RoMed Kliniken

Value Of PTX Coated Balloons Vs. Uncoated Balloons in BTK Arteries: The SAMBA Study Shows That DCBs Can Work In This Location

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Disclosure

Study support by B.Braun, Biotronic, BSC, CVT, Philips, Medtronic, Shockwave

SAMBA

- **DESIGN:** Prospective, controlled, randomized, multicenter, partially blinded (patient and angiographic core lab)

OBJECTIVE: To compare angiographic and clinical outcome of the paclitaxel-coated SequentPlease balloon (SQP) and uncoated balloons (POBA) in treatment of below the knee lesions

PRIMARY ENDPOINT: Occlusion rate of the target lesion segment before or at 6-month follow-up or clinically driven target lesion reintervention prior 6-month follow-up

HYPOTHESES: Superiority of paclitaxel-coated DCB (SeQuentPlease OTW, SQP) over POBA

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SAMBA

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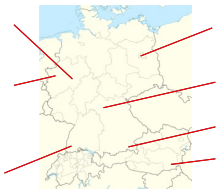

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SAMBA

MAIN INCLUSION CRITERIA

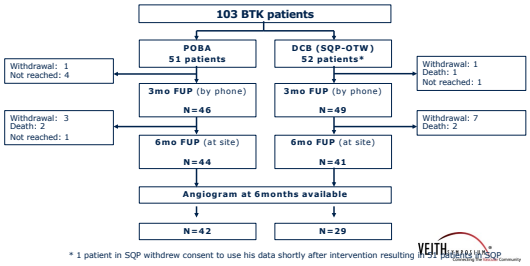
Chronik stenotic or occlusive atherosclerotic disease of the infrapopliteal arteries
- Rutherford classes 2-5
- Minimum diameter stenosis ≥70%

Lesion length 5-25 cm
Maximal 2 BTK lesions

MAIN EXCLUSION CRITERIA

- ISR lesions
- Planned or foreseeable major amputation
- Prior treatment of the index lesion with a drug coated balloon
- Inflow lesion exceeding TASC B
- Acute thrombus in the index limb
- Aneurysm in the index leg
- Index vessel with no run-off to the foot distal to the target lesion

Study patient and follow up chart up to 6 months



* 1 patient in SQP withdrew consent to use his data shortly after intervention resulting in 51 patients in SQP

Patient baseline characteristics

		POBA (n= 51)	SQP OTW (n= 51)
Age, years		74±8 (51)	78±8 (51)
Gender, male		86% (44/51)	71% (36/51)
Body weight, kg		86±17 (51)	78±17 (51)
Obesity (BMI ≥ 30)		31% (16/51)	22% (11/51)
Diabetes		63% (32/51)	55% (28/51)
Hypertension		92% (47/51)	84% (43/51)
Coronary artery disease		51% (26/51)	49% (25/51)
Hyperlipidemia		71% (36/51)	65% (33/51)
Renal disease (late stage)		20% (10/51)	14% (7/51)
Current smoker		14% (7/51)	8% (4/51)
Prior minor amputations at target leg		26% (13/51)	16% (8/51)
Ischaemic wounds at target leg		80% (41/51)	65% (33/51)
Wound size, cm²		4±3 (38)	6±6 (29)
Rutherford stage	**2**	2% (1/51)	2% (1/51)
	3	10% (5/51)	24% (12/51)
	4	4% (2/51)	8% (4/51)
	5	84% (43/51)	67% (34/51)

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Lesion baseline characteristics

¹CRF data ²Corelab analysis

Values are % (n/N) or mean±SD (n)

		POBA (n=51)	SQP (n=51)
Vessel, n (%) ¹	**ATA**	51% (26/51)	35% (18/51)
	PTA	8% (4/51)	16% (8/51)
	PA	22% (11/51)	8% (4/51)
	TPT	6% (3/51)	12% (6/51)
	TPT-PA	10% (5/51)	22% (11/51)
	TPT-PTA	4% (2/51)	8% (4/51)
De novo¹		86% (44/51)	88% (45/51)
Restenotic lesion¹		14% (7/51)	12% (6/51)
Lesion length², mm		131±99 (50)	134±98 (51)
Occlusion²		33% (17/51)	40% (20/50)
Occlusion length², mm		81±98 (17)	57±[illegible]

