Stent Safety: Fear Not

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Director of Interventional Cardiology
Scripps Clinic

Disclosures:
Cordis, Boston, Medtronic: Research Grants
Consultant
Speakers Bureau
Shepherd Scienti Equity
STENTS
DEFIBRILLATORS
SPINAL DISCS
ARTIFICIAL KNEES

Are These
As Safe As
You Think?
Renu Vermani gives informed consent to a DES patient
Influence of Clinical Trials Results and Perception: DES Penetration in the US

Source: Millennium Research Group
DES Penetration in the US

Source: Millennium Research Group

9.5% increase
Lagerqvist et al, NEJM 2007

**SCAAR-**
**Swedish Coronary Angiography**
**and Angioplasty Registry**

DES pts = 13,738
Bare metal pts = 6,033

Long-term outcome
of DES vs BMS
implanted in Sweden
2003 – 2004

RESULTS
Death (Adjusted)

Cumulative risk

Time (years)

RR: 1.18 (1.04, 1.35)

Lagerqvist et al, NEJM 2007
What a difference a year makes!

of DES vs BMS implanted in Sweden
2003 – 2004

RESULTS

Lagerqvist et al, NEJM 2007
2003 – 2005 data: One more year of patients and follow-up. Mortality is no longer higher for DES

Adjusted Death

Total cohort
N=35 262

One stent cohort
N=18 937
DES and Clinical Outcomes: The Mega-Meta Analysis

Ajay J. Kirtane, M.D., S.M.
Gregg W. Stone, M.D.
All-Cause Mortality: All RCTs

8,867 patients, 21 trials

<table>
<thead>
<tr>
<th>Study</th>
<th>Estimate (95% CI)</th>
<th>Weight (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCORPIUS</td>
<td>1.28 (0.35, 4.61)</td>
<td>1.86</td>
</tr>
<tr>
<td>SESAMI</td>
<td>0.43 (0.11, 1.63)</td>
<td>1.70</td>
</tr>
<tr>
<td>Typhoon</td>
<td>1.01 (0.38, 2.65)</td>
<td>3.27</td>
</tr>
<tr>
<td>Passion</td>
<td>0.70 (0.36, 1.36)</td>
<td>6.99</td>
</tr>
<tr>
<td>BASKET (SES only)</td>
<td>0.82 (0.37, 1.84)</td>
<td>4.80</td>
</tr>
<tr>
<td>STRATEGY</td>
<td>0.84 (0.36, 1.96)</td>
<td>4.30</td>
</tr>
<tr>
<td>SES-SMART</td>
<td>0.21 (0.02, 1.71)</td>
<td>0.62</td>
</tr>
<tr>
<td>Seville</td>
<td>1.35 (0.23, 7.78)</td>
<td>1.00</td>
</tr>
<tr>
<td>HAAMU-STENT</td>
<td>2.00 (0.63, 6.38)</td>
<td>2.30</td>
</tr>
<tr>
<td>MISSION!</td>
<td>0.48 (0.09, 2.59)</td>
<td>1.09</td>
</tr>
<tr>
<td>PRISON II</td>
<td>0.50 (0.09, 2.67)</td>
<td>1.07</td>
</tr>
<tr>
<td>Pache et al</td>
<td>1.40 (0.45, 4.35)</td>
<td>2.40</td>
</tr>
<tr>
<td>Ortolani et al</td>
<td>2.00 (0.19, 21.38)</td>
<td>0.55</td>
</tr>
<tr>
<td>DIABETES</td>
<td>1.44 (0.48, 4.33)</td>
<td>2.55</td>
</tr>
<tr>
<td>RAVEL</td>
<td>1.75 (0.73, 4.16)</td>
<td>4.08</td>
</tr>
<tr>
<td>SIRIUS</td>
<td>1.02 (0.67, 1.54)</td>
<td>17.82</td>
</tr>
<tr>
<td>C-SIRIUS</td>
<td>0.68 (0.11, 4.04)</td>
<td>0.95</td>
</tr>
<tr>
<td>E-SIRIUS</td>
<td>1.08 (0.25, 2.24)</td>
<td>2.57</td>
</tr>
<tr>
<td>TAXUS II</td>
<td>1.61 (0.57, 4.53)</td>
<td>2.87</td>
</tr>
<tr>
<td>TAXUS IV</td>
<td>0.89 (0.63, 1.25)</td>
<td>26.29</td>
</tr>
<tr>
<td>TAXUS V</td>
<td>0.97 (0.57, 1.65)</td>
<td>10.92</td>
</tr>
</tbody>
</table>

