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EARLY DETECTION OF MICROALBUMINURIA IN PRIMARY CARE IN PATIENTS WITH DIABETES WITHOUT MONITORING BY SPECIALISTS

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ABSTRACT

Introduction: Diabetes mellitus, especially type 2 (T2DM), is a multifactorial metabolic disorder related to sedentary lifestyle and inadequate diet. Due to its insidious evolution, diagnosis is usually late, when there are already serious complications. In this context, diabetic kidney disease is one of the most common complications, characterized by reduced glomerular filtration rate (GFR) and variable albuminuria. Early detection of microalbuminuria allows intervention in initial phases with better evolution and delayed progression of CKD. **Objective:** This cross-sectional study aimed to evaluate the presence of microalbuminuria in T2DM patients in primary care without specialist follow up. **Methodology:** 187 patients from four PHU in Rolândia, Brazil, had their microalbuminuria tested with a dipstick in a spot urine sample. All participants signed the informed consent form approved by the institution. **Results:** The results showed no significant differences in the association between microalbuminuria and the variables: GFR, glycated haemoglobin (HbA_{1c}), tobacco use and alcoholism. In the study population, there is a prevalence of elderly, female, and white race, with less than 8 years of education. The main comorbidities are arterial hypertension, dyslipidaemia, smoking and alcoholism. **Conclusion:** No significant differences were observed in the association between microalbuminuria and GFR, HbA_{1c}, smoking and alcoholism.

KEYWORDS: Diabetes mellitus; albuminuria; primary health care.

1. INTRODUCTION

Diabetes Mellitus (DM) is a group of metabolic disorders characterised by chronic hyperglycaemia and is one of the most common endocrine dysfunctions. The condition may lead to both microvascular and macrovascular complications, resulting in high rates of morbidity and mortality. Its aetiology is associated with either a deficiency in insulin secretion or resistance to its action in the human body. Consequently, elevated blood glucose levels arise from an absolute or relative deficiency of insulin, insulin resistance, or a combination of both conditions.[1,2]

The main types of DM include type 1 (T1DM), which has an autoimmune origin involving the destruction of pancreatic β-cells and primarily affects children and adolescents, and type 2 (T2DM), characterised by insulin resistance and the progressive decline of insulin secretion. T2DM is the most prevalent form, accounting for approximately 95% of cases, and has a multifactorial origin with both genetic and environmental influences. Factors such as a poor diet and physical inactivity increase the risk of the disease, which is often associated with obesity and metabolic syndrome.[1,2,3]

T2DM may remain asymptomatic for extended periods, and its diagnosis often occurs when chronic complications, such as Chronic Kidney Disease (CKD), are already present. CKD is defined as the presence of structural and/or functional abnormalities in the kidneys lasting for at least three months with health implications. One such criterion is albuminuria, defined as an albumin-to-creatinine ratio (ACR) ≥ 30mg/g (3mg/mmol).[1,4]

According to the markers that define CKD, the disease can be classified into glomerular filtration rate (GFR) categories (G1–G5) and albuminuria categories (A1–A3). Diabetic nephropathy (DN) is one of its principal forms, arising through mechanisms such as hyperfiltration due to high glucose and vasoactive substance concentrations, glomerulosclerosis, and proteinuria/albuminuria, which may progress to renal failure. In this context, diabetic kidney disease (DKD) is a broader term that encompasses DN and other forms of the disease, including non-albuminuric phenotypes.[5,6]

Given the late diagnosis of DM, the associated complications, limited patient access to specialist care, and the costs of treatment, the early detection of renal parenchymal injury markers – such as microalbuminuria – becomes a highly relevant issue. Early identification enables intervention in the initial stages of the condition and improves outcomes by delaying the progression of CKD, including the progressive decline in renal filtration and the eventual need for renal replacement therapy in the medium to long term.[4,7]

In Brazil's Primary Health Care system, there is a high demand for diabetes care, and many patients do not have timely access to specialists such as endocrinologists or nephrologists. For this reason, this study was conducted in collaboration with four Primary Health Units (PHU) in the municipality of Rolândia, Brazil. The study aimed to assess the presence of microalbuminuria using reagent strips on spot urine samples. These reagent strips are an effective, low-cost method that facilitates early diagnosis and intervention within the study population.

2. MATERIALS AND METHODS

2.1. STUDY DESIGN

This is a cross-sectional and analytical study aimed at assessing the presence of microalbuminuria in type 2 diabetic or pre-diabetic patients receiving primary health care who do not have access to specialists (endocrinologists and/or nephrologists).

