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REVIEW, APPROVAL AND ACCEPTANCE

The document mentioned above has been reviewed and accepted by the student's advisor, on behalf of the advisory committee, and by the Assistant Dean for MSN and DNP Studies, on behalf of the program; we verify that this is the final, approved version of the student's DNP Project including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

Whitney R. Munroe, Student

Dr. Nancy R. Kloha, Advisor

Final DNP Project Report

Measuring Providers' Adherence to the American Diabetes Association Screening
Recommendation for Prevention of Diabetic Nephropathy

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College of Nursing

Spring 2015

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Dedication

I would like to dedicate this Capstone project to my mom and sister for always believing in me and providing me with support and encouragement and understanding for the past 4 years as I've completed this program. Also for tolerating my lugging suitcases of books along on trips, and watching Skipperson for me so I could get everything finished. I love my fellow future Golden Girls!!

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Introduction to DNP Practice Inquiry Project

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University of Kentucky

Type 2 diabetes mellitus (DM) has reached epidemic proportions in the United States. Current estimates predict that 29 million people, or approximately one in 11 persons, in the country are currently diagnosed with type 2 DM and an additional 7 million remain undiagnosed, which makes it the 7th leading cause of death nationwide (CDC, 2014). Additionally, 86 million adults 20 years of age have pre-diabetes, which represents a significant increase in the likelihood of progressing to type 2 DM within 10 years if risk factors are not controlled (CDC, 2014).

This disease has an enormous impact on the state of Kentucky, with an estimated 370,000 adults (10.7% of the population 18 years of age) having been diagnosed and an additional 233,000 with pre-diabetes (Kentucky Department for Public Health, 2010). This is higher than the national average of 8.3% and places Kentucky at 7th in the nation for cases of diagnosed type 2 DM. Currently, 40.1% of adults ages 40 to 74 have pre-diabetes, and type 2 DM is the 6th leading cause of death in the state (Kentucky Diabetes Report Card, 2013).

In addition to helping patients reach glycemic targets, primary care providers are also expected to identify and manage a variety of resulting complications, including diabetes-related kidney disease. If identified early, the progression of this condition can be slowed, leading to cost savings and increased patient quality of life. This can be accomplished through screening as recommended by the American Diabetes Association (ADA), which has been shown to be cost-effective and beneficial to the care and treatment goals for patients with type 2 DM.

This Doctorate of Nursing Practice (DNP) Practice Inquiry Project investigates the current screening rates for microalbuminuria, the earliest indicator of renal problems in patients with type 2 DM. This project specifically addresses screening rates in the primary care setting.

The first manuscript is a literature review, which focused on identification and treatment strategies for diabetic kidney disease (DKD). This review examined 10 articles that addressed these areas. This literature review identified monitoring for and early identification of microalbuminuria as the most important factor in preventing renal complications for patients with type 2 DM, which led to the focus of the study.

The second manuscript reviewed a clinical practice guideline from the American Diabetes Association (2015) regarding management of the patient diagnosed with diabetes. While it addresses all areas of screening and management, special emphasis is placed on recommendations for managing the renal complications of type 2 DM. Of these recommendations, recommendation for screening included obtaining an annual urinary albumin excretion level in all patients with type 2 DM, beginning at the time of diagnosis. This led the primary investigator (PI) to the question ‘What are the current rates of screening for urinary albumin excretion levels in the primary care setting’?

The third manuscript serves as the report for a study completed in 2015 addressing provider adherence to the ADA recommendation that all patients diagnosed with type 2 DM receive annual screening for microalbuminuria, beginning at the time of diagnosis. A retrospective chart review was conducted in a primary care setting. Recommendations are also provided regarding future research aimed to improve adherence to this recommendation.

Prevention of Diabetes-Associated Renal Complications: A Literature Review

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Abstract

Purpose: The purpose of this literature review is to review some of the preventive factors for progression of microalbuminuria to overt diabetic kidney disease (DKD), as well as to explore some of the current treatment strategies utilized to delay the onset of renal complications in patients with type 2 diabetes.

Data Sources: The literature review was conducted using the CINAHL, PubMed, and Medline Plus electronic databases. Studies included were published between 1993 and 2013. Key words included in the database search were “type 2 diabetes”, “microalbuminuria”, “diabetic kidney disease”, “nephropathy”, and “renal complications”.

Conclusions: Many of the interventions utilized to treat diabetic kidney disease may delay, but not reverse, the progression of this condition. However, to reduce the progression to end stage renal disease (ESRD), it is imperative that clinicians monitor for and provide adequate treatment of this complication at the time of onset.

Implications for Practice: The most important consideration for preventing renal complications associated with type 2 diabetes is the monitoring for and early identification of microalbuminuria to prevent the progression to overt diabetic kidney disease (DKD).

Keywords: Type 2 diabetes mellitus, diabetic nephropathy, microalbuminuria, interventions

Prevention of Diabetes –Associated Renal Complications: A Literature Review

Type 2 diabetes mellitus (DM) affects approximately 19.6 million Americans aged 18 and older, a statistic that has more than tripled since 1980 (Centers for Disease Control [CDC], 2013). Type 2 DM accounts for 90 to 95% of all persons diagnosed with diabetes in the United States (CDC, 2014). The condition is diagnosed if an individual has a fasting blood glucose of 126 mg/dl on two separate occasions, a random plasma glucose of 200 mg/dL accompanied by classic symptoms of hyperglycemia (i.e., polyuria, polydipsia, weight loss, blurred vision, fatigue), or an HbA1c level 6.5% (American Diabetes Association [ADA], 2015).

Healthy People 2020 identified increased quality of life for diabetic patients as a national health care priority, including a reduction in the development of diabetes-related complications (United States Department of Health and Human Services [DHHS], 2013). A specific objective related to renal complications is Objective D-12 to ‘increase the proportion of persons with diagnosed diabetes who obtain an annual urinary microalbumin measurement’. In 2007, only 33.6 percent of Medicare beneficiaries with diabetes obtained a urinary microalbumin measurement. The goal of this objective is to increase the baseline rate by 10% to achieve at least a 37% measurement rate (U.S. DHHS, 2013). The *2015 Standards of Care* from the American Diabetes Association also contains multiple measures for detection and treatment of diabetes-associated complications, including prevention, identification, and treatment of renal complications (ADA, 2015).

Background

Type 2 DM is defined as a state of hyperglycemia resulting from a combination of insulin resistance and inadequate insulin secretion (American Diabetes Association, 2015). It is a life-long, progressive condition and the presence of a diabetes diagnosis is associated with multiple

complications and comorbidities as the disease progresses. One of the common complications resulting from progression of the disease is diabetic nephropathy. Nephropathy occurs in 20% to 40% of patients with diabetes and is the leading cause of end-stage renal disease (ESRD) (American Diabetes Association [ADA], 2015). Another widely recognized classification for nephropathy is diabetic kidney disease (DKD), which refers to a presumptive diagnosis of kidney disease caused by diabetes (Ahmed, 2014). The first clinical sign and early indicator of this condition is the appearance of albumin in the urine in small amounts, defined as microalbuminuria (Haller et. al, 2006). Microalbuminuria is defined as urinary albumin excretion of 30 mg/24 hours while albuminuria is defined as 300 mg/24 hours (The Diabetes Control and Complications Trial [DCCT], 1993). Important factors to consider in the development of diabetic kidney disease (DKD) include hyperglycemia, duration of the disease, hypertension, lipid abnormalities, albuminuria or proteinuria, ethnicity, genetic predisposition, smoking status, and advancing age (Vivian & Mannebach, 2013).

