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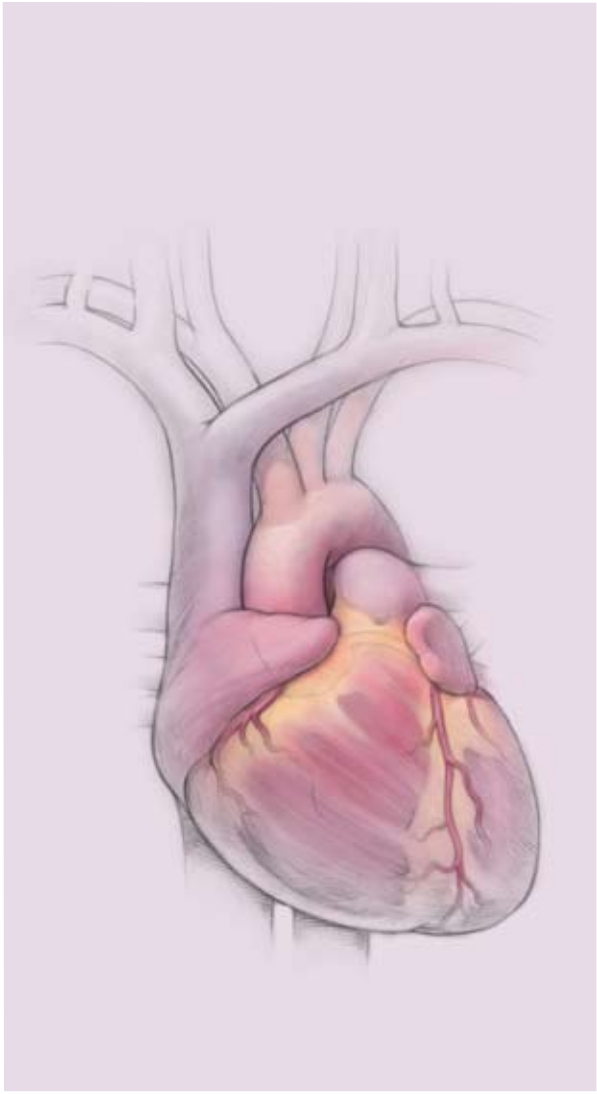
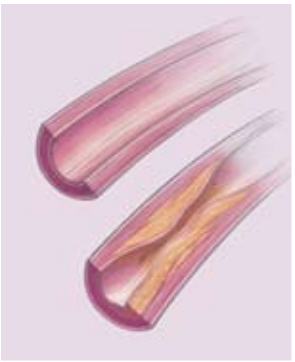
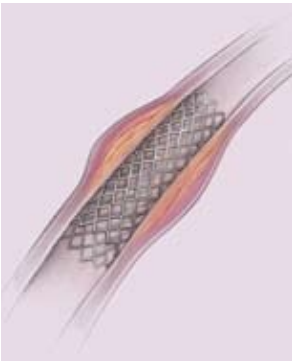
Stent Procedures

ADVANCING THE TREATMENT OF CARDIOVASCULAR DISEASE







UNDERSTAND. TREAT. MAINTAIN.

Name

Date

Instructions

My Doctor's Information

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This educational booklet is provided to patients and physicians as general information about treatment options for coronary heart disease, also known as coronary artery disease.

It is important to understand your procedures and to ask questions that may arise.

2	Introduction
5	What Is Coronary Heart Disease?
9	Causes of Atherosclerosis
13	Making a Diagnosis
16	Treating Coronary Heart Disease
17	→ Surgery
18	→ Balloon Angioplasty
20	→ From Balloons to Stents
22	→ Drug Eluting Stents
24	What to Expect After Your Stent Procedure
25	→ Immediately After the Procedure
27	→ Follow-up Care
28	Drug Eluting Stents and Blood Clots
30	Staying Healthy
32	Glossary of Terms

Advances in treating cardiovascular disease over the last 25 years have been truly amazing.

Heart disease is any disorder that affects the heart's ability to function normally. The most common cause of heart disease is narrowing or blockage of the coronary arteries, which supply blood to the heart. If you or a member of your family have been recently diagnosed with coronary heart disease (CHD), also known as coronary artery disease (CAD), and your doctor has recommended that you receive a stent, you most likely have questions about the disease and its treatment.

In this booklet, you will find information to help you understand CHD, and how stents have revolutionized the treatment of this disease. You will learn about the different types of stents that are used to treat CHD, how a coronary stent is implanted, and what happens after the procedure. In addition, you will find a glossary to help you better understand some of the words and phrases used.

