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XRONİK BÖYRƏK XƏSTƏLİYİNİN 1-3-CÜ MƏRHƏLƏSİNDƏ OLAN XƏSTƏLƏRDƏ UROMODULİN PROFİLİNİN BÖYRƏK FUNKSİYASI İLƏ ƏLAQƏSİ

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Məqalədə XBX-nin 1-3-cü mərhələsində olan xəstələrdə uromodulin (Umod) profilinin böyrək funksiyası ilə əlaqəsini qiymətləndirmək məqsədilə aparılmış tədqiqat işi haqqında məlumat verilmişdir.

Tədqiqat, XBX-nin 1-3-cü mərhələsində olan 91 xəstə (38,46% kişi, 61,54% qadın) üzərində aparılmışdır. XBX diaqnozu KDIGO 2012 meyarlarına əsaslanılmaqla qoyulmuşdur. Uromodulin profilini geniş əhatəli şəkildə qiymətləndirmək üçün sidik uromodulin (uUmod), 24 saatlıq uUmod (uUmod24), serum uromodulin (sUmod), sidik albumin/uromodulin nisbəti (uAlb/uUmod), sidik uromodulinin sidik kreatinini ilə normallaşdırılmış nisbəti (uUmod/uCrea), uUmod/sUmod, uUmod/qlomerulyar filtrasiya sürəti (eGFS), uromodulinin fraksion ifrazı (FeUmod), uromodulinin fraksion sekresiyası (FsUmod), serum uromodulinin qatılığının serum sidik turşusu (sUrAc) qatılığına nisbəti, serum sidik cövhəri (sUrea), qanda sidik cövhəri azotu (BUN) və onların serum kreatinini (sCrea) ilə normallaşdırılmış nisbətləri. eGFR CKD-EPI, MDRD və Cockcroft–Gault (CG) formulaları ilə hesablanmışdır. Statistik analiz EZR v.4.3.1 proqramı ilə aparılmış, Pearson korrelyasiya testi ($p < 0,05$) tətbiq edilmişdir.

Tədqiqat göstərmişdir ki, XBX-nin 1-3-cü mərhələsində olan xəstələrdə uUmod səviyyəsi subnormal göstəricilərə bərabər olur. FeUmod-un artması, kanalikuliyar funksiyanın struktur zədələnmə şəraitində saxlanmasına yönəlmiş kompensator aktivləşməyə səbəb ola bilər. Uromodulin profili, xüsusilə onun fraksional və normallaşdırılmış formaları, xəstə stratifikasiyası və böyrək disfunksiyasının erkən aşkarlanması üçün əlavə funksional biomarker kimi xidmət edə bilər.

Açar sözlər: xronik böyrək xəstəliyi, uromodulin, qlomerulyar filtrasiya sürəti, uromodulinin fraksional ifrazı

Ключевые слова: хроническая болезнь почек, уромодулин, скорость гломерулярной фильтрации, функциональное выделение уромодулина

Key words: chronic kidney disease, uromodulin, glomerular filtration rate, fractional excretion of uromodulin

THE RELATIONSHIP BETWEEN UROMODULIN METABOLISM PARAMETERS AND KIDNEY FUNCTION IN PATIENTS WITH CHRONIC KIDNEY DISEASE STAGE 1–3

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This article provides information about a study conducted to assess the association between uromodulin (Umod) metabolism parameters and kidney function in patients with chronic kidney disease (CKD) stages 1–3.

This cross-sectional study included 91 patients (38.5% men, 61.5% women) diagnosed with CKD according to the KDIGO 2012 criteria. Parameters of uromodulin metabolism were evaluated (urinary uromodulin (uUmod), uUmod24, serum Umod, and their derivatives: uUmod/uCrea, uUmod/sUmod, fractional excretion of Umod), fractional secretion of Umod, etc.), and eGFR was calculated using the CKD-EPI, MDRD, and CG formulas. Statistical analysis was performed using EZR v.4.3.1; correlation analysis was used ($p < 0.05$).

