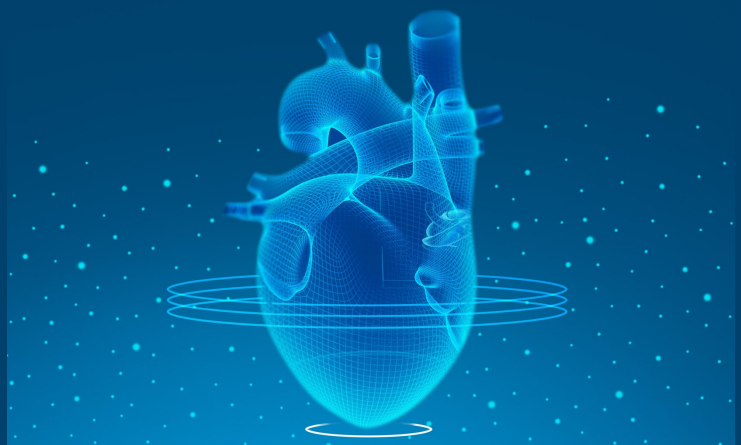
Minneapolis Heart Institute Foundation

GRAND ROUNDS



1

Drug Coated Balloons in CAD Management

Dr. Mishita Goel, PGY-7
Interventional Cardiology Fellow, MHI/HCMC

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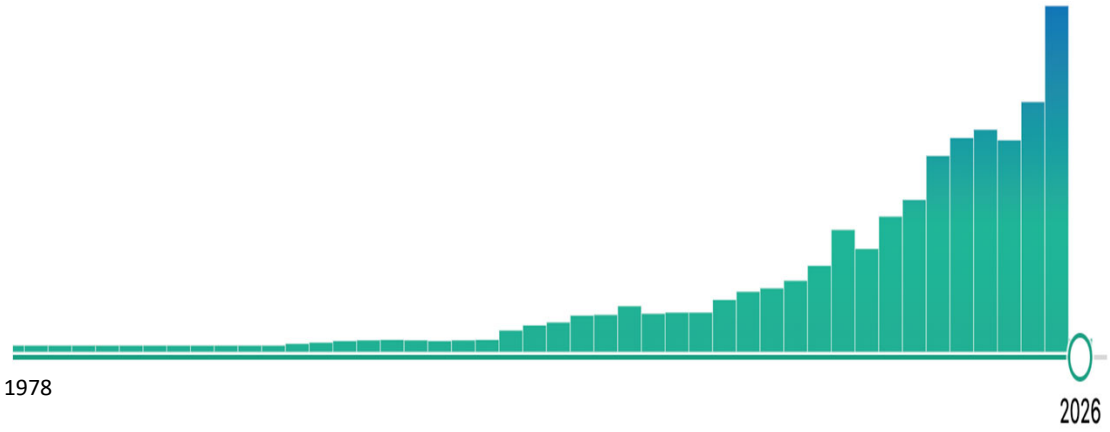
2

DCBs: So Much Evolving Data and Interest!



FROM PUBMED

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3

Learning Objectives

- **Why** DCBs?
  → *Rationale and clinical need*
- **What** are DCBs and what is the evidence?
  → *Mechanism of action and pharmacology, clinical trial data and outcomes across CAD subsets*
- **When** should DCBs be used?
  → *Appropriate patient, lesion, and clinical scenario selection*
- **How** do we use them?
  → *Practical DCB-based strategies in Cath lab*
- **What's next** for DCBs?
  → *Limitations and future directions*

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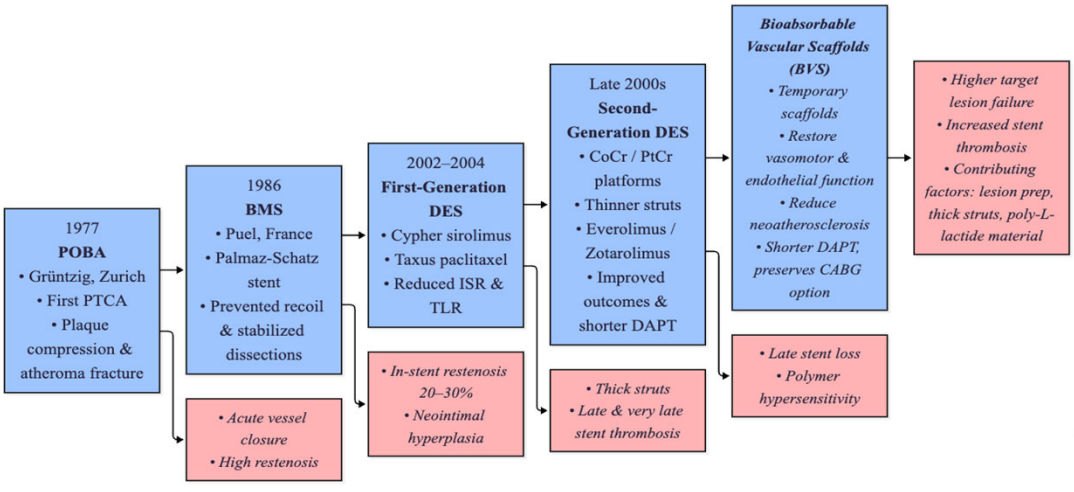
Why DCBs?

- Let's review history!

5

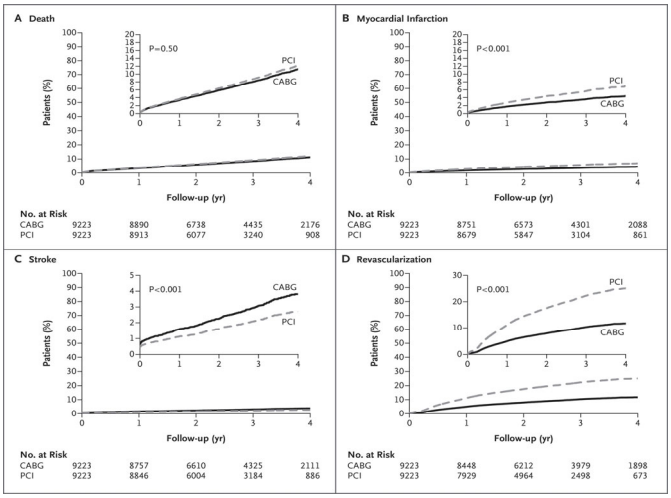
History of PCI



Canfield, John & Totary-Jain, Hana. (2018). 40 Years of Percutaneous Coronary Intervention: History and Future Directions. Journal of Personalized Medicine. 8. 33. 10.3390/jpm8040033.

6

Cumulative Risks of the Study Outcomes in the Matched Cohort.



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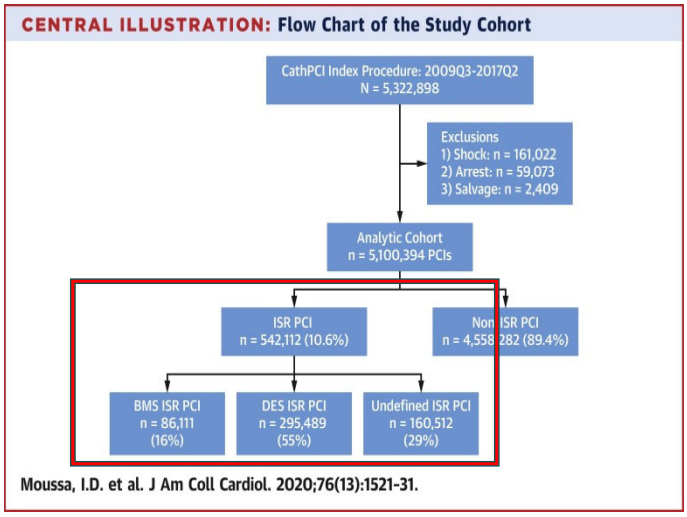
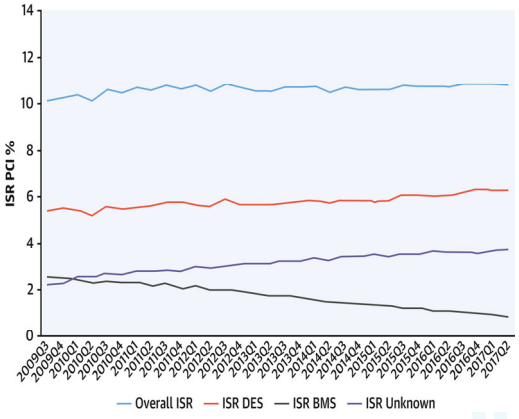
Bangalore S et al. Everolimus-Eluting Stents or Bypass Surgery for Multivessel Coronary Disease N Engl J Med 2015;372:1213-1222

