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Validation of the 2007 kidney disease outcomes quality initiative clinical practice guideline for the diagnosis of diabetic nephropathy and nondiabetic renal disease in Chinese patients

Xiao-min Liu [1], *Zhe-yi Dong* [1], *Wei-guang Zhang, Mo-yan Liu, Jian-hui Zhou, Qian Wang, Xue-feng Sun, Yong Wang, Xue-ying Cao, Xiang-mei Chen* [*]

Department of Nephrology, Chinese PLA General Hospital, Chinese PLA Institute of Nephrology, State Key Laboratory of Kidney Diseases, National Clinical Research Center for Kidney Diseases, Beijing Key Laboratory of Kidney Diseases, Beijing, China

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ABSTRACT

Aims: Diabetes mellitus (DM) has overtaken infection and immunological factors as the most common cause of end-stage renal disease. The 2007 Kidney Disease Outcomes Quality Initiative (KDOQI) guideline is a widely accepted guideline for the clinical diagnosis of diabetic nephropathy (DN) and non-diabetic renal disease (NDRD). Our study sought to verify its diagnostic ability in the Chinese population.

Methods: We included 773 patients with DM who underwent a renal biopsy at the Chinese PLA General Hospital from 2007 to 2016. All patients were divided into three groups according to their pathological findings: isolated DN, isolated NDRD, and DN combined with NDRD.

Results: Good sensitivity and poor specificity were found for the prediction of NDRD in the Chinese population. Rapidly decreasing estimated glomerular filtration rate, systemic disease, refractory hypertension, and the existence of "grey area" patients may have contributed to the poor diagnostic ability.

Conclusions: The diagnostic ability of the 2007 KDOQI guideline for DN and NDRD was unsatisfactory. The high sensitivity and low specificity of the guideline made it more suitable as screening criteria rather than as diagnostic criteria.

1. Introduction

Diabetes is one of the most common metabolic disorders worldwide. In China, the estimated overall prevalence rate of diabetes in adults reached 10.9% in 2013 [1]. Diabetic nephropathy (DN), which is the most common diabetic microvascular complication, accounts for approximately 35% of type 2 diabetes mellitus (DM) cases and increases

* Corresponding author at: Department of Nephrology, Chinese PLA General Hospital, Chinese PLA Institute of Nephrology, State Key Laboratory of Kidney Diseases, National Clinical Research Center for Kidney Diseases, Beijing Key Laboratory of Kidney Diseases, No. 28 Fuxing Road, Beijing 100853, China.
E-mail address: xmchen301@126.com (X.-m. Chen).
[1] These authors contributed equally.
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mortality [2]. The percentage of DN has surpassed that of glomerulonephritis in China and has become the leading cause of chronic kidney disease (CKD) in the general population and hospitalised urban population (1.10 vs. 0.75% in 2015) [3].

Pathology results of CKD patients with DM could be isolated DN, isolated non-diabetic renal disease (NDRD), or DN combined with NDRD. All of these may have different clinical features, treatments, and prognoses. Renal biopsy is the gold standard for diagnosing pathological patterns. It is an invasive test that is associated with several risks. It is believed that some NDRDs, such as IgA nephropathy, are treatable; in contrast, DN is difficult to reverse [4]. Therefore, clinical diagnoses of DN and NDRD are essential before renal biopsy.

In 2007, the Kidney Disease Outcomes Quality Initiative (KDOQI) clinical practice guideline indicated that CKD is associated with DN or NDRD [5]. However, some inconsistences still exist as regard the understanding of this guideline. Some clinicians assume that patients with macroalbuminuria but without diabetic retinopathy (DR) should belong to the DN group [6], whereas others assigned these patients to the NDRD groups [7,8] or believed that they were difficult to diagnose [4]. We have not found a more specific description of this patient group in the KDOQI practice guideline.

Furthermore, most recent studies were conducted to analyse the diagnostic ability of the single criterion of the KDOQI guideline or to find new indicators for NDRD, such as absence of DR and intima-media thickness [7,9], which are seldom used to verify the criteria as a whole. Therefore, in this study, we used the large-scale samples in our centre to verify the diagnostic efficiency of the criteria in the KDOQI guideline for the Chinese population.

