



Drug-Coated Balloons in Acute Coronary Syndromes

The "Leave Nothing Behind" Strategy — Evidence, Pros & Cons
2025–2026 Update

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What Are Drug-Coated Balloons?

Technology, mechanism & drug types

2

Rationale for DCB in ACS

Why consider a stentless approach?

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Key Clinical Trials

REVELATION, PEPCAD NSTEMI, BASKET-SMALL 2, DCB-ACS

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Pros of DCB in ACS

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Sirolimus vs Paclitaxel DCB

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Key Numbers

758

Patients in
BASKET-SMALL 2

120

Patients in
REVELATION (STEMI)

5 yr

Follow-up showing
DCB = DES outcomes

45%

Bailout stent rate
in PEPCAD NSTEMI

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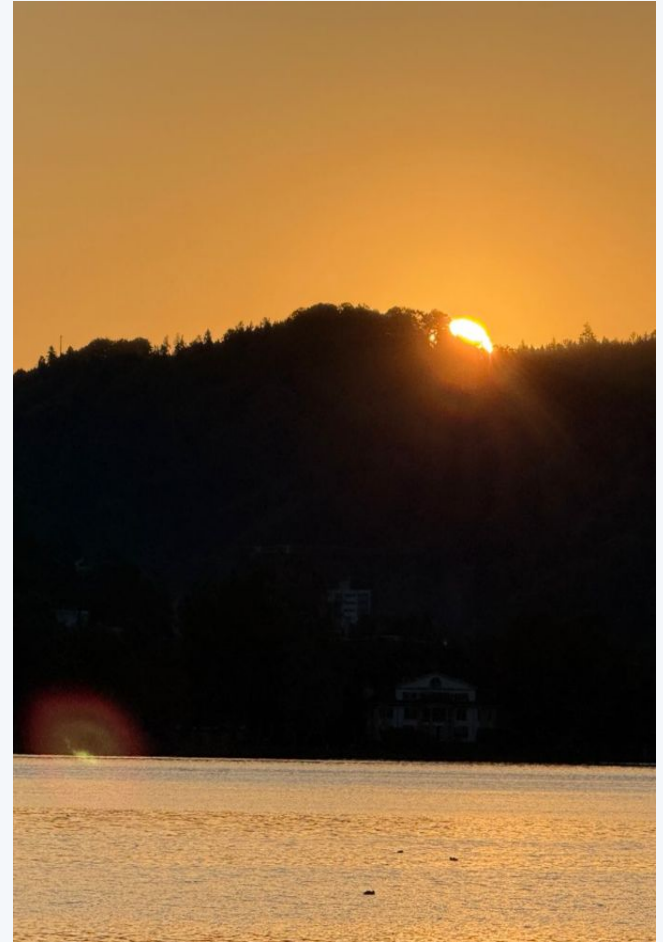
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What Are Drug-Coated Balloons?



Technology Overview

Semi-compliant angioplasty balloons coated with a lipophilic antiproliferative drug matrix

Deliver drug directly into vessel wall during a single brief inflation (30–60 sec)

"Leave nothing behind"

Drug inhibits smooth muscle cell proliferation for 7 days to 3 months, preventing restenosis



Drug Types

Paclitaxel-Coated (1st Gen)

Binds irreversibly to microtubules. High lipophilicity = rapid tissue uptake. Most clinical evidence. Dose: $\sim 3 \mu\text{g}/\text{mm}^2$

Sirolimus-Coated (Next Gen)

mTOR inhibitor with anti-inflammatory properties. Lower lipophilicity — requires nanocarrier technology. Emerging evidence (SIBLINT-ISR, SPACIOUS).



Excipients (iopromide, urea, butylated hydroxytoluene) are critical — they control drug adhesion, transfer, and coating uniformity.

