Head-to-Head Comparison of Sirolimus- Versus Paclitaxel-Coated Balloon Angioplasty in the Femoropopliteal Artery:

Dierk Scheinert, MD and Ulf Teichgräber, MD

The SIRONA Randomized Controlled Trial

Disclosures

Speaker name:

Dierk Scheinert.....

I have the following potential conflicts of interest to report:

- ☒ ***Consulting: Abbott, Acotec, Boston Scientific, Concept Medical,***
- ☐ ***Employment in industry***
- ☐ ***Stockholder of a healthcare company***
- ☐ ***Owner of a healthcare company***
- ☐ ***Other(s):***

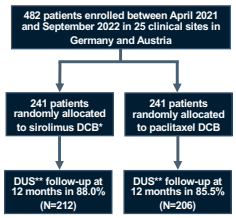
☐ ***I do not have any potential conflict of interest***

SIRONA RCT

Design

- **DESIGN:** Prospective, randomized controlled, multi-center, non-inferiority trial comparing sirolimus-* with paclitaxel coated balloon angioplasty in the femoropopliteal artery
- **PRIMARY OBJECTIVES:** Primary patency and the composite of target vessel revascularization, major amputation, and device or procedure-related death at 12 months
- **PRINCIPAL INVESTIGATOR**
  Ulf Teichgräber, MD
  Jena University Hospital, **Germany**

*MagicTouch™ Concept Medical Inc.,Tampa, USA



**CoreLaboratory adjudicated

Participant Characteristics*

	Sirolimus DCB	Paclitaxel DCB
Age	68 ± 9 years	68 ± 9 years
Sex, male	64%	65%
Current smoker	43%	47%
Former smoker	41%	40%
Diabetes	34%	33%
Hypertension	88%	86%
Hyperlipidemia	76%	80%

*Site-reported results

Participant Characteristics*

	Sirolimus DCB	Paclitaxel DCB
Rutherford-Becker classification		
Category 2	25%	27%
Category 3	73%	69%
Category 4	2%	4%
Category 5	1%	0%
ABI	0.68 ± 0.22	0.69 ± 0.23

*Site-reported results

Lesion Characteristcs*

	Sirolimus DCB	Paclitaxel DCB
Lesion length	84 ± 61 mm	84 ± 60 mm
Total occlusion	34%	34%
Calcification, PACSS Grade 3	45%	46%
Calcification, PACSS Grade 4	29%	28%
Diameter stenosis	83%	82%
< 2 run-off vessels	43%	39%

*CoreLaboratory-reported results

Procedure Characteristics*

	Sirolimus DCB	Paclitaxel DCB
Predilation	100%	100%
> 1 DCB	26%	27%
Dissection	30%	25%
Postdilation	31%	34%
Adjunctive DCB	3%	6%
Bailout stent	23%	20%
Residual stenosis	7%	10%

*Site-reported results

Study Endpoints

Primary efficacy endpoint

Primary patency (PSVR < 2.4* and no TLR) at 12 months (non-inferiority to paclitaxel DCB: non-inferiority margin: -10%)*.

*PSVR: CoreLaboratory adjudicated
Clinical Event Committee (CEC) approval

Primary safety endpoint

Composite of clinically driven target vessel revascularization (TVR), major target limb amputation, and device- or procedure-related death (non-inferiority to paclitaxel DCB).

Data Safety Monitoring Board (DMSB)

Primary Patency

Primary efficacy endpoint

Sirolimus DCB: **73.8%** (152/206)
Paclitaxel DCB: **75.0%** (147/196)

Rate difference: -1.2% (-9.7% to 7.4%)
P = 0.022 (non-inferiority)

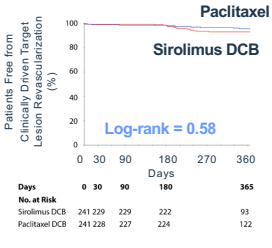
Composite Safety Outcome [1]

Event[2]	Sirolimus DCB	Paclitaxel DCB
cdTVR	21 (16 TLR)	16 (14 TLR)
Major amputation	1	1
Death[3]	0	0
Overall	21/223 (**9.4%**)	16/218 (**7.3%**)

Between-group difference: 2.1% (95%CI: -3.2% to 7.5%)
P = 0.003 (non-inferiority)[4]

[1]DMSB (Data Safety Monitoring Board) approved
[2]at 410 days
[3]Device- or procedure-related death
[4]Farrington-Manning test

Freedom from cdTLR*

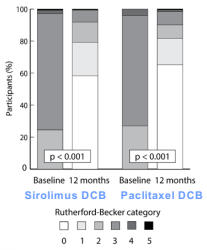


Study group	at 365 days	SE
Sirolimus DCB	92.9%	1.7%
Paclitaxel DCB	95.4%	1.4%

Clinical 12-month FU completed
223 (92.5%)
218 (90.5%)

*CEC (Clinical Event Committee) approved

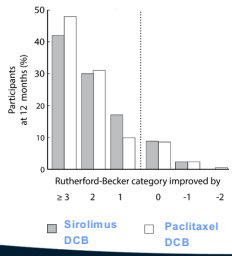
Functional Outcome



Change from baseline to 12 months
Sirolimus DCB (n = 217): **2.0** ± 1.1
Paclitaxel DCB (n = 213): **2.2** ± 1.1

Between-group difference (95% CI):
0.1 (-0.1 to 0.4)
p = 0.19

Functional Outcome



Clinical improvement by ≥ 1 Rutherford category

Sirolimus DCB: **88.9%** (193/217)
Paclitaxel DCB: **88.7%** (189/213)

p = 0.19

Conclusion

The head-to-head comparison of sirolimus DCB with paclitaxel DCB shows comparable results between the study groups.

- Primary patency of sirolimus DCB was non-inferior to that of paclitaxel DCB
- No significant difference between groups in freedom from cdTLR
- Clinical improvement of sirolimus DCB was similiar to paclitaxel DCB
- Safety of sirolimus DCB was non-inferior to that of paclitaxel DCB