resources for the work, not only to improve clinical and scientific standards but also to accomplish efficient utilization of health care resources.

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References


Validation for coronary stenting: a permanent implant for interventional cardiology

See page 1536 for the article to which this Editorial refers

Coronary stenting has been accepted remarkably rapidly as a more definitive method of percutaneous revasculatization than balloon angioplasty, or other newer alternatives such as directional or rotational atherectomy, or laser. In most laboratories where interventional procedures are commonly performed, at least 40-50% of the cases involve stent implantation. This veritable 'sea change' is the most radical transformation in the field of interventional cardiology since its birth in 1977. Indeed, permanent metal prosthetic implants in the coronaries have become an extraordinarily routine procedure. At least 350 000 patients worldwide will have at least one coronary stent implanted in 1997.

Fortunately, intensive clinical investigations have validated the use of stents in particular subsets of patients. Focal, de novo lesions in large, native coronary arteries are the most carefully studied subgroup[1-8], but only represent a small proportion of patients undergoing the procedure. More recently, randomized trial data of patients with saphenous vein graft lesions, chronic total occlusions, and restenotic lesions, have all been quite favourable for the use of stents compared with balloon angioplasty. Interestingly, four small randomized trials of stenting for acute myocardial infarction collectively, demonstrated a 0-6% mortality as compared to a 6-6% in-hospital death rate for balloon angioplasty[5,6]. This new frontier for coronary stenting was an original absolute contraindication when stenting was first initiated in the late 1980s. This certainly confirms the radical changes that have occurred in the field.

In the current issue, the European Society of Cardiology Working Group on Coronary Circulation have published an important paper on stenting[1]. It
nicely chronicles the perseverance that was needed in early clinical research to be able to determine, ultimately, that balloon angioplasty could be superseded by a metal prosthetic device, provided it was of the proper design, was implanted properly, and the patient received the appropriate combined antiplatelet coverage of aspirin and ticlopidine. The Working Group calls for additional long-term surveillance on the part of manufacturers of implanted stents. This is a critical concern, and an entirely appropriate request. Stent manufacturers have made enormous profits, but have put little back into the field to ensure stent safety on a long-term basis. More than a million patients have had a stent implanted, and with a 0-1% late failure rate, potentially catastrophic results could occur in thousands of patients. Over time, there will be many millions of 'inculcating' coronary patients and if long-term assessment is not undertaken, but unexpected late complications occur, we will not know the incidence rate or who is liable. We must avoid repeating the uncertainty engendered with the Shiley prosthetic heart valve, the Telectronics pacemaker, or breast implants.

The indications for stenting have certainly widened since the results from the first trials became available. As discussed by the Working Group[1], a conservative list of current indications is provided with a Table that summarizes the evidence-basis for these recommendations. Perhaps the most difficult unanswered question is: are the long lesions, which are frequently approached by stents, have a significant risk of in-stent restenosis, and the trade-offs of using balloon angioplasty, or recommending bypass surgery, are not known. With the frequent refractory nature of in-stent restenosis, it could ultimately be shown that starting with a balloon dilatation strategy, even with a relatively high rate of recurrence, is more favourable than empiric stenting. This brings us to the critical need for a randomized trial of provisional stenting. In recent trials, such as BENESTENT II, EPILOG and Balloon vs Optimal Atherectomy Trial (BOAT), there was only a 14% use of stenting in the balloon angioplasty control arm but excellent 6 month clinical outcomes which were more 'stent-like' than had been anticipated. Whether the optimal rate should be 30, 40, or 60% stenting, or even higher, remains to be determined. Certainly, long lesions, small vessels, bifurcated lesions, and diffuse, multi-lesion or multi-vessel disease represent potential indications that need assessment via prospective, randomized trials.

One of the biggest current issues in the field is the technology gradient that still exists between Europe, Asia, Canada, South America, the Middle East, parts of Africa as compared to the United States. Except for the original two stents (Palmaz-Schatz and Gianturco–Roubin) or their updated prototypes, other stents may not be approved in the United States for some time. In contrast, most other countries have more than 10 to 20 stent designs available. The impact on both patient care and the economics of interventional cardiology practice is profound. Not only are some of the new, preferred stent designs easier to deploy, but they can be used to access diseased coronary arteries that would otherwise be unapproachable with archaic technology. Furthermore, as evidenced by the new, competitive stent market scene in Canada during 1997, the costs of stents dropped precipitously from $1500 US to less than $800 US. Accordingly, access to the technology edge that is enjoyed in Europe and non-US countries reflects an unacceptable, tortuous governmental regulatory process in our country. The criteria laid out in the Working Group paper for regulatory approval are suitable for inter-continental standards, and not just the European Community[6].

While we still have much to learn and political and economic challenges to contend with, it is abundantly clear that percutaneous coronary revascularization has catapulted forward with the use of stenting. This must be regarded as the most important advance since the introduction of balloon angioplasty 20 years ago. Stents are not only a permanent prosthetic implant for patients with atherosclerotic coronary disease, but are a vital implant in the contemporary and future development of interventional cardiology.

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