FRESENIUS MEDICAL CARE

CRIT-LINE®
Where Therapy and Diagnostics Meet

Case Study

Fluid Assessment – Crit-Line® Monitor Application

Cramping May Not Always Be Associated With Patient UF Tolerance

The case presented is a real-world scenario and addresses how an individual facility chose to address those patient treatments on that day. It is included to assist health care professionals in forming their own conclusions and is not intended to replace the judgment or experience of the attending physician or other medical professionals. The treatment prescription is the responsibility of the attending physician.

Medical History:

Caucasian, male military veteran on chronic dialysis. He has a history of cramping mid-treatment during dialysis, without experiencing any episodes or symptoms of intradialytic hypotension. Given his fear and anticipation of cramping, the patient would insist the staff shut off the ultrafiltration pump.

Treatment Order & Plan:

MD Order: Use Crit-Line for evaluation only, no ultrafiltration rate adjustments to be made based on relative blood volume (RBV) data provided by device.

Treatment Plan: Observe the RBV change during treatment using the Crit-Line device to visualize whether the ultrafiltration rate was set at a higher pace than the patient's refill rate causing him to cramp during treatment.

At 1.6 hours into the treatment, the patient requested his UF be "turned off." When asked, the patient insisted that this was based on an uncomfortable cramping episode during previous treatments. While his percentage of blood volume change was stable at -5% with an average of 3% reduction per hour,[1,2] an indication that increasing UFR would be beneficial, the clinical team honored the patient's request, and the UF pump was turned off. **(Marker #1)**

Within moments of turning off the UF pump, the patient immediately begins to refill indicating excess intravascular volume. At the 2-hour mark, refill continued to increase, with a change in RBV from -5% to -3.5%. This is clearly visible on the Crit-Line monitor screen depicted below, as one could see the physiological manifestation of fluid shifting from the interstitial space to the vascular space. **(Marker #2)**

Per the Crit-Line monitor, there was no indication that this patient was fluid depleted at any time during the treatment. At this point, the staff turned their attention to the patient's O_2 saturation. With the introduction of the Crit-Line monitor to this treatment, the clinical team had immediate, real-time access to O_2 saturation level at the point of dialysis access site.

During the first forty-five minutes of treatment, the O_2 saturation levels are quite stable. During this time, the patient was fully awake and communicating with the staff. Moments later, he dozed off, and O_2 sats

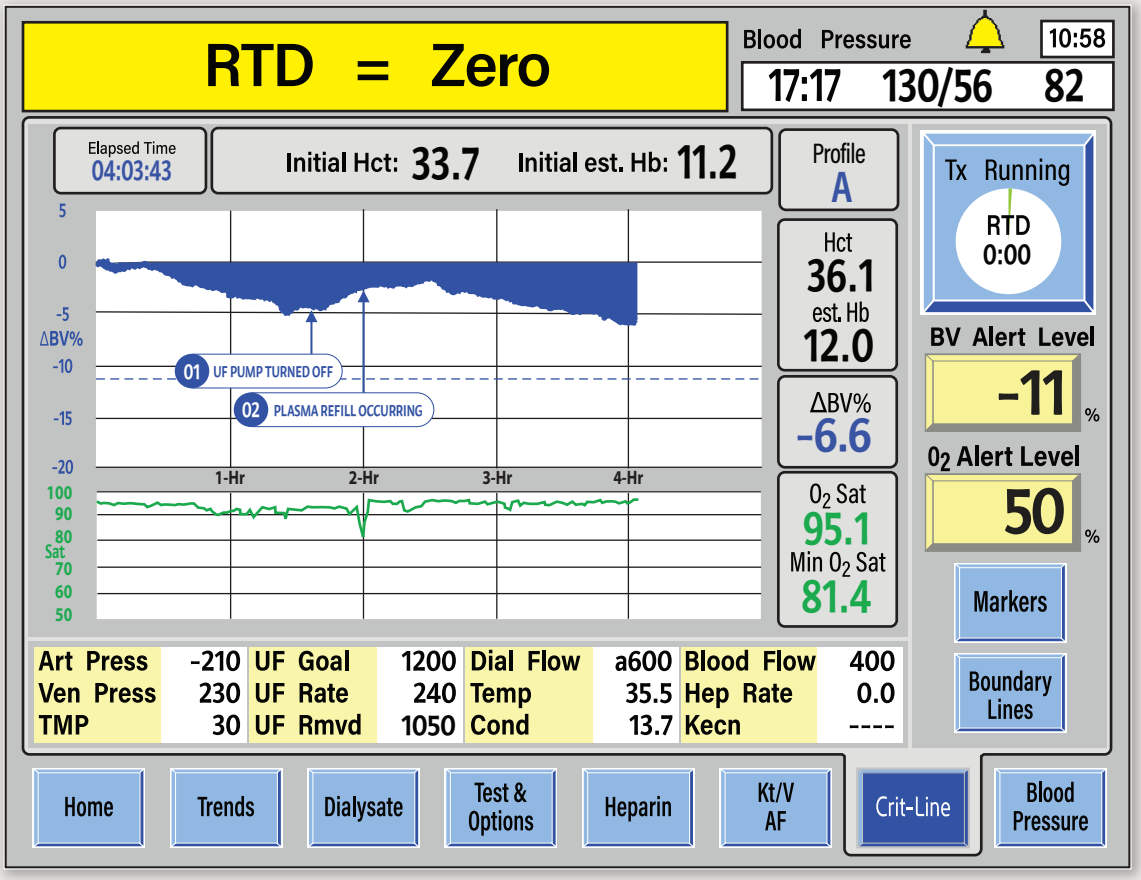
remained stable until the 2-hour mark, at which time there was a rapid decline in his O_2 saturation to 81.4%. He woke up in pain, and shouted out loudly, "I'm cramping!" The staff reminded him the UF pump was off, and his RBV change was clinically appropriate, but that it might be helpful if we gave him supplemental oxygen. Supplemental oxygen was provided and the UF pump was turned on following patient approval. For the remainder of the treatment, even though he dozed off again, his blood did not become desaturated nor did he show any indication of cramping.

