PCI In Specific Subgroups:

PCI IN WOMEN

THE XXX FILES

Α-Δ. ΜΑΥΡΟΓΙΑΝΝΗ
ΚΑΡΔΙΟΛΟΓΟΣ
ΑΙΜΟΔΥΝΑΜΙΚΟ ΕΡΓΑΣΤΗΡΙΟ
Γ.Ν.Θ. «Γ.ΠΑΠΑΝΙΚΟΛΑΟΥ»
ΘΕΣΣΑΛΟΝΙΚΗ
Disclosure Statement of (Financial) Interest

Snake. Apple. You figure it out.
Y Chromosome:
The Runt* of Our Chromosome Litter

*(in a group of animals a runt is a member which is smaller or weaker than the others)*

the Y has only 19 of the approximately 600 genes it once shared with the X, 200 to 300 million years ago

Griffin DK.

Is the Y chromosome disappearing?—both sides of the argument.

Cardiovascular Disease: The Leading Cause of Death in US Women

Deaths (1,000)

Heart disease: 375
Cerebrovascular disease
Lung cancer: 60.6
COPD: 48.9
Pneumonia/Inf.: 45.1
Breast cancer: 43.8
Accidents: 31.9
Diabetes: 33.1
Ovarian cancer: 9.9

Anderson RN. et al.
http://www.cdc.gov/nchs/data/mvsr/supp/mv45_11s2
This is a Man's Man's Man's World…*

*(but it would be nothing, nothing without a woman or a girl)*

<table>
<thead>
<tr>
<th>Location</th>
<th>Age, mean (years)</th>
<th>Male %</th>
<th>Hyperlipidemia %</th>
<th>Smoking %</th>
<th>Hypertension %</th>
<th>Diabetes %</th>
<th>White race %</th>
<th>Height, cm</th>
<th>Weight, kg</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>62.8</td>
<td>71.9</td>
<td>38.3</td>
<td>35.3</td>
<td>59.1</td>
<td>31.6</td>
<td>83.3</td>
<td>163.7</td>
<td>66.3</td>
<td>24.8</td>
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<tr>
<td>Europe</td>
<td>63.3</td>
<td>74.3</td>
<td>50.7</td>
<td>33.4</td>
<td>52.1</td>
<td>20.9</td>
<td>94.6</td>
<td>170.0</td>
<td>79.6</td>
<td>27.2</td>
</tr>
<tr>
<td>Asia</td>
<td>60.0</td>
<td>79.6</td>
<td>68.8</td>
<td>28.6</td>
<td>73.2</td>
<td>30.5</td>
<td>-</td>
<td>171.8</td>
<td>83.9</td>
<td>29.0</td>
</tr>
</tbody>
</table>

Liu E. et al.

Global geographical variation in patient characteristics in percutaneous coronary intervention clinical trials: A systematic review and meta-analysis.