Additionally, the presence of chronic kidney disease (CKD) along with diabetes significantly increases a patient's risk for cardiovascular disease. CKD, particularly with the presence of significant albuminuria, should be considered an additional cardiovascular risk factor (Bakris et. al, 2010). Therefore, the finding of microalbuminuria warrants screening for possible vascular disease as well as aggressive interventions to reduce cardiovascular risk factors such as lowering of LDL cholesterol, antihypertensive therapy, smoking cessation, and weight control (ADA, 2004). These interventions simultaneously decrease the progression of microalbuminuria and decrease the patient's risk for cardiovascular complications such as stroke or myocardial infarction (MI).

Significance for Advanced Practice Nurses

Fortunately, with early detection and intervention, the progression of renal disease and risk for cardiovascular disease can be reduced dramatically. The excess risk of death from any cause in type 2 DM is associated almost entirely with the presence of kidney disease; in the absence of diabetic kidney disease (DKD), the risk of death among persons with diabetes is similar to that of the general population (Himmelfarb & Tuttle, 2013). This illustrates the importance of adequate monitoring for and early management of renal complications in the diabetic patient.

DKD is primarily identified and monitored through assessments of kidney function utilizing glomerular filtration rate (GFR) (<60 mL/min/1.73 m²) and kidney damage by estimating albuminuria (>30 mg/g creatinine) (Tuttle et. al, 2014). Without intervention, 20-40% of type 2 DM patients with microalbuminuria progress to overt nephropathy (ADA, 2004). With proper intervention, progression to overt nephropathy can be prevented or progression slowed. Although factors such as age and ethnicity cannot be controlled, others such as blood pressure and lipid abnormalities can. Adequate control of these modifiable risk factors can prevent renal complications and enhance longevity and quality of life for type 2 DM patients.

Purpose

The aim of this review is to summarize the evidence available regarding identification and treatment of microalbuminuria to prevent progression to development of diabetes-related kidney disease. This review will summarize findings from several high quality randomized controlled trials (RCTs) to determine which interventions have proven the most effective in preventing renal complications among those with type 2 DM.

Methods

In order to ensure a comprehensive view of the current literature regarding prevention of renal consequences related to diabetes, several medical research databases were reviewed, including the Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, and EBSCOhost. Search terms used included “diabetic nephropathy”, “microalbuminuria”, type 2 diabetes”, “renal complications”, “nephropathy”, and “diabetic kidney disease”.

The literature search was performed to identify current treatment strategies utilized in diabetic patients who develop kidney disease as a complication. Inclusion criteria included the study being printed in the English language, published between 2005 and 2015, and including patients with a dual diagnosis of type 2 DM and microalbuminuria. A total of 10 studies meeting this criteria were reviewed.

Results

The key factor in preventing DKD is monitoring for and identification of the presence of microalbuminuria (ADA, 2015). Multiple national guidelines have reached consensus that screening for DKD should include measurement of urinary albumin excretion, serum creatinine, and calculation of estimated glomerular filtration rate (eGFR) (Molitch et. al, 2004; International Diabetes Federation, 2012; National Kidney Foundation, 2007). The *2015 Standards of Care* recommend obtaining a quantitative urine albumin excretion level at the time of diagnosis of type 2 DM and at least yearly thereafter (ADA, 2015).

Other important factors in prevention of diabetic nephropathy are control of HbA1c and blood pressure control. There are many agents useful in preventing the progression of DKD and lowering the risk of cardiovascular events, including beta blockers, calcium channel blockers,

diuretics, angiotensin-converting enzyme (ACE) inhibitors, and angiotensin II receptor blockers (ARBs).

Adequate glycemic control is an important factor in preventing the development of DKD. There have been mixed results in determining whether or not intensive glucose control plays a role in reducing the risk of developing microalbuminuria or overt diabetic nephropathy or decreasing progression of existing impairment. Several large-scale studies such as the DCCT and the United Kingdom Prospective Diabetes Study (UKPDS) show that maintaining HbA1C levels as close to 7% as safely possible prevents microvascular complications such as microalbuminuria and macroalbuminuria (DCCT, 1993; UKPDS, 1998). Many other RCTs and systematic reviews suggest that intensive vs. conventional glucose control reduces the risk for microalbuminuria and other renal complications associated with type 2 DM (Coca et. al, 2012; Perkovic et. al, 2013; ACCORD, 2008). Risk reduction rates achieved through intensive glycemic control are estimated to be between 10% and 60% (Perkovic et. al, 2013; Skyler et. al, 2009). However, tight glycemic control is not without risk, most notably the risk of severe episodes of hypoglycemia (Slinin et. al, 2012; DCCT, 1993; ACCORD, 2008). Many organizations have come to the consensus that better outcomes are obtained with a goal HbA1c level <7% but that lower levels should be attained on an individualized basis (ADA, 2014; National Kidney Foundation, 2012).

Hypertension is recognized as a key contributing factor in the development and progression of kidney disease in patients with type 2 diabetes (Thomas & Atkins, 2006). Both systolic and diastolic hypertension have been shown to accelerate the progression of nephropathy (Vivian & Mannebach, 2013). Therefore, aggressive treatment of hypertension is critical in preventing the onset and progression of microalbuminuria and resultant DKD. Recent guidelines

suggest that diabetic patients should have a goal blood pressure of 130/80 mmHg (ADA, 2015). ACE inhibitors and ARBs, which target the renin-angiotensin system, have been shown to have more potent antiproteinuric effects with similar degrees of blood pressure reduction compared with other classes, and are therefore the preferred agents in patients with type 2 DM (Remuzzi, Macia, & Ruggenti, 2006);

Even in the absence of hypertension, it has been recommended that patients with type 2 diabetes be on either an ACE inhibitor or ARB to slow the progression of microalbuminuria. Extensive literature exists regarding the benefits of such treatment (Strippoli et. al, 2006; Misra & Stevermer, 2009; Juarez et. al, 2013; Yee, 2014). Therefore, the ADA, American Association of Clinical Endocrinologists (AACE), and the International Diabetes Foundation (IDF) all endorse use of either an ACE inhibitor or an ARB in patients with type 2 DM, hypertension, and micro- or macroalbuminuria (ADA, 2014; AACE, 2011; IDF, 2005). Many studies have explored whether or not an additional benefit can be attained by using an ACE inhibitor/ARB combination. The consensus is that combination therapy does not provide any additional benefits and may even increase adverse events and therefore is not recommended (Fried et. al, 2013; Juarez et. al, 2013; Mann et. al, 2013; Vivian & Mannebach, 2013).

The National Kidney Foundation and ADA currently recommend using LDL-cholesterol lowering medications such as statins to reduce the risk of major atherosclerotic events in patients with type 2 DM and renal disease (National Kidney Foundation, 2012; ADA, 2015). Targets should be LDL cholesterol <100 mg/dL, triglycerides <150 mg/dL, and HDL cholesterol >40 mg/dL (ADA, 2014). Higher levels of LDL cholesterol and triglycerides couple with low HDL cholesterol appear to be associated with greater risks of albuminuria and declining GFR; therefore, improvement in these parameters may play a role in reducing albuminuria (MacIsaac,

Ekinci & Jerums, 2014). Studies have shown that statins can play a role in reducing microvascular complications of diabetes without a negative impact on renal outcomes (Colhoun et. al, 2009; ACCORD, 2008; Haffner, 2003).

