with a high risk of ulcer bleeding for H pylori infection.

METHODS:

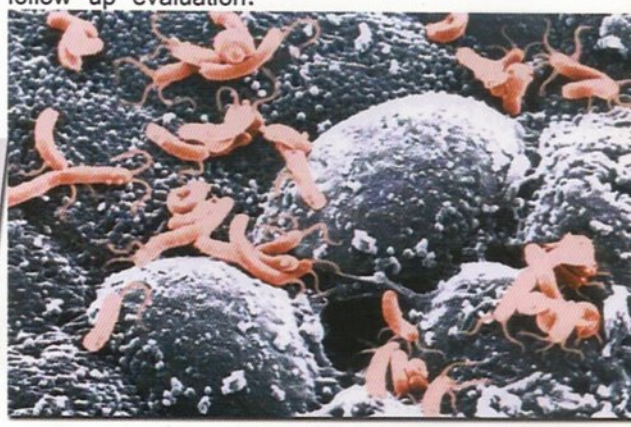
In a prospective study, we recruited 3 cohorts of ASA users (≤160 mg/day). The first group included H pylori positive users of ASAs with bleeding ulcers in whom the infections were eradicated (n = 249). They resumed ASA after ulcer healing and H pylori eradication. The second group included H pylori negative (past and present) users of ASA who developed bleeding ulcers (n = 118). They received enteric-coated ASA after ulcer healing. The average-risk cohort included new users of ASA without a history of ulcers (n = 537). None of the subjects received regular treatment with anti-ulcer drugs. The primary end point was ulcer bleeding with ASA use in 5048 patient-years of follow-up evaluation.

RESULTS:

The incidence of ulcer bleeding (per 100 patient-years) in the H pylori eradicated cohort (0.97; 95% confidence interval [CI], 0.53-1.80) did not differ significantly from that of the average-risk cohort (0.66; 95% CI, 0.38-0.99). The H pylori negative cohort had a high incidence of recurrent bleeding (5.22; 95% CI, 3.04-8.96) (incidence rate ratio, 8.52; 95% CI, 4.29-16.95 vs the average-risk cohort).

CONCLUSIONS:

The long-term incidence of recurrent ulcer bleeding with ASA use is low after H pylori infection is eradicated. ASA users without current or past H pylori infections who develop ulcer bleeding have a high risk of recurrent bleeding. Tests for H pylori infection can be used to assign high-risk ASA users to groups that require different gastroprotective strategies.



Diabetes Obes Metab. 2012 Jan;14

Managing diabetes with gliclazide mr: A matter of numbers.

