Kidney Medicine Original Research

Hemodialysis With the Quanta SC+: Efficacy and Safety of a Self-care Hemodialysis Machine

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Rationale & Objective: Most patients with kidney failure receive hemodialysis 3 times per week in a facility. More frequent and longer duration dialysis prescriptions improve a number of key outcome measures. These prescriptions are best suited to self-care and home regimens. The Quanta SC+ hemodialysis system is a novel device with demonstrated ease of use for patients and health care practitioners through human factors testing. The primary objective of this study is to report the efficacy and safety of the SC+ system using conventional hemodialysis prescriptions.

Study Design: Nonrandomized observational study.

Setting & Participants: Prevalent hemodialysis patients in 4 sites in the United Kingdom were recruited to switch from their current device to the SC+ system with no other changes to their prescription.

Interventions: SC+ hemodialysis system.

Outcomes: Efficacy data were collected in terms of dialysis adequacy, urea reduction ratios, and net fluid removal accuracy.

Results: 60 patients were enrolled in the study, resulting in 1,333 evaluable treatments. The threshold single-pool Kt/V of 1.2 was exceeded in 96.6% of treatments in patients receiving 3-times-weekly regimens, whereas the threshold standard Kt/V of 2.1 was exceeded in 94% of treatments and 97.6% of treatments in patients without significant residual kidney function. Ultrafiltration accuracy was determined by measuring net fluid removal and validated to be within acceptable limits. The adverse event profile during treatment was typical of hemodialysis. There were no serious adverse events.

Limitations: Few patients on high-frequency treatment regimens were enrolled.

Conclusions: The SC+ system delivers safe and effective hemodialysis across a range of patients and dialysis prescriptions. It is one of the smallest systems available and has validated usability for patients to perform self-care safely with minimal training. This device may encourage patients to feel empowered to take on home hemodialysis, unlocking beneficial clinical and patient-reported outcomes associated with these modalities.

Visual Abstract included

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The prevalence of kidney failure is increasing globally, with an estimate of more than 4.1 million individuals affected.[1] Although the preferred treatment for kidney failure is transplantation, most patients are treated with facility-based hemodialysis, administered by specialized health care practitioners 3 times per week. Facility-based hemodialysis has been the dominant mode of dialysis delivery in the developed world for more than 30 years, with small incremental improvements in the technology of devices over this time. Health outcomes for patients receiving 3-times-weekly conventional hemodialysis prescriptions are unacceptable, with 1-year mortality of 20% and 5-year mortality of 50%.[2] Patients are known to have poor health-related quality of life and patient advocates have identified key priorities for innovation in improving patient-reported outcome measures, including improved treatment options for patients receiving dialysis.[3,4] In addition, 3-times-weekly facility-based hemodialysis is consistently identified as one of the most costly options for treating kidney failure across multiple health care systems, driven primarily by the need to build and maintain expensive capital infrastructure and highly skilled human resources to sustain patients.[5]

It has been well established that many patients are able to administer their own dialysis safely in their home or in a clinic setting. More frequent and longer hemodialysis prescriptions have been demonstrated to improve important cardiovascular end points in randomized controlled trials and large observational studies.[2] The Advancing American Kidney Health initiative recognizes the growing number of individuals advancing to kidney failure and called for 80% of new patients to receive care through home dialysis or kidney transplant.[6] The coronavirus disease 2019 (COVID-19) pandemic has also exposed transmission risks inherent to center-based hemodialysis that would be substantially mitigated by transition of a greater proportion of in-center patients to home modalities.[7] Although there has been some improvement in the technology to provide user-friendly patient-oriented hemodialysis devices during the past few years, there are limited choices in the market for devices that can be used for home or self-care. Currently, few devices exist that have undergone thorough human factor testing and have been designed in collaboration with patients for self-care.

