News

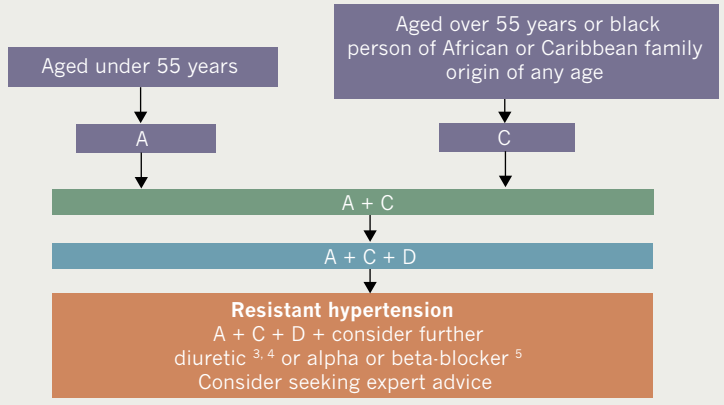
Changes to hypertension guidelines

The National Institute for Health and Clinical Excellence (NICE) has updated its guideline on hypertension, making a number of new recommendations regarding both the diagnosis and treatment of the condition. The new clinical guideline 127 updates and replaces clinical guideline 34, which was published in June 2006.

Key new recommendations include the following:

- Diagnosis of primary hypertension should be confirmed using 24–hour ambulatory blood pressure monitoring, or home blood pressure monitoring, rather than be based solely on measurements of blood pressure taken in the clinic. This is to reduce the occurrence of white coat hypertension, which recent studies have suggested is causing the misdiagnosis of hypertension in up to a quarter of the 12 million patients currently labeled with the condition.
- For the treatment of hypertension, the guideline now recommends that calcium channel blockers (CCBs) should be the first choice of agent used in patients aged over 55 years and to black people of any age. If a CCB is not suitable, for example, because of oedema or intolerance, or if there is evidence or high risk of heart failure, thiazide-like diuretics, such as chlortalidone or indapamide, are recommended in preference to a conventional thiazide diuretic such as bendroflumethiazide or hydrochlorothiazide. For patients aged under 55, angiotensin-coverting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) remain first-line drugs, and CCBs should be added as a second-step drug.
- Patients aged 80 years should be offered the same antihypertensive drug treatment as people aged 55–80 years, taking into account any comorbidities. This is based on the HYVET study of nearly 4,000 hypertensive patients over 80 years, which found standard hypertensive treatment reduced the risk of fatal stroke by almost 40%, heart failure by 64% and all-cause mortality by around 20%.

Figure 1. A summary of antihypertensive drug treatment from the NICE BHS guidance



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Key: A = angiotensin-converting enzyme (ACE) inhibitor or low-cost angiotensin receptor blocker (ARB)[1]; C = calcium channel blocker (CCB)[2]; D = thiazide-like diuretic; BHS = British Hypertension Society

(1) Choose a low-cost ARB. (2) A CCB is preferred but consider a thiazide-like diuretic if a CCB is not tolerated or the person has oedema, evidence of heart failure or a high risk of heart failure. (3) Consider a low dose of spironolactone[4] or higher doses of a thiazide-like diuretic. (4) At the time of publication (August 2011), spironolactone did not have a UK marketing authorisation for this indication. Informed consent should be obtained and documented. (5) Consider an alpha- or beta-blocker if further diuretic therapy is not tolerated, or is contraindicated or ineffective.

The updated four-step antihypertensive drug treatment now recommended is shown in **figure 1**.

The guidance was updated by the National Clinical Guideline Centre in collaboration with the British Hypertension Society. The full guidance can be found on www.nice.org.uk/CG127

Dronedarone to be restricted

The European Medicines Agency has recommended that the anti-arrhythmic, dronedarone (Multaq®), should be restricted.

The Agency has stated that because of the increased risk of liver, lung, and cardiovascular adverse events, dronedarone, should only be prescribed after alternative treatment options have been considered. It advises that patients currently taking dronedarone should have their treatment reassessed by their physician at their next scheduled visit.

Dronedarone is currently approved for the treatment of paroxysmal or persistent atrial fibrillation or atrial flutter. The restriction is based on a review of the PALLAS trial, which was stopped early because of an increased risk of cardiovascular events among patients on dronedarone, as well as other data suggesting an increased risk of severe liver injury and lung effects.

