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

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,1 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.2

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 dialyse at a flow rate (Qd) of 500 ml/min. Vital signs were recorded normally 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 haematoiology 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 StdvKt/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.

Clearance (StdvKt/V)

Dialysis adequacy of SC+ was assessed by measuring the standardised weekly Kt/V for the study patients. Blood samples were collected monthly for each patient in accordance with individual clinic routines. Pre- and post-treatment blood analyses were available for 88 treatments within the study period. Dialysis dose delivered by SC+ was calculated as weekly standardised urea Kt/V (StdvKt/V) from subjects’ urea clearance (Figure 3 plots the StdvKt/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 StdvKt/V 2.1 weekly adequacy target, as recommended by Gotch. 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 using a mean urea reduction ratio (URR) of 74.4% for the available blood data, surpassing the recommended threshold of 65%.

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 achieving a weekly StdvKt/V of greater than 2.1 as recommended by Gotch3 as a weekly adequacy target. 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. UFR performance was acceptable, with actual measured UFR closely matching the target UFR. 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.

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.

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Clinical Settings</th>
<th>Clinical Measurements ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Treatment Time (min)</td>
<td>Target: 241 ± 58.9</td>
<td>238.4 ± 57.9</td>
</tr>
<tr>
<td>Blood Pump Speed (ml/min)</td>
<td>371.6 ± 48.3</td>
<td>369.3 ± 50.2</td>
</tr>
<tr>
<td>Dialysate Temperature (°C)</td>
<td>36.5 ± 0.4</td>
<td>36.5 ± 0.4</td>
</tr>
<tr>
<td>Dialysate Conductivity (mS/cm)</td>
<td>1.8 ± 0.1</td>
<td>1.8 ± 0.1</td>
</tr>
<tr>
<td>Target UF (kg)</td>
<td>9 ± 0.8</td>
<td>9 ± 0.8</td>
</tr>
<tr>
<td>Arterial Pressure (mmHg)</td>
<td>N/A</td>
<td>100 ± 50.2</td>
</tr>
<tr>
<td>Venous Pressure (mmHg)</td>
<td>N/A</td>
<td>100 ± 50.2</td>
</tr>
</tbody>
</table>

Table 1: Distribution of mean blood pump speed

Figure 1: Distribution of mean blood pump speed

Figure 2: Target UF vs weight change pre- and post-treatment

References

2. Fresenius Medical Care Annual Report 2015
3. Poster presented at the 10th International Congress of the ISHD, Marrakech, September 2016
6. 80(12): 1258-70
7. 8. UK Renal Association Guidelines: