PHTHISIOLOGY

TUBERCULOSIS IS NOT AN OBSTACLE TO KIDNEY TRANSPLANTATION

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RESUME

Background. *Monitoring patients with chronic kidney disease during preparation for kidney transplantation, in the immediate postoperative period and then over the years is a unique opportunity to verify the effectiveness of anti-tuberculosis therapy.*
The aim. *To analyse the results of long-term observation of patients with chronic kidney disease stage 5 (CKD stage 5), who received a course of anti-tuberculosis therapy before kidney transplantation.*
Materials and methods. *The analysis of the results of long-term observation of 7 patients with CKD stage 5 who had tuberculosis (TB) while receiving renal replacement therapy (RRT) using the method of programmed hemodialysis and continued observation by a phthisiatrician at the stages of preparation for kidney transplantation and for a year after, was carried out.*
Results. *At the time of tuberculosis diagnosis, the observed multicomorbid patients had been on programmed hemodialysis for an average of 2.9 years. Anti-tuberculosis therapy was administered according to individualized regimens. The average waiting period for kidney transplantation for these patients was 3.6 years. Kidney transplantation was performed successfully in all 7 observed patients, after that all patients received three-component immunosuppressive therapy (tacrolimus, mycophenolate mofetil, methylprednisolone). Control examination to exclude reactivation of tuberculosis was carried out once every 6 months on a planned basis or upon complaints. The average follow-up period for recipients was 3.9 years. Reactivation of tuberculosis after kidney transplantation was recorded in only one patient. Thus, in 6/7 (85.7 %) patients with CKD with tuberculosis infection, kidney transplantation and administration of immunosuppressive therapy were performed without reactivation of tuberculosis.*
Conclusions. *The long-term absence of tuberculosis reactivation in the majority of patients (85.7 %) against the background of not only renal failure, but also immunosuppressive therapy after kidney transplantation was achieved through an individual approach to the treatment and management of each patient with CKD and interdisciplinary interaction of doctors.*

Key words: *tuberculosis, chronic kidney disease, hemodialysis, kidney transplantation antituberculosis therapy*

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ТУБЕРКУЛЕЗ – НЕ ПРЕГРАДА ДЛЯ ТРАНСПЛАНТАЦИИ ПОЧКИ

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РЕЗЮМЕ

Обоснование. *Наблюдение за больными хронической болезнью почек в процессе подготовки к пересадке почки, в ближайшем послеоперационном периоде и далее в течение лет, является уникальной возможностью убедиться в эффективности противотуберкулезной терапии.*
Цель исследования. *Провести анализ длительного наблюдения за больными хронической болезнью почек (ХБП 5 ст.), прошедших курс противотуберкулезной терапии перед трансплантацией почки.*
Методы. *Проведен анализ результатов длительного наблюдения 7 больных хронической ХБП 5ст., перенесших туберкулез (ТБ) во время получения заместительной почечной терапии (ЗПТ) методом программного гемодиализа и продолживших наблюдение у фтизиатра на этапах подготовки к трансплантации почки и в течение года после проведения пересадки почки.*
Результаты. *На момент диагностики туберкулеза наблюдаемые мультиморбидные больные находились на программном гемодиализе в среднем 2,9 лет. Противотуберкулезная терапия проводилась по индивидуализированным режимам. Срок ожидания трансплантации почки для данных больных в среднем составил 3,6 лет. Трансплантация почки была выполнена всем 7 наблюдаемым больным успешно, после трансплантации почки все больные получали трехкомпонентную иммуносупрессивную терапию (такролимус, микофенолата мофетил, метилпреднизолон). Контрольное обследование для исключения реактивации туберкулеза проводилось 1 раз в 6 месяцев в плановом порядке или по жалобам. Срок наблюдения за реципиентами почечного трансплантата в среднем составил 3,9 лет. Реактивация туберкулеза после пересадки почки была зафиксирована лишь у одного больного. Таким образом, у 6/7 (85,7 %) больных ХБП с туберкулезной инфекцией трансплантация почки и назначение иммуносупрессивной терапии выполнены без реактивации туберкулеза.*
Заключение. *Многолетнее отсутствие реактивации туберкулеза у большинства больных (85,7 %) на фоне не только почечной недостаточности, но и иммуносупрессивной терапии после трансплантации почки достигнуто за счет индивидуального подхода к лечению и ведению каждого больного ХБП и междисциплинарного взаимодействия врачей.*

