Drug-eluting stents found safe, superior to bare metal stents

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Drug-eluting stents were safe and superior to bare metal stents in preventing death and heart attacks among 262,700 "real-world" patients enrolled in a nationwide registry of cardiovascular disease, according to researchers from Duke University Medical Center.

The findings were presented today at the i2Summit at the American College of Cardiology's 58th Annual Scientific Session. They also appear online in the Journal of the American College of Cardiology.

The study is the largest of its kind to date and may end years of controversy over the safety of the devices.

"We hope these findings will finally lay to rest any doubt about the safety of drug-eluting stents," says Pamela Douglas, M.D., a cardiologist and member of the Duke Heart Center at Duke University Medical Center and the lead author of the study. "Our results clearly show that drug-eluting stents are indeed safe."

Stents are small tubes that can prop open blocked coronary arteries. The earliest versions were made of bare metal mesh, but later models were designed to release a medication that could suppress restenosis, or the growth of new tissue that could cause the artery to clog up again. Physicians have been debating their relative merit for years.

After initially proving more effective than bare metal stents in preventing restenosis, drug-eluting stents suffered a setback when recent

clinical trials found them associated with higher long-term death rates. Those findings led to warnings from the Food and Drug Administration and confusion over which option is better.

Douglas and colleagues followed patients over age 65 enrolled in the National Cardiovascular Data Registry who had received stents from 2004 through 2006. Most of the patients had received a drug-eluting stent; only 17 percent were implanted with the bare metal variety. Investigators matched the patients' data with their Medicare claims and followed them for two and one-half years, measuring rates of death, heart attack, stroke, bleeding and the need for additional artery-opening procedures.

They found that over the 30-month period, patients in the drug-eluting stent group had a 25 percent reduction in death and 24 percent reduction in heart attacks, when compared with those who received bare metal stents, but no significant difference in the incidence of stroke, major bleeding or need for additional artery-opening procedures.

Douglas says the study is important on several fronts. "First, the data show that over a two and one-half year follow up, drug-eluting stents are safe among patients in a real-world, highly variable environment. Patients who enroll in clinical trials are generally younger, healthier and on fewer medications that the population at large, and that means that clinical trials can generate findings that may not hold up in larger, more variable, community populations," says Douglas.

"In addition, we believe this is the first time that anyone has been able to link so much clinical data with Medicare claims. What that essentially has given us is an excellent model for future post-marketing evaluation," says Douglas, who adds that such studies may be particularly attractive to payers, health care policy makers and anyone interested in health care reform who needs real-world data, as opposed to that generated by

clinical trials.

Source: Duke University Medical Center