Original Article

Designing a Registration System for Kidney Transplant Patients with BK Virus Infection in the Transplant Centers of Isfahan Province: Objectives, Design, and Introducing Under Study Indices

Abstract

Background: Notice to the importance of BK virus infection in kidney transplant patients, the present study aimed to present a protocol related to design aspects and implement a registration system for kidney transplant patients with BK virus infection in Isfahan Province, Iran. **Method:** The design process and different aspects of implementation and preparation of the platform for the registration of kidney transplant patients with BK virus infection were presented in this study. Indices related to the diagnosis, monitoring of the course of the disease, and the most important criteria related to the disease caused by BK virus and treatment of BK virus infection in kidney transplant patients were searched in reliable scientific databases such as PubMed, Scopus, Up-To-Date, ScienceDirect, and Web of Science. A team consisting of experts in nephrology, biostatistics, and epidemiology evaluated the specified variables as an expert panel and evaluated the content validity of the checklists designed quantitatively and qualitatively to finalize them. **Results:** The checklist was finalized in three sections: 1) demographic variables (age, gender, education,…), 2) clinical variables (primary cause of kidney failure, disease history, history of kidney disease in the family, laboratory and diagnostic parameters, clinical manifestations…), and 3) microbiologic information of BK virus infection. This information can be used for the diagnosis, treatment, and follow-up of the patient. **Conclusions:** Our registry for kidney transplant patients with BK virus infection among the few ones in the world can provide a comprehensive valuable information collection about the risk factors and the course of changes in various indices in these patients and may improve the treatment process.

Keywords: *BK virus, disease registration system, kidney failure, kidney transplant, polyoma virus*

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Introduction

Providing proper and high-quality services to patients requires clinical tools guarantee the improvement of services in the long term, and one of these tools is the disease registration system.[1-3] Considering the advancement of information technology in the field of health and treatment, the use of efficient information systems to increase efficiency, effectiveness, and the clients' satisfaction and its effects on increasing the quality of patient care are considered an inevitable necessity.[4-8] The reduction of treatment costs and medical errors, the increase of quality of care, safety, and satisfaction are assumed as the benefits of these systems. One of the new technologies in recent years is the disease registration system.

Disease registration is an organized system for collecting, storing, retrieving, analyzing, and publishing information about people suffering from a specific disease or exposed to substances with known or suspected adverse effects in a specific population and geographical area. This tool is used for the development of clinical research in the field of various diseases. The implementation of this system may improve patient care and planning for providing health services and increase the quality and efficiency of the health service delivery system and patient satisfaction. In addition, it is suitable for collecting critical data and information of patients' history and following clinical tests. Registering diseases has an effective role in diagnosing and measuring the spread of a specific disease or a health event in society and enables the health system to monitor the quality of health services better and more effectively. This system provides a suitable source for

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diagnosis of patients to conduct further studies such as cohort studies and clinical trials.

The most significant similar research was the registration system related to the information of 542 children in 52 organ transplant centers in North America, conducted in 2004–2005, where the prevalence, risk factors, clinical manifestations, and clinical consequences of nephropathy caused by BK virus were evaluated in them.[9] Most of the variables of this system were included in our checklist.

Kidney transplant patients are susceptible to special infections that can damage the transplanted tissue and other body organs. BKV-induced nephropathy is one of the important causes of kidney transplant failure. BK virus belongs to the group of human polyoma viruses that infects almost four percent of kidney transplant recipients.[1]

During its incubation period, BK virus settles in the tubular cells of the epithelium, and the reactivation of this virus occurs with the weakness of the immune system and suppression of the immune system and tissue damage. The appearance of the virus in urine or serum occurs earlier than the occurrence of nephropathy associated with BK virus. The detection of BK virus DNA in urine samples may be the first evidence of infection with this virus, but detection of BK virus in plasma with a load of more than a thousand copies per ml by DNA PCR is more specific for detecting BK virus nephropathy compared to its detection with urine samples, and definitive diagnosis of nephropathy with BK virus requires kidney biopsy and immunohistochemical staining. Nephropathy caused by BK virus occurs in transplanted kidney on average 9 months after kidney transplant.

