PCI Guidelines: Essentials for Understanding the Appropriate Use Criteria

J. Jeffrey Marshall, MD, FSCAI

December 8, 2013
Disclosures

None
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PCI Guidelines: Essentials for Understanding the Appropriate Use Criteria

- Why do we have guidelines and AUCs?
- What is the history of guidelines and AUC?
- What are the processes that produce the AUC?
- Have the AUC been validated and what does this teach us?
Tools for Guiding Clinical Practice

Antman, E.M, and Peterson, E.D.  Tools for guiding clinical practice from the AHA and the ACC.  What are they and how should clinicians use them?  *Circulation.*  2009;119:1180-1185
Why do we need Guidelines and AUCs?

Variations in utilization rates of PCI
PCI rates / 1000 Medicare enrollees

There's no regional difference in patient outcomes, so these variations in utilization (the non-uniform treatment of patients) suggest widespread underuse and overuse.

http://www.dartmouthatlas.org/
Donald Berwick, MD

Past President and CEO, Institute for Healthcare Improvement
Administrator, CMS: 7/10 – 12/11

“Unintended variation is stealing healthcare blind”

“20-30% of health spending is waste with no benefit to patients, because of overtreatment, failure to coordinate care, administrative complexity and fraud”
The Saga of St. Joe’s
Towson, MD

- December 2010
- Senate Finance Committee issues report
  - “a clear example of potential fraud, waste and abuse”
  - “shocking, disturbing and shameful”
The Conclusion

Physician’s license revoked

- Unprofessional conduct in the practice of medicine
- Willfully making a false report or record in the practice of medicine
- Gross overutilization of health care services
- Violations of the standards of quality care
- Failure to keep adequate records

Increased Federal oversight
- $22 million in fines
- 24% drop in admissions
- $62 million drop in revenue
- Further liabilities pending
- Hospital sold

Maryland General Assembly Mandates Stent Necessity Review.

MedPage Today (4/13, Kaiser) reports, "In the aftermath of several high-profile cases of ‘overstenting,’ the Maryland General Assembly has passed legislation establishing an independent review process to ensure the medical necessity of coronary stent placement.” This legislation, passed as part of a larger bill dealing with cardiac surgery and stenting, calls for independent, external review that is ‘free of bias and politics,’ said Marc Mugmon, MD, president of the Maryland chapter of the American College of Cardiology (ACC), in a statement.” MedPage Today points out that “the ACC, the Maryland chapter of the ACC, and the SCAI have been working with Maryland legislators and the Maryland Health Care Commission for the last several years to come up with a process of oversight that wasn’t too onerous but was tough enough to forestall any more cases of egregious overstenting.”
The Lawnwood Regional Medical Center in Fort Pierce, Fla.

In the summer of 2010, a troubling letter reached the chief ethics officer of the hospital giant HCA, as private insurers for medically unnecessary cardiac procedures. The chief ethics officer of the hospital giant HCA, C. T. Tomlinson, was a registered nurse at one of the company’s hospitals in Florida.

In a follow-up interview, the nurse said he was at the Lawnwood Regional Medical Center, a hospital in the small coastal city of Fort Pierce, that he had been performing heart procedures on patients who did not need them, putting their lives at risk. "It bothered me," the nurse said in a telephone interview. "I care about my patients."

In less than two months, an internal investigation by HCA concluded the nurse was right. "The allegations related to unnecessary procedures being performed in the cath lab are substantiated," according to a confidential memo written by a company ethics officer and reviewed by The New York Times. Mr. Tomlinson’s contract was not renewed, a move that Mr. Johnson said in the memo was in retaliation for his complaints.

But the nurse’s complaint was far from the only evidence that unnecessary—even dangerous—procedures were taking place at some HCA hospitals, driving up costs and increasing profits.
Implications

Utilization Review of all PCIs (e.g., Oregon)

Reimbursement Cuts for PCI Pre-authorization by insurers

WAS YOUR STENT UNNECESSARY?

