DCB in Diabetics

2y FU of the BIOLUX P-III All Comers Registry

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Herz- & Gefäßzentrum
am Krankenhaus Neu-Bethlehem

Disclosure

Speaker name: Prof. Dr. Johannes Dahm

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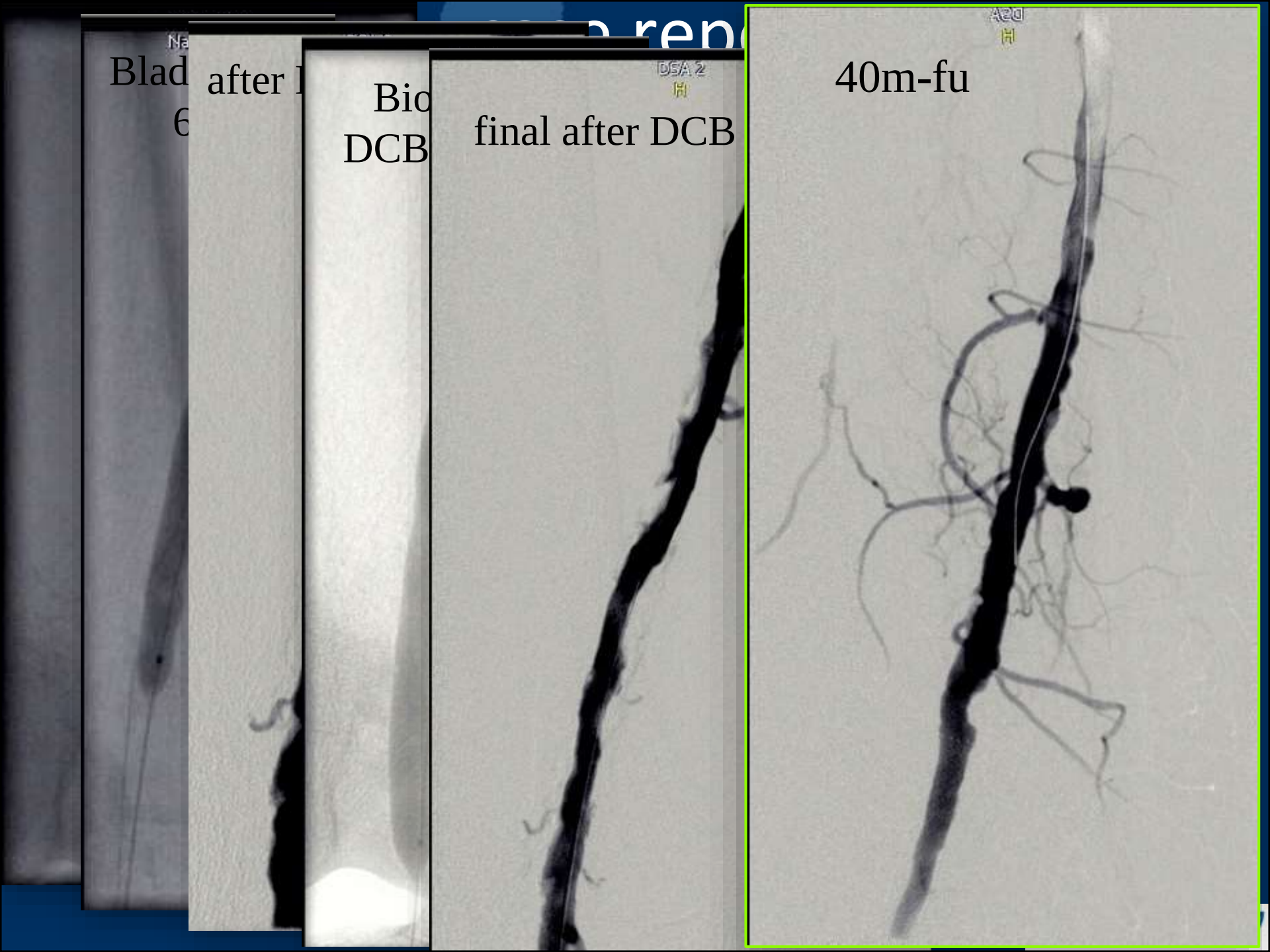
I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☒ Other(s): Speakers fee: Sanofi, Astra, Novartis, Sankyo