2.2. SETTING AND PERIOD

The collection of epidemiological data and urine samples for testing with reagent strips was carried out in four Primary Health Units (PHU) in the municipality of Rolândia, Brazil, affiliated with the Pontifical Catholic University of Paraná (PUCPR) as teaching centres, under the supervision of university faculty. The data collection period began in December 2023 and concluded in February 2025.

2.3. STUDY POPULATION AND INCLUSION CRITERIA

The target population of this study comprised patients with T2DM or those classified as pre-diabetic within the primary care system at four PHU in Rolândia, Brazil, who were not under specialist care. Thus, the inclusion criteria were patients aged 18 or older, those diagnosed with type 2 diabetes or pre-diabetes, and who were not receiving follow-up from an endocrinologist and/or nephrologist but were being monitored by the participating PHU. Additionally, all participants agreed to take part by signing an informed consent form.

Given that the expected prevalence of microalbuminuria in individuals with diabetes is approximately 24% and considering a 95% confidence level and a 5% margin of error, the sample size calculation would suggest 300 individuals. However, due to the availability of only 200 reagent strip kits, this number was adopted as the study sample size.

2.4. EXCLUSION CRITERIA

Exclusion criteria were patients under the age of 18; those who were regularly followed by an endocrinologist and/or nephrologist; pregnant women; patients with T1DM; patients presenting with fever at the time of sample collection; or those exhibiting pyuria or gross haematuria (visible red blood and/or clots in the sample). Lastly, individuals who did not agree to participate in the study were excluded.

2.5. DATA COLLECTION

Participation in the study involved the collection of a single spot urine sample, with a volume ranging from 10 to 50 millilitres. The sample was collected on the day of the interview, with no subsequent collections. At the same time, epidemiological data were obtained via a questionnaire developed by the researchers, administered in a face-to-face interview lasting approximately 20 minutes, conducted at the PHU itself. Clinical and demographic data were recorded, including age, sex, duration of diabetes diagnosis, arterial hypertension, body mass index (BMI), current treatment, among others. Additionally, serum creatinine and glycated haemoglobin (HbA1c) values were obtained based on records from the patient's medical file at the respective PHU.

2.6. ETHICAL CONSIDERATIONS

Patients were selected by the researchers at four PHU facilities in Rolândia, Brazil, based on the general aim of the study, by reviewing medical records to identify those with type 2 diabetes who were not under current follow-up by endocrinologists or nephrologists.

Subsequently, patients were invited to take part in the study as volunteers and were informed about the importance of early microalbuminuria detection in terms of outcomes and the progression of diabetic kidney disease. Volunteers were instructed, through the informed consent form provided by the researchers, that the participation would involve collecting an urine sample, answering a structured questionnaire, and a face-to-face interview. It was emphasised that there would be no personal benefit from participating in the study, except for the benefit of microalbuminuria screening and the potential for early intervention in the target population.

Participants were also informed that they would not be exposed to unnecessary risks, that they could refuse to participate or withdraw their consent at any time, and that data collected through the questionnaire would remain confidential and under the responsibility of the researchers. They were also given the opportunity to contact the researchers at any time for clarification regarding the progress of the study. Finally, they were assured that no discrimination would occur in participant selection, except according to the exclusion criteria established by the study's objective.

Before data collection began, this project was submitted

for ethical review by the Research Ethics Committee for Human Subjects at the Pontifical Catholic University of Paraná, in accordance with Resolution No. 466/2012 of the Brazilian National Health Council and was approved under opinion number 6.785.550 and CAAE 75531423.0.0000.0020.

2.7. STATISTICAL ANALYSIS

Initial data tabulation was carried out in Microsoft Excel and subsequently imported into SPSS (Statistical Package for the Social Sciences) for statistical analysis. A descriptive analysis was first conducted to assess the distribution of demographic data and the variables of interest (microalbuminuria, glomerular filtration rate, creatinine, and glycated haemoglobin). Student's t-test was used for normally distributed variables, while the non-parametric Mann–Whitney test was applied to non-normally distributed variables. Continuous variables were presented as means and standard deviations or medians and interquartile ranges, depending on the distribution. Categorical variables were reported as frequencies and proportions, also depending on the distribution. Qualitative categorical variables were presented as absolute and percentage frequencies and analysed using the χ^2 test. Statistical tests were considered significant when $p < 0.05$ (5% significance level).

