

Winter 2005



BARI 2Day & 2Morrow

Message from the National Heart, Lung, and Blood Institute (NHLBI) Project Officer, Suzanne Goldberg, RN, MSN

Dear BARI 2D Participant:

I am pleased to have the chance to speak with you about The National Institutes of Health (NIH), which is dedicated to improving the health of Americans by conducting and funding medical and behavioral research. The NIH is composed of 27 Institutes and Centers, which includes the National Heart, Lung, and Blood Institute (NHLBI), the primary sponsor for the BARI 2D trial. The NHLBI has a long history of providing leadership in the prevention, diagnosis, and treatment of diseases of the heart, lung, blood vessels, and blood. Since its establishment in 1948, the NHLBI has initiated many programs which have played a major role in improving public health, such as the National High Blood Pressure Education Program (NHBPEP), the National Cholesterol Education Program (NCEP), the National Heart Attack Alert Program, and most recently, the Heart Truth, a national awareness program for women about heart disease.

In addition to developing educational programs, the NHLBI supports both basic science research and clinical investigation. Clinical research funded by the NHLBI is federally regulated with built-in safeguards to protect participants. The first step in the process is a thorough scientific review of the study plan to assess scientific merit, safety and ethical concerns. In addition, the NHLBI

program office assists throughout the study with scientific and administrative issues related to the management of the trial. The Institute seeks advice from a panel of experts who regularly monitor the safety of the study and provide scientific input as needed. NIH-sponsored clinical research offers the latest therapies in contemporary medicine, and access to new drugs, medical devices, and procedures that are often unavailable outside of the research setting.

Through the knowledge we've gained from clinical research, we now know there is a clear connection between diabetes and the severity of heart disease. Cardiovascular disease is the leading cause of death in adults with Type 2 diabetes and people with diabetes are more likely to develop problems with their heart and blood vessels. As a BARI 2D participant, you know that controlling cholesterol and blood pressure is just as critical as keeping your blood glucose in check. By making changes in lifestyle such as diet, weight management and increased physical activity, you can also prevent the development of complications. The purpose of the BARI 2D trial is to determine what the best management plan is for patients with coronary artery disease and diabetes. With your help, we hope to answer this question. ■

Sincerely,

Suzanne Goldberg



BEATING DIABETES: Focus on Smoking Cessation

Nicotine is a powerful, addictive drug and the body quickly learns to crave it! Your BARI 2D healthcare team would like to help you succeed in quitting, when you're ready!

For people with heart disease and diabetes, quitting smoking reduces the risk of repeat heart attacks and death from heart disease by 50 percent. Your overall energy level gradually increases after you quit smoking, along with these benefits to look forward to:



- ◆ Within 20 minutes: your blood pressure, heart rate, temperature of the hands and feet may return to normal
- ◆ Within 8 hours: the amount of oxygen in your blood increases
- ◆ Within 24 hours: your sense of smell and taste improve
- ◆ Within 3 days: your lung capacity increases, the bronchial tubes relax and your breathing may be easier
- ◆ 2 weeks to 3 months: your circulation improves; walking is easier; lung function increases
- ◆ At 1 year: the risk of heart disease is reduced by half
- ◆ At 5-15 years: the risk of heart disease, stroke and cancer continues to decrease

Call it quits. We can help! Remember, second-hand smoke contains over 4000 chemicals. Fifty of these chemicals are known to cause cancer. Quitting the habit is not only healthy for you—it's healthy for your friends and family. Your BARI 2D coordinator has many tools to assist you in this process. Did you know that nicotine replacement therapy is now available in an inhaled form? Ask your BARI 2D staff for more information.

WE WILL SUPPORT YOU IN ANY WAY WE CAN. JUST ASK! ■

Adapted from the *City of Ottawa Public Health Fact Sheet and RAO Health Education Fact Sheet*

BEAT OF BARI 2D: Your Heart at Work—How Is It Measured?

Have you wondered why your physician ordered you to have a stress test?

A stress test, more accurately called a cardiopulmonary exercise test, is usually performed on a treadmill or bicycle. You exercise at a gradually increasing intensity until you get tired or other changes occur that might mean a heart problem. If you are unable to use a treadmill or bicycle, you may be given a medication that makes your heart act as if you were exercising.

