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The accuracy of a continuous volumetric balancing system in pediatric continuous renal replacement therapy

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Abstract

Background—In pediatric continuous renal replacement therapy (CRRT) patients, accurate ultrafiltration (UF) measurement is essential, as both over- and under-UF may result in suboptimal outcomes. Traditionally, CRRT has relied on scale-based UF measurements; however, the recent development of a continuous volumetric balancing system has allowed for the advent of scale-less CRRT.

Methods—To assess the accuracy of the volumetric balancing system, we designed a continuously measuring digital scale, which accounted for dialysate use and collected effluent, allowing us to independently measure UF volume and compare it with the machine reported UF volume.

Results—In four low weight (6.9–16.7 kg) pediatric CRRT patients, we measured the UF volume over 20 separate runs, comprising a total of 318 hours. Over this time, the total measured UF volume was 50,550 mL $\pm$ 296 mL, whereas the total reported UF volume was 50,733 mL, a difference of 183 mL $\pm$ 296 mL (0.6 $\pm$ 0.9 mL/hr), or 0.4 $\pm$ 0.6%. For each patient, over 48–112 hours per patient, the differences between the total measured and total reported UF volumes ranged from -7.8 ± 1.7 mL/hr to $+9.7 \pm 1.8$ mL/hr, or $-6.0 \pm 1.3\%$ to $+5.4 \pm 1.0\%$.

Conclusion—In low weight pediatric CRRT patients, the scale-less continuous volumetric balancing system delivers accurate ultrafiltration over prolonged periods of time.

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Disclosures

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Keywords

Ultrafiltration; Hemodialysis; Pediatrics; Acute kidney injury

Introduction

In pediatric acute kidney injury (AKI) patients, continuous renal replacement therapy (CRRT) is widely used to manage fluid and electrolyte abnormalities. Studies have shown that both fluid overload [1] and hypotension [2] at dialysis initiation are independent risk factors for mortality in pediatric CRRT patients. It is likely that continued intradialytic fluid overload and/or hypotension is also associated with poor outcomes in this population. As such, proper volume management, appropriate ultrafiltration (UF), and the accurate measurement of UF during CRRT are important, as both under-UF, possibly resulting in fluid overload, and over-UF, possibly resulting in hypotension, may lead to suboptimal outcomes. Smaller patients are especially at risk, as slight UF errors may result in relatively large changes in fluid balance and/or hemodynamic status.

In order to achieve the appropriate UF volume during CRRT, scale-based technology, allowing for the direct measurement of ultrafiltrate, has traditionally been used. However, a CRRT machine (NxStage® System One™, Lawrence, MA) that utilizes a scale-less, continuous volumetric balancing system has been available for use since 2004 [3]. Within the machine cartridge, coupled replacement fluid and waste pumps continuously fill dual volumetric balancing chambers, while a UF pump enables net fluid removal [4]. *In vitro* simulations have demonstrated the accuracy of the volumetric balancing system; however, it has not been evaluated *in vivo* in low weight pediatric patients, a population in which inaccurate UF may be most likely to adversely affect clinical status. Thus, in order to assess the *in vivo* accuracy of the volumetric balancing system in small pediatric patients, we designed a continuously measuring digital scale, which accounted for dialysate use and collected effluent, allowing us to independently measure UF volume and compare it with the UF volume reported by the dialysis machine. We hypothesize that the volumetric balancing system UF is accurate to within 10% of our gravimetric UF measurements.

Materials and Methods

We constructed a two-tier, hanging, continuously measuring digital scale (Figure 1). The digital scale (25 kg capacity or 45 kg capacity Salter Brecknell® ElectroSamson™ models (Fairmont, MN), accurate to ± 0.02 kg and ± 0.05 kg, respectively) hung from a six foot tall aluminum pole on wheels. From the scale's hook, we hung a two-tier, multi-armed IV pole that was able to hold dialysate bags and effluent collection bags.

