Research Article

Evaluation of urinary albumin/creatinine ratio strip assay: a reliable screening alternative to replacing the quantitative biochemical methods

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Abstract

Background: Clinical laboratories play a crucial role in the diagnosis and monitoring of chronic kidney disease. Quantitative measurement of urinary albumin, expressed as the albumin/creatinine ratio (ACR), is the most commonly used biomarker for this purpose. This study evaluates the feasibility of using urinary strips as a screening tool for ACR, compared with conventional biochemical methods. Specifically, we assessed the diagnostic performance of the urinary strip and the potential economic impact of implementing this screening approach.

Materials and methods: This study included 1,257 samples obtained in primary care, with systematic assessment of requests for urinary strip tests and biochemical quantification of urinary albumin and creatinine. Semi-quantitative measurements were performed using Unamax autoanalyzer and quantitative determinations were conducted using AU5800 autoanalyzer. Diagnostic indicators for ACR were calculated for different albumin and creatinine levels. Economic effects were analyzed based on the costs of both testing methods.

Results: Results at different cut-off values for albumin and creatinine showed optimal performance at 10 mg/L and above 100 mg/dL, respectively. 666 biochemical quantification tests (53.85% screening) for urinary albumin and creatinine could have been avoided during the study period, resulting in total savings of 522.81€.

Conclusions: The present study supports the use of Unamax autoanalyzer for ACR measurement as a screening tool, avoiding unnecessary quantitative measurement, as well as allowing early identification of patients with pathological albuminuria levels. The economic impact was significant, demonstrating effective optimisation of financial resources and workflow efficiency in clinical laboratories.

Introduction

Urinalysis is the third most commonly requested test in clinical laboratories and is often included in annual medical check-ups requested from patients as a control measure [1-2]. Untreated proteinuric nephropathies can cause irreversible damage to the renal parenchyma, chronic kidney disease (CKD), and ultimately lead to end-stage renal failure. CKD is considered a major global public health problem worldwide due to the high associated comorbidities, poor prognosis, and high resource consumption for the healthcare system [3]. Therefore, the early detection of CKD in at-risk patients should be considered a top health priority, as this could allow the implementation of strategies to slow disease progression to advanced stages and mitigate associated complications [4].

CKD usually has an insidious onset and therefore may go unnoticed in its earliest phases, remaining asymptomatic or silent until advanced phases of the disease. However, this disease can initially be suspected through routine laboratory tests, such as glomerular filtration rate (GFR) or the detection of markers of renal damage. Therefore, the clinical laboratory plays a crucial role in the diagnosis, prognosis, and follow-up of CKD [5].

The presence of elevated protein or albumin concentrations in urine, along with GFR, forms the basis of the current diagnostic and staging criteria for CKD [6]. Albumin is the most abundant and common protein in the urine of normal individuals, which is why albuminuria, and more specifically the albumin/creatinine ratio (ACR), is considered to be the most frequently used biomarker, as it is the most sensitive and early for the assessment and detection of kidney damage and CKD [7]. Moreover, this test is also a predictor of the development and progression of both diabetic and non-diabetic kidney disease, as well as being a systemic marker of endothelial dysfunction, arterial remodelling and a predictor of incident hypertension and cardiovascular mortality [8-9]. It is worth noting that patients with diabetes and hypertension, two of the three most prevalent diagnoses in primary care (PC), are at significant risk of nephropathy [10]. Current guidelines for the correct use of albuminuria testing are clear for both patient groups: the test should be used diagnostically, prognostically, and then annually for follow-up [11-12].

The normal ACR value for healthy adults is less than 30 mg/g. ACR values between 30 and 300 mg/g indicate moderately increased albuminuria, while values exceeding 300 mg/g represent severely increased albuminuria [6]. A persistent ACR ≥30 mg/g over three months, confirmed by three different determinations spaced within those months, is indicative of renal damage [3, 13].

The development of tools that allow mass screening of CKD in the general population could be highly valuable. In recent years, several manufacturers have incorporated the semi-quantitative estimates of albumin, creatinine, and ACR concentrations into their urinalysis reagent strips. This provides laboratories with a more economical, efficient, and widely applicable screening tool to the general population particularly for patients at risk of CKD.

The hypothesis of this study is that the semiquantitative determination of ACR using Labusticks 14F strips could serve as an effective screening tool for urine samples from PC patients. The objective was to compare these measurements with those obtained using the biochemistry autoanalyzer and to assess the feasibility, cost-effectiveness, and impact on laboratory workflow of implementing dipstick testing as a routine screening method. This approach could help avoid unnecessary quantitative testing, optimize resource utilization, and reduce turnaround times, particularly in samples with negative results.

