CLINICAL PRACTICE RECOMMENDATIONS FOR SCREENING PATIENTS WITH TYPE-2 DIABETES FOR VITAMIN D DEFICIENCY: AN INTEGRATIVE LITERATURE REVIEW

by

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As members of the DNP Project Committee, we certify that we have read the DNP Project prepared by Stephanie Eileen Geier entitled "Clinical Practice Recommendations for Screening Patients with Type-2 Diabetes for Vitamin D Deficiency: An Integrative Literature Review" and recommend that it be accepted as fulfilling the DNP Project requirement for the Degree of Doctor of Nursing Practice.

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DEDICATION

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ABSTRACT

Type-2 diabetes is a nationally growing health concern. Previous literature has implicated that vitamin D deficiency and type-2 diabetes are interconnected. At this time there are no guidelines in place to guide the evaluation or treatment of vitamin D deficiency in type-2 diabetic patients. In order to create up to date guidelines for the treatment and evaluation of vitamin D deficiency in type-2 diabetic patients an integrative literature review was conducted using EMBASE, PubMed, and CINAHL. The literature review resulted in 44 articles that met the inclusion and exclusion criteria. The literature review resulted in the creation of five clinical recommendations. The most significant change to current clinical standards includes screening all type-2 diabetic patients for vitamin D deficiency. Vitamin D supplementation is not recommended for use in treating type-2 diabetes, diabetic complications, or preventing the progression from prediabetes to diabetes. However, type-2 diabetic patients with vitamin D deficiency should be treated with vitamin D supplementation to improve indirect health outcomes and prevent morbidity and mortality.

INTRODUCTION

Type-2 diabetes is a growing national epidemic with nearly 1.7 million people newly diagnosed each year (American Diabetes Association, 2014). If the current trend continues, it is estimated that one out of three adults will be diagnosed with type-2 diabetes by the year 2050 (Lazear & Kupustin, 2014). In 2010, type-2 diabetes was the seventh leading cause of death in the United States (American Diabetes Association, 2014). Patients diagnosed with type-2 diabetes are at increased risk of developing complications and comorbid disease conditions, including hypoglycemia, hypertension, dyslipidemia, cardiovascular disease, myocardial infarction, stroke, blindness, and kidney disease (American Diabetes Association, 2014). In order to address this growing health disparity and improve patient outcomes, it is important to update the clinical guidelines related to the treatment and prevention of type-2 diabetes. Recent research literature has identified a link between vitamin D deficiency and type-2 diabetes (Kruel-Poel, 2014). This research suggests that vitamin D may play a role in the progression of type-2 diabetes in the adult population. In order to improve patient care modalities in treating patients with type-2 diabetes it is important to understand the relationship between vitamin D deficiency and its impact on the disease process.

Background Knowledge

Type-2 diabetes is a chronic disease caused by insulin resistance and relative impairment in insulin secretion (McCulloch & Robertson, 2016). Patients are diagnosed with type-2 diabetes mellitus based on the following findings: fasting plasma glucose greater than 126 mg/dL, hemoglobin A1C greater than 6.5 percent, two-hour plasma glucose greater than 200 mg/dL, or a random plasma glucose of greater than 200 mg/dL with the presence of symptoms (McCulloch &

Hayward, 2016). Patients at risk for type-2 diabetes include those with first-degree relatives with type-2 diabetes, patients older than 45 years, patients with a body mass index (BMI) greater than 25, patients with dyslipidemia or hypertension, or those patients with a history of vascular disease (McCulloch & Hayward, 2016). The current treatment for patients with type-2 diabetes includes patient education, evaluation for micro- and macrovascular complications, minimizing cardiovascular risk, avoidance of drugs that lead to impaired glucose metabolism, and attempts to maintain a normal blood glucose level (McCulloch, 2016). It is important for patients with type-2 diabetes to maintain near normal blood sugar levels in order to reduce the risk of microvascular and macrovascular complications; therefore it is important to explore all possible methods for improving glucose control and insulin secretion (McCulloch, 2016). Recent literature has suggested that patients with vitamin D deficiency are at increased risk of developing microvascular diseases, such as diabetic peripheral neuropathy (Lv et al., 2014).