This brochure has been provided to doctors to help educate you, your family, and your friends about the options available for treating CHD. This information does not replace medical advice. Only a doctor can diagnose your health problem and determine which treatment is best for you.

- Understanding the heart
- How the heart works
- The main coronary arteries that supply the heart with the oxygen-rich blood it needs to keep the body healthy

Like any muscle, the heart needs a constant supply of oxygen and nutrients, which are carried to it by the blood in the coronary arteries. This section provides a brief description of the heart and how it works.

Notes & Questions

What Is Coronary Heart Disease?

To understand coronary heart disease, a brief description of the heart and how it works is helpful.

The heart is a muscle that acts like a pump. It pumps blood that carries oxygen and nutrients to every organ and muscle, so that the body can work efficiently and stay healthy. And, like every other organ in the body, the heart needs its own supply of blood to keep it working well. The tubes or vessels that supply oxygen-rich blood to the heart are called coronary arteries. There are two main coronary arteries: the left main coronary artery and the right coronary artery (see **Figure 1**).[1] The left main coronary artery divides into two main branches called the left anterior descending (LAD) artery and the left circumflex artery.

Coronary arteries are about the width of a drinking straw, just 0.16 inches (4.1 mm) wide.[2] As the arteries subdivide to feed all the layers of the heart muscle, they get smaller. These small marginal artery branches run around the outside of the heart, sending even smaller branches inward.

What should I do if I have risk factors for CHD? [3]

Answer: *Some risk factors you can't change, others you can. You can't do anything about unchangeable risk factors like age, family history, race, or gender. But you can lower your risk by changing some of your habits. Eating a balanced diet, exercising, stopping smoking, and taking medicine, if needed, to control high blood pressure, lower cholesterol, or manage diabetes are all important steps to help reduce the risk of CHD.*

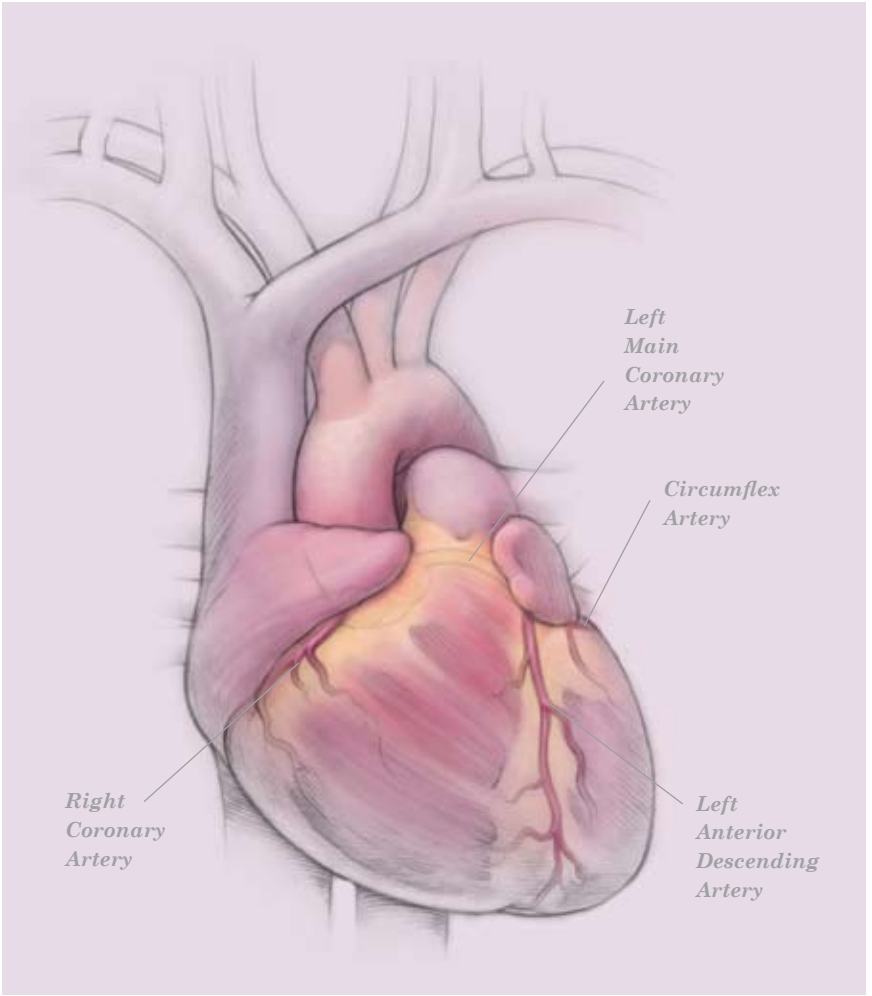

Figure 1
The heart is a powerful muscle that continually pumps blood to the rest of the body. The tubes or vessels that supply the heart with blood are called coronary arteries, and can be seen on the surface of the heart muscle. There are two main coronary arteries: the left main coronary artery and the right coronary artery. The left main coronary artery divides into two main branches called the left anterior descending (LAD) artery and the left circumflex artery.

