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). With 2.8 million End Stage Renal Disease (ESRD) patients routinely receiving dialysis, the vast majority of patients dialyse 3 times weekly in-center, with limited treatment alternatives. Quanta’s Dialysis Technologies have developed high-performance, compact and easy-to-use haemodialysis (HD) systems, such as the SC+ System. The system was developed to bring flexibility to the dialysis community by allowing a greater choice in treatment protocols, thereby enabling subjects to remain enrolled in the study. Quanta decided, in consultation with the Post Market Clinical Follow-up (PMCF) study, to assess the safety, efficacy and usability of SC+. This analysis reports the results of 915 study treatments conducted between 3 June 2015 and 5 May 2017, and provides an update on the results previously reported.

Study Design

A prospective, multi-center, 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 voluntary basis. Each dialysis therapy was performed using boreless, low-flux dialyzers at a membrane rate of 500 milliamps. Vital signs were recorded before and after each treatment, and clinical laboratory evaluations of chemistry and haematology were performed pre- and post-treatment. Adverse events were recorded. Blood samples were taken for clinical laboratory evaluations of chemistry and haematology.

Results

A total of 55 subjects with a mean age of 61 years were treated with SC+ in treatment regimens ranging from two times weekly to seven times per week. Subjects were screened by the PI at the clinic in line with the protocol requirements and intended use of SC+. Subjects who had significant residual kidney function (RKF) were excluded. Clinical parameters are reported in Table 1. The mean duration of each treatment was 240.9 minutes, with a mean blood flow rate of 355.9 ml/min and dialysate rate of 550 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 220 ml/min and a maximum of 450 ml/min.

Only one ADE (Adverse Event Device) 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 383 AEs (Adverse Events) were observed. The exception of the single event described above, all AEs related to more common complications common to non-haemodialysis patients. The most frequent of these was hypoglycaemia, with 295 observations in 147 treatment sessions (16%) of treatment sessions, which is well within the normal range as documented in the literature.

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, sub dialus and total intra. Uf target matched with NFR achieved, with both parameters averaging 2.0 kg. The RRR for data is well within the NFR error specified by International Standards for haemodialysis. It should be noted that measurements of NFR obtained in clinical practice using weighing scales are prone to error due to the influence of variables such as weight distribution in the body, the time interval between weighing and completion of dialysis, and on the accuracy of the weighing methods, which is a result of the variable blood volume and body fat.

Clinical performance was further demonstrated by a mean study URR of 74.5%, surpassing the recommended guidelines of 65% for 3-times weekly treatments. Mean blood pump speed was 241.9 ± 43.0 ml/min, with a mean blood flow rate of 355.9 ml/min and dialysate rate of 550 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 220 ml/min and a maximum of 450 ml/min.

Blood samples were collected monthly for each patient in accordance with individual clinic routines. Pre- and post-dialysis blood samples were taken for the 100 treatments conducted over a 12-month period and single spot polyfluor (polyfluor) for urine was used. Values were extrapolated to weekly standard urea Kt/V. Figure 3 plots the data points for all available blood analysis conducted on a 5 or 7 times weekly sessions regimen displayed higher weekly urea clearances, with a study maximum of 4.74 in a patient dialysing 7 times per week at home. The mean of the data points were above the Stelow 2.1 weekly adequacy target, as recommended by Gotch et al.

Eleven data points did not reach this threshold. In 10 of these treatments the patient had significant residual kidney function (RKF) and the other patient was on a 3-times per week regimen (three hour treatment duration) had urine output of 1200 ml/hour resulting in this low-adequacy result. The remaining data point that did not reach the adequacy threshold was from a patient who had been Listed prior to dialysis involving hospital admission resulting in pre-treatment urine may have been collected at reduced fluid intake. Mean StdKt/V for patients without RRF was 2.41. Clinical performance was further demonstrated by a mean urea reduction ratio (URR) of 75.8% for the available blood data from patients without RRF, surpassing the recommended threshold of 70%. Clinical performance was demonstrated by subjects consistently attaining a weekly StdKt/V of greater than 2.1 as recommended by Gotch & colleagues (Kidney Int. Dec 2011; 80(12): 1258-70).

Technical Performance

The SC+ system consistently delivered treatment parameters in line with the settings input by the operator, as shown in Table 2. In addition, deviation of dialysate temperature from the target set point was negligible. Mean deviation of dialysate temperature was 0.7°C and mean deviation of target urea ratio was 0.05 mmol/l.

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 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 as a weekly adequacy goal. Clinical performance was further demonstrated by a mean study URR of 75.8%, surpassing the recommended guidelines of 65% for 3-times weekly dialysis. Uf performance was acceptable, with actual measured UF closely matching the target UF. SC+ performed consistently across all treatments, with results observed on a single-center blood pump speed and dialysate temperature and pressure. Clinical performance was also observed on the rejection of treatment sessions 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 issues identified.