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DIABETIC KIDNEY DISEASE

POSITION PAPER OF THE MACEDONIAN SOCIETY OF NEPHROLOGY, DIALYSIS, TRANSPLANTATION AND ARTIFICIAL ORGANS (MSNDTAO), MACEDONIAN SOCIETY OF CARDIOLOGY (MSC), AND SCIENTIFIC ASSOCIATION OF ENDOCRINOLOGISTS AND DIABETOLOGISTS OF MACEDONIA (SAEDM)

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ABSTRACT

Diabetic kidney disease (DKD) is a significant and growing global health concern, affecting a substantial proportion of individuals with diabetes mellitus. This position paper of Scientific societies of endocrinologists, nephrologists and cardiologists has been consensually brought at a couple of mutual meetings, aiming to synthesize current knowledge on screening, diagnosis and staging of DKD, emphasizing the need for an early detection and intervention in order to prevent progression to end-stage renal disease (ESRD). The role of glycemic control, blood pressure management, lipid management and the use of reno and cardioprotective agents, including angiotensin-converting enzyme inhibitors, sodium-glucose co-transporter 2 inhibitors and non-steroidal mineralocorticisteroid receptor antagonist has been entirely considered. Furthermore, we highlight the importance of a multidisciplinary approach in the care of patients with DKD, integrating lifestyle modifications and patient education into the clinical practice. This paper advocates for the implementation of standardized screening protocols and the development of personalized treatment strategies to optimize patient outcomes. By addressing the complexities of DKD, we aim to provide a comprehensive framework for healthcare professionals to enhance the quality of care for individuals at risk of or living with this condition.

Keywords: Diabetic kidney disease, angiotensin-converting enzyme inhibitors, sodium-glucose co-transporter 2 inhibitors, non-steroidal mineralocorticosteroid receptor antagonist, lifestyle modifications

INTRODUCTION

Type 2 diabetes presents as a persistent and intricate condition, necessitating a comprehensive approach involving both behavioral (hygieno-dietetic) adjustments and medication to halt or delay target organ complications while preserving quality of life. In fact, the primary goal of diabetes care is to prevent complications through an effective management and treatment, improving overall health and quality of life in the presence of disease. This holistic approach encompasses regulating blood glucose levels, managing weight, addressing cardiovascular risk factors, handling concurrent health issues, and mitigating complications. Implementing care in an organized and systematic manner, as outlined in the chronic care model, is crucial. Moreover, adopting a person-centered approach fosters active participation in self-care tasks activities [1]. Tailoring

treatment goals and strategies to each individual patient requires careful consideration of its social determinants of health and their preferences [2].

Individuals with diabetes face an elevated risk of developing cardiovascular disease (CVD), as combination of conditions like coronary artery disease (CAD), heart failure (HF), atrial fibrillation (AF), stroke, as well as an aortic and peripheral artery diseases (PAD). Furthermore, diabetes significantly enhances the risk of chronic kidney disease (CKD), which in turn additionally exacerbates the CVD risk. Recent years have settled-up significant advancements in therapeutic options for high-risk patients with diabetes, particularly through large-scale cardiovascular outcome trials (CVOTs). Novel glucose-lowering agents like sodium– glucose cotransporter- 2 inhibitors (SGLT2i), glucagon-like peptide-1 (GLP-1) receptor agonists, and non-steroidal mineralocorticoid receptor antagonists (nsMRAs) such as Finerenone have expanded the therapeutic armamentarium, resulting in evidence-based recommendations for managing this patient population [3, 4].

