Preliminary angiographic and clinical 6-month results of the CONSEQUENT trial

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ClinicalTrials.gov Identifier:
NCT01970579

Disclosures

Speaker name: Thomas Albrecht

I have the following potential conflicts of interest to report:

- ■ Consulting (Braun Melsungen, Boston Scientific, Pharmacept, Olympus)
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ I do not have any potential conflict of interest

Aim

To assess the safety and efficacy of the paclitaxel-coated balloon catheter SeQuent® Please OTW (B.Braun Melsungen AG) to treat steno-occlusive lesions of the superficial femoral artery and the proximal two segments of the popliteal artery.

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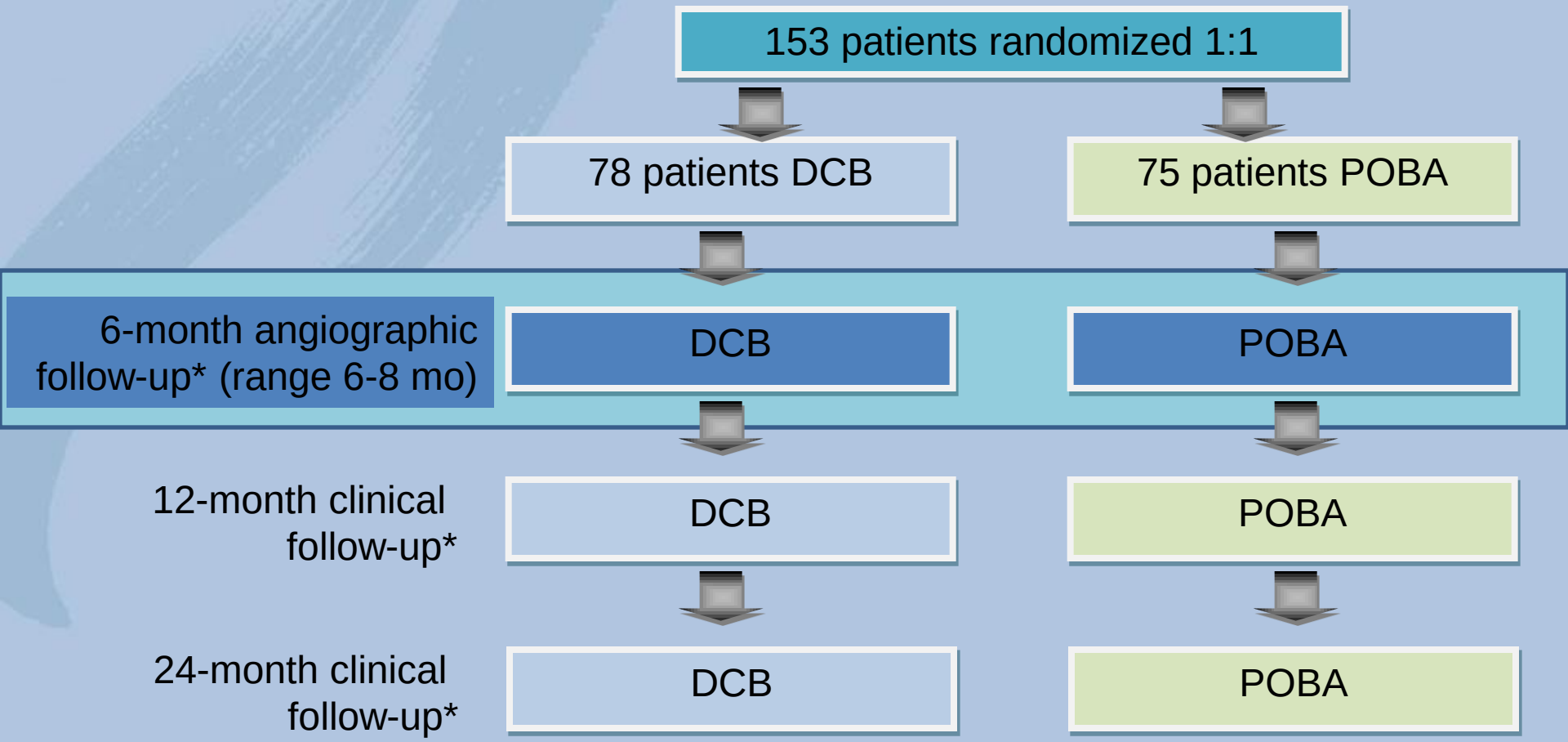
Study design



