would say that apart from the fact that the sirolimus is further along the process of regulatory approval, I think paclitaxel with a polymer seems to be an encouraging approach. I think paclitaxel without a polymer as we saw in the Cook approach may be less clear."

The big question, says Chronos, is how these stents will fare in a head-to-head comparison. "An even bigger question for subsequent trials will be, if 1 drug-eluting stent gets approved, are we now going to change the way we're doing clinical trials? Instead of having a bare metal stent as a comparator, maybe it will be the Cypher stent against everything else."

Faxon anticipates that manufacturers will not be enthusiastic about a head-to-head comparison of the sirolimus and paclitaxel stents and that, assuming both stents are approved, data on superiority may ultimately come from registry information. The more pressing issue, Faxon says, is the economics of the new devices.

"If you said to me, you can use drug-eluting stents and it will cost not a penny more than a bare stent, I would venture that everyone would put them in for everything. The concern in the US is that the reimbursement rates being quoted are only a modest increase over the stents we currently buy, which means that hospitals would have to make up the difference, and they're not going to do that for a long period of time, or for many patients."

Hospital limits, he says, will force operators to be restrictive until the price comes down, something he believes will happen when more than 1 drug-eluting stent is on the market. Last month, the FDA's **Circulatory Systems Device Panel** voted to recommend approval of the Cypher stent for the treatment of de novo lesions.

-SW

The ongoing TAXUS trials

Dr Stephen G Ellis

Dr Stephen G Ellis (Cleveland Clinic) showed preliminary 30-day results from the 1326 patients in the TAXUS IV-SR (slow-release) trial. The study is examining the EXPRESS™ stent coated with 1 μg/mm^2 of paclitaxel for the treatment of de novo lesions. The data has not yet been unblinded, so Ellis showed only that MACE rates at 30 days were 0 in both groups, which, he said, "was reassuring with regard to safety." Nine-month results will be available by the summer of 2003, Ellis stated.

One-year results from TAXUS I, which randomized patients with de novo lesions to either a bare stent or a slow- or fast-release paclitaxel-coated NIR Conformer stent were presented by **Dr Sigmund Silber** (Cardiology Assoc, Gruenwald, Germany). Silber reported that the binary restenosis rate using the slow-release formula stent at 6 months was 0%, "just as lucky as the **RAVEL** investigators," compared with 10% in the control patients, although the numbers were not statistically different. One-year MACE was 10% in the control group and 3% in the coated-stent group.

Dr Sigmund Silber

Related links

1. Sirolimus-eluting stent recommended for approval by unanimous vote [*HeartWire* > *News*; Oct 23, 2002]
2. After SIRIUS and TAXUS II: Waiting for approval [*HeartWire* > *IndustryPulse*; Oct 4, 2002]
3. TAXUS II: 6-month data show significant benefits of paclitaxel-eluting stents [*HeartWire* > *News*; Sep 27, 2002]
4. SIRIUS final results show 3.2% in-stent, 8.9% in-segment restenosis rates with sirolimus-eluting stents [*HeartWire* > *News*; Sep 24, 2002]
5. High cost preventing extensive use of sirolimus stent in Europe [*HeartWire* > *News*; Sep 10, 2002]

Shelley Wood
shelley@conceptis.com