ASSESSMENT OF THE SAFETY, EFFICACY AND USABILITY OF THE QUANTA SC+ HAEMODIALYSIS SYSTEM

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Introduction and Background

Ten per cent of the worldwide adult population have some form of kidney disease, and every year millions die prematurely of complications related to Chronic Kidney Disease (CKD),[1] with 2.8 million End Stage Renal Disease (ESRD) patients routinely receiving dialysis.[2] The vast majority of patients dialyse 3 times per week in-centre, with limited treatment alternatives. Quanta Dialysis Technologies has developed a high-performance, compact, easy-to-use haemodialysis (HD) system called SC+. The SC+ system is designed to bring flexibility to the dialysis community by allowing a greater choice in treatment frequency, setting location and regimen for dialysis patients. Quanta is conducting a Post Market Clinical Follow-up (PMCF) study to assess the safety, efficacy and usability of SC+. This analysis reports the results of the first 660 treatments completed between 30 June 2015 and 31 December 2016, 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 50 kg. Each clinic's Principal Investigator (PI) screened the patients on a volunteer basis. Each dialysis therapy was performed at an outpatient clinic using bicarbonate-buffered dialysate at a flow rate (Qd) of 500 ml/min. Vital signs were recorded nominally every 30 minutes, subject symptoms were monitored during every treatment and any adverse events were recorded. 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 StdKt/V. Usability observations were also collected for each dialysis therapy.

Results

A total of 47 subjects with a mean age of 61 years were treated with SC+ on treatment regimens ranging from 3 times weekly to 7 times per week. Subjects were screened by the PI at the clinic in line with the protocol requirements and stated intended use of SC+, with subjects' dry weights ranging from 50 to 157 kg. Table 1 summarises the patient characteristics of the study population. A total of 706 dialysis treatments were completed according to protocol during the period, for which 660 evaluable patient records are available. Clinical parameters are reported in Table 2. The mean duration of each treatment was 238.4 minutes, with a mean blood flow rate setting of 371.6 ml/min 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 180 ml/min and a maximum of 450 ml/min.

Number of Subjects	47
Number of Evaluable Treatments	660
Date Range	30 June 2015 - 31 December 2016
Patient Age Range (years)	22 to 85; Mean 61
Patient Gender	26 Males, 21 Females
Dry Weight Range (Kg)	50 to 157; Mean 83.5
Treatments per Week	3/wk (n = 43); 4/wk (n = 1); 5/wk (n = 2); 7/wk (n = 1)
Anti-coagulant Type	Heparin (n = 1); LMWH (n = 38)*; Saline flush (n = 1); None (n = 7)**
LMWH Total Dose (mg)	Dalteparin 2.5 - 5 (n = 9); Enoxaparin 2.5 - 60 (n = 28); Tinzaparin 0.45 - 3.5 (n = 1)
Needle Size (G)	14 Sharp (n = 5); 14 Buttonhole (n = 2); 15 Sharp (n = 25); 15 Buttonhole (n = 9); 16 Sharp (n = 6)
Vascular Access	Radial AVF (n = 13); Brachial Cephalic AVF (n = 26); Brachial Cephalic AVG (n = 3); Femoral Graft (n = 5)
Blood Pump Speed (Qb) Range (ml/min)	180 - 450 (n = 660)
Dialyser Size Range	FX-60 (n = 137); FX-80 (n = 110); FX-100 (n = 227); Polyflux 170H (n = 72); Polyflux 210H (n = 114)
Dialysate Flow Rate (Qd) (ml/min)	500 (n = 660)

*3 Patients receiving Warfarin in addition to their dialysis prescription
** 1 Patient receiving Warfarin in addition to their dialysis prescription

