2011 ACCF/AHA/SCAI Guideline for PCI

What’s new?
Outline

• Brief historical perspective
• Background
• Major changes & additions
• Honorable mentions
• Discussion
Guidelines for the Performance of Percutaneous Transluminal Coronary Angioplasty

Prepared by
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SUMMARY
Percutaneous transluminal coronary angioplasty is a unique procedure that requires special training of the physician who performs it. Appropriate laboratory facilities and surgical support are essential. The guidelines in this report express the opinion of the committee on the safe performance of percutaneous transluminal coronary angioplasty.

The physician

The physician who performs PTCA should be thoroughly experienced in performing routine diagnostic coronary catheterization and angiographic procedures. He must satisfy previously published criteria for performance of coronary arteriography. In addition, he must have a record of performing coronary angioplasty procedures during at least 3000 catheterization procedures, including 300 or more coronary angioplasty procedures during the past 2 years.

Laboratory

The angiographic equipment required to assess a patient for PTCA or to perform PTCA in the catheterization laboratory is not prohibitively expensive. Film, however, is still required. X-ray equipment required for routine diagnostic angiography are not required for performance of PTCA. Film, however, is still required. X-ray equipment required for routine diagnostic angiography are not required for performance of PTCA.

References
Guidelines for Percutaneous Transluminal Coronary Angioplasty

A Report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Subcommittee on Percutaneous Transluminal Coronary Angioplasty)

Subcommittee Members
Thomas J. Ryan, MD, FACC, Chairman; David P. Faxon, MD, FACC;
Rolf M. Gunnar, MD, FACC; J. Ward Kennedy, MD, FACC;
Spencer B. King III, MD, FACC; Floyd D. Loop, MD, FACC; Kirk L. Peterson, MD, FACC;
T. Joseph Reeves, MD, FACC; David O. Williams, MD, FACC;
William L. Winters Jr., MD, FACC

Task Force Members
Charles Fisch, MD, FACC, Chairman; Roman W. De Sanctis, MD, FACC;
Harold T. Dodge, MD, FACC; T. Joseph Reeves, MD, FACC;
Sylvan Lee Weinberg, MD, FACC

Preamble
It is becoming more apparent each day that despite a strong national commitment to excellence in health care, the resources and personnel are finite. It is, therefore, appropriate that the medical profession examine the impact of developing technology on the practice and cost of medical care. Such an analysis, carefully conducted, could potentially impact on the cost of medical care without diminishing the effectiveness of that care.

To this end, the American College of Cardiology and the American Heart Association established a Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures with the following charge:

The Task Force of the American College of Cardiology and the American Heart Association shall define the role of specific noninvasive and invasive procedures in the diagnosis and management of cardiovascular disease.

The Task Force shall address, when appropriate, the contribution, uniqueness, sensitivity, specificity, indications, contraindications, and cost-effectiveness of each specific procedure.

The Task Force shall include a Chairman and four members, two representatives from the American Heart Association and two representatives from the American College of Cardiology. The Task Force may select ad hoc members as needed upon the approval of the Presidents of both organizations. Recommendations of the Task Force are forwarded to the President of each organization.

The members of the Task Force are: Roman W. De Sanctis, MD; Harold T. Dodge, MD; T. Joseph Reeves, MD; Sylvan Lee Weinberg, MD; and Charles Fisch, MD, Chairman.

The Subcommittee on Percutaneous Transluminal Coronary Angioplasty was chaired by Thomas J. Ryan, MD; and the members included the following: David P. Faxon, MD; Rolf M. Gunar, MD; J. Ward Kennedy, MD; Spencer B. King III, MD; Floyd D. Loop, MD; Kirk L. Peterson, MD; T. Joseph Reeves, MD; David O. Williams, MD; and William L. Winters Jr., MD.

This document was reviewed by the officers and other responsible individuals of the two organizations and received final approval in March 1988. It is being published simultaneously in Circulation and Journal of the American College of Cardiology.

The potential impact of this document on the practice of cardiology and some of its unavoidable shortcomings are clearly set out in the introduction.

