

# Treatment Satisfaction in Renal Transplant Patients Taking Tacrolimus Once Daily

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## ABSTRACT

**Background:** Adherence to immunosuppressive therapy, which is important to prevent rejection after organ transplantation, is influenced by satisfaction of patients with their medication regimen.

**Objective:** We investigated the effect of introducing a simplified medication regimen for renal transplant patients on treatment satisfaction, in particular, convenience.

**Methods:** In a prospective cohort study, treatment was switched from tacrolimus twice daily to tacrolimus once daily with a simultaneous change to a once-daily formulation of other drugs when applicable. Treatment satisfaction was measured in 75 participants with the validated Treatment Satisfaction Questionnaire for Medication version II.

**Results:** The treatment convenience score increased from a mean (SD) of 66.0 (14.5) to 78.5 (14.5) ( $P < 0.001$ ). The mean (SD) daily number of medication ingestion time points diminished from 2.4 (0.7) to 1.6 (0.7) ( $P < 0.001$ ), and the mean (SD) daily number of tablets decreased from 12.4 (3.3) to 9.1 (2.6) ( $P < 0.001$ ). The self-reported adherence to the medication regimen increased from 79.7% to 94.6% ( $P < 0.001$ ).

**Conclusions:** The introduction of a simplified medication regimen enabled by the use of a once-daily formulation of tacrolimus increases treatment convenience after renal transplantation. This regimen had a beneficial effect on self-reported adherence. (*Clin Ther.* 2013;35:1821–1829) © 2013 Elsevier HS Journals, Inc. All rights reserved.

**Key words:** adherence, kidney transplantation, tacrolimus once daily, treatment satisfaction.

nonadherence to immunosuppressive therapy is ~25%.<sup>1,2</sup> It has been estimated that nonadherence contributes to 20% of late acute rejection episodes and 16% to 36% of graft losses, with a 7-fold increased risk of graft loss in nonadherent compared with adherent patients.<sup>1,2</sup> The percentage of kidney transplant patients who are not adherent is higher than in recipients of other solid organs, possibly because of the nonvital nature of the renal graft.<sup>3</sup> In addition, the adherence to the nonimmunosuppressive treatment is lower than to immunosuppressive drug therapy.<sup>4,5</sup>

A complex medication regimen is one of the risk factors for nonadherence.<sup>6</sup> Evidence from several fields of pharmacotherapy indicates that simplification of the drug regimen leads to a better adherence.<sup>7–9</sup> In the past, the use of calcineurin inhibitors prohibited simplification of the medication regimen in many renal transplant recipients because tacrolimus and cyclosporine had to be taken twice daily. A modified-release formulation of tacrolimus, which can be taken once daily, was approved for use in Europe in 2007. A recently published systematic review indicates that the efficacy of tacrolimus once daily is comparable to that of the twice-daily formulation.<sup>10</sup> The frequency and type of adverse effects also did not differ.<sup>11</sup>

Most tacrolimus-treated renal transplant patients use several other drugs, such as other immunosuppressive agents and antihypertensive drugs. The conversion from the twice-daily to the once-daily formulation of tacrolimus will be especially beneficial in case the concomitantly used drugs can be prescribed in a once-daily formulation as well. Simplification of the entire drug regimen can enable patients to take drugs at 1 or 2 convenient time points per day (eg, early in the

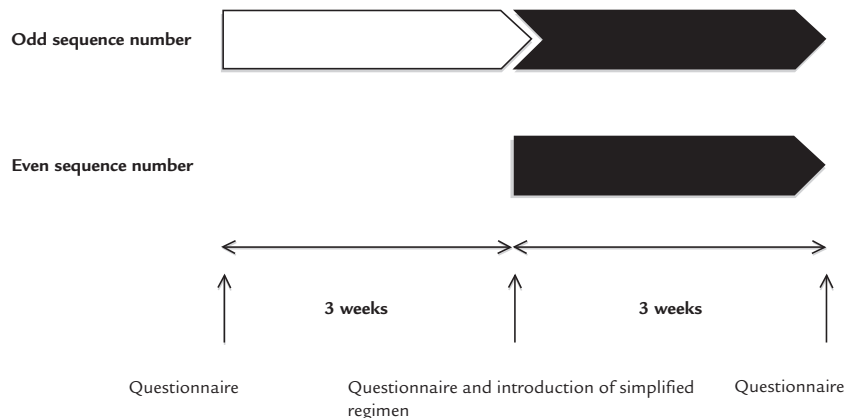
## INTRODUCTION

Nonadherence to medication therapy is a serious health concern among renal transplant recipients. Review articles describe that the prevalence of

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**Figure.** Study design. Participants completed questionnaires before introduction of the simplified regimen and 3 weeks afterward. In a subgroup of patients with an odd hospital-specific sequence number of renal transplantation, a questionnaire was also completed 3 weeks before the introduction of the simplified medication regimen.

morning and at bedtime). It permits patients to remain free of drug intake during work or social activities. Such a simplified medication regimen might improve treatment satisfaction and thereby enhance medication adherence. A validated questionnaire has been developed to measure treatment satisfaction.<sup>12</sup> With this questionnaire, Atkinson et al<sup>12</sup> found that treatment satisfaction, especially treatment convenience, is correlated with medication adherence.

Our study aimed to investigate the effect of introducing a simplified medication regimen in tacrolimus-treated renal transplant patients on treatment satisfaction, in particular, convenience. In addition, we studied the effect of simplification on the self-reported adherence. Finally, we aimed to quantify the proportion of an unselected cohort of tacrolimus-treated renal transplant recipients who would be eligible for a simplified drug regimen.

## PATIENTS AND METHODS

### Study Design

We performed a prospective cohort study to investigate the effect of introducing a simplified drug regimen on treatment satisfaction, in particular, convenience. A simplified medication regimen was defined as a regimen in which every drug is prescribed in a once-daily preparation, enabling a drug intake limitation of 1 or 2 convenient time points per day (eg, early in the morning and/or at bedtime). Although exclusively once-daily preparations were used, 2 ingestion

times per day were allowed because some drugs must be taken at specific time points for optimal effectiveness. Measurements of treatment satisfaction (see below) were performed immediately before introduction of the simplified regimen and 3 weeks afterward (Figure). In a random subgroup of patients, we performed the same measurements 3 weeks before the introduction of the simplified medication regimen to assess the potential effects of participation in a study and repeated measuring on the outcome parameters. This subgroup was composed of patients within the study population with an odd hospital-specific sequence number of renal transplantation. All patients were followed up for 6 months after introduction of the simplified regimen to check whether adverse events occurred. Moreover, we performed a cross-sectional review of the records of all patients who underwent renal transplantation in our hospital between August 2006 and July 2010 to assess the proportion of these patients who could be treated with a simplified medication regimen, including tacrolimus once daily.

### Study Population

Adult renal transplant patients with a stable renal function were eligible for enrollment in the conversion study if they used tacrolimus twice daily in an unchanged dose in the preceding 3 months with a trough level within the target range of 5 to 10 µg/L. An additional inclusion criterion was that every other drug that the patient used could be taken once daily. In

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