Am Heart J. 2018 Jan;195:39-49
Problems with PCI in Women

- **Later Diagnosis** → elderly with more comorbidities
- **More Diabetes** → restenosis
- **Smaller Coronaries** → restenosis
- **Coronary Tortuosity** → difficulty tracking equipment, dissections, rigid stents straighten vessels and may fracture
- **Hemodynamics** → low cardiac output despite normal EF: unable to tolerate coronary occlusion
- **Bleeding Complications**
<table>
<thead>
<tr>
<th></th>
<th>Women (n 1,164)</th>
<th>Men (n 3,721)</th>
<th>Difference (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, years</strong></td>
<td>67.1 (10.5)</td>
<td>63.0 (10.7)</td>
<td>4.09 (3.39 to 4.79)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Cardiac Risk Factors</strong></td>
<td></td>
<td></td>
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<tr>
<td>diabetes</td>
<td>315 (27.1)</td>
<td>804 (21.6)</td>
<td>5.46 (2.66 to 8.25)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>insulin requiring</td>
<td>134 (42.6)</td>
<td>253 (31.5)</td>
<td>11.08 (4.86 to 17.31)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>obese</td>
<td>336 (28.9)</td>
<td>903 (24.4)</td>
<td>4.52 (1.64 to 7.40)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>hypertension</td>
<td>889 (76.4)</td>
<td>2,531 (66.0)</td>
<td>8.36 (5.28 to 11.44)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>hypercholesterolemia</td>
<td>751 (64.5)</td>
<td>2,426 (65.2)</td>
<td>-0.68 (-3.37 to 2.01)</td>
<td>0.62</td>
</tr>
<tr>
<td>creatinine &gt;2.0 mg/ l</td>
<td>15 (1.3)</td>
<td>57 (1.6)</td>
<td>-0.26 (-1.08 to 0.55)</td>
<td>0.52</td>
</tr>
<tr>
<td>current smoking</td>
<td>272 (23.4)</td>
<td>1,067 (28.7)</td>
<td>-5.31 (-8.33 to -2.29)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Clinical History</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>previous MI</td>
<td>285 (24.7)</td>
<td>1,186 (32.2)</td>
<td>-7.51 (-10.55 to -4.46)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>previous PCI</td>
<td>338 (29.0)</td>
<td>1,173 (31.5)</td>
<td>-2.49 (-5.21 to 0.23)</td>
<td>0.07</td>
</tr>
<tr>
<td>previous CABG</td>
<td>73 (6.3)</td>
<td>428 (11.5)</td>
<td>-5.23 (-7.25 to -3.21)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Clinical Indication</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.29</td>
</tr>
<tr>
<td>SCAD</td>
<td>540 (46.4)</td>
<td>1,738 (46.7)</td>
<td>-0.32 (-0.90 to 0.27)</td>
<td></td>
</tr>
<tr>
<td>N STEACS</td>
<td>444 (38.1)</td>
<td>1,321 (35.5)</td>
<td>2.64 (-2.22 to 7.50)</td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>180 (15.5)</td>
<td>662 (17.8)</td>
<td>-2.33 (-6.61 to 1.95)</td>
<td></td>
</tr>
<tr>
<td>LVEF &lt;50</td>
<td>167 (21.1)</td>
<td>581 (22.5)</td>
<td>-1.43 (-4.70 to -1.84)</td>
<td>0.39</td>
</tr>
<tr>
<td>SYNTAX Score</td>
<td>12.9±8.4</td>
<td>13.8±8.7</td>
<td>0.95 (1.55 to 0.34)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Multi Vessel Disease</strong></td>
<td>280 (24.1)</td>
<td>980 (26.3)</td>
<td>2.25 (5.37 to 0.87)</td>
<td>0.39</td>
</tr>
</tbody>
</table>
Extention of Coronary Artery Disease in NSTE ACS

FEMALE N=3152   MALE N=7260
TOTAL N 10412

Restricted to patients in invasive arms, ≥50% stenosis

Mehta SR. et al
JAMA. 2005 Jun 15;293(23):2908-17
Absence of Significant CAD

Mehta SR. et al
JAMA. 2005 Jun 15;293(23):2908-17
### Newer Generation Stents May Have Leveled the Playing Field for Women

<table>
<thead>
<tr>
<th>Study</th>
<th>Results</th>
</tr>
</thead>
</table>
| SES vs BMS  
4 randomized trials (n=1748)  
J Am Coll Cardiol. 2007 Nov 27;50(22):2111-6 | Gender not predictive of MACE  
SES ↓ restenosis  
- Women 6.3 vs 43.8%  
- Men 6.4 vs 35.6% |
| TAXUS IV  
Randomized Trial (n=1314)  
J Am Coll Cardiol. 2005 Apr 19;45(8):1165-71 | Gender not predictive of MACE  
PES ↓ restenosis  
- Women 8.6% vs 29.2%  
- Men 7.6% vs 25.6% |
| Arts I and II  
Arts 1 = BMS vs CABG  
Arts 2 = SES  
EuroIntervention. 2009 Jan;4(4):492-501 | Gender not predictive of MACE after SES  
Improved outcome in both men and women with SES |
| NHLBI Dynamic Registry  
Am J Cardiol. 2007 Mar 1;99(5):626-31 | Gender not predictive of MACE after DES or BMS  
Reduction in TVR after DES similar in males and females |
Patient Level Pooled Analysis of 26 DES Trials in 11,557 Women Events at 3 Years (BMS/ SES/ PES/ EES/ ZES/ BES)

