



Drug-coated balloons in below-the-knee arteries – data from the Heidelberg registry

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Disclosure

Speaker name:

Felicitas Stoll

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest in the past 12 months

Background – DCB below-the-knee (1)

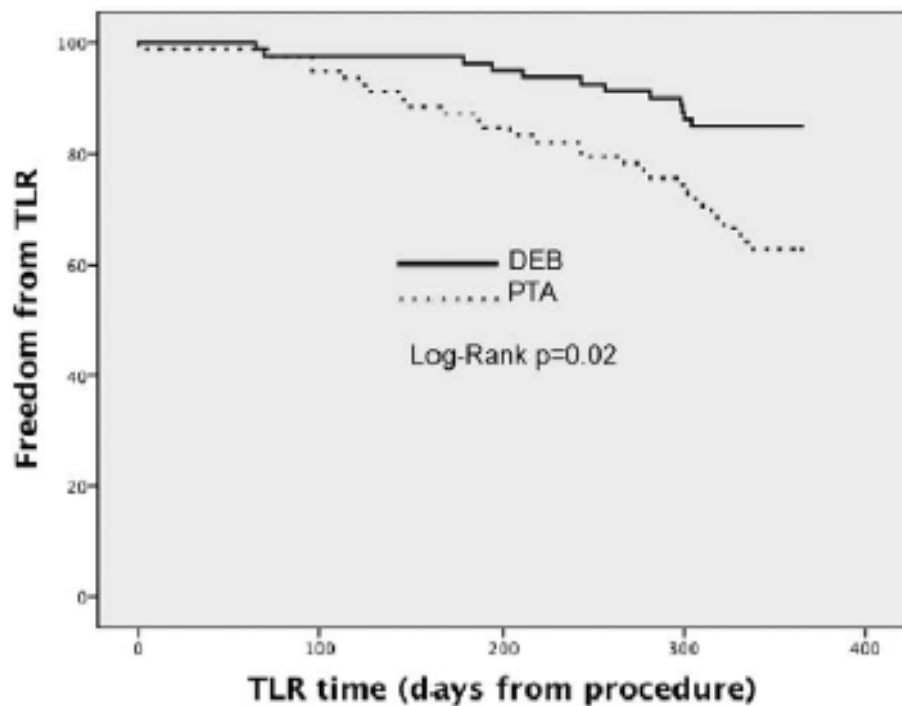
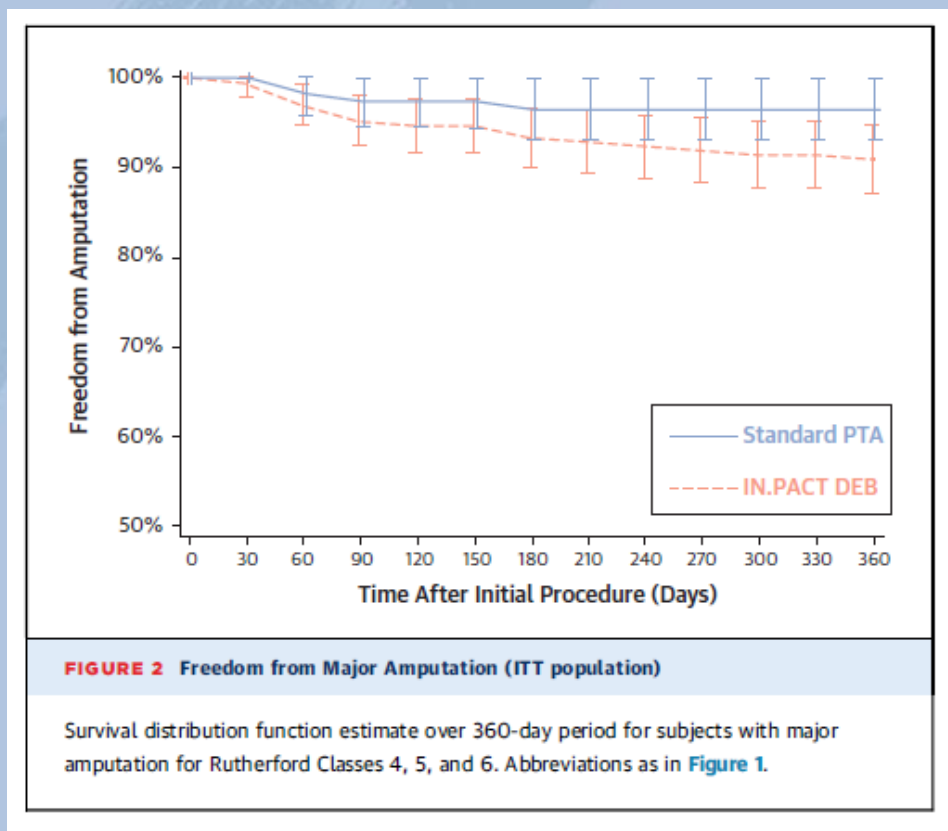


Figure 2. Kaplan–Meier analysis for survival free from target lesion revascularization (TLR) in both study groups. DEB indicates drug-eluting balloon; and PTA, percutaneous transluminal angioplasty.