Conclusion

Many clinical trials intensifying the control of conventional risk factors have not shown improved outcomes. However, interventions such as treatment with ACE inhibitors or ARBs, lowering LDL cholesterol, and optimizing blood pressure control have proven somewhat effective in treating and preventing the progression of diabetic kidney disease. With the decreases in length and quality of life and health costs related to this complication, it is vital to continue to explore safe and effective management strategies. Many of the interventions identified in reducing the risk for diabetic nephropathy relate directly to controlling the modifiable risk factors.

The most important consideration in preventing renal complications associated with type 2 DM is the monitoring for and early identification of microalbuminuria to prevent the progression to DKD. Once identified, renoprotective and cardioprotective measures can be initiated to prevent the progression and delay complications.

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Table 1: *Summary of Articles Assessed in Literature Review*

Interventions to Decrease Diabetic Kidney Disease and Associated Increase in CVD risk					
Citation	Design	Sample	Purpose	Findings	Implications
Coca et. al, 2012	Systematic review	7 RCTs involving 28,065 adults monitored between 2 to 15 years	To summarize the benefits of intensive vs. conventional glucose control on kidney-related outcomes for adults with type 2 DM	Intensive glycemic control reduced the risk for microalbuminuria and macroalbuminuria, but not doubling of the serum creatinine level or death from renal disease compared with conventional control	Intensive glucose control reduces the risk for microalbuminuria and macroalbuminuria, but evidence is lacking that it reduces the risk for significant clinical renal outcomes such as doubling of the serum creatinine level, ESRD, or death from renal disease.
Colhoun et. al, 2009	Randomized placebo-controlled trial	2,838 patients with type 2 diabetes and no previous CVD	To examine whether atorvastatin affects diabetic kidney disease and whether the effect of atorvastatin on CVD varies by kidney status in patients	Atorvastatin treatment was associated with a modest improvement in annual change in GFR that was most apparent in those with albuminuria	The data from this study provide reassurance that the use of statins in the majority of patients with diabetes delivers substantial microvascular benefits, even in those with modest impairment in kidney function, is safe in regard to renal outcomes, and may even demonstrate a benefit on eGFR.

			with diabetes		
Diabetes Control and Complications Trial, 1993	Multi-center RCT	1,441 patients	To compare conventional with intensive diabetes therapy with regard to their effects on the development and progression of the early vascular and neurologic complications of IDDM.	Microalbuminuria (urinary albumin excretion of 40 mg/24 hours) or albuminuria (urinary albumin excretion 300 mg/24 hrs) developed in fewer patients in the intensive-therapy group than in the conventional therapy group. Intensive therapy decreased the mean adjusted risk of microalbuminuria from 43-56% between the two cohorts	Due to the demonstrated reduction in risks, it is recommended that most patients with IDDM be treated with closely monitored intensive regimens with the goal of maintaining their glycemic status as close to the normal range as safely possible. Intensive therapy should be implemented with caution due to risk of hypoglycemia.

Fried et. al, 2013 (VA NEPHRON-D Study)	Multi-center, double-blind, randomized controlled study	1448 veterans with diabetes and estimated GFR 30 to 89.9 mL/min/1.73m ² and a urinary albumin-to-creatinine ratio of at least 300	To determine the safety and effect of combining ACE inhibitor and ARB therapy in preventing the progression of kidney disease in the presence of proteinuria	Combination therapy with an ACE inhibitor and an ARB was associated with increased risk of adverse events among patients with diabetic nephropathy	Due to the increased risk of adverse events, this combination in patients with proteinuric diabetic kidney disease does not provide an overall clinical benefit
Juarez et. al, 2013	Randomized controlled trial (RCT)	133 patients with type 2 diabetic nephropathy aged 58-74	To compare the efficacy of combining the ACE inhibitor Lisinopril and the ARB irbesartan with that of each drug in monotherapy in slowing the progression of type 2 diabetic nephropathy	There were no significant differences in proteinuria reduction or blood pressure control between the 2 groups. The number of adverse events such as hyperkalemia was the same between all 3 groups.	Did not demonstrate a benefit of the combination of Lisinopril/irbesartan compared to either drug alone at optimal high doses or
Mann et. al, 2013	Randomized controlled	9,628 patients with diabetes,	To assess the safety of the	SBP decreased more with dual vs.	A combination of ACE inhibitors and ARBs does not increase strokes or alter other major

	trial	mean age of 66 years. 3,163 of the participants had nephropathy and 6,465 did not	addition of an ACE inhibitor (Ramipril) to an ARB (telmisartan) versus monotherapy in light of a recent study suggesting an increase in stroke risk in people with diabetes and renal disease	monotherapy and the same number of strokes occurred between the two groups. Stroke rate was higher in participants with than those without diabetic nephropathy, but effects of dual therapy vs. monotherapy were not different in either subgroup	cardiovascular or renal events in patients with diabetes, irrespective of the presence of nephropathy
Perkovic et. al, 2013 (ADVANCE)	RCT	11,140 total participants; 5,571 in the intensive group and 5,569 in the standard treatment group	To study the effect of intensive glucose control on major kidney outcomes in type 2 diabetes	Intensive glucose control significantly reduced the risk of ESRD by 65%, microalbuminuria by 9%, and macroalbuminuria by 30%. Additionally, the progression of albuminuria was significantly reduced by 10% and regression significantly increased by 15%.	Improved glucose control will improve major kidney outcomes in patients with type 2 diabetes.

Slinin et. al, 2012	Systematic review	5 RCTs related to intensive vs. conventional glycemic control, 5 RCTs for lipid-management strategies, and 11 RCTs for management of albuminuria	To evaluate data on the glycemic, lipid, and albuminuria management in patients with diabetes and CKD	Intensive vs. conventional glycemic control reduced the development of micro- and macroalbuminuria but did not reduce the incidence of primary or secondary clinical outcomes and was associated with a 2.5-fold increase in severe hypoglycemia. Statins did not reduce all-cause mortality or stroke compared to placebo in adults with diabetes and CKD. Fenofibrate increased regression of microalbuminuria to normoalbuminuria compared to placebo.	Intensive glycemic control and lipid interventions did not improve clinical outcomes in patients with type 2 DM. Although interventions typically improved albuminuria, evidence was insufficient to determine whether treatment of albuminuria in normotensive patients provides beneficial effects on clinical outcomes. More intensive management of patients with diabetes and CKD has inherent risks, including severe hypoglycemia, which should be considered when formulating treatment strategies.
Strippoli et. al, 2006	Systematic review	49 studies involving a total of 12,067	To evaluate the benefits and harms of	The effects of ACE inhibitors and ARBs on	The role of ACE inhibitors in the management of patients with DKD is well established. There is RCT evidence that ARBs are not as

		patients	ACE inhibitors and ARBs in patients with DKD	renal outcomes such as ESRD, doubling of serum creatinine, prevention of progression of micro- to macroalbuminuria, and remission of micro- to normoalbuminuria were similarly beneficial	effective in preventing deaths in patients with DKD as ACEIs. Both agents prevent progression of nephropathy and promote regression to a more favorable clinical pattern of normoalbuminuria. Data suggest that the cheaper class of agent with proven survival benefit (ACEIs) should be used as first line treatment.
Vivian & Mannebach, 2013	Review	Adult patients 18 years with diabetic nephropathy	To compare the benefit of additional blockage of the renin—angiotensin—aldosterone system through combination therapy with an ACE inhibitor and ARB, or a direct renin inhibitor (DRI), to monotherapy	Combination therapy with an ACE inhibitor or ARB, or DRI, has not been found to be more effective than monotherapy with either an ACEI or ARB. Furthermore, the combination may increase the risk of hyperkalemia or acute kidney injury	Although ACE inhibitors and ARBs remain first-line treatment for slowing the progression of diabetic nephropathy, recent studies suggest that combining the agents may increase adverse events without any clinical benefit to offset them

Table 2: *Healthy People 2020 Goal Related to Diabetic Kidney Disease*

Goal	Objective	Baseline Rate	Target Rate
D-12	To increase the proportion of those diagnosed with diabetes who obtain an annual urinary microalbumin measurement	33.6%	37%

(U.S. DHHS, 2013)

Clinical Practice Guideline Analysis: Standards of Medical Care in Diabetes

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Abstract

Purpose: To analyze the 2015 *Standards of Medical Care in Diabetes* published by the American Diabetes Association (ADA), with a special emphasis on the sections related to managing renal complications in patients with type 2 diabetes mellitus (DM).