This position paper of Scientific societies of endocrinologists, nephrologists and cardiologists has been consensually brought at a couple of mutual meetings, aiming to synthesize current knowledge on screening, diagnosis and staging of DKD, primarily emphasizing the need for an early detection and intervention in order to prevent progression to end-stage renal disease (ESRD). All the consensual positions have been based on a high-quality evidence, mainly from randomized clinical trials, especially those for the new break-through drug therapies, and recommendations from the professional societies for use of these agents. Here, we have certainly adopted and followed the recommendations from the most respectful associations and groups as the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO) [5, 6]. Their guidelines have been certainly created on the base of a thoroughly structured process from literature search and data extraction up to the development of final rigorous and evidence-based guidelines for adults with diabetes and CKD. Certainly, all cited references have passed through the same consensus or the guidelines production process according to the best existing evidence at that particular moment. However, all the guidelines are created globally, but the implementation stays locally and thus, we have tried to incorporate and/or eventually slightly adapt if necessary, based on top of the existing national documents [7, 8].

Chronic kidney disease (CKD) in diabetes

Chronic kidney disease is increasing public health issue over the last decades. Diabetes is the most common cause of kidney failure requiring kidney transplantation or dialysis worldwide [9].

Screening, diagnosis and staging

CKD is defined as a persistently (for at least 3 months) low estimated glomerular filtration rate (eGFR) < 60 ml/min/1.73 m2 and/or urinary albumin/creatinine ratio (UACR) ratio ≥ 30 mg/g. So, consecutive measurements are needed to confirm the diagnosis [10].

In most type 1 diabetes (T1D) and type 2 diabetes (T2D) patients, CKD is not identified as a result of symptoms. Therefore, CKD may be timely diagnosed only through a routine screening that is underutilized in North Macedonia. Hence, Primary Care Physician (PCP) and Family medicine doctors should recommend the annual screening of patients with diabetes for CKD [7].

CKD screening should be started at the time of diagnosis of T2D / or in all patients with T2D irrespective of treatment, also at 5 years from the diagnosis of T1D, and proceed annually thereafter [5].

Currently, the major societies recommend eGFR should be calculated by Chronic Kidney Disease Epidemiology Collaboration 2021 (CKD-EPI) equation as standard [11, 12].

UACR should be measured by early morning urine or from a spot urine sample. Due to the high individual variability of albumin excretion, it is recommended for diagnosing albuminuria, using the "2 out of 3 rule": If two consecutive urine samples analyzed within 3–6 months are both positive (albumin excretion > 30 mg/g creatinine), albuminuria is proven, and if negative it is ruled out. If the albumin excretion of one urine sample is negative and the second one is positive, a third urine sample should be tested for albuminuria. As an exception some positive findings can be found in acute febrile illnesses, urinary tract infections, arterial hypertension, in heart failure, menstruation and after physical exertion, regardless of the kidney damage. Since the collection of 24-hour urine requires time, the determination of UACR from spontaneous urine, has become a referred standard method [6].

In patients with established CKD, monitoring of urinary UACR and e GFR, should be done 1- 4 times, annually, depending on the CKD stage, they are in [5].

eGFR and UACR are required in order to classify the patients into respective stages of the disease. Our scientific societies have also endorsed the KDIGO - CKD classification scheme [13], based on eGFR and albuminuria that is endorsed by the ADA, as well, Table 1.

This classification scheme represents the risk of CKD progression, risk of cardiovascular events, and mortality with increasing albuminuria or decreasing eGFR, recommending also the guidance for frequency of laboratory monitoring, treatment, and referral to nephrology care (eGFR < 45 ml/min/1.73 m2 and / or albuminuria - UACR ≥300 mg/g). The aim of this scheme is also to overcome treatment inertia by emphasizing the initiation of the treatment in any stage as needed [8].

