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70th ESCVS
International congress of the European Society
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7th IMAD meeting

Review on contemporary BTK trials: how to improve current clinical data?

Jos C. van den Berg MD PhD

The reality of RCTs in CLI (DCB and DES)

- Concluded (and published)

- DEBATE BTK
- INPACT DEEP
- BIOLUX PII
- LUTONIX BTK
- ACOART II
- ACOART BTK

- Concluded (and published)

- YUKON
- ACHILLES
- DESTINY

- Recruiting

- SAVAL

PTA vs. BMS

[Intervention Review]

Angioplasty versus stenting for infrapopliteal arterial lesions in chronic limb-threatening ischaemia

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PTA vs. BMS

- Trials show that the immediate technical success rate of restoring luminal patency is higher in the stent group
- No differences in short-term patency at six months between infrapopliteal arterial lesions treated with PTA with stenting versus those treated with PTA without stenting
- No clear differences between groups in periprocedural complications, major amputation, and mortality
- Use of different regimens for pre-treatment and post-treatment antiplatelet/anticoagulant medication and the duration of its use within and between trials may have influenced the outcomes

DES vs. BMS (7 trials)

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REVIEW

PERIPHERAL ARTERIAL DISEASE



The use of drug-eluting stents in infrapopliteal arteries: an updated systematic review and meta-analysis of randomized trials

Ramon L. VARCOE ^{1, 2, 3} *, Sharath C. PARAVASTU ^{1, 4},
Shannon D. THOMAS ^{1, 2, 3}, Michael H. BENNETT ^{2, 5}

DES vs. BMS

- At midterm follow-up DES significantly improved rates of primary patency, re-intervention, Rutherford class improvement and major amputation for the treatment of atherosclerotic disease of infrapopliteal arteries compared to control therapy
- No effect on patient survival
- Stents coated with sirolimus analogues were more effective than paclitaxel

DCB vs. PTA

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PERIPHERAL

Drug-Coated Balloons for Revascularization of Infrapopliteal Arteries

A Meta-Analysis of Randomized Trials



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Sebastian Kufner, MD,^a Ilka Ott, MD,^a Karl-Ludwig Laugwitz, MD,^{d,e} Heribert Schunkert, MD,^{a,e}
Adnan Kastrati, MD,^{a,e} Massimiliano Fusaro, MD^a

DCB vs. PTA

TABLE 1 Main Characteristics of Patients Enrolled Among Trials Included in the Study

Trial (Ref. #)	Patients, n	Age, yrs	Men, %	Diabetes, %	CKD, %	CLI, %	Lesion Length, mm	Diameter Stenosis, %	Severe Calcification, %	Occlusion, %
BIOLUX PII (9)	72	71.3	79	67	28	78	114.1	72.3	5	NR
DEBATE BTK (6)	132	74.5	80	100	11	100	130.0	97.2	27	80
DEBELLUM* (7)	30	66.5	73	52	NR	52	77.0	86.5	18	21
IDEAS (8)	50	71.5	76	70	54	100	137.5	86.0	47	17
IN.PACT DEEP (10)	358	72.5	73	72	11	100	115.0	85.2	21	42

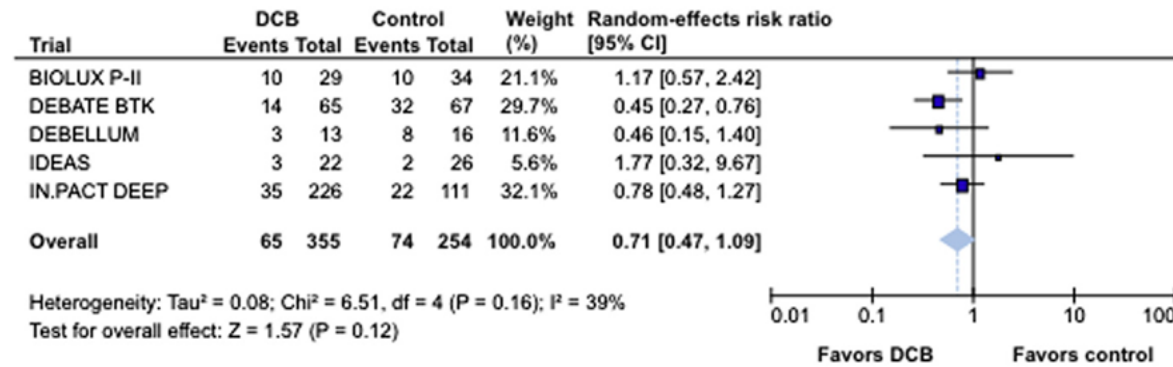
Overall mean values are reported. *Patients presenting with infrapopliteal lesions only.

