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CLINICAL EXPERIENCE WITH A NEW HEMODIALYSIS SYSTEM DESIGNED FOR IN-CENTER SELF-CARE HEMODIALYSIS

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ABSTRACT

INTRODUCTION: The vast majority patients on hemodialysis have their treatments managed in clinics by health professionals. Studies indicate that self-care hemodialysis would be selected by many patients if available and offers advantages for patients and clinics. The Tablo® Hemodialysis System (Tablo) is a device designed for self-care use. Patients performing self-care must be able set up the device to start their treatment and to resolve machine alarms that indicate a problem during therapy. The purpose of this study was to assess actual patient experience on Tablo with respect to the time required to set up the machine, the frequency of alarms and the time required to resolve the alarms.

METHODS: 733 treatments on Tablo in 50 patients at four dialysis units were monitored for the frequency and type of alarms. In a predetermined subset of 356 treatments in 20 patients doing in-center self-care hemodialysis using Tablo, the time required to set up the disposables needed to start therapy with Tablo, alarm frequency and the time required to resolve alarms were recorded.

FINDINGS: Ninety percent (18/20) of patients set up the disposables needed to initiate therapy in less than 5 minutes. There were no alarms in 354 (48%) and one alarm in 136 (19%) of treatments. On average there were 1.3 alarms per treatment. The most common alarms (65%) were related to arterial and venous pressures. Patients resolved all alarms successfully. Eighty six percent of alarms were resolved in less than one minute and the average time for alarm resolution was 22 seconds.

DISCUSSION: Patients using Tablo can successfully and rapidly set up the device for in-center self-care hemodialysis. The number of alarms per treatment was low. Alarm resolution was rapid and complete. These results confirm previously published Tablo human factors studies.

BACKGROUND

Hemodialysis serves as life-saving therapy for a growing number of people around the world. In the United States, almost 460,000 patients are dialysis dependent. The cost to U.S. Medicare

approached 38 billion dollars, or 7.2% of the Medicare budget in 2016. Approximately 88% of dialysis patients receive in-center hemodialysis (ICHD) which involves going to a dialysis clinic three times per week, usually for 3 to 4 hours of dialysis, to have their dialysis treatments performed by healthcare professionals. The remaining 12% are on home dialysis modalities. In home dialysis modalities, the patients are trained to manage their own dialysis. The predominant home dialysis modality is peritoneal dialysis; fewer than 2% of patients perform hemodialysis in their homes[1] However, previous studies indicate that most patients and physicians, when given a choice, would choose a modality other than ICHD and up to 70% of patients on ICHD express an interest in performing in-center self-care hemodialysis[2] which would allow patients to manage their own dialysis treatments in a dialysis clinic setting after adequate training.

In-center self-care hemodialysis is a modality in which the patients go to the dialysis clinic and manage their own treatment including: setting up the dialysis machine, monitoring the treatment and documenting the treatment in keeping with clinic standards. It offers patients many of the advantages of home hemodialysis including patient empowerment, control and increased flexibility. Unlike home hemodialysis, in-center self-care hemodialysis relieves the patients of the fear of being away from clinic support in the case of an emergency and prevents the intrusion of dialysis treatments and equipment into the home[3,4].

One of the barriers to self-care hemodialysis adoption has been the complexity of hemodialysis devices which have been designed with a professional end-user in mind. It is difficult for patients to learn how to operate the dialysis equipment confidently and requires extensive staff training time to establish patient competency in operating the device.

The Tablo® Hemodialysis system (Tablo) is a hemodialysis machine that has been specifically designed for patient-driven self-care using inputs from an iterative human factors process, with key design objectives being to facilitate learning and to minimize staff training time. Human factors studies done in a laboratory setting have demonstrated that patients can accurately learn and manage Tablo after a brief training period[5]. Figure 1 shows a patient using the Tablo system.

Figure 1

The purpose of this study was to extend the previous Tablo human factors studies by measuring, in a clinical setting, the time required for patients using the device to set up the disposable components of the system that must be put in place for each therapy in order to initiate their treatment. In addition, we recorded the type and frequency of alarms. An alarm sounds when there is a problem

detected and the treatment is stopped. The time to successfully resolve an alarm is defined as the time between the alarm occurrence and the time taken by the patients to resolve the alarm and resume their treatment, or in some cases, if the alarm indicates an unsafe condition, to terminate the treatment. This is used to determine the frequency and intensity of patient-system interaction during self-care hemodialysis treatment.

METHODS

The study included 50 patients using Tablo who were treated in four dialysis units. A total of 733 dialysis treatments were monitored for alarms. The Tablo system records the number and type of alarms that occur during therapy onto a log file that is transmitted wirelessly after each treatment to a cloud-based, Health Insurance Portability and Accountability Act compliant server.

