10.5152/turkjnephrol.2023.21156237

Original Article

Turkish Journal of Nephrology

Affecting Factors in Medication Adherence in Kidney Transplant Recipients

Yaprak Sarıgöl Ordin[1], Özgül Karayurt[2], Nermin Ertan[3], Aylin Durmaz Edeer[1], Serkan Yıldız[4]

[1]Department of Surgical Nursing, Dokuz Eylül University, Faculty of Medicine, İzmir, Türkiye
[2]Department of Nursing, İzmir University of Economics, Faculty of Health Science, İzmir, Türkiye
[3]Division of Nephrology, Department of Internal Medicine, Dokuz Eylül University Hospital, İzmir, Türkiye
[4]Department of Nephrology, Medicana Hospital, İzmir, Türkiye

ABSTRACT

Objective: This study aimed to determine the risk factors related to immunosuppressive medication adherence in kidney transplant recipients.
Methods: The study adopted a retrospective design. It was carried out on 208 kidney transplant recipients. The social cognitive theory was used for understanding and addressing the issues of nonadherence to immunosuppressive medication. Data were collected with a self-reported–Immunosuppressant Therapy Adherence Scale and biological assays. Descriptive analyses and logistic regression were used to analyze data.
Results: According to the self-reported assessment, medication adherence of the patients receiving transplants from live donors was 0.503 times lower than that of the patients receiving transplants from deceased donors. The biological assays did not show any affecting factors in medication adherence.
Conclusion: The results of the study showed the importance of combining methods to assess medication adherence. In the self-reported assessment, live donor transplantation was found to negatively affect medication adherence. Türkiye is the country with the highest number of kidney transplantations from live donors in the world. Health professionals must be more careful in assessing medication adherence after live donor transplantations.
Keywords: Immunosuppressive medication, medication adherence, transplant nursing

Corresponding author: Yaprak Sarıgöl Ordin ✉ yapraksarigol@gmail.com

Received: December 3, 2021 **Accepted:** March 16, 2022
Publication Date: January 1, 2023

Cite this article as: Sarıgöl Ordin Y, Karayurt Ö, Ertan N, Durmaz Edeer A, Yıldız S. Affecting factors in medication adherence in kidney transplant recipients. *Turk J Nephrol.* 2023;32(1):48-54.

INTRODUCTION

Graft survival in kidney transplant recipients (KTRs) is known to decrease gradually in the long term.[1] Long-term kidney graft function is affected by medication nonadherence, lifestyle factors, and recurrence of native kidney disease.[2] In the past 15 years, meta-analysis and numerous systematic reviews have focused on the rates of medication nonadherence after kidney transplantation.[3-7] The rate of medication adherence (MA) after organ transplantation is 22.6%. Kidney transplant recipients have the highest rate of MA (35.6%).[5] In a study performed in Türkiye, the rate of medication nonadherence in KTRs was 19.8%.[8]

Medication nonadherence in organ transplant recipients is defined as forgetting to take at least one medication a month or taking the wrong medication. Besides, it refers to taking medication 2 or 2.5 hours late at least once a month.[3] It is suggested in a systematic review that MA is assessed through blood levels of medications together with a self-report method.[7] In KTRs, the rates of MA assessed using the self-report method and blood assay were 86% and 65-91% respectively.[9-11] Risk factors of medication nonadherence need to be determined. There is no consensus about risk factors related to medication nonadherence in systematic reviews.[5-7]

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It is necessary to explain the variables that affect MA by using a conceptual framework. The social cognitive theory can be utilized in an effort to understand and address the issues of immunosuppressive medication nonadherence. Bandura's social cognitive theory involves individual, environmental, and behavioral factors.[12] This study focuses on the individual and behavioral factors of the theory. The aim of the present study was to determine the factors related to immunosuppressive MA in kidney transplant recipients.

METHODS

Study Design

The study design is retrospective.

Participants

The study was carried out on 208 KTRs. Data were collected between October 2017 and March 2019 in kidney transplant outpatient clinic. Convenience sampling was used. Inclusion criteria were age of over 18 years, voluntariness to participate in the study, and having undergone kidney transplantation. Exclusion criteria were multiorgan transplantations and staying in the hospital. While calculating the sample size, the lowest regression coefficient of 0.25 was taken into account in order to obtain the largest sample size. The sample size calculation was performed using the G Power 3.0.10 program. The sample size was 81 based on the 0.25 regression coefficient, 0.05 type I error (alpha), and 0.20 type II error (beta).

