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The Society for Cardiovascular Angiography and Interventions

SCAI President's Page

The Survey

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Questions, questions, questions. We are always being asked questions. Questions aren't bad, but it is nice to get the answers sometimes. Through our on-line surveys we have asked our members questions from time to time. Within the past year we have queried you twice regarding drug-eluting stents (DES). In the next few paragraphs I wanted to give you some answers. As you know, in response to the first survey, we initiated a process of review and recommendations regarding the implications of DES in interventional cardiology [1]. Subsequently, a Task Force was convened and the consensus report from that effort appears in the May 2004 issue of this Journal [2]. One year following the original DES survey and approximately 6 months following commercial introduction of DES to the US market, we repeated the DES survey using similar questions to allow appropriate comparison. Within a few days we had a 26% response rate!

The most important observation I made after reviewing the two surveys is that time has not brought clarity to the DES situation (Table I). In the 2002 survey, prior to the introduction of DES, 56% of you thought your hospital or practice would develop guidelines for the use of DES. After their release and use for 6 months, only 44% of you actually have a policy in place. More than half of you practice with no written guideline or policy. On the other extreme, 21% of you reported that your hospital has a policy to restrict DES use based on financial or other considerations. These data would suggest that the policies developed to date have often been practice restricting and not practice enabling. While approximately 70% of cases of restriction were "condition" based (e.g. acute infarction, vessel size, etc) and 20% guideline evidence- or study-based, roughly 10% were clearly financially motivated. Individual responses bear this out: "Protocol to follow patient and lesion subtypes evaluated in SIRIUS; avoid non-studied indications"; "a maximum of 2 DES per admit in separate vessels (one in LAD and one in RCA)"; "we are capping our utilization to 80% of our total stent usage"; "limit one DES per case." (The full survey is available to view on the Society's web site: www.SCAI.org).

While a scientific case could be made to use these new and relatively untested devices only in selected patients

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TABLE I

	2003	2002	Change
Hospitals that have produced guidelines for use of DES vs. those expected (in 2002) to produce such guidelines	44%	56%	−12%
Patients who do receive (2003) DES vs. those expected to receive them (2002)			
All PCI cases	9%	19%	−10%
Some PCI cases	89%	77%	12%
No PCI cases	2%	4%	−2%
Cases in which DES are used (2003) vs. cases in which DES were expected to be used (2002)			
Diabetics	84%	90%	−6%
Multivessel CAD	49%	55%	−6%
Vessels of 2.0 to 2.5 mm diameter	52%	62%	−10%
Vessels of 2.6 to 3.0 mm diameter	79%	52%	27%
Vessels of 3.1 to 3.5 mm diameter	56%	25%	31%
Vessels of 3.6 mm diameter or greater	11%	5%	6%
In-stent restenosis	39%	70%	−31%
Acute coronary syndromes and acute myocardial infarction	21%	22%	−1%
Chronic total occlusion	45%	63%	−18%
Saphenous vein grafts	17%	42%	−25%
Those concerned that there could be medico-legal implications for NOT using DES	47%	65%	−18%
Those who practice in the United States	84%	76%	8%

for whom good data exist, there is no reason that our medical decision making should be influenced by concern about reimbursement or inventory levels. More than half of you (54%) responded that you have had problems with DES availability in your hospital. Of these problems over 85% were due to limited specific size supply or global supply exhaustion before replenishment. A few of you confirmed the undesirable practice of physicians' hoarding stents for personal cases at the detriment of other lab operators and their patients.

It goes without saying that proper implantation technique and vessel/stent size matching should always be practiced. Nonetheless, with artificial use restrictions imposed by hospitals compounded by limited commercial supply, it is easy to suspect that some stents were being implanted under less than ideal conditions. In July 2003, the FDA and Cordis issued the first of three successive alerts regarding Cypher DES implantation and reports of complications (primarily sub acute thrombosis (SAT)). As further data became available, it was apparent that the actual rate of DES SAT was actually quite low. Subsequent FDA alerts have described this and allayed some of the fears generated by the initial reports. We must remember, however, that DES have the same mechanical properties as bare metal stents. Careful attention to sizing and appropriate expansion remains critical. Careful documentation of the indication for PCI and the rationale for use of a DES (or non-use) remains important.

Medico-legal issues remain a concern of the survey respondents. Nearly half of the respondents are still concerned about malpractice arising from non-use of DES. This may in part explain overzealous use of limited stent sizes in less than optimal situations. This is again of concern, since we are not practicing evidence-based medicine, but rather practicing irrationally. As noted in the Task Force document, careful documentation and well-informed consent are the cornerstones of a good patient-physician relationship. A few of you felt that the most important information that the SCAI could provide was clarification of the medico-legal implications. Such a request furthers my suspicion that DES introduction has influenced our practice dramatically. While in years past we debated which stent design was more flexible or had better hoop strength, the cocktail party banter now revolves around finding ways to sneak in that third stent or how to keep Mr. Smith from filing suit if he gets a restenosis after your 4.5 × 8 mm bare metal stent!

The level of confusion was most manifest by your responses to the question: "Based on your experience with DES to date, what do you believe is the SINGLE MOST IMPORTANT thing that SCAI's updated DES policy statement should address?" Fully two thirds of you took time to write in a response, and there was a striking lack of consensus! A rough categorization of responses was as follows:

- Clarify indications and contraindications–30%
- Discuss use in specific (often single) conditions–13%
- Cost and cost-effectiveness–10%
- Medico-legal issues–5%
- Evidence-based typical guidelines–12%
- Exceptions to FDA-labeled indications–2%
- Discussion of SAT and complications–5%

Again, the theme is clear: DES have not only been a dramatic improvement for the field of interventional cardiology, they have also been very disruptive. Your Society is working hard to increase communication and clarity at many levels. Through our Task Force, we have seen cooperation among over twenty professionals from all sides of the DES issue. Your advocacy committee and leadership are in communication with CMS and the FDA to offer assistance and advice when needed. Through our surveys we are attempting to keep abreast of your needs and then take steps to address them. The DES issues will not be solved immediately or without additional discomfort. We are confident, however that resolution will be less painful if we approach the problems with a spirit of cooperation and professionalism. As I mentioned in my first President's Page, in the end "it's all about the patient." With that in mind, we will find the best solutions and the answers we all seek.

REFERENCES

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