Following his 4-hour treatment, his final O_2 sat was 95% and ending RBV change was -6.6%, which represents an average RBV reduction of -1.6% per hour congruent with fluid overload.

Following treatment, the clinician consulted MD who ordered a sleep study. Literature documents a higher incidence of sleep-disordered breathing and sleep apnea in the dialysis population.[3,4]

Initial data support the cramping was most likely due to hypoxia, and not due to RBV reduction. His RBV at the time of the cramping (2-hour mark) was the same as his RBV at the 1-hour mark when he did not have any cramping.

The patient may also benefit from additional challenge to the target weight during treatment, which could potentially improve an assumed episode of sleep apnea.[5]



1. Preciado, P, et al, All-cause mortality in relation to changes in relative blood volume during hemodialysis, Nephrol Dial Transplant (2018) 1-8.
2. Sinha, A. et al., "Relative plasma volume monitoring during hemodialysis AIDS the assessment of dry weight." Hypertension 55.2 (2010): 305-311.
3. Kimmel PL, Miller G, Mendelson WB: Sleep apnea syndrome in chronic renal disease. Am J Med 86: 308–314, 1989
4. Unruh ML, Sanders MH, Redline S, Piraino BM, Umans JG, Hammond TC, Sharief I, Punjabi NM, Newman AB: Sleep apnea in patients on conventional thrice-weekly hemodialysis: Comparison with matched controls from the Sleep Heart Health Study. J Am Soc Nephrol 17: 3503–3509, 2006
5. Manisha J et al., Volume overload as a mechanism for obstructive sleep apnea in CKD?, Nephrology Dialysis Transplantation, Volume 27, Issue 4, April 2012, Pages 1291–1293.

Use: Crit-Line Technology is designed to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. The technology employs a sensor clip which emits multiple wavelengths of light to trans-illuminate the blood in the Crit-Line blood chamber. The differences in light absorption between blood constituents allow for the identification and measurement of the hematocrit. The measurement of hematocrit, percent change in blood volume and oxygen saturation in real-time during hemodialysis is intended to provide a more effective treatment for both the dialysis patient and the clinician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, can intervene (i.e., by increasing or decreasing the rate at which fluid is removed from the blood) to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common complications of dialysis which include nausea, cramping and vomiting. The technology is available as a stand-alone device (Crit-Line IV Monitor) or as an optional module on the 2008T hemodialysis machine (CLiC™ device).

Caution: Federal (US) law restricts these devices to sale by or on the order of a physician.

Note: Read the Instructions for Use for safe and proper use of these devices. For a complete description of hazards, contraindications, side effects and precautions, see full package labeling at www.fmcna.com.

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