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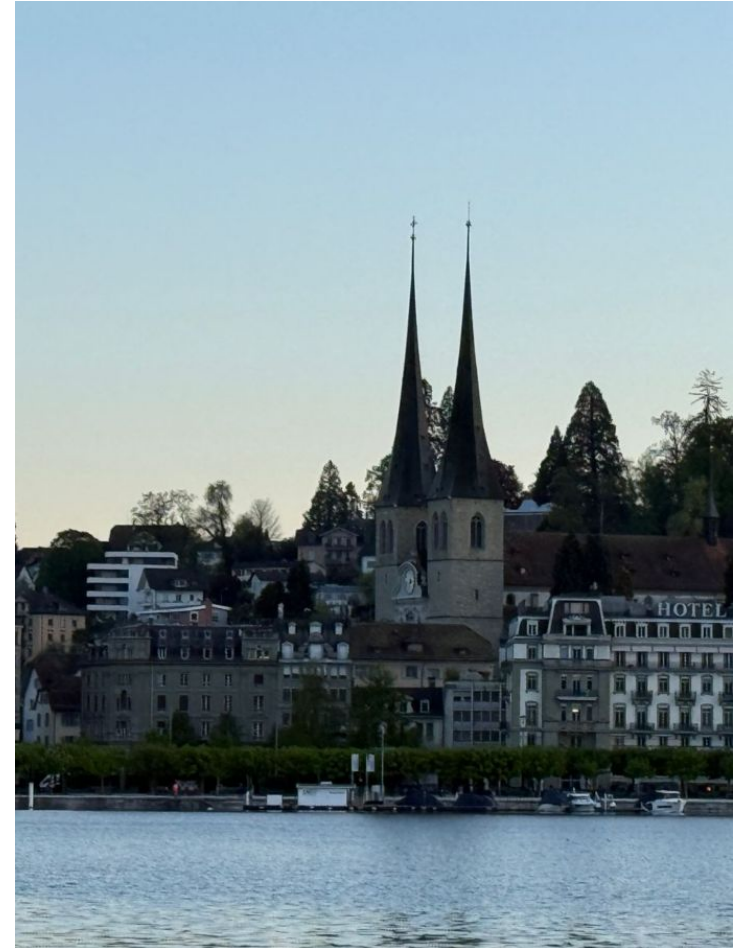
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Why Consider DCB in ACS?

Thrombotic Milieu

- ACS lesions are thrombus-rich.
- Malapposition risk,
- late stent thrombosis, and
- no-reflow phenomenon.

DAPT Burden

- Prolonged dual antiplatelet therapy (6–12 months)
- DCB : shorter DAPT,
- High bleeding risk patients.

Vessel Healing

- No permanent scaffold
- Allows positive vessel remodeling,
- Preserved vasomotion
- No chronic inflammation.

Future Options

- No in-stent restenosis (possible in segment Restenosis)
- Easier re-access for future PCI
- preserved surgical options for CABG.

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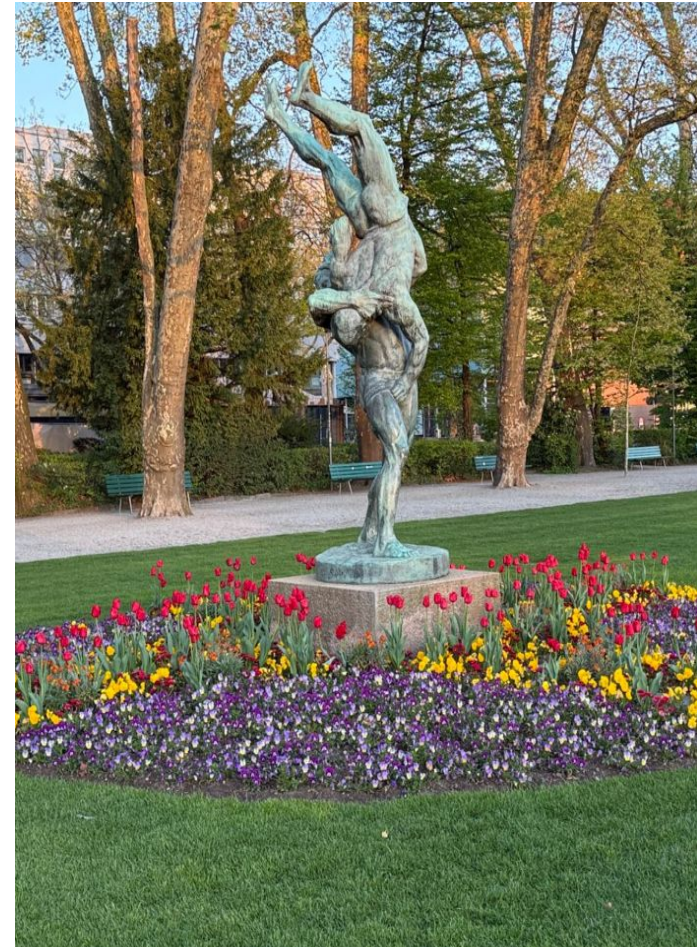
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Overview of Evidence