☐ I do not have any potential conflict of interest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Passeo-18 Lux Paclitaxel-Coated Balloon

Passeo-18 balloon Platform

Controlled compliance
Low profile
Highly deliverable

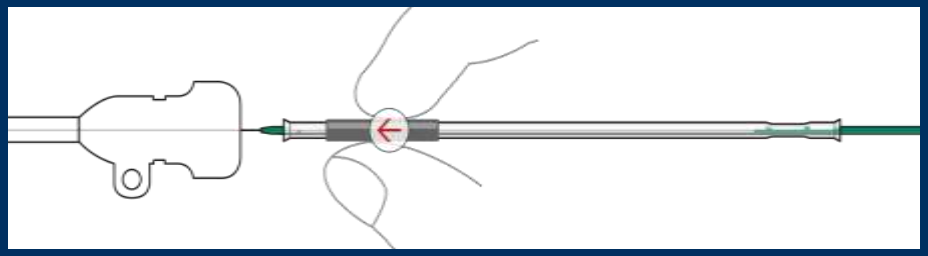
Paclitaxel 3 µg/mm2

Excipient BTHC (Butyryl-tri-hexyl citrate), Hydrophobi

Sizes available 2.0 – 7.0 mm diameter
40-80-120 mm length

SAFE GUARD Insertion Aid

- Protects the user and coating from contact and damage
- Reduces drug loss due to friction within the introducer sheath
- Pre-mounted on the balloon and does not require any preparation prior to use



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BIOLUX P-III Study Design

first/only study in infra-inguinals, 47 sites, 16 countries (EU, Australia, Asia)
no patient- or lesion-characteristic limitations; all devices allowed

DESIGN Prospective, global, multi-centre, real world All-Comers registry

STUDY GOALS efficacy and safety of Passeo-18 Lux DCB efficacy and safety in infra-inguinal arteries in a real world scenario

PRIMARY ENDPOINTS Freedom from MAE[1] at 6 months
Freedom from CD-TLR[2] at 12 months

INCLUSION CRITERIA Infra-inguinal Lesion(s) suitable for Passeo-18 Lux-DCB

EXCLUSION CRITERIA Failure to successfully cross the target lesion with a guide wire

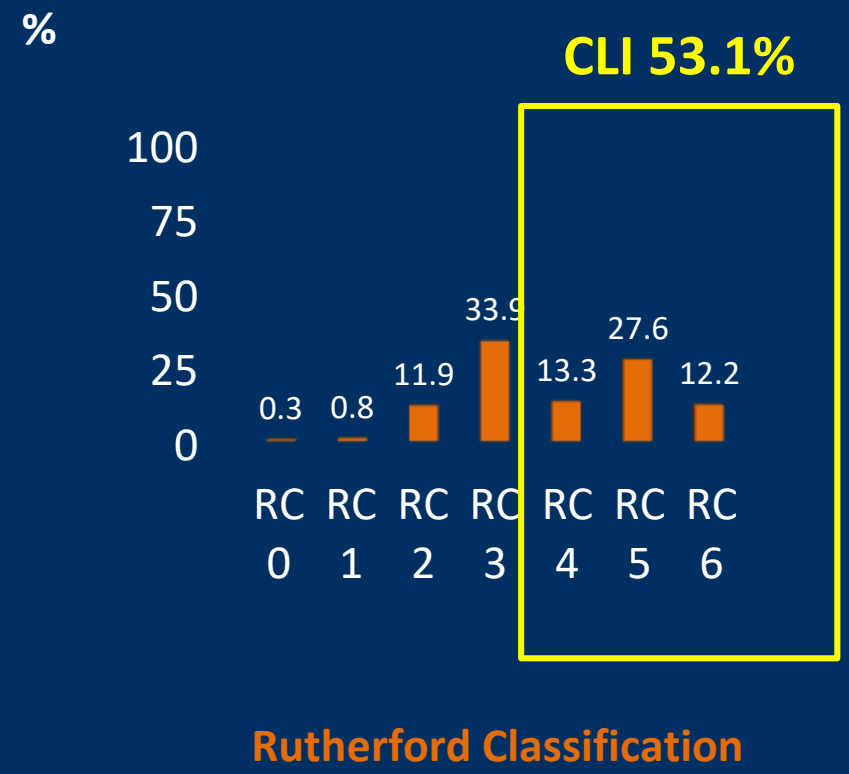
(1) Major Adverse Event : Composite of device and procedure related mortality through 30 days, major target limb amputation and clinically driven target lesion revascularization (TLR). MAE are adjudicated by an independent Clinical Events Committee

