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РЕГИСТР РЕАЛЬНОЙ КЛИНИЧЕСКОЙ ПРАКТИКИ ВЫЯВЛЯЕМОСТИ АЛЬБУМИНУРИИ СРЕДИ ПАЦИЕНТОВ С РАНЕЕ НЕДИАГНОСТИРОВАННОЙ ХБП — АУРА

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Real Clinical Practice Register of Albuminuria Detection in Patients with Previously Undiagnosed Chronic Kidney Disease

Резюме

Цель: сбор данных о фенотипе пациента с наибольшим риском развития альбуминурии и оценка её распространенность в выявленных фенотипах, а также получение данных о характеристиках, назначаемой терапии, сопутствующей патологии пациентов с и без выявленной альбуминурией. **Материалы и методы.** Информация о распространенности альбуминурии в популяции собирается одновременно в рамках регистра реальной клинической практики. Все пациенты, обращающиеся за медицинской помощью, оценены на предмет наличия альбуминурии и её степени, все данные собраны в обезличенном виде и внесены в электронную регистрационную карту. Критерии включения: 1) мужчины и женщины в возрасте от 40 лет и старше на момент регистрации данных; 2) возможность выполнить тест на альбуминурию с использованием тест-полосок и/или анализа на микроальбуминурию или соотношение альбумин/креатинин в разовой порции мочи. Критерии невключения: 1) нежелание пациента участвовать в регистре; 2) наличие диагноза ХБП выставленного до момента скрининга в регистр; 3) наличие диагнозов сахарный диабет 1 и 2 типа, выставленных до момента скрининга в регистр; 4) беременность; 5) бег на длинные дистанции или очень тяжелая физическая нагрузка за последние 24 часа. **Результаты.** На момент предоставления данного материала проходит активная фаза набора пациентов в регистр с учётом заявленной мощности. С учетом предполагаемой скорости набора участников регистра в 45–50 центрах ожидается, что в регистр будут включены данные по 12.000–15.000 пациентам. Если удастся набрать менее чем 12.000 субъектов и расчетная скорость набора в регистр будет недостаточной, может быть увеличено количество исследовательских центров или расширен период скрининга. **Заключение.** Несмотря на установленную прогностическую значимость данных об АУ, в широкой практике данный анализ назначается лицам из групп риска по развитию ХБП или пациентам с уже установленной нефрологической патологией. Проведение локального регистра, объединяющего различные популяции пациентов, в первую очередь, включающего пациентов не только из установленных групп риска по развитию ХБП, а также с использованием тест полосок на определение АУ представляет научный и практический интерес и может быть использовано при написании национальных рекомендаций, учебно-методических пособий, использоваться в клинической практике.

Ключевые слова: альбуминурия, хроническая болезнь почек, регистр

Конфликт интересов

Авторы заявляют, что данная работа, её тема, предмет и содержание не затрагивают конкурирующих интересов

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Abstract

Aim. To collect data on the patient phenotype at the highest risk of developing albuminuria, to assess the prevalence of albuminuria in the identified phenotypes, and to collect data on the characteristics, prescribed therapy, and comorbidities of patients with and without identified albuminuria. **Materials and methods.** Data on presence or absence of albuminuria are collected in this register of real clinical practice instantaneously. All patients seeking medical attention are screened for the presence and extent of albuminuria. All data are collected in anonymized form and entered into an electronic case report form. Inclusion criteria: 1) men and women aged 40 years and older at the time of data collection; 2) the possibility to perform an albuminuria test using dipsticks and/or a test for microalbuminuria or urine albumin/creatinine ratio in a spot urine sample. Exclusion criteria: 1) the patient's reluctance to participate in the registry; 2) diagnosis of CKD made before screening for the registry; 3) diagnosis of diabetes mellitus type 1 or 2 made before screening for the registry; 4) pregnancy; 5) long distance running or very heavy physical activity in the last 24 hours. **Results.** At the time of submission of this material, the active phase of patient recruitment for the registry with the specified power has been ongoing. Based on the expected recruitment rate at 45–50 sites, the registry is expected to include data from 12,000–15,000 patients. If fewer than 12,000 patients are recruited and the estimated recruitment rate for the registry is insufficient, the number of study sites or the screening period may be extended. **Conclusion.** Despite the established prognostic significance of the data on AU, the test is prescribed in routine practice to individuals at risk of developing CKD or to patients with an established nephrological disorder. A local registry that combines diverse patient populations, namely patients not only from established CKD risk groups but also patients with a dipstick test for AU, is of scientific and practical interest and can be used in the development of national clinical guidelines and educational materials and used in clinical practice.