The risk factors of BKV-associated nephropathy include high dose of immunosuppression, use of steroid pulse to treat graft rejection, ischemia–reperfusion injury, increase in the number of HLA mismatch (human leukocyte antigen) between donor and recipient, severity of viremia in the pathogenesis of the disease, and retransplant of kidney.[2] According to a review article, the incidence of BKVN in a transplant program exceeds 2.1%. The incidence of BKVN in a transplant program exceeds 2.1%.[10]

There is no registration system for kidney transplant patients with BK virus in Iran. However, among the kidney disease registration programs in our country, we can refer to the kidney transplant registration in Gilan Province, as well as the kidney transplant registration in Mashhad University of Medical Sciences, which has been in place since 2017, and the treatment information and health-related outcomes of 350 kidney transplant patients have been recorded.[11] Considering the importance of the registration system and the lack of such a system for kidney transplant patients with BKV in Iran, the present study takes into account the design of the registration system for kidney transplant patients with BKV. Considering that there is no other proven treatment for this disease apart from reducing immunosuppression, this system can help to understand the strengths and weaknesses of the existing treatments. In addition, quick access to patient information, including demographic and laboratory information, is facilitated. Furthermore, it is possible to determine the course of BKV-induced nephropathy after kidney transplant, the prevalence of BKV in kidney transplant patients, the outcome of patients with BKV-induced nephropathy, and the factors affecting the course of the disease. Therefore, in the first step, it is necessary to record the information of kidney transplant patients with BKV, addressed in this study. Therefore, the present study aimed to present a protocol related to design aspects and implement a registration system for kidney transplant patients with BK virus infection in Isfahan Province, Iran.

Registering the study design and protocol

The current study presents the protocol of an observational cohort study that has been designed to construct a registry system to follow-up kidney transplant patients with BK virus infection in Isfahan Province, Iran, and it was approved by the Ethics Committee of Isfahan University of Medical Sciences with the code of IR.MUI.MED.REC.1396.3.340. It was conducted in 2021 in Al-Zahra (PBUH) and Noor referral hospital affiliated to Isfahan University of Medical Sciences Isfahan, Iran. Their infection with BKV through one of the kidney biopsy methods or positive BKV PCR from the blood sample was proven.[12]

Inclusion criteria: People over 18 years of age who have undergone the kidney transplant with diagnosis of BK virus nephropathy based on kidney biopsy or positive blood PCR.

Exclusion criteria: In the case of patient's dissatisfaction, death, or need of dialysis, the patient's information were entered in the registration system, but it was not possible to follow-up and suspected of having two types of nephropathy (dibasic and related to BKV).

Development of data collection tool

The data collection tool includes a checklist designed using the Delphi method.[13] The research approach is to compile a checklist that possesses a uniform structure and various aspects of the treatment and care needs of patients and can be implemented and uploaded to the hospital's electronic file. Thus, besides the main information about kidney transplant patients with BKV, secondary information was also collected for the checklist design to develop a relatively comprehensive tool and contribute to the treatment process in all stages.

To design the tool and prepare its content, first of all, various tools and indices in reliable information sources and databases such as PubMed, Scopus, Up-To-Date, ScienceDirect, and Web of Science and the domestic databases of Magiran and SID were examined regarding BKV infection in kidney transplant recipients.

Based on the available tools, the most important variables related to kidney transplant patients with BKV were selected, including demographic variables, medication records, laboratory information, disease symptoms, epidemiology, risk factors, lifestyle, prognosis, complications, and treatments.

In the next step, the selected variables for the design of the checklist were examined by a panel of experts, including seven nephrology subspecialists, three nephrology fellowships, and statistics and epidemiology experts; they were asked to evaluate the selected variables from a scientific point of view (according to the items in scientific sources) and announce their opinions about them. In addition, the aforementioned checklist was examined in terms of simplicity, relevance, clarity, necessity, selection of appropriate words and sentences, and comprehensibility.