Stress tests are measured by rating the perceived exertion. This means it measures how you are feeling during the test, along with physical changes, to give a more complete picture of your tolerance for the test. Symptoms that occur during the test tell physicians a lot about your heart health. If excessive shortness of breath, chest pain, or confusion occur, the test is stopped. However, such symptoms can indicate a heart problem.

Heart rate is measured in beats per minute and should increase as your level of exercise increases. Maximum heart rate is calculated by subtracting your age from 220 for men or from 226 for women. However, these figures are estimates only. For more specific information on your heart rate, consult your physician.

Resting heart rate typically ranges from 60 to 80 beats per minute. If you take beta blockers, your heart rate will not be affected in the same way by exercise and will tend to be lower while at rest.

Systolic blood pressure, the top number of a blood pressure measurement, is the force that delivers blood to the working muscles along with your heart rate. Systolic blood pressure should increase with exercise. Diastolic blood pressure, the bottom number, represents the time during which the heart is filling with blood for the next delivery. Diastolic blood pressure should stay the same or perhaps decrease during exercise.

Your doctor will look at the results of the stress test and be able to tell you how your heart is doing. The stress test is one measure that can help your doctor decide if changes in your treatment are necessary to help you stay as healthy as possible. ■

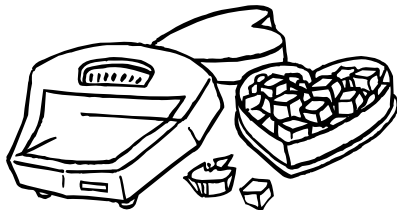
FOOD FOR THOUGHT: Put Your Diet on a Diet

Another new year! Magazines and newspapers abound with ads for the latest in exercise equipment and diet products. You may have tried dieting in the past, but now it's time to put your meals on a diet!

In the United States, "super-sized portions" often interfere with successful weight management. We have all become so accustomed to seeing and consuming huge portions in restaurants and at home that it's a way of life for most Americans. People from other countries are amazed at the food amounts consumed in the United States.

Here are some great tips to help you curb those portions. Remember, you don't need to cut out, just cut down on the amounts of food you eat. Here's how:

- ▶ Try using a smaller plate than usual. This may "trick" yourself into thinking that you are eating more, because it takes less food to fill your plate. Some people even use smaller forks and spoons.
- ▶ Serve yourself from the stove rather than family-style with the food on the table in front of you. You may not be tempted to eat more than you planned if the food is out of sight.
- ▶ Control entrée portion sizes. Most of the calories in a meal come from the meat and starch categories. Limit each of these to 1/4 of your plate. Reserve the other half for vegetables—they are filling, colorful, and satisfying in fiber and texture.
- ▶ Use limited amounts of high fat foods to garnish your meals. For example, a half-ounce of cheese, grated, can be sprinkled over an entire bowl of salad to give it a tasty zip. Slivered almonds can be used in small amounts to add crunch to a casserole. If you use butter, cream or oil, limiting portions will limit calories as well.
- ▶ Eat slowly. Allow your brain time to register that you have, indeed, ingested some tasty food. Savor each bite—this requires giving your full attention to eating, not to the TV or the newspaper.
- ▶ Skip "seconds." Eat a variety of different foods, but limit your helpings to one. If you still feel hungry after a meal, wait 20 minutes then drink water, broth or a hot beverage. Eat more vegetables if you must have "seconds."
- ▶ Choose the highest quality food possible! Since you are going to eat a limited amount of steak or scalloped potatoes or applesauce, make it the best tasting choice you can find!
- ▶ Then, go brush your teeth. The fresh taste in your mouth will remind you not to eat soon. ■



PATIENT SUCCESS STORIES: C.W.'s Story

In June 2003, 63-year-old C.W. was seen in the cardiology clinic to follow up on an abnormal stress test. He has a history of diabetes, high blood pressure, high cholesterol and known heart disease. He also had bypass surgery just a few years ago. His wife, a nurse and also a diabetic, always tried to keep a close watch on diet and medications.

He underwent a cardiac catheterization and was found to have one artery with some blockage which, fortunately for him, was not severe. After reviewing his cardiac cath films and discussing his options with the cardiologist, he was told he would be a good candidate for the BARI 2D Study.

He and his wife looked forward to having someone else "watching over" him and helping him to get his diabetes and other health issues under control. C.W. and his wife decided he should join the BARI 2D Study. He was randomized to revascularization for his coronary artery disease and underwent a stent placement in his partially blocked artery. He was also randomized to insulin sensitizing medications for his diabetes.

