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

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INTRODUCTION

Quanta Dialysis Technologies has developed a novel, high-performance, portable, easy-to-use haemodialysis (HD) system called SC+, which is designed to bring flexibility to the dialysis community by allowing a greater choice in treatment frequency and location for dialysis patients.

A Post Market Clinical Follow-up (PMCF) pilot study is being conducted to assess the safety, efficacy and usability of SC+. This interim analysis reports the results of the first 77 treatments completed and provides an update on the initial results previously reported[1].

Figure 1: SC+ Haemodialysis System

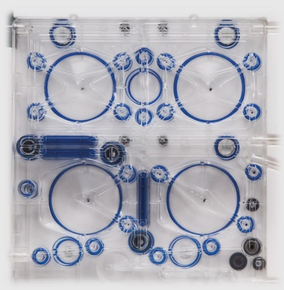

Figure 2: SC+ Disposable Dialysate Cartridge

BACKGROUND

End Stage Renal Disease (ESRD) affects 2.8 million dialysis patients worldwide[2]. The vast majority of patients dialyse 3x weekly, in-centre with limited treatment alternatives.

SC+ is designed to provide flexibility across a range of care settings and treatment programmes, enabling patients to seamlessly transition through different care settings while still receiving the optimum treatment at every stage.

STUDY DESIGN

An anonymised open-label, single-arm, pilot study was conducted with ESRD subjects weighing over 50 kg and aged over 18 years. The clinic's Principal Investigator (PI) selected the patients on a volunteer basis. Each dialysis therapy was performed on an outpatient basis using bicarbonate-buffered dialysate at a flow rate (Qd) of 500 mL/min.

Vital signs were recorded, nominally every 30 minutes, and subject symptoms were monitored during every treatment. Blood samples for clinical laboratory evaluations of chemistry and haematology were taken pre-and post-dialysis in 27 of the 77 dialysis sessions. Additional data collected included subjects' mass (pre- and post-dialysis), free-text treatment notes, subjects' symptoms, SC+ usability observations and adverse events.

Clinical performance of SC+ was assessed by StdKt/V and URR for the study population.

STUDY RESULTS

Between June and November 2015, 21 subjects on a 3x weekly dialysis regimen and 2 subjects on a 5x weekly dialysis regimen successfully completed 77 dialysis treatments with no device-related adverse events or safety issues. No sessions were prematurely terminated due to any technical or clinical issues. Subjects were selected by the PI at the clinic in-line with the intended use of SC+, with subjects' dry weights ranging from 50 to 158 kg. Table 1 summarises the dialysis specification ranges across the therapies.

Two subjects on Warfarin (coumadin) as a maintenance medication did not use an anticoagulant as part of their dialysis regimen. Another subject had a left thigh graft, all other subjects received their HD therapy using upper extremity arteriovenous fistulas (AVF) or arteriovenous grafts (AVG).

The study subject UF rate for therapies ranged from 133 mL/hour to 1000 mL/hour and the mean study UF rate was 456 mL/hour.

Number of Subjects	23
Number of Treatments	77
Date Range	30-Jun-2015 to 25-Nov-2015
Patient Age Range (years)	22 to 80
Patient Gender Split	11 Males, 12 Females
Dry Weight Range (kg)	50 to 158
Anti-Coagulant Type	Enoxaparin, warfarin and enoxaparin, warfarin only
Enoxaparin Total Dose (mg)	0-60
Needle Size (G)	14, 15, 15 buttonhole, 16
Vascular Access	Right Radial AVF Right Brachial Cephalic AVG Left Brachial Cephalic AVF Left Brachial Cephalic AVG Left Femoral Graft
Blood Pump Speed (Qb) Range (mL/min)	220 to 450
Dialyser Size Range	FX-60, 80 and 100
Dialysate Flow Rate Qd (500 mL/min)	500

AVF = Arteriovenous Fistula; AVG = Arteriovenous Graft

Table 1: Dialysis specification ranges for 77 treatments

PERFORMANCE

SC+ performed consistently across the 77 treatments. All treatments were completed to the target treatment time set at the clinic.

