Some statins have unintended effects and warrant closer monitoring, study finds

May 26 2010

The type and dosage of statin drugs given to patients to treat heart disease should be proactively monitored as they can have unintended adverse effects, concludes a new study published in the *BMJ*.

Researchers at The University of Nottingham found that some statins can lead to an increased risk of liver dysfunction, acute renal failure, myopathy and cataracts in patients.

Cardiovascular disease is a leading cause of premature death and a major cause of disability in the UK. The use of statins is often recommended to reduce the risk of cardiovascular disease among high risk patients.

Julia Hippisley-Cox, professor of clinical epidemiology and general practice, and Carol Coupland, associate professor in medical statistics, both at The University of Nottingham, wanted to measure the unintended effects of statins on certain clinical outcomes, taking into account the type, dose and duration of use.

They studied data collected from 368 general practices contributing to the QResearch database on 2,004,692 patients aged 30-84 years including 225,922 patients who were new statin users and prescribed a range of statins. The patients' adverse outcomes were studied from January 2002 to June 2008.

The researchers estimated the effects of type, dose and duration of statin use on clinical outcomes that have been associated previously with

statins and then calculated the numbers needed to treat and harm.

They found there was no significant association between use of individual statins and risk of Parkinson's disease, rheumatoid arthritis, venous thrombo-embolism, dementia, osteoporotic fracture, or many cancers including gastric, colon, lung, renal, breast or prostate. There was a reduced risk associated with statin use for oesophageal cancer.

There was, however, an increased risk associated with using statins for moderate or serious liver dysfunction, acute renal failure, moderate to serious myopathy and cataracts and evidence of a dose response for acute renal failure and liver dysfunction with higher doses being associated with greater risk.

Adverse effects were similar for all of the different statins taken except for liver dysfunction, where the highest risks were found for fluvastatin. All of the increased risks persisted during the treatment, but were highest in the first year.

Overall, for every 10,000 high risk women treated with statins, there would be approximately 271 fewer cases of cardiovascular disease, 8 fewer cases of oesophageal cancer; 74 extra patients who experience liver dysfunction; 23 extra patients with acute renal failure, 307 extra patients with cataracts, and 39 extra patients with myopathy. Similar figures were found for men except rates of myopathy were higher. Some of the effects might be due to better detection rates since patients taking statins will consult their doctor more.

The authors said: "At national level, our study is likely to be useful for policy and planning purposes. Our study may also be useful for informing guidelines on the type and dose of statins."

A companion paper by the same researchers, published today in the

journal *Heart*, shows that their newly-developed and validated risk prediction algorithms could be used to identify patients at high risk of adverse events from statins so that they can be monitored more closely. A web calculator suitable for use by doctors can be found at www.qintervention.org

In an accompanying editorial, two senior cardiologists say that, like any intervention in medicine, statins are not entirely free of adverse events, but that when used according to current guidelines, the benefits outweigh the risks.

More information: See the study at:
www.bmj.com/cgi/doi/10.1136/bmj.c2197
See the accompanying editorial at:
www.bmj.com/cgi/doi/10.1136/bmj.c2240
Companion paper in the journal Heart:
heart.bmj.com/site/misc/HeartJnl199034.pdf

Provided by University of Nottingham