Up to four 5-liter Prisma™ dialysate solution bags (Gambro®, Daytona Beach, FL) were hung from the upper level of the IV pole. At all times, the only dialysate running into the machine was from the dialysate bags hanging from the scale. From the bottom level, up to four 5-liter bags were hung to collect the dialysate effluent (Figure 2). We connected the effluent drainage line to the effluent collection bags using the branched dialysate tubing. As we connected the effluent drainage line to the effluent collection bags, we noted the weight

displayed on the digital scale, ensuring that all of the bags were freely hanging and not in contact with the scale apparatus pole. We also noted the time, as shown on the machine's display. Several hours later, at the end of the run, we noted the digital scale weight and the machine time, then disconnected the effluent line from our collection bags. As only dialysate hanging from the scale flowed into the machine, and as all effluent was collected in our collection bags, the difference between the weight at the beginning of the run and the weight at the end of the run represented the weight of ultrafiltrate removed from the patient. Using the machine's on-screen history function, we calculated the reported UF over the same time period, then compared our directly measured UF weight to the UF volume reported by the machine.

In order to validate the accuracy of our scale, in one patient, we also used a 20 kg capacity digital infant scale, accurate to ± 0.005 kg, to directly measure UF weight. Before each run using the infant scale, full dialysate bags and empty effluent collection bags were weighed on the infant scale. At the end of the run, the empty dialysate bags and full effluent collection bags were again weighed on the infant scale. The difference between the weight at the beginning of the run and the weight at the end of the run represented the weight of ultrafiltrate removed from the patient, which we compared to the UF volume reported by the machine over the same time period.

Four pediatric continuous veno-venous hemodialysis (CVVHD) patients were enrolled in the study; all were on the NxStage[®] machine with the hemofilter 400. For each patient, multiple runs were conducted. The measured UF weights from each run, with their associated measurement errors, ranging from ± 0.005 kg to ± 0.05 kg depending on the scale used, were added together. For each patient, and for all patients cumulatively, we calculated the difference between the total measured UF and the total reported UF by the machine in mL, mL/hr, mL/kg/hr, and percentage difference. The percent fluid balance error for each patient was calculated via the following formula: (machine reported UF – measured UF in liters) / weight in kg $\times 100\%$. Results are reported as sums or differences, with associated errors. Linear regression was used to assess the relationship between measured and reported UF values. Bland-Altman analysis was used to compare the two measurement techniques (volumetric vs. gravimetric UF).

Results

Table 1 shows patient characteristics and CRRT parameters. UF rates varied and were changed as needed by the patient's primary care team; over the course of the study, actual ultrafiltration rates ranged from approximately 15 to 21 mL/kg/hr. Four to six runs were conducted for each patient, ranging in length from 4 to 26 hours, with a total of 20 independent runs. Table 2 shows the differences between measured and machine reported UF, for each run, for each patient, and cumulatively.

Over the cumulative 318 hours that data was collected, the measured UF volume was $50,550 \pm 296$ mL, and the reported UF volume was $50,733$ mL; the difference was $183 \text{ mL} \pm 296 \text{ mL}$ (0.6 ± 0.9 mL/hr), or $0.4 \pm 0.6\%$. For each of the 20 runs, the reported UF volume correlated well with the measured UF volume ($R^2 = 0.99$) (Figure 3). The Bland-Altman

plot shows little systemic bias (mean difference of only +1.7 mL/hr) and no proportional bias ($R^2 = 0.05$) (Figure 4). Among the enrolled patients, the individual differences between machine reported UF and measured UF ranged from -7.8 ± 1.7 mL/hr to $+9.7 \pm 1.8$ mL/hr, or $-6.0 \pm 1.3\%$ to $+5.4 \pm 1.0\%$ (machine reported UF volumes ranging from 6% less than to 5.4% greater than the actual UF volumes). These UF discrepancies translated into percent fluid balance errors for each patient ranging from $-9.9 \pm 2.2\%$ (over 93 hours) to $+5.8 \pm 1.1\%$ (over 48 hours).

For the patient in whom we also used the infant scale, accurate to ± 5 grams, we conducted eight independent runs, ranging in length from 7 to 20 hours. The total run time was 108 hours, over which the measured UF volume was $15,605 \pm 25$ mL, and the reported UF volume was 15,712 mL; the difference was 107 ± 25 mL (1.0 ± 0.2 mL/hr), or $0.7 \pm 0.2\%$, thus showing our hanging scale apparatus to be as accurate as the infant scale (data not shown).

