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Risks and Benefits of Statin Use When at Target Goal

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## RISKS AND BENEFITS OF STATIN USE WHEN AT TARGET GOAL

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## RISKS AND BENEFITS OF STATIN USE WHEN AT TARGET GOAL

### Abstract

The American College of Cardiology and the American Heart Association published the most recent guidelines on the treatment of hyperlipidemia in 2013. The approach of treatment shifted from target based interventions to risk based interventions. When applying this to practice, it can be difficult to decide when to adjust medication therapy or if adjusting medication is recommended at all. The guidelines do not take into account adverse reactions from statin therapy.

When presented with a patient who has diabetes mellitus and an abnormal lipid panel, the provider needs to decide what to do for a patient who is already on statin therapy. The patient should be part of the health care team, but to make informed decisions about care, the provider needs to present all risks and benefits of treatment options. Current guidelines appear to be one size fits all, however, providers must make individualized care plans for patient. A literature search will help define if treatment focusing on a combination of risk based interventions with target based interventions is an effective strategy for management of hyperlipidemia in a diabetic patient with lipid panel in normal limits.

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### **Background**

Management of diabetes mellitus involves more than management of blood glucose levels. Diabetes can have an effect on the eyes, kidney, heart, blood vessels, and neuropathy affecting the lower extremities. The provider's role is to assist the patient in preventing complications that arise from diabetes by controlling diabetes. Routine assessments for individuals with diabetes mellitus include eye exams, lab work, and sensation assessments. Pharmacologic interventions can also be helpful to minimize the risk of complications.

Hyperlipidemia is associated with diabetes mellitus. Guidelines are routinely published to assist providers in managing hyperlipidemia. The newest guidelines were published in 2013 by the American College of Cardiology (ACC) and American Heart Association (AHA). These guidelines changed the management of hyperlipidemia from target based interventions to risk based interventions for patient populations. There has been controversy over this shift in guidelines and the effects on patient care.

The idea of risk based interventions for hyperlipidemia has increased the number of patients on statin therapy. Concerns over adverse effects of statin therapy and continued management of lipid levels have been elevated and have contributed to the controversy. This paper discusses the risks and benefits of statin therapy for individuals at target goal and how the current guidelines play a role in pharmacologic management.

### **Case Report**

A sixty-five year old male presents to the clinic for a six month follow-up for diabetes mellitus. He states he takes his medications as ordered. He does not engage in regular exercise and reports an increase in weight. He does check his blood sugars two to three times a week

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which are fasting and post prandial. He believes his blood sugar reading this morning was in the one hundred seventy to two hundred twenty range.

His medications include glipizide 10mg daily, lisinopril 10mg daily, Toprol XL 50mg daily, Zocor 20mg daily, Janumet 50-1000mg BID, aspirin 81mg daily, and a once daily multivitamin. He reports no known allergies. Past medical history includes obesity, hyperlipidemia, diabetes mellitus type two, and actinic keratosis. Past surgical history includes cataract surgery, colonoscopy with polyp removal, and carpal tunnel surgery. He denies tobacco use and reports social alcohol use. He is not up to date with his health maintenance as he is due for a pneumonia vaccine, tetanus vaccine, and colonoscopy.

On physical exam, his vital signs were blood pressure of 138/80, pulse of 72, respirations of 18, weight is 269 pounds, and a body mass index of 36.5. Pupils were equal, round, and reactive to light, no scleral icterus noted and neck was supple. Cardiac exam revealed regular rate and rhythm without murmur, no jugular neck vein distention and no swelling in lower extremities. Respiratory exam revealed clear lung sounds bilaterally. Abdomen was soft and non-tender. Extremities were without swelling, normal range of motion present, sensation intact with monofilament testing completed.

Lab results were obtained. Urine creatinine and microalbumin were within normal range. Lipid panel results were as follows: cholesterol 133, triglycerides 167, HDL 39, and LDL 61. Hemoglobin A1C was 9.5. Comprehensive metabolic panel revealed normal results except for glucose of 324 and a bilirubin total of 1.1.

The patient is diagnosed with uncontrolled diabetes mellitus type 2, instructed to start liraglutide 0.6mg daily for one week, then increase to 1.2mg daily. Stop glipizide. Check blood sugars twice a day and call clinic with results in two weeks. Repeat hemoglobin A1C in four

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months. Referral to diabetic resource center to see nurse and dietician. Weight reduction recommended.

Options were discussed for exercise such as physical therapy referral which patient declined at this time. Education provided on getting sixty minutes of exercise most days of the week. This can be accomplished with walking outside when weather improves, doing the steps within the patient's home, and making laps within floor plan of home. Patient states he will consider a physical therapy referral for exercise recommendations at next appointment. Referral to dietician was made as well.