Variables

Medication Adherence

Self-report and biological assay methods were used to evaluate MA.

Self-Reported–Immunosuppressant Therapy Adherence Scale: *Immunosuppressant Therapy Adherence Scale (ITAS)* was developed to assess adherence to antihypertensive drugs in patients with hypertension by Morisky et al. in 1986. Chisholm et al[13] adapted the scale to organ transplant recipients in 2005. ITAS® is composed of 4 questions regarding immunosuppressive treatment adherence behavior in the prior 3 months. Each response to the questions is classified into 0%, 1-20%, 21-50%, and greater than 50%. The total score on the scale ranges between 0 and 12, with higher scores indicating better adherence. The original scale was reported to have high validity and reliability.[13] The scale was adapted to Turkish culture by Madran et al.[14] In the present study, the 106 patients who had full marks (12 points) on ITAS® were considered to have MA.

Biological Assay: Blood plasma levels of 3 immunosuppressive medications were evaluated in the center where this research was conducted. Tacrolimus levels were closely and correctly monitored in the center. There was no standardization in the measurements since sometimes C_0 and C_2 levels were monitored in the evaluation of cyclosporine levels. Eight patients used everolimus in our center, and this may have caused some errors since the drug levels of these patients were evaluated by a different center. Therefore, only tacrolimus was included in the biological assay evaluation.

The study of Shemesh et al[15] is the most referenced study evaluating biological assay. In their study, in the 2-year evaluation, tacrolimus levels were evaluated minimum 2 times and maximum 10 times and the standard deviation (SD) for the mean tacrolimus levels was found to be 2.48. Therefore, 5 tacrolimus blood plasma levels were evaluated retrospectively in a minimum of 7 months and a maximum of 2.5 years considering the outpatient follow-up of the patients in this study according to KTRs follow-up. The SD of tacrolimus levels was calculated for each patient. The patients with an SD of <2.48 were considered to have MA.

Factors Related to Medication Nonadherence

Individual Factors: A questionnaire was used to evaluate individual factors related to the patients. The questionnaire included questions about sociodemographic (age, gender, education, financial status, employment status, and marital status) and clinical variables (date of transplantation, number of transplantations, kidney replacement time, donor type, and rejection history and number). Variables about medication use comprised the type of medication and medication number and frequency.

Behavioral Factors: Self-Efficacy: Self-efficacy is a significant predictor of human behavior according to social cognitive theory.[15] The self-efficacy of the KTRs was evaluated with the General Self-Efficacy Scale.[16] The scale has a 2-factor structure: general self-efficacy and social self-efficacy. The general self-efficacy factor does not define a specific behavioral domain. The social self-efficacy factor defines efficacy expectations in various social situations. Items in the original questionnaire were rated on a 14-point scale. Later, it was converted to a 5-point Likert-type scale.[16] In the present study, the 5-point Likert form was used. The total scale score ranges between 17 and

MAIN POINTS

- Several methods have been recommended to evaluate medication adherence in the literature. Combining methods is the gold standard for evaluating medication adherence.
- In outpatient clinical settings, nurses play an important role in assessing medication adherence. They provide follow-up support for patients nonadherent to their medications.
- The study showed that live donor transplantation negatively affected medication adherence.
- Health professionals must be more careful in preparing candidate recipients for transplantation from live donors and assessing medication adherence after transplantation.

85, and higher scores indicate a higher level of belief in one's self-efficacy. The scale was adapted into Turkish first by Gözüm and Aksayan.[17] Later, the scale was revised (2010) and reduced to a 17 item-scale by Yildirim and Ilhan,[18] and we used the 17-item version.[18]

Social Support: Patients' perceptions of social support were assessed with Multidimensional Scale of Perceived Social Support, which was developed by Zimet et al.[19] The scale is composed of 12 items that subjectively assess the adequacy of social support from 3 different sources (family, friend, and private person). Each item is rated on a 7-point Likert-type scale ranging from strongly disagree (1) to strongly agree (7). The total scale score ranges between 12 and 84, and higher scores indicate a higher level of social support. The validity and reliability of the scale in the Turkish population were last tested by Meral and Cavkaytar.[20]

Ethical Consideration

Informed consent was obtained from all the participants prior to data collection. The noninvasive research ethical committee (Approval number: 2017/04/07, Date: March 2, 2017) at the authors' institution approved the study protocol.

