

## EDITORIAL COMMENT

# Class I Indications for Coronary Artery Bypass Graft Surgery

## What Is the Appropriate Therapy for Patients With Multivessel Coronary Disease?\*

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In this issue of *JACC: Cardiovascular Interventions*, Frutkin et al. (1) have examined the attempt rates of drug-eluting stents (DES) using the NCDR (National Cardiovascular Data Registry) dataset during 3 time periods: pre-DES (before April 2003), DES diffusion (April 2003 through December 2004), and DES (January 2005 through September 2006). Using this dataset, they have shown an increasing use of DES in patients with American College of Cardiology class I indications (essentially multivessel disease and or left main disease) for coronary artery bypass graft (CABG) surgery during this period. Is this an appropriate use of DES? As pointed out by Frutkin et al. (1), outcomes in patients with class I indications for CABG surgery who receive DES instead need further study. Outcomes after DES in this group of patients are important because they will serve as a key determinant of the appropriateness of care when comparing 2 or more therapies such as CABG and percutaneous coronary intervention (PCI).

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What is appropriateness? The Oxford English Dictionary defines *appropriateness* as special fitness, suitability, or applicability. To know the appropriateness of a procedure device or drug versus another requires an adequate evidence base on which to compare the various options. Although we have been comparing different therapies for many years using randomized clinical trials, these studies typically only answer clinical questions in a highly defined, and therefore limited, patient population. It will never be possible to do randomized trials to answer all of the potentially important clinical questions. How are we to determine the appropriate approach in more complex patient populations or where

events are rare? One approach is comparative effectiveness research, which allows outcomes from other sources of data such as the NCDR database, other well-designed registries, and other datasets to be used to answer important clinical questions. This approach has taken on added visibility since Congress earmarked over \$1 billion for comparative effectiveness research in the recently enacted American Recovery and Reinvestment Act of 2009. Although appropriateness criteria for revascularization have been published, these criteria are limited by the evidence base for percutaneous intervention in patients with more complex multivessel disease, such as those with class I indications in the article of Frutkin et al. (1), with many receiving an uncertain categorization (2). Additionally, as was recently pointed out (3), previously published American College of Cardiology/American Heart Association guidelines are only based on multiple randomized trials or meta-analyses 11% of the time. Clearly, we need more evidence. To know the appropriate approach to the individual patient with multivessel disease we not only need to know typical demographics and other patient characteristics, we must also know the extent of their multivessel disease because not all multivessel is the same. Several definitions of multivessel disease have been used in previous studies comparing percutaneous intervention and surgery, but they have lacked granularity of coronary and lesion detail (4). Therefore, in my mind, the real questions to be answered before we can address appropriateness are: Exactly what is multivessel disease? Do all patients currently with class I indications for CABG need surgery as an initial revascularization strategy?

There is clearly a difference, from a percutaneous and surgical standpoint, between a patient with multivessel and single-lesion or multilesion disease and a patient with diffuse multivessel/multilesion disease who is not a candidate for any revascularization procedure. Although this example represents the extremes, coronary disease varies greatly, and it is overly simplistic to lump that complexity into neat little categories of 1-, 2-, or 3-vessel disease. My patient has 3-vessel disease involving the proximal right coronary, left anterior descending, and circumflex arteries. Is multivessel DES the most appropriate option for my patient? Maybe it depends: the right coronary artery has bifurcation disease at the posterior descending involving both branches; the left anterior descending artery has disease at the bifurcation with a large diagonal that also has disease at its ostium; and the circumflex artery has ostial disease as well as 3 sequential lesions in its body. The answer to the question is potentially as complex as the anatomy described and the anatomy is less complex than some, including the important impact of concomitant left main artery disease if it is present. Lesion complexity is perhaps less important with CABG, but with PCI it is especially critical to acute and chronic outcomes, including cost, in patients undergoing revascularization by percutaneous tech-

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niques. Without more sophisticated descriptions of multivessel disease, even with outcomes, Frutkin et al. (1) and others will not be able to answer the ultimate question of whether use of DES in patients with class I indications is appropriate.

The recently published SYNTAX (Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) trial (5) answers some of these questions but is limited at this time to only 12-month follow-up. The SYNTAX score, a more elegant assessment of the extent of multivessel coronary disease, was introduced to the cardiovascular community in this trial. This scoring system is the first significant attempt in recent memory to more accurately define the complexity of multivessel disease and to test percutaneous and surgical techniques in a group of patients with similarly complex coronary artery disease. Although the overall trial showed the superiority of CABG over PCI using the Taxus DES (Boston Scientific, Natick, Massachusetts), there are nuances that should be examined and given weight. Patients with low to intermediate scores ( $\leq 32$ ) had similar primary outcomes, suggesting that these patients with multivessel disease could have PCI without significantly different outcomes. Although the score has yet to be rigorously tested in other trials and has limited follow-up, it is this type of granularity of lesion complexity that will be needed to answer questions of outcome particularly with respect to percutaneous revascularization. This information can then be used to inform decisions regarding appropriateness.

There may also be patients with multivessel disease who might benefit from aggressive medical therapy alone that has not been seriously tested for more than 20 years (6,7). The ongoing FREEDOM (Future REvascularization Evaluation in patients with Diabetes mellitus: Optimal management of Multivessel disease) trial (8), where aggressive medical management of diabetes is an integral part of the trial, may shed some new light on the topic, but a brighter and broader light needs to be shined on the question, considering the multitude of medical treatments developed for coronary disease in the past 2.5 decades.

We cannot continue to compare 2 techniques of revascularization, 1 of which is more dependent on lesion characterization than the other, simply by analyzing them as though they were the same. Unfortunately, there are no large datasets, including the NCDR database, with this level of detail regarding coronary anatomy. We need this information going forward, because there is much more to

multivessel coronary disease than the 3 epicardial vessels and a percent diameter stenosis.

To quote the 2007 Institute of Medicine Roundtable on Evidence-Based Medicine: "As ever-increasing options evolve in health care, current gaps in knowledge and practice about which care works best will persist or worsen without the appropriate information on which to base healthcare decisions (9)." I could not agree more.

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