Bare Metal and Drug Eluting Stents

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Learning Objectives

- To know the structure and types of different stents
- To know the difference between BMS and DES
- Available stents in the Egyptian market
- Tips and tricks of stenting
- How to select the proper stent for a specific lesion
- Ostial
  - Bifurcating lesion
- LMT
  - SVG
- Why should we keep BMS?
- Stents for patient waiting non-cardiac surgery
Rationale of Stent:

- Mechanical scaffold to the artery
- Recreate a larger circular lumen
- Prevent abrupt vessel closure
- Prevent late restenosis

Three Generations of Stents

Bare Metal Stents
Restenosis, neo-intimal hyperplasia
Factors affect efficacy

Common Metallic Materials Used in Stent Development & Manufacturing

<table>
<thead>
<tr>
<th>Key Element</th>
<th>Stainless Steel (S16L)</th>
<th>Cobalt Chrome (C276, MP35N, G-85)</th>
<th>Titanium (CP, Ti-6-4)</th>
<th>Nitinol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron</td>
<td>63%</td>
<td>1-15%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Titanium</td>
<td></td>
<td>90-100%</td>
<td>45%</td>
<td></td>
</tr>
<tr>
<td>Nickel</td>
<td>14%</td>
<td>15-35%</td>
<td></td>
<td>55%</td>
</tr>
<tr>
<td>Chromium</td>
<td>18%</td>
<td>20%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cobalt</td>
<td></td>
<td>40-50%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Mo, Mn</td>
<td>Mo, Mn, W</td>
<td>Al, V</td>
<td></td>
</tr>
</tbody>
</table>

Factors affect efficacy

Material + Structure + Design
Stent Design Performance

How Do you Increase Stent Deliverability Maintaining Visibility and Strength?

Visibility: radiopaque material

Strength: material + design + stent strut thickness

Flexibility: material + design + stent strut thickness

Deliverability: material + design + stent strut thickness + stent delivery system
Factors affect efficacy
Strength

Definition of Metal Strength
“Ability of the material to withstand an applied stress without failure”

<table>
<thead>
<tr>
<th>Material</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stainless Steel</td>
<td>Medium 300/560 MPa</td>
</tr>
<tr>
<td>Cobalt-Chrome</td>
<td>High 600/1140 MPa</td>
</tr>
<tr>
<td>Titanium</td>
<td>High 880/950 MPa</td>
</tr>
<tr>
<td>Nitinol</td>
<td>High 500/1400 MPa</td>
</tr>
</tbody>
</table>

Factors affect efficacy
Stiffness

Metal Stiffness: What is it?
“Resistance of an elastic material to deformation by an applied force”

<table>
<thead>
<tr>
<th>Material</th>
<th>Stiffness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stainless Steel</td>
<td>High 200 GPa</td>
</tr>
<tr>
<td>Cobalt-Chrome</td>
<td>High 200 GPa</td>
</tr>
<tr>
<td>Titanium</td>
<td>Moderate 90 GPa</td>
</tr>
<tr>
<td>Nitinol</td>
<td>Very Low ~25 GPa</td>
</tr>
</tbody>
</table>

Nitinol
The "ideal" stent design has to achieve a perfect balance between material selection, design and strut thickness.

**Factors affect efficacy**

**Impact of Metal Properties on Stent Performance**

**Factors affect efficacy**

Design

**Features & Variables of Stent Design**

- slotted-tube (Palmaz-Schatz)
- coil (Gianturco-Roubin)
- self-expanding mesh (Wallstent)
- multicellular or corrugated ring (majority of current stents)
- open-cell or closed cell
A Typical “bare” Coronary Stent
(Balloon Expandable, tubular, laser cut design)

Clinically Desirable properties

- Minimal recoil (radial and axial)
- Minimal surface area (coverage)
- Radial Stiffness
- Good fluoroscopic visibility
- MRI compatibility
- Thrombo-resistant material/surface
- Mechanically durable

Expectations of Stent Technology

Efficacy
- Deliverable
- Low TLR
- Low Restenosis
- Low Late Lumen Loss
- Cost-Effective

Safety
- No Device Malfunction
- No Early MACE
  - Q AMI
  - Non-Q AMI
- No Stent Thrombosis
BMS in Egypt

- Liberte (FDA approved)
- Integrity (FDA approved)
- Vision (FDA approved)
- Omega
- Clearflex
- Chrono
- Suna
- Prokinetic
- Tsunami

Restenosis

**Causes**

- Recoil & Negative Remodeling (70%)
- Neointimal Hyperplasia (30%)

**Solution**

1. A stent to block recoil and remodeling
2. A therapeutic agent to prevent neointimal hyperplasia
Drug – Eluting Stents
The Concept

STENT CHOICE

Life is a Matter of “Balance”
The DES Scale

Risk
Stent thrombosis
MI, Death, TLR

Benefit
Reduced restenosis
**2011 ACCF/AHA/SCAI Guidelines for PCI**

DES is useful as an alternative to BMS to reduce the risk of restenosis in cases in which the risk of restenosis is increased and the patient is likely to be able to tolerate and comply with prolonged DAPT.

