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Continuous Veno-Venous Hemodialysis Using the Cardio-Renal Pediatric Dialysis Emergency Machine™: First Clinical Experiences

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Keywords
Continuous veno-venous hemodialysis · Neonates · Infants · Cardio-renal pediatric dialysis emergency machine

Abstract
We report the first worldwide experience with continuous veno-venous hemodialysis (CVVHD) in children using the last generation Cardio-Renal Pediatric Dialysis Emergency Machine (CARPEDIEM)™ device. Thirteen children received 1,008 h of CVVHD during 95 sessions, using a 0.15 ($n = 7$) or a 0.25 m^2 ($n = 6$) hemofilter. The median weight was 3 kg (interquartile range [IQR] 2.5–6.2). In 10 patients, CVVHD was conducted using a 5 Fr double-lumen central vascular access, whereas in 3 children, bigger sizes were used (6.5 and 8 Ch). The median prescribed Qb was 17 mL/min (IQR 10–29.5), with a median Qd of 10 mL/min. Circuits were primed with 5% albumin in 12 out of 13 patients, using anticoagulation with heparin in all 13 cases. The median delivered/prescribed time ratio yielded a 100% result (95–100%). The most common cause for "downtime" was clotting that however occurred in only 3% of all treatments. Survivals at continuous renal replacement therapy discontinuation and ICU discharge were 100 and 69% respectively. The CARPEDIEM™ machine allowed successful delivery of diffusive blood purification modality to very small patients, using small catheters, no blood primes, and excellent concordance between delivered and prescribed treatment duration.

Introduction

The use of continuous renal replacement therapy (CRRT) in neonates was first described by Ronco et al. [1]. Four newborns of ages ranging from 2 to 12 days,

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and with acute kidney injury (AKI) of different etiologies, were treated with a specially modified continuous arteriovenous hemofiltration circuit. In particular, blood lines were shortened in order to reduce the pressure drop and a minifilter (0.005 m^2) was applied in order to optimize transmembrane pressure and ultrafiltration. Further developments took place over the years [2–4], but only recently, the development of new machines for CRRT in neonates and small infants (either adapted or specifically conceived), has transformed infant hemodialysis from an orphan technology to an advanced care [5, 6].

Our group has developed the first dedicated platform for CRRT in infants and children as reported in the literature [7], and in 2014, we described the first-in-human use of a miniaturized Cardio-Renal Pediatric Dialysis Emergency Machine (CARPEDIEM™, Bellco-Medtronic, Mirandola, Italy) to provide a wide range of extracorporeal therapies to newborns and small infants weighting less than 10 kg [8].

In 2014, the Newcastle Infant Dialysis and Ultrafiltration System has been designed to provide single-lumen hemodialysis and ultrafiltration to children weighting between 800 g and 8 kg [9]. In 2016, Askenazi et al. [10] have adapted the Aquadex™ machine to provide predilution continuous venovenous hemofiltration (CVVH) in small children requiring renal support. Furthermore, in the same year, a Japanese group has described the in vitro use of an automated syringe-driven extracorporeal renal replacement therapy system with an ultra-small volume circuit that might be suitable for neonates without blood priming [11]. Nevertheless, the CARPEDIEM equipment has proven to be the most complete and uniquely dedicated platform for CRRT in infants and children with specific features. CARPEDIEM has been initially conceived to perform both pre- and post-dilution CVVH, and – since January 2016 – its hardware, software, and disposable circuits have been implemented to perform both therapeutic plasma exchange [12] and co-current continuous veno-venous hemodialysis (CVVHD) [13].

During CVVHD, solute removal depends on the diffusive movement occurring via Brownian motion of the solute. Small-molecular-weight solutes have greater kinetic energy and are preferentially removed based on the level of their concentration gradient. Therefore, molecules such as creatinine, blood urea nitrogen, potassium and ammonium can be efficiently cleared by hemodialysis, without the limits imposed by filtration fraction. Thus, implementation of a diffusive-based modality in the CARPEDIEM system might expand its use in small children with chronic kidney and metabolic diseases.

Here, we would like to present our first experiences with CARPEDIEM using CVVHD in a group of neonates and small children.

