

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

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Abstract

To examine new evidence linking expanded hemodialysis (HDx) using a medium cut-off (MCO) membrane with hospitalizations, hospital days, medication use, costs, and patient utility. This retrospective study utilized data from Renal Care Services medical records database in Colombia from 2017 to 2019. Clinics included had switched all patients from high flux hemodialysis (HD HF) to HDx and had at least a year of data on HD HF and HDx. Data included demographic characteristics, comorbidities, years on dialysis, hospitalizations, medication use, and quality of life measured by the 36 item and Short Form versions of the Kidney Disease Quality of Life survey at the start of HDx, and 1 year after HDx, which were mapped to EQ-5D utilities. Generalized linear models were run on the outcomes of interest with an indicator for being on HDx. Annual cost estimates were also constructed. The study included 81 patients. HDx was significantly associated with lower dosing of erythropoietin stimulating agents, iron, hypertension medications, and insulin. HDx was also significantly associated with lower hospital days per year (5.94 on HD vs. 4.41 on HDx) although not with the number of hospitalizations. Estimates of annual hospitalization costs were 23.9% lower using HDx and patient utilities did not appear to decline. HDx was statistically significantly associated with reduced hospitalization days and lower medication dosages. Furthermore, this preliminary analysis suggested potential for HDx being a dominant strategy in terms of costs and utility and should motivate future work with larger samples and better controls.

KEYWORDS

costs, expanded hemodialysis, hospitalization, medium cut-off membranes, utility

1 | INTRODUCTION

Dialysis remains an essential treatment for patients with conditions such as chronic kidney disease (CKD) and

kidney failure (KF) in which kidneys stop functioning. Dialysis has been proven to extend life in patients with KF, but it is also limited in terms of long-term outcomes and quality of life [1]. A known problem with low flux

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hemodialysis is that while it filters small urine-related toxic molecules, it is not able to filter potentially toxic medium-size molecules [2]. High flux hemodialysis (HD HF) was an improvement but remains limited in medium-size molecule filtration [1, 3]. A relatively recent improvement known as hemodiafiltration (HDF) can improve medium-size molecule filtration, but it generally requires a complex infrastructure for ultrapure water, HDF-specific hemodialysis monitors, as well as personnel with appropriate clinical experience and training which may be associated with higher costs [4–10]. Most recently, an innovation called expanded hemodialysis (HDx), which uses an MCO membrane that allows for improved removal of molecules with a size of 25 kDa and above, including larger uremic toxins. Furthermore, expanded hemodialysis can be used with the same process and personnel as HD, which means that it can be implemented with relatively low costs, and early clinical evidence suggests that using HDx has the potential to improve patient outcomes and quality of life [11, 12]. However, evidence of the potential economic value of using of HDx remains limited. The purpose of this study is to provide an initial assessment of the impact of switching patients to expanded hemodialysis on hospitalizations, hospital days, medication use, hospitalization and drug-related costs, and patient utilities.

2 | PATIENTS AND METHODS

The study was undertaken in the Renal Therapy Services (RTS)-Colombia network to track and compare outcomes of patients over the age of 18 using HDx. The study included clinical surveillance as well as collection of periodic survey data related to the quality of life [13]. The data for this retrospective analysis came from a subset of the patients available within the RTS database in Colombia selected from clinics with high-quality electronic medical record data such that there was complete data for every patient. In addition, each of the clinics included had switched all of their patients to HDx and had at least a year of follow-up data after having in the past treated the same patients with HD HF for at least a year. For these patients, it was possible to capture annual counts of hospitalizations, total length of stay, use of medications, and quality of life as measured by the kidney disease quality of life (KDQOL)-36 (referred to below as KDQOL scores) at the start of HDx and 1 year after HDx. Demographic and clinical data of the population at the beginning of follow-up are included.

There was also detailed information on comorbidities from which a modified Charlson comorbidity index validated in ESRD patients was used as a measure of severity [14]. Specifically, this index was calculated based on

comorbidities in the RTS data base as follows: 2 (myocardial infarction) +2 (congestive heart failure) +1 (peripheral vascular disease) + 2 (cerebral vascular disease) + 1 (dementia) + 1 (chronic lung disease) +1 (rheumatological disease) +1 (peptic ulcer) +2 (diabetes) +1 (diabetes with complications) +2 (moderate or severe liver disease) + 10 (metastatic disease) +2 (leukemia) +5 (lymphoma). An indicator for having a score greater than 3 was then formed.

The annual count of hospitalizations and hospital days as well as annual doses of a pertinent medications were captured. Hospital days were monetized based on a recent estimate of cost per day for dialysis-related hospitalizations conducted by RTS [15]. Drug costs were also estimated based on published prices in Colombia [16, 17]. 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 in 2019 (3338.27 pesos per US dollar) [18]. 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 [19]. As a sensitivity analysis, a related method for generating utility scores based solely on the short form (SF)-12 results of the KDQOL was also used [20].