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**Guidelines on myocardial revascularization**

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

<table>
<thead>
<tr>
<th>Class*</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>A</td>
</tr>
</tbody>
</table>

DESs are recommended for reduction of restenosis/re-occlusion, if no contraindication to extended DAPT.

**Indications for drug-eluting stent**

DES with proven efficacy should be considered by default in nearly all clinical conditions and lesion subsets, except if there are concerns or contraindications for prolonged DAPT (Table 35).

Evidence-Based Medicine Recommendations for the Use of DES

**Stable CAD** (Wijns W et al. Eur Heart J 2010)
- DES are recommended for reduction of restenosis/re-occlusion
  IA

**NSTE-ACS** (Hamm C et al. Eur Heart J 2011)
- DES are indicated based on an individual basis taking into account baseline characteristics, coronary anatomy, and bleeding risk
  IA

**STEMI** (Steg PG et al. Eur Heart J 2012)
- Stenting is recommended for primary PCI
  IA
- DES should be preferred over BMS if the patient has no contraindications to prolonged DAPT and is likely to be compliant
  Ila A

**Table 11. Clinical Situations Associated With DES or BMS Selection Preference**

<table>
<thead>
<tr>
<th>DES Generally Preferred Over BMS (Efficacy Considerations)</th>
<th>BMS Preferred Over DES (Safety Considerations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left main disease</td>
<td>Unable to tolerate or comply with DAPT</td>
</tr>
<tr>
<td>Small vessels</td>
<td>Anticipated surgery requiring discontinuation of DAPT within 12 mo</td>
</tr>
<tr>
<td>In-stent restenosis</td>
<td>High Risk of bleeding</td>
</tr>
<tr>
<td>Bifurcations</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
</tr>
<tr>
<td>Long lesions</td>
<td></td>
</tr>
<tr>
<td>Multiple lesions</td>
<td></td>
</tr>
<tr>
<td>Saphenous vein grafts</td>
<td></td>
</tr>
</tbody>
</table>

BMS indicates bare-metal stent(s); DAPT, dual antiplatelet therapy; and DES, drug-eluting stent(s).

www.escardio.org/guidelines
1st Generation:
- Sirolimus (Cypher)®
- Paclitaxel (Taxus)®

2nd Generation:
- Zotarolimus (Resolute)®
- Everolimus (Promus Element)® & (Xience)®

3rd Generation:
- Sirolimus (Orsiro)®
- Paclitaxel (Amazonia)®
- Paclitaxel (Nile Pax)®
- Biolimus A9 (Biomatrix)®, (Nobori)®
- Tarcolimus (Optima)®
- Sirolimus (Cre 8®)

Early- and New-Generation DES: Platforms, Polymer, and Drug Characteristics

<table>
<thead>
<tr>
<th>Platform Material</th>
<th>Strut Thickness (μm)</th>
<th>Polymer Coating Thickness (μm)</th>
<th>Type of Polymer</th>
<th>Drug Released</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stainless Steel</td>
<td>Stainless Steel</td>
<td>Stainless Steel</td>
<td>Durable</td>
<td>Paclitaxel</td>
</tr>
<tr>
<td>152</td>
<td>140</td>
<td>120</td>
<td>Durable</td>
<td>Sirolimus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8</td>
<td>Biodegradable</td>
<td>Biolimus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>Durable</td>
<td>Everolimus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6</td>
<td>Biodegradable</td>
<td>Zotarolimus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4</td>
<td>Durable</td>
<td>Everolimus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7</td>
<td>Biodegradable</td>
<td>Sirolimus</td>
</tr>
</tbody>
</table>
Basic Principle of Stent - Based PCI

- Optimization of stent deployment during PCI is a key element to obtain the most favorable immediate and long term results

  The Bigger = The Better

- Achieving adequate stent expansion during PCI is important to reduce restenosis, the need for TVR and minimize the risk of stent thrombosis
**Stenting Strategy**

<table>
<thead>
<tr>
<th>Lesion characteristics</th>
<th>Direct stenting</th>
<th>Predilation + stenting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-ostial</td>
<td>Non-ostial</td>
<td>Ostial</td>
</tr>
<tr>
<td>Uniform</td>
<td>Uniform</td>
<td>Non-uniform</td>
</tr>
<tr>
<td>Non-calcified</td>
<td>Non-calcified</td>
<td>Calcified</td>
</tr>
<tr>
<td>Acute lesion (thrombectomy)</td>
<td>Acute lesion (thrombectomy)</td>
<td>Occluded</td>
</tr>
<tr>
<td>Simple</td>
<td>Simple</td>
<td>Complex (long, bifurcations)</td>
</tr>
</tbody>
</table>