Vitamin D deficiency has been identified as a growing health concern worldwide. It is estimated that approximately one billion people are deficient in vitamin D (Krul-Poel, 2014). The Endocrine Society's Clinical Practice Guideline for the Evaluation, Treatment, and Prevention of Vitamin D Deficiency defines vitamin D deficiency as a serum circulating 25-hydroxyvitamin D [25(OH)D] level below 20 ng/ml (500 nmol/liter), and vitamin D insufficiency as 25(OH)D between 21-29 ng/ml (525-725 nmol/liter) (Holick et al., 2011). The major causes of vitamin D deficiency are decreased intake or absorption, reduced sun exposure, decreased endogenous synthesis (within the liver and kidney from UVB exposure), end-organ resistance to vitamin D, and increased hepatic catabolism (Dawson-Hughes, 2016). Interestingly, patients with renal failure, often times a complication of uncontrolled type-2 diabetes, are at

higher risk of vitamin D deficiency due to decreased calcitriol (1,25 dihydroxyvitain D) production secondary to decreased glomerular filtration (Agus & Drezner, 2016). Furthermore, the link between type-2 diabetes and vitamin D deficiency is hypothesized to be due to vitamin D receptors (VDR) located on the pancreatic beta cells (Jorde et al., 2016). The Endocrine Society's Clinical Guidelines for the Evaluation, Treatment, and Prevention of Vitamin D Deficiency explains that most tissues in the body have VDR and these receptors influence the expression of one third of the human genome and chronic diseases, including colon cancer, breast cancer, pancreatic cancer, type 1 and 2 diabetes, rheumatoid arthritis, and Crohn's disease (Holick et al., 2011). Additionally, the Endocrine Society's Scientific Statement in 2012 explains that the relationship between vitamin D deficiency and type-2 diabetes has not been established by RCTs (Rosen et al., 2012). The scientific statement based their research findings on a meta-analysis and systematic review of vitamin D and cardiovascular outcomes as well as a randomized control trial of the effect of calcium and vitamin D supplementation on the risk of diabetes in postmenopausal women (Rosen et al., 2012). The systematic review and meta-analysis of 51 studies by Elamin et al. (2011) showed that there was no significant association between vitamin D level and glucose, lipid fractions, or blood pressure. The RCT conducted by de Boer et al. (2008) on the effects of calcium and vitamin D supplementation in postmenopausal women found that calcium and vitamin D supplementation did not reduce the risk of developing diabetes over a 7-year period. De Boer (2008) hypothesized that the results of this study may indicate that higher doses of vitamin D may be required for glucose control, as only 400 IU vitamin D was supplemented in this study. The Endocrine Society explained that most of the evidence as of 2012 shows correlational data that has revealed a relationship between type-2

diabetes and vitamin D deficiency based on observational and longitudinal studies. A review of more current research is indicated in order to gain a better understanding of the relationship between type-2 diabetes and vitamin D deficiency.

Recent research studies have revealed that a deficiency in vitamin D also leads to decreased insulin secretion (Jorde et al., 2016). A systematic review and meta-analysis of prospective studies found that the baseline vitamin D status in healthy adults is inversely associated with the future risk of type-2 diabetes (Khan, Kunutsor, Franco, Chowdhury, 2013). Afzal, Bojensen, & Nordestgard (2013) conducted a prospective cohort study and meta-analysis that revealed that patients with low vitamin D levels were more likely to develop type-2 diabetes compared to a patient with normal levels of vitamin D.

However, there is still conflicting research regarding the impact of vitamin D deficiency on type-2 diabetes. For example, a randomized controlled trial (RCT) was conducted to determine whether vitamin D supplementation improved glucose tolerance in type-2 diabetes, and the results did not support the notion that vitamin D improves insulin resistance (Jorde et al., 2016). The lack of success in finding an improvement in glucose control in RCTs may be due to the short duration of the RCTs, as T2DM is a slowly progressing disease and effect of vitamin D supplementation on diabetes may take years to become evident (Jorde et al., 2016).