- Healthy arteries
- Atherosclerosis and how it causes heart disease
- Risk factors for atherosclerosis

Both men and women can get CHD. This section describes healthy coronary arteries and the most common cause of CHD, known as atherosclerosis. Several factors that increase the risk of CHD and heart attack are reviewed.

Notes & Questions

Causes of Atherosclerosis

Coronary heart disease most often results from a condition known as atherosclerosis, which occurs when one or more of the coronary arteries becomes narrowed or totally blocked by a gradual build-up of a waxy substance (called plaque) inside the artery wall (see **Figure 2**).[4] Risk factors that may lead to the development of plaque and atherosclerosis are listed in **Table 1** on the following page. The more risk factors you have, the higher your risk.

The build-up of plaque reduces the flow of blood to the heart muscle. As a result, the heart muscle does not get the oxygen-rich blood that it needs, causing symptoms ranging from chest pain (called angina) to a heart attack (also known as a myocardial infarction). Coronary heart disease is the leading cause of death for both men and women in the United States each year.[5,6]

What is plaque? [4]

Answer: *Plaque is made up of deposits of fat and cholesterol. When the coronary arteries become narrowed or clogged by plaque and cannot supply enough blood to the heart, you may experience chest pain, called angina. If the blood supply to a portion of the heart is completely cut off by total blockage of a coronary artery, the result is a heart attack.*

Figure 2
Over time, fatty, waxy deposits called plaque can build up on the inside of the artery wall, clogging the vessel opening. This build-up affects the ability of blood to flow through the artery and deliver oxygen and nutrients to the heart. A heart attack occurs when either a main coronary artery or one of the major branches supplying blood to the heart becomes blocked.

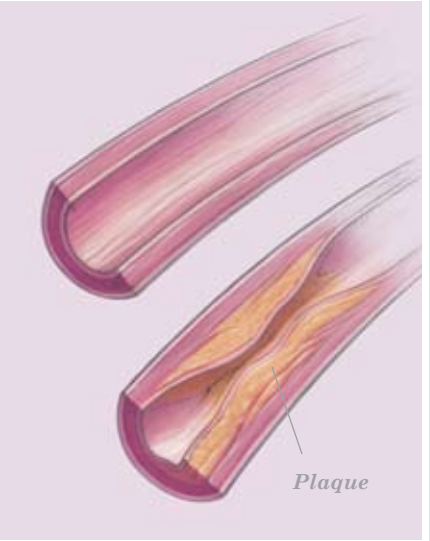

Table1 *Risk Factors for the Development of Plaque and Atherosclerosis* [3, 4, 6]

High blood pressure (hypertension)
High levels of cholesterol and triglycerides in your blood
Diabetes
Obesity and overweight
Gender
Smoking
Lack of physical activity
Age over 65 years
Family history of heart disease

→ Talk with your doctor about how to lower your risk

- Questions your doctor will ask you to help diagnose CHD
- Tests, such as an electrocardiogram, a stress test, and angiography, that determine whether you have CHD and help you and your doctor decide on a treatment plan

There is no single test to diagnose CHD. This section reviews how your doctor studies the test results and then determines whether you have CHD before deciding on a treatment plan.

Notes & Questions

Making a Diagnosis

When making a diagnosis, your doctor will ask you about [7, 8]:

- Your current symptoms and previous medical history
- Your family history
- Your risk factors

Before deciding on a treatment plan, your doctor may recommend that you have a chest X-ray and/or blood tests. You may also take a test to measure how well your heart is working. This test, called an electrocardiogram (or ECG), records your heart's electrical activity while you sit or lie quietly. An exercise ECG (also called a stress test) shows how your heart responds to increasing levels of physical activity. Both tests are able to show whether your heart is working improperly because of a lack of oxygen.

