Newer Drug-Eluting Stent as Effective as Old

VITALS

Major Finding: At 9 months, the rate of MACE was 4.9% in the 1,390 Xience-treated patients and 5.2% in 1,384 Cypher-treated patients in ISAR-TEST 4. At 2 years, target lesion revascularization was 16% with Xience and 18.8% with Cypher in SORT OUT 4.

Data Source: Two prospective, randomized industry-independent studies conducted in Europe: ISAR-TEST 4 and SORT OUT 4.

Disclosures: Dr. Jensen reported that she has a financial interest/arrangement or affiliation with Cordis, Johnson & Johnson, and Abbott. Dr. Byrne reported that he had no relevant disclosures.

BY CHRISTINE KILGORE

FROM TRANSCATHETER CARDIOVASCULAR THERAPEUTICS 2010

WASHINGTON – Two European head-to-head comparisons of the second-generation everolimus-eluting stent with the first-generation sirolimus-eluting stent have failed to detect any significant clinical differences between the two stents in patients with coronary artery disease, investigators reported.

"The sirolimus-eluting stent demonstrated the least amount of late lumen loss among previously released first-generation drug-eluting stents, but its efficacy and safety have not [previously] been compared head-to-head with the second-generation everolimus-eluting stent," Dr. Lisette Okkels Jensen said in describing the rationale for her team's SORT OUT IV trial.

Nine-month data from this prospective randomized study, which involved patients in a population-based health care setting and was powered to detect noninferiority, show that the everolimus-eluting Xience V stent (Abbott Vascular) was noninferior to the sirolimus-eluting Cypher Select Plus stent (Cordis) when it came to the primary end point of major adverse cardiac events (MACE) – a composite of cardiac death, myocardial infarction, definite stent thrombosis, and target vessel revascularization.

The rate of MACE was 4.9% in the 1,390 Xience-treated patients and 5.2% in the 1,384 Cypher-treated patients, reported Dr. Jensen of Odense (Denmark) University.

Approximately 55% of the patients in each arm had stable angina, and almost 33% in each arm had NSTEMI/unstable angina. In most of the remaining patients, STEMI drove the need for percutaneous coronary intervention.

The other head-to-head drug-eluting stent comparison was part of the larger randomized, two-center ISAR-TEST 4 trial designed to compare a biodegradable polymer DES with permanent polymer stents. Within the permanent polymer arm of 1,304 subjects, patients were randomized 1:1 to receive either the Xience or Cypher stent.

At 2 years – a longer follow-up period than in SORT OUT I – there were no significant differences in the combined primary end point of cardiac death, target-vessel–related myocardial infarction, and target lesion revascularization (16% in Xience-treated patients and 18.8% in Cypher-treated patients), reported Dr. Robert A. Byrne of Deutsches Herzzentrum in Munich.

The rates of definite or probable stent thrombosis at 2 years – the secondary, safety end point of the study – were also similar (1.4% in those who received the everolimus-eluting stent and 1.9% in patients treated with the sirolimus-eluting stent).

There was a trend toward superior antirestenotic efficacy with the Xience stent, but "specifically powered studies are needed to evaluate the clinical significance of this finding," said Dr. Byrne. (Target lesion revascularization occurred in 9.9% of Xience-treated patients and 13.5% of the Cypher-treated patients.)

The Cypher Select Plus sirolimus-eluting stent that was used in the SORT OUT IV trial is a version of the Cypher stent that is not commercially available in the United States. U.S. physicians who discussed the trial said they have no reason to believe results would be different with other Cypher stent products. ■