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SCAI President's Page

The Stent

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Well, it's finally here. Just a few weeks ago (April 24th to be exact), the United States Food and Drug Administration approved the first drug-eluting stent (DES) for marketing. After years of anticipation, we now have an awaited technology in our hands; at least some of us do, pending widespread availability of sufficient inventory. Clearly, the scientific data regarding the efficacy of DES are impressive. A look back over the years indicates that DES are a significant advance in the treatment of restenosis. Early balloon angioplasty resulted in restenosis rates of 31–37% [1,2,3]. [For the purposes of these comparisons, I have chosen early, single vessel, angiographically-controlled trials of each device.] Later introduction of "new devices" (directional atherectomy for example) saw the restenosis rate fall slightly to 31% [4,5], but expanded the lesions we could approach. Subsequently, widespread introduction of stenting (even first generation low pressure devices) lowered it further (22–31%) [6,7]. We also changed our focus from angiographic restenosis to target lesion revascularization (TLR), a more appropriate indication of clinical efficacy. Introduction of high-pressure stenting (prompted by IVUS) and application of non-angiographic guiding technologies was another step forward, with restenosis rates between 10 and 24% [8,9]. Now DES enter with restenosis rates of 9% [10]. Table 1 displays these and other pertinent data regarding device costs.

I have graphed this progression and its associated cost in an admittedly non-rigorous way, but I believe a fairly accurate one (Fig 1). I have corrected the device costs for inflation and expressed them in 2002 US dollars. As you can see, for a progressive improvement in restenosis, DES come at a price increase which appears in line with prior advances. One could argue that the development costs or the complexity of these new stents does not warrant such an increase, but I believe that once a competitive device hits the market, traditional market forces will mediate the cost issues. In the meantime, although formal cost-effectiveness evaluations of the SIRIUS trial data [11] suggest that "society" is willing to pay the additional cost to achieve lower TLR rates, it is widely expected that significant hospital losses will occur. There is no mechanism for redistributing the societal gains

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TABLE I. Various Interventional Therapies Since 1980

Device	Restenosis rate (%)	TLR (%)	Year	Original cost ($)	2002 cost ($)	References
Balloon	30–37	24	1982	750	1640	1–3
DCA	31–32	28	1990	1750	2414	4,5
Stent	22–31	12	1994	1750	2128	6,7
Stent-optimized	10–24	8	1997	2100	2360	8,9
DES	9	5	2003	3000	3000	10

DCA, Directional coronary atherectomy; DES, drug-eluting stent; TLR, target lesion revascularization

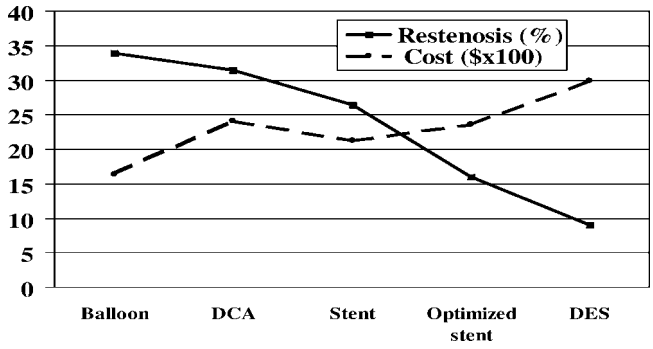

Fig 1. Estimates of restenosis rates and costs (2002 US$) for various devices in single vessel disease near the time of their introduction. DCA: directional coronary atherectomy, DES: drug-eluting stent.

from reduced repeat procedures back to the hospital that originally bought the DES. This reality is still present in many countries outside the United States despite DES marketing approval of greater than one year. In these countries, adoption generally remains less than 15%.

I recently polled several US colleagues as to how they expected to deal with the use of DES in their institutions. I was distressed by the variety of plans ranging from universal use (for some due to a belief that DES would be best in all lesions; for some out of fear of litigation), to a very rigid scoring system based on anticipated restenosis risk. Some in the mid ground planned to use one DES per case with bare metal stents for the additional vessel/lesions (this seemed to be the most fiscally sound, capturing the added reimbursement while limiting the outlay). I was distressed because the planned use had little to do with scientific data, but rather in many cases was driven by financial considerations or fear of litigation. This only confirmed the SCAI poll taken last October and reported in the Spring Newsletter [12]. In the Society's DES position statement [13], we suggested the formation of a task force to address these issues. During the annual scientific sessions in Boston, we convened the first task force meeting. Many different interest groups were represented, including the American College of Cardiology, American Heart Association, Council of Cardiovascular Organizations, three device manufacturers, payers, hospital administrators and health care economists. We had a very congenial meeting and agreed to work on three areas with the intent of providing some guidance to interventionalists during these DES "growing pains".

The first area was to explore the economic impact of DES from four different perspectives: the patient, the hospital, the payers and the health care system. With SCAI leadership, an analysis of this complex problem will be developed in the near future. The second area of focus for the task force is to look at the impact of DES on health care delivery. Due to the economics, supply issues and differing practice patterns, there may be variability in access to these devices. Additionally, there may be dramatic programmatic changes; for example, if the proposed shift from coronary bypass surgery to multivessel DES implantation occurs at a rate of 10–15%/year, some lower volume surgery programs may become non-viable. For example, in Ohio, where an open-heart program is required on-site to do angioplasty, such reductions may lead to closure of interventional programs in an odd paradox of self-inflicted regulatory suicide. Innovative new programs that maximize appropriate delivery of the entire spectrum of cardiac revascularization will need to be developed.

The final area of discussion for the task force is the medical-legal implications surrounding DES use. As noted in the SCAI survey last fall, the majority of US-based interventionalists are concerned about the legal ramifications of using DES or bare metal stents. The task force will explore the reality of these concerns and offer some guidance in this area. In summary, the charge of the DES Task Force is to provide up-to-date guidance on the non-scientific aspects of DES implementation. It is our hope that this guidance will be useful in empowering the interventionalists to practice optimal medicine without fear of economic, legal or programmatic consequences.

At the Boston meeting, I also noted an interesting presentation. Sharifi, et. al. reported a new interventional therapy that, in the first-in-man series, resulted in a TLR rate of 0% at 14 months [14]. Sounds reminiscent of the original DES data. In this series, however, there were no new devices, only application of an old concept: hyper-

baric oxygen therapy (HOT). Of course, the TLR will unlikely remain 0% as more patients are studied, but it put in perspective what we do and how we evaluate our procedures. Ultimately, we need new devices (e.g. stents), we need new pharmacology (e.g. sirolimus), we need adjunctive techniques (e.g. FFR, IVUS), and we need thinking "outside the box" (HOT).

We are in exciting times; restenosis is now in the single digits. The treatment of coronary disease in some ways has never been easier, but in other ways, never so complex. We should embrace the science of DES, but be careful not to lose sight of the other exciting advances of the past 15 years. And certainly, we cannot rest in our pursuit of even greater accomplishments, while always keeping the optimal care of our patients paramount. I will keep you informed of the task force findings as they become available. I trust they will offer some guidance for us all.

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