

Fall 2004



BARI 2Day & 2Morrow

Message from the Study Principal Investigator Dr. Katherine Detre University of Pittsburgh

Dear BARI 2D Participant:

I am very pleased to have this opportunity to thank you for your participation in this extremely important study. In the past, other studies, including the original BARI Trial, have looked at the best way to treat heart disease in all patients. Our BARI 2D study is the first of its kind to find the best way to treat patients who have both type 2 diabetes and heart disease.

The BARI 2D study has been largely funded by the National Heart, Lung, and Blood Institute (NHLBI) with support by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The NHLBI and NIDDK are divisions of the National Institutes of Health (NIH), an agency of the US government whose mission includes supporting and overseeing medical research projects. The NIH and a group of world experts oversee BARI 2D so that you receive safe and state-of-the-art medical care during the time you are in the study. The study has also received support from several industry sponsors. Without the generous support from these sponsors, we would not be able to conduct a study as important and large as BARI 2D.

It has long been known that the combination of heart disease and diabetes increases the risk of health complications. For some time, there have been two basic approaches to treating heart disease: intensive medical therapy or immediate intervention with

angioplasty or bypass surgery. At the same time, there are two different approaches to treating type 2 diabetes: one that increases the ability of the body to use the insulin it produces or one that directly provides more insulin into the body. Different doctors have strong opinions as to which approaches are the best for patients with both diabetes and heart disease. BARI 2D will be able to answer the question who is right.

That is why our most important partner in this venture is you! As one of more than 2,000 volunteers from 49 centers, your continued participation is a vital part of the study's success. It is critical to the outcome of the study to maintain follow-up on every patient, particularly over time. Your participation over the course of the whole study provides the best information for BARI 2D. We count on you to do your part by keeping your clinic appointments. Even if you have missed clinic visits, it is not too late to make a new appointment. Call your study nurse or coordinator to arrange your next visit. Without you, BARI 2D would not be possible.

Thank you for your contributions to the future of medicine and treatment of diabetes and heart disease.

Sincerely,

Katherine Detre



BARI 2D Frequently Asked Questions:

Have you ever had a question that you were afraid to ask your health care provider, either because you were too embarrassed or because you thought it was a "stupid" question? If so, you are not alone! And we're here to tell you that there is no such thing as a "stupid" question! A well-informed patient is more inclined to take an active role in his/her self care.

The following are examples of frequently "unasked" questions:

- ◆ Is there any connection between diabetes and erectile dysfunction?
- ◆ Is it important to have my meals at the same time every day?
- ◆ If I skip a meal, should I still take my medication?
- ◆ If the insulin is cold, will the injection be more painful?
- ◆ If my blood sugars are under control, can I have alcohol in moderation?
- ◆ I get bloating and gas. What can I do about this?
- ◆ When I check my blood pressure on the machine at the drugstore, it's really high. Should I talk with my physician about this?
- ◆ A friend told me she has "white coat hypertension" and wondered if I have the same problem. What is it?

Bottom line: Don't be shy about asking your physician or nurse any questions you have related to your health. The more you know, the better you can take care of yourself.

PATIENT SUCCESS STORIES:

J.J.'s Journey

Elaine Massaro, MS, RN, CDE

Coordinator, Northwestern University,
Feinberg School of Medicine

In July 2002, sixty-year-old J.J., already diagnosed with Type 2 diabetes, high blood pressure, high cholesterol and obesity, had a terrifying experience. He was admitted to the hospital with chest pain and had an abnormal Thallium stress test. His physicians ordered an angiogram to see if any heart blockage was present. J.J. was informed that he had a blockage in a coronary artery. After reviewing all options, his physicians agreed that J.J. was a perfect candidate for the BARI 2D study.

J.J. decided to join the study, stating that this was a good opportunity to "learn how to take care of my body, and to change some bad habits." He realized that it would be a "tall order" to get his HbA1c, blood pressure and weight to goal, but he was fairly confident that he could change his old habits and develop a new and healthier plan.

J.J.'s immediate concern was to have more control over his health. With the help of the BARI 2D staff, he was able to develop an action plan that was specific, achievable and realistic. To complete his goal planning, he discussed various obstacles slowing his success.

Since enrolling in BARI 2D, J.J. has retired. He has developed an exercise plan tailored to his lifestyle: long walks and bike rides 6 – 7 days a week. He chops wood 2 days a week to increase strength. When he feels the urge to eat, "I deliberately get busy and find ways to distract myself until the urge subsides."

J.J. faced many months of frustration. When trying to regulate his blood sugar, he ate more. The increase in calories led to weight gain. These frustrations were discussed at regularly scheduled clinic visits, as well as during follow-up telephone calls with the BARI 2D staff. The staff helped J.J. regulate his blood sugar while controlling the types of foods he ate. These visits and calls were key to his success as the education, recommendations and continuous support helped him to make informed decisions to achieve his goals and overcome barriers.