Discussion

In order to optimize outcomes, and minimize continued fluid overload and/or hypotension, recent attention has focused on eliminating the potential for either inadequate or excessive ultrafiltration during CRRT. Our novel, two-tier, continuously measuring digital scale allowed us to assess the ultrafiltration accuracy of a volumetric balancing fluid management system. This *in vivo* study demonstrates that this volumetric balancing system provides accurate ultrafiltration, over prolonged periods of time, in small pediatric CRRT patients.

Appropriate fluid management in low-weight pediatric AKI patients is critical. Observational studies of pediatric AKI patients requiring CRRT have found that fluid overload [1, 5–7] at CRRT initiation is associated with increased morbidity and mortality. In a multicenter prospective study of 297 children requiring CRRT, Sutherland et al found that patients with at least 20% fluid overload had an adjusted mortality rate over eight times that of patients with less than 20% fluid overload [1]. As excessive fluid administration may contribute to fluid overload and suboptimal outcomes in AKI patients, fluid should be considered a drug, with dose modifications made based on AKI etiology (pre-renal vs. intrinsic) and AKI stage (early vs. established). The degree of fluid overload in AKI patients should be calculated and monitored over time. In this manner, quantifying fluid overload may help guide clinical management, aiding physicians in modifying IV fluid regimens, deciding when to initiate renal replacement therapy, and establishing ultrafiltration goals.

In addition to fluid overload, hypotension at dialysis initiation is a risk factor for morbidity and mortality in pediatric CRRT patients [2]. Furthermore, intradialytic hypotension, which may be contributed to by excessive ultrafiltration, is associated with increased morbidity and mortality in dialysis patients [8,9]. As such, ultrafiltration rates and fluid status goals much be constantly re-assessed, aiming to avoid both inadequate and excessive ultrafiltration, which may contribute to continued fluid overload or intradialytic hypotension, respectively, resulting in worsened clinical outcomes.

Appropriate ultrafiltration management in CRRT patients depends on accurate ultrafiltrate measurement. *In vitro* simulations of the volumetric balancing system, targeting 4 kilograms of net fluid removal over 12–24 hours, found that daily fluid balance was accurate within 0.5 kilograms, and that the average hourly fluid balancing accuracy was 9.2 ± 14.8 mL/hr [10]. Although smaller UF volumes were targeted in our patients, our *in vivo* results are similar to these simulations. Furthermore, the percentage UF differences for each run ranged from $-8.4 \pm 2.7\%$ to $+7.7 \pm 1.4\%$, and for each patient ranged from $-6.0 \pm 1.3\%$ to $+5.4 \pm 1.0\%$, all within the product specified UF accuracy of $\pm 10\%$ [11].

The patient percent fluid balance errors ranged from $-9.9 \pm 2.2\%$ (over 93 hours) to $+5.8 \pm 1.1\%$ (over 48 hours), representing an actual percent fluid balance ranging from 9.9% more negative to 5.8% more positive than that calculated with machine reported values. The hourly patient percent fluid balance errors ranged from $-0.11 \pm 0.02\%$ to $+0.12 \pm 0.02\%$. As CRRT may be provided for days at a time, the additive effects of these percent fluid balance errors may become significant; however, it is unlikely that the magnitude and direction (positive or negative) of the hourly percent fluid balance error would remain constant over time.

Two technical issues with our scale design should be mentioned. Firstly, we did not account for the effluent in the tubing between the dialysis cartridge and the effluent collection bags. Although this was likely a relatively small volume of fluid, it may have contributed to slight underestimations of our gravimetric UF values. Secondly, we compared the measured UF weight to the reported UF volume, assuming that the effluent density was 1 g/mL. However, at room temperature (20–25 degrees Celsius), the density of water ranges from 0.9970 g/mL to 0.9982 g/mL. Assuming that the density of the collected effluent is identical to that of water (slightly less than 1 g/mL), then our measured UF volumes should actually be slightly higher.