Table 1. *Risk stratification category of CKD, initiation of the treatment and monitoring of diseases [13].*

Number of control visits during the year according to eGFR and UACR				Stage of albuminuria (UACR) mg/mmol or mg/g		
				A1 Normal to mildly increased	**A2 Moderately increased**	**A3 Severely increased**
				<3 <30	3-29 30-299	≥30 ≥300
Stages according to eGRF (ml/min/1.73m²)	G1	Normal to high	≥90	**Screening (1)**	**Treat (1)**	**Treat (2)**
	G2	Mildly reduced	60-89	**Screening (1)**	**Treat (1)**	**Treat (2)**
	G3a	Slightly to moderately reduced	45-59	**Treat (1)**	**Treat (2)**	**Treat (3)**
	G3b	Moderately to strongly reduced	30-44	**Treat (2)**	**Treat (3)**	**Treat (3)**
	G4	Strongly reduced	15-29	**Treat (3)**	**Treat (3)**	**Treat (4+)**
	G5	End stage kidney disease	<15	**Treat (4+)**	**Treat (4+)**	**Treat (4+)**

Comprehensive care

The treatment of multiple risks and multi-morbidity in people with T2D requires a comprehensive and holistic, patient-centered medical care to improve overall patient outcomes as emphasized by both ADA and KDIGO [5, 6]. It means the patients should be treated as a "whole" person with an active involvement of health professionals from multiple specialties, starting from primary, through secondary to the tertiary level. Today, the multidisciplinary approach in the treatment of this condition, which is popularly called cardio-reno-diabetes, is increasingly important.

Coordinated multidisciplinary approach should incorporate lifestyle measures, risk stratification, primary and secondary prevention strategies and multidisciplinary decision shared treatment.

Continuous monitoring is inevitable to monitor the disease progression but also to modify risk factors and respective treatment.

Patient education and empowerment

Patient education is very important, and they should take an active role in the management of their disease [5, 6]. They should be educated about their risks for developing complications and know how that may influence the risk reduction. They should take ownership of some measures like diet, physical activity smoking cessation, responsibility of glycemic monitoring and adherence to prescribed treatments [14]. Regarding nutrition and dietary protein intake, the KDIGO and ADA guidelines recommend 0.8 g/kg body weight per day [5, 6]. However, it should not exceed 1.3 g/kg body weight per day, lower protein intake that the recommended seems not to have

any additional benefit. In addition, avoiding industrially processed foods is recommended and a reduction in salt (sodium chloride) intake to 5 g/day is suggested, or <2g of sodium per day [6, 15]. The result of the treatment may depend very much on implementation of these measures [14]..

Multidisciplinary care

Diabetes is a complex medical condition comprised from cardiovascular, renal, and metabolic disorders. Hence, the treatment of patients with diabetes and concurrent cardiovascular and renal risks requires a collaborative, patient-centered approach involving the patient itself and healthcare professionals from various disciplines (such as general/family medicine, internal medicine, diabetology, cardiology, nephrology, neurology, and other relevant specialties)[2, 5, 6]. An effective cooperation among these professionals is essential for timely prevention of cardiovascular complications. The treatment decision should consider all identified risk factors rather than focusing solely on one aspect (such as hyperglycemia) without acknowledging the potential adverse effects on other factors (such as weight gain).

Early identification of cardiovascular and renal risks and the initiation of medications with cardioprotective properties and favorable effects on cardiorenometabolic parameters are crucial in the early stages of diabetes. This approach, independent of glycemic control or other antihyperglycemic therapies, is vital for preventing cardiovascular complications in individuals with type 2 diabetes.

Treatment strategies

Diabetic patients face with an elevated risk of developing CVD, encompassing conditions like CAD, HF, AF, stroke, as well as an aortic and PAD. Furthermore, diabetes significantly enhances the risk of CKD, which further exacerbates CVD risk. The convergence of diabetes with these cardio-renal comorbidities amplifies the likelihood of cardiovascular events and mortality, underlining the importance of an effective management. Albuminuria as an early predictor for cardiovascular risk and progression of CKD has been involved as treatment target, so in patients with CKD and >300 mg/g UACR, a reduction of 30% or greater in mg/g urinary albumin is recommended in order to retard the CKD progression [5]. Recent years have witnessed significant advancements in therapeutic options for high-risk patients with diabetes, particularly through large-scale CVOTs. Novel glucose-lowering agents like SGLT2i, GLP-1 receptor agonists, and nsMRAs such as Finerenone have expanded the therapeutic armamentarium, resulting in evidence-based recommendations for managing this patient population. Their use have been spread out from a simple glycemic control to cardio-renal benefits.

