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Bucindolol trial yields neutral and negative outcomes for CHF patients

'Treat blacks with beta-blockers until we have more evidence'

Surprising new findings revealed at the American Heart Association meeting in Atlanta last fall from the BEST trial include both neutral and negative outcomes that the beta-blocker bucindolol has had for some CHF patients. When the drug was administered to patients with advanced CHF, no benefit was seen, and subgroup analyses revealed that blacks, 23% of the study population, in general did not benefit and may even have been harmed by the drug.

BEST (Beta-blocker Evaluation of Survival Trial), sponsored by the National Heart, Lung and Blood Institute (NHLBI) and the Department of Veterans Affairs, randomized nearly 3,000 mainly NYHA Class III and IV heart failure patients on standard therapy to the nonselective beta-blocker bucindolol or placebo and followed the patients for a mean of two years.

Unlike previous beta-blocker studies, BEST placed a significant emphasis on the enrollment of women. While women over age 60 comprise approximately half of the 3 million Americans who suffer from heart failure, they typically comprise less than a fifth of the patients enrolled in heart failure studies. One of the goals of BEST was to achieve an enrollment of at least one-third women in order to evaluate the effectiveness of beta blockade in both men and women with CHF.

Although findings showed that bucindolol (marketed by

KEY POINTS

- The Beta-blocker Evaluation of Survival Trial trial showed that bucindolol does not reduce deaths from CHF, contradicting other studies of beta-blockers.
- Reasons for the unexpected results are not yet clear.
- The study was stopped prematurely due to evident harm produced by the drug.

Intercardia of Research Triangle Park, NC) reduced deaths by 10% overall, those data were not statistically significant; patients with more advanced disease in particular did not benefit.

Carvedilol and metoprolol studies have had clearly positive results. What went wrong with BEST? Discussion at the meeting focused on several issues:

1. **Most of the other beta-blocker trials focused on Class II patients, with some Class IIIs and just a few Class IVs.** "Carvedilol is not recommended in Class IV or unstable patients even with lesser symptoms," wrote Michael H. Crawford, MD, in the December issue of *Clinical Cardiology Alert*.

2. **Bucindolol is nonselective like carvedilol, but bucindolol does not have the alpha-blocking properties that carvedilol has.**

3. **The relative lack of effect in blacks who comprised about a quarter of the patients may have skewed the results of an otherwise positive trial.** The Scandinavian metoprolol trials and the carvedilol studies done in Southeast Asia included few black patients.

A medical mystery

"But the answer is not yet clear," says **Josh Hare**, MD, assistant professor of medicine and associate director of the heart transplant program at Johns Hopkins Hospital in Baltimore. "This is one of the puzzles in medicine that we have to confront from time to time. I don't think anyone knows the answer. All we can do is look at the results and put them in the context of other studies we've done and try to come up with a uniform picture." He says the answer could be something completely intangible and adds that investigators can go on for decades developing drugs for specific reasons, then only much later come up with new discoveries that show that the reasons they were using them were wrong all along.

"We think these [beta-blocker] drugs work by blocking the beta receptor, and we know there are different beta receptors — 1, 2, and 3," says Hare. "And we also know there are alpha receptors." Drugs such as metoprolol are selective for the beta 1 receptor. Bucindolol is nonselective, but there's another nonselective drug, carvedilol, that is known to work. The reason for the BEST results may have to do with something investigators don't know right now. We have to have a level of humility as scientific researchers," he says. "We have to accept the fact that there are some things we don't understand. Also, these studies are imperfect."

Hare says statistical chance is a given, and even with studies that are done on thousands of patients and cost millions of dollars, it's still possible to come up with an incorrect answer. "It may be as simple as that the investigators and the patients enrolled in this particular trial were unlucky and that the results they came up with were incorrect by chance. If the study were to be repeated in its exact form, it's conceivable that the answers would be different."

He says in many other areas in which multiple studies have been done, every once in a while a study will come up with an opposite and different answer from the body of studies. "We have to examine the totality of evidence, therefore, from all the different trials, and the totality of evidence about beta-blockers is that they work. This one may be just a fluke."