Positive correlations were identified between uUmod and its derivatives, as well as between eGFR and uUmod/eGFRCKD. Inverse correlations were found between sCrea and eGFR, and between sUrea and uUmod/BUN. FeUmod showed a positive correlation with sCrea and BUN, while FsUmod correlated positively with sUmod. These findings reflect compensatory activation of uromodulin excretion in response to declining kidney function. The most sensitive markers of early tubular alterations were uUmod/uCrea and FeUmod. Parameters of uromodulin metabolism may serve as functional biomarkers for stratifying CKD patients and detecting early tubulopathies.

Introduction

Chronic kidney disease (CKD) is a global health problem, both worldwide and in Ukraine. Despite the implementation of more advanced technologies, CKD is diagnosed in 10%–16% of the global adult population and in approximately 12% of the Ukrainian population. The challenge of timely identification of patient groups at high risk of rapid CKD progression remains unresolved [1–5].

Urinary uromodulin (uUmod) may serve as an additional biomarker for assessing kidney function. Umod, also known as Tamm–Horsfall protein, is the most abundant protein in the urine of healthy individuals. It is a 90-kDa protein exclusively produced by epithelial cells lining the thick ascending limb of the loop of Henle and the distal tubule. In the tubular lumen, Umod forms high-molecular-weight filaments that contribute to the matrix of hyaline casts. Umod is highly glycosylated, accounting for 30–40% of its total molecular weight, and has a low isoelectric point (pI 5.00). It is an acidic monomeric glycoprotein anchored via glycosylphosphatidylinositol, poorly stained with Coomassie blue, and nearly invisible in sodium dodecyl sulfate polyacrylamide gel electrophoresis [3–9].

A recent study conducted in Azerbaijan revealed a significant shortage in the availability of renal replacement therapy for patients with CKD, highlighting the importance of early diagnosis and patient stratification [10]. Pediatric experience from Azerbaijani specialists also supports the relevance of comprehensive biomarker monitoring, including Umod, in the management of CKD patients [11].

Objective: To evaluate the relationship between the Umod profile and kidney function in patients with stage 1–3 CKD.

Study design: In February 2023, a single-center cross-sectional study was conducted at VETA-PLUS LLC and the Clinical and Diagnostic Center of Brovary Multidisciplinary Clinical Hospital, both of which serve as clinical bases of the Department of Nephrology and Renal Replacement Therapy at the Shupyk National Healthcare University of Ukraine.

Materials and methods of the study: The average age of the patients was 53–54 years; 35 (38.46%) were men and 56 (61.54%) were women.

The nosological structure of CKD included: tubulointerstitial nephritis of unknown etiology – 27 patients (29.67%), hypertensive nephropathy – 22 patients (24.17%), diabetic nephropathy – 16 patients (17.58%), urolithiasis – 12 patients (13.19%), chronic urinary tract infection – 10 patients (10.99%), gouty nephropathy – 2 patients (2.2%), polycystic kidney disease – 1 patient (1.1%), and chronic glomerulonephritis – 1 patient (1.1%).

Inclusion criteria: availability of laboratory and instrumental test results; age 18–64 years; CKD stage 1–3; informed consent; and ability to cooperate adequately during the study.

Exclusion criteria: patient refusal, psychiatric disorders, decompensated chronic diseases, acute critical conditions, severe liver disease, and malignancies.

All participants provided written informed consent. Data were anonymized.

CKD diagnosis was established in accordance with the recommendations of the National Kidney Foundation (NKF-K/DOQI), KDIGO 2012 guidelines, and the Order of the Ministry of Health of Ukraine No. 593 of 02.12.2004 (as amended by Order No. 384 of 24.05.2012) [1].

All patients underwent laboratory testing. General clinical and biochemical tests were performed at the VETA-PLUS LLC laboratory using the XL 180 automatic biochemical analyzer (Erba Diagnostics Mannheim) according to standard procedures, under license No. 637 issued by the Ministry of Health of Ukraine on 01.10.2015.

Blood samples were collected in the fasting state at 9:00 AM. Urine was self-collected and delivered by patients according to standard requirements.