Data Sources: American Diabetes Association (ADA) *Standards of Medical Care in Diabetes*, literature review articles

Implications for Practice: There are a variety of screening and management measures that should be taken in regard to all patients with type 2 DM. Clinicians should take special care in not only optimizing glucose control, but also in screening for and preventing complications such as cardiovascular and renal disease.

Conclusion: The *Standards of Medical Care in Diabetes* offers providers guidelines for providing high-quality, comprehensive care to patients with type 2 diabetes mellitus (DM). It includes management of the condition and prevention of complications, including interventions and treatment specifically directed toward decreasing morbidity and mortality associated with renal complications.

Keywords: Type 2 diabetes mellitus, management, guidelines, complications

Clinical Practice Guideline Analysis: Standards of Medical Care in Diabetes

The clinical practice guideline reviewed for this analysis was *Standards of Medical Care in Diabetes* developed by the American Diabetes Association (ADA). The guideline was originally developed in 1988 and was most recently updated in January 2015.

Scope and Purpose

Type 2 diabetes mellitus (DM) is defined as a state of hyperglycemia resulting from a combination of insulin resistance and inadequate insulin secretion (ADA, 2015). It is a life-long, progressive condition and the presence of a diabetes diagnosis is associated with multiple complications and comorbidities as the disease progresses. For example, type 2 diabetes is the leading cause of new cases of kidney failure, non-traumatic lower extremity amputations, and blindness among adults (Schellenberg, Dryden, Vandermeer, Ha, & Korownyk, 2013; CDC, 2014; Ratner, 2012). Furthermore, patients with diabetes have a two to four-fold greater risk for heart disease and stroke than those without the disease (Ginsberg & MacCallum, 2009; Unachukwu & Ofori, 2012; Stratmann & Tschoepe, 2011; Duan et. al, 2014).

Nationwide, type 2 diabetes has reached epidemic proportions. In the United States, its prevalence has more than tripled in the time period from 1980 to 2011; there are currently an estimated 20.9 million people living in the country with this diagnosis and an additional 7 million still undiagnosed (CDC, 2011). Additionally, it is projected that this rate will continue to increase and by 2020 nearly half of all Americans will be affected (United Health Group, 2010; CDC, 2012; Aston, 2013). If the current predictions based on prevalence and incidence for Type 2 diabetes hold steady, more than 10% of the world's population, or 552 million people, will have the disease by 2030 (Hu, 2011; Hirsch et. al, 2012; International Diabetes Federation, 2013). Financially this condition has an enormous impact on the health care system, costing an

estimated \$174 billion, with \$116 billion accounting for direct costs and \$58 billion for indirect costs such as lost productivity, disability, and premature mortality (Sease, Franklin, & Gerrald, 2013; Dall et. al, 2014). As demonstrated above, type 2 DM has costs both financially and in terms of quality of life of the patients affected.

Diabetes is the 6th leading cause of death in the state of Kentucky (Kentucky Diabetes Report, 2013). The 2010 Kentucky Behavioral Risk Factor Survey shows that as many as 370,000 adults in Kentucky have been diagnosed with diabetes and an additional 233,000 adults have prediabetes (Kentucky Department for Public Health, 2010). Rates vary from 3% of the population in Oldham County to 16% in Casey County (Kentucky Institute of Medicine, 2007). Costs in the state equaled \$4.8 billion in 2011, with total hospitalization charges of \$183 million and \$23 million for emergency department visits alone (Dickson, 2013).

Objective

The objective of the '*Standards of Medical Care in Diabetes*' guideline developed by the American Diabetes Association is to provide clinicians, patients, researchers, payers, and other interested individuals with the components of diabetes care, general treatment goals, and tools to evaluate the quality of care provided (ADA, 2015). Since diabetes is such a complex condition, this guideline provides some consistency in terms of treatment modalities, monitoring recommendations, and management of complications resulting from progression of the disease.

Stakeholder Involvement

The professional group responsible for the development of the *Standards of Medical Care in Diabetes* is the American Diabetes Association (ADA). The professional practice committee involved in the development of the Standards of Care is a multidisciplinary group comprised of physicians, diabetes educators, registered dietitians, and others who have a wide

range of expertise in areas such as adult and pediatric endocrinology, epidemiology, public health, lipid research, hypertension, and preconception and pregnancy care (ADA, 2015).

Upon review of the member list of the professional practice committee, it appears that all relevant groups were represented. There were multiple physicians and a few advanced practice nurses, a couple of whom specialized in diabetes. This is important because these groups are often directly involved in the diagnosis and management of patients with diabetes. It is important to have registered dietitians as part of the team because they are often involved in the advanced dietary teaching and concepts such as carb counting that are so critical to the patient's self-management success.

The target users of the guideline are clearly identified as APRNs, allied health professionals, dietitians, hospitals, nurses, patients, physician assistants, physicians, and public health departments (ADA, 2015). All of these groups are important to include due to direct involvement and expertise in certain aspects of the management of type 2 diabetes.

Rigor of Development

The most recent revisions to the guideline were developed using a systematic review of the Medline electronic database for current, relevant studies addressing each subsection that had been published since January 1, 2014. The first publication of the clinical practice guidelines was in 1988 and each year the practice committee performs an extensive literature search and updates the recommendations based on the quality of new evidence that has been released during the previous year (ADA, 2015). The recommendations are revised based on new evidence or, in some cases, to clarify prior recommendations or match the strength of the wording to the strength of the evidence.

The ADA developed a grading system in 2002 that is used to rate the strength of the

evidence reviewed as either A, B, C, or E. A grade of A is applied to well-conducted and generalizable randomized controlled trials (RCTs); B to supportive evidence from well-conducted case-control/cohort studies; C to supportive evidence from poorly or uncontrolled studies, such as observational studies or RCTs with methodological flaws; and E to expert consensus or clinical experience (ADA, 2015). All levels of grading were represented in the recommendation statements with special emphasis given to those with A or B ratings.

There appears to be a strong link between the recommendations and supporting evidence. For example, the ADA and the European Association for the Study of Diabetes (EASD) formed a joint task force to evaluate data and develop recommendations for use of anti-hyperglycemic agents in type 2 diabetic patients (ADA, 2015). This statement reaffirms the use of metformin as a first line agent due to a long-standing evidence base surrounding its efficacy, safety, and potential for reducing the risk of cardiovascular events (Holman, Paul, Bethel, Matthews, & Neil, 2008). Many of the recommendations have strong correlating evidence to support their utility in clinical practice, either for direct treatment or risk reduction.