Table 1. Characteristics of the 3 hemodiafilters

Surface area	0.075 m^2	0.15 m^2	0.25 m^2
Fiber internal diameter, μm	250	200	200
Fiber external diameter, μm	350	350	350
Fiber thickness, μm	50	50	50
Fiber length, mm	127	127	140
Number of fibers	840	2,500	4,000
Housing internal diameter, mm	14	19	24
Length, mm	150	155	180
Priming volume, mL			
Filter	5	11	20
Total circuit	27	33	42
Maximum TMP, mm Hg	500	500	500
Maximum flow, mL/min	50	50	50
KUF, mL/h/mm Hg	1.3	3.0	5.5

Methods

We retrospectively collected data from 95 consecutive CVVHD treatments administered to 13 patients between November 2016 and May 2018 in 4 Italian centers, including Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan; University-Hospital of Padua, Padua; Bambino Gesù Children's Hospital, Rome; Regina Margherita Children's Hospital, Turin. Informed consents for data collection and description were obtained from the patient's parents. Each center had followed local institutional practice with respect to timing and criteria for CRRT initiation, termination, and prescription.

A CARPEDIEM machine 2.0 version was used for all treatments. Three different polyethersulfone hemodialyzers are available with different surface areas (0.075, 0.15, and 0.25 m^2) and a total extracorporeal volume ranging from 27 to 42 mL (Table 1). Peristaltic blood pump can run continuously at flows as low as 1–50 mL/min. Dialysis flow rate can be set from 1 to 10 mL/min, with a maximum effluent flow (net ultrafiltration + dialysate) of 20 mL/min. The maximum patient fluid removal is 1,000 mL per treatment, with an accuracy of 1 mL per h.

Results

We examined 95 CVVHD treatments administered to 13 patients with AKI (n = 6), end-stage renal disease (ESRD, n = 4), and metabolic disease (n = 3). Detailed patient data are presented in Table 2. The median age at

Table 2. Clinical details of the 13 infants treated with CVVHD

Case	Gender	Age, days	Weight, g	Diagnosis at hospital admission	CRRT indication	CVVHD			Outcome (survival)	
						filter, m^2	sessions	hours	CRRT course	hospital discharge
1	F	9	2,300	Metabolic disease	Hyperammonemia	0.25	2	27	Yes	No
2	M	8	2,480	ESRD (CAKUT)	Severe hyperkaliemia	0.15	1	22.5	Yes	Yes
3	F	848	8,800	ESRD (CAKUT)	Radiocontrast procedure	0.25	1	6	Yes	Yes
4	M	53	6,200	Hemofagocitosis (distributive shock)	Fluid overload	0.25	25	467	Yes	No
5	F	7	1,950	Cardiopathy	Fluid overload	0.15	17	279	Yes	Yes
6	F	1,247	10,000	HUS	AKI	0.25	6	36	Yes	Yes
7	F	3	3,000	Birth asphyxia	AKI	0.15	2	9	Yes	Yes
8	M	7	2,500	Fetal tachyarrhythmia	AKI	0.15	2	35	Yes	Yes
9	M	165	5,400	ESRD (primary hyperoxaluria)	Improving oxalate clearance	0.15	20	60	Yes	Yes
10	M	1,755	13,000	ESRD (unknown)	Fluid overload	0.25	2	12	Yes	Yes
11	M	2	1,940	Metabolic disease	Hyperammonemia	0.15	1	12	Yes	No
12	M	4	2,560	Metabolic disease	Hyperammonemia	0.25	1	11	Yes	Yes
13	M	41	3,400	Cardiopathy	Fluid overload	0.15	15	320	Yes	No

CVVHD, continuous veno-venous hemodialysis; CRRT, continuous renal replacement therapy; ESRD, end-stage renal disease; CAKUT, congenital anomaly of kidney and urinary tract; HUS, hemolytic-uremic syndrome; AKI, acute kidney injury.

CRRT start was 9 days (interquartile range [IQR] 7–165) and median body weight was 3,000 g (IQR 2,480–6,200). All but 4 patients started CRRT within 3 months of life. Ten patients were critically ill and admitted to pediatric intensive care units, whereas 3 patients (all affected by chronic kidney disease) were treated electively within the pediatric nephrology units. All 4 ESRD patients were already on peritoneal dialysis: 1 patient (case 2) required extracorporeal therapy because of severe hyperkalemia, 1 patient (case 3) received a 6-h CVVHD session after a radiocontrast procedure, 1 patient (case 9) affected by primary oxalosis received 20 sessions to increase oxalate removal, and 1 patient (case 10) required acute CVVHD initiation because of pulmonary edema with 12% fluid overload. Three neonates with hyperammonemia were treated 48 (case 11), 96 (case 12), and 216 (case 1) hours after birth. In patients with AKI, the median fluid overload at CVVHD start was 5% (IQR 8.5–20.5%).