2. Materials and methods

2.1. Patient selection

Among 851 patients with type 2 DM who underwent renal biopsy between January 2007 and March 2016 at the Chinese PLA General Hospital, a total of 773 patients were enrolled in this study. Inclusion criteria were as follows: age of 18 years or older at renal biopsy (male or female), biopsy-proven renal lesion, and type 2 diabetes. Exclusion criteria were as follows: incomplete data or unclear medical history and complications such as severe infection and malignancy. Indications for renal biopsy were matched with the different criteria for NDRD in the 2007 KDOQI guidelines [10]. This study was approved by the Medicine Ethics Committee of the Chinese People's Liberation Army General Hospital (approval no. S2014-012-01). All patients provided written informed consents.

Based on pathological findings, patients were divided into three groups: patients with isolated DN, patients with isolated NDRD, and patients with DN combined with NDRD. To analyse the differential diagnostic efficiency of the KDOQI guideline, we performed two calculations under two conditions. First, calculations were performed under ideal conditions (isolated DN vs. isolated NDRD). Second, the calculations were performed under actual conditions (DN patients vs. non-DN patients [NDRD with and without DN]) [7,8]. Because of the different understandings of the guideline, we defined patients with macroalbuminuria but without DR as "grey area" patients (n = 105) and individually described them and the remaining patients (n = 668) with clear clinical diagnoses separately to ensure the preciseness and correctness of scientific research.

Data on regarding the following clinical characteristics of enrolled patients were collected: sex, age, medical history of DM and hypertension, body mass index, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure, and presence of complications. Laboratory parameters, including haemoglobin, serum creatinine (Scr), estimated glomerular filtration rate (eGFR; calculated using the CKD epidemiology formula) [11], albumin (ALB), haemoglobin A1c, 24-h urine protein, fasting blood glucose, and presence of glomerular haematuria, were all examined at the time of renal biopsy.

The definitions of type 2 DM, DN, NDRD, DR, haematuria, rapidly decreasing eGFR, systemic disease, refractory hypertension, and hyperuricaemia are listed in the Supplementary.

2.2. Statistical analysis

Statistical analyses were performed using SPSS version 20.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarise the clinical and laboratory parameters. Continuous data were expressed as mean ± SD or median with interquartile range, which were compared using Student's-test or analysis of variance for normally distributed data and the Mann-Whitney *U* test or Kruskal-Wallis test for skewed data. Categorical data were presented as absolute values and percentages, which were compared using chi-square tests. Univariate and multivariate logistic regression analyses were performed to ascertain the differential prognostic ability of the clinical indices for NDRDs, with results reported as odds ratios and 95% confidence intervals. Kappa identity test and receiver operating characteristics (ROC) curve were used for the diagnostic evaluation. Hypothesis testing for kappa identity test value was Z-test. $P < 0.05$ was considered statistically significant.

3. Results

3.1. Biochemical and clinical parameters

We included 773 patients in the final analysis: 249 with isolated DN, 462 with isolated DNRD, and 62 with DN combined with NDRD. The mean age of the enrolled patients was 50.51 ± 11.13 years (range, 19–85 years). The biochemical and clinical parameters of three groups are listed in Table 1. The DN group had higher blood pressure, fasting blood glucose level, Scr concentration, and 24-h urine protein level and had a longer DM course ($P < 0.05$). The NDRD group had higher haemoglobin and cholesterol levels ($P < 0.05$). The pathological findings of NDRD are listed in Supplementary Table 1.

Table 1 – Biochemical and clinical parameters.