STEMI / Primary PCI

- REVELATION (2019)
- PAPPa (Pilot)
- DEBUT (2019)

NSTEMI / Unstable Angina

- PEPCAD ACS (2014)
- AGENT IDE (2024) ★

Small Vessel / Subgroups

- BASKET-SMALL 2 (2018)
- PICCOLETO II (2020)

+ Ongoing: TRANSFORM | SELUTION SLR ACS | OCTIVUS

STEMI / Primary PCI Trials

REVELATION

2019

NEUTRAL

DCB vs DES in STEMI after thrombus aspiration | n=120

Result: No significant difference in FFR at 9 months

⚠ Non-inferiority trend; underpowered

PAPPA

Pilot

FEASIBILITY

DCB after thrombus aspiration in STEMI

Result: Feasibility demonstrated

⚠ Residual stenosis <30% post-prep = key success predictor

DEBUT

2019

DCB SUPERIOR

DCB vs BMS in STEMI

Result: DCB superior — significant MACE reduction

⚠ Limited applicability vs modern DES comparator

REVELATION Trial — 5-Year Follow-Up

120

60:60

Pantera Lux
VS
Orsiro/Xience

FFR at 9m

Results

FFR at 9 months

0.91 ± 0.06 (DCB) vs 0.91 ± 0.06 (DES)

p = 0.27 for non-inferiority

5-Year Clinical Outcomes

**MACE rates comparable
between groups**

Only 1/60 DCB patients
had acute vessel closure



Limitation: Small sample, single center, not powered for hard endpoints

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NSTEMI / Unstable Angina Trials

PEPCAD ACS

2014

DCB INFERIOR

DCB vs DES (paclitaxel-eluting) in ACS — predominantly NSTEMI

Result: Non-inferiority NOT met for late lumen loss at 6 months

⚠ **Critical limitation:** No mandatory lesion pre-preparation before DCB deployment

AGENT IDE

2024 ★ LANDMARK

NON-INFERIOR

Largest RCT of DCB in de novo CAD including ACS patients | SeQuent Please Neo DCB vs DES