Analysis

IBM Statistical Package for Social Sciences software version 24.0 (IBM Inc., Armonk, NY, USA) was used for statistical analysis. Data about descriptive characteristics were evaluated by using numbers, percentages, mean, and SD. Kolmogorov–Smirnov test was utilized to analyze normality of the data. The *t* test for independent groups was used to determine whether age had an effect on MA. Binary logistic regression was performed on the affecting factors for MA. Before the binary logictic regression analysis, the correlation of the influencing factors and the dependent variable with each other was determined using the multiple correlation test. The statistical significance was set at $P < .05$.

RESULTS

The mean age of the patients was 44.88 ± 12.38 years (min-max: 19-77), and the mean time after transplantation was 9.85 ± 5.51 years (min-max: 0-24). Of all the patients, 61.06% were male, 66.35% were married, 96.16% were primary school graduates, and 58.65% were unemployed or retired (Table 1). The majority of the patients (n = 199, 95.67%) had their first kidney transplantation, and 87.50% received kidney replacement treatment before transplantation. The live donor rate was 57.21%. Biopsy was performed in 49.04% of the patients, and the rate of the patients with organ rejection was 28.37%. All the patients received immunosuppressive therapy and more than half of them received tacrolimus (n = 109, 52.40%; Table 2). Patients used a mean number of 6.6 ± 1.94 drugs daily. Immunosuppressive medication had to be changed in 38.46% of the patients.

Table 1. Sociodemographic Characteristics of Kidney Transplant Recipients (n = 208)

Variables	Mean ± SD (min-max)
Age	44.88 ± 12.38 (19-77)
Time after transplantation (years)	9.85 ± 5.51 (0-24)
	n %
Time after transplantation	
0-1 year	16 (7.69)
2-5 years	44 (21.15)
6-9 years	46 (22.12)
10 years or longer	102 (49.04)
Gender	
Female	81 (38.94)
Male	127 (61.06)
Marital status	
Single	70 (33.65)
Married	138 (66.35)
Education status	
Primary	200 (96.16)
Secondary	5 (2.40)
University	3 (1.44)
Employment status	
Full time	71 (34.14)
Part time	15 (7.21)
Unemployed/retired	122 (58.65)

SD, standard deviation.

Factors Related to Medication Nonadherence

The mean ITAS® score was 11.21 ± 1.02 (min-max: 6-12) and 106 patients (50.65%) received full marks (12 points) on ITAS®. The mean score on self-efficacy and social support was 63.71 ± 9.26 and 64.21 ± 17.27, respectively. Age, marital status, education status and employment status were not found affecting factor in made analysis before the binary logictic regression analysis ($P > .05$). Therefore, the variables were not included regression model. Logistic regression analysis showed that donor type affected MA, which was evaluated through self-reports. Medication adherence of the patients with transplants from live donors was 0.503 times lower than that of the patients with transplants from deceased donors according to the self-reported assessment (11.14 ± 0.99 vs. 11.30 ± 1.05, respectively, 95% CI 0.281-0.901, $P = .02$; Table 3). Age was not included in the model because it was not an affecting factor (according to ITAS adherence: $t = 0.886$; $P = .337$, according to biological assay: $t = 1.143$, $P = .204$) and it decreased the significance of the regression model.

