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ORIGINAL ARTICLE

Home Hemodialysis

Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis

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ABSTRACT

Introduction: Home hemodialysis remains underutilized despite observational data indicating more favorable outcomes with home compared with in-center hemodialysis. The Tablo Hemodialysis system is designed to be easy to learn and use and to facilitate adoption of home hemodialysis. The objective of the current investigational device exemption (IDE) study was to evaluate the safety and efficacy of Tablo managed in-center by health care professionals and in-home by patients and/or caregivers.

Methods: A prospective, multicenter, open-label, crossover trial comparing in-center and in-home hemodialysis using Tablo. There were 4 treatment periods during which hemodialysis was prescribed 4 times per week: 1-week *Run-In*, 8-week *In-Center*, 4-week *Transition*, and 8-week *In-Home*. The primary efficacy endpoint was weekly standard $Kt/V_{urea} \geq 2.1$. The secondary efficacy endpoint was delivery of ultrafiltration (UF) within 10% of prescribed UF. We collected safety and usability data.

Findings: Thirty participants enrolled and 28 completed all trial periods. Adherence to the protocol requirement of 4 treatments per week was 96% in-center and 99% in-home. The average prescribed and delivered session lengths were 3.4 hours for both the In-Center and the In-Home periods. The primary efficacy endpoint for the intention-to-treat cohort was achieved in 199/200 (99.5%) of measurements during the In-Center period and 168/171 (98.3%) In-Home. The average weekly standard Kt/V_{urea} was 2.8 in both periods. The secondary efficacy UF endpoint was achieved in the ITT cohort in 94% in both in-center and in-home. Two prespecified adverse events (AEs) occurred during the In-Center period and 6 in the In-Home period. None of the AEs were deemed by investigators as related to Tablo. The median resolution time of alarms was 8 seconds in-center and 5 seconds in-home.

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Conclusion: Primary and secondary efficacy and safety endpoints were achieved during both In-Center and In-Home trial periods. This study confirms that Tablo is safe and effective for home hemodialysis use.

Keywords: Adequacy of dialysis, hemodialysis delivery systems, home, hemodialysis, kinetics, volume control

INTRODUCTION

Observational data published over the last 2 decades suggest that patient survival, health-related quality of life, and several objective intermediate outcome measures are improved in patients treated with home-based and intensive hemodialysis when compared with conventional in-center hemodialysis.[1–10] Moreover, these observed outcomes can be achieved with a better patient experience and at lower cost.[11–13] In spite of these data, home hemodialysis remains underutilized, with fewer than 2% of patients in the United States currently treated with this modality.[14]

There are a number of possible reasons for the limited uptake of home hemodialysis in the United States, including (1) gaps in nephrologist training and experience; (2) generally low levels of patient engagement and activation; (3) fear of self-cannulation; (4) lack of 1 or more trained dialysis partners or caretakers; and (5) technical challenges brought on by nonintuitive machine design. These factors and perceptions about the safety of home hemodialysis have been, and remain, barriers to adoption.[15–17]

The Tablo® Hemodialysis system was designed to address several of the barriers to home hemodialysis through a consumer-centric design focused on increasing patient engagement with a system that is easy to learn and use (Figure 1). It is a preconfigured hemodialysis system currently approved by the Food and Drug Administration (FDA) for use in clinic and hospital settings. Tablo features an integrated water purification system, the ability to produce dialysate on demand, a simplified user interface and wireless connectivity for data transfer. Human factors studies have shown that the Tablo system is easy to learn.[18] Studies conducted in the self-care hemodialysis setting indicate that patients can independently, accurately, and rapidly manage treatments with Tablo including setup and resolution of any alarms that may occur.[19]

The objective of the current investigational device exemption (IDE) trial was to evaluate the safety and efficacy of Tablo when used in-center managed by trained health professionals and in-home by trained patients or a care partner.

