

Cardiology at Concorde

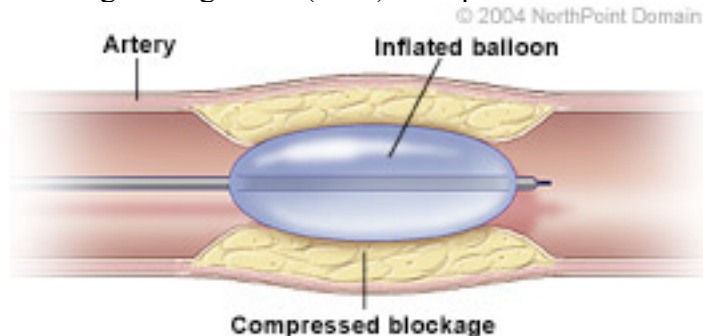
Specializing in Non-Invasive Cardiology



The Stent Debate

In order to understand the current debate about coronary stents, a brief review of the evolution of percutaneous coronary angioplasty (PTCA) would be helpful. Dr. Andreas Gruentzig performed the first balloon angioplasty in 1977 in Zurich, Switzerland. He developed his approach by using techniques that had been developed for other arteries in the body and built the prototype balloons in his kitchen. Emigrating to Emory University in Atlanta, Dr. Gruentzig demonstrated and evolved his technique. Introduced at a time when coronary bypass surgery was frequently used to resolve symptoms from obstructed heart arteries, his procedure was greeted with considerable skepticism.

As balloon and stent technologies evolved, PTCA became more frequently performed than bypass surgery. In 2002, there were 650,000 balloon angioplasties performed in the US compared with 250,000 bypass operations. The rapid growth in the popularity of PTCA is due to several factors. Patients and their cardiologists have been eager to avoid the more invasive procedure of bypass surgery, which involves a chest incision, five or more days of hospitalization and several weeks of convalescence. Also, PTCA is often done at the same time as the diagnostic coronary angiogram and may only involve an overnight stay. In certain patients, bypass surgery is more effective in improving long-term survival and freedom from the need for rehospitalization. When the issue of the relative benefits of bypass surgery vs. angioplasty was evaluated using data from the New York State Registry for the years 1997-2002, bypass surgery was more effective than angioplasty plus bare metal stents in preventing death or rehospitalization. **The current debate** concerns the safety of and the indications for the use of bare metal stents (BMS) vs. drug-eluting stents (DES) to improve the outcomes of patients who have



angioplasties.

(see figure) the balloon is inserted at the site where the coronary artery is narrowest and

During angioplasty

the operator inflates it to its maximum diameter for a minute or so and then deflates it. Dye is injected into the artery to see how much progress has been made and, if necessary, the balloon is inflated again to achieve the smallest amount of narrowing. Often, compared to the caliber of the artery on either side of the blockage, the narrowed area assumes the normal width after the procedure.

As more and more patients were treated with balloon angioplasty alone, a new observation was made. In as many as 25-30% of patients, the artery renarrowed to a significant degree just 6 months after the initial procedure. This re-narrowing or restenosis as it is called, produced recurrent symptoms which required yet another angioplasty. Many subsequent investigations have shown that inflating a balloon inside an artery produces some injury to the lining of the artery. The body responds to this injury by sending inflammatory cells to "heal" the area. Healing is followed by scar tissue formation. These natural responses cause the re-narrowing to take place.

The earliest stents or tiny spring-like devices were deployed on the outside of the balloon and were dilated in place when the balloon was inflated. As the safety of this procedure was established, more bare metal stents (BMS) were used. Nonstandard or "off label" uses included the placement of stents in smaller caliber arteries, over longer lengths and at branch points or "bifurcating" lesions. The use of stents in non-standard situations where the manufacturer and the FDA have not specifically sanctioned them, frames part of the current stent debate. It is important to note that for all patients, the BMS represented a significant advance over PTCA alone, with yearly restenosis rates reduced to about 10-15% annually. For interventional cardiologists, the physicians who perform coronary artery stenting, this restenosis rate remained unacceptably high.

Bare metal stents have been gradually supplanted by drug-eluting stents (DES) as an approach to reducing the restenosis rate further. Drugs that have been used for preventing transplant rejection were thought to be ideal candidates for coating the stents since they prevent the local reaction from occurring. The choice of drugs, which are slowly released from a polymer coating the stent, is presently between sirolimus or paclitaxel depending on whether the DES is manufactured by Johnson and Johnson (sirolimus or Cypher® stents) or Boston Scientific (paclitaxel or Taxus® stents). Both drugs work by delaying the inflammatory response at the stent site, reducing the scarring that would otherwise take place. Early reports of the follow up of patients with DES suggested that the restenosis rate was reduced to 1% in patients receiving them. Interventional cardiologists became enthused about DES and began to use them preferentially in angioplasty patients.

These initially exciting and gratifying results have not been contradicted but rather overshadowed by the problem of "late stent thrombosis" (LST) recently reported in less than one percent of DES patients. Even though late stent occurs in less than 1% of patients, it is accompanied by heart attack or death in a high percentage of cases. In the first 6 months, the formation of clots at the stent site seems to occur more often in patients who have discontinued the double anti-clotting therapy (Aspirin and Plavix®) prescribed for them at the time of DES placement. At later times, and up to 24 months, the frequency of late stent thrombosis seems to occur as frequently in patients who are on or off their blood thinners. Although the incidence of LST is low, the high number of DES placed each year still would produce an unacceptably high number of patients at risk.

Because of concerns over LST, both the FDA and the cardiologists who implant these stents are re-evaluating the indications for DES use in place of the BMS. Stent developers are asking themselves whether smaller doses of the drugs leached off the stents over shorter periods of time can help to reduce the risk of LST. For now, physicians of patients with DES are being asked to think about each patient with a DES in terms of how long the stent has been in place and whether it is safe to discontinue the aspirin and Plavix® for minor dental or surgical procedures especially within the first 6 months after DES implantation. Some cardiologists have concluded that patients may continue aspirin and discontinue Plavix® for short periods. Clinical trials to evaluate stent performance in various kinds of high-risk individuals are being conducted. For instance, the benefit of DES in diabetic patients seems to be much greater when compared with BMS.

If your cardiologist is recommending stent placement, you should have a frank discussion with him or her if you have a prior medical history of gastrointestinal bleeding (ulcer disease, diverticulitis, or bleeding on aspirin type drugs). You should also discuss your plans for elective surgery or dental extractions after stent placement. Another item to consider is the affordability of long term Plavix® therapy. While drug-eluting stents represent the best stent technology available, these issues remain an important part of the current debate.

For more information, see the article on Angioplasty/Stenting in our Patient Learning Center.

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