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A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease

Michael KRAUS,[1] John BURKART,[2] Rebecca HEGEMAN,[3] Richard SOLOMON,[4] Norman COPLON,[5] John MORAN[5]

[1]Indiana University Hospital, Indianapolis, Indiana, U.S.A.; [2]Wake Forest University Medical Center, Winston-Salem, North Carolina, U.S.A.; [3]University of Iowa Hospitals and Clinics, Iowa City, Iowa, U.S.A.; [4]Chittenden County Dialysis, South Burlington, Vermont, U.S.A.; [5]Satellite Healthcare/Wellbound, Mountain View, California, U.S.A.

Abstract

Home hemodialysis has been a therapeutic option for almost 4 decades. The complexity of dialysis equipment has been a factor-limiting adoption of this modality. We performed a feasibility study to demonstrate the safety of center-based vs. home-based daily hemodialysis with the NxStage System One portable hemodialysis device. We also performed a retrospective analysis to determine if clinical effects previously associated with short-daily dialysis were also seen using this novel device. We conducted a prospective, 2-treatment, 2-period, open-label, crossover study of in-center hemodialysis vs. home hemodialysis in 32 patients treated at 6 U.S. centers. The 8-week In-Center Phase (6 days/week) was followed by a 2-week transition period and then followed by the 8-week Home Phase (6 days/week). We retrospectively collected data on hemodialysis treatment parameters immediately preceding the study in a subset of patients. Twenty-six out of 32 patients (81%) successfully completed the study. Successful delivery of at least 90% of prescribed fluid volume (primary endpoint) was achieved in 98.5% of treatments in-center and 97.3% at home. Total effluent volume as a percentage of prescribed volume was between 94% and 100% for all study weeks. The composite rate of intradialytic and interdialytic adverse events per 100 treatments was significantly higher for the In-Center Phase (5.30) compared with the Home Phase (2.10; p=0.007). Compared with the period immediately preceding the study, there were reductions in blood pressure, antihypertensive medications, and interdialytic weight gain. Daily home hemodialysis with a small, easy-to-use hemodialysis device is a viable dialysis option for end-stage renal disease patients capable of self/partner-administered dialysis.

Key words: Daily hemodialysis, end-stage renal disease, hemodialysis, ESRD, hospitalization

INTRODUCTION

An estimated 430,000 people in the United States have end-stage renal disease (ESRD).[1] Globally, that number is more than 1,000,000.[2] While renal transplantation offers a durable treatment for ESRD, chronic hemodialysis remains the mainstay of treatment. Currently, only about 25% of ESRD patients have a functioning transplant.[1] With the vast majority of ESRD patients receiving thrice-weekly dialysis in a clinic environment at an average annual global treatment cost of more than $70,000[3] per patient year, their dialysis care consumes a substantial proportion of health-care resources. Analysis of component costs of

Correspondence to: M. Kraus, MD, Indiana University Hospital, 550 N University Boulevard, UH1115, Indianapolis, IN 46202, U.S.A.
E-mail: mkraus@iupui.edu

chronic hemodialysis identified labor costs as the largest contributor to overall treatment cost.[4] The high cost of clinic-based dialysis coupled with a well-documented shortage of dialysis health-care professionals[5] makes a strong economic case for home-based hemodialysis.

From a medical perspective, home hemodialysis may offer an opportunity to reduce the approximately 23% annual gross mortality rate observed for thrice-weekly clinic-based dialysis.[2,6] Attempts to reduce mortality by increasing delivery dose, using high-flux dialyzers, or increasing peritoneal dialysis clearance have been unsuccessful.[7,8] However, a large 1996 study based on U.S. Renal Data System data found that home hemodialysis reduced mortality by 42% compared with clinic-based hemodialysis.[9] In addition, increased-frequency hemodialysis, nocturnal or daily, has been shown to reduce mortality and hospitalization days compared with intermittent hemodialysis.[10–12] Home therapy may offer better quality of life for ESRD patients in the form of increased flexibility for personal, social, and employment opportunities.

Several studies have shown that many ESRD patients are capable of self care.[13–16] Barriers to home hemodialysis, however, include substantial space requirements for the equipment, as well as the complexity of water processing. Design features of the System One hemodialysis device (NxStage Medical Inc., Lawrence, MA, U.S.A.) allow it to deliver daily hemodialysis in a device that is about the size of a 13-in. television. A drop-in cartridge and sterile, prepackaged dialysate solution eliminate the need for large and complex water-processing equipment and fluid handling. A simple user interface facilitates use of the device by patients and their partners. Storage needs are significant, as patients will store monthly supplies consisting of prepackaged fluids (approximately 20 L per day), cartridges, and dialysis supplies.

