Appropriate Use:
Big Brother is Watching

Jason H. Rogers, MD
Director, Interventional Cardiology
UC Davis Medical Center
Disclosures

• Consultant
  ▪ Boston Scientific, Medtronic, Middle Peak Medical, Millipede, St Jude Medical
Mapping America’s Coronary Stent Hot Spots

While coronary stents have proved effective in restoring blood flow in heart-attack patients, research shows they are no better than medicine, exercise and dietary restrictions in preventing heart attacks in elective patients whose heart disease is deemed stable. When doctors opt for stents, they prop open coronary arteries in a procedure called Percutaneous Coronary Intervention, or PCI. More than 90 percent of PCIs include stenting. To show where the use of stents is high, Bloomberg News ranked regional health-care markets by three measures: the number of PCI procedures for every 1,000 Medicare enrollees; how often they are performed for every 1,000 angiography scans of coronary arteries; and the number per 1,000 cases of diagnosed ischemia — or reduced cardiac blood flow. More procedures in each case may indicate locales where doctors are more inclined to use stents. Click here to read the full story.

There are many ways to interact with this map. Zoom in to see localities & move your cursor over the map for more details. Switch map views in the menu below to see additional data, and search for your city, state or ZIP code.
Cath Lab Banter

- “Is it tight?”
- “Looks tight”
- “Doesn’t look that tight”
- “Looks tight in that view”
- “Take another view”
- “Tight-ish”
Let’s Just Stent It!!
Appropriateness
APPROPRIATENESS CRITERIA

ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization


Endorsed by the American Society of Echocardiography, the Heart Failure Society of America, and the Society of Cardiovascular Computed Tomography

APPROPRIATE USE CRITERIA

ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT

2012 Appropriate Use Criteria for Coronary Revascularization Focused Update


Endorsed by the American Society of Echocardiography and the Heart Rhythm Society
Appropriateness Caveats

• “a framework for discussion”
• “many patients in clinical practice may not be represented”
• “uncertain should not be viewed as excluding the use of revascularization for such patients.”
• “it is not anticipated that all facilities will have 100% of their revascularization procedures deemed appropriate.”
## Intermediate Risk Findings on Noninvasive Study

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Med. Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class III or IV Max Rx</td>
<td>A</td>
</tr>
<tr>
<td>Class I or II Max Rx</td>
<td>A</td>
</tr>
<tr>
<td>Asymptomatic Max Rx</td>
<td>A</td>
</tr>
<tr>
<td>Class III or IV No/min Rx</td>
<td>A</td>
</tr>
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<tr>
<td>Asymptomatic No/min Rx</td>
<td>A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Coronary Anatomy</th>
<th>CTO of 1 vz.; no other disease</th>
<th>1-2 vz. disease; no Prox. LAD</th>
<th>1 vz. disease of Prox. LAD</th>
<th>2 vz. disease with Prox. LAD</th>
<th>3 vz. disease; no Left Main</th>
</tr>
</thead>
</table>
Appropriateness of Percutaneous Coronary Intervention

Paul S. Chan, MD, MSc
Manesh R. Patel, MD
Lloyd W. Klein, MD
Ronald J. Krone, MD
Gregory J. Dehmer, MD
Kevin Kennedy, MS
Brahmajee K. Nallamothu, MD, MPH
W. Douglas Weaver, MD
Frederick A. Masoudi, MD, MSPH
John S. Rumsfeld, MD, PhD
Ralph G. Brindis, MD, MPH
John A. Spertus, MD, MPH

A PROXIMATELY 600,000 PER-
cutaneous coronary interventions (PCIs) are performed in the United States each year, at a cost that exceeds $12 billion. Patients who undergo PCI are exposed to risks of peri-procedural complications and longer-term bleeding.

Context Despite the widespread use of percutaneous coronary intervention (PCI), the appropriateness of these procedures in contemporary practice is unknown.

Objective To assess the appropriateness of PCI in the United States.

Design, Setting, and Patients Multicenter, prospective study of patients within the National Cardiovascular Data Registry undergoing PCI between July 1, 2009, and September 30, 2010, at 1091 US hospitals. The appropriateness of PCI was adjudicated using the appropriate use criteria for coronary revascularization. Results were stratified by whether the procedure was performed for an acute (ST-segment elevation myocardial infarction, non–ST-segment elevation myocardial infarction, or unstable angina with high-risk features) or nonacute indication.

