

Appendix I

Patient information (cf. chapter 4.1)

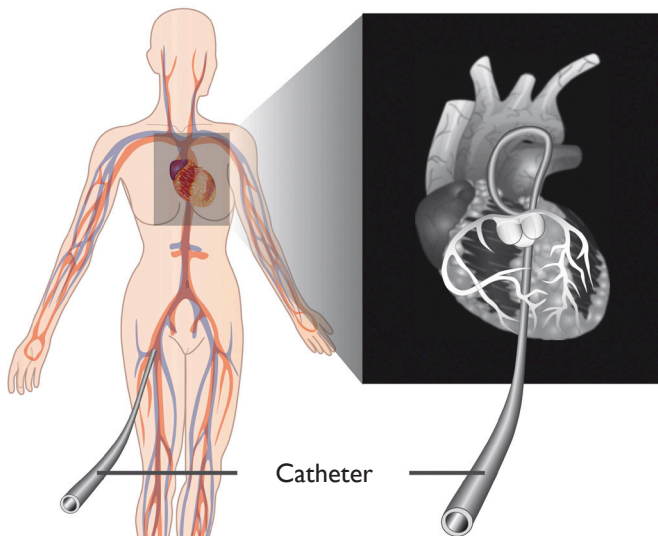
Dear Madam, Dear Sir,

You have been advised to undergo coronary angiography. This examination provides an X-ray image of the coronary arteries, the blood vessels that supply blood to your heart. Coronary angiography reveals the presence of coronary artery disease (CAD), a condition that leads to narrowing or blockage of the coronary arteries. The results of this examination will help your physician to identify the best treatment for you.

Please carefully consider the following information and share your thoughts with your referring physician, your family or close friends. Do not hesitate to ask for further information and explanation if needed. The physician who has proposed that you undergo coronary angiography will certainly provide additional information, as desirable. Keep in mind that after the angiogram, there is no time constraint to make a decision regarding further therapy. This brief commentary is aimed at providing you with the elements necessary to make an informed decision before proceeding to the formal informed consent procedure. Both are necessary to give us the opportunity to provide care for you.

What is significant about coronary artery disease? (CAD)

The coronary arteries represent a tree of vessels providing blood to the heart itself, which is essentially a muscle pumping blood and oxygen through the body. A disease known as “atherosclerosis” affects the wall of the coronary arteries, and their typically smooth inner surfaces become irregular and thickened by a bulky plaque. In certain areas, this may restrict the free flow of blood. A significant reduction in blood supply to the heart causes angina or ischaemic chest pain, while the sudden total interruption of blood to part of the heart can result in a heart attack or myocardial infarction. As it occurs and soon afterwards, infarction implies a risk of dying, or subsequently reduced heart function that may limit physical capacity and shorten survival in the long term.



The diagnosis of CAD by coronary angiography is aimed at selecting a treatment that will reduce the risk of death and infarction, maintaining normal cardiac function and improving quality of life by relieving angina.

Cardiac catheterization and angiography are performed in a sterile catheterisation room. Following local anesthesia of the skin, a long, thin and flexible tube called a catheter is inserted into a blood vessel in the groin or the wrist and it is then advanced as far as the heart. A special dye is injected inside the coronary arteries through a catheter to make them visible on an X-ray. Coronary angioplasty can be performed immediately after diagnostic angiography in some cases.

How is CAD treated?

According to the severity and localisation of CAD in your case, physicians may propose one of three alternatives. These are considered complimentary to the fundamental lifestyle related measures you must undertake yourself, such as adhering to a healthy diet, engaging in regular physical activity and smoking cessation.

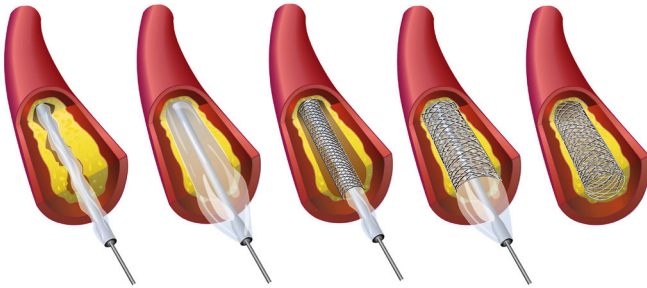
1. Medical treatment

Medical treatment means that you will take medications as prescribed - in many cases for life - to alleviate your heart condition in spite of diseased arteries. There is good evidence that the correct medications provide protection against the occurrence of major cardiac problems (death or heart attack) and will allow you to function according to your general conditions and age, with an acceptable quality of life. Lifestyle changes and medications may be sufficient for long term treatment of your condition although you may have to undergo angioplasty or surgery at a later stage, depending on your response to medications or progression of your condition.