- including walking test, ABI and Duplex

Inclusion criteria

- De novo or restenosis post POBA in SFA or PI/ PII
- Rutherford II-IV
- Reference vessel diameters 4.0 - 7.0 mm
- Lesion lengths 4 - 27 cm
- Diameter stenosis pre-procedure ≥ 70%
- Adequate runoff with ≥ 1 vessel to the foot.

Exclusion criteria

- Restenosis post stent or DCB
- >2 lesions in target vessel
- Chronic total occlusions > 10 cm

Endpoints

Primary endpoint

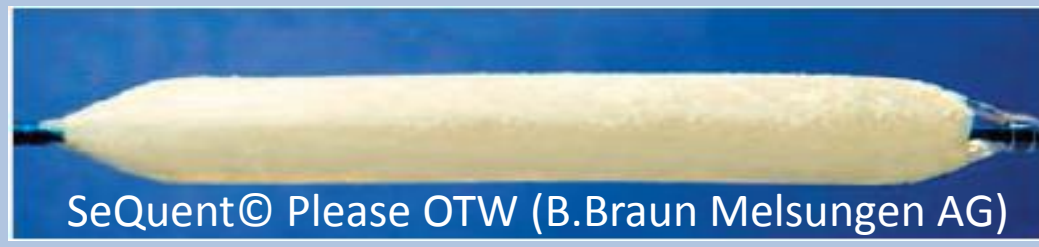
- Late Lumen Loss at 6 months (QA, corelab)

Secondary endpoints

- Binary Restenosis Rate > 50% at 6 months (QA, corelab)
- Clinically driven TLR at 6, 12 and 24 months
- Ankle Brachial Index at 6, 12 and 24 months
- Walking Distance and Rutherford stages at 6, 12 and 24 months