To assess the quality of the checklist content, they were asked to provide the necessary feedback related to the questionnaire, based on which, corrections were made. In addition, two coefficients of content validity ratio (CVR) and content validity index (CVI) were used to quantitatively assess the content validity. This process was carried out for each checklist item, and the necessary corrections were made.[14]

At first, the so-called items were provided to the nephrologist and biostatistician as panel experts in the Isfahan University of Medical Sciences. The validity of the checklist was approved qualitatively and quantitatively, and by determining the CVI and CVR indices, the validity of the checklist was confirmed.

After applying the opinion of the experts' group, the checklist was provided to them again, and their opinions were asked about the more detailed variables (a subset of the main variables) in the checklist. Finally, the final approval was obtained from the scientific point of view, appearance, and writing after collecting the opinions at the second stage and applying them.

In the last stage, after preparing the checklist to carry out the pilot project, 24 questionnaires were completed by the researcher to determine its shortcomings and problems, and the existing problems were identified. After collecting the questionnaires, the shortcomings and problems were raised again in the council of experts, and they were asked for their opinions on these matters. In the end, by applying the opinion of nephrology experts, the observed problems and deficiencies were resolved, and the final version of the checklist was prepared.

Data collection process

The information of all the patients referring to Al-Zahra (PBUH) and Noor hospital was completed, including the patient's complete file and history based on the designed information collection form, and the data were recorded by the researcher (resident of Nephrology) in the system.

The researcher followed all the principles related to research ethics; the patients were provided with explanations about the research and its goals; patient information was kept confidential; the participants are free to leave the study at any time during the research, and the rights of the authors in using printed and electronic texts were respected. To use the registration information, according to the instructions approved by the Ministry of Health, permission was obtained from the ethics committee.

After confirming the registration structure of BK virus nephropathy in the university and checking the adequacy of the system by the university vice chancellor, the system was installed on the laptops of the collaborating nephrologists, and after determining the personnel responsible for collecting and recording, the information the necessary training was given to use the system and also entering and registering the information in this system. The data obtained during each visit were recorded in the system.

The software was designed in such a way that the results of the patients' information evaluation would be monthly informed to the related coworkers through sending messages on the network or mobile phones by the administrator. The reports related to the activity of this registration system were announced annually.

To guarantee the quality control of data registration and to check the performance of the people who enter and register the data in the system, the information were reviewed monthly by the project manager and colleagues (Nephrologist). If the data were found to be missing or outliers, they would be re-examined and the information has been corrected and completed through the reviewing of file or contact with the patient.

The members of the panel expert evaluated the registered information and the results of cross-sectional statistical analysis every 3 months and identified and noted the defects.

Planned statistical analyses

Descriptive reports were presented in the form of brief central and distribution statistical indices, tables, and graphs in the entire sample and in different subgroups of patients. Two-sample and multisample parametric and nonparametric statistical analyses were used to compare numerical variables assuming qualitative variables, depending on the normality of the numerical variables. The correlation of qualitative variables was measured using the Chi-square test univariately. The correlation of quantitative variables was measured via bivariate analyses in the form of Pearson and Spearman correlation coefficients and in the form of multiple linear regression with a set of other variables. Analysis of variance and multivariate regression was performed for comparisons and multivariate correlations. The control of intervening variables was done in the form of covariance analysis and multiple regression. Logistic regression models were used to evaluate the relationship between qualitative response variables and other variables. The course of changes of normal quantitative variables was evaluated using repeated-measures ANOVA and mixed effects model, and the generalized estimating equations approach was used for non-normal and qualitative variables.

Results

Table 1 provides the data obtained to assess the validity of the BKV infection checklist based on the CVI criteria. Since the CVI score was higher than 0.79, it confirmed the validity of the scale content; 20 general topics approved by the professors in terms of their relevance and necessity.[14]

Table 2 shows the frequency of the data obtained to assess the validity of the BKV infection checklist based on the CVR criterion. According to the expert panel, four options needed to be modified out of 20 options with a CVR score of less than 0.99, and the necessary changes were made. Finally, the content validity of the scale was confirmed.