Angiography

Your doctor may also perform a procedure known as angiography (or cardiac catheterization). Angiography is an X-ray technique in which dye is injected into a chamber of your heart. The test, called an angiogram, lets doctors measure blood flow and see if your coronary arteries are clogged.[9] Before the procedure, you will be given

Why do doctors use angiography? Can't an ECG alone diagnose CHD? [7, 8]

Answer: *An ECG can tell your doctor how well your heart is working. It also shows doctors how fast your heart is beating and whether it's beating in a regular pattern.*

Angiography can show any plaque that has built up, causing the arteries to narrow and/or block the blood supply.

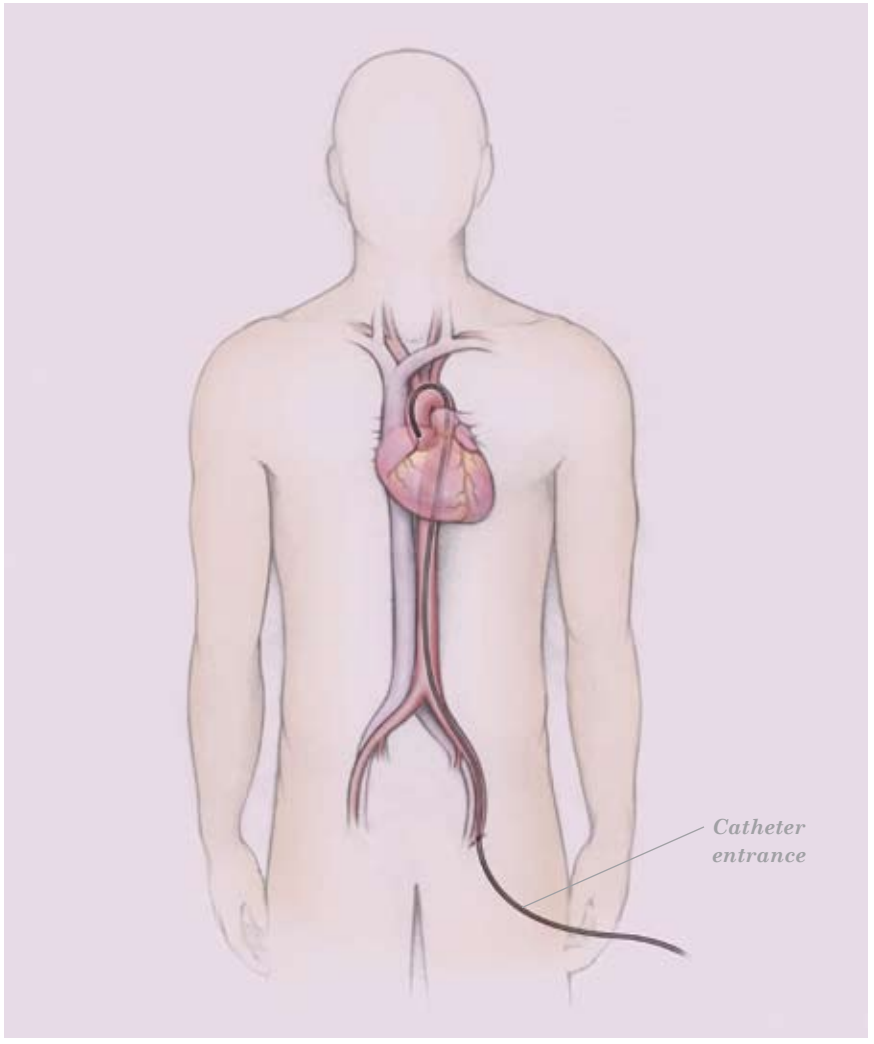

Figure 3
Angiography is a special test for diagnosing atherosclerosis. During this test, a small incision is made in the leg and a thin tube, called a catheter, is advanced through the artery to the heart. A dye is injected into a chamber of the heart, and a series of X-rays are taken. The X-rays show the number of blockages and how serious those blockages are.

medication to help you relax, but you will still be awake. During the procedure, a long, thin tube (called a catheter) is placed into an artery in the leg and threaded into your heart (see **Figure 3**). Once the catheter is in place in the heart, a dye is injected through the catheter and into your heart. It is normal to feel a warm but short "flush" when the dye is injected; tell your doctor or nurse if you feel any pain or discomfort during the procedure. The dye helps the doctor see how the coronary arteries are working. The results of this test will help your doctor decide which treatment is best for you.[9]

- Advances over the years in ways to treat CHD
- Surgery
- Balloon angioplasty
- Bare metal stents
- Drug eluting stents

Treatment for CHD may include lifestyle changes, medicines, and special procedures. This section reviews advances in the treatment of CHD.

