In a discussion following the presentation of the E-SIRIUS data, **Dr Sigmund Silber** (University of Munich, Germany) addressed the small sample size of the E-SIRIUS subanalysis, a limitation in interpreting the results. The lack of randomization in the study arms, said Silber, may also contribute to the favorable outcomes seen in patients who were stented without predilatation.

> ***"I'm not really interested in reducing in-stent MLD or late lumen loss. What I want is to improve the patient's outcome."***

"One of the most important parameters in the success of direct stenting is the degree of calcification in the lesions," said Silber. Based on operator bias, Silber said patients with less calcified coronary lesions might be more likely to be treated by direct stenting in nonrandomized trials.

However, the largest difficulty with the study is the primary end point, said Silber, noting the primary end point of the study was luminal diameter. Secondary end points, including MACE, were insufficiently powered to detect significant differences between the sirolimus-eluting stent and control groups.

"What is our goal?" asked Silber rhetorically. "If we are physicians, it is to treat the patient and our goal is not to improve angiographic parameters. I'm going to be a little provocative and tell you I'm not really interested in reducing restenosis. I'm not really interested in reducing in-stent MLD or late lumen loss. What I want is to improve the patient's outcome."

New SIRIUS: Combined data from European and Canadian sirolimus-eluting stent studies

In addition to presenting 12-month data of the European arm of the SIRIUS study, Schofer also presented pooled data from the European and Canadian study arms involving the Cypher sirolimus-eluting stent. According to Schofer, the results of the analysis—dubbed **New SIRIUS**—should alleviate concerns of possible in-stent restenosis at the proximal margin found in earlier studies with Cypher stent.

"Analysis of the old SIRIUS data revealed a lack of suppression of neointimal hyperplasia at the proximal stent margin," said Schofer. "This lack of efficacy stimulated debate about whether this was device-specific or the result of suboptimal stenting implantation techniques."

While noting the rate of in-stent restenosis was slightly lower in the new SIRIUS study compared with the original US-based SIRIUS trial, the major difference between the two was the rate of in-stent restenosis at the margins.

"When we compare the rate of in-stent restenosis of the proximal stent margins of old SIRIUS with new SIRIUS, the results turn out be statistically significant," said Schofer. "This device effectively suppresses neointimal hyperplasia not only within the stent but also at the proximal and distal stent margins."

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