Based on the results of content validity, the collected variables were categorized into three main sections:

Demographic and epidemiological information

The first part of the patient demographic information checklist includes first name and last name, national ID number, address and phone number, file number, patient code, date of definitive diagnosis, date of entering the system, year of birth, gender, level of education, marital status, date of the first symptom of BK virus infection, systolic and diastolic blood pressure in the first visit, pulse rate, height, weight of the patient, BMI after transplant surgery, at the time of discharge from the hospital, and in the last visit before the diagnosis of BK virus infection.

Information about clinical symptoms

The second part of the checklist included the specialized information related to clinical symptoms. These parts were including the primary cause of kidney failure, underlying diseases, laboratory and diagnostic parameters to reject other diagnoses, drug information, and clinical outcomes. The details of the variables are listed in Table 1.

BK virus infection information

The third part of the checklist included the time of BK virus diagnosis, BK virus infection symptoms, BK virus diagnosis method, BK virus infection consequences, and medication used to treat BK virus infection.

During each visit, the patient undergone the clinical examinations and especially serum creatinine was evaluated. At the beginning of BK virus nephropathy diagnosis of nephropathy, visiting interval was monthly, but it could be

Table 1: Frequency distribution of the content validity index for the checklist of kidney transplant patients with BK virus infection according to the opinion of nephrology department staff

Sections	Propositions	Unrelated	Needs to serious revision	Related but needs to revision	Completely related	CVI score
Information about kidney failure and dialysis	Primary cause of kidney failure	0	0	1	6	1
	Underlying disease	0	1	2	4	0.857
	Time of onset of ESRD	0	0	1	6	1
	pre-transplant dialysis modality	0	0	0	7	1
	Length of time on dialysis prior to transplantation	0	1	3	3	0.857
Information about kidney transplantation and laboratory variables	turn of the transplant	0	0	1	6	1
	transplantation time	0	0	2	5	1
	Serum urea level	0	1	2	4	0.857
	Serum creatinine level	0	1	2	4	0.857
	eGFR	0	0	1	6	1
	complete urinalysis	0	0	0	7	1
Information about BK virus infection and paraclinical measures to help diagnose BK virus	The type of drug and its level	0	1	3	3	0.857
	Time to diagnose BKV	0	0	1	6	1
	Symptoms of BK	0	0	0	7	1
	Consequences of having BK	0	1	2	4	0.857
	BKV diagnosis method	0	3	3	1	0.571
	Paraclinical measures helping to diagnose BKV	0	1	2	4	0.857
	Medications used for kidney transplant before BKV diagnosis	0	0	0	7	1
	Treatments used for BKV	0	1	4	2	0.857
	Clinical outcome (recovery, rejection, death)	0	0	0	7	1

Table 2: The frequency of the data obtained to evaluation of the BKV infection checklist the validity based on the CVR criterion

Row	Propositions	Unnecessary	Related but needs revision	Necessary	CVR score
1	Primary cause of kidney failure	0	0	7	1
2	Underlying disease	0	0	7	1
3	Time of onset of ESRD	0	0	7	1
4	pre-transplant dialysis modality	0	0	7	1
5	Length of time on dialysis prior to transplantation	0	0	7	1
6	turn of the transplant	0	0	7	1
7	transplantation time	0	0	7	1
8	Serum urea level	0	0	7	1
9	Serum creatinine level	0	0	7	1
10	eGFR	0	0	7	1
11	complete urinalysis	0	0	7	1
12	The type of drug and its level	1	1	5	0.42
13	Time to diagnose BKV	0	0	7	1
14	Symptoms of BK	0	0	7	1
15	Consequences of having BK	0	0	7	1
16	BKV diagnosis method	1	2	4	0.14
17	Paraclinical measures helping to diagnose BKV	0	0	7	1
18	Medications used for kidney transplant before BKV diagnosis	0	2	5	0.42
19	Treatments used for BKV	0	0	7	1
20	Clinical outcome (recovery, rejection, death)	0	2	5	0.42

changed based on the clinical condition of the patient and the rate of creatinine and the nephrologist's opinion, and however, the patient's information was registered in the system during each visit. If the patient did not return on time, the necessity of personal referring was reminded to him/her through a contact. After checking the validity of the checklist, according to the opinion of the expert panel, a checklist for examining patients with BK virus in two categories of demographic and epidemiological information and clinical symptoms was designed and presented. The information of the finalized checklist is given in Table 3.