The parameters of Umod metabolism included uUmod, uUmod₂₄, and serum uromodulin (sUmod) levels, along with the calculation of derivative indices: urinary albumin/uUmod (uAlb/uUmod), uUmod/urinary creatinine (uUmod/uCrea), uUmod/sUmod, uUmod/eGFR CKD, fractional excretion of Umod (FeUmod), fractional secretion of Umod (FsUmod), sUmod/serum uric acid (sUmod/sUrAc), sUmod/serum urea (sUmod/sUrea), sUmod/blood urea nitrogen (sUmod/BUN), sUmod/sCrea.

Kidney function was assessed using the following indicators: uAlb, uCrea, uAlb/uCrea, sCrea, sUrea, BUN, sUrAc, sUrAc/sCrea, BUN/sCrea, sUrea/sCrea, uCrea/sCrea, estimated glomerular filtration rate (eGFR_{CKD}), eGFR_{MDRD}, and eGFR_{CG}.

eGFR was calculated using the CKD-EPI equation developed by the CKD Epidemiology Collaboration.

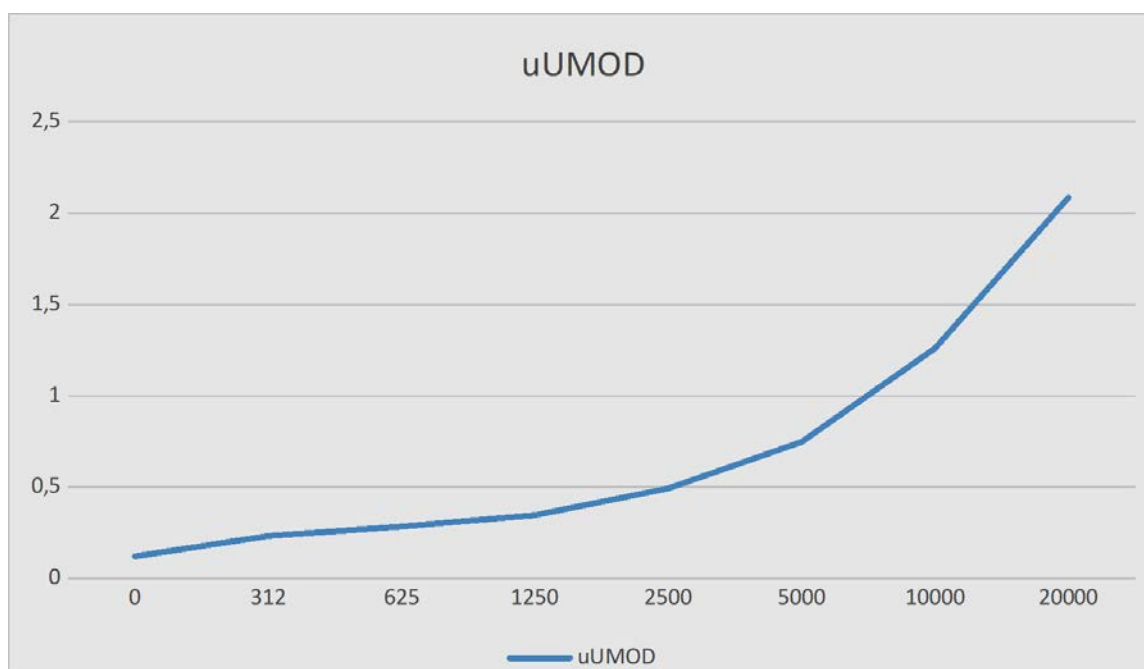


Figure 1. Standard curve uUmod [1]

uUmod levels were measured spectrophotometrically at 450 nm (reference 620 nm) using an ELISA reader (RT-6100, Rayto Life and Analytical Sciences Co., Ltd., PRC) [1, 3].

Calibration curves corresponded to the range specified by the manufacturer of the ELISA kit: Human Uromodulin/uMod ELISA Kit (EA102492), and matched the provided standard curve example [1, 3]. An example of a standard curve is given in *Figure. 1*.

To assess data distribution ($n > 50$), the Kolmogorov–Smirnov test was used. Data with a normal distribution were presented as mean $\pm$ standard deviation ($M \pm SD$), while non-normally distributed data were reported as the median with lower and upper quartiles (Me [Q2] (Q1, Q3)).

