AMERICAN HEALTH CONSULTANTS®

# CHF DISEASE MANAGEMENT™

*The Complete Congestive Heart Failure Resource*

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# Self-contained left-ventricular assist device reduces infection risk

*'Destination therapy' for when transplant is not an option*

*(Last month,* CHF Disease Management *described devices in clinical trials that offer hope for your end-stage patients by pacing and resynchronizing the heart. This month, the newsletter presents a new left-ventricular assist device that avoids infection and an innovative type of temporary heart assist pump.)*

A new heart assist device being tested in Europe may increase the options doctors give their patients who are ineligible for transplant. The LionHeart device awaits approval of the Food and Drug Administration (FDA), after which widespread clinical trials will begin in this country. The device has the potential to improve cardiac function with a lower risk of infection, compared to similar devices.

The LionHeart heart assist device is designed to be a permanent implant — so-called destination therapy — for patients with progressive, irreversible, end-stage Class IV heart failure. Not intended as a bridge to transplant, it is a permanent alternative to transplant.

What makes the device different from other short-term assist devices, the bridges, is that its components are fully implantable, eliminating need for drive and venting lines.

### KEY POINTS

- This new, totally implantable device is now in clinical trials.
- Not a bridge-to-transplant or temporary heart helper, LionHeart is permanent therapy for end-stage heart failure in patients who are not candidates for heart transplant.
- Because it's totally implantable, it lowers the long-term risk of infection and improves a patient's quality of life.

"Currently all assist pumps have drive lines or external tethers that stick out from the body," explains lead investigator **Walter E. Pae Jr.**, MD, a cardiothoracic surgeon and professor of surgery at Penn State's College of Medicine in Hershey. "These lines often cause infections, and we think this device will greatly reduce the risk of infection."

Pae says the device, developed at his facility in conjunction with Reading, PA-based Arrow International, marks a major step forward in heart-assist technology. "This new device is totally implantable, and there are no other fully implantable heart assist devices in clinical trials. It is not a bridge to transplant or temporary heart helper, but rather, a permanent therapy for end-stage heart failure in patients who are not candidates for heart transplant."

### Danger of infection from LVADs

Assist devices that act as a bridge to transplant, such as the LVAD (left ventricular assist device) made by Thoratec, says Pae, are not fully implantable and not meant to be permanent. Cannulas come out through the skin, and they are a constant source of infection.

"Also, the patient is less able to take a shower or submerge himself in water [with traditional LVADs]. All these devices are pulsatile; they take blood out of the left ventricle through a unidirectional valve in a pump, and pump it down to the ascending aorta," he says. By doing that, the pumps take over the work of the left side of the heart. That lowers pressure inside the lungs and provides appropriate forward flow of blood to organs.

"The defining feature of the LionHeart system is the use of pulsatile technology and improving it by combining the control system with the battery and putting it all inside the body," says Pae. "Then it allows energy to pass across the skin through transcutaneous energy transmission. We're able to recharge the batteries to provide a constant source of power without a break in the skin." The patient can untether himself from the wand for 20 minutes and go swimming or take a shower. "That not only eliminates the possibility of infection but also improves a patient's quality of life."

### Observers comment

The strong point of the LionHeart system is that it avoids infection, says **Richard Pozen**, MD, FACC, national medical director of Vivra Heart Services in Fort Lauderdale, FL. "But if something goes wrong with the implanted devices that have external leads, you can unhook them. It seems that this device would be harder to get to [because] it's totally implanted. You'd have to go into the patient to get at it."

"We recognize that heart transplantation is a limited and expensive way to treat advanced heart failure," says **Marc Silver**, MD, who runs the CHF center at Christ Hospital in Chicago, a division of Advocate Healthcare.

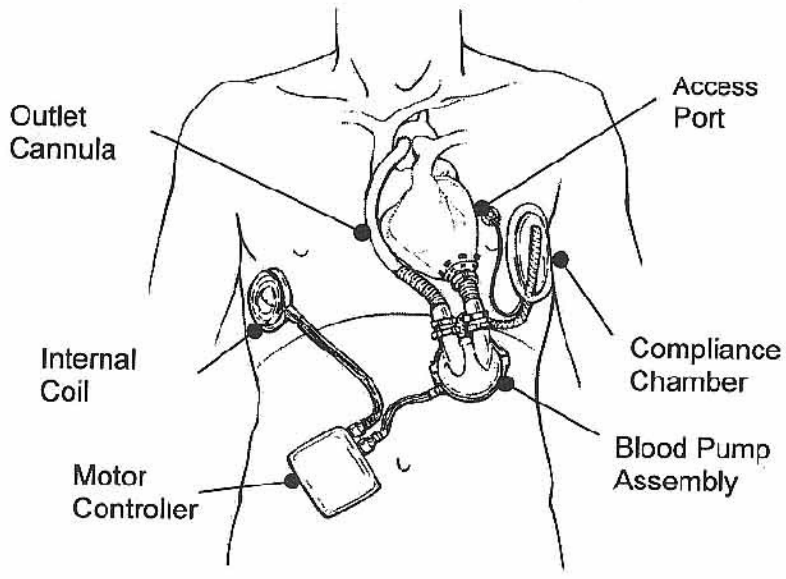
> *"It's not feasible to give a 30-year-old's heart to a 70-year-old recipient with diabetes who probably won't live more than a couple of years, when that same heart could be put into another 30-year-old. This leaves an underserved population with poor quality of life."*