Discussion

The present registration program has been designed based on similar successful registration systems in North American and American centers and collects the specific variables of kidney transplant patients with BK virus, including clinical symptoms, related scores, drugs used, and follow-ups after discharge. Hence, this program may give a wider dimension to data analysis.

For the first time in 2004–2005, the registration system related to the information of 542 children in 52 organ transplant centers in North America (the United States, Canada, Mexico, and Costa Rica) was collected, and the prevalence, risk factors, clinical manifestations, and clinical outcome of nephropathy caused by BKV were evaluated. The results revealed that the mean age of kidney transplant children was 11 years, and the diagnostic method of nephropathy caused by BKV was based on histological diagnosis followed by kidney biopsy. Among the 542 children, 25 children (4.6%) had BKV-induced nephropathy. Analyses showed that two factors of 1) induction treatment with monoclonal antibody and 2) zero HLA DR mismatch were associated with an increased probability of developing BKV-induced nephropathy. The mean time of developing BKV-induced nephropathy was 10.1 months after transplant. In an average period of 2 years after the diagnosis, six patients had graft failure (24%) and 8 out of 25 had graft rejection (32%). This study was conducted based on the pathological criteria on different races in several countries.[11]

Another registration program was the registration system for kidney transplant patients in the United States. An article indexed in PubMed in April 2009 provided the details of a study conducted from 2003 to 2008 on 48292 patients undergoing a single kidney transplant in the United States. The advantages of analysis of large registry data are the multicenter nature of the data and the ability to overcome type II statistical errors (insufficient sample size). The results were as follows: 1) 6.6% of them developed nephropathy caused by BKV within 5 years after transplant, 2) the risk of developing BKV-induced nephropathy was more in people treated with ATG or a combination of tacrolimus and mycophenolate, and 3) the graft from the living person had a protective effect in developing BKV-induced nephropathy.[15]

Other registration programs related to kidney patients include the UK Renal Registry since 1995. In this registration program, data collection was initially limited to people undergoing renal replacement therapy (RRT), i.e. kidney transplant or dialysis. Recently, other registration

Table 3: Information related to the final checklist for registering information on kidney transplant patients with BKV

The main variable	Secondary variables		Explanations
Information about kidney failure and dialysis pre-transplant dialysis modality Length of time on dialysis prior to transplantation	Primary cause of kidney failure	A- Diabetes B- High blood pressure C-Glomerulonephritis D- Polycystic kidney E- Urological problems F - Hereditary causes and - Other causes	It is completed indirectly from the patient's file.
	Underlying disease	A- diabetes B- high blood pressure C- heart disease D- cerebral disease E- Gout F- Rheumatic diseases G- Other	It is determined by the direct method of interviewing the patient or indirectly by using the file.
	Time of ESRD onset	(based on year and month)	It is completed indirectly from the patient's file.
	Pre-transplant dialysis modality	A- Hemodialysis B- Peritoneal dialysis C - Both D - Preemptive transplantation	
	Duration of dialysis before transplantation	based on year and month	
Information about kidney transplant	Turn of transplantation	A- First B- the second C- the third	It is completed indirectly from the patient's file.
	Time of transplantation	Based on year, month and day	
Laboratory variables	BUN, Cr, eGFR	A- At the time of discharge from the hospital	It is completed indirectly from the patient's file.
	Urinalysis test result	B- In the last visit before BKV infection	
	Drug name, drug level	C- At the time of BKV diagnosis	
Information about BKV infection	Time to diagnose BKV	Based on year, month and day	
	Symptoms of BKV	A-creatinine increase B - Hematuria C - Sterile Pyuria	
	Consequences of BK virus infection	ureteral obstruction and ulcer	
	BKV diagnosis method	A- Plasma BKV PCR positivity B- Proof of BKV infection in kidney biopsy	
	Paraclinical measures helpful in BKV diagnosis	A – U/A B – U/C C- Ultrasound of kidneys and urinary tracts D- Result of kidney biopsy: Observation of cytopathic changes in favor of BK virus infection Observation of tubulointerstitial nephritis Positive staining for SV 40 viral antigen Percentage of interstitial fibrosis and tubular atrophy less than 30% 50-30% more than 50%	
Medications used for kidney transplant before BKV diagnosis	ATG	Daily dose of drug (mg)	It is completed indirectly from the patient's file.
	Methylprednisolone pulse	Total dose of drug (mg)	
	Prednisolone tablets	Date of start using	
	Tuberculosis Sept	End of using date	
	Azathioprine	Reason for discontinuation of medication	
	Tacrolimus	Alternative medicine name	