3. RESULTS

The mean age of the patients is 63.8 years, and the sample predominantly consists of female patients (74.3%), individuals of white ethnicity (57.8%), and those with less than eight years of education (69.5%) **(Table 1)**.

Table 1: Sociodemographic data.

Variables	n(%)
	n = 187
Mean age (minimum - maximum) (years)	63,8 (34 - 88)
Sex	
Male	48 (25,7)
Female	139 (74,3)
Race	
White	108 (57,8)
Black	32 (17,1)
Brown	47 (25,1)
Education	
More than 8 years	57 (30,5)
Less than 8 years	130 (69,5)

Regarding diabetes-related factors and comorbidities, the majority of participants had been diagnosed with the condition for less than ten years (59.9%), and a minority were using insulin for glycaemic control (28%). Additionally, a substantial proportion of the sample presented with concomitant arterial hypertension (78.3%), most of whom had a long-standing diagnosis (exceeding ten years). The prevalence of dyslipidaemia among individuals with diabetes was 18.7%, while the proportions of smokers and alcohol consumers were 11.4% and 12.9%, respectively **(Table 2)**.

Table 2: Factor and comorbidities related to diabetes.

Variables	n(%)
	n = 187
Years since DM2 diagnosis	
Less than 10 years	112 (59,9)
10 years or more	75 (40,1)
Insulin use	52 (27,8)
Arterial hypertension	
Total patients	144 (77)
10 years or more since diagnosis	81 (43,3)
Dyslipidaemia	53 (28,3)
Smoking	
Current	21 (11,4)
Former	54 (29,2)
Alcohol drinking	
Current	24 (12,9)
Former	43 (23,3)

The highest frequency of serum creatinine values ranged between 0.6–1.3 mg/dL, representing 84% of the sample. Serum creatinine levels are used as a basis for estimating renal function in terms of glomerular filtration rate (GFR), which varies for a given test result depending on age and sex. More than half of the patients (56.1%) had glycated haemoglobin (HbA1c) values ≥ 6.5%, while 9.1% had HbA1c < 5.7%. A large proportion of the sample presented with negative proteinuria (70.6%), and 66.8% had microalbuminuria < 0.08, whereas 8.6% had a microalbuminuria level of 0.12 **(Table 3)**.

Table 3: Factors associated to diabetic kidney disease.

Variables	n(%)
	n = 187
Serum creatinine (SC) (mg/dL)	
SC ≤ 0,6	4 (2,1)
0,6 < SC < 1,3	157 (84)
SC ≥ 1,3	26 (13,9)
GFR (em ml/min/1,73/m2)	
GFR ≥ 90	54 (28,9)
60 ≤ GFR ≤ 89	89 (47,6)
45 ≤ GFR ≤ 59	32 (17,1)
30 ≤ GFR ≤ 44	8 (4,3)
15 ≤ GFR ≤ 29	4 (2,1)
HbA_{1C} (%)	
$HbA_{1C} < 5,7$	17 (9,1)
$5,7 \leq HbA_{1C} \leq 6,4$	65 (34,8)
$HbA_{1C} \geq 6,5$	105 (56,1)
Proteinuria	
Negative	132 (70,6)
Normal	45 (24,1)
1+	7 (3,7)
2+	3 (1,6)
Microalbuminuria (Malb)(g/L)	
Malb < 0,08	123 (65,8)
Malb = 0,08	48 (25,7)
Malb = 0,12	16 (8,6)

The main associations investigated involved microalbuminuria in relation to GFR, HbA1c, smoking, and alcohol consumption. Using a p value < 0.05 and, consequently, a 95% confidence interval (CI), the following results were obtained:

Table 4: Associations between microalbuminuria and other variables in study.

	Microalbuminuria (g/L)			χ2	p value
	< 0,08 n(%)	0,08 n(%)	0,12 n(%)		
GFR (mL/kg/1,723m^2)					
GFR ≥ 90	36 (66,7)	13 (24,1)	5 (9,3)	11,554	0,172
60 ≤ GFR ≤ 89	60 (67,4)	24 (27)	5 (5,6)		
45 ≤ GFR ≤ 59	22 (68,8)	7 (21,9)	2 (25)		
30 ≤ GFR ≤ 44	3 (37,5)	2 (25)	3 (37,5)		
15 ≤ GFR ≤ 29	2 (5)	2 (50)	0 (0)		
HbA_{1C} (%)					
HbA_{1C} < 5,7	12 (70,6)	5 (29,4)	0 (0)	6,616	0,158
5,7 ≤ HbA_{1C} ≤ 6,4	49 (75,4)	12 (18,5)	4 (6,2)		
HbA_{1C} ≥ 6,5	62 (59)	31 (29,5)	12 (11,4)		
Current smoker					
Yes	12 (57,1)	7 (33,3)	2 (9,5)	0,835	0,659
No	110 (67,1)	41 (25)	13 (7,9)		
Alcohol drinking					
Yes	18 (75)	6 (25)	0 (0)	2,749	0,253
No	104 (64,2)	42 (25,9)	16 (9,9)		

