

Spring / Summer 2008



BARI 2Day & 2Morrow

THE POLICY AND PUBLICATIONS COMMITTEE OF BARI 2D

The purpose of research is to learn new things that will benefit many people. Everything we do in BARI 2D – from planning to asking people like you to participate to analyzing the data – serves this purpose. One of the most important steps comes at the end, when we publish and distribute the findings so that physicians, patients and the public can learn the best ways to treat people with similar conditions.

With this in mind, the designers of BARI 2D decided to create a special group called the Policy and Publications (P&P) Committee. The Committee members include specialists in heart disease, diabetes, and statistics. They come from many of the BARI 2D clinical centers, the National Heart, Lung and Blood Institute, the Coordinating Center, and the trial leadership.

The P&P Committee's job is to ensure that we report what we learn in BARI 2D accurately and distribute it widely. Trial investigators publish articles in journals and give presentations at meetings of health professionals. Before articles are published, they are critically reviewed by knowledgeable editors and scientific reviewers who have no relationship to the trial. Ultimately, we present the major findings to wider audiences through the mass media.

The P&P Committee follows a series of steps for each article and presentation to make sure everything is right. First, study researchers or the Committee propose a topic. The Committee grades each topic, makes sure it does not overlap with other topics, and decides what priority it should have. Once their topic is approved, the researchers select a writing team to work with the statisticians and write the first draft.

Next, the draft is submitted to the Committee. At least two experts who were not on the writing team read the paper. The reviewers provide helpful advice to the authors, who revise the paper based on that advice. The Committee's

co-chairs and the BARI 2D Coordinating Center approve the final draft. Finally, the authors release the paper to a journal or submit the presentation for a meeting.

The results of BARI 2D will not be known until the last participant has finished and the data have been collected and analyzed. At that time, we will release the overall study findings and present them at a major scientific conference. You will receive a newsletter about the findings, and can check the trial website at www.bari2d.org to find out about articles. After the major findings are published, investigators will write papers about other questions, and follow the same steps.

BARI 2D has already published 10 papers and given 33 presentations at meetings. These were about the design of the trial and the medical conditions of those who joined. This is a true credit to those authors and statisticians who have worked on them and is an inspiration for those who will follow.

Of course, there would be no study findings at all without the participation of our dedicated patients. We look forward to sharing the results of BARI 2D with all of you.

Alice Jacobs, MD



George Steiner, MD



Co-chairs, Policy and
Publications Committee

FOOD FOR THOUGHT:

Building Trust in Research

*Contributed by Stephen B. Thomas, PhD
Director, Center for Minority Health, University of Pittsburgh*

Including minorities in research is necessary for results to be meaningful to a wide range of people. The National Institutes of Health (NIH) require studies to include ethnic and racial minorities. However, it is often difficult to recruit and enroll people from minority groups. This limits what conclusions can be drawn.

African Americans are often reluctant to volunteer for research. Such reluctance and distrust toward medical research may be due to past research studies like the Tuskegee Syphilis Study (1932-1972). This study followed 600 black men, more than half of whom had syphilis but did not know it. The study was to last for six to nine months, but became a 40-year experiment that followed these men to "end point" (death).

The real tragedy of the Tuskegee experiment was that the researchers tried to keep the men from receiving proper medical care. When local draft boards let 50 patients know they should be treated during World War II, the U.S. Public Health Service (PHS) had the men in the study dropped so they wouldn't see a doctor. In 1943, the PHS began prescribing penicillin to treat syphilis, but the men of the Tuskegee Syphilis Study were never offered treatment because that would end the experiment. When penicillin became the standard treatment for syphilis in 1951, the PHS insisted that it was even more important for the Tuskegee study to continue because "it made the experiment a never-again-to-be-repeated opportunity."

The Tuskegee Syphilis Study helped contribute to African Americans' distrust of public health authorities and medical research today. Fear of genocide has been reported by public health and community-based professionals who work in black communities. Unfortunately, details of the Tuskegee Study are not well known and continue to be a source of distortion and misinformation.

