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Comparing the Effectiveness of a Low Carbohydrate Diet and Metformin On Glycosylated Hemoglobin Reduction in Type Two Diabetes Mellitus

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Abstract

In this study, a low carbohydrate diet and metformin pharmacotherapy were compared to determine their effect on HbA1c in the type two diabetic patient. Several high quality studies were examined along with each treatments effect on mainly HbA1c, but also other parameters such as body weight, cholesterol, and fasting and post prandial blood glucose levels. The study showed that both the low carbohydrate diet and metformin pharmacotherapy were effective at lowering HbA1c in the type two diabetic patient. The low carbohydrate diet showed a 0.2% increase in HbA1c all the way to a 2.2% decrease in baseline HbA1c in the studies that were examined. The metformin pharmacotherapy showed between a 0.45% decrease up to a greater than 1% decrease from baseline HbA1c in the studies examined within this project. After looking at the other parameters that were affected by each treatment, it was concluded that choosing treatment between the two options studied will be highly dependent on each individual patient and their readiness and willingness to implement lifestyle changes. Both methods of treatment are equally as effective and can be beneficial to different patients.

Introduction

The following research is comparing the effectiveness of a low carbohydrate diet and metformin on reducing a type two diabetic's HbA1c (HbA1c). Initial treatments for T2DM can include, but are not limited to, lifestyle changes and/or metformin. A patient that wishes to use lifestyle interventions will likely use a mix of dietary changes facilitated by a registered dietitian (Grade A recommendation), increased physical activity to improve high density lipoprotein cholesterol levels (Grade B recommendation), and education from a diabetic educator (Grade B recommendation) (DynaMed Plus, 2017a). Metformin is a drug that is often used as initial pharmacologic therapy (Grade A recommendation) for T2DM (DynaMed Plus, 2017e). Metformin lowers basal and postprandial blood glucose levels by decreasing the production of glucose in the liver and decreasing intestinal absorption of glucose in the distal small intestine as described by DynaMed Plus (2017e).

Statement of the Problem

The number of T2DM patients continues to rise each year. Medical providers face the challenge of treating type two diabetes on a daily basis and there are numerous possibilities available as treatment options. Medical providers and patients need to be able to choose their first line treatment based on scientific evidence, effectiveness, and how that treatment will fit in with the patient's personal lifestyle. The low carbohydrate diet and metformin need to be compared in terms of effectiveness on HbA1c as the solo first line treatment of diabetes mellitus.

Research Questions

- In newly diagnosed type two diabetics presenting for initial treatment, does a low carbohydrate diet or metformin have a greater effect on lowering glycosylated hemoglobin?
- What are the advantages of a low carbohydrate diet on lowering glycosylated hemoglobin?
- What are the disadvantages of a low carbohydrate diet on lowering glycosylated hemoglobin?
- What are the advantages of metformin pharmacotherapy on lowering glycosylated hemoglobin?
- What are the disadvantages of metformin pharmacotherapy on lowering glycosylated hemoglobin?

Literature Review

• **Advantages of using diet management as first line treatment of type two diabetes mellitus.** The study done by Kirk et al. (2008) showed that the low carbohydrate diet groups decreased their HbA1c significantly with an average of 0.79%. The original research study done by Yamada et al. (2014) also showed a decrease in HbA1c of 0.6% in the patients that were studied. A meta-analysis done by Huntriss et al. (2017) examined eighteen studies and at the end of the twelve of the seventeen studies that were completed showed a decrease in HbA1c of more than 0.2% and of these studies, four of them had a decrease of more than 0.5%. There was a study done by Ajala et al. (2013) that determined that the low carbohydrate, low GI, Mediterranean, and high protein diets all reduced HbA1c by between 0.12% and 0.5% compared to the control diets within each group. A critical review of carbohydrate restriction on diabetes management that was done by Feinman et al. (2015) showed that a low carbohydrate diet decreased HbA1c by an average of 0.68%. This study was particularly interesting because the low carbohydrate diet was done as a first line treatment for managing diabetes. The study done by Tay et al. (2015) showed that the HbA1c was decreased the same amount in both the low carbohydrate and high carbohydrate diet groups that were being studied. Kodama et al. (2009) compared a high carbohydrate low fat diet with a low carbohydrate high fat diet. The analysis showed that there was no significant difference in the HbA1c outcomes. Jung and Choi (2017) showed there was no difference in HbA1c between the low carbohydrate and high carbohydrate diet groups.