Glycemic control

To reduce the risk and slow the CKD progression, an optimization of glucose management is recommended [5]. It is advised twice-yearly glycemic assessment using HbA1c, if patients have stable glycemia and regularly meet the treatment goals. Quarterly assessments are needed for those who require intensive management since their management strategies are not completed [5, 6].

Individualized glycemic targets may be considered in patient which have characteristics that may modify risks and benefits of intensive glycemic control. In patients with diabetes and CKD individualized HbA1c target should be between < 6.5% to 8.0% [5, 6]. However, besides HbA1c, continuous glucose monitoring to evaluate the treatment efficacy and safety among patients at risk for hypoglycemia, self-monitoring of blood glucose may be an option to adjust the medication [2].

BP management

BP control is crucial for prevention of CKD progression, Atherosclerotic cardiovascular disease (ASCVD), and HF according to ADA and KDIGO recommendations [16, 17]. Optimisation of blood pressure control and its reduced variability enables to reduce the risk of CKD progression and simultaneously reduces the cardiovascular risk [5]. Diabetic patients with hypertension and high CV risk (10-year ASCVD risk ≥15%), have BP target of <130/80 mm Hg, while diabetic patients with hypertension and high CV risk (10-year ASCVD risk <15%) have BP target of <140/90 mm Hg.[16, 17].

The recommended antihypertensive pharmaco-therapy, is renin-angiotensin system (RAS) inhibition, i.e., an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) [5].

Since RCTs have demonstrated that these drugs can decrease the risk of CKD progression especially if the patients have albuminuria. Diabetic patients with hypertension should be titrated to highest tolerated dose. ARBs are better tolerated then ACEi [10]. When RAAS inhibitors are used periodical monitoring of potassium levels and serum creatinine is required.

Multiple antihypertensive drugs can be recommended to attain individualized BP target like dihydropyridine calcium channel blockers and thiazide-like diuretics, especially when patients have higher CV event risks than risks for CKD [10].

Lipid management

Statin therapy is a cornerstone of therapy for the primary and secondary prevention of ASCVD among people with diabetes and CKD [18, 19]. A statin is recommended for all patients with T1D or T2D and CKD, with moderate intensity for primary prevention of ASCVD or high intensity for patients with known ASCVD and some patients with multiple ASCVD risk factors [10].

Glucose lowering agents in T2D and CKD

Consistently implementing guidelines in clinical practice by enhancing the availability of therapeutic options to mitigate cardiovascular and renal risk in diabetes can substantially decrease diabetes-related cardiovascular and renal complications. This approach not only extends patient life expectancy and enhances their quality of life but also increases work capacity, leading to savings within the healthcare system.

The ADA 2024 Standards Care and the KDIGO 2022 guideline recommend early initiation of metformin plus an SGLT2i in most patients with T2D and CKD2 [5, 6]. Additional glucose-lowering agents can then be added as needed to meet individualized glycemic targets. Caution is needed since some of these agents may be limited by eGFR. Table 2 below shows the considerations for selecting glucose-lowering agents in patients with T2D and CKD [10].

Table 2. *Considerations for selecting glucose-lowering agents in patients with T2D and CKD [10].*

	Progression of CKD	ASCVD	Heart failure	Glucose-lowering efficacy	Hypoglycemia risk	Weight effects	Cost
Metformin	Neutral	Potential benefit	Potential benefit	High	Low	Neutral	Low
SGLT2 inhibitors	Benefit[a]	Benefit[c]	Benefit	Intermediate	Low	Loss	High
GLP-1 receptor agonists	Benefit[b]	Benefit[c]	Potential benefit	High	Low	Loss	High
DPP-4 inhibitors	Neutral	Neutral	Potential risk[c] (saxagliptin)	Intermediate	Low	Neutral	High
Insulin	Neutral	Neutral	Neutral	Highest	High	Gain	High (analogs) Low (human)
Sulfonylureas	Neutral	Neutral	Neutral	High	High	Gain	Low
Thiazolidinediones	Neutral	Potential benefit (pioglitazone)	Increased risk	High	Low	Gain	Low
α-Glucosidase inhibitors	Neutral	Neutral	Neutral	Intermediate	Low	Neutral	Low

