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The Efficacy and Safety of Statins in the Primary Prevention of Cardiovascular Disease

Kayla M. Ashton
University of North Dakota

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Atherosclerotic plaques form in the blood vessels from particles of cholesterol. These plaques are a major cause of cardiovascular disease and have the ability to result in fatal cardiovascular events. In researching this topic, Published, the Cochrane Library, DynaMed, and ClinicalKey were all utilized in finding articles published from 2002 to 2018. There are several organizations with conflicting guidelines recommending the use of statins in the primary prevention of cardiovascular disease. The research evaluated discovers data is inconclusive on the benefit of statin medications in this primary prevention as well as the safety of long-term statin use. Some experts have suggested that statins are not the only commonly prescribed medications in the United States. Statin medications continue to be extremely beneficial in the secondary prevention of cardiovascular events, but caution should be applied by providers when prescribing this medication to their patients for primary prevention when referring to conflicting population based guidelines. Providers should identify key risk factors and have conversations with their patients on the risks and benefits of statin medications when they are being utilized for the primary prevention of cardiovascular disease.

Introduction
Atherosclerotic plaques form in the blood vessels from particles of cholesterol. These plaques and are a major cause of cardiovascular disease (CVD) and have the ability to result in fatal cardiovascular events (Baron, 2017).

Data is inconclusive and differ among many studies whether the use of statins is beneficial in primary prevention when evaluating the rate of CVD events, CVD mortality and all-cause mortality.

HMG-CoA reductase is an enzyme involved in the first step in the formation of cholesterol in the liver. By inhibiting HMG-CoA (the mechanism of statin medications), the synthesis of cholesterol is reduced, thereby lowering the levels of cholesterol found in the blood (Malloy & Kane, 2015). With less cholesterol in the blood, atherosclerotic plaques are not as likely to form.

Conflicting recommendation statements can make it difficult for providers to know which patients fall into a statin therapy benefit group. Some patients may fall into a statin therapy benefit group with one organization, but not another (Pagidipati, 2017).

Population-based recommendations have been criticized as it may seem almost all patients can fall into one of the treatment groups. The use of statins in the prevention of cardiovascular events is disputed as we still do not know the exact cause of plaque formation or migration of plaques resulting in cardiovascular events. There is also lack of information on whether statin medications have deleterious long-term effects as the widespread use of statins has been somewhat recent in terms of medical research as statins were first approved for use in 1987 (Baron, 2017).

Statement of the Problem
Statins have made a major contribution in the primary prevention of CVD. Continuing research on other cardiovascular events are truly being prevented by the use of statins or if these medications are being over-prescribed.

Research Question
In patients without existing cardiovascular disease, does taking a statin medication (rather than not taking a statin medication) prevent cardiovascular events?

In patients taking statins, does the benefit of taking statins outweigh the risk of long-term statin use in the primary prevention of cardiovascular disease?

Literature Review
- DeFilipps, Young, and Blaha (2015) evaluated the AHA/ACC ASCVD risk score with 4 other risk scores classifiers to compare their efficacies. In the 4,277 patients evaluated, the researchers discovered 4 out of the 5 stratification tools overestimated risk in men by 37% and 46% and 67% in 3 of the 5 tools in women. ASCVD events were better predicted in women than in men.

- Pagidipati (2017) evaluated 3,416 subjects aged 40 to 75 years without prior CVD. In this population, 21.5% of the subjects were taking statin medications and an additional 15.8% of the subjects would be eligible based on the USPSTF guidelines to an additional 23.4% when looking at the AHA/ACC guidelines. Much of the discrepancy is due to the AHA/ACC guidelines recommending statin therapy in those with diabetes and the USPSTF guidelines do not. Others who were covered under the AHA/ACC guidelines but not the USPSTF guidelines included younger smokers, younger males with dyslipidemia and younger women with diabetes.

- ALLHAT (2002) compared patients with existing HTN with fasting LDL cholesterol levels of 120 to 189 mg/dL. A total of 10,355 participants were included in the study and their treatment was evaluated for up to eight years. The researchers concluded there was no significant difference in all-cause mortality when comparing pravastatin treatment to usual care (p = 0.88).

- Knoepf, D’Emden, Smilde, and Pocock (2006) evaluated 2,410 subjects with diabetes and ASCVD Risk 5+% (grade B) and ASCVD Risk 7.5+% (grade C). Results are inconclusive and differ among many studies whether the use of statins is beneficial in primary prevention when evaluating the rate of CVD events, CVD mortality and all-cause mortality.

- Andersson, Hjelstuen, Hjermann, Bjerkan, and Holme (2005) evaluated 388 patients on whether a statin prescription is appropriate.

- All experts have suggested statins are over prescribed. Many organizations with conflicting guidelines recommending the use of statin medications, the adverse effects found may be 5 cases of myopathy, 50 to 100 new cases of diabetes mellitus, and 5 to 10 hemorrhagic strokes.

Discussion
- There are discrepancies among recommendation guidelines on the prescription of statin medications in the primary prevention of CVD.

- The risk assessment tools do not take into consideration important factors such as diet and exercise, family history, or other comorbidities which may increase or decrease a patient’s risk of CVD.

- There was no significant difference in all-cause mortality when comparing pravastatin treatment to usual care (p = 0.88).

- The researchers concluded that statin use may be a risk factor for developing cardiovascular events in patients who are at high risk. They suggested if statins are started on a high-risk patient, that the patient is monitored closely.

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Recommendation Guidelines
United States Preventive Task Force
- Age ≥ 40 and ASCVD Risk 10% (grade B) or ASCVD Risk 7.5% (grade C) with 1 or more Risk Factor (diabetes, hypertension, smoker)

- With 1-Risk Factor (diabetes, hypertension, smoker) American Heart Association

- LDL < 190 mg/dL and Age ≥ 21 (grade B)

- Diabetes, Age 40-75 and LDL 70-189 mg/dL (grade A)

- No Diabetes, Age 40-75, LDL 70-189 mg/dL, and ASCVD Risk >7.5% (grade B)

- No Diabetes, Age 40-75, LDL 70-189 mg/dL, and ASCVD Risk 5% (grade A)

Applicability to Clinical Practice
- Providers can use this information to make decisions together with their patients on whether a statin prescription is appropriate.

- Long-term usage of statins for more than 15 years of these medications, have yet to be evaluated and is also a consideration providers should take into account when discussing risks with their patients.

- As patients get older with conditions such as diabetes at much younger ages, long-term usage of statins will become more prevalent.

- Side effects should be frequently discussed and risks should be assessed before prescribing a medication to their patients.

- Providers must assess each patient’s benefits versus risks to determine if a statin prescription may have an effect on the primary prevention of CVD.

- With greatest benefit seen in patients with multiple risk factors, patients with single risk factors may have the greatest effect in the risk versus benefit decision when determining statin appropriateness in primary care patients.

References
Crandall, J. P., Mather, K., Haffajee, S. N., Goldberg, R. B., Watson, K., Fox, S., . . . Smallridge, A. E. (2017). Temporal trends in utilisation and needed to treat with rosuvastatin to prevent one event to be 19%. The research showed benefit in some populations, especially those with multiple risk factors. Other populations, such as those with diabetes, did not have a significant benefit which falls against that of the AHA/ACC recommendation guidelines.

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