BIOLUX PII = First-in-Man Study to Compare the Paseo-18 Lux DRB Against POBA in Infrapopliteal Arteries; CKD = chronic kidney disease; CLI = critical limb ischemia; DEBATE BTK = Drug Eluting Balloon in Peripheral Intervention for Below the Knee Angioplasty Evaluation; DEBELLUM = Drug-Eluting Balloon Evaluation for Lower Limb Multilevel Treatment Drug Eluting Stents; IDEAS = Infrapopliteal Drug Eluting Angioplasty Versus Stenting for the Treatment of Long-Segment Arterial Disease; IN.PACT DEEP = IN.PACT Amphirion™ Drug Eluting Balloon vs. Standard PTA for the Treatment of Below the Knee Critical Limb Ischemia; NR = not reported.

DCB vs. PTA

FIGURE 1 Risk Estimates of Target Lesion Revascularization for Drug-Coated Balloon Versus Control Therapy

Target lesion revascularization

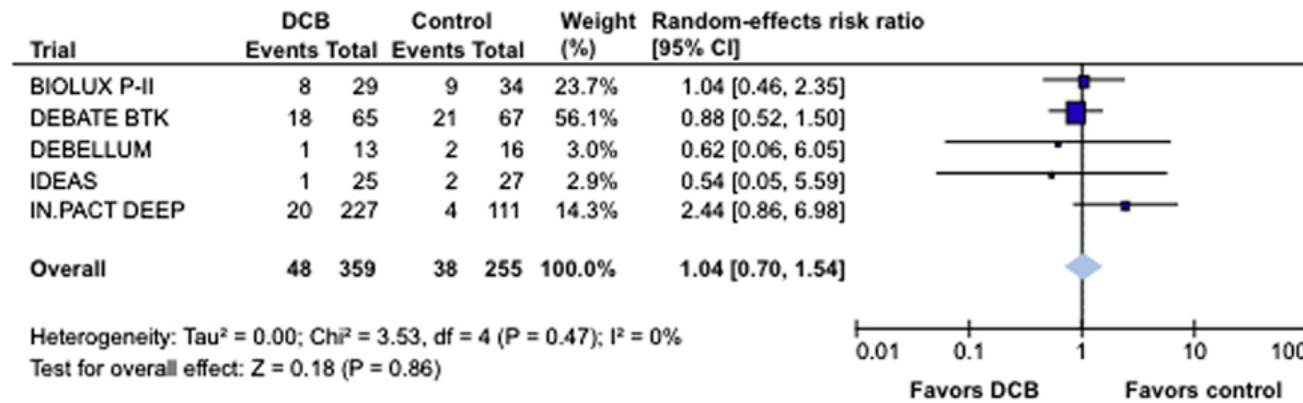


Plots of risk ratio for target lesion revascularization associated with drug-coated balloon (DCB) versus control therapy. The **diamond** indicates the point estimate, and the **left and right ends of the line** indicate the 95% confidence interval (CI). Trial acronyms are defined in [Table 1](#).

