Improving Outcomes for Patients with Heart Failure and Hypertension and the Role of Blood Volume Analysis

The Clinical and Cost Effectiveness of Blood Volume Analysis with the BVA-100® Blood Volume Analyzer and How It Improves Outcomes and Quality of Life for Patients

Heart Disease and Hypertension: A Growing Problem

How BVA Can Save Lives

Treating Heart Failure and Hypertension: The Future
IMPROVING OUTCOMES FOR PATIENTS WITH HEART FAILURE AND HYPERTENSION AND THE ROLE OF BLOOD VOLUME ANALYSIS

Objective measurement of total blood volume, plasma volume and red blood cell volume with a simple blood test

Outcomes Improved with Individualized Care Guided by the BVA-100 Test

56% reduction in 30-day readmissions
82% reduction in 30-day mortality
86% reduction in 365-day mortality

“The BVA is a method that provides an accurate measure of actual blood volume and gives clinicians the opportunity to measure the blood volume as opposed to estimate it. Reliance on surrogate markers of volume could be problematic. The BVA provides an avenue to better understand our approach to patients with heart failure.”

Mарат Фудим, M.D. – Duke University

Significantly Reduce Heart Failure Mortality and Readmissions

Daxor Corporation

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The Burden of Heart Disease and Hypertension
The Link Between Hypertension and Heart Failure
Heterogeneity in TBV & RBCV Status Is Common
Indirect Measures Offer Low Clinical Utility as Indicators of True TBV and RBCV
Clinical Assessment
HCT
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Pressure is Not Volume and Volume is Not Pressure
BNP
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The BVA-100 Key Features
Basic Principle of Blood Volume Analysis
A Strong Body of Clinical Evidence
Cost Effectiveness
Quality of Life

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Heart Failure Outcomes with Volume-Guided Management...JACC-HF, Vol.6, No. 11, 2018
The BVA-100 test is only available in the US

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Foreword

Millions of people suffer from heart failure worldwide and those numbers keep growing, and so does the burden on health providers. The challenge is to reduce the number of deaths, manage costs and improve patients’ quality of life. For that, early intervention is critical but managing this is easier said than done.

Our opening article comes from the Daxor Corporation. The BVA-100 Blood Volume Analyzer is a one of a kind diagnostic test that measures total blood volume, calculates patient specific ideal volumes and translates that into a percentage deviation from the norm. In numerous studies it has been shown to deliver dramatic improvements in accuracy and reliability over traditional indirect methods and clinical observation.

Elsewhere in this Report, Jo Roth will look at the evolution of the BVA test - how it works and the growing body of evidence which suggests this could lead to dramatically improved outcomes for health providers and patients. Both need a new approach to treatment. Inadequacies in monitoring and diagnosis and identification of risk factors such as hypertension mean survival rates and quality of life are much lower than they should be. Many people with hypertension go undiagnosed as the specific medicine (diator or diuretic) is not matched to the cause or driver of hypertension - something that can only be done with blood volume measurement, which means many of the people most at risk of heart disease are not taking remedial action which could save their lives.

Inevitably, this means health providers will be struggling to cope with the financial burden of managing heart failure and, as we move into the future, the costs are likely to grow. As James Butler discovers in our final article, focus is growing on preventative measures which can identify symptoms sooner, improve monitoring and reduce the impact on struggling health providers. Research is driving new guidelines which, in turn, are changing treatment methods. Technology is increasing the amount of data at the hands of clinicians to make assessments. All these innovations will be crucial as health providers move to manage the growing burdens being placed upon them.

Tom Cropper
Editor

Tom Cropper, has produced articles and reports on various aspects of global business over the past 15 years. He has also worked as a copywriter for some of the largest corporations in the world, including ANZ Bank, ING and KPMG.