Result: Met non-inferiority for Target Vessel Failure at 12 months

Significance: Landmark shift for DCB strategy in de novo coronary disease

Shorter DAPT duration remains a key theoretical advantage in ACS

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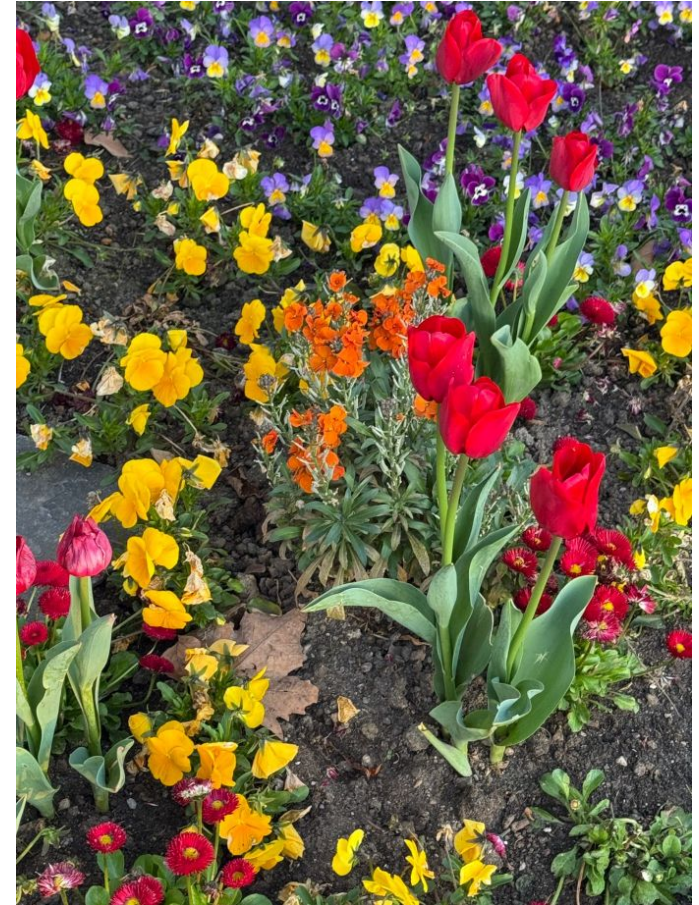
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Advantages of DCB in ACS

No Permanent Implant

Avoids chronic foreign body reaction, neoatherosclerosis, very late stent thrombosis, and the need for future stent layers.

Preserved Vasomotion

Vessel can dilate and constrict normally. Positive remodeling occurs. No jailing of side branches.

Reduced Restenosis Complexity

If restenosis occurs, it's native vessel (easier to treat) rather than in-stent restenosis.

Shorter DAPT Duration

Potential to reduce dual antiplatelet therapy to 1–3 months. Critical for patients with high bleeding risk, upcoming surgery, or on oral anticoagulants.

Lower Thrombotic Occlusion

SCAAR registry (2,400 patients): thrombotic vascular occlusion significantly lower after DCB vs DES at 5 years.

Simpler Future Interventions

No metal in vessel = easier re-PCI, preserved CABG targets, better imaging interpretation.

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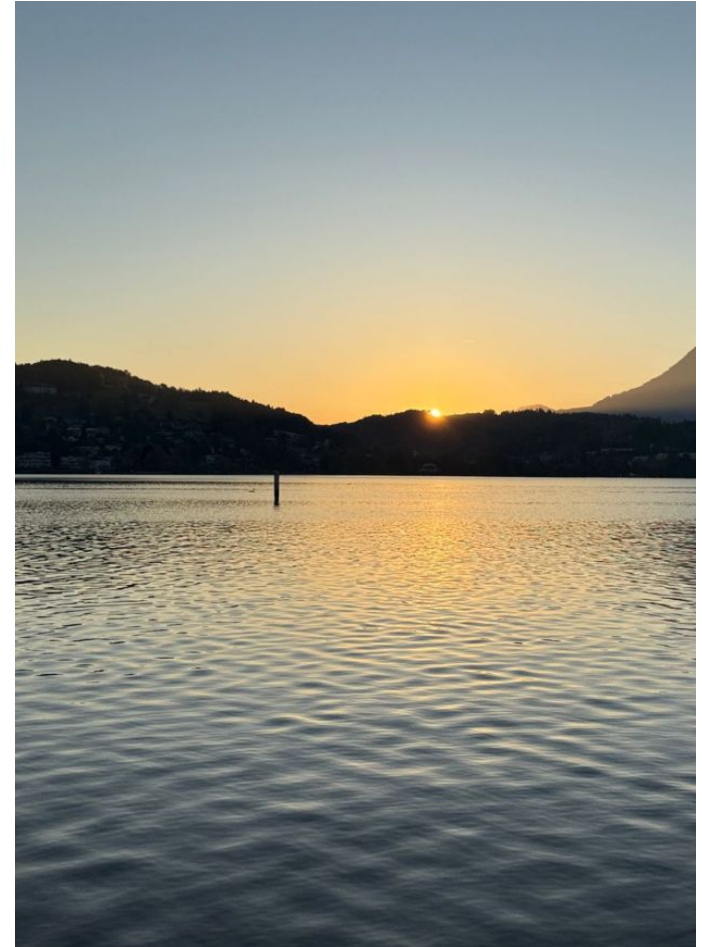
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Limitations & Cons of DCB in ACS

Limited RCT Evidence

Small trials (REVELATION N=120, PEPCAD N=210). No large-scale multi-center RCT powered for hard clinical endpoints. DES has decades of robust data.

