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Why Do We Believe BMS “Safer”?
A Perfect Storm of Observational Evidence

- BMS used since 1995 with ≤ 30 days DAPT, late ST not a problem

- Within months of SES FDA approval in 2003, FDA had 300 reports of subacute ST, 60 deaths
  
  *Muni NI NEJM 2004*

- Pathology of DES ST showed “smoking gun”: delayed healing with incomplete re-endothelialization plus inflammation. Not seen in BMS controls.
  
  *Finn AV Circ 2007*

- After 12 mos, DES (but not BMS) had continued risk of ST (0.6%/yr)
  
  *Daeman J Lancet 2007*

- “Premature” DAPT D/C after DES: HR for ST 161
  
  *Iakovou I JAMA 2005*

- Extended use (> 1yr) of DAPT ↓ death/MI in DES but not BMS
  
  *Eisenstein EL JAMA 2007*
BMS Restenosis vs DES Stent Thrombosis: Perceptions of the Worst Case Scenario

- Restenosis after BMS:
  a benign nuisance (TVR, no effect on death/MI)

- Stent thrombosis after DES:
  “most feared complication”

  “catastrophic… occupies a central place in the risk-benefit equation of PCI”

  JACC Interv 2014

  JACC 2010
Mayo Clinic Bare Metal Stent Experience (1994-2000): Very Late ST Does Occur. Restenosis Not Always Benign

4503 PCI pts with BMS, median F/U 7.9 yrs
MI after ST (74 pts) and after restenosis (84 pts) both risk of death

Doyle B et al, Circ 2007
Death Rates With DES Late/Very Late ST: Half the Rate of Early ST (10% at 2 years)

8146 PCI pts (2002 – 2005) at U Bern & Thoraxcenter
47% SES, 53% PES
192 definite ST (48% early, 52% late/very late)
Overall mortality at 2 yrs 15.6%

Death after dx definite ST occurred in 0.4% of study cohort, accounted for 3.9% of 702 deaths

Wenaweser P et al, JACC 2008
PARIS Registry to Study DAP Withdrawal in PCI: Most Events Occur on Continued DAP

5018 PCI pts (16% BMS, 14% 1<sup>st</sup> gen DES, 70% 2<sup>nd</sup> gen DES)
15 sites (US, EU) 2009-2010
2 yr F/U: DAPT cessation rate 57%

<table>
<thead>
<tr>
<th>Continued DAPT</th>
<th>MD-directed D/C</th>
<th>Interrupted For Surgery (&lt;14 days)</th>
<th>Disrupted (Bleed, noncompliance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cohort</td>
<td>2304 (46%)</td>
<td>1611 (32%)</td>
<td>412 (8%)</td>
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<tr>
<td>Def/prob ST</td>
<td>80%</td>
<td>4%</td>
<td>1%</td>
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<td>(N=71)</td>
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<tr>
<td>MI</td>
<td>64%</td>
<td>10%</td>
<td>4%</td>
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<tr>
<td>(N=180)</td>
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<tr>
<td>Cardiac Death</td>
<td>68%</td>
<td>10%</td>
<td>5%</td>
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<tr>
<td>(N=148)</td>
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</tbody>
</table>

Mehran R et al, Lancet 2013
DAPT Trial BMS vs DES Comparison: What Have We Learned?

- BMS not safer from patient perspective
- Risk of ST does continue after 12 mos for both BMS + DES
- Most (80 – 85%) of late CV events after PCI not due to stent choice
- Current DAPT can ↓ but not eliminate both ST and non-stent related CV events
Choice of Tools vs Choice of Therapy: Patients Want Better Outcomes

Medicare beneficiaries age ≥ 66
Multivessel CABG or PCI
“BMS era” 1/1999 – 4/2003

“Introduction of DES did not alter comparative effectiveness of CABG and PCI with respect to hard cardiac outcomes”

Hlatky MA et al, AHJ, 2014