Variable	Isolated DN (n = 249)	Isolated NDRD (n = 462)	NDRD combined with DN (n = 62)	P-value
Sex (male, %)	177 (71.1%)	294 (63.6%)	450 (64.5%)	0.130
Age (years)	50.89 ± 9.96	50.13 ± 11.86	51.85 ± 9.86	0.417
SBP (mmHg)	180.43 ± 23.04	162.30 ± 26.22	176.11 ± 23.29	<0.001
DBP (mmHg)	101.73 ± 13.53	99.05 ± 17.75	104.94 ± 21.63	0.011
Mean arterial pressure (mmHg)	127.98 ± 14.41	120.16 ± 19.09	128.65 ± 19.25	<0.001
SBP–DBP (mmHg)	78.67 ± 20.29	63.21 ± 18.35	71.16 ± 23.28	<0.001
Hypertension (%)	241 (96.8%)	393 (85.1%)	60 (96.8%)	<0.001
NS (%)	89 (35.7%)	187 (40.5%)	28 (45.2%)	0.289
DR (%)	187 (79.2%)	42 (11.8%)	32 (53.3%)	<0.001
CCVD (%)	81 (32.5%)	78 (16.9%)	16 (25.8%)	<0.001
DM course (months)	144 (72.00, 192.00)	29.50 (4.75–72.00)	96.00 (57.00–168.00)	<0.001
Hypertension course (months)	24.00 (4.00, 72.00)	18.50 (18.50–180.00)	120.00 (24.00–240.00)	0.148
HbA1c (%)	7.09 ± 1.54	6.84 ± 1.35	7.29 ± 1.46	0.021
BMI (kg/m^2)	26.40 ± 3.30	27.15 ± 3.83	28.19 ± 3.73	0.001
Haemoglobin (g/L)	112.99 ± 21.17	132.59 ± 22.32	121.47 ± 24.80	<0.001
Cholesterol (mmol/L)	5.17 ± 1.54	5.84 ± 2.39	5.31 ± 2.11	<0.001
Scr (mg/dL)	113.80 (89.50, 173.80)	86.60 (65.75, 117.88)	107.40 (83.95, 147.70)	<0.001
FBG (mmol/L)	6.83 ± 2.49	6.01 ± 1.87	6.63 ± 1.69	<0.001
ALB (g/L)	32.28 ± 5.88	32.92 ± 9.25	32.35 ± 8.81	0.592
Proteinuria (g/24 h)	3.82 (1.99–6.18)	2.66 (1.05–5.22)	2.28 (1.24, 5.73)	<0.001
eGFR ($mL/min/1.73\ m^2$)	58.64 ± 28.17	77.39 ± 32.13	62.73 ± 28.62	<0.001
UOSM (mOsm/L)	477.44 ± 146.13	588.66 ± 186.12	530.88 ± 159.37	<0.001
Hyperuricaemia (%)	36 (14.5%)	92 (19.9%)	15 (24.2%)	0.098

DN, diabetic nephropathy; NDRD, non-diabetic renal disease; SBP, systolic blood pressure; DBP, diastolic blood pressure; NS, nephrotic syndrome; DR, diabetic retinopathy; CCVD, cardiovascular and cerebrovascular diseases; DM, diabetes mellitus; HbA1c, haemoglobin A1c; BMI, body mass index; Scr, serum creatinine; FBG, fasting blood glucose; ALB, albumin; eGFR, estimated glomerular filtration rate; UOSM, osmotic pressure of urine.

Table 2 – Prediction of NDRD.

	Isolated DN vs. isolated NDRD	Isolated DN vs. non-DN
Sensitivity	96.14%	93.92%
Specificity	40.63%	40.63%
PPV	73.77%	75.82%
NPV	85.85%	77.12%
Kappa statistic	0.286; P < 0.001	0.268; P < 0.001

DN, diabetic nephropathy; NDRD, nondiabetic renal disease; PPV, positive predictive value; NPV, negative predictive value.

3.2. *Diagnostic efficiency of the kidney disease outcomes quality initiative guideline*

We validated the differential diagnostic efficiency of the KDOQI guideline for NDRD, isolated NDRD or non-DN, in 668 patients with a clear diagnosis using chi-square test and kappa test. For the isolated NDRD group, the sensitivity was 96.14% and the specificity was 40.63%. The positive predictive value (PPV) and negative predictive value (NPV) were 73.77% and 85.85%, respectively. The result of kappa test was 0.286 (P < 0.001). For the non-DN group, the sensitivity was 93.92% and the specificity was 40.63%. The PPV and NPV were 75.82% and 77.12%, respectively. The result of kappa test was 0.268 (P < 0.001). Results are listed in Table 2.

Subsequently, we separately analysed the diagnostic efficiency of the criteria under two conditions (isolated DN vs. isolated NDRD and isolated DN vs. non-DN) by kappa test, sensitivity, specificity, PPV, and NPV. Details are shown in Table 3. Overall, all criteria showed lower sensitivity and NPV and higher specificity and PPV. Absence of DR, glomerular haematuria and rapidly increasing proteinuria or nephrotic syndrome were able to distinguish the two kinds of diseases (P < 0.001) under two conditions. Systemic disease, rapidly decreasing eGFR and refractory hypertension barely showed any capability for differential diagnosis under two conditions.