SeQuent© Please OTW matrix coating

- 3 µg Paclitaxel per 1 mm² balloon surface.
- Matrix builder Resveratrol
- Resveratrol occurs naturally: anti-oxidative, antiinflam-matory, vaso-active
- Maximum Resveratrol load of largest balloon 2.5 mg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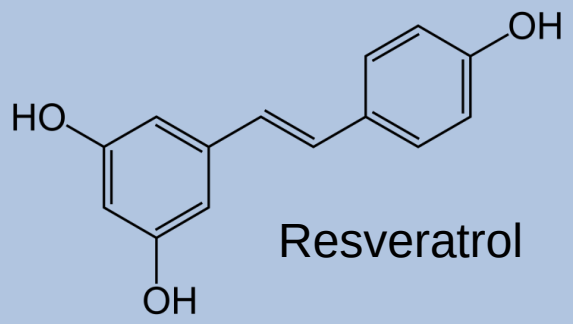
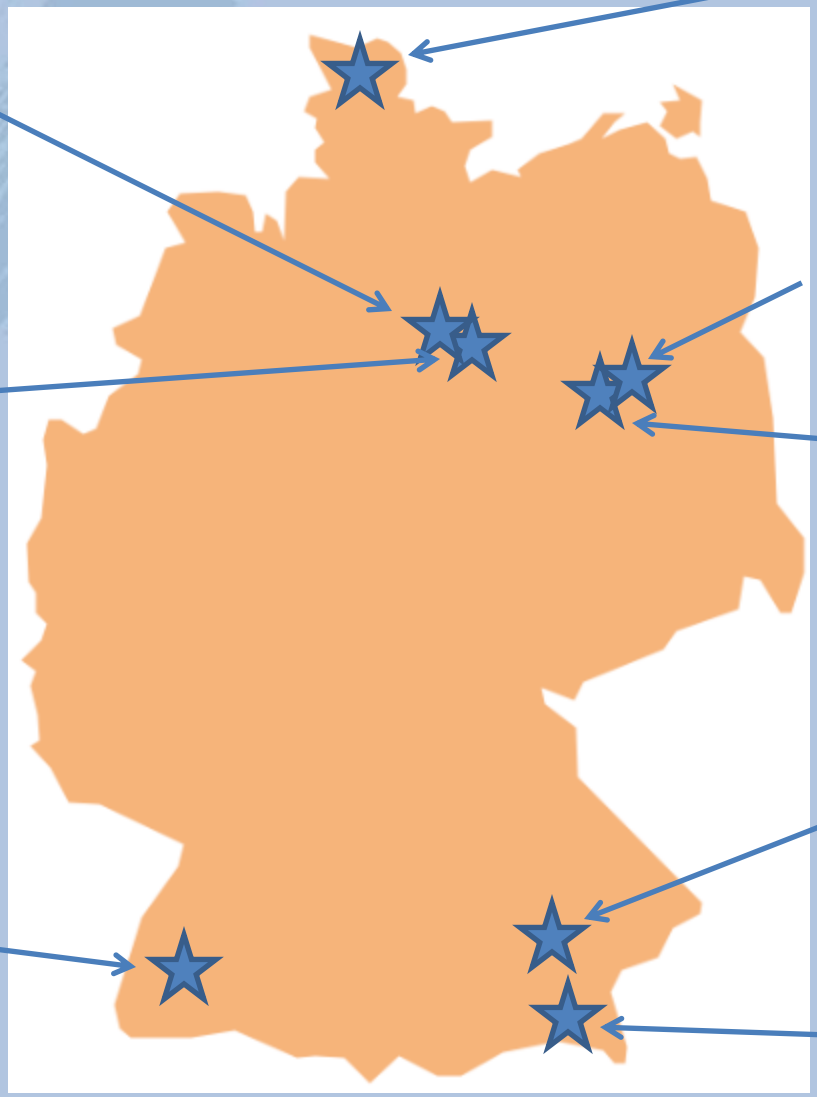


Resveratrol

8 study centres



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Patient demographics

	All patients	Drug Coated Balloon	Uncoated Balloon	p-value
Patients	153	78	75	-
Lesions	171	87	84	-
Age, years	68.1±8.7	68.2±8.5	68.0±9.0	0.884
Male gender	104 (68.0%)	47 (60.3%)	57 (76.0%)	0.037
Diabetes mellitus	56 (36.6%)	27 (34.6%)	29 (38.7%)	0.603
insulin dependent	24 (31.6%	9 (23.1%)	15 (40.5%)	0.102
Hypertension	120 (78.4%)	60 (76.9%)	60 (80.0%)	0.697
Hypercholesteremia	83 (54.4%)	44 (56.4%)	39 (52.0%)	0.584
Dialysis dependent	6 (3.9%)	2 (2.6%)	4 (5.3%)	0.378
Obesity BMI≥30	40 (26.1%)	21 (26.9%)	19 (25.3%)	0.346
Cigarette smoking	73 (47.7%)	36 (46.2%)	37 (49.2%)	0.694
TIA during last 2 years	9 (5.9%)	5 (6.4%)	4 (5.3%)	0.777
Coronary artery disease	63 (41.2%)	33 (42.3%)	30 (40.0%)	0.772
Previous amputation	2 (1.3%)	1 (1.3%)	1 (1.3%)	0.978
Rutherford …2 …3 …4	 8 (5.2%) 145 (94.8%) 0 (0.0%)	 4 (5.1%) 74 (94.9%) 0 (0.0%)	 4 (5.3%) 71 (94.7%) 0 (0.0%)	0.955