**Which Stent to Use?**

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>BMS</th>
<th>DES</th>
</tr>
</thead>
<tbody>
<tr>
<td>No diabetes</td>
<td></td>
<td>Diabetes</td>
</tr>
<tr>
<td>Low-risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major co-morbidity</td>
<td></td>
<td>Low bleeding risk</td>
</tr>
<tr>
<td>(surgery intended,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>terminal cancer,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘palliative’ PCI – CABG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>intended)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lesion characteristics</th>
<th>RD $\geq$ 3.5 mm</th>
<th>RD 2.75 – 3.5 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
46 y ♀ diabetic with inferior STEMI / post thrombolysis BMS (Vision, 4.0 × 23 mm) in RCA lesion

Final Result
Stent Dimensions

- Stent diameter
  - Artery : stent ratio = 1 : 1.1
  - Do not oversize
  - Plan possibility of post - dilation
- Stent length
  - Lesion coverage
  - DES – 1 - 2 mm proximal & distal to stent to ensure complete plaque coverage : normal to normal

*IVUS to assess result*
## Nominal Pr. ID Card:

**PROMUS Stent System Compliance**

Nominal pressure for each diameter indicated by bold font.

Rated Burst Pressure (RBP): 16 ATM (1621 kPa)

<table>
<thead>
<tr>
<th>Pressure (atm)</th>
<th>Pressure (kPa)</th>
<th>Stent ID (mm) by System Size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2.25mm</td>
</tr>
<tr>
<td>8</td>
<td>811</td>
<td>2.27</td>
</tr>
<tr>
<td>9</td>
<td>912</td>
<td>2.33</td>
</tr>
<tr>
<td>10</td>
<td>1013</td>
<td>2.38</td>
</tr>
<tr>
<td>11</td>
<td>1115</td>
<td>2.43</td>
</tr>
<tr>
<td>12</td>
<td>1216</td>
<td>2.47</td>
</tr>
<tr>
<td>13</td>
<td>1317</td>
<td>2.50</td>
</tr>
<tr>
<td>14</td>
<td>1419</td>
<td>2.53</td>
</tr>
<tr>
<td>15</td>
<td>1520</td>
<td>2.56</td>
</tr>
<tr>
<td>16 (RBP)</td>
<td>1621</td>
<td>2.59</td>
</tr>
<tr>
<td>17</td>
<td>1723</td>
<td>2.62</td>
</tr>
<tr>
<td>18</td>
<td>1824</td>
<td>2.64</td>
</tr>
</tbody>
</table>

## Stent Deployment

**Stent procedure**

- Slow inflation to nominal pressure
- Short inflation (15 - 20 sec)
- Optimal inflation pressure > 14 A
- Analyze angiographic result in orthogonal views
Stent Deployment

Post-dilatation

• Select semi-compliant or non-compliant balloon
• Routine high-pressure (> 18 A) to ensure adequate stent expansion
• Stent under-expansion (focal or generalized) ?
  IVUS for stent assessment, especially if DES

Bifurcational Lesions

➢ DES decreased restenosis rates and repeat revascularizations
➢ Open cell design stents are preferred
➢ Openings between the struts that can easily permit passage of a balloon or secondary stent into the side branch
➢ Slotted –tube stents are suitable

Why protect SB’s from Closure

• Occlusion of SB’s > 1mm associated with 14 % incidence of myocardial infarction
• SB closure associated with periprocedural MI
56 Y male pt. non diabetic / Rescue PCI

Long bifurcation lesion stenting

DES (Resolute) : 3×38 mm
Non-Compliant Balloon : 3.5×15 mm

Non Compliant Balloon Selection and Maneuver

Angiography-guided strategy
When to Suspect Suboptimal Stent Deployment

- Stent undersizing (Balloon to artery ratio < 1)
- Severe and diffuse target vessel disease
- Small vessel (vessel over stretch)
- Acute coronary syndrome
- Severe stenosis
- Direct stenting
- Bifurcation lesion
- Osteal lesion (Fibrosis)
- Long lesion (proximal–distal mismatch, overlapping)

Stenting in acute MI

- Direct stenting is preferred to avoid distal embolization and improved myocardial perfusion than predilatation

- When selecting a stent diameter, take care of the vasospasm in the infarct related artery. If the BP is sufficient (100 mmHg), liberal 50 to 200 Mcg boluses of intracoronary nitroglycerin should be given to reduce vascular tone and evaluate vessel size, especially after predilatation

- The use of drug eluting stents during AMI is safe and decreases TVR
Late Presentation of Acute Anterior MI