Figure 1 Tablo hemodialysis system. [Color figure can be viewed at wileyonlinelibrary.com]

METHODS

Study design

The IDE trial was a prospective, multicenter, open-label, crossover trial comparing in-center and in-home hemodialysis performance using the Tablo Hemodialysis system. Each participant served as his or her own control in terms of treatment period comparisons. The original study protocol and amendments were approved by the US FDA and were registered on http://www.clinicaltrials.gov (NCT02460263). Participants remained in the trial for approximately 21 weeks during which time they were

prescribed hemodialysis with Tablo 4 times per week. The trial consisted of 4 treatment periods during which Tablo was utilized: a *Run-In* period of 1 week in-center, an *In-Center* period of 32 treatments (approximately 8 weeks) during which the dialysis staff managed the treatments, a *Transition* period of up to 4 weeks to train the patient and care partner to manage the dialysis, and a final *In-Home* period of 32 treatments (approximately 8 weeks). The decision regarding who would learn cannulation was determined by participants and their partner(s). All training on cannulation and proper use of Tablo was performed during the Transition period. Participants and their care partner(s) were required to demonstrate competency prior to entering the In-Home treatment period utilizing training checklists to ensure that they were adequately trained.

Trial endpoints

The primary efficacy endpoint was achievement of a weekly standard $Kt/V_{urea} \geq 2.1$ for participants during the In-Center and In-Home treatment periods. The site provided pre- and post-dialysis blood urea nitrogen values, and data from Tablo were used for treatment time and fluid removed, which were used to compute the single pool (Kt/V_{urea}) and weekly standard Kt/V_{urea} using the second-generation formula of Daugirdas.[20]

The primary safety endpoint was the number of adverse events (AEs), from a prespecified list (Table S1), observed during a dialysis interval that was categorized as intradialytic, interdialytic, or pretreatment. A Clinical Events Committee consisted of 3 physicians experienced in dialysis care who were not enrolling patients in the trial adjudicated AEs to determine if the events were among those prespecified (or others), and whether the AEs were related to use of the Tablo, to dialysis itself, or to a pre-existing condition. All AEs which occurred during the trial were recorded and classified using MedDRA® terminology.

The secondary efficacy endpoints were the achieved ultrafiltration (UF) volume and rate relative to the prescribed UF volume and rate. Successful delivery of UF was defined as having achieved an UF rate within 10% of the prescribed value during each treatment period.

Additional recorded observations included the number of clinically significant alarms (Table 2), time to alarm resolution, and the number of alarms that ended treatment.

Participant selection

Patients from 8 sites were enrolled in the trial after a HIPAA-compliant, IRB-approved consent form was signed. Inclusion criteria included adult patients (age 18-75 years) with end-stage kidney disease (ESKD) treated with maintenance hemodialysis who consistently achieved a single pool $Kt/V_{urea} \geq 1.2$ and who were stable for at least 3 months with a vascular access providing a blood flow of at least 300 mL/min. Participants were expected to be able to adhere to the trial protocol including a willingness to do home hemodialysis and the ability to train on Tablo. Exclusion criteria included the inability to read English or Spanish, life expectancy of less than 12 months (as determined by the site investigator), a persistent pre-dialysis systolic blood pressure below 100 mm Hg or above 180 mm Hg despite maximal tolerated therapy, New York Heart Association Class III or IV heart failure or an ejection fraction of less than 30%, and the presence of other ongoing serious illness as determined by the site investigator.

Data collection

Throughout the trial, each investigator maintained complete and accurate documentation, including but not limited to participants' medical and study records with any supporting/source data, correspondence with their governing IRB and any regulatory agencies, and any other records per applicable regulations. All trial data were collected and recorded using unique study ID numbers. Only study site personnel directly involved with the study and Sponsor monitors or designee(s) had access to the documentation that linked the study ID numbers to identifying participant information.

Relevant treatment data were continuously collected by Tablo during each treatment and stored in the form of a log file that could either be wirelessly transmitted or stored on a USB for future data extraction.

The trial Sponsor maintained data in an electronic data capture system as per the Data Management Plan for the IDE Trial. Study Monitors performed quality assurance checks to ensure complete and accurate data capture according to the sponsors SOP for monitoring for clinical trials.

Statistical plan

The sample size of 30 participants for the trial was based on the safety endpoint (the number of prespecified, serious, system-related, treatment-emergent AEs during a dialysis interval). This sample size calculation assumed a standard deviation of 0.8 AEs per dialysis interval and a within-patient correlation of prespecified AE counts of $\rho = .50$. This sample size exceeded that required (11 participants for >90% power) to detect the primary efficacy

endpoint of a mean weekly standard Kt/V_{urea} statistically significantly greater than 2.1 during the treatment periods.