DCB vs. PTA

FIGURE 2 Risk Estimates of Amputation for Drug-Coated Balloon Versus Control Therapy

Amputation

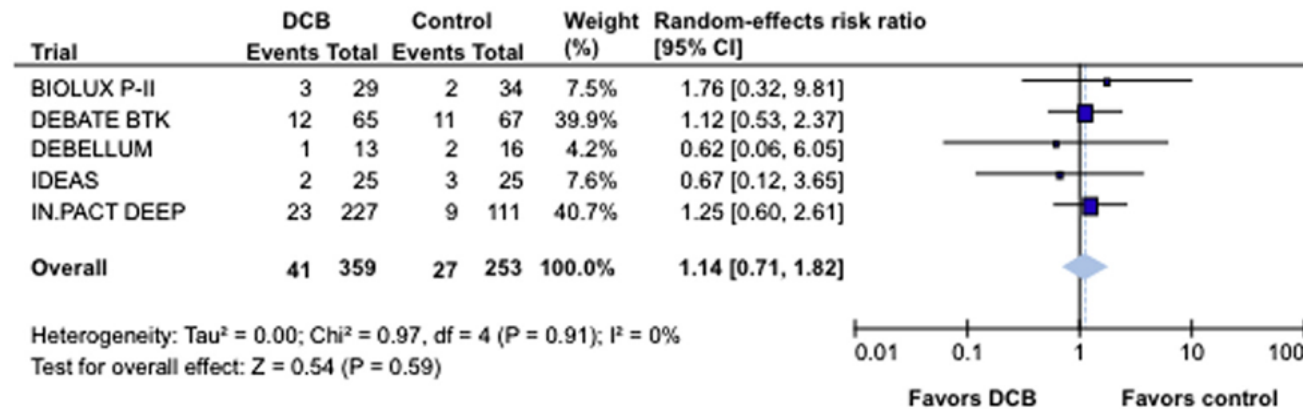


Plots of risk ratio for amputation associated with drug-coated balloon (DCB) versus control therapy. The **diamond** indicates the point estimate, and the **left and right ends of the line** indicate the 95% confidence interval (CI). Trial acronyms are defined in [Table 1](#).

DCB vs. PTA

FIGURE 3 Risk Estimates of Death for Drug-Coated Balloon Versus Control Therapy

Death

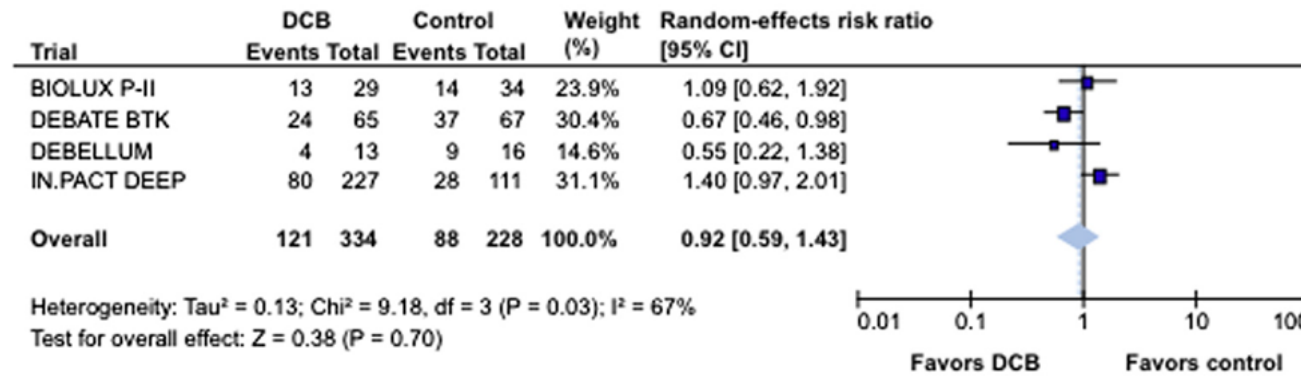


Plots of risk ratio for death associated with drug-coated balloon (DCB) versus control therapy. The **diamond** indicates the point estimate, and the **left and right ends of the line** indicate the 95% confidence interval (CI). Trial acronyms are defined in [Table 1](#).