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Lesion baseline characteristics

		POBA (n=51)	SQP (n=51)
RVD proximal², mm		3.0±0.4 (47)	3.2±0.5 (41)
RVD distal², mm		2.3±0.4 (50)	2.4±0.5 (46)
MLD², mm		0.4±0.4 (51)	0.4±0.5 (50)
Diameter stenosis², %		85±15 (51)	86±17 (50)
Transverse-view vessel area (TVA) ², mm²		190±152 (50)	211±186 (50)
Calcification (PACCS), - Corelab	0	8% (3/38)	9% (4/45)
	1 - 2	8% (3/38)	13% (6/45)
	3 - 4	84% (32/38)	78% (35/45)

Values are % (n/N) or mean±SD (n)

¹CRF data ²Corelab analysis

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Procedural data

	POBA (n=51)	SQP (n=51)
Pre-dilation¹	80% (41/51)	98% (50/51)
Bail out stenting²	2% (1/51)	4% (2/51)
Treated length², mm	174±113 (49)	174±107 (49)
Post-procedural MLD², mm	1.8±0.5 (51)	1.97±0.5 (51)
Post-procedural MLD location², mm proximal end of TL to MLD post	116±95 (51)	113±102 (49)
Post-procedural diameter stenosis², %	30±15 (51)	29±16 (51)
Post-procedural transverse-view vessel area, TVA², mm²	343±263 (50)	364±268 (51)

Values are % (n/N) or mean±SD (n) | ¹ CRF data; ² Corelab analysis

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6 months: Efficacy and safety results

6 month Corelab data

	POBA (n=51)	SQP (n=51)
6 months DSA data available	84% (43/51)	55% (28/51)
Diameter stenosis, %	72±25 (42)	66±28 (27)
Late Lumen Loss, mm	1.1±0.8 (42)	0.9±0.6 (27)
MLD, mm	0.7±0.7 (42)	1.0±0,9 (27)
MLD location (proximal end of TL to MLD at reangio), mm	57±47 (42)	103±93 (26)
Transverse-view vessel area, TVA, mm²	176±173 (42)	248±230 (28)
Transverse-view vessel area loss, TVAL (%)	36±31 (42)	28±32 (28)

Values are % (n/N) or mean±SD (n)

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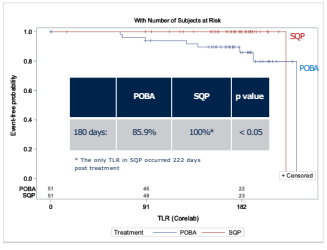
Freedom from CD-TLR up to 6months



	POBA (n= 51)	SQP OTW (n= 51)
Occlusion at target lesion up to 6mo (CoreLab data)	11	8

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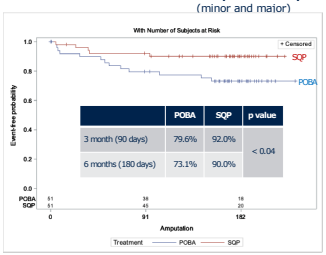
Freedom from amputations up to 6months
(minor and major)



	POBA	SQP	p value
3 month (90 days)	79.6%	92.0%	< 0.04
6 months (180 days)	73.1%	90.0%	

Major amputations:
1 per group (both up to 6mo)

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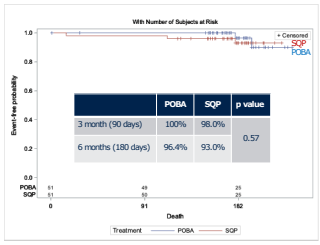
Freedom from death up to 6 months



	POBA	SQP	p value
3 month (90 days)	100%	98.0%	0.57
6 months (180 days)	96.4%	93.0%	

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Summary and Conclusion

Sequent Please PCB with less TLR compared to POBA

Sequent Please PCB with less amputations compared to POBA

More angiographic documented total reocclusions in the POBA group
but less f/u angiograms in the Sequent Please group (DUS under evaluation)

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