



Heart Failure
TODAY

SUMMER 2013

WHICH PATIENTS
BENEFIT
FROM HIGH-DOSE
BETA BLOCKERS

NOVEL BIOMARKER
PREDICTS
HYPERTENSION

REDUCING
HEART FAILURE HOSPITAL
READMISSIONS



GRANDPA'S
A
CEREAL
TESTER,
TOO!

ST2 is the perfect biomarker for serial testing. Levels of the biomarker ST2 change rapidly in response to changes in a heart failure patient's condition, helping you to quickly adjust care.

ST2 significantly improves the accuracy of patient prognosis over natriuretic peptide markers and is not adversely affected by confounding factors such as age, body mass index, smoking, anemia and impaired renal function.

ST2 has a single cutpoint, removing any guesswork. If your patient's ST2 level is over 35*, that's a warning sign.

ST2 can satisfy your hunger for a serial biomarker. Don't start your morning without it. To learn more about the Presage ST2 Assay, go to www.criticaldiagnostics.com or call 1-877-700-1250.

ST2 testing is available from these preferred laboratories:



* 35ng/ml.



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The latest heart failure news and views, including five lifestyle changes with compelling evidence behind them that can help a heart stay healthy, identifying patients who can benefit from high-dose beta blockers, and a simple test for detecting hypertension.

4 Facts About Heart Failure
Some 80 million Americans have some form of heart disease. We list some of the more interesting facts about this condition.

AS WE GO TO PRESS...ACC/AHA GUIDELINES ON HEART FAILURE MANAGEMENT INCLUDE ST2

On June 5 the American College of Cardiology Foundation/American Heart Association Task Force jointly released its 2013 report on Practice Guidelines for management of heart failure and called the biomarker ST2, "not only predictive of hospitalization and death in patients with HF [heart failure] but also additive to natriuretic peptide levels in [its] prognostic value."

The guidelines – which put a single reference source at clinicians' fingertips – has been published since 1980. Writing committees – made up of experts in the subject selected by the ACCF and AHA – regularly review and evaluate all available evidence to develop balanced, patient-centric recommendations for clinical practice. This is the first update to the guidelines since 2008.

"Having ST2 included in the 2013 ACC/AHA Guidelines is unprecedented," notes David Geliebter, CEO of Critical Diagnostics. "We only received FDA clearance in December of 2011. No cardiac biomarker that we know of has ever achieved this acceptance so quickly. We are honored the task force recognized the depth and breath of clinical evidence for the use of ST2."

If you'd like to learn more about Critical Diagnostics and the Presage® ST2 Assay, please visit our website: www.criticaldiagnostics.com

Gratefully,

David Geliebter, Publisher

Heart Failure TODAY is a publication of Critical Diagnostics, makers of the Presage® ST2 Assay. This information is to educate our readers and is not intended as medical advice or a substitute for consulting a physician. The Presage® ST2 Assay is CE Marked and has received 510(k) clearance from the US FDA for use in risk stratification of chronic heart failure patients. © Copyright 2013. All rights reserved.



News & Views

{And A Warning About Booze}

5 Lifestyle Changes For A Heart Healthy Life.

Here are five lifestyle changes with compelling evidence behind them that can help a heart stay healthy.

1. **Smoking.** Somehow the old movie stars like Humphrey Bogart and Lauren Bacall made smoking seem sexy, but there's nothing sexy about its link to cardiovascular disease, as well as stroke and cancer.
2. **Exercise.** Thirty minutes of moderate to vigorous exercise, ideally daily, can help keep the heart healthy – and helps justify that expensive workout outfit you bought!
3. **Diet.** We know that the Western diet – with its high intake of fat, sugars and calories – damages the arterial endothelium and promotes obesity, diabetes, and heart attacks. In April 2013, in probably the largest and longest diet study ever undertaken, five years of the Mediterranean diet, with high olive oil and nuts reduced heart attacks, strokes and total mortality, all versus a standard low fat diet. So next time someone says nuts to you, say thank you!
4. **Weight.** Studies show that fat around the middle – abdominal fat – is closely linked to increased heart disease and diabetes. Therefore a body mass index of 25 or below is vital for keeping the heart healthy. Let's not waist any more time on this one...
5. **Alcohol.** This fifth protective factor (and part of the Mediterranean diet) is a two-faced friend. A little alcohol helps, but more than that harms substantially. I'll drink to that – okay, just one glass!

