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New devices offer options to your advanced CHF patients

Cardiologists guardedly optimistic about pacing and resync gear

(Editor's note: This is the first of a two-part series on new therapies that offer hope for your end-stage patients. Some are improved bridges to transplant, and some are designed as permanent therapy for patients with no other alternatives. This month, you'll read about new devices that are gaining on the problem. They take an electrophysiological approach by pacing and resynchronizing the heart. Next month, CHF Disease Management *will present other new strategies that promise to improve and extend your patients' lives.)*

According to some cardiologists and cardiac electrophysiologists, there's new hope for CHF patients in the advanced stages of their disease. Some of those who are most enthusiastic about new technologies are physicians who have been instrumental in testing four new, life-saving devices. But others are guardedly optimistic as well. Technology manufacturers say with half a million new heart failure cases diagnosed each year, and because up to half of those with advanced heart failure develop abnormal rhythms of the heart, it is those patients that the following innovative devices are designed to help.

"For patients with CHF, the heart's pumping ability is severely impaired, resulting in a poor quality of life and high morbidity," says **Richard A. Gray**, PhD, in the Cardiac Rhythm Management Laboratory at the University of Alabama at Birmingham. "Improving the function

KEY POINTS

- Four new devices are anticipated to provide permanent therapy for advanced heart failure in patients with ventricular asynchrony or poorly coordinated heart contractions.
- The companies are neck and neck with their ongoing clinical trials.

MIRACLE researchers comment on implant

Early in November, **John Messenger**, MD, medical director of cardiovascular services at Long Beach (CA) Memorial Medical Center, implanted Minneapolis-based Medtronic's cardiac resynchronization device as part of the Multicenter InSync Randomized Clinical Evaluation (MIRACLE), a parallel study to the MIRACLE ICD trial. He says there are always technical problems in a new arena, but he started putting in coronary sinus pacemakers in 1975, so getting into the coronary sinus was not difficult for him.

"Many people involved in these studies are electrophysiologists who are very familiar with the coronary sinus, and they place leads there all the time," he says. "But others have not had the practice that we have had putting leads in the coronary sinus. Skill levels across the country vary from zero to excellent. Unlike going to the right ventricle, which is basically very easy, this is a challenge and requires planning and luck."

What does luck have to do with it? "The anatomy of the patient has a lot to do with it," he explains. "The final placement of the lead in the ideal position — high left lateral wall — is easy if you're lucky enough to get a patient with a nice vein at that site. If the patient doesn't, you have to go somewhere else on the left ventricle."

John Boehmer, MD, medical director of the Heart Failure Center and the heart transplant program at the Hershey (PA) Medical Center has implanted Minneapolis-based Guidant's Contak in patients. He says he has had two cases that were problematic: In one, the middle cardiac vein corkscrewed so the surgeons had trouble getting the wire through it. "We ended up using the great cardiac vein. In the other difficult case, staying in the coronary sinus was the problem."

Under what circumstances will this procedure improve the condition of a patient, and how long will that effect remain active? "Those questions remain unanswered at this point," says Messenger, "but my gut feeling is, the procedure will dramatically improve a patient and that improvement will continue. As patients improve, the dramatic changes go away and their conditions becomes the norm." He predicts a success rate of 90% for the device he implanted.

"When we make a heart better, it tends to get smaller, and that results in a very good improvement from a physiological standpoint," Messenger explains. "The volumes of the heart diminish — the actual physical volumes — so it takes less biochemical work to generate the same cardiac output. If my goal is for a heart to generate five liters per minute cardiac forward flow, and we do it with a heart that is 400 cc to 500 cc in diameter, it doesn't take much to do that even with an [ejection fraction] of 10%. We achieve that output by heart rate, the ability to squeeze, and the volume of the heart. That's 50 cc forward flow — 50 cc times a heart rate of a hundred is 5 liters a minute. The average cardiac output is 4.5 liters to 5.5 liters per minute in all humans."

Messenger says the success of these pacing-resync devices will depend on the development of better catheters, and that problem is well on its way to being solved. "In left ventricular pacing, the technical development of the electrodes and the ability to get them into the coronary sinus go hand in hand. I think we're still early in the development of that. There's lots more to come."

He says the procedure is not that extraordinarily expensive or dangerous to the patient. "No physician is going to stop helping people get better. If we are able to show that we can reduce hospital returns, the devices will more than pay for themselves five times over. And the quality of life of patients will be truly improved. The 'ifs' are what we're trying to answer with this program." ■

of the heart has the potential to improve their lifestyle and life span. Presumably, increasing the synchrony of the heart's contraction sequence will help to improve its pumping ability."