The diabetes treatment was a tough one for C.W., since he had been on a maximum dose of glyburide and metformin with an A1c of 9.1, which was far from goal.

(Continued on next page)

BARI 2D Frequently Asked Questions

The BARI 2D healthcare team believes that every question is a good one. Below, we've answered some commonly asked questions about insulin.

Why do I have to take insulin?

Some patients with Type 2 diabetes have to take insulin because the pancreas no longer makes enough insulin. In order to keep blood sugar regulated, insulin must be injected into the blood stream.

Can insulin be taken as a pill?

Insulin is a protein. If you took insulin as a pill, your body would break it down and digest it before it got into your blood to lower your blood sugar. Therefore, insulin cannot be taken in a liquid or pill form.

How does insulin work?

Insulin lowers blood sugar by moving sugar from the blood into cells of your body. Once inside the cells, sugar provides energy. Insulin lowers your blood sugar, whether or not you eat. If you take insulin, it is important that you eat on time.

How often should I take insulin?

Most people with diabetes need at least two insulin shots a day for good blood sugar control. Some people take three or four shots a day to have a more flexible diabetes plan.

When should I take insulin?

If you take regular insulin alone or with a longer-acting insulin, you should take it 30 minutes before a meal. If you take insulin lispro or aspart (Humalog or Novolog), these insulins work very quickly so you should take your shot just before you eat. If you are unsure when to take your insulin, be sure to ask your healthcare provider.

His primary care provider told him that insulin was the next step. He was reluctant to start insulin and was anxious to try our treatment regimen that would not include insulin at this time. He and his wife worked very hard over the next several months, weaning off his glyburide, adding Avandia (rosiglitazone), very closely monitoring his diet and walking once or twice daily for 30 minutes. His A1c went over 10 before the downward trend to the current 6.7 and has been at goal for nearly a year. He is currently on his diabetes treatment assignment of metformin and Avandia, with acarbose, and is doing quite well. He has also lost 18 pounds over the last year, stepping closer to his weight goal.

How should I store insulin?

- If you use a whole bottle of insulin within 30 days, keep it at room temperature. On the label, write the date that is 30 days away. This is when you should throw out the bottle with any remaining insulin.
- If you do not use a whole bottle of insulin within 30 days, then store it in the refrigerator all the time. The exceptions are rapid-acting insulins (Humalog and Novolog) which should be disposed of 30 days after opening, as the action becomes ineffective.
- If insulin gets too hot or cold, it breaks down and does not work. Do not keep insulin in very cold places, such as a freezer, or in hot places, such as a window sill, or in the car's glove compartment during warm weather.
- Keep at least one extra bottle of each type of insulin you use in your home. Store the extra insulin in the refrigerator.

What are possible side effects of insulin?

- A low blood sugar reaction (hypoglycemia)
- Weight gain
- Feeling better as your blood sugar normalizes ■

Adapted from *Medicines for People with Diabetes*, National Institutes of Health.

Did you know...

That mixing short-acting or regular insulin with NPH insulin and storing for use later in the day will change some of the regular insulin to a longer acting form.

His wife's A1c has also come down from 9.8 to 7.1, which she and her doctor haven't seen in years. It took several months for C.W. to reach his goals, and he says it wasn't easy. "It is a lifestyle change for us," C.W. said.

Success came slowly for C.W. and his wife, but they have both done well by encouraging each other and working together to reach their goals. ■

Please note: Each participant will have different experiences while in the trial, some of which may be less positive for various reasons.

CHUNKY VEGGIE CHILI

Serving Size: 1 Cup (Total Servings: 8)

- 1 tbsp. olive oil
- 1 large onion, chopped
- 2 cans (14 1/2 ounces each) diced, tomatoes, undrained
- 2/3 cup hot salsa
- 1 1/2 tsp. chili powder
- 1 1/2 tsp. ground cumin
- 2 cans (15-16 ounces each) red kidney beans, rinsed and drained
- 1 large red bell pepper, chopped
- 1 large zucchini, cut into 1/2-inch chunks
- 1 medium-sized (about 2 cups raw) yellow winter squash, cut into 1/2-inch chunks

1. In a large saucepan, heat the oil over medium heat. Add the onion and sauté for 2 to 3 minutes.
2. Add the tomatoes, salsa, chili powder, and cumin. Reduce the heat to low, cover and simmer for 10 minutes.
3. Add the remaining ingredients, cover and simmer for 20 to 25 minutes, or until the vegetables are tender. Ladle into bowls and serve.

