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ORIGINAL ARTICLE

Quality of Life, Outcomes

Economic evaluation of expanded hemodialysis with the Theranova 400 dialyzer: A post hoc evaluation of a randomized clinical trial in the United States

Michael J. Blackowicz[1] | **Luke Falzon**[2] | **Werner Beck**[3] | **Ha Tran**[1] | **Daniel E. Weiner**[4]

[1]Baxter Healthcare Corporation, Deerfield, Illinois, USA

[2]Baxter Healthcare Corporation, San Gwann, Malta

[3]Baxter Healthcare Corporation, Hechingen, Germany

[4]Tufts Medical Center, Boston, Massachusetts, USA

Correspondence
Luke Falzon, MS Baxter Healthcare Corporation Malta Life Sciences Park San Gwann, SGN3000, Malta.
Email: luke_falzon@baxter.com

Abstract

Introduction: The Theranova 400 is a medium cut-off dialyzer that allows for superior clearance of larger middle molecules than traditional high-flux dialyzers. This study evaluates the association of expanded hemodialysis (HDx) using the Theranova dialyzer versus conventional hemodialysis (HD) with a high-flux dialyzer on hospitalization rates and healthcare costs as compared to conventional HD in a post hoc analysis of a randomized controlled trial.

Methods: In a non-concealed, 24-week clinical trial, maintenance HD patients were randomized to receive treatment with either Theranova 400 or a similar size high-flux dialyzer. Hospitalization rate and average length of stay were calculated from trial data. Use of erythropoiesis-stimulating agents and iron were assumed to be equal and therefore excluded from the model. Average cost per inpatient day was obtained from a publicly available published source. Probabilistic sensitivity analyses were conducted to account for variability in model inputs.

Findings: There were 86 patients (389 patient-months) in the Theranova group and 85 patients (366 patient-months) in the high-flux HD group. All-cause hospitalization rate was 45% lower with Theranova compared to high-flux HD (IRR = 0.55; $p = 0.05$). Average annual estimated cost of hospitalization was $6098 lower with Theranova compared to high-flux HD. Compared to high-flux HD, average annual estimated cost associated with Theranova use was $4772 lower per patient. Hospitalization rate and hospital length of stay were the main drivers of cost.

Conclusions: Use of the Theranova dialyzer is associated with lower estimated costs of care among maintenance HD patients, driven by fewer hospitalization events.

KEYWORDS

chronic kidney disease, cost consequence, economic evaluation, hemodialysis

INTRODUCTION

Poor health outcomes related to kidney failure are a burden on both patients and the healthcare system. In 2018 there were more than 785,000 people living with kidney failure in the United States, including approximately 485,000 receiving maintenance hemodialysis (HD), a number which has doubled within the last 20 years.[1] Around three-fourths of all kidney failure patients in the United States are funded by Medicare for their dialysis treatments.[1] Although less than 1% of all Medicare enrollees live with kidney failure, they account for 7.2% of all paid Medicare claims.[1,2]

The accumulation of solutes in patients with chronic kidney disease may be associated with complications resulting in poorer outcomes, including higher morbidity and mortality. These uremic retention solutes, also known as uremic toxins, range widely in size from small molecules less than 0.5 kDa to middle molecules with a molecular weight between 0.5 and 60 kDa. Larger middle molecules, defined as those over 25 kDa in size, are associated with comorbid conditions that are common in dialysis patients such as inflammation and cardiovascular events.[3,4]

Conventional dialysis modalities such as high-flux HD are able to adequately remove small molecules and smaller middle molecules. New therapy options are necessary to improve the removal of large middle molecules. Expanded hemodialysis (HDx) refers to a technique that combines diffusion and convection in a hollow-fiber dialyzer with a medium cut-off membrane. The Theranova 400 (Baxter Healthcare Corporation, Deerfield, IL), a medium cut-off dialyzer recently approved by the FDA in August 2020, provides an expanded solute removal profile with increased removal of various middle molecules (up to 45 kDa) that may play a pathologic role in the uremic clinical syndrome. In a randomized controlled trial in which 172 patients were randomized to receive treatment via HDx with Theranova or high-flux dialysis, HDx with Theranova was shown to be superior to high-flux HD in removing larger middle molecules such as lambda-free light chains, while maintaining adequate serum albumin levels.[5]