Contd...

Table 3: Contd...

The main variable	Secondary variables		Explanations
	Cyclosporine		
	Sirolimus		
	Everolimus		
	Rituximab		
	IV IG		
Treatments used to BKV	1. Taking cidofovir	Yes/No	It is completed indirectly from the patient's file.
	2. Use of fluoroquinolone	In case of using IV IG, the method of administration is mentioned.	
	3. Taking leflunomide		
	4. Consumption of IV IG	In case of trying to reduce the use of immunosuppressive drugs, alternative drugs are mentioned	
	5. Reducing the use of immunosuppressive drugs		
clinical outcome	recovery	The date of infection is mentioned in year, month and day	It is completed indirectly from the patient's file.
	Cellular Rejection		
	Humoral rejection		
	ESRD		
	Death		

programs have been developed for gaining information on acute kidney injury (AKI) patients in primary and secondary care in England and advanced chronic kidney disease (CKD) patients in secondary care in England and Wales.[16]

Registry programs for various types of kidney diseases have been implemented in other countries, such as the Danish Nephrology Registry (which records the admission and discharge data of all patients with renal failure and the ERA-EDTA biochemical quality indicators). The objective of the registry program is to ensure and improve clinical quality of treatment for this group of patients. Dutch Renal Registry (RENINE) was launched in the Netherlands. Italian Registry of Dialysis and Transplantation (RIDT/SIN) in Italy registers the information on dialysis and transplant patients. Norwegian Renal Registry is the system of registering kidney patients in Norway. Scottish Renal Registry (SRR) is the renal registry program in Scotland. Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) is the registry program for dialysis and kidney transplant patients in Australia and New Zealand.[17] Moreover, the review of studies regarding the establishment of a disease registration system showed that the lack of registration system for kidney transplant patients with BKV in Iran. Similar registration programs including the Kidney Transplant Registry in Gilan Province, which was conducted for the first time in Iran, and the Kidney Transplant Registry in Mashhad University of Medical Sciences, starting in 2017 that recording the treatment and health outcomes of 350 kidney transplant patients.[18]

Conclusion

By creating a registration system for kidney transplant patients suffering from BK virus in Al-Zahra and Noor hospitals in Isfahan Province, it is possible to determine the prevalence and occurrence of the disease, facilitate the monitoring of services and treatment of patients, enable to survival analysis and evaluation of clinical care consequences, identify patients with higher risk for emergency treatment, and determine the results of drug interventions and intervention activities in these patients. In addition, this registration system can provide a database for conducting the studies; create a source for clinical trials, case–control, and cohort studies; facilitate the evaluation of the cost effectiveness of interventions and the estimation of costs and budget allocation; and take effective steps to advance research goals. Therefore, the use of registration systems and online software in health-related fields should be considered to provide an opportunity to fill important gaps in the knowledge of diseases such as kidney transplant patients with BK virus infection through national and international cooperations.

Research Limitations and strengths

The limitations of this research include some patients refused to participate during different stages of the project, the noncooperation of the individuals involved in the project implementation, and the lack of funds.

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Conflicts of interest

There are no conflicts of interest.

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