Main Outcome Measures Proportion of acute and nonacute PCIs classified as appropriate, uncertain, or inappropriate; extent of hospital-level variation in inappropriate procedures.

Results Of 500,154 PCIs, 355,417 (71.1%) were for acute indications (ST-segment elevation myocardial infarction, 103,245 [20.6%]; non–ST-segment elevation myocardial infarction, 105,708 [21.1%]; high-risk unstable angina, 146,464 [29.3%]), and 144,737 (28.9%) for nonacute indications. For acute indications, 350,469 PCIs (98.6%) were classified as appropriate, 1055 (0.3%) as uncertain, and 3893 (1.1%) as inappropriate. For nonacute indications, 72,911 PCIs (50.4%) were classified as appropriate, 54,988 (38.0%) as uncertain, and 16,838 (11.6%) as inappropriate. The majority of inappropriate PCIs for nonacute indications were performed in patients with no angina (53.8%), low-risk ischemia on noninvasive stress testing (71.6%), or suboptimal (≤1 medication) antianginal therapy (95.5%). Furthermore, although variation in the proportion of inappropriate PCI across hospitals was found, locally inappropriate PCI was also common. A hierarchical model of care organizations to support the rational and judicious use of PCI. The inclusion of the appropriate use criteria in

500,154 PCIs
ACC-NCDR Registry
July 2009 – Sept 2010

Corresponding Author: Paul S. Chan, MD, MSc, Saint Luke’s Mid America Heart and Vascular Institute, 4401 Wornall Rd, Fifth Floor, Kansas City, MO 64111 (pchan@ccc-ncdr.com).
Heart of the Matter
How angioplasty procedures in the U.S. rated, according to appropriateness guidelines, based on 500,000 cases:

IN PATIENTS WITH...
...HEART ATTACK OR HIGH-RISK
UNSTABLE CHEST PAIN
(71% OF CASES)

...NON-ACUTE
HEART DISEASE
(29% OF CASES)

11.6%
38.0%

11.2%
50.4%

Procedure deemed appropriate
98.6%
of the time

Source: Journal of the American Medical Association

4.1%

Benefit uncertain

84.6%

Procedure inappropriate

Wall Street Journal 2011
Clinical Indication (ACS vs. Stable)
Angina Severity (CCS Class)
Extent of Ischemia
Presence of High Risk Features (EF)
Medical Therapy
Coronary Anatomy
Stress Testing

• HIGH
  1. Severe resting left ventricular dysfunction (LVEF < 35%)
  2. High-risk treadmill score (score ≤ -11)
  3. Severe exercise left ventricular dysfunction (exercise LVEF < 35%)
  4. Stress-Induced large perfusion defect (particularly if anterior)
  5. Stress-Induced multiple perfusion defects of moderate size
  6. Large, fixed perfusion defect with LV dilation or increased lung uptake (thallium-201)
  7. Stress-Induced moderate perfusion defect with LV dilation or increased lung uptake (thallium-201)
  8. Echocardiographic wall motion abnormality (involving greater than two segments) developing at low dose of dobutamine (less than or equal to 10 mg/kg/min) or at a low heart rate (< 120 beats/min)
  9. Stress echocardiographic evidence of extensive ischemia

• MEDIUM
  1. Mild/moderate resting left ventricular dysfunction (LVEF = 35% to 49%)
  2. Intermediate-risk treadmill score (-11 < score < 5)
  3. Stress-Induced moderate perfusion defect without LV dilation or increased lung intake (thallium-201)
  4. Limited stress echocardiographic ischemia with a wall motion abnormality only at higher doses of dobutamine involving less than or equal to two segments

• LOW
  1. Low-risk treadmill score (score ≥ 5)
  2. Normal or small myocardial perfusion defect at rest or with stress
  3. Normal stress echocardiographic wall motion or no change of limited resting wall motion abnormalities during stress