Charles Fisch, MD, FACC

Circulation 1988;78(2)
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 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 stents; DAPT, dual antiplatelet therapy; and DES, drug-eluting stent(s).
**Classification of Recommendations and Levels of Evidence**

<table>
<thead>
<tr>
<th>Level A</th>
<th>Multiple populations evaluated*</th>
<th>Data derived from multiple randomized clinical trials or meta-analyses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recommendation that procedure or treatment is useful/effective</td>
<td>Evidence from multiple randomized trials or meta-analyses</td>
</tr>
<tr>
<td></td>
<td>Sufficient evidence from multiple randomized trials or meta-analyses</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level B</th>
<th>Limited populations evaluated*</th>
<th>Data derived from a single randomized trial or nonrandomized studies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recommendation that procedure or treatment is useful/effective</td>
<td>Evidence from single randomized trial or nonrandomized studies</td>
</tr>
<tr>
<td></td>
<td>Sufficient evidence from single randomized trial or nonrandomized studies</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level C</th>
<th>Very limited populations evaluated*</th>
<th>Only consensus opinion of experts, case studies, or standard of care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recommendation that procedure or treatment is useful/effective</td>
<td>Only diverging expert opinion, case studies, or standard of care</td>
</tr>
<tr>
<td></td>
<td>Sufficient evidence from single randomized trial or nonrandomized studies</td>
<td></td>
</tr>
</tbody>
</table>

**Estimate of Certainty (Precision) of Treatment Effect**

**Benefit >> Risk**
- Additional studies with focused objectives needed; additional registry data would be helpful to confirm the benefit.
- Procedure/Treatment may be considered.

**Benefit ≥ Risk**
- Additional studies with broad objectives needed; additional registry data would be helpful to confirm the benefit.
- Procedure/Treatment may be considered.

**Benefit or No Benefit**
- Procedure/Treatment is not useful/effective and may be harmful.
- Sufficient evidence from multiple randomized trials or meta-analyses.

**No Benefit or Harm**
- Procedure/Treatment is not useful/effective and may be harmful.
- Sufficient evidence from multiple randomized trials or meta-analyses.

**Excess Cost**
- Procedure/Treatment is not useful/effective and may be harmful.
- Sufficient evidence from multiple randomized trials or meta-analyses.

**Harm**
- Procedure/Treatment is not useful/effective and may be harmful.
- Sufficient evidence from multiple randomized trials or meta-analyses.

**A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.**

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.*

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.
COR & LOE: Simplified

- **A**: Multiple RCTs or Meta-analyses
- **B**: One RCT or Non-RCTs
- **C**: Consensus or Standard of care

<table>
<thead>
<tr>
<th></th>
<th>I</th>
<th>IIa</th>
<th>IIb</th>
<th>III</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td><strong>HARM</strong></td>
<td><strong>BENEFIT</strong></td>
<td><strong>BENEFIT ≥ HARM?</strong></td>
<td><strong>NO BENEFIT or HARM</strong></td>
</tr>
<tr>
<td>B</td>
<td><strong>BENEFIT &gt; HARM</strong></td>
<td><strong>BENEFIT ≥ HARM?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td><strong>BENEFIT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **I**: Should be done
- **IIa**: Reasonable
- **IIb**: Can consider
- **III**: “NO”
The Heart Team
Outcomes in Patients With De Novo Left Main Disease Treated With Either Percutaneous Coronary Intervention Using Paclitaxel-Eluting Stents or Coronary Artery Bypass Graft Treatment in the Synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery (SYNTAX) Trial

Marie-Claude Morice, MD; Patrick W. Serruyts, MD, PhD; A. Pieter Kappetein, MD, PhD; Ted E. Feldman, MD; Elisabeth Stähle, MD; Antonio Colombo, MD; Michael J. Mack, MD; David R. Holmes, MD; Lucia Torracca, MD; Gerrit-Anne van Ex, PhD; Katrin Leadley, MD; Keith D. Dawkins, MD; Friedrich Mohr, MD

Background—The prospective, multinational, randomized Synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery (SYNTAX) trial was designed to assess the optimal revascularization strategy between percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG), for patients with left main (LM) and/or 3-vessel coronary disease.

Methods and Results—This observational hypothesis-generating analysis reports the results of a prespecified powered subgroup of 705 randomized patients who had LM disease among the 1800 patients with de novo 3-vessel disease and/or LM disease randomized to PCI with paclitaxel-eluting stents or CABG in the SYNTAX trial. Major adverse cardiac and cerebrovascular event rates at 1 year in LM patients were similar for CABG and PCI (13.7% versus 15.8%; Δ2.1% [95% confidence interval −3.2% to 7.4%]; P=0.44). At 1 year, stroke was significantly higher in the CABG arm (2.7% versus 0.3%; Δ=2.4% [95% confidence interval −4.2% to −0.1%]; P=0.009), whereas repeat revascularization was significantly higher in the PCI arm (6.5% versus 11.8%; Δ=5.3% [95% confidence interval 1.0% to 9.6%]; P=0.02), there was no observed difference between groups for any end points. When patients were treated for anatomic complexity, those with higher baseline SYNTAX scores had significantly worse outcomes with PCI than did patients with low or intermediate SYNTAX scores; outcomes for patients with CABG did not correlate with baseline SYNTAX score, but baseline EuroSCORE significantly predicted outcomes for both treatments.