He adds new technology may be a reasonable way to improve heart function in CHF patients through ventricular pacing. "The ability to implant leads transvenously provides the opportunity to offer treatment for CHF patients without the difficulties associated with open heart surgery." But he says this treatment path raises some important questions that need to be addressed: How many pacing sites are needed? Where should the leads be placed? What should be the relative timing of the pacing stimuli in relation to the patients' normal rhythm and among various pacing sites?

"Clearly, the patients we are treating today with advanced heart failure often need something more than medicines to 'turn off' all the abnormalities that accompany advanced heart failure," says **Marc Silver**, MD, who runs the CHF center at Christ Hospital in Chicago, a division of Advocate Healthcare. "Nonpharmacologic therapy, such as multisite pacing, often provides that little bit to get those patients over the hump and allows their hearts to slowly begin to recover and may allow the medications to work. Many patients would prefer a device over still another pill."

Silver says cardiologists think they know some of the ways this process works, but the clinical

trials now under way are going to help define who will benefit, for how long, and perhaps why. "This approach of multisite pacing is still another demonstration of the fact that we continue to learn — namely that even the very advanced heart of someone with heart failure may be recoverable if we can support it and get the patient into a more 'advantaged' position."

"The theory behind biventricular pacing makes good sense, and the early trial results are encouraging," says **Edward F. Philbin**, MD, in the Section of Heart Failure and Cardiac Transplantation at Henry Ford Hospital in Detroit. "Appropriately, there is a lot of enthusiasm for biventricular pacing among academic heart failure cardiologists. However, we need to see the results of larger trials, and we need mortality data."

Philbin points out that researchers shooting for better CHF treatments have suffered their share of misfires. Therapeutic agents can produce promising results in small, early studies, but then in subsequent definitive studies, they can still fail to show a lower-mortality benefit among patients who receive them.

It's still not known if promising concepts in electrophysiology will translate into better treatments. "Current implantable defibrillators are not biventricular, and dual chamber pacing must be achieved by another source," says **Richard Pozen**, MD, national medical director of Vivra Heart Services in Fort Lauderdale, FL. "These new devices offer both a defibrillator and a pacemaker capacity. It has been well known that people who lose synchrony have a reduction in cardiac output. That is the main reason why biventricular pacing developed."

Pozen adds, however, that it is unclear that the improvement in cardiac performance is significant enough and sustained long enough to provide adequate therapy for CHF patients. "These devices have some new twists such as using the coronary sinus [which produces left atrial rather than conventional right atrial pacing] and using right and left ventricular leads instead of traditional right ventricular ones only.

"So far, the number of patients tested seems small compared to the size of the potential population. The bottom line is that physiologically, these devices make sense but the issue is whether the improvements will be substantial enough to improve quality or duration of life and whether results will be sustainable. This may be a unique subset of patients who have both life threatening arrhythmias and CHF, and these devices may offer some advantage over current devices."

Three companies, all located within a short radius of Minneapolis and St. Paul, MN, find themselves revving up at the starting gate. They have products in development, which enable concurrent biventricular pacing and resynchronizing in heart failure patients. Three devices already have been

MIRACLE Studies' Inclusion and Exclusion Criteria

The MIRACLE trial

Patient inclusion criteria

- NYHA Class III or IV
- QRS duration >/= 130 ms*
- Ejection fraction <35%
- Left ventricular end-diastolic dimension >/= 55 mm
- Stable medical regimen** for at least one month
- If taking beta-blockers, stable regimen for at least three months

Patient exclusion criteria

- Unstable angina or acute MI
- Coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within the past three months
- Prior pacing systems or pacing indications
- Existing implantable cardioverter defibrillator (ICD)
- Chronic atrial arrhythmias
- Life expectancy < 6 months for reasons unrelated to heart failure

The MIRACLE ICD trial

Patient inclusion criteria

- NYHA CLASS II, III, or IV
- QRS duration > 130 ms
- Ejection fraction < 35%
- Left ventricular end-diastolic dimension >/= 55 mm
- Stable medical regimen
- If taking beta-blockers, stable for 3 months
- Indicated for an ICD

Patient exclusion criteria

- Unstable angina
- CABG
- Chronic atrial arrhythmias

* ms=milliseconds
** Including at least ACE inhibitors or an ACE inhibitor substitute, unless contraindicated or not tolerated by the patient.

