Stent Choice in Patients with Acute Myocardial Infarction

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Scientific Advances and Cardiovascular Mortality


- **1958**: Coronary arteriography developed (Sones)
- **1962**: First beta-blocker developed (Black)
- **1969**: First description of CABG (Favalaro)
- **1972**: NHBPEP
- **1976**: First HMG CoA reductase inhibitor described (Endo)
- **1980**: First implantable cardioverter-defibrillator developed (Mirowski)
- **1979**: Coronary angioplasty developed (Grüntzig)
- **1983**: CASS
- **1985**: TIMI 1
- **1986**: GISSI and
- **1992**: SAVE
- **1993**: Superiority of primary PCI vs. fibrinolysis in acute MI noted
- **2002**: Efficacy of drug-eluting vs. bare-metal stents determined
- **2007**: Benefit of cardiac resynchronization therapy in patients
- **2009**: Left-ventricular assist device as destination therapy in advanced heart failure shown to be effective
- **2009**: Genomewide association in early-onset MI described
- **2009**: Deep gene sequencing for responsiveness to cardiovascular drugs performed
Primary PCI versus Thrombolysis in AMI


Meta-Analysis
-N=7739 patients
-23 randomized trials
-8x: streptokinase vs PCI
-15x: tPA vs PCI

23 death prevented and 44 MI’s and 11 strokes avoided for every 1000 pts treated with primary PCI instead of thrombolysis
Early Generation Drug-Eluting Stents versus Bare Metal Stents in Patients With STEMI

Kalesan B et al. Eur Heart J 2012

15 RCTs Comparing DES and BMS in 7,843 STEMI Patients

- **Death**: RR 0.91 (0.71-1.15) P=0.63
- **Cardiac death**: RR 1.01 (0.73-1.40) P=0.90
- **MI**: RR 0.94 (0.78-1.14) P=0.98
- **TVR**: RR 0.51 (0.43-0.61) P<0.001
- **Definite ST**: RR 1.08 (0.82-1.43) P=0.46

% 20 15 10 5 0

Death Cardiac death MI TVR Definite ST

**DES**

**BMS**
Stent Choice in AMI

- Vessel and Stent Size in AMI
- Discontinuation of Antiplatelet Therapy
- Newer Generation DES and AMI
- Plaque Architecture and Inflammation in AMI
- Thrombus Burden and AMI
Vessel Size and Culprit Lesion Location in Acute Myocardial Infarction

Reference Vessel Diameter

<table>
<thead>
<tr>
<th>Vessel</th>
<th>Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PASSION</td>
<td>3.2</td>
</tr>
<tr>
<td>DEDICATION</td>
<td>3.2</td>
</tr>
<tr>
<td>HORIZON-AMI</td>
<td>2.9</td>
</tr>
<tr>
<td>COMFORTABLE</td>
<td>3.0</td>
</tr>
</tbody>
</table>

Culprit Lesion Location

![Bar chart showing the percentage of lesions at different locations](image)

- **Prox**: 2.2%, 13%
- **Mid**: 16.3%, 16.3%
- **Distal**: 4.4%, 5.4%, 9.8%
- **PDA/PLV**: 1.1%, 3.3%, 4.4%

*p = 0.001

![Graph showing the relationship between lesion location and distance](image)
Paclitaxel-Eluting Stents versus Bare-Metal Stents in Acute Myocardial Infarction: HORIZONS-AMI


**Repeat Revascularization @ 3 Years**

<table>
<thead>
<tr>
<th></th>
<th>Clinically-Indicated TLR</th>
<th>Clinically-Indicated TVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paclitaxel-Eluting</td>
<td>9.4% (P&lt;0.0001, NNT=18)</td>
<td>12.4% (P=0.0003, NNT=19)</td>
</tr>
<tr>
<td>BMS</td>
<td>15.1%</td>
<td>17.6%</td>
</tr>
</tbody>
</table>

*PES (N=2257) BMS (N=749)*
Target-Lesion Revascularization With New Generation DES versus Bare-Metal Stents in Patients with STEMI

**EXAMINATION**
Sabaté M et al. Lancet 2012

- 1 yr HR
  0.42 (0.24-0.76)
  P=0.004

- %

- 2.1

- EES

- 5.0

- BMS

**COMFORTABLE AMI**
Räber L et al. JAMA 2012

- 1 yr HR
  0.28 (0.13-0.59)
  P<0.001

- %

- BMS 5.7 %

- BES 1.6 %
Issues Related to Thrombus Burden in AMI and Impact on Stent Choice

- Thrombus burden and risk of stent thrombosis
- Thrombus resolution and stent malapposition
- Distal embolization and no-reflow phenomenon