The Committee for Medicinal Products for Human Use (CHMP) notes, however, that there are limited treatment options for patients with non-permanent atrial fibrillation, so dronedarone might still be a useful treatment option in selected patients. It says that: "the benefits of Multaq® outweigh its risks in these patients, provided that further

changes to the information for prescribers and patients will be introduced to minimise the risk of injury to the liver, lung, and heart".

It adds that dronedarone should be restricted to patients with paroxysmal or persistent atrial fibrillation when sinus rhythm is obtained and should not be used when atrial fibrillation is still present. It should not be used in permanent atrial fibrillation or in patients with heart failure or those with left ventricular systolic dysfunction. It should also not be used in patients with a previous lung or liver injury following treatment with amiodarone. Patients with non-permanent atrial fibrillation treated with dronedarone should be monitored by a specialist and have their lung, liver, and heart-rhythm function checked regularly.

Rivaroxaban reduces events in ATLAS-ACS

Bayer has announced that the oral anticoagulant, rivaroxaban, has reduced ischaemic events but increased bleeding in acute coronary syndrome (ACS) patients in the large-scale trial ATLAS-ACS 2 TIMI 51.

The company said the drug was associated with a statistically significant reduction in the primary composite end point of cardiovascular death, myocardial infarction, and stroke versus placebo. However, it was also associated with a significant increase in the primary safety end point: major bleeding events not associated with coronary artery bypass surgery.

Bayer says the results will be presented "as soon as possible at a forthcoming scientific congress," and also plans to file for market authorisation by the end of 2011.

This announcement suggests that rivaroxaban has had at least some success in the treatment of ACS, whereas another one of the new oral anticoagulants – apixaban – was discontinued in this indication after showing an unacceptable bleeding rate in the APPRAISE-2 trial.

While these agents have been successful in venous thrombosis and in the prevention of stroke in atrial fibrillation patients, their use in ACS is more difficult as they are being added onto dual antiplatelet therapy, so the bleeding risks are much higher. The big question is now whether the reduction in ischaemic events with rivaroxaban outweighs the increased bleeding risk.

European approval recommendation for AF and DVT

Separately, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has issued positive opinions for rivaroxaban for two new indications:

- the prevention of stroke and systemic embolism in nonvalvular atrial fibrillation, based on the ROCKET-AF trial
- the treatment of venous thromboembolism, deep vein thrombosis, and pulmonary embolism, based on the EINSTEIN-DVT and EINSTEIN Extension studies.

In brief

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UK cholesterol awareness low

Millions of people in the UK hold incorrect beliefs about the risks of cardiovascular disease (CVD), according to HEART UK research.

The research, which tested 1,177 people on their knowledge and concerns about high cholesterol, revealed that more than 40% of respondents wrongly thought that raised cholesterol resulted from drinking too much, while almost 60% did not know that the condition can be inherited. Almost half the population have never had a cholesterol check and only 2% of those surveyed named high cholesterol as their biggest health concern. The top health worry for people was cancer, even though CVD is still the biggest killer in the UK.

HEART UK ambassador, Dr Chris Steele, said: "Raised cholesterol isn't called the silent killer for nothing and I never cease to be amazed at how few people can be bothered to find out what their cholesterol level is. It is vital that people in the UK start to take their cholesterol level seriously."

Four of the top five foods thought to have a cholesterol-lowering effect, by members of the public, do not directly lower cholesterol at all and almost a fifth of people had no idea at all of which foods can do so.

"The results of this survey underline the challenges we continue to face about the public's misunderstanding of the condition," said HEART UK Chief Executive Jules Payne. "Younger people in particular don't think that raised cholesterol or heart disease can affect them."

Majority of patients now receive angioplasty

The majority of patients in the UK are receiving primary angioplasty rather than thrombolysis, according to figures from the tenth annual

Myocardial Ischaemia National Audit Project (MINAP) audit. In England, from April 2010 to March 2011, the number of patients receiving primary angioplasty rose from 63% to 82%, in Wales from 22% to 30%, and in Belfast from 59% to 99%, the figures showed.

Dr Clive Weston, Clinical Director of MINAP, said: "During the past decade, MINAP has documented major changes in the care provided to people who suffer heart attack. What has not changed in that time

is the commitment of individual clinicians, managers and administrators who, through their participation in MINAP, continue to promote the values of national clinical audit – to compare their performance against nationally-agreed best practice, and so to assure and enhance the quality of that care. The remarkable improvement in survival after heart attack bears testimony to their efforts".