"We have learned from using LVADs that we can safely support people for a long time, if needed, and that many people can recover significant heart function. Growing out of these observations are two strategies: bridges to recovery and destination therapy. What is open for debate now is which approach is more practical and economical." Silver says that having a totally implantable device without a break in the skin overcomes one

### COMING IN FUTURE MONTHS

- News about on-line patient-caregiver links
- Alternative opinions on alternative therapies
- The trouble with subgroup analyses: Time will tell
- Treating the geriatric population: Special concerns
- Treating other special populations: Asthmatics, diabetics

## How Does the LionHeart Work?




Implantable components of the LionHeart LVAS — combined, they weigh 3.2 pounds (1.3 kg).

The blood pump, connected to the native circulation via inlet and outlet cannulae, is electrically powered and implanted in the preperitoneal space, beneath the left costal margin. It features a motor, a pusher plate mechanism, a smooth blood sac, and two tilting disk valves for unidirectional flow.

The motor controller and internal coil control the operation of the blood pump. The pump and controller are powered by either external sources of rechargeable batteries located in the controller. External power is received transcutaneously by the coil and sent to the controller and pump for continuous operation. Internal power is delivered by the controller's rechargeable batteries and allows the patient to function totally free of the external power source for about 20 minutes. The controller is placed under the anterior abdominal wall in the preperitoneal space, beneath the right costal margin. The coil is placed in the subcutaneous tissue of the chest wall.

The compliance chamber and access port serve as a gas-volume accumulator. The chamber provides gas to evacuated chambers of the blood pump during its operation. It is periodically charged via the access port with room air. The compliance chamber is placed in the left pleural space and access port passed through the intercostal space and located in the subcutaneous tissue over the left anterior chest wall.

*Source:* Arrow International Inc., 2400 Bernville Road, Reading, PA 19605. Telephone: (610) 378-0131.

of the major limitations of LVAD therapy — risk of infection.

"Now we await the longer term outcome studies of this approach," he says. "It should certainly reduce the infections, but may not reduce them altogether since a foreign body always increases this risk."

The concept of shorter term support with current LVADs for a period of time that reduces the risk of infection, but still allows some recovery, is another approach being taken at several centers. Silver and Pozen note they have no connection to the company that produces LionHeart.

"We clearly have better medium- and long-term options for patients with advanced heart failure today," adds Silver.

Pae, also director of transplantation at The Milton S. Hershey (PA) Medical Center, assisted German surgeons at Herzentrum Nordrhein-Westflaen hospital in Bad Oeynhausen when they implanted the LionHeart device in a 67-year-old man last October. The patient had a diagnosis of dilated cardiomyopathy and was considered ineligible for transplantation.

### *Patients can untether for a shower*

The LionHeart device incorporates a power transmitter/coil feature that transfers energy across intact skin to implanted batteries, allowing patients to be "untethered" for approximately 20 minutes.

Percutaneous drive lines and external tethers are eliminated. The power transmitter/coil is connected to a power pack that can be pulled on a handcart or, if the patient is able, worn on the belt or carried in a backpack or shoulder harness.

The device weighs about 8 pounds when loaded with two rechargeable battery packs, each of which provides two to three hours of power for mobile operation. **(See illustration of placement of the device, at left.)**

"This is for patients with end-stage

heart failure who are not transplant candidates," says Pae. "There is a very large population of patients with Class IV heart failure. The trial is designed to pick a very sick population who have prognostic indicators of one-year survival — patients who, if treated medically, would have survival chances of less than 50%. And it is for patients who are not transplant candidates due to age or comorbidities that prohibit them from taking anti-rejection drugs."

Pae says donor organs are a scarce resource. "It's not feasible to give a 30-year-old's heart to a 70-year-old recipient with diabetes who probably won't live more than a couple of years, when that same heart could be put into another 30-year-old. This leaves an underserved population with poor quality of life."