Table A2. Noninvasive Risk Stratification

<table>
<thead>
<tr>
<th>High-Risk (greater than 3% annual mortality rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Severe resting left ventricular dysfunction (LVEF &lt; 35%)</td>
</tr>
<tr>
<td>2. High-risk treadmill score (score ≤ -11)</td>
</tr>
<tr>
<td>3. Severe exercise left ventricular dysfunction (exercise LVEF &lt; 35%)</td>
</tr>
<tr>
<td>4. Stress-Induced large perfusion defect (particularly if anterior)</td>
</tr>
<tr>
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<tr>
<td>7. Stress-Induced moderate perfusion defect with LV dilation or increased lung uptake (thallium-201)</td>
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<td>8. Echocardiographic wall motion abnormality (involving greater than two segments) developing at low dose of dobutamine (less than or equal to 10 mg/kg/min) or at a low heart rate (&lt; 120 beats/min)</td>
</tr>
<tr>
<td>9. Stress echocardiographic evidence of extensive ischemia</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intermediate-Risk (1% to 3% annual mortality rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mild/moderate resting left ventricular dysfunction (LVEF = 35% to 49%)</td>
</tr>
<tr>
<td>2. Intermediate-risk treadmill score (-11 &lt; score &lt; 5)</td>
</tr>
<tr>
<td>3. Stress-Induced moderate perfusion defect without LV dilation or increased lung intake (thallium-201)</td>
</tr>
<tr>
<td>4. Limited stress echocardiographic ischemia with a wall motion abnormality only at higher doses of dobutamine involving less than or equal to two segments</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Low-Risk (less than 1% annual mortality rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Low-risk treadmill score (score ≥ 5)</td>
</tr>
<tr>
<td>2. Normal or small myocardial perfusion defect at rest or with stress*</td>
</tr>
<tr>
<td>3. Normal stress echocardiographic wall motion or no change of limited resting wall motion abnormalities during stress*</td>
</tr>
</tbody>
</table>
Canadian Cardiovascular Society
Angina Class

- CCS I
  Ordinary physical activity does not cause angina, such as walking, climbing stairs. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation.

- CCS II
  Slight limitation of ordinary activity. Angina occurs on walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Angina occurs on walking more than 2 blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal condition.

- CCS III
  Marked limitations of ordinary physical activity. Angina occurs on walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at a normal pace.

- CCS IV
  Inability to carry on any physical activity without discomfort—anginal symptoms may be present at rest.

Table B. Grading of Angina Pectoris by the Canadian Cardiovascular Society Classification System
Maximal Anti-Ischemic Medical Therapy

As previously stated, the indications assume that patients are receiving risk factor modification according to guideline-based recommendations. For the purposes of the clinical scenarios presented, maximal antianginal medical therapy is defined as the use of at least 2 classes of therapies to reduce anginal symptoms.
### Patients WITHOUT Acute Coronary Syndrome (Test Metric):
Proportion of evaluated PCI procedures that were appropriate

<table>
<thead>
<tr>
<th></th>
<th>My Hospital</th>
<th>US Hospitals 50th Pctl</th>
<th>US Hospitals 90th Pctl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion</td>
<td>49.5%</td>
<td>50.3%</td>
<td>75.0%</td>
</tr>
</tbody>
</table>

Proportion of PCI procedures that were evaluated as "Appropriate", among patients without ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1583]

### Patients WITHOUT Acute Coronary Syndrome (Test Metric):
Proportion of evaluated PCI procedures that were of uncertain appropriateness

<table>
<thead>
<tr>
<th></th>
<th>My Hospital</th>
<th>US Hospitals 50th Pctl</th>
<th>US Hospitals 90th Pctl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion</td>
<td>39.2%</td>
<td>37.8%</td>
<td>60.5%</td>
</tr>
</tbody>
</table>

Proportion of PCI procedures that were evaluated as "Uncertain", among patients without ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1584]

### Patients WITHOUT Acute Coronary Syndrome (Test Metric):
Proportion of evaluated PCI procedures that were inappropriate

<table>
<thead>
<tr>
<th></th>
<th>My Hospital</th>
<th>US Hospitals 50th Pctl</th>
<th>US Hospitals 90th Pctl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion</td>
<td>11.3%</td>
<td>9.5%</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