Conclusions—Patients with LM disease who had revascularization with PCI had safety and efficacy outcomes comparable to CABG at 1 year; longer follow-up is required to determine whether these 2 revascularization strategies offer comparable medium-term outcomes in this group of complex patients.

Key Words: stents • coronary artery bypass grafting • angioplasty, transluminal, percutaneous coronary


All randomized patients
N=1,800

Patients with 3-vessel disease
n=1,095

Patients with left main disease
n=705

CABG
n=348

PCI
n=357

Withdraw consent n=12

Lost to follow-up n=1

Discontinued treatment* n=1

12-month clinical follow-up
CABG
n=336 (96.6%)

12-month clinical follow-up
PCI
n=355 (99.4%)

DOI: 10.1161/CIRCULATIONAHA.109.899211
Circulation is available at http://circ.ahajournals.org.

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SYNTAX

A

Cumulative Event Rate (%)

MACCE

P=0.44*

5.8%

13.6%

Months Since Allocation

0 6 12

B

Cumulative Event Rate (%)

Death (all-cause)

P=0.88

4.4%

4.2%

Months Since Allocation

0 6 12

C

Cumulative Event Rate (%)

Myocardial Infarction

P=0.97

4.3%

4.1%

Months Since Allocation

0 6 12

D

Cumulative Event Rate (%)

CVA

P=0.009*

2.7%

0.3%

Months Since Allocation

0 6 12

E

Cumulative Event Rate (%)

Repeat Revascularization

P=0.02*

12.0%

6.7%

Months Since Allocation

0 6 12

F

Cumulative Event Rate (%)

Death/CVA/MI

P=0.29

9.1%

7.0%

Months Since Allocation

0 6 12

Circulation. 2010;121:2645-2653
SYNTAX

Cumulative incidence of MACE in patients with 3-vessel CAD based on SYNTAX score at 3-year follow-up

Low Score (0-22)

Intermediate Score (23-32)

High Score (>33)

Circulation. 2010;121:2645-2653
A Heart Team approach to revascularization is recommended in patients with unprotected left main or complex CAD.

Calculation of the STS and SYNTAX scores is reasonable in patients with unprotected left main and complex CAD.

“Recommendations that refer to SYNTAX scores use them as surrogates for the extent and complexity of CAD”
Welcome to the SYNTAX Score website. The SYNTAX Score is a unique tool to score complexity of coronary artery disease. However, it is very important to use this new scoring tool correctly, hence, it is strongly recommended to complete the tutorial first.

Calculator updated to version 2.1

Version 2.1 of the SYNTAX Score calculator contains the latest three-year SYNTAX Score dataset made in scoring total occlusions and the definition of diffusely diseased and nontortuous lesions. The current version can be downloaded here.

SYNTAX Score Calculator 2.1

For a detailed changelog select read more below.
survival vs. symptoms
Improve Survival

- **CABG**
  - > 50% stenosis
  - Only class I rec.

- **PCI**
  - Syntax score <22
  - STS > 5% mortality
  - Ostial or trunk lesion

- **PCI**
  - UA/NSTEMI
  - LM is culprit lesion
  - Not CABG candidate

- **PCI**
  - STEMI; LM = Culprit
  - Distal flow < TIMI 3
  - PCI faster & safer
Improve Survival

Stable patient
Unfavorable anatomy for PCI
Good CABG candidate.
Improve Survival

3-vessel disease or Proximal LAD + 1

SCD survivors Ischemic VT ≥ 70% in 1 vessel

CABG or PCI:
- SIHD
- ≥ 1 stenoses (<70% or FFR >0.80)
Improve Symptoms

- **A**
  - > 70% stenosis
  - Amenable
  - Angina despite GDMT

- **C**
  - > 70% stenosis
  - Amenable
  - Unacceptable angina
  - Cannot do GDMT

- **C**
  - < 50% LM
  - < 70% non-LM
  - FFR > 0.80
Dual Anti-platelet Therapy

Stenting **should not be performed** if the patient is not likely to be able to tolerate and comply with DAPT.

Prasugrel **should not be administered** to patients with prior stroke or TIA\(^1\).