In a subset of 356 treatments in 20 patients who had elected to do in-center self-care hemodialysis using Tablo, we recorded the time required to set up the disposables components of the device needed to start therapy. After each set up step was completed, a flag was logged in the data log file. The time between flags was measured until completion of the set up process to determine total set up time.

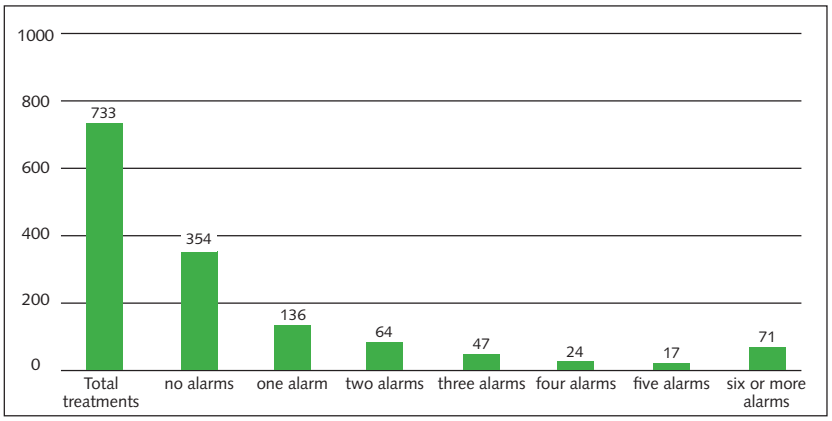
The time from an alarm occurrence to final resolution of the alarm, indicated by allowing therapy to resume, was also captured using internal electronic log files. The patients were assisted in set up and alarm resolution by following instructions on a touch screen. Tablo does not record, capture or maintain protected health information.

RESULTS

A total of 733 Tablo dialysis treatments on 50 patients were monitored from 4 dialysis clinics. In the subset of 356 treatments in which the patients were performing self-care using Tablo, the 20 patients included 9 men and 11 women ranging in age from 28-69 years. None of the patients had any dexterity, visual or auditory impairments as deemed by their attending nephrologist.

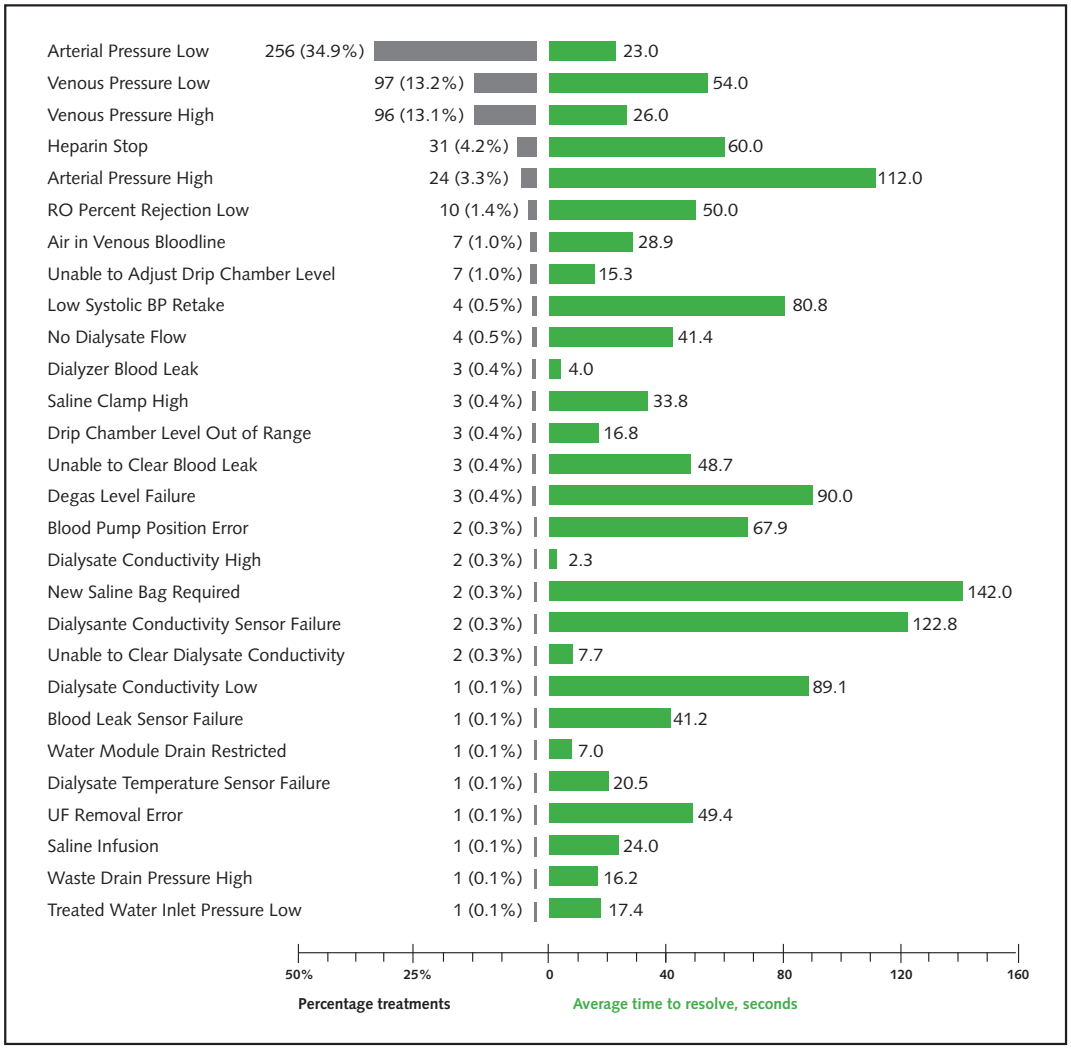
The frequency of alarms is summarized in Figure 2. Overall, there were no alarms in 354 (48%) and one alarm in 136 (19%) of the treatments monitored in the study. On average, there were 1.3 alarms per treatment.