Random Effects
*Fixed Effects (I²=0.0%)
All-Cause Mortality: All Registries

169,595 patients, 31 registries

NOTE: Weights are from random effects analysis

D+L Overall (I-squared = 70.9%, p = 0.000)

SMART

Melbourne

Massachusetts (matched)

Washington Hosp Center (matched)

Multicenter SVG (adjusted)

I-V Overall

Rotterdam Off-Label

ACUITY (from RCT)

REAL (adjusted)

Liverpool (matched)

Wake Forest (adjusted)

Mayo FFR Substudy

Cedars Acute MI

Erac (adjusted)

ACUITY (from RCT)

GHOST (adjusted)

Mayo FFR Substudy

Liverpool (matched)

Sussex Elderly

ERACI III (from RCT)

Ontario (matched)

MIDAS (adjusted)

RESTEM

ARTS II (from RCT)

Northern New England (adjusted)

Sussex Elderly

ERACI III (from RCT)

Ny State (adjusted, unmatched)

Ontario (matched)

MIDAS (adjusted)

German FFR Substudy

Northern New England (adjusted)

NHLBI (off label, adjusted)

NHLBI (on label, adjusted)

Germany Metabolic Syndrome

Ontario (matched)

Mayo FFR Substudy

Italian Diabetic Multivessel (adjusted)

McMaster STEMI (adjusted)

Germany Metabolic Syndrome

NHLBI (off label, adjusted)

NHLBI (on label, adjusted)

0.78 (0.71, 0.86), p<0.001

0.81 (0.78, 0.85)
TVR: All RCTs

7,291 patients, 16 trials

NOTE: Weights are from random effects analysis

D+L Overall  (I-squared = 53.2%, p = 0.006)

Pache et al
HAAMU-STENT
C-SIRIUS
Typhoon
STRATEGY
SIRIUS
SCANDSTENT
TAXUS II
E-SIRIUS
MISSION!
Ortolani et al
SESAMI
I-V Overall
TAXUS V
RAVEL
SIRIUS
C-SIRIUS
E-SIRIUS
TAXUS II
TAXUS IV
TAXUS V

*Random Effects (I²=53.2%)
Fixed Effects

Mean f/u 3.2 yrs

0.45 (0.37, 0.54), p<0.001
0.51 (0.45, 0.57)

Favors DES

Favors BMS

1

10

Estimate (95% CI)  Weight (%)

0.36 (0.17, 0.79)  4.36
0.42 (0.25, 0.69)  7.20
0.34 (0.16, 0.77)  4.22
0.33 (0.09, 1.19)  1.91
0.38 (0.17, 0.85)  4.08
0.37 (0.19, 0.69)  5.49
0.38 (0.23, 0.64)  7.14
0.58 (0.25, 1.36)  3.78
0.17 (0.09, 0.33)  5.44
0.51 (0.25, 1.04)  4.83
0.48 (0.37, 0.62)  11.51
0.30 (0.10, 0.93)  2.45
0.35 (0.21, 0.56)  7.45
0.61 (0.35, 1.08)  6.44
0.57 (0.45, 0.72)  11.94
0.77 (0.60, 0.98)  11.75

Ajay J. Kirtane and Gregg W. Stone, 2008

7,291 patients, 16 trials
Is there a DES safety problem?

- Probably NOT!
- There may even be a safety advantage for some DES patient subgroups
- TVR benefit makes DES the right choice for most patients
Do DES patients need prolonged dual antiplatelet therapy?