Descriptive analyses were run to examine patient characteristics along with hospitalizations and hospital days per year, frequency and doses of medications such as erythropoietin stimulating agents (ESA), iron, insulin, and treatments for hypertension as well as changes in the utility scores of the patients at baseline compared with 1 year after starting on HDx. Further analyses were conducted to examine the relationship between HDx and hospitalizations, hospital days, the proportion of patients taking ESA, iron, insulin, and hypertension-related medications, and measures of dosing of those medications. In addition, univariate generalized linear model analyzes were used to compare the differences in the results according to HDx.

Rates of hospitalization and hospital days were estimated where the numerator was constituted by the number of events and the denominator by the time contributed by each patient within the study phase. These rates were presented with their respective 95% confidence intervals. The incidence rates pre- and post-HDx were compared using the incidence rate ratio (IRR). The hospitalization event was counted if the duration was 1 day or more.

Generalized linear Poisson multivariable model was conducted to assess the effect of HDx on hospitalization days controlling for some demographic and clinical confounding variables. Variables that after univariate regression had probability less than or equal to 0.2 were included in the multivariable model, as well as those with recognized clinical importance. The backward regression method was applied to have a more parsimonious model.

Deviance and Pearson test were used to evaluate goodness-of-fit. In addition, annual cost estimates for a patient on HD and HDx were calculated along with percent changes across time.

All analyses were performed using Stata version 14 (StataCorp LLC, College Station, TX, USA). As this was a retrospective study, where the procedure of HD treatment was not changed in any respect, the study was considered to be without ethical risk. Furthermore, all patients were provided written informed consent and the study was conducted in accordance with the principles of the Helsinki Declaration and Good Clinical Practices. The study protocol was approved by the clinical research ethics committee of RTS, December 11, 2018 (minute item number 025).

3 | RESULTS

Of 175 patients in the three clinics with complete data and that had switched all their patients to HDx, 23 did not meet the eligibility criteria, 48 were lost to follow-up while receiving HD HF and 23 were lost to follow-up while receiving HDx. At baseline, the 81 patients included in the study had an average age of 61.1 years, 64.2% were male, 98.8% were from urban areas and 39.5% had diabetes as the cause of CKD (see Table 1). In addition, the median on dialysis vintage was 3.8 years, 25.9% of them had a modified Charlson comorbidity index of 3 or greater.

At the before phase (HD HF), the hospitalization rate was 0.77 events per patient-year and the rate on after phase (HDx) was 0.71. Hospitalization days showed a sizeable and statistically significant reduction from 5.94 hospital days per patient-year for those on HD HF to 4.41 for patients on HDx ($P < 0.01$; see Table 2). Looking at the use of prescription medications, the proportion of patients seen on ESA, iron, insulin, and hypertension-related medications was roughly the same for patients on HD HF and HDx. However, in available aggregate measures of dosing of these medications, the doses per patient were significantly lower for HDx patients than for HD HF patients ($P < 0.01$; see Table 2). In addition, the average utility of the patients, where 1 signifies perfect health, was 0.70 for HD HF patients and 0.72 for HDx using a KDQOL-based estimate and it was 0.83 for both HD HF and HDx patients using the SF-12-based utility estimate. In testing for univariate statistical significance of the variables of interest with HDx, the Poisson functional form was chosen for the count variables including dosing and hospital days and a gamma form was chosen for utilities.

Table 3 illustrates the cost estimates related to hospitalizations and pertinent prescriptions. Notably, estimates

TABLE 1 Baseline patient characteristics

Patient demographics	N = 81	
Age, years (mean, SD)	61.1	12.6
Male (n; %)	52	64.2
CKD cause (n; %)		
Diabetes mellitus	32	39.5
Hypertension	23	28.4
Obstructive	5	6.2
Glomerular/autoimmune	3	3.7
Unknown	13	16.0
Other	5	6.2
Charlson index ≥ 3 (n; %)	21	25.9
Live in an urban setting (n; %)	80	98.8
Vintage on therapy, years (median, IQR)	3.8	1.7, 11.0
Vascular access (n; %)		
Vascular catheter	19	23.5
Arteriovenous fistula	62	76.5
Time per HD HF session, hours (mean, SD)	4	0
Dialysate flow rate, mL/min (mean, SD)	500	0
Blood flow rate, mL/min (mean, SD)	391.5	50.2
Ultrafiltration, L (mean, SD)	2.0	0.7
Body mass index, kg/m ² (mean, SD)	25	4
Systolic blood pressure, mmHg (mean, SD)	131	18
Diastolic blood pressure, mmHg (mean, SD)	75	16
Hemoglobin, g/dL (median, IQR)	11.9	10.8, 13.1
Albumin, g/dL (median, IQR)	4.0	3.8, 4.2
Phosphorous, mg/dL (median, IQR)	4.5	3.7, 5.4

Abbreviations: CKD, chronic kidney disease; HD HF, high flux hemodialysis; IQR, interquartile range.

for annual average costs of hospitalization were nearly 24% lower with HDx (HD \$1822 and HDx \$1394), and sizably lower for many of the medication-related estimates of costs per patient year.