(2) Clinically driven TLR is any re-intervention performed for ≥50% diameter stenosis (visual estimate) at the target lesion after documentation of recurrent clinical symptoms of the patient

Baseline Details BIOLUX PIII

Diabetics

# Subjects	N = 460
Age, yrs (mean ± SD)	69.7 ± 9.7
Male (n, %)	288 (68.9%)
Hypertension (n, %)	371 (88.8%)
Hyperlipidemia (n, %)	294 (70.3%)
Smoking history (n, %)	260 (62.2%)
Current Smokers	*86 (33.1%)*
History of PAOD (n, %)	252 (60.3%)
Previous PVI /Surgeries (n, %)	215 (51.4%)
Coronary Artery Disease (n, %)	214 (51.2%)
Cerebrovascular Disease (n, %)	85 (20.3%)
Renal Disease (n, %)	175 (41.9%)
ABI target limb (mean± SD)	0.7 ± 0.2
Cancer	34 (8.1%)



Baseline Details BIOLUX PIII

Diabetics

Lesion Characteristics	N=516
Lesion Length, mm (mean ± SD)	85.63 ± 73.25
Reference Vessel Diameter, mm (mean ± SD)	4.52 ± 1.17
Diameter Stenosis (%)	86.93 ± 12.76
De novo Lesion (n, %)	294 (57.0%)
Occlusion (n, %)	116 (22.5%)
In Stent Restenosis (n, %)	50 (9.7%)
Re-Stenosis (n, %)	56 (10.9%)
Calcification (n=514, %)	
None	106 (20.6%)
Mild	160 (31.1%)
Moderate	156 (30.4%)
Heavy	92 (17.9%)
TASC Classification (n=508,%)	
A	183 (36.0%)
B	144 (28.3%)
C	102 (20.1%)
D	79 (15.6%)

Lesion Location	N (%)
Iliac	3 (0.6)
Common femoral	4 (0.8)
SFA	256 (49.6)
Popliteal artery	108 (20.9)
Other fem-pop	17 (3.3)
ATA	41 (7.9)
PTA	30 (5.8)
Tibioperoneal trunc	26 (5.0)
Peroneal artery	21 (4.1)
Dorsalis Pedis	2 (0.4)
Other BTK	1 (0.2)
Other (bypass)	8 (1.6)

79.4% Calcified lesions

48.3% moderate/heavily calc.

35.7% TASC C/D

23.4% BTK-lesions

BIOLUX PIII Study
Results (Diabetics)

Vessel Preparation	72.7% (375/516)
Pre-dilation	73.6% (380/516)
Cutting/scoring balloon	4.46% (23/516)
Rotational thrombectomy	2.33% (12/516)
Atherectomy	2.52% (13/516)

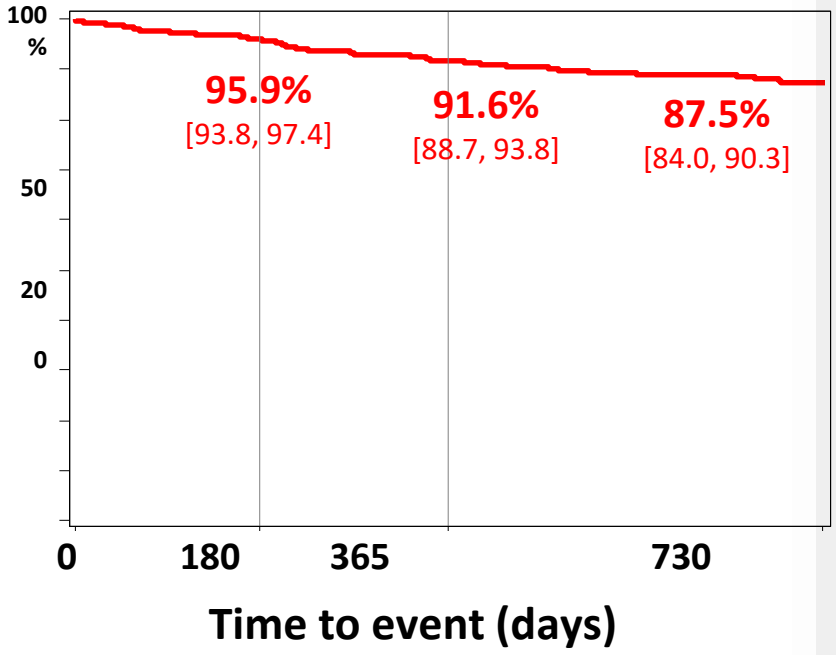
Technical success[1]	98.6% (509/516)
Bailout Stenting	14.1% (73/516)