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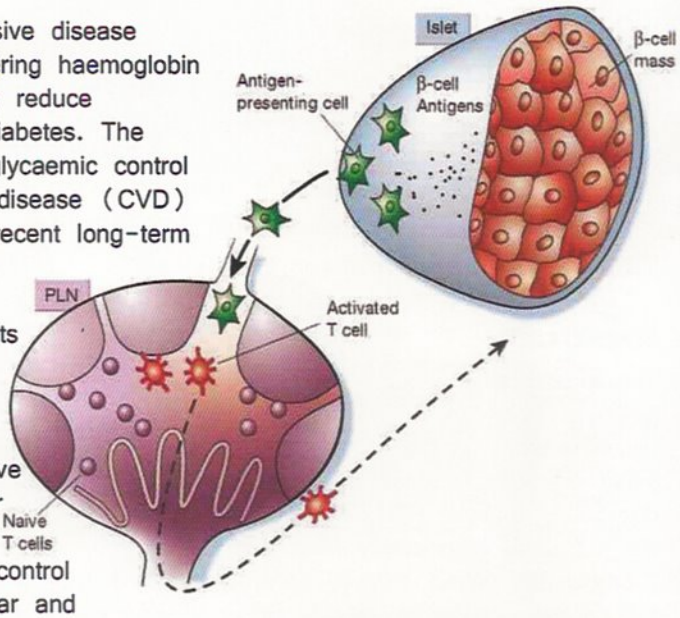
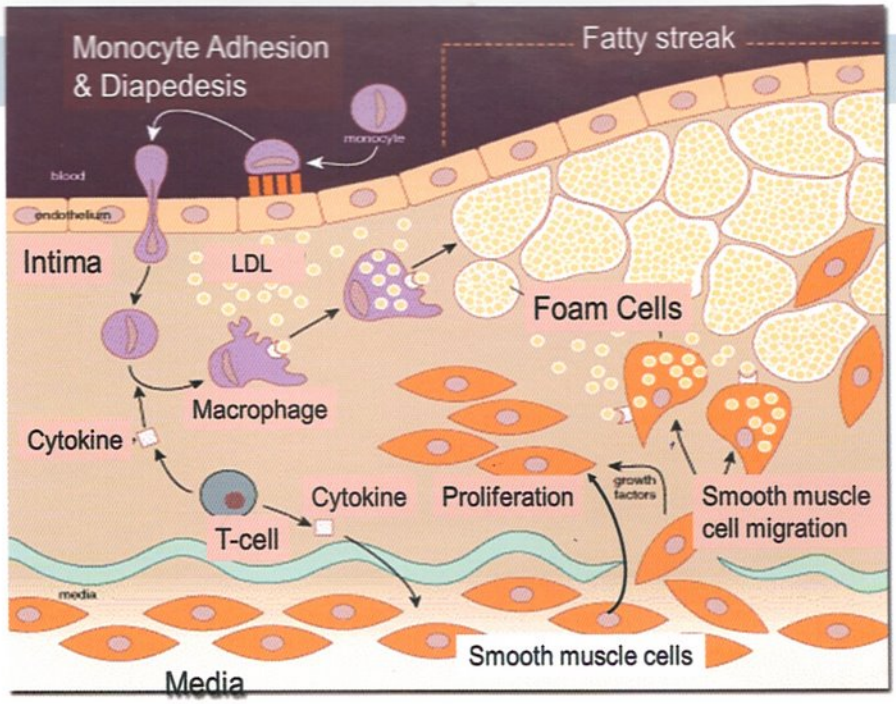
Avogaro A.

Abstract

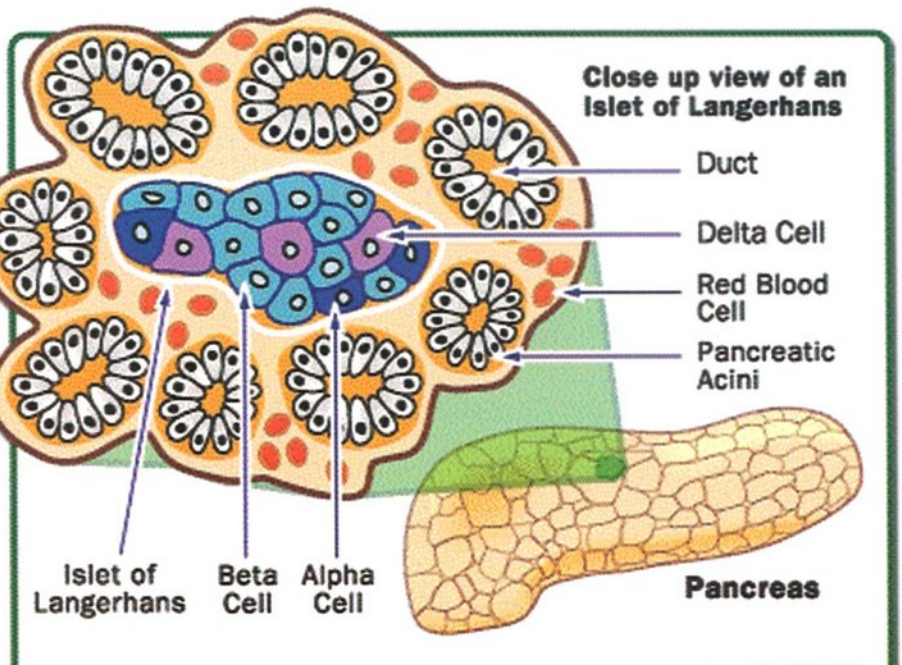
Type 2 diabetes mellitus (T2DM) is a progressive disease characterized by worsening hyperglycaemia. Lowering haemoglobin A1c to below or around 7% has been shown to reduce microvascular and neuropathic complications of diabetes. The ongoing uncertainty regarding whether intensive glycaemic control can reduce the increased risk of cardiovascular disease (CVD) in people with T2DM stirred the launch of the recent long-term megatrials. These trials compared the effects of intensive vs. standard control on vascular complications in relatively high CV risk participants with T2DM. While in Veterans Affairs Diabetes Trial and Action to Control Cardiovascular Risk in Diabetes, the effect of glucose optimization resulted either in no protection or in an excessive CVD death, the Action in Diabetes and Vascular Disease: Gliclazide Modified Release Controlled Evaluation trial showed that intensive glycaemic control reduced the risk of combined major macrovascular and microvascular events. In this trial, the glucose control strategy was based on gliclazide MR at randomization in all patients and then further sequential addition of other glucose-lowering drugs. Several studies showed that