Subgroup analysis and unexpected results

Is there something about the black patient that makes a difference? "This is the only study to my knowledge to date that shows such a difference, and I would not want to conclude on the basis of these data that blacks don't respond to beta-blockers," Hare says. He adds that the BEST trial was not designed to look at differences between races.

"History is replete with examples where you come up with some kind of observation from a subgroup analysis to try and help you give yourself an answer to an unexpected result," he says.

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"And when those observations are put to the test in subsequent trials, they have been proven wrong."

Hare says if the medical community feels that there is a difference between blacks and Caucasians, the only way to get a definitive answer is to test that concept prospectively in another study.

"Based on the history of clinical trials, it would not come as a great surprise if the subgroup analysis from this study was not borne out in a subsequent study. The results may even be reversed." Hare says it is concerning to have an outcome like this, because it may lead to anxiety on the parts of both patients and physicians as to what to do. "For now, you do nothing on the basis of the BEST trial. You continue to treat blacks with beta-blockers until such time as there is true evidence that they don't benefit from it."

Eric Eichhorn, MD, BEST study co-chairman and director of the cardiac cath lab at the Dallas VA Medical Center, says bucindolol was chosen for the BEST study because at the time the trial began, there were only two beta-blockers on which any data existed. Do the drug's properties explain the results of the trial? The subanalysis results suggest that bucindolol was not beneficial and may even have had an adverse effect. "The drug itself does not explain that though, because if it were the drug, I would have expected the same effect in Caucasian patients as we got in black patients," he says.

Do blacks respond differently to beta-blockers than Caucasians? "Maybe," Eichhorn says. "We don't know for sure. This was a subgroup analysis, and whenever you do a subgroup analysis, you find something by chance. Would we have had a better response with another agent such as carvedilol or metoprolol? Maybe. Unless we did a head-to-head comparison, we won't know."

Eichhorn says the results are in part explained by the fact that the study group was a much sicker group of patients than in the other major trials, Metroprolol CR/XL Randomized Intervention Trial (MERIT) and Cardiac Insufficiency Bisoprolol Study (CIBIS). MERIT included 5% blacks, and CIBIS included less than 1%.

"Our placebo mortalities were higher," he says. "We were pushing beta-blockers to the limits. By the time patients get that sick, there's nothing left to salvage. It's often too late."

"There was a quirky response in blacks," Eichhorn says. "If we were to go to a less sick population of blacks, my guess would be that they would respond to the drug." He says there are unpublished data that support the fact that blacks benefit from this type of therapy, but there are so few blacks in the other major trials, with such little follow-up, the confidence intervals for making any sort of mortality claim about that subgroup is impossible. "There are not enough data out there on blacks." Eichhorn says they plan to go back and look at their data to see if there's something that explains the outcome.

"The data at least raise the suspicion that blacks with advanced CHF may not respond as well to bucindolol as Caucasians, but we don't know for sure. The bottom line is that this study is hypothesis-generating, but not conclusive.

"What's interesting is that the beneficial response we got was in the same type of patients that were studied by MERIT and CIBIS — male Caucasians," Eichhorn says. We need to re-examine this issue." He says that in practice he has found his black patients with mild to moderate CHF benefit when taking beta-blockers. "If they show good response in ejection fraction and symptoms, I tend to leave them on that therapy." ■

Trial included one-third women, one-fourth blacks

The Beta-Blocker Evaluation of Survival Trial (BEST) tested the hypothesis that the addition of a beta adrenergic blocking agent to standard therapy — diuretics, digitalis, and an ACE inhibitor — would reduce mortality in men and women with moderate to severe CHF.

Gina Edness, RN, BSN, cardiomyopathy research nurse coordinator at Johns Hopkins Medical School in Baltimore had the responsibility of screening and recruiting patients for BEST. Once patients were in the study, she arranged close follow-up. "When there was uptitration of meds, they came in every two weeks in addition to frequent telephone calls. We had to ensure that they knew to call if there were any adverse events or side effects to the drug," she explains.