To justify its utilization, particularly within a financially capitated system, economic evaluations to assess the realized cost of a new health technology, such as HDx, from the perspective of the patient, the healthcare provider, the healthcare payer, or society as a whole must be performed.

We theorized that the enhanced removal of middle molecules and the improvements shown in some biomarkers can lead to better clinical outcomes for patients treated with HDx. We compared the hospitalization rate between HDx enabled by Theranova 400 and a similar size high-flux dialyzer, and compared the healthcare costs, including costs of Erythropoietic stimulating agents (ESA) and iron use, of Theranova 400 versus high-flux HD.

MATERIALS AND METHODS

Randomized controlled trial

The evaluated clinical trial was a prospective, randomized, controlled, open-label, parallel study in patients receiving maintenance dialysis treatment with the Theranova 400 dialyzer or a similar performance high-flux dialyzer for 3 weekly sessions over 24 weeks. The objectives of the study were to demonstrate that HDx with Theranova 400 maintained serum albumin levels (safety), with resultant significantly lower λ-free light chain levels (efficacy) compared to high-flux HD.[5] The trial was registered at ClinicalTrials.gov (NCT03257410) on 18 August, 2017 and approved by an Institutional Review Board.

Patients were eligible to enroll if they met the following criteria: age 18–21 years weighing over 40 kg or 22 years and over; clinically stable without acute medical events for 30 days prior to enrollment; received HD with a high-flux dialyzer for at least 3 months; they were expected to maintain an acceptable urea clearance (Kt/V) with a dialyzer of an approximate surface area of 1.7 m^2; and had stable functioning vascular access. Patients were excluded for any of the following: history of acute infection within 4 weeks of anticipated randomization or had chronic liver disease, paraprotein-associated disease, hepatitis, HIV, bleeding disorders, active cancer, monoclonal or polyclonal gammopathy. Patients with known serum κ-/λ-free light chain ratio less than 0.37 or greater than 3.1, suggestive of monoclonal plasma diseases, were also excluded.

A total of 172 patients were randomized and 171 patients were treated with either Theranova 400 (Baxter International Inc.) or a conventional high-flux dialyzer in 21 centers in the United States between September 2017 and October 2018.

Clinical outcomes

Hospitalization was defined in the study by the occurrence of any serious adverse event which contained a hospitalization admission date. The hospitalization rate was defined by treatment as total number of hospitalizations divided by total person-years of follow-up during the trial period. Hospital length of stay was defined as the number of days between admission and discharge. Hospitalization events still ongoing at the end of the trial, and thus not having a discharge date, were excluded from

calculation of average hospital length of stay but were counted in the calculation of hospitalization rate.

Erythropoietic stimulating agents (ESA) use at baseline was defined, according to the protocol, as any ESA taken in the 30 days prior to the patient giving informed consent. Usage and dose of ESAs and iron were to be reported monthly for the duration of the study. However, this reporting was incomplete resulting in a lack of significant difference in change from baseline in ESA or iron use or dose between the Theranova and high-flux dialyzer groups. As a result, the use and dose of ESAs and iron were assumed to be equal, and not included in the cost consequence model. Additional information on ESA and iron use can be found in the supplemental material.

Costs

Cost of hospitalization was obtained from the Kaiser Family Foundation average cost per inpatient day in the United States for the year 2018.[6] Total cost of hospitalization was calculated by treatment group as the product of hospitalization rate, average hospital length of stay, and inpatient hospital cost per day. The annual cost of dialyzers for each group was calculated as the cost of each dialyzer multiplied by 3 dialyzers/week over 52 weeks.