Proportion of PCI procedures that were evaluated as "Inappropriate", among patients without ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1585]
format similar to the original document. In addition to the changes reflected in Table A, the fractional flow reserve (FFR) cut point was updated from 0.75 to 0.80 in indication 22 to reflect new literature since the publication of the original document and to maintain consistency with guidelines (18).
### H. Lesions and Devices (Complete for each PCI attempted or performed)

<table>
<thead>
<tr>
<th>Lesion Counter&lt;sup&gt;7100&lt;/sup&gt;</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Segment Number(s)&lt;sup&gt;7105&lt;/sup&gt;</td>
<td>_____, _____, _____, _____, _____</td>
<td>_____, _____, _____, _____, _____</td>
</tr>
</tbody>
</table>

If CAD Presentation<sup>5000</sup> is ‘STEMI’, ‘Non-STEMI’, or ‘Unstable angina’, Culprit Lesion<sup>7110</sup>:

| O No | O Yes | O Unknown | O No | O Yes | O Unknown |

Stenosis Immediately Prior to Rx<sup>7115</sup>:

- → If 100%, Chronic Total Occlusion<sup>7120</sup>:
- → If 40-70%, IVUS<sup>7125</sup>:
- → If 40-70%, FFR<sup>7130</sup>:
  - → If Yes, FFR Ratio<sup>7135</sup>:

| _____ | _____ |

- → If Yes, O No | O Yes
- → If Yes, O No | O Yes
- → If Yes, O No | O Yes
Intermediate stenosis lesions (40-70%): Further invasive evaluation performed (IVUS or FFR).

[Detail Line: 1728, 1729, 1730]
iCath

Appropriate Use Criteria for iOS

iCath is a free tool available for your iOS device designed to assist health care professionals in determining the appropriateness of diagnostic catheterization and revascularization based upon the latest 2012 appropriate use criteria.

Download from iTunes
SCAI QIT App

A

B

C

D

Snapz Pro X
4.4. Adjunctive Diagnostic Devices

4.4.1. Fractional Flow Reserve

**CLASS IIa**

1. Fractional flow reserve is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful for guiding revascularization decisions in patients with SIHD (89,244–247). *(Level of Evidence: A)*
Fractional Flow Reserve (FFR)
Angiography alone cannot determine hemodynamic significance of intermediate stenoses (40-70%).

Angiography: Limitations

Nissen SE. Cleveland Clinic Journal of Medicine. 66(8):479-85, 1999 Sep
Which Coronary Factor is Constant? Pressure, Flow, or Vessel Size?

<table>
<thead>
<tr>
<th>Pressure (mm Hg)</th>
<th>Flow (Q) (mL/min)</th>
<th>Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>200</td>
<td>4.0</td>
</tr>
<tr>
<td>100</td>
<td>150</td>
<td>3.5</td>
</tr>
<tr>
<td>100</td>
<td>100</td>
<td>3.0</td>
</tr>
<tr>
<td>100</td>
<td>75</td>
<td>2.5</td>
</tr>
<tr>
<td>100</td>
<td>50</td>
<td>2.0</td>
</tr>
<tr>
<td>100</td>
<td>25</td>
<td>1.5</td>
</tr>
<tr>
<td>APEX</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Fractional Flow Reserve (FFR)

In the presence of maximal hyperemia

$$\text{FFR} = \frac{P_d}{P_a}$$

(mean distal pressure)

(mean aortic pressure)

In the presence of maximal hyperemia

$$\text{FFR} < 0.80 \sim \text{ischemia}$$

St. Jude

0.014” PressureWire Aeris
175 and 300 cm lengths

RadiAnalyzer or Quantien

Volcano

0.014” Verrata Wire
185 and 300 cm lengths

ComboMap
• It is important to induce hyperemia to unmask stenosis significance

## Inducing Hyperemia

<table>
<thead>
<tr>
<th></th>
<th>Adenosine</th>
<th>Adenosine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Route</strong></td>
<td>IV</td>
<td>IC</td>
</tr>
<tr>
<td><strong>Dosage</strong></td>
<td>140 mcg/kg/min</td>
<td>30-60 mcg LCA, 20-30 mcg RCA</td>
</tr>
<tr>
<td><strong>Time to hyperemia</strong></td>
<td>≤1 – 2 min</td>
<td>5-10 sec</td>
</tr>
<tr>
<td><strong>Advantage</strong></td>
<td>Gold Standard</td>
<td>Short action</td>
</tr>
<tr>
<td><strong>Disadvantage</strong></td>
<td>↓BP by 10-15%, Chest burning</td>
<td>AV delay, ↓BP</td>
</tr>
</tbody>
</table>
FFR Threshold for Ischemia