We studied delivery of hemodialysis with the System One in the center vs. home settings to determine whether the 2 environments are equivalent on a per-treatment basis. In addition, we retrospectively collected baseline data on hemodialysis treatment parameters (e.g., hemodialysis prescription, laboratory values, prescribed medications) to compare with treatment parameters using the System One.

MATERIALS AND METHODS

Study design

We conducted a prospective, multicenter, open-label, crossover, feasibility study in which patients received center-based hemodialysis followed by home-based hemodialysis all with the NxStage System One. Participants had received a minimum of 2 weeks of hemodialysis with the System One in a center environment before study initiation. In the first phase (In-Center), hemodialysis was performed with the System One in 6 dialysis centers in the United States 6 times per week for 8 weeks. The In-Center Phase was followed by a 2-week transition period in which patients transitioned to home hemodialysis with the System One. After the Transition Phase, the Home Phase began, which also consisted of 6 treatments per week for 8 weeks. The Institutional Review Boards at participating sites approved the study protocol and signed informed consent was obtained.

Regular blood chemistry monitoring was performed at sites on weeks 2, 4, and 8 of the In-Center and Home Phases and on week 2 of the Transition Phase. In addition, Kt/V labs were performed weekly and medication profiles were evaluated on an ongoing basis. Vital signs (weight, sitting blood pressure, pulse, temperature) and total effluent and ultrafiltration goals were recorded before and after treatment during the In-Center and Home Phases.

Device description

The System One hemodialysis device (Figure 1) consists of an electromechanical cycler (pump); single-use, γ-sterilized cartridges with preattached, high-permeability filters; and a fluid warmer to warm the dialysate. The prescription fluid is a sterile prepackaged, premixed dialysate. The cycler pumps blood from the patient through the filter and returns blood to the patient. In addition, the cycler balances the removal of effluent with the inlet flow of sterile, premixed dialysate plus ultrafiltration. The device also monitors treatment parameters, performs pressure and alarm tests, and monitors operating parameters critical for patient safety. The System One can achieve blood flow of up to 600 mL/min and fluid exchange of up to 12 L/hr (dialysate volume plus ultrafiltration volume). The device is portable, with a weight of approximately 70 pounds and dimensions of $15 \times 15 \times 18$ in.

Patient selection

Thirty-two patients with ESRD, a life expectancy of at least 1 year, and currently receiving hemodialysis at least thrice weekly for a minimum of 3 months were enrolled. A multispecialty team determined participants' appropriateness for home hemodialysis. Appropriateness for home dialysis was defined by each center, although each patient

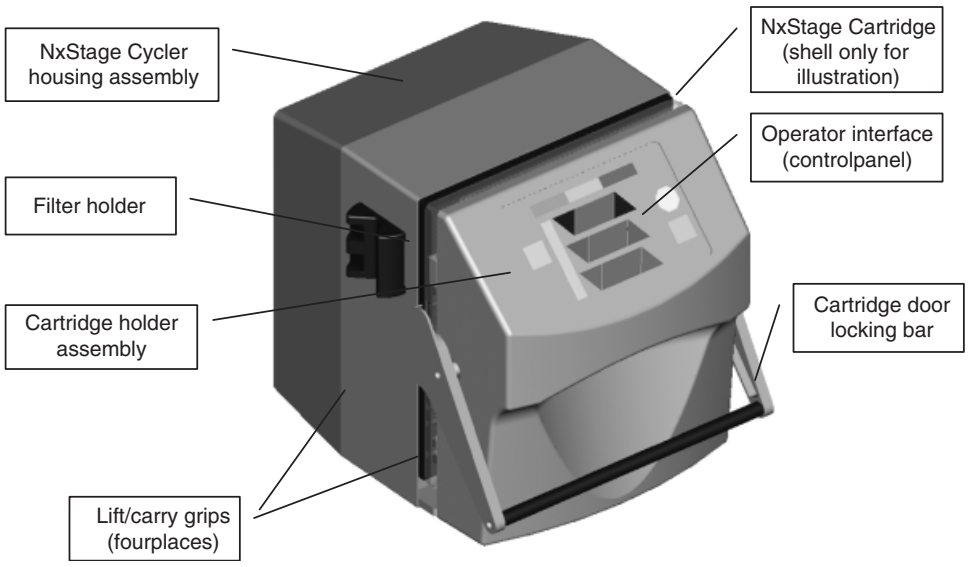

Figure 1 System One hemodialysis unit (dimensions: 15 × 15 × 18 in.; weight: approximately 70 lbs).

had to have an identifiable partner. Study participants were ≥18 years of age with a vascular access capable of a minimum blood flow rate of 350 mL/min and could be treated with a delivered single-pool (sp) Kt/V of 0.45 in ≤3.5 hr. Exclusion criteria included estimated glomerular filtration rate >6 mL/min/1.73 m^2 as estimated by 24-hr urine in the presence of greater than 400 cm^3 urine in 24 hr, liver disease, uncontrolled hypertension, symptomatic intradialytic hypotension, hemoglobin <10 g/dL, active infectious or inflammatory disease, documented noncompliance, and malignancy other than superficial skin carcinomas.