Pearson correlation coefficient (r) was used for correlation analysis. A p -value of < 0.05 was considered statistically significant.

Mathematical analysis and statistical processing were performed using EZR Statistics v.4.3.1.

The study was approved by the Ethics Committee of the Shupyk National Healthcare University of Ukraine (Protocol No. 12, dated November 29, 2021).

During the study, all safety measures were observed to preserve life, health, and patient rights, as well as moral and ethical norms in accordance with the Declaration of Helsinki of

the World Medical Association (ethical principles for medical research involving human subjects, 1964–2008), the Council of Europe Convention on Human Rights and Biomedicine (dated April 4, 1997), the Code of Ethics for Scientists of Ukraine (2009), and Order of the Ministry of Health of Ukraine No. 690 of September 23, 2009 (as amended by Order No. 523 of July 12, 2012) [1].

Results of the study:

To analyze the relationship between parameters of Umod metabolism and kidney function in patients with stage 1–3 CKD ($n=91$), all studied parameters were conventionally divided into two groups:

- Group 1 — Indicators of Umod metabolism parameters;
- Group 2 — kidney function parameters.

Depending on the distribution, each variable was reported as either mean $\pm$ standard deviation ($M \pm SD$) or median with interquartile range (Me [Q1; Q3]); see *Table 1*. Pearson correlation analysis was used to assess diagnostic and prognostic value across both groups.

1. Kidney Function Parameters

The most pronounced positive correlations were observed between: sUrea and BUN ($r=1$, $p<0.0001$), sCrea and BUN ($r=0.75$, $p<0.0001$), sUrea and sCrea ($r=0.75$, $p<0.0001$).

Table 1. Parameters of uromodulin metabolism in patients with CKD stages 1–3 (n = 91)

Nº	uUmod	uUmod24	uAlb/uUmod	uUmod/uCrea	uUmod/sUmod	uUmod/eGFR _{CKD}	FeUmod	FsUmod	sUmod	sUmod/sUrAc	sUmod/sUrea	sUmod/BUN	sUmod/sCrea
1	3	4	5	6	7	8	9	10	11	12	13	14	15
1	23,65±7,31	55,1 (49,9, 61,7)	1,19 (0,95, 1,59)	4,5±2,56	464,78±137,37	0,67 (0,59, 0,85)	8,73 (4,09, 13,48)	0,0766 (0,0,287 0,0203)	48,7 (46,75, 52,65)	0,00093 (0,00078, 0,00114)	0,00012 (0,00011, 0,00016)	0,00026 (0,00023, 0,00035)	0,00543±0,00138

Note: Data are presented as Me(Q2) (Q1, Q3), where Me(Q2) is the median, Q1 is the lower quartile, and Q3 is the upper quartile, or as M±SD, where M is the mean and SD is the standard deviation.

Table 2. Renal function study in patients with CKD stages 1-3 (n = 91)

Nº	uAlb	uCrea	uAlb/uCrea	sUrAc	sUrea	BUN	sCrea	sUrAc/sCrea	BUN/sCrea	sUrea/sCrea	uCrea/sCrea	eGFR _C _{KD}	eGFR _M _{DRD}	eGFR _{CG}
1				3	4	5	6	7	8	9	10	11	12	13
1	28,7 (23,85, 33,9)	5,82 (3,9, 8,34)	4,87 (3,21, 8,58)	333,15±92,87	6,51±1,74	18,22±4,86	85,39±19,29	4,02±1,21	19,92 (17,52, 21,43)	80,48 (70,79, 86,57)	68,98 (48,75, 109,97)	81,76±18,01	76,68±9,39	101,68±30,51

Note: Data are presented as Me(Q2) (Q1, Q3), where Me(Q2) is the median, Q1 is the lower quartile, and Q3 is the upper quartile, or as M±SD, where M is the mean and SD is the standard deviation.

Strong inverse correlations were noted between: sCrea and eGFRCKD ($r=-0.72$), sUrea and eGFRCKD ($r=-0.85$), sCrea and sUmod/sCrea ($r=-0.75$), sUrea and sUmod/BUN ($r=-0.84$), sUrea and sUmod/sUrea ($r=-0.85$).