Statistical analysis

Mean length of stay per hospitalization was estimated using a Poisson (log-count) general linear model. All-cause hospitalization and dialyzer costs were calculated for each treatment group by multiplying the risk and/or quantity by its associated unit cost along with the incremental cost difference between Theranova and the high-flux dialyzer. Costs were not calculated per life year gained or quality-adjusted life year gained since there were no significant survival nor quality of life differences noted for the duration of the 6-month trial as reported by Weiner et al.[5]

A univariate sensitivity analysis was also included to evaluate the impact of observed variability on itemized and cumulative incremental cost difference between Theranova and high-flux HD. A tornado plot was generated as a graphic representation of the impact of input variability using the observed 95% CI around each clinical input and a predetermined 20% difference in cost inputs on overall cost difference between Theranova and high flux HD. Further, for each treatment group, itemized and total costs were calculated through random sampling of all input parameters based on the closest approximation of their observed distributions and cost difference was calculated cumulatively and for each item. This was repeated over 10,000 simulations and summarized by item with mean and 95% confidence intervals.

Assumptions

The proportion of patients receiving medications, medication doses, and patient-reported health utility scores were assumed to be equal between HDx and high-flux HD based on clinical trial results and were therefore excluded from the model (see supplemental material). The cost per high-flux dialyzer was assumed to be $6.50 while the cost of the Theranova was priced at $15.00 per dialyzer. All other costs associated with dialysis activity (i.e. devices, fluids, maintenance, facilities, nursing time, nephrology consultations, etc.) were assumed to be equal and were not included in the model.

RESULTS

Demographics

Of 172 patients, 86 received treatment with Theranova and 85 received treatment with a high-flux dialyzer (1 patient in the high-flux HD was not treated); 39% of patients were female and the average age of patients was 59 ± 13 years (Table 1). Baseline demographic and clinical characteristics were similar between the two groups. Hemoglobin levels remained consistent throughout the study across both study arms (see supplemental material). In general, the study population tended to be younger than the general end-stage renal disease (ESRD) patient population on HD in the United States, with just 8% of patients over 75 years of age in each study group, compared to 22% of HD patients in the overall US population. Patients in both groups in the study also were on HD over a longer period of time compared to the general US population (5.4 and 4.7 years vs. 2.9 years; see Table 1).

Clinical outcomes

Hospitalization and length of stay

There were 18 hospitalizations in the Theranova group over an average follow-up of 4.5 months for a total of 389 patient-months (32.4 patient-years) and a hospitalization rate of 0.56 (95% CI: 0.30, 0.81) per patient-year. In the high-flux HD group, there were 31 hospitalizations over an average follow-up of 4.3 months for a total of

TABLE 1 Patient characteristics at randomization

Patient characteristics	Theranova (*N* = 86)	High-flux HD (*N* = 86)	USRDS (2018)[a] (*N* = 495,402)
Age			
0–21	0 (0%)	0 (0%)	<1%
22–44	8 (9%)	12 (14%)	11%
45–64	46 (54%)	45 (52%)	40%
65–75	25 (29%)	22 (26%)	26%
75+	7 (8%)	7 (8%)	22%
Sex			
Male	54 (63%)	51 (59%)	58%
Female	32 (37%)	35 (41%)	42%
Race/ethnicity			
Non-Hispanic White	24 (28%)	22 (25%)	39%
Non-Hispanic Black	33 (38%)	35 (41%)	34%
Hispanic	19 (22%)	23 (27%)	29%
Other	10 (12%)	6 (7%)	8%
Primary kidney diagnoses			
Diabetes	34 (40%)	43 (50%)	47%
Hypertension	36 (42%)	24 (28%)	30%
Others	16 (18%)	19 (22%)	24%
Vascular access			
AV fistula	68 (79%)	74 (86%)	66%
AV graft	12 (14%)	12 (14%)	17%
Catheter	6 (7%)	0	18%
Comorbid conditions[b]			
Hypertension	78 (90.7%)	75 (87.2%)	88%
Diabetes (Type 2)	47 (54.7%)	55 (64.0%)	54%
Coronary artery disease	13 (15.1%)	11 (12.8%)	Not reported
Heart failure	17 (19.8%)	18 (20.9%)	20%
Other cardiac disease	26 (30.2%)	34 (39.5%)	19%
Body mass Index (Mean ± SD)	31.1 ± 7.52	32.7 ± 8.04	Not reported
Years on HD (Mean ± SD)	5.4 ± 5	4.7 ± 4	2.9[c]
Hemoglobin (Mean ± SD; g/dl)	11.3 ± 1.48	11.1 ± 1.10	10.8[d]