(1) Technical success: Successful completion of the endovascular procedure and immediate morphological success with ≤ 50% residual diameter reduction of the treated lesion (visual estimation)

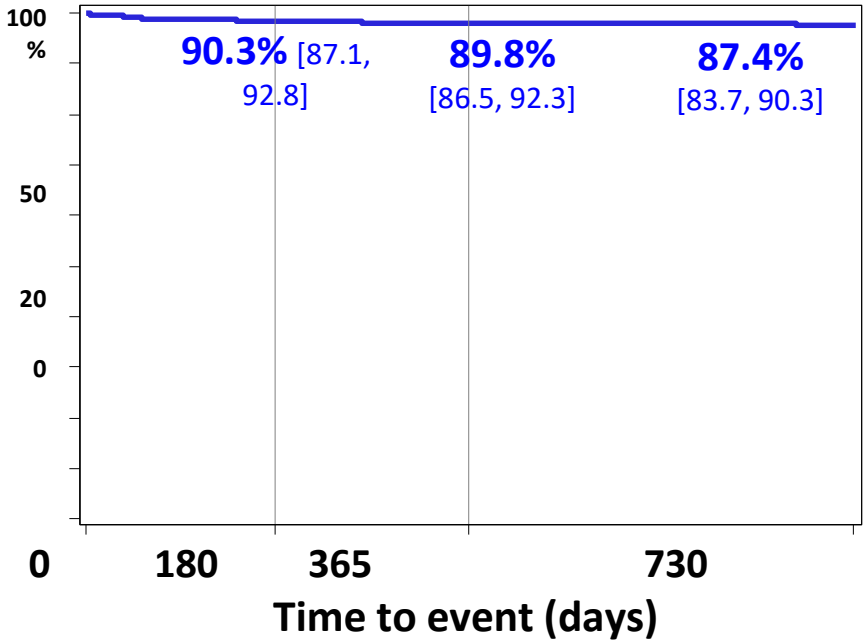
BIOLUX PIII Study

Results (Diabetics)

Freedom from TLR clinically driven



Freedom from major target limb amputations



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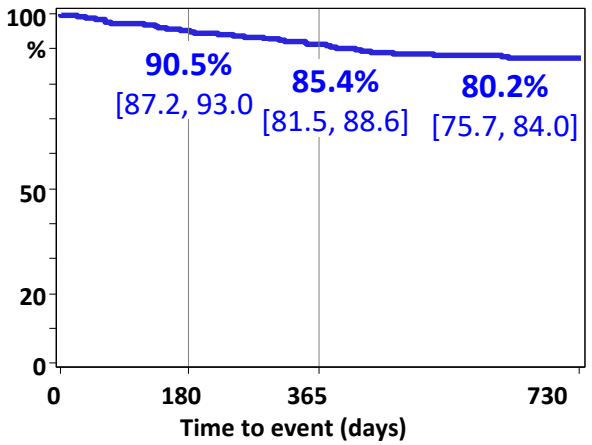
(2) Any re-intervention performed for ≥ 50% diameter stenosis (visual estimate) at the target lesion after documentation of recurrent clinical symptoms of the patient adjudicated by an independent CEC

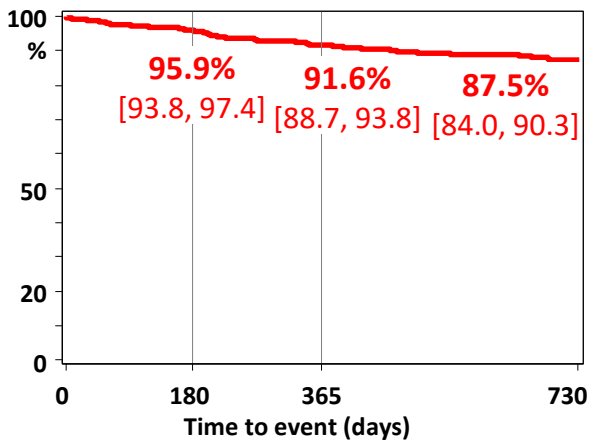
BIOLUX PIII Study

Results (Diabetics)

