

# Do heart catheters and the insertion of stents really help?

**Catheterization and stents are sacrosanct, holy and inviolable.** If one speaks ill of a heart patient's stent, he will probably get very angry. The stent saved his life. There is nothing that can shake this belief.

**This would be fine, but unfortunately the story of the balloon catheter and the stent is a sad one.** For those readers who do not suffer from heart disease: the heart catheter displays the coronary arteries on an x-ray screen. Balloon catheters are used to widen stenoses in the arteries: this means that the arteriosclerotic bulges or "plaques" as they are called in medical language, are flattened under high-pressure with the aid of an inflatable balloon. A "stent" is a fine metal mesh tube, inserted in the artery to prevent further stenosis at this point.



Assuming that these stenoses are the crucial culprit in heart complaints and heart attacks, these procedures are logical and meaningful. Many heart attacks could be prevented and the life of many patients would be saved by balloons and stents. If one assumes that serious stenoses in the coronary arteries do not reduce the blood circulation due to collaterals, then it is reasonable to doubt this. Evaluating the results of this type of intervention should clarify this apparent contradiction concerning the significance of coronary artery stenosis.

Balloons and stents are inserted for two reasons. Heart patients suffering from heart complaints when under strain undergo this intervention. These patients are said to have "**chronic stable angina**". Secondly, balloons and stents are inserted when new symptoms occur or existing symptoms acutely worsen. These patients, in whom there is threat of a possible heart attack, are said to be suffering from "**acute unstable angina**".

## Illusion and Reality

**Chronic stable angina:** In 2003, a very good publication from the Mayo Clinic (1), USA, which I have already quoted on the subject of "bypass surgery" (Section 1) stated the following:

- **Balloon and stents are suitable for reducing complaints, i.e. for relieving symptoms.**
- **Balloons and stents do not prevent heart attacks and do not prolong life.**
- **Stents prevent the development of renewed stenoses at the same location in the vessel, but do not reduce the frequency of heart attacks or deaths.**

Since 2003, this picture has hardly altered. When examining scientific studies, occasionally a tendency was recognized that suggests that these interventions not only do **not** help, but have a tendency to cause damage, as it is not rare for the intervention itself to cause a heart attack. This is not surprising, as flattening the plaques in the vessel walls not only regularly leads to bleeding into the vessel wall, but sometimes small lumps become detached and float to the periphery with the blood stream, where they can cause an acute heart attack.

**Acute unstable angina:** When catheterization became really popular in the 90s', heart attacks were redefined. Until then, there had been three criteria for diagnosing a heart attack: typical heart complaints, typical alterations in the ECG and certain blood values. In the new definition the alterations in the ECG were omitted and the indicators in the blood were reduced to a single item. The "NSTEMI" was born. I assure you, I can't pronounce this any better than you! NSTEMI: N = non, STE = ST elevation (a typical sign of heart attack in the ECG), and MI = myocardial infarction (heart attack). This is a heart attack that is not seen on the ECG. It is an acute heart attack in its developing phase, before the ECG shows the destruction of the tissue that takes place in the following minutes or hours.

The diagnosis "NSTEMI" is based on the slight rise in a single substance in the blood called "troponin". This substance is released into the bloodstream during a heart attack, but also after an attack of acute angina pectoris. A rise in troponin levels can have still other causes. Great excitement accompanied by a wave of adrenaline, particularly in conjunction with alcohol, can increase troponin levels in the blood (40). This has nothing to do with a heart attack, but is not unusual in daily life. A heart seizure, which disappears after 10 minutes, leads to a slight rise in troponin levels about 4 hours later. If the patient is taken to a clinic, the emergency doctor will diagnose a "NSTEMI heart attack. "



Taking a closer look, it is insupportable to diagnose a heart attack exclusively on the basis of a rise in the level of this substance. **What lead to this theoretical nonsense?** The diagnosis "NSTEMI" validates and calls for the immediate use of the heart catheter. **The birth of the NSTEMI legitimized the uninhibited use of catheterization.** As a large proportion of the population in industrial countries have arteriosclerotic alterations to the coronary arteries, one nearly always find alterations to the coronary vessels during catheterization, which retrospectively validate the intervention. Occasionally, an acute blockage is discovered, but usually more or less pronounced older stenoses are found in the coronary arteries, or older blockages, with which the patient has already lived for a long time without any complaints and symptom-free. These stenoses are declared to be the cause of an acute "NSTEMI" attack; the vessel is then widened with a balloon and a stent is inserted.

## **On balance, how effective is catheterization in acute heart disease?**

Scientific studies can be structured so as to produce a certain outcome. This is a known fact and is an art in itself. The structure of the study often decides its outcome. The aim of this introduction is to explain why one can rely on certain studies rather than others. British epidemiology or clinical studies have a good reputation and are known for their objectivity. The British study “RITA 2” (41) was therefore an important milestone in the evaluation the use of catheterization in chronic stages of heart disease. “RITA 2” precisely shows the uselessness and potential damage that can be caused by this intervention in chronic heart disease. In “RITA 3” (42), also carried out in Great Britain, the benefits of catheterization at the acute stage were investigated.

Acute stage means “unstable angina” or “NSTEMI”. In “RITA 3” “invasive” interventions were compared with “conservative” or non-invasive interventions. The interventions mainly consisted of a balloon + stent, or occasionally bypass surgery. In the control group the patients were only treated with medication. After one year, the same number of heart attacks and deaths were reported in both groups. **Although catheterization and stents had been claimed to be life-saving measures, they do not prevent heart attacks or save lives.**

After 5 years, however, the results of the interventions were more favorable. In the “RITA 3” study, of 100 patients 3 more survived in the “invasive” group than in the group receiving only drugs (43). When evaluating the therapeutic effect of a treatment, the number of interventions required to save one life per year is calculated. This is always an understandable and illustrative value. The lower the number, the more effective the treatment. This “Number Needed to Treat” (“NNT”) is 165 in this study. In 165 interventions (balloon/stent or bypass) one life was saved per year. That is better than nothing. If one were to tell a patient, however, that his chance of survival is improved by 1:165 per year, then he would probably scratch his head in a thoughtful manner.