7

~10% of PCI in the US are for ISR





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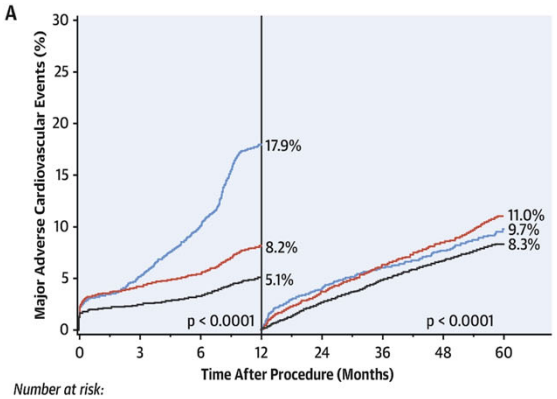
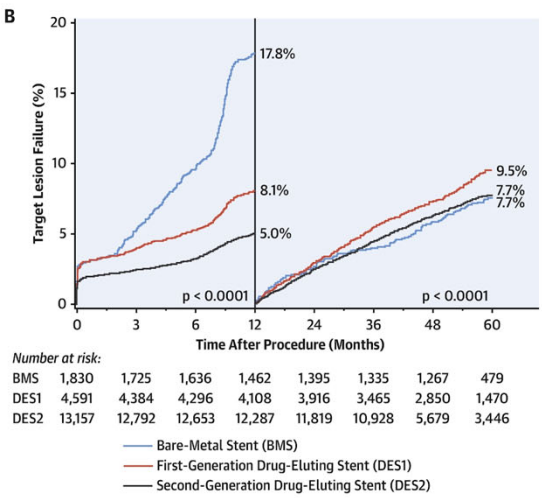
8

Late stent-related CV events (2-3%/yr with all stents)





Madhavan, M.V. et al. J Am Coll Cardiol. 2020;75(6):590-604.

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9

Why DCBs?

Limitations of Permanent Metallic Scaffolds

- Impaired vasomotion and late lumen enlargement
- Vascular inflammation, neoatherosclerosis, and risk of very late stent thrombosis
- Distal lesions limiting future bypass
- Bifurcation lesions with recurrent SB ostium restenosis

Growing interest in a "Leave Nothing Behind" strategy:
Deliver antiproliferative therapy while avoiding long-term limitations of metallic scaffolds

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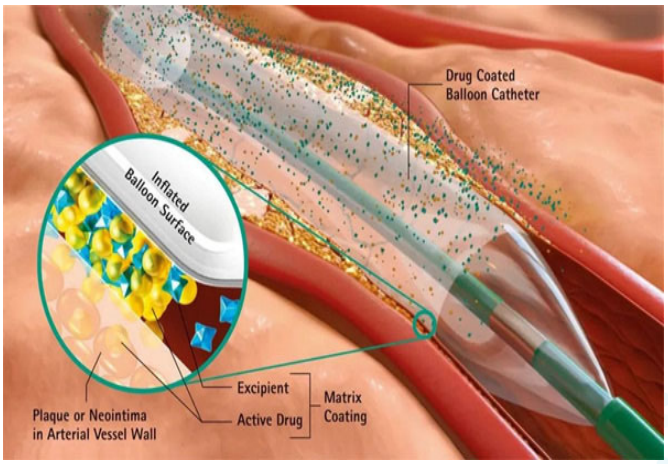
10

What is DCB?

- SC Balloon + Antiproliferative Drug coating + Excipient for facilitating transfer from balloon to the vessel wall
- Drug transferred through single inflation
- Larger surface area with homogeneous drug-to-tissue transfer



Jeger RV, Eccleshall S, Wan Ahmad WA, et al. *JACC Cardiovasc Interv*. 2020;13(12):1391-1402.

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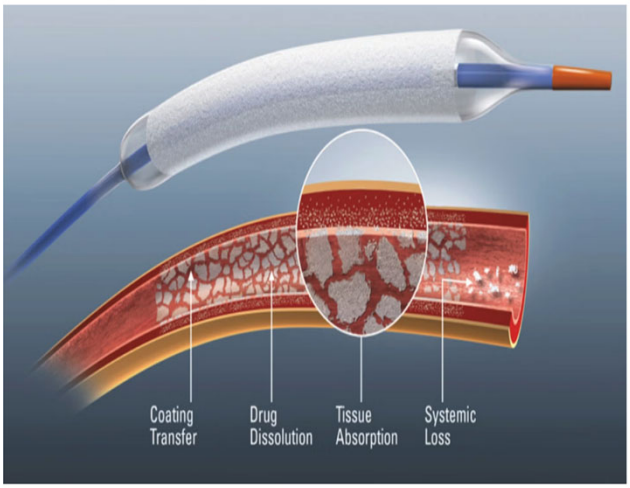
11

DRUG DELIVERY MECHANISM

➢ Excipient: major role in influencing DCB pharmacokinetics

- Drug retention on balloon during transit
- Provides adhesion of the drug to the vessel wall
- Promotes drug deposition in the tissue
- Minimizing particulate release

➢ Excipient characteristics, drug formulation (crystal/amorphous), and coating technology strongly affects DCB performance.



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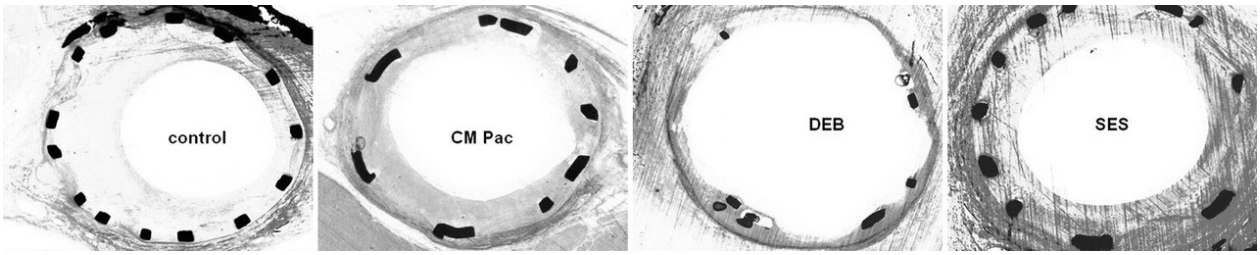
12

Neointima Inhibition: Comparison of Effectiveness of Non–Stent-based Local Drug Delivery and a DES in Porcine Coronary Arteries (2006)



At 4 weeks: Neointimal area significantly lower than all other groups

- **Sustained drug release from a permanent polymer is not necessary for effective neointimal inhibition, rather sustained biological effect despite shorter inflation/exposure.**
- **The mode of drug delivery, rather than the stent itself, is the critical determinant of efficacy.**

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Speck U. Published Online: August 01, 2006 https://doi.org/10.1148/radiol.2402051248

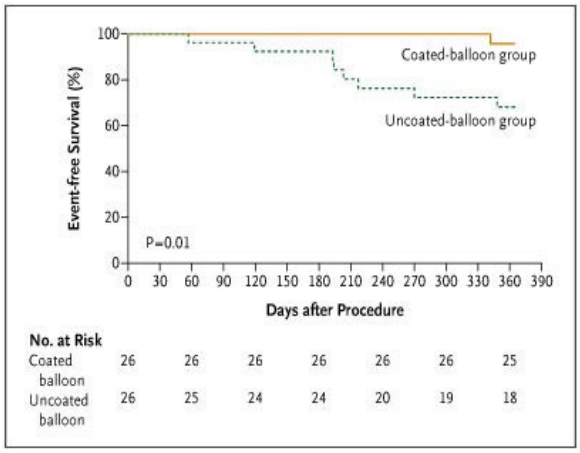
13

First In-Human Trial for coronary ISR (2006)

- 52 patients with ISR enrolled
- PCB vs uncoated balloon

- At 6 months, late luminal loss significantly lower in DCB group
- Lower 1 year MACE driven by lower TLR (none in 12 months f/u for DCB).

Thus, decreased events in recurrent ISR with PCB.