Quanta Dialysis Technologies has developed SC+, a compact personal hemodialysis system designed and

PLAIN-LANGUAGE SUMMARY

SC+ is a small easy-to-use hemodialysis system that was designed for use by patients at home without compromising on dialysis performance. The study described showed that SC+ delivered safe and effective hemodialysis in a diverse population of 60 patients, representative of a typical dialysis population, using regimens between 2 and 7 treatments per week. The system may encourage more patients to feel empowered to take on self-care and home hemodialysis, unlocking the clinical and patient-reported outcome benefits associated with these modalities.

validated as easy to use by patients with a low user error rate after minimal training.[8] A key purported differentiator of the Quanta SC+ hemodialysis system is its ability to be used across a continuum of hemodialysis prescriptions, from conventional 3 times per week, as typically experienced by most patients globally, to the clinically preferred frequent and long prescriptions. The primary objective of this study was to demonstrate the safety and efficacy of the SC+ system in a clinical setting using conventional thrice-weekly hemodialysis prescriptions.

METHODS

Study Design and Population

A prospective observational study design was used to assess the dialysis efficacy and safety of the SC+ hemodialysis system. Treatments were conducted in 4 hemodialysis facilities within the United Kingdom. The SC+ system received its CE (Conformité Européene) mark in 2015. The system is designed to treat patients with kidney failure with or without ultrafiltration (UF) and can be used for hemodialysis in both home and clinic environments. The system is indicated for use by patients weighing more than 40 kg who have a typical vascular access site such as an arteriovenous fistula or graft or a central venous catheter.

Prevalent hemodialysis patients within selected sites were recruited to dialyze using the SC+ device with no substantive changes in their typical dialysis prescription in terms of duration, frequency, dialysate composition, or dialyzer. Individuals older than 18 years were considered for a trial of the SC+ device provided they weighed more than 40 kg, were able to speak English and provide informed consent, had a stable well-functioning permanent vascular access, had no transplant or modality switches planned within 12 months, and had no comorbid conditions that, in the opinion of their consultant nephrologist, would preclude successful participation in the study. These comorbid conditions included unstable cardiac disease or blood pressure, advanced malignancies, or other conditions or frailty that may influence mortality within a 12-month period. Patients were excluded from the study if they had demonstrated nonadherence with attending treatments or dietary and/or fluid restrictions within the previous 3 months, had current or planned hospitalization or major surgery, had planned or active pregnancy, had off-label prescriptions, or were using a hemodialysis device outside the scope of the CE mark and intended instructions for use of the SC+.

Patients who met the selection criteria provided informed consent for a change in their hemodialysis device and to have their usual clinical data recorded for evaluation and reporting purposes. Research ethics board review was waived as per National Health Service guidance because no randomization, off-label use, or generalizability claims were to be made outside the domain of this study.[9]

Measurements and Data Collection

Baseline demographic and comorbid condition characteristics of the patients recruited were collected, including age, sex, type of vascular access, cause of kidney failure, dialysis vintage, and the presence of diabetes, cardiovascular disease, peripheral arterial disease, hypertension, cerebrovascular accident, bleeding disorders, malignancy liver failure, and a host of other less common comorbid conditions. A detailed medication history was taken at baseline for each patient. The study's primary end point was to measure device performance of the SC+. System performance was measured by a composite of dialysis adequacy as measured by a delivered single-pool Kt/V (spKt/V) > 1.2 as per NKF-KDOQI (National Kidney Foundation Kidney Disease Outcomes Quality Initiatives) guidelines, weekly standard Kt/V (stdKt/V), and net fluid removal (NFR) accuracy.[10-12]

At each dialysis run, typical dialysis parameters were collected at the point of care, including venous and arterial pressures, blood pressures throughout treatment, pre- and posttreatment weight, and estimates of mass of fluid and food intake during treatment. Actual UF achieved was calculated from pre- and posttreatment weights and adjusted for fluid and dietary intake during treatment, as well as any other salient intradialytic events such as vomiting or toilet visits. Patient blood work was taken as per each facility's usual protocol and dialysis adequacy was measured using spKt/V and stdKt/V calculations.[12-14]