Cook S et al. Circulation 2007
Impact of Thrombus Burden on Risk of Stent Thrombosis With DES in Patients With STEMI

**Independent Predictors of ST**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hazard Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.6</td>
<td>0.4-0.8</td>
</tr>
<tr>
<td>Index ST</td>
<td>6.2</td>
<td>2.1-18.9</td>
</tr>
<tr>
<td>Bifurcation</td>
<td>4.1</td>
<td>1.6-10.0</td>
</tr>
<tr>
<td>Thrombectomy</td>
<td>0.1</td>
<td>0.01-0.8</td>
</tr>
<tr>
<td>Large thrombus</td>
<td>8.7</td>
<td>3.4-22.5</td>
</tr>
</tbody>
</table>

![Graph showing cumulative IRA-ST rate](LTB vs. STB, p<0.001)
Acute Stent Malapposition in HORIZONS-AMI

Guo N et al. Circulation 2010;122:1088-84

241 STEMI patients enrolled into HORIZONS-AMI undergoing IVUS at baseline and 13 months follow-up
Predictors of Stent Thrombosis
van Werkum et al. *Circulation* 2009;119:828-834

**Dutch Stent Thrombosis Registry**

21,009 pts

437 (2.1%) pts with definite ST

**Timing**
- early: 74%
- late: 13%
- very late: 12%

**Stent Type**
- BMS: 62%
- DES: 35%
- BMS+DES: 4%
Self-Expanding Versus Balloon-Expandable Stents in AMI: APPOSITION II

van Geuns RJ et al. *JACC CV Interv* 2012;5:1209-19

**Malapposition – Patient Level**

- **Post-Procedure**
  - Self-expanding Stent: 13.9%
  - Balloon-expandable Stent: 37.1%
  - $P=0.03$

- **At 3 Days**
  - Self-expanding Stent: 0%
  - Balloon-expandable Stent: 28%
  - $P<0.001$
Impact of Post-Procedure TIMI Flow on Survival

Stone G. *Circulation* 2008;118:538-51

- 92.5% of patients
- 6% of patients
- 1.5% of patients

6 month mortality:
- TIMI 3: 2.8%
- TIMI 2: 7.5%
- TIMI 0/1: 22.2%

Log-rank p for trend = 0.0003
Mesh-Covered Versus Balloon-Expandable Stents in AMI: MASTER Trial

Stone G et al. JACC 2012;60:1975-84

Mesh-protected Stent
Microcirculatory protection

ST-Segment Resolution
TIMI Flow Grade 3

Polyethylene terephthalate micronet 150x180 µm
Stent Choice in AMI

- Vessel and Stent Size in AMI
- Discontinuation of Antiplatelet Therapy
- Newer Generation DES and AMI
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- Plaque Architecture and Inflammation in AMI
Correlation between fibrous cap thickness and % uncovered struts

AMI lesions (with Plaque Rupture)

Stable Lesions (with Fibroatheroma and thick cap)

\[ p = 0.0006, \ r = -0.60 \]
Neoatherosclerosis of Coronary Artery Stents

Nakazawa G et al. *J Am Coll Cardiol* 2011;57:1314-22

*Independent predictors of neoatherosclerosis*
- younger age, longer implant duration
- PES use, SES use

![Graph showing Neoatherosclerosis percentages for BMS (N=197) and DES (N=203)]

- BMS (N=197): Neoatherosclerosis 16%, TCFA 4%
- DES (N=203): Neoatherosclerosis 31%, TCFA 1%

*P = 0.001*  
*P = 0.17*
Fully Biodegradable Stent Platforms

Van der Giessen Circulation

1996

Animal studies polymeric scaffolds revealing excessive inflammatory reactions

Igaki Tamai First fully biodegradable non drug eluting scaffold N=15

Tamai Circulation

2000

AMS-1 first bioabsorbable metallic non drug-eluting scaffold N=64

Erbel Lancet

2007

IDEAL BDS Polyanhidride ester and salicylic acid, drug-eluting scaffold N=11

Ormiston Lancet

2008

Bioresorbable vascular scaffold first bioabsorbable drug eluting scaffold N=31

Jabara PCR 2009

2009

REVA Polycarbonate stent, radiopaque, non drug-eluting scaffold N=31

Abizaid TCT 2009

2009

AMS-1 first bioabsorbable metallic non drug-eluting scaffold N=64

Haude PCR 2011

2011

DREAMS first drug-eluting bioabsorbable metallic scaffold N=22
Potential of Fully Bioresorbable Vascular Scaffolds in STEMI