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Incidence %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>5.7%</td>
</tr>
<tr>
<td>MI</td>
<td>5.9%</td>
</tr>
<tr>
<td>Def./ Prob. ST</td>
<td>4.5%</td>
</tr>
<tr>
<td>TLR</td>
<td>1.6%</td>
</tr>
</tbody>
</table>

For Women:
- Death: 5.7%
- MI: 5.5%
- Def./ Prob. ST: 4.5%
- TLR: 1.6%

For Overall:
- Death: 8%
- MI: 4.5%
- Def./ Prob. ST: 1.6%
- TLR: 8.3%

Stefanini GG. et al.
Safety and efficacy of drug-eluting stents in women: a patient-level pooled analysis of randomised trials.
Lancet. 2013 Dec 7;382(9908):1879-88
Angiographic Outcomes Among Women and Men
Pooled Analysis from SIRTAX/ LEADERS/ RESOLUTE All Comers
n 5011 pts. 2 years F.U

Stefanini GG. et al.
Impact of sex on clinical and angiographic outcomes among patients undergoing revascularization with drug-eluting stents.
Long-Term Outcomes in Women Undergoing PCI With DES Impact of Clinical Presentation

Giustino G. et al.
Yearly Rates of In-Hospital Death for Men and Women with Acute STEMI BMC2 Data Base n 8.771 pts. from 2003-2008

Jackson EA. et al.
The association of sex with outcomes among patients undergoing primary percutaneous coronary intervention for ST elevation myocardial infarction in the contemporary era: Insights from the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2).
Am Heart J. 2011 Jan;161(1):106-112.e1
### O.R for Outcomes: Women vs. Men, STEMI pts. 2003-2008