The method used to formulate the recommendations was expert consensus. The recommendations were reviewed and approved by the Executive Committee of ADA's Board of Directors, which includes health care professionals, scientists, and lay people (ADA, 2015). They also underwent internal review by the professional practice committee and consensus was reached between the two groups before publication of the recommendations.

Clarity and Presentation

The recommendations provided are very specific. There are a total of 14 subsections, with more specific recommendations under each heading that are directly related to the topic presented. The lab values needed for diagnosis are very precise, as well as the conditions under

which they need to be obtained. There is an easy to follow algorithm for initiating drug therapy for hyperglycemia that can be individualized for many circumstances such as for elderly patients, cost minimization, prevention of hypoglycemia, etc. The recommendations are also clear that unless contraindications exist, metformin should be the initial therapy for all diabetic patients (ADA, 2015). Concrete values are provided for different areas of management, such as 150 minutes/week for physical activity and parameters to track such as HbA1c, microalbuminuria, and blood pressure and cholesterol targets for risk reduction. There is also a section dedicated to changes made in comparison to the prior year's recommendations, which allows clinicians already familiar with many of the recommendations to focus exclusively on what has changed.

One important area of focus is the section on screening for and diagnosis of type 2 diabetes because it serves as a basis for the remainder of the recommendations. The *Standards of Care* recommendations are very specific in stating that diagnosis must be made with a fasting plasma glucose level, a 2 hour oral glucose tolerance test, or the recently added option of HbA1c level $\geq 6.5\%$ (International Expert Committee, 2009). Additionally, the screening recommendations include all individuals 45 years of age or older as well as those identified at increased risk (i.e. first degree relative with diabetes, hypertension, women with PCOS, BMI ≥ 25 , individuals identified as being prediabetic) (ADA, 2015). Once a patient is identified as having the condition, the remainder of the practice recommendations may be utilized.

The key recommendations of this guideline are numerous. However, the standards of care are divided into 14 specific areas of recommendations as follows:

- Strategies for Improving Care
- Classification and Diagnosis of Diabetes
- Initial Evaluation and Diabetes Management Planning

- Foundations of Care: Education, Nutrition, Physical Activity, Smoking Cessation, Psychosocial Care, and Immunization
- Prevention or Delay of Type 2 Diabetes
- Glycemic Targets
- Approaches to Glycemic Treatment
- Cardiovascular Disease and Risk Management
- Microvascular Complications and Foot Care
- Older Adults
- Children and Adolescents
- Management of Diabetes in Pregnancy
- Diabetes Care in the Hospital, Nursing Home, and Skilled Nursing Facility
- Diabetes Advocacy

More targeted recommendations are provided under each subsection as relevant to that content area. These subsections are designed to facilitate access to information of interest in a timelier manner by providing it in a logical and relevant manner.

There are a total of 207 recommendations within this guideline. The key recommendations are easily identifiable in the ‘Executive summary’ section of the document, with the subsections in bold text and capital letters and the relevant key recommendations bulleted underneath. The full text of the guideline offers more detailed explanations for each of the specific recommendations, including a summary of the evidence surrounding them. The recommendations can be easily located within purple boxes in each relevant section.

Guideline Application

Organizational barriers in applying the recommendations include time involved for direct

patient care, reimbursement rates, and resources available in terms of electronic systems and multidisciplinary team members. For example, various patient insurance coverage levels may serve to hinder the utility of some of the recommendations surrounding oral agents. If a particular medication is not covered, it is unlikely that the patient will follow the treatment plan. Staffing and changes in workflow required to meet the high educational demands of a newly diagnosed diabetic patient may not meet the level set forth in the recommendations. Additionally, in rural settings access may be limited to specialized providers such as endocrinologists and ophthalmologists specializing in diabetic care and prevention of complications. These barriers were not explicitly stated in the text of the *Standards of Care* document.

The document containing the recommendations set forth by the ADA is very lengthy and therefore is not ideal for timely use in the practice setting. However, many abbreviated documents such as the executive summary and clinical algorithms have been developed to make the recommendations more user-friendly and applicable. Additionally, the document is divided into sections, making it easier for a clinician to access content relevant to current needs.

It is explicitly stated that a formal cost analysis was not performed nor were published cost analyses reviewed during the development of this guideline (ADA, 2015). However, it was stated that most of the interventions recommended have been shown to be cost effective. Furthermore, it is inherent that early recognition and prevention of complications common with diabetes will help decrease long term costs.

Theoretical Framework

Type 2 diabetes management is quite complex, and the use of such evidence based clinical practice guidelines as the *Standards of Medical Care in Diabetes* can help enhance the

ability of health care practitioners to effectively address all the needs of these patients. Since revisions are made to the recommendations annually, it is important for practicing clinicians to keep up to date on the changes and implement them into the clinical setting. A theoretical framework that could be used to enhance this process is the diffusion of innovations theory.

Developed by E.M. Rogers in 1962, this theory consists of four distinct stages of adoption: the *knowledge* phase, the *persuasion* stage, the *decision* stage, and the *final* stage (Moulding, Silagy, & Weller, 1999). Knowledge and attitude change alone are thought to lead to changes in practice. Each year when the new revision is released, the information has to be disseminated to clinicians, which represents the knowledge phase. This involves the publication of the revisions on the ADA website, in-services about the changes, etc. The persuasion stage involves the attitude, either positive or negative, about the new recommendations. In this stage, people want to know the advantages and disadvantages of the recommendations and how these will influence them. The decision stage tests whether or not individuals and groups find the recommendations acceptable, and the final stage leads to the actual adoption or rejection of the guideline into practice (Moulding, Silagy, & Weller, 1999). During the process, these steps address any gaps in practitioner knowledge about the guideline, which allows more effective implementation into practice.

Editorial Independence

This guideline was developed and funded by the American Diabetes Association (ADA). The development of the standards is funded by the organization and no outside support is used. The *Standards of Care* are based on scientific evidence, but this annual document also serves as the position statement for the ADA, and the statements in this section represent official ADA opinions on selected topics not adequately covered elsewhere (ADA, 2015). There is a

disclosure stating that all members of the professional practice committee were required to disclose potential conflicts of interest with industry, and there is a table on page S88-S89 of the manuscript listing all individuals and their financial or other potential conflicts of interest during the 12 months leading up to the publication date.

Recommendation

While the *Standards of Care* is likely the most highly recognized diabetes management guideline in the United States, there are similar guidelines published by other organizations pertaining to type 2 diabetes recognition and treatment that are also useful in clinical practice. These organizations include the American Association of Clinical Endocrinologists (AACE) and the International Diabetes Federation (IDF). Both of these guidelines also focus on diagnosis and comprehensive evaluation and management of diabetic patients.

The AACE ‘Medical Guidelines for Clinical Practice for Developing a Diabetes Mellitus Comprehensive Care Plan’ share many of the recommendations as those put forth by the ADA. The diagnostic parameters are identical, and both guidelines share the recommendations for medical nutrition therapy and highlight the importance of concomitant therapeutic lifestyle changes such as diet and exercise. However, the AACE’s recommendations for oral therapy are not as specific, and metformin is not singled out as the preferred first-line therapy (Handelsman et al., 2011). The AACE has developed a set of ten algorithms to make the application of the recommendations simple to apply in a time-saving manner.