Notes & Questions

Treating CHD

When atherosclerosis is identified at an early stage, its consequences can be controlled by the use of medications and by lifestyle changes, such as exercising, eating healthy foods, and quitting smoking. In many cases, however, such as when one or more coronary arteries is more than 50% blocked (or occluded), more direct procedures are needed to clear the blockage.[10]

Initially, there were only two treatments a cardiologist could use to clear blockages in the coronary arteries: coronary artery bypass graft or balloon angioplasty. Both therapies have been clinically proven among carefully selected patients. The option used depended on how much narrowing there was, how many arteries were affected, the location of the narrowing, how much heart muscle was at risk, and individual patient factors, such as age and overall health.

Surgery

Coronary artery bypass graft, or "CABG" (pronounced "cabbage"), is a common surgical procedure that removes a section of an artery from your chest, another part of the body or a portion of vein in your leg.[11] This vessel is then connected (grafted) to the coronary artery at the site of blockage. This creates a new path for blood to flow around (bypass) the blocked artery to your heart. After surgery, you most likely will stay in the hospital for about a week.[10] However, hospitalization may last longer, depending upon the rate of your recovery and the occurrence of any complications related to the surgery. The hospitalization is followed by a recovery period at home.

Balloon Angioplasty

Angioplasty is performed by a cardiologist and a team of specialized cardiovascular nurses and technicians, usually in a special part of the hospital called the cardiac catheterization lab.

General anesthesia isn't needed, so you are awake during the procedure. You will receive fluids and medications for relaxation and mild sedation through an intravenous catheter. You will also get blood-thinning medications (anticoagulants) to reduce the risk of blood clotting, and other medications to relax your coronary arteries.

When you are comfortable, a specialist inserts a thin, flexible catheter with a deflated balloon at its tip into your arm or leg. The catheter is threaded through the artery until it reaches and passes through the blockage (see **Figure 4A**).[12] At this point, the balloon is slowly inflated, flattening the plaque against the artery wall (see **Figure 4B**).[12] This process widens the artery opening and allows blood to flow again at a normal (or near normal) rate (see **Figure 4C**).[12] If other coronary arteries are blocked, the catheter is moved, and the procedure is repeated.

It is normal to have some chest pain when the balloon is inflated. Tell your doctor or nurse if you feel any pain or discomfort during the procedure.

Angioplasty is not a cure for CHD. About 35% to 40% of patients develop restenosis, a renarrowing of the artery, within a year following angioplasty.[12] Two processes are thought to cause restenosis. First, when an angioplasty is performed, the artery is stretched open by a balloon.

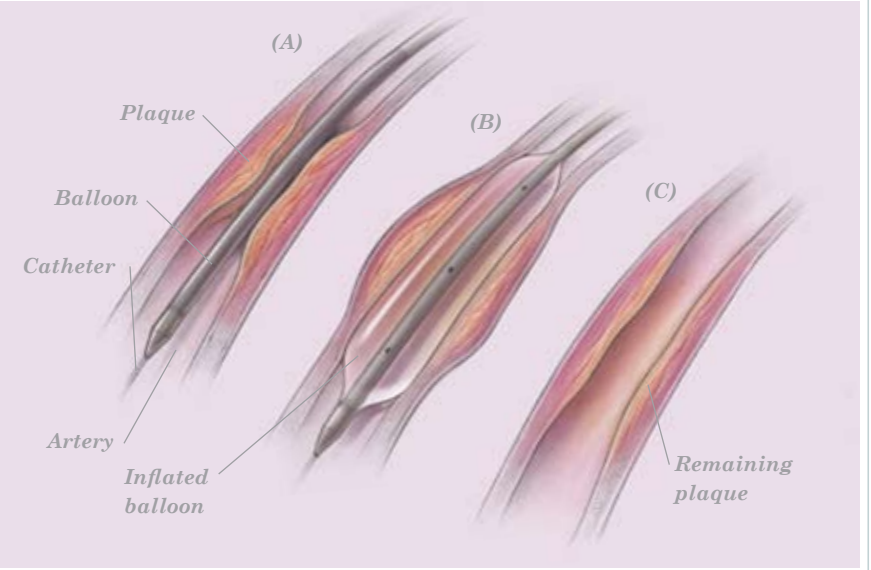

Figure 4
(A) Catheter holding a small deflated balloon on its tip is slipped over a guidewire and positioned at the blockage. **(B)** Inflated balloon compresses the plaque against the artery wall. **(C)** Enlarged artery opening allows blood to flow normally. After treatment, the guidewire, catheter, and balloon are removed. The procedure may be repeated if the plaque build-up returns.