The Clinical and Cost Effectiveness of Blood Volume Analysis with the BVA-100® Blood Volume Analyzer and How It Improves Outcomes and Quality of Life for Patients

Daxor Corporation

Heart failure and hypertension are major public health concerns as well as significant financial burdens to the US healthcare system. Providing evidence-based care is crucial to improving patient outcomes and managing costs. The BVA-100® Blood Volume Analyzer test offers a major advance in informing clinicians of the patient’s actual total intravascular blood volume, red blood cell volume and plasma volume vs. the patients ideal volumes based on height, weight and gender with 98% accuracy so they can optimize treatment plans and individualize care, therefore improving outcomes and reducing duration and cost of care.

The Burden of Heart Disease and Hypertension1-3

Over 6 million Americans have heart failure and by 2030, the prevalence is expected to increase by 46%. The lifetime risk of developing heart failure currently stands at one in five with nearly half of patients dying within five years of diagnosis. Aside from the danger to health and well being, heart failure represents a $31 billion annual financial burden to the US healthcare system and remains the leading cause of hospital 30-day readmissions with Medicare penalties costing hospitals $564 million in 2017.

Linked to this is the fact that more and more Americans suffer from high blood pressure. About one in three adults or approximately 78 million people have high blood pressure with only about half having their high blood pressure under control. That puts them in the higher risk category for a range of health conditions. Seven out of ten people having their first heart attack also have high blood pressure. The same figures hold true for people with chronic heart failure while 80% of those having their first stroke have high blood pressure. People who have kidney disease are also significantly more likely to have problems with their blood pressure.

The Link Between Hypertension and Heart Failure

Over 70% of heart failure patients have a known history of hypertension.4 Heart failure is a condition where the heart is unable to pump enough blood through the body. This happens when blood vessels become narrow or blocked causing high blood pressure or hypertension - something that can only be done with blood volume measurement, which means many of the people most at risk of heart disease are not taking remedial action which could save their lives.

The accurate assessment of volume derangements to achieve “euvolemia” (a term...
Being able to distinguish between dilutional versus true anemia is critical in making decisions around red cell management (such as IV iron, transfusions, EPO use and phlebotomy), as well as getting the patient to an overall level of total ideal volume or euvoeulmia.

Hypovolemia Persists Following Inpatient Diuresis

The investigators concluded that the extent, composition, and distribution of volume overload in decompensated heart failure are highly variable, and this variability needs to be taken into account in the approach to individualized therapy instead of a “one size fits all” decongestion strategy. Red blood cell volume derangements are far more prevalent than thought as shown in a study of 245 patient admissions in a published study in JACC-Heart Failure whereby true anemia was present in 62% of the cohort and 11% of the patients were identified as polycythemic through direct blood volume analysis.7

HCT

Hematocrit (Hct) is a common indirect or surrogate measure of blood volume status. Hct is the ratio of the volume of red blood cells to the total volume of blood. It is normally 47% ± 5% for men and 42% ± 5% for women. Hct is considered to be an indirect measure because patients with the same Hct may be highly discordant in true RBCV status. The illustration shows that sample tubes 1 and 3 both have a normal Hct of 40%. However, true anemia is masked by hypovolemia in sample tube 3. Unlike Hct, direct BVA will quantify RBCV accurately and reliably even in volume deranged patients.

Haim formula, which calculates blood volume using a formula calculating hematocrit relative to dry body weight. The second, the Strauss formula, estimates changes in plasma volume over time using hemoglobin and hematocrit measurement. The study ultimately showed neither formula demonstrated an accurate blood volume estimate compared to the BVA-100. These formulas varied in their accuracy between 16% and 68% compared to the BVA-100.15

The BVA-100 Solution

Clinicians have struggled to manage volume and LV function with a lack of accepted diagnostic criteria and a poor correlation between changes in BNP and measured changes of blood volume which may help to explain why BNP has not proven a reliable marker to target for volume adjustment to euvoeulmia.16

The BVA-100 Blood Volume Analyzer is a FDA-cleared diagnostic that measures of total blood volume and plasma volume. Users of the BVA-100 who prefer a shorter tech time have the option to calculate blood volume using as little as three blood draws. The five point test reports BNP and calculated a slope to give the measure of the albumin transudation rate which is an indicator of capillary permeability. All results are calculated with patient specific ideal volumes based on height, weight and gender.