Patient is due for health care maintenance in terms of pneumonia vaccines. PCV13 given today in clinic. Patient will need PPSV23 one year from now. Tetanus vaccine administered in clinic today. Patient is also due for colonoscopy with referral placed to provider of choice.

Screening lipid panel was completed with stable lipid panel. Triglycerides are elevated which is likely related to increased blood sugar levels. Discussion with the patient regarding adjusting statin medication therapy at this time. There are risks and benefits to adjusting medications and other factors to consider were discussed with the patient. We will not adjust statin medication at this time due to LDL level being at 61. Diet modifications recommended and patient was referred to dietician. Will repeat lipid panel in four months' time.

### **Literature Review**

A literature review was conducted using CINAHL Complete. The search terms utilized were risk and benefit, statin, and at goal. Other criteria included academic journals and year range of 2013-2019. These criteria yielded twenty-nine articles. After further review of these articles, criteria were further refined to exclude studies that focused on only one pharmacologic

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therapy, pharmacologic therapies that did not include statins, and studies focusing on blood pressure. The final yield was seven articles.

Further analysis of the seven articles included entering them into the SCOPUS program. For each article entered, the articles that referenced the original article were reviewed with the same inclusion or exclusion criteria as mentioned above. This search revealed six additional articles to be included in the synthesis.

When determining lipid disorder treatment for individuals, patients can be placed in two categories. The first category are those who are using statins as a primary prevention method and the second category are those who are using statins as a secondary prevention method. Literature varies with recommendations between the two prevention types and thus they will be discussed separately.

There are at risk groups who would benefit from primary prevention with statin use for cardiovascular disease. These at risk groups include those who are age 40 to 75 with diabetes mellitus and those who have an atherosclerotic cardiovascular disease (ASCVD) risk of greater than or equal to seven and one half percent (ACC & AHA, 2013; Bibbins-Domingo et al., 2016; Egan et al., 2016; Katz, Intwala & Stone, 2014; Li et al., 2018; Lopez-Jimenez et al., 2014; Ross, Shah & Leeper, 2016; Waite, Phan & Spinler, 2016; Zhang, Pingsheng, Zhang, Wang & Zhang, 2016). The inclusion and criteria for these groups encompasses a larger number of individuals eligible for statin therapy who previously were not. The large inclusion group leads some to question whether or not this is what is best for the patient. The ASCVD risk percentage is debated in the literature as well. The US Preventive Services Task Force uses ten percent as the benchmark for treatment with ASCVD risk (Bibbins-Domingo et al., 2016). There is also the

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question of whether or not there is enough emphasis on lifestyle modifications rather than going right to medication therapy.

The use of statins for secondary prevention are for those who have ASCVD and those who have an LDL greater than or equal to one hundred and ninety (ACC & AHA, 2013; Alla et al., 2013; Waite et al., 2016; Egan et al., 2016; Li et al., 2018; Lopez-Jimenez et al., 2014).

There is lack of evidence in using statins for secondary prevention in part because of how well they work at lowering cholesterol which in turn lowers risk of a cardiovascular event occurring again. There is some debate on whether or not adjunctive medications should be utilized as well with statin therapy. These adjunctive medications include aspirin, niacin, fenofibrate, and omega-3 fatty acids.

Another common theme in the research is the fact that there are more adverse reactions to statin therapy when the intensity of statin is increased or the dose of statin is increased (Alla et al., 2013; Li et al., 2018; Heller et al., 2017; Lopez- Jimenez et al., 2014). Many individuals are aware that statin medications have side effects. Providers need to be aware of potential side effects when attempting to initiate statin therapy. When patients experience side effects and discontinue the medication, it can be difficult to get them to agree to another medication in the same drug class. This also can lead to a lack of trust from the patient's point of view. When a patient does not trust his or her provider, it is difficult for the provider to propose alternative options for treatment without skepticism from the patient.

There has also been limited research on adverse reactions to statin therapy (Alla et al, 2013; Heller et al., 2017; Lopez-Jimenez et al., 2014; Ross et al., 2016). Statin therapy has proven to have many benefits for those who need the medication, but all medication therapy comes with adverse reactions. There are various adverse reactions that can occur with statin

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therapy include myopathy, arthralgias, tendon rupture, increase liver enzymes, risk for diabetes mellitus, insomnia, cognitive impairment, ataxia, or irritability (Alla et al., 2013). Implications of adverse reactions and the long term effects for patients has not been studied as thoroughly either. These implications include the adverse reaction issues as well as pill burden on patients as they age (Heller et al., 2017). Overall, further studies need to be done to determine the overall risks and benefits in terms of adverse reactions for patients who are taking statins or who have taken statins in the past.

