

DRUG-ELUTING STENT SOLUTIONS



Addressing Misconceptions About Drug-Eluting Stents

This monthly column in Cath Lab Digest reviews important points of distinction in drug-eluting stents, from characteristics to techniques, to provide valuable and relevant information about this technology.

This article, the last of a three-part series on drug-eluting stent education, focuses on misconceptions about drug-eluting stents. Part two, in last month's issue, discussed communicating the benefits of this technology to patients.

By Dean J. Kereiakes, MD

Dr. Kereiakes received his undergraduate and medical degrees from the University of Cincinnati. He completed an internship and residency at the University of California, San Francisco, a senior residency at Massachusetts General Hospital in Boston and a chief residency at the University of California, San Francisco. He then completed fellowships in adult cardiology at the University of California, San Francisco, and in coronary angioplasty at the San Francisco Heart Institute and the Sequoia Hospital. In addition to his clinical practice, Dr. Kereiakes serves as Medical Director at the Heart Center of Greater Cincinnati and the Carl and Edyth Lindner Center for Research and Education. Dr. Kereiakes is also a Professor of Clinical Medicine at Ohio State University and was previously the Chief Executive Officer of Ohio Heart and Vascular Center. His accomplishments include being prior section editor for *Circulation*, the official medical journal of the American Heart Association, and editorial board member for *The Journal of the American College of Cardiology*, *The American Heart Journal*, *The American Journal of Cardiology*, *The Journal of Invasive Cardiology*, *Circulation* and *Reviews in Cardiovascular Medicine*. Dr. Kereiakes is board-certified in internal medicine and cardiovascular disease.

Q Drug-eluting stents (DES) were introduced in 2002. Why is this technology considered revolutionary for the treatment of coronary artery disease (CAD)?

A The primary reason DES have such a major impact on the treatment of CAD is the marked improvement in preventing coronary artery restenosis. In randomized clinical trials, DES have shown a significant reduction in the need for additional revascularization procedures – traditionally the Achilles heel of percutaneous interventions – when compared to bare-metal stents (BMS). Furthermore, the cumulative safety profile of DES, particularly in regards to death and myocardial infarction (MI), is similar to BMS.

Q Are DES your preferred treatment option for CAD?

A DES are the preferred treatment option for the majority of my patients, but not all of them. I may not recommend a DES for a patient who requires a non-cardiac surgical procedure in the foreseeable future. Additionally, DES may not be the best option for patients who simply cannot afford long-term dual anti-platelet therapy and patients who have an elevated risk of significant bleeding.

Q What types of misconceptions do patients have in regards to DES?

A The media has focused on a very slight numerical difference in late-stent thrombosis observed with DES, which has been blown out of proportion. Unfortunately, the public has completely missed the fact that the incidence

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of death and MI remains equal between DES and BMS patients. The media has also lost track of the fact that there is an approximately 50-percent reduction in the need to have another revascularization procedure and that there remains a net clinical benefit in favor of DES compared to BMS.

By characterizing DES as “ticking time bombs” and “dangerous devices,” the media is misrepresenting the technology and inappropriately terrorizing the American public.

Q How can interventional cardiologists optimize the use of DES?

A It is essential to follow the ACC/AHA Science Advisory guidelines* regarding dual anti-platelet therapy, which is clopidogrel for 12 months and aspirin indefinitely. I personally recommend patients remain on dual anti-platelet therapy indefinitely if possible. If patients require surgical procedures beyond one year from the time of stent deployment, I stop Plavix® five days prior to the procedure, which is in line with current ACC/AHA guidelines. I do not stop the administration of daily aspirin, which should be maintained if at all possible through the procedure. If stent thrombosis does occur, in most instances it is due to the recommendation of a non-cardiology physician, oral surgeon or dentist, who may discontinue both Plavix and aspirin for 7-10 days prior to a procedure.

Another action we can take is to optimize stent deployment. I think we have become lazy in our deployment strategy for DES, in part because we think that the drugs are going to prevent restenosis and we no longer feel the need to optimize stent expansion. High-pressure post-dilatation, according to the product label, is an excellent strategy that should be employed in every patient to maximize DES outcomes.

Q Many interventional cardiologists believe BMS should be placed in larger caliber vessels. What are your thoughts on this?

A My colleagues and I published the first research that linked lesion and stent length to BMS restenosis rates in the *American Journal of Cardiology* in 2000. Using a stent database, we predicted restenosis rates based on in-stent minimum lumen diameter and stent length. For a 3.5-mm vessel with a short lesion, the binary angiographic restenosis rate was in the single digits for either a 15-mm or 18-mm stent. Unfortunately, only BMS were utilized in this analysis.