Data were captured at the point of care using data collection worksheets during treatments at the outset of the study. No unique patient identifiers were collected on the data capture worksheets aside from a patient ID number. The worksheets were completed by the Quanta clinical team and retained for subsequent electronic data entry. These paper records formed the study's source data and were subsequently used for source data verification and database validation audits. In addition, during source data verification, these records were cross-referenced with electronic "data logger" files collected during treatments by the machine if required. An internal system, referred to

as the "Pilot Diary," and subsequently a commercial clinical trial database system SMART-TRIAL (MEDEI ApS) comprised the databases used to enter, retain, and report the clinical data collected for this study. Quality control checks included preprogrammed audits in SMART-TRIAL and manual data review. Data were exported from the electronic data capture systems into Microsoft Excel for analysis. The database was formally audited periodically to identify potential discrepancies. Entries relating to these discrepancies were subsequently verified against source data and the database was updated when required.

Systematic adjustment took place when dialysis treatments were at least 15 minutes shorter than the targeted time. In these cases, the target UF weight was adjusted according to the percentage completed of the target treatment time. This reflects the linear nature of fluid removal over the course of the treatment and allows a revised more accurate target to be calculated for comparison to the patient weight loss over the treatment and thereby a more meaningful assessment of NFR. In some cases, UF was paused or adjusted during treatment. The UF target was adjusted in cases in which the actual amount of fluid removed was materially lower than the target UF. In these cases, total UF time and rate were determined by reference to the data logger record (coming off the device), when available.

Periprocedural adverse event data were collected as part of the study. Events were reviewed to ascertain causality. Device-related adverse events causing harm or potential harm would, per protocol, constitute a failure to meet the primary safety end point. Examples of these events include serious adverse device effects and adverse device effects with serious potential. Events categorized as an adverse device effect are considered related to SC+ and/or proprietary consumables. All other events are considered unrelated to the system and have been assessed for trends compared with conventional hemodialysis therapy. Adverse events that could potentially be considered serious were reviewed by Quanta's Medical Advisory Board to adjudicate whether they should be considered to be serious and/or device related.

Expected procedural adverse events common during hemodialysis treatments, including but not limited to hypotension, dizziness, cramping, nausea, and vomiting, were also captured during procedures.

Statistical Analysis

Summary statistics (mean, sample size, standard deviation, minimum and maximum, and median with 25th and 75th percentiles) were computed to characterize patient background parameters and determine the effectiveness of treatment with respect to urea clearance and UF. Clearance was calculated from pre- and posttreatment serum urea nitrogen values and expressed as urea reduction ratio (URR), spKt/V, and stdKt/V. Mean ± standard deviation or median with 25th and 75th percentiles are presented, as appropriate. Pearson correlation coefficient, fit line, and intercept were calculated for the measured weight loss and target weight loss data sets.

RESULTS

Baseline Statistics

From June 2015 to January 2018, a total of 1,333 hemodialysis treatments were successfully conducted in 60 patients who completed at least 3 treatments using the SC+ device. Patients were recruited from 4 hemodialysis programs across the United Kingdom: Nottingham University Hospital, Guy's and St. Thomas, University Hospitals Birmingham, and Central Manchester University. Demographic and comorbid condition characteristics of patients are reported in Table 1. Patients ranged in age from 22 to 85 (median, 59; 25th and 75th percentiles, 49.5 and 79.5, respectively) years with 45% of users being women. Weights of patients ranged from 50 to 157 (mean, 82.3 ± 25.3) kg and 51 patients were on a conventional 3-times-weekly dialysis prescription. Most patients used an arteriovenous fistula for dialysis access. Blood flow rates ranged from 200 to 450 (mean, 376.5 ± 47.0) mL/min, and all patients received standard dialysate flows of 500 mL/min.

Dialysis Adequacy

Pre-and posttreament serum urea nitrogen values were available for 134 treatments according to center protocols (monthly blood analyses). The median spKt/V that was delivered for treatments in patients receiving 3-times-weekly regimens was 1.73 (25th and 75th percentiles, 1.50 and 1.89, respectively; Fig 1). The threshold spKt/V of 1.2 was exceeded in 96.6% of treatments in patients receiving 3-times-weekly regimens. Treatments in patients receiving 3 treatments per week falling below the guideline threshold all occurred in patients with significant residual kidney function, with the exception of 1 patient who had been very unwell in the days before treatment, resulting in severely diminished food intake and a correspondingly low pretreatment urea concentration. Table 2 shows spKt/V values across a range of dialysis prescriptions in terms of time and frequency in patients with and without significant residual kidney function.