1-888-DR-LEGAL

COKKITT LAW FIRM, PC

Colkitt Law Firm, P.C. Indiana, PA, 15701
with offices in Pittsburgh and Johnstown
Tools for Guiding Clinical Practice

Future Sources of Evidence: Comparative Effectiveness, Patient Preferences

EVIDENCE (RCTs, Registries) —> EXPERT CONSENSUS —> CLINICAL PRACTICE GUIDELINES

PERF MEASURES

APPROPRIATE USE CRITERIA

1. Increase Use of Effective Therapies
2. Decrease Use of Inappropriate, Unnecessary, Potentially Harmful Therapies

Improve Patient Outcomes
Reduce Costs of Healthcare Delivery

Clinical Practice Guidelines

• 1984 – Government recognized high variability in the utilization of pacemaker implantation

• Government regulators asked AHA and ACC to use EVIDENCE to develop recommendations for practice

• This led to the first Clinical Practice Guideline (CPG)

• Now 17 CPG in areas mainly focused on disease management (e.g. ACS, USAP and NSTEMI, STEMI)

• What we CAN do
Clinical Practice Guidelines

These practice guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches for the diagnosis, management, and prevention of specific diseases or conditions. These guidelines attempt to define practices that meet the needs of most patients in most circumstances. These guideline recommendations reflect a consensus of expert opinion after a thorough review of the available, current scientific evidence and are intended to improve patient care. If these guidelines are used as the basis for regulatory/payer decisions, the ultimate goal is quality of care and serving the patient's best interests. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all of the circumstances presented by that patient. There are circumstances where deviations from these guidelines are appropriate.

- Intended to assist in clinical decision making
- Guidelines attempt to define practices that meet the needs of most patients in most circumstances - a consensus of expert opinion based on current scientific evidence
- Ultimate judgment for care of individual patient must be made between patient and doctor
- There are circumstances where deviation from guidelines are appropriate
Clinical Practice Guidelines

SIZE OF TREATMENT EFFECT

CLASS I
Benefit >> Risk
Procedure/Treatment SHOULD be performed/administered

CLASS Ia
Benefit >> Risk
Additional studies with focused objectives needed
IT IS REASONABLE to perform procedure/administer treatment

CLASS Iib
Benefit ≥ Risk
Additional studies with broad objectives needed; additional registry data would be helpful
Procedure/Treatment MAY BE CONSIDERED

CLASS III
Risk ≥ Benefit
Procedure/Treatment should NOT be performed/administered SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL

LEVEL A
Multiple populations evaluated*
Data derived from multiple randomized clinical trials or meta-analyses

Recommendation that procedure or treatment is useful/effective
Sufficient evidence from multiple randomized trials or meta-analyses

LEVEL B
Limited populations evaluated*
Data derived from a single randomized trial or nonrandomized studies

Recommendation that procedure or treatment is useful/effective
Evidence from single randomized trial or nonrandomized studies

LEVEL C
Very limited populations evaluated*
Only consensus opinion of experts, case studies, or standard of care

Recommendation that procedure or treatment is useful/effective
Only expert opinion, case studies, or standard of care

Suggested phrases for writing recommendations:

- Should
  - is recommended
  - is useful/effective/beneficial

- Is indicated
  - can be useful/effective/beneficial
  - is probably recommended or indicated

- May/might be considered
  - usefulness/effectiveness is unknown/unclear/uncertain or not well established

- Is not recommended
  - is not indicated
  - is not useful/effective/beneficial

- May/might be harmful
  - may/might be reasonable
  - harmful
Tools for Guiding Clinical Practice

Performance Measures

• Derivatives of the Clinical Practice Guidelines

• Focus on the most critical recommendations to provide quantitative **metrics** for measuring quality (e.g. Door to Balloon time, statins and ASA at D/C after STEMI, etc.)

• What we MUST do
Tools for Guiding Clinical Practice

Future Sources of Evidence:
Comparative Effectiveness
Patient Preferences

EVIDENCE
(RCTs, Registries)

EXPERT
CONSENSUS

CLINICAL PRACTICE GUIDELINES

PERF MEASURES

APPROPRIATE USE CRITERIA

1. Increase Use of Effective Therapies
2. Decrease Use of Inappropriate, Unnecessary, Potentially Harmful Therapies

Improve Patient Outcomes
Reduce Costs of Healthcare Delivery

Appropriate Use Criteria

• Derivatives of the Clinical Practice Guidelines

• These criteria supplement the recommendations of the Clinical Practice Guidelines

• AUCs are based on specific clinical scenarios for clinicians to use as benchmarks for their performance

• What we SHOULD do
How did Appropriate Use Criteria Start?