• **Disadvantages of using diet management as first line treatment of type two diabetes mellitus.** The most prominent disadvantage of using a low carbohydrate diet as first line treatment for T2DM is adherence. One thing that Feinman et al. (2015) noted was that the low carbohydrate diet group had unlimited access to food, but they had to restrict their carbohydrate intake which they thought was easier to adhere to than other types of diets that had a strict reduction in calories leading to a lower adherence rate. Although many of these studies showed that the low carbohydrate diet was beneficial for several health parameters, Kirk et al. (2008) discussed their concern about the sustainability of the results achieved by the low carbohydrate diet once the patient goes back to a higher carbohydrate intake. Another disadvantage of using a low carbohydrate diet as a first line treatment of T2DM is that, as stated above in several studies, the low carbohydrate diet is not improving diabetic parameters significantly more than any other type of diet. The important thing seems to be a reduction in the patient's weight which can be obtained by any type of diet that causes a person to decrease their weight.

• **Advantages of using metformin as first line treatment of type two diabetes mellitus.** The study done by Gonzalez-Ortiz et al. (2012) showed a greater than one percent drop in HbA1c in more than 60% of the participants at the completion of the study. Kashi, Mahrooz, Kianmehr, and Alizadeh (2016) found that over a three-month period, the patients undergoing metformin therapy had a 0.65% decrease in HbA1c. The study done by Nichols et al. (2016) was broken down into adherence groups. Adherence below 50% showed no statistical difference in HbA1c, adherence between 50% and 79% had an average decrease of 0.45% in HbA1c, and the adherence group of 80% or greater was associated with a decrease of 0.73% in their HbA1c. Romanelli et al. (2015) studied two groups that initiated metformin therapy at different times. During this study, the researchers found that the early initiation group had a 0.36% greater decrease in HbA1c and were also more likely to reach a HbA1c target value of less than 7%. Williams et al. (2014) found that the patients that were on the maximum dose of metformin had a 0.61% greater decrease in their HbA1c compared to the untreated group.

• **Disadvantages of using metformin as first line treatment of type two diabetes mellitus.** The disadvantages of using metformin include, but are not limited to, possible hypoglycemic events, lactic acidosis, cost, and also the risk of not making any lifestyle changes to reverse the disease itself. Since metformin prevents the formation of glucose, this can decrease the amount of glucose in the bloodstream and cause hypoglycemia. (DynaMed Plus, 2017e) This can also be caused by a patient missing or skipping a meal, excessively exercising, or drinking alcohol. This risk is increased if the patient moves from solo metformin pharmacotherapy to combination therapy using metformin and another antihyperglycemic drug. According to Buse et al. (2016) the accumulation of metformin can lead to lactic acidosis. The use of metformin in a patient with other comorbidities such as heart failure, renal insufficiency, hypoxia, or sepsis can increase the risk of lactic acidosis (DynaMed Plus, 2017e). With the amount of people diagnosed with T2DM, there is potentially 54 billion dollars being spent on metformin alone every year making it a financial burden on those involved. The final disadvantage of using metformin as initial therapy for T2DM is not actually treating the underlying cause of the T2DM. As described by Roumie et al. (2016), once patients are put on metformin pharmacotherapy without initiating lifestyle changes (such as dietary management, physical activity, or diabetic education), these patients have a 50% chance of intensifying their pharmacotherapy to combination therapy within four years.

Discussion

In newly diagnosed type two diabetics presenting for initial treatment, does a low carbohydrate diet or metformin have a greater effect on lowering HbA1c?