Material and Methods

Ethics statement

This study was approved by the Institutional Research Ethics Committee of Valencia General University Hospital, Valencia, Spain. The need for written informed consent was waived due to the nature of the study and the anonymity of the data. All personal information, such as patient name, hospital registration number, date of birth, and national resident registration number, was deleted after assigning a research subject number to ensure anonymity. The study was performed in accordance with the Declaration of Helsinki.

Setting and patients

The clinical laboratory is located in a 503-bed urban university hospital serving an assigned population of 383.162 inhabitants within the Valencia-West Interdepartmental Health Area. The laboratory processes samples from urgent care, hospitalized patients, outpatient clinics, and PC from 24 different collection centres. The most common clinical indications for laboratory tests in PC within our health district are pathologies associated with cardiovascular risk such as dyslipidemia, essential hypertension, and diabetes mellitus.

Study design

A retrospective and unicentric cross-sectional study were designed from 24-31 July 2024.

Laboratory methods

A total of 1.257 samples were processed over one week. For urine strip tests, Labusticks 14F strips (Menarini Diagnostics®, Badalona, Spain) analyzed with the Unamax device (Menarini Diagnostics®, Badalona, Spain) were used. For quantitative biochemical determinations of urinary albumin and creatinine, the AU5800 autoanalyzer (Beckman Coulter®, California, USA) was employed.

The Unamax analyzer utilizes the technique of reflectance spectrophotometry to provide semi-quantitative measurements of albumin, creatinine, and ACR based on these two parameters. The detection system uses a contact image sensor. The possible results provided include: for albumin, ≤10, 30, 80, ≥150 mg/L;

and for creatinine, 10, 50, 100, 200, 300 mg/dL.
The AU5800 autoanalyzer determined urinary albumin using the immunoturbidimetric method. This involves the specific reaction of human serum albumin with anti-human serum albumin antibodies to form insoluble complexes. The absorbance of these complexes is proportional to the albumin concentration in the sample.
Creatinine determination in AU5800 autoanalyzer used the technique of kinetic colourimetry (Jaffé method) traceable to the reference method of isotope dilution mass spectrometry. In this method, creatinine forms a yellow-orange compound with picric acid in an alkaline medium. The rate of absorbance change at 520/800 nm is proportional to the creatinine concentration in the sample.
Conventional reagents for the AU5800 (Beckman Coulter®, California, USA) were used for both determinations.

Cross-sectional study

This retrospective study included 1,257 first-morning urine samples from PC patients. The inclusion criterion was the simultaneous request for both semiquantitative ACR testing using urine strips and quantitative biochemical analysis. Semiquantitative measurements were performed using an automated urine strip analyzer (Unamax), while quantitative determinations of albumin, creatinine, and ACR were conducted on the AU5800 biochemistry platform. Both methods were applied to each sample, allowing for direct comparison of diagnostic performance.
Patient demographic data from PC, along with quantified values of urinary albumin and creatinine, and the three determinations provided by urine strips (ACR, albumin, and creatinine), were collected using the Laboratory Information System (LIS) (Modulab®).
Calculations were conducted under four different scenarios depending on urine strip results: in the first one, no data adjustments were made, and only ACR values ≤30 mg/g (normal or non-pathological) were considered. In the second scenario, data selection was based on the criteria of albumin = 10 mg/L and creatinine ≥10 mg/dL. The third scenario applied the criteria of albumin = 10 mg/L and creatinine ≥50 mg/dL. The fourth scenario used the criteria of albumin = 10 mg/L and creatinine ≥100 mg/dL. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and screening percentage were calculated.
The number of immunoturbidimetric tests potentially avoided was estimated, and an economic estimate was made taking into account that for negative results it would no longer be necessary to analyze them by the reference method (quantification). An economic analysis was conducted based on the costs of the two tests (€0.98 for quantitative albumin and creatinine tests and €0.195 for a urine strip). The costs considered in this study are limited to reagent expenses, without accounting for personnel costs or time invested.

Statistical analysis

Data were statistically processed and analyzed using RStudio (Version 4.3.2) and Microsoft Excel. Results from the Unamax analyzer were cross-referenced with those from the AU5800 autoanalyzer, considering only requests containing both tests. The VLOOKUP function in Excel was used to search matches, and contingency tables were populated using the COUNTIFS function. Subsequently, data were extracted for sensitivity, specificity, PPV, NPV, and screening percentages.
For the cost-benefit analysis, we estimated potential savings by comparing the cost of quantitative albumin and creatinine measurements with that of the labusticks 14F strips.