The safety population consisted of all participants enrolled in the study. The primary efficacy analysis was based on the intention-to-treat (ITT) population with no imputation of missing values. We also performed sensitivity analyses using multiple imputation of missing values. The per protocol population consisted of all participants who were enrolled, successfully completed at least 75% of their dialysis treatments, had at least 1 valid value of the primary efficacy variable, and had no major protocol deviations while enrolled in the trial.

The analysis of the primary efficacy endpoint was conducted on the ITT population with a supportive analysis on the per protocol population. The weekly standard Kt/V_{urea} values were computed for each participant during the In-Center and In-Home periods. We counted the number of weeks of dialysis during which the weekly standard Kt/V_{urea} values were less than 2.1 for each participant by treatment period.

We computed summary statistics (mean, sample size, SD, minimum, maximum, and median) on the number of prespecified AEs per dialysis interval for each treatment period. We also calculated the rate of prespecified AEs per 100 hemodialysis sessions.

Table 1 Patient baseline characteristics

Characteristic	N = 30 (%)
Age, y	52.3 ± 11.6
Weight, kg	93.8 ± 17.0
Men	19 (63)
Race	
White	17 (57)
Black or African American	13 (43)
Hispanic or Latino	8 (27)
Not Hispanic or Latino	21 (70)
Ethnicity not reported	1 (3)
New to home hemodialysis	17 (57)
Vascular access type	
Fistula	23 (77)
Catheter	4 (13)
Graft	3 (10)
Comorbid conditions	
Coronary artery disease	12 (40)
Congestive heart failure	1 (3)
Diabetes	18 (60)
Hypertension	29 (96)
Hypercholesterolemia	20 (66)
Carotid artery disease	6 (20)
Peripheral artery disease	5 (16)
Arrhythmia	7 (23)
Systemic inflammatory conditions	3 (10)
Tobacco use (current)	4 (13)
Tobacco use (former)	7 (23)

RESULTS

A total of 30 participants from 8 centers entered the Run-In period and were enrolled in the study. During the Transition period, 1 participant died due to cardiac arrest during the interdialytic period. This event was deemed unrelated to dialysis and unrelated to Tablo. One participant decided not to continue with the study and withdrew consent prior to entering the In-Home period. A total of 28 (93%) participants completed all 4 study periods (Figure 2).

Baseline characteristics for all enrolled participants are summarized in Table 1.

There were 1806 treatments conducted during the 2 observation periods of the study. The maximal number of potential hemodialysis sessions that might have been completed during the In-Center period was 960 (30 participants × 8 total weeks × 4 sessions per week). Nine hundred twenty-two hemodialysis sessions were completed during the In-Center period of the study, yielding an

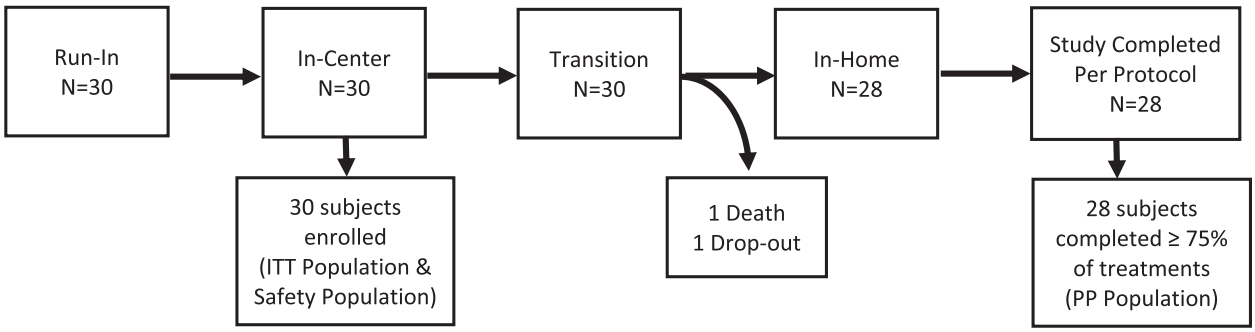

Figure 2 Patient flow and protocol overview.

adherence rate of 96%. Given the 1 participant death and 1 participant withdrawal during the Transition period, the maximal number of hemodialysis sessions during the In-Home period was 896 (28 participants × 8 total weeks × 4 sessions per week). Eight hundred eighty-four hemodialysis sessions were completed during the In-Home period of the study, yielding an adherence rate of 99%. If any element required for calculation of primary and secondary endpoints was missing from the treatment information, those treatments were not included in the endpoint calculations. The mean prescribed and delivered session lengths were 3.4 hours during both periods of observation (In-Center and In-Home).