Ключевые слова: *туберкулез, хроническая болезнь почек, гемодиализ, трансплантация почки, противотуберкулезная терапия*

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BACKGROUND

Infectious processes represent the most formidable potential complications following organ transplantation, particularly in the context of immunosuppressive therapy [1]. Among these, tuberculosis (TB) is one of the most severe, as its reactivation can occur at any stage, both before and after transplantation [2]. The presence of active TB infection is defined as an absolute contraindication to kidney transplant surgery, while the presence of latent TB infection or residual post-TB changes necessitates a course of chemoprophylaxis [1]. The higher incidence of tuberculosis in patients with stage 5 chronic kidney disease (CKD) in the post-transplant period compared to the general population (2,700 cases per 100,000 people) is evidently associated with the use of prolonged immunosuppressive therapy (methylprednisolone, mycophenolate mofetil or mycophenolic acid, tacrolimus/extended-release tacrolimus). From the moment of TB diagnosis, mycophenolate mofetil/mycophenolic acid is discontinued, and patients receive dual-component immunosuppressive therapy [3]. According to WHO clinical guidelines on tuberculosis preventive treatment (TPT), patients with stage 5 CKD receiving renal replacement therapy (RRT) and awaiting kidney transplantation are indicated for a course of TB chemoprophylaxis. The recommended regimens include the use of isoniazid, rifampicin, and their various combinations, with variations in dosages and duration of administration [4]. However, in real-world clinical practice, prescribing these medications is often not feasible [5].

However, a review of published studies on the outcomes of tuberculosis chemoprophylaxis in patients with stage 5 CKD reveals that methods for monitoring the effectiveness of such preventive therapy courses in patients on hemodialysis are rarely described; in most cases, this objective was not included in the study design [6, 7, 8, 9]. The available data are primarily focused on the application of standard chemoprophylaxis regimens [10, 11]. Furthermore, no data are available on the effectiveness of individualized courses of anti-tuberculosis therapy based on long-term follow-up observations.

THE AIM OF THE STUDY

To analyze the long-term follow-up results of patients with stage 5 CKD treated with anti-tuberculosis therapy for tuberculosis infection.

MATERIALS AND METHODS

The study included 7 patients with stage 5 chronic kidney disease (CKD) receiving renal replacement therapy (RRT) via maintenance hemodialysis. These patients were under the observation of the Central Tuberculosis Research Institute (CTRI) from 2016 to 2024 and had received a course of anti-tuberculosis therapy for tuberculosis infection. Specialists at the CTRI monitored tuberculosis infection activity both before and after kidney transplantation. The study group consisted of 4 women and 3 men. Patient ages ranged from 35 to 50 years, with a mean age of 39.86 years (SD = 6.09). In all patients, a diagnosis of tuberculosis was first established at the CTRI based on the results of a comprehensive examination. A patient-centered approach to treatment strategy was applied to the patients included in the study. This approach was based on a careful assessment to determine the optimal risk/benefit ratio when prescribing anti-tuberculosis medications, as well as joint monitoring by relevant specialists (e.g., nephrologist, cardiologist). Follow-up examinations by a phthisiatrician, including analysis of chest CT results (incorporating expert radiological interpretation), were conducted once every 6 months.

The study project was approved by the Ethics Committee of the Central Tuberculosis Research Institute (CTRI) (Protocol No. 1/2 dated March 31, 2015), in strict adherence to the principles of the World Medical Association's Declaration of Helsinki (1964, as revised in 2013), as well as the norms and regulations of clinical practice in the Russian Federation (Order of the Ministry of Health of the Russian Federation No. 200n dated April 1, 2016). The study was conducted after obtaining informed consent from all participants.