Albumin 5% was used to prime the extracorporeal circuits in 12 cases; in the remaining patient, the circuit was primed with normal saline only. There was no need for blood priming with the small volume filters and line sets. In all treatment sessions, hemodynamic stability (less than 20% modification of systolic arterial pressure with respect to baseline) was reported at initiation and during the course of treatment. The anticoagulation procedure for all treatments was performed with unfractioned heparin administered continuously at a median dosage of 25 IU/kg/h (IQR 10–40) to achieve a systemic target activated clotting time of 180–220 s.

Data about central venous lines (CVL) and dialysis prescription are reported in Table 3. In 10 out of 13 patients, vascular access was achieved by a 5 Ch double-lumen venous catheter, mainly placed in the right internal jugular vein. In 1 patient, a 6.5 Ch catheter was utilized and in 2 cases, an 8 Ch catheter was used. The median

Table 3. Dialysis parameters

Case	CVL		Qb		Qd, mL/min	Prescribed: delivered ratio	Cause of treatment downtime
	location	size (Ch)	mL/min	mL/kg/min			
1	RIJV	5	10	4.3	10	1.00	
2	RIJV	5	10	4.2	10	0.94	Coagulation
3	RIJV	5	14	1.6	10	1.00	
4	RFV	5	10	1.6	10	0.96	Coagulation (2/25 sessions)
5	LIJV	5	20	10.3	10	0.58	High pre-filter pressure and CVL dysfunction
6	LFV	6.5	50	5	10	1.00	
7	LFV	5	30	10	10	1.00	
8	RIJV	5	30	12	10	1.00	
9	LIJV	8	50	9.3	10	1.00	
10	LIJV	8	50	3.8	10	1.00	
11	RIJV	5	30	15.5	10	1.00	
12	RIJV	5	28	10.9	10	1.00	
13	RIJV	5	10	2.9	2	0.89	CVL dysfunction

CVL, central venous line; RIJV, right internal jugular vein; LIJV, left internal jugular vein; RFV, right femoral vein; LFV, left femoral vein.

blood flow rate (Qb) resulted of 5 mL/kg/min (IQR 3.8–10.2); the prescribed dialysate flow rate (Qd) was 600 mL/h in 12 patients and 120 mL/h in one. In 4 out of 13 patients, dialysis prescription was applied intermittently for 3–6 h, while in the remaining cases, it was a continuous procedure. Intermittent renal replacement therapy was prescribed to 3 out of 4 ESRD patients (case 3, 9, and 10); moreover, 6 sessions of 6 h were prescribed to a 2.5-years-old patient admitted because of a Verocytotoxin-producing *Escherichia coli* hemolytic-uremic syndrome (case 6).

In AKI and ESRD patients, median serum blood urea nitrogen was 97 mg/dL (IQR 68.5–168.5) at the start of CVVHD and 25 mg/dL (IQR 25–92.5) after the first session; median serum creatinine was 4.3 mg/dL (IQR 3.7–5.6) at the start of CVVHD and 2.1 mg/dL (IQR 1.9–2.9) at the end of the first session (Fig. 1). In the 3 patients with hyperammonemia, 50% reduction of ammonia was achieved within 12 h of CRRT: in particular, after 1 dialysis session, ammonia decreased from 713 to 189 μmol/, 1,443 to 358 μmol/L, and 514 to 91 μmol/L in case 1, case 11 and case 12 respectively.

The median CVVHD duration was 27 h (IQR 12–60), with a median prescribed/delivered ratio of 100% (IQR 96–100). At the start of treatments, median arterial and venous circuit pressure values were –65 mm Hg (IQR –85 to –50) and +50 mm Hg (IQR +25 to +60) respectively; at the end of treatments, median arterial and venous pressure values were –75 mm Hg (IQR –100 to –60) and +50 mm Hg (IQR +40 to +75) respectively (Fig. 2). Causes of downtime were clotting in 3/95 sessions (3%) and CVL dysfunction in 2 patients. In 1 patient (case 5), Qb was set at high values (median of 10.3 mL/kg/min), resulting in several high pre-filter pressure alarms and a subsequent significant treatment downtime (prescribed/delivered ratio of 58%).