ST2 Identifies Chronic Heart Failure Patients To Benefit From High-Dose Beta Blocker Therapy

4 Times The Risk of A Cardiovascular Event

"Individuals with high ST2 concentrations and low beta blocker dose were more than four times as likely to experience a cardiovascular event and the least likely to survive."



The findings of a study conducted through the Massachusetts General Hospital and reported at the 2013 ACC Annual Meeting, "Circulating Concentrations of Soluble ST2 Identify Benefit of High Dose Beta Blocker in Chronic Heart Failure: Results from the ProBNP Outpatient Tailored Chronic Heart Failure Therapy (PROTECT) Study," highlighted the cardiac

biomarker ST2's ability to identify those patients most likely to benefit from high-dose beta blockers and thus reduce risk from cardiovascular complications.

The participants were followed for 10 months and ST2 levels were measured using the Presage ST2 Assay. Individuals with high ST2 concentrations and low beta blocker dose were more than four times as likely to experience a cardiovascular event and the least likely to survive, by comparison to those with low

ST2 concentrations and high beta blocker dosage. Furthermore, ST2 levels "predicted time-to-first cardiovascular event above and beyond NT-proBNP and baseline clinical characteristics."

"ST2 holds the link in potentially improving outcomes for heart failure patients through its unique ability to identify those who can benefit most from high-dose beta blocker treatment," states Dr. James Snider, President of Critical Diagnostics.

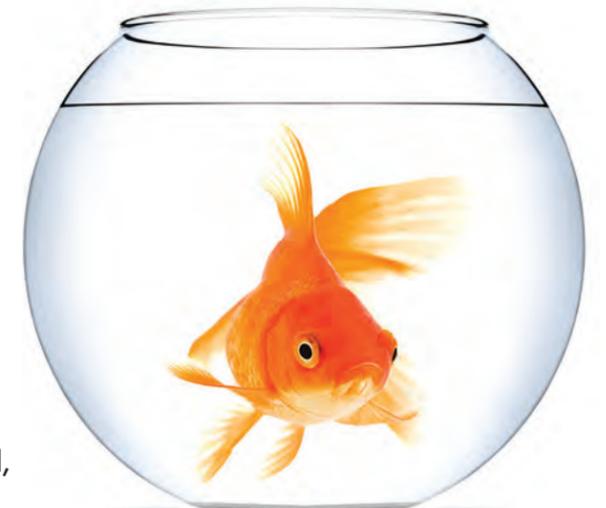
Fishing For Answers About Fish Oil

Eating fish is good for your heart, but taking fish oil capsules doesn't help people at high risk of heart problems.

Previous studies have suggested that fish oil capsules could lower heart risk in people with heart failure or who have already suffered a heart attack. The new study, led by the Mario Negri Institute for Pharmacological Research in Milan, tested 1 gram a day of fish oil versus dummy capsules in 12,513 people throughout Italy.

They had not suffered a heart attack but were at high risk of having one because of diabetes, high blood pressure, high cholesterol, smoking, obesity or other conditions. Most already were taking cholesterol lowering statins, aspirin and other medicines to lower their chances of heart problems.

After five years the incidence of death, heart attacks, strokes



and hospitalizations was about the same for each group – 12 percent.

Makers of fish oil supplements helped pay for the study. We assume someone in marketing got tossed overboard. Ciao, baby!

