BASE-ACS: Could a bare-metal stent be "noninferior" to a leading DES?

MAY 17, 2011 | Shelley Wood

Paris, France – Few people remember the last time a bare-metal stent made waves at an interventional cardiology meeting, but a new twist on an old standard is at least causing ripples here at EuroPCR 2011. BASE-ACS, presented by **Dr Pasi Karjalainen** (Heart Center, Satakunta Hospital, Pori, Finland) here during the late-breaking clinical-trials session, showed the **Titan-2 BAS** (Hexacath) bare-metal stent to have nearly identical rates of major adverse cardiovascular events (MACE) as the market-leading **Xience V** (Abbott Vascular) at 12 months, in ACS patients.

"The present study suggests that a stent coated with titanium nitride-oxide represents a safe and effective alternative to Xience V everolimus-eluting stents in ACS patients," Karjalainen concluded.

The Titan-2 BAS uses a stainless-steel platform with no polymer and no drug coating but instead is coated with titanium nitride-oxide. In a morning press conference, Karjalainen explained that previous studies have shown that this particular combination of elements inhibits platelet aggregation and promotes vascular healing.

The study randomized 827 ACS patients 1:1 to either the Titan-2 or the Xience V at sites in Finland, Belgium, Spain, Switzerland, the UK, and Indonesia. Just under half of the ACS patients in both arms were non-STEMI patients, and 38% in both arms were STEMI patients; on average, 1.2 lesions were treated per patient. Dual antiplatelet therapy was recommended for six months in both groups and ultimately used for nine months in the Titan-2 group and 10.5 months in the Xience V group.

At 12 months, MACE were similar between groups, at 9.6% for Titan-2 and 9.0% for Xience, a difference that easily met the predefined criteria for noninferiority. When individual components were evaluated separately, rates of MI were actually significantly different between the groups, favoring Titan-2 at 2.2% vs Xience V at 5.9%, although Karjalainen emphasized that the trial was not powered to detect differences between secondary end points. Rates of stent thrombosis were low in both groups.

Dr Laura Mauri (Brigham and Women's Hospital, Boston, MA), who discussed the trial after its presentation today, pointed out that drug-eluting stents (DES) were originally optimized to prevent restenosis in the setting of more stable coronary disease but that new stent features are worth exploring to more specifically target the presence of thrombus in the setting of ACS. As with some of the first small trials looking at DES in ACS that were subsequently followed by larger trials, like HORIZONS, Mauri said it will be important to look to larger trials to be more definitive about the promising results in the BASE-ACS trial.

Dr William Wijns (Cardiovascular Center Aalst, Belgium), who moderated the morning press conference, spoke more frankly about the novelty of seeing a bare-metal stent perform so well but agreed that larger and longer-term trials are needed.

"This is definitely going to shake the tree," he said. "The device obviously may have an advantage in terms of risk of early stent thrombosis because of its low propensity for thrombus formation, but of course in the past there have been studies showing that the rates of reintervention and restenosis might be a bit higher [with bare-metal stents] than we have seen in stents like Xience V."

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