LVADs vs. Resync Devices

Both left-ventricular assist devices (LVAD) and resynchronization are combined with pharmacological therapy to help the heart failure patient. But how do the new biventricular pacing-resynchronization devices differ from LVADs? **Chuck Yerich** of Medtronic explains the differences:

- ☐ Cardiac resynchronization is applied much earlier in the course of the disease progression than are LVADs.
- ☐ Resynchronization devices and wires are completely implanted via a small incision in the patient's upper chest area.
- ☐ Like a traditional cardiac pacemaker, the patient and family are unlikely to be aware of the action the resynchronization device is performing on each heartbeat to resynchronize the heart — 100,000 heartbeats, on average, each day.
- ☐ Resynchronization devices are intended for long-term/chronic use. ■

tested in Europe and are being evaluated now in American clinical trails. From Medtronic come the InSync and InSync ICD implantable cardioverter defibrillator (ICD) and the Attain family of leads — Attain LV, Attain SD, and Attain CS; from Guidant come the Contak CD and its Easytrak lead; and from St. Jude Medical come the Frontier system and the Aescula LV lead.

St. Jude's approach is somewhat different from the other two companies. They are investigating the use of left ventricular pacing for patients with both CHF and atrial fibrillation. According to a financial report, the niche population represents approximately 25% of CHF patients.[1]

All the systems are anticipated to allow permanent therapy for symptomatic advanced heart failure in patients. And the leads are specifically designed to access the heart through a noninvasive transvenous approach.

Physicians at more than 35 centers in the United States and two in Canada are evaluating the performance of Medtronic's products on about 300 patients as part of two clinical trials: Multicenter InSync Randomized Clinical Evaluation (MIRACLE) and MIRACLE ICD.

MIRACLE involves Medtronic's InSync device, and MIRACLE ICD involves Medtronic's InSync ICD device. Primarily, both studies will measure the effects of cardiac resynchronization therapy on patients' level of heart failure, on the patients' ability to perform physical activity, and on their subjective quality of life. In addition, the studies will measure the effects of the treatment on the following factors:

- ❒ the timing of the contractions of the heart's chambers;
- ❒ oxygen use during exercise;
- ❒ the size and performance of the heart;
- ❒ levels of certain hormones associated with heart failure;
- ❒ the amount of health care services used by participants;
- ❒ length of life.

Angel Leon, MD, of Emory Health Care / Crawford Long Hospital in Atlanta is a consultant for Medtronic and a trial investigator. Early in November, the cardiac electrophysiologist implanted the InSync ICD with the Attain SD lead into a 70-year-old male who presented with symptomatic advanced heart failure and ventricular conduction abnormalities, and who was at risk for possibly lethal heart rhythm disturbances. The patient was otherwise healthy, but was beyond the age limit when transplant programs would consider him. Leon had been following his case for six years.

"Initially he had coronary artery disease and myocardial infarction. And over the past year and a half, his heart had progressively become weaker and he'd developed symptoms of CHF. His heart had enlarged, it wasn't pumping efficiently, and he had shortness of breath and was accumulating fluid," says Leon. "On top of that, we'd seen some nonsustained bursts of ventricular tachycardia." So he had a combination of heart failure as well as signs of a potentially dangerous rhythm problem.

"He was maxed out on medical therapy," Leon continues. The patient had been treated with at least two diuretics and the beta-blocker carvedilol. Leon says the patient was an ideal candidate for a device that could both pace the heart in a biventricular mode and protect him against arrhythmia.

The device will stay in the patient's chest until the batteries weaken, at which time Leon's team will implant a new power unit under a flap of skin on the chest. "The wires stay in for the rest of his life unless there's a break that would force us to remove them," he says. "My hope is that it stays in a long time because that will reflect the fact that he's living a long time."

Leon implanted the InSync device through his patient's venous system in the pectoral region. "It

is a micro-invasive procedure," says the physician, "as all pacemakers are implanted today." Because they didn't have to open the chest, the patient went home four days after implantation. "The intent of the biventricular pacing was to see if we could help him," says Leon, "but if his meds can be reduced, that would be an extra benefit." As *CHF Disease Management* was in to press, the patient was doing well.

This was the first time Leon implanted the InSync device with the Attain lead. He'd done a number of similar implants with other devices and with devices that he had modified to accomplish the same result. "Before these devices were available," says Leon, "the only thing we could do if we wanted to achieve the biventricular pacing capability was to modify existing standard defibrillators and adapt them to pace both ventricles."