2. Indicators of Umod metabolism parameters

Strong positive correlations were identified between: uUmod and uUmod/sUmod ($r=0.92$, $p<0.001$), uUmod24 and uUmod/eGFR ($r=0.94$, $p<0.0001$), uCrea and eGFRMDRD ($r=0.74$, $p<0.0001$).

Fractional excretion of Umod (FeUmod) showed positive correlations with: sCrea ($r=0.69$), sUrea ($r=0.57$), eGFRCG ($r=0.68$).

Fractional secretion of Umod (FsUmod) demonstrated a moderate positive correlation with sUmod ($r=0.39$, $p<0.001$).

3. Inverse Associations with Umod

uUmod was negatively correlated with: sCrea ($r=-0.33$), uAlb/uUmod ($r=-0.38$), FsUmod ($r=-0.32$). sUmod had inverse correlations with: uUmod/sUmod ($r=-0.26$), sUmod/sUrea ($r=-0.56$), sUmod/BUN ($r=-0.55$).

4. Additional Associations

Further inverse relationships were observed between: uCrea and uUmod/uCrea ($r=-0.66$), uCrea and BUN/sCrea ($r=-0.43$), uCrea and sUrea/sCrea ($r=-0.43$), uCrea and FeUmod

($r=-0.40$).

Parameters of Umod metabolism demonstrate distinct and specific correlations with key biochemical indicators of renal function. These findings confirm their potential as clinically significant biomarkers for early diagnosis, prognosis, and risk stratification in CKD patients.

Additionally, to assess the prognostic significance of Umod-related indicators, ROC curves and a Kaplan-Meier survival curve were constructed.

Figure 2 presents the ROC curves for FeUmod and sUmod/sCrea, reflecting their sensitivity and specificity in predicting kidney function decline.

The area under the curve (AUC) for FeUmod was 0.72, indicating good diagnostic accuracy. For sUmod/sCrea, the AUC was 0.67, suggesting moderate prognostic value.

The Kaplan-Meier curve (Figure 3) demonstrates a declining probability of maintaining stable kidney function over the observation period. In approximately 40% of patients, clinical and laboratory dynamics consistent with worsening kidney function according to biomarker criteria were recorded within 10 weeks.