Pae, a consultant for Arrow, says that at the same time LionHeart is being submitted to the FDA for approval, investigators are working on coming up with lighter, more compact energy sources to power the device to make it more convenient for these end-stage patients. ■

# New short-term assist device on the horizon

*Compression cuff is a bailout tool*

Cardio Technologies of Pine Brook, NJ, is on the brink of releasing its new CardioSupport System. The minimally invasive, fully reversible therapeutic device is intended to be used on a short-term basis, usually for seven to 10 days, in patients with severely compromised heart function.

The system is different from other ventricular assist devices in use in that it employs a soft cuff-like device that is placed around the failing or unbeating heart. It applies external pressure directly to both ventricular chambers of the heart, squeezing it and helping it through its failed or unbeating state. It supports a failing heart until function recovers or until a more-definitive medical therapy can be performed.

To date, the developer has supported studies on use of the external pulsation device only in animals that its representatives say have proven the cuff's ability to support the heart until additional help is applied.

Researchers from Columbia University in New York City ran a study on canine hearts using the system and concluded that direct cardiac compression is "a feasible alternative form of ventricular assist."[1] The same lead author reported on another study, "Nonuniform direct cardiac compression significantly improves the left and right ventricular pressure-generating capability and, in the setting of acute heart failure, can increase CO and mean arterial pressure."[2]

**Eric Rose**, MD, a cardiovascular surgeon and chief of surgery at Columbia-Presbyterian Medical Center in New York City, has been involved in the animal trials. "The Cardio Support system will be a temporary measure for patients with life-threatening, severe CHF," he says.

"It compresses the heart rhythmically along with the heart beat in order to propel more blood forward and restore cardiac output. Then the heart can either receive therapies that improve its function, or the patient can undergo reparative therapy such as revascularization, or ultimately the heart can be assisted with a longer-lasting device such as an LVAD [left ventricular assist device], or transplant," Rose says.

### Déjà vu *all over again for a narrow niche*

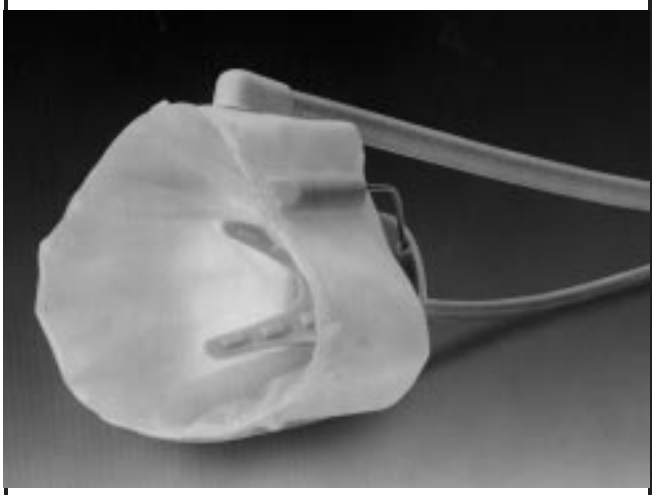
An earlier study on cardiomyoplasty, sponsored by Minneapolis-based Medtronic, took a patient's own back muscle and wrapped it around the failing heart. **(See *CHF Disease Management*, February 1999, p. 16.)** In much the same way as CardioSupport assists the heart, that technique used mechanical compression. The patient's latissimus dorsi muscle-wrap was "trained" to respond to electric pacing, beating with the heart in an attempt to improve cardiac performance.

Citing a dwindling patient enrollment, Medtronic ended its study. **(See *Circulation* 1995;**

**KEY POINTS**

- This promising biventricular assistance device can be inserted in 15 minutes.
- It inflates and contracts, providing mechanical massage.
- Minimally invasive, there's no blood contact, and heart anatomy is preserved.
- It costs about $10,000.

## CardioSupport System



*Source:* Cardio Technologies, Pine Brook, NJ.

**91:2,314-2,318 and 1997; 96:3,665-3,671.)** In testing cardiomyoplasty, investigators found that the advantage of the muscle wrap had more to do with curbing the dilation and chamber remodeling that occurs in advanced CHF than with the muscle helping the heart beat.

**Reynolds M. Delgado III**, MD, of the Texas Heart Institute in Houston, has seen the external pulsation device demonstrated. He says there are various ways to treat advanced heart failure with assist devices, and each has its niche of utility. "The utility of this device is very narrow, because it's for patients who have a very acute problem."