Scheller B, Hehrlein C, Bocksch MD, Rutsch W. *Treatment of Coronary In-Stent Restenosis with a Paclitaxel-Coated Balloon Catheter.*

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14

Antiproliferative drugs on DCBs

Paclitaxel	Sirolimus
Cytotoxic	Cytostatic
Irreversibly binds β-tubulin → stabilizes microtubules → inhibits mitosis	Binds FKBP12-rapamycin domain→ inhibits mTOR signaling
G2/M cell-cycle arrest	G1/S cell-cycle arrest
Promotes VSMC apoptosis & neointima inhibition	Causes reversible cytostasis
Hydrophobic and highly lipophilic → rapid uptake, long retention	**Less lipophilic** → shorter retention
Tissue levels after single DCB inflation	**Requires advanced excipients for sustained delivery** (Phospholipid encapsulation and crystalline coating technologies)
Positive vessel remodeling	

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Drug Coated Balloons and Excipient

DCB Platform	Drug	Drug Dose (µg/mm²)	Excipient / Carrier	Company
Agent™ DCB	Paclitaxel	2.0	Acetyltributylcitrate	Boston Scientific
IN.PACT / Prevail	Paclitaxel	3.5	Urea	Medtronic
SeQuent Please NEO	Paclitaxel	3.0	Iopromide	B. Braun
Restore	Paclitaxel	3.0	Shellac	Cardionovum
Magic Touch	Sirolimus	1.27	Phospholipid	Concept Medical
Selution	Sirolimus	1.0	Cell-adherence technology	MedAlliance
SeQuent SCB	Sirolimus	4.0	BHT	B. Braun
BA9 BCB	Biolimus	3.0	Polyethylene oxide	Biosensors Europe
SirPlux Duo	Sirolimus + Paclitaxel	1.35 / 0.15	Biodegradable nanoparticle	Advanced NanoTherapies

2024 FDA approved

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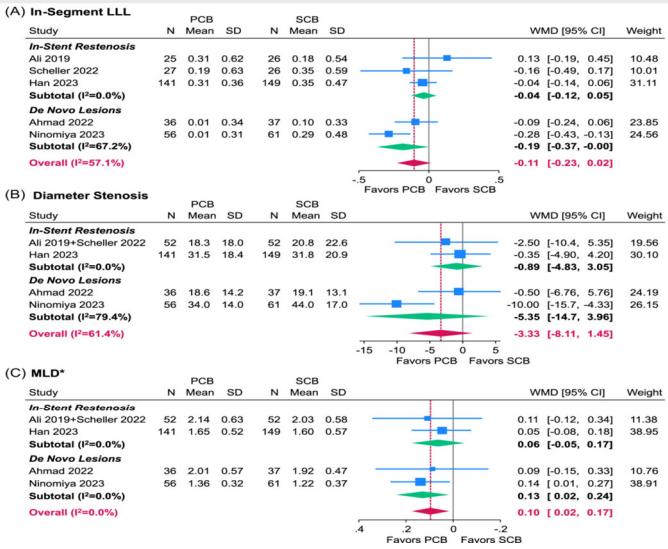
Verde N, et al. Contemporary Use of Drug-Coated Balloons for Coronary Angioplasty: A Comprehensive Review. J Clin Med. 2024;13(20):6243.

16

ANGIOGRAPHIC OUTCOMES (6-9 months follow up)

5 RCTs +
3 Observational studies

N= 1861



Shin D, Singh M, Shlofmitz E, et al. Paclitaxel-coated versus sirolimus-coated balloon angioplasty for coronary artery disease: A systematic review and meta-analysis. *Catheter Cardiovasc Interv*. 2024;104(3):425-436.

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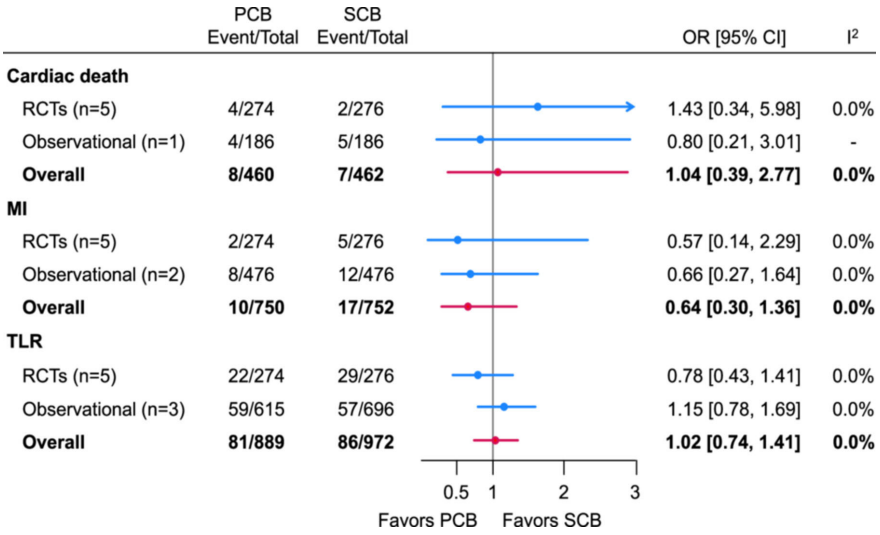
17

CLINICAL OUTCOMES (9-12 months follow up)



Shin D, Singh M, Shlofmitz E, et al. Paclitaxel-coated versus sirolimus-coated balloon angioplasty for coronary artery disease: A systematic review and meta-analysis. *Catheter Cardiovasc Interv*. 2024;104(3):425-436.

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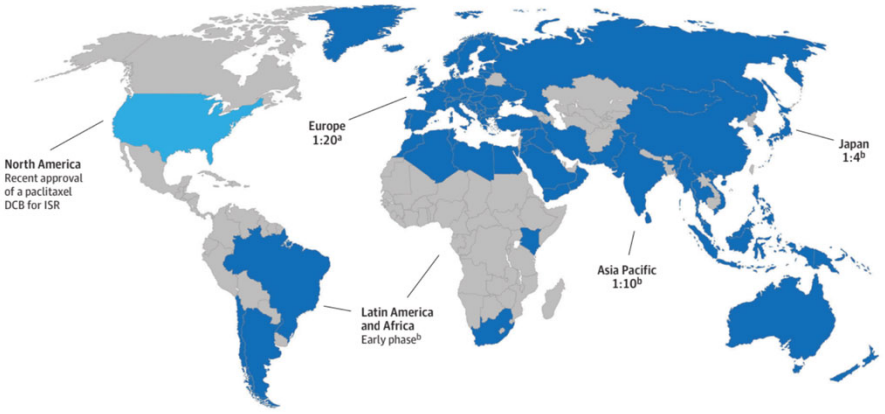
18

Worldwide DCB Use



World distribution of a paclitaxel drug-coated balloon (DCB):drug-eluting stent (DES) ratio for percutaneous coronary intervention (PCI). The map outlines the penetration of a paclitaxel DCB (SeQuent Please [B. Braun]) usage across the globe. Usage of DCB vs DES for PCI is expressed as DCB:DES ratio. Figure readapted from B. Braun Melsungen AG. EUCOMED indicates European database on medical devices; ISR, in-stent restenosis.
[a]EUCOMED-Data Europe, 2022.
[b]EUCOMED-Data, 2022 & Internal Data B. Braun Melsungen AG.

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JAMA cardiology, 2025-02-01, ISSN: 2380-6591, Volume 10, Issue 2, p. 189

19

Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg

All Cause Death at 2 years

Study	Paclitaxel Events	Paclitaxel Total	Control Events	Control Total	RR	95%-CI	Weight (fixed)	Weight (random)
ZILVER-PTX [19]	19	297	7	177	1.62	[0.69; 3.77]	20.8%	20.6%
FINN-PTX [18]	1	23	0	18	2.36	[0.10; 54.68]	1.3%	1.5%
IN.PACT SFA [82]	16	198	1	106	8.57	[1.15; 63.70]	3.1%	3.7%
FEMPAC [29]	7	45	3	42	2.18	[0.60; 7.88]	7.4%	8.9%
LEVANT I [27]	4	49	5	52	0.85	[0.24; 2.98]	11.5%	9.4%
LEVANT II [26]	21	278	7	140	1.51	[0.66; 3.47]	22.1%	21.4%
CONSEQUENT [30]	2	70	1	65	1.86	[0.17; 20.00]	2.5%	2.6%
ILLUMENATE EU [32]	13	199	3	59	1.28	[0.38; 4.36]	11.0%	9.9%
ISAR-STATH [51]	3	48	1	107	6.69	[0.71; 62.66]	1.5%	2.9%
ISAR-PEBIS [55]	3	28	0	29	7.25	[0.39; 134.09]	1.2%	1.7%
ACOART I [40]	8	96	6	95	1.32	[0.48; 3.66]	14.3%	14.2%
IN.PACT SFA JAPAN [41]	4	66	1	29	1.76	[0.21; 15.05]	3.3%	3.2%
Fixed effect model	**1397**		**919**		**1.84**	**[1.27; 2.68]**	**100.0%**	--
Random effects model					**1.68**	**[1.15; 2.47]**	--	**100.0%**