Lesion details – target lesions

	All patients	Drug Coated Balloon	Uncoated Balloon	p-value
Target lesions	153	78	75	-
Location SFA P1/P2 SFA + P1/P2	 122 (79.7%) 9 (5.9%) 22 (14.4%)	 63 (80.8%) 4 (5.1%) 11 (14.1%)	 59 (78.7%) 5 (6.7%) 11 (14.7%)	0.912
TASC A TASC B TASC C TASC D	54 (35.3%) 63 (41.2%) 26 (17.0%) 10 (6.5%)	28 (35.9%) 31 (39.7%) 13 (16.7%) 6 (7.7%)	26 (34.7%) 32 (42.7%) 13 (17.3%) 4 (5.3%)	0.934
Diameter stenosis, %	76.6 ± 18.1	76.0 ± 17.7	77.1 ± 18.5	0.703
Total occlusions	40 (26.1%)	18 (23.1%)	22 (29.3%)	0.462
Lesion length, cm	13.2 ± 10.4	13.7 ± 12.2	12.6 ± 8.2	0.540
Reference diameter, mm	5.22 ± 0.87	5.06 ± 0.77	5.38 ± 0.94	0.050
2nd non-target lesion	18 (11.8%)	9 (11.5%)	9 (12.0%)	0.929

Procedural details - target lesions

	All patients	Drug Coated Balloon	Uncoated Balloon	p-value
Target lesions	153	78	75	-
Intraluminal passage Subintimal passage	132 (86.3%) 21 (13.7%)	68 (87.2%) 10 (12.8%)	64 (85.3%) 11 (14.7%)	0.740
Predilatation	85 (55.6%)	41 (52.6%)	44 (58.7%)	0.448
Balloon diameter, mm	5.2 ± 0.8	5.1 ± 0.7	5.3 ± 0.8	0.05
Balloon length, mm	106.5 ± 37.5	105.6 ± 38.0	107.5 ± 37.0	0.701
Inflation time, sec	146.8 ± 43.2	149.8 ± 41.8	143.7 ± 44.8	0.294
Bailout stenting	25 (16.3%)	11 (14.1%	14 (18.7%)	0.445
Residual stenosis, %	33.2 ± 11.1	33.1 ± 10.0	33.2 ± 12.2	0.986
Procedural success	153 (100%)	78 (100%)	75 (100%)	-

Angiographic 6-month results – target lesions (QA, corelab)