The device manufactured by Guidant, Contak CD, has similar capabilities for similar situations. It is also in clinical trials at Emory, and while the intended benefits are similar, the studies have somewhat different inclusion criteria. Both trials are focused on the same patient — NYHA III or IV, wide QRS duration, ejection fraction (EF) <35%, and stable drug regime. **(See box delineating the two MIRACLE studies' inclusion and exclusion criteria, p. 3.)**

Candidates for Guidant's study must have symptomatic heart failure despite optimal drug therapy and must have had at least one episode of cardiac arrest manifested by loss of consciousness due to an irregular heart beat, or have ventricular tachyarrhythmias. Some individuals who have pre-existing defibrillators in need of change out may also be eligible. Leon points out that inclusion criteria change continually over time due to U.S. Food and Drug Administration requirements.

Diana Campau of Medtronic explains that the MIRACLE ICD trial is a prospective, multicenter, randomized, parallel controlled study. "Parallel controlled means that all patients will be implanted with the InSync ICD device," she says. "However they will be assisted to one of two active treatment schedules. One group will receive heart resynchronization beginning immediately; the other group will not receive heart resynchronization for the first six months of the study, but will be switched to therapy after six months. Until then, they will receive only drug therapy.

"At the end of the period, results of the two groups will be compared to their status before receiving the implant. They will then be followed in the study for at least six months afterward. The design of this study provides a very high level of scientific validity for the results, so investigators, sponsors, and regulatory authorities can be certain whether this treatment has benefited the participants," Campau explains.

MIRACLE ICD study participants are monitored at one month, three months, and every six months thereafter. The study is expected to last 12 to 24 months.

John Boehmer, MD, medical director of the Heart Failure Center and the heart transplant program at the Hershey (PA) Medical Center, recently implanted Guidant's Contak in several patients as a part of one of that company's three ongoing clinical trials. The trials are PATH-CHF (pacing therapy for heart failure), Vigor CHF, and Ventak CHF.

Treatment returned patient to active life

His most recent implant was performed on an 80-year-old male who presented with ventricular tachycardia. "He had a sustained rate of 190," says Boehmer, a Guidant consultant. "He had been out with a pickup truck picking up a load of mulch. On the way to his son's house, he had a sudden onset, and his son called for an ambulance." Medication failed to cardiovert him, and so, with the patient's informed consent, Boehmer's team implanted the device.

"He had a very large heart and an EF of 20%," says Boehmer. "Clinically he was functional Class II prior to this. We first discussed defibrillators, then offered him the Contak." The patient had exertional dyspnea and he fatigued, but he wanted to remain as active as he had been. On advice of his physicians, he thought the device might afford him a better opportunity to maintain his exercise capacity.

"He was implanted successfully," says Boehmer. "He had some nonsustained ventricular tachycardia afterward but is doing well. The tricky part of this procedure had been cannulating and maintaining the coronary sinus, but the Easytrak lead tracks well and goes in nicely. It has not been difficult." Clinically, the patient is back to Class II, and shortly after his surgery, he finished putting out his mulch. "He was in the hospital for three days after implant, five days after presentation, because we had a little trouble with his creatinines."

St. Jude's new technology for resync-pacing has not yet been approved in Europe, but its

FDA-approved Aescula LV lead is stylet-driven and features a tractable S-curve in the distal segment that enhances its maneuverability during implantation in the left ventricle and provides stability after stylet removal. The first implant in this country was performed at the Orlando (FL) Regional Medical Center by principal investigator Aurelio Duran, MD.

Boehmer says St. Jude's stylet-type lead has characteristics somewhat similar to the Medtronic lead. "Researchers using that lead have been able to gain access to the left heart with the same level of success as ours," he says.

Reference

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Suggested reading

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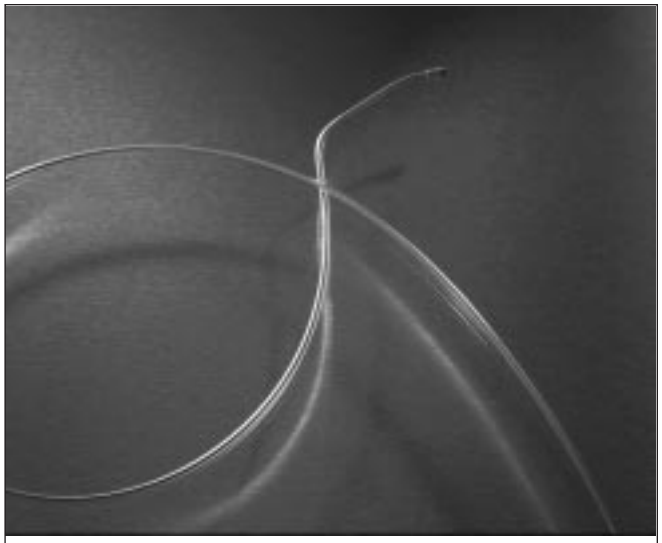
New device's goal is to deliver synchrony