Heterogeneity: I^2 = 0%, τ^2 = 0, p = 0.80

Risk Ratio: 0.01, 0.1, 1, 10, 100

All Cause Death up to 5 years

Study	Paclitaxel Events	Paclitaxel Total	Control Events	Control Total	RR	95%-CI	Weight (fixed)	Weight (random)
THUNDER [57]	12	48	8	54	1.69	[0.75; 3.78]	23.9%	26.9%
ZILVER-PTX [9,19]	42	297	12	177	2.09	[1.13; 3.85]	47.7%	46.3%
IN.PACT SFA [10,66]	24	184	7	103	1.92	[0.86; 4.30]	28.5%	26.8%
Fixed effect model	**529**		**334**		**1.94**	**[1.28; 2.96]**	**100.0%**	--
Random effects model					**1.93**	**[1.27; 2.93]**	--	**100.0%**

Heterogeneity: I^2 = 0%, τ^2 = 0, p = 0.92

Risk Ratio: 0.5, 1, 2

- Dose of Paclitaxel (>100mcg on Taxus stents)
- Crystalline paclitaxel formulation (longer t1/2)
- FDA issued letter of caution and convened a public advisory committee meeting in 2019

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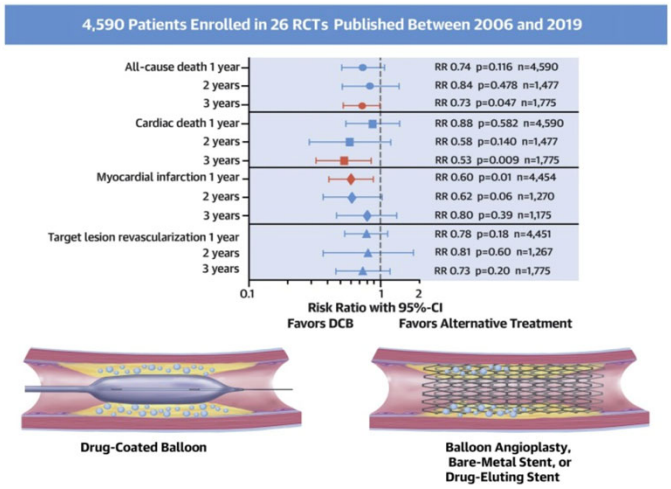
Katsanos K, Spiliopoulos S, Kitrou P, Krokidis M, Karnabatidis D.. *J Am Heart Assoc.* 2018;7(24):e011245.

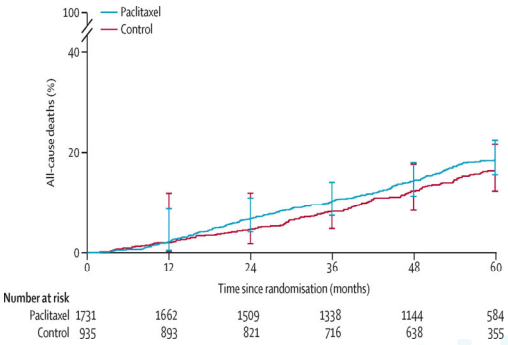
20

Survival after PCI with Paclitaxel DCB for coronary ISR or de-novo lesions



Scheller, B. et al. J Am Coll Cardiol. 2020;75(9):1017-28.

The 5-year cumulative incidence of all-cause death for Fem-pop interventions



Parikh SA, Schneider PA, Mullin CM, Rogers T, Gray WA. *Lancet*. 2023;402(10415):1848-1856.

The ARC position statement (2025) confirmed that paclitaxel tissue levels achieved with DCBs (50-60 ng/mg initially, declining to 2-10 ng/mg after 1 week) are well below the 100 ng/mg threshold at which cytotoxic effects are observed.

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21

When and how should DCBs be used?

1. In stent restenosis
2. Denovo disease : small vessels, bifurcations, diffuse disease
3. Chronic total occlusions
4. Acute coronary syndrome
5. Diabetics
6. High bleeding risk patients

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INDICATIONS

1. IN-STENT RESTENOSIS

-Strongest evidence

-Multiple trials

-Superior to POBA and comparable with DES

AGENT-IDE TRIAL (JAMA 2024):

600 patients with ISR

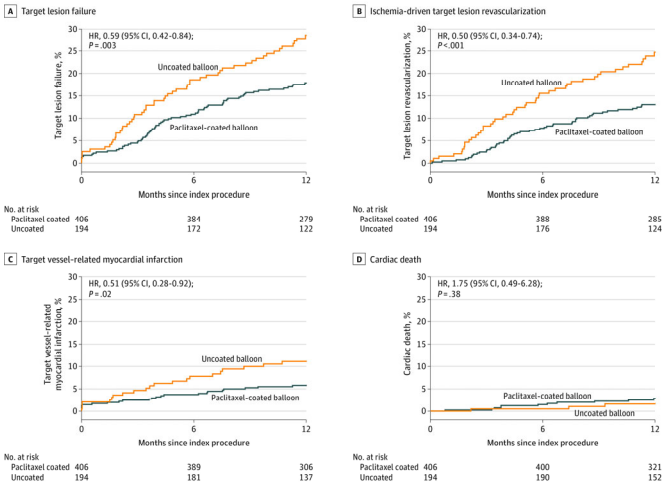
PCB vs uncoated balloon

Lesion length <26 mm and RVD 2-4 mm)

40 centers across the US (2021-2022)

Primary end point of 1-year TLF (composite of B,C,D)

RRR for TLF : 41% (NNT =9 pts)



Yeh RW, Shlofmitz R, Moses J, et al. Paclitaxel-Coated Balloon vs Uncoated Balloon for Coronary In-Stent Restenosis: The AGENT IDE Randomized Clinical Trial. *JAMA*. 2024;331(12):1015-1024. doi:10.1001/jama.2024.1361

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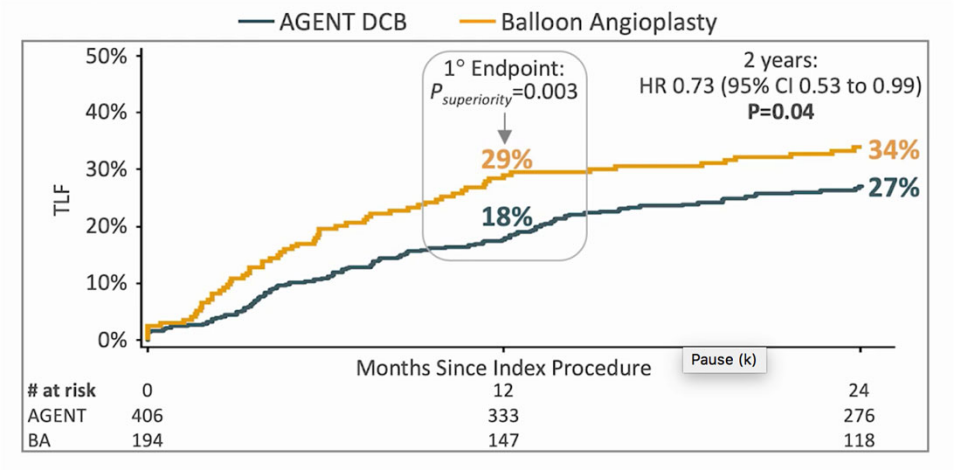
23

AGENT IDE: TLF - 2 years



Moses JW. CRT 2025

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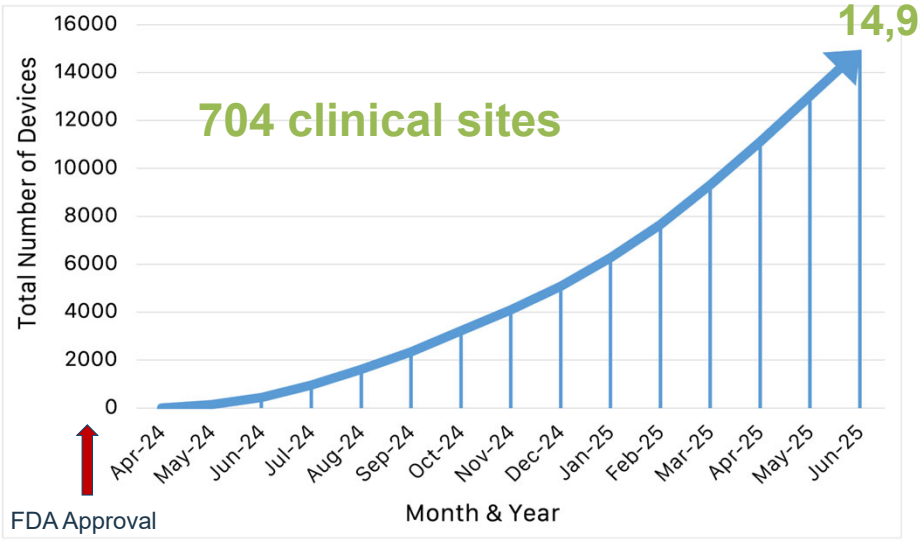
24

