

Adherence to Immunosuppressive Medication in Renal Transplant Recipients From Follow-up Outpatient in China: Association of 2 Different Measurement Methods

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ABSTRACT

Purpose: Our aim was to investigate the association between self-report measure and serum concentration fluctuation of immunosuppressive medication (IM) in renal transplant recipients in China and examine the relationship between post-transplantation time and IM adherence.

Methods: Renal transplant recipients at least 3 months post transplantation were recruited from a follow-up outpatient clinic. Both self-reported Morisky Medication Adherence Scale and serum concentration of IM (cyclosporine trough level and tacrolimus trough level) were used to measure drug adherence.

Findings: Two hundred and nine patients were recruited in the study. The majority of the patients received grafts from deceased donors (70.3%), were male (63.2%), and were married (83.3%). The non-adherence to IM was 31.7%, as measured by the Morisky Medication Adherence Scale. A statistically significant association between self-reported adherence and serum concentration fluctuation of tacrolimus trough level was identified ($P < 0.001$), but not for cyclosporine ($P = 0.997$). Serum concentration fluctuation of tacrolimus trough levels and self-report adherence of IM were associated with transplantation time ($P < 0.001$ and $P = 0.003$, respectively).

Implications: The Morisky Medication Adherence Scale appears valid in measuring drug adherence when compared with serum concentration fluctuation. Both self-report questionnaire and serum concentration fluctuation of tacrolimus changed with different post-transplantation time. These 2 measurements could be

integrated into routine clinical practice for renal transplant recipients. (*Clin Ther.* 2015;37:2572–2580) © 2015 Elsevier HS Journals, Inc. All rights reserved.

Key words: adherence, immunosuppressive medication, MMAS-4, Morisky Medication Adherence Scale, renal transplantation, serum concentration.

INTRODUCTION

Renal disease is a global health concern. The incidence and prevalence of renal disease are increasing, which leads to poor health outcomes and economic burden.^{1–3} Organ transplantation is a progressive and innovative field. For patients with end-stage renal disease, renal transplantation is the treatment of choice, offering improved quality of life by restoring metabolism and freedom from dialysis.⁴ A successful transplantation not only results in restored health and quality of life, but also brings along new challenges regarding careful adherence to immunosuppressive medication (IM) and care of the graft and patient.^{5,6}

Nonadherence (i.e., not taking medication as prescribed) is a major challenge for modern medicine.⁷ It can involve not having the prescription filled, taking too much or not enough medication, failure to follow dosing intervals, not taking the medication for the full duration of treatment, and taking medications that were not

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prescribed.⁸ Nonadherence with the immunosuppressive regimen is a major risk factor for poor outcomes after renal transplantation.^{9,10} Many studies have shown that rates of poor medication adherence in adult renal transplant recipients ranged from 4% to 65%.^{11–13} A recent systematic review reported that >40% of patients were nonadherent post transplantation.¹⁴ Compared with recipients of other solid organ transplants, renal transplant recipients were found to have higher rates of nonadherence, and it is important to accurately assess this.¹⁵

Measurement of adherence to prescribed medication is difficult, with no test being without limitations.¹⁶ Detection of adherence can be obtained by objective direct measures, including directly observing self-administration of medication, assays of medication concentration in blood or urine, electronic monitoring, and measurement of biologic markers in the blood. However, objectivity and sophistication rise in parallel with cost and difficulty in administration.¹⁷ The use of electronic monitors can alter patient behavior temporarily, and opening of drug containers might not correspond to medication ingestion for reasons other than non-adherence.¹⁰ In addition, one-time blood or urine level monitoring might not be a reliable measure because patients might improve medication adherence just before an office visit to obtain therapeutic drug levels.¹⁸ On the other hand, fluctuation between individual blood levels of drugs might better indicate adherence, that is, more fluctuation increased with less adherence.¹⁹ Indirect measures, including self-report questionnaires and patient or caregiver interviews, are economical and convenient, however, indirect measures rely on the honesty and memory ability of patients or caregivers, so results might not be accurate.²⁰ Many studies have adopted either direct or indirect measures in medication adherence. The validity of the results could be questionable because of the limitations of each individual measure.^{9,12} It should be more reliable and accurate to combine both direct and indirect measures to examine medication adherence.^{12,17,19,21} Limited studies have used both measurements in renal transplant recipients. No studies have been reported in the Chinese population.

In this study, we combined serum concentration fluctuation of medication in the blood and a self-report questionnaire to measure medication adherence of IM in renal transplant recipients in China. The specific aims of the study were to (1) examine IM adherence using a self-reported measure; (2) examine

IM adherence using serum concentration fluctuation; (3) examine the association between self-report measure and serum concentration fluctuation; and (4) examine the relationship between post-transplantation time and IM adherence, controlling for demographic factors.

METHODS

Design

A cross-sectional study was conducted in a follow-up outpatient clinic of an organ transplantation center in Changsha City, Hunan Province, China. This study was approved by the Human Subjects Institutional Review Board at the Third Xiangya Hospital of Central South University in July 2014.

Sample

Patients who came to the follow-up outpatient clinic were invited to participate in the study from October 2014 to February 2015. Individuals meeting the following criteria were included: (1) aged 18 year or older; (2) prescribed an IM (cyclosporine or tacrolimus) every day; (3) at least 3 months post transplantation; (4) more than 3 follow-up results of serum IM concentration in the center's laboratory; (5) ability to speak, hear, and understand Mandarin; (6) functioning renal transplant (not on dialysis); (7) transplantation physician's and nephrologist's assents that recipient is able to participate in the study; and (8) informed consent given. Exclusion criterion was having had more than 1 renal transplantation.

Study Procedures

When patients came for the follow-up visits, physicians who work in the outpatient clinic invited them to participate to this study. Interested patients then met with a research nurse in this outpatient clinic. Patients who met the inclusion criteria received an informed consent form during the consultation with the nurse. All patients filled in the questionnaire in a separate quiet room in the outpatient clinic under the supervision of the nurse. After completing the questionnaire, patients were given a free copy of the book, *Essentials You Need to Know after Kidney Transplantation*, in appreciation of the participation.²²

Measurements

Sociodemographic Information

Demographic characteristics included age, gender, marital status, education, income, medical insurance, post-transplantation time, and donor type.

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