- Evils of dual antiplatelet therapy
  - Bleeding
  - Bruising
  - Cost
  - Need for unplanned surgery
  - Endless, daily, phone calls and questions from physicians and patients
BASKET Trial: 18 Month MACE
N=836 (All pts with 18 month FU)

Kaiser C et al. ESC 2006.
BASKET LATE Trial: 6-18 Mo MACE
N=743 (pts with early events excluded)

Pfisterer M. ACC 2006
Antiplatelet Therapy and DES

6-Month Landmark Analysis
Adjusted Cumulative Rates of Death or Nonfatal MI

<table>
<thead>
<tr>
<th>Group</th>
<th>% (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>DES+C – DES-C</td>
<td>-4.1 (-7.6, -0.6)</td>
<td>0.021</td>
</tr>
<tr>
<td>DES+C – BMS-C</td>
<td>-2.9 (-5.3, -0.5)</td>
<td>0.017</td>
</tr>
<tr>
<td>DES+C – BMS+C</td>
<td>-2.4 (-5.6, 0.9)</td>
<td>0.16</td>
</tr>
<tr>
<td>BMS+C – BMS-C</td>
<td>-0.5 (-3.2, 2.2)</td>
<td>0.70</td>
</tr>
<tr>
<td>DES-C – BMS-C</td>
<td>1.2 (-1.8, 4.2)</td>
<td>0.44</td>
</tr>
</tbody>
</table>

Number at Risk
- DES+C: 637
- DES-C: 579
- BMS+C: 417
- BMS-C: 1976

Graph shows percent cumulative incidence rate over 6, 12, 18, and 24 months with data from Duke Clinical Research Institute.

Eisenstein et al. JAMA 2007
Will new stent technology improve stent safety and reduce the need for long term antiplatelet therapy?
Polymer and Drug Matrix

PC Basecoat
(≈ 1μm thick)

Drug Layer
90% Zotarolimus (10μg/mm)
10% PC
(≈ 2-4μm thick)

PC Overspray
(≈ 0.1 μm thick)

Stent Strut

Illustrative
Not to Scale

Tissue

Blood

3.0 mm Stents
500x magnification

New Gen
DES

Cypher

Taxus

Illustrative
Not to Scale
ENDEAVOR Safety Considerations

Design Features

Stent design = reduced injury (rounded thin struts)

Rapid drug elution

PC Basecoat
(≈ 1μm)

Drug Layer
90% Zotarolimus
10% PC (≈ 2-4μm)

Safe formulation
Source: Medtronic Vascular Data Presentation, TCTMD; TAXUS IV SR Presentation, TCTMD; Cypher Presentation, TCTMD; Data on file at Abbott Vascular.
ENDEAVOR IV – 3yr FU

Clinical Trial Design
PIs: Martin B. Leon and David E. Kandzari

Single De Novo Native Coronary Lesion
Vessel Diameter: 2.5–3.5 mm
Lesion Length: ≤ 27 mm
Pre-dilatation required

Endeavor Stent
n = 774

1:1 randomization
N = 1,548 patients
80 sites
US

Taxus Stent
n = 774

Clinical/MACE
30d 6mo 8mo 9mo 12mo 2yr 3yr 4yr 5yr

Angiography/IVUS
QCA and IVUS Subset
(328 total = 21.2%)

Primary Endpoint: TVF at 9 months
Secondary Endpoints: In-segment % DS at 8 months; TLR and TVR at 9 months
Drug Therapy: ASA and Clopidogrel/Ticlid ≥6 months
Zotarolimus Dose: 10 µg per mm stent length
ENDEAVOR IV – 3yr FU
CD/MI to 36 months

Cumulative Incidence of Cardiac Death/MI

Time after Initial Procedure (days)

Endeavor Taxus

1-year HR
0.66 [0.35, 1.25]
P=0.201

3.1%

2.1%

3.6%

3-year HR
0.52 [0.32, 0.82]
P = 0.004

7.1%

3.5%

Values are the KM estimates
P values were calculated by Log Rank Test
ENDEAVOR IV – 3yr FU