---

ASA Dose

- 81-325mg before PCI if on daily ASA therapy (75-325mg in 2005)
- 325mg non-enteric if not taking daily ASA (300-325mg in 2005)

- 81mg daily after PCI, in preference to higher doses
  (325mg from 1 to 6 months, depending on type of stent, in 2005)
**P2Y<sub>12</sub> Inhibitors**

Loading dose of a P2Y<sub>12</sub> to patients undergoing PCI with stenting:

- **Clopidogrel 600mg** – ACS & non-ACS patients *(300mg in 2005)*
- **Prasugrel 60mg** – ACS patients
- **Ticagrelor 180mg** – ACS patients  
  \[
  \text{New}
  \]

Maintenance after PCI with stenting for ACS BMS or DES):  **12 mo.**

- **Clopidogrel 75mg**
- **Prasugrel 10mg**
- **Ticagrelor 90mg BID**  
  *(Unchanged for non-ACS patients)*

Continuing P2Y<sub>12</sub> inhibitors beyond 12 months after PCI with DES
P2Y$_{12}$ Inhibitors & PPIs

- **Prior GI Bleed**
- **High risk of GI bleed**
- **Routine PPI use**

<table>
<thead>
<tr>
<th></th>
<th>Omeprazole</th>
<th>Placebo</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding</td>
<td>1.1%</td>
<td>2.9%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CV Events</td>
<td>4.9%</td>
<td>5.7%</td>
<td>0.96</td>
</tr>
</tbody>
</table>
Clopidogrel Use

- High risk for poor outcome
- Inadequate platelet inhibition

I  IIa  IIb  III

Genetic Testing
CYP2C19 polymorphism

Change to:
Prasugrel or Ticagrelor

Platelet Function Testing

Routine testing
P2Y12 % Inhibition

<table>
<thead>
<tr>
<th>Lab Results</th>
<th>02/08/12 11:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR</td>
<td>1.10 sec*H</td>
</tr>
<tr>
<td>APTT</td>
<td>69 sec*H</td>
</tr>
<tr>
<td>P2Y12 % Inhibition</td>
<td>0 %*</td>
</tr>
<tr>
<td>PF P2Y12 Assay</td>
<td>390 PRU</td>
</tr>
<tr>
<td>PF Baseline</td>
<td>299 Baseline P</td>
</tr>
<tr>
<td>Color, U</td>
<td>50</td>
</tr>
<tr>
<td>Transparency U</td>
<td>25</td>
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</table>
hybrid
revascularization
Hybrid Revascularization

Cardiology in Review 2011;19: 101–107
## Hybrid Revascularization

<table>
<thead>
<tr>
<th>HCR Strategy</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCI followed by Mid-CAB</td>
<td>1. Minimize risk of ischemia during Mid-CAB</td>
<td>1. Risk of stent thrombosis with discontinuation of antiplatelet inhibitors and inflammation of Mid-CAB</td>
</tr>
<tr>
<td></td>
<td>2. Conventional CABG as fallback is suboptimal PCI result</td>
<td>2. Increased bleeding if Mid-CAB performed on dual antiplatelet therapy</td>
</tr>
<tr>
<td></td>
<td>3. HCR is possible in the setting of PCI for myocardial infarction in non-LAD targets</td>
<td>3. Cannot routinely image LIMA-LAD</td>
</tr>
<tr>
<td>Mid-CAB followed by PCI</td>
<td>1. Aggressive continuous antiplatelet therapy following PCI</td>
<td>1. Mid-CAB is performed in the setting of residual coronary lesions</td>
</tr>
<tr>
<td></td>
<td>2. Routine angiography of LIMA-LAD</td>
<td>2. Fallback conventional CABG leads to higher morbidity if suboptimal PCI result</td>
</tr>
<tr>
<td>Simultaneous Mid-CAB and PCI</td>
<td>1. Immediate angiography of LIMA-LAD</td>
<td>1. Bleeding risk with dual antiplatelet therapy at the time of surgery</td>
</tr>
<tr>
<td></td>
<td>3. Complete revascularization out of operating room</td>
<td>3. Economic and logistic issues</td>
</tr>
</tbody>
</table>


Mid-CAB indicates minimally invasive coronary artery bypass graft; PCI, percutaneous coronary intervention; HCR, hybrid coronary revascularization; LIMA-LAD, left internal mammary artery-left anterior descending artery; CABG, coronary artery bypass grafting.
Hybrid Revascularization

> 1 of the following:
• Limitations to CABG
• Lack of graft conduits
• LAD unfavorable to PCI

Alternative to CABG or MV-PCI to improve risk/benefit ratio
radiation safety
Radiation Safety

Core Curriculum

Radiation Safety Program for the Cardiac Catheterization Laboratory

Charles E. Chambers, MD, Kenneth A. Fetterly, PhD, Ralf Holzer, MD, Pei-Jan Paul Lin, PhD, James C. Blankenship, MD, Stephen Bailer, PhD, and Warren K. Laskey, MD

The Society of Cardiovascular Angiography and Interventions present a practical approach to assist cardiac catheterization laboratories in establishing a radiation safety program. The importance of this program is emphasized by the appropriate concerns for the increasing use of ionizing radiation in medical imaging, and its potential adverse effects. An overview of the assessment of radiation dose is provided with a review of basic terminology for dose management. The components of a radiation safety program include essential personnel, radiation monitoring, protective shielding, imaging equipment, and training/education. A procedure based review of radiation dose management is described including pre-procedure, procedure and post-procedure best practice recommendations. Specific radiation safety considerations are discussed including women and fluoroscopic procedures as well as patients with congenital and structural heart disease. © 2011 Wiley-Liss, Inc.