Training

During the In-Center Phase, qualified medical personnel, home dialysis nurses, and/or technicians trained each subject and the subject's partner how to perform dialysis with the System One. Training consisted of individual sessions involving all phases of dialysis including setup, treatment, posttreatment care, machine alarms, and disaster preparedness. Subjects and their partners were required to successfully complete the System One Skills Checklist and achieve a score of 100% on a written exam before the first treatment of the Home Phase. Subjects and partners were trained to record pretreatment and posttreatment vital signs and total effluent and ultrafiltration goals, as well as complete standard dialysis flow sheets used at the site and a study diary documenting how subjects felt during and between dialysis treatments.

Training took place during the In-Center Phase of the study. Timing of training was determined separately at each center. Duration of training was the time from the first training session to successful completion of partner and patient tests and the decision by staff that the patient could safely be released to home for dialysis.

Study endpoints

The primary efficacy endpoint of this study was successful delivery of the prescribed fluid volume, defined as delivered volume that was at least 90% of prescribed volume at each dialysis session. The delivered volume was the total effluent volume (spent dialysate plus net ultrafiltrate) as measured electronically by the device. The volume variable was an effective means of assessing the impact the environment may have on the ability to deliver the therapy. SpKt/V per treatment was measured weekly as a secondary endpoint to confirm the prescribed and delivered treatment volumes and determine the adequacy of treatment volumes. The initial dialysate volume was prescribed by the nephrologist, generally based on a weight-based and sex-based nomogram to deliver a daily spKt/V of 0.5 or greater. The nephrologist was allowed to vary the prescription based on measured spKt/V, no uniform protocol was used. The primary safety endpoint was the composite measure of intradialytic and interdialytic adverse events, defined as any unfavorable or unintended sign, symptom, or disease temporally associated with use of the device. Achievement of target ultrafiltra-

tion volume per treatment was accounted for in the calculation of total effluent volume. Other secondary endpoints included delivered spKt/V (based on blood urea nitrogen [BUN] values), the Kidney Disease Quality of Life (KDQOL) Short form (completed at baseline and at the end of In-Center and Home Phases), clinical utility of the device (number and frequency of device alarms, response times, and treatment times), and successful completion of the training program by the subject and the subject's partner.

Data collection

The Cycler component of the device electronically recorded and stored treatment parameters, times, and alarms. Dialysis dose delivery was measured once per week to confirm achievement of the specified target for delivered therapy. Adverse event data were collected via each subject's dialysis diary and medical records.

Retrospective analysis

We conducted a retrospective review of subjects' medical records at 5 study centers to collect data on the conventional thrice-weekly hemodialysis treatment parameters for these patients immediately before initiation of the current study. Subjects who had completed at least 1 week of the Home Phase were included in this analysis. Retrospective data collection included hemodialysis prescription and mid-week predialysis blood pressures. In addition, we assessed 4 consecutive weeks of predialysis and postdialysis weights, 2 months of laboratory levels, and medication history. History of hospitalizations within 1 year before initiation of the study was also collected.

Statistical analysis

An estimated sample size of 25 was required to detect a difference between treatment groups for the adverse event rates as well as the primary endpoint, assuming a dropout rate of no greater than 10 patients, the original goal was to recruit 35 patients. Statistical comparisons were 2-sided with a significance level of <0.05 using SAS software version 8.2 or higher (SAS Institute, Cary, NC, U.S.A.).

The primary efficacy endpoint, the successful delivery of $\geq 90\%$ of prescribed volume, was compared between the 2 treatment environments (In-Center vs. Home) using a generalized linear model with generalized estimating equations (GEE). Adverse event data were compared between treatment environments using a generalized linear model. Ultrafiltration volume and delivered spKt/V were analyzed using a linear mixed model.

For the retrospective analysis, hemodialysis treatment parameters immediately preceding the System One study were compared with treatment parameters during the In-Center and Home Phases. Comparisons of normally distributed continuous data were summarized and analyzed using paired t tests with a significance level of <0.05. Nonparametric continuous comparisons were analyzed using a Wilcoxon signed-rank test with a significance level of 0.05.