Table 2 summarises the SC+ technical measurements taken for each treatment to monitor performance. UF performance was assessed by comparing UF target with UF achieved, which was calculated based on changes in patient mass. UF performance was acceptable, with both the target UF and the actual UF achieved, averaging 1.8 kg.

	Mean	Median	Min	Max
Dialysate Temp (°C)	36.7	37.0	36.0	38.0
Dialysate Conductivity (mS/cm)	13.7	13.7	13.6	13.9
Ultrafiltration (UF) Rate mL/hour	456	413	133	1000
Total Treatment Time (min)	232.6	240.0	180.0	270.0
Target UF (kg)	1.8	3.3	0.4	4.0

Table 2: Technical performance of the SC+ measured by stability of the dialysate temperature and conductivity; total therapy time and UF error within acceptable limits for study population.

STANDARDISED Kt/V

Clinical performance of SC+ was determined by measuring the standardised weekly Kt/V for the study subjects. Figure 3 plots the StdKt/V where blood samples were collected, as per the clinic procedure. Subjects on a 5x weekly dialysis regimen displayed higher clearance values, with a study maximum of 3.29. Apart from one value, all data points were above StdKt/V 2.1, as recommended by Gotch[3] as a weekly adequacy equivalence target.

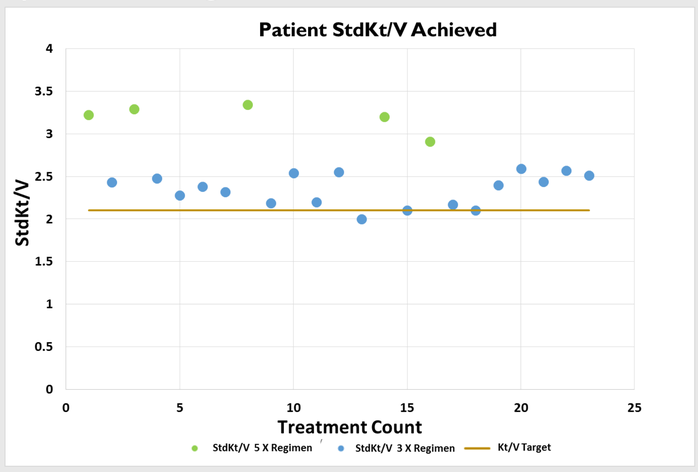

Figure 3: StdKt/V plotted for study population relative to the target of 2.1

Clinical performance was further demonstrated by a mean urea reduction ratio (URR) of 72.3% for the study population, surpassing the recommended guidelines of 65%[4].

USABILITY

SC+ usability feedback collected from nurse operators and study subjects post treatment did not identify any significant usability issues. Below are highlights of the most common observations:

- System size is small and compact (n = 11)
- Subjects like the simplicity of the system for potential self-care (n = 11)
- Black background on the system graphical user interface, and stepwise instructions on the dialysis process flow, praised for ease of use (n = 8)

CONCLUSION

SC+ performed safely with acceptable clinical and technical performance in the ESRD subject population. There was no measured loss of therapy time, UF error was acceptable, no significant usability issues were noted, and there were no safety issues or device-related adverse events recorded during the study.

in this subject population. Clinical performance was demonstrated by subjects attaining a weekly StdKt/V of greater than 2.1, recommended as a weekly adequacy equivalence by Gotch[2]. The maximum achieved study StdKt/V was 3.29.

Clinical performance was further demonstrated by a mean study URR, of 72.3%, surpassing the recommended guidelines of 65% for 3x weekly dialysis[3].

REFERENCES

1. Poster presented at ADC Seattle, February 2016
2. Fresenius Annual Report 2015
3. Gotch FA. The current place of urea kinetic modelling with respect to different dialysis modalities. Nephrol Dial Transplant 1998;13 (Suppl 6):S10-4
4. UK Renal Association Guidelines: http://www.renal.org/guidelines/modules/haemodialysis#sthash.KJYcP0so.dpbs, accessed on 16 May 16