President's Page

Stent Wars (continued)

Dimitrios Th. Kremastinos

2nd University Department of Cardiology, University General Hospital "Attikon", Athens, Greece

The introduction of percutaneous coronary intervention (PCI) in cardiology dramatically changed the therapeutic management of coronary artery disease and in particular the management of acute coronary syndromes. The combination of PCI with the implantation of bare metal stents (BMS) significantly enhanced the efficacy of the technique by stabilising the result of PCI and protecting against vessel recoil and the local dissection.[1]

The recent development of stents covered by antimitotic agents, the drug eluting stents (DES), advanced the technique further by dramatically reducing the rate of restenosis due to intima-media hyperplasia.[2,3] The ensuing optimism of physicians and researchers, however, was compromised by a series of observations, first by Virmani and then by other investigators, according to which DES might be associated with an increased risk of late thrombosis and hence increased mortality.[4-7] Stent thrombosis is a serious complication that may potentially lead to acute myocardial infarction with significantly greater morbidity and mortality than other myocardial infarctions.

The general unrest caused by the above observations has led to a new series of trials and meta-analyses aiming at the comparative evaluation of DES and BMS in terms of efficacy and safety in different patient populations. Hitherto, these later studies have shown that DES are better than BMS in reducing the rate of restenosis and the need for target vessel revascularisation, being at the same time generally safe when double anti-platelet therapy is prolonged beyond one year of implantation and the special features of patient and lesion are taken into account.[8-12]

The factors linked with an increased risk of late stent thrombosis concern the implantation technique, the patient, the clinical conditions under which the implantation takes place, and finally the anti-platelet therapy. Although the issue is still open, it has become clear that patients with DES require long-term dual anti-platelet therapy with aspirin and clopidogrel, a fact that may render them susceptible to haemorrhagic complications when subjected to an unscheduled surgical procedure or an injury.

After recognising the conflict and the general unrest caused by the issue, the U.S. Food and Drug Administration re-evaluated DES use by conducting a series of hearings. Those hearings concluded that DES are safe when used only in circumstances defined by the indications for which they have been approved. Consequently, the only secure approach to the clinical use of DES for the moment is the proper and comprehensive evaluation of patients and strict compliance with the guidelines published by the Cardiology Societies.

References

1. Kremastinos DT. Stent wars. Hellenic J Cardiol 2007; 48: 387.
2. Moses JW, Leon MB, Popma JJ, et al. Sirolimus-eluting stents versus standard stents in patients with stenosis in a native coronary artery. N Engl J Med. 2003; 349: 1315-1323.
3. Stone GW, Ellis SG, Cannon L, et al. Comparison of a polymer-based paclitaxel-eluting stent with a bare metal stent in patients with complex coronary artery disease: a randomized controlled trial. JAMA. 2005; 294: 1215-1223.
4. Virmani R, Guagliumi G, Farb A, et al. Localized hypersensitivity and late coronary thrombosis secondary to a sirolimus-eluting stent: should we be cautious? Circulation. 2004; 109: 701-705.
5. Pfisterer M, Brunner-La Rocca HP, Buser PT, et al; BASKET-LATE Investigators. Late clinical events after clopidogrel discontinuation may limit the benefit of drug-eluting stents: an observational study of drug-eluting versus bare-metal stents. J Am Coll Cardiol. 2006; 48: 2584-2591.
6. Lagerqvist B, James S, Stenestrand U, et al; for the SCAAR

Study Group. Long-term outcomes with drug-eluting stents versus bare-metal stents in Sweden. N Engl J Med. 2007; 356: 1009-1019.
7. Daemen J, Wenaweser P, Tsuchida K. Early and late coronary stent thrombosis of sirolimus-eluting and paclitaxel-eluting stents in routine clinical practice: data from a large two-institutional cohort study. Lancet. 2007; 369: 667-678.
8. Shishehbor M, Goel S, Kapadia S, et al. Long-term impact of drug-eluting stents versus bare-metal stents on all-cause mortality. J Am Coll Cardiol. 2008; 52: 1041-1048.
9. Mauri L, Silbaugh TS, Wolf RE, et al. Long-term clinical outcomes after drug-eluting and bare-metal stenting in Massachusetts. Circulation. 2008; 118: 1817-1827.
10. Kirtane AJ, Ellis SG, Dawkins KD, et al. Paclitaxel-eluting coronary stents in patients with diabetes mellitus: pooled analysis from 5 randomized trials. J Am Coll Cardiol. 2008; 51: 708-715.
11. Stettler C, Allemann S, Wandel S, et al. Drug eluting and bare metal stents in people with and without diabetes: collaborative network meta-analysis. BMJ. 2008; 337: 1331.
12. Groeneveld P, Matta M, Greenhut A, et al. Drug-eluting compared with bare-metal coronary stents among elderly patients. J Am Coll Cardiol. 2008; 51: 2017-2024.