A prospective cohort study and meta-analysis conducted by Afzal, Bojensen & Nordestgaard (2013) found that patients with decreased plasma vitamin D levels were found to have increased risk of type-2 diabetes. Furthermore, this study implicated the vitamin D status in two essential biologic processes of type-2 diabetes: insulin secretion and insulin resistance (Afzal, Bojensen & Nordestgaard, 2013). The findings of this study are similar to the findings

presented by Song et al. (2013), a meta-analysis that identified that low levels of circulating plasma vitamin D levels increased the risk of type-2 diabetes. Forouhi et al. (2012) also conducted a cohort study and meta-analysis on the relationship between type-2 diabetes and vitamin D status. The results of this study found a strong inverse relationship between low serum vitamin D levels and type-2 diabetes (Forouhi et al., 2012).

Krul-Poel (2014) conducted a randomized placebo-controlled trial to determine the effect of vitamin D supplementation on the glycemic control in patients diagnosed with type-2 diabetes. Interestingly, there was no significant change in insulin resistance HOMA-IR, HOMA-B, fasting glucose, or fasting insulin levels in patients with type-2 diabetes and vitamin D deficiency who were treated with 50,000 IU D3 given once monthly (Krul-Poel, 2014). However, there was a significant change in A1C levels in patients with type-2 diabetes and severe vitamin D deficiency who were supplemented with the same dose of vitamin D3 after 6 months (Krul-Poel, 2014). This study revealed that patients with type-2 diabetes and severe vitamin D deficiency (less than 30 nmol/l) saw improved A1C levels after supplementation of D3. Similarly, an open-label, within-subject, before-and-after prospective study found a 37% increase in insulin sensitivity in patients with impaired fasting glucose levels and vitamin D deficiency who were treated with 10,000 IU D3 supplementation daily for 4 weeks (Nazarian et al., 2011).

A meta-analysis of prospective studies by Song et al. (2013) was conducted to determine whether there is a relationship between plasma vitamin D level and type-2 diabetes. Fifteen studies were included in the meta-analysis and the results revealed that there is an inverse relationship between plasma vitamin D levels and the incidence of type-2 diabetes (Song et al., 2013). The results of this meta-analysis conflict with the results of a randomized double-blind,

placebo-controlled trial of ethnic minorities with prediabetes and vitamin D deficiency. The results of this study showed no change in fasting plasma glucose levels or oral glucose tolerance test results after vitamin D levels were raised to 65-90 ng/mL (Davidson, Duran, Lee, & Freidman, 2013).

Due to the conflicting research regarding the association between vitamin D deficiency and type-2 diabetes some researchers have studied whether there is a genetic component to the relationship. Wang et al. (2014) conducted a meta-analysis and systematic review to test the association between vitamin D binding protein (DBP) and the incidence of type-2 diabetes. The results of this study showed that there is no association between DBP and T2DM in Asians and Caucasians, however, studies done on Japanese and Pima Indians showed a relationship between DBP and T2DM (Wang et al., 2014). Similarly, Afzal et al. (2014) conducted a mendelian randomization study to determine whether low vitamin D levels are caused by a genetic variant that is also associated with the development of T2DM. The results of this study concluded that genotypes associated with high BMI are also associated with low vitamin D levels (Afzal et al., 2014). Additionally, genetic variants to the DHCR7 and CYP2R1 are associated with increased risk of type-1 diabetes and low vitamin D levels (Afzal et al., 2014).

A review of literature needs to be conducted in order to determine whether there is a association between vitamin D deficiency and type-2 diabetes. It is important to determine whether there is a connection between these two variables in order to improve care provided to patients with type-2 diabetes.