AGENT Use in CathPCI Registry Since FDA Approval



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Lalani C. et al. TCT 2025

25

DCB for ISR

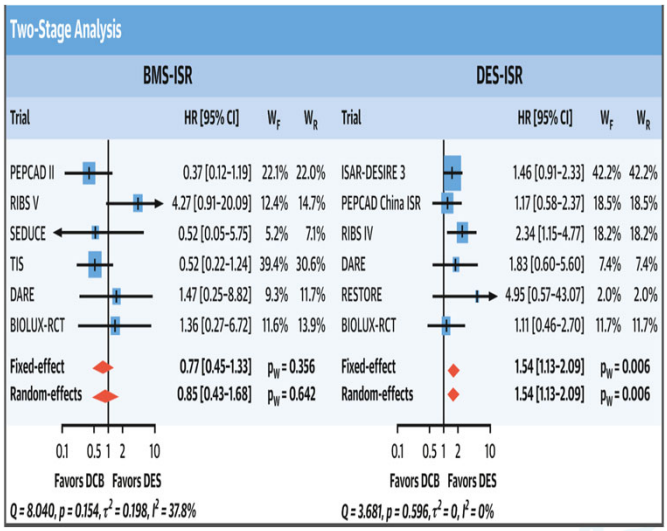
DAEDALUS meta-analysis of 10 RCTs (JACC 2020)

- **1,976 patients** with coronary ISR
- DCB vs DES
- **TLR at 3 yrs**
- No difference in safety endpoint (composite of all-cause death, MI, or target lesion thrombosis) at 3 yrs

ESC Guidelines

2018 Revascularization:
DCBs for ISR after **BMS and DES** (Class I)

2024 CCS
DES preferred over DCB for **DES-ISR** (Class I)



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Giacoppo D, Alfonso F, Xu B, et al. *J Am Coll Cardiol.* 2020;75(21):2664-2678.

26

DCB ARC Position statement on Indications for ISR

- **Imaging + optimal lesion prep essential!!**
- DCB first approach, particularly for pts with multiple prior stents, ISR in small vessels or bifurcation stents.
- Additional DES layer reserved if DCB fails.
- Repeat DES suitable for DES ISR in large vessels or if failure d/t late neo-atherosclerosis

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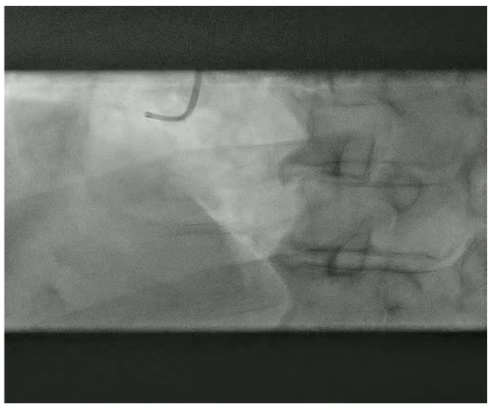
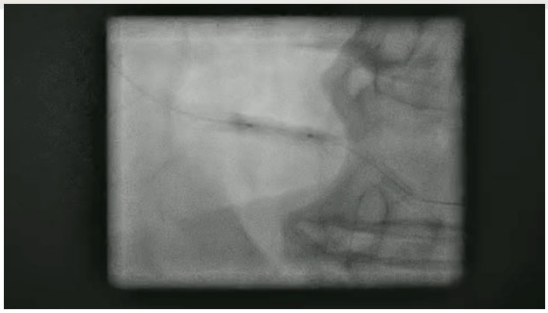
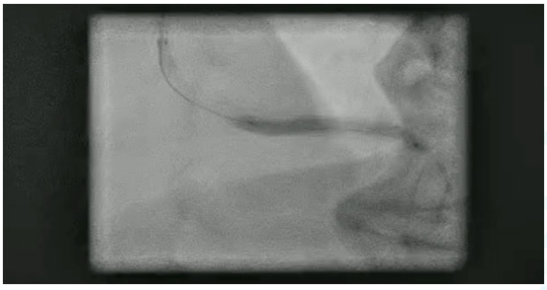
Fezzi S, Serruys PW, Cortese B, et al. Indications for use of drug-coated balloons in coronary intervention: Academic Research Consortium position statement. *J Am Coll Cardiol.* 2025;86(15):1170-1202.

27

Case: 64 yoM h/o dRCA PCI (2 layers of DES), recurrent ISR treated with POBA/DCB, abnormal PET w/ inferior ischemia due to persistent angina while on 3 antianginals







IVUS > cutting balloon 3.5 x 12 mm unable to cross > Guideliner > NC f/b scoring 3 x 12mm > cutting > DCB 3.5 x 30mm for 66 sec

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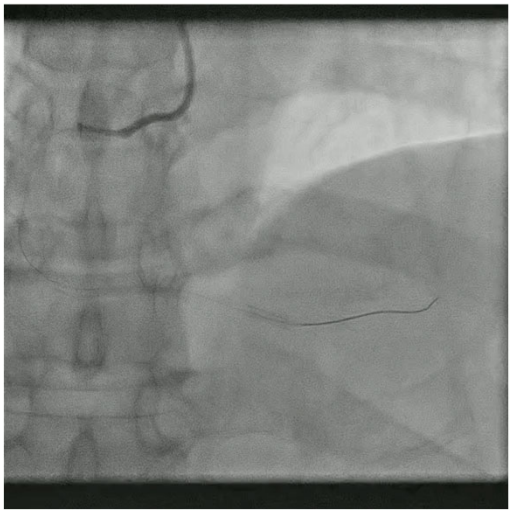
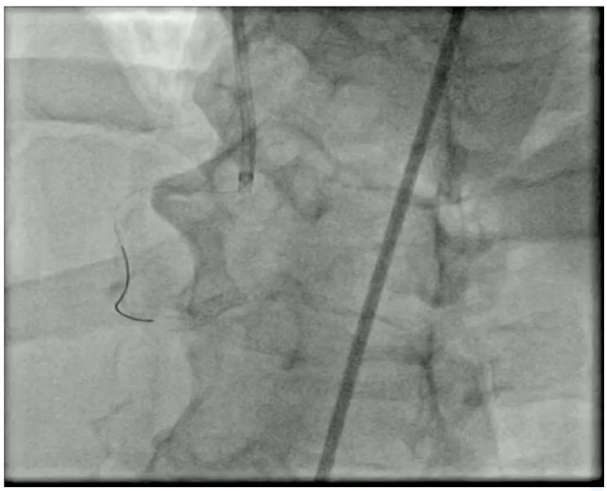
28

Final angio following DCB



Angio after 6 weeks



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3 month f/u visit recently: no complaints

29

FUTURE DIRECTIONS

- AGENT IDE (Active)
- PREVAIL GLOBAL (Medtronic): Recruiting
- MAGICAL ISR (MagicTouch Sirolimus- Coated Balloon): Recruiting

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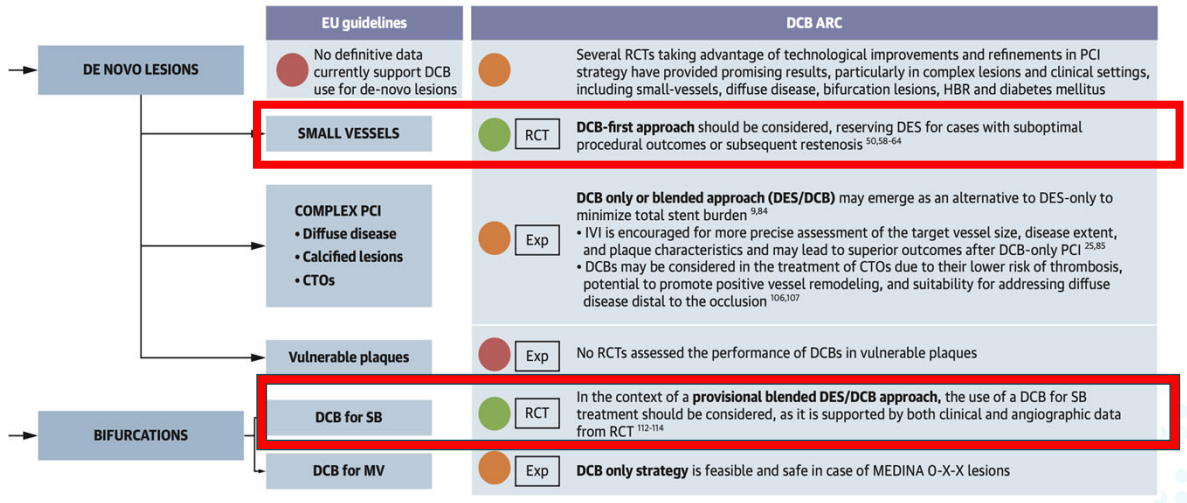
30