One limitation of our study is that we included only four patients; however, with these four patients, we conducted a total of 20 independent runs using the scale, amounting to 318 total hours of data. Another limitation of our study is that we did not directly compare the scale-less volumetric balancing system to a scale-based CRRT system. Although future studies could explore this issue, given the UF accuracy demonstrated here, it is unlikely that a clinically significant difference would be found in favor of either system. However, there are some potential advantages in utilizing a scale-less system, such as the ability to pre-hang dialysate bags, or simply add bags as needed, and the lack of effluent collection required. Additionally, conventional scales are sensitive to movement and other environmental disturbances which may affect accuracy. These practical comparisons were not addressed in the current study.

Conclusions

In summary, this study demonstrates that the *in vivo* ultrafiltration accuracy of the volumetric balancing system is comparable to *in vitro* studies and within the limits of the product-specified UF accuracy. Although future studies are needed in order to explore the

possible practical advantages of using a scale-less CRRT system, the volumetric balancing system provides accurate UF in the management of small children with acute kidney injury.

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Informed Consent:

Approval of the Institutional Review Board was obtained. The study was approved by the UCLA Human Subject Protection Committee, and informed consent was obtained from all parents.

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Figure 1.

In order to assess the accuracy of the scale-less volumetric balancing system, we designed a two-tier, hanging, continuously measuring digital scale.

Figure 2.
Dialysate solution bags were hung from the top level, and effluent collection bags were hung from the bottom level. This scale design accounted for dialysate use and collected effluent.

Figure 3. Linear regression plot of the machine reported and measured ultrafiltrate (UF) volumes, with line of best fit displayed.

Figure 4. Bland-Altman plot comparing the differences between the machine reported (volumetric) and measured (gravimetric) ultrafiltrate (UF) values. Mean bias is denoted by the solid line, and the limits of agreement are denoted by the dotted lines.

Patient characteristics and CRRT parameters. Qb: blood flow rate; Qd: dialysate flow rate; HD cath: size and position of hemodialysis catheter; RCA: regional citrate anticoagulation; HRS: hepatorenal syndrome; Percent FO: percent fluid overload at hemodialysis initiation; Pre BUN: pre-hemodialysis blood urea nitrogen; Pre Cr: pre-hemodialysis creatinine.

Table 1

Pt	Age (mo)	Weight (kg)	Qb (mL/min)	Qd (mL/hr)	HD Cath	RCA	AKI Etiology	Percent FO	Pre BUN (mg/dL)	Pre Cr (mg/dL)
1	9	8.0	40	500–1000	8F Ax	Yes	HRS	40%	56	1/0
2	64	16.7	60	700	8F RIJ	Yes	Hypovolemic shock	Unknown	72	3.5
3	14	7.3	30–40	500–600	8F RIJ	Yes	Septic shock	43%	105	2.2
4	11	6.9	30	500–600	8F RIJ	Yes	HRS	99%	58	1.8

Table 2

Run data. Measured UF and differences between measured UF and machine UF are reported as sums or differences $\pm$ associated errors.