Non-ischemic Range: 1.00

Ischemic Range: 0.00

Significant stenosis: 0.80

FFR vs. Noninvasive Testing

Figure 2. Relation between Myocardial FFR in the Study Patients and the Results of Three Noninvasive Tests.

Pijls, et al. NEJM 1996;334:1703
Non-Ischemic FFR: Generally $\geq 0.80$
Ischemic FFR: Generally <0.75
FFR

“If It Isn’t Broken, Don’t Fix It”
THE DEFER STUDY: RANDOMIZATION

If FFR < 0.75  →  performance of PCI
    reference group (n=144)

If FFR > 0.75  →  randomization followed
                defer PCI  perform PCI
                (n=91)      (n=90)

Bech. Circulation 2001;103:2928
Supporting Clinical Study: DEFER 5Y Follow-Up

Cardiac Death and Acute MI Rates

Pijls et De Bruyne, CRT 2007
Case

FFR 0.88
140 mcg/kg/min
Case

FFR 0.72

140 mcg/kg/min
FAME

Patient with stenoses ≥ 50% in at least 2 of the 3 major epicardial vessels

Indicate all stenoses ≥ 50% considered for stenting

Randomization

Angiography-guided PCI

Stent all indicated stenoses

FFR-guided PCI

Measure FFR in all indicated stenoses

Stent only those stenoses with FFR ≤ 0.80

N=496

1-year follow-up

N=509
FAME: Freedom from Death, MI, Revasc

Fewer stents are better than more stents!

Days since Randomization

Survival Free from Major Adverse Cardiac Events

FFR-Guided

Angio-Guided

Pijls. JACC 2010;56.
Angiography versus FFR in the FAME study

Proportions of functionally diseased coronary arteries in patients with angiographic 3 vessel disease

“3 Vessel Disease”

P. Tonino et al ESC 2009
Stable CAD patients scheduled for 1, 2 or 3 vessel DES-PCI
N = 1220

FFR in all target lesions

Randomized Trial

At least 1 stenosis with FFR \leq 0.80 (n=888)

Randomization 1:1

PCI + MT

MT

73%

Registry

When all FFR > 0.80 (n=332)

MT

27%

Follow-up after 1, 6 months, 1, 2, 3, 4, and 5 years

Registry

50% randomly assigned to FU
**Primary Outcomes**

- PCI+MT vs. MT: HR 0.32 (0.19-0.53); p<0.001
- PCI+MT vs. Registry: HR 1.29 (0.49-3.39); p=0.61
- MT vs. Registry: HR 4.32 (1.75-10.7); p<0.001
FAME 2: FFR-Guided PCI versus Medical Therapy in Stable CAD

Urgent Revascularization

- PCI+MT vs. MT: HR 0.13 (0.06-0.30); p<0.001
- PCI+MT vs. Registry: HR 0.63 (0.19-2.03); p=0.43
- MT vs. Registry: HR 4.65 (1.72-12.62); p=0.009
Patients with urgent revascularization

- Unstable angina only: 51.8%
- Myocardial Infarction: 21.4%
- Unstable angina + evidence of ischemia on ECG: 26.8%
Early Stenting Best for Some Heart Patients: Study
Those who started on drug therapy alone were more likely to later need urgent stent placement

Aug 28, 2012

Heart study favors stent-drug combo

Aug 28, 2012
2012 Key Elements of Appropriateness For Revascularization in Stable Angina

- Symptoms consistent with angina
- Document CCS Class
- Trial of medical therapy
- Ischemia documented by stress testing or FFR
Clarity? Every Patient is Different
Summary

• Public Reporting of Appropriateness is Here

• Knowledge of Appropriateness Metrics is Essential

• FFR is an important tool in the catheterization laboratory for lesion assessment and treatment
Thank You