The device poses a high risk for infection. It can only be used for a week or less, he says, because it provides a direct link to outside the body, and infection will set in after that brief time. "What we need is a similar device that can be used for many months — one we can put in and forget, one that allows mobility with no infection risk."

Delgado says that's what the new Jarvik artificial heart will provide and that his facility will start using the Jarvik 2000 in humans in the next month. The Texas Heart Institute is the first center in the country to use the Jarvik 2000.

He says the Institute started doing the latissimus dorsi cardiomyoplasty procedure several years ago, then stopped doing it after a few years because, although it worked well in the short term, it did not in the long term.

"The technique is not an optimum solution," says Delgado. "Cardiomyoplasty used one of the skeletal muscles to help the pumping function of the heart, and skeletal muscles are not designed to continually contract for weeks and weeks. They wear out and stop working after a while. Only heart muscles are designed for that kind of continuous work."

How is the external pulsation device better than cardiomyoplasty? "Like the Jarvik, it is a device; it won't wear down until it breaks. Theoretically, there is no limit on how long you can use a device like that," he says.

He does see another disadvantage of the CardioSupport System. "It may traumatize the outside tissues of the heart because it sits on its surface. Especially if there are delicate veins of bypass grafts there, it could disrupt those grafts when you apply this device that is pumping at high pressures."

He says he doesn't think the system will be used to a large extent because of its narrow niche and short use potential. "But it could be helpful for people in very specific circumstances where they are literally dying within hours and minutes."

### *Animal studies show effectiveness*

European animal studies have shown that the cuff can raise cardiac output from heart failure levels up to normal resting levels and have proven that the system is capable of sensing the EKG signal to assist the heart synchronize to its native heart rhythms.

The single-use CardioSupport System slips over the outer surface of the heart and increases cardiac output through external compression in synchronization with the normal heart rhythm. **(See photo of device, above left.)** The cuff is pneumatically driven and controlled by a console that keeps track of the timing and pressure of its inflation as well as monitoring the patient's condition. Composed of biocompatible polyurethane and titanium, the cuff is flexible enough to collapse and be introduced through a standard 10 cm thoracotomy.

**John Bichan**, a representative of Cardio Technologies, says the surgeons who participated in preclinical trials say the device can be collapsed and inserted, and the heart supported, within 15 minutes of the start of the implantation procedure. No sternotomy is required.

**Mehmet C. Oz**, MD, a cardiothoracic surgeon at Columbia-Presbyterian, calls this "a superb system. Avoidance of bleeding and ease of

insertion are the main advantages."

The system was developed to acutely support cardiogenic shock patients regardless of cause. The clinical protocol specifies seven-day support of patients who typically have either rapidly decompensated CHF or acute myocardial infarction (AMI), or who are post-cardiotomy. CHF patients who have suddenly decompensated for reasons surrounding diet, exercise, and/or flu, cold, or pneumonia will tip over into shock, explains Bichan.

AMI patients who have developed cardiogenic shock also need acute support before their heart is able to recover. And post-cardiotomy support is still a problem for the 4% of the half million people who have open heart surgery and cannot be weaned off the heart-lung machine readily.

The system rapidly perfuses the organs, allowing the surgeon to stabilize the patient and still maintain all his surgical/interventional therapy options because the normal cardiac anatomy is kept intact. If the surgeon feels the patient requires long-term support, he can then implant an LVAD.

"Physicians aren't burning bridges when they use this device," says Bichan. His company has received ethics committee approval for its clinical protocol from seven investigative institutions in Europe, and clinical trials are anticipated to start early next year.

### No contact with the bloodstream

The system is anticipated to provide the same cardiac output in humans as LVADs at a fraction of the surgery time, invasiveness, and cost; its cost is about one-sixth of the major LVADs on the market. The main difference between the device and the DeBakey heart and Jarvik 2000 is that it does not come in contact with the bloodstream.

"Such . . . devices can potentially avoid the complications associated with currently available ventricular support devices that involve a blood/device interface," wrote Columbia University researchers.[1]

According to Bichan, LVADs are typically only implanted into patients who are transplant candidates, leaving out the many people who will die from cardiogenic shock.

"There is only a 1% chance that a patient who has an LVAD will not go on to heart transplant," he says.

### References

1. Artrip JH, Wang J, Leventhal AR, et al. Hemodynamic effects of direct biventricular compression studied in isovolumic and ejecting isolated canine hearts. *Circulation* 1999; 99:2,177-2,184.