The IDF ‘Global Guideline for Type 2 Diabetes’ also addresses many of the same areas of management for patients diagnosed with diabetes. Both the IDF and ADA guidelines agree on a target HbA1C level of 7%, while the AACE guideline leaves this area more open to interpretation by stating that these targets should be individualized based on age, comorbidities,

and duration of disease (Handelsman et al., 2011) rather than specifying a value. Since the IDF guideline was developed by a worldwide panel of organizations, the recommendations set forth encompass a broader view of diabetes management globally (IDF Clinical Guidelines Task Force, 2010).

All of the aforementioned guidelines emphasize the importance of optimization of blood glucose levels in order to prevent complications and assist practitioners in navigating the complex management of type 2 diabetes. All three are useful adjuncts to practice and address many important care issues such as appropriate monitoring, timeframes, and follow-up to assist in organizing appropriate management strategies and ensuring that all patients receive the highest quality of care possible.

The National Kidney Foundation (NKF) has also developed a guideline specifically relating to the screening for and diagnosis of diabetic kidney disease. Like the ADA guideline, this guideline also recommends screening for microalbuminuria at the time of diagnosis of type 2 DM and annually thereafter (National Kidney Foundation, 2007). Additionally, the recommendations are also the same in terms of initiating treatment with an ACE inhibitor or ARB if microalbuminuria is present. Recommendations differ in that the NKF guideline specifically recommends that urine be collected utilizing first morning urine or overnight collection, while the ADA guideline does not. Also, the NKF guideline advises that 2 to 3 samples should be positive for micro- or macroalbuminuria before classification is determined. Since this guideline relates specifically to diabetes-associated kidney disease, it is more comprehensive in this specific area than the ADA's *Standards of Care*.

Application in Practice

The ADA *Standards of Care* have a long-standing reputation for recommending quality

evidence-based strategies for type 2 diabetes management that are relevant to the current evidence. It holistically addresses all aspects of care and provides clinical algorithms for application in the clinical setting. The fact that this guideline is revisited and updated annually is a benefit because it increases the likelihood that the latest scientific evidence is translated into practice sooner. This guideline is particularly useful in the primary care setting because it is applicable to patients in all age ranges and also addresses special populations such as pregnant patients and those in institutionalized settings. Since type 2 diabetes affects each individual differently, it is not rigid and allows flexibility and individualization based on patient needs. For these reasons, it can be very useful in guiding the actions of health care practitioners in the high quality management of this chronic condition.

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Table 3. ADA Recommendations Regarding Diabetic Nephropathy

<ul style="list-style-type: none"> Optimize glucose control to reduce the risk or slow the progression of DKD <u>Strength of Recommendation: A</u> Optimize blood pressure control to reduce or slow the progression of DKD <u>Strength of Recommendation: A</u>
<p>Screening</p> <ul style="list-style-type: none"> At least once per year, quantitatively assess urine albumin (utilizing urine albumin-to-creatinine-ratio [UACR] and estimated GFR) in patients with type 1 diabetes with a duration of 5 years and in all patients with type 2 diabetes <u>Strength of Recommendation: B</u>
<p>Treatment</p> <ul style="list-style-type: none"> An ACE inhibitor or ARB is <u>not</u> recommended for primary prevention of DKD in patients who are normotensive and have a normal UACR (<30 mg/g) <u>Strength of Recommendation: B</u> Either an ACE inhibitor or ARB is suggested for the treatment of the non-pregnant patient with modestly elevated urinary albumin excretion (30-299 mg/day) and is recommended for those with levels >300 mg/day <u>Strength of Recommendation: A</u> Serum creatinine and potassium levels should be monitored when ACE inhibitors, ARBs, or diuretics are used to assess for increased creatinine or changes in potassium <u>Strength of Recommendation: E</u> Continued monitoring of UACR is reasonable for patients with albuminuria to monitor progression of the condition <u>Strength of Recommendation: E</u> Evaluate and manage potential complications of CKD when GFR is <60 mL/min/1.73m² <u>Strength of Recommendation: E</u> Consider referral to a renal specialist when there is uncertainty about the etiology of kidney disease, management issues, or advanced kidney disease <u>Strength of Recommendation: B</u>
<p>Nutrition</p> <ul style="list-style-type: none"> For patients with DKD, reducing protein intake below the recommended daily intake of 0.8g/kg/day is not recommended because it does not alter glycemic measures, CV risk measures, or the course of GFR decline <u>Strength of Recommendation: A</u>

Note: Table adapted from ADA's 2015 *Standards of Medical Care in Diabetes* (ADA, 2015)

Assessment of Screening Practices for Diabetic Kidney Disease in a Primary Care Setting: A

Retrospective Chart Review

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Abstract

Purpose: The purpose of this study was to evaluate provider adherence to the ADA's recommendation for an annual screening urinary albumin excretion level to check for the presence of microalbuminuria. A secondary objective was to assess for adequate treatment (i.e. ACE inhibitor or ARB prescription) in those patients with microalbuminuria present.

Methods: A retrospective chart review was conducted on 60 randomly selected patients seen within a primary care practice in an urban university setting between January 1st, 2014 and December 31st, 2014. Inclusion criteria included age ≥ 18 years and an active diagnosis of type 2 DM as evidenced by ICD codes 250.00-250.93. Data collected included age, gender, ethnicity, marital status, insurance type, BMI, tobacco use status, presence or absence of a urinary albumin excretion level collected within the specified timeframe, and presence or absence of an active ACE inhibitor/ARB prescription. A database of 972 qualifying patients was provided by the university's Division of Biomedical Informatics and 60 patients were randomly sampled from this database utilizing a random number generator.

Results: The retrospective chart review demonstrated only 1 out of the 60 charts reviewed had received screening for microalbuminuria within the previous calendar year, as recommended by the national guidelines.

Conclusion: Increasing urinary albumin excretion rate screening is essential in early recognition and management of renal complications in patients with type 2 DM. Current rates in many practice settings appear to be suboptimal and there exists an opportunity for quality improvement and identifying strategies for improving screening rates.

Keywords: microalbuminuria, type 2 diabetes, diabetic kidney disease, diabetic nephropathy

Assessment of Screening Practices for Diabetic Kidney Disease in a Primary Care Setting: A Retrospective Chart Review

Type 2 diabetes mellitus (DM) is a complex condition, affecting nearly all organ systems in the body. As a result, management focuses not only on optimizing glucose control, but also on decreasing micro- and macrovascular complications. One of the most common microvascular complications resulting from type 2 DM is the development of diabetic nephropathy, which over time can progress to end stage renal disease (ESRD).

Currently, 10 to 40 percent of all patients with a diagnosis of type 2 DM will eventually develop diabetic nephropathy, which is the leading cause of ESRD in the United States (Lepore, Maglio, & LeRouth, 2008; Ganesh & Lee, 2011; National Kidney Foundation, 2015). Approximately 40 percent of all new cases of ESRD in the United States each year occur in patients with diabetes (American Diabetes Association [ADA], 2007). This is a result of a direct insult to the small vessels of the renal system that develops over time. In addition to leading to the need for dialysis and/or renal transplantation and decreasing overall quality of life, the costs associated with treatment of patients with type 2 diabetes with ESRD exceeds \$15.6 billion (United States Renal Data System, 2012).

In Kentucky, renal complications from diabetes comprise a small percentage of hospitalizations at only 2.4%. However, these hospitalizations rank 2nd in the longest average length of stay at 6.88 days, have the highest average charge of \$58,830 per patient, and represent the highest billed charges in 2013 at \$24,179,328 (Kentucky Diabetes Report, 2015). Therefore, reductions in renal complications related to type 2 DM could result in significant healthcare cost savings throughout the state.