After initial uptitration, they were seen every three months and given MUGA scans — radionuclide ventriculograms — as well as chest X-rays and EKGs to look for reverse remodeling. "In cardiomyopathy patients, the heart gets smaller as ejection fraction improves." After that, there's

follow-up every six months, then at 12 months. At 12 months, the team repeated the MUGAs, chest X-rays, and EKGs. "Of course at every visit, we did a physician exam and discussed the side effects and any hospitalizations the patient may have had," she explains.

Edness says BEST had a veteran population, and that had a lot to do with the larger percentage of black patients. "Also, we intentionally wanted to look at more blacks and more women. Typically in research white males are included in studies more than blacks and women."

❒ **Inclusion criteria:**
- Age > 18 years
- Left ventricular ejection fraction < 0.35
- NYHA Functional Class III or IV
- Female patients of childbearing potential must have a negative pregnancy test and use a reliable method of contraception.
- Current treatment (for at least 30 days) with an ACE inhibitor if tolerated and digitalis unless contraindicated
- Competent to give informed consent

❒ **Exclusion criteria:**
- CHF due to uncorrected primary valvular disease, uncorrected thyroid disease, obstructive/hypertrophic cardiomyopathy, pericardial disease, amyloidosis, active myocarditis, or malfunctioning artificial heart valve
- Heart transplant candidates
- Acute myocardial infarction within six months
- CABG, PTCA, or other cardiac surgery within 60 days; PTCA or cardiac surgery contemplated
- Severe or unstable angina (use of > six sublingual NTG weekly)
- Excluded medications: beta-blockers, calcium channel blockers, methylxanthines, tricyclic and tetracyclic antidepressants, MAO inhibitors, beta agonists, sympathomimetics, inotropes other than digitalis, certain antiarrhythmics with negative inotropic properties and amiodarone, or any other investigational agent
- Contraindication to beta adrenergic blockade
- Life expectancy < three years due to other life-threatening disease
- Active liver (total bilirubin > 3.0 mg %) or renal (creatinine > 3.0 mg %) disease, or any other disease that may affect the safety or efficacy of the study drug or life expectancy of the patient
- Uncontrolled diabetes mellitus with a history of hypoglycemic episodes
- Unstable decompensated heart failure
- An automatic, implantable cardiologic defibrillator that fired within three months
- Asymptomatic resting but awake heart rate < 50 bpm or symptomatic bradycardia with a heart rate < 60 bpm
- High degree AV block
- Active abuse of ethanol — > 00 gm ethanol/day
- Demonstrated noncompliance with previous medications ■

Compliance can cut costs, speed patient recovery

Patients need support system as well as education

Two-thirds of CHF patients do not comply with recommendations on diet, smoking cessation, reduced alcohol consumption, and prescriptions, according to the American Heart Association (AHA) in Dallas. In fact, half of Americans with all chronic diseases do not follow their physicians' medication and lifestyle guidance. Prescriptions are taken improperly, 80% of patients don't exercise enough, and only 50% of men and 68% of women recognize regular checkups as important to staying well.

"CHF costs a lot," says **Randall Williams**, MD, director of the CHF Program at Evanston (IL) Hospital. "And 75% of that cost is driven by hospitalizations. Sixty percent of those hospitalizations are attributed to patient noncompliance — problems with medications, diet, or self-monitoring — or to patients not notifying their providers that they are having an exacerbation." Failure to recognize symptoms is a major factor in decompensation.

Many factors affect compliance, according to the AHA, among them how easy it is to incorporate a doctor's recommendations into the patient's rou-

(Continued on page 43)

KEY POINTS

Compensate for patients' noncompliance by:
- setting up a plan to keep track of your patient;
- reinforcing what you've taught;
- incorporating compliance strategies into your practice.

Are You Compliant?

Patient Quiz

While many people think they are following their doctor's recommendations, most people truly aren't doing everything they can to live a healthy lifestyle.

Directions: Answer the following questions by checking "yes" or "no".

