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SODIUM IN EFFERVESCENT, DISPERSIBLE AND SOLUBLE MEDICINES PUTS PATIENTS AT INCREASED RISK OF CARDIOVASCULAR EVENTS

Commonly prescribed effervescent, dispersible and soluble medicines containing sodium – used by millions of patients every day – are placing them at a significantly increased risk of cardiovascular events, a new study from the University of Dundee and University College London has shown.

Researchers found that taking the maximum daily dose of some sodium-containing formulations of medicines such as dispersible paracetamol exceeded the recommended daily sodium intake for an adult with just one medication.

The study showed that patients taking these sodium-containing effervescent, dispersible and soluble medications had a 16 per cent increased risk of having a heart attack, stroke or death from a vascular cause. Patients were also seven times more likely to develop high blood pressure and overall death rates were also 28% higher in this group. These events are largely driven by an increased risk of stroke.

“Excess sodium in our diets is a major public health problem worldwide,” said Dr Jacob George, Senior Clinical Lecturer and Honorary Consultant Physician in Clinical Pharmacology at the University of Dundee and lead author of the study.

“Major efforts have been made to reduce salt intake through diet. However, unlike foods, manufacturers are not placed under any legal restrictions or obligations with regards to sodium content or labeling of these sodium-containing medications.

The study tracked the health of more than 1.2 million patients through the UK Clinical Practice Research Datalink database, which covers around seven per cent of the UK population.

“We followed up patients who were taking these sodium-containing effervescent, soluble and dispersible formulations and compared them to other patients who were taking non-effervescent, non-dispersible and non-soluble versions of those same medications,” said Dr George

“To put these findings into context, the average sodium consumption from sodium-containing medications was higher than the current total recommended daily dietary intake. If people are taking these medications and then also eating their regular diet, they are likely to far exceed the recommended daily limits for sodium.

“The cumulative effect of that is they are being put at a significantly increased risk of cardiovascular events. There is also the issue of over-the-counter preparations that contain sodium but we did not study the effects of these preparations in this study”

“Our conclusions are that physicians should prescribe sodium-containing formulations with caution and only if there are compelling reasons to do so. Sodium loaded effervescent, soluble or dispersible tablets should, if possible, be avoided in patients at risk of hypertension, and patients prescribed these drugs should be carefully monitored for the emergence of hypertension”

Further quotes from the authors:

Dr Jacob George, lead author for the study and Senior Clinical lecturer in Clinical Pharmacology and Consultant in Acute Medicine said:

“Our team has shown that there is clearly a risk associated with these medications. The data from this study will enable patients and their doctors to make an informed choice on whether they should start or continue these medications.

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Dr Li Wei the senior author and guarantor for the study said:

"This study demonstrates the importance of using anonymised health care data for the benefit of public health. Were more data more easily available it is likely that public health could be significantly improved by further similar research".

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Another author, **Prof Tom MacDonald** who is also **President** of the **British Hypertension Society** said:

"It is worrying that these formulations of medicines are associated with the development of high blood pressure (hypertension) and increased stroke risk. In the UK, someone has a stroke every 45min. Avoiding possible causes such as taking tablets with a high sodium content could help to start reducing this awful disease".

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Dr Isla Mackenzie Clinical Senior Lecturer in Clinical Pharmacology and Consultant Physician who is also a member of the **British Hypertension Society Executive Committee** said:

"The pharmaceutical industry should strive to produce soluble and effervescent medicines that do not contain as much sodium wherever possible. Such a technological advance would contribute significantly to public health".

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The results of the study have been published online by the British Medical Journal.

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British Hypertension Society: www.bhsoc.org

The British Hypertension Society provides a medical and scientific research forum to enable sharing of cutting edge research in order to understand the origin of high blood pressure and improve its treatment.

BACKGROUND

Many patients take soluble or effervescent tablets. Some take these for good reason such as swallowing difficulties but others just prefer these preparations. The sodium content of such

medications is not disclosed on the Summary of Product Characteristics (SPC) or on the Patient Information Leaflet (PIL). This is curious because even foodstuffs have to be clearly labelled with such data. In order to discover how much sodium is in medications George et al had to contact each individual manufacturer.

The association between salt intake and high blood pressure has been researched over many years. People living in tribes in the Amazon have very little salt in their normal diet. These cultures do not show an increase in blood pressure with age whereas 'Westernised' societies show a sustained increase.

The link between sodium intake and adverse outcome is now firmly agreed. As a result the UK Food Standards Agency has extolled UK residents to consume less salt in a bid to improve public health. Food producers have reduced the sodium content of products and consumers can with confidence determine the salt content of foods by reading the labels. This is not the case with medicines.

Interestingly, drugs that increase the excretion of sodium (diuretic drugs) are one of the major medicine classes used in the treatment of high blood pressure. The effectiveness of these medicines is decreased in the face of high salt intake. Thus, a high salt intake not only makes it more likely that someone will develop high blood pressure but it also makes control of high blood pressure harder.

High blood pressure is one of the leading preventable causes of death worldwide. It is the dominant preventable cause of stroke a devastating condition that leads to substantial death & disability. Even relatively modest increases in blood pressure of a few mmHg translate into big increases in adverse outcome. This is why the findings of the George et al study are so important.

Ends