Results

A total of 1.257 samples were analyzed by urine strip and biochemical quantification. Their demographic characteristics and percentage of negative quantified ACR values (ACR < 30 mg/g) are shown in Table 1.

Table 1: Study population characteristics.

Population characteristics	
Patients, n	1257
Men, n (%)	608 (48.4%)
Women, n (%)	649 (51.6%)
Age, years (mean ± SD) [range]	59 ± 17 [7–95]
Negative results of ACR (<30 mg/g)	
Patients, n (%)	1023 (81.4%)

Table 2 shows the diagnostic indicators and potential cost savings across the four different scenarios. The greatest cost savings were achieved for "normal or non-pathological" urine strip results (ACR ≤30 mg/g) (Table 2, Columns I). Significant savings were also observed for urine analysis with strip albumin values of 10 mg/L and creatinine strip results exceeding 10 mg/dL (Table 2, Columns II), though this came at the expense of a 5.40% false-negative (FN) rate. For urinalysis with strip albumin values of 10 mg/L and creatinine strip results exceeding 50 mg/dL (Table 2, Column III), the FN rate dropped below 2.62%, and sensitivity improved. However, the best results were observed in the fourth scenario

(Table 2, Column IV), which showed a high NPV of 98.38% and a sensitivity of 93%.

Based on the results of the best scenario (Table 2, Column IV), 666 biochemical quantification tests for albumin and creatinine in urine could have been avoided during the study period (53.85% screening), corresponding to a total cost savings of 522.81€. Considering that the results pertain exclusively to one-week, systematic application of this strategy over a year (52 weeks) could hypothetically save 34.632 biochemical tests and 27.186.12€.

Table 2: Diagnostic indicators and potential savings, considering negative values when the ACR value of the strip is normal (column I), and when the albumin value = 10 mg/L, with creatinine values above 10, 50, and 100 mg/dl, respectively (column II, II and IV).

Results	I ACR≤30 mg/g	II Albumin=10 mg/L Creatinine≥10 mg/dl	III Albumin=10 mg/L Creatinine≥50 mg/dl	IV Albumin=10 mg/L Creatinine≥100mg/dl
Negatives	1023	1001	954	666
False negatives	36 (2.86%)	68 (5.40%)	33 (2.62%)	11 (1.65%)
NPV (%)	96.60%	93.64%	96.66%	98.38%
PPV (%)	63.70%	50%	47.76%	27.90%
Screening (%)	84.24%	85.04%	78.52%	53.85%
Specificity (%)	93.50%	91.50%	87.20%	60.88%
Sensitivity (%)	77.60%	58%	80%	93%
Savings (€)	803.05€	785.78€	748.89€	522.81€

Discussion

The epidemiological significance of CKD lies not only in its high prevalence but also in the significant reduction in quality of life, the elevated morbidity and mortality rates, and the associated healthcare and social costs. It is estimated that more than 850 million people (10% of the adult population) worldwide suffer from kidney diseases, the majority of which have CKD [14]. The estimated global prevalence of CKD ranges from 8% to 16% [15]. Internationally, CKD was responsible for 1.2 million deaths and 35 million years lived with disability (YLD) in 2016 [16]. The global incidence, prevalence, mortality, and YLD rates of CKD have risen dramatically since 1990, driven by population growth, aging, and the increasing number of individuals with diabetes and hypertension [16], which, along with glomerulonephritis, are the main causes of CKD [16-17]. Additionally, common non-renal complications of CKD, such as myocardial infarction, stroke, heart failure, and infections, further contribute to its burden [18]. This is an important issue, as the prevalence of stages 3-5 of CKD among adults over 20 years of age is 4.7% in men and 5.8% in women, and more than 50% of CKD cases going undetected if albuminuria is ignored [6, 19].

Proteins are excreted variably throughout the day depending on hydration status, physical activity, or protein intake. This makes 24-hour urine collection the reference specimen for measuring proteinuria or albuminuria [6]. However, the preanalytical challenges and collection issues associated with this method have led to the search for alternative specimens, such as single-void urine samples. In adults, most guidelines recommend evaluating proteinuria by determining the ACR preferably in the first-morning urine [3, 6, 20].

