IMPLEMENTATION OF A COMPACT HAEMODIALYSIS SYSTEM IN A REAL-WORLD ENVIRONMENT: ASSESSMENT OF USER UPTAKE, SAFETY, PERFORMANCE AND USABILITY

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Introduction and Background

Ten per cent of the worldwide adult population have some form of kidney disease with five year survival rates for renal replacement therapies currently at 32.5% for patients aged 65 years and older[1]. There are 3.2 million End Stage Renal Disease (ESRD) patients routinely receiving dialysis.[2] The vast majority of patients dialyse three times weekly in-centre with limited treatment alternatives. Quanta Dialysis Technologies has developed a small, simple and powerful haemodialysis (HD) system called SC+. The SC+ System is designed to bring flexibility to the dialysis community by enabling a greater choice in treatment frequency, duration, setting location and regimen for dialysis patients. Quanta has conducted a pilot study to assess the safety, efficacy and usability of SC+. The study was completed on 31 January 2018. This analysis reports the results of 1,346 treatments completed during the study, and provides an update on the results previously reported.[3]

Study Design

A prospective, multi-centre, open-label, single-arm observational study using SC+ was conducted with adult ESRD subjects receiving regular haemodialysis and weighing at least 40 kg. Subjects who met broad inclusion / exclusion criteria reflecting the wide range of patients requiring dialysis in real life were approached by the clinic's Principal Investigator (PI) to participate. Each dialysis therapy was performed using bicarbonate-based dialysate at a flow rate (Qd) of 500 ml/min and blood flow rates of between 200 and 450 ml/min. Vital signs were recorded nominally every 30 minutes, symptoms were monitored during every treatment and any adverse events were recorded. Monthly blood samples for clinical laboratory evaluations of chemistry and haematology were taken pre- and post-dialysis in accordance with local practice, and subjects' mass was recorded before and after each treatment. Dialysis adequacy of SC+ was assessed by calculation of StdKt/V. Following completion of 1,000 Quanta-led treatments, a group of patients and healthcare professionals (HCPs) progressed to undergo training, competency sign-off and subsequently conduct treatments using SC+ themselves. The objective of this assessment of user uptake was to gain feedback on training set-up and identify areas for optimisation. Within this 'user-led' phase, participants were additionally monitored to assess training comprehension and what, if any, support was required from technical experts following competency sign-off.

Results

A total of 60 subjects with a mean age of 60 years were treated with SC+ on treatment regimens ranging from two times weekly to seven times per week. Subjects' dry weights ranged from 50 to 157 kg with a mean of 82 kg. Table 1 summarises the patient characteristics of the study population. A total of 1,346 treatment records were collected as part of the study. Clinical parameters are reported in Table 2. The mean duration of each treatment was 241.4 minutes (SD 41.7), with a mean blood flow rate setting of 376.5 ml/min (SD 46.9) and dialysate flow rate of 500 ml/min. The range of blood pump speeds programmed on SC+ for the study population is displayed in Figure 1, with a study minimum of 200 ml/min and a maximum of 450 ml/min.

Only one ADE (Adverse Device Effect) was reported, where the device's safety system correctly detected a fault towards the end of treatment, immediately instructing the operator to end the session and not to wash back the blood circuit. The small volume of blood within the extra corporeal circuit was lost. This single event was not classified as serious and the safety system of SC+ acted as intended to protect the patient. With the exception of the single event noted above, all Adverse Events (AEs) related only to minor complications common in normal haemodialysis and causality was not attributed to the device. The most frequent of these was hypotension, with 285 observations in 172 (13%) of treatment sessions, which is well within the normal range as documented in the literature.[4]

The association between ultrafiltration (UF) target and net fluid removal (NFR) achieved was assessed and is displayed in Figure 2. NFR achieved was determined by measuring the difference in patient mass before and after treatment (by using clinical scales) and adjusted for priming, washback volumes, saline bolus and total oral intake. UF target matched with NFR achieved, with both parameters averaging 2.0 kg. The fit line for the data is well within the NFR error specified by International Standards for haemodialysis.[5]