Among the overall cohort of patients, all survived their CVVHD course, while survival to hospital discharge was 69% (9/13). Two patients with hyperammonemia due to urea cycle disorders died because of encephalopathy (cases 1 and 11), 1 patient died because of multi-organ dysfunction in the context of hemophagocytic lymphohistiocytosis (case 4), and 1 patient died during the course after the surgical procedure for pulmonary atresia with intact ventricular septum (case 13).

Discussion

The optimal modality for pediatric CRRT has not been defined yet. The choice to use diffusive (CVVHD) or convective (CVVH) therapies is based more on contingent aspects than on specific outcome data. The possibility to achieve adequate small solute clearances with a diffusive modality eliminates the requirement of high blood flows in case of convective mode (to limit filtration fraction), and this is likely to improve filter life [14]. This concept is particularly emphasized when very low Qb are available, as is the case of neonatal and infant CRRT due to small indwelling catheters. Furthermore, in case of hyper-

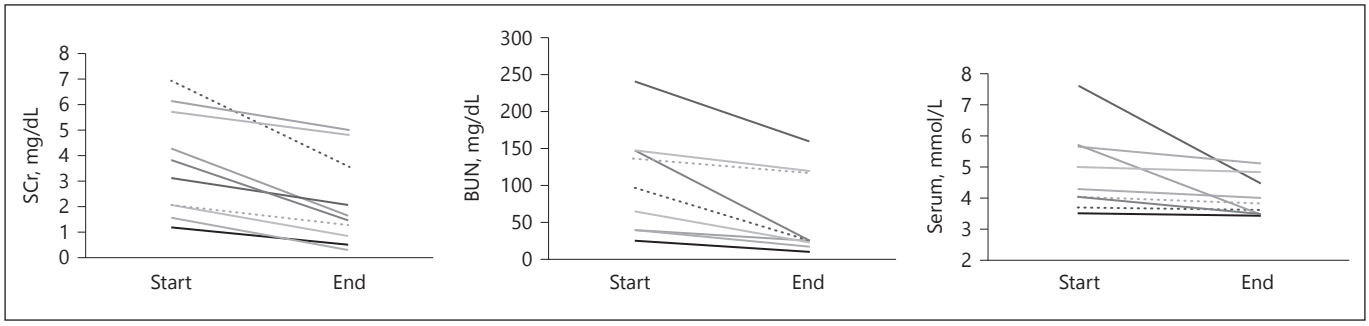

Fig. 1. Changes in serum creatinine (SCr), blood urea nitrogen (BUN), and serum potassium during the first dialysis session in the AKI and ESRD cases.

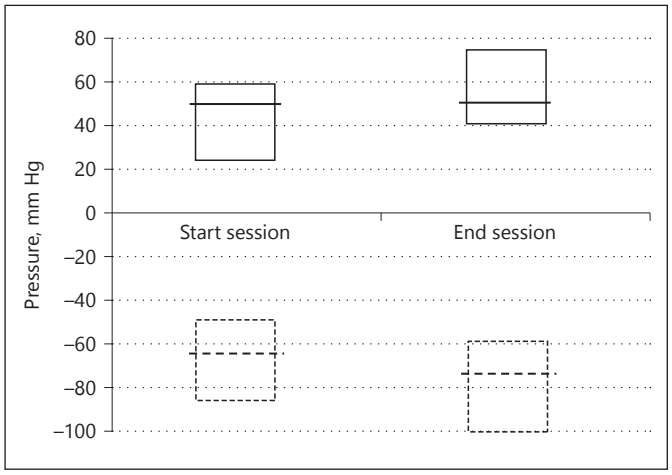

Fig. 2. Extracorporeal circuit pressures at the beginning and the end of CVVHD sessions. Data are expressed as median and IQR. Negative values (and dotted lines) refer to arterial pressure; positive values (and continuous lines) refer to venous pressure.

catabolic states or other severe metabolic disorders, small patients might require relatively higher solute clearances as compared with older children [15]. As a consequence, although presenting some beneficial aspects such as larger solute clearances, convective therapies in small children may result in limited blood purification efficiency for small solutes and insufficient clearances. These considerations also apply to the new CARPEDIEM equipment. Originally designed for convective therapies only and CVVH in patients below 10 kg of body weight, the CARPEDIEM equipment has now been implemented with a new software and circuit designed for CVVHD. This was achieved with a specific blood and dialysate circuit layout to reduce complexity and length of blood lines and circuitry. In a previous study, we demonstrated that such co-current blood-to-dialysate CVVHD configuration resulted in the desired enhancement of small solute clearance compared to CVVH [13].