Side effects of statin therapy can be positive or negative depending on the result and various side effects are seen with this medication class (Alla et al., 2013; Lopez- Jimenez et al., 2014; Zhang et al., 2016). Rosuvastatin was found to increase proteinuria while atorvastatin decreased proteinuria (Alla et al., 2013). Research has also uncovered a potential protection from prostate cancer, adenocarcinoma of the colon, non-Hodgkin's lymphoma and endometrial cancer in individuals who take statin medications (Alla et al., 2013). The mechanisms behind these protections are not fully understood thus further research is warranted. It is important to consider the positive side effects as well as the negative when educating patients on this medication. This allows the patient to make an informed decision regarding statin medication. The negative side effects include myopathy, arthralgias, tendon rupture, increase liver enzymes, risk for diabetes mellitus, insomnia, cognitive impairment, ataxia, irritability, etcetera (Alla et al., 2013). There are also some positive side effects that are attributed to statin therapy. These include renoprotective factors as well as a protection from certain cancers (Alla et al., 2013). Studies have shown that statins help reduce microalbuminuria, proteinuria, and clinical deaths in individuals with chronic kidney disease (Zhang et al., 2016). Alla et al., (2013), found that there was varying degrees of protectiveness which is based on individuals drugs within the class.

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Another common theme among the literature includes the responsibility of the provider to educate the patient and participate in shared decision making when determining the use of statin therapy (Alla et al., 2013; Heller et al. 2017; Lopez- Jimenez et al., 2014; Katz et al., 2014). It is the responsibility for the provider to educate the patient on any medication therapy he or she is considering starting. When providing this information in regard to statin therapy, benefit of ASCVD risk reduction, side effects, and drug to drug interactions should be discussed (Katz et al., 2014). Patient preferences should also be considered when decisions about medication therapy are made (Katz et al., 2014). It is imperative that the patient has a good grasp on the intervention proposed so that he or she can make an informed decision with the provider.

There are other factors that should be considered by the prescribing provider such as using a combination of risk-based goals and target-based goals (Alla et al., 2013; Cesena et al., 2017; Katz et al., 2014; Li et al., 2018; Pletcher et al., 2017; Ross et al., 2016; Waite et al., 2016). The idea of risk based goals does encompass a larger population who would receive statin therapy. There is not much debate about treating a larger number of individuals who are at risk for cardiovascular events. The concern arises with individuals who are intolerant of statin medication, those who are on statins but are not at goal, and those who are on not on the right intensity of statin but are at goal. Recommendations proposed by the ACC/AHA 2013 guidelines only address statin therapy. If a patient is intolerant of statins, there is not an existing guideline from the ACC/AHA to assist providers in management strategies. There are other medications available to treat different aspects of a lipid profile to help lower levels. The other concern is what to do with the lipid profile numbers for individuals who are at goal on a lower intensity statin according to the ACC/AHA 2013 guidelines and those who are on the appropriate intensity statin according to the ACC/AHA 2013 guidelines but are not at goal. As mentioned

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before, there are risks associated with increased dosage and intensity of statin medications. How does a provider weigh the risks and benefits for a patient when only looking at risk factors? It appears that a combination of both risk based and target based therapy may be warranted.

The final theme among research is emerging technologies to assess risk factors for cardiovascular disease and these technologies play a role in treatment for patients (Alla et al., 2013; Katz et al., 2014; Pletcher et al., 2018). The idea of novel risk factors has evolved in the recent years as factors to consider when treating dyslipidemia in patients (Pletcher et al., 2018). There are various novel risk factors to consider which can be detected with technology such as coronary artery calcium, carotid intima media thickness, carotid plaque detection, c-reactive protein levels, homocysteine levels, ankle-brachial index, and genetic testing just to name a few (Pletcher et al., 2018). The concept is that combining some of the novel risk factor results with the ACC/AHA 2013 guidelines would assist providers in risk based treatment as well as target based treatment.

Overall, the literature supports using clinical judgement, emerging technology, and factoring in patient preference to determine whether or not statin therapy should be adjusted. The literature supports using risk based assessments to start stain therapy for patients as seen with the ACC/AHA 2013 guidelines. After statin therapy is started, those guidelines are not useful. This is when management needs to be individualized for each and every patient.

### **Learning Points**

- Risk based treatment for primary prevention of ASCVD is a great way to reduce cardiovascular events, but once individuals are being treated a target based approach is needed to minimize adverse reactions for individuals.

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- Statin therapy for secondary prevention of cardiovascular events the superior method of treating individuals.
- Shared decision making between the provider and the patient is needed to obtain the best outcomes for the patient. The patient needs to make informed decisions with knowledge of risks and benefits with various treatment options.
- Novel risk factors should be taken into account when choosing the path of treatment for individuals along with risk based assessments.

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