Abbreviations: AV, arteriovenous; HD, hemodialysis; USRDS, United States Renal Data System.
[a]Prevalent HD patients in 2018 [USRDS Annual Report 2020; Reference Table D.7].
[b]Comorbidity terms as coded in the Medical Dictionary of Regulatory Activities (MedDRA); for the USRDS comparison for coronary artery disease, atherosclerotic heart disease is reported.
[c]Years on HD was not directly reported in USRDS. This was calculated as the (center value of each 5-year age group) * (number of patients in age bucket) averaged across all age group.
[d]Hemoglobin measurements were only taken in new (incident) HD patients. This is not necessarily representative of all (prevalent) HD patients.

366 patient-months (30.5 patient-years) and a hospitalization rate of 1.02 events per patient-year (95% CI: 0.57, 1.24). Hospitalization was 45% lower in patients treated with Theranova compared to patients treated with high-flux HD (IRR = 0.55; 95% CI: 0.30, 1.00; $p = 0.042$). The mean length of stay for the hospitalization events was 4.6 days (95% CI: 3.9, 5.5) for the 18 events in the Theranova group versus 4.1 days (95% CI: 3.3, 5.2) for the 31 events in the high-flux HD group. This difference in length of stay was not statistically significant ($p = .41$;

TABLE 2 Clinical outcomes

Health resource utilization	Theranova ($n = 86$)	High-flux HD ($n = 85$)[a]	p-value
Hospitalization events	18	31	–
Total hospital days	74	139	–
Total patient-years	32.4	30.5	–
Hospitalization rate per PY (SE)	0.56 (0.13)	1.02 (0.12)	0.042
Hospital length of stay (mean days [SE])	4.11 (0.57)	4.63 (0.58)	0.406

Abbreviation: HD, hemodialysis.
[a]One high-flux HD randomized participant did not complete baseline.

Table 2). There was no apparent difference between the two groups in the distribution of causes for hospitalization, with a trend toward fewer events with Theranova across most categories (see Data S1).

Economic evaluation

Hospitalization costs

The mean per-person costs associated with all-cause hospitalization in the high-flux HD group were $11,853 compared to $5756 in the Theranova group, an amount $6091 lower compared to high-flux HD.

Dialyzer costs

Mean dialyzer costs were $2340 in the Theranova group and $1014 in the high-flux HD group, which represents an increase of $1326 in costs with Theranova compared to high-flux HD, largely attributable to an $8.50 higher price per Theranova dialyzer. All other dialysis-related costs were assumed to be equal between the two treatment groups.

Cumulatively, with a cost incorporating both hospitalizations and dialyzers of $8096 for treatment with Theranova vs $12,867 for treatment with high-flux HD, treatment with Theranova in this study was associated with $4772 lower cost than treatment with high-flux HD (Table 3).

Probabilistic sensitivity analysis

After accounting for observed variability in each model input (separately), hospitalization rates were the main drivers of cost difference in the model, particularly in the high-flux HD group. The results favored Theranova at the upper and lower thresholds for all inputs (Figure 1).