RESULTS

At the stage of analyzing the clinical and anamnestic data of the observed patients, the underlying causes of chronic kidney disease were determined. It was found that in 5 out of 7 individuals, the etiology of chronic kidney disease was chronic glomerulonephritis (histologically verified); in one patient, it was diabetic nephropathy; and in another patient, the nature of CKD was unknown.

The duration of renal replacement therapy (RRT) at the time of referral to a phthisiatrician among the observed patients ranged from 2 months to 11 years, with a mean of 2.886 years (SD = 3.736). None of the patients were receiving immunosuppressive therapy at the time of tuberculosis infection diagnosis. All patients had 2 or more comorbidities in addition to kidney disease and its complications. Comorbidities observed in the study patients included: hepatitis C (in 3 patients), aseptic necrosis of the femoral head, nonspecific osteomyelitis of the mandible, chronic erosive gastritis, and others.

An analysis of the initial clinical forms of tuberculosis diagnosed in the observed patients during the renal replacement therapy period was performed (Table 1).

As shown in Table 1, the majority of patients (5/7 individuals; 71.4 %) were followed up with residual pulmonary changes after tuberculosis, while two patients

had an active tuberculosis process. According to the activity of the tuberculous process, the observed patients with stage 5 CKD undergoing renal replacement therapy received anti-tuberculosis treatment as follows: 5 patients received a prophylactic course, and 3 patients received a full course of anti-tuberculosis chemotherapy.

The observed patients did not exhibit bacterial excretion. *Mycobacterium tuberculosis* was identified in only one patient with infiltrative pulmonary tuberculosis, based on the results of a bronchoalveolar lavage fluid culture, which revealed multidrug resistance (MDR). In the other CKD patients, *M. tuberculosis* was not detected; therefore, in accordance with clinical guidelines, treatment for drug-sensitive tuberculosis was indicated. However, considering a number of factors (including comorbidities and ongoing therapy for complications of renal failure), the standard regimens for tuberculosis chemotherapy and chemoprophylaxis were not applicable to the observed patients. In most cases, anti-tuberculosis treatment was administered according to individualized regimens.

An analysis of the actual versus recommended anti-tuberculosis treatment (ATT) regimens in patients with stage 5 CKD is presented in Table 2.

As shown in Table 2, among patients receiving a course of tuberculosis chemoprophylaxis (CP), only one patient received a standard regimen (a combination of H and E daily for 3 months), while the remaining CKD patients received individualized regimens. Patients with active tuberculosis undergoing renal replacement therapy also received individualized anti-tuberculosis treatment regimens, both in cases of identified MDR *M. tuberculosis* and when following a drug-sensitive tuberculosis regimen.

TABLE 1

CLINICAL FORMS OF TUBERCULOSIS IN PATIENTS INCLUDED IN THE STUDY

Clinical forms of tuberculosis	Number of patients
Residual pulmonary changes after tuberculosis	5
Focal pulmonary tuberculosis	1
Infiltrative pulmonary tuberculosis	1

The duration of preventive treatment in most cases was 2 months, using a combination of two anti-tuberculosis medications.

The treatment duration for infiltrative pulmonary tuberculosis with MDR *Mycobacterium tuberculosis* (MTB) was 12 months, while the duration of treatment for a patient with focal pulmonary tuberculosis following a drug-sensitive TB regimen was 8 months.

An analysis of the reasons for such individualization of anti-tuberculosis treatment in the observed patients was performed (Table 3).

As shown in Table 3, 5 out of 6 patients for whom rifampicin was indicated had contraindications to this drug: either at baseline (hepatic impairment, in one patient combined with adverse drug interactions with antifungal agents) or identified upon initial drug administration (hematotoxic reactions) – 3 out of 6 patients. Contraindications to isoniazid use in the form