DCB vs. PTA

FIGURE 4 Risk Estimates of Major Adverse Events for Drug-Coated Balloon Versus Control Therapy

Major adverse events

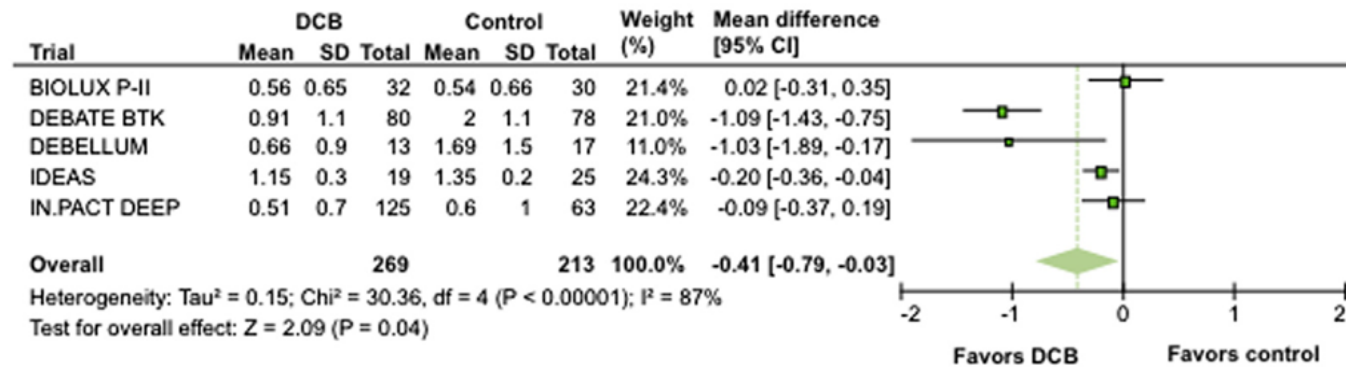


Plots of risk ratio for major adverse events associated with drug-coated balloon (DCB) versus control therapy. The **diamond** indicates the point estimate, and the **left and right ends of the line** indicate the 95% confidence interval (CI). Trial acronyms are defined in [Table 1](#).

DCB vs. PTA

FIGURE 6 Risk Estimates of Late Lumen Loss for Drug-Coated Balloon Versus Control Therapy

Late lumen loss



Plots of weighted mean difference for late lumen loss associated with drug-coated balloon (DCB) versus control therapy. The **diamond** indicates the point estimate, and the **left and right ends of the line** indicate the 95% confidence interval (CI). Trial acronyms are defined in [Table 1](#).

DCB vs. PTA

Eur J Vasc Endovasc Surg (2020) 59, 265–275

SYSTEMATIC REVIEW

Editor's Choice — Drug Coated Balloon Angioplasty vs. Standard Percutaneous Transluminal Angioplasty in Below the Knee Peripheral Arterial Disease: A Systematic Review and Meta-Analysis

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WHAT THIS PAPER ADDS

This systematic review and meta-analysis is an update on the role of drug coated balloons in the endovascular treatment of infrapopliteal arterial disease. Based on the results of this paper no statistically significant differences were found between drug coated balloon angioplasty and standard percutaneous transluminal angioplasty.

- 10 studies (not only RCTs)
- Limb salvage rate DCB 94.0% vs. PTA 95.7%
- Survival rate DCB 89.8% vs. PTA 92.9%
- Restenosis rate (12 months) DCB 32.9% vs. PTA 62.0% (OR 2.87)
- TLR rate DCB 14% vs PTA 27.8% vs. 32.9% (OR 2.76)
- 12 month AFS rate for DCB 82.5% vs. PTA 88.7% (OR 0.79)
- No statistically significant differences

DCB BTK

- Should we give up?
- Two recent studies (ACOTEC)