<table>
<thead>
<tr>
<th>In-hospital outcomes</th>
<th>All data</th>
<th></th>
<th></th>
<th>Matched data</th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>95% CI</td>
<td>P value</td>
<td>OR</td>
<td>95% CI</td>
<td>P value</td>
</tr>
<tr>
<td>Emergency CABG</td>
<td>1.06</td>
<td>0.70-1.58</td>
<td>.79</td>
<td>1.04</td>
<td>0.60-1.79</td>
<td>.64</td>
</tr>
<tr>
<td>All CABG</td>
<td>0.83</td>
<td>0.64-1.08</td>
<td>.17</td>
<td>0.85</td>
<td>0.61-1.19</td>
<td>.35</td>
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<tr>
<td>Gastrointestinal Bleeding</td>
<td>1.74</td>
<td>1.36-2.21</td>
<td>&lt;.0001</td>
<td>1.19</td>
<td>0.87-1.63</td>
<td>.33</td>
</tr>
<tr>
<td>Contrast Nephropathy</td>
<td>1.75</td>
<td>1.46-2.11</td>
<td>&lt;.0001</td>
<td>1.09</td>
<td>0.87-1.37</td>
<td>.44</td>
</tr>
<tr>
<td>Nephropathy requiring Dialysis</td>
<td>1.28</td>
<td>0.79-2.06</td>
<td>.31</td>
<td>0.85</td>
<td>0.48-1.50</td>
<td>.56</td>
</tr>
<tr>
<td>Post Procedure Transfusion</td>
<td>2.84</td>
<td>2.48-3.24</td>
<td>&lt;.0001</td>
<td>1.88</td>
<td>1.57-2.24</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Stroke</td>
<td>1.85</td>
<td>1.15-2.97</td>
<td>.01</td>
<td>1.37</td>
<td>0.76-2.49</td>
<td>.29</td>
</tr>
<tr>
<td>MI</td>
<td>1.01</td>
<td>0.64-1.60</td>
<td>.96</td>
<td>0.87</td>
<td>0.49-1.57</td>
<td>.87</td>
</tr>
<tr>
<td>Death</td>
<td>1.79</td>
<td>1.45-2.22</td>
<td>&lt;.0001</td>
<td>1.30</td>
<td>0.98-1.72</td>
<td>.07</td>
</tr>
<tr>
<td>TLR</td>
<td>1.19</td>
<td>0.80-1.78</td>
<td>.38</td>
<td>1.31</td>
<td>0.76-2.26</td>
<td>.33</td>
</tr>
<tr>
<td>Vascular Complication</td>
<td>2.13</td>
<td>1.75-2.59</td>
<td>&lt;.0001</td>
<td>1.65</td>
<td>1.26-2.14</td>
<td>.0002</td>
</tr>
<tr>
<td></td>
<td>Underweight, 139 (1.0%)</td>
<td>Normal Weight, 2,740 (29.0%)</td>
<td>Overweight, 3,430 (36.0%)</td>
<td>Obese, 1,920 (20.0%)</td>
<td>Severely Obese, 1,191 (13.0%)</td>
<td>p Value</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------------</td>
<td>-------------------------------</td>
<td>--------------------------</td>
<td>----------------------</td>
<td>-------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>Age, years</strong></td>
<td>69.76 ± 12.20</td>
<td>68.75 ± 10.68</td>
<td>67.86 ± 10.27</td>
<td>66.23 ± 10.60</td>
<td>63.45 ± 10.16</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Weight, Kg</strong></td>
<td>43.17 ± 6.62</td>
<td>56.83 ± 7.49</td>
<td>69.45 ± 7.91</td>
<td>81.68 ± 8.36</td>
<td>100.14 ± 13.89</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Height, cm</strong></td>
<td>157.67 ± 11.45</td>
<td>158.98 ± 8.54</td>
<td>160.27 ± 7.97</td>
<td>160.05 ± 7.28</td>
<td>159.92 ± 7.36</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>BMI, Kg/m²</strong></td>
<td>17.26 ± 1.08</td>
<td>22.42 ± 1.53</td>
<td>27.01 ± 1.44</td>
<td>31.83 ± 1.42</td>
<td>38.99 ± 4.24</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Median IQR</strong></td>
<td>18.00 (17.00–18.00)</td>
<td>23.00 (21.00–24.00)</td>
<td>27.00 (26.00–28.00)</td>
<td>32.00 (30.80–33.00)</td>
<td>37.98 (36.00–40.97)</td>
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</table>

**Risk Factors**

<table>
<thead>
<tr>
<th></th>
<th>diabetes</th>
<th>hypertension</th>
<th>hyperchol./mia</th>
<th>creatinin mg/dl</th>
<th>smoking</th>
<th>family history</th>
<th>previous MI</th>
<th>previous PCI</th>
<th>previous CABG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>24 (17.3)</td>
<td>91 (65.5)</td>
<td>68 (48.9)</td>
<td>1.07 ± 1.11</td>
<td>45 (32.4)</td>
<td>34 (26.0)</td>
<td>27 (19.4)</td>
<td>35 (25.4)</td>
<td>5 (3.6)</td>
</tr>
<tr>
<td></td>
<td>606 (22.1)</td>
<td>1,842 (67.2)</td>
<td>1,676 (61.2)</td>
<td>0.95 ± 0.91</td>
<td>721 (26.3)</td>
<td>918 (35.0)</td>
<td>479 (17.6)</td>
<td>578 (21.1)</td>
<td>116 (4.2)</td>
</tr>
<tr>
<td></td>
<td>1,022 (29.8)</td>
<td>2,617 (76.3)</td>
<td>2,337 (68.2)</td>
<td>0.91 ± 0.84</td>
<td>872 (25.5)</td>
<td>1,239 (37.8)</td>
<td>622 (18.2)</td>
<td>723 (21.1)</td>
<td>172 (5.0)</td>
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<td></td>
<td>733 (38.2)</td>
<td>1,548 (80.6)</td>
<td>1,396 (72.9)</td>
<td>0.93 ± 0.65</td>
<td>553 (28.9)</td>
<td>783 (42.9)</td>
<td>373 (19.5)</td>
<td>440 (22.9)</td>
<td>126 (6.6)</td>
</tr>
<tr>
<td></td>
<td>657 (55.2)</td>
<td>1,035 (86.9)</td>
<td>855 (72.1)</td>
<td>0.93 ± 0.393</td>
<td>334 (28.2)</td>
<td>535 (48.1)</td>
<td>227 (19.3)</td>
<td>264 (22.2)</td>
<td>75 (6.3)</td>
</tr>
</tbody>
</table>