RESULTS

Patient disposition and characteristics

The 32 patients enrolled in this study and who completed at least one study dialysis treatment comprise the intent-to-treat (ITT) population. Of those patients, 25 (78%) completed the study (per-protocol population) as defined by missing fewer than 9 treatments in a given phase (In-Center or Home) and missing fewer than 14 treatments during the entire study (In-Center and Home). This paper presents analysis of the ITT population; results in the per-protocol population did not differ substantially. Of the 32 patients recruited for the study, 31 were on thrice-weekly dialysis with conventional dialysis, 5 at home, and 26 In-Center. One patient was on short-daily dialysis at home with conventional dialysis equipment. Of the 7 subjects who did not complete the study, 4 withdrew consent (2 subjects for partner issues, one for machine problems, one did not like daily dialysis), 2 were withdrawn by the investigator when the site withdrew from the study, and one withdrew for kidney transplant.

Patient characteristics are noted in Table 1. Patient recruitment varied at each center. All patients desired to perform a home therapy and many had an interest in the new device. The subjects in general are a younger dialysis population, mean age being 51 years, with 63% male and 75% Caucasian. Only 41% were smokers and 47% were anuric. The primary cause of ESRD was diabetes in only 16% and hypertension in 13% of the subjects.

Treatment compliance (defined as completing 43–48 treatments in a given phase) was comparable between the 2 treatment environments (88% In-Center vs. 89% Home). The mean number of dialysis treatments per week was the same in both treatment environments (5.8 out of a possible 6.0, 1160 treatments performed out of a possible 1200 treatments for the 25 patients completing the study).

Table 1 Baseline patient characteristics

Characteristic	Total (n=32)
Age, years (range)	51 (18.0, 71.0)
Gender, n (%)	
Male	20 (63%)
Female	12 (38%)
Race, n (%)	
White	24 (75%)
Black or African American	6 (19%)
American Indian or Alaskan native	1 (3%)
Asian	1 (3%)
Smoking, n (%)	13 (41%)
Current	2 (6%)
Previous	11 (34%)
Alcohol use, n (%)	12 (38%)
Current	7 (22%)
Previous	5 (16%)
Subject anuric, n (%)	
Yes	15 (47%)
No	17 (53%)
Primary etiology of renal disease, n (%)	
Diabetes	5 (16%)
Hypertension	4 (13%)
Glomerulonephritis	8 (25%)
Polycystic disease	4 (13%)
Other	11 (34%)

Primary endpoint

Successful delivery of at least 90% of prescribed fluid volume was achieved in 98.5% of treatments in the In-Center environment and in 97.3% in the Home environment for both the ITT and per protocol populations. The total effluent volume as a percentage of prescribed volume fluctuated between 94% and 100% for all study weeks, regardless of treatment environment.

Adverse events

As shown in Table 2, adverse event rates per 100 treatments were significantly higher for the In-Center Phase (5.30) compared with the Home Phase (2.10; p=0.007). Because dysgeusia was a reccurring event, we reexamined the adverse event data excluding dysgeusia and found that the difference in event rates remained statistically significant (In-Center 5.24 vs. Home 2.45; p=0.008). Twenty-four patients (75%) reported at least one adverse event during the In-Center Phase compared with 13 patients (48.1%) during the Home Phase. Similarly, the absolute number of adverse events was higher in the In-Center Phase (76) than the Home Phase (25). Anticipated treatment observations (ATOs) were adverse events that are generally associated with hemodialysis. Of the 29 defined ATOs, 23 were reported in greater than 5% of patients during the In-Center Phase compared with 10 in the Home Phase. Anticipated treatment observations occurring in greater than 1.0 per 100 hemodialysis treatments were similar across the 2 treatment environments: blood underheating, muscle cramping, and hypotension both In-Center and Home; headache, dizziness, and fatigue In-Center only.

Secondary endpoints

Mean values for delivered spKt/V (In-Center 0.53 ± 0.09, Home 0.54 ± 0.11) and standard Kt/V (In-Center

Table 2 Adverse events occurring in >5% of subjects in either treatment environment