2. Percutaneous Coronary Intervention (PCI) or angioplasty

This procedure is used to widen a narrowed artery or re-open a totally blocked artery. So-called stented angioplasty or stenting is accomplished by inserting a metallic mesh tube called a stent which remains in the coronary artery wall to keep the vessel open. One or more stents may be

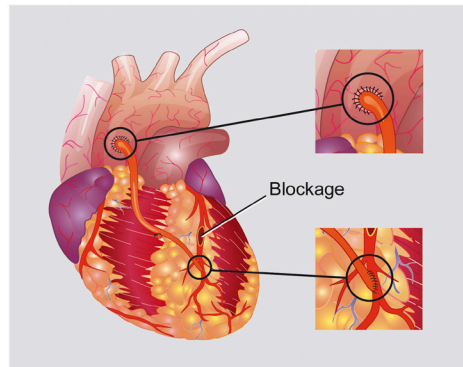
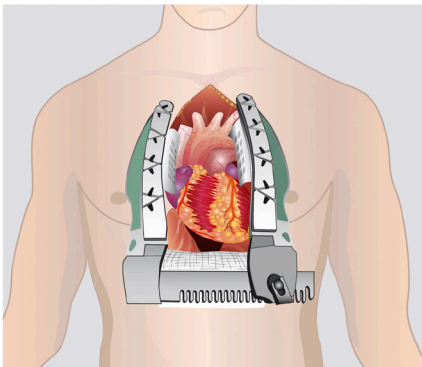
necessary to treat your disease. This intervention takes place through a small, 2-3 mm incision in the groin, the wrist or forearm. Like coronary angiography, angioplasty is usually performed under local anesthesia, and you will remain fully awake or mildly sedated. Angioplasty may take 15 minutes in the simplest case, and up to 2 or 3 hours in complicated cases. After uncomplicated angioplasty, the hospital stay is limited to 24 to 48 hours.



Angioplasty: an expandable balloon catheter is placed at the site of the artery obstruction and inflated, this presses the plaque against the artery wall, and the balloon is then removed. A second balloon catheter carrying a metallic mesh called a stent is inflated at the same site, the stent is deployed against the artery wall and remains there intact, while the balloon is removed.

3. Coronary artery bypass grafting (CABG) or bypass surgery

Bypass surgery is a major operation under general anesthesia which requires the opening of the chest. During the operation, the heart may be stopped and the patient supported with a heart lung machine (cardiopulmonary bypass) to allow the surgeon to perform the bypass(es) operation. Alternatively, the operation can be performed on the beating heart without resorting to a cardiopulmonary bypass.



A coronary artery bypass operation consists of inserting an extra vessel which detours the blocked segment of vessel to restore blood supply to the heart. The best vessels used for bypassing are the mammary arteries from the inner wall of the front of the chest, and surgeons often also use veins from the leg or arteries from the forearm. Altogether a bypass operation takes 3 to 5 hours. After uncomplicated bypass surgery, the hospital stay ranges from 7 to 12 days. Rehabilitation is recommended after 4-6 weeks of recovery to return to normal activities.

Angioplasty: advantages and disadvantages at a glance

The major advantages of angioplasty relate to its less intrusive nature compared to surgery. Angioplasty causes less inconvenience and results in a shorter hospital stay, thereby permitting a more rapid return to normal activities.

The downside of angioplasty is its imperfect ability to maintain a wide open coronary vessel in the long term. Indeed, within the first year after angioplasty and if a stent is used, there is up to 1 in 10 chance that repeat angioplasty will be required since the stent may become partially blocked. Angioplasty can be repeated several times, but requires coronary angiography each time. Furthermore, after stented angioplasty, specific medication is required for one year or more to increase blood fluidity and prevent clot formation. This may interfere with undergoing other operations if needed. This medication is associated with a small increased risk of superficial or internal bleeding.

Generally, angioplasty is more appropriate for less severe cases, repeat angiography and stenting are required in 10% to 20% of cases in the first two years, and it may happen that bypass surgery will be needed later.

Bypass surgery: advantages and disadvantages at a glance

Compared with angioplasty, the major advantage of bypass surgery is its long-lasting efficacy in controlling angina. Bypass surgery may provide longer survival in some specific cases, i.e. patients with very severe coronary artery disease, those with diabetes, kidney failure, or those who have suffered previous heart attacks and have a weakened heart muscle. The risk of dying, suffering from myocardial infarction, stroke or other severe complications during the hospital stay can be reliably estimated and should be clearly explained by the surgeon in your care. Trauma related to the opening of the chest and the healing of other scars remain the most uncomfortable aspects of bypass surgery. Generally, bypass surgery is more appropriate for more severe cases of CAD. The operation is more invasive than angioplasty but offers a single treatment that may solve your problem in the long term. Some bypass grafts may become blocked or close as early as one year after the operation and their ability to remain open varies according to the graft material used. While an arterial graft to the left coronary artery remains open in roughly 90% of the cases after 10 years, 50% of vein grafts may close after 5 years, thereby requiring angioplasty or even, in rare cases, a second operation.