"Indirect assessments of plasma volume or blood volume are limited by their inaccuracy. Our study shows that this is true for formula-based volume assessment or the measure of hemococoncentration, and similarly poor correlation has previously been shown for the physical exam and even intra-cardiac pressure assessment.” – Dr. Marat Fudim, Duke University

Improve Adherence & Outcome

Hypovolemia Persists Following Inpatient Diuresis

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Improve Adherence & Outcome
Saving lives and saving costs with direct blood volume analysis helps to guide individualized therapy in heart failure patients, reduces readmissions and eliminates the need for unnecessary surrogate tests.

**Improving Outcomes for Patients with Heart Failure and Hypertension and the Role of Blood Volume Analysis**

Research was presented in *The American Journal of Cardiology* whereby unrecognized hypervolemia in chronic heart failure was evaluated with the BVA-100 in relation to clinical status, hemodynamics and patient outcomes. Correct clinical assessment of volume status was achieved only 51% of the time. Patients who were normovolemic or hypovolemic had a 0% risk of death during the entire study whereas hypervolemic patients had a risk of death of 39% at 1-year and 55% at 2-years. The investigators concluded that clinically unrecognized intravascular volume overload may contribute to worsening symptoms and disease progression in patients with chronic heart failure. Persistent volume overload congestion and renal dysfunction have been hallmarks of poor outcome and shown to be significant prognostic factors in patients with chronic heart failure. Whether volume interacts with renal function or markers of renal function to exacerbate or mitigate the increase in mortality is an area of ongoing investigation. The American Society of Echocardiography (ASE) has its own guidelines on the use of echocardiography in the evaluation of patients with chronic heart failure. At least 60% of the patients had severe (SD 3.5) or moderate (SD 2.6) left ventricular systolic dysfunction or an estimated glomerular filtration rate of less than 60 mL/min/1.73 m². The presence of hyperechogenicity in the posterior wall of the left ventricle was an independent predictor of both 30-day and 1-year mortality. This finding is consistent with previous reports that have shown an association between left ventricular hypertrophy and increased mortality in patients with chronic heart failure.

**Three Easy Steps to Perform the BVA-100 Test**

The **Indicator Dilution Technique**

Blood samples are centrifuged to separate the red blood cells from the plasma and 1 cc aliquots of plasma are pipetted into counting tubes and then placed in the analyzer carousel along with the corresponding standards. The BVA-100 generates a report that details the results to guide their treatment path in heart failure. Propensity score matching analysis was performed on a mixed (HFpEF/HFrEF) cohort of 245 serial admissions for heart failure in a community hospital. The study found that the average cost for a heart failure admission is $14,000 with an average per-patient readmission cost of $3,500. BVA guided care can potentially reduce readmissions by 56% generating a potential savings of $1,500 per readmitted patient based upon this cost analysis. Commonly ordered in-patient surrogate tests such as pulmonary wedge pressure, echocardiogram, BNP and EKGs can add up to an additional cost of $1,000 per hospitalized patient. By incorporating blood volume analysis into standard clinical practice, this cost can be reduced by $1,000 per patient. The Centers for Medicare and Medicaid (CMS) has now instituted hospital penalties up to 3% for readmissions including heart failure. In 2017, 60% of hospitals were penalized at a cost of $364 million in lost reimbursements. Saving lives and saving costs with direct blood volume analysis helps to guide individualized therapy in heart failure patients, reduces readmissions and eliminates the need for unnecessary surrogate tests. The BVA-100 test is fully reimbursed by Medicare and private payers in both the inpatient and outpatient settings.

**Quality of Life**

Maintaining a good quality of life to perform normal physical and social activities is as important as survival to most patients living with a chronic, progressive illness such as heart failure. Patients with heart failure often experience various physical symptoms such as difficulty breathing, fatigue, edema, and chest pain which are often due to volume overload and anemia that limits their ability to perform daily activities. Blood volume analysis with the BVA-100 test better informs clinicians of the true blood volume status (mild-moderate vs. severe plasma volume expansion) to CKD-related risk markers such as serum creatinine, eGFR, BUN and NT-proBNP in patients with chronic HF. The results showed that blood volume has a direct connection with kidney function, demonstrating additional risk markers with both heart failure and impaired kidney function. The use of the BVA-100 provided investigators with accurate plasma volume measurement in order to assess total risk.