In this study, we describe the first results of the in vivo utilization of CVVHD with CARPEDIEM. The new machine allowed successful delivery of continuous and intermittent diffusive blood purification modality to very small-sized patients, using small CVLs, no blood primes, and excellent concordance between delivered and prescribed treatment duration.

CRRT in neonates and infants requires a high precision of fluid balance and hemodynamic stability. In a case series of 174 children requiring CRRT, hypotension on connection was detected in 53 patients (30.4%) [16]. Extracorporeal circuit priming volume ideally should not exceed 10% of a patient's circulating blood volume in order to avoid acute blood depletion from the circulation at the start of the extracorporeal treatment. When priming volume exceeds 10% of circulating volume of the patient, a pre-filling of the circuit with blood is strongly recommended [17]. As an example, a 3-kg neonate requiring CRRT would have an overall blood volume of about 240 mL. Existing adult machines with pediatric set circuits have an extracorporeal prime volume in the range of 59–100 mL, thus exceeding the safe extracorporeal volume. The CARPEDIEM machine has a circuit layout designed to avoid blood priming and thus patient size rather than performance dictates the optimal filter selection (Table 1). In our experience, neither patient required a blood prime nor hypotensive episodes were recorded at the time of connection and CRRT initiation.

A prerequisite for the successful deployment of extracorporeal CRRT is adequate circuit blood flow. Difficulty in attaining adequate vascular access in small children has consistently been viewed as a major barrier to the use of CRRT. The experience from the Pediatric Prospective

CRRT Registry has confirmed that functional CRRT circuit survival in children is favored by a larger catheter diameter, and the use of catheters smaller than 7 Ch has been discouraged [18]. However, complications of catheterization are more common in small children because of the technical difficulties and catheter caliber used in infants, proportionally larger than in older children [14]. Moreover, larger catheters relative to vessel size have the additional risk of causing central vessel stenosis, and this can significantly impact the dialysis options of ESRD neonates and infants who will have a long history of renal replacement therapy ahead of them. The CARPEDIEM machine is coupled with a 3-miniaturized-rollers-peristaltic pump that allows very low stroke volumes, facilitating the management of flows also in small CVLs as compared with a classical adult 2-rollers pump. In our clinical experience, this facilitated the possibility to operate with a 5-Ch catheter and with a Qb in the range of 2–15 mL/kg/min.

In our series, solute control resulted adequate in both AKI/ESRD and metabolic patients. Due to high depurative needs, Qd was set at a maximum level (10 mL/min) in a majority of cases. However, it should be emphasized that a high dialysate flow rate places infants at risk of excessive drug and solute clearance and disequilibrium [15]. Our in vitro study already showed that lower Qd values can be set when the use of CVVHD is not determined by a high dialysis dose requirement but by a limited blood flow rate [13].

Our study is retrospective in nature and therefore presents limitations related to the non-prospective data collection. Nevertheless, data are fully and accurately recorded during treatments in such small patients and this guarantees a real "field-test" for the equipment in different conditions. The analyzed sample is small, although this is typical for a pediatric population and similar to other studies previously reported in the literature [9, 10, 19, 20]. The possibility to treat such infants with a simplified and safe new method will also induce in the future the treating physician to apply CVVHD earlier and for extended indications.

In conclusion, CVVHD with the CARPEDIEM machine appeared to be a safe and effective modality in a heterogeneous group of critically and non-critically ill neonates and infants. It is possible that the application of CVVHD instead of CVVH with the new CARPEDIEM equipment will further facilitate the application of extracorporeal blood purification in such patients, not only in case of extreme clinical condition (i.e., rescue therapy for patients with severe fluid overload and peritoneal dialysis failure) but also for other indications requiring timely CRRT start, such as fluid balance control, hyperammonemia, drug intoxication, and short transient oliguric states with hypercatabolic complications.

Ethics Statement

Informed consent for data collection and description was obtained from the patient's parents.

Disclosure Statement

The authors declare that they have no conflicts of interest to disclose.

Author's Contribution

E.V. collected data, analyzed data and drafted the paper. E.C., F.P., Z.R., F.G., L.P., and L.M. collected data and drafted the paper. C.R. provided critical revision of the manuscript. All authors read and approved the final manuscript.

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