VERBATIM

'It's arrogance. Just because they may be the best cardiologist in the world, for example, they think that makes them a star at investing in bonds, in real estate, or in anything.'

Dr. Robert M. Doroghazi, on financial planning for physicians, p. 82

For Restenosis, Sirolimus Stent Beats Brachytherapy

BY MITCHEL L. ZOLER
Philadelphia Bureau

DALLAS — Treatment of coronary artery in-stent restenosis with sirolimus-eluting stents cut the rate of target-vessel failure by more than 40%, compared with brachytherapy, in a study with 384 patients.

As of now, brachytherapy is the only treatment approved by the Food and Drug Administration for treating in-stent restenosis, Dr. David R. Holmes Jr. said at the annual scientific sessions of the American Heart Association. But in practice, brachytherapy has been largely abandoned, whereas drug-eluting stents have become widely used for many coronary-stenting applications.

At 9 months after treatment, the rate of the study's primary end point—target-vessel failure defined as death, myocardial infarction, or the need for target-vessel revascularization—was 12% in 259 patients who received a sirolimus-eluting stent, compared with 22% in 125 patients treated with brachytherapy, a statistically significant difference, reported Dr. Holmes, professor of medicine at the Mayo Medical School in Rochester, Minn.

The study was sponsored by Cordis Corp., a division of Johnson & Johnson,

The target-vessel failure rate was 12% with a sirolimus-eluting stent and 22% in patients who had brachytherapy.

DR. HOLMES

which markets the sirolimus-eluting coronary stent (Cypher). Dr. Holmes has not reported any financial relationship with Cordis or Johnson & Johnson.

The study enrolled patients during February 2003–July 2004 at 26 centers in the United States. The patients had in-stent restenosis in a native coronary artery that was 15-40 mm long and 2.5-3.5 mm in diameter. They were randomized in a 2:1 fashion, with more patients treated with sirolimus-eluting stents.

Several secondary end points were also measured. The rate of binary angiographic restenosis at 6 months after treatment was 20% in the sirolimus-eluting stent group and 30% in the brachytherapy group; the difference just missed statistical significance.

Other secondary measures that were significantly different between the two study groups included the rate of target-lesion revascularization after 9 months (9% with the sirolimus-eluting stent compared with 19% with brachytherapy), and the rate of target-vessel revascularization (11% in the sirolimus-eluting stent group compared with 22% in the brachytherapy group). The average diameter stenosis in the analysis segment of the treated coronary artery 6 months after treatment was 32% in the sirolimus-eluting stent group and 41% in the brachytherapy group.

The advantages of the sirolimus-eluting stent over brachytherapy were seen regardless of whether patients had diabetes and regardless of gender. The benefit from the sirolimus-eluting stent compared with brachytherapy was greatest in medium-sized coronary arteries, compared with smaller benefits when the arteries were narrower or wider. ■