ARC VLAST 12-36 mos

Values are the event rates
P values were calculated by Fisher Exact Test

Endeavor (n=734)
Taxus (n=734)

<table>
<thead>
<tr>
<th>Category</th>
<th>Endeavor</th>
<th>Taxus</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARC Definite</td>
<td>0.8%</td>
<td>0.0%</td>
<td>0.124</td>
</tr>
<tr>
<td>ARC Probable</td>
<td>0.7%</td>
<td>0.0%</td>
<td>0.062</td>
</tr>
</tbody>
</table>

RRR 91%
NNT: 71
P=0.006

Columbia University Medical Center
The University Hospital of Columbia and Cornell
### Endeavor Clinical Program

**Pooled Safety and Efficacy Analyses**

<table>
<thead>
<tr>
<th>Premarket Safety and Efficacy Package</th>
<th>1yr</th>
<th>2yr</th>
<th>3yr</th>
<th>4yr</th>
<th>5yr</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ENDEAVOR I</strong></td>
<td></td>
<td></td>
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<tr>
<td>Single Arm First-in-Man (n = 100)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5yr</td>
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<tr>
<td><strong>ENDEAVOR II</strong></td>
<td></td>
<td></td>
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<tr>
<td>1:1 RCT vs. BMS (E = 598, D = 599) PK (n = 106)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5yr</td>
</tr>
<tr>
<td><strong>ENDEAVOR II CA</strong></td>
<td></td>
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<td></td>
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<tr>
<td>Continued Access Single Arm (n = 296)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4yr</td>
</tr>
<tr>
<td><strong>ENDEAVOR III</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3:1 RCT vs. Cypher® (E = 323, C = 113)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4yr</td>
</tr>
<tr>
<td><strong>ENDEAVOR IV</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1:1 RCT vs. Taxus® (E = 773, T = 775)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3yr</td>
</tr>
<tr>
<td><strong>ENDEAVOR PK</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacokinetic Study (n = 43)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3yr</td>
</tr>
<tr>
<td><strong>ENDEAVOR Japan</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Single Arm (n = 99)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2yr</td>
</tr>
</tbody>
</table>

*Included in Pooled Safety and Efficacy Analyses (N=2132)*
Pooled Endeavor: Long-term safety

ARC Definite/Probable ST to 4 years

Before 1 year
Endeavor: 0.7%
Driver: 1.2%

After 1 year (VLST)
Endeavor: 0.1%
Driver: 0.3%

E I (5 yr), E II (4 yr), E IICA (4 yr), E III (3 yr), E IV (2 yr) & E PK (1 yr).

p-values are unadjusted for multiple comparisons. Pooled Kaplan-Meier analysis.
SPIRIT IV Study Algorithm

3690 pts enrolled at 66 U.S. sites
RVD ≥2.5 mm - ≤3.75 mm; Lesion length ≤28 mm
Max. 3 lesions with a maximum of 2 per epicardial vessel

Pre-rand: ASA ≥300 mg, clopidogrel ≥300 mg load unless on chronic Rx

Randomized 2:1 XIENCE V®:TAXUS® Express²
Stratified by diabetes and presence of complex lesions
Pre-dilatation mandatory

Everolimus-eluting

Everolimus-eluting XIENCE V

Paclitaxel-eluting

Paclitaxel-eluting TAXUS

Aspirin ≥80 mg QD for 5 years; clopidogrel 75mg QD for at least 12 mos (if not at high risk for bleeding)

Clinical f/u only: 1, 6, 9 months and yearly for 1-5 years
### Death and MI at 1 Year