DEBATE BTK

- Reduction of
 - 1-year restenosis
 - target lesion revascularization
 - target vessel occlusioncompared to PTA in diabetic patients with critical limb ischemia

Background – DCB below-the-knee (2)



IN.PACT.DEEP

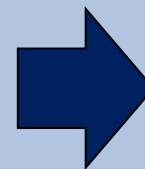
- IA-DEB had comparable efficacy to PTA
- However trend towards increased major amputation rate compared to PTA

Zeller T. et al.; Drug-eluting balloon versus standard balloon angioplasty for infrapopliteal arterial revascularization in critical limb ischemia: 12-month results from the IN.PACT DEEP randomized trial.; J Am Coll Cardiol. 2014 Oct 14;64(15):1568-76.

DCB BTK – Heidelberg

Age	73 yrs (SD 9)
Male	60% (41/68)
Diabetes mellitus	62% (42/68)
Hypertension	91% (62/68)
Hyperlipidemia	72% (49/68)
Obesity	31% (21/68)
Active Smoker	25% (17/68)
Renal insufficiency	NI 4: 6% (4/68) NI 5: 9% (6/68)
Rutherford Category	3 39% (29/75) 4 13% (10/75) 5 25% (19/75) 6 23% (17/75)
ABI	0,53 (SD 0,30)
ABI ≥1.3	20%

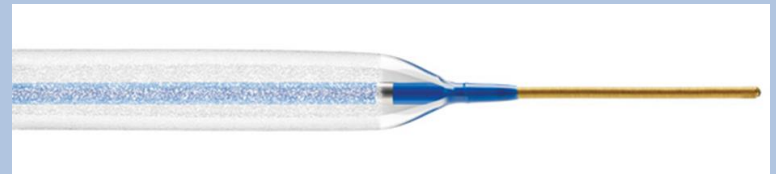
- Retrospective study
- 75 interventions in 68 patients between January 2013 and July 2014



CLI in 61% of patients

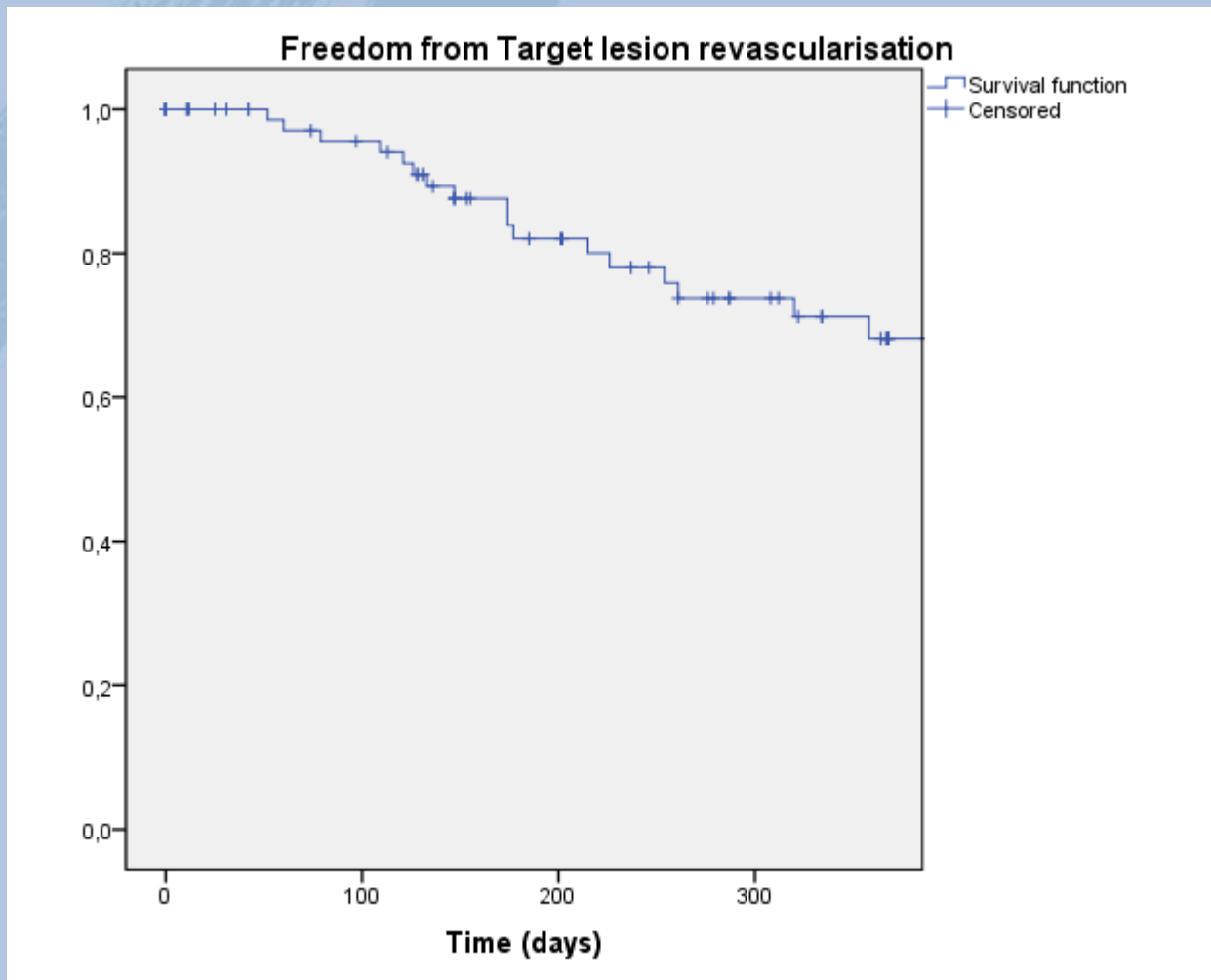
Heidelberg DCB BTK: Procedural and Angiographic Characteristics