2. Artrip JH, Yi G-H, Levin HR, et al. Physiological and hemodynamic evaluation of nonuniform direct cardiac compression. *Circulation* 1999; 100:236-243. ■

## New devices serve a tiny population

*An expert comments on end-stage technology*

**Richard Pozen**, MD, FACC, national medical director of Vivra Heart Services in Fort Lauderdale, FL, says both the LionHeart and the CardioSupport systems accomplish something of value. *(Pozen is not connected to the companies that produce LionHeart or CardioSupport.)*

"The LionHeart operates along the lines of a LVAD; the other seems to me to be similar to EECP [enhanced external counterpulsation] in that it uses mechanical force to assist the heart. They both make sense," he adds.

"But both these items affect such a trivial percentage — probably less than 1% — of the CHF population," says Pozen.

"You're not looking at a therapy that's going to be reasonable to use in a large proportion of patients. The patients these devices are directed at are very end stage, and the devices act either as a bridge to transplant or as a substitute for transplant. Neither one is looking at achieving any long-term benefits," he adds. CardioSupport is expressly a short-term system. But LionHeart too typically would not be in the patient for more than a year, because that's the life expectancy of these patients.

Why are companies spending research money on devices that may not be reimbursed or financially successful?

"It's like throwing spaghetti on the ceiling; if one or two devices stick, they can make companies a lot of money. I compare the devices we're talking about to EECP. There's no strong evidence that that technology applies to a large population, or that it helps people. There's only anecdotal evidence. Yet EECP got FDA approval, and once that happened, it got Medicare endorsement.

And it is now installed in hospitals. When patients need help, they'll go anywhere for it."

What are the chances of third-party payers paying for these devices? "In my opinion, they may get FDA-approved, but they won't be covered by traditional insurance companies on a routine basis. The population they benefit is too small, and those patients will die soon anyway."

Pozen says it comes down to bioethical issues. "It's similar to the issues surrounding terminal cancer. Can you buy six months or a year by putting someone through more chemotherapy? Yes, but is it going to make a real difference?"

"If these companies spent all the money that they are spending on developing these devices on making certain that patients were taking adequate doses of ACEIs [angiotensin converting enzyme inhibitors]," says Pozen, " they'd get more bang for their buck."

He says that in his opinion, there are never going to be enough test cases for the devices to make a real clinical significance.

"Investigators may have enough cases to produce a paper and say their trial is statistically significant. But they're not going to have a couple thousand patients who have this implanted compared to a couple thousand who don't, and then be able to make clinically important conclusions. If you take this limited population and increase the survival of everyone by a month, that makes a very statistically significant result. But is that clinically significant?" asks Pozen.

His opinion extends to the resynchronization-defibrillator-pacing devices. **(See *CHF Disease Management*, January 2000, pp. 1-7.)** Pozen says they are for people who have arrhythmia as their primary problem.

"They combine the ICD [implantable cardioverter defibrillator] function with some coordination function. There are lots of studies that show that when you synchronize the left and right ventricles or the atrium and ventricle, there is increase in cardiac output. There's no evidence, though, that the synchronization sustains itself for a long period of time or that it really makes a clinical difference. Patients are not saying, 'Now I can walk my three miles a day and can breathe better,'" adds Pozen.

He says all these devices are the tip of the iceberg. "Physiologically and biomechanically they make a lot of sense.

Will the FDA approve CardioSupport and LionHeart? Probably yes. "All [the FDA] requires is that the devices be put through the appropriate clinical testing and show efficacy and safety," he says. "The FDA doesn't care if they will be paid for and what percentage of the population they could help." ■

## Pumps compared to the pacing/resync devices

Implanted by cardiac surgeons through thoracotomy, the CardioSupport device, manufactured by Cardio Technologies in Pine Brook, NJ, is used in an acute episode of heart failure.

The pump assists the heart temporarily by helping it move blood forward. It is typically used for patients waiting for transplant who have had massive heart attacks and need something to keep them alive.

In contrast, the pacemaker-defibrillator-resynchronization devices provide long-term, continuous therapy. They are designed to stay in place for the life of the patient and are "permanent treatments given to patients who will leave the hospital shortly after the device is implanted," says **Angel Leon**, MD, a cardiac electrophysiologist at Emory Health Care/Crawford Long Hospital in Atlanta. "They will go home and not need anything else."

Devices like InSync and InSync ICD made by Minneapolis-based Medtronic are not pumps; they provide a stimulus, "a way to electrically stimulate both chambers of the heart to let the heart do the work better as opposed to an assist device that actually does the pumping," explains Leon. ■

# Don't forget Heart Failure Week: Feb. 14-21

Every reader of this newsletter should know that heart failure (HF) is the most common cause for hospital admissions for patients over 65 and that there are many new treatments available, even for patients with advanced disease. Some treatments can be as basic as sodium restriction and exercise.