TABLE I. Typical Effective Dose Estimates for Select Procedures Performed Using Ionizing Radiation

<table>
<thead>
<tr>
<th>Study</th>
<th>Typical effective dose estimate (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest X-ray</td>
<td>0.1</td>
</tr>
<tr>
<td>Chest CT (standard)</td>
<td>7.0</td>
</tr>
<tr>
<td>Chest CT (cardiac)</td>
<td>16</td>
</tr>
<tr>
<td>Diag. coronary angio.</td>
<td>7.0</td>
</tr>
<tr>
<td>PCI</td>
<td>15.0</td>
</tr>
<tr>
<td>RF arrhythmia ablation</td>
<td>15.0</td>
</tr>
<tr>
<td>TIPS</td>
<td>70.0</td>
</tr>
<tr>
<td>ERCP</td>
<td>4.0</td>
</tr>
<tr>
<td>Tc-99m heart (stress-rest)</td>
<td>11.4</td>
</tr>
<tr>
<td>Thallium heart (stress-rest)</td>
<td>16.9</td>
</tr>
<tr>
<td>General exposure</td>
<td></td>
</tr>
<tr>
<td>Typical effective radiation dose (mSv)</td>
<td></td>
</tr>
<tr>
<td>Natural background</td>
<td>3.1</td>
</tr>
<tr>
<td>Average US medical</td>
<td>3.0</td>
</tr>
</tbody>
</table>

Modified from Mettler et al. [18] and Laskey et al. [19].

Catheterization and Cardiovascular Interventions 2011;77:546-556
Cath labs should:

- Routinely record radiation dose data
  - Total air kerma at international reference point \([K_{a,r}]\)
  - Air kerma area product \([P_{KA}]\)
  - Fluoroscopy time
  - Number of cine images

- Define dose thresholds with corresponding follow-up protocols
contrast myths
### Adverse Reactions to Intravascularly Administered Contrast Media

**A Comprehensive Study Based on a Prospective Survey**

*By William H. Shehadi, M.D.*

**Byram, Connecticut**

<table>
<thead>
<tr>
<th>Type of Allergy</th>
<th>(1) Total Number of Patients Examined</th>
<th>(2) Total Number of Patients with Reactions</th>
<th>(3) Incidence of Reactions</th>
<th>(4) Missing Data</th>
<th>(5) No RX</th>
<th>(6) RX</th>
<th>(7) RX in Hospital</th>
<th>(8) Fatal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>340</td>
<td>18</td>
<td>11.11</td>
<td>1</td>
<td>16</td>
<td>18</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Hay fever, grass—ragweed</td>
<td>551</td>
<td>57</td>
<td>10.33</td>
<td>2</td>
<td>37</td>
<td>18</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Allergy, general (not specified)</td>
<td>2,063</td>
<td>270</td>
<td>13.56</td>
<td>4</td>
<td>155</td>
<td>109</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Penicillin</td>
<td>2,486</td>
<td>151</td>
<td>6.88</td>
<td>2</td>
<td>90</td>
<td>63</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sulfa drug</td>
<td>449</td>
<td>33</td>
<td>7.55</td>
<td>4</td>
<td>18</td>
<td>13</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Seafood, shell fish</td>
<td>307</td>
<td>31</td>
<td>10.16</td>
<td>0</td>
<td>14</td>
<td>11</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Fruits, strawberry plant</td>
<td>235</td>
<td>29</td>
<td>12.45</td>
<td>0</td>
<td>14</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Eggs, milk, chocolate</td>
<td>56</td>
<td>18</td>
<td>32.02</td>
<td>1</td>
<td>4</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Morphine, codeine</td>
<td>394</td>
<td>26</td>
<td>6.86</td>
<td>1</td>
<td>14</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Barbiturates, sodium pentothal, phenobarbital, aminophyllin</td>
<td>95</td>
<td>9</td>
<td>9.47</td>
<td>1</td>
<td>5</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Aspirin, salicylates</td>
<td>318</td>
<td>11</td>
<td>3.47</td>
<td>1</td>
<td>10</td>
<td>10</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Anaphylactoid prophylaxis in patients with allergy to shellfish or seafood.
Contrast-Induced Nephropathy

- Common
- Morbidity
- Mortality\(^1\)
- Cost
- Preventable

Contrast-Induced AKI

Assess for **RISK** of contrast-induced AKI before PCI.