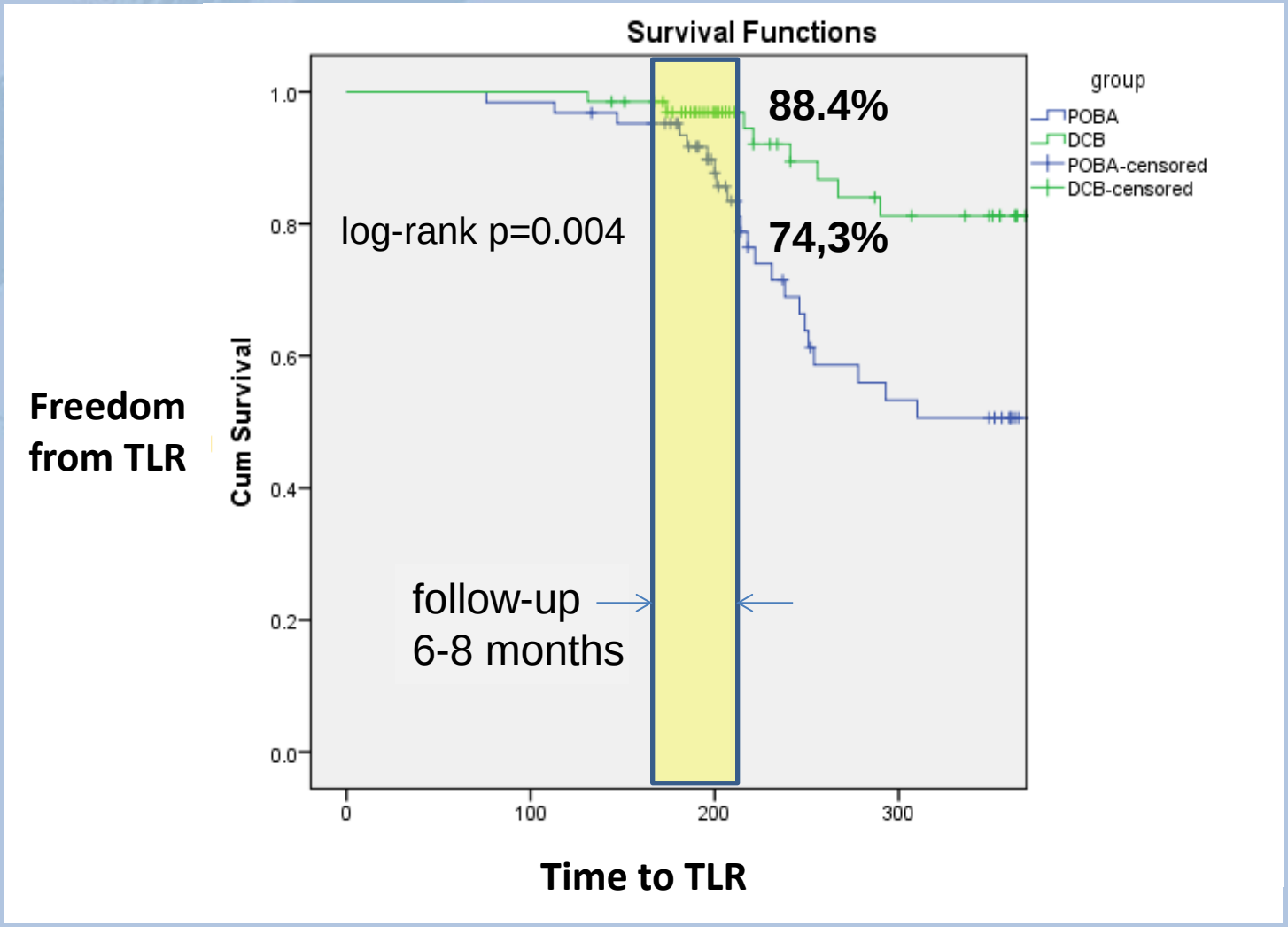
	All patients	Drug Coated Balloon	Uncoated Balloon	p-value
Follow-up, months	6.5±1.0	6.5±0.8	6.5±1.0	0.924
Target lesions available for analysis (20.01.2016)	106/153 (69.3%)	52/78 (66.7%)	54/75 (72.0%)	-
Late Lumen Loss, mm	**0.73 ± 1.09**	**0.49 ± 1.14**	**0.98 ± 1.01**	**0.017**
Positive Remodelling, LLL<0mm	**26 (24.5%)**	**19 (36.5%)**	**7 (13.0%)**	**0.005**
Binary restenosis (>50%)	**36 (34.3%)**	**11 (21.2%)**	**25 (47.2%)**	**0.005**

Clinical 6-month results

	All patients	Drug Coated Balloon	Uncoated Balloon	p-value
Target lesion revascularization	**26 (18.7%)**	**8 (11.6%)**	**18 (25.7%)**	**0.033**
Increase in walking distance (censored[1], n=85), m	**104 ± 148**	**137 ± 160**	**71 ± 130**	**0.039**
Target leg ABI (censored w/o TLR, n=108)	**0.93 ± 0.19**	**0.97 ± 0.14**	**0.89 ± 0.22**	**0.035**
Cardiac death Non-cardiac death	1 (0.7%) 2 (1.4%)	1 (1.4%) 1 (1.4%)	0 (0.0%) 1 (1.4%)	0.600
Amputations, target leg major minor	 0 (0.0%) 1 (1.4%)	 0 (0.0%) 1 (2.4%)	 0 (0.0%) 0 (0.0%)	0.312

[1] Patients with prior TLR of the target leg and all patients with non-vascular limitations of the walking distance (dyspnea, joint disease, …) were excluded

Kaplan-Meier curve - freedom from TLR



Conclusions

- Late lumen loss (primary endpoint) was significantly lower in the DCB group:
  0.49±1.14 vs. 0.98±1.01 mm, p=0.017
- Lower clinically driven TLR rates for DCB group:
  11.6% vs. 25.7%, p=0.033
- Higher walking distance increase in DCB patients:
  137 vs. 71 m, p=0.039
- Longer lesions (13.2 cm) than in any other previously published DCB study

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