

Kidney transplantation registry program in Mashhad university of medical sciences; design and rationale

Maryam Miri¹, Masoumeh Akbari², Narges Ghoreishi¹, Khalil Kimiafar³, Maryam Hami¹¹Kidney Transplantation Complications Research Center, Mashhad University of Medical Sciences, Mashhad, Iran²Department of Medical Informatics, Mashhad University of Medical Sciences, Mashhad, Iran³Department of Medical Records and Health Information Technology, School of Paramedical Sciences, Mashhad University of Medical Sciences, Mashhad, Iran

ARTICLE INFO

Article Type:
Original

Article History:

Received: 14 August 2020

Accepted: 3 November 2020

ePublished: 20 November 2020

Keywords:

Kidney
Transplantation
Registry

ABSTRACT

Introduction: Kidney transplantation was conducted in Mashhad University of Medical Sciences (MUMS) for more than 20 years. In recent years, about 160 kidney transplantation has been conducted here annually, that consisted of both cadaveric and living donor programs. Objectives: Since transplant outcomes have not been systematically monitored, we try by registration of this group of patients, donors and recipients, to analyze and share kidney transplantation outcomes.

Patients and Methods: The kidney transplant registry program in Mashhad, Khorasan Razavi, started in 2016. This registry is a prospective, single center, longitudinal program, designed as a dynamic observational cohort that enrolls all transplant recipients and donors. Demographic data, etiology of chronic kidney disease and patient and graft survival were analyzed.

Results: Baseline characteristics, treatment data, patient and donor condition before and after surgery, potential clinical events including hospitalization, co-morbidities and graft failure are all collected. Follow-up visits in recipients have been conducted in 1st, 3rd months and every year after operation. Data quality is ensured by automatic software validation and a manual data review process.

Conclusion: By this system, it is easy to adhere to input. Likewise data is adequate for rapid statistical processing.

Implication for health policy/practice/research/medical education:

Kidney transplantation registry program has been provided in Mashhad University of Medical Sciences for systematically monitoring of recipients and donors in renal transplantation. We try to analyze and share kidney transplantation outcome through registration of this group of patients in our center.

Please cite this paper as: Miri M, Akbari M, Ghoreishi N, Kimiafar K, Hami M. Kidney transplantation registry program in Mashhad university of medical sciences; design and rationale. J Renal Inj Prev. 2021; 10(x): x-x. doi: 10.34172/jrip.2021.xx.

Introduction

Kidney transplantation is a method of choice in patients with end-stage renal diseases who need renal replacement therapy since patient survival is much better than dialysis (1). Although there are many advances in the management and treatment of these patients, the short-term and long-term survival of them are far from ideal. The main problems after kidney transplantation are graft rejection, infections, malignancy, that affect graft and patient survival (2). Therefore transplant researches and centers have engaged to understand the mechanism of these problems to raise the survival (3). In each disease, the main way for its better management is focusing on previous studies in all aspects

of disorder consist of symptoms, signs, epidemiologic and laboratory data of it (4). For achieving this aim, researchers need intense collaborative clinical researches to assess the results to help them to improve their knowledge. In single center studies there are limited data that is not enough for elucidation of the way (1). For this reason, having a unique registry system in transplantation help scientists to diagnose better complications and try to solve them (3). Each qualified registry system is based on a minimum dataset (MDS) that is the main collection of data. MDS is prepared by strategic registry committee that confirmed by management committee of national bioinformatics to prepare the data set according to intended disorder

(5,6). The purpose of MDS preparation is ability to compare different registries data and also it helps to better evaluation of them (7).

Although there are many prospective observational studies, clinical trials in Europe and North America (8), we cannot use them totally due to difference in ethnicity, different treatment protocols and health care systems. Thereby, we need our regional registry program for clinical research to build our research community by ourselves. In our country, Iran, there are many transplantation centers, about 30 centers. Transplantation was begun in Iran in 1968 in Shiraz. At first most of the transplantation was done by living donors that most of them were unrelated donors. Cadaveric kidney donation was done since 2001 in Iran (see <http://ehda.sbmu.ac.ir/?fkeyid=&siteid=489&fkeyid=&siteid=489&pageid=34337>). Now it is a priority in most transplantation centers in the whole of Iran.

Almost each transplantation center has a different protocol. Therefore, it is obvious that a suitable registry system help us to diagnose and improve our common regional problems.

Objectives

Unfortunately despite this widespread network of transplantation in Iran there was not a unique registry system here to received data and evaluate them for strategic program and planning for the future. For this reason, we tried to prepare a registry program with MDS data in Mashhad and we hope this program is used in all transplant centers as a national registry and MDS data in the whole of Iran.