**Patients treated with balloons and stents had far fewer heart complaints in the first year.** As with the patients who had undergone bypass surgery, two mechanisms must be taken into consideration. **Firstly, it is not rare for the inflated balloon to injure the vessel wall, and the nerve fibers that surround the vessel and transmit pain are lastingly crushed and numbed. Secondly, this intervention is accompanied by a great placebo effect.**

## **The placebo effect is never mentioned**

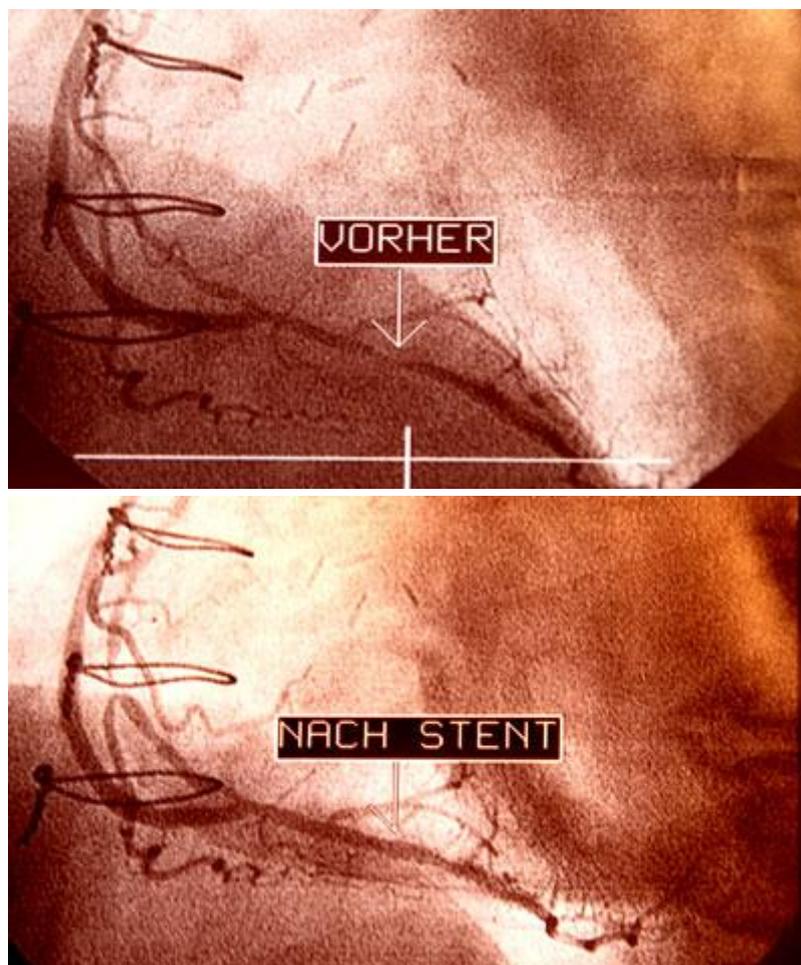
Just imagine that you have had acute heart complaints and in the hospital the heart specialist frees you from a stenosis or a developing thrombosis; in addition, he has widened the narrowing with a balloon and inserted a stent, so that such an attack will not happen again. You would be the happiest person in the world. If the acute pain had also disappeared (what would you know about the interruption of pain transmission due to the numbed nerve?), one can understand just how comforting this intervention is for a patient. The belief that one is now safe disperses all insecurities and fears. This belief can move mountains; it improves the feeling of well-being and can effectively prevent further complaints. One would think that this effect could prolong life.

## **The overall result is shattering**

After “RITA 3”, another large study took place on the same subject. “ICTUS” (44) was carried out in Amsterdam and is an equally respectable study. 1200 patients with acute heart disease were treated either “invasively” or “conservatively”. The survival rate was the same in both groups after 1,3, and 5 years. This means that according to this study, **no lives are saved by balloon catheterization and stent interventions during acute stages of heart disease (“unstable angina” or “NSTEMI”)**. In the group treated with balloons and stents, the rate of heart attacks was even clearly higher. **In up to 10% of the patients in this study, a heart attack was caused by the intervention itself (44)**. Crushing the arterial plaques is not without risk. There is damage, but little substantial benefit.

**Catheterization with a balloon and stent would have long been thrown onto the historical rubbish heap, if it were not for the great sums of money earned by using the procedures.** Industrial interests, cardiologists’ prestige and also basic practical constraints are involved. The more severe the diagnosis and complex the treatment, the more money hospitals receive from health insurance companies. The inflationary increase in the diagnosis “unstable angina” and “NSTEMI” in the past years, which many general practitioners criticise, is understandable in this light. The use of the heart catheter is running at full throttle.

The question put at the beginning of this chapter as to whether the results of balloon and stent interventions can contribute any information on the significance of coronary stenoses can be clearly answered. The results of catheterization and stenting cannot be reconciled with the classical concept of heart attack. This should have consequences. Conclusions should be drawn from these results.



These pictures of catheterization, before and after insertion of a stent, show nicely that the coronary stenosis has disappeared after widening with a balloon and insertion of the stent. But nothing has altered in the circulation due to this intervention. The coronary artery was already well-filled beyond the stenosis before the intervention. The insertion of the stent could not improve on this.