Afterwards, because of the elastic properties of the artery wall, the vessel renarrows, or recoils, to something close to its original size.

Second, after angioplasty a certain amount of scar tissue develops. Usually the amount of scar tissue is very small. Sometimes, however, the scar tissue can be quite thick and may obstruct the flow of blood through the artery. Restenosis is caused by the combination of vessel recoil and growth of scar tissue.

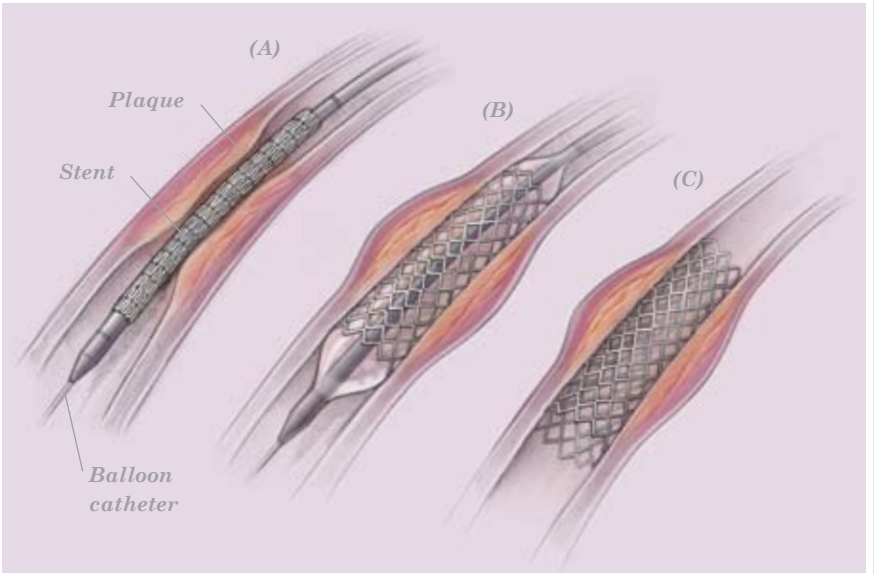

Figure 5
(A) A balloon catheter with the unexpanded stent mounted. **(B)** Expanded stent after balloon inflation. **(C)** Stent permanently implanted in the artery to hold the plaque against the artery wall, provide structural support to keep the artery open, and improve blood flow to the heart.

From Balloons to Stents

Stents were developed to prevent an artery from collapsing after balloon angioplasty, and have reduced the high incidence of restenosis in people undergoing the procedure. Various generations of bare metal stents have been used for more than 10 years, with each new generation offering increased flexibility and deliverability. In fact, the insertion of a metal stent is now becoming common practice in order to hold the vessel open and maintain blood flow, reducing the incidence of both restenosis and abrupt closure of the artery.

Before undergoing a stent procedure, you should be treated with aspirin combined with clopidogrel (Plavix®).[14] Your doctor may also recommend ticlopidine as an alternative. Implanting a stent does not require surgery. Instead, your doctor will make a small incision in your groin or forearm and insert a catheter into the artery, similar to the balloon angioplasty procedure (see **Figure 5**).[15,16] A specially designed balloon catheter is used to deliver the stent to the blocked area of the artery. Once there, the balloon is inflated and expands the stent, thereby squeezing the plaque against the vessel wall and widening the artery opening. After the balloon is deflated and removed, the stent remains in the artery permanently, acting like a scaffolding to hold the plaque against the artery walls and provide structural support to keep the artery open.

Conventional bare metal stents are made of various metals, but stainless steel stents are the most common. Stents come in various sizes, depending on the diameter of the artery to be treated.

Stenting, like angioplasty, is less invasive than traditional CABG surgery. It involves a shorter hospital stay—usually 1 to 2 days—and a faster recovery than surgery.[3] However, it does have its potential risks. Also, a condition called in-stent restenosis occurs in as many as 25% of patients who receive conventional bare metal stents.[13] The most common reason for in-stent restenosis is that scar tissue from uncontrolled muscle growth forms inside the stent. If in-stent restenosis occurs, patients may need to have another balloon angioplasty or stent procedure. Until recently, doctors have had few options for preventing in-stent restenosis.

