Accurate Fluid Balancing with a Novel Volumetric Control System

Goetz Friederichs, Ph.D.[1], Patrick Murray, M.D.[2], Michael Kraus, M.D.[3], and Kyle Ellsworth, M.S.[1]

[1]R&D NxStage Medical, Inc., Lawrence MA; [2]University of Chicago, Chicago IL; and [3]Indiana University, Indianapolis IN.

Introduction

Recent publications describe benefits of high volume CRRT therapy (>35 mL/kg/hr, or nearly 65 L daily for a 75 kg patient). (Ronco et al. Lancet 2000). As volume increases, so does the importance of accurate fluid balancing. In addition, ease of fluid handling is essential to minimize nursing interventions.

Scale-based systems, prevalent today, are accurate but have shortcomings exacerbated in high volume applications. Effluent must be collected to monitor balance. Scale capacity limitations make frequent solution and effluent bag changes necessary. In addition, scales are sensitive to user error, movement, and other operating environment disturbances.

The System One from NxStage Medical incorporates a novel continuous volumetric balancing approach and the ability to deliver high volumes of therapy (Q_B: up to 600 mL/min, Q_{UF}: up to 14.4 L/hour). Volumetric balancing eliminates the need to collect effluent and thus reduces the frequency of fluid-related interventions. Incorporating the volumetric balancing circuit into a disposable cartridge simplifies setup and maintenance.

Objective

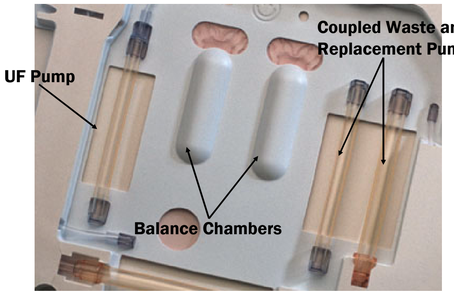
Characterize the accuracy of the NxStage System One volumetric fluid balancing system under intensive care therapy conditions.

Methods

The overall patient fluid balance in the NxStage System One is managed by a volumetric system. The disposable NxStage Cartridge showing the UF pump and the coupled replacement and waste pumps are depicted in Figure 1.

The In-vitro conditions were defined to represent high-volume CRRT (64 liters over 24 hours), “conventional” volume CRRT (44 liters over 24 hours) and extended daily therapy (44 liters over 12 hours). The “patient” was simulated using a measured volume of fluid. Each condition was repeated 6 times (twice each on three NxStage systems). Blood flows were 250 mL/min, and 4 kg of net fluid removal was targeted.

Figure 1: System One Cartridge



Results

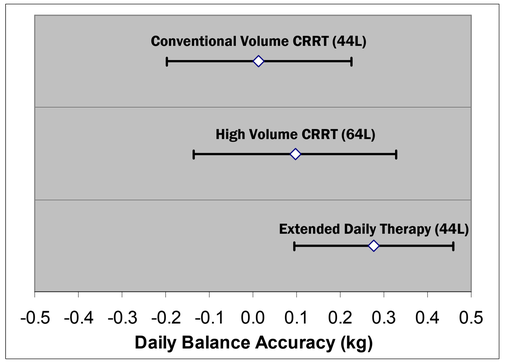
Accuracy is expressed as the difference between actual and targeted patient weight at the end of the simulation, both in absolute volume and as a percentage of therapy volume. The results are shown in Table 1 and Figure 2.

In all tests, daily fluid balance was accurate within 0.5 kilogram. Average hourly fluid balancing accuracy was 9.2 ± 14.8 mL/hr.

Table 1: Fluid Balance Accuracy Results

Condition	N	Difference Actual vs. Target Average ± Stdev(kg)	Percentage of total therapy volume Average ± Stdev(%)
Conventional volume CRRT (44L)	6	0.01 ± 0.21	0.03 ± 0.34
High volume CRRT (64L)	6	0.10 ± 0.23	0.15 ± 0.36
Extended daily therapy (44L)	6	0.28 ± 0.18	0.63 ± 0.48
Overall	18	0.13 ± 0.23	0.27 ± 0.48

Figure 2: Fluid Balance Accuracy Results (n = 18, Average and StDev)



Discussion

The volumetric fluid balancing system consists of the UF, replacement fluid and waste pumps and the balancing chambers. The UF pump performs the net-removal of fluid from the patient as programmed by the user. The coupled replacement and waste pumps fill the volumetric balancing chambers. The disposable cartridge contains two sets of paired flexible PVC chambers. Each pair consists of a bag for the “clean” replacement fluid and a bag for the “dirty” effluent from the filter. The Cartridge is dropped in between the two door plates of the System One. This establishes a fixed volume for these chambers. The RF pump pushes “clean” fluid into one chamber, displacing the effluent into the waste line. At the same time, the waste pump pushes the effluent into the waste chamber of the other pair of chambers displacing the “clean” into the replacement fluid line to the filter. Once the chambers are completely full of effluent and replacement fluid, the cycle reverses. Balancing is thus physically linked and happens on a 1:1 basis.

Daily fluid balance accuracy of 0.5 kilograms compares favorably with specifications of common scale-based systems, despite the higher therapy volumes and flow rates evaluated (e.g. Prisma 0.6 L/day, which can be impacted by room temperature changes and routine scale calibration).

In an ICU environment, Daily balance accuracy of 0.5 kg is well within tolerances/errors of other measurements (urine output, perspiration, IV pump infusion, manual drips).

Conclusion

Volumetric control as practiced by the NxStage System One provides accurate fluid balancing in a simplified format that minimizes fluid-related interventions.