On July 25, 1972, The Washington Star reported on the study, which was still going on at that time. The story became front-page news and the subject of editorials across the nation. Officials in the Department of Health, Education, and Welfare (HEW) and the PHS joined the public outcry condemning the study, but made little effort to defend or justify the experiment.

Finally, in 1997 President Bill Clinton issued the first formal apology for what the government did to the men in the Tuskegee Study. I was honored to be present at the White House ceremony. Eight men from the Tuskegee Study were still alive to witness the apology. President Clinton said that, "...what was done cannot be undone, but we can heal the pain." So began a new chapter in our national effort to right the wrongs of the past and move forward with new resolve that all research participants would be treated ethically and with respect. Participants can only join a research study after it has been fully explained, including any risks or problems that might come from the study, and the participant understands and agrees to join.

In that same spirit, BARI 2D has focused on making sure that each participant understands all the risks and benefits of the study. We make sure you hear and understand any new information or new treatments that might help you safely reach your goals within your treatment assignment. If you have questions or concerns at any time, please contact your BARI 2D nurse and/or doctors to discuss these issues. In this way, BARI 2D moves beyond the legacy of pain and distrust and can serve as a lesson for ethical treatment of participants in research. We are grateful that you continue to work with us in finding the best way to treat type 2 diabetes and heart disease.



PATIENT SUCCESS STORIES: C.L.'s Story

C.L. received her BARI 2D ID in June 2002. She was diagnosed with type 2 diabetes at the age of 47 and, like many others, her world came crashing down not knowing how to handle this disease. With a strong family history of cardiac disease, high cholesterol and high blood pressure, C.L. needed to readjust her whole life and learn many new things.

Just one year after enrolling in BARI 2D, C.L.'s HbA1c was controlled, but her weight was becoming a problem. With the weight gain, other things began to go wrong; her HbA1c went from 6.3 percent to 9.4 percent, her blood pressure went up, and at one point her triglycerides were 202 mg/dl.

It was very clear that we had a lot to work on. We needed to find out the source of C.L.'s weight gain and improve her quality of life. In February of 2004, shortness of breath became a problem and C.L. got another stent. She had reached the point of no return, with everything progressing in the wrong direction.

On one particular study visit, the patient revealed that she drank regular Pepsi quite often and said that she should take on the name "Pepsi Lady."

It was clear that besides her medication compliance, C.L. needed to learn healthy eating and exercise habits. For her next visit, one of the diabetes doctors prepared a little surprise, and presented C.L. with a bottle of Diet Pepsi. It was at that particular moment that C.L. made the connection within herself that diabetes, cardiac disease, and eating habits/portion control are all related.

In one year, C.L. lost about 15 pounds and her latest HbA1c was 6.2 percent. Many things have changed since 2002: the importance of having her meals on time, improved compliance with her medications, and healthier eating habits. (By the way C.L. has replaced regular Pepsi with water and Crystal Light). Now C.L. is preparing herself to leave BARI 2D with the right tools at hand and believes "I am ready."

