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Estimating Health-State Utility Values in Kidney Transplant Recipients and Waiting-List Patients Using the EQ-5D-5L

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ABSTRACT

Objectives: To report health-state utility values measured using the five-level EuroQol five-dimensional questionnaire (EQ-5D-5L) in a large sample of patients with end-stage renal disease and to explore how these values vary in relation to patient characteristics and treatment factors. **Methods:** As part of the prospective observational study entitled “Access to Transplantation and Transplant Outcome Measures,” we captured information on patient characteristics and treatment factors in a cohort of incident kidney transplant recipients and a cohort of prevalent patients on the transplant waiting list in the United Kingdom. We assessed patients’ health status using the EQ-5D-5L and conducted multivariable regression analyses of index scores. **Results:** EQ-5D-5L responses were available for 512 transplant recipients and 1704 waiting-list patients. Mean index scores were higher in transplant recipients at 6 months after transplant surgery (0.83) compared with patients on the waiting list (0.77). In combined regression analyses, a primary renal diagnosis of diabetes was associated with the largest decrement in utility scores. When separate regression models were

fitted to each cohort, female gender and Asian ethnicity were associated with lower utility scores among waiting-list patients but not among transplant recipients. Among waiting-list patients, longer time spent on dialysis was also associated with poorer utility scores. When comorbidities were included, the presence of mental illness resulted in a utility decrement of 0.12 in both cohorts. **Conclusions:** This study provides new insights into variations in health-state utility values from a single source that can be used to inform cost-effectiveness evaluations in patients with end-stage renal disease.

Keywords: end-stage renal disease, EQ-5D-5L, health-state utility values, multivariable regression.

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Introduction

Estimates of health-state utility values are required to undertake cost-effectiveness evaluations in which quality-adjusted life-years are the outcome of interest. Utility estimates can be captured using patient-reported questionnaires as part of a clinical trial or observational study, but in the absence of primary data, estimates are often sourced from published literature.

End-stage renal disease (ESRD) is a chronic condition that has been shown to impact patients’ health status. Numerous studies have been conducted to measure utility values among patients receiving renal replacement therapy. Meta-analyses of published studies suggest that higher utility values are generally observed

among patients who receive kidney transplants in comparison with those on dialysis [1,2]. Pooling results across studies can be an appealing approach to obtain a summary estimate (weighted average with associated uncertainty) of a utility value for each health state of interest that can be used to quality-adjust survival in a cost-effectiveness model. However, caution is required when undertaking meta-analyses of health-state utility values because there is often considerable variability in utility scores as a result of using different valuation methods across studies [3]. A further limitation of pooled utility estimates is that they may not be able to take into account heterogeneity of patient characteristics and treatment or measurement factors that could explain variations in utility scores for a given condition. Individual utility studies

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often have small sample sizes and each study may collect only a limited number of covariates that are not comparable across studies or not always relevant to a specific decision problem or patient population.

The Access to Transplantation and Transplant Outcome Measures (ATTOM) study is a prospective observational study that involved collection of a wide range of data on patient characteristics, treatment factors and health outcomes from all 72 renal units in the United Kingdom. As part of this study, we recruited a cohort of incident kidney transplant and simultaneous (combined) pancreas and kidney (SPK) transplant recipients as well as a cohort of prevalent waiting-list patients selected as controls for transplanted patients [4]. Collection of health-state utility values as part of the ATTOM study has facilitated the following objectives of the present analysis:

1. To report health-state utility values for a large sample of patients with ESRD using the five-level version of the EuroQol five-dimensional questionnaire (EQ-5D-5L).
2. To conduct multivariable regression analyses to understand patient and treatment factors associated with variations in health-state utility values among kidney transplant recipients and waiting-list patients that can then be used to inform quality adjustment of life-years in cost-effectiveness evaluations.

Cost-effectiveness analyses involving patients with ESRD have been undertaken to address a wide range of decision problems, including comparisons of dialysis versus transplantation [5–9], alternative dialysis modalities or initiation strategies [10–12], alternative approaches to kidney allocation [13], and different immunosuppressive therapies after transplantation [14–16]. Given that there may be considerable variation among cost-effectiveness analyses in terms of the target population or the data available to researchers on patient characteristics, we present utility values for a range of potential modeling needs. We demonstrate that with access to more detailed information, we can gain greater insight into the extent of variation in health-state utility values among patients with ESRD. To our knowledge, this is the largest study to date to report health-state utility values based on EQ-5D-5L responses collected in both kidney transplant recipients and waiting-list patients in the United Kingdom.