Freedom from major adverse events[1]



Freedom from clinically driven target lesion revascularization[2]



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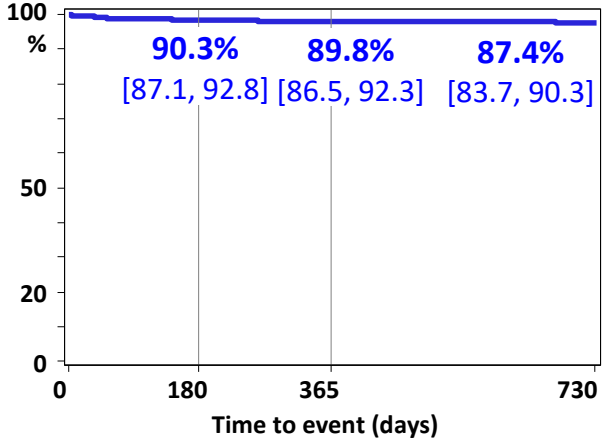

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BIOLUX PIII Study

Mortality rate (total population)

	12 months[1]	24 months[2]
BIOLUX P-I RCT (Fempop)	▪ Passeo-18 Lux: 0% ▪ POBA : 6.7% (2/30)	NA
BIOLUX P-II (BTK)	▪ Passeo-18 Lux: (3/36) ▪ POBA: (2/36)	NA
BIOLUX P-III Full cohort	6.2% (54/878)	10.3% (90/878)
BIOLUX P-III SFA+P1	5.7% (34/593)	8.8% (52/593)
BIOLUX P-III BTK	8.6% (13/151)	17.2% (26/151)
BIOLUX P-III Non CLI	2.9% (13/451)	5.5% (25 / 451)
BIOLUX P-III CLI	10.1% (33/328)	16.2% (53/328)
BIOLUX P-III Diabetes	8.6% (36/418)	13.9% (58/418)

(1) 365 days – (2) 730 days

BIOLUX PIII Study

Mortality rate (total population)

Katsanos et al AJC 2018 2.3% 7.2% + 75%

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BIOLUX PIII Study

Mortality (paclitaxel dose)

Cox regression: Mortality in BIOLUX P-III up to 730 days

Parameter	Standard Error	Chi-Square	p-value	Hazard Ratio
Paclitaxel Dose, mg	0.04123	0.0014	0.9700	0.998
Age, years	0.01393	11.6359	0.0006	1.049
Diabetes	0.25008	6.9299	0.0085	0.518
Renal disease	0.25028	12.3958	0.0004	0.414
Cancer	0.31420	3.4197	0.0644	0.559
CLI (RC>3)	0.25497	14.4314	0.0001	0.380
TASC A	0.38273	4.7266	0.0297	0.435
TASC B	0.34111	0.9618	0.3267	0.716
TASC C	0.34810	0.3017	0.5828	0.826
Lesion length, mm	0.00179	0.1892	0.6636	1.001
No. of balloons	0.21726	0.0287	0.8656	0.964

Dose Distribution vs deaths up to 730 days

Deaths by dose category						
PTX dose mg	=<5	5-10	11-15	16-20	>20	total
# deaths	40	27	12	6	5	90
mortality (%)	10.75	9.22	10.17	11.32	11.90	10.25
p-value: 0.6876						

BIOLUX PIII Study

Conclusions

- Superior results of BIOLUX DCB (infra-inguinal-lesions) in 2nd largest DCB-study (n=878; 418 diabetics)
- Superior results in all-comers Diabetics (n=418):
  - ✓ 80.2% Freedom from clinically-driven TLR
  - ✓ 87.5% Freedom from MAE
  - ✓ 87.4% Freedom from major target limb amputations
- In contrast to Katsanos et al, Biolux-DCB-mortality decreases over time
- No late-Paclitaxel effects (increase in mortality over time)

Thank you

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