Patients and Methods

Study design

This registry is a prospective, single center, longitudinal program, designed as a dynamic observational cohort that enrolls all transplant recipients and donors. Demographic data, etiology of chronic kidney disease, and patient and graft survival were analyzed. It has been conducted from 2016 to the present in Mashhad University Medical Sciences the only transplant center in north east of Iran.

The features of the registry are a flexible patient-case system that allows capturing all kidney transplant scenarios and collection of patient-specific and allograft-specific data. The system uses detailed basic data questionnaires in combination with follow-up visits.

The dataset is designed and established using a two round Delphi method in two versions (minimum and extended), followed by a detailed data dictionary. Every decision has been made by a group of panelists specialized in nephrology and urology (Figure 1).

The dataset is divided into two groups: minimal and extended. The minimal dataset consisted of the data that is mandatory to complete them. Fulfilling the extended data is optional and includes supplementary dataset deeper

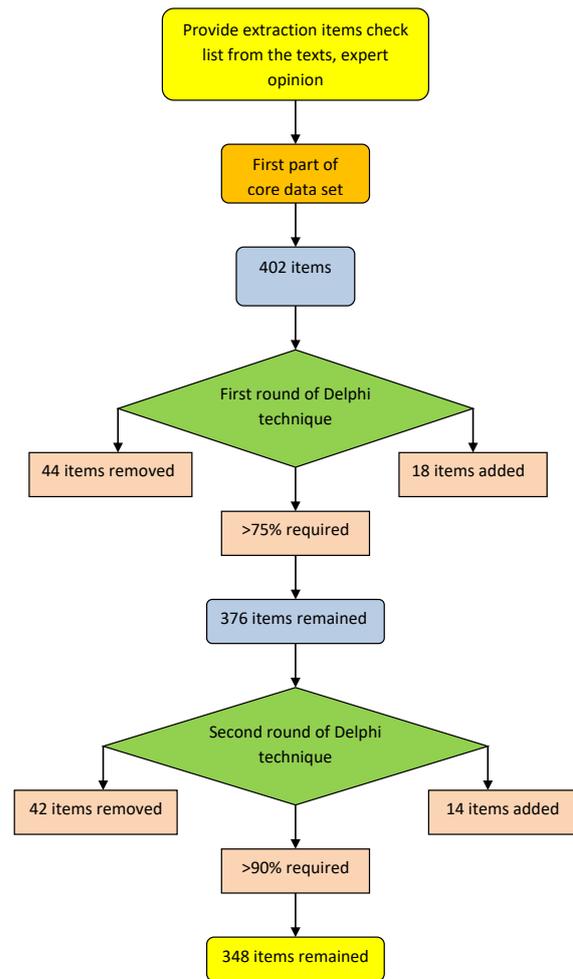


Figure 1. The Process of Establishing of Dataset.

researches. The extended dataset can be defined partly in different centers (Figure 2).

Data sharing protocols

The rules of data ownership in transplantation registry were created by strategic committee of registry that cleared the rights of ownership in stored data for publication and analysis.

Physicians can use public centers data after approval of system administrator and in private centers, the data can be used just only after approving of physician who is owner of the data.

Full data can be shared with other physicians as a teamwork; however the type of access and its time frame should be specified by data owner.

It is possible to restrict some data by owner before approving to share them.

Physician who is a data owner can determine how often patients' information should be recorded.

There is no ability to print and save patients' data by the applicant's. The program has is able to share data among

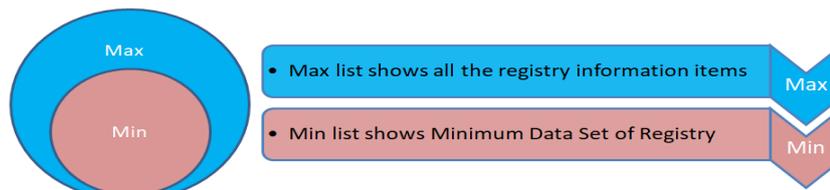


Figure 2. The definition of type of dataset

all physicians in the whole of Iran. For the technical implementation vice-chancellor's office for research in Mashhad University of Medical Sciences (MUMS) helped us to provide this program.

Ethical issues

The research followed the tenets of the Declaration of Helsinki. The research with code IR.MUMS.REC.1394.724 was approved by the Ethical Committee of Mashhad University of Medical Sciences, Mashhad, Iran.