Prescription Medication

1. When you open your medicine cabinet, do you find old prescription bottles with pills still inside? Yes___ No___
2. Do you sometimes stop taking your medication when you feel better? Yes___ No___
3. Do you sometimes forget to take your medicine? Yes___ No___
4. Have you ever run out of medicine before you can get your prescription refilled? Yes___ No___
5. Are you unclear what medications you are taking and why? Yes___ No___
6. Have you ever been confused about what side effects to expect and what to do about them? Yes___ No___

Exercise and Diet

1. Do you forget or ignore your doctor's advice to eat healthier and get more exercise? Yes___ No___
2. Have you ever walked out of your doctor's office with only vague instructions about diet and exercise? Yes___ No___
3. Are you confused about what type of exercise you should be doing? Yes___ No___
4. Do you have questions about what you can and should eat or what types of food to avoid? Yes___ No___
5. Are you confused about how much alcohol is ok to drink, considering your medical conditions and medications? Yes___ No___

Smoking

1. Are you a smoker? Yes___ No___
2. If so, are you confused about how to quit? Yes___ No___

Scoring: If you answered "Yes" to any of the above questions then you are what doctor's call "non-compliant", which means you're not doing all you can to be healthy, and you are putting yourself at risk for future health problems.

Empower yourself and take control of your own health.
Ask your doctor specific questions about diet, exercise, smoking and prescriptions.
Remember, knowledge is power and the best weapon to fight American's hidden health threat.

For more information on how to improve your health and follow your doctor's recommendations visit the American Heart Association website at www.americanheart.org.

Are You Compliant?

Physician's Quiz

Many doctors think they are doing a good job using appropriate treatment guidelines and informing their patients about the importance of compliance and how to improve their health. However, when it comes to actually improving patient outcomes research shows that isn't always the case. As a physician, are you doing everything you can? Take this quiz to find out.

Directions: Answer the following questions by checking "yes" or "no".

1. I always use American Heart Association Guidelines for Cardiovascular Disease or similar guidelines in diagnosing every single patient. Yes___ No___
2. I ask each patient about his or her diet, exercise, smoking status and alcohol consumption at every visit. Yes___ No___
3. I always ask what other prescriptions, over the counter medications, herbal supplements and vitamins a patient regularly takes. Yes___ No___
4. Whenever I write a prescription for a patient, I inquire at the next visit or by a follow-up phone call how the medication is working, if they are experiencing any side effects and if they are taking it exactly as prescribed. Yes___ No___
5. When writing a prescription I give my patients both written and verbal information about the medication, its benefits, when to take it, how to take it, why to take it, what to do if a dose is missed, etc. Yes___ No___
6. I suggest compliance tools, such as pillboxes and alarms, to help my patients remember to take medications on time. Yes___ No___
7. I spend enough time with my patients to create an open forum for discussing all health questions. Yes___ No___
8. I ask my patients open-ended questions about their diet, exercise and prescriptions, so I get a complete picture of their health. Yes___ No___
9. Whenever I make diet recommendations I carefully explain why the changes are important. I also suggest what foods and cooking methods to avoid and new things to try Yes___ No___
10. Whenever I suggest an increase in physical activity, my patients come away from my office with a clear understanding of what types of activities to do, how long to do them and how often. Yes___ No___
11. My patients who smoke receive counseling on why and how to quit, including helpful information on tools to help them quit (such as gum and patches) and support group contacts. Yes___ No___
12. When it comes to developing a health regimen, I involve my patients in the decision, getting their input on prescriptions, diet and exercise changes. Yes___ No___

Scoring: If you answered "No" to any of the above questions, as a doctor you aren't always doing everything you can to help your patients be compliant.

Try to work the ideas expressed above into every patient contact. When you make compliance a priority in your practice, your patients are more likely take your recommendations seriously and incorporate them into their everyday lives.

Research shows that informed patients are more compliant patients – and a more compliant patient has a better chance of becoming and staying healthy.

For more information on how to help your patients follow their health regimen, see the enclosed document "***How the Healthcare Community Can Help Increase Patient Compliance***".

Source: American Heart Association Compliance Action Program, 2000. An educational effort funded by the American Heart Association's Pharmaceutical Roundtable, Dallas.

(Continued from page 40)

tine, the cost of care and medications, and the complexity of getting prescriptions refilled. But physicians play a role as well. Many do not incorporate compliance strategies into their practices. Some lack the skills or resources to provide counseling services, or when they do, they are not adequately reimbursed for them.