Relevance to Clinical Practice

Clinical practice guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances and represent an attempt to distill a large body of health care knowledge into a convenient, readily usable format" (DiCenso, Ciliska, Dobbins, & Guyatt, p. 155, 2005). At this time there are no clinical practice guidelines for the evaluation, treatment, or prevention of vitamin D deficiency in type-2 diabetes. In 2011 the Endocrine Society published clinical practice guidelines related to the evaluation, treatment, and prevention of vitamin D deficiency, which stated that "numerous epidemiological studies have suggested that a 25(OH)D blood level above 30 ng/ml may have additional health benefits in reducing the risk of common cancers, autoimmune diseases, type 2 diabetes, cardiovascular disease, and infectious diseases" (Holick et al., p. 1925, 2011). This clinical practice guideline did not provide recommendations for the evaluation or treatment of vitamin D deficiency in patients with type-2 diabetes. Similarly, the *Standards of Medical Care in Diabetes* (2016) does not have recommendations for screening or treating vitamin D deficiency. However, an Endocrine Society Scientific Statement on *The Nonskeletal Effects of Vitamin D* published in 2012, discusses that there may be a relationship between vitamin D deficiency and type-2 diabetes, yet more research needs to be done (Rosen et al., 2012). At this time, the Endocrine Society and the American Diabetes Association do not have specific recommendations for screening or treating type-2 diabetic patients for vitamin D deficiency. Moreover, the U.S. Preventive Services Task Force (2014) states "no recommendation" for screening community-dwelling, nonpregnant, asymptotic adults over the age of 18, due to

insufficient evidence. Thus, there is no current recommendation for screening patients with type-2 diabetes for vitamin D deficiency.

Despite the lack of guideline recommendations for routine population screening of patients for vitamin D deficiency, there continues to be an increase in vitamin D testing (Tapley et al., 2015). The Medicare Benefits Schedule expenditure on vitamin D testing increased from $109.0 million in 2009 to $151.1 million in 2012 (Boyages, 2016). A study conducted by Bilinski & Boyages (2013) on the evidence of over testing for vitamin D revealed that there is an unsustainable increase in vitamin D testing reflecting the growing awareness of the health consequences of vitamin D deficiency, however the lack of guidelines for vitamin D testing is responsible for inappropriate screenings. Without evidence-based clinical recommendations to guide screening practices for vitamin D deficiency in type-2 diabetes indiscriminant screening can occur, which is costly to the healthcare system as well as the patient population. In order to provide a rationale for screening type-2 diabetic patients for vitamin D deficiency, a current review of the literature should be performed to determine whether patients with type-2 diabetes are at increased risk of complications secondary to low vitamin D levels. By collecting current literature related type-2 diabetes and vitamin D deficiency it will be possible to formulate evidence-based practice recommendations for implementation into the clinical practice setting.

Evidence-based nursing is at the core of the practice for a doctorally prepared family nurse practitioner. Evidence-based practice involves integrating the best evidence with clinical expertise and patient values into the decision making process at the clinical level (DiCenso, Ciliska, & Guyatt, 2005). DiCenso, Ciliska, & Guyatt (2005) explain that the term best evidence refers to methodologically sound and clinically relevant research about the effectiveness of

nursing interventions, accuracy of assessment measures, strength of causal relationships, and the power of prognostic markers. The key element of evidence-based practice is personalizing the evidence to fit a specific patient's circumstances (DiCenso, Ciliska, & Guyatt, 2005).

Purpose

The purpose of this DNP project is to conduct an integrative review of current literature related to vitamin D deficiency and diabetes (HbgA1C, fasting blood glucose, random blood glucose, insulin levels, and diabetic complications), and develop recommendations for implementing this information into clinical practice. Acquiring information related to the relationship between vitamin D deficiency and type-2 diabetes will help guide several aspects of care provided to patients with type-2 diabetes. First, a review of the current literature will determine whether there is a relationship between vitamin D deficiency and the onset and progression of type-2 diabetes. A review of literature may also provide information on the effects of vitamin D deficiency on the progression of diabetic complications, such as peripheral neuropathy. Next, the data obtained in this literature review will provide health care providers with necessary information to guide screening vitamin D deficiency in type-2 diabetic patients. Lastly, a review of literature will determine whether there is sufficient evidence to recommend a change to current clinical practice guidelines related to type-2 diabetes and vitamin D deficiency. It is important to determine whether there is enough evidence to support the recommendations of routine screening of vitamin D deficiency in patients with type-2 diabetes. With the obesity epidemic at an all time high and an increasing number of patients diagnosed with type-2 diabetes it is imperative to examine all factors contributing to the progression of this chronic disease. If the current research reveals a connection between vitamin D deficiency and the progression of

insulin resistance it would provide valuable information to health care providers who routinely treat type-2 diabetic patients. The findings of this literature review could help guide the implementation of evidence based practice guidelines for type-2 diabetic patients.