Drug Eluting Stents

New stents, called drug eluting stents, have been developed to help prevent restenosis. Like bare metal stents, a drug eluting stent is a tiny metal scaffold used to prop up arteries following plaque-clearing procedures. However, a drug eluting stent is coated with a tiny amount of a drug that slowly seeps into surrounding tissue to help prevent the formation of scar tissue that can reclog a treated artery.[13] Compared to bare metal stents, drug eluting stents significantly reduce the risk of renarrowing within the stent. Drug eluting stent trials have shown a great reduction in the formation of scar tissue and a much lower need for repeat procedures to unclog arteries.

However, drug eluting stents may not be appropriate for every patient with CHD. Potential complications include the formation of blood clots. Studies show blood clots may be more likely with some drug eluting stents than with bare metal stents.[15] Some people may have an allergic reaction to the drug used in the drug eluting stent. Drug eluting stents also may not be suitable for patients who have had recent heart surgery, women who are nursing or pregnant, or patients who might not be able to tolerate antiplatelet inhibitors that need to be taken for the prescribed duration. Your doctor can advise you as to whether or not you are a good candidate for this treatment option.

- What to expect after your stent procedure while you are in the hospital
- Care you will need when you return home

After you receive your stent, you are carefully monitored by your doctor and nurses. This section describes what to expect, things you should do, and the medicines you will need to take after your stent procedure, both in the hospital and when you return home.

Notes & Questions

What to Expect After Your Stent Procedure

Immediately After the Procedure

You will be asked to lie flat for several hours after the procedure. You also will be told not to bend your leg or arm, depending on where the doctor inserted the catheter. Pressure will be placed on the area. In some cases, your doctor may use a device that seals the small hole in the artery. If this device is used, you may be allowed to get up and walk around sooner.

Your catheter site will be checked for bleeding or swelling, and your blood pressure and heart rate will be monitored. Your doctor will prescribe medication to protect against spasm of the arteries and to prevent blood clots. If a contrast dye was used during the procedure, you will urinate often in order to rid your body of this material. You may be asked to drink extra fluids.

To prevent blood clots (thrombus) from forming in the weeks or months after stent implantation, cardiologists prescribe two medications: aspirin and a stronger drug, clopidogrel (commonly known as Plavix®). Both drugs inhibit the function of platelets, the blood cells that clump together to begin the process that results in the formation of a blood clot. Usually, patients take aspirin for the rest of their lives after a stent procedure. Plavix® is taken for at least 1 month after implantation of a bare metal stent and for 3 to 6 months or longer after implantation of a drug eluting stent. Your doctor will tell you the appropriate dosage of Plavix® that is best for you.

It is very important that you take all of your medications, including Plavix®, for the time period prescribed. There are a number of reasons why Plavix® is prescribed. If another doctor asks you to stop the medications your cardiologist has prescribed, be sure to ask him or her to first discuss this with the cardiologist who performed your stent procedure.

Patients usually stay overnight and return home the day after the procedure. However, depending on your rate of recovery and the development of any complications, your hospital stay may last up to 2 days.

After you return home, if you have any chest pain, discomfort, or bleeding from your puncture site, call your doctor immediately. If you can't reach your doctor, call for an ambulance to take you to the closest hospital emergency room.[18]

Follow-up Care

For the first 2 weeks at home, you should avoid putting pressure on the puncture site or lifting heavy items. You can gradually resume activities such as exercise and work after about a week.[19]

You will be asked to return to your doctor for follow-up visits. The first visit is usually 2 to 4 weeks after your stent procedure, with follow-up visits at 6 and 12 months. It is very important that you keep all of your follow-up appointments.

You should inform any doctor who treats you in the future that you have a coronary stent. If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a stent implant. According to the American Heart Association, an MRI scan should not be done for the next 4 weeks after a stent procedure without a cardiologist's approval.[20] In addition, tell any dentist or doctor who treats you for any reason that you have a coronary stent implant.

- Drug eluting versus bare metal stents
- Late stent thrombosis
- The importance of always taking your medication as advised by your doctor
- Things you need to do to help keep yourself well and avoid future heart problems

Having a stent implanted has both benefits and risks. This section reviews the important responsibilities that all patients with stents have after the procedure. By following the suggestions listed on the following pages, you will help give yourself the best chance of staying healthy and preventing the artery with the stent from reclogging.