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

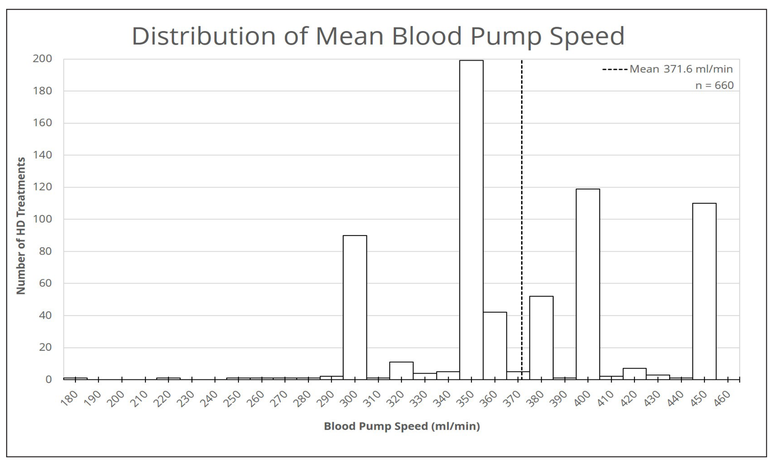

Figure 1: Distribution of mean blood pump speed

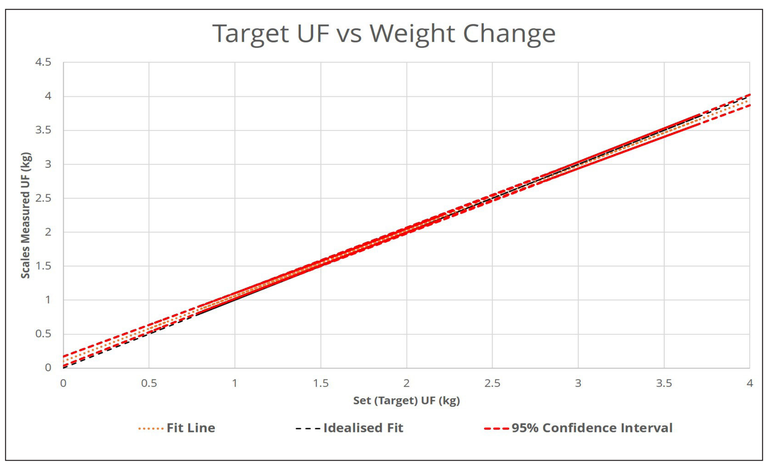

Figure 2: Target ultrafiltration on SC+ plotted against the actual fluid removed by weight change pre- and post-treatment

Only one ADE (Adverse Device Effect) was reported, where the device's safety system correctly detected a fault towards the end of treatment and subsequently instructed the operator to immediately end the session. As washback was not possible, the small volume of blood within the extra corporeal circuit was lost. This event was not classified as serious and the safety system of SC+ acted as intended to protect the patient. A total of 90 AE (Adverse Event) observations were reported. With the exception of the single event noted above, all AEs related only to minor complications common in normal haemodialysis. The most frequent of these was hypotension, with 74 observations in 43 treatment sessions (6.5%) 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 corrected for priming, washback volumes, saline bolus and total oral intake. UF target matched with NFR achieved, with both parameters averaging 1.9 kg. The fit line for the data is well within the NFR error specified by International Standards for haemodialysis.[5] It should be noted that measurements of NFR obtained in clinical practice using weighing scales are prone to experimental error due to the influence of a number of variables that are difficult to control sufficiently in a real-world setting, such as intradialytic food and fluid intake and changes in articles of clothing and personal items.

Clearance (StdKt/V)

Dialysis adequacy of SC+ was assessed by measuring the standardised weekly Kt/V for the study subjects. Blood samples were collected monthly for each patient in accordance with individual clinic routines. Pre- and post- treatment blood analyses were available for 86 treatments within the study period. Dialysis dose delivered by SC+ was calculated as weekly standard urea Kt/V (StdKt/V) from spKt/V.[6] Figure 3 plots the StdKt/V for all available blood analyses. Subjects on a 5-times or 7-times per week dialysis regimens displayed higher clearance values, with a study maximum of 4.74 in a patient dialysing 7-times per week at home. The majority of data points were above the StdKt/V 2.1 weekly adequacy target, as recommended by Gotch.[7] Eight data points did not reach this threshold and, in all cases, these patients had residual renal function and the dialysis prescriptions were adjusted accordingly. Clinical performance was further demonstrated by a mean urea reduction ratio (URR) of 74.4% for the available blood data, surpassing the recommended threshold of 65%.[8]