Figure 2: Distribution of treatments by total number of alarms experienced



The types of alarms recorded in the 733 treatments are shown on Figure 3. The most common alarms were related to high or low arterial (38%) and venous (26%) pressure.

Figure 3: Alarm occurrence by percentage of treatments and time to resolve

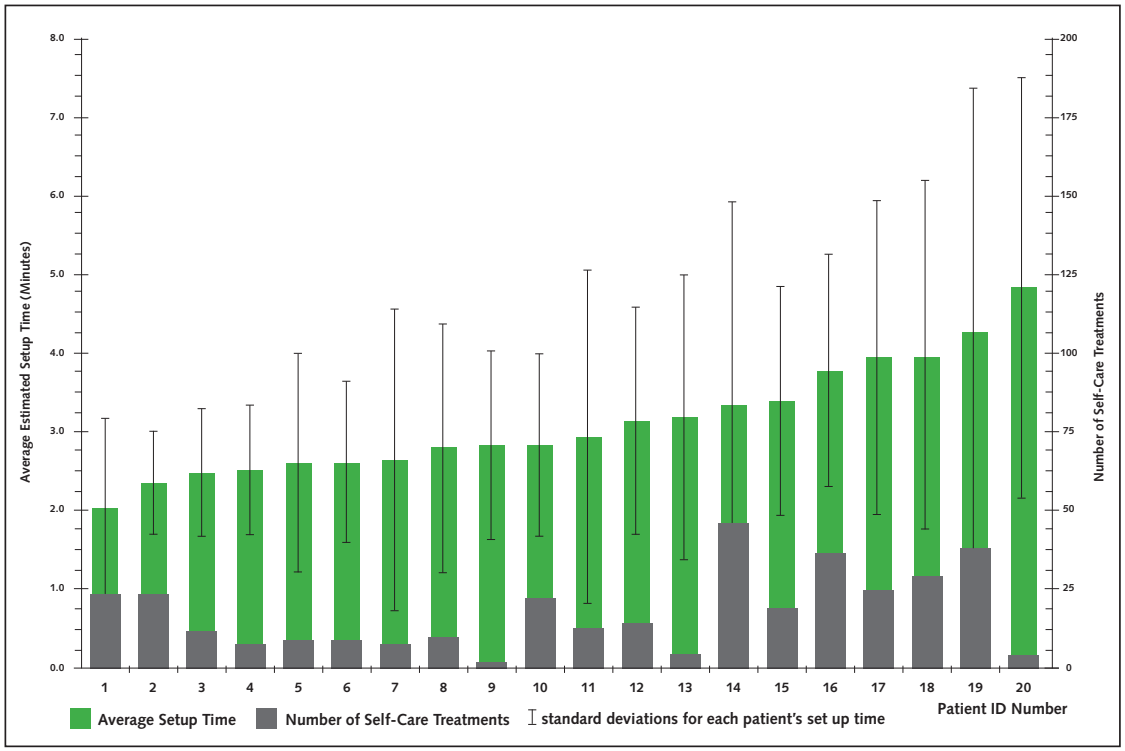


For the subset of 356 treatments in which the patients were performing self-care using Tablo, Figure 4 shows the number of treatments monitored for each patient. This ranged from 2-46 treatments.

The time required to set up the disposables for Tablo is also shown in Figure 4. In 90% of the treatments, patients were able to set up the system disposables in less than 5 minutes. There was no significant correlation between the number of treatments monitored per patient and the time to set up the disposables.