The review of literature will be conducted in the format of an integrative review of literature. An integrative review is a comprehensive methodological approach to reviewing literature related to a clinical problem using diverse methods (Souza, Silva, & Carvalho, 2010). An integrative review of literature will provide a study of the current information related to the relationship between vitamin D deficiency and type-2 diabetes. After the conducting the review of literature, clinical practice recommendations will be made based on the findings. Practitioners can use the results of the integrative review to guide changes to current clinical practice and improve care provided to patients with type-2 diabetes and vitamin D deficiency.

Study Question

Based on an integrative review of current literature, what is the relationship between type-2 diabetes and vitamin D deficiency and how can these results be applied to current practice standards for patients with type-2 diabetes?

FRAMEWORK & SYNTHESIS OF EVIDENCE

Theoretical Framework

The theoretical framework that will be used to guide this DNP project is the ACE STAR Model of Knowledge Transformation. The ACE Star Model was developed by The Academic Center for Evidence-Based Practice as a model to guide the translation of comprehensive research into clinical practice (Stevens, 2013). The model guides both translation and implementation of research into clinical practice (Schaffer, Sandau, & Diedrick, 2012). This

model is based on a five-point star that conveys crucial steps to take when converting knowledge into practice (Stevens, 2013). The five points include: research discovery, evidence summary, translation into guidelines, practice integration, and process and outcome evaluation (Stevens, 2013). See figure 1 for a depiction of the model created by Stevens (2012). This model offers benefits such as ease of use, due mainly to its close resemblance of the nursing process, and emphasizes the importance of knowledge transformation in advanced practice nursing-guided quality improvement projects (Schaffer, Sandau, & Diedrick, 2012). The goal of the ACE Star Model is *knowledge transformation,* defined as "the conversion of research findings from primary research results, through a series of stages and forms, to impact health outcomes by way of [evidence-based] care" (Gawlinski & Rutledge, p. 298, 2008).

The first step in the ACE Star Model is discovery of knowledge. In the case of this DNP project, the discovery of research stage includes the research related to the practice question that has already been completed. This DNP project begins with the second point in the ACE Star Model, the summary of evidence. In the second point, a rigorous review process will be completed in the form of an integrative review of literature related to type-2 diabetes and vitamin D deficiency. Integrative reviews are successful at evaluating the strength of current scientific evidence and identifying gaps in current research in order to contribute to a body of knowledge (Russell, 2005). The third step is the translation of the evidence into clinical practice (Schaffer, Sandau, & Diedrick, 2012). The translation stage is aimed at suggesting changes to current clinical standards based on the findings of the research. It is in this step that the findings of the literature will be used to determine whether changes should be made to the current standards of care provided to patients with type-2 diabetes. In this DNP project specific clinical practice

recommendations will be made based on the results of the literature review. The fourth step is the integration of the recommended change into clinical practice (Schaffer, Sandau, & Diedrick, 2012). The fourth step in the ACE Star Model is not part of this DNP project, however it remains an imperative part of the full implementation of the findings. The fourth step is the practice integration stage, which focuses on implementing the findings of this DNP project into clinical practice in the primary care setting. In this DNP project, recommendations for implementation at the local level will be discussed. Lastly, the fifth step is the evaluation of the implemented clinical practice change based on its contribution to the quality of care (Schaffer, Sandau, & Diedrick, 2012). This step will not be completed within the realms of this DNP project, however this step remains an imperative part of the full implementation of the findings of this DNP project at the level of the clinical setting. The goal of this DNP project is to complete the second and third point within the ACE Star Model, and the expectation is that the fourth and fifth be completed at the local level of the clinical setting that implements the recommendations from this project. The ACE Star Model of Knowledge Transformation provides an organized and practical framework for implementing findings of this DNP project into clinical practice.