TABLE 2

ANALYSIS OF ACTUAL AND RECOMMENDED ANTI-TB TREATMENT REGIMENS IN CKD STAGE 5 PATIENTS

Anti-tuberculosis treatment regimen	Recommended ATT regimen	Actual ATT regimen
Preventive (*n* = 5)	H 6–9 months daily R, H 3 months daily H, E 3 months daily H, P 3 months once weekly H, P 1 month daily H, Z 3 months daily	R, E 2 months daily E, Mfx 2 months daily H, E 2 months daily H, E 3 months daily Z, E 2 months daily
Full course (*n* = 3)	H, R, Z, E/S (*n* = 1) 6–7 months Bq, Lzd, Fq, Cs\Ter, E\Z\Cm (*n* = 1) 12 months (for limited disease)	H, Z, E 8 months daily Bq, Imp, Z, Mfx, Ter 12 months

Notes. H – isoniazid, R – rifampicin, Z – pyrazinamide, E – ethambutol, S – streptomycin, P – rifapentine, Mfx – moxifloxacin, Bq – bedaquiline, Lzd – linezolid, Fq – fluoroquinolones, Cs – cycloserine, Ter – terizidone, Cm – capreomycin.

TABLE 3

ANALYSIS OF THE REASONS FOR INDIVIDUALIZATION OF ANTI-TUBERCULOSIS THERAPY REGIMENS IN CKD 5 STAGE PATIENTS

Recommended drug	Reasons for prescribing individualized anti-tuberculosis treatment regimens		Number of patients with contraindications to the drug
	Condition	Number of cases	
isoniazid	psychopathy	1	*n* = 3
	heart failure	3	
pyrazinamide	drug intolerance	1	*n* = 4
	liver dysfunction	2	
	adverse drug interactions (anti-gout medications)	1	
rifampicin	adverse drug interactions (anti-fungal agents)	1	*n* = 5
	liver dysfunction	2	
	hematotoxic reactions	3	
linezolid	polyneuropathy	1	*n* = 1

of decompensated heart failure were present; in one female patient, this was combined with a psychiatric disorder. Four out of seven patients for whom pyrazinamide was recommended in the treatment regimen had contraindications to this drug, mainly at baseline – hepatic impairment and concomitant use of anti-gout medications; and one patient developed drug intolerance identified after the initial dose. One patient with MDR-TB was indicated for linezolid according to clinical guidelines; however, due to severe polyneuropathy, the use of this drug was not possible.

After completing ATT, all 7 patients with stage 5 CKD awaited kidney transplantation for varying periods, ranging from 2 months to 15.5 years. The mean waiting time for transplantation was 3.63 years (SEM = 2.09, SD = 5.54, median = 1.2 years). Kidney transplantation was successfully performed in all 7 observed patients: 6 patients received a deceased donor kidney, and 1 patient received a kidney from their mother. Following kidney transplantation, all patients received triple immunosuppressive therapy (tacrolimus, mycophenolate mofetil, methylprednisolone). The follow-up period after kidney transplant surgery ranged from 1 to 6.5 years (mean = 3.85 years, SD = 2.23).

All patients were followed up by a nephrologist and concurrently by a phthisiatrician. Follow-up examinations to rule out tuberculosis reactivation were performed routinely every 6 months or upon presentation of complaints. Tuberculosis reactivation after kidney transplantation was recorded in only one patient: this patient was diagnosed with tuberculous lymphadenitis 13 months after receiving an allograft from their mother. This patient received anti-tuberculosis therapy according to an individualized regimen and underwent lymphadenectomy. Graft function remained satisfactory, and the patient continued follow-up. Thus, in 6 out of 7 patients with stage 5 CKD and tuberculosis infection, kidney transplantation and the initiation of immunosuppressive therapy were accomplished without tuberculosis reactivation.

A clinical case from practice serves as a clear example of the profile of this category of patients with stage 5 CKD and tuberculosis infection, both before and after kidney transplantation.

Patient K., born in 1976 (44 years old at the time of referral), was referred to the CTRI by a nephrologist to determine eligibility for kidney transplantation.

Life history. The patient is a resident of the Moscow region. Family history and allergy history are unremarkable.

Phthisiatric history. The patient had previously been followed up at a tuberculosis clinic at her place of residence in 2006; however, the medical records have not been preserved, and the patient herself does not recall receiving any anti-tuberculosis medications. No documented contact with a tuberculosis patient has

been identified. She underwent annual chest X-rays, which revealed no pathology.