The time required to resolve the alarms is shown in Figure 3. The majority of the alarms were resolved in less than one minute (86%). The weighted average time taken for patients to independently resolve an alarm was 22 seconds.

Figure 4: Disposables set-up time & number of treatments



DISCUSSION

Research indicates that up to 70% of patients and nephrologists are interested in-center self-care hemodialysis as a dialysis modality[3]. In-center self-care hemodialysis empowers and activates patients, providing more flexibility in their dialysis schedule and, by virtue of their self-care training, more knowledge about their therapy and their overall management including fluid management, dialysis time and frequency. These are advantages also offered by home hemodialysis[3], but unlike home hemodialysis, in-center self-care hemodialysis provides patients the security of being in a dialysis center with professional staff available in case of an emergency. Furthermore, in-center self-care hemodialysis avoids the intrusion of dialysis into the home and the personal expenses associated with home hemodialysis[6-9].

An important barrier to in-center self-care hemodialysis has been the complexity of existing dialysis machines[3]. This obstacle makes considering a hemodialysis self-care modality intimidating for patients and requires long training times with the nursing staff, which is both time consuming and costly. Moreover, there is a shortage of experienced nurse educators capable of providing extensive training on complex machines. Training must include machine set up and alarm resolution. Some alarms occur infrequently and therefore training for alarm resolution is challenging unless the machine is designed to aid the patient through the appropriate steps to resolve the alarm.

Human factors studies indicate that the design of Tablo allows patients after a brief training to easily and correctly interact with the system to both set it up and to resolve issues[5]. The current

study provides direct evidence in an actual clinic setting, rather than a laboratory environment, that patients who are performing hemodialysis with the Tablo system can quickly set up the device and resolve alarms quickly, accurately and independently.

The set up times did not correlate with the number of dialysis treatments performed by any given patient. Some patients who had used the machine less often were able to set it up more quickly and others who had performed many treatments on Tablo took longer, suggesting that the set up time is more patient specific rather than something that is likely to decrease markedly with repeated use. In nearly all cases, the set up times were less than 5 minutes, which will allow the patients to quickly establish their therapy and minimize time spent in a dialysis unit preparing for treatment. This efficiency can provide additional operational advantages in a commercial dialysis clinic setting.

The ability of patients to quickly establish their therapy, combined with the lack of waiting for staff, who might be otherwise occupied with turnover in the in-center setting, could also allow for a longer, more effective hemodialysis session without a net increase in the hours spent by the patient in the dialysis clinic.

Overall, the number and frequency of alarms was low. The most common alarms were related to venous and arterial pressures suggesting issues related to the vascular access, but these alarms were quickly resolved. It is noteworthy that even alarms that occurred rarely were able to be resolved quickly. This indicates that the patients were not resolving the alarms through memory based on recurring events, but were able to interface correctly with Tablo by following the user touch screen instructions that guide them through each alarm. By quickly and correctly resolving alarms, the patients can minimize interruptions during therapy and can complete treatments as expected. This study provides real life confirmation of the published human factors data.

Many patients want to have more control over their treatment and patient engagement with their therapy is associated with better outcomes[2]. It is therefore important that patients treated with hemodialysis have access to self-care in care settings beyond the home. The ability to offer patients a hemodialysis system that is easy to learn and to manage should increase the number of patients who can perform self-care hemodialysis in center or at home. These data indicate that Tablo can be adopted successfully by patients in a in-center self-care hemodialysis environment.

There is a potential economic advantage to in-center self-care dialysis. The United States Renal Data System (USRDS), a nearly complete data registry for patients receiving dialysis or kidney transplantation with end-stage renal disease reports that the annual cost to Medicare of a hemodialysis patient is $87,638[1]. This cost has many components of patient care in it, including the dialysis itself, hospitalizations and medications. However, a large component of the cost of the delivery of hemodialysis therapy is the cost of the healthcare professionals including nurses and dialysis technicians who manage the dialysis. If patients can successfully take responsibility for their dialysis treatments, there is an opportunity to reduce the cost of personnel dedicated to managing the routine dialysis treatments and/or to reassign these professionals to other value added activities that support the dialysis patient population.

In conclusion, patients using Tablo can successfully and rapidly prepare the system for self-care hemodialysis after appropriate training. The number of alarms per session was low and alarm resolution was rapid and complete. This confirms previously published human factors studies on Tablo.

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Conflict of Interest: Luis Alvarez, Dean Hu and Paul Chen are employees of Outset Medical Inc. (Outset Medical). Sarah Prichard and Glenn Chertow are advisors to Outset Medical. The Tablo® Hemodialysis System is manufactured by Outset Medical Inc. 1830 Bering Dr, San Jose, CA 95112

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