**Clinical History**

<table>
<thead>
<tr>
<th></th>
<th>previous MI</th>
<th>previous PCI</th>
<th>previous CABG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>27 (19.4)</td>
<td>35 (25.4)</td>
<td>5 (3.6)</td>
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<tr>
<td></td>
<td>479 (17.6)</td>
<td>578 (21.1)</td>
<td>116 (4.2)</td>
</tr>
<tr>
<td></td>
<td>622 (18.2)</td>
<td>723 (21.1)</td>
<td>172 (5.0)</td>
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<td></td>
<td>373 (19.5)</td>
<td>440 (22.9)</td>
<td>126 (6.6)</td>
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<tr>
<td></td>
<td>227 (19.3)</td>
<td>264 (22.2)</td>
<td>75 (6.3)</td>
</tr>
</tbody>
</table>

**p Value** <0.0001 for all comparisons.
The Quintessential Question: Is Bigger Better?  
(Insights Into the Obesity Paradox)

Faggioni M. et al.  
Effects of Body Mass Index on Clinical Outcomes in Female Patients Undergoing Percutaneous Coronary Intervention With Drug-Eluting Stents: Results From a Patient-Level Pooled Analysis of Randomized Controlled Trials.  
JACC Cardiovasc Interv. 2018 Jan 8;11(1):68-76
The Age Paradox: Older is Better
( I Wish… )

Epps KC. et al.
Sex Differences in Outcomes Following Percutaneous Coronary Intervention According to Age. Circ Cardiovasc Qual Outcomes.
2016 Feb;9(2 Suppl 1):S16-25
# Vascular Injury Complications by Gender

<table>
<thead>
<tr>
<th></th>
<th># Women/Men</th>
<th>Women</th>
<th>Men</th>
<th>P-value</th>
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<tbody>
<tr>
<td><strong>Chiu 2004:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>5,301/12,738</td>
<td>12%</td>
<td>4%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Major hematoma</td>
<td></td>
<td>5%</td>
<td>2%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td></td>
<td>0.6%</td>
<td>0.3%</td>
<td>0.005</td>
</tr>
<tr>
<td><strong>Lansky 2002:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major hematoma</td>
<td>562/1,520</td>
<td>2.5%</td>
<td>1.5%</td>
<td>0.005</td>
</tr>
<tr>
<td>Retropertoneal bleed</td>
<td></td>
<td>0.5%</td>
<td>0.2%</td>
<td>0.05</td>
</tr>
<tr>
<td>Surgical repair</td>
<td></td>
<td>3.8%</td>
<td>2.4%</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Welty 2001:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vascular injury</td>
<td>2,101/3,888</td>
<td>1.6%</td>
<td>0.6%</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Peterson 2001:</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Vascular injury</td>
<td>35,571/74,137</td>
<td>5.4%</td>
<td>2.7%</td>
<td>0.001</td>
</tr>
</tbody>
</table>
Lessons Learnt from REPLACE 2:
Impact of Gender on Bleeding Complications in PCI Patients