3.3. *Grey area*

3.3.1. *Baseline data and pathological findings for grey area patients*

There were 105 grey area patients in total, with their mean age being 48.87 ± 11.42 years (range, 20–73). The clinical features of patients are listed in Supplementary Table 2. The DN group was more likely to have hyper-proteinuria, higher SBP and DBP, longer DM course, and lower haemoglobin and ALB levels than the NDRD group. Pathological findings for grey area patients are listed in Supplementary Table 3.

3.3.2. *Clinical diagnosis*

We assigned the grey area patients to clinically diagnosed DN or NDRD groups. The details of kappa tests are shown in Table 4. Kappa tests indicated that both predictive values of the guideline under two conditions were not significant (P = 0.97), suggesting that grey area patients should be further defined.

Table 3 – Prediction of criteria in the guideline.

Criteria	Isolated NDRD					Non-DN				
	Sensitivity	Specificity	PPV	NPV	Kappa test	Sensitivity	Specificity	PPV	NPV	Kappa test
Absence of DR	85.21%	88.63%	90.98%	81.66%	0.678; P < 0.001	78.04%	88.63%	91.64%	71.65%	0.601; P < 0.001
Rapidly decreasing eGFR	10.03%	92.41%	69.64%	37.16%	0.012; P = 0.446	9.23%	92.41%	70.69%	33.93%	0.007; P = 0.623
Rapidly increasing proteinuria or nephrotic syndrome	54.46%	85.98%	85.07%	56.27%	0.275; P < 0.001	52.91%	85.98%	86.43%	51.98%	0.254; P < 0.001
Refractory hypertension	8.23%	68.30%	31.07%	30%	0.052; P < 0.001	10.59%	68.30%	39.83%	27.82%	0.045; P < 0.001
Glomerular haematuria	33.43%	94.17%	90.77%	45.22%	0.174; P < 0.001	30.88%	94.17%	91.30%	40.76%	0.147; P < 0.001
Systemic disease	18.51%	87.05%	71.29%	38.09%	0.03; P = 0.151	18.02%	87.05%	73.39%	34.88%	0.025; P = 0.177

NDRD, nondiabetic renal disease; DN, diabetic nephropathy; DR, diabetic retinopathy; eGFR, estimated glomerular filtration rate; PPV, positive predictive value; NPV, negative predictive value.

Table 4 – Kappa test for grey area patients.

Conditions	Grey area assigned to DN	Grey area assigned to NDRD	P-value
Isolated NDRD	0.287; P < 0.001	0.384; P < 0.001	0.97
Non-DN	0.269; P < 0.001	0.364; P < 0.001	0.97

DN, diabetic nephropathy; NDRD, non-diabetic renal disease.

Table 5 – Correlation between clinical indexes and NDRD (with and without DN) in grey area patients identified by multivariate logistic regression analysis.

Factor	OR	95% CI	P value
Univariate logistic regression analysis			
SBP (mmHg)	0.979	0.961–0.997	0.025
SBP–DBP (mmHg)	0.963	0.936–0.990	0.008
Hyperuricemia	8.542	1.087–67.120	0.041
Hypertriglyceridemia	2.685	1.068–6.750	0.036
DM course (months)	0.985	0.977–0.992	<0.001
Haemoglobin (g/L)	1.036	1.009–1.064	0.010
ALB (g/L)	1.120	1.09–1.208	0.003
Multivariate logistic regression analysis			
Hyperuricaemia	9.87	1.041–93.534	0.046
DM course (months)	0.984	0.976–0.992	<0.001
ALB (g/L)	1.116	1.024–1.216	0.012

OR, odds ratio; CI, confidence interval; SBP, systolic blood pressure; DBP, diabolic blood pressure; DM, diabetes mellitus; ALB, albumin.