Adequate preparatory **hydration**

Minimize **contrast volume** in patients with Cr-Cl < 60 mL/min
A Simple Risk Score for Prediction of Contrast-Induced Nephropathy After Percutaneous Coronary Intervention
Development and Initial Validation

Roxana Mehran, MD,*† Eve D. Aymong, MD, MSc, FACC,* Eugenia Nikolsky, MD, PhD,*† Zoran Lasic, MD, FACC,* Ioannis Iakovou, MD,* Martin Fahy, MSc,* Gary S. Mintz, MD, FACC,* Alexandra J. Lansky, MD, FACC,*† Jeffrey W. Moses, MD, FACC,*† Gregg W. Stone, MD, FACC,*† Martin B. Leon, MD, FACC,*† George Dangas, MD, PhD, FACC*†
New York, New York
## Predicting CIN Risk

### Risk Factors

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Integer Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypotension</td>
<td>5</td>
</tr>
<tr>
<td>IABP</td>
<td>5</td>
</tr>
<tr>
<td>CHF</td>
<td>5</td>
</tr>
<tr>
<td>Age &gt;75 years</td>
<td>4</td>
</tr>
<tr>
<td>Anemia</td>
<td>3</td>
</tr>
<tr>
<td>Diabetes</td>
<td>3</td>
</tr>
<tr>
<td>Contrast media volume</td>
<td>1 for each 100 cc³</td>
</tr>
<tr>
<td>Serum creatinine &gt; 1.5 mg/dl</td>
<td>4</td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>eGFR &lt; 60 ml/min/1.73 m²</td>
<td></td>
</tr>
<tr>
<td>eGFR (ml/min/1.73 m²) = 186 x (SCr)^1.154 x (Age)^0.203 x (0.742 if female) x (1.210 if African American)</td>
<td>4</td>
</tr>
</tbody>
</table>

### Risk Score Calculation

<table>
<thead>
<tr>
<th>Risk Score</th>
<th>Risk of CIN</th>
<th>Risk of Dialysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 5</td>
<td>7.5%</td>
<td>0.04%</td>
</tr>
<tr>
<td>6 to 10</td>
<td>14.0%</td>
<td>0.12%</td>
</tr>
<tr>
<td>11 to 16</td>
<td>26.1%</td>
<td>1.09%</td>
</tr>
<tr>
<td>≥ 17</td>
<td>57.3%</td>
<td>12.6%</td>
</tr>
</tbody>
</table>

Contrast-Induced AKI

Administration of **NAC** for prevention of contrast-induced AKI

**Acetylcysteine for Prevention of Renal Outcomes in Patients Undergoing Coronary and Peripheral Vascular Angiography**

Main Results From the Randomized Acetylcysteine for Contrast-Induced Nephropathy Trial (ACT)

**ACT Investigators**

**Background**—It remains uncertain whether acetylcysteine prevents contrast-induced acute kidney injury.

**Methods and Results**—We randomly assigned 2308 patients undergoing an intravascular angiographic procedure with at least 1 risk factor for contrast-induced acute kidney injury (age >70 years, renal failure, diabetes mellitus, heart failure, or hypertension) to acetylcysteine 1200 mg or placebo. The study drugs were administered orally twice daily for 2 doses before and 2 doses after the procedure. The allocation was concealed (central Web-based randomization). All analysis followed the intention-to-treat principle. The incidence of contrast-induced acute kidney injury (primary end point) was **12.7%** in the acetylcysteine group and **12.7%** in the control group. Relative risk, 1.00; 95% confidence interval, 0.81 to 1.25; P=0.97). A combined end point of mortality or need for dialysis at 30 days was also similar in both groups (2.2% and 2.3%, respectively; hazard ratio, 0.97; 95% confidence interval, 0.56 to 1.69; P=0.92). Consistent effects were observed in all subgroups analyzed, including those with renal impairment.

**Conclusions**—In this large randomized trial, we found that acetylcysteine does not reduce the risk of contrast-induced acute kidney injury or other clinically relevant outcomes in at-risk patients undergoing coronary and peripheral vascular angiography.

