

Pulsar – PEACE

PEACE

Pulsar Efficacy: an All-ComErs registry: 12-month results¹

Conclusions

- Pulsar stents showed favorable study results at 12-months in patients with an average lesion length of 11.2 cm
 - A Primary Patency (PP) at 12-months of 79.5 % and Freedom of Target Lesion Revascularization (FTLR) of 81.0 %
 - Results are similar to published data in similar lesion lengths, including 4EVER (Pulsar-18) with a PP of 73.4 % and a FTLR of 85.2 %
- No significant difference between TASC A/B vs. TASC C/D lesions ($p = 0.55$) and diabetics vs. non-diabetics ($p = 0.92$)

Study design

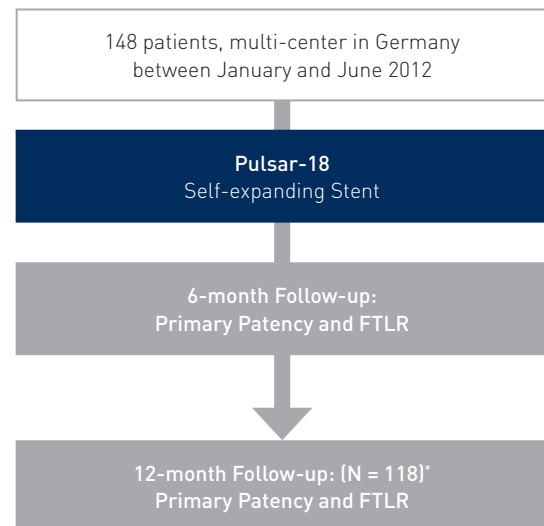
- Multi-center, prospective all-comers registry
- C.C.I. Dr. M Lichtenberg, Arnsberg, Germany and Prof. G Wittenberg, Bielefeld, Germany
- Enrollment 148 patients*
- Follow-up at 6- and 12-months

Endpoint(s)

- Primary Patency** (PP) at 6- and 12-months
- Freedom from Target Lesion Revascularization (FTLR)

Participating centers

- P.I. Prof. B Hailer, Essen, Germany
- P.I. Prof. C Nolte-Ernsting, Mülheim, Germany
- P.I. Prof. C Tiefenbacher, Wesel, Germany
- P.I. Dr. J Arjumand, Wuppertal, Germany
- P.I. Dr. M Lichtenberg Arnsberg, Germany
- P.I. Prof. G Wittenberg, Bielefeld, Germany



¹ Lichtenberg M, JEVT, 2014, 21:373-380

* 30 patients lost before 12-month Follow-up (18 declined re-evaluation, 5 withdrew consent and 7 died)

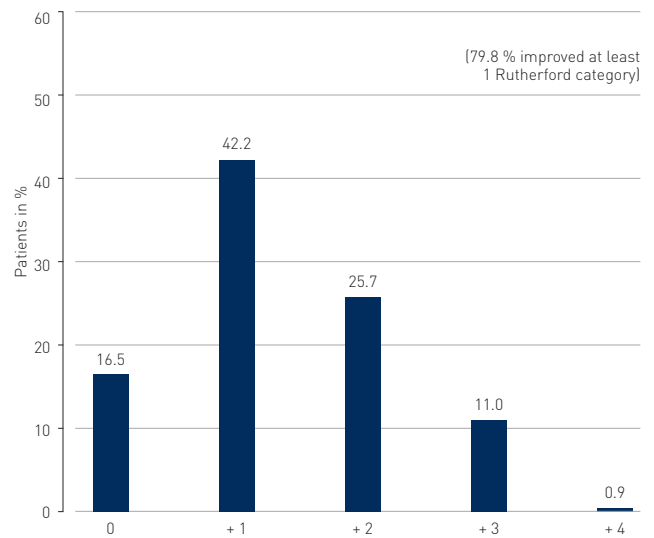
** = Defined as binary duplex ultrasound PSVR < 2.5 at the stented target lesion(s) and freedom from Target Lesion Revascularization (TLR)

Patient demographics

	Baseline
Mean Rutherford Class	3.06 ± 0.97
Smoker	37.3 %
Diabetics	31.4 %
Hyperlipidemia	69.5 %
Hypertension	92.4 %
Renal insufficiency	12.1 %

	Baseline
Occlusions (OCCL)	56.7 %
Average Lesion Length (ALL)	11.2 ± 7.1 cm
TASC II A	23.6 %
B	24.8 %
C	19.4 %
D	32.2 %
Popliteal segment	18.7 %
Stent ratio per patient	1.28

Rutherford change at 12 months



Results

	6 months	12 months
Primary Patency	87.4 %	79.5 %
FTLR	93.2 %	81.0 %
Rutherford improvement > 1	84.4 %	79.8 %
Rutherford unchanged	13.8 %	16.5 %

Sub-group data

Primary Patency	6 months	12 months
Diabetics	86.0 %	79.2 %
Lesions > 100 mm	82.9 %	78.0 %
Occlusions	89.2 %	78.1 %
Popliteal segment	75.0 %	71.4 %
Renal insufficiency	82.8 %	82.7 %

PEACE Primary Patency and Freedom from TLR in perspective

Studies	ALL	PP	FTLR	OCCL
PEACE	11.2 cm	79.5 %	81.0 %	57 %
PEACE >100 mm	-	78.0 %	-	-
4EVER (overall)	7.1 cm	81.4 %	89.3 %	21 %
4EVER (Pulsar-18)	10.8 cm	73.4 %	85.2 %	32 %
ABSOLUTE	10.1 cm	63.0 %	-	37 %
DURABILITY	9.6 cm	72.2 %	79.1 %	40 %
SUPERA	9.0 cm	84.7 %	-	31 %