3.1. DISCUSSION

The results obtained from urine sample testing using reagent strips in diabetic and pre-diabetic patients demonstrated that the vast majority had associated arterial hypertension or another comorbidity, such as dyslipidaemia, smoking, or alcohol consumption.

A cross-sectional study involving 77,581 patients conducted in the southern zone of São Paulo, Brazil, which explored glycated haemoglobin, lipid profiles, and albuminuria in the general population, yielded findings consistent with those of the present study: a predominance of female participants and dyslipidaemia as the most prevalent comorbidity, appearing almost ubiquitously. Only a small fraction of diabetic patients (a subgroup of the total sample) were tested for microalbuminuria, with a reported prevalence of 22.8%.[8]

It is well established that diabetes is a major contributor to the progression to chronic kidney disease (CKD). Despite heterogeneous prevalence across different populations, the condition significantly increases the risk of CKD, with odds ratios ranging from 1.3 to 4.6. The Brazilian Society of Nephrology estimates that approximately 32% of patients undergoing dialysis for CKD are diabetic, further highlighting the adverse relationship between diabetes and CKD.[9,10]

A retrospective study involving hypertensive patients with no initial signs of renal impairment revealed that elevated blood pressure was a significant risk factor for the development of renal insufficiency (GFR < 60 ml/min/1.73 m²). Similarly, dyslipidaemia also poses an increased risk for diabetic kidney disease (DKD). Among patients with type 2 diabetes, elevated cholesterol and triglyceride levels were identified as risk factors for the progression of nephropathy and the need for renal replacement therapy. Moreover, when these lipid abnormalities co-occur with other comorbidities such as hypertension, the risk of renal function decline is further amplified.[11,12]

In the present analysis, 11.4% of patients with type 2 diabetes were current smokers and 12.9% reported current alcohol consumption. Although these figures represent a minority of the sample, they warrant clinical attention, particularly in light of the fact that 29.2% were former smokers and 23.3% former alcohol consumers. Both smoking and regular alcohol intake have been associated with an increased risk of developing microalbuminuria and progression of diabetic nephropathy in individuals with type 2 diabetes, potentially due to mechanisms involving endothelial inflammation and increased renal oxidative stress.[11,12]

In this study, the prevalence of creatinine values among patients ranged between 0.6-1.3mg/dL, while the most frequent microalbuminuria value was < 0.08g/L. The measurement of urinary albumin in a spot urine sample is a recommended method for screening diabetic kidney disease; a meta-analysis of 14 studies reported a sensitivity of 85% and a specificity of 88% for this method.[14] Microalbuminuria is a well-established indicator of renal disease progression in diabetic patients, often preceding overt proteinuria, elevated serum

creatinine, and a more rapid decline in glomerular filtration rate (GFR).

Clinical trials such as the IDNT (Irbesartan Diabetic Nephropathy Trial) and RENAAL (Reduction of Endpoints in Non-Insulin Dependent Diabetes Mellitus with the Angiotensin II Antagonist Losartan) demonstrated that diabetic and hypertensive patients with microalbuminuria had an increased risk of progressing to end-stage renal disease and of doubling their serum creatinine levels over time.[15]

The majority of patients in the sample exhibited HbA_{1C} values above 6.5%. A longitudinal study demonstrated that moderate and rising levels of glycated haemoglobin are associated with a higher risk of progression to chronic kidney disease (CKD), with 35.6% of patients experiencing unfavourable outcomes. This reinforces the role of poor glycaemic control in CKD progression.[16]

Statistical analysis using the chi-square (χ^2) test was employed to assess the association between microalbuminuria and clinically relevant variables in the diabetic patients included in the study. Based on the data, no statistically significant associations ($p > 0.05$) were identified between microalbuminuria and GFR ($\chi^2 = 11.554$, below the critical $\chi^2 = 15.507$; 8 degrees of freedom), HbA1c ($\chi^2 = 6.616$, below the critical $\chi^2 = 9.488$; 4 degrees of freedom), alcohol consumption, or smoking, as shown in **Table 4**.

