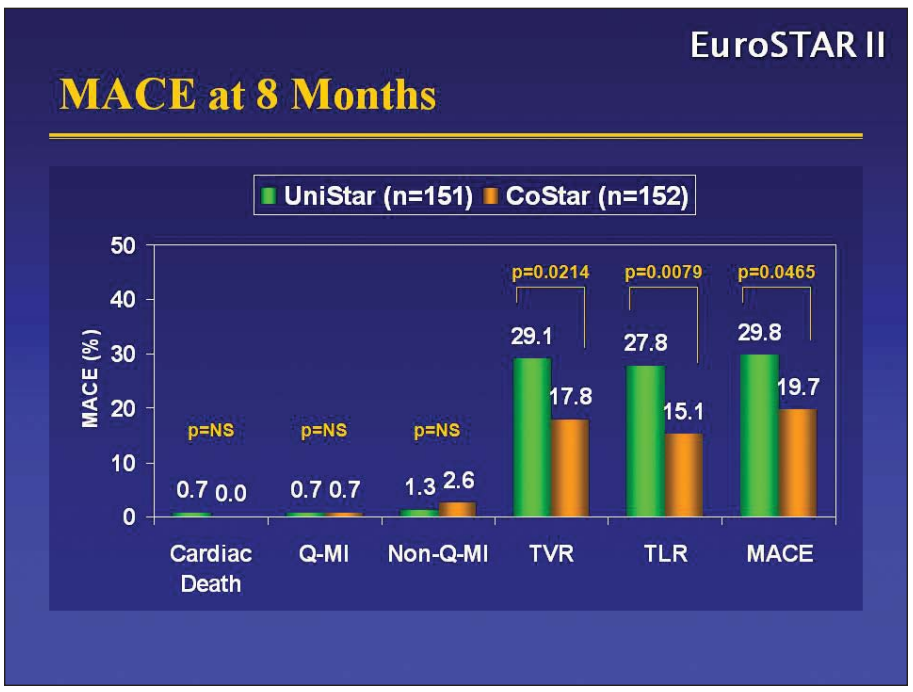
CoStar Reduces Binary In-segment Restenosis Rate

EuroSTAR II: Lower rates of restenosis and late loss with CoStar vs. bare-metal stent

LATE BREAKING TRIAL

The CoStar stent showed a significantly lower rate of binary restenosis and late loss than the identical bare-metal UniStar stent, according to results from the EuroSTAR II trial.

The CoStar stent met the trial's primary endpoint of lower in-segment restenosis at 8 months compared with UniStar (17.6% vs. 30.3%, $P = .033$). Both stents are manufactured by Conor Medsystems.



Eight-month follow-up also showed a significant reduction in in-stent and in-segment late loss. The UniStar stent was associated with approximately 0.81-mm in-stent late loss and 0.64-mm in-segment late loss vs. CoStar, which demonstrated an in-stent late loss of approximately 0.41 mm ($P < .0001$) and an in-segment late loss of approximately 0.29 mm ($P < .0001$).

"With comparable vessel size and comparable lesion length to the TAXUS-IV trial, in-stent late loss of the CoStar stent in the EuroSTAR II trial was in the range of the Taxus stent," said **Sigmund Silber, MD,** of the Cardiology Practice and Hospital in Munich, Germany.

At 8-month follow-up, the CoStar stent was also associated with decreased rates of TVR, TLR, and major adverse cardiac events (Figure). CoStar showed no subacute or late-stent thrombosis. UniStar was associated with 0.7% rate of subacute stent thrombosis.

Comparing CoStar with nonpolymer stents

The objective of EuroSTAR II was to compare, via a prospective, randomized, multicenter study, a bare-metal stent with no drug or

Sigmund Silber, MD

polymer with the CoStar coronary stent system, which uses a biodegradable PLGA polymer and a 10-µg dose of paclitaxel eluted over 30 days. The 2 stents were tested in 303 patients at 18 centers.

Lesions were ⩽ 25 mm in length and 2.5 mm to 3.5 mm in diameter.

Key inclusion criteria up to 2 discrete de-novo lesions in 2 native coronary arteries, stenosis between 50% and 99% and TIMI grade I or higher flow.

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ENDEAVOR IV: No Difference in TVF Between Endeavor And Taxus

Endeavor stent also had a similar mortality and repeat procedure rate compared with Taxus.

Late-breaking results from the ENDEAVOR IV trial showed a similar overall clinical efficacy with equivalent rates of mortality, MI and repeat procedures between the Endeavor zotarolimus-eluting stent and the Taxus paclitaxel-eluting stent.

In addition, Endeavor (Medtronic) showed a lower rate of non-Q-wave MI at 30 days, but a higher rate of angiographic late loss at eight months compared with Taxus (Boston Scientific).


Martin Leon, MD

At nine months, TVF was 6.6% with Endeavor and 7.2% with Taxus, which was statistically significant for noninferiority, meeting the study's primary endpoint. At 12 months, TVF with Endeavor was still noninferior to that of Taxus (see Figure 1 on page 34).

Treatment with Endeavor was associated with a lower rate of MI at 30 days (0.8% vs. 2.3%) driven by a significant reduction in non-Q-wave MI (0.5% vs. 2.2%). This reduction contributed to a significant difference in major adverse cardiac events at 30 days (1.2% vs. 3%), but there was no significant difference in death, stent thrombosis, TLR and TVR.

By nine months, the differences in death and MI were not statistically significant, with similar findings at 12 months.

However, in the cohort of patients

*(**ENDEAVOR IV,** continued on page 34)*

SPIRIT III at 1 Year: Xience V Noninferior to Taxus

Patients with the second-generation drug-eluting stent had fewer periprocedural MIs and fewer TLR procedures, at 6 to 12 months.

With 1-year follow-up in the multicenter randomized SPIRIT III trial, the Xience V everolimus-eluting stent demonstrated noninferior rates of target vessel failure compared with the Taxus paclitaxel-eluting stent, and patients with the Xience V stent had fewer TLR procedures than those with the Taxus stent at 6 to 12 months.

Gregg W. Stone, MD, who presented the 1-year results of SPIRIT III, said the rates of death, MI, and stent thrombosis in the trial were not significantly different between the Xience V (Abbott Laboratories) and Taxus (Boston Scientific) stents.

Larger studies will be required to determine whether there are significant differences between the two devices in low-frequency safety events and in certain subgroups of interest, such as diabetic patients, said Stone, chairman of the Cardiovascular Research Foundation.

*(**SPIRIT III,** continued on page 33)*

Tribute Paid to Andreas Gruentzig

In the midst of late-breaking trials and live sessions, attendees took time to remember a defining moment in interventional cardiology:

30 YEARS OF ANGIOPLASTY

when the late **Andreas Gruentzig, MD,** performed the first coronary angioplasty on Dolf Bachmann on September 16, 1977.

*(**Tribute,** continued on page 31)*