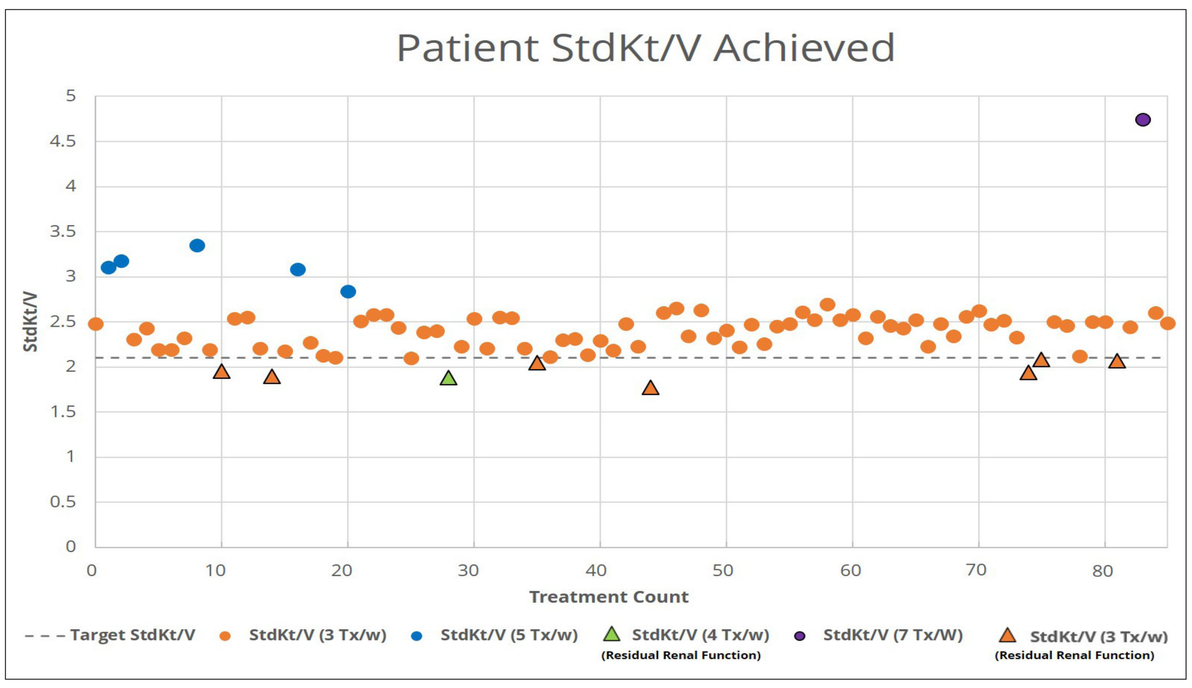

Figure 3: StdKt/V plotted for study population relative to the target of 2.1

Technical Performance

The SC+ system 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.

	Clinical Settings Mean ± SD	**Clinical Measurements Mean ± SD**
Mean Treatment Time (min)	Target: 241.1 ± 58.9	238.4 ± 57.9
Blood Pump Speed (ml/min)	371.6 ± 48.3	369.2 ± 50.2
Dialysate Temperature (°C)	36.5 ± 0.4	36.5 ± 0.4
Dialysate Conductivity (mS/cm)	13.8 ± 0.1	13.8 ± 0.1
Target UF (kg)	1.9 ± 0.8	1.9 ± 0.8
Arterial Pressure (mmHg)	N/A	-369.2 ± 50.2
Venous Pressure (mmHg)	N/A	175.8 ± 32.2

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

Discussion and Conclusion

This PMCF 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. Clinical performance was demonstrated by subjects consistently attaining a weekly StdKt/V of greater than 2.1 as recommended by Gotch[7] as a weekly dialysis adequacy. Clinical performance was further demonstrated by a mean study URR of 74.4%, surpassing the recommended guidelines of 65% for 3-times per week dialysis. 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 haemodialysis. Results further show that SC+ can be used safely and effectively in a population of adult haemodialysis patients representative of those found in a typical dialysis clinic, with no significant safety or usability issues identified.

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