- Benign NIH
- Expansive Remodeling
- In-Scaffold Restenosis
- Plaque Regression
- Vulnerable Plaque
- Plaque Sealing
- Plaque Regression

Late Lumen Enlargement

- Antithrombotic Restenosis inhibition
- Biodegradation
- Lumen enlargement Atherosclerosis regression
Stent Choice in AMI

- Vessel and Stent Size in AMI
- Thrombus Burden and AMI
- Discontinuation of Antiplatelet Therapy
- Newer Generation DES and AMI
- Plaque Architecture and Inflammation in AMI
Progress With Newer Generation Drug-Eluting Stents

Newer Generation DES Efficacy and Safety

Everolimus-Eluting versus Sirolimus-Eluting Stents

Target Lesion Revasc

<table>
<thead>
<tr>
<th>Study</th>
<th>ISAR-TEST 4</th>
<th>SORT-OUT IV</th>
<th>EXCELLENT</th>
<th>BASKET-PROVE</th>
<th>ESSENCE-DIABETES</th>
<th>Long DES</th>
<th>SEA-SIDE</th>
<th>RESET</th>
<th>Sakabaira et al.</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>77/852</td>
<td>36/1390</td>
<td>29/1079</td>
<td>29/774</td>
<td>1/149</td>
<td>7/224</td>
<td>5/75</td>
<td>65/1597</td>
<td>3/50</td>
</tr>
<tr>
<td>95/852</td>
<td>45/1384</td>
<td>6/384</td>
<td>33/775</td>
<td>4/151</td>
<td>5/226</td>
<td>5/226</td>
<td>5/75</td>
<td>76/1600</td>
<td>9/50</td>
</tr>
<tr>
<td>Event Rate</td>
<td>0.81 (0.61, 1.07)</td>
<td>0.80 (0.52, 1.23)</td>
<td>1.46 (0.61, 3.52)</td>
<td>0.88 (0.54, 1.43)</td>
<td>0.25 (0.03, 2.24)</td>
<td>1.41 (0.46, 4.38)</td>
<td>1.00 (0.30, 3.31)</td>
<td>0.86 (0.62, 1.18)</td>
<td>0.33 (0.10, 1.16)</td>
</tr>
</tbody>
</table>

Definite ST

<table>
<thead>
<tr>
<th>Study</th>
<th>ISAR-TEST 4</th>
<th>SORT-OUT IV</th>
<th>EXCELLENT</th>
<th>BASKET-PROVE</th>
<th>ESSENCE-DIABETES</th>
<th>RESET</th>
<th>ESSENCE-DIABETES</th>
<th>Burzotta et al.</th>
<th>Sakabaira et al.</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>4/652</td>
<td>3/1390</td>
<td>3/1079</td>
<td>2/774</td>
<td>5/1597</td>
<td>5/1597</td>
<td>0/149</td>
<td>0/75</td>
<td>0/50</td>
</tr>
<tr>
<td>Event Rate</td>
<td>0.44 (0.14, 1.44)</td>
<td>0.25 (0.07, 0.88)</td>
<td>0.34 (0.07, 1.66)</td>
<td>0.67 (0.11, 3.96)</td>
<td>0.83 (0.26, 2.73)</td>
<td>(Excluded)</td>
<td>(Excluded)</td>
<td>(Excluded)</td>
<td>(Excluded)</td>
</tr>
</tbody>
</table>

Overall (I-squared = 0.0%, p = 0.663)

- Favors EES
- Favors SES

Overall (I-squared = 0.0%, p = 0.698)

- Favors EES
- Favors SES

Updated Meta-Analysis N = 11,167
Biodegradable Polymer DES Versus Durable Polymer SES

Stefanini G et al. *Eur Heart J* 2012; 33, 1214–1222

**Target-Lesion Revasc @ 4 Years**

<table>
<thead>
<tr>
<th>Trial</th>
<th>BP No. of patients with event/total no.</th>
<th>DP No. of patients with event/total no.</th>
<th>Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISAR-TEST 3</td>
<td>21/202</td>
<td>28/202</td>
<td>0.69 (0.39, 1.21)</td>
</tr>
<tr>
<td>ISAR-TEST 4</td>
<td>169/1299</td>
<td>96/652</td>
<td>0.87 (0.68, 1.12)</td>
</tr>
<tr>
<td>LEADERS</td>
<td>74/857</td>
<td>93/850</td>
<td>0.78 (0.57, 1.05)</td>
</tr>
<tr>
<td>Overall</td>
<td>264/2358</td>
<td>217/1704</td>
<td>0.82 (0.68, 0.98)</td>
</tr>
</tbody>
</table>