Number of Subjects	60
Number of Evaluable Treatments	1,346
Date Range	30 June 2015 – 31 January 2018
Patient Age Range (years)	22 – 85; Mean 60.1
Patient Gender	33 Males, 27 Females
Dry Weight Range (Kg)	50 – 157; Mean 82.3
Treatments per Week	2/wk (n=1) ; 3/wk (n=51); 4/wk (n=4); 5/wk (n=3); 7/wk (n=1)
Anti-coagulant Type	Heparin (n=1); LMWH (n=47); Saline flush (n=1); None (n=11)
LMWH Total Dose (mg)	Dalteparin 1.25 – 5 IU (n = 9); Enoxaparin 2.5 – 60 mg (n = 28); Tinzaparin 0.45 – 3.5 mg (n = 10)
Needle Size (G)	14 Sharp (n=6); 14 Buttonhole (n=15); 15 Sharp (n=32); 15 Buttonhole (n=9); 16 Sharp (n=9)
Vascular Access	Radial AVF (n=17); Brachial Cephalic AVF (n =36); Brachial Cephalic AVG (n=3); Femoral Graft (n=4)
Blood Pump Speed (Qb) Range (ml/min)	200 – 450
Dialyser Size Range	FX-60 (n=213); FX-80 (n=264); FX-100 (n=379); FX-120 (n=115) Polyflux 170H (n=172); Polyflux 210H (n=198); Nipro 190H (n=5)
Dialysate Flow Rate (Qd) (ml/min)	500

Table 1: Baseline patient characteristics and dialysis treatment parameters for evaluable patients

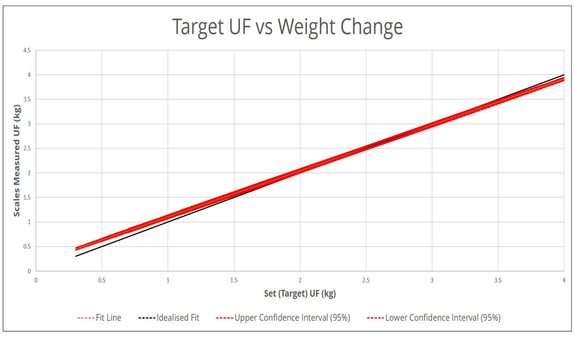

Figure 2: Target ultrafiltration on SC+ plotted against the actual fluid removed by weight change pre- and post-treatment

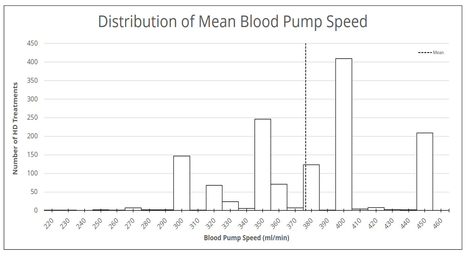

Figure 1: Distribution of mean blood pump speed

Clearance (StdKt/V)

Blood samples were collected monthly for each patient in accordance with individual clinic routines. Pre- and post- treatment blood analyses were available for 134 treatments within the study period and single pool Kt/V (spKt/V) for urea was calculated. These values were extrapolated to weekly standard urea Kt/V.[6] Figure 3 plots the StdKt/V for all available blood analyses. Subjects on a 5-times or 7-times weekly dialysis regimen displayed higher weekly clearance values, with a study maximum of 4.74 in a patient dialysing 7-times per week at home. 99% of blood values achieved adequate clearance. In one instance the patient did not reach the adequacy threshold,[7] as they were unwell prior to dialysis meaning that pre-treatment urea may have been low due to reduced food intake. Mean StdKt/V for patients without residual renal function (RRF) was 2.49. Clinical performance was further demonstrated by a median urea reduction ratio (URR) of 77.18% for patients receiving three-times weekly dialysis for the available blood data, surpassing a recommended threshold of 65%.[8]