Last year the AHA launched a three-year Compliance Action Program that educates physicians, pharmacists, payer organizations, and patients. **(See special quizzes for physicians and patients on compliance, pp. 41-42.)**

Williams relates information about a case in point that is representative of compliance as a patient behavioral issue: A 63-year-old male with a disjointed social network and an estranged wife and grown children was hospitalized six weeks ago with CHF. He was started on a course of treatment, then discharged on therapy with instructions on how to take his medications and on lifestyle issues and dietary restrictions.

"However, he was discharged without being placed in a support system to make sure therapies were effective or that he was taking them in the recommended way," Williams says. Six weeks later he returns with an exacerbation of CHF.

"That patient typifies patient compliance-related problems," Williams says. "He was told he had CHF and needed to follow recommendations, yet no network was put in place to make sure that when he went home he would be monitored. No system would catch a problem in an early stage if the man's health started to deteriorate." No strategy was implemented for him to change his behavior. The patient received education about what was wrong and what he needed to do and watch for.

"But as important as the education component — that just gets you in the game — is to set up a plan to keep track of the patient and reinforce what you've taught." If the reinforcement is not working, institute a way to catch problems early so the patient doesn't show up in the emergency department (ED), he says.

"When a CHF patient presents in the ED, there is an 85% to 95% chance that he will be admitted to the hospital rather than treated and discharged." In the case of other chronic diseases such as asthma, patients are typically discharged from the ED. CHF patients typically show up in the ED, and then are in the hospital for several days, he says.

Adherence to a treatment plan is a major goal in managing CHF. "CHF patients are treated with multiple medications, and the combination is vital in creating the therapeutic synergy that keeps things under control. But diuretics play an important role in preventing fluid accumulation, and fluid overload is the cause of many exacerbations," says Williams. Patients sometimes have trouble taking their diuretics, especially if they're told to take it at the wrong time of day, and they have to make multiple trips to the bathroom during the night.

"Also, patients sometimes are noncompliant with their diuretics if they are on the go. The holidays are particularly vulnerable times for patients to be noncompliant. They are not careful about diet, and they tend to travel more than usual," he explains.

Williams says smoking is the most difficult to modify of all chronic behavior. "That represents a crossroad between good sound clinical care and the issues of real world behavior interventions. You have to learn which patients have potential problems in terms of their willingness to adopt the best behaviors, and you have to come up with strategies that match those needs."

[To order a "Physician's Compliance Tool Kit" and/or a patient education brochure "Knock Out America's Hidden Health Threat," call the AHA at (800) 242-8721.] ■

A phone call a week cut costs by $800 per patient

CHF program tracks three indicators

The outcomes for the Heart Failure Program at University Health Systems of Eastern Carolina in Greenville, NC, are astounding. The cost to the health care facility for 12 patients tracked during the first six months dropped from $3,300 per patient to $2,500 post-program. The Heart Failure Program, launched in October 1998, currently has 75 enrollees. More data will become available each month as more and more patients are involved long enough to track.

To determine the effectiveness of the program, three outcomes are analyzed, according to **Susan Ingram**, BSN, program coordinator. These include the number of admissions pre- and post-program, the average length of stay (LOS), and cost per

Script prompts the right questions

One of the main reasons the Heart Failure Program at the University Health Systems of Eastern Carolina in Greenville, NC, has been successful is that patients receive weekly telephone calls. During the conversation, **Susan Ingram**, BSN, program coordinator, not only reinforces education, but helps the patient learn how to take this newfound knowledge and apply it to his or her life. As a result, behavior is changed.

Following is a list of questions Ingram uses during phone follow-up and information on how she conducts the conversation. To help develop a relationship with the patients, Ingram doesn't always ask the questions as written:

1. Have you been taking your medications as the doctor ordered? If no, explain.

Often she asks if the patient has run out of medications or had any side effects.

2. Are you keeping a daily record of your weight? If no, why not? If yes, specify weight for the last two days.

Mostly, Ingram simply asks patients what their weight is for that day. If they didn't weigh, she uses the opportunity to reinforce education, explaining that they need to weigh daily at the same time every day and what that information reveals about their heart muscle. If they need scales, she provides them.