Paces at two sites and coordinates contraction

The Minneapolis-based Medtronic's InSync ICD was developed to detect and treat potentially lethal heart rates and, at the same time, deliver cardiac resynchronization therapy to both sides of the heart. That restores left and right ventricular synchrony by simultaneously pacing both ventricles, improving the heart's pumping efficiency. Due to its size, 4-French in diameter, the Attain lead also made by Medtronic can be easily and quickly positioned into the left ventricle. **(See photos, above and p. 7.)**



Medtronic's Attain SD lead is, according to representatives of the company, the world's smallest diameter left-ventricular lead that is designed for use with implantable systems that treat heart failure. It is part of a family of leads which includes the Attain LV and Attain CS leads.

Source for both photos in this story: Medtronic, Minneapolis.

"The small size of the new lead allowed me to position it precisely where I wanted," says **Angel Leon**, MD, of Emory Health Care / Crawford Long Hospital in Atlanta and a Medtronic consultant.

"Since no two patients present similar cardiac venous anatomies, one lead option may not be sufficient," adds **Steve Mahle**, president of Medtronic's cardiac rhythm management department. His company produces a number of left-heart leads in varying configurations, but all of them have a distal curved shape allowing steerability in small cardiac veins and include the familiar stylet delivery techniques used for placement of all pacing leads today.

Investigators at the Mayo Clinic in Rochester, MN, have also had experience with the InSync pacemaker-defibrillator as Mayo is one of the MIRACLE trial centers. **(See related article on the study, p. 1.)** "The device delivers small electrical impulses to the left and right chambers of the heart to better synchronize contractions," says **Paul Friedman**, MD, a cardiologist and study investigator at Mayo. He says the pacemaker-defibrillator device is the size of a small pager and is implanted under the skin in the chest area. It can deliver up to 34 joules of defibrillation energy. Three thin lead wires are run through veins from the device to the left and right chambers of the

Medtronic's InSync ICD combines two distinctive therapies into one system to treat patients with heart failure and who are at risk of sudden cardiac death from too-fast heart rates. It provides detection and treatment of life-threatening tachyarrhythmias from the right side of the heart, as achieved in current Medtronic defibrillation systems, and at the same time, delivers resynchronization therapy, intended to restore left and right ventricular synchrony by simultaneously pacing both ventricles and thereby improve the heart's pumping efficiency.

heart. Only a small incision is required to implant the device. The procedure takes two to three hours to perform and requires patients to stay in the hospital at least overnight.

"The trial at Mayo is just starting up, but we hope to be implanting InSync within a few weeks. It's a matter of appropriate patient selection," he says. "The ideal patient is someone who has depressed ventricular function and is at high risk for sudden death for arrhythmia." The device stays in the patient's chest until death or until the battery runs out. Then minor surgery is involved to replace the battery.

"The device sits under the skin below the collarbone like any pacemaker or defibrillator," he says. "Change-out surgery is done under local or twilight anesthesia." If defibrillator testing is necessary, general anesthesia is administered because arrhythmia testing involves giving painful shocks to the heart to induce and terminate rhythms.

Friedman provides the following distinction between pacemaker and defibrillator technology:

1. "Pacemakers deliver very low energy [impulses] that cannot be felt by the patient. They are for people whose heart pump function is uncoordinated. This new device provides pacing at two sites in the ventricle resulting in a more coordinated ventricular contraction. That's what's unique about the system. The goal is to improve mechanical pump function by improving the electrical activation."

2. "The role of the defibrillator in preventing sudden death is well established. It's for people who have weak heart muscles and who are at risk for developing abnormal rhythms. The defibrillator function of this device is similar to other approved defibs. What's being tested is whether, by improving electrical coordination, mechanical coordination can be improved as well so people will be able to walk farther, have fewer symptoms of shortness of breath, and have less fatigue [i.e.], whether they will have less heart failure." ■

Roundtable spreads the word on CHF's 'Top 10'

PCPs and cardiologists share practice modes

Last fall, **Marc Silver**, MD, a cardiologist who runs the CHF center at Christ Hospital in Chicago, invited cardiologists and primary care physicians from the entire Advocate Healthcare System in Oakbroak, IL, to spend a day talking about CHF and how care could be improved. About 100 people attended the roundtable which was held at nearby McDonald's corporate headquarters — Hamburger U.