These findings may be explained by factors such as the small sample size, which may have been insufficient to detect the heterogeneity of the condition and therefore limits the generalisability of the results to other populations. Another relevant factor is the limited sensitivity of the diagnostic method employed (reagent strips), which, while recommended for screening microalbuminuria, is not the gold standard for analysis.

A discrepancy in the colour change of the reagent strip, particularly when assessing microalbuminuria, hindered result interpretation, as described in Appendix C. During the course of the study, AVE 14 reagent strips (Goyazes Biotecnologia Ltda) were used to detect microalbuminuria. However, following data collection, a Technovigilance Alert (No. 3998/2023) issued by the Brazilian Health Regulatory Agency (ANVISA) was identified, which reported issues with the device's sensitivity in detecting urinary proteins, as detailed in Annex B. This technical limitation may have compromised the accuracy of the results and could be a contributing factor to the absence of statistically significant findings in the chi-square (χ^2) test.[17]

The most notable trend observed in this study – reflected by the χ^2 value closest to the critical threshold – was the association between microalbuminuria and GFR. This relationship is widely reported in the literature, as microalbuminuria is recognised as an early marker of renal damage and, if present, is typically associated with a more rapid decline in GFR compared to individuals without this abnormality. One such example is a retrospective Japanese cohort study involving 6,618 patients, which found that the presence of microalbuminuria was associated with progressive and faster deterioration of renal function.[18]

Microalbuminuria is more commonly observed in patients with HbA1c levels ≥ 6.5%, occurring in 24.2% of those analysed. In the present study, using the same threshold, a prevalence of 11.4% was identified.[9]

Regarding behavioural factors, a cross-sectional study conducted in Cairo with 280 participants demonstrated that both active and passive smoking, as well as advanced age, were significantly associated with the presence of microalbuminuria.[18] Similarly, a cross-sectional study carried out in Goiânia identified alcohol consumption as a variable associated with microalbuminuria, with a prevalence of 32.5% among alcohol consumers, suggesting a potentially important role of alcohol use in subclinical renal injury in individuals with type 2 diabetes.[20]

Despite the limitations discussed, the findings of the present study provide valuable contributions by highlighting that early screening for microalbuminuria in diabetic patients should be widely adopted. Many patients may be asymptomatic, yet already exhibit altered albuminuria levels indicative of early renal impairment.

4. CONCLUSION

The prevalence of microalbuminuria among diabetic and pre-diabetic patients in the context of primary health care in the municipality of Rolândia, Brazil, was 8.6%. Some trends were identified that may indicate risk factors for diabetes, such as reduced glomerular filtration rate (GFR), elevated HbA1c, and behaviours such as smoking and alcohol consumption. The epidemiological profile of these patients is predominantly female, with white individuals being the most prevalent ethnic group and an education level below eight years.

The findings of this study reinforce the importance of early and continuous screening for diabetic kidney disease, particularly given the high prevalence of associated comorbidities such as hypertension, dyslipidaemia, smoking, and alcohol consumption — all recognised risk factors for adverse renal outcomes. Moreover, screening gains further relevance considering limited access to specialist care, which may delay early diagnosis and lead to complications that could otherwise have been prevented.

Although no statistically significant associations were observed between microalbuminuria and the variables glycated haemoglobin (HbA1c), glomerular filtration rate (GFR), smoking, or alcohol consumption, a trend

towards an association with GFR was noted, aligning with findings from the scientific literature.

Methodological limitations such as sample size and the accuracy of the reagent strips may have affected the sensitivity of the results. Nonetheless, the data suggest that microalbuminuria assessment should be systematically incorporated into clinical practice, aiding in the early detection of diabetic kidney disease.

Therefore, early diagnosis based on markers such as GFR and microalbuminuria is crucial for individual risk stratification and for implementing timely and effective therapeutic interventions to prevent progression to diabetic kidney disease.

This study has thus contributed to scientific knowledge by demonstrating the importance of early detection of microalbuminuria to avoid adverse renal outcomes.

It is recommended that future cross-sectional studies involve larger and more heterogeneous samples of diabetic patients, as early detection of microalbuminuria using simple diagnostic methods such as reagent strips is a viable strategy for monitoring and preventing adverse outcomes in the target population. Likewise, patients presenting with significant microalbuminuria on reagent strips should be advised of the need for further investigation using complementary diagnostic tests, to ensure appropriate clinical follow-up.

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CONFLICT OF INTERESTS

This study has no conflict of interest.

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