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ALLHAT - the Antihypertensive and Lipid Lowering treatment to prevent Heart Attack Trial

Hypertension - thiazide diuretics remain first choice

What do we know?

The benefits of antihypertensive drugs are well established but the relative merits of older drugs, e.g. thiazide diuretics, and newer drugs, e.g. ACE inhibitors or calcium antagonists, have remained a matter of debate.

The ALLHAT trial

The ALLHAT trial¹ was the largest of all antihypertensive drug trials with over 33,000 participants from 623 centres and a planned follow-up period of 4 to 8 years. Its objective was to determine which of four drugs (chlorthalidone, amlodipine, lisinopril or doxazosin) was the most effective first-line treatment in hypertension. The doxazosin arm was stopped prematurely after reported excess congestive heart failure compared with the reference drug, chlorthalidone.

Design - randomised double blind active controlled

Subjects - 33,357 hypertensives aged 55 years or older (mean 67 years) with at least one other CHD risk factor

Treatment - the drugs included in the trial were:

chlorthalidone (thiazide diuretic) 12.5-25mg daily, lisinopril 10-40mg daily and amlodipine 2.5-10mg daily. Target BP was <140/90mm Hg and achieved by titrating the allocated drug and adding other agents as necessary.

Follow-up - mean 4.9 years

Primary outcome measure - fatal CHD or non-fatal MI

Results

The primary outcome occurred in 2,956 participants, and no differences were found between the rates with the reference drug chlorthalidone (11.5%), and amlodipine (11.3%) and lisinopril (11.4%). This

equivalence was found for both sexes and in the presence or absence of diabetes. Four major secondary end points were pre-specified including all cause mortality, fatal and non-fatal stroke, combined CHD, and combined cardiovascular disease. No difference was found between chlorthalidone and amlodipine for any of these major secondary end points. No difference was found between lisinopril and chlorthalidone for all cause mortality or combined CHD but lisinopril was significantly less effective at reducing stroke and combined cardiovascular disease.

Key messages:

- The trial reaffirms current national and Lothian recommendations that a thiazide diuretic is first choice treatment for hypertension in older patients.
- The trial suggests that thiazide diuretics are first choice for both diabetic and non-diabetic patients with hypertension.
- Combinations of several drugs will be required for most patients with 63% of patients in ALLHAT requiring two or more drugs to control blood pressure to less than 140/90mm Hg.

And the trial concluded ...

Thiazide-type diuretics are superior in preventing one or more major forms of cardiovascular disease and are less expensive. They should be preferred for first-step antihypertensive therapy.



LJF recommendations:

bendroflumethiazide (bendrofluazide) first choice thiazide diuretic

Reference

1. The ALLHAT Officers and Co-ordinators for the ALLHAT Collaborative Research Group. Major outcomes in high-risk hypertensive patients randomised to angiotensin-converting enzyme inhibitor or calcium channel blocker vs diuretic: the antihypertensive and lipid lowering treatment to prevent heart attack trial (ALLHAT). JAMA 2002;288:2981-97.

New Lothian Policy:

All patients are advised to take their own medicines into hospital

Use of patients' own medicines in hospital is central to the redesign of hospital medicine supply services with the aim of making the best use of medicines across Lothian.

Traditionally nurses administer medicines to patients from a trolley, and on discharge patients are given a week's supply of medicines.

There is currently no uniform system to deal with patients' own medicines when they are admitted to hospital.

Two key targets identified in *'The Right Medicine - A Strategy for Pharmaceutical Care in Scotland'*¹ are:

- the dispensing of patient packs*
- the implementation of self-medication administration on wards

What does the redesigned system involve?

It involves patients using their own medicines which continue to be prescribed during their stay in hospital. If a patient requires a supply of a newly prescribed or continued medicine this will be dispensed as a patient pack.

Individually labelled medicines and lockable cabinets facilitate self-administration of medicines on wards, allowing patients to take their medicines as they would at home.

A clinical pharmacist or nurse reviews patients' medications on admission. When appropriate a patient's ability to take their own medicines can be assessed.