"The purpose of the roundtable," explains Silver, "was to update everyone on where we stood with CHF initiatives across our system and to let them know how best to improve the outcomes of their patients with heart failure." Several initiatives are going on at Advocate to improve the quality of care of heart failure patients regardless of where they enter Advocate's diverse system.

"One of our goals was to make primary care doctors recognize that they are extremely important in helping CHF patients. They have to realize

Is a roundtable feasible at your facility?

Advocate Healthcare System in Oakbroak, IL, spent a little more than $8,000 to put on its CHF roundtable at nearby McDonald's corporate headquarters — Hamburger U. It received funding from two pharmaceutical companies. According to **Patti Ludwig-Beymer**, PhD, RN, director of care management and administrator of research and education at Advocate, much less could be spent on food at another facility.

The expense breakdown:

Conference room	$750
Food (breakfast, lunch, snacks)	$5,140
Brochure	$315
Syllabus	$486
Staff support	$1,500
Total	$8,191

it's not just the cardiologists," says Silver. "The primary care doctors have to do the right thing in their offices, and we're here to help them. We're here to provide them with the technology and research opportunities for their patients in their offices and in the hospitals."

This was the kickoff, but prior to the roundtable, Silver and his team had been strengthening the CHF infrastructure throughout the system. They made sure that in each of Advocate's hospitals there is a nurse coordinator whose primary responsibility is to educate and train the staff and coordinate heart failure activities. There are also physicians who have volunteered to be physician leaders for the heart failure initiative. In addition, and most important, he says, "Over the past year, we have worked on creating a standard set of orders that cover heart failure admissions through all our hospitals. They have been agreed upon and now are being used in all Advocate venues. No matter if a patient comes in through an emergency department [ED], or directly to the floor, or to a critical care unit, a standard admission evaluation and treatment can be done on all patients with heart failure."

Heart failure, he says, is one area where there's a tremendous diversity in how patients receive care, particularly on the inpatient side. "A lot of the guidelines and consensus statements address outpatient care, but not so much that of inpatients. We decided to put our ideas into a set of working orders that tell people what steps to take to improve patient care.

"Our first goal is to improve the care of these patients. But in doing that, we have standardized the product we deliver. The managed care organizations are aware of what we're delivering, how we're delivering it, and the fact that we're measuring to see what the outcomes are. If it's a good process, the outcomes will be good. If they are not, we'll change it."

Throughout the roundtable day, Silver and his colleagues addressed the following "Top 10" items (not presented in order of importance):

1. Prevention. Prevention is the "ultimate" solution. The presenters talked about the many secondary prevention measures and how to make prevention a daily practice. "We discussed preventing the diseases that cause CHF — diabetes and hypertension," says Silver. "We also talked about screening patients at high risk for developing CHF."

2. "Doctor means teacher. Education from the physician or nurse has the greatest impact," says Silver.

3. Using the systemwide resources at Advocate. There are educational materials, home nursing, health advisors, support groups, and research and clinical trials. "We wanted to make sure cardiologists and primary care physicians alike know that there are CHF coordinators and CHF educational programs in place throughout this health system," says Silver. "We wanted to make sure they know that there's a lot of clinical research trials going on in CHF throughout the system, and they are available." Advocate also has a software program called Health Advisor that calls patients on a regular basis asking them questions about their heart failure. By virtue of those phone calls, Silver says, patients can improve their care at home.

4. Tidbits. Presenters talked about digoxin (Glaxo Wellcome's Lanoxin) and about spironolactone (Searle's Aldactone) and the Randomized Aldactone Evaluation Study (RALES) trial. They also discussed when to use angiotensin II receptor antagonists, the role of statins in CHF, salt restriction, and exercise. "These other modalities may be very helpful. Heart failure, like all chronic disease, is focused in the details. Those are all accessories that can make a big difference in how doctors can alter prognosis in CHF," says Silver.

5. Using beta-blockers at target dose. Clinical trials in over 10,000 patients confirm that long-term treatment with beta-blockers improves

symptoms and clinical status, and prevents hospitalization and death. Start in your office. Titrate slowly, but progressively. Evaluate volume status. Ask for help if needed. "We tried to make the drugs understandable so the primary care physician would feel comfortable using them in a wider spectrum of patients."