**Cost Effectiveness**

The reality of modern healthcare is that clinical measurement in order to assess total risk is often not available or not feasible. The average cost for a heart failure admission is $14,000 with an average per-patient readmission cost of $3,500. BVA guided care can potentially reduce readmissions by 56% generating a potential savings of $1,500 per readmitted patient based upon this cost analysis. The average cost for a heart failure admission is $14,000 with an average per-patient readmission cost of $3,500. BVA guided care can potentially reduce readmissions by 56% generating a potential savings of $1,500 per readmitted patient based upon this cost analysis. At Daxor Corporation, we have always been passionate about delivering innovative medical instrumentation and biotechnology advances focused on blood volume analysis to improve patient quality of life and reduce the cost of healthcare.

**Outcomes Improved with Individualized Care Guided by Direct Blood Volume Analysis**

- **82%** reduction in absolute risk
- **51%** reduction in relative risk
- **56%** 365-day mortality

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**Basic Principle of Blood Volume Analysis**

The BVA-100 Blood Volume Analyzer is recognized as the “gold standard” methodology in quantifying circulating blood volume. This radiolabeled albumin technique is recommended for quantitative assessment of blood volume by the International Committee for Standardization in Hematology for its precision and reproducibility compared to alternate methods. Normal values for this technique have been well established with 98% accuracy. The illustration depicts the basic principle of how the BVA-100 test works. A dose of Volumex® Albunin 1:131 tracer is injected intravascularly. Once the tracer has fully circulated in the bloodstream, a series of small blood samples are drawn. The BVA-100 automatically calculates patient blood volume by comparing the concentration of undiluted tracer prior to injection to the tracer concentration diluted in the patient blood samples.
There is widespread use of formula-derived estimates of plasma volume in heart failure patients despite these methods having been proven to be inaccurate compared to measured volume status enabling customization of symptom management and optimized treatment strategies so heart failure patients can live longer, more productive lives and reduce their risk of hospital readmissions. At Daxor Corporation, we have always been passionate about delivering innovative medical instrumentation and biotechnology advances focused on blood volume analysis to improve patient quality of life and reduce the cost of healthcare. The BVA-100 Blood Volume Analyzer is a rapid, clinically-available, FDA-cleared diagnostic to provide direct measurement of a patient’s blood volume in a broad range of medical and surgical conditions. A vast library of studies have established the value of the BVA-100, confirming that accurate blood volume analysis leads to better informed physicians, better treatment strategies, and improves patient outcomes and resource utilization. As we move into the future, our goal is to partner with hospitals and physicians to integrate direct blood volume measurement into standard clinical practice.

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Improving Outcomes for Patients with Heart Failure and Hypertension: A Growing Problem
Tom Cropper, Editor

The growing burden of hypertension is putting healthcare infrastructure under pressure. What’s the solution?

Heart disease and hypertension: A growing problem

In the quest to deliver world class healthcare, professionals can often feel as if they are facing a tough choice. On the one hand they have to manage costs, but on the other they are expected to improve care outcomes. All too often you can’t do one without impacting the other. New treatments focusing on patients with hypertension at risk from heart failure promise to do exactly that. By improving diagnosis, reducing mortality and readmission rates, they can not only save lives but ease the burden on health services.