Medical history. The onset of kidney disease occurred in November 2019, when the patient developed lower extremity edema and elevated blood pressure. A medical examination at an outpatient clinic revealed the presence of proteinuria. The patient was hospitalized and was diagnosed with stage 5 CKD. On November 20, 2019, an arteriovenous fistula (AVF) was created. Renal replacement therapy via maintenance hemodialysis was initiated on June 29, 2020. However, the patient tolerated the procedures poorly, experiencing elevated blood pressure during sessions and weight loss down to 39 kg.

In October 2020, a complication in the form of an AVF thrombosis was identified, and hemodialysis was continued using a central venous catheter. The patient was consistently receiving antiplatelet and antihypertensive therapy (losartan, bisoprolol, amlodipine), Mircera® as an erythropoiesis-stimulating agent, and alfacalcidol as a regulator of calcium and phosphorus metabolism.

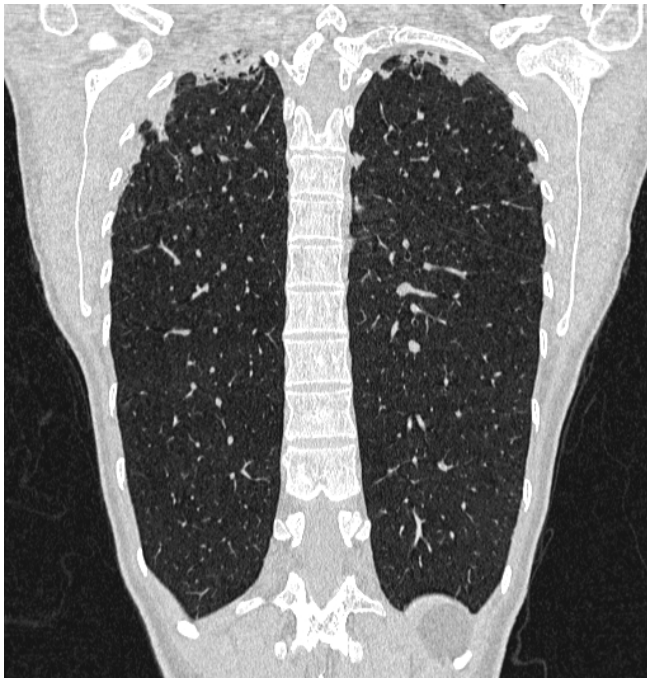
Considering the patient's medical history, recommendations from a nephrologist, and the ongoing COVID-19 pandemic, the patient underwent a chest CT scan on September 26, 2020. The scan was performed independently in preparation for a planned kidney transplantation. The scan revealed focal fibrotic changes in the upper lobes of the lungs.

On December 15, 2020, the patient presented to the consultative department of the Center for Diagnosis and Rehabilitation of Respiratory Diseases at the CTRI with complaints of general weakness and blood pressure fluctuations. At the time of examination, there were signs of anemia and malnutrition: the skin and visible mucous membranes were pale, and the patient had a significant body weight deficit (weight is 39 kg, BMI 14.7). There was no edema present. Auscultation revealed vesicular breathing without wheezing. Heart sounds were clear and rhythmic with a regular rhythm. The heart rate was 100 bpm, and blood pressure was 100/80 mmHg. The abdomen was soft and non-tender. Bowel movements occurred once a day with formed brown stools. The patient was receiving renal replacement therapy through maintenance hemodialysis three times a week for 3 hours via a central venous catheter.

An analysis of the patient's clinical and laboratory records revealed the following: a significant body weight deficit, signs of asthenia, a history of venous thrombosis, difficulty tolerating hemodialysis treatments, and moderate anemia, with a hemoglobin level reduced to 68 g/L. A borderline leukocyte count of 4.9×10^9/L (reference range $4.8–9.0\times10^9$/L) was also noted.