Key words: albuminuria, chronic kidney disease, registry

Conflict of interests

The authors declare no conflict of interests

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BP — blood pressure, AH — arterial hypertension, AU — albuminuria, ARA — angiotensin 2 receptor antagonists, ARNI — angiotensin receptor and neprilisin inhibitors, ACE inhibitors — angiotensin converting enzyme inhibitors, IHD — ischemic heart disease, BMI — body mass index, CRF — case record form, HDL — high-density lipoproteins, LDL — low-density lipoproteins, KSD — kidney stone disease, IFG — impaired fasting glycaemia, IGT — impaired glucose tolerance, non-HDL — non-high-density lipoproteins, IEC — Independent Ethics Committee, OAC — oral anticoagulants, TC — total cholesterol, POAC — peroral anticoagulants, DM — diabetes mellitus, e-GFR — estimated glomerular filtration rate, GFR — glomerular filtration rate, ESR — erythrocyte sedimentation rate, CRP — C-reactive protein, CVD — cardiovascular diseases, TG — triglycerides, RF — risk factors, CKD — chronic kidney disease, COPD — chronic obstructive pulmonary disease, CCF — chronic cardiac failure, RR — respiratory rate, HR — heart rate, EC — ethics committee, EDG — electronic data gathering, IRB — Institutional Review Board, CKD-EPI 2021 — Chronic Kidney Disease Epidemiology Collaboration 2021, iSGLT 2 — sodium glucose linked transporter inhibitors, KDIGO — Kidney Disease: Improving Global Outcomes



Introduction

Albuminuria (AU) is the presence of albumin in urine, where the normal urine concentration in the morning can be $< 30 \text{ mg/mL}$ ($< 3 \text{ mg/mmol}$) [1]. AU is a sign of impaired kidney function and is associated with a higher risk of progressive loss of kidney functions over time. At early stages, a majority of kidney disorders are symptomatic, while the therapy of terminal CKD, including dialysis and kidney transplant, is expensive. Therefore, it is crucial to search for markers of early CKD. In 2012, the KDIGO (Kidney Disease: Improving Global Outcomes) published recommendations for CKD diagnosis and management, with a new classification based on a combined measurement of the rate of glomerular filtration rate reduction and albuminuria/proteinuria severity [1].

In addition to its role in early diagnosis and risk assessment for CKD patients, AU is an important prognostic marker of cardiovascular diseases (CVD) and diabetes mellitus (DM). Schmieder et al. assessed the role of increased AU levels in spot urine over time in 23,480 patients with CVDs and DM. It has been shown that at least 2-fold increase in AU over 2 years vs. baseline is greatly associated with CVD mortality, combined cardiovascular outcomes (cardiovascular death, myocardial infarction, stroke and hospitalisation for cardiac failure) and renal outcomes, including dialysis and doubled serum creatinine levels [2, 3].

The National CKD Clinical Recommendations are based also on mandatory AU screening in patients with a high risk of CKD, and four albuminuria stages have been identified depending on albumin concentrations in 24-hour urine or albumin-creatinine ratio in spot urine

[4]. It is worth mentioning that if a patient has CKD and CVD, it forms a vicious circle, where one condition causes progression of the other. In particular, it has been proven that AU contributes to endothelial dysfunction development and aggravation in DM patients. In AH, DM, CCF and obesity, albuminuria monitoring is essential for early diagnosis of CKD, and it is advisable to use assessment of urine albumin-creatinine ratio.

Besides, changes in AU levels with the use of renoprotective therapy are also a marker of therapy efficacy, making AU an CKD monitoring marker.

Despite the identified prognostic value of AU data, in real life this test is indicated for individuals in CKD risk groups or for patients with a diagnosed renal pathology. However, it is still necessary to obtain data on albuminuria prevalence in patients with and without known CKD risk factors and to identify qualitative characteristics in the identified population.

The common goal of this register is to gather information on a patient phenotype with the highest risk of albuminuria and to assess its prevalence in identified phenotypes, as well as to obtain information on characteristics, therapy, comorbidity in patients with and without diagnosed albuminuria.

Register Design, Endpoints, Organisation and Data Gathering

The AURA Register is a multicenter, non-interventional register of actual clinical practice. No patient follow-up is planned (cross-sectional design). Patient

enrolment start date is March 6, 2023; enrolment is expected to end on April 1, 2024.

All study sites use standardised case record forms (CRF). Information is gathered by GPs strictly in accordance with inclusion and non-inclusion criteria. Each CRF is reviewed by organiser's Monitors. According to good clinical practice, all data entered in the Register by Investigators are anonymised. Each patient is assigned a unique ID number when information is entered in CRF.

The main purpose of the Register is to obtain descriptive data on main phenotypes of patients with albuminuria and to study therapies in these patients with due account of comorbidities.

The Register territory is 45–50 sites in 7 federal districts of the Russian Federation (Privolzhsky, Northwest, North Caucasian, Siberian, Ural, Central, Southern). The expected Register capacity is 12,000 patients.

