An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia

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BACKGROUND

An innovation called Expanded Hemodialysis (HDx) with a middle cut-off (MCO) dialyzer membrane allows for superior removal of molecules up to 45 kDa, including conventional/large middle molecule uremic toxins compared with traditional high flux (HF) hemodialysis (HD). Early clinical evidence suggests that HDx enabled by the Theranova (MCO) dialyzer membrane has the potential to improve patient outcomes and Quality of Life (QoL).

OBJECTIVE

The purpose of this retrospective, before and after study was to provide an initial health economic assessment of the impact of switching patients from HF HD to HDx therapy with MCO dialyzer membrane, on hospitalizations, hospital days, medication use, hospitalization and drug related costs, and patient utilities.

METHODS

Study Design

This retrospective study was undertaken in the Renal Therapy Services (RTS)-Colombia network to track and compare outcomes of a subset of patients over the age of 18 prior to, and after switching from HF-HD to HDx with the Theranova (MCO) dialyzer membrane. Patients who had received HF-HD (Polyflux 140; Revaclear 300 or 400, Baxter, Deerfield, IL, USA) three times weekly for 4 hours, for at least 12 months, were switched to receive HDx (Theranova; Baxter, Deerfield, IL, USA). The patient's prescriptions (*Q*D, *Q*B, target Kt/V, duration, and dialysate) were not changed as part of this study. The study included clinical surveillance and periodic survey data related to quality of life between 2017 - 2019. The data for this analysis came from clinics in the RTS database in Colombia that had high-quality electronic medical record data with complete data for every patient. In addition, clinics included had switched all of their patients from HF-HD to MCO-HDx, and had at least a year of data prior to, as well as after the switch to HDx.

Eighty-one (81) patients qualified for inclusion in the study, and data in both the HF-HD phase and the MCO-HDx phase of the study were collected.

Data Collection and Analysis

The annual count of hospitalizations, hospital length of stay, use of selected medications and QoL as measured by the Kidney Quality of Life (KDQoL)-36 were collected during the 1 year prior to initiation of HDx with Theranova (MCO) dialyzer membrane, while patients were receiving HF HD, and during the 1 year after initiation of HDx with Theranova (MCO) dialyzer membrane. Detailed information on comorbidities was used to calculate severity using a modified Charlson comorbidity index validated in End Stage Kidney Disease (ESKD) patients.

Costs were estimated for hospitalization and medications. Hospital days were monetized based on a recent estimate of cost per day for dialysis-related hospitalizations conducted by RTS. Drug costs were estimated based on published prices, in Colombia. The hospital and drug-related cost estimates were then converted to US dollars based on an average of the US Colombian exchange rate from March to September 2019 (3,338.27 pesos per US dollar). To examine patient utility associated with the treatment change, a published algorithm based on results from a population in Spain was used to convert the KDQoL results into EQ-5D utility scores. As a sensitivity analysis, a related method for generating utility scores based solely on the Short Form (SF)-12 results of the KDQoL-36 was also used; a patient utility score of 1 signifies perfect health.

A generalized linear multivariable model was conducted to assess the effect of HDx with Theranova (MCO) dialyzer membrane on hospitalization days, which were controlled for some demographic and clinical confounding variables. In addition, annual cost estimates for a patient on HF-HD and MCO-HDx were calculated along with percent changes over time. All analyses were performed using Stata version 14.

Study Limitations

- With a before and after design, time trends in medication use and hospitalizations may confound the treatment effect. The main analysis controlled for statistically relevant patient characteristics, which helps alleviate the potential for bias related to time-varying factors, but bias may still be present.
- The results are from three clinics from one network in Colombia. Practices may vary to other settings; generalizing results should be performed with care.
- The cost results reflect Colombian rates for hospitalizations and medications that are unlikely to match those in other countries.
- The EQ-5D utilities mapped from the KDQoL are based on a scoring algorithm developed in Spain and may not adequately reflect Colombian preferences.
- This analysis has focused solely on estimating the impact of HDx with Theranova (MCO) dialyzer membrane, in reducing the cost of hospitalizations and medications. The potential cost savings/cost-avoidances of this technology will depend on pricing dynamics and the contracting models for such treatments, over time.

RESULTS

Patient Characteristics

Baseline characteristics of the 81 patients enrolled in the study included:

- Average age: 61.1 years
- 64.2% male, 35.8% female
- 98.8% from urban areas
- Primary cause of Chronic Kidney Disease (CKD): 39.5% diabetes, 28.4% hypertension
- Median dialysis vintage: 3.8 years
- 25.9% with a modified Charlson comorbidity index of 3 or greater