BEATING DIABETES: Facing the Challenge of Change

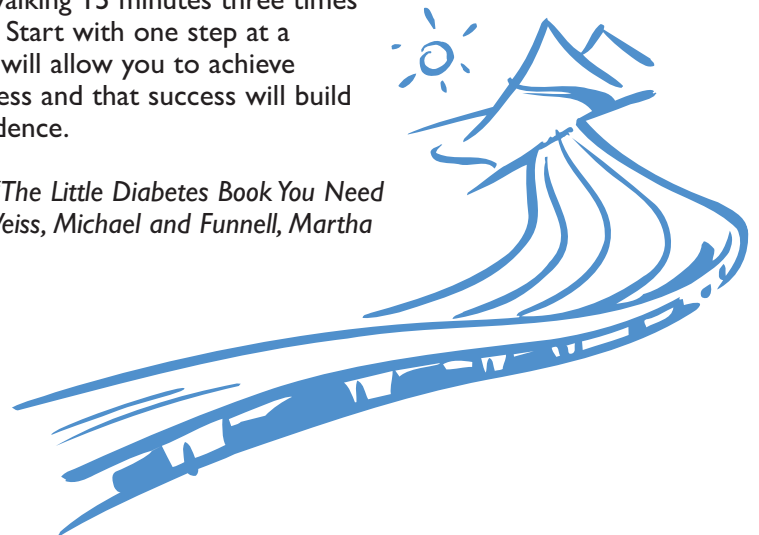
Throughout your journey in the BARI 2D trial, your diabetes team discussed various strategies to reach your target goals, but now you have approached the most challenging part of your diabetes management — experimenting with and evaluating your action plan. You have challenged yourself to achieve targets, but making changes along the way is often a struggle. You might try to do too much at one time and then get discouraged if these efforts fail. Facing these failures can lead to loss of confidence in your abilities and you might feel like giving up.

The important thing to remember when you have setbacks is to learn from your attempts and keep going. It may also be helpful to think about a past experience you had making a change. Whether it worked well or not does not matter; lessons can be learned from failures as well as successes. A good starting point for making changes is to consider what helped or hindered you in the past. This exercise allows you to learn more about yourself based on past experiences.

You may be considering changes that were suggested by your health care team and other people around you. However, deciding to make changes is still up to you. You are in the driver's seat when it comes to managing your diabetes. The first step in taking control is to set a long-term goal and then short-term goals as steps toward reaching it. When choosing your long-term goal, aim for an outcome you feel is worth all your efforts. If you do not believe that it is worthwhile, you will struggle to stay motivated and keep on track. The level of confidence you have in your ability to reach the goal is as important as the priority you give it. It may be helpful to identify some of the negative influences you may encounter that could cause you to view the goal as less important or lower your confidence in reaching the goal. Before you begin working on your goals, focus on strategies to increase your confidence and the level of importance before you begin working on it.

When you choose your long-term goal you will need to think about how you will reach it. It is often helpful to prepare a list of ideas that include things that you may have tried before. After reviewing your list, pick one step you can take to get started but be specific. For example, you may decide to be more active by walking 15 minutes three times this week. Start with one step at a time. This will allow you to achieve some success and that success will build your confidence.

Reference: "The Little Diabetes Book You Need to Read"; Weiss, Michael and Funnell, Martha (2007).





FRESH THAI SALSA

This is a nice variation to that special dish usually known for its Mexican roots. You can create your own version of salsa by making it sour or spicy. Colorful salsas are loaded with healthy antioxidants and can brighten any meal.

Makes 4 servings

Ingredients:

3 diced tomatoes
½ cup diced cucumber
2 tablespoons slivered fresh basil
2 teaspoons minced cilantro
1 tablespoon rice, red or cider vinegar

1 tablespoon canola or peanut oil
1 minced garlic clove
1 teaspoon finely minced fresh ginger
Fresh ground pepper to taste
Salt or salt substitute, if needed
Optional: 1 teaspoon low-sodium soy sauce

Cooking Instructions:

Combine all ingredients. Adjust seasoning and vegetables according to your taste. You can make nice variations by adding beans, corn and fruits like mango, peaches, avocado, etc. You can use salsa to serve with fish or chicken or even to marinate and flavor tofu!

Nutrition Information: (Per Serving)

60 calories
3 gm total fat
0 gm saturated fat
6 gm carbohydrate
1 gm dietary fiber
1 gm protein

Exchanges:

1 serving = 1 vegetable and ½ fat

BEAT OF BARI 2D: Diabetes and Gum Disease: What is the link?

Periodontal diseases are infections of the gums and bone that secure the teeth in place. Poorly controlled diabetes increases the risk of developing such problems. The narrowing of blood vessels that can occur with diabetes impairs the flow of nutrients and removal of wastes from body tissues. This can affect the gums and bone, making them more susceptible to infection.