3. Do you know what to do with a three- to five-pound weight gain? Explain.

4. Do you understand your low-sodium diet? If no, tell me why. If yes, specify.

"Sometimes I just ask what patients had for breakfast," says Ingram. Patients usually don't have questions until they have been discharged from the hospital and start pulling food from the cupboard to cook a meal, she says.

5. Are you keeping a record of your sodium intake? If no, do you feel you could? If yes, specify.

6. Are you keeping a daily record of your fluid intake? If no, do you feel you could? Explain.

Ingram often asks if patients are watching their fluid intake and if they are aware of how much they are drinking each day.

7. Are you able to perform your daily routine activities without becoming weak, tired, or short of breath?

At times, Ingram asks if the patient is doing any regular exercise and if he or she has had any trouble with shortness of breath or dismount exertion.

8. Have you changed your activity since you were last seen/interviewed?

9. Have you had any trouble with the following since you were last seen/interviewed: shortness of breath, dyspnea on exertion, paroxysmal nocturnal dyspnea, orthopnea?

10. Have you noticed any swelling in your ankles or abdomen? If yes, explain.

11. Have you been to the emergency department or hospital since you were last seen/interviewed? If yes, why?

During the interview, Ingram reinforces education. "Patients have a hard time making the connection that shortness of breath has something to do with their heart," she says. Also, during the telephone conversation, Ingram tries to identify any special needs patients might have that would call for the services of a social worker. For example, a patient might not have the socioeconomic support that would enable him or her to stick to a low-sodium diet. ■

patient. The 12 patients tracked were admitted to the hospital a total of 19 times before they were enrolled, and only five times post-program. Their average LOS dropped as well, from 3.4 days to 2.6 days.

"The basis of this system is to provide patients with a program that is aimed at self-management. The cornerstones of the program are intensive patient education and continuous outpatient case management," says Ingram.

There are a number of inpatient and outpatient strategies that affect the outcomes, she explains. When patients are referred to the program, Ingram evaluates them to establish a baseline. She asks a series of lifestyle questions to determine some of the dynamics that will play a role in patients' ability to comply, such as whether they are living alone, are hard of hearing, or speak little English. About 85% of program enrollees are inpatient referrals.

The evaluation also helps her determine the extremity of the heart failure, such as whether

patients must sleep with three pillows or if they are short of breath at rest or with minimal exercise. The information helps her to determine whom she needs to incorporate into the teaching. For example, if someone plans and prepares the patient's meals, that person will need to be included in the education so that he or she understands the patient's diet.

At the consultation, the initial teaching is provided, unless a caregiver needs to be included. In that case, the teaching is scheduled for a later date. During the session, patients learn how a normal heart functions and how differently an abnormal heart functions. They also learn about their medications; the importance of adhering to a low-sodium diet, exercise, and weight management; and symptom management. Patients receive a booklet containing the information for future referral and a pocket diary that has the warning signs of heart failure, a calendar to track weight gain, and helpful compliance reminders.

Behavioral modification used in phone calls

While the initial teaching session introduces patients to the four areas they must concentrate on in order to control their heart failure symptoms, behavior change takes place over time as patients work with Ingram via the telephone. During the phone call, Ingram doesn't just go over the information; she works with patients until they understand how to apply the lessons. For example, she helped one patient create a low-sodium menu for one week. Patients are encouraged to call her as well — and they do. One patient called to ask for help in interpreting the label on a canned food product.

"The success of the program is after the patient has gone home. I am doing phone compliance and behavioral modification over the phone. I am going through a questionnaire that speaks specifically about weight monitoring and exercise, symptom management, low-sodium diet, and medication compliance. I talk to these patients weekly," says Ingram. **(For details on the telephone interview, see story, p. 44.)**

During the initial evaluation, patients are entered in either phase one or phase two of the program. Those who understand heart failure and what type of exercise and diet they need to adhere to and are doing a good job controlling symptoms are placed in phase one. Those patients receive a phone call once a month. The phase two patients are called weekly. Patients who have had multiple hospital admissions are automatically enrolled in phase two. The initial telephone call usually takes place two to three days after discharge.