Meta-analysis



Original Contribution

Drug-Coated Versus Uncoated Percutaneous Transluminal Angioplasty Balloons for the Treatment of Infrapopliteal Peripheral Artery Disease: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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- 10 studies (RCT's only)
- 1479 patients
- DCB use decreased target-lesion revascularization, restenosis or occlusion and late lumen loss
- DCB use increased complete healing and shorter time to healing
- No difference in all-cause mortality, major amputation or amputation-free survival

DES and DCB

Original Manuscript

Systematic Review and Meta-Analysis of Drug-Eluting Balloon and Stent for Intrapopliteal Artery Revascularization

**Jianbin Zhang, MD^{1,2}, Xiaojie Xu, MD², Jie Kong, MD^{1,2},
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Xia Zheng, MD¹, Bo Ma, MD¹, Mingsheng Sun, MSc¹,
Zhidong Ye, MD¹, and Peng Liu, MD^{1,2}**

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DES and DCB

- Compared with standard PTA/BMS, DES may decrease the risk of clinically driven TLR, restenosis rate, and
- amputation rate without any impact on mortality
- DEB has no obvious advantage in the treatment of infrapopliteal disease
- More randomized controlled trials, especially those for DEB, are necessary

PTA/BMS/DES/DCB

Meta-analysis

Comparative Effectiveness of Plain Balloon Angioplasty, Bare Metal Stents, Drug-Coated Balloons, and Drug-Eluting Stents for the Treatment of Infrapopliteal Artery Disease: Systematic Review and Bayesian Network Meta-analysis of Randomized Controlled Trials

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Stavros Spiliopoulos, MD, PhD, EBIR³, Athanasios Diamantopoulos, MD, PhD¹,
and Dimitris Karnabatidis, MD, PhD, EBIR²**

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PTA/BMS/DES/DCB

- Infrapopliteal DES significantly reduced restenosis and TLR compared with BMS and PTA
- DCB reduced TLR compared with PTA and BMS
- DES was the only treatment that significantly reduced limb amputations compared with PTA, DCB or BMS
- DES significantly improved wound healing compared with PTA or BMS

PTA/BMS/DES/DCB

- DES associated with significantly lower rates of restenosis, TLR, and amputations and improved wound healing compared to BA and BMS
- DES significantly reduced amputations compared with DCB

PTA/BMS/DES/DCB



Diagn Interv Radiol 2016; 22:436–443

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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Network meta-analysis of balloon angioplasty, nondrug metal stent, drug-eluting balloon, and drug-eluting stent for treatment of infrapopliteal artery occlusive disease

Yaowen Xiao

PTA/BMS/DES/DCB

- DES is a better treatment with respect to short-term patency and limb salvage rate
- BMS may provide a better technical success.
- DCB and DES are good choices for reducing revascularization

RCTs BTK

- New studies (DCB)-new hope
 - Latest PTX trials
 - Role of –limus drugs; first clinical results registries promising
- Optimal sizing
 - Angiographic analysis after procedure in Lutonix BTK demonstrated a final mean residual stenosis of $29.5 \pm 13.8\%$ in the DCB group and $30.0 \pm 12.8\%$ in the PTA group
- Optimal (and standardized) woundcare

RCTs BTK-keep in mind

- Not compatible with real-world population
 - Positive results with DES (but unrealistic short lesions)
 - No (longterm) positive effects with DCB
- Exclusion of
 - Long lesions
 - Patients with CKD
- Severe recruitment problems in all

Conclusions

- BMS does not provide better results than PTA (with bail-out stenting)
- Various meta-analyses demonstrate a superiority of DES over PTA and BMS for short lesions
- Evaluation of early trials and comparative registries do not demonstrate a benefit of DCB in BTK application
- Latest trials show promising results
- More attention should be paid to optimal sizing and standardization of wound care
- For longer lesions conflicting (and missing) data

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Review on contemporary BTK trials: how to improve current clinical data?

Jos C. van den Berg MD PhD