Public Statement of the

Oregon Chapter of the American College of Cardiology and

The Society for Cardiovascular Angiography and Interventions

Before the Oregon’s Health Evidence Review Commission’s
Subcommittee on Evidence-based Guidelines

On its Initial Draft of Coverage Guidance for
Coronary Artery Revascularization for Stable Angina

November 6, 2014
Portland Oregon

By

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Thank you for the opportunity to speak at this meeting. We appreciate the effort that Oregon’s Health Evidence Review Commission has devoted to the important topic of “Coronary artery revascularization for stable angina.”

I am Arthur Lee, MD, FACC FSCAI and I am representing the Oregon Chapter of the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions (SCAI) which is the specialty society focusing on the provision of percutaneous coronary interventions along with other percutaneous procedures.

We support HERC’s efforts to oversee appropriate utilization and to ensure that high quality necessary care is available to covered Oregonians. To this end, we respectfully wish to suggest numerous changes and hope to have open communications with HERC staff as this initial draft is being revised.

In the short time allotted we will note the following about the initial draft.

We agree with the HERC that most stable angina patients should undergo optimal evidence-based medical therapy (OMT) before considering PCI. That is and has been a key recommendation in our guidelines. The need for PCI should only be considered in these patients when for that patient OMT has failed.

We caution however about excessive reliance on the COURAGE Trial results. First it only enrolled a small subset of patients who were screened for the study (less than 10%) and does not represent all patients with stable angina. As physicians we understand that all clinical decisions must be based on an individual’s circumstances. Secondly, 1/3 of the OMT patients crossed over to having PCI during the trial. Thirdly, that throughout the VA and other participating sites for the trial OMT patients had better than typical patient follow-up in order to maximize patient compliance with OMT (see: http://circoutcomes.ahajournals.org/content/1/1/4.full). Such careful attention to individualization of care is not currently practical in a real world setting. It is also important to recognize that patients receiving PCI rather than OMT in that trial had less angina for at least two years. There is robust literature on quality of life improvements after PCI. The relief of symptoms is a valuable benefit to patients and should not be overlooked. Some entire fields of medicine such as orthopedics are devoted to the relief of symptoms. An additional concern is that most of the literature reviewed did not include widespread use of drug eluting stents which have been shown to reduce restenosis or the use of IVUS or FFR which allow for a
more precise evaluation of which patients are most likely to benefit from PCI rather than OMT. More current data clearly show even better outcomes for PCI.

We appreciate that the HERC has cited our multisocietal guidelines on the treatment of patients with “Stable Ischemic Heart Disease” as a source of information to this subcommittee but it is not a “trusted source.” Given that the HERC is also considering limits on PCI for multivessel disease, we suggest that the Commission and this subcommittee review the “2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention” (see: http://content.onlinejacc.org/article.aspx?articleid=1147816) We are puzzled by the statement on page 16 of the initial draft that our SIHD guideline “receives a poor rating, primarily because study selection criteria are not specified, and no assessment of study quality” Our guidelines involve the experts in the field who know the literature well. The guidelines specifically address the quality of evidence and robustness of data in the second part of the recommendation. For example the level of evidence A designates multiple populations evaluated and that data is derived from multiple randomized clinical trials, this indicates a robust data set.

The recommendation that PCI not be allowed on patients over age 75 is not based on any current evidence and it would deny patients the choice between two procedures with relatively similar outcomes. In 2013 NCDR database, 23% of PCI patients were over 75 in age. We are not aware of any coverage restricting for PCI for patients over age 75. See for example the British NICE programs recommendations on PCI at: http://www.nice.org.uk/guidance/cg126/chapter/1-guidance#investigation-and-revascularisation.

Limiting all patients with multivessel disease to CABG as their only invasive treatment option is not appropriate. It is inappropriate to lump all multivessel disease into one category. Our 2011 Guidelines on PCI make important distinctions about the number of vessels involved (with two vessel disease being considered more viable for PCI than 3+ vessel disease), the type of vessel involved (with left main disease involvement tilting the scale toward CABG and the presence of diabetes being an important factor that nuances how patients are treated. For many years the treatment of multivessel disease has been the grey area when deciding between PCI and CABG. It is important to note however that most contemporary studies comparing PCI and CABG have enrolled only the sickest patients, those with 3+ vessel involvement, left main disease and/or diabetes. Our guidelines recommend CABG for these patients. More recent studies
like the SYNTAX trial have helped us develop angiographic scores to risk stratify patients for PCI or CABG based on the severity of coronary disease and lesions. Furthermore, two recent RCT’s have found that patients undergoing primary PCI have a mortality benefit if they undergo treatment of the second, non-culprit vessel.ii, iii The benefits of complete revascularization.

Finally, we note that it is common in our practices for surgeons to decline to operate on patients with multi-vessel disease that are at high risk for complications, when there is a non-surgical alternative. In these cases our colleagues the surgeons ask us to provide revascularization for patients desperately needing it, but who are too sick to tolerate major surgery. In summary, patients with multiple diseased coronary arteries at either end of the spectrum of sickness – the least sick and the most sick – are better treated by coronary stenting than surgery.

In summary, we appreciate the Commission’s efforts and we hope we can work with the Commission in refining this initial draft.

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