Test for Heterogeneity P = 0.71
Test for Inconsistency I² = 0%
Test for Overall Effect z = -2.19 (P = 0.03)

**Definite ST @ 4 Years**

<table>
<thead>
<tr>
<th>Trial</th>
<th>BP No. of patients with event/total no.</th>
<th>DP No. of patients with event/total no.</th>
<th>Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISAR-TEST 3</td>
<td>1/202</td>
<td>2/202</td>
<td>0.47 (0.04, 5.04)</td>
</tr>
<tr>
<td>ISAR-TEST 4</td>
<td>9/1299</td>
<td>10/652</td>
<td>0.45 (0.18, 1.12)</td>
</tr>
<tr>
<td>LEADERS</td>
<td>20/857</td>
<td>32/850</td>
<td>0.62 (0.35, 1.08)</td>
</tr>
<tr>
<td>Overall</td>
<td>30/2358</td>
<td>44/1704</td>
<td>0.56 (0.35, 0.90)</td>
</tr>
</tbody>
</table>

Test for Heterogeneity P = 0.84
Test for Inconsistency I² = 0%
Test for Overall Effect z = -2.43 (P = 0.02)

*N = 4,062 – IPD Pooled Analysis of LEADERS, ISAR-TEST 3 and 4*
**Everolimus-Eluting Stent versus Bare Metal Stent in ST-Elevation MI**


**Clinical Outcomes @ 12 Months**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>EES - Xience (N=751)</th>
<th>BMS - Vision (N=747)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac Death</td>
<td>3.2%</td>
<td>2.8%</td>
<td>0.68</td>
</tr>
<tr>
<td>MI</td>
<td>1.4%</td>
<td>2.1%</td>
<td>0.30</td>
</tr>
<tr>
<td>TLR</td>
<td>2.2%</td>
<td>3.9%</td>
<td>0.003</td>
</tr>
<tr>
<td>TVR</td>
<td>5.1%</td>
<td>7%</td>
<td>0.007</td>
</tr>
<tr>
<td>Death, MI, any Revasc</td>
<td>12%</td>
<td>14.4%</td>
<td>0.16</td>
</tr>
</tbody>
</table>
Everolimus-Eluting Stent versus Bare Metal Stent in ST-Elevation MI


**Stent Thrombosis @ 12 Months**

**Definite**

<table>
<thead>
<tr>
<th></th>
<th>EES - Xience (N=751)</th>
<th>BMS - Vision (N=747)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definite</td>
<td>0.5</td>
<td>1.9</td>
</tr>
<tr>
<td><em>P</em>=0.01</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Definite or Probable**

<table>
<thead>
<tr>
<th></th>
<th>EES - Xience (N=751)</th>
<th>BMS - Vision (N=747)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definite or Probable</td>
<td>0.9</td>
<td>2.6</td>
</tr>
<tr>
<td><em>P</em>=0.01</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Biodegradable Polymer BES versus Bare Metal Stents in STEMI – COMFORTABLE AMI

Räber L et al. JAMA 2012;308:777-87

1° EP – Cardiac Death, TV-MI or ci-TLR @ 1 Year

1 yr HR
0.49 (0.30-0.80)
P = 0.004

MACE (%) vs Days since index procedure

- BMS 8.7%
- BES 4.3%

No at risk
- BMS: 582, 546, 539, 531, 525, 519, 514
- BES: 575, 543, 541, 540, 537, 534, 530
Biodegradable Polymer BES versus Bare Metal Stents in STEMI – COMFORTABLE AMI

Räber L et al. JAMA 2012;308:777-87

Individual Components of Primary Endpoint

Cardiac Death (%) | TV-MI (%) | TLR (%) |
--- | --- | --- |
BES | 2.9 | 0.5 | 1.6 |
BMS | 3.5 | 2.7 | 5.7 |

P=0.53 | P=0.01 | P<0.001
Definite Stent Thrombosis

1 yr HR: 0.42 (0.15-1.19), P=0.10

BES 0.9 %
BMS 2.1 %

No at risk
BMS 582 547 545 540 538 534 481
BES 575 545 543 542 540 538 494

Biodegradable Polymer BES versus Bare Metal Stents in STEMI – COMFORTABLE AMI
Räber L et al. JAMA 2012;308:777-87
## Risk of Adverse Events With New Generation DES versus BMS in STEMI