3.3.3. *Correlation between clinical indexes and nondiabetic renal disease in grey area patients*

We evaluated the correlation between clinical indexes and NDRD (with and without DN) using univariate and multivariate logistic regression analyses. All indexes associated with NDRD ($P < 0.05$) are listed in Table 5. Multivariate logistic regression analysis showed that hyperuricaemia, shorter DM course, and higher ALB levels were the three indexes that had the highest correlation with NDRD. Subsequently, we obtained the following equation for the prognosis of NDRD:

$$P_{NDRD} = \exp(9.866\text{Hua} + 1.116\text{ALB} + 0.984\text{Dm}) / [1 + \exp(9.866\text{Hua} + 1.116\text{ALB} + 0.984\text{Dm})]$$

where Hua refers to hyperuricemia (1, yes; 0, no); ALB, albumin (g/L); and Dm, diabetic mellitus course (months).

The ROC curve for the diagnosis of non-DN in grey area patients is showed in Supplementary Fig. 1. The area under the ROC curve was 0.860. The cut off value was 0.87, with sensitivity of 67.5%, specificity of 92%, PPV of 96.42% and NPV of 46.94% (Supplementary Table 4).

4. Discussion

With the rapid increase in DM in the population, DN has become the leading cause of end-stage renal disease [12]. KDOQI guideline published in 2007 offered the diagnostic criteria for DN and NDRD, and the causes for NDRD are often regarded as renal biopsy criteria for patients with CKD and DM. For the one hand, KDOQI guideline has been published more than 10 years. On the other hand, all the diagnosis causes for NDRD are dichotomous index. Thus, we made use of large groups of population in our centre around 10 years to evaluate the guideline, which showed that the sensitivity was high, but the specificity was poor. Rapidly decreasing eGFR, systemic disease, and refractory hypertension may have contributed to the poor diagnostic ability.

The varied scope and incidence rates of target-organ damage for systemic diseases might be the main reason for the low capability of determining a differential diagnosis. The incidence of secondary renal injury of some systemic diseases may be even lower than DN of DM (35–40%) [12], such as Hepatitis B-related nephritis (3%) [13], scleroderma nephropathy (10–20%) [14], and renal Behcet disease (2.6–36%) [15,16].

The unclear definition of rapidly decreasing eGFR in the guideline could also be associated with the low diagnostic efficacy. There are different means of understanding, and we used the definition of acute kidney injury (AKI) provided by the KDOQI guideline [17]. The rapidly decreasing eGFR included in the KDOQI guideline could possibly be considered other kidney diseases, which could be a second problem for patients with DM [5]. However, patients with CKD are more likely to have AKI than those without CKD [18]. Some evidence showed that AKI could occur frequently in patients with diabetes, which could be associated with tubular injury and inflammation markers [19]. Therefore, rapidly decreasing eGFR might reflect renal function changes in diabetic nephropathy.

Refractory hypertension was included in the criteria for NDRD in the KDOQI guideline because it could be a hallmark of renal artery stenosis [5]. In our study, diagnostic efficiency of refractory hypertension isn't high. In a study of diabetes, approximately 50–60% of patients with diabetes had hypertension and only 22–37% of them had good blood pressure control, which might be due to the stimulation of sympathetic nervous system or activation of the renin–angiotensin system [20]. For DN, previous evidence showed that patients with DN have higher blood pressure than those with NDRD and believed that lower blood pressure was a good indicator of NDRD [9,10,21], which is consistent with the findings of our study.

Our results and previous studies showed that DR is a valuable risk factors for DN [22]. Both DR and DN are important microvascular complications of DM and might have similar pathogenetic pathways. But they are not always consistent in type 2 diabetes. Previous research showed that biopsy-proven type 2 DN in approximately 15.3–38% of patients does not coexist with DR [23–25]. Moreover, our study showed that 23.81% of grey area patients with macroalbuminuria but without DR had DN. Taken together, renal biopsy still has important clinical significance, although these clinical indicators could offer some information.

This study has some limitations. This was a single-centre, retrospective study. The factor mentioned in the KDOQI guideline (>30% reduction in glomerular filtration rate within 2–3 months after initiation of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker) was not analysed in our study owing to the difficulty in defining this criterion and lacking data.

In conclusion, we found that the diagnostic efficiency of the KDOQI guideline for DN and NDRD in the Chinese population is unsatisfactory. Furthermore, the difficulty diagnosing grey area patients added further complexity. The high sensitivity and low specificity of the guideline make it more suitable as screening criteria than as diagnostic criteria. Renal biopsy remains to have important clinical significance in the diagnosis of DN and NDRD.

Conflicts of interest

None.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2018.11.008.

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