6. Using ACE inhibitors at target dose. All patients with CHF due to left ventricular dysfunction should receive an ACE inhibitor unless they have been shown to be intolerant or have a contraindication. ACE inhibitors can also decrease the risk of developing heart failure in asymptomatic patients with left ventricular dysfunction. Document their use (or adverse effect). Titrate up to target doses. Why ACE inhibitors are not used:

— hypotension;
— elderly;
— renal insufficiency;
— hyperkalemia;
— cough.

"Our rationale was the outcome measures associated with proper use of ACE inhibitors," says Silver. "We talked about why they are not used as much as they should be and about ways to circumvent that. Basically, we tried to allay fears about using them."

7. Using the standing orders. Standing orders for CHF patients are developed to make life easier, to make documentation better, to guide proper therapy, and to help our patients. "We talked about the impetus to develop them, what they contain, and the importance of using them," says Silver. "We tried to get people to buy into using them in a consistent fashion and get their feedback on them."

8. Using the emergency department. Estimates are that nearly half of the patients admitted can be safely discharged from the ED. Encourage your ED teams to use standing orders, and work towards observation areas. Avoid unneeded testing. "Most hospitals across the country admit 80% of their patients through the ED," says Silver, "and I talked about what can be done there." Advocate's CHF orders initiate care right away in the ED — "It's fairly aggressive," he says. "In our Christ Hospital, where the CHF Institute is centered, we have a program in place to rapidly diurese people in the ED, and we're hoping to discharge at least 30% to 40% of patients who normally get admitted directly from the ED."

9. Measuring and recording ejection fraction (EF). EF helps to stratify causes of heart failure and may help to alert patient and physician of disease status and severity. Measure EF when stable; document the EF. "That distinguishes between systolic and diastolic dysfunction, and the treatments are different," says Silver. "I emphasize the importance of recording the ejection fraction so it doesn't need to be repeated admission after admission. There's no need for routine serial determinations."

If EF is low, indicating systolic dysfunction, explains Silver, and something happens — CHF worsens or the patient has an acute myocardial infarction (AMI) — it is likely only to be lower and therefore not useful to measure. Occasionally if a patient has normal LVEF and then has an AMI or the heart failure is unresponsive, you may repeat. One of the issues is whether routine repeats of the echo, to evaluate the effectiveness of beta-blocker therapy, for example, is valid. Here the experts are split, he says, but generally this is an expensive approach for the majority of patients.

Determining why patients have heart failure

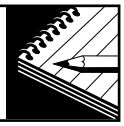
10. Determining an etiology for the heart failure. Common etiologies of heart failure are coronary artery disease, hypertension, alcohol, and valvular arrhythmia. Simply determining the cause(s) of a patient's heart failure can set you on the proper therapeutic course. Document your search. "It's important to know why someone has the disease mainly because some of the causes are potentially reversible," says Silver.

The existing guidelines mandate making sure patients have or don't have ischemic heart disease, he says. "Sometimes it's known when the patient comes into the hospital, and sometimes it's not known. If it's not known, it's worth spending time in the hospital figuring out etiology because it will guide therapy and may even prevent future admission."

The presenters used an interactive keypad system so they could see people's responses to each of the 10 areas before they were discussed. "That kept people integrated and involved in the program. No one fell asleep," says Silver.

What's next? "The next step is to go back to each of the individual hospitals and revisit the same topics," he says. "We'll keep reinforcing them. Interest in this roundtable has been a very strong message from our system that CHF is a common problem that's not going away. In fact, the numbers are growing." ■

GUEST COLUMN



Maybe you should revise your CHF pathways

By **Elgin K. Kennedy**, MD
Editor
The Assertive Utilization and Quality Report

A recent, large double-blind study has shown that adding the aldosterone-receptor blocker spironolactone (Searle's Aldactone) to the medication regimen of patients with severe congestive heart failure (CHF) substantially reduces both morbidity and death.[1] The accompanying editorial suggests that "the standard of care for the treatment of patients with moderate or severe symptomatic heart failure should be broadened to include spironolactone."[2]

At present, aldosterone-receptor blockers are used infrequently for heart failure. This is because these drugs are only weak diuretics, and because they have a potential for causing serious hyperkalemia.

This new study, however, shows dramatic benefits from its use. Investigators suspect that the beneficial effects are due to largely unrecognized physiologic actions of the drugs, such as inhibition of myocardial fibrosis, improvement of new vessel formation, and improvement of excitability and contractility of individual myocardial cells.