The results: At the two year mark, J.J. has lost 50 pounds, his HbA1c is 6.3% and lipids and blood pressure are in good control.

A take home message from this success story: If an action plan doesn't work, it doesn't mean that you're not trying to do your very best. It simply means that you need to keep trying until you figure out a plan that will work for you.

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

BEATING DIABETES: Take Care of Your Feet

Monica Voudris, BA

Coordinator, Boston Medical Center

Why is foot care especially important to people with diabetes? Diabetes can damage nerves in the body, known as diabetic neuropathy, and can result in pain or loss of feeling in the feet, as well as changes in the shape of your feet and toes. Diabetes can also cause the blood vessels of the foot and leg to narrow and harden, resulting in poor circulation. Poor blood flow makes it more difficult for your feet to fight infection and to heal.

Diabetes-related foot problems start with a loss of feeling in your feet, which makes it hard for you to tell if you've had an injury. You could walk around all day with a stone in your shoe, or a blister could develop and you wouldn't feel it! If these wounds are left untreated, they can become infected and turn into more serious complications, even an amputation. Nearly 55,000 people with diabetes have amputations each year, and most could have been prevented. Paying proper attention to the care of your feet is extremely important.

Here are some helpful guidelines for you to follow:

- Check your feet every day. If you can't see parts of your feet, use a mirror!
- Wash your feet every day with lukewarm (not hot) water and mild soap.
- Dry your feet well, especially between the toes.
- Keep the skin of your feet smooth by applying cream or lotion to avoid cracking. Do not put creams or oils between your toes, as the extra moisture can lead to infection.
- Cut toenails straight across using toenail clippers with a straight edge. Never cut into corners, as this could trigger an ingrown toenail. The best time to cut your toenails is after bathing.
- Never cut calluses or corns yourself, as it can result in ulcers and infection. Leave this to your health care provider.
- Don't go barefoot, even in your home or on the beach.
- Wear properly fitting shoes. If you develop an ulcer, see your health care provider right away.
- Always wear socks or stockings with your shoes.
- See a podiatrist (foot doctor) regularly.

Start today! Though it may seem like a lot of work, by taking an active role in your own diabetes care through prevention and self-care, you can avoid foot problems or spot them early and lead a healthier life.

BEAT OF BARI 2D: Pills, Pills and More Pills

Tammy Touchstone, RN

Coordinator, Memphis VA Medical Center/University of Tennessee

You are not alone if you have difficulty taking all of your medications as prescribed. While sometimes it may be a struggle to keep up with the correct dosages at the correct times, it is extremely important to take all medications as directed by your physician.

To keep track of your pills and any changes in your health, keep detailed information on every medication you take.

Write the reason for taking a medication on each bottle. Bring all medication bottles, prescription and over-the-counter, to your clinic visit so that we can see what you are actually taking. [\(continued on next page\)](#)

BEAT OF BARI 2D: Continued

Here is a list to help you discuss with your physician or nurse what you should know about your medications.

- ▼ What is the name of the medication?
- ▼ Does it have a generic name?
- ▼ What does it treat?
- ▼ When should I take it? How often? How long?
- ▼ What should I avoid while taking it?
- ▼ What side effects should I look for?
- ▼ What should I do if I have problems taking it?
- ▼ What should I do if I miss a dose?

The most common reason for missing medication is forgetting to take it. Here are a few tips to avoid missing your medications:

- Take your medication at the same time each day. Combine it with something you do routinely.
- Set an alarm clock to alert you when to take it.
- Have a friend or relative call to remind you.
- Place the medicine where you can see it: on the kitchen table or nightstand, by the coffee pot, etc.
- Use a pillbox to help you organize your medications. If the box is still full, you know you haven't taken them yet.

Lastly, never stop taking your medication on your own because you feel better or because you have finished the bottle. If you are uncertain whether to continue a medication, call your study nurse or physician.

FOOD FOR THOUGHT: Net Carbohydrates

BARI 2Day & 2Morrow Committee

You have finally mastered how to count carbohydrates. Now a new term shows up on the front of food labels: "Net Carbs." You're thinking, "This is too good to be true. I only have to worry about net carbs."

But is that true? And what does the term "net carbs" (also known as "impact carbs" or "effective carbs") mean?

Let's look at the types of carbohydrates: starch, sugar and sugar alcohols, and fiber. Starch is a mix of simple sugars forming complex carbohydrates. It is the main source of volume and calories in food. Sugar is made of simple sugars (glucose and fructose) and includes table sugar and corn syrup. Sugar alcohols are processed sweeteners made from different plants. Sugar alcohols may be used to sweeten a "sugar-free" product. Fiber is the part of plant foods that is not digested.