Chest CT findings from December 15, 2020: apical superimpositions extending along the dorsal regions to the interlobar fissure, appearing as areas of consolidation with a partially preserved air bronchogram; a single subpleural nodule in segment S9 of the left lung measuring up to 6 mm. The lumens of the upper lobe bronchi are unevenly dilated (Figure).

The results of the immunological skin tests (Diaskintest and Mantoux test with 2 TU PPD-L) showed complete anergy, as the reaction to both tests was negative and limited to the injection site.



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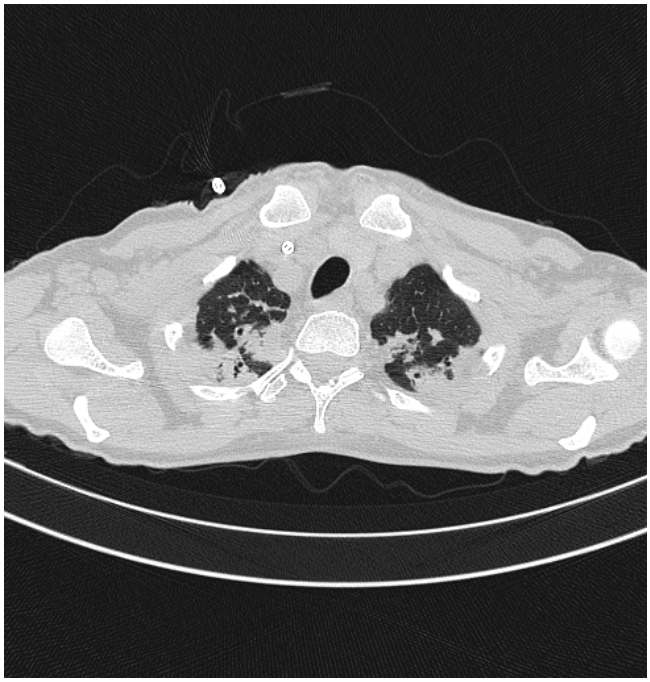

B

FIG. 1.
Data of the CT-scan chest of patient K. at the time of admission: A – in the coronal projection, B – in the axial projection

Functional assessment findings: the pulmonary ventilatory function was within normal limits. However, the ECG analysis conducted on January 12, 2021, showed: sinus rhythm with a heart rate of 80 bpm, a normal electrical axis of the heart, an incomplete right bundle branch block, and signs of left ventricular hypertrophy.

To clarify the activity of pulmonary changes and verify the diagnosis, a bronchoscopy with bronchoalveolar lavage (BAL) was performed on January 14, 2021. Cytological and comprehensive microbiological analysis of the BAL fluid was conducted. Examination of the tracheobronchial tree revealed endoscopic signs of diffuse, bilateral, and deforming atrophic bronchitis. Analysis of the BAL fluid for *M. tuberculosis* revealed no acid-fast bacilli (AFB) and no *M. tuberculosis* DNA. The BAL cytogram revealed a predominance of alveolar macrophages (89 %), neutrophils (3 %), and lymphocytes (8 %); atypical cells and AFB were not observed during cytological examination.

BAL fluid culture using the BACTEC MGIT 960 liquid culture system did not show any growth of *Mycobacterium tuberculosis* complex. Based on the examination results, the following diagnosis was established: residual post-tuberculosis pulmonary changes in the form of fibrous pleuroapical superimpositions and dense pulmonary nodules; chronic deforming atrophic bronchitis in remission; bronchiectasis of the upper lung lobes; MBT (-); stage 5 CKD due to tubulointerstitial nephritis; maintenance hemodialysis since June 29, 2020; moderate secondary anemia; stage 3 secondary arterial hypertension with a cardiovascular complication risk of 4; left ventricular hypertrophy; CHF class 2 according to NYHA classification, FC 2; AVF thrombosis on October 25, 2020, and central venous catheter implantation on October 27, 2020, as well as severe body weight deficit.

The patient was recommended to undergo a course of chemoprophylaxis to prevent tuberculosis reactivation. According to the clinical guidelines, isoniazid and rifampin/rifampicin should be the first-line drugs of choice.