2. DE NOVO LESIONS



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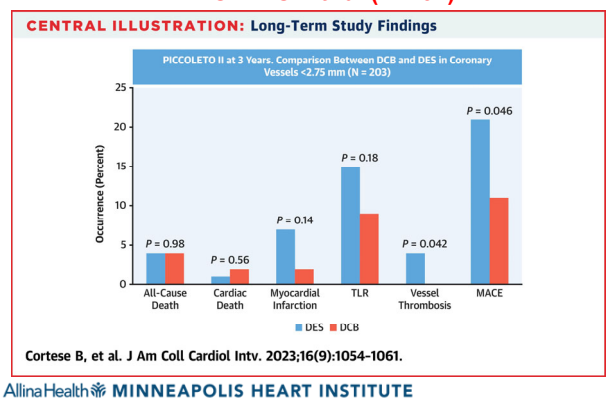
Fezzi S, Serruys PW, Cortese B, et al. Indications for use of drug-coated balloons in coronary intervention: Academic Research Consortium position statement. *J Am Coll Cardiol.* 2025;86(15):1170-1202.

31

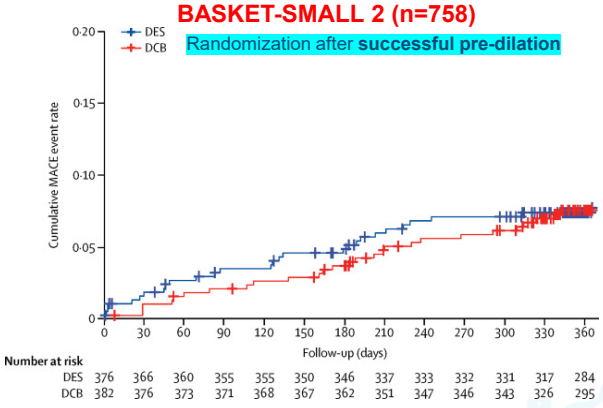
2a. De novo Small Vessel Disease (SVD)

- Higher risk of ISR
- RVD <2.75mm used in most RCTs
- **DCB vs newer gen DES**
- **3 year follow ups:** efficacy & safety comparable or superior

PICCOLETO II trial (n=232)



BASKET-SMALL 2 (n=758)



Jeger RV, Farah A, Ohlow MA, et al. Lancet. 2018;392(10150):849-856.

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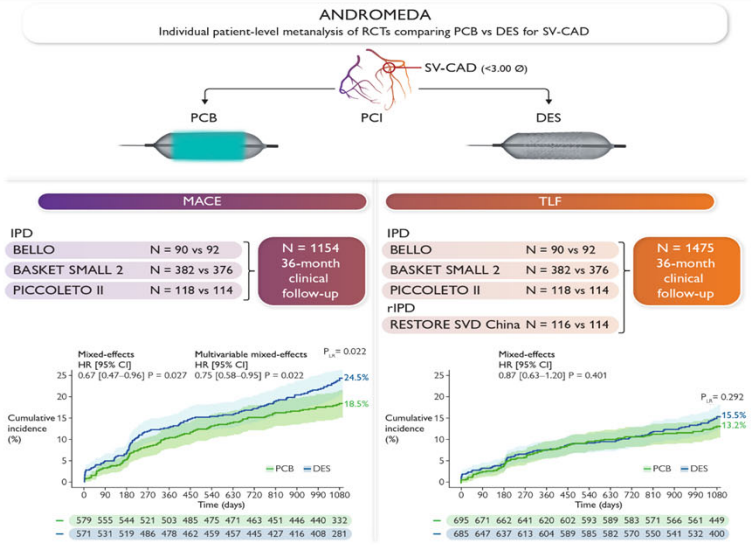
32

2a. De novo Small Vessel Disease (SVD)



In summary, treating SVD with an initial DCB strategy reasonable, with DES use reserved for suboptimal procedural outcomes or subsequent restenosis.

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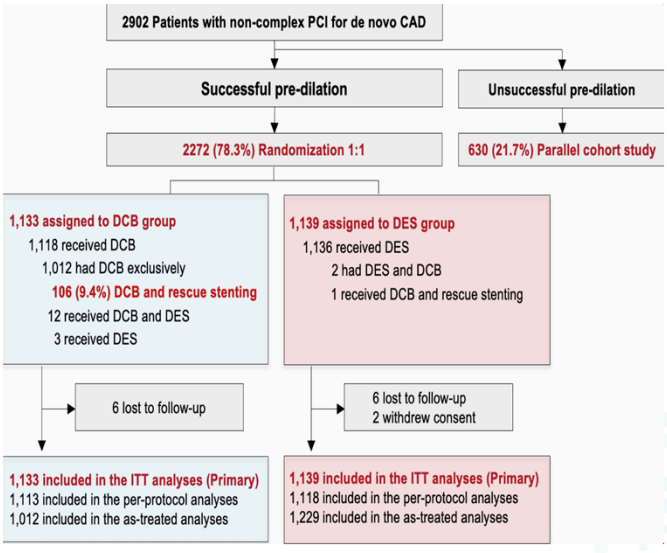
Fezzi S. et al. Eur Heart J. 2025 46:1586-1599

33

2b. DENOVO large vessels

REC CAGEFREE I

- Chinese open-label, randomized non-inferiority trial
- 2,272 patients irrespective of vessel diameter
- After successful lesion preparation, 1:1 randomized to the **Swide PCB** (balloon coated with a mixture of paclitaxel and iopromide) with rescue stenting VS **Intended 2nd gen SES**



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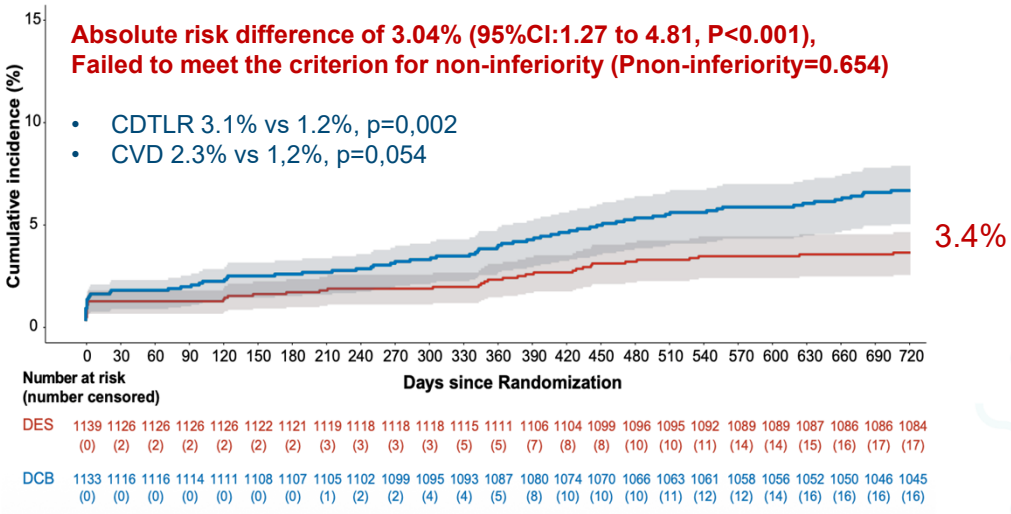
Gao C. et al. Lancet 2024; 404: 1040–50

34

REC CAGEFREE I
Device Oriented Composite Endpoint (DOCE) @2y

Absolute risk difference of 3.04% (95%CI:1.27 to 4.81, P<0.001),
Failed to meet the criterion for non-inferiority (Pnon-inferiority=0.654)