"Net carbs" is actually a term used to highlight foods that have less impact on blood sugar. The theory behind "net carbs" is that people need to count only the carbs in a product that cause rapid increases in blood glucose levels. The belief is that sugar alcohols and fiber do not increase glucose levels, and thus do not need to be counted. However, the "net carbs" theory has no scientific basis

FOOD FOR THOUGHT: Continued

and is not approved by the United States Food and Drug Administration (FDA).

The American Diabetes Association (ADA) guidelines for people with diabetes who are counting carbohydrates allow half of the grams of sugar alcohols to be subtracted from total carbohydrates, since only about half are digested, and dietary fiber to be subtracted only if the fiber content is five or more grams per serving. It has been shown that some sugar alcohols DO have a significant effect on blood sugar.

Many companies are now cashing in on the "net carb" craze by replacing carbohydrates with glycerin, sugar substitutes like sucralose (Splenda), or sugar alcohols like sorbitol, xylitol, or mannitol. Some also add more fiber. After these ingredients are added, the companies calculate "net carbs" by subtracting them from the total carbohydrate content.

Bottom line: ALL carbohydrates, except fiber, have calories: 1 gm carbohydrate = 4 calories. Foods low in "net carbs" can still be high in calories and total carbohydrates. Even if fiber and sugar alcohols have a minimal impact on blood sugar, you still have to be aware of the calories.

Beware: "net carbs" can be misleading. Check your blood sugars as directed by your doctor, watch your meal portions and count your calories!

SHOPPING TIPS

1. If buying "low carb" products, choose those with high fiber content.
2. Watch the saturated fat, sodium and total calories listed on the package.
3. Avoid excessive use of "low carb" products containing sugar alcohols (especially sorbitol and mannitol) as they can have a laxative effect.

MOVING RIGHT ALONG: Staying Mentally Fit 365 Days of the Year

Melissa Hill, MS

Coordinator, University of Chicago Medical Center

During your time in the BARI 2D trial, a lot of emphasis is placed on taking care of your physical health. You work hard to keep your blood sugar in control, your blood pressure and cholesterol at healthy levels, not to mention maintaining a healthy diet and exercising regimen! With all of the importance placed on physical health, we sometimes forget about taking care of our mental health.

As we approach the busy holiday season, keeping stress at a low level in our lives is just as important as resisting that extra piece of pumpkin pie. Keep these steps in mind to help you maintain good mental health:

- Control how you react to stress on a daily basis. This will help to keep stress from building up.
- Sleep, exercise and a healthy diet are just as important to your mental health as they are to your physical health. Make sure you are getting the right amounts of sleep and exercise, and resist the temptation to eat lots of sweets!
- Make time for the activities you enjoy. Having an activity that you like to do can actually renew and refresh your energy.
- Surround yourself with people who support you. Friends and family that give love and support are essential to our mental well-being.
- Give of yourself to others. Giving of your time and talents can make you feel needed and useful.
- Try to keep a positive perspective on life. Find ways that help you put an emphasis on the positive, rather than the negative, things in your life.
- Lastly, don't hesitate to seek help if you need it. If you want to learn ways to reduce stress or develop a more positive outlook, your local BARI 2D staff will be glad to provide you with helpful resources.

Best wishes for a happy and healthy holiday season. Don't forget to maintain your mental health all year long!

WHAT'S A YAM, MA'AM?

Chris Kwong, RD, MPH, CDE

*Coordinator, University of
Minnesota*

What IS the difference between a yam and a sweet potato? Yams in the United States are actually sweet potatoes. Sweet potatoes were being cultivated here by Native Americans/First Nations hundreds of years ago. "Yam" is a term adapted from the African "nyami," a starchy, edible root. In the 1950's, bright orange sweet potatoes grown in Louisiana were labeled "yams" to differentiate them from the paler, drier sweet potato grown in the northern United States.

Sweet potatoes are high in vitamin C, and a good source of fiber and beta-carotene. One 2" x 5" tuber contains 25 grams of carbohydrates (2 carb units) and about 110 calories. It is best to store sweet potatoes at room temperature.

Crisp Sweet Potato Chips

1. Heat oven to 425°F.
2. Wash and thinly slice sweet potato.
3. Cover a cookie sheet with aluminum foil, lightly spray with vegetable oil spray, such as Pam. Lay the potato slices on the foil; do not overlap.
4. Spray overall with vegetable oil spray and salt lightly, if desired.
5. Bake for 5-7 minutes, or until browned.

Each serving (1/2 sweet potato) contains:

55 calories
13 g carbohydrate (1 carb unit)
1 g protein
Trace of fat

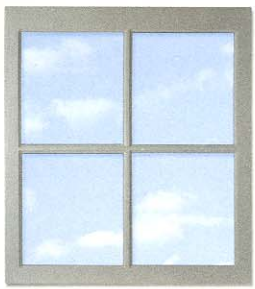
Exchanges: 1 starch or carbohydrate

Contact:

If you have further questions, please contact your doctor or your local BARI 2D clinical site.



BARI 2D
A Clinical Study



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