The Rising Cost of Healthcare

Heart failure is one of the biggest health problems in the world. It affects 26 million people globally, with around six million of those being located in the US.2 Around half of those diagnosed with heart failure die within five years. It is a major cause of mortality and inevitably also has a massive drain on resources. Data from the American Heart Association (AHA) claims that 100 million Americans have high blood pressure,3 which increases the risk of a range of health conditions including heart failure and strokes. Seven out of ten people having their first heart attacks also have high blood pressure as do eight out of ten people having their first stroke. Additionally, 70% of people suffering with heart failure have high blood pressure,4 Most long-standing incidents of hypertension lead to heart failure unless the sequence of events is interrupted. A Framingham Heart Study of a population of 5,143 patients found that hypertension antagonised the development of heart failure in 91% of newly diagnosed heart failure patients. The hazard for developing heart failure among hypertensive patients, compared with normal or healthy patients, was two-fold for men and three-fold for women, after adjusting for age and other heart failure risk factors5.

Impact on Health Services

All these health problems have a significant impact on health services. A report from Ronald S Chamberlain et al found that five million people have chronic heart conditions, which lead to one million hospitalisations6. It is the main cause of hospitalisation among people over the age of 65 with many patients requiring multiple readmissions. Reducing the rate of readmission is key to improving patient outcomes as well as reducing the fiscal burden on healthcare services. Under the Hospital Readmission Reduction Program of the Affordable Care Act, for example, Centers for Medicare and Medicaid Services were required to reduce payments to hospitals with excess readmissions.
A Framingham Heart Study of a population of 5,143 patients found that hypertension antedated the development of heart failure in 91% of newly diagnosed heart failure patients.

The key to doing so will be early, accurate diagnosis and prompt interventions. This could reduce mortality rates, improve outcomes for patient and limit the number of people requiring urgent readmissions and expensive ongoing treatment.

**Links to Hypertension**

One way to do this would be with closer examination of conditions such as hypertension and high blood pressure, which are linked to an increased risk of heart failure. As we’ve already seen, patients who experience heart failure are also much more likely to have had hypertension, but signs are often overlooked.

A report into the life-saving potential of early hypertension diagnosis raises this hypothetical scenario: imagine a woman who presents to a primary care provider with itching hands as a result of eczema. The chances of her having an associated higher blood pressure are 50-60% but, in all probability, she will not be aware of this and doctors will not test for it.

Signals such as these are being missed and with them, the chance to identify patients with a higher probability of going on to develop heart failure. Identifying patients at the earliest stage with a simple diagnostic by measuring their blood volume, will make it easier for primary care providers to monitor for early onset signs of hypertension and determine the correct medication early in the cycle to correct the problem.

Unfortunately, many of the diagnostic approaches are relatively ineffective and rely on indirect observation and assessments. The ability to directly measure blood volume can improve the accuracy of assessments and arm doctors with better information to make better clinical decisions.

**Reducing the rate of readmission is key to improving patient outcomes as well as reducing the fiscal burden on healthcare services**

The use of indirect estimates means clinicians are working on data which is unlikely to be perfectly accurate, which makes it harder to manage early interventions or design appropriate treatments.

**MAINTAINING ADEQUATE** good volume blood volume is crucial to ensuring vital organs, such as the heart, continue to function normally. Volumes can be too high or too low in a range of different conditions including hypertension and congestive heart failure. However, evidence suggests that the direct measurement of blood volume is a major step forward. Blood volume measurement has shown to deliver a more accurate assessment of intravascular blood volume leading to more individualized care which, in turn, is delivering better outcomes for patients and hospitals.

**The Role of BVA**

Inadequacies in the effectiveness of clinical assessment have long been recognized. Clinicians may rely on clinical observation and physical signs of congestion such as abnormal sounds from the lungs, elevated jugular pressure or other anomalies to make their assessments. Unfortunately, these are vague and prone to error.

The standard formula used to estimate blood volume was first presented back in 1962 and has been criticized for being inaccurate as today’s population has more adiposity and fat tissues require less vascularization. Other commonly used measures, such as central venous pressure also offer low levels of accuracy in reflecting intravascular volume status.

Inadequacies in existing testing methodologies can lead to severe complications. Early warning signs are missed, care plans are inadequate or wrong; which in some cases can lead to serious complications. In general, it makes it much more difficult to deliver prompt, effective and successful care and leads to increased readmission rates, higher treatment costs and a higher probability of mortality for patients.

