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Reply to Dr. Gifford-Jones' article on 23rd October 2003 in the Windsor Star

It is with dismay and incomprehension that I read the article written by Dr. Gifford-Jones that appeared in the 23rd October 2003 issue of the Windsor Star. His knowledge of this rapidly-expanding field leaves much to be desired.

The era of the most important class of cholesterol-lowering drugs called statins began with the work of Drs. Michael Brown and Joseph Goldstein from Dallas, Texas. They discovered how cholesterol is regulated and fine-tuned in the cell by an intricate process involving the low density lipoprotein (LDL)-receptor. LDL-cholesterol is the so-called bad cholesterol. Drs. Brown and Goldstein received the Nobel prize in medicine in 1986 for their work. It took a few more years for the first statin to undergo clinical testing and be made available for human use. Thus the ground work was laid to do major clinical studies in the 1990s to test the hypothesis that lowering blood cholesterol level could indeed reduce the risk of coronary heart disease.

It was known from observational studies in the past that there is a statistical association between high blood cholesterol levels and the risk of coronary heart disease. However to prove the point scientifically, one must do interventional studies of statin treatment versus placebo in a double-blinded manner so that neither the physician nor the patients know to which treatment patients are assigned. In the last 8 years, a plethora of such studies have been completed and published in major medical journals. These studies were done in both healthy people and those with established coronary artery disease. Very conveniently Dr. Gifford-Jones also omitted to mention all these major clinical trials (for example, the 4S, LIPID, CARE, GREACE, AVERT, HPS, WOSCOPS, AFCAPS, ASCOT). They showed that we need to treat 13 to 33 patients for 5 years in order to prevent a major coronary event when the patient has established coronary artery disease. They also showed that we need to treat 40 to 49 patients for 5 years to prevent a major event when the patient has no known coronary heart disease. To put things in perspective, we have to treat 48 to 88 patients for 5 years to prevent a stroke when we treat patients for high blood pressure. The number of patients needed to be treated to prevent a major coronary event using statins is considered by to be highly cost-effective and cost-beneficial.

It is true that deaths have resulted from using these drugs. However, Dr. Gifford Jones has omitted to mention that the chance of dying from rhadomyolysis (severe muscle damage) using Lipitor (the best-selling statin in the world to date) is 1 per 25,000,000 prescriptions! This is considered by the regulatory authorities to be very acceptable.

The old studies that were quoted by Dr. Gifford-Jones were done prior to the age of the statins. The slight increase in accidental and homicidal deaths were reported to be associated with gemfibrozil. These deaths were investigated by the FDA. One patient stopped taking his medicine one year prior to his death. He became drunk and drove a tractor which overturned thus killing him. Another patient had stopped his gemfibrozil two years prior to a homicide that he committed. He had a row with his neighbour and he proceeded to settle his dispute with a shot-gun and killed his neighbour. Since they were enrolled in a clinical study, these deaths had to be included as adverse events in the active treatment group due to a statistical process called "intention-to-treat".

When the FDA eliminated these very irrelevant deaths from consideration, they found no difference in the rates of accidental/homicidal/suicidal deaths between gemfibrozil treatment and placebo.

In the newer interventional studies using statins, none of the trials showed an increase in cancer rates, cancer deaths, accidental deaths or hemorrhagic strokes. Actually the trials also showed that statins prevent strokes and decrease the need for coronary artery bypass procedures and angioplasties.

One of the first things we teach in medical schools is “prima non nocere”. Translated, it means “first do no harm”. I am very concerned that if Dr. Gifford-Jones’ message is heeded by patients who are at high risk for coronary heart disease, great harm may be done to them if they stop taking their statins!

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