

Intravascular Radiotherapy

*A Guide
for Patients*

October 2001

GUIDANT

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A Patient's Guide to Intravascular Radiotherapy

Introduction

Your physician is considering intravascular radiotherapy to treat your heart disease.

Intravascular radiotherapy uses radiation to keep open blocked arteries in the heart. It is a recent medical advance, but it has been performed on hundreds of people all over the world. It is done along with *angioplasty* in the *catheterization* laboratory.

The more you know about your condition and its treatment, the better. This booklet will help you understand coronary artery disease and its treatments, including intravascular radiotherapy. As you read, you may have some questions. Feel free to discuss them with your doctor or nurse. You'll find common questions and answers in the back of this guide, as well as a page for your own notes.

radiotherapy:
treatment
using radiation

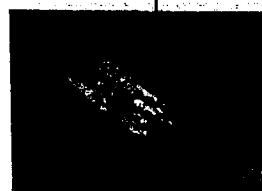
intravascular:
in or through
blood vessels

angioplasty:
procedure using a
balloon to open a
clogged artery

catheterization:
procedure in which
a tiny tube is placed
in the arteries of
the heart to look
for narrowing or
blockages

Coronary Artery Disease *The Cause*

Coronary artery disease (CAD) is caused by a buildup of cholesterol and other fatty substances, sometimes called *plaque*. This buildup narrows the artery and reduces the blood flow.



plaque: buildup of a
fatty material in the
coronary artery
causing a narrowing
or a blockage

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coronary artery:
heart artery

angina:
chest pain caused by
not enough
oxygenated blood
for the heart

**cardiac
catheterization
laboratory:** area of
hospital where
minimally invasive
procedures like
angioplasty are
performed

vascular catheter:
small tube through
which fluids or
objects can be
moved in or out
of the body

stent: small
metallic scaffold
that is expanded
in the artery to
make a larger
channel for
improved blood
flow; keeps the
artery from
collapsing

People who have a family history of **coronary artery** disease (CAD) or certain conditions, like diabetes and high blood pressure, are at risk of CAD. Certain lifestyle choices can also put people at risk — smoking, being overweight, lack of exercise, and stress.

The Result

When an artery becomes so blocked that the blood cannot easily pass through it, the heart cannot receive enough oxygen. When this happens, **angina** may result, or — eventually — a heart attack.

Treatments

A doctor decides how to treat CAD based on a patient's medical history and medical tests. Sometimes it is treated with medication. At other times, bypass surgery is needed. In many cases, angioplasty or stent placement is the right treatment.

Angioplasty — Angioplasty is a common procedure that takes place in the **cardiac catheterization laboratory**. The doctor guides a **vascular catheter** with a small balloon through a blood vessel to the narrowed section of the artery. When the balloon is inflated, it pushes out against the wall of the artery and compresses the plaque. This makes the inside of the blood vessel larger and helps the blood flow better.

Stent Procedure — Fatty deposits tend to build up repeatedly. A **stent** is sometimes placed in an artery to help keep it open. A stent can be inserted during the same procedure as the angioplasty. The stent remains in place permanently.

Restenosis

Unfortunately, the results of angioplasty are temporary in about 30 to 50 percent of patients, and even stents cannot always keep an artery open. In about 20 percent of cases, within a year, tissue around the stent begins to grow, and the artery becomes blocked again.

This re-narrowing of a blood vessel after angioplasty or a stent procedure is called **restenosis**. Restenosis can cause the symptoms of CAD to return.

Your doctor is considering intravascular radiotherapy for you because you have restenosis.

Intravascular Radiotherapy — Restenosis is sometimes treated with a second angioplasty procedure. Your doctor may also recommend angioplasty *with intravascular radiotherapy*. The use of radiation can reduce the cycle of restenosis by preventing future blockages.

Intravascular radiotherapy is usually performed right after angioplasty during the same procedure. It takes only a few extra minutes, and patients do not feel anything different.

As with angioplasty, the doctor guides a catheter to the treatment site. A radioactive source is inserted through the catheter. This radioactive source is never in direct contact with your artery or blood. The doctor, with the help of other health professionals, delivers an exact dose of radiation to the treatment site. After the dose is delivered, he or she removes the radioactive source and catheter. No radiation remains in the body afterward.



restenosis:
the re-narrowing of a
blood vessel after
angioplasty or stent
placement

**Intravascular
radiotherapy:**
treatment using
radiation through
the blood vessels

The GALILEO™ Intravascular Radiotherapy System

Description

The GALILEO™ System is used in the catheterization lab to treat restenosis using radiotherapy.

beta radiation: type of radiation that cannot travel far, so it is able to treat a very small area of the body

The type of treatment system your physician is considering is the **GALILEO™ Intravascular Radiotherapy System**.

The GALILEO™ System uses **beta radiation** to slow (stop) the growth of tissue inside a stent. Beta radiation does not travel more than a fraction of an inch and will not enter the rest of your body. The dose of radiation that patients receive is less than the amount received during a regular chest x-ray.

During the brief procedure, the doctor guides a catheter through the artery until it reaches the treatment site. The GALILEO™ System automatically sends a wire containing radiation through the catheter to the treatment site, where the source treats (provides radiation to) the artery. After a few minutes, the radioactive wire is automatically removed, and the procedure is over.



Indications for Use

The GALILEO™ Intravascular Radiotherapy System is approved for people who have developed restenosis (re-blockage) after the placement of a stent in a coronary artery. Your doctor will help you understand the risks and benefits of this therapy and whether it is right for you.