One of the most important factors in delaying the development of diabetic kidney disease and progression to ESRD is early identification. This is accomplished through the annual screening for microalbuminuria recommended by the American Diabetes Association (ADA), beginning at the time of diagnosis for all patients with type 2 DM (ADA, 2015).

Background

Although diabetic nephropathy occurs in patients with type 1 DM as well, it occurs earlier and in higher proportions in patients with type 2 DM due to presence of the disease for longer periods prior to diagnosis (ADA, 2004). There is also a higher proportion of patients with type 2 DM who also have a diagnosis of hypertension, which further increases the change of microalbuminuria and resultant renal disease.

Presence of microalbuminuria in the urine is not only the earliest clinical marker for diabetic nephropathy, but it also signifies an increased risk of cardiovascular morbidity and mortality (Weir, 2007; Adachi, 2014). Therefore, its presence should also alert clinicians to intensify interventions to reduce cardiovascular risk factors and to screen for cardiovascular disease.

Healthy People 2020 identified a goal specific to management of renal complications associated with type 2 DM, which is to increase the proportion of Medicare patients with an annual urinary albumin excretion measurement to at least 37 percent (United States Department of Health and Human Services [DHHS], 2013). This would reflect an increase of 10 percent in the current screening rate of only 33.7%. Since 2007, data has been monitored annually; there has been an increase in screening rates each year, and in 2011 the screening rate was at 40.8 percent. Therefore, this goal should be achieved if current practices remain consistent.

The ADA *Standards of Medical Care in Diabetes* guideline provides clinicians with specific guidance on screening for and management of microalbuminuria in patients with diabetes. One of the recommendations of this guideline pertains to obtaining an annual urinary albumin excretion level in patients with type 2 DM beginning at the time of diagnosis and treatment of patients with microalbuminuria with either an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) (ADA, 2015).

Timed 24-hour urine collections are considered the gold standard in screening for the presence of albuminuria. However, the use of these tests in the primary care practice setting can be impractical due to factors such as improper collection by patients, inconvenience, and cost. As a result, many studies have identified a spot albumin-to-creatinine ratio (ACR) as an acceptable and cost-effective screening method in the primary care setting (Lepore et. al, 2002; Younes et. al, 2010; Wu et. al, 2014; Teo et. al, 2015). While first morning void is preferred as albumin levels can fluctuate throughout the day, these studies found urine collection at the time of appointment to be sufficient as long as a repeat test was performed to confirm elevated levels. Microalbuminuria is present if the result is ≥ 30 mg/g creatinine.

Purpose

The purpose of this study was to evaluate provider adherence to the American Diabetes Association's (ADA) recommendation to obtain an annual urinary albumin excretion level for the early identification of renal complications associated with type 2 DM. A secondary aim was to assess adequate treatment in those identified as higher risk, as evidenced by urinary albumin excretion levels ≥ 30 mg/g creatinine.

Methods

Design

A retrospective review of 60 medical records of patients with type 2 DM was performed in March 2015 to assess for the presence or absence of a urinary albumin excretion level collected within the previous calendar year as evidenced by documentation in the electronic health record (EHR). If a level was obtained and found to be elevated, assessment for whether or not an intervention was made (i.e. prescription for an ACE-I or ARB) was also performed.

Human Subject and Research Approval Procedures

After obtaining committee approval for the project, permission to conduct the study was sought and obtained from the university's institutional review board (IRB). A waiver of informed consent was obtained as the data collected was retrospective in nature and de-identified prior to receipt by the primary investigator. As such, there was minimal risk to participants involved in the study. A permission letter allowing the primary investigator to access the electronic health record (EHR) was obtained from the practice prior to data collection. Proper documentation and training was completed through the Division of Biomedical Informatics prior to data release.

Data Extraction and Study Population

This study was conducted at a primary care clinic within a university setting. This clinic employs two full-time physicians and two nurse practitioners. The patient population ranges from newborn to elderly and includes a wide range of services and management of both acute and chronic conditions, including diabetes. A list of 972 patients from this clinic meeting inclusion criteria was extracted by the Division of Biomedical Informatics within the Center for Clinical and Translational Science at this university. Inclusion criteria included having been

seen in the clinic between the dates of January 1st, 2014 to December 31st, 2014; age 18 years, and an active diagnosis of type 2 DM as evidenced by an ICD code of 250.00-250.93. All data was de-identified prior to receipt. From this list, the primary investigator narrowed the sample to 60 charts using systematic sampling utilizing a random number generator. All data collected was entered into a Microsoft Excel spreadsheet and stored in REDCap®, which is a secure, password protected web-based application utilized by the university (Harris et. al, 2009).

Data Analysis

Data analysis was performed using the SPSS statistical software package. Demographic data collected included gender, age, ethnicity, insurance type, presence or absence of a urinary albumin excretion level obtained between January 1st, 2014 to December 31st, 2014, and presence of a prescription for treatment medications (ACE inhibitor or ARB), if applicable. These measures were assessed using descriptive statistics including frequencies, percentages, standard deviations, and means.

Results

Of the 60 patient charts selected for review, 23 (38.3%) were male and 37 (61.7%) were female. Ages ranged from 22.32 to 95.17 years for a mean of 53.86 years (SD=15.6). Forty-eight and 3/10 percent of the subjects (29/60) were Caucasian, while 45 percent (27/60) were African American, 3.3 percent (2/60) were Hispanic, 1.7% (1/60) Asian, and the ethnicity of one subject was unreported. Mean body mass index (BMI) of this sample was 33.7 (SD=9.6), although this is likely skewed since over half of the charts reviewed had no recorded BMI. Fifty percent (30/60) of the patients whose charts were reviewed were identified as current tobacco users, which is significant since smoking has been identified as an independent risk factor for

microalbuminuria and faster progression of DKD (Cederholm et. al, 2005; Voulgari, Katsilambros, & Tentolouris, 2011)

Only one of the 60 charts reviewed had a documented urinary albumin excretion level charted within the preceding calendar year for a rate of 1.7%. This patient had microalbuminuria present but did not have an active prescription for an ACE inhibitor or ARB as recommended per the guidelines. Of the 60 patients whose charts were reviewed, 19 (31.7%) were prescribed an ACE inhibitor and two (3.3%) were prescribed an ARB, although indication for these medications is unclear. Although specific indications are not known (i.e. prescribed for elevated blood pressure, microalbuminuria, etc.), blood pressure control may also be important for prevention of renal issues.

An incidental finding of this chart review is that many of the patients whose charts were reviewed had no body mass index (BMI) recorded, which is important clinical data, especially for patients with diabetes. Of the 60 charts reviewed, 35 (58.3%) were missing this information. This is significant to this study since some studies have shown an association between BMI and the presence of microalbuminuria and risk for developing diabetic nephropathy (Kramer et. al, 2009; Pavan et. al, 2011; Svensson et. al, 2015).

Recommendation

Based on the findings from this retrospective chart review, it is recommended that this facility institute quality improvement measures to increase their screening for microalbuminuria among the patient population diagnosed with type 2 DM. Once quality improvement measures have been identified and implemented, follow-up should be performed to determine if any significant improvements have been made.

Discussion

The screening for and early identification of microalbuminuria in patients with type 2 DM is essential in the prevention or delay of diabetic nephropathy. Appropriate interventions will hopefully increase patient quality of life by slowing progression to ESRD and the possible need for dialysis or renal transplant. It will also decrease costs associated with these complications. The ADA's *Standards of Care*, the National Kidney Foundation's KDOQI, and the American Association of Clinical Endocrinologist (AACE) guidelines are all concurrent on the recommendation that this screening be performed annually, beginning at the time of diagnosis.