On discharge these medicines are used for the discharge prescription, avoiding additional dispensing and further delay.

**Patient packs - Manufacturer's original pack, e.g. may contain a month's supply, two months or complete course.*

Previously, patients went home with one week's supply of drugs. With the advent of patient packs, patients will increasingly have larger quantities of prescribed medicines for their own use on discharge.

What are the benefits of the redesigned system?

Benefits include:

- accurate medication histories, fewer missed doses and reduced delay on discharge
- improved communication between primary and secondary care
- reduced risk of adverse medication incidents
- patient satisfaction and improved knowledge about their medicines
- compliance with EU directive on Patient Information Leaflets
- reduced waste and inefficiencies in supply systems

This system has been piloted successfully in St John's Hospital and the Royal Infirmary of Edinburgh for over one year.

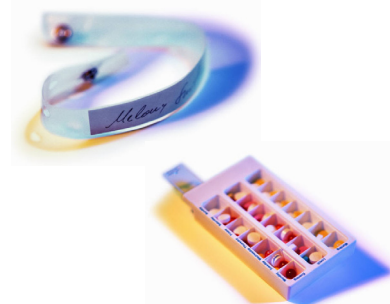
How is this being implemented across Lothian?

All three Trusts have arrangements to implement the system. The system will be in place throughout the new Royal Infirmary at Little France.

Staff have been appointed to assist with the changes. A pan-Lothian Redesign Implementation Group has ensured effective communication and consultation with all interested groups, such as Lothian Health Council, General Practitioners, the Ambulance Service, Area Professional Committees and Care Home Managers.

Key messages:

- Advise patients to bring all their own medicines with them into hospital.
- Redesigning hospital medicine supplies allows us to work towards
 - dispensing of patient packs.
 - implementation of self-medication administration schemes in hospital.



If you have any comments or questions on this process, feedback on this article would be appreciated by:
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Elaine Rankine, Pharmacy Department, Royal Edinburgh Hospital (elaine.rankine@lpct.scot.nhs.uk)

Reference:

1. Scottish Executive Health Department. The Right Medicine: A Strategy for Pharmaceutical Care in Scotland. February 2002.

New Guidance on the Use of Intravenous Potassium

Several incidents of death or serious injury have been reported in the UK following the inappropriate intravenous administration of concentrated potassium chloride solutions. They occurred when the potassium chloride solutions were inadvertently being used for reconstitution or dilution of injections, or due to inadequate mixing on addition to infusion solutions. A National Patient Safety Agency Alert, July 2002¹, set out action required by the NHS to reduce the risk of accidental overdose arising from the use of concentrated potassium solutions. As a result each Trust in Lothian has drawn up a new policy for the handling of concentrated potassium solutions. These policies state that:

- Wherever possible, intravenous potassium solutions should be prescribed in concentrations that are available from the pharmacy in ready-to-use solutions, i.e. requiring no further dilution before administration.
- Concentrated potassium solutions should only be stored in wards, theatres and other clinical areas where their use is justified, i.e. when potassium solutions urgently needed for use, and the ready-

to-use diluted solutions that are available from the pharmacy, are not appropriate concentrations.

- Concentrated potassium solutions should be stored and handled in wards, theatres and other clinical areas in the same way as controlled drugs.
- Concentrated potassium solutions should not be borrowed or transferred between wards, theatres and other clinical areas. They should always be obtained directly from the pharmacy.
- Concentrated potassium solutions should only be handled by staff who have been trained and are competent in their use.
- Infusions involving the addition of concentrated potassium solutions should be prepared using a procedure that avoids the risk of pooling and incomplete distribution, and incorporates an independent check by a second practitioner for all aspects of the preparation, set up and start of administration.

This article has been adapted from a recent LPCT Medicines Bulletin².

Key messages:

- Intravenous potassium is potentially lethal if not administered with care.
- Check your hospital policy.

References:

1. National Patient Safety Agency. Patient Safety Alert. Preventing accidental overdose of intravenous potassium. 23 July 2002.
2. LPCT Medicines Bulletin. Strong Potassium Chloride Solution Safety Alert. No.14 December 2002.

Generic Update - Significant Savings for Lothian

Four Lothian Joint Formulary (LJF) drugs are now available in generic form. These are: lisinopril, paroxetine, clotrimazole pessaries and ofloxacin. Two examples of estimated Lothian savings are listed below:

Drug	% saving when prescribed generically (at Drug Tariff price April 2003)	Current rate of generic prescribing in Lothian	Estimated annual Lothian saving
lisinopril	28%	99%	>£400,000
paroxetine	12%	98%	>£140,000

Generic omeprazole update: Generic omeprazole capsules are currently 20% lower than the proprietary price and the price continues to fall. Please note, the dispersible tablets (Losec MUPS[®]) are patent protected and are significantly more expensive than generic omeprazole capsules.

Scottish Medicines Consortium (SMC) and Lothian Formulary Committee recommendations are detailed in the enclosed supplement. We aim to provide up-to-date information via these supplements on a regular basis.

Orlistat (Xenical®) and Sibutramine (Reductil®)

Anti-obesity agents - new Lothian guidance

Prescribing guidelines for orlistat and sibutramine have recently been approved by the Lothian Formulary Committee and the Area Drug and Therapeutics Committee (ADTC). These drugs have been recommended by the National Institute for Clinical Excellence (NICE) and the Health Technology Board for Scotland (HTBS) in certain clinical circumstances. The Lothian Joint Formulary (LJF) until now has not recommended drug treatment for obesity and will now be adjusted in line with these new recommendations.

Diet and lifestyle changes are the mainstay of the management of obesity - with or without drug treatment. Patients should first be entered into a minimum three month structured weight management programme and demonstrate weight loss. This is to confirm that they can comply with dietary restriction and will minimise the risk of GI side effects from treatment with orlistat.

It is recommended that anti-obesity drugs can be considered for patients:

- With morbid obesity, i.e. BMI>40kg/m², or BMI>35kg/m² and one or more co-morbid risk factor(s).
- When weight loss is necessary in order for surgery to proceed and BMI>35kg/m².
- Referred by the specialist service with an obesity-related infertility problem and BMI>35kg/m².

Which drug?

Each drug is unique in its site of action, either in the GI tract (orlistat) or in the CNS (sibutramine). Orlistat is recommended for general use where indicated. Sibutramine is recommended for hospital use only. Combination therapy is not recommended.

Common side effects with orlistat occur in 10 to 25% of patients and are limited by dietary compliance (decreased fat intake). It is therefore essential that these are discussed with the patient beforehand.

Side effects are relatively common with sibutramine and similar to side effects seen with SSRIs.

Discontinuing Treatment

- Anti-obesity drugs are only licensed for continuous use up to one year (sibutramine) or 2 years (orlistat). Evidence of efficacy and safety is limited beyond this period.
- Treatment must be discontinued after three months in patients who have failed to lose 5% of their starting body weight. They are otherwise at risk of drug side effects in the absence of any therapeutic benefit.
- Patients should be informed prior to treatment that drug therapy will be discontinued if they fail to lose weight or there is significant progressive weight regain (3-5kg) on treatment after an initial weight loss.

- Further courses should only be considered after a suitable time interval and patients should again demonstrate the ability to lose weight on a suitable diet.
- Discontinue treatment if progressive weight regain over three months or BMI falls below 30kg/m².

Referrals

Referrals can be made to Dr Casey Stewart at the Weight Management Clinic now operating in the new Royal Infirmary at Little France.

More information

The full Lothian Prescribing Guideline can be viewed on the LPCT intranet site in the Guidelines section via http://lpctweb/elib/2_ClinicalPractice/home_cp.htm or the link via www.ljf.scot.nhs.uk.

Key messages:

- Diet and lifestyle changes remain the mainstay of the management of obesity.
- Prior to drug treatment patients should demonstrate weight loss.
- Orlistat is available for general use for suitable patients.
- Sibutramine is recommended for hospital use only.



New telephone number for ...

**Medicines Information at the
new Royal Infirmary, Little France**

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