<table>
<thead>
<tr>
<th></th>
<th>XIENCE V 2458 pts</th>
<th>TAXUS 1195 pts</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death, all</td>
<td>1.0%</td>
<td>1.3%</td>
<td>0.61</td>
</tr>
<tr>
<td>- Cardiac</td>
<td>0.4%</td>
<td>0.4%</td>
<td>1.00</td>
</tr>
<tr>
<td>- Non cardiac</td>
<td>0.6%</td>
<td>0.8%</td>
<td>0.52</td>
</tr>
<tr>
<td>MI, all</td>
<td>1.9%</td>
<td>3.1%</td>
<td>0.02</td>
</tr>
<tr>
<td>- Q-wave</td>
<td>0.1%</td>
<td>0.4%</td>
<td>0.13</td>
</tr>
<tr>
<td>- Non Q-wave</td>
<td>1.7%</td>
<td>2.8%</td>
<td>0.05</td>
</tr>
<tr>
<td>All death or MI</td>
<td>2.8%</td>
<td>4.1%</td>
<td>0.05</td>
</tr>
<tr>
<td>Cardiac death or MI</td>
<td>2.2%</td>
<td>3.3%</td>
<td>0.07</td>
</tr>
</tbody>
</table>

MI = Target Vessel MI + Non-Target Vessel MI

Categorical data, 365 ± 28 days
Stent Thrombosis (ARC Def or Prob)

HR [95%CI] = 0.27 [0.11, 0.67]
p=0.003

Δ 0.77%

Number at risk

<table>
<thead>
<tr>
<th></th>
<th>XIENCE V</th>
<th>TAXUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 0</td>
<td>2458</td>
<td>1229</td>
</tr>
<tr>
<td>At 3</td>
<td>2426</td>
<td>1195</td>
</tr>
<tr>
<td>At 6</td>
<td>2412</td>
<td>1184</td>
</tr>
<tr>
<td>At 9</td>
<td>2388</td>
<td>1174</td>
</tr>
<tr>
<td>At 12</td>
<td>2376</td>
<td>1166</td>
</tr>
</tbody>
</table>
COMPARE - Study Outline

Eligible Patients for PCI

Guide-wire passage ± Predilatation

Operator blinded 1:1 Randomization

Clinical events were adjudicated by an independent CEC

Target vessel revascularizations were analysed by an independent QCA core lab.

Expected MACE
9% versus 14% (delta 5%)
Power 85%

1800 patients
COMPARE Trial

- AMI 25%
- Calcification 34%
- Direct stenting 34%
- Multistenting 62%
- Ostial 19%
- Thrombus 24%
- CTO 4%
- Left main 2%
- Bifurcation 10%
- Diabetes 18%
- Saphenous graft 2%
- Multivessel 27%
- NSTEMI 23%
- Chronic renal failure 3%
- Multivessel 27%
- Diabetes 18%
- Left main 2%
COMPARE – 2\textsuperscript{ry} Endpoint Result

Early and Late Stent Thrombosis (definite & probable according ARC)

Cumulative Incidence of Events (%)

Days Since Index Procedure

- Taxus
- Xience

\[ P = 0.002 \text{ (log-rank test)} \]

\[ RR = 0.26 \text{ (0.11-0.64)} \]

2.6 %

0.7 %
Are we creating Plavix Addicts?

“"I gotta have my Plavix"
Endeavor Clinical Program

Dual Antiplatelet Therapy Usage (average)

<table>
<thead>
<tr>
<th>Period</th>
<th>% on DAPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post procedure</td>
<td>98.7</td>
</tr>
<tr>
<td>30 days</td>
<td>95.6</td>
</tr>
<tr>
<td>6 months</td>
<td>76.3</td>
</tr>
<tr>
<td>9 months</td>
<td>42.7</td>
</tr>
<tr>
<td>1 year</td>
<td>26.3</td>
</tr>
<tr>
<td>2 years</td>
<td>9.9</td>
</tr>
</tbody>
</table>

Data on file Medtronic Inc. UC200802485a
Pooled Endeavor: Reassuring long-term safety