Unfortunately, there still is very little awareness about HF among the general public. For that reason, there is a nationwide effort under way to raise awareness about HF and what can

*(Continued on page 22)*

# Patient Education: What is Heart Failure?

## DEALING WITH HEART FAILURE

More people are surviving heart attacks than ever before. That's the good news. The bad news is that heart attack survivors may have damaged heart muscles. In fact, the most common cause of heart failure is injury from a heart attack.

## WHAT IS HEART FAILURE?

Heart failure doesn't mean the heart stops beating. A failing heart simply doesn't pump as well as it should. It can't circulate enough blood to keep up with the body's demand for oxygen and other nutrients. This poor circulation causes a person to fatigue easily, and also causes the lungs, legs, and other body parts to become congested with fluid.

There are two types of heart failure, depending on the heart's pumping cycle:

- ❤ In systolic failure, the heart muscle is too flabby and weak to pump with enough force.
- ❤ In diastolic heart failure, the heart muscle is stiff and resists filling with blood.

These varieties can coexist.

## THE HIGH STAKES

Heart failure is a serious condition, both deadly and expensive. Medicare spends more on heart failure than on heart attacks and cancer combined. Meanwhile, the outcomes for people with heart failure continue to worsen, even though outcomes for other kinds of heart disease are improving.

## CAUSES OF HEART FAILURE:

There are other causes of heart failure besides heart attack. These common causes include:

- ❤ Coronary artery disease: Arteries that supply blood to the heart become narrowed or blocked.
- ❤ Hypertension: Pumping against persistent high blood pressure injures the heart muscle (diastolic heart failure).
- ❤ Chronic lung disease: Pumping blood through severely damaged lungs also damages the heart.
- ❤ Alcohol and street drugs: Cocaine and others can act like a poison on the heart muscle.
- ❤ Valve disease: Back flow from floppy heart valves or resistance from valves that are stiff or rigid can stretch and weaken the heart.
- ❤ Infection: Germs or a virus can infect and destroy the heart.
- ❤ Genetic or congenital heart disease: Defects are present in the heart at birth or can be passed on through generations of family members.

## HOW DO I KNOW IF I HAVE HEART FAILURE?

Because heart failure can develop slowly over time, at first you may only find yourself getting tired more easily. As heart failure gets worse, even light activity may rob you of energy. Other symptoms depend on where the blood backs up. Swelling, known as edema, occurs when blood backs up in blood vessels. Your feet, ankles, and hands are puffy and tight with fluid. As you retain fluid, you may gain weight. When blood backs up in the lungs, you may feel short of breath. Doctors call this dyspnea. You may need to sit upright to breathe or prop yourself up on pillows to sleep. Sometimes, you may find yourself waking up at night feeling like you can't get enough air. Since other conditions can cause shortness of breath, your doctor will want to do tests. People who have their heart function measured generally receive better management of their condition. Treatment is more carefully tailored to their individual needs.

## WHAT TESTS ARE NEEDED TO DIAGNOSE HEART FAILURE?

Every patient with heart failure needs to have a heart function measure taken. Heart function is expressed by a measure called ejection fraction, or EF — the percentage of the blood inside the heart that is pumped out with each heartbeat. Normally this is about 60%.

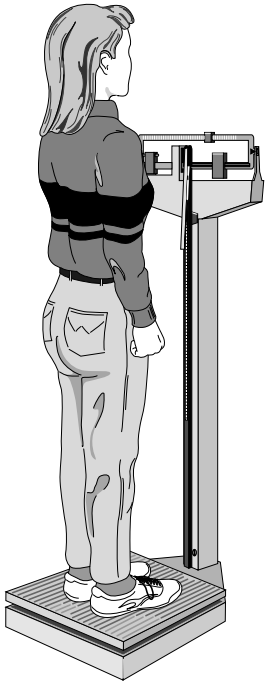
Three kinds of tests can be used to measure heart function:

- ECHO (echocardiogram): Sound waves (ultrasound) are used to look at the heart as it pumps.
- MUGA (Radionucleotide Ventriculogram or Multi-Gated Acquisition Scan): Some red blood cells are tagged with a radioisotope dye. As these cells flow through the heart, they show up as an image of the heart on a computer terminal.
- CATH (cardiac catheterization): X-ray dye is injected into the heart from a blood vessel. This test is more invasive and is used when more information is needed, such as checking for blockage in coronary arteries.

