

Study looks at impact of increasing stent use

Are we doing the right thing? What *are* we doing? Those were the questions guiding a recent study by a group of DHMC cardiologists. Over the past few years, more and more patients with complex heart disease have become candidates for—and are choosing—noninvasive, catheter-based procedures over surgery. But is that a good thing?

Study: Patients “we probably would not have treated” several years ago are now getting such procedures, says cardiologist Craig Thompson, M.D., who led the study. “And frankly,” he adds, “things that even surgeons wouldn’t try to do bypass on, we’re doing fairly routinely these days.”

Catheter-based procedures to treat heart disease involve feeding a flexible tube through an artery in the abdomen or leg, then into the diseased blood vessel on the surface of the heart. The tube, or catheter, functions like a highway, allowing cardiologists to insert tools to clean the vessel and to expand the vessel walls. Then a metal mesh tube, called a stent, is fed through the catheter and placed in the artery to prop it open and help maintain the blood flow. The procedure requires only a small incision, which is why it is considered noninvasive, and it has a much shorter recovery time than open-heart surgery. As stent technology has improved, cardiologists have begun treating patients with ever more severe heart disease.

But “by doing more challenging cases, were we compromising our patient outcomes?” Thompson and his colleagues wondered. The answer, according to their study, seems to be no. DHMC cardiologists have maintained a success rate of about 95%. “Despite increasing complexity,” says Thompson, “we were still holding our own as far as technically being able to do it without causing additional harm.”

Changes: A second aim of the study, explains Thompson, “was to get a sense of what are some of the technical changes in what we’re doing? Are the stents longer? Are they

larger? Do we use more stents per case?”

To attempt to answer these questions, the researchers looked at two groups of patients—of about 1,000 each—who received stents at DHMC. One group got stents between May 2002 and April 2003, and the other between May 2003 and April 2004. The two time periods, though consecutive, differ considerably because of a breakthrough in stent technology. During the first period, DHMC cardiologists were using primarily bare-metal stents. During the second period, they began using drug-eluting stents (DESs), which slowly release medicine that is intended to prevent the formation of abnormal scar tissue and the re-narrowing of the arteries. By the end of the second period, 84% of the procedures were done with DESs. Thompson and his colleagues looked at the data from both periods to see how DESs affected practice patterns and outcomes.

Future: “The DES era has been characterized by longer, more complex procedures involving an increased number of lesions and vessels treated, a longer average stent length, and a [longer] total stent length per patient, despite a similar number of angiographically defined disease vessels,” wrote Thompson and his colleagues in the *American Journal of Cardiology*. These findings are important for the future of stent technology and design.

“There are different device manufacturers, for instance, who would be interested in knowing this” information, says Thompson, whose research was not funded by device manufacturers. His study, which appeared in the journal’s September issue, relied on data from the large catheterization database at DHMC. Since 1993, every patient treated in the catheterization lab—the clinical area where catheter-based procedures are performed—has been entered into a database, which logs demographic information and the medical histories of patients, as well as technical details about the catheterization procedure they received. Roughly 30,000 patients



Craig Thompson doesn't just do stent procedures, he also evaluates how they're done, whether they're done for the right reasons, and what their outcomes are.

have been treated in the DHMC catheterization lab since 1993, making the database “pretty powerful,” says Thompson. “By most standards, we’re one of the highest-volume centers in the country.” The database is primarily used for “internal quality assurance,” he says, but it’s also a great research tool.

Two more studies using the database are due out in early 2006. One looks at DES outcomes in women compared with men. “We’re trying to tease out why women don’t tend to do as well,” says Thompson, “and specifically which women” do not do well. Cardiology studies usually include a “disproportionately low number of women,” he explains, “and occasionally there are gender-specific issues.” The third study focuses on outcomes in patients over 75, who are typically excluded from randomized trials—the studies on which FDA approval of devices is based.

Next, Thompson plans to evaluate the two different brands of DESs now on the market. “What is the relative value of one stent versus the other when it comes to real, live, very complicated patients?” Thompson and his colleagues wonder. “That’s where we’re going with this,” he says. JENNIFER DURGIN