High Bailout Stent Rate

In PEPCAD NSTEMI, ~45% of DCB-arm patients still needed a bailout stent. This reflects the real-world difficulty of stent-free results in ACS.

Distal Embolization Risk

Theoretical concern: balloon inflation in thrombotic lesions may cause distal embolization and exacerbate no-reflow phenomenon.

Acute Recoil & Dissection Risk

No scaffold = elastic recoil like plain balloon angioplasty. Dissections may be flow-limiting. Requires excellent lesion preparation.

Operator Anxiety & Learning Curve

Many interventionalists uncomfortable leaving a non-stent-like result. ACS setting magnifies this — flow restoration is paramount.

Not Suitable for All Lesions

Severely calcified, heavily thrombotic, or long lesions with >50% residual stenosis after pre-dilation are poor candidates.

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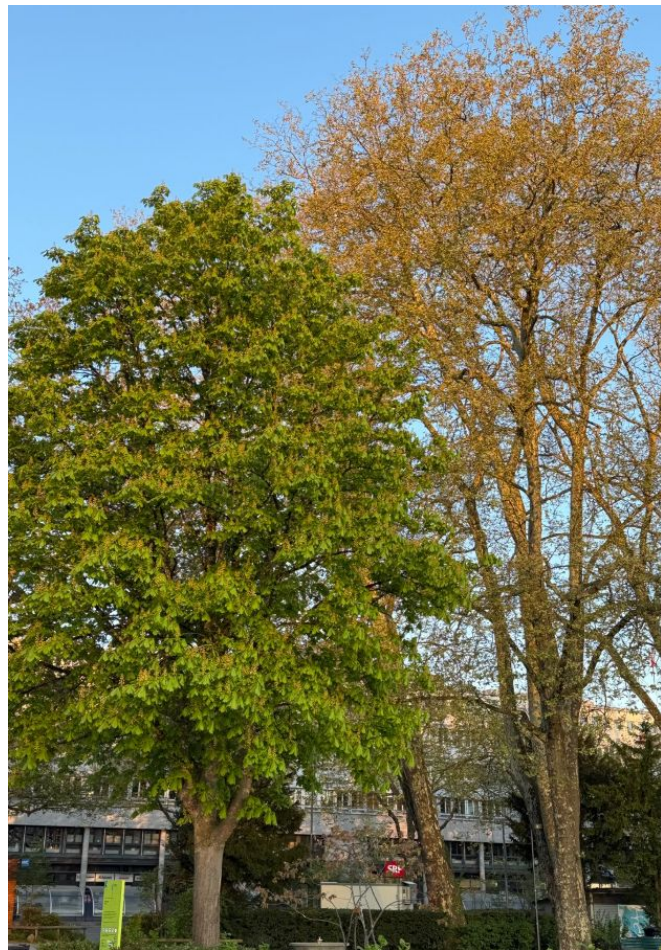
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DCB vs DES in ACS

Head-to-Head Comparison

Parameter	DCB	DES
Permanent Implant	None	Yes — metallic scaffold
DAPT Duration	1–3 months (potential)	6–12 months standard
Vessel Remodeling	Preserved vasomotion	Constrained by stent
Late Thrombosis	Very low risk	Low but persistent
Acute Results	Depends on prep (recoil risk)	Immediate scaffold support
Evidence Base	Limited RCTs in ACS	Decades of robust data
Lesion Complexity	Best for simple-moderate	Handles complex lesions
Operator Comfort	Learning curve needed	Standard practice

Sirolimus vs Paclitaxel DCB

Paclitaxel DCB (Established)