In the multivariable analysis for the outcome hospital days (see Table 4), we can observe that HDx has a statistically significant effect on the reduction of days of hospitalization when we control for confounding variables such as age, vintage on therapy, history of diabetes, albumin, hemoglobin, phosphorus, and vascular access.

In addition, we observe a reduction in hospital days consumption, especially for infectious events (− 66 days) and related with dialysis (−20 days). Also, we found a reduction in the number of hospitalization events by cardiovascular causes (17 vs. 14) and related with dialysis (17 vs. 12), details are presented in Table 5.

TABLE 2 Hospitalizations, medication utilization, and patient utilities with HD HF or HDx

Outcome	HD HF mean (95% CI) N = 81	HDx mean (95% CI) N = 81
Yearly hospitalization rate	0.77 (0.60–0.98)	0.71 (0.55–0.92)
Yearly hospitalization days	5.94 (5.41–6.50)	4.41 (3.97–4.90) ^a
Proportion using ESA	0.85 (0.77–0.93)	0.88 (0.80–0.94)
Dosage per patient per year of ESA in international units	181 318 (151 647– 210 988)	168 124 (138 452–197 794) ^a
Proportion of patients using Iron	0.81 (0.70–0.90)	0.78 (0.69–0.87)
Dosage per patient per year of iron in milligrams	959 (760–1158)	759 (560–958) ^a
Proportion of patients using insulin	0.35 (0.24–0.45)	0.35 (0.24–0.45)
Dosage per patient per year of insulin in international units	5383 (3274–7490)	3434 (1327–5543) ^a
Proportion using hypertension medications	0.78 (0.69–0.87)	0.74 (0.65–0.84)
Number of tablets per patient per year of hypertension medications	1183 (970–1394)	731 (518–943) ^a
KDQOL based EQ-5D utility score	0.70 (0.65–0.75)	0.72 (0.67–0.77)
SF-12 based EQ-5D Utility Score	0.83 (0.80–0.86)	0.83 (0.80–0.86)

Abbreviations: ESA, erythropoietin stimulating agents; HD HF, high flux hemodialysis; HDx, expanded hemodialysis.

^aStatistically significant difference found in corresponding univariate GLM analysis of outcome on HDx. All had a *P*-value <0.01.

TABLE 3 Annual costs with HD HF and with HDx

Annual per patient cost category	Average Annual costs with HD HF	Average Annual costs with HDx	Percent change HDx vs. HD HF
Hospitalizations	\$1822	\$1394	–23.9%
ESA	\$385	\$357	–7.27%
Iron	\$4.32	\$3.42	–20.83%
Insulin	\$242	\$163	–32.64%
Antihypertensives	\$189	\$132	–30.16%

Abbreviations: ESA, erythropoietin stimulating agents; HD HF, high flux hemodialysis; HDx, expanded hemodialysis.

Hospital days	Coefficient	<i>p</i>	95% CI	
Expanded hemodialysis (HDx)	–0.2	<0.01	–0.4	–0.1
Age, years	0.0	<0.01	–0.0	0.0
Vintage on therapy <1 years	Reference			
Vintage on therapy, 1–3 years	–0.4	<0.01	–0.7	–0.2
Vintage on therapy, >3 years	–0.2	0.14	–0.4	0.1
History of diabetes mellitus	0.2	0.01	0.1	0.4
Albumin ≥ 3.5 g/dL	–1.6	<0.01	–1.9	–1.3
Hemoglobin ≥ 10 g/dL	–0.5	<0.01	–0.6	–0.4
Phosphorus >5.5 mg/dL	0.1	<0.01	0.1	0.2
Vascular access: catheter	Reference			
Vascular access: arteriovenous fistula	–0.5	<0.01	–0.6	–0.3

TABLE 4 Generalized linear Poisson model of hospital days

4 | DISCUSSION

Recently, expanded hemodialysis (HDx) by medium cut-off dialyzers has shown efficacy and safety outcomes [11,

21–24]; however, few studies report effectiveness outcomes or economic analyzes. This study provides a first look at the potential impact of using HDx relative to HD HF in patients in Colombia. Most notably, the univariate and