The median stdKt/V that was delivered was 2.46 (25th and 75th percentiles, 2.27 and 2.56, respectively). The threshold stdKt/V of 2.1 was exceeded in 94.0% of treatments. When patients with significant residual kidney function were excluded, 97.6% of treatments exceeded the threshold of 2.1. Two treatments that did not meet the stdKt/V threshold were marginally below (2.03 and 2.07), while the other was the patient who had been unwell, as described in the previous paragraph.

The median URR achieved was 76.1% (25th and 75th percentiles, 70.6% and 79.7%, respectively), with patients undergoing a standard 3-times-weekly dialysis prescription having a median URR of 77.2%. The mean URR for all

Table 1. Patient and Dialysis Characteristics

Characteristic	n
No. of enrolled patients	63
No. of qualified patients	60
No. of evaluable treatments	1,333
Age, y	60.1 ± 15.9 (22-85)
Sex (female/male)	27 (45%)/33 (55%)
Dry weight, kg	82.3 ± 25.3 (50-157)
Treatment regimen	
2×/wk	1 (2%)
3×/wk	51 (85%)
4×/wk	4 (7%)
5×/wk	3 (5%)
7×/wk	1 (2%)
Anticoagulant type	
Heparin	1 (2%)
LMWH	47 (78%)
Saline flush	1 (2%)
None	11 (18%)
LMWH total dose	
Dalteparin 1.25-5 IU	9 (15%)
Enoxaparin 2.5-60 mg	28 (47%)
Tinzaparin 0.45-3.5 mg	10 (17%)
Needle size, G	
14 Sharp	6 (10%)
14 Button Hole	4 (7%)
15 Sharp	32 (53%)
15 Button Hole	9 (15%)
16 Sharp	9 (15%)
Vascular access	
Brachial fistula	36 (60%)
Brachial graft	3 (5%)
Radial fistula	17 (28%)
Radial graft	0 (0%)
Femoral graft	4 (7%)
Blood pump speed, mL/min	376.5 ± 47.0 (200-450)
Dialyzer size range (no. of treatments)	
Fresenius FX-60	213 (16%)
Fresenius FX-80	261 (20%)
Fresenius FX-100	374 (28%)
Fresenius FX-120	114 (9%)
Gambro 170H	171 (13%)
Gambro 210H	195 (15%)
Nipro 190H	5 (0.4%)
Dialysate flow rate, mL/min	500

Note: Values expressed as mean ± standard deviation (range), number, or number (percent).
Abbreviation: LMWH, low-molecular-weight heparin.

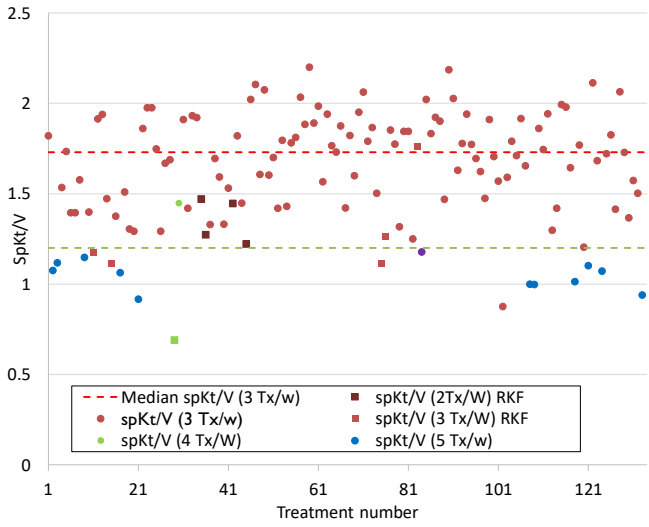

Figure 1. Dialysis adequacy as reported by single-pool Kt/V (spKt/V). Abbreviations: RKF, residual kidney function; Tx, treatment.