Total LAD Occlusion

LAD Wiring

Post PTCA without IC Nitroglycerin

Post PTCA after IC Nitroglycerin
DES (Resolute) : 3.5 × 18 mm

Final Result

TRIFURCATION LESIONS
50 y. male diabetic patient: STEMI, Pharmaco-invasive approach

Wiring of LAD_D1 & D2

Residual post stenosing 30% stenosis

(Resolute®) 3 x 23 mm
Final Result

NC (Quantum)® balloon

46 Y Male pt., non diabetic / Unstable angina
Bifurcating LAD/D2 lesion
Wiring of LAD & D2

Post Balloon (2.0×15 mm) Dilation

DES (Xience V) : 3×18 mm
Ostial Lesions

➢ Aorto-ostial ➔ Slotted – tube design, preferably with strong radial support, low recoil, and radiologic visibility, is the most appropriate

➢ Coronary-ostial ➔ Use of thicker struts to provide greater resistance when dealing with lesions involving the true coronary ostia or the aortic insertion of a saphenous vein graft
Total LAD (in-stent restenosis) DES (Cypher) : $3.5 \times 33$ mm

50 Y diabetic pt. / Crescendo angina

Osteal LAD subtotal occlusion
### Wiring of LAD & CX

<table>
<thead>
<tr>
<th><strong>Direct Stenting</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Nobori 3.5 × 18 mm</td>
</tr>
</tbody>
</table>

### Calcified Lesions

- Slotted tube stent with minimal recoil and good radial strength
- In very calcific arteries the operator may need to use a second, so-called “buddy” wire in order to advance the stent to the lesion
Stenting Saphenous Venous Grafts

- Always plan for direct stenting
- Vein grafts are always oversized
- Stent size that matches the target native vessel provides adequate flow
- Small stent in large veins is a safe approach (decrease acute and long-term MACE)
- Advantage of DES vs BMS in large SVG’s is not settled at this point

Problems with Today’s DES

- Need for prolonged DAPT
- Polymer associated problems
- Earlier neo-atherosclerosis?
- More very-late thrombosis?
- DES use should be limited to patients or lesions at high risk for restenosis
Next Generation metallic DES

- Deliverable, Visible, Trackable, Conformable
- No Stent Thrombosis ('BMS' like)
- Short DAPT duration
- Low TLR, Low Clinical Symptom Recurrence

Stent Delivery System
- Stent Material
- Thinner Struts
- Modified Stent Geometry
- Enhanced side-branch access
- Surface Coating

Facilitating re-endothelialization
- Polymer facilitating endothelialization
  - Durable, but more biocompatible
- Reduced Polymer Load
  - Abdominal Polymer
  - No Polymer
  - Biodegradable Polymer
- Reduced Drug Load

Less/no effect on endothelial function

Non Polymeric DES

<table>
<thead>
<tr>
<th>DES System</th>
<th>Drug</th>
<th>Polymer</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yukon DES</td>
<td>Sirolimus</td>
<td>None</td>
<td>Translumina</td>
</tr>
<tr>
<td>Biofreedom</td>
<td>Biolimus A9</td>
<td>None</td>
<td>Bioramak</td>
</tr>
<tr>
<td>VESTAsync</td>
<td>Sirolimus</td>
<td>None</td>
<td>MIV Therapeutics</td>
</tr>
<tr>
<td>Amazon Pax</td>
<td>Paclitaxel</td>
<td>None</td>
<td>Minasys</td>
</tr>
<tr>
<td>Optima</td>
<td>Tacrolimus</td>
<td>None</td>
<td>CID</td>
</tr>
<tr>
<td>Crt8</td>
<td>Sirolimus</td>
<td>None</td>
<td>CID</td>
</tr>
</tbody>
</table>
Why Should We Keep BMS?

- No reduction in death or MI rates
- Benefit limited in vessels >3 mm
- Need for prolonged DAPT Vs Bleeding
- Uncertainty of patient compliance
- Increased rate of very late stent thrombosis?
- Earlier neo-atherosclerosis?

Stents for Patients Waiting Non-Cardiac Surgery

**TITAN 2**

**CATANIA**

Short duration of DAPT (1 month except in ACS)
67 y♂ diabetic pt. presented with early post infarction angina. He had haematemesis 2ry to rupture oesph. varices 2 months ago

Take home message

Not all stents model are the same

The ideal stent design has to achieve a perfect balance between material selection, design and strut thickness

Stent design and construction have an impact on the immediate and long term clinical outcome

Although DES have become the primary choice of PCI, it can not be used in all patients and lesions

DES use should be selective, limited to patients or lesions at high risk for restenosis

New generations DES showed superior clinical outcomes to the first generation DES
THANK YOU FOR YOUR ATTENTION