To keep track of calls, Ingram keeps a spreadsheet that helps her quickly identify who needs a phone call. About 99% of the referrals are initially enrolled into phase two of the program. After eight to 16 calls, most are moved into phase one and receive monthly follow-up calls. There is no time limit on the program.

In addition to the Heart Failure Program, University Health Systems of Eastern Carolina has implemented a care path for patients with heart failure that is followed when patients are admitted to the hospital. A complementary home health care path was created to proceed with the continuum of care.

The key to the program has been in helping patients find ways to comply so they can better manage their heart failure, says Ingram. "I think the follow-up phone calls are definitely the catalyst for changing their behaviors," she says. ■

ABSTRACT & COMMENTARY

Cyclical breathing in heart failure patients

Synopsis: *Cyclical breathing in CHF patients is associated with autonomic dysfunction and a poor prognosis, and modulation of peripheral chemosensitivity may have beneficial effects.*

Source: Ponikowski P, et al. *Circulation* 1999; 100:2,418-2,424.

Ventilatory rate acceleration and deceleration with apnea or Cheyne-Stokes respiration (CSR) are common during sleep in CHF patients, and ventilatory oscillation without apnea or periodic breathing (PB) can be seen in awake patients. However, the clinical significance of cyclical breathing (CSR or PB) in CHF patients is not fully understood. Thus, Ponikowski and colleagues studied 74 stable CHF patients in sinus

rhythm by observing breathing patterns, analyzing heart rate variability and baroreflex sensitivity, and assessing the response to peripheral chemoreceptor suppression. Cyclical respiration was exhibited by 66% of the patients with approximately equal numbers displaying CSR and PB. Cyclical breathing was associated with more advanced CHF symptoms, impaired autonomic balance, and increased peripheral chemosensitivity. Also, cyclical breathing was associated with nonsustained ventricular tachycardia on ambulatory ECG monitoring (more than 50% of cyclical patients vs. 10% of normal breathing patients; $P < 0.01$). In addition, mortality was higher over an average 524 days follow-up on cyclical compared to normal breathers (37% vs. 12%) and cyclical breathing was independent of peak oxygen (O_2) consumption and NYHA class. Finally, hyperoxia abolished cyclical breathing in seven of eight patients tested and dyhydrocodeine reduced peripheral chemosensitivity, abolishing PB in four patients and converting CSR to PB in two. Ponikowski, et al conclude that cyclical breathing in CHF patients is associated with autonomic dysfunction and a poor prognosis, and that modulation of peripheral chemosensitivity may have beneficial effects in CHF patients.

Comment by Michael H. Crawford, MD, Robert S. Flinn Professor, Chief of Cardiology, University of New Mexico, Albuquerque

CSR is well-described in CHF patients and has been related to the severity of hemodynamic abnormalities in other studies. In fact, an inverse relationship between cardiac output and the total cycle length of a CSR cycle has been proposed. Also, the poor prognosis of CSR and its relationship to ventricular tachyarrhythmias has been reported. CSR is usually observed during sleep. This study shows that the more common awake breathing abnormality is PB without apnea. Also, this study shows that CSR and PB are a continuum and have the same implications and should be considered one entity — cyclical breathing. Although there are no hemodynamic measurements in this study, cyclical breathing was related to NYHA class, ventricular tachycardia, and reduced survival, supporting their hypothesis that CSR and PB are different manifestations of the same phenomenon.

That concepts suggest that cyclical breathing is a consequence of CHF and poor cardiac output, which would delay transmission of signals related to O_2 and CO_2 levels to the brain because of reduced circulation time. However, Ponikowski, et al hypothesize that enhanced peripheral sensitivity to O_2 and CO_2 may be the dominant mechanism and demonstrate that two therapies (oxygen and dihydroxodeine) that reduce hemosensitivity improve cyclic breathing. If cyclical breathing is the real culprit leading to periods of hypoxia, increased sympathetic drive, ventricular arrhythmias, and sudden death (as in sleep apnea), then therapies to reduce it could decrease mortality in CHF. This is a novel concept that their study supports, but it also raises further questions. What is the best therapy for cyclical breathing? Is specific therapy better than just intensifying standard CHF care? Is reduced cyclical breathing associated with reduced arrhythmias and death? Further experimentation along these lines seems justified and is in concert with the current approach to treating CHF — blocking every adverse neurohormonal effect with a designer drug. Until gene therapy for CHF emerges, improving the modulation of peripheral chemosensitivity may be a worthy goal for the pharmaceutical industry. ■

