INTRODUCTION
Over 6 million Americans suffer from heart failure (HF). High rates of rehospitalization and mortality and high treatment costs have persisted for decades despite advances in care. Clinical guidelines recommend assessment of blood volume and clinical management to euvolemia, but standard methods of diagnosing volume status are unreliable. FDA-cleared Blood Volume Analysis (BVA) [Daxon BVA-100™] is based on the gold standard indicator dilution technique. BVA quantifies otherwise undiagnosed volume derangements. Retrospective analyses have demonstrated that BVA-guided HF care reduces rehospitalization and mortality. ¹

KEY ELIGIBILITY CRITERIA
Inclusion:
1. Age > 18 years.
2. Hospitalized male and female patients with primary or secondary admission diagnosis of acute HF exacerbation, inclusive of all ejection fraction.
3. Able and willing to provide informed consent.

Exclusion:
1. Diagnosed with current acute strokes.
2. Pregnant women.
3. Severe hypotension requiring resuscitation, intubation or circulatory support.
5. Patients with known cardiac amyloid and hypotension.
6. Known allergy to iodine or iodinated albumin.

OBJECTIVES
This is the first prospective study of directly quantified volume change over a multi-month period immediately following hospital discharge, a clinical phase that is understood to be challenging due to high variability of patient status, physiology, and compliance. The primary objective is to quantify changes to Total Blood Volume (TBV), plasma volume (PV) and red blood cell volume (RBCV) over a 12-week post-discharge for inpatient HF care.

PROTOCOL
Hospitalized acute HF patients will be administered BVA tests prior to discharge, at first outpatient follow-up (7-10 days post-discharge), and after weeks 4, 8 and 12 post-discharge. BVA tests will be compared and analyzed over time to determine if, and quantify how much, subject TBV, PV, and RBCV change over time.

PROCEDURES

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<th>Procedure</th>
<th>Day 0</th>
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<th>Week 4</th>
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¹NT-ProBNP, BMP, CBC, Galectin-3, ST2, Ferritin, Erythropoietin
²Echocardiogram, Electrocardiogram, Chest X-ray

OUTCOME MEASURES
Primary: Quantify PV and RBCV changes over a 12-week period following discharge for acute HF care.

REFERENCES

STUDY INFORMATION
Source of Support: Daxon as a sub awardee to Center for Advancing Point of Care Technologies (CAPCaT) per NIH S5U4HL143541-03.

Trial design: Prospective, single-center, observational open-label study.

Leadership: Brendan Carry (Clinical & Site PI) & Jonathan Feldschuh (PI).

Participating centers: Geisinger Medical Center.

Estimated study duration: August 1, 2021 – October 30, 2022.

Contact information: For information about research opportunities with Daxon, contact Soren Thompson, Vice President, stthompson@daxor.com.