The primary efficacy endpoint of delivering a weekly standard Kt/V_{urea} of ≥2.1 was achieved. The point estimates of the means of the weekly standard Kt/V_{urea} from both the In-Center and In-Home periods were 2.8. For the ITT cohort, the mean weekly standard Kt/V_{urea} was achieved in 99.5% (199/200) of weeks in the In-Center period and 98.3% (168/171) of weeks in the In-Home period. The average weekly standard Kt/V_{urea} for each individual participant was between 2.40 and 3.24 for the In-Center period and between 2.42 and 3.12 for the In-Home period. The median number of weekly standard Kt/V_{urea} collected for each patient was 7 during both the In-Center and In-Home periods. Table 2 shows the weekly standard Kt/V_{urea} data for each patient.

Table 3 shows the results for the secondary (UF-related) efficacy endpoints. In the ITT cohort, 94% of the treatments in-center and 94% of the treatments in-home successfully achieved the goal.

Table 2 Patient weekly standard Kt/V_{urea} results

	In-Center			In-Home		
Subject ID	Count of stdKt/V Values	Average stdKt/V	Range	Count of stdKt/V Values	Average stdKt/V	Range
1	7	3.24	(3.12, 3.51)	3	3.12	(2.71, 3.40)
2	3	2.82	(2.69, 2.89)	6	2.72	(2.62, 2.84)
3	8	2.67	(2.61, 2.73)	7	2.53	(2.35, 2.70)
4	7	2.88	(2.72, 3.05)	5	2.84	(2.25, 3.24)
5	8	2.96	(2.85, 3.08)	7	2.83	(2.66, 2.94)
6	8	3.03	(2.90, 3.22)	3	3.06	(2.85, 3.27)
7	8	2.77	(2.37, 3.18)	5	2.63	(1.84, 2.98)
8	5	2.51	(2.37, 2.60)	7	2.62	(2.49, 2.75)
9	4	2.92	(2.73, 3.00)	7	2.85	(2.68, 3.03)
10	8	2.82	(2.38, 2.99)	N/A	N/A	N/A
11	8	3.00	(2.77, 3.12)	4	3.15	(2.89, 3.29)
12	5	2.70	(2.58, 2.91)	6	2.78	(2.40, 3.10)
13	7	2.61	(2.30, 2.88)	3	2.69	(2.50, 2.80)
14	8	2.51	(2.40, 2.86)	8	2.39	(2.28, 2.51)
15	7	2.71	(2.55, 2.89)	7	2.85	(2.55, 3.77)
16	8	2.95	(2.74, 3.09)	8	2.87	(2.71, 3.03)
17	7	2.98	(2.86, 3.19)	6	3.01	(2.47, 3.27)
18	8	2.93	(2.16, 3.92)	4	2.85	(2.71, 2.94)
19	6	3.03	(2.98, 3.09)	N/A	N/A	N/A
20	8	3.16	(2.96, 3.53)	8	2.99	(2.62, 3.17)
21	6	2.87	(2.73, 3.04)	7	2.90	(2.70, 3.07)
22	5	2.97	(2.55, 3.81)	7	3.03	(2.88, 3.12)
23	7	2.56	(2.46, 2.68)	6	2.32	(1.87, 2.65)
24	5	2.81	(2.59, 2.96)	5	2.89	(2.73, 3.09)
25	7	3.04	(2.88, 3.12)	7	3.06	(2.92, 3.21)
26	4	2.40	(1.97, 2.93)	7	2.56	(2.45, 2.77)
27	7	2.91	(2.74, 3.07)	8	2.86	(2.73, 3.04)
28	7	2.50	(2.36, 2.67)	8	2.43	(2.26, 2.63)
29	6	2.85	(2.41, 3.11)	5	2.42	(1.44, 2.86)
30	8	2.80	(2.67, 2.93)	7	2.75	(2.56, 2.87)

N/A, not applicable.