**Clinical Trial Registration**—http://www.clinicaltrials.gov. Unique identifier: NCT00736866.

(Circulation. 2011;124:1250-1259.)
on-site surgical backup
On-Site Surgical Backup

Percutaneous coronary intervention without on site surgical back-up; two-year registry of a large Dutch community hospital


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Available online 31 January 2008

Nonemergent coronary angioplasty without on-site surgical backup: A randomized study evaluating outcomes in low-risk patients

Tor Melberg, MD, a Dennis W.T. Nilsson, PhD, MD, a,b Alf Inge Larsen, PhD, MD, a,b Håkon Barvik, MD, a, Vernon Bonnarjee, PhD, MD, a Karel K.J. Kulper, MD, a and Jan Erik Nordrehaug, PhD, MD a,b

Stavanger and Bergen, Norway

Nonemergent coronary angioplasty without on-site surgical backup: A randomized study evaluating outcomes in low-risk patients

Outcomes of Nonemergent Percutaneous Coronary Intervention With and Without On-site Surgical Backup: A Meta-Analysis

Param Puneet Singh, MD,* Mukesh Singh, MD, Updesh Singh Bedi, MD, Sasikanth Adigopula, MD, Sarabjeet Singh, MD, Vamsi Kodumuri, MD, Janos Molnar, MD, Aziz Ahmed, MD, Rohit Arora, MD, and Sandeep Khosla, MD

Despite major advances in percutaneous coronary intervention (PCI) techniques, the current guidelines recommend against elective PCI at hospitals without on-site cardiac surgery backup. Nonetheless, an increasing number of hospitals without on-site cardiac surgery in the United States have developed programs for elective PCI. Studies evaluating outcome in this setting have yielded mixed results, leaving the question unanswered. Hence, a meta-analysis comparing outcomes of nonemergent PCI in hospitals with and without on-site surgical backup was performed. A systematic review of literature identified four studies involving 6817 patients. Three clinical end points were extracted from each study and included in-hospital death, myocardial infarction, and the need for emergency coronary artery bypass grafting. The studies were homogeneous for each outcome studied. Therefore, the combined relative risks (RRs) across all the studies and the 95% confidence intervals (CIs) were computed using the Mantel-Haenszel fixed-effect model. A two-sided alpha error less than 0.05 was considered to be statistically significant. Compared with facilities with on-site surgical backup, the risk of in-hospital death (RR, 2.7; CI, 0.6–12.9; P = 0.18), nonfatal myocardial infarction (RR, 1.3; CI, 0.7–2.2; P = 0.29), and need of emergent coronary artery bypass grafting (RR, 0.46; CI, 0.06–3.1; P = 0.43) was similar in those lacking on-site surgical backup. The present meta-analysis suggests that there is no difference in the outcome with regard to risk of nonfatal myocardial infarction, need for emergency coronary artery bypass grafting, and the risk of death in patients undergoing elective PCI in hospitals with and without on-site surgical backup.

Thrombolytic Therapy vs Primary Percutaneous Coronary Intervention for Myocardial Infarction in Patients Presenting to Hospitals Without On-site Cardiac Surgery: A Randomized Controlled Trial

American Journal of Therapeutics 2011:18:e22-28
On-Site Surgical Backup

**Primary PCI** is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished.

**Elective PCI** might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection.
Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capabilities for transfer.

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On-Site Surgical Backup

Table 5. SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup

- Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.
- On-call schedule with operation of laboratory 24 h/365 d/y.
- Experienced coronary care unit nursing staff comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, and management of IABP. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.
- Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services (eg, respiratory care, blood bank).
- Written agreements for emergency transfer of patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of 2 times per year.
- Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability and IABP equipment compatible with transport vehicles. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is ideal.
- Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. Pressure wire device and IVUS equipment are optional but not mandatory. Rotational or other atherectomy devices should be used cautiously in these facilities because of the greater risk of perforation.
- Meticulous clinical and angiographic selection criteria for PCI (Tables 6 and 7).
- Performance of primary PCI as the treatment of first choice for STEMI to ensure streamlined care paths and increased case volumes. Door-to-balloon times should be tracked, and <90 min outlier cases should be carefully reviewed for process improvement opportunities.
- On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.
- Participation in a national data registry where available, such as the ACC NCDR in the United States.

Table 6. SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup

1. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility.
2. Cardiac surgeon must have privileges at the referring facility to allow review of treatment options as time allows.
3. Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.
4. Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request, and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at this time.
5. Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.
6. Hospital administrations from both facilities endorse transfer agreement.
7. Transferring and receiving facilities establish a rigorous protocol for rapid transfer of patients, including the proper personnel with appropriate experience.
8. A transport provider is available to begin transport within 20 min of the request and provide vehicle/helicopter with necessary life-sustaining equipment, including IABP and monitoring capability.
9. Transferring physician obtains consent for surgery from patient or appropriate surrogate.
10. Initial informed consent for PCI discloses that the procedure is being done without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery (approximately 0.3%) and state that a written plan for transfer exists.
11. As part of the local continuous quality improvement program, a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of any improvement opportunities.