Results

Program specification

This electronic registry system is a dynamic web-based system, so it is possible for users to access it without any location restriction or need to reinstallation. This program also can be used on tablets or mobiles and runs on all browsers. The system is displayed in two languages (Persian and English).

Software specifications

Technologies used in software design consist of HTML5, CSS3, and AJAX. PHP5 and JQUERY as programming languages, and for the data storage MySQL database were used.

Centers and users

It can be available in all medical centers, hospitals, and private clinics and offices.

This program has three different types of users with different access levels that consist of registry admin, physicians, and data managers.

To ensure intuitive usage of the registry application, data entry staff members such as study nurses have been involved in its development at an early stage.

Software output

It is possible to import previous patients' information to their physician database. Data extraction can be done in XML, CSV and Excel formats. It can extract statistical reports from data as charts or graphs. The data validated spontaneously over time. In addition, a manual quality assurance process has been incorporated into the system that checks the data periodically. The data will be rechecked whenever they want to use it for research. The data entry starts before the surgery initially, followed by after it in 1st, 3rd months and every year after operation.

As it is mentioned, 348 items remained in data set that 60 of them were accepted as MDS that their fulfilling are mandatory and 288 of them were prepared as extended data set.

Totally 342 kidney transplant recipients and 338 kidney donors consisted of 39 alive that 3% (8 recipients) were related and 9% (31 recipients) were unrelated. Likewise, 244 (71.3%) cadaveric donors were registered until now.

Among recipients, 154 (45%) were men and 188 (55%) were women. In donors 195 (58%) were men and 86 (25%) were female. The remainder of donors' gender was not registered as it is in extended dataset.

Discussion

Before preparing the registry program in our center, data collection for registration and tracking was conducted by using paper with manual computer input similar to the Japanese renal transplant registry before 2009 (9). Registration and tracking of clinical cases must be performed using electronic media, because of the volume of data and the necessity for precision. Recently, over 150 renal transplantation cases have been performed annually, requiring lengthy priors of input, data collection and correction, necessitating that the tracking occurred yearly. The advantages of the new system are the ease of input, the comprehensiveness of the data, and the rapidity of statistical processing.

The first electronic version of Japanese transplantation registry prepared only for recipients' data in 2009 (9), we tried to provide a registry system contained both recipients and donors and it is web based from the beginning. However the next version of Japanese registry in 2012 was a web based registry they provide both recipients and donors data set (10).

Until now we do not have a single integrated registry program in kidney transplantation in Iran. Therefore, we prepare a registry program for our local transplantation center in northeast of Iran in Khorasan Razavi province. Based on its data it is possible to perform more comprehensive research in this ground in our region. It is very important to have connection with other transplantation centers in Iran for better decision and policy for future planning on this ground.

Our registry program has a flexibility of data set as ESPN/ERA-EDTA registry (11) to integrate other variables to it, based on different characteristics of patients in various parts of Iran or even in other countries. The

collaborative Brazilian pediatric renal transplant registry has also this capability and they reported their pediatric patients' survival and graft outcome in 2004 in the whole of Brazil (12).

Our program like the Japanese's version (11) can be updated to new version by saving previous data during the time. We are also providing this ability that other similar registry of other centers of Iran integrates to our registry with their common data without the workload for adding their data to our registry.

Each transplantation center has different registry form. However our registry program was matched with Shiraz registry program.

It is better the registration committee of the Iranian Society of Nephrology plan to establish a web registration system using the internet after resolving problems.

Conclusion

Preparing a unique registry program in Iran helps to all physicians who works on kidney transplantation for having a better estimation of condition of this matter in Iran and can help policy-makers to plan a more suitable and pervasive program for the future.

Limitations of study

This program is used only in our center in Mashhad. For better estimation of kidney transplantation condition in whole of Iran, it is better all transplant centers have a coordinated execution based on the same program that approved by all of centers and worked on the web.

Acknowledgements

We thank the Research Deputy of Mashhad University of Medical Sciences (MUMS) especially Dr. Saeed Eslami Hasanabadi and Dr. Khalil Kimiafar in registry group for supporting this program.

Authors' contribution

MH and MM were the principal investigators of the study. NG and MA were included in preparing the concept and design. KK revised the manuscript and critically evaluated the intellectual contents. All authors have read and approved the content of the manuscript and confirmed the accuracy or integrity of any part of the work.

Conflicts of interest

The authors declared no competing interests.

Ethical considerations

Ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

Funding/Support

This study was provided by the research vice chancellor of Mashhad University of Medical Sciences (Grant # 941635)

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