Research leads to change in medicine labelling for salt content

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University of Dundee research that showed high salt levels in common medicines put patients at increased risk of cardiovascular events has led to a recommendation for a Europe-wide change in labelling legislation for medication.

The 2013 study, led by Dr Jacob George from the University's School of Medicine alongside collaborators from University College London, showed that millions of patients were exceeding the recommended daily limits for sodium, without any additional dietary intake.

Many commonly prescribed medicines have sodium added to improve their absorption into the body but excess salt is harmful to heart health. Dr George and his colleagues compared the risk of cardiovascular events (non-fatal heart attack, non-fatal stoke, or vascular death) in patients taking sodium-containing effervescent, dispersible and soluble medications with those taking non-sodium versions of the same drugs between 1987 and 2010.

Overall, patients taking the sodium-containing effervescent, dispersible and soluble medications had a 16 per cent increased risk of a heart attack, stroke or vascular death compared with other patients taking the non-sodium versions of those exact medications.

As a result, the researchers called for the public to be warned about the potential dangers of high sodium intake from prescribed medicines and for sodium-containing formulations to be prescribed with caution only if

the perceived benefits outweigh the risks. They also called for the sodium content of medicines to be clearly labelled in the same way as foods are.

The European Medicines Agency (EMA) has now used this evidence to recommend a continent-wide change in labelling for all medicines manufactured, sold, distributed and consumed in Europe.

Dr George said, "We are delighted that our research has had this impact and has led to the EMA to recommend this action. It is vital that the public are given the correct information about the medicine they are taking to ensure it does not lead to more serious health complications.

"Prescription of these sodium-containing formulations should be done with caution, and patients prescribed them should be closely monitored for the emergence of hypertension and heart problems. Taking the maximum daily dose of some medicines can significantly increase the chances of cardiovascular events so this is a matter of public health importance and we felt it was vitally important for salt content of medicines to be labelled in same way as foods."

In carrying out their research, Dr George's team considered factors likely to affect the results, such as body mass index, smoking, alcohol intake, history of various chronic illnesses and use of certain other medications.

Patients with high blood pressure were seven times more likely to have been prescribed high salt medicines and overall death rates were also 28 per cent higher in this group. These events are largely driven by an increased risk of hypertension and stroke.

Citing this study, the Pharmacovigilance Risk Assessment Committee of the EMA has recommended that the labelling of medicines should be updated to make the sodium content clearer for patients and health care

professionals. They agreed that medicines which contain above a certain threshold should be clearly labelled as being high in sodium and that these changes should come into force at the soonest opportunity.

Provided by University of Dundee