The authors enrolled 1,663 patients who had severe CHF and who were being treated with an ACE inhibitor, a loop diuretic such as furosemide, and, in most cases, digoxin. The patients were randomized, and half were given po spironolactone 25 mg QD, and the other half were given placebo. After an average treatment time of 24 months, there were only 284 deaths in the spironolactone group while there were 386 deaths in the placebo group — a reduction in the death rate of 30%. Also, the frequency of hospitalization for worsening heart failure was 35% lower in the spironolactone group than in the placebo group. Finally, the spironolactone patients showed significant improvement in their symptoms of heart failure, as assessed with the New York Heart Association functional class methodology.

Overall, patients tolerated the spironolactone well: 8% of the spironolactone patients discontinued treatment because of adverse events as compared to 5% of the placebo patients. Only 14 patients in the spironolactone group and 10 patients in the placebo group developed serious hyperkalemia.

This could be a good time to create, or update, your CHF pathways and practice guidelines. See if they match the two widely accepted standards for the management of CHF:

• Guidelines for the evaluation of management of heart failure: Report of the American College of Cardiology / American Heart Association Task Force on Practice Guidelines (Committee on Evaluation and Management of Heart Failure). *J Am Coll Cardiol* 1995; 26(5):1,376-1,398.

• Heart failure: Evaluation and care of patients with left-ventricular systolic dysfunction. U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research; 1994 June. (Clinical practice guideline; no. 11.)

Both guidelines can be found in their entirety at the National Guideline Clearinghouse Web site: www.guideline.gov.

[Editor's note: The preceding article was first published in the October 1999 issue of The Assertive Utilization and Quality Report *— $60 per year (12 issues). For more information, contact Elgin Kennedy, MD, at 204 Second Ave., No. 334, San Mateo, CA 94401. Telephone: (415) 348-3647.]*

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1. Pitt B, Zannad F, Remme WJ, et al. The effect of spironolactone on morbidity and mortality in patients with severe heart failure. *N Engl J Med* 1999; 341:709-717.

2. Weber KT. Aldosterone and spironolactone in heart failure, Editorial. *N Engl J Med* 1999; 341:753-755. ■

COMING IN FUTURE MONTHS

- More on new therapies for your irreversible, end-stage patients
- CoQ10: Promise or false hope? The experts comment
- A beta-blocker's unexpected, unwelcome results for black patients
- Aspirin's impact on the benefits of ACE inhibitors
- A special series on hypertension: New findings, new therapies

A 40-year-old drug is still viable

Spironolactone (Searle's Aldactone) has been on the market since 1960 and costs as little as 10 cents a day. **(See *CHF Disease Management*, September 1999, p. 102.)** The drug suppresses aldosterone, a steroidal hormone secreted by the adrenal glands that retains sodium, depletes potassium, and stiffens the tissues of the heart and blood vessels, worsening other cardiovascular risks.

Aldosterone also elevates norepinephrine, stressing the heart. Spironolactone was generally abandoned when ACE inhibitors — thought to work against aldosterone as well — came on the scene in the 1970s, and the standard regimen for severe heart failure became ACE inhibitors, diuretics, and others. But then researchers found that after several months of treatment with ACE inhibitors, their effect is transitory, and aldosterone returns at least to its previous level. Searle had not promoted Aldactone's use in the United States in 20 years, but then decided to fund the study referenced above. **(See related story, p. 10.)**

Special offer for alternative medicine nursing newsletter

American Health Consultants, publisher of *CHF Disease Management* and *Alternative Medicine Alert*, is pleased to announce a new monthly publication for nurses on alternative medicine and holistic nursing.

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Pitt and associates tested the hypothesis that adding an aldosterone antagonist (25 mg spironolactone) to traditional heart failure therapy with ACE inhibitors would reduce mortality. The trial was designed to last for up to three years, but was halted a year early because the benefits to patients were unmistakable.

According to a recent article in *U.S. News & World Report*,[1] in 1994, a study published in the *New England Journal of Medicine* surveyed 1,211 doctors about their use of heart attack drug therapies that had been in the medical literature for up to a decade. Almost 22% of cardiologists, 37% of internists, and 47% of family practitioners were not using one or more of the beneficial drugs —

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and 5% to 26% were using other drugs that had been largely discredited.

This fall, researchers at Searle will begin testing a drug called Eplerenone that may prove to reduce the side effects of spironolactone because about 10% of men using it experience gynecomastia or impaired sex drive. Hyperkalemia occurred in 10% of study participants as well.

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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. ■