treatments in qualified patients was 74.3% (n = 134) with a standard deviation of 7.4%. These figures are well above the 65% that has been proposed as a threshold for 3-times-weekly dialysis in patients without residual kidney function in the NKF-KDOQI guidelines.[10] Figure 2 shows the percentage of URRs falling within specific 5% bounds for patients on a 3-times-weekly regimen. Only 1 value was markedly below the threshold of 65%. This was the same patient who presented below the threshold spKt/V due to being unwell before treatment. They also presented with a low pretreatment serum urea nitrogen level. Two of the other values not reaching the threshold were in patients with residual kidney function, while the remaining value was only marginally lower at 64%.

Net Fluid Removal

Overall, mean UF target matched with mean NFR achieved, with parameters averaging 2.20 ± 0.95 and 2.26 ± 0.97 kg, respectively. The fit line for the data is within the NFR error specified by international standards for hemodialysis (100 mL/h or 400 mL/treatment over a 4-hour treatment), as shown in Figure 3.[15] The correlation between programmed fluid removal (adjusted for shortened treatments) and recorded weight loss was strong ($R^2 = 0.876$). Median deviation (positive or negative) from idealized fluid removal was 0.06 kg/h (25th and 75th percentiles, 0.03 and 0.09, respectively).

Safety

During this study, symptomatic events were captured irrespective of whether an intervention was made to resolve the event (Table 3). All reported adverse event observations were related to minor complications that are common in hemodialysis (Tables 4 and 5). The most frequent of these was hypotension, which was observed in 13% of all reported treatments. This is well within the normal range, as previously documented. The frequency of other reported events is also in keeping with that expected for patients undergoing hemodialysis.

One adverse device effect without serious potential was reported. This comprised a system failure before the end of treatment. Blood was not returned to the patient as per unit protocol and 1 circuit of blood was lost. No symptoms or adverse events were reported in association with this event.

Table 2. Dialysis Adequacy as Measured by spKt/V Stratified by Dialysis Time, Frequency, and Residual Kidney Function

	All Patients			Patients Without RKF		
Treatments per wk	Duration, h	spKt/V	n	Duration, h	spKt/V	n
2	3.0 ± 0.03	1.4 ± 0.12	4	NA	NA	0
3	4.0 ± 0.30	1.7 ± 0.26	116	4.1 ± 0.27	1.7 ± 0.24	111
4	4.0 ± 0.04	1.1 ± 0.54	2	4.0	1.4	1
5	3.9 ± 0.42	1.0 ± 0.07	11	3.9 ± 0.42	1.0 ± 0.07	11
6	NA	NA	0	NA	NA	0
7	3.5	1.2	1	3.5	1.2	1

Note: Values expressed as mean ± standard deviation. The n value refers to the number of data points derived from pre- and posttreatment blood urea nitrogen values taken monthly as part of standard of care.
Abbreviations: NA, non applicable; RKF, residual kidney function; spKtV, single-pool Kt/V.

Root cause analysis revealed a loose blood pump controller cable. The safety systems integrated into SC+ correctly prevented dialysis from continuing.

DISCUSSION

The results of this study demonstrate that SC+ is a safe and effective hemodialysis system when using a range of conventional dialysis prescriptions in a population broadly reflective of a typical hemodialysis population. We report the results of 1,333 hemodialysis treatments performed in 60 prevalent hemodialysis patients who largely dialyze in facility-based centers. Patients displayed a typical distribution of age and weights and demonstrated a median spKt/V of 1.73 (25th and 75th percentiles, 1.50 and 1.89, respectively) in those who received 3-times-weekly prescriptions. No system-related serious adverse events were reported and UF accuracy was well within acceptable limits.

