In the E-SIRIUS trial, direct stenting was performed in a nonrandomized fashion in 26% of patients. As a consequence of the operator selection, lesions treated with direct stenting had a significantly lower preprocedural diameter stenosis than predilated lesions. Direct stenting appears to be as safe and as effective as predilatation plus stenting. In patients who underwent direct stenting of an SES, late loss tended to be lower. There were no cases of restenosis (0%) at the proximal or distal edge in SES patients who underwent direct stenting, a finding that was in contrast to that of SES patients who underwent deployment after predilatation or bare metal stents.

Discussant: Sigmund Silber, MD, University of Munich (Munich, Germany)

Dr. Silber commented that this subgroup analysis from the E-SIRIUS study is very interesting, particularly when taking into consideration the results from the TAXUS II trial. In TAXUS II, only 23 patients underwent direct stenting with the polymer-based paclitaxel-eluting (*TAXUS*, Boston Scientific, Natick, Massachusetts) stent and 26 with the bare metal stent, while 234 underwent predilatation of the *TAXUS* stent and 242 underwent predilatation of the bare metal stent. Restenosis was 0% in the direct stenting group compared with 1.3% in the *TAXUS* predilatation group.

There is no doubt that the small number of patients is a serious limitation and that we have to be cautious in our conclusions. According to Dr. Silber, the most important limitation is the lack of randomization and retrospective analysis. The most important parameter for success is the degree of calcification of the lesion, and since the decision for direct stenting or predilatation was left to the operator's discretion, there might have been a bias toward more severe calcification in the predilatation group.

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E-SIRIUS: Sirolimus-Eluting Stent in Long Lesions -- Direct Stenting vs Predilatation

Disclosures

Luis Gruberg, MD

Presenter: Joachim Schofer, MD, Center for Cardiology and Vascular Interventions (Hamburg, Germany)

The European Sirolimus-Eluting Stent in De Novo Native Coronary Lesions (E-SIRIUS) trial was a double-blind, randomized trial that compared the *Cypher* sirolimus-eluting stent (SES; Cordis Corporation; Miami, Florida) stent with the bare metal *BX Velocity* stent (Cordis, Johnson and Johnson) in patients with single, de novo coronary artery lesions. In this study, direct stenting (without predilatation) was permitted, according to the discretion of the operator, in centers where direct stenting is a standard current practice. The current analysis compared direct stenting vs predilatation and included comparisons between 4 study groups (Figure 1):

1. SES: direct stenting (n = 45)
2. SES: predilatation (n = 130)
3. Control: direct stenting (n = 47)
4. Control: predilatation (n = 130)

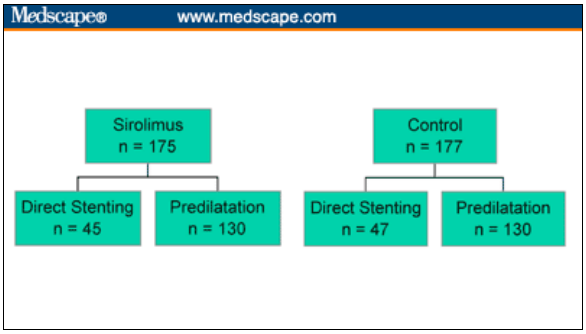

Figure 1. E-SIRIUS: study design.

Results

There were no differences among the 4 groups of patients with respect to the number of diseased vessels, vessel location, lesion length, or lesion morphology. The baseline clinical characteristics of SES patients, classified into direct or predilatation treatment groups, are shown in the following Table.

Table. E-SIRIUS: Baseline Clinical Characteristics of SES-Treated Patients

	Direct (n = 45)	Predilatation (n = 130)
Age (yrs)	61	69
Male gender (%)	76	69
Diabetes (%)	16	20
Hypertension (%)	58	65
Hyperlipidemia (%)	78	76
Smoking (%)	40	35
Prior revascularization (%)*	33	15
Prior MI (%)	36	43

*P = .009

Device success was achieved in all patients and procedural success in 98% of patients in all groups. Lesions treated with direct stenting had a significantly lower preprocedural stenosis than predilated lesions. There were 2 cases of stent thrombosis in the sirolimus arm, 1 in the direct and 1 in the predilatation arm. The minimum lumen diameter was larger in the direct stenting group compared with the predilatation group, and consistently larger in vessels treated with the SES compared with control, regardless of treatment strategy (Figures 2 and 3).