- Through the above research, it was found that using a low carbohydrate diet almost always decreased the patient's HbA1c.
- There was between a 0.2% decrease (Huntriss et al., 2017) and a 2.2% decrease (Kirk et al., 2008) in HbA1c.
- Metformin showed a 0.45% decrease in HbA1c (Nichols et al., 2016) up to a greater than one percent decrease in HbA1c as expressed by Gonzalez-Ortiz et al. (2012).
- A problem that was encountered with this research was that the amount of studies within the past ten years were limited.

What are the advantages of a low carbohydrate on lowering HbA1c?

- Provides additional improvement in health parameters including weight, high density lipoprotein cholesterol, triglycerides, and HbA1c.
- Many of the studies showed no significant difference between the HbA1c effects from the low carbohydrate diet versus the other types of diets studied. Ajala et al. (2013) Tay et al. (2015), Kodoma et al. (2009), and Jung and Choi (2017)

What are the disadvantages of a low carbohydrate diet on lowering HbA1c?

- Many of the studies did not specify what they meant by low carbohydrate. Because of this, it is not clear that the patients were consuming the same amount of carbohydrates in all of the studies.
- The final disadvantage is adherence. Not every patient is going to be willing to adhere to a low carbohydrate diet in order to lower their HbA1c.

What are the advantages of metformin pharmacotherapy on lowering HbA1c?

- The studies show that a patient taking metformin has a decrease in HbA1c ranging from 0.45% to greater than 1% (Nichols et al., 2016; Gonzalez-Ortiz et al. 2012).
- Romanelli et al. (2015) found that patients that started taking metformin within approximately three weeks of their diagnosis had a significantly higher chance of reaching the goal range of less than 7% in HbA1c. This group also had a 0.36% greater decrease in HbA1c during the study.
- Nichols et al. (2016) found that in the group that had a lower than 50% adherence to their prescribed treatment, there was no change in HbA1c. The group that had between 50% and 79% adherence saw a decrease in HbA1c of approximately 0.45% and the group with 80% or greater adherence to their metformin therapy saw a decrease of about 0.73% in their HbA1c.

What are the disadvantages of metformin pharmacotherapy on lowering HbA1c?

- The main two serious side effects that should be watched for with metformin are hypoglycemia and lactic acidosis (Bardal et al., 2011; Buse et al., 2016).
- The cost of metformin can be a huge expense which could be up to 54 billion dollars per year being spent on T2DM metformin pharmacotherapy in the United States alone (Epocrates, 2012).
- Finally, Qaseem et al. (2017) found that most diabetic drugs were shown to lower HbA1c to approximately the same level. This means that there are different pharmacotherapy options available that can decrease HbA1c and possibly improve other health parameters as well.

Applicability to Clinical Practice

- Almost one tenth of the population of the United States of America is currently diagnosed with T2DM according to the American Diabetes Association (2017). Throughout the research done for this project, it has become evident that there is more than one way to treat T2DM. The two treatments that have been compared in depth are metformin pharmacotherapy and a low carbohydrate diet.
- With a low carbohydrate diet, a patient is able to lower their body weight and BMI, raise their high density lipoprotein cholesterol, lower their triglycerides, and decrease their HbA1c. The problem is that not every patient is going to be ready and willing to adhere to a strict diet to treat their type two diabetes. This is where education comes in. It is important to educate these patients and even involve the registered dietitian and diabetic educator. The low carbohydrate diet is effective at treating T2DM only in the patients who are ready and willing to adhere to the diet and make a lifestyle change to improve their health.
- Metformin, on the other hand, has been used as a first line treatment for T2DM for centuries (Bardal et al., 2011). It has been proven to be effective and is an oral drug that is not difficult to add into a person's every day routine. It is believed that even if a patient begins metformin pharmacotherapy immediately at diagnosis of T2DM, there must be consultation with a diabetic educator and registered dietitian with frequent follow ups.
- It was not found that either the low carbohydrate diet or metformin pharmacotherapy was more effective. They were both proven to be effective at lowering a patient's HbA1c, but the main thing that was found was that each patient is different and a treatment that fits well in one patient's life may not be reasonable in another patient's life. Each patient that is diagnosed with T2DM must be educated on the treatment options and provided the support they need to both decide on a treatment option and adhere to it.

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