	In-Center		Home		Difference in event rates (In-Center − Home)	
Adverse event	n (%)	Event rate[a]	n (%)	Event rate[a]	Difference	Confidence interval
All adverse events	24 (75.0%)	5.30	13 (48.1%)	2.10	3.16	(0.79, 5.54)
Back pain	3 (9.4%)	0.21	0 (0.0%)	0.00	n/a	n/a
Arthralgia	2 (6.3%)	0.42	2 ((7.4%)	0.17	0.25	(−0.48, 0.99)
Night cramps	2 (6.3%)	0.14	2 (7.4%)	0.25	−0.09	(−0.37, 0.19)
Neck pain	2 (6.3%)	0.14	0 (0.0%)	0.00	n/a	n/a
Dysgeusia	10 (31.3%)	0.70	0 (0.0%)	0.00	n/a	n/a
Dizziness	3 (9.4%)	0.21	0 (0.0%)	0.00	n/a	n/a
Tremor	2 (6.3%)	0.14	0 (0.0%)	0.00	n/a	n/a
Sinusitis	3 (9.4%)	0.21	1 (3.7%)	0.08	0.12	(−0.16, 0.41)
Nausea	1 (3.1%)	0.07	2 (7.4%)	0.17	−0.10	(−0.37, 0.17)

[a]Event rate is per 100 hemodialysis treatments.
n/a=not applicable.

Table 3 Mean treatment duration, patient weight, delivered volume, and spKt/V by study center

	In-Center					Home				
	n	Treatment duration (hrs)	Patient weight (kg)	Delivered volume (L)	SpKt/V	n	Treatment duration (hrs)	Patient weight (kg)	Delivered volume (L)	SpKt/V
Overall	32	2.8 ± 0.58	82.3 ± 15.7	19.7 ± 4.4	0.53 ± 0.09	27	2.8 ± 0.61	80.7 ± 16.8	19.9 ± 5.6	0.54 ± 0.11
Center #1	2	2.7 ± 0.21	95.9 ± 4.1	20.4 ± 3.8	0.55 ± 0.17	0	—	—	—	—
Center #2	5	2.7 ± 0.30	71.5 ± 15.0	19.4 ± 4.1	0.62 ± 0.12	4	2.8 ± 1.2	65.4 ± 15.6	16.4 ± 4.9	0.66 ± 0.15
Center #3	9	2.3 ± 0.24	85.3 ± 11.1	18.9 ± 3.6	0.52 ± 0.05	8	2.3 ± 0.33	83.1 ± 11.6	19.3 ± 3.4	0.51 ± 0.08
Center #4	8	3.1 ± 0.55	89.5 ± 16.6	20.7 ± 4.2	0.51 ± 0.07	8	3.0 ± 0.66	90.0 ± 15.2	21.5 ± 4.3	0.52 ± 0.10
Center #5	4	2.7 ± 0.49	77.4 ± 22.8	20.0 ± 5.6	0.57 ± 0.10	3	2.7 ± 0.58	79.1 ± 27.1	20.4 ± 5.2	0.65 ± 0.10
Center #6	4	3.2 ± 0.70	72.4 ± 10.7	19.2 ± 5.1	0.47 ± 0.05	4	3.1 ± 0.69	74.0 ± 13.4	19.8 ± 5.6	0.50 ± 0.07

—, Patients from this center did not participate in the Home Phase.
Numbers are mean ± standard deviation.

2.26 ± 0.04, Home 2.27 ± 0.03) were consistent across treatment environments. The consistency of spKt/V across treatment centers is shown in Table 3. No significant differences were observed between treatment environments for any items on the KDQOL short form. Mean time to complete device training was similar for study subjects (14.5 days) and subjects' partners (11.6 days). On average, subjects and their partners took the examination 1.1 times to achieve a score of 100%. The overall alarm rate (number of alarms divided by number of treatments) was similar between treatment environments (In-Center 2.19 vs. Home 2.10), as was the mean response time (In-Center 130.8 s vs. Home 102.8 s).

Treatment duration

Mean treatment duration (Table 3) was the same in both treatment settings (2.8 hr); however, notable inter-center variability was observed (range: 2.3–3.2 hr). While mean dialysis time varied across centers, it did not change substantially from the In-Center to the Home environment. Although treatment time is related to patient size and fluid volume, other prescription parameters, such as blood flow and the ratio of blood flow to dialysate flow ("flow fraction"), influence treatment time. As a result of different prescribing practices, treatment times differed by nearly 30% between the centers with shortest (2.3 hr) and longest (3.2 hr) duration despite similar average patient size, spKt/V, and delivered volume (Table 3).

Retrospective analysis

Twenty-six patients were included in the retrospective data collection of treatment parameters immediately preceding the study and comparative analysis with the study treatment phases. As expected, patients averaged 3 dialysis sessions per week, with 81% receiving dialysis in a center setting and 19% at home. Mean treatment duration was 3.48 hr.