Neutral
Potential benefit or intermediate glucose-lowering efficacy
Benefit (organ protection, high efficacy, low hypoglycemia risk, weight loss, or low cost)
Potential risk or high cost to patient
Increased risk for adverse effects

Metformin is recommended for patients with T2D, CKD, and eGFR >30 ml/min/1.73 m2; the dose should be reduced to 1000 mg daily for patients with eGFR 30–44 ml/ min/1.73 m2 and for some patients with eGFR 45–59 ml/ min/1.73 m2 who are at high risk of lactic acidosis [10].

Glucose lowering agents with additional cardiorenal benefits

SGLT2i, lower plasma glucose levels by increasing urinary glucose excretion. Despite variations in glycemic efficacy based on eGFR, their use has been expanded due to their favorable outcomes in cardiovascular and renal studies [20- 23] .

These medications have demonstrated efficacy in reducing the risk of CKD progression, HF and ASCVD risk in patients with T2D and CKD. While an SGLT2i will usually be added to lifestyle and metformin therapy, SGLT2i treatment without metformin may be reasonable for patients with eGFR too low for safe prescription of metformin, who do not tolerate metformin, or who do not need metformin to achieve glycemic targets [20, 21,22]. In order to express its cardio and renoprotective effect SGLT2i should be used in individuals with eGFR >20 mL/min/1.73 m2 and both categories of urinary ACR ranging from normal to 200 mg/g or >200 mg/g[5].GLP-1 receptor agonists enhance glucose-dependent insulin secretion, suppress glucagon release, delay gastric emptying, regulate post meal glycemic spikes, and reduce appetite, energy intake, and body weight [23]. Certain GLP-1 receptor agonists have received approval not only for improving glycemic control but also for reducing major adverse cardiovascular events (MACE) in adults with established CVD or multiple cardiovascular risk factors and for chronic weight management. GLP-1 receptor agonist with proven cardiovascular benefit is recommended for patients with T2D and CKD who do not meet their individualized glycemic target with metformin and/or an SGLT2i, or who are unable to use these drugs [24- 27],

Renin-angiotensin-aldosterone system inhibition

ACE inhibitors and ARBs

RAS inhibition with ACEi or ARBs has been standard of care in patients with T1D and T2D and CKD. ACEi or ARBs are the preferred first-line agent for BP treatment among patients with diabetes, hypertension, and UACR ≥300 mg/g because of their proven benefits for prevention of CKD progression. The recommended antihypertensive pharmaco-therapy, is RAS inhibition, i.e., an ACEi or ARB for patients with UACR 30-299 mg/g, and highly recommended for UACR > 300mg/g and e GFR < 60 ml/min/ 1.73m2. [5, 6] In the setting of lower levels of albuminuria (30–299 mg/g), ACEi or ARB therapy has been demonstrated to reduce progression to more advanced albuminuria (≥300 mg/g) and cardiovascular events but not progression to kidney failure. These drugs are not recommended for primary prevention of CKD in diabetic patients with normal blood pressure, UACR < 30mg/g and normal e GFR, Also periodical monitoring of serum creatinine (sCr) and potassium level is needed when these drugs or ns MRA and diuretics are used.

RAS inhibition due to an increased mild to moderate sCr (<30%) should not be discontinued in the absence of extracellular volume depletion [5].