Ticagrelor receives NICE draft recommendation

The National Institute for Health and Clinical Excellence (NICE) has recommended the use of the novel antiplatelet medicine ticagrelor (Brilique,™ AstraZeneca) by the National Health Service in England and Wales.

In its Final Appraisal Determination (FAD), NICE concludes that ticagrelor, in combination with low dose aspirin, is a cost effective treatment option in adult patients with acute coronary syndromes (ACS), which includes myocardial infarction (MI) and unstable angina.

The final step of the appraisal process is for NICE to issue the completed Technology Appraisal Guidance (TAG) later this year, should no appeals be submitted, after which time the NHS will have a three month period to implement the guidance.

Organ transplant to receive boost

A new anticoagulant solution infused into the donor organ can increase the number of viable organs for transplantation, according to a study being carried out by Imperial College under the London Renal and Transplant Centre at Hammersmith Hospital. The new technique perfuses the organ with proteins to pre-condition it, and prevent clotting.

Dr Vassilios Papalois, the consultant transplant surgeon at Hammersmith Hospital who is overseeing the project, says "We hope that we will be able to use organs that are currently considered to be not suitable for transplantation and also increase the chances of post-transplant survival and long-term function of those organs". The research is being funded by national transplant charity Live Life Then Give Life.

The Danish innovator of transcatheter aortic valve implantation (TAVI) recently found his father benefitting from his invention. Dr Henning Andersen (Consultant Cardiologist, Aarhus University Hospital, Denmark) was a pioneer in the early development of transcatheter heart valves. "When I first had the idea, TAVI was only a distant pipe dream," he said. Now his 86-year old father, Mr Jorgen R Andersen, has been successfully treated at Aarhus University Hospital for aortic stenosis, having the above Sapien XT™ (Edwards) valve implanted.

FH film launched to raise awareness

AstraZeneca has partnered with HEART UK to launch an awareness film about familial hypercholesterolaemia (FH) (available at: www.youtube.com/watch?v=jZKZseU8qvY). Jules Payne, Chief Executive of HEART UK says the charity welcomes the film. "We are concerned with the number of ticking 'time bombs' out there with undiagnosed FH. Once identified the condition is treatable."

Dabigatran accepted by SMC

Dabigatran etexilate (Pradaxa®, Boehringer Ingelheim) has been accepted for use by the Scottish Medicine Consortium (SMC) for use within NHS Scotland. The drug is licensed for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (AF) and one or more risk factors.

Professor Adrian Brady (Consultant Cardiologist, Glasgow Royal Infirmary) comments: "This decision marks a significant advance for patients and clinicians affected by AF".

Improved patient satisfaction with liraglutide

Patients who switch from oral therapy with sitagliptin to once-daily injectable therapy with liraglutide (Victoza®, Novo Nordisk) had an increase in overall treatment satisfaction, as well as further reductions in glycated haemoglobin (HbA1c) and body weight, according to data from a recent study presented at the 47th Annual Meeting of the European Association for the Study of Diabetes (EASD).

Treatment satisfaction was evaluated using the Diabetes Treatment Satisfaction Questionnaire (DTSQ) at 52 and 78 weeks to assess the impact of switching from an oral therapy to an injectable one. The once daily injectable therapy was also ranked by patients as equally convenient and flexible as the oral therapy with sitagliptin.

New annuloplasty ring approved

A new annuloplasty ring for the treatment of tricuspid heart valve insufficiency (Carpentier-Edwards Physio Tricuspid Annuloplasty Ring, Edwards Lifesciences) has been launched, having received both European Conformity (CE) Mark approval for European sales and 510(k) clearance from the US Food and Drug Administration (FDA).

The ring features a three-dimensional waveform shape, allowing it to conform to the natural shape of a patient's tricuspid annulus during valve closure, and is designed to allow the native valve to maintain its natural movement.

Prasugrel reduces CV events in ACS

Treatment with prasugrel (in combination with aspirin) was associated with a 26% reduction in relative risk of significant cardiovascular (CV) events, compared to treatment with clopidogrel, according to a new post-hoc sub-analysis of patients from the TRITON-TIMI 38 study.

The analysis focused on the study's 10,804 "core clinical cohort" of patients with acute coronary syndrome (ACS), managed with percutaneous coronary intervention (PCI), which excluded those considered to be at a higher risk for bleeding by the US Food and Drug Administration and the European Medicines Agency in their regulatory approval of prasugrel.