- CDTLR 3.1% vs 1.2%, p=0,002
- CVD 2.3% vs 1,2%, p=0,054



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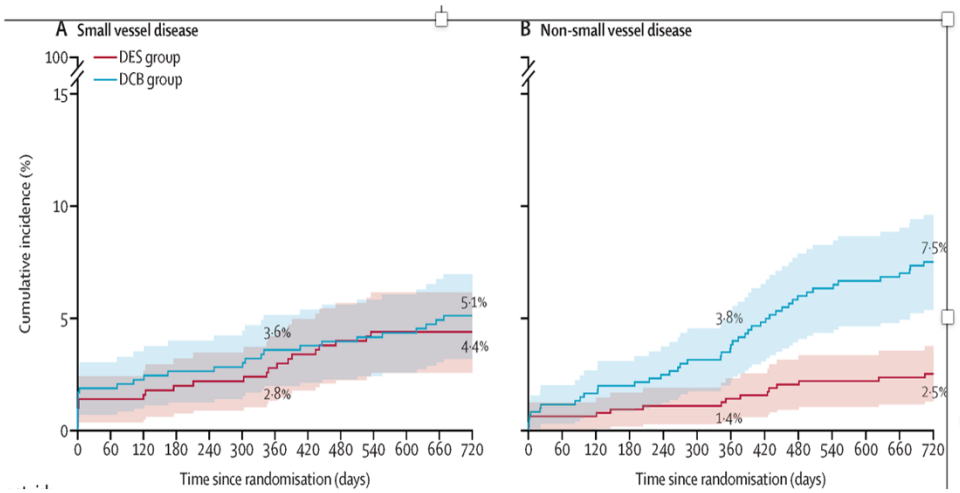
Gao C. et al. Lancet 2024; 404: 1040–50

35

REC CAGEFREE I
DOCE at 2yrs



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Gao C. et al. Lancet 2024; 404: 1040–50

36

SELUTION DeNovo – Study Design

Prospective, randomized, open label, multicenter, non-inferiority trial

Candidates for PCI who satisfied trial inclusion / exclusion criteria — **N = 3,341**

↓

Randomized 1:1 BEFORE PROCEDURE

SELUTION DEB Strategy	**DES Strategy**
Lesion preparation & SELUTION DEB	DES according to local practice
Provisional DES if needed	*Other devices only if failure to deliver DES*

First Co-Primary endpoint = non-inferiority for TVF* at 1 year

Second Co-Primary endpoint = non-inferiority for TVF at 5 years
Conditional superiority analysis if non-inferiority established

*TVF: target vessel failure, a composite of cardiac death, target vessel related MI and clinically driven target vessel revascularization

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Spaulding C, Krackhardt F, Bogaerts K, et al. *Am Heart J*. 2023;258:77-84. doi:10.1016/j.ahj.2023.01.007

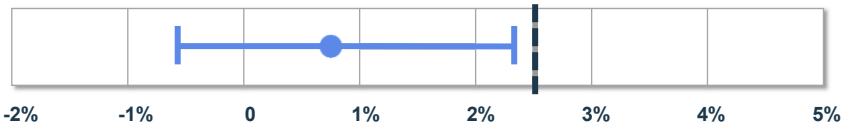
Late-breaking science from TCT 2025

37

Primary Endpoint Results: TVF (CVD, MI and TVR) at 1-Year

DES Strategy (N = 1,662)	SELUTION DEB Strategy (N = 1,661)	Risk Difference: 0.91%	*P*-value non-inferiority
4.4%	5.3%	Upper 2-sided 95% CI: 2.38%	0.02

Non-inferiority Margin = 2.44%



Non-inferiority Met

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Late-breaking science from TCT 2025

38

2b. DENOVO large vessels

Emerging data is promising but long-term outcomes needed

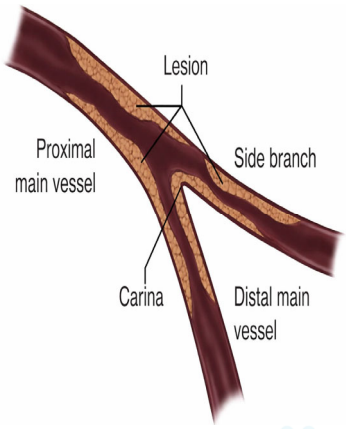
- **SELUTION DeNovo** 5 yr results
- **TRANSFORM II trial** : SEB (Magictouch)

Enrollment completed last yr, results pending

- **AGENT DCB STANCE:** Safety and Effectiveness of PCB vs DES for de Novo Coronary Lesions (NCT06959524): recruiting

2c. Bifurcations

- **Avoids carina shift**
- Studies support DCB use for SB in the context of provisional MV stenting
- Limited evidence on timing and sequence for DCB use in bifurcation PCI, and LM bifurcation (concern with KBI, and DCB use after DES of MV)



Technical tips:

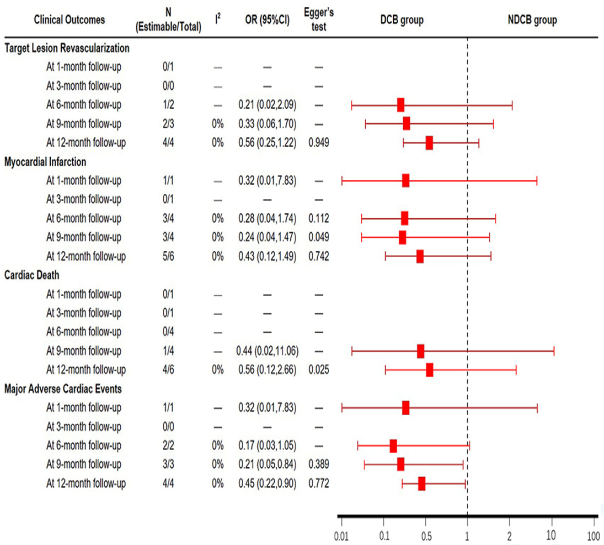
- Sequential DCB inflations instead of kissing balloons to prevent drug loss.
- Treat SB before MV stenting if feasible.
- Adequate lesion prep (<30% residual stenosis) required for DCB success.

Fezzi S, Scheller B, Rissanen TT, et al. Drug-coated balloons for coronary bifurcation lesions. EuroIntervention. 2025;21(20):e1177-e1197.

2c. Bifurcations

Key Trials & Evidence

- **DCB-BIF (landmark RCT, 784 pts, JACC 2024):**
  - SB DCB vs SB NC balloon after MV stenting
  - Reduced 1-year MACE (7.2% vs 12.5%, p=0.013)
- **Meta-analysis in 2021 by Zhen et al** (5RCTs, 5 observational studies, 934 pts)
  - DCB vs NCB (SB protection in de novo bifurcation
  - Lower MACE (TLR, MI and CD) at 9 and 12-mon f/u.
  - Angiographic outcomes with DCB: Less LLL, diameter stenosis(DS) and Binary restenosis (DS of at least 50%) and the higher MLD



Zheng Y, Li J, Wang L, et al. Effect of drug-coated balloon in side branch protection for de novo coronary bifurcation lesions: A systematic review and meta-analysis. *Front Cardiovasc Med*. 2021;8:758560.

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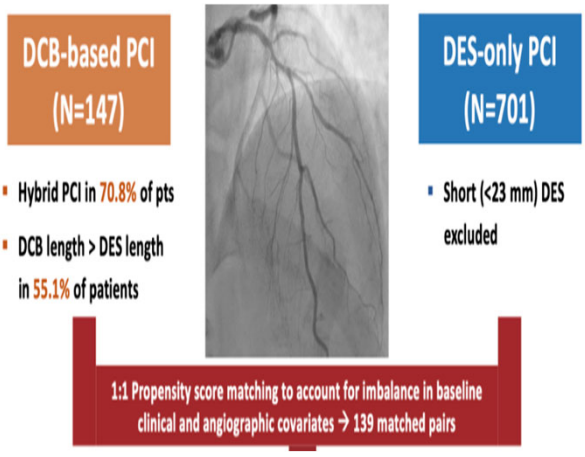
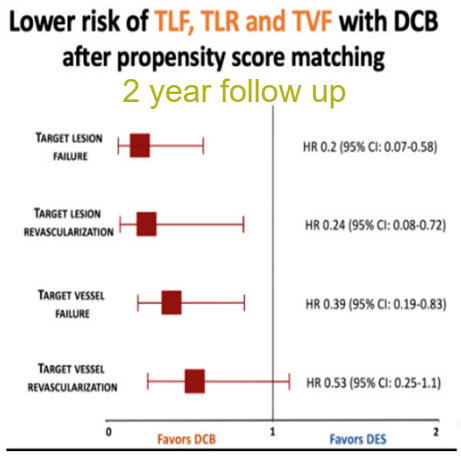
41

2c. Diffuse disease (Observational data mostly)





Gitto M, Sticchi A, Chiarito M, et al. Drug-coated balloon angioplasty for DE Novo lesions on the left anterior descending artery. *Circ Cardiovasc Interv*. 2023;16(12):e013232.