TABLE 5 Hospitalization cause according to before or after phase

Hospitalization causes	Total hospital days Before phase	Total hospital days After phase	Difference (days)	Before phase n (%)	After phase n (%)
Cardiovascular disease	107	89	-18	17 (27.9)	14 (24.6)
Related with dialysis	71	51	-20	17 (27.9)	12 (21.1)
Infectious causes	89	23	-66	8 (13.1)	10 (17.5)
Others causes	206	190	-16	19 (31.1)	21 (36.8)

multivariate results suggest that the use of HDx was significantly associated with reduced hospital days per patient-year and lower doses of several key medications. Looking at the costs, the estimated valuation of hospital days and amounts of drugs used suggests a potential for cost savings. The results on utility show little change and suggest that there was not any negative impact over time. Preliminary results from a recent larger study of KDQOL scores with patients on HDx relative to HD HF have found a significant positive impact of HDx on the domains of symptoms, effects of kidney disease, and mental health. Although beyond the scope of our analysis, it is possible that converting the KDQOL-36 to EQ-5D utilities results in a loss of sensitivity such that patient gains from HDx are not adequately captured. Overall, while the results on hospital days and drug dosing offer suggestive mechanisms for potential cost savings, more rigorous analyses with larger patient populations are warranted to better understand the impact of HDx on both costs and utilities.

One aspect to consider is that due to the type of design, we evaluated a stable population during the 2 years of follow-up (before and after the dialyzer's switch), which means that it does not necessarily fully represent the population on dialysis. However, this caveat could be balanced by recent evidence showing the efficacy and safety of HDx in a much larger population of patients in routine HD practice [24].

The effect of reducing hospitalization days associated with the change of dialyzer (switch to HDx) was evaluated, controlling for other clinical and demographic variables, which could confound the result; These effects are presented in Table 4 and indicate critical aspects of adequacy in dialysis.

There are several limitations to consider in interpreting the results. To begin, the analyses rely on a before and after design. Consequently, time trends in medication use and hospitalizations may confound the treatment effect. The main analysis presented here, controlled for statistically relevant patient characteristics, helps alleviate the potential for bias related to time-varying factors, but bias may still be present. Future work should incorporate cohorts of control patients that remain on HD HF during the same time period. In addition, the results are

from one set of clinics, from the RTS network in Colombia. Hence, generalizing the results to other settings should be performed with care. The cost results reflect Colombian rates for hospitalizations and medications that are unlikely to match those in other countries. Finally, the EQ-5D utilities mapped from the KDQOL are based on a scoring algorithm developed in Spain that may not adequately reflect Colombian preferences. Among the available scoring mechanisms from Europe, culturally, Spain was deemed to be the closest match. However, a Colombian-specific algorithm may be more accurate if and when it becomes available.

This analysis has focused solely on estimating the impact of HDx in reducing the cost of hospitalizations and medications. In this sense, the potential cost savings/cost-avoidances of this technology will depend on the dynamics of prices and the contracting models for these treatments over time.

The before-and-after nonexperimental design is a reasonable option for an early real-world evaluation for those kinds of technologies. Although it suffers from some threats to internal validity, it could provide preliminary evidence and hypothesis on intervention effectiveness. The before-and-after design could be useful in demonstrating the impacts of short-term exposures as we did. Potential history threats to internal validity, as change in personnel or process of care, are not expected to affect these results, as all the patients were treated in the same centers under the similar institutional protocols of care.

Nevertheless, this study offers novel evidence for the potential impact of using HDx from the clinical perspective and suggests cost savings. The data are among the first collected that allow for an examination of trends in utilization, costs, and utilities across the use of HD HF and HDx. The results on hospital days and drug utilization were especially robust and provide a significant signal that HDx could result in cost savings.

5 | CONCLUSIONS

Expanded hemodialysis (HDx) has shown promise as an important advancement in dialysis-related care and this

analysis has provided evidence that HDx was statistically and significantly related to reduced hospitalization days and lower doses of medications in a real-world setting. Furthermore, this analysis was suggestive of a potential for cost savings with HDx (\$593 USD per patient per year) in Renal Therapy Services-Colombia facilities and should motivate future work with larger samples and better controls. In addition, the results on utility projections provided initial evidence that HDx was not associated with EQ-5D utility scores reduction for patients over time. Future research should examine more rigorously the potential of HDx to be considered as a dominant treatment.

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CONFLICT OF INTEREST

Mr. Ariza is full-time employee of Baxter-Latin America, Bogotá, Colombia. Mr. Walton has received honorarium for consultancy from Baxter Healthcare Corporation. Ms. Suarez and Ms. Vesga are full-time employees of Renal Therapy Services-Colombia, Bogotá, Colombia. Dr. Sanabria is a full-time employee of Renal Therapy Services-Latin America, Bogotá, Colombia.

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