### A Pooled Analysis of COMFORTABLE and EXAMINATION


### Definite ST

<table>
<thead>
<tr>
<th></th>
<th>HR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COMFORTABLE</strong></td>
<td>0.42 (0.15-1.20)</td>
<td>0.10</td>
</tr>
<tr>
<td><strong>EXAMINATION</strong></td>
<td>0.28 (0.09-0.86)</td>
<td>0.03</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td>0.35 (0.16-0.75)</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

### Death, MI, or Revasc

<table>
<thead>
<tr>
<th></th>
<th>HR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COMFORTABLE</strong></td>
<td>0.68 (0.47-0.98)</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>EXAMINATION</strong></td>
<td>0.82 (0.62-1.08)</td>
<td>0.16</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td>0.76 (0.61-0.96)</td>
<td>0.02</td>
</tr>
</tbody>
</table>
Arterial Healing After Coronary Stents Implantation

Stent Choice in AMI

- Vessel and Stent Size in AMI
- Discontinuation of Antiplatelet Therapy
- Newer Generation DES and AMI
- Thrombus Burden and AMI
- Plaque Architecture and Inflammation in AMI
Discontinuation of Antiplatelet Therapy as Predictor of Stent Thrombosis

HR = 19.2 (5.6-65.5)
OR = 4.8 (2.0-11.1)
HR = 13.7 (4.0-46.7)
HR = 13.8 (8.8-21.6)
HR = 4.6 (1.4-15.35)

Odds/Hazard Ratio

Park et al Am J Card 2006
Kuchulakanti et al Circulation 2006
Airoldi et al Circulation 2007
Lasala et al Circ Card Intv 2009
Van Werkum et al JACC 2009
Impact of Polymer-Drug Coating and Platform Design on Early Stent Thrombogenicity

Kolandaivelu K et al. *Circulation* 2011;123:1400-1409.

\[ P = 0.011 \]

\[ P = 0.036 \]

**Pooled BMS:** ML Vision, Driver, Taxus, Bx Velocity

**Pooled DES:** Xience V, Endeavor, Taxus Libertè, Cypher
RESOLUTE Pooled On DAPT Analysis

Timing of ST Events On and Off DAPT Through 1 Year

1 Month

<table>
<thead>
<tr>
<th>Subsequent ST (ARC Def/Prob) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>On DAPT</td>
</tr>
<tr>
<td>OFF DAPT</td>
</tr>
<tr>
<td># of pts at risk at baseline</td>
</tr>
<tr>
<td>3,858</td>
</tr>
<tr>
<td>169</td>
</tr>
<tr>
<td># of events</td>
</tr>
<tr>
<td>26</td>
</tr>
<tr>
<td>5†</td>
</tr>
<tr>
<td># of days to interruption (median)</td>
</tr>
<tr>
<td>NA</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>95% CI</td>
</tr>
<tr>
<td>[0.44%, 0.99%]</td>
</tr>
<tr>
<td>[0.97%, 6.77%]</td>
</tr>
<tr>
<td>[0.09%, 0.41%]</td>
</tr>
<tr>
<td>[0.00%, 0.33%]</td>
</tr>
</tbody>
</table>

* of which 617 patients discontinued (did not restart) and 219 patients temporarily stopped DAPT

† 4 of the events involved discontinuation within 1st 2 days – all probable ST (unexplained/cardiac death within 30 days). 1 event followed interruption at day 3 – definite ST at day 22.
Definite ST According to Discontinuation of DAPT in the COMFORTABLE-AMI Trial

Räber L et al. JAMA 2012;308:777-87
# Efficacy and Safety of DES, BMS, and CABG According to Clinical Indication


<table>
<thead>
<tr>
<th>Outcome and Intervention</th>
<th>Stable Coronary Artery Disease</th>
<th>Acute Myocardial Infarction</th>
<th>Diabetes</th>
<th>Multivessel Disease</th>
<th>Left Main Coronary Artery Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Restenosis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implantation of bare-metal stent</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Implantation of drug-eluting stent</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Early-generation</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>New-generation</td>
<td>+++</td>
<td>+++</td>
<td>++</td>
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<td><strong>Cardiac death, myocardial infarction, or stent thrombosis</strong></td>
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<td>Implantation of bare-metal stent</td>
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<td>Implantation of drug-eluting stent</td>
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<td>Early-generation</td>
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<td>New-generation</td>
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</table>
Recommendations for the Use of DES in Acute Coronary Syndromes

- **No safety concerns**
- **Consistent reduction in repeat revascularization procedures with the use of DES**

**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  
  I A

**STEMI** Steg PG et al. *Eur Heart J* 2012

- Stenting is recommended for primary PCI  
  I A

- DES should be preferred over BMS if the patient has no contraindications to prolonged DAPT and is likely to be compliant  
  Ila A