Patient	Run	Time (hr)	Machine UF (mL)	Measured UF (g)	Difference (mL)	Difference (%)	Difference (mL/hr)	Difference (mL/kg/hr)	Percent Error (Diff/Wt $\times$ 100)
1	1	4	655	620 $\pm$ 28	35 $\pm$ 28	5.3 $\pm$ 4.2	8.8 $\pm$ 7.0	1.1 $\pm$ 0.9	
	2	8	1255	1200 $\pm$ 28	55 $\pm$ 28	4.4 $\pm$ 2.2	6.9 $\pm$ 3.5	0.9 $\pm$ 0.5	
	3	12	2037	1880 $\pm$ 28	157 $\pm$ 28	7.7 $\pm$ 1.4	13.1 $\pm$ 2.3	1.6 $\pm$ 0.3	
	4	24	4567	4350 $\pm$ 71	217 $\pm$ 71	4.8 $\pm$ 1.6	9.0 $\pm$ 2.9	1.1 $\pm$ 0.4	
Total		48	8514	8050 $\pm$ 86	464 $\pm$ 86	5.4 $\pm$ 1.0	9.7 $\pm$ 1.8	0.2 $\pm$ 0.04	5.8 $\pm$ 1.1
2	1	12	3021	3000 $\pm$ 71	21 $\pm$ 71	0.7 $\pm$ 2.4	1.8 $\pm$ 6.1	0.1 $\pm$ 0.3	
	2	8	1851	1800 $\pm$ 71	51 $\pm$ 71	2.8 $\pm$ 3.9	6.4 $\pm$ 8.9	0.4 $\pm$ 0.6	
	3	16	4497	4500 $\pm$ 71	-3 $\pm$ 71	-0.1 $\pm$ 1.6	-0.2 $\pm$ 4.7	-0.01 $\pm$ 0.2	
	4	7.5	1868	1800 $\pm$ 71	68 $\pm$ 71	3.6 $\pm$ 3.8	9.1 $\pm$ 9.5	0.5 $\pm$ 0.5	
	5	15.75	4016	4000 $\pm$ 71	16 $\pm$ 71	0.4 $\pm$ 1.8	1.0 $\pm$ 4.4	0.06 $\pm$ 0.3	
	6	6.5	1218	1200 $\pm$ 71	18 $\pm$ 71	1.5 $\pm$ 5.9	2.8 $\pm$ 11	0.2 $\pm$ 0.8	
Total		65.75	16,471	16,300 $\pm$ 173	171 $\pm$ 173	1.0 $\pm$ 1.0	2.6 $\pm$ 2.6	0.2 $\pm$ 0.2	1.0 $\pm$ 1.0
3	1	18	2690	2800 $\pm$ 71	-110 $\pm$ 71	-4.1 $\pm$ 2.6	-6.1 $\pm$ 3.9	-0.8 $\pm$ 0.5	
	2	11	1628	1750 $\pm$ 71	-122 $\pm$ 71	-7.5 $\pm$ 4.4	-11.1 $\pm$ 6.5	-1.5 $\pm$ 0.9	
	3	17.75	2207	2300 $\pm$ 71	-93 $\pm$ 71	-4.2 $\pm$ 3.2	-5.2 $\pm$ 4.0	-0.7 $\pm$ 0.5	
	4	22.25	2928	3100 $\pm$ 71	-172 $\pm$ 71	-2.5 $\pm$ 1.0	-7.7 $\pm$ 3.2	-1.1 $\pm$ 0.4	
	5	24	2675	2900 $\pm$ 71	-225 $\pm$ 71	-8.4 $\pm$ 2.7	-9.4 $\pm$ 3.0	-1.3 $\pm$ 0.4	
Total		93	12,128	12,850 $\pm$ 158	-722 $\pm$ 158	-6.0 $\pm$ 1.3	-7.8 $\pm$ 1.7	-1.1 $\pm$ 0.2	-9.9 $\pm$ 2.2
4	1	25	2558	2400 $\pm$ 71	158 $\pm$ 71	6.2 $\pm$ 2.8	6.3 $\pm$ 2.8	0.9 $\pm$ 0.4	
	2	23	2849	2700 $\pm$ 71	149 $\pm$ 71	5.2 $\pm$ 2.5	6.5 $\pm$ 3.1	0.9 $\pm$ 0.4	
	3	14	1749	1650 $\pm$ 71	99 $\pm$ 71	5.7 $\pm$ 4.1	7.1 $\pm$ 5.1	1.0 $\pm$ 0.7	
	4	23.5	2817	2900 $\pm$ 71	-83 $\pm$ 71	-2.9 $\pm$ 2.5	-3.5 $\pm$ 3.0	-0.5 $\pm$ 0.4	
	5	26	3647	3700 $\pm$ 71	-53 $\pm$ 71	-1.5 $\pm$ 1.9	-2.0 $\pm$ 2.7	-0.3 $\pm$ 0.4	
Total		111.5	13,620	13,350 $\pm$ 158	270 $\pm$ 158	2.0 $\pm$ 1.2	2.4 $\pm$ 1.4	0.3 $\pm$ 0.2	3.9 $\pm$ 2.2
Cumulative	20	318.25	50,733	50,550 $\pm$ 296	183 $\pm$ 296	0.4 $\pm$ 0.6	0.6 $\pm$ 0.9	n/a	n/a