BARE METAL STENTS (BMS): ROLE AND CLINICAL SCENARIOS

Prepared by **Dr. Sidhartha Mullapudi**, DrNB (Cardiology), MD (General Medicine)
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I CORE CONCEPTS AND THE "DES REVOLUTION"

- **The Clinical Decline:** Since the introduction of second- and third-generation **Drug-Eluting Stents (DES)**, the clinical use of Bare Metal Stents (BMS) has declined to a **very small fraction of all PCIs**.
- **Pathophysiology of BMS Failure:** Because BMS lack an antiproliferative drug coating (such as Sirolimus, Everolimus, or Zotarolimus), they are associated with high rates of **In-Stent Restenosis (ISR)** driven by uncontrolled vascular smooth muscle cell proliferation and neointimal hyperplasia.

II HISTORICAL CLINICAL SCENARIOS FOR BMS

- **Short Dual Antiplatelet Therapy (DAPT) Requirement:** Historically, BMS were selected when only **1 month of DAPT** could be tolerated, whereas early first-generation DES required 6 to 12 months of DAPT:
- **High Bleeding Risk (HBR):** Patients with active bleeding risks or those requiring long-term oral anticoagulation.
- **Urgent Non-Cardiac Surgery:** Patients requiring major non-cardiac surgery within 4 to 6 weeks of PCI to minimize stent thrombosis during DAPT interruption.
- **Medication Non-Adherence:** Patients deemed unable to comply with a prolonged 6-to-12-month DAPT regimen.

III THE PARADIGM SHIFT: THE OBSOLESCENCE OF BMS

- **Neutralization of the "Short-DAPT" BMS Advantage:** Landmark randomized trials using contemporary thin-strut polymer-free or biocompatible-polymer DES proved that **1 month of DAPT is safe with modern DES**, completely eliminating the historical rationale for BMS:
- **LEADERS FREE Trial:** Proved that in High Bleeding Risk (HBR) patients treated with a strict **1-month DAPT** regimen, a polymer-free **Drug-Coated Stent (BioFreedom)** was both safer and more effective (significantly lower clinically driven target lesion revascularization and MI) than a BMS.
- **ONYX ONE Trial:** Demonstrated that a durable-polymer **Zotarolimus-Eluting Stent (Resolute Onyx)** was non-inferior to the BioFreedom stent with only **1 month of DAPT** in HBR patients.
- **SENIOR Trial:** Confirmed that in elderly patients **aged 75 years or older**, implanting a bioabsorbable-polymer DES with a short DAPT regimen (1 month in stable CAD, 6 months in ACS) significantly reduced Major Adverse Cardiovascular Events (MACE) and repeat revascularization compared to BMS.
- **MASTER DAPT Trial:** Validated that abbreviated **1-month DAPT** following biodegradable-polymer Sirolimus-Eluting Stent implantation in HBR patients was non-inferior for net and ischemic clinical events while significantly reducing major or clinically relevant non-major bleeding.

Landmark Trial	Target Population	Stent & DAPT Regimen	Definitive Clinical Finding
LEADERS FREE	High Bleeding Risk (HBR) patients	**BioFreedom (DCS) vs. BMS** with **1-month DAPT**	BioFreedom superior to BMS for both efficacy (lower TLR) and safety (lower MI/stent thrombosis)
ONYX ONE	High Bleeding Risk (HBR) patients	**Resolute Onyx (DES)** with **1-month DAPT**	Proved safety and efficacy of polymer-based DES with 1-month DAPT in HBR cohorts
SENIOR	Elderly patients (**>= 75 years old**)	**DES vs. BMS** with **1- to 6-month DAPT**	DES significantly reduced MACE and repeat revascularization without increasing bleeding
MASTER DAPT	High Bleeding Risk (HBR) patients	**Modern DES** with **1-month vs. standard DAPT**	1-month DAPT preserved ischemic protection while significantly reducing bleeding

IV CONTEMPORARY GUIDELINES AND RARE RESIDUAL SCENARIOS

- **Stent-Type-Independent DAPT Guidelines:** Contemporary ESC and ACC/AHA guidelines recommend **new-generation DES over BMS across all patient and lesion subsets (Class I)**, with DAPT duration dictated entirely by the patient's **ischemic versus bleeding risk profile (ARC-HBR criteria)** rather than stent type.
- **Rare Residual Circumstances:**
  - **Severe Resource Constraints:** Extremely resource-limited settings where DES are unavailable.
  - **Documented Hypersensitivity:** Extremely rare patients with documented severe allergy to specific antiproliferative drugs or polymers used on DES. (Note: Even in large-diameter vessels exceeding 4.0 mm, modern DES remain superior to BMS for preventing restenosis.)

V THE INDIAN CLINICAL CONTEXT

- **Universal DES Coverage in Public Schemes:** National and state public health insurance programs in India (such as Ayushman Bharat) and NPPA price caps cover modern **Drug-Eluting Stents**, rendering BMS virtually obsolete in both public and private Indian catheterization laboratories.
- **Managing the High-Bleeding-Risk Indian Patient:** In elderly Indian patients or those at high risk for gastrointestinal bleeding, the evidence-based strategy is **implantation of a modern DES followed by abbreviated 1-to-3-month DAPT** (per the **MASTER DAPT** protocol) rather than implanting a BMS.

KEY REFERENCES

- **Urban P, Meredith IT, Abizaid A, et al. (LEADERS FREE Investigators):** Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk, *New England Journal of Medicine*.
- **Varenne O, Cook S, Sideris G, et al. (SENIOR Investigators):** Drug-eluting stents in elderly patients with coronary artery disease (SENIOR): a randomised single-blind trial, *The Lancet*.
- **Valgimigli M, Frigoli E, Heg D, et al. (MASTER DAPT Investigators):** Dual Antiplatelet Therapy after PCI in Patients at High Bleeding Risk, *New England Journal of Medicine*.