- Mechanism: Microtubule stabilization (irreversible binding)
- High lipophilicity = rapid tissue uptake
- 15+ years of clinical data
- Class I evidence for ISR
- Devices: SeQuent Please, Pantera Lux, Agent, IN.PACT Falcon
- Paclitaxel mortality signal (2018 meta-analysis) largely resolved for coronary use

Sirolimus DCB (Emerging)

- Mechanism: mTOR inhibition (cytostatic, anti-inflammatory)
- Low lipophilicity — needs nanocarrier/excipient tech
- Stronger anti-inflammatory properties vs paclitaxel
- SIBLINT-ISR: Non-inferior to PCB for ISR (LLL at 9 mo)
- SPACIOUS: Non-inferior for bifurcation SB
- Devices: SeQuent SCB, MagicTouch, Selution SLR

2026 meta-analysis (Mandal et al.): SCB and PCB show comparable safety and efficacy in ISR — class equipoise emerging

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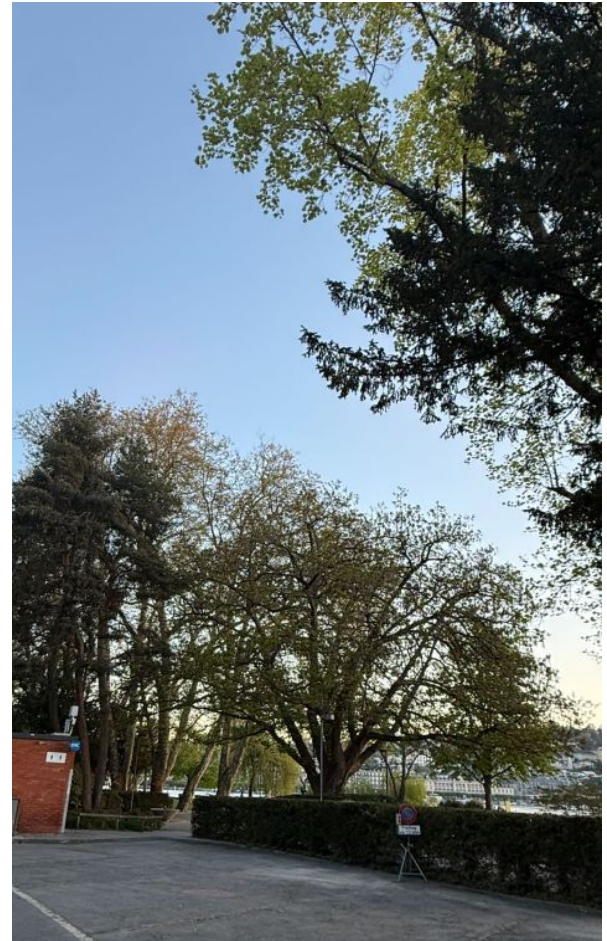
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Current Guidelines & Consensus Statements

ESC Guidelines (2023–2024)

- DES remains standard of care for ACS (Class I)
- DCB acknowledged as option in select settings
- ISR: Class IA for DCB or new-gen DES
- "Use of DCB in NSTEMI-ACS requires further investigation"

ARC Position Statement (JACC 2025)

- First comprehensive DCB consensus from Academic Research Consortium
- Classifies DCB technologies, drugs, coatings
- Provides suggestions for ACS, diabetes, HBR, multivessel disease

Asia-Pacific & Japanese Consensus

- More permissive: explicitly endorse DCB as alternative in select ACS/CAD
- Support DCB-only approach in small vessels and high bleeding risk patients with ACS



Bottom Line

DES is still first-line for ACS in formal guidelines. DCB is increasingly recognized in a "niche role" — supported by consensus documents even if guideline classes remain conservative.