During the 1990s, the ACR recognized the need to define national guidelines for appropriate use of imaging technologies. These guidelines became known as the ACR Appropriateness Criteria® (ACR AC). In 1993, the ACR AC were formally introduced by K.K. Wallace, MD (former chair of ACR Board of Chancellors) during testimony to the U.S. House Ways and Means Committee. Dr. Wallace stated that the ACR was ready to create guidelines for radiology to eliminate inappropriate utilization of radiologic services. 1, 2

The ACR Task Force on Appropriateness Criteria was created and panel chairs were appointed in late 1993. In 1994, deliberations had begun to develop nationally accepted, scientifically-based guidelines to assist referring physicians in making appropriate imaging decisions for given patient clinical conditions in order to provide the College’s perspective on how to best use limited health care resources.

What about diagnostic imaging for patients with acute chest pain?
The RAND Corporation’s Modified Delphi Process
Why was it Developed
Is the Terminology Correct?

RAND – Research ANd Development

It was developed in the 1950s to predict the impact of nuclear weapons technology on warfare – really, use this process and language in clinical medicine?

Modified Delphi lexicon was not designed for issues where public perception would be an issue, like medicine – but the process is useful for evaluating scenarios

The media, our patients and their families do not understand the terminology and the different categories
Coronary revascularization is appropriate when the expected benefits, in terms of survival or health outcomes (symptoms, functional status, and/or quality of life) exceed the expected negative consequences of the procedure.
Developing the Appropriateness Use Criteria

The Writing Committee

Define “Appropriateness” for Coronary Revascularization

What are the known indications for coronary revascularization?
- Major randomized trials
- Guidelines
- Other sources

Assumptions and Definitions

Extensive literature review and synthesis of the evidence

≥ 70% stenosis significant (>50% for LM)
Maximum medical therapy (use of ≥ 2 drug classes)
High, Intermediate, low-risk stress tests
High-risk clinical features (ECG, biomarkers, exam findings)
Developing the Appropriateness Use Criteria: The Number of Clinical Scenarios is too Low to Capture Current Clinical Practice

The Writing Committee

- Sobering realization as to how complex our daily decisions really are
  - ~4000 possible combinations
- Needed an understandable framework built upon known data and clinical practice

Define “appropriateness”
- Literature search
- Assumptions & definitions

Develop clinical scenarios

How are we going to do this?
Developing the Appropriateness Use Criteria: Evaluation of Clinical Scenarios in Current Clinical Practice

• The Technical Panel
  – Nominated by professional societies
  – Selected for balance by the writing committee and Task Force
    • 4 interventional cardiologists
    • 4 CT surgeons
    • 8 cardiologists
    • 1 Health plan officer

Provided with:
- The definition
- Summary of all literature
- Assumptions & definitions
- 180 clinical scenarios

We need many more clinical scenarios and ones that mimic the complexities of current clinical practice (e.g. FFR, elderly CABG turntowns, etc).
Clinical Scenarios Scored by the Technical Panel

Appropriateness Score
(7-9) Appropriate
(4-6) Possibly Appropriate/Uncertain
(1-3) Inappropriate

Independent 1st round ratings
Ratings tabulated – agreement determined
Face-to-face meeting – ratings discussed
Independent 2nd and final round ratings
Clinical Scenarios

Four Major Groups

Patients with acute coronary syndromes (ACS)
Patients without prior bypass surgery
Patients with prior bypass surgery (but no ACS)
Method of revascularization in patients with advanced CAD
Framework for Decision Making

Five Core Variables

- **SYMPTOMS**
  - Stable angina
  - Class I ASx
  - None
  - None
  - No sig. CAD

- **STABILITY**
  - Low risk
  - None

- **ISCHEMIA**
  - None

- **MEDICAL Rx**
  - None

- **ANATOMY**
  - LM + 3v CAD
<table>
<thead>
<tr>
<th>Rating</th>
<th>What it means</th>
<th>What it does NOT mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate (7-9)</td>
<td>Test is generally acceptable and is a reasonable approach for the indication</td>
<td>Does not mean mandatory</td>
</tr>
<tr>
<td>Uncertain (4-6)</td>
<td>Test may be generally acceptable and may be a reasonable approach for the indication. Consensus opinion not achievable.</td>
<td>Does not mean inappropriate or questionable. Does mean the clinician is confused!</td>
</tr>
<tr>
<td>Inappropriate (1-3)</td>
<td>Test is not generally acceptable and is not a reasonable approach for the indication. Goal is not 0%, however, a consistent inappropriate pattern should be reviewed.</td>
<td>Does not equal deceit or fraud.</td>
</tr>
</tbody>
</table>
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