Figure 2 illustrates a downward trend observed for systolic and diastolic blood pressures from the retrospective period to the In-Center and Home Phases. Compared with the retrospective period, mean systolic pressure was lower by 17.6 mmHg ($p < 0.0001$) in the In-Center Phase and 23.9 mmHg ($p < 0.0001$) in the Home Phase. Diastolic pressure also decreased from the retrospective period, with a reduction of 3.6 mmHg ($p = 0.20$) In-Center and 6.9 mmHg ($p = 0.01$) in the Home Phase. Similarly, mean pulse pressures declined from the retrospective period (68.2 mmHg) compared with In-Center (54.5 mmHg, a reduction of 14.0 mmHg [$p < 0.0001$]) and Home (51.7 mmHg, a reduction of 17.1 [$p = 0.0006$]). The normalizing of blood pressure was accompanied by a reduction in antihypertensive medications. In the retrospective period, 20 patients were taking a total of 50 antihypertensive drugs (mean 2.50 per patient). This number declined to 13 patients taking 29 drugs (mean 1.45) by study end (i.e., end of the Home Phase). Seven patients (35%) stopped antihypertensives completely by study end. Ten patients (50%) decreased the dose of an antihypertensive agent and 2 (10%) increased the dose of an antihypertensive agent during the study treatment phases. Owing to patients taking multiple antihypertensives, dose increases and decreases could occur in the same patients, albeit for different medications. Variability of antihypertensive prescribing practices among centers was evident.

As shown in Figure 3, a decrease from the retrospective period to the treatment phases was also evident for mid-

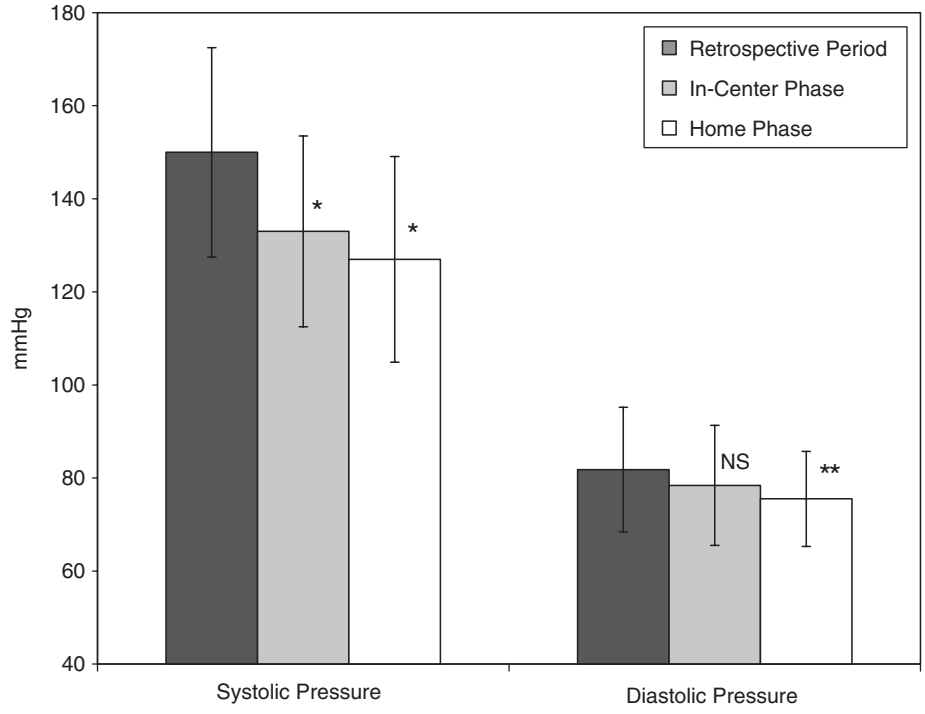

Figure 2 Average blood pressures across study periods. *p<0.0001 for change from the retrospective period; **p=0.01 for change from the retrospective period; NS=not significant.

week interdialytic weight gain. Mean postdialysis weights did not change across study periods.

Hematocrit, phosphorus, BUN, calcium, and CO_2 levels were in the expected range for dialysis patients and did not change significantly from the retrospective period through the In-Center and Home Phases. Significant reductions in creatinine were consistently observed during both treatment phases compared with the retrospective period, indicating improved creatinine clearance as might be expected with daily dialysis. Similarly, potassium levels were consistently lower in the treatment phases compared with the retrospective period. Albumin levels did not change significantly over time, except for a single reduction of 0.43 g/dL (p=0.03) observed at week 8 of the Home Phase compared with the retrospective period. As shown in Figure 4, this decrease was attributable to 3 patients with albumins below 3.0 g/dL in Home week 8. These patients had considerable comorbidities, including (1) amyloidosis and persistent poor nutrition, (2) hypervolemia and an infected access site, and (3) a severe active vascular access infection. A reduction in hemoglobin of 1.1 g/dL (p=0.03) from the retrospective period to week 8 of the Home Phase was not corroborated by an associated change in hematocrit.