Additionally, poorly controlled diabetes leads to higher glucose levels in the mouth fluids. This encourages the growth of bacteria that can cause gum disease.

Another risk factor, smoking, is harmful to oral health. A person with diabetes who smokes has a greater risk for gum disease than a smoker who does not have diabetes.

Coupled with poor oral hygiene, diabetes can lead to gingivitis and eventually periodontitis, a severe form of gum disease.

Research has emerged that suggests that the relationship between gum disease and diabetes goes both ways. The presence of gum disease actually increases blood sugar levels. Prevention and treatment of gum disease will therefore increase one's ability to control blood sugar.

What are the symptoms of gum disease?

Any of the following may occur and differ among individuals:

- ◆ red, swollen, tender gums
- ◆ bleeding while brushing or flossing
- ◆ receding gums
- ◆ loose teeth
- ◆ persistent odorous breath
- ◆ change in the way dentures fit
- ◆ pus between the teeth and gums
- ◆ a change in bite

What are the different types of periodontal disease?

- * Gingivitis, the mildest form affects the gums. They become red, swollen and tender, and bleed easily with brushing or flossing. Treatment by a dentist and good consistent care at home help to resolve this problem.
- * Mild Periodontitis stems from untreated gingivitis. This stage shows evidence of erosion of the bone around the tooth. Prompt medical attention is required to prevent further damage.
- * Moderate to advanced periodontitis shows significant bone and tissue loss around the teeth.

Your dentist will determine treatment which may include:

- ▲ Deep cleaning to remove plaque and infected tissue in the early stages of gum disease, while smoothing damaged root surfaces of the teeth. The gums can then be reattached to the teeth.
- ▲ Medication
- ▲ Surgery in advanced disease to clean infected areas under the gums and to reshape or replace the tissues.
- ▲ Dental implants

Diabetes and other oral problems:

- Thrush, a fungal infection of the mouth, occurs more often with diabetes because of high sugar levels in the saliva. Fungus thrives on glucose.
- Dry mouth may be associated with high blood sugar. Reduced saliva can make tasting, chewing, swallowing food, and talking more difficult. A dry mouth is more prone to infections and tooth decay. Tips to prevent dry mouth symptoms include taking frequent sips of water or sugarless fluids, avoiding caffeine, drinking fluids during meals, avoiding tobacco and alcohol, and chewing sugarless gum.

How can I prevent periodontal disease and other oral problems?

- Proper care of your teeth and gums will help prevent the onset of oral complications associated with diabetes.
- ▼ Brush twice daily with a soft nylon brush with rounded tips and fluoride toothpaste. Use small circular motions and short back and forth motions. Brush the tongue frequently.
 - ▼ Flossing cleans between the teeth and the gums. Use an 18-inch segment and use a "sawing" motion in-between the teeth. At the gum line, curve the floss around each tooth and scrape up and down several times, from below the gum to the top of the tooth. Rinse after flossing.
 - ▼ See your dentist regularly.
 - ▼ In addition to proper hygiene, remember that good blood sugar control will reduce your risk of developing gum disease.

References:

Website: http://www.healthsystem.virginia.edu/uvahealth/adult_diabetes/oral.cfm
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Kiran M, Arpak N, Unsal E, Erdoğan MF. The effect of improved periodontal health on metabolic control in type 2 diabetes mellitus. *J Clin Periodontol.* 2005 Mar;32(3):266-7

BARI 2D Frequently Asked Questions

What does HbA1c mean?

● Every three months in the BARI 2D study, patients have their hemoglobin (HbA1c) level measured. The HbA1c test measures your average blood sugar levels over a three-month period by taking a sample of HbA1c molecules—a specific component of your red blood cells. Some blood sugar (or glucose) naturally attaches itself to these HbA1c molecules as they move through your bloodstream. When this happens, the molecule is considered "glycated." The more sugar in your blood, the higher the percentage of glycated HbA1c molecules you will have. Once a cell has been glycated, it stays that way. And since each HbA1c molecule has a lifespan of about four months, your HbA1c sample will include cells that are a few days, a few weeks and a few months old. That is how the test result covers a span of about three months.