Many CHF patients not getting care in guidelines

Patients are not receiving the care recommended in clinical guidelines, according to a recent nationwide study conducted by The Medstat Group, a division of Thomson Health Care in Ann Arbor, MI. Investigators compared care actually received to care recommended for individuals with heart failure as well as asthma and diabetes, and results revealed a significant gap between what is recommended by leading health care organizations and what actually occurs.

• Of nearly 4,000 heart failure patients, only 40% received an echocardiography within three months of their initial diagnosis, despite its recommendation by the Agency for Healthcare Research and Quality.

• Of about 2,500 heart failure patients, only 46% received a chest X-ray — recommended by the American Board of Family Practice — during the 12-month period following diagnosis.

• Of the nearly 16,000 diabetics followed, only about a quarter received an annual eye exam and less than half received an annual total cholesterol test, both of which are recommended by the Alexandria, VA-based American Diabetes Association.

Those rates are significantly below expectations, says **Louis H. Diamond**, MD, vice president and medical director at The Medstat Group. "While we might not expect 100% of patients to receive the care recommended, we must certainly expect most patients to receive it."

In addition, a review of about 6,500 asthma cases showed that only 27% received an inhaled anti-inflammatory drug as recommended by the National Heart, Lung and Blood Institute. ▼

Depression linked to death among CHF patients

Depressed mood is significantly related to increased mortality risk among people with CHF, according to a new Norwegian report.[1] A hospital outpatient cardiology practice conducted the study on two groups of patients — one with severe depression and one without — and found that those with severe depression were approximately four times as likely to die within two years after they entered the study than the other group.

"This study has important implications for the treatment of congestive heart failure patients," reported Terje A. Murberg, MSc, the lead researcher. "The results suggest that health professionals should be especially alert to depression in congestive heart failure patients and should strive to provide appropriate treatment for depression when needed."

Murberg's co-author, **Torbjørn Aarsland**, RN, tells *CHF Disease Management* the best approach for treating these patients. "Appropriate treatment involves primarily psychological therapy aiming at coping and stress management. This type of intervention should be a natural part of the patient follow-up in heart failure. Chemical treatment should be added if warranted based on regular clinical evaluation. In this patient population, no single antidepressant can be favored, this must again be based on the individual status of disease and the risk of side effects."

Participants in the study included 119 clinically stable CHF patients, average age 66, and average time since onset of heart failure, five years. The researchers evaluated each study participant for depressive symptoms, emotional problems related to CHF, patients' perceptions of their physical limitation and dyspnea, and severity. The results showed that patients who died (20) had significantly higher scores on the self-rating scale used to measure depression than did those who survived. Furthermore, a quarter of the depressed patients died, compared to 11% of the nondepressed patients. **(See related articles in *CHF Disease Management*, February 1999, pp. 18, 19, 21.)**

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Reference

1. Murberg TA, Bru E, Svebak S, et al. Depressed mood and subjective health symptoms as predictors of mortality in patients with congestive heart failure: A two-year follow-up study. *Int J Psychiatry Med* 1999; 29:311-326. ▼

AMI guidelines updated on-line

The American College of Cardiology and the American Heart Association have updated their recommendations for the management of patients with acute myocardial infarction (AMI) and have posted them on their Web sites at www.acc.org and www.americanheart.com. The organizations indicate changes to the text with strikeouts and indicate additions with shading. The updated guidelines include these recommendations:

• Glycoprotein IIb/IIIa inhibitors and low-molecular-weight heparins should be used to treat unstable angina and MI without ST-segment elevation.

• Bypass surgery or angioplasty is preferred for the treatment of cardiogenic shock patients under 75.

• Hormone replacement therapy should not be started after AMI but can be continued in women who were receiving it prior to AMI. ■

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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. ■