Despite a national emphasis on the early detection of renal complications associated with type 2 DM, minimal information is known about actual screening practices in the primary practice setting. Few published studies are available that have measured screening rates, and very few recent studies were located. Studies in the literature have shown screening rates for microalbuminuria to be between 12%-49% (Kraft et. al, 1999; Weiner et. al, 1995; Kirkman et. al, 2002; Gill et. al, 2006; Hellemons et. al, 2012; Anabtawi & Mathew, 2013). Although screening rates from this chart review were expected to be suboptimal, actual results were much lower than expected. As stated above, only one of the 60 patients in the randomly selected sample had a urinary albumin excretion rate performed within the previous year. Even when considering all patients in the initial database, only 39 out of 972 had the appropriate screening for a rate of 4%. This is not to say it is representative of the clinic as a whole or that these patients had never been screened for microalbuminuria, but it definitely signifies an opportunity for improvement in meeting the recommendations of annual screening in all patients with type 2 DM.

Limitations

A major limitation in this study was the small size and homogeneity of the sample. Since only a small population from one clinic was studied generalizability to a larger population is unclear.

Also, it appears that enough clinical data was not obtained to allow any significant associations to be shown. Since only one chart had a urinary albumin excretion level present within the preceding calendar year, no relationships between screening rates and patient characteristics could be inferred. Additionally, no indications were provided for ACE inhibitor or ARB therapy so it was not possible to conclude whether they were being used for microalbuminuria specifically or for another use such as hypertension.

Finally, this study did not assess for the presence of regular screening of estimated glomerular filtration rate (eGFR). The ADA clinical practice guideline recommends the annual screening of both urinary albumin excretion levels and eGFR. While similar studies also had not assessed for this level and it takes longer for the eGFR to be affected than for microalbuminuria to appear, it could have increased confidence that renal function was being evaluated in some capacity.

Implications for Practice

Existing literature as well as data from the Healthy People 2020 illustrates that despite guideline recommendations, screening for urine microalbuminuria remains low (U.S. DHHS, 2013). This retrospective chart review likewise demonstrates suboptimal screening practices and an opportunity for quality improvement in this area.

Future research should be directed towards barriers that prevent clinicians from obtaining an annual urinary albumin excretion level as recommended by guidelines. Useful strategies

possibly include use of a tool such as the Diabetes Care Tool provided by the Kentucky Diabetes Network or a reminder prompt integrated into the clinic's electronic health record (EHR).

Additional strategies may include a provider focus group to identify potential barriers or an educational session to raise clinicians' awareness of the ADA's recommendations. The effectiveness of these interventions could be tested utilizing a pre- and post-intervention design.

Conclusion

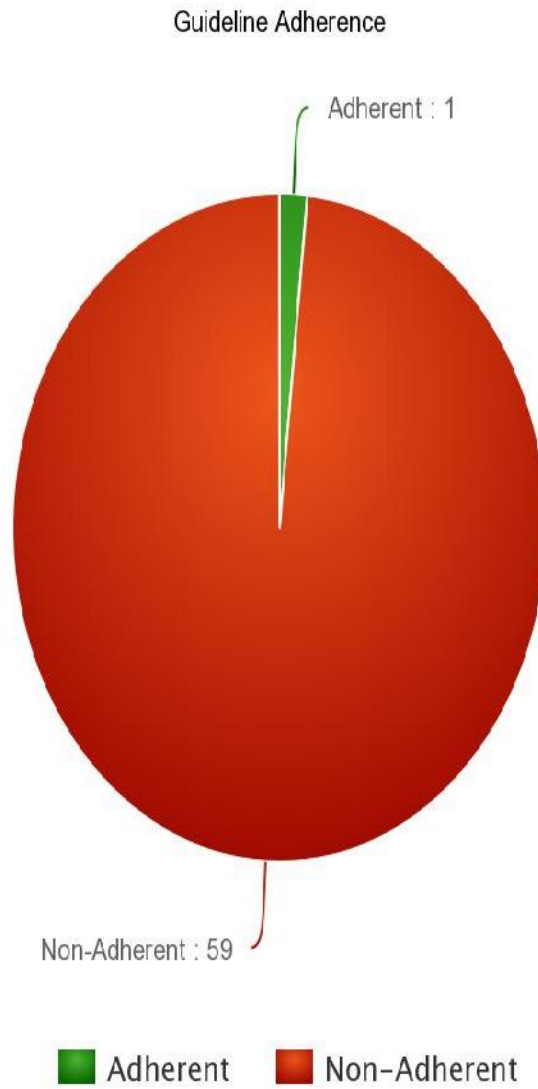
Type 2 DM affects almost every organ system in the body, including the renal system. Significant progress needs to be made in the clinical setting to reach the goal set forth by Healthy People 2020 to increase annual urine microalbumin measurements to at least 37% (U.S. DHHS, 2013). This chart review showing low levels of adherence is consistent with findings from other studies. Because screening for microalbuminuria and initiation of proper treatment can delay the progression to overt nephropathy, this should be considered essential in the care of every patient diagnosed with type 2 DM.

Additional research is needed to determine whether suboptimal screening rates are due to factors such as lack of time, lack of knowledge, lack of organizational support/resources, or other factors. Once this is identified, interventions for improving screening rates can be tailored to target the identified reasons.

Table 4. *Characteristics of Patient Sample from Retrospective Chart Review*

	N	%
Gender		
Male	23	38.3
Female	37	61.7
Ethnicity		
Caucasian	29	48.3
African American	27	45
Hispanic	2	3.3
Asian	1	1.7
Unknown	1	1.7
Insurance Type		
Medicaid	18	30
Medicare Part A	7	11.7
Medicare Part B	9	15
Commercial Insurance	9	15
Self Pay	5	8.3
Clinical Research	2	3.3
	Mean	SD
Age	53.6	15.6
BMI	33.7	9.6

Figure 1. *Guideline Adherence Rates from Retrospective Chart Review*



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Conclusion to DNP Practice Inquiry Project

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Care of the diabetic patient is complex, and certain aspects of care sometimes get neglected in the patient care setting. As suggested through literature review, Healthy People 2020 data, and this pilot chart review, annual screening for urinary albumin excretion is likely one of these dimensions that is often overlooked. Whether this is due to lack of time, lack of knowledge, lack of organizational support, etc., further research should be conducted to explore options for increasing the overall screening rates. Most patients with type 2 DM are seen in the clinic every 3 to 6 months, so as long as clinicians identify that screening needs to occur, there is ample opportunity to do so.

By improving screening, primary care providers are helping provide high-quality, comprehensive care to all patients while also decreasing morbidity and mortality and associated health care costs. This step is imperative because it is what leads the clinician to identify a potential problem and initiate appropriate treatment to prevent further complications.

The screening rate at the clinic utilized for this study were much lower even than suggested by the literature. Therefore, recommendations include identifying barriers to obtaining UACR levels in this setting, as well as instituting quality improvement strategies to ensure that it is being performed. Once these measures have been implemented, a repeat chart review should be performed to assess for improvement.

Further research should also be conducted regarding specific strategies that may improve screening rates, such as the use of prompts integrated into a facility's EHR or a tool such as the Diabetes Care Tool supplied by the Kentucky Diabetes Network. Organizational support and emphasizing the need for improvement in this area to providers can assist in meeting the nationwide goal set forth by *Healthy People 2020* for improving the overall screening rates to at least 37%.

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