Chacko M. et al.
Ischemic and bleeding outcomes in women treated with bivalirudin during percutaneous coronary intervention: a subgroup analysis of the Randomized Evaluation in PCI Linking Angioma to Reduced Clinical Events (REPLACE)-2 trial.
Am Heart J. 2006 May;151(5):1032.e1-7
Predictors of Major Bleeding in ACS: ACUITY/HORIZONS-AMI Major Bleeding Risk Score

<table>
<thead>
<tr>
<th>Predictors of any serious bleeding</th>
<th>HR (95% CI)</th>
<th>P value</th>
<th>Strength of association with bleeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female sex</td>
<td>1.77 (1.44-2.18)</td>
<td>&lt;0.001</td>
<td>28.79</td>
</tr>
<tr>
<td>GPIIb/IIa inhibitor used</td>
<td>1.59 (1.29-1.95)</td>
<td>&lt;0.001</td>
<td>19.33</td>
</tr>
<tr>
<td>Age, by decade</td>
<td>1.22 (1.09-1.38)</td>
<td>&lt;0.001</td>
<td>11.07</td>
</tr>
<tr>
<td>Assignment to Prasugrel vs. Clop.</td>
<td>1.34 (1.12-1.60)</td>
<td>0.001</td>
<td>10.19</td>
</tr>
<tr>
<td>ST segment elevation MI</td>
<td>1.35 (1.10-1.66)</td>
<td>0.005</td>
<td>7.98</td>
</tr>
<tr>
<td>Femoral access</td>
<td>1.60 (1.07-2.39)</td>
<td>0.02</td>
<td>5.23</td>
</tr>
<tr>
<td>Creatinine clearance per 10ml/min</td>
<td>1.05 (1.01-1.09)</td>
<td>0.03</td>
<td>4.84</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>0.82 (0.68-0.99)</td>
<td>0.04</td>
<td>4.34</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.24 (1.00-1.54)</td>
<td>0.05</td>
<td>4.02</td>
</tr>
</tbody>
</table>

Mehran R. et al.  
A risk score to predict bleeding in patients with acute coronary syndromes.  
J Am Coll Cardiol. 2010 Jun 8;55(23):2556-66
In-hospital Mortality and Degree of Anticoagulation: CRUSADE Registry

Predictors of Excessive Anticoagulation in ACS Patients: CRUSADE Registry

- Older age
- Female gender
- Lower weight
- Chronic renal insufficiency
- Diabetes mellitus
- Congestive heart failure

Women significantly underrepresented in prior trials
Women present a unique challenge
  - Higher bleeding risk but radial approach underused
  - Smaller radial arteries
  - Potentially higher transradial procedure failure rate

Bertrand OF. et al.
Comparison of transradial and femoral approaches for percutaneous coronary interventions: a systematic review and hierarchical Bayesian meta-analysis.
Radial Artery Internal Diameter in Men and Women

Saito S. et al.
The Study of Access site For Enhancement of PCI for Women: (SAFE-PCI for Women) Trial

Female patient undergoing PCI or cardiac cath w/poss. PCI

Best background medical therapy
Bivalirudin, P2Y12 inhibitors
2b3a at investigator’s discretion

N=3000 pts randomized for 1800 PCI pts
Patent hemostasis required
Vascular closure devices allowed

Radial

Femoral

Primary Efficacy Endpoint (72 hrs or hospital discharge):
BARC Types 2, 3, or 5 bleeding or Vascular Complications requiring intervention

Primary Feasibility Endpoint: Access site crossover

Secondary endpoints: Procedure duration, total radiation dose, total contrast volume, 30-day death/vascular complications/unplanned revascularization

Rao SV. et al.
A registry-based randomized trial comparing radial and femoral approaches in women undergoing percutaneous coronary intervention: the SAFE-PCI for Women (Study of Access Site for Enhancement of PCI for Women) trial.
Results - Primary Efficacy and Feasibility Endpoints: PCI Cohort/ Total Randomized Cohort