Coronary Revascularization Writing Group

Manesh R. Patel, MD, Chair
Gregory J. Dehmer, MD, FACC, FACP, FSCAI, FAHA*
John W. Hirshfeld, MD†

Peter K. Smith, MD, FACC‡
John A. Spertus, MD, MPH, FACC†

*Society for Cardiovascular Angiography and Interventions Representative; †American College of Cardiology Foundation Representative; ‡Society of Thoracic Surgeons Representative
ACCF/SCAI/STS/AATS/AHA/ASNC 2012
Appropriateness Criteria for Coronary Revascularization

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

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The AUC is Young

An Awkward Adolescent

Revascularization AUC
2009
2012
### Appropriate Use Ratings by Cath Anatomy, Non-Invasive Imaging and Angina Class in patients Without Bypass Surgery

#### Table: Low-Risk Findings on Noninvasive Study

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<tbody>
<tr>
<td>Class III or IV</td>
<td>U A A A A A</td>
<td>High Risk Max Rx</td>
<td>U A A A A A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max Rx</td>
<td></td>
<td>High Risk No/min Rx</td>
<td>U U A A A A</td>
<td></td>
<td></td>
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<tr>
<td>Asymptomatic</td>
<td>I I U U U U</td>
<td>Int. Risk Max Rx</td>
<td>U U U U U A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max Rx</td>
<td></td>
<td>Low Risk Max Rx</td>
<td>I I U U U U</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>I I U U U U</td>
<td>Low Risk No/min Rx</td>
<td>I I U U U U</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No/min Rx</td>
<td></td>
<td>Coronary Anatomy</td>
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<tr>
<td>Asymptomatic</td>
<td>I I U U U U</td>
<td>CTO of 1-vz: no other disease</td>
<td>I I U U U U</td>
<td>Low Risk No/min Rx</td>
<td>I I U U U U</td>
</tr>
</tbody>
</table>

#### Coronary Anatomy

- CTO of 1-vz: no other disease
- 1-2-vz disease; no prox. LAD
- 1-vz disease; prox. LAD
- 2-vz disease with prox. LAD
- 3-vz disease; no left main

---

RAND Method with Modified Delphi Process

The SCAI-QIT – AUC Tool
The Quality Committee – Dr. Kalon Ho
Validation of AUC

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

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
Appropriateness of Percutaneous Coronary Intervention

- NCDR study of 499,676 PCIs from July 1, 2009 – September 30, 2010

- 71.1% were for acute indications (STEMI, NSTEMI, high risk USAP)
  28.9% for non-acute, elective indications

  - Acute interventions
    98.6% appropriate
    0.3% uncertain
    1.1% inappropriate

  - Non-acute interventions
    50% appropriate
    38% uncertain
    12% inappropriate

Inappropriate PCIs in Non-acute Patients

Most Common Inappropriate Indications for Non-acute PCI

- No angina: 53.8%
- Low risk non-invasive study: 71.3%
- < 1 Anti-anginal medication: 95.8%

Did Dr. Oz Get it Right?

50% of all PCIs are inappropriate

12% of all PCIs are inappropriate
Steps Towards Maturity:
The Terminology is now more **Appropriate** for Clinical Medicine

- **Appropriate** → Appropriate Care
- **Uncertain** → May Be Appropriate Care
- **Inappropriate** → Rarely Appropriate Care

New and Improved!!
(2/22/13)
Validation of AUC:
Is there underuse and overuse?

Assessing the Association of Appropriateness of Coronary Revascularization and Clinical Outcomes for Patients With Stable Coronary Artery Disease

Dennis T. Ko, MD, MSc,*†‡ Helen Guo, MSc,* Harindra C. Wijeysundera, MD, PhD,*†‡ Madhu K. Natarajan, MD, MSc,§ A. Dave Nagpal, MD,¶ Christopher M. Feindel, MD,¶‡ Kori Kingsbury, MSN,# Eric A. Cohen, MD,†‡ Jack V. Tu, MD, PhD,*†‡ for the Cardiac Care Network (CCN) of Ontario Variations in Revascularization Practice in Ontario (VRPO) Working Group

Toronto, Hamilton, and London, Ontario, Canada
Appropriateness and Outcomes of Percutaneous Coronary Intervention

- A retrospective chart review study of 1625 patients in Ontario, CANADA from April 1, 2006 – March 31, 2007 to examine the appropriateness of coronary revascularization and long term outcomes [Cardiac Care Network of Ontario Variations in Revascularization Practice in Ontario (VPRO)]