Notes & Questions

Drug Eluting Stents and Blood Clots

With the increasing use of drug eluting stents, we are learning more and more about their benefits and risks. Conventional bare metal stents are associated with in-stent restenosis that may require a repeat procedure.[21] In contrast, drug eluting stents may greatly reduce renarrowing, but some can have a problem of late stent thrombosis (blood clotting in the stent) a month or more after your procedure, which can result in heart attacks.[21] A higher incidence of late stent thrombosis is associated with patients who have stopped taking their antiplatelet medications before the prescribed duration. Late stent thrombosis with some drug eluting stents may have a higher rate of stent thrombosis than with bare metal stents, thus emphasizing the importance of antiplatelet therapy.[17]

It is important to follow your doctor's orders on taking antiplatelet drugs and to understand the risks of prematurely discontinuing antiplatelet therapy. If a surgical or dental procedure is recommended after the stent is implanted and you are still on prescribed Plavix®, the risks and benefits of the procedure should be weighed by your cardiologist against the possible risk associated with discontinuing antiplatelet therapy. Before any surgical or dental procedure or emergency treatment, always tell the doctor or dentist that you are taking this medicine.[19] In addition, be sure to ask him or her to discuss this with the doctor who first performed your stent procedure.

Staying Healthy

Once you have undergone a stent procedure, you have important responsibilities to help yourself stay healthy[22]:

- You should make important diet, exercise, and lifestyle changes. For example, reducing cholesterol and fats in your diet may reduce the risk of redeveloping blockages within the stent.
- Eating healthy foods in the right amounts may also help you achieve and maintain a healthy weight to reduce the risk of a reblockage.
- If you smoke, it is extremely important to quit. Smoking increases both the risk of worsening CHD and the chance of the stent site becoming reblocked.
- Make an effort to reduce the stress in your life and work with your doctor to develop a controlled exercise program.
- Medications are important! If you have undergone a stent procedure, you MUST take your medications exactly and for as long as prescribed by your doctor. Taking aspirin and Plavix® is especially important to help avoid late stent thrombosis if you received a drug eluting stent.
- In addition, take other medications as prescribed by your doctor and make lifestyle changes to reduce the risk of future heart problems.

With ongoing research and the development of new drug delivery systems, the future is bright for newer and safer drug eluting stents to help prevent the renarrowing of coronary arteries in patients with CHD.

Glossary of Terms

Angina Chest pain or discomfort that occurs when the heart muscle doesn't get enough blood flow and oxygen supply.

Angiogram A special X-ray procedure that indicates the number, exact location, and extent of narrowed or blocked coronary arteries.

Anticoagulants Blood-thinning medications that help prevent the formation of blood clots.

Atherosclerosis A disease that involves the build-up of a waxy substance called plaque on the inside of arteries.

Balloon angioplasty A nonsurgical medical procedure in which a specially designed balloon catheter is used to open a narrowed or blocked artery.

Bare metal stent A conventional uncoated stent. See "Stent."

Catheterization A procedure in which a thin hollow tube, called a catheter, is inserted into an artery in your leg or arm for the purpose of visualizing the heart and blood vessels, and for diagnosing and treating heart disease.

Cholesterol The most plentiful fatty substance in animal tissues. High levels in the diet contribute to the development of atherosclerosis.

Coronary arteries Blood vessels on the outside of the heart that provide it with oxygen-rich blood. There are two main coronary arteries: the left main and right coronary arteries.

Coronary artery bypass graft (CABG) A common surgical procedure that grafts a section of an artery from your chest or a vein in your leg to create an alternative route for blood to flow around a narrowed or blocked artery.

Drug eluting stents Stents coated with drugs that help keep arteries from renarrowing after in-stent restenosis.

Electrocardiogram (ECG) A medical test in which several electronic sensors are placed on your body to monitor electrical activity associated with the heartbeat.

Endothelialization The healing of the inner surfaces of coronary arteries.

Exercise ECG See "Stress test."

Heart attack A disruption in heart function that occurs when a coronary artery is completely blocked or almost completely blocked. This results in damage to or death of an area of your heart muscle. Also called a myocardial infarction, or MI.

Myocardial infarction See "Heart attack."

Plaque A waxy substance, consisting of fats and cholesterol, that can build up on the lining of your arteries.

Platelet inhibitors Drugs that inhibit the function of platelets, the blood cells that clump together to begin the process that results in the formation of a blood clot.

Restenosis Renarrowing of an artery at the site of angioplasty and/or stent implant due to the overgrowth of normal tissue.

Stent A tiny metal device used to prop open arteries following plaque-clearing procedures.

Stress test A test, also called an exercise ECG, that shows how your heart responds to increasing levels of physical activity, and that can tell if your heart is not working properly due to a lack of oxygen.

Thrombus A blood clot.

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