gliclazide has antioxidant properties, reduces markers of endothelial inflammation, and prevents glucose-induced apoptosis of endothelial cells. These positive antioxidant effects are not confined to the vascular wall but they are effective also in the β cells. These properties are important because



(i) in patients with atherosclerotic process, microvascular abnormalities may hasten disease progression and
(ii) slowing the microvascular complications may have a potentially remarkable effect on the natural history of macrovascular disease.



Diabetes Res Clin Pract. 2010 Aug

The efficacy of lowering HbA1c with a gliclazide mr

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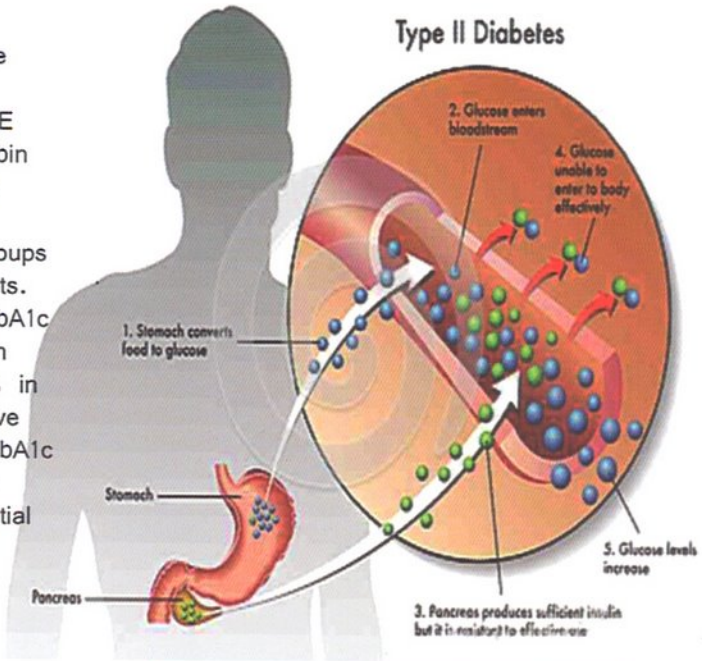
Zoungas S1, et al

Abstract

The aim of these analyses was to examine the efficacy of the intensive gliclazide MR-based glucose lowering regimen used in the ADVANCE trial in lowering the level of glycated haemoglobin (HbA1c). All 11,140 randomised patients were included in analyses of treatment efficacy. Treatment efficacy was also examined in subgroups defined by baseline characteristics and treatments. At the end of 5 years follow-up, the mean HbA1c was reduced from 7.5% at baseline to 6.5% in those on intensive glucose control and to 7.3% in those on standard glucose control. With intensive glucose lowering greater proportions achieved HbA1c levels of < or =7.0%, < or =6.5% and < or =6.0%. With intensive glucose lowering substantial reductions in HbA1c were observed across subgroups defined by baseline age, sex, duration of diabetes, BMI, HbA1c or treatment regimen (p<0.0001). The main independent predictors of reduction in HbA1c during follow-up were baseline HbA1c, duration of diabetes and BMI. There was no weight gain in the intensive glucose control group and severe hypoglycaemia was uncommon, though more frequent than in the standard control group.



Intensive glucose control with a gliclazide MR-based regimen was well tolerated and consistently effective in lowering HbA1c across a broad range of patient with type 2 diabetes.