Methods

The EQ-5D is a widely used generic instrument for describing and valuing health in terms of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The original version of the EQ-5D has three levels of response categories for each dimension, ranging from no problems to extreme problems [17]. More recently, a five-level version of the questionnaire was developed in an attempt to improve the instrument's sensitivity and to reduce ceiling effects [18].

Patients aged 18 to 75 years who received a kidney or SPK transplant in the United Kingdom between November 1, 2011, and September 30, 2013, were approached for recruitment into the ATTOM study. Patients were asked to complete the EQ-5D-5L at recruitment (within 90 days of transplant). Patients who were enrolled during the first 6 months of the ATTOM study were approached at approximately 6 months post-transplant to complete the EQ-5D-5L again. It was not possible to capture EQ-5D-5L responses at 6 months in all transplant recipients because study nurses were only available on site to administer questionnaires for a total period of 12 months. The present analysis focuses only on the EQ-5D-5L data collected at 6 months because this is likely to be a more stable reflection of post-transplant health status than data collected within 90 days of transplant when patients may still be recovering from surgery.

Patients on the kidney transplant waiting list were selected as matched controls for every incident transplant recipient on the basis of the following criteria: transplant center, age (within 5 years), time on the waiting list, type of transplant (kidney only or SPK), diabetes status (as a primary renal diagnosis), and dialysis status (at the time of listing) [4]. The selection of patients on the waiting list as matched controls in the ATTOM study was designed for the purpose of studying survival as an outcome rather than specifically for the measurement of health status. Because patients were not necessarily matched on the basis of health status, this article will refer to the two cohorts as transplant recipients and waiting-list patients (rather than matched controls). For waiting-list patients, EQ-5D-5L responses were captured within 90 days of recruitment. Waiting-list patients were prevalent patients who had been receiving dialysis for varying periods of time. Therefore, the EQ-5D-5L assessment at recruitment in these patients did not represent the start of dialysis as a treatment modality. Recruitment of a prevalent cohort of waiting-list patients facilitates an analysis of health-state utility values in relation to the length of time that patients had been receiving dialysis.

Questionnaire responses were converted to index scores using the preliminary EQ-5D-5L value set for England, which can be accessed via a link on the EuroQol Web site (www.euroqol.org) [19]. We undertook ordinary least squares (OLS) regression with robust standard errors to explore the influence of transplant versus waiting-list status with and without the addition of age, gender, ethnicity, and diabetes as a primary renal diagnosis and summarized model fit by reporting Akaike information criterion values. To investigate the effect of additional patient characteristics collected in the ATTOM study on health-state utility values, we also fitted separate multivariable regression models for transplant recipients and waiting-list patients. This allowed us to explore the effect of donor type (deceased versus living donor) and kidney alone versus SPK transplant among transplant recipients and time on dialysis among patients on the waiting list. For both patient populations, we also considered smoking status and comorbidities that occurred in at least 5% of patients. Final multivariable models were based on covariates that were significant at a P-value cut-off point of 0.10.

Comorbidity information was missing for less than 1% of transplant recipients and waiting-list patients and these observations were omitted from the separate multivariable regression analyses. Among patients on the waiting list, approximately 30% had missing information about time on dialysis and therefore we performed multiple imputation creating 10 imputed data sets using ordered logistic regression before fitting the multivariable model.

All analyses were conducted in Stata version 14 (StataCorp, College Station, TX).

Results

Tables 1 and 2 summarize the characteristics of all patients who were recruited into the ATTOM study in each cohort in comparison with the characteristics of the subset of patients who completed the EQ-5D-5L in each cohort. For waiting-list patients, EQ-5D-5L responses were available in 87% of the cohort and the characteristics of the patients who completed the questionnaire were broadly consistent with those of the overall population. For transplant recipients, EQ-5D-5L responses at 6 months post-transplant were available only in 23% of the cohort, with some under-representation from patients of nonwhite ethnicity, SPK transplants, and patients who experienced graft failure or death.

The proportion of transplant recipients and waiting-list patients reporting each level of problems for each dimension on the EQ-5D-5L is shown in Figure 1. The largest differences between transplant recipients and waiting-list patients are seen

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