Table 3 Secondary efficacy outcome—Achieved versus prescribed ultrafiltration (UF)

	In-Center (n = 866)	In-Home (n = 800)
Prescribed UF volume (mL)/tx	2141 ± 1049	2232 ± 1118
Prescribed treatment time (min)	205 ± 27	207 ± 24
Prescribed UF rate (mL/min)	10.3 ± 4.5	10.6 ± 4.8
Actual UF volume/tx	2133 ± 1056	2223 ± 1119
Actual treatment time (min)	202 ± 32	203 ± 31
Actual UF rate (mL/min)	10.4 ± 4.8	10.7 ± 4.9
Success rate %	94	94

The overall AE rate was comparable between in-center (17 events, 1.9%) and in-home (16 events, 1.8%). There were 2 prespecified AEs during the In-Center period of which one was categorized as severe after the participant suffered an arm fracture from a fall on the way to dialysis. There were 6 AEs in the In-Home period of which 3 were severe. One patient missed 2 treatments and was hospitalized with volume overload. A second patient fell twice during this period while ambulating without his prescribed mobility aid. None of the AEs were considered to be related to Tablo.

There were 632 clinically significant alarms in the In-Center period and 585 in the In-Home period resulting in an overall rate of 1.3 alarms per treatment in both periods. The median time to resolve the alarms by dialysis staff during the In-Center period was 8 seconds with an interquartile range of 11 seconds (4-15 seconds). The median time for treatment alarm resolution was 5 seconds with an interquartile range of 7 seconds (3-10 seconds) for patients or their trained care partner in the In-Home period.

In the Transition period, the number of treatments completed was 380. The rate of successful delivery of weekly standard $Kt/V_{urea} \geq 2.1$ was 99.1% with an average standard Kt/V_{urea} of 2.8 ± 0.3. For the secondary efficacy endpoint, the actual UF rate was delivered within 10% of the prescribed rate for 94% of the treatments.

DISCUSSION

In this study, patients treated in-center and in-home using the Tablo Hemodialysis system achieved all of the primary and secondary efficacy and safety endpoints. The average weekly standard Kt/V_{urea} was 2.8 in both periods, the compliance to the protocol treatment schedule was over 95%, achieved UF was within 10% of target in 94% of treatments, and the median time to resolution of alarms was 8 seconds in-center and 5 seconds in-home.

Home hemodialysis offers patients with ESKD the opportunity to perform a hemodialysis modality with the potential to improve clinical outcomes and quality of life.[1–14] The home setting also facilitates more frequent (>3 times per week) hemodialysis. In order to give patients and health care professionals the confidence to move from in-center to home-based hemodialysis, the hemodialysis equipment used in the home must be safe, effective, and easy to learn and manage. This study confirms that Tablo meets those requirements.

The current study confirms and extends previous studies on usability of Tablo.[19,20] It confirms that Tablo can be successfully learned and used in the home in a diverse cohort of patients, including older patients and patients with considerable comorbidity. The modest duration of the Transition period confirms and extends previously published human factors studies wherein nurses and patients could learn how to use Tablo, and independently, accurately, and rapidly set up the system. Although details on all aspects of the training and the patient interface with the device are not part of the current study, the rapid resolution of alarms in the clinic by staff and in the home by patients or their care partners is a good indicator of the ease of use of the system.

There are several important strengths of this study. We recruited participants from 8 sites in 6 states, from hemodialysis practices caring for patients from a broad range of age, race, socioeconomic and educational backgrounds. The patients were nearly split between those new to home hemodialysis (57%) and those currently undergoing home hemodialysis (43%). There were no exclusions based on major comorbid conditions, vascular access type, or home location (ie, house, apartment, recreational vehicle). There are several limitations. First, the number of patients was relatively small, and the duration of each study period was relatively brief. There are several additional limitations related to generalizability. The average age of the patients was younger than the average age of the patients receiving dialysis in the United States, although consistent with other studies on in-home hemodialysis. Given that the willingness to do hemodialysis at home was an inclusion criterion, study participants were more likely to have an ease with medical technology and an interest in self-care which may also contribute to selection bias. Other, less motivated patients may not have achieved similar results.

In summary, this prospective crossover trial of Tablo used in-center and at home successfully met its primary and secondary efficacy and safety targets. These data confirm and substantially extend previously published results and highlight that Tablo is a novel hemodialysis system with the potential to expand the usage of in-center self-care and home-based hemodialysis.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1 Supporting Information