<table>
<thead>
<tr>
<th></th>
<th>PCI cohort</th>
<th>Radial (N=345)</th>
<th>Femoral (N=346)</th>
<th>OR (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>BARC 2, bleeding</td>
<td>Radial</td>
<td>Radial (N=893)</td>
<td>Femoral (N=894)</td>
<td>OR (95% CI)</td>
<td>P</td>
</tr>
<tr>
<td>Complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Access site crossover</td>
<td></td>
<td>0.6%</td>
<td>1.7%</td>
<td>0.3 (0.1-0.9)</td>
<td>0.03</td>
</tr>
<tr>
<td>Total randomized</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cohort</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BARC 2, 3, 5 bleeding</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>or Vasc Complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Access site crossover</td>
<td></td>
<td>6.7%</td>
<td>1.9%</td>
<td>3.7 (2.1-6.4)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Interactions for primary efficacy endpoint not significant for ACS vs. Non-tertiles of site radial volume.

Most common reason for needing to convert from radial to femoral access to complete the procedure was radial artery spasm (42.9% of crossovers).

Rao SV. et al.
Impact of Sex on Comparative Outcomes of Radial Versus Femoral Access

MATRIX Access Trial: n 8,804 pts. 30 days

Gargiulo G. et al.
Impact of Sex on Comparative Outcomes of Radial Versus Femoral Access in Patients With Acute Coronary Syndromes Undergoing Invasive Management: Data From the Randomized MATRIX-Access Trial.
JACC Cardiovasc Interv. 2018 Jan 8;11(1):36-50
Main Outcomes of Radial Versus Femoral Access Stratified by Antithrombin in Female Patients

Gargiulo G. et al.
Impact of Sex on Comparative Outcomes of Radial Versus Femoral Access in Patients With Acute Coronary Syndromes Undergoing Invasive Management: Data From the Randomized MATRIX-Access Trial.
JACC Cardiovasc Interv. 2018 Jan 8;11(1):36-50
Platinum Diversity Primary Endpoint
Death/ MI/ TVR

Women vs White Men

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Odds Ratio (95% CI)</th>
<th>P-value</th>
<th>C-statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death/MI/TVR</td>
<td>1.1 [0.87, 1.47]</td>
<td>0.35</td>
<td></td>
</tr>
<tr>
<td>Death/MI</td>
<td>1.6 [1.11, 2.39]</td>
<td>0.01</td>
<td>0.74</td>
</tr>
<tr>
<td>Death</td>
<td>1.4 [0.91, 2.28]</td>
<td>0.11</td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>1.7 [0.91, 3.09]</td>
<td>0.09</td>
<td></td>
</tr>
<tr>
<td>TVR</td>
<td>0.87 [0.63, 1.19]</td>
<td>0.42</td>
<td></td>
</tr>
</tbody>
</table>

Multivariate Analysis

Outcomes in Women and Minorities Compared With White Men 1 Year After Everolimus-Eluting Stent Implantation: Insights and Results From the PLATINUM Diversity and PROMUS Element Plus Post-Approval Study Pooled Analysis.

JAMA Cardiol. 2017 Dec 1;2(12):1303-1313

Batchelor W. et al.
In Conclusion…

- CAD burden is high in women, particularly young women who should be better represented in clinical trials.
- While representation is high in TAVI studies, enrollment in PCI trials continues to lag.
- Trials specifically designed to collect sex and gender specific risk factors, may better ensure equal representation of males and females.

After All…

We are XX for a reason
Snake. Apple. Go figure it.!
Outcomes in Women and Minorities Compared With White Men 1 Year After Everolimus-Eluting Stent Implantation: Insights and Results From the PLATINUM Diversity and PROMUS Element Plus Post-Approval Study Pooled Analysis.

Batchelor W. et al. JAMA Cardiol. 2017 Dec 1;2(12):1303-1313