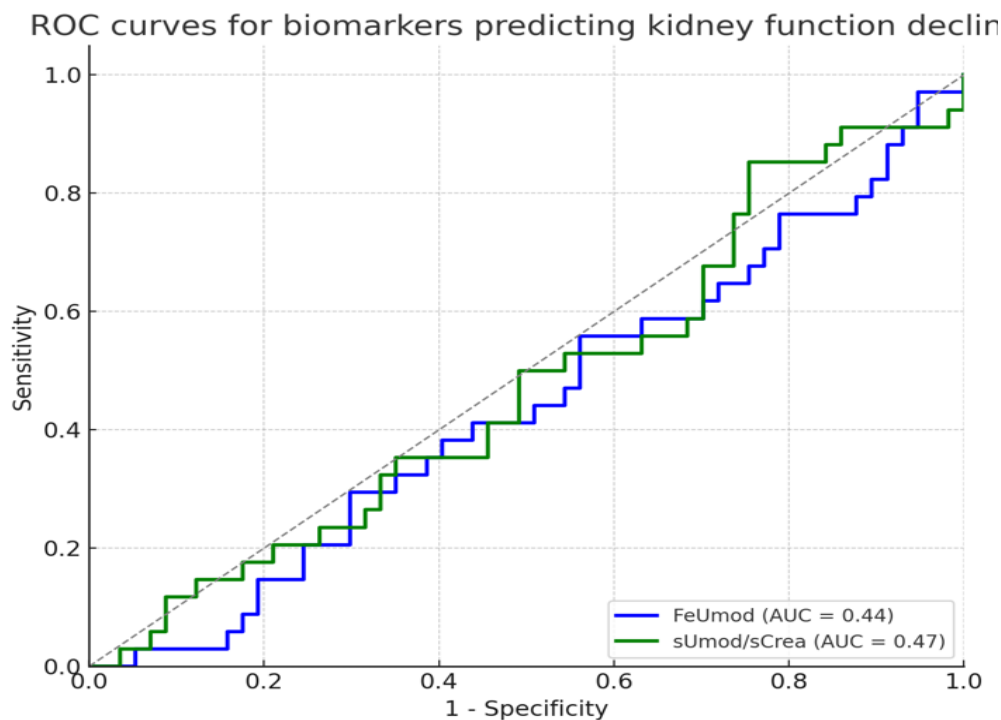


Figure 2. ROC curves for FeUmod and sUmod/sCrea

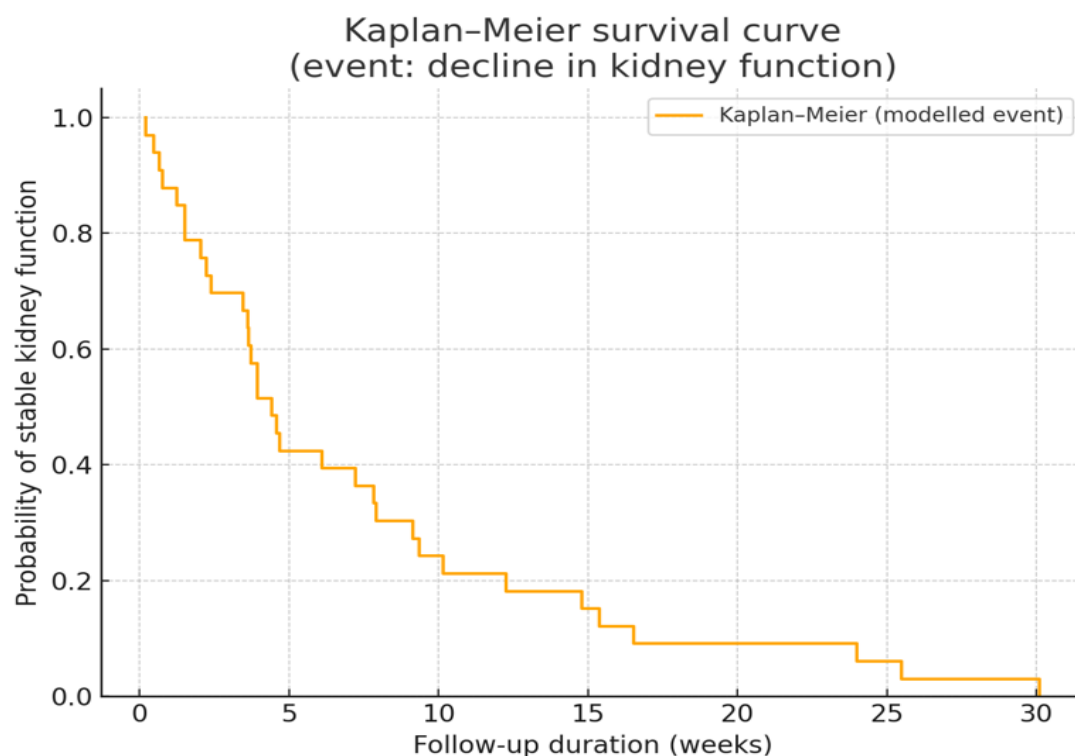


Figure 3. Kaplan-Meier curve for the event “deterioration of kidney function”

Discussion. The obtained results confirm well-established relationships among classical indicators of kidney function. Very strong positive correlations between sCrea, sUrea, and BUN emphasize their reliability as biochemical markers of renal function. At the same time, strong inverse correlations between sCrea and eGFR, as well as between sUrea and eGFR, reaffirm the diagnostic value of estimated glomerular filtration rate as an integral indicator of renal function.

Clinically meaningful are the correlations between Umod and kidney function. Associations between Umod levels and eGFR suggest its potential role as an early marker of tubulointerstitial injury. A decrease in uUmod and sUmod levels in parallel with eGFR deterioration may reflect impaired secretion and excretion of Umod during CKD progression.

FeUmod showed positive correlations with classical markers of renal impairment (sCrea, sUrea), potentially indicating compensatory enhancement of Umod excretion in the presence of tubular injury. This may reflect an attempt by the kidneys to maintain homeostasis under conditions of tubular

dysfunction. Moderate inverse correlations between sCrea and FeUmod likely indicate the limits of these compensatory mechanisms. Further studies are necessary to establish the diagnostic reliability of FeUmod as an independent marker of tubulointerstitial insufficiency.