**ARC Definite/Probable cumulative ST to 4 years**

- **Before 1 year**
  - Endeavor: 0.7%
  - Driver: 1.2%

- **After 1 year (VLST)**
  - Endeavor: 0.1%
  - Driver: 0.3%

**Days**

<table>
<thead>
<tr>
<th>Days</th>
<th>Endeavor</th>
<th>% CI</th>
<th>Driver</th>
<th>% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>2132</td>
<td>0.0%</td>
<td>596</td>
<td>0.2%</td>
</tr>
<tr>
<td>30</td>
<td>2131</td>
<td>0.3%</td>
<td>595</td>
<td>1.2%</td>
</tr>
<tr>
<td>270</td>
<td>2114</td>
<td>0.5%</td>
<td>587</td>
<td>1.3%</td>
</tr>
<tr>
<td>360</td>
<td>2068</td>
<td>0.6%</td>
<td>576</td>
<td>1.3%</td>
</tr>
<tr>
<td>720</td>
<td>2036</td>
<td>0.7%</td>
<td>570</td>
<td>1.3%</td>
</tr>
<tr>
<td>1080</td>
<td>1650</td>
<td>0.7%</td>
<td>559</td>
<td>1.5%</td>
</tr>
<tr>
<td>1440</td>
<td>1087</td>
<td>0.7%</td>
<td>543</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

Pooled Kaplan-Meier analysis.

P = 0.071
Thienopyridine x 6 months:

- Single *de novo* atherosclerotic lesion with diameter stenosis 50% to 100% (includes total coronary occlusions
- Lesion length ≤40 mm
- Reference vessel diameter ≥2.25 mm to 4.0 mm
- Lesion not involving side-branch intended to be stented
- Ostial or non-ostial location
- In-stent restenosis not treated with prior brachytherapy
- 1 or 2 vessels per patient (up to two lesions per vessel with each lesion meeting anatomic criteria above)
- Saphenous vein or arterial bypass graft
Bedside Monitoring of Platelet Reactivity: Accumetrics VerifyNow Assay for Plavix responsiveness

Insert assay device
Add blood sample
Read result in minutes
Stent Thrombosis after DES Implantation at 6 Month Follow-up

6 episodes of stent thrombosis

Plavix “resistant”

Plavix sensitive

Price MJ et al, ACC 2007
Increasing Risk With Greater Residual Reactivity After Clopidogrel According to VerifyNow P2Y12 Assay

Event Rates In Prospective PCI Studies Stratified By PRU Quartile

Stent Thrombosis Rates at End of Study

Tritron Study

Based on Kaplan-Meier estimates.
*Stent thrombosis defined as Academic Research Consortium definite or probable.

Please see Important Safety Information, including Boxed Warning, and Full Prescribing Information provided.
Successful PCI with DES (with 600mg clopidogrel load) without major complication or GPIIb/IIIa use

VerifyNow P2Y12 Assay 12-24 hours post-PCI

PRU ≥ 230?

Yes

Non-Responder

“Tailored Therapy” clopidogrel 600-mg*, then clopidogrel 150-mg/day

No

Resiner

“Standard Therapy” placebo loading dose, then clopidogrel 75mg +placebo/day

Random Selection

N = 1100

“A” ACS

N = 1100

“Standard Therapy” placebo loading dose clopidogrel 75mg +placebo/day

N = 583

B

Clinical Follow-up And Platelet Function Assessment at 30 days, 6M

Primary Endpoint: 6 month CV Death, Non-Fatal MI, ARC definite/prob ST

Safety Endpoint: GUSTO Moderate or Severe Bleeding

Price MJ et al, Am Heart J 2009

*total first day dose
Clopidogrel, Genotype, and Clinical Outcomes in ACS
TRITON Results According to Carriage of Reduced Fxn CYP2C19 Allele in ACS Patients Receiving Clopidogrel

FEAR NOT

- Stent Thrombosis scare was never justified
- New DES technology has significantly improved safety
  - Stent Thrombosis rates are lower
  - Duration of dual anti-platelet requirement may be shorter
- Personalized medicine - titrating anti-platelet therapy to individual’s genotype and platelet reactivity has likely further improved stent safety