You must understand that a regime of medications is necessary after both angioplasty and bypass surgery, and that maintaining a healthy lifestyle is essential. This will include smoking cessation and participation in specific psycho-physical rehabilitation programs to reduce the risk of further problems in the future.

Lastly, please consider the following.

Your decision should be made after carefully considering all relevant information. Today, while you think about the meaning of life, health and disease, please consider that:

- In medicine, there are options that may prove more appropriate than others, but very often different options can apply to the same case. Absolute and unequivocal indications for medical treatment, angioplasty or bypass surgery are infrequent, but do exist. In that case, your physician may not leave you with many choices.
- Any recommendation proposed by your physician is based entirely on the intention of offering you the best care for your particular case, without consideration of any other interest. Take your time to decide; in your case, treatment is not an emergency.
- Success rates and complication rates are supported by extensive knowledge and experience derived from more than 40 years of research and practice. The options that are proposed to you represent established therapies. Any aspect of your treatment that would be experimental will be explained to you specifically.
- In this hospital both treatment alternatives, angioplasty and surgery, are available on site.
- In this hospital only angioplasty is available on site. Your case and the possibility of surgical treatment, has been discussed with Dr _____ from the _____ hospital with whom you can meet on _____ (days) _____ from _____ to _____ (hours).

Sincerely,

On behalf of your cardiologists.

Contact cardiologist(s) of the institution

Contact cardiac surgeon(s) of the institution

Appendix 2

Schematic diagram of carotid artery showing the different methods for measuring angiographic stenosis severity (cf. chapter 9.4.1)

Method used in NASCET and VA309

$$(1 - N/D) \times 100 = \% \text{ stenosis}$$

eg, $N = 2.5$ - $D = 5.0$

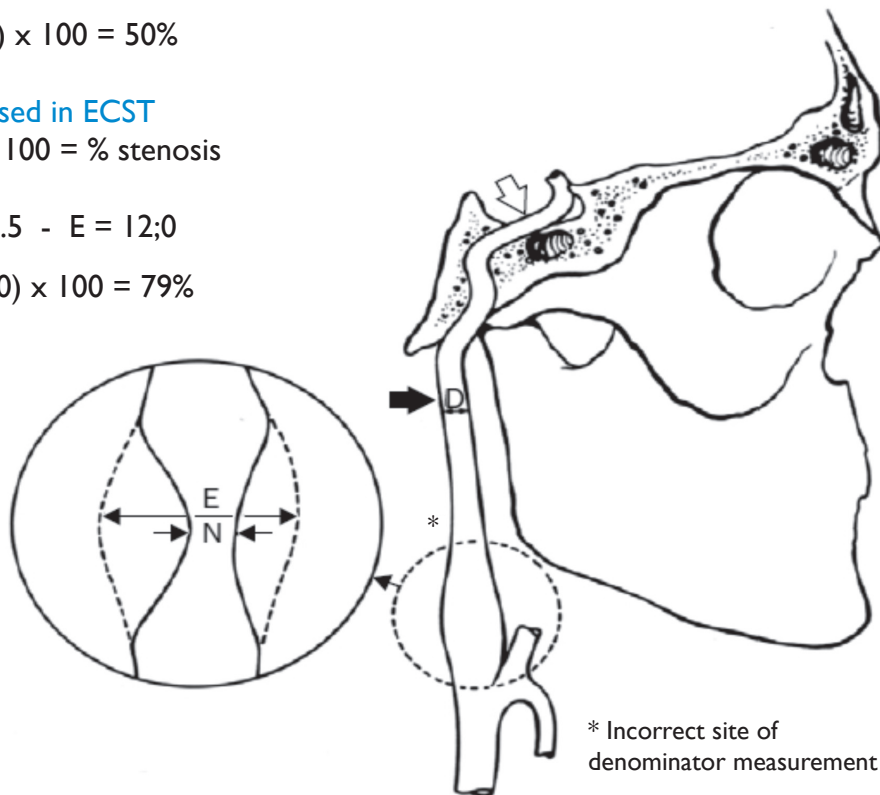
$$(1 - 2.5/5.0) \times 100 = 50\%$$

Method used in ECST

$$(1 - N/E) \times 100 = \% \text{ stenosis}$$

eg, $N = 2.5$ - $E = 12.0$

$$(1 - 2.5/12.0) \times 100 = 79\%$$



Schematic diagram of carotid bifurcation and internal carotid artery, showing methods of measurement of the degree of carotid stenosis on an arterial angiogram.