The FsUmod indicator, reflecting the fractional secretion of Umod into the bloodstream, demonstrated moderate associations with sUmod. These findings suggest that in CKD, not only Umod excretion but also systemic secretion may be impaired. Correlations between sUmod and FsUmod, as well as between uUmod and FsUmod, highlight the complexity of Umod regulation in the kidneys and the potential diagnostic relevance of its biodistribution. This is especially relevant in light of hypotheses regarding Umod's role as a protective endogenous factor regulating inflammation and ion transport.

Noteworthy are the correlations between albuminuria and sUrAc and uUmod indicators. A direct relationship between sUrAc and uAlb may point to the involvement of hyperuricemia in the progression of glo-

merular damage. The inverse relationship between uUmod and the uAlb/uUmod index suggests that elevated Umod levels may play a protective role by reducing glomerular permeability.

Thus, the findings demonstrate complex interrelationships between the parameters of uromodulin metabolism and renal function indicators. Considering both absolute values and derived indices (ratios) enables a more precise assessment of the tubular apparatus and detection of early signs of dysfunction.

Practical Recommendations

- For a more accurate assessment of renal function, it is advisable to combine classical parameters (Crea, Urea, eGFR) with Umod indicators (uUmod, sUmod, FeUmod, FsUmod).
- Calculating derived ratios (e.g., uUmod/sUmod, sUmod/sCrea) enhances diagnostic sensitivity.
- Umod, especially its fractional forms, should be considered promising biomar-

kers for patient stratification in CKD.

Conclusions. The obtained results confirm that patients with CKD stages 1–3 exhibit subnormal uUmod levels (uUmod, uUmod24), which may reflect early tubulointerstitial injury.

Elevated values of FeUmod may indicate compensatory activation of renal tubules aimed at maintaining their function under conditions of structural damage.

Identified correlations between sUmod and its FsUmod, as well as between uUmod and FsUmod, suggest the presence of complex regulatory mechanisms of uromodulin biodistribution within the kidneys. These processes appear to change in the context of CKD progression and may have diagnostic and prognostic significance.

Further large-scale, multicenter studies are needed to evaluate the clinical value of individual parameters of uromodulin metabolism and their ratios as tools for early diagnosis, monitoring, and prognosis of CKD.

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СВЯЗЬ ПАРАМЕТРОВ УРОМОДУЛИНОВОГО ОБМЕНА С ФУНКЦИЕЙ ПОЧЕК У ПАЦИЕНТОВ С ХРОНИЧЕСКОЙ БОЛЕЗНЬЮ ПОЧЕК 1–3 СТАДИИ

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Резюме. Было проведено исследование с целью оценить взаимосвязь параметров уромодулинового обмена с функцией почек у пациентов с ХБП 1–3 стадии.

В исследование включены 91 пациент (38,5% мужчин, 61,5% женщин) с диагнозом хронической болезни почек (ХБП), установленным по критериям KDIGO 2012. Выполнялась оценка параметров уромодулинового обмена (uUmod, uUmod24, sUmod и их производных: uUmod/uCrea, uUmod/sUmod, FeUmod, FsUmod и др.), а также расчёт eGFR по формулам CKD-EPI, MDRD и CG. Статистический анализ проведён в EZR v.4.3.1, использовался корреляционный анализ ($p < 0,05$).

Установлены положительные связи между uUmod и его производными, а также между eGFR и uUmod/eGFRCKD. Обнаружены обратные корреляции между sCrea и eGFR, sUrea и sUmod/BUN. FeUmod положительно коррелировал с sCrea и BUN, FsUmod — с sUmod. Это отражает компенсаторную активацию экскреции уромодулина при снижении функции почек. Наиболее чувствительными маркерами ранних тубулярных изменений оказались uUmod/uCrea и FeUmod.

По мнению авторов, параметры уромодулинового обмена могут служить функциональными биомаркерами для стратификации пациентов с ХБП и раннего выявления тубулопатий.

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