A Dozen Facts About HEART DISEASE

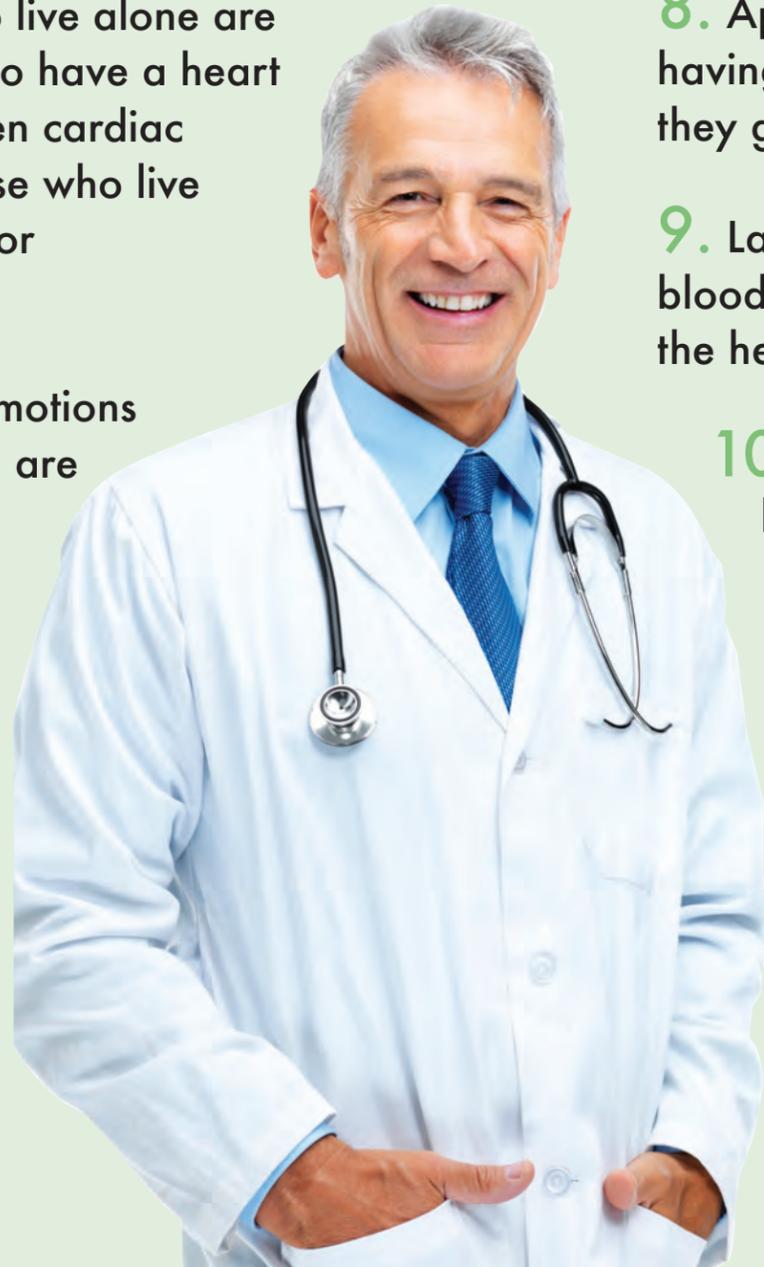
Heart disease is the number one killer in the United States, accounting for 40% of all U.S. deaths in both men and women, more than all types of cancer. Some 80 million Americans (about one in four) have some form of heart disease. Here are some more interesting facts about heart disease:

1. More women (38%) than men (25%) die from heart disease.
2. More than one in three women in the U.S. will die from heart disease, compared to one in 30 from breast cancer.
3. A Danish study claims that men and women with thighs that measure less than 23.62 inches in circumference have a higher risk of developing heart disease.

4. Researchers suggest that people who stay up late may be more prone to heart disease, even if they get eight hours' sleep.

5. People who live alone are twice as likely to have a heart attack or sudden cardiac death than those who live with a partner or roommate.

6. Negative emotions and depression are risk factors for heart attack and stroke. Conversely, happier people are less likely to develop heart disease.



7. Age is the most significant risk factor of developing heart disease – followed by gender, family history coupled with ethnic background, smoking, obesity, lack of exercise, high blood pressure, diabetes and high blood cholesterol.

