

NOTE: This is a fictitious patient record and is intended for demonstration purposes only.

Patient Name: Dodson, Madge .  
Date of Birth: 3/9/1933  
Medical Record Number: 20729-36607-41011

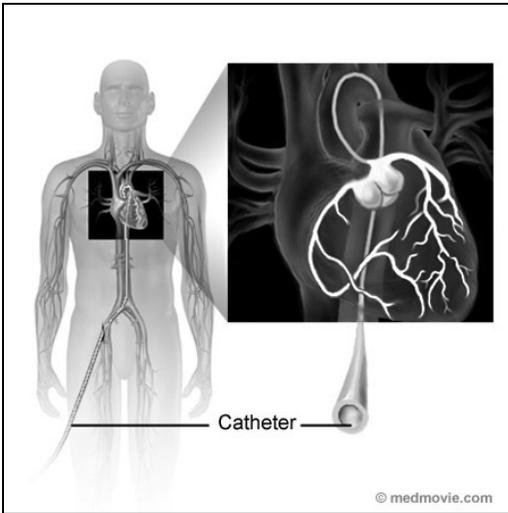
Consent for Coronary Angiography ("Heart Dye-Study") and/or  
an Intervention Procedure ("Opening blood vessels in the heart")

We are asking you to sign this form because it is very important that you be part of the decisions about your care. It is important to understand the procedure, its risks, benefits and alternatives. Your doctor will talk with you about these. Be sure you get your questions answered before you sign this Consent Form. Please initial and date here to show that you understand.

\_\_\_\_\_  
Patient's initials or authorized individual

\_\_\_\_\_  
Date

I hereby authorize Dr.  and any associates/assistants to perform the following procedure: Coronary angiogram with possible percutaneous coronary intervention.



Cardiac catheterization is a medical procedure used to diagnose and treat certain heart conditions. A long, thin, flexible tube called a catheter is put into a blood vessel in the arm, upper thigh (groin), or neck and threaded up into the heart. Through the catheter, doctors can perform diagnostic tests and treatments on the heart.

During the procedure, a special dye is put into the catheter to make the inside of the heart and blood vessels show up on x-rays; this is known as coronary angiography (Figure 1). Angiography can help your doctors determine if the blood vessels that supply your heart have any blockages that may be giving you symptoms or may put you at increased risk for a heart attack.

Figure 1

If a vessel is blocked, your doctor may decide to treat the blockage with an angioplasty and/or a stent implant. (If your doctor decides that surgery is needed instead of a procedure, a coronary artery bypass graft (CABG) may be done at a later time.)

Patient Identifier Label

Angioplasty: In this procedure an expandable balloon on a catheter is used to help unblock arteries. The balloon expands and presses the plaque blockage against the artery wall (Figure 2). The procedure opens the artery and allows better blood flow.

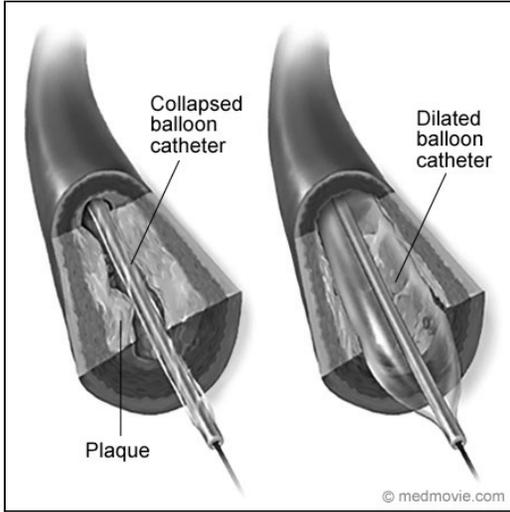


Figure 2

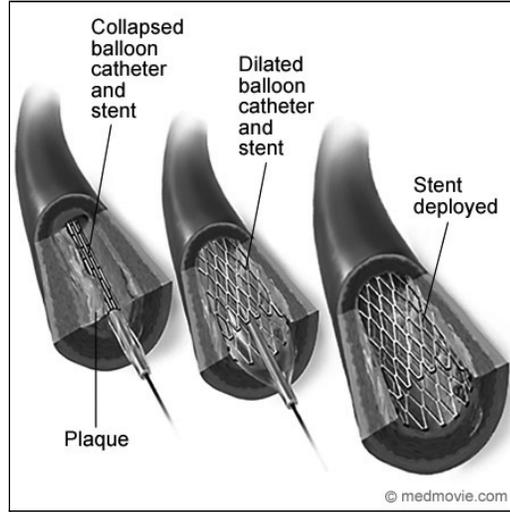
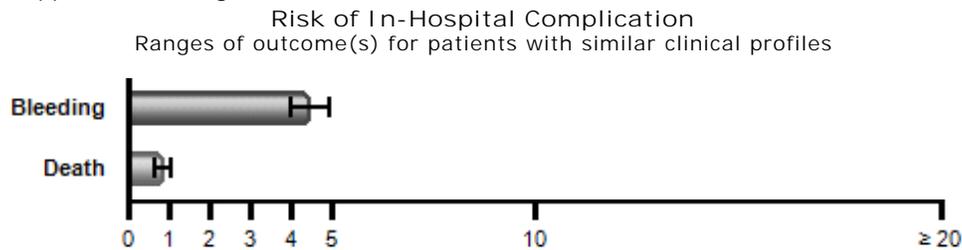


Figure 3

Stent Implant: A catheter is used to deliver a small metal mesh tube (stent) to a blockage in an artery (Figure 3). A stent, which helps keep the artery open, is often implanted after angioplasty.