However, due to the presence of heart failure and malnutrition, the isoniazid administration was not advisable. Additionally, considering drug interactions (rifampicin reduces the activity of beta-blockers and calcium channel blockers), as well as the high risk of hematotoxic reactions with concurrent rifampicin and isoniazid administration, given the patient's baseline blood count abnormalities, an individualized chemoprophylaxis regimen was required.

After excluding pathology of the optic nerve and retina through an ophthalmological examination, the patient was prescribed a combination of 1000 mg pyrazinamide and 400 mg ethambutol daily. The medications were taken daily for two months on dialysis days, after the hemodialysis procedure. Clinical and laboratory tolerance to the anti-tuberculosis drugs was satisfactory (the patient underwent regular examinations at the dialysis center and outpatient clinic).

Following the completion of the two-month preventive anti-TB therapy course, a medical team approved kidney transplantation. Approximately two months after finishing the chemoprophylaxis regimen, in spring 2021, the patient received a deceased donor kidney allotransplantation.

Subsequently, the patient received triple immunosuppressive therapy (Advagraf, mycophenolate mofetil, methylprednisolone) and was regularly monitored by a phthisiatrician. Over a three-year period, no signs of tuberculosis reactivation were observed. Moreover, the patient reported an improvement in their overall well-being, an increase in exercise tolerance, a gain of 10 kg in weight, normalization of hemoglobin levels, and a significant improvement in quality of life.

DISCUSSION

The problem of tuberculosis among candidates for organ transplantation, particularly kidney transplantation, has been widely recognized. This condition is a common cause of renal graft loss and/or death of the kidney recipient themselves. Over the years, researchers in the Russian Federation and other countries have investigated the characteristics of tuberculosis in kidney transplant recipients and sought to determine the optimal strategy for tuberculosis treatment. In 1999, Indian researchers, followed by Russian specialists, attempted to develop anti-tuberculosis treatment (ATT) regimens that did not include rifampicin due to potential drug interactions with cyclosporine A and everolimus. Alternatives to rifampicin such as ofloxacin and prothionamide were suggested. However, high mortality rates continued to persist, and treatment success was achieved only in short-term follow-up studies. All authors emphasized the importance of early detection of tuberculosis and the timely initiation of appropriate treatment [12-15].

Undoubtedly, addressing the challenge of managing anti-tuberculosis treatment for patients with stage 5 CKD before and after kidney transplantation is beyond the expertise of a single medical specialty. Rather, it requires continuous collaboration among professionals from various fields, primarily including phthisiatricians, nephrologists, gastroenterologists, internal medicine specialists, and transplant surgeons. Currently, most research focuses on short-term studies covering either the preparation period for kidney transplantation or the initial year following surgery. This publication differs significantly in that it presents the results of a long-term follow-up study of patients with stage 5 CKD that encompasses both the pre-transplant phase and the postoperative period. Prolonged follow-up periods allow specialists from various fields to validate the clinical strategy chosen: phthisiatricians can attest to the high effectiveness of anti-tuberculosis therapy, based not only on the lack of tuberculosis recurrence over many years, but also in the context of ongoing

immunosuppressive therapy; nephrologists and transplant surgeons can assess treatment efficacy, including the viability of kidney transplantation, administration of immunosuppressive therapy, and significant improvement in the quality of life of CKD patients who have survived tuberculosis.

CONCLUSION

Patients with chronic kidney disease who are receiving renal replacement therapy and have tuberculosis infection represent a complex and multimorbid group of patients that requires long-term follow-up and continuous interdisciplinary collaboration between various specialists.

The high effectiveness of an individualized approach to the treatment and management for each CKD patient has been demonstrated by the fact that the majority of these patients have had no reactivation of TB over the long term, not only during renal failure but also during the period of immunosuppressive therapy after transplantation.

Our results from the treatment and management of CKD patients with tuberculosis infection before and after kidney transplantation show that tuberculosis infection is not a barrier to kidney transplantation, but rather a factor that unites the efforts of medical professionals from different specialties.

Conflicts of interest

The authors declare no conflicts of interest.

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