8. Approximately 40% of people having a heart attack die before they get to a hospital.

9. Laughing relaxes and expands blood vessels, which helps protect the heart.

10. A person is more likely to have a heart attack on a Monday morning than on any other day of the week.

11. Approximately 30% of the people who die from heart disease are smokers.

12. Secondhand smoke increases the risk of coronary heart disease by 25%.



Having A Pet Might Lower Risk of Heart Disease

Pet ownership is likely associated with a decreased risk of heart disease, according to a study out of Baylor College of Medicine.

Owning pets may be associated with lower blood pressure and cholesterol levels and a lower incidence of obesity, plus pets can have a positive effect on the body's reactions to stress.

Dog ownership in particular may help reduce cardiovascular risk because people with dogs typically engage in more physical activity because they walk them. And for those with large dogs, we add the calorie-burning value in lugging home huge bags of dog food.

Coming Soon To A Doctor Near You?

A Simple Test Can Tell If You're Likely To Develop Hypertension in The Future

A study titled, "Soluble ST2 Predicts Elevated SBP in the Community," published in the *Journal of Hypertension*, shows that a cohort of otherwise healthy individuals – in other words, no clinical signs or symptoms – except that they have high levels of the biomarker ST2 in their blood, were almost twice as likely to develop hypertension in the future than those with low ST2 levels.

The implications of this finding are enormous. With this knowledge in hand, one day physicians may be able to offer patients tailored treatment options as part of a preventative approach to medicine that could delay or even forestall the onset of hypertension entirely.

Study investigators evaluated 1,834 individuals from the Framingham Offspring Study Cohort to determine the predictive utility of ST2. The participants were followed over a period of three years. The results illustrated that



those subjects whose ST2 level was elevated had a significantly greater chance of becoming hypertensive.

"ST2 is emerging as an important mediator of ventricular remodeling, as well as a valuable prognostic marker in cardiovascular disease," state the authors. "Our findings support a robust link between sST2 and multiple [blood pressure] measures."

"The encouraging data in this

recent study highlights the clinical utility of ST2 beyond the management of heart failure," notes David Geliebter, CEO of Critical Diagnostics. "The findings are profound and again speak to the potential role of ST2 in primary disease prevention, as it allows for the early identification of risk for cardiovascular disease in apparently healthy individuals which presently goes undetected until they are symptomatic, and that is far too late."

Heart Failure Population Expected To Surge Nearly 50 Percent



According to the American Heart Association, cases of heart failure are set to jump a dramatic 46 percent by 2030. As the population ages and more of us develop various heart conditions, the number of those with heart failure will rise from just over 5 million today to 8 million in 2030 –

while the direct and indirect costs to treat heart failure could more than double from \$31 billion to \$70 billion.

"If we don't improve or reduce the incidence of heart failure by preventing and treating the underlying conditions, there will be a large monetary and health burden on the country," said Dr. Paul Heidenreich of the Stanford University School of Medicine, who led the analysis published in the association's journal *Circulation: Heart Failure*.

How SEX Helps The Heart

Having an active sex life could cut a man's risk of dying from heart disease in half. Whether sex works as well for women's hearts is unclear, but a healthy love life seems to equate to good overall health.

For one thing, sexual activity is an excellent stress buster. It's also great exercise – burning about 85 calories per half-hour session. The key is to avoid lighting up a cigarette afterward and destroying all the positive effects!

ST2 Offers Great Promise For Reducing The Scourge Of Hospital Readmissions

In a *Clinical Chemistry* article, "Are Biomarkers the Answer to the Heart Failure Readmissions Problem?," ST2 was declared to be "the most potent predictor of rehospitalization of all biomarkers assessed."

Moreover, the study out of the Mayo Clinic, from which the data was drawn, demonstrated that serial changes in ST2 were superior to both BNP and troponin – the two most-often used cardiac biomarkers – in the prediction of adverse events in otherwise stable chronic heart failure patients.

The paper highlights two potential roles for biomarkers in a strategy to reduce hospital readmissions for heart failure patients. The first is to help doctors identify people at risk for readmission, and then to monitor serial values in the outpatient setting to allow for early intervention aimed at reducing readmissions.