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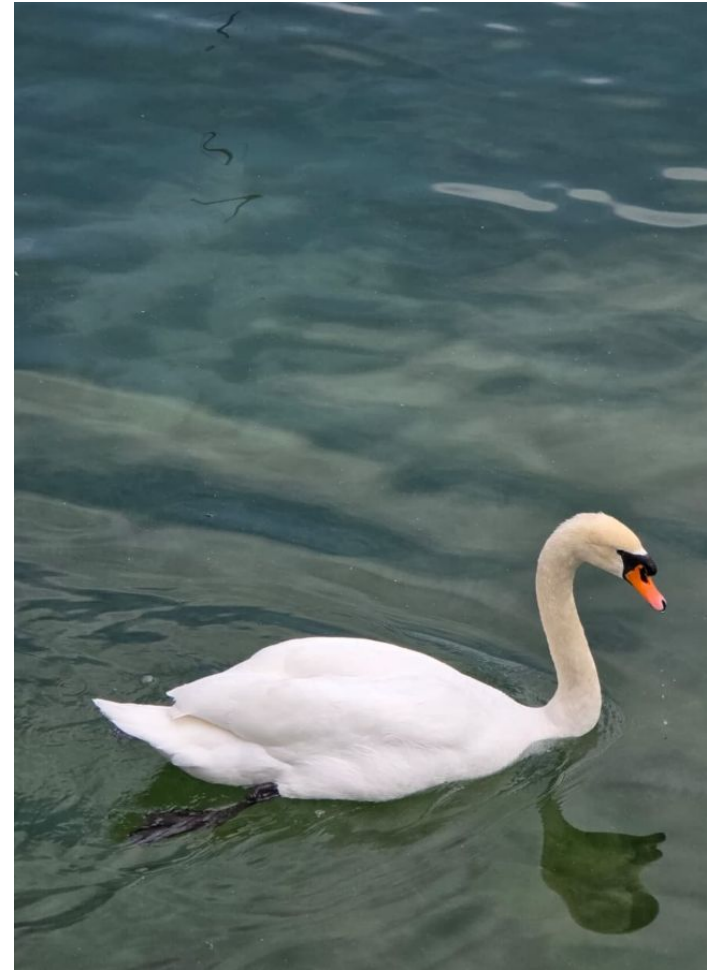
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Patient Selection & Practical Tips



Ideal Candidates for DCB in ACS

- Small vessel disease (<2.75 mm)
- High bleeding risk (elderly, on OAC, upcoming surgery)
- In-stent restenosis presenting as ACS
- Bifurcation lesions (DCB for side branch)
- Diffuse disease where multiple stents would be needed
- STEMI with <50% residual stenosis post pre-dilation



Procedural Essentials

- Lesion preparation is CRITICAL — use scoring/cutting balloons, non-compliant balloons
- Balloon:vessel ratio 0.8–1.0:1
- DCB inflation 30–60 seconds minimum
- DCB sized 1:1 to vessel reference diameter
- Accept NHLBI type A/B dissections if flow is preserved
- Use IVUS/OCT when possible for optimal assessment
- Have DES available for bailout (flow-limiting dissection, >30% residual stenosis)



Avoid DCB-only in: severely calcified lesions, residual stenosis >50%, heavy thrombus burden requiring aspiration, left main disease, cardiogenic shock

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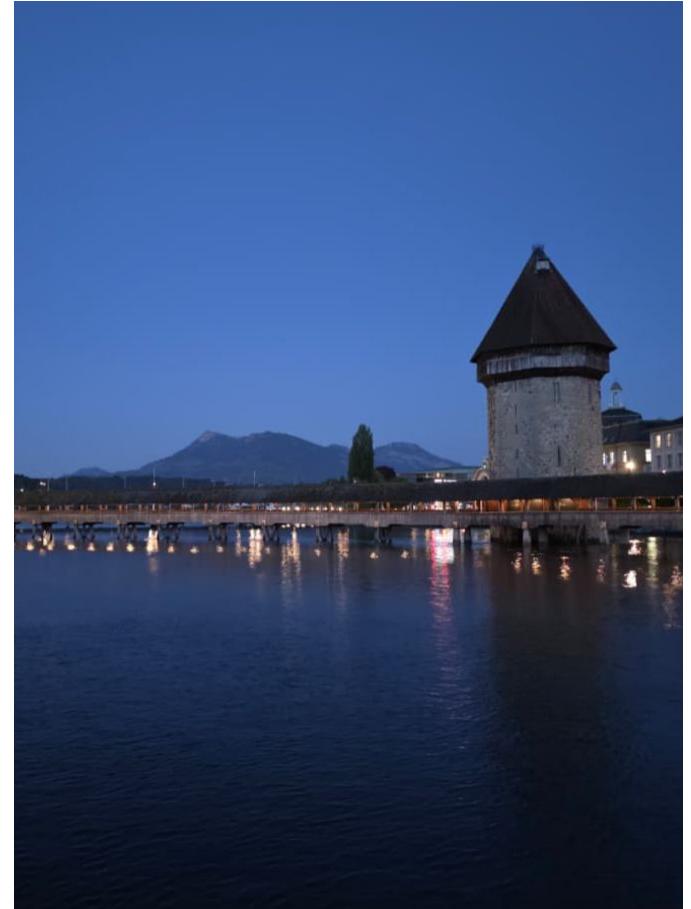
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Future Directions & Ongoing Trials