At 35 kg and 37 × 45 × 48 cm in size, the SC+ is one of the smallest and lightest hemodialysis devices currently available. Where smaller devices typically use lower dialysate flows and dialyzers, this study demonstrates that the SC+ system can use dialysate flows of 500 mL/min and conventional off-the-shelf dialyzers and thus it delivers identical performance to much larger conventional facility-based hemodialysis devices. Dialysate fluid is prepared on a dedicated cartridge that draws in standard acid and bicarbonate solutions and mixes it to the right concentration. Treatment settings are entered simply on a large colorful graphical user interface that guides the user through the setup and tear-down processes, as well as alarm states. A proprietary blood line is also required; however, the rest of the consumables set can be selected by the prescriber.

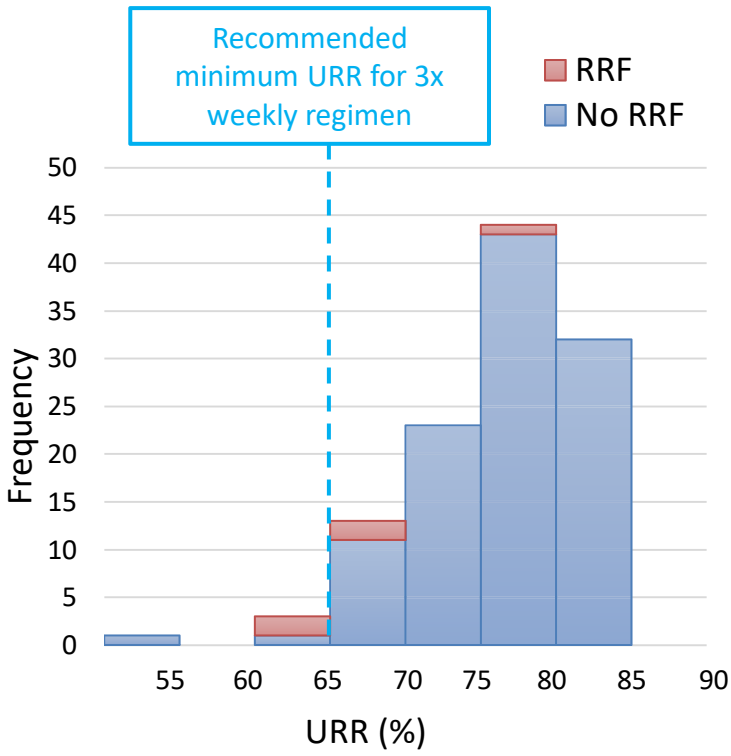

Figure 2. Dialysis adequacy as measured by urea reduction ratio (URR). Abbreviation: RRF, residual renal function.