Of the expected 1.1 million patients hospitalized for heart failure in the U.S. each year, one in four will be readmitted within 30 days of

discharge. With an average cost per patient for rehospitalization of \$22,700, and \$35,800 per patient death, this high incidence of rehospitalization and mortality has a powerful negative impact on hospitals and the healthcare system as a whole.

The use of BNP was "no better than a flip of a coin."

Effective last October, hospitals with rates of rehospitalization significantly higher than expected will lose one percent of their Medicare reimbursement across the board, meaning all Medicare reimbursements, not just heart failure. Under the law, next year that loss in reimbursements doubles to two percent, and then jumps to three percent in 2015.

As the paper pointed out, the use of BNP was "no better than a flip of a coin" in predicting hospital readmissions, and therefore in helping address this healthcare

dilemma. Furthermore, the wide biological variation of BNP, which is affected by such confounding factors as age, body mass index, renal failure, smoking and other comorbidities common to heart failure patients, means "marked changes are necessary with BNP measures to be sure they are not simply due to spontaneous variation."

By contrast, numerous peer-reviewed published studies have shown ST2 to add clinical value across all four stages of heart failure, with the lowest level of biological variability of any cardiac biomarker, and ST2 levels are not adversely affected by the normal confounding factors.

"Our objective is to help medical professionals harness the prognostic power of ST2 in implementing personalized biomarker-guided disease management programs that include serial monitoring of ST2 changes to reduce 30-day rehospitalization and mortality rates," notes David Geliebter, CEO of Critical Diagnostics.



Recent **Advancements** Made In Diagnosing And Treating **Heart Failure** Could Save And Improve The **Lives Of Millions**

As recently reported in the Journal of the American College of Cardiology, a Cleveland Clinic pilot study of 41 patients indicated that an experimental breath analysis device may be able to help diagnose patients with heart failure.

In much the same way as a breath test may one day detect heart failure, there is a FDA cleared test on the market now that is changing the way physicians care for the 26 million diagnosed heart failure patients around the world. It's the ST2 test from Critical Diagnostics.

Numerous published studies have demonstrated that the level of ST2 in blood can best predict heart failure patient outcomes. Knowing this information, allows physicians to select those patients who require focused, personalized care.

"The ability to diagnosis heart failure patients earlier and more accurately offers promise," notes James Snider, President of Critical Diagnostics. "The question, then, becomes how do we identify high-risk patients, how do we best treat them, how do we improve the quality of their lives, and at the same time, not overburden the healthcare system? The answer is through better prognosis. This is where ST2 is making a difference."



DON'T
TRUST
ANYONE
OVER
35



When treating chronic heart failure, the cardiac biomarker ST2 significantly improves the accuracy of patient prognosis over natriuretic peptide markers—plus ST2 has a single cutpoint, removing any guesswork. If your patient's ST2 level is over 35*, that's a warning sign.

ST2 levels change rapidly in response to changes in the patient's condition, helping you to focus on patients requiring immediate medical attention and to quickly adjust care, if needed.

Unlike natriuretic peptide markers, ST2 is not adversely affected by confounding factors such as age, body mass index, smoking, anemia and impaired renal function.

Easy. Accurate. The one to trust. ST2 from Critical Diagnostics. To learn more about the Presage ST2 Assay, go to www.criticaldiagnostics.com or call 1-877-700-1250.

ST2 testing is available from these preferred laboratories:



* 35ng/ml.

CRITICAL DIAGNOSTICS

3030 BUNKER HILL STREET
SUITE 117A
SAN DIEGO, CA 92109



THE PRESAGE® ST2 ASSAY is a simple blood test that aids physicians in risk assessment of chronic heart failure patients. Elevated ST2 levels are indicative of increased risk of an adverse event, hospitalization or death.

*"ST2 gives prognostic information above and beyond natriuretic peptide measurements."
Alan Maisel, MD, VA Hospital, San Diego*

*"We continue to find that ST2 is a valuable prognostic tool in assessing patients across various stages of cardiovascular disease."
James Januzzi, Jr., MD., Mass. General Hospital*

THE PRESAGE ST2 ASSAY IS AVAILABLE FROM THESE PREFERRED LABORATORIES:

