Catheterization and Cardiovascular Interventions 58:397–399 (2003)

SCAI Statement on Drug-Eluting Stents: Practice and Health Care Delivery Implications

John McB. Hodgson,[1*] MD, Spencer B. King III,[2] MD, Ted Feldman,[3] MD, Michael J. Cowley,[4] MD, Lloyd W. Klein,[5] MD, and Joseph D. Babb,[6] MD, prepared on behalf of the Society for Cardiac Angiography and Interventions

Key words: coronary artery disease; stents; percutaneous transluminal coronary angioplasty; restenosis; health policy

INTRODUCTION

Coronary artery disease remains a major health problem throughout the world. Since the inception of percutaneous transluminal coronary angioplasty in 1978 and the addition of stents in the early 1990s, much progress has been made in the treatment of atherosclerotic obstructive coronary artery disease. Percutaneous coronary intervention (PCI) has eclipsed coronary artery bypass grafting surgery as the treatment of choice for many patients with obstructive coronary lesions. PCI, however, has been limited by restenosis, the incidence of which is highly variable, ranging from less than 5% to over 50% in certain clinical and anatomic subgroups.

While restenosis rates have fallen consistently over the past 10 years due to stent use, ancillary guidance techniques, and possibly adjunctive pharmacology, the recent development of antiproliferative drug-eluting stents (DES) is a major breakthrough in preventing restenosis after initial PCI.

The use of DES in the treatment of obstructive coronary disease will have major beneficial medical impact on the care of patients, but also will create additional medicolegal, financial, and programmatic ramifications. This statement will provide a preliminary framework to address the multifactorial issues surrounding the introduction of DES into widespread practice.

AVAILABLE DATA

While a number of different drug coatings and binding polymer configurations are under investigation, the majority of clinical data exist for sirolimus and paclitaxel. Randomized trials using both sirolimus and paclitaxel coatings have shown important reductions in target lesion revascularization rates (in the range of 70%–80%). Subgroup analyses are limited, but indicate similar relative success in many traditionally high-risk groups (e.g., diabetic patients, small vessels and lesions located in the proximal left anterior descending coronary artery). Based on these encouraging results, it is widely expected that the U.S. Food and Drug Administration will approve sale of DES devices by early 2003.

It is important to realize that the data for DES are still being collected and analyzed and should therefore be considered preliminary. Data for many challenging subgroups are lacking. Additionally, not all DES results have been favorable. At least three clinical trials with alternative drug formulations have been discontinued after poor or even detrimental effects were observed. The long-term effects of profound inhibition of the healing response following stent implantation are unknown; relatively few patients have been followed for more than 2 years. Finally, many technical questions surrounding DES remain unanswered. Examples include the impact of strut malapposition, the longevity of strut coatings, peristent restenosis, and the implications of DES restenosis.

[1]Heart and Vascular Center, MetroHealth Medical Center, Cleveland, Ohio
[2]Cardiology of Georgia, Atlanta, Georgia.
[3]Evanston Hospital, Evanston, Illinois.
[4]Medical College of Virginia, Richmond, Virgina.
[5]Rush-Presbyterian St. Luke's Medical Center, Chicago, Illinois
[6]East Carolina University-Brody School of Medicine, Greeneville, North Carolina

Statement approved by the SCAI Publications Committee on 4 December 2002 and by the SCAI Executive Committee on 5 December 2002.

*Correspondence to: Dr. John McB. Hodgson, Heart and Vascular Center, MetroHealth Medical Center, 250 MetroHealth Drive, Cleveland, OH 44109. E-mail: jhodgson@metrohealth.org

Received 7 January 2003; Revision accepted 7 January 2003

DOI 10.1002/ccd.10513
Published online in Wiley InterScience (www.interscience.wiley.com).

Early favorable results using bare metal stents (BMS) in conjunction with oral pharmacologic (including sirolimus) adjunctive treatment, and excellent results with intravascular ultrasound (IVUS) or pressure guidance, as well as new strut or coating designs and new pharmacologic agents, continue to be reported. Alternative BMS designs and use of BMS with adjunctive measures have resulted in target lesion revascularization rates near those reported for DES in many lower-risk patient and anatomic subgroups.

Medical therapy for obstructive coronary disease has also advanced. Recent evidence suggests that PCI for some intermediate-severity lesions may be safely deferred (with a low subsequent event rate), especially when coupled with aggressive risk factor modification.

In summary, while DES represent an important advance in the treatment of coronary lesions, available controlled data do not support universal use. Careful attention to proper patient and lesion selection including documentation of physiologic significance may provide acceptable clinical results in many patient or lesion subsets.

POTENTIAL USES FOR DES

Current PCI Candidates

If DES were applied to current patients, available controlled data would support their use in small to medium vessels (2.25–3.5 mm) with lesions up to 30 mm in length.

Additional PCI Candidates

DES appear very effective even in traditionally high-restenosis-risk subgroups (e.g., diabetic patients, lesions in proximal LAD, vessels < 3.0 mm). It is reasonable to consider that their availability might eventually prompt expansion of the types of patients who could be treated with PCI. These might include patients with complicated bifurcation lesions, left main coronary lesions, multiple prior restenosis, lesions in saphenous vein grafts, ostial lesions, and multiple lesions. It is important to note, however, that no long-term controlled data currently exist for such applications. Long-term controlled data will be needed to establish the safety and relative benefit in these and other subsets that have not been studied.

COMPARISON TO CURRENT PRACTICE

Migration to the use of DES rather than BMS should be technically uncomplicated. DES are functionally similar to their BMS predecessors. Implantation techniques should require little modification. Inventory issues (shelf life, sterility, temperature sensitivity, etc.) should be easily addressed. While initial lengths and diameters may be limited, a full range of sizes will ultimately be available.

OTHER ISSUES

Medicolegal

Concern is expressed by some that despite the lack of long-term scientific evidence to prompt universal application of DES, there may be considerable pressure to use DES for all lesions due to fear of litigation arising from cases of restenosis where BMS were implanted. Use of DES in nonapproved applications could also carry risk. Specific issues related to the use (or nonuse) of DES will require much more clinical experience with the use of DES.

Economic

Current projected pricing for DES is approximately threefold above that for BMS. In some countries where DES are already approved, this differential approaches sevenfold. Given the expected demand for use in existing PCI candidates and the prospect of expansion to new patient subgroups, the economic burden may be substantial. Decreased restenosis and diminished rates of coronary bypass graft surgery will offset some of the expenditures for DES. Governmental agencies have approved an increase in repayment for the use of DES during PCI (to begin in April 2003). The additional payment will be insufficient to cover the increased hospital costs associated with the use of multiple DES per vessel or the treatment of multiple vessels per patient.

Preliminary analyses suggest that DES may be cost-effective in patients estimated to have a clinical restenosis rate with BMS greater than 12%–14%. These calculations are very dependent on the price of the DES. Clinical restenosis probability for individual lesions may be estimated using published tables. Examples include diabetic patients with vessels ≤ 3.0 mm, or nondiabetic patients with vessels ≤ 2.5 mm. A critical evaluation of the health care economic implications of this exciting but expensive technology will be required.

Programmatic

The impact of DES use during percutaneous intervention on coronary bypass surgery is unclear. Some projections include a 10%–50% reduction in surgical case volume. Such dramatic shifts would have profound impact on hospitals, training programs, and reimbursement.

RECOMMENDATIONS

Based on the limited available data and lack of practical experience with DES use, SCAI recommends an evidence-

based adoption strategy recognizing that physicians are concerned about offering the best possible patient care. Intervention should be employed only after documentation of the clinical and/or physiologic significance of individual lesions. The patient's physician should make this assessment based on objective evidence.

DES have shown significant reductions in restenosis in each group in which they have been formally tested. These include diabetics, LAD stenoses, small vessels, and both short and relatively long lesions. Some subgroups for which there are few data include patients with saphenous vein graft disease, bifurcation lesions, very small or very large arteries, prior brachytherapy, in-stent restenosis, and acute myocardial infarction. A large spectrum of the coronary disease population will have benefit from reduced recurrence rates after treatment with DES. However, there remain patients for whom this therapy requires further study.

The society also recognizes the role of physicians as important participants in societal health care delivery issues. Interventional cardiologists are highly trained physicians concerned with not only the technical tools of the trade but the important impact that their care has on patient lives and productivity. To address the scientific advances in stent technology without consideration of the societal impact would be inadequate.

SCAI therefore suggests the following: that national databases for collection of interventional data be updated as soon as possible to allow tracking of DES patient outcomes, and that a multidisciplinary task force be appointed to address the financial and medicolegal consequences of DES implementation.

SCAI recognizes that development of this new technology is evolving rapidly. SCAI thus plans to review this document in 6 months, or sooner should new data so warrant.