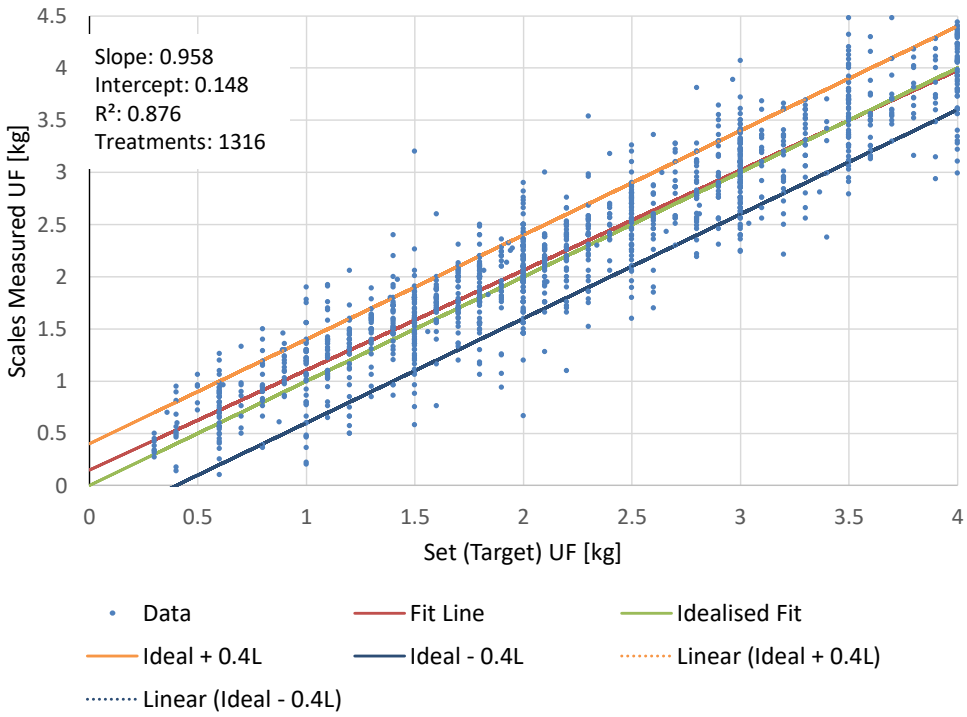

Figure 3. Target ultrafiltration (UF) versus scales measured UF.

Previously published human factors testing work validates the design principles of the SC+ system in terms of patient usability with minimal training.[8] For this reason, the SC+ system is a well-suited hemodialysis device for patient use across a wide range of dialysis prescriptions in the home and in facilities. The device requires reverse-osmosis quality water and can be simply installed into the ring main of a dialysis clinic or with a single-station reverse-osmosis unit. Quanta has developed a water solution that contains an reverse-osmosis unit and all standard prefiltration requirements that has a similar "footprint" to SC+. This simplifies the installation of the SC+ system, requiring only a dedicated electrical circuit, water outlet, and drain tube in a home setting. This cart-based solution, on which the SC+ can be placed, also enables easy redeployment should a patient change treatment modality, for example, receiving a transplant. The commercial system also includes a suite of digital health tools that automatically and securely transfer treatment data to the clinic, as well as providing information on the performance of the machine, enabling preemptive maintenance. This will support effective remote management of the patient.

Our study has several strengths. It selected 4 distinct dialysis programs with unique characteristics and patient care protocols and had a patient population with significant age and weight ranges. The study had participants using a range of dialysis prescriptions, varying in number of treatments per week and type of treatment (nocturnal, short daily, and conventional 3 times per week). Over a significant number of treatments there were no observed machine-related adverse device events and patient adverse events were at an acceptable level for a typical dialysis

Table 3. Symptoms Reported

Event	Percentage of All Treatments With Recorded Events (n = 1,333)	Percentage of Treatments Removing >100 mL/h Above Target With Recorded Events (n = 143)
Hypotension	13.4%	15.4%
Dizziness	2.0%	0%
Nausea & vomiting	0.9%	0.7%

Table 4. Adverse Events Reported

Adverse Event Type	Treatment (Total) Occurrences
Adverse events	277 (475)
Adverse device effects with serious potential	0 (0)
Adverse device effects without serious potential[a]	1 (1)
Serious adverse device effects	0 (0)

[a]System failure before end of treatment. Blood not returned to patient as per unit protocol and lost 1 circuit of blood. No symptoms or adverse events. Root cause analysis revealed a loose blood pump controller cable. Safety systems correctly prevented dialysis from continuing.

Table 5. Nonserious Adverse Events

Adverse Event Categorization	Total Events	Total Treatment Occurrences	Percentage Total Evaluable Treatments (n = 1,333)
Headache	26	22	1.65%
Nausea & vomiting	15	11	0.83%
Dizziness	29	26	1.95%
Cramping	51	36	2.70%
Hypertension	57	45	3.38%
Hypotension	290	178	13.35%
Other	7	7	0.53%
Total	475	277[a]	20.78%

[a]Treatments in which 1 or more adverse event occurred.

population receiving mainly conventional thrice-weekly dialysis.

This study has some weaknesses. A few patients were below the standards for dialysis adequacy that we try to achieve. Most patients who were below acceptable clearances were all explained by the presence of significant residual kidney function or transient illness, which is typical in a facility-based hemodialysis program. Few patients were included in the study on treatment frequencies greater than 3 times weekly. The protocol specified that patients recruited should continue on their current prescription. The high proportion of patients on 3-times-weekly treatment regimens reflects the prevailing prescriptions in center-based hemodialysis, the pool from which most patients were recruited. Future studies will examine the performance of SC+ in patients prescribed higher frequency regimens. Consistent historical data are not available for all patients so we cannot report on a comparison between SC+ and the prior machine.