- Average target lesion length: 14 cm
 - Complete vessel occlusion: 60%
 - Average calcification grade: 1.65 (mild to moderate)
 - Additional treatment of inflow lesion in 69%
 - One covered stent due to perforation, one stent due to dissection
- DCB
 - Medtronic InPact Amphirion
 - Bard Lutonix
 - (Sequent Please DEB)



	%
Anterior tibial artery	61
Tibioperoneal tract	56
Posterior tibial artery	28
Peroneal artery	32

Heidelberg DCB BTK: Target lesion revascularisation



Freedom from TLR
after 1 year: **68%**

Heidelberg DCB BTK: Primary and Secondary Patency Rates*



*as defined by freedom from clinically driven TLR and/or DUS/angiography

Heidelberg DCB BTK: Primary Patency* after 12 months

			Balloon		Total
			InPact Amphirion	Lutonix	
Patency (12 mo)	no	Count % in Balloon	11 32,4%	9 75,0%	20
	yes	Count % in Balloon	23 67,6%	3 25,0%	26
Total		Count % in Balloon	34 100%	12 100%	46

(P = 0,01)

*as defined by freedom
from clinically driven TLR
and/or DUS/angiography

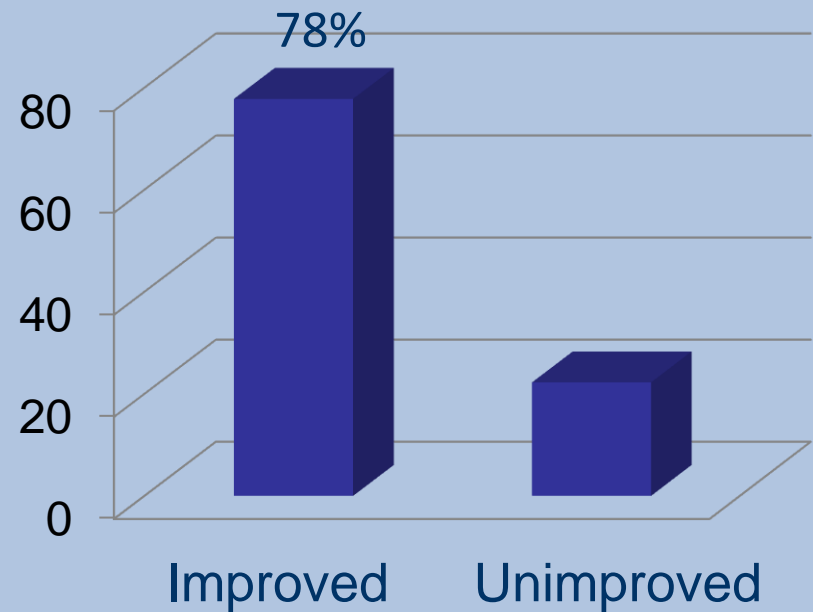
Heidelberg DCB BTK: Ulcer Healing

Ulcer localisation

	%
Toes	61
Heel	17
Ankle	8
Calf	22
Foot	8

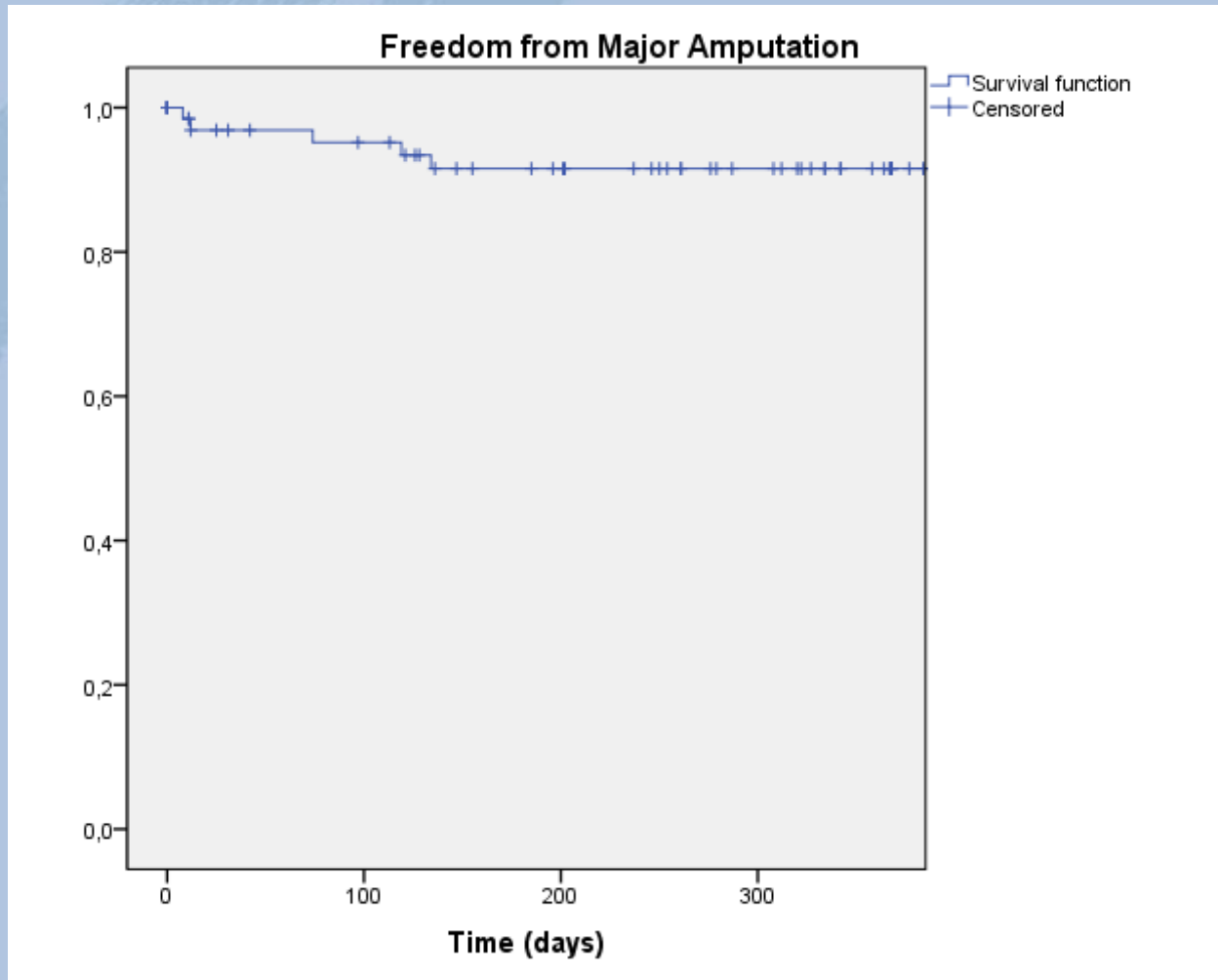
- In 68% angiosome-driven angioplasty

Ulcer healing after 6 months



n = 25

Heidelberg DCB BTK: Amputation

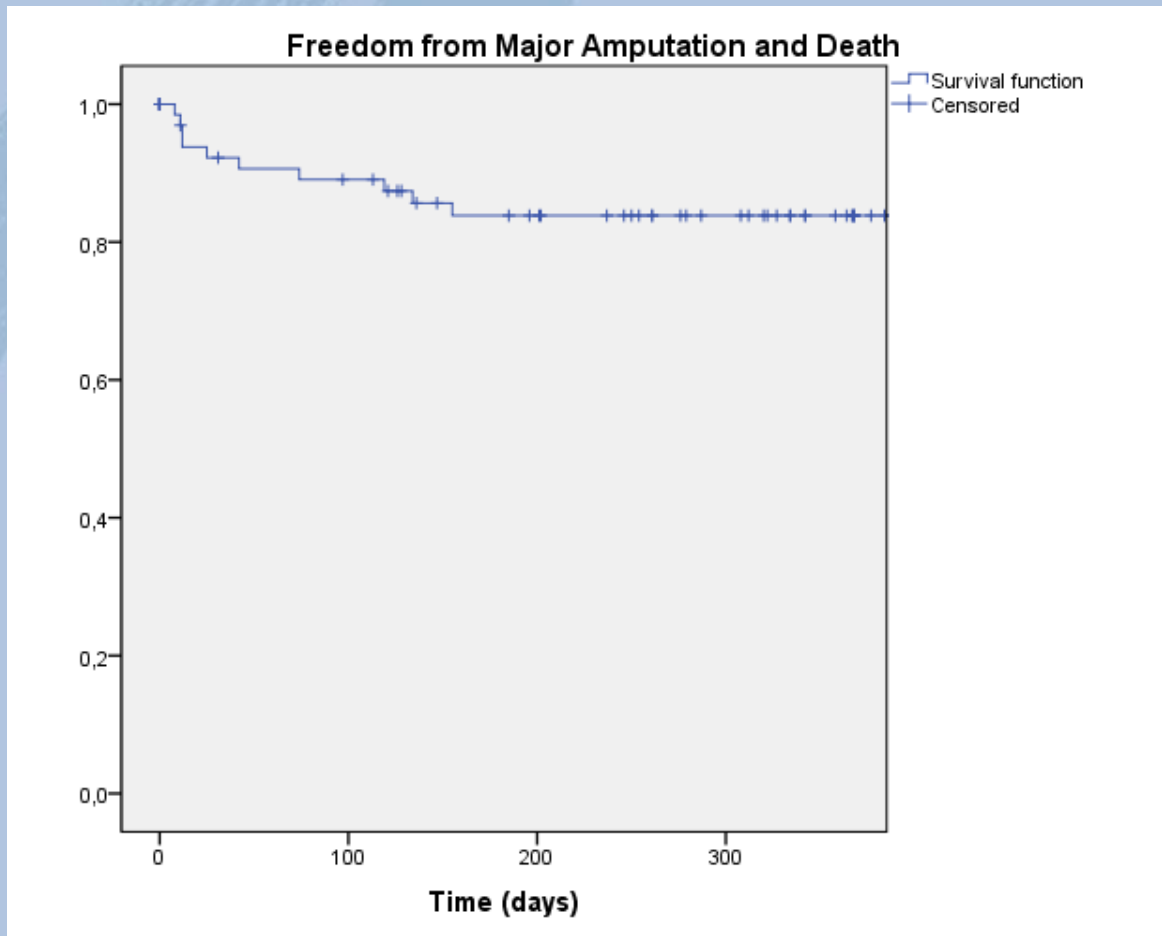


Freedom from Major Amputation after 1 year: **92%**

➤ For CLI patients: **86%**

Freedom from Minor Amp: 88%
(CLI: 81%)

Heidelberg DCB BTK: Amputation and Death



Freedom from Major Amputation and Death after 1 year: **84%**

➤ For CLI patients: **74%**

Heidelberg DCB BTK - Limitations

- Single-center retrospective registry
- Limited number of patients
- Heterogenous patient cohort (Rutherford 3-6)
- Heterogenous lesion morphologies
 - high rate of occlusions compared to other studies
 - long lesion lengths
- No comparison to plain balloon angioplasty

Heidelberg DCB BTK - Conclusions

- DCB treatment could be safely performed (no device malfunctions)
- Low rate of major amputations and deaths in CLI patients
- Low rate of stent implantation
- No definite conclusion can be drawn regarding an increased patency rate after DCB treatment
- Large randomized controlled studies are needed to further analyze the benefit of DCB in BTK arteries

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Thank you for your attention!



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