TABLE 3 Economic evaluation

Item	Unit cost	Per-patient cost: Theranova	Per-patient cost: High-flux HD	Per-patient cost: Difference
All-cause Hospitalization[a]	$2518 per day	$5756	$11,853	−$6097
Dialyzer cost[b]	$15.00 ea/ $6.50 ea	$2340	$1014	$1326
Cumulative		$8096	$12,867	−$4771

Abbreviation: HD, hemodialysis.
[a]All-cause hospitalization was defined as any serious adverse event that resulted in hospitalization.
[b]Theranova dialyzer was priced at $15 in the United States and high-flux dialyzer was assumed to cost $6.50.

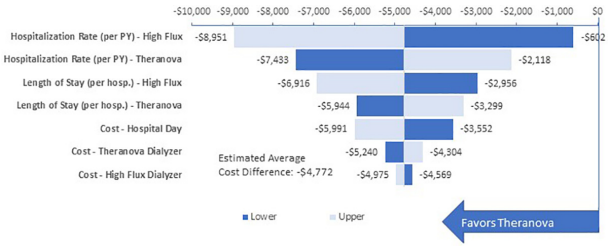

FIGURE 1 Univariate sensitivity analysis. After accounting for observed variability in each model input (separately), hospitalization rates were the main drivers of cost difference in the model, particularly in the high-flux HD group. The results favored Theranova at the upper and lower thresholds for all inputs [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 4 Simulated summary methods of mean cost difference

Item	Per-patient cost difference: Mean	Per-patient cost difference: (95% CI)
All-cause hospitalization (per day)	−$6103	(−$11,604 to −$601)
Dialyzer cost	$1326	–
Cumulative	−$4777	(−$10,278 to $725)
Proportion of simulations demonstrating theranova cost-saving over high-flux HD	95.7%	

Abbreviation: HD, hemodialysis.

Summary estimates over 10,000 simulations of costs demonstrated similar results for mean difference in cost between Theranova and high-flux HD (Table 4). The introduction of observed variability resulted in confidence intervals for all-cause hospitalization below $0 even at the upper bound. Probabilistic analysis determined that Theranova was associated with lower costs in 96% of the 10,000 simulations.

DISCUSSION

In a post hoc analysis of a randomized clinical trial, HDx with the Theranova dialyzer was associated with lower healthcare costs than standard high-flux HD, largely driven by lower risk of hospitalization rate in kidney failure patients treated with HDx via the Theranova as compared to high-flux HD.

Current literature on health economics and patient outcomes of HDx is scarce, but there are a small number of new studies on the topic. The results of this study are supported by another economic evaluation of HDx in Colombia which compares patients before and after switching from high flux HD to HDx with Theranova.[7] That study also reported lower costs of HDx driven largely by lower costs of hospitalization, but differed from the current study in that it also demonstrated lower dose of ESAs, iron, and insulin. However, it is important to highlight that a before/after study design is limited by inherent bias whereby the "after" time period is at higher risk of poor health outcomes than the "before" due to the natural progression of morbidity among HD-dependent individuals.

The lower hospitalization rate observed in the current study is further supported by a retrospective observational study comparing HD patients on HDx with those on high-flux HD.[8] This study demonstrated 18% lower risk of hospitalization (IRR = 0.82; 95% CI: 0.69–0.98; $p = 0.03$) in HD patients treated with HDx as compared to those treated with high-flux HD with no significant difference in hospital length of stay.