The doctor has explained the benefits of the procedure(s) to me. I understand there is no guarantee that I will achieve those benefits. I understand that unknown things may happen during this procedure. Because of that, a different procedure may be needed. Therefore, I authorize the doctor, associates, or assistants to perform any procedure(s) needed to best take care of me. I authorize sedation and/or anesthesia to be given to me for my comfort, well-being, and safety. This would be done by:

The doctor has explained to me that there are risks with this procedure. It is possible that unexpected things may happen. These might include, but are not limited to:



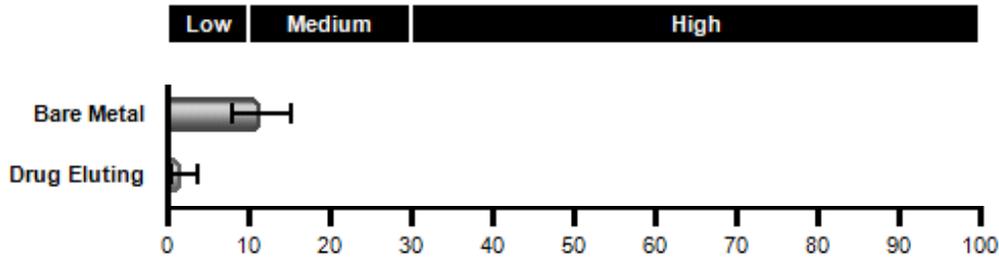
Percent (%) chance.

where Death denotes the risk of death and Bleeding denotes the risk of major bleeding. It is important to understand that your risk of dying in the hospital after the procedure is mostly related to how sick or healthy you are prior to the procedure. Death as a direct result of the procedure is a very rare event.

Patient Identifier Label

Sometimes after opening a blocked artery the artery closes again. This procedure may need to be done again. There are 2 types of stents that can be used to keep arteries open, bare metal stents or drug eluting stents. After either type of stent, patients must take aspirin plus a blood thinner, like Plavix. Patients with drug eluting stents need to take this medicine for longer than patients with a bare metal stent. Patients with a drug eluting stent may need to take the medicine for at least 1 year. This extra medicine can be costly, depending on your insurance. It is important to take the medicine until your doctor tells you to stop. The graphs show your chance for another procedure in the next year if you are treated with a bare metal or a drug eluting stent:

Risk of Blood Vessel Closing within a Year  
Range of outcome(s) at one year for patients with similar clinical profiles



Percent (%) chance of needing a repeat procedure within a year.

where Bare Metal is the risk of the vessel closing within the next year when a bare metal stent is used, and Drug Eluting is the risk of the vessel closing within the next year when a drug eluting stent is used.

*NOTE: These graphs use data from many previously treated patients. It is important to know that your results may differ from these prior patients, even though they had similar medical conditions to you. It is impossible to predict for certain what will happen in your case. This information is not a guarantee of your results.*

I understand that I may need a blood transfusion during the procedure. I know that there are risks with a transfusion. This might be fever, a kidney reaction, hepatitis, Acquired Immune Deficiency Syndrome (A.I.D.S.) or other infections.

Possible alternatives to the procedure have been explained to me. This includes not having this procedure at all. Other alternatives might include, but are not limited to:

If I get a medical device, my Social Security number can be released to the maker of the device. This is because of the Federal Food and Cosmetic Act section 519(e).

Because this facility is an academic hospital, my medical record may be used for scientific purposes. I understand I may be contacted in the future about my recovery from this procedure

I consent to any photographing or videotaping of the procedure(s). The pictures or the words describing the pictures will not reveal my identity. I also consent to students or equipment representatives being in the procedure room. This is for medical education or to get important product information.

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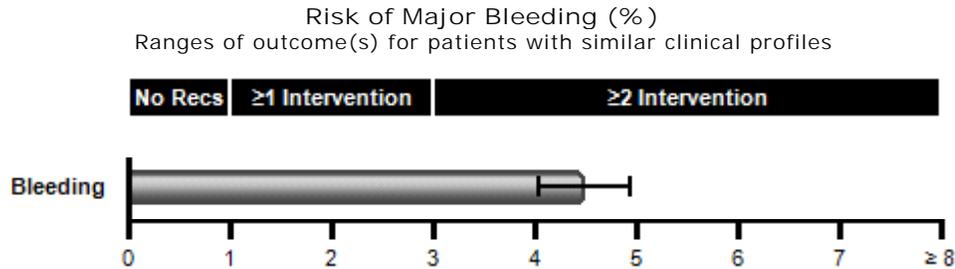
# Saint Luke's Health System

## Patient-Specific Risk Profile for PCI - For Physician Use Only

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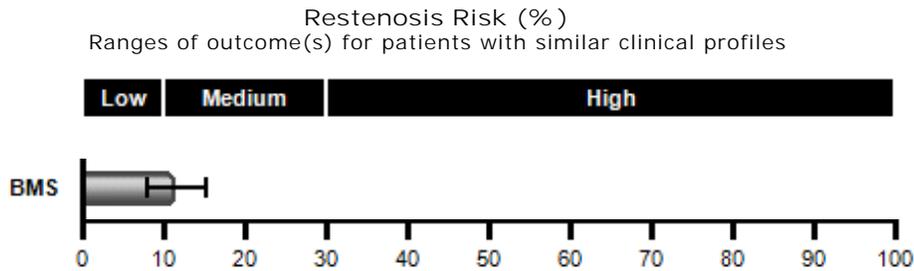
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### Patient-Specific Risk Assessments for PCI



Potential interventions include:

Bleeding avoidance therapies: (1) bivalirudin, (2) closure device, and/or (3) radial case.  
Additional actions: (1) inpatient admission, and/or (2) small sheath sizes.



Consider BMS for low risk patients, and DES for high risk patients.