Table 2. Clinical Charecteristics of Kidney Transplant Recipients (n = 208)

Variables	n (%)
Donor type	
Live	119 (57.21)
Deceased	89 (42.79)
Donor relationship (n = 119)	
Mother	44 (36.97)
Father	21 (17.65)
Children	10 (8.40)
Sibling	22 (18.49)
Cousin	1 (0.84)
Spouse	21 (17.65)
Ethiology	
Polycystic kidney disease	18 (8.65)
Hypertension	41 (19.71)
Diabetes mellitus	7 (3.37)
Glomerular nephritis	30 (14.42)
Unknown cause	51 (24.52)
Chronic pyrexanephritis	8 (3.85)
Focal segmental glomerulosclerosis	9 (4.33)
Vesicoureteral reflux	9 (4.33)
Amyloidosis	6 (2.88)
*Other	29 (13.94)
Biopsy number	
No	106 (50.96)
1	69 (33.17)
2	26 (12.50)
3	4 (1.92)
4	3 (1.45)
Rejection	
Yes	59 (28.37)
No	149 (71.63)
Rejection number, n = 59	
1	51 (86.44)
2	6 (10.17)
3	2 (3.39)
Chronic disease	
Yes	144 (69.23)
No	64 (30.77)
Immunosupressive medication therapy	
Tacrolimus	109 (52.40)
Cyclosporine	59 (28.37)
Sirolimus	10 (4.81)
Everolimus	19 (9.14)
Corticosteroid + Mycophenolate mofetil/ Azathioprine	11 (5.28)
Medication number	**Mean ± SD**
	6.66 ± 1.94
	n (%)
Medication exchange number	
No	128 (61.54)
1	61 (29.33)
2	15 (7.21)
3	4 (1.92)

***Hyperoxaluria, hemolytic uremic syndrome, atrophic kidney, gunshot injury, obstruction, nephrolithiasis, septic abortion, stone disease, renal hyperplasia, membrane nephritis, nephrotic syndrome, Alport syndrome, IgA nephropathy**

The mean blood tacrolimus level was 6.21 ± 2.78 ng/dL (min-max: 0-14.46). The SD for the blood tacrolimus level was 1.81 ± 1.35 (min-max: 0-7.98). The number of patients adherent to their medications, who had an SD of <2.48 for tacrolimus, was 82 (75.22%). Donor type, rejection, self-efficacy, and social support were not found to be factors affecting MA, which was evaluated by tacrolimus levels ($P > .05$; Table 4).

DISCUSSION

It is important to utilize different methods to accurately evaluate MA[5,7] in KTRs with the highest rate of nonadherence.[5] Considering clinical outcomes of medication nonadherence, it is necessary to determine risk factors to prevent it.[5] The MA in the present study was found to be a little higher than that stated in previous studies according to both self-reported data[8,10,14] and biological assay results.[9,11] It is attributed to the limitations of the 2 methods. The limitations of the self-reported method are possible underreporting of nonadherence because of a recall bias and depending on the patients' ability to understand the questionnaire and to answer the questions honestly.[7,21] On the other hand, in the biological assay, results are affected by conditions such as laboratory conditions, the patients' diet or other medications, and the patients' special attention to medication intake just before clinical controls.[21] The blood plasma medication level is evaluated as soon as patients arrive at their clinical control, and it is assumed that the patient has this drug level measured between the 2 clinical controls. However, the value is only obtained in the current clinical control. Patients pay more attention to medication intake before their clinical control, and this is defined in the literature as the white-coat effect.[22] A systematic review suggested the use of both biological assay and self-reports for assessing medication nonadherence of patients.[7] The present study showed that combining the methods is the gold standard for evaluating MA. In the future, devices recording medication events may be used to assess MA of recipients to obtain objective data about MA and to perform a real-time assessment.

In the present study, the individual factors of age, donor type, and rejection were evaluated according to the social cognitive theory. Age was not found to be a significant factor in MA. It was stated in the literature that younger age[6,23] and older age were affecting factors.[10,24] In the current study, the mean age of the recipients was 44.88 ± 12.38 (19-77) years. The distribution of the recipients by age was normal, and the number of young and old recipients was low. Therefore, age may not have emerged as an affecting factor in MA. Further studies with special age groups should be conducted to elucidate the role of age.