Each serving contains approximately:

- 162 calories
- 2 g total fat
- 29 g carbohydrate
- 9 g protein
- 0 mg cholesterol
- 396 mg sodium

Exchanges:

- 1 1/2 starch
- 2 vegetable ■

Recipe from *Mr. Food's Quick & Easy Diabetic Cooking* by Art Ginsberg. Supported by the American Diabetes Association.

MOVING RIGHT ALONG: All about Peripheral Artery Disease

Why is it important for you to learn about peripheral artery disease (PAD), also known as peripheral vascular disease (PVD)? Individuals with diabetes are much more likely to develop PAD. This disease can lead to other health problems such as heart attack and stroke.

What is PAD?

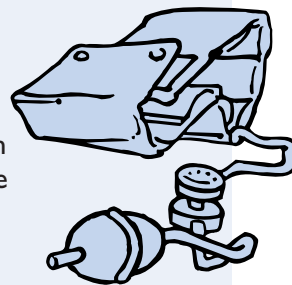
Arteries are found throughout your body and are the routes through which oxygen-rich blood travels. Arteries located in the legs are called "peripheral arteries." PAD refers to the clogging and hardening of peripheral arteries by the buildup of a fatty substance called "plaque." Blood flow to your feet and legs decreases as this plaque builds up and can make healing of sores more difficult.

What are the warning signs of PAD?

Many individuals with diabetes and PAD have no symptoms. Some may have mild leg pain, particularly when walking or exercising, which disappears after a few minutes of rest. There may also be a feeling of numbness, tingling or coldness in the lower legs or feet.

How is PAD diagnosed?

Blood pressure measurements are taken on your arms and legs. These blood pressures are compared with each other. A blood pressure in your leg that is much lower than the blood pressure in your arm may indicate narrowing of the artery.



Who is at risk for PAD?

Any of the following can put you at high risk for developing PAD:

- ✗ Smoking
- ✗ High blood pressure
- ✗ Abnormal blood cholesterol levels
- ✗ Obesity
- ✗ Physical inactivity

How can you lower your risk for PAD?

If you have one or more of the risk factors outlined above, follow these steps to take charge of your heart health:

- ✓ Seek help if you smoke. Programs to stop smoking are available in your area. Or, talk with your BARI 2D study coordinator.
- ✓ Aim for a HbA1c goal of less than 7.
- ✓ Lower your blood pressure to less than 130/80.
- ✓ Keep your LDL (bad) cholesterol goal below 100.
- ✓ Discuss aspirin or antiplatelet therapy with your doctor or nurse.
- ✓ Become more physically active. Studies have shown that exercise, such as walking, can be used to prevent and treat PAD.

Take home message: Taking care of your diabetes and the health problems that come with it can lower your chances of PAD. While you cannot change certain factors, such as your age and family history, you can take charge by keeping your eye on the goals listed above. Your BARI 2D team is ready to help, but the rest is up to you. ■

A Clinical Study
BARI 2D



BARI 2Day & 2Morrow

Winter 2005

BARI 2Day & 2Morrow Staff

Dominique Auger, RN
Institut de Cardiologie de
Québec/Hôpital Laval

Sharon Crow, BS
BARI 2D Coordinating Center
University of Pittsburgh

Gilles Dagenais, MD
Institut de Cardiologie de
Québec/Hôpital Laval

Jorge Escobedo, MD
Instituto Mexicano del
Seguro Social

Suzy Foucher, RN, BA
Institut de Cardiologie de
Montréal/Hotel-Dieu-CHUM

Madeleine Gourgues
Institut de Cardiologie de
Québec/Hôpital Laval

Susan Hagar, RN
Ottawa Heart Institute

Amanda Kengersky, BA
Jack Horner Communications

Chris Kwong, RD, MPH, CDE
University of Minnesota

Joan MacGregor, MS
BARI 2D Coordinating Center
University of Pittsburgh

Elaine Massaro, MS, RN, CDE
Northwestern University/
Feinberg School of Medicine

Susan McClinton, BSN
Ottawa Heart Institute

Judith Nicastro, RN
Texas Health Science at San
Antonio/South Texas Veterans
Health Care System

Tammy Touchstone, RN, BSN
VAMC Memphis

Bernardo Vargas, BS
NYU School of Medicine