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The Effect of Statins in Primary Prevention on All-Cause Mortality

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Abstract
During routine yearly physicals, primary care providers often evaluate serum laboratory lipid levels. Many of these patients have no past medical history of cardiovascular events related to atherosclerotic disease. Some patients do not have secondary risk factors, such as diabetes mellitus or smoking history. Previous cardiovascular events provide stronger indications for the use of HMG-CoA reductase inhibitors (statins). In the absence of these, the provider may turn to current guidelines, in this case the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults.

There is however, controversy, even within the evidence to this guideline, about the effect of statins in primary prevention with respect to the reduction that they have on all-cause mortality. There are many factors that could influence the use of statin therapy for primary prevention. These could include non-fatal myocardial infarction, non-fatal cerebral vascular accident, among others. One of the biggest factors is all-cause mortality.

A review of the evidence cited for these guidelines demonstrates that the majority of the clinical trials did not show a reduction in all-cause mortality, in primary prevention. It is important to understand that this evidence comes directly from the same evidence that the ACC/AHA used to create the primary prevention guidelines.

Statement of the Problem
ALL-CAUSE MORTALITY in PRIMARY PREVENTION
• Without factoring in any other data sets, evidence is controversial.
• By only focusing on one specific factor, the hope is to paint a clear picture of that factor, thereby facilitating a better decision making process.
• All-cause mortality is one of the end points that is most easily tracked without interruption needed.

Research Question
Does the use of statins, in the primary prevention setting, with additional risk factors, affect all-cause mortality?

The answer is that a review of the evidence used in the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults, the Cholesterol Treatment Trialsists’ (CTT), demonstrates more evidence that not that statin therapy does not reduce the risk of all-cause mortality.

Literature Review
JUPITER – “Rosuvastatin also significantly reduced the incidence of death from any cause.”
AFCAPS/TexCAPS – “Rates for overall mortality, cardiovascular mortality, noncardiovascular mortality, and fatal cancer were low, and there were no treatment group differences.”
CARDS – “We recorded a 27% fall in all-cause mortality in patients allocated atorvastatin.”
WOSCOPS – “treating 1000 middle-aged patients with pravastatin for five years will result in ... 2 fewer deaths from other causes than would be expected in the absence of treatment.”
4D – “Atorvastatin had no significant effect on the individual components of the primary end point.”
ALLHAT-LDL – “All-cause mortality was not significantly reduced”
ASCOT-LDL – “All-cause mortality was non-significantly reduced.”
APSEN – “Composite end point reductions were not statistically significant.”
AURORA – “Rosuvastatin had no benefit in any subgroup examined, including patients with diabetes”
MEGA – “Although treatment with pravastatin was associated with lower total mortality than with diet alone, this result was not significant.”

Discussion
26 = Number of Cholesterol Treatment Trialsists’ (CTT) 11 = Number of Trials in CTTs that are actually PRIMARY PREVENTION 3 = Number of CTT’s that show all cause mortality REDUCTION 8 = Number of CTT’s that show NO all cause mortality reduction
Eight out of eleven studies appears to be a wide margin of evidence supporting no effect on all-cause mortality in the primary prevention setting. To come to a different conclusion would be to put more weight on the three positive studies, which would seem unlikely to be true given the evidence.

Applicability to Clinical Practice
Cardiovascular disease would include strokes, myocardial infarctions, arrhythmias, peripheral arterial disease, or heart valve problems.
An event from one of these conditions can have a profound effect on a patient’s life, but not cause death.
This is important to remember because the conclusion that statins do not reduce all-cause mortality in the primary prevention setting does not mean that statins will not protect against such cardiovascular events.

Although patients may end up living about the same amount of years, whether they take statins or not, it does not mean that they will have a better quality of life during those years.
Where the research from this project can be useful in the clinical setting, especially primary care, is when patients have difficulty with the side effects of statins.
Clinicians should discuss the risks and benefits to statin therapy before starting a regimen. This project will aid in that discussion.

References

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