Measured weight loss, as adjusted for fluid and food intake during treatment, is compared with the target UF volume to determine the NFR error. In accordance with the relevant standards and our system specification, the acceptable limit of NFR error is ± 100 mL/h or 400 mL per 4-hour treatment. SC+ has consistently demonstrated conformity with these limits when evaluated under appropriate controlled laboratory settings, as reported in formal verification testing. Although there is variability in the NFR error data obtained in treatments conducted with SC+, this appears to be related to real-world variability (such as unanticipated intradialytic fluid and food intake during treatment or changes in clothing and personal items while being weighed) rather than the performance of SC+ and is consistent with usual clinical experience. Additionally, no treatments longer than 5 hours were tested in this study. The commercial version of the SC+ platform has a 300-mL/min dialysate flow rate setting in addition to the high-flow (500 mL/min) setting used in all treatments in this study. This enables treatments up to 8 hours in duration and will be tested in future studies of the platform. An infusion port is incorporated into the blood-line to accommodate the delivery of heparin. The lower flow setting could also be used to reduce overall water requirements compared with the high-flow setting in locations in which water is scarce or expensive.

We did not perform a structured usability or human factors component to this study. However, it is reassuring that qualitative feedback on the device was generally positive and many patients expressed an interest in remaining on the device beyond the study period, and some patients transitioned to self-care who were previously dependent on clinic staff.

After 30 years of minor incremental improvements to hemodialysis devices, it is encouraging that there are now some emerging options for patients wishing to try self-care or home hemodialysis on a global scale. Exciting results in terms of usability, improved cardiovascular outcomes, and patient recovery have been published with the NxStage device.[16-19] The Tablo device (Outset Medical) is an emerging device with similarly encouraging usability that may encourage more patients to become empowered with self-care.[20] It is our hope that more choice in the market for both providers and patients will grow the use of self-care and more frequent home dialysis prescriptions, achieving better patient outcomes at lower cost to providers.

With this study, the SC+ hemodialysis system demonstrates key differentiating features from existing hemodialysis devices by delivering the power of large conventional devices in a patient-friendly form with demonstrated usability. SC+ is flexible across a variety of dialysis prescriptions, including conventional, 3-times-weekly, short daily, and nocturnal dialysis. The system has also been validated on patients with a broad range of sizes and weights. The SC+ system could be greatly used in the Advancing American Kidney Health initiative for increased home dialysis in all new patients experiencing kidney failure.[6] It could also assist in transitioning many in-center patients to the home as a lower-risk environment in the context of the COVID-19 pandemic. It is our hope that this device empowers many more patients to engage with self-care dialysis and enjoy its improved clinical and patient-reported health outcomes while unlocking greater value for providers.

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Does the Quanta SC+ system provide effective and safe hemodialysis?

Kidney Medicine

Methods and Cohort

- 4 centers in the UK
- Prospective, observational study
- 60 participants
- Average weight 82 kg (Range 50 – 157 kg)

Quanta SC+

1333 treatments

Findings

Dialysis Adequacy (prescribed over 3x/week)

spKt/V > 1.2 in 96.6% (Median 1.73)

stdKt/V > 2.1 in 94% (Median 2.46)

Net Fluid Removal (NFR) Accuracy

Mean UF Target: 2.20 (SD 0.95 kg)

Mean NFR achieved: 2.26 (SD 0.97 kg)

Adverse Events

Adverse event profile was typical of hemodialysis with no serious adverse events, or device-related adverse events

Conclusion: The SC+ system delivers safe and effective hemodialysis across a range of patients and dialysis prescriptions. It is one of the smallest systems available and has validated usability for patients to perform self-care safely with minimal training.

Reference: Komenda PVJ, Harper G, Wilson LM et al. Haemodialysis with the Quanta SC+: efficacy and safety of a self-care haemodialysis machine. *Kidney Medicine*, 2020.

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