Therefore, both KDIGO and the ADA recommend an ACEi or ARB for treatment of hypertension among people with T1D or T2D who have hypertension and UACR ≥30 mg/g [5, 6, 17].

ns-MRAs (Finerenone)

Finerenone demonstrated cardiovascular and kidney benefits among people with T2D who were treated with standard of care (including an RAS inhibitor at maximally tolerated doses and good control of glycemia and BP) who were at high residual risk, based largely on albuminuria (UACR ≥30 mg/g) [28]. So Finerenone as ns MRA is recommended for cardiovascular risk reduction and slowing the progression of CKD [5]. These effects appear to be additive, based on preclinical studies, to those of SGLT2i and GLP-1 receptor agonist, though, further clinical research on these combinations is warranted. Therefore, it is reasonable to add finerenone to the treatment regimen of patients with T2D who have any level of persistent albuminuria despite current standard of care treatment with glucose-lowering and antihypertensive medication [10]. During treatment potassium monitoring should be done [5].

CONCLUSION

At present, there is a sufficient knowledge and armamentarium for prevention of diabetic complications. For us as professionals, the organization of the multidisciplinary diabetic care is of paramount importance, along with the motivation and education of our patients, as they are the crucial part of the chain for better diabetic control and maintained quality of life and a longer professional activity. Finally, the accessibility of the modern therapy should be more approachable and under the health insurance budget, since it will be the way for a greater financial saving in patients with preserved comorbidity and heavy complications that needs comprehensive hospital treatment.

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Резиме

ДИЈАБЕТИЧНА БУБРЕЖНА БОЛЕСТ

ПОЗИЦИОНЕН ТРУД НА МАКЕДОНСКОТО ЗДРУЖЕНИЕ ЗА НЕФРОЛОГИЈА, ДИЈАЛИЗА, ТРАНСПЛАНТАЦИЈА И ВЕШТАЧКИ ОРГАНИ (МЗНДТВО), МАКЕДОНСКОТО ЗДРУЖЕНИЕ ПО КАРДИОЛОГИЈА (МЗК) И НАУЧНОТО ЗДРУЖЕНИЕ НА ЕНДОКРИНОЛОЗИ И ДИЈАБЕТОЛОЗИ НА МАКЕДОНИЈА (НЗЕДМ)

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Дијабетичната бубрежна болест (ДББ) е значајна и растечка глобална здравствена грижа, која засега значителен дел од поединците со дијабетес мелитус. Овој заеднички документ на научните здруженија на ендокринолозите, на нефролозите и на кардиолозите беше консензуално донесен на неколку заеднички состаноци, со цел да го синтетизира тековното знаење за скринингот, дијагнозата и одредувањето на стадиумот на ДББ, нагласувајќи ја потребата за рано откривање и интервенција за да се спречи прогресијата до терминална бубрежна болест (ТББ). Улогата на гликемиската контрола, регулирањето на крвниот притисок, липидите и употребата на ренопротективните и кардиопротективните агенси, вклучувајќи ги инхибиторите на ангиотензин-конвертирачкиот ензим, инхибиторите на натриум-глукозниот котранспортер 2 и антагонисти на нестероидните минералокортикостероидни рецептори, е целосно разгледана. Понатаму, ја нагласуваме важноста на мултидисциплинарниот пристап во грижата за пациентите со ДББ, интегрирајќи ги модификациите на животниот стил и едукација на пациентите во клиничката практика. Овој документ се залага за имплементацијата на стандардизирани протоколи за скрининг и развој на персонализирани стратегии за лекување и оптимизација на исходите на пациентите. Со адресирање на комплексностите на ДББ нашата цел е да обезбедиме сеопфатна рамка за здравствените професионалци за да се подобри квалитетот на грижата за пациентите што имаат ризик или што живеат со оваа состојба.

Клучни зборови: дијабетична бубрежна болест, инхибитори на ангиотензин-конвертирачкиот ензим, инхибитори на натриум-глукозниот котранспортер 2, антагонисти на нестероидните минералокортикостероидни рецептори, модификации на начинот на живот