Donor type was an affecting factor in the present study. Few studies have focused on the effect of donor type on MA since they have been conducted in countries in Northern/Western Europe and the United States, where the rates of live donors are low. These studies have shown that recipients with transplants from a live donor have lower adherence.[6,9] Previous studies

Table 3. Factors Affecting Medication Adherence According to Self-Reported Data (n = 208)

Variable	*B*	SE	Wald	Sig.	95% CI		
					Exp (*B*)	Lower	Upper
Donor type	0.687	0.297	5.333	**.020**	0.503	0.281	0.901
Gender	0.531	0.300	3.134	.077	0.588	0.327	1.059
Rejection	-0.302	0.323	0.872	.350	1.352	0.718	2.547
Self-efficacy	-0.023	0.016	2.056	.152	0.977	0.946	1.009
Social support	-0.011	.009	1.462	.227	0.989	0.972	1.007
Sig.				**0.050**			

SE, standard error.

Table 4. Factors Affecting Medication Adherence According to Biological Assay (n = 109)

Variable	*B*	SE	Wald	Sig.	95% CI		
					Exp (*B*)	Lower	Upper
Donor type	0.024	0.482	0.002	.961	1.024	0.398	2.635
Gender	-0.668	0.476	1.975	.160	0.513	0.202	1.302
Rejection	0.380	0.577	0.434	.510	1.462	0.472	4.531
Self-efficacy	-0.034	0.028	1.402	.236	0.967	0.915	1.022
Social support	-0.004	0.017	0.053	.818	0.996	0.964	1.029
Sig.				**.388**			

SE, standard error.

carried out in Germany and Brazil showed that donor type did not affect MA.[25,26] The reasons for decreased MA in recipients with transplants from live donors may be shorter time spent on the waiting list for an organ and the psychosocial burden of live donation. Therefore, it is necessary to give importance to education about posttransplant lifestyle changes and medications in candidate recipients before live donor transplantation. Also, MA should be followed more carefully in these patients after transplantation.

Gender was not a significant factor in MA in the present study. Similarly, several studies revealed that gender was not an affecting factor in medication nonadherence.[10,27] However, some studies showed that MA was significantly correlated with gender.[6,27] There is no consensus regarding the effect of gender on MA in the literature.

History of rejection was not an affecting factor in the present study. It is generally suggested in the literature that MA affects rejection development.[26,28] Denhaerynck et al[4] reported in their review that 20% of chronic rejections and 16% of graft losses developed in patients because of medication nonadherence. However, KTRs with a rejection history have higher MA because of their desire to prevent rejection.[28] Also, those with low MA can be considered at risk in terms of rejection. However, there is not sufficient evidence about it in the literature.

In the present study, the behavioral factors of self-efficacy and social support were assessed according to the social cognitive theory. Self-efficacy and social support were not affecting factors. Previous studies except for the one by Pazer et al showed that self-efficacy,[4,25,28-30] and social support[4-6,30] were significant factors of MA. Patzer et al[24] stated that social support was not an affecting factor in MA. In the current study, the mean self-efficacy and the mean social support were found to be high. In Turkish culture, family and social support are very important concepts. All patients always come to follow-up assessments with family members in our center. This shows that the patients have strong social support. Because all the patients had high social support, it was not found to be an affecting factor. Future studies need to include patients with low self-efficacy and without social support.

The study has 3 limitations. First, it is retrospective and cross-sectional; blood levels of immunosuppressive therapies were evaluated retrospectively and patients' self-reports about their MA were utilized. Second, MA was assessed with biological assays and self-reports. Both methods have many disadvantages in terms of assessment of MA behavior. Third, the patients had high self-efficacy and social support. Therefore, these factors may not have affected MA. Future studies need to include patients who have low self-efficacy and lack social support.

In this study, MA was assessed with self-report tools and biological assays. In the self-reported assessment, live donor transplantation was found to negatively affect MA. However, the biological assay assessment did not show any affecting factors. The results underline the importance of combining methods to assess MA. Health professionals must be more careful in preparing candidate recipients before transplantation from live donors and assessing MA after transplantation.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of Dokuz Eylül University (Date: March 2, 2017, Decision No: 2017/04/07).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – Y.S.O.; Design – Y.S.O., Ö.K., S.Y.; Data Collection and/or Processing – Y.S.O., S.Y., N.E.; Analysis and/or Interpretation – Y.S.O., A.D.E.; Literature Review – Y.S.O., Ö.K.; Writing – Y.S.O., Ö.K., S.Y., N.E., A.D.E.

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: The authors declared that this study has received no financial support.

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