The results of this study should be interpreted in the context of a common limitation of clinical trials in which selection of more stable participants can limit external validity of results to the general patient population. In the general US dialysis population, patients receiving HD often are elderly and frail with multiple comorbid conditions and frequent hospitalizations.[9] In contrast, the patients included in this study were younger, healthier, and only eligible for enrollment if they were medically stable. As a result, the hospitalization rate and average hospital length of stay in high flux HD patients observed in this study were substantially lower than the general US dialysis population. The hospitalization rate among in-center dialysis patients treated with high flux HD was 1.02 with a 4.3 day average length of stay while the most recent pre-pandemic USRDS data demonstrated that the overall adjusted rate of hospitalization among Medicare beneficiaries with kidney failure treated with HD in 2018 was 1.60 hospitalizations per person-year with a 6-day average length of stay per hospitalization.[9] Given this difference in patient health between the current study and the general patient population, it is anticipated that the true effect would potentially be larger in the real-world setting where patients are treated for longer than 6 months and tend to be older, have more comorbidities, more frequent hospitalizations, and be less clinically stable.

Despite limitations in external validity, successful randomization ensured few threats to internal validity. Since patient characteristics were balanced across both treatment arms, the lower all-cause hospitalization event rate observed in HDx patients compared to high-flux HD patients was not confounded by age, gender, comorbid conditions, dialysis vintage, or other unknown confounders. Other potential confounders reported in Weiner et al.,[5] such as ultrafiltration volume, blood flow rate, and Kt/V, also show balance across treatment arms and are therefore unlikely to confound the main associations reported here.

A limitation of examining all-cause hospitalization is that events not relevant to dialysis effectiveness, such as trauma from a motor vehicle accident, may be included. However, occurrence of these events is expected to be random with respect to dialysis treatment and therefore unlikely to introduce bias in the all-cause hospitalization rate ratio except for potentially a slight attenuation toward null findings.

While the small number of hospitalization events over the 6-month trial made it impossible to draw sound statistical conclusions from comparison of category-specific hospitalization rates (specifically, infection-related or cardiovascular-related), the difference in outcomes seen in the Theranova arm trends favorably across most primary causes of hospitalization. Despite these limitations, the favorable trend and overall lower all-cause hospitalization rate is encouraging as prior large, well-run randomized trials studying various doses and dialysis membranes such as the HEMO study[10] and the MPO study[11] have not demonstrated a statistical difference in all-cause hospitalizations.

As with any cost model, certain assumptions were required. Notably, while there was no apparent difference in ESA or iron dose change from baseline or proportion of patients using those medications, post-baseline medication reporting was incomplete and unreliable. For these reasons, medications were excluded from the model and were therefore assumed to be equal between patients treated with HDx and those treated with high-flux

HD. Furthermore, while the randomized controlled trial was conducted over a period of 6 months, this economic evaluation model covers a full year of treatment and therefore health outcomes such as hospitalization rates were assumed to be constant over the first year.

These results are of potential importance in completed and upcoming payment models in kidney care in the United States.[12] The Comprehensive End-Stage Renal Disease Care Model, known as the ESCO, was a shared savings-loss model in dialysis care, with overall cost differences largely driven by hospitalization. Similarly, the upcoming Kidney Care Choices model includes several shared savings/losses tracks as well as a metric for overall cost of care within the Kidney Care First track, emphasizing the ability to reduce hospitalizations and length of stay as key drivers of financial success.[13]

CONCLUSIONS

This study provides evidence that, in addition to Theranova's superior removal of large middle molecules, HDx may also be a cost-saving therapy driven largely by a significant reduction in patient hospitalization events.

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CONFLICT OF INTEREST

Michael J. Blackowicz, Luke Falzon, and Ha Tran are employees of Baxter Healthcare Corporation and may hold stock in the company. Werner Beck has patents WO2015/118045 and WO2015/118046 issued and is a full-time employee of Baxter International Inc. Daniel E. Weiner receives salary support paid to his institution for clinical research efforts by Dialysis Clinic Inc. He was a site principal investigator in the clinical trial on whose data this article is based on and received no funding from Baxter Healthcare International beyond this role, with trial support paid to his institution. He has consulted for Akebia, Janssen, and Tricida. He reports receiving personal fees from Cara Therapeutics.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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