Concepts

When conducting an integrative review, it is important to maintain methodological rigor by objectively basing the research question on a theoretical framework with clear concepts, thus guiding all subsequent stages of the review (Soares et al., 2013). In understanding this DNP project it is important to define vitamin D deficiency, vitamin D insufficiency, vitamin D levels, vitamin D supplementation, type-2 diabetes, prediabetes, diabetic complications, insulin sensitivity, and insulin resistance.

According to The Endocrine Society, the definition of vitamin D deficiency is a circulating serum 25-hydroxyvitamin D [25(OH)D] level below 20 ng/ml (50 nmol/liter) (Holick et al., 2011). Vitamin D insufficiency is defined as a 25(OH)D level of 21-29 ng/ml (52.5-72.5 nmol/liter) (Holick et al., 2011). For the purpose of this paper, plasma/serum vitamin D levels will be defined as the lab value of 25-hydroxyvitamin D [25(OH)D] measured by a reliable assay. At this time, it is not recommended by the Endocrine Society to use the 1,25-dihydroxyvitamin D [1,25(OH)2D] lab assay when measuring serum vitamin D serum levels (Holick et al., 2011). In the event that a lab test other than the 25(OH)D test the lab test measures will be specified.

Vitamin D supplementation is an important concept in this DNP project. Vitamin D is a fat-soluble vitamin that can be obtained through diet or via dermal synthesis from sunlight (Pazirandeh & Burn, 2016). Vitamin D plays a significant role in health because of its relationship with calcium homeostasis and bone formation (Pazirandeh & Burn, 2016). There are two different types of vitamin D supplementation: D3 (cholecalciferol) and D2 (ergocalciferol). Vitamin D2 is created from radiation of ergosterol plants, mold, and plankton (Pazirandeh & Burn, 2016). Vitamin D3 is synthesized in the skin of animals from UVB wavelengths and becomes 7-dehydrocholesterol, which then becomes previtamin D3, essentially becoming D3 with further thermal isomerization (Tripkovic et al., 2012). Currently, both vitamin D3 (cholecalciferol) and D2 (ergocalciferol) are available in the form of dietary supplements. In this DNP project vitamin D supplementation will be defined as either vitamin D3 or D2, as both forms are used in current clinical studies related to vitamin D deficiency and type-2 diabetes.

For the purpose of this DNP project, type-2 diabetes is used to describe the patient population of interest. This DNP project will include studies that include patients with type-2 diabetes and prediabetes. Patients with type-2 diabetes are defined as those patients who have been diagnosed with type-2 diabetes by a health care professional based on clinical criteria. Patients with prediabetes are those patients who do not meet the diagnostic criteria of type-2 diabetes but still have elevated blood glucose levels (American Diabetes Association, 2016). According to the American Diabetes Association (2016) patients are considered prediabetic with a fasting blood glucose level of 100-125 mg/dL or an A1C level of 5.7-6.4%. Patients with type-2 diabetes and prediabetes are at risk for complications secondary to chronically elevated blood glucose levels (American Diabetes Association, 2016). For the purpose of this DNP project, diabetic complications will be defined as microvascular complications or macrovascular complications. Microvacular complications are complications that occur secondary to chronically elevated blood glucose levels that cause damage to blood vessels in the eyes, kidneys, and nerve tissues (Leontis & Hess-Fischl, 2014). The microvascular damage to vessels may lead to retinopathy, nephropathy, or peripheral neuropathy (McCulloch, 2016). Macrovascular complications are those that result from damage to larger vessels in the heart, brain, and systemic blood vessels (Leontis & Hess-Fischl, 2014; McCulloch, 2016). Macrovascular damage can result in ischemic heart disease, peripheral vascular disease, or cerebral vascular disease (McCulloch, 2016). Diabetic complications are a result of insulin resistance and decreased insulin sensitivity seen in patients with prediabetes and type-2 diabetes. Insulin resistance is defined as the inability of exogenous or endogenous insulin to increase glucose uptake and