An ethics review of this Register was performed by the Ethics Committee at the Federal State Autonomous Educational Institution of Higher Education N. I. Pirogov Russian National Research Medical University of the Ministry of Health of Russia on February 22, 2022 (Excerpt No. 226 from the LEC meeting minutes).

Registration number of the study at ClinicalTrials.gov is NCT-05690009.

Patient Population

The Register includes both male and female patients over 40 years of age who were previously diagnosed with such diseases as CKD, type 1 DM, type 2 DM. For a detailed description of inclusion and non-inclusion criteria, please refer to Table 1.

Other characteristics are detailed in Section 7.1.3. of the Register Protocol.

Table 1. Criteria for inclusion and non-inclusion in the registry AURA

Inclusion criteria

- Men and women 40 and older at the time of data registration
- Ability to perform an albuminuria test using test strips and/or albumin/creatinine ratio analysis in a single urine sample

Inclusion criteria

- Patient's unwillingness to participate in the registry
- Presence of a diagnosis of CKD made prior to screening in the registry
- Type 1 and type 2 DM diagnosed prior to screening in the registry
- Pregnancy
- Physical activity in the last 24 hours

Statistical Analysis

Statistical processing comprises the following stages:

- 1) Exploratory analysis: identification of outliers; a check of normality of quantitative variable distribution; preliminary identification of correlations using correspondence analysis, correlation matrix and graphic analysis.
- 2) Data cleaning and transformation: replacement of missing values, removal of outliers, data normalisation and conversion if necessary (creation of new variables, numeric variable grouping, categorical variable re-grouping).
- 3) If necessary, sample reduction (exclusion of observations) to secure representativity.
- 4) If necessary, formation of additional hypotheses based on the exploratory analysis, e.g. differences between patients with varying degrees of albuminuria, correlations between individual laboratory/instrumental results, etc.
- 5) Preparation of descriptive statistics: qualitative variable frequencies, measures for alignment and dispersion of quantitative variables (2 groups: patients with and without albuminuria):
 - Albuminuria incidence within the Register
 - Sex and age characteristics of patients
 - Results of laboratory and instrumental diagnostics
 - Comorbidities and concomitant therapy
- 6) Analysis of correlation between individual variables and the presence of albuminuria and/OR albuminuria severity (chi-square criterion, analysis of variance/Kruskall-Wallis test)
- 7) Multiple factor analysis of the risk of AU: logit regression and/or decision trees.

Model robustness will be achieved due to a) pre-selection of predictors at step 6, and b) repeated iterative evolution of the model using random patient subsamples.

- 8) If necessary, testing of additional hypotheses generated at step 4. Data will be processed using IBM SPSS Statistics 25 package.

Discussion

Despite the identified prognostic value of AU data, in real life this test is indicated for individuals in CKD risk groups or for patients with a diagnosed renal pathology. In a meta-analysis by Coresh et al. of 693,816 patients, of which 80 % had confirmed DM, changes in the ratio of albumin/creatinine or protein/creatinine in spot urine

over 2 years were evaluated [5]. A meta-analysis by Matsushita et al., where AU was used as a prognostic factor of a cardiovascular risk, included 637,315 patients with confirmed cardiovascular pathologies [6]. Besides, such AU assessments use measurement of albumin/creatinine ratio in spot urine or daily urine albumin excretion [7]. Sumida et al. studied patients over 18 years of age, of which 56 % had DM and 72 % had arterial hypertension. 919,383 patients were screened using both standard laboratory methods (albumin/creatinine ratio in spot urine) and AU test strips, which complies with KDIGO recommendations [1, 8].

Within the scope of a prospective non-interventional observational study "Early diagnosis of chronic kidney diseases in primary healthcare facilities" in real clinical practice, which was conducted in 12 regions of the Russian Federation, 1,124 patients out of 13,968 patients who visited primary healthcare facilities had risk factors of CKD and were referred to an initial consultation by a nephrologist [9].

Also, among Russian studies of CKD, of interest is CHRONOGRAPH (a non-interventional observational open-label multicenter program to gather information on CKD markers in patients with arterial hypertension with or without type 2 DM in the Russian Federation) [10]. In this program, 1,363 patients with AH and/or type 2 DM had their GFR calculated and AU measured using the albumin-creatinine ratio in morning urine.

Conclusion

This data suggest that a local register of various patient populations, including first of all patients not only from identified groups of CKD risk, but also using AU test strips, has scientific and practical potential and can be used in the preparation of national recommendations, study guides and also in clinical practice.

The authors realise that occasionally identified albuminuria is not a sign of CKD, but just a laboratory phenomenon, which in some cases is physiological (functional). Therefore, CKD verification requires a repeated measurement 3 months later, and it was proposed to the patients outside this protocol. Meanwhile, even a single event of albuminuria should be included in risk factors of renal and cardiovascular pathologies; this was demonstrated earlier in a number of studies and, therefore, is a useful screening tool for preselection of patients for a more thorough, also repeated examination.

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