## PLAY YOUR CARDS RIGHT

Try to avoid behaviors that may lead to a heart attack. If you've had a heart attack, take care of yourself to avoid serious complications, troublesome symptoms, and costly unpleasant trips to the hospital:

- Check to see if your heart function has been measured.
- Know your EF.
- Take your medications regularly (ACE inhibitors, diuretics, digoxin, and others).
- Follow a heart-healthy diet and avoid sodium.
- Get a flu shot every year and make sure you get a pneumonia shot, too. You don't need the flu and pneumonia on top of heart failure.
- Weigh yourself every morning. An increase of two pounds in a day can mean you are retaining fluid and may need more medicine.
- Avoid tobacco and alcohol.
- Stay active — follow your doctor's advice about regular exercise. The better your other muscles work, the easier it is on your heart.
- Preserve your energy. Don't stress and strain; pace yourself.
- Report signs of worsening heart failure early. Don't wait to see your doctor in the emergency room.



## HOW IS HEART FAILURE TREATED?

Treatments for heart failure are chosen to ease the workload of your heart, to avoid complications, and to prevent further loss of heart function.

- ACE Inhibitors (angiotensin converting enzyme inhibitors): These are the mainstay of heart failure treatment. No other medication is as well proven to improve symptoms and reduce the risk of complications and death. Most everyone who has heart failure should be taking ACE inhibitors.
- Diuretics: Water pills remove excess fluid by prompting the kidneys to make more urine.
- Digoxin (lanoxin, digitalis): These drugs boost the pumping strength of your heart and controls the rate and rhythm of your heartbeat.
- Other medications: Those few people who are not suitable for ACE inhibitors can take other medications. Nitrates and hydralazine are alternatives. Angiotensin II receptor blockers (ARBs), certain beta-blockers (carvedilol and metoprolol), and spironolactone can be helpful when ACEs can't be used or when more than one drug is needed. They may also provide further benefit when used along with ACE inhibitors.

*Source:* Adapted with permission from *Medicare Talk*, a publication of Arkansas Foundation for Medical Care, 2201 Brooken Hill Drive, P.O. 180001, Fort Smith, AR 72918-0001. Telephone: (501) 649-8501. Web site: www.afmc.org. The Medicare Beneficiary HelpLine number is 800-272-5528. *Medicare Talk* recently won the 1999 Banner Award for outstanding ongoing publications from the American Hospital Association.

## Pathways to good health

For people with atrial fibrillation, a condition that causes an irregular heartbeat, the risk of stroke is five times greater than normal. Atrial fibrillation can be the source of blood clots that float to the brain and cause a stroke.

If you have atrial fibrillation, your doctor may prescribe warfarin which inhibits blood clotting to reduce your risk of stoke by 68%. If you are taking a blood thinning drug, have your blood tested monthly and keep track of your international normalized ratio (INR) number to make sure you are being treated safely and effectively. ■

be done for it. The Heart Failure Society of America based in Minneapolis has designated the week of Feb. 14-21 National Heart Failure Awareness Week and CNN's talk show host Larry King has agreed to be the effort's national spokesman.

Various hospitals have planned coordinating activities to participate in the special week. Christ Hospital and Medical Center in Chicago has a variety of patient, staff, and physician activities planned that week. Patients will be able to obtain information on the latest treatments of heart failure, learn simple things that they can do to improve their quality of life, and learn who is at risk for heart failure.

"The goal," says **Marc Silver**, MD, director of the Christ Heart Failure Institute, "is to raise the level of awareness about heart failure so that people are better informed on earlier detection and improved treatment — similar to what has taken place with breast cancer awareness or AIDS awareness. We will be distributing yellow ribbons, which the Heart Failure Society of America has designated the symbol of heart failure awareness."

For Heart Failure Awareness Week, Silver recommends:

✔ Physicians make sure HF patients are getting proper treatment (review their medication and diet) and instruct them on proper exercise.

✔ Patients increase their knowledge about HF and the current treatments. Often, simple changes in diet or medication can alter how people feel and how long they live. **(See patient education handout on HF, p. 22, and blurb at left.)**

✔ Family members and friends of a person who has HF need to know about basic things like exercise, diet, and medications.

✔ Patients at risk for developing HF need to discuss with their doctors early symptoms of HF such as shortness of breath, fatigue, or leg swelling, as well as their risk of getting HF. Doctors have found that the earlier HF is diagnosed and treated the more can be done for a person. People at risk are:

— the elderly;
— those with previous angina or heart attack;
— those with previous bypass surgery or angioplasty;
— diabetics;
— those with high blood pressure;
— smokers;
— alcoholics;
— those with a family history of heart failure.

"We are hoping this will be the beginning of more awareness and publicity surrounding heart failure," says Silver. He says that unless people get educated, this disease will reach epidemic proportions in the decades to come.