Table 7. SCAI Expert Consensus Document Requirements for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals Without On-Site Cardiac Surgery

- Avoid intervention in patients with
  - >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired
  - Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography
  - Lesions in other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms)
  - Lesions with TIMI flow grade 3 that are not amenable to stenting in patients with left main or 3-vessel disease that will require coronary bypass surgery
  - Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention

Transfer emergently for coronary bypass surgery patients with
- High-grade left main or 3-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support
- Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer
vascular access
Percutaneous Transradial Artery Approach for Coronary Stent Implantation

Ferdinand Kiemeneij, MD, and Gert Jan Laarman, MD, PhD

A new approach for implantation of Palmaz Schatz coronary stents is reported. We describe the technique and rationale of coronary stenting with miniaturized angioplasty equipment via the radial artery.

This technique is illustrated in three patients. One patient underwent Palmaz Schatz stent implantation for a saphenous vein coronary bypass graft stenosis, the second patient for a restenosis in the anterior descending coronary artery after atherectomy, and the third patient for a second restenosis after balloon angioplasty in the circumflex coronary artery.

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Association Between Vascular Access Site for PCI and Outcomes

Am Heart J 2009;157: 132– 40
RIFLE - STEACS

30-Day NACE

- Radial: 13.6%
- Femoral: 21%

p = 0.003
RIFLE - STEACS

30-day MACE

- **Cardiac Death**
  - Radial: 5.2%
  - Femoral: 9.2%
  - Significance: $p = 0.02$

- **MI**
  - Radial: 1.2%
  - Femoral: 1.4%
  - Significance: $p = 1.0$

- **TV Revasc.**
  - Radial: 1.2%
  - Femoral: 1.8%
  - Significance: $p = 0.6$

- **CVA**
  - Radial: 0.8%
  - Femoral: 0.6%
  - Significance: $p = 0.725$
RIFLE - STEACS

30-day Significant Bleeding

- **Bleeding**
  - Radial: 7.8%
  - Femoral: 12.2%
  - **p = 0.026**

- **Access Site Related**
  - Radial: 2.6%
  - Femoral: 6.8%
  - **p = 0.002**

- **Non-Access**
  - Radial: 5.2%
  - Femoral: 5.4%
  - **p = 1.0**
<table>
<thead>
<tr>
<th>Advantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced bleeding risk</td>
</tr>
<tr>
<td>Reduced length of stay and costs</td>
</tr>
<tr>
<td>Early ambulation</td>
</tr>
<tr>
<td>Improved patient comfort</td>
</tr>
<tr>
<td>Obviates discontinuation of oral anticoagulant therapy</td>
</tr>
<tr>
<td>Same-day discharge possible</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Learning curve</td>
</tr>
<tr>
<td>Not routinely taught in fellowship programs</td>
</tr>
<tr>
<td>Limits guide catheter size</td>
</tr>
<tr>
<td>Possible greater radiation exposure to operator*</td>
</tr>
<tr>
<td>Long-term consequences to radial artery (e.g., for re-access or for use as bypass graft) unknown</td>
</tr>
</tbody>
</table>
Radial artery access can be useful to decrease access site complications.
Vascular Closure Devices

**Decrease:**
Time to hemostasis

**Do not decrease:**
Vascular complications
Bleeding complications
Need for transfusion.

Vascular Closure Devices

1. I Ila IIb III
   Femoral angiogram to ensure anatomic suitability for deployment.

2. I Ila IIb III
   For achieving faster hemostasis and earlier ambulation compared with the use of manual compression.

3. I Ila IIb III
   Routine use of vascular closure devices **is not recommended** decreasing vascular complications.
honorables mentions
Door-to-Balloon Time

Fig 2 | Adjusted in hospital mortality as function of door-to-balloon time (modelled as fractional polynomial) with 95% confidence intervals

Door-to-Ballooon Time

Primary PCI in STEMI patients presenting to a hospital without PCI capability within 120 minutes of 1st medical contact.
Honorable Mentions

- Angiographic success
  - 20%
  - 10%

- Statins
  - High-dose statins to reduce peri-procedural MI risk.
  - *(LOE: A statin naïve, B chronic therapy)*
1) To assess intermediate (50-70%) stenoses
2) For guiding revascularization decision in SIHD

- Indeterminate LM stenosis
- 4w, 6w & 1y after transplant to detect donor CAD, Tx vasculopathy & prognosis.

Mechanism of stent restenosis

Routine assessment when PCI or CABG are not being considered.
Summary

• Simple, concise, objective & up-to-date
• Collaborative
• Heart team
• New medicines & interventions
• Patient safety
• Recommendations for contrast