- **Another HYPER Study (Italy, 2024), N=106**
  - DeNovo diffuse ds w/ Hybrid strategy
  - 1 yr improved angiographic outcomes

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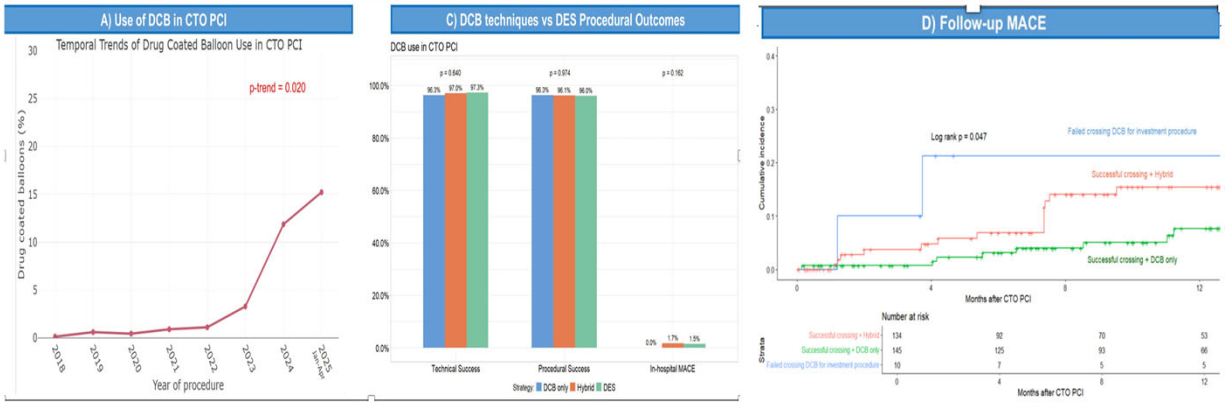
42

3. Chronic total occlusions (CTO)

PROGRESS-CTO Registry: Impact of Drug-Coated Balloon use in CTO PCI Among 13,874 Patients in 2018 to 2025 DCB=454



Mutlu D, Rempakos A, Strepkos D, et al. *Catheter Cardiovasc Interv*. 2025;106(7):3783-3795. doi:10.1002/ccd.70240

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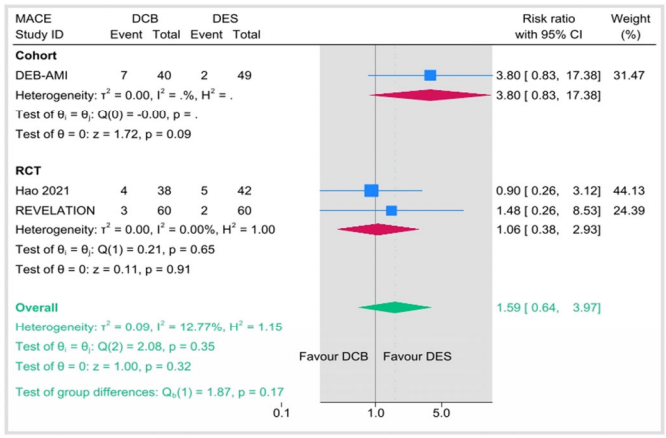
The **Co-CTO trial** (NCT04881812) will be the first RCT exploring a hybrid strategy.

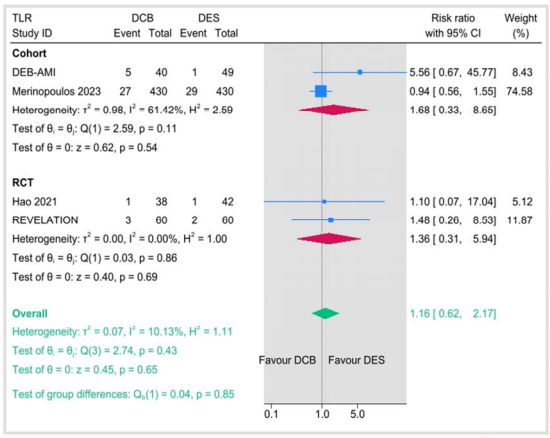
43

4. Acute Myocardial Infarction

MACE



TLR



Also, no significant diff in MI, cardiac death and follow up angiographic outcomes.

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Elbeny AM et al. CCI 2025

44

5. CLINICAL CONDITIONS

➢**DIABETES MELLITUS**

- Associated with diffuse disease, restenosis, and impaired healing after DES
- Trials and registries show **comparable TLR and MACE**

➢**HIGH BLEEDING RISK**

- DCB PCI allows **shorter DAPT (1 month but not specifically studied)**
- **DEBUT Trial** (DCB superior to BMS in HBR pts)
- **Similar ischemic outcomes vs DES** with reduced bleeding exposure

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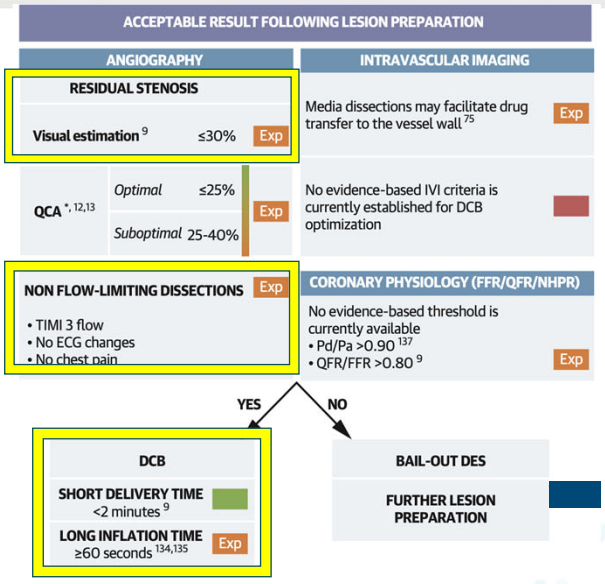
45

DCB-ARC (Lesion prep for DCB success)

OPTIMAL LESION PREP BEFORE DCB

- Standard balloon 1:1 distal RVD
- Long inflations (>30 sec) recommended
- Intravascular imaging for plaque morphology and sizing.
- Specialty balloons recommended to improve lesion prep.
- Calcium debulking in case of mod-severe calcified lesions. Expert Panel Consensus



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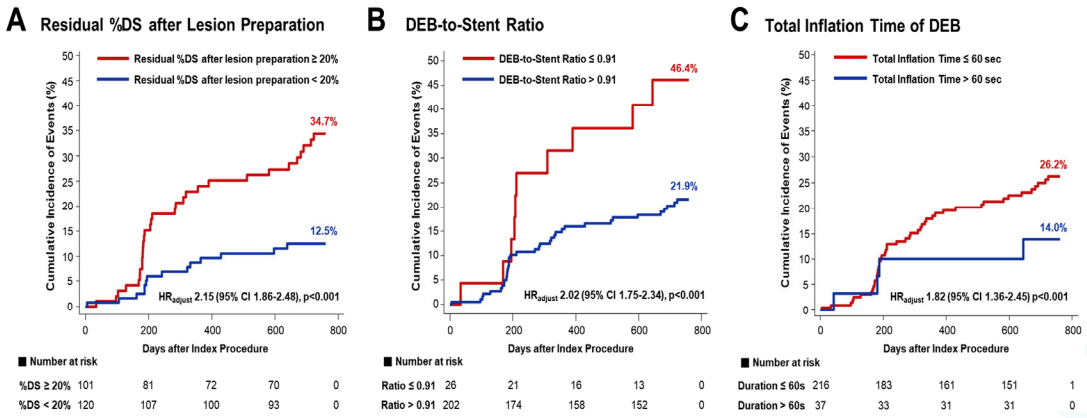
Fezzi S. et al. J Am Coll Cardiol. 2025;86:1170-1202

46

Cumulative Incidence of TLF according to procedure related factors



N-256
DES ISR pts treated with DEB
4 centers in Korea

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Rhee, T, et al. JACC: Cardiovascular Interventions 11.10 (2018): 969-978

47

REIMBURSEMENT FOR DCBs

AGENT DCB - U.S. Medicare Updates

OPPS (Outpatient):

- **Transitional Pass-Through (TPT)** (*Effective Jan 1, 2025)*
- Separate device reimbursement for coronary DCBs as innovative Rx

*Effective January 1, 2026, U.S. CMS has updated the APC assignment to **Level 3***
*For **CPT 0913T** for DCB PCI procedures under the OPPS.*

IPPS (Inpatient):

New Technology Add-on Payment (NTAP) *(Effective Oct 1, 2025)*

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Courtesy of Boston Scientific

48

Take-Home Messages

- DCBs are not just POBA with drug.
- **Optimal Lesion prep is critical!!**
- **NOT A CLASS EFFECT:** study design and device specifics
- Strong evidence for ISR (& even DeNovo SVD) and data is encouraging for other indications.
- More data on long term outcomes needed for expanding indications.

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49

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- **Dr. Yader Sandoval**
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50


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51