Contraindication

This therapy should not be used for patients who cannot receive **antiplatelet** and/or **anticoagulant therapy**.

antiplatelet therapy: medication to prevent parts of the blood (platelets) from sticking together and forming a clot

anticoagulation therapy: medication to prevent the formation of a clot

Benefits

Radiotherapy has been studied in many clinical trials. The findings so far are very encouraging:

- Of the patients treated for in-stent restenosis:
 - Nearly half the patients needed another procedure within six to 12 months because of restenosis.
 - Patients treated with radiotherapy were half as likely to need a repeat angioplasty or to have a heart attack within nine months of the radiotherapy procedure.
- Patients with in-stent restenosis and treated with radiotherapy experienced a 50% decreased chance of restenosis than those who had not had radiotherapy.

Risks

Of course, all medical procedures have risks. Most of the risks associated with intravascular therapy are the same as those you have already faced with angioplasty or placement of a stent — circulatory problems, reaction to the contrast material, infection, irregular heart rate, chest pain, heart damage, heart attack, and even stroke or death.

Radiotherapy adds only a few other risks, such as accidental exposure to beta radiation and reaction to the necessary medications.

You should discuss all the risks in detail with your doctor, and make sure you understand all the terms.

Alternative Treatments

There are alternative methods to treat CAD: balloon angioplasty with or without a stent, atherectomy, (a catheterization procedure that uses a tiny cutting device to cut the tissue blocking an artery), **bypass surgery**, and medication.

bypass surgery:
procedure in which
a blood vessel is sewn
in place to permit blood
to travel to an area of
the heart that was
previously blocked

After the Procedure

Recovery

Recovery from radiotherapy is the same as it is after angioplasty. You will return to a special room for at least six hours where your heart rhythm, blood pressure, and catheter entry site will be watched closely. You will need to drink lots of fluids. Frequent urination will help remove the contrast material used from your body as quickly as possible. In 12 to 24 hours, you should be able to get up. Gradually, your doctor will allow you to become more active.

You will probably feel some mild chest pain right after the procedure, but it should disappear in one or two hours. If the pain increases or returns, tell the nurse immediately.

You may stay in the hospital for one or two days before going home. At home, if you have any discomfort, pain, or bleeding, contact your doctor immediately.

Medications

Medications are an important part of the treatment. The drugs your doctor prescribes will help prevent blood clots in the treated artery. **Tell your doctor if your medications cause problems, but do not stop taking them unless your doctor tells you.** He or she may be able to give you something else that does not cause you any problems.

Lifestyle Changes

Many of the factors that lead to heart disease and other heart-related conditions are caused by lifestyle. Some common risk factors are diabetes, smoking, being overweight, high blood pressure, family history, male gender, lack of exercise, and stress.

Talk to Your Doctor...

With treatment and lifestyle changes, many people with coronary artery disease can lead full, active lives. At some point soon, talk to your doctor about your risks and about making any needed changes in your lifestyle.

Common Questions and Answers

When you talk to your doctor, be sure you understand your condition, your treatment options, and your lifestyle choices. Ask all your questions and get answers that you can understand. Then you can make an informed decision about your treatment and your health.

The questions below are ones commonly asked by other patients.

1 Why has my doctor recommended intravascular radiotherapy? After angioplasty or stent placement, up to 50 percent of patients have symptoms again within six months. This is due to a re-narrowing of the coronary artery, known as restenosis. Intravascular radiotherapy has been shown to reduce restenosis by 50%. During clinical studies, patients who received intravascular radiotherapy were less likely to need repeat treatment for restenosis.

2 How does the GALILEO™ System work? A special balloon is placed at the treatment site, and a wire containing the radiation is placed inside the balloon. An exact dose of radiation is then delivered to the treatment site. After the radiation has been delivered, the wire and balloon are removed.

3 How long does intravascular radiotherapy treatment take? Intravascular radiotherapy adds only about 10 minutes to the regular angioplasty procedure, which takes about 90 minutes.

4 **Is the radiation painful?** No. You will not notice the presence of radiation. The procedure will feel like a regular angioplasty procedure. Also, you are *not* radioactive during treatment or after.

5 **How long has this treatment been available?** Radiotherapy has been used to treat certain diseases, cancer, for example, for many decades. However, its use for coronary artery disease is fairly new. The procedure was first used in clinical trials in 1996. Since then, it has been used to treat hundreds of patients throughout the world.

6 **How safe is intravascular radiotherapy?** The GALILEO™ System uses beta radiation and limits the radiation to a small treatment area within the coronary artery. The risk of complications resulting from the use of beta radiation is considered to be low. The amount of radiation is calculated carefully, and only the exact amount of radiation needed is delivered. The dose of radiation used by the GALILEO™ System is less than that received during a regular chest x-ray.

Glossary

angina: chest pain caused by not enough oxygenated blood for the heart

angioplasty: procedure using a balloon to open a clogged artery

anticoagulation therapy: medication to prevent the formation of a clot

antiplatelet therapy: medication to prevent parts of the blood (platelets) from sticking together and forming a clot

beta radiation: type of radiation that cannot travel far, so it is able to treat a very small area of the body

bypass surgery: procedure in which a blood vessel is sewn in place to permit blood to travel to an area of the heart that was previously blocked

cardiac catheterization laboratory: area of hospital where minimally invasive procedures like angioplasty are performed

catheterization: procedure in which a tiny tube is placed in the arteries of the heart to look for narrowing or blockages

coronary artery: heart artery

intravascular: in or through blood vessels

intravascular radiotherapy: treatment using radiation through the blood vessels

plaque: buildup of a fatty material in the coronary artery causing a narrowing or a blockage

radiotherapy: treatment using radiation

restenosis: the re-narrowing of a blood vessel after angioplasty or stent placement

stent: small metallic scaffold that is expanded in the artery to make a larger channel for improved blood flow; keeps the artery from collapsing

vascular catheter: a small tube through which fluids or objects can be moved in or out of the body

Your Notes

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