FRESENIUS MEDICAL CARE

CRIT-LINE®
Where Therapy and Diagnostics Meet

Case Study

Fluid Assessment – Crit-Line® Monitor Application in Hospital-Setting

Additional Data to Help Interpret and Assess Blood Pressure and Blood Volume

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:

Patient is a 48-year-old, Hispanic female with end stage kidney disease (ESKD), secondary to hypertension. She has been on hemodialysis for 15 years and has a history of atherosclerotic heart disease, atrial fibrillation, and multiple infections. She experienced diffuse leg and hip pain for which she was treated with a T9 fusion. This led to the development of a peri-vertebral abscess causing paraplegia and subsequent Stage IV decubiti. Patient was admitted to the hospital for wound management of her abscess and for skin grafting. She subsequently became hypotensive due to sepsis and required intubation from which she was later successfully weaned. During admission, her systolic blood pressures ranged from 60-110 mmHg. Patient received TPN and lipids and was on IV dopamine titration. Chest X-ray showed "suboptimal aerated lungs, pulmonary vascular congestion may be present, retrocardiac atelectasis and/or consolidation." For two days prior to dialysis, patient had a total intake of 6,155 ml and an output of 0 ml.

Order & Treatment Plan:

MD Order: Use the Crit-Line monitor to optimize fluid removal during 3-hour dialysis treatment. Patient's pre-dialysis BP was 91/43. Initial ultrafiltration rate was set for 1200 ml per hour for the 3-hour treatment, making the initial UF goal 3600 ml.

Within the first 30 minutes of treatment, RBV decreases rapidly to -5%. Based on the chest X-ray finding of possible pulmonary vascular congestion, it was evident the patient had excess fluid.

However, the rapid decrease in RBV per Crit-Line profile indicates this excess fluid was not available in the vascular space for removal during treatment. To help promote fluid shift from the interstitial spaces to the vascular space, the patient was given albumin **(Marker 1*)**. Following the albumin infusion, the patient's vascular space began to refill, as noted on the Crit-Line monitor RBV profile. Based on this information, the staff had the opportunity to increase the ultrafiltration rate to remove excess fluid.

Once the albumin infusion was complete **(Marker 2)**, the patient's RBV increased to +3%. At this time, however, her BP declined to 76/39. After reviewing the RBV data from Crit-Line, it was

decided by the medical team that her decrease in BP was not due to hypovolemia, but rather it was due to hypervolemia secondary to the influx of fluid shifting into the vascular compartment.

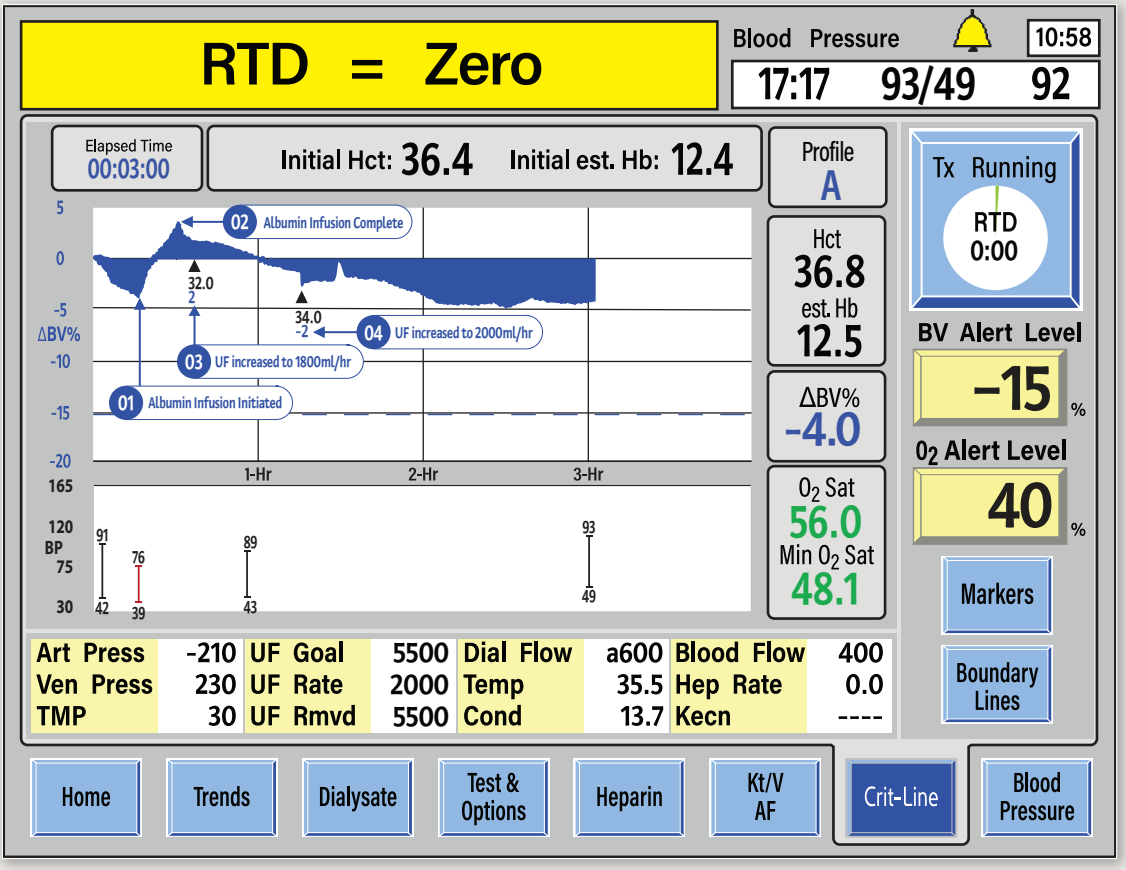
Accordingly, UFR was increased to 1800 ml/hr. **(Marker 3)**. The RBV started to decline, and her BP improved. One hour and 15 minutes into treatment, her BP increased to 89/43. Fluid was being removed, and her RBV was -2%. **(Marker 4)**. Patient was still fluid overloaded, so the medical team ordered an increase in the UFR to 2,000 ml/hour.

At treatment end, a UF of 5500 ml was achieved with a post-dialysis BP of 93/49 and an ending RBV of -4% after 3 hours. This was an average RBV change of -1.3% per hour. This data is indicative of continued fluid overload, validating chest X-ray findings. Following two additional consecutive treatments, a total volume of 14.4 L was removed.

In order for the patient's blood pressure to improve, excess fluid needed to be removed. In this case, this could only be accomplished by reducing the vascular volume through aggressive ultrafiltration. Independent studies have shown an inverse relationship between blood volume and blood pressure. An increase or decrease in cardiac output will result in a corresponding increase or decrease in mean arterial pressure.[1,2] Thus, fluid removal can then lead to improved cardiac output and blood pressure.

In this case, ultrafiltration treated the cause of hypotension which was visually represented in real-time using the Crit-Line device.

Hypotension, in this case, was misdiagnosed as volume depletion, when, in fact, it was due to volume overload.



1. Diroll A, Hlebovy D. Inverse relationship between blood volume and blood pressure. Nephrol Nurs J. 2003 Aug;30(4):460-1.
2. Smith, J. J., & Kampine, J. P. (1990). Circulatory Physiology: The Essentials (3rd ed.). Baltimore: Williams & Wilkins.

* In this case study, the Crit-Line technology is used according to the FDA-cleared indications for use, however, this study discusses use of the Crit-Line Monitor during treatments with albumin infusion, which is not part of the FDA-cleared indications for use. No studies support concomitant use.

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.*