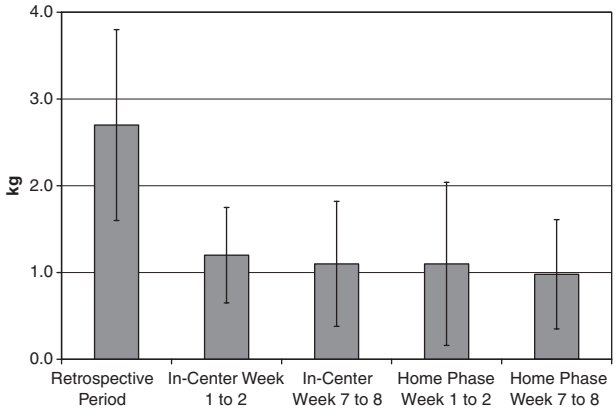

Figure 3 Interdialytic weight gain (midweek measurements).

There were 15 hospitalizations in the year before the study treatment phases, 3 during the 8-week In-Center Phase, and one in the 8-week Home Phase. The rate of hospitalizations per days of follow-up declined from 0.15

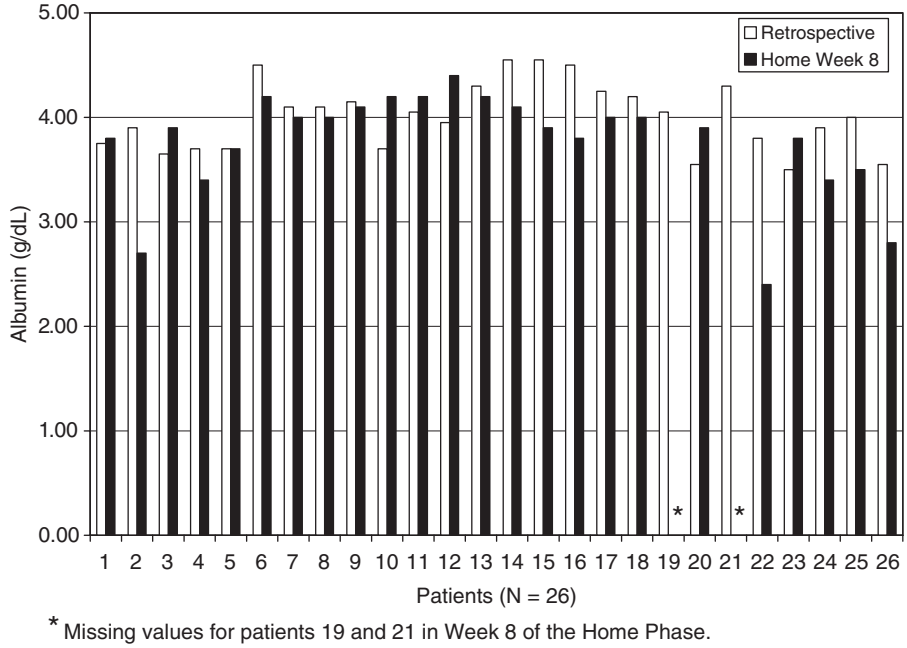

Figure 4 Albumin levels by patient in the retrospective period and week 8 of the Home Phase. *Missing values for patients 19 and 21 in week 8 of the Home Phase.

during the retrospective period to 0.08 in the Home Phase (final study phase), though this trend did not reach statistical significance.

DISCUSSION

This is the first multicenter study to evaluate the safety of a novel dialysis device in the home setting. In this small, nonrandomized study, daily hemodialysis using the System One device showed no significant difference with regard to delivery of prescribed volume, urea Kt/V, and quality of life in the home and center-based treatment using the System One. Successful delivery of prescribed volume was chosen as a primary endpoint, as the study was designed to determine the safety of a device in the home setting.

The safety of daily, home-based treatment with the System One was demonstrated by a lower adverse event rate per 100 treatments during the Home Phase as compared with the In-Center Phase. There is a potential bias in the reporting of adverse events because In-Center Phase was always the initial phase of the study; hence, there may be an increase of reported events due to the novel nature of the start of therapy. Additionally, subjects may be more prone to report events in the In-Center Phase due to the observational nature of In-Center dialysis. However, the data are consistent with the interpretation that use of the device in the home setting is not significantly worse than in-center.

Safety of dialysis long term is certainly also related to the ability to deliver adequate dialysis. Standard Kt/V and spKt/V were secondary endpoints. Each center prescribed the therapy independently. Goals for spKt/V in daily dialysis are controversial but should be >0.5. Chronic goals may be 0.53 to allow for variability. This study was not designed to determine the ideal Kt/V.