- CABG or PCI was performed in only 69% of patients who had appropriate indications for revascularization (31% of patients who should have had revascularization did NOT get it)

- Three year F/U

Appropriateness and Outcomes of Percutaneous Coronary Intervention

Patients with stable CAD undergoing Cath (% who had appropriate indication for revascularization)

Appropriateness and Outcomes of Percutaneous Coronary Intervention


<table>
<thead>
<tr>
<th>ACC Appropriateness Categories</th>
<th>Proportion of Cardiac Catheterization (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inappropriate</td>
<td>45%</td>
</tr>
<tr>
<td></td>
<td>7%</td>
</tr>
<tr>
<td></td>
<td>18%</td>
</tr>
<tr>
<td>Uncertain</td>
<td>54%</td>
</tr>
<tr>
<td></td>
<td>8%</td>
</tr>
<tr>
<td></td>
<td>23%</td>
</tr>
<tr>
<td>Appropriate</td>
<td>69%</td>
</tr>
<tr>
<td></td>
<td>85%</td>
</tr>
<tr>
<td></td>
<td>60%</td>
</tr>
</tbody>
</table>

% of total who had PCI: 60%

% of total who had CABG: 85%

% of each category who had revasc: 69%
Overuse and underuse of revascularization are identified in clinical practice.

Revascularization of patients deemed “inappropriate” by the current criteria had NO INCREASED HAZARD – maybe the decision making process is more complex than the “adolescent” AUC can handle.

Failing to treat patients who are “appropriate” for revascularization is associated with increased risk for adverse events at 3 years.

We need to be cautious that the AUC process itself does not drive interventionalists to inappropriately undertreat patients who need interventional therapies.

Conclusions

• AUC have been triggered by the Variations in Utilization Rates for Dx and Tx (e.g. imaging, PCI), the rare cases of fraudulent procedures and the desire to improve delivery of Appropriate Care

• AUC are but one tool for guiding clinical practice (CPGs and Perf Meas)
  What we “should do” for our patients

• AUC utilizes the Research AND Development Corporation’s Modified Delphi Method to rate multiple clinical scenarios

• RAND does not stand for Research AND Done

• This is a process that will take time – like the scientific method – gather data, make a hypothesis, test the hypothesis, record data, make conclusions, gather data, etc.

• While the AUC matures, we need to be aware of several issues,…
Conclusions

• Retrospective analyses of PCI using the AUC show that ICs are already proficient in providing **Appropriate Care**

• We need many more clinical scenarios (e.g. FFR, complex, elderly, CABG turndowns, etc.)

• The new and improved Terminology may help “Un-confuse” the media, our patients and the public

• Use the SCAI-QIT calculator to help in **real time** with AUC

• Initiate the ACE Accreditation process for YOUR cath lab

• Improve documentation – get credit for what you are already doing!

• AUC validations have shown there is overuse and **underuse** of revascularization

• When in doubt,…. FFR

• Finally,....
AUC

Interventional Cardiologist

I wish for a shoehorn!
Revascularization AUC
2009
2012
New Panel is Selected
See You in Las Vegas!

SCAI 2014
Las Vegas, NV | May 28-31, 2014

Celebrating 37 Years of the Best of the Best in Interventional & Invasive Cardiology Education

www.SCAI.org/SCAI2014
### Patient Information
- CCS II (Slight limitation of ordinary activity)
- Minimal Therapy (1 class of medications)
- Intermediate-risk stress test findings: cardiac mortality 1-3%/year
- No Previous CABG

### Indications

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Description</th>
<th>Indication</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2 VD</td>
<td>with no Prox LAD</td>
<td>16</td>
<td>5</td>
</tr>
<tr>
<td>3 VD without LM</td>
<td></td>
<td>44</td>
<td>7</td>
</tr>
<tr>
<td>PCI</td>
<td>3 VD with high SYNTAX Score or CTO</td>
<td>67</td>
<td>3</td>
</tr>
<tr>
<td>CABG</td>
<td>3 VD with high SYNTAX Score or CTO</td>
<td>67</td>
<td>9</td>
</tr>
</tbody>
</table>

**Notes:**
- PCI: 3 VD with high SYNTAX Score or CTO (Indication 67; Score 3)
- CABG: 3 VD with high SYNTAX Score or CTO (Indication 67; Score 9)