ENHANCEMENT OF SOLUTE CLEARANCE USING EXPERIMENTAL PULSATILE PUSH–PULL DIALYSATE FLOW FOR THE QUANTA SC+: A PERSONAL CLINIC-TO-HOME HAEMODIALYSIS SYSTEM

SC+

Background

SC+ is a high performance, compact, easy-to-use[1] personal haemodialysis system for treating patients with kidney failure. The system has been designed for ease-of-training and use by patients whilst not compromising on clinical performance. SC+ uses standard high flux, bicarbonate-buffered dialysate and widely available, off-the-shelf consumables with dialysate flow rates (Qd) of 500 mL/min.

Haemodialysis (HD), which is based on diffusive clearance, is generally accepted as the standard of care for Renal Replacement Therapy (RRT). Hemodiafiltration (HDF) has been developed as an alternative form of RRT that also includes convective flows as a means of improving middle molecular weight clearance. Various studies suggest there may be clinical benefits to HDF, however the body of evidence so far remains inconclusive[2].

The additional complexity of managing an HDF treatment can create barriers making this inaccessible to self-care and home patients. Quanta has developed a prototype variant of SC+ that delivers convective flows equivalent to HDF without any additional complexity to the user, potentially making this therapy more accessible.

Hypothesis

It is hypothesised that using a prototype variant of the standard SC+ with a modified fluidic management system, the fluid flow through the dialyser could be adapted to generate a pulsatile push–pull flow, thereby enhancing solute transport of middle weight molecules across the dialyser. This will result in equivalent dialysis clearance to existing HDF concepts.

The proposed mechanism has the potential to modify protein fouling of the dialyser membrane to better maintain the dialyser surface area available for solute and fluid transport. Meanwhile, convective flows may enhance solute transfer and improve middle molecule clearance.

Method

The pumping action generated by the prototype SC+ was modified by altering the sequence and timings of the valves and pumps associated with the flow balancing chambers that push and pull dialysate to and from the dialyser.

Ex-vivo solute clearance performance was assessed across a range of molecular weights, using human donor blood, comparing the prototype SC+ alongside a reference device (Nikkiso DBB-05) operating in pre-dilution HDF mode. Rates of clearance of solutes were sampled at various intervals over a 4-hour session.

Discussion

Modifying the valve and pump timings delivers middle weight molecular clearance comparable to HDF, without the need for additional sterile tubing sets and blood pumps. Thus SC+ has the potential to offer performance equivalent to that of the Nikkiso DBB-05 and other existing HDF machines at the simple press of a button.

The pulsatile pumping action generated by SC+ appears to reduce membrane fouling, which in turn may reduce the incidence of nuisance alarms improving usability. This appears to maintain the rate of clearance of the dialyser for the full treatment duration.

While clearance of middle weight molecular toxins is enhanced, albumin levels are not depleted at a rate in excess of HDF.

Results

Aqueous solute clearance data established using urea, creatinine, phosphate and inulin, based on three experiments using the modified SC+ system, were compared with those established using the Nikkiso DBB-05 dialysis system in conventional HD and pre-dilution HDF modes (Table 2). The clearance measurements gathered were in broad agreement with the values specified by the manufacturer for the Leoceed 18H haemodialyser.

Plasma water solute clearances measured at 30, 120 and 240 minutes are shown in Charts 1 and 2. Data are presented as mean ± SD based on five experiments. Comparing the different time points, the modified SC+ shows constant clearances over all time points when compared to the Nikkiso DBB-05. The modified SC+ shows a 16% improvement for Myoglobin overall (30 - 240 minutes) and a 28% increase in the last two hours (120 - 240 minutes).

Mean albumin loss data for the whole study are given in Table 1. The modified SC+ showed lower albumin loss based on five experiments compared to the Nikkiso DBB-05 in pre-dilution HDF mode, but the difference was small and not statistically significant.

		Albumin Lost
Machine	**Mode**	**(g)**
Quanta SC+	Pulsatile Push-Pull HD	0.80 ± 0.49
Nikkiso DBB-05	Pre-dilution HDF	0.88 ± 0.40

Table 1: Albumin loss over 240 minutes

		Aqueous Solute Clearance (mL/min)			
Machine	**Mode**	**Urea**	**Creat-inine**	**Phos-phate**	**Inulin**
Quanta SC+	Pulsatile Push-Pull HD	254 ± 7	239 ± 9	227 ± 9	114 ± 13
Nikkiso DBB-05	Pre-dilution HDF	266 ± 7	249 ± 8	236 ± 7	100 ± 16
Dialyser Data Sheet*	HD	274 ± 7	260	247	n/a

Table 2: Aqueous solute clearances for low molecular weight, *Leoceed 18H Haemodialyser

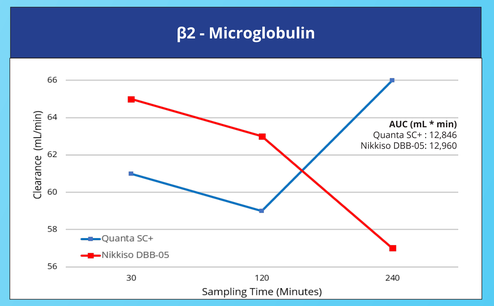

Chart 1: β2 - Microglobulin clearances

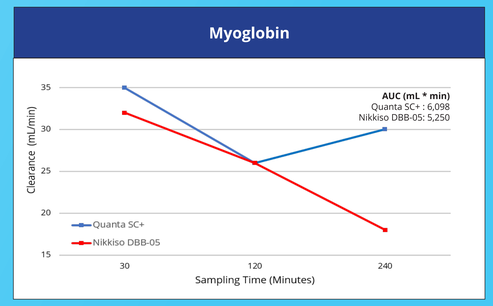

Chart 2: Myoglobin clearances

Conclusion

The pumping action generated by the prototype SC+ demonstrated an enhancement of middle molecular weight clearance comparable with that achieved using pre-dilution haemodiafiltration. This establishes feasibility that a small, easy-to-use, personal haemodialysis system is potentially capable of delivering a therapy comparable to HDF without any added complexity to the user.

The observed enhancement of solute transport is attributed to (1) the push–pull convective flows generated and (2) the disruption of protein fouling along the boundary layers of the fluid-membrane interface, which maintains the surface area available for mass and fluid transport throughout the treatment period.

SC+ is not yet cleared for sale in the USA.

[1]Harasemiw O, Day C, Milad JE, Grainger J, Ferguson T, Komenda P. Human factors testing of the Quanta SC+ hemodialysis system: An innovative system for home and clinic use. Hemodialysis International 2019; DOI:10.0000/hdi.12757
[2]Schiffl, H. Online hemodiafiltration and mortality risk in end-stage renal disease patients: A critical appraisal of current evidence. Kidney Res Clin Pract 2019; 38(2):159-168.

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