

Study offers reassurance on commonly prescribed drug

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(PhysOrg.com) -- Researchers at the University of Dundee have found that a drug which is commonly prescribed for patients with conditions including high blood pressure, heart failure and liver disease is safer than a previous study had indicated.

Spironolactone is an old medicine that has undergone a resurgence in use in the last 10 years and is now quite commonly prescribed. The reason for this increased use had been studies showing its benefit in patients with [high blood pressure](#) and [heart failure](#) and also being commonly prescribed in patients with [liver disease](#).

However, in August 2004 a Canadian study published in the [New England Journal of Medicine](#) found that Spironolactone appeared to cause kidney problems and consequent high blood potassium levels. The researchers in Dundee were puzzled by this as it was not their experience when using this drug within the NHS.

Now they have published their own research in the [British Medical Journal](#) showing that Spironolactone appears much safer than the Canadian study suggested. In fact, despite a large increase in prescribing within the NHS, hospital admission for kidney problems or high blood potassium levels actually fell.

'I think this is due to a combination of the thoughtful prescribing of lower doses and careful monitoring of blood chemistry in the NHS,' said Professor Tom MacDonald, Head of the Medicines Monitoring Unit

(MEMO) at the University of Dundee and senior author of the new study. 'Our family doctors are excellent at using this drug safely and as a result patients get the substantial benefits without any significant risks.'

Another member of the research team, Professor Allan Struthers said, 'Spironolactone is a very effective medicine in patients with heart failure. Our study shows that careful monitoring is the key to safe prescribing. To put this benefit of Spironolactone into perspective, in a large study called the RALES study done in heart failure patients, Spironolactone reduced deaths by about one third.'

Dr Alex Watson, a general practitioner in Tayside, said the results of the Dundee study would offer reassurance to both doctors who are prescribing the drug and the patients who are receiving it.

'This study will allay the fears of family doctors who were concerned at the results presented when the Canadian data was published,' said Dr Watson. 'With this new study, GPs can now be reassured that starting with a low dose of Spironolactone and carefully monitoring blood chemistry is very safe. Patients can now be reassured that measuring the blood chemistry regularly is in their best interest.'

Professor Tom Fahey, professor of General Practice and Principal of the HRB Centre for Primary Care Research in Dublin, who contributed to the study, said it showed that careful monitoring of renal function in patients taking Spironolactone was an essential component of safe clinical practice. 'These results are reassuring and mean that the benefits of spironolactone can be realised in community-based patients,' said Professor Fahey.

The authors carried out their research by linking prescribing data, biochemistry lab data and hospitalisation data of patients, all of which are routinely recorded in the healthcare system. The data is completely

anonymised when used by the researchers.

Background

First approved in the USA in 1960, spironolactone is a medicine that acts by blocking the action of the hormone aldosterone. Aldosterone is released from the adrenal glands (that sit on top of the kidneys) and the main action of this hormone is to tell the kidneys to conserve salt. The kidney does this by absorbing salt (sodium) from the urine. In order to keep salt in, the kidney swaps the sodium for potassium. So aldosterone keeps salt in but gets rid of potassium.

By blocking aldosterone, spironolactone blocks the accumulation of sodium in the body and also blocks the excretion of potassium.

Spironolactone is used to treat heart failure, a condition where the body tends to accumulate salt. It is extremely effective in severe heart failure where it prolongs life and makes people live longer.

It is also used to treat certain forms of liver disease where the liver cannot clear aldosterone from the blood and salt and water accumulates.

Spironolactone is also used to treat aldosteronism (a special form of which is known as Conn's syndrome), a condition where the body overproduces aldosterone.

Spironolactone can also be used to treat low potassium levels.

Although not a licensed indication, spironolactone has been found to be very effective in patients with hard to control blood pressure (so called resistant hypertension). Some of these patients may have a mild form of aldosteronism.

The potential to accumulate too much potassium (hyperkalaemia) or to get rid of too much salt and water resulting in kidney impairment have long been recognised with spironolactone. The British National Formulary recommends the monitoring of blood in patients taking this medicine particularly if they have pre-existing kidney problems.

In Canada, there were a lot of hospitalisations for high potassium levels and other kidney problems reported in 2004 . This appeared to be mainly in patients with bad heart failure and may have been due to patients getting quite big doses of spironolactone without being monitored carefully.

In the UK, a more cautious approach to prescribing (low doses first) and adequate monitoring of blood appears to have occurred. Indeed, in the present study, some patients almost had high potassium levels but because the doctors detected this, they either stopped the drug or reduced the dose and avoided further problems.

This monitoring and careful dose adjustment is called risk-management. Appropriate risk-management enables patients to enjoy the considerable benefits of this medicine without suffering the potentially serious problems. Starting with very low doses of spironolactone, monitoring carefully and then gradually increasing the dose allows patients to keep taking the medicine carefully. Giving an inappropriately large dose and/or not monitoring can result in quite serious problems, said the study authors. In addition, the patient has to stop the drug and never goes back onto it even though it could be very beneficial.

Spironolactone is available in 25mg, 50mg and 100mg tablets. It is also available as a suspension in 5mg/5ml, 10mg/5ml, 25mg/5ml, 50mg/5ml, and 100mg/5ml.

In the authors opinion, patients with risk factors for problems (those

with pre-existing kidney problems, patients with heart failure, those taking other drugs that keep in potassium, those taking multiple cardiovascular/renal drugs, those with diabetes and the elderly) are best treated initially with very low doses such as half a 25mg tablet every second day (because the effects of this tablet are very long lasting it works well every second day). In practice it is easier giving the suspension (5mg every day or 10mg every second day). If the kidney function is OK after 10-14 days, the dose can be increased. In patients without risk factors, 25mg per day is a reasonable starting dose.

Provided by University of Dundee

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