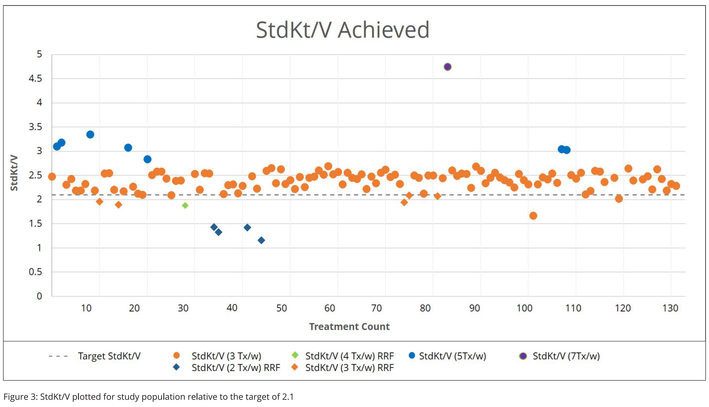

Figure 3: StdKt/V plotted for study population relative to the target of 2.1

Technical Performance

SC+ consistently delivered key treatment parameters in line with the settings input by the operator, as shown in Table 2. In addition, deviation of dialysate temperature and conductivity from the target set point was negligible. Mean deviation of dialysate temperature was 0.1°C and mean deviation in conductivity was 0.01 mS/cm, demonstrating that SC+ maintains tight control over these parameters.

	Machine Settings Mean ± SD	Machine Measurements Mean ± SD
Mean Treatment Time (min)	241.4 ± 41.7	244.2 ± 40.9
Blood Pump Speed (ml/min)	376.5 ± 46.9	375.5 ± 51.7
Dialysate Temperature (°C)	36.4 ± 0.4	36.4 ± 0.2
Dialysate Conductivity (mS/cm)	13.8 ± 0.1	13.7 ± 0.2
Target UF Setting (kg)	2.2 ± 0.9	2.1 ± 1.0
Arterial Pressure (mmHg)	N/A	-128.7 ± 40.1
Venous Pressure (mmHg)	N/A	171.8 ± 32.3

Table 2: Clinical settings and machine measurements for evaluable treatments conducted

Assessment of User-Led Treatments

Naïve users were permitted to begin operating SC+ for clinic treatments following the completion of 1,000 treatments led by Quanta staff. Users were trained, assessed and signed off as competent before conducting treatments independently. Both HCPs and patients were included to understand different needs. During this phase, participants were monitored in order to assess training comprehension and determine what, if any, intervention was required from technical experts following competency sign-off.

Each intervention was reviewed to ascertain if it was safety related, usability related or a prompt / reminder. Prompts and reminders were not considered significant as they largely related to subject confidence. Only one safety intervention was made where a subject required assistance disconnecting following a non-machine related episode of severe cramping. Nine interventions were identified as significant and usability related, involving deviations from the Instructions For Use (IFU). These have been incorporated into training programme revisions and IFU improvements. Mean StdKt/V was observed to be 2.5 in the user-led phase compared to 2.4 in the full data set; adverse event observations were also similar to those observed in the whole population.

Discussion and Conclusion

This pilot study supports the safety and performance of the SC+ Haemodialysis System with acceptable clinical and technical performance in a diverse sample of haemodialysis subjects. There was only one ADE, which was minor, with the safety system of SC+ acting as intended to protect the patient from harm. All other AEs were typical of dialysis treatments and not device-related. In a population of established dialysis patients regularly receiving standard thrice-weekly prescriptions, clinical performance was demonstrated by subjects consistently attaining a weekly StdKt/V of greater than 2.1, as recommended by Gotch as a weekly dialysis adequacy.[7] UF performance was acceptable, with actual measured UF closely matching the target UF. SC+ performed consistently across all treatments, with results overall demonstrating that patients treated with SC+ achieve adequate clearance using standard treatment regimens traditionally used in in-centre haemodialysis. No material differences were observed in the safety and performance of SC+ between the overall patient population and user-led sub-set with efficacy and adverse event rates displaying similar trends between the two groups. Patients were able to routinely conduct treatments unassisted, suggesting that SC+ can be used in the absence of a care partner. Combined with previous usability studies,[9] the user-led phase validates that SC+ can be used independently by patients and HCPs in standard practice creating an opportunity for a paradigm shift in renal care.

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