*[For more information, contact: Heart Failure Society of America, Box 358, 420 Delaware St. S.E., Minneapolis, MN 55455. Telephone: (612) 626-3864. Fax: (612) 624-2174. Web site: http://www.hfsa.org.]* ■

# ACE inhibitor: Screen of protection for diabetes

*Ramipril protects against heart disease*

The news was so good for diabetics and other heart patients that even the *New England Journal of Medicine* couldn't wait to release the results. The angiotensin-converting enzyme (ACE) inhibitor ramipril offers broad protection against cardiovascular disease in diabetics, prevents complications, and may even prevent the onset of the disease.

Results from the Heart Outcomes Prevention Evaluation (HOPE) study was to be published in the Jan. 20 issue of the journal, but editors thought the news was too important. They released the article more than two months early on the publication's Web site at www.NEJM. org.

The multinational HOPE study shows ramipril has a vast impact on the overall incidence of cardiovascular disease in the general population. More importantly, for diabetic patients, a full dose of 10 mg per day reduced cardiovascular events by 50% and offered a bonus: strong protection against diabetic complications and new cases of diabetes.

The study's authors say the benefits are so marked that clinicians should consider adding ramipril to the pharmaceutical regimen for diabetics and heart patients.

"Our findings show that ramipril, an [ACE] inhibitor, is beneficial in a broad range of patients without evidence of left ventricular systolic dysfunction or heart failure who are at risk for cardiovascular events," wrote the research team based at McMaster University in Hamilton, Ontario, Canada.

In addition, the researchers concluded, "Treatment with ramipril reduced the rates of death, myocardial infarction, stroke, coronary revascularization, cardiac arrest, and heart failure, as well as the risk of complications related to diabetes and of diabetes itself."

## *Tissue-binding properties*

Ramipril's power lies in its tissue-binding effects, speculates lead researcher **Salim Yusuf**, MD, PhD, director of cardiology at McMaster University. "The results would likely be similar for other long-acting ACE inhibitors if you can calculate the appropriate dosage."

"This shows ACE inhibitors should be first link in the treatment chain for diabetics, particularly those who have already manifested signs of cardiovascular disease," says **William Castelli**, MD. Castelli is a cardiovascular epidemiologist who spent more than 20 years working on the Framingham Heart Study and is now director of the Framingham (MA) Cardiovascular Institute. He agrees that ACE inhibitors like ramipril, quinapril, and captopril seem to have particularly beneficial effects.

Castelli theorizes ramipril may be somewhat unique "because of its ability to localize in the cells, where other ACE inhibitors don't get taken up as well."

Part of the beneficial effect, says Yusuf, is the direct protection of vessel walls and its indirect effect on insulin resistance through improved blood flow to skeletal muscles, causing better glucose uptake.

Yusuf's team said there was a "marked" reduction in complications related to diabetes as well as in anticipated new cases of diabetes. Team members suggest ramipril increases insulin sensitivity, decreases hepatic clearance of insulin, has an anti-inflammatory effect, improves blood flow to the pancreas, or has an effect on abdominal fat. In addition, treatment with an ACE inhibitor such as ramipril or the similar captopril, slows the progression of nephropathy in patients with Type 2 diabetes.

The benefits of ramipril held even in patients who were already taking several effective treatments, including aspirin, beta-blockers, and lipid-lowering agents, says Yusuf. "That means the inhibition of angiotensin-converting enzyme

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offers an additional way to prevent atherothrombotic complications," he says.

The study showed only a small blood pressure reduction of 3 mm Hg systolic and 2 mm Hg diastolic. Yusuf and his fellow researchers believe that small reduction means there are other important effects. The majority of the 9,541 patients who participated in the HOPE study did not have hypertension at the beginning of the study. The mean blood pressure of the patients in the HOPE study was 139/79.

Yusuf thinks the high level of benefit from a relatively low reduction in blood pressure validates the Hypertension Optimal Treatment Study, which suggested that high-risk patients, especially those with diabetes, might benefit from reducing blood pressure even if they are normotensives.

The HOPE researchers determined that treating 1,000 patients with ramipril for four years prevents about 150 cardiovascular events in approximately 70 patients. HOPE study patients were recruited at 129 centers in Canada, 27 in the United States, 76 centers in 14 western European countries, 30 in Argentina and Brazil, and five in Mexico. ■



## SourceKit

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# CE objectives

After reading *CHF Disease Management*, health care professionals will be able to:

1. Identify management, clinical, educational, and financial issues relevant to the care of CHF patients.

2. Explain how those issues affect CHF patients and the providers who care for them.

3. Describe practical ways to solve problems commonly encountered by care providers in their daily activities. ■