When one looks at BMS versus DES in large reference vessel diameter vessels (≥ 3.4 mm diameter) out to four years of follow-up from the TAXUS® Stent database, there is a highly significant reduction ($p=0.0005$) in target lesion revascularization (TLR) from 11.5 percent with BMS to 5.8 percent with the TAXUS Stent (Figure 1). Additionally, it is extremely interesting

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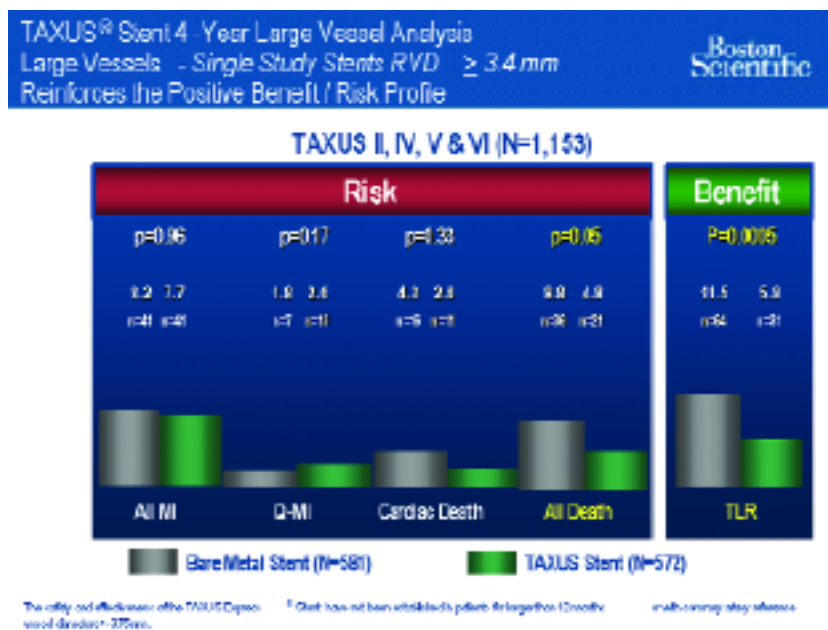


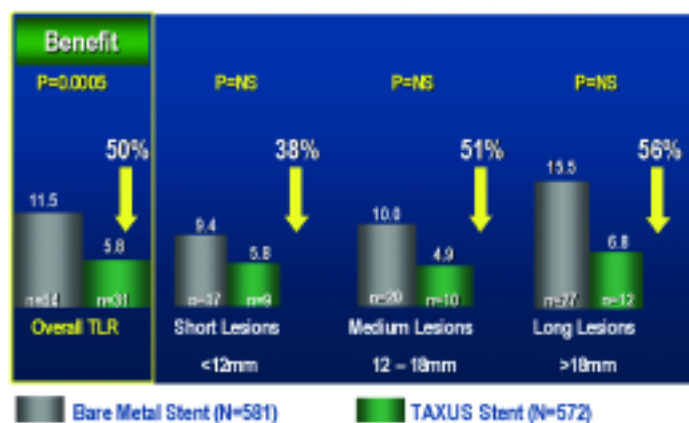
Figure 1. TAXUS Stent benefit/risk profile in vessels ≥ 3.4 mm

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TAXUS® Stent 4-year Meta-analysis Large Vessels (≥ 3.4 mm)
TLR Benefit Consistent Across Lesion Lengths



TAXUS II, IV, V, & VI (N=1,153)



The safety and effectiveness of the TAXUS Express® Stent have not been established in patients with coronary artery reference vessel diameters <2.5 mm or >3.75 mm or in lesions longer than 12 mm.

Figure 2. TLR benefit analysis in vessels ≥ 3.4 mm

to note there is a statistically significant reduction ($p=0.05$) in death from 8.8 percent with BMS to 4.8 percent with the TAXUS Stent.

Some interventionalists have started to put BMS in larger-diameter reference vessels, particularly if a patient has shorter lesions. They believe that the relative benefit of DES versus BMS is less in larger vessels with short stenosis. Patients with lesions ≥ 12 mm had more than a 50-percent reduction in TLR with the TAXUS Stent compared to BMS in a four-year large vessel meta-analysis. Even patients with lesions <12 mm had a 38-percent reduction in TLR (Figure 2) with the TAXUS Stent, compared to BMS. I think this dispels the myth that large vessels do not need DES.

Q Are new technologies currently in development for the treatment of CAD?

A Fortunately, the field of interventional cardiology is very dynamic. There is an ongoing evolution in DES platforms, including bioreabsorbable polymers and even bioreabsorbable stent platforms. In addition, there are multiple strategies to enhance healing and endothelial stent coverage. These include passive, surface modifications of the stent itself, as well as active pro-healing therapies to enhance endothelial coverage. Furthermore, there is evolution in oral anti-platelet therapies with newer, more effective platelet receptor inhibitors. These agents provide more rapid, more effective and more uniform platelet inhibition and thus should reduce the risks associated with percutaneous interventions.

The safety and effectiveness of the TAXUS® Express® Stent have not been established in patients with coronary artery reference vessel diameters <2.5 mm or >3.75 mm or for longer than 12 months.

<http://www.acc.org/qualityandsafety/clinical/guidelines/percutaneous/update/index.pdf>

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