Given the novel nature of hemodialysis with this device, there is a possible concern that previously described benefits of increased-frequency dialysis, either nocturnal or short-daily, may not be applicable to short-daily dialysis with the NxStage System One. We, therefore, performed a retrospective study to evaluate the clinical response to therapy and to determine whether findings were consistent with previously described responses to increased-frequency dialysis regimens. Although the feasibility study was not intended to compare daily dialysis with conventional thrice-weekly dialysis, the retrospective comparison of study phases with the period immediately preceding the study suggests the potential for improved blood pressure control and reduced need for antihypertensive medication with the daily regimen. Additionally, it appears that more frequent dialysis may improve clearance of creatinine and potassium without adversely affecting other laboratory measurements.

The lower mean albumin observed at Home week 8 is likely explained by the comorbid conditions of 3 patients. The lower albumin over time in the initial study requires further investigation. Owing to the relatively short follow-up period in this study, we conducted extended follow-up through 1 year, during which time no significant fluctuations in albumin were observed (data not shown).

Additionally, the rate of hospitalizations did decrease, although due to the size of study and length of follow-up, this did not reach statistical significance. It does, however, correspond with previously described clinical effects of increased-frequency dialysis with conventional devices. While the retrospective nature of this analysis is a limitation, these findings serve to encourage further investigation of the potential benefits of daily hemodialysis.

Despite the potential of home hemodialysis to reduce health-care costs, reduce mortality, improve patient quality of life, and facilitate daily dialysis, adoption of this dialysis modality has declined from 40% at the inception of the Medicare ESRD program in 1973 to $<1\%$ today.[2,17] Reasons for low adoption of home dialysis include large equipment, space constraints, complex setup and disinfection processes, and special water processing requirements. The System One device evaluated in this study decreases these barriers to home hemodialysis through its modest size ($15 \times 15 \times 18$ in.), portability, simple user interface, and sterile, premixed, prepackaged dialysate, which eliminates the need for large, complex water processing equipment. There is a need for significant storage space and delivery of supplies monthly. The ability of patients and partners to successfully deliver the prescribed dose of therapy with this dialyzing device at home is evident from the average training time of no more than 2 weeks observed in this study.

The nonrandomized design of this study and the relatively small sample of selected dialysis patients preclude broad extrapolation to all ESRD patients. Woods et al. have described the impact of case mix on study outcomes in an analysis comparing dialysis in home vs. center settings. In that retrospective analysis of data from the U.S. Renal Data System, patients selected for home dialysis were 10 years younger on average than center-based dialysis patients and significantly less likely to have comorbid conditions, such as diabetes-related ESRD, obesity, cerebrovascular disease, congestive heart failure, and previous myocardial infarction.[9] The patient population in the current study reflected a similar profile to the home-based dialysis patients described by Woods, in terms of age (mean 51 years) and a low percentage of diabetes-induced ESRD (16%), though prevalence of obesity and coronary and cerebrovascular diseases were not collected in the current study. Perhaps the more important finding of the Woods study is that patient age and comorbidities did not account for the 42% reduced mortality risk observed in home dialysis patients.[9] The Woods study demonstrated a substantial mortality reduction independent of case mix.

The effect of case mix on outcomes in the current study may also have played a role in the failure to detect significant quality-of-life differences between treatment environments. All patients in this study received short, daily hemodialysis starting from 2 weeks to 5 months before study initiation, thus precluding comparison of daily, home-based therapy with the current practice of thrice-weekly dialysis delivered in a center environment. Kidney Disease Quality of Life scores were high at the start of the study and study size was too small to detect a difference in a population already on daily dialysis with high KDQOL scores.

This is the first study to demonstrate the safety and effectiveness of daily, home-based hemodialysis performed by selected patients and their partners using a novel portable hemodialysis device. The performance of this device in the hands of nonhealthcare professionals with approximately 2 weeks of comprehensive training suggests that with properly designed equipment (e.g., simple user interface and sterile, premixed, prepackaged dialysate) and a relatively brief training period, some hemodialysis patients are capable of successful daily hemodialysis at home with the help of a trained partner. The retrospective analysis also shows changes in blood pressure previously described with increased-frequency dialysis with conventional devices are seen with this device as well.

CONCLUSIONS

Daily home hemodialysis with the System One hemodialysis device is a safe and viable option for select ESRD patients capable of home/self-care dialysis. This represents a novel device that provides a simplified process compared with the traditional hemodialysis machines. The future of this home-based hemodialysis option will depend on determining which patients will benefit from this therapy and which factors most influence patient adoption of home, self-administered hemodialysis.

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