**BVA-100 test provides an objective and accurate measurement of blood volume that enables clinicians to assess volume derangements and create effective treatment plans.**

**How BVA Can Save Lives**

Jo Roth, Staff Writer

Indirect or surrogate analysis has been shown to be ineffective in delivering clear and definite results. Can a blood volume test make a difference?

**The BVA Test**

Daxor Corporation has developed a rapid, accurate and objective way to directly measure total intravascular blood volume and evidence is mounting in support of its effectiveness.

Numerous studies have shown that a more precise analysis of blood volume can enable clinicians to develop more effective and individualized care plans.

In a study published in JACC Heart Failure, Strombeck et al. hypothesized that individual quantitative blood volume analysis could reduce death and rehospitalization due to heart failure. Their results showed that blood volume analysis guided care reduced heart failure 30-day readmissions by 56%, 30-day mortality by 82% and 1-year mortality by 86% in a propensity-matched control group from the Centers for Medicare and Medicaid data.

The data showed that thirty-seven percent of the patients who were thought to be volume overloaded by clinical assessment were more than 10% over the patient norm. They also found that 62% of the patients had anemia further demonstrating that BVA differentiates between true anemia and dilutional anemia.

Each patient within the group received a minimum of one BVA test at or close to...
Directly measuring intravascular blood volume makes it possible to individualize the decongestion strategy according to the confirmed and quantified need of each patient.
As tests continue to develop and research adds to the knowledge base, we can gain new insights into the links between hypertension, blood pressure and heart disease.

RBCV and FV and that SBP does not correlate with direct blood volume measurement.

The report’s authors suggested the findings showed that blood volume measurement should play a critical role in hypertensive therapy. Blood volume analysis is not entirely new, but it has been on a path of evolution to deliver a form of test which is effective and applicable in a clinical setting. Analysis such as this has been made possible thanks to the availability of direct blood volume analysis with the BVA-100 which is discussed in more detail elsewhere in this Report.

As tests continue to develop and research adds to the knowledge base, we can gain new insights into the links between hypertension, blood pressure and heart disease. It is possible to identify at-risk individuals at a much earlier point in disease progression, and improve testing and diagnosis to ensure a better standard of treatment.

Although the BVA-100 test has been available for quite some time, awareness and utility has been expanding with new evidence. The BVA-100 test is the future as more clinicians become educated on the benefits of direct BVA. The technology has been proven. The clinical evidence is strong showing improved mortality and patient outcomes.

The Use of Data

The move towards monitoring sees a greater onus being placed on primary care and self-management. Studies comparing self-monitoring to no self-monitoring in hypertensive patients found that it appears to reduce blood pressure readings at home and also connecting them to their primary care providers. A host of innovations are coming to market offering a various methods to improve early detection of heart disease. These include:

- **Big data:** A study from Yajuan Wang et al looked at how data from electronic health records could be used to aid earlier detection rates. As health services become better at collecting, storing and managing patient data, they have a huge amount of information about each case. If this can be analyzed effectively it can help to identify causation links and improve early detection.
- **Artificial Intelligence:** Researchers at Oxford University have developed an AI device capable of analyzing scans of heart disease and cancer patients picking up various conditions at a much earlier stage.
- **Researchers in Ireland have developed a handheld device which can detect changes in arteries to detect the early stages of heart disease and alleviate the burden on hospitals.** Technology offers a number of ways in which this gap can be plugged, by making it easier for patients to take blood pressure readings at home and also connecting them to their primary care providers. A host of innovations are coming to market offering a various methods to improve early detection of heart disease. These include:

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- Technology such as these increase the amount of data available to doctors and patients. As information grows in both volume and reliability, diagnosis improves and conditions are caught at a much earlier stage. This makes it easier to devise appropriate care plans, reduce mortality and ensure patients enjoy a much higher quality of life. Readmissions will be lower, hospital stays shorter and emergency cases can be avoided. Delivering the very best standard of care will become easier and more affordable. The impact on hospitals, carers and patients could be profound.
Hospital Reports

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