Why is an HbA1c important?

■ The HbA1c is used along with daily blood sugar readings to help better understand how well a person is controlling their sugars. Because it gives a long-term view, a person with frequent highs and lows could have an average HbA1c that looks normal. The only way to get a complete picture of blood sugar control is by reviewing your daily log along with your regular HbA1c tests, and working closely with your healthcare provider to set goals and determine if the treatment plan is working. Maintaining a near normal blood sugar level may help protect you from many of the serious problems that are related to diabetes such as progressive damage to body organs like the kidneys, eyes, cardiovascular system, and nerves.

Know your numbers!

▲ In the BARI 2D trial, the goal for the HbA1c level is less than 7 percent. This is also the recommendation of the American Diabetes Association. On the right is a chart that shows how the HbA1c compares to your blood sugar levels. This chart may help you keep your blood sugars on target between visits to your healthcare provider.

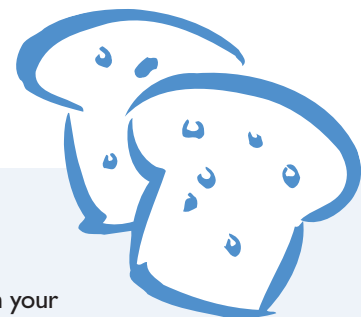
Relationship of HbA1c to Average Whole Blood and Plasma Glucose Levels

HbA1c%	Mean Blood Glucose (mg/dl)	Average Plasma Glucose (mg/dl)	Interpretation
4	61	65	Non-Diabetic Range
5	92	100	
6	124	135	
7	156	170	Target for Diabetes in Control
8	188	205	Action Suggested According to ADA Guidelines
9	219	240	
10	251	275	
11	283	310	
12	314	345	

Table from www.A1cnow.com

How often should the HbA1c be measured?

* Depending on how well your diabetes is controlled, an HbA1c may be measured two to four times each year (every three or six months). When someone is first diagnosed with diabetes or if control is not good, HbA1c tests might be ordered more frequently.



MOVING RIGHT ALONG: SLOW AND STEADY

Many people who are motivated to start living a healthier life see it as a decision to eat food that tastes bad or to start a vigorous and disciplined exercise plan. This is probably why many people have trouble sticking with healthy changes. If you force yourself to eat food that isn't tasty, you will crave food that tastes good; if you see physical activity as "work," you won't want to do it. If you've tried and failed to change your lifestyle in the past, here are some ideas you might want to experiment with to slowly alter your habits.

Exercise has gotten a bad rap over the years. Calling it "working out" brings to mind images of personal trainers and pain. It's no wonder that people try to avoid physical activity! Actually, anything that you do while on your feet or moving around is good for you and beneficial for your diabetes. Sometimes, you may be physically active without even realizing it, for example, golfing or gardening. Active play with grandkids or a pet "counts"

too. Any activity that has you on your feet is better for you than just sitting around. Staying active requires a) finding physical activities that you like to do, and b) setting aside a regular time to do them.

In the same way, try to find healthy foods that you like to eat and find ways to eat them more often. Love apples? Try 'em baked, sweetened with a few raisins. Find ways to have higher calorie foods less often or see if there are low-fat versions to prepare. The easiest way to eat fewer calories in a meal is to eat smaller portions. If you still feel hungry, add more vegetables. Or try a high fiber side, such as a crunchy slice of whole grain toast.

It is as important to enjoy the healthy decisions that you make and have fun; otherwise it's easy to become discouraged. Eventually, as you see progress being made, you may find that the progress you make is actually motivating you to become healthier!

A Clinical Study
BARI 2D



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