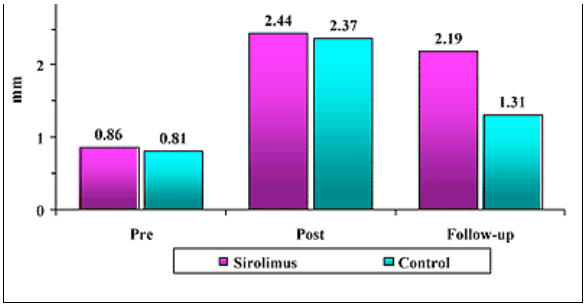

Figure 2. E-SIRIUS: minimum lumen diameter - predilatation.

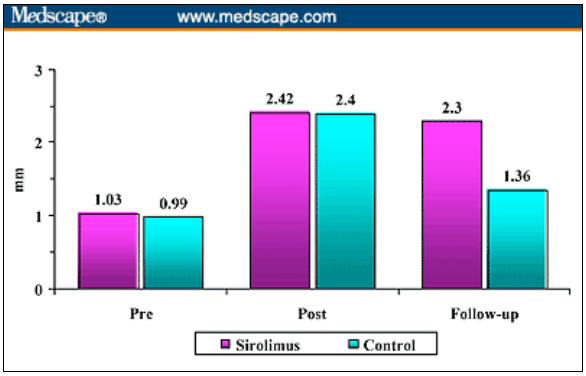

Figure 3. E-SIRIUS: minimum lumen diameter -- direct stenting.

In patients who underwent balloon predilatation, patients treated with an SES showed less of a difference in late loss compared with the bare metal stent group (0.23 mm vs 1.05 mm). The same finding was noted in patients who underwent direct stenting; SES patients also had less of a difference in late lumen loss compared with control patients (0.73 mm vs 1.04 mm, respectively).

Therefore, predilatation did not affect late loss rates in the bare stent arm, whereas in the SES, in-stent late loss was lower in patients who underwent predilatation (0.23 mm vs. 0.73 mm). Similarly, restenosis rates were lower in patients who underwent direct stenting (Figure 4). Interestingly, there were no cases of edge restenosis (proximal or distal) in patients who underwent direct SES implantation.

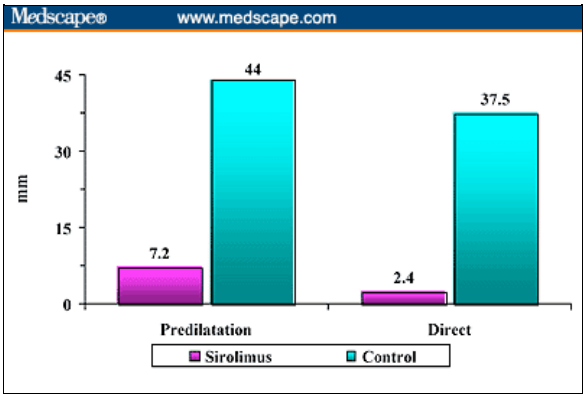

Figure 4. E-SIRIUS: in-lesion restenosis.

At 9 months, the rate of major adverse cardiac events was lower in the direct arm, although this difference did not achieve statistical significance (Figure 5).

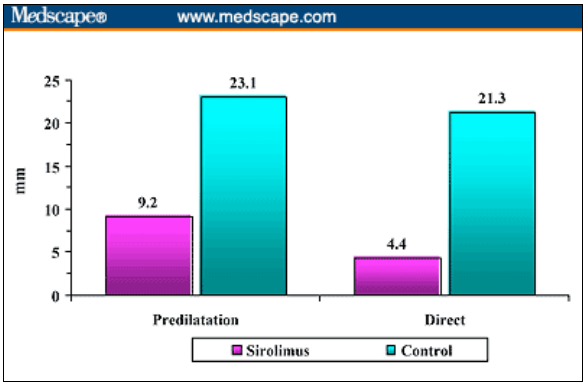

Figure 5. E-SIRIUS: clinical events at 9-month follow-up.

Conclusions