Proteinuria may increase in certain situations, such as the presence of fever, stress, high protein intake, heart failure, or intense physical exercise, and this can be corrected after the causative factor disappears. Similarly, urinary tract infections or menstruation can lead to false positive results. Therefore, it is advisable to avoid urine collection for albuminuria/proteinuria assessment under these circumstances. Moreover, smoking and obesity have also been associated with the presence of albuminuria, and up to 25% of individuals over 80 years old show this condition. In this scenario, PC plays a crucial role in the early detection of CKD, managing patients in these situations, controlling progression factors, and addressing early-stage complications [3].

Our data show good concordance and a NPV close to 98.3%, which facilitated the screening of ACR results below 30 mg/g in Unamax, without the need for quantitative determination in AU5800. In our study, this corresponded to 53.85% of the samples. Considering the sensitivity (93%) and NPV (98.3%) indicators, ACR testing using urine strips can be considered an effective screening method for patients who require regular monitoring of this parameter, such as those with diabetes, hypertension, and renal disease. For patients with a semi-quantitative positive ACR result, it would be useful to extend further quantitative determination, as this would aid in the early diagnosis of patients at risk of renal damage.

Our best scenario indicates that the screening method using reagent strips has a sensitivity of 93% and a specificity

of 60.88%, with PPV and NPV of 27.9% and 98.38%, respectively. In previous studies that evaluated others strip tests, the sensitivity, specificity, PPV and NPV for detecting albuminuria was 97–97.5%, 44–67%, 22–70.3% and 97.1–99% respectively. These studies have demonstrated positive correlations between urinary albumin and ACR determinations using urine test strips, compared to biochemical assays employing immunonephelometric and immunoturbidimetric methods, emphasizing both their cost-effectiveness and potential for automation [12, 21-23]. The variability may be attributed to differences in study populations, inclusion/exclusion criteria, methodologies used for urine strip tests and ACR quantitative determination and differences in the definition of the cut-off. To date, our study is the first to evaluate and validate the use of Unamax autoanalyzer specifically, thus providing novel evidence supporting their applicability and reliability for clinical screening purposes.

The implementation of the findings from this study in clinical laboratories could lead to significant savings in both economic resources and personnel time, mainly due to the high screening percentage achieved (53.85%). Additionally, the low cost, speed, and ease of use allow it feasible for analyzing many samples, reducing the need for quantitative determinations and thus lowering overall costs. This workflow has the potential to generate substantial resource savings, as previously described in other studies [12]. In addition to financial benefits, the time and effort saved by staff can be redirected toward more critical tasks, enhancing overall laboratory efficiency [24].

The high prevalence of pathologies such as diabetes, hypertension, and CKD itself, in which ACR is used as an early marker of kidney damage, along with other renal injury markers and GFR, has led to a significant increase in the number of requests for these ratios from PC. Therefore, clinical laboratories play a crucial role in the diagnosis and subsequent monitoring of these conditions [12]. Additionally, they are responsible for adequate and efficient demand management, which requires laboratories to establish good workflows to accommodate this increase in healthcare demand while reducing associated costs. This management could be solved by implementing an ACR screening system using test strips in urine autoanalyzers.

In conclusion, the present study demonstrated that semi-quantitative determinations of albuminuria and creatinuria in urine strips using Unamax are a valid and cost-effective method for identifying patients without pathological albuminuria values, thus preventing unnecessary subsequent quantification. According to our analysis, with this strategy we can obviate the quantitative measurement of approximately 53.85% of the requested urinary albumin test, resulting in significant economic savings. Moreover, this method helps exclude patients without renal risk and can be used as a screening tool due to its lower cost, high sensitivity, and ease of application across the population. By applying only a simple condition in the LIS, screening results significantly improve while maintaining a high screening percentage. Implementing the findings of this study can lead to substantial savings in both economic costs and time, thus producing an improvement in laboratory workflow.

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Author Contributions

The corresponding author takes full responsibility that all authors on this publication have met the following required criteria of eligibility for authorship: (a) significant contributions to the conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting or revising the article for intellectual content; (c) final approval of the published article; and (d) agreement to be accountable for all aspects of the article thus ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved. Nobody who qualifies for authorship has been omitted from the list.

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Abbreviations

ACR: Albumin/Creatinine Ratio
CKD: Chronic Kidney Disease
FN: False Negative
GFR: Glomerular Filtration Rate
LIS: Laboratory Information System
NPV: Negative Predictive Value
PC: Primary Care
PPV: Positive Predictive Value

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