→ Larger ACS-Specific RCTs

DCB-ACS trial (China) is the first large multi-center RCT of DCB vs ZES specifically in ACS with de novo lesions. Results will shape future guidelines.

→ Sirolimus DCB Expansion

SELUTION4ISR and next-gen sirolimus DCBs may overcome paclitaxel concerns. Nanocarrier technology improving tissue retention.

→ Hybrid Strategies

Combining DCB with bioresorbable scaffolds or using DCB after ELCA (excimer laser) in thrombotic STEMI lesions showing feasibility.

→ Imaging-Guided DCB

IVUS/OCT-guided DCB protocols to standardize lesion preparation and define optimal post-DCB results. Pd/Pa (pressure ratio) guided approach emerging.

→ Special Populations

DCB in SCAD (spontaneous coronary artery dissection) — vessel fragility makes stent-free approach particularly appealing. Early case series encouraging.

→ FDA & Regulatory

MagicTouch sirolimus DCB granted FDA breakthrough device designation



Take-Home Messages

- 1** DCB is a viable alternative to DES in select ACS patients — evidence is growing but not yet definitive for routine use.
- 2** DES remains standard of care per current ESC/ACC guidelines. DCB is best positioned for small vessels, ISR, bifurcations, and high bleeding risk.
- 3** REVELATION 5-year data and BASKET-SMALL 2 subanalysis support safety of DCB in ACS with comparable outcomes to DES.
- 4** Lesion preparation is the single most important determinant of DCB success — invest time in proper vessel preparation.
- 5** Sirolimus DCBs are emerging as a promising next-generation technology with non-inferior efficacy to paclitaxel DCBs.
- 6** Larger, adequately powered RCTs (like DCB-ACS) are needed before DCB can be recommended as first-line therapy in ACS.

Key References

1. Niehe et al. REVELATION 5-Year Follow-Up. TCTMD, Oct 2025.
2. Scheller et al. PEPCAD NSTEMI trial. EuroIntervention 2020;15:1527-33.
3. Jeger et al. BASKET-SMALL 2 ACS subanalysis. Circ Cardiovasc Interv 2022.
4. Fezzi et al. DCB ARC Position Statement. JACC 2025;86(15):1170-1202.
5. Camaj et al. DCB Review. JAMA Cardiol 2025;10(2):189-198.
6. Gherasie et al. Paclitaxel vs Sirolimus DCB Review. Life 2026;16(1):63.
7. Liu et al. SIBLINT-ISR Trial. JACC Cardiovasc Interv 2025.
8. Scheller & Eccleshall. DCB for ACS. EuroIntervention 2024.
9. Abdelaziz et al. DCB in AMI Meta-Analysis. 2023 (13 studies, 2,644 pts).
10. Zhou et al. SPACIOUS Trial. EuroIntervention 2025;21:e307-e317.
11. Marchetta et al. Expanding DCB Frontiers. JCDD 2025;12:176.
12. Mandal et al. SCB vs PCB Meta-Analysis. World J Methodol 2026.



Thank You

Questions & Discussion

"The best stent is no stent — when the evidence supports it."